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

Selection Criteria:

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

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

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

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

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
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Detailed Report

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2000	3463581	NON-EXPEDITED	Y	OT	A001296		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Viagra			S	Oral	100.00 Mg Total, Daily, Oral		Not Reported
	Lexapro			S				Not Reported
	Unspecified Ingredient			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2001	3697588	EXPEDITED (15-DAY)	Y	DE	T01-FIN-01573-01		49 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Aspiration; Cardiac Arrest; Chest Pain; Circulatory Collapse; Dermatitis; Fatigue; Libido Decreased; Sudden Death; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Unspecified Ingredient			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2001	6747114	EXPEDITED (15-DAY)	Y	HO, LT	T01-FIN-01527-01		25 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Disorder; Confusional State; Fall; Hallucination; Injury; Joint Dislocation; Pelvic Fracture; Toxicologic Test Abnormal; Urinary Bladder Rupture; Wrist Fracture	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Ibusal (Ibuprofen)			C				Not Reported
	Rennie			C				Not Reported
	Ibumetin (Ibuprofen)			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2001	3701320	EXPEDITED (15-DAY)	Y	HO	T01-UKI-01263-01		89 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest X-Ray Abnormal; Circulatory Collapse; Coma; Femoral Neck Fracture	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Zoladex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2001	3789982	DIRECT	N	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Escitalopram Oxalate			S	Oral	30 Mg Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2002	3789229	EXPEDITED (15-DAY)	Y	HO	T01-GER-01618-01		53 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Cholinesterase Increased; Blood Triglycerides Increased; Diarrhoea; Dilatation Atrial; Eye Pain; Gait Disturbance; Gamma-Glutamyltransferase Increased; Hypertension; Laboratory Test Abnormal; Transient Ischaemic Attack; Ventricular Hypertrophy; Vomiting	Escitalopram Oxalate			S				Not Reported
	Venlafaxine			S	Oral	75 Mg Qd; Po		Not Reported
	Placebo			S	Oral	2 Capsule Qd; Po		Not Reported
	Levothyroxine Sodium			C				Not Reported
	Metomerck (Metoprolol Tartrate)			C				Not Reported
	Antra Mups (Omeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2002	6035453	EXPEDITED (15-DAY)	Y	DE	S02-SWI-00915-01		53 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Asphyxia; Completed Suicide	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lexotanil (Bromazepam)			C				Not Reported
	Somnium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2002	3843398	DIRECT		OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Panic Attack	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2002	3843988	DIRECT	N	LT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome	Paxil			S	Oral	20 Mg 3 X Daily Oral		Glaxo Wellcome
	Lexapro			S	Oral	10 Mg Once Daily Oral		Glaxo Wellcome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2002	3848788	DIRECT	Y				15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lexapro			S	Oral	10 Mg Po		Forest
	Loxitane			S		10mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2002	3848219	DIRECT	N	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Insomnia; Movement Disorder; Pain In Jaw; Paraesthesia; Suicidal Ideation; Thinking Abnormal	Lexapro			S		10mg - A Tablet Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2002	3851235	DIRECT	Y	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lexapro			S				Forest
	Loxapine Succinate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2002	4160684	DIRECT	Y				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2002	3853977	DIRECT	Y	OT			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2002	3855981	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia	Lexapro			S	Oral	10mg Po Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2002	3850095	EXPEDITED (15-DAY)	Y	OT	T02-USA-02084-01		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Transient; Migraine; Nausea; Vasoconstriction; Vasospasm; Vision Blurred; Visual Field Defect	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Depakote			C				Not Reported
	Celexa			C				Not Reported
	Trileptal			C				Not Reported
	Seroquel (Quetiapine) (Quetiapine Fumarate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2002	3857267	EXPEDITED (15-DAY)	Y	HO	S02-USA-02227-01		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S				Not Reported
	Prozac			S		80 Mg Qd		Not Reported
	Prozac			S		40 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2002	3857274	EXPEDITED (15-DAY)	Y	HO	S02-USA-02254-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Confusional State; Delirium; Disorientation; Loss Of Consciousness; Memory Impairment; Respiratory Failure; Syncope	Lexapro			S				Not Reported
	Permax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2002	3856038	DIRECT	Y	RI, OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Retinal Detachment	Lexapro			S		10 Mg Qd		Not Reported
	Trazodone Hydrochloride			S		25 Mg Qhs	2 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2002	3858080	EXPEDITED (15-DAY)	Y	DS	T02-USA-00199-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Type 2 Diabetes Mellitus	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Darvocet-N			C				Not Reported
	Zolpidem			C				Not Reported
	Ranitidine			C				Not Reported
	Ibuprofen			C				Not Reported
	Phenergan			C				Not Reported
	Nicotine			C				Not Reported
	Q-Bid La (Guaifenesin)			C				Not Reported
	Cephalexin			C				Not Reported
	Cough Syrup (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2002	3858111	EXPEDITED (15-DAY)	Y	OT	S02-USA-02406-01		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2002	3861036	EXPEDITED (15-DAY)	Y	LT	S02-DEN-02491-01		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Lexapro			S	Oral	10 Mg Once Po		Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bradycardia; Drug	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Large Intestine Perforation	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Unspecified Ingredient		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2002	3870307	EXPEDITED (15-DAY)	Y	OT	PHEH2002US09578		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Trileptal			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	10 Mg, Qd, Oral		Not Reported
	Sonata			C				Not Reported
	Klonopin			C				Not Reported
	K-Dur			C				Not Reported
	Phenergan			C				Not Reported
	Vioxx			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2002	3871236	EXPEDITED (15-DAY)	Y	HO, RI, OT	C2002-3228.01		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bradycardia; Drug Interaction; Hypotension	Lexapro			S	Oral	10mg Qd, Oral		Forest
	Atenolol			S	Oral	100 Mg Qd, Oral		Not Reported
	Alprazolam			C				Not Reported
	Lovastatin			C				Not Reported
	Telmisartan			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2002	3869597	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Lexapro			S	Oral	10 Mg Po Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2002	3869598	DIRECT	Y	OT			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Lexapro			S	Oral	10 Mg Po Bid	3 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2002	3870097	DIRECT	Y	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphoria; Tremor	Lexapro			S	Oral	10mg Po Qd	6 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2002	3872086	EXPEDITED (15-DAY)	Y	DE	S02-USA-03135-01		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2002	3871605	DIRECT	N	HO, OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Nausea; Panic Attack; Vomiting	Lexapro			S	Oral	10mg 1x Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2002	3872426	DIRECT	Y	HO, RI			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Dizziness; Hypertension; Hyponatraemia; Nausea	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Avalide		S	Oral	12.5 Bid Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2002	3873867	DIRECT	N	OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Back Pain; Dyskinesia; Gait Disturbance; Headache; Insomnia; Migraine; Nausea; Tremor; Vomiting	Lexapro			S	Oral	10mg 1x A Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2002	3875689	EXPEDITED (15-DAY)	Y	HO	S02-USA-03137-01		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2002	3857922	EXPEDITED (15-DAY)	Y	HO, LT, RI	S02-USA-02265-01		45 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Aggression; Agitation; Brain Oedema; Clonic Convulsion; Hallucination, Auditory; Hiatus Hernia; Hyporeflexia; Hypotension; Inappropriate Antidiuretic Hormone Secretion; Muscle Injury; Myocardial Infarction; Myocardial Ischaemia; Oxygen	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celexa			S	Oral	10 Mg Bid Po		Not Reported
	Risperdal			C				Not Reported
	Lithium			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Dizziness; Hypoaesthesia; Nausea; Vertigo; Vision Blurred	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Amnesia; Injury; Loss Of Consciousness; Screaming	Mirtazapine			S	Oral	30 Mg		Not Reported
	Cipralex			S	Oral	10 Mg		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Plasma Cell Leukaemia; Renal Failure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2002	3879043	EXPEDITED (15-DAY)	Y	OT	S02-UKI-03389-01		37 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Schizophreniform Disorder	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2002	3880400	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychomotor Hyperactivity	Lexapro			S	Oral	1/2 Tab(S) Po Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2002	3891069	NON-EXPEDITED	Y	HO	S02-USA-03049-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2002	3891073	NON-EXPEDITED	Y	HO	S02-USA-02974-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Malaise	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2002	3891076	NON-EXPEDITED	Y	OT	S02-USA-02282-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2002	3891078	NON-EXPEDITED	Y	OT	S02-USA-02223-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2002	3891084	NON-EXPEDITED	Y	OT	S02-USA-02208-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperglycaemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2002	3891087	NON-EXPEDITED	Y	HO	S02-USA-02133-01		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2002	3891091	NON-EXPEDITED	Y	RI, OT	S02-USA-02005-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Headache; Hypersensitivity; Nausea; Neck Pain; Pain; Paraesthesia; Photophobia; Pruritus; Pyrexia; Rash	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celexa			S	Oral	20 Mg Qd Po		Not Reported
	Vitamins Nos			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2002	3878602	DIRECT	Y	DE			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S	Oral	20mg Oral		Forest
	Klonopin			C				Not Reported
	Ambien			C				Not Reported
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2002	3882535	EXPEDITED (15-DAY)	Y	DE	S02-UKI-03446-01		82 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Sudden Death	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2002	3882543	EXPEDITED (15-DAY)	Y	DS	S02-SWI-03423-01		43 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Use; Amnesia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Remeron			S	Oral	30 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2002	3882568	EXPEDITED (15-DAY)	Y	HO	S02-UKI-03434-01		18 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2002	3881802	DIRECT	Y	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Insomnia;	Lexapro			S	Oral	5mg Qd Oral		Forest

Muscle Tightness;
Psychomotor Hyperactivity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2002	3891707	NON-EXPEDITED	Y	HO	200227030BWH		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test	Avelox			S				Not Reported
Abnormal	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2002	3866698	EXPEDITED (15-DAY)	Y	HO	S02-USA-02610-01		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Hydrochlorothiazide			C				Not Reported
	Remeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2002	3866731	EXPEDITED (15-DAY)	Y	HO	S02-USA-02658-01		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Memory Impairment; Speech Disorder	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Sumanirole			C				Not Reported
	Alcohol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2002	3866744	EXPEDITED (15-DAY)	Y	HO	S02-USA-02680-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2002	3884353	EXPEDITED (15-DAY)	Y	HO	S02-UKI-03481-01		96 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Frusemide			C				Not Reported
	Gliclazide			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2002	3891820	NON-EXPEDITED	Y	HO, OT	A0383258A		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Wellbutrin			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	10 Mg / Per Day / Oral		Not Reported
	Fluoxetine			S	Oral	80 Mg / Per Day / Oral		Not Reported
	Fluoxetine			S	Oral	40 Mg / Per Day / Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2002	3883577	DIRECT	Y	HO, RI			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Sodium Decreased; Dysarthria	Lexapro			S	Oral	10mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2003	3886913	EXPEDITED (15-DAY)	Y	HO, OT	S02-USA-03345-01		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastritis Haemorrhagic; Haematemesis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Coumadin			C				Not Reported

	Fosamax	C	Not Reported
	Protonix	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2003	3887021	EXPEDITED (15-DAY)	Y	DE	2002139883US		37 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning	Xanax			S	Oral	Oral		Not Reported
	Alcohol (Ethanol)			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	See Image		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2003	3888231	EXPEDITED (15-DAY)	Y	HO	T02-FRA-00027-01		62 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Fall; Femoral Neck Fracture	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Placebo			S				Not Reported
	Mediator(Benfluorex Hydrochloride)			C				Not Reported
	Adalate Lp			C				Not Reported
	Acetaminophen			C				Not Reported
	Inipomp			C				Not Reported
	Optruma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2003	3875692	EXPEDITED (15-DAY)	Y	OT	S02-USA-03204-01		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysgeusia; Glossitis; Glossodynia; Impaired Healing; Tongue Disorder; Tongue Haemorrhage; Tongue Oedema	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2003	3888332	EXPEDITED (15-DAY)	Y	HO	T01-CZE-01612-01		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Placebo			S				Not Reported
	Defobin (Chlordiazeproxide)			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2003	3888334	EXPEDITED (15-DAY)	Y	OT	T01-UKI-01695-01		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Paralysis; Nausea	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Placebo			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2003	3888335	EXPEDITED (15-DAY)	Y	OT	T02-EST-00049-01		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Mood Altered; Suicide Attempt	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Placebo			S	Oral	1 Tablet Qd Po		Not Reported
	Valerian			S	Oral	27 Tablet Qd Po		Not Reported
	Diclomelan (Diclofenac Sodium)			C				Not Reported
	Ciprinol (Ciprofloxacin)			C				Not Reported
	Novalis (Meloxicam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2003	3888337	EXPEDITED (15-DAY)	Y	OT	T01-UK1-01694-01		56 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Disorder	Lexapro			S	Oral	10 Mg Qd Oral		Forest

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epileptic Aura	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Tegretol			S	Oral	600 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Olanzapine			S	Oral	10 Mg Qd Po		Not Reported

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

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

	Asa			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2003	3870970	EXPEDITED (15-DAY)	Y	OT	S02-USA-02893-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S		10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2003	3893175	DIRECT	Y	HO, RI			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Zyprexa			S	Oral	7.5mg Qhs Oral		Not Reported
	Lexapro			S	Oral	10mg Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2003	3893740	EXPEDITED (15-DAY)	Y	OT	S02-USA-03235-01		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain; Head Injury; Medication Error; Migraine; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ativan			S		3 Mg Qd		Not Reported
	Demerol			S				Not Reported
	Vicodin			S				Not Reported
	Nicotine			S		14 Mg Qd		Not Reported
	Tylenol (Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2003	3896275	DIRECT	N				29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Disturbance In Attention;	Lexapro			S	Oral	20mg Once Daily Oral		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2003	3895984	EXPEDITED (15-DAY)	Y	DE	S02-UK1-03446-01		82 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cardiac Failure Congestive; Myocardial Ischaemia; Sudden Death	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			C				Not Reported
	Digoxin			C				Not Reported
	Furosemide			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2003	3896486	EXPEDITED (15-DAY)	Y	HO	S03-USA-00181-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Dystonia; Hypokalaemia; Hyponatraemia; Hypotension; Intentional Overdose; Vomiting	Lexapro			S		70 Mg Once Po		Not Reported
	Lexapro			S		10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2003	3896537	EXPEDITED (15-DAY)	Y	HO	S03-USA-00180-01		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Flushing; Palpitations; Serotonin Syndrome	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2003	3898157	EXPEDITED (15-DAY)	Y	DE	S03-USA-00260-01		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Muscle Spasms; Seizure; Vomiting	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Celexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2003	3867749	EXPEDITED (15-DAY)	Y	HO	S02-USA-02750-01		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Reglan			C				Not Reported
	Coumadin			C				Not Reported
	Macrobid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2003	3871764	EXPEDITED (15-DAY)	Y	HO	S02-USA-02964-01		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenal Ulcer Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported
	Synthroid			C				Not Reported
	Zocor			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2003	3883239	EXPEDITED (15-DAY)	Y	OT	T02-USA-03428-01		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Male Orgasmic Disorder;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Phlebitis	Claritin	C		Not Reported
	Viagra	C		Not Reported
	Wellbutrin Sr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2003	3898231	DIRECT	Y	LT			95 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biopsy Bone Marrow Abnormal; Bone Marrow Disorder; Cellulitis; Decreased Appetite; Malaise; Neutrophil Count Decreased; White Blood Cell Count Decreased	Lexapro			S	Oral	5 Mg Po Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2003	3898882	EXPEDITED (15-DAY)	N	HO	S03-USA-00215-01		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Somnolence; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2003	3900187	DIRECT	Y	HO			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate			S	Oral	10mg Qd Po	2 WEEK	Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2003	3872117	EXPEDITED (15-DAY)	N	HO	S02-USA-03124-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2003	3904409	EXPEDITED (15-DAY)	Y	RI	03P-163-0209312-00		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Depression; Drug Interaction; Drug Withdrawal Syndrome; Fall; Head Injury; Migraine; Seizure; Tenderness; Tongue Biting	Vicodin			S				Not Reported
	Lexapro			S	Oral	10 Mg, 1 In 1 D, Per Oral		Not Reported
	Lorazepam			S		3 Mg, 1 In 1 D		Not Reported
	Pethidine Hydrochloride			S				Not Reported
	Nicotine			S		14 Mg, 1 In 1 D		Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2003	3904635	EXPEDITED (15-DAY)	Y	HO	S03-USA-00357-01		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza; Leukopenia; Thrombocytopenia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2003	3932655	DIRECT	Y	HO, RI			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Blood Pressure Systolic Increased; Confusional State; Depression; Mental Status	Lexapro			S	Oral	Oral		Not Reported
	Aciphex			C				Not Reported
	Premarin			C				Not Reported
	Vioxx			C				Not Reported

Changes; Psychomotor Hyperactivity	Metoprolol	C	Not Reported
	Hctz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2003	3902999	EXPEDITED (15-DAY)	Y	OT	S03-FRA-00475-01		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Flushing; Syncope; Thyroid Disorder	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2003	3903002	EXPEDITED (15-DAY)	Y	HO	S03-IRL-00422-01			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2003	3904626	EXPEDITED (15-DAY)	Y	OT	HQWYE071329JAN03		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Eye Pain; Fall; Head Injury; Migraine; Seizure; Tenderness; Tongue Biting; Tremor	Ativan			S	Oral	3 Mg 1x Per 1 Day, Oral		Not Reported
	Demerol			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	10 Mg 1x Per 1 Day, Oral		Not Reported
	Nicotine			S	Transdermal	14 Mg 1x Per 1 Day, Transdermal		Not Reported
	Vicodin			S	Oral	Six To Eight Tablets Per Day For Three To Four Days Per Week, Oral		Not Reported
	Tylenol (Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2003	3905275	EXPEDITED (15-DAY)	Y	HO	S03-USA-00450-01		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Acyclovir			C				Not Reported
	Disulfiram			C				Not Reported
	Neurontin			C				Not Reported
	Seroquel			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2003	3905289	EXPEDITED (15-DAY)	Y	HO	S03-USA-00416-01		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dialysis; Mental Status Changes; Rhabdomyolysis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Dexatrim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2003	3867072	EXPEDITED (15-DAY)	Y	OT	T02-USA-02780-01		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Epileptic Aura; Fall; Flushing; Generalised Tonic-Clonic Seizure; Head Injury; Headache; Hyperhidrosis; Malaise; Micturition Urgency; Nausea; Nervousness; Somnolence; Syncope; Urinary Incontinence; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multivitamins With Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2003	3906282	EXPEDITED (15-DAY)	Y	OT	S03-UKI-00508-01		54 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Implant Site Reaction; International Normalised Ratio Increased; Prothrombin Time Prolonged	Lexapro			S	Oral	20 Mg Daily Oral		Not Reported
	Demadex			C				Not Reported
	Losartan Potassium			C				Not Reported
	Duragesic			C				Not Reported
	Coumadin			C				Not Reported
	Calcium			C				Not Reported
	Kcl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2003	3906903	NON-EXPEDITED	Y		2002136869US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction; Feeling Hot; Heart Rate Increased	Zyvox			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2003	3910501	EXPEDITED (15-DAY)	Y	HO, RI	S03-USA-00532-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amylase Increased; Biliary Tract Disorder; Gallbladder Disorder; Lipase Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Diovan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2003	3910504	EXPEDITED (15-DAY)	Y	HO	S03-USA-00557-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Palpitations	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2003	3910512	EXPEDITED (15-DAY)	Y	HO	S03-USA-00469-01		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningitis Aseptic; Otitis Media	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2003	3932666	DIRECT	Y	RI			90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; International Normalised Ratio Increased; Prothrombin Time Prolonged	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported
	Coumadin			C				Not Reported
	Nifedipine			C				Not Reported
	Levothyroxine			C				Not Reported
	Lasix			C				Not Reported
	Oscal			C				Not Reported
	Catapres-Tts			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2003	3906993	DIRECT	Y	HO			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Movement Disorder; Seizure; Staring; Tremor	Lexapro			S	Oral	10mg Po Qhs[~2 Days Prior To Event]		Not Reported
	Ultrase			C				Not Reported
	Mt-12			C				Not Reported
	Darvocet-N 100			C				Not Reported
	Aricept			C				Not Reported
	Aciphex			C				Not Reported
	Librox			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2003	3909541	DIRECT	Y	OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Flushing; Nausea	Lexapro			S	Oral	20mg 1/2 Tab Po Qd		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2003	3912172	EXPEDITED (15-DAY)	Y	OT	A-US2003-01993		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching; Neuropathy Peripheral; Tremor	Tracleer			S		62.5; 125 Mg Q12hrs, 62.5; 125 Mg Q12hrs,		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2003	6999074	DIRECT	Y	HO			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Muscle Spasms; Trismus	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2003	3891860	EXPEDITED (15-DAY)	Y	HO	T03-USA-00078-01		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Hallucinations, Mixed; Skin Abrasion; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lipitor			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2003	3883194	EXPEDITED (15-DAY)	Y	OT	S02-USA-03236-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2003	3911635	DIRECT	N				71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Lexapro			S		Oral Used One Time Only		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2003	3913119	EXPEDITED (15-DAY)	N	HO	2003-103077-NL			Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Suicidal Ideation	Remeron			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd; Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2003	3922592	NON-EXPEDITED	N		SU-2003-000406		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Agitation; Hyperhidrosis; Hypoacusis; Vision Blurred	Benicar			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lortab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2003	3857286	EXPEDITED (15-DAY)	Y	OT	T02-USA-02309-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Level Increased; Fall; Nausea	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Tegretol			S	Oral	1000 Mg Qd Po		Not Reported
	Tegretol			S	Oral	1000 Mg Qd Po		Not Reported
	Topamax			C				Not Reported
	Imitrex (Sumatriptan)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2003	3909920	EXPEDITED (15-DAY)	Y	DE	S03-BEL-00502-01		67 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Novothyral			C				Not Reported
	Remergon			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Inderal			C				Not Reported
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2003	3914948	EXPEDITED (15-DAY)	Y	OT	S03-USA-00729-01		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Narcolepsy; Road Traffic Accident	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Hydrocodone			C				Not Reported
	Elavil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2003	6035455	EXPEDITED (15-DAY)	Y	OT	S03-UKI-00764-01		41 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Neutropenia; Vertigo	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

	Prochlorperazine	C		Not Reported
	Microgynon	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2003	3913890	DIRECT	N	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Ejaculation Disorder; Somnolence	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2003	3915348	EXPEDITED (15-DAY)	Y	OT	S03-USA-00744-01		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Dystonia; Tardive Dyskinesia; Tic	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Albuterol			C				Not Reported
	Trileptal (Oxcarbamazepine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2003	3916399	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Loxitane			S				Watson
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2003	5946613	EXPEDITED (15-DAY)	Y	OT	S03-UKI-00773-01		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Dysphemia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2003	6035456	EXPEDITED (15-DAY)	Y	OT	S03-UKI-00772-01		40 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Feeling Abnormal; Physical Assault; Spousal Abuse	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lansoprazole			C				Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2003	3916889	EXPEDITED (15-DAY)	Y	OT	S03-USA-00666-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Decreased Appetite; Initial Insomnia; Intentional Self-Injury; Irritability; Obsessive-Compulsive Disorder; Psychomotor Hyperactivity; Refusal Of Treatment By Relative; Treatment Noncompliance	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Celexa			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2003	3917492	EXPEDITED (15-DAY)	Y	DS	S03-UKI-00832-01		59 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Generalised; Rash Pruritic; Urticaria	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Sodium Citrate			C				Not Reported
	Norfloxacin			C				Not Reported
	Nitrofurantoin			C				Not Reported
	Influvac (Influenza Virus Vaccine Polyvalent)			C				Not Reported
	Tolterodine			C				Not Reported
	Fluticasone			C				Not Reported
	Albuterol			C				Not Reported

	Potassium			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2003	3914109	DIRECT	Y	HO			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Pain In Extremity; Skin Discolouration	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2003	3918245	EXPEDITED (15-DAY)	Y	OT	S03-UKI-00844-01		20 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Orthostatic Hypotension; Syncope	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Dianette			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2003	3883099	EXPEDITED (15-DAY)	Y	HO	S02-USA-03287-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Drug Ineffective; Intracranial Pressure Increased; Meningioma; Papilloedema; Temporal Arteritis	Lexapro			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Celexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2003	3918173	EXPEDITED (15-DAY)	Y	HO	S02-USA-03107-01		37 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment; Seizure; Stress; Toxicity	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Seizure	Cipralex			S				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neurosis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2003	3924248	NON-EXPEDITED	Y	OT	S03-USA-00279-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Depression	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2003	3924249	NON-EXPEDITED	Y	HO	S03-USA-00444-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Remeron			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2003	3924250	NON-EXPEDITED	Y	HO	S02-USA-03205-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Syncope	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2003	3924251	NON-EXPEDITED	Y	HO	S02-USA-03344-01		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Triamterene And Hydrochlorothiazide			S				Not Reported
	Coumadin			C				Not Reported
	Toprol Xl			C				Not Reported
	Lanoxin			C				Not Reported
	Amaryl			C				Not Reported
	Lipitor			C				Not Reported

	Vitamins Nos	C	Not Reported
	Chondroitin Sulfate (Bovine)\Glucosamine Sulfate	C	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Malaise; Suicide Attempt	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ambien			S	Oral	75 Mg Once Po		Not Reported
	Ambien			S	Oral	5 Mg Qhs Po		Not Reported
	Wellbutrin			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity; Skin Discolouration	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Disinhibition	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Tranxene T-Tab			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Tanakan			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Haemoglobin Decreased; Maternal Drugs Affecting Foetus; Postpartum Haemorrhage; Retained Placenta Or Membranes	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2003	3922548	DIRECT	Y	HO			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dehydration; Dizziness; Drug Interaction; Hypotension; Lethargy; Renal Failure	Zanaflex			S	Oral	4mg Qd Oral		Not Reported
	Atenolol			S	Oral	50 Qd Oral		Not Reported
	Lexapro			S	Oral	10mg Qd Oral		Not Reported
	Diovan			C				Not Reported
	Norvasc			C				Not Reported
	Vioxx			C				Not Reported
	Aspirin			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2003	3923437	EXPEDITED (15-DAY)	Y	HO	PHEH2003US02008		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Memory Impairment; Seizure; Toxicity To Various Agents; Vision Blurred	Tegretol			S		800 Mg, Qd; See Image 800 Mg, Qd; See Image		Not Reported
	Lexapro			S				Not Reported
	Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2003	3925537	EXPEDITED (15-DAY)	Y	OT	S03-USA-01053-01		92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Insomnia; Intraocular Pressure Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Synthroid			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2003	4119551	EXPEDITED (15-DAY)	Y	DE	S03-UKI-01093-01		62 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Cipralex			S	Oral	10 Mg Qd; Po		Not Reported
	Spiriva			S	Respiratory (inhalation)	18 Mcg, Unk, Ih		Not Reported
	Temazepam			C				Not Reported
	Budesonide			C				Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2003	3879586	EXPEDITED (15-DAY)	Y	DE	S02-USA-03224-01		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardio-Respiratory Arrest; Cardiomegaly; Confusional State; Hepatic Congestion; Pulmonary Embolism; Sleep Disorder	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Ortho Tri Cyclen			S		1 Tablet Qd		Not Reported
	Unknown Birth Control Medication			C				Not Reported
	Unknown Asthma Inhaler			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2003	3918159	EXPEDITED (15-DAY)	Y	HO	S03-USA-00791-01		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dizziness; Hypotension; Intentional	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2003	3929028	EXPEDITED (15-DAY)	Y	LT	S03-UKI-01165-01		64 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenal Ulcer; Haematemesis; Melaena	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Ibuprofen			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2003	3929832	EXPEDITED (15-DAY)	Y	HO	S03-USA-01204-01		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Accident; Delusion Of Grandeur; Fatigue; Injury; Mania; Road Traffic Accident; Somnolence; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Zyprexa			C				Not Reported
	Percocet			C				Not Reported
	Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2003	3929862	EXPEDITED (15-DAY)	Y	HO, RI	S03-USA-00471-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S				Not Reported
	Remicade			S				Not Reported
	Flagyl			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Nexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2003	3929885	EXPEDITED (15-DAY)	Y	DS	S03-FRA-01170-01		33 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diplopia	Escitalopram Oxalate		S	Oral	10 Mg Qd Po	Not Reported
	Oxazepam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2003	3910494	EXPEDITED (15-DAY)	Y	HO	S03-USA-00576-01		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrolyte Imbalance	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2003	3925543	EXPEDITED (15-DAY)	Y	RI, OT	S03-USA-01034-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Increased; Feeling Abnormal; Gastrooesophageal Reflux Disease; Gravitational Oedema; Hyperparathyroidism	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Imitrex			C				Not Reported
	Vivelle (Estradiol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2003	3928640	DIRECT	Y	HO			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10mg Qd Po	1 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2003	3930508	EXPEDITED (15-DAY)	Y	HO	S03-USA-01213-01		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Inappropriate Antidiuretic Hormone Secretion	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Advair Diskus		C			Not Reported
	Multivitamin (Nos)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2003	3928398	DIRECT	Y	OT			20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Lexapro			S	Oral	10 Mg Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2003	3930605	DIRECT	Y	LT			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Chest Pain; Respiratory Arrest; Seizure	Lexapro			S	Oral	10 Mg Bid/Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2003	3931570	DIRECT	Y	OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Infection	Lexapro			S	Oral	10 Mg Po Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2003	3934717	EXPEDITED (15-DAY)	Y	HO	S03-USA-01365-01		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported
	Plavix			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2003	3934756	EXPEDITED (15-DAY)	Y	HO	S03-USA-01366-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S	Oral	40 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2003	3868165	EXPEDITED (15-DAY)	Y	HO	S02-USA-02890-01		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Communication Disorder; Kidney Infection; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celebrex			C				Not Reported
	Enalapril			C				Not Reported
	Premarin			C				Not Reported
	Atenolol			C				Not Reported
	Librium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2003	3930541	EXPEDITED (15-DAY)	Y	HO	S03-USA-01189-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Hepatitis Fulminant; Overdose	Lexapro			S				Not Reported
	Tylenol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2003	3935654	EXPEDITED (15-DAY)	Y	HO, RI	S03-USA-01401-01		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hypertension	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lipitor			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2003	3920479	EXPEDITED (15-DAY)	Y	HO	T03-USA-00902-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Schizophrenia; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celexa			C				Not Reported
	Propranolol La (Propranolol)			C				Not Reported
	Zyprexa			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2003	3934784	EXPEDITED (15-DAY)	Y	HO	T03-USA-01358-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akinesia; Blood Cholesterol Increased; Cardiac Failure Congestive; Coronary Artery Restenosis; Depression; Diabetes Mellitus; Drug Interaction; Ejection Fraction Decreased; Hypotension; Myocardial Ischaemia; Syncope; Treatment Noncompliance; Ventricular Hypokinesia	Lexapro			S	Oral	10 Mg, Qd; Po		Not Reported
	Toprol Xl			S	Oral	50 Mg, Qd; Po		Not Reported
	Altace			C				Not Reported
	Lopid			C				Not Reported
	Glucophage			C				Not Reported
	Humalog			C				Not Reported
	Humalog			C				Not Reported
	Zocor			C				Not Reported
	Kcl (Potassium Chloride)			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2003	3934022	DIRECT	Y	HO			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Dizziness; Drug Interaction;	Lexapro			S				Forest
	Alprazolam			S				Not Reported

Emotional Distress

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2003	3935196	DIRECT	Y	HO			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypophagia; Oligodipsia; Stevens-Johnson Syndrome	Lamictal			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2003	3937377	DIRECT	Y	HO			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	10mg Po Qd		Not Reported
	Acyclovir			C				Not Reported
	Desulturam			C				Not Reported
	Levothyroxine			C				Not Reported
	Olanzapine			C				Not Reported
	Quetrapine			C				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2003	3937044	DIRECT	N	OT			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome; Emotional Disorder; Headache	Lexapro			S	Oral	10 Mg Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2003	3939546	EXPEDITED (15-DAY)	Y	HO	S03-USA-01482-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Movement Disorder	Lexapro	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2003	3939549	EXPEDITED (15-DAY)	Y	DS	S03-USA-01586-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphemia; Mental Impairment	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Clonazepam			C				Not Reported
	Glucosamine			C				Not Reported
	Methylsulfonylmethane			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Vitamin E			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2003	3939569	EXPEDITED (15-DAY)	Y		S03-USA-01575-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Respiratory Arrest	Lexapro			S				Not Reported
	Xanax			C				Not Reported
	Zyprexa			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2003	3931399	EXPEDITED (15-DAY)	Y	OT	S03-USA-01378-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Tongue Biting	Lexapro			S				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2003	3940614	EXPEDITED (15-DAY)	Y	OT	S03-USA-01592-01		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Tachycardia;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Drugs Affecting Foetus; Maternal Drugs Affecting Foetus	Oxcarbazepine			S		600 Mg Day		Not Reported
	Lexapro			S	Oral	50 Mg Po		Not Reported
	Zoloft			S				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Ultram			S		Oral		Not Reported

	Lexapro			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2003	3942033	EXPEDITED (15-DAY)	Y	HO	1671967A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Hepatitis Fulminant; Overdose	Tylenol			S	Oral	Po		Not Reported
	Lexapro			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2003	3929878	EXPEDITED (15-DAY)	Y	OT	S03-IRL-01258-01		64 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety Disorder; Delirium; Headache; Nausea; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Hypericin			S		900 Mcg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2003	3943740	EXPEDITED (15-DAY)	Y	OT	S03-UKI-01691-01		55 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Loss Of Consciousness	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Antibiotics			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2003	3961889	NON-EXPEDITED	N		ZONI001059		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Zonegran			S	Oral	Oral		Not Reported
	Lexapro			S		10 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2003	3942293	EXPEDITED (15-DAY)	Y	HO	S03-FRA-01830-01		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Mydriasis; Overdose; Somnolence	Escitalopram Oxalate			S	Oral	600 Mg Once Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2003	3944555	DIRECT	Y	OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Chills; Insomnia; Nasopharyngitis	Escitalopram Oxalate			S	Oral	10mg Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2003	3945728	EXPEDITED (15-DAY)	Y	OT	S03-USA-01641-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Use; Condition Aggravated	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			S		7 Units Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2003	3883229	EXPEDITED (15-DAY)	Y	HO	S02-USA-03285-01		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Angiopathy; Asthenia; Aura; Brain Scan Abnormal; Contusion; Dyskinesia; Fatigue; Fear; Feeling Abnormal; Generalised	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ambien			C				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2003	3940924	EXPEDITED (15-DAY)	Y		S03-IRL-01600-01		50 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melanocytic Naevus	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2003	3946906	EXPEDITED (15-DAY)	Y	HO	S03-USA-01827-01		121 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis Viral; Maternal Exposure During Breast Feeding; Metabolic Acidosis	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2003	3862676	EXPEDITED (15-DAY)	Y	OT	S02-USA-02581-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2003	3940879	EXPEDITED (15-DAY)	Y	OT	S03-USA-01582-01		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Focal Dyscognitive Seizures; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Depakote			C				Not Reported
	Tegretol Xr			C				Not Reported
	Gabitril			C				Not Reported
	Dilantin			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2003	5946618	EXPEDITED (15-DAY)	Y	OT	S03-SWE-01919-01		37 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Neoplasm; Hyperprolactinaemia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Fluoxetine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2003	3966572	NON-EXPEDITED	Y	OT	327494		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Pegasys			S	Subcutaneous	1 Per Week; Subcutaneous		Not Reported
	Lexapro			S	Oral	10 Mg Daily; Oral		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S	Oral	2 Per Day; Oral		Not Reported
	Ambien			S	Oral	1 Per Day; Oral		Not Reported
	Phenergan			S		1 Per; Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2003	3948804	EXPEDITED (15-DAY)	Y	OT	S03-USA-02001-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Disorientation; Fatigue; Seizure; Syncope; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Paxil Cr			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Analgisic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2003	3948931	DIRECT	N	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Heart Rate Irregular; Nervous System Disorder; Panic Attack; Sleep Disorder	Paxil			S	Oral	Paxil 20 Mg Oral		Not Reported
	Lexapro			S	Oral	Lexapro 10 Mg Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2003	3949757	DIRECT	N	OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Discomfort; Fluid Retention; Irritability; Nervous System Disorder; Suicidal Ideation; Tension; Thinking Abnormal; Vision Blurred; Weight Increased	Lexapro			S	Oral	One Pill Once Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2003	3919004	EXPEDITED (15-DAY)	Y	DE	S03-UKI-00910-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2003	3936491	EXPEDITED (15-DAY)	Y		S03-USA-01478-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Coordination Abnormal; Dyskinesia; Muscle Spasms; Pupils Unequal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2003	3944153	EXPEDITED (15-DAY)	Y	DE	T03-USA-01694-01		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2003	3951492	DIRECT	N	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Genital Pain; Mucosal Discolouration; Vaginal Disorder; Vaginal Odour	Lexapro			S	Oral	Once Daily Oral		Not Reported
					Oral	Once Daily Oral		
	Singulair			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2003	3951076	DIRECT	Y	HO			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Erythema Multiforme; Hypophagia; Pain; Stevens-Johnson Syndrome; Stomatitis; Tongue Ulceration	Lamictal			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2003	3952732	DIRECT	Y				44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Lexapro			S		10 Mg One Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2003	3953057	DIRECT	Y	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism	Lexapro			S	Oral	1 Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2003	3954981	EXPEDITED (15-DAY)	Y	OT	S03-UKI-02244-01		77 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Insomnia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Pizotifen			C				Not Reported
	Intralgin			C				Not Reported
	Lormetazepam			C				Not Reported
	Fluticasone Propionate\Salmeterol Xinafoate			C				Not Reported
	Atorvastatin			C				Not Reported
	Coracten (Nifedipine)			C				Not Reported
	Peptac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2003	3937358	EXPEDITED (15-DAY)	Y	DE	S03-USA-01477-01		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Drug Interaction	Lexapro			S		10 Mg Qd Po		Not Reported
	Reglan			S				Not Reported

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Seizure	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2003	3955425	EXPEDITED (15-DAY)	Y	OT	S03-USA-02161-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Rash; Somnolence	Lexapro			S		10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2003	3955434	EXPEDITED (15-DAY)	Y	OT	S03-USA-02159-01		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Loss Of Employment	Lexapro			S		10 Mg Qd Po		Not Reported
	Wine			S				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2003	3955439	EXPEDITED (15-DAY)	Y	RI	S03-USA-02127-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Lexapro			S		10 Mg Qd Po		Not Reported
	Prozac			C				Not Reported
	Terbutaline Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2003	3955488	EXPEDITED (15-DAY)	Y	DE	S03-USA-02188-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2003	3955500	EXPEDITED (15-DAY)	Y	OT	T02-USA-03191-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Aenolol			C				Not Reported
	Doxycycline			C				Not Reported
	Depakote (Valproate Semisodium)			C				Not Reported
	Ultram			C				Not Reported
	Hydrocodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2003	3862781	EXPEDITED (15-DAY)	Y	OT	S02-USA-02474-01		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Level Of Consciousness; Dizziness; Drug Withdrawal Syndrome; Dyslexia; Insomnia; Irritability; Memory Impairment; Panic Attack; Seizure; Somnolence	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Buspar			C				Not Reported
	Lisinopril			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2003	3807587	EXPEDITED (15-DAY)	Y	HO, LT	T02-USA-01012-01		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Aspiration; Blood Alcohol Increased; Body Temperature Decreased; Coma; Dilatation Atrial; Drug Level Increased; Eye	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Tylenol			S		See Image See Image		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2003	3941507	EXPEDITED (15-DAY)	Y	OT	T03-USA-01534-01		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Amitriptyline			C				Not Reported
	Bextra			C				Not Reported
	Desyrel			C				Not Reported
	Neurontin			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2003	3951678	EXPEDITED (15-DAY)	Y	LT, RI	S03-USA-02020-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Lexapro			S				Not Reported
	Allegra-D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2003	3952239	EXPEDITED (15-DAY)	Y	HO, LT, RI	S03-USA-02126-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Dissection; Myocardial	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Infarction	Lexapro	S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2003	3958164	EXPEDITED (15-DAY)	Y	OT	S03-UKI-02292-01		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hallucination, Visual; Hypophagia; Insomnia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Thyroxine (Levothyroxine Sodium)			C				Not Reported
	Aumenon (Estradiol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2003	3958209	EXPEDITED (15-DAY)	Y	OT	S03-USA-02310-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2003	3957857	DIRECT	N	HO			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Dehydration; Diarrhoea; Dizziness; Dyspnoea; Hyperhidrosis; Incoherent; Malaise; Micturition Urgency; Migraine; Nausea; Peripheral Coldness; Renal Pain; Somnolence; Tremor; Viral Infection	Lexapro			S	Oral	5mg 1 X Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2003	3959073	EXPEDITED (15-DAY)	Y	DE	S03-IRL-02369-01			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2003	3959299	EXPEDITED (15-DAY)	Y	HO	S03-USA-02420-01		57 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Lotrel			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2003	3959321	EXPEDITED (15-DAY)	Y	HO	S03-USA-02426-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriospasm Coronary; Myocardial Infarction	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Estradiol			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2003	3959323	EXPEDITED (15-DAY)	Y	HO	S03-USA-02395-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Disorientation; Dizziness; Nausea; Serotonin Syndrome	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	3960191	EXPEDITED (15-DAY)	Y	DE	S03-UKI-02368-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Fluanxol (Flupentixol Dihydrochloride)			C				Not Reported
	Temazepam			C				Not Reported
	Bumetanide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	3960516	EXPEDITED (15-DAY)	Y	DE	S03-UKI-02367-01		33 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Mental Disorder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Antabuse			C				Not Reported
	Stelazine			C				Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	3988899	NON-EXPEDITED	Y	OT	S03-USA-02002-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parosmia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Corgard			C				Not Reported
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	3988901	NON-EXPEDITED	Y	HO	S02-USA-03199-03		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Lexapro			S	Oral	20- Mg Qam Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	3988902	NON-EXPEDITED	Y	HO	S03-USA-00665-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Headache	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zoloft			C				Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	3991310	NON-EXPEDITED	Y	HO, OT	S02-USA-03346-01		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Syncope; Ventricular Extrasystoles	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	3991315	NON-EXPEDITED	Y	HO	S03-USA-01026-01		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Thromboplastin Decreased; Hypermagnesaemia; Hyperventilation; Hypocalcaemia; Hypochloraemia; Hypokalaemia; Hypomagnesaemia; Hyponatraemia; Hypophosphataemia; Laboratory Test Abnormal; Leukocytosis; Pollakiuria; Thrombocytosis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prozac			C				Not Reported
	Lipitor			C				Not Reported
	Zantac			C				Not Reported
	Xanax			C				Not Reported
	Compazine			C				Not Reported
	Multivitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	3991318	NON-EXPEDITED	Y	HO	S03-USA-01218-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	4008503	NON-EXPEDITED	N	HO	S03-USA-01599-01		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Injury	Lexapro			S				Not Reported
	Blood Pressure Medications			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	4008506	NON-EXPEDITED	Y	HO	S03-USA-01483-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported
	Desipramine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	4008511	NON-EXPEDITED	Y	OT	S03-USA-01305-01		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2003	4008513	NON-EXPEDITED	Y	HO	S03-USA-01296-01		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthritis; Chest Pain; Hypertonia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Calcium With Vitamin D			C				Not Reported
	Vitamins Nos			C				Not Reported
	Estraderm			C				Not Reported
	Glucosamine			C				Not Reported
	Fish Oil			C				Not Reported
	Vitamin B1			C				Not Reported
	Vitamin E			C				Not Reported
	Aspirin			C				Not Reported
	Seroquel			C				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2003	3902099	EXPEDITED (15-DAY)	Y	OT	S03-USA-00354-01		95 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Cellulitis; Disease Recurrence; Fatigue; Feeling Abnormal; Haemoglobin; Lymphocyte Morphology Abnormal; Platelet Count; Weight Decreased; White Blood Cell Count	Lexapro			S	Oral	5 Mg Qd; Po		Not Reported
	Unspecified Ingredient			C				Not Reported
	Flomax Mr (Tamsulosin Hydrochloride)			C				Not Reported
	Proscar			C				Not Reported
	Sonata			C				Not Reported
	Coreg			C				Not Reported
	Plavix			C				Not Reported
	Bumex			C				Not Reported
	Norvasc			C				Not Reported
	Imdur			C				Not Reported
	Baby Aspirin			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Oxygen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2003	3959683	DIRECT	N	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Crying; Drug Withdrawal Syndrome; Feeling Abnormal; Increased Appetite; Malaise; Maternal Drugs Affecting Foetus; Pregnancy; Weight Increased	Lexapro			S	Oral	20 Mg Once A Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2003	3935650	EXPEDITED (15-DAY)	Y	HO	S03-USA-01402-01		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Electrocardiogram Change; Serotonin Syndrome	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Celexa (Citalopram Hdrobromide)			C				Not Reported
	Levaquin			C				Not Reported
	Solu-Medrol			C				Not Reported
	Neurontin			C				Not Reported
	Synthroid			C				Not Reported
	Ambien			C				Not Reported
	Melatonin			C				Not Reported
	Propranolol			C				Not Reported
	Rocephin			C				Not Reported
	Cetaben			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2003	3956568	EXPEDITED (15-DAY)	Y	HO	S03-USA-02309-01		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2003	3958160	EXPEDITED (15-DAY)	Y	OT	S03-FRA-02288-01		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Oedema; Localised Oedema; Oedema Peripheral; Swelling Face	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2003	3962377	EXPEDITED (15-DAY)	Y	OT	S03-UKI-02432-01		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Gingival Bleeding; Menorrhagia	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2003	3962385	EXPEDITED (15-DAY)	Y	HO	S03-USA-02485-01		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2003	3962633	EXPEDITED (15-DAY)	Y	OT	PHEH2003US04897		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Drugs Affecting Foetus; Maternal Drugs Affecting Foetus	Trileptal			S	Oral	600 Mg, Qd, Oral		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Zoloft			S				Not Reported
	Vitamin B12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2003	3963824	EXPEDITED (15-DAY)	Y	HO, RI	S03-USA-02041-01		65 YR	Female	USA

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Seizure; Tremor	Lexapro			S	Oral	Once Daily Oral		Not Reported
	Remeron			S	Oral	15 Mg Tid Oral		Not Reported

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

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

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2003	3965050	EXPEDITED (15-DAY)	Y	DS, LT	S03-SWI-02587-01		51 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Fluctuation; Depression; Malaise; Nausea; Persistent Depressive Disorder; Suicide Attempt	Cipralex			S				Not Reported
	Glucophage			S				Not Reported
	Insulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2003	3965063	EXPEDITED (15-DAY)	Y	CA, HO	S03-DEN-02599-01		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Anencephaly; Maternal Drugs Affecting Foetus; Maternal Drugs Affecting Foetus	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Vitamins			C				Not Reported
	Gravitamon			C				Not Reported
	Haem-Jern (Iron)			C				Not Reported
	Kenacutan			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2003	3961138	EXPEDITED (15-DAY)	Y	OT	S03-UKI-02374-01		35 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Asthenopia; Dissociation; Dyspnoea; Eye Disorder; Feeling Abnormal; Myalgia; Visual Impairment	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Flixonase			C				Not Reported
	Zopiclone			C				Not Reported
	Diazepam			C				Not Reported
	Piriton (Chlorphenamine Maleate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2003	3963532	EXPEDITED (15-DAY)	Y	DE	S03-ARG-02592-01		23 YR	Male	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2003	3965551	EXPEDITED (15-DAY)	Y	OT	S03-UKI-02651-01		34 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Somnambulism	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2003	3958420	EXPEDITED (15-DAY)	Y	HO	WAES 0306FRA00043		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Bicarbonate Decreased; Disorientation; Hyperhidrosis; Memory Impairment; Tremor	Noroxin			S	Oral		2 DAY	Merck
	Escitalopram Oxalate			S	Oral		36 DAY	Not Reported
	Escitalopram Oxalate			S	Oral		9 DAY	Not Reported
	Cola Nut\Crataegus\Passion Flower\Valerian			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2003	3965235	DIRECT	Y	OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Dizziness; Fatigue; Libido Decreased; Treatment Noncompliance; Verbal Abuse	Lexapro			S	Oral	1 Table Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2003	3967198	EXPEDITED (15-DAY)	Y	RI	03P-163-0222363-00		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Interaction; Fluid Retention; Oedema Peripheral; Pulmonary Hypertension; Tricuspid Valve Incompetence; Weight Increased	Biaxin			S	Oral	500 Mg, 2 In 1 D, Per Oral		Not Reported
	Lexapro			S	Oral	10 Mg, 1 In 1 D, Per Oral		Not Reported
	Fexofenadine Hcl			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Glipizide			C				Not Reported
	Iron			C				Not Reported
	Salbutamol			C				Not Reported
	Fluticasone Propionate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2003	3968386	EXPEDITED (15-DAY)	Y	HO, LT, RI	ZANA001086		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Torsade De Pointes	Zanaflex			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2003	3963856	EXPEDITED (15-DAY)	Y	HO, LT	S03-USA-02555-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anoxia; Coma; Drug Interaction; Kidney Infection; Movement Disorder; Speech Disorder	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Taxol			S				Not Reported
	Cisplatin			S				Not Reported
	Norco			C				Not Reported
	Klonopin			C				Not Reported

Neurontin	C		Not Reported
Oxycontin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2003	3969136	EXPEDITED (15-DAY)	Y	OT	S03-USA-02707-01		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Ganglion Degeneration; Coordination Abnormal; Dysarthria	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celexa			S	Oral	20 Mg Qd Po		Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2003	3969914	EXPEDITED (15-DAY)	Y	HO	03P-009-0222841-00		38 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Generalised Tonic-Clonic Seizure	Akineton			S	Oral	4 Mg, 1 In 1 D, Per Oral		Not Reported
	Clozapine			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
	Haloperidol			S	Oral	See Image		Not Reported
					Oral	See Image		
	Cipralex			S	Oral	See Image		Not Reported
					Oral	See Image		
	Buspirone Hydrochloride			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Enalapril Maleate			C				Not Reported
	Simvastatin			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2003	3970445	EXPEDITED (15-DAY)	Y	HO	S03-AUT-02739-01		38 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electroencephalogram Abnormal; Generalised Tonic-Clonic Seizure; Tongue Biting	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Haldol			S	Oral	20 Mg Qd Po		Janssen
	Haldol			S	Oral	10 Mg Qd Po		Janssen
	Biperiden Hydrochloride			S	Oral	4 Mg Qd Po		Not Reported
	Clozapine			S	Oral	100 Mg Qd Po		Novartis
	Clozapine			S	Oral	250 Mg Qd Po		Novartis
	Clozapine			S	Oral	400 Mg Qd Po		Novartis
	Clozapine			S	Oral	500 Mg Qd Po		Novartis
	Clozapine			S	Oral	400 Mg Qd Po		Novartis
	Clozapine			S	Oral	300 Mg Qd Po		Novartis
	Bespar			C				Not Reported
	Selokeen			C				Not Reported
	Mepril (Enalapril Maleate)			C				Not Reported
	Omeprazole			C				Not Reported
	Tannalbin (Albumin Tannate)			C				Not Reported
	Zocor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2003	3968928	DIRECT	Y	OT			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Flushing; Product Quality Issue; Restlessness; Serotonin Syndrome	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2003	3969744	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Bextra			S				Searle

	Lexapro			S					Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2003	3958216	EXPEDITED (15-DAY)	Y	DE	S03-USA-02324-01		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2003	3971551	EXPEDITED (15-DAY)	Y	OT	S03-USA-02802-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Depakote			C				Not Reported
	Hyoscyamine Sulfate			C				Not Reported
	Reglan			C				Not Reported
	Zantac			C				Not Reported
	Lactulose			C				Not Reported
	Adderall			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2003	3967633	EXPEDITED (15-DAY)	N	LT	GB-GLAXOSMITHKLINE-B0303716A		58 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Lithium Carbonate			S	Oral	800mg At Night	17 MTH	Glaxosmithkline
	Escitalopram Oxalate			S	Oral	20mg Per Day		Not Reported
	Lansoprazole			C	Oral	30mg Per Day		Not Reported
	Levothyroxine Sodium			C	Oral	75ug Per Day		Glaxosmithkline
	Lamotrigine			C	Oral	25mg Twice Per Day		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2003	3969944	DIRECT	Y	OT			27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Prozac			S	Oral	40mg Po Qd		Not Reported
	Lexapro			S	Oral	10mg Po Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2003	3972583	EXPEDITED (15-DAY)	N	OT	S03-USA-02873-01		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Autonomic Neuropathy; Dysuria; Pancreatitis	Lexapro			S		10 Mg Qd Po		Not Reported
	Darvocet-N 100			S		200 Mg Once Po		Not Reported
	Prevacid			C				Not Reported
	Allegra (Fexafenadine Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2003	3959871	EXPEDITED (15-DAY)	Y	OT	S03-USA-02409-01		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eating Disorder; Fatigue; Fibromyalgia; Gait Inability; Myoclonus; Parkinson'S Disease; Sleep Disorder; Somnolence	Lexapro			S		10 Mg Qd Po		Not Reported
	Lexapro			S		15 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Celebrex			C				Not Reported
	Ibuprofen			C				Not Reported
	Hyzaar			C				Not Reported
	Wellbutrin - Slow Release (Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2003	3973736	EXPEDITED (15-DAY)	Y	HO	2003-01176		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyarrhythmia; Bradycardia; Dizziness;	Diazepam			S	Oral	See Image		Watson

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Trismus	Lexapro			S	Oral	10mg 1 Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2003	3975831	EXPEDITED (15-DAY)	Y	LT	S03-UKI-02779-01		58 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Lithium			S	Oral	800 Mg Qd Po		Not Reported
	Lansoprazole			C				Not Reported
	Thyroxine(Levothyroxine Sodium)			C				Not Reported
	Lamotrigine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2003	3920259	EXPEDITED (15-DAY)	Y	OT	S03-USA-00895-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torsade De Pointes; Ventricular Extrasystoles; Ventricular Extrasystoles; Ventricular Tachycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Valium			C				Not Reported
	Potassium Chloride			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2003	3947472	EXPEDITED (15-DAY)	Y	OT	S03-USA-01939-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Petit Mal Epilepsy; Treatment Noncompliance	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Tegretol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2003	3972133	EXPEDITED (15-DAY)	Y	OT	S03-BEL-02783-01		67 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Lexapro			S				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Road Traffic Accident	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2003	3978719	EXPEDITED (15-DAY)	Y	OT	S03-USA-03007-02		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Coumadin			S				Not Reported
	Coumadin			S				Not Reported
	Levaquin			C				Not Reported
	Uniphyl			C				Not Reported
	Digoxin			C				Not Reported
	Acid Blocker (Nos)			C				Not Reported
	Cardiazem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2003	3978730	EXPEDITED (15-DAY)	Y	OT	S03-USA-03007-01		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Coumadin			S				Not Reported
	Coumadin			S				Not Reported
	Aricept (Conepezil Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2003	3972130	EXPEDITED (15-DAY)	Y	LT	S03-UKI-02841-01		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Eye Inflammation	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Enalapril			C				Not Reported
	Atorvastatin			C				Not Reported

Atenolol	C		Not Reported
Omeprazole	C		Not Reported
Dextropopoxyphene/Paracetamol	C		Not Reported
Aspirin (Acetylsalicylic Acid)	C		Not Reported
Isosorbide	C		Not Reported
Paroxetine Hydrochloride	C		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Syncope	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Salbutamol			C				Not Reported
	Beclomethasone (Beclomethasone Dipropionate)			C				Not Reported
	Microgynon			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Amlodipine			C				Not Reported
	Bendrofluazide			C				Not Reported

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

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2003	3964896	EXPEDITED (15-DAY)	Y	DE	S03-USA-02639-01		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Dilantin			C				Not Reported
	Synthroid			C				Not Reported
	Captopril			C				Not Reported
	Lanoxin			C				Not Reported
	Aspirin			C				Not Reported
	Plavix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2003	3971548	EXPEDITED (15-DAY)	Y		S03-USA-02825-01		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Coumadin			C				Not Reported
	Toprol Xl			C				Not Reported
	Aspirin			C				Not Reported
	Restoril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2003	3972131	EXPEDITED (15-DAY)	Y	HO	S03-BEL-02784-01		49 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Amylase Increased; Aspartate Aminotransferase Increased; Blood Glucose Increased; Blood Lactate Dehydrogenase Increased; Blood	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Depakine (Valproate Sodium)			C				Not Reported
	Triazolam			C				Not Reported

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2003	3983566	EXPEDITED (15-DAY)	Y	HO	S03-UKI-03136-01		38 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subarachnoid Haemorrhage	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Seretide Mite			C				Not Reported

	Salbutamol	C	Not Reported
	Fluticasone Propionate\Salmeterol Xinafoate	C	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt	Lexapro			S				Not Reported

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis	Lexapro			S				Not Reported

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

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

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

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

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

Uniphyl	C		Not Reported
Digoxin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2003	3985555	EXPEDITED (15-DAY)	Y	HO	S03-USA-03196-01		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Renal Failure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Norvasc			C				Not Reported
	Atenolol			C				Not Reported
	Klonopin			C				Not Reported
	Flomax			C				Not Reported
	Protonix			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2003	3971584	EXPEDITED (15-DAY)	Y	HO	S03-USA-02706-01		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Anaemia; Antinuclear Antibody Positive; Aspartate Aminotransferase Increased; Autoimmune Disorder; Blood Albumin Decreased; Bone Marrow Failure; Liver Function Test Abnormal; Oedema; Pneumonia; Protein Total Decreased; Serum Ferritin Increased; Thrombocytopenia; Urinary Incontinence; White Blood Cell Count Decreased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celexa			S	Oral	80 Mg, Qd Po		Not Reported
	Valium			C				Not Reported
	Synthroid			C				Not Reported
	Neurontin			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2003	3984192	DIRECT	N	OT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anger; Cosmetic Body Piercing; Delusion; Family Stress; Fatigue; Feeling Abnormal; Hallucinations, Mixed; Insomnia; Intentional Self-Injury; Paraesthesia; Suicidal Ideation	Lexapro			S	Oral	Daily Pill Oral		Not Reported
	Paxil			S	Oral	Daily Pill Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2003	3987208	EXPEDITED (15-DAY)	Y	HO	S03-USA-03197-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Overdose	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2003	3998189	DIRECT	N	RI, OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Caries; Gingival Atrophy	Lexapro			S	Oral	One/Per Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2003	3986049	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lexapro			S				Forest
	Oxycontin			S				Purdue Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2003	3989093	EXPEDITED (15-DAY)	Y	HO	2003031837			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Muscle Spasms; Muscle Spasms	Neurontin			S		2100 Mg (Daily),		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (Daily), Oral		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2003	3969803	EXPEDITED (15-DAY)	Y	DS, LT, RI	03P-013-0222847-00		49 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Coma; Crush Syndrome; Dialysis; Drug Level Decreased; Hyperkalaemia; Obsessive Thoughts; Serotonin Syndrome	Depakene			S	Oral	1000 Mg, 1 In 1 D, Oral		Not Reported
	Sipralexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2003	3990001	EXPEDITED (15-DAY)	Y	HO	S03-USA-03273-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Fluid Retention; Protein Total Decreased; Renal Failure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2003	3983985	EXPEDITED (15-DAY)	Y	HO	S03-USA-03195-01		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2003	3986126	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Gingival Bleeding	Lexapro			S	Oral	10 Mg Po Qd		Forest
	Prometrium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2003	3988941	EXPEDITED (15-DAY)	Y	HO	S03-USA-03353-01		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Necrosis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Imuran			S				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2003	3966014	EXPEDITED (15-DAY)	Y	HO	S03-USA-02648-01		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorea; Insomnia; Mania	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Coumadin			C				Not Reported
	Atenolol			C				Not Reported
	Levoxyl			C				Not Reported
	Pravachol			C				Not Reported
	Plavix			C				Not Reported
	Accupril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2003	3991199	EXPEDITED (15-DAY)	Y	HO, LT	S03-UKI-03364-01		78 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Bendrofluazide			C				Not Reported
	Doxazosin			C				Not Reported
	Fosamax			C				Not Reported
	Calcihew (Calcium Carbonate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2003	5833349	DIRECT	Y	HO			13 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Abilify			S		10mg Daily		Not Reported
	Lexapro			S		10mg Daily		Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2003	3940609	EXPEDITED (15-DAY)	N	OT	S03-USA-01591-01		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Condition Aggravated; Decreased Appetite; Nausea; Pain; Sleep Disorder; Vomiting; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Pravachol			C				Not Reported
	Cozaar			C				Not Reported
	Lopresor			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2003	3987538	EXPEDITED (15-DAY)	Y	HO	WAES 0308USA01626		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2003	3970302	EXPEDITED (15-DAY)	Y	HO	S03-USA-02708-01		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyarrhythmia; Dizziness; Fatigue; Feeling Abnormal; Hypotension; Nausea; Paradoxical Drug Reaction; Sinus Bradycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Diazepam			S		10 Mg Tid		Not Reported
	Belladonna			S		0.4 Mg Once		Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2003	3991312	EXPEDITED (15-DAY)	Y	HO	S03-USA-00781-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hip Fracture; Injury; Suicide Attempt; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2003	3995277	EXPEDITED (15-DAY)	N	HO	S03-USA-03426-01		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Psychiatric Symptom; Vomiting	Lexapro			S	Oral	10 Mg Qhs Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2003	3995281	EXPEDITED (15-DAY)	Y	HO	S03-USA-03464-01		94 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Tequin	C				Not Reported
	Flagyl	C				Not Reported
	Norvasc	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2003	4019637	EXPEDITED (15-DAY)	Y	DS	S03-UKI-03442-01		32 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Speech Disorder	Cipralex			S		10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2003	3993490	DIRECT	Y	DS, HO, LT, RI, OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cognitive Disorder; Crying; Depression; Flashback; Memory Impairment; Nightmare; Speech Disorder; Tremor	Lexapro			S		Once Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2003	3954792	EXPEDITED (15-DAY)	Y	HO	S03-USA-02160-01		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Diverticulitis; Fall; Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Tylenol Extra-Strentgh (Paracetamol)			C				Not Reported
	Lotrel			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Levaquin			C				Not Reported
	Flagyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2003	3994082	DIRECT	N	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dyschezia	Lexapro			S	Oral	10 Mg 1/Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2003	3994171	DIRECT	Y	OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depression; Dizziness; Dyspepsia; Fatigue; Hypoaesthesia; Insomnia; Malaise; Paraesthesia; Somnolence; Weight Increased; White Blood Cell Count Increased	Lexapro			S	Oral	20 Daily Oral		Not Reported
	Wellbutrin			S	Oral	300 Daily Oral		Glaxosmithkline
	Nasonex			C				Not Reported
	Motrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2003	3997930	EXPEDITED (15-DAY)	Y	OT	S03-USA-03556-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2003	3998022	EXPEDITED (15-DAY)	Y	HO	S03-SWI-03571-01		80 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Stupor; Suicide Attempt	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Flurazepam Hydrochloride			S	Oral	80 Tablet Once Po		Not Reported
	Flurazepam Hydrochloride			S	Oral	30 Mg Qd Po		Not Reported

	Prednisone		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2003	3998582	EXPEDITED (15-DAY)	Y	OT	S03-UKI-03572-01		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Maculo-Papular	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lofepramine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2003	3998679	EXPEDITED (15-DAY)	N	OT	S03-USA-03542-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Drugs Affecting Foetus; Medication Error; Overdose	Lexapro			S	Oral	100 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2003	3999430	NON-EXPEDITED	Y	HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-12322251		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2003	3956595	EXPEDITED (15-DAY)	Y	OT	S03-USA-02308-01		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Glucose Increased; Drug Withdrawal Syndrome; Eosinophil Percentage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2003	3997066	DIRECT	N	HO, RI			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Drug Withdrawal Syndrome; Feeling Of Body Temperature Change; Flushing; Headache; Hypokalaemia	Lexapro			S	Oral	1 Per Day Oral		Not Reported
	Adipex-P			S	Oral	1/2 Per Day Oral		Not Reported
	Atacand			C				Not Reported
	Norvasc			C				Not Reported
	Adipex-P			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2003	3998122	DIRECT	Y	HO			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Blood Albumin; Blood Magnesium; Hyponatraemia; Seizure	Trileptal			S	Oral	300 Mg Po Bid	1 WEEK	Not Reported
	Lexapro			S	Oral	25 Mg Po Daily		Not Reported
	Detrol			C				Not Reported
	Trileptal			C				Not Reported
	Clonazepam			C				Not Reported
	Haldol			C				Not Reported
	Pamelor			C				Not Reported
	Zestril			C				Not Reported
	Inderal La			C				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2003	4000950	EXPEDITED (15-DAY)	Y	HO	S03-USA-03622-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Serotonin Syndrome	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Diflucan			C				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Sobril (Oxazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2003	3995289	EXPEDITED (15-DAY)	Y	OT	S03-USA-03512-02		12 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electroencephalogram Abnormal; Petit Mal Epilepsy; Pyrexia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Albuterol			C				Not Reported
	Ritalin - Slow Release (Metylphenidate Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2003	4000702	DIRECT	Y	OT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Tearfulness; Visual Impairment	Lexapro			S	Oral	20 Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2003	4001031	DIRECT	Y	OT			25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Irritability; Memory Impairment; Middle Insomnia; Restlessness; Retrograde Amnesia	Lexapro			S	Oral	10 Mg Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2003	4001023	DIRECT	Y	OT			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2003	4008508	NON-EXPEDITED	Y	OT	S03-USA-01375-01		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Lexapro			S		20 Tablet Once Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2003	4061449	NON-EXPEDITED	Y	OT	S03-USA-02910-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2003	4061518	NON-EXPEDITED	Y	HO	S03-USA-02883-01		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hyponatraemia	Lexapro			S		10 Mg Qd Po		Not Reported
	Captopril			C				Not Reported
	Xanax			C				Not Reported
	Atenolol			C				Not Reported
	Pepcid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2003	4061576	NON-EXPEDITED	Y	HO	S03-USA-03010-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Lexapro			S		10 Mg Qd Po		Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2003	4061614	NON-EXPEDITED	N	HO	S03-USA-03352-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis	Lexapro			S		20 Mg Qd Po		Not Reported
	Lexapro			S		10 Mg Qd Po	4 DAY	Not Reported
	Seroquel			C				Not Reported
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2003	4061697	NON-EXPEDITED	N	OT	S03-USA-03253-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Intentional Overdose; Suicide Attempt	Lexapro			S		10 Mg Qd Po		Not Reported
	Xanax			S		26 Tablet Once Po	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2003	4061725	NON-EXPEDITED	N	OT	S03-USA-02017-01		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphemia; Memory Impairment; Tremor	Lexapro			S		20 Mg Qd Po	11 DAY	Not Reported
	Amoxicillin			C				Not Reported
	Darvocet-N 100			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2003	4061799	NON-EXPEDITED	Y	HO	S02-USA-02963-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Lexapro			S		20 Mg Qd Po		Not Reported
	Lexapro			S		10 Mg Once Po	2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2003	3995291	EXPEDITED (15-DAY)	Y	OT	S03-USA-03513-01		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Agitation; Alcohol Withdrawal Syndrome; Dehydration; Dizziness; Feeling Abnormal; Feeling Hot; Hyperhidrosis; Loss Of Consciousness; Nausea; Postictal State; Rash Pruritic; Retrograde Amnesia; Seizure; Serotonin Syndrome; Somnolence; Tongue Biting; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported
	Allegra			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2003	4004737	DIRECT	Y	RI				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cold Sweat; Heart Rate Increased	Lexapro			S	Oral	10 Mg Po Qd		Not Reported
	Thiamine			C				Not Reported
	Folic Acid			C				Not Reported
	Valproic Acid			C				Not Reported
	Acetaminophen			C				Not Reported
	Oxazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2003	4008398	EXPEDITED (15-DAY)	Y	HO	S03-SWI-03871-01		27 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Screen Positive; Loss Of Consciousness; Mental Disorder; Overdose; Oxygen Saturation Decreased; Somnolence; Suicide Attempt	Cipralex			S		3 Tablet Once Po		Not Reported
	Cipralex			S				Not Reported
	Bromazepam			S		Tablet Once Po		Not Reported
	Bromazepam			S				Not Reported
	Diphenhydramine\Lorazepam			S				Not Reported
	Diphenhydramine\Lorazepam			S		Tablet Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2003	3988975	EXPEDITED (15-DAY)	Y	HO	S03-USA-03323-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Faeces Discoloured; Fatigue; Nausea	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2003	4001070	EXPEDITED (15-DAY)	Y	DE	S03-BRA-03664-01		53 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2003	4008938	EXPEDITED (15-DAY)	Y	OT	S03-USA-03835-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuritis	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2003	4160678	EXPEDITED (15-DAY)	Y	HO	S03-USA-03893-01		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Blood Creatine Phosphokinase Increased; Blood Glucose Increased; Blood Potassium Decreased; Chest Pain; Diplopia; Dizziness; Hyperhidrosis; Tachycardia; Tattoo; White Blood Cell Count	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported

Increased

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropod Bite; Aspartate Aminotransferase Increased; Dehydration; Encephalitis; Musculoskeletal Stiffness; Myalgia; Nausea; Pyrexia; Thrombocytopenia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Quinine Sulfate			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Loss Of Consciousness; Seizure	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Depakote			C				Not Reported
	Tegretol			C				Not Reported
	Tegretol			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Inappropriate Antidiuretic Hormone Secretion; Mental Status Changes; Restlessness	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Hydrochlorothiazide			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Creatinine Increased; Cinchonism; Dehydration; Encephalitis; Myalgia; Thrombocytopenia	Quinine			S				Watson
	Lexapro			S	Oral	10 Mg Daily, Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2003	4061258	NON-EXPEDITED	Y	OT	S02-USA-03279-01		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Epistaxis	Celexa			S	Oral	30 Mg Qd Po		Not Reported
	Celexa			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Nitroglycerin Patch			S		0.4 Mg Q1hr		Not Reported
	Nitroglycerin Patch			S		0.6 Mg Q1hr		Not Reported
	Norvasc			S				Not Reported
	Zaroxolyn			S				Not Reported
	Prinivil			S		40 Mg Qd		Not Reported
	Lasix			S				Not Reported
	Aldactazide			S				Not Reported
	Digoxin			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2003	4010592	EXPEDITED (15-DAY)	Y	LT	S03-UKI-03874-01		38 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2003	4010643	EXPEDITED (15-DAY)	Y	DE	S03-UKI-03957-01		58 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2003	3966022	EXPEDITED (15-DAY)	Y	HO	S03-USA-01403-01		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Asthenia; Blood Pressure Increased; Cerebrovascular Accident; Hemiparesis; Lacunar Infarction	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			S		50 Mg Qd		Not Reported
	Hydrochlorothiazide			C				Not Reported
	Ambien			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2003	3983925	EXPEDITED (15-DAY)	Y	HO	S03-USA-03158-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2003	4011274	EXPEDITED (15-DAY)	Y	OT	S03-USA-03894-02		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Maternal Exposure During Breast Feeding; Neonatal Disorder; Neonatal	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Lexapro			S				Not Reported

Tachypnoea; Weight Gain
Poor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2003	4012151	EXPEDITED (15-DAY)	Y	OT	S03-UKI-03955-01		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoventilation; Loss Of Consciousness; Somnolence; Vomiting	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2003	3985499	EXPEDITED (15-DAY)	Y	OT	S03-USA-03198-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Eye Haemorrhage; Retinopathy	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Desogen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2003	3994038	EXPEDITED (15-DAY)	Y	OT	T03-USA-02443-01		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Bronchospasm; Cough; Discomfort; Drug Hypersensitivity; Erythema; Laboratory Test Abnormal; Musculoskeletal Stiffness; Nasal Congestion; Platelet Count Increased; Rash Pruritic; Serum Sickness; Urticaria; Wheezing	Escitalopram Oxalate			S	Oral	1 Tablet Qd Po		Not Reported
	Placebo			S	Oral	1 Tablet Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2003	4012360	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parasomnia; Somnambulism	Lexapro			S		10 Mg /D		Not Reported
	Amitriptyline			S		200 Mg /D [Long Term]		Not Reported
	Celexa			S		20 Mg /D		Not Reported
	Neurontin			C				Not Reported
	Hydrocodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2003	4014732	EXPEDITED (15-DAY)	Y	OT	S03-IRL-04039-01		15 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2003	4013096	DIRECT	Y	HO			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine; International Normalised Ratio Increased	Coumadin			S	Oral	5 Mg Po Qd		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2003	4012828	DIRECT	Y	HO			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Blood Pressure Increased; Drug Interaction; Heart Rate Increased	Linezolid			S	Intravenous (not otherwise specified)	600mg Q12h Intravenous		Not Reported
	Lexapro			S	Oral	10 Mg Q24 Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2003	3976750	EXPEDITED (15-DAY)	Y	OT	S03-FRA-02869-01		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Inipomp			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2003	4000965	EXPEDITED (15-DAY)	Y	HO	S03-USA-03626-01		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Oedema	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lasix			S				Not Reported
	Zaroxolyn			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2003	4006569	EXPEDITED (15-DAY)	Y	OT	S03-USA-03747-01		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis Viral; Insomnia; Lymphocyte Count Increased; Nausea; Pyrexia; Renal Pain; Retching; Somnolence; Vomiting	Lexapro			S	Oral	10 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2003	4010591	EXPEDITED (15-DAY)	Y	OT	S03-IRL-03876-01		21 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Decreased Appetite; Urinary Incontinence	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2003	4013283	DIRECT	Y	HO			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Insomnia; Lethargy; Nausea; Palpitations; Tachycardia; Vomiting	Remeron			S	Oral	15 Every Day Oral		Organon
	Lexapro			S	Oral	10 Every Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2003	4013299	DIRECT	Y	OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nervous System Disorder	Effexor Xr			S	Oral	37.5 To 2 Times Oral		Wyeth Ayerst
	Lexapro			S	Oral	10mg Once A Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2003	4015815	EXPEDITED (15-DAY)	Y	OT	S03-USA-04079-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2003	4015816	EXPEDITED (15-DAY)	Y	HO	S03-USA-04029-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Postictal State	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2003	4015818	EXPEDITED (15-DAY)	Y	LT	S03-USA-04019-02		5 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Neonatal Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2003	4015871	EXPEDITED (15-DAY)	Y	OT	S03-BRA-04045-01		19 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Loss Of Consciousness; Overdose; Suicide Attempt; Tachycardia	Lexapro			S	Oral	60 Mg Once Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zoloft			C				Not Reported
	Rivotril (Clonazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2003	3963816	EXPEDITED (15-DAY)	Y	OT	S03-USA-02530-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2003	4000130	EXPEDITED (15-DAY)	N	RI	S03-USA-03617-01		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Caries; Gingival Recession	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2003	4017566	EXPEDITED (15-DAY)	Y	OT	S03-USA-04120-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Nausea; Serotonin Syndrome	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Ambien			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2003	4017581	EXPEDITED (15-DAY)	Y	OT	S03-USA-04098-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2003	4063593	NON-EXPEDITED	N	OT	2003171096US		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Xanax			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	10 Mg, Qd, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2003	4018170	EXPEDITED (15-DAY)	Y	OT	S03-UKI-04172-01		36 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome	Cipralex			S	Oral	1 Qd Po		Not Reported
	Calcipotriol			C				Not Reported
	Hyoscyamine Hydrobromide			C				Not Reported
	Paroxetine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2003	4018612	EXPEDITED (15-DAY)	Y	OT	S03-USA-03450-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; Hypomania; Increased Appetite;	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Galactorrhoea	Lexapro	S	Oral	10mg Once Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2003	4019390	EXPEDITED (15-DAY)	Y	OT	S03-USA-04094-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incision Site Haemorrhage; Platelet Aggregation Abnormal; Post Procedural Haemorrhage; Post Procedural Haemorrhage; Vaginal Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			S				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2003	4019399	EXPEDITED (15-DAY)	Y	OT	S03-USA-04122-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2003	4019407	EXPEDITED (15-DAY)	Y	OT	S03-USA-04123-01		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Insomnia; Tooth Injury; Trismus	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Cozaar			C				Not Reported
	Norvasc			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Nasacort			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2003	4015003	DIRECT	N	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Feeling Of Body Temperature Change; Hyperhidrosis; Neck Pain; Speech Disorder; Thinking Abnormal	Lexapro			S	Oral	One Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2003	4008924	EXPEDITED (15-DAY)	Y	OT	T03-USA-03803-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Generalised Tonic-Clonic Seizure; Glossodynia; Hypoaesthesia; Respiratory Rate Increased; Sensory Disturbance; Skin Abrasion; Tongue Biting; Tongue Disorder; Treatment Noncompliance	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Librax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2003	4020050	EXPEDITED (15-DAY)	Y	DE	S03-USA-04055-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level Increased; Completed Suicide	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S				Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Supraventricular Tachycardia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2003	4017716	DIRECT	N				66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Back Pain; Chills; Drooling; Eye Irritation; Gastrooesophageal Reflux Disease; Hallucination; Headache; Hyperhidrosis; Hypoaesthesia Oral; Oedema Peripheral; Pain; Palpitations; Pruritus Generalised; Restless Legs Syndrome; Skin Ulcer; Vision Blurred	Lexapro			S		10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2003	4015861	EXPEDITED (15-DAY)	Y	OT	S03-UKI-04033-01		44 YR	Male	UKR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Propantheline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2003	4017024	DIRECT	Y	HO			92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Blood Chloride Decreased; Blood Sodium Decreased; Dizziness; Pco2 Decreased; Vomiting	Lexapro			S	Oral	10mg Qd Oral		Forest
	Levothroid			C				Not Reported
	Celebrex			C				Not Reported
	Fosamax			C				Not Reported
	Hctz			C				Not Reported
	Xanax			C				Not Reported
	Norvasc			C				Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Somnolence	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Keppra			C				Not Reported
	Clonazepam			C				Not Reported
	Synthroid (Levothryoxine Sodium)			C				Not Reported
	Lupron			C				Not Reported
	Vinblastine			C				Not Reported

Multi-Vitamin	C		Not Reported
Vitamin C	C		Not Reported
Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2003	3981232	EXPEDITED (15-DAY)	N	OT	S03-USA-03102-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Deja Vu; Fatigue; Petit Mal Epilepsy	Lexapro			S	Oral	10 Mg, Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Dilantin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2003	4026816	EXPEDITED (15-DAY)	Y	OT	S03-USA-04353-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Reglan			S				Not Reported
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2003	4027548	EXPEDITED (15-DAY)	Y	DE	S03-USA-04388-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2003	4028517	EXPEDITED (15-DAY)	Y	OT	S03-UKI-04344-01		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

Dothiepin	C			Not Reported
Zolpidem	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2003	4029062	EXPEDITED (15-DAY)	Y	OT	S03-USA-04080-01		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Asthenia; Fatigue; Hepatitis B	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2003	4011048	EXPEDITED (15-DAY)	Y	HO, LT	S03-USA-03926-01		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Decreased Appetite; Guillain-Barre Syndrome; Overdose; Respiratory Arrest; Respiratory Depression; Somnolence	Lexapro			S		10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2003	3964536	EXPEDITED (15-DAY)	Y	HO, LT	S03-USA-02601-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged; Torsade De Pointes	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zanaflex			S				Not Reported
	Zanaflex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2003	4028719	EXPEDITED (15-DAY)	Y	HO	S03-SWE-04409-01		76 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Infection; Toxic Epidermal Necrolysis	Cipralex	S	Not Reported
	Allopurinol	S	Not Reported
	Tramadol Hydrochloride	S	Not Reported
	Selokeen	C	Not Reported
	Furosemide	C	Not Reported
	Tamoxifen Citrate	C	Not Reported
	Celebra "Pfizer" (Celecoxib)	C	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Road Traffic Accident; Seizure	Lexapro			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lexapro			S		Tablet		Not Reported
	Celexa			S				Not Reported

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

GLAXOSMITHKLINE-A0413937A

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Decreased	Lexapro			S	Oral	20 Mg Po Qd		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Vision Blurred	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Tramadol Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2003	4033660	EXPEDITED (15-DAY)	Y	OT	S03-UKI-04499-01		70 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Hallucination, Visual	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Stemetil "Aventis Pharma" (Prochlorperazine)			C				Not Reported
	Ziimovane (Zopiclone)			C				Not Reported
	Innovace (Enalaprill Maleate)			C				Not Reported
	Losec (Omeprazole)			C				Not Reported
	Plendil			C				Not Reported
	Qvar (Beclometasone Dipropionate)			C				Not Reported
	Paramol-118			C				Not Reported
	Ventolin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2003	4000943	EXPEDITED (15-DAY)	Y	HO, OT	S03-BRA-03652-01		30 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Blister; Oropharyngeal Blistering; Thrombocytopenia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2003	4014764	EXPEDITED (15-DAY)	Y	OT	S03-USA-04018-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Singulair			C				Not Reported
	Nasacort			C				Not Reported
	Allegra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2003	4035257	EXPEDITED (15-DAY)		HO	HQWYE542027OCT03		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin; Intentional Overdose; Suicide Attempt	Serax			S	Oral	"Excessive Ingestion" (Dose Unknown) Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	10 Mg 1 X Per 1 Day Oral		Not Reported
	Lexapro			S		20 Mg 1x Per 1 Day		Not Reported
	Neurontin			S		300 Mg 3x Per 1 Day		Not Reported
	Neurontin			S		'Excessive Ingestion" (Dose Unknown)		Not Reported
	Corgard			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2003	4035484	EXPEDITED (15-DAY)	Y	DS, HO, LT	S03-SWI-04574-01		40 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cachexia; Loss Of Consciousness; Miosis; Respiratory Rate Increased; Thrombocytopenia; Toxicologic Test Abnormal	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Valproate Sodium			S	Oral	500 Mg Qd Po		Not Reported
	Imovane (Zopiclone)			C				Not Reported
	Kapanol (Morphine Sulfate)			C				Not Reported
	Seresta Forte (Oxazepam)			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Benerva (Thiamine Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2003	4029739	DIRECT	Y	DS, LT, RI			19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour;	Lexapro			S				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2003	4033053	DIRECT	Y	HO			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Circulatory Collapse; Syncope	Lexapro			S	Oral	10 Mg Qd Oral		Forest
	Colace			C				Not Reported
	Senokot			C				Not Reported
	Abilify			C				Not Reported
	Multivitamins			C				Not Reported
	Citrucel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2003	4030478	DIRECT	N	DS			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Asthenia; Depressed Mood; Drug Dependence; Drug Withdrawal Syndrome; Feeling Abnormal; Irritability; Pruritus	Lexapro			S		5 Mg 1 Time Dai		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2003	4036706	EXPEDITED (15-DAY)	Y	OT	SUSI-2003-00426		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Delusional Disorder, Persecutory Type; Drug Interaction; Hallucination, Visual; Heart Rate Increased;	Adderall Xr			S		20 Mg, 1x/Day, Qd		Not Reported
	Lexapro			S		10 Mg, , 1x/Day, Qd		Not Reported

Social Avoidant Behaviour

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2003	4032188	DIRECT	Y	RI			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism; Spontaneous Penile Erection	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported
	Trazodone Hydrochloride			S	Oral	50 Mg Hs-One T Oral		Not Reported
	Mylanta			C				Not Reported
	Bisacodyl			C				Not Reported
	Nicorette			C				Not Reported
	Ibuoprofen			C				Not Reported
	Imitrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2003	4032189	DIRECT	Y				47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Aggression; Alcohol Use; Amnesia; Apathy; Back Pain; Drug Withdrawal Syndrome; Loss Of Consciousness; Suicidal Ideation	Lexapro			S	Oral	10 Mg Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2003	3905298	EXPEDITED (15-DAY)	Y	HO	S03-USA-00415-01		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anaemia; Asthenia; Balance Disorder; Coordination Abnormal; Dysphonia; Dyspnoea; Dyspnoea Exertional; Fatigue; Gait	Lexapro			S				Not Reported
	Acyclovir			S				Not Reported
	Cozaar			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Flomax Mr (Tamsulosin Hydrochloride)			C				Not Reported

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2003	4038537	EXPEDITED (15-DAY)	Y	DE	S03-UKI-04745-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2003	4038907	EXPEDITED (15-DAY)	Y	HO	S03-USA-04755-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Hepatitis; Hepatomegaly; Pruritus	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2003	4039042	EXPEDITED (15-DAY)	N	HO	S03-USA-04754-01		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Dry Mouth; Polydipsia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Metoprolol			C				Not Reported
	Tamoxifen Citrate			C				Not Reported
	Diovan			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2003	4034004	NON-EXPEDITED	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-12416723		2 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose	Abilify			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2003	4034441	DIRECT		HO			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Heart Rate Increased	Lexapro			S	Oral	10 Mg 1 Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2003	4034471	DIRECT	Y	HO			12 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory; Paranoia	Lexapro			S	Oral	40 Mg Every Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2003	4035580	DIRECT	Y	HO, LT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Lexapro			S	Oral	1 Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2003	4036511	DIRECT	Y	DS			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Hypoaesthesia; Hypoaesthesia Oral; Paraesthesia; Polyneuropathy; Rash Maculo-Papular; Sensory Loss	Lexapro			S		Once 10 Mg Am	4 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2003	3976614	EXPEDITED (15-DAY)	Y	HO	S03-USA-02912-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Mental Status Changes; Paraesthesia; Viral Infection; White Blood Cell Count Decreased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2003	3994061	EXPEDITED (15-DAY)	Y	HO	S03-USA-03538-01		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Hepatitis	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2003	4008955	EXPEDITED (15-DAY)	Y	DE	S03-USA-03768-01		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lisinopril			C				Not Reported
	Glucovance			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2003	4035983	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lexapro			S		Tablet		Not Reported
	Loxitane			S		Capsules		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2003	4041181	EXPEDITED (15-DAY)	Y	DE	S03-USA-04763-01		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2003	4041198	EXPEDITED (15-DAY)	Y	HO, OT	S03-USA-04762-01		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Stenosis; Aortic Aneurysm; Arteriosclerosis Coronary Artery; Atrophy; Balance Disorder; Cardiomegaly; Dysuria; Fall; Gait Disturbance; Gait Disturbance; Hypochloraemia; Inappropriate Antidiuretic Hormone Secretion; Osteoarthritis; Pain; Physical Examination Abnormal; Spinal Osteoarthritis; Spinal Stenosis; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prevacid			C				Not Reported
	Lopressor			C				Not Reported
	Norvasc			C				Not Reported
	Lipitor			C				Not Reported
	Acetaminophen\Hydrocodone Bitartrate			C				Not Reported
	Ascriptin			C				Not Reported
	Lidoderm(Lidocaine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2003	4041200	EXPEDITED (15-DAY)	Y	RI, OT	S03-USA-04759-01		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Hypercoagulation; Pelvic Pain; Thrombophlebitis Superficial; Varicose Vein	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2003	4036891	DIRECT	Y	DS			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Hypoaesthesia Oral; Orgasm Abnormal; Paraesthesia; Polyneuropathy; Rash Maculo-Papular	Lexapro			S		Once 10 Mg Am	4 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2003	4041804	EXPEDITED (15-DAY)	Y	OT	S03-UKI-04822-01		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Condition Aggravated; Constipation; Diarrhoea Haemorrhagic	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Clotrimazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2003	4041805	EXPEDITED (15-DAY)	Y	LT	S03-UKI-04817-01		53 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Buspirone			S				Not Reported
	Mirtazapine			S	Oral	15 Mg Po		Not Reported
	Nitrazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2003	6035458	EXPEDITED (15-DAY)	Y	OT	S03-UKI-04827-01		53 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Sunburn	Cipralex			S	Oral	1 Tablet Qd Po		Not Reported

	Kliovance	C	Not Reported
	Propranolol Hydrochloride	C	Not Reported
	Olanzapine	C	Not Reported
	Betnovate (Betamethasone)	C	Not Reported
	Unspecified Ingredient	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2003	4038249	DIRECT	Y	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Drugs Affecting Foetus; Maternal Drugs Affecting Foetus	Lexapro			S	Oral	1 Tablet Oral		Not Reported
	Trazodone Hydrochloride			S	Oral	1 Tablet Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2003	4038781	EXPEDITED (15-DAY)	Y	HO	S03-BEL-04679-01		82 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall; General Physical Health Deterioration; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Tenormin			C				Not Reported
	Lorazepam			C				Not Reported
	Movicol			C				Not Reported
	Omeprazole			C				Not Reported
	Risperidone			C				Not Reported
	Oxybutynin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2003	4040481	DIRECT	Y	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Disorder; Sensory Disturbance	Lexapro			S	Oral	1 Tab Po Qd		Not Reported
	Aciphex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2003	3987985	EXPEDITED (15-DAY)	Y	DE	S03-IRL-03292-01		60 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2003	3995655	EXPEDITED (15-DAY)	Y	DE	S03-IRL-03508-01			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2003	4027771	EXPEDITED (15-DAY)	Y	HO	S03-GER-04340-01		30 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Restlessness; Suicidal Ideation	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipramil (Citalopram Hydrochloride)			C				Not Reported
	Lorazepam			C				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2003	4043536	EXPEDITED (15-DAY)	Y	CA	S03-UKI-04904-01		34 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anembryonic Gestation; Maternal Exposure During Pregnancy	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2003	4014205	EXPEDITED (15-DAY)	Y	OT	S03-USA-04011-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Ecchymosis; Somnolence	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported
	Adderall			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2003	4044642	EXPEDITED (15-DAY)	Y	DS	S03-SWI-04930-01		34 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Decreased Appetite; Parosmia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2003	4044741	EXPEDITED (15-DAY)	Y	OT	S03-UKI-04921-01		59 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Amitriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2003	4045303	EXPEDITED (15-DAY)	Y	HO	HQWYE311226NOV03		83 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Depression;	Venlafaxine Hydrochloride			S	Oral Oral	See Image Oral See Image Oral		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2003	4041402	DIRECT		OT			18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Abnormal	Lexapro			S	Oral	10 Mg 1/2 X 4 D 1 Oral		Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agoraphobia; Claustrophobia; Dizziness; Loss Of Personal Independence In Daily Activities; Panic Attack; Somnambulism; Weight Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Intentional Overdose; Loss Of Consciousness; Seizure; Suicide Attempt	Effexor Xr			S	Oral	Overdose Amount, Unknown; Oral		Not Reported
	Atenolol			S		Overdose Amount Unknown		Not Reported

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2003	3990154	EXPEDITED (15-DAY)	Y	OT	S03-USA-03382-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2003	4024405	EXPEDITED (15-DAY)	Y	HO, LT	S03-USA-04275-01		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Atrioventricular Block First Degree; Atrioventricular Block Second Degree; Band Neutrophil Count Increased; Bronchitis; Bundle Branch Block Right; Dehydration; Diarrhoea; Gastritis Viral; Gastrooesophageal Reflux Disease; Haematocrit Decreased; Hand Fracture; Headache; Injury; Lymphocyte Count Decreased; Monocyte Count Increased; Nasopharyngitis; Neutrophil Count Decreased; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2003	4047265	EXPEDITED (15-DAY)	Y	OT	S03-USA-03828-03		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Blood Potassium Decreased	Lexapro	S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2003	4047429	EXPEDITED (15-DAY)	N	OT	S03-USA-04848-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Fall; Generalised Tonic-Clonic Seizure; Tongue Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Verelan (Verapamil Hydrochloride)			C				Not Reported
	Singulair			C				Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2003	4047514	EXPEDITED (15-DAY)	Y	HO	S03-USA-04961-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis; Platelet Count Decreased	Lexapro			S		10mg Pd Po		Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Prilosec			C				Not Reported
	Percocet			C				Not Reported
	Atenolol			C				Not Reported
	Clarinex			C				Not Reported
	Patanol			C				Not Reported
	Serevent Diskus			C				Not Reported
	Pulmicort Flexhaler			C				Not Reported
	Flexeril (Cloclobenzaprine Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2003	4047768	EXPEDITED (15-DAY)	N	OT	S03-USA-05039-01		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Alcohol Interaction; Alcohol	Lexapro			S				Not Reported
	Alcohol			S				Not Reported

Poisoning; Legal Problem;
Road Traffic Accident

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2003	3991317	NON-EXPEDITED	Y	HO	S03-USA-01206-01		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Trazodone Hydrochloride			S		50 Mg Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2003	4076394	NON-EXPEDITED	Y	OT	S03-USA-03891-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Mania	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2003	4076397	NON-EXPEDITED	Y	OT	S03-USA-04012-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Hydrochlorothiazide			C				Not Reported
	Hyzaar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2003	4076406	NON-EXPEDITED	Y	HO	S03-USA-04521-01		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2003	4076408	NON-EXPEDITED	Y	HO	S03-USA-04183-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2003	4076410	NON-EXPEDITED	Y	HO	S03-USA-04180-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lots Of Medication			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2003	4076412	NON-EXPEDITED	N	RI	S03-USA-04146-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Vision Blurred	Lexapro			S				Not Reported
	Celexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2003	4076896	NON-EXPEDITED	Y	DE	S03-USA-03784-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2003	4076910	NON-EXPEDITED	N	OT	S03-USA-03628-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal;	Lexapro			S				Not Reported
Insomnia; Weight	Remeron			S				Not Reported
Increased	Remeron			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2003	4076926	NON-EXPEDITED	Y	HO	S03-USA-03623-01		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Norvasc			C				Not Reported
	Synthroid			C				Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2003	4048511	EXPEDITED (15-DAY)	Y	OT	S03-USA-05002-01		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Feeling Hot; Muscular Weakness	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2003	4048514	EXPEDITED (15-DAY)	Y	OT	S03-USA-05065-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2003	4024949	EXPEDITED (15-DAY)	Y	HO	S03-GER-04322-01		41 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Extrapyramidal Disorder; Salivary Hypersecretion; Sedation	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lithium			C				Not Reported
	Solian (Amisulpride)			C				Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Agitation; Hallucination, Auditory; Headache; Insomnia; Pollakiuria; Trismus	Lexapro		S	Oral	1 Tab Daily Oral	Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Confusional State; Headache; Myalgia; Serotonin Syndrome	Wellbutrin	S	300mg Per Day		Glaxosmithkline
	Lexapro	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2003	4047539	EXPEDITED (15-DAY)	N	OT	US-GLAXOSMITHKLINE-A0443378A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Headache; Myalgia; Serotonin Syndrome	Wellbutrin			S		300mg Per Day		Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2003	4049495	DIRECT	N	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2003	4054524	EXPEDITED (15-DAY)	Y	OT	S03-USA-05194-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Dizziness; Hallucination; Memory Impairment; Platelet Count Decreased; White Blood Cell Count Decreased	Lexapro			S				Not Reported
	Copegus			S				Not Reported
	Pegasys (Peginterferon Alfa-2a)			S				Not Reported
	Percocet			C				Not Reported
	Valtrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2003	4075817	NON-EXPEDITED	Y	HO	CEL-2003-03429-ROC		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Zaroxolyn			S				Not Reported

	Lasix	S				Not Reported
	Lexapro	S	Oral	10 Mg (10 Mg, Qd, Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2003	4054776	DIRECT	Y	DE			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Hepatic Steatosis	Lexapro			S	Oral	10 Mg One Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2003	4029258	EXPEDITED (15-DAY)	Y	OT	S03-IRL-04345-01		25 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Drug Withdrawal Syndrome; Headache; Insomnia; Thinking Abnormal	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2003	4055703	EXPEDITED (15-DAY)	Y	HO	8004818		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cerebral Infarction; Confusional State; Coordination Abnormal; Cough; Encephalopathy; Extrapyramidal Disorder; Haematocrit Decreased; Hyponatraemia;	Keppra			S	Oral	Po		Not Reported
	Lexapro			S	Oral	50 Mg Po		Not Reported
	Lexapro			S	Oral	20 Mg Po		Not Reported
	Lithium			C				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2003	4055717	EXPEDITED (15-DAY)	Y	HO	S03-USA-05196-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Hypotension; Loss Of Consciousness	Lexapro			S	Oral	40 Mg Once Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2003	4055723	EXPEDITED (15-DAY)	Y	OT	S03-USA-05222-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported
	Ultram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2003	4055933	EXPEDITED (15-DAY)	Y	OT	S03-UASA-04291-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Retinal Oedema; Eye Haemorrhage; Hyperhidrosis; Intraocular Pressure Increased; Open Angle Glaucoma; Retinal Haemorrhage; Vision Blurred	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported
	Valium			C				Not Reported
	Neurontin			C				Not Reported
	Insulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2003	4055939	EXPEDITED (15-DAY)	Y	OT	S03-UKI-05258-01		30 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2003	4020691	EXPEDITED (15-DAY)	Y	DS, OT	S03-USA-04165-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Condition Aggravated; Muscle Spasms; Tardive Dyskinesia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2003	4041178	EXPEDITED (15-DAY)	Y	DE	S03-USA-04761-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Obsessive-Compulsive Disorder	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported
	Ambien			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2003	4059260	EXPEDITED (15-DAY)	Y	HO	S03-USA-05190-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Confusional State; Hyponatraemia; Urosepsis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Protonix			C				Not Reported
	Detrol			C				Not Reported
	Dilantin			C				Not Reported
	Neurontin			C				Not Reported
	Klonopin			C				Not Reported
	Flexeril			C				Not Reported

	Megace	C		Not Reported
	Darvocet	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2003	4059263	EXPEDITED (15-DAY)	Y	HO	S03-USA-05300-01		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Antibodies Positive; Cardiolipin Antibody Positive; Deep Vein Thrombosis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2003	4073674	NON-EXPEDITED	Y	HO	HQWYE909629SEP03		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose; Serotonin Syndrome	Effexor Xr			S	Oral	Overdose Amount Unknown, Oral		Not Reported
	Lexapro			S	Oral	Overdose Amount Unknown, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2003	4059540	EXPEDITED (15-DAY)	Y	HO	S03-USA-05299-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplastic Anaemia; Bone Marrow Failure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alesse 28			S		1 Tablet Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2003	4059557	EXPEDITED (15-DAY)	N	OT	S03-USA-05295-01		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Dissociation; Disturbance In Attention; Drug Ineffective; Drug Withdrawal Syndrome; Feeling Abnormal; Migraine; Nausea	Zoloft			S	Oral	Varied Per Mornin Oral		Not Reported
	Paroxetine Hydrochloride			S	Oral	5-60 Mg''S Per Mornin Oral		Not Reported
	Lexapro			S	Oral	Varied Per Morning Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2004	4027543	EXPEDITED (15-DAY)	Y	OT	S03-USA-03493-01		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Blood Triglycerides Increased; Body Mass Index Increased; Cholelithiasis; High Density Lipoprotein Decreased; Type 2 Diabetes Mellitus	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2004	4045440	EXPEDITED (15-DAY)	Y	OT	S03-USA-04960-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Effexor			S		75 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2004	4066359	DIRECT	N	RI			10 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2004	4057848	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0422162A		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Wellbutrin			S	Oral			Glaxosmithkline
	Lexapro			S	Oral	10mg Unknown		Not Reported
	Buspar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2004	4057859	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0422844A		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Wellbutrin			S	Oral	100mg Twice Per Day		Glaxosmithkline
	Lexapro			S	Unknown	20mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2004	4059546	EXPEDITED (15-DAY)	Y	HO	S03-USA-05302-01		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Diarrhoea; Electrocardiogram Qt Prolonged; Inappropriate Antidiuretic Hormone	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Biaxin			S				Not Reported
	Reglan (Metoclompramide)			C				Not Reported
	Cipro			C				Not Reported

Secretion; Vomiting	Colchichine (Colchicine)	C		Not Reported
	Amikacin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2004	4011272	EXPEDITED (15-DAY)	Y	HO	S03-USA-03925-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Treatment Noncompliance; Urine Ketone Body Present	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2004	4019386	EXPEDITED (15-DAY)	Y	HO	S03-USA-04093-01		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Pulmonary Embolism	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Risperdal			S		2.5 Mg Qd		Not Reported
	Lithium			S		1500 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2004	4035103	EXPEDITED (15-DAY)	Y	OT	S03-USA-04545-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Disorientation; Dizziness; Fall; Fatigue; Hypersomnia; Hypoglycaemia; Loss Of Consciousness; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2004	4054516	EXPEDITED (15-DAY)	Y	HO	S03-USA-05139-01		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Bradycardia; Cold Sweat; Fibrin D Dimer Increased; Syncope	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Carafate			C				Not Reported
	Fosamax			C				Not Reported
	Protonix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2004	4062353	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0401802A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Tremor	Wellbutrin			S	Oral			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2004	4070279	EXPEDITED (15-DAY)	Y	RI	S04-USA-00022-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Condition Aggravated	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2004	4091655	NON-EXPEDITED	Y	OT	A03200300177		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Demerol			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported
	Ativan			S		3 Mg Qd Unknown		Not Reported
	Vicodin			S				Not Reported

Nicotine		S	Transdermal	14 Mg Qd Transdermal		Not Reported
Tylenol		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2004	4071781	DIRECT	N	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Drug Ineffective; Pruritus Generalised	Lexapro			S	Oral	10 Mg 1x Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2004	4041202	EXPEDITED (15-DAY)	Y	HO	S03-USA-04711-01		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Crying; Delirium; Incoherent; Meningitis Viral; Nausea	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2004	4074076	EXPEDITED (15-DAY)	Y	HO	HQWYE057005JAN04		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplastic Anaemia; Bone Marrow Failure	Alesse 28			S	Oral	1 Tablet Daily, Oral		Not Reported
	Lexapro			S	Oral	10 Mg Daily, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2004	4074631	EXPEDITED (15-DAY)	N	OT	S04-USA-00095-01		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Self-Medication; Suicidal Ideation; Treatment	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2004	4067466	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0394874A		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Herpes Simplex	Valtrex			S	Oral			Glaxosmithkline
	Valtrex			S	Oral	500mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2004	4024877	EXPEDITED (15-DAY)	Y	OT	S03-USA-04291-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Retinal Oedema; Hyperhidrosis; Open Angle Glaucoma; Post Procedural Complication; Retinal Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Valium			C				Not Reported
	Kenalog			C				Not Reported
	Neurontin			C				Not Reported
	Insulin Nos			C				Not Reported
	Triphasil-21			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2004	4065720	NON-EXPEDITED	N	OT	2003039759		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Vision Blurred	Relpax			S	Oral	40 Mg (Prn), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2004	4078180	DIRECT	N	HO			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Nausea; Palpitations; Syncope; Vomiting	Lexapro			S				Not Reported
	Effexor			S				Not Reported
	Skelaxin			C				Not Reported
	Prevacid			C				Not Reported
	Pepcid			C				Not Reported
	Premarin			C				Not Reported
	Celebrex			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2004	4078541	EXPEDITED (15-DAY)	N	OT	S04-USA-00023-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hot Flush; Hyperhidrosis; Hypertension; Hypoaesthesia; Stress	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Allegra			C				Not Reported
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2004	4041184	EXPEDITED (15-DAY)	Y	OT	S03-USA-04764-01		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Encephalomalacia; Optic Neuritis; Papilloedema	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2004	4080378	DIRECT		OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching	Lexapro			S	Oral	5 Mg Once Daily Oral		Forest
	Benadryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2004	4055934	EXPEDITED (15-DAY)	Y	DE, HO	S03-UKI-05243-01		83 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction; Transient Ischaemic Attack	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Digoxin			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Paracetamol			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Frusemide			C				Not Reported
	Candesartan			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2004	4081946	EXPEDITED (15-DAY)	Y	HO	04P-163-0247227-00		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Diarrhoea; Electrocardiogram Qt Prolonged; Inappropriate Antidiuretic Hormone Secretion; Vomiting	Biaxin			S				Not Reported
	Lexapro			S	Oral	10 Mg, 1 In 1 D, Per Oral		Not Reported
	Metoclopramide			C				Not Reported
	Ciprofloxacin Hydrochloride			C				Not Reported
	Colchicine			C				Not Reported
	Amikacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2004	3962771	EXPEDITED (15-DAY)	Y	OT	S03-USA-02049-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Increased; Dysarthria; Electroencephalogram Abnormal; Gait Disturbance; Injury; Pulmonary Oedema; Seizure; Syncope; Urinary	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Detrol			C				Not Reported
	Advil			C				Not Reported
	Neurontin			C				Not Reported
	Valium			C				Not Reported
	Serzone			C				Not Reported
	Bextra			C				Not Reported

Incontinence	Nicotine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2004	4008950	EXPEDITED (15-DAY)	Y	OT	S03-USA-03786-01		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cardiac Disorder; Euphoric Mood; Fatigue; Hyperhidrosis; Loss Of Consciousness; Nausea; Seizure; Syncope	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Lithium			C				Not Reported
	Aleve			C				Not Reported
	Aspirin			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Calcium			C				Not Reported
	Vitamin E			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2004	4017553	EXPEDITED (15-DAY)	Y	OT	S03-USA-04121-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2004	4081711	DIRECT	N				39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Abnormal Dreams; Anxiety; Decreased Appetite; Depression; Dizziness; Dysuria; Feeling Abnormal; Feeling Hot; Hallucination, Visual; Heart Rate Increased; Hypoacusis; Hypoaesthesia; Panic	Lexapro			S	Oral	10 Mg 1 Tab Dai Oral		Forest

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

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

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

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

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

	Multi-Vitamin	C		Not Reported
	Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2004	4087521	EXPEDITED (15-DAY)	Y	OT	S04-UK1-00235-01		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dizziness; Hypotension; Malaise	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Atorvastatin			C				Not Reported
	Atenolol			C				Not Reported
	Perindopril			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2004	4087695	EXPEDITED (15-DAY)	Y	LT	S04-USA-00311-01		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Road Traffic Accident	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2004	4087698	EXPEDITED (15-DAY)	Y	OT	S04-USA-00277-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2004	4088056	EXPEDITED (15-DAY)	Y	HO	S04-GER-00302-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2004	4089215	EXPEDITED (15-DAY)	Y	HO, LT, OT	S04-UKI-00245-01		82 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Orthostatic Hypotension	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Nitrazepam			C				Not Reported
	Nasonex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2004	4089833	EXPEDITED (15-DAY)	Y	HO	L04-USA-00370-01		75 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2004	3995285	EXPEDITED (15-DAY)	Y	OT	S03-USA-03512-01		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Electroencephalogram Abnormal; Epilepsy; Haematocrit Decreased; Headache; Loss Of Consciousness; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Risperdal			S		1 Mg Tid		Not Reported
	Risperdal			S		1 Mg Bid		Not Reported
	Trileptal			S		300 Mg Qam		Not Reported
	Trileptal			S		6 00 Mg Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2004	4022969	EXPEDITED (15-DAY)	Y	HO	S03-USA-04218-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Chest Pain; Dyspnoea; Myalgia; Somnolence	Lipitor			S	Oral	10 Mg (Daily), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2004	4089306	DIRECT	Y	OT			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment	Lexapro			S	Oral	20 Mg Daily Oral		Not Reported
	Deseryl			C				Not Reported
	Aciphex			C				Not Reported
	Advair Diskus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2004	4089425	DIRECT	Y	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pruritic	Lexapro			S		10 Mg Qd		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2004	4091874	DIRECT	Y	OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

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

	Multi-Vitamin	C	Not Reported
	Saw Pallmetto	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2004	4093241	EXPEDITED (15-DAY)	Y	LT, RI	S04-USA-00402-01		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2004	4093525	EXPEDITED (15-DAY)	Y	OT	S04-USA-00414-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Driving Ability; Legal Problem; Nystagmus	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2004	4093527	EXPEDITED (15-DAY)	Y	OT	S03-USA-04963-01		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Dementia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2004	4107010	NON-EXPEDITED	Y	HO	A03200300326		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Ambien			S	Oral	75 Mg Qd -Oral		Not Reported
	Ambien			S	Oral	5 Mg Hs - Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd - Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd - Oral		Not Reported
	Bupropion Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2004	4091824	DIRECT	Y	HO			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue	Lexapro			S	Oral	10 Mg Po Qd Prior To Admission		Not Reported
	Vicodin Es			C				Not Reported
	Soma			C				Not Reported
	Benadryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2004	4094237	EXPEDITED (15-DAY)	Y	HO	S04-USA-00471-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Magnesium Decreased; Bronchospasm; Chest Discomfort; Flushing; Loss Of Consciousness; Myoclonus; Nausea; Oedema Peripheral; Restlessness; Swelling Face; Tremor	Lexapro			S				Not Reported
	Premarin			C				Not Reported
	Skelaxin			C				Not Reported
	Tizanidine Hydrochloride			C				Not Reported
	Percocet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2004	4128248	NON-EXPEDITED	Y	RI	345691		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Depression; Hallucination; Hallucination, Auditory; Insomnia; Mental Disorder; Overdose; Platelet Count Decreased; Restlessness; White Blood	Pegasys			S				Not Reported
	Lexapro			S	Oral	Oral		Not Reported

Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2004	4088597	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0412825A		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Insomnia; Rash; Sleep Disorder; Vision Blurred	Lamictal			S	Oral			Glaxosmithkline
	Lexapro			S	Oral			Not Reported
	Seroquel			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2004	4088737	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0431553A		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nystagmus	Lamictal			S	Oral	100mg Per Day		Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Depakote Er			C		500mg Per Day		Not Reported
	Lithobid			C	Unknown	900mg Per Day		Glaxosmithkline
	Reopro			C	Unknown		3 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2004	4088776	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0432782A		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nystagmus	Lamictal			S	Oral	100mg Per Day		Glaxosmithkline
	Lexapro			S	Unknown	10mg Per Day		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Muscle Spasms; Polyuria	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Aldactazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2004	4093305	DIRECT	Y	HO			19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Heart Rate Increased	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2004	4093616	DIRECT	Y	OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Sensory Disturbance	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2004	4093632	DIRECT	Y	LT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Anxiety; Drug Ineffective; Feeling Abnormal; Pain; Restlessness; Self-Injurious Ideation; Suicidal Ideation	Zoloft			S				Not Reported
	Paxil			S				Not Reported
	Lexapro			S				Not Reported
	Prozac			S				Not Reported
	Risperidone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2004	5812608	DIRECT					37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Medication Error; Product Dispensing Error	Lexapro		S	Tabs	Forest
	Levoxyl		S	Tabs	Not Reported
	Xanax		S	Tabs	Mylan

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Concerta	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2004	4095085	DIRECT	Y				51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Insomnia; Tremor	Lexapro			S	Oral	1 Tab Po Qd		Not Reported
	Amaryl			C				Not Reported
	Calcuim			C				Not Reported
	Protonix			C				Not Reported
	Vit C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2004	4100256	EXPEDITED (15-DAY)	Y	OT	ZONI001325		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Echocardiogram Abnormal; Electrocardiogram Qt Prolonged	Zonegran			S	Oral	Oral		Not Reported
	Lexapro			S		20 Mg Daily		Not Reported
	Klonopin			C				Not Reported
	Flexeril			C				Not Reported
	Bextra			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2004	4049728	EXPEDITED (15-DAY)	Y	OT	T03-GER-05096-01		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity Vasculitis	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Celebrex			C				Not Reported
	Omep(Omeprazole)			C				Not Reported
	Palladon(Hydromorphone Hydrochloride)			C				Not Reported
	Metoclopramide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2004	4101842	EXPEDITED (15-DAY)	Y	OT	S04-UKI-00584-01			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicidal Ideation	Cipralex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2004	4095605	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0494728A		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Menstrual Disorder	Wellbutrin Xl			S	Oral	150mg Per Day		Glaxosmithkline
	Lexapro			S		20mg Per Day		Not Reported
	Oxycontin			C				Not Reported
	Benadryl			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2004	4095643	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0496282A		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Wellbutrin Xl			S	Oral	150mg Per Day	1 MTH	Glaxosmithkline
	Lexapro			S			1 MTH	Not Reported
	Advair Diskus			C	Respiratory (inhalation)			Glaxosmithkline
	Flonase			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2004	4035732	EXPEDITED (15-DAY)	Y	LT	T03-GER-04646-01		38 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Food Allergy;	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2004	4102825	EXPEDITED (15-DAY)	Y	HO	S04-USA-00724-01		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Pancreatitis; Pseudocyst	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2004	4038617	EXPEDITED (15-DAY)	Y	HO	T03-GER-04806-01		57 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hypertension; Hypertensive Crisis; Tachycardia; Weight Decreased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2004	4104759	EXPEDITED (15-DAY)	N	OT	2004010841		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Delayed Recovery From Anaesthesia; Depressed Mood; Diplopia; Drug	Neurontin			S	Oral	1800 Mg (600 Mg Tid), Oral		Not Reported
	Topiramate			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S				Not Reported

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Metoclopramide			C				Not Reported
	Zopiclone			C				Not Reported
	Esomeprazole			C				Not Reported
	Bisoprolol			C				Not Reported

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Lactic Acidosis	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Liothyronine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2004	4154131	DIRECT	Y	DE			14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Adderall Xr			S	Oral	20 Mg Q Day Oral		Not Reported
	Lexapro			S	Oral	10 Mg Q Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2004	4106258	DIRECT	N				28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Dizziness; Fatigue; Headache; Nervousness; Tinnitus; Weight Increased	Lexapro			S		10 Mg 1x Per Day 10 Mg 1x Per Day		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2004	4109252	EXPEDITED (15-DAY)	Y	OT	S04-GER-00592-01		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2004	4109265	EXPEDITED (15-DAY)	Y	DE	T04-GER-00858-01		64 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Condition Aggravated; Depression; Restlessness	Cipralex		S	Oral	5 Mg Qd Po	Not Reported
	Remergil (Mirtazapine)		C			Not Reported
	Haldol Decanoate (Haloperidol Decanoate)		C			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Escitalopram Oxalate			S	Oral	30mg Once Daily Oral		Forest

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyponatraemia	Lexapro		S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4109974	EXPEDITED (15-DAY)	Y	HO	S04-SWE-00867-01		78 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Haemoglobin Decreased; Hiatus Hernia; Rectal Haemorrhage	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Plavix			S	Oral	75 Mg Qd Po		Not Reported
	Terazosin Hydrochloride			C				Not Reported
	Pantoprazole Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4110314	EXPEDITED (15-DAY)	Y	OT	T04-GER-00879-01		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Conversion Disorder; Crying; Fear; Nausea; Restlessness; Tremor	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4110457	EXPEDITED (15-DAY)	Y	OT	S04-USA-01056-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4111776	NON-EXPEDITED	Y	HO	S04-USA-00313-01		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4112056	NON-EXPEDITED	N	RI	S03-USA-04962-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Menorrhagia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Tenormin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4113363	NON-EXPEDITED	Y	HO	S03-USA-04556-01		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Gabapentin			C				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4113372	NON-EXPEDITED	Y	HO	S04-USA-00601-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4113373	NON-EXPEDITED	Y	LT, RI	S04-USA-00531-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4113376	NON-EXPEDITED	Y	HO	S04-USA-00278-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Mania	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Lithium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4113380	NON-EXPEDITED	Y	HO	S04-USA-00210-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4113381	NON-EXPEDITED	Y	HO	S04-USA-00065-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2004	4113383	NON-EXPEDITED	Y	HO	S03-USA-05406-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2004	4110645	DIRECT	Y				52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Nausea; Nervous System Disorder	Lexapro			S		5 Mg Od Hs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2004	4112620	EXPEDITED (15-DAY)	Y	HO	S04-USA-01062-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2004	4059168	EXPEDITED (15-DAY)	Y	OT	S03-GER-05270-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Viral Load Increased; Viral Myocarditis	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2004	4103721	EXPEDITED (15-DAY)	Y	DE	S04-USA-00833-01		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Antidepressant Drug Level Increased; Asphyxia; Completed Suicide; Food Interaction; Refusal Of Treatment By Patient	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2004	4105180	EXPEDITED (15-DAY)	Y	HO	S04-NOR-00786-01		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Toxicity To Various Agents; Vomiting	Cipralex			S	Oral	240 Tablet Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2004	4113322	EXPEDITED (15-DAY)	N	OT	S04-USA-01210-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Ventricular Fibrillation; Ventricular Tachycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Amitriptyline			S		50 Mg Qd		Not Reported
	Coumadin			C				Not Reported
	Digoxin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2004	4113882	EXPEDITED (15-DAY)	N	DE	S04-USA-01085-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective; Weight Increased	Lexapro			S				Not Reported
	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2004	4080650	EXPEDITED (15-DAY)	Y	HO	CH-GLAXOSMITHKLINE-B0320863A		80 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Activity; Depressed Level Of Consciousness; Fall; Gait Disturbance; Haemoglobin Decreased; Haemothorax; Rash; Rib Fracture; Sedation; White Blood Cell Count Decreased	Lamictal			S	Oral	100mg Per Day	20 DAY	Glaxosmithkline
	Escitalopram Oxalate			S	Oral	15mg Per Day	77 DAY	Not Reported
	Lorazepam			S	Oral	3mg Per Day	34 DAY	Not Reported
	Olanzapine			S	Oral	5mg Per Day	24 DAY	Not Reported
	Mirtazapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2004	4110317	EXPEDITED (15-DAY)	Y	OT	T04-GER-00940-01		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Erythema; General Physical Health	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Simvastatin			C				Not Reported

Deterioration; Loss Of Consciousness; Petit Mal Epilepsy

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression	Lexapro			S		Unknown		Not Reported
	Xanax			S		Unknown When Neede		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S		2 Daily		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Depression; Dyskinesia; Feeling	Lexapro			S				Not Reported
	Ambien			C				Not Reported
	Xanax			C				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2004	4114712	DIRECT	N	LT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Decreased Appetite; Dizziness; Drug Ineffective; Feeling Abnormal; Indifference; Insomnia; Marital Problem; Suicidal Ideation; Thinking Abnormal; Weight Increased	Lexapro			S	Oral	10 Mg Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2004	4115815	EXPEDITED (15-DAY)	Y	HO	S04-AUS-01156-01		26 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urea Decreased; Electrocardiogram Qt Prolonged; Overdose	Lexapro			S				Not Reported
	Alprazolam			S	Oral	0.25 Mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2004	4114718	DIRECT	N	RI, OT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anger; Anxiety; Apathy; Condition Aggravated; Depression; Diarrhoea; Disturbance In Attention; Fatigue; Feeling	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported
	Lexapro			S	Oral	15 Mg, 20 Mg Daily Oral		Not Reported
	Adderall			C				Not Reported

Abnormal; Irritability;
Nausea; Stress

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2004	4114757	DIRECT	N	DE			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Irritability; Suicide Attempt; Thinking Abnormal	Lexapro			S	Oral	Oral		Not Reported
	Zoloft			S	Oral	Oral		Not Reported
	Lexapro			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2004	4115113	DIRECT	N	LT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Apathy; Condition Aggravated; Depression; Drug Ineffective; Indifference; Sedation; Suicidal Ideation	Lexapro			S	Oral	10 Mg Once Per D Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2004	4115214	DIRECT	N	HO			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Gait Disturbance; Mania; Movement Disorder; Speech Disorder	Lexapro			S	Oral	10 Mg 1 Time Oral		Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anxiety; Dissociation; Dizziness; Dyspnoea; Feeling Abnormal; Feeling Cold; Flushing; Headache; Impaired Work Ability; Panic Attack; Somnolence; Suicidal Ideation; Tachycardia; Thinking Abnormal	Lexapro			S	Oral	One Once Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2004	4119473	EXPEDITED (15-DAY)	Y	DS	S04-UKI-01087-01		86 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Ischaemia; Dyskinesia; Hallucination, Visual; Parkinsonism; Somnolence	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			C				Not Reported
	Ranitidine			C				Not Reported
	Citalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2004	4124335	NON-EXPEDITED	Y		US-JNJFOC-20040104233			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Reminyl			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	10 Mg, 1 In Day, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2004	4102883	EXPEDITED (15-DAY)	Y	HO	DSA_24006_2004		80 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level Increased; Asthenia;	Lorazepam			S	Oral	1.5 Mg Q Day Po		Not Reported

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S		Daily		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Lexapro			S	Oral	20 Mg Po Qd		Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2004	4039039	EXPEDITED (15-DAY)	Y	OT	S03-USA-04385-01		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Blood Testosterone Decreased; Gynaecomastia; Pituitary Tumour Benign; Sinus Polyp	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ritalin			C				Not Reported
	Ritalin Sr			C				Not Reported
	Wellbutrin Sr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2004	4120337	DIRECT	N	DE			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Completed Suicide; Intentional Self-Injury	Lexapro			S	Oral	Once A Day Oral		Not Reported
	Wellbutrin			S	Oral	Once A Day Oral		Not Reported
	Ambien			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Trazidone			C				Not Reported
	Maxalt			C				Not Reported
	Flonase			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2004	4120545	DIRECT	N	OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Dizziness; Fatigue; Headache; Mood Altered; Social Avoidant Behaviour; Suicidal Ideation; Tremor	Lexapro			S	Oral	10 Mg Once Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2004	4123542	EXPEDITED (15-DAY)	N	RI, OT	S04-USA-01551-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Heart Rate Increased; Weight Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2004	4091077	EXPEDITED (15-DAY)	Y	HO	S04-SWI-00443-01		80 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Depressed Level Of Consciousness; Dermatitis Allergic; Drug Level Increased; Fall; Feeding Disorder; Haematocrit Decreased; Haemoglobin Decreased; Haemothorax; Leukopenia; Pruritus; Rash; Rib Fracture; Urinary Tract Infection; Walking Disability	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	15 M Qd Po		Not Reported
	Lamictal			S	Oral	100 Mg Qd Po		Not Reported
	Lamictal			S				Not Reported
	Zyprexa			S	Oral	2.5 Mg Qd Po		Not Reported
	Zyprexa			S	Oral	5 Mg Qd Po		Not Reported
	Remeron			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2004	4121022	DIRECT	Y	OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysgeusia; Food Intolerance; Insomnia; Mania; Mydriasis; Olfactory Nerve Disorder; Palpitations; Parosmia; Sensory Disturbance; Skin	Lexapro			S	Oral	1 Po Q Day		Not Reported
	Clonidine Hydrochloride			C				Not Reported

Burning Sensation

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2004	4095767	EXPEDITED (15-DAY)	Y	OT	S04-USA-00470-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Loss Of Consciousness; Road Traffic Accident	Lexapro			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2004	4098612	EXPEDITED (15-DAY)	Y	HO	S04-USA-00578-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Hepatitis; Jaundice; Protein Total Decreased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Clozapine			S		650 Mg Qd		Not Reported
	Haldol			S		2 Mg Q4hr		Not Reported
	Prevacid			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Surfak Stool Softener			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2004	4107265	EXPEDITED (15-DAY)	Y	OT	S04-USA-00917-01		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Generalised Tonic-Clonic Seizure; Hypersomnia; Status Epilepticus; Treatment Noncompliance	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported
	Lotrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2004	4113374	EXPEDITED (15-DAY)	Y	HO	S04-USA-00400-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypoacusis; Tic	Relpax			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S				Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2004	4116901	EXPEDITED (15-DAY)	Y	OT	S04-USA-01369-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Mania; Maternal Drugs Affecting Foetus; Maternal Drugs Affecting Foetus; Pregnancy	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Albuterol			C				Not Reported
	Topical Cortisone Cream			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2004	4124420	EXPEDITED (15-DAY)	Y	HO	S04-USA-01534-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Body Temperature Increased; Dehydration; Nausea; Vertigo; Vomiting; White Blood Cell Count Decreased	Lexapro			S				Not Reported
	Celexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2004	4124764	EXPEDITED (15-DAY)	Y	OT	S04-USA-01556-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2004	4128568	EXPEDITED (15-DAY)	Y	HO, OT	S04-GER-01375-01		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Apathy; Aspartate	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Erectile Dysfunction; Leukopenia; Neutropenia; Somnolence;	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported

Therapeutic Product Effect Decreased	Cipralex		S	Oral	10 Mg Qd Po	Not Reported
	Allopurinol		S		300 Mg Od	Not Reported
	Allopurinol		S		300 Mg Qd	Not Reported
	Captopril		S		100 Mg Qd	Not Reported

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Dyspnoea	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Zyprexa			C				Not Reported
	Risperdal			C				Not Reported
	Tavor (Lorazepam)			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Leukopenia; Neutropenia	Cipralex	S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2004	4128109	EXPEDITED (15-DAY)	Y	RI	2004PK00586		82 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cerebrovascular Accident; Hepatic Enzyme Increased; Hepatocellular Injury; Urinary Tract Infection	Nexium			S	Oral	20 Mg Daily		Not Reported
	Cipralex			S	Oral	20 Mg Daily		Not Reported
	Augmentin			C				Not Reported
	Morphin Streuli			C				Not Reported
	Dafalgan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2004	4131863	NON-EXPEDITED	Y	RI	03I-163-0235748-00		44 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Below Therapeutic; Seizure	Depakote			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
	Lexapro			S	Oral	20; 10 Mg, 1 In 1 D, Per Oral		Not Reported
					Oral	20; 10 Mg, 1 In 1 D, Per Oral		
	Carbamazepine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2004	4128692	EXPEDITED (15-DAY)	Y	DS	S04-SWI-01446-01		82 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis;	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Family Stress	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2004	4129887	EXPEDITED (15-DAY)	Y	HO	T04-GER-01528-01		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Addison'S Disease; Alanine Aminotransferase Increased; Blood Cholesterol Increased; Depression; Medication Error; Refusal Of Treatment By Patient; Serotonin Syndrome	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Tryptophan (Tryptophan, L-)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2004	4130383	EXPEDITED (15-DAY)	Y	OT	S04-UKI-01520-01		22 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Albuterol Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2004	4094434	EXPEDITED (15-DAY)	Y	DE	2004UW02477		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis Coronary Artery; Coma; Toxicity To Various Agents	Seroquel			S				Not Reported
	Neurontin			S				Not Reported
	Lexapro			S				Not Reported
	Clonazepam			S				Not Reported
	Oxycontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2004	4128526	DIRECT	Y	RI			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased	Lexapro			S	Oral	10 Mg Day Oral		Forest
	Lantus			C				Not Reported
	Humalog			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2004	4130788	EXPEDITED (15-DAY)	Y	DE	S04-USA-01895-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2004	4132323	EXPEDITED (15-DAY)	N	OT	S04-USA-01887-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Appetite; Insomnia; Seizure; Weight Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Toprol Xl			C				Not Reported
	Altace			C				Not Reported
	Plavix			C				Not Reported
	Aspirin			C				Not Reported
	Potassium			C				Not Reported
	Water Pills			C				Not Reported
	Phenobarbital			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2004	4127695	EXPEDITED (15-DAY)	Y	OT	DE-GLAXOSMITHKLINE-D0043604A		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2004	4130136	DIRECT	N	LT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Conversion Disorder; Impaired Work Ability; Suicidal Ideation; Yawning	Lexapro			S	Oral	10 Mgs 1 X Daily Oral		Not Reported
	Lexapro			S	Oral	05 Mgs 1 X Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2004	4130783	DIRECT	Y	DE			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Lexapro			S		Lexapro 15 Qd, Over 1 Year		Not Reported
	Seroquel			S				Not Reported
	Carbamazepine			S		Carbamazepine 800 Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2004	4124418	EXPEDITED (15-DAY)	N	HO	S04-USA-01533-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Glyburide			C				Not Reported
	Lisinopril			C				Not Reported
	Clarinex			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2004	4132210	DIRECT	N	DE			18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Completed Suicide; Fear	Lexapro			S	Oral	1 Pill Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2004	4134542	EXPEDITED (15-DAY)	Y	OT	S04-UKI-01670-01		35 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2004	4134796	EXPEDITED (15-DAY)	N	OT	S04-USA-00541-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported
	Levoxyl			C				Not Reported
	Fosamax			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2004	4094951	EXPEDITED (15-DAY)	Y	HO, RI	S04-USA-00559-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Disease Recurrence; Ovarian Cyst; Pain	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2004	4133224	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Irregular; Palpitations	Lexapro			S	Oral	20 Milligram Oral		Not Reported
	Multi-Vitamin			C				Not Reported
	Vit C			C				Not Reported
	Vitamin E			C				Not Reported
	Magnesium			C				Not Reported
	Soya Lecithin			C				Not Reported
	Prostate-Vitamin/Herb Supplement			C				Not Reported
	Baby Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2004	4133573	DIRECT	Y	OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Nausea; Vomiting	Lexapro			S	Oral	20 Mg Po Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2004	4133622	DIRECT	N	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Fatigue; Nausea; Suicidal Ideation; Tension Headache	Lexapro			S		5 Mg Daily 5 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2004	4123513	EXPEDITED (15-DAY)	N	OT	S04-USA-01403-01		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

Pyrexia; Serotonin Syndrome

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonic Convulsion	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Zolpidem			C				Not Reported

	Oxazepam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2004	4139417	NON-EXPEDITED	Y	OT	US-JNJFOC-20031205539			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Ultram			S	Oral	Oral		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2004	4122524	EXPEDITED (15-DAY)	N	OT	S04-USA-01407-01		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Fatigue; Hyperhidrosis; Loss Of Consciousness; Medication Error; Nausea; Seizure; Tongue Biting; Vomiting	Lexapro			S	Oral	10 Mg Qam Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2004	4138335	EXPEDITED (15-DAY)	Y	OT	2004S1001092		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Blood Creatinine Increased; Blood Potassium Increased; Blood Urea Increased; Confusional State; Disorientation; Drug Interaction; Influenza Like Illness; International Normalised Ratio Increased; Lethargy; Medication Error; Nausea;	Lexapro			S	Oral	30mg Bid, Oral		Not Reported
	Lexapro			S	Oral	10 Mg Qd, Oral		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Maxzide			S				Not Reported
	Enalapril			S	Oral	10 Mg Qd Po		Not Reported
	Warfarin Sodium			C				Not Reported

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersomnia; Syncope	Cipralex	S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2004	4138622	EXPEDITED (15-DAY)	Y	DE	S04-USA-02243-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Oxycontin			S				Not Reported
	Oxycontin			S	Oral	50 Mg Po		Not Reported
	Oxycodone			S				Not Reported
	Elavil			C				Not Reported
	Seroquel			C				Not Reported
	Neurontin			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2004	4136819	DIRECT	N	OT			25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Condition Aggravated; Depression; Somnolence	Lexapro			S		10 Mg Daily At Night	1 YR	Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2004	4136957	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lexapro			S		Tablet		Forest
	Loxapine			S		Capsule		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2004	4138963	EXPEDITED (15-DAY)	Y	HO	S04-USA-02246-01		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Dizziness; Dyskinesia; Feeling Jittery; Intentional Overdose; Muscle Twitching; Restlessness; Serotonin Syndrome; Suicide Attempt	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Flexeril			S				Not Reported
	Flexeril			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2004	4131360	EXPEDITED (15-DAY)	Y	DS	S04-PRT-01661-01		57 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Glucose Increased; Gamma-Glutamyltransferase Increased; Liver Function Test Abnormal	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lorezepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2004	4139714	EXPEDITED (15-DAY)	Y	HO	HQWYE571722APR04			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anal Incontinence; Drug Ineffective; Hepatotoxicity; Nausea; Oedema Peripheral; Rash; Sunburn; Urinary Incontinence	Effexor Xr			S	Oral Oral	See Image Oral See Image Oral		Not Reported
	Lexapro			S				Not Reported
	Buspar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2004	4140292	EXPEDITED (15-DAY)	Y	OT	SO4-USA-02247-01		50 YR	Male	USA

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akathisia; Hypoaesthesia	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Ofloxacin			S	Oral	500 Mg Bid Po		Not Reported
	Metoclopramide			C				Not Reported
	Novalgin (Metamizole Sodium)			C				Not Reported

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

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

	Cpap		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2004	4141317	EXPEDITED (15-DAY)	Y	HO	S04-USA-02275-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2004	7136022	NON-EXPEDITED	N	HO	PHEH2003US09932		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Blood Sodium Decreased; Cardiac Disorder; Dysarthria; Gait Disturbance; Seizure; Vision Blurred	Tegretol			S	Oral	Oral		Not Reported
	Atacand (Candesartan Cilexetil)			S				Not Reported
	Lexapro			S				Not Reported
	Tiazac			S				Not Reported
	Seroquel			S				Not Reported
	Synthroid			C				Not Reported
	Klonopin			C				Not Reported
	Multiple Psychiatric Medications			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2004	4070488	EXPEDITED (15-DAY)	Y	HO	S03-USA-05404-01		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Ventricular Tachycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zestril			S		25 Mg Qd		Not Reported
	Dobutrex			C				Not Reported
	Lovenox (Heparin-Fracture, Sodium Salt)			C				Not Reported
	Lopresor			C				Not Reported
	Darvocet			C				Not Reported
	Morphine			C				Not Reported
	Percocet			C				Not Reported
	Ventolin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2004	4089548	EXPEDITED (15-DAY)	Y	OT	S04-USA-00316-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Heart Rate Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lipitor			C				Not Reported
	Lopid			C				Not Reported
	Evista			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2004	4139817	DIRECT	Y	DE			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cardio-Respiratory Arrest; Chest Injury; Completed Suicide; Craniocerebral Injury; Disorder Of Orbit; Haemothorax; Hypoxia; Intentional Overdose; Jaw Fracture; Oxygen Saturation Decreased; Pneumothorax; Road Traffic Accident	Lexapro			S	Oral	One Daily Orally		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2004	4113117	EXPEDITED (15-DAY)	Y	HO	S04-SWI-01001-01		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Delirium; Fluid Retention; Inappropriate Antidiuretic Hormone Secretion;	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

Polydipsia; Staring

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2004	4142493	EXPEDITED (15-DAY)	N	HO	A0509409A		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bleeding Time Prolonged	Calcium Carbonate			S	Oral	Oral	4 YR	Not Reported
	Lexapro			S				Not Reported
	Potassium Salt			C				Not Reported
	Omeprazolam			C				Not Reported
	Alprazolam			C				Not Reported
	Methylcellulose			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2004	4143395	EXPEDITED (15-DAY)	Y	OT	S04-UKI-01868-01		24 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Overdose	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Co-Codamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2004	4140428	DIRECT	N	DE			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Pain	Lexapro			S	Oral	1 Daily Oral		Not Reported
	Flexeril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2004	4122438	EXPEDITED (15-DAY)	N	OT	2004017393			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Nausea; Somnolence; Uterine Polyp	Nardil	S	Oral	Oral		Not Reported
	Lexapro	S	Oral	Oral		Not Reported
	Estrogens	C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported
	Dyazide			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2004	4143442	DIRECT	N				31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Headache; Hyperhidrosis; Influenza Like Illness; Insomnia; Paraesthesia	Lexapro			S	Oral	1 Daily Oral		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Trismus	Cipralex			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Rebound Effect	Cipralex		S	Oral	1 Tablet Qd Po	Not Reported

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2004	4143597	DIRECT		OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Divorced; Family Stress; Medication Error; Mid-Life Crisis; Partner Stress; Personality Change	Lexapro			S	Oral	15mg Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2004	4147432	EXPEDITED (15-DAY)	Y	HO	S04-USA-02686-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Risperidone			S	Oral	0.5 Mg Qd Po		Not Reported
	Risperidone			S	Oral	1 Mg Qd Po		Not Reported
	Risperidone			S	Oral	1.5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2004	4147434	EXPEDITED (15-DAY)	Y	HO	S04-USA-02760-01		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Obsessive Thoughts; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2004	4147544	EXPEDITED (15-DAY)	Y	HO	S04-UKI-02072-01		79 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Circulatory Collapse; Diarrhoea; Hyponatraemia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Perindopril			C				Not Reported
	Calcichew-D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2004	4127402	EXPEDITED (15-DAY)	Y	HO	S04-AUS-01383-01		43 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Legal Problem; Mania; Paranoia; Persecutory Delusion; Psychotic Disorder; Self-Medication	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2004	4148611	EXPEDITED (15-DAY)	Y	HO	2004UW09432		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Ventricular Tachycardia	Zestril			S	Oral	25 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Diflucan			S				Not Reported
	Ventolin			S		8 Puff Daily		Not Reported
	Dobutrex			C				Not Reported
	Lovenox			C				Not Reported
	Lopresor			C				Not Reported
	Darvocet-N 100			C				Not Reported
	Morphine			C				Not Reported
	Percocet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2004	4148848	EXPEDITED (15-DAY)	Y	OT	S03-USA-05111-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction	Lexapro			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphadenopathy; Pain	Wellbutrin Xl			S	Oral	300mg In The Morning		Glaxosmithkline
	Lexapro			S	Oral	10mg In The Morning		Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2004	4144799	DIRECT	N	RI			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Withdrawal Syndrome; Hypersensitivity; Plantar Fasciitis; Weight Increased; Weight Loss Poor	Lexapro		S	Oral	10mg 1x Day Oral	Forest
	Synthroid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2004	4148828	EXPEDITED (15-DAY)	Y	OT	S04-UKI-02080-01		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dysarthria; Somnolence	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2004	4148833	EXPEDITED (15-DAY)	Y	DS	S04-FRA-02223-01		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea Exertional	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Preterax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2004	4148838	EXPEDITED (15-DAY)	Y	OT	S04-UKI-02076-01		77 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2004	4147010	DIRECT		OT			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rash	Lexapro			S	Oral	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2004	4147868	DIRECT	Y	DE			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Fatigue; Insomnia; Mood Swings	Lexapro			S		5 Mg X 11 Days; 10 Mg X 5 Days		Not Reported
	Paxil			S		Paxil 12.5 X 3 Days		Not Reported
	Elavil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2004	4150369	EXPEDITED (15-DAY)	Y	OT	S04-GER-02146-01		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Dyskinesia; Memory Impairment; Personality Change; Social Avoidant Behaviour	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Seroxat "Ciba-Geigy" (Paroxetine Hydrohchloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2004	4150371	EXPEDITED (15-DAY)	Y	OT	S04-IRL-02153-01		44 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Seizure; Syncope	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Mefac(Mefenamic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2004	4123515	EXPEDITED (15-DAY)	Y	LT	S04-USA-01411-01		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Hepatic Cirrhosis; Hepatic Failure	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Aldactone			C				Not Reported
	Protonix			C				Not Reported
	Procrit			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2004	4147947	DIRECT	N	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anger; Marital Problem; Personality Change	Lexapro			S	Oral	15 Mg Daily Orally		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2004	4149738	EXPEDITED (15-DAY)	Y	OT	S04-USA-02795-01		7 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2004	4153767	EXPEDITED (15-DAY)	Y	OT	S04-UKI-02151-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Dizziness; Drug Withdrawal Syndrome; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2004	4148557	DIRECT	N	DE			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Lexapro	S	1 Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2004	4127401	EXPEDITED (15-DAY)	Y	DS	S04-AUS-01448-01		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2004	4132311	EXPEDITED (15-DAY)	Y	OT	S04-USA-02050-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Ambien			C				Not Reported
	Lopresor			C				Not Reported
	Zetia			C				Not Reported
	Zyrtec			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2004	4140951	EXPEDITED (15-DAY)	Y	OT	S04-TUR-01932-01		34 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Blood Prolactin Increased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2004	4150224	DIRECT	N	LT, RI			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Psychiatric Symptom; Self-Injurious Ideation; Suicide Attempt	Lexapro		S	Oral	10 Mg Daily Oral	Not Reported
	Trazodone Hydrochloride		S	Oral	Nightly Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2004	4150521	DIRECT	N	DE			14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	1/2 Dose Ea Mornin Oral		Not Reported
	Adderall Xr			S	Oral	1 Dose Ea. Mornin Oral		Not Reported
	Adderall Xr			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2004	4150981	DIRECT	N	HO, LT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Diarrhoea; Insomnia; Intentional Overdose; Muscle Contractions Involuntary; Restlessness; Stress; Suicidal Ideation; Suicide Attempt	Paxil			S				Not Reported
	Prozac			S				Not Reported
	Effexor			S				Not Reported
	Celexa			S				Not Reported
	Remeron			S				Not Reported
	Lexapro			S				Not Reported
	Serzone			S				Not Reported
	Wellbutrin			S				Not Reported
	Zoloft			S				Not Reported
	Sleep Pills			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2004	4152924	EXPEDITED (15-DAY)	Y	DE	2004-116341-NL		37 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Mirtazapine			S		15 Mg	24 DAY	Not Reported
	Lorazepam			S		See Image See Image	1 DAY 21 DAY	Not Reported

	Escitalopram Oxalate	S	See Image See Image	1 DAY 24 DAY		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2004	4153296	EXPEDITED (15-DAY)	Y	OT	S04-USA-02799-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Petit Mal Epilepsy	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2004	4137087	EXPEDITED (15-DAY)	Y	HO	S04-USA-02240-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Serotonin Syndrome; Vision Blurred; Visual Impairment	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2004	4146036	EXPEDITED (15-DAY)	Y	HO	04P-163-0259510-00		38 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Depressed Level Of Consciousness; Electrocardiogram St Segment; Intentional Overdose; Self-Medication	Depakote			S	Oral	10 Mg, Unknown Amount, Oral		Not Reported
	Lexapro			S				Not Reported
	Olanzapine			S				Not Reported
	Alcohol			S				Not Reported
	Cocaine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2004	4153381	EXPEDITED (15-DAY)	Y	DS	S04-UKI-02284-01		34 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyskinesia; Gait Disturbance; Restlessness; Tremor	Cipralex		S	Oral	10 Mg Qd Po	Not Reported
	Aspirin		C			Not Reported
	Ibuprofen		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2004	3939698	EXPEDITED (15-DAY)	Y	HO, LT	S03-USA-01380-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Palpitations; Torsade De Pointes; Treatment Noncompliance; Ventricular Fibrillation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zestril			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2004	4132342	EXPEDITED (15-DAY)	Y	RI, OT	S04-USA-01892-01		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd; Po		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2004	4147393	EXPEDITED (15-DAY)	Y	OT	T04-USA-02082-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Restlessness	Escitalopram Oxalate			S	Oral	2.5 Mg Qd; Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd; Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd; Po		Not Reported
	Triamterene			C				Not Reported
	Atenolol			C				Not Reported
	Cenestin (Estrogens Conjugated)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2004	4149781	EXPEDITED (15-DAY)	Y	OT	S04-USA-02794-01		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Alcoholism; Anxiety; Drug Interaction; Road Traffic Accident	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Strattera			S		60 Mg Qd		Not Reported
	Strattera			S		40 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2004	4152165	DIRECT		OT			13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Withdrawal Syndrome; Epistaxis; Myalgia; Vomiting	Lexapro			S	Buccal	10 Mg Once A Day Buccal		Forest
	Tylenol With Codeine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2004	4154865	EXPEDITED (15-DAY)	Y	OT	S04-USA-02956-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Unknown	Unk		Not Reported
	Birth Control Pills			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2004	4154872	EXPEDITED (15-DAY)	Y	OT	S04-USA-02969-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Nausea; Photopsia; Seizure; Somnolence; Visual Impairment; Vomiting	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported
	Accutane			S		20 Mg Qd		Not Reported
	Accutane			S	Oral	30 Mg Qd; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2004	4149977	EXPEDITED (15-DAY)	Y	OT	US-ROCHE-369062		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Klonopin			S	Unknown			Roche
	Lexapro			S	Oral		22 DAY	Not Reported
	Lexapro			S	Oral		21 DAY	Not Reported
	Lasix			C				Not Reported
	Kcl			C				Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2004	4153119	DIRECT	N	DE			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	Once Daily Oral		Not Reported
	Remeron			S	Oral	30 Mg Once Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2004	4153629	DIRECT	N				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Feeling Abnormal; Mood Swings; Personality Change; Suicidal Ideation	Lexapro			S	Oral	1 Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2004	4157030	EXPEDITED (15-DAY)	Y	OT	S04-USA-02584-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension; Discomfort; Fluid Retention; Treatment Noncompliance; Varicose Vein; Vascular Pain; Weight Increased	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Remeron		C			Not Reported
	Klonopin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2004	4136806	EXPEDITED (15-DAY)	N	DE	S04-USA-02237-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Alcohol Use; Completed Suicide; Gun Shot Wound; Treatment Noncompliance	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Valium			C				Not Reported
	Vicodin			C				Not Reported
	Spinal Epidermal Injections			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2004	4153873	DIRECT	N	DE, OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Condition Aggravated; Depression; Feeling Abnormal; Gun Shot Wound	Lexapro			S	Oral	10 Mg Daily / Oral		Forest
	Simvastatin			C				Not Reported
	Famotidine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Verapamil Hydrochloride			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2004	4155158	DIRECT	Y	HO, OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Erythema; Oedema Peripheral	Lexapro	S	2 Doses Only 2 Doses Only		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2004	4157594	EXPEDITED (15-DAY)	Y	OT	S04-USA-03007-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Seizure	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Bid Po		Not Reported
	Seroquel			C				Not Reported
	Trileptal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2004	4157597	EXPEDITED (15-DAY)	Y	DE	S04-USA-03003-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Completed Suicide; Insomnia	Lexapro			S				Not Reported
	Prozac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2004	4157895	EXPEDITED (15-DAY)	Y	OT	T04-GER-02370-01		73 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Cipralex			S		10 Mg Qd		Not Reported
	Voltaren			C				Not Reported
	Allopurinol			C				Not Reported
	Lorzaar (Losartan Potassium)			C				Not Reported
	Metoprolol			C				Not Reported
	Valoron N			C				Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2004	4153104	EXPEDITED (15-DAY)	Y	HO, LT	2004006851		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Aspartate Aminotransferase Abnormal; Blood Creatine Phosphokinase Increased; Blood Lactic Acid Increased; Coma; Hepatic Function Abnormal; Pneumonia; Prothrombin Time Prolonged; Pyrexia; Sepsis	Lamictal			S	Oral	3tab Three Times Per Day		Glaxosmithkline
	Trileptal			S	Oral	3tab Three Times Per Day		Not Reported
	Cipralex			S	Oral	1.5tab Per Day		Not Reported
	Folic Acid			S	Oral	1tab Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4048501	EXPEDITED (15-DAY)	Y	HO, RI, OT	S03-USA-05064-02		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Delivery; Caesarean Section; Jaundice Neonatal; Maternal Exposure During Pregnancy; Neonatal Aspiration; Premature Baby	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Lexapro			S	Transplacental	10 Mg Qd Po		Not Reported
	Prenatal Vitamins			C				Not Reported
	Effexor			C				Not Reported
	Wellbutrin Sr			C				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported
	Insulin Insulatard Nph Nordisk			C				Not Reported
	Humalog			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4070262	EXPEDITED (15-DAY)	Y	HO	S04-USA-00021-01		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Bruxism; Depression; Diarrhoea; Headache; Hyperhidrosis; Hyperphagia; Insomnia; Pain; Restlessness; Somnolence; Suicidal	Lexapro			S	Oral	10 Mg Bid Po		Not Reported
	Lexapro			S				Not Reported
	Buspar			C				Not Reported
	Seroquel			C				Not Reported
	Paxil			C				Not Reported

Ideation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4120495	EXPEDITED (15-DAY)	Y	HO, OT	S04-GER-01225-01		82 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Duodenitis; Gastric Ulcer Haemorrhage; General Physical Health Deterioration; Haematemesis; Haematocrit Decreased; Haemoglobin Decreased; International Normalised Ratio Decreased; Platelet Count Increased; Prothrombin Time Shortened; Vertigo; Vomiting	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			S		100 Mg Qd		Not Reported
	Beloc [Metoprolol Tartrate]			C				Not Reported
	Ovestin (Estriol)			C				Not Reported
	Unat (Torasemide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4151290	EXPEDITED (15-DAY)	Y	HO, OT	T04-GER-02281-01		82 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Duodenitis; Gastric Ulcer Haemorrhage; General Physical Health Deterioration; Haematemesis; Haematocrit Decreased; Haemoglobin Decreased; International Normalised Ratio Decreased; Platelet Count Increased; Prothrombin Time Shortened; Vertigo	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			S		100 Mg Qd		Not Reported
	Beloc Zok (Metoprolol Succinate)			C				Not Reported
	Ovestin (Estriol)			C				Not Reported
	Unat (Torasemide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4154133	EXPEDITED (15-DAY)	Y	HO	S04-DEN-02358-01		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Gastroenteritis; Hepatitis Toxic; International Normalised Ratio Decreased; International Normalised Ratio Increased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Bendroflumethiazide			C				Not Reported
	Warfarin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4159006	EXPEDITED (15-DAY)	N	OT	S04-USA-03103-01		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hypoaesthesia; Paraesthesia; Seizure	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Gabitril			C				Not Reported
	Phenobarb (Phenobarbital Sodium)			C				Not Reported
	Lisinopril			C				Not Reported
	Allopurinol			C				Not Reported
	Pepcid			C				Not Reported
	Dantrum (Dantrolene Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4159008	EXPEDITED (15-DAY)	N	DE	S04-USA-03104-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4159089	EXPEDITED (15-DAY)	Y	OT	S04-USA-03132-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4159538	EXPEDITED (15-DAY)	Y	HO, RI, OT	S03-USA-05064-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Pregnancy; Premature Labour	Lexapro			S	Oral	10 Mg Qam Po		Not Reported
	Effexor Xr			C				Not Reported
	Wellbutrin Sr			C				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported
	Prenatal Vitamins			C				Not Reported
	Nph Insulin			C				Not Reported
	Humalog			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4160395	NON-EXPEDITED	Y	HO	S04-USA-01536-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4160397	NON-EXPEDITED	Y	HO	S04-USA-01536-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4160399	NON-EXPEDITED	N	RI	S04-USA-01368-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersensitivity	Lexapro	S	Oral	10 Mg Qod Po		Not Reported
	Lexapro	S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4160402	NON-EXPEDITED	Y	HO	S04-USA-01404-01		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Hydrochlorothiazide			C				Not Reported
	Toprol Xl			C				Not Reported
	Lisinopril			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4160403	NON-EXPEDITED	Y	HO	S04-USA-01207-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4162862	NON-EXPEDITED	Y	HO	S04-USA-02761-01		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis; Somnolence	Lexapro			S	Oral	See Image		Not Reported
					Oral	See Image		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4162870	NON-EXPEDITED	Y	DE	S04-USA-02676-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S				Not Reported
	Benadryl			C				Not Reported

	Skelaxin			C						Not Reported
	Ambien			C						Not Reported
	Ritalin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4162880	NON-EXPEDITED	Y	HO	S04-USA-02242-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depersonalisation/Dereali sation Disorder	Lexapro			S				Not Reported
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4162883	NON-EXPEDITED	N	HO	S04-USA-02273-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicidal Ideation	Lexapro			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4162886	NON-EXPEDITED	Y	HO	S04-USA-02274-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	See Image		Not Reported
	Ambien			C				Not Reported
	Ritalin			C				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4162903	NON-EXPEDITED	Y	HO	S04-USA-01684-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2004	4162923	NON-EXPEDITED	Y	HO	S04-USA-01893-01		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zyvox			S		600 Mg Qd		Not Reported
	Vancomycin			C				Not Reported
	Lortab			C				Not Reported
	Catapres-Tts			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2004	4123206	EXPEDITED (15-DAY)	N	HO	S04-USA-01406-01		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Dehydration; Diarrhoea; Dizziness; Fall; Loss Of Consciousness; Mitral Valve Incompetence; Nausea; Weight Decreased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Synthroid			C				Not Reported
	Klonopin (Clonazepma)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2004	4126030	EXPEDITED (15-DAY)	Y	OT	S04-USA-01682-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2004	4132306	EXPEDITED (15-DAY)	Y	HO	S04-USA-01885-01		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Overdose;	Lexapro		S	Oral	400 Mg Once Po	Not Reported
Suicide Attempt; Treatment Noncompliance	Lexapro		S	Oral	20 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2004	4157107	DIRECT	N	OT			30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Influenza Like Illness; Irritability; Nausea; Tremor; Trismus	Lexapro			S	Oral	10 Mg Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2004	4157116	DIRECT	Y	DE			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Fluoxetine			S	Oral	20 Mg Daily Oral		Not Reported
	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported
	Nadolol			C				Not Reported
	Triamterene And Hydrochlorothiazide			C				Not Reported
	Allegra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2004	4161051	EXPEDITED (15-DAY)	Y	HO	S04-USA-03152-01		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Chloride Decreased; Blood Potassium Decreased; Confusional State; Depression; Hyponatraemia; Therapeutic Product Effect Decreased	Lexapro			S	Oral	10 Mg Po		Not Reported
	Norvasc			C				Not Reported
	Protonix			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2004	4161414	EXPEDITED (15-DAY)	Y	RI, OT	S04-USA-03109-01		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tooth Disorder	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Norvasc			C				Not Reported
	Plavix			C				Not Reported
	Flomax			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2004	4070040	EXPEDITED (15-DAY)	Y	OT	S03-USA-04750-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bleeding Time Prolonged; Coagulation Factor Viii Level Increased; Condition Aggravated; Educational Problem; Iron Deficiency Anaemia; Leukopenia; Menorrhagia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Celexa			C				Not Reported
	Ortho Tri Cyclen			C				Not Reported
	Levlite			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2004	4158712	DIRECT	N				41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Aggression; Arthralgia; Crying; Disturbance In Attention; Drug Withdrawal Syndrome; Influenza Like Illness; Memory Impairment; Myalgia; Nightmare; Pain; Pruritus; Tinnitus	Lexapro			S	Oral	Once Day Oral		Not Reported
	Wellbutrin Sr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2004	4159218	EXPEDITED (15-DAY)	Y	HO	S04-SWE-02566-01		79 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Balance Disorder; Cerebral Haemorrhage; Headache; Vomiting	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Plavix			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2004	4157447	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Celexa			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2004	4159168	DIRECT	N	HO			12 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Acne; Affective Disorder; Blood Glucose Abnormal; Condition Aggravated; Depression; Hair Growth Abnormal; Polycystic Ovaries; Suicidal Ideation; Thinking Abnormal; Weight Increased	Abilify			S	Oral	15mg Daily Oral		Bristol Myers Squibb
	Lexapro			S	Oral	30 Mg Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2004	4146409	EXPEDITED (15-DAY)	Y	CA, DE	S04-USA-02755-01		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Induced; Limb Malformation; Maternal Drugs Affecting Foetus; Oligohydramnios; Potter'S Syndrome; Pregnancy; Stillbirth	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Lexapro		S	Oral	10 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2004	4159712	DIRECT	N				24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Decreased Appetite; Dizziness; Headache; Irritability; Medication Error; Mobility Decreased; Nausea	Lexapro			S	Oral	10 Mg 1 Time A D Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2004	4161929	EXPEDITED (15-DAY)	Y	HO, LT	S04-SWI-02501-01		35 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Thrombocytopenia	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2004	4163143	EXPEDITED (15-DAY)	Y	DE, HO	S04-BEL-02509-01		55 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Completed Suicide; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Trazolan (Trazodone Hydrochloride)			C				Not Reported
	Buronil (Melperone Hydrochloride)			C				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2004	4093519	EXPEDITED (15-DAY)	Y	HO	S04-USA-00532-02		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Calcium Increased; Blood Osmolarity Increased; Blood Potassium Increased; Blood Thyroid Stimulating Hormone Decreased; Body Temperature Increased; Condition Aggravated; Nephropathy; Rash; Renal Failure; Tubulointerstitial Nephritis; Weight Increased	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Concerta			C				Not Reported
	Ambien			C				Not Reported
	Buspar			C				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported
	Methylphenidate Hydrochloride			C				Not Reported
	Seroquel			C				Not Reported
	Omeprazole			C				Not Reported
	Topamax			C				Not Reported
	Risperdal			C				Not Reported
	Ativan			C				Not Reported
	Synthroid			C				Not Reported
	Mirtazapine			C				Not Reported
	Abilify /Usa/ (Aripirazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2004	4140232	EXPEDITED (15-DAY)	Y	HO	S04-USA-02172-01		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Coma; Depressed Level Of Consciousness; Drug Abuser; Electrocardiogram St Segment; Medication Error; Overdose; Self-Medication	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Depakote			S				Not Reported
	Zyprexa			S				Not Reported
	Alcohol			S				Not Reported
	Cocaine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2004	4164025	EXPEDITED (15-DAY)	Y	HO	S04-EST-02356-01		13 YR	Female	EST

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Anxiety; Arthropathy; Circulatory Collapse; Conversion Disorder; Coordination Abnormal; Cyanosis; Dysarthria; Dyspnoea; Hyperventilation; Muscular Weakness; Panic Attack; Psychotic Disorder; Respiratory Disorder; Tremor	Cipralex	S	Oral	10 Mg Qd Po	Not Reported
	Cipralex	S	Oral	5 Mg Qd Po	Not Reported
	Trexan (Methortrexate)	C			Not Reported
	Antrex (Folic Acid)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2004	4196800	NON-EXPEDITED	Y	OT	US-JNJFOC-20030604021		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Haldol			S		5 Mg, 1 In 4 Hour		Not Reported
	Haldol			S		3 Mg, 1 In 1 Day		Not Reported
	Lexapro			S		10 Mg, 1 In 1 Day		Not Reported
	Ativan			C				Not Reported
	Risperdal			C				Not Reported
	Vasotec			C				Not Reported
	Lopresor			C				Not Reported
	Nitroglycerin			C				Not Reported
	Hydrodiuril			C				Not Reported
	Potassium			C				Not Reported
	Slow-Mag (Magnesiukm Chloride Anhydrous)			C				Not Reported
	Premarin			C				Not Reported
	Synthroid			C				Not Reported
	Alphagan P			C				Not Reported
	Levaquin			C				Not Reported
	Lidex			C				Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported
	Vicodin			C				Not Reported
	Protonix			C				Not Reported
	Prilosec			C				Not Reported
	Gaviscon			C				Not Reported

Maalox (Maalox)	C		Not Reported
Milk Of Magnesia	C		Not Reported
Theragram (Theragran)	C		Not Reported
Vitamin E	C		Not Reported
Ensure (Ensure)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2004	4093521	EXPEDITED (15-DAY)	Y	HO	S04-USA-00532-03		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Bruit; Acute Kidney Injury; Asthenia; Blood Calcium Decreased; Blood Magnesium Increased; Cardiac Failure Congestive; Cardiac Murmur; Chronic Kidney Disease; Chronic Obstructive Pulmonary Disease; Communication Disorder; Diastolic Dysfunction; Gastritis; Kidney Small; Mitral Valve Incompetence; Musculoskeletal Chest Pain; Pneumonia; Protein Urine Present; Pulmonary Hypertension; Red Blood Cells Urine Positive; Renal Artery Stenosis; Respiratory Distress; Respiratory Rate Increased; Tachycardia; White Blood Cells Urine Positive	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celexa			S	Oral	30 Mg Qd Po		Not Reported
	Lisinopril			S		2.5 Mg Bid		Not Reported
	Lasix			S	Oral	20 Mg Qd Po		Not Reported
	Kayexalate			C				Not Reported
	Coreg			C				Not Reported
	Protonix			C				Not Reported
	Ativan			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported
	Vitamin B12			C				Not Reported
	Colace			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Maalox		Y	C				Not Reported
	Milk Of Magnesia			C				Not Reported
	Norvasc			C				Not Reported
	Aspirin			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Avelox			C				Not Reported
	Albuterol			C				Not Reported
	Xanax			C				Not Reported
	Combivent			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2004	3959067	EXPEDITED (15-DAY)	Y	OT	US-SHR-03-008382		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Depression; Disturbance In Attention; Dizziness; Feeling Abnormal; Irritability; Menopause; Mood Swings; Sinus Tachycardia	Climara			S	Transdermal	See Image		Not Reported
					Transdermal	See Image		
	Lexapro			S				Not Reported
	Vitamins			C				Not Reported
	Testosterone			C				Not Reported
	Remeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2004	4139685	EXPEDITED (15-DAY)	Y	HO	2004UW08247		83 YR	Female	ARE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Potassium Decreased; Blood Pressure Systolic Increased; Body Temperature Increased; Cardiac Murmur; Depression; Eating Disorder; Fatigue; Helicobacter Infection; Inappropriate Antidiuretic Hormone Secretion; Myositis; Nausea; Pco2 Decreased; Pedal Pulse Decreased; Respiratory Rate Increased; Vomiting	Crestor			S	Oral	10 Mg Po		Not Reported
	Lexapro			S		10 Mg		Not Reported
	Diovan Hct			S				Not Reported
	Cardizem			C				Not Reported
	Xanax			C				Not Reported
	Protonix			C				Not Reported
	Biaxin			C				Not Reported
	Priniviil			C				Not Reported
	Dextra			C				Not Reported
	Theosol			C				Not Reported
	Nitroglycerin			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2004	4156434	EXPEDITED (15-DAY)	Y	OT	S04-IRL-02365-01		59 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Disease Recurrence; Overdose	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2004	4166386	DIRECT	N	OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Zoloft			S		100mg Once A Day		Pfizer
	Lexapro			S		15mg Once A Day		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2004	4139458	EXPEDITED (15-DAY)	Y	HO	DE-MERCK-0405DEU00077		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Creatine Phosphokinase Increased; Central Nervous System Inflammation; Exhibitionism; Myopathy; Overdose; Personality Change	Maxalt-Mlt			S	Oral			Merck
	Cipralex			S	Unknown			Not Reported
	Domperidone			C	Oral			Not Reported
	Ergotamine Tartrate			C	Unknown			Not Reported
	Metoclopramide			C	Oral			Not Reported
	Petasites			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2004	4141327	EXPEDITED (15-DAY)	Y	OT	S04-USA-02268-01		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Mouth; Extrapyramidal Disorder; Fear; Neck Pain; Sedation; Vomiting	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Allegra			C				Not Reported
	Protopic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2004	4167452	EXPEDITED (15-DAY)	N	OT	S04-USA-03273-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Altered Visual Depth Perception; Depressed Level Of Consciousness; Road Traffic Accident	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2004	4167519	EXPEDITED (15-DAY)	Y	HO	S04-USA-03513-01		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Decreased Appetite; Depression; Drug Ineffective; Emotional Distress; Insomnia; Near Drowning; Restlessness; Schizoaffective Disorder; Seizure; Thinking Abnormal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Risperdal			S		3 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2004	4182830	NON-EXPEDITED	Y	DE	2003013970		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Erectile Dysfunction; Gastric Disorder; Homicide; Insomnia; Mood Swings; Sexual Dysfunction	Zoloft			S	Oral	150 Mg (Daily), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Alprazolam (Alprazolam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2004	4182896	NON-EXPEDITED	Y	OT	2004026989		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Alanine Aminotransferase	Zoloft			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S				Not Reported

Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Diarrhoea; Urinary Tract Infection; Vomiting	Lansoprazole	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2004	4038107	EXPEDITED (15-DAY)	Y	HO	S03-USA-04702-01		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multiple Medications (Nos)			C				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2004	4106583	EXPEDITED (15-DAY)	Y	DE	T04-USA-00730-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arteriosclerosis Coronary Artery; Arteriospasm Coronary; Coronary Artery Stenosis; Pulmonary Oedema; Sudden Cardiac Death	Lexapro			S				Not Reported
	Celexa			S				Not Reported
	Alcohol			C				Not Reported
	Methadone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2004	4145737	EXPEDITED (15-DAY)	Y	RI, OT	S04-USA-02757-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2004	4167206	DIRECT	N	LT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hostility; Personality Change; Social Avoidant Behaviour; Suicide Attempt	Lexapro			S				Forest
	Fluvoxamine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2004	4167988	EXPEDITED (15-DAY)	Y	DE	T04-USA-03454-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arteriosclerosis Coronary Artery; Coronary Artery Stenosis; Pulmonary Oedema; Sudden Cardiac Death	Celexa			S				Not Reported
	Lexapro			S				Not Reported
	Alcohol			C				Not Reported
	Methadone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2004	4168072	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Lexapro			S	Oral	10 Mg Q Day Oral		Forest
	Benztropine Mesylate			C				Not Reported
	Clonazepam			C				Not Reported
	Risperidone			C				Not Reported
	Valproic Acid			C				Not Reported
	Vitamin E			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2004	6035461	EXPEDITED (15-DAY)	Y	OT	TOR-2004-0001		63 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Depression; Gait	Fareston			S	Oral		4 YR	Not Reported

Disturbance; Lower Respiratory Tract Infection; Nystagmus; Overdose; Tremor	Cipralex		S	Oral	20 Mg (20 Mg, 1 In 1d)	10 MTH	Not Reported
	Diazepam		S				Not Reported
	Anadin Extra		S				Not Reported
	Ketoprofen		C				Not Reported
	Misoprostol		C				Not Reported
	Fibrogel		C				Not Reported
	Venlafaxin		C				Not Reported
	Olanzapine		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2004	4153953	EXPEDITED (15-DAY)	Y	HO	T04-USA-02228-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Benign Laryngeal Neoplasm; Coma; Conversion Disorder; Fall; Gaze Palsy; Generalised Tonic-Clonic Seizure; Headache; Hemiplegia; Leukoplakia; Musculoskeletal Chest Pain; Panic Reaction; Paraesthesia; Post Procedural Complication; Somnolence; Vision Blurred	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Fentanyl			S				Not Reported
	Isoflurane			S				Not Reported
	Ativan			C				Not Reported
	Omeprazole			C				Not Reported
	Benzoyl Peroxide (Benzoyl Peroxide)			C				Not Reported
	Calcium With Vitamin D			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported
	Vitamins Nos			C				Not Reported
	Acetaminophen W/Oxycodone			C				Not Reported
	Sodium Chloride			C				Not Reported
	Dermophil Indien Sun Screen			C				Not Reported
	Tretonoin			C				Not Reported
	Triamcinolone Acetinide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2004	4169851	EXPEDITED (15-DAY)	Y	OT	S04-USA-02247-01		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Fluctuation; Hyperglycaemia;	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Hypoglycaemia; Self-Medication	Ativan	C		Not Reported
	Captopril	C		Not Reported
	Lipitor	C		Not Reported
	Aspirin	C		Not Reported
	Buspar	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2004	4169855	EXPEDITED (15-DAY)	Y	HO	S04-USA-03701-01		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Conversion Disorder; Gait Disturbance; Headache; Paralysis; Seizure; Tendonitis	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2004	6511307	DIRECT	Y	HO, LT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder; Serotonin Syndrome	Zyvox			S		600 Mg Iv/Po Q12h		Not Reported
	Lexapro			S	Oral	10 Mg Po Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2004	4158587	EXPEDITED (15-DAY)	Y	DS	T04-AUT-02502-01		38 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Blood Triglycerides Increased; Metabolic Disorder	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qdpo		Not Reported
	Mianserin Hydrochloride			S	Oral	120 Mg Qd Po		Not Reported
	Oxazepam			S	Oral	150 Mg Qd Po		Pliva
	Panthenol			S				Not Reported
	Dominal (Prothipendyl Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2004	4171109	EXPEDITED (15-DAY)	Y	OT	S04-USA-03697-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Cholesterol Increased; Blood Triglycerides Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Diovan Hct			C				Not Reported
	Alprazolam			C				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported
	Viagra			C				Not Reported
	Toprol Xl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2004	4169848	DIRECT	N	RI, OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Attention; Fear; Feeling Abnormal; Feeling Of Despair; Headache; Insomnia; Morbid Thoughts	Lexapro			S	Oral	1/2 Tablet Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2004	4169959	NON-EXPEDITED	Y	HO	US-BRISTOL-MYERS SQUIBB COMPANY-12302923		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypotension; Toxicity To Various Agents	Coumadin			S				Bristol Myers Squibb
	Lovenox			C				Not Reported
	Protonix			C				Not Reported
	Zetia			C				Not Reported
	Carafate			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Elavil			C				Not Reported

	Peri-Colace	C		Dose 2 Capsules Daily.	Not Reported
	Robaxin	C			Not Reported
	Reglan	C			Not Reported
	Lortab	C			Not Reported
	Multi-Vitamin	C			Not Reported
	Nystatin	C			Apothecon
	Sodium Chloride	C		Dose: "100 Units".	Not Reported
	Toprol Xl	C			Not Reported
	Diovan	C			Not Reported
	Lexapro	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2004	4170130	NON-EXPEDITED	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-12374955		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Coumadin			S		Dose: 5 Mg Alternated With 2.5 Mg/Day. Expected To Re-Start.		Bristol Myers Squibb
	Lexapro			S	Oral		8 DAY	Not Reported
	Insulin Nos			C				Not Reported
	Colchicine			C				Not Reported
	Prinivil			C				Not Reported
	Furosemide			C				Not Reported
	Ranitidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2004	4061534	EXPEDITED (15-DAY)	Y	OT	S03-USA-05298-02		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Transient Ischaemic Attack	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Megace			C				Not Reported
	Lopresor			C				Not Reported
	Nitrotab (Glyceryl Trinitrate)			C				Not Reported
	Norvasc			C				Not Reported
	Plavix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2004	4152032	EXPEDITED (15-DAY)	N	OT	US-GLAXOSMITHKLINE-A0513591A		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Haemorrhage; Macular Degeneration; Visual Acuity Reduced	Advair Diskus			S	Respiratory (inhalation)		2 MTH	Glaxosmithkline
	Lexapro			S				Not Reported
	Vitamins			C				Not Reported
	Hypericum			C				Not Reported
	Carotenoids			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2004	4172743	DIRECT	Y				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Feeling Abnormal; Muscle Spasms	Lexapro			S		Qd		Not Reported
	Unisom			C		Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2004	4175380	EXPEDITED (15-DAY)	N	OT	S04-USA-03834-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Monoplegia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Calcium Channel Blocker (Nos)			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2004	4168150	DIRECT	N	HO, RI			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury;	Zelnorm			S		1 Daily By Mouth		Novartis

Constipation; Diarrhoea; Drug Ineffective; Hydronephrosis; Hypertension; Nausea; Rectal Haemorrhage; Retroperitoneal Fibrosis; Therapeutic Product Effect Decreased; Ureteric Obstruction; Vomiting	Lexapro	S	1 Daily By Mouth		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2004	4176120	EXPEDITED (15-DAY)	Y	HO	T04-GER-02230-01		72 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Apathy; Bladder Diverticulum; Condition Aggravated; Cystitis; Cystoscopy Abnormal; Dehydration; Dementia; Depression; Drug Ineffective; Feeling Abnormal; Haematuria; Haemoglobin Decreased; Irritability; Memory Impairment; Pyelonephritis Acute; Stupor; Vasodilatation	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Hydrochlorothiazide			S				Not Reported
	Ramipril			C				Not Reported
	Carvedilol			C				Not Reported
	Amiodarone			C				Not Reported
	Triamteren (Triamterene)			C				Not Reported
	Allopurinol			C				Not Reported
	Allopurinol			C				Not Reported
	Zocor			C				Not Reported
	Ass (Acetylsalicylic Acid) (Acetylsalicylic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2004	4177136	EXPEDITED (15-DAY)	Y	OT	S04-USA-03937-01		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bipolar Disorder; Depression; Family Stress; Irritability; Memory Impairment; Psychomotor Hyperactivity; Refusal Of	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Treatment By Relative

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2004	4173642	DIRECT	Y	HO			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Asthenia; Decreased Appetite; Feeling Abnormal; Irritability; Libido Decreased; Self Esteem Decreased; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Weight Decreased	Interferon Nos			S				Not Reported
	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2004	4177665	EXPEDITED (15-DAY)	Y	OT	S04-USA-04010-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pericarditis	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2004	4178335	EXPEDITED (15-DAY)	Y	OT	S04-GER-02984-01		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; White Blood Cell Count Decreased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2004	4178339	EXPEDITED (15-DAY)	Y	OT	S04-GER-02987-01		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Monocyte Count	Cipralex			S				Not Reported

Increased; Paraesthesia; Photosensitivity Reaction; Pruritus Generalised; Skin Abrasion

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2004	5823357	EXPEDITED (15-DAY)	Y	HO	S04-USA-04007-01		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Pneumonia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Benicar Hct			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2004	4177624	EXPEDITED (15-DAY)	Y	OT	S04-USA-04076-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2004	4116255	EXPEDITED (15-DAY)	Y	OT	S04-GER-01170-01			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Epidermolysis; Pemphigoid	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			S	Oral	50 Mg Qd Po		Not Reported
	Unspecified Ingredient			S		150 Mg Qd		Not Reported
	Omep 20 (Omeprazole)			C				Not Reported
	Tegretol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2004	4169815	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-12487039		10 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acne; Constipation; Dyskinesia; Fear; Glucose Tolerance Impaired; Insulin Resistance; Nightmare; Polycystic Ovaries; Sleep Disorder; Weight Increased	Abilify		S	Oral	Not Reported
	Lexapro		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2004	4173227	EXPEDITED (15-DAY)	Y	HO	T04-SWE-02787-01		69 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuser; Generalised Tonic-Clonic Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Bid Po		Not Reported
	Actos (Pioglitazone) (Pioglitazone)			C				Not Reported
	Novonorm (Repaglinide)			C				Not Reported
	Allopurinol			C				Not Reported
	Ramipril			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Norvasc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2004	4136926	EXPEDITED (15-DAY)	N	HO	US-JNJFOC-20040405349		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Alcohol Poisoning; Apathy; Depression; Impulse-Control Disorder; Weight Increased	Concerta			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		
	Lexapro			S	Oral	See Image		Not Reported
					Oral	See Image		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2004	4147438	EXPEDITED (15-DAY)	Y	DE	S04-USA-02762-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Craniocerebral Injury; Family Stress; Gun Shot Wound; Insomnia; Marital Problem; Medication Error; Treatment Noncompliance	Lexapro			S				Not Reported
	Ambien			S				Not Reported
	Valium			S				Not Reported
	Wellbutrin			S				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2004	4152332	EXPEDITED (15-DAY)	Y	DE	2004032706		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Geodon			S		240 Mg (80 Mg, 3 In 1 D)		Not Reported
	Lorazepam			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Topiramate			C				Not Reported
	Diazepam (Diazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2004	4176687	DIRECT	Y	HO			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Lethargy	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2004	4129416	EXPEDITED (15-DAY)	Y	DE	S04-USA-01686-01		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Diabetes Mellitus Inadequate Control; Family Stress; Feeling Abnormal; Hyperhidrosis; Prostate Cancer; Sleep Disorder	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ativan			C				Not Reported
	Insulin Nos			C				Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2004	4177339	DIRECT	N	OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Fatigue; Headache; Loss Of Personal Independence In Daily Activities; Photosensitivity Reaction; Weight Increased	Celexa			S	Oral	40 Mg Daily Oral		Forest
	Lexapro			S	Oral	10 Mg Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2004	6747123	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20040703092		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Bradycardia; Decreased Appetite; Depression; Disease Recurrence; Drug Ineffective; Emotional Distress; Insomnia; Medication Error; Restlessness; Schizoaffective Disorder; Treatment Noncompliance	Risperdal			S	Oral	3 Mg, In 1 Day, Oral		Not Reported
	Escitalopram Oxalate			S		See Image See Image See Image		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2004	4177772	DIRECT	N	DE			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Circulatory Collapse; Completed Suicide; Constipation; Diarrhoea; Dizziness	Lexapro			S		1 A Day		Not Reported
	Zyrexa			C				Not Reported
	Atenolol			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2004	4181230	EXPEDITED (15-DAY)	Y	OT	S04-UKI-02859-01		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Hyperhidrosis; Hypoaesthesia; Lethargy	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2004	4181542	EXPEDITED (15-DAY)	Y	OT	S04-GER-02985-01		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Trimipramine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2004	4180332	DIRECT	N	LT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Autoimmune Thyroiditis; Chest Discomfort; Crying; Depression; Drug Withdrawal Syndrome; Fear; Feeling Abnormal; Gastrooesophageal Reflux Disease; Influenza Like Illness; Mental Disorder; Migraine; Muscle Spasms; Nightmare; Pain; Panic Attack; Suicidal Ideation; Weight Increased	Paxil Cr			S	Oral	1 Pill Once Daily Oral		Not Reported
	Lexapro			S	Oral	1 Pill Twice Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2004	4176345	EXPEDITED (15-DAY)	Y	OT	PHEH2004US07790		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oropharyngeal Swelling	Zelnorm			S				Novartis
	Senokot			S				Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Seroquel			C				Not Reported
	Risperdal			C				Not Reported
	Klonopin			C				Not Reported
	Dulcolax (Bisacodyl)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2004	4177621	EXPEDITED (15-DAY)	Y	HO	04H-163-0266755-00		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Aggression; Alcohol Use; Anaesthetic Complication; Coma; Conversion Disorder; Fall; Gaze Palsy; Head Injury; Headache; Hemiplegia; Musculoskeletal Chest Pain; Paraesthesia; Seizure; Somnolence; Vision Blurred	Fentanyl Citrate			S				Not Reported
	Isoflurane			S				Not Reported
	Escitalopram Oxalate			S	Oral	Per Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2004	4180966	DIRECT	Y				50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Medication Error	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2004	4181725	DIRECT	N	OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysgeusia; Nausea; Parosmia	Lexapro			S	Oral	10 Mg 1 A Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2004	4184920	EXPEDITED (15-DAY)	Y	DE	S04-USA-04303-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Road Traffic Accident; Toxicity To Various Agents	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2004	4175403	EXPEDITED (15-DAY)	Y	HO	S04-USA-03833-01		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cachexia; Chorea; Choreoathetosis; Conversion Disorder; Depressed Level Of Consciousness; Dizziness; Dystonia; Gait Disturbance; Gait Disturbance; Gait Inability; Hypoaesthesia; Insomnia; Intentional Overdose; Memory Impairment; Mental Status Changes; Suicide Attempt; Wheelchair User	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	270 Mg Once Po		Not Reported
	Excedrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2004	4183485	DIRECT	N	OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sensation In Eye; Diplopia; Vision Blurred; Visual Brightness; Visual Field Defect; Visual Impairment	Lexapro			S	Oral	1 Tablet Per Day Oral		Walgreen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2004	4187669	EXPEDITED (15-DAY)	Y	LT	S04-GER-03130-01		35 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Morbid Thoughts; Nervousness; Obsessive Thoughts; Suicidal Ideation	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Remergil (Mirtazapine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2004	4164950	EXPEDITED (15-DAY)	Y	OT	2004219679GB		19 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholangitis; Contusion; Hepatitis Chronic Active	Depo-Provera			S	Intramuscular	150 Mg, Last Injection, Intramuscular		Not Reported
					Intramuscular	150 Mg, Last Injection, Intramuscular		
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2004	4187328	EXPEDITED (15-DAY)	Y	HO	S04-BRA-03329-01		83 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Non-Cardiogenic Pulmonary Oedema; Therapy Non-Responder; Urinary Tract Infection	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Levothyroxine Sodium			C				Not Reported
	Insulin Nos			C				Not Reported
	Amlodipine			C				Not Reported

Captopril	C		Not Reported
Phenytoin	C		Not Reported
Pravastatin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2004	4188585	EXPEDITED (15-DAY)	Y	OT	S04-USA-04386-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Topamax			S		100 Mg Qam		Not Reported
	Topamax			S		200 Mg Qhs		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S		200 Mg Bid		Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2004	4188606	EXPEDITED (15-DAY)	N	DE	S04-USA-02797-01		3 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Mood Swings	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2004	4188619	EXPEDITED (15-DAY)	Y	OT	S04-USA-04368-01		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage; Macular Degeneration; Visual Impairment	Lexapro			S				Not Reported
	Advair			S	Oral	1 Puff Bid Po		Not Reported
	Advair			S	Oral	1 Puff Qd Po		Not Reported
	Advair			C				Not Reported
	Lutein			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2004	4207673	NON-EXPEDITED	Y	HO	US-JNJFOC-20030906650		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Pulmonary Embolism	Risperdal			S	Oral	2.5 Mg, 1 In 1 Day, Oral		Not Reported
	Lithium (Lithium)			S		1500 Mg, 1 In 1 Day		Not Reported
	Escitalopram Oxalate			S		10 Mg, 1 In 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2004	4207716	NON-EXPEDITED	N	HO	US-JNJFOC-20040305938		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Suicidal Ideation	Risperdal			S	Oral	0.5 Mg, 1 In 1 Day, Oral; 1 Mg, 1 In 1 Day, Oral; 1.5 Mg, I 1 Day, Oral		Not Reported
					Oral	0.5 Mg, 1 In 1 Day, Oral; 1 Mg, 1 In 1 Day, Oral; 1.5 Mg, I 1 Day, Oral		
					Oral	0.5 Mg, 1 In 1 Day, Oral; 1 Mg, 1 In 1 Day, Oral; 1.5 Mg, I 1 Day, Oral		
	Lexapro			S	Oral	10 Mg, 1 In 1 Day, Oral; 20 Mg, 1 In 1 Day, Oral; 30 Mg, 1 In 1 Day, Oral		Not Reported
					Oral	10 Mg, 1 In 1 Day, Oral; 20 Mg, 1 In 1 Day, Oral; 30 Mg, 1 In 1 Day, Oral		
					Oral	10 Mg, 1 In 1 Day, Oral; 20 Mg, 1 In 1 Day, Oral; 30 Mg, 1 In 1 Day, Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2004	4208438	NON-EXPEDITED	Y	OT	US-JNJFOC-20030900220		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Risperdal			S	Oral	1 Mg, 3 In 1 Day; Oral		Not Reported
	Lexapro			S	Oral	10 Mg, 1 In 1 Day,Oral		Not Reported
	Trileptal			S	Oral	900 Mg 1 In 1 Day; Oral		Not Reported
	Oxcarbazepine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2004	4189191	EXPEDITED (15-DAY)	Y	DE	S04-NOR-03402-01		23 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2004	4189500	EXPEDITED (15-DAY)	N	HO	S04-USA-04401-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Burns Second Degree; Euphoric Mood; Feeling Drunk; Hypophagia; Memory Impairment; Overdose; Speech Disorder	Lexapro			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Celebrex			C				Not Reported
	Oil Of Oregano			C				Not Reported
	Inderal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2004	3910218	EXPEDITED (15-DAY)	Y	OT	S03-FRA-00523-01		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glycosuria; Hyperglycaemia; Ketonuria	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Imovane (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2004	4190490	EXPEDITED (15-DAY)	Y	DS	S04-FRA-03409-01		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Haemorrhagic Disorder; Pain; Pain In Extremity; Swelling	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Lexomil (Bromazepam)			C				Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2004	4192591	EXPEDITED (15-DAY)	Y	HO, OT	S04-USA-04485-01		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Alcoholism; Apathy; Belligerence; Depression; Disinhibition; Legal Problem; Personality Change; Physical Assault; School Refusal; Thinking Abnormal; Weight Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Concerta			S		135 Mg Qd		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2004	4192599	EXPEDITED (15-DAY)	Y	HO	S04-USA-04403-01		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Hyponatraemia	Lexapro			S	Oral	20 Mg Qod Po		Not Reported
	Lexapro			S	Oral	10 Mg Qod Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2004	4086860	EXPEDITED (15-DAY)	Y	DE, DS, HO	T03-GER-05233-01		82 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cardiac Failure; Cerebral Ischaemia; Decreased Appetite; Depression; Diabetes Mellitus Inadequate Control; Diet Refusal; Disturbance In Attention; Feeling Abnormal; Gait Inability; Mental Disorder; Multiple Organ Dysfunction Syndrome; Nausea; Pneumonia; Pneumonia; Psychomotor Retardation; Refusal Of Treatment By Patient; Thinking Abnormal; Transient Ischaemic Attack; Treatment Noncompliance	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Actos			S		30 Mg Qd		Not Reported
	Amaryl			C				Not Reported
	Unat (Torasemide)			C				Not Reported
	Glucobay			C				Not Reported
	Godamed			C				Not Reported
	Enahexal (Enalapril Maleate)			C				Not Reported
	Glucophage			C				Not Reported
	Zincum (Zinc)			C				Not Reported
	Neuralgin			C				Not Reported
	Gingium (Ginkgo Biloba Extract)			C				Not Reported
	Laif (Hypericum Extract)			C				Not Reported
	Remergil (Mirtazapine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2004	4191862	DIRECT	Y	HO			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Syncope	Lexapro			S	Oral	Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2004	4192525	EXPEDITED (15-DAY)	Y	HO	S04-GER-02852-01			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Intentional Overdose; Seizure; Suicide Attempt	Cipralex			S				Not Reported
	Citalopram Hydrobromide			S	Oral	600 Mg Once Po		Not Reported
	Citalopram Hydrobromide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2004	4112369	EXPEDITED (15-DAY)	Y	OT	S04-USA-01206-01		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Dysarthria; Euphoric Mood; Nuclear Magnetic Resonance Imaging Brain Abnormal; Treatment Noncompliance; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2004	4169852	EXPEDITED (15-DAY)	Y	OT	S04-USA-03696-01		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported
	Bextra			C				Not Reported
	Lovastatin			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2004	4185089	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0491579A		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Feeling Jittery; Headache; Mental Impairment; Muscle Twitching; Sleep Disorder; Thirst	Paxil			S	Oral	20mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Strattera			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2004	4185094	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0491910A		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Hypoaesthesia; Paraesthesia; Vomiting; Weight Decreased	Paxil			S	Oral	30mg Per Day	1 YR	Glaxosmithkline
	Lexapro			S	Unknown		3 DAY	Not Reported
	Prevacid			C				Not Reported
	Zantac			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2004	4186422	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0504277A		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Paxil			S				Glaxosmithkline
	Lexapro			S		10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2004	4186542	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0504843A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Dyspnoea; Palpitations	Paxil			S				Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2004	4186780	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0504223A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nightmare	Paxil Cr			S	Oral			Glaxosmithkline
	Lexapro			S				Not Reported
	Seroquel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2004	4191613	DIRECT	Y	RI			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Decreased; Blood Pressure Systolic Increased; Dyspnoea; Eye Disorder; Feeling Abnormal; Hypersensitivity; Pain; Rash Generalised; Seizure; Tremor	Lexapro			S	Oral	10 Mg Po Daily 1 Dose Only		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2004	4193214	EXPEDITED (15-DAY)	Y	DE	S04-GER-03471-01		45 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2004	4193269	EXPEDITED (15-DAY)	Y	DE	S04-GER-03466-01		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Death Of Companion; Drug Interaction	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2004	4193495	EXPEDITED (15-DAY)	Y	DE	S04-USA-04603-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Completed Suicide; Overdose; Toxicity To Various Agents	Lexapro			S	Oral	280 Mg Once Po		Not Reported
	Lexapro			S				Not Reported
	Lamotrigine			C				Not Reported
	Seroquel			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2004	5823358	EXPEDITED (15-DAY)	Y	HO	SO4-USA-04007-01		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Basophil Count Increased; Blood Calcium Decreased; Blood Chloride Decreased; Blood Creatinine Decreased; Blood Urea Decreased; Haemoptysis; Hyponatraemia; Pneumonia; White Blood Cell Count Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Benicar Hct			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Diovan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2004	4161880	EXPEDITED (15-DAY)	N	RI, OT	S04-USA-03236-01		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypertension	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Atacand (Candesarta Cilexetil)			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Zocor			C				Not Reported
	Zyrtec			C				Not Reported
	Allegra			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Advil			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2004	4193852	EXPEDITED (15-DAY)	Y	HO	S04-ESP-03543-01		79 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertensive Crisis	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2004	4193890	EXPEDITED (15-DAY)	Y	DS, HO	HQWYE700902AUG04		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Csf Test Abnormal; Feeling Abnormal; Headache; Hypersomnia; Impaired Work Ability; Migraine; Sleep Disorder; Subdural Haematoma	Effexor Xr			S	Oral	Started With 75 Mg, Then 150 Mg, Then 225 Mg/Day. Increased At 75 Mg Intervals Over A Year, Oral		Not Reported
	Lexapro			S				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2004	4194855	DIRECT	Y	HO, RI			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative; Drug Eruption; Dyspnoea; Erythema; Pruritus; Pyrexia; Throat Tightness; Urticaria	Lexapro			S	Oral	10 Mg Po Qd		Not Reported
	Glipizide			C				Not Reported
	Albuterol			C				Not Reported
	Prednisone			C				Not Reported
	Potassium			C				Not Reported
	Amitriptyline			C				Not Reported
	Aspirin			C				Not Reported
	Westcort			C				Not Reported
	Advair Diskus			C				Not Reported
	Diflucan			C				Not Reported
	Zyrtec			C				Not Reported
	Metoprolol			C				Not Reported
	Lisinopril			C				Not Reported
	Lasix			C				Not Reported
	Xanax			C				Not Reported
	Norvasc			C				Not Reported
	Nystatin			C				Not Reported
	Diclofenac			C				Not Reported
	Calcium W/Vit D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2004	4196198	DIRECT	Y				58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Mental Status Changes; Tremor	Escitalopram Oxalate			S	Oral	40 Mg Po Daily		Not Reported
	Bupropion			S	Oral	150 Mg Po Q Day		Not Reported
	Benazepril			C				Not Reported
	Metronidazole			C				Not Reported
	Benicar			C				Not Reported
	Advair Diskus			C				Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2004	4103762	EXPEDITED (15-DAY)	Y	CA	S04-USA-00732-02		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Limb Malformation; Maternal Exposure During Pregnancy; Multiple Congenital Abnormalities	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2004	4157603	EXPEDITED (15-DAY)	Y	HO	S04-USA-03034-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Coma; Confusional State; Depression; Overdose; Rebound Effect; Suicidal Ideation; Treatment	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Noncompliance

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2004	4195461	EXPEDITED (15-DAY)	Y	CA	S04-UKI-03475-01		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Central Nervous System Anomaly; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2004	4196808	EXPEDITED (15-DAY)	Y	OT	S04-USA-03511-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Drug Interaction; Loss Of Consciousness; Syncope	Lexapro			S				Not Reported
	Metoprolol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2004	4211081	NON-EXPEDITED	Y	HO	200318869US		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lasix			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po	4 MTH	Not Reported
	Metolazone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2004	4172146	EXPEDITED (15-DAY)	Y	HO	S04-USA-03774-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression; Amnesia; Coma; Diarrhoea; Dyskinesia; Hyperhidrosis; Hypertension; Malaise; Refusal Of Treatment By Patient; Somatic Symptom Disorder; Speech Disorder; Suicidal Ideation; Tremor; Urticaria; Vomiting	Lexapro	S	Oral	10 Mg Qd; Po		Not Reported
	Lexapro	S	Oral	10 Mg Qd; Po		Not Reported
	Vioxx	C				Not Reported
	Elavil	C				Not Reported
	Gabitril	C				Not Reported
	Abilify	C				Not Reported
	Zyprexa	C				Not Reported
	Toradol	C				Not Reported
	Sonata	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2004	4191149	EXPEDITED (15-DAY)	N		US-GLAXOSMITHKLINE-A0521812A		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Medication Error; Somnolence	Wellbutrin			S	Oral	300mg Per Day		Glaxosmithkline
	Lexapro			S				Not Reported
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2004	4195892	DIRECT	Y	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Dysphoria; Headache; Hot Flush; Restless Legs Syndrome	Lexapro			S	Oral	20 Qd Po		Not Reported
	Prozac			S	Oral	20 Qd Po		Not Reported
	Klonoprin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2004	4196055	DIRECT	Y	HO			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contusion; Epistaxis	Lexapro		S	Oral	20mg Daily Oral	Forest
	Lorazepam		C			Not Reported
	Acetaminophen		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2004	4195970	EXPEDITED (15-DAY)	Y	HO, RI	S04-USA-04868-01		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Depressed Level Of Consciousness; Dizziness; Epistaxis; Haematocrit Decreased; Haemoglobin Decreased; Haemorrhage; Injury; Mean Cell Haemoglobin Decreased; Mean Platelet Volume Decreased; Platelet Count Increased; Platelet Disorder; Platelet Function Test Abnormal; Thrombocytosis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Low Dose Hormone (Nos)			C				Not Reported
	Aspirin			C				Not Reported
	Claritin-D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2004	4195983	EXPEDITED (15-DAY)	Y	DE	S04-USA-04852-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level Above Therapeutic; Fall; Forearm Fracture; Myocardial Infarction; Procedural Pain; Respiratory Failure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Methadone Hydrochloride			S				Not Reported
	Ativan			S				Not Reported
	Amitriptyline			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2004	4196134	EXPEDITED (15-DAY)	Y	HO	S04-USA-04615-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2004	4196492	EXPEDITED (15-DAY)	Y	DE	2004UW16878		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Cardiac Arrest; Coma; Respiratory Arrest; Sudden Death	Seroquel			S	Oral	25 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
					Oral	30 Mg Qd Po		
					Oral	30 Mg Qd Po		
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Neurontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2004	4197225	DIRECT	Y	OT			19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Oral	Bid Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2004	4100774	EXPEDITED (15-DAY)	Y	RI	S04-USA-00713-01		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Blood Thyroid Stimulating Hormone Decreased; Catecholamines Urine Increased; Condition Aggravated; Epinephrine Increased; Metanephrine Urine Increased;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Hytrin			C				Not Reported
	Lipitor			C				Not Reported
	Viagra			C				Not Reported

Onychomycosis;
Onychomycosis; Panic Attack;
Phaeochromocytoma;
Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2004	4199248	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate			S	Oral	10 Mg Q Day Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2004	4199907	EXPEDITED (15-DAY)	N	OT	S04-USA-04906-01		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2004	4199911	EXPEDITED (15-DAY)	N	DE	S04-USA-04856-01		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Completed Suicide; Compulsions; Condition Aggravated; Crying; Depression; Dyspepsia; Flatulence; Insomnia; Irritability; Loss Of Libido; Tremor	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2004	4194036	EXPEDITED (15-DAY)	Y	OT	IE-GLAXOSMITHKLINE-B0342249A			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lamictal			S				Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2004	4199894	EXPEDITED (15-DAY)	Y	OT	S04-USA-04981-01		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Morphine			C				Not Reported
	Fentanyl			C				Not Reported
	Toprol Xl			C				Not Reported
	Zantac			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2004	4103030	EXPEDITED (15-DAY)	Y	DS	S04-PRT-00593-01		57 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Hepatic Steatosis; Hepatomegaly	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2004	4194929	EXPEDITED (15-DAY)	N	OT	S04--USA-04732-01		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Belligerence; Confusional State; Delusion; Mania; Paranoia	Wellbutrin			S	Oral	300mg Per Day	5 YR	Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day	2 MTH	Not Reported
	Ambien			C	Oral			Not Reported
	Trazodone Hydrochloride			C	Unknown	25mg Per Day		Not Reported
	Lipitor			C	Unknown			Not Reported
	Aciphex			C	Unknown			Not Reported

	Aspirin	C	Unknown	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2004	4199552	DIRECT	N	DS, HO, RI			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Confusional State; Dysarthria; Dyskinesia; Gait Disturbance; Impaired Work Ability; Muscle Contractions Involuntary; Muscle Twitching; Speech Disorder; Tremor; Weight Increased	Lexapro			S	Oral	10 Mg Tablet Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2004	4213798	NON-EXPEDITED	N		PHEH2004US07700		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyperhidrosis; Rash Erythematous; Rash Macular; Rash Pruritic	Zelnorm			S	Oral	6 Mg Bid Oral		Not Reported
	Lexapro			S				Not Reported
	Potassium Chloride			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Klonopin			C				Not Reported
	Estraderm			C				Not Reported
	Celebrex			C				Not Reported
	Nexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2004	4147386	EXPEDITED (15-DAY)	Y	OT	S04-USA-02765-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastritis; Hepatitis; Lipase Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ditropan			C				Not Reported

	Buspar	C	Not Reported
	Armour Thyroid	C	Not Reported
	Effexor	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2004	4198227	DIRECT	Y	RI			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	20 Mg Once Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2004	4199228	EXPEDITED (15-DAY)	Y	DE	S04-USA-05502-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Dilatation Ventricular; Injury; Intentional Overdose; Pulmonary Oedema; Road Traffic Accident	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celexa			S				Not Reported
	Celexa			S	Oral	40 Mg Qd Po		Not Reported
	Darvocet-N 100			S				Not Reported
	Flexeril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2004	4199234	EXPEDITED (15-DAY)	Y	OT	S04-USA-05501-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contusion; Depressed Level Of Consciousness; Depression; Fall; Loss Of Consciousness; Muscle Spasms; Nystagmus; Postictal State; Seizure; Suicidal Ideation; Tongue Injury	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2004	4201459	EXPEDITED (15-DAY)	Y	DS	S04-DEN-03815-01		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Mechanical Urticaria; Miosis; Nausea; Pruritus; Rash; Urticaria	Cipralex			S				Not Reported
	Zyrtec			S				Not Reported
	Salures-K			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2004	4162917	EXPEDITED (15-DAY)	Y	HO	S04-USA-01889-01		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Back Pain; Ceruloplasmin Increased; Condition Aggravated; Hepatic Steatosis; Hepatitis Toxic; Hepatotoxicity; Hypoaesthesia; Musculoskeletal Discomfort; Nausea; Therapeutic Product Effect Decreased; Urinary Tract Infection	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Neurontin			C				Not Reported
	Glucotrol			C				Not Reported
	Copaxone			C				Not Reported
	Nonsteroidal Antiinflammatory			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2004	4200310	EXPEDITED (15-DAY)	Y	OT	HQWYE139228MAY04		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Condition Aggravated; Drug Ineffective; Drug Withdrawal Syndrome; Emotional Distress; Feeling Abnormal; Panic Attack; Product Quality	Effexor Xr			S	Oral Oral	See Image See Image		Not Reported
	Lexapro			S		See Image See Image		Not Reported
	Singulair			C				Not Reported
	Clarinex			C				Not Reported

Issue; Suicidal Ideation	Synthroid	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2004	5714342	EXPEDITED (15-DAY)	Y	DE	2003-UK-00153UK		62 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Unevaluable Event	Spiriva			S	Respiratory (inhalation)	18 Mcg (18 Mcg, Ih)		Not Reported
	Escitalopram Oxalate			S		10 Mg		Not Reported
	Temazepam			C				Not Reported
	Budesonide (Budesonide)			C				Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2004	4201804	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Medication Error	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2004	4202242	EXPEDITED (15-DAY)	Y	OT	S04-AUT-03818-01		22 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2004	4202244	EXPEDITED (15-DAY)	Y	HO	S04-UKI-03884-01		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Cipralex			S				Not Reported
	Flucloxacillin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2004	4195976	EXPEDITED (15-DAY)	Y	HO	S04-USA-04867-01		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Angle Closure Glaucoma; Arthralgia; Circadian Rhythm Sleep Disorder; Cystitis Interstitial; Diplopia; Dry Mouth; Gastric Disorder; Hyperhidrosis; Hypersensitivity; Insomnia; Intervertebral Disc Degeneration; Medication Error; Metastases To Bone; Metastases To Liver; Muscle Injury; Muscle Spasms; Myalgia; Osteoarthritis; Pelvic Floor Muscle Weakness; Pneumonia Bacterial; Renal Disorder; Swollen Tongue; Tearfulness; Urethral Disorder; Urge Incontinence; Urinary Retention	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	10 Mg Qam Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prozac			S	Oral	20 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported
	Digoxin			C				Not Reported
	Tiazac 9diltiazem Hydrochloride)			C				Not Reported
	Methotrexate			C				Not Reported
	Omega 3 Fatty Acids			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Nitroglycerin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2004	4204656	EXPEDITED (15-DAY)	Y	HO	S04-UKI-03828-01		81 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Atrophy;	Cipralex			S				Not Reported

Circulatory Collapse; Dizziness; Lacunar Infarction; Myoclonus; Seizure	Venlafaxine Hydrochloride	S	Oral	37.5 Mg Qd Po		Not Reported
	Simvastatin	C				Not Reported
	Aspirin (Acetylsalicylic Acid)	C				Not Reported
	Cephalexin	C				Not Reported
	Imdur	C				Not Reported
	Teoptic (Carteolol Hydrochloride)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2004	4176131	EXPEDITED (15-DAY)	Y	OT	S04-GER-02983-01			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Cipralex			S		10 Mg Qd		Not Reported
	Cipralex			S		5 Mg Qd		Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2004	4204489	DIRECT	N	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Asthenia; Crying; Feeling Of Despair; Paraesthesia; Self-Injurious Ideation	Lexapro			S	Oral	1 A Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2004	4206217	EXPEDITED (15-DAY)	Y	OT	S04-USA-05503-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Foetal Heart Rate Decreased; Maternal Exposure During Pregnancy; Peripartum Haemorrhage; Pregnancy	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2004	4206273	EXPEDITED (15-DAY)	Y	OT	S04-UKI-03883-01		19 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholangitis; Contusion; Liver Disorder; Liver Function Test Abnormal	Cipralex			S				Not Reported
	Depo-Provera			S	Intramuscular	150 Mg Im		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2004	4160204	EXPEDITED (15-DAY)	Y	OT	S04-USA-03133-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Amnesia; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Dysphoria; Headache; Hepatotoxicity; Hot Flush; Liver Function Test Abnormal; Restless Legs Syndrome; Serotonin Syndrome	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prozac			S		20 Mg Qd		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2004	4171821	EXPEDITED (15-DAY)	Y	HO	S04-USA-03703-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Ii Disorder; Road Traffic Accident; Suicide Attempt	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2004	4177625	NON-EXPEDITED	Y	OT	S04-USA-04077-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Wellbutrin Xl			S	Oral	450mg Per Day	4 MTH	Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2004	4200585	NON-EXPEDITED	N	OT	US-GLAXOSMITHKLINE-A0515395A		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Depressed Level Of Consciousness; Eye Movement Disorder; Generalised Tonic-Clonic Seizure; Postictal State; Tongue Biting; Tonic Clonic Movements	Wellbutrin			S	Oral	450mg Per Day	3 MTH	Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day	442 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2004	4204792	EXPEDITED (15-DAY)	N	OT	S04-USA-05535-01		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Breath Alcohol Test Positive; Potentiating Drug Interaction	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Strattera			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2004	4147390	EXPEDITED (15-DAY)	Y	OT	S04-USA-02766-01		87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coma	Lexapro	S	Oral	5 Mg Qd Po	Not Reported
	Buspirone	C			Not Reported
	Doxozosin	C			Not Reported
	Exelon	C			Not Reported
	Furosemide	C			Not Reported
	Mirtazapine	C			Not Reported
	Nitro-Dur	C			Not Reported
	Plavix	C			Not Reported
	Potassium Chloride	C			Not Reported
	Sotalol Hydrochloride	C			Not Reported
	Synthroid	C			Not Reported
	Vitamin C	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2004	4195940	EXPEDITED (15-DAY)	Y	HO	S04-SWI-03547-01		82 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury; Thrombosis	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Pravastatin Sodium			S	Oral	20 Mg Qd Po		Not Reported
	Enalapril Maleate			S	Oral	10 Mg Qd Po		Not Reported
	Torem (Torasemide)			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2004	4206127	DIRECT	Y				33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lexapro			S		5 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2004	4148760	EXPEDITED (15-DAY)	Y	OT	S04-USA-02791-01		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Coma; Depressed Level Of Consciousness; Dizziness; Seizure; Sensory Disturbance; Syncope	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Lexapro	S	Oral	5 Mg Qd Po		Not Reported
	Norvasc	C				Not Reported
	Cardizem Cd	C				Not Reported
	Diovan	C				Not Reported
	Lisinopril	C				Not Reported
	Pletal	C				Not Reported
	Haldol	C				Not Reported
	K-Dur	C				Not Reported
	Coumadin	C				Not Reported
	Insulin Nos	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2004	4206764	DIRECT	Y	HO			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction	Lexapro			S	Oral	10 Mg/Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2004	4208435	EXPEDITED (15-DAY)	Y	HO	S04-USA-05846-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalitis; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2004	4205519	NON-EXPEDITED	Y	OT	2004UW09813		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash Maculo-Papular; Skin Exfoliation	Crestor			S	Oral	10 Mg Dialy Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2004	4208557	DIRECT	Y	HO			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Natriuretic Peptide Increased; Haemoglobin Decreased; Hyponatraemia; Pulmonary Oedema; Urinary Tract Infection; White Blood Cell Count Increased	Lexapro			S	Oral	10 Mg Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2004	4090167	EXPEDITED (15-DAY)	Y	HO	S04-SWI-00380-01		79 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematocrit Decreased; Haemoglobin Decreased; Thrombocytopenia	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Betolvex (Cyanocobalamin-Tannin Complex)			C				Not Reported
	Haldol			C				Janssen
	Insulin Nos			C				Not Reported
	Norvasc			C				Not Reported
	Convulex (Valproate Sodium) "Byk Gulden"			C				Not Reported
	Orfiril Desitin (Valproate Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2004	4201203	EXPEDITED (15-DAY)	Y	OT	S04-ESP-03760-01		78 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness Postural; Nystagmus; Vertigo	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Xeloda			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2004	4208711	DIRECT	N	HO, LT			14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Hallucination, Visual; Mood Swings; Obsessive-Compulsive Disorder; Suicide Attempt; Thinking Abnormal	Lexapro			S		10mg/Day Fall 2001 Winter 2004		Not Reported
	Luvox			S		30mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2004	4212574	EXPEDITED (15-DAY)	Y	OT	CH-JNJFOC-20040809666		26 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Thrombocytopenia	Risperdal			S	Oropharingeal			Not Reported
	Cipralex			S	Oropharingeal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2004	4173248	EXPEDITED (15-DAY)	Y	DE	S04-UKI-02778-01		45 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Completed Suicide; Dyspepsia; Dysphemia; Insomnia; Muscle Twitching; Nausea; Panic Attack; Paraesthesia; Pollakiuria; Treatment Noncompliance	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2004	4211724	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Speech Disorder	Ambien			S	Oral	10 Mg At Hs Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zestril			C				Not Reported
	Norvasc			C				Not Reported
	Vancocin			C				Not Reported
	Flagyl			C				Not Reported
	Diflucan			C				Not Reported
	Phenergan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2004	4212314	EXPEDITED (15-DAY)	Y	HO	T04-USA-00447-01		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Barrett'S Oesophagus; Cerebral Ischaemia; Choking; Cough; Dandy-Walker Syndrome; Dizziness; Duodenal Neoplasm; Duodenal Ulcer; Dysphagia; Ectopic Gastric Mucosa; Gastrointestinal Disorder; Gastrointestinal Obstruction; Gastrooesophageal Reflux Disease; Generalised Tonic-Clonic Seizure; Hiatus Hernia; Hypothyroidism; Metaplasia; Mucosal Inflammation; Nausea; Peptic Ulcer; Vomiting	Memantine Hydrochloride			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram			S	Oral	10 Mg Qd Po		Not Reported
	Versed			S	Intravenous (not otherwise specified)	1 Mg Once Iv		Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2004	4212321	EXPEDITED (15-DAY)	Y	HO	S04-USA-05944-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Interaction; Haemorrhage; International Normalised Ratio Increased; Mental Disorder	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Warfarin Sodium			S	Oral	5 Mg Qd Po		Not Reported
	Bethanecol			C				Not Reported
	Clotrimazole			C				Not Reported
	Levofloxacin			C				Not Reported
	Prednisone			C				Not Reported
	Risperidone			C				Not Reported
	Tamulosin			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4191672	EXPEDITED (15-DAY)	N	HO	S04-USA-04404-01		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Electroencephalogram Abnormal; Feeling Abnormal; Generalised Tonic-Clonic Seizure; Headache; Vision Blurred	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ortho Evra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4196776	EXPEDITED (15-DAY)	Y	OT	S04-USA-04782-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Amnesia; Aphasia; Depressed Level Of Consciousness; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Hypoaesthesia; Mental	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celexa			S	Oral	20 Mg Qd Po		Not Reported
	Strattera			S		80 Mg Qd		Not Reported
	Celexa			C	Oral	40 Mg Qd Po		Not Reported

Impairment; Muscle Spasms; Myoclonus; Seizure; Sensory Disturbance

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4202235	EXPEDITED (15-DAY)	Y	HO	S04-DEN-03746-01		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210499	NON-EXPEDITED	N	LT	S04-USA-03249-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210502	NON-EXPEDITED	N	OT	S04-USA-03106-01		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Muscle Spasms; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210505	NON-EXPEDITED	N	OT	S04-USA-03101-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Confusional State; Mania; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported

Ultram	S	Unknown	Unk		Not Reported
Ultram	C				Not Reported
Vicodin	C				Not Reported
Prilosec	C				Not Reported
Zantac	C				Not Reported
Synthroid	C				Not Reported
Atenolol	C				Not Reported
Unspecified Ingredient	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210507	NON-EXPEDITED	N	OT	S04-USA-03008-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210509	NON-EXPEDITED	N	OT	S04-USA-02804-01		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210514	NON-EXPEDITED	Y	OT	S04-USA-02763-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Lethargy; Suicide Attempt	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Trazodone Hydrochloride			S		150 Mg Once		Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Depakote			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210516	NON-EXPEDITED	N	OT	S04-USA-03072-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Amnesia; Overdose; Suicidal Ideation	Lexapro			S	Oral	120 Mg Qd Po		Not Reported
	Lexapro			S	Oral	60 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210524	NON-EXPEDITED	N	HO	S04-USA-04974-01		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Flushing; Nausea	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Nexium (Esomeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210526	NON-EXPEDITED	Y	RI, OT	S04-USA-03011-01		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210528	NON-EXPEDITED	N	OT	S04-USA-04959-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Mysoline			C				Not Reported

	Gabitril	C	Not Reported
	Geodon	C	Not Reported
	Adderall Ar	C	Not Reported
	Doxepin	C	Not Reported
	Cogentin	C	Not Reported
	Levoxyl	C	Not Reported
	Nexium (Esomeprazole)	C	Not Reported
	Crestor	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210530	NON-EXPEDITED	Y	HO	S04-USA-03010-01		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bleeding Time Prolonged; Hypersensitivity	Lexapro			S	Unknown	Unk		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Potassium			C				Not Reported
	Prilosec			C				Not Reported
	Xanax			C				Not Reported
	Citrucel (Methylcellulose)			C				Not Reported
	Zocor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210540	NON-EXPEDITED	N	OT	S04-USA-04957-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210543	NON-EXPEDITED	N	OT	S04-USA-04943-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Hypotension; Somnolence; Tongue Blistering	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Toprol Xl			C				Not Reported
	Aspirin			C				Not Reported

	Plavix	C		Not Reported
	Klonopin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210546	NON-EXPEDITED	Y	HO	S04-USA-04851-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210550	NON-EXPEDITED	Y	OT	S04-USA-04613-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Electrocardiogram Qt Prolonged; Vertigo	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210555	NON-EXPEDITED	Y	OT	S04-USA-04181-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Lexapro			S				Not Reported
	Paxil			C				Not Reported
	Methadone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210605	NON-EXPEDITED	Y	OT	S04-USA-03938-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia	Lexapro			S	Oral	25 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported
	Atarax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210608	NON-EXPEDITED	Y	OT	S04-USA-03771-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210610	NON-EXPEDITED	Y	HO	S04-USA-03713-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210611	NON-EXPEDITED	N	HO	S04-USA-03700-01		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210613	NON-EXPEDITED	Y	OT	S04-USA-03699-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Lexapro			S				Not Reported
	Celexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210616	NON-EXPEDITED	Y	OT	S04-USA-03597-04			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210618	NON-EXPEDITED	Y	OT	S04-USA-03597-03			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210620	NON-EXPEDITED	Y	OT	S04-USA-03597-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210622	NON-EXPEDITED	Y	OT	S04-USA-03597-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210623	NON-EXPEDITED	Y	HO	S04-USA-03279-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	4210934	EXPEDITED (15-DAY)	Y	OT	S04-UKI-03968-01		24 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastritis; Gastrooesophageal Reflux Disease; Haematemesis; Upper Gastrointestinal	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

Haemorrhage

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2004	5664250	NON-EXPEDITED	Y	HO	S04-USA-01957-01		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2004	4092603	EXPEDITED (15-DAY)	Y	OT	S04-USA-00419-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dilatation Atrial; Electrocardiogram Qt Prolonged; Mitral Valve Incompetence; Treatment Noncompliance; Ventricular Hypertrophy	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Zonegran			S				Not Reported
	Klonopin			C				Not Reported
	Flexeril			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Bextra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2004	4212128	EXPEDITED (15-DAY)	Y	HO	LBID00204003065		10 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Atrioventricular Block First Degree; Blood Thyroid Stimulating Hormone Decreased; Chest Pain; Conduction Disorder; Diarrhoea; Disorientation; Dizziness; Drug Level	Lithium Carbonate			S	Oral	Po, 300 Mg Qid Po		Not Reported
	Methylphenidate Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Clonidine (Clonidine)			S				Not Reported

Above Therapeutic; Electrocardiogram Qrs Complex Prolonged; Fluid Intake Reduced; Hyperhidrosis; Hypophagia; Hypotension; Mania; Pallor; Palpitations; Tachyarrhythmia; Toxicity To Various Agents; Ventricular Extrasystoles; Ventricular Tachycardia; Vomiting; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2004	4212818	DIRECT	Y	DS			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Burning Sensation; Disorientation; Medication Error; Pain In Extremity; Pruritus	Lexapro			S		1 / Day		Not Reported
	Neurontin			S		2 / Day As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2004	4206275	EXPEDITED (15-DAY)	Y	CA	S04-SAF-03887-01		41 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Complication Of Pregnancy; Maternal Exposure During Pregnancy; Stress; Unintended Pregnancy	Cipralex			S	Oral	5mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2004	4212352	DIRECT	Y	OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Influenza Like Illness; Insomnia; Paraesthesia; Sexual Dysfunction	Lexapro			S	Oral	1 Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2004	4212533	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Lexapro			S	Oral	20 Mg Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2004	4214988	EXPEDITED (15-DAY)	Y	DE	S04-USA-06016-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Teventen (Eprosartan)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2004	4213177	DIRECT	N	DE			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Homicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2004	4214067	DIRECT	Y	LT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bipolar I Disorder; Condition Aggravated; Depression;	Zoloft			S		100 Mg Am	1 YR	Not Reported
	Lexapro			S		10 Mg Am	1 MTH	Not Reported

Feeling Of Despair; Feelings Of Worthlessness; Insomnia; Irritability; Panic Reaction; Paranoia; Psychotic Disorder; Speech Disorder; Stress; Suicidal Ideation; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2004	4215373	DIRECT	Y	HO			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Dizziness; Dyspnoea; Medication Error; Palpitations	Lexapro			S	Oral	2 Tablets Po/ Prior To Admssion		Not Reported
	Xanax			C				Not Reported
	Feosol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2004	4216026	DIRECT	N	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Child Abuse; Euphoric Mood; Feeling Abnormal; Hallucinations, Mixed; Mania; Sexual Abuse; Sexual Dysfunction	Lexapro			S		2 At Bedtime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2004	4209581	EXPEDITED (15-DAY)	Y	HO	US-BRISTOL-MYERS SQUIBB COMPANY-12696381		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Fall; Mental Status Changes;	Sinemet			S				Bristol Myers Squibb
	Lexapro			S	Oral			Not Reported

Parkinson'S Disease

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2004	4215861	EXPEDITED (15-DAY)	Y	OT	S01-USA-06025-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; Premature Baby	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2004	4217347	DIRECT	N	HO, OT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Off Label Use; Seizure	Neurontin			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2004	4220999	NON-EXPEDITED	Y	OT	US-JNJFOC-20040304012		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Topamax			S		300 Mg, In 1 Day		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S		200 Mg, 2 In 1 Day		Not Reported
	Lexapro			S		20 Mg, In 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2004	4218910	EXPEDITED (15-DAY)	Y	HO	T04-USA-04025-00		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Interaction;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Hypersensitivity; Toxicity To Various Agents	Vistaril	S	Oral	50 Mg Qd Po	Not Reported
	Alprazolam	S	Oral	0.25 Mg Qd Po	Not Reported
	Metrogel	S			Not Reported
	Metrogel	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2004	4221160	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Feeling Abnormal; Hypoaesthesia; Pain; Product Quality Issue; Sensory Disturbance; Thinking Abnormal	Prozac			S		20 -60 Mg		Not Reported
	Lexapro			S		10 Mg		Not Reported
	Sonata			C				Not Reported
	Premarin Cream			C				Not Reported
	Ultracet			C				Not Reported
	Lasix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2004	4221498	DIRECT		OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anger; Condition Aggravated; Crying; Delusion; Depressed Mood; Disturbance In Attention; Drug Ineffective; Feeling Abnormal; Feeling Of Despair; Hypophagia; Irritability; Loss Of Employment; Personality Change; Social Fear; Thinking Abnormal; Weight Decreased	Lexapro			S		20 Mg Daily		Not Reported
	Lexapro			S		10 Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2004	5682296	NON-EXPEDITED	Y	HO	S03-USA-05040-01		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Celexa			S	Oral	60 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Gabapentin			C				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2004	4208840	EXPEDITED (15-DAY)	Y	DS	S04-SWI-03896-01		48 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Loss Of Consciousness; Road Traffic Accident	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S				Not Reported
	Femoston Estradiol/ Dydrogesterone			C				Not Reported
	Ponstel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2004	4219123	EXPEDITED (15-DAY)	Y	OT	S04-UKI-04153-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous Complete; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2004	4219797	EXPEDITED (15-DAY)	Y	DE	S04-USA-06113-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Economic Problem; Gun Shot Wound; Refusal Of Treatment By Patient	Lexapro			S				Not Reported
	Effexor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2004	6747133	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20040903645		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bicarbonate Decreased; Blood Calcium Decreased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Ph Decreased; Blood Potassium Increased; Bradycardia; Cardiac Arrest; Coma; Hypertension; Hypotension; Pco2 Decreased; Po2 Decreased; Respiratory Depression; Suicide Attempt	Tylenol		Y	S	Oral	Oral		Not Reported
	Desipramine Hydrochloride			S	Oral	Oral		Not Reported
	Lorazepam			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2004	7879635	NON-EXPEDITED	Y	HO, OT	163-20785-03110514		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Depressed Level Of Consciousness; Depression; Fatigue; Generalised Tonic-Clonic Seizure; Headache; Hypoaesthesia; Musculoskeletal Stiffness; Oedema Peripheral;	Thalomid			S	Oral Oral	See Image See Image		Not Reported
	Temodar			S				Not Reported
	Celebrex			S				Not Reported
	Lexapro			S				Not Reported
	Ambien			S				Not Reported
	Dilantin			S				Not Reported
	Lasix			C				Not Reported

Restlessness; Sedation; Somnolence; Tremor	Premarin	C		Not Reported
	Decadron	C		Not Reported
	Nexium (Esomeprazole)	C		Not Reported
	Ativan	C		Not Reported
	Zofran	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2004	4177605	EXPEDITED (15-DAY)	N	RI, OT	S04-USA-04018-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Pressure Fluctuation; Erectile Dysfunction; Exostosis; Fracture; Hypertension; Joint Dislocation; Nausea; Somnolence	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lotrel			S				Not Reported
	Clonidine			S		0.2 Mg Bid		Not Reported
	Amiloride Hcl W/ Hydrochlorothiazide			S				Not Reported
	Percocet			S				Not Reported
	Percocet			S				Not Reported
	Wellbutrin Sr			S		150 Mg		Not Reported
	Bextra			S				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Carisoprodol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2004	4202970	EXPEDITED (15-DAY)	Y	OT	S04-USA-05546-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diastolic Dysfunction; Mitral Valve Incompetence; Tricuspid Valve Incompetence; Ventricular Extrasystoles	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Loestrin 1.5/30 21 Day			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2004	4215606	EXPEDITED (15-DAY)		HO, OT	2004-DE-04634GD		10 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Atrioventricular Block First Degree; Chest Pain; Diarrhoea; Disorientation; Dizziness; Drug Interaction; Hyperhidrosis; Hypophagia; Hypotension; Hypothyroidism; Pallor; Palpitations; Rhythm Idioventricular; Toxicity To Various Agents; Ventricular Extrasystoles; Ventricular Tachycardia; Vomiting; White Blood Cell Count Increased	Lithium Carbonate			S		1200 Mg Twice Daily		Not Reported
	Clonidine Hydrochloride			S		0.4 Mg (Twice Daily)		Not Reported
	Methylphenidate			S		36 Mg (Once Daily) (In The Morning)		Not Reported
	Escitalopram Oxalate			S		10 Mg (Once Daily)		Not Reported
	Oxcarbazepine			S		600 Mg (Once Daily)		Not Reported
	Depakote			S		See Image		Not Reported
	Levothyroxine Sodium			S		0.05 Mg (Once Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2004	4219865	EXPEDITED (15-DAY)	N	DE	S04-USA-06147-01		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2004	4221115	DIRECT	Y	RI			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Interaction; Haematoma	Warfarin Sodium			S		7.5 Mg M/W/F & 5 Mg Other		Not Reported
	Lexapro			S		Alt 1 Tab Qd W/ 0.5 Qod		Not Reported
	Coreg			C				Not Reported
	Atacand			C				Not Reported
	Lipitor			C				Not Reported
	Furosemide			C				Not Reported
	Propoxy/Apap			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2004	4104971	EXPEDITED (15-DAY)	Y	OT	S04-USA-00838-01		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Facial Paralysis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported
	Arthrotec			C				Not Reported
	Ativan			C				Not Reported
	Vicodin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2004	4194866	EXPEDITED (15-DAY)	N	OT	S04-USA-04729-01		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration; Tongue Ulceration	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zoloft			S	Oral	150 Mg Qd Po		Not Reported
	Topamax			S		25 Mg Qd		Not Reported
	Vioxx			S		25 Mg Qd		Not Reported
	Zocor			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Mirapex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2004	4222983	EXPEDITED (15-DAY)	Y	OT	S04-USA-06150-01		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Clozaril	S		500 Mg Qd		Not Reported
	Colace	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2004	4222470	DIRECT	Y	OT			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2004	4223302	DIRECT	N	HO, LT, RI			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased; Malignant Hypertension	Lexapro			S	Oral	10 Mg Once Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2004	4223909	EXPEDITED (15-DAY)	Y	HO	S04-SWE-04214-01		12 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Overdose	Cipralex			S	Oral	220 Mg Once Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Remeron			S		90 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2004	4224703	EXPEDITED (15-DAY)	Y	DE	S04-USA-06176-01		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Completed Suicide; Gun Shot Wound; Intentional	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Buspar			C				Not Reported
	Insulin Nos			C				Not Reported

Self-Injury; Stress	Metformin	C	Not Reported
	Starlix	C	Not Reported
	Lantus	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2004	4188598	EXPEDITED (15-DAY)	Y	HO	S04-USA-04373-01		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2004	4199905	EXPEDITED (15-DAY)	Y	OT	S04-USA-04958-01		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diabetes Mellitus Inadequate Control; Hypoglycaemia; Loss Of Consciousness; Vision Blurred	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported
	Percocet			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2004	4129526	EXPEDITED (15-DAY)	N		US-GLAXOSMITHKLINE-A0506106A		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal; Libido Disorder; Medication Error; Nausea; Nightmare; Tobacco User	Wellbutrin Xl			S	Oral			Glaxosmithkline
	Wellbutrin			S		150mg Per Day		Glaxosmithkline
	Paxil Cr			S		12.5mg See Dosage Text		Glaxosmithkline
	Xanax			S				Not Reported
	Lexapro			S				Not Reported
	Seroquel			C				Not Reported
	Advair Diskus			C				Glaxosmithkline
	Albuterol			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2004	4223963	DIRECT	N	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Asthenia; Crying; Feeling Abnormal; Paraesthesia; Self-Injurious Ideation	Lexapro			S	Oral	1 A Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2004	4224883	DIRECT	Y	DS, RI			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Lexapro			S	Oral	10 Mg Daily Oral		Forest
	Kcl			C				Not Reported
	Celebrex			C				Not Reported
	Amaryl			C				Not Reported
	Nifedipine			C				Not Reported
	Zocor			C				Not Reported
	Toprol Xl			C				Not Reported
	Plavix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2004	4196124	EXPEDITED (15-DAY)	N	OT	S04-USA-04780-01		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Blood Pressure Fluctuation; Catecholamines Urine Increased; Chest Pain; Dyspnoea; Fatigue; Heart Rate Increased; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Verapamil Hydrochloride			C				Not Reported
	Accupril			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2004	4206216	EXPEDITED (15-DAY)	Y	OT	S04-USA-05564-01		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Asthenia; Blood Thyroid Stimulating Hormone Decreased; Haemorrhage In Pregnancy; Human Chorionic Gonadotropin Decreased; Maternal Exposure During Pregnancy; Pregnancy; Respiratory Rate Increased; Stress; Tobacco Abuse; Vaginal Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Methamphetamines			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2004	4223860	EXPEDITED (15-DAY)	Y	HO, OT	S04-AUS-04156-01		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Electrocardiogram Change; Electrocardiogram T Wave Inversion	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Triphasil-21			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2004	5666892	EXPEDITED (15-DAY)	Y	HO	S04-BEL-04992-01		67 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Erythema; Pruritus; Rash Maculo-Papular	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2004	4105356	EXPEDITED (15-DAY)	Y	HO	S04-USA-00834-01		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Asthenia; Atelectasis; Blood Creatine Phosphokinase Increased; Blood Creatine Phosphokinase Mb Abnormal; Blood Glucose Increased; Blood Sodium Decreased; Candida Infection; Catatonia; Cerebral Infarction; Chest X-Ray Abnormal; Coma; Communication Disorder; Confusional State; Corneal Reflex Decreased; Cortisol Increased; Csf Myelin Basic Protein Increased; Culture Urine Positive; Cyst; Decreased Appetite; Diarrhoea; Eating Disorder; Encephalitis Viral; Fatigue; Feeling Abnormal; Haematuria; Hepatic Enzyme Increased; Hyponatraemia; Hypothyroidism; Inappropriate Antidiuretic Hormone Secretion; Liver Function Test Abnormal; Meningoencephalitis Herpetic; Myalgia; Nausea; Pleural Effusion; Pneumonia; Pneumonia Aspiration; Respiratory	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celebrex			C				Not Reported
	Lorazepam			C				Not Reported
	Xanax			C				Not Reported
	Aciphex			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported

Disorder; Restlessness; Rhabdomyolysis; Shift To The Left; Status Epilepticus; Troponin I Increased; Vomiting; Weight Decreased; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2004	4116787	EXPEDITED (15-DAY)	Y	CA, OT	S04-USA-01398-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Vulvovaginitis; Chlamydial Infection; Creatinine Urine Decreased; Maternal Exposure During Pregnancy; Pregnancy; Uterine Contractions During Pregnancy	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Valium			C				Not Reported
	Prenatal Vitamins			C				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2004	4136007	EXPEDITED (15-DAY)	Y	OT	S04-USA-02164-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Eye Haemorrhage; Eye Pain; Retinal Disorder; Retinal Vein Occlusion; Somnolence; Vasodilatation; Visual Acuity Reduced; Visual Field Defect	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Cosamin Ds			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2004	4214986	EXPEDITED (15-DAY)	Y	HO	S04-USA-06024-01		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Affective Disorder; Aggression; Agitation; Blood Pressure Increased; Condition Aggravated; Dyskinesia; Hallucination, Visual; Heart Rate Increased; Intentional Self-Injury; Intentional Self-Injury; Intermittent Explosive Disorder; Major Depression; Personality Change Due To A General Medical Condition; Social Avoidant Behaviour; Suicidal Ideation; Wound	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Dilantin			C				Not Reported
	Seroquel			C				Not Reported
	Depakote			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2004	4215652	EXPEDITED (15-DAY)	N	HO	2004062385		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Interaction; Hypersensitivity; Toxicity To Various Agents	Vistaril			S	Oral	50 Mg (1 In 1 D), Oral		Not Reported
	Alprazolam (Alprazolam)			S	Oral	0.25 Mg (1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (1 In 1 D), Oral		Not Reported
	Metronidazole			S	Topical	(2 In 1 D), Topical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2004	5665174	DIRECT	Y	HO			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Blood Pressure Decreased; Faeces Discoloured; Hepatic Enzyme Increased;	Lexapro			S		10 Mg Once Daily		Not Reported
	Trileptal			S		Mg Bid		Not Reported
	Levaquin			C				Not Reported
	Prevacid			C				Not Reported

Myopathy; Pneumonia; Respiratory Disorder; Weight Decreased	Albuterol	C	Not Reported
	Trileptal	C	Not Reported
	Remeron	C	Not Reported
	Lexapro	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2004	5665328	EXPEDITED (15-DAY)	Y	CA, OT	S04-USA-01398-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Maternal Exposure During Pregnancy; Pulmonary Artery Atresia; Truncus Arteriosus Persistent; Uterine Contractions During Pregnancy	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Valium			C				Not Reported
	Prenatal Vitamins			C				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2004	5665400	DIRECT	N	HO, RI			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Hostility; Legal Problem; Suicidal Ideation	Zoloft			S	Oral	1 Pill Daily Oral		Not Reported
	Lexapro			S		1 Pill Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2004	5665507	DIRECT	N					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mood Swings; Suicidal Ideation	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported
	Microgestin Fe			C				Not Reported
	Claritin			C				Not Reported
	Flonase			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2004	6564589	EXPEDITED (15-DAY)	Y	HO	2004070771		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation; Condition Aggravated; Confusional State; Disorientation; Disturbance In Attention; Drug Ineffective; Hallucinations, Mixed; Incoherent; Mood Swings; Speech Disorder	Ziprasidone Hydrochloride			S		40 Mg (20 Mg , 2 In 1 D)		Not Reported
	Carbamazepine			S		400 Mg (200 Mg, 2 In 1 D)		Not Reported
	Gabapentin			S		900 Mg (300 Mg In 1 D)		Not Reported
	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2004	4180784	EXPEDITED (15-DAY)	Y	OT	S04-USA-04184-01		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Headache; Incoherent; Memory Impairment; Seizure; Tongue Biting	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2004	4209226	EXPEDITED (15-DAY)	Y	HO	S04-USA-05888-01		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Concussion; Confusional State; Drug Interaction; Fall; Gait Disturbance; Mental Status Changes	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Sinemet			S				Not Reported
	Sinemet			S				Not Reported
	Sinemet			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2004	5667120	DIRECT	N	DS, HO			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Disorientation; Dizziness; Fatigue; Feeling Abnormal; Influenza Like Illness; Loss Of Libido; Nausea; Suicidal Ideation; Weight Increased	Lexapro			S	Oral	10mg Once A Day Oral		Forest
	Cardizem			C				Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2004	5667133	DIRECT	N	DS, HO			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Disorientation; Dizziness; Fatigue; Feeling Abnormal; Influenza Like Illness; Loss Of Libido; Nausea; Suicidal Ideation; Weight Increased	Lexapro			S	Oral	10mg Once A Day Oral		Forest
	Cardizem			C				Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2004	5668232	EXPEDITED (15-DAY)	Y	DE	S04-USA-06434-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose; Toxicologic Test Abnormal	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2004	4224938	EXPEDITED (15-DAY)	Y	OT	PHEH2004US10486		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Above Therapeutic; Hallucination, Auditory	Clozaril			S	Oral	500 Mg, Qd		Novartis
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Colace			C		100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2004	5669264	EXPEDITED (15-DAY)	Y	HO	T04-GER-06043-01		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Drug Interaction; Gastrointestinal Ulcer Haemorrhage; Haemorrhagic Diathesis	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	20 Mg Qd, Sc		Not Reported
	Clopidogrel			S	Oral	75 Mg Qd Po		Not Reported
	Vioxx			S	Oral	12.5 Mg Qd Po		Not Reported
	Avelox			C				Not Reported
	Disalunil (Hydrochlorothiazide)			C				Not Reported
	Pantozol (Pantoprazole Sodium)			C				Not Reported
	Zocor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2004	5650248	EXPEDITED (15-DAY)	Y	DE, OT	2004070987		29 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest	Doxepin Hydrochloride			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2004	5666981	EXPEDITED (15-DAY)	Y	HO	A044-002-005206		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dizziness; Drug Interaction; General Physical Health Deterioration; Hyperkalaemia; Nausea; Renal Failure; Vomiting	Aricept			S	Oral	5 Mg, 1 In 1 D, Oral		Not Reported
	Cipralex			S	Oral	20 Mg, 1 In 1 D, Oral		Not Reported
	Digitoxin			S	Oral	0.07 Mg 5x Weekly, Oral		Not Reported
	Verapamil Hydrochloride			S	Oral	80 Mg, 1 In 1 D, Oral		Not Reported
	Aldactone			S	Oral	25 Mg, 1 In 1 D, Oral		Not Reported
	Bextra			S	Oral	20 Mg, 1 In 1 D, Oral		Not Reported
	Enalapril Maleate			S	Oral	10 Mg, 1 In 1 D, Oral		Not Reported
	Furosemide (Furosemide)			S	Oral	40 Mg, 1 In 1 D, Oral		Not Reported
	Clopidogrel			S	Oral	75 Mg, 1 In 1 D, Oral		Not Reported
	Insulin Nos			C				Not Reported
	Thioctic Acid			C				Not Reported
	Insulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2004	5668363	DIRECT	Y	OT			13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Pyromania	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2004	4061567	EXPEDITED (15-DAY)	Y	HO	S03-USA-05282-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Body Temperature Decreased; Condition Aggravated; Confusional State; Depression; Disorientation; Heart Rate Increased; Hepatic Encephalopathy; Hepatic	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lactulose			C				Not Reported
	Aldactone			C				Not Reported
	Inderal			C				Not Reported
	Lasix			C				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported

Failure; Hepatitis C; Platelet Count Decreased; Prothrombin Time Prolonged; Somnolence; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2004	4145738	EXPEDITED (15-DAY)	Y	HO	S04-USA-02679-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Blood Pressure Increased; Confusional State; Delusion Of Grandeur; Delusional Perception; Dermatitis Exfoliative; Drug Ineffective; Encephalopathy; Grandiosity; Impulsive Behaviour; Limb Injury; Mania; Meningoencephalitis Herpetic; Menorrhagia; Mental Disorder; Nail Discolouration; Neck Pain; Nuclear Magnetic Resonance Imaging Brain Abnormal; Post-Traumatic Neck Syndrome; Pruritus; Psychotic Disorder; Road Traffic Accident; Sexually Transmitted Disease; Tinea Pedis; West Nile Viral Infection	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Vioxx			C				Not Reported
	Protonix			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2004	5650899	DIRECT	Y	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Overdose	Meperidine	S	Intravenous (not otherwise specified)	10 Mg Iv Prn (Pca)	Not Reported
	Escitalopram Oxalate	S		20 Mg Daily	Not Reported
	Claritin	C			Not Reported
	Combivent	C			Not Reported
	Serevent Diskus	C			Not Reported
	Lexapro	C			Not Reported
	Flonase	C			Not Reported
	Seroquel	C			Not Reported
	Flovent	C			Not Reported
	Zyrtec	C			Not Reported
	Prevacid	C			Not Reported
	Asa	C			Not Reported
	Singulair	C			Not Reported
	Pravachol	C			Not Reported
	Gentamicin	C			Not Reported
	Zosyn	C			Not Reported
	Flagyl	C			Not Reported
	Benadryl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2004	5652362	DIRECT	N	LT			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Dizziness; Economic Problem; Hostility; Impulsive Behaviour; Irritability; Job Dissatisfaction; Mania; Obsessive-Compulsive Disorder; Partner Stress; Personality Change; Stress; Suicidal Ideation; Verbal Abuse	Lexapro			S	Oral	1 Tab Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2004	4130374	EXPEDITED (15-DAY)	Y	DS	S04-GER-01524-01		62 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Tenderness; Muscle Spasms; Nausea; Tinnitus; Tremor	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2004	4184924	EXPEDITED (15-DAY)	Y	DE	S04-USA-04304-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Cardiac Arrest; Coma; Drug Screen Positive; Dyspnoea; Pulmonary Oedema	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Seroquel			S		25 Mg Qd		Not Reported
	Neurontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2004	5652287	EXPEDITED (15-DAY)	Y	DE	K200401533		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Cytomel			S	Oral	Oral		Not Reported
	Fluoxetine			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2004	5652940	EXPEDITED (15-DAY)	Y	LT	S04-GER-02774-01		86 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Laceration; Suicide Attempt	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2004	5669377	EXPEDITED (15-DAY)		HO, OT	DE-ABBOTT-04P-062-0276717-00		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Bradycardia; Dialysis; Dizziness; Drug Interaction; Fluid Intake Reduced; General Physical Health Deterioration; Hyperkalaemia; Nausea; Renal Failure; Vomiting	Verapamil Hydrochloride			S	Oral		3 YR	Not Reported
	Cipralex			S			3 YR	Not Reported
	Digitoxin			S			10 YR	Not Reported
	Spironolactone			S			5 YR	Not Reported
	Valdecoxib			S			10 DAY	Not Reported
	Enalapril Maleate			S			5 YR	Not Reported
	Furosemide			S				Not Reported
	Clopidogrel Bisulfate			S				Not Reported
	Donepezil Hydrochloride			S				Not Reported
	Insulin Nos			C				Not Reported
	Lipon Acid			C				Not Reported
	Insulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2004	5651719	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Epistaxis; Feeling Abnormal; Hypoaesthesia; Mydriasis	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2004	5651879	DIRECT	N	LT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Anger; Anxiety; Condition Aggravated; Indifference	Lexapro			S	Oral	Morning Night Oral		Forest
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2004	5683271	NON-EXPEDITED	Y	HO, OT	2003115804		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Neurontin			S		900 Mg Tid		Not Reported
	Escitalopram Oxalate			S		10 Mg Daily		Not Reported
	Praxiten Pliva (Oxazepam) (Oxazepam)			S		30 Mg Tid		Not Reported
	Alcohol			S				Not Reported
	Nadolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2004	5683281	NON-EXPEDITED	Y	OT	2003035281		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Depression; Vision Blurred	Neurontin			S	Oral	300 Mg Tid Oral		Not Reported
	Escitalopram Oxalate			S		10 Mg Daily		Not Reported
	Methylphenidate Hydrochloride			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2004	4147426	EXPEDITED (15-DAY)	Y	DE	S04-USA-02684-01		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Carbon Monoxide Poisoning; Completed Suicide; Condition Aggravated; Death Of Relative; Decreased Appetite; Decreased Interest; Disturbance In Attention; Emotional Distress; Feeling Abnormal;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported
	Remeron			C				Not Reported

Generalised Anxiety Disorder; Hypersomnia; Major Depression; Malaise; Mood Altered; Paraesthesia; Partner Stress; Reading Disorder; Restlessness; Sleep Disorder; Terminal Insomnia; Therapeutic Product Effect Decreased; Thinking Abnormal; Weight Decreased	Zoloft	C	Not Reported
	Lorazepam	C	Not Reported
	Trazodone Hydrochloride	C	Not Reported
	Zyprexa	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2004	4191690	EXPEDITED (15-DAY)	Y	OT	S04-USA-04606-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diabetic Nephropathy; Polyuria	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2004	5653904	DIRECT	Y	OT			273 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Congenital Anomaly; Developmental Delay; Foetal Hypokinesia; Hypotonia; Maternal Drugs Affecting Foetus	Lexapro			S	Oral	10-20 Mg Qd Oral		Forest
	Zoloft			S	Oral			Pfizer
	Zantac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2004	5654213	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Inappropriate Antidiuretic Hormone Secretion	Lexapro	S	Oral	20 Mg Po Qd [Pta Prior To 2 WEEK Admission]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2004	5655046	EXPEDITED (15-DAY)	Y	OT	S04-USA-06734-02			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pregnancy; Treatment Noncompliance; Trisomy 21	Lexapro			S	Oral	40 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2004	4189307	EXPEDITED (15-DAY)	Y	OT	S04-USA-04405-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Loss Of Consciousness; Postictal State; Seizure; Tongue Biting; Tonic Clonic Movements	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Dilantin			C				Not Reported
	Klonopin			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2004	5655810	EXPEDITED (15-DAY)	Y	OT	S04-USA-06766-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Band Neutrophil Count Increased; Burning Sensation; Confusional State; Feeling Hot; Generalised Tonic-Clonic Seizure; Neutrophil Count Increased; Postictal State; White Blood Cell Count Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Estratest			C				Not Reported
	Menest			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2004	4148655	EXPEDITED (15-DAY)	Y	DS, HO, OT	S04-GER-02020-01		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Atrioventricular Block; Blood Pressure Systolic Increased; Bradycardia; Bradypnoea; Coma; Cyanosis; Electrocardiogram Qt Prolonged; Heart Rate Increased; Hypotension; Impulsive Behaviour; Intentional Overdose; Major Depression; Malaise; Pallor; Suicide Attempt; Syncope; Tongue Disorder; Tremor; Vertigo	Escitalopram Oxalate			S	Oral	480 Mg Once Po		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Zyprexa			S	Oral	67 Tablet Once Po		Not Reported
	Zyprexa			S				Not Reported
	Doxepin Hydrochloride			S	Oral	20 Tablet Once Po		Not Reported
	Doxepin Hydrochloride			S	Oral	10 Mg Tid Po		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2004	5654693	DIRECT	Y	RI			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Miconazole Nitrate			C				Not Reported
	Ranitidine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2004	5658334	EXPEDITED (15-DAY)	Y	HO	S04-GER-02574-01		38 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Withdrawal Syndrome; Hypertension; Intracardiac Thrombus; Mood Altered;	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Epivir			S	Oral	300 Mg Qd Po		Not Reported
	Kaletra			S	Oral	6 Qd Po		Not Reported

Sinus Tachycardia; Suicidal Ideation	Videx	S	Oral	400 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2004	5656204	DIRECT	N	LT, OT			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lexapro			S				Not Reported
	Alprazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2004	5659527	EXPEDITED (15-DAY)	N	RI	2004UW21436		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy; Hepatic Failure	Nexium			S	Oral	40 Mg Daily Po	2 YR	Not Reported
	Lexapro			S			2 WEEK	Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2004	5661674	EXPEDITED (15-DAY)	Y	DE	S04-USA-06880-01		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	20 Mg Qd; Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported
	Alcohol			C				Not Reported
	Concerta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2004	4167471	EXPEDITED (15-DAY)	Y	DE	S04-USA-03515-02		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atelectasis Neonatal; Blood Ph Decreased;	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported

Cyanosis Neonatal; Death Neonatal; Endotracheal Intubation Complication; Hypotonia Neonatal; Maternal Exposure During Pregnancy; Neonatal Respiratory Arrest; Neonatal Tachycardia; Pallor; Pulmonary Hypoplasia; Pulse Absent; Respiratory Disorder Neonatal; Sudden Death; White Blood Cell Count Increased	Zofran	C	Transmammary		Not Reported
	Phenergan	C			Not Reported
	Prenatal Vitamins	C			Not Reported
	Macrobid	C			Not Reported
	Compazine	C			Not Reported
	Stool Softeners	C			Not Reported
	Amoxicillin	C			Not Reported
	Monistat	C			Not Reported
	Tums (Calcium Carbonate)	C			Not Reported
	Antacids Nos	C			Not Reported
	Calcium	C			Not Reported
	Vitamin D Nos	C			Not Reported
	Vitamin K	C			Not Reported
	Erythromycin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2004	4167501	EXPEDITED (15-DAY)	Y	HO, OT	S04-USA-03515-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Dry Skin; Dyspepsia; Fungal Infection; Maternal Exposure During Pregnancy; Nasopharyngitis; Nausea; Premature Separation Of Placenta; Rash; Urethral Disorder; Urinary Tract Infection; Uterine Prolapse; Vaginal Prolapse; Vomiting; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Prenatal Vitamins			C				Not Reported
	Stool Softeners			C				Not Reported
	Calcium			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2004	4200180	EXPEDITED (15-DAY)	Y	OT	S04-USA-04732-01		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Agitation; Belligerence; Confusional State; Delusion; Diet Refusal; Insomnia; Mania; Paranoia	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Lexapro		S	Oral	20 Mg Qd Po	Not Reported
	Wellbutrin (Bupropion Hydrochloride)		S	Oral	300 Mg Qd	Not Reported
	Wellbutrin (Bupropion Hydrochloride)		S	Oral	150 Mg Qd	Not Reported
	Ambien		C			Not Reported
	Trazodone Hydrochloride		C			Not Reported
	Lipitor		C			Not Reported
	Aciphex		C			Not Reported
	Aspirin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2004	5657322	DIRECT	Y	HO			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall; Mental Status Changes; Somnolence	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported
	Ms Contin			C				Not Reported
	Oxycodone			C				Not Reported
	Lorazepam			C				Not Reported
	Humibi La			C				Not Reported
	Combivent			C				Not Reported
	Furosemide			C				Not Reported
	Atenolol			C				Not Reported
	Methimazole			C				Not Reported
	Prednisone			C				Not Reported
	Cyclobenzaprine Hydrochloride			C				Not Reported
	Aspirin			C				Not Reported
	Advair			C				Not Reported
	Sucralfate			C				Not Reported
	Miralax			C				Not Reported
	Gefitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2004	5658530	EXPEDITED (15-DAY)	Y	OT	S04-USA-06959-01		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coagulopathy; Platelet Adhesiveness Increased	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2004	5661796	EXPEDITED (15-DAY)	Y	OT	S04-UKI-06842-01		40 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Status Epilepticus	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Carbamazepine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2004	5652949	EXPEDITED (15-DAY)	Y	DE, HO	S04-UKI-06403-01		64 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Withdrawal Syndrome; Hyperhidrosis; Intentional Overdose; Tremor	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Diazepam			S				Not Reported
	Diazepam			S				Not Reported
	Atenolol			S		25 Mg Qd		Not Reported
	Atenolol			S		25 Mg Qd		Not Reported
	Atenolol			S				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2004	5660318	DIRECT	N	DS, HO			17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Work Ability; Panic Attack	Paxil Cr			S	Oral	1 Day Oral		Not Reported
	Lexapro			S	Oral	1 Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2004	5660363	DIRECT	N	DE			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Medication Error	Lexapro			S	Oral	1/2 To 1 Per Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2004	5660893	EXPEDITED (15-DAY)	Y	HO	S04-USA-06960-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Drug Interaction; Loss Of Consciousness	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Gabitril			S		2 Mg Qd		Not Reported
	Gabitril			S		4 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2004	5662289	EXPEDITED (15-DAY)	Y	OT	S04-GER-07036-01			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema; Thrombosis	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2004	4096509	EXPEDITED (15-DAY)	Y	DS	S04-GER-00523-01		43 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impulse-Control Disorder; Peroneal Nerve Palsy	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Remergil (Mirtazapine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2004	4206280	EXPEDITED (15-DAY)	Y	HO	S04-USA-05601-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Amnesia;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Blood Glucose Increased; Confusional State; Drug Screen Positive; Headache; Mental Status Changes; Metabolic Acidosis; Psychotic Disorder; Respiratory Alkalosis; White Blood Cell Count Increased	Hydrocodone	C	Not Reported
	Remicade	C	Not Reported
	Pepcid Ac	C	Not Reported
	Paxil	C	Not Reported
	Lantus	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2004	4218960	EXPEDITED (15-DAY)	Y	DE	S04-USA-06118-01		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Overdose; Self-Medication; Toxicity To Various Agents	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Clozapine			S		300 Mg		Not Reported
	Vicodin			C				Not Reported
	Topamax			C				Not Reported
	Depakote			C				Not Reported
	Lopid			C				Not Reported
	Inderal			C				Not Reported
	Doxepin			C				Not Reported
	Flexeril			C				Not Reported
	Promethazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2004	4224264	EXPEDITED (15-DAY)	Y	DS	S04-GER-04155-01		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Monocytosis; Peroneal Nerve Palsy; Weight Increased	Cipralex			S	Oral	10 Mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2004	5654792	EXPEDITED (15-DAY)	Y	OT	US-JNJFOC-20041005895		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Drug Interaction	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Lexapro			S	Oropharingeal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2004	5660406	DIRECT	N	HO, LT			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Overdose; Suicidal Ideation	Lexapro			S	Oral	10 Mg Per Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2004	5660541	DIRECT	Y	OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased	Escitalopram Oxalate			S	Oral	10 Mg Oral		Forest
	Dexamethasone			C				Not Reported
	Lorazepam			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Tamsulosin Hydrochloride			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Vitamin E			C				Not Reported
	Celecoxib			C				Not Reported
	Ramipril			C				Not Reported
	Fluconazole			C				Not Reported
	Insulin Nos			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2004	5662795	EXPEDITED (15-DAY)	Y	OT	S04-UKI-07039-01		17 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alcohol Use; Hallucination, Auditory; Hallucination, Tactile	Cipralex		S	Oral	20 Mg Qd Po	Not Reported
	Cipralex		S	Oral	10 Mg Qd Po	Not Reported
	Pulmicort Flexhaler		C			Not Reported
	Bricanyl		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2004	5662306	EXPEDITED (15-DAY)	Y	DS, LT	2004067358		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bipolar Ii Disorder; Depression; Feelings Of Worthlessness; Irritability; Panic Attack; Paranoia; Psychotic Disorder; Sleep Disorder; Speech Disorder; Stress; Suicidal Ideation; Weight Increased	Zoloft			S		100 Mg (1 In1 D)	1 YR	Not Reported
	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)	1 MTH	Not Reported
	Semisodium Valproate			S				Not Reported
	Olanzapine (Olanzapine)			S				Not Reported
	Topiramate			S		50 Mg		Not Reported
	Quetiapine Fumarate			S		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2004	5663031	EXPEDITED (15-DAY)	N	OT	S04-USA-07061-01		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Thyroiditis; Weight Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Strattera			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2004	4146407	EXPEDITED (15-DAY)	Y	HO	S04-USA-02672-01		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Blood Glucose Increased; Constipation; Diarrhoea; Diverticulum; Drug	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qod Po		Not Reported
	Lexapro			S	Oral	7.5 Mg Qod Po		Not Reported

Interaction; Fatigue; Glossodynia; Hypersomnia; Pyrexia; Tongue Coated; Urinary Tract Infection; Weight Decreased	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Lexapro		S	Oral	5 Mg Qd Po	Not Reported
	Lexapro		S	Oral	2.5 Mg Qd Po	Not Reported
	Lexapro		S			Not Reported
	Ceclor		S			Not Reported
	Lanoxin		C			Not Reported
	Cozaar		C			Not Reported
	Tenormin		C			Not Reported
	Maxzide		C			Not Reported
	Prilosec		C			Not Reported
	Percocet		C			Not Reported
	Diazepam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2004	5673158	EXPEDITED (15-DAY)		DE	2004-BP-10345RO		29 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Overdose	Mirtazapine			S				Not Reported
	Doxepin Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2004	4200342	EXPEDITED (15-DAY)	Y	HO, LT	US-ROCHE-372529		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Anxiety; Aspartate Aminotransferase Increased; Depression; Drug Screen Positive; Homicidal Ideation; Nausea; Overdose; Paranoia; Psychotic Disorder; Suicidal Ideation; Suicide Attempt; Tremor	Peginterferon Alfa-2a			S	Subcutaneous	Unknown Dose Given Weekly	155 DAY	Roche
	Ribavirin			S	Oral	Given Daily	159 DAY	Roche
	Lexapro			S	Unknown			Not Reported
	Multivitamins			C				Not Reported
	Vitamin E			C				Not Reported
	Ambien			C				Not Reported
	Hydrocodone			C		Total Daily Dose Was Variable		Not Reported
	Ibuprofen			C		Total Daily Dose Was		Not Reported

							Variable			
	Lotrisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2004	5664750	EXPEDITED (15-DAY)	Y	OT	S04-USA-06177-01		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bipolar Disorder; Cyclothymic Disorder; Hypomania; Loss Of Employment; Mania; Refusal Of Treatment By Patient; Treatment Noncompliance	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2004	5673314	DIRECT	Y	HO			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10 Mg Qd Oral		Forest
	Aspirin			C				Not Reported
	Synthroid			C				Not Reported
	Nifedipine			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Diovan Hct			C				Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2004	5676571	EXPEDITED (15-DAY)	Y	DE	S04-USA-07132-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Respiratory Failure	Lexapro			S				Not Reported
	Demerol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2004	5653406	EXPEDITED (15-DAY)	Y	DE, OT	2004237015NO		84 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hepatic Failure; Hepatitis; Hyperhidrosis; Hyperventilation; International Normalised Ratio Increased; Multiple Organ Dysfunction Syndrome; Pain; Pancreatitis; Rales; White Blood Cell Count Increased	Aldactone			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg, Qd, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2004	4193688	EXPEDITED (15-DAY)	Y	DE	S04-USA-04678-01		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Anxiety; Insomnia; Pulmonary Congestion; Pulmonary Oedema; Toxicity To Various Agents	Lexapro			S				Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Propoxyphene			S				Not Reported
	Klonopin			C				Not Reported
	Ativan			C				Not Reported
	Remeron			C				Not Reported
	Alcohol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2004	5657270	EXPEDITED (15-DAY)	Y	HO	S04-USA-06767-01		39 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2004	5679638	EXPEDITED (15-DAY)	Y	OT	S04-USA-07186-01		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Tinnitus	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2004	5681181	EXPEDITED (15-DAY)	Y	HO	S04-ESP-07168-01		84 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Tamsulosine (Tamsulosin)			C				Not Reported
	Diosmine/ Hesperidine			C				Not Reported
	Betahistine Hydrochloride			C				Not Reported
	Timolol Maleate			C				Not Reported
	Lormetazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2004	5679587	EXPEDITED (15-DAY)	Y	DS	S04-NOR-07415-01		68 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Dysphonia; Facial Paresis; Lethargy; Listless; Rash Erythematous; Rash Pruritic	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Paracetamol			C				Not Reported
	Thyroxin-Natrium (Levothyroxine Sodium)			C				Not Reported
	Cozaar			C				Not Reported
	Ibux (Ibuprofen)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2004	5679747	EXPEDITED (15-DAY)	Y	OT	SO4-USA-06959-01		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Platelet Aggregation Increased; Thrombocytopenia	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Yasmin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2004	4221601	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20040908837		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Cardio-Respiratory Arrest; Coma; Completed Suicide; Heart Rate Increased; Intentional Overdose; Loss Of Consciousness; Oxygen Saturation Decreased; Pupil Fixed; Status Epilepticus	Tylenol With Codeine			S	Oropharingeal			Not Reported
	Acetaminophen\Hydrocodone			S	Oropharingeal			Not Reported
	Acetaminophen\Hydrocodone			S	Oropharingeal			Not Reported
	Amitriptyline			S	Oropharingeal			Not Reported
	Baclofen			S				Not Reported
	Zolpidem			S				Not Reported
	Valdecoxib			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Fentanyl			S				Not Reported
	Orphenadrine			S				Not Reported
	Pantoprazole Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2004	4194833	EXPEDITED (15-DAY)	Y	HO, RI	S04-USA-04604-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autonomic Nervous System Imbalance; Dizziness; Dizziness Postural; Hypertension; Hypotension; Syncope; Vocal Cord Paralysis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Clonidine			C				Not Reported
	Keppra			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2004	5654096	EXPEDITED (15-DAY)	Y	DE	S04-NOR-06614-01		84 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Hepatic Failure; Hepatitis; Hyperhidrosis; Hyperventilation; International Normalised Ratio Increased; Multiple Organ Dysfunction Syndrome; Pain; Pancreatitis; Right Ventricular Failure	Cipralex	S	Oral	5 Mg Qd Po		Not Reported
	Aldactone	S	Oral	12.5 Mg Qd Po		Not Reported
	Digitoxin	C				Not Reported
	Synalar (Fluocinolone Acetonide)	C				Not Reported
	Betnovate (Betamethasone)	C				Not Reported
	Phu Chee	C				Not Reported
	Konakion	C				Not Reported
	Warfarin Sodium	C				Not Reported
	Amoxicillin	C				Not Reported
	Paracet (Paracetamol)	C				Not Reported
	Cozaar	C				Not Reported
	Furosemide	C				Not Reported
	Lipitor	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2004	4194134	EXPEDITED (15-DAY)	N	OT	US-MERCK-0408USA01341		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration; Tongue Ulceration	Vioxx			S	Oral			Merck
	Zoloft			S	Oral			Not Reported
	Topamax			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Zocor			C	Oral			Not Reported
	Nexium			C	Unknown			Not Reported
	Mirapex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2004	5673141	EXPEDITED (15-DAY)	Y	HO	DE-GLAXOSMITHKLINE-D0045166A		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Paroxetine Hydrochloride			S	Oral	10mg Per Day	39 DAY	Glaxosmithkline

Circulatory Collapse; Cold Sweat; Cyanosis; Depression; Dizziness; Drug Interaction; Heart Rate Increased; Ill-Defined Disorder; Nausea; Pallor; Poor Peripheral Circulation; Pulse Abnormal	Cipralex	S	Oral	10mg Per Day		Not Reported
	Amitriptyline Hydrochloride	C	Unknown	25mg Per Day		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2004	5654946	EXPEDITED (15-DAY)	Y	DE, HO	2004GB02412		64 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Withdrawal Syndrome; Overdose; Suicide Attempt	Atenolol			S		25 Mg Daily		Not Reported
	Cipralex			S	Oral	10 Mg Daily Po		Not Reported
	Cipralex			S	Oral	20 Mg Daily Po		Not Reported
	Diazepam			S		2.5-5 Mg /Day		Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2004	5662539	EXPEDITED (15-DAY)	Y	HO	S04-BRA-07037-01		30 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Coma; Hallucination; Loss Of Consciousness; Unevaluable Event	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2004	5679893	DIRECT	N	DE			27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Clonazepam			S	Intravenous (not	3 Time Day Intravenou		Not Reported

					otherwise specified)			
	Lexapro			S	Intravenous (not otherwise specified)	Once Day Intravenou		Not Reported
	Verapamil Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2004	5681200	DIRECT	Y	HO			86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	# 1 Po Daily	30 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2004	5683628	DIRECT	Y	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Panic Disorder	Lexapro			S	Oral	10 Mg One Po Q Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2004	5684463	EXPEDITED (15-DAY)	Y	HO	S04-USA-07340-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Delusion; Drug Interaction; Hallucination	Lexapro			S				Not Reported
	Adderall			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2004	5684469	EXPEDITED (15-DAY)	Y	HO	S04-USA-07307-01		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Delusional Disorder, Persecutory Type; Depression; Social Avoidant Behaviour;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Treatment Noncompliance

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2004	5686256	EXPEDITED (15-DAY)	N	HO	RS004775-USA		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Chills; Disorientation; Influenza Like Illness; Nausea; Vomiting	Aciphex			S	Oral	60 Mg, 1 In 1 D, Oral		Not Reported
	Provigil			S	Oral Oral Oral	See Image See Image See Image		Not Reported
	Klonopin			S	Oral	2.25 Mg, 1 In 1 D, Oral		Not Reported
	Neurontin			S	Oral	1200 Mg, 1 In 1 D, Oral		Not Reported
	Hydrochlorothiazide (Hydrochlorothiazide)			S	Oral	100 Mg, 1 In 1 D, Oral		Not Reported
	Doryx			S	Oral	100 Mg, 1 In 1 D, Oral		Not Reported
	Lexapro			S	Oral	10 Mg, 1 In 1 D, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2004	5686620	EXPEDITED (15-DAY)	Y	OT	S04-UKI-07609-01		24 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Olanzapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2004	5686344	EXPEDITED (15-DAY)	Y	HO	US014248		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Drug Interaction; Loss Of Consciousness	Gabitril			S	Oral	2 Mg Qd Oral		Not Reported
	Gabitril			S	Oral	4 Mg Qd Oral		Not Reported
	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported
	Lexapro			S	Oral	20 Mg Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2004	5653999	EXPEDITED (15-DAY)	Y	HO, OT	2004075222		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia; Depression; Foot Operation; Gastritis; Headache; Mania; Neuralgia; Sleep Disorder; Somnolence; Suicidal Ideation; Therapeutic Product Effect Decreased; White Blood Cell Count Increased	Neurontin			S	Oral	600 Mg, Oral		Not Reported
	Prednisone			S	Oral	60 Mg (15 Mg, 4 In 1 D), Oral		Not Reported
	Vicodin			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Provella-14 (Estrogens Conjugated, Medroxyprogesterone Acetate)			C				Not Reported
	Nifedipine			C				Not Reported
	Propranolol Hydrochloride (Propranolol Hydrochloride)			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported
	Lansoprazole (Lansoprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2004	5654074	EXPEDITED (15-DAY)	Y	OT	S04-UKI-06633-01		24 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Olanzapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2004	5681482	EXPEDITED (15-DAY)	Y	OT	S04-USA-07280-01		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Namenda			S	Oral	5 Mg Qd Po		Not Reported

Lexapro	S	Oral	10 Mg Qd Po		Not Reported
Lexapro	S	Oral	20 Mg Qd Po		Not Reported
Lexapro	S	Oral	10 Mg Qd Po		Not Reported
Detrol	C				Not Reported
Plavix	C				Not Reported
Lovastatin	C				Not Reported
Levoxyl	C				Not Reported
Zantac	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2004	5688053	EXPEDITED (15-DAY)	Y	HO, OT	S04-UKI-07537-01		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glycosylated Haemoglobin Increased; Hypoglycaemia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported
	Humalog			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2004	5688057	EXPEDITED (15-DAY)	Y	OT	S04-UKI-07418-01		43 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anger; Paranoia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2004	5688312	DIRECT	N	DS			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Lexapro			S	Oral	Once A Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2004	5688443	EXPEDITED (15-DAY)	N	HO	2004090030			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Sedation; Suicide Attempt	Geodon			S				Not Reported
	Diphenhydramine Hydrochloride			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2004	4196797	EXPEDITED (15-DAY)	Y	OT	S04-USA-04731-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Gangrene; Infarction; Limb Discomfort; Raynaud'S Phenomenon; Skin Discolouration; Skin Irritation; Skin Ulcer	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2004	5662294	EXPEDITED (15-DAY)	Y	OT	S04-GER-06841-01		20 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Blood Thyroid Stimulating Hormone Increased; Galactorrhoea; Hypothyroidism; Thyroxine Free Increased; Weight Decreased; Weight Increased	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported
	Neurocil (Levomepromazine Maleate)			C				Not Reported
	Biviol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2004	5687368	DIRECT	Y	LT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Decreased Appetite; Gastric Disorder; Headache; Insomnia; Simple Partial Seizures;	Tagamet Hb			S	Oral	200 Mg Bid Oral		Not Reported
	Lexapro			S	Oral	20 Mg Qd Oral		Forest

Stress; Toxicity To Various Agents; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2004	5691448	DIRECT	N	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Lexapro			S	Oral	10 Mg Daily , Orally		Not Reported
	Meprobamate			C				Not Reported
	Proscar			C				Not Reported
	Ambien			C				Not Reported
	Lisinopril			C				Not Reported
	Amoxicillin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2004	4126692	EXPEDITED (15-DAY)	N	HO	S04-USA-01550-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease Progression; Intentional Self-Injury; Personality Disorder; Suicidal Ideation	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2004	5657807	EXPEDITED (15-DAY)	Y	HO	S04-ESP-06636-01		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Confusional State; Dystonia; Hyponatraemia; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Metoclopramide			S				Not Reported
	Lorazepam			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2004	5661788	EXPEDITED (15-DAY)	Y	OT	S04-FIN-06912-01		50 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Fibrillation; Blood Pressure Increased; Bradycardia; Extrasystoles; Long Qt Syndrome	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Indapamide			C				Not Reported
	Opamox (Oxazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2004	5680354	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0429814A		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Irritability; Sexual Dysfunction	Wellbutrin			S	Oral	300mg Per Day		Glaxosmithkline
	Zoloft			S	Unknown			Not Reported
	Effexor			S	Unknown			Not Reported
	Paxil			S	Unknown			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Lithium			C	Unknown			Glaxosmithkline
	Armour Thyroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2004	5681035	NON-EXPEDITED	N		2004S1001835		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Wellbutrin Sr			S	Oral	150mg Unknown		Glaxosmithkline
	Lotrel			S	Oral	10mg Per Day		Not Reported
	Lexapro			S	Oral	10mg Unknown		Not Reported

Clonidine Hydrochloride	C	Oral	.2mg Twice Per Day		Not Reported
Amiloride Hcl W/ Hydrochlorothiazide	C	Oral	50mg Per Day		Not Reported
Percocet	C	Oral	10mg Unknown		Not Reported
Trazodone Hydrochloride	C	Unknown	150mg Unknown		Not Reported
Nexium	C	Unknown	40mg Per Day		Not Reported
Bextra	C	Unknown	20mg Unknown		Not Reported
Carisoprodol	C	Unknown	350mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2004	5681068	NON-EXPEDITED	N		S04-USA-04583-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive	Wellbutrin Sr			S	Oral	300mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2004	5663732	EXPEDITED (15-DAY)	Y	DE, HO	M2004-1630		64 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Drug Withdrawal Syndrome; Intentional Overdose; Suicide Attempt	Atenolol			S		25 Mg Daily		Not Reported
	Diazepam			S		2.5-5 Mg Daily		Not Reported
	Cipralex			S		10-20 Mg Daily		Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2004	5689339	EXPEDITED (15-DAY)	Y	DE	A03200403896		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased;	Demerol			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

Respiratory Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2004	5690931	EXPEDITED (15-DAY)	Y	HO	DSA_25380_2004		44 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral; Weight Decreased; Weight Increased	Lorazepam			S	Oral	Df Q Day Po		Not Reported
	Cipralex			S	Oral	10 Mg Q Day Po		Not Reported
	Nolvadex			S	Oral	20 Mg Q Day Po		Not Reported
	Surmontil			S	Oral	75 Mg Q Day Po		Not Reported
	Surmontil			S	Oral	50 Mg Q Day Po		Not Reported
	Zyprexa			S	Oral	2.5 Mg Q Day Po		Not Reported
	Zyprexa			S	Oral	5 Mg Q Day Po		Not Reported
	Zyprexa			S	Oral	10 Mg Q Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2004	5690274	EXPEDITED (15-DAY)	Y	OT	2004083738		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Geodon			S	Oral	40 Mg (1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (1 In 1 D), Oral		Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2004	5692187	DIRECT	N	LT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Self-Injurious Ideation; Suicide Attempt	Lexapro			S		1/2 Tab X 6 Days Then 1 Tab After		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2004	4223243	EXPEDITED (15-DAY)	Y	RI, OT	S04-USA-06175-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intracranial Pressure Increased	Lexapro			S	Oral	25 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Naprosyn			C				Not Reported
	Pseudoephedrine Hydrochloride			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2004	5677399	EXPEDITED (15-DAY)	N	HO	A03200403628		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Loss Of Consciousness; Overdose; Suicide Attempt	Plavix			S	Oral	1500 Mg Once Oral		Not Reported
	Ambien			S	Oral	130 Mg Once - Oral		Not Reported
	Depakote			S	Oral	4 Gr Once Oral		Not Reported
	Xanax			S	Oral	Oral		Not Reported
	Klonopin			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Clopidogrel Bisulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2004	5681235	EXPEDITED (15-DAY)	N	OT	S04-USA-07259-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phlebitis	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Klonopin			S	Oral	8 Mg Qd Po		Not Reported
	Abilify			S	Oral	5 Mg Qd Po		Not Reported

	Trileptal	S	Oral	900 Mg Qd Po		Not Reported
	Zocor	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2004	5690152	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia	Lexapro			S	Oral	10 Mg Po Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2004	5692623	EXPEDITED (15-DAY)	Y	OT	S04-USA-05880-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Confusional State; Drug Interaction; Electroencephalogram Abnormal; Eye Movement Disorder; Fatigue; Focal Dyscognitive Seizures; Headache; Mental Disorder; Tardive Dyskinesia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Tigan			S				Not Reported
	Fentanyl Transdermal System			C				Not Reported
	Klonopin			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Vicodin			C				Not Reported
	Estrogens			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2004	5692917	EXPEDITED (15-DAY)	Y	HO	SUS1-2004-00788			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Delusion; Drug Interaction; Hallucination	Adderall			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2004	5693043	EXPEDITED (15-DAY)	Y	OT	S04-USA-07493-01		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anosmia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Tegretol			C				Not Reported
	Propranolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2004	5693090	EXPEDITED (15-DAY)	Y	HO	L04-USA-07679-01		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Blood Creatine Phosphokinase Increased; Chorea; Disturbance In Attention; Heart Rate Increased; Logorrhoea; Nausea; Pyrexia; Tremor	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Mixed Amphetamine Salts			S		45 Mg Tid		Not Reported
	Mixed Amphetamine Salts			S		20 Mg Bid		Not Reported
	Mixed Amphetamine Salts			S		30 Mg Tid		Not Reported
	Methylphenidate Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2004	5693638	EXPEDITED (15-DAY)	Y	CA, HO	S04-FRA-07819-02		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract Congenital; Maternal Exposure During Pregnancy	Escitalopram Oxalate			S				Not Reported
	Seropram (Citalopram Hydrobromide)			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Selokeen			S	Transplacental	200 Mg Qd Transplacental		Not Reported
	Stagid (Metformin Embonate)			S				Not Reported
	Benfluorex Hydrochloride			S	Transplacental	150 Mg Qd Transplacental		Not Reported
	Spironolactone			S	Transplacental	50 Mg Qd Transplacental		Not Reported

Tranxene T-Tab	S		Not Reported
Zolpidem Tartrate	S		Not Reported
Lysanxia	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2004	5687184	NON-EXPEDITED	N		S04-USA-02595-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Mastitis	Augmentin			S	Unknown			Glaxosmithkline
	Lexapro			S	Oral			Not Reported
	Levaquin			S	Unknown			Not Reported
	Caltrate			C				Glaxosmithkline
	Actonel			C				Not Reported
	Fosamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2004	4206282	EXPEDITED (15-DAY)	Y	DE	S04-USA-05603-01		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Depression	Lexapro			S	Oral	20 Mg Qam Po		Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2004	4209331	EXPEDITED (15-DAY)	Y	DE	S04-USA-05897-01		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Cardiomegaly; Feeling Abnormal; Road Traffic Accident	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2004	5666200	EXPEDITED (15-DAY)	Y	DE	S04-USA-06268-01		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose; Toxicity To Various Agents	Lexapro			S				Not Reported
	Lamictal			C				Not Reported
	Lithium			C				Not Reported
	Unisom Sleep Aid			C				Not Reported
	No-Doz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2004	5693813	EXPEDITED (15-DAY)	Y	OT	S04-USA-07554-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Recurrence; Ovarian Cancer	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2004	5694315	DIRECT	Y	DE			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Myocardial Infarction; Poisoning; Toxicity To Various Agents	Ultracet			S	Oral	1 4-6 Hrs Oral		Not Reported
	Lexapro			S	Oral	1 Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2004	5694521	DIRECT	N	OT			13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Imprisonment; Intentional Self-Injury; Suicidal Ideation	Lexapro			S	Oral	Oral		Forest
	Seroquel			S	Oral	Oral		Astrazeneca
	Seroquel			C				Not Reported
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2004	4224055	EXPEDITED (15-DAY)	Y	HO	S04-USA-06202-01		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Alkaline Phosphatase Increased; C-Reactive Protein Increased; Diarrhoea; Nausea	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Coreg			C				Not Reported
	Amaryl			C				Not Reported
	Lotrel			C				Not Reported
	Zocor			C				Not Reported
	Aspirin			C				Not Reported
	Lasix			C				Not Reported
	Potassium Chloride			C				Not Reported
	Humulin N			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2004	5695948	EXPEDITED (15-DAY)	N	HO, RI	S04-USA-07587-01		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Treatment Noncompliance	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2004	5681131	EXPEDITED (15-DAY)	Y	HO	S04-SWE-07227-01		57 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Blood Sodium Decreased; Diarrhoea; Painful Respiration	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2004	5691139	EXPEDITED (15-DAY)	N	OT	PHEH2004US12835		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Limb Discomfort; Thrombophlebitis	Trileptal			S		900 Mg, Qd		Novartis
	Escitalopram Oxalate			S	Oral	15 Mg, Qd		Not Reported

	Clonazepam	S	8 Mg, Qd	Not Reported
	Aripiprazole	S	5 Mg, Qd	Not Reported
	Simvastatin	C	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2004	5695487	EXPEDITED (15-DAY)	Y	OT	S04-UKI-07892-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Faeces Discoloured	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Promazine			C				Not Reported
	Trimethoprim			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported
	Thyroxine "Aps" (Levothyroxine Sodium)			C				Not Reported
	Co-Amilofruse			C				Not Reported
	Sumatriptan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2004	5695515	EXPEDITED (15-DAY)	Y	DS	S04-DEN-07964-01		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinson'S Disease	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2004	4061550	EXPEDITED (15-DAY)	Y	DE, HO	S03-USA-05298-01		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Cerebrovascular Accident; Generalised Tonic-Clonic Seizure; Lethargy	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zyprexa			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Levothroid			C				Not Reported
	Lortab			C				Not Reported

Ativan	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2004	5664048	EXPEDITED (15-DAY)	Y	OT	S04-GER-07158-01		28 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased; Rhabdomyolysis	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2004	5700006	DIRECT	Y	RI			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drooling; Dyskinesia; Fall; Mydriasis; Pyrexia; Reduced Facial Expression; Refusal Of Treatment By Patient; Respiratory Disorder; Urinary Incontinence	Lexapro			S	Oral	10 Mg Po Qd		Not Reported
	Dextromethorphan\Guaifenesin			S	Oral	600mg/30mg Po Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2004	5700028	EXPEDITED (15-DAY)	Y	OT	S04-UKI-07954-01		35 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Diazepam			C				Not Reported
	Buspirone			C				Not Reported
	Trimethoprim			C				Not Reported
	Eugynon (Ethinyl			C				Not Reported

Estradiol\Norgestrel)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2004	4160400	NON-EXPEDITED	Y	RI, OT	S04-USA-01391-01		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Face Oedema; Mental Status Changes; Migraine; Muscle Twitching	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2004	4210521	NON-EXPEDITED	Y	HO	S04-USA-03012-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gamma-Glutamyltransferase Increased; Rhabdomyolysis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			S	Oral	300 Mg Bid Po		Not Reported
	Neurontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2004	5664251	NON-EXPEDITED	Y	HO	S04-USA-04369-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Depression	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lamictal			S		150 Mg Qd		Not Reported
	Nexium (Esomeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2004	5690576	EXPEDITED (15-DAY)	Y	HO	S04-USA-07469-01		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Dementia; Encephalopathy; Hallucination; Psychotic Disorder	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Mirapex			S	Oral	1.5 Mg Qd Po		Not Reported
	Mirapex			S	Oral	0.75 Mg Qd Po		Not Reported
	Mirapex			S				Not Reported
	Mirapex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2004	5701035	EXPEDITED (15-DAY)	Y	DE	S04-UKI-07898-01		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Metformin Hydrochloride			C				Not Reported
	Pioglitazone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2004	5701890	NON-EXPEDITED	Y	HO	S04-USA-07134-01		87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Fall; Hyponatraemia; Skin Laceration	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Detrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2004	5703495	EXPEDITED (15-DAY)	Y	HO	T04-USA-07469-01		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Confusional State; Delirium; Dementia; Encephalopathy; Hallucination; Psychotic	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Mirapex			S	Oral	1.5 Mg Qd Po		Not Reported
	Mirapex			S	Oral	0.75 Mg Qd Po		Not Reported
	Mirapex			S		Unk		Not Reported

Disorder	Mirapex	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2004	5715385	NON-EXPEDITED	N		2004241306US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychomotor Hyperactivity; Weight Increased	Bextra			S	Oral	10 Mg, Qd, Oral		Not Reported
	Wellbutrin			S				Not Reported
	Lexapro			S	Oral	10 Mg, Qd, Oral		Not Reported
	Multivitamins (Panthenol, Retinal, Ergocalciferol)			C				Not Reported
	Vitamin E			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2004	5703474	EXPEDITED (15-DAY)	Y	OT	S04-USA-07767-01		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Sedation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2004	4218862	EXPEDITED (15-DAY)	Y	OT	S04-USA-06119-01		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Seizure	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2004	5703921	EXPEDITED (15-DAY)	Y	RI	S04-USA-06697-01		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Citric Acid Increased; Blood Creatinine Increased;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qod Po		Not Reported

Dizziness; Hypercalciuria; Hyperoxaluria; Nephrolithiasis; Ureterolithiasis; Urine Output Increased	Lexapro	S	Oral	10 Mg Biw Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2004	5703934	EXPEDITED (15-DAY)	Y	OT	S04-USA-07725-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Treatment Noncompliance	Lexapro			S	Oral	20 Mg Once Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ultram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2004	5711683	NON-EXPEDITED	Y	OT	HQWYE691410MAR04			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Disturbance In Attention; Drug Ineffective For Unapproved Indication; Drug Withdrawal Syndrome; Gait Disturbance; Gynaecomastia; Headache; Insomnia; Vomiting; Weight Increased	Effexor Xr			S	Oral	150 Mg 1x Per 1 Day, Oral; See Image		Not Reported
					Oral	150 Mg 1x Per 1 Day, Oral; See Image		
	Lexapro			S				Not Reported
	Paxil			S				Not Reported
	Zoloft			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2004	5704523	EXPEDITED (15-DAY)	N	OT	S04-USA-07777-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2004	5704802	EXPEDITED (15-DAY)	Y	OT	S04-UKI-08105-01		55 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Nephrotic Syndrome	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qod Po		Not Reported
	Penicillin V "Aliud Pharma" (Phenoxymethylpenicillin Potassium)			C				Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2004	5715695	NON-EXPEDITED	N		2004-BP-08982BP		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Swollen Tongue	Spiriva			S	Respiratory (inhalation)	18 Mcg (18 Mcg) Ih		Not Reported
	Lexapro			S				Not Reported
	Prednisolone			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2004	7385659	EXPEDITED (15-DAY)	Y	OT	K200401860		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Aphasia; Confusional State; Depressed Level Of Consciousness; Disorientation; Drug Interaction; Electroencephalogram Abnormal; Eye Movement Disorder; Fatigue; Fear; Headache; Mental	Tigan			S				Not Reported
	Lexapro			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
	Fentanyl			C				Not Reported
	Klonopin			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Vicodin			C				Not Reported

Impairment; Partial Seizures; Tardive Dyskinesia	Estrogen Nos	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2004	5705736	EXPEDITED (15-DAY)	Y	HO	S04-USA-07808-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Priapism	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Trazodone Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2004	5690544	EXPEDITED (15-DAY)	Y	DS	S04-ITA-07674-01		63 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nerve Compression; Optic Nerve Disorder; Optic Neuropathy; Pituitary Tumour; Retinal Vascular Disorder; Toxicity To Various Agents; Visual Acuity Reduced	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Altiazem (Diltiazem Hydrochloride)			C				Not Reported
	Enalapril			C				Not Reported
	Cardioaspirin (Acetylsalicylic Acid)`			C				Not Reported
	Xanax			C				Not Reported
	Azyr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2004	5695491	EXPEDITED (15-DAY)	Y	HO	S04-SWE-07890-02		10 DAY	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Body Temperature Increased; Drug Withdrawal Syndrome; Hyperreflexia; Hypertension Neonatal; Hypertonia Neonatal; Irritability; Maternal	Cipralex			S				Not Reported
	Valproic Acid			S				Not Reported
	Trandate			C				Not Reported

Exposure During
Pregnancy; Nervousness;
Screaming; Tremor
Neonatal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2004	5695498	EXPEDITED (15-DAY)	Y	HO, OT	S04-SWE-07890-01			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pre-Eclampsia	Cipralex			S				Not Reported
	Valproate Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2004	5699344	EXPEDITED (15-DAY)	N	HO	US-ROCHE-389132		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Overdose; Overdose	Klonopin			S	Unknown	Dose Reported As Large Amount		Roche
	Plavix			S	Oral			Not Reported
	Plavix			S	Oral			Not Reported
	Ambien			S	Oral		1 DAY	Not Reported
	Depakote			S	Unknown			Not Reported
	Lexapro			S	Unknown	Dose Reported As Large Amount		Not Reported
	Xanax			S	Unknown	Dose Reported As Large Amount		Not Reported
	Acetylsalicylic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2004	5704969	EXPEDITED (15-DAY)	Y		S04-USA-07795-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Seizure	Lexapro			S				Not Reported

	Lexapro			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2004	5705543	EXPEDITED (15-DAY)	Y	DE	MK200412-0150-1		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Fluoxetine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Liothyronine Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2004	5681485	EXPEDITED (15-DAY)	N	OT	S04-USA-07285-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Amnesia; Breast Discharge; Feeling Abnormal; Incoherent; Nasopharyngitis; Purulence; Shoplifting; Tooth Abscess	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Depo-Provera			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2004	5689751	EXPEDITED (15-DAY)		HO, OT	SE-ABBOTT-04P-150-0281644-00			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pre-Eclampsia	Valproic Acid			S			1 YR	Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2004	5689753	EXPEDITED (15-DAY)		HO	SE-ABBOTT-04P-150-0281642-00		< 1 DAY	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Body	Valproic Acid			S				Not Reported

Temperature Increased; Drug Withdrawal Syndrome; Drug Withdrawal Syndrome Neonatal; Hyperreflexia; Hypertension; Hypertonia; Irritability; Maternal Exposure During Pregnancy; Nervousness; Tremor	Cipralex		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2004	5704189	EXPEDITED (15-DAY)	Y	OT	S04-USA-07773-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Impaired Gastric Emptying; Oesophageal Dysplasia; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2004	5687648	EXPEDITED (15-DAY)		HO	US-ABBOTT-04P-163-0281753-00		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cerebrovascular Accident; Depression Suicidal; Encephalopathy; Hyperammonaemia; Hypotension; Intentional Overdose; Lethargy; Loss Of Consciousness; Pneumonia Haemophilus	Depakote			S	Oral			Not Reported
	Depakote			S				Not Reported
	Depakote			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Clopidogrel Bisulfate			S	Oral			Not Reported
	Clopidogrel Bisulfate			S	Oral			Not Reported
	Clopidogrel Bisulfate			S				Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Zolpidem Tartrate			S				Not Reported
	Alprazolam			S	Oral			Not Reported

	Alprazolam	S			Not Reported
	Clonazepam	S	Oral		Not Reported
	Clonazepam	S			Not Reported
	Phenergan	S			Not Reported
	Acetylsalicylic Acid	C	Oral		Not Reported
	Dihydroergotamine Mesylate	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2004	5708823	EXPEDITED (15-DAY)	Y	OT	S04-GER-08107-01		34 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuser; Medication Error; Overdose; Restlessness; Self-Medication; Therapeutic Product Effect Increased; Treatment Noncompliance	Cipralex			S	Oral	160 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Solian (Amisulpride)			C				Not Reported
	Methadon (Methadone)			C				Not Reported
	Diazepam			C				Not Reported
	Cocaine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2004	5708978	EXPEDITED (15-DAY)	N	OT	2004113561		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Dysstasia; Incoherent	Neurontin			S	Oral	(400 Mg), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Alprazolam (Alprazolam)			C				Not Reported
	Meloxicam (Meloxicam)			C				Not Reported
	Tizanidine Hydrochloride			C				Not Reported
	Quetiapine Fumarate (Quetiapine Fumarate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2004	5706160	DIRECT	N	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Depression; Emotional Disorder; Feeling Of Despair; Suicidal Ideation; Thinking Abnormal	Lexapro	S		Not Reported
	Lopresor	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2004	5710160	EXPEDITED (15-DAY)	Y	HO, LT	S04-AUS-08252-01		27 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Mouth; Systemic Lupus Erythematosus; Throat Tightness; Urticaria	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Pamol (Paracetamol)			C				Not Reported
	Contraceptive Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2004	5711284	EXPEDITED (15-DAY)	Y	HO, OT	KII-2004-0014321		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Aspiration; Drug Withdrawal Syndrome; Hyperhidrosis; Hypertension; Mydriasis; Overdose; Pyrexia; Somnolence; Tachycardia; Therapy Non-Responder	Oxycontin			S	Oral	Oral		Not Reported
	Lexapro			S				Not Reported
	Tetrahydrocannabinol (Tetrahydrocannabinol)			S				Not Reported
	Skelaxin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2004	4223523	EXPEDITED (15-DAY)	N	HO, OT	2004S1002746		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Hypersensitivity; Drug Interaction; Toxicity To Various Agents	Vistaril			S	Oral	50 Mg Qd, Oral		Not Reported
	Lexapro			S	Oral	10 Mg Qd, Oral		Not Reported
	Alprazolam			S	Oral	0.25 Mg Qd, Oral		Not Reported

Metrogel	S	Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2004	5676544	EXPEDITED (15-DAY)	Y		T04-USA-07232-01		83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Potassium Increased; Blood Urea Increased; Condition Aggravated; Dehydration; Dyspepsia; Dysstasia; Gait Inability; Gastrooesophageal Reflux Disease; Hypertension; Hypophagia; Insomnia; Orthostatic Hypotension	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prevacid			C				Not Reported
	Detrol - Slow Release (Tolterodine L-Tartrate)			C				Not Reported
	Digoxin			C				Not Reported
	Lasix			C				Not Reported
	Coumadin			C				Not Reported
	Lipitor			C				Not Reported
	Lisinopril			C				Not Reported
	Potassium			C				Not Reported
	Reglan			C				Not Reported
	Prednisone			C				Not Reported
	Calcium With Vitamin D			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2004	5711792	DIRECT	N				31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Medication Error; Nausea	Lexapro			S		Tablet		Not Reported
	Lipitor			S		Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2004	5711840	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lexapro			S		Tablet		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2004	5711619	EXPEDITED (15-DAY)	Y	HO	2004AL001968		29 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Dependence; Drug Withdrawal Syndrome; Fear; Maternal Exposure During Pregnancy	Oxazepam			S	Oral	15mg, Tid; Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg; Qd; Po		Not Reported
	Lamotrigine			S	Oral	100 Mg Qd; Po		Not Reported
	Trazodone Hydrochloride			S	Oral	100 Mg Qd; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2004	5655800	EXPEDITED (15-DAY)	Y	OT	S04-USA-06678-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Attention Deficit/Hyperactivity Disorder; Autoimmune Thyroiditis; Depression; Disease Recurrence; Oropharyngeal Pain; Ovulation Pain; Therapeutic Product Effect Decreased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Minocycline\Minocycline Hydrochloride			C				Not Reported
	Dicyclomine Hydrochloride			C				Not Reported
	Clarinex			C				Not Reported
	Prilosec			C				Not Reported
	Effexor Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2004	5669464	EXPEDITED (15-DAY)	Y	DE	S04-USA-06411-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Craniocerebral Injury; Gun Shot Wound; Insomnia; Medication Error	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Restoril			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2004	5712096	EXPEDITED (15-DAY)	Y	DS	S04-UKI-08245		58 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2004	7385701	NON-EXPEDITED	Y	DE	04-06-0954		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Clozapine			S	Oral	300mg Hs Oral		Ivax
	Lexapro			S	Oral	30mg Am Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2005	5662314	EXPEDITED (15-DAY)	Y	DE, OT	2004080312		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Brain Death; Circulatory Collapse; Fall; Loss Of Consciousness; Post Procedural Complication	Geodon			S				Not Reported
	Zyrtec			S				Not Reported
	Lipitor			S				Not Reported
	Ibuprofen (Ibuprofen)			S				Not Reported
	Oxcarbazepine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Lorazepam			C				Not Reported
	Metoprolol			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Methylphenidate Hydrochloride			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2005	5712848	DIRECT	Y	DE			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Knee Arthroplasty	Meperidine	S	Intravenous (not otherwise specified)	Pca Cont. + Demand Intravenous		Abbott
	Lexapro	S	Oral	30mg Daily Oral		Not Reported
	Prevacid	C				Not Reported
	Klonopin	C				Not Reported
	Corgard	C				Not Reported
	Ferrous Sulfate	C				Not Reported
	Pepcid	C				Not Reported
	Colace	C				Not Reported
	Kefzol	C				Not Reported
	Zofran	C				Not Reported
	Narcan	C				Not Reported
	Morphine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2005	5709701	EXPEDITED (15-DAY)	Y	OT	S04-USA-06933-01		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Feeling Abnormal; Feeling Hot; Hyperhidrosis; Hypertension; Hypoaesthesia; Pain In Extremity; Paraesthesia; Vision Blurred	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Cozaar			C				Not Reported
	Toprol Xl (Metyoprolol Succinate)			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Clonidine			C				Not Reported
	Vivelle			C				Not Reported
	Alphagan P			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2005	5718118	EXPEDITED (15-DAY)	Y	RI	S04-USA-05530-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; False Labour; Induced Labour; Maternal Exposure During Pregnancy; Pregnancy	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2005	5708009	EXPEDITED (15-DAY)	Y	HO	S04-ITA-08108-01		80 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Hyponatraemia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Gabapentin			C				Not Reported
	Deltacortene (Prednisone)			C				Not Reported
	Lioresal "Ciba-Geigy" (Balclofen)			C				Not Reported
	Enapren (Enalapril Maleate)			C				Not Reported
	Moduretic "Du Pont"			C				Not Reported
	Lansox (Lansoprazole)			C				Not Reported
	Pradif (Tamsulosin Hydochloride)			C				Not Reported
	Asa (Acetylsalicylic Acid)			C				Not Reported
	Topical Broncodilatators For Inhalation			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2005	5717041	DIRECT	Y	OT			19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Self-Injury; Skin Laceration	Lexapro			S		10mg Am 047 11/7-11/24 ; 20mg Am 047 11/25-12/30 10mg Am 047 11/7-11/24 ; 20mg Am 047 11/25-12/30		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2005	5717749	EXPEDITED (15-DAY)	N	LT	S05-USA-00011-01		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Impulsive Behaviour; Mental Disorder; Suicide Attempt	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2005	5718477	DIRECT	Y	OT			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Dementia; Diarrhoea; Haematochezia; Memory Impairment; Vision Blurred	Lexapro			S		10mg Daily Decreased To 1/2 Tablet Daily		Forest
	Zocor			C				Not Reported
	Actonel			C				Not Reported
	Zyrtec			C				Not Reported
	Levocabastine Hydrochloride			C				Not Reported
	Levoxyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2005	5674107	EXPEDITED (15-DAY)	Y	HO, OT	S04-USA-07135-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depression; Dizziness; Eating Disorder; Fatigue; Sinus Bradycardia; Weight Decreased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2005	5714027	EXPEDITED (15-DAY)	Y	OT	2005000542		18 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Intentional Overdose; Overdose; Somnolence; Suicide Attempt	Lithium Carbonate			S	Oral	9450mg Single Dose		Glaxosmithkline
	Risperdal			S	Oral	17.5mg Single Dose		Not Reported
	Trileptal			S	Oral	11550mg Single Dose		Not Reported
	Cipralex			S	Oral	350mg Single Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2005	5720917	EXPEDITED (15-DAY)	Y	OT	S05-USA-00062-01		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2005	5761479	NON-EXPEDITED	Y	DE	HQWYE177723SEP04		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Effexor			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2005	5655808	EXPEDITED (15-DAY)	Y	HO, RI	S04-USA-06784-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Post Procedural Complication; Priapism; Thrombosis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			S		400 Mg Qd		Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2005	5661474	EXPEDITED (15-DAY)	Y	DE	T04-SWI-06911-01		79 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Cardiac Arrest; Cardiac Failure; Dermatitis Allergic; Multiple Organ Dysfunction Syndrome; Oxygen Saturation Decreased; Rash	Ebixa			S	Oral	15 Mg Qd Po		Not Reported
	Ebixa			S	Oral	10 Mg Qd Po		Not Reported
	Ebixa			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Metolazone			S				Not Reported
	Konakion			S	Oral	5 Mg Qd Po		Not Reported

Beloc Zok (Metoprolol Succinate)	S	Oral	25 Mg Qd Po		Not Reported
Digoxin	S	Oral	0.125 Mg Qd Po		Not Reported
Trospium Chloride	S	Oral	40 Mg Qd Po		Not Reported
Aspirin	S	Oral	100 Mg Qd Po		Not Reported
Tramadol Hydrochloride	S	Oral	50 Mg Qd Po		Not Reported
Zyrtec	S	Oral	10 Mg Qd Po		Not Reported
Zaroxolyn	C				Not Reported
Paragol	C				Not Reported
Calcium Gluconate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2005	5711447	EXPEDITED (15-DAY)	Y	OT	S04-USA-07931-01		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Electrocardiogram Pr Prolongation; Electrocardiogram Qt Prolonged	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Androgel			C				Not Reported
	Ambien			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2005	5722409	EXPEDITED (15-DAY)	Y	OT	S04-USA-07916-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Generalised; Skin Burning Sensation; Stevens-Johnson Syndrome; Vasculitis	Lexapro			S				Not Reported
	Ativan			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2005	5722818	EXPEDITED (15-DAY)	Y	DE	S05-USA-00083-01		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Gun Shot Wound; Intentional Self-Injury; Scratch	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Lexapro		S	Oral	20 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2005	5662669	EXPEDITED (15-DAY)	Y	DE	T04-SWI-06971-01		48 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Completed Suicide	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Chlorprothixene Hydrochloride			S	Oral	60 Mg Qd Po		Not Reported
	Lorazepam			S	Oral	1 Mg Qd Po		Not Reported
	Lorazepam			S	Oral	0.5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2005	5726806	EXPEDITED (15-DAY)	Y	HO	US013912		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atelectasis; Balance Disorder; Disorientation; Dizziness; Hypotension; Influenza Like Illness; Lung Infiltration; Myalgia; Pneumonia; Pyuria; Seizure; Septic Shock; Urinary Tract Infection; Vomiting	Provigil			S	Oral	100 Mg Qd Oral		Not Reported
	Provigil			S	Oral	200 Mg Qd Oral		Not Reported
	Provigil			S	Oral	50 Mg Once Oral		Not Reported
	Klonopin			S	Oral	2.25 Mg Qd Oral		Not Reported
	Neurontin			S	Oral	1200 Mg Qd Oral		Not Reported
	Aciphex			S	Oral	60 Mg Qd Oral		Not Reported
	Hydrochlorothiazide			S	Oral	100 Mg Qd Oral		Not Reported
	Doryx			S	Oral	100 Mg Qd Oral		Not Reported
	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2005	5727110	EXPEDITED (15-DAY)	Y	HO	T04-SWI-08295-01		32 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acoustic Neuroma; Antipsychotic Drug Level Above Therapeutic; Encopresis; Enuresis; Hypertonic Bladder; Incontinence; Therapy Non-Responder; Urinary Tract Infection	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Clozapine			S	Oral	300 Mg Qd Po		Not Reported
	Clozapine			S	Oral	275 Mg Qd Po		Not Reported
	Clozapine			S	Oral	287.5 Mg Qd Po		Not Reported
	Orfiril (Valproate Sodium)			C				Not Reported
	Magnesiocard (Magnesium Aspartate Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2005	5727324	EXPEDITED (15-DAY)	Y	RI	S05-USA-00188-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2005	5727328	EXPEDITED (15-DAY)	Y	OT	S04-USA-07366-01		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Use; Spousal Abuse	Lexapro			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2005	5727344	EXPEDITED (15-DAY)	Y	HO	S05-USA-00195-01		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Combivent			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2005	5728754	DIRECT	Y	DE			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Amnesia; Anger; Completed Suicide; Drug Interaction; Economic Problem; Fear; Gun Shot Wound; Insomnia; Movement Disorder; Overdose; Salivary Hypersecretion; Serotonin Syndrome; Speech Disorder; Thinking Abnormal; Tremor	Lexapro			S	Oral	1 Daily Po		Not Reported
	Phentermine			S	Oral	1 Daily Po		Not Reported
	Avandamet 4/500			C				Not Reported
	Glyburide			C				Not Reported
	Synthroid			C				Not Reported
	Temazapam			C				Not Reported
	Esgic-Plus			C				Not Reported
	Lipitor			C				Not Reported
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2005	5673287	EXPEDITED (15-DAY)	Y	DE	DSA_25219_2004		56 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Completed Suicide	Lorazepam			S	Oral	0.5 Mg Q Day Po		Not Reported
	Lorazepam			S	Oral	1 Mg Q Day Po		Not Reported
	Chlorprothixene Hydrochloride			S		60 Mg Q Day		Not Reported
	Cipralex			S		20 Mg Q Day		Not Reported
	Cipralex			S		15 Mg Q Day		Not Reported
	Cipralex			S		10 Mg Q Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2005	5658471	EXPEDITED (15-DAY)	Y	HO	S04-USA-06881-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intracranial Hypotension;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Migraine; Nausea; Post Procedural Complication; Therapy Non-Responder; Vomiting	Lexapro		S	Oral	5 Mg Qd Po	Not Reported
	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Unspecified Ingredient		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2005	5676569	EXPEDITED (15-DAY)	Y	OT	S04-USA-07185-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2005	5684451	EXPEDITED (15-DAY)	Y	OT	S04-USA-07370-01		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Loss Of Consciousness	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2005	5712288	EXPEDITED (15-DAY)	N	OT	S04-USA-07926-01		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Amnesia; Blood Alcohol Increased; Concussion; Delirium; Drug Screen Positive; Fall; Gait Disturbance; Head Injury; Headache; Loss Of Consciousness; Sedation	Lexapro			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2005	5731866	EXPEDITED (15-DAY)	N	HO	S05-USA-00194-01		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Influenza Like Illness; Pulmonary Embolism	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Adderall	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2005	5731867	EXPEDITED (15-DAY)	N	OT	S05-USA-00234-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Eye Disorder; Eye Haemorrhage; Maculopathy	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2005	5732483	EXPEDITED (15-DAY)	Y	OT	S05-UKI-00210-01		87 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Albuterol			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Ramipril			C				Not Reported
	Rabeprazle (Rabeprazole)			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2005	5650833	EXPEDITED (15-DAY)	Y	OT	S04-USA-06456-01		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Hyperthyroidism; Palpitations	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qod Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2005	5712269	EXPEDITED (15-DAY)	N	OT	S04-USA-07727-01		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Furuncle; Immune System Disorder; Therapy Non-Responder; Vaginal Abscess	Lexapro			S				Not Reported
	Tamoxifen Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2005	5719085	EXPEDITED (15-DAY)	Y	OT	S04-USA-08050-01		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Generalised Tonic-Clonic Seizure; Status Epilepticus	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Protonix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2005	5724614	NON-EXPEDITED	N		S03-USA-04967-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Wellbutrin			S	Oral	200mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2005	5724615	NON-EXPEDITED	N		S03-USA-04869-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Alopecia	Wellbutrin			S	Oral		6 MTH	Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day	1 YR	Not Reported
	Risperdal			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2005	5724642	NON-EXPEDITED	N		S03-USA-05410-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Feeling Abnormal; Impaired Driving Ability	Wellbutrin			S	Oral			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2005	5724813	NON-EXPEDITED	Y	OT	20040304012		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenic Purpura; Platelet Count Decreased	Wellbutrin			S	Oral	200mg Twice Per Day		Glaxosmithkline
	Topamax			S	Unknown	300mg Per Day	317 DAY	Not Reported
	Lexapro			S	Unknown	20mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2005	5724822	NON-EXPEDITED	Y	OT	S04-USA-04203-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Weight Increased	Wellbutrin			S	Oral			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2005	5725209	EXPEDITED (15-DAY)	N	HO	US-ROCHE-391291		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Withdrawal Syndrome	Valium			S	Oral			Roche
	Unspecified Ingredient			S	Intrathecal	Generic: Ziconotide		Not Reported
	Norco			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Avinza			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2005	5730766	EXPEDITED (15-DAY)	Y	HO	S05-AUT-00145-01		59 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Burning Sensation; Chest Pain; Duodenal Ulcer; Gastrointestinal Haemorrhage; Overdose	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Minipress			C				Not Reported
	Atacand (Candesartan Cilexetil)			C				Not Reported
	Zocor			C				Not Reported
	Glyburide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2005	5712271	EXPEDITED (15-DAY)	N	OT	S04-USA-07918-01		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Abscess; Furuncle; Immune System Disorder; Subcutaneous Abscess; Vaginal Abscess	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2005	5676565	EXPEDITED (15-DAY)	Y	OT	S04-USA-07189-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuritis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2005	5705662	EXPEDITED (15-DAY)	N	HO, OT	PHEH2004US13574		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Drug Withdrawal Syndrome; Headache; Heart Injury; Transient Ischaemic	Vivelle Dot			S	Transdermal	0.05mg/Day		Novartis
	Lexapro			S				Not Reported

Attack

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2005	5727755	EXPEDITED (15-DAY)	Y	HO	US-MERCK-0501USA04023		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Chills; Diarrhoea; Disorientation; Dizziness; Electroencephalogram Abnormal; Fatigue; Feeling Abnormal; Hypotension; Influenza Like Illness; Lung Infiltration; Myalgia; Nausea; Pleural Effusion; Pneumonia; Pyrexia; Pyuria; Seizure; Urinary Tract Infection; Vomiting; White Blood Cell Count Increased	Hydrodiuril			S	Oral			Merck
	Provigil			S	Oral			Not Reported
	Provigil			S	Oral		1 DAY	Not Reported
	Provigil			S	Oral			Not Reported
	Provigil			S	Oral		1 DAY	Not Reported
	Lexapro			S	Oral			Not Reported
	Doryx			S	Oral			Not Reported
	Neurontin			S	Oral			Not Reported
	Aciphex			S	Oral			Not Reported
	Klonopin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2005	3980648	EXPEDITED (15-DAY)	Y	OT	T03-SWI-02920-01		37 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electroencephalogram Abnormal; Hypersomnia; Hyperventilation; Syncope; Tremor	Escitalopram Oxalate			S				Not Reported
	Placebo			S	Oral	1 Tablet Qd Po		Not Reported
	Similasan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2005	6747135	EXPEDITED (15-DAY)	Y	DE	T05-JPN-00135-01		54 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cold Exposure Injury; Completed Suicide;	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

Micturition Disorder; Stress	Escitalopram Oxalate		S	Oral	20 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2005	4197942	EXPEDITED (15-DAY)	Y	OT	S04-IRL-03671-01		46 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypochromic Anaemia; Menorrhagia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Amitriptyline Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2005	5729160	EXPEDITED (15-DAY)	Y	HO	ES-BRISTOL-MYERS SQUIBB COMPANY-12837597		78 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Deprax (Trazodone Hydrochloride)			S	Oral		14 DAY	Apothecon
	Escitalopram Oxalate			S	Oral		14 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2005	5741073	EXPEDITED (15-DAY)	Y	HO	1722		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Withdrawal Syndrome	Avinza			S	Oral	120 Mg Daily Po		Not Reported
	Avinza			S	Oral	60 Mg Daily Po		Not Reported
	Ziconotide			S		0.3 Mcg		Not Reported
	Acetaminophen\Hydrocodone Bitartrate			S				Not Reported
	Valium			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2005	4161881	EXPEDITED (15-DAY)	N	OT	S04-USA-03238-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Level Decreased; Electroencephalogram Abnormal; Seizure; Simple Partial Seizures	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Depakote			C				Not Reported
	Levothroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2005	5718063	EXPEDITED (15-DAY)	Y	OT	2005001209		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Condition Aggravated; Heart Rate Increased; Supraventricular Extrasystoles	Tikosyn			S				Not Reported
	Escitalopram Oxalate			S	Oral	See Image		Not Reported
					Oral	See Image		
	Ezetimibe			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2005	5718982	EXPEDITED (15-DAY)	N	HO	US-GLAXOSMITHKLINE-A0540443A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Coma; Drug Ineffective; Drug Interaction; Medication Error	Wellbutrin			S	Oral	300mg See Dosage Text		Glaxosmithkline
	Lexapro			S				Not Reported
	Atenolol			C				Not Reported
	Avandia			C				Glaxosmithkline
	Nexium			C				Not Reported
	Aspirin			C				Glaxosmithkline
	Aricept			C				Not Reported
	Neurontin			C				Not Reported
	Centrum Silver			C				Not Reported
	Magnesium			C				Not Reported
	Potassium			C				Not Reported
	Duragesic			C				Not Reported
	Cyanocobalamin			C				Glaxosmithkline
	Hydrocodone			C				Not Reported
	Zocor			C				Not Reported

	Diazepam	C	Not Reported
	Isosorbide	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2005	5739827	EXPEDITED (15-DAY)	Y	OT	S05-UKI-00220-01		28 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Self-Injurious Ideation; Suicidal Ideation	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2005	5730301	EXPEDITED (15-DAY)		OT	US-ABBOTT-05P-163-0288882-00		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Depression; Drug Interaction; Feeling Hot; Hyperhidrosis; Seizure; Suicidal Ideation	Biaxin			S				Not Reported
	Biaxin			S				Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2005	5726393	EXPEDITED (15-DAY)	Y	DE	S05-ISR-00201-01		24 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Cholesterol Increased; Hepatitis Fulminant; Pyrexia; Renal Failure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Clonazepam			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Normiten (Atenolol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2005	5740253	EXPEDITED (15-DAY)	Y	OT	S05-UKI-00351-01		30 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dissociation; Gait Disturbance; Paranoia; Vision Blurred	Cipralex	S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2005	5740261	EXPEDITED (15-DAY)	Y	OT	S05-UKI-00353-01		55 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prostatitis; Urethritis	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2005	5700173	EXPEDITED (15-DAY)	Y	OT	S04-FRA-07953-01		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertensive Crisis	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Zyprexa			S	Oral	7.5 Mg Qd Po		Not Reported
	Seropram (Citalopram Hydrobromide)			C				Not Reported
	Atarax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2005	5732224	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0523042A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Paroxetine Hydrochloride			S				Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2005	5733144	NON-EXPEDITED	N		S03-USA-05182-01		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger;	Paxil			S	Oral	20mg Per Day		Glaxosmithkline

Headache; Insomnia; Mental Impairment; Muscle Twitching; Thirst	Lexapro		S	Oral	20mg Per Day	Not Reported
	Strattera		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2005	5741539	EXPEDITED (15-DAY)	Y	OT	S05-UKI-00436-01		78 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Flushing	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Temazepam			C				Not Reported
	Aspirin			C				Not Reported
	Betahistine (Betahistine)			C				Not Reported
	Losartan (Losartan)			C				Not Reported
	Ranitidine			C				Not Reported
	Prochlorperazine			C				Not Reported
	Risedronate Sodium (Residronate Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2005	5744003	DIRECT	Y	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Abnormal; Drug Ineffective; Product Quality Issue; Sexual Dysfunction; Thinking Abnormal	Prozac			S		Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2005	6962477	EXPEDITED (15-DAY)	Y	OT	S05-USA-00455-02		60 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Breast Feeding; Social Problem; Somnolence; Weight Gain Poor	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Mircette			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2005	4219898	EXPEDITED (15-DAY)	Y	OT	S04-USA-06121-01		10 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Loss Of Consciousness; Seizure	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Strattera			S	Oral	40 Mg Po		Not Reported
	Strattera			S		25 Mg		Not Reported
	Strattera			S		18 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2005	5744252	EXPEDITED (15-DAY)	Y	LT	S05-UKI-00435-01		45 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Mental Impairment; Negativism; Self-Injurious Ideation	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2005	5744363	EXPEDITED (15-DAY)	Y	OT	S05-USA-00559-01		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choking	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2005	5656345	EXPEDITED (15-DAY)	Y	DE	2004AL000785		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Completed Suicide; Hypotension; Intentional Overdose; Therapy Non-Responder	Verapamil Hydrochloride			S	Oral	Po		Not Reported
	Clonazepam			S	Oral	Po		Purepac
	Atorvastatin			S	Oral	Po		Not Reported

	Escitalopram Oxalate	S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2005	5657530	EXPEDITED (15-DAY)	Y	DE	2004AL000733		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Haemodialysis; Hyperglycaemia; Hypotension; Overdose; Renal Failure; Therapy Non-Responder	Clonidine Hydrochloride			S	Oral	Po		Purepac
	Amlodipine Besylate\Benazepril Hydrochloride			S	Oral	Po		Not Reported
	Glimepiride			S	Oral	Po		Not Reported
	Promethazine Hydrochloride			S	Oral	Po		Alphapharm
	Diazepam			S	Oral	Po		Purepac
	Lorazepam			S	Oral	Po		Purepac
	Risperidone			S	Oral	Po		Not Reported
	Escitalopram Oxalate			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2005	5657623	EXPEDITED (15-DAY)	Y	DE	2004AL000681		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bicarbonate Decreased; Blood Calcium Decreased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Ph Decreased; Blood Potassium Decreased; Bradycardia; Cardiac Arrest; Completed Suicide; Hypotension; Overdose;	Lorazepam			S	Oral	Po		Purepac
	Childrens Acetaminophen			S	Oral	Po		Alphapharm
	Acetaminophen			S				Alphapharm
	Desipramine Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

Oxygen Saturation Decreased; Pco2 Decreased; Po2 Decreased; Respiratory Arrest; Respiratory Depression

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2005	5657624	EXPEDITED (15-DAY)	Y	DE, HO	2004AL000823		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Body Temperature Increased; Cardiac Arrest; Coma; Completed Suicide; Electrocardiogram Qt Prolonged; Haemodialysis; Hypotension; Hypoxia; Intentional Overdose; Nodal Rhythm; Pneumonia Aspiration; Renal Failure; Respiratory Arrest; Supraventricular Tachycardia; Therapy Non-Responder	Lorazepam			S	Oral	Po		Purepac
	Diltiazem Hydrochloride			S	Oral	Po		Purepac
	Benzotropine			S	Oral	Po		Not Reported
	Escitalopram Oxalate			S	Oral	Po		Not Reported
	Ziprasidone			C				Not Reported
	Fenofexadine			C				Not Reported
	Oxcarbazepine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2005	5659632	EXPEDITED (15-DAY)	N	OT	S04-USA-06883-01		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased; Sinusitis	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prosom (Estazolam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2005	5712064	EXPEDITED (15-DAY)	Y	HO	S04-AUS-08256-01		41 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg Qid Po		Not Reported
	Seroquel			C				Not Reported
	Edronax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2005	5745037	EXPEDITED (15-DAY)	Y	RI	S05-USA-00383-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anaemia; Drug Ineffective; Drug Interaction; Lichen Planus; Uterine Leiomyoma	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lupron			S	Intramuscular	3.75 Mg Im		Not Reported
	Lupron			S				Not Reported
	Lupron			S				Not Reported
	Topamax			S	Oral	100 Mg Qd Po		Not Reported
	Unisom Sleeptabs			S	Oral	1 Tablet Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2005	5692881	EXPEDITED (15-DAY)	Y	HO	S04-USA-07514-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Decreased; Blood Bicarbonate Decreased; Blood Glucose Increased; Blood Ph Increased; Blood Potassium Decreased; Coma; Encephalopathy; Hyperammonaemia; Hypotension; Intentional Overdose; Lethargy; Pco2 Decreased; Pneumonia	Lexapro			S	Oral	300 Mg Once Po		Not Reported
	Lexapro			S	Oral	80 Mg Qd Po		Not Reported
	Plavix			S		20 Tablet Once		Not Reported
	Plavix			S		75 Mg Qd		Not Reported
	Ambien			S		130 Mg Once		Not Reported
	Ambien			S				Not Reported
	Depakote			S		4 G Once		Not Reported
	Depakote			S		125 Mg Bid		Not Reported
	Depakote			S				Not Reported
	Xanax			S				Not Reported
	Xanax			S		0.5 Mg Tid		Not Reported
	Klonopin			S				Not Reported

Haemophilus; Suicide Attempt	Klonopin	S	5 Mg Tid		Not Reported
	Phenergan	S			Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Migranal	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2005	4217727	EXPEDITED (15-DAY)	N	DE	DSA_24891_2004		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Completed Suicide; Condition Aggravated; Depression; Disease Recurrence; Gun Shot Wound; Lung Disorder	Teveten			S	Oral	250 Mg Q Day Po		Not Reported
	Lexapro			S		5 Mg Qhs		Not Reported
	Protonix			S		40 Mg Qhs		Pharmacia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2005	5692597	EXPEDITED (15-DAY)	Y	HO	S04-USA-07506-01		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Crying; Depression; Panic Attack; Psychotic Disorder; Suicidal Ideation	Lexapro			S	Oral	10 Mg Tid Po		Not Reported
	Lexapro			S	Oral	5 Mg Tid Po		Not Reported
	Lexapro			S	Oral	10 Mg Tid Po		Not Reported
	Lexapro			S	Oral	10 Mg Tid Po		Not Reported
	Lexapro			S	Oral	10 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	10 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 Mg Tid Po		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2005	5717674	EXPEDITED (15-DAY)	N	OT	S05-USA-00020-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Generalised Tonic-Clonic Seizure	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Advair Diskus		C			Not Reported
	Allerx		C			Not Reported
	Nexium (Esomeprazole)		C			Not Reported
	Unspecified Ingredient		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2005	5737550	NON-EXPEDITED	N		S04-USA-02836-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Lamotrigine			S	Oral	25mg Per Day	5 WEEK	Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported
	Lexapro			S	Oral	5mg Per Day		Not Reported
	Abilify			C	Unknown	30mg Per Day		Not Reported
	Benadryl			C	Unknown	50mg Per Day		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2005	5737858	NON-EXPEDITED	N	HO	S04-USA-04591-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choreoathetosis; Hypomania	Lamictal			S	Oral	150mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported
	No Concurrent Medications			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2005	5738437	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0501198A		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lamictal			S	Oral	200mg Per Day	666 DAY	Glaxosmithkline
	Risperidal			S	Oral	1mg Per Day		Not Reported
	Lexapro			S	Oral	20mg Per Day		Not Reported

Centrum Silver	C			Not Reported
Neurontin	C	600mg Per Day		Not Reported
Klonopin	C			Not Reported
Adderall	C			Not Reported
Synthroid	C	.025mg Per Day		Glaxosmithkline
Omega 3 Fatty Acids	C			Glaxosmithkline
Vitamin E	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2005	5738539	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0505421A		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Dizziness; Eye Irritation; Nausea	Lamictal			S	Oral	100mg Twice Per Day	1 MTH	Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2005	5739677	EXPEDITED (15-DAY)	Y		S05-USA-00396-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Restless Legs Syndrome	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2005	5709666	EXPEDITED (15-DAY)	N	OT	US-MERCK-0412USA03322		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged; Heart Rate Increased; Supraventricular Extrasystoles	Zetia			S	Oral			Merck
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Tikosyn			S	Unknown			Not Reported
	Tikosyn			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2005	5746112	DIRECT	Y				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Lexapro			S	Oral	1 Po Daily		Forest
	Clonepin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2005	5746115	DIRECT	N	OT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Drug Withdrawal Syndrome; Panic Attack	Lexapro			S		Sample Size 1/Day Oral		Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2005	5747471	DIRECT	Y	RI			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Gambling	Lexapro			S		Per Orem	2 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2005	5749490	DIRECT	N	DE			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S		10 Mg 1 Per Day		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2005	5749862	DIRECT	Y	DE			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypertrophic Cardiomyopathy; Nausea; Toxicity To Various Agents	Lexapro			S	Oral	45 Mg, Single Dose, Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2005	4143267	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0500360A		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Decreased Appetite; Drug Ineffective; Energy Increased; Stress; Weight Decreased	Wellbutrin Xl			S	Oral	200mg Per Day	2 YR	Glaxosmithkline
	Lexapro			S	Oral			Not Reported
	Aspirin			C				Glaxosmithkline
	Zocor			C				Not Reported
	Prilosec			C				Glaxosmithkline
	Klonopin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2005	5752634	EXPEDITED (15-DAY)	Y	OT	S05-USA-00704-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2005	5719079	EXPEDITED (15-DAY)	N	DS	S05-USA-08124-01		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Cerebrovascular Accident; Insomnia; Nightmare	Lexapro			S				Not Reported
	Celebrex			S				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2005	5722983	EXPEDITED (15-DAY)	Y	OT	S05-USA-00077-01		7 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Posturing; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Concerta			C				Not Reported
	Klonopin			C				Not Reported
	Risperdal			C				Not Reported
	Benadryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2005	5750434	DIRECT	Y	RI			13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lexapro			S	Oral	5 Mg Q Hs Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2005	4190766	EXPEDITED (15-DAY)	Y	OT	S04-GER-03331-01		54 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Vioxx			S				Not Reported
	Propecia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2005	5751423	EXPEDITED (15-DAY)	Y	HO	S05-USA-00780-01		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Dyskinesia; Fall; Hip Fracture; Lip Discolouration; Seizure; Swelling Face; Tongue Discolouration	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lisinopril			S				Not Reported
	Armour Thyroid			C				Not Reported
	Norpace			C				Not Reported
	Digoxin			C				Not Reported
	Antivert			C				Not Reported
	Zetia			C				Not Reported

	Lipitor	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2005	5752812	DIRECT	N	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Withdrawal Syndrome; Feeling Abnormal; Hallucination; Hypoaesthesia; Insomnia; Paraesthesia; Product Quality Issue; Tremor	Lexapro			S		1 A Day		Not Reported
	Paxil Cr			S		1 A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2005	5733849	EXPEDITED (15-DAY)	Y	HO	S05-DEN-00341-01		79 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hiatus Hernia; Nausea; Vomiting	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lansoprazole			C				Not Reported
	Primperan			C				Not Reported
	Novazulid			C				Not Reported
	Odrik (Trandolapril)			C				Not Reported
	Furosemide			C				Not Reported
	Keleorid (Potassium Chloride)			C				Not Reported
	Selozok			C				Not Reported
	Remeron			C				Not Reported
	Acetaminophen			C				Not Reported
	Albyl-Enterosolubile			C				Not Reported
	Fosamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2005	5753742	EXPEDITED (15-DAY)	Y	HO	2005AC00283		74 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Antipsychotic	Lisinopril			S	Oral	20 Mg Daily Po		Not Reported

Drug Level Above Therapeutic; Apathy; Blood Creatinine Increased; Confusional State; Dehydration; Drug Interaction; Drug Level Above Therapeutic; Dysarthria; Nervous System Disorder; Neurotoxicity; Oliguria; Overdose; Somnolence; Toxicity To Various Agents; Tremor	Lisinopril	S	Oral	30 Mg Daily Po		Not Reported
	Irbesartan	S		300 Mg Daily		Not Reported
	Risperidone	S		0.25 Mg Bid		Not Reported
	Lithium	S		250 Mg Tid		Not Reported
	Escitalopram Oxalate	S		10 Mg Daily		Not Reported
	Levomepromazine	S		6.25 Mg Daily		Not Reported
	Spironolactone	S		50 Mg Daily		Not Reported
	Furosemide	S		30 Mg Daily		Not Reported
	Dexetimide	C				Not Reported
	Lormetazepam	C				Not Reported
	Metformin	C				Not Reported
	Repaglinide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2005	5753779	DIRECT	Y				24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Insomnia	Lexapro			S	Oral	2.5 Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2005	5763742	NON-EXPEDITED	Y	DE	041-163-0276180-00		31 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fat Tissue Increased; Toxicity To Various Agents; Unevaluable Event	Vicodin			S				Not Reported
	Lexapro			S	Oral	30 Mg, 1 In 1 D, Per Oral		Not Reported
	Clozapine			S		300 Mg, 1 In 1 D		Not Reported
	Topiramate			C				Not Reported
	Valproate Semisodium			C				Not Reported
	Cyclobenzaprine Hydrochloride			C				Not Reported
	Promethazine			C				Not Reported
	Doxepin			C				Not Reported
	Propranolol Hydrochloride			C				Not Reported
	Gemfibrozil			C				Not Reported
	Over The Counter Medications			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2005	5739757	EXPEDITED (15-DAY)	Y	HO	S05-FRA-00352-01		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Infection; Diabetes Mellitus; Herpes Simplex; Stevens-Johnson Syndrome	Escitalopram Oxalate			S	Oral	1 Tablet Qd Po		Not Reported
	Tetrazepam			S	Oral	1 Qd Po		Not Reported
	Celebrex			S		1 Qd Rc		Not Reported
	Zolpidem			S	Oral	1 Q Po		Not Reported
	Acetaminophen			S	Oral	2 G Qd Po		Not Reported
	Mopral (Omeprazole)			S	Oral	1 Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2005	5757139	EXPEDITED (15-DAY)	Y	OT	S05-USA-00822-01		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Drug Interaction; Temporal Arteritis; Therapeutic Product Effect Decreased	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Prednisone			S		40 Mg Daily		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S		10 Mg Daily		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2005	4127825	EXPEDITED (15-DAY)	Y	OT	2004021501		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Condition Aggravated; Depression; Drug Interaction; Fall; Feeling	Neurontin			S		300 Mg (Daily)		Not Reported
	Escitalopram Oxalate			S		20 Mg (Daily)		Not Reported
	Allegra-D			C				Not Reported

Drunk; Gait Disturbance; Gait Disturbance; Hallucination, Visual; Migraine; Nightmare	Propacet	C		Not Reported
	Pantoprazole (Pantoprazole)	C		Not Reported
	Docusate (Docusate)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2005	5723001	EXPEDITED (15-DAY)	Y	OT	S05-USA-00079-01		8 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Risperdal			C				Not Reported
	Buspar			C				Not Reported
	Benadryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2005	5757115	EXPEDITED (15-DAY)	Y	HO	S05-USA-00936-01		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Generalised Tonic-Clonic Seizure; Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Benicar Hct			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2005	5722989	EXPEDITED (15-DAY)	Y	HO, OT	S05-USA-00078-01		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2005	5750312	EXPEDITED (15-DAY)	N	HO	A001-002-006386		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coronary Artery Disease; Gait Disturbance; Hyperhidrosis; Intentional Self-Injury; Medication Error; Suicidal Ideation; Suicide Attempt; Weight Decreased	Aricept		S	Oral	5 Mg, 1 In 1 D, Oral	Not Reported
	Aricept		S	Oral	150 Mg, 30 In 1 D, Oral	Not Reported
	Aricept		S	Oral	5 Mg, 1 In 1 D, Oral	Not Reported
	Lexapro		S	Oral	10 Mg, 1 In 1 D, Oral	Not Reported
	Lithium (Lithium)		C			Not Reported
	Valium		C			Not Reported
	Soma		C			Not Reported
	Percocet		C			Not Reported
	Prevacid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2005	5755936	DIRECT	Y	OT			16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Metrorrhagia	Lexapro			S		5 Mg To 10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2005	5756292	DIRECT	Y	DS, HO, LT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage Intracranial	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2005	5756323	DIRECT	N	DS, HO, LT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anxiety; Burning Sensation; Drug Intolerance; Emotional Distress; Fear; Feelings Of Worthlessness; Intentional Overdose; Suicidal Ideation; Thinking	Lexapro			S	Oral	5mg10mg20mg Daily Oral		Not Reported

Abnormal; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2005	5756943	DIRECT	Y	OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Product Quality Issue	Lexapro			S		1 Tab Qd		Forest
	Synthroid			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2005	5758343	EXPEDITED (15-DAY)	Y	HO	T05-GER-00858-01		47 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Jaundice	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Pegasys (Peginterferon Alfa-2a)			S	Subcutaneous	135 Mg Qw Sc		Not Reported
	Copegus			S	Oral	1200 Mg Qd Po		Not Reported
	Metoprolol Tartrate			S	Oral	35 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2005	4140997	EXPEDITED (15-DAY)	Y	HO	L04-TUR-01939-01		32 YR	Female	DZA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Electrocardiogram Qt Prolonged; Hyperthermia; Hyporeflexia; Hypotension; Intentional Overdose; Leukocytosis; Nausea; Sinus Tachycardia; Somnolence; Suicide Attempt; Vertigo	Cipralex			S	Oral	190 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2005	5730738	EXPEDITED (15-DAY)	N	RI	S05-USA-00224-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Drug Ineffective; Intervertebral Disc Protrusion; Myalgia; Pain; Pain In Extremity	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Mirapex			C				Not Reported
	Vivelle			C				Not Reported
	Estrogel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2005	5758273	EXPEDITED (15-DAY)	Y	HO	S05-USA-00988-01		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenal Ulcer; Stress	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2005	5758426	DIRECT	N	OT			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Diarrhoea; Muscle Spasms	Lexapro			S		1 Pill Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2005	5732508	EXPEDITED (15-DAY)	Y	DE	S05-SWE-00274-01		36 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis Coronary Artery; Bronchitis Chronic; Cardiomegaly; Cardiopulmonary Failure;	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Zuclopenthixol Decanoate			S	Oral	5 Mg Qd Po		Not Reported

Dilatation Atrial; Dilatation Ventricular; Lung Hyperinflation; Mucosal Disorder	Clozapine		S	Oral	100 Mg Q4hr Po	Not Reported
	Atarax		C			Not Reported
	Akineton		C			Not Reported
	Stesolid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2005	5759122	EXPEDITED (15-DAY)	Y	OT	S05-USA-01033-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2005	5759944	EXPEDITED (15-DAY)	Y	HO	TO5-USA-00286-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Chest Pain; Constipation; Diarrhoea; Dyspnoea; Electrocardiogram Qt Prolonged; Electrocardiogram St-T Segment Abnormal; Granulocytopenia; Hyperhidrosis; Hypokalaemia; Myocardial Ischaemia; Pericarditis; Sinus Bradycardia; Supraventricular Extrasystoles; Tachypnoea; Torsade De Pointes; Ventricular Tachycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Phenergan			C				Not Reported
	Multivitamins			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Peginterferon Alfa-2a			C				Not Reported
	Ribavirin			C				Not Reported
	Ibuprofen			C				Not Reported
	Pepto-Bismol (Bismuth Subsalicylate)			C				Not Reported
	Advil			C				Not Reported
	Lortab			C				Not Reported
	Otc Antacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2005	5759949	EXPEDITED (15-DAY)	N	OT	S05-USA-01015-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Focal Dyscognitive Seizures; Night Sweats; Simple Partial Seizures	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Lamictal			C				Not Reported
	Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2005	5730740	EXPEDITED (15-DAY)	N	OT	S05-USA-00268-01		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Asthenia; Chills; Circadian Rhythm Sleep Disorder; Depression; Drug Interaction; Feeling Hot; Heart Rate Increased; Hyperhidrosis; Mania; Panic Attack; Paranoia; Pyrexia; Seizure; Suicidal Ideation; Vomiting	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	19 Mg Qd Po		Not Reported
	Lexapro			S	Oral	17 Mg Qd Po		Not Reported
	Biaxin			S		500 Mg Bid		Not Reported
	Cedax			C				Not Reported
	Nystatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2005	4137304	EXPEDITED (15-DAY)	Y	HO	S04-USA-02241-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Paranoia; Scratch; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2005	5763429	DIRECT		RI			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abnormal Dreams; Animal Scratch; Back Pain; Balance Disorder; Choking; Contusion; Diarrhoea; Dyskinesia; Ecchymosis; Fall; Flatulence; Gastrooesophageal Reflux Disease; Haemorrhage; Hallucination; Headache; Hyperhidrosis; Impaired Healing; Joint Swelling; Oesophagitis; Pain In Extremity; Palpitations; Paraesthesia; Pruritus; Purulent Discharge; Raynaud'S Phenomenon; Restless Legs Syndrome; Serotonin Syndrome; Skin Ulcer; Visual Impairment	Lexapro			S		10 Mg Daily - A.M.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2005	5763665	EXPEDITED (15-DAY)	Y	OT	S05-USA-01145-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea; Electrocardiogram T Wave Abnormal; Mitral Valve Prolapse	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2005	5763904	EXPEDITED (15-DAY)	Y	OT	S05-USA-01142-01		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Multiple Sclerosis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Copaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2005	5763905	EXPEDITED (15-DAY)	N	OT	S05-USA-01148-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Gout; Seizure; Somnolence; Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2005	5764509	DIRECT	Y	HO			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Encephalitis; Neuroleptic Malignant Syndrome; Seizure	Venlafaxine			S	Oral	75 Mg Daily Oral		Not Reported
	Lexapro			S	Oral	20 Mg At Bedtime Oral		Not Reported
	Risperdal			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2005	5797273	NON-EXPEDITED	N		2005-BP-00463BP		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea	Spiriva			S	Respiratory (inhalation)	18 Mcg (18 Mcg), Ih		Not Reported
	Lexapro			S				Not Reported
	Albuterol & Atrovent			C				Not Reported
	Enalapril			C				Not Reported
	Lasix			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2005	4206276	EXPEDITED (15-DAY)	Y	OT	S04-USA-05599-01		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Foaming At Mouth; Intentional Overdose; Lethargy; Loss Of Consciousness; Mood Altered; Refusal Of Treatment By Patient; Seizure; Suicide Attempt; Tremor	Lexapro			S	Oral	40 Mg Once Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Gabitril			S	Oral	24 Mg Once Po		Not Reported
	Prozac			S				Not Reported
	Prozac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2005	5743470	EXPEDITED (15-DAY)	Y	OT	S05-USA-00453-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colour Blindness Acquired	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported
	Minocycline\Minocycline Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2005	5746038	EXPEDITED (15-DAY)	N	RI, OT	S05-USA-00618-01		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Biliary Dilatation; Depression; Duodenal Stenosis; Melaena; Occult Blood Positive; Pancreatic Neoplasm	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			S	Oral	81 Mg Qd Po		Not Reported
	Zetia			C				Not Reported
	Xalatan			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Omega3 (Fish Oil)			C				Not Reported
	Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2005	5750576	EXPEDITED (15-DAY)	N	OT	S05-USA-00702-01		11 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Breast Feeding; Selective Eating Disorder; Somnolence Neonatal	Lexapro			S		10 Mg Qd Bf		Not Reported
	Lexapro			S		15 Mg Qd Bf		Not Reported
	Hydrocodone			C				Not Reported
	Ibuprofen			C				Not Reported
	Stoll Softener (Docusate Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2005	5757132	EXPEDITED (15-DAY)		OT	DE-ABBOTT-05I-062-0292831-00		38 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Post Procedural Haemorrhage	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2005	5760161	EXPEDITED (15-DAY)	Y	DS, OT	2005034830		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Cerebrovascular Accident; Insomnia; Nightmare	Celebrex			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2005	5763695	DIRECT	Y	OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Lexapro			S	Oral	10 Mg 1/2 Po Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2005	5767542	EXPEDITED (15-DAY)	Y	OT	S05-USA-01276-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Tardive Dyskinesia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5701892	NON-EXPEDITED	Y	HO	S04-USA-07142-01		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Intentional Product Misuse; Suicide Attempt	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Tablet Once Po		Not Reported
	Unspecified Ingredient			S	Oral	30 Tablet Once Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5734144	EXPEDITED (15-DAY)	N		S05-USA-00320-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome; Hyperhidrosis; Loss Of Consciousness; Seizure; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5741542	EXPEDITED (15-DAY)	Y	DE	S05-UKI-00427-01		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Cipralex			S				Not Reported
	Quinine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5745070	EXPEDITED (15-DAY)	Y	LT	S05-DEN-00492-01		41 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Discomfort; Dizziness; Drug Withdrawal Syndrome; Paraesthesia; Road Traffic Accident; Sleep Talking; Somnambulism	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			C	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5757141	EXPEDITED (15-DAY)	Y	HO, LT	S05-USA-00823-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Pruritus; Purpura; Thrombocytopenia	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5759428	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0537918A		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Headache; Muscle Spasms; Toxicity To Various Agents	Compazine			S				Glaxosmithkline
	Lexapro			S	Oral			Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5766414	EXPEDITED (15-DAY)	Y	HO	S05-USA-01285-01		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Obstruction; White Blood Cell Count Increased	Lexapro			S	Oral	10 Mg Qam Po		Not Reported
	Clozapine			S	Oral	575 Mg Qd Po		Not Reported

Benztropine Mesylate	S	1 Mg Qam	Not Reported
Benztropine Mesylate	S	2 Mg Qhs	Not Reported
Clonazepam	S	1 Mg Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5766792	EXPEDITED (15-DAY)	Y	OT	S05-UKI-00928-01		47 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Clonus; Extensor Plantar Response; Fatigue; Reflexes Abnormal	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5766802	EXPEDITED (15-DAY)	Y	OT	S05-UKI-00929-01		49 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dysuria; Ejaculation Failure; Urine Flow Decreased	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5766815	EXPEDITED (15-DAY)	Y	DS	S05-DEN-01000-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia; Osmotic Demyelination Syndrome	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5767038	NON-EXPEDITED	N	OT	S04-USA-07588-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Confusional State; Disorientation; Dizziness; Fatigue	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Femhrt	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5767040	NON-EXPEDITED	Y	OT	S04-USA-07589-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5767043	NON-EXPEDITED	Y	HO	S04-USA-07563-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Intentional Product Misuse; Migraine; Overdose; Psychiatric Symptom; Suicide Attempt	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ibuprofen			S				Not Reported
	Concerta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5767046	NON-EXPEDITED	N	OT	S04-USA-07553-01		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Upper Respiratory Tract Infection	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ativan			C				Not Reported
	Atenolol			C				Not Reported
	Levoxyl			C				Not Reported
	Zocor			C				Not Reported
	Triamterene			C				Not Reported
	Centrum			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795200	NON-EXPEDITED	Y	HO	S05-USA-00318-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Flatulence; Nausea; Pancreatitis Acute	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lorazepam			C				Not Reported
	Allegra			C				Not Reported
	Hydrocodone			C				Not Reported
	Vitamin B12			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795202	NON-EXPEDITED	Y	HO	S05-USA-00196-01		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive; Overdose	Lexapro			S				Not Reported
	Methadone Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795212	NON-EXPEDITED	Y	OT	S05-USA-00042-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Gm Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795217	NON-EXPEDITED	Y	HO	S04-USA-07866-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Oedema; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported
	Zoloft			C				Not Reported
	Paxil			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795218	NON-EXPEDITED	Y	OT	S04-USA-07387-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Neurontin			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795219	NON-EXPEDITED	N	OT	S04-USA-07372-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Disturbance In Attention; Headache; Hyperhidrosis; Nausea; Panic Attack; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lortab			C				Not Reported
	Toprol Xl			C				Not Reported
	Interferon Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795222	NON-EXPEDITED	Y	HO, LT, RI	S04-USA-06047-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Injury; Muscle Spasms; Night Sweats; Suicidal Ideation; Suicide Attempt; Upper Limb Fracture	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Marijuana			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795241	NON-EXPEDITED	Y	OT	S04-USA-06055-01		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Nephrolithiasis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Avandia			C				Not Reported
	Lasix			C				Not Reported
	Synthrod (Levothyroxine Sodium)			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Percocet			C				Not Reported
	Vioxx			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795244	NON-EXPEDITED	Y	HO	S05-USA-00524-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Tachycardia	Lexapro			S				Not Reported
	Lexapro			S	Oral	750 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795245	NON-EXPEDITED	N	OT	S05-USA-00475-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zocor			C				Not Reported
	Zetia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795246	NON-EXPEDITED	N	HO	S05-USA-00365-01		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Nightmare; Panic Attack; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lipitor			C				Not Reported

	Ditropan	C	Not Reported
	Estradiol	C	Not Reported
	Vitamins	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795247	NON-EXPEDITED	N	OT	S05-USA-00333-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Levoyxl (Levothyroxine Sodium)			C				Not Reported
	Estrace			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795250	NON-EXPEDITED	Y	OT	S04-USA-07841-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lipitor			S				Not Reported
	Ultram			C				Not Reported
	Klonopin			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795252	NON-EXPEDITED	Y	HO	S04-USA-07774-01		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Coumadin			C				Not Reported
	Lanoxin			C				Not Reported
	Miacalcin			C				Not Reported
	Macrodantin			C				Not Reported
	Colace			C				Not Reported

	Lactulose	C		Not Reported
	Pepcid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795254	NON-EXPEDITED	Y	OT	S04-USA-07763-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	An Unknown Anti-Hypertensive (Nos)			C				Not Reported
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795255	NON-EXPEDITED	Y	HO	S04-USA-07729-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795256	NON-EXPEDITED	Y	HO	S04-USA-07729-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795257	NON-EXPEDITED	Y	HO	S04-USA-07729-03			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795260	NON-EXPEDITED	Y	HO	S04-USA-07729-04			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2005	5795264	NON-EXPEDITED	N	OT	S04-USA-07704-01		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Fatigue; Headache; Heart Rate Increased; Insomnia; Nausea; Pain; Panic Reaction; Restlessness; Tremor	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lanoxin			C				Not Reported
	Xanax			C				Not Reported
	Valium			C				Not Reported
	Zoloft			C				Not Reported
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2005	5767481	EXPEDITED (15-DAY)	Y	OT	S05-BRA-00998-01		29 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Foetal Death; Maternal Exposure During Pregnancy; Pregnancy	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2005	6035462	EXPEDITED (15-DAY)	Y	HO	S05-GER-01073-01			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrolyte Imbalance	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2005	5694480	EXPEDITED (15-DAY)	Y	DE	L04-USA-07403-66		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Ph Decreased; Cardiac Arrest; Coma; Completed Suicide; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haemodialysis; Hypotension; Hypoxia; Nodal Rhythm; Overdose; Pco2 Decreased; Pneumonia Aspiration; Po2 Decreased; Renal Failure; Supraventricular Tachycardia; Therapy Non-Responder	Diltiazem			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Lorazepam			S				Not Reported
	Benztropine Mesylate			S				Not Reported
	Ziprasidone			C				Not Reported
	Fexofenadine Hcl			C				Not Reported
	Oxcarbazepine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2005	5694783	EXPEDITED (15-DAY)	Y	DE, HO	L04-USA-07403-24		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Cardiac Arrest; Completed Suicide; Ejection Fraction	Lexapro			S	Oral	340 Mg Once Po		Not Reported
	Bupropion Hydrochloride			S	Oral	2550 Mg Once Po		Not Reported
	Paroxetine Hydrochloride			S	Oral	340 Mg Once Po		Not Reported

Decreased; Intentional Overdose; Mental Status Changes; Nausea; Nervous System Disorder; Seizure; Ventricular Dysfunction	Clonazepam		S	Oral	8.5 Mg Once Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2005	5694785	EXPEDITED (15-DAY)	Y	DE	L04-USA-07403-19		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Apnoea; Atrial Fibrillation; Brain Death; Coma; Completed Suicide; Dialysis; Hypotension; Intentional Overdose; Pneumonia Aspiration; Vomiting	Lexapro			S				Not Reported
	Valproic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2005	5694788	EXPEDITED (15-DAY)	Y	DE	L04-USA-07403-32		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Aspiration; Blood Bicarbonate Decreased; Blood Chloride Increased; Blood Creatine Phosphokinase Increased; Blood Glucose Increased; Blood Ph Decreased; Coma; Completed Suicide; Drug Screen Positive; Dyskinesia; General Physical Health Deterioration; Hyperhidrosis; Intentional	Lexapro			S				Not Reported
	Fluoxetine Hcl			S				Not Reported
	Liothyronine Sodium			S				Not Reported
	Lamotrigine			S				Not Reported

Overdose; Muscle Twitching; Pco2 Increased; Petit Mal Epilepsy; Po2 Increased; Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2005	5694791	EXPEDITED (15-DAY)	Y	DE, HO	L04-USA-07403-31		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Areflexia; Blood Ph Decreased; Blood Pressure Systolic Increased; Cardiac Arrest; Coma; Completed Suicide; Heart Rate Increased; Intentional Overdose; Pco2 Decreased; Pupil Fixed; Torsade De Pointes; Unresponsive To Stimuli; Ventricular Extrasystoles; Ventricular Tachycardia	Lexapro			S				Not Reported
	Doxepin			S				Not Reported
	Mirtazapine			S				Not Reported
	Ziprasidone Hydrochloride			S				Not Reported
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2005	5696170	EXPEDITED (15-DAY)	Y	DE	L04-USA-07403-58		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree; Blood Pressure Systolic Decreased; Body Temperature Decreased; Cardio-Respiratory Arrest; Completed Suicide; Heart Rate Increased; Intentional Overdose; Lethargy; Somnolence;	Tiazac			S				Not Reported
	Lexapro			S				Not Reported
	Ibuprofen And Pseudoephedrine Hydrochloride			S				Not Reported
	Calcium Gluconate			S				Not Reported
	Vitamin C			S				Not Reported
	Iron\Vitamins Nos			S				Not Reported
	Benzodiazepine			C				Not Reported

Therapy Non-Responder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2005	5768794	DIRECT	Y	HO			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Lethargy; Mental Status Changes; Metastasis; Urinary Retention	Lexapro			S	Oral	Po [4 Days Prior To Admission]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2005	5663029	EXPEDITED (15-DAY)	N	HO	S04-USA-07114-01		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Memory Impairment	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2005	5726381	EXPEDITED (15-DAY)	Y	HO	S05-NOR-00143-01		84 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Pinex			C				Not Reported
	Paralgin Forte			C				Not Reported
	Atenolol			C				Not Reported
	Rivotril (Clorazepam)			C				Not Reported
	Albyl-E			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2005	5735601	EXPEDITED (15-DAY)	Y	HO	S05-USA-00319-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Potassium Decreased; Coma; Fatigue; Lethargy; Loss Of Consciousness; Mouth Injury; Seizure; Skin Laceration; Urine Barbiturates; Vomiting	Lexapro		S	Oral	5 Mg Qd Po	Not Reported
	Ortho Tri Cyclen		C			Not Reported
	Albuterol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2005	5752636	EXPEDITED (15-DAY)	Y	DS	S05-USA-00714-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Driving Ability; Panic Attack; Tremor	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Klonopin			C				Not Reported
	Valium			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2005	5768276	EXPEDITED (15-DAY)	Y	LT, RI	S05-USA-01287-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hyperhidrosis; Hypotension; Loss Of Consciousness; Pallor; Tachycardia; Vision Blurred	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2005	5768854	EXPEDITED (15-DAY)	Y	HO, OT	S05-GER-01005-01		55 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Fear; Insomnia; Logorrhoea; Paranoia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Insidon (Opipramol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2005	5768857	EXPEDITED (15-DAY)	Y	HO	S05-UKI-01006-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Supraventricular Tachycardia; Ventricular Tachycardia	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2005	5763575	EXPEDITED (15-DAY)	Y	HO	BE-MERCK-0503USA02984		74 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Apathy; Blood Creatinine Increased; Confusional State; Creatinine Renal Clearance Decreased; Dehydration; Diarrhoea; Drug Interaction; Dysarthria; Lethargy; Motor Dysfunction; Oliguria; Performance Status Decreased; Somnolence; Toxicity To Various Agents; Tremor	Prinivil			S	Oral			Merck
	Lithium Carbonate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Levomepromazine			S	Unknown			Not Reported
	Irbesartan			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Spironolactone			S	Unknown			Not Reported
	Dexetimide Hydrochloride			S	Unknown			Not Reported
	Lormetazepam			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported

	Repaglinide			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2005	5770179	EXPEDITED (15-DAY)	Y	OT	S05-USA-01390-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Enamel Anomaly; Gingival Disorder	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Vitamins Nos			C				Not Reported
	Remeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2005	5699105	EXPEDITED (15-DAY)	Y	OT	S04-USA-07700-01		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Azithromycin			S				Not Reported
	Flonase			C				Not Reported
	Allegra			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2005	5761440	EXPEDITED (15-DAY)	Y	OT	S05-GER-00905-01		38 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Haemoglobin Decreased; Post Procedural Complication; Post Procedural Haemorrhage	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Embolex			C				Not Reported
	Somatostatin			C				Not Reported
	Pantoprazol (Pantoprazole)			C				Not Reported
	Remergil (Mirtazapine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2005	5769382	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism	Lexapro			S	Oral	5mg Qd Oral		Not Reported
	Vitamin B12			C				Not Reported
	Oscal			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Synthroid			C				Not Reported
	Senokot			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2005	5770138	EXPEDITED (15-DAY)	Y	OT	S05-USA-01437-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Female Orgasmic Disorder; Headache; Hypertension	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2005	5770537	DIRECT	Y	RI			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Depression; Feeling Abnormal; Hot Flush; Insomnia; Suicidal Ideation	Lexapro			S	Oral	One Tab Each Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2005	5765235	EXPEDITED (15-DAY)	Y	HO	US-MERCK-0503USA03019		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Constipation; Intestinal Obstruction	Cogentin		S	Oral	Merck
	Cogentin		S	Oral	Merck
	Clozapine		S	Oral	Not Reported
	Clonazepam		S	Oral	Not Reported
	Lexapro		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2005	5744369	EXPEDITED (15-DAY)	Y	DE	S05-USA-00560-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level Increased; Blood Alcohol Increased; Carboxyhaemoglobin Increased; Completed Suicide; Intentional Self-Injury; Overdose; Thermal Burn	Lexapro			S				Not Reported
	Unspecified Ingredient			C				Not Reported
	Diphenhydramine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2005	5771865	EXPEDITED (15-DAY)	Y	DE, DS, LT, OT	S05-UKI-01168-01		37 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2005	5772053	EXPEDITED (15-DAY)			2005-126603-NL		57 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Hypertension; Serotonin Syndrome; Tachycardia	Mirtazapine			S	Oral	45 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd	10 DAY	Not Reported
	Amisulpride			C				Not Reported
	Zolpidem Tartrate			C				Not Reported

Lorazepam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2005	4138850	EXPEDITED (15-DAY)	Y	OT	S04-PRT-01934-01		70 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Dizziness; Drug Interaction; Hypocoagulable State; Tremor	Cipralex			S	Oral	5 Mg Bid Po		Not Reported
	Warfarin Sodium			S	Oral	5 Mg Qd Po		Not Reported
	Warfarin Sodium			S	Oral	2.5 Mg Qd Po		Not Reported
	Pravocol (Pravastatin)			C				Not Reported
	Lasix			C				Not Reported
	Lopresor			C				Not Reported
	Vastarel			C				Not Reported
	Sermion (Nicergoline)			C				Not Reported
	Cordarone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2005	5718329	EXPEDITED (15-DAY)	Y	LT	S04-DEN-08294-01		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Headache; Loss Of Consciousness	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2005	5728424	EXPEDITED (15-DAY)	Y	HO	S05-USA-00293-01		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Cardiolipin Antibody Positive; Gangrene; Vascular Occlusion; Vasculitis	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Inh			C				Not Reported
	Rifampin			C				Not Reported
	Rifabutin			C				Not Reported
	Pyrazinamide			C				Not Reported

	Ethambutol	C	Not Reported
	Vitamin B6	C	Not Reported
	Bactrim Ds	C	Not Reported
	Nystatin	C	Not Reported
	Ibuprofen	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2005	5754494	EXPEDITED (15-DAY)	N	OT	S05-USA-00789-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Stress	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Hydrochlorothiazide			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2005	5773795	EXPEDITED (15-DAY)	N	OT	SUSI-2005-00203		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Diplopia; Drug Interaction; Hyperhidrosis; Vision Blurred	Carbatrol			S				Not Reported
	Lexapro			S		10 Mg, 1x/Day, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2005	5749285	EXPEDITED (15-DAY)	Y	HO	S05-USA-00682-01		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carotid Artery Aneurysm; Cerebral Haemorrhage; Circulatory Collapse; Confusional State; Dizziness; Fatigue; Loss Of Consciousness; Petit Mal Epilepsy; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Bid Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Fentanyl			S				Not Reported
	Effexor			C				Not Reported
	Depakote			C				Not Reported
	Ativan			C				Not Reported

Procrit	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2005	5773982	EXPEDITED (15-DAY)	Y	OT	S05-USA-00450-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dissociation; Fall; Focal Dyscognitive Seizures; Hallucinations, Mixed; Incoherent; Mydriasis; Seizure; Somnolence; Staring	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2005	5749283	EXPEDITED (15-DAY)	Y	LT, OT	S05-USA-00683-01		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burns Second Degree; Burns Third Degree; Completed Suicide; Depression; Paranoia; Psychotic Disorder; Suicidal Ideation; Suicide Attempt; Suspiciousness	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2005	5769055	EXPEDITED (15-DAY)	Y	HO	US-ROCHE-399151		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Intestinal Obstruction	Klonopin			S	Oral	1mg At Bedtime As Needed.		Roche
	Clozapine			S	Oral			Not Reported
	Benzatropine			S	Unknown	1 Mg Taken In The Morning And 2 Mg Taken		Not Reported

	Lexapro			S	Oral	An Bedtime. Taken In The Morning.				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2005	5773396	DIRECT	Y	HO, LT, RI			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chills; Cough; Dizziness; Headache; Hepatic Enzyme Increased; Nausea; Pyrexia; Vomiting	Lexapro			S	Oral	10 Mg Bid Oral		Not Reported
	Iron			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2005	5773508	DIRECT	Y	OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash Macular	Lexapro			S		10mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2005	5769837	EXPEDITED (15-DAY)	Y	HO	BE-BRISTOL-MYERS SQUIBB COMPANY-12907242		74 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Confusional State; Dehydration; Diarrhoea; Drug Interaction; Dysarthria; Lethargy; Oliguria; Toxicity To Various Agents; Tremor	Lithium Carbonate			S				Not Reported
	Levomepromazine			S				Not Reported
	Furosemide			S				Not Reported
	Spironolactone			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Lormetazepam			C				Not Reported
	Metformin Hydrochloride			C				Bristol Myers Squibb
	Repaglinide			C				Not Reported
	Irbesartan			S				Bristol Myers Squibb
	Prinivil			S	Oral			Not Reported
	Risperidone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2005	5758156	EXPEDITED (15-DAY)	Y	HO	S05-USA-01016-01		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2005	5763103	EXPEDITED (15-DAY)	Y	HO	S04-USA-07520-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Complication Of Delivery; Maternal Exposure During Pregnancy; Postpartum Haemorrhage; Pregnancy	Lexapro			S	Oral	25 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2005	5763104	EXPEDITED (15-DAY)	Y	OT	S05-USA-01134-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported
	Demerol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2005	5776131	EXPEDITED (15-DAY)	Y	OT	S04-USA-07942-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Condition Aggravated; Dissociative Disorder; Schizoaffective Disorder; Stress; Syncope	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Risperdal			C				Not Reported
	Trileptal			C				Not Reported
	Depakote Er (Divalproex)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2005	5808745	NON-EXPEDITED	Y	OT	2004023507			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Body Temperature Increased; Bruxism; Drug Interaction; Dyskinesia; Seizure	Geodon			S	Oral	60 Mg (Daily), Oral		Not Reported
	Escitalopram Oxalate			S		Unk (Daily), Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2005	5808965	NON-EXPEDITED	Y	OT	2004076507			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder	Geodon			S	Oral	160 Mg (80 Mg,2 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2005	3880031	EXPEDITED (15-DAY)	N	HO	2001070033US		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Asthenia; Blood Glucose Fluctuation; Constipation; Decreased Appetite; Depression; Discomfort; Drug Dependence; Drug Tolerance Increased; Drug Withdrawal Syndrome; Dysphagia; Dyspnoea; Family Stress; Feeling Abnormal; Feeling Jittery; Gait Disturbance; Hepatocellular Injury;	Xanax			S	Oral	2 Mg (3 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Unspecified Ingredient			C				Not Reported
	Nefazodone Hydrochloride			C				Not Reported
	Fluoxetine Hydrochloride (Fluoxetine Hydrochloride)			C				Not Reported
	Hydrochlorothiazide (Hydrochlorothiazide)			C				Not Reported
	Estradiol			C				Not Reported
	Paroxetine Hydrochloride			C				Not Reported

Hyperventilation; Hypophagia; Impaired Driving Ability; Loss Of Personal Independence In Daily Activities; Muscle Spasms; Myalgia; Panic Attack; Product Quality Issue; Tension Headache; Therapeutic Product Effect Decreased; Treatment Noncompliance; Vision Blurred; Visual Acuity Reduced; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2005	5703309	EXPEDITED (15-DAY)	Y	HO	L04-TUR-08102-01		53 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Irritability; Major Depression; Persecutory Delusion; Suicide Attempt	Cipralex			S	Oral	10 Mg Bid Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2005	5770832	EXPEDITED (15-DAY)	Y	OT	L05-ITA-01092-01		60 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis; Rectal Haemorrhage	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Venlafaxine			S	Oral	150 Mg Qd Po		Not Reported
	Venlafaxine			S	Oral	100 Mg Qd Po		Not Reported
	Venlafaxine			S	Oral	37.5 Mg Qd Po		Not Reported
	Mirtazapine			S	Oral	15 Mg Qd Po		Not Reported

	Mirtazapine	S	Oral	7.5 Mg Qd Po		Not Reported
	Omeprazole	C				Not Reported
	Irbesartan	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2005	5659089	EXPEDITED (15-DAY)		DE	US-ABBOTT-04P-163-0279298-00		56 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Apnoea; Atrial Fibrillation; Brain Death; Cardio-Respiratory Arrest; Coma; Completed Suicide; Hypotension; Overdose; Overdose; Pneumonia Aspiration; Unresponsive To Stimuli; Vomiting	Valproic Acid			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2005	5778534	EXPEDITED (15-DAY)	Y	OT	S05-USA-01686-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Bilirubin Increased; Hepatic Enzyme Increased; Jaundice; Nausea	Lexapro			S				Not Reported
	Actos			S	Oral	30 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2005	5778833	DIRECT	N	RI			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Condition Aggravated; Disorientation; Insomnia	Lexapro			S	Oral	10 Mg A Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2005	5749525	EXPEDITED (15-DAY)	N	OT	2005026789		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Adverse Event; Anxiety; Back Pain; Balance Disorder; Choking; Coordination Abnormal; Drug Ineffective; Dysphonia; Dystonia; Feeling Abnormal; Gait Disturbance; Headache; Memory Impairment; Neck Pain; Nuclear Magnetic Resonance Imaging Brain Abnormal; Opisthotonus; Oropharyngeal Pain; Road Traffic Accident; Somnolence; Speech Disorder; Thinking Abnormal; Tremor; Vision Blurred	Gabapentin (Gabapentin)			S	Oral	2400 Mg (3 In 1 D), Oral		Not Reported
	Nefazodone Hydrochloride			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Clonazepam			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2005	5727164	EXPEDITED (15-DAY)	Y	HO	S05-USA-00167-01		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Eating Disorder; Myopathy; Oesophageal Disorder; Paralysis; Speech Disorder; Weight Decreased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2005	5781950	EXPEDITED (15-DAY)	Y	RI, OT	S05-USA-01758-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy; Pregnancy; Skeletal Dysplasia; Ultrasound Antenatal Screen Abnormal	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2005	5780350	EXPEDITED (15-DAY)	Y	OT	S05-USA-01760-01		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Corneal Scar; Eye Pain; Facial Pain; Stevens-Johnson Syndrome	Lexapro			S	Oral	20 Mg Qd; Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd; Po		Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2005	5780647	EXPEDITED (15-DAY)	Y	OT	GBWYE554604APR05		32 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Acuity Reduced	Minocin			S	Oral	100mg (Frequency Unknown)	29 DAY	Not Reported
	Cipralex			S	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2005	5782342	DIRECT		OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Withdrawal Syndrome; Therapeutic Response Decreased	Effexor			S		75-150 Every Day		Not Reported
	Lexapro			S		10 Mg Everyday		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2005	5781658	EXPEDITED (15-DAY)	N	OT	S05-USA-00006-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Diarrhoea; Dysgeusia; Feeling Abnormal; Feeling Hot; Nasal Congestion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Zyrtec			C				Not Reported
	Bactrim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2005	5783612	EXPEDITED (15-DAY)	Y	HO	KII-2005-0016028		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Abnormal; Confusional State; Hypercapnia; Hyponatraemia; Mental Status Changes; Miosis; Opiates Positive; Therapy Non-Responder	Morphine Sulfate			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported
	Prednisone			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2005	5703329	EXPEDITED (15-DAY)	Y	DS, HO, LT	S04-GER-08030-01		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Affect Lability; Device Related Sepsis; Dialysis; Enterococcal Infection; Escherichia Urinary Tract Infection; Glomerulonephritis Proliferative; Henoch-Schonlein Purpura; Mental Disorder Due To A	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Carnigen (Oxilofrine Hydrochloride)			C				Not Reported

General Medical
Condition; Normochromic
Normocytic Anaemia;
Thrombocytopenia;
Vasculitis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2005	5789037	DIRECT	N	HO			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination	Lexapro			S				Forest
	Synthroid			C				Not Reported
	Inderal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2005	5784479	EXPEDITED (15-DAY)	Y	OT	S05-USA-01868-01		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Use;	Lexapro			S				Not Reported
Anger; Physical Assault;	Lexapro			S				Not Reported
Screaming	Alcohol			S				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2005	5719100	EXPEDITED (15-DAY)	N	OT	S04-USA-08018-01		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Premature Ejaculation; Prostatic Specific Antigen Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2005	5781949	EXPEDITED (15-DAY)	Y	HO, OT	S05-USA-00632-01		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Eating Disorder; Hyponatraemia; Mental Status Changes	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Pamelor			C				Not Reported
	Lorazepam			C				Not Reported
	Accupril			C				Not Reported
	Protonix			C				Not Reported
	Ultracet			C				Not Reported
	Detrol La			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2005	4167391	EXPEDITED (15-DAY)	N	DE	S04-USA-03514-01		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2005	5745790	EXPEDITED (15-DAY)	Y	RI	S05-USA-00537-01		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Blood Creatine Phosphokinase Decreased; Blood Creatinine Increased; Blood Urea Increased; Bursitis; Cerebrovascular Accident; Confusional State; Contusion; Diarrhoea; Facial Bones Fracture; Fall; Fatigue; Haematoma; Hallucination, Visual; Hypertrophy; Inflammation; Intervertebral Disc	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Imuran			C				Not Reported
	Lopresor			C				Not Reported
	Prednisone			C				Not Reported
	Plavix			C				Not Reported
	Lasix			C				Not Reported
	Potassium			C				Not Reported
	Baby Aspirin			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported
	Citracal (Calcium Citrate)			C				Not Reported
	Centrum Silver			C				Not Reported

Protrusion; Intervertebral Disc Space Narrowing; Intracranial Aneurysm; Loss Of Consciousness; Muscle Atrophy; Muscle Rupture; Muscular Weakness; Nausea; Nerve Conduction Studies Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Red Blood Cell Sedimentation Rate Increased; Renal Artery Stenosis; Skin Laceration; Somnolence; Spinal Fracture; Spinal Osteoarthritis; Swelling Face; Tri-Iodothyronine Uptake Increased; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2005	5788750	EXPEDITED (15-DAY)		DE	S05-USA-01997-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Head Injury; Skin Laceration	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2005	5788454	EXPEDITED (15-DAY)	N	OT	S05-USA-01983-01		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Fatigue; Intentional Self-Injury; Skin Laceration	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2005	5791330	EXPEDITED (15-DAY)	Y	DS, LT, OT	S05-UKI-01491-01		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obsessive-Compulsive Disorder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2005	5791333	EXPEDITED (15-DAY)	Y	DS, LT, OT	S05-UKI-01493-01		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obsessive-Compulsive Disorder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2005	5791862	DIRECT	N	OT				Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Chills; Fear; Heart Rate Increased; Hyperhidrosis; Mydriasis; Night Sweats; Palpitations; Tremor	Cipralex			S	Oral	1x 20mg Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2005	5811501	NON-EXPEDITED	Y	OT	US-JNJFOC-20041008443		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Ultram			S	Oral	400 Mg, In 1 Day, Oral		Not Reported
	Lexapro			S	Oral	8 Mg, In 1 Day, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2005	5811656	NON-EXPEDITED	Y	OT	US-JNJFOC-20041207311			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Ultram			S				Not Reported
	Lexapro			S	Oral	See Image		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2005	5811462	NON-EXPEDITED	Y	OT	2004111059		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus	Azithromycin			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Fluticasone Propionate			C				Not Reported
	Fexofenadine Hydrochloride			C				Not Reported
	Lansoprazole (Lansoprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2005	5768281	EXPEDITED (15-DAY)	Y	HO	S05-USA-01342-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Concussion; Confusional State; Fall; Hyponatraemia; Perseveration; Personality Change; Seizure; Skin Laceration	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Mellaril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2005	5783688	EXPEDITED (15-DAY)	N	HO	2005055158		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Drug Interaction; Hypoaesthesia; Panic Attack	Flagyl		S			Not Reported
	Escitalopram Oxalate		S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral	Not Reported
	Ciprofloxacin		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2005	5789300	EXPEDITED (15-DAY)	N	HO	2005059988		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Depression; Drug Interaction; Drug Level Decreased; Fatigue; General Physical Health Deterioration; Malaise; Product Quality Issue; Self-Medication; Sleep Disorder; Weight Increased	Geodon			S				Not Reported
	Lithium (Lithium)			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Topiramate			S				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2005	5792229	EXPEDITED (15-DAY)	Y	HO, RI	S05-USA-02156-01		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Fall; Hypertension; Hyponatraemia; Loss Of Consciousness; Pneumothorax; Pyrexia; Rib Fracture; Seizure; Skin Abrasion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Flomax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2005	5792750	EXPEDITED (15-DAY)	Y	OT	S05-USA-02075-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Hydrochlorothiazide	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2005	5794796	EXPEDITED (15-DAY)	Y	DE	2005-127760-NL		89 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Atrial Fibrillation; Blood Pressure Fluctuation; Coma; Heart Rate Irregular; Hemiparesis; Hypertension; Salivary Hypersecretion	Mirtazapine			S	Oral Oral	15 Mg, Oral 15 Mg, Oral		Not Reported
	Risperidone			S	Oral	Mg, Oral	144 DAY	Not Reported
	Buspirone Hydrochloride			S	Oral	15 Mg, Oral	131 DAY	Not Reported
	Galantamine Hydrobromide			S	Oral Oral	Mg/24 Mg, Oral Mg/24 Mg, Oral	13 DAY 124 DAY	Not Reported
	Valproate Sodium			S	Oral	Mg, Oral	127 DAY	Not Reported
	Mineral Oil\Phenolphthalein			S		10 Mg	6 MTH	Not Reported
	Escitalopram Oxalate			S		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2005	5758275	EXPEDITED (15-DAY)	Y	OT	S05-USA-00987-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foaming At Mouth; Lethargy; Loss Of Consciousness; Road Traffic Accident; Seizure; Self-Medication	Lexapro			S				Not Reported
	Ultram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2005	5776213	EXPEDITED (15-DAY)	N	HO	S05-USA-01620-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychiatric Symptom; Self-Injurious Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2005	5794671	DIRECT	N	DE			16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S		10 Mg 2x Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2005	5796740	DIRECT	Y	HO			4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage Neonatal; Intraventricular Haemorrhage; Maternal Exposure During Pregnancy; Neonatal Seizure; Subarachnoid Haemorrhage Neonatal; Subdural Haemorrhage Neonatal	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2005	5788738	EXPEDITED (15-DAY)	Y	OT	L05-USA-01419-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Crying; Drug Interaction; Panic Attack; Therapeutic Product Effect Decreased; Treatment Noncompliance	Citalopram			S		20 Mg Qd		Not Reported
	Citalopram			S		40 Mg Qd		Not Reported
	Citalopram			S		60 Mg Qd		Not Reported
	Citalopram			S		60 Mg Qd		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Rifampin			S	Oral	600 Mg Bid Po		Not Reported
	Bupropion			C				Not Reported
	Lorazepam			C				Not Reported
	Clonazepam			C				Not Reported

	Clindamycin	C	Not Reported
	Vancomycin	C	Not Reported
	Sulfamethoxazole & Trimethoprim	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2005	4042368	EXPEDITED (15-DAY)	Y	HO, LT	S03-USA-04774-01		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Behaviour; Activated Partial Thromboplastin Time Prolonged; Acute Kidney Injury; Areflexia; Arrhythmia; Balance Disorder; Blood Sodium Decreased; Confusional State; Cyanosis; Demyelination; Depressed Level Of Consciousness; Dialysis; Drug Abuser; Drug Level Decreased; Drug Withdrawal Syndrome; Dyspnoea; Encephalitis; Encephalopathy; Fall; Haematocrit Increased; Haemoconcentration; Haemodynamic Instability; Haemoglobin Increased; Herpes Simplex; Herpes Zoster; Hypocalcaemia; Hypotension; Loss Of Consciousness; Meningitis; Meningoencephalitis Herpetic; Metabolic Acidosis; Mydriasis; Nausea; Neuroleptic	Lexapro			S				Not Reported
	Elavil			S		150 Mg Qd		Not Reported
	Elavil			S		75 Mg Qd		Not Reported
	Topamax			C				Not Reported
	Klonopin			C				Not Reported
	Ativan			C				Not Reported
	Neurontin			C				Not Reported
	Tambocor			C				Not Reported
	Percocet			C				Not Reported
	Oxycontin			C				Not Reported
	Zanaflex			C				Not Reported
	Lasix			C				Not Reported
	K-Dur			C				Not Reported
	Allopurinol			C				Not Reported
	Lidoderm (Lidocaine)			C				Not Reported
	Nitroglycerin			C				Not Reported
	Risperdal			C				Not Reported
	Lithium (Lithium)			C				Not Reported
	Ambien			C				Not Reported

Malignant Syndrome; Nuchal Rigidity; Oliguria; Palpitations; Paraplegia; Polymyositis; Pupillary Reflex Impaired; Rhabdomyolysis; Serotonin Syndrome; Shock; Sinus Tachycardia; Urine Abnormality; Vulvovaginal Mycotic Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2005	5796099	EXPEDITED (15-DAY)	Y	OT	DSA_26337_2005		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Memory Impairment	Ativan			S				Not Reported
	Lexapro			S	Oral	10 Mg Q Day Po		Not Reported
	Lexapro			S	Oral	5 Mg Q Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2005	5796565	EXPEDITED (15-DAY)	Y	OT	S05-USA-02236-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2005	5797001	EXPEDITED (15-DAY)	Y	OT	S05-SWI-01568-01		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Condition Aggravated; Dizziness; Dyspnoea; Fatigue; Muscular Weakness; Somnolence; Tongue Disorder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Tizanidine Hydrochloride			S				Not Reported
	Feldene			C				Not Reported
	Mefenamic Acid			C				Not Reported
	Xefo (Lornoxicam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2005	5797005	EXPEDITED (15-DAY)	Y	OT	S05-ESP-01633-01		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria	Cipralex			S				Not Reported
	Acenocoumarol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2005	5797660	DIRECT	Y	OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2005	5798318	DIRECT	N				66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Lexapro			S		10 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2005	5775035	EXPEDITED (15-DAY)	Y	DE	S05-NOR-01249-01		50 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2005	5796719	EXPEDITED (15-DAY)	Y	OT	S05-UKI-01647-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Self-Injurious Ideation; Suicidal Ideation	Cipralex		S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2005	5796809	EXPEDITED (15-DAY)	Y	HO	S05-GER-00504-01		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Loss Of Consciousness; Orthostatic Hypotension; Subdural Haematoma; Syncope	Cipralex			S		10 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2005	5796838	EXPEDITED (15-DAY)	Y	OT	S05-UKI-01571-01		27 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Psychomotor Hyperactivity; Sleep Disorder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2005	5798018	DIRECT	N	DS, OT			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphemia; Muscle Twitching; Weight Increased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2005	5746209	EXPEDITED (15-DAY)	Y	HO	2005024283		60 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Gastric Ulcer Haemorrhage; Gastrointestinal Haemorrhage; Haematemesis	Celebrex		S	Oral	200 Mg (200 Mg, 1 In 1 D), Oral	Not Reported
	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Chlorprothixene Hydrochloride		C			Not Reported
	Symbicort Turbuhaler		C			Not Reported
	Acetaminophen And Codeine Phosphate		C			Not Reported
	Metoprolol Succinate		C			Not Reported
	Tramadol Hydrochloride		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2005	5773965	EXPEDITED (15-DAY)	N	HO, RI	S05-USA-01466-01		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Balance Disorder; Blood Pressure Increased; Dizziness; Drug Interaction; Fall; Hypertension; Rib Fracture; Seborrhoeic Dermatitis; Urinary Incontinence; Urinary Retention	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Erythromycin			S		250 Mg Tid		Not Reported
	Namenda			C				Not Reported
	Atenolol			C				Not Reported
	Synthroid			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2005	5798879	EXPEDITED (15-DAY)	N	OT	S05-USA-02325-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Breast Mass; Increased Tendency To Bruise; Menorrhagia; Nasopharyngitis; Thrombosis	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Calcium Gluconate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2005	5793279	EXPEDITED (15-DAY)	Y	DE	CH-JNJFOC-20050501114			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Atrial Fibrillation; Blood Pressure Fluctuation; Cerebrovascular Accident; Coma; Depression; Hemiparesis; Salivary Hypersecretion; Sleep Disorder	Risperdal			S	Oropharingeal	1.5 - 2.5 Mg		Not Reported
	Buspar			S	Oropharingeal			Not Reported
	Reminyl			S	Oropharingeal			Not Reported
	Reminyl			S	Oropharingeal	8-16 Mg		Not Reported
	Convulex (Valproate Sodium)			S	Oropharingeal	100-200 Mg		Not Reported
	Remeron			S	Oropharingeal			Not Reported
	Remeron			S	Oropharingeal			Not Reported
	Cipralex			S	Oropharingeal			Not Reported
	Agar			S	Oropharingeal			Not Reported
	Agar			S	Oropharingeal			Not Reported
	Phenolphthalein			S	Oropharingeal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2005	5803724	DIRECT	N	DS, HO, LT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Drug Intolerance; Dysarthria; Dysgraphia; Economic Problem; Fear; Feeling Abnormal; Feelings Of Worthlessness; Hypersensitivity; Impaired Work Ability; Inappropriate Schedule Of Product Administration; Injury; Intentional Product Misuse; Tension; Tremor	Lexapro			S	Oral	5 Mg - 20mg/Day, Orally		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2005	5787801	EXPEDITED (15-DAY)	Y	HO	S05-USA-00972-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Drug Screen Positive; Fatigue; Feeling Abnormal; Intentional Product Misuse; Maternal Exposure During Pregnancy; Maternal Use Of Illicit Drugs; Nausea; Overdose; Palpitations; Pharyngitis Streptococcal; Sensory Disturbance; Suicide Attempt; Treatment Noncompliance; Tremor; Vaginal Infection	Lexapro			S	Oral	220 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			S				Not Reported
	Amphetamine			S				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2005	5654664	EXPEDITED (15-DAY)	Y	HO	S04-USA-06698-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematocrit Decreased; Haematuria; Haemoglobin Decreased; Platelet Count Decreased; Rectal Haemorrhage; Victim Of Abuse; White Blood Cell Count Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2005	5795195	EXPEDITED (15-DAY)	N	HO, LT	2005UW07199		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Depression; Drug Ineffective; Intentional Product Misuse; Mania; Overdose; Personality Change; Social Avoidant Behaviour; Suicide Attempt; Weight Increased	Seroquel		S	Oral	3 YR	Zeneca
	Lexapro		S	Oral		Not Reported
	Lithium		S			Not Reported
	Lamictal		S			Not Reported
	Abilify		S			Not Reported
	Trazodone Hydrochloride		S		3 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2005	5801872	EXPEDITED (15-DAY)	Y	HO	S05-UKI-01725-01		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hallucination, Auditory; Hallucination, Visual; Hyponatraemia; Paranoia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Bendrofluazide			S	Oral	2.5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2005	5802918	EXPEDITED (15-DAY)	N	HO	2005-127881-NL		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Nervousness	Remeron			S	Oral	Oral	10 YR	Not Reported
	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2005	5892222	EXPEDITED (15-DAY)	Y	OT	ACO_0144_2005		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dizziness; Dyspnoea; Muscular Weakness; Somnolence; Sudden Onset Of Sleep; Tongue Disorder	Tizanidine			S	Oral	4 Tab Qday Po		Not Reported
	Cipralex			S	Oral	10 Mg Nightly Po		Not Reported
	Felden			C				Not Reported
	Ponstan			C				Not Reported
	Xefo			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2005	5909823	EXPEDITED (15-DAY)	Y	HO	2005AP02618		59 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenal Ulcer; Gastrointestinal Haemorrhage; Melaena; Overdose	Atacand			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Minipress			S	Oral			Not Reported
	Zocor			S	Oral			Not Reported
	Daonil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2005	5803418	DIRECT					53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Suicidal Ideation	Lexapro			S		1 Dose - One Time		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2005	5703491	EXPEDITED (15-DAY)	Y	HO	S04-USA-07716-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Gait Inability; Guillain-Barre Syndrome; Headache; Myalgia; Nausea; Speech Disorder; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2005	5743491	EXPEDITED (15-DAY)	Y	HO	S05-USA-00523-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Sinusitis; Anaemia Of Chronic Disease; Asthenia; Back Pain; Bacterial Sepsis; Blood Glucose Increased; Chest Pain; Clostridium Colitis; Coma; Confusional State; Depression; Device Related Sepsis; Disease Recurrence; Drug Interaction; Electrolyte Imbalance; Fall; Fluid Overload; Hypercapnia; Hyperkalaemia; Hypotension; Hypoxia; Metabolic Acidosis; Musculoskeletal Chest Pain; Musculoskeletal Discomfort; Neuropathy Peripheral; Pneumonia Bacterial; Pulmonary Hypertension; Respiratory Failure; Staphylococcal Infection; Stenotrophomonas Infection; Syncope; Tremor; Urinary Tract Infection	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S	Oral	300 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S		150 Mg Bid		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S	Oral	300 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S	Oral	150 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported
	Potassium			C				Not Reported
	Zocor			C				Not Reported
	Aspirin			C				Not Reported
	Nexium			C				Not Reported
	Aricept			C				Not Reported
	Duragesic			C				Not Reported
	Hydrocodone			C				Not Reported
	Centrum Silver			C				Not Reported
	Magnesium			C				Not Reported
	Vitamin B12			C				Not Reported
	Diazepam			C				Not Reported
	Altace			C				Not Reported
	Demadex			C				Not Reported
	Skelaxin			C				Not Reported
	Isordil(Isosorside Dinitrate)			C				Not Reported
	Glucophage			C				Not Reported
	Acetazolamide			C				Not Reported
	Xalatan			C				Not Reported
	Oxycontin			C				Not Reported
	Miconazole			C				Not Reported
	Humulin R			C				Not Reported
	Astelin			C				Not Reported
	Meclizine			C				Not Reported
	Norvasc			C				Not Reported

	Rocephin	C	Not Reported
	Tobramycin	C	Not Reported
	Hydralazine	C	Not Reported
	Protonix	C	Not Reported
	Valium	C	Not Reported
	Lorcet Plus	C	Not Reported
	Diamox Sequels	C	Not Reported
	Avandia (Rosilglitazone Maleate)	C	Not Reported
	Nitrol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2005	5797206	EXPEDITED (15-DAY)	N	HO	US-GLAXOSMITHKLINE-A0558030A		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisocial Behaviour; Depression; Drug Ineffective; Intentional Product Misuse; Mania; Overdose; Personality Change; Suicidal Ideation; Suicide Attempt; Weight Increased	Lamictal			S	Oral			Glaxosmithkline
	Lithium			S	Unknown	600mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Abilify			S	Unknown	15mg Per Day		Not Reported
	Seroquel			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2005	5798789	EXPEDITED (15-DAY)	N	HO	S05-USA-02258-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Dry Skin; Fatigue; Feeling Abnormal; Gait Disturbance; Heart Rate Decreased; Incoherent; Nausea	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Metadate (Methylphenidate)			C				Not Reported
	Protonix			C				Not Reported
	Nasacort			C				Not Reported
	Zyrtec-D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2005	5800702	EXPEDITED (15-DAY)	Y	OT	S05-USA-02263-01		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydrocephalus; Papilloedema	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Diovan			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2005	5818377	NON-EXPEDITED	N	HO	S05-USA-00335-01		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Interaction; Fall; Hypersomnia; Loss Of Consciousness; Pelvic Fracture; Tremor	Namenda			S	Oral	50 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Namenda			S	Oral	15 Mg Qd Po		Not Reported
	Namenda			S	Oral	10 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Lexapro			S				Not Reported
	Aricept			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2005	5887774	EXPEDITED (15-DAY)	N	HO	US-KINGPHARMUSA00001-K200500576		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Autoimmune Thyroiditis; Blood Pressure Decreased; Drug Interaction; Heart Rate Increased; Irritability;	Cytomel			S	Oral	12.5 Mcg, Qd		King
	Cytomel			S	Oral	25 Mcg, Qd		King
	Cytomel			S	Oral	37.5 Mcg, 1.5		King

Lethargy; Mood Swings; Overdose; Suicidal Ideation					Tablet/25mcg Qd	
	Cytomel		S	Oral	25 Mcg, Qd	King
	Cytomel		S	Oral	12.5 Mcg, Qd	King
	Abilify		S	Oral	10 Mg, Qd	Not Reported
	Strattera		S	Oral	18 Mg, 2qd	Not Reported
	Lexapro		S	Oral	30 Mg, Qd	Not Reported
	Lexapro		S	Oral	2.5 Mg, Qd	Not Reported
	Lexapro		S	Oral	5 Mg, Qd	Not Reported
	Lexapro		S	Oral	2.5 Mg, Qd	Not Reported
	Klonopin		S	Oral	Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2005	5781932	EXPEDITED (15-DAY)	N	OT	S05-USA-01768-01		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Use; Amnesia; Drug Interaction; Loss Of Consciousness	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Herbal Nos			S	Oral	2 Tablet Once Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2005	5798047	EXPEDITED (15-DAY)	Y	DS, OT	GB-BRISTOL-MYERS SQUIBB COMPANY-12948212		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Gait Disturbance; Movement Disorder; Muscle Rigidity; Tremor	Abilify			S	Oral	15 Mg/Day 16-Mar-05; Reduced To 10 Mg/Day		Not Reported
	Amisulpride			C	Oral			Not Reported
	Unspecified Ingredient			C	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2005	5804653	EXPEDITED (15-DAY)	N	DE	S05-USA-02494-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Nervous System Disorder	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2005	5805043	EXPEDITED (15-DAY)	Y	OT	S05-UKI-01792-01		47 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Blood Creatine Phosphokinase Increased; Coordination Abnormal; Dyskinesia; Fatigue; Headache; Hyperreflexia; Injury; Muscle Rigidity; Muscle Tightness; Muscle Twitching; Myoclonus; Restlessness	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2005	5804638	DIRECT	N	OT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Use; Condition Aggravated; Psychotic Disorder	Lexapro			S	Oral	10 Mg Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2005	5804642	DIRECT	Y				40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abscess; Acute Kidney Injury; Diverticular Perforation; Granulomatous Liver Disease	Lexapro		S	Oral	10 Mg Daily Oral	Not Reported
	Altace		S	Oral	2.5 Daily Oral	Not Reported
	Prevacid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2005	6278137	EXPEDITED (15-DAY)	N	HO, RI, OT	2005-01660		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Intentional Product Misuse; Mania; Off Label Use; Overdose; Personality Change; Suicide Attempt; Weight Increased	Trazodone Hydrochloride			S	Oral	Oral		Watson
	Lexapro			S	Oral	20 Mg, Daily, Oral		Not Reported
	Lithium			S	Oral	600 Mg, Daily, Oral		Not Reported
	Lamictal			S	Oral	50 Mg, Bid, Oral		Glaxo Wellcome
	Aripiprazole			S	Oral	15 Mg, Daily, Oral		Not Reported
	Seroquel			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2005	5800669	EXPEDITED (15-DAY)	Y	OT	US-KINGPHARMUSA00001-K200500633			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granulomatous Liver Disease	Altace			S				King
	Lexapro			S				Not Reported
	Prevacid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2005	5719092	EXPEDITED (15-DAY)	Y	OT	S04-USA-08048-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Condition Aggravated; Hallucination, Auditory; Homicide; Nervousness;	Lexapro			S				Not Reported

Thinking Abnormal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2005	5771195	EXPEDITED (15-DAY)	Y	OT	S05-USA-01454-01		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disorientation; Fall; Head Injury; Hypersomnia; Seizure; Tongue Biting; Tremor	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Bupropion Hydrochloride			S		300 Mg Qam		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2005	5801839	EXPEDITED (15-DAY)	Y	HO	AU-MERCK-0505AUS00102		59 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenal Ulcer; Gastrointestinal Haemorrhage; Melaena; Overdose	Zocor			S	Oral			Merck
	Escitalopram Oxalate			S	Oral			Not Reported
	Prazosin Hydrochloride			S	Oral			Not Reported
	Candesartan Cilexetil			S	Oral			Not Reported
	Glyburide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2005	5751253	EXPEDITED (15-DAY)	Y	OT	S05-USA-00778-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2005	5803825	EXPEDITED (15-DAY)	Y	HO	S05-USA-01759-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia; Drug Interaction; Facial Paralysis; Nausea; Vertigo; Vomiting	Wellbutrin			S	Oral	150mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	40mg Per Day	357 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2005	5792752	NON-EXPEDITED	Y	OT	S05-USA-02072-01		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Wellbutrin			S	Oral	450mg Per Day	3 WEEK	Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2005	5806281	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0550253A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Visual Impairment	Wellbutrin Xl			S	Oral	150mg Per Day	3 DAY	Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2005	5806423	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0553620A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Interaction; Hyperhidrosis; Tremor	Wellbutrin Xl			S	Oral		3 DAY	Glaxosmithkline
	Lexapro			S	Unknown		1 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2005	5811875	EXPEDITED (15-DAY)	Y	OT	S05-NOR-01883-01		42 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Keratitis	Cipralex	S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2005	5811876	EXPEDITED (15-DAY)	Y	DS, OT	S05-UKI-01892-01		21 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Malaise; Myalgia; Seizure; Syncope	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Evra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2005	5816204	EXPEDITED (15-DAY)	N	DE	142209USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Fluoxetine			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2005	5776118	EXPEDITED (15-DAY)	Y	OT	S05-UKI-01324-01		78 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adams-Stokes Syndrome; Amnesia; Aphasia; Arrhythmia; Atrioventricular Block First Degree; Balance Disorder; Blood Potassium Decreased; Blood Thyroid Stimulating Hormone Increased; Bundle Branch Block Right; Dysarthria; Dyspnoea; Fall; Gastroenteritis; Malaise; Treatment Noncompliance; Vitamin B12 Decreased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Adalat			C				Not Reported
	Haloperidol			C				Not Reported
	Bendrofluazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2005	5804455	EXPEDITED (15-DAY)	N	DS	S05-USA-02405-01		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Connective Tissue Disorder; Depression; Paraesthesia; Post-Traumatic Neck Syndrome; Road Traffic Accident; Tinnitus	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Levoxyl			C				Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2005	5805038	EXPEDITED (15-DAY)	Y	HO	S05-ITA-01739-01		69 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyarrhythmia; Electrocardiogram Abnormal	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Esomeprazole			C				Not Reported
	Colimicin (Colistin Sulfate)			C				Not Reported
	Indoxen (Indometacin)			C				Not Reported
	Polase			C				Not Reported
	Aminomal (Aminophylline)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2005	5817199	DIRECT	Y	RI			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parosmia	Lexapro			S		10mg Qd	8 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2005	5818059	EXPEDITED (15-DAY)	Y	OT	S05-GER-01969-01		23 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amylase Increased; Back Pain; Lipase Increased	Cipralex	S	Oral	15 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2005	5792754	EXPEDITED (15-DAY)	N	HO	S05-USA-02019-01		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Pressure Systolic Increased; Cerebrovascular Accident; Confusional State; Dry Mouth; Feeling Hot; Nervousness; Syncope	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Remeron			S				Not Reported
	Blood Pressure Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2005	5818338	EXPEDITED (15-DAY)	N	HO	S05-USA-02719-01		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Dizziness; Drug Hypersensitivity; Fall; Gait Disturbance	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prinivil			C				Not Reported
	Glucophage			C				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2005	5818362	EXPEDITED (15-DAY)	N	OT	S05-USA-02256-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fall; Hypotension; Loss Of Consciousness; Nausea; Nervousness; Tremor	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Risperdal			S				Not Reported
	Lipitor			C				Not Reported
	Lasix			C				Not Reported
	Tenormin			C				Not Reported
	Prevacid			C				Not Reported
	Humalog			C				Not Reported
	Lantus			C				Not Reported
	Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2005	5809415	EXPEDITED (15-DAY)	Y	HO	S05-USA-02499-01		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Bilirubin Increased; Diverticulitis; Granulomatous Liver Disease; Intestinal Perforation	Lexapro			S				Not Reported
	Prevacid			C				Not Reported
	Altace			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2005	5821717	EXPEDITED (15-DAY)	Y	HO	S05-UKI-01977-01		59 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Bendrofluazide			S	Oral	2.5 Mg Qd Po		Not Reported
	Atorvastatin			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported
	Levothyroxine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2005	5813307	EXPEDITED (15-DAY)	Y	OT	2005PK00950		31 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Psychotic Disorder; Serum Serotonin Increased; Sleep Disorder	Seroquel			S	Oral		24 DAY	Zeneca
	Seroquel			S	Oral		4 DAY	Zeneca
	Seroquel			S	Oral			Zeneca
	Cipralex			S	Oral		18 DAY	Not Reported

Cipralex	S	Oral			Not Reported
Trazodone Hydrochloride	C	Oral			Not Reported
Zolpidem	C	Oral		15 DAY	Not Reported
Diazepam	C	Oral		18 DAY	Not Reported
Diazepam	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2005	5744361	EXPEDITED (15-DAY)	Y	HO	S05-USA-00558-01		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Disease; Feeling Cold; Gait Disturbance; Hyperhidrosis; Marital Problem; Overdose; Personality Change; Suicide Attempt; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aricept			S		5 Mg Qd		Not Reported
	Lithium			C				Not Reported
	Valium			C				Not Reported
	Soma			C				Not Reported
	Percocet			C				Not Reported
	Prevacid			C				Not Reported
	Remeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2005	5819419	EXPEDITED (15-DAY)	N	OT	S05-USA-02744-01		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Asthenia; Blood Cholesterol Increased; Dizziness; Dyspnoea; Fall; Irritable Bowel Syndrome; Lethargy; Sinus Bradycardia; Syncope; Weight Increased	Lexapro			S	Oral	40 Mg Once Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Estraderm			C				Not Reported
	Actonel			C				Not Reported
	Nasalcrom			C				Not Reported
	Os-Cal (Calcium)			C				Not Reported
	Diazepam			C				Not Reported
	Aspirin			C				Not Reported
	Vitamin E			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2005	5821349	NON-EXPEDITED	Y	OT	370649			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Accutane			S		20 Mg Daily		Not Reported
	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2005	5820673	DIRECT	Y	HO, RI			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Status Changes	Prozac			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2005	5820679	DIRECT	Y	HO			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Nausea; Sedation; Vomiting	Risperdal			S	Oral	0.5 Mg Orally Hs	4 WEEK	Not Reported
	Lexapro			S	Oral	5 Mg Orally Daily	4 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2005	5822587	EXPEDITED (15-DAY)	Y	HO	S05-USA-02869-01		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion; Mental Status Changes	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Hydrochlorothiazide			S				Not Reported
	Lisinoril			C				Not Reported
	Norvasc			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2005	5823293	EXPEDITED (15-DAY)	Y	OT	S05-SAF-02038-01		84 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Exelon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2005	5821337	DIRECT	N	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neck Pain; Pain In Extremity	Lexapro			S	Oral	1 Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2005	5823695	EXPEDITED (15-DAY)	Y	HO	2005081856		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anxiety; Arthralgia; Depression; Drug Hypersensitivity; Fall; Rash; Rash Papular	Bextra			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S				Not Reported
	Morphine			S				Not Reported
	Zonegran			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	4162920	NON-EXPEDITED	Y	HO	S04-USA-01891-01		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Diarrhoea; Flatulence	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Celexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5729844	NON-EXPEDITED	Y	HO	S05-USA-00304-01		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Lexapro			S				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5795203	NON-EXPEDITED	Y	OT	S05-USA-00175-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Norvasc			C				Not Reported
	Zaroxolyn			C				Not Reported
	Protonix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5795214	NON-EXPEDITED	Y	HO	S04-USA-08046-01		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5795215	NON-EXPEDITED	Y	OT	S04-USA-07990-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Hot Flush; Panic Attack; Vomiting	Lexapro			S	Oral	10 Mg Qhs Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5795216	NON-EXPEDITED	Y	OT	S04-USA-07975-01		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Loss Of Libido; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lipitor			C				Not Reported
	Atenolol			C				Not Reported
	Tricor			C				Not Reported
	Cymbalta			C				Not Reported
	Flomax			C				Not Reported
	Effexor Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5795251	NON-EXPEDITED	N	OT	S04-USA-07779-01		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged; Heart Rate Increased; Supraventricular Extrasystoles	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Tikosyn			S				Not Reported
	Tikosyn			S				Not Reported
	Zetia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5795269	NON-EXPEDITED	Y	HO	S04-USA-07648-01		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Intentional Product Misuse; Suicide Attempt	Lexapro			S	Oral	20 Mg Bid Po		Not Reported
	Xanax Xr			S	Oral	16 Tablet Once Po		Not Reported

	Xanax Xr		S	Oral	1 Mg Prn Po	Not Reported
	Alcohol		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822508	NON-EXPEDITED	N	OT	S05-USA-02391-01		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Amnesia; Crying; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Singulair			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822509	NON-EXPEDITED	N	OT	S05-USA-02338-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Feelings Of Worthlessness	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822512	NON-EXPEDITED	N	OT	S05-USA-02170-01		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Muscle Strain	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822515	NON-EXPEDITED	Y	HO	S05-USA-02074-01		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822519	NON-EXPEDITED	Y	OT	S05-USA-01382-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822524	NON-EXPEDITED	Y	OT	S04-USA-02747-01		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Derealisation; Disturbance In Attention; Dystonia; Headache; Heart Rate Increased; Hypersensitivity; Hypertension; Monocyte Count Increased; Nightmare; Vision Blurred	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Folic Acid			C				Not Reported
	Thiamine			C				Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822527	NON-EXPEDITED	N	DS	S05-USA-00708-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Migraine	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822536	NON-EXPEDITED	Y	OT	S05-USA-02502-01		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Tic	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822541	NON-EXPEDITED	N	OT	S05-USA-01602-01		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Heart Rate Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lopresor			S				Not Reported
	Klonopin			C				Not Reported
	Altace			C				Not Reported
	Hytrin			C				Not Reported
	Norvasc			C				Not Reported
	Water Pills (2) (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822542	NON-EXPEDITED	N	OT	S05-USA-01594-01		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression; Mental Impairment; Suicidal Ideation; Tinnitus	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822543	NON-EXPEDITED	Y	DE	S05-USA-01986-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822545	NON-EXPEDITED	Y	OT	S05-USA-01948-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Suicide Attempt	Lexapro			S				Not Reported
	Lexapro			S	Oral	800 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822547	NON-EXPEDITED	N	OT	S05-USA-01917-01		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Erectile Dysfunction; Insomnia; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Risperdal			C				Not Reported
	Accupril			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822548	NON-EXPEDITED	Y	HO	S05-USA-01869-01		56 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822555	NON-EXPEDITED	Y	HO, RI	S05-USA-01825-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Suicide Attempt	Lexapro			S	Oral	800 Mg Once Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822575	NON-EXPEDITED	Y	OT	S05-USA-00971-01		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Allegra-D			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822579	NON-EXPEDITED	Y	OT	S05-USA-00964-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822581	NON-EXPEDITED	Y	OT	S05-USA-00824-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Flat Affect; Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822584	NON-EXPEDITED	Y	OT	S05-USA-00781-01		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Inderal La			S		80 Mg Qd		Not Reported
	Captopril			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822585	NON-EXPEDITED	N	OT	S05-USA-01359-01		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Motrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822588	NON-EXPEDITED	N	OT	S05-USA-01343-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Mania	Lexapro			S	Oral	10 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822592	NON-EXPEDITED	N	HO, LT	S05-USA-01055-01		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Hyperhidrosis; Road Traffic Accident; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822593	NON-EXPEDITED	Y	LT	S05-USA-01024-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822596	NON-EXPEDITED	Y	OT	S05-USA-01021-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Lexapro			S				Not Reported
	Provigil			C				Not Reported
	Advicor			C				Not Reported
	Minocycline\Minocycline Hydrochloride			C				Not Reported
	Flovent			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822597	NON-EXPEDITED	N	OT	S05-USA-01666-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gastrooesophageal Reflux Disease	Lexapro	S	Oral	5 Mg Qd Po		Not Reported
	Risperdal	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822598	NON-EXPEDITED	Y	OT	S05-USA-01624-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822600	NON-EXPEDITED	Y	HO	S05-USA-01624-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822603	NON-EXPEDITED	N	OT	S05-USA-01611-01		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contusion; Fall; Loss Of Consciousness; Somnolence	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Micardis			C				Not Reported
	Triamterene And Hydrochlorothiazide			C				Not Reported
	Synthroid			C				Not Reported
	Actonel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822718	NON-EXPEDITED	Y	OT	S04-USA-06983-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Clonazepam			C				Not Reported

	Serevent Diskus	C	Not Reported
	Advair	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822723	NON-EXPEDITED	Y	OT	S04-USA-05972-01		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Epistaxis; Insomnia; Panic Attack; Psychiatric Symptom; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Folic Acid			C				Not Reported
	Vitamin B Complex (Vitamin B Complex)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822743	NON-EXPEDITED	N	HO	S05-USA-02549-01		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Fall; Hypersensitivity; Rash	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Morphine			S				Not Reported
	Bextra			S				Not Reported
	Zonegran			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2005	5822745	NON-EXPEDITED	N	OT	S05-USA-02505-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Feeling Abnormal; Suicidal Ideation; Thinking Abnormal	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Gemzar			C				Not Reported
	Taxotere			C				Not Reported
	Aleve			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2005	5783676	EXPEDITED (15-DAY)	Y	OT	S05-USA-01901-01		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Drunk; Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Postictal State; Tonic Clonic Movements	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2005	5800523	EXPEDITED (15-DAY)	N	OT	S05-USA-02309-01		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Diovan			C				Not Reported
	Sular			C				Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2005	5823313	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Hypoxia; Pulmonary Embolism	Lexapro			S	Oral	10 Mg Daily Po		Not Reported
	Nexium			S	Oral	40 Mg Daily Po		Not Reported
	Avodart			S	Oral	0.5 Mg Daily Po		Not Reported
	Aricept			S	Oral	5 Mg Daily Po		Not Reported
	Norvasc			S		10 Mg Daily Po		Not Reported
	Lipitor			S	Oral	10 Mg Daily Po		Not Reported
	Cardura			S	Oral	4 Mg Daily Po		Not Reported
	Iressa			S	Oral	250 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2005	5823855	EXPEDITED (15-DAY)	Y	OT	S05-UKI-02111-01		63 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Memory Impairment; Somnolence; Thirst	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2005	5823861	DIRECT	N	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Dysuria; Flatulence; Hyperhidrosis; Impaired Work Ability; Irritability; Loss Of Libido; Muscle Spasms; Prostatic Disorder	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2005	5825631	EXPEDITED (15-DAY)		OT	S05-USA-02895-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Pressure Systolic Increased; Dizziness; Muscle Spasms	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2005	5804662	EXPEDITED (15-DAY)	Y	OT	S05-USA-02386-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage;	Lexapro			S	Oral	15 Mg Qd Po		Not Reported

Hypertension	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Aspirin		C			Not Reported
	Calcium-D		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2005	5826361	EXPEDITED (15-DAY)	Y	DE	S05-USA-02978-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Increased	Celexa			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2005	5823939	DIRECT	N	RI			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Menorrhagia	Lexapro			S	Oral	20mg 1x/Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2005	5824497	DIRECT	Y	OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Seizure	Lexapro			S		10 Mg Daily	1 WEEK	Not Reported
	Lamictal			C				Not Reported
	Tegretol			C				Not Reported
	Depakote			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2005	5824389	DIRECT	Y	HO			17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition; Suicidal Ideation	Lexapro			S	Oral	20 Mg Po Q Am	1 MTH	Not Reported

	Doxicycline	C	Not Reported
	Metoprolol	C	Not Reported
	Risperdal	C	Not Reported
	Clonidine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2005	5771652	EXPEDITED (15-DAY)	N	DE	S05-USA-01523-01		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Apathy; Asphyxia; Asthenia; Cardiomyopathy; Completed Suicide; Conjunctival Hyperaemia; Disease Recurrence; Drug Ineffective; Fatigue; Hepatomegaly; Insomnia; Intervertebral Disc Protrusion; Irritability; Lymphadenopathy; Non-Hodgkin'S Lymphoma; Petechiae; Restlessness; Skin Abrasion; Skin Discolouration; Social Avoidant Behaviour; Spinal Stenosis; Splenomegaly; Ventricular Hypertrophy; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Fluoxetine			S		20 Mg Qd		Not Reported
	Librax			C				Not Reported
	Xanax			C				Not Reported
	Hydrocodone			C				Not Reported
	Vicodin			C				Not Reported
	Hydromet Syrup (Hydrocodone)			C				Not Reported
	Lanoxin			C				Not Reported
	Accupril			C				Not Reported
	Quinidine Hydrochloride			C				Not Reported
	Lomotil (Diphenoxylate And Atropine)			C				Not Reported
	Coumadin			C				Not Reported
	Guaibid (Guaifenesin)			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2005	5791335	EXPEDITED (15-DAY)	Y	DE	S05-ISR-01560-01			Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S				Not Reported
	Risperidone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2005	5825602	DIRECT	Y	OT			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Psychomotor Hyperactivity; Thinking Abnormal	Lexapro			S	Oral	10mg 1 Q Hs Oral		Not Reported
	Caffeine\Phenylpropanolamine			S	Oral	1 Tab 1 Q Am Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2005	5832453	EXPEDITED (15-DAY)	Y	DE	S05-USA-03134-01		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Asphyxia; Completed Suicide; Hostility	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg, Qd, Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2005	5824372	EXPEDITED (15-DAY)	Y	OT	DE-JNJFOC-20050603246			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Depression	Haloperidol			S	Unknown			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Seroquel			S				Not Reported
	Amisulpride			S				Not Reported
	Cipralex			S	Oropharingeal	Start Date = End Of Apr-2005		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2005	5826937	DIRECT	Y				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Depressed Level Of	Wellbutrin Sr			S				Not Reported
	Lexapro			S				Not Reported

Consciousness; Disorientation; Road Traffic Accident; Status Epilepticus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2005	5830425	EXPEDITED (15-DAY)	Y	DS	S05-CAN-02203-01		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Dizziness; Nausea; Paranoia; Somnolence; Vertigo; Vomiting	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Mirtazapine			C				Not Reported
	Mirapex			C				Not Reported
	Fosamax			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Rabeprazole Sodium			C				Not Reported
	Duragesic			C				Not Reported
	Tylenol With Codeine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2005	5830521	EXPEDITED (15-DAY)	Y	HO	S05-SWI-02210-01		44 YR	Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash Maculo-Papular	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Deroxate (Paroxetine Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2005	5832034	EXPEDITED (15-DAY)	Y	HO	L05-BEL-02196-01		74 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Apathy; Blood Creatinine Increased; Dehydration; Drug Interaction; Dysarthria; Neurotoxicity; Oliguria; Somnolence; Toxicity To Various Agents; Tremor	Escitalopram Oxalate	S	Oral	10 Mg Qd Po		Not Reported
	Lithium	S		250 Mg Tid		Not Reported
	Levomepromazine	S		6.25 Mg Qd		Not Reported
	Lisinopril	S		30 Mg Qd		Not Reported
	Lisinopril	S		20 Mg Qd		Not Reported
	Irbesartan	S		300 Mg Qd		Not Reported
	Spironolactone	S		50 Mg Qd		Not Reported
	Risperidone	S		0.25 Mg Qd		Not Reported
	Furosemide	C				Not Reported
	Repaglinide	C				Not Reported
	Metformin	C				Not Reported
	Lormetazepam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2005	5830385	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Tremor	Lexapro			S	Oral Oral	10 Mg Po Daily 10 Mg Po Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2005	7495034	EXPEDITED (15-DAY)	Y	LT	2005PK01088		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Tamponade; Cardiogenic Shock; Coagulopathy; Drug Interaction; Intestinal Ischaemia; Ischaemic Hepatitis; Lung Infiltration; Multiple Organ Dysfunction Syndrome; Pericardial Haemorrhage;	Cipralex			S	Oral			Not Reported
	Nadroparin Calcium			S	Subcutaneous		21 DAY	Not Reported
	Daflon (Diosmin/Hesperidin)			C	Oral			Not Reported
	Xanax			C	Oral			Not Reported
	Detrol			C	Oral			Not Reported
	Rivotril			C	Oral			Not Reported
	Thiamine Hydrochloride			C	Oral			Not Reported

Pulseless Electrical Activity; Seroma; Skin Graft	Ascorbic Acid\Biotin\Dexpanthenol\Pyridoxine\Riboflavin\Thiamine		C	Oral		Not Reported
	Madopar		C	Oral		Not Reported
	Pyridoxine		C	Oral		Not Reported
	Flunitrazepam		C	Oral		Not Reported
	Dhea		C	Oral		Not Reported
	Etilefrine Hydrochloride		C	Oral		Not Reported
	Mebeverine Hydrochloride		C	Oral		Not Reported
	Acemetacin		C	Oral		Not Reported
	Morphine Sulfate		C	Oral		Not Reported
	Morphine		C	Oral		Not Reported
	Omeprazole		S	Oral		Not Reported
	Nadroparin Calcium		S	Subcutaneous	18 DAY	Not Reported
	Sintrom		S	Oral		Not Reported
	Aspirin Cardio		S	Oral		Not Reported
	Zocor		S	Oral		Not Reported
	Xenical		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2005	5835193	EXPEDITED (15-DAY)	Y	HO	2005-BP-10433RO		74 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Apathy; Blood Creatinine Increased; Confusional State; Dehydration; Diarrhoea; Drug Interaction; Dysarthria; Lethargy; Oliguria; Somnolence; Toxicity To Various Agents; Tremor	Lithium Carbonate (Lithium Carbonate)			S	Oral	250 Mg Tid, Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg/Day, Po		Not Reported
	Levomepromazine			S	Oral	6.25 Mg/Day, Po		Not Reported
	Lisinopril (Lisinopril)			S		30 Mg/Day		Not Reported
	Irbesartan			S		300 Mg/Day		Not Reported
	Furosemide (Furosemide)			S		30 Mg/Day		Not Reported
	Spironolactone			S		50 Mg/Day		Not Reported

	Risperidone (Risperidone)	S	0.25 Mg Bid (2 In 1 D)		Not Reported
	Lormetazepam (Lormetazepam)	C			Not Reported
	Metformin (Metformin)	C			Not Reported
	Rapaglinide (Repaglinide)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2005	5835208	EXPEDITED (15-DAY)	Y	OT	2005-BP-10595RO		60 YR	Male	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis; Platelet Aggregation; Rectal Haemorrhage	Mirtazapine (Mirtazapine)			S	Oral	15 Mg Daily, Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Daily, Po		Not Reported
	Venlafaxine			S	Oral	150 Mg Daily, Po		Not Reported
	Omeprazole			C				Not Reported
	Irbesartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5828954	EXPEDITED (15-DAY)	Y	LT	CH-MERCK-0506CHE00030		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Intestinal Ischaemia; Multiple Organ Dysfunction Syndrome	Zocor			S	Oral			Merck
	Nadroparin Calcium			S	Subcutaneous		18 DAY	Not Reported
	Nadroparin Calcium			S	Subcutaneous		21 DAY	Not Reported
	Acenocoumarol			S	Oral			Not Reported
	Acenocoumarol			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Orlistat			S	Oral			Not Reported
	Mebeverine Hydrochloride			C	Oral			Not Reported
	Acemetacin			C	Oral			Not Reported
	Morphine Sulfate			C	Oral			Not Reported

	Morphine	C	Unknown	Not Reported
	Diosmin	C	Oral	Not Reported
	Alprazolam	C	Oral	Not Reported
	Tolterodine Tartrate	C	Oral	Not Reported
	Clonazepam	C	Oral	Not Reported
	Thiamine Hydrochloride	C	Oral	Not Reported
	Ascorbic Acid	C	Oral	Not Reported
	Benserazide Hydrochloride\Levodopa	C	Oral	Not Reported
	Pyridoxine Hydrochloride	C	Oral	Not Reported
	Flunitrazepam	C	Oral	Not Reported
	Prasterone	C	Oral	Not Reported
	Dihydroergotamine Mesylate\Etilefrine Hydrochloride	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5831426	DIRECT	Y	OT			17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S				Not Reported
	Abilify			C				Not Reported
	Depakote			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5831439	DIRECT	Y	OT			15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S	Oral	10 Mg Po Qd		Not Reported
	Adderall			C				Not Reported
	Depakote			C				Not Reported
	Clonidine			C				Not Reported
	Abilify			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5831452	DIRECT	Y	OT			14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S	Oral	10 Mg Po Qd		Not Reported
	Risperdal			C				Not Reported
	Tetracycline			C				Not Reported
	Trileptial			C				Not Reported
	Strattera			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5831464	DIRECT	Y	OT			15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S	Oral	5 Mg Po Qd		Not Reported
	Trileptal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5832628	DIRECT	Y	OT			15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S	Oral	Po 5 Mg Qd		Not Reported
	Risperdal			C				Not Reported
	Trileptal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5832634	DIRECT	Y	OT			17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S	Oral	10 Mg Po Qd		Not Reported
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5832641	DIRECT	Y	OT			18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S	Oral	10 Mg Po Qd		Not Reported
	Depakote Er			C				Not Reported
	Tetracycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5832653	DIRECT	Y	OT			16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S	Oral	10 Mg Po Qd		Not Reported
	Clonidine			C				Not Reported
	Trileptal			C				Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5832657	DIRECT	Y	OT			17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S	Oral	10 Mg Po Qd		Not Reported
	Lithium Carbonate Er			C				Not Reported
	Trileptal			C				Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5832662	DIRECT	Y	OT			14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S	Oral	10 Mg Po Qd		Not Reported
	Depakote Er			C				Not Reported

	Seroquel			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5832670	DIRECT	Y	OT			18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5838608	NON-EXPEDITED	N	HO	385651		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Chills; Disorientation; Hypotension; Myalgia; Nausea; Pyrexia; Vomiting	Klonopin			S	Oral	2.25 Mg Daily Oral		Not Reported
	Provigil			S	Oral	50 Mg 1 Per One Dose Oral		Not Reported
	Neurontin			S	Oral	1200 Mg Daily Oral		Not Reported
	Aciphex			S	Oral	60 Mg Daily Oral		Not Reported
	Hydrochlorothiazide (Hydrochlorothiazide)			S	Oral	100 Mg Daily Oral		Not Reported
	Doryx			S	Oral	100 Mg Daily Oral		Not Reported
	Lexapro			S	Oral	10 Mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2005	5838609	NON-EXPEDITED	N	OT	385724		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis	Klonopin			S	Oral	8 Mg Daily Oral		Not Reported
	Abilify			S	Oral	5 Mg Daily Oral		Not Reported
	Lexapro			S	Oral	15 Mg Daily Oral		Not Reported
	Trileptal			S		900 Mg Daily		Not Reported
	Zocor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2005	5792271	EXPEDITED (15-DAY)	Y	HO	S05-GER-01552-01		61 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Syncope	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2005	5830518	EXPEDITED (15-DAY)	Y	LT	S05-UKI-02208-01		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Impulsive Behaviour; Overdose; Personality Change	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Diazepam			S	Oral	70 Mg Once Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2005	5836040	EXPEDITED (15-DAY)	N	OT	S05-USA-03216-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Ocular Icterus	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2005	5837336	NON-EXPEDITED	N	OT	2004033534			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Anxiety; Drug Ineffective;	Zoloft			S	Unknown			Not Reported

Haematoma; Haemorrhage; Insomnia; Maternal Exposure During Pregnancy; Panic Attack; Weight Increased	Paroxetine Hydrochloride		S	Unknown	Not Reported
	Escitalopram Oxalate		S	Unknown	Not Reported
	Unspecified Ingredient		C		Not Reported
	Unspecified Ingredient		C		Not Reported
	Vitamins Nos		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2005	5837895	NON-EXPEDITED	Y	HO	2005044707		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Sodium Decreased; Depression; Inappropriate Antidiuretic Hormone Secretion	Zoloft			S	Unknown			Not Reported
	Fluoxetine Hydrochloride (Fluoxetine Hydrochloride)			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Diazepam (Diazepam)			C				Not Reported
	Clonazepam (Cloazepam)			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Hydrochlorothiazide (Hydrochlorothiazide)			C				Not Reported
	Lisinopril (Lisinopril)			C				Not Reported
	Oxybuprocaine Hydrochloride (Oxybuprocaine Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2005	5754496	EXPEDITED (15-DAY)	Y	DE	S05-USA-00818-01		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Feeling Abnormal; Self-Medication	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Tylenol With Codeine			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2005	5788758	EXPEDITED (15-DAY)	Y	OT	S05-USA-01991-01		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apnoea; Confusional State; Cyanosis; Depressed Level Of Consciousness; Depression; Emotional Disorder; Feeling Abnormal; Generalised Tonic-Clonic Seizure; Memory Impairment; Muscle Twitching; Seizure	Lexapro	S	Oral	10 Mg Qd Po	Not Reported
	Lexapro	S	Oral	5 Mg Qd Po	Not Reported
	Lexapro	S	Oral	5 Mg Qd Po	Not Reported
	Ativan	C			Not Reported
	Ortho Evra	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2005	5809414	EXPEDITED (15-DAY)	N	OT	S05-USA-02503-01		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Hypertension; Sinusitis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ativan			C				Not Reported
	Protonix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2005	5830575	EXPEDITED (15-DAY)	N	LT	CH-ROCHE-408911		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Disorder; Cardiac Perforation; Cardiac Tamponade; Cardiogenic Shock; Drug Interaction; Hepatic Necrosis; Intestinal Ischaemia; Multiple Organ Dysfunction Syndrome; Pericardial Haemorrhage; Pulseless Electrical Activity	Xenical			S	Oral	Therapy Duration Reported As 'Long Term'		Roche
	Omeprazole			S	Oral	Therapy Duration Reported As Long Term Trade Name Was Reported As Antra 20		Not Reported
	Zocor			S	Oral	Therapy Duration Of Use Reported As Long Term Trade Name Reported As Zocor 20mg		Not Reported
	Cipralex			S	Oral	Therapy Duration Reported As Long Term		Not Reported
	Aspirin			S	Oral	Therapy Duration		Not Reported

			Reported As Long Term Doseform Reported As Film Coated Tablets		
Acenocoumarol	S	Oral			Not Reported
Acenocoumarol	S	Oral	Therapy Duration Reported As Long Term Trade Name Reported As Sintrom 1 Mitis		Not Reported
Acenocoumarol	S	Oral	Dose Decreased		Not Reported
Nadroparin Calcium	S	Subcutaneous	Dose Increased Total Therapy Duration Reported As 39 Days	21 DAY	Not Reported
Nadroparin Calcium	S	Subcutaneous		18 DAY	Not Reported
Daflon (Diosmin/Hesperidin)	C	Oral			Not Reported
Xanax	C	Oral			Not Reported
Detrol	C	Oral	Doseform Reported As Film Coated Tablets		Not Reported
Rivotril	C	Oral			Not Reported
Benerva	C	Oral			Not Reported
Ascorbic Acid\Biotin\Cyanocobalamin\Riboflavin\Thiamine	C	Oral			Not Reported
Madopar	C	Oral	Strength Reported As 100mg/25mg		Not Reported
Pyridoxine	C	Oral			Not Reported
Flunitrazepam	C	Oral	Doseform Reported As Film Coated Tablets		Not Reported
Dhea	C	Oral			Not Reported
Effortil Plus	C	Oral			Not Reported
Duspatalin	C	Oral			Not Reported
Acemetacin	C	Oral	Doseform Reported As Membrane Capsules		Not Reported
Morphine	C	Oral	Doseform Reported As Membrane Capsules		Not Reported

	Morphine			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2005	5834109	DIRECT	N	DE			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Amitriptyline			S	Oral	3 Tabs @Bedt Oral		Not Reported
	Lexapro			S	Oral	1 Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2005	5834167	DIRECT	N	DE			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Lexapro			S	Oral	1 Daily Oral		Not Reported
	Xanax			S	Oral	1-2 Bedtime Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2005	5834243	DIRECT	N	DE			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Asphyxia; Completed Suicide; Social Avoidant Behaviour	Lexapro			S	Oral	1 Pill 1 A Day Oral		Not Reported
	Norvasc			C				Not Reported
	Relafen			C				Not Reported
	Flomax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2005	5835698	EXPEDITED (15-DAY)	Y	OT	S05-USA-03279-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2005	5837620	EXPEDITED (15-DAY)	Y	OT	S05-SAF-02198-01		27 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Cold Sweat; Confusional State; Dissociation; Eye Movement Disorder; Fall; Flat Affect; Hallucination, Auditory; Hallucination, Visual; Palpitations; Seizure; Speech Disorder; Vomiting	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Purata (Oxazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2005	5837623	EXPEDITED (15-DAY)	Y	DS	S05-DEN-02282-01		56 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Burning Sensation; Condition Aggravated; Eye Pain; Eyelid Disorder; Musculoskeletal Stiffness; Myopia; Pain; Sensory Disturbance; Vision Blurred	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Alopam (Oxazepam)			C				Not Reported
	Stilnoct (Zolpidem Tartrate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2005	5837871	EXPEDITED (15-DAY)	Y	RI	S05-USA-02311-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Breech Presentation; Caesarean Section; Maternal Exposure During Pregnancy	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Prenatal Vitamins			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2005	5835104	DIRECT	Y	LT			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Neutropenia	Lexapro			S	Oral	10 Mg Daily Oral		Forest
	Lasix			C				Not Reported
	Norvasc			C				Not Reported
	K-Dur			C				Not Reported
	Prevacid			C				Not Reported
	Toprol Xl			C				Not Reported
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2005	5835116	DIRECT	N	LT, RI			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Condition Aggravated; Depression; Disorientation; Nervousness; Suicidal Ideation; Tremor	Lexapro			S	Oral	75 Mg Daily Oral		Forest
	Diovan			C				Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2005	5838319	EXPEDITED (15-DAY)	Y	HO	S05-DEN-02284-01		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypokalaemia; Hypomagnesaemia; Hyponatraemia; Hypophosphataemia; Seizure	Cipralex			S	Oral	10 Mg Qd; Po		Not Reported
	Fluoxetine Hydrochloride			S	Oral	20 Mg Qd; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2005	5803842	EXPEDITED (15-DAY)	Y	OT	PK-GLAXOSMITHKLINE-B0380854A		43 YR	Female	PAK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Drug Hypersensitivity; Headache; Hypertension; Insomnia; Palpitations; Urticaria	Lamictal			S	Oral	50mg Per Day	23 DAY	Glaxosmithkline
	Cipralex			S	Oral	10mg Twice Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2005	5820131	EXPEDITED (15-DAY)	Y	HO	2005079018		74 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Apathy; Blood Creatinine Increased; Coma Scale Abnormal; Confusional State; Creatinine Renal Clearance Decreased; Dehydration; Diarrhoea; Drug Interaction; Dysarthria; General Physical Health Deterioration; Lethargy; Neurotoxicity; Oliguria; Overdose; Renal Impairment; Somnolence; Therapy Non-Responder; Toxicity To Various Agents; Tremor	Lithium (Lithium)			S		750 Mg (250 Mg, 3 In 1 D)		Not Reported
	Levomepromazine			S		6.25 Mg		Not Reported
	Lisinopril (Lisinopril)			S		30 Mg		Not Reported
	Risperidone (Risperidone)			S		0.5 Mg (0.25 Mg, 2 In 1 D)		Not Reported
	Escitalopram Oxalate			S		10 Mg		Not Reported
	Irbesartan			S		300 Mg		Not Reported
	Lormetazepam (Lormetazepam)			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Furosemide (Furosemide)			C				Not Reported
	Repaglinide (Repaglinide)			C				Not Reported
	Spironolactone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2005	5834478	DIRECT	Y	OT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contusion	Lexapro		S	Oral	1q.Day Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2005	5839784	EXPEDITED (15-DAY)	Y	OT	T05-GER-02286-01		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Circulatory Collapse; Dizziness; Nausea; Treatment Noncompliance	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Paroxetine Hydrochloride			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2005	5836932	DIRECT	Y	HO			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Mental Status Changes	Lexapro			S	Oral	20mg Qday Oral		Not Reported
	Mirapex			C				Not Reported
	Cardura			C				Not Reported
	Vasotec			C				Not Reported
	Lexapro			C				Not Reported
	Depakote			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Ultram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2005	5837570	EXPEDITED (15-DAY)	Y	LT	200511978GDS		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Disorder; Cardiac Perforation; Cardiac Tamponade; Cardiogenic Shock; Drug Interaction; Intestinal Ischaemia; Ischaemic Hepatitis; Lung Infiltration; Multiple Organ	Aspirin (Acetylsalicylic Acid)		Y	S	Oral	300 Mg, Total Daily, Oral		Not Reported
	Nadroparin Calcium			S	Subcutaneous	0.4 Mg, Total Daily, Subcutane; See Image		Not Reported
					Subcutaneous	0.4 Mg, Total Daily, Subcutane; See Image		
					Subcutaneous	0.4 Mg, Total Daily, Subcutane; See Image		

Dysfunction Syndrome; Pericardial Haemorrhage; Pulseless Electrical Activity; Skin Ulcer; Superinfection	Acenocoumarol	S	Oral	1 Mg, Total Daily, Oral; See Image	Not Reported
			Oral	1 Mg, Total Daily, Oral; See Image	
	Escitalopram Oxalate	S	Oral	20 Mg, Total Daily, Oral	Not Reported
	Simvastatin	S	Oral	20 Mg, Total Daily, Oral	Not Reported
	Omeprazole	S	Oral	20 Mg, Total Daily, Oral	Not Reported
	Orlistat	C			Not Reported
	Daflon (Diosmin/Hesperidin)	C			Not Reported
	Xanax	C			Not Reported
	Detruaitol	C			Not Reported
	Rivotril	C			Not Reported
	Benerva	C			Not Reported
	Becozyme C	C			Not Reported
	Madopar	C			Not Reported
	Vitamine B6	C			Not Reported
	Rohypnol	C			Not Reported
	Dhea	C			Not Reported
	Effortil Plus /Gfr/	C			Not Reported
	Duspatalin	C			Not Reported
	Tilur	C			Not Reported
	Kapanol	C			Not Reported
	Morphine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2005	8291105	EXPEDITED (15-DAY)	Y	LT	S05-SWI-02300-01		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Perforation; Cardiac Tamponade; Cardiogenic Shock; Coagulation Time Abnormal; Infection; Intestinal Ischaemia; Ischaemic Hepatitis; Lung Infiltration; Multiple Organ Dysfunction Syndrome; Pericardial Haemorrhage; Pulseless Electrical	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Nadroparin Calcium			S	Subcutaneous	0.4 Ml Qd Sc		Not Reported
	Nadroparin Calcium			S	Subcutaneous	0.6 Ml Qd Sc		Not Reported
	Sintrom			S	Oral	Mg Qd Po		Not Reported
	Sintrom			S	Oral	Mg Qd Po		Not Reported
	Aspirin			S	Oral	300 Mg Qd Po		Not Reported
	Zocor			S	Oral	20 Mg Qd Po		Not Reported

Activity; Renal Failure; Skin Ulcer	Omeprazole	S	Oral	20 Mg Bid Po	Not Reported
	Xenical	S	Oral	120 Mg Bid Po	Not Reported
	Daflon (Diosmin)	C			Not Reported
	Xanax	C			Not Reported
	Rivotril (Clonazepam)	C			Not Reported
	Benerva (Thiamine Hydrochloride)	C			Not Reported
	Becozyme C	C			Not Reported
	Madopar	C			Not Reported
	Vitamin B6	C			Not Reported
	Rohypnol (Flunitrazepam)	C			Not Reported
	Dhea	C			Not Reported
	Effortil Plus	C			Not Reported
	Duspatalin (Mebeverine)	C			Not Reported
	Tilue (Acemetacin)	C			Not Reported
	Kapanol (Morphine Sulfate)	C			Not Reported
	Morphine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2005	5762623	EXPEDITED (15-DAY)	Y	DS, OT	S05-GER-00904-01		45 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Adenoma; Lactose Intolerance; Large Intestine Polyp; Retroperitoneal Fibrosis	Citalopram Hydrobromide			S	Oral	40 Mg Qd Po		Not Reported
	Cipralex			S		20 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2005	5804494	EXPEDITED (15-DAY)	Y	OT	S05-SWE-01740-01		24 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Hepatocellular Injury; Nervousness	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Valproic Acid			S	Oral	500 Mg Bid Po		Not Reported
	Mirtazapine			S	Oral	30 Mg Qd Po		Not Reported
	Olanzapine			C				Not Reported
	Effexor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2005	5828933	EXPEDITED (15-DAY)	Y	OT	2005087479		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Breast Cyst; Gynaecomastia	Geodon			S	Oral	120 Mg (60 Mg, 2 In 1 D), Oral		Not Reported
	Lexapro			S		(30 Mg)		Not Reported
	Norvasc			C				Not Reported
	Hydrochlorothiazide (Hydrochlorothiazide)			C				Not Reported
	Flonase			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2005	5674622	EXPEDITED (15-DAY)	Y	HO	T04-NLD-07228-01		77 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Cirrhosis; Serum Ferritin Increased	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Amaryl			C				Not Reported
	Metformin			C				Not Reported
	Ascal (Acetylsalicylate Calcium)			C				Not Reported
	Legendal (Lactulose)			C				Not Reported
	Duratears			C				Not Reported
	Nortrilen Filmtabletten			C				Not Reported
	Tranxene T-Tab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2005	5787304	EXPEDITED (15-DAY)	Y	HO, OT	S05-USA-01947-01		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Agitation; Alcohol Interaction; Alcoholism; Anger; Anxiety; Apathy; Attention Deficit/Hyperactivity Disorder; Bipolar Disorder;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported

Borderline Personality Disorder; Delusion; Diarrhoea; Drug Dependence; Drug Ineffective; Erectile Dysfunction; Generalised Anxiety Disorder; Hallucination; Headache; Homicidal Ideation; Insomnia; Irritability; Judgement Impaired; Malaise; Memory Impairment; Mood Swings; Nervousness; Restlessness; Sexual Abuse; Sluggishness; Somnolence; Suicidal Ideation; Toxicity To Various Agents; Treatment Noncompliance

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2005	5798780	EXPEDITED (15-DAY)	N	HO, LT	S05-USA-02250-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Ineffective; Mania; Overdose; Personality Change; Suicide Attempt; Weight Increased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lithium			S		600 Mg Qd		Not Reported
	Lamictal			S		50 Mg Bid		Not Reported
	Abilify			S		15 Mg Qd		Not Reported
	Seroquel			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2005	5820724	EXPEDITED (15-DAY)	Y	OT	S05-USA-02782-01		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Parkinsonism	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Lexapro	S	Oral	20 Mg Qd Po		Not Reported
	Lexapro	S				Not Reported
	Prozac	S	Oral	80 Mg Qd Po		Not Reported
	Prozac	S	Oral	20 Mg Qd Po		Not Reported
	Prozac	S	Oral	40 Mg Qd Po		Not Reported
	Abilify	S		30 Mg Qhs		Not Reported
	Depakote	C				Not Reported
	Lisinopril	C				Not Reported
	Diovan	C				Not Reported
	Coreg	C				Not Reported
	Wellbutrin (Bupropion Hydrochloride)	C				Not Reported
	Hydrocodone/Apap	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2005	5844337	EXPEDITED (15-DAY)	Y	OT	S05-USA-03438-01		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyperhidrosis; Loss Of Consciousness; Seizure; Vomiting	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Pegintron			S				Not Reported
	Ribavirin			S				Not Reported
	Buspar			C				Not Reported
	Protonix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2005	5793334	EXPEDITED (15-DAY)	N	HO	US-GLAXOSMITHKLINE-A0556917A		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Discomfort; Fatigue; Heart Rate Increased; Hypoaesthesia; Intentional Product Misuse; Muscle	Wellbutrin Xl			S	Oral	900mg Single Dose		Glaxosmithkline
	Lexapro			S	Oral		15 DAY	Not Reported
	Unspecified Ingredient			C				Not Reported

Contracture; Paraesthesia;
Posture Abnormal;
Seizure; Suicide Attempt;
Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2005	5802710	EXPEDITED (15-DAY)	N	HO	S05-USA-02393-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Fatigue; Hypoaesthesia; Ill-Defined Disorder; Intentional Product Misuse; Muscle Contractions Involuntary; Paraesthesia; Seizure; Tremor	Wellbutrin Xl			S	Oral			Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day	15 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2005	5838923	EXPEDITED (15-DAY)	Y	HO	US-ROCHE-410336		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Agitation; Drug Screen False Positive; Gait Disturbance; Irritability; Overdose; Psychomotor Retardation; Sedation; Stupor	Klonopin			S	Oral		1 DAY	Roche
	Soma			S	Unknown		1 DAY	Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Relafen			S	Unknown			Not Reported
	Cyproheptadine Hydrochloride			C				Not Reported
	Claritin			C				Not Reported
	Inderal			C				Not Reported
	Doxycycline			C				Not Reported
	Melatonin			C				Not Reported
	Hydroxyzine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2005	5791128	EXPEDITED (15-DAY)	Y	OT	S05-USA-01761-01		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoacusis; Viral Infection	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Calcium Gluconate			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2005	5812772	EXPEDITED (15-DAY)	N	HO	S05-USA-02675-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Condition Aggravated; Depression; Drug Ineffective; Hallucination; Intentional Product Misuse; Overdose; Post-Traumatic Stress Disorder; Suicidal Ideation; Suicide Attempt; Treatment Noncompliance	Lexapro			S	Oral	50 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	50 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Elavil			S		50 Mg Qd		Not Reported
	Klonopin			S		1 Mg Qd		Not Reported
	Ritalin			S		30 Mg Qd		Not Reported
	Abilify			S				Not Reported
	Geodon			S	Oral	40 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2005	5822539	EXPEDITED (15-DAY)	N	HO, OT	S05-USA-02498-01		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Delusion; Depression; Gastrooesophageal Reflux Disease; Gun Shot Wound; Headache; Serratia Infection; Suicide	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	60 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported

Attempt; Thinking Abnormal; Urinary Tract Infection; Vision Blurred; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2005	5847861	EXPEDITED (15-DAY)	N	HO	S05-USA-03510-01		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Interaction; Alcohol Use; Paranoia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2005	5847785	DIRECT	N	DE			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Obstructive Airways Disorder; Swelling	Lexapro			S				Not Reported
	Wellbutrin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2005	5802758	EXPEDITED (15-DAY)	Y	DE	S05-USA-02406-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exercise Electrocardiogram Abnormal; Fall; Loss Of Consciousness; Resuscitation; Syncope	Lexapro			S				Not Reported
	Geodon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2005	5842630	NON-EXPEDITED	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-12797510		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Gastrointestinal Haemorrhage	Coumadin		S	Oral	Dose Unk, But Kept At Approx 3.5 (Units Not Given); Commenced Years Ago.	Bristol Myers Squibb
	Lexapro		S	Oral	Aug2004 To 22nov2004:10 Mg Qd, 23nov04-27nov04:20 Mg Qd	Not Reported
	Ambien		C			Not Reported
	Multi-Vitamin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2005	5842646	NON-EXPEDITED	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-12808283		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Decreased	Coumadin			S				Bristol Myers Squibb
	Lexapro			S	Oral			Not Reported
	Paclitaxel			C				Bristol Myers Squibb

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2005	5842806	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-12925921			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Coumadin			S				Bristol Myers Squibb
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2005	5845358	EXPEDITED (15-DAY)	Y	LT	S05-NLD-02364-02		1 DAY	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Asphyxia; Maternal Exposure During Pregnancy; Meconium	Escitalopram Oxalate			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Oxazepam			S	Transplacental	20 Mg Qd Transplacental		Not Reported

Abnormal; Neonatal
Respiratory Depression

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2005	5770905	EXPEDITED (15-DAY)	Y	DE, DS	US-ROCHE-400261		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ammonia Increased; Colon Cancer Metastatic; Mental Status Changes; Metastases To Liver	Xeloda			S	Oral		2 DAY	Roche
	Lexapro			S	Oral	Dosage Regimen Reported As Every Day		Not Reported
	Seroquel			S	Oral	Dosage Regimen Reported As Every Night		Not Reported
	Methadone Hydrochloride			S	Oral			Not Reported
	Oxaliplatin			C				Not Reported
	Avastin			C				Not Reported
	Megace			C	Oral			Not Reported
	Protonix			C		Dosage Regimen Reported As Daily		Not Reported
	Senokot			C				Not Reported
	Colace			C				Not Reported
	Combivent			C				Not Reported
	Prochlorperazine			C		Dosage Regimen Reported As Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2005	5849875	DIRECT	N	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome	Lexapro			S	Oral	10mg 1x/Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2005	5816266	EXPEDITED (15-DAY)	Y	HO, LT, OT	PHEH2005US06346		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Drug Ineffective; Hallucination; Overdose; Post-Traumatic Stress Disorder; Suicidal Ideation; Suicide Attempt	Ritalin		S	Oral	30 Mg, Qd		Novartis
	Lexapro		S	Oral	10 Mg, Qd	10080 MIN	Not Reported
	Lexapro		S	Oral	20 Mg, Qd	10080 MIN	Not Reported
	Lexapro		S	Oral	30 Mg, Qd	10080 MIN	Not Reported
	Lexapro		S	Oral	40 Mg, Qd	10080 MIN	Not Reported
	Lexapro		S	Oral	50 Mg, Qd		Not Reported
	Lexapro		S	Oral	30 Mg, Qd		Not Reported
	Lexapro		S	Oral	50 Mg, Qd		Not Reported
	Elavil		S	Oral	50 Mg, Qd		Not Reported
	Klonopin		S	Oral	1 Mg, Qd	341 DAY	Not Reported
	Abilify		S	Oral	Unk, Unk	135 DAY	Not Reported
	Geodon		S	Oral	40 Mg, Qd	46080 MIN	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2005	5844722	NON-EXPEDITED	N		US013232			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Flushing	Dyazide			S	Oral			Glaxosmithkline
	Provigil			S				Not Reported
	Estraderm			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lipitor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2005	5851086	EXPEDITED (15-DAY)	Y	OT	S05-USA-03548-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Maternal Exposure During Pregnancy	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2005	5776226	EXPEDITED (15-DAY)	Y	OT	S05-USA-01603-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activated Partial Thromboplastin Time Prolonged; Alanine Aminotransferase Decreased; Anion Gap Increased; Aspartate Aminotransferase Increased; Blood Albumin Decreased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Calcium Decreased; Blood Chloride Increased; Blood Creatine Phosphokinase Increased; Blood Creatine Phosphokinase Mb Increased; Blood Creatinine Increased; Blood Fibrinogen Decreased; Blood Glucose Increased; Blood Phosphorus Decreased; Blood Phosphorus Increased; Blood Potassium Increased; Blood Sodium Decreased; Blood Sodium Increased; Blood Urea Increased; Haematocrit Decreased; Haemoglobin Decreased; International Normalised Ratio Increased; Lymphocyte Count Decreased; Mitral Valve Repair; Neutrophil Count	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Warfarin Sodium			S	Oral	5 Mg Qd Po		Not Reported
	Warfarin Sodium			S	Oral	2.5 Mg Qd Po		Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Restoril			C				Not Reported
	Quinapril			C				Not Reported
	Prednisone			C				Not Reported
	Lopressor Xl (Metoprolol)			C				Not Reported
	Megestrol			C				Not Reported
	Losartan Potassium			C				Not Reported
	Loratadine			C				Not Reported
	Insulin Nos			C				Not Reported
	Pepcid			C				Not Reported
	Epogen			C				Not Reported
	Clonidine			C				Not Reported

Increased; Pco2
Decreased; Platelet Count
Decreased; Protein Total
Decreased; Prothrombin
Time Prolonged; Red
Blood Cell Count
Decreased; Tricuspid
Valve Repair; Troponin
Increased; White Blood
Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2005	5811849	EXPEDITED (15-DAY)	Y	HO, RI	S05-USA-01774-01		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Calcium Increased; Parathyroid Gland Operation	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Fosamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2005	5838395	EXPEDITED (15-DAY)	Y	DE	S05-GER-02285-01		19 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Incorrect Dose Administered; Insomnia	Cipralex			S	Oral	10 Mg Qd; Po		Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2005	5850898	DIRECT	N	RI			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Energy	Lexapro			S	Oral	20 Mg 1/Day-Morning Oral		Not Reported
	Oxazepam			C				Not Reported

Increased; Insomnia; Muscle Tightness; Nicotine Dependence; Restlessness; Serotonin Syndrome; Trismus; Yawning	Alprazolam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2005	5851702	EXPEDITED (15-DAY)	Y	HO, LT	T05-FIN-02514-01		44 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Blood Pressure Diastolic Decreased; Depression; Dizziness; Injury; Intentional Product Misuse; Joint Swelling; Loss Of Consciousness; Overdose; Poisoning; Seizure; Suicide Attempt; Wheezing	Escitalopram Oxalate			S		800 Mg Once		Not Reported
	Escitalopram Oxalate			S		20 Mg Qd		Not Reported
	Alcohol			C				Not Reported
	Diazepam			C				Not Reported
	Lanexat (Flumazenil)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2005	4215859	EXPEDITED (15-DAY)	N	OT	2004063520		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Body Height Decreased; Chest Discomfort; Depression; Disturbance In Attention; Divorced; Drug Ineffective; Drug Interaction; Dyspnoea; Feeling Abnormal; Headache; Heart Rate Increased; Mood Altered; Myocardial Infarction; Neck Pain; Panic Attack;	Neurontin			S	Oral	300 Mg (300 Mg, 1 In 1 D), Oral		Not Reported
	Zoloft			S	Oral	(1 In 1 D), Oral		Not Reported
	Xanax			S				Not Reported
	Lexapro			S				Not Reported
	Gabapentin			S	Oral	Oral		Not Reported
	Claritin			S	Oral	Oral		Not Reported
	Buspar			C				Not Reported
	Prozac			C				Not Reported
	Zyprexa			C				Not Reported
	Zyrtec			C				Not Reported

Psychomotor Hyperactivity; Road Traffic Accident; Stress; Suicidal Ideation; Therapeutic Product Effect Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2005	5707932	EXPEDITED (15-DAY)	Y	HO	S04-GER-08106-01		80 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplastic Anaemia	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2005	5847245	EXPEDITED (15-DAY)	N	OT	US-GLAXOSMITHKLINE-A0566775A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Dysgraphia; Fear; Impaired Driving Ability; Malaise; Memory Impairment; Self-Injurious Ideation; Thinking Abnormal; Visual Acuity Reduced; Weight Increased	Paxil			S	Oral		3 YR	Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2005	5853653	EXPEDITED (15-DAY)	Y	OT	S05-CAN-02530-01		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Liver Function Test Abnormal	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2005	5854220	DIRECT	Y	HO, LT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dehydration; Hypotension; Nausea; Oxygen Saturation Decreased; Pulmonary Embolism; Vomiting	Iressa			S	Oral	250 Mg Daily Po		Not Reported
	Xanax			S	Oral	0.25 Mg Q6h Po		Not Reported
	Phenergan			S	Oral	12.5 Mg Q6h Prn Po		Not Reported
	Protonix			S	Oral	40 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 Mg Daily Po		Not Reported
	Colace			S	Oral	100 Mg Tid Po		Not Reported
	Percocet			S	Oral	5 Mg Q4h Prn Po		Not Reported
	Duragesic			S	Transdermal	50 Mcg Q3days Derm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2005	5854475	EXPEDITED (15-DAY)	Y	OT	S05-FRA-02534-01		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Tremor	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Ebixa			S	Oral	10 Mg Bid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2005	5854478	EXPEDITED (15-DAY)	Y	DE, HO	S05-FRA-02533-01		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Confusional State; Gastrointestinal Haemorrhage; Hypokalaemia; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Levothyroxine Sodium			S				Not Reported
	Flecainide Acetate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2005	5850018	EXPEDITED (15-DAY)	N	OT	S05-USA-03547-01		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alcohol Use; Homicide	Lexapro	S	Not Reported
	Cholesterol Medications (Nos)	C	Not Reported
	Unspecified Ingredient	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2005	5853192	DIRECT	N	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Attention; Fear; Feeling Abnormal; Hallucination, Auditory; Hyperhidrosis; Muscle Twitching; Paranoia; Tremor	Lexapro			S	Oral	5mg Per Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2005	5855185	EXPEDITED (15-DAY)	Y	LT	S05-UKI-02525-01		45 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Asthma	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Levothyroxine Sodium			C				Not Reported
	Liothyronine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2005	5858686	EXPEDITED (15-DAY)	Y	DE	S05-USA-03655-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer; Hepatic Failure; Hepatomegaly; Mental Status Changes; Metastases To Liver	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported
	Combivent			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2005	5858688	EXPEDITED (15-DAY)	Y	OT	S05-USA-03667-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2005	5860434	EXPEDITED (15-DAY)	Y	OT	S05-GER-02622-01		51 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Movement Disorder	Cipralex			S		10 Mg Qd		Not Reported
	Cipralex			S		20 Mg Qd		Not Reported
	Mareen (Doxepin Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2005	5860892	EXPEDITED (15-DAY)	Y	LT	S05-SAF-02624-01		39 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage; International Normalised Ratio Increased	Cipralex			S	Oral	5 Mg Qd, Po		Not Reported
	Warfarin Sodium			S	Oral	5 Mg Qd, Po		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2005	5855434	DIRECT	Y	OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Hallucination, Visual; Palpitations	Lexapro			S	Oral Oral	Po 15 -> 20mg Po 15 -> 20mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2005	5821767	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-12998167		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Hallucination; Intentional Product Misuse; Post-Traumatic Stress Disorder; Suicidal Ideation; Suicide Attempt	Abilify			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Elavil			S	Oral			Not Reported
	Klonopin			S				Not Reported
	Ritalin			S				Not Reported
	Geodon			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2005	5857609	DIRECT	Y	HO, LT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chromaturia; Faeces Discoloured; Nausea; Scleral Discolouration	Lexapro			S	Oral	60mg Once Daily Oral		Not Reported
	Synthroid			C				Not Reported
	Femhrt			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2005	5857870	DIRECT	N	HO, OT			20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Crying; Depression; Dysphagia; Feeling Abnormal; Headache; Hostility; Hypoaesthesia; Malaise; Mania; Muscle Tightness; Nightmare; Pain; Psychotic Disorder; Suicidal Ideation	Neurontin			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2005	5862028	EXPEDITED (15-DAY)	Y	OT	S05-UKI-02692-01		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Epilepsy; Loss	Cipralex			S	Oral	5 Mg Qs Po		Not Reported

Of Consciousness	Sertraline Hydrochloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2005	5862416	EXPEDITED (15-DAY)	Y	DE	S05-USA-03721-01		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exsanguination; Skin Laceration	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Aspirin			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2005	4218537	EXPEDITED (15-DAY)	Y	HO	DE-MERCK-0409DEU00158		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Duodenal Ulcer Haemorrhage	Vioxx			S	Oral			Merck
	Escitalopram Oxalate			S	Oral			Not Reported
	Enoxaparin Sodium			S	Subcutaneous			Not Reported
	Clopidogrel Bisulfate			S	Oral			Not Reported
	Moxifloxacin Hydrochloride			C	Oral		11 DAY	Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Pantoprazole Sodium			C	Oral			Not Reported
	Simvastatin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2005	5788457	EXPEDITED (15-DAY)	Y	HO	S05-USA-01998-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Serotonin Syndrome	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Buspar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2005	5836977	EXPEDITED (15-DAY)	N	OT	S05-USA-03346-01		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Condition Aggravated; Fatigue	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Navane			S	Oral	10 Mg Qd Po		Not Reported
	Anafranil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2005	5863278	EXPEDITED (15-DAY)	N	OT	S05-USA-03739-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Condition Aggravated; Focal Dyscognitive Seizures; Hallucination; Insomnia	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lamictal			C				Not Reported
	Depakote			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2005	5855605	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0554040A		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Withdrawal Syndrome; Fear; Vomiting	Paxil Cr			S	Oral	25mg Per Day		Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2005	5857076	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0560134A		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Drug Ineffective; Nervousness; Panic Attack	Paroxetine Hydrochloride		S	Oral	30mg Per Day		Glaxosmithkline
	Lexapro		S	Oral	10mg Per Day	6 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2005	5795210	EXPEDITED (15-DAY)	Y	OT	S05-USA-00052-01		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Impaired Driving Ability; Nervous System Disorder; Vascular Dementia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported
	Inderal			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2005	5831739	EXPEDITED (15-DAY)	N	HO	S05-USA-03181-01		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Feeling Jittery; Refusal Of Treatment By Patient; Suicidal Ideation	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2005	5845729	EXPEDITED (15-DAY)	N	HO	US-ROCHE-410971		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hallucination; Intentional Self-Injury; Overdose; Post-Traumatic Stress Disorder; Suicidal Ideation; Suicide Attempt	Klonopin			S	Unknown		341 DAY	Roche
	Klonopin			S	Unknown	Overdose Therapy.		Roche
	Lexapro			S	Oral		7 DAY	Not Reported
	Lexapro			S	Oral		7 DAY	Not Reported
	Lexapro			S	Oral		7 DAY	Not Reported
	Lexapro			S	Oral		7 DAY	Not Reported
	Lexapro			S	Oral			Not Reported

	Lexapro		S	Oral			Not Reported
	Lexapro		S	Oral			Not Reported
	Elavil		S	Unknown			Not Reported
	Ritalin		S	Unknown			Not Reported
	Ritalin		S	Unknown	The Patient Was Weaned Off The Drug.		Not Reported
	Abilify		S	Unknown		135 DAY	Not Reported
	Geodon		S	Oral		32 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2005	5861007	DIRECT	N				27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Oral	1 Day Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2005	5829175	EXPEDITED (15-DAY)	Y	OT	13148		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia	Wellbutrin			S		150mg Per Day	30 DAY	Glaxosmithkline
	Lexapro			S		10mg Per Day	134 DAY	Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2005	5863889	EXPEDITED (15-DAY)	Y	HO	S05-FRA-02780-01		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Confusional State; Diet Refusal; Disorientation; Negativism; Persecutory Delusion	Escitalopram Oxalate			S	Oral	1 Tablet Qd Po		Not Reported
	Lexomil (Bromazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2005	5863892	EXPEDITED (15-DAY)	Y	DE	S05-UKI-02764-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Flupentixol Dihydrochloride			S				Not Reported
	Zopiclone			C				Not Reported
	Quinine Bisulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2005	5844333	EXPEDITED (15-DAY)	N	HO	S05-USA-03429-01		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cough; Dizziness; Drug Interaction; Heart Rate Increased; Heart Rate Irregular; Laryngitis	Lexapro			S	Oral	10 Mg Qd, Po		Not Reported
	Dextromethorphan\Guaifenesin			S				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2005	5864704	EXPEDITED (15-DAY)	Y	OT	05-08-1390		60 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Rectal Haemorrhage	Mirtazapine			S		15-7.5mg Qd		Not Reported
	Venlafaxine			S		150-37.5mg Qd		Not Reported
	Escitalopram Oxalate			S		20-5mg		Not Reported
	Omeprazole			C				Not Reported
	Irbesartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2005	5864779	DIRECT	Y	HO, LT, RI			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Hyponatraemia; Medication Error	Lexapro	S	Oral	10 Mg Po Daily	6 DAY	Not Reported
	Lisinopril	C				Not Reported
	Calcium +D	C				Not Reported
	Aspirin	C				Not Reported
	Vitamin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2005	5866540	EXPEDITED (15-DAY)	N	HO, LT	S04-USA-07194-02		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Immature Respiratory System; Infantile Colic; Maternal Exposure During Pregnancy; Premature Baby	Celexa			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	50 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Claritin			C				Not Reported
	Natelle (Prenatal Vitamins)			C				Not Reported
	Rocephin			C				Not Reported
	Zofran			C				Not Reported
	Terbutaline Sulfate			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Procardia			C				Not Reported
	Spinal Analgesia/Aneshtesia (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2005	5866541	EXPEDITED (15-DAY)	N	HO	S04-USA-06296-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Dizziness; Drug Ineffective; Maternal Exposure During Pregnancy; Nausea; Pain; Pregnancy; Premature Labour; Procedural Pain; Vomiting	Lexapro			S	Oral	50 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Claritin			C				Not Reported
	Natelle			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2005	5866521	EXPEDITED (15-DAY)	Y	OT	S05-USA-03889-01		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Maternal Exposure During Pregnancy	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Zofran			C				Not Reported
	Benadryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2005	5864819	EXPEDITED (15-DAY)	N	OT	US-ROCHE-414054		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Gastric Ulcer; Gastrooesophageal Reflux Disease; Oesophageal Ulcer	Cellcept			S	Oral	600mg Weekly.		Roche
	Fosamax			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Gemfibrozil			S	Oral			Not Reported
	Morphine			S	Oral			Not Reported
	Temazepam			S	Oral			Roche
	Unspecified Ingredient			S	Oral			Not Reported
	Calcium Gluconate			C	Oral			Not Reported
	Multi-Vitamin			C	Oral			Not Reported
	Ibuprofen			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2005	5867638	EXPEDITED (15-DAY)	N	DE	S05_USA_03912-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Gun Shot Wound; Head Injury	Lexapro	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2005	5868149	DIRECT	N	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Burning Sensation; Completed Suicide; Gun Shot Wound; Insomnia; Restlessness; Thinking Abnormal	Lexapro			S	Oral	10 Mg 1 X Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2005	5798492	EXPEDITED (15-DAY)	Y	OT	S05-USA-02235-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Tardive Dyskinesia	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Citalopram			C				Not Reported
	Lorazepam			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2005	5869414	EXPEDITED (15-DAY)	Y	HO	DSA_26863_2005		50 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Coma Scale Abnormal; Depressed Level Of Consciousness; Hypercapnia; Miosis; Overdose; Sopor; Suicide Attempt	Lorazepam			S	Oral	Df Once Po		Not Reported
	Cipralex			S	Oral	1 Df Once Po		Not Reported
	Zopiclone			S	Oral	Df Once Po		Not Reported
	Clorazepate Dipotassium			S	Oral	Df Once Po		Not Reported
	Trazodone			S	Oral	Df Once Po		Not Reported
	Chlorprothixene			S	Oral	Df Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2005	5870914	EXPEDITED (15-DAY)	Y	OT	SO5-USA-03682-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Porphyria; Rash	Lexapro			S	Oral	10 Mg Qd, Po		Not Reported
	Procrit			S		30000 Units Qmon		Not Reported
	Coumadin			C				Not Reported
	Ivig (Immunoglobulin)			C				Not Reported
	Tarka			C				Not Reported
	Coreg			C				Not Reported
	Bovina (Irbandronate)			C				Not Reported
	Orpn (Iron)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2005	5855183	EXPEDITED (15-DAY)	Y	CA	S05-SWI-02528-02		< 1 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Foetal; Caesarean Section; Congenital Anomaly; Foetal Growth Restriction; Maternal Exposure During Pregnancy	Cipralex			S	Transplacental	15 Mg Qd Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2005	5766153	EXPEDITED (15-DAY)	Y	OT	S05-USA-01213-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Decreased Activity; Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Neonatal Disorder; Selective Eating	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Lexapro			S		20 Mg Qd Bf		Not Reported
	Tylenol Pm			C				Not Reported
	Stadol			C				Not Reported
	Darvocet			C				Not Reported

Disorder; Small For Dates
Baby; Somnolence
Neonatal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2005	4076963	NON-EXPEDITED	Y	DE	USA-2003-0006530		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Overdose	Oxycontin			S		20 Mg, Q12h		Not Reported
	Reglan			S		10 Mg, Qid Prn		Not Reported
	Lexapro			S		10, Daily		Not Reported
	Percocet			S		5 Mg, Q4h Prn		Not Reported
	Zantac			S		300 Mg, Bid Prn		Not Reported
	Zanaflex			S				Not Reported
	Flagyl			S		500 Mg, Bid		Not Reported
	Cyclobenzaprine Hydrochloride			C				Not Reported
	Amoxicillin			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Methadone Hydrochloride			C				Not Reported
	Amitriptyline			C				Not Reported
	Celebrex			C				Not Reported
	Zoloft			C				Not Reported
	Concerta			C				Not Reported
	Mavik			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2005	5796570	EXPEDITED (15-DAY)	Y	HO	S05-USA-02225-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phlebitis; Treatment Noncompliance	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2005	5871878	DIRECT	Y	HO			7 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Hyperexplexia; Hyperreflexia; Maternal Exposure During Pregnancy; Neonatal Seizure; Subarachnoid Haemorrhage; Subdural Haemorrhage	Lexapro			S				Not Reported
	Prednisone			C				Not Reported
	Augmentin			C				Not Reported
	Ranitidine Hydrochloride			C				Not Reported
	Advair Diskus			C				Not Reported
	Flonase			C				Not Reported
	Penicillin			C				Not Reported
	Clacium			C				Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5803024	NON-EXPEDITED	N	HO, LT	US-BRISTOL-MYERS SQUIBB COMPANY-12965893		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Intentional Product Misuse; Mania; Suicide Attempt; Weight Increased	Abilify			S				Not Reported
	Trazodone Hydrochloride			S				Apothecon
	Lexapro			S	Oral			Not Reported
	Lithium			S				Not Reported
	Lamictal			S				Not Reported
	Seroquel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5868944	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-12960563			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Drug Interaction; Irritability; Mood Swings	Abilify			S				Not Reported
	Cytomel			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5868967	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-12971420		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension;	Abilify		S			Not Reported
Amenorrhoea; Blister; Constipation; Face Oedema; Hypomenorrhoea; Increased Tendency To Bruise; Menorrhagia; Polymenorrhoea; Vision Blurred	Lexapro		S	Oral	Increased To 20 Mg/Day After 1 Week Of Therapy.	Not Reported
	Lexapro		S	Oral	Increased To 20 Mg/Day After 1 Week Of Therapy.	Not Reported
	Topamax		C			Not Reported
	Ambien		C			Not Reported
	Ativan		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5869013	NON-EXPEDITED	Y	HO	US-BRISTOL-MYERS SQUIBB COMPANY-12984332		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Drug Interaction; Intentional Product Misuse; Irritability; Lethargy; Suicidal Ideation	Abilify			S				Not Reported
	Cytomel			S				Not Reported
	Klonopin			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Strattera			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5869153	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-13043013		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Abilify			S	Oral			Not Reported
	Lexapro			S	Oral	Dosage: Increased To 20mg Daily On 03-Jan-2005		Not Reported
	Prozac			S	Oral	Dosage: 20mg Daily 07-Feb-2005 To Unknown, 40mg Daily 24-Apr-2005 To Continuing		Not Reported
	Depakote			C				Not Reported
	Lisinopril			C				Not Reported

	Diovan	C			Not Reported
	Coreg	C			Not Reported
	Wellbutrin	C	Dosage: Decreased To 200mg Daily On 11-Apr-2005 And Continuing		Not Reported
	Acetaminophen\Hydrocodone Bitartrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5869533	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0558167A		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Insomnia	Wellbutrin Xl			S	Oral	150mg Per Day	8 WEEK	Glaxosmithkline
	Effexor Xr			S	Oral	37.5mg Per Day	4 YR	Not Reported
	Lexapro			S	Oral			Not Reported
	Celebrex			C				Not Reported
	Neurontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5869575	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0559560A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis	Wellbutrin Xl			S	Oral			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5869690	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0562623A		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Myalgia	Wellbutrin			S	Oral	150mg Per Day	6 DAY	Glaxosmithkline
	Lexapro			S				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5870084	EXPEDITED (15-DAY)	Y	HO, LT	2005UW12747		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardio-Respiratory Arrest; Liver Disorder; Multiple Organ Dysfunction Syndrome	Seroquel			S	Oral			Zeneca
	Lithium			S				Not Reported
	Vistaril			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5871968	EXPEDITED (15-DAY)	Y	OT	S05-USA-04051-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5871969	EXPEDITED (15-DAY)	N	OT	S05-USA-04045-01		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Weight Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Antibiotics			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2005	5871970	EXPEDITED (15-DAY)	Y	OT	S05-USA-04027-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Platelet Disorder	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2005	5874213	EXPEDITED (15-DAY)	Y	CA	S05-UKI-03089-02			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Dysmorphism; Finger Deformity; Maternal Exposure During Pregnancy	Cipralex			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Prochlorperazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2005	5874236	EXPEDITED (15-DAY)	Y	DE	S05-UKI-03087-01		54 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Head Injury; Multiple Injuries	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2005	5874657	EXPEDITED (15-DAY)	N	DE	S05-USA-03967-01		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Completed Suicide; Condition Aggravated; Drug Ineffective; Drug Withdrawal Syndrome; Insomnia; Nervousness; Restlessness; Tremor	Lexapro			S	Unknown	Unk		Not Reported
	Effexor			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2005	5874663	EXPEDITED (15-DAY)	Y	HO, RI	S05-USA-06025-01		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorectal Disorder;	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Forceps Delivery; Maternal Exposure During Pregnancy; Muscle Strain; Pregnancy; Premature Labour; Vaginal Haemorrhage	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Prenatal Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2005	5859869	EXPEDITED (15-DAY)	Y	HO	S05-PRT-02685-01		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Depression; Diarrhoea; Faeces Pale; Hyperhidrosis	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Warfarin Sodium			C				Not Reported
	Digoxin			C				Not Reported
	Amiloride Hcl W/ Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2005	5874892	EXPEDITED (15-DAY)	Y	OT	S05-USA-04059-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2005	5874922	EXPEDITED (15-DAY)	Y	OT	S05-USA-04061-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicidal Ideation; Physical Assault	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2005	5875407	EXPEDITED (15-DAY)	Y	OT	GXKR2005IT01511		60 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Epistaxis; Platelet Aggregation Increased; Rectal Haemorrhage	Mirtazapine	S	15 Mg, Qd; 7.5, Qd	Not Reported
	Venlafaxine Hydrochloride	S	150 Mg, Qd; 100 Mg, Qd; 37.5 Mg, Qd	Not Reported
	Escitalopram Oxalate	S	20 Mg, Qd; 15 Mg, Qd; 5 Mg, Qd	Not Reported
	Omeprazole	C		Not Reported
	Irbesartan	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2005	5849936	EXPEDITED (15-DAY)	Y	OT	2005PK01362		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Incomplete; Abortion Missed; Maternal Exposure During Pregnancy; Pregnancy	Seroquel			S		50 Mg Up To 400 Mg		Zeneca
	Seroquel			S		50 Mg Up To 400 Mg		Zeneca
	Seroquel			S				Zeneca
	Seroquel			S				Zeneca
	Seroquel			S			7 DAY	Zeneca
	Seroquel			S			7 DAY	Zeneca
	Seroquel			S				Zeneca
	Seroquel			S				Zeneca
	Seroquel			S				Zeneca
	Seroquel			S				Zeneca
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral		5 DAY	Not Reported
	Cipralex			S	Oral		5 DAY	Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2005	5872246	EXPEDITED (15-DAY)	N	HO, OT	2005116861		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropod Bite; Drug Ineffective; Dry Mouth; Foot Fracture; Hip Arthroplasty; Hyperhidrosis; Incorrect Dose Administered; Insomnia; Migraine	Detrol La			S	Oral	4 Mg (4 Mg, 1 In 1 D), Oral		Not Reported
	Soma			S				Not Reported
	Lexapro			S				Not Reported
	Celebrex			C				Not Reported
	Plaquenil			C				Not Reported
	Neurontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2005	5876716	DIRECT	N	CA, DS, LT, RI			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Balance Disorder; Brain Injury; Bruxism; Chills; Disturbance In Attention; Dysstasia; Fall; Headache; Heart Rate Increased; Hyperacusis; Hypersensitivity; Hypertension; Panic Reaction; Paraesthesia; Photophobia; Premature Ejaculation; Sexual Dysfunction; Sleep Disorder; Vertigo; Weight Increased	Lexapro			S				Not Reported
	Zoloft			S				Not Reported
	Provigil			C				Not Reported
	Trileptal			C				Not Reported
	Seroquel			C				Not Reported
	Buspar			C				Not Reported
	Ultramadol			C				Not Reported
	Flexeril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2005	5877001	EXPEDITED (15-DAY)	Y	HO	T05-USA-03086-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anhedonia; Antibody Test Positive; Caesarean Section; Depressed Mood; Feeling Guilty; Gestational Diabetes; Initial Insomnia; Libido Decreased; Maternal Exposure During Pregnancy; Metrorrhagia; Mitral Valve Prolapse; Pneumonia; Pre-Eclampsia; Pregnancy; Premature Baby; Stress; Tachycardia; Upper Respiratory Tract Infection; Urinary Tract Infection	Escitalopram Oxalate	S	10 Mg Qd		Not Reported
	Claritin	C			Not Reported
	Zoloft	C			Not Reported
	Prenatal Vitamins	C			Not Reported
	Rhogam	C			Not Reported
	Albuterol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2005	5877003	EXPEDITED (15-DAY)	Y	HO	S05-USA-04134-01		93 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Febrile Neutropenia; Hepatotoxicity	Lexapro (Escitalopram)			S	Oral	20 Mg Qd Po		Not Reported
	Zelnorm			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2005	5877262	EXPEDITED (15-DAY)	Y	OT	S05-UKI-03165-01		34 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Fluoxetine			C				Not Reported
	Arthrotec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2005	5880276	EXPEDITED (15-DAY)	Y	HO	S05-UKI-03169-01		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Sinus Arrhythmia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2005	5864509	EXPEDITED (15-DAY)	Y	HO	S05-USA-01042-01		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Dizziness; Dry Mouth; Escherichia Infection; Nausea; Therapeutic Response Unexpected; Urinary Retention; Urosepsis	Lexapro			S	Oral	20 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Trileptal			C				Not Reported
	Crestor			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2005	5863883	EXPEDITED (15-DAY)	Y	HO, LT	S05-AUS-02778-01		53 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Ramipril			C				Not Reported
	Metoprolol			C				Not Reported
	Norvasc			C				Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported
	Clopidogrel			C				Not Reported
	Allopurinol			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2005	5872623	EXPEDITED (15-DAY)	Y	OT	S05-USA-03979-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Dry Mouth; Insomnia; Postmenopausal Haemorrhage; Urinary Tract Infection	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Progesterone		S			Not Reported
	Estrogens		S			Not Reported
	Wellbutrin (Bupropion Hydrochloride)		C			Not Reported
	Lisinopril		C			Not Reported
	Singulair		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2005	4215792	EXPEDITED (15-DAY)	Y	HO, RI	S04-USA-06025-01		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Forceps Delivery; Labour Complication; Labour Induction; Maternal Exposure During Pregnancy; Muscle Strain; Premature Labour; Vaginal Haemorrhage	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Prenatal Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2005	5880535	DIRECT	N	OT			31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Androgenetic Alopecia	Lexapro			S	Oral	10 Mg Qd Po		Forest
	Bactrim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2005	5880592	DIRECT	N	OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Oral	10 Mg Qd Po		Forest
	Ortho Tri Cyclen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2005	5880808	EXPEDITED (15-DAY)	N	OT	S05-USA-04116-01		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Confusional State; Constipation; Dementia Alzheimer'S Type; Gait Disturbance; Treatment Noncompliance	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Namenda			S	Oral	15 Mg Qd Po		Not Reported
	Namenda			S	Oral	10 Mg Bid Po		Not Reported
	Reminyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2005	5881328	EXPEDITED (15-DAY)	Y	HO, OT	S05-UKI-03255-01		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis; Melaena	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5795242	NON-EXPEDITED	Y	HO, OT	S05-USA-00617-01		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Depression; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Saizen			S				Not Reported
	Metadate Cd			S	Oral	20 Mg Bid Po		Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5804657	EXPEDITED (15-DAY)	N	HO	S05-USA-01759-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diplopia; Drug Interaction; Facial Paralysis; Nausea; Vertigo; Vomiting	Wellbutrin		S	Oral	150mg Per Day		Glaxosmithkline
	Lexapro		S	Oral	40mg Per Day	357 DAY	Forest
	No Concurrent Medications		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5822551	NON-EXPEDITED	Y	HO	S05-USA-01861-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Haemorrhage	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Aspirin			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5822589	NON-EXPEDITED	Y	HO	S05-USA-01146-01		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Trivora			C				Not Reported
	Dynacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5822739	NON-EXPEDITED	Y	HO	S05-USA-02568-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Blood Pressure Decreased; Drug Interaction; Heart Rate Increased; Intentional Product Misuse; Irritability; Lethargy; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported

	Cytomel	S	Not Reported
	Abilify	S	Not Reported
	Klonopin	S	Not Reported
	Strattera	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5827206	EXPEDITED (15-DAY)	Y	HO	S05-NOR-02118-01			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Diarrhoea; Dysphonia; Tremor	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5844939	EXPEDITED (15-DAY)	Y	LT, OT	S05-UKI-02358-01		59 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intracranial Aneurysm; Subarachnoid Haemorrhage	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Clopidogrel			S	Oral	75 Mg Qd Po		Not Reported
	Aspirin (Acetylsalicylic Acid)			S	Oral	75 Mg Qd Po		Not Reported
	Salmeterol			C				Not Reported
	Terbutaline Sulfate			C				Not Reported
	Lekovit Ca			C				Not Reported
	Tiotropium Bromide (Tiotropium Bromide)			C				Not Reported
	Atorvastatin			C				Not Reported
	Pantoprazole Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5877657	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20050901973		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cerebral Infarction; Completed	Acetaminophen And Codeine Phosphate			S	Oral			Not Reported
	Acetaminophen\Hydrocodone			S				Not Reported

Suicide; Intentional Product Misuse; Liver Function Test Abnormal; Pneumonia; Renal Failure	Acetaminophen\Hydrocodone		S		Not Reported
	Escitalopram Oxalate		S		Not Reported
	Ibuprofen		S		Not Reported
	Celecoxib		S		Not Reported
	Zolpidem		S		Not Reported
	Metronidazole		S		Not Reported
	Diazepam		S		Not Reported
	Metaxalone		S		Not Reported
	Amitriptyline		S		Not Reported
	Citalopram		S		Not Reported
	Metformin		S		Not Reported
	Aspirin		S		Not Reported
	Bupropion		S		Not Reported
	Codeine		S		Not Reported
	Promethazine		S		Not Reported
	Nabumetone		S		Not Reported
	Ibuprofen	Y	S		Not Reported
	Asa	Y	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5881347	DIRECT	Y	OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Oral	20 Mg Qd Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5881891	EXPEDITED (15-DAY)	Y	DE	S05-USA-04205-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Partner Stress; Treatment Noncompliance	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5882911	DIRECT	N	DE			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Confusional State; Intentional Product Misuse	Zoloft			S	Oral	1 Day Po		Not Reported
	Lexapro			S		1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5883009	EXPEDITED (15-DAY)	Y	DS, HO	S05-UKI-03314-01		33 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Magnesium Decreased; Generalised Tonic-Clonic Seizure	Cipralex			S	Oral	20 Mg Po		Not Reported
	Granisetron			S	Subcutaneous	2 Mg Daily Sc		Not Reported
	Feldene			C				Not Reported
	Oxybutynin			C				Not Reported
	Gabapentin			C				Not Reported
	Lorazepam			C				Not Reported
	Loperamide			C				Not Reported
	Levomepromazine			C				Not Reported
	Metronidazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5883403	EXPEDITED (15-DAY)	Y	LT, OT	S05-UKI-03317-01		41 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Gastrointestinal Haemorrhage	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Zumeston			C				Not Reported
	Lormetazepam			C				Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5883408	EXPEDITED (15-DAY)	Y	OT	S05-CAN-03318-01		80 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Product Quality Issue;	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			C				Not Reported

Seizure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5883412	EXPEDITED (15-DAY)	Y	OT	S05-UKI-03313-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Cipralex			S		10 Mg Po		Not Reported
	Zolpidem			C				Not Reported
	Dothiepin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5884729	NON-EXPEDITED	Y	HO	S05-USA-03909-01		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5884732	NON-EXPEDITED	N	DS	S05-USA-03754-01		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Diplopia	Lexapro			S				Not Reported
	Digoxin			C				Not Reported
	Coumadin			C				Not Reported
	Altace			C				Not Reported
	Pravachol			C				Not Reported
	Allopurinol			C				Not Reported
	Synthroid			C				Not Reported
	Lasix			C				Not Reported
	Singulair			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5884734	NON-EXPEDITED	N	HO	S05-USA-03625-01		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Zyprexa			C				Not Reported
	Aricept			C				Not Reported
	Lisinopril			C				Not Reported
	Ambien			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5884737	NON-EXPEDITED	N	HO, LT	S05-USA-03610-01		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Fatigue; Irritability; Suicide Attempt	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5884739	NON-EXPEDITED	N	HO	S05-USA-03603-01		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Malaise; Suicide Attempt	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Tenex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	5884740	NON-EXPEDITED	N	HO	S05-USA-03515-01		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dry Mouth; Dysuria; Genital Burning Sensation; Rib Fracture; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

	Clonazepam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2005	6299532	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20050902024		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Hepatic Enzyme Increased; Hyperpyrexia; Hypotension; Muscle Rigidity; Ventricular Tachycardia	Haldol			S				Not Reported
	Ziprasidone Hydrochloride			S				Not Reported
	Benztropine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Clonazepam			S				Not Reported
	Simvastatin			S				Not Reported
	Buproprion			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2005	5879232	EXPEDITED (15-DAY)	Y	DE	CH-JNJFOC-20050901541			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Haldol			S	Oral	Reported As 3-4mg		Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Remeron			S	Oral			Not Reported
	Remeron			S	Oral			Not Reported
	Remeron			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported

	Cipralex	S	Oral			Not Reported
	Cipralex	S	Oral			Not Reported
	Agar\Phenolphthalein	S	Oral			Not Reported
	Agar\Phenolphthalein	S	Oral			Not Reported
	Agar\Phenolphthalein	S	Oral			Not Reported
	Cosaar Plus	S	Oral			Not Reported
	Cosaar Plus	S	Oral	Had Been Taken For Years		Not Reported
	Sortis	S	Oral	Had Been Taken For Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2005	5879627	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20050902016		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block; Cardiac Arrest; Completed Suicide; Intentional Product Misuse; Loss Of Consciousness; Overdose; Serotonin Syndrome	Topamax			S				Not Reported
	Bupropion			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Oxcarbazepine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2005	5879631	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20050901926		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone And Acetaminophen			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

	Quetiapine	S	Oral		Not Reported
	Gabapentin	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2005	6747156	NON-EXPEDITED	N	OT	US-JNJFOC-20040806645		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration	Topamax			S	Oral	25 Mg, In 1 Day, Oral		Not Reported
	Escitalopram Oxalate			S	Oral	25 Mg, In 1 Day , Oral; See Image		Not Reported
					Oral	25 Mg, In 1 Day , Oral; See Image		
	Zoloft			S	Oral	150 Mg, In 1 Day, Oral		Not Reported
	Vioxx			S		25 Mg, In 1 Day		Not Reported
	Zocor			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Mirapex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2005	5837867	EXPEDITED (15-DAY)	Y	OT	S05-USA-03294-01		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Basal Ganglion Degeneration; Dry Mouth; Dysarthria; Nervous System Disorder; Nervousness; Nuclear Magnetic Resonance Imaging Brain Abnormal; Restlessness; Speech Disorder; Tardive Dyskinesia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Namenda			S	Oral	10 Mg Bid Po		Not Reported
	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Namenda			S	Oral	15 Mg Qd Po		Not Reported
	Aricept			S		10 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2005	5842005	EXPEDITED (15-DAY)	Y	DE	S05-UKI-02357-01			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2005	5866528	EXPEDITED (15-DAY)	N	OT	S05-USA-03905-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Petit Mal Epilepsy	Lexapro			S	Oral	10 Mg Qhs Po		Not Reported
	Zonegran			C				Not Reported
	Phenobarbital			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2005	5885544	EXPEDITED (15-DAY)	Y	HO	S05-ITA-03334-01		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Urticaria	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2005	5836038	EXPEDITED (15-DAY)	Y	HO	S05-USA-03276-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Feeling Abnormal; Heart Rate Irregular; Loss Of Consciousness; Sinus Bradycardia; Sinus Tachycardia; Supraventricular Extrasystoles	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Vioxx			S	Oral	25 Mg Qd Po		Not Reported
	Fosamax			S	Oral	70 Mg Qw Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2005	5845150	EXPEDITED (15-DAY)	Y	DE	S05-USA-03457-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Gun Shot Wound	Lexapro		S	Oral	10 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2005	5885323	DIRECT	N	DE			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S			30 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2005	5835587	EXPEDITED (15-DAY)	Y	HO, LT, OT	S05-PAN-02194-01		16 YR	Female	PAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Intentional Product Misuse; Overdose; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Zolpidem			S	Oral	10 Mg Qd Po		Not Reported
	Zolpidem			S	Oral	400 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2005	5886500	EXPEDITED (15-DAY)	Y	OT	S05-PRT-03392-01		28 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Drug Ineffective; Psychomotor Hyperactivity	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Bromazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2005	5886748	EXPEDITED (15-DAY)	Y	DE	S05-USA-04155-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Lexapro			S	Oral	10 Mg Bid Po		Not Reported

	Lexapro	S	Oral	20 Mg Bid Po	Not Reported
	Percocet	C			Not Reported
	Klonopin	C			Not Reported
	Seroquel	C			Not Reported
	Fioricet	C			Not Reported
	Caltrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2005	5883634	EXPEDITED (15-DAY)	Y	DE	2005AC01406		40 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Quetiapine			S		Route: Aspiration		Zeneca
	Escitalopram Oxalate			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2005	5885462	EXPEDITED (15-DAY)	Y	DE	2005AC01471		25 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Amitriptyline			S	Oral			Zeneca
	Alprazolam			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2005	5890407	EXPEDITED (15-DAY)	Y	OT	S05-FRA-03473-01		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Prazepam			S				Not Reported
	Equanil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2005	5891112	EXPEDITED (15-DAY)	Y	DE	2005129275		25 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Intentional Product Misuse; Overdose	Alprazolam (Alprazolam)			S				Not Reported
	Amitriptyline Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2005	5891475	EXPEDITED (15-DAY)	Y	DE	2005129277		50 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Doxepin Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Metoprolol Tartrate			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2005	5854479	EXPEDITED (15-DAY)	Y	HO	S05-FRA-02532-01		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hypertension; Hypokalaemia	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2005	5874651	EXPEDITED (15-DAY)	N	DE	S05-USA-04006-01		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Suicidal Ideation; Thinking Abnormal; Toxicologic Test Abnormal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Tramadol			C				Not Reported
	Minocycline\Minocycline Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2005	5874894	EXPEDITED (15-DAY)	N	OT	S05-USA-04044-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bulimia Nervosa; Depression; Restlessness; Weight Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Abilify			S		20 Mg Qd		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2005	5892694	EXPEDITED (15-DAY)	N	OT	S05-USA-04330-01		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Drug Interaction	Lexapro			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2005	5892695	EXPEDITED (15-DAY)	N	OT	S05-USA-04289-01		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Calcinosis; Herpes Zoster; Hyperthyroidism; Thyroid Neoplasm	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Flomax			C				Not Reported
	Proscar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2005	5892703	EXPEDITED (15-DAY)	Y	OT	S05-USA-04381-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Decreased Appetite; Drug Interaction; Feeling Abnormal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lipitor			S				Not Reported
	Lipitor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2005	5888143	EXPEDITED (15-DAY)	N	LT	US-JNJFOC-20050905751		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Tylenol		Y	S				Not Reported
	Tylenol			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2005	5712077	EXPEDITED (15-DAY)	Y	DE	S04-UKI-08243-01		17 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Completed Suicide; Depression; Victim Of Homicide	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2005	5889229	EXPEDITED (15-DAY)	N	LT	US-JNJFOC-20050905735		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Motrin			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2005	5892030	DIRECT	Y	HO			95 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Pyrexia; White Blood Cell Count	Lexapro			S			3 WEEK	Forest

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2005	4032971	EXPEDITED (15-DAY)	N	DS, HO, OT	2003114592		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Bradyphrenia; Cholelithiasis; Coordination Abnormal; Depression; Diplegia; Disorientation; Dizziness; Drug Dependence; Drug Interaction; Drug Withdrawal Syndrome; Dry Mouth; Dysarthria; Feeling Abnormal; Feeling Cold; Gait Disturbance; Gait Inability; Glossodynia; Hallucination; Headache; Hot Flush; Hyperhidrosis; Impaired Work Ability; Major Depression; Mental Disorder; Mood Swings; Oral Pain; Panic Attack; Paranoia; Photophobia; Photopsia; Psychotic Disorder; Schizoaffective Disorder; Sjogren'S Syndrome; Stupor; Suicidal Ideation	Geodon			S	Oral	80 Mg (Daily), Oral		Not Reported
	Xanax			S				Not Reported
	Lexapro			S				Not Reported
	Topamax			S		100 Mg		Not Reported
	Prozac			S		40 Mg (Qd Interval: Every Day)		Not Reported
	Cymbalta			S				Not Reported
	Climara			C				Not Reported
	Adderall			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2005	5892185	DIRECT	N	LT			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Personality Change; Suicidal Ideation;	Strattera			S	Oral	One Pill Per Day One Per Day Po		Eli Lilly And Co

Suicide Attempt; Thinking Abnormal; Threat Of Redundancy	Lexapro		S	Oral	One Per Day One Per Day Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2005	5896027	EXPEDITED (15-DAY)	N	DE	S05-USA-04408-01		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation; Anger; Anxiety; Completed Suicide; Condition Aggravated; Depressed Mood; Depression; Drug Ineffective; Drug Ineffective For Unapproved Indication; Educational Problem; Hostility; Intentional Self-Injury; Overdose; Suicidal Ideation; Suicide Attempt	Lexapro			S				Not Reported
	Lexapro			S	Oral	20 Mg Po		Not Reported
	Lexapro			S	Oral	10 Mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2005	5896030	EXPEDITED (15-DAY)	N	HO	S05-USA-04399-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Diplopia; Feeling Jittery; Heart Rate Increased; Intentional Self-Injury; Muscle Spasms; Mydriasis; Thinking Abnormal; Tremor	Lexapro			S	Oral	40 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Adderall			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2005	5896686	EXPEDITED (15-DAY)	Y	DE	DSA_27145_2005		58 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse; Overdose	Lorazepam			S	Oral	Df Unk Po		Not Reported
	Valproic Acid			S	Oral	Df Unk Po		Not Reported
	Escitalopram Oxalate			S	Oral	Df Unk Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2005	5803797	EXPEDITED (15-DAY)	Y	DE	S05-IRL-01738-01		24 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2005	5897973	EXPEDITED (15-DAY)	Y	DE	DSA_70813_2005		42 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Methadone			S	Oral	Df Po		Not Reported
	Tramadol			S	Oral	Df Po		Not Reported
	Escitalopram Oxalate			S	Oral	Df Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2005	5898957	EXPEDITED (15-DAY)	Y	DE	PAR_0269_2005		50 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Doxepin			S	Oral	Df Unk Po		Not Reported
	Escitalopram Oxalate			S	Oral	Df Unk Po		Not Reported
	Metoprolol			S	Oral	Df Unk Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2005	5900575	EXPEDITED (15-DAY)	Y	DE	AND_0038_2005		55 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Acetaminophen And Codeine			S	Unknown	Df Unk Unk		Not Reported
	Acetaminophen\Hydrocodone			S	Unknown	Df Unk Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	Df Unk Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2005	5901942	EXPEDITED (15-DAY)	Y	DE	PAR_0326_2005		58 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Valproic Acid			S	Oral	Df Po		Not Reported
	Escitalopram Oxalate			S	Oral	Df Po		Not Reported
	Lorazepam			S	Oral	Df Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2005	5903182	DIRECT	Y	HO, LT, RI			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Heart Rate Irregular; Intentional Product Misuse; Overdose; Syncope	Escitalopram Oxalate			S	Oral	Po Tid		Not Reported
	Bupropion			S	Oral	Po		Not Reported
	Folic Acid			C				Not Reported
	Thiamine			C				Not Reported
	M.V.I. Adult			C				Not Reported
	Pancrelipase			C				Not Reported
	Oxazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2005	5903358	DIRECT	Y	DE			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Geodon			S	Oral	Po		Not Reported
	Lexapro			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2005	5903480	DIRECT	Y	CA			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypermetropia; Maternal Exposure During Pregnancy; Small For Dates Baby; Strabismus	Lexapro			S	Oral	20mg Daily Po	2 YR	Not Reported
	Prenatal Vitamins			C				Not Reported
	Phenergan			C				Not Reported
	Antivert			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2005	5904313	DIRECT	Y	HO			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Intentional Product Misuse; Intentional Self-Injury; Overdose	Oxycodone			S				Not Reported
	Seroquel			S				Not Reported
	Lexapro			S				Not Reported
	Ativan			S				Not Reported
	Topamax			S				Not Reported
	Tylenol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2005	5806087	EXPEDITED (15-DAY)	Y	HO	S05-USA-02559-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis Neonatal; Maternal Exposure During Pregnancy; Neonatal Hypoxia	Lexapro			S				Not Reported
	Prenatal Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2005	5809412	EXPEDITED (15-DAY)	Y	HO	S05-USA-02558-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During	Lexapro			S				Not Reported

Pregnancy; Neonatal Hypoxia	Prenatal Vitamins	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2005	5899542	DIRECT	Y	HO			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2005	5905382	EXPEDITED (15-DAY)	Y	DS	S05-NOR-03580-01		85 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Decreased Appetite; Insomnia; Nausea; Restlessness	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qod Po		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2005	5905387	EXPEDITED (15-DAY)	Y	DE	S05-NLD-03579-01		79 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Haemorrhage	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported
	Lorazepam			C				Not Reported
	Dextran			C				Not Reported
	Amaryl			C				Not Reported
	Metformin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2005	5904068	EXPEDITED (15-DAY)	Y	HO	S05-FRA-03644-01		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Escitalopram Oxalate			S				Not Reported

Glaucoma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2005	5904073	EXPEDITED (15-DAY)	Y	HO	A044-002-005755		85 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Faeces Discoloured; Gastritis Erosive; Gastrointestinal Haemorrhage; Melaena; Rectal Haemorrhage; Upper Gastrointestinal Haemorrhage	Aricept			S	Oral	10 Mg, 1 In 1 D, Oral		Not Reported
	Escitalopram Oxalate			S	Oral Oral	See Image See Image		Not Reported
	Bendroflumethiazide (Bendroflumethiazide)			C				Not Reported
	Latanoprost			C				Not Reported
	Timolol Maleate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2005	5904230	EXPEDITED (15-DAY)	Y	DE	2005-BP-12458RO		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ammonia Increased; Blood Bilirubin Increased; Mental Status Changes	Methadone Hydrochloride			S	Oral	5 Mg Bid (5 Mg), Po 1 To 2 Weeks		Not Reported
	Seroquel			S	Oral	125 Mg Qhs Po 1 To 2 Weeks		Not Reported
	Lexapro			S	Oral	10 Mg/Day Po 1 To 2 Weeks		Not Reported
	Xeloda			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2005	5905472	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased	Lexapro			S		20ml Via J-Tube Daily		Not Reported
	Protonix			C				Not Reported
	Synthroid			C				Not Reported
	Imipenim			C				Not Reported

Insulin Nos	C		Not Reported
Procrit	C		Not Reported
Dilaudid	C		Not Reported
Zofran	C		Not Reported
Acetaminophen	C		Not Reported
Vancomycin Hydrochloride	C		Not Reported
Ativan	C		Not Reported
Lasix	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2005	5906704	EXPEDITED (15-DAY)	Y	DE	IMP_0922_2005		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Bupropion			S	Oral	Df, Po		Not Reported
	Escitalopram Oxalate			S		Df,		Not Reported
	Oxcarbazepine			S		Df,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2005	5907141	EXPEDITED (15-DAY)	Y	DE	IMP_0943_2005		39 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Bupropion			S	Oral	Df Po		Not Reported
	Escitalopram Oxalate			S		Df		Not Reported
	Topiramate			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2005	5907144	EXPEDITED (15-DAY)	Y	DE	IMP_0942_2005		52 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Bupropion			S	Oral	Df Po		Not Reported
	Escitalopram Oxalate			S		Df		Not Reported
	Paroxetine Hydrochloride			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2005	5853109	NON-EXPEDITED	Y	HO	2005SP000329			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Erythema Multiforme	Lunesta			S	Oral	2 Mg; Hs; Oral		Not Reported
	Lexapro			S	Oral	10 Mg; Qd; Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2005	5905842	DIRECT	N	RI			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Withdrawal Syndrome; Fatigue; Headache; Influenza Like Illness; Insomnia; Pain; Urinary Tract Disorder	Lexapro			S	Oral	1 10mg Pill Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2005	5906070	DIRECT	N	HO			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Dizziness; Hallucination, Auditory; Hallucination, Visual; Nausea; Nervous System Disorder; Vomiting	Lexapro			S	Oral	10mg Once Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2005	5902276	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-13083746		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bulimia Nervosa; Depression; Increased	Abilify			S	Oral			Not Reported

Appetite; Restlessness	Lexapro		S	Oral	Dosage: Increased To 20 Mg Dialy On 06-Aug-2005 To Continuing	Not Reported
	Klonopin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2005	5908207	EXPEDITED (15-DAY)	Y	OT	S05-GER-03775-01		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed; Foetal Death; Maternal Exposure During Pregnancy	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Seroquel			S		50 Mg Qd		Not Reported
	Seroquel			S		100 Mg Qd		Not Reported
	Seroquel			S		250 Mg Qd		Not Reported
	Seroquel			S		400 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2005	5878894	EXPEDITED (15-DAY)	Y	OT	S05-USA-04148-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Disease Recurrence; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zonegran			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2005	5907978	DIRECT	Y	HO			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Dyspnoea; Feeling Abnormal; Flushing; Heart Rate Increased; Rash	Lexapro			S	Oral	10mg Qd Po		Forest

Macular; Sensation Of Foreign Body; Skin Burning Sensation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2005	5909888	EXPEDITED (15-DAY)	Y	OT	S05-USA-04588-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Paraesthesia; Self-Injurious Ideation; Suicidal Ideation; Vertigo; Weight Decreased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2005	5909892	EXPEDITED (15-DAY)	N	DE	S05-USA-04561-01		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Completed Suicide; Gun Shot Wound; Homicidal Ideation; Physical Assault	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2005	5909911	EXPEDITED (15-DAY)	N	HO	S05-USA-04578-01		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Blood Sodium Decreased; Drug Interaction	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			S		25 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2005	5909965	EXPEDITED (15-DAY)	Y	HO	S05-USA-04587-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal	Lexapro			S				Not Reported
Syndrome	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2005	5885194	EXPEDITED (15-DAY)	Y	DE	T05-SWI-03337-01		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asphyxia; Completed Suicide; Depressive Symptom; Mutism; Restlessness; Sleep Disorder; Thinking Abnormal	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Remeron			S	Oral	30 Mg Qd Po		Not Reported
	Remeron			S	Oral	60 Mg Qd Po		Not Reported
	Haldol			S	Oral	3.5 Mg Qd Po		Not Reported
	Haldol			S	Oral	2 Mg Qd Po		Not Reported
	Haldol			S	Oral	1 Mg Qd Po		Not Reported
	Haldol			S	Oral	2 Mg Qd Po		Not Reported
	Haldol			S	Oral	4 Mg Qd Po		Not Reported
	Lorazepam			S	Oral	1 Mg Qd Po		Not Reported
	Lorazepam			S	Oral	3 Mg Qd Po		Not Reported
	Lorazepam			S	Oral	2 Mg Qd Po		Not Reported
	Lorazepam			S	Oral	1.5 Mg Qd Po		Not Reported
	Lorazepam			S	Oral	0.5 Mg Qd Po		Not Reported
	Lorazepam			S	Oral	1.5 Mg Qd Po		Not Reported
	Atorvastatin			S	Oral	20 Mg Qd Po		Not Reported
	Paragar			C				Not Reported
	Cosaar (Losartan Potassium)			C				Not Reported
	Fluoxetine			C				Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2005	5842006	EXPEDITED (15-DAY)	Y	OT	S05-FRA-02360-01		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Malaise; Muscle Tightness; Paraesthesia; Tachycardia; Tremor; Trismus; Vertigo	Escitalopram Oxalate			S	Oral	10 Mg Once Po		Not Reported
	Atarax			C				Not Reported
	Stresam (Etifoxine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2005	5905561	EXPEDITED (15-DAY)		DE	US-ABBOTT-05P-163-0313856-00		38 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S		Not Reported		Not Reported
	Escitalopram Oxalate			S		Not Reported		Not Reported
	Clonazepam			S		Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2005	5905596	EXPEDITED (15-DAY)		DE	US-ABBOTT-05P-163-0314050-00		58 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse; Overdose	Valproic Acid			S		Not Reported		Not Reported
	Escitalopram Oxalate			S		Not Reported		Not Reported
	Lorazepam			S		Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2005	5914395	EXPEDITED (15-DAY)	Y	OT	S05-CAN-03792-01		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pruritus; Urticaria	Cipralex	S	Oral	10 Mg Qd Po		Not Reported
	Ibuprofen	C				Not Reported
	Tylenol (Paracetamol)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2005	5914401	EXPEDITED (15-DAY)	Y	HO	S05-UKI-03788-01		84 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyuria	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2005	6475976	EXPEDITED (15-DAY)	Y	OT	US-KINGPHARMUSA00001-K200501325		51 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma Scale Abnormal; Dizziness; Loss Of Consciousness; Muscle Twitching; Myoclonus	Kemadrin			S	Oral	15 Mg, Qd		King
	Kemadrin			S		5 Mg, Qd		King
	Zyprexa			S	Oral	5 Mg, Qd		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Cipralex			S	Oral	30 Mg, Qd		Not Reported
	Midazolam			S	Oral	15 Mg, Qd		Not Reported
	Midazolam			S		30 Mg, Qd		Not Reported
	Valium			S	Intravenous (not otherwise specified)	10 Mg, Unk	1440 MIN	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2005	5906307	EXPEDITED (15-DAY)		OT	CA-ABBOTT-05P-028-0313974-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pruritus; Urticaria	Cipralex	S	Oral		Not Reported
	Ibuprofen	C			Not Reported
	Paracetamol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2005	7385661	EXPEDITED (15-DAY)		OT	US-ABBOTT-05P-163-0313540-00		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer In Situ	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Multivitamins			C				Not Reported
	Minoxidil			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2005	5903103	EXPEDITED (15-DAY)	Y	DE	AND_0141_2005		38 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Overdose; Respiratory Arrest	Acetaminophen W/Hydrocodone			S	Oral	Df, Po		Not Reported
	Escitalopram Oxalate			S	Oral	Df, Po		Not Reported
	Clonazepam			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2005	5917404	EXPEDITED (15-DAY)	Y	HO	S05-USA-04628-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Holding; Heart Rate Decreased; Oxygen Saturation Decreased	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Lexapro			S		10 Mg Qd Bf		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2005	5910774	DIRECT	N	HO, LT			22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Emotional Disorder; Intentional Self-Injury; Suicide Attempt	Lexapro		S	1 Tablet Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2005	5918117	EXPEDITED (15-DAY)	N	OT	S05-USA-04683-01		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Euphoric Mood; Headache; Loss Of Consciousness; Refusal Of Treatment By Patient; Seizure; Tinnitus; Tonic Clonic Movements	Lexapro			S				Not Reported
	Protonix			C				Not Reported
	Zofran			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2005	5918170	EXPEDITED (15-DAY)	Y	HO	S05-UKI-03864-01		28 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Malaise; Rash Pruritic; Vomiting	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2005	5910756	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation	Escitalopram Oxalate			S	Oral	5 Mg Tid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2005	5884736	EXPEDITED (15-DAY)	Y	HO, LT	S05-USA-03614-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Obstruction;	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

Pancreatitis Acute; Pseudocyst	Maxzide		S	Oral	75 Mg Po	Not Reported
	Mavik		S	Oral	8 Mg Po	Not Reported
	Trazodone Hydrochloride		C			Not Reported
	Indocin		C			Not Reported
	Reglan		C			Not Reported
	Erythromycin		C			Not Reported
	Premarin		C			Not Reported
	Zyrtec		C			Not Reported
	Singulair		C			Not Reported
	Provigil		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2005	5904889	EXPEDITED (15-DAY)	Y	HO	S05-AUT-03578-01		30 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Generalised Non-Convulsive Epilepsy; Loss Of Consciousness; Malaise; Shock	Cipralex			S	Oral	10 Mg Bid Po		Not Reported
	Dietary Supplement			S		30 Drops Prn		Not Reported
	Aspirin			S	Oral	100 Mg Qd Po		Not Reported
	Lisinopril			S	Oral	5 Mg Qd Po		Not Reported
	Pravacol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2005	5915109	EXPEDITED (15-DAY)	Y	LT	S05-GER-03738-01		69 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Circulatory Collapse; Hyperkalaemia; Mydriasis	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lyrica			C				Not Reported
	Valoron N			C				Not Reported
	Voltaren			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Kalinor (Potassium Chloride)			C				Not Reported
	Metoclopramide			C				Not Reported
	Fragmin (Heparin-Fraction, Sodium Slat)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2005	5895847	EXPEDITED (15-DAY)	N	OT	S05-USA-04382-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cluster Headache; Feeling Abnormal; Loss Of Personal Independence In Daily Activities; Nausea	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qod Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2005	5906309	EXPEDITED (15-DAY)		LT	DE-ABBOTT-05P-062-0313996-00			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Circulatory Collapse; Mydriasis	Cipralex			S	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Lyrica			C				Not Reported
	Valoron N			C	Oral			Not Reported
	Voltaren			C	Oral			Not Reported
	Esomeprazole			C	Oral			Not Reported
	Potassium Chloride			C				Not Reported
	Metoclopramide			C				Not Reported
	Enoxaparin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2005	5920625	EXPEDITED (15-DAY)	Y	OT	S05-USA-04273-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Stem Infarction; Dystonia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2005	5886077	EXPEDITED (15-DAY)	Y	OT	S05-USA-04272-01		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; International Normalised Ratio Increased; Thrombosis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2005	5904090	EXPEDITED (15-DAY)	N	OT	S05-USA-04514-01		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Blood Pressure Fluctuation; Diarrhoea; Dyspnoea; Heart Rate Abnormal; Mydriasis; Visual Impairment	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported
	Depakote			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2005	5921604	EXPEDITED (15-DAY)	Y	HO	S05-FRA-03996-01		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Pyrexia; Self-Medication; White Blood Cell Count Decreased	Escitalopram Oxalate			S				Not Reported
	Tetrazepam			S				Not Reported
	Aceprometazine\Meprobamate			C				Not Reported
	Amaryl			C				Not Reported
	Visceralgine Forte			C				Not Reported
	Aspirin Lysine			C				Not Reported
	Mopral (Omeprazole)			C				Not Reported
	Vastarel			C				Not Reported
	Calcium W/Colecalciferol (Calcium W/Colecalciferol)			C				Not Reported
	Sectral			C				Not Reported
	Victan (Ethyl Loflazepate)			C				Not Reported
	Atorvastatin Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2005	6685340	EXPEDITED (15-DAY)	Y	OT	S05-SWI-03647-01		52 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Myoclonus	Cipralex			S	Oral	10 Mg Tid Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Zyprexa			S	Oral	5 Mg Qd Po		Not Reported
	Dormicum (Midazolam)			S	Oral	15 Mg Bid Po		Not Reported
	Dormicum (Midazolam)			S	Oral	15 Mg Qd Po		Not Reported
	Kemadrin			S	Oral	5 Mg Po		Not Reported
	Valium			S	Intravenous (not otherwise specified)	10 Daily Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2005	5916815	EXPEDITED (15-DAY)		HO	2005UW16044		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Blood Sodium Decreased; Drug Interaction	Seroquel			S	Oral			Zeneca
	Lexapro			S	Oral		7 DAY	Not Reported
	Lexapro			S	Oral		7 DAY	Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2005	5921270	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome; Headache; Medication Error; Pain; Product Dispensing Error; Wrong Product Administered	Lexapro			S		Tablet		Forest
	Lipitor			S		Tablet		Pfizer
	Crestor			S		Tablet		Astrazeneca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2005	5923271	EXPEDITED (15-DAY)	Y	OT	S05-UKI-04156-01		42 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alcohol Use; Dissociative Amnesia; Treatment Noncompliance	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2005	5923273	EXPEDITED (15-DAY)	Y	OT	S05-UKI-04005-01		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrested Labour; Caesarean Section; Maternal Exposure During Pregnancy	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Clotrimazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2005	5880868	EXPEDITED (15-DAY)	N	DS, HO, LT, OT	2005-09-0270		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Aphasia; Blood Pressure Diastolic Decreased; Blood Pressure Systolic Increased; Cerebrovascular Accident; Gait Inability; Hypersensitivity; Liver Tenderness; Loss Of Consciousness; Memory Impairment; Mental Disorder; Myocardial Infarction; Neoplasm Malignant; Renal Failure;	Pegintron			S	Subcutaneous	50 Mcg Subcutaneous		Not Reported
	Rebetol			S	Oral	600 Mg Oral		Not Reported
	Lexapro			S	Oral	20 Mg Oral		Not Reported
	Clonidine Hydrochloride			C				Not Reported
	Morphine Sulfate Tablets			C				Not Reported
	Nexium (Esomeprazole Magnesium)			C				Not Reported
	Xanax			C				Not Reported
	Klonopin			C				Not Reported

Seizure; Skin Discolouration; Skin Exfoliation; Spinal Compression Fracture; Wheelchair User

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2005	5892698	EXPEDITED (15-DAY)	N	OT	S05-USA-04393-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Metrorrhagia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Humalog			C				Not Reported
	Femhrt`			C				Not Reported
	Lipitor			C				Not Reported
	Ditropan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2005	5907971	EXPEDITED (15-DAY)	Y	HO	S05-FRA-03152-01		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus Inadequate Control; Hypertriglyceridaemia; Pancreatitis Acute	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported
	Risperdal			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Mianserin Hydrochloride			C				Not Reported
	Lorazepam			C				Not Reported
	Theraline (Alimemazine Tartrate)			C				Not Reported
	Dipiperon (Pipamperone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2005	5925054	EXPEDITED (15-DAY)	Y	HO	S05-USA-03846-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Depression; Inappropriate Schedule Of Product Administration;	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Mental Disorder; Paranoia; Psychotic Disorder; Somnolence	Lexapro		S	Oral	20 Mg Qd Po	Not Reported
	Lexapro		S	Oral	20 Mg Qd Po	Not Reported
	Wellbutrin (Bupropion Hydrochloride)		S			Not Reported
	Risperdal		S	Oral	3 Mg Qd Po	Not Reported
	Risperdal		S			Not Reported
	Risperdal		S	Oral	0.5 Mg Qd Po	Not Reported
	Multi-Vitamin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2005	5921657	DIRECT	Y	OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased	Lexapro			S	Oral	10 Mg, Decreased To 5 Mg Qd Po	532 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2005	5922289	DIRECT	N	OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Crying; Drug Hypersensitivity; Drug Withdrawal Syndrome; Dyskinesia; Feeling Drunk; Heart Rate Increased; Muscle Spasms; Psychiatric Symptom; Somnolence; Tremor	Zoloft			S	Oral	1 Per Day Po		Not Reported
	Lexapro			S	Oral	1 Per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2005	5877011	EXPEDITED (15-DAY)	Y	HO	S05-USA-04139-01		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Hypertensive Crisis; Hypoaesthesia; Loss Of Consciousness; Renal Failure; Urosepsis	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Metoprolol			C				Not Reported
	Antiretrovirals (Nos)			C				Not Reported
	Dapsone			C				Not Reported
	Prevacid			C				Not Reported
	Diovan			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Cephalexin			C				Not Reported
	Zithromax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2005	5892685	EXPEDITED (15-DAY)	Y	OT	S05-FRA-03472-01		37 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Homicidal Ideation; Suicidal Ideation	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Paroxetine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2005	5888191	EXPEDITED (15-DAY)	Y	HO	S05-NOR-03396-01		25 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Sobril (Oxazepam)			C				Not Reported
	Vallergran (Alimemazine Tartrate) (Alimemazine Tartrate)			C				Not Reported
	Imovane (Zopiclone)			C				Not Reported
	Furosemide			C				Not Reported
	Docusate Sodium			C				Not Reported

	Sennosides (Sennoside A+B Calcium)	C	Not Reported
	Metoprolol	C	Not Reported
	Potassium Chloride	C	Not Reported
	Ipratropium/Salbutamol 20/120 Mg (Salbutamol W/Ipratropium)	C	Not Reported
	Acetaminophen (Paracetamol) (Acetaminophen)	C	Not Reported
	Sodium Phosphate (Sodium Phosphate (32 P))	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2005	5926685	EXPEDITED (15-DAY)	N	DE	S05-USA-04850-01		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5874896	EXPEDITED (15-DAY)	N	OT	S05-USA-04099-01		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Confusional State; Dizziness; Hypertension; Mania; Palpitations	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lotensin			C				Not Reported
	Seroquel			C				Not Reported
	Paxil			C				Not Reported
	Entex Pse			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Lipitor			C				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5877002	EXPEDITED (15-DAY)	N	HO, LT	S05-USA-04098-01		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Ascites; Cerebrovascular Accident; Drug Hypersensitivity; Fall; Foot Fracture; Hepatitis; Mental Disorder; Myocardial Infarction; Neoplasm Malignant; Nightmare; Oedema Peripheral; Refusal Of Treatment By Patient; Renal Disorder; Renal Failure; Seizure; Somnambulism; Spinal Compression Fracture; Weight Increased	Lexapro	S	Oral	20 Mg Qd Po		Not Reported
	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Pegintron	S	Subcutaneous	50 Mcg Sc		Not Reported
	Rebetol	S	Oral	600 Mg Po		Not Reported
	Morphine Sulfate	C				Not Reported
	Clonidine	C				Not Reported
	Xanax	C				Not Reported
	Nexium (Esomeprazole)	C				Not Reported
	Cannabis (Cannabis)	C				Not Reported
	Klonopin	C				Not Reported
	Fentanyl	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5899802	EXPEDITED (15-DAY)	Y	OT	S05-GER-03563-01		20 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased	Cipralex			S	Oral	5 Mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5914398	EXPEDITED (15-DAY)	Y	HO	S05-FRA-03799-01		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Scan Abnormal; Cerebral Disorder; Dysarthria; Dyskinesia; Headache; Inflammation; Nystagmus	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Sulfamethoxazole			C				Not Reported
	Norvir			C				Not Reported
	Epivir			C				Not Reported
	Viread			C				Not Reported
	Fosamprenavir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5922072	EXPEDITED (15-DAY)		OT	PHEH2005US12219			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Palpitations	Lamisil			S	Oral			Novartis
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5927870	EXPEDITED (15-DAY)	Y	DE	2005AL003957		38 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest	Clonazepam			S	Oral	Po		Not Reported
	Escitalopram Oxalate			S	Oral	Po		Not Reported
	Acetaminophen W/Hydrocodone			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5928943	EXPEDITED (15-DAY)	Y	HO	S05-BEL-04796-01		35 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dyskinesia; Tremor	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5928945	EXPEDITED (15-DAY)	Y	DE	S05-FRA-04479-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5929199	EXPEDITED (15-DAY)	Y	HO	2005-11-0034		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Clarinex			S	Oral	Oral		Not Reported

Domperidone	S	Oral	3 Qd Oral		Not Reported
Furosemide	S	Oral	20 Mg Qd Oral		Not Reported
Omeprazole	S	Oral	20 Mg Qd Oral		Not Reported
Cipralex	S	Oral	10 Mg Qd Oral		Not Reported
Tamsulosin Hydrochloride	S	Oral	0.4 Mg Qd Oral		Not Reported
Perindopril Erbumine	C				Not Reported
Zopiclone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5929943	EXPEDITED (15-DAY)	Y	OT	S05-GER-04478-01			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5931138	EXPEDITED (15-DAY)	Y	DE	2005AL004172		40 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Cardiac Arrest; Overdose; Respiratory Arrest; Unevaluable Event	Clonazepam			S				Purepac
	Quetiapine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5932888	EXPEDITED (15-DAY)	Y	DE	2005AL004031		24 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Chlorpromazine Hydrochloride			S	Unknown	Unknown		Alphapharm
	Amitriptyline			S	Unknown	Unknown		Not Reported
	Escitalopram Oxalate			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5932968	EXPEDITED (15-DAY)	Y	DE	2005AL004018		58 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Lorazepam			S	Oral	Unknown; Unk; Po		Not Reported
	Valproic Acid			S	Oral	Unknown; Unk; Po		Not Reported
	Escitalopram Oxalate			S	Oral	Unknown; Unk; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5932976	EXPEDITED (15-DAY)	Y	DE	2005AL004024		25 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Respiratory Arrest; Unevaluable Event	Alprazolam			S	Oral	Unknown; Unk; Po		Not Reported
	Amitriptyline			S	Oral	Unknown; Unk; Po		Not Reported
	Escitalopram Oxalate			S	Oral	Unknown; Unk; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5933315	EXPEDITED (15-DAY)	N	DE, HO	S05-USA-04849-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Self-Injury; Multiple Injuries; Overdose	Lexapro			S				Not Reported
	Acetaminophen			S				Not Reported
	Acetaminophen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2005	5933436	EXPEDITED (15-DAY)	Y	DE	2005AL004226		42 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Overdose	Tramadol Hydrochloride			S	Oral	Po		Not Reported
	Methadone Hydrochloride			S	Oral	Po		Not Reported

	Escitalopram Oxalate			S	Oral	Po			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2005	5904908	EXPEDITED (15-DAY)	Y	OT	S05-NOR-03632-01		33 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoeic Attack; Dizziness Postural; Fall; Hypertension; Orthostatic Hypotension; Tremor	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2005	5927586	DIRECT	N	OT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2005	5927638	DIRECT	N				56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Depression; Diarrhoea; Drug Withdrawal Syndrome; Nervousness	Lexapro			S	Oral	20 Mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2005	5928802	EXPEDITED (15-DAY)	Y	RI, OT	S05-USA-04589-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Infarction; Intestinal Ischaemia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2005	5929039	EXPEDITED (15-DAY)	Y	DE	S05-UKI-04974-01		67 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Intentional Self-Injury	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Flupentixol Dihydrochloride			S	Oral	1 Tablet Qd Po		Not Reported
	Zopiclone			S		7.5 Mg Qd		Not Reported
	Quinine Bisulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2005	5929043	EXPEDITED (15-DAY)	Y	DS	S05-FRA-04968-01		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Oedema	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Lexomil (Bromazepam)			C				Not Reported
	Nexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2005	5929154	EXPEDITED (15-DAY)	Y	HO, OT	S05-UKI-04967-01		48 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention; Urinary Tract Infection	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2005	5929538	EXPEDITED (15-DAY)	Y	HO, LT	2005S1010719		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Obstruction; Pancreatic Pseudocyst; Pancreatitis Acute	Lexapro			S	Oral	20 Mg;Qd;Oral		Not Reported
	Maxzide			S	Oral	Oral		Not Reported

	Mavik	S	Oral	8 Mg;Po	Not Reported
	Trazodone Hydrochloride	C			Not Reported
	Indomethacin	C			Not Reported
	Erythromycin	C			Not Reported
	Metoclopramide Hydrochloride	C			Not Reported
	Estrogens Conjugated	C			Not Reported
	Cetirizine Hydrochloride	C			Not Reported
	Montelukast Sodium	C			Not Reported
	Modafinil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2005	5929433	DIRECT	Y	HO			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Hyponatraemia; Hypophagia; Lethargy	Escitalopram Oxalate			S	Oral	10 Mg Daily Po		Not Reported
	Maxzide			S	Oral	25 Mg Daily Po	2 MTH	Not Reported
	Aspirin			C				Not Reported
	Celebrex			C				Not Reported
	Folic Acid			C				Not Reported
	Xalatan			C				Not Reported
	Levoxyl			C				Not Reported
	Reglan			C				Not Reported
	Lescol Xl			C				Not Reported
	Multivitamins			C				Not Reported
	Toprol Xl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2005	5931662	DIRECT	N	RI			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Erythema; Hot Flush; Skin Disorder; Skin Tightness	Lexapro			S	Oral	10mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2005	5933485	EXPEDITED (15-DAY)	Y	DE	2005-BP-19471RO		42 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Methadone Hydrochloride			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2005	5934608	EXPEDITED (15-DAY)	Y	HO, OT	S05-USA-04906-01		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Inappropriate Schedule Of Product Administration; Psychotic Disorder	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Intron A			S	Subcutaneous	19 Mu Tiw Sc		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2005	5934662	EXPEDITED (15-DAY)	Y	DE	2005-BP-19502RO		25 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Respiratory Arrest	Alprazolam			S				Not Reported
	Amitriptyline			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2005	5931471	DIRECT	Y	LT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Homicidal Ideation; Nausea; Suicidal Ideation	Lexapro			S	Oral	Half Tablet Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2005	5933131	EXPEDITED (15-DAY)	Y	OT	S05-USA-04923-01		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Attention-Seeking Behaviour; Intentional Overdose; Partner Stress	Lexapro		S	Oral	220 Mg Once Po	Not Reported
	Lexapro		S	Oral	10 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2005	5933208	EXPEDITED (15-DAY)	N	HO	S05-USA-04940-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Chest Pain; Hypoaesthesia; Paraesthesia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2005	5933544	EXPEDITED (15-DAY)	Y	OT	S05-NLD-05158-01		79 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colour Blindness; Visual Acuity Reduced	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Alprazolam			C				Not Reported
	Ascal (Acetylsalicylate Calcium)			C				Not Reported
	Lormetazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2005	5805051	EXPEDITED (15-DAY)	Y	DS, OT	S05-UKI-01727-01		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gait Disturbance; Movement Disorder; Muscle Rigidity; Tremor	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Abilify			S	Oral	15 Mg Qd Po		Not Reported
	Abilify			S	Oral	10 Mg Qd Po		Not Reported
	Amisulpride (Amisulpride)			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2005	5811872	EXPEDITED (15-DAY)	Y	OT	T05-SWI-01891-01		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Drug Dependence; Epilepsy; Loss Of Consciousness; Myoclonus; Overdose; Somatic Symptom Disorder	Cipralex			S	Oral	30 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Zyprexa			S	Oral	5 Mg Qd Po		Not Reported
	Kemadrin			S	Oral	15 Mg Qd Po		Not Reported
	Procyclidine Hydrochloride			S	Oral	5 Mg Qd Po		Not Reported
	Dormicum (Nitrazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2005	5874655	EXPEDITED (15-DAY)	Y	DE	S05-USA-04037-01		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuser; Ecchymosis; Lividity; Overdose	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Heroin			S				Not Reported
	Flexeril			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Allegra			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Atarax			C				Not Reported
	Orphenadrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2005	5927061	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-12754743			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Suicidal Ideation	Pravachol			S				Bristol Myers Squibb
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2005	5929942	EXPEDITED (15-DAY)	Y	OT	S05-FRA-04644-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Victim Of Sexual Abuse	Escitalopram Oxalate		S	Oral	10 Mg Daily Po	Not Reported
	Lormetazepam		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2005	5932278	DIRECT	Y	HO			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Malnutrition	Lexapro			S	Oral	10 Mg Daily Po		Not Reported
	Coumadin			C				Not Reported
	Spironolactone			C				Not Reported
	Altace			C				Not Reported
	Digoxin			C				Not Reported
	Coreg			C				Not Reported
	Furosemide			C				Not Reported
	Lupron			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2005	5936017	EXPEDITED (15-DAY)	Y	DS	S05-UKI-05160-01		77 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Etoricoxib			C				Not Reported
	Temazepam			C				Not Reported
	Co-Amilofruse			C				Not Reported
	Digoxin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2005	5952061	NON-EXPEDITED	Y	OT	2005019371		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Pain; Depression; Haemorrhoids; Hepatitis	Lipitor			S	Oral	20 Mg,Oral		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Clonazepam			C				Not Reported

	Lorazepam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2005	4028712	EXPEDITED (15-DAY)	Y		S03-SWI-04412-01		73 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Anxiety; Dermatitis Allergic; Disturbance In Attention; Drug Eruption; Fall; Gamma-Glutamyltransferase Increased; Insomnia; Monocyte Count Increased; Neutrophil Count Increased; Parkinsonism; Reading Disorder	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Vioxx			S	Oral	12.5 Mg Qd Po		Not Reported
	Vioxx			S	Oral	12.5 Mg Qd Po		Not Reported
	Vioxx			S	Oral	12.5 Mg Qd Po		Not Reported
	Vioxx			S	Oral	12.5 Mg Qd Po		Not Reported
	Vioxx			S	Oral	25 Mg Qd Po		Not Reported
	Vioxx			S	Oral	12.5 Mg Qd Po		Not Reported
	Vioxx			S	Oral	12.5 Mg Qd Po		Not Reported
	Vioxx			S	Oral	12.5 Mg Qd Po		Not Reported
	Vioxx			S	Oral	12.5 Mg Qd Po		Not Reported
	Zyprexa			C				Not Reported
	Temesta (Lorazepam)			C				Not Reported
	Duphalac			C				Not Reported
	Paragol			C				Not Reported
	Fig Syrup			C				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2005	5858691	EXPEDITED (15-DAY)	Y	OT	S05-USA-03682-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Porphyria; Rash; Skin Ulcer	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Procrit			S		30000 Units Qmon		Not Reported
	Coumadin			C				Not Reported
	Ivig (Immunoglobulin)			C				Not Reported
	Tarka			C				Not Reported

	Coreg	C		Not Reported
	Bovina (Ibandronate)	C		Not Reported
	Iron	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2005	5885611	EXPEDITED (15-DAY)	N	OT	S05-USA-04237-01		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Libido Decreased; Painful Erection; Penile Curvature; Spontaneous Penile Erection	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2005	5923504	EXPEDITED (15-DAY)	Y	HO	S05-USA-04814-01		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ativan			C				Not Reported
	Pravachol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2005	5937410	EXPEDITED (15-DAY)	Y	DE	2005-BP-19668RO		58 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Lorazepam			S				Not Reported
	Valproic Acid			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2005	5722533	EXPEDITED (15-DAY)	Y	DE	PHBS2005SE01249		36 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis Coronary Artery; Bronchitis; Cardiomegaly; Cardiopulmonary Failure; Myocardial Ischaemia	Leponex			S	Oral	600 Mg/D		Novartis
	Clopenthixol Hydrochloride			S	Oral	5 Mg/D		Not Reported
	Cipralex			S	Oral	20 Mg/D		Not Reported
	Atarax			C	Oral			Not Reported
	Akineton			C	Oral	2 Mg/D		Not Reported
	Diazepam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2005	5919689	EXPEDITED (15-DAY)	Y	HO	S05-SWI-03869-01		55 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Amylase Increased; Gamma-Glutamyltransferase Increased; Lipase Increased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Zoloft			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2005	5806971	EXPEDITED (15-DAY)		OT	CH-ABBOTT-05P-151-0301153-00		52 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Epilepsy; Overdose	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Procyclidine Hydrochloride			S	Oral			Not Reported
	Procyclidine Hydrochloride			S	Oral			Not Reported

	Midazolam	C	Oral		Not Reported
	Midazolam	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2005	5915194	EXPEDITED (15-DAY)	Y	DE, HO, LT	US016178		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Depressed Level Of Consciousness; Feeling Abnormal; Intentional Overdose; Myocardial Infarction; Pulmonary Oedema; Sepsis; Tachycardia	Gabitril			S				Not Reported
	Acetaminophen\Hydrocodone			S				Not Reported
	Amitriptyline			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Cyclobenzaprine Hydrochloride			S				Not Reported
	Pioglitazone Hydrochloride			S				Not Reported
	Lovastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2005	5928942	EXPEDITED (15-DAY)	Y	HO	S05-ESP-04485-01		78 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Dyspnoea; Generalised Tonic-Clonic Seizure; Hyponatraemia; Respiratory Tract Infection	Cipralex			S	Oral	5 Mg Po		Not Reported
	Chlorthalidone			S	Oral	50 Mg Po		Not Reported
	Levothroid			C				Not Reported
	Neosidantoina (Phenytoin Sodium)			C				Not Reported
	Tavanic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2005	5930127	EXPEDITED (15-DAY)	Y	HO	S05-ESP-05141-01		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			C				Not Reported
	Nolotil (Metamizole Magnesium)			C				Not Reported

	Omeprazole	C		Not Reported
	Lorazepam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2005	5932057	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-13112339		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restlessness; Weight Increased	Abilify			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Oxybutynin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2005	5932761	NON-EXPEDITED	N		S05-USA-04395-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Breath Odour; Cough; Dizziness; Dysgeusia; Eructation; Headache; Hot Flush; Hyperhidrosis; Nausea	Wellbutrin Xl			S	Oral	150mg Per Day		Glaxosmithkline
	Lexapro			S	Oral			Forest
	Strattera			C	Unknown			Not Reported
	Vicodin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2005	5938770	EXPEDITED (15-DAY)	Y	HO	2005S1011109		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Desloratadine			S	Oral	Oral		Not Reported
	Domperidone			S	Oral	Qd; Oral		Not Reported
	Furosemide			S	Oral	20 Mg; Qd; Oral		Not Reported
	Omeprazole			S	Oral	20 Mg; Qd; Oral		Not Reported
	Cipralex			S	Oral	10 Mg; Qd; Oral		Not Reported
	Tamsulosin Hydrochloride			S	Oral	0.4 Mg; Qd; Oral		Not Reported
	Perindopril			C				Not Reported

	Zopiclone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2005	5956694	NON-EXPEDITED	N	HO	200510661BWH		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Panic Attack	Ciprofloxacin Extended-Release			S				Not Reported
	Lexapro			S	Oral	30 Mg, Qd, Oral		Not Reported
	Flagyl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2005	5868602	EXPEDITED (15-DAY)	Y	HO	S05-USA-03963-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Syncope	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2005	5933839	EXPEDITED (15-DAY)		HO	ES-ABBOTT-05P-144-0317753-00		89 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Atrophy; Cerebral Ischaemia; Hypokalaemia; Hyponatraemia	Cipralex			S	Oral		10 DAY	Not Reported
	Indapamide			S	Oral			Not Reported
	Lormetazepam			C	Oral			Not Reported
	Gabapentin			C	Oral			Not Reported
	Timolol Maleate			C	Topical			Not Reported
	Gliclazide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2005	5852727	EXPEDITED (15-DAY)	Y	HO	S04-USA-06025-02		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Foetal Hypokinesia; Forceps Delivery; Labour Complication; Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Pilonidal Cyst Congenital; Premature Baby; Small For Dates Baby; Umbilical Cord Around Neck; Umbilical Hernia	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Prenatal Vitamins			C				Not Reported
	Albuterol			C				Not Reported
	Pitocin			C				Not Reported
	Fentanyl Epidural			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2005	5881906	EXPEDITED (15-DAY)	N	OT	S05-USA-04179-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Optic Neuritis	Lexapro			S				Not Reported
	Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2005	5936380	EXPEDITED (15-DAY)	Y	HO	S05-ESP-05322-01		89 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Atrophy; Cerebral Ischaemia; Hypokalaemia; Hyponatraemia	Cipralex			S	Oral	5 Mg Po		Not Reported
	Indapamide			S				Not Reported
	Noctamid (Lormetazepam)			C				Not Reported
	Gabapentin			C				Not Reported
	Timoptil (Timolol Maleate)			C				Not Reported
	Gliclazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2005	5938398	DIRECT	N				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Nausea	Lexapro			S	Oral	1 10mg Tablet Once A Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2005	5940002	EXPEDITED (15-DAY)	N	OT	S05-USA-05004-01		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Asthma; Drug Interaction; Panic Reaction; Respiratory Tract Infection	Advair Diskus			S	Respiratory (inhalation)			Glaxosmithkline
	Albuterol			S	Respiratory (inhalation)			Glaxosmithkline
	Ipratropium			S	Respiratory (inhalation)			Glaxosmithkline
	Lexapro			S		10mg Per Day		Not Reported
	Singulair			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2005	5865035	EXPEDITED (15-DAY)	Y	HO, OT	S05-USA-03744-01		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported
	Advair Diskus			C				Not Reported
	Atrovent			C				Not Reported
	Diovan			C				Not Reported
	Aciphex			C				Not Reported
	Lipitor			C				Not Reported
	Niaspan			C				Not Reported
	Aspirin			C				Not Reported
	Mycobutin			C				Not Reported
	Biaxin			C				Not Reported
	Ethambutol			C				Not Reported
	Ambien			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2005	5884733	EXPEDITED (15-DAY)	Y	HO	S05-USA-03626-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Chest Pain; Contusion; Dizziness; Electrocardiogram Abnormal; Hypercholesterolaemia; Hypokalaemia; Injury; Ligament Sprain; Loss Of Consciousness; Migraine; Mitral Valve Incompetence; Musculoskeletal Pain; Nervous System Disorder; Periorbital Haematoma; Road Traffic Accident; Skin Laceration; Syncope	Lexapro			S	Oral	20 Mg Qhs Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2005	5935620	EXPEDITED (15-DAY)	N	OT	DE-BRISTOL-MYERS SQUIBB COMPANY-13196712		51 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Drug Interaction	Abilify			S	Oral			Not Reported
	Ergenyl			C				Not Reported
	Sortis			C				Not Reported
	Beloc-Zok			C				Not Reported
	Euglucon N			C				Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2005	5938498	DIRECT	N	OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Hypotrichosis; Maternal Exposure During Pregnancy; Stress	Lexapro	S	Oral	20 Mg Once A 'Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2005	5909914	EXPEDITED (15-DAY)	Y	OT	S05-USA-04573-01		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Fatigue; Hyperhidrosis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Toprol Xl			C				Not Reported
	Pravachol			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2005	5936007	EXPEDITED (15-DAY)	N	DE, HO	US-JNJFOC-20051200227		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Injury; Overdose	Tylenol		Y	S				Not Reported
	Tylenol			S				Not Reported
	Excedrin			S				Not Reported
	Excedrin			S				Not Reported
	Excedrin			S				Not Reported
	Excedrin			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2005	5947209	EXPEDITED (15-DAY)	Y	OT	S05-USA-05091-01		12 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Focal Dyscognitive Seizures	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2005	5971598	NON-EXPEDITED	Y	OT	2005108481		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Erectile Dysfunction; Erection Increased; Headache; Nervousness; Vision Blurred	Viagra			S	Oral	100 Mg (100 Mg, As Necessary), Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported
	Lorazepam			C				Not Reported
	Atenolol (Atenolol)			C				Not Reported
	Insulin Nos			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Acetylsalicylic Acid (Acetylsalicylic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2005	5905615	EXPEDITED (15-DAY)	Y	DE, HO	T05-USA-02375-01		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Dehydration; Depressed Level Of Consciousness; Failure To Thrive; Hypophagia; Respiratory Rate Increased; Serotonin Syndrome; Urinary Tract Infection	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aricept			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Multivitamins			C				Not Reported
	Ativan			C				Not Reported
	Warfarin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2005	5926345	EXPEDITED (15-DAY)	N	OT	S05-USA-03951-01		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Feeling Abnormal; Gait Disturbance; Heat Stroke;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Levoxyl			C				Not Reported

Impaired Work Ability;
Judgement Impaired;
Malaise; Somnolence;
Vertigo; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2005	5939893	EXPEDITED (15-DAY)	Y	HO	S05-SWI-05313-01		69 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paralysis	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2005	5941878	EXPEDITED (15-DAY)	Y	OT	S05-UKI-05522-01			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Sexual Abuse	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2005	5948138	EXPEDITED (15-DAY)	Y	OT	S05-USA-05102-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Seizure	Lexapro			S	Oral	20 Mg Bid Po		Not Reported
	Lexapro			S	Oral	20 Mg Bid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2005	5948732	EXPEDITED (15-DAY)	Y	HO	S05-UKI-05537-01		41 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Somnolence	Cipralex			S	Oral	20 Mg Qd; Po		Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Montelukast			C				Not Reported
	Terbutaline Sulfate			C				Not Reported

	Symbicort	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2005	5948733	EXPEDITED (15-DAY)	Y	DE	S05-UKI-05536-01		43 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Impulsive Behaviour; Mental Disorder	Cipralex			S	Oral	5 Mg Qd; Po		Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2005	5948804	EXPEDITED (15-DAY)	Y	HO	S05-FIN-05535-01		57 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Movement Disorder	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Hydantin (Phenytoin)			C				Not Reported
	Acetaminophen			C				Not Reported
	Trineurin			C				Not Reported
	Levolac (Lactulose)			C				Not Reported
	Keppra			C				Not Reported
	Emgesan (Magnesium Hydroxide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2005	5948807	EXPEDITED (15-DAY)	Y	OT	S05-GER-05625-01		69 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cognitive Disorder; Generalised Tonic-Clonic Seizure; Hemiparesis; Muscle Spasticity	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Metoclopramide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2005	7385665	EXPEDITED (15-DAY)		DE	US-ABBOTT-05P-163-0318303-00		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2005	5939576	EXPEDITED (15-DAY)	Y	OT	IE-BRISTOL-MYERS SQUIBB COMPANY-13202320		82 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokinesia; Hypotension; Pupil Fixed; Salivary Hypersecretion; Seizure; Tremor	Abilify			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Amlodipine Besylate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2005	5948380	DIRECT	N	HO, RI			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Medication Error	Lexapro			S	Oral	1 Tab 1 Time Per Day Po		Forest
	Ultracet			S	Oral	2 Tabs 3 Times Per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2005	5949494	EXPEDITED (15-DAY)	Y	DE	MK200512-0053-1		55 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Acetaminophen And Codeine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Acetaminophen\Hydrocodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2005	5934949	EXPEDITED (15-DAY)	Y	HO	PHBS2005FR17166		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Coma Scale Abnormal; Electrocardiogram Qrs Complex Abnormal; Endotracheal Intubation; Intentional Product Misuse; Overdose; Sinoatrial Block	Tegretol			S	Oral		1440 MIN	Novartis
	Anafranil			S	Oral		1440 MIN	Not Reported
	Tranxene T-Tab			S	Oral		1440 MIN	Not Reported
	Zopiclone			S	Oral		1440 MIN	Not Reported
	Effexor			S	Oral		1440 MIN	Not Reported
	Escitalopram Oxalate			S	Oral		1440 MIN	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2005	5951150	EXPEDITED (15-DAY)	Y	OT	S05-UKI-01574-01		20 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2005	5951233	EXPEDITED (15-DAY)	Y	HO	2005162372		30 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Toxicity To Various Agents	Atarax			S				Not Reported
	Flupentixol Dihydrochloride			S				Not Reported
	Zolpidem Tartrate			S	Oral	Oral		Not Reported
	Olanzapine (Olanzapine)			S		Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Mianserin Hydrochloride			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2005	5963823	NON-EXPEDITED	Y	HO	2004095999		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression Suicidal; Intentional Overdose; Loss Of Consciousness	Xanax	S	Oral	Oral		Not Reported
	Clopidogrel Bisulfate	S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Zolpidem Tartrate	S	Oral	130 Mg (130 Mg, Once), Oral		Not Reported
	Semisodium Valproate	S	Oral	4 Gram (4 Gram, Once), Oral		Not Reported
	Clonazepam	S				Not Reported
	Escitalopram Oxalate	S				Not Reported
	Acetylsalicylic Acid (Acetylsalicylic Acid)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2005	5963827	NON-EXPEDITED	Y	HO	2004112623		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicide Attempt	Xanax			S	Oral	16 Tablets (Once), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	40 Mg (20 Mg, 1 In 2 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2005	5895421	EXPEDITED (15-DAY)	Y	HO	S05-GER-03552-01		68 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Toxic	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Edronax			C				Not Reported
	Novodigal (Digoxin)			C				Not Reported
	Glucophage (Metformin Hydrochloride) (Metformin)			C				Not Reported
	Doxepin			C				Not Reported
	Aprovel (Irbesartan)			C				Not Reported
	Aquaphor Tablet (Xipamide)			C				Not Reported
	Asa (Acetylsalicylic Acid)			C				Not Reported
	Clorazepate Dipotassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2005	5934471	EXPEDITED (15-DAY)	N	OT	US-MERCK-0511USA04559		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Asthma; Drug Interaction; Panic Reaction; Respiratory Tract Infection	Singulair			S	Oral			Merck
	Advair Diskus			S	Unknown			Not Reported
	Ipratropium Bromide			S	Unknown			Not Reported
	Albuterol			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2005	5941076	EXPEDITED (15-DAY)	N	CA, HO	US-GLAXOSMITHKLINE-A0585524A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Disease; Atrial Septal Defect; Bicuspid Aortic Valve; Coarctation Of The Aorta; Maternal Exposure During Pregnancy; Mitral Valve Disease; Mitral Valve Incompetence; Ventricular Septal Defect	Paxil			S	Oral	12.5mg Per Day	15 MTH	Glaxosmithkline
	Lexapro			S	Oral	10mg Unknown		Not Reported
	Prenatabs Fa			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Iron Supplement			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2005	5951334	EXPEDITED (15-DAY)	Y	OT	S05-UKI-05646-01		75 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pyrexia; Rash;	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Amlodipine			C				Not Reported

Tachycardia	Trandolapril	C	Not Reported
	Galfer (Ferrous Fumarate)	C	Not Reported
	Lansoprazole	C	Not Reported
	Actonel	C	Not Reported
	Calcichew (Calcium Carbonate)	C	Not Reported
	Atorvastatin	C	Not Reported
	Acetylsalicylic Acid	C	Not Reported
	Multivitamins	C	Not Reported
	Fortisip	C	Not Reported
	Calogen (Calcitonin, Salmon)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2005	5929730	EXPEDITED (15-DAY)	Y	OT	PHEH2005US12505		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Dysphagia; Dyspnoea; Hypertension; Hypoaesthesia; Pharyngeal Oedema	Zelnorm			S		6 Mg, Bid	1440 MIN	Novartis
	Lexapro			S	Oral	10 Mg, Qd	1440 MIN	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2005	5950889	DIRECT	Y	LT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Condition Aggravated; Dysgeusia; Fatigue; Flatulence; Hepatic Enzyme Increased; Hepatotoxicity; Impaired Work Ability; Increased Tendency To Bruise; Infectious Mononucleosis; Nausea; Pruritus	Lexapro			S	Oral	10 Mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2005	5951554	EXPEDITED (15-DAY)	N	HO	S05-USA-05129-01		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Intentional Self-Injury; Muscle Twitching; Overdose; Panic Attack; Screaming; Skin Laceration; Suicidal Ideation; Tremor	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Allegra			C				Not Reported
	Albuterol			C				Not Reported
	Singulair			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2005	5903751	EXPEDITED (15-DAY)		DE, HO, LT	US-ABBOTT-05P-163-0313859-00		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Cardiac Arrest; Completed Suicide; Intentional Overdose; Mental Status Changes; Myocardial Infarction; Pulmonary Oedema; Sepsis; Tachycardia; Unresponsive To Stimuli	Acetaminophen\Hydrocodone Bitartrate			S	Oral			Not Reported
	Tiagabine Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Cyclobenzaprine Hydrochloride			S	Oral			Not Reported
	Pioglitazone Hydrochloride			S	Oral			Not Reported
	Lovastatin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2005	5942707	EXPEDITED (15-DAY)	Y	HO	2005CG02059		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Thrombosis; Depression; Dyslipidaemia; Musculoskeletal Pain;	Inexium			S	Oral			Astrazeneca
	Cyamemazine			S	Oral			Not Reported
	Vastarel			S	Oral			Not Reported

Peripheral Artery Thrombosis; Pulmonary Embolism	Stilnox		S	Oral	Not Reported
	Zyprexa		S	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Not Reported
	Victan		C		Not Reported
	Xanax		C		Not Reported
	Cortancyl		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2005	5952035	EXPEDITED (15-DAY)	N	OT	S05-USA-05174-01		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Diarrhoea; Impaired Driving Ability; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2005	5952092	EXPEDITED (15-DAY)	Y	OT	GXKR2005GB01850		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impulsive Behaviour; Overdose; Suicide Attempt	Diazepam			S		60-70 Mg		Not Reported
	Cipralex			S	Oral	5-20 Mg, Oral		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2005	5952238	EXPEDITED (15-DAY)	Y	LT	S05-USA-04566-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Strattera			S				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2005	5953239	DIRECT	Y	HO, LT, RI			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Neuroleptic Malignant Syndrome	Ziprasidone Hydrochloride			S	Oral	60 Mg Twice Daily Po		Not Reported
	Lexapro			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2005	5896020	EXPEDITED (15-DAY)	Y	HO	T05-USA-03407-01		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Creatinine Increased; Blood Glucose Increased; Blood Urea Increased; Dehydration; Eosinophil Count Increased; Fluid Intake Reduced; Hypernatraemia; Sedation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Tylenol (Paracetamol)			C				Not Reported
	Vicodin			C				Not Reported
	Ativan			C				Not Reported
	Donepezil Hydrochloride			C				Not Reported
	Ranitidine			C				Not Reported
	Torsemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2005	5933203	EXPEDITED (15-DAY)	N	OT	S05-USA-04937-01		9 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Heart Rate Increased; Loss Of Consciousness; Tremor	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2005	5948592	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-SYNTHELABO-A02200503241		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arterial Thrombosis; Blood Cholesterol Increased; Blood Triglycerides Increased; Dyslipidaemia; Pulmonary Embolism	Stilnox	S	Oral	10 Mg		Not Reported
	Cyamemazine	S	Oral	50 Mg		Not Reported
	Vastarel	S	Oral	35 Mg		Not Reported
	Zyprexa	S	Oral	Unk		Not Reported
	Inexium	S	Oral	20 Mg		Not Reported
	Escitalopram Oxalate	S	Oral	Unk		Not Reported
	Xanax	C	Oral	Unk		Not Reported
	Cortancyl	C	Oral	Unk		Not Reported
	Victan	C	Oral	Unk		Not Reported
	Tramadol Hydrochloride	C	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk		Not Reported
	Anetholtrithion	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2005	5954053	EXPEDITED (15-DAY)	Y	DS	S05-UKI-05669-01		55 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychiatric Symptom; Self-Injurious Ideation; Suicidal Ideation	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Amitriptyline			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2005	5954470	EXPEDITED (15-DAY)	Y	OT	S05-USA-03830-01		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Depression; Insomnia; Mania	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Adderall (Amphetamines)			C				Not Reported
	Depakote			C				Not Reported
	Lamictal			C				Not Reported
	Sonata			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2005	5955133	EXPEDITED (15-DAY)	Y	OT	S05-UKI-05681-01		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Gait Disturbance	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported
	Bendrofluazide			C				Not Reported
	Livial			C				Not Reported
	Eprosartan			C				Not Reported
	Lansoprazole			C				Not Reported
	Doxazosin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2005	5834764	EXPEDITED (15-DAY)	Y	OT	S05-USA-03200-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Birth Control Pills			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2005	5953754	EXPEDITED (15-DAY)	Y	DS	S05-NLD-05699-01		22 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Mydriasis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Oxazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2005	5926631	EXPEDITED (15-DAY)	Y	OT	S05-FRA-04643-01		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cholestasis; Hepatic Failure; Hepatitis; Prothrombin Time Ratio	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

Decreased; Weight Decreased	Bromazepam	C		Not Reported
	Aceprometazine\Meprobamate	C		Not Reported
	Hept-A-Myl (Hepataminol Hydrochloride)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2005	5951370	EXPEDITED (15-DAY)	Y	HO, OT	GB-SANOFI-SYNTHELABO-A01200508847			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intracranial Aneurysm; Ruptured Cerebral Aneurysm; Subarachnoid Haemorrhage	Clopidogrel			S	Oral			Not Reported
	Cipralex			S	Oral		3 DAY	Not Reported
	Aspirin			S	Oral			Not Reported
	Salmeterol			C	Respiratory (inhalation)	2 Puffs Bid Unk		Not Reported
	Terbutaline Sulfate			C	Respiratory (inhalation)	2 Puffs Bid Unk		Not Reported
	Adcal-D3			C	Oral	Unk		Not Reported
	Spiriva			C	Respiratory (inhalation)	Unk		Not Reported
	Atorvastatin			C	Oral			Not Reported
	Pantoprazole Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2005	6747136	EXPEDITED (15-DAY)	Y	DE	MK200512-0423-1		38 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest	Acetaminophen\Hydrocodone Bitartrate			S	Oral	Po		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2005	5957648	EXPEDITED (15-DAY)	Y	DE	MK200512-0494-1		42 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Methadose			S	Oral	Po		Not Reported
	Tramadol Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2005	5958578	EXPEDITED (15-DAY)	Y	DE	S05-GER-05719-01		19 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Sudden Death	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2005	5926281	EXPEDITED (15-DAY)	Y	HO	S05-USA-04746-01		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Agitation; Anaemia; Azotaemia; Blood Bicarbonate Increased; Blood Chloride Decreased; Blood Glucose Increased; Chronic Kidney Disease; Condition Aggravated; Depression; Hypophagia; Hypovolaemia; Inappropriate Antidiuretic Hormone Secretion; Mental Disorder; Metabolic Alkalosis; Nephrosclerosis; Paranoia; Skin Turgor Decreased; Specific Gravity Urine Increased; Weight Decreased	Lexapro			S				Not Reported
	Demadex			S				Not Reported
	Ziac			S				Not Reported
	Norvasc			C				Not Reported
	Seroquel			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2005	5951279	EXPEDITED (15-DAY)	Y	OT	S05-USA-05098-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2005	5956147	DIRECT	Y	OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Eructation; Flatulence; Nausea	Lexapro			S	Oral	20 Mg Daily Po		Not Reported
					Oral	20 Mg Daily Po		
	Wellbutrin Xl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2006	5960040	EXPEDITED (15-DAY)	Y	HO	S05-USA-05285-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis; Sepsis; Ureteric Obstruction	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Toprol Xl			C				Not Reported
	Aspirin			C				Not Reported
	Crestor			C				Not Reported
	Vitamins			C				Not Reported
	Prempro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2006	5960042	EXPEDITED (15-DAY)	Y	OT	S05-USA-05286-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Lexapro			S				Not Reported
	Adderall			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2006	6035464	EXPEDITED (15-DAY)	Y	HO, LT	AT-JNJFOC-20051205044		21 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Respiratory Depression	Durogesic			S	Transdermal			Not Reported
	Cipralex			S	Unknown			Not Reported
	Morphine Hydrochloride			S	Other			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Flunitrazepam			S	Unknown			Not Reported
	Gewadal			S	Unknown			Not Reported
	Gewadal			S	Unknown			Not Reported
	Caffeine			S	Unknown	1 Ampoule		Not Reported
	Voltaren			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2006	5953953	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-12840021		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Desyrel			S	Oral	Duration Of Therapy: "A While"		Apothecon
	Desyrel			S	Oral	Duration Of Therapy: "A While"		Apothecon
	Lexapro			S				Not Reported
	Toprol Xl			C				Not Reported
	Lipitor			C				Not Reported
	Lopid			C				Not Reported
	Fioricet			C				Not Reported
	Lortab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2006	5954782	EXPEDITED (15-DAY)	N	HO	US-GLAXOSMITHKLINE-A0569235A		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Disorientation; Drug Ineffective; Nausea; Panic Attack; Stress	Paxil Cr			S	Oral	12.5mg Per Day	6 WEEK	Glaxosmithkline
	Paxil			S	Oral	10mg Per Day	2 YR	Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Paroxetine Hydrochloride			S	Oral	10mg Per Day	1 MTH	Glaxosmithkline
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2006	5956617	DIRECT	Y	LT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Substance Abuse; Suicidal Ideation	Lexapro			S		X1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2006	5961915	EXPEDITED (15-DAY)	Y	OT	S05-FRA-05748-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Salivary Gland Calculus	Escitalopram Oxalate			S				Not Reported
	Flecainide Acetate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2006	5961917	EXPEDITED (15-DAY)	Y	HO	S05-FRA-05749-01		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Thrombosis; Blood Cholesterol Increased; Blood Triglycerides	Escitalopram Oxalate			S				Not Reported
	Cyamemazine			S	Oral	50 Mg Qd Po		Not Reported

Increased; Chest X-Ray Abnormal; Dyslipidaemia; Musculoskeletal Pain; Peripheral Artery Thrombosis; Pulmonary Embolism	Vastarel		S	Oral	35 Mg Qd Po	Not Reported
	Zolpidem Tartrate		S	Oral	10 Mg Qd Po	Not Reported
	Zyprexa		S			Not Reported
	Inexium		S	Oral	25 Mg Qd Po	Not Reported
	Xanax		C			Not Reported
	Victan (Ethyl Loflazepate)		C			Not Reported
	Unspecified Ingredient		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2006	5720021	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-12762043		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Insomnia	Serzone			S	Oral			Bristol Myers Squibb
	Lexapro			S	Oral	11-Oct-04 To 12-Oct-04 10mg/D; Oct-04 - Oct-04 5 Mg/D; 2.5 Mg/D Oct-04 To 26-Oct-2004.		Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2006	5959056	EXPEDITED (15-DAY)	N	OT	S05-USA-05264-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyskinesia	Lamictal			S	Oral			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2006	5961120	EXPEDITED (15-DAY)	N	DE	S05-USA-05297-02		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2006	5961123	EXPEDITED (15-DAY)	N	DE	S05-USA-05298-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2006	5961163	EXPEDITED (15-DAY)	N	DE	S05-USA-05298-02			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2006	5961258	EXPEDITED (15-DAY)	N	DE	S05-USA-05298-03			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2006	5921752	EXPEDITED (15-DAY)	Y	DS	S05-PRT-03940-01		49 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Chloride Decreased; Blood Glucose Increased; Drug Withdrawal Syndrome; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Headache;	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Selegiline Hydrochloride			C				Not Reported
	Piridexil			C				Not Reported
	Sinemet			C				Not Reported
	Ticlopidine			C				Not Reported
	Risidon (Metformin Hydrochloride)			C				Not Reported
	Insulin Nos			C				Not Reported
	Insulin Nos			C				Not Reported

Hyperaemia; Hyperhidrosis; Hypertension; Somnolence	Pergolide	C	Not Reported
	Mixtard Human 70/30	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2006	5960054	DIRECT	Y	OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Eructation; Flatulence; Muscle Spasms; Nausea	Lexapro			S	Oral	20 Mg Daily Po		Not Reported
	Wellbutrin Xl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2006	5962913	EXPEDITED (15-DAY)	Y	HO	KII-2005-0020491		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lethargy; Overdose; Oxygen Saturation Decreased; Respiratory Rate Decreased; Tachycardia	Oxycontin			S	Oral	See Text, Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2006	5887829	EXPEDITED (15-DAY)	Y	DE	2005-132313-NL		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asphyxia; Autism Spectrum Disorder; Completed Suicide; Depressive Symptom; Morbid Thoughts; Restlessness; Sleep Disorder	Mirtazapine			S	Oral	30 Mg/60 Mg Oral	8 WEEK	Not Reported
					Oral	30 Mg/60 Mg Oral	6 DAY	
	Haloperidol			S	Oral	3 Mg/2 Mg/1 Mg/2 Mg/4 Mg Oral	11 DAY	Not Reported
					Oral	3 Mg/2 Mg/1 Mg/2 Mg/4 Mg Oral	16 DAY	
					Oral	3 Mg/2 Mg/1 Mg/2 Mg/4 Mg Oral	1 WEEK	

			Oral	3 Mg/2 Mg/1 Mg/2 Mg/4 Mg Oral	5 DAY	
			Oral	3 Mg/2 Mg/1 Mg/2 Mg/4 Mg Oral	17 DAY	
	Escitalopram Oxalate	S	Oral	5 Mg/10 Mg/15 Mg Oral	23 DAY	Not Reported
			Oral	5 Mg/10 Mg/15 Mg Oral	18 DAY	
			Oral	5 Mg/10 Mg/15 Mg Oral	1 WEEK	
	Lorazepam	S	Oral	1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral	5 DAY	Not Reported
			Oral	1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral		
			Oral	1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral	2 WEEK	
			Oral	1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral	8 DAY	
			Oral	1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral	4 DAY	
			Oral	1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral	1 WEEK	
	Mineral Oil\Phenolphthalein	S				Not Reported
	Cosaar	C				Not Reported
	Atorvastatin Calcium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2006	5895823	EXPEDITED (15-DAY)	Y	DE	S05-ISR-03498-01		66 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Citalopram			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Oxazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2006	5961913	EXPEDITED (15-DAY)	Y	OT	S05-CAN-05751-01		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Drug Hypersensitivity; Drug Screen Positive; Drug Withdrawal Syndrome; Hallucination; Laboratory Test Interference; Seizure; Serotonin Syndrome; Suicidal Ideation	Cipralex		S	Oral	10 Mg Qd Po	Not Reported
	Ativan		C			Not Reported
	Cogentin		C			Not Reported
	Benadryl		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2006	5929974	EXPEDITED (15-DAY)	Y	DE	S05-USA-04897-01		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose; Toxicity To Various Agents	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2006	5963467	DIRECT	Y				52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough	Lexapro			S	Ophthalmic	10 Mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2006	5959667	EXPEDITED (15-DAY)	Y	OT	GB-BRISTOL-MYERS SQUIBB COMPANY-13237417		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Hepatic Steatosis; Liver Function Test Abnormal	Abilify			S	Oral	Dosage: Reduced To 10 Mg Daily, Then Withdrawn		Not Reported
	Cipralex			S	Oral			Not Reported
	Tegretol			C	Oral			Not Reported
	Levothyroxine Sodium			C	Oral			Not Reported
	Levothyroxine Sodium			C				Not Reported

	Theophylline			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2006	6014103	NON-EXPEDITED	N		2005SP003485		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Somnolence	Lunesta			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg;Qd;Oral		Not Reported
	Singulair			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2006	5892691	EXPEDITED (15-DAY)	N	DS	S05-USA-04333-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Streptococcus Test Positive	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2006	5969372	EXPEDITED (15-DAY)	Y	HO, LT	S06-USA-00162-01		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Arrest; Ventricular Tachycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Concerta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2006	5969864	EXPEDITED (15-DAY)	Y	OT	S06-UKI-00033-01		32 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Dreams; Emotional Distress; Fear; Hallucination, Visual	Cipralex		S	Oral	20 Mg Qd Po	Not Reported
	Cipralex		S	Oral	20 Mg Qd Po	Not Reported
	Bisoprolol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2006	5962537	EXPEDITED (15-DAY)	N	HO	US-GLAXOSMITHKLINE-A0589290A		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Suicidal Ideation; Suicide Attempt	Paxil			S	Oral			Glaxosmithkline
	Lamictal			S	Oral		3 YR	Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Effexor			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2006	5947626	EXPEDITED (15-DAY)	Y	OT	S05-USA-05093-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Intentional Overdose	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2006	5963715	EXPEDITED (15-DAY)	Y	OT	US-MERCK-0511USA00567		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Headache; Hepatic Steatosis; Hepatotoxicity; Hypertensive Crisis; Hypoaesthesia; Oedema	Vytorin			S	Ophthalmic		40 DAY	Merck
	Lopid			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Vytorin			S	Ophthalmic		40 DAY	Merck
	Seroquel			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

Peripheral	Coreg		C	Unknown	Not Reported
	Ecotrin		C	Unknown	Not Reported
	Toprol Xl		C	Unknown	Not Reported
	Furosemide		C	Unknown	Not Reported
	K-Dur		C	Unknown	Not Reported
	Clonidine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2006	5973108	EXPEDITED (15-DAY)	Y	HO	S06-USA-00178-01		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Magnesium Decreased; Bronchitis; Feeling Abnormal; Hyponatraemia; Tremor	Lexapro			S	Oral	10 Mg Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2006	5788450	EXPEDITED (15-DAY)	Y	HO, LT, RI	S05-USA-01992-01		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Chemical Poisoning; Condition Aggravated; Dehydration; Drug Ineffective; Dysphagia; Intentional Overdose; Intestinal Infarction; Loss Of Consciousness; Oesophagectomy; Suicide Attempt	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd; Po		Not Reported
	Remeron			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2006	5971575	DIRECT	N	HO, LT, OT			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Alcoholism; Divorced; Gastric Haemorrhage; Hallucination; Legal Problem; Obsessive-Compulsive Disorder	Lexapro			S	Oral	10 Mg Once Daily Po		Not Reported
	Alcohol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2006	5971634	DIRECT	N	HO			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Malaise; Nausea; Vasculitis	Lexapro			S	Oral	10 Mg Once Daily Po		Not Reported
	Apri -Birth Control-			C				Not Reported
	Allegra			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2006	5895393	EXPEDITED (15-DAY)	Y	DS	T05-GER-03487-01			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Lichen Planus; Photosensitivity Reaction; Scratch; Skin Abrasion; Skin Atrophy	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2006	5906892	EXPEDITED (15-DAY)	Y	HO, OT	2005122045		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Pain; Blood Cholesterol Increased; Blood Pressure Fluctuation;	Neurontin			S	Oral	600 Mg (200 Mg, 3 In 1 D), Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported

Cerebrovascular Accident;	Lexapro		S			Not Reported
Condition Aggravated;	Zyprexa		S	Oral	12.5 Mg, Oral	Not Reported
Drug Hypersensitivity; Neuropathy Peripheral;	Cymbalta		S		60 Mg (1 D)	Not Reported
Retching; Throat	Lithium (Lithium)		S			Not Reported
Tightness; Tongue	Klonopin		S			Not Reported
Paralysis; Tremor	Depakote		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2006	5974002	EXPEDITED (15-DAY)	N	HO, OT	2006008257			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Hypersensitivity; Dyspnoea; Hypertension; Lung Disorder	Zyrtec-D			S				Not Reported
	Lexapro			S				Not Reported
	Lorazepam			C				Not Reported
	Zantac			C				Not Reported
	Singulair			C				Not Reported
	Albuterol (Salbutamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2006	5974885	EXPEDITED (15-DAY)	Y	HO, OT	2006-01-0993		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dry Eye; Eye Irritation; Muscle Spasms	Loratadine			S	Oral Oral Oral Oral	Oral Oral Oral Oral		Not Reported
	Lexapro			S		See Image See Image See Image See Image		Not Reported
	Prilosec			C				Not Reported
	Niacin			C				Not Reported
	Calcium Gluconate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2006	6001155	NON-EXPEDITED	Y	OT	PERC20050029		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Abuser; Emotional Disorder	Percocet			S				Endo
	Lexapro			S	Oral	10 Mg Daily Po		Forest
	Marijuana			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2006	5957079	EXPEDITED (15-DAY)	Y	OT	S05-USA-05238-01		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus-Like Syndrome	Lexapro			S				Not Reported
	Ibuprofen			C				Not Reported
	Pseudoephedrine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2006	5961698	EXPEDITED (15-DAY)	Y	HO	S05-IRL-05766-01		61 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased; Melaena	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Mobic			S	Oral	15 Mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2006	5976232	EXPEDITED (15-DAY)	Y	RI	S06-USA-00219-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Discharge; Breast Mass	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Claritin			C				Not Reported
	Skelaxin			C				Not Reported
	Advair Diskus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2006	5976237	EXPEDITED (15-DAY)	Y	OT	S06-USA-00216-01		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2006	5926966	EXPEDITED (15-DAY)	Y	HO	US-ROCHE-424968		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Agitation; Anaemia; Blood Bicarbonate Increased; Depression; Hypovolaemia; Inappropriate Antidiuretic Hormone Secretion; Mental Disorder; Metabolic Alkalosis; Paranoia; Tremor; Weight Decreased	Demadex			S	Unknown			Roche
	Lexapro			S	Unknown			Not Reported
	Ziac			S	Unknown			Not Reported
	Norvasc			C				Not Reported
	Seroquel			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2006	5939155	EXPEDITED (15-DAY)	Y	HO	HQWYE548414NOV05		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia; Blood Glucose Increased; Depression; Hypertension; Hypovolaemia; Inappropriate Antidiuretic Hormone Secretion; Metabolic Alkalosis; Nephrosclerosis;	Ziac			S				Not Reported
	Demadex			S				Not Reported
	Effexor			S				Not Reported
	Lexapro			S				Not Reported
	Norvasc			C				Not Reported
	Seroquel			C				Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported

Paranoia; Tremor; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2006	5962468	EXPEDITED (15-DAY)	N	HO	2006002050			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Rash Generalised	Lyrica			S	Oral	Oral		Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2006	5974794	DIRECT	N	DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported
	Wellbutrin Xl			S				Not Reported
	Wellbutrin Sr			S				Not Reported
	Celexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2006	5977867	EXPEDITED (15-DAY)	Y	OT	S06-USA-00218-01		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Alcohol Withdrawal Syndrome; Alcoholism; Condition Aggravated; Drug Abuser; Drug Withdrawal Syndrome; Seizure; Self-Medication; Thinking Abnormal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	60 Mg Qd Po		Not Reported
	Lexapro			S	Oral	80 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Xanax			S		2 Mg Qd		Not Reported
	Xanax			S		1 Mg Qid		Not Reported
	Xanax			S				Not Reported
	Buspar			C				Not Reported
	Remeron			C				Not Reported

	Wellbutrin (Bupropion Hydrochloride)	C		Not Reported
	Effexor	C		Not Reported
	Klonopin	C		Not Reported
	Paxil	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2006	5925021	EXPEDITED (15-DAY)		HO, LT	US-ABBOTT-05P-163-0308010-00		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Obstruction; Pancreatitis; Pseudocyst	Mavik			S	Oral		25 YR	Not Reported
	Lexapro			S	Oral		51 DAY	Not Reported
	Dyazide			S	Oral		25 YR	Not Reported
	Hydrochlorothiazide			S			25 YR	Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Indomethacin			C				Not Reported
	Metoclopramide			C				Not Reported
	Erythromycin			C				Not Reported
	Estrogens Conjugated			C	Oral			Not Reported
	Cetirizine Hydrochloride			C	Oral			Not Reported
	Singulair			C				Not Reported
	Modafinil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2006	5970616	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0537084A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dry Mouth; Insomnia; Paraesthesia	Wellbutrin			S	Oral	75mg Per Day	13 YR	Glaxosmithkline
	Strattera			S				Not Reported
	Ziagen			S				Glaxosmithkline
	Truvada			S				Not Reported
	Prevacid			S				Not Reported
	Zoloft			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2006	5970655	NON-EXPEDITED	N		S05-USA-00081-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Tenderness	Wellbutrin			S	Oral	300mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day	2 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2006	5970863	NON-EXPEDITED	N		SO5-USA-03431-01		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Fatigue; Headache; Insomnia; Mental Impairment; Nausea; Tinnitus	Wellbutrin			S	Oral	150mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day	13 MTH	Not Reported
	Diazepam			C				Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2006	5970885	NON-EXPEDITED	N		S05-USA-03669-01		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Withdrawal Syndrome; Headache; Libido Decreased; Nausea; Rash Generalised	Wellbutrin			S	Oral		7 DAY	Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day	3 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2006	5970886	NON-EXPEDITED	N		S05-USA-03678-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Dizziness; Feeling Hot; Headache; Insomnia;	Wellbutrin			S	Oral	450mg Per Day		Glaxosmithkline

Myalgia; Tremor	Lexapro	S	Oral	40mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2006	6016889	NON-EXPEDITED	Y	OT	2005159086			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lyrica			S	Unknown	Unknown (50 Mg, Unknown)		Not Reported
	Lexapro			S	Unknown	10 Mg Unknown		Not Reported
	Wellbutrin Xl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2006	6026243	NON-EXPEDITED	Y	HO	05-02-0255		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Intestinal Obstruction	Clozapine			S	Oral	575mg Qd, Oral		Not Reported
	Benztropine			S		1mg Qam; 2mg Hs		Not Reported
	Clonazepam			S	Oral	1mg Hs Prn, Oral		Not Reported
	Lexapro			S	Oral	10mg Qam, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2006	5941584	EXPEDITED (15-DAY)	Y	HO	006062		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Agitation; Anaemia; Depression; Hypertension; Hypovolaemia; Inappropriate Antidiuretic Hormone Secretion; Metabolic Alkalosis; Paranoia; Skin Turgor Decreased; Tremor;	Ziac			S				Not Reported
	Demadex			S				Not Reported
	Effexor			S				Not Reported
	Lexapro			S				Not Reported
	Norvasc			C				Not Reported
	Seroquel			C				Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported

Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2006	5975566	DIRECT	N	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Drug Withdrawal Syndrome; Nightmare	Lexapro			S		10 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2006	6024776	NON-EXPEDITED	Y	OT	141582USA		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury; Jaundice; Liver Function Test Abnormal	Copaxone			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2006	5866527	EXPEDITED (15-DAY)	Y	DE	S05-USA-03889-02		121 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Hilar Lymphadenopathy; Laboratory Test Interference; Lymphadenopathy; Maternal Condition Affecting Foetus; Maternal Exposure During Pregnancy; Neonatal Disorder; Oedema; Pulmonary Congestion; Pulmonary Haemorrhage; Respiratory Disorder Neonatal; Skin Discolouration; Sudden	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Lexapro			S		20 Mg Qd Bf		Not Reported
	Zofran			C				Not Reported
	Benadryl			C				Not Reported

Infant Death Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2006	5951256	EXPEDITED (15-DAY)	N	OT	S05-USA-05109-01		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Diabetes Mellitus; Weight Increased	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Hyzaar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2006	5987321	EXPEDITED (15-DAY)	Y	OT	S06-FRA-00093-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2006	5987604	EXPEDITED (15-DAY)	Y	OT	S05-USA-05384-01		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prostate Cancer	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2006	5987607	EXPEDITED (15-DAY)	N	OT	S06-USA-00295-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Amnesia; Condition Aggravated;	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Birth Control Pills			C				Not Reported

Depression; Feeling Abnormal; Intentional Overdose; Physical Assault; Pyromania; Suicide Attempt	Ritalin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2006	5942506	EXPEDITED (15-DAY)	Y	OT	S05-USA-05055-01		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Headache; Memory Impairment; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2006	5955051	EXPEDITED (15-DAY)	N	OT	S05-USA-05240-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Oral Candidiasis; Red Blood Cells Urine; Sjogren'S Syndrome; Urinary Tract Infection	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			S				Not Reported
	Evoxac			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2006	5959430	EXPEDITED (15-DAY)	Y	DE	S05-PRT-05744-01		31 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuser	Cipralex			S				Not Reported
	Unspecified Ingredient			C				Not Reported
	Methadone			C				Not Reported
	Mirtazapine			C				Not Reported
	Oxazepam			C				Not Reported
	Triazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2006	5983973	DIRECT	Y	DE			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Cardio-Respiratory Arrest; Dyspnoea; Nausea; Sudden Death	Lexapro			S	Oral	10 Mg Daily Po		Not Reported
	Seroquel			S	Oral	800 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2006	5986008	EXPEDITED (15-DAY)	Y	HO, LT, RI	2006-137687-NL		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Chemical Burn; Dehydration; Drug Ineffective; Dysphagia; Intentional Self-Injury; Intestinal Infarction; Self-Medication; Suicide Attempt	Remeron			S				Not Reported
	Lexapro			S	Oral	5 Mg Daily Oral, Increasing To 10 Mg		Not Reported
	Lexapro			S	Oral	10 Mg Daily Oral, About One Or Two Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2006	5978823	NON-EXPEDITED	N		S05-USA-02987-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Hyperhidrosis; Nausea; Pain; Panic Attack; Weight Increased	Paxil			S	Oral	30mg Per Day		Glaxosmithkline
	Lexapro			S	Oral		15 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2006	5979096	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0569243A		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disability; Dizziness; Drug Withdrawal Syndrome; Hyperhidrosis; Nausea; Nightmare; Urticaria	Paxil			S	Oral		6 MTH	Glaxosmithkline
	Lexapro			S	Unknown		4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2006	5979170	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0570854A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Ineffective; Feeling Abnormal; Irritability	Paxil			S	Oral	40mg Per Day		Glaxosmithkline
	Paxil Cr			S	Oral	25mg Per Day		Glaxosmithkline
	Lexapro			S			4 MTH	Not Reported
	Celebrex			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2006	5979772	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0578760A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack; Sexual Dysfunction; Tinnitus	Paxil			S	Oral	20mg Per Day	7 YR	Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2006	5985270	DIRECT	Y	DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Alcoholism; Drowning	Lexapro			S	Oral	10 Mg Daily Po		Not Reported
	Seroquel			S	Oral	100 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5889050	EXPEDITED (15-DAY)	N	RI, OT	S05-USA-04309-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Ageusia; Amnesia; Anal Incontinence; Anosmia; Anxiety; Asthenia; Cerebral Disorder; Cholecystectomy; Confusional State; Dizziness; Feeling Abnormal; Headache; Hepatic Steatosis; Hypoaesthesia; Impaired Work Ability; Insomnia; Nausea; Ovarian Cyst; Pain; Palpitations; Paraesthesia; Product Dose Omission; Tension Headache; Teratoma; Vision Blurred	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Depo-Provera			C				Not Reported
	Fastin			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5921728	EXPEDITED (15-DAY)	Y	DE, HO	L05-USA-03935-41		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Brain Oedema; Encephalopathy; Haemodialysis; Hyperammonaemia; Overdose; Posturing; Seizure; Self-Medication; Suicide Attempt	Escitalopram Oxalate			S				Not Reported
	Valproic Acid			S				Not Reported
	Lorazepam			S				Not Reported
	Metformin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5921732	EXPEDITED (15-DAY)	Y	DE, HO	L05-USA-03935-46		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Completed Suicide; Foaming At Mouth; Loss Of Consciousness; Overdose; Pneumonia Aspiration; Pulseless Electrical Activity	Escitalopram Oxalate			S				Not Reported
	Bupropion Hydrochloride			S				Not Reported
	Oxcarbazepine			S				Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5921736	EXPEDITED (15-DAY)	Y	DE	L05-USA-03935-44		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Anuria; Brain Herniation; Completed Suicide; Disseminated Intravascular Coagulation; Drug Screen Positive; Haemorrhage Intracranial; Hallucination; Hypotension; Intentional Overdose; Multiple Organ Dysfunction Syndrome; Pupil Fixed; Seizure; Tachycardia; Tremor	Escitalopram Oxalate			S				Not Reported
	Bupropion			S		75 Mg		Not Reported
	Paroxetine Hydrochloride			S		30 Mg		Not Reported
	Amphetamine Sulfate			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5921799	EXPEDITED (15-DAY)	Y	DE	L05-USA-03935-40		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Blood Pressure Systolic Decreased; Cyanosis; Hypoxic-Ischaemic	Escitalopram Oxalate			S				Not Reported
	Methadone Hydrochloride			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported

Encephalopathy; Loss Of Consciousness

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5921803	EXPEDITED (15-DAY)	Y	DE, HO	L05-USA-03935-38		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Urea Increased; Cardiac Failure Congestive; Cerebral Infarction; Coma; Completed Suicide; Hypertension; International Normalised Ratio Increased; Loss Of Consciousness; Pneumonia; Posturing; Troponin Increased	Escitalopram Oxalate			S				Not Reported
	Citalopram			S				Not Reported
	Acetaminophen And Codeine			S				Not Reported
	Acetaminophen W/Hydrocodone Bitartrate			S				Not Reported
	Ibuprofen			S				Not Reported
	Nabumetone			S				Not Reported
	Celecoxib			S				Not Reported
	Zolpidem			S				Not Reported
	Metronidazole			S				Not Reported
	Diazepam			S				Not Reported
	Metaxalone			S				Not Reported
	Amitriptyline			S				Not Reported
	Metformin			S				Not Reported
	Aspirin (Acetylsalicylic Acid)			S				Not Reported
	Bupropion			S				Not Reported
	Codeine\Promethazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5921807	EXPEDITED (15-DAY)	Y	DE	L05-USA-03935-43		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Escitalopram Oxalate			S				Not Reported
	Amitriptyline			S				Not Reported
	Chlorpromazine			S				Not Reported
	Mirtazapine			S				Not Reported
	Acetaminophen\Aspirin\Butalbital			S				Not Reported
	Misoprostol			S				Not Reported
	Nabumetone			S				Not Reported

Diclofenac	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5921809	EXPEDITED (15-DAY)	Y	DE, HO	L05-USA-03935-42		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardiac Arrest; Electrocardiogram Qrs Complex Prolonged; Loss Of Consciousness; Respiratory Arrest	Lexapro			S				Not Reported
	Amitriptyline			S				Not Reported
	Xanax			S				Not Reported
	Amphetamine			S				Not Reported
	Meperidine Hcl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5922394	EXPEDITED (15-DAY)	Y	DE	L05-USA-03935-37		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Chest Pain; Drug Abuser; Respiratory Rate Increased; Toxicity To Various Agents	Lexapro			S				Not Reported
	Cardizem			S				Not Reported
	Potassium			S				Not Reported
	Cocaine			S				Not Reported
	Nifedipine			S				Not Reported
	Hydrochlorothiazide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5923180	EXPEDITED (15-DAY)	Y	DE	L05-USA-03935-50		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Aspiration; Blood Creatinine Increased; Blood Ph Decreased; Brain Death; Cardiac Arrest; Drug Screen Positive; Hypoxic-Ischaemic	Lexapro			S				Not Reported
	Seroquel			S				Not Reported
	Clonazepam			S				Not Reported
	Metformin			S				Not Reported
	Depakote			S				Not Reported
	Haldol			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Phencyclidine			S				Not Reported

Encephalopathy; Loss Of Consciousness; Respiratory Arrest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5923188	EXPEDITED (15-DAY)	Y	DE, HO	L05-USA-03935-49		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Electroencephalogram Abnormal; Loss Of Consciousness; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Ambien			S				Not Reported
	Atenolol			S				Not Reported
	Klonopin			S				Not Reported
	Neurontin			S				Not Reported
	Topamax			S				Not Reported
	Xanax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5923193	EXPEDITED (15-DAY)	Y	DE	L05-USA-03935-48		50 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Arteriosclerosis; Arteriosclerosis Coronary Artery; Blood Pressure Decreased; Cardiomegaly; Completed Suicide; Heart Rate Decreased; Loss Of Consciousness; Toxicologic Test Abnormal	Lexapro			S				Not Reported
	Doxepin			S				Not Reported
	Lopresor			S				Not Reported
	Plavix			S				Not Reported
	Temazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5923200	EXPEDITED (15-DAY)	Y	DE, HO	L05-USA-03935-47		16 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S				Not Reported
	Dextroamphet Saccharat, Amphet Aspartate, Dextroamphet Sulfate And			S				Not Reported

Amphet Sulfat

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5940251	EXPEDITED (15-DAY)	Y	OT	S05-USA-05035-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5957082	EXPEDITED (15-DAY)	Y	OT	S05-USA-05241-01		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Drug Abuser; Loss Of Consciousness; Treatment Noncompliance	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			C				Not Reported
	Marijuana			C				Not Reported
	Effexor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5961117	EXPEDITED (15-DAY)	N	DE	S05-USA-05297-01		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5982022	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0567941A		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Insomnia; Nervousness;	Paxil Cr			S	Oral	12.5mg Per Day		Glaxosmithkline

Somnolence	Paxil		S	Oral	20mg Per Day	2 WEEK	Glaxosmithkline
	Lexapro		S	Unknown			Not Reported
	Biotin		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5985946	DIRECT	Y	OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Rash	Lexapro			S	Oral	10mg Po Q Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5986875	DIRECT	N	HO, LT			35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Pancreatic Necrosis; Pancreatitis Acute; Treatment Noncompliance	Lexapro			S	Oral	Daily Po	1 YR	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5993032	EXPEDITED (15-DAY)	Y	DE	L05-USA-03935-45		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Atrioventricular Block First Degree; Bundle Branch Block; Bundle Branch Block Left; Cardiac Arrest; Completed Suicide; Drug Level Above Therapeutic; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Hypotension; Hypoxia; Loss Of	Escitalopram Oxalate			S				Not Reported
	Bupropion			S				Not Reported
	Topiramate			S				Not Reported
	Oxcarbazepine			S				Not Reported
	Phenytoin			S				Not Reported

Consciousness; Muscle Twitching; Serotonin Syndrome; Toxicity To Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5993250	EXPEDITED (15-DAY)	Y	HO	S06-USA-00343-01		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Areflexia; Cerebral Atrophy; Cerebral Ischaemia; Cerebral Ventricle Dilatation; Chronic Sinusitis; Confusional State; Diarrhoea; Dysarthria; Dystonia; Extrapyramidal Disorder; Fall; Gait Disturbance; Gait Inability; Hallucination; Joint Stiffness; Muscle Rigidity; Nervous System Disorder; Normal Pressure Hydrocephalus; Peroneal Nerve Palsy; Sciatica; Somnolence; Spinal Cord Compression; Spinal Stenosis; Tardive Dyskinesia; Vomiting; Weight Decreased	Celexa			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Haldol			S				Not Reported
	Risperdal			S	Oral	0.5 Mg Bid Po		Not Reported
	Aricept			S	Oral	2.5 Mg Qd Po		Not Reported
	Aricept			S	Oral	5 Mg Qd Po		Not Reported
	Synthroid			C				Not Reported
	Lopresor			C				Not Reported
	Epogen			C				Not Reported
	Protonix			C				Not Reported
	Promod (Proglumide)			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Vitamin E			C				Not Reported
	Multivitamin (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5994005	EXPEDITED (15-DAY)	Y	DE	S06-USA-00459-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2006	5996183	EXPEDITED (15-DAY)	Y	HO	S06-ESP-00413-01		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hyponatraemia; Nervousness	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported
	Plantaben (Ispaghula Husk)			C				Not Reported
	Plavix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2006	5941201	EXPEDITED (15-DAY)	Y	HO	S05-USA-05053-01		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Enterocolitis Infectious; Influenza Like Illness	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2006	5992864	EXPEDITED (15-DAY)	Y	HO	S06-USA-00344-01		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenic Purpura	Lexapro			S	Oral	10 Mg Po		Not Reported
	Atenolol			C				Not Reported
	Zocor			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2006	5992928	EXPEDITED (15-DAY)	N	OT	S06-USA-00457-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Condition Aggravated; Depression; Dizziness; Erectile Dysfunction; Suicidal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Ideation; Treatment
Noncompliance; Type 2
Diabetes Mellitus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2006	5960041	EXPEDITED (15-DAY)	N	OT	S05-USA-05284-01		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Constipation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lisinopril			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Armour Thyroid			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2006	5996826	EXPEDITED (15-DAY)	Y	OT	S06-FRA-00439-01		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Legal Problem	Escitalopram Oxalate			S				Not Reported
	Prozac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2006	5926636	EXPEDITED (15-DAY)	Y	OT	S05-FRA-04645-01		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Kleptomania	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2006	5997257	EXPEDITED (15-DAY)	Y	OT	S06-ISR-00602-01		44 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mastitis; Purulence	Cipralex			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2006	5997268	EXPEDITED (15-DAY)	Y	DS	S05-CAN-05735-01		19 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoacusis; Sudden Hearing Loss	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2006	5921802	EXPEDITED (15-DAY)	Y	DE	L05-USA-03935-39		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Acetaminophen W/Hydrocodone Bitartrate			S				Not Reported
	Klonopin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2006	5991952	DIRECT		RI			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Muscle Twitching; Panic Attack; Paraesthesia; Restlessness; Thinking Abnormal	Paxil			S	Oral	20 Mg 1 Day Po 10 Years On And Off	10 YR	Not Reported
	Lexapro			S	Oral	20 Mg 1 Day Po Ten Years On And Off	10 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2006	5999345	EXPEDITED (15-DAY)	N	DE	S06-USA-00507-01		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Incorrect Dose Administered;	Lexapro			S	Oral	10 Mg Qd, Po		Not Reported
	Klonopin (Bupropion Hydrochloride)			C				Not Reported

Treatment Noncompliance	Wellbutrin (Bupropion Hydrochloride)	C		Not Reported
	Ambien	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2006	5999445	EXPEDITED (15-DAY)	Y	HO	S06-USA-00548-01		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Glomerulosclerosis	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Altace			S		5 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2006	5952033	EXPEDITED (15-DAY)	Y	HO	S05-USA-05176-01		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Therapy Non-Responder	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Albuterol			C				Not Reported
	Atrovent			C				Not Reported
	Advair Diskus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2006	5987316	EXPEDITED (15-DAY)	Y	HO	S06-SWI-00096-01		57 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Epilepsy; Flushing; Inappropriate Antidiuretic Hormone Secretion; Respiration Abnormal; Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Zyprexa			S	Oral	5 Mg Bid Po		Not Reported
	Enalapril Maleate			C				Not Reported
	Fluvastatin Sodium			C				Not Reported
	Temesta (Lorazepam)			C				Not Reported
	Pantozol (Pantoprazole Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2006	5988715	EXPEDITED (15-DAY)	Y	OT	US-JNJFOC-20060203259		< 1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Breast Feeding; Sedation; Selective Eating Disorder	Topamax			S				Not Reported
	Lexapro			S				Not Reported
	Abilify			S				Not Reported
	Remeron			S				Not Reported
	Zyprexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2006	6000625	EXPEDITED (15-DAY)	Y	OT	S06-USA-00553-01		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Pregnancy; Seizure	Lexapro			S				Not Reported
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2006	6045286	NON-EXPEDITED	N	OT	HQWYE594417NOV05		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Headache	Protonix			S				Not Reported
	Lecithin (Lecithin)			S				Not Reported
	Lexapro			S	Oral	10 Mg 1x Per 1 Day, Oral		Not Reported
					Oral	10 Mg 1x Per 1 Day, Oral		
	Premarin			C				Not Reported
	Multivitamins, Plain (Multivitamins, Plain)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2006	4144647	EXPEDITED (15-DAY)	N	DE, HO	US-GLAXOSMITHKLINE-A0511773A		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardioactive Drug Level Increased; Decreased Appetite; Drug Interaction; Hypertension; Loss Of Consciousness; Renal Failure; Transient Ischaemic Attack; Weight Decreased	Lanoxin	S	Oral		Glaxosmithkline
	Lexapro	S			Not Reported
	Inderal	C			Not Reported
	Megace	C			Not Reported
	Digibind	C			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2006	5954527	EXPEDITED (15-DAY)	Y	OT	S05-USA-05183-01		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Condition Aggravated; Dysarthria; Dyskinesia; Feeling Abnormal; Hyperhidrosis; Insomnia; Paraesthesia	Lexapro			S	Oral	20 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	5 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	10 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	15 Mg Qhs Po		Not Reported
	Ambien			C				Not Reported
	Seroquel			C				Not Reported
	Zoloft			C				Not Reported
	Concerta			C				Not Reported
	Allegra			C				Not Reported
	Xanax			C				Not Reported
	Pulmicort Flexhaler			C				Not Reported
	Hydrocodone			C				Not Reported
	Albuterol			C				Not Reported
	Atrovent			C				Not Reported
	Floradil (Formoterol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2006	5959436	EXPEDITED (15-DAY)	Y	OT	S05-FRA-05747-01		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mallory-Weiss Syndrome; Oesophagitis; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Minocin			S	Oral	100 Mg Qd Po		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2006	6000380	EXPEDITED (15-DAY)	Y	HO	S06-FRA-00797-01		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyelonephritis Acute; Transaminases Increased	Escitalopram Oxalate			S				Not Reported
	Antibiotics			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2006	6000941	EXPEDITED (15-DAY)	N	RI	S06-USA-00555-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Gestational Diabetes; Maternal Exposure During Pregnancy; Pregnancy; Umbilical Cord Around Neck	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Toprol Xl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2006	5888207	EXPEDITED (15-DAY)	Y	DE	DSA_26954_2005		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Asphyxia; Bipolar I Disorder; Completed Suicide; Depressive Symptom; Feeling Abnormal; Mutism; Sleep Disorder	Lorazepam			S	Oral	1 Mg Q Day Po		Not Reported
	Lorazepam			S	Oral	3 Mg Q Day Po		Not Reported
	Lorazepam			S	Oral	2 Mg Q Day Po		Not Reported
	Lorazepam			S	Oral	1.5 Mg Q Day Po		Not Reported
	Lorazepam			S	Oral	1.5 Mg Q Day Po		Not Reported
	Lorazepam			S	Oral	0.5 Mg Q Day Po		Not Reported
	Cipralex			S	Oral	5 Mg Q Day Po		Not Reported
	Cipralex			S	Oral	10 Mg Q Day Po		Not Reported
	Cipralex			S	Oral	15 Mg Q Day Po		Not Reported

Remeron	S	Oral	30 Mg Q Day Po		Not Reported
Remeron	S	Oral	60 Mg Q Day Po		Not Reported
Haldol	S		Van Q Day		Not Reported
Haldol	S		2 Mg Q Day		Not Reported
Haldol	S		1 Mg Q Day		Not Reported
Haldol	S		2 Mg Q Day		Not Reported
Haldol	S		4 Mg Q Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2006	5942869	EXPEDITED (15-DAY)	Y	OT	US-ABBOTT-05P-163-0319075-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased; Jaundice; Platelet Count Increased; Tachypnoea	Lexapro			S				Not Reported
	Prenatal Vitamins			C				Not Reported
	Antidepressants			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2006	6001798	EXPEDITED (15-DAY)	Y	DE	S06-UKI-00626-01		48 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Co-Phenotrope			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Ranitidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2006	5905524	EXPEDITED (15-DAY)	N	DE, HO	US-ABBOTT-05P-163-0313788-00		55 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Acetaminophen\Hydrocodone Bitartrate			S		Not Reported		Not Reported
	Escitalopram Oxalate			S		Not Reported		Not Reported

Increased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Urea Increased; Cardiac Failure Congestive; Cerebral Infarction; Coma; Completed Suicide; Hypertension; Intentional Overdose; Pneumonia; Troponin Increased	Ibuprofen	S	Not Reported	Not Reported
	Acetaminophen\Codeine	S	Not Reported	Not Reported
	Phosphate			
	Citalopram	S	Not Reported	Not Reported
	Nabumetone	S	Not Reported	Not Reported
	Celecoxib	S	Not Reported	Not Reported
	Zolpidem	S	Not Reported	Not Reported
	Metronidazole	S	Not Reported	Not Reported
	Diazepam	S	Not Reported	Not Reported
	Metaxalone	S	Not Reported	Not Reported
	Amitriptyline	S	Not Reported	Not Reported
	Metformin	S	Not Reported	Not Reported
	Acetylsalicylic Acid	S	Not Reported	Not Reported
	Bupropion	S	Not Reported	Not Reported
	Codeine\Promethazine	S	Not Reported	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2006	6002401	EXPEDITED (15-DAY)	Y	HO	S05-USA-04943-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported
	Unspecified Ingredient			S				Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2006	5886170	NON-EXPEDITED	Y	OT	S05-USA-04021-01		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Nasopharyngitis	Lamictal			S	Oral	75mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	2.5mg Per Day		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2006	5993528	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0549616A		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash	Lamictal			S	Oral	100mg Per Day	2 WEEK	Glaxosmithkline
	Lexapro			S	Oral			Not Reported
	Wellbutrin Xl			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2006	5994338	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0580822A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oropharyngeal Blistering; Photopsia; Toothache	Lamictal			S	Oral	175mg Per Day	16 MTH	Glaxosmithkline
	Lexapro			S	Oral	5mg At Night		Not Reported
	Lexapro			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2006	5994452	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0584204A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Depression; Malaise; Nausea; Weight Decreased; Weight Increased	Lamictal			S	Oral	150mg Unknown		Glaxosmithkline
	Wellbutrin			S	Oral	300mg Unknown		Glaxosmithkline
	Lexapro			S	Unknown	20mg Unknown		Not Reported
	Seroquel			S	Unknown	100mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2006	5994503	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0555421A		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rash	Lamictal		S	Oral	25mg Per Day	1 MTH	Glaxosmithkline
	Lexapro		S	Unknown	10mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2006	5994685	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0560556A		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lamictal			S	Oral	200mg Unknown		Glaxosmithkline
	Lexapro			S	Unknown	10mg Unknown		Not Reported
	Ativan			S	Unknown	5mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2006	5994740	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0562100A		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Hyperhidrosis	Lamictal			S	Oral	100mg Twice Per Day	1 YR	Glaxosmithkline
	Lexapro			S				Not Reported
	Klonopin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2006	5995241	NON-EXPEDITED	N		S05-USA-00407-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction	Imitrex			S	Unknown			Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2006	5995361	NON-EXPEDITED	N		S05-USA-03818-01		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Asthenia; Disturbance In Attention; Drug Interaction; Fatigue; Migraine	Imitrex		S	Unknown		Glaxosmithkline
	Lexapro		S	Oral	10mg Per Day	Not Reported
	Prevacid		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2006	5999036	EXPEDITED (15-DAY)	Y	OT	S06-FRA-00607-01		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Interaction; Supraventricular Extrasystoles	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Interferon Alfa			S				Not Reported
	Ribavirin			S				Not Reported
	Levothyroxine Sodium			S				Not Reported
	Acetaminophen			C				Not Reported
	Zolpidem			C				Not Reported
	Urbanyl			C				Not Reported
	Domperidone			C				Not Reported
	Diosmin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2006	6004092	EXPEDITED (15-DAY)	Y	OT	S06-BEL-00806-01		98 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transient Ischaemic Attack	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Loperamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2006	6004958	EXPEDITED (15-DAY)	Y	OT	S06-USA-00600-1			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2006	6004991	EXPEDITED (15-DAY)	Y	DE, HO	A001-002-006789		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Amnesia; Anger; Cardiopulmonary Failure; Confusional State; Delusion; Dementia; Depression; Frustration Tolerance Decreased; Hallucination; Hypotension; Muscle Spasms; Nocturia; Overdose; Screaming; Urinary Incontinence; Urinary Tract Infection	Aricept			S	Oral	Oral		Not Reported
	Diflucan			S	Oral	Oral		Not Reported
	Seroquel			S				Not Reported
	Risperdal			S				Not Reported
	Lexapro			S				Not Reported
	Naprosyn			S				Not Reported
	Exelon			C				Not Reported
	Atarax			C				Not Reported
	Lisinopril (Lisinopril)			C				Not Reported
	Lotrel			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported
	Vistane			C				Not Reported
	Depakote			C				Not Reported
	Depakene			C				Not Reported
	Cogentin			C				Not Reported
	Ativan			C				Not Reported
	Ciprofloxacin			C				Not Reported
	Probiotica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	5991482	EXPEDITED (15-DAY)	Y	OT	FR-ABBOTT-06P-056-0324872-00		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Interaction; Supraventricular Extrasystoles	Levothyrox			S				Not Reported
	Paracetamol			C				Not Reported
	Zolpidem			C				Not Reported
	Clobazam			C	Oral			Not Reported
	Domperidone			C				Not Reported
	Diosmin			C				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Peginterferon Alfa-2a			S				Not Reported

Ribavirin		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6002981	DIRECT	N	LT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Self-Injurious Ideation; Suicide Attempt	Lexapro			S		1/2 Tab X 6 Than 1 Tab After		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6005505	EXPEDITED (15-DAY)	N	HO	S06-USA-00546-01		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Magnesium Abnormal; Blood Potassium Abnormal; Blood Sodium Abnormal; Chest Pain; Electrolyte Imbalance; Musculoskeletal Pain	Lexapro			S				Not Reported
	Dessicare (Nos)			C				Not Reported
	Fosamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6005511	EXPEDITED (15-DAY)	Y	OT	S06-USA-00638-03			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6005515	EXPEDITED (15-DAY)	Y	LT, OT	S06-USA-00638-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6005528	EXPEDITED (15-DAY)	N	DE	S06-USA-00641-01		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Alcohol Problem; Completed Suicide; Multiple Injuries	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6005530	EXPEDITED (15-DAY)	N	DE	S06-USA-00598-03		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6005532	EXPEDITED (15-DAY)	N	DE	S06-USA-00598-02			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6005534	EXPEDITED (15-DAY)	N	DE	S06-USA-00598-01		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6006606	EXPEDITED (15-DAY)	Y	OT	S06-USA-00638-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6006608	EXPEDITED (15-DAY)	Y	HO, LT	S06-USA-00648-01		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Iatrogenic Injury; Inappropriate Antidiuretic Hormone Secretion; Influenza Like Illness; Respiratory Arrest; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lisinopril			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6006609	EXPEDITED (15-DAY)	N	OT	S06-USA-00645-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hernia; Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2006	6045035	NON-EXPEDITED	N		S06-USA-00306-01		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia	Campral			S	Oral	666 Mg Tid Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2006	6005900	EXPEDITED (15-DAY)	Y	HO, LT	SEWYE440601MAR06		69 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia; Seizure	Effexor			S	Oral	75 Mg 1x Per 1 Day Oral	11 DAY	Not Reported
	Cipralex			S	Oral	10 Mg 1x Per 1 Day Oral	9 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2006	6035465	EXPEDITED (15-DAY)	Y	HO	CH-JNJFOC-20060300686		47 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Drug Interaction; Intentional Overdose; Intentional Overdose; Serotonin Syndrome; Suicide Attempt	Tramadol Hydrochloride			S	Oral	Duration: Once		Not Reported
	Cipralex			S	Oral			Not Reported
	Bromazepam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2006	5893996	EXPEDITED (15-DAY)	Y	HO	S05-USA-04347-01		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Status Changes; Seizure	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Tegretol			C				Not Reported
	Lopresor			C				Not Reported
	Synthroid (Lelvothyroxine Sodium)			C				Not Reported
	Glipizide			C				Not Reported
	Aciphex			C				Not Reported
	Doxycycline			C				Not Reported
	Coumadin			C				Not Reported
	Reglan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2006	5949477	EXPEDITED (15-DAY)	Y	HO	US-ABBOTT-05P-163-0319679-00		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Enterocolitis Infectious	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2006	5955052	EXPEDITED (15-DAY)	N	OT	S05-USA-05178-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dyspepsia; Eructation; Platelet Count Decreased; Red Blood Cell Macrocytes Present; Splenomegaly; White Blood Cell Count Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Multi-Vitamin			C				Not Reported
	Folic Acid			C				Not Reported
	Calcium Gluconate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2006	6007638	EXPEDITED (15-DAY)	N	OT	S06-USA-00597-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Asphyxia; Completed Suicide; Disease Recurrence; Fear; Hallucination, Auditory; Influenza Like Illness; Nephrolithiasis; Obsessive Thoughts; Scratch; Treatment Noncompliance	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2006	6007639	EXPEDITED (15-DAY)	N	HO	S06-USA-006644-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Decreased Appetite; Fatigue; Feeling Cold; Hypersomnia; Nausea; Somnolence	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Percocet			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Carisoprodol			C				Not Reported

	Clorazepate Dipotassium	C	Not Reported
	Premarin	C	Not Reported
	Clarinex	C	Not Reported
	Singulair	C	Not Reported
	Zantac	C	Not Reported
	Flovent	C	Not Reported
	Albuterol	C	Not Reported
	Finacea	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2006	6008076	EXPEDITED (15-DAY)	N	OT	S06-USA-00596-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiration Abnormal; Urticaria	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2006	6008369	EXPEDITED (15-DAY)	Y	OT	S06-GER-00822-01		57 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2006	5798822	EXPEDITED (15-DAY)	N	HO	S05-USA-02268-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour;	Lexapro			S				Not Reported
Bipolar I Disorder; Stress;	Lexapro			S				Not Reported
Suicidal Ideation	Hormones (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2006	5992746	EXPEDITED (15-DAY)	Y	OT	S06-USA-00347-01		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Insomnia; Irritability; White Blood Cell Count Increased	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Seroquel			S	Oral	100 Mg Qhs Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2006	5996682	EXPEDITED (15-DAY)	Y	OT	S06-USA-00487-01		30 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Divorced Parents; Failure To Thrive; Maternal Exposure During Breast Feeding; Suppressed Lactation; Treatment Noncompliance; Weight Gain Poor	Lexapro			S				Not Reported
	Mircette			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2006	6002451	EXPEDITED (15-DAY)	Y	HO	T06-USA-00793-01		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis Intestinal Haemorrhagic	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Placebo			S	Oral	1 Capsule Qd Po		Not Reported
	Aspirin (Acetylsalicylic Acid)			S	Oral	650 Mg Bid Po		Not Reported
	Furosemide			C				Not Reported
	Lipitor			C				Not Reported
	Potassium			C				Not Reported
	Diovan			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2006	6009025	EXPEDITED (15-DAY)	Y	OT	S06-USA-00681-02		2 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Neonatal Oversedation; Selective Eating Disorder	Lexapro			S	Transplacental	Mg Transplacental		Not Reported
	Lexapro			S		Mg Bf		Not Reported
	Topamax			S	Transplacental	Mg Transplacental		Not Reported
	Topamax			S		Mg Bf		Not Reported
	Abilify			S	Transplacental	Mg Transplacental		Not Reported
	Abilify			S		Mg Bf		Not Reported
	Remeron			S	Transplacental	Mg Transplacental		Not Reported
	Remeron			S		Mg Bf		Not Reported
	Zyprexa			S	Transplacental	Mg Transplacental		Not Reported
	Zyprexa			S		Mg Bf		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2006	6009026	EXPEDITED (15-DAY)	Y	HO	S06-USA-00682-01		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	200 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2006	6009029	EXPEDITED (15-DAY)	N	DE	S06-USA-00727-01		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Head Injury	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Clonazepam			C				Not Reported
	Temazepam			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2006	6008867	EXPEDITED (15-DAY)	Y	OT	S06-UKI-00983-01		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Loratadine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2006	6008870	EXPEDITED (15-DAY)	Y	LT	S06-UKI-00993-01		55 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Donepezil Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2006	6009631	EXPEDITED (15-DAY)	Y	OT	2006-139169-NL		2 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Neonatal Disorder; Nervous System Disorder; Sedation; Selective Eating Disorder	Remeron			S				Not Reported
	Topamax			S				Not Reported
	Lexapro			S				Not Reported
	Abilify			S				Not Reported
	Zyprexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2006	6001834	EXPEDITED (15-DAY)	Y	OT	S06-CAN-00629-01		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Generalised Tonic-Clonic Seizure; Loss Of Consciousness	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qod Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2006	6002611	EXPEDITED (15-DAY)	Y	DE, HO, OT	2006024700		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Amnesia; Anger; Cardiopulmonary Failure; Condition Aggravated; Confusional State; Delusion; Dementia Alzheimer'S Type; Frustration Tolerance Decreased; Hallucination; Hypotension; Muscle Spasms; Muscle Twitching; Nocturia; Overdose; Urinary Tract Infection; Vomiting	Diflucan			S	Oral	150 Mg, Oral		Not Reported
	Seroquel			S				Not Reported
	Risperdal			S				Not Reported
	Lexapro			S				Not Reported
	Naprosyn			S				Not Reported
	Aricept			C				Not Reported
	Exelon			C				Not Reported
	Atarax			C				Not Reported
	Lisinopril (Lisinopril)			C				Not Reported
	Lotrel			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Depakote			C				Not Reported
	Depakene			C				Not Reported
	Cogentin			C				Not Reported
	Ativan			C				Not Reported
	Ciprofloxacin Hydrochloride			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2006	6010700	EXPEDITED (15-DAY)	Y	OT	S06-FRA-00984-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Pyrexia; Red Blood Cell Sedimentation Rate Increased	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Tegretol			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Oromone (Estradiol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2006	6010711	EXPEDITED (15-DAY)	Y	OT	S06-BEL-00982-01		69 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Dysarthria; Dyskinesia; Impaired Driving Ability; Muscle Rigidity;	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Prazepam			C				Not Reported

Nervousness; Self-Medication; Tardive Dyskinesia	Symbicort	C		Not Reported
	Tiotropium Bromide	C		Not Reported
	Lorazepam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2006	5920630	EXPEDITED (15-DAY)	Y	OT	T05-USA-03925-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aleve			S		4180 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2006	6007590	DIRECT	N	DE			22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Partner Stress	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2006	6008530	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Lexapro			S	Oral	1/2 Tablet Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2006	6010599	EXPEDITED (15-DAY)	Y	DE	S06-FRA-00997-01		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Completed Suicide; Gun Shot Wound	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Seropram (Citalopram Hydrobromide)			S	Intravenous (not otherwise specified)	40 Mg Qd Iv		Not Reported

	Buspar	C	Not Reported
	Atarax	C	Not Reported
	Anafranil	C	Not Reported
	Abilify	C	Not Reported
	Oxazepam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2006	6010600	EXPEDITED (15-DAY)	Y	HO	S06-ESP-00996-01		26 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Nystagmus; Vertigo	Escitalopram Oxalate			S	Oral	5 Mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2006	5850803	EXPEDITED (15-DAY)	Y	DE	T05-FIN-02354-01		44 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Accidental Poisoning; Alcohol Interaction; Cardiomegaly; Contusion; Drug Interaction; Drug Level Below Therapeutic; Drug Screen Positive; Hyperglycaemia; Lactic Acidosis; Scar; Skin Abrasion; Sudden Death; Toxicity To Various Agents	Cipralex			S		20 Mg Qd		Not Reported
	Viagra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2006	6009023	EXPEDITED (15-DAY)	Y	OT	S06-USA-00709-01		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported

Actos (Piogtlitazone)	C		Not Reported
Crestor (Rosuvatatin)	C		Not Reported
Aspirin	C		Not Reported
Plavix	C		Not Reported
Hydrochlorothiazide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2006	6012038	EXPEDITED (15-DAY)	N	DE	S06-USA-01050-01		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Head Injury	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2006	6012040	EXPEDITED (15-DAY)	Y	OT	S06-USA-01051-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2006	6012083	EXPEDITED (15-DAY)	Y	HO	S06-USA-00750-01		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2006	6012089	EXPEDITED (15-DAY)	Y	HO	S06-USA-00749-01		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Large Intestinal Ulcer Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2006	6002642	EXPEDITED (15-DAY)	Y	DE	S04-USA-03204-01		91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Decreased Appetite; Dehydration; Loss Of Consciousness; Renal Failure; Toxicity To Various Agents; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Digoxin			S				Not Reported
	Inderal			C				Not Reported
	Celebrex			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Statin Medication			C				Not Reported
	Enlarged Heart Medication			C				Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2006	6011391	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Skin Abrasion; Tooth Erosion; Tooth Injury	Lexapro			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2006	6013135	EXPEDITED (15-DAY)	Y	OT	S06-USA-01064-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Headache; Malaise	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Premarin			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2006	6015371	EXPEDITED (15-DAY)	Y	OT	S06-UKI-01014-01		19 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Balance Disorder; Chest Discomfort; Diarrhoea; Dizziness; Jaw Disorder; Malaise; Tremor; Visual Impairment	Cipralex		S	Oral	20 Mg Daily Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2006	6010753	DIRECT	N	HO			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Reaction; Anxiety; Chest Discomfort; Chest Pain; Dyspnoea; Muscle Twitching; Panic Attack; Pruritus; Rash; Thinking Abnormal; Tremor	Lexapro			S	Oral	1 Daily Po		Forest
	Clonazepam			C				Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2006	6014319	EXPEDITED (15-DAY)	Y	DE, HO	PAR_0535_2006		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Blood Creatinine Increased; Blood Urea Increased; Body Temperature Increased; Cardiac Failure Congestive; Cerebral Infarction; Coma; Completed Suicide; Drug Screen Positive; Hypertension;	Ibuprofen			S		Df		Not Reported
	Aspirin			S		Df		Not Reported
	Citalopram			S		Df		Not Reported
	Diazepam			S		Df		Not Reported
	Amitriptyline			S		Df		Not Reported
	Metformin			S		Df		Not Reported
	Escitalopram Oxalate			S	Oral	Df Po		Not Reported
	Acetaminophen And Codeine			S		Df		Not Reported
	Acetaminophen\Hydrocodone Bitartrate			S		Df		Not Reported

International Normalised Ratio Increased; Loss Of Consciousness; Pneumonia; Posturing; Troponin Increased	Nabumetone	S	Df	Not Reported
	Zolpidem	S	Df	Not Reported
	Celecoxib	S	Df	Not Reported
	Metronidazole	S	Df	Not Reported
	Metaxalone	S	Df	Not Reported
	Bupropion	S	Df	Not Reported
	Promethazine And Codeine	S	Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2006	5987327	EXPEDITED (15-DAY)	Y	DS	S06-FRA-00090-01		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Galactorrhoea; Nausea; Photopsia; Vomiting	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2006	6007015	EXPEDITED (15-DAY)	Y	OT	2006UW04073		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Flutter; Palpitations	Seroquel			S	Oral			Zeneca
	Depakote Er			S				Not Reported
	Lexapro			S				Not Reported
	Neurontin			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2006	6016828	EXPEDITED (15-DAY)	Y	HO, LT	S06-DEN-01202-01		69 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Hyponatraemia; Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2006	6007740	EXPEDITED (15-DAY)	Y	OT	US-JNJFOC-20060303621		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Drug Interaction; Electrocardiogram Qt Prolonged; Palpitations; Sinus Tachycardia; Supraventricular Extrasystoles; Vertigo	Flexeril			S			2 DAY	Not Reported
	Clonidine			C	Oral		13 DAY	Not Reported
	Valium			C	Oral	Varying Doses	3 DAY	Not Reported
	Vistaril			C	Oral			Not Reported
	Trazodone			C	Oral			Not Reported
	Ibuprofen			C	Oral		8 DAY	Not Reported
	Ibuprofen			C	Oral		8 DAY	Not Reported
	Toradol			C			4 DAY	Not Reported
	Toradol			C		30 Mg, Once, Intramuscular	4 DAY	Not Reported
	Keflex			C	Oral		8 DAY	Not Reported
	Tigan			C	Oral		3 DAY	Not Reported
	Diflucan			C	Oral			Not Reported
	Rozerem			S	Oral			Not Reported
	Seroquel			S	Oral	50mg Q8hrs And 100mg Hs		Not Reported
	Lexapro			S	Oral		13 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2006	6012239	DIRECT	Y	OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Fatigue	Lexapro			S	Oral	20 Mg Daily, Hs Po (Intermittent)		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2006	5999423	EXPEDITED (15-DAY)	Y	OT	S06-USA-00518-01		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Aphasia; Disturbance In Attention; Drug Ineffective; Economic Problem; Emotional Disorder; Musculoskeletal Pain; Speech Disorder	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2006	6005474	EXPEDITED (15-DAY)	Y	HO	S06-USA-00570-01		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diastolic Dysfunction; Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported
	Lasix			C				Not Reported
	Lisinopril			C				Not Reported
	Lortab			C				Not Reported
	Aspirin			C				Not Reported
	Pepcid			C				Not Reported
	Ativan			C				Not Reported
	Kay Ciel			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Mylicon Drops			C				Not Reported
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2006	6008507	EXPEDITED (15-DAY)	Y	HO	2006PK00508		73 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Confusional State; Dehydration;	Seroquel			S	Oral		2 MTH	Zeneca
	Beloc Mite (Metoprolol Tartrate)			C	Oral			Not Reported

Disorientation; Drug Interaction; Headache; Hypophagia; Mydriasis; Serotonin Syndrome; Toxicity To Various Agents; Tremor	Aspirin	C	Oral			Not Reported
	Lorazepam	C	Oral			Not Reported
	Pravastatin	C	Oral			Not Reported
	Calcimagon-D3	C	Oral			Not Reported
	Fosamax	C	Oral			Not Reported
	Lithium Carbonate	S	Oral		2 MTH	Not Reported
	Cipralex	S	Oral		2 MTH	Not Reported
	Remeron	S	Oral		2 MTH	Not Reported
	Valproate Sodium	S	Oral		2 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2006	6019154	EXPEDITED (15-DAY)	Y	OT	S06-USA-01092-01		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2006	6019157	EXPEDITED (15-DAY)	Y	HO	2006-139622-NL		73 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Confusional State; Drug Interaction; Fluid Intake Reduced; Headache; Hypophagia; Mydriasis; Serotonin Syndrome; Toxicity To Various Agents; Tremor	Mirtazapine			S	Oral	Df	2 MTH	Not Reported
	Potassium Sulfate			S		660 Mg	2 MTH	Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg	2 MTH	Not Reported
	Valproate Sodium			S	Oral	Df	2 MTH	Not Reported
	Quetiapine Fumarate			S	Oral	300 Mg	2 MTH	Not Reported
	Metoprolol Tartrate			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Lorazepam			C				Not Reported
	Pravastatin			C				Not Reported
	Calcimagon-D3			C				Not Reported
	Alendronate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2006	5951680	EXPEDITED (15-DAY)	Y	RI, OT	TPA2005A01628		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Long Qt Syndrome; Palpitations; Sinus Tachycardia; Supraventricular Extrasystoles; Vertigo	Rozerem			S	Oral	8 Mg, Qhs, Per Oral		Not Reported
	Seroquel			S	Oral	50 Mg, Every 8 Hrs And 100 Mg At Hs, Per Oral		Not Reported
	Lexapro			S	Oral	10 Mg, 1 In 1 D, Per Oral		Not Reported
	Flexeril			S		10 Mg, Qam & Qhs		Not Reported
	Diflucan			C				Not Reported
	Clonidine			C				Not Reported
	Valium			C				Not Reported
	Vistaril			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Ibuprofen			C				Not Reported
	Toradol			C				Not Reported
	Keflex			C				Not Reported
	Tigan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2006	6016841	EXPEDITED (15-DAY)	Y	OT	S06-FRA-01028-01		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Seretide Diskus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2006	6018281	EXPEDITED (15-DAY)	N	OT	2006036438		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Feeling Abnormal; Haematemesis; Mood Swings; Nausea; Oesophageal Disorder;	Geodon			S		40 Mg (40 Mg, 1 In 1 D),		Not Reported
	Lexapro			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported

Retching; Vomiting	Klonopin	S	1 Mg (0.5 Mg, 2 In 1 D),		Not Reported
	Biovan "Novartis" (Valsartan)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2006	6018591	EXPEDITED (15-DAY)	Y	OT	L06-GER-00428-01		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder; Serotonin Syndrome; Therapy Non-Responder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Zotepine			S	Oral	50 Mg Qd Po		Not Reported
	Mesalazine			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Propranolol			C				Not Reported
	Glimepiride			C				Not Reported
	Phenprocoumon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2006	6018593	EXPEDITED (15-DAY)	Y	OT	S06-ESP-00809-01		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Hallucination; Paronychia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2006	3914213	EXPEDITED (15-DAY)	Y	HO, LT	PHFR2003IE00498		31 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Blood Bicarbonate Decreased; Blood Chloride Increased; Blood Electrolytes	Clozaril			S	Oral	450mg/Day	2413 DAY	Novartis
	Clozaril			S	Oral	80-100x100mg/Overdose	2880 MIN	Novartis
	Clozaril			S	Oral	5.5 G		Novartis

Abnormal; Blood Urea Abnormal; Blood Urea Increased; Carbon Dioxide Decreased; Coma; Haematocrit Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Neutrophil Count Increased; Overdose; Pneumonia Aspiration; Po2 Increased; Red Blood Cell Count Decreased; Tonic Clonic Movements; Urinary Retention	Valproate Sodium		S	Oral	100mg/Day	Not Reported
	Valproate Sodium		S		Overdose	Not Reported
	Lexapro		S		Overdose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2006	5987475	EXPEDITED (15-DAY)	N	OT	2006UW02448		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Irritability; White Blood Cell Count Increased	Seroquel			S	Oral			Zeneca
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral		2 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2006	6014446	DIRECT	N				80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Gait Disturbance; Medication Error; Product Dispensing Error; Tremor; Visual Impairment	Lexapro			S		20 Mg Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2006	5906312	EXPEDITED (15-DAY)	Y	HO	US-ABBOTT-05P-163-0313440-00		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Status Changes; Seizure	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Carbamazepine			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Glipizide			C				Not Reported
	Rabeprazole Sodium			C				Not Reported
	Doxycycline			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Metoclopramide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2006	6018785	DIRECT	N	RI			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hypotrichosis	Lexapro			S		10 Mg 1 Each Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2006	6020034	EXPEDITED (15-DAY)	N	RI	S06-USA-01156-01		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2006	6019104	EXPEDITED (15-DAY)	Y	OT	S06-USA-01098-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S		200 Mg Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2006	6024452	EXPEDITED (15-DAY)	Y	OT	S05-USA-01230-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Amniotic Fluid Volume Increased; Maternal Exposure During Pregnancy; Pregnancy	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2006	5960387	EXPEDITED (15-DAY)	Y	HO	S05-USA-04689-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Asthenopia; Back Injury; Bipolar Disorder; Condition Aggravated; Crying; Depression; Drug Interaction; Dry Eye; Eye Irritation; Eye Pruritus; Family Stress; Fatigue; Feeling Abnormal; Food Craving; Idiosyncratic Drug Reaction; Impaired Driving Ability; Impaired Work Ability; Irritability; Muscle Spasms; Obsessive-Compulsive Disorder; Photosensitivity Reaction; Self-Injurious Ideation; Sinusitis; Vision Blurred	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Claritin			S				Not Reported
	Prilosec			C				Not Reported
	Niacin			C				Not Reported
	Calcium			C				Not Reported
	Pamelor			C				Not Reported
	Ativan			C				Not Reported
	Lamictal (Lamotrigine)			C				Not Reported
	Ability (Aripiprazole)			C				Not Reported
	Celexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2006	5998782	EXPEDITED (15-DAY)	Y	HO	S06-USA-00517-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Seizure	Lexapro	S	Oral	20 Mg Qd Po		Not Reported
	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Lexapro	S	Oral	15 Mg Qd Po		Not Reported
	Lexapro	S	Oral	20 Mg Qd Po		Not Reported
	Xanax	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2006	6015437	EXPEDITED (15-DAY)	Y	HO	2006PK00569		27 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Epilepsy; Generalised Tonic-Clonic Seizure	Seroquel			S	Oral		17 DAY	Zeneca
	Levothyroxine Sodium			C	Oral			Not Reported
	Enalapril			C	Oral			Not Reported
	Seroquel			S	Oral		10 DAY	Zeneca
	Seroquel			S	Oral			Zeneca
	Fluctine			S	Oral		15 DAY	Not Reported
	Fluctine			S	Oral		1 DAY	Not Reported
	Melperone			S	Oral		15 DAY	Not Reported
	Melperone			S	Oral		12 DAY	Not Reported
	Melperone			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2006	6016826	EXPEDITED (15-DAY)	Y	OT	S06-GER-01029-01		75 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bifascicular Block; Bundle Branch Block Left; Bundle Branch Block Right; Coronary Artery Disease;	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

Depression; Treatment Noncompliance	Pipamperone		S	Oral	25 Mg Qd Po	Not Reported
	Pipamperone		S	Oral	50 Mg Qd Po	Not Reported
	Valproate Sodium		C			Not Reported
	Pantozol (Pantoprazole Sodium)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2006	6016842	EXPEDITED (15-DAY)	Y	HO	S06-FRA-01201-01		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prostatic Adenoma; Urinary Retention	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Diazepam			S				Not Reported
	Mianserin Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2006	6025023	EXPEDITED (15-DAY)	Y	OT	S06-USA-00836-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2006	6012036	EXPEDITED (15-DAY)	Y	OT	S06-USA-01048-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Cholesterol Medciation (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2006	6016591	EXPEDITED (15-DAY)	Y	HO	DE-JNJFOC-20060305526		68 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism;	Haldol			S	Oral			Not Reported

Pleurothotonus	Haldol		S	Oral	Not Reported
	Haldol		S	Oral	Not Reported
	Cipralex		S	Oral	Not Reported
	Cipralex		S	Oral	Not Reported
	Beloc-Zok		C	Oral	Not Reported
	Losartan Potassium		C	Oral	Not Reported
	Amiodarone Hydrochloride		C	Oral	Not Reported
	Kalinor (Potassium Chloride)		C		Not Reported
	Aspirin		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2006	6025335	EXPEDITED (15-DAY)	Y	OT	S06-CAN-01279-01		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Dysaesthesia; Feeling Of Body Temperature Change; Insomnia; Musculoskeletal Stiffness; Nausea; Tachycardia; Vomiting	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2006	6025338	EXPEDITED (15-DAY)	Y	OT	S06-CAN-01280-01		38 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Aphonia; Confusional State; Dizziness; Drug Withdrawal Syndrome; Euphoric Mood; Muscle Twitching; Panic Reaction; Paraesthesia; Suicidal Ideation; Vomiting	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2006	6025345	EXPEDITED (15-DAY)	Y	HO	S06-FRA-01305-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Urinary Retention	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2006	6025359	EXPEDITED (15-DAY)	N	HO	S06-USA-00644-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Decreased Appetite; Fatigue; Feeling Cold; Nausea; Somnolence	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Percocet			C				Not Reported
	Tramadol			C				Not Reported
	Carisoprodol			C				Not Reported
	Clorazepate Dipotassium			C				Not Reported
	Premarin			C				Not Reported
	Clarinex			C				Not Reported
	Singulair			C				Not Reported
	Zantac			C				Not Reported
	Flovent			C				Not Reported
	Albuterol			C				Not Reported
	Finacea			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2006	5996252	EXPEDITED (15-DAY)	Y	OT	S06-SAF-00423-01		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchospasm; Chest Discomfort; Face Oedema; Throat Irritation; Urticaria	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Ferrimed			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2006	6024168	DIRECT	N	OT			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Flat Affect; Hyposmia; Loss Of Personal Independence In Daily Activities	Lexapro			S	Oral	5 Mg Daily In Evening Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2006	5955540	EXPEDITED (15-DAY)	Y	HO	S05-NOR-05682-01		81 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Withdrawal Syndrome; Fatigue; General Physical Health Deterioration; Listless; Sleep Disorder	Cipralex			S	Ophthalmic	5 Mg Qd Po		Not Reported
	Valsartan			C				Not Reported
	Anastrozole			C				Not Reported
	Plavix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2006	6015376	EXPEDITED (15-DAY)	Y	OT	S06-GER-01017-01		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Cervical Incompetence; Complication Of Pregnancy; Gestational Diabetes; Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Premature Labour	Cipralex			S	Oral	20 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2006	6024572	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicide Attempt	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2006	6061420	NON-EXPEDITED	Y	HO	2005139095			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polydipsia	Geodon			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2006	6061476	NON-EXPEDITED	Y	OT	2005095397		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Feeling Hot; Flushing; Heart Rate Increased; Hypertension; Malaise; Pyrexia	Geodon			S	Oral	(2 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported
	Klonopin			C				Not Reported
	Amitriptyline Hydrochloride			C				Not Reported
	Ritalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2006	5957086	EXPEDITED (15-DAY)	Y	HO	S05-USA-05219-01		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Chest Pain; Nausea; Sinus Tachycardia	Lexapro			S	Oral	10 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2006	6028191	EXPEDITED (15-DAY)	Y	OT	S06-USA-00875-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tuberculosis	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Strattera			C				Not Reported
	Ritalin			C				Not Reported
	Imitrex (Sumatriptan)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2006	6029093	EXPEDITED (15-DAY)	Y	OT	2006042057			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Hypertrophy; Condition Aggravated; Urinary Retention	Neurontin			S		1500 Mg (1 D)		Not Reported
	Clozapine			S				Not Reported
	Abilify			S				Not Reported
	Lexapro			S				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2006	6064994	NON-EXPEDITED	Y	OT	SUS1-2006-00046			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Adderall Xr			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2006	6020784	EXPEDITED (15-DAY)	N	HO	FR-GLAXOSMITHKLINE-B0419288A		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Diarrhoea; Hyponatraemia; Orthostatic Hypotension;	Clamoxyl (Amoxicillin)			S	Oral	1g Twice Per Day	6 DAY	Glaxosmithkline
	Inexium			S	Oral	20mg Per Day	12 DAY	Unknown

Vomiting	Perindopril Erbumine	S	Oral	4mg Per Day	55 DAY	Unknown
	Escitalopram Oxalate	S	Oral	10mg Twice Per Day	44 DAY	Unknown
	Vastarel	C	Oral	35mg Twice Per Day	57 DAY	Unknown
	Carvedilol	C	Oral	25mg Per Day		Unknown
	Aspirin Lysine	C	Oral	75mg Per Day		Unknown
	Risperdal	C	Unknown	1.5mg Per Day		Unknown
	Stilnox	C	Oral	1tab Per Day		Unknown
	Econazole Nitrate	C	Other		21 DAY	Unknown
	Pravastatin Sodium	C	Oral	20mg Per Day		Unknown
	Omeprazole	C	Oral	20mg Per Day		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2006	6031427	EXPEDITED (15-DAY)	N	OT	2006045197		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Contusion; Fall; Haematocrit Decreased; Haemoglobin Decreased; Platelet Count Decreased; Red Blood Cell Count Abnormal; Red Cell Distribution Width Increased; Skin Laceration; Wheelchair User	Lyrica			S		150 Mg (75 Mg, 2 In 1 D),		Not Reported
	Lexapro			S		10 Mg (10 Mg, 1 In 1 D),		Not Reported
	Metoprolol Tartrate			C				Not Reported
	Synthroid			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Miacalcin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2006	5936959	EXPEDITED (15-DAY)	Y	OT	S05-USA-04945-02		7 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident;	Lexapro			S				Not Reported
Foetal Disorder;	Lexapro			S				Not Reported
Haemoglobin Decreased;	Prenatal Vitamins			C				Not Reported

Jaundice Neonatal; Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Neonatal Disorder; Neonatal Tachypnoea; Nervous System Disorder; Platelet Count Increased	Unspecified Ingredient		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2006	6019107	EXPEDITED (15-DAY)	Y	HO, OT	L06-USA-01021-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depressed Mood; Dry Mouth; Dystonia; Suicidal Ideation; Weight Decreased	Escitalopram Oxalate			S		10 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2006	6022535	EXPEDITED (15-DAY)	Y	OT	2006037513			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Brain Operation; Cardiac Operation; Depression; Gingival Swelling; Weight Decreased	Dilantin			S		40 Mg (40 Mg, 1 In 1 D),		Not Reported
	Lipitor			S				Not Reported
	Xalatan			S				Not Reported
	Lexapro			S				Not Reported
	Valium			C				Not Reported
	Dyazide			C				Not Reported
	Armour Thyroid			C				Not Reported
	Metoprolol			C				Not Reported
	Klor-Con			C				Not Reported
	Aspirin			C				Not Reported
	Trusopt			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2006	6022878	EXPEDITED (15-DAY)	Y	HO, OT	DE-JNJFOC-20060305521			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Dependence On Respirator; Fatigue; Gastrointestinal Sounds Abnormal; Overdose; Seizure; Suicide Attempt	Risperdal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Trimipramine Maleate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2006	6024422	EXPEDITED (15-DAY)	Y	DE	S06-USA-01163-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Fatigue; Loss Of Consciousness; Malaise; Toxicity To Various Agents	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Synthroid			C				Not Reported
	Aricept			C				Not Reported
	Aldactone			C				Not Reported
	Effexor			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Folate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2006	6026284	DIRECT	Y	OT			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Interaction; Gallbladder Disorder; Gastrooesophageal Reflux Disease; Vomiting	Lexapro			S	Oral	1 Tab Daily Po		Forest
	Omeprazole			S	Oral	2 Tabs Twice A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2006	6027066	EXPEDITED (15-DAY)	N	OT	S06-USA-00834-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy; Urticaria	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	1 Ml Qd Po		Not Reported
	Lexapro			S	Oral	0.5 Ml Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2006	6032140	EXPEDITED (15-DAY)	Y	OT	S06-FRA-01352-01		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Discomfort; Galactorrhoea; Hyperprolactinaemia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2006	6032201	EXPEDITED (15-DAY)	Y	HO	S06-NOR-01350-01		81 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hyperreflexia; Muscle Rigidity	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lithium			S	Oral	42 Mg Qd Po		Not Reported
	Alopam (Oxazepam)			C				Not Reported
	Imovane (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2006	5964790	EXPEDITED (15-DAY)	N	HO	S06-USA-00114-01		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Condition Aggravated; Fall; Hangover; Head Injury;	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Humerus Fracture; Injury; Insomnia; Nightmare; Pain; Somnambulism; Somnolence; Syncope	Lexapro	S	Oral	5 Mg Qd Po		Not Reported
	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Ambien Cr	S	Oral	25 Mg Once Po		Not Reported
	Ambien Cr	S	Oral	12.5 Mg Qhs Po		Not Reported
	Ambien Cr	S	Oral	12.5 Mg Qhs Po		Not Reported
	Ambien Cr	S	Oral	18.75 Mg Once Po		Not Reported
	Risperdal	C				Not Reported
	Lunesta	C				Not Reported
	Avapro	C				Not Reported
	Sotalol Hydrochloride	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2006	6007636	EXPEDITED (15-DAY)	N	HO, LT	S06-USA-00647-01		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Asthenia; Coma; Diffuse Alveolar Damage; Dizziness; Drug Hypersensitivity; Respiratory Failure; Toxicity To Various Agents; Viral Infection	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lopresor			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2006	6007637	EXPEDITED (15-DAY)	N	HO	S06-USA-00637-01		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Mania; Muscle Twitching; Obsessive Thoughts; Pneumonia; Seizure; Speech Disorder; Tic; Urosepsis; Verbigeration	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Moban			C				Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2006	6023929	EXPEDITED (15-DAY)	Y	DE, HO	FR-SANOFI-SYNTHELABO-A02200600883		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Haematemesis; Haemobilia; Peritoneal Haemorrhage; Shock	Plavix			S	Oral		20 DAY	Not Reported
	Selokeen			C	Oral			Not Reported
	Digitaline			C	Oral			Not Reported
	Pravastatin Sodium			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Nicorandil			C	Oral			Not Reported
	Vastarel			C	Oral	3 Unit		Not Reported
	Ramipril			C	Oral			Not Reported
	Unspecified Ingredient			C	Oral	Unk		Not Reported
	Doliprane			C	Unknown	Unk		Not Reported
	Bicarbonate Ion\Sodium Bicarbonate			C	Buccal	Unk		Not Reported
	Eludril			C	Buccal	Unk		Not Reported
	Fungizone			C	Unknown	Unk		Not Reported
	Aspirin Lysine			S	Oral		8 YR	Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral		19 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2006	6029244	EXPEDITED (15-DAY)	Y	HO, LT	S06-FRA-01316-01		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	1 Tablet Once Po		Not Reported
	Lexomil (Bromazepam)			S	Oral	15 Tablet Once Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2006	6034545	EXPEDITED (15-DAY)	Y	HO	S06-UKI-01326-01		46 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory; Mental Disorder; Overdose; Paranoia; Psychotic Disorder	Cipralex			S	Oral	Tablet Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2006	5959505	EXPEDITED (15-DAY)	Y	LT	S05-PRT-05743-01		36 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alveolitis; Depressed Level Of Consciousness; Dizziness; Drug Abuser; Drug Interaction; Headache; Herpes Simplex; Hypotension; Loss Of Consciousness; Malaise; Respiratory Acidosis; Respiratory Arrest; Respiratory Distress; Somnolence; Tachycardia	Cipralex			S	Oral	40 Mg Qd Po		Not Reported
	Methadone			S				Not Reported
	Mirtazapine			C				Not Reported
	Oxazepam			C				Not Reported
	Triazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2006	5999464	EXPEDITED (15-DAY)	Y	DE, HO	S06-USA-00510-01		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Aortic Arteriosclerosis; Asthenia; Atonic Urinary Bladder; Blood Pressure Systolic Increased; Cardiac Failure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported
	Cholesterol Medication (Nos)			C				Not Reported
	Congestive Heart Failure Medication			C				Not Reported

Congestive;	Aspirin	C	Not Reported
Cardiomegaly; Condition	Plavix	C	Not Reported
Aggravated; Confusional	Imdur	C	Not Reported
State; Coronary Artery	Lovastatin	C	Not Reported
Disease; Decreased	Coreg	C	Not Reported
Appetite; Disorientation;	Digoxin	C	Not Reported
Fatigue; Formication;	Procrit	C	Not Reported
Gastrooesophageal Reflux	Ferrous Sulfate	C	Not Reported
Disease; Heart Rate	Humibid (Guaifenesin)	C	Not Reported
Decreased; Heart Sounds	Rocephin	C	Not Reported
Abnormal; Hypoxia;	Zithromax	C	Not Reported
Insomnia; Mental Status	Lasix	C	Not Reported
Changes; Muscle	Protonix	C	Not Reported
Twitching; Nausea;	Os-Cal Plus Vitamin D (Calcium	C	Not Reported
Osteoporosis; Pleural	Carbonate/Vitamin D)		
Effusion; Pneumonia;	Reglan	C	Not Reported
Pulmonary Oedema;	Vasotec	C	Not Reported
Renal Artery Stenosis;	Lantus	C	Not Reported
Renal Failure; Renal	Demadex	C	Not Reported
Impairment; Respiratory	Flonase	C	Not Reported
Failure; Restlessness;	Bumex	C	Not Reported
Rhinitis Allergic; Staring;	Hycodan [Hydrocodone	C	Not Reported
Tremor; Urinary Retention;	Bitartrate]		
Vomiting; Weight	Avelox	C	Not Reported
Increased	Novolin N	C	Not Reported
	Hydralazine	C	Not Reported
	Folate	C	Not Reported
	Niaspan	C	Not Reported
	Keflex	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2006	6034039	EXPEDITED (15-DAY)	Y	HO	S06-USA-00972-01		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis;	Lexapro			S				Not Reported
Pancreatitis; Sepsis	Requip			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2006	6034043	EXPEDITED (15-DAY)	Y	HO	S06-USA-00957-01		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2006	6930039	EXPEDITED (15-DAY)	Y	DS, HO	2006-BP-03613RO		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urea Increased; Confusional State; Decreased Appetite; Dehydration; Delirium; Depressed Mood; Disturbance In Attention; Drug Interaction; Fall; Hypersomnia; Hyponatraemia; Hypophagia; Impaired Self-Care; Lethargy; Memory Impairment; Pneumonia; Staring	Methadone Hydrochloride			S		High 20mg/D Decr To 10mg/D Then Tapered To Discontinue		Not Reported
	Dextromethorphan\Guaifenesin			S		600mg/30 Mg Bid (2 In 1 D)		Not Reported
	Sertraline			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Acetaminophen\Hydrocodone Bitartrate			S				Not Reported
	Ipratropium Bromide			C				Not Reported
	Metoclopramide Hydrochloride			C				Not Reported
	Metolazone			C				Not Reported
	Warfarin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2006	5939176	EXPEDITED (15-DAY)	Y	OT	S05-USA-05006-02		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Hyperbilirubinaemia Neonatal; Hypertension Neonatal; Hypoglycaemia Neonatal; Large For Dates Baby; Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Lexapro			S	Transmammary	10 Mg Qd Bf		Not Reported
	Prenatal Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2006	5954087	EXPEDITED (15-DAY)	Y	HO, OT	S05-UKI-05679-01		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Loss Of Consciousness; Pallor	Cipralex			S	Oral	10 Mg Po		Not Reported
	Rivastigmine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2006	6001836	EXPEDITED (15-DAY)	Y	OT	S06-GER-00627-01			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Csf Pressure Increased; Overdose	Cipralex			S		40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2006	6025213	EXPEDITED (15-DAY)	Y	HO, OT	S06-GER-00070-01		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Focal Dyscognitive Seizures	Cipralex			S	Oral	20 Mg Daily Po		Not Reported
	Cipralex			S	Oral	5 Mg Daily Po		Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2006	6031853	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Scratch	Lexapro			S	Oral	10mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2006	6035547	EXPEDITED (15-DAY)	Y	DE	S06-FRA-01340-01		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; International Normalised Ratio Increased; Somnolence; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg Qd Po		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg Bid Po		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg Daily Po		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg Qod Po		Not Reported
	Previscan (Fluindione)			S	Oral	30 Mg Qod Po		Not Reported
	Anafranil			S	Oral	75 Mg Qd Po		Not Reported
	Ciprofloxacin Hydrochloride			C				Not Reported
	Parkinane (Trihexyphenidyl Hydrochloride)			C				Not Reported
	Cyamemazine			C				Not Reported
	Haloperidol			C				Not Reported
	Imovane (Zopiclone)			C				Not Reported
	Tranxene T-Tab			C				Not Reported
	Effexor			C				Not Reported
	Valproate Sodium			C				Not Reported
	Risperdal			C				Not Reported
	Zolpidem			C				Not Reported
	Lexomil (Bromazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2006	6064562	NON-EXPEDITED	N		2005SP004452		83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hangover; Therapeutic Product Effect Decreased	Lunesta			S	Oral	3 Mg;Hs;Oral		Not Reported
	Lexapro			S				Not Reported
	Simvastatin			C				Not Reported
	Multivitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2006	6068160	NON-EXPEDITED	Y		2006SP000025		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Nausea; Retching	Lunesta	S	Oral	Oral	Not Reported
	Lexapro	S	Oral	10 Mg;Qd;Oral	Not Reported
	Uroxatal	C			Not Reported
	Depakote	C			Not Reported
	Tricor	C			Not Reported
	Atorvastatin	C			Not Reported
	Metoprolol Succinate	C			Not Reported
	Nexium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2006	6068471	NON-EXPEDITED	Y	OT	US-JNJFOC-20050600763		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Ultram			S				Not Reported
	Lexapro			S		Generic: Escitalopram Oxalate		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2006	5998785	EXPEDITED (15-DAY)	Y	DE	S06-USA-00506-01		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Back Pain; Body Temperature Increased; Drug Abuser; Drug Screen Positive; Drug Withdrawal Syndrome; Erythema; Serotonin Syndrome; Ventricular Fibrillation; Ventricular Tachycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Cocaine			S				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2006	6035832	EXPEDITED (15-DAY)	Y	HO	S06-FRA-01365-01		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Chest	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported

Pain; Cholecystitis; International Normalised Ratio Increased; Prothrombin Time Prolonged

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2006	6036066	EXPEDITED (15-DAY)	Y	OT	S06-CAN-01349-01		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Psychiatric Symptom; Self-Injurious Ideation	Cipralex			S	Oral	5 Mg Qod Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Artane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2006	5992432	EXPEDITED (15-DAY)	Y	OT	S06-USA-00384-01		8 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Depression; Educational Problem; Incorrect Dose Administered	Lexapro			S	Oral	7.5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2006	6032435	DIRECT	Y	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Dizziness; Drug Withdrawal Syndrome; Eye Movement Disorder; Fatigue; Feeling Abnormal; Nausea; Nervous System Disorder; Nightmare; Sleep Disorder	Lexapro			S	Oral	10 Mg 1 Time Per Day Po		Forest
	Lexapro			S	Oral	20 Mg 1 Time Per Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2006	6035315	EXPEDITED (15-DAY)	N	OT	2006031609			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Back Pain; Condition Aggravated; Depressed Level Of Consciousness; Depression; Exostosis; Insomnia; Off Label Use; Sedation; Somnolence; Spinal Osteoarthritis; Suicidal Ideation; Treatment Noncompliance	Neurontin			S				Not Reported
	Ambien			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2006	6036556	EXPEDITED (15-DAY)	Y	HO	S06-FRA-01382-01		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Withdrawal Syndrome; Physical Assault	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2006	6036558	EXPEDITED (15-DAY)	Y	OT	S06-FRA-01376-01		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Sinusitis	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Beconase Aq			S				Not Reported
	Desloratadine			C				Not Reported
	Serevent Diskus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2006	6036899	EXPEDITED (15-DAY)	Y	OT	S06-USA-01444-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Lexapro			S				Not Reported
	Plavix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2006	6037221	EXPEDITED (15-DAY)	Y	HO	S06-USA-01459-01		77 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2006	6030429	EXPEDITED (15-DAY)	Y	DE	S06-FRA-01309-01			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Escitalopram Oxalate			S				Not Reported
	Acepromazine Maleate\Meprobamate			S				Not Reported
	Oxetorone Fumarate			S				Not Reported
	Bromazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2006	6036144	EXPEDITED (15-DAY)	Y	HO	S06-NLD-01354-01		46 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Hypoglycaemia	Lexapro			S				Not Reported
	Clorazepate Dipotassium			C				Not Reported
	Glyceryl Trinitrate			C				Not Reported
	Folic Acid			C				Not Reported
	Carbasalate Calcium			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Simvastatin			C				Not Reported
	Ranitidine			C				Not Reported
	Insulin Nos			C				Not Reported
	Insulin Glargine			C				Not Reported
	Diltiazem Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2006	6038684	EXPEDITED (15-DAY)	Y	OT	S06-USA-01448-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Supraventricular Tachycardia; Syncope; Ventricular Tachycardia	Lexapro			S		10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2006	6038690	EXPEDITED (15-DAY)	N	HO	S06-USA-01447-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Stress Test	Lexapro			S				Not Reported
Abnormal; Condition Aggravated; Drug Ineffective; Fatigue; Gastrooesophageal Reflux Disease; Headache; Mood Swings; Oesophageal Spasm	Anti-Seizure Medications			C				Not Reported
	Doxepin			C				Not Reported
	Restless Leg Syndrome Medication			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2006	6041014	EXPEDITED (15-DAY)	Y	HO	S06-FRA-01378-01		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Decreased; Dehydration; Diarrhoea; Hypokalaemia; Hyponatraemia; Orthostatic Hypotension; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported
	Clamoxyl (Amoxicillin)			S	Oral	1 G Bid Po		Not Reported
	Inexium (Esomeprazole)			S	Oral	20 Mg Qd Po		Not Reported
	Perindopril Erbumine			S	Oral	4 Mg Qd Po		Not Reported
	Vastarel			C				Not Reported
	Carvedilol			C				Not Reported
	Aspirin Lysine			C				Not Reported
	Risperdal			C				Not Reported

	Zolpidem Tartrate	C	Not Reported
	Pevaryl (Econazole Nitrate)	C	Not Reported
	Pravastatin	C	Not Reported
	Mopral (Omeprazole)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2006	6037156	DIRECT	N	DS, HO, LT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Intentional Overdose; Loss Of Consciousness; Respiratory Arrest; Suicide Attempt	Lexapro			S	Oral	20 Mg Once Daily Po		Cvs Caremark

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2006	5951964	EXPEDITED (15-DAY)	Y	OT	S05-IRL-05648-01		82 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokinesia; Hypotension; Pupil Fixed; Salivary Hypersecretion; Seizure; Tremor	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Aripiprazole			S	Oral	10 Mg Qd Po		Not Reported
	Amlodipine Besylate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2006	6022641	EXPEDITED (15-DAY)	N	HO	S06-USA-01095-02		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Caesarean Section; Maternal Exposure During Pregnancy; Pulmonary Oedema Neonatal	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Prenatabs Fa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2006	6031649	EXPEDITED (15-DAY)	Y	HO	US-GLAXOSMITHKLINE-A0600926A		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis; Pain; Pancreatitis; Sepsis	Requip			S	Oral			Glaxosmithkline
	Lexapro			S				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2006	6034915	EXPEDITED (15-DAY)	Y	HO	2006048301		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urea Increased; Confusional State; Decreased Appetite; Dehydration; Delirium; Depressed Mood; Disturbance In Attention; Drug Interaction; Fall; Hypersomnia; Hyponatraemia; Hypophagia; Lethargy; Memory Impairment; Pneumonia; Staring	Sertraline			S				Not Reported
	Methadone Hydrochloride			S		20 Mg (1 D)		Not Reported
	Guaifenesin			S		60 Mg (30 Mg, 2 In 1 D),		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Acetaminophen\Hydrocodone Bitartrate			S		(As Necessary)		Not Reported
	Ipratropium Bromide			C				Not Reported
	Metoclopramide			C				Not Reported
	Metolazone			C				Not Reported
	Warfarin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2006	6037342	DIRECT	Y	HO			20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactoid Reaction; Diplopia; Keratopathy; Staphylococcal Infection; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis;	Lamictal			S	Oral	25 Daily Po		Not Reported
	Lexapro			S	Oral	5 Daily Po		Not Reported

Vision Blurred

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2006	6041679	EXPEDITED (15-DAY)	Y	HO	S06-GER-01552-01		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Dependence On Respirator; Fatigue; Gastrointestinal Sounds Abnormal; Overdose; Seizure; Suicide Attempt	Cipralex			S	Oral	400 Mg Qd Po		Not Reported
	Risperdal			S	Oral	45 Mg Qd Po		Not Reported
	Cymbalta			S	Oral	4800 Mg Qd Po		Not Reported
	Trimipramine Maleate			S	Oral	250 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2006	6042920	EXPEDITED (15-DAY)	N	DE	S06-USA-01443-01		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Agitation; Amnesia; Anhedonia; Anxiety; Completed Suicide; Gun Shot Wound; Hypoaesthesia; Irritability; Pain; Self-Injurious Ideation; Weight Decreased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2006	6043001	EXPEDITED (15-DAY)	N	HO, OT	S06-USA-01144-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Mental Disorder; Nausea; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2006	6034912	EXPEDITED (15-DAY)	Y	DE, OT	2006046439		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Alcohol Use; Belligerence; Cardio-Respiratory Arrest; Completed Suicide; Drug Abuser; Hostility; Insomnia; Paranoia	Geodon			S	Oral	160 Mg (80 Mg, 2 In 1 D), Oral		Not Reported
	Lexapro			S		20 Mg (20 Mg, 1 In 1 D),		Not Reported
	Lamictal			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2006	6043026	EXPEDITED (15-DAY)	N		TPA2006A00679		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Feeling Jittery	Rozerem			S	Oral Oral	See Image See Image		Not Reported
	Lunesta			S	Oral	2 Tab., Qhs, Per Oral		Not Reported
	Lexapro			S	Oral	10 Mg, 2 In 1 D, Per Oral		Not Reported
	Xanax (Alprazolam) (0.25 Milligram)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2006	6033706	EXPEDITED (15-DAY)	Y	HO	DE-ABBOTT-06P-062-0331308-00			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Dependence On Respirator; Fatigue; Gastrointestinal Sounds Abnormal; Intentional Overdose; Seizure; Suicide Attempt	Cipralex			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Trimipramine Maleate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2006	6045020	EXPEDITED (15-DAY)	Y	HO	S05-USA-04736-01		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Cerebrovascular Accident; Dizziness; Hyponatraemia	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Glipizide	C				Not Reported
	Avandamet (Rosglitazone/Metformin)	C				Not Reported
	Lotensin	C				Not Reported
	Mobic	C				Not Reported
	Ativan	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2006	6045207	EXPEDITED (15-DAY)		OT	HQWYE871419APR06		60 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis; Platelet Aggregation Abnormal; Rectal Haemorrhage; Serum Serotonin Increased	Effexor			S		See Image	4 WEEK	Not Reported
	Escitalopram Oxalate			S		See Image	1 WEEK	Not Reported
	Mirtazapine (Mirtazapine)			S		See Image See Image	4 WEEK 1 WEEK	Not Reported
	Omeprazole			C				Not Reported
	Irbesartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2006	6045154	EXPEDITED (15-DAY)	Y	OT	S06-USA-01536-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Lexapro			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2006	6045159	EXPEDITED (15-DAY)	Y	HO	S06-USA-01535-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Condition Aggravated; Crohn'S Disease	Lexapro			S				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2006	6036061	EXPEDITED (15-DAY)	Y	DE, HO	S06-FRA-01366-01		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiac Arrest; Drug Interaction; Haematemesis; International Normalised Ratio Increased; Intra-Abdominal Haematoma; Peritoneal Haemorrhage; Shock	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Aspirin Lysine			S	Oral	75 Mg Qd Po		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg Qd Po		Not Reported
	Plavix			S				Not Reported
	Selokeen			C				Not Reported
	Digoxine Nativelle (Digoxine)			C				Not Reported
	Pravastatin			C				Not Reported
	Mopral (Omeprazole)			C				Not Reported
	Ikorel (Nicorandil)			C				Not Reported
	Trimetazidine Hydrochloride			C				Not Reported
	Ramipril			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Acetaminophen			C				Not Reported
	Eludril			C				Not Reported
	Fungizone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2006	6042661	DIRECT	N				54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain	Lexapro			S	Oral	10mg 1 Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2006	6043226	DIRECT	N	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bruxism; Depression; Feeling Abnormal; Hyperhidrosis; Hypersomnia; Product	Lexapro			S	Oral	5-10 Mgs Sid Po		Forest

Quality Issue; Thirst; Tinnitus; Treatment Noncompliance

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2006	5963238	EXPEDITED (15-DAY)	Y	OT	2005173641			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Occlusive Disease; Blood Cholesterol Increased; Chest Pain; Depression; Electrocardiogram Abnormal; Malaise; Pain; Treatment Noncompliance	Celebrex			S	Oral	200 Mg (200 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2006	6036031	EXPEDITED (15-DAY)	N	HO	FR-GLAXOSMITHKLINE-B0421412A		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuser	Ventolin			S	Respiratory (inhalation)			Glaxosmithkline
	Acetaminophen\Propoxyphene Hydrochloride			S	Unknown			Unknown
	Oxazepam			S	Unknown			Unknown
	Risperdal			S	Unknown			Unknown
	Methadone Hydrochloride			S	Unknown			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Codeine			C	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2006	6043160	DIRECT	Y	HO			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Inappropriate Antidiuretic Hormone Secretion	Lexapro	S	Oral	One Tablet Daily Po		Not Reported
	Evista	C				Not Reported
	Klonopin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2006	6046806	EXPEDITED (15-DAY)	Y	DE	S06-USA-01613-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2006	6046815	EXPEDITED (15-DAY)	Y	OT	S06-USA-01612-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2006	6047337	EXPEDITED (15-DAY)	Y	HO	S06-USA-01615-01		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Perforation; Haematemesis; Pyrexia; Retching; Vomiting	Lexapro			S	Oral	10 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	10 Mg Qhs Po		Not Reported
	Lithium			C				Not Reported
	Trileptal			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Tricor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2006	6045156	EXPEDITED (15-DAY)	Y	OT	S06-USA-01529-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional	Lexapro			S				Not Reported

State; Depression; Disturbance In Attention; Hallucination, Visual; Hepatic Pain; Influenza Like Illness; Insomnia; Post Procedural Complication; Psoriasis	Pegintron	S	Not Reported
	Ribavirin	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2006	6047361	EXPEDITED (15-DAY)	Y	HO	S06-DEN-01310-01		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Hyponatraemia; Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Salures-K			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2006	6047963	EXPEDITED (15-DAY)	N	OT	S06-USA-01637-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Withdrawal Syndrome	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2006	6047968	EXPEDITED (15-DAY)	Y	OT	S06-USA-01639-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2006	6048489	EXPEDITED (15-DAY)	Y	HO	S06-UKI-01584-01		23 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Balance Disorder; Cold Sweat; Confusional State; Coordination Abnormal; Dysarthria; Intentional Overdose; Malaise; Somnolence; Tremor	Cipralex	S	Oral	20 Mg Qd Po	Not Reported
	Cipralex	S	Oral	400 Mg Once Po	Not Reported
	Cipralex	S			Not Reported
	Risperidone	S	Oral	0.5 Mg Bid Po	Not Reported
	Risperidone	S	Oral	10 Mg Once Po	Not Reported
	Risperidone	S			Not Reported
	Lansoprazole	C			Not Reported
	Zopiclone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2006	5951255	EXPEDITED (15-DAY)	Y	DE	S05-USA-05128-01		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Blood Potassium Increased; Blood Sodium Increased; Blood Urea Increased; Carbon Dioxide Abnormal; Completed Suicide; Drug Level Increased; Ovarian Cyst	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lamictal			C				Not Reported
	Topamax			C				Not Reported
	Klonopin			C				Not Reported
	Vitamin K			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2006	6062460	DIRECT	N	DE			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2006	7385666	EXPEDITED (15-DAY)	Y	HO	US-ABBOTT-06P-163-0331919-00		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2006	5992741	EXPEDITED (15-DAY)	Y	HO, RI	S06-USA-00451-01		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchial Hyperreactivity; Maternal Exposure During Pregnancy; Pneumonia; Pre-Eclampsia; Pregnancy; Premature Labour	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Hydroxyzine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2006	5992929	EXPEDITED (15-DAY)	Y	HO	S06-USA-00451-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotonia Neonatal; Maternal Exposure During Pregnancy; Premature Baby; Resuscitation	Lexapro			S	Transplacental	30 Mg Qd Transplacental		Not Reported
	Magnesium Sulfate			S				Not Reported
	Hydroxyzine			C				Not Reported
	Rocephin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2006	6001861	EXPEDITED (15-DAY)	Y	HO	S05-USA-01297-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypotonia Neonatal; Maternal Exposure During Pregnancy; Pre-Eclampsia; Somnolence Neonatal; Treatment Noncompliance	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prenatal Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2006	6007635	EXPEDITED (15-DAY)	N	OT	S06-USA-00588-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hyperaesthesia; Insomnia; Irritability; Lethargy; Muscle Tightness; Nausea; Pain; Photophobia; Restlessness	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Bid Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Loratadine\Pseudoephedrine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2006	6049688	EXPEDITED (15-DAY)	Y	OT	S06-UKI-01754-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Change; Electrocardiogram Qt Prolonged	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2006	6005525	EXPEDITED (15-DAY)	N	OT	S06-USA-00636-01		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage; Injury Corneal	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2006	6039199	EXPEDITED (15-DAY)	Y	HO	PHEH2006US05418		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Depressed Level Of Consciousness; Hallucination; Product Administration Error; Sedation; Somnolence; Unresponsive To Stimuli	Stalevo			S	Oral	150 Mg, Qd		Orion
	Lexapro			S		10 Mg, Qd		Not Reported
	Lexapro			S		5 Mg, Qd		Not Reported
	Aricept			S				Not Reported
	Zyprexa			S				Not Reported
	Oxybutynin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2006	6041069	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20060500545		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuser	Risperdal			S	Oral			Not Reported
	Acetaminophen\Propoxyphene Hydrochloride			S	Oral			Not Reported
	Acetaminophen\Propoxyphene Hydrochloride			S	Oral			Not Reported
	Oxazepam			S				Not Reported
	Ventolin			S	Respiratory (inhalation)			Not Reported
	Methadone Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2006	6627381	EXPEDITED (15-DAY)	Y	HO	S06-FRA-01752-01		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchial Obstruction; Lactic Acidosis; Oxygen Saturation Decreased; Respiratory Distress	Escitalopram Oxalate			S	Oral	1 Units Qd Po		Not Reported
	Acetaminophen			S	Oral	500 Mg Qd Po		Not Reported
	Acetaminophen\Biclotymol\Chlorpheniramine\Eucalyptol\Guaifenesin			S				Not Reported
	Ramipril			S	Oral	5 Mg Qd Po		Not Reported

	Metformin Hydrochloride		S	Oral	850 Mg Tid Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2006	6042656	EXPEDITED (15-DAY)	Y	HO	US-KINGPHARMUSA00001-K200600550		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lactic Acidosis	Altace			S	Oral	5 Mg, Qd		King
	Dafalgan			S	Oral	500 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	1 U, Qd		Not Reported
	Acetaminophen\Chlorpheniramine Maleate\Guaifenesin\Phenylephrine			S	Oral			Not Reported
	Metformine "Merck"			S	Oral	850 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2006	6043404	EXPEDITED (15-DAY)	N	OT	US-GLAXOSMITHKLINE-A0604964A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anger; Bipolar Disorder; Euphoric Mood; Feeling Abnormal; Mania	Wellbutrin			S	Oral			Glaxosmithkline
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2006	5795994	NON-EXPEDITED	N		S05-USA-02246-01		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive	Relafen			S	Oral	750mg Twice Per Day		Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Cyproheptadine Hydrochloride			C	Unknown	4mg Per Day		Not Reported
	Claritin			C	Unknown	10mg Per Day		Not Reported

Hydroxyzine	C	Unknown			Not Reported
Inderal	C	Unknown	160mg Per Day		Not Reported
Doxycycline	C	Unknown			Not Reported
Melatonin	C	Unknown	3mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2006	5959449	EXPEDITED (15-DAY)	Y	LT	S05-PRT-05742-01		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Eyelid Oedema; Metabolic Acidosis; Respiratory Distress; Somnolence	Cipralex			S				Not Reported
	Methadone Hydrochloride			S				Not Reported
	Lorazepam			C				Not Reported
	Triazolam			C				Not Reported
	Oxazepam			C				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2006	6045015	EXPEDITED (15-DAY)	Y	OT	S06-USA-01530-01		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Eye Disorder; Somnolence	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2006	6050992	DIRECT	Y				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea; Palpitations	Lexapro			S	Oral	One Daily 10mg P.O		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2006	6053368	EXPEDITED (15-DAY)	Y	HO	S06-FRA-01593-01		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dehydration; Diarrhoea; Hypokalaemia; Hyponatraemia; Malaise; Orthostatic Hypotension; Vomiting	Escitalopram Oxalate	S	Oral	20 Mg Qd Po		Not Reported
	Perindopril Erbumine	S	Oral	4 Mg Qd Po		Not Reported
	Inexium (Esomeprazole)	S	Oral	20 Mg Qd Po		Not Reported
	Clamoxyl (Amoxicillin)	S	Oral	2 Units Qd Po		Not Reported
	Vastarel	C				Not Reported
	Inexium (Esomeprazole)	C				Not Reported
	Zolpidem Tartrate	C				Not Reported
	Carvedilol	C				Not Reported
	Pravastatin	C				Not Reported
	Duphalac	C				Not Reported
	Aspirin Lysine	C				Not Reported
	Risperdal	C				Not Reported
	Mopral (Omeprazole)	C				Not Reported
	Pevaryl	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2006	4103820	EXPEDITED (15-DAY)	Y	DE	S04-USA-00729-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Completed Suicide; Condition Aggravated; Depression; Dizziness; Fatigue; Gastrooesophageal Reflux Disease; Gun Shot Wound; Insomnia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Protonix			C				Not Reported
	Elavil			C				Not Reported
	Paxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2006	5871570	EXPEDITED (15-DAY)	Y	HO, OT	T05-JPN-03077-01		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Depression; Disease Recurrence; Drug Withdrawal Syndrome; Electroencephalogram Abnormal; Hyperventilation;	Escitalopram Oxalate			S				Not Reported
	Luvox			S	Oral	50 Mg Qd Po		Not Reported
	Luvox			S	Oral	100 Mg Qd Po		Not Reported
	Lorazepam			C				Not Reported

Insomnia; Intentional Overdose; Intentional Self-Injury; Joint Injury; Loss Of Consciousness; Nasopharyngitis; Pruritus Generalised; Rash Generalised

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2006	6027752	EXPEDITED (15-DAY)	Y	OT	S06-NLD-01246-01		40 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Work Ability; Nephrolithiasis; Pain	Escitalopram Oxalate			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2006	6047608	EXPEDITED (15-DAY)	Y	HO	L06-TUR-01591-01		38 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Parkinsonism	Cipralex			S				Not Reported
	Sertraline Hydrochloride			S		50 Mg Qd		Not Reported
	Tianeptine			S	Oral	12.5 Mg Tid Po		Not Reported
	Tianeptine			S		12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2006	6080216	NON-EXPEDITED	N		S06-USA-01466-01		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Nausea; Vomiting	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zocor			C				Not Reported
	Levoxyl			C				Not Reported
	Lanoxin			C				Not Reported
	K-Dur			C				Not Reported

	Coreg	C	Not Reported
	Vicodin	C	Not Reported
	Prevacid	C	Not Reported
	Lasix	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2006	6081038	NON-EXPEDITED	N		S06-USA-00697-01		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Xanax			C				Not Reported
	Elavil			C				Not Reported
	Vistaril (Hydroxyzine Embonate)			C				Not Reported
	Premarin			C				Not Reported
	Synthroid			C				Not Reported
	Prevacid			C				Not Reported
	Atenolol			C				Not Reported
	Reglan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2006	7385667	EXPEDITED (15-DAY)	Y	HO	US-ABBOTT-06P-163-0332658-00		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Nausea; Suicide Attempt	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2006	6019106	EXPEDITED (15-DAY)	Y	HO, RI	S06-USA-01099-01		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2006	6046540	EXPEDITED (15-DAY)	Y	HO	GB-JNJFOC-20060502055		23 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Cold Sweat; Confusional State; Coordination Abnormal; Dysarthria; Malaise; Overdose; Overdose; Somnolence; Tremor	Risperidone			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Zopiclone			S		As Necessary		Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2006	6047073	EXPEDITED (15-DAY)	Y	DE, HO	S06-FRA-01387-01		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Blood Creatine Phosphokinase Increased; Cardio-Respiratory Arrest; Chills; Delusion; Feeling Hot; Human Chorionic Gonadotropin Positive; Lactic Acidosis; Malaise; Maternal Exposure During Pregnancy; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Retained Placenta Or Membranes; Sepsis	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Tiapride			S	Oral	100 Mg Qd Po		Not Reported
	Aripiprazole			S	Oral	15 Mg Qd Po		Not Reported
	Cytotec			S		400 Mcg Bid		Not Reported
	Mifepristone			S	Oral	600 Mg Qd Po		Not Reported
	Prazepam			C				Not Reported
	Imovane (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2006	6054211	EXPEDITED (15-DAY)	N	HO	S06-USA-01729-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Attention Deficit/Hyperactivity Disorder; Bipolar Disorder; Skin Laceration; Suicide Attempt	Lexapro	S	Oral	10 Mg Bid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2006	6054219	EXPEDITED (15-DAY)	Y	OT	S06-USA-01817-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Lexapro			S	Oral	10 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2006	5980478	EXPEDITED (15-DAY)	Y	HO	US016653		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Drug Ineffective; Feeling Abnormal; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Provigil			S	Oral	100 Mg Qd Oral		Not Reported
	Risperdal			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2006	6055366	EXPEDITED (15-DAY)	Y	OT	S06-USA-01830-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Neurontin			C				Not Reported
	Ritalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2006	6015379	EXPEDITED (15-DAY)	Y	HO	T06-IND-01018-01		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Akathisia; Decreased Appetite; Restlessness	Cipralex	S	Oral	10 Mg Daily Po	Not Reported
	Cipralex	S	Oral	20 Mg Qd Po	Not Reported
	Larpose (Lorazepam)	C			Not Reported
	Vinturin	C			Not Reported
	Haloperidol Decanoate	C			Not Reported
	Sizodon	C			Not Reported
	Becosules	C			Not Reported
	Topaz	C			Not Reported
	Qutipin	C			Not Reported
	Pacitane (Trihexyphenidyl Hydrochloride)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2006	6082046	NON-EXPEDITED	N	OT	2005092466		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Headache; Osteoporosis	Depo-Provera			S	Intramuscular Intramuscular Intramuscular	See Image See Image See Image		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2006	6076132	NON-EXPEDITED	N	HO	ZONI002161		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Fall; Hypersensitivity; Rash	Zonegran			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	40 Mg, 1 In 1 D, Oral		Not Reported
	Morphine			S				Not Reported
	Bextra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2006	5923798	EXPEDITED (15-DAY)	Y	DE	FR-BRISTOL-MYERS SQUIBB COMPANY-13171186		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Pain	Abilify		S	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Not Reported
	Levomepromazine		C	Oral	Not Reported
	Oxazepam		C	Oral	Not Reported
	Oxazepam		C	Oral	Not Reported
	Meprobamate		C	Oral	Not Reported
	Acetaminophen\Codeine Phosphate		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2006	6057238	EXPEDITED (15-DAY)	N	HO	S06-USA-01876-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Condition Aggravated; Depression; Frustration Tolerance Decreased; Intentional Self-Injury; Irritability; Nervousness; Self-Injurious Ideation; Tremor	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Trileptal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2006	6057245	EXPEDITED (15-DAY)	Y	OT	S06-USA-01891-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Breast Feeding; Polycythaemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2006	6057544	EXPEDITED (15-DAY)	Y	DE, LT	2006063621		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accident; Anoxia; Back Pain; Blood Creatine Phosphokinase Increased; Cardiac Failure; Cardiac Procedure Complication; Cardio-Respiratory Arrest; Chills; Cyanosis; Delirium; Dyspnoea; Feeling Cold; Feeling Hot; Human Chorionic Gonadotropin Positive; Lactic Acidosis; Malaise; Maternal Exposure During Pregnancy; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Necrotising Colitis; Obstetric Procedure Complication; Pallor; Pyrexia; Retained Placenta Or Membranes; Rhabdomyolysis; Seizure; Troponin Increased	Cytotec	S	Vaginal	800 Mcg (200 Mcg, 2 In 2 D), Vaginal	Not Reported
	Tiapride	S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral	Not Reported
	Escitalopram Oxalate	S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral	Not Reported
	Abilify	S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral	Not Reported
	Prazepam	C			Not Reported
	Imovane (Zopiclone)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2006	6050289	EXPEDITED (15-DAY)	Y	OT	S06-USA-01684-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia	Lexapro			S				Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2006	6056083	DIRECT	Y	DE			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Completed Suicide	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2006	6058883	EXPEDITED (15-DAY)	N	OT	S06-USA-01894-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Bipolar Disorder; Euphoric Mood; Feeling Abnormal; Incorrect Dose Administered; Mania	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Wellbutrin Xl			S				Not Reported
	Wellbutrin Xl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2006	6032141	EXPEDITED (15-DAY)	Y	OT	S06-GER-01324-01		17 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Olfactory	Cipralex			S	Oral	10 Mg Daily Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2006	6044105	EXPEDITED (15-DAY)		HO	2006-141460-NL		31 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Ectopic Pregnancy; Maternal Exposure During Pregnancy	Mirtazapine			S	Oral	15 Mg/Df		Not Reported
	Escitalopram Oxalate			S		Df/20 Mg		Not Reported
	Terbutaline Sulfate			C				Not Reported
	Budesonide			C				Not Reported
	Fluticasone Propionate			C				Not Reported
	Clemastine Fumarate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2006	6058109	DIRECT	N	DE			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Ill-Defined Disorder; Nervousness	Lexapro	S	10 Mg Tablet 1 A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2006	6058900	DIRECT	Y	OT			19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Computerised Tomogram Abnormal; Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	One Daily Po		Not Reported
	Lexapro			S	Oral	One Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2006	6059155	EXPEDITED (15-DAY)	Y	HO	ENTC2006-0132		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Loss Of Consciousness; Obsessive Thoughts; Sedation	Stalevo			S	Oral	600 Mg, 4 In 1 D, Oral		Not Reported
	Lexapro			S		50 Mg, 1 In 1 D,		Not Reported
	Zyprexa			S				Not Reported
	Aricept			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2006	5992727	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0587079A		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Ineffective; Fatigue; Medication Error; Somnolence	Wellbutrin Xl			S	Oral	150mg Per Day	4 MTH	Glaxosmithkline
	Lexapro			S	Oral			Not Reported
	Valtrex			C				Glaxosmithkline
	Nordette			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2006	6054468	NON-EXPEDITED	Y	OT	US-GLAXOSMITHKLINE-A0597343A		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Suicidal Ideation; Tremor	Wellbutrin Xl			S	Oral	150mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported
	Flomax			C				Not Reported
	Glipizide			C				Not Reported
	Metformin			C				Not Reported
	Lipitor			C				Not Reported
	Tricor			C				Not Reported
	Oxaprozin			C				Not Reported
	Cialis			C				Not Reported
	Aspirin			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2006	6054850	EXPEDITED (15-DAY)	N	OT	US017195		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction	Wellbutrin Xl			S	Oral	300mg Per Day		Glaxosmithkline
	Provigil			S	Oral	200mg Per Day		Not Reported
	Lexapro			S	Oral	10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2006	6063555	EXPEDITED (15-DAY)	Y	OT	S06-USA-01929-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Lexapro			S				Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2006	6053109	EXPEDITED (15-DAY)	Y	DE	S06-NLD-01788-01		55 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anger; Completed Suicide;	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

Indifference	Zyprexa		S	Oral	5 Mg Qd Po	Not Reported
	Xanax		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2006	6065367	EXPEDITED (15-DAY)	Y	HO	S06-UKI-01998-01		88 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Urinary Tract Infection	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Amitriptyline			C				Not Reported
	Calfovit D3			C				Not Reported
	Codeine Phosphate			C				Not Reported
	Docusate			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Ranitidine			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2006	6083167	NON-EXPEDITED	N	OT	2005098254		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Colestipol Hydrochloride			S	Oral	2 Gram (1 Gram, 2 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Nortriptyline Hydrochloride			C				Not Reported
	Hydrochlorothiazide/Triamterene (Hydrochlorothiazide, Triamterene)			C				Not Reported
	Norvasc			C				Not Reported
	Centrum Silver (Ascorbic Acid, Calcium, Minerals Nos, Retinol, Tocopheryl Acetate, Vitamin B Nos...)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2006	6044528	EXPEDITED (15-DAY)	Y	HO	2006CG00789		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Rhabdomyolysis	Omeprazole			S	Oral			Not Reported
	Cyamemazine			S	Oral			Not Reported
	Zopiclone			S				Not Reported
	Zyprexa			S	Oral			Not Reported
	Tareg			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Pinaverium Bromide			S				Not Reported
	Esberiven			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2006	6063902	DIRECT	Y	OT			87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Head Titubation; Tremor	Lexapro			S	Oral	10 Mg Qam Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2006	6089915	NON-EXPEDITED	N		2006PV007552		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hunger; Insomnia	Byetta			S	Subcutaneous	5 Mcg;Bid;Sc		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2006	7136028	NON-EXPEDITED	Y		US200603006324		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Blood Glucose Decreased; Blood Glucose Increased; Gastrooesophageal Reflux Disease	Cymbalta		S	See Image See Image See Image See Image	 3 DAY 3 DAY 3 DAY	Not Reported
	Lexapro		S			Not Reported
	Strattera		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2006	6066451	EXPEDITED (15-DAY)	Y	OT	S06-USA-02019-01		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Hepatic Steatosis; Weight Increased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Inderal La			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2006	6066794	EXPEDITED (15-DAY)	Y	DE	S06-USA-02031-01		70 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2006	6067392	EXPEDITED (15-DAY)	Y	HO, OT	S06-ITA-02163-01		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Abnormal; Condition Aggravated; Discomfort; Job Dissatisfaction; Loss Of Consciousness; Muscle Spasms; Neuralgia	Cipralex			S	Oral	10 Mg Qod Po		Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2006	5845453	EXPEDITED (15-DAY)	Y	HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-13044078		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Diarrhoea; Dyspnoea; Fatigue; Pulmonary Embolism	Cetuximab			S	Intravenous (not otherwise specified)	Init Tx:02-Jun-05 400 Mg/M2/Act Dose:800 Mg. Actual Dose This Inf: 500mg/Tot This Course = 1500 Mg.		Not Reported
	Cisplatin			S	Intravenous (not otherwise specified)	Initiated 02-June-2005 60 Mg/Reduced To Level 1 Due To Fatigue/50 Mg 23-Jun & 30 Jun.		Bristol Myers Squibb
	Effexor			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Prevacid			S				Not Reported
	Propoxyphene Hydrochloride			S				Not Reported
	Xanax			S	Oral			Not Reported
	Klonopin			C				Not Reported
	Wellbutrin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2006	6020029	EXPEDITED (15-DAY)	Y	HO	S06-USA-01100-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Cardio-Respiratory Arrest; Conversion Disorder; Crying; Gastric Disorder; Heart Rate Decreased; Heart Rate Increased; Heart Rate Irregular; Insomnia; Muscle Spasms; Myocardial Infarction; Nervousness;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Protonix			C				Not Reported
	Lorazepam			C				Not Reported

Procedural Complication;
Seizure; Thrombosis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2006	6037222	EXPEDITED (15-DAY)	Y	OT	S06-USA-01441-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Injury; Fall; Heart Rate Decreased; Hypotension; Loss Of Consciousness; Tooth Fracture; Tooth Injury	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2006	6068746	EXPEDITED (15-DAY)	Y	HO, OT	HQWYE547725MAY06		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Catecholamines Increased; Chest Pain; Drug Interaction; Drug Intolerance; Lethargy; Pallor; Pharyngeal Erythema; Serotonin Syndrome	Effexor Xr			S		See Image See Image See Image	2 DAY 1 DAY 4 DAY	Not Reported
	Escitalopram Oxalate			S		10 Mg 1x Per 1 Day	2 DAY	Not Reported
	Methylphenidate			S		10 Mg (2 Doses), Given 3 Hours Apart		Not Reported
	Mirtazapine (Mirtazapine)			S		15 Mg 1x Per 1 Day	3 DAY	Not Reported
	Trazodone Hydrochloride			S		100 Mg 1x Per 1 Day	6 DAY	Not Reported
	Lamotrigine			C				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2006	5993296	EXPEDITED (15-DAY)	Y	HO	S06-USA-00351-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Albumin Decreased; Blood Alkaline	Lexapro			S				Not Reported
	Provigil			S	Oral	100 Mg Qd Po		Not Reported

Phosphatase Decreased; Hypophagia; Scab; Somnolence; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Risperdal	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2006	6014950	EXPEDITED (15-DAY)	Y	OT	S06-FRA-01011-01		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Food Allergy	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Lexomil (Bromazepam)			C				Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2006	5919693	EXPEDITED (15-DAY)	Y	OT	S05-FRA-03870-01		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Psychomotor Hyperactivity	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Stresam (Etifoxine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2006	5981743	EXPEDITED (15-DAY)	Y	HO, OT	US-JNJFOC-20060200563		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Somnolence; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Risperdal			S	Oral			Not Reported
	Provigil			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2006	6004068	EXPEDITED (15-DAY)	Y	OT	S06-FRA-00802-01		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Epistaxis; International Normalised Ratio Increased; Prothrombin Level Decreased	Escitalopram Oxalate		S	Oral	20 Mg Qd Po	Not Reported
	Previscan (Fluindione)		S			Not Reported
	Xanax		C			Not Reported
	Aceprometazine\Meprobamate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2006	6070589	EXPEDITED (15-DAY)	Y	HO	S06-FRA-02170-01		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Osmolarity Decreased; Cerebral Atrophy; Epilepsy; Hypokalaemia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Loss Of Consciousness; Seizure	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Equanil			C				Not Reported
	Haldol			C				Not Reported
	Aceprometazine\Meprobamate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2006	5928950	EXPEDITED (15-DAY)	Y	HO	S05-ISL-04800-01		17 YR	Male	ISL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Delusional Disorder, Unspecified Type; Paranoia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2006	6035673	EXPEDITED (15-DAY)	N	OT	S06-USA-01437-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Amnesia; Arthralgia; Blood Glucose Decreased; Chest Pain; Disturbance In	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Trileptal			S		450 Mg Qd		Not Reported

Attention; Drug Interaction; Fatigue; Feeling Cold; Intervertebral Disc Protrusion; Laboratory Test Abnormal; Road Traffic Accident	Flexeril	S		Not Reported
	Ultracet	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2006	6051622	EXPEDITED (15-DAY)	Y	HO	S06-FRA-01783-01		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Drug Abuser; Intentional Overdose	Escitalopram Oxalate			S	Oral	100 Mg Once Po		Not Reported
	Acetaminophen\Codeine Phosphate			S				Not Reported
	Oxazepam			S				Not Reported
	Ventolin			S				Not Reported
	Risperdal			S				Not Reported
	Methadone Hydrochloride			S				Not Reported
	Codeine			S		2 Tablet Qd		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2006	6061824	EXPEDITED (15-DAY)	N	OT	2006UW11450		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Heart Rate Decreased	Toprol Xl			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2006	6045005	EXPEDITED (15-DAY)	Y	HO	S06-USA-01516-02		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Maternal	Lexapro			S				Not Reported

Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Restlessness; Screaming	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2006	6064540	EXPEDITED (15-DAY)	Y	DE	T06-CAN-02004-01		22 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2006	6071373	EXPEDITED (15-DAY)	Y	OT	S06-USA-02149-01		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejaculation Failure; Progressive Multiple Sclerosis; Sexual Dysfunction	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Rebif			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2006	6064031	EXPEDITED (15-DAY)	Y	HO	2006UW11453		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Decreased; Anxiety; Blood Urea Nitrogen/Creatinine Ratio Decreased; Depression; Drug Interaction; Family Stress; Homicidal Ideation; Insomnia; Suicidal Behaviour; Suicidal	Seroquel			S	Oral			Zeneca
	Zonegran			C				Not Reported
	Zonegran			C				Not Reported
	Wellbutrin Xl			C				Not Reported
	Lexapro			S	Oral		186 DAY	Not Reported
	Lexapro			S	Oral			Not Reported
	Marijuana			S				Not Reported

Ideation; Tearfulness;
Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2006	6074788	EXPEDITED (15-DAY)	Y	OT	S06-USA-02236-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly	Campral			S				Not Reported
	Lexapro			S				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2006	6075010	EXPEDITED (15-DAY)	Y	OT	S06-ITA-02360-01		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2006	6075011	EXPEDITED (15-DAY)	Y	HO, OT	L06-IND-02195-01			Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Insomnia; Restlessness; Therapy Non-Responder	Escitalopram Oxalate			S		20 Mg Qd		Not Reported
	Olanzapine			S		7.5 Mg Qd		Not Reported
	Lamotrigine			C				Not Reported
	Thyroxin (Levothyroxine Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2006	5989406	EXPEDITED (15-DAY)	Y	HO	S06-USA-00349-01		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Jaundice Cholestatic	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Unspecified Ingredient		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2006	6076275	EXPEDITED (15-DAY)	Y	OT	T06-USA-02371-01		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Poisoning; Crying; Intentional Self-Injury; Malaise; Suicidal Ideation	Escitalopram Oxalate			S	Oral	1 Tablet Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Placebo			S	Oral	1 Tablet Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2006	5999439	EXPEDITED (15-DAY)	Y	OT	S06-USA-00458-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Cholesterol Increased; Blood Triglycerides Increased; Bronchoscopy Abnormal; Chest X-Ray Abnormal; Condition Aggravated; Fatigue; Fungal Infection; Hyperlipidaemia; Low Density Lipoprotein Increased; Lung Infection; Lung Infiltration; Lung Neoplasm; Lung Neoplasm Malignant; Lymphadenopathy Mediastinal; Metastatic Neoplasm; Osteopenia; Platelet Count Increased;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Rheumatoid Arthritis; Sarcoidosis; Sinusitis; Staphylococcal Infection; Systemic Lupus Erythematosus; Treatment Noncompliance; Turner'S Syndrome; Type 2 Diabetes Mellitus; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2006	6044971	EXPEDITED (15-DAY)	Y	OT	S06-ITA-01558-01		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Condition Aggravated; Depression; Family Stress; Homicide	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Carbolithium (Lithium Carbonate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2006	6054845	EXPEDITED (15-DAY)	Y	DE, HO	S06-USA-01700-01		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level Below Therapeutic; Completed Suicide; Suicidal Ideation	Wellbutrin			S	Oral	150mg Per Day		Glaxosmithkline
	Lexapro			S	Oral			Not Reported
	Celexa			S	Oral	40mg Per Day		Not Reported
	Klonopin			S	Oral	1mg At Night		Not Reported
	Trazodone Hydrochloride			S		100mg At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2006	6073474	EXPEDITED (15-DAY)	Y	OT	S06-HRV-02352-01		48 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Female Orgasmic	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

Disorder; Libido Increased	Cilazil (Cilazapril)		C	Not Reported
	Atenolol		C	Not Reported
	Furosemide		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2006	6076365	EXPEDITED (15-DAY)	N	HO	S06-USA-02306-01		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Labour	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Methadone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2006	6010591	EXPEDITED (15-DAY)	Y	CA, OT	S06-GER-01001-01			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Paternal Drugs Affecting Foetus; Trisomy 21	Cipralex			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Lithium			S	Oral	900 Mg Qd Po		Not Reported
	Quetiapine			S	Oral	300 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2006	6020542	EXPEDITED (15-DAY)	Y	OT	S06-GER-01001-02		40 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Paternal Drugs Affecting Foetus; Sperm Analysis Abnormal; Trisomy 21	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Lithium			S	Oral	900 Mg Qd Po		Not Reported
	Quetiapine			S	Oral	300 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2006	6069469	EXPEDITED (15-DAY)	Y	DE	2006CG01064		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asphyxia; Completed Suicide	Inexium		S	Oral		Astrazeneca
	Cyamemazine		S	Oral		Not Reported
	Escitalopram Oxalate		S	Oral	84 DAY	Not Reported
	Ramipril		S	Oral		Not Reported
	Glucophage		S	Oral		Not Reported
	Tahor		S	Oral		Not Reported
	Aspirin		C			Not Reported
	Lasix		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2006	5749953	EXPEDITED (15-DAY)	Y	DS	S05-NOR-00571-01		41 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Dyskinesia; Muscle Contractions Involuntary; Torticollis	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2006	6039439	EXPEDITED (15-DAY)	N	OT	PHEH2006US05401		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Amnesia; Arthralgia; Blood Glucose Decreased; Chest Pain; Disturbance In Attention; Drug Interaction; Fatigue; Feeling Cold; Intervertebral Disc Protrusion; Laboratory Test Abnormal; Road Traffic Accident	Trileptal			S	Oral	450 Mg, Qd		Novartis
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Lexapro			S	Oral	Unk, Unk		Not Reported
	Flexeril			S		Unk, Unk		Not Reported
	Ultracet			S		Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2006	6077793	EXPEDITED (15-DAY)	Y	HO	S06-SWE-02400-01		31 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Ectopic Pregnancy; Maternal Exposure During Pregnancy	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Remeron			S	Oral	15 Mg Qd Po		Not Reported
	Bricanyl			C				Not Reported
	Rhinocort			C				Not Reported
	Flutide			C				Not Reported
	Tavegyl (Clemastine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2006	6077799	EXPEDITED (15-DAY)	Y	HO	S06-GER-02398-01		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Generalised	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Clozapine			C				Not Reported
	Abilify			C				Not Reported
	Nervendragees-Ratiopharm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2006	6425863	EXPEDITED (15-DAY)	Y	OT	8017325		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Seizure; Suicide Attempt	Keppra			S	Oropharingeal	Once Po		Not Reported
	Cipralex			S	Oral	Once Po		Not Reported
	Lyrica			S	Oral	Once Po		Not Reported
	Mirtazapine			S	Oral	Once Po		Not Reported
	Nexium			S	Oral	Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2006	6075253	EXPEDITED (15-DAY)	Y	HO	L06-USA-02193-01		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chest Pain; Confusional State; Dizziness; Drug Interaction; Fall; Flushing; Hallucination; Hyperventilation; Labile Blood Pressure; Lethargy; Muscle Rigidity; Pain; Pallor; Pharyngeal Erythema; Pyrexia; Serotonin Syndrome; Tremor	Escitalopram Oxalate			S		10 Mg Qd		Not Reported
	Methylphenidate Hydrochloride			S		10 Mg Bid		Not Reported
	Venlafaxine Hydrochloride			S		75 Mg Qd		Not Reported
	Venlafaxine Hydrochloride			S		150 Mg Qd		Not Reported
	Venlafaxine Hydrochloride			S		225 Mg Qd		Not Reported
	Lamotrigine			C				Not Reported
	Gabapentin			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2006	6075254	EXPEDITED (15-DAY)	Y	DS, OT	S06-HRV-02168-01		47 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Anxiety; Gastric Disorder; Headache; Insomnia; Restless Legs Syndrome; Tension; Tremor	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Oxazepam			C				Not Reported
	Cerson (Nitrazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2006	6076174	DIRECT	N	HO, LT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Lexapro			S	Oral	20 Mg Once A Day Po		Fleming

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2006	6079377	EXPEDITED (15-DAY)	Y	DE	S06-USA-02325-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2006	4155085	EXPEDITED (15-DAY)	Y	DS, HO, OT	2004035108		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abscess; Alanine Aminotransferase Increased; Anger; Anxiety; Arthralgia; Arthropod Bite; Asthenia; Blood Creatine Phosphokinase Increased; Blood Pressure Systolic Increased; Bowel Movement Irregularity; Burning Sensation; Cerebral Disorder; Chills; Confusional State; Constipation; Cough; Crying; Decreased Appetite; Diarrhoea; Discomfort; Disturbance In Attention; Diverticulum Intestinal; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Erythema; Exercise Tolerance Decreased; Fatigue; Feeling Abnormal; Feeling Drunk;	Lipitor			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Meclizine			S				Not Reported
	Keflex			S		500 Mg (500 Mg, 1 In 1 D)		Not Reported
	Trazodone Hydrochloride			S	Oral	Oral		Not Reported
	Prozac			S				Not Reported
	Lexapro			S				Not Reported
	Ritalin			C				Not Reported
	Prednisone			C				Not Reported
	Effexor Xr			C				Not Reported
	Amitriptyline Hydrochloride			C				Not Reported
	Provigil			C				Not Reported
	Minocycline\Minocycline Hydrochloride			C				Not Reported
	Namenda			C				Not Reported
	Carnitor (Levocarnitine)			C				Not Reported

Fibrocystic Breast Disease; Fibromyalgia; Frustration Tolerance Decreased; Gait Disturbance; Gastrointestinal Hypermotility; Goitre; Hepatic Lesion; Hyperhidrosis; Hypoaesthesia; Hypotonia; Inflammation; Influenza Like Illness; Intervertebral Disc Degeneration; Loss Of Personal Independence In Daily Activities; Lymphoid Tissue Hyperplasia; Major Depression; Malaise; Mass; Mitochondrial Myopathy; Muscle Atrophy; Muscle Injury; Muscle Spasms; Myalgia; Nausea; Neuropathy Peripheral; Oedema Peripheral; Oropharyngeal Pain; Osteochondroma; Pelvic Inflammatory Disease; Pruritus; Psychomotor Hyperactivity; Rash; Rhinorrhoea; Sneezing; Soft Tissue Disorder; Spinal Osteoarthritis; Swelling; Tearfulness; Therapy Non-Responder; Tinnitus; Tremor; Urine Output Decreased; Vertigo; Weight Fluctuation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2006	6057600	EXPEDITED (15-DAY)	Y	OT	S06-TUR-01973-01		21 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Intentional Overdose; Photophobia; Suicide Attempt; Tinnitus	Cipralex			S	Oral	22 Tablet Once Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2006	6079474	EXPEDITED (15-DAY)	Y	DE	S06-DEN-02592-01			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Citalopram			S				Not Reported
	Citalopram			S				Not Reported
	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Chlorprothixene Hydrochloride			S				Not Reported
	Chlorprothixene Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2006	6082725	EXPEDITED (15-DAY)	Y	OT	2006077913		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Diabetes Mellitus; Drug Interaction; Iiird Nerve Paralysis; Mitochondrial Myopathy Acquired; Tinnitus	Lipitor			S				Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Starlix			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2006	6082822	EXPEDITED (15-DAY)	Y	OT	S06-HRV-02596-01		49 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ejaculation Failure; Erectile Dysfunction; Loss Of Libido	Cipralex		S	Oral	5 Mg Qd Po	Not Reported
	Thiamazole		C			Not Reported
	Atenolol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2006	6076975	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-13421599		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased; White Blood Cell Count Decreased	Abilify			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2006	6022642	EXPEDITED (15-DAY)	Y	OT	S06-USA-01131-02		< 1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Infantile Apnoea; Maternal Exposure During Pregnancy; Premature Baby	Lexapro			S	Transplacental	40 Mg Qd Transplacental		Not Reported
	Lexapro			S	Transmammary	40 Mg Qd Bf		Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2006	6022644	EXPEDITED (15-DAY)	Y	OT	S06-USA-01131-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pregnancy; Premature Labour	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2006	6077621	EXPEDITED (15-DAY)	Y	OT	PHEH2006US08337		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Catheter Placement; Drug Interaction; Urinary Retention	Ritalin	S	10 Mg, Bid	15840 MIN	Novartis
	Lexapro	S	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2006	6081849	DIRECT	Y	HO			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertensive Crisis	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2006	6084759	EXPEDITED (15-DAY)		HO, OT	DEWYE800826JUN06		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delirium; Disorientation; Disturbance In Attention; Drug Interaction; Memory Impairment; Restlessness; Sleep Disorder; Speech Disorder; Thinking Abnormal	Venlafaxine Hydrochloride			S	Oral Oral Oral	See Image See Image See Image	1 DAY 1 DAY 18 DAY	Not Reported
	Akineton			S			3 DAY	Not Reported
	Aricept			S		5 Mg	8 DAY	Not Reported
	Cipralex			S		5 Mg	4 DAY	Not Reported
	Lithium Carbonate			S	Oral Oral Oral Oral	See Image See Image See Image See Image	1 DAY 6 DAY 1 DAY	Not Reported
	Seroquel			S	Oral Oral Oral Oral Oral Oral Oral	See Image See Image See Image See Image See Image See Image See Image	13 DAY 1 DAY 1 DAY 3 DAY 2 DAY 1 DAY 11 DAY	Not Reported
	Zoloft			S		See Image See Image	6 DAY	Not Reported
	Presomen (Estrogens Conjugated)			C				Not Reported

Iodide (Iodide)	C		Not Reported
Tavor (Lorazepam)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2006	6040717	EXPEDITED (15-DAY)	Y	HO, LT	S06-FRA-01380-01		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Blood Calcium Decreased; Blood Chloride Decreased; Cardio-Respiratory Arrest; Cardiogenic Shock; Cardiomyopathy; Cerebral Disorder; Confusional State; Dialysis; Ejection Fraction Decreased; Hypokalaemia; Liver Disorder; Lung Infection; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Nosocomial Infection; Paraesthesia; Protein Total Decreased; Renal Failure; Renal Tubular Necrosis; Status Epilepticus; Syncope; Torsade De Pointes; Ventricular Fibrillation; Ventricular Tachycardia; Vomiting	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2006	6064542	EXPEDITED (15-DAY)	Y	DE	S06-BRA-02000-01		45 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Suicide	Clonazepam	C		Not Reported
	Valproate Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2006	6070591	EXPEDITED (15-DAY)	Y	OT	S06-FRA-02185-01		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Effexor			S		75 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2006	6070593	EXPEDITED (15-DAY)	Y	LT	S06-FRA-02186-01		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Chloride Decreased; Generalised Oedema; Hyponatraemia; Weight Increased	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Gaviscon			C				Not Reported
	Brompheniramine Maleate\Pseudoephedrine Hydrochloride			C				Not Reported
	Iperten (Manidipine Hydrochloride)			C				Not Reported
	Seretide			C				Not Reported
	Furosemide			C				Not Reported
	Fozitec (Fosinopril)			C				Not Reported
	Rilmenidine			C				Not Reported
	Inipomp			C				Not Reported
	Xalatan			C				Not Reported
	Permixon (Serenoa Repens)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2006	6077801	EXPEDITED (15-DAY)	Y	HO	S06-AUT-02401-01		74 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Benign Prostatic Hyperplasia;	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

Blood Lactate Dehydrogenase Increased; Colitis; Depression; Hyperuricaemia; Large Intestine Polyp; Megacolon; Pancreatic Atrophy; Subileus; Supraventricular Tachycardia; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2006	6078663	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0594771A		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Product Quality Issue; Tension Headache	Lotronex			S	Oral	1mg Per Day		Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Uniretic			C				Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2006	6085095	EXPEDITED (15-DAY)	Y	OT	S06-USA-02478-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anaemia; Colitis Ischaemic; Hypersomnia; Hypothyroidism; Infection; Malaise; Rash Pruritic; Urticaria	Lexapro			S				Not Reported
	Pegasys (Peginterferon Alfa-2a)			S	Subcutaneous	180 Mcg Qw Sc		Not Reported
	Ribavirin			S	Oral	800 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2006	6086128	EXPEDITED (15-DAY)	Y	HO	S06-GER-02616-01		22 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Seizure; Weight Increased	Cipralex	S	Oral	20 Mg Qd Po		Not Reported
	Topamax	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2006	5996732	EXPEDITED (15-DAY)	Y	HO	S06-FRA-00445-01		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Overdose; Weight Decreased	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	40 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Aripiprazole			S	Oral	20 Mg Qd Po		Not Reported
	Heptaminol Hydrochloride			C				Not Reported
	Imovane (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2006	6044172	EXPEDITED (15-DAY)	Y	HO	2006-141543-NL		44 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury; Ultrasound Biliary Tract Abnormal	Mirtazapine			S	Oral	30 Mg Qd Oral	32 YR	Not Reported
	Escitalopram Oxalate			S	Oral	Df Oral		Not Reported
	Zolpidem Tartrate			C				Not Reported
	Codeine/Phenyltoloxamine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2006	6090099	EXPEDITED (15-DAY)	Y	OT	S06-CAN-02625-01		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Duodenal Ulcer	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Meloxicam			S	Oral	15 Mg Qd Po		Not Reported
	Alprazolam			C				Not Reported
	Atenolol			C				Not Reported
	Flovent			C				Not Reported
	Folic Acid			C				Not Reported

	Lorazepam	C	Not Reported
	Norvasc	C	Not Reported
	Phenytoin	C	Not Reported
	Albuterol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2006	6062218	EXPEDITED (15-DAY)	Y	HO	S06-USA-01901-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Decreased; Anxiety; Blood Urea Nitrogen/Creatinine Ratio Decreased; Condition Aggravated; Depression; Divorced; Drug Interaction; Homicidal Ideation; Insomnia; Legal Problem; Loss Of Employment; Stress; Suicidal Behaviour; Suicidal Ideation; Tearfulness; Treatment Noncompliance; Weight Decreased	Lexapro			S	Oral	30 Mg Qd; Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd; Po		Not Reported
	Seroquel			S		200 Mg Qhs		Not Reported
	Marijuana			S				Not Reported
	Zonegran			C				Not Reported
	Wellbutrin Xl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2006	6063882	EXPEDITED (15-DAY)	Y	OT	8016846		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Craniocerebral Injury; Depression; Dysstasia; Lethargy; Memory Impairment; Sedation; Status Epilepticus	Keppra			S	Oral	1000 Mg 2/D Po		Not Reported
	Abilify			S	Oral	10 Mg /D Po		Not Reported
	Lexapro			S	Oral	D Po		Not Reported
	Carbatrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2006	6069578	EXPEDITED (15-DAY)	N	HO	S06-USA-02081-01		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Asthenia; Dehydration; Drug Ineffective; Gun Shot Wound; Hallucination; Headache; Increased Insulin Requirement; Nausea; Psychotic Disorder; Pyrexia; Suicidal Ideation; Suicide Attempt; Urinary Retention; Weight Decreased; Weight Increased; White Blood Cell Count Increased	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd; Po		Not Reported
	Insulin Nos			C				Not Reported
	Unknown Antihypertensive Medication			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2006	6079711	EXPEDITED (15-DAY)	Y	HO	2006PK01460		35 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Hepatitis; Hepatocellular Injury; Jaundice; Nausea	Seroquel			S	Oral		387 DAY	Zeneca
	Exjade			S	Oral		50 DAY	Not Reported
	Cipralex			S	Oral		2 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2006	6088726	EXPEDITED (15-DAY)	N	OT	S06-USA-02525-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Fluctuation	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported
	Lantus			C				Not Reported
	Humalog			C				Not Reported
	Fexofenadine			C				Not Reported

	Furosemide	C	Not Reported
	Lisinopril	C	Not Reported
	Levothyroxine	C	Not Reported
	Potassium	C	Not Reported
	Iron	C	Not Reported
	Vitamin C	C	Not Reported
	Aspirin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2006	6088979	EXPEDITED (15-DAY)	N	OT	S06-USA-02524-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Insomnia; Nausea; Seizure; Tremor; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2006	6080512	EXPEDITED (15-DAY)	Y	DE	US-KINGPHARMUSA00001-K200600865		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Paranoia	Altace			S	Oral	2.5 Mg, Qd		King
	Cyamemazine			S	Oral	1 U, Qd	11520 MIN	Not Reported
	Cyamemazine			S	Oral	Iu, Unk	11520 MIN	Not Reported
	Glucophage			S	Oral	1700 Mg, Qd		Not Reported
	Tahor			S	Oral	40 Mg, Qd		Not Reported
	Inexium			S	Oral	20 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Qd	84 DAY	Not Reported
	Lasix			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2006	6085861	DIRECT	Y	HO			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Decreased Appetite; Dry Mouth; Dysphagia; Insomnia	Lexapro		S	Oral	10 Mg Q Day Oral	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2006	6039773	EXPEDITED (15-DAY)	Y	HO	T06-AUT-00057-01		29 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Decreased; Body Temperature Decreased; Brain Oedema; Delirium; Disorientation; Drug Level Increased; Eosinophil Percentage Increased; Hallucination, Visual; Obsessive-Compulsive Personality Disorder; Restlessness	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Bid Po		Not Reported
	Clozapine			S	Oral	200 Mg Qd Po		Novartis
	Clozapine			S	Oral	300 Mg Qd Po		Novartis
	Clozapine			S	Oral	350 Mg Qd Po		Novartis
	Clozapine			S	Oral	500 Mg Qd Po		Novartis
	Clozapine			S	Oral	600 Mg Qd Po		Novartis
	Clozapine			S	Oral	800 Mg Qd Po		Novartis
	Augmentin			S	Oral	3000 Mg Qd Po		Not Reported
	Solian (Amisulpride)			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Aerius (Desloratadine)			C				Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2006	6041554	EXPEDITED (15-DAY)	Y	OT	S06-IRL-01557-01		85 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoptysis; Nausea	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2006	5904066	EXPEDITED (15-DAY)	Y	LT	S05-UKI-03649-01		61 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebrovascular Accident; Deep Vein Thrombosis; Myocardial Infarction	Cipralex		S	Oral	10 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2006	6116252	NON-EXPEDITED	Y		2006SP002390		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysgeusia; Hypoaesthesia; Muscle Spasms; Nervousness	Lunesta			S	Oral	Prn Oral		Not Reported
	Lexapro			S	Oral	10 Mg; Oral		Not Reported
	Remeron			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2006	6119081	NON-EXPEDITED	N		2006SP002286		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Middle Insomnia	Lunesta			S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Hydroxyzine			S	Oral	Hs;Oral		Not Reported
	Lexapro			S	Oral	Hs;Oral		Not Reported
	Tamsulosin Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2006	5987601	EXPEDITED (15-DAY)	Y	OT	S06-USA-00290-01		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Asthenia; Blood Creatinine Increased; Blood Urea Increased; Decreased Appetite; Hypersomnia; Malaise; Renal Impairment;	Lexapro			S	Oral	22.5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

Tubulointerstitial Nephritis	Aciphex	S		Not Reported
	Aciphex	S		Not Reported
	Lotrel	S		Not Reported
	Triamterene And Hydrochlorothiazide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2006	6083155	EXPEDITED (15-DAY)	Y	HO	2006PK01488		54 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Fall; Medication Error; Muscle Rigidity; Myoclonus; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Seroquel			S	Oral		17 DAY	Zeneca
	Amisulpride			S	Oral		92 DAY	Not Reported
	Cipralex			S	Oral		81 DAY	Not Reported
	Edronax			S	Oral		52 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2006	6091925	DIRECT	Y	OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Oral	1 Tablet Daily Po	6 WEEK	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2006	5998357	EXPEDITED (15-DAY)	Y	OT	S06-USA-00149-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Decreased; Blood Glucose Decreased; Brain Natriuretic Peptide Decreased; Dementia; Disorientation; Generalised Tonic-Clonic Seizure; Granulocyte	Namenda			S	Oral	10 Mg Qd Po		Not Reported
	Namenda			S	Oral	15 Mg Qd Po		Not Reported
	Namenda			S	Oral	10 Mg Bid Po		Not Reported
	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Bid Po		Not Reported

Count Increased; Monocyte Count Increased; Myoglobin Blood Increased; Nasal Cyst; Postictal State; Road Traffic Accident; Screaming; Treatment Noncompliance; White Blood Cell Count Increased	Namenda		S	Oral	5 Mg Qd Po	Not Reported
	Namenda		S	Oral	5 Mg Bid Po	Not Reported
	Namenda		S	Oral	15 Mg Qd Po	Not Reported
	Namenda		S	Oral	10 Mg Bid Po	Not Reported
	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Risperdal		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2006	6077039	EXPEDITED (15-DAY)	Y	HO	T06-SWI-02396-01		70 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Gait Inability; Impaired Self-Care; Parkinsonism	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Aricept			C				Not Reported
	Marcumar			C				Not Reported
	Insulin Nos			C				Not Reported
	Aldactone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2006	6086186	EXPEDITED (15-DAY)	Y	DE	S06-FRA-02604-01		69 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Paranoia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Glucophage			S	Oral	1700 Mg Qd Po		Not Reported
	Cyamemazine			S	Oral	0.5 Units Bid Po		Not Reported
	Atorvastatin Calcium			S	Oral	40 Mg Qd Po		Not Reported
	Inexium (Esomeprazole)			S	Oral	20 Mg Qd Po		Not Reported
	Ramipril			S	Oral	1.25 Mg Bid Po		Not Reported
	Aspirin			S	Oral	75 Mg Qd Po		Not Reported
	Lasilix (Furosemide)			S	Oral	40 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2006	6091893	DIRECT	N	DE			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	20 Mg Daily Po	10 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2006	6093124	EXPEDITED (15-DAY)	Y	HO	S06-USA-02722-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Pain	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aripiprazole			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2006	6081508	EXPEDITED (15-DAY)	Y	HO	S06-FRA-02576-01		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Albumin Increased; Blood Chloride Decreased; Blood Glucose Increased; Blood Sodium Decreased; Blood Urea Decreased; Clonus; Confusional State; Dizziness; Hot Flush; Hyperhidrosis; Hyponatraemia; Malaise; Myoclonus; Nausea; Neurological Examination Abnormal; Pco2 Decreased; Salivary Hypersecretion; Seizure; Speech Disorder; Tachypnoea; Tremor	Escitalopram Oxalate			S	Oral	1 Units Qd Po		Not Reported
	Buflomedil Hydrochloride			S	Oral	300 Mg Bid Po		Not Reported
	Lansoprazole			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Oxazepam			C				Not Reported
	Polyethylene Glycols			C				Not Reported
	Acetaminophen\Caffeine\Dextropropoxyphene			C				Not Reported
	Sedatif Pc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2006	6088983	EXPEDITED (15-DAY)	Y	OT	S06-USA-02484-01		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Headache; Pain; Postictal State; Seizure	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Tramadol Hydrochloride			S	Oral	50 Mg Po		Not Reported
	Lortab			C				Not Reported
	Lisinopril			C				Not Reported
	Claritin			C				Not Reported
	Nabumetone (Relafen)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2006	6093584	EXPEDITED (15-DAY)	Y	OT	S06-GER-02856-01		46 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Rash	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Atorvastatin Calcium			C				Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2006	5798218	EXPEDITED (15-DAY)	N	OT	US-GLAXOSMITHKLINE-A0558615A		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Aggression; Disturbance In Attention; Dizziness; Drug Withdrawal Syndrome; Fatigue; Headache; Nausea; Vertigo	Paxil			S	Oral	20mg Per Day		Glaxosmithkline
	Paxil Cr			S	Oral			Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported
	Celexa			S	Oral	20mg Per Day		Not Reported
	Hyoscyamine			C				Not Reported
	Clonazepam			C				Not Reported
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2006	6016668	EXPEDITED (15-DAY)	Y	OT	ES-MERCK-0603ESP00042			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypocalcaemia	Aldomet			S				Merck
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2006	6086112	EXPEDITED (15-DAY)	Y	OT	S06-GER-02617-01		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Neutrophil Count Decreased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Mirtazapine			C				Not Reported
	Tavor (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2006	6094265	EXPEDITED (15-DAY)	Y	HO	S06-SWI-02698-01		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Depressed Level Of Consciousness; Fall; Hyperhidrosis; Medication Error; Muscle Rigidity; Myoclonus; Pyrexia; Toxicity To Various Agents	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Seroquel			S	Oral	800 Mg Qd Po		Not Reported
	Amisulpride			S	Oral	600 Mg Qd Po		Not Reported
	Edronax			S	Oral	600 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2006	6094665	EXPEDITED (15-DAY)	Y	OT	L06-GER-02656-02		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Myoclonus	Escitalopram Oxalate			S		10 Mg Qd		Not Reported

	Escitalopram Oxalate	S	20 Mg Qd	Not Reported
	Lamotrigine	S	200 Mg Qd	Not Reported
	Lamotrigine	S	300 Mg Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2006	6095506	EXPEDITED (15-DAY)	N	OT	S06-USA-02766-01		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Anhedonia; Arthralgia; Asthenia; Condition Aggravated; Fatigue; Loss Of Control Of Legs; Loss Of Personal Independence In Daily Activities; Pain In Extremity	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Effexor Xr			C				Not Reported
	Allegra			C				Not Reported
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2006	6096438	EXPEDITED (15-DAY)	Y	HO, LT	S06-GER-02877-01		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Activity; Delirium; Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Solvex			C				Not Reported
	Exelon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2006	6025330	EXPEDITED (15-DAY)	Y	HO, LT	T06-UKI-01264-01		69 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blindness Unilateral; Road Traffic Accident; Ruptured Cerebral Aneurysm	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2006	6075217	EXPEDITED (15-DAY)	N	OT	S06-USA-02249-01		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dyspnoea; Fatigue; Feeling Abnormal; Heart Rate Irregular; Respiratory Tract Congestion; Sinus Congestion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Lexapro			C	Oral	5 Mg Qd Po		Not Reported
	Vytorin (Exetimibe/Simvastatin)			C				Not Reported
	Prevacid			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Pacerone			C				Not Reported
	Ambien			C				Not Reported
	Centrum Sliver (Multivitamin/Multimineral)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2006	6083425	EXPEDITED (15-DAY)	N	DE	DK-ROCHE-454316		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Xenical			S	Oral			Roche
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2006	6090661	EXPEDITED (15-DAY)	Y	DE	FR-MERCK-0607FRA00047		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Zocor			S	Oral			Merck
	Escitalopram Oxalate			S	Oral		20 DAY	Not Reported
	Metformin			C	Oral			Not Reported
	Labetalol Hydrochloride			C	Oral			Not Reported
	Labetalol Hydrochloride			C	Oral			Not Reported

	Valsartan	C	Oral	Not Reported
	Clopidogrel Bisulfate	C	Oral	Not Reported
	Aspirin	C	Oral	Not Reported
	Repaglinide	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2006	6100007	EXPEDITED (15-DAY)	Y	OT	2006088984			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Oedema Peripheral; Pain; Skin Discolouration; Venous Occlusion	Cabergoline			S	Oral	6 Mg, Oral		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Levothyroxine Sodium			S				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2006	6091506	EXPEDITED (15-DAY)	Y	DE	FR-SANOFI-SYNTHELABO-A02200601867		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cough; Myocardial Ischaemia; Sudden Death	Plavix			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral		20 DAY	Not Reported
	Tareg			S	Oral			Not Reported
	Zocor			S	Oral			Not Reported
	Trandate			S	Oral	Unk		Not Reported
	Metformin			S	Oral	Unk		Not Reported
	Repaglinide			C	Oral	Unk		Not Reported
	Aspirin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2006	6086788	EXPEDITED (15-DAY)	Y	OT	S06-FRA-02618-01		64 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Loss Of Consciousness; Malaise; Seizure	Escitalopram Oxalate		S	Oral	20 Mg Qd Po	Not Reported
	Buspar		C			Not Reported
	Levothyroxine Sodium		C			Not Reported
	Zolpidem Tartrate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2006	6090750	EXPEDITED (15-DAY)	Y	OT	S06-HRV-02674-01		33 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Male Orgasmic Disorder; Sexual Dysfunction	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Alofalk (Mesalazine)			C				Not Reported
	Imuran			C				Not Reported
	Decortin (Prednisone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2006	6101555	EXPEDITED (15-DAY)	Y	HO	S06-SWI-02900-01		94 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delirium; Disorientation; Fatigue; Hallucination	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Tramadol Hydrochloride			S	Oral	100 Mg Qd Po		Not Reported
	Buprenorphine Hydrochloride			S	Sublingual	0.4 Mg Qd Sl		Not Reported
	Trileptal			S	Oral	150 Mg Qd Po		Not Reported
	Surmontil			C				Not Reported
	Brufen (Ibuprofen)			C				Not Reported
	Xatral (Alfuzosin)			C				Not Reported
	Risperdal			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2006	6101557	EXPEDITED (15-DAY)	Y	OT	S06-SWI-02899-01		54 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Epistaxis; Formication; Hepatic Pain;	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

Hypotension; Nausea

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2006	6093275	EXPEDITED (15-DAY)	Y	HO	CH-JNJFOC-20060705583		93 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delirium; Disorientation; Fatigue; Hallucination; Sleep Disorder	Tramadol Hydrochloride			S	Oral			Not Reported
	Buprenorphine Hydrochloride			S	Sublingual			Not Reported
	Trileptal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Surmontil			C	Oral			Not Reported
	Ibuprofen			C	Oral			Not Reported
	Xatral			C	Oral			Not Reported
	Risperdal			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2006	6100786	EXPEDITED (15-DAY)	Y	DE	S06-USA-02794-01		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Economic Problem; Loss Of Employment	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Toprol Xl			C				Not Reported
	Altocor			C				Not Reported
	Hyzaar (Losartan/Hydrochlorothiazide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2006	6100798	EXPEDITED (15-DAY)	Y	OT	S06-USA-02791-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Drug Interaction; Heart Rate	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Decreased; Loss Of Consciousness; Syncope	Trileptal	S	150 Mg Bid		Not Reported
	Strattera	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2006	6100140	DIRECT	N	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Pain Of Skin; Pruritus; Skin Disorder	Lexapro			S		10mg Once A Day 047		Not Reported
	Advair Diskus			C				Not Reported
	Synthroid			C				Not Reported
	Leena 28 (Birth Control)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2006	6102717	EXPEDITED (15-DAY)	Y	OT	2006S1006538		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Loss Of Consciousness; Pain; Postictal Headache; Postictal State; Seizure	Lexapro			S	Oral	20 Mg;Qd;Po		Not Reported
	Tramadol Hydrochloride			S	Oral	50 Mg; Po		Not Reported
	Hydrocodone Bitartrate And Acetaminophen			C				Not Reported
	Lisinopril			C				Not Reported
	Loratadine			C				Not Reported
	Nabumetone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2006	5986542	EXPEDITED (15-DAY)		OT	PHEH2006US01749		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Asthenia; Blood Creatinine Increased; Blood Urea Increased; Decreased Appetite; Hypersomnia; Tubulointerstitial Nephritis	Lotrel			S	Oral			Novartis
	Aciphex			S	Oral			Not Reported
	Aciphex			S	Oral			Not Reported
	Lexapro			S		20 Mg, Qd		Not Reported
	Lexapro			S		20 Mg, Qd		Not Reported

Lexapro	S	Oral	20 Mg, Qd		Not Reported
Lexapro	S	Oral	22.5 Mg, Qd		Not Reported
Lexapro	S	Oral	15 Mg, Qd		Not Reported
Hydrochlorothiazide W/Triamterene	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2006	6061031	EXPEDITED (15-DAY)	Y	OT	S06-UKI-01993-01		36 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Brain Injury; Cognitive Disorder; Homicidal Ideation; Overdose; Parkinsonism; Tardive Dyskinesia	Cipralex			S	Oral	30 Mg Qd Po		Not Reported
	Citalopram Hydrobromide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2006	6078561	EXPEDITED (15-DAY)	Y	OT	S06-FRA-02374-01		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Rash; Skin Burning Sensation; Skin Discolouration; Vascular Skin Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Caltrate			C				Not Reported
	Actonel			C				Not Reported
	Alprazolam			C				Not Reported
	Arimidex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2006	6092666	EXPEDITED (15-DAY)	Y	LT	GXKR2006DK03939		32 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Sensory Loss	Citalopram Hydrobromide			S	Oral	20 Mg, Qd, Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Qd, Oral		Not Reported
	Insulin Nos			C				Not Reported
	Isophane Insulin (Isophane			C				Not Reported

Insulin) Injection)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2006	6101564	EXPEDITED (15-DAY)	Y	DS	S06-UKI-02901-01		46 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; Disorientation; Hepatic Enzyme Abnormal; Nausea; Polydipsia; Tremor	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Stilnoct (Zolpidem Tartrate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2006	6105925	EXPEDITED (15-DAY)	Y	OT	S06-USA-02935-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2006	6028186	EXPEDITED (15-DAY)	Y	OT	S06-USA-00892-01		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Blood Pressure Increased; Chest Discomfort; Condition Aggravated; Dry Mouth; Headache; Heart Rate Increased; Incorrect Dose Administered; Nausea; Palpitations; Sensation Of Foreign Body; Treatment Noncompliance	Lexapro			S	Oral	5 Mg Once Po		Not Reported
	Ativan			S		0.5 Mg Qid		Not Reported
	Cardizem			C				Not Reported
	Dyazide			C				Not Reported
	Tenormin			C				Not Reported
	Aspirin			C				Not Reported
	Vitamin E			C				Not Reported
	Calcium Gluconate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2006	6078559	EXPEDITED (15-DAY)	Y	DE	S06-ISR-02567-01		81 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Suicidal Ideation	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Verapamil Hydrochloride			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Calcimore (Calcium Carbonate)			C				Not Reported
	Ipratropium Bromide			C				Not Reported
	Tamsulosin Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2006	6097019	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-13290234		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased	Coumadin			S				Bristol Myers Squibb
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2006	6097094	NON-EXPEDITED	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-13331293		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage; Haematocrit Decreased; Platelet Count Decreased	Coumadin			S				Bristol Myers Squibb
	Verapamil Hydrochloride			C				Not Reported
	Arsenic Trioxide			C				Not Reported
	Melphalan			C				Not Reported
	Aspirin			S				Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2006	6097168	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-13370374			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Dizziness; Fall; Haemorrhage; Hallucination, Visual; Skin Laceration	Coumadin			S				Bristol Myers Squibb
	Lexapro			S				Not Reported
	Cytomel			C				Not Reported
	Strattera			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2006	6104354	EXPEDITED (15-DAY)	Y	OT	S06-FRA-02919-01		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Neutropenia; White Blood Cell Count Decreased	Seropram (Citalopram Hydrobromide)			S	Oral	20 Mg Bid Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2006	6104359	EXPEDITED (15-DAY)	Y	HO	S06-SWI-03091-01		37 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Petechiae; Platelet Disorder	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Paroxetine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2006	6104520	DIRECT	Y				80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea	Lexapro			S		Q Day # 30		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2006	6094683	EXPEDITED (15-DAY)	Y	DE, OT	2006080082		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Condition Aggravated; Coronary Artery Bypass; Paranoia	Atorvastatin			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Glucophage			S	Oral	1700 Mg (1700 Mg, 1 In 1 D), Oral		Not Reported
	Cyamemazine			S	Oral	1 Dose Form (2 In 1 D), Oral		Not Reported
	Inexium (Esomeprazole Magnesium)			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Ramipril			S	Oral	2.5 Mg (2.5 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin			C				Not Reported
	Lasilix (Furosemide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2006	6033240	EXPEDITED (15-DAY)	Y	OT	S06-FIN-01353-01		32 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aura; Cerebral Infarction; Depression; Hepatitis; Hepatotoxicity; Musculoskeletal Discomfort; Neck Pain; Paraesthesia; Vertebrobasilar Insufficiency; Visual Impairment	Cipralex			S				Not Reported
	Fragmin			C				Not Reported
	Fragmin-Marevan (Warfarin)			C				Not Reported
	Alprazolam			C				Not Reported
	Voltaren			C				Not Reported
	Burana (Ibuprofen)			C				Not Reported
	Panacod			C				Not Reported
	Dolan			C				Not Reported
	Para-Tabs (Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2006	6082870	EXPEDITED (15-DAY)	Y	OT	2006-06-2113		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Blood Thyroid Stimulating Hormone Increased; Depression; Diarrhoea; Drug Hypersensitivity; Fluid Intake Reduced; Goitre; Headache; Heart Rate Increased; Hypophagia; Hypothyroidism; Impaired Work Ability; Neck Pain; Somnolence; Stress; Throat Irritation; Ulcer; Urticaria; Vomiting	Pegintron			S	Subcutaneous	120 Mcg Qwk Subcutaneous		Not Reported
	Rebetol			S	Oral	1000 Mg Qd Oral		Not Reported
	Effexor			S	Oral	37.5 Mg Qd		Not Reported
	Lexapro			S				Not Reported
	Protonix			C				Not Reported
	Aspirin			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2006	6099241	EXPEDITED (15-DAY)		DE	PHRM2006FR02218		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Fatigue; Ischaemia; Productive Cough; Sudden Death	Tareg			S	Oral	80 Mg, Qd		Novartis
	Metformin			S	Oral	Unk, Unk		Not Reported
	Trandate			S	Oral			Not Reported
	Zocor			S	Oral	40 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Plavix			S	Ophthalmic	75 Mg, Qd		Not Reported
	Aspirin			C	Oral			Not Reported
	Repaglinide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2006	6104612	EXPEDITED (15-DAY)	N	HO	S06-USA-01052-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Increased; Chest Pain; Diarrhoea; Heart Rate Increased; Hypertension; Neutrophil Count Increased; Panic Attack; Tachycardia; White Blood Cell Count Increased	Wellbutrin Sr			S	Oral	150mg At Night	9 DAY	Glaxosmithkline
	Dyazide			S	Oral			Glaxosmithkline
	Lexapro			S	Oral		8 DAY	Not Reported
	Lasix			C		20mg Per Day		Glaxosmithkline
	Estrostep			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2006	6010148	EXPEDITED (15-DAY)	Y	OT	S06-USA-00723-01		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bifascicular Block; Blood Pressure Increased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Qrs Axis Abnormal	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Wellbutrin			S	Oral	150 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S	Oral	300 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S	Oral	450 Mg Qd Po		Not Reported
	Armour Thyroid			S	Oral	60 Mg Qd Po		Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2006	6108647	EXPEDITED (15-DAY)	N	OT	S06-USA-02981-01		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Triglycerides Increased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Narproxen			C				Not Reported
	Goodys			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2006	6111990	EXPEDITED (15-DAY)	N	HO	S06-USA-02980-01		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Gun Shot Wound; Suicide Attempt	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2006	6000623	EXPEDITED (15-DAY)	Y	OT	S06-USA-00552-01		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Diovan Hct			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2006	6101243	EXPEDITED (15-DAY)		DE	FR-AVENTIS-200612714FR		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Ventricular Fibrillation	Lasix			S	Oral			Aventis
	Pravastatin Sodium			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Perindopril Erbumine			S	Oral			Not Reported
	Glucophage			S	Oral			Not Reported
	Dafalgan			C				Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported
	Gliclazide			C	Oral			Not Reported
	Acarbose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2006	6106093	EXPEDITED (15-DAY)	Y	DE	S06-NOR-02918-01		53 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Furadantin			C				Not Reported
	Hiprex			C				Not Reported
	Vagifem			C				Not Reported
	Livial			C				Not Reported
	Stilnoct (Zolpidem Tartrate)			C				Not Reported
	Sobril (Oxazepam)			C				Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2006	6027181	EXPEDITED (15-DAY)	Y	DE, HO, LT	FR-BRISTOL-MYERS SQUIBB COMPANY-13340856		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Chills; Malaise; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Respiratory Arrest	Abilify			S	Oral			Not Reported
	Tiapride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Cytotec			S				Not Reported
	Zopiclone			C				Not Reported
	Prazepam			C		Dosage: 10 Mg To 40 Mg		Not Reported
	Mifegyne			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2006	6111283	DIRECT	N	DS, HO, LT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Confusional State; Depressed Level Of Consciousness; Drug Hypersensitivity; Feeling	Lexapro			S	Oral	Twice Daily Po		Not Reported

Abnormal; Hyperhidrosis;
Loss Of Consciousness;
Pain; Seizure; Tinnitus;
Tongue Biting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2006	6081340	EXPEDITED (15-DAY)	Y	HO	S06-USA-02472-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Drug Withdrawal Syndrome Neonatal; Maternal Exposure During Pregnancy	Lexapro			S				Not Reported
	Methadone Hydrochloride			S	Transplacental	35 Mg Bid Transplacental		Not Reported
	Prenatabs Fa			C				Not Reported
	Synthroid			C				Not Reported
	Vitamin B6			C				Not Reported
	Propranolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2006	6093062	EXPEDITED (15-DAY)	Y	OT	S06-USA-02553-01		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Cardiac Valve Disease; Insomnia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			C				Not Reported
	Garlic Pills			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2006	6103205	EXPEDITED (15-DAY)	N	DE, HO	FR-BRISTOL-MYERS SQUIBB COMPANY-13467808		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Multiple Organ Dysfunction Syndrome; Ventricular Fibrillation	Glucophage			S	Oral			Bristol Myers Squibb
	Pravastatin Sodium			S	Oral			Bristol Myers Squibb
	Lasix			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Oral			Not Reported
	Perindopril Erbumine			S	Oral			Not Reported

Escitalopram Oxalate	S	Oral		12 WEEK	Not Reported
Dafalgan	C				Not Reported
Aspegic [Acetylsalicylate Lysine]	C				Not Reported
Gliclazide	C	Oral			Not Reported
Acarbose	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2006	6103493	EXPEDITED (15-DAY)		DE	FR-SOLVAY-00206002538		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Coma; Coronary Artery Disease; Ventricular Fibrillation	Perindopril Erbumine			S	Oral	Daily Dose: 2 Milligram(S)		Not Reported
	Escitalopram Oxalate			S	Oral	Daily Dose: 10 Milligram(S)	84 DAY	Not Reported
	Bisoprolol Fumarate			S	Oral	Daily Dose: 1 Dosage Form		Not Reported
	Glucophage			S	Oral	Daily Dose: 2550 Milligram(S)		Not Reported
	Lasix			S	Oral	Daily Dose: 1 Dosage Form		Not Reported
	Pravastatin Sodium			S	Oral	Daily Dose: 1 Dosage Form		Not Reported
	Aspegic [Acetylsalicylate Lysine]			C	Unknown	Daily Dose: Unknown		Not Reported
	Dafalgan			C	Unknown	Daily Dose: Unknown		Not Reported
	Diamicron			C	Unknown	Daily Dose: Unknown		Not Reported
	Glucor			C	Unknown	Daily Dose: Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2006	6103561	EXPEDITED (15-DAY)	N	OT	PHEH2006US09800		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Drug Interaction; Heart Rate Decreased; Loss Of	Trileptal			S		150 Mg, Bid		Novartis
	Lexapro			S		10 Mg, Qd		Not Reported

Consciousness; Syncope	Strattera	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2006	6103655	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0586836A		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling	Paroxetine Hydrochloride			S	Oral	40mg Per Day		Glaxosmithkline
	Lexapro			S		2.5mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2006	6103903	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0593709A		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Depression; Insomnia; Weight Decreased	Paxil			S	Oral		22 DAY	Glaxosmithkline
	Lexapro			S				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2006	6113157	EXPEDITED (15-DAY)	Y	HO	S06-USA-03018-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Procedural Haemorrhage	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2006	6113160	EXPEDITED (15-DAY)	Y	HO	S06-USA-03020-01		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Namenda			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Norvasc			C				Not Reported
	Metoprolol			C				Not Reported

Tylenol (Paracetamol)	C		Not Reported
Exelon	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2006	6115046	EXPEDITED (15-DAY)	Y	HO, RI	S06-USA-03017-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis Perforated; Haematoma Infection; Haemoglobin Decreased; Incisional Hernia; Procedural Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6034042	EXPEDITED (15-DAY)	Y	HO	S06-USA-00959-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme	Lexapro			S				Not Reported
	Vitamin B12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6057243	EXPEDITED (15-DAY)	N	HO	S06-USA-01877-01		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Bacterial Infection; Dehydration; Diarrhoea; Gastrointestinal Infection; Hyperacusis; Mental Impairment; Nausea; Panic Attack; Paraesthesia; Pharyngeal Oedema; Pruritus	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6100804	EXPEDITED (15-DAY)	Y	HO	S06-USA-02838-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Breast Neoplasm; Breast Cyst; Breast Discharge; Intentional Overdose; Intentional Self-Injury; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Depakote			S				Not Reported
	Depakote			S				Not Reported
	Risperdal			S		2 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6113476	EXPEDITED (15-DAY)	N	HO	S06-USA-03031-01		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Immune Thrombocytopenic Purpura	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lipitor			C				Not Reported
	Flonase			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6113479	EXPEDITED (15-DAY)	Y	OT	S06-USA-03037-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pregnancy; Thrombosis; Vaginal Haemorrhage	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Wellbutrin Xl			S		300 Mg Qd		Not Reported
	Prenatal Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6114164	EXPEDITED (15-DAY)	N	RI, OT	S06-USA-03023-01		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Electrocardiogram Abnormal; Product Dose Omission	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6167874	NON-EXPEDITED	N		S06-USA-02517-01		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Flomax			C				Not Reported
	Proscar			C				Not Reported
	Pill To Increase Appetite (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6167897	NON-EXPEDITED	N		S06-USA-02544-01		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Namenda			S	Oral	10 Mg Bid Po		Not Reported
	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Namenda			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Synthroid			C				Not Reported
	Plavix			C				Not Reported
	Norvasc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6167902	NON-EXPEDITED	N		S06-USA-02715-01		87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Namenda			S	Oral	15 Mg Qd Po		Not Reported
	Namenda			S	Oral	15 Mg Qd Po		Not Reported
	Namenda			S	Oral	10 Mg Bid Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Aricept			C				Not Reported
	Flomax			C				Not Reported
	Singulair			C				Not Reported
	Toprol Xl			C				Not Reported
	Prilosec			C				Not Reported
	Zocor			C				Not Reported
	Aspirin			C				Not Reported
	Multivitamin (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6168195	NON-EXPEDITED	N		S06-USA-01874-01		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Namenda			S	Oral	15 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Qd Po		Not Reported
	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aricept			C				Not Reported
	Lipitor			C				Not Reported
	Gemfibrozil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6168738	NON-EXPEDITED	N		S06-USA-01632-01		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Food Interaction; Retching	Namenda			S	Oral	10 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			S				Not Reported
	Aricept			C				Not Reported
	Digoxin			C				Not Reported
	Coumadin			C				Not Reported
	Fosamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6173913	NON-EXPEDITED	Y		S06-USA-02147-01		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance	Namenda			S	Oral	10 Mg Bid Po		Not Reported
	Namenda			S				Not Reported
	Lexapro			S				Not Reported
	Razadyne			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2006	6179370	NON-EXPEDITED	N		S06-USA-01867-01		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Namenda			S	Oral	5 Mg Qs Po		Not Reported
	Namenda			S	Oral	5 Mg Bid Po		Not Reported
	Lexapro			S	Oral	15 Mg Qhs Po		Not Reported
	Aricept			C				Not Reported
	Plavix			C				Not Reported
	Norvasc			C				Not Reported
	Premarin			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2006	6112346	DIRECT	N	OT			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Affect Lability; Aggression; Cold Sweat; Depression; Disturbance In Attention; Drug Withdrawal Syndrome; Inappropriate Schedule Of Product Administration; Loss Of Personal Independence In Daily Activities; Suicidal Ideation	Lexapro			S	Oral	20 Mg Once Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2006	6114356	EXPEDITED (15-DAY)	Y	HO	S06-UKI-03127-01		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Intertrigo; Rash Generalised; Rash Pustular; Skin Abrasion	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	L-Thyroxine (Levothyroxine)			C				Not Reported
	Dipyridamole			C				Not Reported
	Furosemide			C				Not Reported
	Atorvastatin			C				Not Reported
	Spiriva			C				Not Reported
	Symbicort			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2006	6094664	EXPEDITED (15-DAY)	Y	OT	L06-GER-02656-01		22 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Myoclonus	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S		30 Mg Daily		Not Reported
	Lamotrigine			S		25 Mg Qd		Not Reported

	Lamotrigine	S	100 Mg Qd		Not Reported
	Lamotrigine	S	250 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2006	6104396	EXPEDITED (15-DAY)	Y	DE	S06-FRA-03073-01		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Myocardial Ischaemia; Productive Cough	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Stagid (Metformin Embonate)			S				Not Reported
	Trandate			S				Not Reported
	Zocor			S	Oral	40 Mg 1qd Po		Not Reported
	Tareg			S	Oral	80 Mg Qd Po		Not Reported
	Plavix			S	Oral	75 Mg Qd Po		Not Reported
	Aspirin			S				Not Reported
	Repaglinide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2006	6108953	EXPEDITED (15-DAY)	Y	DS	S06-DEN-03089-01		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Fatigue; Initial Insomnia; Malaise; Middle Insomnia; Muscle Contractions Involuntary; Nausea; Night Sweats; Nightmare; Poor Quality Sleep; Weight Decreased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Mirtazapine			C				Not Reported
	Stilnoct (Zolpidem Tartrate)			C				Not Reported
	Alopam (Oxazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2006	6007630	EXPEDITED (15-DAY)	Y	OT	S06-FRA-00810-01		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rectal Haemorrhage	Escitalopram Oxalate		S	Oral	10 Mg Qd Po	Not Reported
	Risperdal		C			Not Reported
	Lormetazepam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2006	6069055	EXPEDITED (15-DAY)	Y	HO	S06-FRA-02007-01		49 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Haemoglobin Decreased; Rectal Haemorrhage	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg Qd Po		Not Reported
	Prazepam			C				Not Reported
	Innohep			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2006	6069057	EXPEDITED (15-DAY)	Y	HO	S06-FRA-02006-01		49 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Haemoglobin Decreased; Phlebitis; Rectal Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2006	6071599	EXPEDITED (15-DAY)	N	OT	S06-USA-02141-01		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Lexapro			S	Oral	25 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported
	Diuretics			C				Not Reported
	Potassium			C				Not Reported
	Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2006	6108192	EXPEDITED (15-DAY)	Y	HO	S06-FRA-03076-01		69 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Valve Vegetation; Drug Eruption; Erythema; Hyperthermia; Rash Macular; Urticaria; Vascular Purpura	Escitalopram Oxalate			S				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2006	6117933	EXPEDITED (15-DAY)	N	DE	S06-USA-03223-01		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Thinking Abnormal	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2006	6064047	EXPEDITED (15-DAY)	Y	OT	S06-USA-01735-01		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Headache	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Ativan			C				Not Reported
	Metoprolol			C				Not Reported
	Diovan Hct			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2006	6093120	EXPEDITED (15-DAY)	N	OT	S06-USA-02724-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Loss Of Employment; Obsessive-Compulsive Disorder; Trichotillomania	Lexapro		S	Oral	20 Mg Bid Po	Not Reported
	Lexapro		S	Oral	20 Mg Qd Po	Not Reported
	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Lexapro		S	Oral	10 Mg Qod Po	Not Reported
	Glucophage		C			Not Reported
	Inderal		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2006	6094367	EXPEDITED (15-DAY)	Y	HO	S06-SWI-02669-01		36 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatocellular Injury; Serum Ferritin Increased	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Seroquel			S	Oral	300 Mg Qd Po		Not Reported
	Exjade			S		1500 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2006	6035749	EXPEDITED (15-DAY)	Y	DE	S06-USA-00386-01		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acid Base Balance Abnormal; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Pressure Decreased; Blood Sodium Decreased; Blood Urea Increased; Breath Sounds Abnormal; Cardiac Failure; Cardio-Respiratory Arrest; Coagulation Factor V Level Decreased; Coagulation Factor Vii	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Coumadin			S		5 Mg		Not Reported
	Ativan			C				Not Reported
	Heparin			C				Not Reported
	Lovenox			C				Not Reported
	Norco (Hydrocodone/Acetaminophen)			C				Not Reported
	Lasix			C				Not Reported

Level Decreased; Coagulation Factor X Level Decreased; Drug Interaction; Heart Rate Increased; Hypercalcaemia; International Normalised Ratio Increased; Lipase Increased; Metabolic Acidosis; Pericardial Effusion; Peripheral Coldness; Pleural Effusion; Postpericardiotomy Syndrome; Prothrombin Level Decreased; Urine Output Decreased; Ventricular Extrasystoles; Ventricular Fibrillation; Vomiting; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2006	6117442	DIRECT	N	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive	Lexapro			S	Oral	10 One By Mouth Od Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2006	6119980	EXPEDITED (15-DAY)	Y	HO	8018352		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Pressure Increased; Chest Pain; Dizziness; Drug Intolerance; Flushing; Hallucination; Headache;	Methylphenidate Hydrochloride			S	Oral	10 Mg Twice Po		Not Reported
	Venlafaxine			S	Oral	75 Mg /D Po	2 DAY	Not Reported
	Venlafaxine			S	Oral	150 Mg /D Po	1 DAY	Not Reported
	Venlafaxine			S	Oral	225 Mg /D Po	4 DAY	Not Reported

Hyperventilation; Lethargy; Movement Disorder; Pain; Pallor; Pharyngeal Erythema; Serotonin Syndrome	Escitalopram Oxalate		S	Oral	10 Mg /D Po	Not Reported
	Lithium		C			Not Reported
	Lamotrigine		C			Not Reported
	Trazodone Hydrochloride		C			Not Reported
	Mirtazapine		C			Not Reported
	Gabapentin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2006	6111237	EXPEDITED (15-DAY)	Y	RI	S06-USA-02961-01		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Ear Congestion; Ear Discomfort; Ear Infection; Insomnia; Middle Ear Effusion; Muscle Tightness; Nasal Congestion; Productive Cough; Rhinorrhoea	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zestril			C				Not Reported
	Atenolol			C				Not Reported
	Lipitor			C				Not Reported
	Flomax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2006	6120914	EXPEDITED (15-DAY)	Y	OT	S06-USA-03230-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Legal Problem	Campral			S	Oral	666 Mg Tid Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2006	6113473	EXPEDITED (15-DAY)	N	OT	S06-USA-03036-01		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Haemorrhage In Pregnancy; Normal Newborn; Peripartum	Wellbutrin Xl			S	Oral	300mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Prenatal Vitamins			C				Not Reported

Haemorrhage

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2006	6113772	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0608387A		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Disorientation; Fall	Malarone			S	Oral	1tab Per Day	3 DAY	Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported
	Diovan			C	Oral	320mg Twice Per Day		Not Reported
	Hydrochlorothiazide			C	Oral	25mg Twice Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2006	6122550	EXPEDITED (15-DAY)	N	OT	DSA_28575_2006		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Blood Pressure Increased; Chest Discomfort; Drug Withdrawal Syndrome; Dry Mouth; Headache; Inappropriate Schedule Of Product Administration; Insomnia; Nausea; Palpitations; Sensation Of Foreign Body; Treatment Noncompliance	Ativan			S	Oral	0.5 Mg Qid Po		Not Reported
	Lexapro			S	Oral	5 Mg Once Po		Not Reported
	Cardizem			C				Not Reported
	Dyazide			C				Not Reported
	Tenormin			C				Not Reported
	Vitamin E			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2006	5804716	EXPEDITED (15-DAY)	Y	OT	8010447		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Placenta Praevia; Pregnancy	Keppra			S	Oral	1000 Mg/D Po		Not Reported
	Keppra			S	Oral	1500 Mg/D Po		Not Reported

Lexapro	S	Oral	20 Mg /D Po		Not Reported
Seroquel	S	Oral	100 Mg /D Po		Not Reported
Baby Aspirin	S	Oral	Po		Not Reported
Prenatal Vitamins	S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2006	6091155	EXPEDITED (15-DAY)	Y	DE, HO, OT	2006082942		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Loss Of Consciousness	Geodon			S		160 Mg (160 Mg, 1 In 1 D),		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Cogentin			S	Oral	2 Mg (2 Mg, 1 In 1 D), Oral		Not Reported
	Haldol			S	Intramuscular	150 Mg (150 Mg, 1 In 4 Wk), Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2006	6121170	DIRECT	Y	HO, RI			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Infection; Skin Toxicity; Subcutaneous Abscess; Therapy Non-Responder	Iressa			S	Oral	250 Mg Daily Po		Not Reported
	Prednisone			S	Oral	5 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 Mg Daily Po		Not Reported
	Levoxyl			S	Oral	75 Mg Daily Po		Not Reported
	Pepcid			S	Oral	20 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2006	6121810	DIRECT	Y	HO, LT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Caesarean Section; Maternal Exposure During Pregnancy; Neonatal Seizure; Posturing	Lexapro		S	Oral	10 Mg Daily Po At Least 9 Months	Not Reported
	Ephedrine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2006	6013137	EXPEDITED (15-DAY)	Y	OT	S06-USA-01049-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Haematemesis; Upper Respiratory Tract Infection; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2006	6020051	EXPEDITED (15-DAY)	Y	HO	S06-USA-01155-01		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Angiodysplasia; Haematocrit Decreased; Platelet Count Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Coumadin			S		2 Mg Qd		Not Reported
	Aspirin			S		325 Mg Qd		Not Reported
	Verapamil Hydrochloride			C				Not Reported
	Arsenic			C				Not Reported
	Melphalan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2006	6094983	EXPEDITED (15-DAY)	Y	HO	S06-USA-02768-01		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Body Temperature Increased; Drug Interaction; Vomiting	Lexapro			S				Not Reported
	Demerol			S	Intramuscular	50 Mg Im		Not Reported
	Trileptal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2006	6120590	EXPEDITED (15-DAY)	Y	DE	S06-FRA-03346-01		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Coma; Coronary Artery Bypass; Multiple Organ Dysfunction Syndrome; Ventricular Fibrillation	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Bisoprolol Fumarate			S	Oral	1 Qd Po		Not Reported
	Perindopril Erbumine			S	Oral	2 Mg Qd Po		Not Reported
	Glucophage			S	Oral	850 Mg Tid Po		Not Reported
	Lasilix (Furosemide)			S	Oral	1 Tablet Qd Po		Not Reported
	Pravastatin			S	Oral	20 Mg Qd Po		Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported
	Dafalgan (Paracetamol)			C				Not Reported
	Gliclazide			C				Not Reported
	Acarbose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2006	6064076	EXPEDITED (15-DAY)	N	OT	2006066943		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Cerebrovascular Accident; Chest Pain; Depression; Dyspnoea; Emotional Disorder; Myocardial Infarction; Transient Ischaemic Attack	Bextra			S		Unknown (1-2 Times A Day); Unknown		Not Reported
	Vioxx			S				Not Reported
	Lexapro			S				Not Reported
	Lorcet Plus			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2006	6074948	EXPEDITED (15-DAY)	Y	OT	S06-FRA-02369-01		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence;	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported

Retinal Vein Occlusion

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2006	6109298	EXPEDITED (15-DAY)	Y	HO	T06-CAN-03124-01		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Cell Carcinoma	Escitalopram Oxalate			S				Not Reported
	Norfloxacin			C				Not Reported
	Percocet			C				Not Reported
	Levaquin			C				Not Reported
	Septra Ds			C				Not Reported
	Tylenol Extra Strength			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2006	6116920	NON-EXPEDITED	Y		S06-USA-01834-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Wellbutrin Xl			S	Oral	150mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported
	Hyzaar			C	Oral	50mg Per Day		Not Reported
	Klonopin			C	Oral	.5mg As Required		Not Reported
	Vistaril			C	Oral	25mg As Required		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2006	6119375	EXPEDITED (15-DAY)	Y	HO, OT	S06-USA-03204-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Hypertension; Transient Ischaemic Attack	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Effexor			S				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2006	6122139	DIRECT	N	OT			30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S	Oral	1 Once A Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2006	6076269	EXPEDITED (15-DAY)	Y	DE	S06-USA-02235-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Head Injury; Maternal Exposure During Pregnancy; Product Dose Omission; Refusal Of Treatment By Patient; Treatment Noncompliance	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2006	6126342	EXPEDITED (15-DAY)	Y		S06-USA-03415-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Hyponatraemia	Lexapro			S	Oral	60 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Trileptal			C				Not Reported
	Seroquel			C				Not Reported
	Fentanyl Patch			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2006	6177311	NON-EXPEDITED	N		S06-USA-02083-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dyspepsia; Flatulence	Campral			S	Oral	666 Mg Tid Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Minocycline\Minocycline			C				Not Reported

	Hydrochloride									
	Xanax			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2006	6079829	EXPEDITED (15-DAY)	N	OT	S06-USA-02444-01		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Withdrawal Syndrome; Muscle Twitching	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qod Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Benicar			C				Not Reported
	Crestor			C				Not Reported
	Zantac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2006	6127001	EXPEDITED (15-DAY)	Y	HO	S06-USA-03411-01		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Irritability; Mania; Paranoia	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2006	7136013	DIRECT	Y				56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Chest Pain; Pain	Actonel			S	Oral	35 Mg 1q Week Po [Only One Dose Taken]		Not Reported
	Toprol Xl			S				Not Reported
	Lexapro			S				Not Reported
	Midrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2006	6106253	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20060800535		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Breast Neoplasm; Breast Cyst; Breast Discharge; Intentional Self-Injury; Suicidal Ideation	Risperdal			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Depakote Er			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2006	6123764	DIRECT	N	HO, LT			13 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Anxiety; Hallucination; Ill-Defined Disorder; Mania; Nervousness; Restlessness; Suicide Attempt; Thinking Abnormal	Lexapro			S	Oral	20mg Once A Day Po		Not Reported
	Zoloft			S	Oral	100mg Once A Day Po		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2006	6125078	DIRECT	N				38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia	Lexapro			S	Oral	One 5-Mg Tab Per Day Once Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2006	6126660	EXPEDITED (15-DAY)	Y	OT	S06-UKI-03383-01		54 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Increased; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Orthostatic Hypotension; Respiratory Rate Increased	Cipralex		S	Oral	20 Mg Qd Po	Not Reported
	Clozapine		S	Oral	700 Mg Qd Po	Not Reported
	Lamotrigine		C			Not Reported
	Levothyroxine Sodium		C			Not Reported
	Zopiclone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2006	6108955	EXPEDITED (15-DAY)	Y	HO	S06-GER-03084-01		35 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2006	6125127	DIRECT	Y	HO, LT, RI			19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Depressed Level Of Consciousness; Dyskinesia; Loss Of Consciousness; Somnolence	Lexapro			S	Oral	Lexapro 10 Mg Po Q 24 H		Not Reported
	Nexium			C				Not Reported
	Synthroid			C				Not Reported
	Centrum Mvi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2006	6125459	EXPEDITED (15-DAY)	Y	HO	S06-FRA-03350-01		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Haemophilia; Activated Partial Thromboplastin Time Abnormal; Acute Coronary Syndrome; Anaemia; Anti Factor Viii Antibody Positive; Atrial Fibrillation;	Escitalopram Oxalate			S	Oral	1 Units Qd Po		Not Reported
	Fluindione			S	Oral	10 Mg Qd Po		Not Reported
	Pulmicort Flexhaler			C				Not Reported
	Combivent			C				Not Reported
	Flecainide Acetate			C				Not Reported
	Josir (Tamsulosin Hydrochloride)			C				Not Reported

Condition Aggravated; Haematoma; Haemorrhage; International Normalised Ratio Increased; Rhabdomyolysis	Aricept	C		Not Reported
	Epogen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2006	6127623	EXPEDITED (15-DAY)	Y	OT	S06-GER-03394-01		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2006	6129057	EXPEDITED (15-DAY)	N	OT	S06-USA-03466-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2006	6072585	EXPEDITED (15-DAY)	Y	DE	S06-USA-02204-01		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	20 Mg Qd;Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2006	6108579	EXPEDITED (15-DAY)	N	HO, LT, RI	S06-USA-02938-01		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Cancer; Cardiac Murmur; Coronary Arterial	Lexapro			S	Oral	30 Mg Qd Po		Not Reported

Stent Insertion; Drug Ineffective; Myocardial Infarction; Ureteral Stent Insertion	Lexapro		S	Oral	20 Mg Qd Po	Not Reported
	Lexapro		S	Oral	50 Mg Qd Po	Not Reported
	Pilocarpine Hydrochloride		C			Not Reported
	Lipitor		C			Not Reported
	Colace		C			Not Reported
	Aspirin		C			Not Reported
	Sodium Bicarbonate		C			Not Reported
	Folic Acid		C			Not Reported
	Calcium Gluconate		C			Not Reported
	Ferrous Sulfate		C			Not Reported
	Multi-Vitamin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2006	6125899	DIRECT	Y	OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anembryonic Gestation; Caesarean Section; Foetal Death; Haemoglobin Decreased; Haemorrhage; Haemorrhage In Pregnancy; Maternal Exposure During Pregnancy	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Wellbutrin Xl			S	Oral	150 Mg 2 Tabs Qam Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2006	6129474	EXPEDITED (15-DAY)	N	HO	S06-USA-03465-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypomania; Psychotic Disorder	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Strattera			S		100 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2006	6129477	EXPEDITED (15-DAY)	N	OT	S06-USA-02796-01		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Confusional State; Constipation; Decreased Appetite; Dementia; Depressed Level Of Consciousness; Drug Ineffective; Memory Impairment; Muscle Spasms	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Razadyne			C				Not Reported
	Lunesta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2006	6131539	DIRECT	Y	DS			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Escitalopram Oxalate			S	Oral	10mg Daily Po	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2006	7385668	EXPEDITED (15-DAY)	N	HO	US-JNJFOC-20060900247			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Confusional State; Drug Interaction; Motor Dysfunction; Seizure	Tramadol Hydrochloride			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2006	7385702	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0609224A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Interaction; Oral Pain; Teeth Brittle	Requip			S	Oral			Glaxosmithkline
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2006	6094669	EXPEDITED (15-DAY)	Y	DS, HO	S06-FRA-02858-01		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Dyskinesia; Impaired Work Ability; Refusal Of Treatment By Patient; Social Avoidant Behaviour; Tic; Trismus	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2006	6123324	EXPEDITED (15-DAY)	Y	HO	CH-JNJFOC-20060900125		65 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Toxicity To Various Agents	Risperdal			S	Oral			Not Reported
	Lormetazepam			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Aspirin			C	Oral			Not Reported
	Norvasc			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2006	6132295	EXPEDITED (15-DAY)	Y	OT	S06-UKI-03567-01		42 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Scintillating Scotoma	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2006	6135038	EXPEDITED (15-DAY)	Y	HO	S06-SWI-03573-01		55 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Epilepsy	Cipralex	S	Oral	10 Mg Qd Po		Not Reported
	Cipralex	S	Oral	5 Mg Qd Po		Not Reported
	Unspecified Ingredient	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2006	6105695	EXPEDITED (15-DAY)	N	HO	US-ABBOTT-06P-163-0339293-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Breast Neoplasm; Breast Cyst; Breast Cyst Drainage; Intentional Overdose; Intentional Self-Injury; Self-Injurious Ideation; Suicidal Ideation; Suicide Attempt	Depakote Er			S				Not Reported
	Depakote Er			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Risperidone			S			4 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2006	6115950	EXPEDITED (15-DAY)	Y	HO, OT	US-ABBOTT-06P-163-0341064-00		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Breast Neoplasm; Breast Cyst; Breast Discharge; Intentional Overdose; Intentional Self-Injury; Self-Injurious Ideation; Suicidal Ideation; Suicide Attempt	Depakote Er			S				Not Reported
	Depakote Er			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Risperidone			S			4 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2006	6068773	EXPEDITED (15-DAY)	Y	HO	S06-USA-02078-01		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Lactate	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Dehydrogenase Increased; Dizziness; Headache; Nausea; Neck Pain; Pyrexia	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Inhaler (Nos)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2006	6077035	EXPEDITED (15-DAY)	Y	HO	T06-SWI-02397-01		22 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Abnormal; Epilepsy; Generalised Tonic-Clonic Seizure; Schizophrenia; Treatment Noncompliance	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			S	Oral	600 Mg Qd Po		Not Reported
	Tegretol			S	Oral	400 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2006	6137792	EXPEDITED (15-DAY)	Y	OT	S06-FRA-00440-01		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alpha Globulin Increased; Haematocrit Decreased; Haemoglobin Decreased; Hypergammaglobulinaemia; Hypoalbuminaemia; Laboratory Test Abnormal; Mean Cell Volume Increased; Myelocyte Percentage Increased; Protein Total Increased; Red Blood Cell Count Decreased; Thrombocytopenia; White Blood Cell Count Decreased	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Insulatard Nph Human			C				Not Reported
	Glcophage (Metformin)			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Noctran 10			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Elevit Vitamine B9			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2006	6126553	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20060902269		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Death; Pulmonary Oedema; Toxicity To Various Agents	Cyclobenzaprine Hydrochloride			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Phentermine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2006	6126840	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20060902039		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Topiramate			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Hctz			S	Oral			Not Reported
	Iron			S	Oral			Not Reported
	Glucophage			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2006	6076366	EXPEDITED (15-DAY)	N	HO, LT	S06-USA-02306-02			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Methadone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2006	6112430	EXPEDITED (15-DAY)	Y	OT	PHEH2006US10511		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Pain; Depressed Level Of Consciousness; Fear; Feeling Abnormal; Headache; Hyperhidrosis; Hypotension; Loss Of Consciousness; Tremor; Visual Impairment	Diovan	S	Oral	80 Mg, Qd	4320 MIN	Novartis
	Prilosec	C		Unk, Prn		Not Reported
	Tagamet	C		Unk, Prn		Not Reported
	Lexapro	S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2006	6127078	EXPEDITED (15-DAY)	Y	HO, OT	S06-CAN-03104-01		54 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Hypersensitivity; Drug Ineffective	Cipralex			S				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2006	6127580	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-13380589		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Dyskinesia; Fatigue	Buspar			S				Bristol Myers Squibb
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2006	6129475	EXPEDITED (15-DAY)	Y	OT	S06-USA-03464-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Supraventricular Tachycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2006	6137392	EXPEDITED (15-DAY)	N	OT	S06-USA-03606-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Pharyngitis Streptococcal	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Ortho Cyclen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2006	6137398	EXPEDITED (15-DAY)	Y	HO	S06-USA-03548-01		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Atrophy; Mental Status Changes	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multiple (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2006	6138630	EXPEDITED (15-DAY)	Y	DE	S06-FRA-03756-01		72 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Urbanyl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2006	6191952	NON-EXPEDITED	Y	HO	S06-USA-01446-01		77 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Celexa			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2006	6091045	EXPEDITED (15-DAY)	Y	OT	S06-USA-02547-01		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Monopril			C				Not Reported
	Synthroid			C				Not Reported

	Prevacid	C	Not Reported
	Fosamax	C	Not Reported
	Dyazide (Triamterene/Hydrochlorothiazide)	C	Not Reported
	Coumadin	C	Not Reported
	Amaryl	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2006	6124204	EXPEDITED (15-DAY)	Y	HO, LT	CHWYE731318AUG06		43 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Intentional Overdose; Pneumonia Aspiration	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cipralex			S		Unknown		Not Reported
	Voltaren			S		Unknown		Not Reported
	Unspecified Ingredient			S		Unknown		Not Reported
	Tramadol Hydrochloride			S		Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2006	6207163	NON-EXPEDITED	Y	OT	US-JNJFOC-20050805935		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Therapeutic Response Unexpected; Weight Decreased	Topamax			S				Not Reported
	Lexapro			S	Oral	See Image		Not Reported
	Morphine Sulfate			C				Not Reported
	Clonidine			C				Not Reported
	Xanax			C				Not Reported
	Cannabis			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Chemotherapy (Antineoplastic Agents)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2006	6130302	EXPEDITED (15-DAY)	N	HO, OT	CA-ABBOTT-06P-028-0343572-00		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Cipralex			S				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2006	6140028	EXPEDITED (15-DAY)	Y	OT	S06-USA-03687-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Driving Ability	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2006	6140056	EXPEDITED (15-DAY)	Y	OT	S06-USA-03683-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Headache; Restless Legs Syndrome	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	14 Mg Qd Po		Not Reported
	Clonazepam			C				Not Reported
	Birth Control Pills			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2006	6138466	DIRECT	N	HO, LT, RI			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Lexapro			S	Oral	One A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2006	6140151	EXPEDITED (15-DAY)	Y	OT	FR-2006-027140		93 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura Non-Thrombocytopenic; Skin Discolouration; Skin Lesion	Sotalol Hydrochloride			S	Oral	Oral		Not Reported
	Calciparine			S	Subcutaneous	0.2, 2x/Day, Subcutaneous		Not Reported
	Escitalopram Oxalate			S	Intravenous (not otherwise specified)	Intravenous		Not Reported
	Atarax			C				Not Reported
	Eupantol			C				Not Reported
	Oliclimonel			C				Not Reported
	Inexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2006	6141276	EXPEDITED (15-DAY)		HO	2006-147869-NL		69 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Drug Interaction	Mirtazapine			S		60 Mg		Not Reported
	Olanzapine			S		5 Mg		Not Reported
	Escitalopram Oxalate			S		5 Mg	6 DAY	Not Reported
	Tamsulosin Hydrochloride			C				Not Reported
	Levothyroxine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2006	6093707	EXPEDITED (15-DAY)	Y	DE	S06-DEN-02855-01		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Orlistat			S	Oral	140 Mg Qd Po		Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2006	6132348	EXPEDITED (15-DAY)	Y	OT	S06-ITA-03570-01			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Lymphocytic Leukaemia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2006	6132388	EXPEDITED (15-DAY)	Y	HO	S06-GER-03562-01		60 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2006	6389951	EXPEDITED (15-DAY)	Y	HO	S06-SWI-03799-01		66 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Coordination Abnormal; Drug Abuser; Overdose; Sluggishness; Somnolence	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Lormetazepam			S				Not Reported
	Risperdal			S	Oral	4 Mg Qd Po		Not Reported
	Aspirin			C				Not Reported
	Norvasc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2006	6119691	EXPEDITED (15-DAY)	N	HO	US-ROCHE-460948		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Pegasys			S	Subcutaneous	Form Reported As Prefilled Syringes.	40 DAY	Roche
	Copegus			S	Oral		40 DAY	Roche

	Lexapro		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2006	5941886	EXPEDITED (15-DAY)	Y	OT	S05-GER-05519-01		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea Haemorrhagic	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2006	5953133	EXPEDITED (15-DAY)	Y	LT, RI, OT	S05 USA-05179-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Cervical Incompetence; Dysmenorrhoea; Infection; Lymphocyte Percentage Decreased; Maternal Exposure During Pregnancy; Nasopharyngitis; Neutrophil Percentage Increased; Placental Disorder; Premature Labour; Premature Separation Of Placenta; Rhesus Antibodies Positive; Therapy Non-Responder; Tocolysis; Vaginal Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prenatabs Fa			C				Not Reported
	Epidural (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2006	5954526	EXPEDITED (15-DAY)	Y	DE	S05-USA-05179-02		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Heart Rate Deceleration Abnormality;	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported

Infection; Maternal Exposure During Pregnancy; Placental Disorder; Premature Labour; Premature Separation Of Placenta	Prenatal Vitamins		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2006	6108954	EXPEDITED (15-DAY)	Y	OT	S06-CAN-03072-01		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Convulsive Threshold Lowered; Generalised Tonic-Clonic Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Topamax			C				Not Reported
	Risperdal			C				Not Reported
	Clonazepam			C				Not Reported
	Detrol			C				Not Reported
	Ibuprofen			C				Not Reported
	Lithium			C				Not Reported
	Monistat (Miconazole Nitrate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2006	6142514	EXPEDITED (15-DAY)	Y	HO, OT	S06-UKI-03790-01		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Ectopic Pregnancy; Maternal Exposure During Pregnancy	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2006	6142619	EXPEDITED (15-DAY)	N	OT	S06-USA-03690-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Crying; Decreased Appetite; Depressed Mood; Diarrhoea;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	7.5 Mg Qd Po		Not Reported

Disturbance In Attention; Drug Dependence; Dry Mouth; Headache; Hot Flush; Insomnia; Memory Impairment; Nausea; Paraesthesia; Self-Injurious Ideation; Thinking Abnormal; Uterine Leiomyoma; Vision Blurred; Weight Increased	Lexapro	S	Oral	5 Mg Qd Po		Not Reported
	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Paxil	C				Not Reported
	Synthroid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2006	6142687	EXPEDITED (15-DAY)	Y	DS	S06-UKI-03791-01		39 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Agitation; Myoclonus; Nausea; Tremor	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	7.5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Citalopram Hydrobromide			C				Not Reported
	Beclomethasone Dipropionate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2006	6143913	EXPEDITED (15-DAY)	N	OT	HQWYE934320SEP06		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Impaired Work Ability; Morbid Thoughts; Therapeutic Product Effect Decreased	Effexor Xr			S	Oral	150 Mg 3x Per 1 Day, Oral		Not Reported
	Depakote			S	Oral	500 Mg 3x Per 1 Day, Oral		Not Reported
	Lexapro			S	Oral	10 Mg 3x Per 1 Day, Oral		Not Reported
	Vistaril			S	Oral	50 Mg X 3-4 Hs, Oral		Not Reported
	Alcohol (Ethanol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2006	6141860	DIRECT	N	LT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Psychotic Disorder; Suicidal Ideation	Celexa			S		20 Mg. 1 X Day		Not Reported
	Lexapro			S		20 Mg 1 X Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2006	6144052	EXPEDITED (15-DAY)	Y	DE	2006111647		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Apnoea; Aspartate Aminotransferase Increased; Blood Creatine Increased; Blood Creatine Phosphokinase Increased; Blood Methaemoglobin Present; Blood Ph Decreased; Blood Potassium Increased; Body Temperature Increased; Carboxyhaemoglobin Increased; Cardio-Respiratory Arrest; Completed Suicide; Hypotension; Hypotonia; Loss Of Consciousness; Myoglobin Blood Increased; Ophthalmological Examination Abnormal; Overdose; Pco2 Increased; Po2 Increased; Subarachnoid Haemorrhage; Tachycardia; Urinary Retention	Pseudoephedrine Hydrochloride			S	Oral	Oral		Not Reported
	Ibuprofen (Ibuprofen)			S	Oral	Oral		Not Reported
	Acetylsalicylic Acid (Acetylsalicylic Acid)			S	Oral	Oral		Not Reported
	Paracetamol+Codeine			S	Oral	Oral		Not Reported
	Naproxen (Naproxen)			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Cyclobenzaprine Hydrochloride			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2006	6120972	EXPEDITED (15-DAY)	Y	DE	S06-USA-03239-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Parent-Child Problem	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2006	6138799	EXPEDITED (15-DAY)	N	HO	US-ABBOTT-06P-163-0344469-00		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypomania; Psychotic Disorder	Biaxin			S				Not Reported
	Escitalopram Oxalate			S	Oral		1 YR	Not Reported
	Strattera			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2006	6140794	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-06P-163-0344438-00		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Irritability; Suicidal Ideation	Lexapro			S	Oral			Not Reported
	Alavert Allergy			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2006	6144779	EXPEDITED (15-DAY)	Y	OT	S06-UKI-03829-01		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2006	6145009	EXPEDITED (15-DAY)	Y	OT	S06-USA-03739-01		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicide	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aricept			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2006	6145018	EXPEDITED (15-DAY)	Y	OT	S06-USA-03860-01		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lunesta			C				Not Reported
	Imdur			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2006	6145021	EXPEDITED (15-DAY)	Y	HO	S06-USA-03862-01		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Urinary Retention	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2006	6108952	EXPEDITED (15-DAY)	Y	HO, OT	S06-ESP-03094-01		70 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection; Immune Thrombocytopenic Purpura; Iron Deficiency Anaemia; Viral Infection	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Zolpidem Tartrate			C				Not Reported
	Paracetamol			C				Not Reported
	Lansoprazole			C				Not Reported
	Lactulose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2006	6139787	EXPEDITED (15-DAY)	Y	OT	US-GLAXOSMITHKLINE-A0621483A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Dry Mouth; Hallucination; Serotonin Syndrome	Wellbutrin Xl			S	Oral	300mg Per Day		Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2006	6145045	DIRECT	Y				56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Product Dispensing Error	Synthroid			S		Tablet		Boots
	Lexapro			S		Tablet		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2006	6146398	EXPEDITED (15-DAY)	N	OT	2006114136			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Alcohol Use; Amnesia; Feeling Abnormal; Hallucination; Ill-Defined Disorder; Malaise; Nightmare; Psychotic Disorder; Reading Disorder; Thinking Abnormal; Vomiting	Zoloft			S		100 Mg (100 Mg, 1 In 1 D)		Not Reported
	Seroquel			S		300 Mg (300 Mg, 1 In 1 D)		Not Reported
	Lexapro			S				Not Reported
	Atenolol (Atenolol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2006	6112315	EXPEDITED (15-DAY)	Y	OT	S06-SWI-03122-01		56 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Serotonin Syndrome	Cipralex	S	Oral	20 Mg Qd Po		Not Reported
	Cipralex	S	Oral	10 Mg Qd Po		Not Reported
	Remeron	S		45 Mg Qd		Not Reported
	Remeron	S		22.5 Mg Qd		Not Reported
	Lorazepam	C				Not Reported
	Trittico (Trazodone)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2006	6135468	EXPEDITED (15-DAY)	Y	OT	S06-SWI-03758-01		44 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Diarrhoea; Haematemesis; Nausea; Tachypnoea; Tremor; Visual Impairment; Vomiting	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2006	6147618	EXPEDITED (15-DAY)	Y	HO	060926-0000826			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Suicide Attempt	Tranxene T-Tab			S	Oral	Several Tablets; Po		Not Reported
	Escitalopram Oxalate			S	Oral	28 Tab; Po		Not Reported
	Trimeprazine Tartrate			S	Oral	2 Bot; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2006	5995702	EXPEDITED (15-DAY)	Y	HO	S06-ITA-00438-01		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Potassium Decreased; Blood Sodium Decreased; Contusion; Electrolyte	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Felodipine			C				Not Reported
	Irbesartan			C				Not Reported
	Propafenone Hydrochloride			C				Not Reported

Imbalance; Fall; Injury; Poverty Of Speech; Somnolence	Karvea Hct		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2006	6018999	EXPEDITED (15-DAY)	Y	OT	S06-USA-01074-01		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Attention Deficit/Hyperactivity Disorder; Diabetes Mellitus; Hyperreflexia; Hypoaesthesia; Intervertebral Disc Protrusion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Depakote			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2006	6146524	EXPEDITED (15-DAY)	Y	HO	S06-CZE-03806-01		17 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Dehydration; Depression; Disease Recurrence; Galactorrhoea; Insomnia; Nausea	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	7.5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2006	6149021	EXPEDITED (15-DAY)	Y	DE, HO, LT, OT	29643		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrioventricular Block Complete; Blood Creatine Phosphokinase Increased; Blood Potassium Decreased; Blood Pressure Decreased;	Flecainide Acetate			S	Oral	6 Gm (6 Gm, Once) Oral		Not Reported
	Escitalopram Oxalate			S	Oral	1 In 1 Day(S) Oral		Not Reported

Blood Sodium Increased; Body Temperature Increased; Bundle Branch Block Right; C-Reactive Protein Increased; Cardiogenic Shock; Drug Level Above Therapeutic; Electrocardiogram Qrs Complex Prolonged; Extrasystoles; Genital Discharge; Incorrect Dose Administered; Intentional Product Misuse; Loss Of Consciousness; Malaise; Nausea; Phlebectomy; Suicide Attempt; Tendon Rupture; Ventricular Tachycardia; Vertigo; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2006	6089036	EXPEDITED (15-DAY)	Y	HO	S06-FRA-02612-01		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emphysema; Gas Poisoning; Intentional Overdose; Intentional Self-Injury; Interstitial Lung Disease; Pleural Effusion; Suicide Attempt	Escitalopram Oxalate			S	Oral	25 Tablet Once Po		Not Reported
	Escitalopram Oxalate			S	Oral	1.5 Units Qd Po		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Mopral (Omeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2006	6148180	DIRECT	N	HO, RI			14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Colitis Ulcerative;	Lexapro			S				Not Reported

Diarrhoea; Mental Disorder; Rectal Haemorrhage; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2006	6149020	DIRECT	N	OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Paraesthesia	Lexapro			S	Oral	10 Mg 1x Daily Po	3 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2006	6151587	DIRECT	Y	DE			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Asphyxia; Cardio-Respiratory Arrest; Petechiae; Pulse Absent; Pupil Fixed; Skin Discolouration	Lexapro			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2006	6045946	EXPEDITED (15-DAY)	Y	HO	S06-SWI-01568-01		44 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Hepatocellular Injury	Cipralex			S	Oral	30 Mg Qd Po		Not Reported
	Remeron			S				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Codipront			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2006	6126345	EXPEDITED (15-DAY)	Y	DE	S06-USA-03298-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Level Increased; Overdose	Lexapro	S				Not Reported
	Kadian	S	Oral	60 Mg Qd Po		Not Reported
	Valium	S				Not Reported
	Amitriptyline	S				Not Reported
	Oxycontin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2006	6150507	DIRECT	N	DS, HO, LT, OT			10 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Attention-Seeking Behaviour; Coma; Post-Traumatic Stress Disorder; Suicidal Ideation; Suicide Attempt	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2006	6150516	EXPEDITED (15-DAY)	Y	OT	S06-USA-04017-01		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Legal Problem	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2006	6151360	EXPEDITED (15-DAY)	Y	DE	S06-CZE-04218-01		63 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2006	6151685	EXPEDITED (15-DAY)	Y	HO	S06-FRA-04153-01		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Hyponatraemia	Escitalopram Oxalate		S	Oral	15 Mg Qd Po	Not Reported
	Tenstaten (Cicletanine)		C			Not Reported
	Vastarel		C			Not Reported
	Propranolol		C			Not Reported
	Noctran		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2006	6152592	EXPEDITED (15-DAY)	Y	OT	S06-USA-04122-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence; Mitral Valve Prolapse; Ventricular Extrasystoles; Ventricular Hypertrophy	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported
	Celebrex			C				Not Reported
	Non-Steroidal Anti-Inflammatories (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2006	6152615	EXPEDITED (15-DAY)	N	HO, RI	S06-USA-03903-01		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Aggression; Disorientation; Irritability; Nightmare; Ovarian Cancer	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			S				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2006	6152642	EXPEDITED (15-DAY)	Y	DS	2006-148501-NL		38 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Libido Decreased	Mirtazapine			S	Oral	7.5 Mg Oral	24 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Oral	24 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2006	6057724	EXPEDITED (15-DAY)	Y	OT	S06-UKI-01969-01		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Raynaud'S Phenomenon	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2006	6142672	EXPEDITED (15-DAY)	Y	HO	S06-FRA-03794-01		93 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura Non-Thrombocytopenic	Escitalopram Oxalate			S	Subcutaneous	1 Unk Bid Sc		Not Reported
	Sotalol Hydrochloride			S				Not Reported
	Calciparine			S				Not Reported
	Atarax			C				Not Reported
	Eupantol			C				Not Reported
	Inexium (Esomeprazole)			C				Not Reported
	Clinomel			C				Not Reported
	Sucralfate			C				Not Reported
	Tianeptine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2006	6152855	EXPEDITED (15-DAY)	Y	DE	2006000584		29 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Arrest	Methadone Hydrochloride			S	Oral	Oral		Not Reported
	Alprazolam			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6032139	EXPEDITED (15-DAY)	Y	DS, OT	S06-FRA-01327-01		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Epidermal Necrosis; Photosensitivity Reaction; Sunburn	Escitalopram Oxalate		S	Oral	10 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6148816	EXPEDITED (15-DAY)	Y	OT	S06-FRA-03944-01		70 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Extrasystoles; Nervous System Disorder	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220431	NON-EXPEDITED	N	OT	S05-USA-04328-01		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression; Suicidal Ideation	Lexapro			S				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220434	NON-EXPEDITED	Y	OT	S05-USA-04305-01		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Toprol Xl			C				Not Reported
	Avalide			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220435	NON-EXPEDITED	N	OT	S05-USA-04306-01		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypertension	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Lexapro	S	Oral	5 Mg Qd Po		Not Reported
	Effexor	C				Not Reported
	Altace	C				Not Reported
	Klonopin	C				Not Reported
	Hydrochlorothiazide	C				Not Reported
	Zyprexa	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220437	NON-EXPEDITED	Y	OT	S05-USA-04253-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Bactrim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220471	NON-EXPEDITED	Y	OT	S05-USA-04254-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220473	NON-EXPEDITED	Y	LT	S05-USA-04213-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Dyspepsia; Rash; Urticaria	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Pepcid			S				Not Reported
	Tylenol (Paracetamol)			S				Not Reported
	Motrin			S				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220498	NON-EXPEDITED	Y	OT	S05-USA-04192-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy; Tachycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S	Oral	150 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220499	NON-EXPEDITED	Y	OT	S05-USA-04087-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220519	NON-EXPEDITED	N	OT	S05-USA-04043-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Ineffective; Hostility; Hot Flush; Hyperhidrosis; Nightmare; Somnolence; Suicidal Ideation; Tremor	Lexapro			S	Oral	40 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	30 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	20 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	30 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	20 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	10 Mg Qhs Po		Not Reported
	Lexapro			S	Oral	20 Mg Qhs Po		Not Reported
	Cymbalta			S		30 Mg Qd		Not Reported
	Cymbalta			S		60 Mg Qd		Not Reported
	Cymbalta			S		60 Mg Qd		Not Reported
	Lorazepam			C				Not Reported
	Synthroid			C				Not Reported
	Benadryl			C				Not Reported

	Flonase	C		Not Reported
	Acyclovir	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220557	NON-EXPEDITED	Y	OT	S05-USA-04022-01		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Irritability; Mania	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220566	NON-EXPEDITED	N	OT	S05-USA-04014-01		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Fatigue; Melaena; Paranoia	Lexapro			S	Oral	20 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aciphex			C				Not Reported
	Elavil			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2006	6220570	NON-EXPEDITED	Y	HO	S05-USA-01297-02		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokinesia Neonatal; Hypotonia Neonatal; Somnolence Neonatal	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Magnesium Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2006	6223941	NON-EXPEDITED			2006SP003156			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Somnolence	Lunesta	S	Oral	Oral		Not Reported
	Provigil	S	Oral	Oral		Not Reported
	Lexapro	S	Oral	Oral		Not Reported
	Vitamin B Complex	S	Oral	Oral		Not Reported
	Mobic	S	Oral	Oral		Not Reported
	Estradiol	S	Oral	Oral		Not Reported
	Clonazepam	S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2006	6234974	NON-EXPEDITED			2006SP003217			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Somnolence	Lunesta			S	Oral	Oral		Not Reported
	Provigil			S				Not Reported
	Oxycontin			S				Not Reported
	Percocet			S				Not Reported
	Lexapro			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Ginkgo			S				Not Reported
	Vitamin C			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2006	6113471	EXPEDITED (15-DAY)	Y	HO	S06-USA-03022-01		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Chloride Decreased; Blood Creatine Phosphokinase Increased; Blood Creatine Phosphokinase Mb Increased; Blood Glucose Increased; Bradycardia; Chest Pain; Epigastric Discomfort; Hiccups; Hyponatraemia; Muscle	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Diovan			C				Not Reported
	Cardura			C				Not Reported
	Lopresor			C				Not Reported

Spasms; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2006	6130227	EXPEDITED (15-DAY)	Y	OT	S06-USA-03504-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Bipolar Disorder; Dizziness; Drug Dependence; Euphoric Mood; Feeling Abnormal; Hot Flush; Influenza Like Illness; Intentional Product Misuse; Intentional Self-Injury; Irritability; Night Sweats; Pain In Extremity; Self-Medication; Skin Laceration; Suicidal Ideation; Victim Of Sexual Abuse	Lexapro			S				Not Reported
	Klonopin			C				Not Reported
	Neurontin			C				Not Reported
	Valium			C				Not Reported
	Percocet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2006	6131996	EXPEDITED (15-DAY)	Y	HO, OT	S06-USA-03509-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Below Therapeutic; Chronic Obstructive Pulmonary Disease; Decreased Appetite; Enuresis; Ischaemic Cerebral Infarction; Seizure; Somnolence; Status Epilepticus; Toxicity To Various Agents	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Dilantin			S		300 Mg		Not Reported
	Dilantin			S		200 Mg		Not Reported
	Verapamil Hydrochloride			C				Not Reported
	Zocor			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Zantac			C				Not Reported
	Tricor			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2006	6138347	EXPEDITED (15-DAY)	Y	OT	S06-USA-03607-01		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Ovarian Cancer; Recurrent Cancer	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Estrogens			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2006	6140333	EXPEDITED (15-DAY)	N	RI	S06-USA-03493-01		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hunger; Retinal Tear; Weight Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2006	6148518	EXPEDITED (15-DAY)	Y	OT	S06-FRA-03792-01		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Hallucination, Auditory; Mental Disorder; Nervous System Disorder; Suicide Attempt	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Zopiclone			S	Oral	7.5 Mg Qd Po		Not Reported
	Inexum			C				Not Reported
	Stagid (Metformin Embonate)			C				Not Reported
	Forzaar			C				Not Reported
	Amlodipine Besylate			C				Not Reported
	Bisoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2006	6157578	EXPEDITED (15-DAY)		RI	S06-USA-04252-01		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Pain	Lexapro			S				Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2006	6158868	EXPEDITED (15-DAY)	Y	LT	S06-UKI-04215-01		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Overdose; Parosmia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Paracetamol			S				Not Reported
	Paroxetine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2006	6159348	EXPEDITED (15-DAY)	N	OT	CHPA2006US09880		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Abuser	Excedrin Extra Strength		Y	S	Oral	1 Df, Qd, Oral		Not Reported
	Lexapro			S	Oral	5 Mg, Qd, Oral		Not Reported
	Pravachol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2006	6152222	DIRECT		OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Disturbance In Attention; Dizziness; Prostatic Disorder	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2006	6152772	DIRECT	Y	HO, LT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Contraindication To Medical Treatment; Depression; Diarrhoea;	Lexapro			S	Oral	10 Mg Daily Po		Not Reported
	Maxalt			S	Oral	10 Mg 1 Tab Onset + 1 Prn2 Po		Merck

Headache; Mental Disorder; Nausea; Palpitations; Suicidal Ideation	Synthroid	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2006	6153456	DIRECT	N	HO			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Ativan			S	Oral	.5mg Once Daily Orally		Not Reported
	Lexapro			S	Oral	20mg Once Daily Orally		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2006	6106066	EXPEDITED (15-DAY)	Y	OT	S05-USA-04816-02		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice Neonatal; Maternal Exposure During Pregnancy; Neonatal Disorder	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Lexapro			S				Not Reported
	Lamictal			C				Not Reported
	Magnesium			C				Not Reported
	Epidural (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2006	6161510	EXPEDITED (15-DAY)	N	DE	S06-USA-04266-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Completed Suicide; Condition Aggravated; Depressed Mood; Gun Shot Wound; Hostility; Suicidal Ideation	Lexapro			S	Oral	10 Mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	5885527	EXPEDITED (15-DAY)	Y	HO	T05-CAN-03319-01		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Blood Pressure Decreased; Cerebral Cyst; Electroencephalogram Abnormal; Encephalitis Japanese B; Hepato-Lenticular Degeneration; Mitochondrial Encephalomyopathy; Pineal Neoplasm; Seizure; Serum Ferritin Decreased; Somnolence; Speech Disorder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Aspirin (Acetylsalicylic Acid)			S	Oral	81 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6001830	EXPEDITED (15-DAY)	Y	OT	S06-BEL-00800-01		78 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transient Ischaemic Attack	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Cloxazolam			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Lisinopril			C				Not Reported
	Lorazepam			C				Not Reported
	Metoclopramide			C				Not Reported
	Bisoprolol			C				Not Reported
	Paracetamol			C				Not Reported
	Lactulose			C				Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6022076	EXPEDITED (15-DAY)	Y	DE	S06-BEL-01236-01		78 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Lung Infection	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Remergon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6025333	EXPEDITED (15-DAY)	Y	OT	S06-BEL-01260-01		16 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Nausea; Scratch; Skin Lesion	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Paroxetine Hydrochloride			S	Oral	20 Mg Qd Po		Not Reported
	Sedanxio (Passiflora Incarnata)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6123989	EXPEDITED (15-DAY)	Y	OT	S06-DEN-03367-01		44 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity Vasculitis	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Zyprexa			S	Oral	10 Mg Qd Po		Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6138636	EXPEDITED (15-DAY)	Y	DS, LT	S06-GER-03759-01		53 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Antidepressant Drug Level Decreased; Fall; Paranoia; Paraplegia; Psychotic Disorder; Suicide Attempt	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Ximovan (Zopiclone)			C				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6139087	EXPEDITED (15-DAY)	N		S06-USA-03637-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Maternal Exposure During Pregnancy; Panic Attack; Pregnancy; Stress	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6150817	EXPEDITED (15-DAY)	N	OT	US-BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.-2006		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer; Drug Interaction; Dysuria; Loss Of Libido; Somnolence; Urinary Retention	Flomax			S	Oral			Boehringer Ingelheim
	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Glucophage			C				Not Reported
	Benicar			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6161843	EXPEDITED (15-DAY)	Y	HO	S06-SWI-04326-01		67 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Cognitive Disorder; Condition Aggravated; Drug Interaction; Serotonin Syndrome	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Tramadol Hydrochloride			S				Not Reported
	Depakin (Valproate Sodium)			C				Not Reported
	Clonazepam			C				Not Reported
	Norvasc			C				Not Reported
	Sintrom			C				Not Reported
	Xatral Uno (Alfuzosin Hydrochloride)			C				Not Reported
	Minirim (Desmopressin Acetate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6161850	EXPEDITED (15-DAY)	N	DE	S06-USA-04303-01		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Asthenia; Completed Suicide; Disturbance In Attention; Fatigue; Flat Affect; Gun Shot Wound; Indifference; Intentional Self-Injury; Irritability; Pain; Psychomotor Hyperactivity; Weight Decreased	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lorazepam			C				Not Reported
	Remeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6162148	EXPEDITED (15-DAY)	Y	HO	S06-SWE-04335-01		35 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Antidepressant Drug Level Decreased; Seizure	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Mirtazapine			S	Oral	30 Mg Qd Po		Not Reported
	Betnoderm (Betamethasone)			C				Not Reported
	Atarax			C				Not Reported
	Emovat (Clobetasone Butyrate)			C				Not Reported
	Imovane (Zopiclone)			C				Not Reported
	Canoderm (Urea)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6162314	EXPEDITED (15-DAY)	N	DE	S06-USA-04294-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Completed Suicide; Gun Shot Wound; Head Injury; Intentional Self-Injury; Physical	Lexapro			S				Not Reported

Assault

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6162376	EXPEDITED (15-DAY)	Y	HO	L06-USA-04237-01		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fall; Fanconi Syndrome; Inappropriate Antidiuretic Hormone Secretion; Renal Tubular Disorder	Escitalopram Oxalate			S		10 Mg		Not Reported
	Mirtazapine			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Ramipril			C				Not Reported
	Donepezil Hydrochloride			C				Not Reported
	Alendronic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2006	6162380	EXPEDITED (15-DAY)	Y	OT	S06-USA-04281-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2006	6124988	EXPEDITED (15-DAY)	Y	HO	S05-USA-05038-02		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis Neonatal; Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Postmature Baby; Respiratory Disorder Neonatal; Selective Eating Disorder	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Lexapro			S		10 Mg Qd Bf		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2006	6158006	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mydriasis	Lexapro			S	Oral	10 Mg Tablet Once Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2006	6163035	EXPEDITED (15-DAY)	N	HO, OT	2006124396		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bacterial Infection; Dizziness; Dry Throat; Ear Congestion; Malaise; Middle Ear Effusion; Nausea; Panic Attack; Somnolence; Throat Irritation; Toxicity To Various Agents; Vision Blurred	Xanax			S		Unknown		Not Reported
	Zyrtec			S		Unknown (10 Mg)		Not Reported
	Unspecified Ingredient			S		Unknown		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2006	6163220	EXPEDITED (15-DAY)	Y	OT	S06-USA-04282-01		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			S	Oral	81 Mg Qd Po		Not Reported
	Other Medicaton (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2006	6163802	EXPEDITED (15-DAY)	Y	OT	S06-USA-0875-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tuberculosis	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Strattera			C				Not Reported

	Ritalin	C		Not Reported
	Imitrex (Sumatriptan)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2006	6131993	EXPEDITED (15-DAY)	Y	OT	S06-USA-03510-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2006	6164398	EXPEDITED (15-DAY)	N	DE	S06-USA-04381-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Completed Suicide; Dysphagia; Gun Shot Wound; Insomnia; Irritability; Rash; Self-Injurious Ideation; Suicidal Ideation	Lexapro			S	Oral	10 Mg Po		Not Reported
	Lexapro			S	Oral	5 Mg Po		Not Reported
	Lexapro			S	Oral	10 Mg Po		Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2006	6164407	EXPEDITED (15-DAY)	N	DE	S06-USA-04321-01		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Crying; Dizziness; Emotional Disorder; Negative Thoughts; Sleep Disorder; Toxicologic Test Abnormal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2006	6165817	EXPEDITED (15-DAY)	Y	OT	S06-AUT-04384-01		35 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Parkinsonism	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Amisulpride			S	Oral	200 Mg Daily Po		Not Reported
	Amisulpride			S	Oral	400 Mg Daily Po		Not Reported
	Amisulpride			S	Oral	800 Mg Daily Po		Not Reported
	Oxazepam			C				Not Reported
	Mirtaron 30			C				Not Reported
	Zyrtec			C				Not Reported
	Effectin (Bitolterol Mesilate)			C				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2006	6169173	EXPEDITED (15-DAY)	N	DE	S06-USA-04377-01		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Conjunctival Haemorrhage; Drug Level Increased; Mouth Haemorrhage; Petechiae; Skin Abrasion; Unevaluable Event	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2006	6146532	EXPEDITED (15-DAY)	Y	OT	S06-FRA-03801-01		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2006	6150282	EXPEDITED (15-DAY)	Y	DE	S06-FRA-03987-01		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Delirium; Euphoric Mood; Gun Shot Wound; Homicide; Major Depression; Marital Problem	Escitalopram Oxalate		S	Oral	10 Mg Qd Po	Not Reported
	Prazepam		S	Oral	40 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2006	6153983	EXPEDITED (15-DAY)	Y	HO	PHBS2006US16131		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Calcium Decreased; Blood Chloride Decreased; Blood Creatinine Decreased; Blood Osmolarity Decreased; Blood Phosphorus Decreased; Blood Sodium Decreased; Blood Urea Decreased; Blood Uric Acid Decreased; Confusional State; Creatinine Urine Increased; Drug Interaction; Fall; Glycosuria; Ph Urine Increased; Renal Tubular Disorder	Hydrochlorothiazide			S				Novartis
	Ramipril			S				Not Reported
	Donepezil Hydrochloride			S				Not Reported
	Mirtazapine			S				Not Reported
	Escitalopram Oxalate			S		10 Mg/Day		Not Reported
	Citalopram			S				Not Reported
	Alendronic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2006	6159286	EXPEDITED (15-DAY)	Y	HO	S06-FRA-04253-01		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Hypokalaemia; Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Gliclazide			S	Oral	80 Mg Qd Po		Not Reported
	Metformin Hydrochloride			S	Oral	850 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2006	6224735	NON-EXPEDITED	N	OT	2006117858		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Complex Regional Pain Syndrome; Drug Ineffective; Dry Eye; Eye Pain; Fatigue; Hand Fracture; Headache; Muscle Spasms; Myalgia; Vision Blurred	Lyrica			S		50 Mg (50 Mg 1 In 1 D)		Not Reported
	Lexapro			S		5 Mg (5 Mg, 1 In 1 D)		Not Reported
	Vicodin			C				Not Reported
	Armour Thyroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2006	6042922	EXPEDITED (15-DAY)	Y	OT	S06-USA-01505-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Valtrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2006	6167926	EXPEDITED (15-DAY)	Y	HO	S06-USA-04405-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foot Fracture; Gait Inability; Mobility Decreased; Pulmonary Embolism	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Yasmin			S				Not Reported
	Abilify			C				Not Reported
	Cabatrol (Carbamazepine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2006	6148521	EXPEDITED (15-DAY)	Y	HO	S06-FRA-03986-01		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Coronary Artery Thrombosis	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2006	6155847	EXPEDITED (15-DAY)	Y	OT	AU-BRISTOL-MYERS SQUIBB COMPANY-13556451		99 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Peripheral Ischaemia	Irbesartan			S				Bristol Myers Squibb
	Coumadin			S				Bristol Myers Squibb
	Benadryl			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Unspecified Ingredient			S				Not Reported
	Lucrin			C				Not Reported
	Norvasc			C				Not Reported
	Rocaltrol			C				Not Reported
	Xalatan			C				Not Reported
	Azopt			C				Not Reported
	Pred Forte			C				Not Reported
	Aratac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2006	6158393	EXPEDITED (15-DAY)	Y	HO	S06-USA-04170-01		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Dyazide (Triamterene/Hydrochlorothiazide)			C				Not Reported
	Inderal			C				Not Reported
	Lipitor			C				Not Reported

Plavix	C		Not Reported
Clarinex	C		Not Reported
Atenolol	C		Not Reported
Lidoderm Patch	C		Not Reported
Sonata	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2006	6165059	DIRECT	Y	RI			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cerebellar Ataxia; Confusional State; Coordination Abnormal; Depressed Level Of Consciousness; Migraine; Somnolence; Tremor	Axert			S	Oral	12.5 Bid Po		Not Reported
	Lexapro			S	Oral	15 Mg Q Day Po		Not Reported
	Climara			C				Not Reported
	Synthroid			C				Not Reported
	Vicoprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2006	6094877	EXPEDITED (15-DAY)	Y	DE	S06-IRL-02685-01		63 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis; Asphyxia; Completed Suicide; Ear Haemorrhage; Hepatic Steatosis; Hepatomegaly; Hyperhidrosis; Mediastinal Haemorrhage; Nightmare; Petechiae; Pulmonary Congestion; Pulmonary Oedema; Renal Haemorrhage; Self-Medication; Sleep Disorder; Staring	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2006	6131999	EXPEDITED (15-DAY)	Y	OT	S06-USA-03509-02		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Carbon Dioxide Decreased; Condition Aggravated; Depression; Disease Recurrence; Drug Level Above Therapeutic; Mood Swings; Nausea; Pharyngitis; Seizure; Vomiting	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Ms Contin			S	Oral	15 Mg Bid Po		Not Reported
	Zanaflex			C				Not Reported
	Duragesic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2006	6148515	EXPEDITED (15-DAY)	Y	HO	S06-FRA-03951-01			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Overdose; Parkinsonism	Escitalopram Oxalate			S	Oral	30 Mg Qd Po		Not Reported
	Zyprexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2006	6158794	EXPEDITED (15-DAY)	Y	OT	S06-USA-01943-01		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Bupropion Hydrochloride			S	Oral	200mg Twice Per Day		Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Lunesta			S	Unknown	3mg Unknown		Not Reported
	Adderall Xr			S	Unknown			Not Reported
	Uroxatral			S	Unknown	10mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2006	6081516	EXPEDITED (15-DAY)	Y	HO, LT	S06-FRA-02575-01		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

	Escitalopram Oxalate	S	Not Reported
	Fludrocortisone	C	Not Reported
	Hydrocortisone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2006	6099730	EXPEDITED (15-DAY)	Y	OT	S06-FRA-02890-01		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2006	6170311	EXPEDITED (15-DAY)	Y	HO	S06-FRA-04407-03			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Premature Baby	Escitalopram Oxalate			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Escitalopram Oxalate			S	Transplacental	5 Mg Qd Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2006	6170312	EXPEDITED (15-DAY)	Y	HO	S06-FRA-04407-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Pregnancy; Premature Baby	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2006	6168803	DIRECT	N	OT			22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Anger; Condition Aggravated; Depression; Dissociation; Drug Dependence; Drug Withdrawal Syndrome; Emotional Disorder; Memory Impairment; Mental Disorder; Mental Status Changes; Muscle Spasms; Pain; Panic Reaction; Paranoia; Social Avoidant Behaviour; Social Problem	Lexapro	S	1 Tablet Every Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2006	6093598	EXPEDITED (15-DAY)	Y	DS	S06-DEN-02851-01		32 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Diabetes Mellitus Inadequate Control; Feeling Abnormal	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Citalopram			S	Oral	20 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported
	Isophane Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2006	6144777	EXPEDITED (15-DAY)	Y	OT	S06-HRV-03932-01		43 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obesity	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Zyprexa Velotab			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2006	6161522	EXPEDITED (15-DAY)	N	HO	USA-04330-01		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blepharospasm; Legal Problem; Loss Of Consciousness; Seizure; Tremor	Lamictal		S	Oral	Glaxosmithkline
	Lexapro		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2006	6163628	EXPEDITED (15-DAY)	Y	OT	S06-IRL-04360-01		40 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Muscle Spasms; Seizure; Tremor	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Omega 3 Fish Oil			C				Not Reported
	Alprazolam			C				Not Reported
	Flurazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2006	6171526	EXPEDITED (15-DAY)	Y	LT	S06-SAF-04581-01			Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Road Traffic Accident	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2006	6171530	EXPEDITED (15-DAY)	Y	OT	S06-AUS-04520-01		24 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2006	6170076	EXPEDITED (15-DAY)	Y	OT	T06-USA-03771-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning;	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

Amnesia; Victim Of Sexual Abuse	Escitalopram Oxalate	S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg Qd Po		Not Reported
	Placebo	S	Oral	1 Tablet Qd Po		Not Reported
	Yaz	C				Not Reported
	Iron Supplement (Iron)	C				Not Reported
	Pseudoephedrine Hydrochloride	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2006	6171956	EXPEDITED (15-DAY)	Y	HO, OT	2006129875		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Above Therapeutic; Chronic Obstructive Pulmonary Disease; Condition Aggravated; Decreased Appetite; Enuresis; Platelet Count Increased; Seizure; Somnolence; Status Epilepticus; Toxicity To Various Agents	Dilantin			S		300mg Alternating With 200mg (1 D)		Not Reported
	Lexapro			S	Oral	20 Mg (1 D), Oral		Not Reported
	Verapamil Hydrochloride			C				Not Reported
	Zocor			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Zantac			C				Not Reported
	Tricor			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2006	6170581	EXPEDITED (15-DAY)	N	OT	US-MERCK-0611USA01366			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Insomnia; Language Disorder	Zocor			S	Oral			Merck
	Pepcid Ac			S	Oral			Not Reported
	Nexium			S	Unknown			Not Reported
	Toprol Xl			S	Unknown			Not Reported
	Ambien			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Dyazide			S	Unknown			Not Reported

	Iron	S	Unknown		Not Reported
	Calcium	S	Unknown		Not Reported
	Vitamins	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2006	6171587	DIRECT	N	LT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Self-Injurious Ideation; Suicidal Ideation	Lexapro			S		1/2 Tab. X 6 Days Then 1 Tab After		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2006	6083811	EXPEDITED (15-DAY)	Y	HO, OT	S06-USA-02448-01		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contusion; Epistaxis; Fall; Generalised Tonic-Clonic Seizure; Head Injury; Loss Of Consciousness; Postictal State	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2006	6093113	EXPEDITED (15-DAY)	Y	OT	S06-USA-02095-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Wellbutrin Xl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2006	6164701	EXPEDITED (15-DAY)	Y	DE	US-ABBOTT-06P-163-0348893-00		75 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levothyroxine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Unspecified Ingredient			S		Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2006	6174897	EXPEDITED (15-DAY)	Y	OT	HQWYE560206NOV06		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Hypertension; Suicidal Ideation	Effexor Xr			S		150 Mg 1x Per 1 Day		Not Reported
	Lexapro			S	Oral	10 Mg 1x Per 1 Day, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2006	6175169	EXPEDITED (15-DAY)	N	OT	S06-USA-04594-01		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Dizziness; Loss Of Consciousness	Lexapro			S	Oral	20 Mg Qhs Po		Not Reported
	Inderal La			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2006	6165599	EXPEDITED (15-DAY)	Y	DE, HO	FR-ROCHE-466256		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Shock	Loxen Lp			S	Oral		1 DAY	Roche
	Loxen Lp			S	Oral			Roche
	Quinapril			S	Oral		1 DAY	Not Reported
	Quinapril			S	Oral			Not Reported
	Levothyrox			S	Oral		1 DAY	Not Reported

	Levothyrox	S	Oral			Not Reported
	Atarax	S	Oral		1 DAY	Not Reported
	Atarax	S	Oral			Not Reported
	Escitalopram Oxalate	S	Oral		1 DAY	Not Reported
	Escitalopram Oxalate	S	Oral			Not Reported
	Calcifediol	C				Not Reported
	Vitamin D3	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2006	6086176	EXPEDITED (15-DAY)	Y	DE	S06-FRA-02605-01		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cholestasis; Coagulopathy; Haemodynamic Instability; Hepatic Failure; Hepatic Pain; Hepatic Steatosis; Hepatitis; Hepatomegaly; Hypoxia; Intentional Overdose; Jaundice; Jaundice Cholestatic; Lung Disorder; Septic Shock; Somnolence; Speech Disorder; Thrombocytopenia; Vomiting	Escitalopram Oxalate			S	Oral	20 Tablet Once Po		Not Reported
	Escitalopram Oxalate			S	Oral	1 Tablet Qd Po		Not Reported
	Oxazepam			S	Oral	60 Tablet Once Po		Not Reported
	Oxazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2006	6143375	EXPEDITED (15-DAY)	Y	OT	S06-USA-03691-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2006	6173405	DIRECT		DS, HO, LT, RI, OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Glaucoma; Pruritus; Rash; Swelling Face	Lamictal			S		100 Mg		Glaxo Wellcome
	Geodon			S		40 Mg		Pfizer
	Lexapro			S		20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2006	6176529	DIRECT	N	HO			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Amnesia; Hallucination, Visual; Loss Of Consciousness	Lexapro			S		10 Mg Bid		Not Reported
	Geodon			S		40 Mg Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2006	6176722	EXPEDITED (15-DAY)	Y	OT	L06-MEX-04556-01		13 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Hypersensitivity	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2006	5886074	EXPEDITED (15-DAY)	Y	OT	S05-GER-03316-01		22 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pregnancy On Oral Contraceptive	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Ethinyl Estradiol			S	Oral	Po		Not Reported
	Levonorgestrel			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2006	6161471	EXPEDITED (15-DAY)	N	DE	S06-USA-04279-01		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Asphyxia; Completed Suicide; Condition Aggravated; Depression; Irritability; Skin Abrasion; Suicidal Ideation; Vomiting	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Clonidine			C				Not Reported
	Singulair			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2006	6167516	EXPEDITED (15-DAY)	Y	OT	US-GLAXOSMITHKLINE-A0627043A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Serotonin Syndrome	Requip			S	Oral	2mg Per Day		Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2006	6176187	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Medication Error; Medication Error; Product Dispensing Error	Lexapro			S		Tablet Vial, Multi-Dose		Forest
	Nexium			S		Capsule Vial, Multi-Dose		Astrazeneca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2006	6176314	EXPEDITED (15-DAY)	Y	DS	S06-UKI-04634-01		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Confusional State; Muscle Twitching; Tremor	Cipralex			S	Oral	20 Mg Daily Po		Not Reported
	Propranolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2006	6177927	EXPEDITED (15-DAY)	Y	HO	S06-USA-04730-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Hypoaesthesia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Azmacort			C				Not Reported
	Restoril			C				Not Reported
	Vicodin			C				Not Reported
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2006	6177984	EXPEDITED (15-DAY)	Y	HO	S06-USA-04682-01		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2006	6177988	EXPEDITED (15-DAY)	Y	DE	S06-USA-04680-01		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Serotonin Syndrome	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Elavil			S				Not Reported
	Orthonovum (Norethindrone/Ethinyl Estradiol)			C				Not Reported
	Xanax			C				Not Reported
	Skelaxin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2006	6235872	NON-EXPEDITED	Y		S06-USA-03527-01		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disturbance In Attention; Dizziness; Nail Discolouration; Nail Disorder; Nail Growth Abnormal	Namenda	S	Oral	10 Mg Bid; Po		Not Reported
	Namenda	S	Oral	5 Mg Bid; Po		Not Reported
	Namenda	S	Oral	5 Mg, Bid; Po		Not Reported
	Namenda	S	Oral	15 Mg Qd; Po		Not Reported
	Namenda	S	Oral	5 Mg, Qd; Po		Not Reported
	Lexapro	S	Oral	20 Mg Qd; Po		Not Reported
	Trazodone Hydrochloride	C				Not Reported
	Alprazolam	C				Not Reported
	Prilosec	C				Not Reported
	Singulair	C				Not Reported
	Furosemide	C				Not Reported
	Potassium	C				Not Reported
	Albuterol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2006	6151369	EXPEDITED (15-DAY)	Y	DS, HO	S06-FRA-04185-01		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Incorrect Dose Administered; Speech Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Hemidigoxine (Digoxin)			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Rabeprazole Sodium			C				Not Reported
	Motilium			C				Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2006	6162149	EXPEDITED (15-DAY)	Y	HO	S06-PRT-04356-01		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis A	Cipralex			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Cipralex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6000729	EXPEDITED (15-DAY)	Y	HO, LT	US016832		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation; Alcohol Use; Anterograde Amnesia; Burning Sensation; Cognitive Disorder; Condition Aggravated; Conversion Disorder; Delirium; Delusion; Drug Dependence; Drug Ineffective; Drug Interaction; Epilepsy; Fall; Fear; Hallucination; Incorrect Dose Administered; Injury; Insomnia; Irritability; Loss Of Consciousness; Major Depression; Nightmare; Overdose; Pain; Paranoia; Post-Traumatic Stress Disorder; Psychotic Disorder; Refusal Of Treatment By Patient; Retrograde Amnesia; Scar; Seizure; Self-Medication; Status Epilepticus; Suicidal Behaviour; Suicidal Ideation	Gabitril			S	Oral	16 Mg Up To 120-130 Mg Daily Oral		Not Reported
	Adderall			S	Oral	30 Mg Bid Oral		Not Reported
	Xanax			S		1 Q 1-2 Hours; A Few Years		Not Reported
	Neurontin			S		Up To 2400mg Daily		Not Reported
	Lexapro			S	Oral	30 Mg Bid Oral		Not Reported
	Synthroid			C				Not Reported
	Keppra			C				Not Reported
	Remeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6168906	EXPEDITED (15-DAY)	N	HO	AU-JNJFOC-20061101818			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Circulatory Collapse; Drooling; Dysphagia; Fall; Musculoskeletal Stiffness; Staring	Risperdal		S	Oral	Not Reported
	Lexapro		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6178240	DIRECT	N	LT, OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Heart Rate Increased; Nervous System Disorder; Nervousness; Panic Attack; Paraesthesia; Paranoia; Suicidal Ideation	Lexapro			S	Oral	10 Mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6178264	DIRECT	Y	LT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Megacolon	Lexapro			S	Oral	10 Mg Every Night Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6178268	DIRECT	N	RI			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Decreased; Loss Of Libido	Lexapro			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6179425	EXPEDITED (15-DAY)	Y	DE	L06-USA-04699-10		28 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest	Escitalopram Oxalate		S	Not Reported
	Amitriptyline		S	Not Reported
	Olanzapine		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6179432	EXPEDITED (15-DAY)	Y	DE	L06-USA-04699-08		35 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S				Not Reported
	Topiramate			S				Not Reported
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6180090	EXPEDITED (15-DAY)	Y	DE	L06-USA-04699-15		18 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Venlafaxine Hydrochloride			S				Not Reported
	Bupropion Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6180092	EXPEDITED (15-DAY)	Y	DE	L06-USA-04699-14		34 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Alprazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6180095	EXPEDITED (15-DAY)	Y	DE	L06-USA-04699-13		75 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide;	Escitalopram Oxalate			S				Not Reported

Intentional Overdose	Levothyroxine	S		Not Reported
	Venlafaxine Hydrochloride	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6180098	EXPEDITED (15-DAY)	Y	DE	L06-USA-04699-12		45 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S				Not Reported
	Gabapentin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6180100	EXPEDITED (15-DAY)	Y	DE	L06-USA-04699-18		35 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S				Not Reported
	Clonazepam			S				Not Reported
	Venlafaxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6180102	EXPEDITED (15-DAY)	Y	DE	L06-USA-04699-17		28 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Atropine			S				Not Reported
	Clozapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6180106	EXPEDITED (15-DAY)	Y	DE	L06-USA-04699-16		18 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Acetaminophen And Codeine Phosphate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6180690	EXPEDITED (15-DAY)	Y	DE	L06-USA-04699-09		36 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Amitriptyline			S				Not Reported
	Phenobarbital			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2006	6180692	EXPEDITED (15-DAY)	Y	DE	L06-USA-04699-11		39 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Chlorpheniramine			S				Not Reported
	Alprazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2006	6179319	DIRECT	N	DS, LT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Zoloft			S				Not Reported
	Lexapro			S				Not Reported
	Zoloft			C				Not Reported
	Lexapro			C				Not Reported
	Bispirone			C				Not Reported
	Zomig			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2006	6179409	DIRECT	Y	LT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dizziness;	Lexapro			S	Oral	10 Mg Every Night Po One		Not Reported

Megacolon

Dose Only

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2006	6180888	EXPEDITED (15-DAY)	Y	LT	S06-NOR-04853-01		36 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Asphyxia; Disturbance In Attention; Ill-Defined Disorder; Intentional Self-Injury; Paraesthesia; Sensory Disturbance; Suicide Attempt	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2006	6181522	EXPEDITED (15-DAY)	Y	DE	PAR_0949_2006		35 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Clonazepam			S	Oral	Df Po		Not Reported
	Escitalopram Oxalate			S	Oral	Df Po		Not Reported
	Venlafaxine Hydrochloride			S	Oral	Df Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2006	6182657	EXPEDITED (15-DAY)	N	DE	28027		18 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Pseudoephedrine		Y	S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2006	8086640	DIRECT	Y	HO			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Serotonin Syndrome	Lexapro	S	Oral	10 Mg Daily Po	Not Reported
	Ultracet	S	Oral	2 Tabs Q4 Prn Po	Not Reported
	Darvocet	C			Not Reported
	Zetia	C			Not Reported
	Benicar	C			Not Reported
	Amitriptyline	C			Not Reported
	Synthroid	C			Not Reported
	Combivent	C			Not Reported
	Flovent	C			Not Reported
	Clonazepam	C			Not Reported
	Nexium	C			Not Reported
	Sucralfate	C			Not Reported
	Hctz	C			Not Reported
	Topamax	C			Not Reported
	Liquid Iron	C			Not Reported
	Glucosamine	C			Not Reported
	Chondroitin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2006	6171456	EXPEDITED (15-DAY)	Y	DE	US-KINGPHARMUSA00001-K200601462		75 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levoxyl			S	Oral			King
	Escitalopram Oxalate			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2006	6265174	NON-EXPEDITED	N		TPA2006A01676		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Initial Insomnia; Libido Decreased	Rozerem			S	Oral	8 Mg, Qhs, Per Oral		Not Reported
	Lexapro			S				Not Reported
	Klonopin			C				Not Reported
	Amoxicillin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2006	6183677	EXPEDITED (15-DAY)	Y	DE	2006138308		29 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Arrest	Alprazolam (Alprazolam)			S				Not Reported
	Methadone Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2006	6183960	EXPEDITED (15-DAY)	Y	DE	2006138633		34 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2006	6184177	EXPEDITED (15-DAY)	Y	DE	2006138570		39 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents	Alprazolam (Alprazolam)			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Chlorpheniramine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2006	6186761	EXPEDITED (15-DAY)	Y	OT	2006141077			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Geodon			S				Not Reported
	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2006	6187209	EXPEDITED (15-DAY)	Y	DE	IMP_2540_2006		18 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning; Respiratory Arrest	Bupropion			S	Oral	Df Po		Not Reported
	Venlafaxine Hydrochloride			S	Oral	Df Po		Not Reported
	Escitalopram Oxalate			S	Oral	Df Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2006	6173652	EXPEDITED (15-DAY)	Y	OT	DE-GLAXOSMITHKLINE-D0051554A		64 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sopor; Suicide Attempt	Lithium Carbonate			S	Oral	6750mg Single Dose	1 DAY	Glaxosmithkline
	Amitriptyline			S	Oral	1350mg Single Dose	1 DAY	Not Reported
	Cipralex			S	Oral	140mg Single Dose	1 DAY	Not Reported
	Euthyrox			S	Oral	2.4mg Single Dose	1 DAY	Glaxosmithkline
	Flupentixol			S	Oral	100mg Single Dose	1 DAY	Not Reported
	Glimepiride			S	Oral		1 DAY	Glaxosmithkline
	Glucophage			S	Oral	10g Single Dose	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2006	6181456	DIRECT	Y	HO			< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Caesarean Section; Hypoglycaemia Neonatal; Maternal Exposure During Pregnancy; Metabolic Acidosis; Muscle Disorder; Neonatal Disorder;	Lexapro			S	Oral	30 Mg Daily Po		Forest
	Lexapro			S				Not Reported

Prolonged Labour;
Respiratory Disorder
Neonatal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2006	6185374	EXPEDITED (15-DAY)	Y	DE	AND_AAPCC_2006_0959		18 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Acetaminophen And Codeine Phosphate			S		Df Unk 047		Not Reported
	Pseudoephedrine Hydrochloride			S		Df Unk 047		Not Reported
	Escitalopram Oxalate			S		Df Unk 047		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2006	6188274	DIRECT	N	RI			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Lexapro			S		10mg	1 YR	Not Reported
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2006	6142689	EXPEDITED (15-DAY)	Y	OT	S06-FRA-03796-01		33 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Basophil Count Increased; Hepatitis; Hyperhidrosis; Lymphocyte Count Increased; Monocyte Count Increased; Platelet Count Decreased; Pyrexia; Splenomegaly; Treatment Noncompliance; White Blood Cell Count	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Atarax			C				Not Reported

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2006	6163233	EXPEDITED (15-DAY)	Y	OT	S06-USA-04250-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Decreased; Chest Discomfort; Impulsive Behaviour; Insomnia; Muscle Twitching; Musculoskeletal Pain; Myalgia; Restlessness; Supraventricular Extrasystoles; Supraventricular Tachycardia; Ventricular Extrasystoles	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Toprol Xl			S	Oral	50 Mg Unk Po		Not Reported
	Toprol Xl			S	Oral	25 Mg Unk Po		Not Reported
	Flexeril			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2006	6169032	EXPEDITED (15-DAY)	Y	HO	S06-FRA-04495-01		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prostatic Specific Antigen Increased; Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Moclamine (Moclobemide)			C				Not Reported
	Colchicine			C				Not Reported
	Tranxene T-Tab			C				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2006	6189660	EXPEDITED (15-DAY)	Y	DE	6027523		75 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Overdose	Levothyroxine Sodium		S	Oral	Oral	Not Reported
	Escitalopram Oxalate		S			Not Reported
	Venlafaxine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2006	6189673	EXPEDITED (15-DAY)	N	HO	S06-USA-04863-01		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Generalised Tonic-Clonic Seizure; Head Injury; Loss Of Consciousness; Migraine; Myoclonus; Swelling; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lamictal			C				Not Reported
	Keppra			C				Not Reported
	Yasmin (Estrogen/Progestin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2006	6190116	EXPEDITED (15-DAY)	N	DE	2006P1000493		57 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Injury; Intentional Overdose; Lung Infiltration; Myocarditis; Pneumothorax; Shock; Somnolence	Nicardipine Hydrochloride			S	Oral	900 Mg, Unk; Po		Not Reported
	Levothyroxine Sodium			S	Oral	675 Ug, Unk; Po		Not Reported
	Quinapril Hydrochloride			S	Oral	180 Mg; Unk; Po		Not Reported
	Hydroxyzine			S	Oral	225 Mg, Unk; Po		Not Reported
	Escitalopram Oxalate			S	Oral	180 Mg; Unk; Po		Not Reported
	Calcifediol			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2006	6191914	EXPEDITED (15-DAY)	Y	OT	S06-USA-04932-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Serotonin Syndrome	Lexapro			S				Not Reported

Requip		S	2 Mg Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2006	6191951	EXPEDITED (15-DAY)	N	OT	S06-USA-046862-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Decreased Appetite; Depression; Diarrhoea; Dysuria; Feeling Abnormal; Hot Flush; Hyperhidrosis; Libido Decreased; Self-Injurious Ideation; Suicidal Ideation; Tunnel Vision; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ambien			C				Not Reported
	Tenormin			C				Not Reported
	Tenex			C				Not Reported
	Benadryl			C				Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2006	6004309	EXPEDITED (15-DAY)	Y	DS, HO	S06-FRA-00803-01		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; General Physical Health Deterioration; Leukoencephalopathy; Motor Dysfunction; Speech Disorder; Syncope; Viral Infection	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Seropram (Citalopram Hydrobromide)			C				Not Reported
	Depakote			C				Not Reported
	Tropatepine Hydrochloride			C				Not Reported
	Sulfarlem (Anethole Trithione)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2006	6144098	EXPEDITED (15-DAY)	Y	DE, OT	US-PURDUE-USA_2006_0025313		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Accidental Overdose; Akathisia; Blood Gases	Oxycontin			S		Unk, Unk		Not Reported
	Cardizem			S				Not Reported
	Doxepin			S				Not Reported

Abnormal; Cardio-Respiratory Arrest; Confusional State; Depressed Level Of Consciousness; Dyskinesia; Hypoglycaemia; Muscle Twitching; Respiratory Distress; Snoring; Suicidal Ideation; Tremor; Unresponsive To Stimuli	Seroquel	S	Not Reported
	Lexapro	S	Not Reported
	Lidocaine	S	Not Reported
	Caffeine	S	Not Reported
	Insulin Nos	C	Not Reported
	Lyrica	C	Not Reported
	Ambien	C	Not Reported
	Cortef	C	Not Reported
	Allopurinol	C	Not Reported
	Protonix	C	Not Reported
	Coumadin	C	Not Reported
	Lipitor	C	Not Reported
	Depakote	C	Not Reported
	Clonidine	C	Not Reported
	Lasix	C	Not Reported
	Diovan	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2006	6175372	NON-EXPEDITED	N	OT	US-GLAXOSMITHKLINE-A0586456A		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Generalised Tonic-Clonic Seizure	Wellbutrin			S	Oral	200mg Twice Per Day	38 DAY	Glaxosmithkline
	Lexapro			S	Oral			Not Reported
	Unspecified Ingredient			C	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2006	6175911	EXPEDITED (15-DAY)		HO	US-ROXANE LABORATORIES, INC-2006-DE-06211GD		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Drug Interaction; Fall; Fanconi Syndrome Acquired; Glycosuria; Hyperphosphaturia; Hypouricaemia;	Hydrochlorothiazide			S		Maintenance Dose	3 WEEK	Roxane
	Escitalopram Oxalate			S				Not Reported
	Mirtazapine			S		Maintenance Dose		Roxane
	Ramipril			S		Maintenance Dose		Not Reported

Inappropriate Antidiuretic Hormone Secretion; Renal Tubular Disorder; Urine Electrolytes Increased	Donepezil Hydrochloride		S	Maintenance Dose	Not Reported
	Alendronic Acid		S	Maintenance Dose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2006	6181412	EXPEDITED (15-DAY)	Y	DE	S06-USA-04758-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Haemorrhage; Toxicity To Various Agents	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Hydromorphone Hydrochloride			S	Oral	8 Mg Prn Po		Not Reported
	Diphenhydramine			S				Not Reported
	Alcohol			S				Not Reported
	Promethazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2006	6192025	EXPEDITED (15-DAY)	Y	OT	S06-USA-04889-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Hemianopia Homonymous; Ischaemic Stroke; Ocular Vascular Disorder; Optic Nerve Disorder	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lipitor			C				Not Reported
	Thyroid Medication (Nos)			C				Not Reported
	Lisinopril			C				Not Reported
	Estrogen Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2006	6176794	NON-EXPEDITED	Y		S06-USA-02815-01		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Enlargement; Gynaecomastia	Wellbutrin Xl			S	Oral	300mg Per Day	2 YR	Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day	2 YR	Not Reported
	No Concurrent Medications			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2006	6176895	NON-EXPEDITED	N		BPC-XL-06-054			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Agitation; Anxiety; Crying; Hypersensitivity; Pruritus; Rash; Urticaria	Wellbutrin Xl			S	Unknown	300mg Unknown		Glaxosmithkline
	Lexapro			S	Unknown	10ml Unknown	5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2006	6176900	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0619907A		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Wellbutrin Xl			S	Oral		2 WEEK	Glaxosmithkline
	Lexapro			S			2 WEEK	Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2006	6177831	NON-EXPEDITED	N		805-USA-01707-01		10 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Drug Interaction	Amoxicillin & Clavulanate Potassium			S	Oral	600mg Twice Per Day		Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported
	Biaxin			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2006	6177844	NON-EXPEDITED	N		S06-USA-03614-01		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Headache	Augmentin			S	Unknown			Glaxosmithkline

	Lexapro	S	Oral	10mg Per Day		Not Reported
	Ativan	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2006	6198329	EXPEDITED (15-DAY)	Y	HO, LT	S06-BEL-04780-01		74 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Olmesartan			C				Not Reported
	Barnidipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2006	5766522	EXPEDITED (15-DAY)	Y	HO	T05-USA-00114-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Adnexa Uteri Mass; Back Pain; Blood Pressure Diastolic Increased; Blood Urea Increased; Bronchitis; Gingival Pain; Headache; Heart Rate Increased; Neutropenia; Normochromic Normocytic Anaemia; Ovarian Neoplasm; Pancytopenia; Pelvic Pain; Pruritus; Rectal Haemorrhage; Therapy Non-Responder; Uterine Enlargement	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Multi-Vitamin			C				Not Reported
	Calcium			C				Not Reported
	Peginterferon Alfa-2a			C				Not Reported
	Ribavirin			C				Not Reported
	Doxycycline			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported
	Generic Sleep Aid			C				Not Reported
	Ibuprofen			C				Not Reported
	Pepto-Bismol			C				Not Reported
	Tylenol Pm			C				Not Reported
	Otc Anti-Nausea Liquid			C				Not Reported
	Otc Antacid			C				Not Reported
	Advil			C				Not Reported
	Lortab			C				Not Reported
	Ultram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2006	5766548	EXPEDITED (15-DAY)	Y		T05-USA-00911-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adnexa Uteri Pain; Anaemia; Anal Fissure; Back Injury; Back Pain; Feeling Abnormal; Fungal Infection; Genital Rash; Intervertebral Disc Degeneration; Lymphocyte Count Decreased; Muscle Spasms; Neutrophil Count Decreased; Platelet Count Decreased; Rectal Haemorrhage; Thrombosis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Phenergan			C				Not Reported
	Multivitamins			C				Not Reported
	Calcium			C				Not Reported
	Peginterferon Alfa-2a			C				Not Reported
	Ribavirin			C				Not Reported
	Ibuprofen			C				Not Reported
	Pepto-Bismol (Bismuth Subsalicylate)			C				Not Reported
	Advil			C				Not Reported
	Lortab			C				Not Reported
	Otc Antacid			C				Not Reported
	Doxycycline			C				Not Reported
	Celebrex			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Naproxen (Naproxen)			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported
	Prevacid			C				Not Reported
	Generic Sleep Aid			C				Not Reported
	Otc Anti-Nausea Liquid			C				Not Reported
	Diclofenac			C				Not Reported
	Ultram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2006	6094989	EXPEDITED (15-DAY)	Y	DE, HO	S06-USA-02769-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose; Suicidal Ideation	Lexapro			S	Oral	30 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2006	6118468	EXPEDITED (15-DAY)	Y	HO, OT	S06-GER-03150-01		84 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Cipralex			S	Oral	3 Drops Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2006	6151362	EXPEDITED (15-DAY)	Y	DE	S06-CZE-04182-01		46 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2006	6159901	EXPEDITED (15-DAY)	Y	OT	S06-SWI-04297-01		34 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Type Ii Hypersensitivity; Urticaria	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lamictal			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2006	6199729	EXPEDITED (15-DAY)	Y	OT	S06-USA-04931-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sperm Concentration Decreased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2006	6093587	EXPEDITED (15-DAY)	Y	OT	S06-GER-02854-01		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Lipomatosis; Oedema Peripheral	Escitalopram Oxalate		S	Oral	5 Mg Qd Po	Not Reported
	Escitalopram Oxalate		S	Oral	5 Mg Qd Po	Not Reported
	Citalopram		S	Oral	10 Mg Qd Po	Not Reported
	Blopress (Candesartan Cilexetil)		C			Not Reported
	Nebivolol Hydrochloride		C			Not Reported
	Ovestin (Estriol)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2006	6168089	EXPEDITED (15-DAY)	N	OT	S06-USA-04394-01		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Hallucination, Visual	Paxil			S	Oral			Glaxosmithkline
	Lexapro			S				Not Reported
	Xanax			C				Not Reported
	Neurontin			C				Not Reported
	Amitriptyline			C		10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2006	6203042	EXPEDITED (15-DAY)	Y	HO, LT	S06-UKI-03755-01		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder; Suicidal Ideation	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2006	6203070	EXPEDITED (15-DAY)	Y	OT	S06-DEN-04949-01		54 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Gingival Disorder; Hypoaesthesia; Movement Disorder; Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2006	6192192	DIRECT	Y	HO, LT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eating Disorder; Feeling Abnormal; Hallucinations, Mixed; Incorrect Dose Administered; Memory Impairment; Suicide Attempt; Weight Decreased	Lexapro			S	Oral	10 Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2006	6202858	EXPEDITED (15-DAY)	Y	HO, LT	SPV1-2006-01902		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anterograde Amnesia; Cognitive Disorder; Compulsions; Confusional State; Delirium; Depression Suicidal; Drug Dependence; Drug Ineffective; Drug Interaction; Drug Screen Positive; Fall; Incorrect Dose Administered; Injury; Intentional Overdose; Loss Of Consciousness; Major Depression; Nightmare; Pain; Post-Traumatic Stress Disorder; Psychotic Disorder; Refusal Of Treatment By Patient; Retrograde Amnesia; Scar; Status Epilepticus; Suicidal Behaviour; Suicidal Ideation; Suicide	Adderall			S	Oral	30 Mg, 2x/Day: Bid, Oral		Not Reported
	Gabitril			S	Oral	16 Mg Up To 120 30 Mg, Oral		Not Reported
	Xanax			S		1		Not Reported
	Neurontin			S		2400 Mg, 1x/Day: Qd,		Not Reported
	Lexapro			S	Oral	30 Mg, 2x/Day: Bid, Oral		Not Reported
	Synthroid			C				Not Reported
	Keppra			C				Not Reported
	Remeron			C				Not Reported

Attempt; Thinking
Abnormal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2006	6203293	EXPEDITED (15-DAY)	Y	HO	S06-FRA-05028-01		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behcet'S Syndrome; Blindness; Condition Aggravated; Dilatation Atrial; Dilatation Ventricular; Haemoglobin Decreased; Hepatitis; International Normalised Ratio Increased; Neutrophil Count Decreased; Prothrombin Time Shortened	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Mirtazapine			C				Not Reported
	Valproate Sodium			C				Not Reported
	Aredia			C				Not Reported
	Zocor			C				Not Reported
	Lorazepam			C				Not Reported
	Noctran 10			C				Not Reported
	Cyclophosphamide			C				Not Reported
	Uromitexan (Mesna)			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Ramipril			C				Not Reported
	Plavix			C				Not Reported
	Colchicine			C				Not Reported
	Prednisone			C				Not Reported
	Coumadin			C				Not Reported
	Actonel			C				Not Reported
	Sulfamethoxazole & Trimethoprim			C				Not Reported
	Speciafoldine (Folic Acid)			C				Not Reported
	Diamox Sequels			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2006	6228167	EXPEDITED (15-DAY)	Y	HO, OT	2006145694		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alcohol Use; Anterograde Amnesia; Anxiety; Blepharospasm; Burning Sensation; Cognitive Disorder; Compulsions;	Xanax			S				Not Reported
	Neurontin			S		2400 Mg		Not Reported
	Gabitril			S	Oral	Oral		Not Reported
	Adderall			S	Oral	60 Mg (30mg, 2 In 1 D), Oral		Not Reported

Confusional State; Delusion; Disturbance In Attention; Dizziness; Drug Dependence; Drug Ineffective; Drug Interaction; Drug Screen Positive; Dysarthria; Electroencephalogram Abnormal; Excessive Eye Blinking; Fall; Fear; Flashback; Hallucination; Incorrect Dose Administered; Insomnia; Irritability; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Major Depression; Nightmare; Overdose; Paranoia; Post-Traumatic Stress Disorder; Psychotic Disorder; Refusal Of Treatment By Patient; Retrograde Amnesia; Scar; Seizure; Self-Medication; Sensory Disturbance; Speech Disorder; Suicidal Ideation; Thinking Abnormal; Toxicity To Various Agents	Lexapro	S	60 Mg (30 Mg, 2 In 1 D)	Not Reported
	Synthroid	C		Not Reported
	Keppra	C		Not Reported
	Remeron	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2006	5860893	EXPEDITED (15-DAY)	Y	HO, LT, OT	2005075333		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Cardio-Respiratory Arrest; Dyskinesia; Extrapyramidal Disorder; Fall; Obstructive Airways	Geodon			S	Oral	60 Mg (20 Mg, 3 In 1 D), Oral		Not Reported
	Lexapro			S				Not Reported

Disorder; Swollen Tongue

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2006	6093591	EXPEDITED (15-DAY)	Y		S06-USA-02720-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect; Caesarean Section; Cardiac Failure Congestive; Maternal Exposure During Pregnancy; Neonatal Disorder; Pregnancy; Trisomy 21	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prenatal Vitamin (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2006	6182768	EXPEDITED (15-DAY)	Y	DE	2006UW27263		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression	Seroquel			S	Oral			Zeneca
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2006	6205084	EXPEDITED (15-DAY)	Y	OT	S06-BEL-05062-01		75 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Diabetes Mellitus; Disease Recurrence; Weight Increased	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Depakene			C				Not Reported
	Lambipol (Lamotrigine)			C				Not Reported
	Amarylle (Glimepiride)			C				Not Reported
	Sertraline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2006	6205086	EXPEDITED (15-DAY)	Y	DS, OT	S06-CAN-05056-01		60 YR	Female	ALB

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Diarrhoea; Dizziness; Dysphagia; Headache; Nausea; Pharyngeal Oedema; Pruritus	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Bid Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Flovent			C				Not Reported
	Spiriva			C				Not Reported
	Breba (Salbutamol W/Ipratropium)			C				Not Reported
	Altace			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2006	6205128	EXPEDITED (15-DAY)	N	CA, HO	S06-USA-02720-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect; Caesarean Section; Cardiac Failure Congestive; Maternal Exposure During Pregnancy	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Prenatal Vitamin (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2006	6202419	DIRECT					47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Administration Error; Medication Error; Product Dispensing Error	Lexapro			S		Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2006	6203067	EXPEDITED (15-DAY)	Y	HO, LT	S06-ESP-04950-01		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Seizure	Cipralex	S	Oral	15 Mg Qd Po	Not Reported
	Depakine (Valproate Sodium)	S	Oral	1000 Mg Qd Po	Not Reported
	Omeprazole	C			Not Reported
	Aldactone	C			Not Reported
	Digoxin	C			Not Reported
	Enalapril	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2006	6203068	DIRECT	N	HO, LT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicidal Behaviour; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	40mg 1 X Per Day Orally		Forest
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2006	6203346	DIRECT	N				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Dispensing Error; Medication Error	Lipitor			S		Tablet		Pfizer
	Lexapro			S		Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2006	6205032	EXPEDITED (15-DAY)	Y	OT	S06-CAN-05119-01			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anhidrosis; Anuria; Arthralgia; Decreased Appetite; Depersonalisation/Dereali sation Disorder; Diarrhoea; Dizziness; Dry Mouth; Electric Shock; Hypertension; Insomnia;	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

Mydriasis; Nausea;
Nightmare; Palpitations;
Suicidal Ideation; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2006	6206375	EXPEDITED (15-DAY)	Y	HO	2006S1011034		10 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Atrioventricular Block First Degree; Chest Pain; Diarrhoea; Disorientation; Dizziness; Drug Interaction; Hyperhidrosis; Hypophagia; Hypotension; Hypothyroidism; Pallor; Palpitations; Rhythm Idioventricular; Toxicity To Various Agents; Ventricular Extrasystoles; Ventricular Tachycardia; Vomiting; White Blood Cell Count Increased	Levothyroxine Sodium			S	Oral	50 Ug; Qd; Po		Not Reported
	Lexapro			S	Oral	10 Mg; Qd; Po		Not Reported
	Lithium			S	Oral	1200 Mg; Bid; Po		Not Reported
	Clonidine			S	Oral	0.4 Mg; Bid; Po		Not Reported
	Methylphenidate Hydrochloride			S	Oral	36 Mg; Qd; Po		Not Reported
	Oxcarbazepine			S	Oral	600 Mg; Qd; Po		Not Reported
	Depakote			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2006	6206610	EXPEDITED (15-DAY)	Y	OT	S06-CAN-05120-01		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depersonalisation/Dereali sation Disorder; Euphoric Mood; Panic Reaction	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Celexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2006	6276770	NON-EXPEDITED	Y	RI	E3810-00075-SPO-US		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Tubulointerstitial Nephritis	Aciphex	S	Oral Oral	Oral Oral		Not Reported
	Lotrel	S				Not Reported
	Lexapro	S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Hydrochlorothiazide (Hydrochlorothiazide)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2006	7466173	EXPEDITED (15-DAY)	N	HO	FR-GLAXOSMITHKLINE-B0449038A		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Blood Lactic Acid Increased; Cardiac Aneurysm; Coordination Abnormal; Extrapyramidal Disorder; Facial Paralysis; Gait Inability; Hypertriglyceridaemia; Hypotension; Loss Of Consciousness; Malaise; Neurogenic Bladder; Sensory Loss	Telzir			S	Oral	700mg Twice Per Day		Glaxosmithkline
	Kivexa			S	Oral	1unit Per Day		Glaxosmithkline
	Norvir			S	Oral	100mg Twice Per Day		Unknown
	Escitalopram Oxalate			S	Oral	15mg Per Day		Unknown
	Cyamemazine			S	Oral	10mg Three Times Per Day		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2006	6139061	EXPEDITED (15-DAY)	Y	HO, LT	S06-USA-03634-01		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Lethargy; Medication Error; Nausea; Renal Failure	Lexapro			S	Oral	140 Mg Once Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Hydrochlorothiazide			C				Not Reported
	Atenolol			C				Not Reported

Accupril	C		Not Reported
Amitriptyline	C		Not Reported
Lisinopril	C		Not Reported
Prilosec	C		Not Reported
Norco (Hydrocodone/Acetaminophen)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2006	6173538	EXPEDITED (15-DAY)	Y	HO	AU-ROCHE-450410		64 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection	Peginterferon Alfa-2a			S	Subcutaneous			Roche
	Ribavirin			S	Oral			Roche
	Rabeprazole Sodium			S	Unknown	Drug Taken For Eleven Years.		Not Reported
	Lexapro			S	Unknown			Not Reported
	Indapamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2006	6206916	EXPEDITED (15-DAY)	Y	DE	S06-USA-05105-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2006	6207815	EXPEDITED (15-DAY)	Y	HO, LT	231633K06USA		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Focal Dyscognitive Seizures; Generalised Tonic-Clonic	Rebif			S	Subcutaneous	44 Mcg, 3 In 1 Weeks, Subcutaneous		Not Reported
	Doxepin			S		2 Dosage Forms, Once, Not Reported		Not Reported

Seizure; Incorrect Dose Administered; Insomnia; Memory Impairment; Viral Infection	Lexapro		S	Oral	10 Mg, 1 In 1 Days, Oral	Not Reported
	Ambien		C			Not Reported
	Dilantin		C			Not Reported
	Depakote		C			Not Reported
	Dalmane		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2006	6281013	NON-EXPEDITED	Y	HO, RI	2004UW22593		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Priapism	Seroquel			S	Oral	400 Mg Daily Po		Not Reported
	Lexapro			S				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2006	6281281	NON-EXPEDITED	Y	HO	2004UW20277			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Seroquel			S	Oral	900 Mg Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2006	6282247	NON-EXPEDITED	Y	HO	2004UW12190		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gamma-Glutamyltransferase Increased; Rhabdomyolysis	Seroquel			S	Oral	100 Mg Bid Po		Not Reported
	Seroquel			S	Oral	100 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Neurontin			C				Not Reported
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2006	6178146	EXPEDITED (15-DAY)	Y	HO, LT, OT	ES-ABBOTT-06P-144-0351571-00		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Depakene			S	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Spironolactone			C	Oral			Not Reported
	Digoxin			C	Oral			Not Reported
	Enalapril			C	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2006	6181252	EXPEDITED (15-DAY)	Y	DE	US-ABBOTT-06P-163-0351715-00		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Haemorrhage; Toxicity To Various Agents	Hydromorphone Hydrochloride			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Diphenhydramine			S				Not Reported
	Alcohol			S				Not Reported
	Promethazine			C	Oral			Not Reported
	Promethazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2006	6206536	DIRECT	Y	LT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Seizure	Lexapro			S	Oral	5 Mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2006	6206600	EXPEDITED (15-DAY)	Y	HO	S06-UKI-05127-01		86 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram Oxalate			S				Not Reported
	Ventolin			C				Not Reported
	Symbicort			C				Not Reported
	Cozaar (Lostarn Potassium)			C				Not Reported
	Spironolactone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2006	6276740	NON-EXPEDITED	N		IND-AE-06-SAN-047		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Sanctura			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported
	Metamucil (Psullium)			C				Not Reported
	Levoxyl			C				Not Reported
	Diovan			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported
	Motrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2006	6175122	EXPEDITED (15-DAY)	Y	DS, LT	S06-FRA-04599-01		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Parasomnia; Skin Injury; Somnambulism	Escitalopram Oxalate			S		10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Trileptal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2006	6178979	EXPEDITED (15-DAY)	Y	OT	S06-HRV-04767-01		55 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obesity	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lorazepam			C				Not Reported
	Non Steroid Antirheumatic Agents (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2006	6208773	EXPEDITED (15-DAY)	Y	HO	S06-USA-05134-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Occlusion	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Caduet			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2006	6143373	EXPEDITED (15-DAY)	Y	OT	S06-USA-03737-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Anxiety; Bipolar Disorder; Decreased Appetite; Diarrhoea; Dyskinesia; Hallucination; Hallucinations, Mixed; Headache; Hyperhidrosis; Imprisonment; Insomnia; Panic Attack; Psychotic Disorder; Suicide Attempt; Vomiting	Lexapro			S				Not Reported
	Seroquel			S				Not Reported
	Zoloft			S				Not Reported
	Atenolol			C				Not Reported
	Inderal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2006	6150524	EXPEDITED (15-DAY)	N	HO	S06-USA-04039-01		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Attention Deficit/Hyperactivity Disorder; Blindness; Loss Of Consciousness; Nervousness; Restlessness; Seizure; Tremor	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2006	6211402	DIRECT	Y	HO			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Muscle Spasms; Serotonin Syndrome; Tremor	Escitalopram Oxalate			S	Oral	20mg Daily Po		Not Reported
	Nortriptyline Hydrochloride			S	Oral	10 Mg Daily Po		Not Reported
	Fentanyl			C				Not Reported
	Albuterol			C				Not Reported
	Flovent			C				Not Reported
	Birth Control Pills			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2006	6210561	DIRECT	Y	LT, RI				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Crying; Personality Change; Social Problem; Suicidal Ideation; Suicide Attempt	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2006	6212939	EXPEDITED (15-DAY)	Y	HO	S06-USA-05312-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypertension; Overdose; Suicide Attempt	Lexapro			S				Not Reported
	Lunesta			S	Oral	54 Mg Once Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2006	6213295	EXPEDITED (15-DAY)	Y	HO	S06-ISR-05260-01		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Menometrorrhagia	Escitalopram Oxalate			S		10 Mg Qd		Not Reported
	Cinnarizine			C				Not Reported
	Propoxyphene (Propoxyphene)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2006	5925014	EXPEDITED (15-DAY)	Y	LT, OT	DE-ABBOTT-05P-062-0316195-00		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Cipralex			S	Oral			Not Reported
	Cipralex			S				Not Reported
	Valproate Sodium			S	Oral			Not Reported
	Olanzapine			C	Oral			Not Reported
	Amitriptyline Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2006	6201568	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20061205114		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Increased; Depression; Dizziness; Drug Interaction; Feeling Of Despair; Feelings Of Worthlessness; Hallucination, Visual; Headache; Insomnia; Mental Impairment; Nightmare; Tinnitus	Risperdal		S	Not Reported
	Risperdal		S	Not Reported
	Tegretol		C	Not Reported
	Lexapro		S	Not Reported
	Lexapro		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2006	6212898	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Oedema; Pruritus; Rash	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2006	6046615	EXPEDITED (15-DAY)	N	OT	S06-USA-01617-01		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Evista			C				Not Reported
	Actonel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2006	6055707	EXPEDITED (15-DAY)	Y	HO, OT	S06-IRL-01956-01		56 DAY	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Maternal Exposure During Pregnancy; Platelet Count Decreased	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2006	6181405	EXPEDITED (15-DAY)	N	OT	S06-USA-04772-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Intentional Overdose; Intentional Self-Injury; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Abilify			C				Not Reported
	Focalin (Dexmethylphenidate)			C				Not Reported
	Effexor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2006	6209797	EXPEDITED (15-DAY)	Y	OT	S06-CAN-05236-01		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lorazepam			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2006	6209809	EXPEDITED (15-DAY)	Y	HO	S06-FRA-05153-01		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aneurysm; Atrial Septal Defect; Coordination Abnormal; Csf Lactate Increased; Facial Paralysis; Gait Disturbance; Hypertriglyceridaemia; Hypotension; Loss Of Consciousness; Malaise; Neurogenic Bladder;	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Cyamemazine			S	Oral	10 Mg Tid Po		Not Reported
	Norvir			S	Oral	100 Mg Bid Po		Not Reported
	Telzir			S	Oral	700 Mg Bid Po		Not Reported
	Kivexa			S	Oral	1 Qd Po		Not Reported

Nuclear Magnetic Resonance Imaging Brain Abnormal; Pyramidal Tract Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2006	6213668	EXPEDITED (15-DAY)	N	OT	S06-USA-04862-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Condition Aggravated; Decreased Appetite; Depression; Diarrhoea; Dysuria; Feeling Abnormal; Hot Flush; Hyperhidrosis; Loss Of Libido; Suicidal Ideation; Tunnel Vision; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ambien			C				Not Reported
	Tenormin			C				Not Reported
	Tenex			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Guanfacine Hydrochloride			C				Not Reported
	Benadryl			C				Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2006	6213719	EXPEDITED (15-DAY)	Y	OT	S06-USA-05307-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Dilantin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2006	6213721	EXPEDITED (15-DAY)	N	HO	S06-USA-05371-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Intentional Self-Injury; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2006	6214473	DIRECT	N	HO, OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Muscle Injury; Musculoskeletal Disorder	Lexapro			S	Oral	10 Mg Daily Po	6 MTH	Not Reported
	Lexapro			S	Oral	5 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2006	6171532	EXPEDITED (15-DAY)	Y	DE	S06-CZE-04576-01		65 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2006	6182220	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-06P-056-0351864-00		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Facial Paralysis; Gait Inability; Hypotension; Loss Of Consciousness; Malaise; Neurogenic Bladder; Paraesthesia; Pyramidal Tract Syndrome	Ritonavir			S	Oral			Not Reported
	Cyamemazine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Fosamprenavir Calcium			S	Oral			Not Reported
	Abacavir\Lamivudine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2006	6188068	EXPEDITED (15-DAY)	Y	OT	S06-NOR-04910-01		33 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fatigue; Headache; Nocturia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Flutide			C				Not Reported
	Ventolin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2006	6211685	EXPEDITED (15-DAY)	Y	OT	S06-USA-05272-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Fatigue; Loss Of Consciousness; Seizure	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2006	6213649	DIRECT	N	HO, LT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt	Lexapro			S	Oral	40 Mg 1 X Per Day Orally		Not Reported
	Lorazepam Tabs			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2006	6213880	EXPEDITED (15-DAY)	Y	OT	S06-USA-05324-01		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2006	7466174	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-06P-056-0352740-00		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Brain Stem Syndrome; Cardiac Aneurysm; Coordination Abnormal; Csf Lactate Increased; Facial Paralysis; Gait Disturbance; Hypertriglyceridaemia;	Norvir			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported
	Fosamprenavir Calcium			S	Oral			Not Reported
	Kivexa			S	Oral			Not Reported
	Cyamemazine			S	Oral			Not Reported

Hypotension; Loss Of Consciousness; Malaise; Mass; Neurogenic Bladder; Pyramidal Tract Syndrome; Sensory Loss	Cyamemazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2006	6204478	EXPEDITED (15-DAY)	N	OT	US-GLAXOSMITHKLINE-A0632596A		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Below Therapeutic; Drug Ineffective; Drug Interaction; Seizure	Lamictal			S	Oral	100mg Twice Per Day		Glaxosmithkline
	Lovenox			S				Not Reported
	Folic Acid			S				Not Reported
	Synthroid			S				Glaxosmithkline
	Pentoxifylline			S				Not Reported
	Fosamax			S				Not Reported
	Lexapro			S				Not Reported
	Nexium			S				Not Reported
	Gabapentin			S				Not Reported
	Furosemide			S				Glaxosmithkline
	Trazodone Hydrochloride			S				Not Reported
	Calcium			S				Not Reported
	Aspirin			S				Glaxosmithkline
	Vitamin D Nos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2006	6214930	DIRECT	N	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Erythema; Treatment Noncompliance	Lexapro			S	Oral	10 Mg Tab Daily Oral	3 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2006	6215610	EXPEDITED (15-DAY)	Y	LT	2006-152044-NL		46 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension; Acute Hepatic Failure; Coagulopathy; Hepatomegaly; Hypotension; Oxygen Saturation Decreased; Post Procedural Complication; Somnolence; Stridor; Tachycardia; Tachypnoea	Vecuronium Bromide	S			1 DAY	Not Reported
	Amoxicillin	S				Not Reported
	Diclofenac	S	Intravenous (not otherwise specified)	Intravenous (Nos)		Not Reported
	Escitalopram Oxalate	S				Not Reported
	Fentanyl	S				Not Reported
	Glycopyrrolate	S				Not Reported
	Isoflurane	S				Not Reported
	Morphine	S				Not Reported
	Neostigmine	S				Not Reported
	Nitrous Oxide	S				Not Reported
	Ondansetron	S				Not Reported
	Oxygen	S				Not Reported
	Propofol	S				Not Reported
	Co-Dydramol	C				Not Reported
	Diazepam	C				Not Reported
	Escitalopram Oxalate	C				Not Reported
	Norethindrone Acetate	C				Not Reported
	Zolpidem	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2006	6049302	EXPEDITED (15-DAY)	Y	HO, LT	2006S1003754		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Ineffective; Focal Dyscognitive Seizures; Generalised Tonic-Clonic Seizure; Incoherent; Incorrect Dose Administered; Insomnia; Memory Impairment; Mobility Decreased; Speech Disorder; Suicidal Ideation; Viral Infection	Rebif			S		44 Ug; Tiw;		Not Reported
	Doxepin Hydrochloride			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	10 Mg; Qd; Po		Not Reported
	Ambien (Con.)			C				Not Reported
	Dilantin /00017401/ (Con.)			C				Not Reported
	Depakote (Con.)			C				Not Reported
	Dalmane (Con.)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2006	6086854	EXPEDITED (15-DAY)	Y	HO, OT	S06-AUT-02641-01		46 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Withdrawal Syndrome; Hallucination; Illusion; Major Depression; Restlessness	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Bromazepam			S		6 Mg Unk		Not Reported
	Bromazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2006	6168088	EXPEDITED (15-DAY)	Y	OT	S06-USA-04370-01		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Confusional State; Disorientation; Loss Of Consciousness; Seizure	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Effexor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2007	6213280	EXPEDITED (15-DAY)	Y	HO	T06-GER-05238-01			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicide Attempt	Cipralex			S	Oral	10 Mg Bid Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Tavor (Lorazepam)			C				Not Reported
	Doxepin			C				Not Reported
	Seroquel			C				Not Reported
	Carbamazepine			C				Not Reported
	Insulin Human			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2007	6215004	DIRECT	N	DE			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Lexapro			S	Oral	20/ Then 40 Mg Per Day Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2007	6215534	EXPEDITED (15-DAY)	Y	DE, HO	2006-151988-NL		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium Tremens; Drug Ineffective; Neuroleptic Malignant Syndrome; Nosocomial Infection; Pseudomonas Infection; Respiratory Failure	Mirtazapine			S	Oral Oral	15 Mg/30 Mg Oral 15 Mg/30 Mg Oral	19 DAY 11 DAY	Not Reported
	Escitalopram Oxalate			S	Oral Oral	10 Mg/20 Mg Oral 10 Mg/20 Mg Oral	19 DAY 11 DAY	Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2007	6216906	DIRECT	Y	HO			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Mental Status Changes; Oesophagitis	Zelapar			S	Oral	1.25mg Daily Oral		Not Reported
	Lexapro			S	Oral	10mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2007	6294461	NON-EXPEDITED	Y	HO	A03200605028			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Pyrexia	Demerol			S				Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2007	6205027	EXPEDITED (15-DAY)	Y	OT	S06-FRA-05124-01		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gingivitis Ulcerative	Escitalopram Oxalate	S	Oral	10 Mg Qd Po		Not Reported
	Magnesium	C				Not Reported
	Prazepam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2007	6212949	EXPEDITED (15-DAY)	Y	HO	T06-GER-05321-01		53 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Metformin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2007	6217291	EXPEDITED (15-DAY)	Y	OT	S06-FRA-05416-01		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Guttate Psoriasis	Escitalopram Oxalate			S				Not Reported
	Depakote			S				Not Reported
	Mianserin Hydrochloride			S				Not Reported
	Imovane (Zopiclone)			S				Not Reported
	Beta Lactamase Inhibitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2007	6217292	EXPEDITED (15-DAY)	Y	OT	S06-DEN-05428-01		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Intentional Self-Injury; Nightmare; Skin Laceration; Sleep Disorder; Thinking Abnormal	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2007	6217294	EXPEDITED (15-DAY)	Y	OT	S06-IRL-05461-01		58 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Pravastatin			C				Not Reported
	Ideos			C				Not Reported
	Stilnoct (Zolpidem Tartrate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2007	6218351	EXPEDITED (15-DAY)	Y	OT	S06-IRL-05457-01		31 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2007	6122906	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20060900698		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Interaction; Drug Withdrawal Syndrome; Nightmare; Panic Attack	Ultram Er			S	Oral			Not Reported
	Ultram Er			S	Oral			Not Reported
	Voltaren			C				Not Reported
	Nasonex			C				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2007	6143635	EXPEDITED (15-DAY)		OT	2006UW18327		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anxiety; Bipolar Disorder; Decreased Appetite; Diarrhoea; Dyskinesia; Hallucination; Headache; Hyperhidrosis; Loss Of Consciousness; Mental	Seroquel			S	Oral		17 MTH	Zeneca
	Lexapro			S	Oral		3 MTH	Not Reported
	Lexapro			S	Oral		15 MTH	Not Reported
	Zoloft			S			17 MTH	Not Reported
	Strattera			S				Not Reported

Impairment; Panic Attack; Suicide Attempt; Vomiting	Atenolol	C		Not Reported
	Inderal	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2007	6175121	EXPEDITED (15-DAY)	Y	OT	S06-GER-04602-01			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased	Escitalopram Oxalate			S		20 Mg Qd		Not Reported
	Seroquel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2007	6180886	EXPEDITED (15-DAY)	Y	OT	S06-CAN-04850-01		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree; Dizziness; Hypoaesthesia; Loss Of Consciousness; Peripheral Coldness	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2007	6209453	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2006118689		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bipolar Disorder; Decreased Appetite; Diarrhoea; Dyskinesia; Hallucination; Headache; Hyperhidrosis; Insomnia; Mental Impairment; Panic Attack; Suicide Attempt; Vomiting	Zoloft			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Seroquel			S				Not Reported
	Alcohol			S				Not Reported
	Atenolol			C				Not Reported
	Inderal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2007	6209633	EXPEDITED (15-DAY)	Y	OT	FR-ABBOTT-06P-056-0354457-00		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Guttate Psoriasis	Depakote			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Mianserin Hydrochloride			S				Not Reported
	Zopiclone			S				Not Reported
	Beta Lactamase Inhibitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2007	6220294	DIRECT	N	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abnormal Dreams; Arthralgia; Back Pain; Balance Disorder; Burning Sensation; Chills; Choking; Corneal Infiltrates; Corneal Oedema; Derealisation; Diarrhoea; Diplopia; Dyskinesia; Ecchymosis; Eye Irritation; Fall; Flatulence; Gastrooesophageal Reflux Disease; Hallucination; Headache; Hyperhidrosis; Joint Swelling; Pain In Extremity; Palpitations; Paraesthesia; Pruritus Generalised; Purulence; Raynaud'S Phenomenon; Restless Legs Syndrome; Skin Ulcer; Vision Blurred; Visual Impairment	Lexapro			S		10 Mg 1 Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2007	6152626	EXPEDITED (15-DAY)	Y	HO	S06-USA-04137-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Major Depression; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Maxalt			S				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2007	6161840	EXPEDITED (15-DAY)	Y	HO, LT	S06-USA-04285-01		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypertension; Intentional Overdose; Respiratory Failure; Suicide Attempt; Tachycardia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Remeron			S				Not Reported
	Remeron			S				Not Reported
	Aspirin			C				Not Reported
	Toprol Xl			C				Not Reported
	Zetia (Ezetimibe)			C				Not Reported
	Lipitor			C				Not Reported
	Niacin			C				Not Reported
	Vicodin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2007	6213724	EXPEDITED (15-DAY)	Y	HO	S06-USA-05267-01		93 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Full Blood Count Decreased; Hypersensitivity	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Zestril			S				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2007	6215795	EXPEDITED (15-DAY)	N	HO	2006SP004205			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypertension; Overdose	Wellbutrin			S	Unknown			Glaxosmithkline

	Lunesta		S	Oral	54mg Single Dose	Not Reported
	Lexapro		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2007	6220931	EXPEDITED (15-DAY)	N	HO	S07-USA-00016-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Drug Ineffective; Mood Swings; Overdose; Self-Injurious Ideation; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2007	6140339	EXPEDITED (15-DAY)	Y	HO	S05-USA-04861-02		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acoustic Stimulation Tests Abnormal; Bradycardia Neonatal; Caesarean Section; Developmental Delay; Maternal Condition Affecting Foetus; Maternal Exposure During Pregnancy; Premature Baby; Premature Rupture Of Membranes	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Prenatabs Fa			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2007	6140342	EXPEDITED (15-DAY)	Y	HO	S05-USA-04861-01		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acoustic Stimulation Tests Abnormal; Bradycardia Neonatal; Caesarean Section; Dizziness;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prenatal Vitamin (Nos)			C				Not Reported

Feeling Abnormal; Infection; Maternal Exposure During Pregnancy; Paraesthesia; Pregnancy; Premature Baby; Premature Rupture Of Membranes

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2007	6211461	EXPEDITED (15-DAY)		HO	PHEH2007US00502		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Trileptal			S		Unk, Once/Single		Novartis
	Lexapro			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2007	6211898	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-13223219		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Restlessness; Weight Increased	Abilify			S			1 YR	Not Reported
	Lexapro			S				Not Reported
	Tegretol			C				Not Reported
	Lorazepam			C				Not Reported
	Relafen			C				Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2007	6212288	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-13370382		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia; Communication Disorder; Depression; Drug Interaction; Lethargy;	Abilify			S	Oral	Duration Of Therapy: 1.5 To 2 Years		Not Reported
	Lexapro			S	Oral			Not Reported

Somnolence	Keppra	S	Oral		Not Reported
	Carbatrol	C			Not Reported
	Vitamins	C			Not Reported
	Tegretol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2007	6212657	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-13503735		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Cogentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2007	6212743	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-13534342		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Extrapyramidal Disorder	Abilify			S			4 YR	Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2007	6221337	EXPEDITED (15-DAY)	N	HO	S07-USA-00061-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Bipolar Disorder; Drug Interaction; Incorrect Dose Administered; Product Prescribing Error; Psychotic Disorder	Lexapro			S				Not Reported
	Biaxin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2007	6222346	EXPEDITED (15-DAY)	Y	OT	S06-UKI-04786-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2007	6213678	EXPEDITED (15-DAY)	Y	HO	FR-MERCK-0701FRA00012		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyponatraemia	Hyzaar			S	Oral			Merck
	Althiazide\Spironolactone			S	Oral			Not Reported
	Carbamazepine			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Celiprolol Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2007	6224728	EXPEDITED (15-DAY)	Y	OT	S07-UKI-00039-01		67 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Feeling Abnormal; Malaise; Myalgia; Tremor	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported
	Kalms			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2007	5657242	EXPEDITED (15-DAY)	Y	DS, OT	S04-USA-06735-01		9 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Affective Disorder; Anxiety; Bipolar Disorder; Chorea; Condition Aggravated; Diarrhoea; Electroencephalogram Abnormal; Enuresis; Libido Increased; Seizure; Self-Injurious Ideation; Sexual Dysfunction; Suicidal Ideation; Suicide Attempt	Lexapro	S	Oral	5 Mg Qd Po	Not Reported
	Seroquel	C			Not Reported
	Lithium	C			Not Reported
	Zyprexa	C			Not Reported
	Tenex (Guanfacine Hdyrochloride)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2007	6062210	EXPEDITED (15-DAY)	Y	HO	S06-USA-01914-01		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Lexapro			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2007	6222626	DIRECT		OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Erythema; Infusion Related Reaction; Paraesthesia; Pruritus; Urticaria	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2007	6224231	EXPEDITED (15-DAY)	Y	OT	S07-USA-00081-01		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Below Therapeutic; Disease Recurrence; Drug Interaction; Seizure	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lamictal			S		100 Mg Bid		Not Reported
	Lovenox			S				Not Reported

	Synthroid	S	Not Reported
	Pentoxifylline	S	Not Reported
	Fosamax	S	Not Reported
	Nexium (Esomeprazole)	S	Not Reported
	Gabapentin	S	Not Reported
	Furosemide	S	Not Reported
	Trazodone Hydrochloride	S	Not Reported
	Aspirin	S	Not Reported
	Calcium	S	Not Reported
	Folic Acid	S	Not Reported
	Vitamin D Nos	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2007	6224367	EXPEDITED (15-DAY)	Y	DE	S07-USA-00118-01		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Carbon Monoxide Poisoning; Completed Suicide; Overdose	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			S				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2007	6224378	EXPEDITED (15-DAY)	Y	DE	S07-USA-00150-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported
	Venlafaxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2007	6224386	EXPEDITED (15-DAY)	Y	OT	S07-USA-00090-01		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dissociative Amnesia; Legal Problem	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2007	6289002	NON-EXPEDITED	N		2006SP004186		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Amnesia; Confusional State; Depression; Hypotrichosis	Lunesta			S	Oral	2 Mg; Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2007	6289082	NON-EXPEDITED	N		2006SP004237		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia	Lunesta			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
	Lexapro			S	Oral	Oral		Not Reported
	Ambien			C				Not Reported
	Lexapro			C				Not Reported
	Paxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2007	6290138	NON-EXPEDITED	N		2006SP003706		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Lunesta			S	Oral	Hs;Oral		Not Reported
	Lexapro			S	Oral	10 Mg;Qd;Oral		Not Reported
	Neurontin			C				Not Reported
	Xanax			C				Not Reported
	Amlodipine			C				Not Reported
	Zestril			C				Not Reported
	Multivitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2007	6292290	NON-EXPEDITED	N		2006SP003859		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Lunesta			S	Oral	3 Mg;Oral		Not Reported
	Lexapro			S	Oral	20 Mg;Qd;Oral		Not Reported
	Adderall			C				Not Reported
	Uroxatral			C				Not Reported
	Bupropion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2007	6216569	EXPEDITED (15-DAY)	Y	OT	2007UW00498		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Below Therapeutic; Drug Ineffective; Drug Interaction; Seizure	Nexium			S	Oral			Astrazeneca
	Lamictal			S	Oral			Not Reported
	Lovenox			S				Not Reported
	Folic Acid			S				Not Reported
	Synthroid			S				Not Reported
	Pentoxifylline			S				Not Reported
	Fosamax			S				Not Reported
	Lexapro			S				Not Reported
	Gabapentin			S				Not Reported
	Furosemide			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Aspirin			S				Not Reported
	Calcium			S				Not Reported
	Vitamin D2			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2007	6224234	EXPEDITED (15-DAY)	N	HO	S07-USA-00073-01		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Lexapro			S				Not Reported

Anxiety; Bipolar Ii	Lexapro	S		Not Reported
Disorder; Dizziness;	Lexapro	S		Not Reported
Feeling Abnormal;	Adderall Xr	S		Not Reported
Nausea; Overdose; Panic	Dextrostat	S		Not Reported
Attack; Paranoia;	Advil	S		Not Reported
Restlessness; Suicidal	Lamictal	C		Not Reported
Ideation	Provigil	C		Not Reported
	Wellbutrin (Bupropion Hydrochloride)	C		Not Reported
	Cymbalta	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2007	6636400	EXPEDITED (15-DAY)	N	HO	SPV1-2007-00094		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Adderall Xr			S				Not Reported
Accidental Overdose;	Dextrostat			S				Not Reported
Affect Lability; Agitation;	Unspecified Ingredient			S				Not Reported
Alcohol Use; Anger;	Lexapro			S				Not Reported
Crying; Delusion;	Effexor /01233801/(Venlafaxine)			C				Not Reported
Depressed Mood;	Zyprexa			C				Not Reported
Dizziness; Dysgeusia; Electrocardiogram Abnormal; Insomnia; Intentional Self-Injury; Irritability; Loss Of Consciousness; Nausea; Panic Attack; Paranoia; Partner Stress; Self-Injurious Ideation; Self-Medication; Skin Laceration; Substance Abuse; Suicide Attempt; Thinking Abnormal; Weight Decreased								

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2007	6161835	EXPEDITED (15-DAY)	Y	OT	S06-FRA-04270-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Myalgia	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2007	6176704	EXPEDITED (15-DAY)	Y	DS	S06-FRA-04633-01		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematospermia; Mental Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2007	6207635	EXPEDITED (15-DAY)	N	OT	PHFR2006GB03759		37 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Depression; Fatigue; Gait Disturbance; Hemiparesis; Mental Disorder; Mental Impairment; Paranoia; Partial Seizures	Tegretol			S	Unknown	800mg Mane & 800mg Nocte		Novartis
	Topamax			S		600mg Mane & 600mg Nocte		Not Reported
	Phenytoin Sodium			S		400mg/Mane		Not Reported
	Escitalopram Oxalate			S		10mg Mane		Not Reported
	Zyprexa			S		7.5mg Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2007	6216355	EXPEDITED (15-DAY)	Y	OT	S06-FRA-05391-01		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Discomfort;	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

Gamma-Glutamyltransferase Increased; Hepatitis A Antibody Positive; Pyrexia	Cyamemazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2007	6129478	EXPEDITED (15-DAY)	N	OT	S06-USA-03467-01		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Agitation; Confusional State; Depressed Mood; Pneumonia; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Sinemet			C				Not Reported
	Synthroid			C				Not Reported
	Flomax			C				Not Reported
	Proscar			C				Not Reported
	Imdur			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2007	6218708	EXPEDITED (15-DAY)	Y	DE	US-ROCHE-477722		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Completed Suicide; Hypotension; Pyrexia; Tachycardia; Unresponsive To Stimuli	Naproxen			S	Unknown			Roche
	Cyclobenzaprine Hydrochloride			S	Unknown			Not Reported
	Acetaminophen And Codeine			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Roche
	Escitalopram Oxalate			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2007	6224937	DIRECT	N	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Insomnia; Panic Attack	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2007	6225060	DIRECT	Y	HO			< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Persistent Foetal Circulation; Premature Baby	Lexapro			S	Oral	10mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2007	6552608	EXPEDITED (15-DAY)	Y	OT	US-ABBOTT-07P-163-0355702-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Below Therapeutic; Drug Ineffective; Drug Interaction; Seizure	Synthroid			S				Not Reported
	Lexapro			S				Not Reported
	Lamotrigine			S	Oral			Not Reported
	Enoxaparin Sodium			S				Not Reported
	Folic Acid			S				Not Reported
	Pentoxifylline			S				Not Reported
	Fosamax			S				Not Reported
	Nexium			S				Not Reported
	Gabapentin			S				Not Reported
	Furosemide			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Calcium			S				Not Reported

Aspirin	S		Not Reported
Ergocalciferol	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2007	6205329	EXPEDITED (15-DAY)	Y	LT, OT	PHEH2006US15365		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Interaction; Hypersomnia; Insomnia; Nausea; Oesophagitis; Productive Cough	Zelnorm			S	Oral	6 Mg, Bid	41760 MIN	Novartis
	Zelnorm			S		6 Mg, Qd		Novartis
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Cymbalta			S	Oral	30 Mg, Qd	86400 MIN	Not Reported
	Cymbalta			S		Unk, Unk		Not Reported
	Dexidrine			C		10 Mg, Qd		Not Reported
	Tegretol			C	Oral	1200 Mg, Qd		Not Reported
	Atenolol			C	Oral	25 Mg, Qd		Not Reported
	Doxycycline			C	Oral	20 Mg, Qd		Not Reported
	Lortab			C	Oral	Unk, Tid		Not Reported
	Oxycodone			C	Oral	Unk, Qd2sdo		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2007	6225698	DIRECT	N					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia	Lexapro			S		1 Tablet Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2007	6228791	EXPEDITED (15-DAY)	Y	OT	S07-GER-00294-01		61 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Hypoglycaemia	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Humalog			C				Not Reported

	Ramipril	C	Not Reported
	Stangyl (Trimipramine Maleate)	C	Not Reported
	Aspirin	C	Not Reported
	Cotrim	C	Not Reported
	Lantus	C	Not Reported
	Akineton	C	Not Reported
	Fluanxol Depot (Flupentixol Decanoate)	C	Not Reported
	Zocor	C	Not Reported
	Levothyroxine Sodium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2007	6228892	EXPEDITED (15-DAY)	N	OT	S07-USA-00149-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Physical Assault	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2007	6220532	EXPEDITED (15-DAY)	Y	OT	US-AVENTIS-200710405US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Seizure	Lovenox			S	Oral	Dose: Unk		Aventis
	Lamictal			S				Not Reported
	Folic Acid			S		Dose: Unk		Not Reported
	Thyroxine Sodium			S		Dose: Unk		Not Reported
	Pentoxifylline			S		Dose: Unk		Not Reported
	Alendronate Sodium			S		Dose: Unk		Not Reported
	Lexapro			S		Dose: Unk		Not Reported
	Nexium			S		Dose: Unk		Not Reported
	Gabapentin			S		Dose: Unk		Not Reported
	Furosemide			S		Dose: Unk		Not Reported
	Trazodone Hydrochloride			S		Dose: Unk		Not Reported
	Calcium			S		Dose: Unk		Not Reported

	Aspirin	S	Dose: Unk	Not Reported
	Vit D	S	Dose: Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2007	6221057	EXPEDITED (15-DAY)		DE	US-ROXANE LABORATORIES, INC-2007-BP-00824RO		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death	Mirtazapine			S				Roxane
	Codeine			S				Roxane
	Escitalopram Oxalate			S				Not Reported
	Fentanyl			S				Not Reported
	Hydrocodone/Apap			S				Not Reported
	Zolpidem			S				Not Reported
	Tizanidine Hydrochloride			C				Not Reported
	Lorazepam			C				Not Reported
	Depakote			C				Not Reported
	Doxepin			C				Not Reported
	Celecoxib			C				Not Reported
	Neurontin			C				Not Reported
	Zonisamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2007	6165807	EXPEDITED (15-DAY)	Y	HO	S06-AUT-04443-01		43 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Activated Partial Thromboplastin Time Abnormal; Blood Disorder; International Normalised Ratio Increased; Muscle Haemorrhage; Platelet Disorder; Pneumonia; Prothrombin Time Prolonged; White Blood Cell Count Increased	Cipralex			S	Oral	30 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Marcumar			S	Oral	1.5 Mg Unk Po		Not Reported
	Marcumar			S	Oral	2.25 Mg Unk Po		Not Reported
	Marcumar			S	Oral	1.5 Mg Unk Po		Not Reported
	Seroquel			C				Not Reported
	Alna (Tamsulosin Hydrochloride)			C				Not Reported
	Visken			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2007	6205503	EXPEDITED (15-DAY)	Y	HO	S06-SWE-05057-01		86 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Warfarin Sodium			C				Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2007	6213887	EXPEDITED (15-DAY)	N	HO	S06-USA-04369-01		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Coronary Artery Bypass; Coronary Artery Thrombosis; Erythema; Feeling Drunk; Feeling Hot; Myocardial Infarction; Nausea; Night Sweats; Peripheral Coldness; Staphylococcal Infection; Swelling; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Nitroglycerin			C				Not Reported
	Glucophage			C				Not Reported
	Insulin Nos			C				Not Reported
	Lipitor			C				Not Reported
	Hyzaar			C				Not Reported
	Prazosin			C				Not Reported
	Captopril			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Atenolol			C				Not Reported
	Ultram			C				Not Reported
	Aspirin			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2007	6227736	DIRECT	Y	OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Erythema; Hyperhidrosis; Joint Swelling; Nausea; Sunburn	Lexapro			S	Oral	10mg Daily Po		Not Reported
	Xanax			S	Oral	1mg Or Less Prn Po		Not Reported
	Birth Control Pills -Kariva-			C				Not Reported
	Zyrtec-D			C				Not Reported

Benadryl	C		Not Reported
Ibuprofen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2007	6231038	EXPEDITED (15-DAY)	Y	HO	S07-FRA-00242-01		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyponatraemia	Escitalopram Oxalate			S				Not Reported
	Aldactazine			S				Not Reported
	Tegretol			S				Not Reported
	Risperdal			S	Oral	2 Mg Bid Po		Not Reported
	Hyzaar			S				Not Reported
	Selectol (Celiprolol Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2007	6232303	EXPEDITED (15-DAY)	N	DE	S07-USA-00275-01		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Feeling Of Despair; Gun Shot Wound	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2007	6232311	EXPEDITED (15-DAY)	Y	OT	S07-USA-00264-01		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Loss Of Consciousness; Thinking Abnormal	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2007	6234716	DIRECT	N	HO			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Trazodone Hydrochloride			S	Oral	One 50mg Pill Evenings Po		Not Reported
	Lexapro			S	Oral	One 10mg Pill Mornings Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2007	6168768	EXPEDITED (15-DAY)	Y	OT	S06-USA-04431-01		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Self-Injurious Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Allegra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2007	6222786	EXPEDITED (15-DAY)	Y	HO	US-BAYER-200710177BCC		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Blood Creatinine Increased; Constipation; Decreased Appetite; Flank Pain; Haematuria; Hypertension; Nasal Congestion; Nasal Discomfort; Nausea; Nephrolithiasis; Renal Failure; Rhinorrhoea;	Aleve			S	Oral			Bayer
	Lexapro			S	Oral	Total Daily Dose: 50 Mg Unit Dose: 50 Mg	1110 DAY	Not Reported
	Excedrin			S	Oral			Not Reported
	Buspar			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

Sinus Headache; Sinusitis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2007	6229237	DIRECT	Y	HO			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Dizziness; Paraesthesia	Lexapro			S	Oral	Po		Not Reported
	Toprol Xl			C				Not Reported
	Zetia			C				Not Reported
	Allopurinol Sodium			C				Not Reported
	Benicar Hct			C				Not Reported
	Vitamins			C				Not Reported
	Asa			C				Not Reported
	Advair Diskus			C				Not Reported
	Singulair			C				Not Reported
	Albuterol			C				Not Reported
	Combivent			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2007	6229269	DIRECT	Y	HO			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash Maculo-Papular	Lexapro			S	Oral	5 Mg Po Qd		Not Reported
	Diabetes Pills			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2007	6232644	EXPEDITED (15-DAY)	Y	DE	T200601597		18 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Acetaminophen\Codeine Phosphate			S	Oral	Oral		Not Reported
	Pseudoephedrine Hydrochloride			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2007	6223677	EXPEDITED (15-DAY)	Y	HO	PHRM2007FR00519		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Fall; Hyponatraemia	Tegretol			S	Oral			Novartis
	Aldactazine			S	Oral			Not Reported
	Risperdal			S	Oral	2 Mg, Bid		Not Reported
	Hyzaar			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Celectol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2007	6203606	EXPEDITED (15-DAY)	Y	HO, LT	S06-USA-04970-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alcohol Use; Amnesia; Anxiety; Cognitive Disorder; Delirium; Drug Dependence; Drug Interaction; Drug Screen Positive; Fall; Incorrect Dose Administered; Injury; Insomnia; Irritability; Loss Of Consciousness; Major Depression; Nervous System Disorder; Nightmare; Overdose; Pain; Post-Traumatic Stress Disorder; Psychotic Disorder; Refusal Of Treatment By Patient; Scar; Seizure; Self-Medication; Status Epilepticus; Suicidal	Lexapro			S	Oral	30 Mg Bid Po		Not Reported
	Gabitril			S				Not Reported
	Adderall			S	Oral	30 Mg Bid Po		Not Reported
	Xanax			S		1 Tablet		Not Reported
	Neurontin			S				Not Reported
	Synthroid (Levothyroid Sodium)			C				Not Reported
	Keppra			C				Not Reported
	Remeron			C				Not Reported

Behaviour; Suicidal Ideation; Suicide Attempt

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2007	6212933	EXPEDITED (15-DAY)	Y	HO, OT	S06-USA-05213-01		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Decreased; Bradycardia; Cardiac Failure Congestive; Dehydration; Dialysis; Fall; Haematocrit Decreased; Haematoma; Haemoglobin Decreased; Head Injury; Hyperkalaemia; Hyperphosphataemia; Hypoglycaemia; Renal Failure; Respiratory Rate Increased; Skin Laceration; Somnolence	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Levoxyl			C				Not Reported
	Captopril			C				Not Reported
	Metoprolol			C				Not Reported
	Aspirin			C				Not Reported
	Lasix			C				Not Reported
	Potassium			C				Not Reported
	Norvasc			C				Not Reported
	Glucophage			C				Not Reported
	Glucotrol			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Colace			C				Not Reported
	Haldol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2007	6213078	EXPEDITED (15-DAY)	Y	OT	S06-USA-05213-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Renal Disorder	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2007	6216377	EXPEDITED (15-DAY)	Y	DE	S06-ESP-05375-01		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Lung Infection; Neuroleptic Malignant Syndrome; Respiratory Failure;	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

Rhabdomyolysis	Cipralex		S	Oral	5 Mg Qd Po	Not Reported
	Mirtazapine		S	Oral	30 Mg Qd Po	Not Reported
	Mirtazapine		S	Oral	15 Mg Qd Po	Not Reported
	Clorazepate Dipotassium		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2007	6225292	NON-EXPEDITED	N		S05-USA-05361-01		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Constipation; Endoscopy Abnormal; Fatigue; Nausea; Weight Decreased	Wellbutrin			S	Oral		75 DAY	Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2007	6225327	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0593706A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Wellbutrin			S	Oral			Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2007	6225587	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0622978A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Wellbutrin			S	Oral		2 YR	Glaxosmithkline
	Lexapro			S	Unknown		2 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2007	6231181	DIRECT	N	RI			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cognitive Disorder	Lexapro			S	Oral	10mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2007	6235944	EXPEDITED (15-DAY)	Y	HO	T07-GER-00282-01		63 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Madopar			C				Not Reported
	Diclo (Diclofenac Sodium)			C				Not Reported
	Dociton (Propranolol Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2007	6235971	EXPEDITED (15-DAY)	Y	DS	S07-UKI-00288-01		46 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Disturbance In Attention; Dizziness; Fatigue; Hyperhidrosis; Nausea; Overdose; Palpitations; Somnolence; Tremor	Escitalopram Oxalate			S	Oral	40 Mg Daily Po		Not Reported
	Escitalopram Oxalate			S	Oral	30 Mg Daily Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Daily Po		Not Reported
	Citalopram Hydrobromide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2007	6581099	EXPEDITED (15-DAY)	Y	HO	CHPA2007US01146		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Constipation; Decreased Appetite; Haematuria; Headache; Hypertension; Nasal Congestion;	Lexapro			S	Oral	50 Mg, Qd, Oral		Not Reported
	Excedrin Migraine		Y	S		Prn		Not Reported
	Aleve			S		Bid		Not Reported

Nausea; Nephrolithiasis; Pain; Renal Failure; Renal Impairment; Rhinorrhoea; Sinusitis; Tenderness; Ureterolithiasis	Buspar	C		Not Reported
	Trazodone Hydrochloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2007	6220412	EXPEDITED (15-DAY)	N	DE, OT	US-BAYER-200710481GDS		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Completed Suicide; Hypotension; Pyrexia; Tachycardia; Unresponsive To Stimuli	Naproxen			S	Unknown			Bayer
	Acetaminophen			S	Unknown			Not Reported
	Codeine			S				Not Reported
	Acetylsalicylic Acid		Y	S	Unknown			Bayer
	Ibuprofen			S	Unknown			Bayer
	Cyclobenzaprine Hydrochloride			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2007	6227001	EXPEDITED (15-DAY)	Y	HO	S07-FRA-00155-01		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phlebitis; Pulmonary Embolism	Escitalopram Oxalate			S	Oral	0.5 Qd Po		Not Reported
	Lexomil (Bromazepam)			S				Not Reported
	Cerazette (Desogestrel)			S	Oral	1 Qd Po		Not Reported
	Depakote			S	Oral	500 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2007	6236992	EXPEDITED (15-DAY)	N	OT	S07-USA-00443-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebrovascular Accident	Lexapro	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2007	6047953	EXPEDITED (15-DAY)	Y	HO, LT	S06-USA-01633-01		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Focal Dyscognitive Seizures; Incorrect Dose Administered; Influenza; Insomnia; Memory Impairment; Overdose; Seizure; Speech Disorder; Therapy Non-Responder	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Once Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Doxepin			S	Oral	2 Tablet Once Po		Not Reported
	Rebif			S	Subcutaneous	44 Mcg Tiw Sc		Not Reported
	Dilantin			C				Not Reported
	Ambien			C				Not Reported
	Depakote			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2007	6104401	EXPEDITED (15-DAY)	Y	HO	L06-TUR-03075-01		33 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Chloride Decreased; Blood Creatine Phosphokinase Increased; Blood Creatine Phosphokinase Mb Increased; Blood Lactate Dehydrogenase Increased; C-Reactive Protein Increased; Cerebellar Syndrome; Electroencephalogram Abnormal; Epstein-Barr Virus Antigen Positive; Hyponatraemia;	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S		10 Mg Unk		Not Reported
	Lithium			S		1200 Mg Unk		Not Reported
	Lamotrigine			C				Not Reported

Lymphocyte Percentage Decreased; Nausea; Pneumonia; Red Blood Cell Sedimentation Rate Increased; Toxicity To Various Agents; Tremor; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2007	6204361	EXPEDITED (15-DAY)	Y	LT, OT	S06-GER-05065-01		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Amitriptyline Hydrochloride			S	Oral	75 Mg Unk Po		Not Reported
	Valproate Sodium			S	Oral	1200 Mg Unk Po		Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2007	6228063	EXPEDITED (15-DAY)		HO	TR-ROXANE LABORATORIES, INC-2007-BP-01412RO		31 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Anxiety; Aspartate Aminotransferase Increased; Blood Chloride Decreased; Blood Creatine Phosphokinase Increased; Blood Creatine Phosphokinase Mb Increased; Blood Lactate Dehydrogenase Increased; Blood Sodium Decreased; C-Reactive Protein Increased; Cerebellar Syndrome; Coordination Abnormal;	Lithium Carbonate			S		1200 Mg/Day	4 MTH	Roxane
	Lamotrigine			S		300 Mg/Day	4 MTH	Not Reported
	Escitalopram Oxalate			S		10 Mg/Day	4 MTH	Not Reported

Dysarthria; Dyskinesia;
Dyspnoea; Gait
Disturbance; Nausea;
Nystagmus; Pneumonia;
Pyrexia; Tremor; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2007	6228230	EXPEDITED (15-DAY)	Y	DE, OT	US-PFIZER INC-2007006699		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Xanax			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2007	6235812	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Mental Impairment	Lexapro			S			2 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2007	6236655	DIRECT		OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Paxil			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Lexapro			S				Not Reported
	Cymbalta			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2007	6239758	EXPEDITED (15-DAY)	Y	OT	L07-IND-00341-02		65 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Hyponatraemia	Escitalopram Oxalate			S		10 Mg Qd		Not Reported

	Atenolol	C		Not Reported
	Amlodipine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2007	7226089	EXPEDITED (15-DAY)	Y	HO, OT	US-PFIZER INC-2006145694			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anterograde Amnesia; Anxiety; Confusional State; Delirium; Depression; Drug Interaction; Fall; Ill-Defined Disorder; Intentional Overdose; Irritability; Jamais Vu; Lethargy; Nervous System Disorder; Pain; Post-Traumatic Stress Disorder; Psychotic Disorder; Retrograde Amnesia; Scar; Seizure; Speech Disorder; Suicidal Ideation; Vitreous Floaters	Xanax			S		Text:Unknown		Not Reported
	Neurontin			S		Daily Dose:2400mg		Not Reported
	Lexapro			S				Not Reported
	Synthroid			C				Not Reported
	Keppra			C				Not Reported
	Remeron			C				Not Reported
	Gabitril			S	Oral	Text:Unknown		Not Reported
	Gabitril			S				Not Reported
	Adderall			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2007	5867382	EXPEDITED (15-DAY)	Y	OT	S05-USA-03944-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Effusion; Ciliary Body Disorder	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Benadryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2007	6151363	EXPEDITED (15-DAY)	Y	HO	S06-ITA-04131-01		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Caesarean Section; Disease Recurrence; Investigation Abnormal; Maternal Exposure During Pregnancy; Pregnancy; Therapeutic Product Effect Decreased	Cipralex		S	Oral	5 Mg Qd Po	Not Reported
	Cipralex		S	Oral	10 Mg Qd Po	Not Reported
	Lormetazepam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2007	6211301	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-07P-056-0354840-00		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Pulmonary Embolism; Thrombophlebitis; Weight Increased	Depakote			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Desogestrel			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2007	6223799	EXPEDITED (15-DAY)	Y	HO, OT	2006SP004474		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Metastases To Lymph Nodes; Stress; Thyroid Cancer	Lunesta			S	Oral	3 Mg; Hs; Oral		Not Reported
	Lexapro			S		10 Mg; 20 Mg 10 Mg; 20 Mg		Not Reported
	Ativan			S		0.5 Mg; Bid		Not Reported
	Asacol			C				Not Reported
	Nexium			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2007	6229139	EXPEDITED (15-DAY)	Y	OT	US-MERCK-0701USA04738		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Interaction; Seizure	Fosamax	S	Oral	Merck
	Lamictal	S	Oral	Not Reported
	Lovenox	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Synthroid	S	Unknown	Not Reported
	Pentoxifylline	S	Unknown	Not Reported
	Lexapro	S	Unknown	Not Reported
	Nexium	S	Unknown	Not Reported
	Gabapentin	S	Unknown	Not Reported
	Furosemide	S	Unknown	Not Reported
	Trazodone Hydrochloride	S	Unknown	Not Reported
	Lonazolac Calcium	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Vitamin D Nos	S	Unknown	Not Reported
	Calcium (Unspecified)	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2007	6232630	EXPEDITED (15-DAY)	Y	HO	T07-GER-00239-01		55 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Anxiety; Condition Aggravated; Depressive Symptom	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	L-Thyroxin (Levothyroxin Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2007	7385678	EXPEDITED (15-DAY)	N	HO	US-ABBOTT-07P-163-0356700-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Bipolar Disorder; Drug Interaction;	Biaxin			S				Not Reported
	Lexapro			S				Not Reported

Psychotic Disorder	Lexapro	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2007	6226235	EXPEDITED (15-DAY)	Y	OT	S07-GER-00132-01		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Generalised Tonic-Clonic Seizure	Escitalopram Oxalate			S	Oral	10 Mg Po		Not Reported
	Seroquel			S	Oral	600 Mg Po		Not Reported
	Seroquel			S	Oral	400 Mg Po		Not Reported
	Seroquel			S	Oral	500 Mg Po		Not Reported
	Levothyroxine Sodium			C				Not Reported
	Benalapril (Enalapril)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2007	6241121	EXPEDITED (15-DAY)	Y	HO	S07-USA-00476-01		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Tylenol (Paracetamol)			C				Not Reported
	Albuterol			C				Not Reported
	Clonidine			C				Not Reported
	Epogen			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Arixtra			C				Not Reported
	Lasix			C				Not Reported
	Kytril			C				Not Reported
	Insulin			C				Not Reported
	Ativan			C				Not Reported
	Reglan			C				Not Reported
	Metoprolol			C				Not Reported
	Pancrelipase			C				Not Reported
	Potassium			C				Not Reported
	Unasyn			C				Not Reported
	Fentanyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2007	6241993	EXPEDITED (15-DAY)	Y	LT	L07-LUX-00452-01		60 YR	Female	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cerebral Hypoperfusion; Condition Aggravated; Loss Of Consciousness; Respiratory Failure	Escitalopram Oxalate			S		5 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2007	5339538	NON-EXPEDITED	Y		15993		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Self Esteem Decreased; Weight Increased	Paxil Cr			S				Glaxosmithkline
	Lamictal			S	Oral			Glaxosmithkline
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2007	6231615	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0627555A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Paxil			S	Oral			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2007	6238487	DIRECT	N				28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased; Weight Loss Poor	Lexapro			S	Oral	15 Mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2007	6238819	DIRECT	Y	DE			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2007	6202341	EXPEDITED (15-DAY)	Y		S06-UKI-04995-01		22 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Aripiprazole			S				Not Reported
	Lorazepam			C				Not Reported
	Lactulose			C				Not Reported
	Valproate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2007	6242033	DIRECT	Y	DE			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Serotonin Syndrome	Fluoxetine			S		Pta Not Known Not Sure		Not Reported
	Escitalopram Oxalate			S		Pta Not Known Not Sure		Not Reported
	Tramadol Hydrochloride			S		Pta Not Known		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2007	6243819	EXPEDITED (15-DAY)	Y	HO	S07-USA-00484-01		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia; Mouth Haemorrhage; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2007	6245934	EXPEDITED (15-DAY)	Y	OT	S07-IRL-00526		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lichen Planus	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2007	6242076	DIRECT	N	LT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Irritability; Pain; Suicidal Ideation; Tremor	Lexapro			S		15 Mg Once A Day		Forest
	Lexapro			S		10 Mg Once A Day		Forest
	Wellbutrin			C				Not Reported
	Zyprexa			C				Not Reported
	Remeron			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2007	6269151	DIRECT	Y	LT, RI			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Hypoaesthesia; Hypokinesia; Injury; Intentional Self-Injury; Limb Operation; Musculoskeletal Pain; Pain; Peroneal Nerve Palsy; Suicide Attempt; Surgery	Lexapro			S	Oral	10 Milligrams Daily Po	1 WEEK	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2007	6093053	EXPEDITED (15-DAY)	Y	OT	L06-USA-02654-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Effusion; Ciliary Body Disorder; Corneal Oedema; Drug Ineffective	Lexapro			S		20 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2007	6203105	EXPEDITED (15-DAY)	Y	HO	S06-USA-04921-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Amnesia; Anxiety; Blood Pressure Increased; Chest Discomfort; Condition Aggravated; Crying; Decreased Appetite; Depressed Mood; Diarrhoea; Disturbance In Attention; Dizziness; Dysphemia; Dysuria; Fatigue; Insomnia; Malaise; Memory Impairment; Muscle Rigidity; Nausea; Serotonin Syndrome; Somnolence; Speech Disorder; Thinking Abnormal	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported
	Prozac			S	Oral	20 Mg Qd; Po		Not Reported
	Prozac			S	Oral	40 Mg Qd; Po		Not Reported
	Zithromax			C				Not Reported
	Depo-Provera			C				Not Reported
	Tylenol With Codeine			C				Not Reported
	Tizanidine Hydrochloride			C				Not Reported
	Women'S Multivitamin (Nos)			C				Not Reported
	Ppd Injection			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2007	6213718	EXPEDITED (15-DAY)	Y	OT	S06-USA-05334-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Headache; Loss Of Consciousness; Seizure	Lexapro		S	Oral	10 Mg Qd; Po	Not Reported
	Multi-Vitamin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2007	6234859	EXPEDITED (15-DAY)	Y	HO	NO-NOMAADVRE-RELISS-2007-3577		83 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Interaction; Thalamic Infarction	Ziprasidone			S				Not Reported
	Magnesium Oxide			C		Text:160mg-Freq:Daily		Not Reported
	Insulatard			C				Not Reported
	Simvastatin			C		Text:20mg-Freq:Daily		Not Reported
	Cipralex			S		Text:10mg-Freq:Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2007	6235946	EXPEDITED (15-DAY)	Y	HO	T07-GER-00283-01		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Cipralex			S	Oral	10 Mg Bid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2007	6234543	EXPEDITED (15-DAY)	Y	DE, RI, OT	PAR_1285_2007		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoeic Attack; Blood Methaemoglobin Present; Blood Ph Decreased; Body Temperature Increased; Completed Suicide; Hypotension; Hypotonia; Loss Of Consciousness; Pco2 Increased; Po2 Increased; Pupillary Disorder; Tachycardia; Urinary	Ibuprofen			S		Df		Not Reported
	Naproxen			S		Df		Not Reported
	Acetaminophen And Codeine			S		Df		Not Reported
	Acetylsalicylic Acid			S		Df		Not Reported
	Cyclobenzaprine			S		Df		Not Reported
	Escitalopram Oxalate			S		Df		Not Reported
	Pseudoephedrine Hydrochloride			S		Df		Not Reported
	Guaifenesin			S		Df		Not Reported

Retention

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2007	6213008	EXPEDITED (15-DAY)	Y	HO	T06-GER-05285-01		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Amitriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2007	6237344	EXPEDITED (15-DAY)		HO, OT	TR-PFIZER INC-2007009017		31 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Depressive Symptom; Drug Interaction; Pneumonia; Toxicity To Various Agents	Lamotrigine			S		Daily Dose:300mg	4 MTH	Not Reported
	Escitalopram Oxalate			S		Daily Dose:10mg		Not Reported
	Lithium			S		Daily Dose:1200mg	4 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2007	6243821	EXPEDITED (15-DAY)	Y	DE	S07-USA-00483-01		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Diarrhoea; Gun Shot Wound; Intentional Self-Injury	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
					Oral	20 Mg Qd Po		
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2007	6247106	EXPEDITED (15-DAY)	Y	OT	S07-USA-00600-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Loss Of Consciousness; Nausea; Seizure; Somnolence; Urinary Incontinence; Vomiting	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Lexapro		S	Oral	5 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2007	6250506	EXPEDITED (15-DAY)	Y	HO	S07-NOR-00603-01		83 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cerebral Infarction; Cerebrovascular Accident; Confusional State; Depression; Paranoia; Restlessness	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Ziprasidone			S	Oral	20 Mg Bid Po		Not Reported
	Simvastatin			C				Not Reported
	Insulatard Nph Human			C				Not Reported
	Albyl-Enterosolubile			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2007	6250507	EXPEDITED (15-DAY)	Y	HO	S07-FRA-00604-01		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Bones Fracture; Fall; Orthostatic Hypotension	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2007	5848296	EXPEDITED (15-DAY)	Y	OT	2005S1005862		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Lexapro			S	Oral	30 Mg; Daily; Oral		Not Reported
	Lexapro			S	Oral	15 Mg; Daily; Oral		Not Reported
	Lexapro			S	Oral	10 Mg; Daily; Oral		Not Reported
	Lexapro			S	Oral	5 Mg; Daily; Oral		Not Reported

	Clozapine		S	Oral	50 Mg; Daily; Oral	Not Reported
	Clozapine		S	Oral	See Image	Not Reported
				Oral	See Image	
	Lorazepam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2007	6247037	DIRECT	Y	HO			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Mental Status Changes; Toxicity To Various Agents	Phenytoin Sodium			S	Oral	200 Mg Tid Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2007	6251435	EXPEDITED (15-DAY)	Y	DE	2007-00632		35 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Clonazepam			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Venlafaxine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2007	6773592	EXPEDITED (15-DAY)	Y	OT	US-ABBOTT-07P-163-0357223-00		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Below Therapeutic; Drug Interaction; Overdose; Seizure	Lexapro			S	Oral			Not Reported
	Synthroid			S				Not Reported
	Lamotrigine			S	Oral			Not Reported
	Enoxaparin Sodium			S				Not Reported
	Pentoxifylline			S				Not Reported
	Alendronate Sodium			S				Not Reported
	Esomeprazole			S				Not Reported
	Gabapentin			S				Not Reported
	Furosemide			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported

Acetylsalicylic Acid	S		Not Reported
Calcium	S		Not Reported
Folic Acid	S		Not Reported
Ergocalciferol	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2007	6240129	EXPEDITED (15-DAY)	Y	OT	S06-UKI-04468-01		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Labour Complication; Maternal Exposure During Pregnancy; Pregnancy; Treatment Noncompliance	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Promazine			S	Oral	75 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2007	6244814	DIRECT	N	RI, OT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Decreased Appetite; Weight Decreased	Lexapro			S	Oral	10 Mg Once Daily Po	6 WEEK	Forest
	Diazepam			C				Not Reported
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2007	6244873	EXPEDITED (15-DAY)	N	OT	S07-USA-00475-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; General Symptom; Loss Of Consciousness; Maternal Exposure During Pregnancy; Premature Menopause; Seizure; Serotonin Syndrome	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lupron			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2007	6146538	EXPEDITED (15-DAY)	Y	OT	T06-CAN-02619-01		85 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Loss Of Consciousness	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Phenobarbital			C				Not Reported
	Altace			C				Not Reported
	Furosemide			C				Not Reported
	Lipitor			C				Not Reported
	Novasen (Acetylsalicylic Acid)			C				Not Reported
	Allopurinol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2007	6090967	EXPEDITED (15-DAY)	Y	HO, OT	CH-RB-3626-2006		93 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Fatigue; Hallucination; Insomnia; Somnolence	Buprenorphine Hydrochloride			S	Oral			Reckitt Benckiser
	Buprenorphine Hydrochloride			S	Oral			Reckitt Benckiser
	Cipralex			S	Oral			Not Reported
	Trileptal			S	Oral			Novartis
	Tramadol Hydrochloride			S	Oral			Not Reported
	Tramadol Hydrochloride			S	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Risperdal			C	Oral			Janssen
	Xatral			C	Oral			Not Reported
	Brufen			C	Unknown			Not Reported
	Surmontil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2007	6170318	EXPEDITED (15-DAY)	Y	HO	T06-GER-03572-01		44 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Blood Lactate Dehydrogenase Increased; Cardiac Disorder; Cerebral Infarction; Coronary Artery Occlusion; Hypercholesterolaemia; Hyperlipidaemia; Hypertriglyceridaemia; Myocardial Infarction; Pneumonia; Therapy Non-Responder; Total Cholesterol/Hdl Ratio Increased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Bezafibrate			S				Not Reported
	Citalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2007	6183018	EXPEDITED (15-DAY)	Y	OT	S06-CAN-04852-01		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electroencephalogram Abnormal; Overdose; Seizure	Cipralex			S	Oral	30 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2007	6241503	EXPEDITED (15-DAY)	N	HO, OT	US-PURDUE-USA_2007_0026467		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hallucination; Heart Rate Increased; Hyperhidrosis; Staphylococcal Infection	Oxycontin			S		Unk, Q12h		Not Reported
	Vicodin			S		Unk, Unk		Not Reported
	Fentanyl			S	Transdermal	Unk, Unk		Not Reported
	Ambien			S		Unk, Unk		Not Reported
	Lexapro			S		Unk, Unk		Not Reported
	Coumadin			S		Unk, Unk		Not Reported

	Darvocet-N 100	S	Unk, Unk		Not Reported
	Dilaudid	S	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2007	6214800	EXPEDITED (15-DAY)	Y	OT	S06-FRA-05365-01		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Seizure	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported
	Lamictal			C				Not Reported
	Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2007	6242429	EXPEDITED (15-DAY)	Y	HO	US-BRISTOL-MYERS SQUIBB COMPANY-12956249		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Suicidal Ideation	Aripiprazole			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2007	6245017	EXPEDITED (15-DAY)	Y	HO	S07-FRA-00238-01		46 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biliary Dilatation; Hepatitis; Lymphadenitis	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Imovane (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2007	6254867	EXPEDITED (15-DAY)	N	OT	1022556-2007-00034		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Faeces; Anxiety; Depression; Drug Interaction	Unisom Sleeptabs		Y	S		1 Tablet Dsily		Not Reported
	Lexapro			S		20 Mg Daily		Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Tylenol Simply Sleep (Diphenhydramine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2007	6171825	EXPEDITED (15-DAY)	Y	HO	2006-149661-NL		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Interaction; Electrolyte Imbalance; Fall; Inappropriate Antidiuretic Hormone Secretion	Mirtazapine			S		Maintenance Dose		Not Reported
	Escitalopram Oxalate			S		10 Mg Daily		Not Reported
	Hydrochlorothiazide			S		Maintenance Dose		Not Reported
	Ramipril			C				Not Reported
	Donepezil Hydrochloride			C				Not Reported
	Alendronic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2007	6237027	EXPEDITED (15-DAY)	Y	HO	S06-ESP-04202-01		45 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Interaction; Hyponatraemia	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Oxcarbazepine			S				Not Reported
	Antabus (Disulfiram)			C				Not Reported
	Clorazepate Dipotassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2007	6251890	EXPEDITED (15-DAY)	Y	HO	T07-GER-00629-01		43 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapy Non-Responder	Cipralex	S	Oral	10 Mg Qd Po		Not Reported
	Cipralex	S	Oral	20 Mg Qd Po		Not Reported
	Lyrica	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2007	6253185	EXPEDITED (15-DAY)	Y	OT	S07-USA-00545-01		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Back Pain; Bone Pain; Depression; Emotional Distress; Hypoaesthesia; Muscle Injury; Myopathy; Nerve Injury; Pain; Pain In Extremity; Self-Injurious Ideation	Lexapro			S	Oral	10 M G Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2007	6256678	EXPEDITED (15-DAY)	Y	OT	S07-USA-00682-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Seizure	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2007	6310472	NON-EXPEDITED	N	DE	HQWYE284115DEC06			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Effexor			S			6 DAY	Not Reported
	Lexapro			S			4 WEEK	Not Reported
	Remeron			S			5 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2007	6108920	EXPEDITED (15-DAY)	Y	HO	S06-USA-02841-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Inhibitory Drug Interaction; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Aripiprazole			S		2 Mg Qd		Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2007	6209799	EXPEDITED (15-DAY)		HO	S06-FRA-05152-01		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Blood Creatine Increased; Blood Glucose Increased; Blood Urea Increased; Diarrhoea; Faecaloma; Proteus Infection; Urinary Retention; Urinary Tract Infection	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Seropram (Citalopram Hydrobromide)			S	Oral	20 Mg Qd Po		Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Prednisone			C				Not Reported
	Naproxen Sodium			C				Not Reported
	Clonazepam			C				Not Reported
	Lansoprazole			C				Not Reported
	Tamoxifen Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2007	6253017	EXPEDITED (15-DAY)	Y	HO	S07-USA-00614-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Major Depression; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Aripiprazole			S		2 Mg Qd		Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2007	6259962	EXPEDITED (15-DAY)	N	HO, OT	L07-USA-00671-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Caesarean Section; Foetal Disorder; Haematochezia; Hypophagia; Lethargy; Lung Disorder; Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Necrotising Colitis; Neonatal Respiratory Distress Syndrome; Pneumatosis Intestinalis	Escitalopram Oxalate			S		20 Mg Qd Bf		Not Reported
	Escitalopram Oxalate			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Prenatal Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2007	6255920	DIRECT	Y	HO, OT			15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bradycardia; Depressed Level Of Consciousness; Drug Withdrawal Syndrome; Fatigue; Heart Rate Irregular; Hypersomnia; Hypotension; Mood Altered; Muscle Twitching; Personality Change; Sleep Apnoea Syndrome; Tremor; Ventricular Extrasystoles	Lexapro			S	Buccal	20 Mg Every Evening Buccal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2007	4006525	EXPEDITED (15-DAY)	N	OT	S03-USA-03330-01		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abnormal Dreams; Animal Scratch; Back Pain; Balance Disorder; Chills; Choking; Corneal Infiltrates; Corneal Oedema; Diarrhoea; Drooling; Dyskinesia; Ecchymosis; Eye Irritation; Fall; Flatulence; Gastrooesophageal Reflux Disease; Hallucination, Visual; Headache; Hyperhidrosis; Hypoaesthesia Oral; Joint Swelling; Middle Insomnia; Nausea; Neuralgia; Neurosis; Ophthalmoplegia; Pain In Extremity; Palpitations; Paraesthesia; Pruritus Generalised; Rash Vesicular; Restless Legs Syndrome; Skin Disorder; Vision Blurred; Vitreous Floaters	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Inderal			C				Not Reported
	Premarin			C				Not Reported
	Valium			C				Not Reported
	Tylenol (Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2007	6149138	EXPEDITED (15-DAY)	Y	HO	US-MERCK-0610USA09501		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Major Depression; Suicidal Ideation	Maxalt			S	Oral			Merck
	Lexapro			S	Oral		52 DAY	Not Reported

	Synthroid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2007	6216872	EXPEDITED (15-DAY)	Y	HO	US-MERCK-0701USA01266		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Major Depression; Suicidal Ideation	Maxalt			S	Unknown			Merck
	Lexapro			S	Oral		52 DAY	Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2007	6237318	EXPEDITED (15-DAY)	Y	DE	ES-BRISTOL-MYERS SQUIBB COMPANY-13673223		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Respiratory Arrest	Sinemet			S				Bristol Myers Squibb
	Neurontin			S	Oral			Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2007	6258882	EXPEDITED (15-DAY)	Y	HO	S07-FRA-00797-01		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Seizure	Escitalopram Oxalate			S	Oral	30 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2007	6258902	EXPEDITED (15-DAY)	Y	OT	S07-ESP-00816-01			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Product Dose Omission; Serotonin	Cipralex			S				Not Reported
	Unspecified Ingredient			S				Not Reported

Syndrome	Ertapenem	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2007	6262246	EXPEDITED (15-DAY)	N	OT	S07-USA-00823-01		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Loss Of Employment	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2007	6247904	NON-EXPEDITED	N		S06-USA-00217-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Interaction; Muscular Weakness; Neck Pain; Sluggishness; Somnolence	Imitrex			S				Glaxosmithkline
	Lexapro			S	Oral	40mg Per Day		Not Reported
	Celexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2007	6248630	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0599517A		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness	Lamictal			S	Oral	10mg Per Day		Glaxosmithkline
	Lexapro			S	Oral			Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2007	6248731	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0601692A		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Drug Ineffective	Lamictal			S	Oral	25mg Per Day		Glaxosmithkline

Lexapro	S	Oral	5mg Per Day	29 WEEK		Not Reported
Strattera	S	Oral	80mg Per Day			Not Reported
Zyprexa	S	Oral	2.5mg Per Day	21 DAY		Not Reported
Unspecified Ingredient	C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2007	6248794	NON-EXPEDITED	Y	OT	US-GLAXOSMITHKLINE-A0603221A		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Mania; Sleep Disorder	Lamictal			S	Oral	25mg Per Day	3 DAY	Glaxosmithkline
	Lexapro			S	Oral	10mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2007	6249372	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0617683A		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Lamictal			S	Oral	100mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day	2 YR	Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2007	6249478	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0620094A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Ill-Defined Disorder; Sensory Disturbance; Skin Reaction	Lamictal			S	Oral			Glaxosmithkline
	Wellbutrin			S	Oral			Glaxosmithkline
	Lithium			S		600mg Per Day	2 YR	Glaxosmithkline
	Lexapro			S		10mg Per Day		Not Reported
	Amiloride			S		5mg Per Day	2 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2007	6249934	NON-EXPEDITED	N		S06-USA-03747-01		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Counterfeit	Lamictal			S	Oral			Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day	4 YR	Not Reported
	No Concurrent Medications			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2007	6250934	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0628004A		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lamotrigine			S	Oral	200mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Vistaril			C	Oral	100mg Unknown		Not Reported
	Abilify			C	Oral	15mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2007	6250965	NON-EXPEDITED	N		S06-USA-04809-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Eye; Insomnia; Thirst	Lamotrigine			S	Oral		241 DAY	Glaxosmithkline
	Lexapro			S	Oral	15mg Per Day		Not Reported
	Vitamins			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2007	6142511	EXPEDITED (15-DAY)	Y	DE	S06-DEN-03800-01		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Lexapro	S	Oral	15 Mg Qd Po		Not Reported
	Alprazolam	S				Not Reported
	Alprazolam	S				Not Reported
	Mirtazapine	S		15 Mg Qd		Not Reported
	Propranolol	S		40 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2007	6235653	EXPEDITED (15-DAY)	Y	OT	S07-USA-00393-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Use; Drug Withdrawal Syndrome; Homicide; Imprisonment	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported
	Avalide			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2007	6252123	EXPEDITED (15-DAY)	Y	HO, LT	FI-ROCHE-483628		56 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Asthenia; Depressed Level Of Consciousness; Hepatic Enzyme Increased; Hypotension; Intentional Overdose; Intentional Overdose; Somnolence; Suicide Attempt; Tachycardia; Vomiting	Xeloda			S	Oral			Roche
	Xeloda			S	Oral		1 DAY	Roche
	Cipralex			S	Unknown		1 DAY	Not Reported
	Zopiclone			S	Unknown		1 DAY	Not Reported
	Herceptin			C	Intravenous (not otherwise specified)			Not Reported
	Aromasin			C				Not Reported
	Clodronate Disodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2007	6252560	EXPEDITED (15-DAY)	Y	HO	US-ABBOTT-07P-163-0360123-00		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Conversion Disorder; Crying; Mental Disorder	Depakote			S	Oral			Not Reported
	Depakote			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Lorazepam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2007	6264101	EXPEDITED (15-DAY)			2007-154951-NL		52 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Mirtazapine			S		Df		Not Reported
	Escitalopram Oxalate			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2007	6264647	DIRECT	Y	OT			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anger; Depression; Drug Interaction; Emotional Disorder; Suicidal Ideation	Nortriptyline Hydrochloride			S	Oral	25 - 50 Mg 1 @ Night Po		Danbury
	Lexapro			S				Not Reported
	Vivactil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2007	6264356	EXPEDITED (15-DAY)	Y	OT	S06-USA-03192-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Pre-Eclampsia; Pregnancy	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported
	Buspar			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2007	6264365	EXPEDITED (15-DAY)	Y	HO	S07-USA-00819-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Nasopharyngitis; Seizure; Tonic Clonic Movements	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Nyquil (Acetaminophen/Dextromethorphan/Doxylamine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2007	6245932	EXPEDITED (15-DAY)	Y	HO	S07-SWI-00551-01		85 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Balance Disorder; Blood Creatine Increased; Loss Of Personal Independence In Daily Activities; Sedation; Somnolence	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Risperidone			S	Oral	3 Mg Qd Po		Not Reported
	Risperidone			S	Oral	3 Mg Qd Po		Not Reported
	Risperidone			S	Oral	0.5 Mg Qd Po		Not Reported
	Risperidone			S	Oral	1 Mg Qd Po		Not Reported
	Risperidone			S	Oral	2 Mg Qd Po		Not Reported
	Risperidone			S	Oral	3 Mg Qd Po		Not Reported
	Risperidone			S	Oral	4 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2007	6263867	DIRECT	Y	OT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Heart Rate Irregular	Lexapro			S	Oral	20mg Once A Day Po		Forest
	Imitrex			S	Oral	Imitrex 50 Mg As Needed		Not Reported

Po

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2007	6264786	EXPEDITED (15-DAY)	Y	HO	S07-DEN-00968-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Drug Interaction; Muscular Weakness; Syncope	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Levonorgestrel			S	Oral	1.5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2007	6254036	EXPEDITED (15-DAY)	Y	DE	S07-ESP-00707-01		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Respiratory Failure	Cipralex			S	Oral	15 Mg Po		Not Reported
	Neurontin			S	Oral	300 Mg Po		Not Reported
	Sinemet			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2007	6265536	EXPEDITED (15-DAY)	Y	OT	S07-USA-00886-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Interaction	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Wine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2007	5734947	EXPEDITED (15-DAY)	Y	CA	S05-USA-00377-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Congenital Nose Malformation; Dysmorphism; Maternal	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

Exposure During
Pregnancy; Pregnancy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2007	6217295	EXPEDITED (15-DAY)	Y	DS	S06-SWI-05427-01		71 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Ineffective; Dry Eye; Visual Impairment	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Zocor			C				Not Reported
	Nebivolol Hydrochloride			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2007	6259094	EXPEDITED (15-DAY)	Y	DE	US-ROCHE-484932		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiopulmonary Failure	Pegasys			S	Subcutaneous			Roche
	Copegus			S	Oral			Roche
	Klonopin			S	Unknown			Roche
	Lithium			S	Unknown			Not Reported
	Topamax			S	Unknown			Not Reported
	Ambien			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2007	6268712	DIRECT	N	OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory	Lexapro			S		10mg Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2007	6269424	EXPEDITED (15-DAY)	N	OT	S07-ISR-01029-02			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Seizure	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2007	6224220	EXPEDITED (15-DAY)	Y	HO	S07-USA-00084-01		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Stress; Thyroid Cancer	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lunesta			S		3 Mg Qhs		Not Reported
	Ativan			S		0.5 Mg Bid		Not Reported
	Asacol			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2007	6242009	EXPEDITED (15-DAY)	Y	HO	S07-USA-00445-01		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Gait Inability; Haematocrit Decreased; Haemoglobin Decreased; Hypovolaemia; Inappropriate Antidiuretic Hormone Secretion; Incoherent	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Toprol Xl			C				Not Reported
	Actonel			C				Not Reported
	Cosopt (Dorzolamide/Timolol)			C				Not Reported
	Travatan			C				Not Reported
	Plavix			C				Not Reported
	Lorazepam			C				Not Reported
	Pravachol			C				Not Reported
	Centrum			C				Not Reported
	Micardis			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2007	6262350	EXPEDITED (15-DAY)	Y	OT	DE-JNJFOC-20070300852		46 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Suicide Attempt; Tachycardia	Risperdal			S	Oral			Not Reported
	Amisulpride			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2007	6274354	EXPEDITED (15-DAY)	N	DE	S07-USA-01063-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Completed Suicide; Discomfort; Emotional Distress; Gun Shot Wound; Heart Injury; Hypophagia; Pain; Psychotic Disorder	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2007	6274355	EXPEDITED (15-DAY)	Y	OT	S07-USA-01098-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiac Failure Congestive; Orthostatic Hypertension	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2007	6329398	NON-EXPEDITED	Y	OT	PHEH2006US04704		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Increased Tendency To Bruise; Platelet Count Decreased	Trileptal		S	300 Mg, Bid	Not Reported
	Lexapro		S	5 Mg, Qd, 10 Mg Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2007	6272987	DIRECT	Y	OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Lexapro			S	Oral	10mg One Daily Po		Forest
	Xanax			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2007	6276763	EXPEDITED (15-DAY)	Y	OT	S07-FRA-01085-01		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Polymyalgia Rheumatica; Transaminases Increased; Viral Infection	Seroplex			S	Oral	10 Mg Qd Po		Not Reported
	Seroplex			S	Oral	10 Mg Qd Po		Not Reported
	Seroplex			S	Oral	10 Mg Qd Po		Not Reported
	Seroplex			S	Oral	10 Mg Qd Po		Not Reported
	Prednisone			C				Not Reported
	Estradiol			C				Not Reported
	Actonel			C				Not Reported
	Inexium (Esomeprazole)			C				Not Reported
	Cacit [Calcium Carbonate]			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Meteoxane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2007	6232300	EXPEDITED (15-DAY)	Y	DE	S07-USA-00224-01		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Myocardial Infarction	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Geodon	C				Not Reported
	Lyrica	C				Not Reported
	Esgic	C				Not Reported
	Glucophage	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2007	6277236	EXPEDITED (15-DAY)	Y	HO	S07-FRA-01082-01		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Cardiac Failure	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2007	6277237	EXPEDITED (15-DAY)	Y	DE, OT	S07-FRA-01083-01		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Condition Aggravated	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2007	6214600	EXPEDITED (15-DAY)	Y	DE, OT	US-PFIZER INC-2007001346		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Cardiac Arrest; Lethargy; Somnolence	Geodon			S				Not Reported
	Geodon			S				Not Reported
	Geodon			S				Not Reported
	Geodon			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lyrica			C				Not Reported
	Esgic			C				Not Reported
	Glucophage			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2007	6265439	EXPEDITED (15-DAY)	N	HO	NL-ROCHE-481272		49 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Pulmonary Embolism	Peginterferon Alfa-2a			S	Unknown		27 DAY	Roche
	Ribavirin			S	Unknown		27 DAY	Roche
	Escitalopram Oxalate			S	Oral		29 DAY	Not Reported
	Methadone			C				Not Reported
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2007	6148520	EXPEDITED (15-DAY)	Y	OT	S06-IRL-04008-01		50 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Extrasystoles; Flushing	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Mirtazapine			S		30 Mg Qd Po		Not Reported
	Albuterol			S		100 Mcg/Kg		Not Reported
	Ventolin			S				Not Reported
	Xanax			C				Not Reported
	Alvesco (Cislesonid)			C				Not Reported
	Cefaclor			C				Not Reported
	Gyno-Pevaryl (Econazole Nitrate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2007	6280419	EXPEDITED (15-DAY)	Y	OT	S07-UKI-01198-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Memory Impairment; Paranoia; Suicidal Ideation	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2007	6280592	EXPEDITED (15-DAY)	Y	OT	S07-FRA-01180-01		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Field Defect	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Olanzapine			C				Not Reported
	Depakote			C				Not Reported
	Antivirals (Three Other)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2007	6270719	EXPEDITED (15-DAY)	Y	HO	S07-NOR-01049-01		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Decreased; Blood Magnesium Decreased; Haemoglobin Decreased; Hyponatraemia	Cipralex			S				Not Reported
	Lekovit Ca			C				Not Reported
	Selozok			C				Not Reported
	Cozaar			C				Not Reported
	Vitamin B12 Depot (Hydroxocobalamin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2007	6282773	EXPEDITED (15-DAY)	Y	DE	2007-01365		38 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Clonazepam			S				Watson
	Escitalopram Oxalate			S				Not Reported
	Acetaminophen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2007	6282849	EXPEDITED (15-DAY)	Y	HO	S07-GER-00531-01		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swelling Face	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

Alcohol (Ethanol)	S		Not Reported
Contraceptives (Nos)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2007	6282850	EXPEDITED (15-DAY)	Y	HO	S06-FRA-05459-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura; Somatic Symptom Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2007	6281589	DIRECT	Y	OT			16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Muscle Spasms	Lexapro			S	Oral	10 Mg 1 X A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2007	6282848	EXPEDITED (15-DAY)	Y	HO	S07-USA-01265-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis; Myocardial Infarction; Qrs Axis Abnormal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Percocet			C				Not Reported
	Lisinopril And Hydrochlorothiazide			C				Not Reported
	Spironolactone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2007	6283571	EXPEDITED (15-DAY)	Y	DE	2007-01396		58 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lorazepam			S				Watson
	Valproic Acid			S				Not Reported

	Escitalopram Oxalate			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2007	6283659	EXPEDITED (15-DAY)	N	OT	L07-ISR-01234-01		24 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lichenification; Pigmentation Lip	Escitalopram Oxalate			S				Not Reported
	Harmonet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2007	6283813	EXPEDITED (15-DAY)	Y	DE	2007-01411		16 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Dextroamphetamine Saccharate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2007	6265534	EXPEDITED (15-DAY)	Y	DE, HO	S07-USA-00973-01		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Completed Suicide; Diarrhoea; Dizziness; Dry Mouth; Gun Shot Wound; Head Injury; Headache; Hyperhidrosis; Insomnia; Nausea; Somnolence	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Coumadin			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2007	6267422	EXPEDITED (15-DAY)	Y	OT	T06-GER-02691-00		19 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Aggression; Agitation; Depression; Fall; Impulse-Control	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Pegasys (Peginterferon Alfa-2a)			S	Subcutaneous	180mcg Qw Sc		Not Reported

Disorder; Intentional Self-Injury	Ribavirin	C	Not Reported
	Paracetamol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2007	6280858	DIRECT	N	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism	Lexapro			S	Oral	15mg 1 Times A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2007	6281965	DIRECT	Y	RI			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Tardive Dyskinesia; Throat Irritation; Tooth Disorder	Lexapro			S	Oral	10mg 1/2 - 1 Tab Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2007	6288318	EXPEDITED (15-DAY)	Y	OT	S07-CAN-01272-01		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Joint Swelling; Oedema Peripheral; Pain; Rash Erythematous; Swelling; Thinking Abnormal	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Wellbutrin Sr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2007	6288421	EXPEDITED (15-DAY)	Y	OT	S07-CAN-01273-01		76 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Osmolarity Decreased; Confusional State; Decreased	Cipralex			S	Oral	12.5 Mg Qd; Po		Not Reported
	Atacand (Candesartan Cilexetil)			C				Not Reported
	Lorazepam			C				Not Reported

Appetite; Epistaxis; Facial Pain; Fall; Gait Disturbance; Hyponatraemia; Somnolence; Urine Flow Decreased	Simvastatin	C	Not Reported
	Sotalol Hydrochloride	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2007	6288422	EXPEDITED (15-DAY)	Y	HO	S07-USA-01250-01		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Electroencephalogram Abnormal; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2007	6244872	EXPEDITED (15-DAY)	Y	CA	S07-USA-00480-02		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect; Cardiac Malposition; Cardiac Murmur; Cardiac Ventricular Disorder; Dextrocardia; Heart Disease Congenital; Malformation Venous; Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Multiple Congenital Abnormalities; Patent Ductus Arteriosus; Pulmonary Valve Stenosis Congenital; Spleen Malformation; Unintended Pregnancy	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Prenatal Vitamin (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2007	6289038	EXPEDITED (15-DAY)	Y	DE	2007-01508		40 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Clonazepam			S				Watson
	Quetiapine Fumarate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2007	6331407	NON-EXPEDITED	Y	HO	K200600280		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia	Altace			S		5 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2007	6202807	EXPEDITED (15-DAY)	N	DE	S06-USA-05038-01		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Akathisia; Anxiety; Arthropathy; Asphyxia; Asthenia; Blood Chloride Decreased; Blood Glucose Increased; Blood Ketone Body Present; Blood Sodium Decreased; Carbon Dioxide Decreased; Cold Sweat; Completed Suicide; Drug Screen Positive; Fear; Hot Flush; Hyperhidrosis; Major Depression; Panic Attack; Poor Quality Sleep; Refusal Of	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Serzone			C				Not Reported
	Cozaar			C				Not Reported
	Humulin N			C				Not Reported
	Humalog			C				Not Reported
	Klonopin			C				Not Reported
	Ambien			C				Not Reported

Treatment By Patient; Restlessness; Suicidal Ideation; Tearfulness; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2007	6234709	EXPEDITED (15-DAY)	N	DE	S07-USA-00274-01		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis; Chest Injury; Completed Suicide; Emphysema; Gun Shot Wound; Hepatic Steatosis; Stress At Work; Weight Decreased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2007	6274910	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2007006695		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Extrapyramidal Disorder; Tardive Dyskinesia; Torticollis	Geodon			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2007	6285282	DIRECT		HO			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Nausea; Vomiting	Gemcitabine Hydrochloride			S		1520 Mg		Not Reported
	Fentanyl Patch			S		150mcg		Not Reported
	Lexapro			S		10mg		Not Reported
	Vicodin			S				Not Reported
	Ambien			C				Not Reported
	Lexapro			C				Not Reported
	Vicodin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2007	6289353	EXPEDITED (15-DAY)	Y	DE	S07-USA-01298-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2007	6289357	EXPEDITED (15-DAY)	Y	DE	S07-USA-01298-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2007	6168772	EXPEDITED (15-DAY)	N	DE	S06-USA-04490-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Asphyxia; Completed Suicide; Disturbance In Attention; Paranoia; Psychomotor Hyperactivity; Vision Blurred	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2007	6173998	EXPEDITED (15-DAY)	N	DE	S06-USA-04663-01		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Condition Aggravated; Depression; Feeling Jittery; Insomnia; Mood Swings; Paranoia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Naproxen Sodium			C				Not Reported
	Ambien			C				Not Reported
	Smz/Tmp Ds 800-160 (Sulfamethoxazole800 Mg/Trimethoprim 160 Mg)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2007	6205605	EXPEDITED (15-DAY)	N	HO, OT	US-PFIZER INC-2005170543		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Encephalopathy; Headache; Mental Status Changes; Nausea; Overdose; Seizure; Suicide Attempt; Tachycardia; Vomiting	Neurontin			S				Not Reported
	Neurontin			S				Not Reported
	Paxil			S				Not Reported
	Gabitril			S				Not Reported
	Lexapro			S				Not Reported
	Depakote			S				Not Reported
	Alprazolam			C				Not Reported
	Acetaminophen\Hydrocodone Bitartrate			C				Not Reported
	Remeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2007	6239777	EXPEDITED (15-DAY)	Y	DE, OT	ES-PFIZER INC-2007009855		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Respiratory Arrest	Neurontin			S	Oral			Not Reported
	Carbidopa And Levodopa			S		Text:200/50 Mg		Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2007	6289535	EXPEDITED (15-DAY)	N	HO, LT	S06-USA-04278-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Blood Ph Decreased; Contusion; Depressed Mood; Drug Ineffective; Fall; Feeling Hot; Fractured Sacrum; General Physical Health Deterioration; Haematoma; Hostility; Jaw	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lovenox			C				Not Reported
	Lamictal			C				Not Reported
	Prevacid			C				Not Reported
	Singulair			C				Not Reported
	Advair			C				Not Reported
	Albuterol			C				Not Reported
	Ativan			C				Not Reported

Fracture; Lumbar Vertebral Fracture; Multiple Fractures; Neck Pain; Pelvic Fracture; Radial Pulse; Sciatic Nerve Injury; Suicidal Ideation; Suicide Attempt; Ulna Fracture; White Blood Cell Count Increased	Phenergan	C	Not Reported
	Clonazepam	C	Not Reported
	Wellbutrin (Bupropion Hydrochloride)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2007	6331529	NON-EXPEDITED	Y	HO	2007UW00835		93 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Zestril			S				Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Antibiotic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2007	6161500	EXPEDITED (15-DAY)	N	DE	S06-USA-04272-01		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Blood Ethanol Increased; Completed Suicide; Condition Aggravated; Depression; Drug Screen Positive; General Physical Health Deterioration; Gun Shot Wound; Head Injury; Hostility; Insomnia; Patella Fracture; Suicidal Ideation; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Vicodin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2007	6347510	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20061106436		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Delirium; Delusion; Hallucination; Overdose; Paranoia; Pericardial Effusion; Pleural Effusion; Tachycardia	Tylenol		Y	S				Not Reported
	Tylenol			S				Not Reported
	Flexeril			S				Not Reported
	Oxycontin			S	Oral			Not Reported
	Lortab			S		5/5000 Mg		Not Reported
	Lexapro			S	Oral			Not Reported
	Fentanyl Citrate			S	Buccal			Not Reported
	Fentanyl Citrate			S	Buccal			Not Reported
	Anti-Anxiety Medications			C				Not Reported
	Zithromax			C				Not Reported
	Seroquel			C				Not Reported
	Albuterol			C				Not Reported
	Bayer Aspirin			C				Not Reported
	Synthroid			C				Not Reported
	Lyrica			C				Not Reported
	Combivent			C				Not Reported
	Nexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2007	6347511	EXPEDITED (15-DAY)	N	HO, OT	US-PURDUE-USA_2006_0025759		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Gases Abnormal; Breakthrough Pain; Cognitive Disorder; Delirium; Delusion; Drug Tolerance; Hallucination; Lethargy; Mental Status Changes; Overdose; Oxygen Saturation Decreased; Pco2 Decreased; Pericardial	Oxycontin			S	Oral	160 Mg, Daily		Not Reported
	Lortab			S		5 Mg, Unk		Not Reported
	Tylenol			S				Not Reported
	Flexeril			S				Not Reported
	Lexapro			S	Oral	10 Unk, Unk		Not Reported
	Fentanyl Citrate			S	Buccal	600 Mcg, Prn	270 DAY	Not Reported
	Fentanyl Citrate			S	Buccal	400 Mcg, Prn	44640 MIN	Not Reported

Effusion; Pericarditis; Pleural Effusion; Pneumonia; Po2 Decreased; Pyrexia; Tachycardia; White Blood Cell Count Increased	Synthroid	C			Not Reported
	Combivent	C			Not Reported
	Azithromycin	C			Not Reported
	Seroquel	C			Not Reported
	Aspirin	C			Not Reported
	Albuterol	C			Not Reported
	Nexium	C	Unk, Unk		Not Reported
	Lyrica	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2007	6227521	EXPEDITED (15-DAY)	Y	OT	S07-USA-00139-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Hypersensitivity; Skin Disorder; Skin Exfoliation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2007	6278459	EXPEDITED (15-DAY)	Y	HO	DE-BRISTOL-MYERS SQUIBB COMPANY-13725650		44 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome; Somnolence	Abilify			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2007	6168684	EXPEDITED (15-DAY)	Y	HO, OT	S06-USA-04318-01		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bundle Branch Block Right; Condition Aggravated; Dizziness; Electrocardiogram Qrs Complex Prolonged; Fall; Hypertension; Loss Of	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Diazepam			C				Not Reported
	Mucinex			C				Not Reported
	Flomax			C				Not Reported
	Aspirin			C				Not Reported

Consciousness; Nausea; Palpitations; Presyncope; Sinus Node Dysfunction; Supraventricular Extrasystoles; Syncope; Ventricular Hypertrophy; Vomiting	Zetia (Ezetimibe)	C	Not Reported
	Synthroid	C	Not Reported
	Lisinopril	C	Not Reported
	Centrum Silver (Vitamin)	C	Not Reported
	Norvasc	C	Not Reported
	Triamterene And Hydrochlorothiazide	C	Not Reported
	Singulair	C	Not Reported
	Nexium (Esomeprazole)	C	Not Reported
	Astelin	C	Not Reported
	Fluticasone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2007	6192004	EXPEDITED (15-DAY)	Y	HO	S06-USA-04908-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Delusion; Disorientation; Hallucination; Lethargy; Mental Status Changes; Overdose; Paranoia; Pericardial Effusion; Pericarditis; Pleural Effusion; Pneumonia; Self-Medication	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Fentanyl Citrate			S	Oral	600 Mg Prn Po		Not Reported
	Fentanyl Citrate			S	Oral	400 Mg Prn Po		Not Reported
	Oxycontin			S	Oral	160 Mg Qd Po		Not Reported
	Lortab			S				Not Reported
	Tylenol (Paracetamol)			S				Not Reported
	Flexeril			S				Not Reported
	Synthroid			C				Not Reported
	Lyrica			C				Not Reported
	Combivent			C				Not Reported
	Seroquel			C				Not Reported
	Albuterol			C				Not Reported
	Aspirin			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2007	6279605	EXPEDITED (15-DAY)	N	DE	US-GLAXOSMITHKLINE-A0645845A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Paxil			S	Unknown			Glaxosmithkline

	Valium	S		Glaxosmithkline
	Lexapro	S		Not Reported
	Risperdal	S		Not Reported
	Naproxen	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2007	6333984	NON-EXPEDITED	Y	OT	2007006695			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Tardive Dyskinesia	Geodon			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2007	6334880	NON-EXPEDITED	N	OT	2006155743		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Pain In Jaw; Swollen Tongue	Geodon			S		(2 In 1 D)		Not Reported
	Lexapro			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2007	6335708	NON-EXPEDITED	Y	OT	2006132809		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Geodon			S				Not Reported
	Carbamazepine			S				Not Reported
	Lexapro			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2007	5910006	EXPEDITED (15-DAY)	N	DE	S05-USA-04577-01		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Anxiety; Completed Suicide; Condition Aggravated; Diarrhoea; Fatigue; Feeling Abnormal; Intentional Self-Injury; Nausea; Overdose; Pulmonary Congestion; Pulmonary Oedema; Restlessness; Social Avoidant Behaviour; Suicidal Ideation; Thinking Abnormal; Toxicity To Various Agents; Tremor; Visceral Congestion; Vomiting	Lexapro	S	Oral	10 Mg Qd; Po		Not Reported
	Oxycodone	S				Not Reported
	Diazepam	S				Not Reported
	Zolpidem	S				Not Reported
	Nordazepam	S				Not Reported
	Morphine	S				Not Reported
	Hydrocodone	S				Not Reported
	Glucophage	C				Not Reported
	Diovan Hcl (Valsartan)	C				Not Reported
	Xanax	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2007	6281063	EXPEDITED (15-DAY)	Y	HO	2007CG00548		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatitis	Omeprazole			S	Oral		20 DAY	Not Reported
	Caffeine			S	Oral		11 DAY	Not Reported
	Cefpodoxime Proxetil			S	Oral		11 DAY	Not Reported
	Zyprexa			S	Oral		19 DAY	Not Reported
	Activelle			S	Oral		11 DAY	Not Reported
	Escitalopram Oxalate			S	Oral		17 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2007	6296055	EXPEDITED (15-DAY)		DS, HO	2007-156434-NL		68 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depersonalisation/Dereali sation Disorder; Drug Ineffective; Dysphagia; Dystonia	Mirtazapine			S	Oral	30 Mg Qd/15 Mg Qd Oral	97 DAY	Not Reported
					Oral	30 Mg Qd/15 Mg Qd Oral	148 DAY	
	Escitalopram Oxalate			S	Oral	10 Mg Qd Oral	22 DAY	Not Reported

Citalopram	S	Oral	20 Mg Qd Oral	3 DAY	Not Reported
Co-Amilofruse	C				Not Reported
Diazepam	C				Not Reported
Digoxin	C				Not Reported
Nicorandil	C				Not Reported
Paracetamol	C				Not Reported
Perindopril	C				Not Reported
Senna	C				Not Reported
Simvastatin	C				Not Reported
Warfarin Sodium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2007	6161841	EXPEDITED (15-DAY)	N	DE	S06-USA-04284-01		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Chest Pain; Completed Suicide; Depressed Mood; Dyspepsia; Dyspnoea; Fatigue; Feeling Cold; Feeling Hot; Gun Shot Wound; Head Injury; Hostility; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zestril			C				Not Reported
	Ativan			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2007	6254731	EXPEDITED (15-DAY)	Y	OT	S07-USA-00457-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Basedow'S Disease; Fall; Foot Fracture; Hypothyroidism	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Seasonale (Ethinyl Estradiol/Levonorgestrel)			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2007	6295979	EXPEDITED (15-DAY)	Y	HO	S07-FRA-01470-01		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Hepatitis; Jaundice; Nausea; Pruritus; Pyrexia	Escitalopram Oxalate			S				Not Reported
	Mopral (Omeprazole)			S				Not Reported
	Zyprexa			S				Not Reported
	Orelox (Cefpodoxime Proxetil)			S				Not Reported
	Activella			S				Not Reported
	Acetaminophen\Caffeine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2007	6296234	EXPEDITED (15-DAY)	N	OT	S07-USA-01369-01		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Physical Assault	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2007	6347512	EXPEDITED (15-DAY)	Y	HO	T200601348		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Cardiac Failure Congestive; Delusion; Drug Screen Positive; Electrocardiogram St-T Change; Hallucination; Lethargy; Overdose; Paranoia; Pericardial Effusion; Pleural Effusion; Self-Medication; Sinus Tachycardia; Treatment Noncompliance; White Blood Cell Count Increased	Lortab			S				Not Reported
	Fentanyl Citrate			S	Buccal	600 Ug, Prn Buccal		Not Reported
	Fentanyl Citrate			S	Buccal	400 Ug, Prn Buccal		Not Reported
	Oxycontin			S	Oral	160 Mg, Qd, Oral		Not Reported
	Lexapro			S	Oral	10 Mg, Qd, Oral		Not Reported
	Tylenol (Paracetamol)			S				Not Reported
	Flexeril			S				Not Reported
	Seroquel			C				Not Reported
	Albuterol (Salbutamol)			C				Not Reported
	Aspirin			C				Not Reported
	Nexium (Esomeprazole Magnesium)			C				Not Reported
	Synthroid			C				Not Reported
	Lyrica			C				Not Reported
	Combivent (Ipratropium Bromide, Salbutamol)			C				Not Reported
	Zithromax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2007	6023873	EXPEDITED (15-DAY)	N	HO	PHNR2006AU00661		77 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Confusional State; Fall; Hallucination	Stalevo			S		6 Tablets (100/25/200mg) Per Day		Orion
	Lexapro			S		10 Mg, Mane		Not Reported
	Lasix			C		40 Mg, Unk		Not Reported
	Lanoxin			C		125 Mg, Unk		Not Reported
	Lansoprazole			C		30 Mg, Nocte		Not Reported
	Zocor			C		10 Mg, Nocte		Not Reported
	Sinemet Cr			C		1 Tablet (200 Mg) Nocte		Not Reported
	Cabergoline			C		2 Mg, Nocte		Not Reported
	Diazepam			C		2.5 Mg, Nocte		Not Reported
	Warfarin Sodium			C		2/3mg Alternating		Not Reported
	Sinemet			C		100/25 X 5 Or 6 Per Day		Not Reported
	Symmetrel			C		1 Tablet Bd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2007	6292113	DIRECT	Y				43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Marital Problem; Personality Change	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2007	6292566	DIRECT	Y	HO			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Presyncope; Skin	Lexapro			S		10mg 1 Time/Day		Not Reported

Discolouration; Vomiting	Levaquin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2007	6296972	EXPEDITED (15-DAY)	Y	HO	S07-USA-01463-01		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Diarrhoea; Drug Interaction; Nausea; Presyncope; Vomiting	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Levaquin			S				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Diovan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2007	6300068	EXPEDITED (15-DAY)	Y	OT	S07--01386-01		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Platelet Count Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Restoril			C				Not Reported
	Librium			C				Not Reported
	Ritalin			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2007	6296887	DIRECT	N				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Medication Error; Product Dispensing Error; Wrong Product Administered	Lisinopril			S	Oral	10mg One Daily Po	5 DAY	Mylan
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2007	6299540	EXPEDITED (15-DAY)	N	CA	S07-USA-01504-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital; Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Transposition Of The Great Vessels	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Tylenol (Paracetamol)			C				Not Reported
	Alka-Seltzer Cold Plus (Acetaminophen/Chlorpheniramine/Phenylephrine)			C				Not Reported
	Prenatal Vitamin (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2007	6299552	EXPEDITED (15-DAY)	Y	HO	S07-USA-01503-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Ibuprofen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2007	6296261	DIRECT	N	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Injury	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2007	6296663	DIRECT	N	RI			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia	Lexapro			S	Oral	25mg Once A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2007	6335959	NON-EXPEDITED			2007SP000781		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Middle Insomnia	Lunesta	S	Oral	See Image		Not Reported
			Oral	See Image		
	Lexapro	S	Oral	10 Mg;Qd;Oral		Not Reported
	Paxil	C				Not Reported
	Pravachol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2007	6337212	NON-EXPEDITED	N		2007SP000185		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Glaucoma; Headache	Lunesta			S	Oral	3 Mg;Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported
	Lorazepam			S	Oral	Oral		Not Reported
	Tamsulosin Hydrochloride			C				Not Reported
	Saw Palmetto			C				Not Reported
	Cozaar			C				Not Reported
	Amlodipine			C				Not Reported
	Lopresor			C				Not Reported
	Digoxin			C				Not Reported
	Xalatan			C				Not Reported
	Solu-Medrol			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Fish Oil			C				Not Reported
	Icaps			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2007	6340007	NON-EXPEDITED	Y		2007SP000029		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysgeusia	Lunesta			S	Oral	3 Mg; Hs; Oral		Not Reported
	Lexapro			S	Oral	10 Mg;Qd;Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2007	6288424	EXPEDITED (15-DAY)	Y	HO	S07-FRA-01270-01		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Neutropenia; Sinusitis	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Zyprexa			C				Not Reported
	Spektramox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2007	6297278	DIRECT	Y	CA, OT			121 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis; Maternal Exposure During Pregnancy; Pregnancy	Lexapro			S	Oral	20mg 1 Time Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2007	6304591	EXPEDITED (15-DAY)	Y	HO	S07-USA-01551-01		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Loss Of Consciousness; Suicide Attempt	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Xanax			S	Oral	0.25 Mg Prn Po		Not Reported
	Xanax			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2007	6306653	EXPEDITED (15-DAY)	N	DE, HO	2007S1001632		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Blood Urine Present; Chest Pain; Completed Suicide; Cystitis; Headache; Hypoaesthesia; Insomnia;	Diazepam Tablets, Usp			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported
	Naproxen			S	Oral	Oral		Not Reported

Neck Pain; Nervousness; Post-Traumatic Stress Disorder; Restlessness; Road Traffic Accident; Suicidal Ideation	Rhinocort	S	Nasal	Nasal	Not Reported
	Paxil	S	Oral	Oral	Not Reported
	Risperdal	S	Oral	Oral	Not Reported
	Paxil Cr	S	Oral	Oral	Not Reported
	Buspirone	S	Oral	Oral	Not Reported
	Gabapentin	S	Oral	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2007	6291710	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20070402130		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Interaction; Dry Eye; Dysphagia; Tremor	Topamax			S				Not Reported
	Lexapro			S				Not Reported
	Seroquel			S				Not Reported
	Klonopin			S				Not Reported
	Depakote			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2007	6297715	DIRECT	N	DE, HO, LT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	20 Mg 1 Per Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2007	6297725	DIRECT	N	DE, LT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	20 Mg 1 Per Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2007	6262279	EXPEDITED (15-DAY)	Y	HO	S07-USA-00773-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorea; Fall; Tardive Dyskinesia; Tremor	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Glucovance (Glyburide/Metformin)			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Ultram			C				Not Reported
	Adipex-P			C				Not Reported
	Levothyroxine			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2007	6292913	EXPEDITED (15-DAY)	N	HO	FR-GLAXOSMITHKLINE-B0453335A		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Dyskinesia; Fall; Musculoskeletal Disorder	Lamictal			S	Oral		2 MTH	Glaxosmithkline
	Escitalopram Oxalate			S	Oral	10mg Per Day	3 MTH	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2007	6305367	EXPEDITED (15-DAY)	Y	HO	S06-UKI-05173-01		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Mania	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Ispaghula Husk Sachets (Ispaghula Husk)			C				Not Reported
	Lactulose Solution (Lactulose)			C				Not Reported
	Diclofenac With Misoprostol (Galenic /Misoprostol/Diclofenac Sodium)			C				Not Reported
	Co-Dydramol			C				Not Reported
	Gaviscon			C				Not Reported
	Levothyroxine			C				Not Reported

	Gabapentin Capsules (Gabapentin)			C						Not Reported
	Risperidone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2007	6561655	EXPEDITED (15-DAY)	N	DE, OT	2007-01857		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Acute Pulmonary Oedema; Anxiety; Completed Suicide; Diarrhoea; Fatigue; Feeling Abnormal; Intentional Overdose; Intentional Self-Injury; Nausea; Partner Stress; Pulmonary Congestion; Skin Laceration; Social Avoidant Behaviour; Suicidal Ideation; Thinking Abnormal; Toxicity To Various Agents; Tremor; Visceral Congestion; Vomiting	Oxycodone And Acetaminophen			S				Watson
	Hydrocodone Bitartrate And Acetaminophen			S				Watson
	Lexapro			S	Oral	10 Mg, Daily, Oral		Not Reported
	Diazepam			S				Not Reported
	Zolpidem			S				Not Reported
	Nordazepam			S				Not Reported
	Morphine			S				Not Reported
	Glucophage			C				Not Reported
	Valsartan			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2007	6265349	EXPEDITED (15-DAY)	Y	HO	S07-FRA-00981-01		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arteritis; Brain Oedema; Central Nervous System Vasculitis; Cerebral Haematoma; Conjunctivitis; Hemianopia; Hemiparesis; Meningorrhagia; Protein	Escitalopram Oxalate			S				Not Reported
	Xanax (Escitalopram)			C				Not Reported
	Effexor			C				Not Reported

Total Increased; Pupils Unequal; Urinary Tract Infection; Urine Alcohol Test Positive

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2007	6275501	EXPEDITED (15-DAY)	Y	DS, HO	S07-FRA-01073-01		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activated Partial Thromboplastin Time Prolonged; Blood Creatinine Increased; Blood Urea Increased; Fall; Haematocrit Decreased; Head Injury; Red Blood Cell Count Decreased; Subdural Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin Lysine			S	Oral	75 Mg Qd Po		Not Reported
	Atacand (Candesartan Cilexetil)			C				Not Reported
	Covarsal (Molsidomine)			C				Not Reported
	Nitriderm (Glyceryl Trinitrate)			C				Not Reported
	Amlodipine Besylate			C				Not Reported
	Ebixa			C				Not Reported
	Modopar			C				Not Reported
	Tadenan (Pygeum Africanum)			C				Not Reported
	Vastarel			C				Not Reported
	Dafalgan (Paracetamol)			C				Not Reported
	Xanax			C				Not Reported
	Pravastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2007	6295114	EXPEDITED (15-DAY)	Y	HO	S07-FRA-00281-01		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Bilirubin Increased; Blood Chloride Decreased; Cognitive Disorder; Fall; Haemodilution; Hyponatraemia; Hypotension	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Furosemide			S	Oral	10 Mg Qd Po		Not Reported
	Kenzen (Candesartan Cilexetil)			C				Not Reported
	Sintrom			C				Not Reported
	Sotalol Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2007	6300990	DIRECT	Y	CA			193 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Congenital Anomaly; Maternal Exposure During Pregnancy	Lexapro			S	Oral	20 Mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2007	6301058	DIRECT	Y	LT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2007	6306834	EXPEDITED (15-DAY)	Y	DE	2007S1003092		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anxiety; Completed Suicide; Diarrhoea; Fatigue; Feeling Abnormal; General Physical Health Deterioration; Intentional Self-Injury; Nausea; Overdose; Pulmonary Congestion; Pulmonary Oedema; Self-Injurious Ideation; Skin Laceration; Sleep Disorder; Social Avoidant Behaviour; Stress; Suicidal Ideation; Thinking Abnormal; Tremor; Visceral	Lexapro			S	Oral	10 Mg;Daily;Oral		Not Reported
	Oxycodone			S				Not Reported
	Diazepam Tablets, Usp			S				Not Reported
	Zolpidem			S				Not Reported
	Morphine			S				Not Reported
	Hydrocodone			S				Not Reported
	Glucophage			C				Not Reported
	Diovan			C				Not Reported
	Xanax			C				Not Reported

Congestion; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2007	6307460	EXPEDITED (15-DAY)	N	HO	S07-USA-01647-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperemesis Gravidarum; Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Pregnancy; Suppressed Lactation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2007	6307462	EXPEDITED (15-DAY)	Y	HO	S07-USA-01671-01		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Energy Increased; Feeling Abnormal; Grandiosity; Hypomania; Mania; Psychotic Disorder; Thinking Abnormal	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2007	6310341	EXPEDITED (15-DAY)	N	HO	070409-0000375		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Dermatitis Allergic; Disorientation; Dyssomnia; Headache; Hypersensitivity; Nausea; Presyncope; Rash; Somnolence; Tremor; Urticaria	Tranxene T-Tab			S	Oral	3.75 Mg; Qd; Po		Not Reported
	Lexapro			S	Oral	10 Mg; Po		Not Reported
	Paxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2007	6290707	EXPEDITED (15-DAY)	Y	HO	DEWYE412411APR07		18 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Drunk; Intentional Overdose; Nausea; Somnolence; Suicide Attempt; Vomiting	Pantozol (Pantoprazole)			S	Oral	1 Tablet (Overdose Amount 40 Mg)	1 DAY	Wyeth
	Tavor (Lorazepam)			S	Oral	2 Tablets (Overdose Amount 2 Mg)	1 DAY	Wyeth
	Risperidone			S	Oral	1 Tablet (Overdose Amount Unknown)	1 DAY	Unknown
	Alcohol			S	Oral	Half A Bottle Of Liqueur	1 DAY	Unknown
	Cipralex			S	Oral	1 Tablet (Overdose Amount 10 Mg)	1 DAY	Lundbeck
	Clonidine			S	Oral	3 Tablets (Overdose Amount 0,225 Mg)	1 DAY	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2007	6308710	EXPEDITED (15-DAY)	Y	HO	S07-FRA-00243-01		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Dyskinesia; Epilepsy; Fall; Muscle Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Lamictal			S	Oral	100 Mg Qd Po		Not Reported
	Lamictal			S	Oral	75 Mg Qd Po		Not Reported
	Lamictal			S	Oral	50 Mg Qd Po		Not Reported
	Lamictal			S	Oral	25 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2007	6375835	NON-EXPEDITED	Y	HO	US-JNJFOC-20060401363			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction;	Ultram			S				Not Reported

Serotonin Syndrome	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2007	6296970	EXPEDITED (15-DAY)	Y	OT	S07-USA-01500-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Many Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2007	6298637	EXPEDITED (15-DAY)	Y	HO, OT	US-PFIZER INC-2007032266		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Overdose; Suicide Attempt	Xanax			S				Not Reported
	Lexapro			S		Daily Dose:20mg		Not Reported
	Lexapro			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2007	6299441	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20070404377		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Nausea; Presyncope	Levaquin			S	Oral			Not Reported
	Nexium			C	Unknown			Not Reported
	Diovan			C	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2007	6300500	NON-EXPEDITED			2006UW18374		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Drug Interaction	Nexium			S	Oral			Astrazeneca

	Levoxyl	C				Not Reported
	Allegra	C				Not Reported
	Lexapro	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2007	6306351	DIRECT	Y	HO, LT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Arrest; Seizure	Tramadol Hydrochloride			S	Oral	400 Mg Daily Po		Not Reported
	Escitalopram Oxalate			S	Oral	30 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2007	6310991	EXPEDITED (15-DAY)	Y	OT	S07-USA-01245-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Intervertebral Disc Protrusion; Muscle Spasms	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Mirapex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2007	6267526	EXPEDITED (15-DAY)	Y	OT	S07-USA-00985-01		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Hepatic Cirrhosis; Hepatic Failure; Hyponatraemia; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lasix			S		20 Mg Qd		Not Reported
	Lasix			S				Not Reported
	Spironolactone			C				Not Reported
	Quinine Sulfate			C				Not Reported
	Neomycin			C				Not Reported
	Prevacid			C				Not Reported
	Magnesium			C				Not Reported
	Lactulose			C				Not Reported

	Oxazepam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2007	6283414	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2007024784		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Enzyme Increased; Hyperventilation; Lymphadenopathy; Pyrexia; Rash Maculo-Papular; Toxic Skin Eruption; Weight Decreased	Unspecified Ingredient			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Indomethacin			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Caffeine\Opium Tincture			S	Oral			Not Reported
	Tetrazepam			S	Oral			Not Reported
	Virginiamycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2007	6286532	EXPEDITED (15-DAY)	Y	HO	FR-NOVOPROD-262406		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Activelle			S	Oral		10 DAY	Novo Nordisk
	Omeprazole			S			19 DAY	Not Reported
	Escitalopram Oxalate			S			16 DAY	Not Reported
	Zyprexa			S			18 DAY	Not Reported
	Orelox			S			10 DAY	Not Reported
	Caffeine			S			10 DAY	Not Reported
	Fluoxetine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2007	6292727	EXPEDITED (15-DAY)	Y	HO	S07-FRA-01358-01		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury;	Escitalopram Oxalate			S				Not Reported

Cholestasis; Cytomegalovirus Test Positive; Disease Recurrence; Drug Reaction With Eosinophilia And Systemic Symptoms; Epstein-Barr Virus Antibody Positive; Hepatic Neoplasm; Hepatitis; Lymphadenopathy; Oxygen Saturation Decreased; Protein Total Increased; Pustular Psoriasis; Splenomegaly	Levothyroxine	S	Oral	125 Mcg Qd Po	Not Reported
	Sulfasalazine	S	Oral	1000 Mg Bid Po	Not Reported
	Acetaminophen\Caffeine	S			Not Reported
	Indomethacin	S	Oral	75 Mg Bid Po	Not Reported
	Tetrazepam	S	Oral	50 Mg, Po	Not Reported
	Mopral (Omeprazole)	C			Not Reported
	Daivobet	C			Not Reported
	Virginiamycin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2007	6312010	EXPEDITED (15-DAY)	Y	OT	S07-UKI-01762-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplastic Anaemia	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2007	6312021	EXPEDITED (15-DAY)	Y	HO	S07-FRA-01760-01		33 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2007	6290189	EXPEDITED (15-DAY)	Y	HO	6031105		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cytomegalovirus Test Positive; Disease Recurrence; Hepatic Enzyme Increased;	Levothyroxine Sodium			S		125 Mcg (125 Mcg, 1 D);		Not Reported
	Sulfasalazine			S	Oral	20000,0 Mg; (1000 Mg, 1 In 1 D) Oral	41 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	Oral	2 DAY	Not Reported

Hypersensitivity; Hyperventilation; Liver Disorder; Lymphadenopathy; Mononucleosis Syndrome; Oxygen Saturation Decreased; Pustular Psoriasis; Pyrexia; Rash Maculo-Papular; Splenomegaly; Urticaria	Acetaminophen\Belladonna Extract\Caffeine\Papaverine	S			2 DAY	Not Reported
	Indocin	S	Oral	150,000 Mg (75 Mg, 2 In 1 D); Oral	49 DAY	Not Reported
	Tetrazepam	S	Oral	Oral		Not Reported
	Virginiamycin	S	Oral Oral	Oral Oral	6 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2007	6213818	EXPEDITED (15-DAY)	Y	HO	PAR_1160_2006		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Amnesia; Anxiety; Apathy; Chest Discomfort; Crying; Decreased Appetite; Depression; Diarrhoea; Disturbance In Attention; Dizziness Postural; Drug Ineffective; Dysphemia; Dysuria; Fatigue; Flight Of Ideas; Insomnia; Malaise; Nausea; Serotonin Syndrome	Cyproheptadine Hydrochloride			S				Not Reported
	Lexapro			S	Oral	10 Mg Oral		Not Reported
	Prozac			S	Oral	20 Mg Oral		Not Reported
	Prozac			S	Oral	40 Mg Oral		Not Reported
	Zithromax			C				Not Reported
	Depo-Provera			C				Not Reported
	Tylenol With Codeine			C				Not Reported
	Tizanidine Hydrochloride			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Ppd Disposable			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2007	6316461	EXPEDITED (15-DAY)	Y	HO, LT	S07-NOR-01831-01		65 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Aphasia; Blood Bilirubin Increased; Blood Calcium Increased; Blood Creatine Abnormal; Blood Phosphorus Decreased; Blood Potassium	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Aldomet			S				Not Reported
	Diural (Furosemide)			C				Not Reported
	Ramipril			C				Not Reported
	Etalpha (Colecalciferol)			C				Not Reported
	Renavit			C				Not Reported

Increased; Blood Pressure Fluctuation; Body Temperature Increased; Brain Injury; C-Reactive Protein Increased; Cerebral Infarction; Confusional State; Csf Test Abnormal; Culture Urine Positive; Drug Interaction; Dysarthria; Dyspraxia; Enterococcal Infection; Generalised Tonic-Clonic Seizure; Haemoglobin Decreased; High Density Lipoprotein Abnormal; Hypertensive Crisis; Muscle Spasticity; Neglect Of Personal Appearance; Neurological Symptom; Oedema Peripheral; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Retinopathy Hypertensive; Serotonin Syndrome; Serum Ferritin Increased; Somnolence; Spinal Osteoarthritis; Tachycardia; Unresponsive To Stimuli; Visual Acuity Reduced; White Blood Cell Count Increased	Nexium (Esomeprazole)	C	Not Reported
	Paracet (Paracetamol)	C	Not Reported
	Albyl-E	C	Not Reported
	Irbesartan	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2007	6282306	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-07P-056-0363384-00		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cell Death; Cholestasis; Drug	Levothyrox			S	Oral			Not Reported

Reaction With Eosinophilia And Systemic Symptoms; Eosinophil Count Increased; Hepatomegaly; Hyperventilation; Lip Oedema; Lymphadenopathy; Lymphocyte Count Increased; Oxygen Saturation Decreased; Protein Total Increased; Pustular Psoriasis; Rash Maculo-Papular; Splenomegaly; Urticaria; White Blood Cell Count Increased	Escitalopram Oxalate	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Acetaminophen\Belladonna\Caffeine\Opium	S	Oral		Not Reported
	Indomethacin	S	Oral		Not Reported
	Tetrazepam	S	Oral		Not Reported
	Omeprazole	C			Not Reported
	Betamethasone Dipropionate	C			Not Reported
	Virginiamycin	C			Not Reported
	Virginiamycin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2007	6305283	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2007034094		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Aggression; Back Pain; Flatulence; Insomnia; Nausea; Nightmare; Parosmia; Weight Increased	Chantix			S				Not Reported
	Lexapro			S				Not Reported
	Lipitor			C				Not Reported
	Lisinopril			C				Not Reported
	Synthroid			C				Not Reported
	Premarin			C				Not Reported
	Sinemet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2007	6312109	DIRECT	N	OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Weight Increased	Lexapro			S	Oral	10 Mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2007	6212932	EXPEDITED (15-DAY)	Y	OT	S06-USA-05338-01		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Macular Degeneration	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2007	6264631	EXPEDITED (15-DAY)	Y	DE, LT	DE-ASTRAZENECA-2007PK00643		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Abuser; Restlessness	Seroquel			S	Oral	75 Mg To 250 Mg Per Day	8 DAY	Zeneca
	Seroquel			S	Oral	75 Mg To 250 Mg Per Day	3 DAY	Zeneca
	Cipralex			S	Oral		15 DAY	Not Reported
	Tavor (Lorazepam)			C	Oral		8 DAY	Not Reported
	Lorazepam			C	Oral		1 DAY	Not Reported
	Lorazepam			C	Oral		1 DAY	Not Reported
	Lorazepam			C	Oral		3 DAY	Not Reported
	Lorazepam			C	Oral		4 DAY	Not Reported
	Lorazepam			C	Oral		1 DAY	Not Reported
	Stilnox			C	Oral		16 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2007	6265287	EXPEDITED (15-DAY)	Y	OT	S07-USA-00895-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Haemorrhage	Lexapro			S				Not Reported
	Lamictal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2007	6289588	EXPEDITED (15-DAY)	Y	HO	S07-GER-01312-01		27 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Hellp Syndrome; Maternal Exposure During Pregnancy; Thrombocytopenia	Cipralex			S				Not Reported
	Citalopram Hydrobromide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2007	6307827	EXPEDITED (15-DAY)	Y	HO	CH-ASTRAZENECA-2007PK00952		85 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Parkinsonism; Product Prescribing Error; Transient Ischaemic Attack	Seroquel			S	Oral			Zeneca
	Risperdal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Trazodone Hydrochloride			S	Oral			Not Reported
	Stilnox			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2007	6313644	EXPEDITED (15-DAY)	Y	HO	S07-USA-01753-01		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Condition Aggravated; Constipation; Dehydration; Dizziness; Feeling Hot; Insomnia; Nausea; Orthostatic Hypotension	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Metoprolol			C				Not Reported
	Isosorbide			C				Not Reported
	Cardizem			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2007	6159729	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20061006565			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Insomnia; Language Disorder	Pepcid Ac		Y	S				Not Reported
	Pepcid Ac			S				Not Reported
	Nexium			S				Not Reported
	Toprol Xl			S				Not Reported
	Ambien			S				Not Reported
	Zocor			S				Not Reported
	Lexapro			S				Not Reported
	Dyazide			S				Not Reported
	Iron			S				Not Reported
	Calcium Chloride			S				Not Reported
	Multi-Vitamin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2007	6300662	EXPEDITED (15-DAY)	Y	HO, LT	NO-MERCK-0704NOR00006		65 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Autonomic Nervous System Imbalance; Blood Pressure Fluctuation; Body Temperature Increased; Confusional State; Drug Interaction; Dyspraxia; Generalised Tonic-Clonic Seizure; Hypertension; Neglect Of Personal Appearance; Neurological Symptom; Serotonin Syndrome; Somnolence; Tachycardia; Unresponsive To Stimuli	Aldomet			S	Oral		2 DAY	Merck
	Escitalopram Oxalate			S	Oral		18 MTH	Not Reported
	Ramipril			C	Oral			Not Reported
	Furosemide			C	Oral			Not Reported
	Aspirin\Magnesium Oxide			C	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Alfacalcidol			C	Unknown			Not Reported
	Esomeprazole Magnesium			C	Oral			Not Reported
	Irbesartan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2007	6318283	EXPEDITED (15-DAY)	Y	HO, LT	DSA_29749_2007		18 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Drunk; Intentional Overdose; Nausea; Somnolence; Suicide Attempt; Vomiting	Tavor /00273201/ (Lorazepam) Tablet			S	Oral	2 Mg 1x Oral		Not Reported
	Cipralex			S	Oral	10 Mg 1x Oral		Not Reported
	Clonidine			S	Oral	225 Mg 1x Oral		Not Reported
	Pantozol			S	Oral	40 Mg 1x Oral		Not Reported
	Risperidone			S	Oral	Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2007	6129750	EXPEDITED (15-DAY)	Y	DE, HO	US-JNJFOC-20060901000		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose; Multiple Organ Dysfunction Syndrome; Pneumonia Aspiration; Sepsis	Tramadol Hydrochloride			S				Not Reported
	Diphenhydramine		Y	S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Hydrocodone/Apap			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported
	Nortriptyline Hydrochloride			S				Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2007	6309638	EXPEDITED (15-DAY)	Y	HO	CH-JNJFOC-20070501238		85 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Extrapyramidal Disorder; Product Prescribing Error	Risperdal			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

	Trazodone Hydrochloride	S	Oral		Not Reported
	Stilnox	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2007	6308153	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2007035757			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Neurontin			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2007	6320090	EXPEDITED (15-DAY)	Y		S07-USA-01931-01		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Nausea; Vomiting; Weight Decreased	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Flomax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2007	6321096	EXPEDITED (15-DAY)	Y	HO	S07-USA-01917-01		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Status Epilepticus	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Depakote			C				Not Reported
	Lamictal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2007	6321099	EXPEDITED (15-DAY)	Y	HO	S07-USA-01950-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2007	6316743	DIRECT		OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia	Lexapro			S	Oral	10 Mg Once Daily Po	1 YR	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2007	6315916	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2007015509		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Cognitive Disorder; Depression; Disorientation; Dizziness; Drug Interaction; Feeling Abnormal; Impatience; Mental Impairment	Chantix			S	Oral			Not Reported
	Gabapentin			C	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Nefazodone Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2007	5654038	EXPEDITED (15-DAY)	Y	DE	DSA_25093_2004		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree; Blood Pressure Decreased; Cardio-Respiratory Arrest; Completed Suicide; Heart Rate Increased; Lethargy; Overdose; Somnolence; Therapy Non-Responder	Diltiazem Hydrochloride			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported
	Calcium Chloride			S				Not Reported
	Iron\Vitamins Nos			S				Not Reported
	Ascorbic Acid			S				Not Reported
	Ibuprofen And Pseudoephedrine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2007	5654260	EXPEDITED (15-DAY)	Y	DE	DSA_25108_2004		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Ph Decreased; Cardiac Arrest; Completed Suicide; Electrocardiogram Qt Prolonged; Haemodialysis; Hypotension; Hypoxia; Pneumonia Aspiration; Renal Failure; Respiratory Arrest; Supraventricular Tachycardia; Toxicity To Various Agents	Lorazepam			S	Oral	(Oral)		Not Reported
	Diltiazem			S	Oral	(Oral)		Not Reported
	Benztropine Mesylate			S	Oral	(Oral)		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Ziprasidone			C				Not Reported
	Fexofenadine			C				Not Reported
	Oxcarbazepine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2007	6276767	EXPEDITED (15-DAY)	Y	HO	S07-FRA-01100-02		1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Blood Glucose Decreased; C-Reactive Protein Increased; Cyanosis Neonatal; Drug Withdrawal Syndrome; Feeding Disorder; Haemoglobin Increased; Heart Rate Decreased; Hypocalcaemia; Large For Dates Baby; Maternal Exposure During Pregnancy; Respiratory Distress; Tachypnoea; Tremor Neonatal; White Blood Cell Count Decreased	Escitalopram Oxalate			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Escitalopram Oxalate			S	Transplacental	5 Mg Transplacental		Not Reported
	Nicotine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2007	6284566	EXPEDITED (15-DAY)		HO	S07-CAN-01255-01		96 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Dysphonia; Laryngospasm; Vocal Cord Disorder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Actonel			C				Not Reported
	Hyzaar			C				Not Reported
	Atenolol			C				Not Reported
	Asa (Acetylsalicylic Acid)			C				Not Reported
	Calcium Chloride			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2007	6324430	EXPEDITED (15-DAY)	Y	OT	S07-FRA-02026-01		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Terminal Insomnia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Athymil (Mianserin Hydrochloride)			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2007	6325383	EXPEDITED (15-DAY)	Y	DS	S07-FRA-02030-01		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Asthenia; Iron Deficiency; Menometrorrhagia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2007	6325684	EXPEDITED (15-DAY)	Y	DE	S07-USA-01984-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2007	6326392	EXPEDITED (15-DAY)	Y	HO	S07-USA-01955-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gallbladder Disorder; Pancreatitis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2007	6328784	EXPEDITED (15-DAY)	Y	HO	S07-USA-02053-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Discomfort; Syncope	Lexapro			S				Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2007	6317907	EXPEDITED (15-DAY)	Y	OT	BE-PFIZER INC-2007038432			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Irritability; Mania	Champix			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2007	6318605	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-13788740		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose	Escitalopram Oxalate			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported
	Placebo			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2007	6322250	DIRECT	N	DS, RI			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Derealisation; Economic Problem; Fear; Flushing; Headache; Insomnia; Loss Of Employment; Nausea; Nervousness; Paraesthesia; Partner Stress; Psychomotor Hyperactivity; Restlessness	Lexapro			S	Oral	10mg. Once A Day Po	1 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2007	6328512	EXPEDITED (15-DAY)	Y	OT	S07-USA-02046-01		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Thrombocytopenia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2007	6330908	EXPEDITED (15-DAY)	Y	HO	S07-USA-01647		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Food Poisoning; Hyperemesis Gravidarum; Maternal Exposure During Pregnancy; Nausea; Pregnancy; Suppressed Lactation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Guaifenesin\Pseudoephedrine Hydrochloride			C				Not Reported
	Tums (Calcium Carbonate)			C				Not Reported
	Zantac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2007	6324084	DIRECT	N	OT			25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Confusional State; Drug Withdrawal Syndrome; Influenza; Mental Disorder; Seizure; Suicidal Ideation	Lexapro			S	Oral	20mn 1 Per Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2007	6205486	EXPEDITED (15-DAY)	Y	OT	S06-GER-04879-01		33 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Convulsions; Dry Mouth; Electroencephalogram Abnormal; Fall; Loss Of Consciousness; Muscle Rigidity	Escitalopram Oxalate			S	Oral	10 Mg Once Po		Not Reported
	Clonazepam			S	Ophthalmic	6 Mg Qd Po		Not Reported
	Clonazepam			S	Oral	0.5 Mg Qd Po		Not Reported
	Prothipendyl Hydrochloride			S	Oral	80 Mg Qd Po		Asta
	Subutex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2007	6293782	EXPEDITED (15-DAY)	Y	OT	S07-ITA-01364-01		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Disorder; Seizure; Speech Disorder; Swelling Face; Swollen Tongue	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2007	6316206	EXPEDITED (15-DAY)	Y	HO	S06-GER-04667-01		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Femigoa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2007	6229489	EXPEDITED (15-DAY)	Y	HO	S07-USA-00232-01		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Fall; Nervous System Disorder; Road Traffic Accident; Syncope	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2007	6296228	EXPEDITED (15-DAY)	Y	OT	S07-USA-01345-01		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Dizziness; Fatigue; Mass; Somnolence	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Humalog			C				Not Reported
	Lantus			C				Not Reported
	Fosamax			C				Not Reported
	Lisinopril And Hydrochlorothiazide			C				Not Reported
	Synthroid			C				Not Reported
	Aspirin			C				Not Reported
	Tylenol Arthritis (Paracematol)			C				Not Reported
	Neurontin			C				Not Reported
	Lipitor			C				Not Reported
	Lunesta			C				Not Reported
	Clarinex			C				Not Reported
	Betagen (Levobunolol Hydrochloride)			C				Not Reported
	Prednisone			C				Not Reported
	Omega-3/Omega-6 Fish Oil			C				Not Reported
	Chondroitin Sulfate (Bovine)\Glucosamine Sulfate			C				Not Reported
	Multivitamin (Nos)			C				Not Reported
	Zinc			C				Not Reported
	Magnesium			C				Not Reported
	Calcium + D			C				Not Reported
	Biotin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2007	6325413	EXPEDITED (15-DAY)	Y	HO	S07-AUT-02017-01		71 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Overdose; Salivary Hypersecretion	Cipralex			S	Oral	50 Mg, Qd; Po		Not Reported
	Cipralex			S	Oral	40 Mg Qd; Po		Not Reported
	Cipralex			S	Oral	30 Mg Qd;Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd;Po		Not Reported
	Cipralex			S	Oral	30 Mg Qd; Po		Not Reported
	Cipralex			S	Oral	40 Mg, Qd; Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd; Po		Not Reported
	Lithium Carbonate			S		450 Mg Qd;		Not Reported
	Lithium Carbonate			S		675 Mg Daily;		Not Reported
	Risperdal			S		1 Mg; Qd;		Not Reported
	Risperdal			S		2 Mg Qd;		Not Reported
	Edronax			C				Not Reported
	Clonazepam			C				Not Reported
	Cerebrosyl			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2007	6328590	EXPEDITED (15-DAY)	Y	HO, OT	S07-GER-02063-01		18 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Drunk; Intentional Overdose; Nausea; Somnolence; Suicide Attempt; Urine Alcohol Test Positive; Vomiting	Cipralex			S	Oral	1 Tablet Once; Po		Not Reported
	Pantozol (Pantoprazole Sodium)			S	Oral	1 Tablet Once; Po		Not Reported
	Lorazepam			S	Oral	2 Tablet Once; Po		Not Reported
	Clonidine			S	Oral	3 Tablet Once; Po		Not Reported
	Risperidone			S	Oral	1 Tablet Once; Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2007	6326349	DIRECT	Y	RI			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hallucination; Tremor	Linezolid			S	Intravenous (not otherwise specified)	Iv Q12h		Not Reported
	Escitalopram Oxalate			S	Oral	Po Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2007	6330904	EXPEDITED (15-DAY)	Y	DE	2007-159055-NL		75 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Skin Laceration	Mirtazapine			S	Oral	45 Mg, Oral	20 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	35 Mg, Oral	7 WEEK	Not Reported
	Bromazepam			S	Oral	30 Mg, Oral	19 WEEK	Not Reported
	Cosaar Plus			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Yeast Dried			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2007	6323276	EXPEDITED (15-DAY)		HO, LT	PHEH2007US07957		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypoxic-Ischaemic Encephalopathy	Ritalin			S				Novartis
	Metadate Cd			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2007	6330902	DIRECT	N	DE			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Lexapro		S	1 Tablet Every Day	Not Reported
	Clonazepam		S	1 Tablet Twice A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2007	6332730	EXPEDITED (15-DAY)	Y		S07-USA-02223-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Cholestasis; Induced Labour; Maternal Exposure During Pregnancy; Pregnancy; Premature Labour	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2007	6335357	EXPEDITED (15-DAY)	Y	OT	S07-USA-02223-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Induced Labour; Jaundice Neonatal; Maternal Exposure During Pregnancy; Premature Baby	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2007	6325574	EXPEDITED (15-DAY)	N	HO	A0653841A		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alcoholism; Asthenia; Blood Pressure Increased; Cardiac Murmur; Decreased Appetite; Dehydration; Depression; Drug Screen Positive;	Wellbutrin Xl			S	Oral	300mg Per Day	33 DAY	Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day	40 DAY	Not Reported
	Alcohol			S	Oral			Not Reported
	Lotrel			C				Not Reported

Drug Withdrawal Syndrome; Feeling Guilty; Grandiosity; Hypophagia; Impulsive Behaviour; Insomnia; Irritability; Mania; Suicidal Ideation; Tachycardia; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2007	6329395	EXPEDITED (15-DAY)	Y	HO	L07-ESP-01966-01		44 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dystonia; Movement Disorder; Muscle Contracture; Pain; Torticollis	Escitalopram Oxalate			S		10 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2007	6325381	EXPEDITED (15-DAY)	Y	DS	S07-FRA-02015-01		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mechanical Urticaria	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Lorazepam			C				Not Reported
	Noctamide (Lormetazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2007	6328589	EXPEDITED (15-DAY)	Y	HO	S07-CAN-02084-01		16 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Head Banging; Intentional Self-Injury; Suicidal Ideation	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Paxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2007	6289590	EXPEDITED (15-DAY)	Y	HO	S06-ISR-05456-01		52 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Coronary Artery Disease; Left Ventricular Dysfunction	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2007	6299488	EXPEDITED (15-DAY)	Y	OT	S07-JPN-01469-01		32 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Blood Potassium Decreased; Condition Aggravated; Decreased Appetite; Depressive Symptom; Diarrhoea; Insomnia; Nasopharyngitis; Protein Total Decreased	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Selbex (Teprenone)			C				Not Reported
	Eve (Ibuprofen)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2007	6329216	EXPEDITED (15-DAY)	Y	HO	S07-SWI-02134-01		57 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Risperdal			S	Oral	2 Mg Qd Po		Not Reported
	Risperdal			S	Oral	1 Mg Qd Po		Not Reported
	Dipiperon (Pipamperone)			C				Not Reported
	Glucophage			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2007	6337377	EXPEDITED (15-DAY)	N	OT	S07-USA-02282-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Pregnancy Of Partner	Lexapro			S		20 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2007	6337387	EXPEDITED (15-DAY)	Y	HO	S07-USA-02269-01		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Ejection Fraction Decreased; Hypoxic-Ischaemic Encephalopathy; Left Ventricular Dysfunction; Loss Of Consciousness; Malaise; Oedema; Palpitations; Pericardial Effusion; Right Ventricular Dysfunction; Sinus Tachycardia; Tachycardia; Tongue Biting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Metadate Cd			S				Not Reported
	Ritalin			S		5 Mg Tid		Not Reported
	Risperdal			C				Not Reported
	Melatonin			C				Not Reported
	Rozarem (Ramelteon)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2007	6337715	EXPEDITED (15-DAY)	Y	OT	S07-UKI-02386-01		41 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Nail Disorder	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2007	6108642	EXPEDITED (15-DAY)	N	DE	S06-USA-02936-02		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asphyxia; Completed Suicide; Discomfort; Feeling Abnormal; Nervousness; Palpitations	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2007	6108644	EXPEDITED (15-DAY)	N	DE	S06-USA-02936-01		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2007	6330540	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20070601540		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome; Suicide Attempt	Tramadol Hydrochloride And Acetaminophen			S	Oral		4 DAY	Not Reported
	Unspecified Ingredient			S				Not Reported
	Xanax			C	Oral			Not Reported
	Voltaren			C	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2007	6338282	EXPEDITED (15-DAY)	Y	OT	S07-USA-02308-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2007	6329256	EXPEDITED (15-DAY)	Y	OT	S07-SWI-02141-01		56 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Sedation; Somnolence	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Remeron			S	Oral	30 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2007	6331086	EXPEDITED (15-DAY)	Y	HO	S07-AUT-02229-01		21 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisocial Behaviour; Apathy; Extrapyramidal Disorder; Fatigue; Ill-Defined Disorder; Musculoskeletal Stiffness; Parkinsonism; Psychotic Disorder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Abilify			S	Oral	15 Mg Qd Po		Not Reported
	Abilify			S	Oral	10 Mg Qd Po		Not Reported
	Abilify			S	Oral	12.5 Mg Qd Po		Not Reported
	Abilify			S	Oral	10 Mg Qd Po		Not Reported
	Abilify			S	Oral	5 Mg Qd Po		Not Reported
	Prothipendyl Hydrochloride			S	Oral	40 Mg Qd Po		Not Reported
	Prothipendyl Hydrochloride			S	Oral	80 Mg Daily Po		Not Reported
	Prothipendyl Hydrochloride			S	Oral	40 Mg Qd Po		Not Reported
	Oxazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2007	6338755	EXPEDITED (15-DAY)	Y	OT	S07-USA-02405-01		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Before Pregnancy; Pregnancy; Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2007	6344747	DIRECT	Y	HO			64 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation; Condition Aggravated; Delusion; Fear; Hallucination; Hallucination, Auditory; Loss Of Employment; Major Depression; Paranoia; Psychotic Disorder	Escitalopram Oxalate			S	Oral	10 Mg Od - Oral		Not Reported
	Glimepiride			C				Not Reported
	Quinapril			C				Not Reported
	Carvedilol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2007	6339809	DIRECT	N	DE			14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Completed Suicide; Condition Aggravated; Depression; Irritability; Panic Attack	Depakote			S	Oral	2 A Day Po		Not Reported
	Lexapro			S	Oral	1 A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2007	6317326	EXPEDITED (15-DAY)	Y	OT	CH-JNJFOC-20070503161		45 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Neutropenia	Risperdal			S				Not Reported
	Risperdal			S				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Pipamperone			C	Oral			Not Reported
	Pipamperone			C	Oral			Not Reported
	Glucophage			C	Oral			Not Reported

	Glucophage	C	Oral	Not Reported
	Glucophage	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2007	6331884	EXPEDITED (15-DAY)	Y	DE	S07-SWI-02228-01			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2007	6339367	EXPEDITED (15-DAY)	Y	OT	S07-USA-02339-01		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased; White Blood Cell Count Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2007	6339391	EXPEDITED (15-DAY)	Y	OT	S07-USA-02466-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Homicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2007	6340572	EXPEDITED (15-DAY)	Y	OT	S07-CAN-02503-01		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Choking; Depersonalisation/Dereali sation Disorder; Salivary Hypersecretion	Cipralex		S	Oral	10 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2007	6340577	EXPEDITED (15-DAY)	Y	DE	S07-CAN-02490-01		44 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Completed Suicide; Impulsive Behaviour; Insomnia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Imovane (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2007	6626006	EXPEDITED (15-DAY)	Y	HO	S07-FRA-02491-01		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Screen Positive; Serotonin Syndrome	Escitalopram Oxalate			S				Not Reported
	Tramadol Hydrochloride And Acetaminophen			S				Not Reported
	Xanax			C				Not Reported
	Voltaren			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2007	6306415	EXPEDITED (15-DAY)	N	OT	S07-USA-01141-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Disturbance In Attention; Dizziness; Drug Withdrawal Syndrome; Emotional Disorder; Heart Rate Increased; Increased Appetite; Libido Decreased; Palpitations; Paraesthesia; Tremor; Weight Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qod Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Xanax			C				Not Reported

	Lexapro Oral Solution (Escitalopram)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2007	6325710	EXPEDITED (15-DAY)	Y	OT	S07-USA-02005-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Self-Medication; Suicide Attempt	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2007	7385679	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2007046318		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bipolar Disorder; Disorientation; Emotional Distress; Hallucination; Movement Disorder; Nausea; Overdose	Zoloft			S				Not Reported
	Chantix			S				Not Reported
	Lexapro			S				Not Reported
	Prempro			C				Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2007	6336833	EXPEDITED (15-DAY)	Y	LT	S07-NLD-02414-01		35 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dystonia; Facial Paresis; Sinusitis	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2007	6339403	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Product Dispensing Error	Lexapro			S		Tablet		Forest
	Lexapro			S		Tablet		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2007	6343653	EXPEDITED (15-DAY)	Y	HO	6034371		78 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Asthenia; Dilatation Atrial; General Physical Health Deterioration; Hypervolaemia; Hypochloraemia; Hypokalaemia; Hyponatraemia; Hypovolaemia; Mitral Valve Incompetence; Myocardial Strain; Nausea; Orthostatic Intolerance	Bisoprolol Fumarate			S	Oral	12, 5000 Mg (12, 5 Mg, 1 In 1 D), Oral		Not Reported
	Torasem			S	Oral	5,00 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Indapamide\Perindopril Erbumine			S	Oral	0,6250 Mg (0, 625 Mg, 1 In 1 D), Oral		Not Reported
	Cipralex			S	Oral	Oral	2 DAY	Not Reported
	Metamucil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2007	6325370	EXPEDITED (15-DAY)	Y	HO	S07-SWI-02038-01		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akinesia; C-Reactive Protein Increased; Chills; Extrapyramidal Disorder; Facial Paralysis; Loss Of Consciousness; Product Prescribing Error	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			S	Oral	25 Mg Qd Po		Not Reported
	Trittico (Trazodone)			S	Oral	100 Mg Qd Po		Not Reported
	Risperdal			S	Oral	2 Mg Tid Po		Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2007	6303484	EXPEDITED (15-DAY)	Y	HO	S07-ISR-01602-01		31 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Delusion; Psychotic	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Risperdal			C				Not Reported

Disorder	Fluphenazine Decanoate	C	Not Reported
	Dekinet (Biperiden Hydrochloride)	C	Not Reported
	Glucopahge (Metformin)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2007	6347170	DIRECT	Y	HO			64 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation; Delusion; Economic Problem; Fear; Hallucination; Hallucination, Auditory; Major Depression; Paranoia; Psychotic Disorder; Unemployment	Escitalopram Oxalate			S	Oral	10 Mg Od - Oral		Not Reported
	Glimepiride			C				Not Reported
	Quinapril			C				Not Reported
	Carvedilol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2007	6347705	EXPEDITED (15-DAY)	N	OT	S07-USA-02540-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive; Impaired Driving Ability; Legal Problem; Loss Of Employment	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2007	5930133	EXPEDITED (15-DAY)	Y	DS, LT, OT	S05-BEL-04979-01		60 YR	Female	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Carotid Artery Occlusion; Carotid Artery Stenosis; Hemiparesis; Hypertension; Ischaemic	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Enoxaparin Sodium			C				Not Reported
	Rosuvastatine (Rosuvastatin)			C				Not Reported
	Pantoprazole Sodium			C				Not Reported

Cerebral Infarction; Malaise; Respiratory Arrest; Syncope	Enoxaparin Sodium			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2007	6340604	EXPEDITED (15-DAY)		HO	US-ROXANE LABORATORIES, INC-2007-DE-03406GD		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Mirtazapine			S			3 DAY	Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Lamotrigine			S				Not Reported
	Venlafaxine Hydrochloride			S				Not Reported
	Gabapentin			S			3 DAY	Not Reported
	Escitalopram Oxalate			S			2 DAY	Not Reported
	Methylphenidate Hydrochloride			S			1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2007	6347957	EXPEDITED (15-DAY)	N	CA	S07-USA-02549-02			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Intellectual Disability; Maternal Exposure During Pregnancy	Lexapro			S				Not Reported
	Oxycodone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2007	6348252	EXPEDITED (15-DAY)	Y	HO	S07-FRA-02579-01		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Nervous System Disorder; Seizure	Escitalopram Oxalate			S	Oral	Tablet Unk Po		Not Reported
	Gemzar			C				Not Reported
	Taxol			C				Not Reported
	Tareg			C				Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2007	6350070	EXPEDITED (15-DAY)	Y	OT	S07-USA-02568-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Road Traffic Accident	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2007	6348323	DIRECT	N	LT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Myocardial Infarction; Nervousness	Lexapro			S	Oral	10 Mg 1 Tablet Per Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2007	6349960	EXPEDITED (15-DAY)	Y	OT	S07-USA-02521-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinson'S Disease	Lexapro			S				Not Reported
	Welbutrin (Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2007	6329303	EXPEDITED (15-DAY)	Y	HO	S07-FRA-02164-01		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Asthenia; Blood Calcium Decreased; Blood Chloride Decreased; Blood Pressure Increased; Body Temperature Decreased; C-Reactive Protein Increased; Creatinine Renal	Escitalopram Oxalate			S	Oral	0.5 Units Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	1.5 Units Qd Po		Not Reported
	Lexomil (Bromazepam)			C				Not Reported
	Fludex (Indapamide)			C				Not Reported
	Ossopan (Durapatite)			C				Not Reported
	Teveten			C				Not Reported

Clearance Decreased; Dyskinesia; Fall; Hyponatraemia; Loss Of Consciousness; Medication Error; Urine Potassium Decreased; Urine Sodium Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2007	6336378	EXPEDITED (15-DAY)	Y	HO	S07-FRA-02359-01		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Confusional State; Hyponatraemia; Loss Of Consciousness; Malaise; Seizure	Escitalopram Oxalate			S				Not Reported
	Atenolol			S				Not Reported
	Lormetazepam			S	Oral	2 Mg Qd Po		Not Reported
	Amlodipine Besylate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2007	6314050	EXPEDITED (15-DAY)	Y	CA	S06-USA-05333-02		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect; Maternal Exposure During Pregnancy; Trisomy 21	Lexapro			S	Transplacental	10 Mg Qd; Transplacental		Not Reported
	Prenatal Vitamin (Nos)			C				Not Reported
	Levoxyl			C				Not Reported
	Rhogam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2007	6343828	EXPEDITED (15-DAY)	N	OT	HQWYE696119JUN07		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hypersensitivity; Pharyngeal Oedema; Swelling Face	Advil			S	Unknown	Unknown		Wyeth
	Aleve			S	Unknown	Unknown		Procter And Gamble
	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2007	6351767	EXPEDITED (15-DAY)	Y	HO	S07-USA-02714-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dizziness; Dyspnoea; Headache; Nausea; Psychotic Disorder; Throat Tightness	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2007	6353024	DIRECT	N	OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Dissociation; Disturbance In Attention; Feeling Abnormal; Impaired Work Ability; Paraesthesia	Lexapro			S		5 Mg 1 Time Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2007	6340974	EXPEDITED (15-DAY)	Y	HO	S07-FRA-02492-01			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Anticoagulant Cit Pros Dex Adenine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2007	6354618	EXPEDITED (15-DAY)	N	OT	S07-USA-02674-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Interaction; Nausea; Retching	Lexapro			S				Not Reported
	Nicotrol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2007	6320314	EXPEDITED (15-DAY)	Y	OT	S07-USA-01860-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Condition Aggravated; Depression; Gun Shot Wound; Intentional Self-Injury	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Cymbalta			S	Oral	60 Mg Po		Not Reported
	Effexor			S				Not Reported
	Xanax			S				Not Reported
	Effexor			S		300 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2007	6328580	EXPEDITED (15-DAY)	Y	OT	S07-NLD-02014-01		22 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Dizziness; Feeling Abnormal; Gastrointestinal Haemorrhage; Hyperhidrosis; Nausea; Tremor; Visual Impairment	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ibuprofen			C				Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2007	6332754	EXPEDITED (15-DAY)	Y	HO	S07-USA-02306-01		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Emotional Distress; Fatigue; Malaise; Seizure; Stress	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2007	6127072	EXPEDITED (15-DAY)	Y	OT	S06-UKI-03379-01		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glossodynia	Escitalopram Oxalate			S	Oral	10 Mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2007	6325378	EXPEDITED (15-DAY)	Y	HO	S07-FRA-01919-01		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Thrombophlebitis	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	40 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	30 Mg Qd Po		Not Reported
	Lorazepam			C				Not Reported
	Imovane (Zopiclone)			C				Not Reported
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2007	6331550	EXPEDITED (15-DAY)	Y	HO	S07-FRA-02226-01		33 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention; Urinary Tract Disorder	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Tranxene T-Tab			C				Not Reported
	Trileptal			C				Not Reported
	Lexomil (Bromazepam)			C				Not Reported
	Polyethylene Glycols			C				Not Reported
	Daflon (Diosmin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2007	6357638	EXPEDITED (15-DAY)	N	DE	S07-USA-02804-01		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Asphyxia; Completed Suicide; Depressed Mood;	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported

Hostility

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2007	6357643	EXPEDITED (15-DAY)	Y	DE	S07-USA-02764-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Lexapro			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2007	6357645	EXPEDITED (15-DAY)	N	HO	S07-USA-02819-01		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Dehydration; Urinary Tract Infection	Lexapro			S	Oral	20 Mg Qd; Po		Not Reported
	Namenda			C				Not Reported
	Aricept			C				Not Reported
	Fosamax			C				Not Reported
	Flecainide			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2007	6357647	EXPEDITED (15-DAY)	Y	OT	S07-USA-02772-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Seizure	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2007	6352986	EXPEDITED (15-DAY)	Y	HO	S07-FRA-02699-01		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fatigue; Inappropriate Antidiuretic Hormone	Escitalopram Oxalate			S		10 Mg Qd		Not Reported
	Motilium			C				Not Reported

Secretion; Nausea

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2007	6330702	EXPEDITED (15-DAY)	Y	HO	S07-USA-02090-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Breech Presentation; Caesarean Section; Eating Disorder; Insomnia; Maternal Exposure During Pregnancy; Pregnancy; Premature Labour; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prenatal Vitamins (Nos)			C				Not Reported
	Ambien			C				Not Reported
	Fioricet (Butalbital/Acetaminophen/Caffeine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2007	6330735	EXPEDITED (15-DAY)	Y	OT	S07-USA-02090-02		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Breech Presentation; Caesarean Section; Maternal Exposure During Pregnancy; Premature Baby	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Prenatal Vitamin (Nos)			C				Not Reported
	Ambien			C				Not Reported
	Fioricet (Butalbital/Acetaminophen/Caffeine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2007	6348438	EXPEDITED (15-DAY)	N	HO, OT	B0477468A		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Electrocardiogram Qt Prolonged; Intentional Overdose; Myoclonus; Pneumonia; Pyrexia;	Lamotrigine			S	Oral			Glaxosmithkline
	Escitalopram Oxalate			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported

Serotonin Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2007	6353210	EXPEDITED (15-DAY)	Y	OT	US-ROCHE-504894		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Brain Neoplasm; Dizziness; Drug Ineffective; Drug Intolerance; Fall	Valium			S	Unknown			Roche
	Klonopin			S	Unknown			Roche
	Diazepam			S	Unknown		3 MTH	Roche
	Lexapro			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Geodon			S	Unknown			Not Reported
	Ativan			S	Unknown			Not Reported
	Xanax			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Zonisamide			S	Unknown			Not Reported
	Zonisamide			S	Unknown	Dose Adjusted		Not Reported
	Lipitor			C				Not Reported
	Prozac			C				Not Reported
	Unspecified Ingredient			C		Reported As "Pain Medication"		Not Reported
	Lopresor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2007	6354335	EXPEDITED (15-DAY)	Y	HO	163-20785-07060907		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Ischaemia; Chest Pain; Colitis; Device Related Infection; Febrile Neutropenia; Haemoglobin Decreased; Hypersomnia; Hypotension; Muscular	Thalomid			S	Oral	100 Mg, Qd; Oral		Not Reported
	Dexamethasone (Dexamethasone)			S	Oral	40 Mg, Oral		Not Reported
	Velcade			S	Intravenous (not otherwise specified)	1 Mg/M2; Intravenous		Not Reported

Weakness; Nuclear Magnetic Resonance Imaging Brain Abnormal; Parainfluenzae Virus Infection; Pneumonia; Sinusitis; Streptococcal Infection; Tachycardia	Cisplatin	S	Intravenous (not otherwise specified)	10 Mg/M2, Intravenous	Not Reported
	Adriamycin	S	Intravenous (not otherwise specified)	10 Mg/M2, Intravenous	Not Reported
	Cyclophosphamide (Cyclophosphamide)	S	Intravenous (not otherwise specified)	400 Mg/M2; Intravenous	Not Reported
	Etoposide (Etoposide)	S	Intravenous (not otherwise specified)	40 Mg/M2, Intravenous	Not Reported
	Melphalan	S		200 Mg/M2;	Not Reported
	Ambien	S	Oral	5 Mg, Qhs; Oral	Not Reported
	Lexapro	S	Oral	20 Mg, Oral	Not Reported
	Acyclovir	C			Not Reported
	Folic Acid	C			Not Reported
	Levaquin	C			Not Reported
	Famotidine (Famotidine)	C			Not Reported
	Heparin	C			Not Reported
	Flagyl	C			Not Reported
	Imodium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2007	6359568	EXPEDITED (15-DAY)	Y	DE	S07-NOR-02886-01		51 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2007	6359748	EXPEDITED (15-DAY)	Y	OT	S07-FRA-02775-01		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Road Traffic Accident; Transaminases Increased	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Prazepam			C				Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2007	6366585	EXPEDITED (15-DAY)	N	DE, HO	2007SI001632		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Completed Suicide; Cystitis; Decreased Appetite; Dyspnoea; Ear Discomfort; Ear Haemorrhage; General Physical Health Deterioration; Hypoaesthesia; Injury; Insomnia; Intervertebral Disc Degeneration; Lethargy; Musculoskeletal Stiffness; Nervousness; Paraesthesia; Restlessness; Throat Irritation	Diazepam			S	Oral	5 Mg; 3 Times A Day; Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported
	Paxil			S	Oral	See Image		Not Reported
	Risperdal			S	Oral	0.5 Mg; 3 Times A Day; Oral		Not Reported
	Paxil Cr			S	Oral	See Image		Not Reported
	Gabapentin			S	Oral	300 Mg; At Bedtime; Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2007	6381123	NON-EXPEDITED	Y	HO	US-2006-033668		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foot Fracture; Pulmonary Embolism	Yasmin			S	Oral	1 Tab(S), 1x/Day, Oral		Not Reported
	Lexapro			S	Oral Oral	See Image See Image		Not Reported
	Abilify			C				Not Reported
	Carbatrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2007	6317210	EXPEDITED (15-DAY)	Y	DS, OT	S07-UKI-01809-01		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Anxiety; Balance Disorder; Dysarthria; Euphoric Mood; Hallucination; Muscle Twitching; Self-Injurious Ideation; Suicidal Ideation; Suicide Attempt	Cipralex	S	Oral	10 Mg Qd; Po		Not Reported
	Propranolol	C				Not Reported
	Zopiclone	C				Not Reported
	Diazepam	C				Not Reported
	Citalopram	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2007	6356495	EXPEDITED (15-DAY)	Y	LT	GB-AVENTIS-200713346EU		56 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension; Intentional Overdose; Somnolence	Frusemide			S				Aventis
	Bisoprolol			S				Not Reported
	Amlodipine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Gtn Spray			C		Dose: 1-2 Puffs		Not Reported
	Nicorandil			C				Not Reported
	Bendroflumethiazide			C				Not Reported
	Ibersartan			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Betahistine			C				Not Reported
	Gabapentin			C				Not Reported
	Dipyridamole Mr			C				Not Reported
	Aspirin			C				Not Reported
	Thiamine			C				Not Reported
	Ranitidine			C				Not Reported
	Rosuvastatin			C				Not Reported
	Insulin Aspart			C		Dose: 58/28		Not Reported
	Hydralazine			C				Not Reported
	Clopidogrel			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2007	6389181	NON-EXPEDITED	N		2007SP001372		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Insomnia	Lunesta		S	Oral	2 Mg;Hs;Oral	Not Reported
	Lexapro		S	Oral	10 Mg;Qd;Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2007	6329276	EXPEDITED (15-DAY)	Y	OT	S07-GER-02132-01			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Transient; Eye Haemorrhage	Escitalopram Oxalate			S		20 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2007	6353939	EXPEDITED (15-DAY)	Y	HO	S07-FRA-02700-01		55 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Toxic Skin Eruption	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported
	Loxapac (Loxapine Succinate)			S	Oral	50 Mg Qd Po		Not Reported
	Loxapac (Loxapine Succinate)			S	Oral	100 Mg Qd Po		Not Reported
	Loxapac (Loxapine Succinate)			S	Oral	150mg Qd Po		Not Reported
	Loxapac (Loxapine Succinate)			S	Intramuscular	100 Mg Qd Im		Not Reported
	Trihexyphenidyl Hydrochloride			S	Oral	5 Mg Bid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2007	6361743	DIRECT	Y	CA				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder; Cleft Lip And Palate; Congenital Anomaly; Maternal Exposure During Pregnancy	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2007	6366019	EXPEDITED (15-DAY)	Y	HO	S07-USA-02902-01		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Glucose Increased; Blood Potassium Decreased; Blood Pressure Increased; Dehydration; Hypophagia; Inappropriate Antidiuretic Hormone Secretion; Pain	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lisinopril And Hydrochlorothiazide			S	Oral	20 Mg Qd Po		Not Reported
	Metoprolol			C				Not Reported
	Glyburide			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2007	6366036	EXPEDITED (15-DAY)	Y	OT	S07-GER-02997-01		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Escitalopram Oxalate			S	Oral	10 Mg Qd; Po		Not Reported
	Sertraline			S	Oral	150 Mg Qd; Po		Not Reported
	Clozapine			C				Not Reported
	Valproate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2007	6346699	EXPEDITED (15-DAY)	Y	DS, HO, OT	L07-CAN-02608-01		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Eye Pain; Insomnia; Intentional Overdose; Photophobia; Photosensitivity Reaction; Suicidal Ideation; Tearfulness; Vision Blurred; Visual Acuity Reduced	Cipralex			S		10 Mg Qd		Not Reported
	Cipralex			S		10 Mg Qd		Not Reported
	Zopiclone			S	Oral	7.5 Mg Qhs Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2007	6367232	EXPEDITED (15-DAY)	Y	DS	S07-NLD-03066-01		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Muscle Rigidity; Muscular Weakness; Pain In Extremity	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qod Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2007	6374590	EXPEDITED (15-DAY)	Y	CA	S07-USA-03018-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Maternal Exposure During Pregnancy	Lexapro			S	Transdermal	30 Mg Qd Transdermal		Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2007	7021337	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20070703871		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Fall	Tavanic			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Tropatepine Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported
	Tramadol Hydrochloride			S	Oral			Not Reported
	Furosemide			C	Unknown			Not Reported
	Forlax			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2007	6306621	EXPEDITED (15-DAY)	Y	OT	S07-USA-01615-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Electroencephalogram Abnormal; Loss Of Consciousness; Petit Mal Epilepsy; Tremor	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2007	6309848	EXPEDITED (15-DAY)	Y	HO	B0470111A		71 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Mobility Decreased	Lithium Carbonate			S	Oral			Glaxosmithkline
	Risperdal			S	Oral		25 DAY	Not Reported
	Cipralex			S	Oral			Not Reported
	Aricept			S	Oral			Not Reported
	Abilify			C	Oral	5mg Per Day		Not Reported
	Cymbalta			C	Oral			Not Reported
	Edronax			C	Oral			Not Reported
	Rivotril			C	Oral			Not Reported
	Cerebrolysin			C	Intravenous (not otherwise specified)	1amp Per Day	10 DAY	Not Reported
	Nexium			C	Oral	20mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2007	6310402	EXPEDITED (15-DAY)	Y	HO	S07-USA-01719-01		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness;	Lexapro			S	Oral	20 Mg Qd; Po		Not Reported

Hyperhidrosis; Musculoskeletal Pain; Pain; Splenic Haemorrhage	Lexapro	S	Oral	20 Mg, Qd; Po		Not Reported
	Protonix	C				Not Reported
	Synthroid	C				Not Reported
	Benicar	C				Not Reported
	Multivitamin (Nos)	C				Not Reported
	Calcium + Vitamin D	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2007	6349822	EXPEDITED (15-DAY)	Y	HO	B0477676A		71 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysstasia; Eating Disorder; Extrapyramidal Disorder; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Parkinsonism; Salivary Hypersecretion	Lithium Carbonate			S	Oral			Glaxosmithkline
	Cipralex			S	Oral			Not Reported
	Nexium			S	Oral	20mg Per Day		Not Reported
	Risperdal			S	Oral			Not Reported
	Aricept			S	Oral	5mg Per Day	11 DAY	Not Reported
	Rivotril			C	Oral	1mg Per Day		Not Reported
	Rivotril			C	Oral	1.5mg Per Day	6 DAY	Not Reported
	Rivotril			C	Oral	1.25mg Per Day		Not Reported
	Rivotril			C	Oral	1mg Per Day	6 DAY	Not Reported
	Rivotril			C	Oral			Not Reported
	Abilify			C	Oral	5mg Per Day		Not Reported
	Cymbalta			C	Oral			Not Reported
	Edronax			C	Oral			Not Reported
	Cerebrolysin			C	Intravenous (not otherwise specified)	1amp Per Day	10 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2007	6369579	EXPEDITED (15-DAY)	N	DE	S07-USA-03081-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Depressed Mood; Depression; Drowning; Drug Ineffective; Suicidal Ideation	Lexapro		S	Oral	10 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2007	6371132	EXPEDITED (15-DAY)	Y	OT	S07-SWI-03109-01		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Levomepromazine			S	Oral	12 Drops Qd Po		Not Reported
	Valproic Acid			S	Oral	300 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2007	6371140	EXPEDITED (15-DAY)	Y	OT	S07-IRL-03110-01			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Self-Injurious Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2007	6329218	EXPEDITED (15-DAY)	Y	DS, HO, LT	S07-ITA-02143-01		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Fall; Haematoma; Humerus Fracture; Hyponatraemia; Loss Of Consciousness	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2007	6349416	EXPEDITED (15-DAY)	Y	HO	S07-FRA-02663-01		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Loss Of Consciousness; Seizure	Escitalopram Oxalate		S	Oral	10 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2007	6303336	EXPEDITED (15-DAY)	Y	DE	S07-GER-01407-01		75 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Fall	Escitalopram Oxalate			S		10 Mg Qd		Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2007	6374166	EXPEDITED (15-DAY)	N	OT	S07-USA-03069-01		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Change; Heart Rate Decreased; Hyperhidrosis; Palpitations; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2007	6375456	DIRECT	Y	LT, OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Withdrawal Syndrome; Gait Disturbance; Headache; Heart Rate Increased; Hyperhidrosis; Impaired Driving Ability; Impaired Work Ability; Medication Error; Muscular Weakness; Nausea; Paranoia; Product Dispensing Error; Product Dose Omission; Suicidal Ideation; Vomiting	Lexapro			S	Oral	20 Mg Qam Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2007	6375575	DIRECT	N	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Cardiometabolic Syndrome; Hypertension; Insulin Resistance; Weight Decreased; Weight Loss Poor	Lexapro			S	Oral	10mg Once Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2007	6355058	EXPEDITED (15-DAY)	Y	OT	S07-USA-02689-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Confusional State; Coordination Abnormal; Depression; Drug Ineffective; Drug Interaction; Extrapyramidal Disorder; Fall; Gait Disturbance; Mania; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Geodon			S		40 Mg Bid		Not Reported
	Geodon			S		40 Mg Qd		Not Reported
	Stelazine			S				Not Reported
	Lamictal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2007	6365966	EXPEDITED (15-DAY)	Y	HO	S07-AUS-02906-01		76 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Status Epilepticus	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Espiride (Sulpiride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2007	6446315	NON-EXPEDITED	N	OT	233923		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Rituxan			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Lexapro			S	Oral	10mg, Qd, Oral		Not Reported
	Levaquin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2007	5787807	EXPEDITED (15-DAY)	Y	HO	S05-USA-01946-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma; Blood Albumin Decreased; Central Nervous System Lymphoma; Confusional State; Drug Ineffective; Dyspnoea; Musculoskeletal Stiffness; Myoglobin Blood Increased; Neurotoxicity; Seizure; Somnolence; Unresponsive To Stimuli	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ferrous Sulfate			C				Not Reported
	Multivitamins			C				Not Reported
	Calcium With Vitamin D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2007	6219309	EXPEDITED (15-DAY)	N	OT	S06-USA-05450-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Abnormal Dreams; Amnesia; Chest Discomfort; Colitis; Condition Aggravated; Depression; Obsessive-Compulsive Disorder	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Imodium			C				Not Reported
	Klonopin			C				Not Reported
	Multivitamin (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2007	6376882	EXPEDITED (15-DAY)	Y	OT	S07-USA-03096-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2007	6377305	EXPEDITED (15-DAY)	Y	HO	S07-FRA-03196-01		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Major Depression; Wound	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Seropram (Citalopram Hydrobromide)			S				Not Reported
	Alprazolam			C				Not Reported
	Athymil (Mianserin Hydrochloride)			C				Not Reported
	Tranxene T-Tab			C				Not Reported
	Cyamemazine			C				Not Reported
	Orocal (Calcium Carbonate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2007	6377747	DIRECT	N	LT, RI			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Osteoporosis; Pain; Product Quality Issue; Thoracic Vertebral Fracture	Lexapro			S	Oral	20mgs Daily Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2007	6377758	DIRECT		DE			27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2007	6378769	DIRECT	Y	DS			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Escitalopram Oxalate			S	Oral	10mg Qam Po		Not Reported
	Hydroxyurea			C				Not Reported
	Lorezapam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2007	6378882	DIRECT	N	HO, OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anorgasmia; Anxiety; Chills; Condition Aggravated; Crying; Depression; Diarrhoea; Dizziness; Drug Withdrawal Syndrome; Furuncle; Hot Flush; Hyperhidrosis; Irritability; Libido Decreased; Myalgia; Nausea; Restless Legs Syndrome; Tremor; Vision Blurred; Visual Impairment; Weight Increased	Lexapro			S	Oral	10mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2007	6379694	EXPEDITED (15-DAY)	Y	DS	S07-UKI-03234-01		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Derealisation; Dysgeusia; Insomnia; Movement Disorder; Panic Attack; Suicidal Ideation;	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

Tearfulness	Amitriptyline	C	Not Reported
	Diazepam	C	Not Reported
	Dosulepin	C	Not Reported
	Zopiclone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2007	6321098	EXPEDITED (15-DAY)	N	HO	S07-USA-01882-01		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Amnesia; Anion Gap Increased; Aspartate Aminotransferase Increased; Asthenia; Base Excess Decreased; Blood Bicarbonate Decreased; Blood Chloride Decreased; Blood Creatinine Increased; Blood Glucose Increased; Blood Osmolarity Decreased; Blood Pressure Systolic Increased; Blood Thyroid Stimulating Hormone Decreased; Body Temperature Decreased; Carbon Dioxide Decreased; Coma; Confusional State; Discomfort; Dizziness; Fall; Feeling Abnormal; Gliosis; Hyponatraemia; Hypoxia; Loss Of Consciousness; Nightmare; Panic Attack; Pco2 Decreased; Postictal State; Road Traffic Accident; Seizure; Speech	Lexapro			S	Oral	20 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 M G Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Zocor			S		40 Mg Qd		Not Reported
	Zocor			S		40 Mg Qd		Not Reported
	Coreg			C				Not Reported
	Xanax			C				Not Reported
	Buspar			C				Not Reported
	Seroquel			C				Not Reported

Disorder; Syncope;
Unevaluable Event;
Unresponsive To Stimuli;
Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2007	6380815	DIRECT	N	HO, LT			18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicide Attempt	Lexapro			S	Oral	5 Mg Daily Po	3 WEEK	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2007	6381035	EXPEDITED (15-DAY)	N	OT	S07-USA-03243-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Intervertebral Disc Degeneration; Osteoporosis; Thoracic Vertebral Fracture	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Methadone Hydrochloride			C				Not Reported
	Provigil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2007	5825486	EXPEDITED (15-DAY)	Y	HO	HQWYE032031MAY05		68 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level Increased; Drug Interaction; Hyponatraemia	Cipralex			S			9 DAY	Lundbeck
	Acetylsalicylic Acid			C	Oral			Unknown
	Venlafaxine Hydrochloride			S	Oral		3 DAY	Wyeth
	Venlafaxine Hydrochloride			S	Oral		1 DAY	Wyeth
	Selokeen			S	Oral			Astrazeneca
	Tegretol			S	Oral		15 DAY	Novartis
	Tegretol			S	Oral		5 DAY	Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2007	6321673	EXPEDITED (15-DAY)	Y	DE	S07-UKI-02019-01			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2007	6332546	EXPEDITED (15-DAY)	Y	OT	FR-PFIZER INC-2007046766		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Interaction; Ecchymosis	Champix			S	Oral			Not Reported
	Doliprane			C	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2007	6381281	DIRECT	Y	HO			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Withdrawal Syndrome; Hypophagia	Lexapro			S	Oral	20 Mg Daily Po	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2007	6382290	EXPEDITED (15-DAY)	Y	LT	GXKR2007GB06442		56 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension; Intentional Overdose; Somnolence	Amlodipine			S		10 Mg,		Not Reported
	Bisoprolol Fumarate			S		5 Mg,		Not Reported
	Furosemide			S				Not Reported
	Escitalopram Oxalate			S		20 Mg,		Not Reported
	Aspirin			C				Not Reported

	Bendrofluazide (Bendroflumethiazide)	C	Not Reported
	Betahistine (Betahistine)	C	Not Reported
	Clopidogrel	C	Not Reported
	Dipyridamole	C	Not Reported
	Gabapentin	C	Not Reported
	Glyceryl Trinitrate (Glyceryl Trinitrate)	C	Not Reported
	Hydralazine Hydrochloride	C	Not Reported
	Irbesartan	C	Not Reported
	Isosorbide Mononitrate	C	Not Reported
	Nicorandil (Nicorandil)	C	Not Reported
	Novomix (Insulin Aspart)	C	Not Reported
	Ranitidine	C	Not Reported
	Rosuvastatin (Rosuvastatin)	C	Not Reported
	Thiamine (Thiamine)	C	Not Reported
	Zopiclone (Zopiclone)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2007	6382835	DIRECT	Y	HO			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinson'S Disease	Lexapro			S	Oral	10 Mg Daily Po	3 MTH	Not Reported
	Seroquel			S	Oral	25 Mg Twice Daily Po	3 WEEK	Not Reported
	Toprol Xl			C				Not Reported
	Lipitor			C				Not Reported
	Aspirin			C				Not Reported
	Avapro			C				Not Reported
	Aricept			C				Not Reported
	Lexapro			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2007	6336957	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2007047955		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Fatigue;	Chantix			S	Oral			Not Reported

Nausea; Somnolence; Weight Increased	Vytorin	C		Not Reported
	Metformin Hydrochloride	C		Not Reported
	Niacin	C		Not Reported
	Lisinopril	C		Not Reported
	Chantix	S		Not Reported
	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2007	6317288	EXPEDITED (15-DAY)	Y	DE	S07-USA-01796-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported
	Buspar			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2007	6359910	EXPEDITED (15-DAY)	N	DE	S07-USA-02875-01		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective; Gun Shot Wound; Social Avoidant Behaviour	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Zocor			C				Not Reported
	Avodart			C				Not Reported
	Flomax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2007	6384905	DIRECT	N	HO, LT, OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Suicidal Ideation	Zoloft 100mg			S	Oral	100mg Daily Po		Not Reported
	Lexapro			S	Oral	10mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2007	6393455	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy; Rubella Antibody Positive	Escitalopram Oxalate			S	Oral	10 Mg Qd - Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2007	6379885	NON-EXPEDITED	N		A0644135A		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive	Paxil			S	Unknown			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2007	6379969	NON-EXPEDITED	N		A0651076A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Diarrhoea; Dizziness; Drug Withdrawal Syndrome; Headache; Hyperhidrosis; Nausea	Paxil			S	Oral		15 YR	Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2007	6380696	EXPEDITED (15-DAY)		HO	IN-ROXANE LABORATORIES, INC-2007-BP-18627RO		16 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urea Increased; Catatonia; Dehydration;	Lithium Carbonate			S			5 MTH	Roxane

Mania; Toxicity To Various Agents; White Blood Cell Count Increased	Olanzapine	S	Not Reported
	Escitalopram Oxalate	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2007	6353188	EXPEDITED (15-DAY)	Y	HO, OT	157766ISR		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Electrocardiogram Qt Prolonged; Intentional Overdose; Myoclonus; Pneumonia; Serotonin Syndrome	Lamotrigine			S	Oral	Oral		Not Reported
	Zopiclone			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Olanzapine			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2007	6378154	EXPEDITED (15-DAY)	Y	DE	S07-FIN-03231-01		73 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Emconcor (Bisoprolol)			C				Not Reported
	Pravachol			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Renitex (Enalapril Maleate)			C				Not Reported
	Furosemide			C				Not Reported
	Primperan			C				Not Reported
	Nasacort			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2007	6387245	EXPEDITED (15-DAY)	Y	LT	6036362		56 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension; Intentional Overdose; Somnolence	Bisoprolol Fumarate			S		(5 Mg)		Not Reported
	Amlodipine			S		(10 Mg)		Not Reported

Escitalopram Oxalate	S	(20 Mg)	Not Reported
Frusemide	S		Not Reported
Aspirin (Acetylsalicylic Acid)	C		Not Reported
Bendroflumethiazide (Bendroflumethiazide)	C		Not Reported
Betahistine (Betahistine)	C		Not Reported
Clopidogrel	C		Not Reported
Dipyridamole	C		Not Reported
Gabapentin (Gabapentin)	C		Not Reported
Glyceryl Trinitrate (Glyceryl Trinitrate)	C		Not Reported
Hydralazine (Hydralazine)	C		Not Reported
Irbesartan	C		Not Reported
Isosorbide Mononitrate	C		Not Reported
Nicorandil	C		Not Reported
Novomix (Insulin Aspart)	C		Not Reported
Ranitidine	C		Not Reported
Rosuvastatin (Rosuvastatin)	C		Not Reported
Thiamine (Thiamine)	C		Not Reported
Zopiclone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2007	6388339	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate			S	Oral	10 Mg Qd - Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2007	6388419	DIRECT	Y	HO, LT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome; Therapy Non-Responder; Toxic Epidermal Necrolysis	Dapsone			S	Oral	Dapsone Daily Po		Not Reported
	Lexapro			S	Oral	Lexapro Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2007	6397764	DIRECT	Y	HO			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation; Delusion; Hallucination, Auditory; Loss Of Employment; Major Depression; Paranoia; Psychotic Disorder	Escitalopram Oxalate			S	Oral	10 Mg Od - Oral		Not Reported
	Glimepiride			C				Not Reported
	Quinapril			C				Not Reported
	Carvedilol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2007	6339385	EXPEDITED (15-DAY)	Y	DE	S07-USA-02438-01		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lodine			C				Not Reported
	Nasonex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2007	6367750	EXPEDITED (15-DAY)	N	HO	B0479582A		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Loss Of Consciousness; Malaise; Urinary Incontinence	Deroxat			S	Oral	20mg Per Day	3 MTH	Glaxosmithkline
	Escitalopram Oxalate			S	Oral	10mg Twice Per Day	1 YR	Unknown
	Anafranil			S	Oral		3 YR	Unknown
	Metformin Hydrochloride			S	Oral	2000mg Per Day	5 MTH	Unknown
	Cozaar			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Benfluorex Hydrochloride			C				Not Reported
	Tahor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2007	6392202	DIRECT	Y	HO			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2007	6393335	EXPEDITED (15-DAY)	Y	HO	S07-FRA-03456-01		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2007	6367682	EXPEDITED (15-DAY)	Y	HO	L07-GER-03072-01		44 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate			S		30 Mg Qd		Not Reported
	Aripiprazole			S		15 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2007	6244259	EXPEDITED (15-DAY)	N	HO	S07-GER-00169-01			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia; Cognitive Disorder; Fluid Intake Reduced; Serotonin Syndrome; Speech Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Antabuse			S		500 Mg Qd		Not Reported
	Antabuse			S		100 Mg Qd		Not Reported
	Elmendos (Lamotrigine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2007	6367545	EXPEDITED (15-DAY)	N	OT	S07-USA-03039-01		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Dysgeusia; Headache; Panic Attack; Seizure; Sensory Disturbance	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2007	6390782	EXPEDITED (15-DAY)	Y	CA	CH-JNJFOC-20070803424		30 YR	Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital	Concerta			S				Not Reported
	Cipralex			S				Not Reported
	Zyprexa			S				Not Reported
	Methadone Hydrochloride			S	Oral			Not Reported
	Oxazepam			S				Not Reported
	Valium			S				Not Reported
	Valium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2007	6405932	EXPEDITED (15-DAY)	N	HO, OT	2007SP016762		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Condition Aggravated; Dehydration; Depression; Drug Ineffective; Dry Mouth; Dysgeusia; Headache; Influenza Like Illness; Insomnia; Nausea; Pneumonia; Seizure; Vomiting; White Blood Cell Count Decreased	Pegintron			S	Subcutaneous	Sc		Not Reported
	Ribavirin			S	Oral	Po		Not Reported
	Lexapro			S				Not Reported
	Percodan			C				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2007	6404761	DIRECT	N	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Gastrooesophageal Reflux Disease	Lexapro			S	Oral	10mg Once Daily Po	7 MTH	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2007	6295135	EXPEDITED (15-DAY)	Y	HO	S07-FRA-01446-01		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Haemoconcentration; Hyponatraemia; Loss Of Consciousness; Orthostatic Hypotension	Escitalopram Oxalate			S				Not Reported
	Bisoprolol Fumarate And Hydrochlorothiazide			S	Oral	5 Mg Qd Po		Not Reported
	Moxonidine			S	Oral	0.4 Mg Qd Po		Not Reported
	Olmetec			S	Oral	20 Mg Qd Po		Not Reported
	Lorazepam			S	Oral	1 Mg Qd Po		Not Reported
	Lansoprazole			S	Oral	30 Mg Qd Po		Not Reported
	Plavix			C				Not Reported
	Fenofibrate			C				Not Reported
	Flecainide Acetate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2007	6408240	EXPEDITED (15-DAY)	Y	HO	S07-FRA-03635-01		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Loss Of Consciousness; Malaise	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported
	Paroxetine Hydrochloride			S	Oral	20 Mg Qd Po		Not Reported
	Anafranil			S				Not Reported
	Metformin Hydrochloride			S	Oral	2000 Mg Qd Po		Not Reported
	Cozaar			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported

	Mediator(Benfluorex Hydrochloride)	C		Not Reported
	Atorvastatin Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2007	6410314	EXPEDITED (15-DAY)	Y	HO, OT	S07-UKI-03633-01		53 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Balance Disorder; Dizziness; Fatigue; Lethargy; Palpitations; Paraesthesia; Vision Blurred	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2007	6410539	EXPEDITED (15-DAY)	N	OT	S07-USA-03565-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Faeces Discoloured; Haematochezia; Nausea; Therapeutic Product Effect Decreased	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Levothyroxine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2007	6378036	EXPEDITED (15-DAY)	N	OT	S07-USA-03190-01		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cancer Pain; Confusional State; Drug Interaction; Dyspnoea; Lung Neoplasm Malignant	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lortab			S		5 Mg Qd		Not Reported
	Gemzar			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2007	6394997	NON-EXPEDITED	N		A0643963A		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction	Wellbutrin Xl			S	Oral	300mg In The Morning		Glaxosmithkline
	Lexapro			S	Oral	10mg At Night		Not Reported
	Seroquel			S	Oral	50mg At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2007	6395319	NON-EXPEDITED	N		A0664339A		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Disorder; Tremor	Wellbutrin Xl			S	Oral	150mg Per Day	2 WEEK	Glaxosmithkline
	Lexapro			S		10mg Per Day	8	Not Reported
	Norvasc			C				Not Reported
	Catapres-Tts			C				Not Reported
	Benicar			C				Not Reported
	Prempro			C				Not Reported
	Aciphex			C				Not Reported
	Potassium Chloride			C				Glaxosmithkline
	Lorazepam			C				Not Reported
	Multivitamins			C				Not Reported
	Folic Acid			C				Not Reported
	Biaxin			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2007	6395445	EXPEDITED (15-DAY)	Y	HO, LT	HQWYE756422AUG07		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Sodium Decreased; C-Reactive Protein Increased; Gamma-Glutamyltransferase	Inipomp			S	Oral		102 DAY	Wyeth
	Escitalopram Oxalate			S	Oral	1/Day 1 Df		Unknown
	Bactrim Forte			S	Oral	Df		Roche
	Oroken			S	Oral	1/Day 1 Df		Aventis
	Simvastatin			C	Oral	1/Day 40 Mg		Unknown
	Fludex (Indapamide)			C	Oral	1/Day 1.5 Mg		Not Reported

Increased; Serum Ferritin	Ramipril		C	Oral	1/Day 5 Mg	Not Reported
Increased; Toxic Epidermal Necrolysis	Hyperium		C	Oral	1/Day 1 Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2007	6411305	EXPEDITED (15-DAY)	Y	HO, LT	S07-FRA-03638-01		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Blood Chloride Decreased; Blood Osmolarity Decreased; Blood Potassium Decreased; Coma Scale Abnormal; Confusional State; Disorientation; Fall; General Physical Health Deterioration; Hyponatraemia; Malaise; Somnolence; Urine Osmolarity Increased	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Fludex (Indapamide)			S		1.5 Mg Qd		Not Reported
	Mopral (Omeprazole)			C				Not Reported
	Plavix			C				Not Reported
	Cozaar			C				Not Reported
	Pravastatin			C				Not Reported
	Propranolol			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2007	6411312	EXPEDITED (15-DAY)	Y	CA	S07-SWI-03636-01		30 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Heart Disease Congenital; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S	Oral	10 Mg Bid Po		Not Reported
	Concerta			S	Oral	54 Mg Qd Po		Not Reported
	Zyprexa			S	Oral	5 Mg Qd Po		Not Reported
	Methadone			S	Oral	25 Mg Qd Po		Not Reported
	Oxazepam			S	Oral	75 Mg Qd Po		Not Reported
	Valium			S	Oral	5 Mg Bid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2007	6412019	EXPEDITED (15-DAY)	Y	CA	S07-DEN-03637-02		365 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Maternal Exposure During Pregnancy	Cipralex			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Zyprexa			S	Transplacental	10 Mg Qd Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2007	6747157	NON-EXPEDITED	Y	OT	200713290US		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Tremor	Lasix			S				Not Reported
	Lasix			S			18 WEEK	Not Reported
	Lasix			S		20 Mg Qd		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Quinine			S				Not Reported
	Spironolactone			C				Not Reported
	Neomycin Sulfate			C				Not Reported
	Prevacid			C				Not Reported
	Magnesium			C				Not Reported
	Lactulose			C				Not Reported
	Oxazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2007	6405602	EXPEDITED (15-DAY)	Y	HO	AU-ASTRAZENECA-2007AP05360		82 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Hyponatraemia; Seizure	Nexium			S	Oral			Astrazeneca
	Escitalopram Oxalate			S	Oral		4 DAY	Not Reported
	Amiloride Hydrochloride\Hydrochlorothiazide			S	Oral			Not Reported
	Carbamazepine			S	Oral			Not Reported
	Lercanidipine Hydrochloride			C				Not Reported
	Prazosin Hydrochloride			C				Not Reported

	Isosorbide Mononitrate	C	Not Reported
	Simvastatin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2007	6391740	EXPEDITED (15-DAY)	Y	HO	S07-AUT-03434-01		28 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotonia; Syncope; Vertigo	Cipralex			S	Oral	10 Mg Qd; Po		Not Reported
	Cipralex			S	Oral	15 Mg Qd; Po		Not Reported
	Lorazepam			S	Oral	1.25 Mg Qd; Po		Not Reported
	Lorazepam			S	Oral	2.5 Mg Qd; Po		Not Reported
	Seroquel			S	Oral	500 Mg Qd; Po		Not Reported
	Seroquel			S	Oral	600 Mgqd; Po		Not Reported
	Seroquel			S	Oral	500 Mg Qd; Po		Not Reported
	Seroquel			S	Oral	400 Mg Qd; Po		Not Reported
	Seroquel			S	Oral	350 Mg Qd; Po		Not Reported
	Seroquel			S	Oral	300 Mg Qd; Po		Not Reported
	Seroquel			S	Oral	200 Mg Qd; Po		Not Reported
	Seroquel			S	Oral	100 Mg Qd;Po		Not Reported
	Seroquel			S	Oral	75 Mg Qd; Po		Not Reported
	Seroquel			S	Oral	100 Mg Qd; Po		Not Reported
	Seroquel			S	Oral	150 Mg Qd; Po		Not Reported
	Seroquel			S	Oral	300 Mg Qd; Po		Not Reported
	Seroquel			S	Oral	400mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2007	6406398	EXPEDITED (15-DAY)	Y	HO	FR-SOLVAY-00207033859		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Osmolarity Increased; Dehydration;	Perindopril Erbumine			S	Oral	Daily Dose: 4 Milligram(S)		Not Reported

General Physical Health Deterioration; Oral Fungal Infection; Scab	Escitalopram Oxalate	S	Oral	Daily Dose: 10 Milligram(S)	Not Reported
	Fraxiparine	C	Unknown	Daily Dose: Unknown	Not Reported
	Aerius (Desloratadine)	C	Unknown	Daily Dose: Unknown	Not Reported
	Levothyrox	C	Unknown	Daily Dose: Unknown	Not Reported
	Speciafoldine	C	Unknown	Daily Dose: Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2007	6413388	DIRECT		CA			< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Craniosynostosis; Maternal Exposure During Pregnancy; Seizure	Lexapro			S	Oral		2 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2007	6413389	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy; Vaginal Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg Qd - Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2007	6418025	EXPEDITED (15-DAY)	Y	HO	DSM-2007-00619		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Increased; Haemoconcentration; Hyponatraemia; Malaise; Orthostatic Hypotension;	Olmetec			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1		Not Reported

Syncope					D),Oral	
	Bisoprolol Fumarate\Hydrochlorothiazide		S		5 Mg/6.25 Mg (1 Dosage Forms, 1 In 1 D), Oral	Not Reported
	Moxonidine		S	Oral	0.4 Mg (0.4 Mg, 1 In 1 D), Oral	Not Reported
	Lorazepam		S	Oral	1 Mg (1 Mg, 1 In 1 D),Oral	Not Reported
	Lansoprazole		S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral	Not Reported
	Plavix		C			Not Reported
	Lipanthyl (Fenofibrate) (Fenofinbrate)		C			Not Reported
	Flecainide Acetate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2007	6338752	EXPEDITED (15-DAY)	Y	HO	S07-USA-02401-01		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2007	6393476	EXPEDITED (15-DAY)	Y	OT	S07-USA-03374-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Feeling Hot; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2007	6419086	EXPEDITED (15-DAY)	Y	DS, HO	S07-FRA-03711-01		28 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Delirium; Emotional Distress; Hallucination, Auditory;	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Zolpidem			C				Not Reported
	Bromazepam			C				Not Reported

Psychotic Disorder;
Speech Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2007	6414701	DIRECT	Y	HO, LT			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Amnesia; Apnoea; Cardiac Disorder; Chest Pain; Conversion Disorder; Generalised Tonic-Clonic Seizure; Headache; Hepatic Enzyme Increased; Hyperreflexia; Hypersomnia; Insomnia; Mania; Mental Status Changes; Muscle Rigidity; Muscle Tightness; Serotonin Syndrome	Ultram			S	Oral	50mg Q4 Hours Prn Po		Not Reported
	Lexapro			S	Oral	20mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2007	6422753	EXPEDITED (15-DAY)	Y	OT	S07-GER-03726-01		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depersonalisation/Dereali sation Disorder; Discomfort; Disturbance In Attention; Dizziness; Drug Withdrawal Syndrome; Fatigue; Feeling Abnormal; Hypoacusis; Impaired Work Ability; Memory Impairment; Nightmare; Pain In Extremity; Panic Attack; Paraesthesia; Sleep	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

Disorder; Suicidal Ideation; Visual Acuity Reduced

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2007	6425702	EXPEDITED (15-DAY)	Y	HO	S07-FRA-03729-01		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Osmolarity Increased; Blood Urea Increased; Dehydration; Eschar; Fungal Infection; General Physical Health Deterioration; Skin Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Perindopril Erbumine			S	Oral	4 Mg Qd Po		Not Reported
	Fraxiparine (Heparin-Fraction, Calcium Salt)			C				Not Reported
	Desloratadine			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Speciafoldine (Folic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2007	6331537	EXPEDITED (15-DAY)	Y	HO, OT	S07-ISR-02250-01		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Loss Of Consciousness	Escitalopram Oxalate			S				Not Reported
	Carbocisteine			C				Not Reported
	Lorapid (Loperamide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2007	6357648	EXPEDITED (15-DAY)	Y	OT	S07-USA-02818-01		12 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Platelet Count Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Adderall Xr (Amphetamine)			C				Not Reported
	Strattera			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2007	6360219	EXPEDITED (15-DAY)	Y	DE	S07-USA-02899-01		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Lescol Xl			C				Not Reported
	Altace			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2007	6382174	EXPEDITED (15-DAY)	Y	HO	S07-FRA-03321-01		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Lip Oedema	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Inipomp			S				Not Reported
	Inipomp			S				Not Reported
	Celectol			C				Not Reported
	Fludex (Indapamide)			C				Not Reported
	Simvastatin			C				Not Reported
	Propoxyphene Hydrochloride And Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2007	6412352	EXPEDITED (15-DAY)	Y	HO	S07-FRA-03626-01		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Lip Oedema	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Inipomp			S				Not Reported
	Celiprolol			C				Not Reported
	Indapamide			C				Not Reported
	Simvastatin			C				Not Reported
	Di-Gesic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2007	6382229	EXPEDITED (15-DAY)	Y	HO, OT	S07-TUN-03345-01		61 YR	Male	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Disorder; Chest Pain; Discomfort; Dyspnoea; Malaise; Vertigo	Escitalopram Oxalate		S	Oral	10 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2007	6415602	NON-EXPEDITED	N		US-ASTRAZENECA-2006UW16035		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive	Seroquel			S	Oral			Zeneca
	Lexapro			S				Not Reported
	Vistaril			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2007	6415926	NON-EXPEDITED	Y	OT	US-ASTRAZENECA-2006UW20293			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Seroquel			S	Oral			Zeneca
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2007	6417360	EXPEDITED (15-DAY)	Y	OT	B0482701A		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Dizziness; Drug Withdrawal Syndrome; Eye Disorder; Headache; Intentional Overdose; Irritability; Migraine; Mood Altered; Nausea; Self-Injurious Ideation; Suicidal Ideation; Tearfulness	Paroxetine			S	Oral			Glaxosmithkline
	Paroxetine			S	Oral			Glaxosmithkline
	Fluoxetine			S				Not Reported
	Cipralex			S				Not Reported
	Sertraline			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2007	6419136	NON-EXPEDITED	N		US-ASTRAZENECA-2007UW06123		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction; Muscle Twitching; Tremor	Seroquel			S	Oral		0 MTH	Zeneca
	Lexapro			S	Oral		0 YR	Not Reported
	Lexapro			S	Oral		0 YR	Not Reported
	Lexapro			S	Oral		0 MTH	Not Reported
	Lexapro			S	Oral		0 MTH	Not Reported
	Lexapro			S			1 YR	Not Reported
	Lexapro			S			1 YR	Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Risperdal			C			0 YR	Not Reported
	Benicar			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2007	6419313	NON-EXPEDITED	N		US-ASTRAZENECA-2007UW07636		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Somnolence	Seroquel			S	Oral			Zeneca
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2007	6419317	NON-EXPEDITED	N		US-ASTRAZENECA-2007UW07432		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dry Eye; Dysphagia; Tremor	Seroquel			S	Oral			Zeneca
	Lexapro			S	Oral			Not Reported
	Klonopin			S	Oral			Not Reported

	Depakote	S	Oral		Not Reported
	Topamax	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2007	6420728	NON-EXPEDITED	Y		US-ASTRAZENECA-2007UW13125		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Muscle Spasms; Nightmare; Somnambulism	Seroquel			S	Oral		2 WEEK	Zeneca
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2007	6420769	NON-EXPEDITED	N		US-ASTRAZENECA-2007UW13713		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Feeling Cold; Sleep Disorder	Seroquel			S		1-1 1/2 50 Mg Po Daily		Zeneca
	Seroquel			S		1-1 1/2 50 Mg Po Daily		Zeneca
	Lexapro			S				Not Reported
	Dilaudid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2007	6420937	EXPEDITED (15-DAY)	Y	OT	NO-ASTRAZENECA-2007SE04515		41 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Lamictal			S				Not Reported
	Lamictal			S				Not Reported
	Lamictal			S				Not Reported
	Lamictal			S				Not Reported

	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Diazepam	S		Not Reported
	Diazepam	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2007	6429618	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Condition Aggravated; Fatigue; Muscle Contractions Involuntary; Muscle Spasms; Paraesthesia; Restless Legs Syndrome; Somnolence; Spinal Disorder; Tenderness; Tooth Disorder; Tremor	Lexapro			S	Oral	20 Mg Once A Day Po	3 YR	Forest
	Nexium			C				Not Reported
	Bupropian			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2007	6431849	EXPEDITED (15-DAY)	Y	DS, HO	100#08#2007-03421		31 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Chloride Decreased; Blood Creatine Phosphokinase Mb Increased; Blood Lactate Dehydrogenase Increased; Blood Sodium Decreased; C-Reactive Protein Increased; Cerebellar Syndrome; Depression; Disease Recurrence; Electrolyte Imbalance; Lymphocyte Percentage Decreased;	Lithium			S		1200 Mg; 4 Months + 3 Months In Remission	4 MTH	Not Reported
	Escitalopram Oxalate			S		10 Mg; 4 Months + 3 Months In Remission	4 MTH	Not Reported
	Lamotrigine (Lamotrigine) (Lamotrigine)			C				Not Reported

Nausea; Neurotoxicity; Neutrophil Percentage Increased; Pneumonia; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Toxicity To Various Agents; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6132299	EXPEDITED (15-DAY)	Y	OT	S06-ITA-03395-01		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gravitational Oedema; Renal Failure; Weight Increased	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Carvedilol			C				Not Reported
	Amiodar (Amiodarone Hydrochloride)			C				Not Reported
	Glurenor (Gliquidone)			C				Not Reported
	Omeprazole			C				Not Reported
	Ziloryc (Allopurinol) (Allopurinol)			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Lasix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6204423	EXPEDITED (15-DAY)	Y	HO	S06-FRA-04734-01		77 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Condition Aggravated; Depression; Paraesthesia; Skin Burning Sensation	Escitalopram Oxalate			S	Oral	10 Mg Qd; Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6353937	EXPEDITED (15-DAY)	Y	HO	S07-FRA-02701-01		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis;	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported

Hepatitis	Abilify	S	Oral	10 Mg Qd Po		Not Reported
	Noctran	C				Not Reported
	Cyamemazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6432672	EXPEDITED (15-DAY)	N	OT	L07-USA-03843-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Seizure; Suicide Attempt	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433155	EXPEDITED (15-DAY)	N	OT	L07-USA-03851-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Respiratory Depression; Tachycardia; Tremor	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433187	EXPEDITED (15-DAY)	N	OT	L07-USA-03844-01		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Overdose; Suicide Attempt	Escitalopram Oxalate			S		10 Tablet Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433192	EXPEDITED (15-DAY)	N	OT	L07-USA-03845-01		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Seizure	Escitalopram Oxalate			S		60 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433198	EXPEDITED (15-DAY)	N	OT	L07-USA-03846-01		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis; Overdose; Suicide Attempt; Vomiting	Escitalopram Oxalate			S		100 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433203	EXPEDITED (15-DAY)	N	OT	L07-USA-03847-01		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Irritability; Lethargy; Overdose; Pneumonitis; Somnolence; Tachycardia	Escitalopram Oxalate			S		18 Tablet Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433212	EXPEDITED (15-DAY)	N	OT	L07-USA-03840-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Agitation; Delusion; Hallucination; Irritability; Overdose; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S		110 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433222	EXPEDITED (15-DAY)	N	OT	L07-USA-03841-01		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lethargy; Overdose; Seizure; Somnolence; Suicide Attempt	Escitalopram Oxalate			S		250 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433298	EXPEDITED (15-DAY)	N	OT	L07-USA-03852-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hyperventilation; Irritability; Nausea; Overdose; Tachypnoea; Tremor	Escitalopram Oxalate			S		1 Tablet Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433314	EXPEDITED (15-DAY)	N	OT	L07-USA-03848-01		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Overdose; Respiratory Depression; Suicide Attempt	Escitalopram Oxalate			S		15 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433340	EXPEDITED (15-DAY)	Y	HO	S07-FRA-05060-01		77 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Polyethylene Glycols			C				Not Reported
	Aspirin			C				Not Reported
	Veratran (Clotiazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433550	EXPEDITED (15-DAY)	Y	HO, OT	S07-UKI-05054-01		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Foot Fracture; Generalised Tonic-Clonic Seizure;	Cipralex			S	Oral	20 Mg Qd; Po		Not Reported

Legal Problem; Petit Mal Epilepsy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433650	EXPEDITED (15-DAY)	N	OT	L07-USA-03842-01		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arrhythmia; Overdose; Suicide Attempt	Escitalopram Oxalate			S		30 Tablet Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433933	EXPEDITED (15-DAY)	N	OT	L07-USA-03850-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lethargy; Overdose; Respiratory Depression; Somnolence; Suicide Attempt	Escitalopram Oxalate			S		12 Tablet Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2007	6433970	EXPEDITED (15-DAY)	N	OT	L07-USA-03849-01		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperventilation; Lethargy; Overdose; Somnolence; Tachypnoea	Escitalopram Oxalate			S		36 Tablet Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2007	6382226	EXPEDITED (15-DAY)	Y	HO	S07-JPN-03322-01		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Blood Potassium Decreased; Blood Sodium Decreased;	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

Bundle Branch Block; Condition Aggravated; Electrocardiogram St-T Change; Fatigue; Hepatitis Acute; Hepatitis Alcoholic; Major Depression; Malaise; Oedema Peripheral; Somnolence; Stomatitis; Therapeutic Product Effect Decreased; Vomiting	Escitalopram Oxalate	S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate	S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg Qd Po		Not Reported
	Lasix	S	Oral	20 Mg Qd Po		Not Reported
	Lasix	S	Oral	20 Mg Qd Po		Not Reported
	Lasix	S	Oral	20 Mg Qd Po		Not Reported
	Lasix	S	Oral	40 Mg Qd Po		Not Reported
	Alcohol	S				Not Reported
	Alprazolam	C				Not Reported
	Rohypnol (Flunitrazepam)	C				Not Reported
	Gasmotin (Mosapride Citrate)	C				Not Reported
	Gaster	C				Not Reported
	Levothyroxine Sodium	C				Not Reported
	Allopurinol	C				Not Reported
	Bisacodyl	C				Not Reported
	Nauzelin	C				Not Reported
	Alesion (Epinastine Hydrochloride)	C				Not Reported
	Medicon (Dextromethorphan Hydrobromide)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2007	6432537	DIRECT					21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Product Dispensing Error	Lipitor			S		Tablet		Pfizer
	Lexapro			S		Tablet		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2007	6433664	DIRECT					40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lexapro			S		Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2007	6435298	EXPEDITED (15-DAY)	Y	HO, LT	S07-FRA-05055-01		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Dehydration; Hepatitis; Hepatitis Cholestatic	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2007	6435358	EXPEDITED (15-DAY)	Y	HO	S07-UKI-05053-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Supraventricular Tachycardia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2007	6435116	EXPEDITED (15-DAY)	Y	DE, LT	S07-TUN-05059-01		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Renal Failure	Escitalopram Oxalate			S				Not Reported
	Levothyroxin (Levothyroxine Sodium)			C				Not Reported
	Insulin Nos			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Gliclazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2007	6321682	EXPEDITED (15-DAY)	Y	HO	S07-BEL-02020-01		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure; Rhabdomyolysis;	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported

Serotonin Syndrome; Syncope	Escitalopram Oxalate		S	Oral	10 Mg Qd Po	Not Reported
	Spasmomen (Otilonium Bromide)		C			Not Reported
	Perenterol Forte (Saccharomyces Boulardii)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2007	6509487	DIRECT	N	DE			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Irritability	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2007	6672213	EXPEDITED (15-DAY)	Y	OT	S07-FRA-05138-01			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alcohol Interaction; Amnesia; Anxiety; Blood Alcohol Increased; Confusional State; Hallucination	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Loprazolam			S				Not Reported
	Alprazolam			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2007	6427903	EXPEDITED (15-DAY)	Y	HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-13916515		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Aripiprazole			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2007	6428065	EXPEDITED (15-DAY)	Y	DS, OT	AU-PFIZER INC-2007071079		61 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Chromaturia; Depression; Liver Function Test Abnormal; Muscular Weakness; Myalgia; Rhabdomyolysis	Lipitor			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Unspecified Ingredient			C				Not Reported
	Allopurinol			C	Oral	Daily Dose:100mg-Freq:Daily		Not Reported
	Allopurinol			C				Not Reported
	Cartia Xt			C	Oral	Daily Dose:100mg-Freq:Daily		Not Reported
	Metoprolol			C	Oral	Daily Dose:25mg-Freq:Daily		Not Reported
	Ramipril			C	Oral	Daily Dose:2.5mg-Freq:Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2007	6434924	DIRECT	Y	HO			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Status Changes; Rhabdomyolysis	Lexapro			S	Oral	Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2007	6438376	EXPEDITED (15-DAY)	Y	CA	S07-USA-05043-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital; Maternal Exposure During Pregnancy; Trisomy 18	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Lexapro			S	Transplacental	5 Mg Qd Transplacental		Not Reported
	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Prenatabs Fa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2007	6439046	EXPEDITED (15-DAY)	N	OT	S07-USA-05170-01		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Neoplasm	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2007	6439424	EXPEDITED (15-DAY)	Y	OT	S07-CAN-05150-01		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome; Fear; Hallucination; Nervousness; Nightmare; Suicidal Behaviour	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2007	7302117	DIRECT	Y	OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Fibrosis; Hepatic Necrosis; Hepatitis C; Hepatitis C Rna Positive; Hepatotoxicity; Liver Injury; Suicidal Ideation	Levaquin			S		500mg/Day		Not Reported
	Lexapro			S		20mg/Day		Not Reported
	Xanax			C				Not Reported
	Vicodin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2007	6360277	EXPEDITED (15-DAY)	Y	OT	S07-USA-02803-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Neck Pain; Odynophagia; Rheumatoid Arthritis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Lexapro	S	Oral	10 Mg Qd Po		Not Reported
Lopresor	C				Not Reported
Nasonex	C				Not Reported
Zocor	C				Not Reported
Loratadine\Pseudoephedrine Sulfate	C				Not Reported
Hydrochlorothiazide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2007	6410604	EXPEDITED (15-DAY)	Y	OT	S07-PRT-03624-01		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transient Ischaemic Attack	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2007	6426565	EXPEDITED (15-DAY)	Y	DS	S07-SWI-03793-01		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photophobia; Xerophthalmia	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2007	6432430	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2007080103		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Crying; Depression; Emotional Distress; Gastrooesophageal Reflux Disease; Irritability; Suicidal Ideation	Chantix			S		Text:Every Day		Not Reported
	Celexa			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2007	6440794	EXPEDITED (15-DAY)	Y	OT	S07-IRL-05277-01			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2007	5846815	EXPEDITED (15-DAY)	Y	HO, LT	A044-002-005675		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Bradycardia; Essential Tremor; Torsade De Pointes	Aricept			S	Oral	10 Mg, 1 In 1 D, Oral		Not Reported
	Inderal			S	Oral	80 Mg, 1 In 1 D, Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, 1 In 1 D, Oral		Not Reported
	Prochlorperazine Maleate			C				Not Reported
	Omeprazole			C				Not Reported
	Ferrous Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2007	6352981	EXPEDITED (15-DAY)	Y	HO	S07-CZE-02734-01		74 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Panic Attack	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Monotab (Isosorbide Mononitrate) (Isosorbide Mononitrate)			C				Not Reported
	Simcalmed (Simvastatin)			C				Not Reported
	Trenaxum (Rilmenidine)			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2007	6415097	EXPEDITED (15-DAY)	Y	OT	B0487285A		41 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Spontaneous; Foetal Heart Rate Abnormal	Lamictal		S	Oral		Glaxosmithkline
	Lyrica		S	Oral	300mg Per Day	Not Reported
	Seroquel		S	Oral	100mg Per Day	Not Reported
	Cipralex		S	Unknown	10mg Per Day	Not Reported
	Diazepam		S	Unknown	100mg As Required	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2007	6438434	DIRECT	Y	HO, LT, RI			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Confusional State; Depression; Dry Mouth; Gait Disturbance; Impaired Self-Care; Musculoskeletal Stiffness; Paresis; Rhabdomyolysis; Therapy Non-Responder	Abilify			S	Oral	30 Mg 1/Day Po	8 MTH	Bristol Myers Squibb
	Lexapro			S	Oral	10 Mg 1/Day Po	4 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2007	6328172	EXPEDITED (15-DAY)	Y	HO	S07-IRL-02108-01		74 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Decreased Appetite; Depression; Lower Respiratory Tract Infection; Meningitis; Serotonin Syndrome; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Claforan			S				Not Reported
	Digoxin			C				Not Reported
	Lanoprazole (Lansoprazole)			C				Not Reported
	Metoprolol			C				Not Reported
	Doxazosin			C				Not Reported
	Ferrous Furmarate			C				Not Reported
	Singulair			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Rohypnol (Flunitrazepam)			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Oxycontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2007	6433660	EXPEDITED (15-DAY)	Y	HO	US-RB-008168-07		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bruxism; Fall; Flushing; Incoherent; Insomnia; Muscle Tightness; Muscle Twitching; Mydriasis; Myoclonus; Paraesthesia; Restlessness; Serotonin Syndrome; Status Epilepticus; Tremor	Buprenorphine			S	Unknown			Not Reported
	Buprenorphine			S	Unknown			Not Reported
	Buprenorphine			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2007	6434340	EXPEDITED (15-DAY)	Y	HO	GB-ASTRAZENECA-2007AC01870		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Torsade De Pointes	Omeprazole			S				Not Reported
	Propranolol			S				Not Reported
	Propranolol			S				Not Reported
	Donepezil Hydrochloride			S			2 YR	Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2007	6434407	EXPEDITED (15-DAY)	Y	OT	GB-PFIZER INC-2007079996			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Dizziness; Drug Withdrawal Syndrome; Eye Disorder; Headache; Intentional Overdose;	Sertraline Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Fluoxetine			S				Not Reported
	Paroxetine Hydrochloride			S	Oral			Not Reported

Irritability; Migraine; Mood Altered; Nausea; Self-Injurious Ideation; Suicidal Ideation; Tearfulness

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2007	6442484	EXPEDITED (15-DAY)	Y	LT	GXKR2007GB08305		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Drug Interaction; Electrocardiogram Qt Prolonged; Essential Tremor; Sinus Bradycardia; Syncope; Torsade De Pointes	Omeprazole			S		20 Mg		Not Reported
	Propranolol			S		80 Mg		Not Reported
	Donepezil Hydrochloride			S		10 Mg		Not Reported
	Escitalopram Oxalate			S		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2007	6442650	EXPEDITED (15-DAY)	Y	OT	6027066		38 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Major Depression; Parkinsonism; Restlessness; Tremor	Sertraline			S		50,000 Mg		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Tianeptine			S		12,5000 Mg (12,5 Mg, Titrated Up To 37.5 Mg); 37,5000 Mg (37,5 1 In 1 D)		Not Reported
	Biperiden Hydrochloride			C				Not Reported
	Lorazepam			C				Not Reported
	Bupropion Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2007	6366786	EXPEDITED (15-DAY)	Y	DE	S07-USA-03006-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Drug Intolerance; Gun Shot Wound; Hypersomnia; Sedation	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Xanax	C				Not Reported
	Zyprexa	C				Not Reported
	Temazepam	C				Not Reported
	Prozac	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2007	6412348	EXPEDITED (15-DAY)	Y	OT	S07-IRL-03645-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2007	6442872	EXPEDITED (15-DAY)	Y	DE	S07-FRA-05252-01		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia Malignant; Toxic Shock Syndrome	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Neoral			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Durogesxc (Prntanyl)			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2007	6453769	EXPEDITED (15-DAY)	Y	OT	2007RR-10221			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Drug Withdrawal Syndrome; Dystonia; Eye Disorder; Inappropriate Schedule Of Product Administration; Intentional Overdose; Reaction To Excipient; Self-Injurious Ideation; Suicidal Ideation	Paroxetine			S	Oral	Oral		Not Reported
	Fluoxetine			S				Not Reported
	Sertraline			S				Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2007	6346703	EXPEDITED (15-DAY)	Y	HO, OT	S07-CAN-02602-01		62 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenic Purpura; Immune Thrombocytopenic Purpura	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Celexa			C				Not Reported
	Metoprolol			C				Not Reported
	Altace			C				Not Reported
	Crestor			C				Not Reported
	Asaphen (Acetylsalicylic Acid)			C				Not Reported
	Inexium (Esomeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2007	6410503	EXPEDITED (15-DAY)	Y	HO	ES-BRISTOL-MYERS SQUIBB COMPANY-13901236		75 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Inappropriate Antidiuretic Hormone Secretion; Restlessness	Coaprovel Tabs 300mg/12.5mg			S	Oral			Bristol Myers Squibb
	Deprax (Trazodone Hydrochloride)			S	Oral			Apothecon
	Risperidone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Tegretol			S	Oral			Not Reported
	Duphalac			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2007	6436287	EXPEDITED (15-DAY)	Y	OT	DE-JNJFOC-20070904459			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apraxia; Maternal Exposure During Pregnancy	Topamax			S				Not Reported
	Cipralex			S				Not Reported
	Levothyroxine			S				Not Reported

Sodium\Potassium Iodide			
Singulair	S		Not Reported
Berotec	S		Not Reported
Symbicort	S		Not Reported
Ibuprofen	S		Not Reported
Methyldopa	S		Not Reported
Folic Acid	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2007	6436477	EXPEDITED (15-DAY)	Y	HO	TR-ASTRAZENECA-2007AC01882		76 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Quetiapine			S	Oral			Zeneca
	Quetiapine			S	Oral			Zeneca
	Quetiapine			S	Oral			Zeneca
	Quetiapine			S	Oral			Zeneca
	Quetiapine			S	Oral			Zeneca
	Quetiapine			S	Oral			Zeneca
	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2007	6442660	DIRECT	Y	HO			35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Presyncope; Serotonin Syndrome; Syncope	Lexapro			S	Oral	10mg Bid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2007	6437689	EXPEDITED (15-DAY)		HO	GB-ROXANE LABORATORIES, INC-2007-BP-21949RO		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction;	Propranolol			S			5 DAY	Roxane

Electrocardiogram Qt Prolonged; Sinus Bradycardia; Syncope; Torsade De Pointes	Propranolol	S		5 DAY	Roxane
	Escitalopram Oxalate	S			Not Reported
	Donepezil Hydrochloride	S		2 YR	Not Reported
	Omeprazole	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2007	6331554	EXPEDITED (15-DAY)	Y	HO, OT	S07-CAN-02227-01		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Loss Of Consciousness	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2007	6354627	EXPEDITED (15-DAY)	Y	DE	S07-USA-02683-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiotoxicity; Myocardial Infarction; Sudden Death	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Neurontin			C				Not Reported
	Tenormin			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2007	6445215	EXPEDITED (15-DAY)	Y	OT	S07-GER-05283-01		85 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S				Not Reported
	Prednisolone			C				Not Reported
	Calcimagon-D3			C				Not Reported
	Carvedilol			C				Not Reported
	Lorzaar Plus			C				Not Reported
	Pravastatin Sodium			C				Not Reported

	Allopurinol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2007	6445219	EXPEDITED (15-DAY)	Y	DS	S07-FRA-05317-01		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dissociation; Disturbance In Attention; Dizziness	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2007	6445220	EXPEDITED (15-DAY)	Y	DS	S07-FRA-05318-01		19 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depersonalisation/Derealisation Disorder; Dissociation; Disturbance In Attention; Dizziness	Escitalopram Oxalate			S				Not Reported
	Several Unspecified Drugs			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2007	6445225	EXPEDITED (15-DAY)	Y	DS	S07-FRA-05316-01		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Depersonalisation/Derealisation Disorder; Dissociation; Disturbance In Attention	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2007	6445497	EXPEDITED (15-DAY)	Y	HO	S07-USA-05272-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Drug Withdrawal Syndrome; Dysphoria; Psychotic	Lexapro			S				Not Reported
	Alcohol			S				Not Reported

Disorder; Treatment Noncompliance

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2007	6201912	EXPEDITED (15-DAY)	Y	OT	T06-GER-05026-01		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vaginal Haemorrhage	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2007	6429573	EXPEDITED (15-DAY)	Y	LT	S07-FRA-02864-01		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2007	6438854	EXPEDITED (15-DAY)	Y	HO	GB-WYE-H00482507		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Torsade De Pointes	Escitalopram Oxalate			S	Unknown	10 Mg		Unknown
	Omeprazole			S	Unknown	20 Mg		Unknown
	Propranolol Hydrochloride			S	Unknown	80 Mg		Wyeth
	Propranolol Hydrochloride			S				Wyeth
	Donepezil Hydrochloride			S	Unknown	10 Mg		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2007	6440625	EXPEDITED (15-DAY)	Y	HO	S07-TUN-05202-01		53 YR	Male	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Ketoacidosis; Treatment Noncompliance	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Insulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2007	6376618	EXPEDITED (15-DAY)	Y	DE	S07-USA-03135-01		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lunesta			S				Not Reported
	Effexor			C				Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2007	6445401	DIRECT	Y	OT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Skin Fissures; Skin Irritation	Lexapro			S	Oral Oral	1po Qd 1po Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2007	6446097	EXPEDITED (15-DAY)	Y	HO, OT	162066ISR		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sinus Bradycardia; Syncope; Torsade De Pointes	Propranolol			S		(80 Mg)		Not Reported
	Donepezil Hydrochloride			S		(10 Mg)	2 YR	Not Reported
	Escitalopram Oxalate			S		(10 Mg)		Not Reported
	Omeprazole			S		(20 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	4061564	NON-EXPEDITED		OT	S03-USA-02642-01		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Adverse Drug Reaction;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Anxiety; Burning Sensation; Dry Mouth; Feeling Abnormal; Night Sweats; Suicidal Ideation; Tremor; Weight Decreased	Lexapro		S	Oral	5 Mg Qd Po	Not Reported
	Lexapro		S	Oral	20 Mg Qd Po	Not Reported
	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Lexapro		S			Not Reported
	Effexor		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	5884742	NON-EXPEDITED		HO	S05-USA-02813-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Headache; Hypersensitivity; Lethargy; Nausea	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lantus			C				Not Reported
	Glipizide			C				Not Reported
	Diovan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6207108	NON-EXPEDITED	Y	HO, OT	S06-USA-04715-01		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lithium			S	Oral	300 Mg Qd Po		Not Reported
	Lithium			S	Oral	1200 Mg Qd Po		Not Reported
	Lithium			S				Not Reported
	Wellbutrin Xl			C				Not Reported
	Geodon			C				Not Reported
	Atenolol			C				Not Reported
	Lipitor			C				Not Reported
	Maxalt			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6474932	NON-EXPEDITED	Y		2007SP002530			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Insomnia	Lunesta			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478476	NON-EXPEDITED		OT	S07-USA-00190-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Accidental Overdose; Confusional State; Hyperhidrosis; Nausea; Thirst	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478524	NON-EXPEDITED		OT	S07-USA-00185-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Emotional Disorder; Myocardial Infarction	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478547	NON-EXPEDITED		OT	S07-USA-00011-01		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Aleve			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478560	NON-EXPEDITED	Y	OT	S06-USA-05394-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478611	NON-EXPEDITED	Y	OT	S06-USA-05167-01		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyperhidrosis; Impatience; Psychomotor Hyperactivity; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Protonix			C				Not Reported
	Diovan			C				Not Reported
	Coreg			C				Not Reported
	Singulair			C				Not Reported
	Lamisil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478613	NON-EXPEDITED	Y	OT	S06-USA-05225-01		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Loss Of Consciousness; Mydriasis; Personality Change; Visual Impairment	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Birth Control Pills			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478617	NON-EXPEDITED	N	HO	S06-USA-05109-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Bradycardia; Disturbance In Attention; Headache; Loss Of Consciousness; Supraventricular	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

Tachycardia; Tachycardia;
Vision Blurred

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478872	NON-EXPEDITED	Y	OT	S07-USA-01044-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Hallucination, Auditory; Libido Increased; Musculoskeletal Stiffness; Suicidal Ideation	Lexapro			S				Not Reported
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478874	NON-EXPEDITED		OT	S07-USA-00820-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hot Flush; Intentional Overdose; Loss Of Consciousness	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478882	NON-EXPEDITED		OT	S07-USA-00821-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Panic Attack; Suicidal Ideation	Lexapro			S				Not Reported
	Bupropion			S		150 Mg Bid		Not Reported
	Alcohol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478894	NON-EXPEDITED		OT	S07-USA-00667-01		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dyspnoea; Insomnia; Paraesthesia;	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinusitis; Suicidal Ideation; Weight Increased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478905	NON-EXPEDITED		OT	S07-USA-00669-01		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Insomnia; Irritability; Mood Altered; Panic Attack; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ambien			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478912	NON-EXPEDITED	N	OT	S07-USA-01632-01		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Coordination Abnormal; Decreased Appetite; Depression; Disturbance In Attention; Fatigue; Nausea; Suicidal Ideation; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478913	NON-EXPEDITED	Y	OT	S07-USA-01605-01		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lithium			C				Not Reported
	Synthroid			C				Not Reported
	Pepcid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478914	NON-EXPEDITED	Y	HO	S07-USA-01588-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478919	NON-EXPEDITED	Y	HO	S07-USA-00511-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478921	NON-EXPEDITED	Y	HO	S07-USA-01527-01		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Lexapro			S				Not Reported
	Diamox Sequels			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478922	NON-EXPEDITED	N		S07-USA-01521-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported
	Elavil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478930	NON-EXPEDITED		OT	S07-USA-00489-01		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Increased; Dry Mouth; Nausea	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Lexapro	S	Oral	5 Mg Qd Po		Not Reported
	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Insulin Nos	C				Not Reported
	Singulair	C				Not Reported
	Unspecified Ingredient	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478932	NON-EXPEDITED		OT	S07-USA-00482-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Orthostatic Hypotension	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478938	NON-EXPEDITED	N	OT	S07-USA-03272-01		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Dizziness; Fall; Hyperhidrosis; Loss Of Consciousness	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478939	NON-EXPEDITED	N	OT	S07-USA-03200-01		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Upper Limb Fracture	Lexapro			S				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478941	NON-EXPEDITED	Y	HO	S07-USA-01394-01		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression; Cardiac Murmur; Decreased Appetite; Dehydration; Depression; Mania; Suicidal Ideation; Tremor	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Wellbutrin Xl		S		300 Mg Qd	Not Reported
	Alcohol		S			Not Reported
	Lotrel		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478944	NON-EXPEDITED	Y	OT	S07-USA-01351-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po,20 Mg Qd Po		Not Reported
					Oral	10 Mg Qd Po,20 Mg Qd Po		
	Effexor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478947	NON-EXPEDITED	Y	HO	S07-USA-01156-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zanaflex			C				Not Reported
	Norvasc			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6478950	NON-EXPEDITED	N	OT	S07-USA-01051-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Diarrhoea; Dizziness; Feeling Hot; Headache; Insomnia; Peripheral	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Avapro			C				Not Reported

Coldness; Restlessness;
Tachycardia; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479006	NON-EXPEDITED	Y	OT	S07-USA-02246-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479008	NON-EXPEDITED	Y	OT	S07-USA-02246-03			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479011	NON-EXPEDITED	Y	OT	S07-USA-02247-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479013	NON-EXPEDITED	Y	OT	S07-USA-02252-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479017	NON-EXPEDITED	Y	OT	S07-USA-02252-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Sodium Decreased	Lexapro	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479021	NON-EXPEDITED		OT	S07-USA-02239-01		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Anxiety; Paranoia	Lexapro			S				Not Reported
	Coumadin			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Lovastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479022	NON-EXPEDITED		OT	S07-USA-02220-01		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flat Affect; Impulse-Control Disorder; Mental Status Changes; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qod Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Pletal			C				Not Reported
	Hydrocodone			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479026	NON-EXPEDITED	N	OT	S07-USA-02197-01		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Dizziness; Fall; Nausea; Syncope	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Amaryl			C				Not Reported
	Plavix			C				Not Reported
	Zetia (Ezetimibe)			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479028	NON-EXPEDITED	N	OT	S07-USA-02166-01		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479031	NON-EXPEDITED	N	OT	S07-USA-02115-01		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479080	NON-EXPEDITED	Y	OT	S07-USA-02267-01		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Accidental Overdose; Chest Pain; Dyspnoea; Fatigue; Nausea; Vomiting	Lexapro			S	Oral	70 Mg Once Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S				Not Reported
	Synthroid			C				Not Reported
	Hormones (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479081	NON-EXPEDITED			S07-USA-02246-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479160	NON-EXPEDITED	N	OT	S07-USA-01427-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Insomnia; Psychomotor Hyperactivity	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Paxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479306	NON-EXPEDITED	Y	HO	S07-USA-02435-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Hypoaesthesia; Hypoaesthesia; Insomnia; Nausea; Suicidal Ideation; Thinking Abnormal	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Risperdal			S	Oral	20 Mg Qd Po		Not Reported
	Ativan			C				Not Reported
	Lamictal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479388	NON-EXPEDITED		OT	S07-USA-00672-01		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Erectile Dysfunction; Suicidal Ideation	Lexapro			S	Oral	10 Mg Bid Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Metoprolol			C				Not Reported
	Clonidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479473	NON-EXPEDITED	N	OT	S06-USA-03505-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Oral	5 Mg Once Po		Not Reported

	Ceftin [Cefuroxime Axetil]	S		Not Reported
	Nasarel (Flunisolide)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479476	NON-EXPEDITED		HO	S06-USA-03507-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479488	NON-EXPEDITED		OT	S06-USA-03508-01		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mood Swings	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Pegasys (Peginterferon Alfa-2a)			S	Subcutaneous	180 Mcg Qw Sc		Not Reported
	Ambien			S		10 Mg Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479498	NON-EXPEDITED	Y	HO	S06-USA-03512-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Orthostatic Hypotension; Urine Output Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479500	NON-EXPEDITED		OT	S06-USA-03228-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479502	NON-EXPEDITED	N	HO, LT	S06-USA-03513-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported
	Cogentin			C				Not Reported
	Vistaril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479503	NON-EXPEDITED		OT	S06-USA-03417-01		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Abilify			S	Oral	15 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479516	NON-EXPEDITED			S06-USA-01165-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Actos			C				Not Reported
	Benicar			C				Not Reported
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479518	NON-EXPEDITED	Y	OT	S06-USA-03231-01		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Pegintron			S				Not Reported
	Ribavirin			S				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479520	NON-EXPEDITED	Y	OT	S06-USA-02748-02			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Hypoglycaemia; Hypotonia	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Geodon			C				Not Reported
	Trileptal			C				Not Reported
	Macrodantin			C				Not Reported
	Flagyl			C				Not Reported
	Fes04 (Ferrous Sulfate)			C				Not Reported
	Epidural (Nos)			C				Not Reported
	Terazol 7 (Terconazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479576	NON-EXPEDITED		OT	S07-USA-03344-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression; Hostility; Hyperhidrosis; Mania; Thinking Abnormal	Lexapro			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479581	NON-EXPEDITED		OT	S07-USA-03340-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479583	NON-EXPEDITED		OT	S07-USA-03340-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479585	NON-EXPEDITED		OT	S07-USA-03328-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479682	NON-EXPEDITED		OT	S06-USA-04031-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Multiple Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479700	NON-EXPEDITED		OT	S06-USA-03740-01		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479707	NON-EXPEDITED	N	OT	S06-USA-03685-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Weight Increased; Weight Loss Poor	Lexapro		S	Oral	30 Mg Qd Po	Not Reported
	Ativan		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479713	NON-EXPEDITED	N	OT	S06-USA-03638-01		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Aggression; Anger; Contusion; Cough; Discomfort; Drug Interaction; Dysphagia; Hyperhidrosis; Mental Impairment; Muscle Rigidity; Pain In Extremity; Panic Attack; Paranoia; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Namenda			S	Oral	10 Mg Bid Po		Not Reported
	Acetaminophen\Dextromethorphan\Pseudoephedrine			S				Not Reported
	Sular			C				Not Reported
	Diovan			C				Not Reported
	Aricept			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479727	NON-EXPEDITED	Y	OT	S06-USA-03547-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Fatigue; Hyperhidrosis; Insomnia; Nausea; Syncope; Tremor; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479728	NON-EXPEDITED	Y	OT	S06-USA-03503-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphoria; Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479744	NON-EXPEDITED	Y	OT	S06-USA-04372-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Lexapro			S				Not Reported
	Risperdal			C				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479746	NON-EXPEDITED	Y	OT	S06-USA-04368-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis Viral; Gastrointestinal Haemorrhage	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479754	NON-EXPEDITED	Y	OT	S06-USA-04331-01		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S	Oral	10 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479921	NON-EXPEDITED	N	OT	S06-USA-04255-01		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hypersensitivity	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479923	NON-EXPEDITED		OT	S06-USA-04219-01		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Drug Ineffective; Insomnia; Palpitations; Suicidal Ideation; Tremor	Lexapro		S	Oral	20 Mg Qd Po	Not Reported
	Lexapro		S	Oral	20 Mg Qd Po	Not Reported
	Lexapro		S			Not Reported
	Seroquel		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479925	NON-EXPEDITED		OT	S06-USA-04179-01		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Erectile Dysfunction; Feeling Hot; Hypersomnia; Mania; Mouth Breathing; Suicidal Ideation; Tremor; Yawning	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Minoxidil			C				Not Reported
	Propranolol			C				Not Reported
	Gemfibrozil			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479927	NON-EXPEDITED			S07-USA-02103-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479928	NON-EXPEDITED	N	OT	S07-USA-02092-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Constipation; Contusion; Dizziness; Fall; Flight Of Ideas; Headache; Nausea; Tinnitus; Vascular Headache; Wrist Fracture	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qod Po		Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479930	NON-EXPEDITED	Y	HO	S07-USA-02047-01		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Burning Sensation; Flushing; Headache; Nausea	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Cardizem			C				Not Reported
	Lisinopril			C				Not Reported
	Tricor			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Glucotrol			C				Not Reported
	Cialis			C				Not Reported
	Lortabs (Acetaminophen/Hydrocodone)			C				Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479934	NON-EXPEDITED		OT	S07-USA-01997-01		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Advair			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479943	NON-EXPEDITED	Y	HO	S07-USA-01981-01		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Avalide			S				Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479945	NON-EXPEDITED	Y	HO	S07-USA-01981-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479948	NON-EXPEDITED		OT	S07-USA-01823-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Once Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479950	NON-EXPEDITED	Y	LT	S06-USA-04052-01		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Depression; Drug Ineffective; Drug Interaction; Malaise; Nausea; Suicidal Ideation	Lexapro			S	Oral	0 Mg Qd Po		Not Reported
	Combunox			S	Oral	5 Mg Tid Po		Not Reported
	Synthroid			C				Not Reported
	Cortef			C				Not Reported
	Xanax			C				Not Reported
	Lisinopril			C				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479957	NON-EXPEDITED	Y	OT	S07-USA-01728-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Cymbalta			S		120 Mg Qd		Not Reported
	Cymbalta			S		60 Mg Qd		Not Reported
	Cymbalta			S		60 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6479964	NON-EXPEDITED		OT	S07-USA-01650-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Syncope	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qod Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6480295	NON-EXPEDITED	Y	OT	S06-USA-05039-01		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6480298	NON-EXPEDITED	N	OT	S06-USA-05000-01		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Unspecified Ingredient			S				Not Reported
	Rituxan			S				Not Reported
	Levaquin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6480300	NON-EXPEDITED	Y	HO	S06-USA-04993-01		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hip Fracture	Lexapro			S				Not Reported
	Xanax			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6480301	NON-EXPEDITED	Y	HO, OT	S06-USA-04854-01		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Headache; Hypertension; Nephrolithiasis; Renal Failure; Sinusitis	Lexapro			S	Oral	50 Mg Qd Po		Not Reported
	Aleve			S				Not Reported
	Excedrin			S				Not Reported
	Buspar			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6480302	NON-EXPEDITED	N	OT	S06-USA-04828-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6480314	NON-EXPEDITED	N	OT	S06-USA-04626-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Depersonalisation/Dereali sation Disorder; Dizziness; Drug Ineffective; Insomnia; Loss Of Libido; Mood Swings; Nausea; Neck Pain; Nightmare; Thinking Abnormal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6480326	NON-EXPEDITED	Y	OT	S06-USA-04598-01		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Ibuprofen			C				Not Reported
	Benadryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6480801	NON-EXPEDITED	Y	HO	S06-USA-03545-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; Hypertension	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Remeron			C				Not Reported
	Tenormin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6491676	NON-EXPEDITED		OT	S07-USA-00680-01		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6491682	NON-EXPEDITED	N	OT	S06-USA-05313-01		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Dizziness; Hypotension; Loss Of Consciousness	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Reglan			C				Not Reported
	Clorazepate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6491683	NON-EXPEDITED	Y	HO	S06-USA-05235-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Overdose; Suicide Attempt	Lexapro		S	Oral	20 Mg Qd Po	Not Reported
	Trileptal		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6491691	NON-EXPEDITED	Y	OT	S06-USA-05051-01		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lunesta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6491712	NON-EXPEDITED	Y	OT	S06-USA-04506-01		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Effexor Xr			S		150 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6491760	NON-EXPEDITED	N	OT	S06-USA-04698-01		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Muscle Spasms; Nausea; Pain In Extremity; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			C				Not Reported
	Prinivil			C				Not Reported
	Hydroxyzine			C				Not Reported
	Famotidne			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6491793	NON-EXPEDITED		OT	S06-USA-03272-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test	Lexapro	S	Not Reported
Abnormal	Multiple Medications (Nos)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6492134	NON-EXPEDITED	Y	HO	S07-USA-02007-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Hydrochlorothiazide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6494030	NON-EXPEDITED	Y	HO	S06-USA-04005-01		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall; Hip Fracture; Listless	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6494032	NON-EXPEDITED	Y	HO	S06-USA-03960-01		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Dizziness; Flight Of Ideas; Palpitations; Syncope; Weight Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6494034	NON-EXPEDITED	Y	OT	S06-USA-04260-01		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

	Stalevo (Levodopa/Carbidopa)	C		Not Reported
	Diovan	C		Not Reported
	Ibuprofen	C		Not Reported
	Excedrin Migraine (Acetaminophen/Aspirin/Caffeine)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6494035	NON-EXPEDITED	Y	OT	S06-USA-04489-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Nexium (Esomeprazole)			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6496620	NON-EXPEDITED	Y		S07-USA-03318-01		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Unisom Sleeptabs			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6496623	NON-EXPEDITED	Y	HO	S07-USA-03167-01		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Heart Rate Increased; Hypoaesthesia; Syncope; Tension Headache	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6496624	NON-EXPEDITED	Y	HO	S07-USA-03176-01		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6496625	NON-EXPEDITED	Y		S07-USA-02978-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6496626	NON-EXPEDITED	Y	HO	S07-USA-02955-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Not Reported
	Numerous Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6496628	NON-EXPEDITED	Y	OT	S07-USA-02837-01		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Thinking Abnormal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lithium			C				Not Reported
	Depakote			C				Not Reported
	Zyprexa			C				Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6496629	NON-EXPEDITED	Y	HO	S07-USA-02661-01		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6497547	NON-EXPEDITED	Y	OT	S07-USA-03187-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6497562	NON-EXPEDITED	N	OT	S07-USA-02565-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Loss Of Consciousness	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Birth Control Pills			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6497563	NON-EXPEDITED	N		S07-USA-02542-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Nausea	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aleve			S				Not Reported
	Advil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6497564	NON-EXPEDITED	Y	OT	S07-USA-02489-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Humalog			C				Not Reported
	Lantus			C				Not Reported
	Glucophage			C				Not Reported
	Benicar			C				Not Reported
	Pravachol			C				Not Reported

	Inhalers (Nos)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6497565	NON-EXPEDITED	N	HO	S07-USA-02462-01		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Pancreatitis	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6497566	NON-EXPEDITED	N	OT	S07-USA-02430-01		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depression; Fatigue; Intervertebral Disc Protrusion; Suicidal Ideation	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Vivelle			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6497568	NON-EXPEDITED	N	OT	S07-USA-02417-01		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Restlessness; Suicidal Ideation	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6506662	NON-EXPEDITED	Y	DE	S06-USA-03741-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6506744	NON-EXPEDITED	Y	HO	S06-USA-04330-01		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blepharospasm; Loss Of Consciousness; Tremor	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lamictal			S				Not Reported
	Lamictal			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6507069	NON-EXPEDITED		HO	S06-USA-02840-01		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression; Intentional Overdose; Speech Disorder; Suicidal Ideation; Tremor	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6507116	NON-EXPEDITED		OT	S06-USA-01889-01		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Attention; Dizziness; Flatulence; Middle Insomnia; Suicidal Ideation; Vision Blurred	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2007	6507239	NON-EXPEDITED		HO	S07-USA-02571-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hypersensitivity	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Lexapro		S	Oral	20 Mg Qd Po	Not Reported
	Prozac		C			Not Reported
	Effexor		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2007	6398009	EXPEDITED (15-DAY)	Y	DE	S07-IRL-03519-01		58 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Completed Suicide; Condition Aggravated; Contusion; Craniocerebral Injury; Gun Shot Wound; Incorrect Dose Administered; Skull Fracture	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2007	6448610	EXPEDITED (15-DAY)	Y	DE	S07-USA-05347-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Hereditary Motor And Sensory Neuropathy; Hypokalaemia; Overdose; Road Traffic Accident; Seizure; Thrombosis; Toxicity To Various Agents	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Potassium Replacement			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2007	6346198	EXPEDITED (15-DAY)	Y	DE	S07-FRA-02578-01		28 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

Risperidone	C		Not Reported
Clonazepam	C		Not Reported
Noctamide (Lormetazepam)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2007	6411603	EXPEDITED (15-DAY)	N	OT	2007AP000908			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression; Hostility; Hyperhidrosis; Mania; Thinking Abnormal	Trazodone Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2007	6443958	NON-EXPEDITED	N		A0619823A		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hypersensitivity; Throat Tightness; Urticaria	Ceftin			S	Unknown		6 DAY	Glaxosmithkline
	Lexapro			S	Oral	5mg Per Day	1 DAY	Not Reported
	Nasarel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2007	6454494	EXPEDITED (15-DAY)	Y	DE	S07-IRL-05115		65 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Paraquat			S				Not Reported
	Pravastatin Sodium			C				Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2007	6455685	EXPEDITED (15-DAY)	Y	LT	S07-FRA-05460-01		52 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gastrointestinal Erosion; Phlebitis; Pulmonary Embolism	Escitalopram Oxalate		S	Oral	20 Mg Qd Po	Not Reported
	Urbanyl		C			Not Reported
	Trimeprazine Tartrate		C			Not Reported
	Prazepam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2007	6365178	EXPEDITED (15-DAY)	Y	DS	S07-IRL-02863-01		45 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vaginal Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Amoxicillin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2007	6426831	EXPEDITED (15-DAY)	Y	HO	S07-ESP-03797-01		75 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cortisol Increased; Drug Interaction; Inappropriate Antidiuretic Hormone Secretion; Restlessness	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported
	Risperidone			S	Oral	2 Mg Qd Po		Not Reported
	Durphalac (Lactulose)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2007	6445693	EXPEDITED (15-DAY)	Y	OT	FR-PFIZER INC-2007086029		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Delirium; Drug Ineffective; Drug Interaction	Zoloft			S				Not Reported
	Aricept			S		Daily Dose:10mg-Freq:Every Day		Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2007	5905961	EXPEDITED (15-DAY)	Y	OT	PHFR2005GB03379		49 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersomnia; Overdose; Sedation	Clozaril			S	Oral	450 Mg/Day		Novartis
	Cipralex			S	Unknown			Not Reported
	Clozaril			S	Oral	1700 Mg Overdose		Novartis
	Clozaril			S	Oral	Overdose - 3 Days Supply		Novartis
	Abilify			S	Unknown	Overdose - 3 Days Supply		Not Reported
	Mirtazapine			S	Unknown	Overdose - 3 Days Supply		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2007	6455918	EXPEDITED (15-DAY)	N	HO	S07-USA-05505-01		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Diarrhoea; Nausea	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Plavix			C				Not Reported
	Imdur			C				Not Reported
	Lopresor			C				Not Reported
	Protonix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2007	6455922	EXPEDITED (15-DAY)	Y	OT	US021474		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Provigil			S	Oral	100 Mg Bid Oral		Not Reported
	Provigil			S	Oral	100 Mg Qd Oral		Not Reported
	Lexapro			S	Oral	10 Mg Qd Oral		Not Reported
	Lorazepam			C				Not Reported
	Zyrtec			C				Not Reported
	Hormone Replacement Therapy (Unspecified)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2007	6456777	EXPEDITED (15-DAY)	Y	OT	S07-FRA-05526-01		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorea	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Sinemet			C				Not Reported
	Depakote			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2007	6457948	DIRECT	N	DE, OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	1 Per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2007	6313300	EXPEDITED (15-DAY)	N	OT	US-BAYER-200711492BCC		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Dizziness; Dyspnoea; Loss Of Consciousness; Vomiting	Aleve			S	Oral	Total Daily Dose: 220 Mg Unit Dose: 220 Mg	1 DAY	Bayer
	Rebif			S	Subcutaneous	Unit Dose: 44 Mg		Not Reported
	Lexapro			S	Oral	Total Daily Dose: 10 Mg Unit Dose: 10 Mg		Not Reported
	Femhrt			C		Total Daily Dose: 1 Mg Unit Dose: 1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2007	6457744	EXPEDITED (15-DAY)	Y	DS	S07-FRA-05540-01		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Sleep Disorder; Tremor	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Mysoline (Primidone)			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2007	6459512	DIRECT	Y	OT			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Headache; Therapy Non-Responder	Lexapro			S				Forest
	Relpax			C				Not Reported
	Phenergan			C				Not Reported
	Excedrin			C				Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported
	Amoxicillin			C				Not Reported
	Nasarel			C				Not Reported
	Hydrocodone			C				Not Reported
	Ibuprofen			C				Not Reported
	Vicodin			C				Not Reported
	Naprosyn			C				Not Reported
	Asa			C				Not Reported
	Midrin			C				Not Reported
	Fish Oil			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2007	6392488	EXPEDITED (15-DAY)	Y	HO	S07-USA-03425-01		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Acetaminophen\Diphenhydramine			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2007	6459259	EXPEDITED (15-DAY)	Y	HO	S07-USA-05456-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Drug Interaction; Dyspnoea; Feeling Abnormal; Intervertebral Disc Degeneration; Serotonin Syndrome; Sinusitis; Swollen Tongue; Tinnitus	Lexapro		S	Oral	10 Mg Qd Po	Not Reported
	Delsym		S			Not Reported
	Levothyroxine		C			Not Reported
	Atacand (Candesartan Cilexetil)		C			Not Reported
	Hydrochlorothiazide		C			Not Reported
	Vytorin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2007	6460994	EXPEDITED (15-DAY)	Y	HO	S07-FRA-05565-01		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Diplopia; General Physical Health Deterioration; Toxicity To Various Agents; Weight Decreased	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Prazepam			S				Not Reported
	Prazepam			S	Oral	0.5 Tid Po		Not Reported
	Propoxyphene Hydrochloride And Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2007	6496095	NON-EXPEDITED	Y	OT	2007US002014		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Vaprisol			S	Intravenous drip	Iv Drip		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2007	6453724	EXPEDITED (15-DAY)	Y	DE	US-ROCHE-526271		35 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Clonazepam			S	Oral	Acute On Chronic. Route: Ingestion.		Roche
	Escitalopram Oxalate			S	Oral	Acute On Chronic. Route: Ingestion.		Not Reported
	Venlafaxine Hydrochloride			S	Oral	Drug Reported As		Not Reported

						Venlafaxine (Long Acting). Acute On Chronic. Route: Ingestion.				
	Unspecified Ingredient			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2007	6433342	EXPEDITED (15-DAY)	Y	HO	S07-GER-05056-01		69 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
High Density Lipoprotein Decreased; Left Ventricular Dysfunction; Stress Cardiomyopathy; Troponin Increased; Vascular Pseudoaneurysm	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Ramipril			S				Not Reported
	Sortis (Atorvastatin0			C				Not Reported
	Concor 5 Plus (Biselect)			C				Not Reported
	Allopurinol			C				Not Reported
	Tavor (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2007	6461859	EXPEDITED (15-DAY)	Y	DE	S07-USA-05552-01		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Drug Level Above Therapeutic	Lexapro			S	Oral	10 Mg Bid Po		Not Reported
	Fentanyl			C				Not Reported
	Hydrocodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2007	6462124	EXPEDITED (15-DAY)	Y	HO, OT	100#03#2007-04173		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Depressive Symptom; Drug Interaction; Essential Tremor; Sinus Bradycardia; Syncope;	Omeprazole			S		20 Mg		Not Reported
	Propranolol			S		80 Mg	5 DAY	Not Reported
	Donepezil			S		10 Mg	2 YR	Not Reported
	Escitalopram Oxalate			S		10 Mg	5 DAY	Not Reported

Torsade De Pointes	Mirtazapine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2007	6462186	EXPEDITED (15-DAY)	Y	HO, LT	DSA_30787_2007		31 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Mydriasis; Somnolence; Suicide Attempt	Tavor /00273201/ (Lorazepam) Tablet			S	Oral	Not The Prescribed Amount, Oral		Not Reported
	Alcohol			S	Oral	Not The Prescribed Amount, Oral		Not Reported
	Cipralex			S	Oral	Not The Prescribed Amount, Oral		Not Reported
	Risperdal			S	Oral	Not The Prescribed Amount, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2007	6462331	EXPEDITED (15-DAY)	Y	OT	2007S1010664		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Torsade De Pointes; Ventricular Tachycardia	Omeprazole			S		10 Mg		Not Reported
	Donepezil Hydrochloride			S		10 Mg		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Propranolol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2007	6462372	DIRECT		HO			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicide Attempt	Escitalopram Oxalate			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2007	6462741	EXPEDITED (15-DAY)	Y	HO	2007RL000477		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Sinus Bradycardia; Syncope; Torsade De Pointes	Propranolol Hydrochloride			S		80 Mg		Not Reported
	Donepezil Hydrochloride			S		10 Mg		Not Reported
	Escitalopram Oxalate			S		10 Mg		Not Reported
	Omeprazole			S		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2007	6464416	EXPEDITED (15-DAY)	N	HO	S07-USA-05653-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Infection; Seizure; Tremor	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2007	6464802	EXPEDITED (15-DAY)	Y	HO	S07-USA-05623-01		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hostility; Irritability; Mental Disorder; Speech Disorder	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2007	6464917	DIRECT	Y				31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Dissociation; Dizziness; Drug Withdrawal Syndrome; Headache; Inappropriate Schedule Of Product Administration; Influenza Like Illness; Initial	Lexapro			S	Oral	20mg Every Day Po		Not Reported
	Loestrin 1.5/30 21 Day			C				Not Reported
	Singulair			C				Not Reported

Insomnia; Lethargy; Middle Insomnia; Myalgia; Nausea; Sleep Disorder; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2007	6466166	DIRECT	N	HO, OT			22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Suicide Attempt	Trazodone Hydrochloride			S		100 Mg 1 X Ea Day		Not Reported
	Lexapro			S		10 Mg 1x Ea Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2007	6363219	EXPEDITED (15-DAY)	Y	HO, OT	S07-UKI-02929-01		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Depressed Level Of Consciousness; Electrocardiogram Qt Prolonged; Intentional Overdose; Myoclonus; Pneumonia; Serotonin Syndrome; Toxicity To Various Agents	Cipralex			S				Not Reported
	Lamotrigine			S				Not Reported
	Zyprexa			S				Not Reported
	Zopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2007	6468101	EXPEDITED (15-DAY)	Y	HO	S07-USA-05692-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Blood Pressure Decreased; Dizziness; Syncope	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lamictal			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2007	6468627	EXPEDITED (15-DAY)	Y	OT	S07-IRL-05775-01			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage	Lexapro			S	Oral	15 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2007	6468986	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Feeling Hot; Hyperhidrosis; Tremor	Lexapro			S	Oral	20mg 1qd Po		Not Reported
	Buproprion			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2007	6469479	EXPEDITED (15-DAY)	Y	DE	S07-FRA-05782-01		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urea Increased; Haematoma; Haemorrhagic Stroke; Hyperkalaemia; Hyperthermia; Hyponatraemia; Increased Bronchial Secretion; Intraventricular Haemorrhage; Meningorrhagia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin Lysine			S	Oral	75 Mg Qd Po		Not Reported
	Zaldiar (Paracetamol/Tramadol)			C				Not Reported
	Acetaminophen			C				Not Reported
	Movicol			C				Not Reported
	Densical D3 (Calcium Carbonate/Colecalciferol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2007	6469480	EXPEDITED (15-DAY)	Y	HO, LT	S07-GER-05781-01		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Hypoglycaemia; Loss Of Consciousness	Cipralex	S	Oral	20 Mg Qd Po		Not Reported
	L-Thyroxin (Levothyroxine)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2007	6440810	EXPEDITED (15-DAY)	Y	HO	S07-AUS-05208-01		64 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Feeling Of Body Temperature Change; Vision Blurred	Escitalopram Oxalate			S	Oral	10 Mg Qd;Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2007	6443594	EXPEDITED (15-DAY)	Y	DS	S07-KOR-05265-01		69 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported
	Clopidogrel			C				Not Reported
	Nicorandil			C				Not Reported
	Thioctic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2007	6466267	EXPEDITED (15-DAY)	Y	OT	S07-FRA-05658-01		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Lymphocytosis; Skin Toxicity; Therapy Non-Responder	Escitalopram Oxalate			S	Ophthalmic	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2007	6472745	EXPEDITED (15-DAY)	Y	OT	S07-FRA-05785-01		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Colitis	Escitalopram Oxalate		S	Oral	20 Mg Qd Po	Not Reported
	Inipomp		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2007	6465732	EXPEDITED (15-DAY)	Y	OT	S07-NLD-05680-01		64 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypoglycaemia	Lexapro			S				Not Reported
	Insulin Aspart			S	Intramuscular	100 Iu, Im		Not Reported
	Oxazepam			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Nebivolol			C				Not Reported
	Simvastatin			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2007	6472700	EXPEDITED (15-DAY)	N	OT	S07-USA-05816-01		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinal Disorder	Lexapro			S	Oral	20 Mg Qd;Po		Not Reported
	Prednisone			C				Not Reported
	Tylenol #3 (Acetaminophen And Codeine)			C				Not Reported
	Methotrexate			C				Not Reported
	Xanax			C				Not Reported
	Orencia (Abatacept)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2007	6472787	EXPEDITED (15-DAY)	Y	HO	S07-USA-05753-01		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Cataract Operation; Heart Rate Decreased; Procedural Complication	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Pentothal			S				Not Reported
	70/30 Nph / Regular Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2007	6472799	EXPEDITED (15-DAY)	Y	OT	S07-USA-05821-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Provigil			S		100 Mg Bid		Not Reported
	Provigil			S		100 Mg Qd		Not Reported
	Hormone Replacement Therapy (Nos)			C				Not Reported
	Lorazepam			C				Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2007	6474943	EXPEDITED (15-DAY)	Y	CA	S07-USA-05717-02		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Craniosynostosis; Maternal Exposure During Pregnancy; Post Procedural Complication; Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2007	6408469	EXPEDITED (15-DAY)	Y	OT	S07-USA-03602-01		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejaculation Delayed; Hypothyroidism	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Chantix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2007	6461427	EXPEDITED (15-DAY)	Y	HO	2007S1010361		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sinus Bradycardia; Syncope; Torsade De Pointes	Propranolol			S		80 Mg;		Not Reported
	Donepezil Hydrochloride			S		10 Mg;		Not Reported
	Escitalopram Oxalate			S		10 Mg;		Not Reported
	Omeprazole			S		20 Mg;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2007	6468198	EXPEDITED (15-DAY)	N	HO	US-ABBOTT-07P-163-0423493-00		9 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2007	6468450	EXPEDITED (15-DAY)		OT	US-ROXANE LABORATORIES, INC-2007-BP-24224RO		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Blood Thyroid Stimulating Hormone Decreased; Hypogonadism	Megestrol Acetate			S				Roxane
	Oxycodone			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported
	Levothyroxine			S				Not Reported
	Fludrocortisone Acetate			S				Not Reported
	Testosterone			C	Topical			Not Reported
	Paclitaxel			C				Not Reported
	Carboplatin			C				Not Reported
	Capecitabine			C				Not Reported
	Dexamethasone			C				Not Reported
	Methylphenidate Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2007	6476259	EXPEDITED (15-DAY)	Y	OT	S07-ESP-05885-01			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypertensive Crisis	Escitalopram Oxalate	S		Not Reported
	Almogran	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2007	6459822	EXPEDITED (15-DAY)	Y	OT	S07-SWI-05567-01		54 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Dehydration; Dizziness; Heart Rate Decreased; Nausea; Orthostatic Hypotension; Parosmia; Respiratory Rate Decreased; Sleep Disorder; Vision Blurred; Vomiting	Cipralex			S	Oral	10 Mg Bid Po		Not Reported
	Ritalin			C				Not Reported
	Clorazepate Dipotassium			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2007	6468631	EXPEDITED (15-DAY)	Y	DS, HO	S07-NOR-05759-01		56 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Dizziness; Influenza; Nausea; Syncope; Vomiting	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Adalat Oros (Nifedipine)			C				Not Reported
	Irbesartan			C				Not Reported
	Lipitor			C				Not Reported
	Furosemide			C				Not Reported
	Levothyroxine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2007	6475945	EXPEDITED (15-DAY)	Y	OT	S07-SWE-05951-01			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling; Oedema Peripheral; Proteinuria	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Concerta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2007	6509523	DIRECT	Y	HO, RI			80 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Dystonia; Ill-Defined Disorder; Jaw Disorder; Mental Status Changes; Respiratory Disorder; Trismus; Vital Functions Abnormal	Lexapro			S				Not Reported
	Quinidine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2007	6462873	EXPEDITED (15-DAY)	Y	HO, LT, OT	CZ-ASTRAZENECA-2007SE05938		17 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Quetiapine			S	Oral		107 DAY	Zeneca
	Escitalopram Oxalate			S			87 DAY	Not Reported
	Escitalopram Oxalate			S			1 DAY	Not Reported
	Lamotrigine			S	Oral		36 DAY	Not Reported
	Rivotril			S	Oral		36 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2007	6470632	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20071105221			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Gait Disturbance; Hallucination	Risperdal			S	Oral			Not Reported
	Modopar			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Ditropan			S	Oral			Not Reported
	Discotrine			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Levothyrox			C				Not Reported

	Praxinor	C	Not Reported
	Calcium Carbonate	C	Not Reported
	Structum	C	Not Reported
	Stilnox	C	Not Reported
	Tanakan	C	Not Reported
	Vastarel	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2007	6476772	DIRECT					18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Occlusion; Medication Error; Product Dispensing Error	Lexapro			S		Tablet		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2007	6477060	EXPEDITED (15-DAY)	Y	HO	S07-USA-05869-01		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Feeling Cold; Muscle Twitching; Panic Reaction; Seizure; Serotonin Syndrome	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2007	6478337	DIRECT	Y	HO, LT, RI, OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alopecia; Amnesia; Anxiety; Back Injury; Chills; Confusional State; Depression; Drug Interaction; Hyperhidrosis; Hypoglycaemia; Impaired	Lexapro			S	Oral	One Tab Daily Po		Not Reported
	Toprol Xl			S	Oral	One Tab Dailt Po		Not Reported

Driving Ability; Impaired Work Ability; Injury; Loss Of Consciousness; Malnutrition; Nausea; Overdose; Road Traffic Accident; Syncope; Tremor; Unresponsive To Stimuli; Vomiting; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2007	6360192	EXPEDITED (15-DAY)	Y	OT	PHNU2007DE02415		57 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Lethargy; Salivary Hypersecretion; Somnolence	Leponex			S	Oral	325mg/Day	89 DAY	Novartis
	Cipralex			S	Oral	15 Mg/Day		Not Reported
	Amisulpride			C	Oral	200 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2007	6377285	EXPEDITED (15-DAY)	Y	HO	S07-FRA-03165-01		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported
	Anafranil			S	Oral	25 Mg Qd Po		Not Reported
	Paroxetine Hydrochloride			C	Oral	20 Mg Qd Po		Not Reported
	Metformin Hydrochloride			C	Oral	2000 Mg Qd Po		Not Reported
	Cozaar			C				Not Reported
	Cardensiel (Bisoprolol)			C				Not Reported
	Mediator (Benfluorex Hydrochloride)			C				Not Reported
	Atorvastatin Calcium			C				Not Reported
	Losartan Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2007	6436517	EXPEDITED (15-DAY)	Y	LT	S07-FRA-05130-01		75 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Anoxia; Arrhythmia; Bundle Branch Block Right; Cardiac Arrest; Coma; Drug Level Increased; Electrocardiogram Qrs Complex Prolonged; Hypertension; Hypertrophic Cardiomyopathy; Hypokalaemia; Malaise; Mydriasis; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	30 Mg Qd Po		Not Reported
	Noctamide (Lormetazepam)			C				Not Reported
	Bisoprolol			C				Not Reported
	Hyzaar			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2007	6480209	EXPEDITED (15-DAY)	Y	HO	071004637		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Interaction; Dyspnoea; Feeling Abnormal; Hypotension; Intervertebral Disc Degeneration; Intervertebral Disc Protrusion; Meniere'S Disease; Serotonin Syndrome; Sinusitis; Swollen Tongue	Lexapro			S	Oral	10mg, Qd, Oral		Not Reported
	Delsym			S				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Atacand (Candesartan Cilexetil)			C				Not Reported
	Hydrochlorothiazide (Hydrochlorothiazide)			C				Not Reported
	Vytorin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2007	6454414	EXPEDITED (15-DAY)	Y	OT	S07-USA-05417-01		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Impaired Driving Ability; Lethargy; Psychomotor Skills Impaired; Somnolence	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lisinopril			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2007	6475793	EXPEDITED (15-DAY)	Y	HO, OT	2007-04652		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Discomfort; Depression; Device Related Sepsis; Diabetes Mellitus; Dysuria; Escherichia Sepsis; Escherichia Urinary Tract Infection; Failure To Thrive; Gastritis; Hyperlipidaemia; Hypertension; Incisional Hernia; Inguinal Mass; Intestinal Stenosis; Malaise; Nausea; Oedema Peripheral; Osteopenia; Osteoporosis; Postoperative Adhesion; Prostate Cancer; Prostatitis; Pubic Pain; Sepsis; Urge Incontinence; Urinary Tract Infection Fungal; Weight Increased	Prednisone			S	Oral	5 Mg, Daily (Long Taper), Oral		Watson
	Prednisone			S	Oral	10-40 Mg, Daily Taper To 5mg, Oral		Watson
	Zyprexa			S				Not Reported
	Lexapro			S				Not Reported
	Pentasa "Pharmacia" (Mesalazine)			C				Not Reported
	Loperamide Hydrochloride			C				Not Reported
	Multivitamins (Retinol, Riboflaving, Nicotinamide, Panthenol)			C				Not Reported
	Fish Oil (Fish Oil)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2007	6483606	EXPEDITED (15-DAY)	Y	HO	T07-TUN-05611-01		21 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypotension	Escitalopram Oxalate	S	10 Mg Qd		Not Reported
	Amisulpride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2007	6529196	NON-EXPEDITED	N	OT	US-JNJFOC-20070206475		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Levaquin			S				Not Reported
	Lexapro			S	Oral	10 Mg, 1 In 1 Day, Oral		Not Reported
	Unspecified Ingredient			S				Not Reported
	Rituxan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2007	6474737	EXPEDITED (15-DAY)	Y	HO	DE-ASTRAZENECA-2007PK02369		24 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Seroquel			S	Oral		13 DAY	Zeneca
	Seroquel			S	Oral		14 DAY	Zeneca
	Seroquel			S	Oral		19 DAY	Zeneca
	Cipralex			S	Oral		5 DAY	Not Reported
	Cipralex			S	Oral		3 DAY	Not Reported
	Cipralex			S	Oral			Not Reported
	Valproic Acid			S	Oral		3 DAY	Not Reported
	Valproic Acid			S	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Diazepam			C	Oral		8 DAY	Not Reported
	Diazepam			C	Oral		15 DAY	Not Reported
	Diazepam			C	Oral		9 DAY	Not Reported
	Diazepam			C	Oral		7 DAY	Not Reported
	Diazepam			C	Oral		7 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2007	6480836	DIRECT	N				57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Ill-Defined Disorder	Lexapro			S	Oral	10 Mg Daily Po	1 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2007	6468197	EXPEDITED (15-DAY)	N	OT	S07-USA-05608-01		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Headache; Muscle Spasms	Lexapro			S	Oral	10 Mg Qod Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	7.5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qod Po		Not Reported
	Lexapro			S	Oral	7.5 Mg Qod Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qod Po		Not Reported
	Lexapro			S	Oral	5 Mg Qod Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2007	6490510	EXPEDITED (15-DAY)	Y	OT	S07-FRA-06092-01		61 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonic Epilepsy	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2007	6490539	EXPEDITED (15-DAY)	Y	HO	S07-GER-06055-01		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Disorientation; Hyponatraemia; Partial Seizures; Seizure; Syncope	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Torsemide			S	Oral	10 Mg Qd Po		Not Reported
	Spironolactone			S	Oral	50 Mg Qd Po		Not Reported
	Zyprexa			C				Not Reported
	Asa (Acetylsalicylic Acid)			C				Not Reported
	Pantozol (Pantoprazole Sodium)			C				Not Reported
	Prednisolone			C				Not Reported
	Allopurinol			C				Not Reported
	Cipramil Filmtabletten (Citalopram)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2007	6490553	EXPEDITED (15-DAY)	Y	HO	S07-GER-06057-01		70 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Cerebral Atrophy; Cerebral Ischaemia; Condition Aggravated; Depression; Gait Disturbance; General Physical Health Deterioration; Psychomotor Retardation; Reduced Facial Expression; Stupor; Transient Ischaemic Attack; Tremor	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Mirtazapine			C				Not Reported
	Tavor (Lorazepam)			C				Not Reported
	Zyprexa			C				Not Reported
	Enalapril			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2007	6336985	EXPEDITED (15-DAY)	Y	DE	S07-SWI-02387-01		76 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asphyxia; Completed Suicide; Overdose	Cipralex		S	Oral	35 Mg Qd Po	Not Reported
	Remeron		S	Oral	45 Mg Qd Po	Not Reported
	Bromazepam		S	Oral	3.75 Mg Qd Po	Not Reported
	Losartan Potassium And Hydrochlorothiazide		C			Not Reported
	Pantoprazole Sodium		C			Not Reported
	Perenterol (Yeast Dried)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2007	6366160	EXPEDITED (15-DAY)	Y	CA, OT	S07-USA-02894-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Ovarian Anomaly; Maternal Exposure During Pregnancy; Ovarian Cyst	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Prenatal Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2007	6445216	EXPEDITED (15-DAY)	Y	DE	S07-GRC-05340-01		75 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Disease; Myocardial Infarction	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Remeron			C				Not Reported
	Stedon (Diazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2007	6471726	EXPEDITED (15-DAY)	N	OT	S07-USA-05799-01		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Groin Pain; Hernia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2007	6477169	NON-EXPEDITED	N	OT	A0639042A		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Panic Attack; Suicidal Ideation	Wellbutrin Sr			S	Oral	150mg Twice Per Day	1 DAY	Glaxosmithkline
	Lexapro			S			3 MTH	Not Reported
	Alcohol			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2007	6477177	NON-EXPEDITED	N		A0641774A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Alcohol Use; Hostility; Overdose	Wellbutrin Sr			S	Oral			Glaxosmithkline
	Phentermine			S				Glaxosmithkline
	Lexapro			S				Not Reported
	Alcohol			S	Oral			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2007	6495665	EXPEDITED (15-DAY)	Y	HO	S07-FRA-06077-01		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Antiepileptics (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2007	6495670	EXPEDITED (15-DAY)	Y	OT	S07-FRA-06073-01		53 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Subileus	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Once Po		Not Reported
	Botulinum Toxin Type A			S				Not Reported
	Lexomil (Bromazepam)			C				Not Reported
	Herbals With Minerals/Vitamins (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2007	6500628	EXPEDITED (15-DAY)	Y	OT	S07-FRA-06076-01		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Antiepileptics (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2007	6503531	EXPEDITED (15-DAY)	Y	HO	S07-FRA-06081-01		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Coronary Artery Disease	Escitalopram Oxalate			S	Oral	10 Mg Qd;Po		Not Reported
	Previscan (Fluindione)			C				Not Reported
	Kardegic (Acetylsalicylate Lysine)			C				Not Reported
	Perindopril Erbumine			C				Not Reported
	Atenolol			C				Not Reported
	Inergy (Ezetimibe/Simvastatin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2007	6287894	NON-EXPEDITED	Y	CA	HQWYE138110APR07			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Foetal Growth Restriction; Foetal Hypokinesia; Trisomy 21	Effexor Xr			S	Transplacental Transplacental Transplacental	See Image See Image See Image		Not Reported
	Cortef			S	Transplacental	Transplacental		Not Reported
	Cytomel			S	Transplacental	Transplacental		Not Reported
	Lexapro			S	Transplacental	Transplacental		Not Reported
	Synthroid			S	Transplacental	Transplacental		Not Reported
	Wellbutrin			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2007	6291355	EXPEDITED (15-DAY)	Y		S07-ITA-00163-01		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Potassium Increased; Caesarean Section; Haematocrit Increased; Hypertension; Maternal Exposure During Pregnancy; Mean Cell Haemoglobin Concentration Increased; Mean Cell Volume Abnormal; Perinatal Depression; Pregnancy; Presyncope	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S				Not Reported
	Sedatol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2007	6468632	EXPEDITED (15-DAY)	Y	OT	S07-GER-05779-01		67 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Basal Cell Carcinoma; Hyperhidrosis; Pruritus; Psoriasis; Vision Blurred	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
					Oral	10 Mg Qd Po		
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			C				Not Reported
	Concor (Bisoprolol Fumarate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2007	6499981	DIRECT	N	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Asthenia; Confusional State; Decreased Activity; Fibromyalgia; Hypoaesthesia; Influenza Like Illness; Muscle Spasms; Muscular Weakness	Celexa		S	Intravenous (not otherwise specified)	1 Tablet Once A Day Iv	Not Reported
	Lexapro		S	Intravenous (not otherwise specified)	1 Tablet Na Iv	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2007	6500630	DIRECT	Y				58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphemia; Metabolic Acidosis; Serotonin Syndrome; Tremor; Urinary Tract Infection	Linezolid			S	Oral	600 Mg Bid Po		Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2007	6507524	EXPEDITED (15-DAY)	Y	HO	S07-FRA-05783-01		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Confusional State	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Disulfiram			S	Oral	1 Tablet Qd Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2007	6569926	NON-EXPEDITED	Y	OT	HQWYE482124OCT06		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Effexor Xr			S	Oral	37.5 Mg 1x Per 1 Day, Oral		Not Reported

	Lexapro			S		20 Mg 1x Per 1 Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2007	6506076	DIRECT	N				54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Lipitor			S		Tablet		Pfizer
	Lexapro			S		Tablet		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2007	6483563	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2007100003			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal;	Lyrica			S				Not Reported
Impaired Work Ability;	Unspecified Ingredient			S				Not Reported
Nausea; Thinking Abnormal	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2007	6570890	NON-EXPEDITED	Y	OT	2007056549			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Viagra			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2007	6434530	EXPEDITED (15-DAY)	Y	DE, OT	US-PFIZER INC-2007081030		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest;	Geodon			S				Not Reported
Electrocardiogram Qt Prolonged; Respiratory Arrest	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported

	Lyrica	C	Daily Dose:150mg	Not Reported
	Glucophage	C	Daily Dose:200mg	Not Reported
	Esgic	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2007	6443577	EXPEDITED (15-DAY)	Y	HO	S07-FRA-05263-01		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Brain Neoplasm; Confusional State; Decreased Appetite; Depressed Mood; Depression; Disturbance In Attention; Psychomotor Retardation; Weight Decreased	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Victan (Ethyl Loflazepate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2007	6487286	EXPEDITED (15-DAY)	Y	OT	A0697996A		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Live Birth; Maternal Exposure During Pregnancy; Nephrolithiasis; Urinary Tract Infection	Wellbutrin			S	Oral	10mg Per Day		Glaxosmithkline
	Lexapro			S				Not Reported
	Tylenol			C				Glaxosmithkline
	Prenatal Vitamins			C				Not Reported
	Vicodin			C				Not Reported
	Pyridium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2007	6501292	EXPEDITED (15-DAY)	Y	OT	S07-NOR-06074-01		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Depression; Dizziness;	Cipralex			S	Oral	20 Mg Qd Po		Not Reported

Drug Interaction; Headache; Mania; Personality Disorder; Seizure; Suicidal Ideation; Vomiting	Cipralex	S	Oral	20 Mg Qd Po		Not Reported
	Strattera	S		60 Mg Qd		Not Reported
	Antabuse	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2007	6510460	EXPEDITED (15-DAY)	Y	HO	S07-FRA-06171-01		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Immunoglobulin A Increased; Drug Interaction; Hypersensitivity Vasculitis	Escitalopram Oxalate			S				Not Reported
	Oxazepam			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Diamicron (Gliclazide)			C				Not Reported
	Tenstaten (Cicletanine)			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Trimeprazine Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2007	6511690	EXPEDITED (15-DAY)	Y	HO, LT, OT	S07-FRA-05254-01		49 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Anxiety; Asphyxia; Impulsive Behaviour; Skin Laceration; Suicidal Ideation; Suicide Attempt	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Inipomp			C				Not Reported
	Havlane (Loprazolam Mesilate)			C				Not Reported
	Lexomil (Bromazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2007	6512323	EXPEDITED (15-DAY)	Y	OT	S07-FRA-05253-01		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cognitive Disorder; Confusional State; Dementia; Disorientation; Disturbance In Attention;	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Selokeen			C				Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported
	Pravastatin			C				Not Reported

Hallucination, Auditory;
Memory Impairment;
Psychomotor Retardation;
Sleep Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2007	6511913	EXPEDITED (15-DAY)	Y	OT	S07-USA-06106-03			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2007	6511918	DIRECT	N	HO, LT, OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Amnesia; Contusion; Drug Abuse; Hallucinations, Mixed; Head Injury; Imprisonment; Poisoning; Psychotic Disorder; Screaming; Seizure; Swelling Face; Thinking Abnormal; Toothache	Lexapro			S	Oral	60 Mg All At Once, Am Po		Forest
	Wellbutrin			S	Oral	450 Mg All At Once, Am Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2007	6511932	EXPEDITED (15-DAY)	Y	OT	S07-USA-06106-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2007	6511940	EXPEDITED (15-DAY)	Y	OT	S07-USA-06106-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2007	6513804	DIRECT	Y	HO, LT, OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alcoholic; Antinuclear Antibody Positive; Diarrhoea; Hypertension; Insomnia; Nerve Injury; Palpitations; Panic Attack; Serotonin Syndrome; Tremor; Vomiting	Lexapro			S		1 Daily		Not Reported
	Zoloft			S		1; Then 4 Then Back To 1 Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2007	6513968	DIRECT	Y	HO			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Major Depression	Escitalopram Oxalate			S	Oral	10 Mg Od - Oral		Not Reported
	Glimepiride			C				Not Reported
	Quinapril			C				Not Reported
	Carvedilol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2007	6513976	EXPEDITED (15-DAY)	Y	HO	DSA_30950_2007		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt; Tachycardia	Tavor /00273201/ (Lorazepam) Tablet			S	Oral	5 Mg 1x .Oral		Not Reported
	Aspirin			S	Oral	15 G 1x . Oral		Not Reported
	Cipralex			S	Oral	6 Df 1x Oral		Not Reported

Acetaminophen	S	Oral	Oral		Not Reported
Mirtazapine	S	Oral	1050 Mg 1x . Oral		Not Reported
Seroquel	S	Oral	20 G 1x . Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2007	6150301	EXPEDITED (15-DAY)	Y	HO	S06-FRA-04081-01		81 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Asthenia; Fall; Hyponatraemia; Loss Of Consciousness; Orthostatic Hypotension; Urinary Incontinence; Urinary Tract Infection	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Exelon			C				Not Reported
	Basdene (Benzylthiouracil)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2007	6436465	EXPEDITED (15-DAY)	N	OT	A0697996B		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Maternal Exposure During Pregnancy; Pulmonary Hypertension	Wellbutrin			S		10mg Per Day		Glaxosmithkline
	Lexapro			S				Not Reported
	Tylenol			C				Glaxosmithkline
	Prenatal Vitamins			C				Not Reported
	Vicodin			C				Not Reported
	Pyridium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2007	6509949	DIRECT	N	CA			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Loss Of Consciousness; Maternal Exposure During Pregnancy; Mitral Valve Disease; Pregnancy;	Lexapro			S	Oral	10 Mg 1tab Daily By Mouth		Not Reported

Syncope

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2007	6513703	DIRECT	N	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation; Fatigue; Fear; Lethargy; Thinking Abnormal	Lexapro			S	Oral	10mg 1 Day Po	2 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2007	6514251	EXPEDITED (15-DAY)	Y	DE	S07-USA-06141-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2007	6516995	DIRECT	Y	HO			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Conduction Disorder; Mitral Valve Incompetence; Nausea; Non-Cardiac Chest Pain; Pulmonary Valve Incompetence; Qrs Axis Abnormal; Sinus Arrhythmia; Tricuspid Valve Incompetence	Escitalopram Oxalate			S	Oral	10 Mg Od - Oral		Not Reported
	Metoclopramide			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Saw Palmetto			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Niacin			C				Not Reported
	Fish Oil			C				Not Reported
	Ginkgo Biloba			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2007	6517770	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anxiety; Confusional State; Fear; Restlessness; Suicidal Ideation	Lexapro			S	Oral	10 Mg Tablet Once A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2007	6515089	EXPEDITED (15-DAY)	N	HO	S07-USA-06211-01		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alcohol Abuse; Mania; Suicidal Ideation; Weight Increased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2007	6452807	EXPEDITED (15-DAY)	Y	OT	S07-USA-05457-01		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Amnesia; Dissociation; Haemorrhage; Intentional Self-Injury; Intentional Self-Injury; Skin Laceration; Suicidal Behaviour	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lamictal			C				Not Reported
	Depakote			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2007	6501387	EXPEDITED (15-DAY)	Y	OT	A0698825A		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Drug Ineffective; Headache	Imitrex			S	Oral	100mg Single Dose	1 DAY	Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2007	6516273	EXPEDITED (15-DAY)	Y	OT	S07-USA-06246-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2007	6517634	EXPEDITED (15-DAY)	Y	OT	S07-USA-06186-01		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Contact; Disorientation; Drug Interaction; Rash; Road Traffic Accident	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Benadryl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2007	6590158	NON-EXPEDITED	Y	OT	2006152713		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction	Doxazosin			S		2 Mg (1 D)		Not Reported
	Escitalopram Oxalate			S		10 Mg (1 D)		Not Reported
	Cozaar			C				Not Reported
	Remeron			C				Not Reported
	Norvasc (Norvasc)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2007	6472751	EXPEDITED (15-DAY)	Y	DS	S07-FRA-05784-01		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Back Pain; Dysuria; Fatigue; Muscle Contracture; Pyrexia;	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Fenofibrate			C				Not Reported
	Fosinopril Sodium And			C				Not Reported

Torticollis	Hydrochlorothiazide		
	Xanax	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2007	6508006	EXPEDITED (15-DAY)	Y	OT	A0699323A		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelinating Polyneuropathy; Intracranial Mass	Wellbutrin Xl			S	Oral	300mg Per Day		Glaxosmithkline
	Effexor Xr			S	Oral	75mg Per Day		Not Reported
	Lexapro			S		20mg Per Day		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2007	6516931	EXPEDITED (15-DAY)	Y	OT	S07-ESP-06274-01		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Infiltration; Pyrexia; Rash	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Idalprem (Lorazepam)			C				Not Reported
	Diltiazem			C				Not Reported
	Edemox (Acetazolamide)			C				Not Reported
	Haloperidol			C				Not Reported
	Vitamin B12			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2007	6517336	EXPEDITED (15-DAY)	Y	HO	S07-FRA-06253-01		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Csf Protein Increased; Dyskinesia; Fall; Gait Disturbance; General Physical Health Deterioration; Generalised Tonic-Clonic Seizure;	Escitalopram Oxalate			S	Oral	2 Unk Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	2 Unk Unk Po		Not Reported
	Acepromazine Maleate\Clorazepate Dipotassium			S	Oral	10 Mg Qd Po		Not Reported
	Acepromazine			S				Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Hyponatraemia; Persecutory Delusion; Post-Traumatic Amnestic Disorder; Therapy Change	Maleate\Clorazepate Dipotassium			S	Oral	2 Unk Qd Po		Not Reported
	Aceprometazine\Meprobamate			C				Not Reported
	Zolpidem			C				Not Reported
	Zocor			C				Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2007	6518209	EXPEDITED (15-DAY)	Y	HO	S07-FRA-06324		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous; Rash Macular; Rash Morbilliform; Toxic Skin Eruption	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Allopurinol			S	Oral	300 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2007	6689512	EXPEDITED (15-DAY)	Y	HO	S07-SWI-06242-01		80 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Dizziness; Feeling Abnormal; Intentional Product Misuse; Nausea; Neurological Examination Abnormal; Syncope; Tremor; Ventricular Hypokinesia	Cipralex			S	Oral	10 Mg Once Po		Not Reported
	Flupentixol\Melitracen			S				Not Reported
	Zocor			C				Not Reported
	Symfona N (Gingko Biloba Extract)			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2007	6454454	EXPEDITED (15-DAY)	N	HO	S07-USA-05438-01		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Generalised Tonic-Clonic Seizure;	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Unknown Hypertension Medication (Nos)			C				Not Reported

Haemorrhagic Stroke; Overdose; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2007	6471062	EXPEDITED (15-DAY)	Y	HO, OT	DE-BRISTOL-MYERS SQUIBB COMPANY-13982640		66 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Serotonin Syndrome	Abilify			S	Oral			Not Reported
	Cipralex			S	Oral	Daily Dosage:From 18-Jul-07 To 23-Jul-07 Is 5 Mg		Not Reported
	Lamotrigine			C	Oral			Not Reported
	Trileptal			C	Oral	Unk/06 To 17/Jul/07 - 300mg/D,18/Jul To 29/Jul - 450mg, 30/Jul To 31/Jul - 600mg, 01/Aug/07 - 900mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2007	6509052	EXPEDITED (15-DAY)	Y	HO	ES-BRISTOL-MYERS SQUIBB COMPANY-14017818		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Delirium; Disorientation; Psychomotor Hyperactivity	Sinemet			S	Oral	1 Dosage Form = 25/100mg Tablet.	25 DAY	Bristol Myers Squibb
	Stalevo			S	Oral	1 Dosage Form= 2 Fixed Dose (25mg+200mg+100mg Tabs)	29 DAY	Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6147461	EXPEDITED (15-DAY)	N	DE	S06-USA-03868-01		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Accidental Death; Analgesic Drug Level Increased; Antidepressant Drug Level Increased; Arrhythmia; Cardiac Arrest; Contusion; Drug Interaction; Heart Rate Increased; Insomnia; Nervous System Disorder; Unresponsive To Stimuli; Weight Decreased	Lexapro			S				Not Reported
	Zoloft			S				Not Reported
	Methadone Hydrochloride			S				Not Reported
	Ambien			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Cold Medicine (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6443532	EXPEDITED (15-DAY)	Y	OT	S07-ESP-05278-01		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Galactorrhoea; Hypothalamo-Pituitary Disorder; Menstruation Irregular; Overdose; Weight Increased	Cipralex			S				Not Reported
	Cipralex			S	Oral	50 Mg Qd Po		Not Reported
	Cipralex			S	Oral	40 Mg Qd Po		Not Reported
	Amitriptyline			S	Oral	25 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6450372	EXPEDITED (15-DAY)	Y	HO	S07-UKI-05382-01		17 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Anxiety; Asthenia; Cardiac Disorder; Chest Pain; Cold Sweat; Conduction Disorder; Decreased Appetite; Depression; Diarrhoea; Dizziness; Drug Withdrawal	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	2.5 Mg Qd Po		Not Reported
	Propranolol			C				Not Reported
	Atenolol			C				Not Reported

Syndrome; Dyspnoea; Euphoric Mood; Extrasystoles; Fear; Feeling Abnormal; Feeling Hot; Frustration Tolerance Decreased; Headache; Heart Rate Decreased; Hyperhidrosis; Hypoaesthesia; Intentional Self-Injury; Malaise; Mood Altered; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Palpitations; Pulse Abnormal; Pulse Pressure Decreased; Respiratory Disorder; Sensory Disturbance; Suicidal Ideation; Vision Blurred	Omeprazole	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6457743	EXPEDITED (15-DAY)	Y	HO, OT	S07-GER-00142-01		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Pregnancy; Sciatica; Symphysiolysis	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S				Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Iron			C				Not Reported
	Folic Acid			C				Not Reported
	Minerals Nos			C				Not Reported
	Jod (Iodine)			C				Not Reported
	Enoxaparin Sodium			C				Not Reported
	Magno Sanol (Magnesium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6468633	EXPEDITED (15-DAY)	Y	OT	S07-FRA-05778-01		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Stress; Ventricular Extrasystoles	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6472693	EXPEDITED (15-DAY)	Y	HO	S07-CAN-05812-01		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis; Viral Infection	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6495696	EXPEDITED (15-DAY)	Y	HO	S07-NLD-06075-01		81 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hyponatraemia; Somnolence; Vomiting	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Hydrochlorothiazide			S	Oral	12.5 Mg Qd Po		Not Reported
	Enalapril			S	Oral	20 Mg Qd Po		Not Reported
	Sotalol Hydrochloride			C				Not Reported
	Carbasalaatcalcium(Carbasalate Calcium)			C				Not Reported
	Nicardipine Hydrochloride			C				Not Reported
	Lorazepam			C				Not Reported
	Levothyroxine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6510400	EXPEDITED (15-DAY)	Y	OT	S07-GER-06173-01		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Drug	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported

Withdrawal Syndrome; Eye Swelling; Gait Disturbance; Heart Rate Increased; Irritability; Micturition Frequency Decreased; Movement Disorder; Muscle Twitching; Refusal Of Treatment By Patient; Restlessness; Thirst; Vertigo; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6512073	EXPEDITED (15-DAY)		HO	PHBS2007ES20811		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Delirium; Disorientation; Psychomotor Hyperactivity	Stalevo			S	Oral	Unk, Bid	41760 MIN	Orion
	Escitalopram Oxalate			S	Oral	10 Mg/D		Not Reported
	Sinemet			S	Oral	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6519202	DIRECT	Y	RI			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Dizziness; Dry Mouth; Serotonin Syndrome	Lexapro			S	Oral	10mg Po Daily	3 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6519204	DIRECT	Y	OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Lexapro			S	Oral	10mg Once Po Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6519377	EXPEDITED (15-DAY)	N	OT	S07-USA-06332-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Lexapro			S				Not Reported
	Alcohol			S				Not Reported
	Adderall			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2007	6520037	EXPEDITED (15-DAY)	Y	OT	231265J07USA		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy	Rebif			S	Subcutaneous	44 Mcg, 3 In 1 Weeks, Subcutaneous		Not Reported
	Lexapro			S				Not Reported
	Klonopin			S				Not Reported
	Atenolol (Atenolol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2007	6514705	EXPEDITED (15-DAY)		HO	IN-ROXANE LABORATORIES, INC-2007-DE-07472GD		56 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Hypomania; Serotonin Syndrome	Sertraline			S			5 WEEK	Roxane
	Trazodone Hydrochloride			S			5 WEEK	Not Reported
	Lithium Carbonate			S				Roxane
	Phenytoin			S				Not Reported
	Escitalopram Oxalate			S			1 WEEK	Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2007	6509749	EXPEDITED (15-DAY)	Y	DE	S07-USA-06105-01		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Fall; Head Injury; Overdose; Self-Medication	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Seroquel			C				Not Reported
	Klonopin			C				Not Reported
	Zyprexa			C				Not Reported
	Restoril			C				Not Reported
	Emsam (Selegiline)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2007	6515199	EXPEDITED (15-DAY)	N	HO	B0500862A		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Epidermal Necrosis; Generalised Erythema; Hyperthermia; Lymphocytic Infiltration; Odynophagia; Pruritus; Rash Maculo-Papular; Toxic Skin Eruption	Lamictal			S	Oral	50mg Per Day	12 DAY	Glaxosmithkline
	Escitalopram Oxalate			S	Oral	10mg Per Day	40 DAY	Unknown
	Ibuprofen			S	Oral	1tab Single Dose	1 DAY	Unknown
	Surmontil			C	Oral		58 DAY	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2007	6524590	DIRECT	N	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Cold Sweat; Diarrhoea; Dizziness; Drug Interaction; Headache; Malaise; Medication Error; Nausea; Product Dispensing Error; Tremor; Viral Infection; Vomiting; Wrong Product Administered	Lexapro			S	Oral	20 Mg 1 Daily Po Once		Not Reported
	Lipitor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2008	6523026	EXPEDITED (15-DAY)	Y	HO	S07-BEL-06123-01		42 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyskinesia; Hyperreflexia; Myoclonus; Serotonin Syndrome; Speech Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Omeprazole			C				Not Reported
	Insidon "Ciba-Geigy" (Opipramol Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2008	6528117	EXPEDITED (15-DAY)	Y	HO	S07-FRA-06491-01		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermal Necrosis; Epstein-Barr Virus Infection; Hyperthermia; Odynophagia; Parvovirus B19 Test Positive; Toxic Skin Eruption	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Lamictal			S	Oral	50 Mg Qd Po		Not Reported
	Ibuprofen			S	Oral	1 Qd Po		Not Reported
	Surmontil			C				Not Reported
	Surmontal (Trimipramine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2008	6490621	EXPEDITED (15-DAY)	Y	HO	S07-GER-06089-01		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Right Ventricular Failure	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Mirtazapine			C				Not Reported
	Irbesartan			C				Not Reported
	Novodigal (Digoxin)			C				Not Reported
	Beloc Zok (Metoprolol Succinate)			C				Not Reported
	Simvastatin			C				Not Reported
	Marcumar			C				Not Reported

	Hct Hexal (Hydrochlorothiazide)	C		Not Reported
	Melperon (Melperone)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2008	6526721	EXPEDITED (15-DAY)	Y	OT	S07-SWI-06495-01		43 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Cholelithiasis; Gamma-Glutamyltransferase Increased; Liver Disorder; Liver Function Test Abnormal	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Crestor			S	Oral	10 Mg Qd Po		Not Reported
	Atacand (Candesartan Cilexetil)			C				Not Reported
	Logimax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2008	6527655	EXPEDITED (15-DAY)	Y	OT	S07-FRA-06475-01		13 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	28 Tablet Once Po		Not Reported
	Tetrazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2008	6480967	EXPEDITED (15-DAY)	Y	DE	S07-USA-03825-01		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Diabetic Complication	Lexapro			S	Oral	10 Mg, Qd; Po		Not Reported
	Geodon			S		80 Mg Qd;		Not Reported
	Geodon			S		20 Mg, Bid,		Not Reported

	Geodon	S	40 Mg, Bid;	Not Reported
	Geodon	S	60 Mg, Bid;	Not Reported
	Lyrica	C		Not Reported
	Glucophage	C		Not Reported
	Esgic (Butalbital And Acetaminophen)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2008	6490689	EXPEDITED (15-DAY)	Y	OT	S07-GER-06063-01		64 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bipolar Disorder; Condition Aggravated; Gamma-Glutamyltransferase Increased; Major Depression	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Chlorprothixene			S	Oral	100 Mg Qd Po		Not Reported
	Zyprexa			S	Oral	10 Mg Qd Po		Not Reported
	Lithium Carbonate			C				Not Reported
	Lithium Carbonate			C				Not Reported
	Asa (Acetylsalicylic Acid)			C				Not Reported
	Pantozol (Pantoprazole Sodium)			C				Not Reported
	Voltaren			C				Not Reported
	Enalapril Maleate			C				Not Reported
	Dyazide			C				Not Reported
	Novamin (Prochlorperazine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2008	6518324	EXPEDITED (15-DAY)	Y	HO, OT	S07-PRT-06345-01		60 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Haemophilia; Blood Thromboplastin Decreased; Gingival Bleeding; Haematoma; Haematuria; Prothrombin Level Abnormal; Treatment Noncompliance	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2008	6528427	EXPEDITED (15-DAY)	Y	OT	S08-CAN-00020-01		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia; Pruritus; Rash Erythematous; Throat Irritation; Tongue Disorder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2008	6459495	EXPEDITED (15-DAY)	Y	OT	S07-USA-05468-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Ambien Cr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2008	6521212	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20071206082		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Durogesic			S	Transdermal			Not Reported
	Entecavir			S	Oral			Not Reported
	Mabthera			S	Unknown		16 DAY	Not Reported
	Cyamemazine			S	Oral			Not Reported
	Aceprometazine\Clorazepate Dipotassium			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Dulcolax (Bisacodyl)			C	Rectal			Not Reported
	Previscan (Fluindione)			C	Oral			Not Reported
	Aerius (Desloratadine)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2008	6521749	EXPEDITED (15-DAY)	N	HO	US-ASTRAZENECA-2008UW00098		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Toprol Xl			S	Oral			Not Reported
	Toprol Xl			S	Oral	Dose Decreased		Not Reported
	Lexapro			S	Oral			Not Reported
	Lipitor			C				Not Reported
	Paxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2008	6524364	EXPEDITED (15-DAY)	Y	HO	S07-USA-06385-01		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Claustrophobia; Headache; No Adverse Event	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Aggrenox			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2008	6525524	DIRECT					33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Product Dispensing Error	Lexapro			S	Oral	Take 1 Tablet By Mouth Every Day Tablet		Forest
	Naprosyn			S	Oral	Take 1 Tablet By Mouth Twice Daily Tablet		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2008	6522274	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20080100478		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Above Therapeutic; Overdose; Serotonin Syndrome	Dextromethorphan Hydrobromide		Y	S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Benztropine Mesylate			S	Oral			Not Reported
	Chlorpheniramine			S	Oral			Not Reported
	Nicotine			C				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2008	6526692	EXPEDITED (15-DAY)	Y	DE	S07-UKI-06442-01		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Prozac			C				Not Reported
	Quetiapine			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2008	6527928	EXPEDITED (15-DAY)	N	OT	S08-USA-00023-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Deafness; Flight Of Ideas; Insomnia; Somnolence; Suicidal Ideation; Vision Blurred	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2008	6524188	EXPEDITED (15-DAY)	Y	DE	US-MERCK-0801USA00490		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Toxicity To Various Agents	Hydrocortone			S	Oral			Merck

	Risperidone	S	Oral	Not Reported
	Metaxalone	S	Oral	Not Reported
	Heparin	S	Oral	Not Reported
	Oxycodone	S	Oral	Not Reported
	Escitalopram Oxalate	S	Oral	Not Reported
	Bupropion Hydrochloride	S	Oral	Not Reported
	Clonidine	S	Oral	Not Reported
	Methadone Hydrochloride	S	Oral	Not Reported
	Albuterol	S	Oral	Not Reported
	Haloperidol	S	Oral	Not Reported
	Acyclovir	S	Oral	Not Reported
	Vancomycin	S	Oral	Not Reported
	Lamotrigine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2008	6225797	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-13587902		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Constipation; Disturbance In Attention; Dry Eye; Dry Mouth; Fall; Fatigue; Somnolence; Vertigo; Weight Increased	Desyrel			S	Oral			Apothecon
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Trileptal			S	Oral			Not Reported
	Klonopin			S				Sandoz
	Zyrtec			C				Not Reported
	Vitamin B			C	Intramuscular			Not Reported
	Grapeseed Extract			C				Not Reported
	Vitamin C			C				Not Reported
	Methylsulfonylmethane			C				Not Reported
	Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2008	6524525	EXPEDITED (15-DAY)	N	OT	US-ROCHE-539562		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Klonopin			S	Unknown			Roche
	Rebif			S	Subcutaneous			Not Reported
	Rebif			S	Subcutaneous			Not Reported
	Lexapro			S	Unknown			Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2008	6524629	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2008AC00096		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Quetiapine			S	Oral			Zeneca
	Escitalopram Oxalate			S	Oral			Not Reported
	Atomoxetine Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2008	6526101	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20080101911		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Hydrocodone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Cocaine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2008	6526156	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20080101065		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Risperidone			S	Oral			Not Reported
	Haloperidol			S	Oral			Not Reported
	Metaxalone			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Clonidine			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported
	Methadone Hydrochloride			S	Oral			Not Reported
	Albuterol			S				Not Reported
	Acyclovir			S	Oral			Not Reported
	Vancomycin			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Heparin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2008	6526385	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2008AC00159		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Quetiapine			S	Oral			Zeneca
	Bupropion			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2008	6526390	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2008AC00142		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Quetiapine			S	Oral			Zeneca
	Escitalopram Oxalate			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2008	6526406	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2008AC00149		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lisinopril			S	Oral			Zeneca
	Acetaminophen			S	Oral			Not Reported
	Hydrocodone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Cocaine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2008	7888834	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2008AC00113		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Quetiapine			S	Oral			Zeneca
	Unspecified Ingredient			S	Oral			Not Reported
	Butalbital Acetaminophen And Caffeine			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Caffeine Citrate			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported

	Fexofenadine			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2008	6515357	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2007105545		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Blood Pressure Decreased; Heart Rate Increased; Hypertension; Nervousness; Panic Reaction; Presyncope; Sedation; Unevaluable Event	Norvasc			S				Not Reported
	Xanax			S				Not Reported
	Clonidine			S				Not Reported
	Lexapro			S				Not Reported
	Valium			C				Not Reported
	Librium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2008	6527099	EXPEDITED (15-DAY)	Y	DE, HO	US-JNJFOC-20080101908		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Trazodone Hydrochloride			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Oxcarbazepine			S	Oral			Not Reported
	Benzodiazepine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2008	6532074	EXPEDITED (15-DAY)	Y	HO	S08-NOR-00119-01		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Bradykinesia; Cognitive	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

Disorder; Extrapyramidal Disorder	Trilafon	S	4 Mg Qod		Not Reported
	Exelon	S	3 Mg Qod		Not Reported
	Seroquel	S	50 Mg Qd		Not Reported
	Duroferon (Ferrous Sulfate)	C			Not Reported
	Akineton	C			Not Reported
	Vi-Siblin	C			Not Reported
	Nexium (Esomeprazole)	C			Not Reported
	Zopiclone	C			Not Reported
	Evista (Raloxine Hydrochloride)	C			Not Reported
	Duphalac	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2008	6532077	EXPEDITED (15-DAY)	Y	OT	S08-IRL-00136-01		70 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	15 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2008	6528021	EXPEDITED (15-DAY)	N	HO	FR-BAYER-200810630GPV		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Intestinal Ischaemia; Vomiting	Betaferon			S	Subcutaneous		8 YR	Bayer
	Escitalopram Oxalate			S	Oral			Not Reported
	Relpax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2008	6528307	EXPEDITED (15-DAY)	Y	HO	B0503596A		59 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Aphasia; Depression; Disorientation;	Zyban			S	Oral		14 DAY	Glaxosmithkline
	Cipralex			S	Oral			Not Reported

Disturbance In Attention; Drug Interaction; Drug Level Increased; Memory Impairment; Pre-Existing Disease; Psychiatric Symptom; Sleep Disorder	Valproate Sodium		C	Oral		Not Reported
	Reniten		C	Oral	10mg Per Day	Not Reported
	Aspirin		C	Oral		Glaxosmithkline
	Metformin Hydrochloride		C	Oral	500mg Per Day	Glaxosmithkline
	Remeron		C	Unknown	15mg Per Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2008	6533320	EXPEDITED (15-DAY)	Y	OT	S08-USA-00096-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Myeloid Leukaemia; Diarrhoea; Dizziness; Headache; Malaise; Nausea; Pain In Extremity	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Famvir			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Vitamin C			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2008	6536011	DIRECT	Y	OT			19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Faeces Discoloured; Haemorrhage; Muscle Injury	Lexapro			S	Oral	1 Pill Per Day Po Qday Since 7/11/07 On 5 Mg, 10mg 8/3/07		Forest
					Oral	1 Pill Per Day Po Qday Since 7/11/07 On 5 Mg, 10mg 8/3/07		
	Dexedrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2008	6470440	EXPEDITED (15-DAY)	Y	OT	S07-FRA-05814-01		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported

Increased; Visual Field Defect	Abilify		S	Oral	1 Tablet Qd Po	Not Reported
	Depakote		S	Oral	500 Mg Bid Po	Not Reported
	Xalatan		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2008	6488878	EXPEDITED (15-DAY)		HO	230297J07USA		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dystonia; Pyrexia; Tremor	Rebif			S	Subcutaneous	44 Mcg, 3 In 1 Weeks, Subcutaneous		Not Reported
	Lexapro			S				Not Reported
	Remeron			C				Not Reported
	Fentanyl (Fentanyl)			C				Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2008	6537927	DIRECT	N	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Counterfeit; Product Quality Issue; Therapeutic Product Effect Decreased	Lexapro			S	Oral	90 Each 1 Daily Po	70 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2008	6383822	EXPEDITED (15-DAY)	N	CA, DE	B0483228A			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Oligohydramnios; Polydactyly; Pulmonary Malformation; Renal Aplasia	Becotide			S				Glaxosmithkline
	Ventolin			S				Glaxosmithkline
	Cipralex			S			3 MTH	Not Reported
	Lithionit			S		83mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2008	6406655	EXPEDITED (15-DAY)	Y	OT	NO-PFIZER INC-2007071541		41 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Lyrica			S	Oral			Not Reported
	Lyrica			S				Not Reported
	Lamictal			S	Oral			Not Reported
	Lamictal			S				Not Reported
	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S				Not Reported
	Diazepam			S				Not Reported
	Diazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2008	6530477	EXPEDITED (15-DAY)	N	HO	FR-GENENTECH-254338		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Mabthera			S	Intravenous (not otherwise specified)	Unk, Unk	16 DAY	Genentech
	Fentanyl			S		50 Âµg, Q3d		Not Reported
	Escitalopram Oxalate			S	Oral	Unk, Unk		Not Reported
	Acepromazine Maleate\Aceprometazine\Clorazepate Dipotassium			S		10 Mg, Qd		Not Reported
	Cyamemazine			S	Oral	25 Mg, Qd		Not Reported
	Entecavir			S	Oral	0.5 Mg, Qd	578 DAY	Not Reported
	Dulcolax (Bisacodyl)			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Aerius (Desloratadine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2008	6530846	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2008002622		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S	Oral			Not Reported
	Unspecified Ingredient			S	Respiratory (inhalation)			Not Reported
	Zolpidem			S	Oral			Not Reported
	Estrogens			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2008	6536198	EXPEDITED (15-DAY)	Y	HO	CH-SANOFI-SYNTHELABO-A01200713881		85 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Subdural Haematoma	Plavix			S	Oral			Not Reported
	Stilnox			C	Unknown	Unk		Not Reported
	Neurontin			C	Oral			Not Reported
	Simvastatin			C	Oral			Not Reported
	Lorazepam			C	Oral			Not Reported
	Trazodone Hydrochloride			C	Oral			Not Reported
	Cotenolol			C	Oral			Not Reported
	Aprovel			C	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2008	6536733	EXPEDITED (15-DAY)	Y	DE	2008001005		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents	Dextromethorphan Hydrobromide		Y	S	Oral	Unspecified, Oral	Not Reported
	Escitalopram Oxalate			S	Oral	Unspecified, Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2008	7462161	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00123-01		62 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Pancreatitis Acute; Pulmonary Embolism	Escitalopram Oxalate			S				Not Reported
	Baraclude			S	Oral	500 Mcg Qd Po		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1 Unk Once Iv		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1 Unk Once Iv		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1 Unk Once Iv		Not Reported
	Cyamemazine			S	Oral	25 Mg Qd Po		Not Reported
	Aceprometazine\Clorazepate Dipotassium			S	Oral	10 Mg Qd Po		Not Reported
	Durogesic			S		50 Mcg Tin Ap		Not Reported
	Dulcolax (Bisacodyl)			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Desloratadine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2008	6530979	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2008003761		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Heparin Sodium			S				Not Reported
	Risperidone			S				Not Reported
	Metaxalone			S				Not Reported
	Oxycodone			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Bupropion			S				Not Reported
	Clonidine			S				Not Reported

	Unspecified Ingredient	S	Not Reported
	Methadone Hydrochloride	S	Not Reported
	Albuterol	S	Not Reported
	Haloperidol	S	Not Reported
	Acyclovir	S	Not Reported
	Vancomycin	S	Not Reported
	Lamotrigine	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2008	6531049	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2008002664		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Ramelteon			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2008	6531070	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2008002666		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Alprazolam			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2008	6531246	EXPEDITED (15-DAY)	Y	DE	US-WYE-H02026408		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Overdose	Dextromethorphan Hydrobromide	S	Oral	Unknown		Wyeth
	Escitalopram Oxalate	S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2008	6531461	EXPEDITED (15-DAY)	Y	OT	FR-ABBOTT-07P-056-0423485-00			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased; Visual Field Defect	Depakote			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Esomeprazole Magnesium			C				Not Reported
	Latanoprost			C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2008	6491601	EXPEDITED (15-DAY)	Y	HO	DE-JNJFOC-20071200209		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyarthritis; Urticaria	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2008	6511571	EXPEDITED (15-DAY)	Y	HO	S07-FRA-06159-01		78 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Memory Impairment; Tremor	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Artane			S	Oral	2 Mg Qd Po		Not Reported
	Lasilix (Furosemide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2008	6519394	EXPEDITED (15-DAY)	N	HO	S07-USA-06282-01		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Toprol Xl			S				Not Reported
	Toprol Xl			S				Not Reported
	Lipitor			C				Not Reported
	Paxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2008	6520130	EXPEDITED (15-DAY)	Y	DE	S07-FRA-06428-01		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Escitalopram Oxalate			S				Not Reported
	Citalopram			S				Not Reported
	Atarax			S				Not Reported
	Valium			S				Not Reported
	Oxazepam			S				Not Reported
	Tranxene T-Tab			C				Not Reported
	Nozinan (Levomepromazine)			C				Not Reported
	Trimeprazine Tartrate			C				Not Reported
	Chlorpromazine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2008	6536808	EXPEDITED (15-DAY)	Y	DE	PAR_01890_2008		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Hydralazine			S	Oral	(Df Oral)		Not Reported
	Amitriptyline			S	Oral	(Df Oral)		Not Reported
	Unspecified Ingredient			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Amphetamine Salts (Not Specified)			C	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2008	6539836	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00225-01		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Depression; Disorientation; Memory Impairment; Mental Disorder; Psychomotor Skills Impaired; Self Esteem Decreased; Self-Medication; Withdrawal Syndrome	Escitalopram Oxalate			S		Anxiety		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2008	6540880	EXPEDITED (15-DAY)	Y	HO	LTI2008A00013		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Epilepsy; Loss Of Consciousness; Malaise; Status Epilepticus	Lansoprazole			S	Oral	15 Mg (15 Mg, 1 - 2) 10 Mg (10 Mg, 1 - Oral	6 DAY	Not Reported
					Oral	15 Mg (15 Mg, 1 - 2) 10 Mg (10 Mg, 1 - Oral		
	Escitalopram Oxalate			S	Oral	Oral 10 Mg (10 Mg, 1 In 1 D); 20 Mg (10 Mg, 2 In 1 D)		Not Reported
					Oral	Oral 10 Mg (10 Mg, 1 In 1 D); 20 Mg (10 Mg, 2 In 1 D)	29 DAY	
	Nisis			C				Not Reported
	Speciafoldine (Folic Acid)			C				Not Reported
	Modopar (Madopar)			C				Not Reported
	Oxazepam			C				Not Reported
	Hydrosol (Hydrosol Polyvitamine)			C				Not Reported
	Gaviscon			C				Not Reported
	Polyethylene Glycols			C				Not Reported
	Anafranil			C				Not Reported

	Diovan Hct			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6526410	EXPEDITED (15-DAY)	Y	HO	NO-ASTRAZENECA-2008SE00042		78 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Bradykinesia; Cognitive Disorder; Drug Interaction; Extrapyramidal Disorder	Seroquel			S	Oral		7 MTH	Zeneca
	Evista			C				Not Reported
	Nexium			C				Not Reported
	Akineton			C			7 MTH	Not Reported
	Ferrous Sulfate			C				Not Reported
	Duphalac			C				Not Reported
	Sodium Chloride\Thiamine Hydrochloride			C				Not Reported
	Zopiclone			C				Not Reported
	Exelon			S				Not Reported
	Cipralex			S			7 MTH	Not Reported
	Trilafon			S			7 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6538381	EXPEDITED (15-DAY)	Y	DS	S08-FRA-00224-01		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Hypermetropia; Presbyopia	Escitalopram Oxalate			S				Not Reported
	Clonazepam			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Acetaminophen\Caffeine\Dextropropoxyphene			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6539301	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00226-01		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Areflexia; C-Reactive Protein Increased;	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

Hyperhidrosis; Malaise; Nuchal Rigidity; Pyrexia; Red Blood Cell Sedimentation Rate Increased	Escitalopram Oxalate		S	Oral	10 Mg Qd Po	Not Reported
	Escitalopram Oxalate		S	Oral	5 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6539633	DIRECT	Y	HO			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Celexa			S	Oral	40mg Daily Po	1 WEEK	Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6541194	EXPEDITED (15-DAY)	Y	DE	PAR_01865_2008		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning; Respiratory Arrest	Ibuprofen			S	Oral	(Df Oral)		Not Reported
	Quetiapine			S	Oral	(Df Oral)		Not Reported
	Unspecified Ingredient			S	Oral	(Df Oral)		Not Reported
	Butalbital Acetaminophen And Caffeine			S	Oral	(Df Oral)		Not Reported
	Aspirin			S	Oral	(Df Oral)		Not Reported
	Acetaminophen			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Caffeine Citrate			S	Oral	(Df Oral)		Not Reported
	Naproxen			S	Oral	(Df Oral)		Not Reported
	Fexofenadine			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6542088	EXPEDITED (15-DAY)	Y	DE	CAR_00142_2008		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Poisoning	Zolpidem		S	Oral	(Df Oral)	Not Reported
	Lamotrigine		S	Oral	(Df Oral)	Not Reported
	Escitalopram Oxalate		S	Oral	(Df Oral)	Not Reported
	Unspecified Ingredient		S	Oral	(Df Oral)	Not Reported
	Ramelteon		S	Oral	(Df Oral)	Not Reported
	Alprazolam		S	Oral	(Df Oral)	Not Reported
	Ibuprofen		S	Oral	(Df Oral)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6542966	EXPEDITED (15-DAY)	Y	DE	IMP_03305_2008		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Alprazolam			S	Oral	(Df Oral)		Not Reported
	Unspecified Ingredient			S	Nasal	(Df Nasal)		Not Reported
	Zolpidem			S	Oral	(Df Oral)		Not Reported
	Unspecified Ingredient			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6543445	EXPEDITED (15-DAY)	Y	DE	BAI_00002_2008		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Poisoning	Albuterol			S	Oral	(Df Oral)		Not Reported
	Risperidone			S	Oral	(Df Oral)		Not Reported
	Metaxalone			S	Oral	(Df Oral)		Not Reported
	Heparin			S	Oral	(Df Oral)		Not Reported
	Oxycodone			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Bupropion			S	Oral	(Df Oral)		Not Reported
	Clonidine			S	Oral	(Df Oral)		Not Reported

	Unspecified Ingredient		S	Oral	(Df Oral)	Not Reported
	Methadone Hydrochloride		S	Oral	(Df Oral)	Not Reported
	Haloperidol		S	Oral	(Df Oral)	Not Reported
	Acyclovir		S	Oral	(Df Oral)	Not Reported
	Vancomycin		S	Oral	(Df Oral)	Not Reported
	Lamotrigine		S	Oral	(Df Oral)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6543476	EXPEDITED (15-DAY)	Y	DE	AVE_00174_2008		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Poisoning	Clonidine			S	Oral	(Df Oral)		Not Reported
	Risperidone			S	Oral	(Df Oral)		Not Reported
	Metaxalone			S	Oral	(Df Oral)		Not Reported
	Heparin			S	Oral	(Df Oral)		Not Reported
	Oxycodone			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Bupropion			S	Oral	(Df Oral)		Not Reported
	Unspecified Ingredient			S	Oral	(Df Oral)		Not Reported
	Methadone Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Albuterol			S	Oral	(Df Oral)		Not Reported
	Haloperidol			S	Oral	(Df Oral)		Not Reported
	Acyclovir			S	Oral	(Df Oral)		Not Reported
	Vancomycin			S	Oral	(Df Oral)		Not Reported
	Lamotrigine			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6543480	EXPEDITED (15-DAY)	Y	DE	PAR_02030_2008		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Poisoning	Zolpidem		S	Oral	(Df Oral)	Not Reported
	Unspecified Ingredient		S	Respiratory (inhalation)	(Df Respiratory (Inhalation))	Not Reported
	Alprazolam		S	Oral	(Df Oral)	Not Reported
	Unspecified Ingredient		S	Oral	(Df Oral)	Not Reported
	Escitalopram Oxalate		S	Oral	(Df Oral)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6543491	EXPEDITED (15-DAY)	Y	DE	PAR_02034_2008		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Zolpidem			S	Oral	(Df Oral)		Not Reported
	Ibuprofen			S	Oral	(Df Oral)		Not Reported
	Lamotrigine			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Zaleplon			S	Oral	(Df Oral)		Not Reported
	Ramelteon			S	Oral	(Df Oral)		Not Reported
	Alprazolam			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6544238	EXPEDITED (15-DAY)	Y	DE	DSA_65077_2008		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning; Respiratory Arrest	Naproxen			S	Oral	(Df Oral)		Not Reported
	Quetiapine			S	Oral	(Df Oral)		Not Reported
	Unspecified Ingredient			S	Oral	(Df Oral)		Not Reported
	Butalbital Acetaminophen And Caffeine			S	Oral	(Df Oral)		Not Reported
	Aspirin			S	Oral	(Df Oral)		Not Reported
	Acetaminophen			S	Oral	(Df Oral)		Not Reported

	Ibuprofen		S	Oral	(Df Oral)	Not Reported
	Escitalopram Oxalate		S	Oral	(Df Oral)	Not Reported
	Caffeine		S	Oral	(Df Oral)	Not Reported
	Fexofenadine		S	Oral	(Df Oral)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6544293	EXPEDITED (15-DAY)	Y	DE	IMP_03371_2008		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning; Toxicity To Various Agents	Alprazolam			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Quetiapine			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6544300	EXPEDITED (15-DAY)	Y	DE	IMP_03370_2008		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Alprazolam			S	Oral	(Df Oral)		Not Reported
	Lamotrigine			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Verucerfont			S	Oral	(Df Oral)		Not Reported
	Zolpidem			S	Oral	(Df Oral)		Not Reported
	Ramelteon			S	Oral	(Df Oral)		Not Reported
	Ibuprofen			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6553111	DIRECT	N				42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour;	Lexapro			S	Oral	20mg One A Day Po	8 MTH	Not Reported

Alcoholism; Amnesia; Mood Swings; Muscle Twitching; Suicidal Ideation; Therapeutic Product Effect Decreased	Effexor		S	Oral	75mg One A Day Po	3 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2008	6634274	EXPEDITED (15-DAY)	Y	DE	CAR_00135_2008		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Poisoning	Acyclovir			S	Oral	(Df Oral)		Not Reported
	Risperidone			S	Oral	(Df Oral)		Not Reported
	Metaxalone			S	Oral	(Df Oral)		Not Reported
	Heparin			S	Oral	(Df Oral)		Not Reported
	Oxycodone			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Bupropion			S	Oral	(Df Oral)		Not Reported
	Clonidine			S	Oral	(Df Oral)		Not Reported
	Unspecified Ingredient			S	Oral	(Df Oral)		Not Reported
	Methadone Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Albuterol			S	Oral	(Df Oral)		Not Reported
	Haloperidol			S	Oral	(Df Oral)		Not Reported
	Vancomycin			S	Oral	(Df Oral)		Not Reported
	Lamotrigine			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2008	6523070	EXPEDITED (15-DAY)	Y	HO	PHBS2008NO00489		78 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Bradykinesia; Cognitive Disorder; Drug Interaction;	Exelon			S	Oral	6 Mg, Qd		Novartis
	Trilafon			S	Oral	8 Mg, Qd	213 DAY	Not Reported

Extrapyramidal Disorder	Cipralex	S	Unknown	10 Mg/D	213 DAY	Not Reported
	Seroquel	S	Unknown	50 Mg/D	213 DAY	Not Reported
	Evista	C				Not Reported
	Duphalac	C				Not Reported
	Nexium	C				Not Reported
	Akineton	C		2 Mg, Qd	213 DAY	Not Reported
	Ferrous Sulfate	C				Not Reported
	Vi-Siblin	C				Not Reported
	Zopiclone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2008	6539224	DIRECT	Y				16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Confusional State; Fear; Obsessive-Compulsive Disorder; Thinking Abnormal	Lexapro			S	Oral	10mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2008	6544839	EXPEDITED (15-DAY)	Y	DE	S08-USA-00176-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Morphine			S				Not Reported
	Codeine			S				Not Reported
	Diazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2008	6401032	EXPEDITED (15-DAY)	N	HO, OT	GB-BRISTOL-MYERS SQUIBB COMPANY-13893086		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Tumour; Hot	Abilify			S	Oral		2 YR	Not Reported

Flush	Escitalopram Oxalate	S	Oral		Not Reported
	Escitalopram Oxalate	S	Oral		Not Reported
	Citalopram	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2008	3783274	NON-EXPEDITED	N		A0667108A		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Fatigue	Wellbutrin			S	Oral	50mg Per Day		Glaxosmithkline
	Provigil			S	Oral	200mg Per Day		Not Reported
	Lexapro			S	Oral	10mg Per Day		Not Reported
	Topamax			S	Oral	50mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2008	6385396	EXPEDITED (15-DAY)	Y	CA, DE	S07-NOR-03383-01			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Congenital Hand Malformation; Maternal Exposure During Pregnancy; Oligohydramnios; Pulmonary Malformation; Renal Aplasia	Cipralex			S		10 Mg Qd		Not Reported
	Ventolin			S				Not Reported
	Lithium Carbonate			S		83 Mg Bid		Not Reported
	Becotide			S	Nasal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2008	6511358	EXPEDITED (15-DAY)	N	OT	US-SANOFI-SYNTHELABO-A03200706860		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Road Traffic Accident; Somnambulism; Therapeutic Product Effect	Ambien Cr			S	Oral		20 DAY	Not Reported
	Asacol			C	Unknown	Unk		Not Reported

Decreased	Plendil	C	Unknown				Not Reported
	Pravastatin	C	Unknown				Not Reported
	Diovan	C	Unknown				Not Reported
	Lexapro	S	Oral	Unk		3 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2008	6537597	NON-EXPEDITED	N		A0651482A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Disorientation; Drug Interaction; Irritability; Paraesthesia; Withdrawal Syndrome	Wellbutrin			S				Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2008	6537690	NON-EXPEDITED	N		A0682164A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder	Wellbutrin			S				Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2008	6537887	EXPEDITED (15-DAY)	Y	DE	US-KINGPHARMUSA00001-K200800094			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Skelaxin			S	Oral			King
	Risperidone			S	Oral			Not Reported
	Heparin			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Bupropion			S				Not Reported

Clonidine	S	Oral		Not Reported
Unspecified Ingredient	S	Oral		Not Reported
Methadone Hydrochloride	S	Oral		Not Reported
Albuterol	S	Oral		Not Reported
Haloperidol	S	Oral		Not Reported
Acyclovir	S	Oral		Not Reported
Vancomycin Hydrochloride	S	Oral		Not Reported
Lamotrigine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2008	6537890	EXPEDITED (15-DAY)	Y	DE	US-KINGPHARMUSA00001-K200800097			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Menest			S	Oral			King
	Unspecified Ingredient			S				Not Reported
	Zolpidem			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2008	6549279	EXPEDITED (15-DAY)	Y	DE	2008S1000033		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Morphine			S				Not Reported
	Fentanyl			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2008	6551228	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00262-01		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebral Haematoma; Haemorrhagic Stroke	Escitalopram Oxalate		S	Oral	20 Mg Qd Po	Not Reported
	Androtardyl(Testosterone Enantate)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2008	6551235	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00269-01		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Faeces; Ascites; C-Reactive Protein Increased; Intestinal Ischaemia; Leukocytosis; Murphy'S Sign Positive; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Betaferon			S	Subcutaneous	250 Qod Sc		Not Reported
	Betaferon			S				Not Reported
	Relpax			S	Oral	1 Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2008	6466266	EXPEDITED (15-DAY)	N	HO	239174K07USA		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Furuncle; Multiple Sclerosis	Rebif			S	Subcutaneous	8.8 Mcg, 3 In 1 Weeks, Subcutaneous		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2008	6530946	EXPEDITED (15-DAY)	Y	DE	2008S1000108		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Methadone Hydrochloride			S				Not Reported
	Amitriptyline			S				Not Reported
	Cocaine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Chloral Hydrate			S				Not Reported
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2008	6552264	EXPEDITED (15-DAY)	Y	DE	PAR_01889_2008		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Haloperidol			S	Oral	(Df Oral)		Not Reported
	Risperidone			S	Oral	(Df Oral)		Not Reported
	Metaxalone			S	Oral	(Df Oral)		Not Reported
	Heparin			S	Oral	(Df Oral)		Not Reported
	Oxycodone			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Bupropion			S	Oral	(Df Oral)		Not Reported
	Clonidine			S	Oral	(Df Oral)		Not Reported
	Unspecified Ingredient			S	Oral	(Df Oral)		Not Reported
	Methadone Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Albuterol			S	Oral	(Df Oral)		Not Reported
	Acyclovir			S	Oral	(Df Oral)		Not Reported
	Vancomycin			S	Oral	(Df Oral)		Not Reported
	Lamotrigine			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2008	6552766	EXPEDITED (15-DAY)	Y	DE	2008S1000101		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Roxicodone			S	Oral	; Po		Not Reported
	Methadone Hydrochloride			S	Oral	; Po		Not Reported
	Duraclon			S	Oral	; Po		Not Reported
	Risperidone			S	Oral	; Po		Not Reported
	Metaxalone			S	Oral	; Po		Not Reported
	Heparin			S	Oral	; Po		Not Reported

	Escitalopram Oxalate	S	Oral	; Po	Not Reported
	Bupropion	S	Oral	; Po	Not Reported
	Unspecified Ingredient	S	Oral	; Po	Not Reported
	Albuterol	S	Oral	; Po	Not Reported
	Haloperidol	S	Oral	; Po	Not Reported
	Acyclovir	S	Oral	; Po	Not Reported
	Vancomycin	S	Oral	; Po	Not Reported
	Lamotrigine	S	Oral	; Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2008	6556519	EXPEDITED (15-DAY)	Y	HO, LT	2008002186		47 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subarachnoid Haemorrhage	Phenylephrine		Y	S	Oral	36.6 Mg, Oral		Not Reported
	Acetaminophen			S	Oral	3000 Mg, Oral		Not Reported
	Caffeine			S	Oral	150mg, Oral		Not Reported
	Escitalopram Oxalate			S		Unspecified,		Not Reported
	Mirtazapine			S		Unspecified,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2008	6526505	NON-EXPEDITED	N		US-BOEHRINGER INGELHEIM GMBH, GERMANY-2008-BP-0040		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Claustrophobia; Headache	Aggrenox			S				Boehringer Ingelheim
	Lexapro			S	Oral			Not Reported
	Levoxyl			C				Not Reported
	Aspirin			C				Not Reported
	Lescol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2008	6540049	EXPEDITED (15-DAY)	Y	DE	US-KINGPHARMUSA00001-K200800135			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Avinza			S	Oral			King
	Fentanyl			S	Transdermal			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2008	6555738	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00308-01		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Interaction; Status Epilepticus	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Lansoprazole			S	Oral	15 Mg Qd Po		Not Reported
	Lormetazepam			S	Oral	1 Gm Qd Po		Not Reported
	Olanzapine			C				Not Reported
	Anafranil			C				Not Reported
	Oxazepam			C				Not Reported
	Modopar			C				Not Reported
	Valsartan And Hydrochlorothiazide			C				Not Reported
	Atorvastatin Calcium			C				Not Reported
	Gaviscon			C				Not Reported
	Polyethylene Glycols			C				Not Reported
	Hydrosol (Vitamins)			C				Not Reported
	Nisis (Valsartan)			C				Not Reported
	Speciafoldine (Folic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2008	6513485	EXPEDITED (15-DAY)	Y	HO	S07-SWE-06190-01		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebral Haemorrhage; Concomitant Disease Aggravated; Deep Vein Thrombosis; Generalised Tonic-Clonic Seizure; Hypertension; Pulmonary Embolism; Treatment Noncompliance	Cipralex		S	Oral	10mg Qd Po	Not Reported
	Fragmin		S	Subcutaneous	2500 Ml Qd Sc	Not Reported
	Warfarin Sodium		S			Not Reported
	Seretide Diskus		C			Not Reported
	Ventolin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2008	6513488	EXPEDITED (15-DAY)	Y	OT	S07-IRL-06189-01		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage Subcutaneous; Overdose	Lexapro			S	Oral	25 Mg Qd Po		Not Reported
	Eskim (Omega-3 Triglycerides)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2008	6530064	EXPEDITED (15-DAY)	Y	DE	US-BAYER-200810997GPV		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Ibuprofen			S	Oral			Bayer
	Acetaminophen			S	Oral			Not Reported
	Aspirin		Y	S	Oral			Bayer
	Naproxen			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported
	Butalbital, Acetaminophen And Caffeine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Fexofenadine			S	Oral			Not Reported
	Caffeine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2008	6542886	EXPEDITED (15-DAY)	Y	DE	US-ABBOTT-08P-163-0435142-00		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level Above Therapeutic; Completed Suicide; Overdose	Morphine			S		Overdose: Unknown Dose		Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Codeine			S		Overdose: Unknown Dose		Not Reported
	Diazepam			S		Overdose: Unknown Dose		Not Reported
	Diazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2008	6556364	EXPEDITED (15-DAY)	Y	DE	PAR_02060_2008		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Clonazepam			S	Oral	(Df Oral)		Not Reported
	Amitriptyline			S	Oral	(Df Oral)		Not Reported
	Methadone Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Cocaine			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Chloral Hydrate			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2008	6557221	EXPEDITED (15-DAY)	Y	OT	100#03#2008-00450		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Fear; Hallucination, Visual	Citalopram Hydrobromide			S	Oral	20 Mg	12 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg	5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2008	6535645	EXPEDITED (15-DAY)	N	HO	S08-USA-00113-01		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2008	6536189	EXPEDITED (15-DAY)	Y	HO	S08-ITA-00121-01		89 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Haematemesis; Melaena	Escitalopram Oxalate			S	Oral	5 Drops Qd Po		Not Reported
	Haloperidol (Meprobamate)			C				Not Reported
	Promazine			C				Not Reported
	Pregabalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2008	6553288	DIRECT		DE			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Seizure	Lexapro			S				Forest
	Zoloft			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2008	6554717	DIRECT	Y	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Lexapro			S	Oral	10 Mg 1 Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2008	6554863	DIRECT	N	HO, LT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal; Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	1 Pill 1 X Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2008	6555588	EXPEDITED (15-DAY)	Y	DE	PAR_02052_2008		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Clonazepam			S	Oral	(Df Oral)		Not Reported
	Lisinopril			S	Oral	(Df Oral)		Not Reported
	Acetaminophen			S	Oral	(Df Oral)		Not Reported
	Hydrocodone			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Cocaine			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2008	6556497	EXPEDITED (15-DAY)	Y	OT	S08-USA-00339-01		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Tinnitus	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2008	6556505	EXPEDITED (15-DAY)	N	DE	S08-USA-00360-01		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Asphyxia; Completed Suicide; Depressed Mood; General Physical Health Deterioration; Hostility	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2008	6557452	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00349-01		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothermia; Overdose	Escitalopram Oxalate			S	Oral	40 Mg Qd Po		Not Reported
	Zuclopenthixol			S	Oral	25 Mg Qid Po		Not Reported
	Alepsal			C				Not Reported
	Valpromide			C				Not Reported
	Dipiperon (Pipamperone)			C				Not Reported
	Tropatepine Hydrochloride			C				Not Reported
	Movicol			C				Not Reported
	Scopolamine			C				Not Reported
	Oxazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2008	6408227	EXPEDITED (15-DAY)	Y	HO	PHBS2007ES14374		75 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Sodium Decreased; Drug Interaction; Inappropriate Antidiuretic Hormone Secretion; Restlessness; Urine Sodium Decreased	Tegretol			S	Oral	200 Mg, Qd		Novartis
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Not Reported
	Risperidone			S	Oral	2 Mg, Qd		Not Reported
	Deprax (Trazodone Hydrochloride)			S	Oral	100 Mg, Qd		Not Reported
	Coaprovel			S		Unk, Qd		Not Reported
	Lactulose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2008	6557545	EXPEDITED (15-DAY)		CA, DE	230864J08USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Foetal Death; Limb Malformation; Maternal Exposure During	Rebif			S	Transplacental	Transplacental		Not Reported
	Neurontin			S	Transplacental	Transplacental		Not Reported

Pregnancy; Skull Malformation	Lexapro		S	Transplacental	Transplacental	Not Reported
	Meclizine		S	Transplacental	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2008	6557775	EXPEDITED (15-DAY)		OT	230895J08USA		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Foetal Disorder; Induced Labour; Maternal Exposure During Pregnancy; Multiple Sclerosis; Pregnancy; Skin Discolouration	Rebif			S	Subcutaneous	44 Mcg, 3 In 1 Weeks, Subcutaneous		Not Reported
	Lexapro			S				Not Reported
	Neurontin			S				Not Reported
	Meclizine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2008	6441579	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2007083215		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Constipation; Diarrhoea; Ill-Defined Disorder; Lung Neoplasm Malignant; Nausea; Vomiting; Weight Decreased	Chantix			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Lexapro			S				Not Reported
	Imipramine			C				Not Reported
	Primidone			C				Not Reported
	Provigil			C				Not Reported
	Topamax			C				Not Reported
	Klonopin			C				Not Reported
	Lamictal			C				Not Reported
	Nexium			C				Not Reported
	Singulair			C				Not Reported
	Requip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2008	6472742	EXPEDITED (15-DAY)	Y	HO	S07-GER-05786-01		86 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiovascular Disorder; Hyponatraemia	Escitalopram Oxalate		S	Oral	10 Mg Qd Po	Not Reported
	Escitalopram Oxalate		S	Oral	20 Mg Qd Po	Not Reported
	Aspirin		C			Not Reported
	Clopidogrel		C			Not Reported
	Metoprolol		C			Not Reported
	Allopurinol		C			Not Reported
	Repaglinid (Repaglinide)		C			Not Reported
	L-Dopa (Levodopa)		C			Not Reported
	Pantoprazol (Pantoprazole)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2008	6558620	EXPEDITED (15-DAY)	Y	DE	IMP_03333_2008		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Bupropion			S	Oral	(Df Oral)		Not Reported
	Quetiapine			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2008	6559397	EXPEDITED (15-DAY)	Y	DE	IMP_03463_2008		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Poisoning	Oxycodone			S	Oral	Df, Oral		Not Reported
	Risperidone			S	Oral	Df, Oral		Not Reported
	Metaxalone			S	Oral	Df, Oral		Not Reported
	Heparin			S	Oral	Df, Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df, Oral		Not Reported
	Bupropion			S	Oral	Df, Oral		Not Reported
	Clonidine			S	Oral	Df, Oral		Not Reported
	Unspecified Ingredient			S	Oral	Df, Oral		Not Reported
	Methadone Hydrochloride			S	Oral	Df, Oral		Not Reported
	Albuterol			S	Oral	Df, Oral		Not Reported

	Haloperidol	S	Oral	Df, Oral		Not Reported
	Acyclovir	S	Oral	Df, Oral		Not Reported
	Vancomycin	S	Oral	Df, Oral		Not Reported
	Lamotrigine	S	Oral	Df, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2008	6559628	EXPEDITED (15-DAY)	Y	OT	2008S1001274		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Fear; Hallucination, Visual	Citalopram Hydrobromide			S	Oral	20 Mg; Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg; Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2008	6561182	EXPEDITED (15-DAY)	Y	OT	S08-UKI-00399-01		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Fear; Hallucination, Visual	Citalopram Hydrobromide			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2008	6548370	EXPEDITED (15-DAY)	Y	HO, LT	ES-ASTRAZENECA-2008AC00381		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Seroquel			S	Oral			Zeneca
	Cipralex			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Seretide			C	Respiratory (inhalation)	50/100 Ug		Not Reported
	Amlodipine			C	Oral			Not Reported
	Atrovent			C	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2008	6548929	EXPEDITED (15-DAY)		DE	US-ABBOTT-08P-163-0436968-00		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydrocodone			S	Oral			Not Reported
	Hydrocodone			S				Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Cocaine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2008	6549038	EXPEDITED (15-DAY)		DE	US-ABBOTT-08P-163-0437347-00		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydrocodone			S	Oral			Not Reported
	Hydrocodone			S				Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Cocaine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2008	6559805	DIRECT	Y	HO			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation; Condition Aggravated;	Escitalopram Oxalate			S	Oral	10 Mg Od - Oral		Not Reported
	Glimepiride			C				Not Reported

Delusion; Fear; Hallucination; Hallucination, Auditory; Major Depression; Marital Problem; Paranoia; Psychotic Disorder; Treatment Noncompliance	Quinapril		C	Not Reported
	Carvedilol		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2008	6560150	EXPEDITED (15-DAY)	Y	DE	US022462		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Fentanyl			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Morphine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2008	6522864	EXPEDITED (15-DAY)	Y	HO	S07-DEN-06438-01		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Decreased; Feeling Abnormal; Palpitations; Restlessness; Stress; Venous Bruit	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Zolpidem			C				Not Reported
	Oxazepam			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Yasmin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2008	6549948	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20080200487		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Feeling Abnormal; Hyperhidrosis; Infected Skin Ulcer; Product Administered At Inappropriate Site; Sleep	Sandoz Fentanyl Trasdermal System			S	Transdermal	2 X 100 Ug/Hr Patches		Not Reported
	Sandoz Fentanyl Trasdermal System			S	Transdermal			Not Reported

Apnoea Syndrome	Fentanyl	S	Transdermal		Not Reported
	Fentanyl	S	Transdermal		Not Reported
	Lexapro	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2008	6557588	DIRECT	N	OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysgeusia; Product Quality Issue	Lexapro			S	Oral	10 Mg Once A Day Po	4 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2008	6142324	EXPEDITED (15-DAY)	N	OT	US-BOEHRINGER INGELHEIM GMBH, GERMANY-2006-BP-1146		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Colon Cancer Stage Ii; Dehydration; Dizziness; Eye Disorder; Gait Disturbance; Insomnia; Lacrimation Increased; Retrograde Ejaculation; Rhinorrhoea; Urinary Retention; Vision Blurred	Flomax			S	Oral			Boehringer Ingelheim
	Lexapro			S				Not Reported
	Benicar			C				Not Reported
	Lipitor			C				Not Reported
	Aleve			C				Not Reported
	Advil			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2008	6565670	EXPEDITED (15-DAY)	Y	DE	2008-00863		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Fioricet			S				Watson
	Trazodone Hydrochloride			S				Watson
	Oxcarbazepine			S				Not Reported
	Zyprexa			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

	Benzodiazepine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2008	6565677	EXPEDITED (15-DAY)	Y	DE	2008-00922		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Ibuprofen			S				Watson
	Zolpidem Tartrate			S				Watson
	Alprazolam			S				Watson
	Lamotrigine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Diazepam			S				Not Reported
	Propamidine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2008	6579021	EXPEDITED (15-DAY)	Y	DE	2008-00885		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Fioricet			S				Watson
	Clonazepam			S				Watson
	Lisinopril			S				Watson
	Hydrocodone Bitartrate And Acetaminophen			S				Watson
	Escitalopram Oxalate			S				Not Reported
	Cocaine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2008	6551355	EXPEDITED (15-DAY)	Y	OT	US-WYE-H02437608		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Intentional Overdose; Road Traffic Accident; Suicidal Ideation; Suicide Attempt	Effexor			S		Overdose Amount Unspecified		Wyeth
	Lithium			S				Unknown
	Risperdal			S				Janssen
	Lexapro			S		Overdose Amount Unspecified		Lundbeck

	Xanax	S			Not Reported
	Xanax	S			Not Reported
	Paroxetine Hydrochloride	C		13 DAY	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2008	6552336	EXPEDITED (15-DAY)	Y	HO	NO-MERCK-0802NOR00015		69 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Confusional State; Drug Interaction; Hyponatraemia	Hyzaar			S	Oral			Merck
	Escitalopram Oxalate			S	Oral			Not Reported
	Carvedilol			C	Oral			Not Reported
	Simvastatin			C	Oral			Not Reported
	Lercanidipine Hydrochloride			C	Oral			Not Reported
	Aspirin\Magnesium Oxide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2008	6565920	EXPEDITED (15-DAY)	Y	DE	2008-01056		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Amitriptyline Hydrochloride\Chlordiazepoxide			S				Watson
	Clonazepam			S				Not Reported
	Methadone Hydrochloride			S				Not Reported
	Cocaine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Chloral Hydrate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2008	6566703	EXPEDITED (15-DAY)	Y	DE	2008-01070		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Hydralazine Hydrochloride			S				Watson
	Chlordiazepoxide And			S				Watson

	Amitriptyline			
	Amphetamine Asp Amphetamine Sulf Dextroamphet Saccharate & Dextr Sulf	S		Watson
	Beta Blocker	S		Not Reported
	Escitalopram Oxalate	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2008	6511361	EXPEDITED (15-DAY)	Y	DE	US-SANOFI-SYNTHELABO-A03200706872		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose	Ambien			S	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported
	Vicodin			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Klonopin			S	Oral	1 Mg Qid Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2008	6564116	EXPEDITED (15-DAY)	Y	DE	2008-01100		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Fentanyl Patches			S				Not Reported
	Morphine Sulfate			S				Watson
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2008	6564287	EXPEDITED (15-DAY)	Y	DE	080206-0000107		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Neoprofen			S	Oral	Po		Not Reported
	Lamotrigine			S	Oral	Po		Not Reported

	Escitalopram Oxalate	S	Oral	Po		Not Reported
	Unspecified Ingredient	S	Oral	Po		Not Reported
	Zolpidem	S	Oral	Po		Not Reported
	Ramelteon	S	Oral	Po		Not Reported
	Alprazolam	S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2008	6564343	DIRECT	N	HO			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Lexapro			S		10 M.G 1 X Daily; 15 M.G. To 20 M.G. 1 X Daily 10 M.G 1 X Daily; 15 M.G. To 20 M.G. 1 X Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2008	6564548	EXPEDITED (15-DAY)	Y	DE	080207-0000129		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Neoprofen			S	Oral	; Po		Not Reported
	Quetiapine			S	Oral	; Po		Not Reported
	Unspecified Ingredient			S	Oral	; Po		Not Reported
	Butalbital Acetaminophen And Caffeine			S	Oral	; Po		Not Reported
	Aspirin			S	Oral	; Po		Not Reported
	Acetaminophen			S	Oral	; Po		Not Reported
	Escitalopram Oxalate			S	Oral	; Po		Not Reported
	Caffeine Citrate			S	Oral	; Po		Not Reported
	Naproxen			S	Oral	; Po		Not Reported
	Fexofenadine			S	Oral	; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2008	6565542	EXPEDITED (15-DAY)	Y	DE	2008-01206		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Fioricet			S				Watson
	Fiorinal			S				Watson
	Ibuprofen			S				Watson
	Naproxen			S				Watson
	Quetiapine Fumarate			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Caffeine Citrate			S				Not Reported
	Fexofenadine Hcl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2008	6553722	EXPEDITED (15-DAY)	Y	HO	AT-JNJFOC-20080201625		33 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Diarrhoea; Hyponatraemia; Vomiting	Haldol			S				Not Reported
	Trileptal			S	Oral			Not Reported
	Trileptal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Ferrous Fumarate			C	Oral			Not Reported
	Akineton			C	Oral			Not Reported
	Amitriptyline Hydrochloride			C	Oral			Not Reported
	Zolpidem Tartrate			C	Oral			Not Reported
	Lamictal			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2008	6564652	DIRECT	N	OT			20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Chills; Crying; Diarrhoea Haemorrhagic; Drug Withdrawal Syndrome; Hypersomnia; Impaired Work Ability; Malaise	Lexapro	S	10 Mg 1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2008	6548249	EXPEDITED (15-DAY)	Y	DE	US-ROCHE-544305		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fatigue; Pain; Toxicity To Various Agents	Pegasys			S	Subcutaneous			Roche
	Ribavirin			S	Oral	Dose: 400 Mg/ 600 Mg Twice Daily.		Not Reported
	Isopropanol			S	Unknown			Not Reported
	Acetone			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Methamphetamine Hydrochloride			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Remeron			S	Unknown			Not Reported
	Cannabinoids			S	Unknown			Not Reported
	Chlorpheniramine			S	Unknown			Not Reported
	Prilosec			C				Not Reported
	Buspar			C				Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2008	6568023	EXPEDITED (15-DAY)	Y	LT	S08-ESP-00436-01		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Respiratory Failure	Cipralex			S				Not Reported
	Seroquel			S				Not Reported
	Lexatin (Bromazepam)			S	Oral	12 Mg Qd Po		Not Reported

Seretide Accuhaler (Seretide)	C		Not Reported
Amlodipine	C		Not Reported
Atrovent	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2008	6570526	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00588-01		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Lymphopenia; Oedema Peripheral; Purpura; Rash Maculo-Papular	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Cetrizine			C				Not Reported
	Actonel			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2008	6570528	EXPEDITED (15-DAY)	Y	OT	S08-UKI-00589-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Overdose	Cipralex			S	Oral	40 Mg Qd Po		Not Reported
	Amitriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2008	6557903	EXPEDITED (15-DAY)		OT	FR-AVENTIS-200810574FR		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Lovenox			S	Subcutaneous			Aventis
	Tavanic			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Augmentin			C				Not Reported
	Rocephin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2008	6570232	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00625-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amylase Increased; Lipids Increased	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2008	6572255	EXPEDITED (15-DAY)	Y	DE	TPA2008A00205		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Rozerem			S	Oral	Per Oral		Not Reported
	Alprazolam (Alprazolam)			S	Oral	Per Oral		Not Reported
	Lamotrigine (Lamotrigine)			S	Oral	Per Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Per Oral		Not Reported
	Unspecified Ingredient			S	Oral	Per Oral		Not Reported
	Zolpidem			S	Oral	Per Oral		Not Reported
	Ibuprofen (Ibuprofen)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2008	6572323	DIRECT	N	DE				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	20 Mg Once Daily Po		Forest
	Clonazepam			S	Oral	0.5 Mg Three Times Daily Po		Caraco

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2008	6574686	EXPEDITED (15-DAY)	Y	HO	S08-NOR-00639-01		69 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Confusional State; Fall; Hyponatraemia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Hydrochlorothiazide\Losartan			S	Oral	1 Qd Po		Not Reported
	Albyl-E			C				Not Reported
	Lercanidipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2008	6575652	EXPEDITED (15-DAY)	Y	OT	S08-USA-00471-01		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Induced Labour; Maternal Exposure During Pregnancy; Pregnancy; Skin Discolouration	Lexapro			S				Not Reported
	Rebif			S	Subcutaneous	44 Mcg Tiw Sc		Not Reported
	Neurontin			S				Not Reported
	Meclizine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2008	6523685	EXPEDITED (15-DAY)	N	HO	S07-USA-06424-01		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Ineffective; Dyskinesia; Seizure; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Minocycline\Minocycline Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2008	6561632	EXPEDITED (15-DAY)	N	HO	CH-BAYER-200813145GPV		61 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Melaena	Aspirin Cardio		Y	S	Oral	Total Daily Dose: 100 Mg Unit Dose: 100 Mg		Bayer
	Phenprocoumon			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	Total Daily Dose: 20 Mg Unit Dose: 10 Mg		Not Reported

	Spironolactone	C	Oral	Total Daily Dose: 50 Mg Unit Dose: 50 Mg	Not Reported
	Metoprolol	C	Oral	Total Daily Dose: 50 Mg Unit Dose: 50 Mg	Not Reported
	Torsemide	C	Oral	Total Daily Dose: 40 Mg Unit Dose: 20 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2008	6571224	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Product Dispensing Error	Lipitor			S		Tablet		Pfizer
	Lexapro			S		Tablet		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2008	6574373	EXPEDITED (15-DAY)	Y	OT	S08-UKI-00481-01		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Suicidal Ideation	Cipralex			S	Oral	10 Mg Qd Por		Not Reported
	Depakote			S	Oral	1 G Qd Po		Not Reported
	Mirtazapine			S	Oral	45 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2008	6574391	EXPEDITED (15-DAY)	Y	OT	S08-UKI-00666-01		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Enuresis; Neuropathy Peripheral; Paraesthesia	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Chlorpromazine			C				Not Reported
	Diclofenac			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2008	6310409	NON-EXPEDITED	Y	OT	HQWYE776330OCT06		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Seizure	Effexor			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	20 Mg, 1x Per 1 Day, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2008	6521046	EXPEDITED (15-DAY)	Y	DE	US-MERCK-0801USA00141		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Prinivil			S	Oral			Merck
	Acetaminophen			S	Oral			Not Reported
	Hydrocodone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Cocaine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2008	6561625	EXPEDITED (15-DAY)	Y	OT	S08-ESP-00456-01		77 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Syncope	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Moduretic 5-50			S	Oral	0.5 Mg Tablet Qd Po		Not Reported
	Atenolol			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2008	6578958	EXPEDITED (15-DAY)	Y	HO	S08-SWI-00710-01		61 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastric Polyps; Gastrointestinal Haemorrhage; International Normalised Ratio Increased	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Marcumar			S	Oral	1 Mg Qd Po		Not Reported
	Aspirin			S	Oral	100 Mg Qd Po		Not Reported
	Aldactone			C				Not Reported
	Beloc [Metoprolol Tartrate]			C				Not Reported
	Torem (Torasemide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2008	6579054	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00686-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2008	6579362	EXPEDITED (15-DAY)	Y	OT	S08-USA-00657-01		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Feeling Abnormal; Hyperhidrosis; Infected Skin Ulcer; Sleep Apnoea Syndrome	Lexapro			S	Oral	20 Mg Qd;Po		Not Reported
	Fentanyl			S		25 Mcg; Id		Not Reported
	Fentanyl			S				Not Reported
	Fentanyl			S		200 Mcg; Id		Not Reported
	Fentanyl			S		100 Mcg; Id		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2008	6510469	EXPEDITED (15-DAY)	Y	OT	S07-FRA-06160-01		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Henoch-Schonlein Purpura	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2008	6557242	EXPEDITED (15-DAY)	Y	DE, HO	L08-USA-00315-01		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Toxicity To Various Agents	Escitalopram Oxalate			S				Not Reported
	Oxcarbazepine			S				Not Reported
	Acetaminophen			S				Not Reported
	Zyprexa			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2008	6557243	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-02		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Escitalopram Oxalate			S				Not Reported
	Acetaminophen			S				Not Reported
	Hydrocodone			S				Not Reported
	Clonazepam			S				Not Reported
	Lisinopril			S				Not Reported
	Cocaine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2008	6557244	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-03		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Escitalopram Oxalate			S				Not Reported
	Lamotrigine			S				Not Reported
	Phenazopyridine Hydrochloride			S				Not Reported
	Zolpidem			S				Not Reported
	Ramelteon			S				Not Reported
	Alprazolam			S				Not Reported
	Ibuprofen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2008	6567277	EXPEDITED (15-DAY)	Y	OT	GB-ABBOTT-08P-167-0437377-00			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Suicidal Ideation	Depakote			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S				Not Reported
	Mirtazapine			S	Oral			Not Reported
	Mirtazapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2008	6580666	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00699-01		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Encephalopathy; Overdose; Renal Failure; Sepsis; Urosepsis	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Flecainide Acetate			S	Oral	100 Mg Bid Po		Not Reported
	Flecainide Acetate			S	Oral	100 Mg Bid Po		Not Reported
	Neoral			S	Oral	50 Mg Bid Po		Not Reported
	Depakene			S	Oral	500 Mg Qid Po		Not Reported
	Prednisone			S	Oral	10 Mg Qd Po		Not Reported
	Claforan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2008	6580676	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00698-01		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Bones Fracture; Fall; Malaise; Obsessive-Compulsive Disorder; Orthostatic Hypotension; Pseudodementia	Escitalopram Oxalate			S				Not Reported
	Nitroglycerin			S				Not Reported
	Trimeprazine Tartrate			S	Oral	15 Drops Qd Po		Not Reported
	Atenolol			S	Oral	50 Mg Qd Po		Not Reported
	Depakote			S	Oral	1.25 G Qd Po		Not Reported

Aspirin	C		Not Reported
Clonazepam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2008	6580696	EXPEDITED (15-DAY)	Y	OT	S08-UKI-00729-02		< 1 DAY	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Maternal Exposure During Pregnancy	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2008	6580978	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00473-01		42 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Brief Psychotic Disorder With Marked Stressors; Hallucination; Mental Disorder; Personality Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2008	6586305	EXPEDITED (15-DAY)	Y	CA, OT	S08-PRT-00707-02			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Congenital Central Nervous System Anomaly; Maternal Exposure During Pregnancy	Cipralex			S	Transplacental	10 Mg Qd Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2008	7051929	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00696-01		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Creatinine Renal Clearance Decreased; Fall; Haemoglobin Decreased; Limb Injury; Thrombophlebitis Superficial; Traumatic Haematoma	Escitalopram Oxalate			S	Oral	15 Mg Qd Po		Not Reported
	Zolpidem			S	Oral	10 Mg Qd Po		Not Reported
	Prazepam			S	Oral	10 Mg Tid Po		Not Reported
	Aceprometazine\Meprobamate			S	Oral	0.5 Qd Po		Not Reported
	Zoxan (Doxazosin Mesilate)			C				Not Reported
	Aspirin			C				Not Reported
	Fenofibrate			C				Not Reported
	Furosemide			C				Not Reported
	Euphytose			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Duphalac			C				Not Reported
	Acetaminophen			C				Not Reported
	Almond Oil (Prunus Dulcis Oil)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2008	6568248	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-08P-056-0439453-00		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy; Renal Failure; Sepsis	Depakene			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Flecainide Acetate			S	Oral			Not Reported
	Flecainide Acetate			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Cefotaxime Sodium			C				Not Reported
	Cefotaxime Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2008	6568388	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-08P-056-0439459-00		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Bones Fracture;	Depakote			S	Oral			Not Reported

Fall; Malaise; Obsessive-Compulsive Disorder; Orthostatic Hypotension; Pseudodementia	Escitalopram Oxalate		S	Oral	Not Reported
	Glyceryl Trinitrate		S	Transdermal	Not Reported
	Trimeprazine Tartrate		S	Oral	Not Reported
	Atenolol		S	Oral	Not Reported
	Aspirin Lysine		C	Oral	Not Reported
	Clonazepam		C	Unknown	Not Reported
	Olanzapine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2008	6582726	EXPEDITED (15-DAY)	Y	HO, LT	S08-FRA-00632-01		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Hepatitis Acute; Intentional Overdose	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd;Po		Not Reported
	Acetaminophen\Caffeine\Morphine			S	Oral	1 Tid;Po		Not Reported
	Ventolin			C				Not Reported
	Cefuroxime			C				Not Reported
	Solupred (Prednisolone Sodium Metazoate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2008	6586462	EXPEDITED (15-DAY)	Y	CA, DE	S08-SWE-00713-02			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Failure; Congenital Hydrocephalus; Foetal Chromosome Abnormality; Maternal Exposure During Pregnancy; Multiple Congenital Abnormalities; Renal Failure; Trisomy 13	Cipralex			S	Transplacental	10 Mg Qd; Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2008	6586490	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00689-01		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Dermatitis Bullous	Escitalopram Oxalate			S	Oral	10 Mg Qd; Po		Not Reported
	Tavanic			S	Oral	500 Mg Qd; Po		Not Reported
	Lovenox			S	Subcutaneous	4000 Iu Qd;Sc		Not Reported
	Zyprexa			S	Oral	5 Mg Qd;Po		Not Reported
	Inexium			S	Oral	20 Mg Qd;Po		Not Reported
	Zolpidem			S	Oral	1 Qd;Po		Not Reported
	Xanax			C				Not Reported
	Augmentin			C				Not Reported
	Rocephin			C				Not Reported
	Zeclar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2008	6586493	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00694-01		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic	Escitalopram Oxalate			S	Oral	10 Mg Qd;Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2008	6586859	DIRECT	N	DE, HO, LT			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Pneumonia; Respiratory Rate Decreased; Snoring	Methadone Hydrochloride			S	Oral	1 3 Times Daily Po	1 DAY	Roxane
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2008	6558556	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-34		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Escitalopram Oxalate			S				Not Reported
	Amitriptyline Hydrochloride			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Hydralazine			S				Not Reported
	Amfetamine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2008	6558560	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-33		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose; Toxicity To Various Agents	Escitalopram Oxalate			S				Not Reported
	Quetiapine			S				Not Reported
	Bupropion			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2008	6561157	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-38		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Overdose; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Amitriptyline Hydrochloride			S				Not Reported
	Methadone Hydrochloride			S				Not Reported
	Cocaine			S				Not Reported
	Chloral Hydrate			S				Not Reported
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2008	6580749	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Lexapro			S	Oral	5mg Qd Po	1 WEEK	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2008	6580799	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hot Flush; Hyperhidrosis; Mastication Disorder; Muscle Tightness; Musculoskeletal Pain; Pain In Jaw; Therapy Non-Responder; Withdrawal Syndrome	Lexapro			S	Oral	10mg Once A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2008	6587006	EXPEDITED (15-DAY)	Y	LT	SO8-FIN-00749-01		70 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Warfarin			S	Oral	3 Mg Qd Po		Not Reported
	Warfarin			S				Not Reported
	Spesicor (Metoprolol Tartrate)			C				Not Reported
	Furosemide			C				Not Reported
	Lipitor			C				Not Reported
	Ramipril Copyfarm (Ramipril)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6550315	EXPEDITED (15-DAY)	N	OT	S08-USA-00219-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Transient; Loss Of Consciousness; Petit Mal Epilepsy	Lexapro			S	Oral	7.5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6557216	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-05		23 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Overdose;	Escitalopram Oxalate			S				Not Reported
	Dextromethorphan			S				Not Reported

Respiratory Arrest Hydrobromide

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6557220	EXPEDITED (15-DAY)	Y	DE, HO	L08-USA-00315-19		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Blood Ph Decreased; Blood Pressure Increased; Brain Oedema; Cardiac Arrest; Delirium; Disseminated Intravascular Coagulation; Haemodialysis; Heart Rate Increased; Hyperhidrosis; Hyperpyrexia; Liver Injury; Lower Gastrointestinal Haemorrhage; Mucosal Haemorrhage; Pulseless Electrical Activity; Renal Failure; Rhabdomyolysis; Toxicity To Various Agents	Escitalopram Oxalate			S				Not Reported
	Cocaine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6557245	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-18		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Overdose; Respiratory Arrest; Toxicity To Various Agents	Escitalopram Oxalate			S				Not Reported
	Quetiapine			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Axotal (Acetaminophen\Butalbital\Caffeine)			S				Not Reported
	Aspirin (Acetylsalicylic Acid)			S				Not Reported
	Acetaminophen (Paracetamol)			S				Not Reported
	Ibuprofen			S				Not Reported
	Caffeine Citrate			S				Not Reported
	Naproxen			S				Not Reported

	Fexofenadine	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6557247	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-17		23 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents	Escitalopram Oxalate			S				Not Reported
	Fentanyl			S				Not Reported
	Morphine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6557258	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-12		24 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Toxicity To Various Agents	Escitalopram Oxalate			S				Not Reported
	Quetiapine			S				Not Reported
	Alprazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6558552	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-21		65 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram Oxalate			S				Not Reported
	Risperidone			S				Not Reported
	Metaxalone			S				Not Reported
	Heparin			S				Not Reported
	Oxycodone			S				Not Reported
	Bupropion			S				Not Reported
	Clonidine			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Methadone Hydrochloride			S				Not Reported
	Albuterol			S				Not Reported
	Haloperidol			S				Not Reported
	Acyclovir			S				Not Reported
	Vancomycin			S				Not Reported
	Lamotrigine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6558554	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-20		19 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose; Toxicity To Various Agents	Escitalopram Oxalate			S				Not Reported
	Quetiapine			S				Not Reported
	Atomoxetine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6558574	EXPEDITED (15-DAY)	Y	DE	L08-USA-00315-15		58 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Escitalopram Oxalate			S				Not Reported
	Zolpidem			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Alprazolam (Alprazolam)			S				Not Reported
	Estrogen Nos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6570188	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20080206136		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Muscle Spasms; Myoclonus; Rhabdomyolysis	Durogesic			S	Transdermal		54 DAY	Not Reported
	Enalapril			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Ferrous Sulfate			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6576707	EXPEDITED (15-DAY)	Y	OT	S08-USA-00528-01		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Increased; Impaired Driving Ability	Lexapro			S	Oral	20 Mg Qam Po		Not Reported
	Klonopin			C				Not Reported
	Tagamet			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2008	6586842	EXPEDITED (15-DAY)	Y	DE	S08-SWI-00815-01		55 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Cardiac Death	Cipralex			S	Oral	30 Mg Qd Po		Not Reported
	Methadone Hydrochloride			S				Not Reported
	Lexotanil (Bromazepam)			C				Not Reported
	Antra			C				Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2008	6519362	EXPEDITED (15-DAY)	Y	HO	S07-SWI-06348-01		85 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Aphasia; Blood Pressure Systolic Increased; Fall; Head Injury; Headache; Mental Disorder; Nausea; Speech Disorder; Subdural Haematoma; Syncope; Vomiting	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Plavix			S	Oral	75 Mg Qd Po		Not Reported
	Irbesartan			C				Not Reported
	Cotenolol			C				Not Reported
	Trittico (Trazodone)			C				Not Reported
	Lorazepam			C				Not Reported
	Simcora (Simvastatin)			C				Not Reported
	Neurotin (Acetylcarnitine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2008	6580976	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00693-01		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dermatitis Allergic; Oedema; Pruritus	Escitalopram Oxalate	S	Oral	10 Mgqd Po		Not Reported
	Stresam (Etifoxine)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2008	6586560	DIRECT	Y	HO			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination	Lexapro			S	Oral	Po	2 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2008	6587581	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00810-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Respiratory Disorder; Sense Of Oppression	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2008	6587593	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00802-01		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Epilepsy; Therapeutic Response Unexpected	Escitalopram Oxalate			S	Oral	10 Mgqd Po		Not Reported
	Citalopram			S				Not Reported
	Clonazepam			C				Not Reported
	Oxazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2008	6587603	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00811-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Respiratory Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2008	6549207	EXPEDITED (15-DAY)	Y	DE	TRP_01020_2008		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fatigue; Pain; Toxicity To Various Agents; Treatment Noncompliance	Ribavirin			S	Oral	1 Df Bid [400 Mg/600 Mg] Oral		Not Reported
	Pegasys			S	Subcutaneous	180 Mg 1/Week Subcutaneous		Not Reported
	Isopropanol			S		Df		Not Reported
	Acetone			S		Df		Not Reported
	Pseudoephedrine Hydrochloride			S		Df		Not Reported
	Methamphetamine Hydrochloride			S		Df		Not Reported
	Lexapro			S		40 Mg Qd		Not Reported
	Remeron			S		As Needed		Not Reported
	Cannabinoids			S		Df		Not Reported
	Chlorpheniramine			S		Df		Not Reported
	Buspar			C				Not Reported
	Prilosec			C				Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2008	6572682	NON-EXPEDITED	N		A0665598A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction	Requip			S	Unknown			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2008	6586578	DIRECT	N	HO, OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Depression; Suicide Attempt	Lexapro	S	Oral	Po		Forest
	Celexa	S	Oral	Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2008	6576283	NON-EXPEDITED	N		US-BAYER-200711416BCC		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrooesophageal Reflux Disease	Aleve			S	Oral			Bayer
	Lexapro			S		Total Daily Dose: 20 Mg Unit Dose: 20 Mg		Not Reported
	Lexapro			S		Total Daily Dose: 10 Mg Unit Dose: 10 Mg	2 YR	Not Reported
	Advil			S				Not Reported
	Excedrin Migraine			S				Not Reported
	Celebrex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2008	6587672	DIRECT	Y				49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro			S	Oral	5mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2008	6593140	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00813-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Coma; Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2008	7025980	DIRECT	Y	HO, LT, RI			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Attention Deficit/Hyperactivity Disorder; Brain Injury; Cerebrovascular Accident; Compulsions; Depression Suicidal; Incorrect Dose Administered; Suicide Attempt	Seroquel		S	Oral	Too Much Too Often Po	Astrazeneca
	Risperdal		S			Not Reported
	Abilify		S			Not Reported
	Tegretal		S	Oral	Ibid Ibid Po	Not Reported
	Depakote		S			Not Reported
	Parnate		S			Not Reported
	Librium		S			Not Reported
	Paxil		S			Not Reported
	Lexapro		S			Not Reported
	Gabapentin		C			Not Reported
	Buspar		C			Not Reported
	Unspecified Ingredient		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2008	6522873	EXPEDITED (15-DAY)	Y	OT	S07-FRA-06439-01		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Calcifications	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Seropram (Citalopram Hydrobromide)			S				Not Reported
	Calciprat (Calcium Carbonate)			C				Not Reported
	Fosamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2008	6527924	EXPEDITED (15-DAY)	Y	DE	S07-ESP-06498-01		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Resistance; Opportunistic Infection; Pseudomonas Infection; Septic Shock; Skin Necrosis; Subarachnoid Haemorrhage; Thrombocytopenia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Menorem (Meropenem)			C				Not Reported
	Fenitoin (Phenytoin)			C				Not Reported
	Ambisome			C				Not Reported
	Vancomycin			C				Not Reported
	Enoxaparin Sodium			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Cancidas			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2008	6576636	NON-EXPEDITED	N	OT	US-BAYER-200711930BCC		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Dyspnoea; Pharyngeal Oedema; Swelling Face	Aleve			S	Oral			Bayer
	Lexapro			S	Oral	Total Daily Dose: 10 Mg Unit Dose: 10 Mg	2 YR	Not Reported
	Advil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2008	6577193	NON-EXPEDITED	N	OT	US-BAYER-200712460BCC		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia; Rectal Haemorrhage	Aleve			S	Oral		5 MTH	Bayer
	Lexapro			S	Oral	Total Daily Dose: 10 Mg Unit Dose: 10 Mg	43 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2008	6589751	EXPEDITED (15-DAY)	N	OT	S08-USA-00847-01		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicide; Indifference; Sexual Abuse; Thinking Abnormal	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2008	6590426	DIRECT	N	HO, LT, RI, OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Communication Disorder; Mental Disorder; Muscle Contractions	Cymbalta			S	Oral	Daily Po 1-2 Months	1 MTH	Not Reported
	Lexapro			S	Oral	10mg Up To 40mg Daily	13 MTH	Not Reported

Involuntary; Social Avoidant Behaviour; Suicidal Ideation; Tardive Dyskinesia	Remeron	C	Po 13-14 Months	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2008	6593783	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00801-01		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Confusional State; Hyperkalaemia; Hyponatraemia	Escitalopram Oxalate			S	Oral	1 Qd Po		Not Reported
	Plavix			C				Not Reported
	Solupred (Prednisolone Sodium Metazoate)			C				Not Reported
	Permixon (Serenoa Repens)			C				Not Reported
	Vastarel			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2008	6531885	EXPEDITED (15-DAY)	N	HO	S08-USA-00107-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Localised Infection; Procedural Pain; Staphylococcal Infection	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Sulindac			C				Not Reported
	Potassium Chloride			C				Not Reported
	Chlorthalidone			C				Not Reported
	Cenestin			C				Not Reported
	Actonel (Risendronate Sodium)			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2008	6574931	EXPEDITED (15-DAY)	Y	HO, LT	PHFR2008GB00826		37 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Body Temperature Increased;	Clozaril			S	Oral	200mg Daily		Novartis
	Diazepam			S	Oral	5 Mg, Prn		Not Reported

Cerebrovascular Accident; Diarrhoea; Dizziness; Fatigue; Headache; Heart Rate Increased; Malaise; Nausea; Vomiting	Aripiprazole		S	Oral	30mg Daily	Not Reported
	Escitalopram Oxalate		S	Oral	20mg Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2008	6578628	EXPEDITED (15-DAY)	Y	OT	US-JNJFOC-20070101079		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Hypothalamo-Pituitary Disorder; Weight Increased	Risperdal			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2008	6591639	DIRECT	Y				76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torticollis	Lexapro			S	Oral	10 Mg Daily Po		Not Reported
	Ciprofloxacin			C				Not Reported
	Belladonna			C				Not Reported
	Amlodipine			C				Not Reported
	Modafinil			C				Not Reported
	Mtx Low Dose			C				Not Reported
	Desidronate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2008	6528510	EXPEDITED (15-DAY)	Y	OT	US-WYE-H01986008		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Neoplasm Benign; Demyelinating Polyneuropathy	Effexor Xr			S	Oral			Wyeth
	Lexapro			S				Lundbeck
	Bupropion Hydrochloride			S	Oral			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2008	6574537	EXPEDITED (15-DAY)	N	OT	B0511476A		58 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Leukopenia; Pancytopenia; Somnolence; Thrombocytopenia; Vitamin B12 Deficiency	Lamictal			S	Oral	200mg Per Day		Glaxosmithkline
	Cipralex			S	Oral	15mg Per Day		Not Reported
	Folic Acid			C				Not Reported
	Behepan			C				Not Reported
	Lithionit			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2008	6593842	EXPEDITED (15-DAY)	Y	OT	S08-UKI-00911-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gallbladder Disorder; Haemolytic Anaemia	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2008	6594057	EXPEDITED (15-DAY)	Y	LT	S08-FIN-00749-01		70 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Warfarin			S	Oral	3 Mg Qd Po		Not Reported
	Warfarin			S				Not Reported
	Spesicor (Metoprolol Tartrate)			C				Not Reported
	Furosemide			C				Not Reported
	Lipitor			C				Not Reported
	Ramipril Copyfarm (Ramipril)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2008	6594134	EXPEDITED (15-DAY)	Y	HO	S08-FRA-00893-01		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Phosphorus Decreased; Condition Aggravated; Diarrhoea; Faeces Discoloured; Hypomagnesaemia; Major Depression; Malnutrition; Overdose; Proteus Infection; Radicular Pain; Rhabdomyolysis; Toxicity To Various Agents; Urinary Tract Infection; White Blood Cell Count Increased	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Enalapril Maleate			S	Oral	5 Mg Qd Po		Not Reported
	Lyrica			S	Oral	25 Mg Qd Po		Not Reported
	Lyrica			S	Oral	1 Unk Qd Po		Not Reported
	Durogesic			S		50 Mcg Biw Ap		Not Reported
	Ferrous Sulfate			S	Oral	80 Mg Qd Po		Not Reported
	Levothyroxine Sodium			S	Oral	50 Mcg Qd Po		Not Reported
	Furosemide			S	Oral	40 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2008	6561628	EXPEDITED (15-DAY)	Y	HO, OT	S08-AUT-00459-01		54 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Oedema	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Risperdal			S	Oral	3 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2008	6587595	EXPEDITED (15-DAY)	Y	HO	S08-CHN-00806-01		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Shock; Suicide Attempt	Escitalopram Oxalate			S	Oral	700 Mg Once Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Diazepam			S	Oral	10 Tablet Once Po		Not Reported
	Diazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2008	6600894	EXPEDITED (15-DAY)	Y	DS	S08-CAN-00995-01		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrooesophageal Reflux Disease; Glossodynia; Therapy Non-Responder; Tongue Blistering; Tongue Ulceration	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Wellbutrin (Bupropion Hydrochloride)			C				Not Reported
	Strattera			C				Not Reported
	Imovane (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2008	6601148	EXPEDITED (15-DAY)	Y	DE, OT	025060		29 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents	Mirtazapine			S	Oral	Oral		Not Reported
	Doxepin Hydrochloride			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2008	6603464	EXPEDITED (15-DAY)	Y	HO	S08-ESP-00951-01		72 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Inappropriate Antidiuretic Hormone Secretion; Muscular Weakness	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2008	6525320	EXPEDITED (15-DAY)	Y	HO	S07-USA-06161-01		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dystonia; Loss Of Consciousness; Muscle Rigidity; Seizure; Vomiting	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported

	Yasmin	S	Not Reported
	Yasmin	S	Not Reported
	Centrum (Multivitamin)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2008	6582757	EXPEDITED (15-DAY)	Y	LT	S08-FRA-00745-01		49 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Gastric Ulcer; Helicobacter Infection	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Voltaren			S	Oral	100 Mg Qd Po		Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2008	6588580	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLIN CKRODT-T200800345			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Methadose			S				Tyco
	Amitriptyline			S				Not Reported
	Cocaine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Chloral Hydrate			S				Not Reported
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2008	6588623	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLIN CKRODT-T200800363			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Morphine			S				Tyco
	Fentanyl			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2008	6601054	DIRECT	N	DS, LT, OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mood Swings; Suicidal Ideation; Wrong Product Administered	Lexapro			S	Oral	10mg Once A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2008	6602528	EXPEDITED (15-DAY)	Y	OT	S08-CHL-01012-01			Female	CHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy	Lexapro			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2008	6603973	EXPEDITED (15-DAY)	N	HO	S08-USA-00918-01		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Contusion; Dizziness; Fall	Lexapro			S				Not Reported
	Coumadin			C				Not Reported
	Oxygen			C				Not Reported
	Inhalers (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2008	6533176	EXPEDITED (15-DAY)	Y	OT	S08-USA-00024-01		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy	Lexapro			S	Oral	20 Mg Qd;Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd;Po		Not Reported
	Rebif			S		44 Mcg Tiw		Not Reported
	Rebif			S		44 Mcg Tiw		Not Reported
	Klonopin			S				Not Reported
	Atenolol			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2008	6567996	EXPEDITED (15-DAY)	Y	OT	S08-CHN-00524-01		30 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Foetal Death; Foetal Growth Restriction; Maternal Drugs Affecting Foetus; Pregnancy	Lexapro			S	Oral	15 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2008	6589713	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2008022451			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rash Erythematous; Weight Decreased	Celebrex			S				Not Reported
	Tylenol			C				Not Reported
	Lipitor			C				Not Reported
	Fosamax			C				Not Reported
	Celebrex			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2008	6589871	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2008023106		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Ischaemia	Relpax			S	Oral	Text:1 Df		Not Reported
	Betaferon			S	Subcutaneous	Text:250ng		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2008	6603276	EXPEDITED (15-DAY)	Y	OT	S08-HKG-00883-01		30 YR	Female	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Induced; Foetal Death; Maternal Exposure During Pregnancy	Lexapro	S	Oral	15 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2008	6570230	EXPEDITED (15-DAY)	Y	OT	S08-IRL-00605-01		35 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Gerax (Alprazolam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2008	6392233	EXPEDITED (15-DAY)	Y	OT	S07-USA-03453-01		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Fall; Hereditary Spastic Paraplegia	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Posamax (Alendronate Sodium)			C				Not Reported
	Topranil (Imipramine Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2008	6603019	DIRECT					31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Product Dispensing Error	Lexapro			S		Tablet		Forest
	Lipitor			S		Tablet		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2008	6574377	EXPEDITED (15-DAY)	Y	HO, LT	S08-FRA-00669-01		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Coma; Intentional	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported

Overdose; Suicide Attempt	Escitalopram Oxalate		S	Oral	5 Mg Qd Po	Not Reported
	Atarax		S	Oral	25 Mg Prn Po	Not Reported
	Lorazepam		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2008	6606884	EXPEDITED (15-DAY)	N	OT	S08-USA-01025-01		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impulsive Behaviour; Irritability; Libido Increased; Panic Attack; Unevaluable Event; Weight Increased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2008	6575095	EXPEDITED (15-DAY)	Y	CA	S08-CZE-00638-01		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Hydatidiform Mole; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2008	6596126	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLINCKRODT-T200800488			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Butalbital Acetaminophen And Caffeine			S	Oral			Tyco
	Quetiapine			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported

	Escitalopram Oxalate	S	Oral		Not Reported
	Caffeine Citrate	S	Oral		Not Reported
	Naproxen	S	Oral		Not Reported
	Fexofenadine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2008	6596130	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLIN CKRODT-T200800492			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Oxycodone			S	Oral			Tyco
	Methadose			S	Oral			Tyco
	Risperidone			S	Oral			Not Reported
	Metaxalone			S	Oral			Not Reported
	Heparin			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Clonidine			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported
	Albuterol			S	Oral			Not Reported
	Haloperidol			S	Oral			Not Reported
	Acyclovir			S	Oral			Not Reported
	Vancomycin Hydrochloride			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2008	6611518	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01142-01		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

	Citalopram Hydrobromide	S	Not Reported
	Equanil	S	Not Reported
	Euthyral	C	Not Reported
	Mirtazapine	C	Not Reported
	Atarax	C	Not Reported
	Cyamemazine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2008	6570540	EXPEDITED (15-DAY)	Y	HO, OT	S08-FRA-00545-01		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cogwheel Rigidity; Cold Sweat; Headache; Initial Insomnia; Nausea; Parkinsonism; Tremor	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Stresam (Etifoxine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2008	6606975	DIRECT	Y	DE			16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	5 Mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2008	6603572	EXPEDITED (15-DAY)	Y	OT	S08-ESP-00730-01		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Blood Cholesterol Increased; Blood Triglycerides Increased; Decreased Appetite; Depressed Mood; Dizziness; Dyspnoea; Fluid Retention; Headache; Hot Flush;	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Alprazolam			C				Not Reported

Vomiting; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2008	6542826	EXPEDITED (15-DAY)	Y	OT	S08-USA-00168-01		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Pressure Decreased; Facial Paralysis; Fatigue; Headache; Hyperhidrosis; Insomnia; Loss Of Personal Independence In Daily Activities; Nausea; Vision Blurred	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Toprol Xl			C				Not Reported
	Nexium (Esomephrazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2008	6591760	EXPEDITED (15-DAY)	Y	HO	GXKR2008CH02125		84 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Decreased; Incorrect Dose Administered; Serotonin Syndrome	Cyclosporine			S		1.25 Mg/Kg,Day		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Azathioprine (Azathioprine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2008	6610323	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01049-01		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Arrhythmia; Sinus Tachycardia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Levothyroxine Sodium			C				Not Reported
	Lexomil (Bromazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2008	6614180	EXPEDITED (15-DAY)	Y	OT	S08-ESP-01192-01		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parosmia	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2008	6611997	DIRECT	N	HO			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea; Nausea	Lexapro			S	Oral Oral	200 Bid Po 200 Bid Po		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2008	6614917	EXPEDITED (15-DAY)	Y	OT	070125-0000141		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Infection; Maternal Exposure During Pregnancy	Clorazepate Dipotassium			S	Oral	20 Mg; ; Po		Not Reported
	Cipralex			S	Oral	; Po		Not Reported
	Alcohol			S	Oral	; Po		Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2008	6615124	EXPEDITED (15-DAY)	Y	HO	S08-USA-01185-01		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Blood Pressure Increased; Condition Aggravated; Depression	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd Po		Not Reported
	Wellbutrin Xl			S		450 Mg Qd		Not Reported
	Wellbutrin Xl			S		300 Mg Qd		Not Reported

	Neurontin	C		Not Reported
	Klonopin	C		Not Reported
	Ambien	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2008	6615126	EXPEDITED (15-DAY)	Y	HO	S08-USA-01207-01		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paranoia; Psychotic Disorder	Lexapro			S				Not Reported
	Topamax			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2008	6592096	EXPEDITED (15-DAY)	Y	HO	S08-USA-00832-01		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplastic Anaemia; Contusion	Lexapro			S	Oral	10 Mg Od Po		Not Reported
	Ferrous Sulfate			C				Not Reported
	Yaz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2008	6600855	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00930-01		62 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Road Traffic Accident	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Amaryl			S				Not Reported
	Selokeen			S		25 Mg Daily		Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2008	6615889	EXPEDITED (15-DAY)	Y	OT	S07-USA-06450-01		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Recurrent Cancer; Testis Cancer	Lexapro		S	Oral	20 Mg Od Po	Not Reported
	Lexapro		S	Oral	10 Mg Od Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2008	6616250	EXPEDITED (15-DAY)	Y	LT	S08-NLD-01250-01		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Oxazepam			S	Oral	10 Mg Qd Po		Not Reported
	Levothyroxine			S	Oral	0.025 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2008	6616258	EXPEDITED (15-DAY)	Y	OT	S08-BEL-01239-01		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2008	6616318	EXPEDITED (15-DAY)	Y	OT	S08-IRL-01241-01		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Wrong Product Administered	Citalopram			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2008	6607826	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-SYNTHELABO-A02200800994		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Depressed Level Of Consciousness; Disorientation; Fall; Hyponatraemia; Sopor	Stilnox	S	Oral	Unk		Not Reported
	Escitalopram Oxalate	S	Oral	Unk	3 DAY	Not Reported
	Lipanthyl	C	Oral	Unk		Not Reported
	Piracetam	C	Oral	Unk		Not Reported
	Vastarel	C	Oral	Unk		Not Reported
	Nisis	C	Oral	Unk		Not Reported
	Ginkor Fort	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2008	6620049	EXPEDITED (15-DAY)	Y	OT	DSA_31640_2008		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Maternal Exposure During Pregnancy; Premature Labour	Lorazepam			S	Oral	(2.5 Mg Qd Oral)		Not Reported
	Alcohol			S				Not Reported
	Cipralex			S		(Df)		Not Reported
	Clorazepate Dipotassium			S	Oral	(10 Mg Bid Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2008	6616545	DIRECT	N	HO, RI, OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Family Stress; Loss Of Employment; Loss Of Personal Independence In Daily Activities	Xanax			S				Not Reported
	Risperdal			S				Not Reported
	Clonopin			S				Not Reported
	Lexapro			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2008	6616567	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Libido	Lexapro			S	Oral	20mg Once A Day Po		Not Reported

Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2008	6592010	EXPEDITED (15-DAY)	Y	OT	S08-CAN-00846-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Petit Mal Epilepsy	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Valproate Sodium			C				Not Reported
	Axert			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2008	6592091	EXPEDITED (15-DAY)	Y	HO	S08-USA-00862-01		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Dysarthria; Furuncle; Gait Inability; Multiple Sclerosis; Urinary Incontinence	Lexapro			S	Oral	10 Mg Qd;Po		Not Reported
	Rebif			S		8.8 Mcg;Tiw;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2008	6611014	EXPEDITED (15-DAY)	Y	OT	GB-JNJFOC-20080401367			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis	Ibuprofen		Y	S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2008	6621722	EXPEDITED (15-DAY)	Y	HO	S08-UKI-01338-01		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatine Phosphokinase Increased; Dizziness; Headache; Vertigo	Cipralex	S		Not Reported
	Contraceptive Pills (Nos)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2008	6622540	EXPEDITED (15-DAY)	Y	HO	S08-NOR-01323-01		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Mouth Haemorrhage; Rectal Haemorrhage; Thrombocytopenia; Vaginal Haemorrhage	Cipralex			S				Not Reported
	Acomplia			S	Oral	20 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2008	6594326	EXPEDITED (15-DAY)	N	OT	2008SP004596		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Constipation; Dyspnoea; Flatulence; Gastrointestinal Disorder; Oedema Mouth; Oesophageal Discomfort; Oesophageal Oedema; Swollen Tongue	Miralax			S	Oral	;Unk;Po		Not Reported
	Advair Hfa			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Lexapro			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Synthroid			C				Not Reported
	Naprosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2008	6613939	EXPEDITED (15-DAY)	Y	OT	S08-NOR-01143-01		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Depression; Drug Intolerance; Hallucination; Malaise; Poisoning; Schizoid Personality	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Delapril			S				Not Reported
	Imovane (Zopiclone)			C				Not Reported

Disorder; Social Anxiety Disorder; Vertigo; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2008	6624549	EXPEDITED (15-DAY)	N	OT	S08-USA-01276-01		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Thyroiditis; Contusion; Dyskinesia; Encephalitis; Fall; Gait Disturbance; Hypertension; Incorrect Dose Administered; Malaise; Thyroid Neoplasm	Lexapro			S	Oral	10 Mg Once Po		Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2008	6291716	EXPEDITED (15-DAY)	Y	HO, OT	S07-ITA-01291-01			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Caesarean Section; Insomnia; Maternal Exposure During Pregnancy; Nervousness; Perinatal Depression; Pregnancy; Toxicity To Various Agents	Cipralex			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Sedatol (Matricaria Recutita)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2008	6591767	EXPEDITED (15-DAY)	Y	HO, OT	NO-PFIZER INC-2008023942		19 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Intolerance; Hallucination;	Zoloft			S	Oral			Not Reported

Poisoning; Social Anxiety Disorder	Triphasil-21		S	Oral	Not Reported
	Citalopram Hydrobromide		S	Oral	Not Reported
	Cipralex		S	Oral	Not Reported
	Zopiclone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2008	6620101	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Medication Error; Product Dispensing Error; Wrong Product Administered	Lexapro			S		Tablet		Not Reported
	Propecia			S		Tablet		Merck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2008	6625843	EXPEDITED (15-DAY)	Y	OT	S08-CAN-01339-01		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Suicidal Ideation; Thinking Abnormal; Tinnitus; Weight Decreased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Seroquel			C				Not Reported
	Valerian Tea (Valeriana Officinalis Extract)			C				Not Reported
	Holy Basil (Herbal)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2008	6641985	DIRECT	N	LT, RI, OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alcohol Use; Anger; Anxiety; Arthralgia;	Lexapro			S	Oral	10 Mg Once A Day Po		Forest

Chills; Deafness; Depersonalisation/Dereali sation Disorder; Fall; Fatigue; Feeling Abnormal; Foot Fracture; Hip Fracture; Hypoaesthesia; Insomnia; Memory Impairment; Nerve Injury; Nervous System Disorder; Palpitations; Rash; Salivary Hypersecretion; Serotonin Syndrome; Sexual Dysfunction; Thinking Abnormal	Lexapro	S	10 Mg Twice A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2008	6576705	EXPEDITED (15-DAY)	N	DE, HO, OT	S08-USA-00566-01		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Confusional State; General Physical Health Deterioration; Musculoskeletal Stiffness; Peripheral Vascular Disorder; Seizure; Somnolence; Tremor	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Isosorbide Dinitrate			C				Not Reported
	Prinivil			C				Not Reported
	Colace			C				Not Reported
	Thiamine			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Neurontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2008	6622826	DIRECT	Y				47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Lexapro			S		5 Mg Qd Inj	2 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2008	6628142	EXPEDITED (15-DAY)	Y	HO	S08-FRA-01395-01		21 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative; Hypotension	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2008	6617729	EXPEDITED (15-DAY)	N	DE	S08-USA-01234-01		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Anxiety; Apnoea; C-Reactive Protein Increased; Cardiac Arrest; Depressed Mood; Depression; Dry Mouth; Fatigue; Feeling Abnormal; Pain; Pulse Absent; Stress Urinary Incontinence; Sudden Death; Toxicity To Various Agents; Unresponsive To Stimuli	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Neurontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2008	6625313	DIRECT	N	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Disorientation; Heart Rate Increased; Hypertension; Libido Decreased; Withdrawal Syndrome	Lexapro			S	Oral	10 Mg Per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2008	6626880	EXPEDITED (15-DAY)	N	DE	S08-USA-01321-01		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Gun Shot Wound	Lexapro		S	Oral	10 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2008	6630127	EXPEDITED (15-DAY)	Y	CA	S08-UKI-01402-02			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diaphragmatic Hernia; Maternal Exposure During Pregnancy	Cipralex			S				Not Reported
	Co-Codamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2008	6630150	EXPEDITED (15-DAY)	Y	HO	S08-FRA-01403-02		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abnormal Faeces; Agitation Neonatal; Bacterial Infection; Drug Withdrawal Syndrome Neonatal; Dysmorphism; Foetal Distress Syndrome; Hypertonia Neonatal; Hypoglycaemia Neonatal; Maternal Exposure During Pregnancy; Meconium In Amniotic Fluid; Neonatal Disorder; Tremor Neonatal	Escitalopram Oxalate			S	Transplacental	10 Mg Bid Transplacental		Not Reported
	Cyamemazine			S	Transplacental	50 Mg Qd Transplacental		Not Reported
	Xanax			S	Transplacental	0.5 Mg Tid Transplacental		Not Reported
	Atarax			S				Not Reported
	Subutex			S	Transplacental	8 Mg Qd Transplacental		Not Reported
	Alcohol			S				Not Reported
	Heroin			S				Not Reported
	Cannabis			S				Not Reported
	Cocaine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2008	6630216	EXPEDITED (15-DAY)	Y	HO	S08-FRA-01396-01		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis; Confusional State; Fall; Hyponatraemia; Pituitary	Escitalopram Oxalate			S				Not Reported
	Zolpidem Tartrate			S				Not Reported
	Nisis			C				Not Reported

Enlargement; Somnolence; Urine Osmolarity Decreased	Vastarel	C		Not Reported
	Nootropyl (Piracetam)	C		Not Reported
	Fenofibrate	C		Not Reported
	Ginkor Biloba/Heptaminol/Troxerutine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2008	6569908	EXPEDITED (15-DAY)	Y	OT	S08-UKI-00607-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis Fugax	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2008	6631413	EXPEDITED (15-DAY)	Y	HO, OT	S08-FRA-01416-01		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ectopic Pregnancy; Maternal Exposure During Pregnancy	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Desogestrel\Ethinyl Estradiol			S				Not Reported
	Lormetazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2008	6561161	EXPEDITED (15-DAY)		HO, OT	CH-ABBOTT-08P-151-0438724-00		84 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Cyclosporine			S	Oral			Not Reported
	Cyclosporine			S	Oral			Not Reported
	Cyclosporine			S		Not Reported		Not Reported
	Cyclosporine			S				Not Reported
	Cipralex			S		Initial Dose 2.5 Mg/D, Gradually Increased To 15 Mg/D		Not Reported
	Cipralex			S		Not Reported		Not Reported
	Cipralex			S				Not Reported

Cipralex	S			Not Reported
Azathioprine	C	Oral		Not Reported
Paracetamol	C	Intravenous (not otherwise specified)		Not Reported
Memantine Hydrochloride	C			Not Reported
Memantine Hydrochloride	C			Not Reported
Haloperidol	C	Oral		Not Reported
Haloperidol	C			Not Reported
Lorazepam	C	Oral		Not Reported
Calcitriol	C	Oral		Not Reported
Calcium-Sandoz	C	Oral		Not Reported
Cefuroxime Axetil	C		Not Reported	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2008	6626589	DIRECT	N	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Malaise	Maxalt			S	Oral	10mg Twice A Day Po		Merck
	Lexapro			S	Oral	10mg Once A Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2008	6631549	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01421-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bulimia Nervosa; Hyperphagia; Weight Increased	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2008	6520465	EXPEDITED (15-DAY)	Y	DE	S07-GRC-06255-01		63 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Myocardial Infarction; Overdose	Cipralex		S	Oral	10 Mg Qd Po	Not Reported
	Cipralex		S	Oral	30 Mg Qd Po	Not Reported
	Amisulpride		C			Not Reported
	Digoxine		C			Not Reported
	Acetylsalicylic Acid		C			Not Reported
	Clopidogrel		C			Not Reported
	Metoprolol		C			Not Reported
	Ramipril/ Hydrochlorothiazide		C			Not Reported
	Albuterol		C			Not Reported
	Ipratropium		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2008	6636411	EXPEDITED (15-DAY)	Y	HO, LT	S08-FRA-01342-01		84 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Syncope; Torsade De Pointes	Escitalopram Oxalate			S				Not Reported
	Furosemide			S				Not Reported
	Sectral			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2008	6623291	EXPEDITED (15-DAY)	Y	OT	DE-WYE-G01393308		75 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Interaction; Fall; Gait Disturbance	Venlafaxine Hydrochloride			S	Oral			Wyeth
	Rythmol			C	Oral			Knoll
	Norvasc			C	Oral			Pfizer
	Sortis			C	Oral			Not Reported
	Levodopa			C	Oral			Unknown
	Kalinor (Potassium Chloride)			C	Oral			Not Reported
	Methionine			C	Oral			Not Reported
	Ascorbic Acid			C	Oral			Not Reported
	Pantoprazole Sodium			C	Oral			Wyeth

	Movicol	C					Not Reported
	Marcumar	C	Oral				Roche
	Venlafaxine Hydrochloride	S	Oral			6 DAY	Wyeth
	Enalapril	S	Oral				Unknown
	Esidrix	S	Oral				Novartis
	Cipralex	S	Oral				Lundbeck
	Lithium Carbonate	S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2008	6631367	EXPEDITED (15-DAY)	Y	HO	S08-FRA-01417-01		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fixed Eruption	Escitalopram Oxalate			S	Oral	1 Unk Qd Po		Not Reported
	Aceprometazine\Meprobamate			S	Oral	1 Unk Bid Po		Not Reported
	Atarax			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2008	6638600	EXPEDITED (15-DAY)	Y	OT	S08-USA-01508-01		47 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Betaseron			S	Subcutaneous	8 Unk Qod Sc		Not Reported
	Iv Steroids (Nos)			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2008	6574375	EXPEDITED (15-DAY)	Y	OT	S08-SWE-00674-01		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Leukopenia; Thrombocytopenia;	Cipralex			S	Oral	15 Mg Qd Po		Not Reported

Vitamin B12 Deficiency	Lamictal	S	Oral	200 Mg Qd Po		Not Reported
	Lithionit (Lithium Sulfate)	C				Not Reported
	Folacin	C				Not Reported
	Behepan (Cyanocobalamin)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2008	6580081	EXPEDITED (15-DAY)	Y	HO	S08-SWE-00705-01		54 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased; Post Procedural Haemorrhage	Cipralex			S	Oral	25 Mg Qd Po		Not Reported
	Enoxaparin Sodium			S	Intravenous (not otherwise specified)	100 Mg Once Iv		Not Reported
	Fish Oil			S	Oral	4 Mg Qd Po		Not Reported
	Ventolin			C				Not Reported
	Pulmicort Flexhaler			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2008	6596961	EXPEDITED (15-DAY)	N	OT	US-RANBAXY-2008US-14022			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis Viral; Pregnancy	Isotretinoin			S	Oral	40 Mg, Qd	14 DAY	Ranbaxy
	Lexapro			S	Oral	Unk		Not Reported
	Wellbutrin			S		Unk,Unk		Not Reported
	Mirena			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2008	6639800	EXPEDITED (15-DAY)	Y	DE	2008-176130-NL		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fatigue; Pain; Toxicity To Various Agents; Treatment Noncompliance	Remeron			S				Not Reported
	Ribavirin			S	Oral	1 Df Bid Oral, 400 Mg / 600 Mg		Not Reported
	Pegasys			S		180 Ug Daily		Not Reported

	Isopropanol	S	Df	Not Reported
	Acetone	S	Df	Not Reported
	Pseudoephedrine Hydrochloride	S	Df	Not Reported
	Methamphetamine Hydrochloride	S	Df	Not Reported
	Lexapro	S	40 Mg Qd	Not Reported
	Cannabinoids	S	Df	Not Reported
	Chlorphenamine	C	Df	Not Reported
	Buspar	C		Not Reported
	Prilosec	C		Not Reported
	Risperdal	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2008	6516650	EXPEDITED (15-DAY)	Y	OT	S07-USA-06226-01		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Threatened; Foetal Heart Rate Decreased; Maternal Exposure During Pregnancy; Pregnancy	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Clonazepam			C				Not Reported
	Ambien			C				Not Reported
	Metamucil Therapy For Regularity			C				Not Reported
	Progesterone			C				Not Reported
	Prenatal Vitamin With Dha (Docosahexaenoic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2008	6571255	EXPEDITED (15-DAY)	Y	HO	S08-USA-00441-01		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Overdose; Substance Abuse;	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	40 Mg Qd Po		Not Reported

Treatment Noncompliance	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Lorcet	C				Not Reported
	Lamictal (Lamotrioine)	C				Not Reported
	Seroquel	C				Not Reported
	Lorazepam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2008	6603723	EXPEDITED (15-DAY)	Y	OT	S08-USA-00948-01		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2008	6608037	EXPEDITED (15-DAY)	Y	OT	2008S1004401		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Albuterol			S				Not Reported
	Risperidone			S				Not Reported
	Metaxalone			S				Not Reported
	Heparin			S				Not Reported
	Oxycodone			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Bupropion			S				Not Reported
	Clonidine			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Methadone Hydrochloride			S				Not Reported
	Haloperidol			S				Not Reported
	Acyclovir Sodium			S				Not Reported
	Vancomycin			S				Not Reported
	Lamotrigine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2008	6635793	DIRECT	Y	HO			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate		S	Oral	20 Mg Every Day Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2008	6636715	DIRECT	N	HO			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Glucose Decreased; Weight Increased	Lexapro			S		One Tablet Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2008	6641547	EXPEDITED (15-DAY)	Y	OT	S08-USA-01484-01		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Extrasystoles	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Tiazac			C				Not Reported
	Cozaar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2008	6629922	EXPEDITED (15-DAY)	Y	DE, OT	US-PFIZER INC-2008035810			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Intentional Self-Injury; Suicidal Ideation; Vascular Operation	Chantix			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2008	6635133	EXPEDITED (15-DAY)	Y	HO	233423J08USA		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Dehydration; Depression; Nausea; Panic Attack; Retching; Tremor	Rebif	S		Not Reported
	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2008	6642525	EXPEDITED (15-DAY)	Y	HO	S08-GER-01562-01			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertensive Crisis	Escitalopram Oxalate			S	Oral	10 Mg Bid Po		Not Reported
	Sartan (Losartan)			C				Not Reported
	St. John'S Wort "Herron" (Hypericum Perforatum)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2008	6642530	EXPEDITED (15-DAY)	Y	OT	S08-SAF-01302-01		41 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dysgeusia; Hypertension; Weight Increased	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2008	6642531	EXPEDITED (15-DAY)	Y	HO, LT	S08-NOR-01521-01		87 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Blood Sodium Decreased; Fall; Hyponatraemia; Loss Of Consciousness	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Selozok			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2008	6643415	EXPEDITED (15-DAY)	Y	LT	S08-NLD-01250		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Oxazepam			S	Oral	10 Mg Qd Po		Not Reported
	Levothyroxine			S	Oral	0.025 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2008	6639822	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Dispensing Error; Medication Error	Lexapro			S		Tablet		Not Reported
	Lipitor			S		Tablet		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2008	6643503	DIRECT	Y	DS, HO			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Lexapro			S		Prior To Admission		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2008	6539805	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20080105813		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Invega			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2008	6702971	NON-EXPEDITED	N	DE	T200701010		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Methadose			S				Not Reported
	Zoloft			S				Not Reported

	Lexapro			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2008	6646248	DIRECT	Y	RI			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Lexapro			S	Oral	One Daily Po	18 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2008	6704367	NON-EXPEDITED	Y	DE	544089		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Naproxen			S	Oral	Oral		Not Reported
	Quetiapine Fumarate			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported
	Acetaminophen, Butalbital And Caffeine			S	Oral	Oral		Not Reported
	Aspirin (Aspirin)			S	Oral	Oral		Not Reported
	Acetaminophen (Paracetamol)			S	Oral	Oral		Not Reported
	Ibuprofen (Ibuprofen)			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Caffeine Citrate			S	Oral	Oral		Not Reported
	Fexofenadine Hcl			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2008	6648695	DIRECT	N	RI				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Constipation; Food Craving; Gait Disturbance; Migraine; Pain In	Lexapro			S		20 Mg		Not Reported

Extremity; Sleep Disorder; Tendon Pain; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2008	6649025	EXPEDITED (15-DAY)	Y	HO	S08-FRA-01681-01		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypertonia; Parkinson'S Disease	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Valium			C				Not Reported
	Athymil (Mianserin Hydrochloride)			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2008	6649026	EXPEDITED (15-DAY)	Y	HO	S08-FRA-01680-01		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Cholangitis Sclerosing; Hepatic Steatosis; Hepatitis; Hepatitis A	Escitalopram Oxalate			S				Not Reported
	Lexomil (Bromazepam)			S	Oral	0.5 Qd Po		Not Reported
	Lexomil (Bromazepam)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2008	6649672	EXPEDITED (15-DAY)	Y	HO	S08-FRA-01660-01		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Pneumonia Aspiration; Septic Shock; Serotonin Syndrome	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Levomepromazine			S				Not Reported
	Levomepromazine			S				Not Reported
	Meprobamate			S				Not Reported
	Meprobamate			S				Not Reported
	Imovane (Zopiclone)			S				Not Reported
	Imovane (Zopiclone)			S				Not Reported

Oxazepam	S		Not Reported
Oxazepam	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2008	6631783	EXPEDITED (15-DAY)	Y	HO, OT	FR-PFIZER INC-2008037040		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension;	Xanax			S				Not Reported
Abdominal Pain; Agitation;	Atarax			S				Not Reported
Anxiety; Hypertonia;	Subutex			S				Not Reported
Hypoglycaemia; Maternal	Escitalopram Oxalate			S				Not Reported
Exposure During	Cyamemazine			S				Not Reported
Pregnancy; Tremor								

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2008	6648579	EXPEDITED (15-DAY)	Y	OT	S08-GER-01644-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Disorder;	Escitalopram Oxalate			S				Not Reported
Leukopenia;	Antiallergics			C				Not Reported
Thrombocytopenia								

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2008	6648929	EXPEDITED (15-DAY)	N	OT	S08-USA-01622-01		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Amnesia; Anger; Feeling Abnormal; Flashback; Headache; Homicide; Imprisonment; Loss Of Consciousness; Tinnitus; Visual Impairment	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2008	6459496	EXPEDITED (15-DAY)	Y	HO, LT, OT	S07-USA-05498-01		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Anxiety; Condition Aggravated; Depression; Homicide; Overdose; Road Traffic Accident; Suicidal Ideation; Suicide Attempt	Lexapro			S				Not Reported
	Lexapro			S	Oral	1 Mg Qd Po		Not Reported
	Xanax			S	Oral	Mg Once Po		Not Reported
	Xanax			S		0.5 Mg Tid		Not Reported
	Xanax			S		0.25 Mg Tid		Not Reported
	Pexeva			S	Oral	Mg Once Po		Not Reported
	Pexeva			S	Oral	20 Mg Qd Po		Not Reported
	Risperdal			C				Not Reported
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2008	6570228	EXPEDITED (15-DAY)	Y	OT	S08-SWI-00608-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Interaction; Hyperhidrosis; Ill-Defined Disorder; Restlessness; Serotonin Syndrome	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Amitriptyline Hydrochloride			S	Oral	25 Mg Qd Po		Not Reported
	Remeron			S	Oral	15 Mg Qd Po		Not Reported
	Meto Zerok			S	Oral	100 Mg Bid Po		Not Reported
	Lorazepam			S	Oral	1 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2008	6649744	EXPEDITED (15-DAY)	N	OT	S08-USA-01629-01		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sensation In Eye; Anger; Hallucination, Auditory; Headache; Loss	Lexapro			S				Not Reported

Of Consciousness;
Sensory Disturbance;
Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2008	6650278	EXPEDITED (15-DAY)	Y	DE	S08-CAN-01694-01		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Cipralex			S				Not Reported
	Zopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2008	6650286	EXPEDITED (15-DAY)	Y	OT	S08-ITA-01716-01		81 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Tactile; Hallucination, Visual	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Amiodarone			C				Not Reported
	Bisoprolole (Bisoprolol)			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Atorvastatine (Atorvastatin)			C				Not Reported
	Glimepiride			C				Not Reported
	Ramipril			C				Not Reported
	Barnidipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2008	6652618	EXPEDITED (15-DAY)	Y	HO	S08-CAN-01713-01		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Drug Interaction; Insomnia; Mood Swings; Palpitations; Sinusitis; Thinking Abnormal	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Biaxin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2008	6636618	EXPEDITED (15-DAY)	Y	OT	S08-ESP-01491-01		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Weight Increased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Lorazepam			C				Not Reported
	Lexatin (Bromazepam)			C				Not Reported
	Lovastatin			C				Not Reported
	Amitriptyline Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2008	6640540	EXPEDITED (15-DAY)	Y	OT	S08-GER-01529-01		75 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Blood Alkaline Phosphatase Increased; Constipation; Depression; Disease Recurrence; Drug Interaction; Fall; Gait Disturbance; Overdose	Escitalopram Oxalate			S	Oral	30 Mg Qd Po		Not Reported
	Lithium Carbonate			S		225 Qd		Not Reported
	Enalapril Maleate			S		10 Mg Qd		Not Reported
	Esidrix			S		25 Mg Qd		Not Reported
	Venlafaxine Hydrochloride			S		75 Mg Qd		Not Reported
	Venlafaxine Hydrochloride			S		75 Mg Qd		Not Reported
	Rythmonorm (Propafenone Hydrchloride)			C				Not Reported
	Norvasc			C				Not Reported
	Sortis (Atorvastatin)			C				Not Reported
	Restex			C				Not Reported
	Kalinor (Potassium Chloride)			C				Not Reported
	Acimethin (Methionine)			C				Not Reported
	Cebion (Ascorbic Acid)			C				Not Reported
	Pantozol (Pantoprazole Sodium)			C				Not Reported
	Movicol			C				Not Reported
	Marcumar (Phenpropcpumon)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2008	6651540	EXPEDITED (15-DAY)	Y	HO	S08-USA-01721-01		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Electrocardiogram Delta Waves Abnormal; Gait Disturbance; Insomnia; Intentional Self-Injury; Mental Impairment	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2008	7334627	EXPEDITED (15-DAY)	Y	OT	S08-USA-01664-01		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contusion; Fall; Seizure; Somnolence; Unresponsive To Stimuli	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lisinopril And Hydrochlorothiazide			S				Not Reported
	Amiodarone			S				Not Reported
	Isosorbide Dinitrate			S				Not Reported
	Fosamax Plus D			S				Not Reported
	Plavix			C				Not Reported
	Coreg			C				Not Reported
	Zetia (Ezetimibe)			C				Not Reported
	Sular			C				Not Reported
	Furosemide			C				Not Reported
	Aspirin			C				Not Reported
	Warfarin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2008	6636607	EXPEDITED (15-DAY)	Y	HO	ES-JNJFOC-20080407429		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Topamax			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Clorazepate			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported

	Clomethiazole	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2008	6655312	DIRECT	N	HO			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective; Dyspnoea; Feeling Abnormal	Lisinopril			S	Oral	20mg Daily Po	12 DAY	Zenith Goldline
	Lexapro			S	Oral	10mg Daily Po	5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2008	6612684	EXPEDITED (15-DAY)	Y	OT	US-BAYER-200818779NA		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Hallucination; Violence-Related Symptom	Avelox			S	Oral	Total Daily Dose: 400 Mg Unit Dose: 400 Mg	1 DAY	Bayer
	Lexapro			S		Total Daily Dose: 10 Mg	6 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2008	6656404	DIRECT	N	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Fatigue; Loss Of Personal Independence In Daily Activities	Lexapro			S	Oral	20 Mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2008	6705476	NON-EXPEDITED	N		TPA2008A00104		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Somnolence	Rozerem			S	Oral	8 Mg, 1 In 1 D, Per Oral		Not Reported

	Lexapro	S	Ophthalmic	10 Mg, 1 In 1 D, Per Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2008	6611555	EXPEDITED (15-DAY)	Y	DE, HO, OT	GB-WYE-G01372008		64 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Fatigue; Hyperkalaemia; Hyponatraemia; Malaise; Mucosal Inflammation	Torisel			S	Intravenous (not otherwise specified)		78 DAY	Wyeth
	Escitalopram Oxalate			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2008	6650929	EXPEDITED (15-DAY)	Y	OT	S07-UKI-05229-01		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Fluoxetine Hcl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2008	6654557	EXPEDITED (15-DAY)	N	OT	S08-USA-01741-01		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis Coronary Artery; Fatigue	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Gemfibrozil			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Calcium Supplement			C				Not Reported
	"Water Pill"			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2008	6585218	EXPEDITED (15-DAY)	Y	OT	S08-USA-00677-01		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Blood Pressure Decreased; Fatigue; Hyperhidrosis; Panic Attack; Sleep Disorder; Withdrawal Syndrome	Lexapro			S	Oral	10 Mg Qd; Po		Not Reported
	Lexapro			S	Oral	2.5 Mg,Qd.Po		Not Reported
	Lexapro			S	Oral	2.5 Mg,Qd;Po		Not Reported
	Lexapro			S	Oral	5 Mg, Qd; Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd;Po		Not Reported
	Lexapro			S	Oral	30 Mg Qd;Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd;Po		Not Reported
	Benicar Hct (Olmesartan/Hydrochlorothiazide)			C				Not Reported
	Aricept			C				Not Reported
	Meloxicam			C				Not Reported
	Aspirin			C				Not Reported
	Vytorin			C				Not Reported
	Protonix			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2008	6605834	EXPEDITED (15-DAY)	Y	OT	S07-USA-06459-01		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Drug Interaction; Genital Haemorrhage; Headache; Intentional Self-Injury; Rash	Lexapro			S	Oral	5 Mg Qd;Po		Not Reported
	Lexapro			S	Oral	10 Mg Qd;Po		Not Reported
	Norgestimate And Ethinyl Estradiol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2008	6642406	EXPEDITED (15-DAY)	Y	HO	CA-ABBOTT-08P-028-0451028-00		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Drug Interaction; Insomnia;	Biaxin			S	Oral			Not Reported

Mood Swings; Palpitations; Sinusitis; Thinking Abnormal	Cipralex		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2008	6658447	DIRECT	N	HO, RI, OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Dehydration; Diarrhoea; Faeces Discoloured; Gastric Ulcer; Impaired Driving Ability; Impaired Work Ability; Menopause; Polyp; Product Quality Issue; Rib Fracture; Tremor; Vertigo; Weight Decreased	Ultram			S	Oral	50 Mg. 8 Times Daily Po		Not Reported
	Lexapro			S	Oral	10 Mg Of Lexapro 4 Times Daily Po		Not Reported
	Cymbalta			S		30-60 Of Cym		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2008	6658642	EXPEDITED (15-DAY)	Y	OT	S08-GER-01834-01		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Sopor; Suicide Attempt	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Alcohol			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Prothipendyl Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2008	6659566	EXPEDITED (15-DAY)	Y	DE	S08-JPN-01849-01		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Depression; Drug Ineffective; Illness Anxiety Disorder; Malaise; Mini Mental Status Examination	Escitalopram Oxalate			S	Oral	10 Mg Qd, Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Qd; Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd;Po		Not Reported

Abnormal; Obesity; Oral Disorder; Ventricular Extrasystoles; Weight Decreased	Mohrus Tape (Ketoprofen)	C	Not Reported
	Ms Onshippo (Methyl Salicylat Comphor Capsicum Extract)	C	Not Reported
	Etizolam	C	Not Reported
	Sennaride (Sennoside A+B)	C	Not Reported
	Magnesium Oxide	C	Not Reported
	Paruleon (Triazolam)	C	Not Reported
	Keflex	C	Not Reported
	Baramycin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2008	6661448	DIRECT	N	RI			24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dry Mouth; Ill-Defined Disorder; Impaired Work Ability; Muscle Spasms; Muscle Tightness; Musculoskeletal Pain; Neck Pain; Therapy Non-Responder	Lexapro			S	Oral	20 Mg 1x/Day Po		Not Reported
	Celexa			S	Oral	40 Mg 1x/Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2008	6661804	EXPEDITED (15-DAY)	Y	HO	S08-NOR-01519-01		16 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Serum Ferritin Decreased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2008	6550308	EXPEDITED (15-DAY)	Y	HO, OT	S08-USA-00201-01		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Cough; Full Blood Count Abnormal; Heart Rate	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Amoxicillin			C				Not Reported

Increased; Leukocytosis; Leukopenia; Lymphadenopathy; Neutropenia; Oropharyngeal Pain; Pharyngitis; Platelet Disorder; Poikilocytosis; Pyrexia; Rash; Rash Maculo-Papular; Red Blood Cell Schistocytes Present; Skin Infection; Ulcer; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2008	6551254	EXPEDITED (15-DAY)	Y	HO	S08-GER-00245-01		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Test Positive; Erythema; Hepatic Steatosis; Hepatomegaly; Joint Effusion; Joint Swelling; Oedema Peripheral; Overdose; Pain In Extremity; Pancreatic Steatosis; Polyarthritis; Protein Urine Present; Pruritus; Rheumatoid Arthritis; Skin Disorder; Upper Respiratory Tract Infection; Urticaria	Escitalopram Oxalate			S	Oral	40 Mg Qd Po		Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2008	6629597	EXPEDITED (15-DAY)	Y	OT	FR-ABBOTT-08P-056-0448858-00		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuritis	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2008	6661376	EXPEDITED (15-DAY)	Y	OT	S08-YUG-01884-01		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Oedema	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2008	6662107	EXPEDITED (15-DAY)	N	OT	CHPA2008US08629		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vaginal Haemorrhage	Excedrin Extra Strength		Y	S	Oral	2 Df, Qd, Oral		Not Reported
	Lexapro			S		1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2008	6663112	EXPEDITED (15-DAY)	Y	CA	S08-USA-01773-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice Neonatal; Maternal Drugs Affecting Foetus; Talipes	Celexa			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2008	6663113	EXPEDITED (15-DAY)	N	OT	S08-USA-01812-01		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Uterine Haemorrhage	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2008	6667093	DIRECT	N	OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Male Orgasmic Disorder	Lexapro			S	Oral	1 Tablet Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2008	6667080	EXPEDITED (15-DAY)	Y	OT	S08-PRT-01905-01		23 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Ventricular Tachycardia	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2008	6655041	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-14196950		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Diabetic Ketoacidosis	Tequin			S	Oral		10 DAY	Bristol Myers Squibb
	Percocet			S				Endo
	Trazodone Hydrochloride			S				Apothecon
	Famvir			S	Oral		7 DAY	Not Reported
	Biaxin			S				Not Reported
	Accupril			S				Not Reported
	Lexapro			S				Not Reported
	Prandin			S				Not Reported
	Avandia			S				Glaxosmithkline
	Prilosec			S				Not Reported
	Oxycontin			S				Endo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2008	6668382	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01883-01		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Levothyroxine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2008	6668384	EXPEDITED (15-DAY)	Y	DE	S08-SWI-01801-01		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Dalmadorm (Flurazepam)			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2008	6669825	EXPEDITED (15-DAY)	Y	HO	DSA_31876_2008		43 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Suicide Attempt; Tachycardia	Tavor (Lorazepam)			S	Oral	Not The Prescribed Amount, Oral		Not Reported
	Cipralex			S	Oral	400 Mg 1x , Not The Prescribed Amount, Oral		Not Reported
	Haldol			S	Oral	Not The Prescribed Amount, Oral		Not Reported
	Mellaril			S	Oral	Not The Prescribed Amount, Oral		Not Reported
	Flurazepam Hydrochloride			S	Oral	Not The Prescribed Amount, Oral		Not Reported
	Zopiclone			S	Oral	Not The Prescribed Amount, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2008	6670730	DIRECT	Y	HO			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Palpitations; Skin Burning Sensation	Lexapro			S	Oral	10 Mg Daily Po		Forest
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2008	6656187	EXPEDITED (15-DAY)	Y	OT	HN-ABBOTT-08P-074-0453051-00		15 YR	Female	HND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Lymphocytic Leukaemia	Sibutramine			S	Oral			Not Reported
	Lexapro			S	Oral		15 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2008	6541833	EXPEDITED (15-DAY)	Y	HO, OT	US-PFIZER INC-2008007755		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Anxiety; Depression; Intentional Overdose; Road Traffic Accident; Suicidal Ideation; Suicide Attempt	Xanax			S	Oral			Not Reported
	Xanax			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Effexor			S				Not Reported
	Paroxetine Hydrochloride			S	Oral			Not Reported
	Paroxetine Hydrochloride			S				Not Reported
	Risperdal			C		Daily Dose:9mg		Not Reported
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2008	6636357	EXPEDITED (15-DAY)	Y	OT	S08-USA-01444-01		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Hallucination; Thinking Abnormal	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Avelox			S		400 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2008	6642526	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01559-01		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuritis	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2008	6670341	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01957-01		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram Oxalate			S	Oral	10 Mg Qd;Po		Not Reported
	Zolpidem			S	Oral	10 Mg Qd;Po		Not Reported
	Motilium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2008	6670386	EXPEDITED (15-DAY)	Y	HO	S08-FRA-01956-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Tranxene T-Tab			C				Not Reported
	Levothyroxine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2008	6670405	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01268-01		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Acepromet azine\Meprobamate			C				Not Reported
	Propranolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2008	6573327	EXPEDITED (15-DAY)	Y	HO	S08-USA-00477-01		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Aggression; Agitation; Bipolar Disorder; Depression; Intermittent Explosive Disorder; Irritability; Overdose; Personality Disorder; Refusal Of Treatment By Patient; Screaming; Social Avoidant Behaviour; Thinking Abnormal	Lexapro	S	Oral	30 Mg Qd Po		Not Reported
	Lexapro	S	Oral	40 Mg Qd Po		Not Reported
	Lexapro	S	Oral	20 Mg Qd Po		Not Reported
	Lexapro	S	Oral	5 Mg Qd Po		Not Reported
	Lexapro	S	Oral	10 Mg Qd Po		Not Reported
	Lexapro	S	Oral	20 Mg Qd Po		Not Reported
	Adderall (Amphetamine Ex Release)	C				Not Reported
	Birth Control (Nos)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2008	6657998	EXPEDITED (15-DAY)	N	HO	B0522808A		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemoglobin Decreased; Hernial Eventration; Subcutaneous Haematoma; Subileus; Thrombosis	Arixtra			S	Subcutaneous	2.5mg Per Day	19 DAY	Glaxosmithkline
	Aspirin			S	Oral	75mg Per Day		Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Propylthiouracil			C	Oral			Not Reported
	Inexium			C	Oral			Not Reported
	Alprazolam			C	Oral			Not Reported
	Triflucan			C	Oral			Not Reported
	Aldalix			C	Unknown			Not Reported
	Cozaar			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2008	6672555	EXPEDITED (15-DAY)	Y	HO	S08-FRA-01958-01		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Pressure Systolic Increased; Fall; Iatrogenic Injury; Loss Of Consciousness; Malaise;	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Lisinopril			C				Not Reported

Pallor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2008	6672563	EXPEDITED (15-DAY)	Y	OT	S08-HND-01978-01		15 YR	Female	HND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Lymphocytic Leukaemia	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Sibutramine Hydrochloride			S	Oral	15 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2008	6672588	EXPEDITED (15-DAY)	Y	DE	S08-SWI-01994-01		43 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Cardiac Arrest; Cyanosis; Overdose; Pulse Absent; Respiratory Arrest; Unresponsive To Stimuli	Cipralex			S	Oral	30 Mg Qd Po		Not Reported
	Seroquel			S	Oral	400 Mg Qd Po		Not Reported
	Chloral Hydrate			S	Oral	500 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2008	6644616	EXPEDITED (15-DAY)	Y	HO	S08-ESP-01594-01		50 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Neoplasm; Cerebral Haemorrhage	Cipralex			S	Oral	3.3 Mg Qd Po		Not Reported
	Cipralex			S	Oral	7 Mg Qd Po		Not Reported
	Bisoprolol			C				Not Reported
	Enalapril Maleate			C				Not Reported
	Sutril (Torasemide)			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2008	6650648	EXPEDITED (15-DAY)	N	OT	NO-WYE-G01584008			Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Dizziness; Drug Withdrawal Syndrome; Erectile Dysfunction; Fatigue; Feeling Abnormal; Suicide Attempt; Unevaluable Event	Effexor	S	Oral	Dose Unknown	Wyeth
	Cipralex	S	Oral	Dose Unknown	Lundbeck
	Levomepromazine	S	Oral	Dose Unknown	Aventis
	Zoloft	S	Oral	Daily Dose 150 Mg	Pfizer
	Anafranil	S	Oral	Dose Unknown	Novartis
	Buprenorphine Hydrochloride	C	Oral	Dose Unknown	Unknown
	Carisoprodol	C	Oral	Dose Unknown	Not Reported
	Codeine Phosphate	C			Not Reported
	Surmontil	C	Oral	Dose Unknown	Not Reported
	Paroxetine Hydrochloride	C	Oral	Dose Unknown	Unknown
	Citalopram Hydrobromide	C	Oral	Dose Unknown	Not Reported
	Akineton	C	Oral	Dose Unknown	Knoll
	Remeron	C	Oral	Dose Unknown	Not Reported
	Caffeine\Carisoprodol	C	Oral	Dose Unknown	Not Reported
	Zantac	C	Oral	Dose Unknown	Not Reported
	Esucos	C	Oral	Dose Unknown	Not Reported
	Zolpidem Tartrate	C	Oral	Dose Unknown	Not Reported
	Zopiclone	C	Oral	Dose Unknown	Not Reported
	Ventolin	C	Respiratory (inhalation)	Dose Unknown	Not Reported
	Valproate Sodium	C	Oral	Dose Unknown	Unknown
	Mianserin Hydrochloride	C	Oral	Dose Unknown	Not Reported
	Chlorprothixene Hydrochloride	C	Oral	Dose Unknown	Not Reported
	Oxazepam	C	Oral	Dose Unknown	Fresenius Kabi
	Zyprexa	C	Oral	Dose Unknown	Not Reported
	Diazepam	C	Oral	Dose Unknown	Not Reported
	Morphine	C			Unknown
	Vallergan	C	Oral	Dose Unknown	Not Reported
	Tramadol Hydrochloride	C	Oral	Dose Unknown	Not Reported
	Rivotril	C	Oral	Dose Unknown	Roche

Alprazolam	C	Oral	Dose Unknown		Not Reported
Lithium Citrate	C	Oral	Dose Unknown		Not Reported
Heroin	C				Unknown
Cannabis	C				Unknown
Amfetamine	C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2008	6673170	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01976-01		75 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2008	6673595	EXPEDITED (15-DAY)		OT	S08-FRA-01975-01		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2008	6655076	EXPEDITED (15-DAY)	Y	HO	FR-ELI_LILLY_AND_COMPANY-FR200805004210		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Fall; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; International Normalised Ratio Increased	Prozac			S	Oral	20 Mg, Daily (1/D)	8 DAY	Eli Lilly And Co
	Eupantol			C	Oral			Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Daily (1/D)	6 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2008	6673848	EXPEDITED (15-DAY)	Y	OT	S08-FRA-02008-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rectal Haemorrhage	Escitalopram Oxalate	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2008	6674941	EXPEDITED (15-DAY)	N	DE	S08-USA-01926-02		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Myocardial Infarction; Post Procedural Complication; Respiratory Distress; Upper Respiratory Tract Infection; Ventricular Septal Defect	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2008	6519387	EXPEDITED (15-DAY)	Y	DE	S07-USA-06329-01		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bipolar Disorder; Completed Suicide; Grief Reaction; Gun Shot Wound; Melanocytic Naevus; Procedural Pain	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Oxycontin			C				Not Reported
	Percocet (Oxycodoen And Acetaminophen)			C				Not Reported
	Avapro			C				Not Reported
	Protonix			C				Not Reported
	Prempro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2008	6646307	EXPEDITED (15-DAY)	N	OT	S08-USA-01576-02		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Eye Movement Disorder; Fatigue; Large For Dates Baby; Maternal Death Affecting Foetus; Maternal	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Lexapro			S		10 Mg Qd Bf		Not Reported

Exposure During Breast Feeding

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2008	6676168	DIRECT	Y	OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain; Mydriasis; Vision Blurred	Lexapro			S	Oral	10 Mg Qam Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2008	6598362	EXPEDITED (15-DAY)	Y	HO	S08-ITA-00366-01		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Disorder; Gastrointestinal Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2008	6662514	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-13805619		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Parkinsonism	Carbidopa & Levodopa			S	Oral			Bristol Myers Squibb
	Wellbutrin			C				Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2008	6679723	EXPEDITED (15-DAY)	Y	OT	2008SP010986			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Status Epilepticus	Temodar			S				Not Reported
	Bactrim			S				Not Reported
	Lexapro			S				Not Reported

	Keppra				S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2008	6650270	EXPEDITED (15-DAY)	Y	DE, DS, HO, OT	S08-UKI-01696-01		64 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Creatinine Increased; C-Reactive Protein Increased; Fatigue; General Physical Health Deterioration; Hyperkalaemia; Hyponatraemia; Malaise; Mucosal Inflammation; Neoplasm Malignant; Refusal Of Treatment By Patient; Renal Cancer Metastatic	Escitalopram Oxalate			S				Not Reported
	Torisel			S	Intravenous (not otherwise specified)	20 Mg Qd Iv		Not Reported
	Sutent			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2008	6663380	EXPEDITED (15-DAY)	Y	OT	US-JNJFOC-20080600582		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Intentional Self-Injury; Metrorrhagia; Nausea; Rash	Norgestimate And Ethinyl Estradiol			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2008	6680270	DIRECT		OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity;	Lexapro	S		Not Reported
Drug Ineffective; Eczema	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2008	6681193	EXPEDITED (15-DAY)	Y	OT	2008014731		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Interaction; Road Traffic Accident	Benadryl		Y	S				Not Reported
	Lexapro			S	Oral	10 Mg Daily (1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2008	6681238	EXPEDITED (15-DAY)	Y	CA	S08-SWI-02030-02			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Drugs Affecting Foetus; Trisomy 21	Cipralex			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Cipralex			S	Transplacental	5 Mg Qd Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2008	6621018	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2008033686		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Urinary Incontinence	Chantix			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Metoprolol			S				Not Reported
	Percocet			S				Not Reported
	Lovastatin			C				Not Reported
	Omeprazole			C				Not Reported
	Topamax			C				Not Reported
	Nifedipine			C				Not Reported
	Niacin			C				Not Reported
	Hydrocodone			C				Not Reported
	Naproxen			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2008	6686578	EXPEDITED (15-DAY)	Y	HO, OT	S08-FRA-01240-01		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia; Speech Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Imovane (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2008	6555740	EXPEDITED (15-DAY)	Y	OT	S08-CAN-00290-01		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Frequent Bowel Movements	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2008	6674610	EXPEDITED (15-DAY)	Y	DS	S08-USA-01938-01		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Chest Pain; Overdose; Pain; Paralysis; Suicide Attempt	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Xanax			C				Not Reported
	Adderall			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2008	6686445	EXPEDITED (15-DAY)	Y	HO	S08-NOR-02080-01		28 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2008	6686449	EXPEDITED (15-DAY)	Y	OT	S08-FRA-02068-01		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Inflammation; Urticaria	Escitalopram Oxalate			S				Not Reported
	Alprazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2008	6648367	EXPEDITED (15-DAY)	Y	OT	S08-USA-01581-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Potassium Decreased; Gallbladder Disorder; Hepatitis Acute; Neutrophil Count Increased; Protein Total Decreased; Pruritus; Pruritus Generalised; Pyrexia; White Blood Cell Count Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Clonazepam			S		0.5 Mg Prn		Not Reported
	Protonix			S		40 Mg Qd		Not Reported
	Labetalol			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2008	6650274	EXPEDITED (15-DAY)	Y	HO	S08-ESP-01708-01		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			S	Oral	100 Mg Qd Po		Not Reported
	Topamax			S	Oral	100 Mg Qd Po		Not Reported
	Clorazepate Dipotassium			S	Oral	10 Mg Qd Po		Not Reported
	Lexatin (Bromazepam)			S	Oral	3 Mg Qd Po		Not Reported
	Clomethiazole Edisylate			S	Oral	3 Mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2008	6687461	EXPEDITED (15-DAY)	Y	HO	S08-FRA-02070-01		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemoglobin Decreased; Prothrombin Level Decreased; Subcutaneous Haematoma	Escitalopram Oxalate			S				Not Reported
	Arixtra			S	Subcutaneous	2.5 Mg Qd Sc		Not Reported
	Arixtra			S	Subcutaneous	2.5 Mg Qam Sc		Not Reported
	Kardegic (Acetylsalicylate Lysine)			S	Oral	75 Mg Qd Po		Not Reported
	Propylthiouracile (Propythiouracil)			C				Not Reported
	Inexium (Esomeprazole)			C				Not Reported
	Alprazolam			C				Not Reported
	Fluconazole			C				Not Reported
	Calciparine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2008	6861420	EXPEDITED (15-DAY)	Y	HO	S08-TUN-00276-01		25 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Threatened; Maternal Drugs Affecting Foetus; Pregnancy	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Temestat (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2008	6672427	EXPEDITED (15-DAY)	Y	DE, OT	US-ROCHE-543673		38 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Clonazepam			S	Oral			Roche
	Hydrocodone Bitartrate & Acetaminophen			S	Oral			Not Reported
	Hydrocodone Bitartrate & Acetaminophen			S	Oral			Not Reported

	Escitalopram Oxalate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2008	6672437	EXPEDITED (15-DAY)	Y	DE, OT	US-ROCHE-543703		40 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Respiratory Arrest	Clonazepam			S	Unknown	Route: Asp And Or Ing.		Roche
	Quetiapine			S	Unknown	Route: Asp And Or Ing.		Not Reported
	Escitalopram Oxalate			S	Unknown	Route: Asp And Or Ing.		Not Reported
	Unspecified Ingredient			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2008	6672454	EXPEDITED (15-DAY)	Y	DE, OT	US-ROCHE-543952		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Clonazepam			S	Unknown	Route Reported As Oral (Ingst) And/Or Parenteral (Par).		Roche
	Amitriptyline			S	Unknown	Route Reported As Oral (Ingst) And/Or Parenteral (Par).		Roche
	Methadone Hydrochloride			S	Unknown	Route Reported As Oral (Ingst) And/Or Parenteral (Par).		Not Reported
	Cocaine			S	Unknown	Route Reported As Oral (Ingst) And/Or Parenteral (Par).		Not Reported
	Escitalopram Oxalate			S	Unknown	Route Reported As Oral (Ingst) And/Or Parenteral (Par).		Not Reported
	Chloral Hydrate			S	Unknown	Route Reported As Oral (Ingst) And/Or Parenteral (Par).		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2008	6672471	EXPEDITED (15-DAY)	Y	DE	US-ROCHE-544122		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Clonazepam			S	Oral			Roche
	Acetaminophen			S	Oral			Roche
	Hydrocodone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Cocaine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2008	6672730	NON-EXPEDITED	N		US-BOEHRINGER INGELHEIM GMBH, GERMANY-2008-BP-0859		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Mirapex			S				Boehringer Ingelheim
	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Xanax			C				Not Reported
	Klonopin			C				Not Reported
	Soma			C				Not Reported
	Vistaril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2008	6689141	EXPEDITED (15-DAY)	Y	HO	S08-FRA-02114-01		29 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Escitalopram Oxalate			S				Not Reported
Headache; Injury;	Escitalopram Oxalate			S				Not Reported
Subdural Haematoma	Kidrolase			S				Not Reported
	Kidrolase			S				Not Reported

Kidrolase	S	Not Reported
Kidrolase	S	Not Reported
Kidrolase	S	Not Reported
Cytarabine	S	Not Reported
Cytarabine	S	Not Reported
Purinethol	S	Not Reported
Purinethol	S	Not Reported
Purinethol	S	Not Reported
Vincristine Sulfate	S	Not Reported
Vincristine Sulfate	S	Not Reported
Vincristine Sulfate	S	Not Reported
Vincristine Sulfate	S	Not Reported
Methotrexate	S	Not Reported
Methotrexate	S	Not Reported
Methotrexate	S	Not Reported
Bactrim	C	Not Reported
Valacyclovir Hydrochloride	C	Not Reported
Cyclophosphamide	C	Not Reported
Prednisone	C	Not Reported
Daunorubicine	C	Not Reported
Etoposide	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2008	6688774	EXPEDITED (15-DAY)	Y	HO	S08-USA-01791-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Labour; Caesarean Section; Maternal Exposure During Pregnancy	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S	Oral	2.5 Mg Qd Po		Not Reported
	Tums (Calcium Carbonate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2008	6690428	EXPEDITED (15-DAY)	Y	HO, OT	PERC20080051		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Confusional State; Dehydration; Diabetic	Percocet			S	Oral	1 Tablet Bid, Prn, Per Oral		Not Reported
	Oxycontin			S				Not Reported

Ketoacidosis; Electrocardiogram T Wave Inversion; Hypertension; International Normalised Ratio Decreased; International Normalised Ratio Increased; Pain; Pneumonia	Avandia	S	Oral	Per Oral		Not Reported
	Prandin	S				Not Reported
	Lexapro	S				Not Reported
	Trazodone Hydrochloride	S				Not Reported
	Accupril	S				Not Reported
	Prilosec	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2008	6674947	EXPEDITED (15-DAY)	N	HO	US-KINGPHARMUSA00001-K200800677			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hyponatraemia	Altace			S	Oral	10 Mg, Qd		King
	Escitalopram Oxalate			S	Oral	Unk, Unk		Not Reported
	Aldactone			S	Oral		5 DAY	Not Reported
	Acepromet azine\Meprobamate			C				Not Reported
	Sulpiride			C				Not Reported
	Aldactazine			C				Not Reported
	Flecainide Acetate			C				Not Reported
	Cordarone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2008	6691696	DIRECT	N	LT			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Crying; Depression; Irritability; Suicidal Ideation	Lexapro			S	Oral	10 Mg Tablet Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2008	6647275	EXPEDITED (15-DAY)	Y	OT	S08-ESP-01628-01		63 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anal Incontinence	Cipralex		S	Oral	15 Mg Qd Po	Not Reported
	Cipralex		S	Oral	7.5 Mg Qd Po	Not Reported
	Unspecified Ingredient		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2008	6693908	DIRECT	N	DE			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Insomnia	Lexapro			S	Oral	10 Mg Qd Po	30 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2008	6692214	DIRECT	N	HO, LT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Major Depression; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	20mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2008	6693846	EXPEDITED (15-DAY)	Y	OT	S08-FRA-02145-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Affective Disorder; Aggression; Agitation; Alopecia; Anxiety; Asthenia; Bulimia Nervosa; Chest Discomfort; Constipation; Crying; Decreased Appetite; Disorientation; Drug Hypersensitivity; Eye Pain; Fatigue; Feeling Cold; Gastrointestinal Disorder; General Physical	Escitalopram Oxalate			S	Oral	5 Mg Qd; Po		Not Reported
	Clonazepam			S				Not Reported
	Acetaminophen\Caffeine			S				Not Reported
	Vastarel			S	Oral	35 Mg Bid; Po		Not Reported

Health Deterioration;
Headache; Hyperhidrosis;
Hypoglycaemia; Influenza
Like Illness; Insomnia;
Musculoskeletal Pain;
Nasal Congestion;
Nausea; Renal Pain;
Respiratory Failure;
Screaming; Skin Reaction;
Sleep Disorder; Tinnitus;
Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2008	6684815	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2008050439		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Depression; Feeling Abnormal; Fungal Infection; Product Administration Error; Suicidal Ideation; Urinary Tract Infection; Vomiting	Chantix			S				Not Reported
	Diflucan			S				Not Reported
	Lexapro			S				Not Reported
	Valium			C				Not Reported
	Colace			C				Not Reported
	Tylenol			C				Not Reported
	Ambien			C				Not Reported
	Hydrocodone			C				Not Reported
	Buprenorphine Hydrochloride\Naloxone Hydrochloride			C				Not Reported
	Asacol			C				Not Reported
	Maxalt			C				Not Reported
	Levonorgestrel And Ethinyl Estradiol			C				Not Reported
	Acyclovir Sodium			C				Not Reported
	Compazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2008	6662500	EXPEDITED (15-DAY)	Y	HO	FR-WYE-H04368308		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Inappropriate Antidiuretic Hormone Secretion	Eupantol		S	Oral	Unknown Dose		Wyeth
	Prozac		S			8 DAY	Not Reported
	Escitalopram Oxalate		S				Lundbeck
	Previscan (Fluindione)		C		Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2008	6687262	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2008052281		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Medication Error	Tikosyn			S				Not Reported
	Cardizem			S				Not Reported
	Methadone Hydrochloride			S				Not Reported
	Methadone Hydrochloride			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Senokot			S				Not Reported
	Senokot			S				Not Reported
	Lidoderm			S				Not Reported
	Lidoderm			S				Not Reported
	Ms Contin			C				Not Reported
	Levothyroxine			C				Not Reported
	Digoxin			C				Not Reported
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2008	6696950	EXPEDITED (15-DAY)	Y	HO	S08-IRL-02180-01		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Intentional Self-Injury; Overdose; Therapeutic Product Effect Decreased	Lexapro			S	Oral	200 Mg Once Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2008	6697709	EXPEDITED (15-DAY)	N	DS	S08-USA-02077-01		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abnormal Dreams; Anxiety; Asthenia; Blister; Breath Odour; Diarrhoea; Dizziness; Dry Mouth; Dysgeusia; Dyspepsia; Dysphonia; Energy Increased; Epistaxis; Fatigue; Feeling Hot; Gastroenteritis Salmonella; Hallucination, Visual; Headache; Hyperhidrosis; Hyperphagia; Hyporeflexia; Impaired Work Ability; Increased Appetite; Influenza; Middle Insomnia; Nausea; Nervousness; Oropharyngeal Pain; Serotonin Syndrome; Tremor; Vertigo; Yawning	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2008	6697798	EXPEDITED (15-DAY)	Y	HO	S08-FRA-02138-01		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Atrial Fibrillation; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Hyponatraemia; Mitral Valve Incompetence; Nausea; Palpitations; Vomiting	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Aldactone			S	Oral	50 Mg Qd Po		Not Reported
	Aldactone			S	Oral	50 Mg Qd Po		Not Reported
	Ramipril			S	Oral	10 Mg Qd Po		Not Reported
	Flecainide Acetate			S	Oral	100 Mg Qd Po		Not Reported
	Cordarone			S				Not Reported
	Aldactazine			C				Not Reported
	Aceprometazine\Meprobamate			C				Not Reported
	Dogmatil (Sulpiride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2008	6586877	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00781-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Micturition Disorder; Urinary Retention	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2008	6615898	EXPEDITED (15-DAY)	Y	OT	S08-USA-01213-02			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Disorder; Foetal Disorder; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	20 Mg Qd Transplacental		Not Reported
	Lexapro			S	Transplacental	10 Mg Qd Transplacental		Not Reported
	Folic Acid			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2008	6631473	EXPEDITED (15-DAY)	Y	OT	S08-GER-01420-01		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Eclampsia; Maternal Exposure During Pregnancy; Pregnancy; Premature Baby	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2008	6681239	EXPEDITED (15-DAY)	Y	DE	S08-MYS-01959-01		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis; Toxicity To Various Agents	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2008	6689275	EXPEDITED (15-DAY)	N	OT	A0734542A		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Hyperthyroidism; Vision Blurred; Weight Increased	Lamictal			S	Oral	350mg Per Day		Glaxosmithkline
	Lexapro			S	Unknown	5mg Per Day		Not Reported
	Lithium			S	Unknown	2700mg Per Day	143 WEEK	Glaxosmithkline
	Synthroid			C				Glaxosmithkline
	Klonopin			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2008	6699577	EXPEDITED (15-DAY)	Y	HO	S08-GER-02218-01		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia	Cipralex			S	Oral	15 Mg Qd Po		Not Reported
	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cipralex			S	Oral	5 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Seroquel			S	Oral	200 Mg Qd Po		Not Reported
	Seroquel			S				Not Reported
	Ramipril			C				Not Reported
	Tavor (Lorazepam)			C				Not Reported
	Hct Hexal (Hydrochlorothiazide)			C				Not Reported
	L-Thyroxin (Levothyroxine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2008	6699578	EXPEDITED (15-DAY)	Y	OT	S08-GRC-02230-01		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Nervous System Disorder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2008	6699584	EXPEDITED (15-DAY)	Y	HO	S08-FRA-01822-01		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Panic Attack; Suicidal Ideation	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Alprazolam			C				Not Reported
	Bion (Multivitamin Complex)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2008	6699586	EXPEDITED (15-DAY)	Y	OT	S08-FRA-02226-01		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Memory Impairment	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2008	6700113	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00474-01		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2008	6670462	EXPEDITED (15-DAY)	Y	DE, HO	S08-TUR-01850-01		26 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activated Partial Thromboplastin Time Prolonged; Blood Sodium Increased; Coma; International Normalised Ratio Increased; Leukocytosis; Liver Function Test Abnormal;	Cipralex			S	Oral	5 Mg Qd Po		Not Reported

Prothrombin Time Prolonged; Pupillary Reflex Impaired; Respiratory Arrest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2008	6622538	EXPEDITED (15-DAY)	Y	OT	S08-GER-01316-01		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysstasia; Fall; Gait Disturbance; Hydrocephalus	Escitalopram Oxalate			S	Oral	20 Mg Qd Po		Not Reported
	Voltaren			C				Not Reported
	Katadolon (Flupirtine Maleate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2008	6700576	EXPEDITED (15-DAY)	Y	HO	S08-FRA-02256-01		28 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Malaise	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Lithium Carbonate			S	Oral	1000 Mg Qd Po		Not Reported
	Lamictal			C				Not Reported
	Clonazepam			C				Not Reported
	Nozinan (Levomepromazine)			C				Not Reported
	Imovane (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2008	6700579	EXPEDITED (15-DAY)	Y	HO	S08-FRA-02228-01		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ovarian Cyst Ruptured	Escitalopram Oxalate			S				Not Reported
	Lexomil (Bromazepam)			C				Not Reported
	Jasminelle			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2008	6701768	EXPEDITED (15-DAY)	Y	LT	S08-SWI-02243-01		42 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Level Decreased; Electrocardiogram Repolarisation Abnormality; Electrocardiogram St Segment Abnormal; Electrocardiogram T Wave Inversion; Schizoaffective Disorder	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Clozapine			S	Oral	300 Mg Qd Po		Not Reported
	Candesartan Cilexetil			C				Not Reported
	Concor (Bisoprolol Fumarate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2008	6701735	EXPEDITED (15-DAY)	N	OT	S08-USA-02210-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Amnesia; Diarrhoea; Headache; Impaired Work Ability; Mood Swings; Nausea; Nightmare; Paraesthesia; Screaming; Sleep Terror; Withdrawal Syndrome	Lexapro			S				Not Reported
	Lexapro			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2008	6703745	DIRECT	Y	HO			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Transposition Of The Great Vessels	Lexapro			S	Oral	10 Mg Daily Po, During First Trimester		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2008	6704039	EXPEDITED (15-DAY)	Y	OT	S08-FRA-02251-01			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dry Eye	Escitalopram Oxalate		S	Oral	10 Mg Qd Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2008	6704128	EXPEDITED (15-DAY)	Y	HO	S08-ESP-02261-01		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Melaena; Upper Gastrointestinal Haemorrhage	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Aspirin			S	Oral	100 Mg Qd Po		Not Reported
	Sinemet			C				Not Reported
	Rivastigmine Tartrate			C				Not Reported
	Cozaar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2008	6704508	EXPEDITED (15-DAY)	Y	CA	S08-FRA-00093-02			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Foetal Cardiac Disorder; Foetal Distress Syndrome; Foetal Growth Restriction; Foetal Heart Rate Decreased; Maternal Drugs Affecting Foetus; Small For Dates Baby	Escitalopram Oxalate			S	Transplacental	5 Mg Qd, Transplacental		Not Reported
	Lexomil (Bromazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2008	6704513	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00093-01		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pregnancy; Suicidal Ideation	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Qd Po		Not Reported
	Lexomil (Bromazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2008	6704764	DIRECT		DE			< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Congenital Anomaly; Dizziness; Feeling Abnormal; Holoprosencephaly; Maternal Drugs Affecting Foetus; Pregnancy; Vision Blurred	Lexapro			S	Oral	20 Mg Daily Po	9 MTH	Not Reported
	Albuterol			S	Respiratory (inhalation)	2 Puffs Every 4 Hr/As Needed Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2008	6706234	EXPEDITED (15-DAY)	Y	OT	S08-UKI-01419-02			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Maternal Drugs Affecting Foetus	Cipralex			S	Transplacental	20 Mg Qd Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2008	6706344	EXPEDITED (15-DAY)	Y	OT	S08-ESP-02260-01		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Hypertension	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2008	6706453	EXPEDITED (15-DAY)	Y	DS	S08-UKI-02311-01		67 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Antisocial Behaviour; Diarrhoea;	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Cipralex			S	Oral	10 Mg Qd Po		Not Reported

Drug Interaction; Eye Disorder; Mania; Mood Swings; Nervous System Disorder	Cipralex		S	Oral	10 Mg Qd Po	Not Reported
	Mirtazapine		S	Oral	30 Mg Qd Po	Not Reported
	Flucloxacillin		C			Not Reported
	Amias (Candesartan Cilexetil)		C			Not Reported
	Carbocisteine		C			Not Reported
	Doxycycline		C			Not Reported
	Lansoprazole		C			Not Reported
	Bendrofluazide		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2008	6306981	EXPEDITED (15-DAY)	Y	OT	S07-USA-01512-01		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Increased; Depression; Drug Ineffective; Ejaculation Failure; Optic Ischaemic Neuropathy; Papilloedema; Somnolence; Visual Impairment; Weight Increased	Lexapro			S	Oral	10 Mg Qd Po		Not Reported
	Lexapro			S	Oral	20 Mg Qd Po		Not Reported
	Lexapro			S	Oral	5 Mg Qd Po		Not Reported
	Ambien			C				Not Reported
	Cymbalta			C				Not Reported
	Clonazepam			C				Not Reported
	Hyzaar (Losartan/Hydrochlorothiazide)			C				Not Reported
	Aspirin			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2008	6654536	EXPEDITED (15-DAY)	Y	OT	S08-SAF-01777-01		16 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Confusional State; Disorientation; Feeling Abnormal; Panic Attack; Repetitive Speech; Restlessness; Tooth Impacted; Weight Increased	Cipralex			S	Oral	10 Mg Qd Po		Not Reported
	Livox (Fluovaxamine Maleate)			C				Not Reported
	Dormicum (Nitrazepam)			C				Not Reported
	Propafol			C				Not Reported
	Sufentanil Citrate			C				Not Reported
	Esmaron (Trichlormethiazide)			C				Not Reported
	Toradol			C				Not Reported
	Dexamethasone			C				Not Reported

Augmentin	C		Not Reported
Neostigmine	C		Not Reported
Atropine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2008	6674451	EXPEDITED (15-DAY)	Y	OT	S08-CAN-02031-01			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis; Weight Increased	Cipralex			S	Oral	15 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2008	6696897	EXPEDITED (15-DAY)	Y	OT	ES-ASTRAZENECA-2008AC01732		53 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Dyskinesia	Seroquel			S	Oral			Zeneca
	Lithium Carbonate			C	Oral			Not Reported
	Seroquel			S	Oral		1 MTH	Zeneca
	Seroquel			S				Zeneca
	Lorazepam			S	Oral	0.1 % 30 Ml Solution		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Tiapride			S	Oral		0 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2008	6697280	EXPEDITED (15-DAY)	Y	DE, OT	US-ROCHE-544089		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Naproxen			S	Oral	Route Reported As Ingestion.		Roche
	Quetiapine			S	Oral	Route Reported As Ingestion.		Not Reported
	Unspecified Ingredient			S	Oral	Route Reported As Ingestion. Drug Reported		Not Reported

				As Angiotensin Receptor Blocker.	
	Butalbital\Caffeine	S	Oral	Route Reported As Ingestion.	Not Reported
	Aspirin	S	Oral	Route Reported As Ingestion.	Not Reported
	Acetaminophen	S	Oral	Route Reported As Ingestion.	Roche
	Ibuprofen	S	Oral	Route Reported As Ingestion.	Roche
	Escitalopram Oxalate	S	Oral	Route Reported As Ingestion.	Not Reported
	Caffeine	S	Oral	Route Reported As Ingestion.	Roche
	Fexofenadine	S	Oral	Route Reported As Ingestion.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2008	6707921	EXPEDITED (15-DAY)	Y	OT	S08-FRA-02312-01		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Inappropriate Affect; Speech Disorder	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Zopiclone			C				Not Reported
	Trophicreme (Estriol)			C				Not Reported
	Cyproterone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2008	6707932	EXPEDITED (15-DAY)	Y	OT	S08-ESP-02318-01		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Oral Candidiasis; Poor Dental Condition	Cipralex			S	Oral	20 Mg Qd Po		Not Reported
	Cymbalta			S	Oral	60 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2008	6707969	EXPEDITED (15-DAY)	Y	OT	S08-FRA-02317-01		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Enuresis	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Not Reported
	Levofloxacin			S				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2008	6711141	EXPEDITED (15-DAY)	N	DE	S08-USA-02339-01		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Head Injury	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2008	6698533	EXPEDITED (15-DAY)		HO	US-ABBOTT-08P-163-0460934-00		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Aripiprazole			C		Not Reported		Not Reported
	Methylphenidate Hydrochloride			C		Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2008	6699614	EXPEDITED (15-DAY)	Y	HO	DE-ASTRAZENECA-2008PK01539		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Generalised	Quetiapine Fumarate			S	Oral		7 DAY	Not Reported
	Cipralex			S			7 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2008	6712428	DIRECT	Y	HO			24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Hallucination, Visual; Myocardial Necrosis Marker Increased	Escitalopram Oxalate			S		See Above		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2008	6712915	DIRECT	Y				24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Erectile Dysfunction; Sexual Dysfunction	Sertraline			S	Oral	100mg Daily Po		Watson
	Escitalopram Oxalate			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2008	6692919	EXPEDITED (15-DAY)	Y	HO	FR-AMGEN-US291390		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depressed Mood; Diarrhoea; Headache; Hepatitis Acute; Hyperhidrosis; Neuropathy Peripheral; Pyrexia; Shock; Skin Burning Sensation; Tremor; Vomiting	Enbrel			S	Subcutaneous			Not Reported
	Rifadine			S	Unknown	Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	1.5 Tablet Total Daily		Not Reported
	Rimifon			S	Unknown	Unknown		Not Reported
	Pyrazinamide			S	Unknown			Not Reported
	Xanax			C	Unknown	2 Mg Total Daily		Not Reported
	Cortancyl			C	Unknown	7 Mg Total Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2008	6699570	EXPEDITED (15-DAY)	Y	HO	S08-GER-02208-01		67 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Remergil			C				Not Reported
	Metoprolol			C				Not Reported
	Aspirin			C				Not Reported
	Delix			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2008	6714041	EXPEDITED (15-DAY)	Y	DS	1000000013		60 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness	Escitalopram Oxalate			S	Oral	20 Mg, Oral		Not Reported
	Metformin (500 Milligram)			C				Not Reported
	Adizem-Xl (300 Milligram)			C				Not Reported
	Coaprovel			C				Not Reported
	Lipitor (10 Milligram)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2008	6717475	EXPEDITED (15-DAY)	Y	OT	1000000018			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Extrapyramidal Disorder; Fatigue; General Physical Health Deterioration; Parkinsonian Gait; Psychomotor Retardation	Escitalopram Oxalate			S	Oral	5 Mg, (5 Mg, 1 In 1 D), Oral		Not Reported
	Exelon			C				Not Reported
	L-Dopa			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Rivotril			C				Not Reported
	Oxazepam			C				Not Reported
	Haloperidol			C				Not Reported
	Motilium			C				Not Reported
	Comtan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2008	8702247	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-08P-163-0462145-00		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Dizziness; Drug Interaction; Feeling Abnormal; Limb Injury; Localised Infection; Loss Of Consciousness; Pain In Extremity; Tremor; Withdrawal Syndrome	Humira			S	Other			Not Reported
	Vicodin			S	Oral	5/500, 3 In 1 D, As Required		Not Reported
	Lexapro			S	Oral			Not Reported
	Chlormezanone			S				Not Reported
	Amitriptyline			S	Oral	75mg Qhs		Not Reported
	Rizatriptan Benzoate			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Cyclobenzaprine Hydrochloride			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Minocycline\Minocycline Hydrochloride			S	Oral			Not Reported
	Clindamycin			S	Oral		7 DAY	Not Reported
	Tetanus Toxoid Nos			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2008	6632456	EXPEDITED (15-DAY)	Y	OT	S08-GER-01420-02		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Eclampsia; Maternal Drugs Affecting Foetus; Pre-Eclampsia; Premature Baby; Small For Dates Baby	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental; 10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2008	6654239	EXPEDITED (15-DAY)	Y	DE	S08-USA-01732-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2008	6705192	EXPEDITED (15-DAY)	Y	HO, OT	FR-PFIZER INC-2008057439		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Child Abuse; Delirium;	Champix			S				Not Reported
Depression; Dissociation;	Prazepam			S				Not Reported
Hallucination;	Escitalopram Oxalate			S				Not Reported
Schizophrenia	Triphasil-21			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2008	6718182	EXPEDITED (15-DAY)	Y	OT	SPV1-2008-01455		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Drug Ineffective	Vyvanse			S	Oral	70 Mg, 1x/Day:Qd, Oral		Not Reported
	Lexapro			S	Oral	Mg, 1x/Day:Qd, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2008	6718630	EXPEDITED (15-DAY)	Y	OT	1000000116			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2008	6640571	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01538-01		16 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Dilatation; Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; Oral		
	Xanax			C				Not Reported
	Atarax			C				Not Reported
	Tercian (Drops)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2008	6670463	EXPEDITED (15-DAY)	Y	HO, LT, OT	S08-FRA-01965-01		82 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Condition Aggravated; Decreased Appetite; Depression; Drug Interaction; Gastrointestinal Disorder; General Physical Health Deterioration; Hypochloraemia; Hypokalaemia; Hyponatraemia; Intentional Overdose; Intentional Self-Injury; Loss Of Personal Independence In Daily Activities; Suicide Attempt	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral; 5 Mg (5 Mg, 1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D),Oral; 5 Mg (5 Mg, 1 In 1 D),Oral		
	Fludex (Indapamide)			S	Oral	1.5 Mg (1.5 Mg), Oral		Not Reported
	Flecainide Acetate			S		(100 Mg,1 In 1 Id)		Not Reported
	Uvimag B6			C				Not Reported
	Temerit			C				Not Reported
	Odrik			C				Not Reported
	Pariet			C				Not Reported
	Zestoretic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2008	6689430	EXPEDITED (15-DAY)	Y	OT	PHHY2008DE11459		51 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Intentional Overdose; Suicide Attempt	Estradiol Valerate			S		4 Mg, Unk		Novartis
	Escitalopram Oxalate			S		Unk		Not Reported

	Mirtazapine	S	Unk	Not Reported
	Quetiapine	S	Unk	Not Reported
	Lorazepam	S	Unk	Not Reported
	Metoclopramide	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2008	6717554	EXPEDITED (15-DAY)	Y	DS	1000000126		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In1 D),Oral		Not Reported
	Valium			C				Not Reported
	Subutex			C				Not Reported
	Cannabis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2008	6719830	EXPEDITED (15-DAY)	Y	HO	1000000045		35 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Rivotril			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2008	6671036	EXPEDITED (15-DAY)	Y	HO	S08-USA-01895-01		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Prostatic Hyperplasia; Memory Impairment; Renal Failure; Somnolence	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lisinopril			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Prilosec (Omeprazole) (Omeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2008	6701141	EXPEDITED (15-DAY)	N	OT	A0737779A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Cholesterol Increased; Blood Pressure Increased; Blood Triglycerides Increased; Bruxism; Depression; Dyskinesia; Feeling Abnormal; Hallucination; Headache; Hyperhidrosis; Insomnia; Intentional Overdose; Nightmare; Pain; Performance Status Decreased; Renal Failure; Road Traffic Accident; Sedation; Seizure; Sleep Apnoea Syndrome; Stress; Suicidal Ideation; Suicide Attempt; Tardive Dyskinesia; Thyroid Disorder; Weight Decreased	Wellbutrin			S	Oral			Glaxosmithkline
	Xanax			S	Oral			Not Reported
	Seroquel			S				Not Reported
	Lexapro			S				Not Reported
	Restoril			S				Not Reported
	Cymbalta			S				Not Reported
	Unspecified Ingredient			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2008	6638832	EXPEDITED (15-DAY)	Y	OT	S08-USA-01516-01		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Seizure; Staring	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		

			Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral	
	Nasacort (Nasal Drops (Including Nasal Spray)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2008	6720370	EXPEDITED (15-DAY)	Y	OT	1000000148		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Drug Ineffective	Lexapro			S	Oral	1 In 1 D, Oral		Not Reported
	Vyvanse			S	Oral	70 Mg (70 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2008	6711607	EXPEDITED (15-DAY)	N	HO	US-JNJFOC-20080704816		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Breakthrough Pain; Depression; Exostosis; Sepsis; Somnolence; Wrong Technique In Product Usage Process	Fentanyl Transdermal System			S	Transdermal			Not Reported
	Fentanyl Transdermal System			S	Transdermal			Not Reported
	Buspar			S	Oral			Not Reported
	Geodon			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Effexor Xr			C	Oral	3x 75 Mg		Not Reported
	Caduet			C	Oral			Not Reported
	Premarin			C	Oral			Not Reported
	Nexium			C	Oral			Not Reported
	Reglan			C	Oral			Not Reported
	Norvasc			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2008	6711743	EXPEDITED (15-DAY)	N	HO	US-TEVA-174573USA		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Diabetic Ketoacidosis; Pain; Restless Legs Syndrome	Trazodone			S	Oral			Teva
	Gatifloxacin			S			10 DAY	Not Reported
	Famciclovir			S			7 DAY	Not Reported
	Clarithromycin			S				Not Reported
	Oxycodone Hydrochloride			S				Not Reported
	Tylox			S				Not Reported
	Quinapril Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Repaglinide			S				Not Reported
	Rosiglitazone Maleate			S				Not Reported
	Omeprazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2008	6720220	EXPEDITED (15-DAY)	Y	HO	1000000229		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diabetes Mellitus Inadequate Control; Drug Interaction; Haemolysis; Hyponatraemia; Malaise; Platelet Count Increased; White Blood Cell Count Increased	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Hydrochlorothiazide\Irbesartan			S	Oral	300 Mg (300 Mg,1 In 1 D),Oral		Not Reported
	Pantoprazole			S	Oral	200 Mg (200 Mg,1 In 1 D),Oral		Not Reported
	Glimepiride			S	Oral	4 Mg (4 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram(Escitalopram Oxalate)			C				Not Reported
	Coaprovel			C				Not Reported
	Inipomp			C				Not Reported
	Amaryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2008	6650935	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01714-01		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Pollakiuria	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Tranxene T-Tab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2008	6700474	EXPEDITED (15-DAY)	Y	DE	S08-FRA-02213-01		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniocerebral Injury; Ecchymosis; Meningorrhagia; Periorbital Haematoma	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		
	Aotal (Acamprosate)			C				Not Reported
	Stresam (Etifoxine)			C				Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2008	6712748	EXPEDITED (15-DAY)	Y	HO	CA-PURDUE-GBR_2008_0004252		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval; Overdose	Morphine Sulfate			S	Unknown	30 Mg, Daily		Not Reported
	Escitalopram Oxalate			S	Unknown	10 Mg, Daily		Not Reported
	Zopiclone			S	Unknown	15 Mg, Daily		Not Reported
	Oxycodone Hydrochloride			S	Unknown	Unk, Unk		Not Reported
	Lorazepam			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2008	6722427	EXPEDITED (15-DAY)	Y	OT	1000000187		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2008	6722435	EXPEDITED (15-DAY)	Y	HO	1000000175		55 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Anaemia; Cardiac Failure; Epistaxis; Heart Transplant; Respiratory Distress	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Sintrom			C				Not Reported
	Hemigoxine			C				Not Reported
	Cordarone			C				Not Reported
	Lasix			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2008	6416424	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-13909163		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Androgen Deficiency; Blood Testosterone Decreased; Blood Thyroid Stimulating Hormone Decreased; Cortisol Decreased; Dyspnoea Exertional; Erythema; Fatigue; Hyperhidrosis; Nocturia; Somnolence	Paclitaxel			S				Bristol Myers Squibb
	Carboplatin			S				Bristol Myers Squibb
	Megestrol Acetate			S				Bristol Myers Squibb
	Oxycodone Hydrochloride			S				Endo
	Fludrocortisone Acetate			S				King
	Capecitabine			S				Not Reported
	Enoxaparin Sodium			S				Not Reported
	Radiation Therapy			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Levothyroxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2008	6461615	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-13971080		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency;	Megestrol Acetate			S				Bristol Myers Squibb
Androgen Deficiency;	Oxycodone Hydrochloride			S				Endo
Dyspnoea Exertional;	Fludrocortisone Acetate			S				King
Erythema; Hyperhidrosis;	Escitalopram Oxalate			S				Not Reported
Nocturia; Somnolence	Levothyroxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2008	6722509	DIRECT	N	OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Bronchospasm; Constipation; Diarrhoea; Drug Withdrawal Syndrome; Dyspnoea; Laryngospasm; Muscle Spasms; Tongue Spasm; Wheezing	Lexapro			S	Oral	5mg Daily Po	2 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2008	6724362	EXPEDITED (15-DAY)	N	CA	1000000296		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anomalous Pulmonary Venous Connection; Atrial Septal Defect; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2008	6724398	EXPEDITED (15-DAY)	N	CA	1000000264		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia; Fallot'S Tetralogy; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2008	6724403	EXPEDITED (15-DAY)	N	CA	1000000291		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital; Maternal Drugs Affecting Foetus; Persistent Foetal Circulation	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2008	6724409	EXPEDITED (15-DAY)	N	CA	1000000295		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2008	6724414	EXPEDITED (15-DAY)	N	CA	1000000293		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2008	6724448	EXPEDITED (15-DAY)	N	CA	1000000290		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maternal Drugs Affecting Foetus; Persistent Foetal Circulation	Lexapro		S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2008	6724688	EXPEDITED (15-DAY)	N	CA	1000000294		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Tricuspid Valve Atresia; Maternal Drugs Affecting Foetus; Transposition Of The Great Vessels	Lexapro			S		Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2008	6724692	EXPEDITED (15-DAY)	N	CA	1000000292		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Dextrocardia; Double Outlet Right Ventricle; Maternal Drugs Affecting Foetus; Pulmonary Artery Stenosis Congenital; Ventricular Septal Defect	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6716245	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-13819560			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Fluctuating	Coumadin Lexapro			S S				Bristol Myers Squibb Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6726645	EXPEDITED (15-DAY)	Y	OT	1000000287		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysgeusia; Urticaria; Vaginal Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6726646	EXPEDITED (15-DAY)	Y	HO	1000000288		70 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Seizure	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6727512	EXPEDITED (15-DAY)	N	CA	1000000297		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6727517	EXPEDITED (15-DAY)	N	CA	1000000299		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Maternal Drugs Affecting Foetus; Pulmonary Artery Atresia	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6727524	EXPEDITED (15-DAY)	N	OT	1000000279			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During	Lexapro			S				Not Reported

Pregnancy; Pregnancy; Premature Labour

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6727528	EXPEDITED (15-DAY)	N	CA, OT	1000000300		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Persistent Foetal Circulation; Premature Baby; Respiratory Disorder; Respiratory Distress	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6727530	EXPEDITED (15-DAY)	N	CA	1000000301		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anomalous Pulmonary Venous Connection; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6727541	EXPEDITED (15-DAY)	N	CA, OT	1000000302		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Double Outlet Right Ventricle; Hypoplastic Left Heart Syndrome; Maternal Drugs Affecting Foetus; Pulmonary Valve Stenosis	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6727555	EXPEDITED (15-DAY)	Y	CA	1000000303		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Maternal Drugs Affecting Foetus; Pulmonary Artery Atresia	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6727578	EXPEDITED (15-DAY)	Y	CA	1000000304		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Maternal Drugs Affecting Foetus; Multiple Congenital Abnormalities	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6727594	EXPEDITED (15-DAY)	N	CA, DE	1000000305		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoplastic Left Heart Syndrome; Maternal Drugs Affecting Foetus; Persistent Foetal Circulation	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6727597	EXPEDITED (15-DAY)	N	CA	1000000306		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Disorder; Atrial Septal Defect; Maternal	Lexapro			S	Transplacental	Transplacental		Not Reported

Drugs Affecting Foetus;
Pulmonary Valve Stenosis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6727611	EXPEDITED (15-DAY)	N	CA, DE	1000000307		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital; Maternal Drugs Affecting Foetus; Persistent Foetal Circulation	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2008	6729746	EXPEDITED (15-DAY)	N	CA	1000000298		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2008	6724687	DIRECT	N	RI			22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anger; Crying; Drug Withdrawal Syndrome; Fatigue; Headache; Influenza Like Illness; Nonspecific Reaction	Lexapro			S	Oral	20 Mg Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2008	6730324	EXPEDITED (15-DAY)	Y	OT	1000000344		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Mass; Cyst	Lexapro	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Trazodone (75 Milligram)	C				Not Reported
	Concerta (18 Milligram)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2008	6730325	EXPEDITED (15-DAY)	Y	OT	1000000361		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Impaired Driving Ability; Imprisonment	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2008	6592651	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00892-01		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dermatitis Exfoliative; Photosensitivity Reaction	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D); Oral		Not Reported
	Paroxetine			C				Not Reported
	Methotrexate			C				Not Reported
	Soriatane (Acitretin) (Acitretin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2008	6642513	EXPEDITED (15-DAY)	N	HO	S08-USA-01542-01		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Iron Decreased; Haemoglobin Decreased; Miosis; Pallor; Somnolence	Lexapro			S	Oral	5 Mg (5 Mg, Once A Day) Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, Once A Day) Oral		Not Reported

	Lexapro	S	Oral	5 Mg (5 Mg, Once A Day) Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2008	6728934	EXPEDITED (15-DAY)	Y	OT	1000000378		69 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Haemorrhage	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D),		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2008	6720687	EXPEDITED (15-DAY)	Y	DS	GB-TEVA-175222ISR		66 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Diarrhoea; Drug Interaction; Mania; Mood Swings; Social Problem; Visual Impairment	Mirtazapine			S	Oral			Teva
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2008	6727083	DIRECT	N	LT, RI			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Butterfly Rash; Cardiac Disorder; Dizziness; Hyperhidrosis; Influenza Like Illness; Irritable Bowel Syndrome; Muscle Injury; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Palpitations; Temperature Intolerance; Tremor; Wheelchair User	Lexapro			S	Oral	1 Pid Po		Not Reported
	Lexapro			S	Oral	1 Pid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2008	6728925	DIRECT	N	RI			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Feeling Abnormal; Pulmonary Hypertension	Lexapro			S		1 Daily	1 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2008	6728940	DIRECT	N				40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Detoxification; Drug Withdrawal Syndrome; Headache; Ill-Defined Disorder; Insomnia; Nausea	Lexapro			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2008	6732512	EXPEDITED (15-DAY)	Y	OT	1000000373		31 YR	Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Condition Aggravated; Depression; Disorientation; Disturbance In Attention; Feeling Abnormal; Hunger; Irritability; Photosensitivity Reaction; Suicidal Ideation	Escitalopram Oxalate			S	Oral	Oral	4 YR	Not Reported
	Clozepam			C				Not Reported
	Milnacipran			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2008	6721847	NON-EXPEDITED	N		A0715016A		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Middle Insomnia; Restless Legs Syndrome	Paxil			S	Oral			Glaxosmithkline
	Lunesta			S	Oral	1va Per Day		Glaxosmithkline
	Lexapro			S	Oral			Not Reported
	Zetia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2008	6721911	NON-EXPEDITED	N		A0732266A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Panic Attack	Paxil			S	Oral	80mg Unknown		Glaxosmithkline
	Lexapro			S	Oral	20mgd Per Day		Not Reported
	Seroquel			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2008	6734049	EXPEDITED (15-DAY)	Y	OT	S08-FRA-02328-01		24 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Decreased Appetite; Hyperhidrosis; Weight Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2008	6735351	EXPEDITED (15-DAY)	Y	HO, LT	GXKR2008CA07241		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activated Partial Thromboplastin Time Prolonged; Blood Calcium Decreased; Blood Creatine Phosphokinase Increased; Blood	Diazepam			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Zopiclone			S	Oral	Oral		Not Reported
	Morphine			S	Oral	Oral		Not Reported

Creatinine Increased; Blood Pressure Decreased; Coma; Drug Screen Positive; Electrocardiogram Qt Prolonged; Heart Rate Decreased; Hyperkalaemia; Intentional Overdose; International Normalised Ratio Decreased; Nodal Rhythm; Oxygen Saturation Decreased; Suicide Attempt	Lorazepam	S	Oral	Oral	Not Reported
	Oxycodone Hydrochloride	S	Oral	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2008	6737050	EXPEDITED (15-DAY)	Y	OT	S08-FRA-02161-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis; Hypokalaemia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2008	6723435	EXPEDITED (15-DAY)	Y	HO, LT	CA-KINGPHARMUSA00001-K200800876			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Hyperkalaemia; Loss Of Consciousness; Overdose; Sinus Tachycardia	Avinza			S		Unk, Unk		King
	Escitalopram Oxalate			S		Unk, Unk		Not Reported
	Diazepam			S		Unk, Unk		Not Reported
	Zopiclone			S		Unk, Unk		Not Reported
	Lorazepam			S		Unk, Unk		Not Reported
	Acetaminophen W/Oxycodone			S		Unk, Unk		Not Reported
	Citalopram			S		Unk, Unk		Not Reported
	Oxycodone Hcl Controlled-			S		Unk, Unk		Not Reported

	Release Oxycodone Hcl Controlled-Release	S	Unk, Unk		Not Reported
	Altace	C	5 Mg, Qd		King

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2008	6728826	DIRECT	N				18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities; Malaise; Middle Insomnia; Tremor	Lexapro			S	Oral	20 Mg Po		Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2008	6728961	DIRECT	N	OT			13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash Generalised	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2008	6735291	EXPEDITED (15-DAY)	Y	DS	GXKR2008GB07118		66 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Diarrhoea; Drug Interaction; Mania; Mood Swings; Negativism; Social Problem; Visual Impairment	Mirtazapine			S	Oral	30 Mg, Oral		Not Reported
	Cipralex			S	Oral	10 Mg, Oral		Not Reported
					Oral	10 Mg, Oral		
					Oral	10 Mg, Oral		
	Amias (Candesartan Cilexetil)			C				Not Reported
	Bendrofiluazide (Bendroflumethiazide)			C				Not Reported
	Carbocysteine			C				Not Reported
	Doxycycline			C				Not Reported
	Flucloxacillin Sodium			C				Not Reported

		Monohydrate Lansoprazole		C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2008	6737562	EXPEDITED (15-DAY)	Y	DS	107-#03#2008-03897		66 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Diarrhoea; Drug Interaction; Mania; Mood Swings; Social Problem; Visual Impairment	Mirtazapine (Mirtazapine)			S	Oral	30 Mg Oral	1 YR	Not Reported
	Cipralex			S	Oral	10 Mg Oral	11 MTH	Not Reported
	Amias (Candesartan Cilexetil)			C				Not Reported
	Bendrofluazide (Bendrofluazide)			C				Not Reported
	Carbocysteine			C				Not Reported
	Doxycycline			C				Not Reported
	Flucloxacillin Sodium			C				Not Reported
	Monohydrate Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2008	6737976	EXPEDITED (15-DAY)	Y	DS	2008S1013585		66 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Diarrhoea; Drug Interaction; Mania; Mood Swings; Social Problem; Visual Impairment	Mirtazapine (Mirtazapine)			S		30 Mg;		Not Reported
	Cipralex			S	Oral Oral Oral	10 Mg; ; Oral 10 Mg; ; Oral 10 Mg; ; Oral		Not Reported
	Amias			C				Not Reported
	Bendrofluazide			C				Not Reported
	Carbocisteine			C				Not Reported
	Doxycycline			C				Not Reported
	Flucloxacillin			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2008	6738991	EXPEDITED (15-DAY)	Y	DE	1000000430		87 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Scan Abnormal; Cerebral Haemorrhage; Coma; Loss Of Consciousness; Mydriasis	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Kardegic (Acetylsalicylate Lysine)			S	Oral	75 Mg, (75mg, 1 In 1 D), Oral		Not Reported
	Cyamemazine			C				Not Reported
	Prazepam			C				Not Reported
	Zolpidem			C				Not Reported
	Levothyrox			C				Not Reported
	Acebutolol Hydrochloride			C				Not Reported
	Colpotrophine			C				Not Reported
	Diprosone (Cream)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2008	6732604	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Product Quality Issue	Lexapro			S	Oral	10mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2008	6734204	DIRECT	N	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Increased; Memory Impairment	Lexapro			S		1 Tablet Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2008	6738111	EXPEDITED (15-DAY)	Y	OT	2008S1012414			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Condition Aggravated; Dizziness; Drug	Fluoxetine			S				Not Reported
	Paroxetine Hydrochloride			S				Not Reported
	Sertraline			S				Not Reported

Withdrawal Syndrome; Eye Disorder; Headache; Intentional Overdose; Irritability; Migraine; Mood Altered; Nausea; Self-Injurious Ideation; Suicidal Ideation; Tearfulness	Cipralex		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2008	6729557	EXPEDITED (15-DAY)	Y	HO	FR-MERCK-0808FRA00015		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Zocor			S	Oral			Merck
	Escitalopram Oxalate			S	Oral		11 DAY	Not Reported
	Indapamide\Perindopril Erbumine			S	Oral			Not Reported
	Bromazepam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2008	6729581	EXPEDITED (15-DAY)	Y	DE	DSA_32196_2008		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Medication Error; Wrong Product Administered	Cardizem La			S		(Df)		Not Reported
	Tikosyn			S		(Df)		Not Reported
	Methadone Hydrochloride			S		(Df)		Not Reported
	Lexapro			S		(Df)		Not Reported
	Senokot			S		(Df)		Not Reported
	Lidoderm			S		(Df)		Not Reported
	Prilosec			S		(Df)		Not Reported
	Ms Contin			C				Not Reported
	Levothyroxine			C				Not Reported
	Digoxin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2008	6729684	EXPEDITED (15-DAY)	Y	DS, LT	1000000332		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Asthenia; Crying; Decreased Appetite; Fatigue; Insomnia; Loss Of Libido; Performance Status Decreased; Restlessness; Skin Burning Sensation; Suicidal Ideation	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,L In 1 D), Oral		Not Reported
	Alprazolam(0.5 Milligram, Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2008	6745779	EXPEDITED (15-DAY)	Y	OT	100000378		69 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2008	6760719	NON-EXPEDITED	Y		TPA2008A00795		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Nausea; Tremor	Rozerem			S	Oral	Per Oral		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2008	6731085	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2008065734		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Postictal State; Seizure	Lyrica			S	Oral			Not Reported
	Tramadol Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	Daily Dose:10mg-Freq:Every Day		Not Reported
	Nifedipine			C				Not Reported
	Hyzaar			C				Not Reported
	Nitroglycerin			C				Not Reported
	Clopidogrel			C				Not Reported
	Omeprazole			C				Not Reported
	Simvastatin			C				Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2008	6736793	DIRECT	Y	HO			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Magnesium Decreased; Blood Potassium Decreased; Electrocardiogram Qt Prolonged; Palpitations; Ventricular Tachycardia	Risperidone			S	Oral	1mg Qhs Po (Duration: Chronic)		Not Reported
	Lexapro			S	Oral	10mg Daily Po (Duration: Chronic)		Not Reported
	Asa			C				Not Reported
	Hctz			C				Not Reported
	Lisinopril			C				Not Reported
	Actos			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2008	6743897	EXPEDITED (15-DAY)	Y	DS	1000000510		75 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Headache; Memory Impairment; Photophobia; Visual Impairment	Escitalopram Oxalate			S	Oral	5 Mg)5 Mg, 1 In 1 D), Oral		Not Reported
	Plavix			C				Not Reported
	Lexomil			C				Not Reported
	Zopiclone			C				Not Reported

	Ideos	C	Not Reported
	Actonel	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2008	6747833	EXPEDITED (15-DAY)	Y	HO	1000000496		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Gastroenteritis; Headache; Seizure	Lexapro			S				Not Reported
	Pegintron			S	Subcutaneous	120 Mcg Qw (120 Mcg, 1 In 1 Wk),Subcutaneous		Not Reported
	Rebetol			S	Oral	Oral		Not Reported
	Advair Diskus			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Valium			S				Not Reported
	Methadone Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2008	6731673	EXPEDITED (15-DAY)	Y	HO	CA-TYCO HEALTHCARE/MALLIN CKRODT-T200801270			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Abnormal; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Nodal Rhythm; Overdose	Morphine			S		Maximum 9500 Mg Possible Ingestion		Tyco
	Morphine			S		Maximum 2640 Mg Possible Ingestion		Tyco
	Morphine			S		Maximum Of 2640 Mg Ingested		Tyco
	Morphine			S		Maximum 420 Mg Possible Ingestion		Tyco
	Oxycodone			S		10 Mg Extended Release		Tyco
	Oxycodone			S		Unk, Unk		Tyco
	Escitalopram Oxalate			S		Maximum 140 Mg Possible Ingestion		Not Reported
	Escitalopram Oxalate			S		Maximum Of 140 Mg		Not Reported

			Ingested	
Diazepam	S	Maximum 1800 Mg Possible Ingestion		Not Reported
Zopiclone	S	Maximum 187.5 Mg Possible Ingestion		Not Reported
Zopiclone	S	Maximum Of 187.5 Mg Ingested		Not Reported
Lorazepam	S	Maximum 30 Mg Possible Ingestion		Not Reported
Acetaminophen W/Oxycodone	S	Unlikley This Was Ingested		Not Reported
Citalopram	S	Possible That Ingested		Not Reported
Ramipril	C	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2008	6731776	EXPEDITED (15-DAY)		HO	GB-EISAI MEDICAL RESEARCH-A044-002-005675		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Electrocardiogram Qt Prolonged; Syncope; Torsade De Pointes	Omeprazole			S	Oral			Not Reported
	Prochlorperazine			C	Oral			Not Reported
	Ferrous Sulfate			C	Oral			Not Reported
	Aricept			S	Oral		2 YR	Not Reported
	Inderal			S	Oral			Not Reported
	Inderal			S				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2008	6744118	EXPEDITED (15-DAY)	Y	OT	1000000364		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Headache; Hypotension; Loss Of	Escitalopram Oxalate			S	Oral	(5 Mg,Once), Oral		Not Reported

Consciousness; Malaise; Vertigo	Lysanxia (10 Milligram)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2008	6711142	EXPEDITED (15-DAY)	Y	OT	S08-USA-02321-01		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Pyrexia; Seizure	Lexapro			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
	Xanax (0.25 Milligram, Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2008	6732631	EXPEDITED (15-DAY)	N	HO	A0743752A		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervicogenic Headache; Drug Intolerance; Gastroenteritis; Seizure	Advair Diskus			S	Respiratory (inhalation)			Glaxosmithkline
	Peginterferon Alfa-2b			S	Subcutaneous	120mcg Weekly		Not Reported
	Rebetol			S	Oral			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Valium			S	Unknown			Glaxosmithkline
	Methadone Hydrochloride			S	Unknown			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2008	6733173	EXPEDITED (15-DAY)	Y	HO	AU-MERCK-0808AUS00075		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chromaturia; Hepatitis; Jaundice	Zocor			S	Oral			Merck
	Escitalopram Oxalate			S	Unknown		12 DAY	Not Reported
	Influenza Virus Split Virion 3v Vaccine Inactivated			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2008	6746752	EXPEDITED (15-DAY)	Y	HO	1000000540		78 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Hyponatraemia; Weight Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Indapamide\Perindopril			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Bromazepam			S	Oral	3 Mg (3 Mg, 1 In 1 D), Oral		Not Reported
	Zocor			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2008	6746790	EXPEDITED (15-DAY)	Y	HO	1000000512		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Loss Of Consciousness; Seizure; Tongue Biting	Escitalopram Oxalate			S	Oral	10 Mg, (10 Mg, 1 In 1 D), Oral		Not Reported
	Tramadol			S	Oral	300 Mg, (150mg, 2 In 1 D), Oral		Not Reported
	Lyrica			S	Oral	300 Mg, (150 Mg, 2 In 1 D), Oral		Not Reported
	Lyrica			S	Oral	Oral		Not Reported
	Topalgic [Tramadol Hydrochloride]			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2008	6746960	EXPEDITED (15-DAY)	Y	HO	1000000558		78 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),		Not Reported

Craniocerebral Injury; Disturbance In Attention; Fall; Psychomotor Retardation; Restlessness; Subdural Haematoma			Oral	Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
			Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
	Memantine Hydrochloride	S	Oral	5 Mg, 5 Mg, 1 In 1 D), Oral		Not Reported
	Valproic Acid	S	Oral	500 Mg (250 Mg, 2 In 1 D), Oral; 750 Mg (750 Mg, 1 In 1 D), Oral		Not Reported
			Oral	500 Mg (250 Mg, 2 In 1 D), Oral; 750 Mg (750 Mg, 1 In 1 D), Oral		
	Loxapac	S	Oral	25 Gtt (25 Gtt, 1 In 1 D), Oral		Not Reported
	Unspecified Ingredient	S				Not Reported
	Aspegic [Acetylsalicylate Lysine]	S		100 Mg (100 Mg, 1 In 1 D)		Not Reported
	Rivotril (Drops (For Oral Use))	C				Not Reported
	Risperidone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2008	6733935	EXPEDITED (15-DAY)	Y	HO	US-ROCHE-580552		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis; Post Lumbar Puncture Syndrome; Seizure	Diazepam			S	Unknown			Roche
	Peginterferon Alfa-2b			S	Subcutaneous			Not Reported
	Ribavirin			S	Oral			Not Reported
	Advair Diskus			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Methadone Hydrochloride			S	Unknown			Not Reported
	Provigil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2008	6734290	NON-EXPEDITED	N		US-ABBOTT-07P-163-0417170-00		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Fatigue	Synthroid			S				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Zolpidem Tartrate			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2008	6734454	NON-EXPEDITED	N		US-ABBOTT-07P-163-0430162-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Screen Positive; Urine Odour Abnormal	Synthroid			S				Not Reported
	Lexapro			S				Not Reported
	Lamotrigine			S				Not Reported
	Modafinil			S				Not Reported
	Levetiracetam			S				Not Reported
	Aripiprazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2008	6734537	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2008067952			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Mental Disorder; Overdose	Chantix			S				Not Reported
	Lyrica			S				Not Reported
	Amitriptyline Hydrochloride			S				Not Reported
	Lisinopril			S				Not Reported
	Metformin			S				Not Reported
	Isosorbide			S				Not Reported
	Lexapro			S				Not Reported
	Vytorin			S		Text:10/20		Not Reported
	Combivent			S		Text:2 Puffs Three Times A Day		Not Reported
	Synthroid			S				Not Reported
	Cilostazol			S				Not Reported
	Coreg			S				Not Reported
	Plavix			S				Not Reported
	Actos			S				Not Reported

Oxycodone	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2008	6325993	EXPEDITED (15-DAY)	Y	LT	S07-USA-02000-02		2 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Fluctuation; Bradycardia Neonatal; Cyanosis Neonatal; Developmental Delay; Dysphagia; Infantile Apnoea; Ischaemic Stroke; Maternal Drugs Affecting Foetus; Maternal Exposure During Breast Feeding; Movement Disorder; Muscle Tightness; Neonatal Disorder; Neonatal Hypotension; Neonatal Seizure; Poor Sucking Reflex; Umbilical Cord Around Neck	Lexapro			S	Transplacental Transplacental Transplacental	See Image See Image See Image		Not Reported
	Cymbalta			C				Not Reported
	Zoloft (Sertraline Hydrochloride) (Sertraline Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2008	6532285	EXPEDITED (15-DAY)	Y	OT	S08-USA-00038-01		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Interstitial Lung Disease	Lexapro			S	Oral	10 Mg, (10 Mg, 1 In 1 D), Oral		Not Reported
	Metformin Hydrochloride			C				Not Reported
	Glyburide			C				Not Reported
	Atenolol			C				Not Reported
	Diovan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2008	6686446	EXPEDITED (15-DAY)	Y	HO	S08-GER-02071-01		32 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Agitation; Drug Interaction	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Buprenorphine\Naloxone			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Omeprazol (20 Milligram)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2008	6689097	EXPEDITED (15-DAY)	Y	HO	S08-JPN-02087-01		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Apathy; Aspartate Aminotransferase Increased; Blood Albumin Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Chloride Increased; Blood Cholesterol Increased; Blood Creatine Phosphokinase Increased; Blood Creatinine Decreased; Blood Glucose Increased; Blood Lactate Dehydrogenase Increased; Blood Potassium Increased; Blood Sodium Increased; Blood Urea Increased; Blood Uric Acid Increased; Constipation; Decreased Appetite; Drug Ineffective; Dysgeusia; Feeling Guilty; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Haematocrit Increased; Haemoglobin	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Norvasc (Amlodipine Besilate) (Tablets) (Amlodipine Besilate)			C				Not Reported
	Gaster			C				Not Reported
	Digosin (Digoxin) (Tablets) (Digoxin)			C				Not Reported
	Persantin (Dipyridamole) (Tablets) (Dipyridamole)			C				Not Reported
	Magmitt (Magnesium) (Tablets)			C				Not Reported
	Primperan (Metoclopramide) (Tablets) (Metoclopramide)			C				Not Reported
	Rize (Clotiazepam) (Tablets) (Clotiazepam)			C				Not Reported
	Rohypnol (Flunitrazepam) (Tablets) (Flunitrazepam)			C				Not Reported
	Alosenn (Tablets)			C				Not Reported
	Myslee (Zolpidem Tartrate) (Tablets) (Zolpidem Tartrate)			C				Not Reported
	Constan (Alprazolam) (Tablets) (Alprazolam)			C				Not Reported
	Tofranil (Imipramine Hydrochloride) (Tablets) (Imipramine Hydrochloride)			C				Not Reported
	Laxoberon (Sodium Picosulfate) (Tablets) (Sodium Picosulfate)			C				Not Reported
	Magnesium Oxide (Tablets)			C				Not Reported

Increased; Initial Insomnia; Insomnia; Intestinal Obstruction; Irritability; Loss Of Personal Independence In Daily Activities; Malaise; Night Sweats; Panic Reaction; Paralysis; Platelet Count Increased; Protein Total Decreased; Psychomotor Retardation; Red Blood Cell Count Increased; Suicidal Ideation; Weight Decreased; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2008	6741940	DIRECT	N	OT			10 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Appetite; Off Label Use; Weight Increased	Lexapro			S	Oral	30 Milligrams Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2008	6744439	DIRECT	N	DE			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Completed Suicide; Disturbance In Attention; Flight Of Ideas; Obsessive Thoughts; Paranoia; Thinking Abnormal	Effexor			S	Oral	75 Mg Qd Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2008	6749751	EXPEDITED (15-DAY)	N	HO	GXBR2008US01673			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Communication Disorder; Disorientation; Feeling Abnormal; Pancreatitis; Road Traffic Accident; Sedation	Trazodone Hydrochloride			S				Not Reported
	Neurontin			S				Not Reported
	Zoloft			S	Oral	Oral		Not Reported
	Alprazolam (Alprazolam)			S	Oral Oral	2 Mg, Bid, Oral 2 Mg, Bid, Oral		Not Reported
	Seroquel			S	Oral	200 Mg, Qhs; Oral; 25 Mg, Qhs, Oral		Not Reported
	Restoril			S	Oral	22.5 Mg, Qd2sdo, Oral		Not Reported
	Wellbutrin Xl			S	Oral	300 Mg, Qd; Oral; 150 Mg, Qd, Oral		Not Reported
	Lexapro			S	Oral	15 Mg, Qd; Oral		Not Reported
	Cymbalta			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2008	6749772	EXPEDITED (15-DAY)	Y	OT	1000000474		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lyme Disease	Lexapro			S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Aciphex			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2008	6749774	EXPEDITED (15-DAY)	Y	HO	1000000337		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Fall; Inappropriate Antidiuretic Hormone Secretion; Subarachnoid	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D); Oral		Not Reported

Haemorrhage

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2008	6750050	EXPEDITED (15-DAY)	Y	HO	080821-0000629		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Intentional Overdose; Toxicity To Various Agents	Tranxene T-Tab			S	Oral	; Po		Not Reported
	Escitalopram Oxalate			S	Oral	; Po		Not Reported
	Zyprexa			S	Oral	; Po		Not Reported
	Atarax			S	Oral	; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2008	6751403	EXPEDITED (15-DAY)	Y	DE	1000000491		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2008	6744732	DIRECT	N	HO, OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2008	6750826	EXPEDITED (15-DAY)	Y	HO	1000000600		63 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Jaundice; White Blood Cell Count Increased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

	Escitalopram Oxalate	S	Oral	4.8 Mg (4.8 Mg, 1 In 1 D), Oral		Not Reported
	Opipram (Tablets)	C				Not Reported
	Aspirin	C				Not Reported
	Calcium (Chewable Tablets)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2008	6751387	EXPEDITED (15-DAY)	Y	OT	1000000611		56 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Prostatic Hyperplasia; Urinary Retention	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Abilify			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Insulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2008	6739506	EXPEDITED (15-DAY)	Y	DE, HO	FR-ABBOTT-08P-056-0471571-00		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Craniocerebral Injury; Death; Disturbance In Attention; Fall; Psychomotor Retardation; Restlessness; Subdural Haematoma	Depakene			S	Oral			Not Reported
	Depakene			S				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported
	Memantine Hydrochloride			S	Oral			Not Reported
	Loxapine			S	Oral			Not Reported
	Mianserin Hydrochloride			S				Not Reported
	Mianserin Hydrochloride			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Clonazepam			C	Oral			Not Reported
	Risperidone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2008	6746905	DIRECT	N	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disturbance In Attention; Feeling Abnormal; Memory Impairment; Restless Legs Syndrome; Weight Increased	Lexapro			S				Not Reported
	Wellbutrin Xl			C				Not Reported
	Synthroid			C				Not Reported
	Nasonex			C				Not Reported
	Gabapentin			C				Not Reported
	Cyclobenzaprine Hydrochloride			C				Not Reported
	Prednisone			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2008	6753445	EXPEDITED (15-DAY)	Y	DS	1000000619		53 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2008	6440617	EXPEDITED (15-DAY)	Y	HO, OT	L07-UKI-05193-01		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Potentiating Drug Interaction; Sinus Bradycardia; Torsade De Pointes; Ventricular Tachycardia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg), Oral		Not Reported
	Propranolol			S		80 Mg (80 Mg, D)		Not Reported
	Donepezil Hydrochloride			S		10 Mg (10 Mg, D)		Not Reported
	Omeprazole			S		20 Mg (20 Mg)		Not Reported
	Ferrous Sulfate			C				Not Reported
	Prochlorperazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2008	6743879	EXPEDITED (15-DAY)	N	OT	PE-PFIZER INC-2008068349		59 YR	Female	PER

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Back Pain; Hepatic Pain; Jaundice; Renal Pain	Xanax Xr			S		Daily Dose:1mg		Not Reported
	Xanax Xr			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2008	6753518	EXPEDITED (15-DAY)		HO	004036		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism; Mental Status Changes; Overdose	Pletal			S		100 Mg, Bid, Unk		Not Reported
	Lexapro			S		10 Mg, Qam, Unk		Not Reported
	Amitriptyline Hydrochloride			S		25 Mg, Qpm, Unk		Not Reported
	Vytorin			S		1 Df, Bid,Unk		Not Reported
	Combivent			S		2 Puff, Tid, Unk		Not Reported
	Synthroid			S		50 Unk, Qam, Unk		Not Reported
	Chantix			S		Unk,Unk,Unk		Not Reported
	Lisinopril			S		40 Mg, Qam, Unk		Not Reported
	Lyrica			S		100 Mg, Tid, Unk		Not Reported
	Metformin Hydrochloride			S		500 Mg,Qam,Unk		Not Reported
	Metformin Hydrochloride			S		1000mg, Qpm,Unk		Not Reported
	Coreg			S		25 Mg, Bid, Unk		Not Reported
	Isosorbide			S		10 Mg, Daily Dose, Unk		Not Reported
	Plavix			S		75 Mg, Daily Dose, Unk		Not Reported
	Actos			S		30 Mg, Daily Dose, Unk		Not Reported
	Oxycodone Hydrochloride			S		5 Mg, Tid, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2008	6760005	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00138		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breech Presentation; Caesarean Section; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate		S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2008	6747112	DIRECT	N	HO			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Swelling Face	Lexapro			S	Oral	Once A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2008	6756816	EXPEDITED (15-DAY)	Y	HO	1000000707		79 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Confusional State; Dehydration; Diarrhoea; Hyponatraemia; Loss Of Consciousness; Orthostatic Hypotension	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Kardegic (Acetylsalicylate Lysine)			C				Not Reported
	Ebixa			C				Not Reported
	Aricept			C				Not Reported
	Coolmetec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2008	6747222	EXPEDITED (15-DAY)		OT	GB-TEVA-176754ISR		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal	Fluoxetine			S				Teva
	Paroxetine Hydrochloride			S				Not Reported
	Sertraline			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Venlafaxine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2008	6748060	EXPEDITED (15-DAY)	Y	DE, HO	FR-ABBOTT-08P-056-0472756-00		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Disturbance In Attention; Fall; Gait Disturbance; Psychomotor Skills Impaired; Subdural Haematoma	Depakene			S	Oral			Not Reported
	Depakene			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Loxapine			S	Oral			Not Reported
	Mianserin Hydrochloride			S	Oral			Not Reported
	Mianserin Hydrochloride			S	Oral	Dose Increased Nos		Not Reported
	Memantine Hydrochloride			S	Oral			Not Reported
	Clonazepam			C	Oral			Not Reported
	Acetylsalicylic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2008	6752735	DIRECT	N	DE			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2008	6760696	EXPEDITED (15-DAY)	Y	OT	1000000712		38 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Decreased Appetite; Depression; Insomnia; Nausea; Sexual Dysfunction; Suicidal Ideation	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D), Oral; 10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg,1 In 1 D), Oral; 10 Mg (10 Mg,1 In 1 D), Oral		

	Multivitamin Nos	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2008	6761489	DIRECT	N	RI			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blepharospasm; Blood Pressure Increased; Burning Sensation; Chest Pain; Condition Aggravated; Depression; Disturbance In Attention; Dizziness; Dry Skin; Ear Discomfort; Eyelid Disorder; Eyelid Oedema; Feeling Abnormal; Haemangioma; Headache; Memory Impairment; Musculoskeletal Stiffness; Nervousness; Penis Disorder; Skin Fissures; Speech Disorder; Swelling; Testicular Disorder; Vasodilatation	Lexapro			S	Oral	10 Mg Per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2008	6730096	EXPEDITED (15-DAY)	Y	DS, HO, OT	AU-PFIZER INC-2008066955		31 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Hypomania	Champix			S	Oral			Not Reported
	Lexapro			S	Oral	Daily Dose:20mg		Not Reported
	Maxolon			C	Oral			Not Reported
	Mirena			C				Not Reported
	Symbicort			C	Respiratory (inhalation)			Not Reported
	Ventolin			C				Not Reported

	Marijuana	C		Not Reported
	Alcohol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2008	6754825	DIRECT	Y	OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dizziness; Hypoaesthesia; Infection; Insomnia; Metabolic Disorder; Muscle Tightness; Muscle Twitching; Myalgia; Nervous System Disorder; Neuropathy Peripheral; Palpitations; Paraesthesia; Restless Legs Syndrome; Tremor; Weight Decreased	Lexapro			S	Oral	20mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2008	6762570	EXPEDITED (15-DAY)	N	OT	1000000738			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased	Lexapro			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2008	6762830	EXPEDITED (15-DAY)	Y	HO, LT	080827-0000645		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Coma; Incorrect Dose Administered; Leukocytosis; Pneumonia Aspiration; Pneumonia Staphylococcal; Rhonchi;	Tranxene T-Tab			S	Oral	10 Mg; ;Op		Not Reported
	Anafranil			S	Oral	75 Mg; ;Op		Not Reported
	Cyamemazine			S	Oral	25 Mg; ;Op		Not Reported
	Escitalopram Oxalate			S	Oral	;Op		Not Reported

Suicide Attempt; Toxicity
To Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2008	6501351	EXPEDITED (15-DAY)	Y	CA, DE, HO	A0687245A		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cardiac Disorder; Death; Heart Disease Congenital; Maternal Exposure During Pregnancy; Patent Ductus Arteriosus; Pneumothorax	Paxil			S				Glaxosmithkline
	Lexapro			S		10mg Per Day		Not Reported
	Prozac			S		10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2008	6751076	EXPEDITED (15-DAY)	Y	OT	GB-ABBOTT-08P-167-0473942-00		58 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Suicidal Ideation	Depakote			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S				Not Reported
	Mirtazapine			S	Oral			Not Reported
	Mirtazapine			S				Not Reported
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2008	6751134	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2008072477		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Syncope	Accupril			S				Not Reported
	Omacor			S				Not Reported
	Sunitinib Malate			S	Oral			Not Reported
	Coreg			S				Not Reported
	Humalog			S		Text:25 Mg In Am; 25 Mg		Not Reported

					In Pm (50/50)	
	Hydralazine Hydrochloride		S			Not Reported
	Lexapro		S			Not Reported
	Novolog		S	Subcutaneous	Text:100 Units/Ml-Freq:Tid	Not Reported
	Pravachol		S			Not Reported
	Acetylsalicylic Acid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2008	6541029	EXPEDITED (15-DAY)	Y	DE	S08-USA-00135-01		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Dysarthria; Dyspnoea; Pulmonary Congestion	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2008	6759646	DIRECT	N	RI			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome	Paxil			S	Oral	75mg 1 Daily Po		Glaxosmithkline
	Lexapro			S	Oral	20mg 1 Dialy Po		Astrazeneca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2008	6764873	EXPEDITED (15-DAY)	N	HO, OT	1000000820		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Output Decreased; Drug Withdrawal Syndrome; Dyspnoea; Hypotension; Irritability	Lexapro			S	Oral	10 Mg (1 In 1 D) Per Oral; 5 Mg, Occasionally		Not Reported
					Oral	10 Mg (1 In 1 D) Per Oral; 5 Mg, Occasionally		
	Yasmin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2008	6764889	EXPEDITED (15-DAY)	Y	OT	1000000782			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Bromazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2008	6765724	EXPEDITED (15-DAY)	Y	OT	1000000806		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dry Mouth; Dyspepsia; Enzyme Abnormality; Weight Decreased	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2008	6765868	EXPEDITED (15-DAY)	Y	DS	1000000831		60 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Field Defect	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Remeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2008	6367471	EXPEDITED (15-DAY)	Y	HO	PHBS2007CH12301		85 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akinesia; Antidepressant Drug Level Increased; Anxiety; C-Reactive Protein Increased; Clonus; Confusional State; Delirium; Disorientation; Drug Interaction; Extrapyramidal Disorder; Fall; General Physical Health Deterioration; Heart Rate Increased; Hyperreflexia; Muscle Rigidity; Personality Change; Pyrexia; Serotonin Syndrome; Urinary Tract Infection	Cefuroxime Axetil			S	Unknown		11 DAY	Not Reported
	Azathioprine			C		75 Mg/D		Not Reported
	Perfalgan			C	Intravenous (not otherwise specified)	1 G/D	2 DAY	Not Reported
	Vancomycin Hydrochloride			C	Intravenous (not otherwise specified)	1500 Mg/D	6 DAY	Not Reported
	Rocephin			C	Intravenous (not otherwise specified)	2000 Mg/D	2 DAY	Not Reported
	Ebixa			C		20 Mg/D		Not Reported
	Haldol			C		Unk, Prn		Not Reported
	Lorazepam			C		1.5 Mg/D		Not Reported
	Rocaltrol			C		0.25 Ug/D		Not Reported
	Calcium			C				Not Reported
	Seroquel			C		12.5 Mg/D	10 DAY	Not Reported
	Sandimmune			S	Unknown	125 Mg/D		Novartis
	Cipralex			S	Unknown	10 Mg/D		Not Reported
	Cipralex			S	Unknown	15 Mg	2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2008	6444401	EXPEDITED (15-DAY)	Y	HO, LT	US-AVENTIS-200714845EU		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea	Lovenox			S	Subcutaneous			Aventis
	Methadone Hydrochloride			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Coumadin			S	Oral			Not Reported

Coumadin	S	Oral	Not Reported
Reglan	C	Oral	Not Reported
Ntg	C	Oral	Not Reported
Gabapentin	C	Oral	Not Reported
Unspecified Ingredient	C	Intravenous (not otherwise specified)	Not Reported
Unspecified Ingredient	C	Intravenous (not otherwise specified)	Not Reported
Unspecified Ingredient	C	Intravenous (not otherwise specified)	Not Reported
Paclitaxel	C	Intravenous (not otherwise specified)	Not Reported
Paclitaxel	C	Intravenous (not otherwise specified)	Not Reported
Paclitaxel	C	Intravenous (not otherwise specified)	Not Reported
Carboplatin	C	Intravenous (not otherwise specified)	Not Reported
Carboplatin	C	Intravenous (not otherwise specified)	Not Reported
Carboplatin	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2008	6700096	EXPEDITED (15-DAY)	Y	HO	S08-DEN-02225-01		51 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Escitalopram Oxalate			S	Oral	20 Mg, (10 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2008	6736403	EXPEDITED (15-DAY)	N	DS, OT	DK-PFIZER INC-2008068205		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tooth Loss	Lyrica			S	Oral	Daily Dose:375mg		Not Reported
	Cipralex			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Chlorprothixene Hydrochloride			S	Oral	Freq:Three Times Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2008	6741345	EXPEDITED (15-DAY)	Y	HO	PHBS2008CH05513		84 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Hyperthermia; Serotonin Syndrome	Ciclosporin			S				Novartis
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2008	6763069	DIRECT	N	CA, DE			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Migraine; Pregnancy	Lexapro			S	Oral	10mg Once Daily Po		Not Reported
	Zoloft			S	Oral	50mg Once Daily Po		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2008	6753355	EXPEDITED (15-DAY)	Y	OT	GB-RANBAXY-2008RR-17654			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal	Fluoxetine			S				Ranbaxy
	Escitalopram Oxalate			S				Not Reported
	Paroxetine Hydrochloride			S				Not Reported
	Sertraline			S				Not Reported
	Venlafaxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2008	6767896	DIRECT	Y	HO			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Confusional State; Delirium; Hallucinations, Mixed; Incorrect Dose Administered; Mental Status Changes; Phaeochromocytoma; Serotonin Syndrome; Somnambulism	Trazodone Hydrochloride			S	Oral	100 Mg Tid Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Every Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2008	6763812	DIRECT	Y	HO			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10mg Daily Po		Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2008	6774185	EXPEDITED (15-DAY)	Y	OT	2008AP002288		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal	Paroxetine Hydrochloride			S				Not Reported
	Sertraline Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Fluoxetine Hcl			S				Not Reported
	Venlafaxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2008	6759283	EXPEDITED (15-DAY)	Y	HO, LT	FR-ASTRAZENECA-2008CG01329		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Drug Interaction; Intentional	Tenormin			S	Oral		1 DAY	Not Reported
	Digoxin			C				Not Reported

Overdose; International Normalised Ratio Increased	Propoxyphene Hydrochloride And Acetaminophen	C				Not Reported
	Havlane	C				Not Reported
	Previscan (Fluindione)	S	Oral		1 YR	Not Reported
	Previscan	S	Oral			Not Reported
	Prozac	S	Oral		1 DAY	Not Reported
	Escitalopram Oxalate	S	Oral			Not Reported
	Cortancyl	S	Oral		1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2008	6766363	DIRECT	N				32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Diarrhoea; Mental Disorder; Product Counterfeit; Product Quality Issue; Rash Pruritic	Lexapro			S	Oral	10mg 1 Daily Po		Forest
	Wellbutrin			S	Oral	200mg 2 Daily Po		Global Pharmaceuticals

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2008	6773107	EXPEDITED (15-DAY)	Y	OT	1000000920		16 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Mydriasis; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral	(80 Mg, Once), Oral		Not Reported
	Unspecified Ingredient			S	Oral	(Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2008	6688771	EXPEDITED (15-DAY)	Y	HO, OT	S08-USA-02110-01		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Cardiac Aneurysm;	Lexapro			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1		Not Reported

Cholecystitis Acute; Cholelithiasis; Clostridial Infection; Condition Aggravated; Drug Ineffective; Fluid Overload; Pancreatic Cyst; Pneumonia; Pulmonary Congestion; Tremor; Ventricular Arrhythmia				Oral	D), Oral 20 Mg (10 Mg, 2 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral	
	Diazepam		C			Not Reported
	Lipitor		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2008	6773993	EXPEDITED (15-DAY)	Y	OT	1000000928		4 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Poisoning; Somnolence; Victim Of Crime	Escitalopram Oxalate			S	Oral	(100 Mg, Once) Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2008	6774272	EXPEDITED (15-DAY)	Y	OT	1000000929		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Female Sexual Arousal Disorder	Escitalopram Oxalate			S				Not Reported
	Fluoxetine			S				Not Reported
	Paroxetine Hydrochloride			S				Not Reported
	Sertraline			S				Not Reported
	Venlafaxine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2008	6774316	EXPEDITED (15-DAY)	Y	OT	1000000942		3 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Dysarthria; Electrocardiogram Qt Prolonged; Muscle Spasms; Somnolence;	Escitalopram Oxalate			S	Oral	(50 Mg, Once), Oral		Not Reported
	Pipamperone			S	Oral	(200 Mg, Once), Oral		Not Reported

Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2008	6774405	EXPEDITED (15-DAY)	Y	OT	1000000912		49 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S	Oral	(70 Mg, Once), Oral		Not Reported
	Zyprexa			S	Oral	(Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2008	6636855	EXPEDITED (15-DAY)	N	LT	B0516569A		38 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adhesion; Dyskinesia; Erythema; Genital Ulceration; Lip Swelling; Pyrexia; Rash; Skin Exfoliation; Skin Hyperpigmentation; Skin Lesion; Stevens-Johnson Syndrome	Lamictal			S	Oral	50mg Per Day	23 DAY	Glaxosmithkline
	Escitalopram Oxalate			S	Oral	10mg Per Day	23 DAY	Not Reported
	Unspecified Ingredient			C	Oral			Not Reported
	Zolpidem Tartrate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2008	6598301	EXPEDITED (15-DAY)	Y	OT	S08-USA-00100-01		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Haemorrhage; Maternal Exposure During Pregnancy; Placenta Praevia; Pregnancy	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 2 D), Oral		Not Reported
	Miralax (Macrogol) (Macrogol)			C				Not Reported
	Vitamins (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2008	6710932	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2008061506		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Crying; Ill-Defined Disorder; Incorrect Dose Administered; Road Traffic Accident; Trichotillomania	Chantix			S	Oral			Not Reported
	Ambien			S				Not Reported
	Lexapro			S				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Valsartan			C				Not Reported
	Lisinopril			C				Not Reported
	Labetalol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2008	6775748	EXPEDITED (15-DAY)	Y	OT	1000000736		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Drug Ineffective; Overdose	Lexapro			S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Clonidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2008	6385149	EXPEDITED (15-DAY)	N	OT	US-TYCO HEALTHCARE/MALLINCKRODT-T200700907			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Dyspnoea	Lortab			S	Oral	5 Mg, Qd	4 DAY	Tyco
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Gemcitabine Hydrochloride			S				Not Reported
	Spiriva			C				Not Reported
	Serevent Diskus			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2008	6717906	EXPEDITED (15-DAY)	Y	DE	1000000065		70 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Mental Disorder	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Metformin Hydrochloride			C				Not Reported
	Crestor			C				Not Reported
	Lecinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2008	6718242	EXPEDITED (15-DAY)	Y	OT	1000000043		53 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Dyskinesia; Escherichia Urinary Tract Infection; Tremor	Escitalopram Oxalate			S	Oral	20 Mg, (10 Mg, 2 In 1 D), Oral		Not Reported
	Seroquel			S	Oral	See Image		Not Reported
					Oral	See Image		
	Tiapride			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
					Oral	100 Mg (100 Mg, 1 In 1 D), Oral		
	Lorazepam			S	Oral	5 Mg (5 Mg, 1 In 1 D),Oral		Not Reported
	Lithium Carbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2008	6765900	EXPEDITED (15-DAY)	Y	OT	US-ABBOTT-08P-163-0476197-00		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Lexapro			S	Oral			Not Reported
	Unspecified Ingredient			S				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2008	6766182	NON-EXPEDITED	Y	HO, OT	FR-VALEANT-2008VX001823		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Librium			S	Oral	Dose Unit:Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	Dose Unit:Unknown		Not Reported
	Pyridoxine Hydrochloride			S	Oral	Dose Unit:Unknown		Not Reported
	Pyridoxine Hydrochloride			S	Oral	Dose Unit:Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2008	6773486	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Muscle Tightness	Lexapro			S	Oral	10mg One Qd Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2008	6778545	EXPEDITED (15-DAY)	Y	OT	1000001011		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bulimia Nervosa	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2008	6767425	NON-EXPEDITED	N		US-ASTRAZENECA-2007UW23647		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive	Seroquel			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2008	6778606	EXPEDITED (15-DAY)	Y	DS, HO, OT	1000000978		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Balance Disorder; Brain Injury; Cognitive Disorder; Dizziness; Fall; Hyponatraemia; Impaired Self-Care; Incontinence	Escitalopram Oxalate			S	Oral	(Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2008	6779038	EXPEDITED (15-DAY)	Y	HO	1000001016		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2008	6604468	EXPEDITED (15-DAY)	Y		NO-PFIZER INC-2008026809			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Intolerance; Hallucination; No Adverse Event	Zoloft			S	Oral			Not Reported
	Citalopram Hydrobromide			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Triphasil-21			C				Not Reported
	Zopiclone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2008	6768342	NON-EXPEDITED	Y		US-ASTRAZENECA-2008UW12500		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Testosterone Abnormal; Hepatitis C; Libido Decreased	Seroquel	S	Oral		Not Reported
	Lexapro	S			Not Reported
	Methadone Hydrochloride	S			Not Reported
	Strattera	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2008	6770139	NON-EXPEDITED	Y	HO, OT	US-ASTRAZENECA-2008UW01599		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2008	6781567	EXPEDITED (15-DAY)	Y	OT	1000001029		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Fluctuation	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2008	6783323	EXPEDITED (15-DAY)	Y	DS	1000001025		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Visual Impairment	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In1 D), Oral		Not Reported
	Etoricoxib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2008	6914727	EXPEDITED (15-DAY)	Y	OT	1000001013		51 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Inappropriate Affect	Escitalopram Oxalate			S	Oral	10 Mg, (10 Mg, 1 In 1 D),Oral		Not Reported
	Difur			C				Not Reported
	Enbrel			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2008	7385690	DIRECT	Y				30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Fatigue; Jaundice; Liver Injury; Pruritus; Weight Decreased	Klonopin			S				Not Reported
	Lexapro			S				Not Reported
	Protonix			C				Not Reported
	Labetalol			C				Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2008	6643578	EXPEDITED (15-DAY)	Y	DE	CH-ASTRAZENECA-2008PK00997		43 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Shock; Toxicity To Various Agents; Vomiting	Seroquel			S	Oral		305 DAY	Not Reported
	Cipralex			S	Oral		427 DAY	Not Reported
	Chloral Hydrate			S	Oral		185 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2008	6770985	NON-EXPEDITED	N		A0669226A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Muscle Twitching	Wellbutrin Xl		S	Oral	Glaxosmithkline
	Lexapro		S	Unknown	Not Reported
	Unspecified Ingredient		C		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2008	6771119	NON-EXPEDITED	N		A0688264A		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Insomnia; Libido Decreased; Mood Altered; Tremor	Wellbutrin Xl			S	Oral	300mcg Per Day		Glaxosmithkline
	Lexapro			S		5mg Per Day	1 MTH	Not Reported
	Lotrel			C				Not Reported
	Crestor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2008	6771510	NON-EXPEDITED	N		A0733132A		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Nervousness; Product Quality Issue; Product Residue Present	Bupropion Hydrochloride			S	Oral	300mg Per Day	53 WEEK	Glaxosmithkline
	Bupropion Hydrochloride			S	Oral			Glaxosmithkline
	Lexapro			S		20mg Per Day		Not Reported
	Lexapro			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2008	6771582	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-14343693		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bradycardia; Hypoglycaemia; Syncope	Pravachol			S				Bristol Myers Squibb
	Accupril			S				Not Reported
	Omacor			S				Not Reported
	Coreg			S				Not Reported

	Humalog	S		25mg In Am:25mg In Pm	Not Reported
	Hydralazine Hydrochloride	S			Not Reported
	Lexapro	S			Not Reported
	Novolog	S	Subcutaneous	1 Df = 100 Units/Ml	Not Reported
	Acetylsalicylic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2008	6776964	DIRECT	Y	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Product Quality Issue	Lexapro			S	Oral	20mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2008	6782457	EXPEDITED (15-DAY)	Y	HO, OT	2008S1016649		78 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Confusional State; Fall	Indapamide			S	Oral	1.5 Mg;Twice A Day;Oral		Not Reported
	Escitalopram Oxalate			S	Oral	1.5 Mg;Twice A Day;Oral		Not Reported
	Atenolol			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2008	6778125	DIRECT	Y	HO			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Burning Sensation; Pruritus; Skin Lesion	Lexapro			S	Oral	1 Tab Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2008	6778380	DIRECT	Y	HO			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Inappropriate Antidiuretic Hormone Secretion	Lexapro		S	Oral	Po	2 DAY	Forest
	Actonel		C				Not Reported
	Claritin		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2008	6781840	EXPEDITED (15-DAY)	N	OT	1000001015		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Poisoning; Physical Assault; Spousal Abuse; Treatment Noncompliance	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Alcohol			S	Oral	Consumed 6 Beers		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2008	6783517	EXPEDITED (15-DAY)	Y	HO	PAR_02346_2008		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Bradycardia; Hypoglycaemia; Syncope; Unresponsive To Stimuli	Hydralazine Hydrochloride			S		(25 Mg Tid)		Not Reported
	Sutent			S	Oral	(50 Mg Qd [Held For 2 Weeks After Every 4 Weeks] Oral)		Not Reported
	Nexavar			S	Oral	(400 Mg Bid Oral)		Not Reported
	Humalog			S		(25 Mg Bid[25 Mg In Am; W5 Mg In Pm] 50/50)		Not Reported
	Accupril			S		40 Mg Qd		Not Reported
	Coreg			S		12.5 Mg Qd		Not Reported
	Lexapro			S		20 Mg Qd		Not Reported
	Pravachol			S		40 Mg Qd		Not Reported
	Omacor			S		1000 Mg Qid		Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Novolog (Not Specified)			C	Subcutaneous	100 Df Tid Subcutaneous		Not Reported
	Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2008	6659592	EXPEDITED (15-DAY)	N	OT	S08-USA-01753-01		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dizziness; Fatigue; Hypotension; Palpitations; Paraesthesia; Tremor	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tamoxifen Citrate			C				Not Reported
	Monopril (Fosinopril Sodium) (Fosinopril Sodium)			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2008	6697753	EXPEDITED (15-DAY)	Y	HO, LT, OT	S08-GER-02195-01		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Respiratory Depression; Somnolence; Suicide Attempt	Escitalopram Oxalate			S	Oral	800 Mg, Once, Oral		Not Reported
	Tramadol			S	Oral	10000 Mg, Once, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2008	6725473	EXPEDITED (15-DAY)	Y	OT	1000000261		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Chloride Decreased; Blood Osmolarity Decreased; Epigastric Discomfort; General Physical Health Deterioration; Hypertension; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion;	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Noroxin			C				Not Reported

Tremor; Urine Osmolarity Decreased; Urine Sodium Decreased; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2008	6752507	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-08P-056-0473999-00		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Drug Interaction; Haemoptysis; Hypotension; International Normalised Ratio Increased; Overdose	Lipanthyl			S	Oral			Not Reported
	Clopidogrel			C	Oral			Not Reported
	Metformin Hydrochloride			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Furosemide			C	Oral			Not Reported
	Chondroitin Sulfate (Bovine)			C	Oral			Not Reported
	Tamsulosin Hydrochloride			C	Oral			Not Reported
	Ultracet			C	Oral			Not Reported
	Perindopril			C	Oral			Not Reported
	Lipanthyl			S				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Acenocoumarol			S	Oral			Not Reported
	Acenocoumarol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2008	6774425	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14100648		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Buspar			S			5 DAY	Bristol Myers Squibb
	Lexapro			S	Oral	10mg Taken From 01sep07 To Oct07 And From Oct07 To Cont		Not Reported
	Lyrica			C				Not Reported
	Keppra			C				Not Reported

	Wellbutrin	C		Not Reported
	Imitrex	C		Not Reported
	Kerlone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2008	6774446	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14186332		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Buspar			S				Bristol Myers Squibb
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2008	6779011	DIRECT	Y				95 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain; Lethargy	Lexapro			S	Oral	10mg Qday Po		Not Reported
	Coumadin			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Benadryl			C				Not Reported
	Docusate			C				Not Reported
	Vitamin B12			C				Not Reported
	Vicodin			C				Not Reported
	Combivent			C				Not Reported
	Digoxin			C				Not Reported
	Diltiazem Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2008	6779240	DIRECT	N	RI			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Loss Of Personal Independence In Daily Activities	Lexapro			S	Oral	20mg Once Daily Po		Forest
	Fluoxetine			C				Not Reported
	Paroxetine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2008	6779246	DIRECT	N	HO			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anal Incontinence; Asthenia; Blood Pressure Decreased; Burning Sensation; Fall; Malaise; Muscle Spasms; Pyrexia; Vein Disorder; Vomiting	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2008	6785126	EXPEDITED (15-DAY)	Y	HO, LT	1000001086		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Generalised Tonic-Clonic Seizure	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Zyprexa			S	Oral	Oral		Not Reported
	Pegasys (Injection)			C				Not Reported
	Copegus			C				Not Reported
	Norvir			C				Not Reported
	Reyataz (200 Milligram)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2008	6914732	DIRECT	N	DE			25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Lexapro			S	Oral	One Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2008	6753350	EXPEDITED (15-DAY)	Y	OT	1000000625		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoacusis; Inner Ear Disorder; Nystagmus; Stress	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2008	6774895	EXPEDITED (15-DAY)	Y	HO	AT-RANBAXY-2008RR-18117		34 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Mania	Topiramate			S		100 Mg, Bid		Ranbaxy
	Escitalopram Oxalate			S		10 Mg, Bid		Not Reported
	Risperidone			C				Not Reported
	Chlorprothixene			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2008	6775674	EXPEDITED (15-DAY)	N	HO	FR-ELI_LILLY_AND_COMPANY-FR200809003749		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Intentional Overdose; International Normalised Ratio Increased	Prozac			S	Oral			Eli Lilly And Co
	Previscan (Fluindione)			C	Oral	20 Mg, Unk		Not Reported
	Hemigoxine			C				Not Reported
	Propoxyphene Hydrochloride And Acetaminophen			C				Not Reported
	Havlane			C				Not Reported
	Prozac			S	Oral	14 D/F, Unk	1 DAY	Eli Lilly And Co
	Tenormin			S	Oral	14 D/F, Unk		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Cortancyl			S	Oral	50 Mg, Daily (1/D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2008	6779695	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dyspnoea	Paxil			S	Intravenous (not otherwise specified)	20 Mg Am Iv		Not Reported
	Lexapro			S	Intravenous (not otherwise specified)	Iv 20 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2008	6782071	DIRECT	N	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Weight Increased	Lexapro			S	Oral	5mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2008	6784176	EXPEDITED (15-DAY)	Y	HO	1000001090		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dementia; Pyrexia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Vastarel			C				Not Reported
	Cacit D3 (Powder)			C				Not Reported
	Tenormin			C				Not Reported
	Minisintrom			C				Not Reported
	Eupressyl (30 Milligram, Capsules)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2008	6784387	EXPEDITED (15-DAY)	Y	HO, LT	1000001060		77 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Drug Interaction; Intentional Overdose; International Normalised Ratio Increased; Sinus Arrest;	Escitalopram Oxalate			S	Oral Oral	Oral; (Once), Oral Oral; (Once), Oral		Not Reported
	Prozac			S	Oral	(14 Dosage Forms, Once) ,Oral		Not Reported

Suicide Attempt	Tenormin	S	Oral	(14 Dosage Forms, Once) ,Oral	Not Reported
	Fluindione	S	Oral	Oral	Not Reported
	Prednisone	S	Oral	(50 Mg, Once) ,Oral	Not Reported
	Previscan (Fluindione)	S			Not Reported
	Hemigoxine	C			Not Reported
	Havlane	C			Not Reported
	Propoxyphene Hydrochloride And Acetaminophen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2008	6692917	EXPEDITED (15-DAY)	Y	OT	S08-GER-02162-01		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteoporosis; Rib Fracture	Escitalopram Oxalate			S	Oral	10 Mg (10mg, 1 In 1 D), Oral		Not Reported
	Insidon			C				Not Reported
	Etilefrin			C				Not Reported
	Berotec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2008	6776161	EXPEDITED (15-DAY)		HO	US-NOVOPROD-279604		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypoglycaemic Unconsciousness	Novolog			S	Subcutaneous	100 Unk, Unk		Novo Nordisk
	Accupril			S	Oral	Unk Mg, Qd		Not Reported
	Icosapent			S	Oral	1000 Mg, Qid		Not Reported
	Coreg			S		12.5 Mg, Qd		Not Reported
	Humalog			S	Subcutaneous	25 Mg, In The Am And Pm		Not Reported
	Hydralazine			S	Oral	25 Mg, Tid		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Pravachol			S	Oral	40 Mg, Qd		Not Reported
	Aspirin			C	Oral	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2008	6778631	EXPEDITED (15-DAY)	Y	OT	1000000996		21 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Injury; Skin Laceration; Tremor; Visual Impairment	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In D) , Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2008	6789576	EXPEDITED (15-DAY)	Y	OT	10000001092			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torticollis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2008	6790807	EXPEDITED (15-DAY)	Y	OT	1000001092			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torticollis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2008	6752847	EXPEDITED (15-DAY)	Y	DS	1000000579		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Tooth Fracture; Tooth Loss	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Chlorprothixene			S	Oral	Oral		Not Reported
	Lyrica			S	Oral	Oral		Not Reported

	Zyprexa		S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2008	6792618	EXPEDITED (15-DAY)	Y	LT, OT	1000004073		19 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Intentional Overdose; Respiratory Depression; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral	(400 Mg, Once), Oral		Not Reported
	Alprazolam			S	Oral	(15 Mg, Once), Oral		Not Reported
	Amitriptyline Hydrochloride			S	Oral	2500 Mg, Once), Oral		Not Reported
	Promethazine Hydrochloride			S	Oral	(250 Mg, Once), Oral		Not Reported
	Edronax			S	Oral	80 Mg, Once) , Oral		Not Reported
	Naltrexone Hydrochloride			S	Oral	(300 Mg, Once) , Oral		Not Reported
	Unspecified Ingredient			S	Oral	1 Bottle (Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2008	6792693	EXPEDITED (15-DAY)	Y	HO	1000001135		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	Oral		Not Reported
	Ultram			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2008	6768556	EXPEDITED (15-DAY)	N	OT	DK-PFIZER INC-2008076539		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction	Champix			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2008	6778415	EXPEDITED (15-DAY)	N	HO	A0750331A		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Syncope	Carvedilol			S	Oral	12.5mg Per Day		Glaxosmithkline
	Lovaza			S	Oral	1000mg Four Times Per Day		Glaxosmithkline
	Accupril			S	Oral	40mg Per Day		Not Reported
	Unspecified Ingredient			S	Oral			Glaxosmithkline
	Humalog			S	Subcutaneous			Not Reported
	Hydralazine Hydrochloride			S		25mg Three Times Per Day		Not Reported
	Lexapro			S		20mg Per Day		Not Reported
	Novolog			S		100unit Three Times Per Day		Not Reported
	Pravachol			S		40mg Per Day		Not Reported
	Aspirin			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2008	6778722	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2008-BP-14			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Eye Pruritus; Rash	Ranitidine			S	Oral	150mg		Boehringer Ingelheim
	Lexapro			S		10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2008	6778770	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2008080121			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Abuse	Xanax			S				Not Reported
	Morphine Sulfate			S				Not Reported
	Oxycontin			S				Not Reported
	Vicodin			S				Not Reported
	Lexapro			S				Not Reported

	Marijuana	S		Not Reported
	Cocaine	S		Not Reported
	2,3-Methylenedioxyamphetamine	S		Not Reported
	Heroin	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2008	6787543	EXPEDITED (15-DAY)	Y	LT, OT	1000001118		29 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Gastric Haemorrhage; Haemodialysis; Hypoxia; Intentional Overdose; Seizure; Suicide Attempt	Escitalopram Oxalate			S	Oral	(Once), Oral		Not Reported
	Metoprolol			S	Oral	(Once), Oral		Not Reported
	Albuterol Sulfate			S	Oral	(Once), Oral		Not Reported
	Tramadol Hydrochloride			S	Oral	(Once), Oral		Not Reported
	Trimipramine			S	Oral	(Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2008	6787555	EXPEDITED (15-DAY)	Y	OT	1000001116		54 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Transient Ischaemic Attack; Vertigo	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2008	6786263	DIRECT		HO				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2008	6788766	EXPEDITED (15-DAY)	Y	CA	1000001124		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hand Malformation; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D),Transplacental		Not Reported
	Imovane (5 Milligram)			C				Not Reported
	Vallergan (10 Milligram)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2008	6788987	EXPEDITED (15-DAY)	Y	OT	1000001185		74 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Urinary Incontinence	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel			S	Oral	200 Mg (100 Mg, 2 In 1 D), Oral		Not Reported
	Reminyl			S	Oral	16 Mg (16 Mg, 1 In 1 D), Oral		Not Reported
	Navixen (600 Milligram, Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2008	6780726	NON-EXPEDITED	N		US-ASTRAZENECA-2008UW02220		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Bone Pain; Insomnia; Joint Swelling	Arimidex			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2008	6796528	EXPEDITED (15-DAY)	Y	OT	1000001209		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intellectual Disability; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	(30 Mg, Once), Oral		Not Reported
	Diphenhydramine			S	Oral	(300 Mg, Once), Oral		Not Reported

	Alcohol		S	Oral	3 Liters (Once), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2008	6790877	DIRECT	Y	HO			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Pain	Lexapro			S	Oral	10 Mg Daily Po Couple Of Years		Forest
	Insulin Glargine			C				Not Reported
	Prandin			C				Not Reported
	Glimepiride			C				Not Reported
	Plavix			C				Not Reported
	Diovan			C				Not Reported
	Labetalol			C				Not Reported
	Norvasc			C				Not Reported
	Fosamax			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Zocor			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2008	6791424	EXPEDITED (15-DAY)	Y	OT	2008S1017200		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Choreoathetosis; Myoclonus	Escitalopram Oxalate			S		10 Mg;Daily		Not Reported
	Paliperidone			S		6 Mg;Daily		Not Reported
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2008	6792603	EXPEDITED (15-DAY)	Y	HO	1000001214		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Macular	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

	Bupropion	S		Not Reported
	Levothyroxine	C		Not Reported
	Metformin Hydrochloride	C		Not Reported
	Advair Diskus	C		Not Reported
	Singulair	C		Not Reported
	Lisinopril	C		Not Reported
	Tricor	C		Not Reported
	Lipitor	C		Not Reported
	Aspirin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2008	6792644	EXPEDITED (15-DAY)	Y	OT	1000001239			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2008	6793040	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000001207			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome; Ventricular Fibrillation	Citalopram Hydrobromide			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20-40 Mg (1 In 1 D), Oral		Not Reported
	Citalopram Hydrobromide			S	Oral	20-40 Mg (1 In 1 D), Oral		Not Reported
	Fluxet			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Urbason (Tablets)			C				Not Reported
	Calciumacetat			C				Not Reported
	Rocaltrol			C				Not Reported
	Dynepo			C				Not Reported
	Fluvastatin			C				Not Reported
	Furosemid			C				Not Reported
	Madopar			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Cellcept			C				Not Reported
	Nifedipine			C				Not Reported
	Amlodipine			C				Not Reported

Pantozol	C	Not Reported
Ramipril	C	Not Reported
Renagel	C	Not Reported
Ranitidine Hydrochloride	C	Not Reported
Mimpara	C	Not Reported
Paracetamol	C	Not Reported
Famotidine	C	Not Reported
Rocephin	C	Not Reported
Metoprolol Retard	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2008	6793480	EXPEDITED (15-DAY)	Y	HO	1000001221			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Panic Attack; Post-Traumatic Stress Disorder	Escitalopram Oxalate			S	Oral	1 Tablet (Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2008	6796943	EXPEDITED (15-DAY)	N	DE, OT	1000001240		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Condition Aggravated; Depression; Gun Shot Wound	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2008	6685081	EXPEDITED (15-DAY)	Y	HO	S08-FRA-02026-01		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Paralysis; Tetany	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2008	6735255	EXPEDITED (15-DAY)	Y	LT, OT	1000000438		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Culture Urine Positive; Diabetes Mellitus Inadequate Control; Dialysis; Drug Interaction; Enterococcal Infection; Generalised Tonic-Clonic Seizure; Hyponatraemia; Incorrect Dose Administered; Pyelonephritis; Serotonin Syndrome; Urosepsis	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Linezolid			S		1200 Mg (600 Mg, 1 In 12		Not Reported
	Metoclopramide			C				Not Reported
	Ondansetron (4 Milligram)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2008	6777830	EXPEDITED (15-DAY)	Y	OT	1000000966		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Inhibitory Drug Interaction	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Varenicline Tartrate			S	Oral	2 Dosage Forms (1 Dosage Froms, 2 In 1 D), Oral		Not Reported
	Varenicline Tartrate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2008	6789969	DIRECT	N	RI, OT			42 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maculopathy; Retinal Disorder; Visual Field Defect	Lexapro	S	Oral	10-20mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2008	6794183	EXPEDITED (15-DAY)	Y	HO, LT	DSA_32337_2008		90 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Serotonin Syndrome	Enalapril Maleate			S		(10 Mg Qd)		Not Reported
	Escitalopram Oxalate			S		(20 Mg Qd)		Not Reported
	Mianserin Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2008	6586364	EXPEDITED (15-DAY)	Y	OT	S08-FRA-00740-01		26 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Therapy Non-Responder	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	2.5 Mg (5 Mg, 1 In 2 D), Oral		Not Reported
	Clonazepam			S	Oral	2 Mg (2 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2008	6786312	EXPEDITED (15-DAY)	Y	OT	ES-JNJFOC-20081001771		74 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Urinary Incontinence	Reminyl			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported

	Navixen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2008	6787539	EXPEDITED (15-DAY)	Y	HO, OT	1000001129		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Drug Interaction; Therapeutic Product Ineffective	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2008	6787589	EXPEDITED (15-DAY)	Y	HO	1000001084		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Chloride Decreased; Blood Potassium Decreased; Carbon Dioxide Decreased; Dehydration; Headache; Hyponatraemia; Memory Impairment; Nausea; Photopsia; Seizure; Tonic Clonic Movements; Urinary Incontinence; Vomiting	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Atenolol			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2008	6792276	DIRECT	N	HO, LT, OT			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sleep Disorder; Suicidal Ideation	Lexapro			S	Oral	10 Mg 1x Daily Po	6 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2008	6794719	EXPEDITED (15-DAY)	N	OT	S08-USA-01937-01		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Oedema Peripheral; Pain In Extremity; Vitamin D Decreased; Weight Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Ambien (Zolpidem Tartrate) (Zolipidem Tartrate)			C				Not Reported
	Metformin (Metformin) (Metformin)			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Vicoprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2008	6795249	EXPEDITED (15-DAY)	Y	HO	6046261		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event; Wrong Product Administered	Levothyroxine Sodium			S	Oral	1 Dosage Forms, 1 In 1 D) Oral		Not Reported
	Bisoprolol Fumarate			S	Oral	5 Mg (5 Mg, 1 In 1 D) Oral		Not Reported
	Nicorandil			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D) Oral		Not Reported
	Vastarel			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D) Oral		Not Reported
	Furosemide			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D) Oral		Not Reported
	Ramipril			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D) Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D) Oral		Not Reported
	Potassium Chloride			S	Oral	1 Dosage Forms (1		Not Reported

Dosage Forms, 1 In 1 D)
Oral

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2008	6795872	EXPEDITED (15-DAY)	Y	HO	1000001274			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroiditis	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2008	6709184	EXPEDITED (15-DAY)	Y	OT	A0738185A		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Decreased; Aura; Constipation; Dizziness; Feeling Abnormal; Gastroenteritis Viral; Headache; Hyperhidrosis; Loss Of Consciousness; Nausea; Pallor; Paraesthesia; Postictal State; Seizure	Lamictal			S	Oral	100mg Twice Per Day		Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2008	6788362	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-08P-056-0481120-00		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Depakote			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2008	6795092	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Product Quality Issue	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2008	6798102	EXPEDITED (15-DAY)	Y	HO, LT	1000001205			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	(Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2008	6317900	EXPEDITED (15-DAY)	Y		US-PFIZER INC-2007038671		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Chantix			S				Not Reported
	Lexapro			S				Not Reported
	Lasix			C				Not Reported
	Advair Diskus			C				Not Reported
	Duoneb			C				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2008	6656597	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01795-01		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tunnel Vision	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Temesta (Lorazepam) (2.5 Milligram, Tablets) (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2008	6737727	EXPEDITED (15-DAY)	Y	OT	1000000386		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Decreased Appetite; Gallbladder Polyp; Hepatic Cyst; Liver Injury; Weight Decreased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; Oral		
	Unspecified Ingredient			S		45/15 Mg Daily, 60/30 Mg Daily 45/15 Mg Daily, 60/30 Mg Daily 45/15 Mg Daily, 60/30 Mg Daily		Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2008	6795840	EXPEDITED (15-DAY)	Y	OT	1000001267		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flat Affect; Suicidal Ideation; Therapy Non-Responder	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2008	6796340	DIRECT	N	HO, LT			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	1.5 Tablets Once A Day Po	2 MTH	Not Reported
	Ic Clonazepam			C				Not Reported
	Ic Bupropion Hcl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2008	6798638	EXPEDITED (15-DAY)	N	OT	1000001348			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gambling Disorder	Lexapro	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2008	6799685	EXPEDITED (15-DAY)	Y	HO	1000001342		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delusion; Drug Interaction	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Azilect			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2008	6799703	EXPEDITED (15-DAY)	Y	HO, LT	1000001363		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Intentional Overdose; International Normalised Ratio Increased; Psychomotor Retardation; Somnolence; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S	Oral	10 Tablets (Once), Oral; Oral		Not Reported
	Anafranil			S	Oral	1 Box (Once), Oral		Not Reported
	Xanax			S	Oral	(2 Dosage Forms, Once), Oral; Oral		Not Reported
	Cyamemazine			S	Oral	(10 Dosage Forms, Once), Oral; Oral		Not Reported
	Previscan (Fluindione)			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2008	6280202	EXPEDITED (15-DAY)	N	HO, OT	US-PFIZER INC-2007024530		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Discomfort; Eye Swelling; Pruritus; Urticaria	Chantix			S				Not Reported
	Lexapro			S				Not Reported
	Albuterol			C				Not Reported
	Lasix			C				Not Reported
	Advair Diskus			C				Not Reported
	Duoneb			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2008	6799809	EXPEDITED (15-DAY)	Y	HO	WAES 0810USA01959		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Disorientation; Drug Interaction; Hypokalaemia; Hyponatraemia; Malaise; Muscular Weakness	Amiloride Hcl W/ Hydrochlorothiazide			S	Oral	5/50 Mg/Daily, Po		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg/Daily, Po		Not Reported
	Adartrel			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Idaptan			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2008	6800222	EXPEDITED (15-DAY)	Y	OT	1000000653		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenic Purpura	Lexapro			S	Oral	5 Mg , 10 Mg ,(5 Mg, 10mg, 1 In 1d), Oral		Not Reported
					Oral	5 Mg , 10 Mg ,(5 Mg, 10mg, 1 In 1d), Oral		
	Haldol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2008	6778708	EXPEDITED (15-DAY)	Y	OT	DK-PFIZER INC-2008075214		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Drug Interaction; Dyskinesia	Lyrica			S	Oral			Not Reported
	Lyrica			S		Text:Bid Daily Tdd:450mg		Not Reported
	Sertindole			S	Oral			Not Reported
	Sertindole			S				Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2008	6810290	EXPEDITED (15-DAY)	Y	OT	1000001497		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Decreased; Constipation; Convulsive Threshold Lowered; Disorientation; Loss Of Consciousness; Overdose; Paraesthesia; Seizure; Somnolence	Lexapro			S	Oral Oral	Oral Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg), Oral		Not Reported
	Lamictal			S	Oral	200 Mg (100 Mg, 2 In I Day), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2008	6726650	EXPEDITED (15-DAY)	Y	LT	1000000266		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemic Unconsciousness	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Insuman Basal Insulin Novorapid			C C				Not Reported Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2008	6776622	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2008-BP-14		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Middle Insomnia; Oedema Peripheral; Pollakiuria	Flomax			S	Oral	.4mg		Boehringer Ingelheim
	Lexapro			S				Not Reported
	Toprol Xl			C				Not Reported
	Zocor			C				Not Reported
	Omeprazole			C				Not Reported
	Maxalt			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2008	6799528	DIRECT	Y	HO			88 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity Vasculitis	Lexapro			S				Not Reported
	Amantadine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2008	6686371	EXPEDITED (15-DAY)	Y	OT	S08-USA-02020-01		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anal Incontinence; Cardiac Flutter; Diarrhoea; Fall; Fatigue; Headache; Loss Of Consciousness; Nausea; Palpitations	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2008	6802045	EXPEDITED (15-DAY)	Y	OT	1000001412		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D) ,Oral; 10 Mg (10 Mg, 1 In 1 D) ,Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D) ,Oral; 10 Mg (10 Mg, 1 In 1 D) ,Oral		
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2008	6802047	EXPEDITED (15-DAY)	Y	OT	1000001409		81 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Apraxia; Delirium; Disorientation	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D) ,Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2008	6802049	EXPEDITED (15-DAY)	Y	OT	1000001408		41 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Mydriasis; Sopor; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S	Oral	(Once) ,Oral		Not Reported
	Doxepin			S	Oral	(Once) ,Oral		Not Reported
	Alcohol			S	Oral	(Once) ,Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2008	6521475	EXPEDITED (15-DAY)	Y	HO	US-WYE-H01814307		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Lethargy; Mydriasis; Overdose; Serotonin Syndrome	Chlorpheniramine Maleate\Dextromethorphan Hydrobromide			S	Unknown	Unknown		Wyeth
	Benztropine Mesylate			S	Unknown	Unknown		Unknown
	Escitalopram Oxalate			S	Unknown	Unknown		Unknown
	Aripiprazole			S	Unknown	Unknown		Bristol Myers Squibb

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2008	6587601	EXPEDITED (15-DAY)	Y	OT	S08-ITA-00825-01			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy; Pregnancy; Premature Separation Of Placenta	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2008	6631553	EXPEDITED (15-DAY)	Y	HO	ES-ASTRAZENECA-2008AC01089		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Seroquel			S	Oral		5 DAY	Not Reported
	Clomethiazole			S	Oral		11 DAY	Not Reported
	Cipralex			S	Oral		4 DAY	Not Reported
	Topamax			S	Oral		4 DAY	Not Reported
	Clorazepate Dipotassium			S	Oral		11 DAY	Not Reported
	Bromazepam			S	Oral		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2008	6746782	EXPEDITED (15-DAY)	Y	HO	1000000513		84 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Blood Urine Present; Dizziness; Haematocrit Decreased; Haemoglobin Decreased; Protein Urine Present; Red Blood Cell Count Decreased; Refusal Of Treatment By Patient; Syncope	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Proscar			C				Not Reported
	Folvite (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2008	6805712	EXPEDITED (15-DAY)	Y	HO	1000001444		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Interaction; Hyponatraemia; Overdose	Escitalopram Oxalate			S	Oral	30 Mg (15 Mg, 2 In 1 D), Oral		Not Reported

	Atacand	S	Oral	16 Mg (16 Mg, 1 In 1 D), Oral		Not Reported
	Madopar (Tablets)	C				Not Reported
	Omeprazole	C				Not Reported
	Cardyl (Tablets)	C				Not Reported
	Osteopor (Tablets)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2008	6813684	DIRECT	Y	LT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Insomnia; Suicidal Ideation; Therapeutic Response Unexpected	Paroxetine Hydrochloride			S	Oral	12.5mg Daily Oral		Not Reported
	Paxil Cr			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2008	6793456	EXPEDITED (15-DAY)	Y	DE	1000001204		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral	10 Mg 910 Mg, 1 In 1 D); Oral		Not Reported
	Lexomil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2008	6802821	DIRECT	Y	HO			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypermetabolism; Hyperthermia; Serotonin Syndrome; Torsade De Pointes; Ventricular Tachycardia	Trazodone Hydrochloride			S				Not Reported
	Lexapro			S				Not Reported
	Azilect			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2008	6812251	EXPEDITED (15-DAY)	Y	OT	1000001457		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Euphoric Mood	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D); Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2008	6803927	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance;	Wellbutrin Sr			S				Not Reported
Hyperhidrosis; Nausea;	Lexapro			S				Not Reported
Urticaria	Sertraline			S				Not Reported
	Paroxetine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2008	6804518	DIRECT	N	HO			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Head Titubation; Muscle Twitching; Serotonin Syndrome; Tremor	Lexapro			S		10 Mg Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2008	6707975	EXPEDITED (15-DAY)	Y	OT	S08-FRA-02314-01		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2008	6787523	EXPEDITED (15-DAY)	Y	OT	1000001138		82 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Decreased; Dementia; Haemoglobin Decreased; Haemoptysis; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Lipanthyl			S	Oral	Oral		Not Reported
	Acenocoumarol			S	Oral	4 Mg (4 Mg, 1 In 1 D), Oral		Not Reported
	Clopidogrel			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Omeprazole			C				Not Reported
	Furosemide			C				Not Reported
	Chondroitin Sulfate (Bovine)			C				Not Reported
	Tamsulosin Hydrochloride			C				Not Reported
	Ultracet			C				Not Reported
	Perindopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2008	6799165	EXPEDITED (15-DAY)	Y	HO	AT-ASTRAZENECA-2008PK02305		40 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperprolactinaemia	Seroquel			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Zyprexa			S	Oral		1 DAY	Not Reported
	Zyprexa			S	Oral		14 DAY	Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral		14 DAY	Not Reported
	Euthyrox			C				Not Reported
	Depakene			C				Not Reported
	Ferrous Sulfate			C	Oral			Not Reported
	Abilify			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2008	6800092	EXPEDITED (15-DAY)	Y	OT	ES-ABBOTT-08P-144-0484269-00		12 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hallucination, Visual	Cipralex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2008	6800402	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2008090022		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Amlodipine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Clotiazepam			S	Oral	Text:Every Day		Not Reported
	Zopiclone			S	Oral			Not Reported
	Niflumic Acid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2008	6778537	EXPEDITED (15-DAY)	Y	HO	1000001007		82 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Drug Interaction; Haemoglobin Decreased; Haemoptysis; Hypotension; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Sintrom			S	Oral	(4 Mg), Oral		Not Reported
	Lipanthyl			S	Oral	Oral		Not Reported
	Plavix			C				Not Reported
	Glucophage			C				Not Reported
	Omeprazole			C				Not Reported
	Coversyl			C				Not Reported
	Lasix			C				Not Reported
	Chondrosulf			C				Not Reported
	Omix			C				Not Reported
	Tramadol Hydrochloride And Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2008	6800973	EXPEDITED (15-DAY)	Y	HO	DE-WYE-G02444108		83 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Antidepressant Drug Level Increased; Dehydration; Delirium	Venlafaxine Hydrochloride	S	Oral		7 DAY	Wyeth
	Venlafaxine Hydrochloride	S	Oral		4 DAY	Wyeth
	Venlafaxine Hydrochloride	S	Oral		8 DAY	Wyeth
	Ziprasidone Hydrochloride	S	Oral			Pfizer
	Cipralex	S	Oral			Lundbeck
	Remergil	S	Oral			Not Reported
	Novodigal (Digoxin)	C	Oral			Not Reported
	Enalapril Maleate	C	Oral			Hexal
	Furosemide	C	Oral			Hexal
	Kalinor (Potassium Chloride)	C	Oral			Not Reported
	Godamed	C	Oral			Not Reported
	Creon	C	Oral			Not Reported
	Lithium Carbonate	C	Oral			Not Reported
	Piretanide	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2008	6801521	EXPEDITED (15-DAY)	Y	OT	FR-SANOFI-SYNTHELABO-A02200803149			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Intentional Overdose	Stilnox			S	Oral		1 DAY	Not Reported
	Acetaminophen			S	Oral		1 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	2 Tablets Once	1 DAY	Not Reported
	Valpromide			S	Oral		1 DAY	Not Reported
	Doliprane			C	Oral	2 To 4 Mg Daily Dose		Not Reported
	Valpromide			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2008	6809539	EXPEDITED (15-DAY)	Y	OT	1000001506		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Hypertensive Crisis; Nausea; Rash; Vertigo	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Optruma (Tablets)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2008	6810244	DIRECT	N	OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicidal Ideation; Thinking Abnormal	Lexapro			S	Oral	10 Mg 1 X Daily Po		Not Reported
	Paxil			S	Oral	25 Mg 1 Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2008	6810563	EXPEDITED (15-DAY)	Y	DE	CHPA2008US18074		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Dextromethorphan Hydrobromide		Y	S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2008	6811593	EXPEDITED (15-DAY)	Y	OT	1000001510			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Ineffective; Self-Injurious Ideation; Weight Increased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D); Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2008	6799623	EXPEDITED (15-DAY)	Y	HO	AT-JNJFOC-20081005023		40 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Hyperprolactinaemia	Haldol			S	Oral			Not Reported

	Risperdal	S	Unknown	Not Reported
	Cipralex	S	Unknown	Not Reported
	Zyprexa	S	Unknown	Not Reported
	Zyprexa	S	Unknown	Not Reported
	Seroquel	S	Unknown	Not Reported
	Etilefrine Hydrochloride	C	Oral	Not Reported
	Euthyrox	C	Unknown	Not Reported
	Depakene	C	Unknown	Not Reported
	Ferro-Gradumet	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2008	6812806	EXPEDITED (15-DAY)	N	DE	1000001525		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Depression	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D) Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2008	6812953	EXPEDITED (15-DAY)	Y	OT	1000001529		32 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2008	6812955	EXPEDITED (15-DAY)	Y	OT	1000001532		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Supraventricular Extrasystoles	Escitalopram Oxalate			S		5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2008	6804111	EXPEDITED (15-DAY)	Y	HO	DE-ASTRAZENECA-2008PK02327			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hepatic Function Abnormal	Cymbalta			S				Not Reported
	Seroquel			S	Oral			Not Reported
	Lamotrigine			S				Not Reported
	Cipralex			S				Not Reported
	Naloxone Hydrochloride\Tilidine Hydrochloride			S				Not Reported
	Ziprasidone Hydrochloride			S				Not Reported
	Sortis			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2008	6813822	EXPEDITED (15-DAY)	Y	DE	1000001544		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg (10 Mg, Once), Oral		Not Reported
	Talcid (Tablets)			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2008	6799008	EXPEDITED (15-DAY)	Y	HO, OT	AU-PFIZER INC-2008082179		19 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Cardiovascular Insufficiency; Generalised Tonic-Clonic Seizure; Neuroleptic Malignant Syndrome; Neutropenia; Pyrexia	Ziprasidone			S				Not Reported
	Clozapine			S				Not Reported
	Haloperidol			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Periactin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2008	6804872	EXPEDITED (15-DAY)	N	DE, HO, LT	BE-BAYER-200829139GPV		57 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Torsade De Pointes	Avelox			S	Oral	Total Daily Dose: 400 Mg Unit Dose: 400 Mg		Bayer
	Daonil			C				Not Reported
	Ramipril			C				Not Reported
	Bisoprolol			C				Not Reported
	Orap			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2008	6812991	DIRECT	Y	HO, LT			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Anaemia; Cerebral Disorder; Cognitive Disorder; Depression; Disturbance In Attention; Drug Hypersensitivity; Infectious Mononucleosis; Insomnia; Memory Impairment; Suicidal Ideation; Tremor	Lexapro			S	Oral	5 Mg. Once A Day Po		Not Reported
	Cymbalta			S	Oral	30 Mg. Once A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2008	6814914	EXPEDITED (15-DAY)	Y	HO	1000001553		28 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Zoloft (100 Miligram)			C				Not Reported
	Stangyl (25 Milligram)			C				Not Reported

	Ximovan	C	Not Reported
	Remergil	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2008	6797423	EXPEDITED (15-DAY)	N	HO	US-GENENTECH-270237			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage Intracranial; Maternal Exposure During Pregnancy; Seizure	Xolair			S	Transplacental			Genentech
	Lexapro			S	Transplacental			Not Reported
	Flonase			S	Transplacental			Not Reported
	Advair Diskus			C	Transplacental			Not Reported
	Medrol			C	Transplacental			Not Reported
	Ranitidine			C	Transplacental			Not Reported
	Zyrtec			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2008	6814503	EXPEDITED (15-DAY)	Y	HO	1000001575		42 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Interaction; Gamma-Glutamyltransferase Increased; Hepatic Function Abnormal; Overdose	Escitalopram Oxalate			S		60 Mg (60 Mg, 1 In 1 D)		Not Reported
	Cymbalta			S		30 Mg (30 Mg, 1 In 1 D); 60 Mg (60 Mg, 1 In 1 D); 90 Mg (90 Mg, 1 In 1 D); 150 Mg (150 Mg, 1 In 1 D) 30 Mg (30 Mg, 1 In 1 D); 60 Mg (60 Mg, 1 In 1 D); 90 Mg (90 Mg, 1 In 1 D); 150 Mg (150 Mg, 1 In 1 D) 30 Mg (30 Mg, 1 In 1 D); 60 Mg (60 Mg, 1 In 1 D); 90 Mg (90 Mg, 1 In 1 D); 150 Mg (150 Mg, 1 In 1 D) 30 Mg (30 Mg, 1 In 1 D); 60 Mg (60 Mg, 1 In 1 D);		Not Reported

			90 Mg (90 Mg, 1 In 1 D); 150 Mg (150 Mg, 1 In 1 D) 30 Mg (30 Mg, 1 In 1 D); 60 Mg (60 Mg, 1 In 1 D); 90 Mg (90 Mg, 1 In 1 D); 150 Mg (150 Mg, 1 In 1 D)		
	Cymbalta	S	180 Mg (180 Mg, 1 In 1 D)		Not Reported
	Lamotrigine	S	200 Mg (200 Mg, 1 In 1 D)		Not Reported
	Seroquel	S	700 Mg (700 Mg, 1 In 1 D)		Not Reported
	Tilidine	S	400 Mg (400 Mg, 1 In 1 D)		Not Reported
	Ziprasidone	S	240 Mg (240 Mg, 1 In 1 D)		Not Reported
	Atorvastatin	S	10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Lithium Carbonate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2008	6809521	EXPEDITED (15-DAY)	Y	OT	1000001514		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Partial Seizures	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5mg,1 In 1 D), Oral : 10 Mg (10 Mg,1 In 1 D), Oral : 5 Mg (5 Mg,1 In 1 D) Oral		Not Reported
					Oral	5 Mg (5mg,1 In 1 D), Oral : 10 Mg (10 Mg,1 In 1 D), Oral : 5 Mg (5 Mg,1 In 1 D) Oral		
	Sertraline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2008	6816135	EXPEDITED (15-DAY)	Y	HO, OT	1000001585			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Psychosis; Drug Interaction; Hallucination, Visual	Escitalopram Oxalate		S			Not Reported
	Champix		S	Oral	Oral	Not Reported
	Elymus Repens Top		S			Not Reported
	Unspecified Ingredient		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2008	6829382	EXPEDITED (15-DAY)	Y	DE	CHPA2008US17934		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Aspirin		Y	S	Oral	Oral		Not Reported
	Caffeine			S	Oral	Oral		Not Reported
	Quetiapine Fumarate			S	Oral	Oral		Not Reported
	Acetaminophen\Butalbital\Caffeine			S	Oral	Oral		Not Reported
	Acetaminophen (Paracetamol)			S	Oral	Oral		Not Reported
	Ibuprofen (Ibuprofen)			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Naproxen (Naproxen)			S	Oral	Oral		Not Reported
	Fexofenadine			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2008	6808496	EXPEDITED (15-DAY)	Y	DE	CH-ASTRAZENECA-2008PK02424		39 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Seroquel			S	Oral		6 DAY	Not Reported
	Seroquel			S	Oral		6 DAY	Not Reported
	Cipralex			S	Oral		6 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2008	6815708	DIRECT	N	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Dermatitis Exfoliative; Hypertension; Paraesthesia; Photopsia; Thyroid Cyst; Vertigo; Withdrawal Syndrome	Lexapro			S	Oral	5 Mg Every Other Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2008	6809756	EXPEDITED (15-DAY)	Y	HO	FR-WYE-H06650808		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Hyponatraemia; Seizure; Tremor	Inipomp			S	Oral			Wyeth
	Escitalopram Oxalate			S	Oral			Lundbeck
	Tegretal			S	Oral			Novartis
	Valsartan And Hydrochlorothiazide			S	Oral			Rhone Poulenc Rorer
	Actonel			C		Unknown		Procter And Gamble

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2008	6816261	EXPEDITED (15-DAY)	Y	HO	1000001587		86 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulum Intestinal; Intestinal Ischaemia; Intestinal Ulcer; Rectal Haemorrhage	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin Lysine			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Triatec (Ramipril)			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2008	6816264	EXPEDITED (15-DAY)	Y	HO	1000001595		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anal Incontinence; Body Temperature Decreased; Dehydration; Delirium; Disorientation; Drug Interaction; Drug Level Increased; Dysarthria; Enuresis; Somnolence	Escitalopram Oxalate		S	20 Mg (20 Mg, 1 In 1 D)	Not Reported
	Venlafaxine Hydrochloride		S	See Image See Image See Image	Not Reported
	Remergil		S	15 Mg (15 Mg, 1 In 1 D)	Not Reported
	Ziprasidone		S	20 Mg (20 Mg, 1 In 1 D)	Not Reported
	Quilonorm		C		Not Reported
	Novodigal (.Beta.-Acetyldigoxin)		C		Not Reported
	Enalapril Maleate		C		Not Reported
	Furorese		C		Not Reported
	Arelix		C		Not Reported
	Kalinor		C		Not Reported
	Godamed		C		Not Reported
	Creon		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2008	6776269	EXPEDITED (15-DAY)	Y	CA	1000000956		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Bradycardia Neonatal; Caesarean Section; Dysmorphism; Ear Malformation; Hypotonia Neonatal; Infantile Apnoea; Maternal Drugs Affecting Foetus; Multiple Congenital Abnormalities; Selective Eating Disorder	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported
	Abilify			S	Transplacental	30 Mg (30 Mg, 1 In 1 D), Tranplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2008	6816590	DIRECT	N	LT			51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Anxiety; Bipolar Disorder; Crying; Drug Withdrawal	Cipralex			S	Oral	20mg Daily Po		Lundbeck

Syndrome; Insomnia;
Irritability; Mania;
Paraesthesia; Physical
Assault; Restlessness

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2008	6800676	EXPEDITED (15-DAY)	Y	DE	1000001380		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Stress	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Atenolol			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Sleep Medication Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2008	6805200	EXPEDITED (15-DAY)	Y	HO	1000001433		70 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Previscan (Fluindione)			S	Oral	Oral		Not Reported
	Kerlone			C				Not Reported
	Digoxine			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2008	6819212	DIRECT	N	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anger	Risperdal			S		3 Mg Once A Day		Not Reported
	Lexapro			S		10mg Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2008	6820393	EXPEDITED (15-DAY)	Y	DE	1000001658		40 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel			S	Oral	12.5 Mg (12.5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2008	6820395	EXPEDITED (15-DAY)	Y	OT	1000001682		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metrorrhagia; Proctitis; Rectal Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2008	6815218	EXPEDITED (15-DAY)	Y	HO	US-GENENTECH-271632		64 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Mucosal Inflammation; Neutrophil Count Decreased	Bevacizumab			S	Intravenous (not otherwise specified)	15 Mg/Kg, Q3w		Not Reported
	Taxotere			S	Intravenous (not otherwise specified)	75 Mg/M2, Q3w		Not Reported
	Cisplatin			S	Intravenous (not otherwise specified)	75 Mg/M2, Q3w		Not Reported
	Lexapro			S	Unknown			Not Reported
	Elocon			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2008	6820951	EXPEDITED (15-DAY)	Y	HO	2008S1019713		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Intentional Overdose; Serotonin Syndrome	Dextromethorphan Hydrobromide			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Benzatropine			C				Not Reported
	Aripiprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2008	6640541	EXPEDITED (15-DAY)	Y	OT	S08-FRA-01558-01		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, Once A Day), Oral		Not Reported
	Atarax (Hydroxyzine Hydrochloride)(Hydroxyzine Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2008	6823392	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000001310		87 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Loss Of Consciousness; Malaise	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 N 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Nitriderm(5 Milligram)			C				Not Reported
	Atenolol (200 Milligram)			C				Not Reported
	Corvasal (2 Milligram)			C				Not Reported
	Previscan (Fluindione)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2008	6790327	EXPEDITED (15-DAY)	Y	DE	US-WYE-H06378608		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Pristiq Extended Release	S			Wyeth
	Lexapro	S	Unknown		Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2008	6816450	NON-EXPEDITED	N		A0731228A		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Middle Insomnia; Product Residue Present; Tremor	Bupropion Hydrochloride			S	Oral	100mg See Dosage Text		Glaxosmithkline
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2008	6816664	NON-EXPEDITED	N		A0752013A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychomotor Hyperactivity; Sleep Disorder	Veramyst			S	Nasal	2spr At Night		Glaxosmithkline
	Lexapro			S	Unknown	10mg Per Day		Not Reported
	Valtrex			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2008	6818578	EXPEDITED (15-DAY)	Y	HO	BE-ASTRAZENECA-2008AC02515		46 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicide Attempt	Seroquel Xr			S	Oral			Not Reported
	Escitalopram Oxalate			S		Suicidal Attempt With 20 Capsules Of Sipralexa		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2008	6826095	DIRECT		HO			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alcohol Use; Blood Pressure Systolic Increased; Confusional State; Electrocardiogram Qt Prolonged; Movement Disorder; Overdose; Suicide Attempt	Lexapro	S	Oral	Lexapro Daily 20mg Po	Not Reported
	Xanax	S	Oral	Xanax 1 Mg Po Tid	Not Reported
	Darvocet	C			Not Reported
	Doxepin	C			Not Reported
	Norvasc	C			Not Reported
	Prevacid	C			Not Reported
	Trazodone Hydrochloride	C			Not Reported
	Temazepam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2008	6829970	EXPEDITED (15-DAY)	Y	HO	1000001730		53 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Blood Glucose Increased; Fatigue; Nausea	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Levemir			C				Not Reported
	Hydrokortison Nycomed			C				Not Reported
	Tostrex Gel			C				Not Reported
	Florinef Acetate			C				Not Reported
	Tetralysal			C				Not Reported
	Oxscand			C				Not Reported
	Novorapid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2008	6832258	DIRECT	N	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anger; Autophony; Disturbance In Attention; Feeling Abnormal; Feeling Cold; Feeling Hot; Flushing; Hyperhidrosis; Ill-Defined Disorder; Mydriasis; Night Sweats; Palpitations; Personality Change; Photophobia	Lexapro			S	Oral	10mg Daily Po		Forest
	Trazodone Hydrochloride			C				Not Reported
	Femring			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2008	6833522	EXPEDITED (15-DAY)	N	OT	1000001694		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Splenic Cyst; Vomiting	Lexapro			S	Oral	5 Mg, (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg, (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		
	Clorazepate Dipotassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2008	6843401	DIRECT	N	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Healing; Increased Tendency To Bruise	Citalopram			S	Oral	20mg Daily Po		Aurobindo
	Celexa			S				Not Reported
	Lexapro			S				Not Reported
	Bupropion			C				Not Reported
	Cozaar			C				Not Reported
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2008	6829009	DIRECT	N	HO, OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Irritation; Fungal Infection; Influenza Like Illness; Lethargy; Migraine; Urinary Tract Infection	Escitalopram Oxalate			S		28 Mgs. 1 Daily At Night Protocol No. Sct Md-50		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2008	6820949	EXPEDITED (15-DAY)		OT	US-AVENTIS-200817910US		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased; Hypoaesthesia; Mydriasis; Panic Attack; Paraesthesia	Allegra-D			S	Oral	Dose: Unk		Aventis
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Skelaxin			S		Dose: Unk		Not Reported
	Unspecified Ingredient			S		Dose: Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2008	6821552	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-14418560		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ulcer	Coumadin			S	Oral			Bristol Myers Squibb
	Lexapro			S	Oral	10 Mg Tabs		Not Reported
	Torsemide			C				Not Reported
	Nadolol			C				Not Reported
	Potassium			C				Not Reported
	Clonidine			C				Not Reported
	Meclizine			C				Not Reported
	Monopril			C				Not Reported
	Neurontin			C				Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2008	6832172	EXPEDITED (15-DAY)	Y	OT	1000001756		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Lexapro			S				Not Reported
	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2008	6833381	EXPEDITED (15-DAY)	Y	OT	1000001765		30 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sleep Sex	Lexapro			S	Oral	(10 Mg), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2008	6833383	EXPEDITED (15-DAY)	Y	HO	1000001753		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Dermatitis Allergic; Eyelid Oedema; Face Oedema; Headache; Hypoaesthesia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2008	6824387	EXPEDITED (15-DAY)	N	HO	US-PFIZER INC-2008097011			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyspnoea; Fatigue; Hypotension	Zyvox			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2008	6659966	EXPEDITED (15-DAY)	Y	CA	S08-USA-01791-02		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Craniosynostosis; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental Transplacental Transplacental Transplacental	See Image See Image See Image See Image		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2008	6799289	EXPEDITED (15-DAY)	Y	OT	1000001269		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis; Nausea	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Symbicort			C				Not Reported
	Proventil Hfa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2008	6815051	EXPEDITED (15-DAY)	Y	HO	1000001574		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Hyponatraemia; Seizure; Tremor	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Tegretol			S	Oral	1200 Mg (400 Mg, 3 In 1 D), Oral		Not Reported
	Pantoprazole			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Hydrochlorothiazide\Valsartan			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In D), Oral		Not Reported
	Carbamazepine			S	Oral	1200 Mg (400 Mg, 3 In 1 D), Oral		Not Reported
	Actonel (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2008	6832522	EXPEDITED (15-DAY)	Y	HO, OT	1000001792		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Breast Cancer; Drug Interaction; Dyspnoea; Fatigue;	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Nosocomial Infection; Staphylococcal Infection	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Avonex			C				Not Reported
	Lipitor			C				Not Reported
	Cozaar			C				Not Reported
	Synthroid			C				Not Reported
	Clonazepam			C				Not Reported
	Aspirin			C				Not Reported
	Vitamins (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2008	6835343	EXPEDITED (15-DAY)	Y	HO	US025061		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Clonus; Delirium; Diarrhoea; Dry Mouth; Hyperhidrosis; Hypervigilance; Mydriasis; Sleep Disorder; Suicide Attempt; Tachycardia	Provigil			S	Oral	200 Mg Oral		Not Reported
	Lexapro			S		10 Mg		Not Reported
	Depakote			C				Not Reported
	Amitriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2008	6836649	EXPEDITED (15-DAY)	Y	HO	1000001760		51 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Oedema Peripheral; Overdose	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, (10 Mg, 1 In 1 D), Oral		Not Reported
	Clozapine			C				Not Reported
	Valproate Sodium			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2008	6838982	DIRECT	N	DS, RI, OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Agitation; Anal Haemorrhage; Chondropathy; Derealisation; Diarrhoea; Dyskinesia; Fatigue; Flat Affect; Formication; Headache; Impaired Work Ability; Insomnia; Muscle Disorder; Muscle Spasms; Myalgia; Nausea; Nightmare; Palpitations; Paraesthesia; Pruritus; Pyrexia; Rash; Tremor; Vertigo	Lexapro			S	Oral	10 Mg Daily Po		Forest
	Cetirizine Hydrochloride			C				Not Reported
	Fluticasone Propionate			C				Not Reported
	Levothyronxin			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2008	6841241	EXPEDITED (15-DAY)	Y	HO	1000001815		89 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Sciatica; Urinary Tract Infection Enterococcal	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Previscan (Fluindione)			C				Not Reported
	Lasix			C				Not Reported
	Olmetec			C				Not Reported
	Efferalgan Codeine			C				Not Reported
	Myorelaxing Agents (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2008	6841252	EXPEDITED (15-DAY)	Y	OT	1000001816		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Drug Withdrawal Syndrome; Pain Of Skin	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Escitalopram Oxalate		S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2008	6841919	DIRECT	N	OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Oral	20 Mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2008	6831257	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20081200324		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Interaction; Eye Movement Disorder; Nausea; Suicidal Ideation; Tremor; Visual Impairment; Vomiting	Flexeril			S	Oral			Not Reported
	Elavil			S	Oral			Not Reported
	Phenergan			C	Oral			Not Reported
	Darvocet			C				Not Reported
	Propranolol			C	Oral			Not Reported
	Hctz			C	Oral			Not Reported
	Metformin Hydrochloride			C	Oral			Not Reported
	Xanax			C	Oral			Not Reported
	Synthroid			C	Oral			Not Reported
	Tri-Sprintec			C				Not Reported
	Centrum			C				Not Reported
	Wellbutrin			C	Oral			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Tramadol Hydrochloride			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2008	6792695	EXPEDITED (15-DAY)	Y	HO	1000001137		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaemia; Asthenia; Decreased Appetite; Haematochezia; Haemorrhage; Nausea	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	15 Mg (15 Mg, 1 In 1 D) Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2008	6831764	EXPEDITED (15-DAY)	Y	HO	US-RB-006932-08		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Dysarthria; Flushing; Hyperhidrosis; Hyperreflexia; Lethargy; Muscle Rigidity; Overdose; Pyrexia; Serotonin Syndrome; Sinus Tachycardia; Tremor	Dextromethorphan Hydrobromide			S	Oral	Large Amount Ingested.		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Aripiprazole			S				Not Reported
	Benzatropine			S				Not Reported
	Chlorphenamine			S				Not Reported
	Nicotine			S				Not Reported
	Marijuana			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Phencyclidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2008	6746796	EXPEDITED (15-DAY)	Y	LT	1000000531		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Left Ventricular Failure	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Furosemide			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Spironolactone			C				Not Reported
	Digoxin			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2008	6835614	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20081201102		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Intentional Overdose; Serotonin Syndrome	Flexeril			S		50-60 Mg Once		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2008	6856079	EXPEDITED (15-DAY)	Y	HO, OT	1000002998		65 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alcoholism; Blood Urea Increased; Disturbance In Attention; Encephalopathy; Gait Disturbance; Hypokinesia; Liver Disorder	Escitalopram Oxalate			S	Oral	6 Mg (6 Mg, 1 In 1 D) ,Oral		Not Reported
	Escitalopram Oxalate			S	Oral	4 Mg (4 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2008	6833399	EXPEDITED (15-DAY)	Y	DE	1000001749		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilic Myocarditis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2008	6863762	EXPEDITED (15-DAY)	Y	HO	1000001476		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Extrapyramidal Disorder; Hyponatraemia;	Escitalopram Oxalate			S	Oral	10 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

Macrocytosis; Pallor; Parkinson'S Disease; White Blood Cell Count Increased	Equanil	C		Not Reported
	Pritor	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2008	6841387	EXPEDITED (15-DAY)	Y	OT	FR-ABBOTT-08P-056-0491113-00		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia	Escitalopram Oxalate			S	Oral			Not Reported
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2008	6863580	EXPEDITED (15-DAY)	Y	OT	1000003033		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Intentional Overdose; Somnolence; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S	Oral	100 Mg (100 Mg, Once) , Oral		Not Reported
	Doxycycline			S	Oral	2000 Mg (2000 Mg, Once), Oral		Not Reported
	Acetaminophen			S	Oral	5000 Mg (5000 Mg, Once), Oral		Not Reported
	Tetrazepam			S	Oral	2500 Mg (2500 Mg, Once), Oral		Not Reported
	Alcohol			S	Oral	Half A Bottle Of Hard Liquor		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2008	6863600	EXPEDITED (15-DAY)	Y	OT	1000003021			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vitreous Detachment	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2008	6864097	EXPEDITED (15-DAY)	N	OT	2008S1021274		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Interaction; Eye Movement Disorder; Food Craving; Headache; Nausea; Pruritus Generalised; Suicidal Ideation; Tremor; Visual Impairment; Vitreous Floaters; Vomiting; Weight Increased	Escitalopram Oxalate			S	Oral	10 Mg; Daily; Oral, 10 Mg; Every Other Day; Oral		Not Reported
					Oral	10 Mg; Daily; Oral, 10 Mg; Every Other Day; Oral		
	Amitriptyline Hydrochloride			S	Oral	10 Mg; Daily; Oral		Not Reported
	Tramadol Hydrochloride			S	Oral	50 Mg; Daily; Oral		Not Reported
	Cyclobenzaprine Hydrochloride			S	Oral	10 Mg; Daily; Oral		Not Reported
	Phenergan			C				Not Reported
	Darvocet /00220901/			C				Not Reported
	Propranolol			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Xanax			C				Not Reported
	Synthroid			C				Not Reported
	Tri-Sprintec			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Wellbutrin Xl			C				Not Reported
	Centrum /00554501/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2008	6841781	EXPEDITED (15-DAY)	N	HO	FR-BRISTOL-MYERS SQUIBB COMPANY-14439194		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Malaise	Glucophage			S		Glucophage 500mg, Morning & Evening	1 YR	Bristol Myers Squibb
	Crestor			S			1 YR	Not Reported
	Inexium			S			1 YR	Not Reported
	Escitalopram Oxalate			S			1 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2008	6841907	NON-EXPEDITED	N		US-AMGEN-KDL274198		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous; Rash Pruritic	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Lexapro			S				Not Reported
	Tricor			S				Not Reported
	Verapamil Hydrochloride			S				Not Reported
	Plavix			S				Not Reported
	Niacin			S				Not Reported
	Magnesium Oxide			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Crestor			S				Not Reported
	Flomax			S				Not Reported
	Singulair			S				Not Reported
	Zetia			S				Not Reported
	Protonix			S				Not Reported
	Symlin			S				Not Reported
	Synthroid			S				Not Reported
	Topamax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2008	6864243	EXPEDITED (15-DAY)	Y	HO	1000003036			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Seizure	Escitalopram Oxalate			S		(1 Dose)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2008	6865142	EXPEDITED (15-DAY)	Y	OT	1000003027		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Petit Mal Epilepsy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg), Oral		Not Reported

Folic Acid	C		Not Reported
Salbutamol (Ampoules)	C		Not Reported
Seretide	C		Not Reported
Calcichew D3	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2008	6773930	EXPEDITED (15-DAY)	Y	OT	1000000944		53 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fall; Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	10 Mg (10 Mg 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2008	6866136	EXPEDITED (15-DAY)	Y	OT	1000003117			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	Oral		Not Reported
	Ultram			S	Oral	300 Mg (300 Mg, 1 In 1 D), Oral		Not Reported
	Flexeril			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2008	6827753	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-SYNTHELABO-A02200803454		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Bones Fracture; Fall	Stilnox			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

	Clotiazepam	S	Oral			Not Reported
	Indapamide\Perindopril Erbumine	S	Oral			Not Reported
	Lercanidipine Hydrochloride	S	Oral			Not Reported
	Doliprane	C	Unknown	Unk		Not Reported
	Pravastatin Sodium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2008	6863469	EXPEDITED (15-DAY)	Y	HO	1000003038		90 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective; Dyspnoea; Pulmonary Oedema; Therapeutic Response Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1in 1 D), Oral		Not Reported
	Escitalopram Oxalate			S		10 Mg (10mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral 10 Mg (10mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral 10 Mg (10mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2008	6866552	EXPEDITED (15-DAY)	N	HO	1000003130		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Intentional Self-Injury	Lexapro			S		Oral		Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2008	6867076	EXPEDITED (15-DAY)	Y	HO	1000003101		81 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Drug Interaction; Fall; Fanconi Syndrome; Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate			S		10 Milligram (10 Mg),Oral; 3 Weeks Prior To Hospitalization	3 WEEK	Not Reported
	Hydrochlorothiazide			S				Not Reported
	Mirtazapine			S				Not Reported
	Ramipril			C				Not Reported
	Donepezil Hydrochloride			C				Not Reported
	Alendronic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2008	6867086	EXPEDITED (15-DAY)	Y	OT	1000003121		69 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delirium; Disorientation; Drug Interaction; Hallucination	Lexapro			S				Not Reported
	Tacrolimus			S				Not Reported
	Propoxyphene Hydrochloride			C				Not Reported
	Promethazine			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2008	6867695	EXPEDITED (15-DAY)	Y	OT	1000003132			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2008	6867703	EXPEDITED (15-DAY)	Y	DS	1000003106		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Speech Disorder; Tourette'S Disorder	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2008	6853975	EXPEDITED (15-DAY)	N	OT	A0760418A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Somnolence	Dexedrine			S	Unknown			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Klonopin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2008	6803782	EXPEDITED (15-DAY)	N	DE	1000001403		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Brain Contusion; Completed Suicide; Gun Shot Wound; Homicide; Left Ventricular Hypertrophy; Pulmonary Haemorrhage; Subarachnoid Haemorrhage; Suicidal Ideation; Treatment Noncompliance	Lexapro			S				Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2008	6855456	EXPEDITED (15-DAY)	Y	HO	FR-WYE-G02769908		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fall; Hypertension; Malaise	Effexor			S	Oral	Unknown		Wyeth
	Stilnox			S	Oral	10 Mg Strength; Frequency Unspecified		Not Reported
	Escitalopram Oxalate			S	Oral	Unknown		Lundbeck
	Atacand			S	Oral	8 Mg Strength; Frequency		Not Reported

						Unspecified				
	Vastarel			S	Oral	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2008	6820487	EXPEDITED (15-DAY)	N	DE	US-BRISTOL-MYERS SQUIBB COMPANY-14414346		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Abilify			S	Oral	Start Date Of Treatment:Over A Year Ago.		Not Reported
	Abilify			S	Oral	Start Date Of Treatment:Over A Year Ago.		Not Reported
	Abilify			S	Oral	Start Date Of Treatment:Over A Year Ago.		Not Reported
	Abilify			S	Oral	Start Date Of Treatment:Over A Year Ago.		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2008	6860212	NON-EXPEDITED	N		US-ASTRAZENECA-2008UW23143		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Crestor			S	Oral			Not Reported
	Lexapro			S	Oral		12 MTH	Not Reported
	Lexapro			S	Oral		12 MTH	Not Reported
	Synthroid			S	Oral		15 YR	Not Reported
	Synthroid			S	Oral	100mcg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2008	6870631	DIRECT	Y				50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Lexapro			S		One To Two Tablets Daily	1 YR	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2008	6861387	EXPEDITED (15-DAY)	Y	DE	US-KINGPHARMUSA00001-K200801415		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levoxyl			S	Oral	Unk		King
	Acetaminophen And Codeine			S	Oral	Unk		Not Reported
	Oxycodone			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Unspecified Ingredient			S	Oral	Unk		Not Reported
	Diphenhydramine Hydrochloride			S	Oral	Unk		Not Reported
	Estradiol			S	Oral	Unk		Not Reported
	Progesterone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2008	6861611	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2008153578		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besylate			S				Pfizer
	Atenolol			S				Pfizer
	Trazodone			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Duloxetine			S				Not Reported
	Losartan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2008	6871516	DIRECT	N	DE			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Other	10 Mg Tablet 1 Tablet Every Mor Other		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2008	6871740	DIRECT	N	DS			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Nervous System Disorder	Cymbalta			S		5 1		Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2008	8268283	EXPEDITED (15-DAY)	N	OT	US-KINGPHARMUSA00001-K200801406		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Heart Rate Increased; Hypoaesthesia; Mydriasis; Panic Attack; Paraesthesia	Skelaxin			S		Unk		King
	Allegra-D			S		Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Qd	1 DAY	Not Reported
	Lexapro			S	Oral	5 Mg, Qd	2 DAY	Not Reported
	Unspecified Ingredient			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2008	6871837	DIRECT		HO, OT			20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anger; Condition Aggravated;	Lexapro			S	Oral	20 Mg 2 Pills Once A Day Po		Not Reported

Confusional State; Contusion; Depression; Diabetes Mellitus; Dry Mouth; Eye Irritation; Facial Pain; Headache; Hostility; Hyperphagia; Hypophagia; Mental Disorder; Nasal Discomfort; Sinus Disorder; Tremor; Urine Flow Decreased; Vision Blurred	Wellbutrin	S	Oral	300 Mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2008	6786190	NON-EXPEDITED	Y	OT	US-WYE-H05280808		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations	Pristiq Extended Release			S	Oral	50 Mg 1x Per 1 Day, Oral		Not Reported
	Lexapro			S		25 Mg 1x Per 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2008	6808113	EXPEDITED (15-DAY)	Y	OT	1000001386		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Anxiety; Buccoglossal Syndrome; Drug Interaction	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Sertindole			S	Oral	24 Mg (24 Mg,1 In 1 D), Oral		Not Reported
	Lyrica			S	Occlusive dressing technique Occlusive dressing technique	Oral, 450 Mg (450 Mg, 1 In 1 D), Oral Oral, 450 Mg (450 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			C				Not Reported
	Sertindole (Tablets)			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2008	6809526	EXPEDITED (15-DAY)	Y	HO	1000001507		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dehydration; Fall; Head Injury; Hyponatraemia; Loss Of Consciousness; Neurodegenerative Disorder; Orthostatic Hypotension; Renal Failure	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Clotiazepam			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Zopiclone			S	Oral	Oral		Not Reported
	Amlodipine			S	Oral	(10 Mg), Oral		Not Reported
	Niflumic Acid			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2008	6823221	EXPEDITED (15-DAY)	Y	HO	1000001683		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dizziness; Gastric Ulcer; International Normalised Ratio Increased; Upper Gastrointestinal Haemorrhage; White Blood Cell Count Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Coumadin			S	Oral	(2.5 Mg), Oral		Not Reported
	Torsemide (10 Milligram)			C				Not Reported
	Nadolol (20 Milligram)			C				Not Reported
	Potassium (10 Milliequivalents)			C				Not Reported
	Clonidine (0.1 Milligram)			C				Not Reported
	Meclizine			C				Not Reported
	Monopril			C				Not Reported
	Neurontin			C				Not Reported
	Vitamins (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2008	6863161	EXPEDITED (15-DAY)	Y	OT	GB-ABBOTT-08P-167-0492788-00			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pancreatitis Acute	Escitalopram Oxalate		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2008	6752466	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000000618		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Atrioventricular Block Second Degree; Drug Interaction; Ventricular Extrasystoles	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		
	Abilify			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2008	6816224	EXPEDITED (15-DAY)	Y	HO, OT	1000001647		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral	260 Mg (260 Mg, Once), Oral		Not Reported
	Clindamycin			S	Oral	2100 Mg (2100 Mg, Once), Oral		Not Reported
	Prothipendyl Hydrochloride			S	Oral	40 (40 Once) , Oral		Not Reported
	Stilnox			S	Oral	90 Mg (90 Mg, Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2008	6834656	EXPEDITED (15-DAY)	Y	OT	1000001801		84 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Memantine Hydrochloride			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Aricept			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2008	6865116	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20081205286		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents	Cyclobenzaprine Hydrochloride			S	Oral			Not Reported
	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported
	Nifedipine			S	Oral			Not Reported
	Piroxicam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2008	6871818	EXPEDITED (15-DAY)	Y	DE	1000003238			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S				Not Reported
	Ativan			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2008	6871824	EXPEDITED (15-DAY)	N	DE	1000003193			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2008	6872214	DIRECT	N	HO, OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Coordination Abnormal; Diplopia; Dyspnoea; Feeling Cold; Headache; Hot Flush; Muscular Weakness; Nausea; Palpitations; Tremor; Vertigo; Vision Blurred; Vomiting	Lexapro			S	Oral	1 Dose/ 10mg 1 Time Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2008	6873413	EXPEDITED (15-DAY)	Y	HO	1000003227		76 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bradyphrenia; Dysstasia; General Physical Health Deterioration; Hypochloraemia; Hypokalaemia; Hyponatraemia; Somnolence	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Indapamide\Perindopril			S				Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported
	Prazepam			C				Not Reported
	Fortimel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2008	6779624	EXPEDITED (15-DAY)	Y	OT	1000001022		32 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2008	6820334	EXPEDITED (15-DAY)	Y	HO, LT	1000001678		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Large Intestine Perforation; Rectal Haemorrhage	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tercian (Drops (For Oral Use))			C				Not Reported
	Temesta (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2008	6865973	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2008153710		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Piroxicam			S	Oral			Pfizer
	Escitalopram Oxalate			S	Oral			Not Reported
	Cyclobenzaprine			S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported
	Nifedipine			S	Oral			Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2008	6874024	EXPEDITED (15-DAY)	Y	HO	1000003233		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Seizure	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2008	6878362	EXPEDITED (15-DAY)	Y	CA	1000003244			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy	Lexapro			S	Transplacental	Tranplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2008	6873658	DIRECT	N				18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Dehydration; Feeling Abnormal; Hunger; Hyperhidrosis; Loss Of Libido; Pain; Thirst	Lexapro			S	Oral	10 Mg Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2008	6867844	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20081205548		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2008	6867860	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20081206435		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Acetaminophen And Codeine Phosphate			S	Oral			Not Reported

	Oxycodone		S	Unknown	Not Reported
	Escitalopram Oxalate		S	Unknown	Not Reported
	Levothyroxine		S	Unknown	Not Reported
	Unspecified Ingredient		S	Unknown	Not Reported
	Acetaminophen\Diphenhydramine		S	Unknown	Not Reported
	Estradiol		S	Unknown	Not Reported
	Progestine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2008	6867968	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2008153731		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S				Pfizer
	Gabapentin			S				Pfizer
	Escitalopram Oxalate			S				Not Reported
	Lamotrigine			S				Not Reported
	Alcohol			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2008	6868129	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2008154117		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S	Oral			Pfizer
	Lorazepam			S	Oral			Pfizer
	Escitalopram Oxalate			S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2008	6868276	EXPEDITED (15-DAY)	N	HO, LT	B0551250A		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaemia; Ascites; Pleural Effusion; Splenic Haemorrhage	Arixtra			S	Unknown			Glaxosmithkline
	Escitalopram Oxalate			S	Oral			Unknown
	Rapamycin			S	Intravenous (not otherwise specified)	25mg Per Day	2 DAY	Unknown
	Depakote			C	Unknown			Unknown
	Forlax			C	Unknown			Unknown
	Stilnox			C	Unknown			Unknown
	Visceralgine			C	Unknown			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2008	6868553	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2008AC03380		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Atenolol			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Duloxetine			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2008	6868691	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2008AC03257		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Pulseless Electrical Activity	Quetiapine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2008	6868710	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-		29 YR	Female	USA

2008AC03255

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Quetiapine			S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2008	6706340	EXPEDITED (15-DAY)	Y	OT	S08-FRA-02344-01		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Haemorrhage; Thrombocytopenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2008	6874652	DIRECT	N	DE			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S		10mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2008	6874865	DIRECT	Y	HO, LT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Nausea; Nodal Arrhythmia; Presyncope;	Lexapro			S	Oral	Mg Qday Po		Not Reported
	Tramadol Hydrochloride			C				Not Reported

Vomiting	Protonix	C		Not Reported
	Lyrica	C		Not Reported
	Carbo Levodopa	C		Not Reported
	Lexapro	C		Not Reported
	Vitamin D Nos	C		Not Reported
	Oxcarbazepine	C		Not Reported
	Diazepam	C		Not Reported
	Asa	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2008	6875063	DIRECT	N	DE			46 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Cymbalta			S				Not Reported
	Lexapro			S				Not Reported
	Effexor Xr			S		37.5 - 75 Mg.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2008	6876621	EXPEDITED (15-DAY)	N	OT	1000003317			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lethargy; Seizure	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2008	6879835	EXPEDITED (15-DAY)	Y	DE	1000003265		48 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2008	6772422	EXPEDITED (15-DAY)	Y	OT	ZM-ABBOTT-08P-189-0477277-00		32 YR	Male	ZMB

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity Vasculitis	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2008	6868116	EXPEDITED (15-DAY)		HO	FR-AVENTIS-200814464FR		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Lasix			S	Oral			Aventis
	Levomepromazine			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Anafranil			S	Oral			Not Reported
	Tysabri			S	Intravenous (not otherwise specified)			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Effexor			S	Oral			Not Reported
	Tranxene T-Tab			S	Oral			Not Reported
	Tahor			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2008	6877319	EXPEDITED (15-DAY)	Y	HO	1000003312		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 1 In 1 D) , Oral		Not Reported
	Taxol			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2008	6878072	DIRECT	N	RI			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Disturbance In Sexual Arousal; Paraesthesia; Sexual Dysfunction	Lexapro			S	Oral Oral	1 Once A Day Po 1 Once A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2009	6765736	EXPEDITED (15-DAY)	Y	HO	1000000810		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dyskinesia; Feeling Jittery; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Buscopan (20 Milligram)			C				Not Reported
	Clonazepam (0.5 Milligram, Tablets)			C				Not Reported
	Lorazepam (0.05 Milligram)			C				Not Reported
	Tylenol With Codeine No 3 (Tablets)			C				Not Reported
	Zopiclone (7.5 Milligram, Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2009	6805691	EXPEDITED (15-DAY)	Y	OT	1000001447		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bleeding Time Prolonged; Ecchymosis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2009	6877380	EXPEDITED (15-DAY)	Y	OT	1000003340		50 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Ill-Defined Disorder; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	4 Tablets Once, Oral		Not Reported
	Carbamazepine			S	Oral	3200 Mg, Once, Oral		Not Reported
	Doxepin Hydrochloride			S	Oral	100 Mg, Once, Oral		Not Reported
	Alcohol			S	Oral	2 Glasses Of Wine, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2009	6877466	EXPEDITED (15-DAY)	Y	OT	1000003333		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alcohol Poisoning; Intentional Overdose; Suicide Attempt; Systolic Hypertension	Escitalopram Oxalate			S	Oral	1000 Mg (1000 Mg, Once), Oral		Not Reported
	Dihydrocodeine Bitartrate			S	Oral	120 Mg (120 Mg, Once), Oral		Not Reported
	Alcohol			S	Oral	Once, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2009	6878022	EXPEDITED (15-DAY)	Y	OT	1000003314		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexomil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2009	6822976	EXPEDITED (15-DAY)	Y	HO	1000001676		52 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Chest Discomfort; Clonus; Cognitive Disorder; Demyelination; Drooling;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg), Oral		Not Reported
	Unspecified Ingredient			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Multivitamins And Mineral			C				Not Reported

Dyskinesia; Dysphagia; Hypertension; Hypertonia; Hypomania; Hyponatraemia; Hypophagia; Major Depression; Muscle Rigidity; Musculoskeletal Stiffness; Mutism; Nasal Discomfort; Reduced Facial Expression; Regurgitation; Therapy Non-Responder; Urinary Incontinence; Vomiting Projectile	Supplement

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2009	6873157	EXPEDITED (15-DAY)		LT, OT	ES-ROXANE LABORATORIES, INC.-2008-RO-00468RO		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Asthenia; Dry Skin; General Physical Health Deterioration; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Motor Dysfunction; Mucosal Dryness; Pallor	Lorazepam			S		1mg		Roxane
	Metformin Hydrochloride			S		1275mg		Not Reported
	Amiodarone			S		200mg		Not Reported
	Levothyroxine			S		50mcg		Not Reported
	Enalapril			S		10mg		Not Reported
	Escitalopram Oxalate			S		10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2009	6914785	DIRECT	N	HO, LT, OT			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Suicidal Behaviour	Zoloft			S	Oral	Low Dosage - Don'T Remember Daily Po		Not Reported
	Lexapro			S	Oral	Low Dosage - Don'T Remember Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2009	6878648	EXPEDITED (15-DAY)	Y	HO	1000003370		20 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Confusional State; Diarrhoea; Headache; Skin Burning Sensation; Tearfulness; Vomiting	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, Once), Oral : 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2009	6879183	DIRECT		DE, DS, LT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Lexapro			S				Not Reported
	Cymbalta			S				Not Reported
	Effexor Xr			S		75mg. Internal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2009	6879191	DIRECT	N	DS, RI, OT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Imprisonment; Sexual Abuse	Ambien			S		Various Daily		Not Reported
	Trazodone Hydrochloride			S		Various Daily		Not Reported
	Temazepam			S		Various Daily		Not Reported
	Paxil			S		Various Daily		Not Reported
	Celexa			S		Various Daily		Not Reported
	Restoril			S		Various Daily		Not Reported
	Lexapro			S		Various Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2009	6879993	EXPEDITED (15-DAY)	Y	CA	1000003363			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Neonatal Disorder; Pyelocaliectasis; Ureteric Obstruction; Vesicoureteric Reflux	Lexapro			S	Transplacental	(20 Mg), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2009	6887386	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Feeling Abnormal; Gastric Disorder; Headache; Nausea; Vomiting	Bupropion			S	Oral	150 Mg Once Qd Po		Not Reported
					Oral	150 Mg Once Qd Po		
	Lexapro			S	Oral	10 Mg Once Po Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2009	4028290	EXPEDITED (15-DAY)	Y	DE	000103		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Completed Suicide; Intentional Product Misuse	Alprazolam			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Lamotrigine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2009	6862740	EXPEDITED (15-DAY)	Y	DS, HO	1000003070		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Artificial Menopause; Generalised Tonic-Clonic Seizure;	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),		Not Reported

Hand Fracture; Premature Menopause; Spinal Fracture; Tremor	Flexeril	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2009	6876127	EXPEDITED (15-DAY)	N	HO, OT	FR-PFIZER INC-2009150668			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Tahor			S	Oral	Every Day Tablets		Pfizer
	Lyrica			S	Oral	600 Mg, Unk		Pfizer
	Levomepromazine			S	Oral	25 Mg, 1x/Day		Not Reported
	Furosemide			S	Oral	20 Mg, 1x/Day		Not Reported
	Rivotril			S	Oral	2 Mg, Unk		Not Reported
	Anafranil			S	Oral	50 Mg, Unk		Not Reported
	Tysabri			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, Unk		Not Reported
	Effexor			S	Oral	75 Mg, Unk		Not Reported
	Tranxene T-Tab			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2009	6876282	EXPEDITED (15-DAY)	Y	OT	ES-JNJFOC-20090100169		89 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Psychotic Disorder	Reminyl			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Lormetazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2009	6881075	EXPEDITED (15-DAY)	Y	DE	DSA_32973_2009			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Ativan	S	Df		Not Reported
	Lexapro	S	Df		Not Reported
	Alcohol	S	Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2009	6881191	EXPEDITED (15-DAY)	N	HO, OT	1000003414		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Herpes Zoster; Imprisonment; Scar; Trigeminal Nerve Disorder	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2009	6881258	EXPEDITED (15-DAY)	Y	DE	000099		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse	Alprazolam			S				Not Reported
	Lorazepam			S				Not Reported
	Acetaminophen			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2009	6887171	EXPEDITED (15-DAY)	Y	DE	8040739		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse	Hydrocodone Bitartrate And Acetaminophen			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2009	6901646	EXPEDITED (15-DAY)	N	OT	B0552853A		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Type 2 Diabetes Mellitus	Fluticasone Propionate\Salmeterol Xinafoate			S	Respiratory (inhalation)			Glaxosmithkline
	Escitalopram Oxalate			S	Oral	30mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2009	7320184	EXPEDITED (15-DAY)	Y	DE	8040746		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse	Hydrocodone Bitartrate & Acetaminophen			S				Not Reported
	Bupropion			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2009	6782703	EXPEDITED (15-DAY)	Y	HO, OT	PT-PFIZER INC-2008083150			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Drug Interaction; Hallucination, Visual	Champix			S	Oral			Pfizer
	Unspecified Ingredient			C				Not Reported
	Trazodone Hydrochloride			S	Oral			Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2009	6722037	EXPEDITED (15-DAY)	Y	HO	1000000179		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism; Therapy Non-Responder	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2009	6878445	EXPEDITED (15-DAY)	N	OT	A0762895A		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Asthenia; Confusional State; Dizziness; Drug Interaction; Feeling Abnormal; Limb Injury; Localised Infection; Loss Of Consciousness; Pain In Extremity; Tremor; Withdrawal Syndrome	Bupropion			S	Oral	150mg Per Day		Glaxosmithkline
	Humira			S	Subcutaneous			Not Reported
	Vicodin			S	Oral	3tab Per Day		Not Reported
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Chlormezanone			S				Not Reported
	Amitriptyline			S	Oral	75mg At Night		Not Reported
	Rizatriptan Benzoate			S	Oral	10mg Per Day		Not Reported
	Pregabalin			S	Oral	50mg Twice Per Day		Not Reported
	Celecoxib			S	Oral	200mg Per Day		Not Reported
	Cyclobenzaprine Hydrochloride			S	Oral	10mg Three Times Per Day		Not Reported
	Unspecified Ingredient			S	Oral	100mg Twice Per Day		Glaxosmithkline
	Clindamycin			S	Oral	100mg Three Times Per Day	7 DAY	Not Reported
	Tetanus Toxoid Nos			S	Intramuscular			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2009	6879194	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20090101314		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Interaction; Loss Of Consciousness; Pain In Extremity; Tremor	Cyclobenzaprine Hydrochloride			S	Oral	As Needed		Not Reported
	Humira			S		40mg/0.8ml		Not Reported
	Vicodin			S		5/500, 3 Times Daily, As Needed		Not Reported
	Lexapro			S	Oral			Not Reported
	Chlormezanone			S	Oral			Not Reported

	Amitriptyline	S	Oral	Not Reported
	Rizatriptan Benzoate	S	Oral	Not Reported
	Pregabalin	S	Oral	Not Reported
	Celecoxib	S	Oral	Not Reported
	Bupropion	S	Oral	Not Reported
	Minocycline\Minocycline Hydrochloride	S	Oral	Not Reported
	Clindamycin	S	Oral	Not Reported
	Tetanus Toxoid Nos	S	Intramuscular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2009	6879507	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2009152367			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Orthostatic Hypotension	Amlodipine Besylate			S	Oral			Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Amisulpride			S	Oral	Unk		Not Reported
	Rilmenidine			S	Oral	Unk		Not Reported
	Acepromazine\Meprobamate			S	Oral	Unk		Not Reported
	Acetaminophen\Propoxyphene Hydrochloride			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2009	6889849	DIRECT	N				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Lexapro			S	Oral	10 Mg Daily Po	5 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2009	6881169	EXPEDITED (15-DAY)	Y	DE	US-MERCK-0901USA00949		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Overdose	Cozaar		S	Oral	Merck
	Atenolol		S	Oral	Not Reported
	Trazodone Hydrochloride		S	Oral	Not Reported
	Amlodipine		S	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Not Reported
	Duloxetine Hydrochloride		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2009	6887232	EXPEDITED (15-DAY)	Y	HO	1000003439		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Dilatation; Cerebrovascular Accident; Cognitive Disorder; Disorientation; Hyponatraemia; Oedema Peripheral	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Celebrex			S	Oral	200 Mg (200 Mg, 1 In 1 D), Oral		Not Reported
	Hydrochlorothiazide\Valsartan			C				Not Reported
	Mopral			C				Not Reported
	Esidrex			C				Not Reported
	Urbanyl			C				Not Reported
	Dafalgan			C				Not Reported
	Propoxyphene Hydrochloride And Acetaminophen			C				Not Reported
	Motilium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2009	6891256	DIRECT	N	OT			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Burning Sensation; Feeling Abnormal; Feeling Hot; Mental Disorder; Pain; Paraesthesia; Pruritus; Sensory Disturbance;	Lexapro			S		Daily		Not Reported
	Effexor Xr			S		Daily		Not Reported
	Lamictal			S		Daily		Not Reported
	Celexa			S		Daily		Not Reported

Shock	Remeron	S	Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2009	6796593	EXPEDITED (15-DAY)	Y	HO, OT	1000001307		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akathisia; Choreoathetosis; Drug Interaction; Hypomania; Nervousness	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Paliperidone			S		6 Mg (6 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2009	6881983	NON-EXPEDITED	N		US-BAYER-200814635BCC		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Mental Disorder	Aleve			S	Oral			Bayer
	Lexapro			S	Oral	Total Daily Dose: 20 Mg Unit Dose: 20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2009	6887697	EXPEDITED (15-DAY)	Y	DE	DSA_33014_2009		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Product Misuse; Respiratory Arrest	Nifedipine			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Cyclobenzaprine Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Acetaminophen			S	Oral	(Df Oral)		Not Reported
	Bupropion			S	Oral	(Df Oral)		Not Reported
	Alcohol			S	Oral	(Df Oral)		Not Reported
	Piroxicam			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2009	6888094	EXPEDITED (15-DAY)	Y	OT	1000003493			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2009	6888270	EXPEDITED (15-DAY)	N	OT	S08-USA-01768-01		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Maternal Exposure During Pregnancy; Mood Swings; Paraesthesia; Paranoia; Postpartum Haemorrhage; Pregnancy	Lexapro			S	Oral	1 In 1 D, Oral; 20 Mg (20 Mg, 1 In 1 D), Oral ; 10 Mg, (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	1 In 1 D, Oral; 20 Mg (20 Mg, 1 In 1 D), Oral ; 10 Mg, (10 Mg, 1 In 1 D), Oral		
					Oral	1 In 1 D, Oral; 20 Mg (20 Mg, 1 In 1 D), Oral ; 10 Mg, (10 Mg, 1 In 1 D), Oral		
					Oral	1 In 1 D, Oral; 20 Mg (20 Mg, 1 In 1 D), Oral ; 10 Mg, (10 Mg, 1 In 1 D), Oral		
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2009	6888310	EXPEDITED (15-DAY)	Y	DE, HO	PAR_02529_2009		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse; Poisoning	Meloxicam			S	Oral	Df, Oral		Not Reported
	Propoxyphene Hydrochloride And Acetaminophen			S	Oral	Df, Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df, Oral		Not Reported
	Unspecified Ingredient			S	Oral	Df, Oral		Not Reported

	Celecoxib			S	Oral	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2009	6888330	EXPEDITED (15-DAY)	Y	HO, LT	GXKR2009AU00536		82 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Coma; Delirium; Disorientation; Endotracheal Intubation; Fall; Gait Disturbance; Illusion; Intentional Overdose; Loss Of Consciousness; Lung Abscess; Mechanical Ventilation; Movement Disorder; Pleural Effusion; Pneumonia Aspiration; Productive Cough; Rhabdomyolysis; Serratia Infection; Staphylococcal Infection; Suicide Attempt	Escitalopram Oxalate			S				Not Reported
	Oxazepam			S				Not Reported
	Sulfamethoxazole\Trimethoprim			S	Oral	1 Df, Q12h; 2 Df, Q12h, Hospital 35-48, Oral	22 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2009	6889127	EXPEDITED (15-DAY)	Y	LT	1000003453		34 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate			S	Oral	(20 Mg), Oral		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6809536	EXPEDITED (15-DAY)	Y	OT	1000001505		60 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Heart Rate Irregular; Malaise;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D)		Not Reported

Musculoskeletal Pain; Ventricular Extrasystoles			,Oral		
	Zurcal (Tablets)	C			Not Reported
	Xalatan	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6816262	EXPEDITED (15-DAY)	Y	HO, LT	1000001596		62 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Haemodialysis; Nephropathy Toxic; Renal Failure; Tubulointerstitial Nephritis	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D) ,Oral		Not Reported
	Alopam (10 Milligram, Tablets)			C				Not Reported
	Crestor			C				Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6883136	EXPEDITED (15-DAY)		DE	US-ABBOTT-09P-163-0497810-00		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levothyroxine			S		Ingestion		Not Reported
	Acetaminophen			S		Ingestion		Not Reported
	Escitalopram Oxalate			S		Ingestion		Not Reported
	Codeine			S		Ingestion		Not Reported
	Oxycodone			S		Ingestion		Not Reported
	Unspecified Ingredient			S		Ingestion		Not Reported
	Diphenhydramine			S		Ingestion		Not Reported
	Estradiol			S		Ingestion		Not Reported
	Progestine			S		Ingestion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6883336	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14013106			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Screen Positive; Urine Odour Abnormal	Abilify			S	Oral			Not Reported
	Provigil			S				Not Reported
	Keppra			S				Not Reported
	Lexapro			S				Not Reported
	Lamictal			S				Not Reported
	Levothyroxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6884386	NON-EXPEDITED	Y		PR-BRISTOL-MYERS SQUIBB COMPANY-14327126			Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Abilify			S		1/2 Tablet,As Adjunctive Therapy		Not Reported
	Abilify			S		1/2 Tablet,As Adjunctive Therapy		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6884426	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14336150		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S		Began 1 1/2 Years Ago, Stopped And Restarted 2 Times		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6884530	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-14351779		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Galactorrhoea; Hyperprolactinaemia	Abilify		S	Dose Reduced To 2.5 Mg And Was Possibly Withdrawn.	20 MTH	Not Reported
	Fluoxetine		S			Not Reported
	Lexapro		S			Not Reported
	Cymbalta		S			Not Reported
	Strattera		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6884598	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-14362313			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Restlessness	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6884662	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-14369326		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Crying; Feeling Jittery	Abilify			S		Interrupted & Restarted On 7oct08. 1/2 Tab On Day 1 And 1/2 Tab On Day 2. Then Discontinued.		Not Reported
	Abilify			S		Interrupted & Restarted On 7oct08. 1/2 Tab On Day 1 And 1/2 Tab On Day 2. Then Discontinued.		Not Reported
	Abilify			S		Interrupted & Restarted On 7oct08. 1/2 Tab On Day 1 And 1/2 Tab On Day 2. Then Discontinued.		Not Reported
	Topamax			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6884786	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14382543			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6885019	EXPEDITED (15-DAY)		DE	US-ABBOTT-09P-163-0497579-00		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone			S		Route: Ingestion		Not Reported
	Escitalopram Oxalate			S		Route: Ingestion		Not Reported
	Trazodone Hydrochloride			S		Route: Ingestion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6885336	EXPEDITED (15-DAY)		DE	US-ABBOTT-09P-163-0497839-00		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S		Route: Ingestion		Not Reported
	Escitalopram Oxalate			S		Route: Ingestion		Not Reported
	Bupropion			S		Route: Ingestion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6890193	EXPEDITED (15-DAY)	Y	LT	1000003508		84 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; General Physical Health Deterioration;	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Omeprazole			S	Oral	Oral		Not Reported

Pancytopenia	Nicorandil	S	Oral	Oral		Not Reported
	Nicorandil	S	Oral	Oral		Not Reported
	Zolpidem	S	Oral	Oral		Not Reported
	Acetaminophen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6892632	EXPEDITED (15-DAY)	Y	DE	DSA_32989_2009		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Lorazepam			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S		(Df)		Not Reported
	Alprazolam			S		(Df)		Not Reported
	Acetaminophen			S		(Df)		Not Reported
	Quetiapine			S		(Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2009	6892706	EXPEDITED (15-DAY)	N	OT	S08-USA-01838-01		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Diarrhoea; Dizziness; Maternal Exposure During Pregnancy; Nausea; Pregnancy; Vaginal Haemorrhage	Lexapro			S	Oral Oral	10 Mg (10 Mg, 1 In 1 D) ,Oral; 20 Mg (20 Mg, 1 In 1 D) ,Oral 10 Mg (10 Mg, 1 In 1 D) ,Oral; 20 Mg (20 Mg, 1 In 1 D) ,Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2009	6886521	EXPEDITED (15-DAY)	Y	DE	US-BRISTOL-MYERS SQUIBB COMPANY-14470447		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Trazodone Hydrochloride			S	Oral			Apothecon

	Atenolol			S	Oral				Sandoz
	Amlodipine			S	Oral				Not Reported
	Escitalopram Oxalate			S	Oral				Not Reported
	Duloxetine Hydrochloride			S	Oral				Not Reported
	Losartan Potassium			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2009	6886543	EXPEDITED (15-DAY)	Y	DE	US-BRISTOL-MYERS SQUIBB COMPANY-14469928		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Trazodone Hydrochloride			S	Oral			Apothecon
	Acetaminophen\Hydrocodone Bitartrate			S	Oral			Endo
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2009	6886654	EXPEDITED (15-DAY)	Y	DE	US-BRISTOL-MYERS SQUIBB COMPANY-14472617		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Trazodone Hydrochloride			S	Oral			Apothecon
	Acetaminophen			S	Oral			Cadence
	Oxcarbazepine			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Benzodiazepine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2009	6821501	EXPEDITED (15-DAY)	Y	OT	1000001582		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Amnesia; Anger; Anxiety; Aphasia; Asbestosis; Attention Deficit/Hyperactivity Disorder; Back Pain; Blood Cholesterol Increased; Blood Triglycerides Abnormal; Bruxism; Condition Aggravated; Constipation; Decreased Appetite; Depression; Dialysis; Emotional Distress; Feeling Abnormal; Hallucination; Headache; Hyperhidrosis; Hypertension; Hypophagia; Hypothyroidism; Incorrect Dose Administered; Insomnia; Lethargy; Loss Of Personal Independence In Daily Activities; Mental Disorder; Muscle Spasms; Muscle Twitching; Night Sweats; Nightmare; Pain; Pallor; Pancreatitis; Panic Attack; Paranoia; Renal Failure; Restless Legs Syndrome; Road Traffic Accident; Screaming; Sedation; Seizure; Sleep Apnoea Syndrome; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Tachycardia; Tardive Dyskinesia; Terminal Insomnia; Thyroid Disorder; Treatment Noncompliance; Tremor;	Lexapro	S	Oral	Oral	Not Reported
	Xanax	S			Not Reported
	Zoloft	S			Not Reported
	Neurontin	S			Not Reported
	Trazodone Hydrochloride	S			Not Reported
	Seroquel	S			Not Reported
	Wellbutrin	S			Not Reported
	Restoril	S			Not Reported
	Cymbalta	S			Not Reported
	Effexor	S			Not Reported
	Fenofibrate	C			Not Reported
	Levothyroxine	C			Not Reported
	Ambien	C			Not Reported
	Hydrochlorothiazide	C			Not Reported
	Acetaminophen\Hydrocodone Bitartrate	C			Not Reported
	Carisoprodol	C			Not Reported
	Lisinopril	C			Not Reported

Urinary Incontinence; Vomiting; Weight Decreased; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2009	6892571	EXPEDITED (15-DAY)	Y	DE	IMP_04058_2009		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Alprazolam			S		Df		Not Reported
	Escitalopram Oxalate			S		Df		Not Reported
	Lamotrigine			S		Df		Not Reported
	Gabapentin			S		Df		Not Reported
	Alcohol			S		Df		Not Reported
	Unspecified Ingredient			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2009	6892575	EXPEDITED (15-DAY)	Y	DE	IMP_04055_2009		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Alprazolam			S	Oral	Df Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df Oral		Not Reported
	Lorazepam			S	Oral	Df Oral		Not Reported
	Acetaminophen			S	Oral	Df Oral		Not Reported
	Quetiapine			S	Oral	Df Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2009	6894441	EXPEDITED (15-DAY)	Y	DE	IMP_04193_2009		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning Deliberate	Oxycodone			S	Oral	(Df Oral)		Not Reported

	Acetaminophen And Codeine Phosphate	S		(Df Oral)	Not Reported
	Escitalopram Oxalate	S	Oral	(Df Oral)	Not Reported
	Levothyroxine	S	Oral	(Df Oral)	Not Reported
	Unspecified Ingredient	S	Oral	(Df Oral)	Not Reported
	Acetaminophen\Diphenhydramine	S	Oral	(Df Oral)	Not Reported
	Estradiol	S	Oral	(Df Oral)	Not Reported
	Progesterone	S	Oral	(Df Oral) , (Df Oral)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2009	6895646	DIRECT	N	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression	Lexapro			S	Oral	10mg Then Upped To 20mg Once A Day Po		Not Reported
	Trazodone Hydrochloride			S	Oral	100mg- 1 D Po		Not Reported
	Ambien Cr			S	Oral	L N Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2009	6896335	EXPEDITED (15-DAY)	Y	HO, LT	1000003529		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Leukocytosis; Pleural Effusion; Splenic Haemorrhage; Thrombocytosis	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Temsirolimus			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	25 Mg (25 Mg, 1 In 1 D), Intravenous; 25 Mg (25 Mg, 1 In 1 D), Intavenous 25 Mg (25 Mg, 1 In 1 D), Intravenous; 25 Mg (25 Mg, 1 In 1 D), Intavenous		Not Reported
	Arixtra			S				Not Reported
	Visceralgine			C				Not Reported
	Depakote			C				Not Reported
	Forlax			C				Not Reported

	Stilnox	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2009	6896501	EXPEDITED (15-DAY)	N	OT	1000003471			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Heart Rate Decreased; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental; 20 Mg (20 Mg, 1 In 1 D),Transplacental		Not Reported
					Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental; 20 Mg (20 Mg, 1 In 1 D),Transplacental		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2009	6897316	EXPEDITED (15-DAY)	Y	DE	1000003556		34 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolam			C				Not Reported
	Tahor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2009	7437756	EXPEDITED (15-DAY)	Y	DE	PAR_02513_2009		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning Deliberate	Amlodipine			S	Oral	(Df Oral)		Not Reported
	Atenolol			S	Oral	(Df Oral)		Not Reported
	Trazodone Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Duloxetine			S	Oral	(Df Oral)		Not Reported

	Losartan Potassium	S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2009	6737811	EXPEDITED (15-DAY)	Y	HO	1000000375		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diarrhoea; Fatigue; Flatulence; Haematemesis; Scan Adrenal Gland Abnormal; Uterine Leiomyoma	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D) ,Oral; Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D) ,Oral; Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2009	6882870	EXPEDITED (15-DAY)	Y	HO	1000003431		44 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Choluria; Hepatitis Cholestatic	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D) ,Oral; 15 Mg (15 Mg, 1 In 1 D) ,Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D) ,Oral; 15 Mg (15 Mg, 1 In 1 D) ,Oral		
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2009	6900052	EXPEDITED (15-DAY)	Y	OT	1000003557		30 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutrophil Count Decreased; Platelet Count Decreased; White Blood Cell Count Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D) ,Oral		Not Reported
	Depakote			S	Oral	1000 Mg (500 Mg, 2 In 1 D) ,Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2009	6900287	EXPEDITED (15-DAY)	Y	DE	IMP_04138_2009		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning Deliberate	Bupropion			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Acetaminophen\Hydrocodone			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2009	6901182	EXPEDITED (15-DAY)	Y	DE	IMP_04118_2009		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Cardiac Arrest; Poisoning; Respiratory Arrest	Bupropion Hydrochloride			S	Oral	Df Oral		Not Reported
	Alcohol			S	Oral	Df Oral		Not Reported
	Tramadol Hydrochloride			S	Oral	Df Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2009	6839882	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2008101316			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Xanax			S	Oral	0.5 Mg, 1x/Day		Pfizer
	Zolpidem			S	Oral	1 Df Daily Every Day Tdd:1 Df		Not Reported
	Escitalopram Oxalate			S	Oral	1 Df Daily Every Day Tdd:1 Df		Not Reported
	Indapamide\Perindopril Erbumine			S	Oral	*4mg/1.25mg Daily Every Day Tdd:4mg/1.25		Not Reported
	Lercanidipine Hydrochloride			S	Oral	1 Df, 1x/Day		Not Reported
	Pravastatin			C				Not Reported
	Paracetamol			C				Not Reported

Macrogol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2009	6862637	EXPEDITED (15-DAY)	N	HO, LT	BR-GENENTECH-273165		49 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma	Xolair			S	Subcutaneous	300 Mg, 2/Week		Genentech
	Xolair			S	Subcutaneous	Unk		Genentech
	Lexapro			S				Not Reported
	Foraseq (Brazil)			C				Not Reported
	Spiriva			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2009	6889769	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009US-20865			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Meloxicam			S	Oral			Ranbaxy
	Escitalopram Oxalate			S	Oral	Unk, Unk		Not Reported
	Celecoxib			S	Oral			Not Reported
	Propoxyphene Hydrochloride And Acetaminophen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2009	6889865	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009US-20959			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen			S	Oral			Ranbaxy
	Escitalopram Oxalate			S	Oral	Unk, Unk		Not Reported
	Alprazolam			S	Oral			Not Reported
	Lorazepam			S	Oral			Ranbaxy
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2009	6899342	EXPEDITED (15-DAY)	Y	OT	2009S1000630		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate			S				Not Reported
	Linezolid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2009	6856102	EXPEDITED (15-DAY)	Y	HO, LT	1000002979		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Asphyxia; Condition Aggravated; Disturbance In Attention; Drug Withdrawal Syndrome; Dyspnoea; Irritability; Malaise; Pharyngeal Oedema; Self-Medication; Speech Disorder; Swollen Tongue	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D) ,Oral		Not Reported
	Stresam			C				Not Reported
	Triella (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2009	6876997	EXPEDITED (15-DAY)	Y	DE	US-BAYER-200910098GPV		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Acetaminophen		Y	S	Oral			Bayer
	Nifedipine			S	Oral			Bayer
	Piroxicam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Cyclobenzaprine Hydrochloride			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2009	6891486	EXPEDITED (15-DAY)	Y	OT	FR-ABBOTT-09P-056-0498576-00		30 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutrophil Count Decreased; Platelet Count Decreased; White Blood Cell Count Decreased	Depakote			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2009	6901541	EXPEDITED (15-DAY)	Y	DE	1000003591		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D) ,Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2009	6903330	EXPEDITED (15-DAY)	Y	DE	PAR_02783_2009		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning Deliberate	Alprazolam			S		(Df)		Not Reported
	Escitalopram Oxalate			S		(Df)		Not Reported
	Lamotrigine			S		(Df)		Not Reported
	Gabapentin			S		(Df)		Not Reported
	Alcohol			S		(Df)		Not Reported
	Unspecified Ingredient			S		(Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2009	6903340	EXPEDITED (15-DAY)	Y	DE	PAR_02778_2009		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Poisoning Deliberate	Alprazolam		S	Oral	(Df Oral)	Not Reported
	Quetiapine		S	Oral	(Df Oral)	Not Reported
	Escitalopram Oxalate		S	Oral	(Df Oral)	Not Reported
	Lorazepam		S	Oral	(Df Oral)	Not Reported
	Acetaminophen		S	Oral	(Df Oral)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2009	6858753	EXPEDITED (15-DAY)	Y	HO, OT	1000003005		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Cervical Vertebral Fracture; Condition Aggravated; Fall; Sedation; Somnolence; Thrombocytopenia; Type 2 Diabetes Mellitus; Violence-Related Symptom	Lexapro			S	Oral Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Xanax			S	Oral	0.5 Mg (0.5 Mg, As Required), Oral		Not Reported
	Lisinopril			C				Not Reported
	Protonix			C				Not Reported
	Norvasc			C				Not Reported
	Cinnamon			C				Not Reported
	Carafate			C				Not Reported
	Miralax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2009	6888084	EXPEDITED (15-DAY)	Y	HO	1000003457		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Blood Pressure Diastolic	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D)		Not Reported

Decreased; Drug Interaction; Malaise; Syncope	Levaxin (Tablets)			C	,Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2009	6893918	EXPEDITED (15-DAY)	Y	DE	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2009-DE-00		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Abuse	Meloxicam			S				Boehringer Ingelheim
	Propoxyphene Hydrochloride And Acetaminophen			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Celecoxib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2009	6902819	DIRECT	N	RI			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaesthesia; Anhedonia; Anorgasmia; Condition Aggravated; Depression; Ejaculation Delayed; Ejaculation Disorder; Genital Disorder Male; Libido Decreased	Lexapro			S	Oral	10mg 1 Daily Po	3 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2009	6575575	EXPEDITED (15-DAY)	Y	CA, DE	S08-USA-00471-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Limb Reduction Defect; Maternal Drugs Affecting Foetus; Skull	Lexapro			S	Transplacental	Transplacental		Not Reported
	Rebif			S	Transplacental	44 Mcg, Three Times Per Week, Transplacental		Not Reported

Malformation; Stillbirth	Neurontin		S	Transplacental	Transplacental	Not Reported
	Meclizine		S	Transplacental	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2009	6894090	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009RR-21001		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Suicidal Ideation	Gabapentin			S	Oral			Ranbaxy
	Lamotrigine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported
	Unspecified Ingredient			S	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2009	6894102	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009RR-21018		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen			S	Oral			Ranbaxy
	Escitalopram Oxalate			S	Oral			Not Reported
	Cyclobenzaprine Hydrochloride			S	Oral			Ranbaxy
	Bupropion			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported
	Nifedipine			S	Oral			Not Reported
	Piroxicam			S	Oral			Agvar Chemicals

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2009	6894523	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20090106401		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Drug Interaction; Hypertonia; Orthostatic Hypotension; Status Epilepticus	Tramadol Hydrochloride And Acetaminophen		S	Oral	Not Reported
	Aricept		S	Unknown	Not Reported
	Hydrochlorothiazide\Valsartan		C	Unknown	Not Reported
	Calcium		C	Unknown	Not Reported
	Fosamax		C		Not Reported
	Escitalopram Oxalate		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2009	6894705	EXPEDITED (15-DAY)	N	OT	AU-SANOFI-SYNTHELABO-A01200900474			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cerebrovascular Accident; Inappropriate Schedule Of Product Administration	Lexapro			S	Oral			Not Reported
	Stilnox			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2009	6894771	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20090104313		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased; Overdose	Acetaminophen\Diphenhydramine		Y	S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2009	6904617	EXPEDITED (15-DAY)	Y	DS	1000003655		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Urinary Incontinence	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D) ,Oral		Not Reported

	Escitalopram Oxalate	S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2009	6895070	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009US-21217			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Atenolol			S	Oral	Unk, Unk		Ohm Lab
	Amlodipine			S	Oral			Ranbaxy
	Trazodone Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Duloxetine			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2009	6895684	NON-EXPEDITED	N		A0702781A		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Drug Interaction; Psychomotor Hyperactivity	Wellbutrin			S				Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Ambien			S	Unknown			Not Reported
	Unspecified Ingredient			S	Unknown			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2009	6895756	NON-EXPEDITED	N		A0729964A		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Glossitis; Headache	Wellbutrin			S	Oral	75mg Three Times Per Day		Glaxosmithkline
	Lexapro			S		10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2009	6898249	EXPEDITED (15-DAY)	Y	DE	1000003543		15 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg, (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral,		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg, (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral,		
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg, (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral,		
	Lerginan			C				Not Reported
	Triobe (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2009	6905766	EXPEDITED (15-DAY)	Y	OT	1000003657			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2009	6905821	EXPEDITED (15-DAY)	Y	OT	1000003652			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperacusis	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2009	6725505	EXPEDITED (15-DAY)	Y	HO	1000000234		64 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Withdrawal Syndrome; Gastritis; Gastrooesophageal Reflux Disease; Hepatic Fibrosis; Hepatic Steatosis; Hepatitis Cholestatic; Oesophageal Ulcer; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Hydrochlorothiazide\Irbesartan			S	Oral	(2 In 1 M), Oral		Not Reported
	Unspecified Ingredient			C				Not Reported
	Benerva			C				Not Reported
	Importal			C				Not Reported
	Supradyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2009	6889281	EXPEDITED (15-DAY)	N	OT	ES-BRISTOL-MYERS SQUIBB COMPANY-14477640			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amylase Increased; Lipase Increased	Baraclude			S				Bristol Myers Squibb
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2009	6897054	EXPEDITED (15-DAY)	N	OT	US-MERCK-0901USA01520		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Dizziness; Drug Interaction; Feeling Abnormal; Limb Injury; Localised Infection; Loss Of Consciousness; Pain In Extremity; Tremor; Withdrawal Syndrome	Maxalt			S	Oral			Merck
	Flexeril			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Vicodin			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Chlormezanone			S	Oral			Not Reported
	Elavil			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported

Celecoxib	S	Oral		Not Reported
Bupropion Hydrochloride	S	Oral		Not Reported
Minocycline\Minocycline Hydrochloride	S	Oral		Not Reported
Clindamycin	S	Oral		Not Reported
Tetanus Toxoid Nos	S	Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2009	6899552	EXPEDITED (15-DAY)	Y	HO	1000003609		35 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatitis	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2009	6907532	EXPEDITED (15-DAY)	Y	HO	1000003665			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Overdose; Unresponsive To Stimuli	Escitalopram Oxalate			S	Oral	90 Mg (90 Mg, Once), Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2009	6907558	EXPEDITED (15-DAY)	Y	DE	1000003683			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2009	6907581	EXPEDITED (15-DAY)	Y	HO	1000003689			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Seizure	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D) Oral		Not Reported
	Aspirin Lysine	C				Not Reported
	Unspecified Ingredient	C				Not Reported
	Unspecified Ingredient	C				Not Reported
	Prazepam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2009	6909529	EXPEDITED (15-DAY)	Y	HO	1000003695		77 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Loss Of Consciousness; Malaise	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Avodart			C				Not Reported
	Aspirin Lysine			C				Not Reported
	Plavix			C				Not Reported
	Omexel			C				Not Reported
	Celiprolol			C				Not Reported
	Coversyl			C				Not Reported
	Crestor			C				Not Reported
	Timoptic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2009	6710135	EXPEDITED (15-DAY)	Y	DE	ZA-ASTRAZENECA-2008SE03481		30 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Seroquel			S	Oral	200 Mg Morning + 400 Mg Night		Not Reported
	Cipralex			S	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2009	6910182	EXPEDITED (15-DAY)	Y	DE	2009S1000118		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Roxicodone		S	Oral	Po	Not Reported
	Acetaminophen And Codeine Phosphate		S	Oral	Po	Not Reported
	Escitalopram Oxalate		S	Oral	Po	Not Reported
	Levothyroxine		S	Oral	Po	Not Reported
	Unspecified Ingredient		S	Oral	Po	Not Reported
	Acetaminophen\Diphenhydramine		S	Oral	Po	Not Reported
	Estradiol		S	Oral	Po	Not Reported
	Progestine		S	Oral	Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2009	6899800	EXPEDITED (15-DAY)	N	OT	US-WYE-H07876809		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Amnesia; Anger; Anxiety; Aphasia; Asbestosis; Attention Deficit/Hyperactivity Disorder; Blood Cholesterol Increased; Blood Triglycerides Increased; Bruxism; Condition Aggravated; Constipation; Decreased Appetite; Depression; Disorientation; Drug Withdrawal Syndrome; Emotional Distress; Feeling Abnormal; Hallucination; Headache; Hyperhidrosis; Hypertension; Hypothyroidism; Insomnia; Intentional Overdose; Lethargy; Loss Of Personal Independence In	Effexor			S	Oral	Unknown		Wyeth
	Lexapro			S	Oral	Unknown		Lundbeck
	Lexapro			S				Lundbeck
	Xanax			S		Unknown		Not Reported
	Xanax			S				Not Reported
	Xanax			S				Not Reported
	Zoloft			S		Unknown		Pfizer
	Neurontin			S		Unknown		Not Reported
	Neurontin			S				Not Reported
	Trazodone Hydrochloride			S		Unknown		Unknown
	Seroquel			S		Unknown		Unknown
	Seroquel			S				Unknown
	Wellbutrin			S		Unknown		Glaxosmithkline
	Wellbutrin			S				Glaxosmithkline
	Restoril			S		Unknown		Not Reported
	Cymbalta			S		Unknown		Eli Lilly And Co
	Levothyroxine			C				Unknown
	Ambien			C				Not Reported

Daily Activities; Mental Disorder; Muscle Spasms; Muscle Twitching; Night Sweats; Nightmare; Pancreatitis; Panic Reaction; Paranoia; Pyrexia; Renal Failure; Restless Legs Syndrome; Road Traffic Accident; Screaming; Sedation; Seizure; Sleep Apnoea Syndrome; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Tachycardia; Tardive Dyskinesia; Terminal Insomnia; Tremor; Urinary Incontinence; Vomiting; Weight Decreased	Hydrochlorothiazide	C	Unknown
	Acetaminophen\Hydrocodone Bitartrate	C	Unknown
	Carisoprodol	C	Unknown
	Lisinopril	C	Unknown
	Fenofibrate	C	Unknown
	Fenofibrate	C	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2009	6908759	EXPEDITED (15-DAY)	Y	DE	2009S1000100		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Darvocet-N 100			S	Oral	; Po		Not Reported
	Escitalopram Oxalate			S	Oral	; Po		Not Reported
	Benzodiazepine			S	Oral	; Po		Not Reported
	Meloxicam			S	Oral	; Po		Not Reported
	Celecoxib			S	Oral	; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2009	6866441	EXPEDITED (15-DAY)	Y	HO	ES-PFIZER INC-2008154990			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia;	Phenytoin Sodium			S	Oral	100 Mg, Unk		Pfizer

Anticonvulsant Drug Level Above Therapeutic; Asthenia; Disorientation; Disturbance In Social Behaviour; Drug Interaction; Dysarthria; Somnolence; Toxicity To Various Agents; Treatment Noncompliance; Tremor	Lormetazepam		C	Oral	Unk	Not Reported
	Pantoprazole		C	Oral	Unk	Not Reported
	Aldactone		C	Oral	100 Mg, Unk	Not Reported
	Duphalac		C	Oral	Unk	Not Reported
	Lactitol		C	Oral	Unk	Not Reported
	Losartan Potassium And Hydrochlorothiazide		C	Oral	Unk	Not Reported
	Sucralfate		C	Oral	Unk	Not Reported
	Escitalopram Oxalate		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2009	6900118	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20090106590			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Fentanyl			S	Transdermal			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Topiramate			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Hydrocodone			S	Unknown			Not Reported
	Unspecified Ingredient			S	Unknown			Not Reported
	Atropine			C	Unknown			Not Reported
	Nicotine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2009	6901095	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2009-00679		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Gabapentin			S		Unknown		Watson
	Alprazolam			S		Unk		Watson
	Escitalopram Oxalate			S				Not Reported
	Lamotrigine			S				Not Reported
	Alcohol			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2009	6909095	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Drug Intolerance; Hyperhidrosis; Nausea; Nervousness; Rash; Vomiting	Effexor			S				Not Reported
	Lexapro			S				Not Reported
	Celexa			C				Not Reported
	Wellbutrin Sr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2009	6864238	EXPEDITED (15-DAY)	Y	HO	1000003029		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arachnoid Cyst; Cerebral Cyst; Condition Aggravated; Meningeal Disorder; Seizure	Escitalopram Oxalate			S	Oral Oral	0.7143 Mg (5 Mg, 1 In 1 Wk), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral 0.7143 Mg (5 Mg, 1 In 1 Wk), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Imovane			C				Not Reported
	Lexomil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2009	6901954	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2009-00636		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Estradiol			S		Unknown		Watson
	Acetaminophen\Codeine Phosphate			S		Unk		Watson
	Oxycodone Hydrochloride			S		Unk		Watson
	Escitalopram Oxalate			S				Not Reported
	Levothyroxine			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Acetaminophen\Diphenhydramine Hydrochloride			S				Not Reported
	Progesterone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2009	6902106	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2009-00686		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Nifedipine			S		Unknown		Watson
	Piroxicam			S		Unk		Watson
	Cyclobenzaprine Hydrochloride			S		Unk		Watson
	Bupropion Hydrochloride			S		Unk		Watson
	Escitalopram Oxalate			S				Not Reported
	Acetaminophen			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2009	6902507	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2009-00601		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Propoxyphene Hydrochloride And Acetaminophen			S		Unknown		Watson

	Meloxicam	S	Unk		Watson
	Escitalopram Oxalate	S			Not Reported
	Benzodiazepine	S			Not Reported
	Celecoxib	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2009	6913016	EXPEDITED (15-DAY)	Y	HO, LT	2009S1001183		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activated Partial Thromboplastin Time Prolonged; Blood Creatine Increased; Blood Creatine Phosphokinase Increased; Blood Ph Decreased; Blood Pressure Decreased; Bundle Branch Block Right; Drug Screen Positive; Heart Rate Decreased; Hyperkalaemia; International Normalised Ratio Increased; Loss Of Consciousness; Nodal Rhythm; Oxygen Saturation Decreased; Sinus Tachycardia	Cipralex			S	Oral	Oral		Not Reported
	Diazepam			S	Oral	Oral		Not Reported
	Zopiclone			S	Oral	Oral		Not Reported
	Lorazepam			S	Oral	Oral		Not Reported
	Ms Contin			S	Oral	Oral		Not Reported
	Ms Contin			S	Oral	Oral		Not Reported
	Ms Contin			S	Oral	Oral		Not Reported
	Oxycocet			S	Oral	Oral		Not Reported
	Celexa			S	Oral	Oral		Not Reported
	Oxycodone Hydrochloride			S	Oral	Oral		Not Reported
	Oxycontin			S	Oral	Oral		Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2009	7437762	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2009-00712		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Amlodipine Besylate			S		Unknown		Watson
	Atenolol			S		Unk		Watson
	Trazodone Hydrochloride			S		Unk		Watson
	Escitalopram Oxalate			S		Unk		Not Reported

	Duloxetine	S	Unk	Not Reported
	Losartan Potassium	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2009	6687881	EXPEDITED (15-DAY)	N	OT	US-TYCO HEALTHCARE/MALLIN CKRODT-T200801054			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Amnesia; Anger; Anxiety; Aphasia; Asbestosis; Attention Deficit/Hyperactivity Disorder; Blood Cholesterol Abnormal; Blood Pressure Increased; Blood Triglycerides Abnormal; Bruxism; Confusional State; Constipation; Depression; Drug Withdrawal Headache; Dyskinesia; Emotional Distress; Feeling Abnormal; Gait Disturbance; Hallucination; Hostility; Hyperhidrosis; Hypothyroidism; Lethargy; Mental Disorder; Mental Impairment; Muscle Spasms; Muscle Twitching; Night Sweats; Nightmare; Pain; Pallor; Pancreatitis; Panic Attack; Paranoia; Pyrexia; Renal Failure; Restless Legs Syndrome; Road Traffic Accident; Screaming; Seizure; Sleep Apnoea Syndrome; Stress; Suicidal Ideation; Suicide	Restoril			S		Unk, Qd		Tyco
	Restoril			S				Tyco
	Seroquel			S		Unk, Qd		Not Reported
	Seroquel			S				Not Reported
	Wellbutrin			S		Unk, Qd		Not Reported
	Wellbutrin			S				Not Reported
	Lexapro			S		Unk, Qd		Not Reported
	Lexapro			S				Not Reported
	Cymbalta			S		Unk, Qd		Not Reported
	Cymbalta			S				Not Reported
	Zoloft			S		Unk		Not Reported
	Zoloft			S				Not Reported
	Xanax			S		Unk, Qd		Not Reported
	Xanax			S				Not Reported
	Xanax			S				Not Reported
	Neurontin			S		Unk		Not Reported
	Neurontin			S				Not Reported
	Trazodone Hydrochloride			S		Unk		Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Lisinopril			C				Not Reported
	Fenofibrate			C				Not Reported
	Fenofibrate			C				Not Reported
	Levothyroxine			C				Not Reported
	Ambien			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Hydrocodone Bitartrate			C				Not Reported
	Carisoprodol			C				Not Reported

Attempt; Tachycardia; Tardive Dyskinesia; Terminal Insomnia; Thyroid Disorder; Tremor; Urinary Incontinence; Vomiting; Weight Decreased; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2009	6889066	EXPEDITED (15-DAY)	Y	OT	1000003430		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Toxic	Escitalopram Oxalate			S		10 Mg (10 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2009	6916347	EXPEDITED (15-DAY)	Y	HO	1000003751		35 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Irritability; Mania; Restlessness; Sleep Disorder	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Isoptin			C				Not Reported
	Ibuprofen			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2009	6863575	EXPEDITED (15-DAY)	Y	OT	1000003022		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Feeling Hot; Nausea; Seizure; Syncope; Tunnel Vision	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2009	6877968	EXPEDITED (15-DAY)	Y	HO	US-RANBAXY-2009RR-20314		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephritis Allergic; Renal Failure	Ibuprofen			S				Ranbaxy
	Lexapro			S		10 Mg, Unk	183 DAY	Not Reported
	Lexapro			S		20 Mg, Unk		Not Reported
	Alprazolam			C		0.5 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2009	6885066	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14466262		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Abilify			S		Started With Aripiprazole 10mg		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2009	6905029	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLINCKRODT-T200900199		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone			S				Tyco
	Acetaminophen And Codeine Phosphate			S				Tyco
	Escitalopram Oxalate			S				Not Reported
	Levothyroxine			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Diphenhydramine Hydrochloride			S				Not Reported
	Estradiol			S				Not Reported
	Progesterone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2009	6906024	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009164309		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Confusional State; Dizziness; Drug Interaction; Feeling Abnormal; Limb Injury; Localised Infection; Loss Of Consciousness; Pain In Extremity; Tremor; Withdrawal Syndrome	Humira		S		1 In 2 Wk	Not Reported
	Vicodin		S	Oral	5/500, 3 In 1 D, As Required	Not Reported
	Tetanus Antitoxin		S	Intramuscular	Once	Not Reported
	Celebrex		S	Oral	200 Mg, 1x/Day	Pfizer
	Lyrica		S	Oral	50 Mg, 2x/Day	Pfizer
	Clindamycin Phosphate		S	Oral	100 Mg, 3x/Day	Pfizer
	Lexapro		S	Oral	20 Mg, 1x/Day	Not Reported
	Chlormezanone		S			Not Reported
	Amitriptyline		S	Oral	75 Mg, 1x/Day At Night	Not Reported
	Rizatriptan Benzoate		S	Oral	10 Mg, 1x/Day	Not Reported
	Cyclobenzaprine Hydrochloride		S	Oral	10 Mg, Every 8 Hours As Required	Not Reported
	Bupropion		S	Oral	150 Mg, 1x/Day	Not Reported
	Minocycline\Minocycline Hydrochloride		S	Oral	100 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2009	6914849	EXPEDITED (15-DAY)	Y	OT	1000003823		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	(20 Mg, Once), Oral		Not Reported
	Alcohol			S	Oral	Unknown Amount Of Alcohol, Oral		Not Reported
	Zopiclone			S	Oral	(97.5 Mg, Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2009	6914909	EXPEDITED (15-DAY)	Y	HO	1000003820		96 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Chloride Decreased; Culture Urine	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Urbanyl			C				Not Reported

Positive; Escherichia Infection; Fall; General Physical Health Deterioration; Heart Rate Decreased; Hyponatraemia	Cordarone	C	Not Reported
	Mediatensyl (Capsules)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2009	6915797	EXPEDITED (15-DAY)	Y	HO	1000003834		64 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Hepatic Encephalopathy; Hepatitis Fulminant; Sleep Disorder	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Nitrazepam			S	Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral		Not Reported
	Morphine Sulfate			S	Oral	60 (60 ,1 In 1 D) ,Oral		Not Reported
	Atrovent			S	Respiratory (inhalation)	Respiratory (Inhalation)		Not Reported
	Durogesic			S	Transdermal	(75 Mcg) ,Transdermal		Not Reported
	Buprenorphine			S	Transdermal	(35 Mcg) ,Transdermal		Not Reported
	Primperan			S				Not Reported
	Dexketoprofen			S		25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2009	6906182	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-SYNTHELABO-A02200900243		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Fall; Gait Disturbance; Muscular Weakness; Rhabdomyolysis	Stilnox			S	Oral			Not Reported
	Ceftazidime			S	Transdermal			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported

Spironolactone	S	Oral			Not Reported
Furosemide	S	Oral			Not Reported
Doliprane	C	Unknown	Unk		Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Unknown	Unk		Not Reported
Tareg	C	Oral	Unk		Not Reported
Inexium	C	Unknown	Unk		Not Reported
Previscan (Fluindione)	C	Oral	Unk		Not Reported
Maxidrol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2009	6914469	DIRECT	N	HO, LT, RI			86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Haematemesis; Screaming; Vomiting	Lexapro			S		1/2 Tablet Every Day	2 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2009	6691999	EXPEDITED (15-DAY)	N	OT	A0736099A		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Aphasia; Asbestosis; Attention Deficit/Hyperactivity Disorder; Back Pain; Blood Cholesterol Abnormal; Blood Pressure Increased; Blood Triglycerides Abnormal; Bruxism; Communication Disorder; Confusional State; Constipation; Decreased Appetite; Depression; Drug	Wellbutrin			S	Oral		4 YR	Glaxosmithkline
	Xanax			S	Unknown		4 YR	Not Reported
	Seroquel			S	Unknown		4 YR	Not Reported
	Lexapro			S	Unknown		3 YR	Not Reported
	Restoril			S	Unknown		4 YR	Not Reported
	Cymbalta			S	Unknown		4 YR	Not Reported
	Zoloft			S				Not Reported
	Neurontin			S				Glaxosmithkline
	Trazodone Hydrochloride			S				Not Reported
	Effexor			S				Not Reported
	Lisinopril			C				Not Reported

Dependence; Dyskinesia; Emotional Distress; Feeling Abnormal; Hallucination; Head Injury; Headache; Hyperhidrosis; Hypertension; Hypothyroidism; Insomnia; Intentional Overdose; Lethargy; Loss Of Personal Independence In Daily Activities; Memory Impairment; Mental Disorder; Muscle Twitching; Night Sweats; Nightmare; Overdose; Pain; Pallor; Pancreatitis; Panic Reaction; Paranoia; Performance Status Decreased; Pyrexia; Regurgitation; Renal Failure; Restless Legs Syndrome; Road Traffic Accident; Sedation; Seizure; Sleep Apnoea Syndrome; Sleep Disorder; Stress; Suicidal Ideation; Suicide Attempt; Tachycardia; Tardive Dyskinesia; Terminal Insomnia; Thyroid Disorder; Tremor; Urinary Incontinence; Vomiting; Weight Decreased; Withdrawal Syndrome	Fenofibrate	C	Not Reported
	Levothyroxine	C	Glaxosmithkline
	Ambien	C	Not Reported
	Hydrochlorothiazide	C	Not Reported
	Acetaminophen\Hydrocodone Bitartrate	C	Not Reported
	Carisoprodol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2009	6901579	EXPEDITED (15-DAY)	Y	OT	1000003576		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction;	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, At		Not Reported

Dyspepsia; Nausea; Tardive Dyskinesia	Itopride		S	Bedtime), Oral 50 Mg (50 Mg, At Bedtime)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2009	6907528	EXPEDITED (15-DAY)	Y	HO, OT	1000003680		34 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Diarrhoea; Intentional Overdose; Mydriasis; Seizure; Suicide Attempt	Escitalopram Oxalate			S	Oral	1280 Mg, Once, Oral		Not Reported
	Seroquel			S	Oral	Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2009	6913013	EXPEDITED (15-DAY)	Y	DE	1000003786		55 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2009	6916343	EXPEDITED (15-DAY)	Y	CA	1000003842		< 1 DAY	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	10 Mg (10 Mg,1 In 1 D),Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2009	6919985	EXPEDITED (15-DAY)	Y	HO	1000003838		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Disorder; Headache; Hyponatraemia; Malaise;	Escitalopram Oxalate			S	Oral	(10 Mg),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1		Not Reported

Vomiting			D),Oral		
	Imovane	C			Not Reported
	Levothyrox	C			Not Reported
	Fosamax	C			Not Reported
	Pantestone	C			Not Reported
	Hydrocortisone	C			Not Reported
	Minirin	C			Not Reported
	Lanzor	C			Not Reported
	Ercefuryl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2009	6920078	EXPEDITED (15-DAY)	Y	DE	1000003860		70 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; General Physical Health Deterioration; Hyponatraemia; Leukocytosis; Respiratory Distress; Somnolence	Escitalopram Oxalate			S	Oral	5 Dosage Forms (5 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Buscapina (10 Milligram, Tablets)			C				Not Reported
	Morphine Hydrochloride(Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2009	6750799	EXPEDITED (15-DAY)	Y	DS, OT	1000000599		59 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Albumin Decreased; Cognitive Disorder; Drug Interaction; Dyskinesia; Influenza Like Illness; Memory Impairment; Motor Dysfunction; Platelet Count Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Disulfiram			S	Oral	228.5714 Mg (1600 Mg, 1 In 1 Wk), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2009	6915720	DIRECT	Y				85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Lexapro			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2009	6917008	DIRECT	Y	HO			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Zyvox			S	Oral	600mg Bid Po	14 DAY	Pfizer
	Lexapro			S	Oral	20mg Daily Po	7 MTH	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2009	6918680	EXPEDITED (15-DAY)	Y	DS	1000003882		80 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Emotional Disorder	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Calchichew D3 Forte			C				Not Reported
	Betahistine			C				Not Reported
	Alendronic Acid			C				Not Reported
	Vitamin B12			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2009	6918734	EXPEDITED (15-DAY)	Y	HO	1000003905		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Creatinine Renal Clearance Decreased; Disorientation; Drug Level Below Therapeutic; Fall; Hypertonia; Hypokalaemia; Orthostatic	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tramadol Hydrochloride And Acetaminophen			S	Oral	3 Dosage Forms (1 Dosage Forms, 3 In 1 D), Oral		Not Reported
	Aricept (Tablets)			C				Not Reported

Hypotension; Posture	Hydrochlorothiazide\Valsartan			C					Not Reported
Abnormal; Status	Cacit D3			C					Not Reported
Epilepticus	Fosamax			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2009	6753453	EXPEDITED (15-DAY)	Y	HO, LT	1000000627		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Coma; Intentional Overdose; Pneumonia Aspiration; Pneumonia Staphylococcal; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Tranxene T-Tab			S	Oral	Oral		Not Reported
	Anafranil			S	Oral	Oral		Not Reported
	Cyamemazine			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2009	6820392	EXPEDITED (15-DAY)	Y	HO	1000001660		65 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrioventricular Block; Pallor; Refusal Of Treatment By Patient; Syncope; Urinary Incontinence; Ventricular Tachycardia	Escitalopram Oxalate			S	Oral	(20 Mg), Oral		Not Reported
	Levemir			C				Not Reported
	Novonorm			C				Not Reported
	Mediator			C				Not Reported
	Allopurinol			C				Not Reported
	Triatec (Ramipril)			C				Not Reported
	Aspirin Lysine			C				Not Reported
	Pravastatin			C				Not Reported
	Atenolol			C				Not Reported
	Lasix			C				Not Reported
	Xatral			C				Not Reported
	Proscar			C				Not Reported
	Noctamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2009	6909487	EXPEDITED (15-DAY)	Y	DE	1000003701		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Stress	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Requip			C				Not Reported
	Sinemet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2009	6919812	EXPEDITED (15-DAY)	Y	HO	1000003923		87 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cognitive Disorder; Confusional State; Disorientation; Urinary Retention	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Topalgic [Tramadol Hydrochloride]			S	Oral	200 Mg (100 Mg, 2 In 1 D), Oral		Not Reported
	Atarax			S	Oral	(100 Mg, As Needed), Oral		Not Reported
	Inipomp			C				Not Reported
	Furosemide			C				Not Reported
	Ramipril			C				Not Reported
	Aspirin Lysine			C				Not Reported
	Vastarel			C				Not Reported
	Creon			C				Not Reported
	Rocaltrol			C				Not Reported
	Allopurinol			C				Not Reported
	Lantus			C				Not Reported
	Doliprane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2009	6921030	EXPEDITED (15-DAY)	N	DE	1000003916		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Death Of Relative	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2009	6921514	DIRECT	N	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	One Tablet By Mouth Per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2009	6924649	EXPEDITED (15-DAY)	Y	HO	1000003915		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplasia; Azotaemia; Back Pain; Bone Marrow Failure; Bone Marrow Toxicity; Bronchoalveolar Lavage Abnormal; Influenza; Lung Disorder; Metabolic Acidosis; Pain; Rales; Renal Failure; Staphylococcal Infection	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D) ,Oral		Not Reported
	Cyamemazine			S	Oral	75 Mg (25 Mg, 3 In 1 D), Oral		Not Reported
	Akineton			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D) ,Oral		Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2009	6925202	EXPEDITED (15-DAY)	Y	DE	CHPA2009US01789		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning Deliberate	Acetaminophen		Y	S	Oral	Oral		Not Reported
	Acetaminophen And Codeine			S	Oral	Oral		Not Reported
	Oxycodone (Oxycodone)			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Levothyroxine Sodium			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported

	Estradiol	S	Oral	Oral		Not Reported
	Progestine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2009	6911147	EXPEDITED (15-DAY)	N	HO	ES-PURDUE-GBR_2009_0004856		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Encephalopathy; Hepatitis Fulminant	Morphine Sulfate			S	Oral	60 Mg, Daily	7200 MIN	Not Reported
	Buprenorphine Hydrochloride			S	Transdermal	35 Mcg, Q1h		Not Reported
	Atrovent			S	Respiratory (inhalation)	60 Capsules		Not Reported
	Nitrazepam			S	Oral	75 Mg, Daily	4320 MIN	Not Reported
	Durogesic			S	Transdermal	75 Mcg, Daily	12960 MIN	Not Reported
	Ketoprofen			S	Oral	25 Mg, Daily	7200 MIN	Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, Daily	11520 MIN	Not Reported
	Metoclopramide			S	Oral			Not Reported
	Ceftriaxone			S	Intramuscular	1 Gram, Daily	5760 MIN	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2009	6911475	EXPEDITED (15-DAY)	Y	DE	PHHY2009US05428		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spina Bifida	Clozaril			S	Oral	300 Mg/Day		Novartis
	Valium			S	Oral	6.5 Mg Daily		Not Reported
	Lexapro			S	Oral	10 Mg Daily		Not Reported
	Ms Contin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2009	6913170	EXPEDITED (15-DAY)	Y	OT	PHHY2009GB04712			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged	Clozapine	S	Unk		Novartis
	Cipralex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2009	6913352	EXPEDITED (15-DAY)	N	HO, OT	US-ROCHE-613546		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Bladder Neoplasm; Dystonia; Hypersensitivity	Peginterferon Alfa-2a			S	Unknown	Form: Pre-Filled Syringe		Roche
	Ribavirin			S	Unknown			Roche
	Meclizine			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2009	6913589	EXPEDITED (15-DAY)		HO	FR-ABBOTT-09P-056-0502983-00		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Back Pain; Chest Pain; Influenza; Metabolic Acidosis; Renal Failure	Biperiden			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2009	6926310	EXPEDITED (15-DAY)	Y	OT	1000003934			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Seizure	Lexapro	S	5 Mg; 10 Mg;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2009	6926328	EXPEDITED (15-DAY)	Y	HO, OT	1000003961			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Post Procedural Haemorrhage	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2009	6915152	EXPEDITED (15-DAY)	Y	HO, OT	CH-ROXANE LABORATORIES, INC.-2009-RO-00138RO		53 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Choreoathetosis; Cognitive Disorder; Delusion; Drug Interaction; Dysarthria; Myoclonus; Toxicity To Various Agents; Transaminases Increased	Lorazepam			S		1mg		Roxane
	Lamotrigine			S		300mg		Roxane
	Lithium Sulfate			S				Not Reported
	Amisulpride			S		800mg		Not Reported
	Escitalopram Oxalate			S		20mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2009	6915196	EXPEDITED (15-DAY)	Y	HO	ES-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2009-ES-00		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Encephalopathy; Hepatitis Fulminant	Atrovent			S	Respiratory (inhalation)			Boehringer Ingelheim
	Dormicum (Midazolam)			S	Oral	75mg		Not Reported
	Durogesic			S	Transdermal	75mcg		Not Reported
	Ketoprofen			S	Oral	25mg		Not Reported
	Escitalopram Oxalate			S	Oral	20mg		Not Reported

Morphine Sulfate	S	Oral	60mg		Not Reported
Metoclopramide Hydrochloride	S	Oral			Not Reported
Rocephin	S	Intramuscular	1 G/3,5 Ml		Not Reported
Buprenorphine	S	Transdermal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2009	6929299	EXPEDITED (15-DAY)	Y	HO, OT	1000003303		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Coordination Abnormal; Dizziness; Nausea	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Aricept			C				Not Reported
	Celebrex			C				Not Reported
	Aspirin			C				Not Reported
	Glucosamine(Tablets)			C				Not Reported
	Namenda			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2009	6929325	EXPEDITED (15-DAY)	Y	DS, HO	1000004799		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Paraplegia; Spinal Cord Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zantac (Tablets)			C				Not Reported
	Movicol			C				Not Reported
	Zestoretic			C				Not Reported
	Lipitor			C				Not Reported
	Tavanic			C				Not Reported
	Myolastan (Tablets)			C				Not Reported
	Dafalgan (Tablets)			C				Not Reported
	Sifrol (Tablets)			C				Not Reported
	Trazolan (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2009	6871738	EXPEDITED (15-DAY)	Y	DE	1000003184		76 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Temazepam			C				Not Reported
	Oxazepam			C				Not Reported
	Dormicum (Tablets)			C				Not Reported
	Nexium (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2009	6871748	EXPEDITED (15-DAY)	Y	DE	1000003187		47 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2009	6916531	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20090204798		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Glucose Decreased; Blood Glucose Increased; Dyspepsia; Irritable Bowel Syndrome	Risperdal			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Strattera			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2009	6917199	EXPEDITED (15-DAY)	Y	OT	PHEH2009US01757		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Laboratory Test Abnormal; Renal Impairment	Femara			S	Oral	2.5 Mg, Qd		Novartis
	Synthroid			S		Unk	3650 DAY	Not Reported
	Lipitor			S		Unk	1825 DAY	Not Reported
	Lexapro			S		Unk	244 DAY	Not Reported

Calcium	S	Unk	730 DAY		Not Reported
Neurontin	S	Unk			Not Reported
Antidepressants	S	Unk			Not Reported
Hormones Nos	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2009	6918131	NON-EXPEDITED			US-ABBOTT-08P-163-0494375-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Dizziness; Flushing; Muscle Spasms; Muscle Twitching; Night Sweats; Paraesthesia; Tension	Simcor			S		500mg/20mg		Not Reported
	Lexapro			S				Not Reported
	Xanax			C				Not Reported
	Allegra			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Asa			C		At Times		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2009	6918355	NON-EXPEDITED			US-ABBOTT-09P-163-0496261-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing	Simcor			S				Not Reported
	Lexapro			S				Not Reported
	Metformin			C				Not Reported
	Lexapro			C				Not Reported
	Asa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2009	6681144	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2008051192			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anger; Asbestosis; Blood Cholesterol Increased; Blood Triglycerides	Xanax			S				Pfizer
	Xanax			S				Pfizer
	Xanax			S				Pfizer
	Zoloft			S				Pfizer

Abnormal; Bruxism;	Zoloft		S			Pfizer
Depression; Feeling	Neurontin		S			Pfizer
Abnormal; Hallucination;	Neurontin		S			Pfizer
Hyperhidrosis;	Trazodone Hydrochloride		S			Not Reported
Hypertension;	Seroquel		S			Not Reported
Hypothyroidism; Incorrect	Wellbutrin		S			Not Reported
Dose Administered;	Lexapro		S			Not Reported
Insomnia; Pain;	Restoril		S			Not Reported
Pancreatitis; Panic Attack;	Cymbalta		S	Unk		Not Reported
Paranoia; Pyrexia; Renal Failure; Road Traffic	Effexor		S	Unk		Not Reported
Accident; Seizure; Sleep	Lisinopril		C			Not Reported
Apnoea Syndrome;	Fenofibrate		C			Not Reported
Suicide Attempt;	Fenofibrate		C			Not Reported
Tachycardia; Tardive	Levothyroxine		C			Not Reported
Dyskinesia; Treatment	Ambien		C			Not Reported
Noncompliance; Urinary	Hydrochlorothiazide		C			Not Reported
Incontinence; Vomiting;	Acetaminophen\Hydrocodone		C			Not Reported
Weight Decreased; Withdrawal Syndrome	Bitartrate Carisoprodol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2009	6920099	EXPEDITED (15-DAY)	Y	HO, LT, OT	AU-ELI_LILLY_AND_COMPANY-AU200902001897		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Intentional Overdose; Neuroleptic Malignant Syndrome; Pneumonia Aspiration; Somnolence	Zyprexa			S		Unk, Unknown		Unknown
	Antibiotics			C	Intravenous (not otherwise specified)	Unk, Unknown		Not Reported
	Zyprexa			S		10 Mg, X 30 = 300 Mg		Unknown
	Chlorpromazine			S		Unk, Unknown		Not Reported
	Chlorpromazine			S		100 Mg, X 7 = 700 Mg		Not Reported
	Escitalopram Oxalate			S		Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2009	6915666	EXPEDITED (15-DAY)	Y	HO, LT	AU-AMGEN-US333842		46 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Headache; Mouth Ulceration; Respiratory Tract Infection; Thrombocytopenia	Enbrel			S	Subcutaneous	25mg 2 Vials Once A Week		Not Reported
	Valproate Sodium			C	Unknown			Not Reported
	Lithium			C	Unknown	Unknown		Not Reported
	Lexapro			S	Unknown	20mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2009	6920664	EXPEDITED (15-DAY)	Y	HO	ES-ROCHE-616181		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Encephalopathy; Hepatitis Fulminant	Rocephin			S	Intramuscular			Roche
	Midazolam			S	Oral			Roche
	Metoclopramide			S	Oral			Not Reported
	Buprenorphine			S	Transdermal			Not Reported
	Atrovent			S	Respiratory (inhalation)			Not Reported
	Durogesic			S	Transdermal	Drug Name Reported As: Durogesic Matrix 75.		Not Reported
	Dexketoprofen			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Morphine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2009	6932331	EXPEDITED (15-DAY)	Y	HO	1000004845		74 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bundle Branch Block Right; Disorientation; Fall; Hepatitis Cholestatic; Rhabdomyolysis	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Furosemide			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported

	Spironolactone	S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral	Not Reported
	Bromazepam	S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral	Not Reported
	Bromazepam	S	Oral	0.25 Dosage Forms (0.25 Dosage Forms, 1 In 1 D), Oral	Not Reported
	Stilnox	S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral	Not Reported
	Nitroglycerin	S	Transdermal	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Transdermal	Not Reported
	Hydrocortisone Butyrate	C			Not Reported
	Locoid	C			Not Reported
	Previscan (Fluindione)	C			Not Reported
	Inexium	C			Not Reported
	Tareg	C			Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C			Not Reported
	Doliprane	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2009	6934047	EXPEDITED (15-DAY)	Y	HO	CHPA2009US04672		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Analgesic Drug Level Increased; Hepatotoxicity; International Normalised Ratio Increased; Overdose	Acetaminophen\Diphenhydramine Hydrochloride		Y	S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Zolpidem			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2009	6922149	NON-EXPEDITED	N		A0722886A		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diplopia; Drug Hypersensitivity; Dry Mouth; Dysgeusia; Emotional Disorder; Nervousness; Rash; Rash Pruritic; Rhinorrhoea; Somnolence; Stress; Tension; Tinnitus	Lamictal	S	Oral	25mg Per Day		Glaxosmithkline
	Paxil	S	Oral	10mg Per Day	1 YR	Glaxosmithkline
	Lunesta	S	Oral	3mg At Night	2 DAY	Glaxosmithkline
	Ambien	S	Oral	10mg At Night		Not Reported
	Lexapro	S				Not Reported
	Unspecified Ingredient	C				Glaxosmithkline
	Vitamins	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2009	6922230	NON-EXPEDITED	N		A0725838A		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive	Lamictal			S	Oral			Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2009	6922405	NON-EXPEDITED	N		A0732290A		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Weight Increased	Lamictal			S	Oral	50mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2009	6922457	NON-EXPEDITED	N		A0733893A		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lamictal			S	Oral	300mg Per Day	6 MTH	Glaxosmithkline
	Lexapro			S				Not Reported
	Strattera			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2009	6923658	NON-EXPEDITED	N		A0714332A		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Nausea	Imitrex			S	Subcutaneous	6mg As Required		Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day	2 DAY	Not Reported
	Sumatriptan Succinate			C				Glaxosmithkline
	Vitamin			C				Not Reported
	Calcium			C				Not Reported
	Prilosec			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2009	6935265	EXPEDITED (15-DAY)	Y	DE	1000004856		30 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Seroquel			S	Oral	600 Mg (600 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2009	6935276	EXPEDITED (15-DAY)	Y	HO	1000004849		78 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Asthenia; Confusional State; Drug Interaction; Fall; Hypoglycaemia; Somnolence	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Insulin Aspart			S	Subcutaneous	66 Iu (66 Iu, 1 In 1 D), Subcutaneous		Not Reported
	Celectol			S	Oral	200 Mg (200 Mg, 1 In 1 D), Oral		Not Reported
	Telfast			C				Not Reported
	Previscan (Fluindione)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2009	6901978	EXPEDITED (15-DAY)	Y	DE	1000003575		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S		Oral		Not Reported
	Levothyroxin			S				Not Reported
	Acetaminophen			S				Not Reported
	Codeine			S				Not Reported
	Oxycodone			S				Not Reported
	Diphenhydramine			S				Not Reported
	Estradiol			S				Not Reported
	Progesterone			S				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2009	6904616	EXPEDITED (15-DAY)	Y	DE	1000003616		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S	Oral	Ingestion		Not Reported
	Acetaminophen\Hydrocodone Bitartrate			S	Oral	Ingestion		Not Reported
	Bupropion			S	Oral	Ingestion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2009	6905677	EXPEDITED (15-DAY)	Y	DE	1000003573		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Percocet			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2009	6914148	EXPEDITED (15-DAY)	Y	DE	1000003735		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Acetaminophen			S				Not Reported
	Propoxyphene Hydrochloride			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Meloxicam			S				Not Reported
	Celecoxib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2009	6914191	EXPEDITED (15-DAY)	Y	HO	1000003790		77 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hallucinations, Mixed; Myoclonus; Posture Abnormal	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Thalidomide			S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
	Rytmonorm (Tablets)			C				Not Reported
	Cortone Acetato (Tablets)			C				Not Reported
	Lasix			C				Not Reported
	Folina (Tablets)			C				Not Reported
	Benxol			C				Not Reported
	Allopurinol			C				Not Reported
	Eprex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2009	6916914	EXPEDITED (15-DAY)	Y	DE	1000003739		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Acetaminophen			S				Not Reported
	Cyclobenzaprine			S				Not Reported
	Bupropion			S				Not Reported
	Alcohol			S				Not Reported
	Nifedipine			S				Not Reported
	Piroxicam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2009	6920820	EXPEDITED (15-DAY)	Y	DE	1000003749		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Overdose	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Bupropion			S				Not Reported
	Alcohol			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2009	6923256	EXPEDITED (15-DAY)	Y	DE	1000003746		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Atenolol			S				Not Reported
	Amlodipine			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Duloxetine			S				Not Reported
	Losartan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2009	6924634	EXPEDITED (15-DAY)	Y	DE	1000003743		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2009	6934626	EXPEDITED (15-DAY)	Y	DE	1000004933		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional	Escitalopram Oxalate			S				Not Reported
	Alprazolam			S				Not Reported

Overdose; Respiratory Arrest	Lorazepam	S		Not Reported
	Acetaminophen	S		Not Reported
	Quetiapine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2009	6539207	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2008007185		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Agitation; Drug Ineffective; Drug Interaction; Loss Of Personal Independence In Daily Activities; Malaise; Mental Disorder; Nausea; Personality Change; Suicidal Behaviour; Suicidal Ideation	Chantix			S		Unk	19 DAY	Pfizer
	Altace			C				Not Reported
	Triamterene And Hydrochlorothiazide			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Lexapro			S		10 Mg, 1x/Day		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2009	6864208	EXPEDITED (15-DAY)	Y	DE	1000003052		30 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Completed Suicide	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2009	6890070	EXPEDITED (15-DAY)	Y	DE	1000003496		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Screen Positive; Gun Shot Wound; Mood Altered	Lexapro			S	Oral	10 Mg (10 Mg, 1in 1 D), Oral		Not Reported
	Ambien			C				Not Reported
	Lunesta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2009	6914147	EXPEDITED (15-DAY)	Y	DE	1000003737		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S		Ingestes & Aspirated		Not Reported
	Alprazolam			S				Not Reported
	Lamotrigine			S		Ingested & Aspirated		Not Reported
	Gabapentin			S		Ingested & Aspirated		Not Reported
	Alcohol			S		Ingested & Aspirated		Not Reported
	Unspecified Ingredient			S		Ingested & Aspirated		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2009	6932061	EXPEDITED (15-DAY)	Y	DE	GXKR2009US01983		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Loss Of Consciousness; Pneumonia; Pulmonary Congestion; Toxicity To Various Agents; Unresponsive To Stimuli	Dextromethorphan			S				Not Reported
	Temazepam			S				Not Reported
	Zyprexa			S				Not Reported
	Lexapro			S				Not Reported
	Ambien			S				Not Reported
	Alcohol			S		Excessive Amount, Unknown		Not Reported
	Naproxen (Naproxen)			C				Not Reported
	Risperdal			C				Not Reported
	Lithium (Lithium)			C				Not Reported
	Metocarbamol (Metocarbamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2009	6941012	EXPEDITED (15-DAY)	Y	HO	1000004966			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Road Traffic Accident; Seizure	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2009	6941423	DIRECT	N	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chills; Conversion Disorder; Drug Dependence; General Physical Health Deterioration; Incorrect Product Administration Duration; Muscle Twitching; Nausea; Palpitations; Paraesthesia; Tremor	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2009	6942341	DIRECT	N				16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Feeling Abnormal; Nervousness	Lexapro			S	Oral	20mg 1 A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2009	6942758	EXPEDITED (15-DAY)	Y	OT	1000004985			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Personality Change; Suicidal Ideation	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D),Oral ; 10 Mg (10 Mg, 1 In 1 D),Oral; 15 Mg (15 Ma, 1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S		5 Mg (5 Mg, 1 In 1 D),Oral; 10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

	Escitalopram Oxalate	S	Oral	15 Mg (15 Mg, 1 In 1 D),Oral	Not Reported
	Escitalopram Oxalate	S		5 Mg (5 Mg, 1 In 1 D),Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2009	6873480	EXPEDITED (15-DAY)	Y	HO, OT	1000003214		24 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Use; Intentional Overdose; Seizure; Somnolence; Suicide Attempt; Vomiting	Escitalopram Oxalate			S	Oral	600-1000 Mg (Once), Oral		Not Reported
	Sertindole			S	Oral	1200 Mg (1200 Mg, Once), Oral		Not Reported
	Caffeine			S	Oral	2 Gm (2 Gm, Once), Oral		Not Reported
	Ibuprofen Lysine			S	Oral	10 Tablets (Once), Oral		Not Reported
	Alcohol			S	Oral	300-500 Ml Of Wine (Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2009	6905763	EXPEDITED (15-DAY)	Y	DE, OT	1000003664		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fall; Parkinsonism; Pulmonary Embolism; Wheelchair User	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Modopar			C				Not Reported
	Ogast			C				Not Reported
	Lactulose			C				Not Reported
	Practazin			C				Not Reported
	Anti-Parkinson Drugs			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2009	6943456	EXPEDITED (15-DAY)	N	HO	1000004996		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Facial Bones Fracture; Fall; Fatigue;	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

Headache; Thyroid Neoplasm	Norvasc	C	Not Reported
	Diovan (Tablets)	C	Not Reported
	Fosamax	C	Not Reported
	Advair (Aerosol For Inhalation)	C	Not Reported
	Combivent (Aerosol For Inhalation)	C	Not Reported
	Calcium (Tablets)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2009	7377498	EXPEDITED (15-DAY)	Y	DE	DSA_62485_2009		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Acetaminophen And Codeine			S	Oral	Df Oral		Not Reported
	Oxycodone			S	Oral	Df Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df Oral		Not Reported
	Levothyroxine			S	Oral	Df Oral		Not Reported
	Unspecified Ingredient			S	Oral	Df Oral		Not Reported
	Acetaminophen\Diphenhydramine Hydrochloride			S	Oral	Df Oral		Not Reported
	Estradiol			S	Oral	Df Oral		Not Reported
	Unspecified Ingredient			S	Oral	Df Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2009	6933430	EXPEDITED (15-DAY)	Y	OT	1000004934		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Dermatitis Bullous	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1in 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1d), Oral		Not Reported
	Acetaminophen\Codeine Phosphate			S		(As Required)		Not Reported
	Celecoxib			S		200-400 Mg/Day (1-2 Times/Day)		Not Reported

	Esomeprazole	S	(40 Mg, As Required)	Not Reported
	Mebeverine Hydrochloride	S		Not Reported
	Chondroitin Sulfate (Bovine)	S	800 Mg (800 Mg, 1 In 1 D)	Not Reported
	Humira	S		Not Reported
	Eltroxin	C		Not Reported
	Arava	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2009	7175203	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLIN CKRODT-T200900387		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Propoxyphene Hydrochloride And Acetaminophen			S	Oral			Tyco
	Escitalopram Oxalate			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported
	Meloxicam			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2009	6946375	EXPEDITED (15-DAY)	Y	OT	1000005047			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Self-Injurious Ideation; Therapeutic Product Effect Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2009	6946379	EXPEDITED (15-DAY)	Y	OT	1000005019			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Intentional Self-Injury; Malaise	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2009	6950204	EXPEDITED (15-DAY)	Y	OT	1000005058		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Cold; Morbid Thoughts; Panic Attack; Violence-Related Symptom	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2009	6908800	EXPEDITED (15-DAY)	Y	OT	US-JNJFOC-20090202630		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral	Risperdal			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Wellbutrin Xl			S	Oral	450 (Units Unspecified) Qd		Not Reported
	Synthroid			C	Oral			Not Reported
	Lithium Carbonate			C	Unknown	600 (Units Unspecified) Bid		Not Reported
	Provigil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2009	6949476	EXPEDITED (15-DAY)	Y	OT	1000005050		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Amnesia; Anger; Anxiety; Decreased Appetite; Dizziness; Fatigue; Feeling Abnormal; Headache; Hyperhidrosis; Nausea; Nervousness; Suicidal	Escitalopram Oxalate			S	Oral	Oral		Not Reported

Ideation; Tremor; Violence-Related Symptom

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2009	6944380	EXPEDITED (15-DAY)	Y	OT	1000003195		55 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Somnolence; Syncope	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral		
	Tanakan			C				Not Reported
	Memantine (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2009	6950377	EXPEDITED (15-DAY)	Y	HO	1000005062		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exfoliative Rash; Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tropatepine			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Depakote			S		100 Mg (100 Mg, 1 In 1 D)		Not Reported
	Bromazepam			S	Oral	120 Mg (120 Mg, Once), Oral		Not Reported
	Loxapac			S	Oral	100 Mg (100 Mg, Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2009	6947224	DIRECT	N	DE, OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Seroquel			S		Unknown		Not Reported
	Lexapro			S		Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2009	6954283	EXPEDITED (15-DAY)	N	OT	1000005097		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Screaming; Seizure	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Dilantin			C				Not Reported
	Lantus			C				Not Reported
	Synthroid			C				Not Reported
	Actos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2009	6948526	DIRECT					49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Urticaria	Prozac			S		4-1-08 - 5-7-08		Not Reported
	Lexapro			S		3-12-08 - 4-2-08		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2009	6950510	EXPEDITED (15-DAY)	Y	HO	1000005068		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Megaloblastic; Diarrhoea; Fall; Nausea; Weight Decreased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

	Lexapro	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported
	Lexapro	S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported
			Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral	
			Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral	
	Aspirin	C			Not Reported
	Metformin (Tablets)	C			Not Reported
	Hydrochlorothiazide	C			Not Reported
	Lipitor	C			Not Reported
	Lisinopril	C			Not Reported
	Detrol	C			Not Reported
	Atenolol	C			Not Reported
	Fosamax	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2009	7175264	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLIN CKRODT-T200900464		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S	Oral			Tyco
	Trazodone Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2009	6954877	EXPEDITED (15-DAY)	Y	HO	1000005132		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Feeling Abnormal; Hallucination, Visual; Intentional Self-Injury; Restlessness; Sleep Disorder; Unevaluable Event	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2009	6957976	EXPEDITED (15-DAY)	Y	DE	1000005241			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2009	6958797	EXPEDITED (15-DAY)	Y	DE	1000005184		70 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate			S				Not Reported
	Zyprexa			S				Not Reported
	Bromazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2009	6541632	EXPEDITED (15-DAY)	Y	HO	US-PFIZER INC-2008005876		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram T Wave Inversion; Hypotension; Sinus Tachycardia	Detrol La			S	Oral	4 Mg, 1x/Day	828 DAY	Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day	18 DAY	Not Reported
	Reboxetine			S	Oral	1 Mg, 1x/Day		Pfizer
	Thiamine			C	Oral			Not Reported
	Folic Acid			C	Oral	Qd		Not Reported
	Multivitamins			C	Oral	1,Qd		Not Reported
	Lisinopril			C	Oral	1,Qd		Not Reported
	Verapamil Hydrochloride			C	Oral	1,Qd		Not Reported

K-Dur	C	Oral			Not Reported
Magnesium Oxide	C	Oral	2 Tabs,Bid		Not Reported
Synthroid	C	Oral	Qd		Not Reported
Amitiza	C	Oral	Bid		Not Reported
Cyanocobalamin	C	Intramuscular	Qmo		Not Reported
Metoprolol	C	Oral	1,Bid		Not Reported
Asa	C	Oral	Qd		Not Reported
Celebrex	C		1,Qd		Not Reported
Protonix	C		1,Qd		Not Reported
Premarin	C		1,Qd		Not Reported
Tramadol Hydrochloride	C		1,Q 6 Hours Prn		Not Reported
Trazodone Hydrochloride	C		1,Qhs		Not Reported
Amitriptyline	C		1,Qpm		Not Reported
Potassium Chloride	C		1,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2009	6941011	EXPEDITED (15-DAY)	Y	OT	1000004984		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Muscle Twitching; Vomiting	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Protium (Tablets)			C				Not Reported
	Larig (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2009	6955915	EXPEDITED (15-DAY)	Y	HO	1000005204		67 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Calcium Decreased; Depressive	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),		Not Reported

Delusion; Electrocardiogram Repolarisation Abnormality; Electrocardiogram St Segment Elevation; Extrapyramidal Disorder; Femoral Neck Fracture; Generalised Tonic-Clonic Seizure; Hyponatraemia; International Normalised Ratio Decreased; Sinus Bradycardia	Valproate Sodium	S	Oral	Oral 1200 Mg (1200 Mg, 1 In 1 D), Oral		Not Reported
	Omeprazole	S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Haldol	S	Oral	1 Mg (1 Mg, 1 In 1 D), Oral		Not Reported
	Haldol	S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Haldol	S	Oral	2 Mg (2 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel	S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel	S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
	Tavor [Lorazepam]	C				Not Reported
	Concor	C				Not Reported
	Simvahexal	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2009	6808462	EXPEDITED (15-DAY)	Y	HO	1000001460		34 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Obsessive Thoughts; Overdose; Sedation	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2009	6947904	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLINCKRODT-T200900477		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest	Tramadol Hydrochloride		S	Oral	Tyco
	Bupropion Hydrochloride		S	Oral	Not Reported
	Alcohol		S	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2009	6947907	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLIN CKRODT-T200900482		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S	Oral			Tyco
	Bupropion			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2009	6955013	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circumstance Or Information Capable Of Leading To Medication Error; Medication Error	Namenda			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2009	6955120	EXPEDITED (15-DAY)	Y	OT	DSA_33316_2009		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disorientation; Drug Interaction; Dysphagia; Dyspnoea; Fall; Insomnia	Xenazine			S	Oral	6.25 Mg Qd Oral		Not Reported
	Lexapro			S		Df		Not Reported
	Invega			C				Not Reported
	Depakote			C				Not Reported
	Deplin			C				Not Reported

	Namenda			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2009	6956195	EXPEDITED (15-DAY)	Y	OT	1000005245		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatine Phosphokinase Increased; Pain	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2009	6956206	EXPEDITED (15-DAY)	Y	OT	1000005280			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	Transplacental		Not Reported
	Subutex			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2009	6913333	EXPEDITED (15-DAY)	Y	DS	1000003759		61 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2009	6948669	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20090303572			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Bladder Neoplasm; Dystonia; Pharyngeal Oedema	Tramadol Hydrochloride			S	Unknown			Not Reported
	Ribavirin			S	Unknown			Not Reported
	Pegasys			S				Not Reported

	Meclizine	S	Unknown	Not Reported
	Lexapro	S	Unknown	Not Reported
	Trazodone Hydrochloride	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2009	6840682	EXPEDITED (15-DAY)	Y	OT	1000001769		80 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pleural Effusion	Escitalopram Oxalate			S	Oral	5 Gtt (5 Gtt, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2009	6902811	EXPEDITED (15-DAY)	Y	HO, OT	1000003606		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Neonatal; Aortic Valve Disease; Biotin Deficiency; Blood Pressure Decreased; Heart Rate Increased; Infantile Apnoea; Maternal Drugs Affecting Foetus; Meconium In Amniotic Fluid; Neonatal Respiratory Depression; Neonatal Seizure; Sepsis Neonatal	Lexapro			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported
	Klonopin			C				Not Reported
	Lortab			C				Not Reported
	Hepatitis B Vaccine(Injection)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2009	6931374	EXPEDITED (15-DAY)	Y	HO	IT-AVENTIS-200911900GDDC		57 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Arava			S	Oral			Aventis
	Arava			S	Oral	Dose: 5 Mg Even		Aventis

				Days/10mg Odd Days		
	Arava		S	Oral		Aventis
	Cipralex		S	Oral		Not Reported
	Cipralex		S	Oral		Not Reported
	Nebivolol Hydrochloride		C	Oral		Not Reported
	Medrol		C	Oral		Not Reported
	Omeprazole		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2009	6949654	EXPEDITED (15-DAY)	N	HO, OT	US-PFIZER INC-2009182620			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Neoplasm; Hypersensitivity	Meclizine Hydrochloride			S				Pfizer
	Trazodone Hydrochloride			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported
	Interferon Alfa-2a			S		180 Ug, Weekly	13 DAY	Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2009	6950210	EXPEDITED (15-DAY)		OT	PHEH2009US02691		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Increased; Decreased Appetite; Drug Interaction; Extrasystoles	Lopresor			S	Oral	25 Mg, Qid		Novartis
	Lexapro			S	Oral	5 Mg, Qd		Not Reported
	Valium			C				Not Reported
	Klonopin			C				Not Reported
	Ativan			C				Not Reported
	Synthroid			C				Not Reported
	Effexor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2009	6950422	EXPEDITED (15-DAY)	Y	HO	NO-ABBOTT-09P-122-0562791-00			Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Lipoatrophy; Lipodystrophy Acquired	Kaletra			S	Oral			Not Reported
	Epivir			S				Not Reported
	Videx			S				Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2009	6957202	EXPEDITED (15-DAY)	N	OT	1000005376		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pelvic Congestion; Thrombosis; Uterine Cyst; Vaginal Haemorrhage	Lexapro			S	Oral Oral	See Image See Image		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2009	6957618	EXPEDITED (15-DAY)	Y	OT	1000005392		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Epistaxis; Oedema Peripheral; Renal Failure	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Levothyroxine (100 Microgram, Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2009	6958946	DIRECT	N	CA, OT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Lung Disorder; Maternal Drugs Affecting Foetus; Neonatal Disorder; Premature Baby	Lexapro			S	Oral	1 A Day Po 6-9 Months		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2009	6951594	EXPEDITED (15-DAY)	Y	HO	US-ROCHE-621957		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysarthria; Hypertension; Intentional Product Misuse	Klonopin			S	Oral			Roche
	Inderal			C				Not Reported
	Allegra-D			C				Not Reported
	Lotensin			C		Drug Reported: Lotension		Not Reported
	Ritalin			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2009	6959381	DIRECT	N	LT			16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Suicidal Ideation	Lexapro			S	Oral	10mg Once A Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2009	6954818	EXPEDITED (15-DAY)		OT	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2009-DE-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Drug Ineffective; Dyskinesia; Hyperphagia; Oculogyric Crisis; Suicide Attempt; Weight Increased	Pramipexole Dihydrochloride			S		Starting Dose Of 0.125 Mg, Titrated To 1.5 Mg Over The Next 4 Weeks		Boehringer Ingelheim
	Trazodone Hydrochloride			S		150mg		Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Lamotrigine			S		50mg		Not Reported
	Escitalopram Oxalate			S		20mg		Not Reported
	Zolpidem			S				Not Reported
	Temazepam			S				Not Reported
	Alprazolam			S				Not Reported
	Levothyroxine			C		150mcg		Not Reported

	Calcium Supplement	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2009	6961230	DIRECT	Y	HO			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Seizure; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	20 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2009	6965633	EXPEDITED (15-DAY)	Y	HO	1000005501		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity Vasculitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Stresam			S		1 To 4 Dr Daily (As		Not Reported
	Clonidine Hydrochloride			C				Not Reported
	Celectol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2009	6966973	EXPEDITED (15-DAY)	Y	HO	1000005522		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Vomiting	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Magne B6			C				Not Reported
	Levothyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2009	6969788	DIRECT	N	OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Disturbance In Attention; Educational Problem; Exercise Tolerance Decreased; Therapy Cessation	Lexapro	S	Oral Oral	5mg/5ml 1 Per Day Po 5mg/5ml 1 Per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2009	6958779	EXPEDITED (15-DAY)	Y	DE	US-ABBOTT-09P-163-0564051-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2009	6958841	EXPEDITED (15-DAY)	N	HO, OT	US-WATSON-2009-01994		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Bladder Neoplasm; Blood Urine Present; Dyskinesia; Hypersensitivity; Pharyngeal Oedema	Trazodone Hydrochloride			S	Unknown	Unk		Watson
	Meclizine Hydrochloride			S	Unknown	Unk		Watson
	Tramadol Hydrochloride			S	Unknown	Unk		Watson
	Peginterferon Alfa-2a			S	Unknown	180 Ug, 1/Week	13 DAY	Not Reported
	Ribavirin			S	Unknown	1000 Mg, Daily	13 DAY	Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2009	6966743	EXPEDITED (15-DAY)	Y	OT	1000005572		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2009	6966749	EXPEDITED (15-DAY)	Y	DE	2009S1004727		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alcohol Poisoning; Pneumonia; Pulmonary Congestion; Toxicity To Various Agents	Zyprexa	S	Not Reported
	Temazepam	S	Not Reported
	Dextromethorphan Hydrobromide	S	Not Reported
	Escitalopram Oxalate	S	Not Reported
	Ambien	S	Not Reported
	Lithium	C	Not Reported
	Risperdal	C	Not Reported
	Lexapro	C	Not Reported
	Naproxen	C	Not Reported
	Methocarbamol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2009	6967927	EXPEDITED (15-DAY)	Y	HO	1000005564		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dizziness; Fatigue; Intentional Overdose; Nausea; Suicide Attempt	Escitalopram Oxalate			S	Oral	1000 Mg (1000mg, Once), Oral		Not Reported
	Alcohol			S	Oral	1/2 Bottle Of Hard Liquor (35-40%) (Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2009	6970602	EXPEDITED (15-DAY)	Y	HO	1000005553		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Cerebrovascular Accident; Overdose	Lexapro			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral; 8-9 Tablets		Not Reported
					Oral	30 Mg (30 Mg, 1 In 1 D), Oral; 8-9 Tablets		
	Ambien			C				Not Reported
	Xanax			C				Not Reported
	Lamictal			C				Not Reported
	Neurontin			C				Not Reported
	Pain Patch (Nos)			C				Not Reported
	Lisinopril			C				Not Reported
	Amitriptyline			C				Not Reported
	Oxycontin			C				Not Reported

	Oxygen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2009	6970637	EXPEDITED (15-DAY)	Y	OT	1000005573		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2009	6987802	EXPEDITED (15-DAY)	Y	OT	1000005468		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported
	Lamictal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2009	6958657	EXPEDITED (15-DAY)	Y	DE	1000005307		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Dilatation Ventricular; Toxicity To Various Agents	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Zyprexa			S				Not Reported
	Seroquel			S				Not Reported
	Trazodone			S				Not Reported
	Benadryl			S				Not Reported
	Dilantin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2009	6958677	EXPEDITED (15-DAY)	Y	DE	1000005305		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Pneumonia; Toxicity To Various Agents	Lexapro			S				Not Reported
	Mirtazapine			S				Not Reported
	Sertraline Hydrochloride			S				Not Reported
	Amitriptyline			S				Not Reported

	Zolpidem	S			Not Reported
	Lorazepam	S			Not Reported
	Trazodone	S			Not Reported
	Phenytoin	S			Not Reported
	Aciclovir	S			Not Reported
	Zyprexa	S	2.5 Mg (2.5 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2009	6958683	EXPEDITED (15-DAY)	Y	DE	1000005306		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Drug Level Increased; Skin Injury; Toxicity To Various Agents	Lexapro			S				Not Reported
	Zyprexa			S				Not Reported
	Fluoxetine			S				Not Reported
	Kemadrin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2009	6959757	EXPEDITED (15-DAY)	Y	HO	US-ASTRAZENECA-2009UW07689		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Dysarthria; Headache; Hypertension; Hypokalaemia; Mental Status Changes; Multiple Drug Therapy	Zestoretic			S	Oral	20/12.5 Mg		Not Reported
	Desvenlafaxine Succinate			S	Oral		107 DAY	Not Reported
	Ibuprofen			S				Not Reported
	Lyrica			S				Not Reported
	Lexapro			S				Not Reported
	Clonazepam			S				Not Reported
	Abilify			S	Unknown			Not Reported
	Fluticasone			S		2 Sprays Daily		Not Reported
	Loratadine			S				Not Reported
	Vicodin			S		5/500		Not Reported
	Ambien			S	Oral			Not Reported
	Vivelle			S		0.1 Mg		Not Reported
	Robaxin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2009	6959999	EXPEDITED (15-DAY)	Y	OT	GB-TEVA-189544ISR		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bladder Anomaly; Pulmonary Malformation; Stillbirth	Amitriptyline			S	Oral			Teva
	Amitriptyline			S				Teva
	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2009	6961889	EXPEDITED (15-DAY)	Y	DE	1000005304		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Fall; Loss Of Consciousness; Pneumonia; Pulmonary Congestion; Toxicity To Various Agents	Lexapro			S		(10 Mg)		Not Reported
	Zyprexa			S				Not Reported
	Lithium			S				Not Reported
	Risperdal			S				Not Reported
	Ambien			S				Not Reported
	Temazepam			S				Not Reported
	Naproxen			S				Not Reported
	Methocarbamol			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2009	6961937	EXPEDITED (15-DAY)	Y	DE	1000005308		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Alcohol Use; Antipsychotic Drug Level Above Therapeutic; Arteriosclerosis; Hepatic Steatosis; Pulmonary Oedema; Snoring; Toxicity To Various Agents	Lexapro			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Zyprexa			S				Not Reported
	Lunesta			S				Not Reported
	Seroquel			S				Not Reported
	Vistaril			S				Not Reported
	Depakote			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2009	6963793	EXPEDITED (15-DAY)	Y	HO	1000005476			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Abdomen; Condition Aggravated; Drug Interaction; Lipoatrophy; Lipodystrophy Acquired	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Kaletra			S	Oral	Oral		Not Reported
	Lamivudine			S				Not Reported
	Didanosine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2009	6961673	EXPEDITED (15-DAY)	Y	DE	US-ABBOTT-09P-163-0566011-00		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Eszopiclone			S				Not Reported
	Quetiapine			S				Not Reported
	Hydroxyzine			S				Not Reported
	Valproate Semisodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2009	6962139	EXPEDITED (15-DAY)	Y	HO	SE-ELI_LILLY_AND_COMPANY-SE200903002257		40 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Major Depression	Duloxetine Hydrochloride			S	Oral	60 Mg, Unk		Eli Lilly And Co
	Escitalopram Oxalate			S	Unknown	10 Mg, Daily (1/D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2009	6962819	EXPEDITED (15-DAY)	Y	HO, OT	CA-ROXANE LABORATORIES, INC.-2009-RO-00333RO		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Hyperkalaemia; Overdose; Sinus Tachycardia	Morphine	S	30mg		Roxane
	Morphine	S			Roxane
	Morphine	S			Roxane
	Morphine	S			Roxane
	Ramipril	S	5mg		Roxane
	Lorazepam	S			Roxane
	Diazepam	S			Roxane
	Citalopram	S			Roxane
	Roxicet	S			Roxane
	Escitalopram Oxalate	S	10mg		Not Reported
	Escitalopram Oxalate	S			Not Reported
	Zopiclone	S	15mg		Not Reported
	Zopiclone	S			Not Reported
	Oxycodone	S			Not Reported
	Oxycodone	S			Not Reported
	Calcium Gluconate	C			Not Reported
	Insulin	C			Not Reported
	Sodium Polystyrene Sulphonate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2009	6970446	EXPEDITED (15-DAY)	Y	HO, OT	1000005099		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Creatine Phosphokinase; Intentional Overdose; Intentional Self-Injury; Suicide Attempt	Escitalopram Oxalate			S	Oral	80 Mg (80 Mg, Once), Oral; Oral		Not Reported
	Ritalin			S	Oral	300 Mg (300 Mg, Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2009	6802723	EXPEDITED (15-DAY)	Y	HO	DE-PFIZER INC-2008091240			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Liver Disorder	Lamotrigine			S				Not Reported
	Lithium Carbonate			C				Not Reported
	Ziprasidone Hydrochloride			S	Oral			Pfizer

	Sortis	S	Oral		Pfizer
	Tilidine	S			Not Reported
	Cymbalta	S			Not Reported
	Cipralex	S			Not Reported
	Seroquel	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2009	6812641	EXPEDITED (15-DAY)	Y	HO, OT	DE-PFIZER INC-2008090861			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Liver Disorder; Transaminases Increased	Zoloft			S				Pfizer
	Tilidine Hydrochloride			S				Not Reported
	Cymbalta			S				Not Reported
	Lithium Carbonate			C				Not Reported
	Sortis			S	Oral			Pfizer
	Ziprasidone Hydrochloride			S				Pfizer
	Lamotrigine			S				Not Reported
	Cipralex			S				Not Reported
	Seroquel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2009	6898476	EXPEDITED (15-DAY)	Y	DS, OT	1000003546		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Developmental Delay; Developmental Hip Dysplasia; Failure To Thrive; Gait Inability; Hypospadias; Hypotonia; Maternal Drugs Affecting Foetus; Selective Eating Disorder; Umbilical Cord Around Neck; Weight Gain Poor	Lexapro			S	Transplacental	5 Mg (5 Mg,1 In 1 D),Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2009	6966738	EXPEDITED (15-DAY)	Y	DE, HO	1000005560		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
					Oral	5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		
					Oral	5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		
	Cymbalta			S	Oral	Oral		Not Reported
	Ativan			C				Not Reported
	Abilify			C				Not Reported
	Remeron			C				Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2009	6970922	EXPEDITED (15-DAY)	Y	HO	1000005611		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Potassium Decreased; Confusional State; Dysarthria; Electrocardiogram St Segment Abnormal; Haematocrit Increased; Headache; Hypertension; Hypokalaemia; Mastoid Disorder; Mental Status Changes; White Blood	Lexapro			S		20 Mg (20 Mg,1 In 1 D)		Not Reported
	Unspecified Ingredient			S	Oral	(Daily),Oral		Not Reported
	Ibuprofen			S		2400 Mg (800 Mg,3 In 1 D)		Not Reported
	Lyrica			S		75 Mg (75 Mg,1 In 1 D)		Not Reported
	Clonazepam			S		2 Mg (1 Mg,2 In 1 D)		Not Reported
	Abilify			S		30 Mg (15 Mg,2 In 1 D)		Not Reported
	Fluticasone			S		(2 Sprays Daily)		Not Reported

Cell Count Increased	Loratadine	S		10 Mg (10 Mg,1 In 1 D)	Not Reported
	Vicodin	S		(Prn)	Not Reported
	Zestoretic	S		(Daily)	Not Reported
	Ambien	S		10 Mg (10 Mg,1 In 1 D)	Not Reported
	Vivelle	S	Transdermal	(0.1 Mg),Transdermal	Not Reported
	Robaxin	S		2250 Mg (750 Mg,3 In 1 D)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2009	6971728	EXPEDITED (15-DAY)	Y	OT	1000005643			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Urinary Retention	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	(1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2009	6959512	EXPEDITED (15-DAY)	Y	HO	235567K07USA		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Fall; Gait Disturbance; Injection Site Erythema; Injection Site Pain; Self-Injurious Ideation; Suicide Attempt	Rebif			S	Subcutaneous	44 Mcg, 3 In 1 Weeks, Subcutaneous		Not Reported
	Lexapro			S		40 Mg, 20 Mg 40 Mg, 20 Mg		Not Reported
	Ibuprofen (Ibuprofen)			C				Not Reported
	Synthroid			C				Not Reported
	Ocybutin (Oxybutynin/00538901/)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2009	6965479	EXPEDITED (15-DAY)	N	DS, OT	PHEH2009US03323			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Headache; Hyperacusis; Hypersensitivity; Hypothalamo-Pituitary Disorder; Muscle Spasms; Sensory Loss	Trileptal			S				Novartis
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2009	6966681	NON-EXPEDITED	N		US-ASTRAZENECA-2009UW01598		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Blood Pressure Increased; Dyspepsia; Joint Swelling	Atenolol			S	Oral			Not Reported
	Xyrem			S	Oral			Not Reported
	Ramipril			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Triamterene And Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2009	6975647	EXPEDITED (15-DAY)	Y	HO	1000005674		87 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer; Gastrointestinal Haemorrhage; Gastrooesophageal Reflux Disease; Haematemesis; Haemoglobin Decreased; Hiatus Hernia; Oesophageal Mucosal	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin			S	Oral	100 Mg 9100 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin			S	Oral	100 Mg 9100 Mg, 1 In 1 D), Oral		Not Reported
	Aricept			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

Hyperplasia	Novonorm (Tablets)	C	Not Reported
	Triatec (Tablets)	C	Not Reported
	Norvasc	C	Not Reported
	Remeron	C	Not Reported
	Leponex (Tablets)	C	Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)	C	Not Reported
	Acidum Folicum (Tablets)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2009	6975649	EXPEDITED (15-DAY)	Y	HO	1000005676		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2009	6976703	EXPEDITED (15-DAY)	Y	OT	1000005675		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Somnolence	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Anxicalm (Tablets)			C				Not Reported
	Lipitor			C				Not Reported
	Zoton (Capsules)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2009	6970393	EXPEDITED (15-DAY)	Y	HO, OT	PHHY2009FR13313		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatine Phosphokinase Increased; Blood Potassium Decreased; Blood Pressure Increased; Hyponatraemia; Nausea; Seizure; Vomiting	Trileptal	S	Oral	150 Mg, Bid	1890 DAY	Novartis
	Keppra	C		1 Tablet Each Morning And 2 Each Evening		Not Reported
	Dipiperon	C		Xv Each Morning, X Each Midday And Xxv Each Evening		Not Reported
	Flupentixol Dihydrochloride	C		20 Mg, Tiw		Not Reported
	Tropatepine Hydrochloride	C		1 Each Morning		Not Reported
	Escitalopram Oxalate	S		1 Each Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2009	6970467	EXPEDITED (15-DAY)	N	OT	A0777897A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Depression; Hallucination; Somnolence	Lamictal			S	Oral		6 YR	Glaxosmithkline
	Paxil			S	Oral			Glaxosmithkline
	Klonopin			S				Not Reported
	Lexapro			S				Not Reported
	Bupropion			S			6 YR	Teva
	Humulin R			C				Not Reported
	Spiriva			C				Not Reported
	Plavix			C				Not Reported
	Simvastatin			C				Not Reported
	Unspecified Ingredient			C				Glaxosmithkline
	Unspecified Ingredient			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2009	6970499	EXPEDITED (15-DAY)	Y	HO	US-ABBOTT-09P-163-0566868-00		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Dysarthria; Headache; Hypertension;	Vicodin			S	Unknown	5/500 As Needed		Not Reported
	Lexapro			S	Unknown			Not Reported

Hypokalaemia; Mental Status Changes; Multiple Drug Therapy	Ibuprofen	S	Unknown		Not Reported
	Desvenlafaxine Succinate	S	Oral		Not Reported
	Desvenlafaxine Succinate	S			Not Reported
	Abilify	S	Unknown		Not Reported
	Ambien	S	Oral		Not Reported
	Clonazepam	S	Unknown		Not Reported
	Fluticasone	S	Unknown	Sprays	Not Reported
	Loratadine	S	Unknown		Not Reported
	Lyrica	S	Oral		Not Reported
	Methocarbamol	S	Unknown		Not Reported
	Vivelle	S	Transdermal		Not Reported
	Zestoretic	S	Unknown	20/12.5 Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2009	6978597	EXPEDITED (15-DAY)	Y	OT	1000005706			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amimia; Dyskinesia; Extrapyramidal Disorder; Eyelid Function Disorder; Muscular Weakness; Parkinsonism	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S		(15 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2009	6978695	EXPEDITED (15-DAY)	Y	OT	1000005713			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Fall; Psychomotor Retardation	Escitalopram Oxalate			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2009	6985715	EXPEDITED (15-DAY)	N	OT	CHPA2009US09086			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dizziness; Dyspnoea	Acetaminophen\Diphenhydramine Hydrochloride\Phenylephrine Hydrochloride		Y	S	Oral	6 Tsp, Once/Single, Oral		Not Reported
	Acetaminophen\Dextromethorphan\Phenylephrine			S	Oral	6 Tsp, Once/Single, Oral		Not Reported
	Lexapro			S		Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2009	6924656	EXPEDITED (15-DAY)	Y	DE	1000003933		72 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Hypovolaemic Shock; Upper Gastrointestinal Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Terbinafine			S	Oral	250 Mg (250 Mg, 1 In 1 D), Oral		Not Reported
	Sifrol (Tablets)			C				Not Reported
	Motilium			C				Not Reported
	Madopar (Tablets)			C				Not Reported
	Nebilet (Tablets)			C				Not Reported
	Lyrinel Oros (Tablets)			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2009	6932334	EXPEDITED (15-DAY)	Y	OT	1000004847		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctival Haemorrhage; Episcleritis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Pariet			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

	Lorazepam	C	Not Reported
	Stilnox	C	Not Reported
	Avlocardyl	C	Not Reported
	Colchicine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2009	6959885	EXPEDITED (15-DAY)	Y	OT	1000005420		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Tachycardia	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Aspirin			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2009	6976336	DIRECT	Y	OT			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased	Lexapro			S	Oral	10mg Qd Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2009	6977964	EXPEDITED (15-DAY)	Y	CA	1000005711			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Pelvi-Ureteric Obstruction; Pyelocaliectasis	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental, 5 Mg (5 Mg, 1 In 1 D), Transplacental		Not Reported
					Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental, 5 Mg (5 Mg, 1 In 1 D), Transplacental		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2009	6978144	EXPEDITED (15-DAY)	Y	OT	GXKR2009GB04313		66 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Sedation; Somnolence	Clonidine Transdermal System			S		Qd		Not Reported
	Escitalopram Oxalate			S		5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2009	6517385	EXPEDITED (15-DAY)	Y	HO, OT	IN-PFIZER INC-2007107508		56 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Hypomania; Serotonin Syndrome	Sertraline Hydrochloride			S			35 DAY	Pfizer
	Amlodipine			C				Not Reported
	Trazodone Hydrochloride			S			35 DAY	Not Reported
	Lithium Carbonate			S				Pfizer
	Phenytoin Sodium			S				Pfizer
	Escitalopram Oxalate			S			7 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2009	6808022	EXPEDITED (15-DAY)	Y	OT	1000001459		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention; Urinary Tract Disorder; Uterine Leiomyoma	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2009	6943357	EXPEDITED (15-DAY)	Y	OT	1000005044		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Blood Thyroid Stimulating Hormone Increased; Gynaecomastia	Escitalopram Oxalate			S		15 Mg (15 Mg,1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2009	6955086	EXPEDITED (15-DAY)	Y	OT	1000005113		61 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Oedema; Respiratory Distress; Wrong Product Administered	Escitalopram Oxalate			S				Not Reported
	Nimesulide			S				Not Reported
	Loxapine			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2009	6974316	EXPEDITED (15-DAY)	Y	HO, OT	1000005649		28 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Intentional Overdose; Sopor; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S	Oral	160 Mg (160 Mg,Once),Oral ; Oral		Not Reported
	Mirtazapine			S	Oral	240 Mg (240 Mg,Once),Oral		Not Reported
	Tavor (Lorazepam)			S	Oral	20 Mg (20 Mg,Once),Oral		Not Reported
	Alcohol			S	Oral	(Once),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2009	6981226	EXPEDITED (15-DAY)	Y	OT	1000004813		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Eye Pain; Headache	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
	Seroquel			C				Not Reported
	Temesta (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2009	6983710	DIRECT	N	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Decreased Appetite; Headache; Nausea	Lexapro			S	Oral	1 Tablet 1x Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2009	7378900	EXPEDITED (15-DAY)	Y	HO, LT	1000005780		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Cardiac Failure; Left Ventricular Dysfunction; Mitral Valve Incompetence; Pulmonary Arterial Hypertension	Escitalopram Oxalate			S	Oral	3 Dosage Forms (3 Dosage Forms,1 In 1 D),Oral		Not Reported
	Benfluorex Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2009	6968549	EXPEDITED (15-DAY)	Y	OT	DE-ABBOTT-09P-062-0566920-00		28 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Intentional Overdose; Sopor; Suicide Attempt; Tachycardia	Cipralex			S	Oral	Overdose: 160mg (10mg, 16 In 1 Day)		Not Reported
	Mirtazapine			S	Oral	Overdose: 240mg (30 Mg, 8 In 1 Day)		Not Reported
	Tavor (Lorazepam)			S	Oral	Overdose: 20 Mg (0.5 Mg, 40 In 1 Day)		Not Reported
	Alcohol			S	Oral	Overdose: Unknown Amount (1.3 Per Mille)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2009	6981317	EXPEDITED (15-DAY)	Y	OT	1000005826		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; General Physical Health Deterioration; Pyrexia; Visual Impairment	Escitalopram Oxalate			S	Oral	5 Mg (5mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2009	6981382	EXPEDITED (15-DAY)	Y	OT	1000005796		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Overdose; Pelvic Fracture; Urinary Retention	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral, 30 Mg (30 Mg, 1 In 1 D), Oral,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2009	6981786	EXPEDITED (15-DAY)	Y	HO, LT	1000005822		34 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma Scale Abnormal; Deep Vein Thrombosis; Eschar; Hypothermia; Hypotonia; Intentional Overdose; Mydriasis; Pneumonia Aspiration; Rhabdomyolysis	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Alprazolam			S	Oral	Oral		Not Reported
	Nordazepam			S	Oral	Oral		Not Reported
	Aceprometazine\Meprobamate			S	Oral	Oral		Not Reported
	Zopiclone			S	Oral	Oral		Not Reported
	Acepromazine\Aceprometazine\ Clorazepate Dipotassium			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2009	6985142	DIRECT	N				44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Crying; Eye Disorder; Fear; Formication; Heart Rate Increased; Hyperacusis; Impaired Driving Ability; Mental Impairment; Nausea; Photophobia; Tremor	Lexapro			S	Oral	10mg 1 Tablet Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2009	6985357	DIRECT	N	DE			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Completed Suicide; Gun Shot Wound; Mood Swings	Lexapro			S	Oral	Once Dailey Po		Not Reported
	Xanax			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2009	6962502	EXPEDITED (15-DAY)	N	DE	US-BRISTOL-MYERS SQUIBB COMPANY-14574263		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Abilify			S	Oral		4 YR	Not Reported
	Lexapro			S	Oral			Not Reported
	Atenolol			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2009	6973126	EXPEDITED (15-DAY)	Y	OT	1000005655		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Fibrillation; Cachexia;	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D),		Not Reported

Cardiac Fibrillation; Decreased Appetite; Personality Change; Restlessness; Sinus Bradycardia; Sinus Tachycardia; Supraventricular Extrasystoles; Ventricular Extrasystoles; Weight Decreased				Oral	
	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Seroquel	S	Oral	650 Mg (650 Mg, 1 In 1 D), Oral; Oral	Not Reported
			Oral	650 Mg (650 Mg, 1 In 1 D), Oral; Oral	
	Seroquel	S	Oral	See Image	Not Reported
			Oral	See Image	
			Oral	See Image	
			Oral	See Image	
			Oral	See Image	
			Oral	See Image	
			Oral	See Image	
	Zyprexa	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported
	Zyprexa	S	Oral	(1 In 1 D), Oral	Not Reported
	Akineton	S	Oral	2 Mg (2 Mg, 1 In 1 D), Oral	Not Reported
	Zopiclone	S			Not Reported
	Pantozol	C			Not Reported
	Diazepam	C			Not Reported
	Levothyroxine Sodium	C			Not Reported
	Osteo Plus	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2009	6973245	EXPEDITED (15-DAY)	N	OT	DE-PFIZER INC-2009195648			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Asthenia; Drug Interaction; Mania; Tremor	Ziprasidone Hydrochloride			S	Oral	40-60mg/Day		Pfizer
	Ziprasidone Hydrochloride			S	Oral	80mg/Day		Pfizer
	Ziprasidone Hydrochloride			S				Pfizer
	Escitalopram Oxalate			S	Oral	10mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2009	6976913	EXPEDITED (15-DAY)	Y	HO, LT	AU-B.I. PHARMACEUTICALS,I			Male	AUS

NC./RIDGEFIELD-2009-AU-00

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Malaise	Micardis			S		40mg		Boehringer Ingelheim
	Escitalopram Oxalate			S	Oral	10mg		Not Reported
	Colgout			C	Oral	500mcg		Not Reported
	Movicol			C				Not Reported
	Mylanta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2009	6983732	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypertension; Serotonin Syndrome; Tachycardia	Linezolid			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2009	6984168	DIRECT					33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Product Dispensing Error	Lexapro			S				Not Reported
	Lipitor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2009	6985253	EXPEDITED (15-DAY)	Y	OT	1000005858		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	1000 Mg (1000 Mg, Once), Oral; Oral		Not Reported
	Alcohol			S	Oral	(Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2009	6987185	EXPEDITED (15-DAY)	Y	HO	1000005916		79 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hyponatraemia	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Citalopram Hydrobromide			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Citalopram			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Amiodarone			C				Not Reported
	Minisintron			C				Not Reported
	Amlodipine			C				Not Reported
	Seretide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2009	6806476	EXPEDITED (15-DAY)	Y	HO	DE-PFIZER INC-2008091321			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Interaction; Somnolence	Venlafaxine Hydrochloride			S	Oral		19 DAY	Not Reported
	Quilonorm			C				Not Reported
	Novodigal (Digoxin)			C				Not Reported
	Enalapril Maleate			C				Not Reported
	Furosemide			C				Not Reported
	Piretanide			C				Not Reported
	Kalinor (Potassium Chloride)			C				Not Reported
	Godamed			C				Not Reported
	Creon			C				Not Reported
	Ziprasidone Hydrochloride			S	Oral			Pfizer
	Cipralex			S				Not Reported
	Remergil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2009	6985889	DIRECT	Y				52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Depression; Dysgeusia; Fatigue; Hypophagia; Irritability; Lethargy; Mental Impairment; Pollakiuria; Tongue Discolouration; Vomiting	Effexor Xr			S	Oral Oral	37.5 Mg Daily (2x) Oral 37.5 Mg Daily (2x) Oral		Not Reported
	Lexapro			S	Oral	10 Mg 1 X Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2009	6986609	EXPEDITED (15-DAY)	N	OT	1000001578		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Depressed Mood; Feeling Abnormal; Inappropriate Schedule Of Product Administration; Muscular Weakness; Obsessive Thoughts; Product Dose Omission; Self-Injurious Ideation; Therapy Cessation; Treatment Noncompliance	Lexapro			S	Oral Oral Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2009	6910170	EXPEDITED (15-DAY)	Y	HO	1000003722		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysarthria; Hypertension; Malaise	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Ritalin			S				Not Reported
	Klonopin			S	Oral	2 Mg (0.5 Mg,4 In 1		Not Reported

							D),Oral		
	Inderal			C					Not Reported
	Lotension			C					Not Reported
	Allegra-D			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2009	6953720	EXPEDITED (15-DAY)	Y	HO	1000005156		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Vomiting	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2009	6967713	EXPEDITED (15-DAY)	Y	OT	DE-ABBOTT-09P-062-0566917-00		33 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Fibrillation; Supraventricular Extrasystoles; Ventricular Extrasystoles	Akineton			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Pantozol (Pantoprazole Sodium)			C	Oral			Not Reported
	Diazepam			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Calcium Carbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2009	6972494	EXPEDITED (15-DAY)	Y	DS	1000005598		32 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy	Escitalopram Oxalate			S	Oral	(20 Mg),Oral		Not Reported
	Lithium Carbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2009	6986715	DIRECT	N	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Family Stress; Impaired Work Ability; Paraesthesia; Quality Of Life Decreased; Tinnitus	Lexapro			S	Oral	Now: .5mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2009	6987558	EXPEDITED (15-DAY)	Y	DE, HO, LT, OT	1000003679		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Coma; Drug Interaction; Fall; Head Injury; Subdural Haematoma	Escitalopram Oxalate			S		20 Mg (20 Mg,1 In 1 D), 10 Mg (10mg1 In 1 D) 20 Mg (20 Mg,1 In 1 D), 10 Mg (10mg1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2009	6436152	EXPEDITED (15-DAY)	Y	DE	S07-IRL-05115-01		64 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis Coronary Artery; Completed Suicide; Hepatic Steatosis; Intentional Overdose; Left	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Unspecified Ingredient			S		Once		Not Reported

Ventricular Hypertrophy; Pneumonia; Poisoning; Pulmonary Oedema	Lipostat (Pravastatin Sodium) (Pravastatin Sodium)	C	Not Reported
	Zispin (Mirtazapine) (Mirtazapine)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2009	6982158	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2009-02802		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Temazepam			S		Unk		Watson
	Lexapro			S		Unk		Not Reported
	Ambien			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported
	Alcohol			S		Unk		Not Reported
	Dextromethorphan Hydrobromide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2009	6989392	EXPEDITED (15-DAY)	Y	HO	1000005945			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Overdose; Suicidal Ideation; Suicide Attempt; Unresponsive To Stimuli; Withdrawal Syndrome	Escitalopram Oxalate			S		60 Mg (60 Mg, 1in 1 D)		Not Reported
	Risperdal			C				Not Reported
	Tiaprid			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Eunerpan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2009	6992571	EXPEDITED (15-DAY)	N	HO	2008S1011439		33 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Induced Labour; Maternal Exposure During	Metoclopramide			S	Oral	10 Mg;Q6h;Oral		Not Reported

Pregnancy; Premature Labour; Premature Rupture Of Membranes	Escitalopram Oxalate		S	Oral	10 Mg;Daily;Oral	Not Reported
	Folic Acid		C			Not Reported
	Lysine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2009	6992578	EXPEDITED (15-DAY)	N	HO	2009S1006607			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice Neonatal; Maternal Drugs Affecting Foetus; Neonatal Infection; Premature Labour; Temperature Regulation Disorder	Metoclopramide			S	Transplacental	10 Mg;Q6h;Transplacental		Not Reported
	Escitalopram Oxalate			S	Transplacental	10 Mg;Daily;Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2009	6992566	DIRECT	N	DE			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Dysphagia; Fear; Nausea; Suicidal Ideation	Lexapro			S	Oral	2-3/Day Po		Forest
	Mirtazapine			S	Oral	15mg As Needed Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2009	6992626	EXPEDITED (15-DAY)	Y	HO	1000006038		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Arthralgia; Blood Creatine Phosphokinase Increased; Myalgia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Prazepam			S	Oral	(As Required),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2009	6541621	EXPEDITED (15-DAY)	Y		US-BAYER-200812372GPV		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Aspirin		Y	S	Unknown			Bayer
	Acetaminophen			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Bayer
	Naproxen			S	Unknown			Not Reported
	Unspecified Ingredient			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Caffeine			S				Not Reported
	Fexofenadine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2009	6986448	EXPEDITED (15-DAY)	Y	HO	FR-BRISTOL-MYERS SQUIBB COMPANY-14602924		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Fatigue; Hallucination, Auditory; Pain In Extremity; Somnolence	Abilify			S	Oral	Initiated On 30mar09,10mg/D Dose Increased To 15mg/D, On 21apr09, Again Dose Increased To 20mg/D		Not Reported
	Abilify			S	Oral	Initiated On 30mar09,10mg/D Dose Increased To 15mg/D, On 21apr09, Again Dose Increased To 20mg/D		Not Reported
	Abilify			S	Oral	Initiated On 30mar09,10mg/D Dose Increased To 15mg/D, On 21apr09, Again Dose Increased To 20mg/D		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Zyprexa			C		Dose Decreased To 5mg, Then Withdrawn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2009	6993569	DIRECT		OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Obsessive Thoughts; Suicidal Ideation	Lexapro			S			6 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2009	6897398	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009159452		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Aggression	Chantix			S		1 Mg, 2x/Day		Pfizer
	Lexapro			S		Unk		Not Reported
	Meclizine			S		Unk		Not Reported
	Unspecified Ingredient			S		Unk		Not Reported
	Flexeril			C		Unk		Not Reported
	Klonopin			C		Unk		Not Reported
	Compazine			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Lortab			C				Not Reported
	Amantadine			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Zanaflex			C		Unk		Not Reported
	Fosamax			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Dextrose			C		Unk		Not Reported
	Solu-Medrol			C		Unk		Not Reported
	Copaxone			C		Unk		Not Reported
	Calcium With Vitamin D			C		Unk		Not Reported

	Flonase	C			Not Reported
	Oxybutynin Hydrochloride	C	Unk		Not Reported
	Lisinopril	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2009	6987915	EXPEDITED (15-DAY)	N	OT	PHEH2009US04143		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disturbance In Attention; Dizziness; Nausea; Paraesthesia; Tinnitus	Reclast			S		Unk		Novartis
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg Qd X 7 Days		Not Reported
	Lexapro			S	Oral	10 Mg Every Other Day X 7 Days		Not Reported
	Lexapro			S	Oral	10 Mg, Qod	8 DAY	Not Reported
	Wellbutrin			C		Unk		Not Reported
	Xanax			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2009	6993934	EXPEDITED (15-DAY)	Y	HO	1000006063		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hyponatraemia	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Lasix			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2009	6993969	EXPEDITED (15-DAY)	Y	HO	1000006061		44 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Generalised Tonic-Clonic Seizure; Malaise; Seizure	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Lexomil (Tablets)		C			Not Reported
	Cartrex		C			Not Reported
	Omeprazole		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2009	6994010	DIRECT	N	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Dizziness; Hyperhidrosis; Nausea	Lexapro			S		20 Mg 1 Tablet Every Night At Bedtime, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2009	6994982	EXPEDITED (15-DAY)	N	DE	1000006099		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2009	6910195	EXPEDITED (15-DAY)	N	HO	PHEH2009US01490		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysarthria; Hypertension	Clonazepam			S		0.5 Mg, Qid		Not Reported
	Inderal			C		Unk		Not Reported
	Lotensin			C		Unk		Not Reported
	Allegra-D			C				Not Reported
	Ritalin			S		Unk, Unk		Novartis
	Lexapro			S	Oral	10 Mg Daily		Not Reported
	Lexapro			S	Oral	20mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2009	6996101	EXPEDITED (15-DAY)	Y	DE	1000006075			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2009	6799506	EXPEDITED (15-DAY)	Y	HO	1000001287		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Pruritus; Rash Maculo-Papular; Seborrhoeic Keratosis	Escitalopram Oxalate			S	Oral	(10 Mg), Oral		Not Reported
	Lansoprazole			S	Oral	Oral		Not Reported
	Symbicort			C				Not Reported
	Lescol			C				Not Reported
	Aspirin Lysine			C				Not Reported
	Sectral			C				Not Reported
	Spironolactone			C				Not Reported
	Altizide			C				Not Reported
	Laxomil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2009	6991001	EXPEDITED (15-DAY)	Y	OT	US-JNJFOC-20090501180		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia; Strabismus	Flexeril			S				Not Reported
	Flexeril			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Cogentin			S				Not Reported
	Cogentin			S				Not Reported
	Seroquel			S				Not Reported
	Seroquel			S				Not Reported
	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Vistaril			S				Not Reported

	Vistaril	S	Not Reported
	Lamictal	S	Not Reported
	Lamictal	S	Not Reported
	Albuterol Inhalers	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2009	6991537	EXPEDITED (15-DAY)	Y	HO	US-WYE-H09179309		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysstasia; Eating Disorder; Fatigue; Insomnia; Movement Disorder; Unevaluable Event	Pristiq Extended Release			S	Oral	Unknown		Wyeth
	Lexapro			S		Unknown		Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2009	6996175	DIRECT					49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2009	6997419	EXPEDITED (15-DAY)	Y	LT	1000005628		69 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Haematuria; Haemorrhagic Disorder; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Previscan (Fluindione)			S		0.75 Dosage Forms (0.75 Dosage Forms, 1 In 1 D)		Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2009	6996234	DIRECT	Y	OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain; Eructation; Flatulence; Muscle Spasms; Nausea	Lexapro		S	Oral	20 Mg Once Daily Po	Not Reported
	Citalopram		S	Oral	20 Mg Three Times Daily Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2009	6997765	DIRECT	Y	LT, OT			10 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abnormal Behaviour; Aggression; Hallucination; Mania; Vomiting	Lexapro			S	Oral	10mg Once Daily Po		Not Reported
	Prozac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2009	6975598	EXPEDITED (15-DAY)	Y	HO	CA-GENENTECH-281154		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Avastin			S	Intravenous (not otherwise specified)	15 Mg/Kg, Q3w	20 DAY	Genentech
	Trastuzumab			S	Intravenous (not otherwise specified)	8 Mg/Kg, Q3w		Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)	75 Mg/M2, Q3w		Not Reported
	Carboplatin			S		1 Unk, Q3w		Not Reported
	Tylenol With Codeine			S	Unknown			Not Reported
	Morphine			S	Unknown	2.5 Mg, Unknown	5 DAY	Not Reported
	Cipralex			S	Unknown	10 Mg, Unknown		Not Reported
	Ciprofloxacin			S	Oral	1000 Mg, Unknown	3 DAY	Not Reported
	Codeine			C				Not Reported
	Ammonium Chloride			C				Not Reported
	Ceftazidime			C		Unk	2 DAY	Not Reported
	Codeine			C		Unk	6 DAY	Not Reported
	Trazodone Hydrochloride			C		Unk		Not Reported

Escitalopram Oxalate	C	Unk			Not Reported
Docusate Sodium	C	Unk	6 DAY		Not Reported
Senna	C	Unk	6 DAY		Not Reported
Lactulose	C	Unk	2 DAY		Not Reported
Mouthwash Nos	C	Unk	4 DAY		Not Reported
Gravol	C	Unk	2 DAY		Not Reported
Simethicone	C	Unk	2 DAY		Not Reported
Piperacillin/Tazobactam	C	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2009	6989431	EXPEDITED (15-DAY)	Y	HO	GB-WYE-G03609809		16 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Condition Aggravated; Diarrhoea; Gastrointestinal Haemorrhage; Haematemesis	Anadin Ibuprofen			S	Oral		7 DAY	Wyeth
	Escitalopram Oxalate			S	Oral		7 DAY	Unknown
	Amoxicillin			C		Unknown		Unknown
	Terbutaline Sulfate			C	Respiratory (inhalation)	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2009	6999254	DIRECT					28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthma; Musculoskeletal Chest Pain; Nausea; Somnolence; Vomiting	Lexapro			S	Oral	10mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2009	7001388	DIRECT	N	OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Burning Sensation; Decreased Appetite; Feeling Abnormal; Feeling Jittery; Insomnia; Mental Disorder; Unevaluable Event	Zoloft	S	50	Not Reported
	Lexapro	S	10	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2009	7002976	EXPEDITED (15-DAY)	N		2009S1007640		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chills; Headache; Weight Decreased	Alprazolam			S	Oral	2.5 Mg; Twice A Day; Oral, 0.5 Mg; At Bedtime; Oral		Not Reported
					Oral	2.5 Mg; Twice A Day; Oral, 0.5 Mg; At Bedtime; Oral		
					Oral	2.5 Mg; Twice A Day; Oral, 0.5 Mg; At Bedtime; Oral		
	Escitalopram Oxalate			S	Oral	At Bedtime; Oral		Not Reported
	Lipitor			C				Not Reported
	Benicar			C				Not Reported
	Evista			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2009	6805527	EXPEDITED (15-DAY)	Y	HO	THQ2008A02085		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Pruritus; Rash Maculo-Papular; Seborrhoeic Keratosis	Lansoprazole (Lansoprazole)			S	Oral		21 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg		Not Reported
	Aspirin Lysine			S				Not Reported
	Acebutolol Hydrochloride			S				Not Reported
	Spironolactone			S				Not Reported
	Altizide			S				Not Reported
	Bromazepam			S				Not Reported
	Omeprazole Sodium			S				Not Reported
	Promoterol Fumarate,			C				Not Reported

	Budesonide									
	Fluvastatin			C						Not Reported
	Budesonide			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2009	6993943	EXPEDITED (15-DAY)	Y	HO	09GB001089		16 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Gastrointestinal Haemorrhage	Ibuprofen		Y	S	Oral	400 Mg Tid Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd Oral		Not Reported
	Amoxicillin Trihydrate			C				Not Reported
	Terbutaline Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2009	7003232	EXPEDITED (15-DAY)	Y	HO	1000006183		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysstasia; Gait Inability; Neuropathy Peripheral	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Aricept			C				Not Reported
	Levothyroxine			C				Not Reported
	Lisinopril			C				Not Reported
	Vivelle Dot			C				Not Reported
	Clonidine			C				Not Reported
	Namenda			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2009	7004444	EXPEDITED (15-DAY)	Y	HO	1000006225		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pruritus Generalised; Rash Papular	Escitalopram Oxalate			S	Oral	10 Mg Oral		Not Reported
	Tahoe			C				Not Reported
	Plavix			C				Not Reported
	Pariet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2009	6949991	EXPEDITED (15-DAY)	Y	DE	1000005098		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose	Escitalopram Oxalate			S		(20 Mg) ; (20 Mg)		Not Reported
	Amitriptyline Hydrochloride			S		(25 Mg)		Not Reported
	Tylenol With Codeine			S				Not Reported
	Diazepam			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2009	6980337	EXPEDITED (15-DAY)	N	HO	1000005842		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Fall; Transient Ischaemic Attack; Upper Limb Fracture	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2009	6993929	EXPEDITED (15-DAY)	Y	OT	1000006046		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Test Positive; Blood Chloride Decreased; Hyponatraemia; Monocyte Count Increased; Nocturia; Oliguria; White Blood Cell Count Increased	Escitalopram Oxalate			S	Ophthalmic	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Mavik			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2009	6996807	EXPEDITED (15-DAY)	Y	OT	US-JNJFOC-20090502781		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Condition Aggravated; Drug Interaction; Paranoia; Psychotic Disorder	Haloperidol			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Ziprasidone Hydrochloride			S	Unknown			Not Reported
	Ziprasidone Hydrochloride			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Varenicline			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2009	7003461	DIRECT	N	LT, RI, OT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Family Stress; Headache; Loss Of Employment; Nausea	Lexapro			S	Oral	1 Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2009	7005981	EXPEDITED (15-DAY)	Y	HO	1000006233		54 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctivitis; Pruritus; Rash Erythematous; Skin Exfoliation	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Phenobarbital			S	Oral	1 Dosage Forms (1 Dosage Forms,1 In 1 D),Oral		Not Reported
	Seresta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2009	7006163	EXPEDITED (15-DAY)	Y	DE, OT	1000006190		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme	Lexapro			S				Not Reported

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2009	7006659	EXPEDITED (15-DAY)	Y	OT	1000006217			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Dyskinesia; Heart Rate Increased; Tremor	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2009	6966970	EXPEDITED (15-DAY)	Y	DS, HO	1000005505		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Citalopram Hydrobromide			S	Oral	Oral		Not Reported
	Citalopram Hydrobromide			S	Oral	0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Prazepam			C				Not Reported
	Cyamemazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2009	7005331	DIRECT	N	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Depressed Mood; Drug Withdrawal Syndrome; Dystonia; Fatigue; Hot Flush; Hyperhidrosis; Impaired Work Ability; Influenza Like Illness; Insomnia; Memory	Effexor Xr			S	Oral	150 Mg. 2 Times A Day Po Several Years		Not Reported
	Lexapro			S	Oral	20 Mg. 2 At Bedtime Po Several Years		Forest

Impairment; Muscular Weakness; Myalgia; Nausea; Paraesthesia; Tearfulness; Vomiting; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2009	7005519	DIRECT	Y				39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hot Flush	Lexapro			S	Oral	1 Daily Po		Forest
	Celexa			S	Oral	1 Daily Po		Dr Reddys

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2009	6907599	NON-EXPEDITED	N	OT	2008S1022493		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Dependence; Drug Withdrawal Syndrome; Malaise; Somnolence	Fentanyl Transdermal System			S	Transdermal	50 Ug;Every Hour; Transdermal		Not Reported
	Fentanyl Transdermal System			S	Transdermal	25 Ug;Every Hour;Transdermal		Not Reported
	Fentanyl Transdermal System			S	Transdermal	12 Ug;Every Hour;Transdermal		Not Reported
	Lisinopril			S	Oral	20 Mg;Daily;Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg;Daily;Oral		Not Reported
	Atenolol			S	Oral	50 Mg;Daily;Oral		Not Reported
	Amlodipine			S	Oral	10 Mg;Daily;Oral		Not Reported
	Pepcid			C				Not Reported
	Omeprazole			C				Not Reported
	Potassium Chloride			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Vitamin D Nos			C				Not Reported

Asa	C		Not Reported
Zoloft	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2009	6978089	EXPEDITED (15-DAY)	Y	HO	1000005704		17 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Fall; Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Malaise; Postictal State; Skin Abrasion	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2009	7007566	DIRECT	N	OT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Disorder; Condition Aggravated; Ulcer	Lexapro			S		5 Mg (Liquid) Daily 5 Mg (Liquid) Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2009	7009109	EXPEDITED (15-DAY)	N	OT	1000006285		30 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Hypoventilation; Irritability; Maternal Drugs Affecting Foetus; Middle Insomnia; Muscle Twitching; Respiratory Rate Increased	Lexapro			S	Transplacental	20 Mg (20 Mg), Transplacental		Not Reported
	Allerx			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2009	7007383	DIRECT	N				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Euphoric Mood; Eye Movement Disorder; Headache; Insomnia; Jaw Disorder; Muscle Twitching; Tic	Lexapro			S	Oral	10 Mg -1 Pill- Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2009	7011091	EXPEDITED (15-DAY)	Y	HO	1000006274		16 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Gastrointestinal Haemorrhage; Haematemesis; Self-Medication	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Ibuprofen			S	Oral	1200 Mg (400 Mg, 3 In 1 D), Oral		Not Reported
	Amoxicillin			C				Not Reported
	Terbutaline Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2009	6996225	EXPEDITED (15-DAY)	Y	HO	GB-RANBAXY-2009RR-24025		16 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Gastrointestinal Haemorrhage; Haematemesis	Ibuprofen			S	Oral	400 Mg, Tid	7 DAY	Ranbaxy
	Escitalopram Oxalate			S	Oral	10 Mg, Qd	7 DAY	Not Reported
	Amoxicillin			C				Not Reported
	Terbutaline Sulfate			C	Respiratory (inhalation)			Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2009	6950332	EXPEDITED (15-DAY)	Y	DE	1000005088		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Delusion; Insomnia	Escitalopram Oxalate		S	Oral	10 Mg 910 Mg, 1 In 1 D), Oral	Not Reported
	Adalat Cc		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2009	7008971	DIRECT	N	LT, OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Communication Disorder; Loss Of Personal Independence In Daily Activities; Speech Disorder	Lexapro			S	Oral	20mg 1 X Day Po		Not Reported
	Lexapro			S	Oral	10 Mg 1 X Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2009	7009013	DIRECT	N	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Condition Aggravated; Depression; Suicidal Ideation; Therapy Non-Responder	Lexapro			S	Oral	20 Mg 1 Daily Po Approx. Feb To May 2009		Not Reported
	Klonopin			C				Not Reported
	Lamictal			C				Not Reported
	Zanaflex			C				Not Reported
	Diovan Hct			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2009	7004357	EXPEDITED (15-DAY)	Y	OT	1000006208		17 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Fatigue; Initial Insomnia; Restlessness; Sleep Disorder; Somnolence; Suicidal Ideation	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2009	7005303	EXPEDITED (15-DAY)	Y	OT	ZA-JNJFOC-20090505630		19 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Condition Aggravated; Disturbance In Attention	Risperdal			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2009	7013606	EXPEDITED (15-DAY)	N	OT	1000006326		29 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Withdrawal Syndrome; Headache; Insomnia; Nausea; Paraesthesia; Piloerection; Sensory Disturbance; Sexual Dysfunction; Suicidal Ideation	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Remeron			C				Not Reported
	Xanor (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2009	6957171	EXPEDITED (15-DAY)	Y	HO	1000003730		15 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Weight Decreased	Escitalopram Oxalate			S	Oral	5-20 Mg/Day, Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2009	6988364	EXPEDITED (15-DAY)	Y	HO	1000005939		19 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Rash Erythematous; White Blood Cell Count Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2009	7015632	EXPEDITED (15-DAY)	Y	HO	1000006443		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Urinary Retention	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2009	7016684	EXPEDITED (15-DAY)	Y	HO	1000006495		71 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Withdrawal Syndrome; Loss Of Consciousness	Lexapro			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
					Oral	5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral		
	Seroquel			C				Not Reported
	Omeprazol (Tablets)			C				Not Reported
	Famotidine			C				Not Reported
	Metamucil (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2009	6836296	EXPEDITED (15-DAY)	Y	HO, OT	1000001773		48 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Alcohol Withdrawal Syndrome; Anticonvulsant Drug Level	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

Below Therapeutic; Depression; Drug Interaction; Lumbar Vertebral Fracture; Road Traffic Accident; Seizure	Escitalopram Oxalate	S	Oral	10 Mg (1 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
			Oral	10 Mg (1 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg (10 Mg, 1 In 1 D), Oral	
			Oral	10 Mg (1 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg (10 Mg, 1 In 1 D), Oral	
	Escitalopram Oxalate	S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D, Oral	Not Reported
			Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D, Oral	
	Modafinil (Tablets)	S	Oral	200 Mg (200 Mg, 1 In 1 D), Oral; 100 Mg 9100 Mg, 1 In 1 D)	Not Reported
			Oral	200 Mg (200 Mg, 1 In 1 D), Oral; 100 Mg 9100 Mg, 1 In 1 D)	
	Modafinil (Tablets)	S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral	Not Reported
	Alcohol	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2009	7008743	EXPEDITED (15-DAY)	Y	HO, OT	AU-TEVA-196331USA		62 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Naltrexone Hydrochloride			S				Barr
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2009	7016501	EXPEDITED (15-DAY)	Y	DE	1000006541		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Thermal Burn; Treatment Noncompliance	Lexapro			S	Oral	10 Mg, Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg, Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2009	7017930	EXPEDITED (15-DAY)	Y	OT	1000006499		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Sedation; Urinary Incontinence	Escitalopram Oxalate			S	Oral	920 Mg), Oral		Not Reported
	Diazepam			S	Oral	(5 Mg), Oral		Not Reported
	Celecoxib			S	Oral	(200 Mg), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2009	7024190	EXPEDITED (15-DAY)	N	OT	1000006532			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dry Mouth; Dysgeusia; Dysphagia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2009	7024609	DIRECT	N	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Amnesia; Anhedonia; Anxiety; Confusional State; Depersonalisation/Dereali	Lexapro			S		Lexapro 10 Mg 1x		Forest
	Klonopin			C				Not Reported

sation Disorder; Dizziness; Emotional Disorder; Hypoaesthesia; Loss Of Employment; Nervous System Disorder; Pain In Extremity; Product Quality Issue; Screaming; Somnolence

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2009	7013725	EXPEDITED (15-DAY)	Y	HO, OT	1000006324		54 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Sounds Abnormal; Intentional Overdose; Rhabdomyolysis; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral	Once, Oral		Not Reported
	Zopiclone			S	Oral	75 Mg (75 Mg, Once) Oral		Not Reported
	Imipramine			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2009	7010534	EXPEDITED (15-DAY)	Y	OT	090520-0000710		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Diplopia; Pupillary Reflex Impaired; Strabismus; Visual Acuity Reduced	Cogentin			S	Oral	Po		Not Reported
	Cyclobenzaprine Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Quetiapine Fumarate			S				Not Reported
	Aripiprazole			S				Not Reported
	Hydroxyzine Pamoate			S				Not Reported
	Lamotrigine			S				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2009	7018031	DIRECT	Y	OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Amnesia; Personality Change	Lexapro	S	Oral	20mg Bid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2009	7023032	EXPEDITED (15-DAY)	Y	HO	1000006593		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Epistaxis; Haematochezia; Sleep Disorder	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Coumadin			S				Not Reported
	Vitamins			C				Not Reported
	Atenolol			C				Not Reported
	Amlodipine			C				Not Reported
	Quinapril			C				Not Reported
	Digoxin			C				Not Reported
	Hyzaar			C				Not Reported
	Welchol			C				Not Reported
	Gemfibrozil			C				Not Reported
	Metformin Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2009	7013107	NON-EXPEDITED	N		A0743970A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction; Tachyphylaxis	Wellbutrin Xl			S	Oral	300mg Per Day		Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	C-Pap			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2009	7013177	NON-EXPEDITED	N		A0752544A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exercise Lack Of	Wellbutrin Xl			S	Oral	150mg Twice Per Day		Glaxosmithkline

	Lexapro	S	Oral	20mg Per Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2009	7013222	NON-EXPEDITED	N		A0758554A		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Wellbutrin Xl			S	Oral	300mg Per Day	26 WEEK	Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2009	7022630	DIRECT	N	OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Chest Pain; Disturbance In Attention; Ejaculation Failure; Fatigue; Hyperhidrosis; Pain In Extremity; Paraesthesia	Lexapro			S	Oral	10mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2009	7024858	EXPEDITED (15-DAY)	Y	HO	1000006616			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Escitalopram Oxalate			S				Not Reported
	Benzodiazepine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2009	6881439	EXPEDITED (15-DAY)	Y	OT	1000003347		70 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic Syndrome; Pancytopenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zolpidem	C				Not Reported
	Bromazepam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2009	7027043	EXPEDITED (15-DAY)	Y	OT	1000006377		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Product Dispensing Error; Restless Legs Syndrome	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Seropram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2009	7028808	EXPEDITED (15-DAY)	Y	HO	1000006607		89 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Creatinine Renal Clearance Decreased; Gastric Ulcer Haemorrhage	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin Lysine			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Nitroderm			C				Not Reported
	Lasix			C				Not Reported
	Imovane (Tablets)			C				Not Reported
	Modopar (Capsules)			C				Not Reported
	Cardensiel			C				Not Reported
	Rivotril			C				Not Reported
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Aluminum Hydroxide And Magnesium Trisilicate			C				Not Reported
	Efferalgan (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2009	7029097	EXPEDITED (15-DAY)	Y	HO	1000006614			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition; Intentional Overdose	Escitalopram Oxalate			S	Oral	28 Dosage Forms (28 Dosage Forms, Once), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2009	7029172	EXPEDITED (15-DAY)	Y	HO	1000006612		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Haemoptysis; Haemorrhage; Metastases To Lung; Overdose; Prothrombin Level Abnormal	Escitalopram Oxalate			S	Oral	40 Mg (20 Mg, 2 In 1 D), Oral		Not Reported
	Vandetanib			S				Not Reported
	Levothyrox			C				Not Reported
	Equanil			C				Not Reported
	Seresta			C				Not Reported
	Aprovel			C				Not Reported
	Isoptin			C				Not Reported
	Seretide			C				Not Reported
	Unspecified Ingredient			C				Not Reported
	Ventolin			C				Not Reported
	Inexium			C				Not Reported
	Loperamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2009	7029515	EXPEDITED (15-DAY)	Y	HO	DE-WYE-G03808809		35 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Respiratory Depression; Seizure;	Venlafaxine Hydrochloride			S	Oral	Overdose	1 DAY	Not Reported
	Amitriptyline Hydrochloride			S	Oral	Overdose	1 DAY	Not Reported

Suicide Attempt	Cipralex		S	Oral	Overdose	1 DAY	Not Reported
	Lyrica		S	Oral	Overdose	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2009	7030072	EXPEDITED (15-DAY)	Y	OT	GB-WYE-G03792809		30 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; International Normalised Ratio Increased	Effexor			S				Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2009	6918681	EXPEDITED (15-DAY)	Y	OT	1000003881			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Caesarean Section; Dyspnoea; Infection; Maternal Drugs Affecting Foetus; Neonatal Tachypnoea	Escitalopram Oxalate			S	Transplacental	Transplacental		Not Reported
	Flovent			C				Not Reported
	Salbutamol (Salbutamol) (Salbutamol)			C				Not Reported
	Advair Hfa			C				Not Reported
	Vitamins (Nos)			C				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2009	6920261	EXPEDITED (15-DAY)	Y	OT	S08-CAN-01736-01		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Labour; Caesarean Section; Maternal Exposure During Pregnancy; Pregnancy; Premature Rupture Of Membranes; Type 2 Diabetes Mellitus	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Flovent			C				Not Reported
	Salbutamol (Salbutamol) (Salbutamol)			C				Not Reported
	Advair Hfa			C				Not Reported
	Vitamins (Nos)			C				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2009	6990685	EXPEDITED (15-DAY)	N	OT	1000006012		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Coronary Artery Disease; Coronary Artery Occlusion; Crying; Irritability; Nervousness; Overdose; Pain In Extremity; Sensory Disturbance; Therapy Cessation	Lexapro			S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Amaryl			C				Not Reported
	Metoprolol			C				Not Reported
	Norvasc			C				Not Reported
	Crestor			C				Not Reported
	Lisinopril			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2009	7030034	EXPEDITED (15-DAY)	Y	OT	1000006656		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Chills; Drug Interaction; Gait Disturbance; Posture Abnormal	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Ziprasidone			S	Oral	120 Mg (60 Mg, 2 In 1 D), Oral		Not Reported
	Ziprasidone			S	Oral	80 Mg (40 Mg, 2 In 1 D), Oral		Not Reported
	Temesta (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2009	7031354	EXPEDITED (15-DAY)	Y	OT	1000006655			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Repolarisation Abnormality	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Ace Inhibitor Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2009	7032922	EXPEDITED (15-DAY)	Y	OT	GXKR2009GB06602		30 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; International Normalised Ratio Increased	Venlafaxine Hydrochloride			S				Not Reported
	Cipralex			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2009	6831933	EXPEDITED (15-DAY)	Y	HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-14428775		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Thrombosis	Anafranil			S	Oral			Sandoz
	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	Tab		Not Reported
	Cyamemazine			S	Oral			Not Reported
	Cyamemazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2009	6896844	EXPEDITED (15-DAY)	N	HO, LT	FR-BRISTOL-MYERS SQUIBB COMPANY-14484257		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Anafranil			S				Sandoz
	Abilify			S	Oral			Not Reported
	Cyamemazine			S				Not Reported
	Escitalopram Oxalate			S		Taken 1 Tablet Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2009	6992561	EXPEDITED (15-DAY)	Y	OT	1000006036		24 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperbilirubinaemia	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	15 Mg (15 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		
					Oral	15 Mg (15 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		
	Xanor (Tablets)			C				Not Reported
	Xanor (Tablets)			C				Not Reported
	Propral (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2009	7022145	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20090601633		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Atrial Flutter; Bradycardia; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Hypertension; Malaise; Nervous System Disorder; Torsade De Pointes; Ventricular Extrasystoles	Galantamine Hydrobromide			S	Unknown			Not Reported
	Fluticasone			S	Respiratory (inhalation)			Not Reported
	Bromazepam			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Inipomp			S	Oral			Not Reported
	Coaprovel			S	Oral			Not Reported
	Fluindione			S	Unknown			Not Reported
	Ibandronic Acid			C	Unknown			Not Reported
	Levothyrox			C	Unknown			Not Reported
	Fluticasone			C	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2009	6993966	EXPEDITED (15-DAY)	Y	HO	1000006062		17 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Gastrointestinal Haemorrhage; Metrorrhagia; Nausea; Suicide Attempt	Escitalopram Oxalate			S	Oral	(20 Mg, Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2009	6997412	EXPEDITED (15-DAY)	Y	OT	1000006120		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Atarax			S	Oral	137.5 Mg (137.5 Mg, 1 In 1 D), Oral; 87.5 Mg (87.5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	137.5 Mg (137.5 Mg, 1 In 1 D), Oral; 87.5 Mg (87.5 Mg, 1 In 1 D), Oral		
	Influenza Virus Vaccine Nos			S		1 Dosage Forms (1 Dosage Forms, Once)		Not Reported
	Topalgic (Tramadol Hydrochloride)			S	Oral	300 To 400 Mg Daily (1 In 1 D), Oral		Not Reported
	Topalgic (Tramadol Hydrochloride)			S	Oral	300 Mg (300 Mg, 1 In 1 D), Oral; 350 Mg (350 Mg, 1 In 1 D), Oral		Not Reported
					Oral	300 Mg (300 Mg, 1 In 1 D), Oral; 350 Mg (350 Mg, 1 In 1 D), Oral		
	Amitriptyline			S	Oral	15 Mg (5 Mg, 3 In 1 D), Oral		Not Reported
	Lovenox			C				Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported

	Stilnox	C	Not Reported
	Oracilline	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2009	7011307	EXPEDITED (15-DAY)	Y	OT	1000006380		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Coeliac Disease; Complication Associated With Device; Haemoglobin Decreased; Vaginal Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Mirena			S	Intra-uterine	(52 Mg), I.U.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2009	7033287	EXPEDITED (15-DAY)	Y	HO	1000006766		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bradycardia; Conduction Disorder; Drug Interaction; Electrocardiogram Qt Prolonged; Hypertension; Loss Of Consciousness; Malaise; Motor Dysfunction; Nervous System Disorder; Torsade De Pointes; Ventricular Extrasystoles	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Galantamine Hydrobromide			S		24 Mg (24 Mg, 1 In 1 D)		Not Reported
	Coaprovel			C				Not Reported
	Fluindone			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Levothyrox			C				Not Reported
	Fluticasone			C				Not Reported
	Bromazepam			C				Not Reported
	Ibandronic Acid			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2009	6795932	EXPEDITED (15-DAY)	Y	OT	1000000723		28 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Maternal Exposure During	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

Pregnancy; Otitis Media;
Pre-Eclampsia; Pregnancy
With Contraceptive Device

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2009	7025058	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-14661680		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Epistaxis; Haematochezia; Sleep Disorder	Coumadin			S				Bristol Myers Squibb
	Lexapro			S	Oral			Not Reported
	Vitamins			C				Not Reported
	Atenolol			C				Not Reported
	Amlodipine			C				Not Reported
	Quinapril			C				Not Reported
	Digoxin			C				Not Reported
	Hyzaar			C		1 Df = 50/12.5mg		Not Reported
	Welchol			C				Not Reported
	Gemfibrozil			C				Not Reported
	Metformin Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2009	7030033	DIRECT	N	CA, HO, LT, RI			1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Pulmonary Hypertension; Maternal Drugs Affecting Foetus	Lexapro			S	Oral	10 Mg 1 Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2009	7026148	EXPEDITED (15-DAY)	Y	OT	GB-MYLANLABS-2009S1009856		30 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; International Normalised Ratio	Venlafaxine Hydrochloride			S				Not Reported
	Cipralex			S	Oral			Alphapharm

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2009	7033218	DIRECT	N				48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Musculoskeletal Stiffness; Neuralgia; Pain	Lexapro			S	Oral	15 Mg 1x Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2009	7035439	EXPEDITED (15-DAY)	Y	LT, OT	1000006795		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Respiratory Depression; Seizure; Suicide Attempt	Escitalopram Oxalate			S	Oral	(Once), Oral; Oral		Not Reported
	Amitriptyline			S	Oral	(Once), Oral		Not Reported
	Lyrica			S	Oral	(Once), Oral		Not Reported
	Venlafaxine Hydrochloride			S	Oral	(Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2009	7035190	DIRECT	Y	CA, DS, HO, LT, RI, OT			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Overdose	Geodon			S		100 Mg		Not Reported
	Lexapro			S		100mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2009	7003809	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009215184			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Bladder Disorder; Depression;	Zoloft			S				Pfizer
	Lexapro			S				Not Reported

Fibromyalgia;
Gastrooesophageal Reflux
Disease; Pain

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2009	7015634	EXPEDITED (15-DAY)	Y	LT	1000006445		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Depression	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1in 1 D),Oral		Not Reported
	Valsartan			S	Oral	80 Mg (80 Mg, 1 In 1 D) , Oral		Not Reported
	Rosuvastatine (Tablets)			C				Not Reported
	Levothyroxine(0.05 Milligram, Tablets)			C				Not Reported
	Phenobarbital			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2009	7056612	NON-EXPEDITED	N		SPV1-2009-00991		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Vyvanse			S	Oral	20 Mg, 1x/Day:Qd, Oral		Not Reported
	Lexapro			S	Oral	20 Mg, 1x/Day:Qd, Oral		Not Reported
	Calcium (Calcium)			C				Not Reported
	Vitamin D Nos (Vitamin D Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2009	6955720	EXPEDITED (15-DAY)	Y	OT	1000005185		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported
	Alprazolam			C				Not Reported

Psychotropics (Nos)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2009	6974766	EXPEDITED (15-DAY)	N	HO	1000005494		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Depression; Haematemesis; Throat Irritation	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin			S				Not Reported
	Nexium			C				Not Reported
	Benicar			C				Not Reported
	Labetalol			C				Not Reported
	Glyburide			C				Not Reported
	Norvasc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2009	7010488	EXPEDITED (15-DAY)	Y	OT	US-RANBAXY-2009RR-24496		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Drug Interaction; Low Density Lipoprotein Increased	Zocor			S				Ranbaxy
	Levothyroxine Sodium			S		0.05 Mg, Unk		Not Reported
	Levothyroxine Sodium			S		0.075 Mg, Qd		Not Reported
	Levothyroxine Sodium			S		0.1 Mg, Qd		Not Reported
	Levothyroxine Sodium			S		0.125 Mg, Qd		Not Reported
	Levothyroxine Sodium			S		0.137 Mg, Qd		Not Reported
	Escitalopram Oxalate			S		5 Mg, Unk		Not Reported
	Vytorin			S		10/40 Mg		Not Reported
	Zetia			S		Unk		Not Reported
	Crestor			S		5 Mg, Qd		Not Reported
	Iodine I-131			C				Not Reported
	Welchol			C		Unk		Not Reported
	Warfarin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2009	7039869	DIRECT	Y				35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depersonalisation/Dereali sation Disorder; Disturbance In Attention; Dizziness; Drug Withdrawal Syndrome; Headache; Irritability; Vertigo	Lexapro			S	Oral	20 Mg Qd Po		Forest
	Deplin			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2009	6790445	EXPEDITED (15-DAY)	Y	OT	DE-ABBOTT-08P-062-0480950-00		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Otitis Media; Pre-Eclampsia	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2009	7032430	EXPEDITED (15-DAY)	Y		US-MYLANLABS-2009S1007640		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chest Pain; Chills; Drug Withdrawal Syndrome; Dyskinesia; Headache; Malaise; Nausea; Retching; Tremor; Weight Decreased	Alprazolam			S	Oral			Alphapharm
	Alprazolam			S	Oral			Alphapharm
	Alprazolam			S	Oral			Alphapharm
	Alprazolam			S	Oral			Alphapharm
	Alprazolam			S	Oral			Alphapharm
	Alprazolam			S	Oral			Alphapharm
	Alprazolam			S	Oral			Alphapharm

	Alprazolam		S	Oral			Alphapharm
	Alprazolam		S	Oral			Alphapharm
	Alprazolam		S	Oral			Alphapharm
	Alprazolam		S	Oral			Alphapharm
	Alprazolam		S	Oral			Alphapharm
	Alprazolam		S	Oral			Alphapharm
	Alprazolam		S	Oral			Alphapharm
	Lexapro		S	Oral		6 MTH	Alphapharm
	Lipitor		C	Oral			Not Reported
	Benicar		C	Oral			Not Reported
	Evista		C	Oral			Not Reported
	Synthroid		C	Oral			Not Reported
	Cipro		C				Not Reported
	Nitrofurantoin		C				Not Reported
	Azithromycin		C				Not Reported
	Doxycycline		C				Not Reported
	Omeprazole		C				Not Reported
	Folic Acid		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2009	7040965	DIRECT	N	RI			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Testosterone Decreased; Erectile Dysfunction; Libido Decreased	Lexapro			S	Oral	1 Once A Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2009	6295116	EXPEDITED (15-DAY)	Y	CA	S07-FIN-01390-02		1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section;	Cipralex			S	Transplacental	10 Mg (10 Mg, Once A		Not Reported

Congenital Anomaly; Dysmorphism; Maternal Drugs Affecting Foetus				Day), Transplacental	
	Selexid (Pevmecillinam Hydrochloride)	S			Not Reported
	Ispaghula	S			Not Reported
	Laxoberon	S			Not Reported
	Xenical	C			Not Reported
	Antepsin	C			Not Reported
	Lansoprazole	C			Not Reported
	Tolterodine Tartrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2009	6936419	EXPEDITED (15-DAY)	N	DE	1000004976		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asphyxia; Completed Suicide; Depression; Pain	Lexapro			S	Oral	(10 Mg), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2009	7041346	DIRECT	N	RI			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Hair Texture Abnormal; Product Label Issue	Lexapro			S	Oral	15mg 1x Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2009	7042988	EXPEDITED (15-DAY)	Y	OT	1000006981		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Intentional Overdose; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S	Oral	10 Tablets, Oral		Not Reported
	Chlorprothixene Hydrochloride			S		500 Mg (50 Mg, 10 In 1 D)		Not Reported
	Seroquel			S		10 Tablets		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2009	7034359	EXPEDITED (15-DAY)	Y	HO	CH-ROXANE LABORATORIES, INC.-2009-RO-00606RO		80 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lesion; Encephalopathy; Toxicity To Various Agents	Levetiracetam			S				Roxane
	Levetiracetam			S				Roxane
	Verapamil Hydrochloride			S				Not Reported
	Propranolol			S				Not Reported
	Metformin Hydrochloride			S				Not Reported
	Oxazepam			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Benserazide\Levodopa			S				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2009	7045211	EXPEDITED (15-DAY)	Y	OT	1000007010			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear; Morbid Thoughts	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2009	6806546	EXPEDITED (15-DAY)	Y	OT	1000001430		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blepharitis; Chorioretinal Disorder; Dry Eye; Eye Pain; Headache; Maculopathy; Overdose; Vision Blurred; Visual Acuity Reduced; Vitreous Disorder; Weight Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	30 Mg (30 Mg, 1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Wellbutrin			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Wellbutrin			C				Not Reported
	Zocor			C				Not Reported

	Xanax	C		Not Reported
	Gabapentin	C		Not Reported
	Topamax	C		Not Reported
	Indomethacin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2009	7044593	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dry Mouth; Gait Inability; Headache; Hyperhidrosis; Hypertension; Palpitations; Panic Attack	Lexapro			S				Not Reported
	Prozac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2009	7045097	DIRECT	N	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Mania	Lexapro			S	Oral	10 Mg 1-Day Oral 15-20 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2009	6906165	EXPEDITED (15-DAY)	Y	HO	FR-ROCHE-612930		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Fall; Orthostatic Hypotension	Rivotril			S	Oral			Roche
	Bromazepam			S	Oral			Roche
	Amitriptyline			S	Oral	Tdd Reported As 15 Doses Daily		Roche
	Vastarel			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Atacand			S	Oral			Not Reported

	Levomepromazine	S	Oral	Not Reported
	Escitalopram Oxalate	S	Unknown	Not Reported
	Omeprazole	C		Not Reported
	Actonel	C		Not Reported
	Calcium Carbonate	C		Not Reported
	Previscan (Fluindione)	C		Not Reported
	Symbicort	C		Not Reported
	Sinemet	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2009	7036393	EXPEDITED (15-DAY)	N	HO	US-RB-017383-09		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mood Swings	Suboxone			S	Sublingual	Varying Dose Up To 12 Mg Daily		Not Reported
	Lexapro			S	Unknown	Unknown Dose		Not Reported
	Lexapro			S	Unknown	Unknown Dose		Not Reported
	Seroquel			S	Unknown	Unknown		Not Reported
	Seroquel			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2009	7040080	EXPEDITED (15-DAY)	Y	OT	FR-PFIZER INC-2009232743		27 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Atarax			S	Oral	137.5 Mg, Unk	3 DAY	Pfizer
	Atarax			S	Oral	87.5 Mg, Unk		Pfizer
	Influenza Virus Vaccine Nos			S		Unk	1 DAY	Not Reported
	Topalgic (France)			S	Oral	350 Mg, Unk	5 DAY	Not Reported
	Topalgic (France)			S	Oral	Unk	44 DAY	Not Reported
	Topalgic (France)			S	Oral	300 Mg, Unk		Not Reported
	Amitriptyline Hydrochloride			S	Oral	5 Mg, 3x/Day		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Unk		Not Reported

Lovenox	C	Subcutaneous	4000 Iu, 1x/Day		Not Reported
Aspegic [Acetylsalicylate Lysine]	C		100 Mg, Unk		Not Reported
Oracilline	C		2 Df, Unk		Not Reported
Stilnox	C	Oral	0.5 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2009	7047868	DIRECT	N	HO, LT, RI			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anger; Anxiety; Depression; Emotional Disorder; Feeling Abnormal; General Physical Health Deterioration; Hypertension; Partner Stress; Serotonin Syndrome; Suicidal Ideation; Thinking Abnormal	Lexapro			S		10 Mg Daily		Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2009	6992559	EXPEDITED (15-DAY)	Y	HO	1000006020		61 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Base Excess Negative; Blood Bicarbonate Decreased; Blood Calcium Decreased; Blood Creatine Phosphokinase Increased; Blood Glucose Increased; Blood Osmolarity Decreased; Blood Ph Decreased; Blood Urea Decreased; Carbon	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Haldol			C				Not Reported
	Albyl-E			C				Not Reported
	Atacand			C				Not Reported
	Sobril			C				Not Reported
	Persantine			C				Not Reported
	Paracetamol			C				Not Reported

Dioxide Decreased; Cerebral Atrophy; Cerebral Infarction; Generalised Tonic-Clonic Seizure; Haemoglobin Decreased; Hyponatraemia; Injury; Mean Cell Volume Decreased; Overdose; Oxygen Saturation Decreased	Simvastatin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2009	7050339	EXPEDITED (15-DAY)	N	OT	1000007143		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer In Situ; Breast Cancer Recurrent; Breast Pain; Breast Swelling; Oestrogen Receptor Assay Positive	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolam			C				Not Reported
	Prevacid			C				Not Reported
	Singulair			C				Not Reported
	Advil			C				Not Reported
	Multivitamins			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2009	7051494	EXPEDITED (15-DAY)	Y	OT	1000007161		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sopor; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Doxepin			S	Oral	Oral		Not Reported
	Seroquel			S	Oral	Oral		Not Reported
	Tavor (Lorazepam)			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2009	6232629	EXPEDITED (15-DAY)	Y	OT	S07-SWI-00279-01		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Infection; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S	Oral	Oral		Not Reported
	Clonazepam			S	Oral	20 Mg (20 Mg), Oral		Not Reported
	Alcohol (Ethanol)			S	Oral	Oral		Not Reported
	Lorazepam			S	Oral	2.5mg (2.5 Mg), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2009	6755074	EXPEDITED (15-DAY)	Y	HO	1000000679		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Headache; Incontinence; Lethargy; Nuclear Magnetic Resonance Imaging Brain Abnormal; Seizure; Unresponsive To Stimuli	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2009	7043308	EXPEDITED (15-DAY)	Y	OT	DE-MYLANLABS-2009S1011285		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura	Lamotrigine			S	Oral	200-0-250-0		Not Reported
	Oxcarbazepine			S	Oral			Not Reported
	Enalapril			S	Oral	Daily Dose: 2 Df Dosage Form Every Day		Genpharm
	Metoprolol			S	Oral	Daily Dose: 2 Df Dosage Form Every Day		Not Reported
	Ferrous Sulfate\Folic Acid			S	Oral	Daily Dose: 1 Df Dosage Form Every Day		Not Reported

	Simvastatin	S	Oral	Daily Dose: 1 Df Dosage Form Every Day	Not Reported
	Baclofen	S	Oral	Daily Dose: 2 Df Dosage Form Every Day	Not Reported
	Hydrochlorothiazide	S	Oral	Daily Dose: 1 Df Dosage Form Every Day	Not Reported
	Cipralex	S	Oral		Alphapharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2009	7049235	DIRECT	N				29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Throat Tightness; Unevaluable Event	Lexapro			S		Once Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2009	7051890	EXPEDITED (15-DAY)	Y	OT	2009S1011285		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura	Lamotrigine			S	Oral	Oral		Not Reported
	Enalapril			S	Oral	1df;Twice A Day; Oral		Not Reported
	Oxcarbazepine (Oxcarbazepine)			S	Oral	2.5 Df;Daily; Oral		Not Reported
	Metoprolol Succinate			S	Oral	1 Df;Twice A Day; Oral		Not Reported
	Ferrous Sulfate			S	Oral	1 Df;Daily; Ora		Not Reported
	Simvastatin			S	Oral	1 Df; Oral; Daily; Oral		Not Reported
	Baclofen			S	Oral	1 Df; Twice A Day; Oral		Not Reported
	Hydrochlorothiazide			S	Oral	1 Df;Daily; Oral		Not Reported
	Cipralex			S	Oral	1.5 Df;Daily; Oral		Not Reported
	Tavor (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2009	7052906	EXPEDITED (15-DAY)	Y	DE	1000007155		30 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S		1 Dosage Forms (1 Dosage Forms, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2009	6959078	EXPEDITED (15-DAY)	N	HO	B0568235A			Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Abdomen; Condition Aggravated; Drug Interaction; Fat Tissue Increased; Lipoatrophy; Lipodystrophy Acquired	Epivir			S	Unknown			Glaxosmithkline
	Videx			S	Unknown			Not Reported
	Kaletra			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2009	7056512	EXPEDITED (15-DAY)	Y	HO	1000007258		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disorientation; Hallucination, Auditory; Hallucination, Visual	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Topalgic (France)			S		200 Mg (100 Mg, 2 In 1 D)		Not Reported
	Previscan (Fluindione)			C				Not Reported
	Paracetamol			C				Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2009	7071116	NON-EXPEDITED	N	OT	IMP_04346_2009			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Depression; Hallucination; Somnolence	Bupropion Hydrochloride			S		(300 Mg)	6 YR	Not Reported
	Lamotrigine			S	Oral	(400 Mg Oral)	6 YR	Not Reported
	Paroxetine Hydrochloride			S	Oral	(Df Oral)		Not Reported

	Clonazepam	S	(Df)		Not Reported
	Lexapro	S	(Df)		Not Reported
	Insulin Human	C			Not Reported
	Tiotropium	C			Not Reported
	Clopidogrel Bisulfate	C			Not Reported
	Simvastatin	C			Not Reported
	Blood Pressure Medication	C			Not Reported
	Apo-Hydroxyzine /0058401/	C			Not Reported
	Metoprolol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2009	7045331	EXPEDITED (15-DAY)	Y	HO	US-TYCO HEALTHCARE/MALLIN CKRODT-T200901305		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Silicon Granuloma	Hydromorphone Hydrochloride			S	Oral			Tyco
	Prednisone			S				Not Reported
	Esomeprazole			S				Not Reported
	Alprazolam			S				Not Reported
	Warfarin Sodium			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2009	7054385	DIRECT	N	LT, OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Hypertension; Mental Disorder; Nervous System Disorder; Palpitations; Thinking Abnormal; Unevaluable Event	Lexapro			S	Oral	10mg One Per Day Po		Forest
	Hctz			C				Not Reported
	Antenolol			C				Not Reported
	Effexor			C				Not Reported
	Avinza			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2009	7054450	DIRECT	N	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Emotional Distress	Lexapro			S		5mg 1 Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2009	7055776	EXPEDITED (15-DAY)	N	HO	1000007199			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thinking Abnormal; Withdrawal Syndrome	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2009	7039129	EXPEDITED (15-DAY)	Y		1000006914		74 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteoarthritis; Rheumatoid Factor Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Mirtazapine			C				Not Reported
	Deanxit (Tablets)			C				Not Reported
	Melitracen (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2009	7043415	EXPEDITED (15-DAY)	Y	OT	1000006931		71 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	10 Mg (10 Mg, 1in 1 D), Oral		Not Reported
	Risperdal			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Nifedipine			C				Not Reported
	Xiaoke Wan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2009	7054411	DIRECT	N				27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Pain; Dysuria; Micturition Urgency	Lexapro			S	Oral	10 Mg 1 Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2009	7055109	DIRECT	N				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Dizziness; Somnolence; Vision Blurred	Lexapro			S	Oral	10mg 1 Time A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2009	7020917	EXPEDITED (15-DAY)	Y	HO	SE-ELI_LILLY_AND_COMPANY-SE200906000405		62 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Kidney Infection; Urinary Retention	Duloxetine Hydrochloride			S		Unk, Unk	50 DAY	Eli Lilly And Co
	Duloxetine Hydrochloride			S		Unk, Unk	5 DAY	Eli Lilly And Co
	Escitalopram Oxalate			S			84 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2009	7055616	DIRECT	Y				21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sensation In Eye; Agitation; Blepharospasm; Dry Mouth; Ear Discomfort; Epigastric Discomfort; Headache; Heart Rate Increased; Hot Flush; Hyperhidrosis; Nasal Discomfort; Nausea; Paraesthesia; Sedation;	Lexapro			S	Oral	10 Mg Once Before Sleep Po (This Was My First Dose)		Not Reported

Tremor; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2009	7055703	DIRECT	Y				20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Frustration Tolerance Decreased; Suicidal Ideation	Lexapro			S		Normal 1 Dose		Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2009	7077857	EXPEDITED (15-DAY)	Y	HO	1000007313		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Cerebellar Syndrome; Dizziness; Eye Pain; Radiculopathy; Vision Blurred; Visual Acuity Reduced; Visual Field Defect	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Femara			S	Oral	(2.5 Mg), Oral		Not Reported
	Femara			S	Oral	Oral		Not Reported
	Cyamemazine			S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported
	Cyamemazine			S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
	Prazepam			S	Oral	Oral		Not Reported
	Sectral			S	Oral	Oral		Not Reported
	Solu-Medrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2009	7049340	EXPEDITED (15-DAY)	Y	HO	AU-ROCHE-642670		48 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sleep-Related Event; Flushing; Mydriasis; Somnambulism;	Valium			S	Oral			Roche
	Codeine Phosphate\Doxylamine			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported

Somnolence	Stilnox	S	Oral		Not Reported
	Lexapro	S	Oral		Not Reported
	Alcohol	S	Unknown		Not Reported
	Caltrate	C		Drug Reported As: Caltrate 600	Not Reported
	Fish Oil	C		Drug: Fish Oil (Nos)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2009	7055989	DIRECT	N	HO, LT, OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Migraine; Suicidal Ideation; Suicide Attempt	Cymbalta			S	Oral	60mg Daily Po		Not Reported
	Lexapro			S	Oral	20mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2009	7060320	EXPEDITED (15-DAY)	Y	OT	1000007292		19 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia; Large Intestinal Haemorrhage	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2009	6974025	EXPEDITED (15-DAY)	Y	HO	1000005568		69 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Confusional State; Disorientation; Mania; Weight Decreased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D) Oral		Not Reported
	Lexomil			C				Not Reported
	Theralene			C				Not Reported
	Pariet			C				Not Reported
	Spasfon Lyoc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2009	7002795	EXPEDITED (15-DAY)	Y	DE	1000006207		41 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S	Oral	1120 Mg (1120 Mg, Once) Oral 10 Mg (10 Mg, 1 In 1 D), Oral 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	1120 Mg (1120 Mg, Once) Oral 10 Mg (10 Mg, 1 In 1 D), Oral 20 Mg (20 Mg, 1 In 1 D), Oral		
					Oral	1120 Mg (1120 Mg, Once) Oral 10 Mg (10 Mg, 1 In 1 D), Oral 20 Mg (20 Mg, 1 In 1 D), Oral		
	Amisulpride			S	Oral	4 Boxes (Once), Oral		Not Reported
					Oral	4 Boxes (Once), Oral		
	Atorvastatin			S	Oral	2 Boxes (Once), Oral		Not Reported
	Piportil (Solution)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2009	7040688	EXPEDITED (15-DAY)	Y	OT	1000006924		48 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Tract Infection; Seizure	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Mianserin (10 Milligram)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2009	7050491	EXPEDITED (15-DAY)	N	OT	ZA-JNJFOC-20090702305			Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Influenza;	Risperdal			S	Unknown			Not Reported

Salivary Gland Calculus; Salivary Gland Disorder	Risperdal		S	Unknown	Not Reported
	Cipralex		S	Unknown	Not Reported
	Effexor		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2009	7062235	EXPEDITED (15-DAY)	Y	HO	1000007370		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Contusion; Fall; Wrist Fracture	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Benadryl			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2009	7065205	DIRECT		HO, OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Mania; Personality Change	Lexapro			S	Oral Oral	10 Mg 1 - Daily Oral 10 Mg 1 - Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2009	6945638	EXPEDITED (15-DAY)	Y	OT	1000005046		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Metrorrhagia	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2009	7014481	EXPEDITED (15-DAY)	Y	HO, OT	DE-PFIZER INC-2009202061			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Drug Dependence; Dysarthria;	Alprazolam			S	Oral	Unk		Pfizer

Fatigue; Indifference; Medication Error; Memory Impairment	Ziprasidone Hydrochloride		S	80 Mg+ 40 Mg/Day	Pfizer
	Cipralex		S	20 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2009	7064730	EXPEDITED (15-DAY)	Y	HO	1000007490		46 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Urticaria	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Clotiazepam			S	Oral	Oral		Not Reported
	Stilnox			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2009	6788997	EXPEDITED (15-DAY)	Y	HO	1000001119		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Delusion; Drug Interaction; Hallucination, Visual	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Rasagiline Mesylate			S	Oral	1 Mg (1 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2009	7063598	DIRECT	Y				23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Feeling Abnormal; Loss Of Libido; Menorrhagia; Menstruation Irregular; Nausea; Palpitations; Sedation; Sexual Dysfunction; Somnolence	Lexapro			S	Oral	10mg Once A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2009	7064761	EXPEDITED (15-DAY)	N	OT	1000007519			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Driving Ability; Legal Problem	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2009	7064822	EXPEDITED (15-DAY)	Y	OT	1000005620		23 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chest Pain; Pleuritic Pain	Lexapro			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2009	7065380	EXPEDITED (15-DAY)	Y	OT	1000007488		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Jaw; Oedema Mouth; Swollen Tongue; Tooth Abscess	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2009	7055978	EXPEDITED (15-DAY)	Y	HO	AU-ASTRAZENECA-2009SE04637			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Unspecified Type; Fall; Orthostatic Hypotension	Seroquel			S	Oral		92 DAY	Not Reported
	Aricept			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2009	7066013	EXPEDITED (15-DAY)	Y	DS	1000007464		60 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Musculoskeletal Pain; Pain In Extremity; Periarthritis	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Prazepam			C				Not Reported
	Solian			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2009	7066022	EXPEDITED (15-DAY)	Y	HO	1000007504		89 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Haemorrhagic Stroke; Head Injury	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin Cardio			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Enatec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2009	7059583	NON-EXPEDITED	Y		US-AMGEN-KDL293623		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fatigue; Feeling Abnormal; Haemoglobin Decreased; Rash	Procrit			S	Subcutaneous			Not Reported
	Lexapro			S				Not Reported
	Lipitor			C				Not Reported
	Lasix			C	Oral			Not Reported
	Unspecified Antihypertensive Agent			C				Not Reported
	Agrylin			C				Not Reported
	Aspirin			C				Not Reported
	Catapres-Tts			C				Not Reported
	Plavix			C				Not Reported
	Antivert			C				Not Reported

	Nitroglycerin	C				Not Reported
	Clonidine	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2009	7008539	EXPEDITED (15-DAY)	Y	HO, LT	1000006266		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Dizziness; Fatigue; Feeling Abnormal; Syncope	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Nuvaring			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2009	7064831	EXPEDITED (15-DAY)	Y	OT	1000007529		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Breast Pain; Breast Swelling; Galactorrhoea; Menstruation Delayed	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Bromazepam (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2009	7068887	EXPEDITED (15-DAY)	N	DE	1000007672			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2009	7064333	NON-EXPEDITED	N		US-ABBOTT-08P-163-0488056-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False	Norvir			S				Not Reported

Positive	Lexapro	S		Not Reported
	Atazanavir Sulfate	S		Not Reported
	Truvada	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2009	7064343	NON-EXPEDITED	N		US-ABBOTT-08P-163-0489481-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive	Norvir			S				Not Reported
	Atazanavir Sulfate			S				Not Reported
	Truvada			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2009	7069544	EXPEDITED (15-DAY)	Y	OT	1000007653		45 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Fatigue; Intentional Overdose; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S	Oral	200 Mg, Once, Oral		Not Reported
	Alcohol			S	Oral	Once, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2009	7071329	DIRECT	N	OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impulse-Control Disorder; Libido Increased; Mania	Lexapro			S		30 Mg. Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2009	7076763	EXPEDITED (15-DAY)	Y	OT	1000007683		45 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury;	Escitalopram Oxalate			S	Oral	200 Mg, Once, Oral		Not Reported

Somnolence; Suicide Attempt; Vascular Injury	Sodium Selenite		S	Oral	200 Mg, Once, Oral	Not Reported
	Opipramol Hydrochloride		S	Oral	250 Mg, Once, Oral	Not Reported
	Levothyroxine		S	Oral	1500 Mcg, Once, Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2009	7073233	EXPEDITED (15-DAY)	Y	HO	1000007543		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Kidney Infection; Urinary Retention	Escitalopram Oxalate			S				Not Reported
	Duloxetine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2009	6706342	EXPEDITED (15-DAY)	Y	CA, OT	S08-FRA-00223-02			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Drugs Affecting Foetus; Trisomy 21	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported
	Xanax (Alprazolam) - (Tablets) (Alprazolam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2009	7050124	EXPEDITED (15-DAY)	Y	HO, OT	FR-ABBOTT-09P-056-0584513-00		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatitis	Tarka			S	Oral			Not Reported
	Tarka			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Bromazepam			C	Oral	1/4 Tablet, 1/4 Tablet, 1/2 Tablet Daily		Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2009	7073454	EXPEDITED (15-DAY)	Y	HO	1000007695		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported
	Blood Pressure Medication (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2009	7073513	EXPEDITED (15-DAY)	N	HO	1000007775		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Headache; Movement Disorder; Muscular Weakness	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1d), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Spironolactone			C				Not Reported
	Synthroid			C				Not Reported
	Mircette			C				Not Reported
	Albuterol (Inhalant)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2009	7075415	EXPEDITED (15-DAY)	Y	OT	1000007727		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Noiafren			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2009	7069415	EXPEDITED (15-DAY)	Y	CA, DE	US-ABBOTT-09P-163-0587271-00		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Neural Tube Defect	Escitalopram Oxalate		S	Transplacental	Not Reported
	Prenatal Vitamins		S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2009	7076588	EXPEDITED (15-DAY)	Y	OT	1000007794		35 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Weight Decreased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2009	6691894	EXPEDITED (15-DAY)	Y	OT	US-ASTRAZENECA-2008UW13210		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anger; Anxiety; Aphasia; Asbestosis; Attention Deficit/Hyperactivity Disorder; Blood Cholesterol Abnormal; Blood Cholesterol Increased; Blood Triglycerides Abnormal; Bruxism; Constipation; Decreased Appetite; Depression; Disorientation; Dissociative Disorder; Emotional Distress; Feeling Abnormal; Gait Disturbance; Hallucination; Headache; Hostility; Hyperhidrosis; Hypertension; Hypothyroidism; Insomnia; Lethargy; Loss Of Personal Independence In	Seroquel			S	Oral		4 YR	Not Reported
	Seroquel			S	Oral		4 YR	Not Reported
	Xanax			S			4 YR	Not Reported
	Xanax			S			4 YR	Not Reported
	Xanax			S			4 YR	Not Reported
	Wellbutrin			S			4 YR	Not Reported
	Wellbutrin			S			4 YR	Not Reported
	Lexapro			S			3 YR	Not Reported
	Lexapro			S			3 YR	Not Reported
	Restoril			S			4 YR	Not Reported
	Restoril			S			4 YR	Not Reported
	Cymbalta			S			4 YR	Not Reported
	Cymbalta			S			4 YR	Not Reported
	Zoloft			S				Not Reported
	Neurontin			S				Not Reported
	Neurontin			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported

Daily Activities; Mental Disorder; Muscle Spasms; Muscle Twitching; Nightmare; Overdose; Pain; Pallor; Pancreatitis; Panic Disorder; Paranoia; Pyrexia; Regurgitation; Renal Failure; Restless Legs Syndrome; Road Traffic Accident; Screaming; Seizure; Sleep Apnoea Syndrome; Stress; Suicidal Ideation; Suicide Attempt; Tachycardia; Tardive Dyskinesia; Thyroid Disorder; Treatment Noncompliance; Urinary Incontinence; Vomiting; Weight Decreased; Withdrawal Syndrome	Effexor	S	Not Reported
	Lisinopril	C	Not Reported
	Fenofibrate	C	Not Reported
	Fenofibrate	C	Not Reported
	Levothyroxine	C	Not Reported
	Ambien	C	Not Reported
	Hydrochlorothiazide	C	Not Reported
	Acetaminophen\Hydrocodone Bitartrate	C	Not Reported
	Carisoprodol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2009	7071083	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-SYNTHELABO-A02200901908		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree; Electrocardiogram Qt Prolonged; Malaise	Stilnox			S	Oral		8 DAY	Not Reported
	Escitalopram Oxalate			S	Oral		8 DAY	Not Reported
	Acetaminophen			S	Oral	6 Df	8 DAY	Not Reported
	Cyamemazine			S	Oral		8 DAY	Not Reported
	Duphalac			S	Oral	6 Df	8 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2009	7078987	DIRECT	N	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Menorrhagia; Weight Increased	Lexapro	S	Oral	1 Tab Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2009	6986675	EXPEDITED (15-DAY)	Y	HO	IE-ABBOTT-09P-229-0571118-00			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Lexapro			S	Oral			Not Reported
	Nu-Seals Aspirin			C				Not Reported
	Perindopril			C				Not Reported
	Glucophage			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Lansoprazole			C				Not Reported
	Lactulose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2009	7129951	DIRECT	N	CA, DS, HO			< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Maternal Drugs Affecting Foetus	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2009	7081741	DIRECT	N	DE			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2009	7085763	EXPEDITED (15-DAY)	Y	HO, OT	100007653		45 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alcohol Poisoning; Fatigue; Hyperhidrosis; Hypertension; Intentional Overdose; Suicide Attempt; Tachycardia	Escitalopram Oxalate		S	Oral	200 Mg, Once, Oral	Not Reported
	Alcohol		S	Oral	Once, Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2009	7074178	EXPEDITED (15-DAY)	N	HO	A0800751A		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Lamictal			S	Unknown			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2009	7081059	EXPEDITED (15-DAY)	N	HO	1000007936		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Sepsis	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2009	7081530	DIRECT	N	HO			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Clonus	Lexapro			S	Oral	10mg Daily Mouth		Not Reported
	Mircette			C				Not Reported
	Spironolactone			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2009	7082703	EXPEDITED (15-DAY)	Y	HO	1000007825		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State;	Escitalopram Oxalate		S	Oral	Oral	Not Reported
Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Malaise;	Disulfiram		S	Oral	500 Mg (500 Mg, 1 In 1 D), Oral	Not Reported
Oedema Peripheral;	Glucor		C			Not Reported
Tongue Biting	Seglor		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2009	7082810	EXPEDITED (15-DAY)	Y	HO, OT	1000007857		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Myalgia; Nausea; Saliva Discolouration; Salivary Hypersecretion	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Plavix			C				Not Reported
	Exetrol			C				Not Reported
	Niaspan			C				Not Reported
	Alby-E			C				Not Reported
	Lipitor			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2009	7082813	EXPEDITED (15-DAY)	Y	HO	1000007882		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delusion; Encephalopathy; Generalised Tonic-Clonic Seizure; Hyponatraemia; Postictal State; Renal Tubular Disorder; Urine Sodium Increased; Vomiting Projectile	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Etifoxine			S	Oral	2 Dosage Firns (2 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Cranberry			S	Oral	4 Dosage Forms (4 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Herbal Nos			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D) Oral		Not Reported
	Ginseng			C				Not Reported

	Elisor	C	Not Reported
	Esberiven Fort	C	Not Reported
	Exomuc	C	Not Reported
	Rhinofluimucil	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2009	7082817	EXPEDITED (15-DAY)	Y	HO	1000007858		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Malaise	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Cyamemazine			S	Oral	50 Mg (25 Mg, 2 In 1 D), Oral		Not Reported
	Zolpidem			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Propoxyphene Hydrochloride And Acetaminophen			S	Oral	6 Dosage Forms (6 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Duphalac			S	Oral	6 Dosage Forms (6 Dosage Forms, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2009	7081946	EXPEDITED (15-DAY)	Y	DS	1000007969		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anhedonia; Apathy; Crying; Depressed Mood; Feeling Guilty; Insomnia; Obsessive Rumination; Obsessive Thoughts	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zolpidem			C				Not Reported
	Lexomil (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2009	7087748	EXPEDITED (15-DAY)	Y	OT	1000005396		52 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Drug Ineffective; Dysphemia; Tremor	Escitalopram Oxalate			S	Oral	10 Mg, (10 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2009	6919577	NON-EXPEDITED	N		A0759303A		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rash; Skin Discolouration; Therapeutic Response Unexpected	Paxil			S	Unknown		7 YR	Glaxosmithkline
	Valtrex			S	Oral	1g Three Times Per Day	1 WEEK	Glaxosmithkline
	Lexapro			S				Not Reported
	Cozaar			C				Not Reported
	Antidepressant			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2009	7076621	EXPEDITED (15-DAY)	Y	DE	1000007808		75 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Coma	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Loftyl(Tablets)			C				Not Reported
	Omeprazole			C				Not Reported
	Omeprazole			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Glucophage			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2009	7083202	EXPEDITED (15-DAY)	Y	OT	1000007978		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Serotonin	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

Syndrome	Midon	C		Not Reported
	Lipitor	C		Not Reported
	Aspirin	C		Not Reported
	Calcichew D3 Forte	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2009	7066907	EXPEDITED (15-DAY)	Y	DE	US-SANOFI-SYNTHELABO-A03200903164		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Ambien Cr			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2009	7077896	EXPEDITED (15-DAY)	Y	HO	AU-ASTRAZENECA-2009SE06774		49 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; Mydriasis; Somnambulism; Somnolence	Seroquel			S	Oral			Not Reported
	Stilnox			S	Oral		8 DAY	Not Reported
	Valium			S	Oral			Not Reported
	Alcohol			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Codeine Phosphate\Doxylamine Succinate			S				Not Reported
	Caltrate			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2009	7084609	EXPEDITED (15-DAY)	Y	HO	1000008012		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Drug Interaction; Drug	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D) Oral		Not Reported

Level Increased; Gamma-Glutamyltransferase Increased			Oral	20 Mg (20 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D) Oral		
	Omeprazole	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2009	7097488	DIRECT	Y	DE			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose; Self-Medication; Toxicity To Various Agents	Celexa			S		Not Prescribed For The Client		Not Reported
	Lexapro			S	Oral	20 Mg At Bedtime Po		Not Reported
	Lamictal			S				Not Reported
	Xanax			S				Not Reported
	Gabapentin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2009	6906823	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2009CG00321		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Fall; Haematoma; Head Injury; Hypotension; Orthostatic Hypotension; Wound	Atacand			S	Oral		1 YR	Not Reported
	Rivotril			S	Oral			Not Reported
	Levomepromazine			S	Oral		30 YR	Not Reported
	Amitriptyline Hydrochloride			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Efferalgan Codeine			S	Oral		1 YR	Not Reported
	Vastarel			S			1 YR	Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Symbicort			C				Not Reported

	Omeprazole	C				Not Reported
	Sinemet	C	Oral		12 DAY	Not Reported
	Sinemet	C	Oral			Not Reported
	Actonel	C				Not Reported
	Calcium Carbonate	C				Not Reported
	Previscan (Fluindione)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2009	7058190	EXPEDITED (15-DAY)	Y	OT	1000007243			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gamma-Glutamyltransferase Increased; Lipase Increased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Nordette			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2009	7085596	DIRECT	N	DS			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Imprisonment; Suicidal Ideation; Thinking Abnormal; Violence-Related Symptom	Clonazepam			S		1 Once Daily		Barr
	Lexapro			S		1 Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2009	7085854	EXPEDITED (15-DAY)	Y	HO	1000007984		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intracranial Pressure Increased; Visual Acuity	Escitalopram Oxalate			S		0.3333 Dosage Forms (1		Not Reported

Reduced; Vitreous Floaters				Dosage Forms,1 In 3 D)		
	Ethinyl Estradiol\Levonorgestrel	S	Oral	Oral		Not Reported
	Prazepam	S		(As Required)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2009	7085858	EXPEDITED (15-DAY)	Y	HO	1000007986		54 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Epilepsy; Malaise	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Zyprexa			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Stilnox			C				Not Reported
	Lercan			C				Not Reported
	Pariet			C				Not Reported
	Flonase			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2009	7085971	DIRECT	N	DE			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zoloft			S		200mg		Not Reported
	Lexapro			S		10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2009	7086337	DIRECT	N	RI			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Imprisonment; Suicidal Ideation; Violence-Related Symptom	Clonazepam			S	Oral	1 Once Daily Po		Not Reported
	Lexapro			S	Oral	1 Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2009	7096721	EXPEDITED (15-DAY)	Y	OT	1000006645		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Congenital Pyelocaliectasis; Hydronephrosis; Maternal Drugs Affecting Foetus; Maternal Exposure During Breast Feeding	Lexapro			S	Transplacental	5 Mg (5 Mg, 1 In 1 D), Transplacental, 5 Mg (5 Mg, 1 In 1 D), Transammary		Not Reported
					Transplacental	5 Mg (5 Mg, 1 In 1 D), Transplacental, 5 Mg (5 Mg, 1 In 1 D), Transammary		
	Levothyroxine			C				Not Reported
	Prenatal Vitamins			C				Not Reported
	Pulmicort Respules			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2009	7007282	EXPEDITED (15-DAY)	Y	OT	1000006211		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Breast Cancer In Situ; Hot Flush; Overdose	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral, 25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral, 25 Mg (25 Mg, 1 In 1 D), Oral		
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral, 25 Mg (25 Mg, 1 In 1 D), Oral		
	Tamoxifen Citrate			S				Not Reported
	Ambien			C				Not Reported
	Oral Contraceptives (Nos) (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2009	7080655	EXPEDITED (15-DAY)	N	HO	B0588059A		32 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Pruritus; Rash Maculo-Papular	Lamictal			S	Unknown			Glaxosmithkline
	Cipralex			S	Unknown	10mg Per Day		Not Reported
	Buspar			S	Unknown	40mg Per Day		Not Reported
	Ritalin			S	Unknown	60mg Per Day		Glaxosmithkline
	Zyprexa			S	Unknown	15mg Per Day		Not Reported
	Chlorprothixene			S	Unknown	30mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2009	7079660	EXPEDITED (15-DAY)	Y	DS, HO	1000007763		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Loss Of Consciousness; Somnolence	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
					Oral	5 Mg (5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral	1 YR	
	Clonidine			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2009	7094796	EXPEDITED (15-DAY)	Y	OT	1000008145		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicidal Ideation; Loss Of Consciousness; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Klonopin			S	Oral	0.25 Mg (0.25 Mg, 1 In 1 D), Oral		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2009	7094902	EXPEDITED (15-DAY)	Y	OT	1000008126		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Tegretol			C				Not Reported
	Zonegran			C				Not Reported
	Albuterol			C				Not Reported
	Advair Hfa			C				Not Reported
	Elavil			C				Not Reported
	Claritin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2009	7095232	EXPEDITED (15-DAY)	Y	OT	1000008034		28 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bile Duct Necrosis	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2009	7014522	EXPEDITED (15-DAY)	Y	HO	1000006365		35 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Anxiety; Cognitive Disorder; Depressed Mood; Gastrointestinal Haemorrhage; Haematemesis; Hypertension; Irritability; Suicidal Ideation; Suicide Attempt; Suspiciousness;	Escitalopram Oxalate			S	Oral	Built Up To 20 Milligram Daily (20 Mg, 1 In 1 D), Oral		Not Reported

Thalassaemia Minor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2009	7095219	DIRECT	Y	OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Dizziness; Dry Mouth; Eye Disorder; Formication; Hyperhidrosis; Insomnia; Mydriasis; Tachycardia; Tremor	Lexapro			S	Oral	10 Mg At Bedtime Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2009	7095544	DIRECT	Y	HO			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Delusion; Panic Reaction; Suicidal Ideation	Lexapro			S	Oral	10mg Qday Po		Not Reported
	Buspar			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2009	7056403	EXPEDITED (15-DAY)	Y	HO	ES-PFIZER INC-2009237098		40 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Ascites; Oedema Peripheral; Oliguria	Champix			S	Oral	Unk	20 DAY	Pfizer
	Cipralex			S	Oral	Unk	20 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2009	7084714	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14407712		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Screen False Positive	Reyataz	S		Bristol Myers Squibb
	Norvir	S		Abbott
	Truvada	S		Not Reported
	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2009	7097677	EXPEDITED (15-DAY)	Y	HO, OT	001460		12 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorea; Clonus; Dyskinesia; Dysphemia; Dystonia; Extensor Plantar Response; Extrapyramidal Disorder; Hyperreflexia; Hypertonia; Muscle Rigidity; Posture Abnormal; Tremor	Alprazolam (Alprazolam)			S		(One Time Dose Of 0.25mg) 1 Day Until Not Continuing;		Not Reported
	Escitalopram Oxalate			S		(10 Mg, One Time Doe Of 10 Mg) 1 Day Until Not Continuing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2009	7097697	EXPEDITED (15-DAY)	Y	HO	1000008187		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Generalised Tonic-Clonic Seizure; Hypomagnesaemia; Overdose	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Bactrim Forte			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Bactrim Forte			S	Oral	Oral		Not Reported
	Imovane			C				Not Reported
	Levothyrox			C				Not Reported
	Dedrogyl			C				Not Reported
	Epoetin Beta			C				Not Reported
	Racecadotril			C				Not Reported
	Xyzall			C				Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			C				Not Reported
	Calcidose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2009	6966967	EXPEDITED (15-DAY)	Y	HO	1000005521		79 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis; Pancytopenia	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Depakene			S	Oral	1000 Mg (500 Mg, 2 In 1 D), Oral		Not Reported
	Fotemustine			S	Intravenous (not otherwise specified)	25.7143 Mg (180 Mg, 1 In 1 Wk) Intravenous (Not Otherwise Specified)		Not Reported
	Lanzor (Capsules)			C				Not Reported
	Furosemide (Tablets)			C				Not Reported
	Aprovel (Tablets)			C				Not Reported
	Tahor (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2009	7085368	EXPEDITED (15-DAY)	N	OT	A0802683A		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anosmia	Wellbutrin			S				Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Verapamil Hydrochloride			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Prilosec			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2009	7085417	EXPEDITED (15-DAY)	Y	HO	D0062649A		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Intentional Overdose; Intentional Overdose;	Lamotrigine			S	Oral	7900mg Per Day	1 DAY	Glaxosmithkline
	Citalopram Hydrobromide			S	Oral		1 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	500mg Per Day	1 DAY	Not Reported

Nystagmus; Suicide Attempt	Zolpidem		S	Oral	200mg Per Day	1 DAY	Not Reported
	Melperone Hydrochloride		S	Oral	2200mg Per Day	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2009	6936796	EXPEDITED (15-DAY)	Y	OT	1000004953		58 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dysuria; Urinary Retention	Escitalopram Oxalate			S	Oral Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Trihexyphenidyl Hydrochloride			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Trihexyphenidyl Hydrochloride			S	Oral	Oral		Not Reported
	Mirtazapine			S	Oral	45 Mg (45 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal			S	Oral	4 Mg (4 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolam			C				Not Reported
	Valpromide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2009	7100202	EXPEDITED (15-DAY)	N	CA, OT	1000008263		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly; Craniosynostosis; Developmental Delay; Injury; Maternal Drugs Affecting Foetus; Talipes	Lexapro			S	Transplacental	Transplacental		Not Reported
	Paxil			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2009	6903906	EXPEDITED (15-DAY)	Y	DE	1000003571		21 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate Quetiapine			S S				Not Reported Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2009	7097833	DIRECT	N	OT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Alopecia; Amnesia; Anger; Impulse-Control Disorder; Trichotillomania	Lexapro			S	Oral	One Tablet Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2009	7098536	DIRECT	N	OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Contusion; Discomfort; Fall; Fatigue; Hypotension; Impaired Work Ability; Musculoskeletal Stiffness; Pruritus; Somnolence; Urticaria	Lexapro			S	Oral	2.5 Mg Once Daily, Am Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2009	7102384	EXPEDITED (15-DAY)	Y	HO	1000008217		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D),		Not Reported

						Oral				
	Pulmicort (Solution)			C						Not Reported
	Cypretyl (Tablets)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2009	7084009	EXPEDITED (15-DAY)	N	OT	1000007893		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Asthenia; Disease Recurrence; Dizziness; Dry Mouth; Eye Movement Disorder; Fatigue; Feeling Hot; Headache; Nystagmus; Pallor; Peripheral Coldness; Restless Legs Syndrome; Tachycardia	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Lamictal			C				Not Reported
	Abilify			C				Not Reported
	Albuterol (Aerosol For Inhalation)			C				Not Reported
	Allegra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2009	7103396	EXPEDITED (15-DAY)	N	OT	1000008333			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Decreased	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		
	Warfarin Sodium			C				Not Reported
	Paracetamol			C				Not Reported
	Concor			C				Not Reported
	Sanval			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2009	7096260	NON-EXPEDITED	N		US-ABBOTT-08P-163-0484585-00		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Synthroid			S	Oral			Not Reported
	Synthroid			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Rosuvastatin Calcium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2009	7068211	EXPEDITED (15-DAY)	Y	OT	1000007541			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Interaction	Escitalopram Oxalate			S				Not Reported
	Lamotrigine			S				Not Reported
	Phenytoin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2009	7097274	EXPEDITED (15-DAY)	N	HO	AU-JNJFOC-20090805657			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Cogwheel Rigidity; Hyperglycaemia; Hypophagia; Hypotension; Mobility Decreased; Neuroleptic Malignant Syndrome; Pyrexia; Tachycardia	Risperidone			S	Unknown			Not Reported
	Amisulpride			S	Unknown			Not Reported
	Donepezil Hydrochloride			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Caltrate			C	Oral			Not Reported
	Aspirin			C	Oral			Not Reported
	Cholecalciferol			C	Unknown			Not Reported
	Metformin Hydrochloride			C	Unknown			Not Reported
	Novomix 30			C	Subcutaneous	16 Unit Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2009	7108377	EXPEDITED (15-DAY)	Y	DE, LT	1000008358		56 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Alveolitis; Aspiration; Blood Calcium Decreased; Blood Chloride Decreased; Cardiogenic Shock; Cholestasis; Coma; Disorientation; Disturbance In Attention; Fall; Haemoglobin Decreased; Haemophagocytic Lymphohistiocytosis; Hepatic Steatosis; Hyponatraemia; Interstitial Lung Disease; Lung Disorder; Pancytopenia; Pleural Neoplasm; Proteinuria; Seizure; Sinus Tachycardia; Urinary Incontinence	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Pneumorel			C				Not Reported
	Biocalyptol (Pholcodine)			C				Not Reported
	Antarene			C				Not Reported
	Rhinofluimucil			C				Not Reported
	Noctran			C				Not Reported
	Temesta (Lorazepam)			C				Not Reported
	Celestene (France)			C				Not Reported
	Thiovalone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2009	7108761	EXPEDITED (15-DAY)	Y	OT	1000008427		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Singulair			C				Not Reported
	Flonase			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2009	6954279	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-09P-056-0563236-00		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Leukopenia; Pancytopenia; Thrombocytopenia	Depakene			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Fotemustine			S	Intravenous (not otherwise specified)			Not Reported
	Aprovel			C	Oral			Not Reported
	Tahor			C	Oral			Not Reported
	Lansoprazole			C	Oral			Not Reported
	Furosemide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2009	7052880	EXPEDITED (15-DAY)	Y	HO	1000007187		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Ascites; Muscle Strain; Oedema Peripheral; Oliguria	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Varenicline Tartrate			S	Oral	0.5 Mg (0.5 Mg, 1 In 1 D), Oral; 1 Mg (0.5 Mg, 2 In 1 D), Oral		Not Reported
					Oral	0.5 Mg (0.5 Mg, 1 In 1 D), Oral; 1 Mg (0.5 Mg, 2 In 1 D), Oral		
	Varenicline Tartrate			S	Oral	2 Mg (1 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2009	7099103	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009US-26584			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zolpidem			S	Unknown	Unk, Unk		Ranbaxy
	Alprazolam			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Carbon Monoxide			S	Unknown			Not Reported
	Estrogens			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2009	7099491	EXPEDITED (15-DAY)	Y	OT	US-ROCHE-652008		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicidal Ideation; Loss Of Consciousness; Suicidal Ideation	Klonopin			S	Oral			Roche
	Lexapro			S	Oral	Other Indication: Anxiety		Not Reported
	Alcohol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2009	7100234	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009US-26713			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Acetaminophen			S	Oral	Unk, Unk		Ranbaxy
	Oxcarbazepine			S	Oral			Ranbaxy
	Zyprexa			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Trazodone Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2009	7100245	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009US-26728			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Acetaminophen		S	Oral	Unk, Unk	Ranbaxy
	Clonazepam		S	Oral		Not Reported
	Lisinopril		S	Oral		Ranbaxy
	Hydrocodone		S	Oral		Not Reported
	Escitalopram Oxalate		S	Oral		Not Reported
	Cocaine		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2009	7101724	EXPEDITED (15-DAY)	Y	HO	CH-ASTRAZENECA-2009SE09380		83 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Failure; Dyspnoea; Electrocardiogram Qt Interval Abnormal; Torsade De Pointes	Nexium			S	Oral		5 DAY	Not Reported
	Cipralex			S	Oral		53 DAY	Not Reported
	Actos			S	Oral			Not Reported
	Simvastatin			C	Oral			Not Reported
	Torom			C	Oral			Not Reported
	Lisinopril			C	Oral			Not Reported
	Aspirin			C				Not Reported
	Fosamax			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2009	7118191	NON-EXPEDITED	N	HO	175700USA		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective; Dyspnoea; Therapeutic Product Effect Decreased	Lisinopril			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2009	7102962	EXPEDITED (15-DAY)	Y	OT	NO-JNJFOC-20090808186			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased	Durogesic			S	Transdermal	Over A Period Of 3 Years		Not Reported
	Iron\Vitamins Nos			S	Unknown			Not Reported
	Eszopiclone			S	Unknown			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported
	Unspecified Ingredient			S	Unknown			Not Reported
	Tpn			S	Unknown			Not Reported
	Arixtra			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Lovaza			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2009	7109398	DIRECT	N	RI			18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Body Temperature Fluctuation; Chills; Dry Eye; Dry Mouth; Dyspepsia; Fatigue; Fear; Feeling Abnormal; Formication; Hallucination; Heart Rate Increased; Hypoaesthesia; Influenza Like Illness; Insomnia; Loss Of Consciousness; Migraine; Muscle Contractions Involuntary; Mydriasis; Nausea; Oropharyngeal Pain; Pyrexia; Rash Generalised; Suicidal	Lexapro			S	Oral	10 Mg Per Day Po	1 DAY	Forest

Ideation; Vision Blurred

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2009	7110656	DIRECT	N	HO				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Crying; Dizziness; Fall	Lexapro			S		10 Mg Once A Day	3 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2009	7116048	EXPEDITED (15-DAY)	Y	HO	TPG2009A00856		83 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Failure; Dyspnoea; Electrocardiogram Qt Interval Abnormal; Pulmonary Embolism; Pulmonary Hypertension; Torsade De Pointes	Actos			S	Oral	45 Mg (45 Mg, 1 In 1 D), Per Oral		Not Reported
	Cipralex			S	Oral	15 Mg (15 Mg, 1 In 1 D), Per Oral	52 DAY	Not Reported
	Nexium (Esomeprazole Magnesium)			S	Oral	40 Mg (40 Mg, 1 In 1 D), Per Oral	4 DAY	Not Reported
	Simcora (Simvastatin)			C				Not Reported
	Torsemide			C				Not Reported
	Lisinopril (Lisinopril)			C				Not Reported
	Acetylsalicylic Acid (Acetylsalicylic Acid)			C				Not Reported
	Fosamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2009	7082706	EXPEDITED (15-DAY)	Y	HO	1000007826		38 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Supraventricular Tachycardia	Lexapro			S	Oral	30 Mg (10 Mg, 3 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported
					Oral	30 Mg (10 Mg, 3 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1		

					D),Oral		
	Lexapro		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Clonazepam		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2009	7107406	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2009264524		69 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Hydroxyzine Hydrochloride			S	Oral	Unk		Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported
	Amitriptyline Hydrochloride			S	Oral	Unk	9 DAY	Not Reported
	Ramipril			S	Oral	Unk		Not Reported
	Zolpidem			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2009	7116254	DIRECT	N	OT			16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Incorrect Dose Administered; Off Label Use	Lexapro			S	Oral	20mg 2.5 Times Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2009	7043335	EXPEDITED (15-DAY)	Y	OT	1000006949		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Fall; Head Injury; Malaise; Orthostatic Hypotension; Syncope	Nebivolol Hydrochloride			S	Oral	2.5 Mg (2.5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Brotizolam			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2009	7108133	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009RR-26971		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zolpidem Tartrate			S	Oral			Ranbaxy
	Lamotrigine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Phenazopyridine Hydrochloride			S	Oral			Not Reported
	Ramelteon			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Ibuprofen			S	Oral			Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2009	7108184	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009RR-27327		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Acyclovir			S	Oral			Ranbaxy
	Risperidone			S	Oral			Ranbaxy
	Haloperidol			S	Oral			Not Reported
	Vancomycin			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Metaxalone			S	Oral			Not Reported
	Heparin			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Clonidine			S	Oral			Not Reported
	Methadone Hydrochloride			S	Oral			Not Reported
	Albuterol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2009	7108323	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009RR-27296		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zolpidem Tartrate			S				Ranbaxy
	Chloral Hydrate			S	Oral			Not Reported
	Carisoprodol			S	Oral			Not Reported
	Hydrocodone			S	Oral			Not Reported
	Marijuana			S				Not Reported
	Cocaine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Carbamazepine			S				Not Reported
	Diazepam			S				Not Reported
	Nordazepam			S				Not Reported
	Morphine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2009	7108326	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2009RR-27306		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen			S	Oral			Ranbaxy
	Aspirin			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Ibuprofen			S	Oral			Ranbaxy
	Escitalopram Oxalate			S	Oral			Not Reported
	Caffeine Citrate			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Fexofenadine			S	Oral			Ranbaxy
	Butalbital Acetaminophen And Caffeine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2009	7109105	EXPEDITED (15-DAY)	Y	HO, OT	PHHY2009FR36661		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Hyponatraemia; Hypoxia; Joint Injury; Skeletal Injury	Hydrochlorothiazide\Valsartan			S		Unk		Novartis
	Ivabradine			S		Unk		Not Reported
	Escitalopram Oxalate			S		1 Df, Qd		Not Reported
	Nicardipine Hydrochloride			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2009	6906497	EXPEDITED (15-DAY)	Y	CA	1000003668			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Cleft Lip; Cleft Palate; Maternal Condition Affecting Foetus	Lexapro			S	Transplacental	See Image		Not Reported
					Transplacental	See Image		
	Levonelle (Tablets)			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2009	7125346	EXPEDITED (15-DAY)	N	OT	1000008691		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Legal Problem	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Alcohol			S		2 Beers (Once)		Not Reported
	Lorzepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2009	7096693	EXPEDITED (15-DAY)	Y	OT	1000007945		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Colitis Ulcerative; Fall; Feeling Abnormal; Hyperhidrosis; Malaise; Musculoskeletal Stiffness; Nausea; Nuclear Magnetic Resonance Imaging Brain Abnormal; Partial Seizures; Tremor; Unresponsive To Stimuli	Lexapro	S	Oral	10 Mg (10 Mg, 1 In 1 D), Per Oral		Not Reported
	Yasmin	C				Not Reported
	Allergy Injections (Nos)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2009	7117093	DIRECT	N				50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Ejaculation Failure; Genital Disorder Male; Male Orgasmic Disorder	Lexapro			S		10mg Daily	6 DAY	Forest
	Lexapro			S		20mg Daily	2 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2009	7125371	EXPEDITED (15-DAY)	Y	OT	1000008666		42 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Dizziness; Paraesthesia; Visual Impairment; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5mg (5 Mg, 1 In 1 D), Oral	1 MTH	Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5mg (5 Mg, 1 In 1 D), Oral		
	Depakote			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2009	7126005	EXPEDITED (15-DAY)	Y	OT	1000008715		38 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Pancytopenia	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	17.8571 Mg/M2 (375 M G/M2, 1 In 21 D), Intravenous (Not Otherwise Specified)		Not Reported
	Doxorubicin (Injection)			C				Not Reported
	Cyclophosphamide (Injection)			C				Not Reported
	Vincristine Sulfate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2009	7117198	DIRECT	N	DE			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S			12 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2009	7130263	EXPEDITED (15-DAY)	Y	OT	1000008727		44 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Erectile Dysfunction; Libido Decreased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2009	7133622	DIRECT	N				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia	Pristiq Extended Release			S	Oral	I Daily Po	1 DAY	Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2009	7133771	EXPEDITED (15-DAY)	Y	DS	S07-FRA-03414*01		66 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Interaction; Mydriasis; Serotonin Syndrome; Visual Impairment; Weight Decreased	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Oxycontin			S	Oral	120 Mg (60 Mg, 2 In 1 D), Oral		Not Reported
	Fentanyl			S	Nasal	800 Mcg (200 Mcg, 4 In 1 D), Nasal		Not Reported
	Morphine Sulfate			S	Oral	60 To 120 Mg Daily (30 Mg), Oral		Not Reported
	Taxotere (Docetaxel) (Docetaxel)			C				Not Reported
	Acetaminophen			C				Not Reported
	Prednisone			C				Not Reported
	Rythmol			C				Not Reported
	Tareg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2009	6259219	EXPEDITED (15-DAY)	N	HO, OT	US-ASTRAZENECA-2006UW21906		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Blood Triglycerides Increased; Diabetes Mellitus; Diabetic Nephropathy; Diabetic Neuropathy; Hyperlipidaemia; Neuroleptic Malignant Syndrome; Ovarian Cyst	Seroquel			S	Oral	100-200 Mg	2 MTH	Not Reported
	Seroquel			S	Oral	100-200 Mg	2 MTH	Not Reported
	Seroquel			S	Oral		1 MTH	Not Reported
	Seroquel			S	Oral		1 MTH	Not Reported
	Seroquel			S	Oral	100 Mg-200 Mg		Not Reported
	Seroquel			S	Oral	100 Mg-200 Mg		Not Reported
	Abilify			S			1 YR	Not Reported
	Abilify			S	Oral			Not Reported
	Geodon			S				Not Reported
	Geodon			S		80 Mg		Not Reported

Risperdal	S			17 MTH	Not Reported
Risperdal	S	Oral			Not Reported
Thorazine	S			1 YR	Not Reported
Thorazine	S				Not Reported
Perphenazine	S			1 YR	Not Reported
Lexapro	S				Not Reported
Trazodone Hydrochloride	S	Oral	100 Mg-150 Mg	4 MTH	Not Reported
Trazodone Hydrochloride	S	Oral	100 Mg-150 Mg	4 MTH	Not Reported
Trazodone Hydrochloride	S	Oral	100 Mg-150 Mg		Not Reported
Trazodone Hydrochloride	S	Oral	100 Mg-150 Mg		Not Reported
Effexor	S	Oral			Not Reported
Paxil	S				Not Reported
Ativan	S				Not Reported
Buspar	S				Not Reported
Amitriptyline Hydrochloride\Perphenazine	S				Not Reported
Remeron	S	Oral			Not Reported
Remeron	S	Oral			Not Reported
Lamictal	C	Oral	25 Mg-200 Mg		Not Reported
Lisinopril	C		10 Mg-20 Mg		Not Reported
Detrol La	C				Not Reported
Codeine	C		300-30 Mg, 1-2 Tablets Every 4 To 6 Hours As Needed		Not Reported
Metronidazole	C				Not Reported
Nabumetone	C				Not Reported
Prozac	C				Not Reported
Wellbutrin	C				Not Reported
Zoloft	C				Not Reported
Xanax	C				Not Reported
Glucophage	C	Oral	500 Mg-2000 Mg		Not Reported
Avandaryl	C	Oral	4/2 Mg		Not Reported
Motrin	C				Not Reported
Albuterol	C		90 Mcg Inhaler		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2009	7132162	EXPEDITED (15-DAY)	Y	DS	1000008749			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus Generalised; Skin Haemorrhage; Somnolence	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolam			S	Oral	3 Mg (0,5 Mg, 6 In 1 D), Oral		Not Reported
	Lexomil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2009	6805702	EXPEDITED (15-DAY)	Y	DS	1000000410		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Gestational Diabetes; Maternal Exposure During Pregnancy; Pregnancy; Visual Impairment; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		
	L-Thxrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2009	7117550	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14559165		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Dyspepsia; Hyperhidrosis	Megace			S	Oral	1 Df = 1 Tab.2008-Jan09:1df; Jan09:2 Df.		Bristol Myers Squibb

	Lexapro	S	Oral	Nov08-Jan09:10mg;Jan09-24feb09:20mg;25feb-10mar:10mg;11mar:20mg.		Not Reported
	Lexapro	S	Oral	Nov08-Jan09:10mg;Jan09-24feb09:20mg;25feb-10mar:10mg;11mar:20mg.		Not Reported
	Xanax	C				Not Reported
	Metoprolol	C				Not Reported
	Percocet	C				Not Reported
	Crestor	C				Not Reported
	Nexium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2009	7117874	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009264035			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction	Xanax			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2009	7136021	DIRECT	Y	DS			15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Heart Rate Decreased; Hyperhidrosis; Pallor; Presyncope; Unresponsive To Stimuli	Lexapro			S				Not Reported
	Xopenex Hfa			S				Not Reported
	Singulair			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2009	7136045	EXPEDITED (15-DAY)	N	OT	1000008833		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Dry Mouth; Dry Throat;	Escitalopram Oxalate			S	Oral	5-10 Mg Daily, Oral		Not Reported

Dysphonia; Fatigue; Nausea; Palpitations; Panic Attack; Restlessness; Sensation Of Foreign Body; Sleep Disorder; Suicidal Ideation; Tremor	Escitalopram Oxalate	S	Oral	5-10 Mg Daily, Oral	Not Reported
	Eltroxin (Tablets)	C			Not Reported
	Centyl (Tablets)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2009	7127713	DIRECT	Y				22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Feeling Abnormal; Mydriasis; Somnolence	Escitalopram Oxalate			S	Oral	Escitalopram 5mg 1 Tab Daily Po		Pfizer
	Ramelteon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2009	6957153	EXPEDITED (15-DAY)	Y	OT	1000005282		51 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2009	7063515	EXPEDITED (15-DAY)	Y	DE	1000007363		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Athymil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2009	7124849	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14372254		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Irritability	Buspar			S	Oral	Dose Reduced To 10mg From Oct2008		Bristol Myers Squibb
	Klonopin			C				Not Reported
	Buspar			S	Oral	Dose Reduced To 10mg From Oct2008		Bristol Myers Squibb
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2009	7124982	EXPEDITED (15-DAY)	Y	OT	IN-ROXANE LABORATORIES, INC.-2009-RO-00959RO		12 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Extrapyramidal Disorder	Alprazolam			S				Roxane
	Alprazolam			S				Roxane
	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Rabeprazole			S			5 DAY	Not Reported
	Rabeprazole			S			5 DAY	Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Diphenhydramine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2009	7077639	EXPEDITED (15-DAY)	Y	HO, OT	DSA_34038_2009			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Aphasia; Arrhythmia; Arteriosclerosis Coronary Artery; Blood Potassium Decreased; Dry Eye; Essential Hypertension; Fall; Gait Inability; Generalised Tonic-Clonic	Cardizem La			S	Oral	180 Mg Oral		Not Reported
	Lexapro			S	Oral	Df; Frequency Qd Oral		Not Reported
	Remeron			S	Oral	Df Oral		Not Reported
	Valium			C				Not Reported
	Benicar			C				Not Reported
	Tylenol			C				Not Reported
	Artificial Tears			C				Not Reported

Seizure; Hypersensitivity; Hypokalaemia; Hyponatraemia; Iron Deficiency Anaemia; Left Ventricular Hypertrophy; Loss Of Consciousness; Mitral Valve Incompetence; Po2 Decreased; Renal Artery Arteriosclerosis; Sinus Tachycardia; Swelling; Syncope; Tricuspid Valve Incompetence; Vision Blurred

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2009	7143253	EXPEDITED (15-DAY)	Y	DS	1000008970		48 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Anxiety; Apathy; Confusional State; Depersonalisation/Derealisation Disorder; Diarrhoea; Dysgeusia; Dyspnoea; Headache; Hyperhidrosis; Intraocular Pressure Increased; Muscle Spasms; Pruritus; Psychiatric Symptom; Restlessness; Sleep Disorder; Suicidal Ideation; Tinnitus; Tremor	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolam			S	Oral	9 Mg (9 Mg, 1 In 1 D), Oral		Not Reported
	Sobril			C				Not Reported
	Sarotex			C				Not Reported
	Nozinan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2009	7145121	EXPEDITED (15-DAY)	Y	HO	1000008968		93 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyperkalaemia; Hyponatraemia; International Normalised Ratio Increased	Escitalopram Oxalate		S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral	Not Reported
	Perindopril		S	Oral	8 Mg (8 Mg, 1 In 1 D), Oral	Not Reported
	Sintrom		S	Oral	1 Mg, As Required, Oral	Not Reported
	Plavix		C			Not Reported
	Levothyroxine		C			Not Reported
	Diltiazem		C			Not Reported
	Torem (Tablets)		C			Not Reported
	Rasilez (Tablets)		C			Not Reported
	Neurontin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2009	6546132	EXPEDITED (15-DAY)	Y	CA, HO, OT	A0680992A		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly; Craniosynostosis; Developmental Delay; Maternal Exposure During Pregnancy; Talipes	Paxil			S				Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2009	7126106	EXPEDITED (15-DAY)	Y	OT	1000008717		28 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Drugs Affecting Foetus; Metrorrhagia; Pregnancy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2009	7128826	NON-EXPEDITED	Y	OT	US-ASTRAZENECA-2009UW17939		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased	Seroquel			S	Oral			Not Reported

Lamictal	S		Not Reported
Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2009	7129767	EXPEDITED (15-DAY)	Y	DS, OT	NO-PFIZER INC-2009266558		48 YR	Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Anxiety; Apathy; Confusional State; Depersonalisation/Dereali sation Disorder; Diarrhoea; Dysgeusia; Dyspnoea; Headache; Hyperhidrosis; Intraocular Pressure Increased; Muscle Spasms; Pruritus; Psychiatric Symptom; Restlessness; Sleep Disorder; Suicidal Ideation; Tinnitus; Tremor	Alprazolam			S	Oral	(2+2+2+3 Mg)		Pfizer
	Cipralex			S	Oral			Not Reported
	Oxazepam			C				Not Reported
	Levomepromazine			C		When Needed		Not Reported
	Amitriptyline Hydrochloride			C	Oral	When Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2009	7138874	DIRECT	N	OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Diabetic Neuropathy; Irritability; Pain; Treatment Failure	Lexapro			S		10 Mg Once A Day Tab		Not Reported
	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2009	7146279	EXPEDITED (15-DAY)	Y	OT	GXKR2009IN10235		12 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Clonus; Dysarthria; Dyskinesia;	Alprazolam			S		0.25 Mg, Once/Single,		Not Reported
	Escitalopram Oxalate			S		10 Mg, Once/Single,		Not Reported

Dysphemia; Dystonia; Extensor Plantar Response; Extrapyramidal Disorder; Hypertonia; Movement Disorder; Muscle Rigidity; Posture Abnormal; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2009	7131505	EXPEDITED (15-DAY)		OT	PHEH2009US11016			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dysphagia; Feeling Hot; Head Titubation; Hyperhidrosis; Hypoaesthesia; Muscle Spasms; Seizure; Vision Blurred	Tekturna Hct			S		150/12.5 Mg		Novartis
	Metoprolol Tartrate			S		50 Mg, Unk		Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2009	7144089	EXPEDITED (15-DAY)	Y	DE	1000009056			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2009	7138850	DIRECT	N	DS, HO, LT, RI, OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Alcohol Use; Anxiety; Blood Pressure Increased; Delusion; Suicide Attempt	Lexapro			S	Oral	10 Mg 1 X Day Po		Forest
	Campral			S	Oral	333 Mg 3 X Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2009	7138854	DIRECT	Y	HO, LT, RI, OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Chest Pain; Divorced; Dyspnoea Exertional; Family Stress; Gastrointestinal Disorder; Insomnia; Suicide Attempt	Lexapro			S	Oral	? Once A Day Po	13 DAY	Not Reported
	Celebrex			S	Oral	200mgs Once A Day Po	8 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2009	7141181	DIRECT	N	DS, RI			35 YR	Male	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Loss Of Libido; Male Sexual Dysfunction; Organic Erectile Dysfunction	Lexapro			S		10mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2009	7147763	EXPEDITED (15-DAY)	Y	OT	1000009040		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt; Systolic Hypertension; Tachycardia	Escitalopram Oxalate			S	Oral	(300 Mg, Once), Oral		Not Reported
	Acetaminophen\Aspirin\Caffeine			S	Oral	(3 Dosage Forms, Once), Oral		Not Reported
	Alcohol			S	Oral	2 Bottles Of Beer, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2009	7133650	EXPEDITED (15-DAY)	N	OT	CA-BAYER-200933522NA		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haemoglobin Decreased; Vaginal Haemorrhage	Mirena		S	Intra-uterine		Bayer
	Cipralex		S	Oral	1 WEEK	Not Reported
	Cipralex		S	Oral	3 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2009	7149193	EXPEDITED (15-DAY)	Y	OT	1000009104		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Suicidal Behaviour	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
	Ibuprofen			C				Not Reported
	Ferrous Gluconate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2009	6258620	EXPEDITED (15-DAY)	Y	HO, OT	US-ASTRAZENECA-2006UW25940		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bipolar Disorder; Bipolar I Disorder; Depression; Diabetes Mellitus; Diabetes Mellitus Inadequate Control; Hallucination, Auditory; Homicidal Ideation; Hyperglycaemia; Major Depression; Mood Swings; Psychotic Disorder; Schizoaffective Disorder; Schizoaffective Disorder Bipolar Type; Schizophrenia; Schizophrenia; Suicidal Ideation; Suicide Attempt;	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral	20-425 Mg		Not Reported
	Seroquel			S	Oral	20-425 Mg		Not Reported
	Abilify			S	Oral			Not Reported
	Haldol			S				Not Reported
	Navane			S				Not Reported
	Risperdal			S	Oral			Not Reported
	Thorazine			S				Not Reported
	Zyprexa			S	Oral	10-20 Mg		Not Reported
	Zyprexa			S	Oral	10-20 Mg		Not Reported
	Lithium			S				Not Reported

Tachyphrenia	Paxil	S			Not Reported
	Lexapro	S	Oral	10-20 Mg	Not Reported
	Cogentin	S			Not Reported
	Depakote	C	Oral		Not Reported
	Nph Insulin	C		50 Units/44 Units, 30 Units/15 Units	Not Reported
	Insulin 70/30	C	Subcutaneous	40 Units Every Morning/30 Units Every Evening, 70 Units	Not Reported
	Glucotrol	C	Oral		Not Reported
	Avandia	C	Oral		Not Reported
	Trileptal	C	Oral		Not Reported
	Tylenol With Codeine	C		Every 6 Hrs	Not Reported
	Tylenol	C	Oral	650 Mg Every 4 Hrs	Not Reported
	Dilantin	C	Oral		Not Reported
	Lopresor	C	Oral	50-200 Mg	Not Reported
	Albuterol	C		2 Puffs Every 4-6 Hrs	Not Reported
	Albuterol	C		2 Puffs Every 4-6 Hrs	Not Reported
	Mavik	C	Oral		Not Reported
	Lasix	C	Oral	20-40 Mg	Not Reported
	Singulair	C	Oral		Not Reported
	Desyrel	C			Not Reported
	Capoten	C			Not Reported
	Benazepril	C	Oral		Not Reported
	Wellbutrin	C	Oral		Not Reported
	Buspar	C	Oral		Not Reported
	Aspirin	C	Oral	81-325 Mg	Not Reported
	Ativan	C			Not Reported
	Restoril	C			Not Reported
	Klonopin	C	Oral	1-6 Mg	Not Reported
	Glucophage	C		500-1500 Mg	Not Reported
	Nitroglycerin	C			Not Reported

	Fluticasone	C	1250 Mcg		Not Reported
	Advair Diskus	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2009	7013039	EXPEDITED (15-DAY)	Y	OT	ES-PFIZER INC-2009220762		51 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Sedation; Urinary Incontinence	Celecoxib			S	Oral	200 Mg, 1x/Day	4 DAY	Pfizer
	Diazepam			S	Oral	5 Mg, 1x/Day	4 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, 1x/Day	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2009	7126172	EXPEDITED (15-DAY)	Y	OT	1000008719		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metrorrhagia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D) Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D) Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2009	7134848	EXPEDITED (15-DAY)	N	HO	US-ASTRAZENECA-2009SE14269		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Delirium; Gastric Bypass; Migraine; Pyrexia; Serotonin Syndrome; Thyroid Disorder; Tremor	Zomig			S				Not Reported
	Lexapro			S				Not Reported
	Amitriptyline			S				Not Reported
	Imitrex			C				Not Reported
	Suboxone			C				Not Reported
	Potassium			C				Not Reported
	Testosterone			C				Not Reported
	Progesterone			C				Not Reported
	Estrogen Patch			C				Not Reported
	Lorazepam			C				Not Reported

	Gabapentin	C	Not Reported
	Hydrocortisone	C	Not Reported
	Cyanocobalamin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2009	7045254	EXPEDITED (15-DAY)	Y	OT	1000007024		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Vaginal Haemorrhage	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	7.5 Mg (7.5 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2009	7071818	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20090709765		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Meniscus Injury; Oedema Peripheral	Risperdal			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2009	7087368	EXPEDITED (15-DAY)	Y	OT	1000008032		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Generalised Tonic-Clonic Seizure; Tinnitus	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Olanzapine			C				Not Reported
	Depo-Provera			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2009	7132504	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14791669		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Gait Disturbance; Hepatic Pain; Hepatomegaly; Mood Swings; Muscle Atrophy; Restlessness	Abilify			S	Oral	Initial Dose:2mg T Am And Tt Hs) Increased To 5mg(04aug09)Bid		Not Reported
	Abilify			S	Oral	Initial Dose:2mg T Am And Tt Hs) Increased To 5mg(04aug09)Bid		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2009	7150296	EXPEDITED (15-DAY)	Y	HO	1000009124		80 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Dysarthria; Hypertonia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Loss Of Consciousness; Malaise; Postictal State; Seizure	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Parkinane			C				Not Reported
	Sinemet			C				Not Reported
	Stilnox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2009	7150983	EXPEDITED (15-DAY)	N	OT	1000009135		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aura; Back Pain; Disorientation; Headache; Loss Of Consciousness; Postictal Headache; Postictal State; Seizure	Lexapro			S	Oral	10 Mg (10 Mg,Once), Oral		Not Reported
	Flonase			C				Not Reported
	Allegra			C				Not Reported
	Singulair			C				Not Reported
	Alprazolan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2009	7079840	EXPEDITED (15-DAY)	Y	DE	1000007891		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Ambien Cr			S	Oral	12.5 Mg, As Required, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2009	7085342	EXPEDITED (15-DAY)	Y	OT	1000007970		83 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Blood Creatinine Increased; Blood Urea Increased; C-Reactive Protein Increased; Refusal Of Treatment By Patient; Supraventricular Extrasystoles; Syncope; Vertigo	Escitalopram Oxalate			S		5 Mg (5 Mg, 1 In 1 D)		Not Reported
	Proscar			C				Not Reported
	Folerite			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2009	7130517	EXPEDITED (15-DAY)	Y	DE	1000008781		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Completed Suicide; Diarrhoea; Nausea; Stress	Lexapro			S	Oral	5 Mg (5mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Cymbalta			S	Oral	20 Mg, Oral		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2009	7148165	DIRECT	Y	HO			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Muscle Spasms; Restlessness; Serotonin Syndrome; Vomiting; Yawning	Lexapro			S	Oral	10 Mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2009	7153161	EXPEDITED (15-DAY)	N	OT	1000009178			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Flank Pain; Kidney Infection; Suicidal Ideation	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Aspirin\Caffeine\Codeine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2009	7153868	EXPEDITED (15-DAY)	N	CA	1000009164		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia; Maternal Drugs Affecting Foetus; Multiple Congenital Abnormalities; Pyloric Stenosis	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2009	6866204	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2008153740		61 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Estradiol			S				Pfizer
	Paracetamol+Codeine			S	Oral			Not Reported
	Diphenhydramine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported

	Oxycodone	S	Oral		Not Reported
	Unspecified Ingredient	S	Oral		Not Reported
	Progesterone	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2009	7155303	EXPEDITED (15-DAY)	Y	OT	1000009198		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate			S		10 Mg (10 Mg,L In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2009	7143541	EXPEDITED (15-DAY)	Y	HO	CH-JNJFOC-20090908578		77 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Phenytoin			S	Oral			Not Reported
	Phenytoin			S	Oral			Not Reported
	Phenytoin			S	Oral			Not Reported
	Phenytoin			S	Oral			Not Reported
	Phenytoin			S	Oral			Not Reported
	Axura			S	Oral			Not Reported
	Axura			S	Oral			Not Reported
	Axura			S	Oral			Not Reported

	Cipralex	S	Oral		Not Reported
	Cipralex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2009	7151549	DIRECT	N	RI, OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisocial Behaviour; Disturbance In Attention; Feeling Abnormal; Hyperhidrosis; Insomnia; Irritability; Phobia	Effexor			S				Not Reported
	Lexapro			S				Not Reported
	Zoloft			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2009	7163357	EXPEDITED (15-DAY)	Y	DE	B0596120A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Sepsis	Escitalopram Oxalate			S		1000 Mg / Per Day /		Not Reported
	Paclitaxel			S		80 Mg/M2 / Weekly /		Not Reported
	Cyclophosphamide			S		60 Mg/M2 /		Not Reported
	Doxorubicin Hydrochloride			S		600 Mg/M2 /		Not Reported
	Trastuzumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2009	6901549	EXPEDITED (15-DAY)	Y	DE, HO	1000003593		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Meningorrhagia	Escitalopram Oxalate			S	Oral	5 Or 10 Mg (1 In 1 D), Oral		Not Reported
	Seresta			C				Not Reported
	Benerva			C				Not Reported
	Nicobion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2009	7085345	EXPEDITED (15-DAY)	Y	HO, OT	1000007973		83 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Bradycardia; Bundle Branch Block Right; Drug Level Increased; Electrocardiogram Repolarisation Abnormality; Myocardial Infarction; Pneumonia; Pulmonary Embolism; Ventricular Extrasystoles	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zestril			C				Not Reported
	Aspirin Cardio			C				Not Reported
	Acidum Folicum			C				Not Reported
	Perenterol			C				Not Reported
	Dipiperon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2009	7144669	EXPEDITED (15-DAY)	Y	DE, LT	CH-JNJFOC-20091001021		22 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Respiratory Arrest	Risperidone			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Trileptal			S	Oral			Not Reported
	Chlorprothixene			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2009	7145104	EXPEDITED (15-DAY)	Y	DE, LT	CH-JNJFOC-20091001797		35 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported

	Risperdal	S	Oral	Not Reported
	Haldol	S	Oral	Not Reported
	Haldol	S	Oral	Not Reported
	Haldol	S	Oral	Not Reported
	Haldol	S	Oral	Not Reported
	Seroquel Xr	S	Oral	Not Reported
	Seroquel Xr	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2009	7146981	EXPEDITED (15-DAY)	Y	HO	ES-MYLANLABS-2009S1016921		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hallucination, Visual	Escitalopram Oxalate			S		10 Mg/Day	2 YR	Alphapharm
	Rasagiline Mesylate			S		1 Mg/Day	3 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	6890107	NON-EXPEDITED	N	OT	1000003170		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vitamin D Deficiency	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	6974767	NON-EXPEDITED	N	OT	1000005699		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chest Pain; Clumsiness; Constipation; Dizziness; Dyspnoea; Fatigue; Nausea; Seizure; Speech	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

Disorder; Transient Ischaemic Attack; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7010348	NON-EXPEDITED	Y	OT	1000005861		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphocytosis; Pleural Effusion	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Diovan			C				Not Reported
	Norvasc			C				Not Reported
	Meloxicam			C				Not Reported
	Lovastatin			C				Not Reported
	Nexium			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Flomax			C				Not Reported
	Xanax			C				Not Reported
	Albuterol			C				Not Reported
	Flonase			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7042673	EXPEDITED (15-DAY)	Y	HO, OT	NO-BRISTOL-MYERS SQUIBB COMPANY-14685168			Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Abdomen; Drug Interaction; Lipoatrophy; Lipodystrophy Acquired	Videx			S				Bristol Myers Squibb
	Cipralex			S		Film Coated Tablets		Not Reported
	Kaletra			S	Oral	Soft Gelatin Capsules		Not Reported
	Epivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7157201	EXPEDITED (15-DAY)	Y	OT	1000009302		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Blood Pressure Increased; Depression; Seizure	Lexapro		S	Oral	Oral	Not Reported
	Symbyax		S		6/25 Mg	Not Reported
	Wellbutrin		S	Oral	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7158608	EXPEDITED (15-DAY)	Y	DE	1000009306		51 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Trileptal			C				Not Reported
	Atarax			C				Not Reported
	Zyprexa			C				Not Reported
	Theralen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7158620	EXPEDITED (15-DAY)	Y	OT	1000009330		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Weight Increased	Escitalopram Oxalate			S	Oral	10 Mg (10mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D)(Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7169611	NON-EXPEDITED	Y	HO	1000005454		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Urinary Tract Infection	Lexapro			S		10 Mg (10 Mg, 1 In 1 D), 20 Mg (20 Mg, 1 In 1 D) 10 Mg (10 Mg, 1 In 1 D), 20 Mg (20 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7169649	NON-EXPEDITED	N	HO	1000005925		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Depression; Diarrhoea; Drug Ineffective; Eating Disorder; Fatigue	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral		
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7169665	NON-EXPEDITED	N	HO	1000006110		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Decreased Appetite; Depression; Diarrhoea; Dizziness; Fatigue; Heart Rate Increased; Nausea; Nervousness; Panic Attack; Restlessness; Somnolence; Tremor	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported
	Nortriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7169743	NON-EXPEDITED	N	OT	1000006486		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1		

			D), Oral	
	Toprol Xl	C		Not Reported
	Florinef Acetate	C		Not Reported
	Vitamins	C		Not Reported
	Pepcid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7169754	NON-EXPEDITED	N	OT	1000006581		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Delusion; Irritability; Mania	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Toprol Xl			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7169775	NON-EXPEDITED	Y	OT	1000007130			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7169777	NON-EXPEDITED	Y	OT	1000007144			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7170029	NON-EXPEDITED	N	HO	1000007337		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

Increased; Disorientation; Dyspnoea; Feeling Jittery; Heart Rate Increased; Hypoaesthesia; Nervousness; Panic Attack; Paraesthesia; Somnolence; Tremor	Lexapro		S	Oral	2.5 Mg (2.5 Mg, 1 In 1 D), Oral	Not Reported
	Alprazolam		C			Not Reported
	Combivent		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7170031	NON-EXPEDITED	Y	HO	1000007702		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Lexapro			S				Not Reported
	Lamictal			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7170039	NON-EXPEDITED	Y	OT	1000008086			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7170049	NON-EXPEDITED	N	OT	1000007480		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Kadian			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7170052	NON-EXPEDITED	N	OT	S07-USA-06169-01		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Anxiety; Depression; Overdose; Paraesthesia; Sleep Disorder; Suicidal Ideation; Tremor	Lexapro			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7170119	NON-EXPEDITED	Y	DE, OT	1000007560		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S				Not Reported
	Zyprexa			S	Oral	30 Mg, Oral		Not Reported
	Symbyax			S		12/25mg (1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7170123	NON-EXPEDITED	N	HO	1000007706		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression; Headache; Insomnia; Nausea	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lamictal			C				Not Reported
	Clonazepam			C				Not Reported
	Pravachol			C				Not Reported
	Zetia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7170124	NON-EXPEDITED	Y	OT	1000005617			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Lexapro			S				Not Reported
	Seroquel			C				Not Reported
	Viagra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7172700	NON-EXPEDITED	Y	HO, LT, OT	S08-USA-02237-01		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Hypersensitivity; Gastrooesophageal Reflux Disease; Overdose; Respiratory Tract Infection	Lexapro			S	Oral	20 Mg (1 In 1 D), Oral : 30 Mg (30 Mg, Daily), Oral		Not Reported
	Unspecified Ingredient			S				Not Reported
	Clonazepam			C				Not Reported
	Inhaler			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7174028	NON-EXPEDITED	Y	OT	1000000518			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7174049	NON-EXPEDITED	N	OT	1000000839		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Feelings Of Worthlessness; Headache; Insomnia; Pain; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7174052	NON-EXPEDITED	Y	HO	1000000888		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7174069	NON-EXPEDITED	Y	OT	1000001035		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Pressure Increased; Dizziness; Dry Mouth; Dyskinesia; Fatigue; Hot Flush; Hyperhidrosis; Insomnia; Tremor	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lantus			C				Not Reported
	Insulin Nos			C				Not Reported
	Nph Insulin			C				Not Reported
	Synthroid			C				Not Reported
	Lorazepam			C				Not Reported
	Darvocet			C				Not Reported
	Meclizine			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Senokot			C				Not Reported
	Avapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7174077	NON-EXPEDITED	Y	HO	1000001048		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypoglycaemia; Syncope	Lexapro			S		20 Mg (20 Mg, Qd)		Not Reported
	Sunitinib			S		50 Mg (Qd)		Not Reported
	Sorafenib			S		800 Mg (400 Mg, Bid)		Not Reported
	Accupril			S		40 Mg (40 Mg, Qd)		Not Reported
	Omacor			S		4000 Mg (1000 Mg, Qid)		Not Reported
	Coreg			S		12.5 Mg (12.5 Mg, Qd)		Not Reported
	Humalog			S		50 Units (25 Units Qam, 25 Units Qpm)		Not Reported
	Hydralazine			S		25 Mg, Tid		Not Reported
	Novolog			S	Subcutaneous	(100 Units/Ml Tid), Subcutaneous		Not Reported
	Pravachol			S		40 Mg (40 Mg, Qd)		Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7174115	NON-EXPEDITED	N	OT	1000001143		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Triglycerides Increased; Dizziness; Headache; Hyperhidrosis; Muscle Spasms; Nausea; Overdose; Suicidal Ideation; Vomiting	Lexapro			S	Oral Oral Oral Oral Oral Oral Oral	See Image See Image See Image See Image See Image See Image See Image		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7174121	NON-EXPEDITED	Y	OT	1000001199			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg (Daily), Oral : 20 Mg (Daily), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7174122	NON-EXPEDITED	Y	OT	1000001206			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7174123	NON-EXPEDITED	Y	HO	1000001222		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7175299	NON-EXPEDITED	Y	OT	1000001454		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Aciphex			C				Not Reported
	Synthroid			C				Not Reported
	Zantac			C				Not Reported
	Tums			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7175321	NON-EXPEDITED	N	OT	1000001288		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Dizziness; Feelings Of Worthlessness; Irritability; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Chantix			S		Daily		Not Reported
	Levoxyl			C				Not Reported
	Lisinopril			C				Not Reported
	Singulair			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7175329	NON-EXPEDITED	Y	OT	1000001321			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7175367	NON-EXPEDITED	Y	OT	1000001502		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Suicidal Ideation	Lexapro	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Darvocet-N 100	C				Not Reported
	Trazodone Hydrochloride	C				Not Reported
	Flonase	C				Not Reported
	Astelin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7176979	NON-EXPEDITED	Y	OT	1000001591		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7177048	NON-EXPEDITED	Y	OT	1000001674		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Interaction; Eye Movement Disorder; Food Craving; Headache; Nausea; Pruritus Generalised; Suicidal Ideation; Tremor; Visual Impairment; Vomiting; Weight Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 Qod), Oral		Not Reported
	Amitriptyline			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tramadol Hydrochloride			S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported
	Flexeril			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Phenergan			C				Not Reported
	Darvocet			C				Not Reported
	Propranolol			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Xanax			C				Not Reported
	Synthroid			C				Not Reported

	Tri-Sprintec	C		Not Reported
	Hydrochlorothiaze	C		Not Reported
	Wellbutrin Xl	C		Not Reported
	Centrum	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7177057	NON-EXPEDITED	Y	OT	1000001737		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Wellbutrin			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7177066	NON-EXPEDITED	N	HO	1000003058		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Vomiting	Lexapro			S	Oral	1 In 1 D, Oral		Not Reported
	Hydroxyurea			C				Not Reported
	Atenolol			C				Not Reported
	Amlodipine Besylate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7177087	NON-EXPEDITED	N	OT	1000003119			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Depression; Feeling Of Body Temperature Change; Hyperhidrosis; Influenza Like Illness; Overdose; Pain; Paraesthesia; Suicidal Ideation; Withdrawal Syndrome	Lexapro			S	Oral Oral	See Image See Image		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7177090	NON-EXPEDITED	Y	HO	1000003177		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State	Lexapro			S	Oral Oral	Oral Oral		Not Reported
	Unspecified Ingredient			S	Oral	2400 Mg (400 Mg, 6 In 1 D), Oral		Not Reported
	Lamotrigine			C				Not Reported
	Levetiracetam			C				Not Reported
	Phenytoin			C				Not Reported
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7179025	NON-EXPEDITED	N	OT	1000003223		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Confusional State; Eating Disorder; Pain; Stress; Suicidal Ideation; Tachyphrenia; Tinnitus	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7179031	NON-EXPEDITED	Y	HO	1000003458		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Toprol Xl			C				Not Reported
	Caduet			C				Not Reported

	Neurontin	C		Not Reported
	Protonix	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7179038	NON-EXPEDITED	Y	OT	1000003667		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		
	Hydroxychloroquine			C				Not Reported
	Prednisone			C				Not Reported
	Azathioprine			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Lantus			C				Not Reported
	Calcium With Vitamin D (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7179054	NON-EXPEDITED	Y	HO	1000004973		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory; Overdose; Suicide Attempt	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 1 Once, Oral, 30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 1 Once, Oral, 30 Mg (30 Mg, 1 In 1 D), Oral		
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 1 Once, Oral, 30 Mg (30 Mg, 1 In 1 D), Oral		
	Unspecified Ingredient			S		Once, High Dose Once, High Dose		Not Reported
	Tylenol			C				Not Reported

Aleve	C		Not Reported
Risperdal	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7179059	NON-EXPEDITED	Y	HO	1000004977			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased	Lexapro			S	Oral	10 Mg (1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7179061	NON-EXPEDITED	Y	HO	1000004993		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Hypertension; Insomnia	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7179070	NON-EXPEDITED	Y	HO	1000005024		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Lexapro			S	Oral	20 Dosage Forms, Once, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7179082	NON-EXPEDITED	Y	HO	1000005208		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged; Syncope	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 40 Mg (40 Mg, 1 In 1 D), Oral		

	Linaclotide (Capsules)	C	Not Reported
	Prempro	C	Not Reported
	Lunesta	C	Not Reported
	Aleve	C	Not Reported
	Dulcolax Tablets	C	Not Reported
	Zithromax	C	Not Reported
	Omnaris (Nasal Drops (Including Nasal Spray)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7179092	NON-EXPEDITED	Y	HO	1000005233		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Lexapro			S				Not Reported
	Aspirin			S				Not Reported
	Numerous Other Medications (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7179147	NON-EXPEDITED	Y	OT	1000005381		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Trileptal			S	Oral	600 Mg (600 Mg), Oral		Not Reported
	Geodon			C				Not Reported
	Neurontin			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Valium			C				Not Reported
	Aciphex			C				Not Reported
	Marinol			C				Not Reported
	Miralax			C				Not Reported
	Boniva			C				Not Reported
	Enablex			C				Not Reported
	Copaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7212251	NON-EXPEDITED	Y	HO	1000006570		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2009	7212300	NON-EXPEDITED	Y	OT	1000000791			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Fulminant	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2009	7139125	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000008871		48 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Respiratory Depression; Seizure; Suicide Attempt; Tachyarrhythmia; Ventricular Fibrillation	Escitalopram Oxalate			S	Oral	(800 Mg, Once), Oral		Not Reported
	Amitriptyline Hydrochloride			S	Oral	(1000 Mg, Once) , Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2009	7148409	EXPEDITED (15-DAY)	Y	DE	CH-ASTRAZENECA-2009SE19259		35 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Seroquel Xr			S	Oral		5 DAY	Zeneca
	Seroquel Xr			S	Oral		4 DAY	Zeneca
	Risperdal			S	Oral		3 DAY	Not Reported

	Risperdal	S	Oral		18 DAY	Not Reported
	Risperdal	S	Oral		5 DAY	Not Reported
	Risperdal	S	Oral		4 DAY	Not Reported
	Risperdal	S	Oral		32 DAY	Not Reported
	Haldol	S	Oral		6 DAY	Not Reported
	Haldol	S	Oral		5 DAY	Not Reported
	Haldol	S	Oral		2 DAY	Not Reported
	Haldol	S	Oral		1 DAY	Not Reported
	Cipralex	S	Oral		1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2009	7150174	EXPEDITED (15-DAY)	N	DE	US-ABBOTT-09P-163-0601310-00		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Subdural Haemorrhage	Vicodin			S		5/500 Mg		Not Reported
	Lexapro			S		10 Mg Or 20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2009	7154973	DIRECT	Y	HO			< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Tremor Neonatal	Wellbutrin			S	Oral	300mg Daily Po During The Pregnancy	9 MTH	Not Reported
	Lexapro			S	Oral	20 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2009	7160859	EXPEDITED (15-DAY)	Y	OT	GXKR2009TR10832		32 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Migraine; Oculogyric Crisis;	Escitalopram Oxalate			S		10 Mg/Day		Not Reported

Serotonin Syndrome; Therapy Non-Responder	Metoclopramide	S	Intravenous (not otherwise specified)	10 Mg, Intravenous		Not Reported
	Analgesics (No Ingredients/Substances)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2009	7156387	DIRECT		HO, LT, OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Phosphorus Abnormal; Blood Potassium Abnormal; Cerebral Haemorrhage; Confusional State; Decreased Activity; Fall; Gait Disturbance; Hallucination; Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	1 Bedtime Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2009	7162552	EXPEDITED (15-DAY)	N	OT	1000009365		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inflammation; Mucosal Disorder; Nasal Polyps; Sinus Disorder	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Ramipril			C				Not Reported
	Uroxatral			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2009	7151969	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2009279348		85 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyponatraemia; Hypotension	Aldactone			S	Oral	75 Mg, 1x/Day		Pfizer

	Escitalopram Oxalate	S	Oral	10 Mg, 1x/Day	2 DAY	Not Reported
	Levothyrox	C		100 Ug, 1x/Day		Not Reported
	Lorazepam	C		1 Mg, 1x/Day		Not Reported
	Caffeine	C				Not Reported
	Glucophage	C				Not Reported
	Diosmine	C				Not Reported
	Arixtra	C		1 Df, 1x/Day	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2009	7152651	EXPEDITED (15-DAY)	Y	OT	TR-MYLANLABS-2009S1017335		32 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Oculogyric Crisis; Serotonin Syndrome	Escitalopram Oxalate			S		10 Mg/Day		Alphapharm
	Metoclopramide			S	Intravenous (not otherwise specified)	10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2009	7162581	EXPEDITED (15-DAY)	N	OT	AUR-APL-2009-00828			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Pressure Fluctuation; Blood Pressure Inadequately Controlled; Fall; Headache; Seizure; Tremor	Lisinopril			S				Not Reported
	Lexapro			S				Not Reported
	Depakote			S				Not Reported
	Oxybutynin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2009	7162593	EXPEDITED (15-DAY)	Y	OT	1000009451		69 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fluid Retention	Escitalopram Oxalate			S	Oral	10 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2009	7162595	EXPEDITED (15-DAY)	Y	OT	1000009391			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Haemorrhage; Petechiae	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2009	7162727	EXPEDITED (15-DAY)	Y	CA	1000009404			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Digeorge'S Syndrome; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	5 Mg (5 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2009	7165124	EXPEDITED (15-DAY)	Y	HO	1000009010		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Condition Aggravated	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2009	7153024	EXPEDITED (15-DAY)	Y	OT	AT-JNJFOC-20090908153		24 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	0-0-0-1		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported

	Risperdal	S	Oral		Not Reported
	Cipralex	S	Oral	2-0-0-0	Not Reported
	Cipralex	S	Oral		Not Reported
	Zyprexa	C	Oral		Not Reported
	Zyprexa	C	Oral		Not Reported
	Zyprexa	C	Oral		Not Reported
	Lorazepam	C	Oral		Not Reported
	Lorazepam	C	Oral		Not Reported
	Lorazepam	C	Oral		Not Reported
	Lorazepam	C	Oral		Not Reported
	Lorazepam	C	Oral		Not Reported
	Lorazepam	C	Oral		Not Reported
	Lorazepam	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2009	7107170	EXPEDITED (15-DAY)	Y	HO, OT	1000008390			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Maternal Exposure During Pregnancy	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2009	7156875	EXPEDITED (15-DAY)	Y	HO	FR-EISAI INC.-E3810-03231-SPO-FR		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Fall; Hyponatraemia	Pariet (Rabeprazole)			S	Oral			Not Reported
	Pariet (Rabeprazole)			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Acetylsalicylate Lysine 75			C				Not Reported
	Acepromazine			C				Not Reported

Maleate\Clorazepate Dipotassium				
Lorazepam	C			Not Reported
Brompheniramine Maleate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2009	7156998	EXPEDITED (15-DAY)	N	HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-14827042		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Asthenia; Diarrhoea; Hyperkalaemia; Muscle Spasms; Nausea; Vomiting	Hydrochlorothiazide\Irbesartan			S		1 Df = 1(Units Not Specified)		Bristol Myers Squibb
	Metformin Hydrochloride			S			2 MTH	Bristol Myers Squibb
	Sitagliptin Phosphate			S		Taken For A Month	1 MTH	Not Reported
	Escitalopram Oxalate			S				Not Reported
	Inexium			C				Not Reported
	Rivotril			C				Not Reported
	Potassium Chloride			C				Not Reported
	Fenofibrate			C		1 Df = 300(Units Not Specified) Secalip 300		Not Reported
	Acepromazine\Aceprometazine\ Clorazepate Dipotassium			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2009	7168678	EXPEDITED (15-DAY)	N	CA	1000009473		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Atresia; Congenital Cystic Kidney Disease; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2009	7169753	EXPEDITED (15-DAY)	Y	OT	1000008494		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Complication Of Delivery; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D) Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2009	7169760	EXPEDITED (15-DAY)	Y	OT	1000009488			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disturbance In Attention; Hyponatraemia; Incorrect Dose Administered; Major Depression; Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D) Oral 20 Mg (20 Mg, 1 In 1 D) Oral	48 HR	Not Reported
	Risperidal			C				Not Reported
	Ixel (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2009	6518322	EXPEDITED (15-DAY)	Y	OT	S07-DEN-06335-01		62 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Muscle Spasms; Myoclonus; Poor Quality Sleep	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Primperan			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Dimitone (Carvedilol) (Carvedilol)			C				Not Reported
	Amlodipine			C				Not Reported
	Cardopax (Isosorbide Dinitrate) (Isosorbide Dinitrate)			C				Not Reported
	Furix (Furosemide) (Furosemide)			C				Not Reported
	Hjertemagnyl			C				Not Reported
	Ramipril			C				Not Reported
	Simvastatin			C				Not Reported
	Spirocort (Budesonide) (Solution) (Budesonide)			C				Not Reported
	Pantoloc			C				Not Reported

	Plavix	C	Not Reported
	Fem-Mono Retard	C	Not Reported
	Bricanyl (Terbutaline Sulfate) (Terbutaline Sulfate)	C	Not Reported
	Spirix (Spironolactone) (Spironolactone)	C	Not Reported
	Travatan (Travoprost) (Liquid) (Travoprost)	C	Not Reported
	Nitroglycerin	C	Not Reported
	Triatec (Tablets)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2009	7171564	EXPEDITED (15-DAY)	Y	HO	1000009562		20 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ammonia Increased; Blood Lactic Acid Increased; Brain Oedema; Drug Level Above Therapeutic; Extrapyramidal Disorder; Intentional Overdose; Nervous System Disorder; Tachycardia	Escitalopram Oxalate			S	Oral Oral	(Once), Oral; Oral (Once), Oral; Oral		Not Reported
	Depakote			S	Oral Oral	(Once), Oral; Oral (Once), Oral; Oral		Not Reported
	Depakote			S	Oral	Oral		Not Reported
	Aripiprazole			S		(Once)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2009	7171623	EXPEDITED (15-DAY)	Y	OT	1000009597			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Pressure Fluctuation; Fall; Gait Disturbance; Headache; Seizure; Tremor	Lexapro			S				Not Reported
	Oxybutynin			S				Not Reported
	Lisinopril			S				Not Reported
	Depakote			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2009	7068001	EXPEDITED (15-DAY)	Y	DE, LT	1000007531		72 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Cerebral Artery Embolism; Completed Suicide; Delirium; Haematemesis; Hallucination, Visual; Intentional Overdose; Psychomotor Hyperactivity; Pulmonary Embolism; Seizure	Escitalopram Oxalate			S	Oral	(60 Mg,Once), Oral; 10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
					Oral	(60 Mg,Once), Oral; 10 Mg (10 Mg,1 In 1 D), Oral		
	Plavix			C				Not Reported
	Cordarone			C				Not Reported
	Triatec (Ramipril)			C				Not Reported
	Omnic			C				Not Reported
	Dormicum (Midazolam Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2009	7172963	EXPEDITED (15-DAY)	Y	HO	DSU-2009-02216		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Atrial Fibrillation; Blood Chloride Increased; Blood Glucose Increased; Blood Potassium Decreased; Electrocardiogram Change; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Abnormal; Hypotension; Mood Swings; Overdose; Pco2 Decreased; Shock	Benicar			S	Oral	Per Oral		Not Reported
	Tarka			S	Oral	4/240 Mg,Per Oral		Not Reported
	Lexapro			S	Oral	Per Oral		Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2009	7173014	EXPEDITED (15-DAY)	Y	DS	1000009659		45 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Pain; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Methadone Hydrochloride	C				Not Reported
	Prazepam	C				Not Reported
	Inexium	C				Not Reported
	Mag 2	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2009	7173058	EXPEDITED (15-DAY)	Y	OT	1000009684			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertensive Crisis	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2009	7166231	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Constipation; Sexual Dysfunction; Urticaria	Bupropion Hydrochloride			S		150 Mg One Daily 9/12/10 For 3 1/2 Weeks		Not Reported
	Lexapro			S		10 Mg One Daily	3 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2009	7166248	DIRECT					57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dry Mouth; Fatigue; Heart Rate Decreased; Loss Of Libido; Palpitations; Sexual Dysfunction; Tinnitus	Lexapro			S		10 Mg 1 A Day 10 Mg 1 A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2009	7178121	EXPEDITED (15-DAY)	Y	HO	1000009631		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Blood Potassium Increased; Confusional State; Disorientation; Gamma-Glutamyltransferase Increased; General Physical Health Deterioration; Hyponatraemia; Loss Of Consciousness; Psychomotor Retardation	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Practazin			C				Not Reported
	Athymil			C				Not Reported
	Debridat			C				Not Reported
	Noctamide			C				Not Reported
	Venlafaxine			C				Not Reported
	Movicol			C				Not Reported
	Zanidip			C				Not Reported
	Kardegic (Powder)			C				Not Reported
	Captopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2009	7048689	EXPEDITED (15-DAY)	N	DS, HO, OT	1000006980		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Asphyxia; Autonomic Nervous System Imbalance; Blood Glucose Increased; Blood Ph Decreased; Blood Pressure Decreased; Blood Pressure Increased; Candida Infection; Disturbance In Attention; Feeding Disorder; Heart Rate Increased; Hyperhidrosis; Hypoxic-Ischaemic	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		
					Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		

Encephalopathy; Hypoxic-Ischaemic Encephalopathy; Loss Of Personal Independence In Daily Activities; Muscle Spasticity; Overdose; Pneumonia; Pneumonia Aspiration; Po2 Decreased; Pupil Fixed; Pyrexia; Respiration Abnormal; Respiratory Rate Increased; Speech Disorder; Suicidal Ideation; Suicide Attempt; Treatment Noncompliance; Unresponsive To Stimuli; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2009	6975622	EXPEDITED (15-DAY)	Y	OT	1000005651		32 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Follicle Stimulating Hormone Decreased; Blood Luteinising Hormone Decreased; Blood Prolactin Increased; Nuclear Magnetic Resonance Imaging Brain Abnormal; Oestradiol Decreased; Somnolence	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2009	7155336	EXPEDITED (15-DAY)	Y	DE, LT	1000009219			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide;	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1		Not Reported

Physical Assault; Restlessness							D),Oral			
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
02-Nov-2009	7169337	EXPEDITED (15-DAY)	Y	DE	1000009468		35 YR	Male	CHE	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Completed Suicide; Depression; Schizoaffective Disorder; Self-Injurious Ideation	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Seroquel Xr			S	Oral	300 Mg (300 Mg, 1 In 1 D),Oral; 100 Mg (100 Mg, 1 In 1 D),Oral		Not Reported
					Oral	300 Mg (300 Mg, 1 In 1 D),Oral; 100 Mg (100 Mg, 1 In 1 D),Oral		
	Risperdal			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
	Haldol			S	Oral	4mg (4 Mg, 1 In 1 D), Oral; 8 Mg (8 Mg, 1 In 1 D),Oral; 10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
					Oral	4mg (4 Mg, 1 In 1 D), Oral; 8 Mg (8 Mg, 1 In 1 D),Oral; 10 Mg (10 Mg, 1 In 1 D),Oral		
					Oral	4mg (4 Mg, 1 In 1 D), Oral; 8 Mg (8 Mg, 1 In 1 D),Oral; 10 Mg (10 Mg, 1 In 1 D),Oral		
					Oral	4mg (4 Mg, 1 In 1 D), Oral; 8 Mg (8 Mg, 1 In 1 D),Oral; 10 Mg (10 Mg, 1 In 1 D),Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2009	7178755	EXPEDITED (15-DAY)	Y	OT	1000009762			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Septic Shock; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2009	7179654	EXPEDITED (15-DAY)	N	DE	1000009795		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2009	7155200	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20091004679		37 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Vomiting	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2009	7180807	EXPEDITED (15-DAY)	N	DE	1000009788		33 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Non-Cardiogenic Pulmonary Oedema	Escitalopram Oxalate			S				Not Reported
	Cannabis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2009	7173138	DIRECT	Y	LT			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Suicidal Ideation	Lexapro			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2009	7173145	DIRECT	Y	HO, OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Emotional Disorder; Flat Affect; Tremor; Vision Blurred	Lexapro			S	Oral	10mg Daily Po		Not Reported
	Cymbalta			C				Not Reported
	Paxil			C				Not Reported
	Wellbutrin			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2009	7177280	EXPEDITED (15-DAY)	N	OT	1000009737		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Road Traffic Accident; Suicidal Ideation; Thinking Abnormal; Wrist Fracture	Lexapro			S	Oral	20 Mg, (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg, (20 Mg, 1 In 1 D), Oral		
	Hydrocodone			S	Oral	Oral		Not Reported
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2009	7181656	EXPEDITED (15-DAY)	Y	OT	1000009759		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Depakene			C				Not Reported
	Benzodiazepine Derivatives			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2009	7181990	EXPEDITED (15-DAY)	Y	OT	1000009811		2 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	60 Mg (60 Mg, 1 In 1 D), Transplacental		Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2009	7169725	EXPEDITED (15-DAY)	Y	HO	1000009475		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Brain Neoplasm; Coma; General Physical Health Deterioration; Hyponatraemia; Hypotension; Inappropriate Antidiuretic Hormone Secretion; Malnutrition; Neoplasm Recurrence	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported
	Dihydroergotamine			S				Not Reported
	Temozolomide			C				Not Reported
	Antiepileptics			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2009	7174144	DIRECT	Y				75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2009	7174345	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Libido Decreased	Escitalopram Oxalate		S	Oral	20 Mg Every Day Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2009	7182088	EXPEDITED (15-DAY)	Y	OT	1000009794		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Dependence; Sleep Disorder	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Bromazepam			S	Oral	12 Mg (12 Mg,1 In 1 D),Oral		Not Reported
	Loxapine			C				Not Reported
	Meprobamate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2009	7182092	EXPEDITED (15-DAY)	Y	OT	1000009781		41 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Bromazepam			S	Oral	9 Mg (9 Mg,1 In 1 D),Oral		Not Reported
	Depakote			C				Not Reported
	Cyamemazine			C				Not Reported
	Ixel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2009	7184139	EXPEDITED (15-DAY)	Y	HO	1000009791		50 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Pain In Jaw; Rash Pustular; Scab	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

				Oral	5 Mg (5 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D), Oral	
	Lorazepam (0.5 Milligram, Tablets)		C			Not Reported
	Ibandronic Acid (Injection For Infusion)		C			Not Reported
	Calcium Gluconate		C			Not Reported
	Valeriana Officinalis (Tablets)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2009	7185139	EXPEDITED (15-DAY)	Y	HO	1000009793		52 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2009	7174958	DIRECT	Y	HO, LT			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Level Of Consciousness; Disturbance In Attention; Haemorrhage; Intentional Self-Injury; Memory Impairment; Restlessness; Suicide Attempt; Treatment Noncompliance; Tremor	Lexapro			S	Oral	10 Mg Daily In Am Po		Not Reported
	Remeron			S	Oral	15 Mg And Increased To 30mg Daily At Night Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2009	6753412	EXPEDITED (15-DAY)	Y	DE	1000000628		42 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Drug Level Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2009	6871403	EXPEDITED (15-DAY)	Y	DE	1000003158		82 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Pleural Effusion	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2009	7169734	EXPEDITED (15-DAY)	Y	OT	1000009620		30 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2009	7186408	EXPEDITED (15-DAY)	N	OT	1000009868		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Imprisonment; Sexual Abuse	Celexa			S	Oral	(20 Mg), Oral		Not Reported
	Lexapro			S	Oral	(10 Mg), Oral		Not Reported
	Restoril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2009	7188928	EXPEDITED (15-DAY)	Y	HO, LT	1000009817		57 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Asthenia; Diarrhoea; Electrocardiogram	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Sitagliptin			S	Oral	100 Mg (100 Mg, 1 In 1 D),		Not Reported

Abnormal; Haemodialysis; Hyperkalaemia; Muscle Spasms; Nausea; Vomiting				Oral	
	Metformin Hydrochloride	S	Oral	3000 Mg (1000 Mg, 3 In 1 D), Oral	Not Reported
	Hydrochlorothiazide\Irbesartan	S	Oral	150/12.5 Mg Daily, Oral	Not Reported
	Esomeprazole	C			Not Reported
	Rivotril	C			Not Reported
	Diffu-K	C			Not Reported
	Secalip	C			Not Reported
	Noctran	C			Not Reported
	Alprazolam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2009	7188936	EXPEDITED (15-DAY)	Y	HO	1000009830		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Neonatal Aspiration; Postmature Baby	Escitalopram Oxalate			S	Transplacental	See Image		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2009	7188973	EXPEDITED (15-DAY)	Y	HO	1000009827		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Medication Error; Overdose; Pallor; Somnolence; Vomiting	Escitalopram Oxalate			S	Oral	40 Mg (20 Mg, 2 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	40 Mg (20 Mg, 2 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		
	Prazepam			S	Oral	40 Mg (20 Mg, 2 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	40 Mg (20 Mg, 2 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2009	7109273	EXPEDITED (15-DAY)	Y	HO, OT	1000008366		7 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Maternal Drugs Affecting Foetus; Neonatal Seizure	Lexapro			S	Transplacental	20 Mg, Transplacental		Not Reported
	Prenatabs Fa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2009	7126919	EXPEDITED (15-DAY)	Y	DE	1000008707		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Lexapro			S	Oral	More Than 1o (Once); 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	More Than 1o (Once); 20 Mg (20 Mg, 1 In 1 D), Oral		
	Oxycontin			S	Oral	(800 Mg, Once); 160 Mg (80 Md, 2 In 1 D), Oral		Not Reported
					Oral	(800 Mg, Once); 160 Mg (80 Md, 2 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2009	7147820	EXPEDITED (15-DAY)	Y	OT	1000009063		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Blood Triglycerides Increased; Cardiometabolic Syndrome; Delusion; Dyslipidaemia; Hypertension; Weight Increased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (10 Mg, 2 In 1 D), Oral		
	Seroquel			S	Oral	600 Mg (600 Mg, 1 In 1 D), Oral, 400 Mg (400 Mg, 1 In		Not Reported

			Oral	1 D), Oral 600 Mg (600 Mg, 1 In 1 D), Oral, 400 Mg (400 Mg, 1 In 1 D), Oral		
	Seroquel	S	Oral	400 Mg (400 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel	S	Oral	200-300 Mg (1 In 1 D), Oral		Not Reported
	Zyprexa	S	Oral	10-15 Mg (1 In 1 D), Oral		Not Reported
	Zyprexa	S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Temesta (Tablets)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2009	7162603	EXPEDITED (15-DAY)	Y	DE	1000009400		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Hypoxic-Ischaemic Encephalopathy; Respiratory Arrest	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Trileptal			S	Oral	900 Mg (900 Mg, 1 In 1 D), Oral		Not Reported
	Chlorprothixene			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal			S	Oral	1.5 Mg (1.5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2009	7189419	EXPEDITED (15-DAY)	Y	OT	1000009858		34 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urine Flow Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Loperamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2009	7197633	NON-EXPEDITED	N		1000008965		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Motion Sickness; Palpitations; Visual Impairment	Milnacipran Hydrochloride			S	Oral	12.5 Mg (12.5 Mg, 1 In 1 D), Oral 25 Mg (12.5 Mg, 2 In 1 D), Oral 50 Mg (25 Mg, 2 In 1 D), Oral		Not Reported
					Oral	12.5 Mg (12.5 Mg, 1 In 1 D), Oral 25 Mg (12.5 Mg, 2 In 1 D), Oral 50 Mg (25 Mg, 2 In 1 D), Oral		
					Oral	12.5 Mg (12.5 Mg, 1 In 1 D), Oral 25 Mg (12.5 Mg, 2 In 1 D), Oral 50 Mg (25 Mg, 2 In 1 D), Oral		
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2009	7179057	DIRECT	Y	HO, LT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Autoimmune Pancreatitis; Cholelithiasis	Lexapro			S	Oral	10mg 1x Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2009	7116188	EXPEDITED (15-DAY)	Y	OT	1000008645		50 YR	Male	NIC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism; Tremor	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D) Oral		Not Reported
	Valproic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2009	7174078	EXPEDITED (15-DAY)	Y	OT	1000009625		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Topalgic (Tramadol Hydrochloride)			C				Not Reported
	Vastarel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2009	7191229	EXPEDITED (15-DAY)	Y	OT	1000009433			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis; Increased Tendency To Bruise; Metrorrhagia	Escitalopram Oxalate			S	Oral	1 Tablet Daily, Oral, 2 Tablets Daily, Oral		Not Reported
					Oral	1 Tablet Daily, Oral, 2 Tablets Daily, Oral		
	Desogestrel			S	Oral	Oral		Not Reported
	Cephaloridine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2009	7192614	EXPEDITED (15-DAY)	Y	DE	1000009996			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2009	7194850	EXPEDITED (15-DAY)	Y	HO	1000009931		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Rectal Haemorrhage	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D),		Not Reported

				Oral	
	Xanax	C			Not Reported
	Singulair	C			Not Reported
	Simvastatin	C			Not Reported
	Advair Diskus	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2009	7053993	EXPEDITED (15-DAY)	Y	OT	1000007097			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Nausea; Vomiting	Lexapro			S	Oral	0.2 Ml (0.2 Ml,1 In 1 D),Oral		Not Reported
	Oxazepam			C				Not Reported
	Temazepam			C				Not Reported
	Paracetamol+Codeine			C				Not Reported
	Ondsansetron (Tablets)			C				Not Reported
	Esoemprazole (Tablets)			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2009	7143254	EXPEDITED (15-DAY)	Y	HO, LT	1000008911		80 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Generalised Tonic-Clonic Seizure; Somnolence	Lexapro			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Insulatard			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Emconcor			C				Not Reported
	Actrapid			C				Not Reported
	Plavix			C				Not Reported
	Zocor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2009	7155694	EXPEDITED (15-DAY)	Y	OT	TR-WATSON-2009-08533		32 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Oculogyric Crisis; Serotonin Syndrome	Metoclopramide Hydrochloride		S	Intravenous (not otherwise specified)	10 Mg, Single	Watson
	Escitalopram Oxalate		S		10 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2009	7171552	EXPEDITED (15-DAY)	Y	OT	1000009563		81 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Hemigoxine			C				Not Reported
	Kardegic			C				Not Reported
	Previscan (Fluindione)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2009	7193633	EXPEDITED (15-DAY)	Y	HO	1000009903		85 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tonic Clonic Movements; Transient Ischaemic Attack	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2009	7174119	EXPEDITED (15-DAY)	Y	OT	1000009596		32 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Oculogyric Crisis; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg), Oral		Not Reported
	Metoclopramide			S	Intravenous (not otherwise specified)	10 Mg, Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2009	7183093	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Myalgia; Pyrexia	Lexapro	S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2009	7196235	EXPEDITED (15-DAY)	Y	OT	1000010007		40 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Clozaril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2009	7179493	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2009S1019216		24 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bipolar Disorder; Dizziness; Nausea; Somnolence; Vomiting	Escitalopram Oxalate			S	Oral			Alphapharm
	Isoptin			C				Not Reported
	Topamax			C				Not Reported
	Prochlorperazine Maleate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2009	7196433	EXPEDITED (15-DAY)	Y	OT	1000010045			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Haemorrhoid Operation; Incorrect Dose Administered; Memory Impairment	Escitalopram Oxalate			S		10 Mg		Not Reported
	Tramadol Hydrochloride			S		20 Gtt		Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2009	7197211	EXPEDITED (15-DAY)	Y	HO, RI	1000010067		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cell Death; Device Related Infection; Fall; Rhabdomyolysis; Staphylococcal Infection; Surgical Procedure Repeated	Escitalopram Oxalate	S	Oral	10 Mg, (10 Mg, 1 In 1 D), Oral	Not Reported
	Bactrim Forte	S	Oral	3 Dosage Forms (1 Dosage Forms, 3 In 1 D), Oral	Not Reported
	Lescol	S	Oral	80 Mg (80 Mg, 1 In 1 D), Oral	Not Reported
	Xanax	S	Oral	0.25 Mg (0.25 Mg, 1 In 1 D), Oral	Not Reported
	Fluconazole	S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral	Not Reported
	Fucidine (Tablets)	C			Not Reported
	Amlor	C			Not Reported
	Previscan (Fluindione)	C			Not Reported
	Tenormin	C			Not Reported
	Inexium	C			Not Reported
	Imovane	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2009	6965339	EXPEDITED (15-DAY)		DS, HO, OT	GB-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2009-UK-00		66 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Somnolence	Catapres-Tts			S				Boehringer Ingelheim
	Catapres-Tts			S				Boehringer Ingelheim
	Escitalopram Oxalate			S		5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2009	7083074	EXPEDITED (15-DAY)		DS, HO, OT	GB-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2009-UK-00		66 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Somnolence	Clonidine Transdermal System			S			2 DAY	Boehringer Ingelheim
	Clonidine Transdermal System			S			2 DAY	Boehringer Ingelheim

Escitalopram Oxalate	S	5 Mg	1 YR	Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2009	7180416	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2009293445		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis	Xanax			S	Oral	0.25 Mg, 1x/Day		Pfizer
	Triflucan			S	Oral	100 Mg, 1x/Day	4 DAY	Pfizer
	Bactrim Forte			S	Oral	1 Df, 3x/Day	30 DAY	Not Reported
	Lescol			S	Oral	1 Df, 1x/Day		Not Reported
	Escitalopram Oxalate			S	Oral	1 Df, 1x/Day		Not Reported
	Amlor			C		Unk		Not Reported
	Fucidin (Fusidate Sodium)			C	Oral	2 Df, 3x/Day		Not Reported
	Previscan (Fluindione)			C		Unk		Not Reported
	Tenormin			C		Unk		Not Reported
	Inexium			C		Unk		Not Reported
	Zopiclone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2009	7183911	DIRECT	Y	HO			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Myoclonus; Serotonin Syndrome; Unresponsive To Stimuli	Maxalt			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2009	7183977	DIRECT					38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Food Craving; Weight Increased	Lexapro	S	1 Tablet 1 X Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2009	7198485	EXPEDITED (15-DAY)	Y	OT	1000010051		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2009	7198490	EXPEDITED (15-DAY)	Y	OT	1000010103			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2009	7220486	EXPEDITED (15-DAY)	Y	HO, OT	091116-0001172		32 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Chills; Dysuria; Impaired Gastric Emptying; Mood Swings; Panic Attack; Self-Injurious Ideation; Suicidal Ideation	Mephobarbital			S		800 Mg; Qd;		Not Reported
	Meprobamate			S		1200 Mg; Qd;		Not Reported
	Trazodone Hydrochloride			S		150 Mg; Qd;		Not Reported
	Escitalopram Oxalate			S		10 Mg; Qd;		Not Reported
	Quetiapine Fumarate			S		500 Mg; Qd;		Not Reported
	Alprazolam			C				Not Reported
	Metazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2009	7181818	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-09P-163-0607783-00		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Imprisonment; Sexual Abuse	Lexapro	S	Oral		Not Reported
	Citalopram Hydrobromide	S	Oral		Not Reported
	Chlormezanone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2009	7185322	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sensation In Eye; Balance Disorder; Dizziness; Dyskinesia; Hypersensitivity; Sleep Disorder; Suicidal Ideation	Lexapro			S		10 Milligrams		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2009	7201901	EXPEDITED (15-DAY)	N	OT	1000010201			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Head Titubation; Overdose; Restlessness; Tremor	Escitalopram Oxalate			S	Oral	Oral; 30 (30 , 1 In 1 D), Oral		Not Reported
					Oral	Oral; 30 (30 , 1 In 1 D), Oral		
	Atacand			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2009	7183618	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2009-BP-13		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zantac			S	Oral	300 Mg		Boehringer Ingelheim
	Lexapro			S	Oral	10 Mg		Not Reported
	Melatonin			C				Not Reported
	Caltrate			C				Not Reported
	Calcium Ascorbate			C				Not Reported

	Centrum Multivitamin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2009	7186251	DIRECT	N	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Crying	Lexapro			S	Oral	1 Tablet 1x Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2009	7186368	DIRECT	N	OT			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous; Rash Pruritic	Lexapro			S	Oral	5mg One Per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2009	7203828	EXPEDITED (15-DAY)	Y	OT	1000010158		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1in 1 D),Oral		Not Reported
	Lorazepam			S	Oral	Oral		Not Reported
	Zopiclone			S	Oral	7.5 Mg (7.5 Mg, 1in 1 D), Oral		Not Reported
	Abilify			C				Not Reported
	Noctamide			C				Not Reported
	Seresta			C				Not Reported
	Zyprexa			C				Not Reported
	Sertraline Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2009	6127508	NON-EXPEDITED	Y	DE	US-JNJFOC-20060901898		18 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Intentional Overdose	Amrix		S			Not Reported
	Pseudoephedrine Hydrochloride		S			Not Reported
	Ibuprofen		S			Not Reported
	Aspirin	Y	S			Not Reported
	Acetaminophen And Codeine Phosphate		S	Oral		Not Reported
	Escitalopram Oxalate		S			Not Reported
	Naproxen		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2009	7164872	EXPEDITED (15-DAY)	Y	HO	1000009066		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Atrophy; Intentional Overdose; Labile Blood Pressure; Suicide Attempt	Escitalopram Oxalate			S		Once		Not Reported
	Zolpidem			S				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Losartan			C				Not Reported
	Atorvastatin			C				Not Reported
	Aliskiren			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2009	7184444	EXPEDITED (15-DAY)	Y	DE	US-BRISTOL-MYERS SQUIBB COMPANY-14849210		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bacteraemia; Faecaloma; Urinary Bladder Rupture	Aripiprazole			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Toprol Xl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2009	7184473	EXPEDITED (15-DAY)	N	HO	US-ASTRAZENECA-2009SE26324			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akathisia; Confusional State; Dizziness; Hypomania;	Seroquel			S	Oral		1 DAY	Zeneca
	Wellbutrin			S	Oral		1 DAY	Not Reported

Overdose; Suicidal Ideation; Swelling Face	Lexapro	S	Oral	2 YR	Not Reported
	Lexapro	S	Oral	0 YR	Not Reported
	Lexapro	S	Oral	7 DAY	Not Reported
	Lexapro	S	Oral	25 MTH	Not Reported
	Lamictal	S		0 YR	Not Reported
	Lamictal	S		0 YR	Not Reported
	Risperdal	S	Oral		Not Reported
	Zyrtec-D	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2009	7184985	EXPEDITED (15-DAY)		HO, OT	AU-PFIZER INC-2009282671		55 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Creatine Phosphokinase Increased; Serotonin Syndrome	Nardil			S	Oral	60 Mg, 1x/Day	20 DAY	Pfizer
	Ziprasidone Hydrochloride			S	Oral	20 Mg, 2x/Day	81 DAY	Pfizer
	Ziprasidone Hydrochloride			S				Pfizer
	Lexapro			S				Not Reported
	Olanzapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2009	7204248	EXPEDITED (15-DAY)	Y	OT	1000010291		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Back Pain; Condition Aggravated; Headache; Neuralgia; Oedema Peripheral; Suicidal Ideation	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2009	7207130	EXPEDITED (15-DAY)	N	OT	1000010307			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dementia; Suicidal Ideation	Escitalopram Oxalate	S	Oral	(10 Mg), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2009	7207132	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000010210		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Hypophagia; Insomnia; Irritability; Maternal Drugs Affecting Foetus; Neonatal Anoxia; Weight Decreased	Escitalopram Oxalate			S	Transplacental	5 Mg (5 Mg, 1 In 1 D), Transplacental; 20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2009	7209004	EXPEDITED (15-DAY)	N	OT	1000010276		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Consciousness; Weight Increased	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2009	7187259	EXPEDITED (15-DAY)	N	HO	A0822180A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akathisia; Confusional State; Dizziness; Hypomania; Suicidal Ideation; Swelling Face	Lamictal			S	Unknown	300mg Per Day		Glaxosmithkline
	Wellbutrin			S	Oral	150mg Per Day	1 DAY	Glaxosmithkline
	Lexapro			S	Oral	30mg Per Day		Not Reported
	Seroquel			S	Oral		1 DAY	Not Reported
	Risperdal			S	Oral	.5mg Twice Per Day		Not Reported
	Zyrtec-D			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2009	7212244	EXPEDITED (15-DAY)	Y	OT	1000010232			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cortisol Decreased; Diabetes Insipidus; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Opipramol Hydrochloride			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2009	6053413	EXPEDITED (15-DAY)	Y	OT	S06-IRL-01778-01		40 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrolyte Imbalance; Seizure	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2009	7188899	EXPEDITED (15-DAY)	Y	LT	FR-JNJFOC-20091106677		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; International Normalised Ratio Increased; Muscle Haemorrhage	Tramadol Hydrochloride And Acetaminophen			S	Oral		8 DAY	Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Propoxyphene Hydrochloride And Acetaminophen			C				Not Reported
	Ramipril			C				Not Reported
	Xanax			C				Not Reported
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Nafronyl Oxalate			C				Not Reported
	Bisacodyl			C				Not Reported
	Lioresal			C				Not Reported
	All Other Therapeutic Products			C				Not Reported
	Previscan (Fluindione)			S				Not Reported
	Previscan (Fluindione)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2009	7189299	EXPEDITED (15-DAY)	Y	HO	ES-SANOFI-AVENTIS-2009SA003303		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria; Thrombocytopenia	Furosemide			S	Oral	Dosage: 1/2-0-0		Not Reported
	Cipralex			S	Oral	1-0-0		Not Reported
	Urbason			C	Oral	1/2-0-0		Not Reported
	Tamsulosin Hydrochloride			C	Oral	Dosage: 1/2-0-1/2		Not Reported
	Lactitol			C	Oral			Not Reported
	Mestinon			C	Oral	1/2-0-1/2		Not Reported
	Enalapril Maleate			C	Oral	Dosage: 1/2-0-1/2		Not Reported
	Ferro "Sanol"			C	Oral	Dosage: 1-1-0		Not Reported
	Calcium Glubionate			C	Oral	Cada 12 Horas		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2009	7214590	EXPEDITED (15-DAY)	Y	OT	1000010202			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2009	7153150	EXPEDITED (15-DAY)	Y	OT	1000009222		93 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Urticaria	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg) Oral		Not Reported
	Risedronate (Tablets_)			C				Not Reported
	Disgren			C				Not Reported
	Calcium -Sandoz Forte-D			C				Not Reported
	Pepticum			C				Not Reported
	Orfidal			C				Not Reported
	Lexatin			C				Not Reported

	Boniva	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2009	7213423	EXPEDITED (15-DAY)	Y	OT	1000010336		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Condition Aggravated; Dysphagia; Hypertension; Swollen Tongue	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Nexium			C				Not Reported
	Zopiclone			C				Not Reported
	Levomepromazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2009	7213448	EXPEDITED (15-DAY)	Y	OT	1000010328		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Decreased; Leukopenia; Thrombocytopenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tamoxifen			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Trimipramine			S	Oral	10-40 Mg, Oral		Not Reported
	Goserelin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2009	6911385	EXPEDITED (15-DAY)	Y	HO	GB-RANBAXY-2009RR-21639		17 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Diarrhoea; Nephritis Allergic	Ibuprofen			S	Oral	Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral	10 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, Unk		Not Reported
	Alprazolam			C		0.5 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2009	7009317	EXPEDITED (15-DAY)	Y	HO	1000006360		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Delirium; Drug Level Decreased; Hallucination; Urinary Incontinence	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg,1 In 1 D),Oral		
	Edronax			S	Oral	4 Mg (4 Mg, 4 In 1 D),Oral		Not Reported
	Edronax			S		8 Mg (8 Mg, 1 In 1 D),Oral		Not Reported
	Wellbutrin			S	Oral	150 Mg (150 Mg, 1 In 1 D), Oral		Not Reported
	Lorazepam			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
	Tegretol			C				Not Reported
	Fosicomb (Tablets)			C				Not Reported
	Norvasc			C				Not Reported
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2009	7192632	EXPEDITED (15-DAY)	N	HO	US-KINGPHARMUSA00001-K200901465		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Blood Pressure Increased; Drug Interaction; Heart Rate Increased; Hyperthyroidism; Restlessness	Levoxyl			S	Oral	137 Mcg, Qd		King
	Atenolol			C	Oral	25 Mg, Qd		Not Reported
	Lipitor			C	Oral	10 Mg, Qd		Not Reported
	Celexa			C		20 Mg, Unk		Not Reported

Ativan	C		Unk	39 DAY	Not Reported
Levoxyl	S	Oral	75 Mcg, Qd	6 DAY	King
Levoxyl	S	Oral	100 Mcg, Qd	7 DAY	King
Levoxyl	S	Oral	125 Mcg, Qd	4 DAY	King
Levoxyl	S	Oral	137 Mcg, Qd		King
Klonopin	S	Oral	1 Mg, Bid		Not Reported
Klonopin	S	Oral	1.0 Mg, Qd		Not Reported
Klonopin	S	Oral	0.5 Mg, Bid		Not Reported
Klonopin	S	Oral	0.5 Mg, Qd		Not Reported
Lexapro	S	Oral	20 Mg, Qd	25 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2009	7192912	EXPEDITED (15-DAY)	Y	OT	B0608394A		37 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dyspnoea; Pneumonia; Respiration Abnormal	Lamotrigine			S	Unknown	300mg Per Day		Glaxosmithkline
	Cipralex			S	Unknown			Not Reported
	Guaifenesin			S	Unknown			Glaxosmithkline
	Lithium			S	Unknown			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2009	7193516	EXPEDITED (15-DAY)	Y	OT	PHHY2009AT46733		57 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicidal Ideation	Diovan			S		2 X 80 Mg		Novartis
	Metformin\Vildagliptin			S	Oral	50 Mg, Bid	33 DAY	Not Reported
	Selokeen			S		2 X 49.5 Mg		Not Reported
	Cipralex			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2009	7193730	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2009303725		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Hepatitis; Overdose; Sinus Tachycardia; Somnolence; Suicide Attempt	Atarax			S	Oral	32 Tablets	1 DAY	Pfizer
	Paroxetine			S	Oral	28 Tablets	1 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	32 Tablets	1 DAY	Not Reported
	Zolpidem			S	Oral	12 Tablets	1 DAY	Not Reported
	Rivotril			S	Oral	7 Tablets	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2009	7217317	EXPEDITED (15-DAY)	Y	CA	1000010233		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydrocephalus; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	Transplacental		Not Reported
	Opipramol			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2009	7218358	EXPEDITED (15-DAY)	Y	HO	1000010292		67 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Blood Thyroid Stimulating Hormone Increased; Dizziness; Head Discomfort; Hyponatraemia; Loss Of Consciousness; Nausea; Thyroxine Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Plavix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2009	7140400	EXPEDITED (15-DAY)	Y	HO	1000008836		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Eating Disorder; Electrocardiogram Repolarisation Abnormality; Hyponatraemia; Somnolence; Status Epilepticus; Tachycardia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Atacand			S	Oral	8 Mg (8 Mg,1 In 1 D),Oral		Not Reported
	Fosvance			C				Not Reported
	Rosuvastatin			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Nebivolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2009	7162570	EXPEDITED (15-DAY)	N	OT	1000005272		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia Supraventricular; Hypoaesthesia; Paraesthesia; Sinus Node Dysfunction	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
					Oral	20 Mg (20 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral		
	Erythromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2009	7192058	EXPEDITED (15-DAY)	Y	HO	1000009478		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Test Positive; Confusional State; Culture Urine Positive; Disorientation; Escherichia Infection; Fall; Haptoglobin Increased; Hyponatraemia; Malaise; Orthostatic Hypotension	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Aldactone			S		75 Mg (75 Mg,1 In 1 D)		Not Reported
	Glucophage			C				Not Reported
	Lorazepam			C				Not Reported
	Levothyrox			C				Not Reported
	Tanakan			C				Not Reported
	Dafalgan			C				Not Reported

Propofan	C			Not Reported
Diosmine	C			Not Reported
Arixtra	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2009	7201430	DIRECT		OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Off Label Use; Suicidal Ideation	Lexapro			S		20 Mg 1 X Day	7 YR	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2009	7220781	EXPEDITED (15-DAY)	Y	OT	1000010385		65 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		
	Paracetamol			C				Not Reported
	Anti-Asthmatics			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2009	7220827	EXPEDITED (15-DAY)	Y	OT	1000010382		62 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Insomnia; Muscle Spasms; Restless Legs Syndrome	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Stresam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2009	7220851	EXPEDITED (15-DAY)	N	OT	1000010447		64 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Hyperhidrosis; Hypothermia; Sinusitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Inexium			C				Not Reported
	Stilnox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2009	7220979	EXPEDITED (15-DAY)	Y	HO	1000010349		17 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Suicide Attempt	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Zopiclone			S	Oral	Oral		Not Reported
	Alprazolam			S	Oral	Oral		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2009	7221366	EXPEDITED (15-DAY)	Y	HO	1000010379		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Hepatitis; Intentional Overdose; Sinus Tachycardia; Somnolence; Suicide Attempt	Escitalopram Oxalate			S	Oral	(640 Mg, Once), Oral		Not Reported
	Hydroxyzine			S	Oral	(3200 Mg, Once), Oral		Not Reported
	Zolpidem			S	Oral	(120 Mg, Once), Oral		Not Reported
	Clonazepam			S	Oral	(14 Mg, Once), Oral		Not Reported
	Paroxetine			S	Oral	(560 Mg, Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2009	6550324	EXPEDITED (15-DAY)	Y	HO	S08-USA-00239-01		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia; Diarrhoea; Eosinophil Count	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20		Not Reported

Increased; Eosinophil Percentage Increased; Faeces Discoloured; Tubulointerstitial Nephritis			Oral	Mg,Once A Day),Oral 10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,Once A Day),Oral	
	Lexapro	S	Oral	20 Mg (20 Mg,1 In 1 D),Oral	Not Reported
	Ibuprofen	C			Not Reported
	Alprazolam (Alprazolam) (Tablets) (Alprazolam)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2009	7194492	EXPEDITED (15-DAY)	Y	DS, HO	1000009962		27 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inflammatory Bowel Disease	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral		
	Copixol-Acuphase-(Injection)			C				Not Reported
	Quetiapine (Injection)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2009	7198406	EXPEDITED (15-DAY)	Y	OT	DE-PFIZER INC-2009304548		36 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Suicide Attempt	Atarax			S	Oral			Pfizer
	Cipralex			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2009	7222011	EXPEDITED (15-DAY)	Y	OT	1000003345			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maternal Exposure During Pregnancy; Pregnancy; Withdrawal Syndrome	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2009	7222017	EXPEDITED (15-DAY)	Y	OT	1000010479		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Miosis; Somnolence; Suicide Attempt; Unevaluable Event	Escitalopram Oxalate			S	Oral	(1000 Mg, Once), Oral		Not Reported
	Pipamperone			S	Oral	(4000 Mg, Once), Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2009	7222018	EXPEDITED (15-DAY)	Y	OT	1000010402		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Sensory Disturbance; Suicidal Ideation; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2009	7223505	EXPEDITED (15-DAY)	Y	OT	1000010490			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Inflammation; Nasopharyngitis; Pleural Effusion	Escitalopram Oxalate			S				Not Reported
	Lamotrigine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2009	7223514	EXPEDITED (15-DAY)	N	OT	1000010494		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Exophthalmos; Hyperthyroidism	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2009	7223553	EXPEDITED (15-DAY)	Y	OT	1000010400		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Tension	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2009	7223892	EXPEDITED (15-DAY)	Y	HO	1000010462		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disorientation; Drug Interaction; Dyspnoea; Pyrexia; Somnolence	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Diazepam			S	Oral	Oral		Not Reported
	Acetaminophen\Tramadol Hydrochloride			S	Oral	37.5 / 325 Mg (1 In 1 D),Oral		Not Reported
	Lyrica			S	Oral	25 Mg (25 Mg,1 In 1 D),Oral		Not Reported
	Tensogradal (Tablets)			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2009	6978964	EXPEDITED (15-DAY)	N	OT	DE-ELI_LILLY_AND_COMPANY-DE200903000619		33 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrooesophageal Reflux Disease; Hiatus Hernia; Hypokalaemia;	Zyprexa			S	Oral	10 Mg, Daily (1/D)	70 DAY	Eli Lilly And Co
	Zopiclone			C	Oral	7.5 Mg, Daily (1/D)	165 DAY	Not Reported
	Pantozol (Pantoprazole Sodium)			C	Oral	40 Mg, Daily (1/D)		Not Reported

Supraventricular Extrasystoles	Leponex	C		375 Mg, Daily (1/D)	1 DAY	Not Reported
	Leponex	C		25 Mg, Daily (1/D)	2 DAY	Not Reported
	Leponex	C		50 Mg, Daily (1/D)	2 DAY	Not Reported
	Leponex	C		75 Mg, Daily (1/D)	3 DAY	Not Reported
	Leponex	C		100 Mg, Daily (1/D)	2 DAY	Not Reported
	Leponex	C		125 Mg, Daily (1/D)	3 DAY	Not Reported
	Leponex	C		175 Mg, Daily (1/D)	2 DAY	Not Reported
	Leponex	C		225 Mg, Daily (1/D)	5 DAY	Not Reported
	Leponex	C		275 Mg, Daily (1/D)	10 DAY	Not Reported
	Leponex	C		300 Mg, Daily (1/D)	1 DAY	Not Reported
	Leponex	C		325 Mg, Daily (1/D)	6 DAY	Not Reported
	Leponex	C		375 Mg, Daily (1/D)	4 DAY	Not Reported
	Leponex	C		425 Mg, Daily (1/D)	15 DAY	Not Reported
	Leponex	C		475 Mg, Daily (1/D)	82 DAY	Not Reported
	Leponex	C		400 Mg, Daily (1/D)	1 DAY	Not Reported
	Leponex	C		350 Mg, Daily (1/D)		Not Reported
	Diazepam	C		10 D/F, Unk	1 DAY	Not Reported
	Levothyroxine Sodium	C		50 Ug, Daily (1/D)		Not Reported
	Calcium Carbonate	C		0.5 D/F, 3/D		Not Reported
	Potassium Bicarbonate\Potassium Citrate	C		1 D/F, Daily (1/D)		Not Reported
	Bifiteral	C		2 D/F, Daily (1/D)	1 DAY	Not Reported
	Unizink	C		50 Mg, Daily (1/D)		Not Reported
	Gastrozepin	C		25 Mg, Daily (1/D)		Not Reported
	Acetylsalicylic Acid	C		100 Mg, Daily (1/D)		Not Reported
	Zyprexa	S	Oral	20 Mg, Daily (1/D)	57 DAY	Eli Lilly And Co
	Zyprexa	S	Oral	10 Mg, Daily (1/D)	52 DAY	Eli Lilly And Co
	Seroquel	S	Oral	75 Mg, Daily (1/D)	1 DAY	Not Reported
	Seroquel	S	Oral	100 Mg, Daily (1/D)	8 DAY	Not Reported
	Seroquel	S	Oral	200 Mg, Daily (1/D)	8 DAY	Not Reported

Seroquel	S	Oral	300 Mg, Daily (1/D)	2 DAY	Not Reported
Seroquel	S	Oral	400 Mg, Daily (1/D)	3 DAY	Not Reported
Seroquel	S	Oral	450 Mg, Daily (1/D)	8 DAY	Not Reported
Seroquel	S	Oral	550 Mg, Daily (1/D)	29 DAY	Not Reported
Seroquel	S	Oral	650 Mg, Daily (1/D)	17 DAY	Not Reported
Seroquel	S	Oral	550 Mg, Daily (1/D)	1 DAY	Not Reported
Seroquel	S	Oral	250 Mg, Daily (1/D)	3 DAY	Not Reported
Seroquel	S	Oral	200 Mg, Daily (1/D)	1 DAY	Not Reported
Seroquel	S	Oral	150 Mg, Daily (1/D)	3 DAY	Not Reported
Seroquel	S	Oral	100 Mg, Daily (1/D)	1 DAY	Not Reported
Cipralex	S	Oral	15 Mg, Daily (1/D)		Not Reported
Cipralex	S	Oral	10 Mg, Daily (1/D)		Not Reported
Akineton	S	Oral	4 Mg, Daily (1/D)	12 DAY	Not Reported
Akineton	S	Oral	2 Mg, Daily (1/D)	73 DAY	Not Reported
Akineton	S	Oral	Unk, Daily (1/D)	20 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2009	7225869	EXPEDITED (15-DAY)	Y	HO, OT	AUR-APL-2009-01411		52 YR	Male	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Anal Incontinence; Benign Prostatic Hyperplasia; Bulbar Palsy; Chest Pain; Deep Vein Thrombosis; Dementia; Depression; Disorientation; Echolalia; Embolism Arterial; Extrapyramidal Disorder; Fall; Gait Disturbance; Head Injury; Hypoacusis; Meniere'S Disease; Polyneuropathy; Rhinitis; Sympathetic Posterior	Mirtazapine			S				Not Reported
	Sulpiride			S				Not Reported
	Venlafaxine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Doxazosin			C				Not Reported
	Finasteride			C				Not Reported
	Piracetam			C				Not Reported

Cervical Syndrome; Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2009	7226141	EXPEDITED (15-DAY)	Y	OT	1000010423		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dysphonia; Muscle Twitching; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral		
	Vitamin B12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2009	6874029	EXPEDITED (15-DAY)	Y	OT	1000003213		29 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Hallucination, Visual; Sensory Disturbance	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2009	7206943	DIRECT	N	OT			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Educational Problem; Loss Of Personal Independence In Daily Activities; Nausea	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2009	7228687	EXPEDITED (15-DAY)	N	OT	1000010568		22 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypermetropia; Myopia; Tension Headache; Visual Field Defect	Escitalopram Oxalate	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2009	7228909	EXPEDITED (15-DAY)	N	OT	1000010529		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Idiopathic Intracranial Hypertension; Migraine	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2009	7232118	EXPEDITED (15-DAY)	Y	OT	1000010410			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromatopsia; Mania	Escitalopram Oxalate			S	Oral	(3 Gitt), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2009	7232564	EXPEDITED (15-DAY)	Y	OT	1000010519		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Concussion; Eye Movement Disorder; Head Injury; Neck Injury; Sports Injury	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2009	7152822	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-09P-056-0601745-00		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ammonia Increased; Blood Lactic Acid Increased; Brain Oedema; Drug Level Above	Depakote			S	Oral	Overdose		Not Reported
	Depakote			S	Oral			Not Reported

Therapeutic; Extrapyramidal Disorder; Intentional Overdose; Tachycardia	Depakote		S	Oral		Not Reported
	Escitalopram Oxalate		S	Oral	Overdose	Not Reported
	Escitalopram Oxalate		S	Oral		Not Reported
	Abilify		S	Oral	Overdose	Not Reported
	Abilify		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2009	7170086	EXPEDITED (15-DAY)	Y	OT	1000009581		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Mydriasis; Palpitations; Sinus Tachycardia	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Allegra			C				Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2009	7210754	EXPEDITED (15-DAY)	N	OT	A0834197A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Suicide Attempt	Paxil			S	Oral			Glaxosmithkline
	Wellbutrin			S	Oral			Glaxosmithkline
	Effexor Xr			S	Oral	75mg Per Day		Not Reported
	Pristiq Extended Release			S	Oral	50mg Per Day		Not Reported
	Lexapro			S	Unknown			Not Reported
	Pexeva			S	Unknown			Glaxosmithkline
	Zoloft			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported
	Vitamins			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2009	7233411	EXPEDITED (15-DAY)	Y	OT	1000010571			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Withdrawal Syndrome; Feeling Abnormal; Hallucination, Auditory; Paraesthesia	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2009	7212902	EXPEDITED (15-DAY)	N	HO	GB-BRISTOL-MYERS SQUIBB COMPANY-14885974		37 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Body Temperature Increased; Cerebrovascular Accident; Diarrhoea Infectious; Dizziness; Fatigue; Headache; Heart Rate Increased; Malaise; Nausea; Vomiting	Aripiprazole			S	Oral			Not Reported
	Clozaril			S	Oral		2 WEEK	Not Reported
	Diazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2009	7234123	EXPEDITED (15-DAY)	Y	HO, OT	1000009741		23 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alanine Aminotransferase Increased; Alcohol Poisoning; Aspartate	Escitalopram Oxalate			S	Oral	(400 Mg,Once), Oral		Not Reported
	Bupropion Hydrochloride			S	Oral	(6000 Mg,Once), Oral		Not Reported
	Acetaminophen			S	Oral	(500 Mg,Once), Oral		Not Reported

Aminotransferase Increased; Blood Lactate Dehydrogenase Increased; Intentional Overdose; Mydriasis; Suicide Attempt; Vomiting; White Blood Cell Count Increased	Alcohol	S	1 Bottle Of Liquor (Once)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2009	7234126	EXPEDITED (15-DAY)	Y	HO	1000010597		81 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Gait Disturbance; Tinnitus; Vertigo	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2009	7234406	EXPEDITED (15-DAY)	Y	OT	1000010656			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate			S				Not Reported
	Oxetorone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2009	7234414	EXPEDITED (15-DAY)	Y	HO	1000010695			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Vomiting	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	6884744	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14378962		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Feeling Abnormal	Abilify		S	Oral	2 WEEK	Not Reported
	Lexapro		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7214760	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14420889			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Depression	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7214786	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-14427603			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7214796	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14429047		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Pamelor			S				Sandoz
	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Lexapro			S				Not Reported
	Wellbutrin			S				Not Reported
	Echinacea, Unspecified			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7214802	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14430953		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Oedema Peripheral	Abilify			S				2 WEEK		Not Reported
	Lexapro			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7214913	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14456891		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Fatigue; Somnolence	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7215170	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14502660			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Suicidal Ideation	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7215398	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14533855		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Incontinence; Muscle Twitching	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7215411	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14535322		12 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dizziness; Pallor	Abilify			S	Oral	Initiated At 2mg Every Day, Titrating Upto 10mg At Bed Time. Dose		Not Reported

							Increased To 10mg Qd			
	Lexapro			S						Not Reported
	Amoxicillin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7215449	NON-EXPEDITED	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-14539753		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7215457	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14540769		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Personality Change;	Abilify			S				Not Reported
Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7215640	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14568091			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7215707	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14579890		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Abilify			S		Taken 5mg Also		Not Reported

	Lexapro				S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7215733	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-14583942		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Feeling Abnormal; Lethargy; Somnolence	Lisinopril			S				Merck
	Abilify			S		Took In The Morning And Also At Night. Later The Dose Was Switched To Bedtime.	2 DAY	Not Reported
	Wellbutrin Sr			S				Not Reported
	Lexapro			S				Not Reported
	Xanax			S		As Needed		Not Reported
	Antidepressant			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7215760	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14587950		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7215852	NON-EXPEDITED	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14602049			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7216051	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14631832			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation	Abilify			S				Not Reported
	Cymbalta			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7216118	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14647598		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Speech Disorder; Tardive Dyskinesia; Tremor	Abilify			S				Not Reported
	Lexapro			S				Not Reported
	Topamax			C				Not Reported
	Depo-Provera			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7216125	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14649461		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria	Abilify			S	Oral	Taken For One Month		Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7216167	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14663140			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7216197	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14668230		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Abilify			S		Initial Dose 2mg For 2weeks		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7216299	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14688253		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anger; Ejaculation Delayed; Memory Impairment; Overdose; Priapism	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Lexapro			S	Oral	10mg Tab,10mg; 20mg (Once Daily), 30mg (Once Daily),Titrated To 40mg Once Daily.		Not Reported
	Lexapro			S	Oral	10mg Tab,10mg; 20mg (Once Daily), 30mg (Once Daily),Titrated To 40mg Once Daily.		Not Reported
	Tegretol Xr			C				Not Reported
	Lovaza			C				Not Reported
	Lisinopril			C				Not Reported
	Vytorin			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Atenolol			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7216527	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14732283		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Skin Hyperpigmentation	Abilify		S	Oral		Not Reported
	Abilify		S	Oral		Not Reported
	Lexapro		S			Not Reported
	Tenex		S		Tenex .5 Am.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7216607	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14745012			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Drug Ineffective; Drug Interaction	Lexapro			S				Not Reported
	Abilify			S				Not Reported
	Tegretol			S		300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7216684	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14755821			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Generalised Tonic-Clonic Seizure; Insomnia	Abilify			S	Oral		1 WEEK	Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7216730	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-14765259		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7216792	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-14780001			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Seizure	Abilify	S		Not Reported
	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7234654	EXPEDITED (15-DAY)	Y	OT	1000010698		37 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Pneumonia; Respiration Abnormal	Escitalopram Oxalate			S				Not Reported
	Lamotrigine			S		300 Mg (300 Mg,1 In 1 D)		Not Reported
	Lithium			S				Not Reported
	Guaifenesin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2009	7235525	EXPEDITED (15-DAY)	Y	OT	1000010644		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Erythema; Phytotherapy; Product Substitution Issue; Pruritus	Escitalopram Oxalate			S		1 Dosage Forms (1 Dosage Forms,1 In 1 D)		Not Reported
	Venlafaxine			S		150 Mg (150 Mg,1 In 1 D)		Not Reported
	Atarax			S		150 Mg (150 Mg,1 In 1 D)		Not Reported
	Effexor			C				Not Reported
	Noctamide			C				Not Reported
	Ginkor Fort			C				Not Reported
	Xanax			C				Not Reported
	Tegretol			C				Not Reported
	Zyprexa			C				Not Reported
	Parkinane			C				Not Reported
	Risperdal			C				Not Reported
	Valpromide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2009	7218371	EXPEDITED (15-DAY)	Y	OT	1000010261		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Epilepsy	Escitalopram Oxalate		S	Oral	5 Mg (5 Mg,1 In 1 D), Oral	Not Reported
	Fosavance		C			Not Reported
	Temerit		C			Not Reported
	Zanidip		C			Not Reported
	Bromazepam		C			Not Reported
	Moxonidine		C			Not Reported
	Cacit [Calcium Carbonate]		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2009	7218566	EXPEDITED (15-DAY)	Y	HO	GB-TEVA-217442ISR		37 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Body Temperature Increased; Cerebrovascular Accident; Diarrhoea Infectious; Dizziness; Fatigue; Headache; Heart Rate Increased; Malaise; Nausea; Vomiting	Diazepam			S	Oral			Barr
	Aripiprazole			S	Oral			Not Reported
	Clozapine			S	Oral		2 WEEK	Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2009	7234959	EXPEDITED (15-DAY)	Y	HO, OT	1000010474		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Joint Stiffness; Oculogyric Crisis	Lexapro			S		Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2009	7236425	EXPEDITED (15-DAY)	Y	HO	1000010647		18 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Lexapro			S	Oral	(10 Mg), Oral		Not Reported
	Nurofen			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2009	7219551	EXPEDITED (15-DAY)	N	OT	DE-BRISTOL-MYERS SQUIBB COMPANY-14891113		38 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Somnolence; Suicide Attempt	Metformin Hydrochloride			S		1df: 5 Tablets		Bristol Myers Squibb
	Abilify			S	Oral	5 Tablets		Not Reported
	Cipralex			S		5 Tablets Of Cipralex 10mg		Not Reported
	Pipamperone			S		5 Tablets Of 20mg		Not Reported
	Levothyroxine Sodium			S		1df: 5tablets		Not Reported
	Ramipril			S		5 Tablets Of Ramipril 5mg		Not Reported
	Tavor (Lorazepam)			S		15 Tablets Of Tavor 2mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2009	7238416	EXPEDITED (15-DAY)	N	HO	1000010781		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bipolar Disorder; Depression; Intracranial Aneurysm; Sedation; Sinusitis; Somnolence	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
	Depakote			S	Oral	1000 Mg (500 Mg, 2 In 1 D), Oral		Not Reported
	Promethazine			S	Oral	25 Mg (25 Mg, 1 In 1 Day), Oral		Not Reported
	Risperidone			S	Oral	1 Mg (1 Mg, 1 In 1 D), Oral		Not Reported
	Klonopin			C				Not Reported
	Activella			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2009	7238484	EXPEDITED (15-DAY)	N	DE, HO	1000009699		91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Delirium; Dysarthria; Dysphagia; Fall; General Physical Health Deterioration; Hallucination; Skin Abrasion; Skin Laceration	Lexapro			S	Oral	10 Mg 910 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg 910 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		
	Carvedilol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2009	7238701	EXPEDITED (15-DAY)	Y	OT	1000010734		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Parkinsonism	Escitalopram Oxalate			S	Oral	(5 Mg), Oral		Not Reported
	Galantamine Hydrobromide			S	Oral	(8 Mg), Oral		Not Reported
	Sinemet			C				Not Reported
	Idalprem			C				Not Reported
	Deprax (Trazodone Hydrochloride)			C				Not Reported
	Akineton			C				Not Reported
	Adiro			C				Not Reported
	Omeprazole			C				Not Reported
	Belmalax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2009	7238712	EXPEDITED (15-DAY)	N	OT	1000010774		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Feeling Abnormal; Hyperhidrosis; Memory Impairment; Sleep Disorder; Weight	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 Iin 1 D), Oral		Not Reported

Increased				Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 Iin 1 D), Oral	
	Metformin (Tablets)		C			Not Reported
	Metoprolol Succinate Retard		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2009	7238726	EXPEDITED (15-DAY)	Y	HO	1000010779		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alanine Aminotransferase Increased; Body Temperature Increased; Cerebrovascular Accident; Diarrhoea Infectious; Dizziness; Fall; Fatigue; Headache; Heart Rate Increased; Malaise; Nausea; Neutrophil Count Increased; Vomiting	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Clozapine			S	Oral	200 Mg (100 Mg, 2 In 1 D), Oral		Not Reported
	Diazepam			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Aripiprazole			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2009	7238728	EXPEDITED (15-DAY)	Y	OT	1000010776		62 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypertensive Crisis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Valdispert (Tablets)			C				Not Reported
	Influvac (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2009	7238729	EXPEDITED (15-DAY)	Y	OT	1000010780			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation Neonatal; Maternal Exposure During Breast Feeding	Escitalopram Oxalate	S	Transmammary	(10 Mg), Transmammary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2009	7224969	NON-EXPEDITED	N		US-ASTRAZENECA-2009SE06350		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hot Flush; Limb Injury; Nausea	Crestor			S	Oral			Astrazeneca
	Lexapro			S	Unknown			Not Reported
	Atenolol			C				Not Reported
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2009	7229786	DIRECT	N	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Work Ability; Motor Dysfunction	Paxil			S				Not Reported
	Lexapro			S				Not Reported
	Pristiq Extended Release			S				Not Reported
	Effexor			S				Not Reported
	Lamictal			S				Not Reported
	Topamax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7143140	EXPEDITED (15-DAY)	Y	OT	1000008923		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Fall; Hypersensitivity; Tremor; Vision Blurred	Escitalopram Oxalate			S		20 Mg (10 Mg, 2 In 1 D)		Not Reported
	Clonazepam			C				Not Reported
	Ventolin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7164886	EXPEDITED (15-DAY)	Y	OT	1000009454		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Candida Infection; Constipation; Culture Stool Positive; Diarrhoea; Flatulence; Gastrointestinal Disorder; Rectal Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Augmentin			C				Not Reported
	Bacilor			C				Not Reported
	Pneumorel			C				Not Reported
	Rubozinc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7171568	EXPEDITED (15-DAY)	Y	HO	1000009512		74 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Decreased Appetite; Dysgeusia; Peripheral Coldness; Tremor; Weight Decreased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Ergenyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7196368	EXPEDITED (15-DAY)	Y	HO	1000010069		76 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hypotension; Mental Impairment; Mental Status Changes; Purpura; Red Blood Cell Count Decreased; Renal Failure	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Asaflow			C				Not Reported
	Diuretic			C				Not Reported
	Cholesterol Drug			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7196427	EXPEDITED (15-DAY)	Y	DE, LT	1000010047		72 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Drowning	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported
			Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral	
	Clomipramine Hydrochloride	C			Not Reported
	Godamed	C			Not Reported
	Nacom	C			Not Reported
	Nacom Retard	C			Not Reported
	Pantozol	C			Not Reported
	Requip	C			Not Reported
	Stilnox	C			Not Reported
	Trazodone Hydrochloride	C			Not Reported
	Torem	C			Not Reported
	Ximovan	C			Not Reported
	Atosil	C			Not Reported
	Terazosin Hydrochloride	C			Not Reported
	Cefixim	C			Not Reported
	Simvahexal	C			Not Reported
	Lyrica	C			Not Reported
	Motilium	C			Not Reported
	Tavor [Lorazepam]	C			Not Reported
	Seroquel	C			Not Reported
	Simethicon	C			Not Reported
	Ibuprofen	C			Not Reported
	Amitriptyline Hydrochloride	C			Not Reported
	Cymbalta	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7199670	EXPEDITED (15-DAY)	Y	OT	1000010155		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate			S	Oral	20 Mg (0 Mg, 1 In 1 D),Oral		Not Reported
					Oral	20 Mg (0 Mg, 1 In 1 D),Oral		
	Serax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7201404	EXPEDITED (15-DAY)	Y	OT	1000010121		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Glossitis; Toxic Skin Eruption	Escitalopram Oxalate			S	Oral	0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D),Oral; 1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
					Oral	0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D),Oral; 1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	1.5 Dosage Forms (1.5 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Influenza Virus Vaccine Nos			S				Not Reported
	Lovenox			C				Not Reported
	Sorafenib Or Placebo			C				Not Reported
	Effexor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7220857	EXPEDITED (15-DAY)	N	OT	1000010418			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Amnesia; Anxiety; Asthenia; Crying; Decreased Appetite; Dizziness; Emotional Disorder; Fatigue; Feeling Abnormal; Feeling Hot; Feeling Of Relaxation; Flushing; Heart Rate Increased; Hot Flush; Hunger; Hyperhidrosis;	Escitalopram Oxalate			S	Oral	10 Mg, Oral		Not Reported
	Ativan			C				Not Reported

Hypersomnia; Insomnia; Irritability; Memory Impairment; Panic Reaction; Somnolence; Stress; Tachyphrenia; Unevaluable Event; Yawning

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7225873	EXPEDITED (15-DAY)	Y	HO	AU-ASTRAZENECA-2009SE32268			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Fluid Volume Decreased; Maternal Exposure During Pregnancy	Atacand			S	Oral			Not Reported
	Unspecified Ingredient			S				Not Reported
	Insulin Nos			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7226166	EXPEDITED (15-DAY)	Y		1000010533		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Escitalopram Oxalate			S	Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Oxcarbazepine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7226580	NON-EXPEDITED			US-ASTRAZENECA-2009UW00302			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Faeces Discoloured	Crestor			S	Oral			Astrazeneca
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7228695	EXPEDITED (15-DAY)	Y	OT	1000010508		19 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oropharyngeal Discomfort; Tongue Oedema	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7238731	EXPEDITED (15-DAY)	Y	OT	1000010775		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Irritability; Nausea; Therapy Cessation	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D), 10 Mg (10 Mg, 1 In 1 D),		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7239703	EXPEDITED (15-DAY)	Y	OT	1000010874		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash; Scar	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral, Oral		Not Reported
	Seropram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7239734	EXPEDITED (15-DAY)	Y	HO	1000010919		24 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Musculoskeletal Disorder; Suicidal Ideation	Escitalopram Oxalate			S		10 Mg (10 Mg 1 In 1 D)		Not Reported
	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D); 15 Mg (15 Mg, 1 In 1 D) 20 Mg (20 Mg, 1 In 1 D);		Not Reported

							15 Mg (15 Mg, 1 In 1 D)			
	Temesta (Lorazepam)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7241239	EXPEDITED (15-DAY)	Y	OT	1000010856		152 DAY	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Maternal Exposure During Breast Feeding; Restlessness; Tension	Escitalopram Oxalate			S	Transmammary	5 Mg, Transmammary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7241276	EXPEDITED (15-DAY)	Y	OT	1000010859			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Mouth; Vertigo	Escitalopram Oxalate			S	Oral	5 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7241761	EXPEDITED (15-DAY)	Y	DS	1000010871		19 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Birth Control Pills			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7243266	EXPEDITED (15-DAY)	Y	OT	1000010794		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Escitalopram Oxalate			S	Oral	0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D), Oral		Not Reported

	Terbinafine		S	Oral	(1 Dosage Forms, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7243334	EXPEDITED (15-DAY)	Y	DE, HO	1000010869			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall; Femur Fracture; Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2009	7243450	EXPEDITED (15-DAY)	Y	OT	1000010852		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatillomania; Pruritus Generalised	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2009	7203765	EXPEDITED (15-DAY)	Y	OT	1000010132			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Feeling Abnormal; Psychiatric Symptom; Social Avoidant Behaviour; Suicidal Ideation	Escitalopram Oxalate			S	Oral Oral	Oral; 20 Mg (20 Mg, 1 In 1 D), Oral Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2009	7229760	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2009-BP-14		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Constipation	Spiriva		S	Respiratory (inhalation)	18 Mcg	Boehringer Ingelheim
	Lexapro		S			Not Reported
	Asa		C			Not Reported
	Cartia Xt		C			Not Reported
	Pantoprazole		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2009	7173024	EXPEDITED (15-DAY)	Y	OT	1000009342		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Endometriosis; Maternal Drugs Affecting Foetus; Pregnancy	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2009	7232108	DIRECT	N	LT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Diarrhoea; Disturbance In Attention; Emotional Disorder; Fear; Feeling Abnormal; Gastrointestinal Disorder; Mania; Restlessness; Weight Decreased	Lexapro			S	Oral	10 Miligrams Once Daily Po		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2009	7230901	EXPEDITED (15-DAY)	Y	OT	ES-JNJFOC-20091204475		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Drug Interaction; Lethargy	Durogesic			S	Transdermal			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

	Cimetidine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2009	7230902	EXPEDITED (15-DAY)	Y	OT	ES-JNJFOC-20091205548		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Parkinson'S Disease	Reminyl			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Deprax (Trazodone Hydrochloride)			C	Oral			Not Reported
	Akineton			C	Oral			Not Reported
	Adiro			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Lactulose			C	Oral			Not Reported
	Lorazepam			C	Oral			Not Reported
	Sinemet			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2009	7231931	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009313148		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Hypoacusis; Scoliosis; Spinal Stenosis; Tinnitus	Lipitor			S	Oral	10 Mg, 1x/Day		Pfizer
	Lexapro			S		Unk		Not Reported
	Centrum Silver			S		Unk		Not Reported
	Ecotrin			C		81 Mg, 1x/Day		Not Reported
	Calcium			C		Frequency: 4x/Day,		Not Reported
	Coenzyme Q10			C		Unk		Not Reported
	D3-Vicotrat			C		Unit Dose: 2000;		Not Reported
	Ergocalciferol\Zeaxanthin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2009	7220825	EXPEDITED (15-DAY)	Y		1000010421		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2009	7235649	DIRECT	N	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sensation In Eye; Adrenal Disorder; Anxiety; Balance Disorder; Dizziness; Dyskinesia; Hyperacusis; Insomnia; Panic Attack; Photophobia; Visual Impairment	Lexapro			S	Sublingual Sublingual	10 Mg 1/Day Sl; 5 Mg 1/Day Sl 10 Mg 1/Day Sl; 5 Mg 1/Day Sl		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2009	7245495	EXPEDITED (15-DAY)	Y	OT	1000010921			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Condition Aggravated; Irritability; Restlessness; Sleep Disorder	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2009	7223473	EXPEDITED (15-DAY)	Y	HO	1000009255		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Asthenia; Atelectasis; Back Pain; Bile Duct Stone; Blood Calcium Decreased; Blood Glucose Increased; Blood Potassium Decreased; Chest Pain; Dyspnoea; Fibrin D Dimer Increased; Haemangioma Of Liver; Headache; Hyponatraemia; Hypoxia; Immune Thrombocytopenic Purpura; Influenza; Injection Site Cellulitis; Injection Site Thrombosis; Lung Infection; Osteoarthritis; Radiculopathy	Lexapro	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Pneumovax 23	C			Not Reported
	Fluvirin Nos	C			Not Reported
	Nexium	C			Not Reported
	Xanax	C			Not Reported
	Estradiol	C			Not Reported
	Valtrex	C			Not Reported
	Trazodone Hydrochloride	C			Not Reported
	Wellbutrin Xl	C			Not Reported
	Colace	C			Not Reported
	Eszopiclone	C			Not Reported
	Zolpidem	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2009	7245724	EXPEDITED (15-DAY)	Y	OT	1000010934		58 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Coronary Artery Disease	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1in 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2009	7245810	EXPEDITED (15-DAY)	Y	OT	1000010935		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Poor Quality Sleep	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1		Not Reported

			D),Oral	
	Ebixa (Tablets)	C		Not Reported
	Tiapridal	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2009	7300801	NON-EXPEDITED	Y	DE	2009RR-21020		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Codeine Phosphate			S	Oral	Oral		Not Reported
	Oxycodone			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Levothyroxine Sodium			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported
	Acetaminophen\Diphenhydramine			S	Oral	Oral		Not Reported
	Estradiol			S	Oral	Oral		Not Reported
	Progestine			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2009	7048841	EXPEDITED (15-DAY)	Y	HO	PHHY2009FR27026		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Cerebellar Syndrome; Eye Pain; Intracranial Pressure Increased; Meningeal Disorder; Spinal Cord Injury; Vertigo; Vision Blurred; Visual Acuity Reduced; Visual Field Defect	Femara			S	Oral	2.5 Mg		Novartis
	Femara			S	Oral	Unk		Novartis
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Cyamemazine			S	Oral	Unk		Not Reported
	Prazepam			S	Oral	Unk		Not Reported
	Sectral			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2009	7247566	EXPEDITED (15-DAY)	Y	OT	1000005256		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pregnancy; Premature Labour	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Olanzapine			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Nicotine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2009	7247627	EXPEDITED (15-DAY)	Y	CA	1000010953		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Congenital Inguinal Hernia; Exomphalos; Maternal Drugs Affecting Foetus; Patent Ductus Arteriosus; Premature Baby	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported
	Olanzapine			S	Transplacental	5 Mg (5 Mg, 1 In 1 D), Transplacental		Not Reported
	Nicotine			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2010	7220935	EXPEDITED (15-DAY)	Y	OT	1000010346		32 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Increased; Breast Mass; Dizziness; Fatigue; Galactorrhoea; Heart Rate Increased; Pallor	Lexapro			S	Oral	10 Mg, Oral		Not Reported
	Sertindole			S	Oral Oral	4 Mg, Oral 8 Mg, Oral 4 Mg, Oral 8 Mg, Oral		Not Reported
	Paroxetine Hydrochloride			C				Not Reported
	Losec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2010	7249314	EXPEDITED (15-DAY)	Y	DE	1000010965		72 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Surgery	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2010	7249315	EXPEDITED (15-DAY)	Y	HO	1000010949			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Depression; Drug Ineffective; Listless; Paraesthesia	Escitalopram Oxalate			S	Oral	10 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2010	7234852	EXPEDITED (15-DAY)	Y	OT	1000010703		38 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Off Label Use	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2010	7293254	DIRECT	Y	HO			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Coagulopathy; Depression; Hepatitis Cholestatic; Insomnia; Mental Status Changes	Lexapro			S	Oral	10 Mg One Daily Oral 047	42 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2010	7239884	EXPEDITED (15-DAY)	Y	HO, OT	1000010924		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dizziness; Fatigue; Pulmonary Embolism	Escitalopram Oxalate			S	Oral	(15 Mg), Oral		Not Reported
	Topamax			S	Oral	(100 Mg), Oral		Not Reported
	Norvasc			S	Oral	(5 Mg), Oral		Not Reported
	Anagastra			C				Not Reported
	Loramet			C				Not Reported
	Sintrom			C				Not Reported
	Sutril			C				Not Reported
	Tranxilium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2010	7251014	EXPEDITED (15-DAY)	Y	OT	1000011005			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pregnancy; Premature Labour	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Pipamperone			S		4 Dosage Forms (4 Dosage Forms, 1 In 1 D)		Not Reported
	Dihydroergotamine Mesylate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Oxazepam			S		75 Mg (75 Mg, 1 In 1 D)		Not Reported
	Loprazolam			S		1 Dosage Forms (1 Dosage Forms, 1 In 1 D)		Not Reported
	Tranxene T-Tab			S		40 Mg (40 Mg, 1 In 1 D)		Not Reported
	Aripiprazole			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2010	7251016	EXPEDITED (15-DAY)	Y	DS	1000010986		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Feeling Abnormal; Malaise; Nausea; Palpitations; Syncope; Tremor;	Escitalopram Oxalate			S	Oral	(5 Mg, Once), Oral		Not Reported

Vomiting; Yawning

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2010	7252939	EXPEDITED (15-DAY)	N	DE	1000011056		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Mood Swings; Self-Medication	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2010	7253275	EXPEDITED (15-DAY)	Y	CA	1000011006		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Foetal Growth Restriction; Maternal Drugs Affecting Foetus; Premature Baby	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1 D),Transplacental		Not Reported
	Pipamperone			S	Transplacental	4 Dosage Forms (4 Dosage Forms, 1 In 1 D), Transplacental		Not Reported
	Dihydroergotamine Mesylate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported
	Oxazepam			S	Transplacental	75 Mg (75 Mg, 1 In 1 D), Transplacental		Not Reported
	Loprazolam			S	Transplacental	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Transplacental		Not Reported
	Tranxene T-Tab			S	Transplacental	40 Mg (40 Mg, 1 In 1 D), Transplacental		Not Reported
	Aripiprazole			S	Transplacental	10 Mg (10 Mg, 1 In 1 D),Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2010	7244062	DIRECT	N	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Irregular	Lexapro			S	Oral	1x Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2010	7251252	EXPEDITED (15-DAY)	Y	OT	1000011131		30 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Overdose; Psychomotor Hyperactivity	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	40 Mg (40 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2010	7240758	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2010SE00531		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Quetiapine			S	Oral			Zeneca
	Phenytoin			S	Oral			Not Reported
	Phenobarbital			S	Oral			Not Reported
	Trazodone Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Tenofovir			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Methylphenidate Hydrochloride			S	Oral			Not Reported
	Metformin Hydrochloride			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Ondansetron			S	Oral			Not Reported

	Pregabalin	S	Oral		Not Reported
	Metoclopramide	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2010	7255202	EXPEDITED (15-DAY)	Y	HO	1000011123		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Aspiration	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2010	7082820	EXPEDITED (15-DAY)	Y	OT	1000007934		37 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Blood Alkaline Phosphatase Increased; Cholestasis; Focal Nodular Hyperplasia; Gamma-Glutamyltransferase Increased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Nocertone			C				Not Reported
	Alprazolam			C				Not Reported
	Zolpidem			C				Not Reported
	Ludeal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2010	7234376	EXPEDITED (15-DAY)	N	HO	US-ABBOTT-09P-163-0616023-00		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bipolar Disorder; Depression; Headache; Intracranial Aneurysm; Sedation; Sinusitis; Somnolence	Depakote			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Promethazine			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Klonopin			C	Oral			Not Reported

	Activella			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2010	7254851	EXPEDITED (15-DAY)	N	OT	1000011163			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Restlessness	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2010	7254869	EXPEDITED (15-DAY)	Y	OT	1000011190		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	(50 Mg, Once), Oral		Not Reported
	Mirtazapine			S	Oral	(600 Mg, Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2010	7254871	EXPEDITED (15-DAY)		OT	1000011159		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depersonalisation/Derealisation Disorder; Depression; Diarrhoea; Fatigue; Hunger; Hypersomnia; Malaise; Metrorrhagia; Oropharyngeal Pain; Overdose; Panic Attack; Paraesthesia; Self-Injurious Ideation; Stomatitis	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Desogestrel And Ethinyl Estradiol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2010	7256252	EXPEDITED (15-DAY)	Y	OT	1000011141		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Deafness Unilateral; Scoliosis; Spinal Stenosis; Tinnitus	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lipitor			S				Not Reported
	Centrum Silver			C				Not Reported
	Ecotrin			C				Not Reported
	Calcium			C				Not Reported
	Coenzyme Q10			C				Not Reported
	D3-Vicotrat			C				Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2010	7256094	EXPEDITED (15-DAY)	Y	HO	1000011207			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Fall; Jaw Fracture	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Lexomil			C				Not Reported
	Cialis			C				Not Reported
	Dogmatil			C				Not Reported
	Noctamide			C				Not Reported
	Teralithe			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2010	7222194	EXPEDITED (15-DAY)	Y	HO	1000010427			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Fluid Volume Decreased; Gestational Diabetes; Maternal Exposure During Pregnancy; Pregnancy	Lexapro			S	Oral	Oral		Not Reported
	Atacand			C				Not Reported
	Elevit Vitamins			C				Not Reported
	Insulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2010	7245192	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2010000966		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Doxepin Hydrochloride			S	Oral			Pfizer
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2010	7245227	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2010001145		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Respiratory Arrest	Doxepin Hydrochloride			S	Unknown			Pfizer
	Sildenafil Citrate			S	Unknown			Pfizer
	Sertraline Hydrochloride			S	Unknown			Pfizer
	Oxybutynin			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Alcohol			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Clonidine			S	Unknown			Not Reported
	Diphenhydramine			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2010	7255312	EXPEDITED (15-DAY)	Y	OT	1000011208		62 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arrhythmia; Malaise	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, `1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2010	7255399	EXPEDITED (15-DAY)	Y	HO	1000011210		53 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Sepsis; Tonic Clonic Movements	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Ciprofloxacin Hydrochloride			S	Intravenous (not otherwise specified)	Intravenous (Not Otherwise Specified)		Not Reported
	Rifater			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2010	7223560	EXPEDITED (15-DAY)	Y	CA, HO	1000010428			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Fluid Volume Decreased; Congenital Bladder Anomaly; Foetal Disorder; Maternal Drugs Affecting Foetus; Neonatal Disorder; Nephrolithiasis; Renal Failure	Lexapro			S	Transplacental	Transplacental		Not Reported
	Atacand			C				Not Reported
	Elevit Vitamins			C				Not Reported
	Insulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2010	7246253	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2010001227		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide	Verapamil Hydrochloride			S	Oral			Pfizer
	Escitalopram Oxalate			S	Oral			Not Reported
	Sucralfate			C				Not Reported
	Atorvastatin			C				Not Reported
	Acetaminophen\Hydrocodone Bitartrate			C				Not Reported
	Omeprazole			C				Not Reported
	Polyethylene Glycols			C				Not Reported
	Montelukast			C				Not Reported

	Zolpidem	C	Not Reported
	Synthroid	C	Not Reported
	Vitamin B12	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2010	7257258	EXPEDITED (15-DAY)	Y	DE	2010SCPR000028		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ondansetron			S	Oral	Oral		Not Reported
	Phenytoin			S	Oral	Oral		Not Reported
	Phenobarbital			S	Oral	Oral		Not Reported
	Quetiapine			S	Oral	Oral		Not Reported
	Trazodone			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Emtricitabine\Tenofovir			S	Oral	Oral		Not Reported
	Oxycodone			S	Oral	Oral		Not Reported
	Methylphenidate			S	Oral	Oral		Not Reported
	Metformin Hydrochloride			S	Oral	Oral		Not Reported
	Zolpidem			S	Oral	Oral		Not Reported
	Pregabalin			S	Oral	Oral		Not Reported
	Metoclopramide			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2010	7259945	EXPEDITED (15-DAY)	Y	DE	2010SCPR000003		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Tramadol Hydrochloride			S	Oral	Oral		Not Reported
	Diazepam			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Paroxetine Hydrochloride			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2010	7153946	EXPEDITED (15-DAY)	Y	OT	1000009193		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Balance Disorder; Burning Sensation; Crying; Dizziness; Feeling Abnormal; Feeling Cold; Headache; Hyperhidrosis; Loss Of Personal Independence In Daily Activities; Movement Disorder; Muscular Weakness; Nausea; Salivary Hypersecretion; Speech Disorder; Tremor	Escitalopram Oxalate			S	Oral	15 Mg (15 M G, 1 In 1 D), Oral		Not Reported
	Mirtazapin (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2010	7247236	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2010001710		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ziprasidone Hydrochloride			S	Oral			Pfizer
	Escitalopram Oxalate			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2010	7247959	EXPEDITED (15-DAY)	Y	HO	US-RANBAXY-2010US-30334			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Disorientation; Overdose; Seizure; Suicide Attempt	Isotretinoin			S	Oral	20 Mg, Bid	30 DAY	Ranbaxy
	Isotretinoin			S	Oral	20 Mg, Tid	96 DAY	Ranbaxy
	Lexapro			S	Oral			Not Reported

	Lexapro	S	Oral	Unk		Not Reported
	Celexa	S	Oral	Unk	20 DAY	Not Reported
	Ultram	S	Oral	50 Mg, Unk	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2010	7221724	EXPEDITED (15-DAY)	Y	HO	CH-001179		71 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Malaise; Nausea	Minirin			S	Oral	(0.1 Mg Oral)		Not Reported
	Cipralex			S	Oral	(1 Df Oral)		Not Reported
	Beloc-Zok			C				Not Reported
	Plavix			C				Not Reported
	Aspirin Cardio			C				Not Reported
	Neo-Mercazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2010	7249209	EXPEDITED (15-DAY)	Y	OT	FR-BRISTOL-MYERS SQUIBB COMPANY-14934616		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Infertility	Abilify			S	Oral	Dose Increased To 30 Mg Per Day		Not Reported
	Escitalopram Oxalate			S	Oral	Dose Inreased To 30mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2010	7249428	EXPEDITED (15-DAY)	Y	HO	GB-WATSON-2010-00372		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Sinus Bradycardia; Syncope; Torsade De Pointes	Omeprazole			S	Oral	20 Mg, Daily		Watson
	Propranolol			S	Unknown	80 Mg, Daily		Watson
	Propranolol			S				Watson
	Escitalopram Oxalate			S	Oral	10 Mg, Daily	6 DAY	Not Reported

	Donepezil Hydrochloride	S	Oral	10 Mg, Unk	730 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2010	7259189	EXPEDITED (15-DAY)	Y	DE	2010SCPR000038		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ibuprofen			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Acetaminophen			S	Oral	Oral		Not Reported
	Methylphenidate			S	Oral	Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2010	7260312	EXPEDITED (15-DAY)	Y	HO	1000011275		52 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2010	7260885	EXPEDITED (15-DAY)	Y	OT	1000011291			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swelling; Weight Increased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2010	7260904	EXPEDITED (15-DAY)	Y	OT	1000011309		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Heart Rate Increased; Hot Flush; Hyperhidrosis; Muscle Spasms; Muscle Strain; Overdose; Palpitations; Panic Attack; Poor Quality Sleep; Tremor; Weight Increased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Co-Codamol			C				Not Reported
	Vitamin C			C				Not Reported
	Zopiclone			C				Not Reported
	Nordette			C				Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2010	7267961	EXPEDITED (15-DAY)	Y	OT	1000011273		27 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cyst; Breast Discomfort; Hyperprolactinaemia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2010	7269930	EXPEDITED (15-DAY)	Y	HO	1000011277		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Malaise; Renal Failure	Citalopram Hydrobromide			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Lasix			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Cordaone			C				Not Reported
	Tareg			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Previscan (Fluindione)			C				Not Reported

Seresta	C		Not Reported
Equanil	C		Not Reported
Paracetamol	C		Not Reported
Forlax	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2010	7284316	EXPEDITED (15-DAY)	Y	DE	2010SCPR000049		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Atrioventricular Block First Degree; Blood Glucose Increased; Blood Ph Decreased; Cardiac Arrest; Completed Suicide; Electrocardiogram Abnormal; Hypotension; Intentional Self-Injury; Lethargy; Non-Cardiogenic Pulmonary Oedema; Overdose; Po2 Decreased; Poisoning; Renal Impairment; Sinus Bradycardia; Unresponsive To Stimuli; Vomiting	Verapamil Hydrochloride			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2010	7247794	EXPEDITED (15-DAY)	Y	HO	1000010855		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Intentional Self-Injury; Overdose	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	>200 Mg (Once), Oral		Not Reported
	Lorazepam			S	Oral	0.5 Mg (0.5 Mg, 1 In 1 D), Oral		Not Reported
	Lorazepam			S	Oral	10 Mg (Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2010	7249927	EXPEDITED (15-DAY)	Y	HO, OT	ES-PFIZER INC-2010004264		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dizziness; Fatigue; Pulmonary Embolism	Norvasc			S	Oral	Unk		Pfizer
	Topamax			S	Oral	Unk	905 DAY	Not Reported
	Cipralex			S	Oral	Unk		Not Reported
	Anagastra			C	Oral	Unk		Not Reported
	Lormetazepam			C	Oral	Unk		Not Reported
	Sintrom			C	Oral	Unk		Not Reported
	Sutril			C	Oral	Unk		Not Reported
	Clorazepate Dipotassium			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2010	7270112	EXPEDITED (15-DAY)	Y	OT	1000011255		34 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatic Calcification; Pancreatitis Acute	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Propranolol			C				Not Reported
	Temesta (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2010	7273500	EXPEDITED (15-DAY)	N	LT, OT	1000011271		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Withdrawal Syndrome; Insomnia; Irritability; Overdose; Suicidal Ideation	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1		

				Oral	D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral	
	Escitalopram Oxalate		S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported
	Escitalopram Oxalate		S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral	Not Reported
				Oral	15 Mg (15 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral	
	Diazepam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2010	7251786	EXPEDITED (15-DAY)	Y	DE, OT	US-JNJFOC-20100107092		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Oxybutynin			S	Unknown			Not Reported
	Doxepin			S	Unknown			Not Reported
	Alcohol			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Clonidine			S	Unknown			Not Reported
	Unspecified Ingredient			S	Unknown			Not Reported
	Diphenhydramine			S	Unknown			Not Reported
	Sildenafil			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2010	7268629	EXPEDITED (15-DAY)	Y	HO	1000011315		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Calcium Decreased; Blood Chloride Decreased; Blood Potassium Decreased; Drug Interaction; Hyponatraemia	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Desmopressin			S	Respiratory (inhalation)	0.5 Dosage Forms (0.5 Dosage Forms, 1 In1 D) Respiratory (Inhalation)		Not Reported
	Vagifem			C				Not Reported
	Toviaz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2010	7268668	EXPEDITED (15-DAY)	Y	OT	1000011316		24 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Mirtazapine			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2010	7269129	EXPEDITED (15-DAY)	Y	DE	2010SCPR000136		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Poisoning; Respiratory Arrest; Toxicity To Various Agents	Doxepin Hydrochloride			S				Not Reported
	Clonazepam			S				Not Reported
	Alcohol			S				Not Reported
	Clonidine Transdermal System			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Diphenhydramine Hydrochloride			S				Not Reported
	Sildenafil			S				Not Reported
	Sertraline			S				Not Reported
	Duloxetine			S				Not Reported
	Oxybutynin			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2010	7269224	EXPEDITED (15-DAY)	Y	DE	2010SCPR000118		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Valproic Acid			S	Oral	Oral		Not Reported
	Aripiprazole			S	Oral	Oral		Not Reported
	Amphetamine			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2010	7284446	EXPEDITED (15-DAY)	Y	DE	2010SCPR000137		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Doxepin Hydrochloride			S	Oral	Oral		Not Reported
	Benzodiazepine			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2010	7042927	EXPEDITED (15-DAY)	Y	DE	1000006963			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Road Traffic Accident	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2010	7252976	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2010-BP-00		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Impatience; Irritability	Spiriva			S	Respiratory (inhalation)	18 Mcg		Boehringer Ingelheim

	Lipitor	S	Not Reported
	Zyrtec	S	Not Reported
	Zetia	S	Not Reported
	Lexapro	S	Not Reported
	Hydrochlorothiazide	C	Not Reported
	Levothyroxine	C	Not Reported
	Ambien	C	Not Reported
	Estradiol	C	Not Reported
	Tramadol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2010	7253110	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20100105556		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Tramadol			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Paroxetine Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2010	7254868	EXPEDITED (15-DAY)	N	OT	1000011162		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Chest Pain; Dyspnoea	Lexapro			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2010	7274376	EXPEDITED (15-DAY)	Y	HO, OT	1000009675		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Homicide; Physical Assault; Suicide Attempt	Lexapro			S		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2010	7253327	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20100106924		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Methylphenidate			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2010	7177780	EXPEDITED (15-DAY)	Y	OT	1000009686		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nightmare; Somnambulism	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2010	7246639	EXPEDITED (15-DAY)	Y	OT	1000010920		60 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Restlessness; Sleep Disorder	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Mono-Mak(Tablets)			C				Not Reported
	Monopril			C				Not Reported
	Hypothiazid (Tablets)			C				Not Reported
	Thrombo (Tablets)			C				Not Reported
	Atenolol			C				Not Reported
	Glurenorm (Tablets)			C				Not Reported
	Liprimar (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2010	7255391	EXPEDITED (15-DAY)	Y	DE, OT	US-JNJFOC-20100107079		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Oxycodone And Acetaminophen			S	Oral			Not Reported
	Acetaminophen\Hydrocodone			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2010	7275886	EXPEDITED (15-DAY)	Y	OT	1000011338		70 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2010	7275919	EXPEDITED (15-DAY)	Y	OT	1000011401			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Genital Hypoaesthesia; Libido Decreased; Paraesthesia	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg Every 2-3 Days, Oral		Not Reported
					Oral	20 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg Every 2-3 Days, Oral		
					Oral	20 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg Every 2-3 Days, Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2010	7169675	EXPEDITED (15-DAY)	Y	OT	US-ABBOTT-09P-163-0605763-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Pressure Fluctuation; Fall; Gait Disturbance; Headache; Seizure; Tremor	Depakote			S				Not Reported
	Lexapro			S				Not Reported
	Oxybutynin Chloride			S				Not Reported
	Lisinopril			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2010	7278212	EXPEDITED (15-DAY)	Y	DE	2010SCPR000179		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Diazepam			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Metoprolol Tartrate			S	Oral	Oral		Not Reported
	Carisoprodol			S	Oral	Oral		Not Reported
	Clopidogrel			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2010	7279849	EXPEDITED (15-DAY)	Y	OT	1000011424		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Oedema	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1d)		Not Reported
	Depakote			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2010	7289031	EXPEDITED (15-DAY)	Y	DE	004605		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone			S				Not Reported

Bitartrate			
Unspecified Ingredient	S		Not Reported
Oxycodone Hydrochloride And Acetaminophen	S		Not Reported
Aripiprazole	S		Not Reported
Escitalopram Oxalate	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2010	6952143	EXPEDITED (15-DAY)	Y	LT, OT	1000005108		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Leukopenia	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg,1 In 1d		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg,1 In 1d		
	Lamotrigine			S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
	Zyprexa			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Valium			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lithium			S	Oral	800 Mg (400 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2010	7279872	EXPEDITED (15-DAY)	Y	HO	1000011437		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Binocular Eye Movement Disorder; Drug Interaction; Eye Movement Disorder; Tremor	Escitalopram Oxalate			S	Oral	10 Mg, (10 Mg, 1 In 1 D), Oral		Not Reported
	Prochlorperazine			S	Oral	30 Mg, (10 Mg, 3 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2010	7279880	EXPEDITED (15-DAY)	Y	HO	1000011425		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Intentional Overdose; Sopor; Suicide Attempt; Vomiting	Escitalopram Oxalate			S	Oral	20 Mg, (10 Mg, 2 In 1 D), Oral 240 Mg (240 Mg, Once) Oral		Not Reported
					Oral	20 Mg, (10 Mg, 2 In 1 D), Oral 240 Mg (240 Mg, Once) Oral		
	Diazepam			S	Oral	Oral Half A Bottle - (Once) Oral		Not Reported
					Oral	Oral Half A Bottle - (Once) Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2010	7283356	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2010	7258804	NON-EXPEDITED	N		A0771217A		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hyperhidrosis; Insomnia	Wellbutrin			S	Oral	300mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Mirtazapine			S	Oral	15mg Per Day		Not Reported
	Lorazepam			C	Oral	1mg Per Day		Not Reported
	Toprol Xl			C	Oral	25mg Per Day		Not Reported
	Isosorbide			C	Oral	30mg Per Day		Not Reported
	Glipizide			C	Oral	4mg Twice Per Day		Not Reported
	Metformin Hydrochloride			C	Oral	500mg Twice Per Day		Glaxosmithkline
	Altace			C	Oral	10mg Per Day		Glaxosmithkline
	Lipitor			C	Oral	10mg Per Day		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2010	7280933	EXPEDITED (15-DAY)	N	OT	1000011410		46 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anxiety; Bereavement; Constipation; Depression; Disease Recurrence; Drug Ineffective; Dry Mouth; Fatigue; Feeling Abnormal; Flatulence; Gastrointestinal Disorder; Gastrooesophageal Reflux Disease; Headache; Hypersomnia; Influenza; Insomnia; Malaise; Musculoskeletal Pain; Nasal Congestion; Nausea; Nightmare; Psychotic Disorder; Suicidal Ideation; Tremor; Weight Increased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2010	7280982	EXPEDITED (15-DAY)		OT	1000011443		61 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Daydreaming; Decreased Appetite; Disturbance In Attention; Dizziness; Dyskinesia; Erectile Dysfunction; Hyposmia; Insomnia; Pruritus; Social Avoidant Behaviour	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Primoteston Depot			C				Not Reported
	Levaksin			C				Not Reported
	Testosterone			C				Not Reported
	Vitamin B12			C				Not Reported
	Lamictal			C				Not Reported
	Nebido			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2010	7280984	EXPEDITED (15-DAY)		HO, OT	1000011453			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Gastric Ulcer	Lexapro			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2010	6946357	EXPEDITED (15-DAY)	N	HO, OT	1000005013		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Epicondylitis; Fatigue; Intervertebral Disc Protrusion; Musculoskeletal Disorder; Nausea; Neck Pain; Sciatica; Suicidal Ideation; Terminal Insomnia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		
	Sertraline Hydrochloride			C				Not Reported
	Painkillers			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2010	6971721	EXPEDITED (15-DAY)	Y	CA, DE	1000005642			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bladder Anomaly; Maternal Drugs Affecting Foetus; Pulmonary Hypoplasia; Stillbirth	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported
	Amitriptyline			S	Transplacental	25 Mg (25 Mg, 1 In 1 D), Transplacental		Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2010	7240650	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2009315902		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Faecaloma; Gastrointestinal Disorder; Hyponatraemia; Urinary Tract Infection Bacterial	Atarax			S	Oral	12.5 Mg, 2x/Day	11 DAY	Pfizer
	Omeprazole			S	Oral	40 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S	Oral	Unk	4 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	Unk	6 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	Unk	4 DAY	Not Reported
	Cilastatin Sodium\Imipenem			C		Unk		Not Reported
	Linezolid			C		Unk		Not Reported
	Ciprofloxacin Hydrochloride			C		Unk		Not Reported
	Zelitrex			C				Not Reported
	Inexium			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Domperidone			C				Not Reported
	Cortancyl			C		5 Mg, Unk		Not Reported
	Domperidone			C				Not Reported
	Fresubin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2010	7284507	EXPEDITED (15-DAY)	Y	HO	1000011472		87 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Melaena	Escitalopram Oxalate			S	Oral	(10 Mg), Oral		Not Reported
	Acenocoumarol			S	Oral	Oral		Not Reported
	Orfidal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2010	7284516	EXPEDITED (15-DAY)	Y	HO	1000011482		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Conversion Disorder	Escitalopram Oxalate		S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2010	7287790	EXPEDITED (15-DAY)	Y	DE	DSA_42412_2010		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Bupropion Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2010	7287910	EXPEDITED (15-DAY)	Y	DE	DSA_42384_2010		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Poisoning; Respiratory Arrest	Bupropion Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Propoxyphene Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Chlordiazepoxide			S	Oral	(Df Oral)		Not Reported
	Methamphetamine			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2010	7243448	EXPEDITED (15-DAY)	N	OT	1000010834		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Breast Tenderness; Contusion; Dizziness; Galactorrhoea; Leukopenia; Mastitis; Oedema Peripheral; Pruritus Generalised; Pyrexia; Rash; Syncope; Thrombocytopenia	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

Lexapro	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
Lexapro	S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2010	7266811	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLINCKRODT-T201000143		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S	Oral	Unk		Tyco
	Oxycodone And Acetaminophen			S	Oral	Unk		Tyco
	Unspecified Ingredient			S	Oral	Unk		Not Reported
	Aripiprazole			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2010	7267031	NON-EXPEDITED	N		A0835418A		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Interaction; Fatigue; Feeling Abnormal; Nausea; Vomiting	Treximet			S	Oral	1tab Single Dose	1 DAY	Glaxosmithkline
	Lexapro			S			5 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2010	7267610	EXPEDITED (15-DAY)	Y	HO	DE-MYLANLABS-2010S1000957		58 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Enalapril Maleate And Hydrochlorothiazide			S				Not Reported
	Bisoprolol			C				Not Reported
	Zopiclone			C				Not Reported

	Lorazepam	C	0.5 Mg-1mg Bei Bedarf	Not Reported
	Enalapril	S		Not Reported
	Cipralex	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2010	7285513	EXPEDITED (15-DAY)	Y	DE	ALA_00412_2010		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Metoclopramide Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Phenytoin			S	Oral	(Df Oral)		Not Reported
	Phenobarbital			S	Oral	(Df Oral)		Not Reported
	Quetiapine			S	Oral	(Df Oral)		Not Reported
	Trazodone Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Emtricitabine And Tenofovir Disoproxil Fumarate			S	Oral	(Df Oral)		Not Reported
	Oxycodone			S	Oral	(Df Oral)		Not Reported
	Methylphenidate			S	Oral	(Df Oral)		Not Reported
	Metformin Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Zolpidem			S	Oral	(Df Oral)		Not Reported
	Ondansetron			S	Oral	(Df Oral)		Not Reported
	Pregabalin			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2010	7287932	EXPEDITED (15-DAY)	Y	HO	1000011497			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Off Label Use	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2010	7288077	EXPEDITED (15-DAY)	Y	OT	1000011498			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Off Label Use	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2010	7288475	EXPEDITED (15-DAY)	Y	OT	1000011499			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Off Label Use	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2010	7289589	EXPEDITED (15-DAY)	Y	DE	NSR_00054_2010		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Metoclopramide Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Phenytoin			S	Oral	(Df Oral)		Not Reported
	Phenobarbital			S	Oral	(Df Oral)		Not Reported
	Quetiapine			S	Oral	(Df Oral)		Not Reported
	Trazodone Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Emtricitabine And Tenofovir Disoproxil Fumarate			S	Oral	(Df Oral)		Not Reported
	Oxycodone			S	Oral	(Df Oral)		Not Reported
	Methylphenidate			S	Oral	(Df Oral)		Not Reported
	Metformin Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Zolpidem			S	Oral	(Df Oral)		Not Reported

Ondansetron	S	Oral	(Df Oral)		Not Reported
Pregabalin	S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2010	7289682	EXPEDITED (15-DAY)	Y	DE, OT	1000011513		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Completed Suicide	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Antipsychotics			C				Not Reported
	Interferon Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2010	7286506	EXPEDITED (15-DAY)	Y	DE	2010S1000052		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Roxicodone			S	Oral	Po		Not Reported
	Escitalopram Oxalate			S	Oral	Po		Not Reported
	Cocaine			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2010	7290075	EXPEDITED (15-DAY)	Y	DE	2010S1000091		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Arrest	Oxybutynin Chloride			S				Not Reported
	Doxepin			S				Not Reported
	Alcohol			S				Not Reported
	Clonazepam			S				Not Reported
	Clonidine			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Diphenhydramine			S				Not Reported
	Sildenafil Citrate			S				Not Reported
	Sertraline Hydrochloride			S				Not Reported
	Duloxetine			S				Not Reported

	Escitalopram Oxalate	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2010	7290231	EXPEDITED (15-DAY)	Y	HO	1000011544		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Feeling Cold; Musculoskeletal Stiffness; Pyrexia; Tremor; Vertigo; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Diosmine			C				Not Reported
	Proctolog			C				Not Reported
	Lysanxia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2010	7291195	EXPEDITED (15-DAY)	Y	DE	AVE_01465_2010		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Poisoning; Respiratory Arrest	Clonidine			S		(Df)		Not Reported
	Doxepin			S		(Df)		Not Reported
	Alcohol			S				Not Reported
	Clonazepam			S		(Df)		Not Reported
	Diphenhydramine			S		(Df)		Not Reported
	Sildenafil Citrate			S		(Df)		Not Reported
	Sertraline Hydrochloride			S		(Df)		Not Reported
	Duloxetine			S		(Df)		Not Reported
	Oxybutynin			S		(Df)		Not Reported
	Escitalopram Oxalate			S		(Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2010	7291430	EXPEDITED (15-DAY)	Y	DE	2010S1000093		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest;	Darvon			S	Oral	Po		Not Reported

Respiratory Arrest	Chlordiazepoxide	S	Oral	Po		Not Reported
	Methamphetamine Hydrochloride	S	Oral	Po		Not Reported
	Escitalopram Oxalate	S	Oral	Po		Not Reported
	Bupropion Hydrochloride	S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2010	7291682	EXPEDITED (15-DAY)	Y	DE	DEP_00324_2010		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Metformin Hydrochloride			S	Oral	Df Oral		Not Reported
	Phenytoin			S	Oral	Df Oral		Not Reported
	Phenobarbital			S	Oral	Df Oral		Not Reported
	Quetiapine			S	Oral	Df Oral		Not Reported
	Trazodone			S	Oral	Df Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df Oral		Not Reported
	Emtricitabine And Tenofovir Disoproxil Fumarate			S	Oral	Df Oral		Not Reported
	Oxycodone			S	Oral	Df Oral		Not Reported
	Methylphenidate			S	Oral	Df Oral		Not Reported
	Zolpidem			S	Oral	Df Oral		Not Reported
	Ondansetron			S	Oral	Df Oral		Not Reported
	Pregabalin			S	Oral	Df Oral		Not Reported
	Metoclopramide Hydrochloride			S	Oral	Df Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2010	7292943	EXPEDITED (15-DAY)	Y	DE	2010S1000051		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Roxicodone			S	Oral	Po		Not Reported
	Phenytoin			S	Oral	Po		Not Reported

Phenobarbital	S	Oral	Po		Not Reported
Quetiapine	S	Oral	Po		Not Reported
Trazodone Hydrochloride	S	Oral	Po		Not Reported
Escitalopram Oxalate	S	Oral	Po		Not Reported
Emtricitabine And Tenofovir Disoproxil Fumarate	S	Oral	Po		Not Reported
Methylphenidate	S	Oral	Po		Not Reported
Metformin	S	Oral	Po		Not Reported
Zolpidem	S	Oral	Po		Not Reported
Ondansetron	S	Oral	Po		Not Reported
Pregabalin	S	Oral	Po		Not Reported
Metoclopramide Hydrochloride	S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2010	7269096	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2010008249		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Urticaria	Xanax			S	Oral	0.25 Mg, 2x/Day	59 DAY	Pfizer
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day	56 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, 2x/Day	4 DAY	Not Reported
	Zopiclone			S	Oral	7.5 Mg, 1x/Day	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2010	7292685	EXPEDITED (15-DAY)	Y	OT	1000011560		40 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corneal Oedema; Glaucoma; Ocular Hyperaemia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2010	7292777	EXPEDITED (15-DAY)	Y	HO	1000011569		40 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Fatigue; Nervousness	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Depakine (Valproate)			C				Not Reported
	Benzodiazepine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2010	7293642	EXPEDITED (15-DAY)	Y	DE	IMP_04750_2010		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Poisoning; Respiratory Arrest	Oxybutynin			S		(Df)		Not Reported
	Doxepin			S		(Df)		Not Reported
	Alcohol			S		()		Not Reported
	Clonazepam			S		(Df)		Not Reported
	Clonidine			S		(Df)		Not Reported
	Diphenhydramine			S		(Df)		Not Reported
	Sildenafil Citrate			S		(Df)		Not Reported
	Sertraline Hydrochloride			S		(Df)		Not Reported
	Duloxetine			S		(Df)		Not Reported
	Escitalopram Oxalate			S		(Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2010	7293672	EXPEDITED (15-DAY)	Y	DE	NSR_00076_2010		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Ibuprofen			S	Oral	Df, Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df, Oral		Not Reported

	Acetaminophen		S	Oral	Df, Oral	Not Reported
	Methylphenidate		S	Oral	Df, Oral	Not Reported
	Alcohol		S	Oral	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2010	7293676	EXPEDITED (15-DAY)	Y	DE	IMP_04752_2010		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Poisoning; Respiratory Arrest	Bupropion Hydrochloride			S	Oral	Df, Oral		Not Reported
	Propoxyphene Hydrochloride			S	Oral	Df, Oral		Not Reported
	Chlordiazepoxide			S	Oral	Df, Oral		Not Reported
	Methamphetamine Hydrochloride			S	Oral	Df, Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2010	7294482	EXPEDITED (15-DAY)	Y	DE	IMP_04766_2010		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Bupropion Hydrochloride			S	Oral	Df Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2010	7299865	EXPEDITED (15-DAY)		OT	1000011547		23 YR	Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Chills; Condition Aggravated; Death Of Relative; Depression; Headache; Pyrexia; Suicidal Ideation	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2010	7301176	EXPEDITED (15-DAY)	Y	DE	1000011540		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2010	7140331	EXPEDITED (15-DAY)		OT	1000008876		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Condition Aggravated; Crying; Drug Withdrawal Syndrome; Hostility; Mood Swings; Muscle Tightness; Panic Reaction; Suicidal Ideation; Surgery; Vomiting	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Champix			S	Oral Oral	Oral Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2010	7247402	EXPEDITED (15-DAY)	Y	OT	1000011030		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lipase Increased; Transaminases Increased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral Oral Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral 5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral 5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1		Not Reported

							D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral			
	Atosil			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2010	7257726	EXPEDITED (15-DAY)	Y	OT	1000011248		55 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Photosensitivity Reaction	Lexapro			S	Oral	10 Mg, (10 Mg, 1 In 1 D), Oral		Not Reported
	Amitriptyline			C				Not Reported
	Oxazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2010	7295088	EXPEDITED (15-DAY)	N	DE	1000011542		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Condition Aggravated; Depression	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2010	7295212	EXPEDITED (15-DAY)	Y	OT	1000011570		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Communication Disorder; Mutism	Escitalopram Oxalate			S	Oral	(10 Mg), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2010	7273080	EXPEDITED (15-DAY)	N	HO, LT, OT	BR-ROCHE-683282		21 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Coordination Abnormal; Crying; Illiteracy; Insomnia; Memory Impairment; Nausea; Overdose; Pulmonary Oedema; Respiratory Disorder; Somatic Symptom Disorder; Suicidal Ideation; Suicide Attempt; Visual Impairment; Vomiting	Rivotril			S	Oral			Roche
	Rivotril			S	Oral	Overdose (4 Mg, 6 Mg Or 8 Mg Daily)		Roche
	Rivotril			S	Oral			Roche
	Pamelor			S	Unknown			Not Reported
	Nadolol			S	Unknown			Not Reported
	Cloxazolam			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown	Drug: Exodus (Escitalopram)		Not Reported
	Depakote			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2010	7274333	EXPEDITED (15-DAY)	N	HO	B0631862A		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Increased; Muscle Contractions Involuntary	Paroxetine Hydrochloride			S	Oral	10mg Alternate Days	13 DAY	Glaxosmithkline
	Escitalopram Oxalate			S	Oral	5drop Per Day	223 DAY	Not Reported
	Ramipril			C				Glaxosmithkline
	Unknown			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2010	7279866	DIRECT	N	HO			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Balance Disorder; Confusional State; Disturbance In Attention; Malaise; Nausea; Seizure; Tremor	Escitalopram Oxalate			S		20mg 1 A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2010	7267710	EXPEDITED (15-DAY)	Y	OT	FR-ABBOTT-10P-056-0621442-00			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Oedema	Depakote			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2010	7256593	EXPEDITED (15-DAY)	N	OT	1000011206		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Legal Problem	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Soma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2010	7274624	EXPEDITED (15-DAY)	Y	HO	PHHY2009IT56912		82 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Cognitive Disorder; Hypokalaemia; Hypokinesia; Hyponatraemia; Somnolence; White Blood Cell Count Increased	Hydrochlorothiazide\Valsartan			S		1 Df, Qd	40 DAY	Novartis
	Esidrex			S	Oral	Unk	40 DAY	Not Reported
	Cipralex			S		0.5 Df, Qd	7 DAY	Not Reported
	Ticlopidine			C		2 Df, Qd		Not Reported
	Atenolol			C		100 Mg, Unk	23 DAY	Not Reported
	Omeprazole			C		20 Mg, Unk		Not Reported
	Polase			C		1 Sachet Daily	23 DAY	Not Reported
	Cogiton Ar			C		Unk	7 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2010	7277460	EXPEDITED (15-DAY)	Y	HO, OT	US-PFIZER INC-2010014376		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Decreased Appetite; Depressed Mood; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Nausea; Nervousness; Tremor; Unevaluable Event	Zoloft			S				Pfizer
	Propylthiouracil			S				Not Reported
	Pristiq Extended Release			S	Oral	50 Mg, 1x/Day		Not Reported
	Ciprofloxacin			S				Not Reported
	Levothyroxine Sodium			S				Not Reported
	Lexapro			S				Not Reported
	Amitriptyline			S				Not Reported
	Perphenazine And Amitriptyline Hydrochloride			S				Not Reported
	Klonopin			C				Not Reported
	Seroquel			C		12.5 Mg, As Needed		Not Reported
	Levothyroxine			C		82 Ug, 1x/Day		Not Reported
	Amlodipine			C				Not Reported
	Propranolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2010	7284149	EXPEDITED (15-DAY)	Y	OT	1000011484		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory; Major Depression; Suicidal Ideation	Escitalopram Oxalate			S	Oral	10 Mg, Oral; 20 Mg, Oral		Not Reported
					Oral	10 Mg, Oral; 20 Mg, Oral		
	Propranolol			S	Oral	80 Mg,Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2010	7299604	EXPEDITED (15-DAY)	Y	HO	1000011662		60 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2010	7299606	EXPEDITED (15-DAY)	Y	HO	1000011636		53 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Skin Exfoliation; Urticaria; Xeroderma	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
	Zopiclone			S	Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			S	Oral	0.5 Mg (0.25 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2010	7285024	DIRECT	Y	HO			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Lexapro			S	Oral	10 Mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2010	7385692	DIRECT	Y	DS, HO, LT, RI, OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Gastric Emptying	Cymbalta			S	Oral	60 Mg Po Daily	3 YR	Not Reported
	Lexapro			S				Not Reported
	Geodon			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2010	7278794	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLIN CKRODT-T201000148		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Tramadol Hydrochloride			S	Oral	Unk		Tyco
	Diazepam			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported

	Paroxetine Hydrochloride		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2010	7279524	EXPEDITED (15-DAY)	Y	DE	US-JNJCH-2010003969		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Toxicity To Various Agents	Pseudoephedrine Hydrochloride			S	Unknown	Text:Unknown		Not Reported
	Escitalopram Oxalate			S	Unknown	Text:Unknown		Not Reported
	Fentanyl			C	Transdermal	Text:Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2010	7280158	NON-EXPEDITED			US-ABBOTT-09P-163-0611316-00		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Mass; Erythema; Feeling Abnormal; Hot Flush; Hypersensitivity; Pain In Extremity; Pruritus; Rash; Swelling	Simcor			S		1000mg		Not Reported
	Simcor			S				Not Reported
	Simcor			S				Not Reported
	Lexapro			S				Not Reported
	Pioglitazone Hydrochloride			C				Not Reported
	Metoprolol			C				Not Reported
	Furosemide			C				Not Reported
	Sitagliptin Phosphate			C				Not Reported
	Ranitidine			C				Not Reported
	Topamax			C				Not Reported
	Aspirin			C				Not Reported
	Centrum Silver			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2010	7284554	EXPEDITED (15-DAY)	Y	HO	1000011474		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Calcium Decreased; Blood Chloride Decreased; Blood	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Tegretal			S	Oral	400 Mg (400 Mg, 1 In 1 D),		Not Reported

Creatinine Decreased; Blood Potassium Increased; Blood Urea Decreased; Drug Interaction; Gamma-Glutamyltransferase Increased; Hyponatraemia; Overdose			Oral	Oral		
	Esidrix	S	Oral	400 Mg (400 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel	C		12.5 Mg (12.5 Mg, 1 In 1 D), Oral		Not Reported
	Ximovan	C				Not Reported
	Euthyrox	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2010	7290715	EXPEDITED (15-DAY)	Y	OT	1000011510		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Escherichia Urinary Tract Infection; Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Marcumar			C				Not Reported
	Durogesic			C				Not Reported
	Co-Epril			C				Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2010	7312836	EXPEDITED (15-DAY)	Y	OT	1000011810		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Urinary Retention	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Temesta (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7171550	EXPEDITED (15-DAY)	Y	OT	1000009564		18 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Intentional Overdose; Palpitations; Poor Quality Sleep; Toxicity To Various Agents; Tremor	Lexapro			S	Oral	(Once), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	(Once), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		
	Benzodiazepine			C				Not Reported
	Cannabis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7238459	EXPEDITED (15-DAY)	N	OT	1000010813		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Atrial Fibrillation; Cerebrovascular Accident; Chest Pain; Condition Aggravated; Constipation; Cough; Dyspnoea; Hyperhidrosis; Hypertension; Musculoskeletal Pain	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Syntrhoid (100 Milligram)			C				Not Reported
	Maalox			C				Not Reported
	Vitamin B Complex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7255216	EXPEDITED (15-DAY)	Y	OT	1000011083		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysgeusia; Macular Degeneration; Retinal Haemorrhage	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Cozaar			C				Not Reported
	Tylenol			C				Not Reported
	Synthroid			C				Not Reported
	Nebulizer			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7271347	EXPEDITED (15-DAY)	Y	HO	2010SP002895		39 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Hypotension; Intentional Overdose; Lactic Acidosis; Oxygen Saturation Decreased; Sinus Tachycardia; Suicide Attempt; Toxicity To Various Agents; Ventricular Hypokinesia	Mirtazapine			S	Oral	730 Mg;Once;Po		Not Reported
	Unspecified Ingredient			S	Oral	12 Gm;Once;Po		Not Reported
	Zolpidem			S	Oral	840 Mg;Once;Po		Not Reported
	Bromazepam (Bromazepam)			S	Oral	540 Mg; Once; Po		Not Reported
	Escitalopram Oxalate			S	Oral	420 Mg;Once;Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7277778	EXPEDITED (15-DAY)	N	OT	1000011433		27 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7303763	DIRECT	Y				49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Isentress			S	Oral	400mg Bid Po		Not Reported
	Lyrica			S				Not Reported
	Lexapro			S				Not Reported
	Lipitor			S				Not Reported
	Requip			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7308416	EXPEDITED (15-DAY)	Y	OT	1000011665		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Trismus	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral	Not Reported
				Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7308768	EXPEDITED (15-DAY)	N	HO	1000011740		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Feeling Cold; Hot Flush; Influenza Like Illness; Insomnia; Supraventricular Extrasystoles; Tachycardia	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg(5 Mg 1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg(5 Mg 1 In 1 D),Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7309221	EXPEDITED (15-DAY)	Y	HO	1000011712		78 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Agitation; Cyanosis; Diarrhoea; Haemorrhage; Hypokalaemia; Hypovolaemia; Livedo Reticularis; Seizure; Urinary Retention	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Theophylline			S	Oral	1200 Mg (400 Mg, 3 In 1 D), Oral		Not Reported
	Athymil			C				Not Reported
	Allopurinol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7310474	EXPEDITED (15-DAY)	N	OT	1000011718		28 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Anxiety; Fatigue; Feelings Of	Escitalopram Oxalate			S	Oral	Oral, 20 Mg (20 Mg, 1 In 1		Not Reported

Worthlessness; Mood Altered; Obsessive Thoughts; Poor Quality Sleep				Oral	D), Oral Oral, 20 Mg (20 Mg, 1 In 1 D), Oral	
	Wellbutrin Xl		S			Not Reported
	Prenasone (Corticosteroid Nos)		C			Not Reported
	Ortho Tri Cyclen		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7310525	EXPEDITED (15-DAY)	Y	HO	1000011613		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Test Positive; Hepatitis; Hepatocellular Injury	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7311141	EXPEDITED (15-DAY)	Y	OT	1000011715		40 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Blood Glucose Fluctuation; Dizziness; Drug Withdrawal Syndrome; Radicular Pain; Tachycardia	Escitalopram Oxalate			S		(10 Mg) ; (5 Mg) (10 Mg) ; (5 Mg)	6 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7311788	EXPEDITED (15-DAY)	Y	OT	1000011664		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Fatigue	Escitalopram Oxalate			S	Oral	(10 Mg,Once), Oral		Not Reported
	Lyrica			S	Oral	(100 Mg,Once), Oral		Not Reported
	Promethazine			S	Oral	(25 Mg,Once), Oral		Not Reported
	Zopiclone			S	Oral	(2 Dosage Forms, Once),		Not Reported

Oral

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2010	7314359	EXPEDITED (15-DAY)	Y	OT	1000011809			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition; Suicidal Ideation	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lexomil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2010	7075992	EXPEDITED (15-DAY)		DS	US-ROXANE LABORATORIES, INC.-2009-RO-00780RO		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breathing-Related Sleep Disorder	Methadone			S		45 Mg		Roxane
	Methadone			S				Roxane
	Diazepam			S				Roxane
	Diazepam			S				Roxane
	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2010	7222019	EXPEDITED (15-DAY)	Y	OT	1000010481		14 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tongue Disorder	Escitalopram Oxalate			S	Oral	5 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2010	7225874	EXPEDITED (15-DAY)	Y	CA	AU-ASTRAZENECA-2009SE32262		121 DAY	Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy;	Atacand			S	Transplacental			Not Reported

Nephrolithiasis; Renal Failure	Minerals\Vitamins		S	Transplacental	Not Reported
	Insulin Nos		S	Transplacental	Not Reported
	Lexapro		S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2010	7284464	EXPEDITED (15-DAY)	Y	HO	GXKR2010GB01763		36 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hallucination, Auditory; Psychotic Disorder; Suicidal Ideation	Propranolol			S	Oral	80 Mg/Day	29 DAY	Novartis
	Escitalopram Oxalate			S	Oral	10 Mg/Day		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2010	7313827	EXPEDITED (15-DAY)	Y	OT	1000011870		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Enlargement; Synovial Cyst	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2010	7313843	EXPEDITED (15-DAY)	Y	HO	1000011862		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Neutropenia	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Zyprexa			S	Oral	Oral		Not Reported
	Zyprexa			S	Oral	Oral		Not Reported
	Oxazepam			S	Oral	Oral		Not Reported
	Oxazepam			S	Oral	Oral		Not Reported
	Combivir			C				Not Reported
	Kaletra			C				Not Reported

Zyprexa	C		Not Reported
Seresta	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2010	7313953	EXPEDITED (15-DAY)	Y	OT	1000011817		32 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Restlessness	Lexapro			S	Oral	5 Mg 95 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg 95 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		
	Cortison			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2010	7316886	EXPEDITED (15-DAY)	Y	HO	1000011811		60 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydronephrosis; Urinary Retention	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Zanidip			C				Not Reported
	Zestril			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2010	7299859	EXPEDITED (15-DAY)	Y	HO, LT	1000011541		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Base Excess; Drug Withdrawal Syndrome Neonatal; Maternal Drugs Affecting Foetus; Oxygen Saturation Decreased; Patent Ductus Arteriosus	Escitalopram Oxalate			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2010	7315684	EXPEDITED (15-DAY)	Y	OT	1000011848			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Drug Interaction; Mood Swings; Restlessness; Unevaluable Event	Escitalopram Oxalate			S				Not Reported
	Sandimmune			S		150 Mg (75 Mg,2 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2010	7315703	EXPEDITED (15-DAY)	Y	OT	1000011530		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Gestational Diabetes; Maternal Exposure During Pregnancy; Meconium In Amniotic Fluid; Pregnancy	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2010	7318633	EXPEDITED (15-DAY)	Y	OT	1000011882		25 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral	(500 Mg,Once), Oral		Not Reported
	Ibu			S	Oral	(13200 Mg,Once), Oral		Not Reported
	Alcohol			S	Oral	1 Liter Of Vodka (Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2010	7319680	EXPEDITED (15-DAY)	Y	OT	1000011450		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Overdose;	Escitalopram Oxalate		S	Oral	30 Mg,Oral	Not Reported
Arthralgia; Discomfort; Musculoskeletal Stiffness;	Escitalopram Oxalate		S	Oral	10 Mg, Oral	Not Reported
Polyneuropathy;	Zopiclone		C			Not Reported
Unevaluable Event	Xanax (25 Milligram)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2010	7085340	EXPEDITED (15-DAY)	Y	OT	1000007976		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnambulism	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2010	7289066	EXPEDITED (15-DAY)	Y	DE	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2010-DE-00		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Clonidine			S	Unknown			Boehringer Ingelheim
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported
	Doxepin			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Unspecified Ingredient			S	Unknown			Not Reported
	Diphenhydramine			S	Unknown			Not Reported
	Sildenafil Citrate			S	Unknown			Not Reported
	Oxybutynin			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2010	7289156	EXPEDITED (15-DAY)	Y	DE	US-ABBOTT-10P-163-		17 YR	Male	USA

0626726-00

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S		Ingestion		Not Reported
	Benzodiazepine			S		Ingestion		Not Reported
	Acetaminophen W/Oxycodone			S		Ingestion		Not Reported
	Aripiprazole			S		Ingestion		Not Reported
	Escitalopram Oxalate			S		Ingestion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2010	7101275	EXPEDITED (15-DAY)	Y	OT	1000008195		49 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Cyst; Generalised Tonic-Clonic Seizure; Hallucination, Visual; Stress	Lexapro			S	Oral	10 Mg, Once, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2010	7260871	EXPEDITED (15-DAY)	Y	HO	1000011281		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Dermatomyositis; Myalgia; Rash	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Influenza Virus Vaccine Nos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2010	7281048	EXPEDITED (15-DAY)	Y	HO	1000011452		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Cardiogenic Shock; Coma; Disturbance In Attention; Electroencephalogram Abnormal; Intentional Overdose; Lactic Acidosis; Suicide Attempt; Tachycardia; Ventricular Hypokinesia	Escitalopram Oxalate	S	Oral	420 Mg (420 Mg, Once), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Aceprometazine Maleate\Meprobamate	S	Oral	12 Gm (12 Gm, Once), Oral, 1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral	Not Reported
	Zolpidem	S	Oral	840 Mg (840 Mg, Once), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Bromazepam	S	Oral	540 Mg (540 Mg, Once), Oral, 3 Mg (3 Mg, 1 In 1 D),Oral	Not Reported
	Mirtazapine	S	Oral	730 Mg (730 Mg, Once), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2010	7299902	DIRECT	N				50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agoraphobia; Anxiety; Dizziness; Drug Ineffective; Hyperhidrosis; Impaired Work Ability; Increased Appetite; Insomnia; Nausea; Panic Attack; Personality Disorder; Pyrexia; Swollen Tongue; Vision Blurred; Visual Acuity Reduced; Weight Increased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2010	7318916	EXPEDITED (15-DAY)	Y	DE, HO	1000011878		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Brain Death; Coma; Herpes Zoster; Respiratory Arrest; Tachycardia; Weight Increased	Lexapro		S	Oral	10 Mg (10 Mg,1 In 1 D),Oral	Not Reported
				Oral	10 Mg (10 Mg,1 In 1 D),Oral	
	Zyprexa		S	Oral	10 Mg (10 Mg,1 In 1 D), Oral	Not Reported
	Fanapt		S	Oral	2 Mg (1 Mg,2 In 1 D),Oral	Not Reported
	Sonata		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2010	7280951	EXPEDITED (15-DAY)	Y	OT	1000011466		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy; Fatigue; Macular Degeneration; Unevaluable Event; Visual Impairment	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In1 D),Oral		Not Reported
	Xyzal			C				Not Reported
	Motilium			C				Not Reported
	Oktanol			C				Not Reported
	Cromohexal (Solution)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2010	7292018	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLINCKRODT-T201000454		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone			S	Oral			Tyco
	Methylin			S	Oral			Tyco
	Phenytoin			S	Oral			Not Reported
	Phenobarbital			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Emtricitabine And Tenofovir Disoproxil Fumarate			S	Oral			Not Reported

	Metformin Hydrochloride			S	Oral				Not Reported
	Zolpidem			S	Oral				Not Reported
	Ondansetron			S	Oral				Not Reported
	Pregabalin			S	Oral				Not Reported
	Metoclopramide Hydrochloride			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2010	7292024	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLIN CKRODT-T201000475		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Temazepam			S	Oral			Tyco
	Escitalopram Oxalate			S	Oral			Not Reported
	Duloxetine			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2010	7292029	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLIN CKRODT-T201000456		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Methylin			S	Oral			Tyco
	Escitalopram Oxalate			S	Oral			Not Reported
	Acetaminophen			S				Not Reported
	Ibuprofen			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2010	7292030	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLIN CKRODT-T201000458		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Completed Suicide	Oxycodone	S	Oral		Tyco
	Escitalopram Oxalate	S	Oral		Not Reported
	Cocaine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2010	7292102	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010019849			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Drug Interaction; Personality Disorder	Chantix			S	Oral	Unk		Pfizer
	Lexapro			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2010	7302776	DIRECT		OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Contamination; Rash	Lexapro			S	Oral	10 Mg Daily Po	8 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2010	7317648	DIRECT	N				52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Withdrawal Syndrome; Dysphonia; Fatigue; Nightmare; Product Substitution Issue; Somnolence	Citalopram			S	Oral	60 Mg Daily Oral		Mylan
	Trazodone Hydrochloride			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2010	7317996	EXPEDITED (15-DAY)	Y	OT	1000011980		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fatigue; Feeling Abnormal; Somnambulism; Tetany	Escitalopram Oxalate		S	Oral	5 Mg (5 Mg,1 In 1 D), Oral	Not Reported
	Oligosol Lithium		C			Not Reported
	Contraceptives Nos		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2010	7319989	EXPEDITED (15-DAY)	N	OT	1000011845		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Lethargy; Seizure	Lexapro			S	Oral	10 Mg (10 Mg,Once), Oral		Not Reported
	Lamictal (200 Milligram, Tablets)			C				Not Reported
	Aricept (1 Milligram, Tablets)			C				Not Reported
	Xanax (1 Milligram, Tablets)			C				Not Reported
	Keppra (500 Milligram, Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2010	7320807	EXPEDITED (15-DAY)	Y	OT	1000011947			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Chromaturia	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2010	7293740	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2010US-31277			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Hydrocodone Bitartrate And Acetaminophen			S	Oral	Unk, Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral			Not Reported
	Oxycodone And Acetaminophen			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2010	7321120	EXPEDITED (15-DAY)	Y	DE	100218-0000207		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Methamphetamine Hydrochloride			S	Oral	Po		Not Reported
	Propoxyphene Hydrochloride			S	Oral	Po		Not Reported
	Chlordiazepoxide			S	Oral	Po		Not Reported
	Escitalopram Oxalate			S	Oral	Po		Not Reported
	Bupropion			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2010	7322248	EXPEDITED (15-DAY)	Y	OT	IDA-00332		36 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Hallucination, Auditory; Psychotic Disorder; Suicidal Ideation	Propranolol			S	Oral	80 Mg Daily Oral	29 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Daily / 20 Mg Daily Oral / Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2010	7324397	EXPEDITED (15-DAY)	Y	OT	1000011984		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gamma-Glutamyltransferase Increased; Headache; Hepatic Function Abnormal; Overdose; Transaminases Increased; Vomiting	Escitalopram Oxalate			S		40 Mg (40 Mg, 1 In 1 D); 5 Mg (5 Mg,1 In 1 D) 40 Mg (40 Mg, 1 In 1 D); 5 Mg (5 Mg,1 In 1 D)		Not Reported
	Edronax			S		12 Mg (12 Mg, 1 In 1 D)		Not Reported
	Abilify			S		1 0 Mg (10 Mg, 1 In 1 D)		Not Reported
	Seroquel			S		25 Mg (25 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2010	7234849	EXPEDITED (15-DAY)	Y	OT	1000009359		25 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Endometriosis; Maternal Exposure During Pregnancy; Platelet Count Decreased; Pregnancy; Small For Dates Baby	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg,1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2010	7234856	EXPEDITED (15-DAY)	Y	HO, OT	1000009358		24 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Ovulation Pain; Polycystic Ovaries; Pregnancy	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2010	7243464	EXPEDITED (15-DAY)	N	OT	1000010827		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Depressed Mood; Dissociation; Dizziness; Drug Ineffective; Fatigue; Hyperhidrosis; Insomnia; Nightmare; Overdose; Presyncope; Self-Injurious Ideation; Somnolence; Suicidal Ideation; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Quetiapine			S	Oral	50 Mg (50 Mg,1 In 1 D), Oral		Not Reported
	Quetiapine			S	Oral	200 Mg (200 Mg,1 In 1 D), Oral		Not Reported
	Wellbutrin			S	Oral	150 Mg (150 Mg,1 In 1 D), Oral		Not Reported
	Bupropion Hydrochloride			S	Oral	300 Mg (150 Mg,2 In 1 D), Oral		Not Reported
	Quetiapine			C	Oral	300 Mg (300 Mg, 1 In 1 D), Oral		Not Reported
	Sleeping Pill			C				Not Reported

	Premarin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2010	7251247	EXPEDITED (15-DAY)		OT	1000011129		46 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Diarrhoea; Dizziness; Dry Eye; Ear Pain; Fatigue; Headache; Hyperhidrosis; Hypotension; Mental Disorder; Myalgia; Neck Pain; Oropharyngeal Pain; Somnolence; Urine Output Increased; Vision Blurred; Weight Decreased	Lexapro			S	Oral	10 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2010	7289679	EXPEDITED (15-DAY)	Y	HO	1000011489		58 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram Oxalate			S		5 Mg		Not Reported
	Enalapril Maleate			S		20 Mg		Not Reported
	Enalapril Maleate And Hydrochlorothiazide			S		10/25 Mg		Not Reported
	Biosoprolol			C				Not Reported
	Zopiclone			C				Not Reported
	Lorazepam			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2010	7296303	NON-EXPEDITED	Y	HO	A0770993A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lamictal			S	Oral			Glaxosmithkline

	Lexapro	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2010	7304273	EXPEDITED (15-DAY)	Y	OT	1000011759			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Bradycardia; Cerebral Ischaemia; Dizziness; Loss Of Consciousness; Off Label Use; Seizure	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg,1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7125735	EXPEDITED (15-DAY)	Y	HO	CH-ASTRAZENECA-2009SE14097		27 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiometabolic Syndrome	Seroquel			S	Oral		242 DAY	Not Reported
	Seroquel			S	Oral		29 DAY	Not Reported
	Lithium			C				Not Reported
	Aripiprazole			C				Not Reported
	Paliperidone			C				Not Reported
	Olanzapine			C				Not Reported
	Cipralex			S	Oral		14 DAY	Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7290264	EXPEDITED (15-DAY)	Y	HO	1000011562		45 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyskinesia; Ejaculation Disorder; Libido Decreased	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Abilify			S		15 Mg (15 Mg, 1 In 1 D)		Not Reported
	Abilify			S		15 Mg (15 Mg, 1 In 1 D);		Not Reported

			10 Mg (10 Mg, 1 In 1 D) 15 Mg (15 Mg, 1 In 1 D); 10 Mg (10 Mg, 1 In 1 D)	
Edronax	S		2 Mg (2 Mg, 1 In 1 D)	Not Reported
Edronax	S		4 Mg (4 Mg, 1 In 1 D), 2 Mg (2 Mg, 1 In 1 D) 4 Mg (4 Mg, 1 In 1 D), 2 Mg (2 Mg, 1 In 1 D)	Not Reported
Zyprexa	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7300184	EXPEDITED (15-DAY)	Y	DE	CHPA2010US03729		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Diphenhydramine Hydrochloride		Y	S				Novartis
	Doxepin			S				Not Reported
	Alcohol			S				Not Reported
	Clonazepam			S				Not Reported
	Clonidine			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Sildenafil Citrate			S				Not Reported
	Sertraline Hydrochloride			S				Not Reported
	Duloxetine			S				Not Reported
	Oxybutynin			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7304457	DIRECT	N	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction	Lexapro			S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7307454	DIRECT	N	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Staring	Lexapro			S		10/Mg 1x Daily In The Morning 10/Mg 1x Daily In The Morning 10/Mg 1x Daily In The Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7324682	EXPEDITED (15-DAY)	Y	DE	1000012072		18 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported
	Diazepam			S				Not Reported
	Paroxetine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7324688	EXPEDITED (15-DAY)	Y	DE	1000012069		53 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram Oxalate			S				Not Reported
	Duloxetine			S				Not Reported
	Zolpidem			S				Not Reported
	Temazepam			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7324691	EXPEDITED (15-DAY)	Y	DE	1000012074		26 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Oxycodone			S				Not Reported
	Cocaine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7324700	EXPEDITED (15-DAY)	Y	DE	1000012070		53 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram Oxalate			S				Not Reported
	Doxepin			S				Not Reported
	Benzodiazepine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7324707	EXPEDITED (15-DAY)	Y	DE	1000012073		20 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram Oxalate			S				Not Reported
	Propoxyphene Hydrochloride			S				Not Reported
	Methamphetamine Hydrochloride			S				Not Reported
	Bupropion Hydrochloride			S				Not Reported
	Chlordiazepoxide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7324716	EXPEDITED (15-DAY)	Y	DE	1000012084		21 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram Oxalate			S				Not Reported
	Acetaminophen			S				Not Reported
	Ibuprofen			S				Not Reported
	Methylphenidate			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7324722	EXPEDITED (15-DAY)	Y	DE	1000012081		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Escitalopram Oxalate			S				Not Reported

	Doxepin	S		Not Reported
	Alcohol	S		Not Reported
	Clonazepam	S		Not Reported
	Clonidine	S		Not Reported
	Unspecified Ingredient	S		Not Reported
	Diphenhydramine	S		Not Reported
	Sildenafil Citrate	S		Not Reported
	Sertraline Hydrochloride	S		Not Reported
	Duloxetine	S		Not Reported
	Oxybutynin	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7324839	EXPEDITED (15-DAY)	Y	DE	1000012126		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Citalopram			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Venlafaxine			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2010	7325506	EXPEDITED (15-DAY)	Y	DE	10000012068		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Metoprolol			S				Not Reported
	Carisoprodol			S				Not Reported
	Clopidogrel			S				Not Reported
	Diazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2010	7276587	EXPEDITED (15-DAY)	Y	OT	1000011372		52 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Symptom; Epistaxis; Gingival Bleeding; Oedema	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

Peripheral; Vascular Rupture	Escitalopram Oxalate		S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
				Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral	
	Q10		C			Not Reported
	Lovaza		C			Not Reported
	Halibut		C			Not Reported
	Femoston		C			Not Reported
	Dafalgan		C			Not Reported
	Aspirin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2010	7301627	EXPEDITED (15-DAY)	Y	DE	US-WYE-H13727410		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ibuprofen			S	Oral	Unknown		Wyeth
	Alcohol			S	Oral	Unknown		Unknown
	Methylphenidate			S	Oral	Unknown		Unknown
	Escitalopram Oxalate			S	Oral	Unknown		Unknown
	Acetaminophen			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2010	7302220	EXPEDITED (15-DAY)	Y	HO	FR-WYE-H13738510		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Inipomp			S	Oral	Daily Dose Unknown		Wyeth
	Furosemide			S	Oral	Unknown		Unknown
	Digoxine			S	Oral	Unknown		Unknown
	Escitalopram Oxalate			S	Oral	Unknown		Lundbeck
	Prinzide			S	Oral	Unknown		Merck Sharp And Dohme
	Vastarel			C		35 Mg, Frequency		Not Reported

				Unknown	
	Ferrous Sulfate		C	80 Mg, Frequency Unknown	Not Reported
	Prednisone		C	20 Mg, Frequency Unknown	Unknown
	Previscan (Fluindione)		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2010	7307039	DIRECT	N				61 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Alcoholism; Loss Of Consciousness	Lexapro			S	Oral	10 Mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2010	7326639	EXPEDITED (15-DAY)	Y	HO	1000012046		87 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Increased; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Lisinopril			S	Oral	Oral		Not Reported
	Digoxin			S	Oral	Oral		Not Reported
	Digoxine			C				Not Reported
	Inipomp			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Vastarel			C				Not Reported
	Prednisolone\Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2010	7326643	EXPEDITED (15-DAY)		OT	1000012079		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Crying;	Escitalopram Oxalate			S	Oral	5 Mg, Oral; 10 Mg, Oral;		Not Reported

Depression; Disturbance In Attention; Drug Ineffective; Fatigue; Feeling Hot; Feeling Of Despair; Irritability; Lethargy; Merycism; Panic Disorder; Paraesthesia; Restlessness; Scratch; Terminal Insomnia; Weight Increased					
			Oral	15 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral; 20 Mg, Oral	
			Oral	5 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral; 20 Mg, Oral	
			Oral	5 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral; 20 Mg, Oral	
			Oral	5 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral; 20 Mg, Oral	
			Oral	5 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral; 20 Mg, Oral	
	Buspar	C			Not Reported
	Amitriptyline	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2010	7289166	EXPEDITED (15-DAY)	Y	DE	US-ABBOTT-10P-163-0626528-00		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Valproic Acid			S		Ingestion		Not Reported
	Escitalopram Oxalate			S		Ingestion		Not Reported
	Aripiprazole			S		Ingestion		Not Reported
	Amphetamine			S		Ingestion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2010	7304245	NON-EXPEDITED	Y		US-ABBOTT-09P-163-0609101-00		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction	Biaxin			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

	Escitalopram Oxalate	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2010	7307603	DIRECT	N	LT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Abnormal Dreams; Emotional Disorder; Hallucination, Visual; Insomnia; Psychomotor Hyperactivity; Thinking Abnormal	Cymbalta			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2010	7310456	EXPEDITED (15-DAY)	Y	OT	1000011812		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Skin Exfoliation	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Lorazepam			C				Not Reported
	Aspirin			C				Not Reported
	Oxycodone Hcl Controlled-Release			C				Not Reported
	Nicotine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2010	7327600	EXPEDITED (15-DAY)	Y	DE	2010020075		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Carisoprodol			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

	Metoprolol		S	Oral	Oral	Not Reported
	Clopidogrel		S	Oral	Oral	Not Reported
	Diazepam		C	Oral	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2010	7327623	EXPEDITED (15-DAY)	Y	OT	1000012133		19 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Condition Aggravated; Hostility	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2010	7345048	EXPEDITED (15-DAY)	Y	HO	1000012497		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Breast Discomfort	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2010	7177203	EXPEDITED (15-DAY)	Y	HO, LT	FR-MERCK-0911FRA00030		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Asthenia; Diarrhoea; Hyperkalaemia; Nausea; Vomiting	Januvia			S	Oral		1 MTH	Merck
	Metformin			S	Oral		1 MTH	Not Reported
	Hydrochlorothiazide\Irbesartan			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Esomeprazole Magnesium			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Fenofibrate			C	Unknown			Not Reported

	Acepromazine\Aceprometazine\ Clorazepate Dipotassium	C	Unknown	Not Reported
	Alprazolam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2010	7207642	EXPEDITED (15-DAY)	N	OT	A0832872A		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Intolerance; Fall; Nausea; Petit Mal Epilepsy; Seizure; Suicidal Ideation; Visual Impairment	Lamictal			S	Oral	200mg Per Day		Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Keppra			S	Oral			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2010	7220906	EXPEDITED (15-DAY)	Y	DE, LT	1000010345		81 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Inflammation; International Normalised Ratio Increased; Muscle Haemorrhage; Necrosis; Sepsis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Acetaminophen\Tramadol Hydrochloride			S	Oral	2 Dosage Forms (2 Dosages Forms, 1 In 1 D), Oral		Not Reported
	Previscan (Fluindione)			S	Oral	0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Previscan (Fluindione)			S	Oral	0.25 Dosage Forms (0.25 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Triatec (Ramipril)			C				Not Reported
	Nafronyl Oxalate			C				Not Reported
	Contalax			C				Not Reported
	Xanax			C				Not Reported
	Lioresal			C				Not Reported

	Propoxyphene Hydrochloride And Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2010	7237039	EXPEDITED (15-DAY)	Y	OT	1000010668		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Haemorrhage; Vaginal Haemorrhage	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Citalopram			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2010	7305140	EXPEDITED (15-DAY)	N	OT	ES-BRISTOL-MYERS SQUIBB COMPANY-14993265		67 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Hydrochlorothiazide\Irbesartan			S	Oral			Bristol Myers Squibb
	Cipralex			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Gemfibrozil			S	Oral			Sandoz
	Alendronate Sodium			C	Oral			Not Reported
	Ropinirole Hydrochloride			C	Oral			Not Reported
	Cholecalciferol			C	Oral			Not Reported
	Simvastatin			C	Oral			Not Reported
	Torasemide			C	Oral			Not Reported
	Zolpidem			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2010	7305869	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2010RR-31735		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen			S	Oral			Ranbaxy
	Escitalopram Oxalate			S	Oral			Not Reported
	Ibuprofen			S	Oral			Ranbaxy
	Methylphenidate			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2010	7305889	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2010RR-31727		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Phenobarbital			S	Oral			Ranbaxy
	Phenytoin			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Trazodone Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Emtricitabine And Tenofovir Disoproxil Fumarate			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Methylphenidate			S	Oral			Not Reported
	Metformin Hydrochloride			S	Oral			Ranbaxy
	Zolpidem			S	Oral			Ranbaxy
	Ondansetron			S	Oral			Natco Pharma
	Pregabalin			S	Oral			Not Reported
	Metoclopramide			S	Oral			Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2010	7329074	EXPEDITED (15-DAY)	Y	HO	1000012132		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alcohol Use; Dysphagia; Fall; Food Intolerance; Gastrointestinal Disorder; Head Injury; Hypokalaemia; Iatrogenic Injury; Inappropriate Antidiuretic Hormone Secretion; Seizure; Vomiting	Escitalopram Oxalate	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Seresta	C				Not Reported
	Stilnox	C				Not Reported
	Gaviscon	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2010	7329554	EXPEDITED (15-DAY)	Y	HO	1000012189		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Glucose Increased; Drug Interaction; Gamma-Glutamyltransferase Increased; Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Omeprazole			S	Oral	40 Mg, Oral		Not Reported
	Spironolactone			S	Oral	25 Mg, Oral		Not Reported
	Atacand			S	Oral	16 Mg, Oral		Not Reported
	Levothyroxine Sodium			C				Not Reported
	Metamizol			C				Not Reported
	Carmen [Lercanidipine Hydrochloride]			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Aspirin			C				Not Reported
	Sotalol Hydrochloride			C				Not Reported
	Diclofenac			C				Not Reported
	Nitrospray			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2010	6944812	EXPEDITED (15-DAY)	N	OT	1000000357		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Anxiety; Blood Pressure Increased; Burning Sensation; Cardiac	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),		Not Reported

Murmur; Hot Flush; Hyperhidrosis; Muscular Weakness; Myalgia; Palpitations; Supraventricular Tachycardia; Tinnitus; Urinary Incontinence; Withdrawal Syndrome	Lexapro	S	Oral	Oral 10 Mg (10 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral	Not Reported
	Metoprolol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2010	7170403	EXPEDITED (15-DAY)	N	OT	1000003105		35 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alcohol Use; Feeling Abnormal; Homicide	Lexapro			S				Not Reported
	Xanax			C				Not Reported
	Alcohol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2010	7284530	EXPEDITED (15-DAY)	Y	HO	1000011473		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Headache; Menstruation Irregular	Escitalopram Oxalate			S		15 Mg (15 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2010	7288507	EXPEDITED (15-DAY)	Y	DE, HO, LT	1000011493		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Fall	Escitalopram Oxalate			S		15-20 Mg Daily		Not Reported
	Risperdal			S		6 Mg (6 Mg, 1 In 1 D)		Not Reported
	Akineton			S		4 Mg (4 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2010	7291851	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2010US-31191			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Overdose	Verapamil Hydrochloride			S	Oral	Unk, Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral	Un, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2010	7306000	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2010RR-31974		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Death	Sertraline Hydrochloride			S	Unknown			Ranbaxy
	Doxepin			S	Unknown			Not Reported
	Alcohol			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Clonidine			S	Unknown			Not Reported
	Diphenhydramine			S	Unknown			Not Reported
	Sildenafil			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported
	Oxybutynin			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2010	7306069	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2010RR-32001		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zolpidem			S	Oral			Ranbaxy
	Escitalopram Oxalate			S	Oral			Not Reported
	Duloxetine			S	Oral			Not Reported

	Temazepam	S	Oral		Not Reported
	Alcohol	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2010	7306871	EXPEDITED (15-DAY)	Y	OT	US-AMGEN-QUU395312			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Mental Disorder	Sensipar			S	Unknown			Not Reported
	Zoloft			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2010	7330161	EXPEDITED (15-DAY)	N	OT	1000011799		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Malaise; Maternal Exposure During Pregnancy; Mental Disorder; Pregnancy; Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2010	7330667	EXPEDITED (15-DAY)	Y	HO	DSA_42676_2010		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Gastric Ulcer; Gastritis; Haemoglobin Decreased; Rectal Haemorrhage; Vertigo	Mono-Tildiem			S	Oral	(Df Oral)		Not Reported
	Folic Acid			S	Oral	(Df Oral)		Not Reported
	Zopiclone			S	Oral	(Df Oral)		Not Reported
	Plavix			S	Oral	(Df Oral)		Not Reported
	Kardegic (Acetylsalicylate Lysine)			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Nicobion			S	Oral	(Df Oral)		Not Reported

Glucophage	S	Oral	(Df Oral)		Not Reported
Micardis	S	Oral	(Df Oral)		Not Reported
Esomeprazole (Esomeprazole)	S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2010	6150289	EXPEDITED (15-DAY)	Y	OT	S06-NOR-04143-01		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy	Cipralex			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Cipralex			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg,1 In 1 D),Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2010	7308065	EXPEDITED (15-DAY)	N	DE	FR-BRISTOL-MYERS SQUIBB COMPANY-14998264		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Abilify			S	Oral		1 YR	Not Reported
	Abilify			S	Oral		1 YR	Not Reported
	Donormyl (Doxylamine Succinate)			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Equanil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2010	7314243	DIRECT	N	OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Dizziness; Headache	Lexapro	S	Oral	10 Mg Once Per Day Po	6 MTH	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2010	7332562	EXPEDITED (15-DAY)	Y	HO	1000012300		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paresis; Seizure	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2010	7043355	EXPEDITED (15-DAY)	N	LT	1000007006		30 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; General Physical Health Deterioration; Gun Shot Wound; Hallucination, Auditory; Mental Impairment; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			S	Oral	0.75 Mg (0.25 Mg,3 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2010	7182202	EXPEDITED (15-DAY)	Y	HO, OT	1000009815		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Cholesterol Increased; Gynaecomastia; Hiatus Hernia; Pain	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Clonazepam			S	Oral	1 Mg (0.5 Mg, 2 In 1 D), Oral		Not Reported
	Clonazepam			S	Oral	1 Mg (0.5 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2010	7318582	DIRECT	N	LT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Lexapro			S	Oral	1 10mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2010	7320390	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000011881		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Ataxia; Blood Creatinine Increased; Muscle Rigidity; Neuroleptic Malignant Syndrome; Overdose; Pneumonia Aspiration; Poisoning Deliberate; Urinary Incontinence	Escitalopram Oxalate			S				Not Reported
	Olanzapine			S		(300 Mg, Once)		Not Reported
	Chlorpromazine			S		(700 Mg, Once)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2010	7331682	EXPEDITED (15-DAY)	Y	HO	1000012306		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Gastritis; Haemoglobin Decreased; Rectal Haemorrhage; Ulcer	Escitalopram Oxalate			S				Not Reported
	Plavix			S				Not Reported
	Aspirin Lysine			S				Not Reported
	Nicobion			C				Not Reported
	Glucophage			C				Not Reported
	Micardis			C				Not Reported
	Speciafoldine			C				Not Reported
	Mono-Tildiem			C				Not Reported
	Imovane			C				Not Reported
	Inexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2010	7331689	EXPEDITED (15-DAY)	Y	OT	1000012284		55 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoptysis; Metrorrhagia	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2010	7331776	EXPEDITED (15-DAY)	Y	OT	1000012320		67 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Pantoprazole			S	Oral	80 Mg (40 Mg, 2 In 1 D), Oral		Not Reported
	Seroquel			S	Oral	(100 Mg), Oral		Not Reported
	Gemfibrozil			S	Oral	600 Mg (600 Mg, 1 In 1 D), Oral		Not Reported
	Irbesartan And Hydrochlorothiazide			S	Oral	150/12.5 Mg, Oral		Not Reported
	Alendronate			C				Not Reported
	Ropinirole Hydrochloride			C				Not Reported
	Bonesil D Flas			C				Not Reported
	Simvastatin			C				Not Reported
	Torasemide			C				Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2010	7331859	EXPEDITED (15-DAY)	Y	OT	1000012281		88 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Hallucination; Loss Of	Escitalopram Oxalate			S	Oral	(10 Mg), Oral		Not Reported

Personal Independence In
Daily Activities

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2010	7350757	NON-EXPEDITED	N		2010SP000842		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Saphris			S				Not Reported
	Lexapro			S		20 Mg		Not Reported
	Plavix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2010	7313854	EXPEDITED (15-DAY)	N	OT	A0849203A		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Chest Discomfort; Crying; Decreased Interest; Depressed Mood; Dissociation; Dizziness; Drug Ineffective; Fatigue; Feeling Hot; Hyperhidrosis; Inappropriate Affect; Insomnia; Negative Thoughts; Presyncope; Somnolence; Suicidal Ideation; Vomiting	Wellbutrin Sr			S	Oral	150mg Per Day	1 MTH	Glaxosmithkline
	Wellbutrin Sr			S	Oral	150mg Twice Per Day		Glaxosmithkline
	Cipralex			S	Oral	10mg Per Day		Not Reported
	Cipralex			S	Oral	20mg Per Day		Not Reported
	Cipralex			S	Oral	30mg Per Day		Not Reported
	Quetiapine			S	Oral	200mg Per Day	1 DAY	Glaxosmithkline
	Quetiapine			S	Oral	100mg Per Day	1 DAY	Glaxosmithkline
	Quetiapine			S	Oral	50mg Per Day	1 DAY	Glaxosmithkline
	Quetiapine			S	Oral	300mg Per Day	31 DAY	Glaxosmithkline
	Premarin			C				Not Reported
	Sleeping Pill			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2010	7320192	EXPEDITED (15-DAY)	Y	OT	1000011892		22 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Euphoric Mood;	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D),		Not Reported

Hypomania; Tremor							Oral			
	Remeron			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2010	7334350	EXPEDITED (15-DAY)	Y	OT	1000012288			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2010	7334351	EXPEDITED (15-DAY)	Y	OT	1000011582		55 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Decreased Appetite; Weight Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexomil			C				Not Reported
	Iperten			C				Not Reported
	Celiprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2010	7213206	EXPEDITED (15-DAY)	Y	OT	DK-ABBOTT-09P-044-0612025-00		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Libido Decreased; Suicidal Ideation	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Pantoprazole			C				Not Reported
	Omega-3-Triglycerides Incl. Other Esters/Acids(Pikasol Gi 60, Axellus)			C				Not Reported
	Folic Acid			C				Not Reported
	Isoniazid			C				Not Reported
	Methotrexate			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2010	7290477	EXPEDITED (15-DAY)	Y	HO	1000011528		27 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Drug Interaction; Erectile Dysfunction; Loss Of Libido	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Amisulpride			S	Oral	200 Mg (200 Mg, 1 In 1 D), Oral 300 Mg (300 Mg, 1 In 1 D), Oral 400 Mg (400 Mg, 1 In 1 D), Oral		Not Reported
					Oral	200 Mg (200 Mg, 1 In 1 D), Oral 300 Mg (300 Mg, 1 In 1 D), Oral 400 Mg (400 Mg, 1 In 1 D), Oral		
					Oral	200 Mg (200 Mg, 1 In 1 D), Oral 300 Mg (300 Mg, 1 In 1 D), Oral 400 Mg (400 Mg, 1 In 1 D), Oral		
	Quilonum			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2010	7330332	EXPEDITED (15-DAY)	Y	CA	1000012166			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroschisis; Maternal Drugs Affecting Foetus; Talipes	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2010	7323393	DIRECT	Y	DE			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Completed Suicide; Feeling Of Despair; Insomnia;	Lexapro			S		Unknown	2 WEEK	Not Reported

Medication Error; Product Prescribing Error

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2010	7336245	EXPEDITED (15-DAY)	Y	HO	1000012338		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Insulin Increased; Hypoglycaemia; Insulin C-Peptide Increased; Seizure	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Teralithe (Tablets)			C				Not Reported
	Lysanxia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2010	7261279	EXPEDITED (15-DAY)	Y	DE	2010VX000024		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Blood Pressure Decreased; Catheter Site Haemorrhage; Completed Suicide; Electrocardiogram Qrs Complex Prolonged; Peritoneal Haemorrhage; Poisoning; Sinus Bradycardia; Urine Output Decreased; Vomiting	Diastat			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Metoprolol			S				Not Reported
	Carisoprodol			S				Not Reported
	Clopidogrel			S				Not Reported
	Candesartan Cilexetil			C				Not Reported
	Verapamil Hydrochloride			C				Not Reported
	Conjugated Estrogen/Medroxyprogesterone Acetate			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2010	7261530	EXPEDITED (15-DAY)	Y	DE	2010VX000049		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Areflexia; Aspiration; Brain Death; Brain Oedema;	Diastat			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported

Completed Suicide; Heart Rate Increased; Hypoxic-Ischaemic Encephalopathy; Intentional Overdose; Poisoning; Pulse Absent; Pupil Fixed; Respiration Abnormal; Respiratory Distress; Thrombosis; Unresponsive To Stimuli	Escitalopram Oxalate	S	Not Reported
	Paroxetine Hydrochloride	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2010	7308368	EXPEDITED (15-DAY)	Y	HO	1000011813		99 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Petit Mal Epilepsy	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lamictal			C				Not Reported
	Levothyrox			C				Not Reported
	Bumex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2010	7319606	EXPEDITED (15-DAY)	Y	OT	DE-ROXANE LABORATORIES, INC.-2010-RO-00249RO		23 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Apathy; Asthenia; Autonomic Nervous System Imbalance; Drug Abuse; Drug Dependence; Panic Attack; Rhinalgia; Tachycardia	Cocaine			S				Roxane
	Bupropion			S		150 Mg		Not Reported
	Bupropion			S		300 Mg		Not Reported
	Bupropion			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2010	7325584	DIRECT	Y	DS, LT, OT			18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dissociation; Hypersomnia; Incorrect Dose Administered; Intentional Self-Injury; Liver Disorder; Suicide Attempt; Vomiting	Lexapro		S	Oral	Lexapro /1 Tab/10mg Q Day Po	14 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2010	7339001	EXPEDITED (15-DAY)	Y	DE	2010VX000097		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning; Pulmonary Oedema; Toxicity To Various Agents	Chlordiazepoxide Hydrochloride			S				Not Reported
	Propoxyphene Hydrochloride			S				Not Reported
	Methamphetamine Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Bupropion			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2010	7339917	EXPEDITED (15-DAY)	Y	HO	1000012427		51 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture	Escitalopram Oxalate			S	Oral	10 Mg, Oral; 20 Mg, Oral; 30 Mg, Oral; 20 Mg, Oral; 30 Mg, Oral; 35 Mg, Oral		Not Reported
					Oral	10 Mg, Oral; 20 Mg, Oral; 30 Mg, Oral; 20 Mg, Oral; 30 Mg, Oral; 35 Mg, Oral		
					Oral	10 Mg, Oral; 20 Mg, Oral; 30 Mg, Oral; 20 Mg, Oral; 30 Mg, Oral; 35 Mg, Oral		
					Oral	10 Mg, Oral; 20 Mg, Oral; 30 Mg, Oral; 20 Mg, Oral; 30 Mg, Oral; 35 Mg, Oral		
					Oral	10 Mg, Oral; 20 Mg, Oral; 30 Mg, Oral; 20 Mg, Oral; 30 Mg, Oral; 35 Mg, Oral		
					Oral	10 Mg, Oral; 20 Mg, Oral;		

	Escitalopram Oxalate		S	Oral	30 Mg, Oral; 20 Mg, Oral; 30 Mg, Oral; 35 Mg, Oral 40 Mg, Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2010	7340626	EXPEDITED (15-DAY)	Y	OT	1000012376		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Intentional Overdose; Suicide Attempt; Unevaluable Event	Escitalopram Oxalate			S	Oral	Dosage (Once), Oral		Not Reported
	Alcohol			S	Oral	(Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2010	7321346	EXPEDITED (15-DAY)	Y	HO	US-ASTRAZENECA-2010SE07606		88 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Atacand			S	Oral			Not Reported
	Levothyroxine Sodium			C	Oral			Not Reported
	Dipyrone			C	Oral			Not Reported
	Lercanidipine			C	Oral			Not Reported
	Metformin Hydrochloride			C	Oral			Not Reported
	Aspirin			C	Oral			Not Reported
	Sotalol			C	Oral			Not Reported
	Diclofenac			C	Oral			Not Reported
	Nitrospray			C		Two Puffs In Case Of Need		Not Reported
	Omeprazole			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Spironolactone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2010	7317320	EXPEDITED (15-DAY)	N	LT, OT	1000011855		29 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Dry Mouth; Fatigue; Headache; Homicidal Ideation; Hyperhidrosis; Insomnia; Panic Attack; Self-Injurious Ideation; Suicidal Ideation; Tremor	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 2.5 Mg (5 Mg, 1 In 2 D), Oral		Not Reported
					Oral	20 Mg (10 Mg, 2 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 2.5 Mg (5 Mg, 1 In 2 D), Oral		
					Oral	20 Mg (10 Mg, 2 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 2.5 Mg (5 Mg, 1 In 2 D), Oral		
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	2 Mg (2 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro Oral Soultion (Escitalopram Oxalate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2010	7344582	EXPEDITED (15-DAY)	Y	OT	1000012501		15 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania; Off Label Use	Escitalopram Oxalate			S	Oral	(10 Mg), Oral		Not Reported
	Clorazepate Dipotassium			C				Not Reported
	Risperdal			C				Not Reported
	Toprimate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2010	6928396	EXPEDITED (15-DAY)	Y	OT	1000004763		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Paranoia	Memantine Hydrochloride			S		20 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	(10 Mg) Oral		Not Reported
	Donepezil Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2010	7241583	EXPEDITED (15-DAY)	Y	OT	1000010863		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fall; Nausea; Overdose; Petit Mal Epilepsy; Seizure; Suicidal Ideation; Visual Impairment	Lexapro			S	Oral	(10 Mg), Oral; (30 Mg), Oral		Not Reported
	Lamictal			S	Oral	(1 In 1 D), Oral; (100 Mg), Oral; (200 Mg), Oral; (475 Mg), Oral; (500 Mg), Oral		Not Reported
					Oral	(1 In 1 D), Oral; (100 Mg), Oral; (200 Mg), Oral; (475 Mg), Oral; (500 Mg), Oral		
					Oral	(1 In 1 D), Oral; (100 Mg), Oral; (200 Mg), Oral; (475 Mg), Oral; (500 Mg), Oral		
					Oral	(1 In 1 D), Oral; (100 Mg), Oral; (200 Mg), Oral; (475 Mg), Oral; (500 Mg), Oral		
	Keppra			S	Oral Oral	Oral; (3000 Mg), Oral Oral; (3000 Mg), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2010	7346643	EXPEDITED (15-DAY)	Y	HO	1000012533		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression Suicidal; Off Label Use; Panic Reaction	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2010	7214107	EXPEDITED (15-DAY)	Y	HO	1000008874		92 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2010	7269303	EXPEDITED (15-DAY)	N	DE, HO	DE-BRISTOL-MYERS SQUIBB COMPANY-14927875		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Abilify			S	Oral	Approximately 20mg Dose Increased To 20mg From 12aug09		Not Reported
	Unspecified Ingredient			S				Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Tavor (Lorazepam)			S	Oral			Not Reported
	Levothyroxine Sodium			C	Oral			Not Reported
	Simeticone			C	Oral	1 Df= 3x40 Gtts		Not Reported
	Movicol			C	Oral	1 Df= 1 Bag		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2010	7330066	DIRECT	N	HO, LT, OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Tightness; Palpitations; Supraventricular Tachycardia; Treatment	Lexapro			S		10mg 1x Day		Forest

Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2010	7330469	DIRECT	N	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Muscle Twitching	Lexapro			S	Oral	10 Mg 1/Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2010	7346975	EXPEDITED (15-DAY)	Y	OT	1000012409			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported
	Risperidone			S	Transplacental	2 In 1 D, Transplacental		Not Reported
	Echinacea Angustifolia			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Multivitamins, Other Combinations			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2010	7153955	EXPEDITED (15-DAY)	Y	OT	1000009197		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Loss Of Consciousness; Presyncope; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Enalapril Maleate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Kaleorid			C				Not Reported
	Hjerdyl			C				Not Reported
	Furosemid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2010	7331694	EXPEDITED (15-DAY)	Y	DE, OT	1000011778		77 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Coma; Hallucination, Visual	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Antihypertensives			C				Not Reported
	Antiaggregant Therapy			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2010	7348986	EXPEDITED (15-DAY)	Y	OT	1000012563		44 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral; Sudden Hearing Loss	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2010	7336990	EXPEDITED (15-DAY)	Y	OT	1000012382		36 YR	Female	EST

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Eye Swelling; Menorrhagia; Oedema Mouth; Pruritus	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral		
	Xanax			C				Not Reported
	Retafer			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2010	7329066	EXPEDITED (15-DAY)	Y	HO, OT	1000012161		47 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral	(Once), Oral		Not Reported
	Bromazepam			S	Oral	(300 Mg,Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2010	7348927	EXPEDITED (15-DAY)	Y	HO	1000012608		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cheilitis; Dysphagia; Oral Disorder; Rash Vesicular; Toxic Skin Eruption	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Tegretol			S	Oral	Oral		Not Reported
	Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2010	7350937	EXPEDITED (15-DAY)	Y	DE	1000012605		30 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Escitalopram Oxalate			S	Oral	30 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2010	7257121	EXPEDITED (15-DAY)	Y	LT, OT	1000011230		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Body Temperature Decreased; Confusional State; Decreased Appetite; Disturbance In Attention; Dizziness; Dry Mouth; Fatigue; Fear; Hypoaesthesia; Incoherent; Muscle Tightness; Muscular	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg), Oral, 5 Mg (5 Mg), Oral		Not Reported
					Oral	10 Mg (10 Mg), Oral, 5 Mg (5 Mg), Oral		
	Imovane			C				Not Reported
	Sobril			C				Not Reported

Weakness; Nausea; Off Label Use; Restlessness; Suicidal Ideation; Tachyphrenia; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2010	7331508	EXPEDITED (15-DAY)	Y	OT	US-BAXTER-2010BH007086		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia	Gammagard Liquid			S	Intravenous (not otherwise specified)			Not Reported
	Gammagard Liquid			S	Intravenous (not otherwise specified)			Not Reported
	Gammagard Liquid			S	Intravenous (not otherwise specified)			Not Reported
	Gammagard Liquid			S	Intravenous (not otherwise specified)			Not Reported
	Lexapro			S	Unknown			Not Reported
	Tylenol			C				Not Reported
	Benadryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2010	7331660	EXPEDITED (15-DAY)	N	HO, LT	FR-BRISTOL-MYERS SQUIBB COMPANY-15025307		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Bradycardia; Confusional State; Drug Interaction; Hypothermia; Pneumonia Aspiration	Buspar			S				Bristol Myers Squibb
	Tiapride			S		1 Dosage Form = 1.5 (Units Not Mentioned).Tiapridal 100mg	3 DAY	Not Reported
	Escitalopram Oxalate			S		Interrupted On 06nov2009. Restarted With 20 Mg/D On 07nov2009 And 08nov2009		Not Reported

	Valium	S	17-Oct-2009 To 26-Oct-2009, Then ½ In The Evening From 26-Oct-2009 To 08-Nov-2009.		Not Reported
	Aceprometazine\Meprobamate	S	1 Dosage Form = 1 Tablet.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2010	7332054	EXPEDITED (15-DAY)	Y	OT	DE-JNJFOC-20100304894		59 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Suicide Attempt; Tachycardia	Risperdal			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2010	7332140	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2010-03464		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Chlordiazepoxide Hydrochloride			S				Watson
	Bupropion Hydrochloride			S				Watson
	Propoxyphene Hydrochloride			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2010	7332328	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2010-03586		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Temazepam			S				Watson
	Zolpidem Tartrate			S				Watson
	Escitalopram Oxalate			S				Not Reported
	Duloxetine			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2010	7351836	EXPEDITED (15-DAY)	N	OT	1000012584			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Headache; Muscle Spasms; Seizure	Lexapro			S	Oral	(1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2010	7353844	EXPEDITED (15-DAY)	Y	HO	1000012631		86 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrolyte Imbalance; Hyperkalaemia; Hyponatraemia	Escitalopram Oxalate			S				Not Reported
	Spironolactone			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Diffu K			S	Oral	Oral		Not Reported
	Trivastal			C				Not Reported
	Kardegic			C				Not Reported
	Dafalgan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2010	7220777	EXPEDITED (15-DAY)	N	OT	1000010422			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Decreased Appetite; Dizziness; Dysarthria; Feeling Abnormal; Malaise; Multiple Allergies; Nausea; Paraesthesia; Presyncope; Suicidal Ideation; Swelling Face; Swollen Tongue; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	(10 Mg),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	(5 Mg),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2010	7332779	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20100306041		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bladder Dilatation; Blood 25-Hydroxycholecalciferol Decreased; General Physical Health Deterioration; Haematoma; Pyrexia; Respiratory Acidosis; Respiratory Disorder; Somnolence	Durogesic			S	Transdermal		8 DAY	Not Reported
	Celebrex			S	Oral			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Piracetam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2010	7333741	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2010-03555		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Fortamet			S		Unk		Watson
	Metoclopramide Hydrochloride			S		Unk		Watson
	Trazodone Hydrochloride			S		Unk		Watson
	Oxycodone Hydrochloride			S		Unk		Watson
	Methylphenidate Hydrochloride			S		Unk		Watson
	Zolpidem Tartrate			S		Unk		Watson
	Phenytoin			S				Not Reported
	Phenobarbital			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Emtricitabine\Tenofovir			S				Not Reported
	Ondansetron			S				Not Reported
	Pregabalin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2010	7333748	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2010-03561		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Ibuprofen			S		Unk		Watson
	Methylphenidate Hydrochloride			S		Unk		Watson
	Escitalopram Oxalate			S				Not Reported
	Acetaminophen			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2010	7333749	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2010-03615		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Verapamil Hydrochloride			S				Watson
	Escitalopram Oxalate			S				Not Reported
	Diphenhydramine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2010	7333858	EXPEDITED (15-DAY)	Y	OT	ZA-PFIZER INC-2010035241		84 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Atorvastatin Calcium			S	Oral	Unk		Pfizer
	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Cozaar			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2010	7333981	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2010034686		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Respiratory Disorder; Somnolence	Celebrex	S	200 Mg, Unk		Pfizer
	Piracetam	S	Unk		Not Reported
	Durogesic	S	Unk	8 DAY	Not Reported
	Escitalopram Oxalate	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2010	7341832	EXPEDITED (15-DAY)	Y	OT	1000009316		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Amnesia; Emotional Disorder; Fear; Head Injury; High Risk Sexual Behaviour; Judgement Impaired; Overdose; Personality Change; Road Traffic Accident	Lexapro			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2010	7300633	EXPEDITED (15-DAY)	Y	HO	1000011505		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Disease Recurrence; Dysphoria; Major Depression; Suicidal Ideation	Escitalopram Oxalate			S	Oral	20 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral		Not Reported
					Oral	20 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral		
					Oral	20 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral		
	Lisinopril			C				Not Reported
	Calcium			C				Not Reported
	Centrum Silver (Capsules)			C				Not Reported
	Aspirin			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2010	7334894	EXPEDITED (15-DAY)		HO, OT	AU-ROXANE LABORATORIES, INC.-2010-RO-00309RO		60 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antipsychotic Drug Level Below Therapeutic; Blood Creatine Phosphokinase Increased; Confusional State; Delirium; Hypertonia; Lower Respiratory Tract Infection; Myalgia; Neuroleptic Malignant Syndrome; Pyrexia; Tachycardia	Clarithromycin			S		500 Mg	2 WEEK	Roxane
	Lithium Carbonate			S				Roxane
	Lithium Carbonate			S		500 Mg		Roxane
	Diazepam			S	Oral	40 Mg		Roxane
	Diazepam			S	Oral	2 Mg		Roxane
	Diazepam			S	Oral			Roxane
	Digoxin			S		62.5 Mcg		Roxane
	Periciazine			S		10 Mg		Not Reported
	Quetiapine			S		125 Mg		Not Reported
	Quetiapine			S		25 Mg		Not Reported
	Escitalopram Oxalate			S		20 Mg		Not Reported
	Aspirin			S		100 Mg		Not Reported
	Perindopril			S		10 Mg		Not Reported
	Simvastatin			S		80 Mg		Not Reported
	Bromocriptine			C	Oral			Not Reported
	Bromocriptine			C	Oral			Not Reported
	Bromocriptine			C	Oral			Not Reported
	Bromocriptine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2010	7355316	EXPEDITED (15-DAY)	N	OT	1000012658		16 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hyperventilation; Loss Of	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Zoloft			C				Not Reported

Consciousness; Seizure	Propavan (Tablets)	C	Not Reported
	Symbicort (Tablets)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2010	7355318	EXPEDITED (15-DAY)	Y	OT	1000012688			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Fatigue; Loss Of Libido; Suicidal Ideation	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2010	9529017	EXPEDITED (15-DAY)	Y	DS, HO, OT	0002350		45 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anxiety; Chills; Cognitive Disorder; Decreased Activity; Depression; Dizziness; Drug Intolerance; Hallucination; Hallucinations, Mixed; Nightmare; Parkinson'S Disease; Pyrexia; Restlessness; Sleep Disorder; Syncope; Therapeutic Product Effect Decreased; Thinking Abnormal; Tremor	Rotigotine			S	Transdermal			Not Reported
	Ropinirole			S				Not Reported
	Azilect			S				Not Reported
	Sifrol			S		(0.35 Mg, Frequency Dose: 2 X 1.5 And 1 X 1) (0.35 Mg, Frequency Dose: 3 X 1.5) 0.18 Mg (Other 3x 1.5))		Not Reported
	Motilium			C				Not Reported
	Aspirine /00002701/			C				Not Reported
	Delix /00885601/			S				Not Reported
	Metformin			C				Not Reported
	Pravastatin			C				Not Reported
	Seroquel			S		25 Mg Tid, 1 - 2 - 0 25 Mg Qid, Frequency Dose: 1 X 1, 1 X 3		Not Reported
	Opipramol			S				Not Reported
	Citalopram (Citalopram)			S				Not Reported
	Cipralex			S				Not Reported
	Clozapin			S		25 Mg, Frequency: Other 2x1/4 25 Mg, Frequency: Other		Not Reported

			2x1/4 And 1x1/2 25 Mg, Frequency: Other 2x1/2 And 1x3/4 25 Mg, Frequency: Other 2x1/2 And 1x1	
	Tavor /00273201/	S	1 Mg As Required 4 Times	Not Reported
	Truxal	S		Not Reported
	Amaryl	C		Not Reported
	Locol (Fluvastatin Sodium)	C		Not Reported
	Irenat	C		Not Reported
	Apo-Primidone	C		Not Reported
	Obsidan (Propranolol Hydrochloride)	C		Not Reported
	Neurocil (Levomepromazine)	C		Not Reported
	Benserazide Hydrochloride W/Levodopa	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2010	7336351	EXPEDITED (15-DAY)	Y	OT	US-WYE-H14189210		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Eye Laser Surgery; Medication Error; Visual Acuity Reduced; Weight Decreased	Pristiq Extended Release			S	Oral			Wyeth
	Celebrex			S	Oral			Not Reported
	Lexapro			S	Oral	Unknown		Lundbeck
	Synthroid			C	Oral	125 Mcg Daily		Not Reported
	Prilosec			C		Unknown		Merck Sharp And Dohme
	Prilosec			C				Merck Sharp And Dohme
	Folic Acid			C		Unknown		Unknown
	Actonel			C	Oral	Unknown		Procter And Gamble
	Glucose			C		Unknown		Unknown
	Calcium			C		Unknown		Unknown
	Vitamin B Complex			C		Unknown		Unknown

	Vitamin D2	C		Unknown	Unknown
	Zocor	C	Oral		Merck Sharp And Dohme

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2010	7336419	EXPEDITED (15-DAY)	Y	HO, LT	FR-ROCHE-693611		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Bradycardia; Confusional State; Drug Interaction; Hypothermia	Valium			S	Oral			Roche
	Valium			S	Oral	In The Evening		Roche
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Tiapride			S	Oral	In The Evening		Not Reported
	Aceprometazine\Meprobamate			S	Unknown	Taken Once		Not Reported
	Buspar			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2010	7337754	EXPEDITED (15-DAY)	Y	DE	US-NICOBRDEVP-2010-03583		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Clonazepam			S				Watson
	Doxepin Hydrochloride			S				Watson
	Clonidine Transdermal System			S				Watson
	Diphenhydramine Hydrochloride			S				Watson
	Sertraline Hydrochloride			S				Watson
	Oxytrol			S				Watson
	Alcohol			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Sildenafil Citrate			S				Not Reported
	Duloxetine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2010	7344690	DIRECT		DS			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hyperhidrosis; Muscle Twitching; Nerve Injury; Tremor	Lexapro			S		1 A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2010	7309172	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20100301425		13 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Malaise	Risperdal			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Enalapril Maleate			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Lucen (Esomeprazole)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2010	7346106	DIRECT	N	HO, RI, OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychiatric Evaluation; Suicidal Ideation	Lexapro			S	Oral	1/2 Tab Every Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2010	7357852	EXPEDITED (15-DAY)	Y	OT	1000012689		74 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition	Lexapro			S	Oral	10 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2010	7340985	EXPEDITED (15-DAY)	Y	OT	US-ABBOTT-10P-163-0633967-00		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Dizziness; Loss Of Consciousness; Suicidal Ideation; Weight Increased	Divalproex Sodium			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Buspirone			C	Oral			Not Reported
	Albuterol			C	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2010	7359578	EXPEDITED (15-DAY)	Y	DE	1000012713			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2010	7359789	EXPEDITED (15-DAY)	Y	OT	1000012726		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Asthenia	Escitalopram Oxalate			S	Oral	10 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2010	7332571	EXPEDITED (15-DAY)	Y	OT	1000012246		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Eating Disorder; Malaise; Nausea; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg (5 Mg, 2 In 1 D), Oral		Not Reported

	Escitalopram Oxalate	S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral	Not Reported
	Avonex	C			Not Reported
	Oral Antidiabetic Drugs	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2010	7359554	EXPEDITED (15-DAY)	Y	HO, LT	1000012904		64 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Bradycardia; Confusional State; Drug Interaction; Hypothermia; Pneumonia Aspiration; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 20 Mg, Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 20 Mg, Oral		
	Valium			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Valium			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Tiapride			S	Oral	150 Mg (150 Mg, 1 In 1 D), Oral		Not Reported
	Acepromet azine Maleate\Meprobamate			S	Oral	(Once), Oral		Not Reported
	Buspar			S	Oral	30 Mg (10 Mg, 3 In 1 D), Oral		Not Reported
	Previscan (Fluindione)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2010	7359556	EXPEDITED (15-DAY)	Y	HO	1000012784		96 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bladder Dilatation; General Physical Health Deterioration; Pyrexia; Respiratory Acidosis; Respiratory Disorder;	Escitalopram Oxalate			S				Not Reported
	Durogesic			S				Not Reported
	Celebrex			S				Not Reported
	Piracetam			S				Not Reported

Somnolence; Vitamin D Deficiency

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2010	7303464	EXPEDITED (15-DAY)	Y	HO	1000011742		57 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Tradazolam (Tablets)			C				Not Reported
	Omeprazole			C				Not Reported
	Lormetazepam (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2010	7344689	EXPEDITED (15-DAY)	Y	OT	GB-MYLANLABS-2010S1004817			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Trazodone Hydrochloride			S				Matrix
	Cipralex			S				Not Reported
	Pregabalin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2010	7323411	EXPEDITED (15-DAY)	Y	HO, LT	AU-JNJFOC-20100303179		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Inversion; Overdose; Serotonin Syndrome	Tramadol Hydrochloride			S	Oral	Estimated Dosage Of 3 G		Not Reported
	Risperidone			S	Oral	Estimated Dosage Of 120 Mg		Not Reported
	Lithium			S	Oral	Estimated Dosage: 13 G		Not Reported
	Escitalopram Oxalate			S	Oral	Estimated Dosage: 560 Mg		Not Reported
	Mirtazapine			S	Unknown	Estimated Dosage: 315 Mg		Not Reported

Quetiapine	S	Oral	Estimated Dosage: 15 G		Not Reported
Fluoxetine	S	Oral	Estimated Dosage: 1.1 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2010	7345358	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20100400017		40 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Sluggishness; Sopor	Haldol			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Trazodone Hydrochloride			S	Oral			Not Reported
	Valium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2010	7360751	EXPEDITED (15-DAY)	Y	OT	1000012927		31 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Euphoric Mood; Middle Insomnia; Suicidal Ideation	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D) Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2010	7158158	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2009SE20715		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Bronchitis; Drug Interaction; Ischaemic Stroke	Omeprazole			S	Oral		3 YR	Not Reported
	Tianeptine			S	Oral			Not Reported
	Forsteo			C	Subcutaneous			Not Reported
	Tareg			C	Oral			Not Reported
	Dafalgan			C	Unknown			Not Reported
	Inexium			S	Oral			Not Reported

Escitalopram Oxalate		S	Oral		1 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2010	7269276	EXPEDITED (15-DAY)	Y	OT	1000011332		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Faeces Hard; Rectal Haemorrhage; Refusal Of Treatment By Patient	Escitalopram Oxalate			S	Oral	5 Mg (5mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zolpidem			C				Not Reported
	Ginko Biloba			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2010	7351082	DIRECT	Y	DS, RI			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2010	7362059	EXPEDITED (15-DAY)	Y	OT	1000012818		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2010	7362062	EXPEDITED (15-DAY)	Y	OT	1000012162		65 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease Recurrence; Overdose; Phobia; Suicidal Ideation	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1		Not Reported

				Oral	In 1 D),Oral 10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D),Oral	
				Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D),Oral	
	Plavix		C			Not Reported
	Aspirin		C			Not Reported
	Crestor		C			Not Reported
	Inexium		C			Not Reported
	Tanakan		C			Not Reported
	Nafronyl Oxalate		C			Not Reported
	Lysanxia		C			Not Reported
	Cyamemazine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2010	7362086	EXPEDITED (15-DAY)	Y	OT	1000012814		89 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Ocular Hyperaemia; Palpitations	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2010	7362335	EXPEDITED (15-DAY)	Y	OT	1000012957			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2010	7196238	EXPEDITED (15-DAY)		LT, OT	1000010004		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Dreams; Adjustment Disorder; Condition Aggravated; Cough; Crying; Depression; Dizziness; Drug Ineffective; Eczema; Emotional Disorder; Fall; Fatigue; Feeling Abnormal; Hyperphagia; Insomnia; Intentional Overdose; Intentional Self-Injury; Nasopharyngitis; Neck Pain; Oropharyngeal Pain; Suicidal Ideation; Unevaluable Event; Weight Increased	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (10 Mg, 2 In 1 D), Oral	Not Reported
				Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (10 Mg, 2 In 1 D), Oral	
	Escitalopram Oxalate		S	Oral	30 Mg, Oral; Reduced From 30 Mg Daily (Nos), Oral	Not Reported
				Oral	30 Mg, Oral; Reduced From 30 Mg Daily (Nos), Oral	
	Amitriptyline Hydrochloride		C			Not Reported
	Levothyroxine		C			Not Reported
	Diclofenac		C			Not Reported
	Paracetamol		C			Not Reported
	Iron		C			Not Reported
	Diazepam		C			Not Reported
	Sleeping Tablets (Nos)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2010	7348236	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20100400351		63 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury	Risperdal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2010	7356497	EXPEDITED (15-DAY)	Y	DE	1000012705		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Vistaril			S	Oral	100 Mg (50 Mg, 2 In 1 D), Oral		Not Reported
	Methadone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2010	7361767	EXPEDITED (15-DAY)	Y	HO, OT	1000012930		40 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Electrocardiogram Repolarisation Abnormality; Intentional Overdose; Overdose; Sinus Bradycardia	Escitalopram Oxalate			S	Oral	(14 Dosage Forms, Once), Oral; 40 Mg (20 Mg, 2 In 1 D), Oral		Not Reported
	Delorazepam			S	Oral	(20 Dosage Forms, Once), Oral; 6 Mg (2 Mg, 3 In 1 D), Oral		Not Reported
	Akineton			S	Oral	(10 Dosage Forms, Once), Oral; 8 Mg (4 Mg, 2 In 1 D), Oral		Not Reported
	Lithium Carbonate			S	Oral	(10 Dosage Forms, Once), Oral; 900 Mg (300 Mg, 3 In 1 D), Oral		Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2010	7299857	EXPEDITED (15-DAY)	Y	OT	1000011496		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Chest Pain; Dizziness; Headache; Hyperhidrosis; Hyperphagia; Suicidal Ideation; Weight Increased	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg,1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S		Oral		Not Reported
	Rivotril			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2010	7304306	EXPEDITED (15-DAY)	N	OT	1000011470			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Crying; Depression; Disease	Escitalopram Oxalate			S	Oral	Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

Recurrence; Disturbance In Attention; Drug Ineffective; Thinking Abnormal					Oral	Oral, 20 Mg (20 Mg, 1 In 1 D), Oral				

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2010	7349934	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010040671		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Dreams; Anxiety; Condition Aggravated; Diverticulitis; Hallucination; Hypertension; Insomnia; Mental Impairment	Zoloft			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2010	7350064	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2010041208		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Erythema; Pruritus	Atarax			S	Oral	150 Mg, 1x/Day		Pfizer
	Venlafaxine			S	Oral	75 Mg, 2x/Day	1 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported
	Lormetazepam			C				Not Reported
	Troxerutin			C				Not Reported
	Xanax			C		Unk		Not Reported
	Tegretol			C		Unk		Not Reported
	Zyprexa			C		Unk	15 DAY	Not Reported
	Trihexyphenidyl			C		Unk	7 DAY	Not Reported
	Risperdal			C				Not Reported
	Valproate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2010	7359630	EXPEDITED (15-DAY)	Y	OT	1000012273		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Hydronephrosis; Renal Impairment; Thrombocytopenia	Escitalopram Oxalate			S	Oral	(5 Mg), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Oral		Not Reported
	Tilcotil			C				Not Reported
	Lamotrigine			C				Not Reported
	Oxapax			C				Not Reported
	Lactulose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2010	6900063	EXPEDITED (15-DAY)	Y	HO, OT	1000003587		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Anxiety; Cholestasis; Decreased Appetite; Fatigue; Headache; Hepatitis; Hepatitis Alcoholic; Hepatomegaly; Hypoaesthesia; Hypokalaemia; Motor Dysfunction; Sleep Disorder; Tension; Urinary Incontinence; Weight Decreased; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
	Tianeptine			C				Not Reported
	Seresta			C				Not Reported
	Aotal			C				Not Reported
	Intrauterine Contraceptive Device With Levonorgestrel)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2010	7249843	EXPEDITED (15-DAY)	Y	HO	PHHY2010BE01035		36 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Antipsychotic Drug Level Below Therapeutic; Anxiety; Depression; Drug Interaction; Overdose; Suicide Attempt	Leponex	S	500 Mg/Day		Novartis
	Telzir	C	700 Mg		Not Reported
	Truvada	C	Unk		Not Reported
	Norvir	C			Not Reported
	Pravastatin Sodium	C			Not Reported
	Leponex	S	600 Mg/Day		Novartis
	Escitalopram Oxalate	S	Unk		Not Reported
	Fluvoxamine Maleate	S	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2010	7352068	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010042037		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dissociation; Drug Interaction	Chantix			S	Oral	0.5 Mg, 1x/Day		Pfizer
	Chantix			S	Oral	1 Mg, 2x/Day		Pfizer
	Seroquel			S	Oral	300 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2010	7357866	DIRECT	Y	DE			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Self-Injury	Lexapro			S	Ophthalmic	10 Mg Daily Ophthalmic	2 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2010	7361385	EXPEDITED (15-DAY)	N	OT	1000012956		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Energy Increased; Homicide; Imprisonment; Insomnia	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2010	7364976	EXPEDITED (15-DAY)	Y	HO	6059258		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Muscle Haemorrhage; Sciatica	Levothyroxine Sodium			S	Oral	1 Df Oral		Not Reported
	Previscan (Fluindione)			S	Oral	1 Df Oral	9 DAY	Not Reported
	Fondaparinux			S	Subcutaneous	1 Df Subcutaneous	7 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	1 Df Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2010	7375434	NON-EXPEDITED	N		1000010793		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness	Bystolic			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2010	7309628	EXPEDITED (15-DAY)	Y	OT	1000009096		56 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		
	Memantine Hydrochloride			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		

	Memantine Hydrochloride	S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral; 15 Mg (7.5 Mg, 2 In 1 D), Oral; 10 Mg (5 Mg, 2 In 1 D), Oral	Not Reported
			Oral	20 Mg (10 Mg, 2 In 1 D), Oral; 15 Mg (7.5 Mg, 2 In 1 D), Oral; 10 Mg (5 Mg, 2 In 1 D), Oral	
			Oral	20 Mg (10 Mg, 2 In 1 D), Oral; 15 Mg (7.5 Mg, 2 In 1 D), Oral; 10 Mg (5 Mg, 2 In 1 D), Oral	
	Osteophos D3 (Solution)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2010	7352052	EXPEDITED (15-DAY)	Y	DS, OT	GXKR2010DK03519		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Bone Disorder; Burning Sensation; Decreased Vibratory Sense; Drug Interaction; Musculoskeletal Pain; Musculoskeletal Stiffness; Oedema Peripheral; Pain In Extremity; Polyneuropathy; Tendon Calcification; Tendon Disorder; Tenolysis; Urge Incontinence	Sertraline			S	Oral	50 Mg, Qd		Novartis
	Zovirax			C	Oral			Not Reported
	Symbicort			C	Respiratory (inhalation)			Not Reported
	Cipramil			C				Not Reported
	Terbinafine			S	Oral	250 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Unk	489 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2010	7360130	DIRECT					27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Alcohol Poisoning; Amnesia; Loss Of	Lexapro			S	Oral	20mg Once Per Day Po		Not Reported

Consciousness; Product Quality Issue; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2010	7382547	NON-EXPEDITED	Y	DE	004597		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Methylphenidate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Acetaminophen			S				Not Reported
	Ibuprofen			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2010	7362392	DIRECT	Y	OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash Erythematous	Lexapro			S	Oral	10 Mg Po Daily		Not Reported
	Benadryl			S	Oral	50 Mg Po Q6 Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2010	7362393	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Fatigue Syndrome; Fibromyalgia	Prozac			S	Oral	20 - 60 Mg Daily Po 1990'S - 2008		Not Reported
	Lexapro			S	Oral	20 Mg Daily Po 2009 (Mar) - 210 (Mar)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2010	7366651	EXPEDITED (15-DAY)	Y	HO	1000013053		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebrovascular Accident; Hypotonia; Overdose; Salivary Hypersecretion	Escitalopram Oxalate	S	10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2010	7213404	EXPEDITED (15-DAY)	N	OT	1000010309		24 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Apathy; Blepharospasm; Blood Glucose Decreased; Depression; Derealisation; Drug Withdrawal Syndrome; Fatigue; Feeling Abnormal; Hyperhidrosis; Hyperreflexia; Irritability; Mania; Nausea; Panic Attack; Paraesthesia; Paranoia; Pyrexia; Somnolence; Suicidal Ideation; Tinnitus; Urinary Tract Infection	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg), Oral, 10 Mg (10 Mg), Oral		Not Reported
					Oral	5 Mg (5 Mg), Oral, 10 Mg (10 Mg), Oral		
	Escitalopram Oxalate			S	Oral	2.5 Mg (5 Mg, 1 In 2 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg), Oral, 10 Mg (10 Mg), Oral		Not Reported
					Oral	10 Mg (10 Mg), Oral, 10 Mg (10 Mg), Oral		
	Ciprofloxacin			S	Oral	2 In 1 D, Oral		Not Reported
	Flagyl			S				Not Reported
	Clonazepam			S	Oral	0.25 Mg (0.25 Mg, 1 In 1 D), Oral, 0.5 Mg (0.5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	0.25 Mg (0.25 Mg, 1 In 1 D), Oral, 0.5 Mg (0.5 Mg, 1 In 1 D), Oral		
	Paroxetine			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Milnacipran			S	Oral	50 Mg, Oral		Not Reported
	Zoloft			S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
	Azitrox			C				Not Reported
	Curam			C				Not Reported
	Doxycycline			C				Not Reported
	Creatine Monohydrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2010	7243275	EXPEDITED (15-DAY)	Y	OT	1000010596		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Family Stress; Muscle Contractions Involuntary; Restless Legs Syndrome; Stress; Treatment Noncompliance	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2010	7273662	EXPEDITED (15-DAY)	Y	HO	1000011407		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Gait Inability; Hypotonia; Muscle Spasms	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Marijuana			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2010	7367150	EXPEDITED (15-DAY)	Y	HO, OT	1000013156		81 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Lower Gastrointestinal Haemorrhage; Off Label Use	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Ibuprofen			S	Oral	Oral		Not Reported
	Tiotropium			C				Not Reported
	Salmeterol			C				Not Reported
	Risperidone			C				Not Reported
	Benserazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2010	7367794	EXPEDITED (15-DAY)	Y	HO	1000013148		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Transient Ischaemic Attack	Lexapro	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Tramadol Hydrochloride	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2010	7365601	DIRECT	N	RI			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Lexapro			S	Oral	One Half Of A 10 Mg. Tablet Each Day Po	7 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2010	7366176	DIRECT	Y	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dry Mouth; Dry Throat; Feeling Hot; Rash Erythematous; Tremor	Lexapro			S				Forest
	Protonix			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2010	6096214	EXPEDITED (15-DAY)	Y	HO, LT	S06-NLD-02883-01		75 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardiac Failure Congestive; Dyspnoea; Electrocardiogram Qt Prolonged	Lexapro			S	Oral	20 Mg (20 Mg, Once A Day), Oral		Not Reported
	Pantozol (Pantoprazole Sodium)			C				Not Reported
	Salbutamol Aer (Salbutamol) (100 Microgram) (Salbutamol)			C				Not Reported
	Seretide Aerosol (25 Microgram)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2010	7178821	EXPEDITED (15-DAY)	Y	HO, OT	PHHY2009FR48631			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Creatinine Renal Clearance Decreased; Seizure	Exelon	S	Transdermal	9.5 Mg Daily		Novartis
	Exelon	S	Transdermal	Unk		Novartis
	Escitalopram Oxalate	S		10 Mg In Morning And 5 Mg In Evening		Not Reported
	Escitalopram Oxalate	S		5 Mg/Day		Not Reported
	Aldactazine	C				Not Reported
	Ginkor	C				Not Reported
	Meteospasmyl	C				Not Reported
	Phenobarbital	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2010	7277782	EXPEDITED (15-DAY)	Y	OT	1000011446		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia; Psychomotor Hyperactivity	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Ativan			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2010	7299605	EXPEDITED (15-DAY)	N	OT	1000011659		28 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Disease Recurrence; Drug Ineffective; Fatigue; Feeling Abnormal; Restlessness; Terminal Insomnia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2010	7315644	EXPEDITED (15-DAY)	Y	HO, LT	1000011919			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest	Lexapro	S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2010	7358671	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2010046461		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Vistaril			S	Oral	50 Mg, 2x/Day		Pfizer
	Lexapro			S	Oral	20 Mg, 1x/Day		Not Reported
	Lexapro			S				Not Reported
	Methadone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2010	7369586	EXPEDITED (15-DAY)	N	OT	1000013226			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Feeling Abnormal; Restlessness	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2010	7375427	EXPEDITED (15-DAY)	Y	OT	100009197		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Loss Of Consciousness; Presyncope; Tremor	Escitalopram Oxalate			S	Oral	0 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Enalapril Maleate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Kaleorid			C				Not Reported
	Hjerdyl			C				Not Reported
	Furosemid			C				Not Reported
	Vagifem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2010	7371017	EXPEDITED (15-DAY)	Y	CA	1000013235			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytogenetic Abnormality; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2010	8092175	EXPEDITED (15-DAY)	Y	HO	1000013206		74 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Valproate Sodium			S	Oral	500 Mg (500 Mg, 1 In 1 D), Oral		Not Reported
	Valproate Sodium			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal			S	Oral	1 Mg (1 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal			S		1 Mg (1 Mg, 1 In 1 D)		Not Reported
	Prothipendyl Hydrochloride			S	Oral	80 Mg (80 Mg, 1 In 1 D), Oral		Not Reported
	Prothipendyl Hydrochloride			S	Oral	120 Mg (120 Mg, 1 In 1 D), Oral		Not Reported
	Magnetrans			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2010	7340605	EXPEDITED (15-DAY)	Y	OT	1000012469		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Dostinex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2010	7369094	DIRECT	N	HO			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus; Restless Legs Syndrome	Lexapro			S	Oral	10 Mg 1x Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2010	7373527	EXPEDITED (15-DAY)	Y	OT	1000013286		90 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Hallucination, Visual; Somnolence	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	2.5 Mg (2.5 Mg, 1 In 1 D), Oral		Not Reported
	Trinitrine			C				Not Reported
	Verapamil Hydrochloride			C				Not Reported
	Trimetazidine			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2010	7307008	NON-EXPEDITED	N		US-JNJFOC-20100300561		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Depression; Gait Disturbance; Injection Site Pain; Insomnia; Irritability; Mania; Migraine; Mood Altered; Psychotic Disorder; Restlessness; Seizure; Therapeutic Response Decreased; Wrong Technique In Product Usage Process	Risperdal Consta			S	Intramuscular			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Topamax			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Prozac			S	Oral			Not Reported
	Vyvanse			C	Oral			Not Reported

	Reclipsen	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2010	7362777	NON-EXPEDITED	N		US-ASTRAZENECA-2009SE18009		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor; Vasodilation Procedure	Toprol Xl			S	Oral		2 YR	Not Reported
	Toprol Xl			S	Oral			Not Reported
	Lexapro			S	Oral		2 YR	Not Reported
	Lexapro			S	Oral		5 DAY	Not Reported
	Lexapro			S	Oral			Not Reported
	Xanax			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Prilosec			C				Not Reported
	Evista			C				Not Reported
	Unithroid			C				Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2010	7362964	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-15015597		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oesophageal Spasm	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Seroquel			S				Not Reported
	Daytrana			S		Patch		Not Reported
	Clonidine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2010	7375488	EXPEDITED (15-DAY)	Y	LT	1000013204		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Off Label Use; Torsade De Pointes	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Inipomp			C				Not Reported
	Xanax			C				Not Reported
	Imovane			C				Not Reported
	Panos			C				Not Reported
	Takadol			C				Not Reported
	Dafalgan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2010	7375523	EXPEDITED (15-DAY)	N	HO	1000013330			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Therapeutic Product Effect Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zuclopenthixol			S	Intramuscular	See Image		Not Reported
	Tropatepine Hydrochloride			C				Not Reported
	Lysanxia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2010	7360968	EXPEDITED (15-DAY)	Y	HO	1000012816		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Insulin			C				Not Reported
	Lisinopril			C				Not Reported
	Lasix			C				Not Reported
	Toprol Xl			C				Not Reported
	Cardizem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2010	7361315	EXPEDITED (15-DAY)	N	OT	US-RB-001798-10		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Hallucination; Hand Fracture; Influenza Like Illness; Poor Quality Sleep	Suboxone			S	Sublingual			Not Reported
	Lexapro			S	Unknown	Dosing Details Unknown		Not Reported
	Wellbutrin			S	Unknown	Dosing Details Unknown		Not Reported
	Lunesta			S	Unknown	Dosing Details Unknown		Not Reported
	Ambien			S	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2010	7371975	DIRECT	N	DS, LT, OT			18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Amnesia; Arthralgia; Arthropathy; Asthenia; Back Pain; Bone Disorder; Decreased Appetite; Depression; Disturbance In Attention; Dizziness; Educational Problem; Headache; Hyperaesthesia; Hypoaesthesia; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Photophobia; Suicide Attempt; Thyroid Disorder; Thyroid Neoplasm; Unevaluable Event	Lupron Depot			S		11.25 Mg Lupron Depot 1 (3mo. Dose)		Abbott
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2010	7376996	EXPEDITED (15-DAY)	Y	OT	1000013211		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropod Bite; Deafness; Dysarthria; Eye Movement Disorder; Infected Bite; Paraesthesia; Sudden Onset Of Sleep; Vision Blurred	Lexapro	S	Oral	20 Mg (10 Mg,2 In 1 D),Oral	Not Reported
	Toprol Xl	C			Not Reported
	Lyrica	C			Not Reported
	Valium	C			Not Reported
	Oxycodone (Tablets)	C			Not Reported
	Celebrex	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2010	7382987	EXPEDITED (15-DAY)	Y	HO	1000012960		20 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Vomiting	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2010	7287879	EXPEDITED (15-DAY)	Y	HO	1000011556		80 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pleurothotonus	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		
	Risperdal			S	Oral	3 Mg (3 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal			S	Oral	4 Mg (4 Mg, 1 In 1 D), Oral, 3 Mg (3 Mg, 1 In 1 D), Oral, 2 Mg (2 Mg, 1 In 1 D), Oral		Not Reported
					Oral	4 Mg (4 Mg, 1 In 1 D), Oral, 3 Mg (3 Mg, 1 In 1 D), Oral, 2 Mg (2 Mg, 1 In 1 D), Oral		
					Oral	4 Mg (4 Mg, 1 In 1 D), Oral, 3 Mg (3 Mg, 1 In 1 D), Oral, 2 Mg (2 Mg, 1 In		

				1 D), Oral	
	Trazodone Hydrochloride		C		Not Reported
	Distraneurin		C		Not Reported
	Lorazepam		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2010	7367891	EXPEDITED (15-DAY)	Y	HO, OT	AU-WATSON-2010-05601			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma Scale Abnormal; Overdose	Promethazine Hydrochloride			S		250 Mg, Unk		Watson
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2010	7377123	EXPEDITED (15-DAY)	Y	OT	1000013366		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Metrorrhagia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tranxene T-Tab			C				Not Reported
	Stresam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2010	7256520	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2010SE02552		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Fibrosis; Hepatitis	Crestor			S	Oral		4 MTH	Not Reported
	Nitrofurantoin			S	Oral		3 YR	Not Reported
	Ibuprofen			S	Oral	As Required (Regular Intakes Estimated At 15 Days Per Month)		Not Reported
	Acetaminophen			S	Oral	As Required (Regular Intakes Estimated At 15 Days Per Month)		Not Reported

	Escitalopram Oxalate	S	Oral		4 MTH	Not Reported
	Caffeine	C				Not Reported
	Hydrocortisone	C			10 YR	Not Reported
	Hydrocortisone	C				Not Reported
	Hydrocortisone	C				Not Reported
	Hydrocortisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2010	7385697	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2010	7234236	EXPEDITED (15-DAY)	Y	DE	1000010624		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Intentional Self-Injury	Escitalopram Oxalate			S		15mg (15 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2010	7364035	EXPEDITED (15-DAY)	Y	OT	1000013035		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Feeling Abnormal; Muscle Tightness; Pain; Paraesthesia; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Atarax			C				Not Reported
	Lorazepam			C				Not Reported
	Zolpidem			C				Not Reported
	Havlane			C				Not Reported
	Propoxyphene Hydrochloride And Acetaminophen			C				Not Reported
	Avlocardyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2010	7376806	DIRECT	Y	OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Bradycardia; Chest Injury; Cognitive Disorder; Dizziness; Electrocardiogram Abnormal; Electroencephalogram Abnormal; Fatigue; Feeling Of Body Temperature Change; Generalised Tonic-Clonic Seizure; Haemorrhage; Head Injury; Headache; Loss Of Consciousness; Post Concussion Syndrome; Presyncope; Seizure; Skin Laceration	Lexapro			S	Oral	10 Mg Qd Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2010	7387779	EXPEDITED (15-DAY)	Y	OT	1000013411			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Attention; Restlessness; Somnolence	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D) Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D) Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2010	7334085	EXPEDITED (15-DAY)	Y	OT	1000012321		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Physical	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1		Not Reported

Assault D),Oral

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2010	7372551	NON-EXPEDITED	N		US-ASTRAZENECA-2010SE08150		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenopia; Burning Sensation	Nexium			S	Oral			Astrazeneca
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2010	7370845	EXPEDITED (15-DAY)	Y	OT	1000013207		24 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Overdose; Polydipsia; Polyuria	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2010	7367249	EXPEDITED (15-DAY)	Y	OT	1000013161			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2010	7374622	NON-EXPEDITED	N		US-ASTRAZENECA-2009UW05839			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dysgeusia; Feeling Abnormal;	Nexium			S	Oral			Astrazeneca
	Lexapro			S				Not Reported

Gastrooesophageal Reflux Disease; Insomnia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2010	7381519	DIRECT	N	RI, OT			35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaesthesia; Anorgasmia; Diarrhoea; Dizziness; Euphoric Mood; Paraesthesia; Sexual Dysfunction; Urogenital Disorder	Lexapro			S	Oral	20mg Once Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2010	7382754	EXPEDITED (15-DAY)	Y	HO	1000013496		29 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; White Blood Cell Count Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2010	7383461	EXPEDITED (15-DAY)	Y	HO	1000013495		82 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Escitalopram Oxalate			S				Not Reported
	Tramadol Hydrochloride And Acetaminophen			S				Not Reported
	Corvasal (Molsidomine)			S	Oral	Oral		Not Reported
	Tareg			S	Oral	(80 Mg), Oral		Not Reported
	Lasix			S	Oral	Oral		Not Reported
	Tahor			C				Not Reported
	Diffu K			C				Not Reported
	Levothyrox			C				Not Reported
	Mopral			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2010	7376020	EXPEDITED (15-DAY)	Y	HO	PHHY2010FR25016		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Lasix			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Tahor			C		10 Mg		Not Reported
	Diffu K			C				Not Reported
	Levothyrox			C				Not Reported
	Omeprazole			C				Not Reported
	Tareg			S	Oral	80 Mg		Novartis
	Corvasal (Molsidomine)			S				Not Reported
	Tramadol Hydrochloride And Acetaminophen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2010	7382982	EXPEDITED (15-DAY)	Y	OT	1000013518			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Off Label Use	Escitalopram Oxalate			S	Oral	20 Mg (20mg, 1 In 1 D), Oral		Not Reported
	Cokenzen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2010	7382985	EXPEDITED (15-DAY)	Y	DS	1000013497		81 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Gastrointestinal Motility Disorder; Muscle Spasticity	Escitalopram Oxalate			S	Oral	10 Mg (10mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2010	7383004	DIRECT	N	HO, LT, RI, OT			86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Abnormal Weight Gain; Atrial Fibrillation; Cerebrovascular Accident; Dizziness; Dysarthria; Dyspnoea; Fall; Feeling Abnormal; Fluid Retention; Gait Disturbance; Haemorrhage; Paraesthesia; Transient Ischaemic Attack	Lexapro			S	Oral	10 Mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2010	7311836	EXPEDITED (15-DAY)	Y	DS	1000011619		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Diarrhoea; Hyperacusis; Libido Increased; Nausea; Overdose; Photophobia; Self-Injurious Ideation; Speech Disorder; Suicidal Ideation; Tinnitus; Visual Impairment	Escitalopram Oxalate			S	Oral	10-30 Mg (1 In 1 D),Oral		Not Reported
	Lithionit			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2010	7319624	EXPEDITED (15-DAY)	Y	OT	1000011973		22 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Food Allergy	Lexapro			S	Oral Oral	10mg, Oral; 15 Mg, Oral 10mg, Oral; 15 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2010	7351932	EXPEDITED (15-DAY)	Y	OT	1000012612		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Night Blindness; Optic Neuropathy; Photophobia	Lexapro			S	Oral	10 Mg (10mg, 1 In 1d), Oral, 5mg (5mg, 1 In1d), Oral 10mg (10mg 1 In 1d Oral) 5 Mg (5mg 1 In1d) Oral		Not Reported
					Oral	10 Mg (10mg, 1 In 1d), Oral, 5mg (5mg, 1 In1d), Oral 10mg (10mg 1 In 1d Oral) 5 Mg (5mg 1 In1d) Oral		
					Oral	10 Mg (10mg, 1 In 1d), Oral, 5mg (5mg, 1 In1d), Oral 10mg (10mg 1 In 1d Oral) 5 Mg (5mg 1 In1d) Oral		
	Fentanyl			C				Not Reported
	Lortab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2010	7385628	DIRECT	Y	DS, RI			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Balance Disorder; Blood Cholesterol Abnormal; Breast Mass; Diabetes Mellitus; Heart Rate Irregular; Hypertension; Muscular Weakness; Musculoskeletal Stiffness; Oedema Peripheral; Periorbital Oedema; Weight Increased	Risperdal			S	Oral	Risperadol Twice A Day Oral Tab		Janssen
	Lexapro			S	Oral	Lexapro Once A Day Oral Tab		Forest
	Benzopropine			C				Not Reported
	Cogentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2010	7386860	EXPEDITED (15-DAY)	N	OT	1000013405		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Euphoric Mood; Seizure	Lexapro			S	Oral	10 Mg (10 Mg), Oral		Not Reported
	Depakote Er			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2010	7158926	EXPEDITED (15-DAY)	Y	OT	1000009248			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Obsessive Thoughts; Psychotic Disorder; Sleep Disorder; Violence-Related Symptom	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (1 In 1 D) Oral 10 Mg (10 Mg, 1 In 1 D), Oral 20 Mg (1 In 1 D) Oral		
	Xanax			C				Not Reported
	Norset			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2010	7381231	EXPEDITED (15-DAY)	Y	DS	US-WYE-H14853710		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Energy Increased; Headache; Irritability; Nervousness	Pristiq Extended Release			S	Oral	Unknown		Wyeth
	Valium			C				Roche
	Lexapro			S	Oral			Lundbeck
	Lexapro			S	Oral			Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2010	7388880	EXPEDITED (15-DAY)	Y	OT	1000013550			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression; Alcohol Interaction; Disinhibition	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2010	7389400	EXPEDITED (15-DAY)	Y	HO	1000013678		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2010	7233425	EXPEDITED (15-DAY)	Y	HO	1000010625		60 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Extrapyramidal Disorder; Fall; Off Label Use; Variant Creutzfeldt-Jakob Disease	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Venlafaxine			S				Not Reported
	Clonazepam			S				Not Reported
	Stilnox			C				Not Reported
	Stresam			C				Not Reported
	Tareg			C				Not Reported
	Lipanthyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2010	7381776	EXPEDITED (15-DAY)	Y	HO, OT	IN-JNJFOC-20100501137		19 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Cognitive Disorder; Drug Interaction; Muscle Rigidity; Reduced Facial Expression; Tremor	Risperidone			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown	At Night		Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2010	7390522	EXPEDITED (15-DAY)	Y	OT	1000013560		91 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Maternal Drugs Affecting Foetus; Maternal Exposure During Breast Feeding; Neonatal Disorder; Rapid Eye Movements Sleep Abnormal; Restlessness	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1) D, Transplacental; 20 Mg (20 Mg, 1 In 1 D), Transmammary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2010	7397945	EXPEDITED (15-DAY)	Y	HO	1000013696		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Pressure Fluctuation; Cerebral Microangiopathy; Headache; Hypertensive Crisis	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Abilify			C				Not Reported
	Athymil			C				Not Reported
	Omeprazole			C				Not Reported
	Cartrol			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2010	7390280	EXPEDITED (15-DAY)	Y	CA	1000013702			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Atresia; Choanal Atresia; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	Transplacental		Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2010	7391982	EXPEDITED (15-DAY)	Y	LT	1000013712		63 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicide	Lexapro			S	Oral	10 Mg, Oral		Not Reported
	Keppra			S	Oral	250 Mg, Oral		Not Reported
	Cyress Capsule			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2010	7392582	EXPEDITED (15-DAY)	Y	OT	1000013738		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg, 1 In 1 D, Oral		Not Reported
	Omeprazole			C				Not Reported
	Aggrenox (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2010	7392592	EXPEDITED (15-DAY)	Y	HO	1000013703		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Intolerance; Drug Ineffective; Lichenoid Keratosis; Toxic Skin Eruption	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Zolpidem			S		10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zithromax			C				Not Reported
	Levothyros (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2010	7392912	EXPEDITED (15-DAY)	Y	HO	1000013488			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2010	7385241	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2010SA025602		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Hypochromic Anaemia; Myelodysplastic Syndrome; Thrombocytopenic Purpura	Plavix			S	Oral			Not Reported
	Equanil			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2010	7385421	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-10P-163-0643069-00		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Euphoric Mood; Seizure	Depakote Er			S		Increased To An Unknown Dose		Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2010	7385544	EXPEDITED (15-DAY)	Y	LT	DE-PFIZER INC-2010055676		45 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Ampicillin And Sulbactam			S	Intravenous (not otherwise specified)	3 G, 3x/Day	5 DAY	Pfizer
	Sulbactam Sodium			S	Intravenous (not otherwise specified)	0.5 G, 3x/Day	7 DAY	Not Reported
	Norvasc			S	Oral	10 Mg, 1x/Day		Pfizer
	Norvasc			S	Oral	20 Mg, 1x/Day		Pfizer
	Hydrochlorothiazide			S	Oral	12.5 Mg, 1x/Day	5 DAY	Not Reported
	Hydrochlorothiazide			S	Oral	12.5 Mg, 2x/Day		Not Reported
	Metamizole Sodium			S	Intravenous (not otherwise specified)	1 G, 2x/Day (Morning,Evening)	4 DAY	Not Reported

Metamizole Sodium	S	Intravenous (not otherwise specified)	1 G, 1x/Day (Morning)	5 DAY	Not Reported
Metamizole Sodium	S	Intravenous (not otherwise specified)	1 G, 2x/Day (Morning, Noon)	1 DAY	Not Reported
Potassium Chloride	S	Intravenous (not otherwise specified)	Unk	16 DAY	Not Reported
Paracetamol	S	Intravenous (not otherwise specified)	Unk	5 DAY	Not Reported
Paracetamol	S	Intravenous (not otherwise specified)	Unk	4 DAY	Not Reported
Paracetamol	S	Intravenous (not otherwise specified)	Unk	6 DAY	Not Reported
Beloc-Zok	S	Oral	Unk	5 DAY	Not Reported
Beloc-Zok	S	Oral	Unk	8 DAY	Not Reported
Beloc-Zok	S		Unk		Not Reported
Norepinephrine	S	Intravenous (not otherwise specified)	Unk	8 DAY	Not Reported
Embolex	S	Subcutaneous	Unk	13 DAY	Not Reported
Zocor	S	Oral	20 Mg, 1x/Day	13 DAY	Not Reported
Sorbitol\Xylitol	S	Intravenous (not otherwise specified)	3.5 %, Unk	1 DAY	Not Reported
Sorbitol\Xylitol	S	Intravenous (not otherwise specified)	3.5 %, Unk	5 DAY	Not Reported
Sorbitol\Xylitol	S	Intravenous (not otherwise specified)	3.5 %, Unk	2 DAY	Not Reported
Potassium	S	Oral	40 Mmol, Unk	3 DAY	Not Reported
Potassium	S	Oral	40 Mmol, Unk	5 DAY	Not Reported
Potassium	S	Oral	40 Mmol, Unk	4 DAY	Not Reported
Fresubin	S	Oral	Unk	13 DAY	Not Reported
Magnesium Chloride Anhydrous\Potassium Chloride\Sodium Acetate\Sodium Chloride	S	Intravenous (not otherwise specified)	Unk	13 DAY	Not Reported

Bifiteral	S	Oral	10 Ml, 3x/Day		Not Reported
Nexium	S	Oral	20 Mg, 1x/Day		Not Reported
Ramipril	S	Oral	5 Mg, 1x/Day	3 DAY	Not Reported
Ramipril	S	Oral	2.5 Mg, 1x/Day		Not Reported
Cipralex	S	Oral	10 Mg, 1x/Day		Not Reported
Midazolam	S	Intravenous (not otherwise specified)	100 Mg, Unk	11 DAY	Not Reported
Propofol	S	Intravenous (not otherwise specified)	2 %, Unk	11 DAY	Not Reported
Insulin Nos	S	Intravenous (not otherwise specified)	Unk	16 DAY	Not Reported
Sufentanil	S	Intravenous (not otherwise specified)	500 Ug, Unk	16 DAY	Not Reported
Erythromycin	S	Intravenous (not otherwise specified)	200 Mg, 3x/Day	5 DAY	Not Reported
Erythromycin	S	Intravenous (not otherwise specified)	200 Mg, 3x/Day	3 DAY	Not Reported
Mucosolvan	S	Respiratory (inhalation)	Unk	9 DAY	Not Reported
Metoclopramide Hydrochloride	S	Intravenous (not otherwise specified)	10 Mg, 2x/Day	11 DAY	Not Reported
Domperidone	S	Oral	10 Mg, 1x/Day	12 DAY	Not Reported
Ipratropium	S	Oral	5 Gtt, 4x/Day	8 DAY	Not Reported
Albuterol Sulfate	S		5 Gtt, 4x/Day	8 DAY	Not Reported
Levothyroxine Sodium	S	Oral	Unk	14 DAY	Not Reported
Piperacillin	S	Intravenous (not otherwise specified)	4 G, 3x/Day	7 DAY	Not Reported
Haloperidol	S	Intravenous (not otherwise specified)	5 Mg, Unk	1 DAY	Not Reported
Solutions For Parenteral Nutrition	S	Intravenous (not otherwise specified)	Unk	4 DAY	Not Reported
Clonidine	S	Intravenous (not otherwise specified)	750 Ug, Unk	7 DAY	Not Reported

Enoxaparin Sodium	S	Subcutaneous	0.4 Ml, Unk		Not Reported
Urapidil	S	Intravenous (not otherwise specified)	Unk	5 DAY	Not Reported
Gastrozepin	S	Oral	25 Mg, 3x/Day	4 DAY	Not Reported
Tavanic	S	Oral	500 Mg, 3x/Day		Not Reported
Paracetamol	S	Rectal	Unk		Not Reported
Atacand	S	Oral	Unk		Not Reported
Levothyroxine Sodium	S	Oral	75 Mg, 1x/Day		Not Reported
Scopolamine	S	Transdermal	Unk		Not Reported
Beloc Zok (Metoprolol Succinate)	C	Oral	Unk Df, 1x/Day	2923 DAY	Not Reported
Ezetimibe/Simvastatin	C	Oral	1df 1x/D, 10 Mg Ezetimibe/20mg Simvastatin	2923 DAY	Not Reported
Allopurinol	C	Oral	300 Mg, 1x/Day	1468 DAY	Not Reported
Metronidazole	C	Intravenous (not otherwise specified)	500 Mg, 3x/Day	4 DAY	Not Reported
Claforan	C	Intravenous (not otherwise specified)	2 G, 3x/Day	4 DAY	Not Reported
Mannitol	C	Intravenous (not otherwise specified)	20%, 125 Ml	1 DAY	Not Reported
Fentanyl	C	Intravenous (not otherwise specified)	Unk	2 DAY	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	5 Mg, Unk	1 DAY	Not Reported
Dobutamine	C	Intravenous (not otherwise specified)	250 Mg, Unk	3 DAY	Not Reported
Acetylcysteine	C	Oral	600 Mg, Unk		Not Reported
Ceruletide Diethylamine	C	Intravenous (not otherwise specified)	Unk	1 DAY	Not Reported
Milax	C	Rectal	Unk	1 DAY	Not Reported
Bisacodyl	C	Rectal	Unk	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2010	7388173	EXPEDITED (15-DAY)	Y	HO	1000013521		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Blood Albumin Decreased; Blood Sodium Decreased; Confusional State; Dehydration; Depression; Diarrhoea; Disease Recurrence; Dizziness; Hypophagia; Malnutrition; Myoclonus; Tachycardia; Tremor; Withdrawal Syndrome	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D), 20 Mg		Not Reported
	Citalopram			S				Not Reported
	Venlafaxine			S				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2010	7400875	EXPEDITED (15-DAY)	Y	HO	1000013757		88 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hallucination; Muscular Weakness; Off Label Use	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Allopurinol			C				Not Reported
	Cozaar			C				Not Reported
	Betolvidon (Tablets)			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2010	7405084	EXPEDITED (15-DAY)	N	OT	1000013761		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Burning Sensation; Drug Ineffective; Insomnia; Off Label Use; Overdose; Vomiting	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg,1 In 1		Not Reported

				D),Oral	
	Escitalopram Oxalate	S	Oral	20 Mg (20 Mg,1 In 1 D),Oral ; 40 Mg (40 Mg,1 In 1 D),Oral	Not Reported
	Escitalopram Oxalate	S	Oral	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2010	6985993	EXPEDITED (15-DAY)	Y	HO	1000005843		76 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amyotrophy; Balance Disorder; Biliary Dilatation; Bradycardia; Cholelithiasis; Decreased Appetite; Dehydration; Delusion; Disease Complication; Drug Interaction; Dysuria; Fall; General Physical Health Deterioration; Humerus Fracture; Memory Impairment; Nervous System Disorder; Orthostatic Hypotension; Therapy Non-Responder; Tremor; Urinary Incontinence; Urinary Retention	Nebivolol Hydrochloride			S	Oral	5 Mg (5 Mg,1 In 1 D), Oral		Not Reported
	Nebivolol Hydrochloride			S	Oral	(1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Furosemide			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Trandolapril			S	Oral	2 Mg (2 Mg, 1 In 1 D), Oral		Not Reported
	Topalgic [Tramadol Hydrochloride]			S	Oral	200 Mg (200 Mg,1 In 1 D), Oral		Not Reported
	Diffu K			C				Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported
	Crestor			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Forlax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2010	7386677	NON-EXPEDITED	N		A0850509A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Interaction; Nausea; Vomiting	Treximet			S	Oral		1 DAY	Glaxosmithkline
	Lexapro			S	Unknown		5 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2010	6970657	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-09P-056-0568066-00		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnestic Disorder; Amyotrophy; Asthenia; Biliary Dilatation; Bradycardia; Cholelithiasis; Decreased Appetite; Dehydration; Drug Interaction; Dysuria; Fall; General Physical Health Deterioration; Humerus Fracture; Hypotension; Jugular Vein Distension; Malaise; Orthostatic Hypotension; Persecutory Delusion; Tremor; Urinary Incontinence; Urinary Retention	Trandolapril			S	Oral			Not Reported
	Topalgic (France)			C				Not Reported
	Diffu K			C				Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported
	Crestor			C				Not Reported
	Forlax			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Temerit			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2010	7299860	EXPEDITED (15-DAY)	Y		1000011579		53 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Hypertension; Tremor; Ulcer	Escitalopram Oxalate			S				Not Reported
	Protedine			C				Not Reported
	Selomax			C				Not Reported
	Losar			C				Not Reported
	Neurobion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2010	7388151	EXPEDITED (15-DAY)	Y	OT	AT-JNJFOC-20100501916		48 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Headache; Hyponatraemia; Nausea	Risperdal	S	Unknown		Not Reported
	Risperdal	S	Unknown		Not Reported
	Mianserin Hydrochloride	S	Unknown	0-0-0-2	Not Reported
	Neurontin	S	Unknown		Not Reported
	Neurontin	S	Unknown		Not Reported
	Seroquel	S	Unknown		Not Reported
	Seroquel	S	Unknown		Not Reported
	Seroquel	S	Unknown	25-100 Mg	Not Reported
	Seroquel	S	Unknown		Not Reported
	Seroquel	S	Unknown		Not Reported
	Seroquel	S	Unknown		Not Reported
	Seroquel	S	Unknown		Not Reported
	Prothipendyl Hydrochloride	S	Unknown		Not Reported
	Prothipendyl Hydrochloride	S	Unknown	0-0-0-1	Not Reported
	Atarax	S	Unknown	1-1-0-1	Not Reported
	Metformin Hydrochloride	S	Unknown	1-0-1-0	Not Reported
	Aspirin	S	Unknown	1-0-0-0	Not Reported
	Nexium	S	Unknown	0-0-0-1	Not Reported
	Ferrous Sulfate	S	Unknown	1-0-0-0	Not Reported
	Neurontin	S	Unknown		Not Reported
	Neurontin	S	Unknown	0-1-0-0	Not Reported
	Akineton	S	Unknown		Not Reported
	Akineton	S	Unknown		Not Reported
	Cipralex	S	Unknown		Not Reported
	Depakene	S	Oral		Not Reported
	Depakene	S	Oral		Not Reported
	Nexium	S	Unknown		Not Reported
	Ferrous Sulfate	S	Unknown		Not Reported

	Depakene	C	Intravenous (not otherwise specified)		Not Reported
	Depakene	C	Intravenous (not otherwise specified)		Not Reported
	Lorazepam	C	Unknown	2.5 - 11.25 Mg	Not Reported
	Lorazepam	C	Unknown		Not Reported
	Lorazepam	C	Unknown		Not Reported
	Lorazepam	C	Unknown		Not Reported
	Lorazepam	C	Unknown		Not Reported
	Lorazepam	C	Unknown		Not Reported
	Tenoretic	C	Unknown		Not Reported
	Mirtazapine	C	Unknown		Not Reported
	Mirtazapine	C	Unknown		Not Reported
	Phenoxybenzamine Hydrochloride	C	Unknown		Not Reported
	Dexibuprofen	C	Unknown		Not Reported
	Dexibuprofen	C	Unknown		Not Reported
	Augmentin	C	Unknown		Not Reported
	Augmentin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2010	7392549	EXPEDITED (15-DAY)	Y	HO	1000013707		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram Oxalate			S	Oral	5 Mg (5mg, 1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolam			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2010	7395478	EXPEDITED (15-DAY)	Y	HO	1000013726		97 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Magnesium Decreased; Blood Potassium Decreased; Blood Pressure Increased; Fall; Inappropriate Antidiuretic Hormone Secretion; Spinal Fracture; Urinary Tract Infection	Lexapro			S	Oral	5 Mg, Oral		Not Reported
	Long Acting Tolterodine Tartrate			C				Not Reported
	Atenolol			C				Not Reported
	Furosemide			C				Not Reported
	Lisinopril			C				Not Reported
	Lorazepam			C				Not Reported
	Docusate			C				Not Reported
	Ciprofloxacin			C				Not Reported
	Methylcellulose			C				Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2010	7397017	EXPEDITED (15-DAY)	Y	OT	1000013818		81 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bile Duct Obstruction; Yellow Skin	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2010	7397130	EXPEDITED (15-DAY)	Y	HO	1000013800		63 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Baklofen			C				Not Reported
	Ibuprofen			C				Not Reported
	Alvedon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2010	7398087	EXPEDITED (15-DAY)	Y	DE	1000013794		52 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose; Pneumonia Aspiration; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral; (400 Mg,Once), Oral		Not Reported
					Oral	10 Mg (10 Mg,1 In 1 D), Oral; (400 Mg,Once), Oral		
	Lamotrigine			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2010	7325717	EXPEDITED (15-DAY)	Y	CA	IE-ASTRAZENECA-2010SE11012		< 1 DAY	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertonia Neonatal; Hypotonia; Poor Sucking Reflex; Talipes	Quetiapine			S	Transplacental		5 WEEK	Not Reported
	Quetiapine			S	Transplacental		5 WEEK	Not Reported
	Escitalopram Oxalate			S	Transplacental		5 WEEK	Not Reported
	Amoxil			S	Transplacental			Not Reported
	Augmentin			S	Transplacental			Not Reported
	Ranitidine			S	Transplacental			Not Reported
	Cyanocobalamin			S	Transplacental			Not Reported
	Lexapro			C	Transplacental			Not Reported
	Antibiotics			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2010	7397018	DIRECT	Y	DS			27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Loss Of Libido	Lexapro			S	Oral	10 Mg 1/Day P/O		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2010	7177793	EXPEDITED (15-DAY)	Y	OT	1000009635		51 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Interaction; Amnesia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Alcohol			S	Oral			Not Reported
	Hydrochlorothiazide\Valsartan			C				Not Reported
	Chronadalate			C				Not Reported
	Simvastatin			C				Not Reported
	Inipomp			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2010	7361774	EXPEDITED (15-DAY)	Y	OT	1000012932		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Mobility Decreased; Oedema; Oedema Peripheral; Pruritus Generalised; Rash Generalised	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Depakene			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2010	7364041	EXPEDITED (15-DAY)	Y	HO	1000013117		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Muscle Haemorrhage; Sciatica	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Fluindione			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Arixtra			S	Subcutaneous	1 Dosage Forms, Subcutaneous		Not Reported
	Levothyrox			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2010	7398668	EXPEDITED (15-DAY)	Y	HO	1000013789		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Interaction	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Plavix			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Lasix (40 Milligram, Tablets)			C				Not Reported
	Glucophage Xr (500 Milligram, Tablets)			C				Not Reported
	Potassium			C				Not Reported
	Toprol Xl			C				Not Reported
	Proventil (Inhalant)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2010	7399128	EXPEDITED (15-DAY)	N	OT	1000013840		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Withdrawal Syndrome; Paraesthesia Oral; Ventricular Extrasystoles	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2010	7399145	EXPEDITED (15-DAY)	Y	OT	1000013850		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Trankimazin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2010	7399151	EXPEDITED (15-DAY)	Y	HO	1000013847		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Clumsiness; Fall; Hyperosmolar State; Hyponatraemia; Rib Fracture; Spinal Compression Fracture	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Omeprazole			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Norset			C				Not Reported
	Seresta			C				Not Reported
	Noctamide			C				Not Reported
	Theralene			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2010	7399170	EXPEDITED (15-DAY)	Y	HO	1000013819		77 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Vasculitis; Confusional State; Depression; Hypokalaemia; Hyponatraemia; Vomiting	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Fludex (Indapamide)			S	Oral	1.5 Mg (1.5 Mg, 1 In 1 D), Oral		Not Reported
	Mono Tildiem (Capsules)			C				Not Reported
	Olmetec (Tablets)			C				Not Reported
	Azopt (Eye Drops)			C				Not Reported
	Xalatan			C				Not Reported
	Lexomil (Tablets)			C				Not Reported
	Inexium (Tablets)			C				Not Reported
	Cardiocalm (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2010	7399387	EXPEDITED (15-DAY)	Y	HO	1000013821		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Hypochromic	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D),		Not Reported

Anaemia; Thrombocytopenic Purpura	Equanil		S	Oral	Oral 800 Mg (400 Mg, 2 In 1 D), Oral	Not Reported
	Plavix		S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2010	7407483	EXPEDITED (15-DAY)	Y	OT	1000013732		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Injury	Lexapro			S	Oral	10 Mg (10mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2010	11950598	EXPEDITED (15-DAY)	Y	OT	011437U		63 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicide	Keppra (Keppra)			S		(5 Mg, 10mg Tablet Times Per 5mg)		Not Reported
	Lexapro (Lexapro) (Not Specified)			S				Not Reported
	Cyress			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2010	7360410	EXPEDITED (15-DAY)	Y	OT	1000012912			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blunted Affect; Dissociation; Drug Interaction; Fatigue; Psychomotor Retardation; Somnolence	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Artane			S		6 Mg (2 Mg, 3 In 1 D)		Not Reported
	Artane			S		4 Mg (2 Mg, 2 In 1 D)		Not Reported

Nebilox	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2010	7375526	EXPEDITED (15-DAY)	Y	CA	1000013312		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2010	7376555	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2010039102			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Dizziness; Haematocrit Increased; Haemoglobin Increased; Hot Flush; Memory Impairment; Nausea; Vision Blurred	Arthrotec			S		Unk		Pfizer
	Lyrica			S	Oral	25 Mg, 1x/Day		Pfizer
	Lyrica			S				Pfizer
	Lyrica			S				Pfizer
	Neurontin			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Estrace			C		Unk		Not Reported
	Fexofenadine			C		Unk		Not Reported
	Avapro			C		300 Mg, Unk		Not Reported
	Avapro			C				Not Reported
	Synthroid			C		0.1 Mg, 1x/Day		Not Reported
	Synthroid			C				Not Reported
	Morphine Sulfate			C		Unk		Not Reported
	Ms Contin			C		15 Mg, 2x/Day		Not Reported
	Estradiol			C		1 Mg, 1x/Day		Not Reported
	Allegra			C		180 Mg, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2010	7396125	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2010SA027745		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypokalaemia; Hyponatraemia	Fludex (Indapamide)			S	Oral			Not Reported
	Mono-Tildiem			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	1 Df Qd Dose:1 Unit(S)		Not Reported
	Olmetec			S	Oral	1 Df Qd Dose:1 Unit(S)		Not Reported
	Azopt			S	Ophthalmic			Not Reported
	Xalatan			S	Ophthalmic			Not Reported
	Bromazepam			S	Oral	0.25 Df Qd Dose:0.25 Unit(S)		Not Reported
	Esomeprazole			S	Oral			Not Reported
	Phenobarbital\Quinine Hydrobromide			S	Oral	Two To Three Df Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2010	7402359	EXPEDITED (15-DAY)	Y	HO	1000013882		86 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Jaundice; Left Ventricular Failure; Urinary Tract Infection	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
	Memantine Hydrochloride			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
	Memantine Hydrochloride			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Equanil			S	Oral	250 Mg (250 Mg, 1 In 1 D), Oral		Not Reported
	Kardegic			C				Not Reported
	Cordarone			C				Not Reported
	Aricept			C				Not Reported
	Cardensiel			C				Not Reported

	Inexium	C	Not Reported
	Lasix	C	Not Reported
	Tianeptine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2010	7396727	EXPEDITED (15-DAY)	N	OT	NL-ASTRAZENECA-2010SE22555			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Caries; Depression; Dry Mouth; Thinking Abnormal; Weight Increased	Seroquel Xr			S	Oral			Astrazeneca
	Citalopram			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Nortriptyline Hydrochloride			S	Unknown			Not Reported
	Paroxetine Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2010	5807234	EXPEDITED (15-DAY)	Y	OT	S05-USA-01283-01		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2010	7404639	EXPEDITED (15-DAY)	Y	OT	1000013548		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inflammation; Leukopenia; Neutropenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zopliclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2010	7404817	EXPEDITED (15-DAY)		OT	BCN-AS-2010-RR-085		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Serotonin Syndrome; Somnolence	Tramadol Hydrochloride			S	Oral	3 Gram (S), Oral		Not Reported
	Quetiapine			S	Oral	15 Gram (S), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	560 Milligram Oral.		Not Reported
	Mirtazapine (Mirtazapine)			S	Oral	315 Milligram (S), Oral		Not Reported
	Fluoxetine			S	Oral	1.1 Gram (S), Oral		Not Reported
	Risperidone (Risperidone)			S	Oral	120 Milligram (S), Oral		Not Reported
	Lithium			S	Oral	13 Gram (S), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2010	7405053	EXPEDITED (15-DAY)	Y	OT	1000013985		24 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oculogyric Crisis	Escitalopram Oxalate			S	Oral	20 Milligram/Milliliters (20 Milligram/Milliliters), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2010	7405055	EXPEDITED (15-DAY)	N	OT	1000013983		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pharyngeal Oedema; Throat Irritation	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2010	7406602	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	10 Mg Daily P.O.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2010	7406603	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	20mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2010	7406604	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	20 Mg Daily P.O.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2010	7398968	EXPEDITED (15-DAY)	Y	HO	AU-MYLANLABS-2010S1008237		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Serotonin Syndrome	Mirtazapine			S	Oral			Not Reported
	Tramadol Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Lithium			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2010	7399042	EXPEDITED (15-DAY)	N	OT	US-WATSON-2010-06562			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Aphasia; Asthenia; Blepharospasm;	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Daily	91 DAY	Watson

Blood Ketone Body; Decreased Appetite; Dehydration; Depressed Level Of Consciousness; Depressed Mood; Dizziness; Drug Interaction; Fall; Feeling Abnormal; Headache; Heart Rate Irregular; Hypokalaemia; Mental Disorder; Mood Altered; Muscle Spasms; Muscle Twitching; Myalgia; Nausea; Paraesthesia; Personality Change; Syncope; Tremor; White Blood Cell Count Increased	Lexapro	S	Oral	10 Mg, Daily	3 DAY	Not Reported
	Lexapro	S				Not Reported
	Mobic	C	Oral	Unk		Not Reported
	Xopenex	C	Respiratory (inhalation)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2010	7406623	DIRECT	Y	OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Eye; Retinal Tear; Vision Blurred	Lexapro			S	Oral	10 Md Qd Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2010	7406632	EXPEDITED (15-DAY)	Y	OT	1000013922		52 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Irregular; Nausea; Restlessness	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 B) ,Oral		Not Reported
	Lorasifar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2010	7407946	EXPEDITED (15-DAY)	Y	OT	1000013988		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Drug Ineffective; Meniscus Injury; Nausea; Poor Quality Sleep; Spinal Fracture	Lexapro		S	20 Mg (20 Mg, 1 In 1 D)	Not Reported
	Celebrex		S	(3 In 1 D)	Not Reported
	Seroquel		S	600 Mg (600 Mg, At Bedtime)	Not Reported
	Tegretol		C		Not Reported
	Lopresor		C		Not Reported
	Glucophage		C		Not Reported
	Prilosec		C		Not Reported
	Dichloralphenazone/Isomethepte ne Mucate/Acetaminophen		C		Not Reported
	Synthroid		C		Not Reported
	Klonopin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2010	7407947	EXPEDITED (15-DAY)	Y	HO	1000013969		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Status Changes	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (200 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (200 Mg, 1 In 1 D), Oral		
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		
	Tacrolimus			S	Oral	Oral		Not Reported
	Acyclovir			C				Not Reported
	Fludrocortisone			C				Not Reported
	Trimethoprim			C				Not Reported
	Magnesium			C				Not Reported
	Lasix			C				Not Reported
	Metoprolol			C				Not Reported
	Omeprazole			C				Not Reported
	Nystatin			C				Not Reported

	Multivitamins	C		Not Reported
	Aspirin	C		Not Reported
	Oxycodone	C		Not Reported
	Cyclobenzaprine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2010	7410435	DIRECT	N	DS				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Impaired Work Ability	Risperidone Odt			S		1 Tablet Once Bedtime		Not Reported
	Lexapro			S		1 Tablet Once Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2010	7319687	EXPEDITED (15-DAY)	Y	DE	1000011867		62 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2010	7365625	EXPEDITED (15-DAY)	Y	OT	1000013054		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dysphonia; Dysuria; Erythema; Headache; Mouth Ulceration; Vasculitis	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Abilify			S		15 Mg (15 Mg, 1 In 1 D)		Not Reported
	Xanax			C				Not Reported
	Mopral			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2010	7409080	EXPEDITED (15-DAY)	Y	DS, HO	1000014090		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Chest Pain; Diplopia; Gaze Palsy; Musculoskeletal Stiffness; Tolosa-Hunt Syndrome	Escitalopram Oxalate		S	Oral	Oral	Not Reported
	Influenza Virus Vaccine Nos		S	Intramuscular	(1 Dosage Forms, Once), Intramuscular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2010	7410918	EXPEDITED (15-DAY)	Y	HO	1000014089		15 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Off Label Use; Somnolence	Escitalopram Oxalate			S		One Blister (Once), Oral		Not Reported
	Zolpidem			S	Oral	One Blister (Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2010	7440815	EXPEDITED (15-DAY)	Y	HO	2010AP001032		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Inversion; Intentional Overdose; Serotonin Syndrome	Escitalopram Oxalate (Escitalopram Oxalate)			S		560 Mg		Not Reported
	Tramadol Hydrochloride			S		3 Gm		Not Reported
	Mirtazapine (Mirtazapine)			S		315 Mg		Not Reported
	Fluoxetine Hydrochloride (Fluoxetine Hydrochloride)			S		1.1 Gm		Not Reported
	Risperidone (Risperidone)			S		120 Mg		Not Reported
	Quetiapine			S		15 Gm		Not Reported
	Lithium (Lithium)			S		13 Gm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2010	7383394	EXPEDITED (15-DAY)	Y	OT	1000013228		33 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Ejaculation Delayed; Insomnia; Libido	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, In 1 D),Oral		Not Reported

Decreased; Poor Quality Sleep; Therapeutic Product Effect Decreased	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2010	7405693	EXPEDITED (15-DAY)	N	OT	US-ASTRAZENECA-2010SE23095		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Drug Ineffective; Insomnia; Meniscus Injury; Nausea; Panic Attack; Thoracic Vertebral Fracture; Thyroid Disorder	Seroquel			S	Oral			Zeneca
	Celebrex			S	Oral			Not Reported
	Effexor			S	Oral		0 YR	Not Reported
	Lexapro			S	Unknown			Not Reported
	Cymbalta			S	Oral		0 MTH	Not Reported
	Neurontin			C				Not Reported
	Glucophage			C				Not Reported
	Prilosec			C				Not Reported
	Dichloralphenazone\Isomethepte ne Mucate			C				Not Reported
	Lorcet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2010	7405738	EXPEDITED (15-DAY)	N	OT	A0860846A		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Confusional State; Hallucination; Suicidal Ideation	Lamictal			S	Oral	175mg Twice Per Day		Glaxosmithkline
	Lexapro			S				Not Reported
	Digoxin			C				Glaxosmithkline
	Coumadin			C				Glaxosmithkline
	Vimpat			C				Glaxosmithkline
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2010	7410379	EXPEDITED (15-DAY)	Y	HO	DSA_43183_2010		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Central Nervous System Vasculitis; Depression; Hypokalaemia; Hyponatraemia; Vomiting	Mono-Tildiem	S	Oral	300 Mg Qd Oral	Not Reported
	Fludex /00340101/	S	Oral	1.5 Mg Qd Oral	Not Reported
	Escitalopram Oxalate	S	Oral	Dose: 1 Unit Daily Oral	Not Reported
	Olmetec	S	Oral	Dose: 1 Unit Daily Oral	Not Reported
	Azopt	S	Ophthalmic	1 Gtt Qd Ophthalmic	Not Reported
	Xalatan	S	Ophthalmic	1 Gtt Qd Ophthalmic	Not Reported
	Bromazepam	S	Oral	0.25 Df Qd, Dose: 0.25 Units Daily Oral	Not Reported
	Esomeprazole (Esomeprazole)	S	Oral	20 Mg Qd Oral	Not Reported
	Phenobarbital\Quinine Hydrobromide	S	Oral	Dose: Daily Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2010	7412458	EXPEDITED (15-DAY)	N	OT	1000014091		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anosmia; Anxiety; Depression; Hepatic Steatosis; Hypersensitivity; Impaired Work Ability; Influenza; Lower Respiratory Tract Infection; Memory Impairment; Oedema Peripheral; Swelling Face; Tinnitus; Upper Respiratory Tract Infection; Weight Increased	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral ; (1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
					Oral	20 Mg (20 Mg,1 In 1 D),Oral ; (1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral		
					Oral	20 Mg (20 Mg,1 In 1 D),Oral ; (1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral		
	Phenylpropanolamine			S	Oral	50 Mg (50 Mg,1 In 1 D),Oral		Not Reported
	Champix			S	Oral	0.5 Mg (0.5 Mg,1 In 1 D),Oral		Not Reported
	Amoxin			S	Oral	Oral		Not Reported
	Oxazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2010	7412480	DIRECT	N	RI			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Dry Mouth; Lip Dry; Muscle Contractions Involuntary; Salivary Hypersecretion; Speech Disorder	Lexapro			S	Oral	1 1/2 Tablets Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2010	7413099	EXPEDITED (15-DAY)	Y	OT	1000014040		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Seizure; Treatment Noncompliance	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			S	Oral	0.5 Mg, Prn, Oral		Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2010	7413407	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	10mg Daily P.O.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2010	7413475	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	20mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2010	7413484	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	20mg Daily P.O.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2010	7413569	EXPEDITED (15-DAY)	Y	HO, LT	USA/AUS/10/0013240		21 YR	Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ileus; Overdose; Serotonin Syndrome	Risperidone			S	Oral	120 Mg, Per Oral		Not Reported
	Fluoxetine			S	Oral	1.1 Gm, Per Oral		Not Reported
	Tramadol Hydrochloride			S	Oral	3 Gm, Per Oral		Not Reported
	Quetiapine			S	Oral	15 Gm, Per Oral		Not Reported
	Escitalopram Oxalate			S	Oral	560 Mg, Per Oral		Not Reported
	Mirtazapine (Mirtazapine)			S	Oral	315 Mg, Per Oral		Not Reported
	Lithium			S	Oral	13 Gm, Per Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2010	7011298	EXPEDITED (15-DAY)	Y	OT	1000005786		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pregnancy; Toxoplasmosis	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Escitalopram Oxalate			S		5 Mg (5 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2010	7320246	EXPEDITED (15-DAY)	Y	OT	1000011889		40 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chorea	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Trazolan	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2010	7416700	EXPEDITED (15-DAY)	Y	OT	1000014098			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Breast Feeding; Neutropenia	Escitalopram Oxalate			S	Transmammary	Transmammary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2010	7416701	EXPEDITED (15-DAY)		OT	1000014125			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Feeling Abnormal	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2010	7994731	EXPEDITED (15-DAY)	N	OT	B0657267A		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Foetal Death; Hellp Syndrome; Maternal Exposure During Pregnancy; Proteinuria; Thrombocytopenia	Clamoxyl (Amoxicillin)			S	Oral	1g Three Times Per Day		Glaxosmithkline
	Amitriptyline Hydrochloride			S	Oral			Unknown
	Bromazepam			S	Oral	48mg Per Day	1 DAY	Unknown
	Rivotril			S	Oral	2unit Per Day		Unknown
	Prazepam			S	Oral			Unknown
	Topiramate			S	Oral			Unknown
	Zyprexa			S	Oral			Unknown
	Zopiclone			S	Oral	7.5mg Per Day	3 MTH	Unknown
	Chlorpromazine			S	Oral	20drop Three Times Per Day		Unknown

Oxazepam	S	Oral	10mg Twice Per Day			Unknown
Spasfon Lyoc	S	Oral	80mg Twice Per Day			Unknown
Effexor	S	Oral	37.5mg Per Day			Unknown
Stilnox	S	Oral	10mg Per Day	1 MTH		Unknown
Trimeprazine Tartrate	S	Oral	100drop Per Day			Unknown
Escitalopram Oxalate	S	Oral	10mg Per Day	16 DAY		Unknown
Akineton	S	Oral	4mg Twice Per Day			Unknown
Periciazine	S	Oral	50drop Per Day			Unknown
Econazole Nitrate	C	Vaginal		6 DAY		Unknown
Flagyl	C	Oral	500mg Twice Per Day	6 DAY		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2010	7399722	EXPEDITED (15-DAY)	Y	OT	1000013845		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperreflexia; Nervous System Disorder; Seizure; Tremor	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2010	7410310	EXPEDITED (15-DAY)	Y	DE, HO, LT	DE-ABBOTT-10P-062-0648697-00		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Akineton			S				Not Reported
	Cipralex			S		15-20mg		Not Reported
	Risperdal			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2010	7417969	EXPEDITED (15-DAY)	Y	HO	1000014254		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Localised Infection;	Escitalopram Oxalate			S				Not Reported

Localised Oedema; Nausea; Nodule; Pain; Pyrexia; Swelling Face	Benzodiazepine Derivatives		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2010	7417970	EXPEDITED (15-DAY)	Y	OT	1000012225		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Fall; Hot Flush; Paraesthesia; Serotonin Syndrome; Vertigo	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D) Oral		Not Reported
	Analgesics			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2010	7418428	EXPEDITED (15-DAY)	Y	OT	1000014234		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Crying; Impulsive Behaviour; Intentional Self-Injury	Citalopram Hydrobromide			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral ; 15 Mg (15 Mg, 1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D),Oral ; 15 Mg (15 Mg, 1 In 1 D),Oral		
	Hydroxizine (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2010	7418438	EXPEDITED (15-DAY)	Y	HO	DSM-2010-00772		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Vasculitis; Confusional State; Depression; Hypokalaemia; Hyponatraemia; Vomiting	Olmetec			S	Oral	(1 In 1 D),Oral		Not Reported
	Fludex (Indapamide)			S	Oral	1.5 Mg (1.5 Mg, 1 In 1 D), Oral		Not Reported

Mono-Tildiem	S	Oral	300 Mg (300 Mg,1 In 1 D),Oral		Not Reported
Escitalopram Oxalate	S	Oral	(1 In 1 D), Oral		Not Reported
Azopt	S	Ophthalmic	1 Get (1 Gtt,1 In 1 D), Ophthalmic		Not Reported
Xalatan	S	Ophthalmic	1 Get (1 Gtt,1 In 1 D), Ophthalmic		Not Reported
Lexomil (Bromazepam) (Bromazepam)	S	Oral	0.25 Units (1 In 1 D), Oral		Not Reported
Esomeprazole	S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
Crataegus	S	Oral	(1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2010	7418944	EXPEDITED (15-DAY)	Y	HO, LT	1000013442		69 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Pressure Increased; Blood Urea Increased; Bradycardia; Cardiac Arrest; Fall; Fibrin D Dimer Increased; Long Qt Syndrome; Torsade De Pointes; Vascular Encephalopathy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Votum (Tablets)			C				Not Reported
	Ass(100 Milligram, Tablets)			C				Not Reported
	Pantoprazol (40 Milligram, Tablets)			C				Not Reported
	Metformin (500 Milligram, Tablets)			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2010	7345199	EXPEDITED (15-DAY)	Y	HO, OT	IT-ABBOTT-10P-083-0634308-00		40 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Electrocardiogram	Akineton			S	Oral	Overdose: 10 Df		Not Reported

Repolarisation Abnormality; Intentional Overdose; Overdose; Sinus Bradycardia	Unspecified Ingredient		S	Oral	Overdose: 20 Df	Not Reported
	Escitalopram Oxalate		S	Oral	Overdose: 14 Df	Not Reported
	Lithium Carbonate		S	Oral	Overdose: 10 Df	Not Reported
	Risperdal		C		2.6786 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2010	7411681	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2010SE24728		24 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Inexium			S	Oral		2 MTH	Astrazeneca
	Bromazepam			S	Oral		7 DAY	Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Efferalgan Codeine			S	Oral	500 Mg As Requested		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2010	7005978	EXPEDITED (15-DAY)	Y	HO	1000006235		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activated Partial Thromboplastin Time Prolonged; Ascites; Blood Albumin Decreased; Blood Bilirubin Increased; Blood Sodium Decreased; C-Reactive Protein Increased; Condition Aggravated; Gastrooesophageal Reflux Disease; Hepatic Cirrhosis; Hepatic Fibrosis; Hepatic Steatosis; Hepatomegaly; Liver Disorder; Ocular Icterus; Red Blood Cell Count Decreased;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zopiclone			S	Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral		Not Reported
	Dolotmin			C				Not Reported

Splenomegaly; Waist Circumference Increased; White Blood Cell Count Increased; Yellow Skin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2010	7360456	EXPEDITED (15-DAY)	Y	DS	1000012909		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Interaction; Impaired Work Ability; Musculoskeletal Pain; Oedema Peripheral; Polyneuropathy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Terbinafine Hydrochloride			S	Oral	250 Mg (250 Mg, 1 In 1 D),Oral		Not Reported
	Sertraline Hydrochloride			S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported
	Zovirax			C				Not Reported
	Symbicort			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2010	7418536	DIRECT	Y	DE			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Completed Suicide; Impaired Work Ability; Insomnia	Lexapro			S	Oral	20 Mg Daily Po		Not Reported
	Xanax			S	Oral	Decreased From 4mg T0 .5 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2010	7420404	EXPEDITED (15-DAY)	Y	LT	1000014265		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Potassium Chloride			S	Oral	Oral		Not Reported
	Mirtazapine			S	Oral	15 Mg, Oral		Not Reported

Seroquel		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2010	7252348	EXPEDITED (15-DAY)	Y	DE, LT	PHHY2010FR02745		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Insomnia; Myalgia; Persistent Depressive Disorder; Suicide Attempt	Glivec			S	Oral	400 Mg, Qd		Novartis
	Baraclude			S	Oral	0.5 Mg, Qd		Not Reported
	Zopiclone			S		Unk		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Zyprexa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2010	7255775	EXPEDITED (15-DAY)	Y	DE, LT	PHHY2010FR03314		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Persistent Depressive Disorder; Suicide Attempt	Glivec			S	Oral	400 Mg, Qd		Novartis
	Baraclude			S		0.05 Mg/Day		Not Reported
	Zyprexa			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Zopiclone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2010	7409341	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2010064874		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypokalaemia; Hyponatraemia	Xalatan			S	Ophthalmic	1 Drop(S);Daily		Pfizer
	Diltiazem Hydrochloride			S	Oral	300 Mg, Daily	38 DAY	Not Reported
	Olmetec			S	Oral	1 Unit Daily	38 DAY	Not Reported
	Fludex (Indapamide)			S	Oral	Unk	9 DAY	Not Reported

	Escitalopram Oxalate	S	Oral	Unk	Not Reported
	Azopt	S	Ophthalmic	Unk	Not Reported
	Bromazepam	S	Oral	Unk	Not Reported
	Esomeprazole	S	Oral	Unk	Not Reported
	Phenobarbital\Quinine Hydrobromide\Valerian Extract	S	Oral	Unk;Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2010	7414258	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2010SA030905		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Hellp Syndrome	Stilnox			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported
	Chlorpromazine			S	Oral	Dose:60 Unit(S)		Not Reported
	Periciazine			S	Oral	Dose:50 Unit(S)		Not Reported
	Amitriptyline Hydrochloride			S	Oral			Not Reported
	Amitriptyline Hydrochloride			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Rivotril			S	Oral	Dose:2 Unit(S)		Not Reported
	Prazepam			S	Unknown			Not Reported
	Topiramate			S	Unknown			Not Reported
	Zyprexa			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Oxazepam			S	Oral			Not Reported
	Spasfon-Lyoc			S	Oral			Not Reported
	Effexor			S	Oral			Not Reported
	Theralene			S	Oral	Dose:100 Unit(S)		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Biperiden Hydrochloride			S	Oral			Not Reported

	Amoxicillin	S	Oral	Not Reported
	Econazole Nitrate	C	Unknown	Not Reported
	Flagyl	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2010	7416706	EXPEDITED (15-DAY)	N	OT	1000014124		48 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Dizziness; Feeling Abnormal; Hyperhidrosis; Restlessness; Suicidal Ideation; Tremor	Lexapro			S	Oral Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Remeron			C				Not Reported
	Foster			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2010	7419521	DIRECT	N	HO, LT, RI, OT			86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Quality Issue; Rectal Haemorrhage; Transfusion	Lexapro			S	Oral Oral	5 Mg 2 X Daily Po 5 Mg 2 X Daily Po		Forest
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2010	7367166	EXPEDITED (15-DAY)	Y	HO, OT	1000013141		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Caesarean Section; Drug Withdrawal Syndrome Neonatal; Hyperglycaemia;	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported

Hypertonia Neonatal; Hypopnoea; Maternal Drugs Affecting Foetus; Selective Eating Disorder; Yawning

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2010	7399719	EXPEDITED (15-DAY)	Y	OT	1000013871		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Diplopia; Dyspnoea; Fear; Frontal Lobe Epilepsy; Loss Of Libido; Muscle Spasms; Paraesthesia; Rash	Escitalopram Oxalate			S	Oral	(20 Mg),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	(60 Mg),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2010	7415524	EXPEDITED (15-DAY)	N	OT	NL-ASTRAZENECA-2010SE22548			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Homicidal Ideation; Libido Decreased; Suicidal Ideation; Tooth Disorder; Weight Increased	Seroquel			S	Oral			Zeneca
	Amitriptyline Hydrochloride			S				Not Reported
	Lexapro			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Prothiaden			S				Not Reported
	Oxazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2010	7415950	NON-EXPEDITED	N		US-ROXANE LABORATORIES, INC.-2010-RO-00694RO		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hypomania; Increased Appetite; Weight Increased	Lithium Carbonate			S	Oral	600 Mg		Roxane
	Lithium Carbonate			S		750 Mg		Roxane
	Lexapro			S	Oral	20 Mg		Not Reported

Lexapro	S	Oral	10 Mg		Not Reported
Lexapro	S	Oral	5 Mg		Not Reported
Tegretol	C	Oral	600 Mg		Not Reported
Ativan	C	Oral	1.5 Mg		Not Reported
Vitamin D2	C				Not Reported
Haldol	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2010	7423926	EXPEDITED (15-DAY)	Y	OT	1000014375		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Movement Disorder	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2010	7402287	EXPEDITED (15-DAY)	Y	HO	AU-WATSON-2010-06800		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Serotonin Syndrome	Mirtazapine			S		315 Mg Single		Watson
	Risperidone			S		120 Mg		Watson
	Fluoxetine			S		1.1 G Single		Watson
	Tramadol Hydrochloride			S		3 G Single		Watson
	Quetiapine			S		15 G Single		Not Reported
	Escitalopram Oxalate			S		560 Mg Single		Not Reported
	Lithium			S		13 G Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2010	7424492	EXPEDITED (15-DAY)	Y	HO	1000014376		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

Aggravated; Creatinine Renal Clearance Decreased; Dizziness; Headache; Hyperkalaemia; Hyponatraemia; Visual Impairment	Glucor	C		Not Reported
	Gliclazide	C		Not Reported
	Beclomethasone Dipropionate	C		Not Reported
	Ramipril	C		Not Reported
	Prazosin Hydrochloride	C		Not Reported
	Lantus	C		Not Reported
	Previscan (Fluindione)	C		Not Reported
	Alteis	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2010	7424519	EXPEDITED (15-DAY)	Y	OT	1000014378		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vasculitis	Escitalopram Oxalate			S				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2010	7427249	EXPEDITED (15-DAY)	Y	HO	2010US001864		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Mental Status Changes	Prograf			S	Oral	Oral		Not Reported
	Lexapro			S	Oral	10 Mg, Uid/Qd, Oral; 5 Mg, Uid/Qd, Oral; 20 Mg, Uid/Qd, Oral		Not Reported
					Oral	10 Mg, Uid/Qd, Oral; 5 Mg, Uid/Qd, Oral; 20 Mg, Uid/Qd, Oral		
					Oral	10 Mg, Uid/Qd, Oral; 5 Mg, Uid/Qd, Oral; 20 Mg, Uid/Qd, Oral		
					Oral	10 Mg, Uid/Qd, Oral; 5 Mg, Uid/Qd, Oral; 20 Mg, Uid/Qd, Oral		
	Acyclovir			C				Not Reported
	Fludrocortisone Acetate			C				Not Reported
	Omeprazole			C				Not Reported
	Nystatin			C				Not Reported
	Multi-Vitamin			C				Not Reported

	Aspirin (Acetylsalicylic Acid)	C	Not Reported
	Oxycodone (Oxycodone)	C	Not Reported
	Cyclobenzaprine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2010	7407509	EXPEDITED (15-DAY)	Y	OT	PHHY2010FR33477		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Loss Of Personal Independence In Daily Activities; Somnolence	Aliskiren			S		300 Mg		Novartis
	Aliskiren			S		150 Mg		Novartis
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2010	7419044	EXPEDITED (15-DAY)	N	OT	NL-ASTRAZENECA-2010SE22612			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Homicidal Ideation; Insomnia; Irritability; Libido Decreased; Nausea; Suicidal Ideation; Weight Increased	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Citalopram			S				Not Reported
	Lexapro			S				Not Reported
	Effexor			S				Not Reported
	Remeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2010	5833301	EXPEDITED (15-DAY)	N	DE, OT	HQWYE547320JUN05		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Completed Suicide; Condition Aggravated; Drug Ineffective; Glycosylated Haemoglobin Increased; Gun Shot Wound; Hypoglycaemia; Impaired	Effexor			S				Wyeth
	Effexor			S				Wyeth
	Lexapro			S				Not Reported

Work Ability; Insomnia;
Mental Impairment;
Nervousness;
Restlessness; Suicidal
Ideation; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2010	7419997	EXPEDITED (15-DAY)	Y	OT	FR-JNJFOC-20100604288		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypotension; Speech Disorder; Syncope	Tramadol Hydrochloride			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Oxazepam			S	Unknown			Not Reported
	Meprobamate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Nortriptyline Hydrochloride			S	Unknown			Not Reported
	Phenobarbital			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Tiapride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2010	7420004	EXPEDITED (15-DAY)	Y	OT	FR-PFIZER INC-2010074215		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypotension; Speech Disorder; Syncope	Sertraline Hydrochloride			S				Pfizer
	Morphine Sulfate			S				Not Reported
	Tramadol			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Clonazepam			S				Not Reported
	Amitriptyline			S				Not Reported
	Oxazepam			S				Not Reported
	Meprobamate			S				Not Reported

	Nortriptyline	S	Not Reported
	Phenobarbital	S	Not Reported
	Tiapride	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2010	7071246	EXPEDITED (15-DAY)	Y	HO	1000007682		74 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Creatine Phosphokinase Increased; Dehydration; Disturbance In Attention; Myoglobin Blood Increased; Urinary Tract Infection	Escitalopram Oxalate			S	Oral	10 Mg (10mg, 1 In 1 D) , Oral		Not Reported
	Pipamperone			S		3 Dosage Forms (3 Dosage Forms, 1 In		Not Reported
	Tiapride			S	Oral	300mg (100mg, 3 In 1 D), Oral		Not Reported
	Risperdal			S		I Mg (0.5 Mg, 2 In 1 D)		Not Reported
	Clexane (0.8 Milligram, Injection)			C				Not Reported
	Concor (2.5 Milligram, Tablets)			C				Not Reported
	Ferro Sanol (40milligram, Tablets)			C				Not Reported
	Folsan (0.4 Milligram, Tablets)			C				Not Reported
	Lisinopril (5milligram, Tablets)			C				Not Reported
	Metformin (500milligram, Tablets)			C				Not Reported
	Vitamin B (1 Dosage Forms, Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2010	7420743	EXPEDITED (15-DAY)	Y	OT	AU-RANBAXY-2010RR-34452		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Serotonin Syndrome	Fluoxetine Hcl			S	Oral	1.1 G, Unk		Ranbaxy
	Tramadol Hydrochloride			S	Oral	3 G, Unk		Not Reported
	Quetiapine			S	Oral	15 G, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	560 Mg, Unk		Not Reported

Mirtazapine	S	Oral	315 Mg, Unk		Not Reported
Risperidone	S	Oral	120 Mg, Unk		Ranbaxy
Lithium	S	Oral	13 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2010	7420844	EXPEDITED (15-DAY)	N	OT	NL-ASTRAZENECA-2010SE22837			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Headache; Homicidal Ideation; Insomnia; Irritability; Libido Decreased; Nausea; Suicidal Ideation; Weight Increased	Seroquel			S	Oral			Zeneca
	Prozac			S				Not Reported
	Lexapro			S				Not Reported
	Amitriptyline Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2010	7427780	DIRECT	N	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Urticaria	Lexapro			S	Oral	10mg Once A Day Po , Appprox 6-8 Months	6 MTH	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2010	7429729	EXPEDITED (15-DAY)	Y	HO	1000014441		24 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Haemorrhage; Hepatitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Inexium			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Bromazepam			S	Oral	6 Mg (6 Mg, 1 In 1 D), Oral		Not Reported
	Efferalgan Codeine			S	Oral	500 Mg, As Required, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2010	7429882	EXPEDITED (15-DAY)	Y	HO	1000014442		79 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrooesophageal Reflux Disease; Hepatitis Acute; Melaena; Oropharyngeal Pain	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lercanidipine			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Tanakan			S	Oral	3 Dosage Forms (3 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Ezetimibe			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Zolpidem			S	Oral	0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Plavix			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Sotalol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2010	7431749	EXPEDITED (15-DAY)	Y	HO	1000014447			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unevaluable Event	Lexapro			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2010	7431939	EXPEDITED (15-DAY)	N	OT	1000011550			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Disturbance In Attention; Fatigue; Headache; Hyperhidrosis; Nervousness; Sleep Disorder	Escitalopram Oxalate	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
			Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral	
	Lormetazepam (Tablets)	C			Not Reported
	Aceclofenac	C			Not Reported
	Zaldiar	C			Not Reported
	Adolonta (Tablets)	C			Not Reported
	Paracetamol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2010	7453600	EXPEDITED (15-DAY)	Y	HO	2010SP032445		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome	Mirtazapine			S	Oral	315 Mg; Po		Not Reported
	Tramadol Hydrochloride			S	Oral	3000 Mg; Po		Not Reported
	Escitalopram Oxalate			S	Oral	560 Mg; Po		Not Reported
	Fluoxetine Hydrochloride (Fluoxetine Hydrochloride)			S	Oral	1100 Mg; Po		Not Reported
	Risperidone (Risperidone)			S	Oral	120 Mg; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2010	7453639	EXPEDITED (15-DAY)	Y	HO	2010SP031915		67 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Delirium; Disorientation; Mental Disorder; Unresponsive To Stimuli	Mirtazapine			S	Oral	45 Mg;Qd;Po; 60 Mg;Qd;Po		Not Reported
					Oral	45 Mg;Qd;Po; 60 Mg;Qd;Po		
	Cipralex			S	Oral	10 Mg;Qd;Po; 20 Mg; Qd; Po; 30 Mg;Qd;Po 15		Not Reported

				Mg;Qd;Po	
			Oral	10 Mg;Qd;Po; 20 Mg; Qd; Po; 30 Mg;Qd;Po 15 Mg;Qd;Po	
			Oral	10 Mg;Qd;Po; 20 Mg; Qd; Po; 30 Mg;Qd;Po 15 Mg;Qd;Po	
			Oral	10 Mg;Qd;Po; 20 Mg; Qd; Po; 30 Mg;Qd;Po 15 Mg;Qd;Po	
	Lithium Carbonate	S	Oral	225 Mg;Qd;Po; 450 Mg;Qd;Po	Not Reported
			Oral	225 Mg;Qd;Po; 450 Mg;Qd;Po	
	Lyrica	S	Oral	50 Mg;Qd;Po; 75 Mg;Qd;Po; 50 Mg;Qd;Po; 25 Mg;Qd;Po	Not Reported
			Oral	50 Mg;Qd;Po; 75 Mg;Qd;Po; 50 Mg;Qd;Po; 25 Mg;Qd;Po	
			Oral	50 Mg;Qd;Po; 75 Mg;Qd;Po; 50 Mg;Qd;Po; 25 Mg;Qd;Po	
			Oral	50 Mg;Qd;Po; 75 Mg;Qd;Po; 50 Mg;Qd;Po; 25 Mg;Qd;Po	
	Allopurinol	C			Not Reported
	Disalunil	C			Not Reported
	Lisinopril	C			Not Reported
	Pantozol	C			Not Reported
	Tavor (Lorazepam)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2010	7752483	EXPEDITED (15-DAY)	Y	OT	1000014437		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Blood Pressure Increased; Fall; Fatigue; Foetal Death;	Escitalopram Oxalate			S	Oral	10 Mg (10mg, 1 In 1d, Oral)		Not Reported

Hellp Syndrome; Maternal Exposure During Pregnancy; Overdose; Pregnancy; Sleep Disorder; Somnolence	Amitriptyline Hydrochloride	S	Oral	One Bottle (Once) Oral	Not Reported
	Bromazepam	S	Oral	48 Mg (Once), Oral	Not Reported
	Rivotril	S	Oral	2 Dosage Forms (2 Dosage Forms, 1 In 1 D), Oral	Not Reported
			Oral	2 Dosage Forms (2 Dosage Forms, 1 In 1 D), Oral	
	Prazepam	S	Oral	Oral	Not Reported
	Topiramate	S	Oral	Oral	Not Reported
	Zyprexa	S	Oral	5mg (5mg, 1 In 1d), Oral	Not Reported
	Zopiclone	S	Oral	7.5 Mg (7.5 Mg, 1 In 1 D) Oral	Not Reported
	Chlorpromazine	S	Oral	60 Gtt (Gtt, 1 In 1 D), Oral	Not Reported
	Oxazepam	S	Oral	20mg (20mg, 1 In 1d), Oral	Not Reported
	Spasfon Lyoc	S	Oral	160 Mg (160 Mg, 1 In 1d) Oral	Not Reported
	Effexor	S	Oral	37.5 Mg, (37.5 Mg, 1 In 1d) Oral	Not Reported
	Stilnox	S	Oral	10mg (10mg, 1 In 1d) Oral	Not Reported
	Theralene	S		100 Gtt (100 Gtt, 1 In 1	Not Reported
	Akineton	S	Oral	8mg (8mg, 1 In 1 D), Oral	Not Reported
	Periciazine	S	Oral	50gtt (50gtt, 1 In 1d), Oral	Not Reported
	Clamoxyl (Amoxicillin)	S	Oral	3gm (3gm, 1 In 1d) Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2010	7423108	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20100603797		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Miosis; Sopor	Haldol			S	Oral			Not Reported
	Depakene			S	Oral			Not Reported

	Delorazepam	S	Oral		Not Reported
	Cipralex	S	Oral		Not Reported
	Seroquel	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2010	7423501	EXPEDITED (15-DAY)	Y	HO	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2010-BP-06		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Tamsulosin Hydrochloride			S	Oral			Boehringer Ingelheim
	Tamsulosin Hydrochloride			S	Oral			Boehringer Ingelheim
	Escitalopram Oxalate			S	Oral			Not Reported
	Rythmol			C				Not Reported
	Selokeen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2010	7428361	DIRECT	Y	DS, HO			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Enterococcal Infection; Foaming At Mouth; Serotonin Syndrome; Somnolence; Wound	Linezolid			S	Oral	600 Mg Every 12 Hours Po		Pfizer
	Escitalopram Oxalate			S	Oral	20 Mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2010	7450812	EXPEDITED (15-DAY)	Y	HO	2010SP032472		30 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma Scale Abnormal; Drug Interaction; Serotonin Syndrome	Remeron			S	Oral	30 Mg;Qd;Po		Not Reported
	Cipralex			S	Oral	20 Mg;Qd;Po		Not Reported
	Zyprexa			S	Oral	10 Mg;Qd;Po		Not Reported
	Stilnox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2010	7454281	EXPEDITED (15-DAY)	Y	HO	612608		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Decreased; Drug Interaction; Hypoxia; Respiratory Acidosis; Serotonin Syndrome	Fentanyl Citrate			S	Intravenous (not otherwise specified)	250 Mg Microgram(S), Intravenous		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Insulin Nos			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	(Gabapentin)			C				Not Reported
	Lasoprazole			C				Not Reported
	Lorazepam			C				Not Reported
	Oxycodone Hydrochloride			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported
	Etomidate			C				Not Reported
	Vecuronium Bromide			C				Not Reported
	Morphine Sulfate			C				Not Reported
	Cefazolin			C				Not Reported
	Ipratropium Bromide And Albuterol Sulfate			C				Not Reported
	Enoxaparin Sodium			C				Not Reported
	Famotidine			C				Not Reported
	Midazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2010	7455526	EXPEDITED (15-DAY)	Y	OT	1000014444		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Respiratory Disorder Neonatal	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Transplacental; 5 Mg (5mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Transplacental; 5 Mg (5mg, 1 In 1 D), Oral		
	Buspar			S	Transplacental	30 Mg (10 Mg, 3 In 1 D), Transplancental		Not Reported

	Effexor	S	Transplacental	75 Mg (75 Mg, 1 In 1 D), Transplacental		Not Reported
	Oxazepam	S	Transplacental	15 Mg (15 Mg, 1 In 1 D), Transplacental		Not Reported
	Trazodone Hydrochloride	S	Transplacental	50 Mg, Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2010	7355641	EXPEDITED (15-DAY)	Y	OT	1000012709		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Crying; Delirium; Dementia; Dysarthria; Parkinsonism; Therapeutic Product Effect Decreased; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2010	7383623	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20100500532		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Pseudomonas Infection; Pyrexia; Somnolence; Staphylococcal Infection	Fentanyl			S	Transdermal			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Unspecified Ingredient			S	Intravenous (not otherwise specified)			Not Reported
	Doxorubicin Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Fluoxetine Hydrochloride			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Ondansetron			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

	Diazepam	S	Unknown	Not Reported
	Paroxetine Hydrochloride	C	Unknown	Not Reported
	Movicol	C	Unknown	Not Reported
	Enoxaparin Sodium	C	Unknown	Not Reported
	Co Trimoxazole	C	Unknown	Not Reported
	Hydrocortisone	C	Unknown	Not Reported
	Dexamethasone	C	Unknown	Not Reported
	Omeprazole	C	Unknown	Not Reported
	Paracetamol	C	Unknown	Not Reported
	Augmentine	C	Unknown	Not Reported
	Urokinase	C	Unknown	Not Reported
	Blood Transfusion	C	Intravenous (not otherwise specified)	Not Reported
	Metoclopramide	C	Unknown	Not Reported
	Domperidone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2010	7437127	EXPEDITED (15-DAY)	Y	DE	1000014486		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haematoma; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Sintrom			S	Oral	Oral		Not Reported
	Dexamethasone			S	Oral	1 Mg (1 Mg, 1 In 1 D), Oral		Not Reported
	Lormetazepam			S	Oral	1 Mg (1 Mg, 1 In 1 D), Oral		Not Reported
	Serc (Tablets)			C				Not Reported
	Omeprazol (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2010	7437144	EXPEDITED (15-DAY)	Y	HO	1000014519		67 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Delirium; Drug Interaction; Overdose	Escitalopram Oxalate	S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral	Not Reported
	Escitalopram Oxalate	S	Oral	15 Mg (15 Mg, 1 In 1 D, Oral)	Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported
			Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral	
	Remergil	S	Oral	60 Mg (60 Mg, 1 In 1 D), Oral	Not Reported
	Remergil	S	Oral	45 Mg (45 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In1 D), Oral	Not Reported
	Lithium	S	Oral	225 Mg (225 Mg, 1 In 1 D), Oral	Not Reported
	Lithium	S	Oral	450 Mg (450 Mg, 1 In 1 D), Oral	Not Reported
	Lyrica	S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral; 50 Mg (50 Mg, 1 In 1 D), Oral	Not Reported
			Oral	75 Mg (75 Mg, 1 In 1 D), Oral; 50 Mg (50 Mg, 1 In 1 D), Oral	
	Lyrica	S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral	Not Reported
	Lyrica	S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral	Not Reported
	Allopurinol	C			Not Reported
	Disalunil	C			Not Reported
	Lisinopril	C			Not Reported
	Pantozol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2010	7465312	EXPEDITED (15-DAY)	Y	HO	2010SP032784		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hypokalaemia; Inappropriate Antidiuretic Hormone Secretion; Malaise; Oedema Peripheral; Weight Decreased	Mirtazapine			S	Oral	15 Mg; Qd; Po		Not Reported
	Prozac			S	Oral	Po		Not Reported
	Aldactazine			S	Oral	25 Mg; Bid; Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg; Qd; Po		Not Reported
	Levothyrox			C				Not Reported
	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2010	7382984	EXPEDITED (15-DAY)	N	OT	1000013348		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Depression; Drug Ineffective; Fear; Feeling Abnormal; Mood Altered; Nervousness; Palpitations; Psychiatric Symptom; Self-Injurious Ideation; Sleep Disorder; Social Avoidant Behaviour; Suicidal Ideation; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2010	7427102	EXPEDITED (15-DAY)	Y	OT	FR-ABBOTT-10P-056-0650779-00		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2010	7435734	DIRECT	N	DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Lexapro			S						Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2010	7436289	DIRECT	N	HO, RI			20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Mania	Lexapro			S	Oral	20 Mg Twice/ Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2010	7281514	EXPEDITED (15-DAY)	Y		GB-TEVA-224097ISR			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Trazodone Hydrochloride			S	Unknown	The Suspect Medication Was Taken By The Father		Barr
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2010	7427873	EXPEDITED (15-DAY)	Y	HO	GXKR2010DE06697		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis	Aspirin			S	Oral	100 Mg, Qd		Not Reported
	Remergil			C				Not Reported
	Fragmin			C				Not Reported
	Simvastatin			C				Not Reported
	Metoprolol			C				Not Reported
	Plavix			S	Oral	75 Mg, Qd		Not Reported
	Cipralex			S		30 Mg, Qd	5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2010	7427945	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-15155708		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Emotional Disorder; Product Dose Omission; Psychotic Disorder	Abilify			S		Pills		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2010	7428201	EXPEDITED (15-DAY)		OT	FR-ABBOTT-10P-056-0650481-00		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Blood Pressure Increased; Fatigue; Foetal Death; Hellp Syndrome; Sleep Disorder; Somnolence	Akineton			S	Oral	Controlled Release Coated Tablet		Not Reported
	Seroplex			S	Oral			Not Reported
	Clamoxyl (Amoxicillin)			S	Oral			Not Reported
	Laroxyl			S	Oral			Not Reported
	Laroxyl			S	Oral	Overdose: 1 Bottle (Unspecified Dose		Not Reported
	Lexomil			S	Oral			Not Reported
	Lexomil			S	Oral	Overdose; 4 Tablets On 16 Nov 2008		Not Reported
	Rivotril			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Lysanxia			S	Oral			Not Reported
	Epitomax			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Largactil			S	Oral	60 Gtt Drops		Not Reported
	Seresta			S	Oral			Not Reported
	Spasfon Lyoc			S	Oral	Oral Lyophilized		Not Reported

	Effexor	S	Oral			Not Reported
	Stilnox	S	Oral			Not Reported
	Theralene	S	Oral	100 Gtt Drops		Not Reported
	Neuleptil	S	Oral	50 Gtt Drops		Not Reported
	Gyno Pevaryl	C	Vaginal			Not Reported
	Flagyl	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2010	7349042	EXPEDITED (15-DAY)	Y	DS	1000012568			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Enteritis	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lysanxia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2010	7383396	EXPEDITED (15-DAY)	Y	DS	1000013490			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Rigidity; Diarrhoea	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lysanxia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2010	7417605	EXPEDITED (15-DAY)	Y	OT	FR-PURDUE-USA-2010-0044363		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Oxycodone Hydrochloride			S	Oral	120 Mg, Daily		Purdue
	Fentanyl			S	Nasal	200 Mcg, See Text		Not Reported
	Escitalopram Oxalate			S		5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2010	7428702	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-		66 YR	Male	ITA

20100605115

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Sluggishness; Tachypnoea	Risperdal			S	Oral	Unspecified Dose Of 2 Mg		Not Reported
	Lorazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2010	7430691	NON-EXPEDITED	Y	HO	US-PFIZER INC-2008015742		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Geodon			S	Oral	Q Hs		Pfizer
	Lexapro			S				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2010	7430881	NON-EXPEDITED	Y		US-PFIZER INC-2008028856			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Metrorrhagia	Depo-Provera			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2010	7458969	EXPEDITED (15-DAY)	N	OT	DSA_43296-2010		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Anxiety; Fatigue; Feelings Of Worthlessness; Mood Swings; Obsessive Thoughts; Poor Quality	Wellbutrin Xl			S	Oral	Df Oral		Not Reported
	Cipralex			S	Oral	Df, Oral, (20 Mg Qd Oral)	2 MTH	Not Reported
	Hydrocortisone			C				Not Reported
	Ortho Tri Cyclen			C				Not Reported

Sleep

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2010	7452900	EXPEDITED (15-DAY)	N	OT	DSA_43299_2010		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Depression; Dizziness; Dry Mouth; Erection Increased; Fatigue; Increased Appetite; Muscular Weakness; Nausea; Somnolence; Suicidal Ideation; Tinnitus; Tremor; Weight Increased	Wellbutrin Xl			S	Oral	300 Mg Qd Oral	3 YR	Not Reported
	Cipralex			S	Oral	10 Mg Qd Oral		Not Reported
	Clonazepam			S	Oral	1 Mg Qd Oral	2 YR	Not Reported
	Seroquel			S	Oral	200 Mg Qd Oral	2 YR	Not Reported
	Echinacea			C				Not Reported
	Horse Chestnut Extract			C				Not Reported
	Silybum Marianum			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2010	7417683	EXPEDITED (15-DAY)	Y	OT	FR-PURDUE-USA-2010-0044495		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypotension; Speech Disorder; Syncope	Tramadol Hydrochloride			S				Purdue
	Morphine Sulfate			S				Purdue
	Oxazepam			S				Not Reported
	Meprobamate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Amitriptyline			S				Not Reported
	Nortriptyline			S				Not Reported
	Phenobarbital			S				Not Reported
	Clonazepam			S				Not Reported
	Sertraline Hydrochloride			S				Not Reported
	Tiapride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2010	7451649	EXPEDITED (15-DAY)	N	HO	1000014566		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Blood Pressure Diastolic Decreased; Dizziness; Lethargy; Loss Of Consciousness; Skin Laceration	Lexapro		S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported
	Geodon		C			Not Reported
	Simvastatin		C			Not Reported
	Trilipix		C			Not Reported
	Remeron		C			Not Reported
	Clonazepam		C			Not Reported
	Azor		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2010	7454270	EXPEDITED (15-DAY)	Y	HO, LT	1000014616		30 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Aspiration; Coma; Intentional Overdose	Escitalopram Oxalate			S	Oral	Once, Oral		Not Reported
	Alprazolam			S	Oral	Once, Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2010	7400874	EXPEDITED (15-DAY)	Y	HO	1000013739		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Condition Aggravated; Decreased Appetite; Suicidal Ideation; Weight Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2010	7442747	EXPEDITED (15-DAY)	Y	LT	GXKR2010DK05980		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Drug Interaction	Mirtazapine			S	Oral			Novartis
	Seroquel			C	Oral	25 Milligram(S)		Not Reported

Bendroflumethiazide	S	Oral	Unk	1241 DAY	Not Reported
Escitalopram Oxalate	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2010	7443773	NON-EXPEDITED	Y		US-PFIZER INC-2007036940			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Decreased	Geodon			S				Pfizer
	Lexapro			S				Not Reported
	All Other Therapeutic Products			C				Not Reported
	Avodart			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2010	7444399	NON-EXPEDITED	N	OT	US-PFIZER INC-2007090114		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Muscle Twitching; Pruritus	Geodon			S	Oral			Pfizer
	Lexapro			S	Oral	Daily		Not Reported
	Xanax			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2010	7444692	NON-EXPEDITED	Y	OT	US-PFIZER INC-2007091513		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lacunar Infarction	Geodon			S				Pfizer
	Geodon			S				Pfizer
	Lexapro			S				Not Reported
	Celebrex			C				Not Reported
	Synthroid			C				Not Reported
	Asa			C				Not Reported
	Lyrica			C				Not Reported
	Oxycontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2010	7444703	NON-EXPEDITED	Y		US-PFIZER INC-2007083863		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Electrocardiogram Qt Prolonged; Panic Reaction; Sinus Arrhythmia; Tic; Wolff-Parkinson-White Syndrome	Geodon			S				Pfizer
	Paliperidone			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2010	7450075	DIRECT	Y				36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough	Lisinopril And Hydrochlorothiazide			S	Oral	1 Tab Daily Po		Lupin
	Lexapro			S	Oral	1 Tab Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2010	7455403	EXPEDITED (15-DAY)	Y	HO	1000014615		56 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Effusion; General Physical Health Deterioration; Hepatic Steatosis; Hepatitis; Hepatomegaly	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Tamsulosin			S	Oral	0.4 Mg (0.4 Mg, 1 In 1 D), Oral		Not Reported
	Rythmol			C				Not Reported
	Selokeen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2010	7455426	EXPEDITED (15-DAY)	Y	OT	1000014623		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Irritability; Tension	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 1 W		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 1 W	1 WEEK	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2010	7455463	EXPEDITED (15-DAY)	Y	OT	1000014634		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Disorientation; Intentional Overdose; Suicide Attempt; Urinary Incontinence; Vomiting	Escitalopram Oxalate			S	Oral	(140 Mg,Once), Oral		Not Reported
	Amitriptyline			S	Oral	(2550 Mg,Once), Oral		Not Reported
	Desogestrel\Ethinyl Estradiol			S		44 Tablets At Most (Once)		Not Reported
	Voltaren			S	Oral	(500 Mg,Once), Oral		Not Reported
	Ibuprofen			S	Oral	(1200 Mg,Once), Oral		Not Reported
	Acetaminophen\Butylscopolamine Bromide			S	Oral	20 Tablets At Most (Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2010	7455560	EXPEDITED (15-DAY)	N	HO	1000014698		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Skin Laceration	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Ativan			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7445082	NON-EXPEDITED	N		US-PFIZER INC-2007079588		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Asthenia; Drug Ineffective; Drug Interaction; Drug Tolerance; Fatigue; Incorrect Dose Administered; Nausea; Pain	Xanax			S				Pfizer
	Zolpidem Tartrate			C				Not Reported
	Klonopin			C				Not Reported
	Hyoscyamine Sulfate			C				Not Reported
	Hyoscyamine Sulfate			C				Not Reported
	Ultram			C				Not Reported
	Xanax			S				Pfizer
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Valium			S		Frequency: Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7445512	NON-EXPEDITED	Y	LT, OT	US-PFIZER INC-2008026143		83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Tachycardia	Tikosyn			S		Every Day		Pfizer
	Atenolol			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Lasix			C				Not Reported
	Spironolactone			C				Not Reported
	Glucosamine			C				Not Reported
	Lexapro			S				Not Reported
	Barium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7445958	NON-EXPEDITED	Y	OT	US-PFIZER INC-2008052204		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Status Changes; Muscle Rigidity; Pyrexia; Serotonin Syndrome	Zyvox			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7445994	NON-EXPEDITED			US-PFIZER INC-2008052576			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Alprazolam			S				Pfizer
	Benadryl			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7446456	NON-EXPEDITED			US-PFIZER INC-2008088248		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Fatigue; Hyperhidrosis	Xanax			S				Pfizer
	Prevacid			C				Not Reported
	Zetia			C				Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7446509	NON-EXPEDITED	Y		US-PFIZER INC-2008085946		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Apathy; Constipation; Depression; Diarrhoea; Drug Interaction; Fatigue; Hypoaesthesia; Impatience; Increased Appetite; Insomnia; Irritability; Restlessness; Rhinorrhoea; Sexual Dysfunction; Urinary Tract Infection; Weight Increased	Xanax			S				Pfizer
	Uroxatral			C		Unk		Not Reported
	Bentyl			C		Unk		Not Reported
	Bentyl			C				Not Reported
	Librax			C				Not Reported
	Librax			C				Not Reported
	Hyoscyamine Sulfate			C		Unk		Not Reported
	Hyoscyamine Sulfate			C				Not Reported
	Mesalazine			C		Unk		Not Reported
	Mesalazine			C				Not Reported
	Ultram			C		Unk		Not Reported

Ambien	C		Unk		Not Reported
Alprazolam	C		Unk		Not Reported
Lexapro	S	Oral	2.5 Mg, 1x/Day		Not Reported
Lexapro	S	Oral	1.5 Mg, 1x/Day		Not Reported
Lexapro	S	Oral	2 Mg, 1x/Day		Not Reported
Lexapro	S	Oral	3 Mg, 1x/Day		Not Reported
Lexapro	S	Oral	3.5 Mg, 1x/Day		Not Reported
Lexapro	S	Oral	4 Mg, 1x/Day		Not Reported
Lexapro	S	Oral	4.5 Mg, 1x/Day		Not Reported
Lexapro	S	Oral	5 Mg, 1x/Day		Not Reported
Valium	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7446543	NON-EXPEDITED	N		US-PFIZER INC-2008088016			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Panic Attack; Somnolence	Xanax			S				Pfizer
	Xanax Xr			S				Pfizer
	Prolixin			S				Not Reported
	Imipramine			S				Not Reported
	Lexapro			S				Not Reported
	Elavil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7446617	NON-EXPEDITED	N		US-PFIZER INC-2008092147			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Eye; Mydriasis; Ocular Hyperaemia; Vision Blurred	Xanax			S				Pfizer
	Lexapro			S				Not Reported
	Effexor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7446642	NON-EXPEDITED	N		US-PFIZER INC-2009154057		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia	Xanax			S		0.25mg 1/2 Tablet At 2:30pm And 1 Tablet At 10pm		Pfizer
	Alprazolam			S				Pfizer
	Lexapro			S				Not Reported
	Lumigan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7446731	NON-EXPEDITED	N		US-PFIZER INC-2008156744			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Visual Impairment	Zyvox			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7446805	NON-EXPEDITED	N		US-PFIZER INC-2008157256		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia; Drug Interaction; Vision Blurred; Visual Acuity Reduced	Procrit			S		Unk		Not Reported
	Fosamax			C		Unk		Not Reported
	Zocor			C		Unk		Not Reported
	Levaquin			C		Unk		Not Reported
	Restoril			C		Unk		Not Reported
	Valtrex			C		Unk		Not Reported
	Lasix			C		Unk		Not Reported
	Potassium			C		Unk		Not Reported
	Amaryl			C		Unk		Not Reported

	Tricor	C		Unk		Not Reported
	Mucinex	C		Unk		Not Reported
	Zyvox	S	Oral	600 Mg, 2x/Day	3 DAY	Pfizer
	Lexapro	S		20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7446892	NON-EXPEDITED	N		US-PFIZER INC-2009177597		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Somnolence	Xanax			S	Oral	Unk		Pfizer
	Lexapro			S	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7447371	NON-EXPEDITED	N		US-PFIZER INC-2009224169		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Night Sweats	Xanax			S		1 Caplet 2-3 Times A Day		Pfizer
	Diphenhydramine Hydrochloride			S	Oral	50 Mg, 1x/Day		Not Reported
	Lexapro			S		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7447442	NON-EXPEDITED	N		US-PFIZER INC-2009225427		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Fatigue	Xanax			S	Oral	Unk		Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Omeprazole			C		Unk		Not Reported
	Claritin			C		Unk		Not Reported
	Advil			C		Unk		Not Reported
	Diphenhydramine			C		Unk		Not Reported

	Vitamins Nos	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7509541	NON-EXPEDITED	Y	OT	US-WYE-H14644910			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Serotonin Syndrome	Pristiq Extended Release			S		50 Mg 1x Per 1 Day		Not Reported
	Lexapro			S		Unspecified Dose Increased Unspecified Dose Increased		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2010	7529715	NON-EXPEDITED	Y		US-WYE-H14057310			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Libido	Pristiq Extended Release			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2010	7388881	EXPEDITED (15-DAY)	Y	HO	1000013554		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Balance Disorder; Carotid Artery Aneurysm; Cerebellar Syndrome; Feeling Drunk; No Reaction On Previous Exposure To Drug; Tremor; Weight Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Lysanxia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2010	7464121	EXPEDITED (15-DAY)	Y	HO	1000014751		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Mania; Mood Altered	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported
	Lexomil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2010	7465582	EXPEDITED (15-DAY)	Y	HO	1000014784		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Extrasystoles; Tachycardia	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2010	7465628	EXPEDITED (15-DAY)	Y	OT	1000014753		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphadenopathy	Escitalopram Oxalate			S				Not Reported
	Mini Pill			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2010	7469284	EXPEDITED (15-DAY)	N	OT	1000014745		59 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gangrene	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2010	7472295	EXPEDITED (15-DAY)	Y	OT	1000014707		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Cold; Paralysis; Seizure	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2010	7367130	EXPEDITED (15-DAY)	Y	HO	1000013181		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Immune Thrombocytopenic Purpura; Splenectomy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1d), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexomil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2010	7452228	EXPEDITED (15-DAY)		HO, OT	IT-ROXANE LABORATORIES, INC.-2010-RO-00776RO		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophil Count Increased; Human Herpesvirus 6 Infection; Relapsing Fever	Lamotrigine			S			34 DAY	Roxane
	Escitalopram Oxalate			S			34 DAY	Not Reported
	Cefixime			S		800 Mg		Not Reported
	Cefixime			S				Not Reported
	Cefixime			S				Not Reported
	Cefixime			S				Not Reported
	Cefixime			S				Not Reported
	Betamethasone			S		1 Mg		Not Reported
	Betamethasone			S	Intravenous (not otherwise specified)			Not Reported
	Betamethasone			S				Not Reported
	Betamethasone			S				Not Reported
	Fexofenadine			S		120 Mg		Not Reported
	Fexofenadine			S				Not Reported
	Azithromycin			S		500 Mg	3 DAY	Not Reported
	Acyclovir			S	Intravenous (not otherwise specified)		8 DAY	Not Reported
	Acyclovir			S			8 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2010	7457618	DIRECT	N	OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Economic Problem; Impulsive Behaviour; Migraine	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2010	7475923	EXPEDITED (15-DAY)	Y	OT	1000014740		90 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Seizure	Lexapro			S				Not Reported
	Multiple Ssri'S (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2010	7453255	EXPEDITED (15-DAY)	Y	OT	TR-RANBAXY-2010RR-34335		31 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism	Fluoxetine			S		20 Mg, Unk		Ranbaxy
	Venlafaxine			S		150 Mg, Unk		Not Reported
	Venlafaxine			S		Unk		Not Reported
	Escitalopram Oxalate			S		10 Mg, Unk		Not Reported
	Venlafaxine			C		37.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2010	7196237	EXPEDITED (15-DAY)	Y	DS, OT	1000010044		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorea; Overdose	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported

	Escitalopram Oxalate	S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2010	7326996	EXPEDITED (15-DAY)	Y	OT	IE-ROCHE-629222			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Complication Of Pregnancy	Trastuzumab			S	Intravenous (not otherwise specified)	Loading Dose. Frequency: One Time Per Odos. Actual Dose: 732 Mg.		Roche
	Trastuzumab			S	Intravenous (not otherwise specified)	Maintenance Dose, Actual Dose Given 549 Mg On 03 Jan, 25 Jan, 13 Feb, 3 Mar And 24 Mar 2006.		Roche
	Lexapro			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Doxorubicin			C				Not Reported
	Cyclophosphamide			C				Not Reported
	Docetaxel			C		Taken Once.		Not Reported
	Citalopram			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2010	7336573	EXPEDITED (15-DAY)	Y	OT	1000012354		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Oedema; Face Oedema; Hypersensitivity	Escitalopram Oxalate			S	Oral	5mg (5mg, 1 In 1d), Oral	15 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10mg (10 Mg, 1 In 1d Oral)		Not Reported
	B12 Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2010	7413804	EXPEDITED (15-DAY)	Y	OT	1000014120		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chest Discomfort; Drug Ineffective; Muscle Twitching; Panic Attack	Escitalopram Oxalate			S		(10mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2010	7431940	EXPEDITED (15-DAY)	Y	HO, OT	1000014451		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Infection; Pancreatitis Acute	Escitalopram Oxalate			S	Oral	10mg (10mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2010	7453726	EXPEDITED (15-DAY)	Y	HO	IT-TEVA-238720ISR		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Lamotrigine			S				Teva
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2010	7454552	EXPEDITED (15-DAY)	Y	OT	US-BAXTER-2010BH017411		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Fentanyl Citrate			S	Intravenous (not otherwise specified)			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Etomidate			C	Unknown			Not Reported
	Vecuronium Bromide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Cefazolin			C	Unknown			Not Reported

Insulin Nos	C	Unknown		Not Reported
Gabapentin	C	Unknown		Not Reported
Lansoprazole	C	Unknown		Not Reported
Lorazepam	C	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported
Cetirizine Hydrochloride	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2010	7454586	EXPEDITED (15-DAY)	Y	OT	FR-TYCO HEALTHCARE/MALLIN CKRODT-T201001513		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Diarrhoea; Drug Interaction; Hyperhidrosis; Mydriasis; Night Sweats; Panic Attack; Serotonin Syndrome; Toxicity To Various Agents; Tremor; Vision Blurred; Visual Impairment; Weight Decreased	Oxycodone			S		120 Mg, Qd For 6 Months		Tyco
	Fentanyl			S	Nasal	4 Puffs Of 200 Ug/Puff		Not Reported
	Escitalopram Oxalate			S		5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2010	7475910	EXPEDITED (15-DAY)	Y	OT	1000014836			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Overdose; Urinary Incontinence	Escitalopram Oxalate			S		110 Mg (110 Mg, 1 In 1 D)		Not Reported
	Buspar			S				Not Reported
	Neurontin			S				Not Reported
	Lyrica			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2010	7364029	EXPEDITED (15-DAY)	Y	HO	1000013013		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Immune Thrombocytopenic Purpura; Mucosal Haemorrhage; Skin Haemorrhage	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Cerazette (Desogestrel)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2010	7389111	EXPEDITED (15-DAY)	Y	OT	1000013450		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Fall; Generalised Tonic-Clonic Seizure; Refusal Of Treatment By Patient	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2010	7455686	EXPEDITED (15-DAY)	Y	DE, OT	US-PFIZER INC-2010079804			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective; Self-Medication	Geodon			S	Oral	40 Mg, 2x/Day		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2010	7455747	EXPEDITED (15-DAY)	Y	OT	PHHY2010BR41874		18 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Lavage; Intentional Overdose; Suicide Attempt	Trileptal			S	Oral			Novartis
	Hydrochlorothiazide			S		12 Tablets		Not Reported
	Alprazolam			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Omeprazole			S		20 Tablet		Not Reported
	Methyldopa			S		10 Tablets		Not Reported

	Orphenadrine Citrate	S			Not Reported
	Caffeine	S			Not Reported
	Metamizole Sodium	S			Not Reported
	Dimenhydrinate	S	8 Tablets		Not Reported
	Norfloxacin	S	14 Tablets		Not Reported
	Ketoprofen	S	20 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2010	7456439	EXPEDITED (15-DAY)	Y	HO	IT-MYLANLABS-2010S1011176		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate			S	Unknown			Alphapharm
	Lamotrigine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2010	7456570	EXPEDITED (15-DAY)	N	DE, HO	B0664190A		18 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Completed Suicide; Intentional Overdose; Intra-Abdominal Haemorrhage; Pulmonary Oedema; Shock Haemorrhagic; Traumatic Shock	Propafenone Hydrochloride			S	Unknown			Glaxosmithkline
	Cipralex			S	Oral	10mg Per Day		Not Reported
	Acetylsalicylic Acid			S	Unknown			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2010	7456861	NON-EXPEDITED	N		US-PFIZER INC-2007071087		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms	Zoloft			S				Pfizer
	Lexapro			S				Not Reported
	Pancrelipase			C				Not Reported
	Reglan			C				Not Reported

	Erythromycin	C		Not Reported
	Vitamins	C		Not Reported
	Calcium	C		Not Reported
	Ambien	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2010	7488336	EXPEDITED (15-DAY)	Y	DE	1000014188		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Completed Suicide; Intentional Overdose; Pulmonary Oedema; Shock Haemorrhagic; Toxicity To Various Agents; Traumatic Haemorrhage; Traumatic Shock	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral		
	Propafenone			S	Oral	Oral		Not Reported
	Acetylsalicylic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2010	7488339	EXPEDITED (15-DAY)	Y		1000014597		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyst; Scar	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Effexor Xr			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Concerta			S	Oral	72 Mg (72 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel			S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
	Abilify			C				Not Reported
	Adderall			C				Not Reported
	Vitamin B12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2010	7488412	EXPEDITED (15-DAY)	Y	OT	1-23137813		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome; Vision Blurred	Oxycodone Hydrochloride		Y	S	Oral	120 Mg/Day, Oral	6 MTH	Not Reported
	Fentanyl			S	Nasal	200 Mcg/Puff X4, Nasal		Not Reported
	Escitalopram Oxalate			S	Oral	5mg/Day, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2010	6255636	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2007014646		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Bladder Disorder; Visual Impairment; Weight Increased	Lyrica			S		50 Mg, 3x/Day		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2010	7459403	NON-EXPEDITED	N		US-PFIZER INC-2006117679		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea	Chantix			S				Pfizer
	Lexapro			S				Not Reported
	Vytorin			C				Not Reported
	Zocor			C				Not Reported
	Lopresor			C				Not Reported
	Cozaar			C				Not Reported
	Isosorbide			C				Not Reported
	Pletal			C				Not Reported
	Fish Oil			C				Not Reported
	Vitamin E			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2010	7459443	NON-EXPEDITED	N	OT	US-PFIZER INC-2006118392		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression	Chantix			S	Oral			Pfizer
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2010	7460110	NON-EXPEDITED	N		US-PFIZER INC-2006140548		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Nausea; Tobacco Withdrawal Symptoms	Chantix			S				Pfizer
	Lexapro			S				Not Reported
	Loratadine			C				Not Reported
	Zocor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2010	7460154	NON-EXPEDITED	N		US-PFIZER INC-2006142998		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disturbance In Attention; Feeling Abnormal	Chantix			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2010	7461053	NON-EXPEDITED	Y		US-PFIZER INC-2006140251		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysgeusia; Fatigue; Hot Flush; Paraesthesia; Somnolence	Chantix			S	Oral			Pfizer
	Verapamil Hydrochloride			C				Not Reported
	Benicar			C				Not Reported
	Ddavp			C				Not Reported
	Montelukast Sodium			C				Not Reported
	Allegra			C				Not Reported
	Famotidine			C				Not Reported
	Premarin			C				Not Reported
	Potassium			C				Not Reported

Theophylline	C				Not Reported
Tiotropium Bromide	C	Respiratory (inhalation)			Not Reported
Chantix	S				Pfizer
Lamictal	S				Not Reported
Lexapro	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2010	7466196	DIRECT	N	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	5mg Everyday Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2010	7492641	EXPEDITED (15-DAY)	N	DS	DSA_43435_2010			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall; Fibromyalgia; Impaired Work Ability; Loss Of Employment; Unevaluable Event; Weight Increased	Wellbutrin Xl			S	Oral	(100 Mg Qd Oral), (150 Mg Qd Oral)		Not Reported
					Oral	(100 Mg Qd Oral), (150 Mg Qd Oral)		
	Lexapro			S		(Df)		Not Reported
	Percocet			C				Not Reported
	Klonopin			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2010	6268075	NON-EXPEDITED	Y	OT	US-PFIZER INC-2007010630		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Decreased; Dizziness; Drug Interaction; Feeling Hot; Heart Rate Increased; Hyperhidrosis;	Chantix			S				Pfizer
	Lexapro			S				Not Reported

Hypotension; Nausea; Serotonin Syndrome; Stress; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2010	6812957	EXPEDITED (15-DAY)	Y	HO	1000001534		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Biliary Tract Disorder; Cholestasis; Gamma-Glutamyltransferase Increased; Hepatitis; Lithiasis; Toxoplasmosis; Visual Acuity Reduced; Visual Impairment	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1d), Oral		Not Reported
	Valproate Sodium			S	Oral	1000 Mg (500 Mg, 2 In 1 D), Oral		Not Reported
	Malocide			C				Not Reported
	Adiazine			C				Not Reported
	Claritin			C				Not Reported
	Tercian (40 Milligram, Drops)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2010	7417995	EXPEDITED (15-DAY)	N	OT	US-SHIRE-SPV1-2010-01039			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Intentional Overdose; Vomiting	Vyvanse			S	Oral	20 - 70 Mg Capsules, One Dose	1 DAY	Not Reported
	Vyvanse			S		70 Mg, 1x/Day:Qd In Am	332 DAY	Not Reported
	Lexapro			S		20mg Daily	2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2010	7420828	EXPEDITED (15-DAY)	Y	HO	1000014119		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Bronchitis; Confusional	Escitalopram Oxalate			S	Oral	14 Tablets Once, Oral 10 Mg (10 Mg, 1 In 1 D) Oral		Not Reported
	Truxol			C				Not Reported

State; Drug Abuse;
Intentional Overdose;
Somnolence

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2010	7424153	EXPEDITED (15-DAY)	Y	DE	1000014405		59 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Decreased Appetite; Dizziness; Erectile Dysfunction; Fumbling; Inappropriate Affect; Insomnia; Negative Thoughts	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D), 15 Mg, 1 In 1 D) 10 Mg (10 Mg, 1 In 1 D), 15 Mg, 1 In 1 D)		Not Reported
	Adiro			C				Not Reported
	Enalapril Maleate			C				Not Reported
	Somnovit			C				Not Reported
	Trankimazin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2010	7454283	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000014604		16 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hypotension; Intentional Overdose; Miosis; Respiratory Failure; Seizure; Suicide Attempt; Vomiting	Escitalopram Oxalate			S	Oral	(100 Mg, Once), Oral, Oral		Not Reported
	Pipamperone			S	Oral	(1600 Mg, Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2010	7462294	EXPEDITED (15-DAY)	Y	HO, OT	DK-ROXANE LABORATORIES, INC.-2010-RO-00816RO		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Ataxia; Blood Albumin Decreased; Blood Sodium Decreased; Confusional State; Dehydration; Depression;	Citalopram			S				Roxane
	Escitalopram Oxalate			S		10 Mg		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S		20 Mg		Not Reported

Diarrhoea; Dizziness; Drug Withdrawal Syndrome; Gait Disturbance; Haemoglobin Decreased; Lethargy; Malnutrition; Myoclonus; Sinus Tachycardia; Therapy Cessation; Treatment Noncompliance; Tremor	Omeprazole	S	40 Mg	Not Reported
	Venlafaxine	S		Not Reported
	Vitamin B Complex	S		Not Reported
	Disulfiram	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2010	7463150	NON-EXPEDITED	N		US-PFIZER INC-2007010045		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anger; Anxiety; Headache; Nervousness; Stress; Withdrawal Syndrome	Chantix			S				Pfizer
	Lexapro			S				Not Reported
	Wellbutrin			C				Not Reported
	Lipitor			C				Not Reported
	Ambien			C				Not Reported
	Zelnorm			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2010	7464244	NON-EXPEDITED	N		US-PFIZER INC-2007020032		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Drug Interaction; Sleep Disorder	Chantix			S				Pfizer
	Metformin Hydrochloride			C				Not Reported
	Crestor			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Saw Palmetto			C				Not Reported
	Omega-3 Triglycerides			C				Not Reported
	Advil			C				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2010	7464284	NON-EXPEDITED	Y		US-PFIZER INC-2007010277		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Chantix			S				Pfizer
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Advair Diskus			C	Respiratory (inhalation)			Not Reported
	Albuterol			C	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2010	7498303	EXPEDITED (15-DAY)	Y	HO	1000014943			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral	2 YR	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2010	7454301	EXPEDITED (15-DAY)	Y	OT	NO-MERCK-1007NOR00003		55 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrasystoles	Zocor			S	Oral			Merck
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2010	7466470	EXPEDITED (15-DAY)	Y	OT	NO-WATSON-2010-09059		55 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Chest Discomfort; Extrasystoles	Simvastatin	S	Unk		Watson
	Cipralex	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2010	7467742	NON-EXPEDITED	N		US-PFIZER INC-2007028656		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abnormal Dreams; Fatigue; Headache; Middle Insomnia; Nausea; Nightmare; Somnolence; Vomiting; Weight Increased	Varenicline			S				Pfizer
	Neurontin			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2010	7468255	NON-EXPEDITED	N	OT	US-PFIZER INC-2007030841		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Dizziness; Lethargy; Mental Impairment; Nausea; Tremor	Chantix			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2010	7475694	DIRECT	Y	LT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Escitalopram Oxalate			S	Oral	2.5mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2010	6799281	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-08P-056-0483616-00		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cholestasis; Gamma-Glutamyltransferase Increased; Hepatitis; Lithiasis; Pyrexia	Depakene		S	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Not Reported
	Pyrimethamine		C	Oral	Not Reported
	Sulfadiazine		C	Oral	Not Reported
	Claritin		C	Oral	Not Reported
	Cyamemazine		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2010	7470318	NON-EXPEDITED	N		US-PFIZER INC-2007037583		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Chantix			S				Pfizer
	Lexapro			S				Not Reported
	Lotrel			C				Not Reported
	Toprol Xl			C				Not Reported
	Gemfibrozil			C				Not Reported
	Zocor			C				Not Reported
	Aspirine			C				Not Reported
	Lunesta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2010	7471000	NON-EXPEDITED	N		US-PFIZER INC-2007041984			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Lethargy	Chantix			S				Pfizer
	Lexapro			S				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2010	7471573	NON-EXPEDITED	N		US-PFIZER INC-2007035298		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysgeusia; Erectile Dysfunction; Flatulence;	Chantix			S				Pfizer
	Lexapro			S				Not Reported

Hypoaesthesia; Nervous System Disorder; Paraesthesia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2010	7471756	NON-EXPEDITED	N		US-PFIZER INC-2007049673		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Emotional Disorder; Ill-Defined Disorder; Vomiting	Chantix			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2010	7472108	NON-EXPEDITED	Y		US-PFIZER INC-2007042410		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Emotional Disorder; Irritability; Malaise; Nausea	Chantix			S				Pfizer
	Acetylsalicylic Acid			C				Not Reported
	Aleve			C				Not Reported
	Opioids			C				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2010	7498495	EXPEDITED (15-DAY)	N	OT	1000014694		31 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Drug Ineffective; Vertigo	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Valerian Officinalis			C				Not Reported
	Clonazepam			C				Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2010	7502918	EXPEDITED (15-DAY)	Y	OT	2010SCPR001150		46 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Anxiety; Blood Follicle Stimulating Hormone Increased; Cerebral Cyst; Condition Aggravated; Drug Interaction; Galactorrhoea; Persistent Depressive Disorder; Sleep Disorder	Imipramine			S		75 Mg/Day	365 DAY	Not Reported
	Escitalopram Oxalate			S		20 Mg, Qd	365 DAY	Not Reported
	Glyburide			S	Oral	5 Mg, Qd, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2010	7504281	EXPEDITED (15-DAY)		OT	1000014956		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vaginal Haemorrhage	Escitalopram Oxalate			S	Oral	13 Gtt (13 Gtt, 1 In 1 D), Oral		Not Reported
	Delorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2010	7504305	EXPEDITED (15-DAY)	Y	HO	1000014979		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Fall; Fractured Ischium; Haematoma; Haemorrhage; Pubis Fracture; Respiratory Distress	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Fluindione			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin Lysine			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Hemigoxine			C				Not Reported
	Candesartan Cilexetil			C				Not Reported

	Inexium	C	Not Reported
	Vastarel	C	Not Reported
	Lorazepam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2010	7299603	EXPEDITED (15-DAY)	Y	OT	1000011612		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Borderline Glaucoma; Ocular Hyperaemia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2010	7391179	EXPEDITED (15-DAY)	N	DE	US-SHIRE-SPV1-2010-00928			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Ventricular Arrhythmia	Vyvanse			S	Unknown	30 Mg, 1x/Day:Qd		Not Reported
	Heroin			S				Not Reported
	Lamictal			S	Unknown	200 Mg, 1x/Day:Qd		Not Reported
	Abilify			S	Unknown	30 Mg, 1x/Day:Qd		Not Reported
	Lexapro			S	Unknown	10 Mg, 1x/Day:Qd		Not Reported
	Clonazepam			S				Not Reported
	Methadone Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2010	7425222	EXPEDITED (15-DAY)	Y	OT	DE-BRISTOL-MYERS SQUIBB COMPANY-15148372		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Generalised Oedema	Abilify			S	Oral		4 WEEK	Not Reported
	Lithium			C				Not Reported
	Escitalopram Oxalate			C				Not Reported
	Lithium Carbonate			S	Oral	Quilonum Retard Taken Before 06apr2010		Not Reported
	Cipralex			S	Oral	Taken Before 06apr2010		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2010	7465641	EXPEDITED (15-DAY)	Y	OT	1000014735		20 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Escitalopram Oxalate			S	Oral	5 Mg (1, In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral Oral	10 Mg, Oral, 5 Mg, Oral 10 Mg, Oral, 5 Mg, Oral		Not Reported
	Trazodone			C				Not Reported
	Risperidone			C				Not Reported
	Aripiprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2010	7474089	NON-EXPEDITED	N		US-PFIZER INC-2007055083		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Interaction	Chantix			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2010	7474353	NON-EXPEDITED	Y		US-PFIZER INC-2007058026		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Headache	Chantix			S				Pfizer
	Percocet			C				Not Reported
	Methadone Hydrochloride			C				Not Reported
	Verapamil Hydrochloride			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Zocor			C				Not Reported
	Tranxene T-Tab			C				Not Reported
	Glucophage			C				Not Reported
	Lexapro			S				Not Reported
	Provigil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2010	7474748	NON-EXPEDITED	Y		US-PFIZER INC-2007061388			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder	Chantix			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2010	7511435	EXPEDITED (15-DAY)	Y	OT	1000015014		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypertonia; Muscle Spasms; Pain	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tylenol With Codeine			S	Oral	(1 Dosage Forms), Oral		Not Reported
	Clonazepam			C				Not Reported
	Paxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2010	7371023	EXPEDITED (15-DAY)	Y	OT	1000013209		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Antidiuretic Hormone Decreased; Polydipsia; Polyuria	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Restex (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2010	7479824	EXPEDITED (15-DAY)	Y	HO	US-BRISTOL-MYERS SQUIBB COMPANY-15187461		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Respiratory Acidosis; Serotonin Syndrome	Morphine Sulfate			S				Endo
	Etomidate			S				Not Reported
	Vecuronium Bromide			S				Not Reported

Cefazolin	S					Sandoz
Trazodone Hydrochloride	S					Apothecon
Escitalopram Oxalate	S					Not Reported
Fentanyl	S	Intravenous (not otherwise specified)	Divided 8doses			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2010	7480093	NON-EXPEDITED	N	OT	US-PFIZER INC-2007080688		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Nervousness; Palpitations	Chantix			S				Pfizer
	Lexapro			S				Not Reported
	Antihypertensives			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2010	7480432	NON-EXPEDITED	N	HO	US-PFIZER INC-2007080965			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Interaction; Headache; Migraine	Chantix			S				Pfizer
	Seroquel			S				Not Reported
	Klonopin			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2010	7480480	NON-EXPEDITED	N		US-PFIZER INC-2007082444		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Emotional Disorder; Feeling Abnormal; Headache; Insomnia; Poor Quality Sleep; Restlessness	Chantix			S		Every Day		Pfizer
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2010	7481721	NON-EXPEDITED	N		US-PFIZER INC-2007088152			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anger; Drug Interaction; Irritability	Chantix			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2010	7482283	NON-EXPEDITED	N		US-PFIZER INC-2007091840		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Chantix			S	Oral			Pfizer
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Nexium			C				Not Reported
	Flexeril			C				Not Reported
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2010	7509896	EXPEDITED (15-DAY)	Y	HO	1000015028		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematocrit Decreased; Haemoglobin Decreased; Overdose; White Blood Cell Count Increased	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 30 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 30 Mg (20 Mg, 1 In 1 D), Oral		
	Gabapentin			C				Not Reported
	Simvastatin			C				Not Reported
	Verapamil Hydrochloride			C				Not Reported
	Lisinopril			C				Not Reported
	Levothroid			C				Not Reported
	Omeprazole			C				Not Reported
	Temazepam			C				Not Reported

	Hydrocodone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2010	7512793	EXPEDITED (15-DAY)	Y	DS	1000015049		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cold Sweat; Headache; Muscular Weakness; Nausea; Vision Blurred	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Nebivolol Hydrochloride (Tablets)			C				Not Reported
	Candesartan Cilexetil (Tablets)			C				Not Reported
	Omeprazole			C				Not Reported
	Simvastatin			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2010	7512796	EXPEDITED (15-DAY)	Y	DS	1000015022		25 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Decreased; Paralysis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2010	7483614	NON-EXPEDITED	N		US-PFIZER INC-2007097486			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Drug Interaction; Irritability	Chantix			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2010	6790883	NON-EXPEDITED	Y	OT	US-PFIZER INC-2008020292		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Depression; Dizziness; Drug Interaction; Fatigue; Hyperphagia; Malaise	Chantix		S	Oral	Pfizer
	Valtrex		C		Not Reported
	Lodine		C		Not Reported
	Zantac		C		Not Reported
	Trazodone Hydrochloride		C		Not Reported
	Lexapro		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2010	7475702	EXPEDITED (15-DAY)	Y	OT	1000014803		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ovarian Cyst	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2010	7486577	EXPEDITED (15-DAY)	Y	HO, OT	US-TEVA-241187USA		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate			S				Not Reported
	Trazodone Hydrochloride			S				Barr
	Fentanyl			S	Intravenous (not otherwise specified)	250 Ug		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2010	7487523	EXPEDITED (15-DAY)	N	DE	A0870970A		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Dependence; Depression; Intentional Product Misuse; Loss Of Consciousness; Withdrawal Syndrome	Lamictal			S				Glaxosmithkline
	Lexapro			S				Not Reported
	Fentanyl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2010	7488682	NON-EXPEDITED	Y		US-PFIZER INC-2008010870		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Disturbance In Attention; Dizziness; Drug Ineffective; Emotional Disorder; Headache; Nausea; Nervousness	Chantix			S	Oral			Pfizer
	Wellbutrin Xl			S				Not Reported
	Lexapro			S				Not Reported
	Chondroitin/Glucosamine			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	All Other Therapeutic Products			C				Not Reported
	All Other Therapeutic Products			C				Not Reported
	Digestives, Incl Enzymes			C				Not Reported
	Calcium			C				Not Reported
	Asacol			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2010	7489171	NON-EXPEDITED	Y	DE, OT	US-PFIZER INC-2008015811			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Chantix			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2010	7489894	NON-EXPEDITED	N		US-PFIZER INC-2008021014		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Fatigue; Vitamin B12 Deficiency; Vitamin D Deficiency	Chantix			S				Pfizer
	Levothyroxine Sodium			C				Not Reported
	Lisinopril			C				Not Reported
	Zetia			C				Not Reported
	Insulin Nos			C				Not Reported
	Vitamin D2			C				Not Reported
	Lumigan			C	Ophthalmic			Not Reported
	Ciclosporin			C				Not Reported

	Cymbalta			C						Not Reported
	Lexapro			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2010	7497317	DIRECT	N				50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Marital Problem; Muscle Twitching; Paranoia; Thinking Abnormal	Lexapro			S	Oral	20mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2010	7522432	EXPEDITED (15-DAY)	Y	OT	1000015087		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ovarian Cyst	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2010	7486938	EXPEDITED (15-DAY)	Y	HO, OT	1000014878			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis; International Normalised Ratio Fluctuation; Overdose	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Previscan (Fluindione)			S		0.75 Dosage Forms (0.75 Dosage Forms 1 In D)		Not Reported
	Previscan (Fluindione)			S		0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D)		Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2010	7521921	EXPEDITED (15-DAY)	N	HO	1000012654		20 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Burnout Syndrome; Condition Aggravated; Confusional State; Decreased Appetite; Depersonalisation/Dereali sation Disorder; Depression; Dyskinesia; Dysuria; Fatigue; Initial Insomnia; Intentional Self-Injury; Muscular Weakness; Nervousness; Panic Attack; Sexual Dysfunction; Somnolence; Suicidal Ideation; Weight Decreased; Yawning	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Stresam (Tablets)			C				Not Reported
	Magne B6 (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2010	7522071	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2010-01712		55 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Extrasystoles	Simvastatin			S				Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2010	7344603	EXPEDITED (15-DAY)	Y	OT	1000012502		15 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania; Off Label Use	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Clorazepate Dipotassium			C				Not Reported
	Risperdal			C				Not Reported
	Topiramate (Tabelts)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2010	7467483	EXPEDITED (15-DAY)	Y	OT	NO-MERCK-1007NOR00008		55 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrasystoles	Simvastatin			S	Oral			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2010	7492551	NON-EXPEDITED	N		US-PFIZER INC-2008023419		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction	Chantix			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2010	7492962	NON-EXPEDITED	Y	OT	US-PFIZER INC-2008025093			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Chantix			S				Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2010	7522491	EXPEDITED (15-DAY)	Y	OT	1000015129		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dizziness; Feeling Abnormal; Vaginal Haemorrhage; Vision Blurred	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2010	7465965	EXPEDITED (15-DAY)	Y	OT	1000014727		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Haematoma; Cholelithiasis; Pancreatitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolam			C				Not Reported
	Stilnox			C				Not Reported
	Athymil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2010	7494766	EXPEDITED (15-DAY)	Y	HO	FR-BRISTOL-MYERS SQUIBB COMPANY-15197809		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Agitation; Fall; Hypotension; Respiratory Tract Inflammation; Somnolence	Coaprovel			S				Bristol Myers Squibb
	Dafalgan Codeine			S				Not Reported
	Ixprim			S		1 Df: 37.5mg/325 Mg	4 DAY	Not Reported
	Zopiclone			S				Not Reported
	Xanax			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Loperamide Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Xatral			S				Not Reported
	Acarbose			C				Not Reported
	Previscan (Fluindione)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2010	7495823	NON-EXPEDITED	N		US-PFIZER INC-2008042251		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anger; Anxiety; Depressed Mood; Drug Interaction;	Chantix			S	Oral			Pfizer
	Lorazepam			C				Not Reported
	Zoloft			C				Not Reported

Emotional Disorder; Fatigue; Loss Of Personal Independence In Daily Activities; Stress	Lexapro			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2010	7496833	NON-EXPEDITED	N		US-PFIZER INC-2008056324		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive; Nausea; Vomiting	Chantix			S				Pfizer
	Lexapro			S				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2010	7527117	EXPEDITED (15-DAY)	Y	HO	1000015158		93 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation; Disorientation; Hallucination, Visual; Overdose; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Piribedil			S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported
	Stilnox			S	Oral	0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Xanax			S	Oral	1.5 Dosage Forms (0.5 Dosage Forms, 3 In 1 D), Oral		Not Reported
	Xyzall			C				Not Reported
	Kardegic			C				Not Reported
	Mecir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2010	7527320	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000014445		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Empyema; Fibrin D Dimer Increased; General Physical Health Deterioration; Haemophilus Infection; Lymphocyte Percentage Increased; Neutrophil Percentage Increased; Normochromic Normocytic Anaemia; Nutritional Condition Abnormal; Platelet Count Increased; Pleural Adhesion; Pleural Effusion; Pneumonia; Streptococcal Infection; Tachycardia; Therapy Non-Responder; White Blood Cell Count Increased	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Mirtazapine			S		15 Mg (15 Mg, 1 In 1 D)		Not Reported
	Zopiclone			S		7.5 Mg (7.5 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2010	7535147	EXPEDITED (15-DAY)	Y	OT	1000015104		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Initial Insomnia; Restlessness; Sleep Disorder	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2010	8354749	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2010SA041272		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Somnolence	Xatral			S	Oral			Not Reported
	Tramadol Hydrochloride And Acetaminophen			S	Oral			Not Reported

Cetirizine Hydrochloride	S	Oral		Not Reported
Zopiclone	S	Oral		Not Reported
Xanax	S	Oral		Not Reported
Dafalgan Codeine	S	Oral		Not Reported
Loperamide	S	Oral		Not Reported
Escitalopram Oxalate	S	Oral		Not Reported
Coaprovel	S	Oral		Not Reported
Acarbose	C	Oral		Not Reported
Previscan (Fluindione)	C			Not Reported
Paracetamol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2010	7369627	EXPEDITED (15-DAY)	Y	OT	1000013222		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Derealisation; Dizziness; Dry Mouth; Headache; Insomnia; Loss Of Consciousness; Malaise; Nausea; Restlessness; Syncope; Tremor	Escitalopram Oxalate			S	Oral	10 Mg 910 Mg, 1 In 1 D), Oral		Not Reported
	Dalacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2010	7383434	EXPEDITED (15-DAY)	Y	OT	1000013471		10 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Hallucination; Insomnia; Off Label Use	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Carbamazepine			S		1600 Mg (800 Mg, 2 In 1 D)		Not Reported
	Carbamazepine			S				Not Reported
	Lamotrigine			S		400 Mg (200 Mg, 2 In 1 D)		Not Reported

	Lamotrigine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2010	7388220	EXPEDITED (15-DAY)	Y	OT	1000013499			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Feeling Abnormal; Hostility; Thinking Abnormal	Escitalopram Oxalate			S		(5 Mg)		Not Reported
	Escitalopram Oxalate			S		(10 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2010	7422756	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000014266		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatomegaly; Myalgia; Nausea; Prothrombin Level Decreased	Escitalopram Oxalate			S	Oral	10 Mg 910 Mg, 1 In 1 D), Oral		Not Reported
	Lamotrigine			S		50 Mg (50 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2010	7498321	EXPEDITED (15-DAY)	Y	HO, OT	1000014947		28 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral	(500 Mg, Once), Oral		Not Reported
	Amitriptyline			S	Oral	(1225 Mg, Once), Oral		Not Reported
	Melperone			S	Oral	(1250 Mg, Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2010	7500815	NON-EXPEDITED	Y		US-PFIZER INC-2009178746			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams	Chantix			S		1 Mg, 2x/Day		Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2010	7509478	EXPEDITED (15-DAY)	Y	DE, HO	1000014857		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Pneumonia; Respiratory Failure; Torsade De Pointes	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Rivastigmine			S		3 Mg		Not Reported
	Lidocaine			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2010	7528665	EXPEDITED (15-DAY)	Y	OT	1000015147			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Amiodarone			C				Not Reported
	Avapro			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2010	7528701	EXPEDITED (15-DAY)	Y	OT	1000015194		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Petit Mal Epilepsy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D) ,Oral		Not Reported
	Triphasil-21			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2010	7528726	EXPEDITED (15-DAY)	Y	HO	1000014788		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
	Alprazolam			S	Oral	Oral, 0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D), Oral		Not Reported
					Oral	Oral, 0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D), Oral		
	Zolpidem			S	Oral	Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		
	Alcohol			S	Oral	1/2 Bottle, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2010	7115698	EXPEDITED (15-DAY)	Y	CA, DE	1000008598			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported
	Prenatal Vitamin (Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2010	7158622	EXPEDITED (15-DAY)	Y	OT	1000009329		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dissociative Identity Disorder; Drug Intolerance; Feeling	Escitalopram Oxalate			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D),		Not Reported

Abnormal; Schizophrenia; Suicidal Ideation; Tremor				Oral	
	Hydrocortisone	C			Not Reported
	Lercan	C			Not Reported
	Flecainide Acetate	C			Not Reported
	Fractal	C			Not Reported
	Kardegic	C			Not Reported
	Orocal D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2010	7491741	EXPEDITED (15-DAY)	Y	OT	1000014898		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Palpitations; Sleep Disorder; Tremor	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Zolodrom			C				Not Reported
	Singulair			C				Not Reported
	Aspirin Cardio			C				Not Reported
	Atorvastatin			C				Not Reported
	Remeron			C				Not Reported
	Eltroxin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2010	7533194	EXPEDITED (15-DAY)	N	HO	1000015225		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Papilloedema	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2010	7533197	EXPEDITED (15-DAY)	Y	OT	1000015226		46 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Galactorrhoea; Hyperprolactinaemia	Escitalopram Oxalate		S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2010	7412813	EXPEDITED (15-DAY)	Y	HO, OT	1000013676		27 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Obsessive Thoughts; Overdose; Restlessness	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	10 Mg 910 Mg, 1 In 1 D), Oral; 20 Mg 920 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg 910 Mg, 1 In 1 D), Oral; 20 Mg 920 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral		
					Oral	10 Mg 910 Mg, 1 In 1 D), Oral; 20 Mg 920 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2010	7502519	EXPEDITED (15-DAY)	N	OT	US-JNJCH-2010016835			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Abnormal;	Benadryl			S	Oral	Text:Several Tablets		Not Reported

Loss Of Consciousness; Road Traffic Accident	Lexapro		S	Unknown	Text:Unknown	Not Reported
	Alcohol		S	Oral	Text:Two Glasses Of Wine	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2010	7503020	EXPEDITED (15-DAY)	Y	HO	US-MYLANLABS-2010S1012425		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate			S	Unknown			Alphapharm
	Insulin Nos			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Lansoprazole			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Cetirizine Hydrochloride			C	Unknown			Not Reported
	Etomidate			C	Unknown			Not Reported
	Vecuronium Bromide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Cefazolin			C	Unknown			Not Reported
	Fentanyl			S	Intravenous (not otherwise specified)	250mcg In Divided Doses Between 8am And 11am		Not Reported
	Trazodone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2010	7530644	EXPEDITED (15-DAY)	Y	OT	1000015233			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicide; Suicide Attempt	Lexapro			S	Oral	Oral		Not Reported
	Zyprexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2010	7533201	EXPEDITED (15-DAY)	Y	OT	1000015213			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mood Altered	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2010	7320185	EXPEDITED (15-DAY)	Y	HO	1000011920		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicidal Ideation; Suicidal Ideation	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	15 Mg (15 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		
	Propoxyphene Hydrochloride And Acetaminophen			C				Not Reported
	Paracetamol			C				Not Reported
	Lexomil (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2010	7370228	EXPEDITED (15-DAY)	Y	OT	1000013185		55 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Palpitations	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Aprovel			C				Not Reported
	Levothyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2010	7382983	EXPEDITED (15-DAY)	Y	HO	1000013472		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autonomic Nervous System Imbalance; Clonus; Dizziness; Drug Interaction; Hyperreflexia; Mydriasis; Restlessness; Serotonin Syndrome; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Tamiflu			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2010	7385940	EXPEDITED (15-DAY)	Y	OT	1000013545		18 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Ejaculation Delayed; Nocturia; Overdose; Polyuria; Prostatic Disorder	Escitalopram Oxalate			S	Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, 30 Mg (15 Mg, 2 In 1 D), Oral		Not Reported
					Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, 30 Mg (15 Mg, 2 In 1 D), Oral		
					Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, 30 Mg (15 Mg, 2 In 1 D), Oral		
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2010	7505174	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20100707467		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Somnolence	Tramadol Hydrochloride And Acetaminophen			S	Oral		4 DAY	Not Reported
	Cetirizine Hydrochloride			S	Oral			Not Reported

	Xatral	S	Oral	Not Reported
	Zopiclone	S	Oral	Not Reported
	Xanax	S	Oral	Not Reported
	Dafalgan Codeine	S	Oral	Not Reported
	Loperamide	S	Oral	Not Reported
	Escitalopram Oxalate	S	Oral	Not Reported
	Coaprovel	S	Oral	Not Reported
	Acarbose	C	Unknown	Not Reported
	Previscan (Fluindione)	C	Unknown	Not Reported
	Paracetamol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2010	7505674	EXPEDITED (15-DAY)	Y	OT	US-ASTRAZENECA-2010SE33504		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Mania	Seroquel			S	Oral			Zeneca
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral		3 DAY	Not Reported
	Lexapro			S	Oral			Not Reported
	Vicodin			S	Unknown			Not Reported
	Xanax			S	Unknown			Not Reported
	Alcohol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2010	7506682	NON-EXPEDITED			US-MYLANLABS-2009S1015568		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lacrimation Increased; Yawning	Lexapro			S	Oral			Alphapharm
	Tramadol Hydrochloride			S	Oral			Alphapharm
	Vicodin			C				Not Reported

	Trazodone	C	Oral		Not Reported
	Trazodone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2010	7517517	DIRECT	N	OT			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dependence; Drug Ineffective; Drug Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	2 X 20mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2010	7521179	EXPEDITED (15-DAY)	Y	OT	1000015056		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activated Partial Thromboplastin Time Prolonged; Haematoma	Escitalopram Oxalate			S	Oral	1-2 Mg (1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	8 Mg (8 Mg, 1 In 1 D), Oral		Not Reported
	Unspecified Ingredient			S	Topical	Topical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2010	8354772	EXPEDITED (15-DAY)	Y	HO, OT	FR-PFIZER INC-2010089675		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Overdose; Somnolence	Xanax			S	Oral	0.25 Mg, 3x/Day		Pfizer
	Tramadol Hydrochloride And Acetaminophen			S	Oral	2 Tablets/Day	4 DAY	Not Reported
	Zopiclone			S	Oral	1 Tablet/Day		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Mg, 1x/Day		Not Reported
	Dafalgan Codeine			S	Oral	Unk	4 DAY	Not Reported
	Loperamide			S	Oral	Unk		Not Reported

	Escitalopram Oxalate	S	Oral	Unk	Not Reported
	Xatral	S	Oral	Unk	Not Reported
	Coaprovel	S	Oral	300 Mg, Unk	Not Reported
	Acarbose	C		100 Mg, 3x/Day	Not Reported
	Previscan (Fluindione)	C			Not Reported
	Paracetamol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2010	7383484	EXPEDITED (15-DAY)	Y	HO	1000013474		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Discomfort; Feeling Hot; Hypertension; Malaise; Middle Insomnia; Nausea; Paraesthesia; Presyncope; Tachycardia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lithium Carbonate			C				Not Reported
	Micronor (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2010	7388754	EXPEDITED (15-DAY)	N	HO	1000013528		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Anaemia;	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
Aspartate Aminotransferase Increased; Blood Potassium Decreased; Dizziness; Fatigue; Oedema Peripheral; Uterine Haemorrhage; Uterine Leiomyoma	Lexapro			S	Oral	(10 Mg, Every Other Day), Oral		Not Reported
	Exforte Hct			C				Not Reported
	Metoprolol			C				Not Reported
	Nexium			C				Not Reported
	Palgic			C				Not Reported
	Aspirin (81 Milligram)			C				Not Reported
	Lutein (20 Milligram)			C				Not Reported
	Calcium (500 Milligram)			C				Not Reported
	Fish Oil			C				Not Reported
	L-Lysine			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2010	7412772	EXPEDITED (15-DAY)	Y	HO	1000013952		62 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Petechiae	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolam			C				Not Reported
	Kardegic			C				Not Reported
	Dafalgan			C				Not Reported
	Morphine			C				Not Reported
	Cortancyl			C				Not Reported
	Gabapentine			C				Not Reported
	Inexium			C				Not Reported
	Imovane			C				Not Reported
	Skenan			C				Not Reported
	Rivotril (Drops (For Oral Use))			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2010	7507451	EXPEDITED (15-DAY)	Y	HO	US-SANOFI-AVENTIS-2010SA042981			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Familial Tremor; Fatigue	Multaq			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Primidone			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2010	7535771	EXPEDITED (15-DAY)	Y	DE, OT	1000015221		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Condition Aggravated; Depression; Drug Dependence; Drug Withdrawal Syndrome; Gun Shot Wound; Intentional Product Misuse; Loss Of Consciousness	Lexapro		S	Oral	(1 In 1 D), Oral	Not Reported
	Fentanyl		S			Not Reported
	Fentanyl Transdermal System		S	Transdermal	100 Mcg (1 In 1 D), Transdermal	Not Reported
	Fentanyl Transdermal System		S	Transdermal	25 Mcg (1 In 1 D), Transdermal	Not Reported
	Lamictal		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2010	7535906	EXPEDITED (15-DAY)	Y	HO, LT	1000012050		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Vasoconstriction; Headache; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			S	Oral	0.75 Mg (0.75 Mg, 1 In 1 D), Oral		Not Reported
	Propranolol			S	Oral	160 Mg (80 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2010	7382989	EXPEDITED (15-DAY)	N	OT	1000013475		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Decreased Appetite; Feeling Abnormal; Feeling Of Despair; Insomnia; Suicidal Ideation	Escitalopram Oxalate			S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2010	7388225	EXPEDITED (15-DAY)		HO	1000013498			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Loss Of Consciousness	Escitalopram Oxalate	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2010	7512161	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010092700		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Dizziness Postural; Ill-Defined Disorder; Nausea; Vomiting	Lipitor			S	Oral	20 Mg, 1x/Day		Pfizer
	Chantix			S	Oral	Unk		Pfizer
	Chantix			S	Oral	1 Mg, 2x/Day		Pfizer
	Lisinopril			S		20 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	20 Mg, 1x/Day		Not Reported
	Humalog			C	Subcutaneous	20 To 40 Units As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2010	7513320	NON-EXPEDITED	N		US-PFIZER INC-2008019934		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Lipitor			S				Pfizer
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Protonix			S				Not Reported
	Menest			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2010	7537828	EXPEDITED (15-DAY)	Y	HO	1000015294		84 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Agitation; Bronchial Obstruction; Confusional State; Fall; Hyperthermia; Hypotension; Inflammation; International	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Tramadol Hydrochloride And Acetaminophen			S	Oral	2 Dosage Forms (2 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Zopiclone			S	Oral	1 Dosage Forms (1		Not Reported

Normalised Ratio Decreased; Mydriasis; Overdose; Paralysis; Productive Cough; Somnolence; Withdrawal Syndrome					Dosage Forms, 1 In 1 D), Oral		
	Xanax		S	Oral	0.75 Mg (0.25 Mg, 3 In 1 D), Oral		Not Reported
	Cetirizine		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Acetaminophen		S	Oral	Oral		Not Reported
	Loperamide		S	Oral	Oral		Not Reported
	Xatral		S	Oral	Oral		Not Reported
	Coaprovel		S	Oral	(300 Mg), Oral		Not Reported
	Glucor		C				Not Reported
	Previscan (Fluindione)		C				Not Reported
	Paracetamol		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2010	7538064	EXPEDITED (15-DAY)	N	OT	DSA_43546_2010			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Mania	Ativan			S		Df		Not Reported
	Lexapro			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2010	7514651	NON-EXPEDITED	N		US-PFIZER INC-2009170707		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fatigue; Flushing; Neuropathy Peripheral; Pain; Paraesthesia; Pruritus	Lipitor			S		20 Mg, 1x/Day		Pfizer
	Acetylsalicylic Acid			S				Pfizer
	Lexapro			S		Unk		Not Reported
	Prilosec			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2010	7420419	EXPEDITED (15-DAY)	Y	HO	1000014257		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Epilepsy; Loss Of Consciousness	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Nordaz (Tablets)			C				Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2010	7507911	EXPEDITED (15-DAY)	N	HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-15212111		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Thrombosis	Abilify			S	Oral			Not Reported
	Xanax			S				Not Reported
	Lexapro			S				Not Reported
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2010	7518089	NON-EXPEDITED	N		US-PFIZER INC-2006126634			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Psoriasis	Norvasc			S	Oral			Pfizer
	Benazepril			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2010	7521947	NON-EXPEDITED	N		US-PFIZER INC-2009151425		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Withdrawal Syndrome; Malaise; Somnolence	Amlodipine Besylate			S		10 Mg, Unk		Pfizer
	Atenolol			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2010	7531319	DIRECT	N				31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Malaise; Product Quality Issue	Lexapro			S	Oral	10mg Daily Po		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2010	7545255	EXPEDITED (15-DAY)	Y	CA, OT	JPI-P-011556			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Transposition Of The Great Vessels; Ventricular Septal Defect	Xyrem			S	Transplacental	Transplacental		Not Reported
	Modafinil			S	Transplacental	200 Mg (200 Mg, 1 In 1 D), Transplacental		Not Reported
	Levothyroxine			S	Transplacental	Transplacental		Not Reported
	Metformin Hydrochloride			S	Transplacental	Transplacental		Not Reported
	Buspirone Hydrochloride			S	Transplacental	Transplacental		Not Reported
	Escitalopram Oxalate			S	Transplacental	Transplacental		Not Reported
	Mometasone Furoate			S	Transplacental	Transplacental		Not Reported
	Ascorbic Acid\Biotin\Minerals\Retinol\Tocopherol\Vitamin B\Vitamin D			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2010	7513039	EXPEDITED (15-DAY)	Y		1000015018		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Dizziness; Dyspnoea; Feeling Hot; Headache; Tinnitus; Vomiting	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
	Caffeine Anhydrou (Tablets)			C				Not Reported

Pantoprazole (Tablets)	C		Not Reported
Alprazolam	C		Not Reported
Isometheptene Mucate (Tablets)	C		Not Reported
Dipyrone Sodium (Tablets)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2010	7522858	EXPEDITED (15-DAY)	N	OT	US-ROXANE LABORATORIES, INC.-2010-RO-00944RO			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rash	Digoxin			S				Roxane
	Feldene			S				Not Reported
	Gabapentin			S				Not Reported
	Folic Acid			S				Not Reported
	Atenolol			S				Not Reported
	Zyrtec			S	Oral			Not Reported
	Tramadol Hydrochloride			S				Not Reported
	Norvir			S				Not Reported
	Ferrous Sulfate			S				Not Reported
	Diphenhydramine			S				Not Reported
	Loperamide			S				Not Reported
	Atrovent			S				Not Reported
	Cozaar			S				Not Reported
	Lexapro			S				Not Reported
	Epogen			S				Not Reported
	Abilify			S				Not Reported
	Carvedilol			S				Not Reported
	Seroquel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2010	7523535	NON-EXPEDITED	N		US-PFIZER INC-2008022181		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Feeling Drunk	Lyrica			S				Pfizer
	Fentanyl			C				Not Reported
	Zocor			C				Not Reported
	Diclofenac			C				Not Reported
	Amitriptyline			S				Not Reported

	Klonopin	S	Not Reported
	Lexapro	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2010	7523956	EXPEDITED (15-DAY)	N	OT	US-MERCK-1007USA03871			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rash	Cozaar			S	Oral			Merck
	Feldene			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Digoxin			S	Unknown			Not Reported
	Atenolol			S	Unknown			Not Reported
	Zyrtec			S	Oral			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Norvir			S	Oral			Not Reported
	Ferrous Sulfate			S	Unknown			Not Reported
	Diphenhydramine Hydrochloride			S	Unknown			Not Reported
	Loperamide Hydrochloride			S	Unknown			Not Reported
	Atrovent			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Epogen			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported
	Carvedilol			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2010	7541045	EXPEDITED (15-DAY)	N	OT	1000015334		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Leukaemia Recurrent	Lexapro	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2010	7541047	EXPEDITED (15-DAY)	Y	HO	1000015381		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis; Pancreatitis	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1d), Oral		Not Reported
	Erectile Dysfunction Medication			C				Not Reported
	Testosterone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2010	7541768	EXPEDITED (15-DAY)	Y	OT	1000015446		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Fatigue; Hyperhidrosis; Menorrhagia; Paraesthesia; Peripheral Coldness; Somnolence; Uterine Leiomyoma; Yawning	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		
	Synthroid			C				Not Reported
	Infufer (Injection)			C				Not Reported
	Amoxicillin-Clavulanic Acid (Capsules)			C				Not Reported
	Mvi (Tablets)			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2010	7393513	EXPEDITED (15-DAY)	Y	HO	1000013758		82 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Conversion Disorder; Insomnia	Escitalopram Oxalate			S	Oral	Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	Oral; 10 Mg (10 Mg, 1 In 1		

					D), Oral		
	Escitalopram Oxalate		S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2010	7441672	EXPEDITED (15-DAY)	Y	HO, OT	1000014510		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Drug Interaction; Dysarthria; Fall; Supraventricular Extrasystoles; Ventricular Extrasystoles	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral		
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral		
	Amitriptyline			S	Oral	175 Mg (175 Mg, 1 In 1 D), Oral; 125 Mg (125 Mg, 1 In 1 D), Oral; 100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
					Oral	175 Mg (175 Mg, 1 In 1 D), Oral; 125 Mg (125 Mg, 1 In 1 D), Oral; 100 Mg (100 Mg, 1 In 1 D), Oral		
					Oral	175 Mg (175 Mg, 1 In 1 D), Oral; 125 Mg (125 Mg, 1 In 1 D), Oral; 100 Mg (100 Mg, 1 In 1 D), Oral		
	Butyrophenone			S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
					Oral	50 Mg (50 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D), Oral		

	Lanitop	C		Not Reported
	Triamteren	C		Not Reported
	Tavor (Lorazepam)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2010	7504257	EXPEDITED (15-DAY)	Y	HO	1000014961		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2010	7525669	NON-EXPEDITED	Y		US-PFIZER INC-2009170500		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia	Lyrica			S		75 Mg, 2x/Day		Pfizer
	Lexapro			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2010	7528187	NON-EXPEDITED	Y		US-PFIZER INC-2008069076			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Lexapro			S				Not Reported
	Selzentry			S				Pfizer
	Zyprexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2010	7539192	EXPEDITED (15-DAY)	N	OT	1000015363		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Aortic Dilatation; Congenital	Lexapro			S	Transplacental	Transplacental		Not Reported

Aortic Valve Incompetence; Maternal Drugs Affecting Foetus; Multiple Congenital Abnormalities; Ventricular Septal Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2010	7543386	EXPEDITED (15-DAY)	Y	HO	1000015411		86 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Pressure Abnormal; Disorientation; Electroencephalogram Abnormal; Hyponatraemia; Malaise; Speech Disorder	Escitalopram Oxalate			S	Oral	5 Mg (5mg, 1 In 1 D), Oral		Not Reported
	Esberiven			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2010	7543387	EXPEDITED (15-DAY)	Y	HO	1000015412		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Fall; Gait Disturbance; Haematoma; International Normalised Ratio Increased; Muscle Haemorrhage	Escitalopram Oxalate			S	Oral	10mg (10mg, 2 In 2d), Oral		Not Reported
	Previscan (Fluindione)			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1d), Oral		Not Reported
	Aotal			C				Not Reported
	Diffu K			C				Not Reported
	Stilnox			C				Not Reported
	Seresta			C				Not Reported
	Vitamine B1 B6			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2010	7543394	EXPEDITED (15-DAY)	Y	HO	1000015382		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Coma; Confusional State; Hallucination, Visual; Heart Rate Increased; Intentional Overdose; Nervous System Disorder; Rhabdomyolysis; Suicide Attempt	Escitalopram Oxalate	S	Oral	(440mg, Once), Oral	Not Reported
	Effexor	S	Oral	(3375 Mg, Once) Oral	Not Reported
	Baclofen	S	Oral	220 Mg, Once), Oral	Not Reported
	Zolpidem	S	Oral	50 Mg Once, Oral	Not Reported
	Lormetazepam	S	Oral	18 Mg, Once, Oral	Not Reported
	Periciazine	S	Oral	30 Mg, Once, Oral	Not Reported
	Alcohol	S	Oral	Several Glasses Of Wiskey And 3 Bottles Of Wine Once Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2010	7528614	EXPEDITED (15-DAY)	Y	HO	FR-WYE-G06457010		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Coma; Confusional State; Hallucination, Visual; Intentional Overdose; Peripheral Motor Neuropathy; Rhabdomyolysis; Suicide Attempt	Effexor Xr			S	Oral	Overdose Amount= 3375 Mg	1 DAY	Wyeth
	Baclofen			S	Oral	Overdose Amount= 220 Mg	1 DAY	Unknown
	Alcohol			S	Oral	Overdose Amount= Several Drings Of Whisky Alcohol And 3 Bottles Of Wine	1 DAY	Unknown
	Lormetazepam			S	Oral	Overdose Amount= 18 Mg	1 DAY	Schering
	Periciazine			S	Oral	Overdose Amount= 30 Mg	1 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	Overdose Amount= 440 Mg	1 DAY	Lundbeck
	Zolpidem			S	Oral	Overdose Amount= 50 Mg	1 DAY	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2010	7529614	EXPEDITED (15-DAY)	Y	HO	US-WATSON-2010-10191		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Serotonin Syndrome	Fentanyl Citrate		S	Intravenous (not otherwise specified)	250 U/G, Single	Watson
	Escitalopram Oxalate		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2010	7536104	DIRECT	Y				31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Crying; Insomnia	Lexapro			S	Oral	Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2010	7475909	EXPEDITED (15-DAY)	Y	OT	1000014822		55 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Change; Extrasystoles	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Simvastatin			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2010	7512963	EXPEDITED (15-DAY)	Y	OT	1000015016		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Constipation; Haemorrhoids; Metrorrhagia; Off Label Use; Proctitis; Rectal Haemorrhage	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Estreva (Gel)			C				Not Reported
	Progesterone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2010	7530595	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-15224348			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Rash	Atenolol	S				Sandoz
	Abilify	S				Not Reported
	Ferrous Sulfate	S				Not Reported
	Feldene	S		Capsule		Not Reported
	Gabapentin	S				Not Reported
	Folic Acid	S				Not Reported
	Digoxin	S				Not Reported
	Zyrtec	S	Oral			Not Reported
	Tramadol Hydrochloride	S				Not Reported
	Norvir	S	Oral			Abbott
	Diphenhydramine	S				Not Reported
	Loperamide	S				Not Reported
	Atrovent	S				Not Reported
	Cozaar	S	Oral			Not Reported
	Lexapro	S	Oral			Not Reported
	Epogen	S				Not Reported
	Carvedilol	S				Not Reported
	Seroquel	S				Not Reported
	Lactose	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2010	7530745	EXPEDITED (15-DAY)	N	HO	DK-PURDUE-GBR-2010-0006579		31 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Rhabdomyolysis; Urinary Retention	Oxycodone Hydrochloride			S	Oral	10 Mg, Bid		Purdue
	Cipralex			S	Oral	20 Mg, Daily	13 DAY	Not Reported
	Tramadol			S	Oral	100 Mg, Qid	391 DAY	Not Reported
	Lyrica			S	Oral	75 Mg, Unk	7 DAY	Not Reported
	Seroquel			S	Oral	100 Mg, Unk	360 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2010	7532002	NON-EXPEDITED	Y		US-PFIZER INC-2008033807		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Potassium Increased; Blood Sodium Increased; Drug Interaction; Fatigue; Malaise	Dilantin	S			Pfizer
	Lexapro	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2010	7543607	EXPEDITED (15-DAY)	Y	OT	DSA_43265_2010		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Movement Disorder	Xenazine			S	Oral	(12.5 Mg Tid Oral)		Not Reported
	Lexapro			S		(Df), (Df) (Df), (Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2010	7522294	EXPEDITED (15-DAY)	N	OT	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2010-BP-08			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rash	Atrovent			S				Boehringer Ingelheim
	Feldene			S				Not Reported
	Gabapentin			S				Not Reported
	Folic Acid			S				Not Reported
	Digoxin			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported
	Norvir			S	Oral			Not Reported
	Atenolol			S				Not Reported
	Zyrtec			S	Oral			Not Reported
	Ferrous Sulfate			S				Not Reported
	Diphenhydramine			S				Not Reported
	Loperamide			S				Not Reported
	Cozaar			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Epogen			S				Not Reported
	Abilify			S				Not Reported

Carvedilol	S		Not Reported
Seroquel	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2010	7533891	EXPEDITED (15-DAY)	N	OT	US-ASTRAZENECA-2010SE35835			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rash	Atenolol			S	Unknown			Zeneca
	Seroquel			S	Oral			Not Reported
	Atrovent			S				Not Reported
	Abilify			S				Not Reported
	Carvedilol			S				Not Reported
	Cozaar			S	Oral			Not Reported
	Digoxin			S				Not Reported
	Diphenhydramine			S				Not Reported
	Epogen			S				Not Reported
	Folic Acid			S				Not Reported
	Ferrous Sulfate			S				Not Reported
	Gabapentin			S				Not Reported
	Loperamide			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Norvir			S				Not Reported
	Feldene			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported
	Zyrtec			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2010	7546167	EXPEDITED (15-DAY)	Y	HO	1000015451		80 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; General Physical Health Deterioration; Headache; Hyponatraemia; Nausea	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Buflomedil			C				Not Reported
	Aldactazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2010	7268639	EXPEDITED (15-DAY)	Y	HO	1000011314		31 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Rhabdomyolysis; Urinary Retention	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Oxycontin			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tramadol			S	Oral	200 Mg (50 Mg, 4 In 1 D), Oral		Not Reported
	Seroquel			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Lyrica			S	Oral	150 Mg (75 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2010	7417964	EXPEDITED (15-DAY)	Y	OT	1000014191		56 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anosmia; Dysgeusia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2010	7537668	EXPEDITED (15-DAY)	Y	HO, OT	1000015260		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alcohol Poisoning; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	(600 Mg, Once), Oral		Not Reported
	Tramadol			S	Oral	(1000 Mg, Once), Oral		Not Reported
	Atacand			S	Oral	(112 Mg, Once), Oral		Not Reported
	Alcohol			S	Oral	(Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2010	7548427	EXPEDITED (15-DAY)	Y	HO	1000014319		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Hypoglycaemic Seizure; Malaise; Maternal Exposure During Pregnancy; Paraesthesia; Pregnancy; Tremor	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Ibuprofen			C				Not Reported
	Timoferol			C				Not Reported
	Antidiabetics Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2010	7455690	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010080715			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rash	Feldene			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Atenolol			S		Unk		Pfizer
	Folic Acid			S		Unk		Not Reported
	Digoxin			S		Unk		Not Reported
	Zyrtec			S	Oral	Unk		Not Reported
	Tramadol			S		Unk		Not Reported
	Norvir			S	Oral	Unk		Not Reported
	Ferrous Sulfate			S		Unk		Not Reported
	Diphenhydramine			S		Unk		Not Reported
	Loperamide			S		Unk		Not Reported
	Atrovent			S		Unk		Not Reported
	Cozaar			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Epogen			S		Unk		Not Reported
	Abilify			S		Unk		Not Reported

Carvedilol	S	Unk	Not Reported
Seroquel	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2010	7537121	EXPEDITED (15-DAY)	N	HO	B0668624A			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Abnormal; Cleft Palate; Cough; Cyanosis; Dehydration; Eye Disorder; Fontanelle Depressed; Haemangioma; Hypertonia; Hypotonia; Malaise; Malnutrition; Maternal Exposure During Pregnancy; Mucosal Dryness; Muscular Weakness; Oesophagitis; Palatal Disorder; Pallor; Poor Sucking Reflex; Regurgitation; Stridor; Vomiting; Weight Gain Poor	Deroxat			S				Glaxosmithkline
	Escitalopram Oxalate			S		20mg Per Day		Unknown
	Syntocinon			C			1 DAY	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2010	7537493	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-10P-163-0662073-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Initial Insomnia; Libido Increased; Photophobia; Restlessness	Lexapro			S				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2010	7556466	EXPEDITED (15-DAY)	Y	HO	1000015519		55 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Meteospasmyl (Alverine Citrate\Dimethicone)			S	Oral	4 Dosage Forms (2 Dosage Forms, 2 In 1 D), Oral		Not Reported
	Unspecified Ingredient			S	Oral	10 Dosage Forms (5 Dosage Forms, 2 In 1 D), Oral		Not Reported
	Ibuprofen			S	Oral	Oral		Not Reported
	Karayal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2010	7405614	EXPEDITED (15-DAY)	Y	OT	FR-ROCHE-705447		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death	Rivotril			S	Unknown			Roche
	Amitriptyline Hydrochloride			S	Oral	18 Drops Morning And Evening		Roche
	Amitriptyline Hydrochloride			S	Oral	Strength: 40 Mg/Ml; Dose: 1 Bottle; Drug Intoxication		Roche
	Bromazepam			S	Unknown			Roche
	Bromazepam			S	Unknown	Drug Intoxication		Roche
	Prazepam			S	Unknown			Not Reported
	Topiramate			S	Unknown			Not Reported
	Zyprexa			S	Unknown	Coated Tablet		Not Reported
	Zyprexa			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Zopiclone			S	Unknown	Form: Divisible Coated Tablet		Not Reported
	Chlorpromazine			S	Oral			Not Reported

	Oxazepam	S	Unknown			Not Reported
	Spasfon-Lyoc	S	Oral	Form: Lyophilisate		Not Reported
	Effexor	S	Unknown			Not Reported
	Effexor	S	Unknown	Dose Increased		Not Reported
	Stilnox	S	Unknown	Form: Divisible Coated Tablet		Not Reported
	Theralene	S	Oral			Not Reported
	Theralene	S	Oral	Dose Reduced		Not Reported
	Escitalopram Oxalate	S	Unknown	Form: Divisible Coated Tablet		Not Reported
	Akineton	S	Unknown	Drug Name: Akineton L.P., Coated Tablet		Not Reported
	Periciazine	S	Oral	10-0-40 Drops		Not Reported
	Clamoxyl (Amoxicillin)	S	Unknown	Form: Dispersible Tablet		Not Reported
	Econazole Nitrate	C	Vaginal		7 DAY	Not Reported
	Flagyl	C	Oral	Coated Tablet	7 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2010	7538214	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-10P-163-0660700-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rash	Norvir			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Feldene			S				Not Reported
	Gabapentin			S				Not Reported
	Folic Acid			S				Not Reported
	Digoxin			S				Not Reported
	Atenolol			S				Not Reported
	Zyrtec			S	Oral			Not Reported
	Tramadol Hydrochloride			S				Not Reported
	Ferrous Sulfate			S				Not Reported
	Diphenhydramine			S				Not Reported
	Loperamide			S				Not Reported

	Atrovent	S			Not Reported
	Cozaar	S	Oral		Not Reported
	Epogen	S			Not Reported
	Abilify	S			Not Reported
	Carvedilol	S			Not Reported
	Seroquel	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2010	7544814	DIRECT	Y	DS, HO			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypophagia; Lethargy; Pyrexia; Seizure; Serotonin Syndrome; Tremor	Zyvox			S	Intravenous (not otherwise specified)	600mg Q12 Iv		Pfizer
	Lexapro			S	Oral	20mg Daily Po		Forest
	Doripenem			C				Not Reported
	Soma			C				Not Reported
	Potassium Chloride			C				Not Reported
	Methadone Hydrochloride			C				Not Reported
	Lovenox			C				Not Reported
	Duoneb			C				Not Reported
	Fluconazole			C				Not Reported
	Zosyn			C				Not Reported
	Protonix			C				Not Reported
	Nystatin			C				Not Reported
	Zofran			C				Not Reported
	Norco			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2010	7344295	EXPEDITED (15-DAY)	N	OT	1000012336		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Dizziness; Drug Ineffective; Hallucination; Tachyphrenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2010	7539898	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2010098512		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Fulminant	Atarax			S	Oral	50 Mg, Daily		Pfizer
	Diffu K			S	Oral	600 Mg, Daily		Not Reported
	Cymbalta			S	Oral	60 Mg, Daily	20 DAY	Not Reported
	Anafranil			S	Oral	25 Mg, Daily		Not Reported
	Lorazepam			S	Oral	1.25 Mg, Daily		Not Reported
	Aspirin			S	Oral	75 Mg, Daily		Not Reported
	Gliclazide			S	Oral	30 Mg, Daily		Not Reported
	Lansoprazole			S	Oral	15 Mg, Daily		Not Reported
	Furosemide			S	Oral	40 Mg, Daily		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Daily		Not Reported
	Tamsulosin Hydrochloride			S	Oral	0.4 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2010	7551802	EXPEDITED (15-DAY)	Y	OT	1000015599			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Blood Alcohol Abnormal; Loss Of Consciousness	Lexapro			S	Oral	Several Tablets, Oral		Not Reported
	Benadryl			S				Not Reported
	Alcohol			S	Oral	2 Glasses Of Wine, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2010	7518200	EXPEDITED (15-DAY)	Y	HO	1000015052		31 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Hyperhidrosis;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

Restlessness; Seizure; Serotonin Syndrome	Escitalopram Oxalate	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2010	7527143	EXPEDITED (15-DAY)	Y	OT	1000015159		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram Oxalate			S			59 DAY	Not Reported
	Escitalopram Oxalate			S			3 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2010	7542411	EXPEDITED (15-DAY)	N	HO	FR-BRISTOL-MYERS SQUIBB COMPANY-15236318		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Fall; Hepatic Steatosis; Hyperkalaemia; Hyponatraemia; Hypothyroidism; Pancreatitis Chronic	Irbesartan			S	Oral			Bristol Myers Squibb
	Escitalopram Oxalate			S	Oral			Not Reported
	Prazepam			C				Not Reported
	Daflon (Diosmin/Hesperidin)			C	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Efferalgan Codeine			C	Oral	1 Df=1 Intake.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2010	7542465	EXPEDITED (15-DAY)	Y	OT	FR-MYLANLABS-2010S1013886		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate			S	Unknown			Alphapharm
	Fentanyl			S	Nasal	200 Microg/Puff		Not Reported
	Oxycodone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2010	7553453	EXPEDITED (15-DAY)	Y	HO	1000015521		87 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Fall; Hepatitis Fulminant; Incoherent; Pleural Effusion; Somnolence	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Cymbalta			S	Oral	60 Mg (60 Mg, 1 In 1 D), Oral		Not Reported
	Atarax			S	Oral	50 Mg (25 Mg, 2 In 1 D), Oral		Not Reported
	Anafranil			S	Oral	25 Mg (25 Mg, 1 In 1 D) , Oral		Not Reported
	Lorazepam			S	Oral	1.25mg (1.25mg , 1 In 1 D), Oral		Not Reported
	Aspirin			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Gliclazide			S		30 Mg (30 Mg, 1 In 1 D),Oral		Not Reported
	Lansoprazole			S		15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Furosemide			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Diffu K			S	Oral	600 Mg (600 Mg, 1 In 1 D), Oral		Not Reported
	Tamsulosin Hydrochloride			S	Oral	0.4 Mg (0.4 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2010	7553535	EXPEDITED (15-DAY)	Y	HO	1000015590		77 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

Amlodipine	C		Not Reported
Aspirin	C		Not Reported
Lansoprazole	C		Not Reported
Nebivolol	C		Not Reported
Simvastatin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2010	7553764	EXPEDITED (15-DAY)	Y	OT	1000015700		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Dry Mouth; Dysphagia; Hypersensitivity	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D) ,Oral, 10 Mg (10 Mg, 1 In 1 D),Oral, 15 Mg (15 Mg, 1 In 1 D),Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D) ,Oral, 10 Mg (10 Mg, 1 In 1 D),Oral, 15 Mg (15 Mg, 1 In 1 D),Oral		
					Oral	5 Mg (5 Mg, 1 In 1 D) ,Oral, 10 Mg (10 Mg, 1 In 1 D),Oral, 15 Mg (15 Mg, 1 In 1 D),Oral		
	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2010	7554035	EXPEDITED (15-DAY)	Y	HO	LTI2010A00161		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hepatitis Fulminant	Lansoprazole			S	Oral	15 Mg (15 Mg,1 In 1 D) Oral		Not Reported
	Cymbalta			S	Oral	60 Mg (60 Mg,1 In 1 D) Oral	19 DAY	Not Reported
	Atarax			S	Oral	25 Mg (25 Mg,1 In 2 D) Oral		Not Reported
	Anafranil			S	Oral	25 Mg (25 Mg,1 In 1 D)		Not Reported

				Oral	
	Lorazepam	S	Oral	1.25 Mg (1.25 Mg, 1 In 1 D) Oral	Not Reported
	Aspirin	S	Oral	75 Mg (75 Mg,1 In 1 D) Oral	Not Reported
	Gliclazide	S	Oral	30 Mg (30 Mg,1 In 1 D) Oral	Not Reported
	Furosemide (Furosemide)	S	Oral	40 Mg (40 Mg,1 In 1 D) Oral	Not Reported
	Potassium Chloride	S	Oral	600 Mg (600 Mg,1 In 1 D) Oral	Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg,1 In 1 D) Oral	Not Reported
	Tamsulosin Hydrochloride	S	Oral	0.4 Mg (0.4 Mg,1 In 1 D) Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2010	7035747	EXPEDITED (15-DAY)	Y	DS, HO, LT, OT	DE-JNJFOC-20090608724		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Cardiac Arrest; Coronary Artery Disease; Electrocardiogram Qt Prolonged; Syncope; Torsade De Pointes	Reminyl			S	Unknown			Not Reported
	Pipamperone			S	Oral			Not Reported
	Cipralex			S	Unknown	Since Three Days		Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Esidrix			S	Unknown			Not Reported
	Esidrix			S	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Marcumar			C	Unknown			Not Reported

	Captopril	C	Unknown	Not Reported
	Captopril	C	Unknown	Not Reported
	Calcium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2010	7413014	EXPEDITED (15-DAY)	Y	OT	FR-WYE-G06194110		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Escherichia Vaginitis; Fall; Fatigue; Foetal Death; Hellp Syndrome; Maternal Exposure During Pregnancy; Proteinuria; Sleep Disorder; Somnolence; Thrombocytopenia; Vaginitis Gardnerella	Effexor Xr			S	Oral	75 Mg Total Daily		Wyeth
	Bromazepam			S	Oral	Unknown From An Unspecified Date To Oct-2008 And Then, Overdose With 48 Mg On 16-Nov-2008		Roche
	Rivotril			S		2 Doses Total Daily		Roche
	Rivotril			S		40 Mg Total Daily		Roche
	Prazepam			S		Unknown		Not Reported
	Topiramate			S		Unknown		Janssen
	Zyprexa			S	Oral			Not Reported
	Zyprexa			S	Oral	7.5 Mg Total Daily	79 DAY	Not Reported
	Zyprexa			S	Oral	20 Mg Total Daily	17 DAY	Not Reported
	Zyprexa			S	Oral			Not Reported
	Zopiclone			S	Oral		3 MTH	Not Reported
	Chlorpromazine Hydrochloride			S	Oral			Not Reported
	Oxazepam			S	Oral	20 Mg Total Daily		Wyeth
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			S	Oral	160 Mg Total Daily		Not Reported
	Stilnox			S	Oral			Not Reported
	Theralene			S	Oral	100 Drops Total Daily		Not Reported
	Theralene			S	Oral	Unknown, But Less Than 100 Drops Per Day		Not Reported

	Escitalopram Oxalate	S	Oral		16 DAY	Lundbeck
	Akineton	S	Oral			Knoll
	Periciazine	S	Oral	50 Drops Total Daily		Not Reported
	Clamoxyl (Amoxicillin)	S	Oral	3 G Total Daily		Unknown
	Amitriptyline Hydrochloride	S	Oral	36 Drops Per Day From An Unspecified Date To Oct-2008; Overdose With One Full Bottle On 16-Nov-2008		Roche

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2010	7479804	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-14921555		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Chondromalacia; Hepatitis; Obstructive Airways Disorder; Osteoarthritis; Pneumonia; Umbilical Hernia	Abilify			S		5 Mg 1/2q		Not Reported
	Lamictal			S		25mg Bid (1x1wk,Bidx2wk)		Not Reported
	Lexapro			S	Oral	(30x2)10mg Oral		Not Reported
	Xanax			S				Not Reported
	Imdur			C				Not Reported
	Nexium			C				Not Reported
	Potassium			C				Not Reported
	Wellbutrin Xl			C		1df=300 Units Nos	5 YR	Not Reported
	Lisinopril			C				Not Reported
	Metoprolol			C				Not Reported
	Requip			C				Not Reported
	Lyrica			C				Not Reported
	Effexor Xr			C				Not Reported
	Prozac			C				Not Reported
	Paxil Cr			C				Not Reported
	Glucophage			C				Not Reported
	Actos			C				Not Reported
	Amaryl			C				Not Reported
	Lopresor			C				Not Reported
	Norvasc			C				Not Reported
	Asa			C				Not Reported

	Multi-Vitamin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2010	7544726	EXPEDITED (15-DAY)	Y	OT	NO-MYLANLABS-2010S1011806		55 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrasystoles	Metoprolol			S				Not Reported
	Cipralex			S				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2010	7547604	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Balance Disorder; Contusion; Dizziness; Drug Withdrawal Syndrome; Feeling Abnormal; Impaired Work Ability; Limb Injury; Pain In Extremity; Paraesthesia	Lexapro			S	Buccal	10mg 1 Tablet Daily Buccal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2010	7548593	DIRECT	N	HO				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Pain In Jaw	Lexapro			S		10 Mg Tablet 1 Pill @ Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2010	7410158	EXPEDITED (15-DAY)	Y	HO, OT	FR-JNJFOC-20100510843		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal	Topiramate			S	Oral			Not Reported

Exposure During Pregnancy; Off Label Use	Econazole Nitrate	S	Vaginal		7 DAY	Not Reported
	Amitriptyline Hydrochloride	S	Oral	1 Bottle		Not Reported
	Amitriptyline Hydrochloride	S	Oral			Not Reported
	Bromazepam	S	Oral			Not Reported
	Bromazepam	S	Oral			Not Reported
	Rivotril	S	Oral			Not Reported
	Rivotril	S	Oral			Not Reported
	Prazepam	S	Oral			Not Reported
	Zyprexa	S	Oral			Not Reported
	Zyprexa	S	Oral			Not Reported
	Zyprexa	S	Oral			Not Reported
	Zyprexa	S	Oral			Not Reported
	Zopiclone	S	Oral			Not Reported
	Chlorpromazine Hydrochloride	S	Oral			Not Reported
	Oxazepam	S	Oral			Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	S	Oral			Not Reported
	Effexor	S	Oral			Not Reported
	Effexor	S	Oral			Not Reported
	Stilnox	S	Oral		1 MTH	Not Reported
	Theralene	S	Oral			Not Reported
	Theralene	S	Oral			Not Reported
	Escitalopram Oxalate	S	Oral		16 DAY	Not Reported
	Akineton	S	Oral			Not Reported
	Periciazine	S	Oral	10 Drops In The Morning / 40 Drops In The Evening		Not Reported
	Clamoxyl (Amoxicillin)	S	Oral			Not Reported
	Flagyl	S	Vaginal		7 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2010	7528620	EXPEDITED (15-DAY)	Y	HO, OT	JP-ASTRAZENECA-2010SE36223		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alcohol Poisoning; Intentional Overdose; Suicide Attempt	Atacand			S	Oral	112 Mg, 14 Tablets Once	1 DAY	Astrazeneca
	Cipralex			S	Oral	600 Mg, 30 Tablets Once	1 DAY	Not Reported
	Tramadol Hydrochloride			S	Oral	1000 Mg, 10 Tablets Once	1 DAY	Not Reported
	Alcohol			S	Oral	Unknown Amount Of Vodka	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2010	7535708	EXPEDITED (15-DAY)	N	OT	1000015297		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Impatience; Insomnia; Irritability; Negative Thoughts; Panic Attack; Restlessness; Tachyphrenia	Escitalopram Oxalate			S	Oral Oral Oral	See Image See Image See Image	1 WEEK 1 WEEK	Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2010	7546987	EXPEDITED (15-DAY)	N	OT	B0670309A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rash	Digoxin			S	Unknown			Glaxosmithkline
	Zyrtec			S	Oral			Glaxosmithkline
	Folic Acid			S	Unknown			Glaxosmithkline
	Atenolol			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Glaxosmithkline
	Norvir			S	Oral			Not Reported
	Ferrous Sulfate			S	Unknown			Glaxosmithkline

	Diphenhydramine	S	Unknown	Glaxosmithkline
	Loperamide	S	Unknown	Not Reported
	Atrovent	S	Unknown	Glaxosmithkline
	Cozaar	S	Oral	Not Reported
	Lexapro	S	Unknown	Not Reported
	Epogen	S	Unknown	Not Reported
	Abilify	S	Unknown	Not Reported
	Carvedilol	S	Unknown	Glaxosmithkline
	Seroquel	S	Unknown	Not Reported
	Feldene	S	Unknown	Glaxosmithkline
	Gabapentin	S	Unknown	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2010	7567320	EXPEDITED (15-DAY)	N	CA	1000015720		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip; Cleft Palate; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2010	7344516	EXPEDITED (15-DAY)	Y	OT	1000012532			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2010	7528661	EXPEDITED (15-DAY)	Y	LT, OT	1000015142		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Intentional Self-Injury;	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

Suicide Attempt	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Disulfiram	C				Not Reported
	Naltrexone	C				Not Reported
	Clonazepam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2010	7543667	EXPEDITED (15-DAY)	N	OT	1000015430		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2010	7554189	DIRECT	N	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Emotional Disorder; Weight Increased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2010	7567342	EXPEDITED (15-DAY)	Y	HO	1000015717		1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ammonia Increased; Cough; Cyanosis Neonatal; Dehydration; Extensor Plantar Response; Eye Movement Disorder; Fontanelle Depressed; Haemangioma; Haemoglobin Decreased;	Escitalopram Oxalate			S	Transplacental	20mg, (20mg, 1 In 1 D), Transplecental		Not Reported
	Deroxat			S	Transplacental	Transplacental		Not Reported
	Syntocinon			C				Not Reported

Hypertonia; Hypophagia; Hyporeflexia; Hypotonia; Leukoplakia Oral; Malaise; Malnutrition; Maternal Drugs Affecting Foetus; Mucosal Dryness; Musculoskeletal Stiffness; Oesophagitis; Palatal Disorder; Pallor; Platelet Count Increased; Poor Sucking Reflex; Regurgitation; Selective Eating Disorder; Stridor; Vomiting; Weight Gain Poor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2010	7550074	EXPEDITED (15-DAY)	Y	OT	US-SANOFI-AVENTIS-2010SA048398		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hand Fracture; Road Traffic Accident; Sleep-Related Eating Disorder; Somnambulism	Ambien			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2010	7550098	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010103404			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Feeling Abnormal; Joint Lock; Serotonin Syndrome	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2010	7550341	NON-EXPEDITED	N		US-PFIZER INC-2010099772			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Interaction; Somnolence	Chantix			S		Unk		Pfizer
	Valproic Acid			S		Unk		Not Reported
	Levetiracetam			S		Unk		Not Reported
	Phenobarbital			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2010	7550667	EXPEDITED (15-DAY)	Y	OT	US-ABBOTT-10P-163-0663761-00		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory; Hallucination, Visual	Lexapro			S	Oral			Not Reported
	Wellbutrin Xl			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2010	7554183	DIRECT	N	DE			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2010	7569609	EXPEDITED (15-DAY)	Y	OT	1000015737		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Intentional Overdose; Somnolence; Suicide Attempt; Unevaluable Event	Escitalopram Oxalate			S	Oral	Single Dosage (Once), Oral; Oral		Not Reported
	Trimipramine			S	Oral	2400 Mg (2400 Mg, Once), Oral		Not Reported
	Opipramol			S	Oral	Single Dosage (Once), Oral		Not Reported

	Alcohol	S	Oral	Single Amount (Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2010	7511436	EXPEDITED (15-DAY)	Y	OT	1000015003		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased; Platelet Count Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
	Bendrofluazide			C				Not Reported
	Levothyroxine			C				Not Reported
	Esomeprazole			C				Not Reported
	Pamidronate (Injection)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2010	7552124	NON-EXPEDITED	N	OT	US-PFIZER INC-2010102775			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Serotonin Syndrome	Zoloft			S		Unk	2920 DAY	Pfizer
	Lexapro			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2010	7557389	DIRECT	N	DE			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Mood Swings; Personality Change	Chantix			S				Pfizer
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2010	7570619	EXPEDITED (15-DAY)	Y	OT	1000015773			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Interaction; Suicidal Ideation	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Champix			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2010	7415415	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2010SA030705		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; C-Reactive Protein Increased; Enteritis; Gamma-Glutamyltransferase Increased; Gastric Ulcer; Gastrooesophageal Reflux Disease; Hepatitis Acute; Hiatus Hernia; Melaena; Throat Irritation; Vomiting	Stilnox			S	Oral		4 YR	Not Reported
	Plavix			S	Oral		5 YR	Not Reported
	Escitalopram Oxalate			S	Oral		2 DAY	Not Reported
	Lercanidipine Hydrochloride			S	Oral		5 MTH	Not Reported
	Tanakan			S	Oral		17 MTH	Not Reported
	Ezetrol			S	Oral		4 YR	Not Reported
	Sotalol Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2010	7546154	EXPEDITED (15-DAY)	Y	OT	1000015429		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unevaluable Event	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2010	7571462	EXPEDITED (15-DAY)	Y	HO	1000015408		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Intentional Overdose; Road Traffic	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported

Accident; Suicide Attempt	Unspecified Ingredient	S	Amount (Once)		Not Reported
	Alcohol	S	Amount (Once)		Not Reported
	Tranxene T-Tab	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2010	7572184	EXPEDITED (15-DAY)	Y	HO	1000015736		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; General Physical Health Deterioration; Hepatic Steatosis; Hyperkalaemia; Hyponatraemia; Hypothyroidism; Mixed Liver Injury; Pancreatitis; Renal Failure	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Irbesartan			S	Oral	300 Mg (300 Mg, 1 In 1 D), Oral		Not Reported
	Lysanxia (Tablets)			C				Not Reported
	Daflon (Diosmin/Hesperidin)			C				Not Reported
	Efferalgan (Tablets)			C				Not Reported
	Efferalgan Codein (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2010	6962401	EXPEDITED (15-DAY)	Y	OT	1000005412		58 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Lymphatic Disorder; Petechiae; Thrombocytopenia	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (10 Mg, 1 In 2 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg 910 Mg, 1 In 1 D), Oral; 20 Mg 920 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg 910 Mg, 1 In 1 D), Oral; 20 Mg 920 Mg, 1 In 1 D), Oral		
	Antihyperintensive Medication			C				Not Reported
	Metformin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2010	7436055	EXPEDITED (15-DAY)	Y	RI	1-22851292		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypoxia; Respiratory Acidosis; Serotonin Syndrome; Somnolence; Tachycardia	Fentanyl Patch			S	Intravenous (not otherwise specified)	250 Mcg, Divided Doses, Intravenous		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Insulin Nos			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Gabapentin			C				Not Reported
	Lansoprazole			C				Not Reported
	Lorazepam			C				Not Reported
	Oxycodone			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported
	Etomidate			C				Not Reported
	Vecuronium Bromide			C				Not Reported
	Morphine			C				Not Reported
	Cefazolin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2010	7554564	EXPEDITED (15-DAY)	Y	HO	FR-NOVOPROD-313515		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Haemorrhage	Victoza			S	Subcutaneous	Uk/Sc		Novo Nordisk
	Escitalopram Oxalate			S		20 Mg, Qd		Not Reported
	Aspirin			S	Oral	300 Mg, Qd		Not Reported
	Glucophage			C	Oral	2000 Mg, Qd		Not Reported
	Simvastatin			C	Oral	20 Mg, Qd		Not Reported
	Lercanidipine Hydrochloride			C		20 Mg, Qd		Not Reported
	Coaprovel			C		300/25mg		Not Reported
	Allopurinol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2010	7554740	EXPEDITED (15-DAY)	Y	DE	GB-PERRIGO-10GB012429		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Ibuprofen			S	Oral	Unk	1 DAY	Perrigo
	Cipralex			S	Oral	220 Mg, Single	1 DAY	Not Reported
	Cipralex			S	Oral	10 Mg, Qd	7 DAY	Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Alcohol			S	Oral	Unk	1 DAY	Not Reported
	Fluoxetine			S	Oral	Unk	1 DAY	Not Reported
	Nortriptyline Hydrochloride			S	Oral	Unk	1 DAY	Not Reported
	Oxazepam			S	Oral	Unk	1 DAY	Not Reported
	Temazepam			S	Oral	Unk	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2010	7573995	EXPEDITED (15-DAY)	Y	HO	1000015775		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Herpes Simplex Test Positive; Hyperthermia; Smooth Muscle Antibody Positive; Weight Decreased	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2010	7582072	EXPEDITED (15-DAY)	Y	OT	OXER20100002		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome; Vision Blurred; Weight Decreased	Oxycodone Hydrochloride			S	Oral	120 Mg, Q Day, Oral		Not Reported
	Fentanyl (Fentanyl)			S	Nasal	Four Puffs Of 200 Ug/Puff, Nasal		Not Reported

	Escitalopram Oxalate	S	5 Mg, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2010	7556390	EXPEDITED (15-DAY)	Y	HO	FR-EISAI INC.-E3810-04030-SPO-FR		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Pariet (Rabeprazole)			S	Oral	Unknown		Not Reported
	Motilium			S	Oral	Unknown		Not Reported
	Previscan (Fluindione)			S	Oral		81 DAY	Not Reported
	Hydrochlorothiazide\Valsartan			S	Oral	Unknown	4 MTH	Not Reported
	Escitalopram Oxalate			S	Oral	Unknown		Not Reported
	Gaviscon			S	Oral	Unknown		Not Reported
	Tahor			S	Oral	Unknown		Not Reported
	Amlodipine			S	Oral	Unknown		Not Reported
	Di-Gesic			C				Not Reported
	Oxybutynin			C				Not Reported
	Nebivolol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2010	7556740	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20100805331		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Relapsing	Topiramate			S	Oral			Not Reported
	Crestor			S	Unknown			Not Reported
	Inexium			S	Unknown			Not Reported
	Propranolol			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Creon			S	Unknown			Not Reported
	Sulpiride			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported

	Humalog	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2010	7557133	EXPEDITED (15-DAY)	Y	DE	GB-JNJFOC-20100808035		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Ibuprofen			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Nortriptyline Hydrochloride			S	Oral			Not Reported
	Oxazepam			S	Oral			Not Reported
	Temazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2010	7574326	DIRECT	Y	OT			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Swelling; Breast Tenderness; Restless Legs Syndrome	Lexapro			S	Oral Oral	5mgm 1x Daily Oral 10mgm 1x Daily Oral 5mgm 1x Daily Oral 10mgm 1x Daily Oral		Forest
	Cardura			C				Not Reported
	Tenormin			C				Not Reported
	Crestor			C				Not Reported
	Nexium			C				Not Reported
	Asa			C				Not Reported

Valium	C		Not Reported
Fish Oil	C		Not Reported
Centrum Silver	C		Not Reported
Vitamin B12	C		Not Reported
Vit E	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2010	7566278	NON-EXPEDITED			-MYLANLABS-2009S1015505		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Gait Disturbance; Osteoporosis; Tremor	Lexapro			S	Oral			Alphapharm
	Metoprolol Tartrate			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2010	7572302	DIRECT	N	RI			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Activity; Dyspepsia; Fear; Feeling Abnormal; Hypophagia; Insomnia; Malaise; Suicidal Ideation; Unevaluable Event	Lexapro			S		10mg 1 Dose		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2010	7527076	EXPEDITED (15-DAY)	Y	HO, OT	1000015135		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Body Temperature Fluctuation; Caesarean Section; Hyperreflexia; Maternal Drugs Affecting	Escitalopram Oxalate			S	Transplacental	30 Mg (30 Mg, 1 In 1 D), Transplacental; 30 Mg (30 Mg, 1 In 1 D), Transmammary		Not Reported

Foetus; Maternal Exposure During Breast Feeding; Respiratory Disorder; Restlessness; Sleep Disorder; Tremor; Vomiting	Seroquel		S	Transplacental	600 Mg (600 Mg, 1 In 1 D), Transplacental; 600 Mg (600 Mg, 1 In 1 D), Transmammary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2010	7567621	EXPEDITED (15-DAY)	Y	OT	IN-TYCO HEALTHCARE/MALLIN CKRODT-T201001847		46 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Interaction; Galactorrhoea; Intracranial Mass; Sleep Disorder	Tofranil-Pm			S		75 Mg, Qd		Tyco
	Escitalopram Oxalate			S		20 Mg, Qd	365 DAY	Not Reported
	Glibenclamide			S		5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2010	7567867	EXPEDITED (15-DAY)	Y	HO	FR-SOLVAY-00310005089		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Creon			S	Oral	Daily Dose: Unknown		Not Reported
	Humalog			S	Subcutaneous	Daily Dose: 64 International Unit(S)		Not Reported
	Acetaminophen			S	Oral	Daily Dose: 3 Gram(S)		Not Reported
	Sulpiride			S	Oral	Daily Dose: 100 Milligram(S)		Not Reported
	Escitalopram Oxalate			S	Oral	Daily Dose: 20 Milligram(S)		Not Reported
	Propranolol			S	Oral	Daily Dose: 80 Milligram(S)		Not Reported
	Nexium			S	Oral	Daily Dose: 40 Milligram(S)		Not Reported
	Topiramate			S	Oral	Daily Dose: 100 Milligram(S)		Not Reported

	Crestor	S	Oral	Daily Dose: 10 Milligram(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2010	7579043	EXPEDITED (15-DAY)	N	HO	1000015932		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Normal Pressure Hydrocephalus; Productive Cough	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D) Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2010	7580429	EXPEDITED (15-DAY)	Y	HO, LT	1000015964		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Hyperhidrosis; Hyperkalaemia; Hypertension; Psychotic Disorder; Pyrexia; Renal Failure; Rhabdomyolysis; Tachycardia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Azilect			S	Oral	1 Mg (1 Mg, 1 In 1 D), Oral		Not Reported
	Ultracet			S	Oral	300 Mg (75 Mg, 4 In 1 D), Oral		Not Reported
	Duragesic			S	Other	4.1667 Mcg (12.5 Mcg, 1 In 3 D), Other		Not Reported
	Stalevo			S	Oral	500 Mg (100 Mg, 5 In 1 D), Oral		Not Reported
	Celebrex			C				Not Reported
	Imovane (Tablets)			C				Not Reported
	Sinemet			C				Not Reported
	Calciferol (Tablets)			C				Not Reported
	Ocuvite Lutein			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2010	7580539	EXPEDITED (15-DAY)	Y	OT	1000015134		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Caesarean Section; Maternal Exposure During Pregnancy; Off Label Use; Overdose; Pregnancy	Escitalopram Oxalate		S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral	Not Reported
	Seroquel		S	Oral	600 Mg (600 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2010	7570156	EXPEDITED (15-DAY)	Y	DE	GXKR2010GB09585		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Temazepam			S	Oral	Unk	1 DAY	Novartis
	Ibuprofen			S	Oral	Unk	1 DAY	Not Reported
	Alcohol			S	Oral	Unk	1 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg/Day		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg/Day	7 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	22 X 10 Mg Tablets (220 Mg)	1 DAY	Not Reported
	Fluoxetine			S	Oral	Unk	1 DAY	Not Reported
	Nortriptyline Hydrochloride			S	Oral	Unk	1 DAY	Not Reported
	Oxazepam			S	Oral	Unk	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2010	7582829	EXPEDITED (15-DAY)	N	OT	1000015941		48 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agoraphobia; Anxiety; Depressed Mood; Dizziness; Dry Mouth; Eating Disorder; Insomnia; Loss Of Libido; Malaise; Multiple Injuries; Muscle Spasms; Muscle Twitching; Suicidal Ideation; Suicide Attempt; Tremor; Withdrawal	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
					Oral	5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral		
	Amoxicillin			C				Not Reported
	Neoclarityn			C				Not Reported

Syndrome	Thiamine	C	Not Reported
	Acamprosate Calcium	C	Not Reported
	Disulfiram	C	Not Reported
	Clonazepam	C	Not Reported
	Mirtazapine	C	Not Reported
	Buspirone	C	Not Reported
	Trazodone Hydrochloride	C	Not Reported
	Valium	C	Not Reported
	Sleeping Tablet (Tablets)	C	Not Reported
	Amitriptyline	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2010	7597462	EXPEDITED (15-DAY)	Y	HO	1000015894		64 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Haemorrhage	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin Lysine			S	Oral	Oral		Not Reported
	Victoza			S	Subcutaneous	2000 Iu Internation Units (1000 Iu,2 In 1 D), Subcutaneous		Not Reported
	Allopurinol			C				Not Reported
	Simvastatin			C				Not Reported
	Lercanidipine			C				Not Reported
	Coaprovel			C				Not Reported
	Glucor			C				Not Reported
	Januvia			C				Not Reported
	Competact			C				Not Reported
	Glucophage			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2010	7491654	EXPEDITED (15-DAY)	Y	DE, OT	US-ABBOTT-10P-163-0657612-00		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Mania	Vicodin			S		Unknown		Not Reported
	Vicodin			S		Accidental Overdose:		Not Reported

				Unknown Dose	
Lexapro	S	Oral			Not Reported
Lexapro	S	Oral			Not Reported
Lexapro	S	Oral			Not Reported
Lexapro	S	Oral		Accidental Overdose: Unknown Dose	Not Reported
Seroquel	S	Oral			Not Reported
Seroquel	S	Oral		Accidental Overdose: Unknown Dose	Not Reported
Seroquel	S				Not Reported
Xanax	S			Unknown	Not Reported
Xanax	S			Accidental Overdose: Unknown Dose	Not Reported
Alcohol	S	Oral			Not Reported
Trazodone Hydrochloride	C				Not Reported
Ultram	C	Oral			Not Reported
Imitrex	C	Oral			Not Reported
Skelaxin	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2010	7548976	EXPEDITED (15-DAY)	Y	OT	FR-WATSON-2010-10844		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Fentanyl Patch			S	Respiratory (inhalation)	200 U/G, Per Puff		Watson
	Oxycodone Hydrochloride			S	Oral	120 Mg, Daily	183 DAY	Watson
	Escitalopram Oxalate			S	Unknown	5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2010	7576023	DIRECT	Y	OT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Anorgasmia; Atrial Fibrillation; Erectile Dysfunction; Restlessness; Tachycardia; Ventricular Extrasystoles	Lexapro		S	Oral	10 Mg Qd Po	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2010	7581902	EXPEDITED (15-DAY)	Y	OT	1000015929			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Serotonin Syndrome	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2010	7410072	NON-EXPEDITED	N		A0858789A		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Appetite; Weight Increased	Lamictal			S	Unknown			Glaxosmithkline
	Wellbutrin			S	Unknown			Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Ambien			S	Unknown			Not Reported
	Klonopin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2010	7580227	DIRECT	N	DE			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Weight Increased	Seroquel			S				Not Reported
	Lexapro			S				Not Reported
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2010	7583863	EXPEDITED (15-DAY)	Y	DE	2010MA002217		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose; Toxicity To Various Agents	Fluoxetine			S	Oral	Po		Alphapharm
	Ibuprofen			S	Oral	Po		Alphapharm
	Oxazepam			S	Oral	Po		Purepac
	Temazepam			S	Oral	Po		Purepac
	Cipralex			S	Oral	220 Mg; Po		Not Reported
	Alcohol (Ethanol)			S	Oral	Po		Not Reported
	Prozac			S				Not Reported
	Cipralex			S	Oral	Po		Not Reported
	Nortriptyline Hydrochloride			S	Oral	Po		Not Reported
	Cipralex			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2010	7585844	EXPEDITED (15-DAY)	Y	HO	1000015407		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Suicidal Ideation	Escitalopram Oxalate			S	Oral	100 Mg (10 Mg, 1 In 1 D) Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2010	7585850	EXPEDITED (15-DAY)	Y	DE, HO	1000015449		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drowning; Intentional Overdose; Road Traffic Accident	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D) Oral		Not Reported
	Unspecified Ingredient			S				Not Reported
	Agomelatine			S		25 Mg (25 Mg, 1 In 1 D)		Not Reported
	Rivotril (Tablets)			C				Not Reported

	Inexium	C		Not Reported
	Sectral	C		Not Reported
	Refresch Collyre (Eye Drops)	C		Not Reported
	Levothyrox	C		Not Reported
	Pravastatin	C		Not Reported
	Lysanxia	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2010	7504275	EXPEDITED (15-DAY)		HO	1000014950		62 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment; Psychotic Disorder; Salivary Hypersecretion; Somnolence; Tremor	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Omeprazole			C				Not Reported
	Octreotide			C				Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2010	7574534	NON-EXPEDITED	N		A0865079A		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyperhidrosis; Nausea; Vomiting	Requip			S	Oral			Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day	6 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2010	7575061	EXPEDITED (15-DAY)	Y	DE	FR-SANOFI-AVENTIS-2010SA051069		27 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Intentional Overdose	Stilnox			S	Oral			Not Reported
	Cyamemazine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

	Diclofenac Sodium		C	Unknown		Not Reported
	Ventolin		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2010	7575166	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20100807875		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Pancreatitis Relapsing	Topiramate			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Ultracet			S	Unknown			Not Reported
	Tramadol Hydrochloride And Acetaminophen			S	Unknown			Not Reported
	Crestor			S				Not Reported
	Inexium			S				Not Reported
	Perfalgan			S	Unknown			Not Reported
	Humalog			S	Unknown			Not Reported
	Acetaminophen			S				Not Reported
	Sulpiride			S	Unknown			Not Reported
	Creon			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Propranolol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2010	7575310	EXPEDITED (15-DAY)	Y	OT	US-ASTRAZENECA-2010SE40565		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hand Fracture; Road Traffic Accident; Sleep-Related Eating Disorder; Somnambulism	Seroquel			S	Oral			Zeneca
	Ambien			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2010	7575635	EXPEDITED (15-DAY)	N	HO, OT	CH-BRISTOL-MYERS SQUIBB COMPANY-15266760		37 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Electrocardiogram Qt Prolonged; Mood Altered	Abilify			S	Oral	Also 15mg/Day,Dosage Interrupted:21apr10		Not Reported
	Prazine (Promazine Hydrochloride)			S	Oral		14 DAY	Not Reported
	Haldol			S			19 DAY	Not Reported
	Haldol			S			19 DAY	Not Reported
	Risperdal			S	Oral	Therapy Dates:22apr10:23apr10,25 apr10:28apr10		Not Reported
	Risperdal			S	Oral	Therapy Dates:22apr10:23apr10,25 apr10:28apr10		Not Reported
	Cipralex			S	Oral			Not Reported
	Stilnox			C	Oral			Not Reported
	Rivotril			C	Oral			Not Reported
	Clothiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2010	7588744	EXPEDITED (15-DAY)	Y	HO	1000016044		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2010	8539218	EXPEDITED (15-DAY)	Y	HO	1000015993		92 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Haemorrhagic Disorder	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Arixtra		S	Subcutaneous	2.5 Mg / 0.5 Ml (1 Dosage Forms), Subcutaneous	Not Reported
	Lasix		C			Not Reported
	Aldactone		C			Not Reported
	Rivotril		C			Not Reported
	Bisoprolol Fumarate		C			Not Reported
	Fosavance		C			Not Reported
	Perindopril Erbumine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2010	6837154	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2008CG01763		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Atacand			S	Oral			Not Reported
	Vastarel			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Effexor			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2010	7537676	EXPEDITED (15-DAY)	Y	HO	1000015323		89 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Osmolarity Decreased; Fall; General Physical Health Deterioration; Hyponatraemia; Psychomotor Retardation	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Lasix			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Inexium			C				Not Reported
	Cordarone			C				Not Reported
	Kardegic			C				Not Reported
	Equanil			C				Not Reported
	Atacand			C				Not Reported

	Pariet	C		Not Reported
	Amlodipine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2010	7566161	EXPEDITED (15-DAY)	Y	DE, HO	1000015589		42 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Completed Suicide; Psychotic Disorder	Escitalopram Oxalate			S	Oral Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Buspar			C				Not Reported
	Risperdal			C				Not Reported
	Spasmag			C				Not Reported
	Uvedose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2010	7570210	EXPEDITED (15-DAY)	N	HO, OT	B0666777A		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Agitation; Asthenia; Decreased Appetite; Depression; Drug Ineffective; Feeling Guilty; Insomnia; Maternal Exposure During Pregnancy; Suicidal Ideation	Paroxetine Hydrochloride			S	Unknown	20mg Per Day		Glaxosmithkline
	Escitalopram Oxalate			S	Unknown	10mg Per Day		Not Reported
	Oxcarbazepine			S	Oral	1tab Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2010	7596988	EXPEDITED (15-DAY)	Y	OT	1000016041		40 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Mental Disorder	Escitalopram Oxalate		S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2010	7571401	EXPEDITED (15-DAY)	N	HO	B0671076A		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Contraindication To Medical Treatment; Haemorrhage; Incorrect Product Administration Duration; Overdose	Arixtra			S	Subcutaneous	2.5mg Per Day	62 DAY	Glaxosmithkline
	Escitalopram Oxalate			S	Oral	10mg Per Day		Unknown
	Lasix			C	Oral	20mg Per Day		Glaxosmithkline
	Aldactone			C	Oral	12.5mg Per Day		Glaxosmithkline
	Rivotril			C	Oral	3drop As Required		Not Reported
	Bisoprolol Fumarate			C	Oral	1.25mg Per Day		Not Reported
	Fosavance			C	Oral	70mg Weekly		Not Reported
	Perindopril Erbumine			C	Oral	2mg Single Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2010	7572170	EXPEDITED (15-DAY)	Y	OT	1000015808		69 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cerebral Haemorrhage	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2010	7578662	EXPEDITED (15-DAY)	Y	OT	US-WYE-H04065608		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Protonix			S		Unknown		Wyeth
	Lexapro			S	Oral			Lundbeck
	Lexapro			S				Lundbeck
	Clonazepam			S		0.5 Mg Prn		Unknown

	Hydrochlorothiazide	C	Unknown		Unknown
	Labetalol	C	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2010	7585851	EXPEDITED (15-DAY)	Y	OT	1000015972		74 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Erectile Dysfunction; Paraesthesia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Pravastatin			C				Not Reported
	Vastarel			C				Not Reported
	Atarax			C				Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2010	7602329	EXPEDITED (15-DAY)	Y	HO	1000016064		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dyskinesia; Fatigue; Sleep Disorder	Escitalopram Oxalate			S	Oral	5 To 15 Mg Per Day (1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2010	7540965	EXPEDITED (15-DAY)	Y		1000015295		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Disorder; Metastases To Stomach; Nausea; Ovarian Neoplasm	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2010	7579254	NON-EXPEDITED	N		US-WYE-H07957709		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dyspepsia; Middle Insomnia	Pristiq Extended Release			S	Oral	Unknown	15 DAY	Wyeth
	Lunesta			S	Oral	3-4.5 Mg		Sunovion
	Lexapro			S	Oral	Unknown	15 DAY	Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2010	7579395	NON-EXPEDITED	N		US-WYE-H08251709		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Dizziness; Headache; Nasopharyngitis; Panic Attack; Tremor; Weight Decreased	Pristiq Extended Release			S	Oral			Wyeth
	Pristiq Extended Release			S				Wyeth
	Lexapro			S	Unknown	Unspecified		Lundbeck
	Xanax			C				Not Reported
	Insulin Nos			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2010	7579512	NON-EXPEDITED	N		US-WYE-H08528409		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fatigue; Insomnia; Irritability	Pristiq Extended Release			S	Oral			Wyeth
	Lexapro			S				Lundbeck
	Lexapro			S			3 DAY	Lundbeck
	Trazodone Hydrochloride			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2010	7579557	NON-EXPEDITED	N		US-WYE-H08654109		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Feeling Jittery; Myalgia; Palpitations	Pristiq Extended Release	S	Oral		Wyeth
	Lexapro	S			Lundbeck
	Vitamin B3	C			Wyeth
	Acetylsalicylic Acid	C			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2010	7579773	NON-EXPEDITED	Y		US-WYE-H08744109		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Feeling Of Body Temperature Change; Hot Flush; Hyperhidrosis; Middle Insomnia; Nausea; Sleep Disorder	Pristiq Extended Release			S	Oral			Wyeth
	Lexapro			S				Lundbeck
	Lexapro			S			1 WEEK	Lundbeck
	Toprol Xl			C				Astrazeneca
	Tamoxifen Citrate			C				Unknown
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2010	7580045	NON-EXPEDITED	N		US-WYE-H08917509		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Nausea; Uterine Pain	Lybrel			S	Oral		15 DAY	Wyeth
	Lexapro			S	Unknown	Unknown	8 DAY	Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2010	7580653	EXPEDITED (15-DAY)	N	OT	A0880541A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Feeling Abnormal; Joint Lock; Serotonin Syndrome	Wellbutrin			S	Unknown			Glaxosmithkline
	Zoloft			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2010	7587843	DIRECT					50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Amnesia; Loss Of Consciousness	Lexapro			S		5 Mg Once/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2010	7594334	DIRECT	N	RI			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cognitive Disorder	Lexapro			S	Oral	10mg Daily Po	5 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2010	7605115	EXPEDITED (15-DAY)	N	OT	1000016048			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Diarrhoea; General Physical Health Deterioration; Tremor	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2010	7582624	EXPEDITED (15-DAY)	Y	OT	1000015962		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Torticollis	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2010	7582912	EXPEDITED (15-DAY)	N	OT	IT-BRISTOL-MYERS SQUIBB COMPANY-15277841		78 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; International Normalised Ratio Increased	Coumadin			S		Interrupted On 18aug2010 Stopped Taking Coumadin For 1 Day Then Reduced		Bristol Myers Squibb
	Cipralex			S	Oral	Film Coated Oral Tabs		Not Reported
	Omeprazole			C	Oral	Dosage:20 Mg Modified Release Oral Caps		Not Reported
	Nebivolol			C	Oral	5mg Tabs		Not Reported
	Hydrochlorothiazide\Olmesartan Medoxomil			C	Oral	Dosage:20mg/25mg Film Coated Oral Tabs		Not Reported
	Alprazolam			C	Oral	Dosage:0.75mg/Ml Oral Drops		Not Reported
	Simvastatin			C	Oral	Dosage:20 Mg Film Coated Oral Tabs		Not Reported
	Glyburide			C	Oral	Dosage:400mg + 2.5mg Film Coated Oral Tabs.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2010	7603795	EXPEDITED (15-DAY)	Y	OT	1000016106			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis	Escitalopram Oxalate			S		10 Mg (10 Mg , 1 In 1 D)	2 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2010	7603806	EXPEDITED (15-DAY)	Y	LT	1000016091		67 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition; Gun Shot Wound; Suicide Attempt	Escitalopram Oxalate			S				Not Reported
	Simvastatin			C				Not Reported
	Plavix			C				Not Reported
	Lysanxia			C				Not Reported
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2010	7605042	EXPEDITED (15-DAY)	Y	OT	1000016072		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hand Fracture; Road Traffic Accident; Sleep-Related Eating Disorder; Somnambulism	Lexapro			S				Not Reported
	Zolpidem			S				Not Reported
	Seroquel			S				Not Reported
	Thyroid Medication Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2010	7544243	NON-EXPEDITED	N	OT	US-PFIZER INC-2010100615			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anxiety; Loss Of Personal Independence In Daily Activities; Sedation	Sertraline Hydrochloride			S	Oral	12.5 Mg, Unk	3 DAY	Pfizer
	Prozac			S		Unk		Not Reported
	Wellbutrin			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Paxil			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	Unk		Not Reported
	Elavil			S		Unk		Not Reported
	Remeron			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2010	7580914	EXPEDITED (15-DAY)	Y	HO	IDA-00417		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Headache; Pancreatitis Acute	Inexium (Esomeprazole Magnesium)			S	Oral	40 Mg Daily Oral	3 DAY	Not Reported
	Crestor			S	Oral	10 Mg Daily Oral		Not Reported
	Topiramate			S	Oral	50 Mg Bid Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Daily Oral		Not Reported

	Creon	S	Oral	12000 Iu Oral		Not Reported
	Sulpiride	S	Oral	50 Mg Bid Oral	3 DAY	Not Reported
	Acetaminophen	S	Oral	1 G Tid Oral		Not Reported
	Humalog	S	Subcutaneous	32 Iu Bid Subcutaneous		Not Reported
	Propranolol	C	Oral	40 Mg Bid Oral		Not Reported
	Tramadol Hydrochloride	C				Not Reported
	Tramadol Hydrochloride And Acetaminophen	C				Not Reported
	Perfalgan	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2010	7583732	EXPEDITED (15-DAY)	N	OT	US-JNJCH-2010020550			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rash	Zyrtec			S	Oral	Text:Unknown		Not Reported
	Diphenhydramine			S	Unknown	Text:Unknown		Not Reported
	Folic Acid			S	Unknown	Text:Unknown		Not Reported
	Atenolol			S	Unknown	Text:Unknown		Not Reported
	Tramadol			S	Unknown	Text:Unknown		Not Reported
	Digoxin			S	Unknown	Text:Unknown		Not Reported
	Norvir			S	Oral	Text:Unknown		Not Reported
	Ferrous Sulfate			S	Unknown	Text:Unknown		Not Reported
	Loperamide			S	Unknown	Text:Unknown		Not Reported
	Atrovent			S	Unknown	Text:Unknown		Not Reported
	Cozaar			S	Oral	Text:Unknown		Not Reported
	Lexapro			S	Oral	Text:Unknown		Not Reported
	Epogen			S	Unknown	Text:Unknown		Not Reported
	Abilify			S	Unknown	Text:Unknown		Not Reported
	Carvedilol			S	Unknown	Text:Unknown		Not Reported
	Seroquel			S	Unknown	Text:Unknown		Not Reported
	Feldene			S	Unknown	Text:Unknown		Not Reported

	Gabapentin		S	Unknown	Text:Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2010	7583992	EXPEDITED (15-DAY)	Y	HO	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2010-FF-00		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compulsions; Obsessive-Compulsive Disorder	Pramipexole Dihydrochloride			S	Oral	3.15 Mg		Boehringer Ingelheim
	Modopar			S	Oral	2000 Mg		Not Reported
	Azilect			S	Oral	1 Mg		Not Reported
	Comtan			S	Oral	1200 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2010	7584389	NON-EXPEDITED	Y	OT	US-PFIZER INC-2009290029		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hostility; Suicidal Ideation	Lyrica			S		Unk		Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Wellbutrin			S	Oral	150mg Am And 100mg Pm, 2x/Day		Not Reported
	Lunesta			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2010	7584813	NON-EXPEDITED	Y		US-PFIZER INC-2009308963		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Lyrica			S		75, Twice Daily		Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2010	7585725	NON-EXPEDITED	N		US-PFIZER INC-2010087665			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Weight Increased	Lyrica			S		50 Mg, In The Evening		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2010	7586089	EXPEDITED (15-DAY)	Y	DE, OT	US-WYE-H07130808		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Circulatory Collapse; Knee Operation	Ibuprofen			S	Unknown	Unknown		Wyeth
	Zyrtec			S	Unknown	Unknown		Not Reported
	Lipitor			S	Unknown	Unknown		Not Reported
	Oxcarbazepine			S	Unknown	Unknown		Unknown
	Geodon			S	Unknown	Unknown		Pfizer
	Escitalopram Oxalate			S	Unknown	Unknown		Unknown
	Lansoprazole			C				Unknown
	Lorazepam			C				Wyeth
	Metoprolol			C				Unknown
	Zolpidem			C				Unknown
	Methylphenidate			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2010	7606333	EXPEDITED (15-DAY)	Y	OT	1000016104		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychiatric Evaluation Abnormal	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2010	7586966	EXPEDITED (15-DAY)	Y	OT	GB-ASTRAZENECA-2010SE41875		69 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Omeprazole			S	Oral	20 Mg		Not Reported
	Cipralex			S		1/1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2010	7588535	NON-EXPEDITED	Y		US-WYE-H10542509			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Paraesthesia; Paraesthesia Oral	Pristiq Extended Release			S	Oral		5 DAY	Wyeth
	Lexapro			S		Weaned Off		Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2010	7607619	EXPEDITED (15-DAY)	Y	OT	1000016174		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Trophoblastic Detachment; Maternal Drugs Affecting Foetus; Metrorrhagia; Pregnancy	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7582629	EXPEDITED (15-DAY)	Y	OT	1000015897		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depressive Symptom	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1		

							D), Oral			
	Xanax			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7589732	EXPEDITED (15-DAY)	Y	OT	GB-MYLANLABS-2010S1016318		69 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Omeprazole			S				Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7589829	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-10P-163-0670468-00		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Nodule	Humira			S				Not Reported
	Lexapro			S				Not Reported
	Ambien Cr			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Flaxseed Oil			C				Not Reported
	Vitamin D2			C				Not Reported
	Lactobacillus Acidophilus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7589867	EXPEDITED (15-DAY)	N	HO, OT	GB-WATSON-2010-12182		69 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Intracranial Aneurysm	Omeprazole			S		Unk		Watson
	Cipralex			S		10 Mg, Daily X16 Days, Then5 Mg Daily For 14 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7602858	EXPEDITED (15-DAY)	Y	OT	1000016045		< 1 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradypnoea; Drug Withdrawal Syndrome	Escitalopram Oxalate		S	Transplacental	10 Mg 910 Mg, 1 In 1 D), Transplacental	Not Reported
Neonatal; Hypotonia Neonatal; Maternal Drugs Affecting Foetus	Invega		S	Transplacental	9 Mg, Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7610085	EXPEDITED (15-DAY)	Y	OT	1000015674			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Movement Disorder	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7610103	EXPEDITED (15-DAY)	N	CA	1000016171		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anomalous Pulmonary Venous Connection; Atrial Septal Defect; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7610112	EXPEDITED (15-DAY)	Y	OT	1000016209			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Gait Disturbance; Movement Disorder	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7610116	EXPEDITED (15-DAY)	Y	OT	1000016210			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Gait Disturbance; Movement Disorder	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7611138	EXPEDITED (15-DAY)	Y	OT	1000016215			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Gait Disturbance; Movement Disorder	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7611139	EXPEDITED (15-DAY)	Y	OT	1000016213			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Gait Disturbance; Movement Disorder	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7611147	EXPEDITED (15-DAY)	Y	DE, HO	1000016169		90 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Decreased; Blood Urea Increased; Bradycardia; Coma; Drug Interaction; Extrapyramidal Disorder; Fall; Inflammation; Monocyte Count Increased; Neutrophil Count Increased; Subdural Haematoma; Wound	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Lovenox			S	Subcutaneous	4000 Iu (4000 Iu, 1 In 1 D), Subcutaneous		Not Reported
	Avlocardyl (Propranolol) (Tablets) (Propranolol)			C				Not Reported
	Aricept (Donepezil) (Tablets) (Donepezil)			C				Not Reported
	Seresta (Oxazepam) (Tablets) (Oxazepam)			C				Not Reported
	Cetornan (Ornithine Ketoglutarate) (Powder) (Ornithine Ketoglutarate)			C				Not Reported
	Forlax (Macrogol) (Powder) (Macrogol)			C				Not Reported

	Diffu K (Potassium Chloride) (Potassium Chloride)	C		Not Reported
	Diafusor (Glyceryl Trinitrate) (Glyceryl Trinitrate)	C		Not Reported
	Doliprane (Paracetamol) (Paracetamol)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2010	7655868	NON-EXPEDITED	N	HO	DKLU1063423		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Sabril			S				Not Reported
	Lexapro			S				Not Reported
	Keppra			S				Not Reported
	Lamictal			S				Not Reported
	Clonazepam			S				Not Reported
	Mebendazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2010	7418971	EXPEDITED (15-DAY)	Y	HO	1000014190			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Induratum; Eye Disorder; Eye Swelling; Skin Plaque	Escitalopram Oxalate			S	Oral	20 Mg 920 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2010	7491510	EXPEDITED (15-DAY)	Y	HO, OT	1000014890		76 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Mood Altered; Suicide Attempt	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Unspecified Ingredient			S		Unknown Amount		Not Reported
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Glucophage			C				Not Reported
	Triatec (Ramipril)			C				Not Reported

	Lyrica			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2010	7546188	EXPEDITED (15-DAY)	Y	OT	1000015448		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Fibrinogen Decreased; Epistaxis; Gastrointestinal Haemorrhage; Haematoma; Thrombocytopenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2010	7587747	EXPEDITED (15-DAY)	Y	HO, OT	1000016024		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Amnesia; Ataxia; Somnolence	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2010	7590472	EXPEDITED (15-DAY)	Y	HO, OT	PHHY2010FR60652		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compulsions; Depression; Obsessive Thoughts; Obsessive-Compulsive Disorder	Comtan			S		1200 Mg, Qd		Orion
	Modopar			S		2000 Mg, Qd		Not Reported
	Pramipexole Dihydrochloride			S		3.5 Mg, Qd		Not Reported
	Azilect			S		1 Mg Per Os At 1 Tablet Daily		Not Reported
	Escitalopram Oxalate			S		Once Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2010	7590815	EXPEDITED (15-DAY)	Y	HO	IT-ASTRAZENECA-2010SE42180		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Electrocardiogram Qt Prolonged; Somnolence	Seroquel			S	Oral		11 DAY	Zeneca
	Escitalopram Oxalate			S	Oral		11 DAY	Not Reported
	Amisulpride			S	Oral		2038 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2010	7592048	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2010-BP-10		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Hyperhidrosis; Musculoskeletal Stiffness	Mobic			S	Oral			Boehringer Ingelheim
	Lexapro			S	Oral	10 Mg		Not Reported
	Lexapro			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2010	7612531	EXPEDITED (15-DAY)	N	DE	1000016234		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Overdose; Toxicity To Various Agents	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2010	7593546	NON-EXPEDITED	N		US-WYE-H10763509		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Headache; Hyperhidrosis	Pristiq Extended Release			S	Oral		6 DAY	Wyeth
	Pristiq Extended Release			S				Wyeth
	Lexapro			S				Lundbeck
	Ramipril			C				Unknown
	Cholestyramine			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2010	7594139	NON-EXPEDITED	N		US-WYE-H12141709		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Withdrawal Syndrome; Feeling Hot; Insomnia; Pain In Extremity; Palpitations	Pristiq Extended Release			S	Oral		15 DAY	Wyeth
	Pristiq Extended Release			S	Oral		2 DAY	Wyeth
	Lexapro			S		Unknown	6 WEEK	Lundbeck
	Lexapro			S		"1/2" Amt Unknown	2 DAY	Lundbeck
	Diovan			S		Unknown		Novartis
	Diazepam			S		Unknown		Unknown
	Lipitor			S		Unknown		Not Reported
	Tramadol			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7595249	NON-EXPEDITED	N	OT	US-ASTRAZENECA-2009SE29840			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Constipation; Decreased Appetite; Diarrhoea; Drug Ineffective; Dry Mouth; Dyskinesia; Muscle Twitching; Nightmare; Suicide Attempt; Therapeutic Product Effect Decreased; Tremor	Seroquel			S	Oral			Zeneca
	Zoloft			S				Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Doxepin Hydrochloride			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Pristiq Extended Release			S	Oral			Not Reported
	Effexor Xr			S	Oral			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Lexapro			S				Not Reported
	Paroxetine Hydrochloride			S				Not Reported
	Cymbalta			S				Not Reported
	Paxil			S				Not Reported
	Prozac			S				Not Reported

	Depakote	S	Unknown		Not Reported
	Vitamins	C			Not Reported
	Fish Oil	C			Not Reported
	Imodium	C			Not Reported
	Kaolin\Pectin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7595259	NON-EXPEDITED	Y	HO	US-ASTRAZENECA-2010SE33313			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Seroquel			S	Oral			Zeneca
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7596456	EXPEDITED (15-DAY)	Y	LT	DE-JNJFOC-20100903271		78 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Syncope; Tachycardia	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Aricept			S	Oral			Not Reported
	Aricept			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7597105	EXPEDITED (15-DAY)	Y	HO	US-ROCHE-727275		83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Speech Disorder	Bevacizumab			S	Intravenous (not otherwise specified)	Last Dose Prior Sae: 26 August 2010		Roche
	Erlotinib Hydrochloride			S	Unknown			Roche
	Cardura			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

Dulcolax (Bisacodyl)	S	Unknown			Not Reported
Ibuprofen	S	Unknown			Not Reported
Novolog	S	Unknown	Reported As Novalog		Not Reported
Salmeterol	S	Unknown			Not Reported
Simvastatin	S	Unknown			Not Reported
Tylenol	S	Unknown			Not Reported
Zofran	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7597425	EXPEDITED (15-DAY)	N	DE, HO	B0675157A		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melaena; Multiple Organ Dysfunction Syndrome; Septic Shock; Toxic Skin Eruption; Urticaria	Isradipine			S	Oral			Glaxosmithkline
	Diffu K			S	Oral			Glaxosmithkline
	Previscan (Fluindione)			S	Oral	5mg At Night	2 DAY	Not Reported
	Urbanyl			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	5mg Twice Per Day		Not Reported
	Unspecified Ingredient			S	Oral	50mg Twice Per Day		Not Reported
	Kardegic			C				Not Reported
	Fucidin (Fusidate Sodium)			C				Not Reported
	Xyzal			C				Glaxosmithkline
	Atarax			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7597996	NON-EXPEDITED	Y	OT	US-TEVA-248234USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Azilect			S	Oral			Teva
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7598134	NON-EXPEDITED			US-ASTRAZENECA-2010SE14712		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Gastrooesophageal Reflux Disease; Weight Increased	Seroquel Xr			S	Oral			Astrazeneca
	Seroquel Xr			S	Oral			Astrazeneca
	Seroquel Xr			S	Oral			Astrazeneca
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7598774	NON-EXPEDITED	N		US-WYE-H12886310		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Insomnia; Palpitations	Pristiq Extended Release			S	Oral			Wyeth
	Lexapro			S	Oral			Lundbeck
	Lexapro			S	Oral			Lundbeck
	Clonazepam			C				Unknown
	Ambien Cr			C				Sanofi Aventis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7598976	NON-EXPEDITED	N		US-WYE-H13405510		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching	Pristiq Extended Release			S	Oral			Wyeth
	Lexapro			S		"Tapering Off"		Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7615655	EXPEDITED (15-DAY)	Y	OT	GB-DEXPHARM-20101450		69 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Increased; Cerebral Haemorrhage; Intracranial Aneurysm	Omeprazole		S	20 Mg Milligram(S)	Not Reported
	Cipralex		S	10 Mg Milligram(S) Sep Dosages/Interval: 1 In 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7616215	EXPEDITED (15-DAY)	N	OT	1000016217		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contusion; Fatigue; Headache; Hyperhidrosis; Hypersomnia; Libido Decreased; Social Anxiety Disorder; Yawning	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2010	7617216	EXPEDITED (15-DAY)	Y	HO	1000016230		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compulsions; Obsessive-Compulsive Disorder	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Rasagiline Mesylate			S	Oral	1 Mg (1 Mg, 1 In 1 D), Oral		Not Reported
	Benserazide\Levodopa			S	Oral	2000 Mg (250 Mg, 8 In 1 D), Oral		Not Reported
	Pramipexole Dihydrochloride			S	Oral	3.15 Mg (3.15 Mg, 1 In 1 D), Oral		Not Reported
	Comtan			S		1200 Mg (200 Mg, 6 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2010	7369621	EXPEDITED (15-DAY)	Y	OT	1000013205		16 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Overdose; Suicidal Ideation	Escitalopram Oxalate	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral	Not Reported
			Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral	
	Alprazolam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2010	7536475	EXPEDITED (15-DAY)	Y	OT	1000015258		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hallucination, Auditory; Hallucination, Visual; Paranoia; Psychotic Disorder	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2010	7606584	DIRECT	Y	HO			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Fall; Hyponatraemia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2010	7609986	DIRECT	N				51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Condition Aggravated; Depression; Disturbance In Attention; Fatigue; Fear; Nausea; Nervousness; Uterine Cancer	Lexapro			S	Oral	10 Mg Once A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2010	7618383	EXPEDITED (15-DAY)	Y	OT	1000016291		17 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphemia; Off Label Use	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Depakote			C				Not Reported
	Lorazepam			C				Not Reported
	Atarax			C				Not Reported
	Sertraline Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2010	7618635	EXPEDITED (15-DAY)	Y	HO	1000016239		83 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption; Urticaria	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
	Fluindione			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Isradipine			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Urbanyl			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Docosanol			S	Oral	100 Mg (50 Mg, 2 In 1 D), Oral		Not Reported
	Potassium Chloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2010	7618637	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000016086		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Coma; Intentional Overdose; Suicide Attempt; Vomiting	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Trimipramine Maleate			S	Oral	(5000 Mg, Once), Oral		Not Reported
	Zolpidem			S	Oral	(200 Mg, Once), Oral		Not Reported

	Cocaine (Cocaine)		S	Nasal	Nasal		Not Reported
	Alcohol (Ethanol)		S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2010	7610915	DIRECT	N	RI			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Libido; Sexual Dysfunction	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2010	7619191	EXPEDITED (15-DAY)	Y	OT	1000016290		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Magnesium (Magnesium)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2010	7622817	EXPEDITED (15-DAY)	Y	OT	1000016331		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Investigation Abnormal	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2010	7469308	EXPEDITED (15-DAY)	Y	OT	1000014759			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bulimia Nervosa; Condition Aggravated;	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Fluoxetine			S				Not Reported

Epilepsy; Focal Dyscognitive Seizures	Alprazolam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2010	7522470	EXPEDITED (15-DAY)	Y	OT	1000015144		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vaginal Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2010	7605667	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010116226		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Dry Eye; Dry Mouth; Fatigue; Feeling Abnormal; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasal Dryness; Pain; Poor Quality Sleep; Pruritus; Rash; Scab; Vitamin D Decreased	Lyrica			S	Oral	75 Mg, 2x/Day		Pfizer
	Lexapro			S		Unk		Not Reported
	Pepcid			C		Unk		Not Reported
	Unspecified Ingredient			C		Unk		Not Reported
	Aciphex			C		Unk		Not Reported
	Norvasc			C		Unk		Not Reported
	Potassium			C		Unk		Not Reported
	Allegra			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2010	7622716	EXPEDITED (15-DAY)	Y	HO	1000016246		67 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatitis	Escitalopram Oxalate			S		(1 Dosage Forms)		Not Reported
	Calciparine			S	Subcutaneous	22500 Iu (7500 Iu, 3 In 1 D), Subcutaneous		Not Reported

	Colchicine		S	Oral	1 Dosage Forms 91 Dosage Forms, 1 In 1 D), Oral	Not Reported
	Polyethylene Glycols		S		(3 Dosage Forms)	Not Reported
	Normacol		S			Not Reported
	Ketoprofen		S	Oral	(2 Dosage Forms), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2010	7625327	EXPEDITED (15-DAY)	Y	OT	1000016334		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Intentional Overdose; Somnolence; Suicide Attempt	Escitalopram Oxalate			S	Oral	(200 Mg, Once), Oral		Not Reported
	Doxepin			S	Oral	(425 Mg, Once), Oral		Not Reported
	Alcohol (Ethanol)			S	Oral	(Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2010	7632840	EXPEDITED (15-DAY)	Y	HO, OT	1000016351		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Coma; Drug Interaction; Hypotension; Muscle Rigidity; Somnolence; Sopor; Tachycardia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Aricept			S	Oral	5 Mg 95 Mg, 1 In 1 D), Oral		Not Reported
	Aricept			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal			S	Oral	1 M (1 Mg, 1 In 1 D), Oral; 0.5 Mg (0.5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	1 M (1 Mg, 1 In 1 D), Oral; 0.5 Mg (0.5 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2010	7359787	EXPEDITED (15-DAY)	Y	HO	1000012903		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Gamma-Glutamyltransferase Increased; Inflammation; Myalgia; Spondylitis; Transaminases Increased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2010	7548420	EXPEDITED (15-DAY)	Y	DE	AU-ASTRAZENECA-2010SE38860		55 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Seroquel Xr			S	Oral	300-400 Mg Daily		Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2010	7613718	DIRECT	Y	HO			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia	Escitalopram			S	Oral	20 Mg Daily Po		Not Reported
	Olanzapine			S	Oral	2.5 Mg Twice Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2010	7628423	EXPEDITED (15-DAY)	Y	DE, HO	1000016374		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Herpes Zoster; Intentional Self-Injury; Nervousness; Overdose; Tongue Disorder; Trismus; Unevaluable Event	Lexapro			S		30 Mg (30 Mg,1 In 1 D)		Not Reported
	Geodon			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral ; 160 Mg (2 In 1 D),Oral		Not Reported
					Oral	20 Mg (20 Mg,1 In 1 D),Oral ; 160 Mg (2 In 1 D),Oral		

	Nortriptyline Hydrochloride	C		Not Reported
	Xanax	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2010	7580296	EXPEDITED (15-DAY)	Y	OT	1000015915		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Drug Dependence	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zimovane (Zopiclone) (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2010	7617208	DIRECT	Y	LT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Flushing; Heart Rate Increased; Hyperhidrosis; Tremor	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2010	7630462	EXPEDITED (15-DAY)	Y	HO, LT	2010AP002029		32 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Rhabdomyolysis	Citalopram Hydrobromide			S	Oral	20 Mg; Qd Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg; Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2010	7465199	EXPEDITED (15-DAY)	Y	OT	1000014719		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Muscle Contracture	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

	Minidril (Eugynon) (Eugynon)	C		Not Reported
	Levothyroxine Sodium	C		Not Reported
	Solupred (Prednisolone Sodium Metazoate)	C		Not Reported
	Panos (Tetrazepam) (Tetrazepam)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2010	7679703	NON-EXPEDITED	N		US-WYE-H15951510		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dizziness; Fatigue; Hypersomnia	Pristiq Extended Release			S				Not Reported
	Effexor Xr			S				Not Reported
	Lexapro			S				Not Reported
	Neurontin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2010	7619541	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Haldol			S	Oral	5 Mg And 0.5 Mg Q 4 Hours Prn Oral/Im, 8/27-9/1		Not Reported
	Lexapro			S		20 Mg Daily Oral, 8/26 - 8/31		Not Reported
	Wellbutrin			C				Not Reported
	Zyprexa			C				Not Reported
	Macrodantin			C				Not Reported
	Geodon			C				Not Reported
	Thorazine			C				Not Reported
	Abilify			C				Not Reported
	Synthroid			C				Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2010	7632902	EXPEDITED (15-DAY)	Y	OT	1000016478		53 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychiatric Evaluation Abnormal	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2010	7632910	EXPEDITED (15-DAY)	Y	OT	1000016468		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Incontinence	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Noiafren			C				Not Reported
	Eutirox (Levothyroxine) (Tablets) (Levothyroxine)			C				Not Reported
	Atorvastatin Calcium (Atorvastatin Calcium) (Tablets) (Atorvastatin Calcium)			C				Not Reported
	Omeprazole (Omeprazole) (Tablets) (Omeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2010	7632927	EXPEDITED (15-DAY)	Y	HO, LT	2010MA002785		32 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Rhabdomyolysis	Citalopram Hydrobromide			S	Ophthalmic	1400 Mg;X1;Po		Not Reported
	Escitalopram Oxalate			S	Oral	980 Mg;X1;Po		Not Reported
	Con Meds			C				Not Reported
	Prev Meds			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2010	7633927	DIRECT	Y	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindication To Medical Treatment;	Hyoscyamine Sulfate\Methenamine\Methylene			S				Mission

Labelled Drug-Drug Interaction Medication Error; Product Prescribing Error	Blue\Phenyl Salicylate\Sodium Phosphate, Dibasic			
	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2010	7635990	EXPEDITED (15-DAY)	Y	HO	2010003910		83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Speech Disorder; Toxicity To Various Agents	Erlotinib Hydrochloride			S	Oral	Oral		Not Reported
	Bevacizumab			S	Intravenous (not otherwise specified)	(975 Mg, Q3w), Intravenous		Not Reported
	Cardura			S				Not Reported
	Lexapro			S				Not Reported
	Dulcolax (Bisacodyl)			S				Not Reported
	Ibuprofen (Ibuprofen)			S				Not Reported
	Novolog			S				Not Reported
	Salmeterol			S				Not Reported
	Simvastatin			S				Not Reported
	Tylenol (Paracetamol)			S				Not Reported
	Zofran			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2010	7385671	EXPEDITED (15-DAY)	Y	HO, LT, OT	US-ABBOTT-06P-163-0352074-00		10 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Atrioventricular Block First Degree; Chest Pain; Conduction Disorder; Diarrhoea; Disorientation; Dizziness; Drug Interaction; Drug Level Above Therapeutic; Electrocardiogram Qrs Complex Prolonged; Hyperhidrosis; Hypophagia; Hypotension;	Lexapro			S	Oral			Not Reported
	Depakote			C	Oral	500mg In Am, 1000mg At Bedtime		Not Reported
	Synthroid			C	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lithium			S	Oral			Not Reported
	Clonidine			S	Oral			Not Reported
	Methylphenidate			S	Oral			Not Reported

Hypothyroidism; Mania; Pallor; Palpitations; Rhythm Idioventricular; Tachyarrhythmia; Toxicity To Various Agents; Ventricular Extrasystoles; Ventricular Tachycardia; Vomiting; White Blood Cell Count Increased	Oxcarbazepine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2010	7541786	EXPEDITED (15-DAY)	Y	DE, OT	US-PFIZER INC-2010099416		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Dyskinesia; Herpes Zoster; Nervousness	Geodon			S		20 Mg, Daily		Pfizer
	Geodon			S		80 Mg, 2x/Day		Pfizer
	Geodon			S				Pfizer
	Lexapro			S		30 Mg, 1x/Day	510 DAY	Not Reported
	Lexapro			S				Not Reported
	Nortriptyline			C		50 Mg, Daily		Not Reported
	Xanax			C		1 Mg Twice Daily As Needed	510 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2010	7634846	EXPEDITED (15-DAY)	Y	HO	LTI2010A00215		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy; Visual Impairment	Lansoprazole			S	Oral	30 Mg (30 Mg, 1 In 1 D) Oral Years		Not Reported
	Lexomil (Bromazepam)			S	Oral	18 Mg (6 Mg, 3 In 1 D) Oral Days		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D) Oral Days		Not Reported
	Aceprometazine\Meprobamate			S	Oral	1 Df (1 Df, 1 In 1 D) Oral		Not Reported

				Days	
	Tareg	S	Oral	160 Mg (160 Mg, 1 In 1 D) Oral Years	Not Reported
	Fenofibrate	S	Oral	200 Mg (200 Mg, 1 In 1 D) Oral Years	Not Reported
	Aspirin	S	Oral	160 Mg (160 Mg, 1 In 1 D) Oral Years	Not Reported
	Nicorandil	S	Oral	40 Mg (20 Mg, 2 In 1 D Oral Years	Not Reported
	Acebutolol Hydrochloride	S	Oral	400 Mg (200 Mg, 2 In 1 D) Oral Years	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2010	7635514	EXPEDITED (15-DAY)	Y	DS, OT	1000016466			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Hallucination, Auditory; Overdose; Personality Disorder	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2010	7635583	EXPEDITED (15-DAY)	Y	OT	1000016484		53 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Erectile Dysfunction; Haematospermia; Myalgia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2010	7637066	EXPEDITED (15-DAY)	Y	HO, LT	1000016378		32 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatine Increased; Overdose; Rhabdomyolysis	Citalopram		S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported
	Escitalopram Oxalate		S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral, (1400 Mg, Once), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2010	7652394	EXPEDITED (15-DAY)	Y	OT	1000016662			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pericardial Effusion	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2010	7636219	EXPEDITED (15-DAY)	Y	OT	1000016503			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Logorrhoea	Escitalopram Oxalate			S				Not Reported
	Temesta (Lorazepam) (Lorazepam)			C				Not Reported
	Cordarone			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2010	7617052	EXPEDITED (15-DAY)	Y	HO	FR-WYE-G06750210		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Disorientation; Thrombocytopenia	Rhinadvil			S	Oral	A Total Of 3 To 4 Tablets In 2 Days	2 DAY	Wyeth
	Budesonide			S	Respiratory (inhalation)	Unknown	2 DAY	Unknown
	Ibuprofen			S	Oral	Unknown	2 DAY	Unknown
	Cefuroxime			S	Oral	Unknown	2 DAY	Unknown
	Escitalopram Oxalate			S	Oral	Unknown		Lundbeck

Duphaston	C	Oral	Unknown		Not Reported
Paracetamol	C	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2010	7617395	EXPEDITED (15-DAY)	N	HO	US-SHIRE-SPV1-2010-01703		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Off Label Use; Tremor	Adderall Xr			S	Oral	20 Mg, 1x/Day:Qd	191 DAY	Not Reported
	Neratinib			S	Oral	240 Mg, 1x/Day:Qd		Not Reported
	Alprazolam			S	Oral	.5 Mg, As Req'D	298 DAY	Not Reported
	Diflunisal			S	Oral	500 Mg, 1x/Day:Qd	113 DAY	Not Reported
	Lexapro			S	Oral	10 Mg, 1x/Day:Qd	205 DAY	Not Reported
	Tamoxifen Citrate			C				Not Reported
	Colecalciferol			C				Not Reported
	Vitamin B12			C				Not Reported
	Valtrex			C				Not Reported
	Loratadine			C				Not Reported
	Tylenol			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2010	7528666	EXPEDITED (15-DAY)	Y	OT	1000015180		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Vitreous Detachment	Escitalopram Oxalate			S	Oral	10 Mg 910 Mg, 1 In 1 D), Oral		Not Reported
	Enaplus (Enalapril Maleate) (Enalapril Maleate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2010	7537829	EXPEDITED (15-DAY)	Y	OT	1000015300		30 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Nausea; Pain; Pharyngeal Oedema; Vomiting	Escitalopram Oxalate	S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral	Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Propavan (Propiomazine Maleate)	C			Not Reported
	Atarax (Atarax) (Atarax)	C			Not Reported
	Oxascand (Oxazepam) (Oxazepam)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2010	7603773	EXPEDITED (15-DAY)	Y	OT	1000016094		28 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S				Not Reported
	Prazepam			S	Oral	30 Mg (10 Mg, 3 In 1 D), Oral		Not Reported
					Oral	30 Mg (10 Mg, 3 In 1 D), Oral		
	Zolpidem			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2010	7652416	EXPEDITED (15-DAY)	Y	HO, OT	1000016602		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ammonia Increased; Blood Alkaline Phosphatase Increased;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

Gamma-Glutamyltransferase Increased; Transaminases Increased	Bromazepam	S	Oral	6 Df (6 Dosage Forms,1 In 1 D),Oral	Not Reported
	Acetaminophen\Propoxyphene Hydrochloride	S	Oral	6 To 10 Df Per Day,Oral	Not Reported
	Tercian (Cyamemazine) (Tablets) (Cyamemazine)	C			Not Reported
	Valium (Diazepam) (Tablets) (Diazepam)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2010	7382986	EXPEDITED (15-DAY)	Y	LT	1000013335		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depressed Mood; Diarrhoea; Fatigue; Suicidal Ideation; Vomiting; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Fluoxetine			C				Not Reported
	Ventolin (Salbutamol) (Salbutamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2010	7437149	EXPEDITED (15-DAY)	Y	OT	1000014551		53 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hyperhidrosis; Insomnia; Malaise; Nausea; Sense Of Oppression; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2010	7622345	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-10P-056-0674737-00		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy; Visual Impairment	Fenofibrate			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported

	Cipralex	S	Oral		Not Reported
	Bromazepam	S	Oral		Not Reported
	Aceprometazine Maleate\Meprobamate	S	Oral		Not Reported
	Tareg	S	Oral		Not Reported
	Aspirin	S	Oral		Not Reported
	Nicorandil	S	Oral		Not Reported
	Acebutolol Hydrochloride	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7169759	NON-EXPEDITED	Y	OT	1000006883		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Formication; Mania; Pruritus; Sleep Disorder; Suicidal Ideation; Visual Impairment	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Vitamins			C				Not Reported
	Caprylic Acid			C				Not Reported
	Hyaluronic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7170038	NON-EXPEDITED	Y	HO, OT	1000007855		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7170047	NON-EXPEDITED	N	OT	1000008091		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Antisocial Behaviour; Asthenia;	Lexapro			S	Oral Oral	See Image See Image		Not Reported

Blood Pressure Increased; Depression; Dizziness; Mental Impairment; Suicidal Ideation			Oral Oral Oral Oral	See Image See Image See Image See Image		
	Avapro	C				Not Reported
	Xanax	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7624966	EXPEDITED (15-DAY)	Y	DS, LT, OT	US-JNJFOC-20101001719		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Incoherent; Loss Of Personal Independence In Daily Activities; Product Administration Error; Product Prescribing Error; Serum Serotonin Increased; Therapeutic Product Effect Increased	Risperidone			S	Oral			Not Reported
	Imitrex			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Remeron			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Keppra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7644636	EXPEDITED (15-DAY)	Y	OT	1000016506		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor; Visual Acuity Reduced	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Citalopram			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698686	NON-EXPEDITED	N	OT	1000009842		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Suicidal Ideation	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

Lexapro	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
		Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		
Cymbalta	C				Not Reported
Vistaril	C				Not Reported
Yaz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698693	NON-EXPEDITED	Y	DE	1000008823		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698694	NON-EXPEDITED	N	DE	1000009312		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698700	NON-EXPEDITED	N	OT	1000010560		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698712	NON-EXPEDITED	Y	OT	1000010594		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression	Lexapro	S	Oral	20 Mg (20 Mg, 1 In 1), Oral		Not Reported
	Lortab	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698713	NON-EXPEDITED	Y	OT	1000010700		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698731	NON-EXPEDITED	N	OT	1000010901		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Dizziness; Hypertension; Restlessness	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		
	Hyzaar			C				Not Reported
	Toprol Xl			C				Not Reported
	Aspirin			C				Not Reported
	Cozaar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698734	NON-EXPEDITED	Y	HO	1000011009		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Albuterol			C				Not Reported

	Vistaril			C						Not Reported
	Trazodone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698736	NON-EXPEDITED	N	OT	1000011079		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698739	NON-EXPEDITED	Y	HO	1000011108		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Klonopin			S	Oral	(15 Mg, Once), Oral		Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698782	NON-EXPEDITED	Y	OT	1000011282		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 210 Mg (210 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 210 Mg (210 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698791	NON-EXPEDITED	Y	OT	1000011630		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pain In Jaw; Tardive Dyskinesia	Lexapro	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Metoclopramide	S	Oral	(3 In 1 D), Oral		Not Reported
	Spironolactone	C				Not Reported
	Diovan	C				Not Reported
	Vytorin	C				Not Reported
	Metoprolol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7698797	NON-EXPEDITED	N	OT	1000011656		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Serotonin Syndrome	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		
	Adderall			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701149	NON-EXPEDITED	Y	OT	1000014382		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Confusional State; Hallucination; Suicidal	Lexapro			S	Oral	Oral		Not Reported

Ideation	Lamictal		S	Oral	350 Mg (350 Mg, 1 In 1 D), Oral	Not Reported
	Digoxin		C			Not Reported
	Coumadin		C			Not Reported
	Vimpat		C			Not Reported
	Seroquel		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701153	NON-EXPEDITED	N	HO	1000014713		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Blood Sodium Decreased; Insomnia; Paraesthesia	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Ativan			C				Not Reported
	Detrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701154	NON-EXPEDITED	N	OT	1000014859			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sedation; Sexual Dysfunction; Suicidal Ideation; Withdrawal Syndrome	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701183	NON-EXPEDITED	Y	HO	1000014936			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Lexapro			S				Not Reported
	Seroquel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701218	NON-EXPEDITED	Y	OT	1000011725		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hot Flush; Paraesthesia; Syncope	Lexapro			S	Oral	2.5 Mg (2.5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
					Oral	2.5 Mg (2.5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral		
	Lexapro			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701219	NON-EXPEDITED	Y	OT	1000015444		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Urticaria	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Vesicare			C				Not Reported
	Simvastatin			C				Not Reported
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701221	NON-EXPEDITED	Y	OT	1000011751		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Clonazepam (0.25 Milligram, Tablets)			C				Not Reported
	Ambien Cr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701222	NON-EXPEDITED	N	OT	1000015549		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Headache; Nausea; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Fioricet			C				Not Reported
	Treximet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701224	NON-EXPEDITED	N	OT	1000011914		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Headache; Lethargy; Malaise; Mental Impairment; Restlessness; Somnolence; Suicidal Ideation	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral ; 1.25 Mg (1.25 Mg,1 In 1 D),Oral		Not Reported
					Oral	20 Mg (20 Mg,1 In 1 D),Oral ; 1.25 Mg (1.25 Mg,1 In 1 D),Oral		
	Armour Thyroid (Thyroid) (30 Milligram, Tablets) (Thyroid)			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701225	NON-EXPEDITED	Y	OT	1000011924			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701229	NON-EXPEDITED	N	OT	1000011971		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Increased Appetite; Insomnia; Panic Attack; Swollen Tongue; Visual Impairment; Weight Increased	Lexapro		S	Oral	10 Mg (10 Mg,1 In 1 D),Oral	Not Reported
	Synthroid (0.1 Milligram)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701233	NON-EXPEDITED	N	OT	1000012025		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Parkinsonism	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701236	NON-EXPEDITED	N	OT	1000012153			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Psychotic Disorder	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701238	NON-EXPEDITED	Y	OT	1000012423			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S	Oral	Oral		Not Reported
	Deplin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701251	NON-EXPEDITED	N	DE	1000012425		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701509	NON-EXPEDITED	Y	OT	1000008238			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701510	NON-EXPEDITED	Y	HO	1000008348		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701519	NON-EXPEDITED	N	OT	1000009071		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Proventil (Inhalant)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701527	NON-EXPEDITED	N	HO	1000009263		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Pancreatitis	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Advair (Inhalant)			C				Not Reported
	Albuterol (Inhalant)			C				Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701530	NON-EXPEDITED	N	OT	1000009315		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Judgement Impaired; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701552	NON-EXPEDITED	N	HO	1000009507			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akathisia; Confusional State; Dizziness; Hypomania; Overdose; Suicidal Ideation; Swelling Face	Lexapro			S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Lamictal			S	Oral	100 Mg Every Morning (100 Mg, 1 In 1 D), Oral; 200 Mg Qhs (200 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel			S	Oral	(1 In 1 D), Oral		Not Reported
	Wellbutrin			S	Oral	150 Mg (150 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal			S	Oral	1 Mg (0.5 Mg, 2 In 1 D), Oral		Not Reported
	Zyrtec-D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701554	NON-EXPEDITED	Y	OT	1000009519		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hostility; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

	Wellbutrin	S	Oral	250 Mg (2 In 1 D), Oral		Not Reported
	Lyrica	S				Not Reported
	Lunesta	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7701559	NON-EXPEDITED	Y	OT	1000009575		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lantus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7702136	NON-EXPEDITED	N	HO	1000012673		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea; Urinary Tract Infection	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax (0.25 Mmilligram, Tablets)			C				Not Reported
	Toprol (50 Milligram,Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7702166	NON-EXPEDITED	Y	HO	1000012757		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7702173	NON-EXPEDITED	N	OT	1000012939		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Extrapyramidal Disorder	Lexapro	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7702187	NON-EXPEDITED	Y	OT	1000012964		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Hypertension; Syncope	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7702195	NON-EXPEDITED	N	HO	1000013165		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Levodopa			C				Not Reported
	Carbidopa			C				Not Reported
	Ritalin			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7702221	NON-EXPEDITED	N	OT	1000013822		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Type 2 Diabetes Mellitus	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7702703	NON-EXPEDITED	Y	OT	1000014963		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Overdose; Suicide Attempt	Lexapro		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7702731	NON-EXPEDITED	Y	OT	1000014083		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7702737	NON-EXPEDITED	N	OT	1000014108		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Prevacid			C				Not Reported
	Simvastatin			C				Not Reported
	Levothyroxine			C				Not Reported
	Lunesta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7702759	NON-EXPEDITED	N	HO	1000014202		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Erectile Dysfunction; Fatigue; Libido Decreased; Paraesthesia; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7702788	NON-EXPEDITED	Y	OT	1000014329		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Dissociation; Intentional Self-Injury; Sleep Disorder; Suicide Attempt	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7703623	EXPEDITED (15-DAY)	Y	HO	1000016588		51 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Bromazepam			S		18 Mg (6 Mg,3 In 1 D)		Not Reported
	Aceprometazine			S	Oral	1 Dosage Forms (1 Dosage Forms,1 In 1 D),Oral		Not Reported
	Tareg			S	Oral	160 Mg (160 Mg,1 In 1 D),Oral		Not Reported
	Fenofibrate			S		200 Mg (200 Mg,1 In 1 D),Other		Not Reported
	Aspirin			S	Oral	160 Mg (160 Mg,1 In 1 D),Oral		Not Reported
	Nicorandil			S	Oral	40 Mg (20 Mg,2 In 1 D),Oral		Not Reported
	Acebutolol Hydrochloride			S	Oral	400 Mg (200 Mg,2 In 1 D),Oral		Not Reported
	Lansoprazole			S	Oral	30 Mg (30 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7746948	NON-EXPEDITED	N	OT	1000012534			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Suicide Attempt	Lexapro	S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2010	7747399	NON-EXPEDITED	Y	HO	1000009395		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Hypoaesthesia Oral; Rash	Lexapro			S	Oral Oral Oral	See Image See Image See Image		Not Reported
	Xanax			C				Not Reported
	Toprol Xl			C				Not Reported
	Aspirin			C				Not Reported
	Cardizem			C				Not Reported
	Colace			C				Not Reported
	Miralax			C				Not Reported
	Slow-Mag			C				Not Reported
	Centrum			C				Not Reported
	Asacol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2010	7585849	EXPEDITED (15-DAY)	Y	HO	1000015887		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Bilirubin Increased; Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Fluindione			S	Oral	Oral		Not Reported
	Diovan Hct			S	Oral	Oral		Not Reported
	Zopiclone			S	Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral		Not Reported
	Tahor (Atorvastatin) (Atorvastatin)			C				Not Reported
	Amlor (Amlodipine) (Amlodipine)			C				Not Reported
	Temerit (Nebivolol Hydrochloride) (5 Milligram) (Nebivolol Hydrochloride			C				Not Reported
	Diantalvic (Di-Gesic) (Di-Gesic)			C				Not Reported
	Ditropan (Oxybutynin			C				Not Reported

Hydrochloride) (Oxybutynin Hydrochloride)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2010	7626206	EXPEDITED (15-DAY)	Y	HO, OT	PHHY2010FR65244		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Optic Neuropathy; Pallor; Visual Acuity Reduced; Visual Evoked Potentials Abnormal	Tareg			S	Oral	60 Mg, Qd		Novartis
	Fenofibrate			S		200 Mg, Qd		Not Reported
	Aspirin			S		160 Mg, Qd		Not Reported
	Nicorandil			S		40 Mg, Daily		Not Reported
	Acebutolol Hydrochloride			S				Not Reported
	Lansoprazole			S		30 Mg, Qd		Not Reported
	Bromazepam			S		18 Mg, Daily		Not Reported
	Escitalopram Oxalate			S		20 Mg, Qd		Not Reported
	Aceprometazine			S		01 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2010	7657447	EXPEDITED (15-DAY)	Y	OT	1000016644		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypotension; Syncope	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Viagra			S	Oral	(50 Mg,As Required),Oral		Not Reported
	Simvastatin			C				Not Reported
	Plavix (Clopidogrel) (Clopidogrel)			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2010	6527296	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20080102280		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Toxicity To Various Agents	Ibuprofen		S	Oral		Not Reported
	Acetaminophen	Y	S	Oral		Not Reported
	Acetaminophen		S	Oral		Not Reported
	Aspirin	Y	S	Oral		Not Reported
	Quetiapine		S	Oral		Not Reported
	Unspecified Ingredient		S	Oral		Not Reported
	Butalbital Acetaminophen And Caffeine		S	Oral		Not Reported
	Escitalopram Oxalate		S	Oral		Not Reported
	Caffeine		S	Oral		Not Reported
	Naproxen		S	Oral		Not Reported
	Fexofenadine Hcl		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2010	7662548	EXPEDITED (15-DAY)	Y	OT	1000016757		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral; Weight Increased	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lamictal			C				Not Reported
	Antihypertensives (Antihypertensives) (Antihypertensives)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2010	7662551	EXPEDITED (15-DAY)	Y	HO	1000016614		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Disorientation; Thrombocytopenia	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Ibuprofen\Pseudoephedrine Hydrochloride			S	Oral	3 Or 4 Dosage Forms, Oral		Not Reported
	Cefuroxime			S	Oral	Oral		Not Reported
	Budesonide			S	Respiratory	Respiratory (Inhalation)		Not Reported

			(inhalation)			
	Ibuprofen	S	Oral	Oral		Not Reported
	Paracetamol (Paracetamol) (Paracetamol)	C				Not Reported
	Duphaston (Dydrogesterone) (Tablets) (Dydrogesterone)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2010	7457896	EXPEDITED (15-DAY)	Y	DE	1000014686		65 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Drug Interaction; Fall; Haemorrhage; Haemorrhagic Stroke; Pulmonary Embolism; Sudden Death	Escitalopram Oxalate			S		5 Mg (5 Mg,1 In 1 D)		Not Reported
	Plavix			S				Not Reported
	Atorvastatin Calcium			C				Not Reported
	Acebutolol (Acebutolol) (Acebutolol)			C				Not Reported
	Cordarone (Amiodarone) (Amiodarone)			C				Not Reported
	Coaprovel (Karvea Hct) (Karvea Hct)			C				Not Reported
	Amlodipine Besylate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2010	7626183	EXPEDITED (15-DAY)	Y	HO	FR-RANBAXY-2010RR-38713		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy; Visual Impairment	Fenofibrate			S	Oral	200 Mg, Unk		Ranbaxy
	Lansoprazole			S	Oral	30 Mg, Unk		Not Reported
	Bromazepam			S	Oral	18 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, Unk		Not Reported
	Acepromazine			S	Oral	1 Df, Unk		Not Reported
	Tareg			S	Oral	160 Mg, Unk		Not Reported
	Aspirin			S	Oral	160 Mg, Unk		Not Reported
	Nicorandil			S	Oral	40 Mg, Unk		Not Reported

	Acebutolol Hydrochloride	S	Oral	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2010	7644809	EXPEDITED (15-DAY)	Y	HO, OT	1000016540			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rebound Effect; Suicidal Ideation	Escitalopram Oxalate			S		20 Mg (20 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2010	7662101	EXPEDITED (15-DAY)	Y	HO	1000016612		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatitis	Escitalopram Oxalate			S	Oral	1 Dosage Form (1 Dosage Forms,1 In 1 D),Oral		Not Reported
	Levonorgestrel And Ethinyl Estradiol			S	Oral	1 Dosage Forms (1 Dosage Forms,1 In 1 D),Oral		Not Reported
	Tea Leaf			S	Oral	4 Dosage Form (4 Dosage Forms,1 In 1 D),Oral		Not Reported
	Zopiclone (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2010	7662943	EXPEDITED (15-DAY)	Y	OT	1000016671		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Hypomania; Impulsive Behaviour; Irritability; Logorrhoea	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2010	7684492	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20101002875		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akinesia; Amnesia; Blood Pressure Systolic Increased; Communication Disorder; Dysstasia; Fall; Gait Disturbance; Haematoma; International Normalised Ratio Increased; Mental Disorder	Haldol			S	Oral	15 Gtt Morning, 20 Gtt Midday And 12 Gtt Evening		Not Reported
	Haldol			S	Oral	6 Gtt On Morning, 6 Gtt On Midday And 10 Gtt On Evening		Not Reported
	Oxazepam			S	Oral	1/2 Tablet Per Day (Evening)		Not Reported
	Oxazepam			S	Oral			Not Reported
	Exelon			S	Cutaneous			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	1/2 Tablet On Morning		Not Reported
	Singulair			C	Oral			Not Reported
	Previscan (Fluindione)			C	Oral			Not Reported
	Ramipril			C	Oral			Not Reported
	Symbicort			C	Respiratory (inhalation)	400/12 Mcg/Dose Twice Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2010	7546370	EXPEDITED (15-DAY)	Y	OT	1000015445		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Dizziness; Fall; Hyponatraemia; Loss Of Consciousness	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Tylenol With Codeine			C				Not Reported
	Klonopin			C				Not Reported
	Hctz			C				Not Reported
	Potassium			C				Not Reported
	Tenormin			C				Not Reported
	Phenergan			C				Not Reported
	Omeprazole			C				Not Reported
	Benadryl			C				Not Reported
	Tylenol			C				Not Reported

	Aspirin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2010	7653177	DIRECT	N	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Diarrhoea; Feeling Abnormal; Weight Decreased	Lexapro			S	Oral	1 One Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2010	7663147	EXPEDITED (15-DAY)	N	OT	1000016679			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Physical Assault; Sexual Abuse	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2010	6527272	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20080101973		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Ibuprofen			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Ramelteon			S	Oral			Not Reported
	Zaleplon			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2010	7601980	EXPEDITED (15-DAY)	N	HO	A0882338A		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Impaired Driving Ability; Seizure; Subdural Haematoma	Flolan			S	Intravenous (not otherwise specified)			Glaxosmithkline
	Flolan			S	Intravenous (not otherwise specified)			Glaxosmithkline
	Aspirin			S	Oral	81mg Per Day		Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Zoloft			C	Unknown			Not Reported
	Astelin			C	Nasal	137mcg Unknown		Glaxosmithkline
	Crestor			C	Oral	5mg Unknown		Not Reported
	Multi-Vitamin			C	Oral	1tab Per Day		Not Reported
	Flonase			C	Nasal			Glaxosmithkline
	Furosemide			C	Oral	40mg Unknown		Glaxosmithkline
	Imodium			C	Oral	2mg Unknown		Not Reported
	Potassium Chloride			C	Oral	20meq Unknown		Glaxosmithkline
	Letairis			C	Oral	10mg Unknown		Glaxosmithkline
	Nexium			C	Oral	4mg Unknown		Not Reported
	Oxygen			C		3l As Directed		Not Reported
	Restasis			C	Ophthalmic			Glaxosmithkline
	Sodium Chloride			C				Glaxosmithkline
	Spironolactone			C	Oral	25mg Unknown		Glaxosmithkline
	Synthroid			C	Oral	125mcg Unknown		Glaxosmithkline
	Tylenol			C	Oral	325mg Unknown		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2010	7602828	EXPEDITED (15-DAY)	Y	OT	1000016049		26 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

	Buprenorphine (Buprenorphine) (Buprenorphine)	C	Not Reported
	Zolpidem (Zolpidem) (Zolpidem)	C	Not Reported
	Alprazolam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2010	7610083	EXPEDITED (15-DAY)	Y	OT	1000016199		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Anger; Impaired Driving Ability; Mood Swings; Road Traffic Accident	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2010	7633646	EXPEDITED (15-DAY)	Y	HO	PHHY2010FR67435		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akinesia; Blood Pressure Systolic Increased; Communication Disorder; Dysstasia; Fall; Feeling Abnormal; Gait Disturbance; Haematoma; Heart Rate Increased; International Normalised Ratio Increased	Exelon Patch			S	Transdermal	4.6 Mg/24 Hr		Novartis
	Haldol			S		47 Drops/Day		Not Reported
	Haldol			S		22 Oral Drops/Day		Not Reported
	Oxazepam			S	Oral	10 Mg/Day		Not Reported
	Oxazepam			S	Oral	5 Mg/Day		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg/Day		Not Reported
	Singulair			C	Oral	10 Mg/Day		Not Reported
	Previscan (Fluindione)			C		20 Mg		Not Reported
	Ramipril			C		5 Mg/Day		Not Reported
	Symbicort			C		400/12 Mcg/Dose, 1 Inhalation Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2010	7664632	EXPEDITED (15-DAY)	Y	DS	1000016808		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Feeling Abnormal	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2010	7664654	EXPEDITED (15-DAY)	Y	HO	1000016787		90 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall; Hyponatraemia; Loss Of Consciousness; Quadriplegia; Somnolence	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Voltarene (Diclofenac Sodium)			C				Not Reported
	Omeprazole			C				Not Reported
	Forlax (Macrogol) (Macrogol)			C				Not Reported
	Actiskenan (Morphine Sulfate) (Morphine Sulfate)			C				Not Reported
	Tareg (Valsartan) (Valsartan)			C				Not Reported
	Vastarel			C				Not Reported
	Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine)			C				Not Reported
	Calciparene (Heparin Calcium) (Heparin Calcium)			C				Not Reported
	Solumedrol (Methylprednisolone Sodium Succinate) (Methylprednisolone Sodium Succinate)			C				Not Reported
	Ofloxacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2010	7664665	EXPEDITED (15-DAY)	Y	HO	1000016685		20 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oculogyric Crisis	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

	Zuclopenthixol	S	30 Mg (30 Mg, 1 In 1 D)		Not Reported
	Valium (Diazepam) (Tablets) (Diazepam)	C			Not Reported
	Akineton (Biperiden) (Tablets) (Biperiden)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2010	7664683	EXPEDITED (15-DAY)	Y	OT	1000016779		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Ineffective	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2010	7664813	EXPEDITED (15-DAY)	Y	HO	IPC201010-000271		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dizziness; Drug Interaction; Dyspnoea; Orthostatic Hypotension; Sinus Arrest; Syncope	Atenolol			S		25 Mg Daily		Not Reported
	Furosemide			S		20 Mg Daily		Not Reported
	Rivastigmine			S		3 Mg Twice Daily		Not Reported
	Levetiracetam			S		500 Mg Twice Daily		Not Reported
	Fosinopril Sodium			S		20 Mg Twice Daily		Not Reported
	Amlodipine			S		5 Mg Daily		Not Reported
	Minoxidil			S		5 Mg Twice Daily		Not Reported
	Aspirin			S		325 Mg Daily		Not Reported
	Clopidogrel			S		75 Mg Daily		Not Reported
	Escitalopram Oxalate			S		5 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2010	7665409	EXPEDITED (15-DAY)	Y	LT, OT	1000016858		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Amitriptyline (Amitriptyline (Amitriptyline)			C				Not Reported
	Mirtazapine			C				Not Reported
	Quetiapine (Quetiapine) (Quetiapine)			C				Not Reported
	Venlafaxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2010	7667562	EXPEDITED (15-DAY)	Y	HO	1000016784		76 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Feeling Drunk; Hypomania; Nausea	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Agomelatine			S	Oral	Oral		Not Reported
	Lexomil (Bromazepam)			S	Oral	1.25 Dosage Form (1.25 Dosage Forms,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2010	7582610	EXPEDITED (15-DAY)	N	OT	1000015944		62 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Compulsions; Condition Aggravated; Confusional State; Dependence; Dizziness; Gambling Disorder; Insomnia; Mania; Marital Problem; Suicidal Ideation; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2010	7667890	EXPEDITED (15-DAY)	N	HO	1000016738			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Hyperhidrosis; Pain In Extremity	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2010	7668786	EXPEDITED (15-DAY)	Y	OT	1000016683		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Dyskinesia; Sopor; Tachycardia	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Olanzapine (Olanzapine)			S		(900 Mg, Once)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2010	7668876	EXPEDITED (15-DAY)	Y	HO	1000016719		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastritis Erosive; Haematemesis	Lexapro			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Nitrazepam (Nitrazepam) (Nitrazepam)			C				Not Reported
	Dexamphetamine (Dexamphetamine Sulfate) (Dexamphetamine Sulfate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2010	7727692	EXPEDITED (15-DAY)	Y	HO	1000016832		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akinesia; Dysstasia; Fall; Haematoma; International	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 N 1 D), Oral		Not Reported
	Haldol			S	Oral	47 Drops (47 Gtt, 1 In 1		Not Reported

Normalised Ratio Increased; Parkinsonian Gait					D), Oral	
	Oxazepam		S	Oral	Oral	Not Reported
	Exelon		S	Cutaneous	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Cutaneous	Not Reported
	Singulair		C			Not Reported
	Previscan (Fluindione)		C			Not Reported
	Ramipril		C			Not Reported
	Symbicort Turbuhaler (Symbicrt Turbuhaler) (Symbicort Turbuhaler)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2010	7637761	EXPEDITED (15-DAY)	Y	OT	BR-PFIZER INC-2010130473		25 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dysphoria; Sedation; Sexual Dysfunction	Sertraline Hydrochloride			S		Unk		Pfizer
	Citalopram			S		Unk		Not Reported
	Clonazepam			S		Unk		Not Reported
	Escitalopram Oxalate			S		20mg/Day		Not Reported
	Venlafaxine			S		225mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2010	7727148	EXPEDITED (15-DAY)	Y	OT	2010MA003629		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor; Visual Field Defect	Citalopram Hydrobromide			S				Purepac
	Escitalopram Oxalate			S	Oral	Po		Not Reported
	Citalopram Hydrobromide			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2010	6527205	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20080102116		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Dextromethorphan Hydrobromide		Y	S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2010	7569986	EXPEDITED (15-DAY)	Y	DS, LT, OT	A0877887A		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Incoherent; Loss Of Personal Independence In Daily Activities; Product Administration Error; Product Prescribing Error; Serum Serotonin Increased; Therapeutic Product Effect Increased	Imitrex			S	Oral	25mg Per Day	6 WEEK	Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Remeron			S	Oral	7.5mg At Night		Not Reported
	Trazodone			S	Oral	50mg At Night	42 DAY	Not Reported
	Risperdal			S	Oral	.25mg At Night		Not Reported
	Keppra			C	Oral	250mg Twice Per Day		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2010	7572203	EXPEDITED (15-DAY)	Y	OT	1000015768		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Proteinuria; Renal Cancer Stage I	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2010	7582173	EXPEDITED (15-DAY)	Y	OT	1000015919		56 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Depression; Dizziness; Dry Mouth; Erection Increased; Fatigue; Increased Appetite; Muscular	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Clonazepam			S	Oral	1 Mg (1 Mg,1 In 1 D),Oral		Not Reported
	Seroquel			S	Oral	200 Mg (200 Mg, 1 In 1 D),		Not Reported

Weakness; Nausea; Somnolence; Suicidal Ideation; Tinnitus; Tremor; Weight Increased				Oral	
	Wellbutrin Xl	S	Oral	300 Mg (300 Mg, 1 In 1 D), Oral	Not Reported
	Echinacea Purpurea	C			Not Reported
	Horse Chestnut Extract (Aesculus Hippocastanum Extract) (Aesculus Hippocastanum Extratc)	C			Not Reported
	Milk Thistle	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2010	7631869	EXPEDITED (15-DAY)	Y	OT	1000016422		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Seresta (Oxazepam) (Oxazepam)			C				Not Reported
	Zolpidem (Zolpidem (Zolpidem)			C				Not Reported
	Naltrexone (Naltrexone) (Naltrexone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2010	7644503	EXPEDITED (15-DAY)	Y	OT	1000016467		33 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2010	7652445	EXPEDITED (15-DAY)	Y	HO, OT	1000016548		17 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Tachycardia	Escitalopram Oxalate		S	Oral	20 Mg, Once), Oral	Not Reported
	Seroquel		S	Oral	(100 Mg, Once), Oral	Not Reported
	Pipamperone Hydrochloride		S	Oral	(40 Mg, Once), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2010	7660515	EXPEDITED (15-DAY)	Y	DS, LT, OT	1000016611		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Incoherent; Loss Of Personal Independence In Daily Activities; Serum Serotonin Increased	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Imitrex			S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
	Remeron			S	Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral		Not Reported
	Trazodone Hydrochloride			S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal			S	Oral	.25 Mg (.25 Mg, 1 In 1 D), Oral		Not Reported
	Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2010	7672562	EXPEDITED (15-DAY)	Y	HO	1000014434		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Atarax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2010	7672593	EXPEDITED (15-DAY)	Y	OT	1000016816		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Alcohol Increased; Impaired Driving Ability	Lexapro		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Alcohol (Ethanol)		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2010	7672883	EXPEDITED (15-DAY)	Y	OT	1000016932		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Sclerosis Relapse	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2010	7611133	EXPEDITED (15-DAY)	Y	OT	1000016223			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Myositis; Tendonitis	Escitalopram Oxalate			S	Oral	5-10 Mg Daily, Oral		Not Reported
	Azilect			S	Oral	1 Mg (1 Mg, 1 In 1 D), Oral		Not Reported
	Lipitor			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Sinemet			C				Not Reported
	Requip (Ropinirole Hydrochloride) (Ropinirold Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2010	7639727	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20101005478		63 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Self-Injury; Sluggishness; Tachycardia	Risperdal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2010	7651830	EXPEDITED (15-DAY)	Y	DE	US-JNJCH-2008001005		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Dextromethorphan Hydrobromide		Y	S	Oral	Text:Unspecified		Not Reported
	Escitalopram Oxalate			S	Oral	Text:Unspecified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2010	7673502	EXPEDITED (15-DAY)	N	OT	1000016879		64 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abnormal Behaviour; Delirium; Hallucination	Memantine Hydrochloride			S	Oral	2 Dosage Form (2 Dosage Forms,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	1 Dosage Form (1 Dosage Forms,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2010	7673512	EXPEDITED (15-DAY)	Y	RI, OT	1000016909			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment; Overdose	Escitalopram Oxalate			S	Oral	Oral ; 30 Mg (30 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2010	7674103	EXPEDITED (15-DAY)	Y	HO	1000016336		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fall; Gait Disturbance; Orthostatic Hypotension	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tareg (Valsartan) (Valsartan)			C				Not Reported
	Eupressyl (Urapidil) (Urapidil)			C				Not Reported

	Seresta (Oxazepam) (Oxazepam)	C		Not Reported
	Modopar (Madopar) (Madopar)	C		Not Reported
	Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine)	C		Not Reported
	Trivastal (Piribedil) (Piribedil)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2010	7674261	EXPEDITED (15-DAY)	Y	DS	1000016867		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Disturbance In Attention; Hypersomnia; Memory Impairment	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2010	7674422	EXPEDITED (15-DAY)	Y	HO, OT	1000015082		59 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholangitis; Hepatitis; Pancreatic Carcinoma	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Lyrica			S	Oral	75 Mg (75 Mg,1 In 1 D),Oral		Not Reported
	Lyrica			S	Oral	150 Mg (50 Mg,3 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2010	7674554	EXPEDITED (15-DAY)	Y	HO	1000016884		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Cerebral Haemorrhage Neonatal; Cerebral	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg,1 In 1), Transplacental		Not Reported

Ventricle Dilatation; Hydrocephalus; Maternal Drugs Affecting Foetus; Premature Baby

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2010	7677519	EXPEDITED (15-DAY)	Y	HO	1000016882		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Artificial Rupture Of Membranes; Caesarean Section; Hellp Syndrome; Maternal Exposure During Pregnancy; Pre-Eclampsia; Pregnancy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2010	7461735	EXPEDITED (15-DAY)	Y	CA, DE, OT	GB-TEVA-239925ISR			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Exposure During Pregnancy	Sertraline Hydrochloride			S	Transplacental			Ivax
	Escitalopram Oxalate			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2010	7499650	EXPEDITED (15-DAY)	Y	CA, DE, OT	GER/UKI/10/0013960			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Death; Hypoxic-Ischaemic Encephalopathy; Maternal Drugs Affecting Foetus; Thymus Disorder; Umbilical Cord Abnormality	Sertraline Hydrochloride			S	Transplacental	100 Mg, Transplacental		Not Reported
	Cipralex			S	Transplacental	20 Mg, Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2010	7644436	EXPEDITED (15-DAY)	N	OT	ZA-JNJFOC-20101005149		7 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Derealisation; Diarrhoea; Faeces Discoloured; Irritability; Mood Swings; Nausea; Syncope; Vomiting	Concerta			S	Oral	1 In Mane		Not Reported
	Cipralex			S	Unknown	Mane		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2010	7645580	EXPEDITED (15-DAY)	Y	DE	US-WYE-H13730310		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Venlafaxine Hydrochloride			S	Oral	Unknown		Wyeth
	Citalopram			S	Oral	Unknown		Unknown
	Alcohol			S	Oral	Unknown		Unknown
	Escitalopram Oxalate			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2010	7645793	NON-EXPEDITED	N		US-WYE-H14973210		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Blood Pressure Increased; Drug Withdrawal Syndrome; Hyperhidrosis; Panic Attack; Somnolence; Therapeutic Product Effect Decreased	Venlafaxine Hydrochloride			S	Oral			Wyeth
	Venlafaxine Hydrochloride			S	Oral			Wyeth
	Pristiq Extended Release			S	Oral			Wyeth
	Pristiq Extended Release			S				Wyeth
	Lexapro			S	Oral			Lundbeck
	Lexapro			S	Oral			Lundbeck
	Lexapro			S		Dose Was Reduced In		Lundbeck

						Order To Taper Off			
	Premarin			C					Wyeth
	Bupropion Hydrochloride			C					Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2010	7646390	NON-EXPEDITED	Y		US-WYE-H18305410		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Protonix			S	Oral			Wyeth
	Coumadin			S		Unspecified Dose, Once Daily		Not Reported
	Coumadin			S				Not Reported
	Lexapro			S	Oral			Lundbeck
	Vitamins Nos			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2010	7665305	DIRECT	Y	DS, OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment	Lexapro			S	Oral	60 Mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2010	7670105	DIRECT	Y	DE			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Lexapro			S	Oral	20mg 1 Daily P.O.		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2010	7676779	EXPEDITED (15-DAY)	Y	HO	1000016670		76 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Psychotic Disorder; Suicide Attempt	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2010	7739453	EXPEDITED (15-DAY)	N	CA	1000016968		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia; Maternal Drugs Affecting Foetus; Ventricular Hypoplasia	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2010	7764850	NON-EXPEDITED	Y	OT	DSA_41897_2009		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hostility; Suicidal Ideation	Wellbutrin			S	Oral	(150 Mg Every Morning And 100 Mg Every Evening Oral)		Not Reported
	Lexapro			S	Oral	(10 Mg Qd Oral)		Not Reported
	Lyrica			S		(Df)		Not Reported
	Lunesta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2010	7461876	EXPEDITED (15-DAY)	Y	OT	GXKR2010GB07270		26 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Exposure During Pregnancy	Sertraline			S	Unknown	100 Mg, Unk		Novartis
	Escitalopram Oxalate			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2010	7582129	EXPEDITED (15-DAY)	N		1000015922		55 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Delusion; Heart Rate Increased; Nausea; Nervousness; Panic Attack; Speech Disorder	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2010	7649785	EXPEDITED (15-DAY)	Y	DE	GXKR2010US11935		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Cardiac Arrest; Cardiac Pacemaker Insertion; Cardioversion; Circulatory Collapse; Coma; Endotracheal Intubation; Long Qt Syndrome; Loss Of Consciousness; Malaise; Mechanical Ventilation; Sinus Rhythm; Torsade De Pointes; Ventricular Fibrillation	Fluoxetine			S	Unknown			Novartis
	Escitalopram Oxalate			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Buspirone			C	Unknown			Not Reported
	Temazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2010	7684316	EXPEDITED (15-DAY)	Y	OT	1000016994		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Dysuria	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		
	Pariet (Rabeprazole Sodium) (Rabeprazole Sodium)			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2010	7684321	EXPEDITED (15-DAY)	Y	DE, HO	1000015734		41 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Condition Aggravated; Depression	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Imovane (Zopiclone) (Tablets) (Zopiclone)			C				Not Reported
	Lysanxia (Prazepam) (Tablets) (Prazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2010	7839480	EXPEDITED (15-DAY)	Y	OT	1000015996		152 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Foetal Growth Restriction; Foetal Heart Rate Deceleration Abnormality; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2010	7651036	NON-EXPEDITED	N		US-WYE-H17330910			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Headache	Pristiq Extended Release			S		Unspecified		Wyeth
	Lexapro			S		Unspecified		Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2010	7238723	EXPEDITED (15-DAY)	Y	DE	1000010771		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Therapeutic Product Effect Decreased	Lexapro	S	Oral	5 Mg (5 Mg,1 In 1 D), Oral ; 10 Mg (10 Mg,1 In 1 D),Oral	Not Reported
			Oral	5 Mg (5 Mg,1 In 1 D), Oral ; 10 Mg (10 Mg,1 In 1 D),Oral	
	Effexor	S	Oral	See Image	Not Reported
			Oral	See Image	
			Oral	See Image	
			Oral	See Image	
			Oral	See Image	
	Zoloft (Sertraline) (Sertraline)	C			Not Reported
	Eryacne (Erythromycin) (Gel) (Erythromycin)	C			Not Reported
	Herbs (Herbals Nos W/Vitamins Nos) (Herbals Nos W/Vitamins Nos)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2010	7420487	EXPEDITED (15-DAY)	Y		1000014312		62 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Paraesthesia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2010	7652661	EXPEDITED (15-DAY)	Y	DE	US-MYLANLABS-2010S1019384		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Long Qt Syndrome; Sinus Tachycardia; Torsade De Pointes	Trazodone			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Temazepam			C	Unknown			Not Reported
	Buspirone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2010	7674391	DIRECT	N	DE, OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Effexor			S		Sample Capsules Sample Capsules		Not Reported
	Cymbalta			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2010	7575852	EXPEDITED (15-DAY)	N	HO, OT	1000015338		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Compulsive Shopping; Hostility; Mania; Paranoia; Refusal Of Treatment By Patient; Restlessness; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Allopurinol			C				Not Reported
	Baby Aspirin (Acetylsalicylic Acid) (Acetylsalicylic Acid)			C				Not Reported
	Potassium (Potassium) (Potassium)			C				Not Reported
	Amilonde (Amlodipine) (Amlodipine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2010	7631871	EXPEDITED (15-DAY)	Y		1000016414		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Practazin (Aldactazine) (Aldactazine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2010	7640373	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000016547		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Sounds Abnormal; Hypotension; Intentional Overdose; Seizure; Sopor; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S	Oral	(240 Mg,Once),Oral		Not Reported
	Seroquel			S	Oral	(12000 Mg,Once),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2010	7653217	EXPEDITED (15-DAY)	Y	DE	US-BRISTOL-MYERS SQUIBB COMPANY-15349954		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome; Torsade De Pointes	Trazodone Hydrochloride			S				Apothecon
	Buspirone			S				Not Reported
	Fluoxetine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Temazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2010	7653381	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010134762		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Knee Arthroplasty; Somnolence; Suicidal Behaviour; Surgery	Zoloft			S	Oral	100 Mg, Unk		Pfizer
	Lexapro			S	Oral	20mg, One And A Half Pill Daily		Not Reported
	Cymbalta			S	Oral	60 Mg, 1x/Day		Not Reported
	Wellbutrin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2010	7653693	EXPEDITED (15-DAY)	Y	HO, LT	FR-JNJFOC-20101006755		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Jaundice; Neonatal Respiratory Distress Syndrome; Premature Baby	Haldol			S	Transplacental			Not Reported
	Tegretol			S	Transplacental			Not Reported
	Escitalopram Oxalate			S	Transplacental			Not Reported
	Tranxene T-Tab			S	Transplacental			Not Reported
	Cyamemazine			S	Transplacental			Not Reported
	Folic Acid			S	Transplacental			Not Reported
	Aldomet			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2010	7653694	EXPEDITED (15-DAY)	Y	OT	FR-JNJFOC-20101006733			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature Labour	Haldol			S	Oral			Not Reported
	Tegretol			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Tranxene T-Tab			S	Oral			Not Reported
	Cyamemazine			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Aldomet			C				Not Reported
	Aldomet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2010	7653975	EXPEDITED (15-DAY)	Y	HO, LT	PHHY2010FR72790			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Foetal Arrhythmia; Foetal Distress Syndrome; Jaundice Neonatal; Maternal Exposure During Pregnancy; Neonatal	Tegretol Lp			S	Transplacental	200 Mg/Day		Novartis
	Escitalopram Oxalate			S	Transplacental	5 Mg/Day		Not Reported
	Tranxene T-Tab			S	Transplacental	15 Mg/Day		Not Reported
	Cyamemazine			S	Transplacental	90 Mg/Ml Daily		Not Reported

Respiratory Distress Syndrome; Premature Baby; Respiratory Distress	Haldol		S	Transplacental	5 Mg/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2010	7654182	NON-EXPEDITED	N		US-ABBOTT-10P-163-0654328-00		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Ear Infection; Fatigue	Biaxin			S	Other			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2010	7678916	DIRECT	N				25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Lexapro			S	Oral	20mg Qam Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2010	7466287	EXPEDITED (15-DAY)	N	HO, OT	GB-WATSON-2010-09064		26 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death	Sertraline Hydrochloride			S	Transplacental	100 Mg, Unk		Watson
	Cipralex			S	Transplacental	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2010	7476863	EXPEDITED (15-DAY)	Y	CA, DE, OT	GB-MYLANLABS-2010S1011808			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Presentation; Encephalopathy; Foetal Death; Maternal Drugs Affecting Foetus; Maternal	Sertraline Hydrochloride			S	Transplacental			Genpharm
	Cipralex			S	Transplacental			Not Reported

Exposure During Pregnancy; Umbilical Cord Abnormality

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2010	7523670	EXPEDITED (15-DAY)	Y	DE, OT	2010AP001416			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Presentation; Foetal Death; Foetal Disorder; Hypoxic-Ischaemic Encephalopathy; Maternal Drugs Affecting Foetus	Sertraline Hydrochloride			S	Transplacental	100 Mg; Trpl		Not Reported
	Cipralex			S	Transplacental	20 Mg;Trpl		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2010	7619152	EXPEDITED (15-DAY)	Y	DE	1000016294		78 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Memantine Hydrochloride			S	Oral	20 Mg (20 Mg,2 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D)		Not Reported
	Amisulpride (Amisulpride) (Tablets) (Amisulpride)			C				Not Reported
	Travoprost (Travoprost) (Travoprost)			C				Not Reported
	Dorzolamide/Timolol (Dorzolamide, Timolol) (Dorzolamide, Timolol)			C				Not Reported
	Brinzolamide (Brinzolamide) (Brinzolamide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2010	7635535	EXPEDITED (15-DAY)	N	HO	1000016469		93 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anal Incontinence; Dyspnoea; Malaise; Nausea; Seizure	Lexapro	S	Oral	2.5 Mg (2.5 Mg,1 In 1 D),Oral	Not Reported
	Temazepam	C			Not Reported
	Pantoprazole Sodium	C			Not Reported
	Prochlorperazine (Prochlorperazine) (Prochlorperazine)	C			Not Reported
	Perindopril (Perindopril) (Perindopril)	C			Not Reported
	Cranberry (Asciorbic Acid) (Ascorbic Acid)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2010	7664659	EXPEDITED (15-DAY)	N	OT	1000012211		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment; Weight Increased	Lexapro			S	Oral	520 Mg (20 Mg, 1 In 1 D) Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	2.5 Mg (5 Mg, Qod), Oral 5 Mg (5 Mg, 1 In 1 D), Oral 2.5 Mg (5 Mg, Qod), Oral		
	Lamictal			C				Not Reported
	Simvastatin (10 Milligram)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2010	7688227	EXPEDITED (15-DAY)	Y	DS	1000017014		75 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuralgia; Paraesthesia; Trigeminal Neuralgia; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	Oral ; (5 Mg,1 In 1 Wk),Oral		Not Reported
					Oral	Oral ; (5 Mg,1 In 1 Wk),Oral		
	Chlorphenamine			C				Not Reported

(Chlorphenamine Maleate)			
(Chlorphenamine Maleate)			
Aspirin	C		Not Reported
Quinine (Quinine Sulphate)	C		Not Reported
(Quinine Sulphate)			
Simvastatin	C		Not Reported
Ventolin (Salbutamol Sulphate)	C		Not Reported
(Salbutamol Sulphate)			

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2010	7690193	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2010-02633		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt; Toxicity To Various Agents	Zolpidem			S	Oral	Oral		Not Reported
	Lamotrigine			S	Oral	Oral		Not Reported
	Ibuprofen			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Alprazolam			S	Oral	Oral		Not Reported
	Ramelteon			C	Oral	Oral		Not Reported
	Zaleplon			C	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2010	7733231	EXPEDITED (15-DAY)	N	RI, OT	1000013743		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Pain; Blood Glucose Abnormal; Blood Pressure Decreased; Drug Ineffective; Fatigue; Hot Flush; Hyperhidrosis; Insomnia; Irritability; Listless; Panic Attack; Paraesthesia; Restlessness; Tachycardia; Tension;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 15 Mg (15 Mg,1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 15 Mg (15 Mg,1 In 1 D),Oral		
	Zopiclon (Zopiclone) (Tablets) (Zopiclone)			C				Not Reported

Thinking Abnormal; Tremor; Uterine Leiomyoma; Weight Increased; Yawning

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2010	7418378	EXPEDITED (15-DAY)	Y	HO	1000014256		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Muscular Weakness; Off Label Use; Paraesthesia; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Chondroprotective Drugs (Chondroprotective Drugs) (Chondroprotective Drugs)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2010	7472328	EXPEDITED (15-DAY)	Y	CA, DE, OT	GB-RANBAXY-2010RR-35623			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Hypoxic-Ischaemic Encephalopathy; Maternal Drugs Affecting Foetus; Thymus Disorder; Umbilical Cord Abnormality; Viral Infection	Sertraline Hydrochloride			S	Transplacental	100 Mg, Unk		Ranbaxy
	Cipralex			S	Transplacental	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2010	7613334	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010119896		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypotension; Syncope	Viagra			S	Oral	100 Mg, As Needed		Pfizer
	Simvastatin			C		40 Mg, 1x/Day (At Night)		Not Reported
	Plavix			C		75 Mg, 1x/Day (1 In The Morning)		Not Reported

Lorazepam	C		1 Or 1.5 As Needed		Not Reported
Ranibizumab	C		Unk In Each Eye		Not Reported
Vitamin C	C		500 Mg, 1x/Day (In The Morning)		Not Reported
Vitamin D2	C		1000 Iu, 1x/Day		Not Reported
Selenium	C		200 Mg, 1x/Day (In The Morning)		Not Reported
Vitamins Nos	C		Unk		Not Reported
Magnesium	C		Unk		Not Reported
Viagra	S	Oral	50 Mg, As Needed		Pfizer
Lisinopril	S		10 Mg (2 In The Morning And 1 At Night)		Not Reported
Lexapro	S	Oral	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2010	7656365	EXPEDITED (15-DAY)	Y	HO	PHHY2010FR72833			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Hyperalbuminaemia; Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature Labour	Tegretol Lp			S	Oral	200 Mg/Day		Novartis
	Escitalopram Oxalate			S	Oral	5 Mg/Day		Not Reported
	Tranxene T-Tab			S	Oral	15 Mg/Day		Not Reported
	Cyamemazine			S		90 Mg/Ml Daily		Not Reported
	Haldol			S	Oral	5 Mg/Day		Not Reported
	Abilify			S		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2010	7688879	EXPEDITED (15-DAY)	N	HO	1000016988		93 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Nausea; Seizure	Lexapro	S	Oral	2.5 Mg (2.5 Mg, 1 In 1 D), Oral	Not Reported
	Temazepam	C			Not Reported
	Pantoprazole Sodium	C			Not Reported
	Prochlorperazine (Prochlorperazine) (Prochlorperazine)	C			Not Reported
	Perindopril (Perindopril) (Perindopril)	C			Not Reported
	Cranberry (Cranberry) (Cranberry)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2010	7688945	EXPEDITED (15-DAY)	N	HO, RI, OT	1000017062		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Death Of Relative; Dizziness; Fatigue; Job Dissatisfaction; Motion Sickness; Nausea; Suicidal Ideation; Vitamin D Deficiency	Escitalopram Oxalate			S				Not Reported
	Gestinyl (Gestinyl) (Tablets) (Gestinyl)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2010	7688992	EXPEDITED (15-DAY)	Y	HO	1000017009			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Intentional Overdose; Product Prescribing Error; Sense Of Oppression	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral, 200 Mg, Once, Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Tercian 9cyamemazine (Cyamemazine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2010	7498436	EXPEDITED (15-DAY)	Y	OT	2010MA000442			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Forceps Delivery; Induced Labour; Maternal Exposure During Pregnancy; Placental Disorder; Polyhydramnios; Postpartum Haemorrhage	Sertraline Hydrochloride			S		100 Mg		Not Reported
	Cipralex			S		20 Mg		Not Reported
	Con Meds			C				Not Reported
	Prev Meds			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2010	7507528	EXPEDITED (15-DAY)	Y	CA, DE, OT	AUR-APL-2010-01692		238 DAY	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Forceps Delivery; Hypoxic-Ischaemic Encephalopathy; Maternal Drugs Affecting Foetus; Placental Disorder; Umbilical Cord Abnormality	Sertraline Hydrochloride			S	Transplacental	100mg, Transplacent		Not Reported
	Cipralex			S	Transplacental	20mg, Transplacent		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2010	7610141	EXPEDITED (15-DAY)	Y	HO	1000016178		37 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Electrocardiogram Qt Prolonged; Mood Altered; Tachycardia; Thinking Abnormal	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Prazine (Promazine Hydrochloride)			S	Oral	150 Mg (150 Mg,1 In 1 D),Oral		Not Reported
	Abilify			S		20 Mg (20 Mg,1 In 1 D)		Not Reported
	Haldol			S		9 Mg (3 Mg,3 In 1 D) ; 9 Mg (3 Mg,3 In 1 D) 9 Mg (3 Mg,3 In 1 D) ; 9 Mg (3 Mg,3 In 1 D)		Not Reported
	Risperdal			S	Oral	4 Mg (2 Mg,2 In 1 D),Oral ;		Not Reported

			Oral	4 Mg (2 Mg,2 In 1 D),Oral 4 Mg (2 Mg,2 In 1 D),Oral ; 4 Mg (2 Mg,2 In 1 D),Oral		
	Stilnox (Zolpidem) (10 Milligram) (Zolpidem)	C				Not Reported
	Rivotril (Clonazepam) (Tablets) (Clonazepam)	C				Not Reported
	Entumin (Clotiapine) (Tablets) (Clotiapine)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2010	7644609	EXPEDITED (15-DAY)	Y	HO, OT	1000016539		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Abuse; Intentional Overdose; Nausea; Poisoning; Restlessness	Escitalopram Oxalate			S	Oral Oral	40 Mg (40 Mg,Once),Oral ; Oral 40 Mg (40 Mg,Once),Oral ; Oral		Not Reported
	Levothyroxine Sodium			S	Oral	(150-200 Mcg, Once),Oral		Not Reported
	Acetaminophen			S	Oral	(1500 Mg,Once),Oral		Not Reported
	Dienogest\Ethinyl Estradiol			S	Oral	(1 Dosage Forms,Once),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2010	7657779	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010139371			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Toviaz			S		Unk		Pfizer
	Xanax			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2010	7658413	EXPEDITED (15-DAY)	Y	HO, OT	CH-WYE-G06901110		31 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Maternal Exposure During Pregnancy	Effexor			S				Wyeth
	Effexor			S				Wyeth
	Seroquel			S			136 DAY	Zeneca
	Fluctine			S		Dose And Frequency Unknown		Eli Lilly And Co
	Zyprexa			S		Dose And Frequency Unknown		Not Reported
	Zyprexa			S				Not Reported
	Cipralex			S		Dose And Frequency Unknown		Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2010	7690686	EXPEDITED (15-DAY)	Y	HO	1000016982		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Head Titubation; Overdose; Polyneuropathy; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg,1 In 1 D),Oral ;15 Mg (15 Mg,1 In 1 D),Oral		Not Reported
					Oral	30 Mg (30 Mg,1 In 1 D),Oral ;15 Mg (15 Mg,1 In 1 D),Oral		
	Venlafaxine			S	Oral	75 Mg (75 Mg,1 In 1 D),Oral		Not Reported
	Omeprazol (Omeprazole) (Omeprazole)			C				Not Reported
	Folacin (Folic Acid) (Tablets) (Folic Acid)			C				Not Reported
	Propavan (Propiomate Maleate) (Tablets) (Propiomazine Maleate)			C				Not Reported
	Theralen (Alimemazine Tartrate)			C				Not Reported

	(Tablets) (Alimemazine Tartrate)									
	Behepan (Cyanocobalamin) (Tablets) (Cyanocobalamin)		C							Not Reported
	Stesolid (Diazepam) (Tablets) (Diazepam)		C							Not Reported
	Bricanyl (Terbutaline Sulfate) (Terbutaline Sulfate)		C							Not Reported
	Watan (Watan) (Watan)		C							Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2010	7690819	EXPEDITED (15-DAY)	Y	HO	1000017008		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Confusional State; Fall; Gamma-Glutamyltransferase Increased; Haemoglobin Decreased; Liver Function Test Abnormal; Subcutaneous Emphysema; Transaminases Increased; Urinary Tract Infection	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Oxycodone Hydrochloride			C	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Oxycontin (Oxycodone Hydrochloride) (Oxycodone Hydrochloride)			C				Not Reported
	Omeprazol Sandoz (Omeprazole) (Omeprazole)			C				Not Reported
	Movicol (Nulytely) (Nulytely)			C				Not Reported
	Kalcipos Forte (Calcium Carbonate) (Calcium Carbonate)			C				Not Reported
	Prednisolon Pfizer (Prednisolone) (Prednisolon)			C				Not Reported
	Nitromex (Glyceryl)			C				Not Reported
	Optimol (Timolol Maleate) Timolol Maleate)			C				Not Reported
	Innohep (Tinzaparin Sodium) (Tinzaparin Sodium)			C				Not Reported
	Trombyl (Acetylsalicylic Acid) (Acetylsalicylic Acid)			C				Not Reported
	Artelac (Hypromellose) (Hypromellose)			C				Not Reported
	Zopiclone Actavis (Zolpiclone) (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2010	8538811	EXPEDITED (15-DAY)	Y	HO	1000017131		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sphincter Of Oddi Dysfunction	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	15 Mg (15 Mg,1 In 1 D),Oral		Not Reported
	Imitrex (Sumatriptan Succinate) (Sumatriptan Succinate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2010	7521888	EXPEDITED (15-DAY)	Y	CA, DE, OT	1000015053			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Presentation; Foetal Death; Hypoxic-Ischaemic Encephalopathy; Maternal Drugs Affecting Foetus; Thrombosis; Umbilical Cord Abnormality	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg,1 In 1 D),Transplacental		Not Reported
	Sertraline Hydrochloride			S	Transplacental	100 Mg (100 Mg,1 In 1 D),Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2010	7659833	EXPEDITED (15-DAY)	Y	HO	CH-ASTRAZENECA-2010SE51641		73 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia	Nexium			S	Oral			Astrazeneca
	Cordarone			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Diphenhydramine Hydrochloride\Lorazepam			C				Not Reported
	Crestor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2010	7690961	EXPEDITED (15-DAY)	Y	OT	1000015684		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Haemorrhage In Pregnancy; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2010	7661955	EXPEDITED (15-DAY)	Y	DE	US-WATSON-2010-14485		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Coma; Long Qt Syndrome; Torsade De Pointes	Fluoxetine			S	Unknown	Unk		Watson
	Trazodone Hydrochloride			S	Oral	Unk		Watson
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2010	7693625	EXPEDITED (15-DAY)	Y	HO	1000017098			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Albumin Increased; Caesarean Section; Gestational Hypertension; Maternal Exposure During Pregnancy; Pre-Eclampsia; Pregnancy; Premature Labour	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D) ,Oral		Not Reported
	Tegretol			S	Oral	200 Mg (200 Mg, 1in 1 D), Oral		Not Reported
	Tranxene T-Tab			S	Oral	15 Mg (15mg, 1in 1 D), Oral		Not Reported
	Cyamemazine			S	Oral	90 Mg (90 Mg, 1in 1 D), Oral		Not Reported
	Haldol			S	Oral	5 Mg (5 Mg, 1in 1 D), Oral		Not Reported
	Abilify (Arip Iprazole) (Aripiprazole)			C				Not Reported

	Folic Acid (Folic Acid) (Folic Acid)			C						Not Reported
	Aldomet			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2010	7745401	EXPEDITED (15-DAY)	Y	HO, LT	1000017099		< 1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Apparent Death; Caesarean Section; Foetal Distress Syndrome; Foetal Heart Rate Disorder; Jaundice Neonatal; Maternal Drugs Affecting Foetus; Neonatal Respiratory Distress Syndrome	Escitalopram Oxalate			S	Oral Oral	5 Mg (5 Mg, 1 In 1 D) ,Oral 5 Mg (5 Mg, 1 In 1 D) ,Oral		Not Reported
	Tegretol			S	Transplacental	200 Mg (200 Mg, 1 N 1 D), Transplacental		Not Reported
	Tranxene T-Tab			S	Transplacental	15 Mg (15 Mg, 1in 1 D),Transplacental		Not Reported
	Cyamemazine			S	Transplacental	90 Mg (90 Mg, 1 In 1 D), Transplacental		Not Reported
	Haldol			S	Oral	5 Mg (5 Mg, 1in 1 D), Transplacental		Not Reported
	Abilify (Arip Iprazole) (Aripiprazole)			C				Not Reported
	Folic Acid (Folic Acid) (Folic Acid)			C				Not Reported
	Aldomet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2010	8268293	NON-EXPEDITED	N		US-KINGPHARMUSA00001-K200801316		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased; Hypoaesthesia; Mydriasis; Panic Attack; Paraesthesia	Skelaxin			S		Unk		King
	Lexapro			S	Oral	10 Mg, Single	1 DAY	Not Reported
	Lexapro			S	Oral	5 Mg, Qd	2 DAY	Not Reported
	Allegra-D			S		Unk		Not Reported
	Unspecified Ingredient			S	Nasal	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2010	7662980	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2010SA066542		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatitis; Lipase Increased; Pancreatitis Acute	Plavix			S	Oral			Not Reported
	Perindopril			S	Oral		3 WEEK	Not Reported
	Tahor			S	Oral		10 WEEK	Not Reported
	Amitriptyline			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral		10 WEEK	Not Reported
	Lioresal			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2010	7663104	EXPEDITED (15-DAY)	N	CA	A0890306A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoacusis; Maternal Exposure During Pregnancy	Lamictal			S				Glaxosmithkline
	Wellbutrin Xl			S		300mg Per Day		Glaxosmithkline
	Lexapro			S		20mg Per Day		Not Reported
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2010	7696453	EXPEDITED (15-DAY)	Y	HO, LT	1000017174		63 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level Above Therapeutic; Antidepressant Drug Level Below Therapeutic; Depressed Level Of Consciousness; Muscle Rigidity; Rhabdomyolysis; Tremor	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Olanzapine			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lithium			S		900 Mg (900 Mg, 1 In 1 D)		Not Reported
	Lorazepam			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported

	Lanzoprazol (Lanzoprazol) (Lanzoprazol)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2010	7696554	EXPEDITED (15-DAY)	Y	RI, OT	1000017157		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Palpitations; Supraventricular Tachycardia; Troponin I Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 Mg In 1 D), Oral		Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2010	7693633	DIRECT	Y				17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Rash Pruritic	Abilify			S	Oral	2 Mg Q Qm Po		Not Reported
	Lexapro			S	Oral	10 Mg Q Am Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2010	7354689	NON-EXPEDITED	N		US-KINGPHARMUSA00001-K200901555			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bladder Discomfort; Malaise; Sleep Disorder	Skelaxin			S		Unk		King
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2010	7657169	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2010137804		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biliary Cyst; Cholestasis; Faecaloma; Hepatitis;	Tahor			S	Oral	10 Mg, 1x/Day	72 DAY	Pfizer

Pancreatitis Acute	Perindopril Erbumine	S	Oral	5 Mg, 1x/Day	25 DAY	Not Reported
	Plavix	S	Oral	75 Mg, 1x/Day		Not Reported
	Amitriptyline Hydrochloride	S	Oral	25 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate	S	Oral	15 Mg, 1x/Day	71 DAY	Not Reported
	Lioresal	S		2 Df, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2010	7665964	EXPEDITED (15-DAY)	N	CA, HO, OT	US-TEVA-254108USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Grunting; Lethargy; Patent Ductus Arteriosus; Persistent Foetal Circulation; Respiratory Distress; Sepsis	Paroxetine Hydrochloride			S	Transplacental			Teva
	Sertraline Hydrochloride			S	Transplacental			Not Reported
	Fluoxetine Hydrochloride			S	Transplacental			Not Reported
	Venlafaxine			S	Transplacental			Not Reported
	Escitalopram Oxalate			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2010	7666516	EXPEDITED (15-DAY)	Y	OT	IE-MYLANLABS-2010S1020320		26 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Supraventricular Tachycardia	Escitalopram Oxalate			S	Unknown			Alphapharm
	Herbal Nos			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2010	7702697	EXPEDITED (15-DAY)	Y	DS	1000017201		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase	Escitalopram Oxalate			S				Not Reported
	Voltaren			C				Not Reported

Increased; Myalgia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2010	7702857	EXPEDITED (15-DAY)	Y	HO	1000017191		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Loss Of Consciousness; Malaise	Escitalopram Oxalate			S	Oral	0.5 Df (0.5 Dosage Forms,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	1 Df (1 Dosage Forms,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2010	7704192	EXPEDITED (15-DAY)	Y	CA	DSA_44277_2010			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Hypoacusis; Maternal Drugs Affecting Foetus	Wellbutrin Xl			S	Transplacental	(300 Mg Qd Transplacental)		Not Reported
	Lamictal			S	Transplacental	(Df Transplacental)		Not Reported
	Lexapro			S	Transplacental	(20 Mg Qd Transplacental)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2010	7748000	EXPEDITED (15-DAY)	Y	HO	1000017192		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cardiac Failure; Iron Deficiency Anaemia	Escitalopram Oxalate			S	Oral	(15 Mg),Oral		Not Reported
	Acenocoumarol			S	Oral	Oral		Not Reported
	Alendronic Acid			S	Oral	10 Mg (70 Mg,1 In 1 Wk),Oral		Not Reported
	Durogesic			C				Not Reported
	Lyrica (Pregabalin) (Tablets) (Pregabalin)			C				Not Reported
	Orfidal (Lorazepam) (Tablets) (Lorazepam)			C				Not Reported

	Motilium (Domperidone) (Tablets) (Domperidone)	C		Not Reported
	Movicol	C		Not Reported
	Almax Comprimidos Masticables (Almagate) (Chewable Tablet) (Almagate)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2010	7653073	EXPEDITED (15-DAY)	N	HO, OT	US-BAYER-201038418NA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dehydration; Ejection Fraction Decreased; Hallucination; Hyperhidrosis; Hypotension; Influenza Like Illness; Migraine; Serotonin Syndrome	Betaseron			S	Subcutaneous	Total Daily Dose: 3 Mg	6 MTH	Bayer
	Avonex			C				Not Reported
	Lexapro			S				Not Reported
	Effexor Xr			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2010	7701736	EXPEDITED (15-DAY)	Y	HO	1000017222		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2010	7636710	EXPEDITED (15-DAY)	Y	HO, LT, OT	DE-ABBOTT-10P-062-0678483-00		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Intentional Overdose; Loss Of Consciousness; Respiratory Depression; Suicide Attempt	Clarithromycin			S	Oral	Overdose: 3000mg(Single Dosage),6 In 1 D		Not Reported
	Escitalopram Oxalate			S	Oral	Unknown Single Dosage		Not Reported
	Paracetamol			S	Oral	Overdose: 8000mg(Single		Not Reported

				Dosage),16 In 1d	
	Ibuprofen	S	Oral	Overdose: 8000-12000 Mg (Single Dosage)	Not Reported
	Bromazepam	S	Oral	Overdose: 180mg(Single Dosage),30 In 1d	Not Reported
	Alcohol	S		Overdose:Unknown Amount(1.4 Per Mille)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2010	7670446	EXPEDITED (15-DAY)	Y	HO, LT	GB-PERRIGO-10GB014738		87 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Naproxen Sodium			S	Oral	250 Mg, Tid		Perrigo
	Aspirin			S	Oral	75 Mg, Qd		Perrigo
	Cipralex			S	Oral	15 Mg, Qd		Not Reported
	Omeprazole			C	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2010	7670944	EXPEDITED (15-DAY)	Y	HO, OT	US-ROXANE LABORATORIES, INC.-2010-RO-01490RO		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Ileus; Overdose; Serotonin Syndrome	Lithium Carbonate			S				Roxane
	Risperidone			S				Roxane
	Midazolam			S	Intravenous (not otherwise specified)	5 Mg		Roxane
	Morphine			S	Intravenous (not otherwise specified)			Roxane
	Diazepam			S	Oral			Roxane
	Tramadol Hydrochloride			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Mirtazapine			S				Not Reported
	Fluoxetine			S				Not Reported

	Suxamethonium		S	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Cyproheptadine Hydrochloride		S		12 Mg	Not Reported
	Olanzapine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2010	7623428	EXPEDITED (15-DAY)	Y	HO	SE-BAXTER-2010BH023718		1 DAY	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abo Incompatibility; Agitation Neonatal; Maternal Drugs Affecting Foetus; Melaena; Necrotising Colitis; Off Label Use; Premature Baby	Gammagard Liquid			S	Intravenous (not otherwise specified)			Not Reported
	Gammagard Liquid			S	Intravenous (not otherwise specified)			Not Reported
	Cipralex			S	Intra-uterine			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2010	7652436	EXPEDITED (15-DAY)	Y	HO	1000016566		80 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrolyte Imbalance; Feeling Abnormal; Hypernatraemia; Hypokalaemia; Nausea; Rhabdomyolysis; Somnolence	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Hydrochlorothiazide			C				Not Reported
	Selokeen (Metoprolol Tartrate)			C				Not Reported
	Lorazepam			C				Not Reported
	Xalatan (Latanoprost) (Eye Drops)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2010	7672857	EXPEDITED (15-DAY)	Y	HO	BE-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2010-BL-00		71 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Varicose Vein; Venous Thrombosis Limb	Pradaxa		S	Oral	220 Mg	Boehringer Ingelheim
	Escitalopram Oxalate		S	Oral	10 Mg	Not Reported
	Dafalgan		C	Oral	4000 Mg	Not Reported
	Pravastatin Sodium		C	Oral	40 Mg	Not Reported
	Asaflow		C	Oral	80 Mg	Not Reported
	Otilonium Bromide		C	Oral	40 Mg	Not Reported
	Zantac		C	Oral	150 Mg	Not Reported
	Indapamide\Perindopril Erbumine		C	Oral	2 Mg	Not Reported
	Levothyroxine Sodium		C	Oral	50 Mcg	Not Reported
	Lorazepam		C	Oral	1 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2010	7713785	EXPEDITED (15-DAY)	Y	HO	1000017242		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Erythema	Nebivolol Hydrochloride			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Iron\Minerals\Vitamins			S	Oral	Oral		Not Reported
	Amiodarone Hydrochloride			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Lasix			S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
	Omeprazole			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	Subcutaneous		Not Reported
	Kepra (Levetiracetam)			C				Not Reported
	Normase (Lactulose)			C				Not Reported
	Dexamethasone Sodium Phosphate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2010	7673498	EXPEDITED (15-DAY)	Y	HO	GB-TEVA-255386ISR		87 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Naproxen			S				Teva
	Acetylsalicylic Acid			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2010	7702701	EXPEDITED (15-DAY)	Y	HO	1000017077		63 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Cholestasis; Faecaloma; Hepatitis; Pancreatitis Acute	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Perindopril			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Plavix			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Atorvastatin Calcium			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Amitriptyline Hydrochloride			S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
	Lioresal			S	Oral	60 Mg (20 Mg, 3 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2010	7714380	EXPEDITED (15-DAY)	Y	LT, OT	1000017320		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metrorrhagia	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Sedoxil (Mexazolam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2010	7717377	EXPEDITED (15-DAY)	Y	HO	1000017301		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Haematemesis; Headache; Nausea	Escitalopram Oxalate			S		5 Mg (5 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2010	7654377	EXPEDITED (15-DAY)	N	DE, OT	1000016561		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Cardiomegaly; Completed Suicide; Left Ventricular Hypertrophy; Nephrosclerosis; Pneumoconiosis; Pulmonary Congestion; Self-Medication; Toxicity To Various Agents; Visceral Congestion	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		
	Xanax			S	Oral	1 Mg (1 Mg, 1 In 1 D), Oral		Not Reported
	Saphris			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Vicodin			S	Oral			Not Reported
	Triamterene (Triamterene) (Triamterene)			C				Not Reported
	Atacand (Candesartan) (Candesartan)			C				Not Reported
	Simvastatin			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2010	7676191	NON-EXPEDITED	N		A0879073A		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth	Wellbutrin Sr			S	Oral	100mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported

	Elavil	C	Oral	5mg As Required		Glaxosmithkline
	Valium	C	Oral	2.6mg As Required		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2010	7690850	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000017070			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psychiatric Evaluation Abnormal; Suicide Attempt	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Analgesic Medications Nos (Analgesics (Analgesics)			C				Not Reported
	Temesta (Lorazepam) (Lorazepam)			C				Not Reported
	Effexor Lp (Venlafaxine Hydrochloride) (Venlafaxine Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2010	7717260	EXPEDITED (15-DAY)	Y	RI, OT	1000017333			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Maternal Drugs Affecting Foetus; Premature Baby	Lexapro			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported
	Abilify			S	Transplacental	30 Mg (30 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2010	7717277	EXPEDITED (15-DAY)	Y	HO	1000017331		93 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Dyspnoea; Malaise; Nausea; Seizure	Lexapro			S	Oral	2.5 Mg (2.5 Mg, 1 In 1 D), Oral		Not Reported
	Pantoprazole (Antoprazole)			C				Not Reported

	Cranberry (Vaccinium)	C		Not Reported
	Perindopril (Perindopril) (Perindopril)	C		Not Reported
	Prochlorperazine Maleate (Prochlorperazine Maleate) (Prochlorperazine Maleate)	C		Not Reported
	Temazepam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2010	7754136	EXPEDITED (15-DAY)	Y	RI, OT	1000017321		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Decreased; Osteonecrosis; Tooth Extraction	Lexapro			S	Oral	Oral		Not Reported
	Effexor Xr			S	Oral	75 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2010	7377183	EXPEDITED (15-DAY)	Y	RI, OT	1000013334		30 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Decreased Appetite; Dizziness; Headache; Pain In Extremity; Sedation; Somnolence	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Insulin Nos (Insulin Nos) (Insulin Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2010	7527650	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2010SA045342		89 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Lichenoid Keratosis; Prurigo	Xatral			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Aerius (Desloratadine)			S	Oral			Not Reported
	Spironolactone			S	Oral			Not Reported

	Escitalopram Oxalate	S	Oral		Not Reported
	Atarax	S	Oral		Not Reported
	Pantoprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2010	7539891	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2010100890		89 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lichenoid Keratosis; Prurigo; Rash; Toxic Skin Eruption	Atarax			S	Oral	Unk		Pfizer
	Spironolactone			S	Oral	Unk		Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Aerius (Desloratadine)			S	Oral	Unk		Not Reported
	Xatral			S	Oral	Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Pantoprazole			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2010	7677984	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2010SA067985		92 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Prurigo; Toxic Skin Eruption	Xatral			S	Oral		3 YR	Not Reported
	Aspirin			S	Oral		3 YR	Not Reported
	Nitrofurantoin			S	Oral		14 DAY	Not Reported
	Pantoprazole			S	Oral		4 MTH	Not Reported
	Escitalopram Oxalate			S	Oral		1 YR	Not Reported
	Spironolactone			S	Oral		2 YR	Not Reported
	Bactrim Forte			S	Oral		11 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2010	7722407	DIRECT	Y	HO, LT, RI			17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	10mg Qd Po		Not Reported
	Wellbutrin			S	Oral	150 Qd Po		Not Reported
	Adderall Xr			S		15mg Qd	18 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2010	7722568	DIRECT	Y	LT, OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Overdose	Lexapro			S		25 Mg. 1x Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2010	7722728	EXPEDITED (15-DAY)	Y	HO	1000017393		67 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Neutrophil Count Increased	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Alprazolam (Alprazolam)			S	Oral	Oral		Not Reported
	Fenofibrate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2010	7498310	EXPEDITED (15-DAY)	Y	RI, OT	1000014945			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metrorrhagia; Overdose	Escitalopram Oxalate			S	Oral	25 Mg (25 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Tavor (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2010	7679864	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20101105032			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Levaquin			S	Unknown			Not Reported
	Toviaz			S	Unknown			Not Reported
	Xanax			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2010	7680078	EXPEDITED (15-DAY)	N	DE, OT	CH-BAYER-201047514GPV		80 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastric Ulcer Haemorrhage; Gastric Ulcer Perforation; Melaena; Peritonitis; Sepsis	Aspirin Cardio			S	Oral	Total Daily Dose: 100 Mg		Bayer
	Olfen [Diclofenac Sodium]			S	Oral			Not Reported
	Cipralex			S				Not Reported
	Sortis			C	Oral			Not Reported
	Stilnox			C	Oral			Not Reported
	Levothyroxine Sodium			C	Oral			Not Reported
	Beloc-Zok			C	Oral			Not Reported
	Ramipril			C	Oral			Not Reported
	Norvasc			C	Oral			Not Reported
	Torem			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2010	7680422	EXPEDITED (15-DAY)	N	HO	A0894413A		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Depression; Drug Ineffective; Fatigue;	Wellbutrin			S	Oral			Glaxosmithkline

Knee Arthroplasty; Somnolence; Suicidal Behaviour	Zoloft		S	Oral	100mg Unknown	Not Reported
	Lexapro		S	Oral	30mgd Per Day	Not Reported
	Cymbalta		S	Oral	60mg Per Day	Not Reported
	Methadone Hydrochloride		C			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2010	7680523	EXPEDITED (15-DAY)	Y	HO, LT	FR-ROCHE-743107		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Toxicity To Various Agents	Rivotril			S	Oral	Strength: 2.5 Mg/Ml. Solution In Drop. Taken In The Evening		Roche
	Escitalopram Oxalate			S	Unknown	Taken In The Evening		Not Reported
	Dafalgan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2010	7680752	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-10P-056-0686450-00		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Fenofibrate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2010	7681308	EXPEDITED (15-DAY)	Y	HO, LT	GB-MYLANLABS-2010S1021053		87 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Naproxen			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2010	7724367	EXPEDITED (15-DAY)	Y	DS, LT, OT	2010SP059735		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Loss Of Personal Independence In Daily Activities; Product Administration Error; Product Prescribing Error; Serum Serotonin Increased; Speech Disorder	Remeron			S	Oral	7.5 Mg;Qd;Po		Not Reported
	Imitrex			S	Oral	25 Mg;Prn;Po ; 25 Mg;Qd;Po		Not Reported
					Oral	25 Mg;Prn;Po ; 25 Mg;Qd;Po		
	Lexapro			S	Oral	20 Mg;Qd;Po		Not Reported
	Trazodone Hydrochloride			S	Oral	50 Mg;Qd;Po		Not Reported
	Risperdal			S	Oral	.25 Mg;Po		Not Reported
	Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2010	7724638	EXPEDITED (15-DAY)	Y	RI, OT	1000017353		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Fall; Hypotension; Parkinsonism; Syncope	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Taxilan (Perazine)			S	Oral	400 Mg (400 Mg,1 In 1 D),Oral ; 350 Mg (350 Mg,1 In 1 D),Oral		Not Reported
					Oral	400 Mg (400 Mg,1 In 1 D),Oral ; 350 Mg (350 Mg,1 In 1 D),Oral		
	Haldol			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
	Haldol			S	Oral	0.5 Mg (0.5 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2010	7748484	EXPEDITED (15-DAY)	Y	DE, HO, RI, OT	2010AP002315		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Cardiac Arrest; Coma; Long Qt Syndrome; Nervous System Disorder; Sinus Tachycardia; Ventricular Fibrillation	Fluoxetine Hydrochloride			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Buspirone			S				Not Reported
	Temazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2010	7239707	EXPEDITED (15-DAY)	Y	RI, OT	1000010858		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelofibrosis; Thrombocytopenia	Escitalopram Oxalate			S		1 Df (1 Dosage Forms, 1 In 1 D)		Not Reported
	Risperidon (Risperidone) (Tablets) (Risperidone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2010	7566226	EXPEDITED (15-DAY)	Y	HO	1000015672		92 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lichenoid Keratosis; Prurigo; Toxic Skin Eruption	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Desloratadine			S	Oral	Oral		Not Reported
	Alfuzosin Hydrochloride			S	Oral	5 Mg (2.5 Mg,2 In 1 D),Oral		Not Reported
	Kardegic (Acetylsalicylate Lysine)			S	Oral	75 Mg (75 Mg,1 In 1),Oral		Not Reported
	Spironolactone			S	Oral	(1 In 1 D),Oral		Not Reported
	Atarax			S	Oral	Oral		Not Reported
	Pantoprazole Sodium			S	Oral	20 Mg (20 Mg,1 In 1		Not Reported

					D),Oral	
	Furadantine		S		100 Mg (50 Mg,2 In 1 D)	Not Reported
	Bactrim Forte		S	Oral	1 Df (1 Dosage Forms, 1 In 1 D),Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2010	7662935	EXPEDITED (15-DAY)	Y	HO, LT	1000016673		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Ventricular Arrhythmia	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lamotrigine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2010	7670573	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2010144796		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Malaise; Seizure	Atarax			S	Oral	25 Mg, 3x/Day	57 DAY	Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Theralene			S	Oral	15 Mg, Unk	43 DAY	Not Reported
	Dihydroergotamine Mesylate			S	Oral	Unk	31 DAY	Not Reported
	Mianserin Hydrochloride			S	Oral	30 Mg, 2x/Day		Not Reported
	Pipamperone			S	Oral	90 Mg, 1x/Day	102 DAY	Not Reported
	Equanil			S	Oral	400 Mg, 4x/Day		Not Reported
	Aceprometazine\Meprobamate			S	Oral	1 Df, 1x/Day	43 DAY	Not Reported
	Seretide			C		1 Unit, 2x/Day		Not Reported
	Ditropan			C		5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2010	7670896	EXPEDITED (15-DAY)	Y	HO, LT, OT	1000016837		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acidosis; Intentional Overdose; Loss Of Consciousness; Respiratory Depression; Suicide Attempt	Escitalopram Oxalate		S	Oral	Single Dosage,Oral	Not Reported
	Bromazepam		S	Oral	(180 Mg,Once),Oral	Not Reported
	Ibuprofen		S	Oral	8000-12000 Mg (Once),Oral	Not Reported
	Clarithromycin		S	Oral	(3000 Mg,Once),Oral	Not Reported
	Acetaminophen		S	Oral	(8000 Mg,Once),Oral	Not Reported
	Alcohol (Ethanol)		S	Oral	Unknown Single Amount (1.4 Per Mille),Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2010	7727858	EXPEDITED (15-DAY)	Y	RI, OT	1000017404			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Diarrhoea	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Antihypertensives (Antihypertensives) (Antihypertensives)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2010	7736850	EXPEDITED (15-DAY)	Y	OT	1000017400			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Headache; Photophobia	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2010	7736851	EXPEDITED (15-DAY)	Y	RI, OT	1000017399		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2010	7736872	EXPEDITED (15-DAY)	Y	RI, OT	1000017386		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Escitalopram Oxalate			S				Not Reported
	Levothyrox (Levothyroxine Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2010	7736905	EXPEDITED (15-DAY)	Y	RI, OT	1000017414		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Malaise; Muscle Spasms; Nausea	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolam			C				Not Reported
	Diane 35 (Diane)			C				Not Reported
	Oroperidys (Domperidone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2010	7491391	EXPEDITED (15-DAY)	Y	HO, OT	2010SP036628		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Hepatitis; Hypomania; Logorrhoea; Major Depression; Tachyphrenia	Mirtazapine			S	Oral Oral	Po Po		Not Reported
	Escitalopram Oxalate			S		10 Mg Bid, Po; 10 Mg, Bid Po; 5 Mg Qd Po; 10 Mg Bid, Po; 10 Mg, Bid Po; 5 Mg Qd Po; 10 Mg Bid, Po; 10 Mg, Bid Po; 5 Mg Qd Po;		Not Reported
	Fenofibrate			S	Oral	Po		Not Reported
	Teralithe			C				Not Reported
	Seresta			C				Not Reported
	Largactil			C				Not Reported

	Imovane	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2010	7693984	EXPEDITED (15-DAY)	Y	RI, OT	1000017068		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Ineffective; Unevaluable Event	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2010	7702839	EXPEDITED (15-DAY)	Y	HO	1000017083		76 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Trimeprazine Tartrate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Dihydroergotamine Mesylate			S	Oral	Oral		Not Reported
	Atarax			S	Oral	75 Mg (25 Mg, 3 In 1 D), Oral		Not Reported
	Mianserin Hydrochloride			S	Oral	60 Mg (20 Mg, 2 In 1 D), Oral		Not Reported
	Pipamperone Hydrochloride			S	Oral	90 Mg (90 Mg, 1 In 1 D), Oral		Not Reported
	Equanil			S	Oral	1600 Mg (400 Mg, 4 In 1 D), Oral		Not Reported
	Equanil			S	Oral	1200 Mg (400 Mg, 3 In 1 D), Oral		Not Reported
	Aceprometazine\Meprobamate			S	Oral	1 Dosage Form (1 Dosage Forms 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			C				Not Reported
	Trimeprazine Tartrate			C				Not Reported
	Ikaran (Dihydroergotamine			C				Not Reported

Mesilate)			
Atarax (Hydroxizine)	C		Not Reported
Athylmil (Mianserin Hydrochloride)	C		Not Reported
Dipiperon (Pipamperone Hydrochloride)	C		Not Reported
Equanil	C		Not Reported
Aceprometazine\Meprobamate	C		Not Reported
Seretide	C		Not Reported
Ditropan (Oxybutynin) (Tablets) (Oxybutynin)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2010	7723221	EXPEDITED (15-DAY)	Y	HO, LT	1000017438		87 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Traumatic Intracranial Haemorrhage	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin (Acetylsalicylic Acid)			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Naproxen (Naproxen)			S	Oral	750 Mg (250 Mg, 3 In 1 D), Oral		Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2010	7723291	EXPEDITED (15-DAY)	Y	HO	1000017432		83 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Bleeding; Hypocoagulable State; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	1 Dosage Form (1 Dosage, Forms, 1 In 1 D), Oral		Not Reported
	Coumadin			S	Oral	(1 Dosage Forms, As Required), Oral		Not Reported
	Allopurinol			C				Not Reported
	Esopral (Esomeprazole) (Esomeprazole)			C				Not Reported

	Aspirin			C						Not Reported
	Rytmonorm (Propafenone) (Propafenone)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2010	7733410	EXPEDITED (15-DAY)	Y	DE	1000017441			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2010	7733431	EXPEDITED (15-DAY)	N	HO, RI, OT	1000017337		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
	Diltiazem (Diltiazem Hydrochloride) (Diltiazem Hydrochloride)			C				Not Reported
	Simvastatin			C				Not Reported
	Zyrtec (Cetirizine) (10 Milligram, Tablets) (Cetirizine)			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2010	7733445	EXPEDITED (15-DAY)	Y	RI, OT	1000017390			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Lexapro			S				Not Reported
	Toviaz			S				Not Reported
	Xanax			S				Not Reported
	Levaquin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2010	7673741	EXPEDITED (15-DAY)	Y	OT	DE-JNJFOC-20101102433		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hypotension; Parkinsonism; Syncope; Vertigo	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Taxilan (Perazine)			S	Oral			Not Reported
	Taxilan (Perazine)			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2010	7685107	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20101106647			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breakthrough Pain; Confusional State; Encephalopathy	Fentanyl			S	Transdermal			Not Reported
	Xanax			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2010	7739942	EXPEDITED (15-DAY)	Y	HO, LT	GER/UKI/10/0016626		87 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Fall	Naproxen (Naproxen)			S	Oral	250 Mg, 3 In 1 D, Oral		Not Reported
	Aspirin (Acetylsalicylic Acid)			S	Oral	75 Mg, 1 In 1 D, Oral		Not Reported

	Cipralex		S	Oral	15 Mg, 1 In 1 D, Oral	Not Reported
	Omeprazole		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2010	7687630	NON-EXPEDITED	N	OT	US-PFIZER INC-2010153602		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Drug Interaction; Pain	Lyrica			S	Oral	100mg		Pfizer
	Lyrica			S				Pfizer
	Lexapro			S	Oral	60 Mg, Unk		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2010	7674606	EXPEDITED (15-DAY)	Y	RI, OT	1000016960		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2010	7741241	EXPEDITED (15-DAY)	N	RI, OT	1000017498		40 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abnormal Dreams; Arthralgia; Asthenia; Blood Sodium Decreased; Confusional State; Depersonalisation/Dereali sation Disorder; Depression; Diarrhoea; Dry Mouth; Erectile Dysfunction; Fall; Fatigue; Heart Rate Decreased; Hyperhidrosis; Hypotonia;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Deniban (Amisulpride) (Amisulpride)			C				Not Reported
	Esilgan (Estazolam) (Estazolam)			C				Not Reported
	Realsil (Realsil) (Realsil)			C				Not Reported

Liver Function Test Abnormal; Malaise; Myalgia; Pain; Product Dispensing Error; Somnolence; Tremor; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2010	7741606	EXPEDITED (15-DAY)	N	DE	1000017495			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Lexapro			S	Oral	(1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2010	7741655	EXPEDITED (15-DAY)	Y	RI, OT	1000017481		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2010	7637178	EXPEDITED (15-DAY)	Y	DS, OT	GB-RANBAXY-2010R1-38864		47 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Condition Aggravated; Hyperreflexia; Hypertonia; Panic Attack; Phobia; Tachycardia; Tremor	Fluoxetine			S	Oral	20 Mg, Unk	10 DAY	Ranbaxy
	Fluoxetine			S				Ranbaxy
	Escitalopram Oxalate			S	Oral	10 Mg, Unk	9 DAY	Not Reported
	Escitalopram Oxalate			S				Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Citalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2010	7689439	EXPEDITED (15-DAY)	Y	HO	FR-RANBAXY-2010RR-39754		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Fenofibrate			S	Oral	Unk		Ranbaxy
	Alprazolam			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2010	7733158	EXPEDITED (15-DAY)	Y	HO, LT	TIF2010A00131		63 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Muscle Rigidity; Rhabdomyolysis; Tremor	Cipralex			S	Oral	15 Mg (10 Mg) Oral	33 DAY	Not Reported
	Olanzapine (Olanzapine)			S	Oral	10 Mg (10 Mg,1 In 1 D) Oral	64 DAY	Not Reported
	Bisoprolol			S		1.25 Mg (1.25 Mg)		Not Reported
	Lansoprazole (Lansoprazole)			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2010	7742865	EXPEDITED (15-DAY)	Y	HO	1000016978		33 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2010	7742867	EXPEDITED (15-DAY)	Y	DS	1000017507		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lipoedema	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Carmen (Lercanidipine) (Lercanidipine)			C				Not Reported

	Amiloretik (Amiloride, Hydrochlorothiazide) (Amiloride, Hydrochlorothiazide)			C						Not Reported
	Hormongel (Estradiol) (Estradiol)			C						Not Reported
	Doxepin (Doxepin) (Doxepin)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2010	7742882	EXPEDITED (15-DAY)	Y	HO	1000017502		76 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akinesia; Confusional State; Iatrogenic Injury; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg,1 In 1 D),Oral		Not Reported
	Oxazepam			S	Oral	20 Mg (10 Mg,2 In 1 D),Oral		Not Reported
	Zolpidem Tartrate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Furosemde (Furosemide)			C				Not Reported
	Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine)			C				Not Reported
	Atorvastatin Calcium			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2010	7743061	DIRECT	N	HO			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dissociative Amnesia; Loss Of Consciousness; Mania	Lexapro			S	Oral	10 Mg Once Per Day Oral, Pill		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2010	7504309	EXPEDITED (15-DAY)	Y	HO	1000014968		66 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hepatitis; Hypomania; Logorrhoea; Major Depression; Tachyphrenia	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg,2 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg,2 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Fenofibrate			S	Oral	Oral		Not Reported
	Mirtazapine			S	Oral	Oral		Not Reported
	Mirtazapine			S	Oral	Oral		Not Reported
	Imovane (Zopiclone) (Zopiclone)			C				Not Reported
	Largactil (Chlorpromazine) (Chlorpromazine)			C				Not Reported
	Seresta (Oxazepam) (Oxazepam)			C				Not Reported
	Teralithe (Lithium Carbonate) (Lithium Carbonate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2010	7691629	NON-EXPEDITED	N		US-PFIZER INC-2010161286			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective	Pristiq Extended Release			S		100 Mg, 1x/Day		Pfizer
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2010	7743895	EXPEDITED (15-DAY)	Y	HO, LT	1000017489		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Delirium; Depression; Poisoning Deliberate; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Clonazepam			S	Oral	15 Gtt (15 Gtt, 1 In 1 D), Oral		Not Reported

	Dafalgan (Paracetamol) (Paracetamol)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2010	7744411	EXPEDITED (15-DAY)	Y	DS, OT	2010MA004769		47 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Condition Aggravated; Hypertonia; Panic Attack; Phobia; Reflexes Abnormal; Serotonin Syndrome; Tachycardia	Fluoxetine			S	Oral	20 Mg; Po		Alphapharm
	Escitalopram Oxalate			S	Oral	10 Mg; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2010	7723817	EXPEDITED (15-DAY)	Y	HO	1000017463		45 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Metabolic Acidosis; Renal Failure; Respiratory Failure; Rhabdomyolysis; Serotonin Syndrome	Escitalopram Oxalate			S				Not Reported
	Methylene Blue			S				Not Reported
	Fentanyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2010	7729238	EXPEDITED (15-DAY)	Y	DS, OT	AUR-APL-2010-02547		47 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Condition Aggravated; Hyperreflexia; Hypertonia; Panic Attack; Phobia; Serotonin Syndrome; Tachycardia	Fluoxetine			S	Oral	20mg-Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10mg-Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2010	7743755	EXPEDITED (15-DAY)	N	CA	1000017521		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Multiple Congenital Abnormalities; Neonatal Respiratory Distress Syndrome; Patent Ductus Arteriosus; Persistent Foetal Circulation; Sepsis Neonatal	Lexapro			S	Transplacental	Transplacental		Not Reported
	Paxil			S	Transplacental	Transplacental		Not Reported
	Zoloft			S	Transplacental	Transplacental		Not Reported
	Prozac			S	Transplacental	Transplacental		Not Reported
	Effexor			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2010	7723061	EXPEDITED (15-DAY)	Y	HO, LT	2010MA004567		87 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Fall	Naproxen			S	Oral	250 Mg; Tid; Po		Purepac
	Acetylsalicylic Acid (Acetylsalicylic Acid)			S	Oral	75 Mg; Qd; Po		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg; Qd; Po		Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2010	7756360	DIRECT					36 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Akathisia; Anger	Lexapro			S	Oral	10mg Daily Po		Forest
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2010	7696492	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000017134		28 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Bipolar Disorder; Condition Aggravated; Depression; Generalised Anxiety Disorder; Mania; Mental Disorder; Post-Traumatic Stress Disorder; Social Anxiety Disorder; Suicidal Ideation	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
	Lamotrigin (Lamotrigine) (Tablets) (Lamotrigine)			C				Not Reported
	Lithionit (Lithium Sulfate) (Tablets) (Lithium Sulfate)			C				Not Reported
	Sobril (Oxazepam) (Tablets) (Oxazepam)			C				Not Reported
	Atarax (Hydroxyzine) (Tablets) (Hydroxyzine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2010	7736907	EXPEDITED (15-DAY)	Y	HO	1000017383		1 DAY	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Haematochezia; Irritable Bowel Syndrome; Maternal Drugs Affecting Foetus; Melaena; Necrotising Colitis; Premature Baby	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2010	7703184	EXPEDITED (15-DAY)	Y	HO	DE-SANOFI-AVENTIS-2010SA034202		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis	Plavix			S	Oral			Not Reported
	Remergil			C	Oral			Not Reported
	Remergil			C	Oral			Not Reported

	Dalteparin Sodium	C	Oral		Not Reported
	Simvastatin	C	Oral		Not Reported
	Metoprolol	C	Oral		Not Reported
	Acetylsalicylic Acid	S	Oral		Not Reported
	Escitalopram Oxalate	S	Oral		Not Reported
	Escitalopram Oxalate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2010	7703555	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20101202533			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Somnolence; Suicidal Ideation; Weight Increased	Invega			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2010	7703741	EXPEDITED (15-DAY)	N	OT	US-BAYER-2010-003121		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Dry Mouth; Urinary Tract Disorder; Vision Blurred	Acetylsalicylic Acid		Y	S		Unk Unk, Q1mon		Bayer
	Fesoterodine			S	Oral	8 Mg, Unk	5 DAY	Not Reported
	Alprazolam			S		Unk Unk, Prn		Not Reported
	Simvastatin			S		Unk Unk, Q1mon		Not Reported
	Lexapro			S				Not Reported
	Seroquel			S		Unk Unk, Q1mon		Not Reported
	Fish Oil			S		Unk Unk, Q1mon		Bayer
	Vitamin D2 (Ergocalciferol)			S		Unk Unk, Q1mon		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2010	7748719	EXPEDITED (15-DAY)	Y	RI, OT	1000017565		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ocular Hypertension; Vision Blurred	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D) Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2010	7567132	EXPEDITED (15-DAY)	Y	RI, OT	1000015705		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Glucose Decreased; Erectile Dysfunction; Loss Of Libido; Polydipsia; Polyuria; Thirst	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D, Oral		Not Reported
	Temesta (Lorazepam) (Lorazepam)			C				Not Reported
	Stilnox (Zolpidem) (Tablets) (Zolpidem)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2010	7749099	EXPEDITED (15-DAY)	N	RI, OT	1000017596			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Suicidal Ideation; Thinking Abnormal	Escitalopram Oxalate			S	Oral Oral Oral	See Image: Oral See Image: Oral See Image: Oral	1 WEEK 1 WEEK	Not Reported
	Insulin Nos			C				Not Reported
	Altace			C				Not Reported
	Chemotherapy			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2010	6362231	EXPEDITED (15-DAY)	Y	RI, OT	S07-GER-02887-01		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Agitation; Alcoholism; Depression; Disease Recurrence; Nervousness; Panic Disorder; Restlessness; Sleep Disorder; Suicidal Ideation; Tension;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Trimipramine Maleate			S	Oral Oral	100 Mg (100 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D),Oral 100 Mg (100 Mg, 1 In 1 D),		Not Reported

Withdrawal Syndrome							Oral; 75 Mg (75 Mg, 1 In 1 D),Oral			
	Bisoprolol Fumarate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2010	7755028	EXPEDITED (15-DAY)	Y	HO, LT	IPC201012-000313		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activated Partial Thromboplastin Time Prolonged; Anaemia; Arrhythmia; Blood Glucose Increased; Cardiac Failure; Continuous Haemodiafiltration; Heart Rate Decreased; Hepatic Failure; International Normalised Ratio Increased; Lactic Acidosis; Leukocytosis; Liver Injury; Neutrophilia; Pancreatitis; Pleural Effusion; Polydipsia; Polyuria; Prothrombin Time Prolonged; Renal Failure; Thrombocytopenia	Metformin Hydrochloride			S		850 Mg 3 Times Daily	2 WEEK	Not Reported
	Acenocoumarol			S				Not Reported
	Bisoprolol			S				Not Reported
	Torsemide			S				Not Reported
	Digoxin			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Lormetazepam			S				Not Reported
	Terbutaline Sulfate			S				Not Reported
	Tiotropium Bromide			S				Not Reported
	Insulin Glargine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7198579	EXPEDITED (15-DAY)	Y	OT	DK-PFIZER INC-2009280745			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Dizziness; Fatigue	Lyrica			S		300 Mg, 2x/Day	1156 DAY	Pfizer
	Cipralex			S		Unk		Not Reported
	Bendroflumethiazide			S		Unk		Not Reported
	Amitriptyline			C		50 Mg, 1x/Day		Not Reported
	Morphine			C		10 Mg, As Needed		Not Reported

Gabapentin	C	1200 Mg, 3x/Day		Not Reported
Tramadol	C	200 Mg, 2x/Day		Not Reported
Ammonium Bromide\Caffeine\Phenobarbital\ Phenytoin\Sodium Bromide	C	300 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7222984	EXPEDITED (15-DAY)	Y	HO	ES-PFIZER INC-2009309733		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction	Lyrica			S	Oral	75 Mg, 1x/Day		Pfizer
	Omeprazole			C	Oral	20 Mg, 1x/Day		Not Reported
	Nitrendipine			C	Oral	20 Mg, 1x/Day		Not Reported
	Tramadol Hydrochloride And Acetaminophen			S	Oral	Unk	4 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported
	Diazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7339797	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010026726		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Ineffective; Fibromyalgia; General Physical Condition Abnormal; Insomnia; Mania; Micturition Frequency Decreased; Neuralgia; Oedema Peripheral; Pain In Extremity; Suicidal Ideation; Thyroid Disorder; Weight Increased	Lyrica			S		50 Mg, 3x/Day		Pfizer
	Lyrica			S	Oral	Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Lithium			S	Oral	Unk		Not Reported
	Elavil			S	Oral	Unk		Not Reported
	Clonazepam			C		1 Mg, Unk		Not Reported
	Klonopin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7342698	EXPEDITED (15-DAY)	Y	OT	GB-PFIZER INC-2010036118			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy Of Partner	Pregabalin			S	Other	Unk		Pfizer
	Trazodone			S	Other	Unk		Not Reported
	Cipralex			S	Other	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7387232	EXPEDITED (15-DAY)	Y	HO	ES-PFIZER INC-2010050324		77 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Lyrica			S	Oral	150 Mg, 1x/Day	12 DAY	Pfizer
	Ciprofloxacin			C	Oral	500 Mg, 1x/Day	9 DAY	Not Reported
	Trazodone			C	Oral	Unk		Not Reported
	Captopril			C	Oral	50 Mg, 1x/Day		Not Reported
	Amoxicillin & Clavulanate Potassium			C	Oral	Unk		Not Reported
	Cipralex			S	Oral	15 Mg, 1x/Day	12 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7407576	EXPEDITED (15-DAY)	Y	HO, OT	DK-PFIZER INC-2010063884		31 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Rhabdomyolysis; Urinary Retention	Lyrica			S	Oral	75 Mg, 2x/Day	7 DAY	Pfizer
	Cipralex			S		20 Mg, 1x/Day	13 DAY	Not Reported
	Oxycontin			S	Oral	10 Mg, 2x/Day		Not Reported
	Tramadol			S	Oral	100 Mg, 4x/Day	391 DAY	Not Reported
	Seroquel			S	Oral	100 Mg, 1x/Day	3 DAY	Not Reported
	Seroquel			S	Oral	100 Mg, 1x/Day	170 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7414848	EXPEDITED (15-DAY)	Y	OT	CH-PFIZER INC-2010067812		19 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion; Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy	Lyrica			S		200 Mg, 1x/Day		Pfizer
	Lyrica			S		125 Mg, 1x/Day	9 DAY	Pfizer
	Neurontin			S		200 Mg, 1x/Day	41 DAY	Pfizer
	Cipralex			S		2 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7454553	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2007014600		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Bladder Disorder; Eye Pain; Vision Blurred; Visual Impairment; Weight Increased	Lyrica			S		50 Mg, 3x/Day		Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7487741	EXPEDITED (15-DAY)	Y	HO	DE-PFIZER INC-2010084293		59 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hepatitis; Jaundice	Lyrica			S		50 Mg, 3x/Day		Pfizer
	Cipralex			S		20/0/0 (Units Not Provided)	20 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7617187	EXPEDITED (15-DAY)	Y	OT	1000016228		91 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Disturbance In Attention; Fatigue	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine)		C			Not Reported
	Corvasal (Molsidomine)		C			Not Reported
	Crestor (Rousvastatin) Rosusvastatin)		C			Not Reported
	Fosavance (Alendronate Sodium, Colecalciferol) (Alendronate Sodium), Colecalciferol)		C			Not Reported
	Vastarel		C			Not Reported
	Xatrel (Alfusion) (Alfusion)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7712462	EXPEDITED (15-DAY)	N	OT	US-PURDUE-USA-2010-0058201		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Detoxification; Intentional Product Misuse; Lethargy; Overdose; Pain; Somnolence	Oxycontin			S		80 Mg, See Text		Purdue
	Morphine Sulfate			S		Unk Unk, See Text		Purdue
	Diazepam			S		Unk Unk, See Text		Not Reported
	Vicodin Es			S		Unk Unk, See Text		Not Reported
	Soma			S		Unk Unk, See Text		Not Reported
	Parafon Forte			S		Unk Unk, See Text		Not Reported
	Zanaflex			S		Unk Unk, See Text		Not Reported
	Klonopin			S		Unk Unk, See Text		Not Reported
	Ativan			S		Unk Unk, See Text		Not Reported
	Phenergan			S		Unk Unk, See Text		Not Reported
	Lexapro			S		Unk Unk, See Text		Not Reported
	Relafen			S		Unk Unk, See Text		Not Reported
	Neurontin			S		Unk Unk, See Text		Not Reported
	Lidoderm			S		Unk Unk, See Text		Not Reported
	Morphine Sulfate			C		Unk Unk, See Text		Not Reported

	Reglan	C	Unk Unk, See Text	Not Reported
	Morphine Sulfate	C	Unk Unk, See Text	Purdue
	Lovastatin	C	Unk, See Text	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2010	7777335	EXPEDITED (15-DAY)	Y	HO	100017301		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Dysaesthesia; Haematemesis; Headache; Malaise; Nausea; Vomiting	Escitalopram Oxalate			S	Oral	5 Mg, (5mg, 1 In 1 D),Oral		Not Reported
	Advil			S	Oral	200 T0 800 Mg, Oral		Not Reported
	Seresta (Ocazepam) (Tablets) (Oxazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2010	7463048	EXPEDITED (15-DAY)	N	HO	FR-ABBOTT-10P-056-0654575-00		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypomania	Lipanthyl			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Lithium Carbonate			C	Oral			Not Reported
	Oxazepam			C	Oral			Not Reported
	Chlorpromazine\Chlorpromazine Hydrochloride			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2010	7759388	EXPEDITED (15-DAY)	Y	HO	1000017691		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Condition Aggravated; Drug Withdrawal Syndrome; Intentional Overdose; Treatment Noncompliance	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Bromazepam			S		(150 Mg, Once) (150 Mg, Once)		Not Reported
	Risperidone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2010	7759393	EXPEDITED (15-DAY)	Y	HO	1000017682		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Drug Interaction; Hallucination; Incoherent; Nervous System Disorder; Tremor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Topalgic [Tramadol Hydrochloride]			S		200 Mg (100 Mg, 2 In 1 D)		Not Reported
	Sinemet Lp (Carbidopa, Levodopa) (25 Milligram, Tablets) (Carbidopa, Levodopa)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2010	7759833	EXPEDITED (15-DAY)	Y	HO	1000017713		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning Deliberate; Somnolence	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Oxazepam			S	Oral	Oral		Not Reported
	Abilify			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2010	7760193	EXPEDITED (15-DAY)	Y	RI, OT	1000017660		18 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Drug Abuse	Escitalopram Oxalate			S	Oral	10 Mg, Once, Oral		Not Reported

	Fluoxetine		S	Oral	1 Dosage Forms, Once, Oral	Not Reported
	Alcohol (Ethanol)		S	Oral	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2010	7790582	EXPEDITED (15-DAY)	Y	RI, OT	1000017646		19 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Alcohol Use; Drug Abuse	Escitalopram Oxalate			S	Oral	10 Mg Once, Oral		Not Reported
	Fluoxetine			S	Oral	1 Dosage Forms, Once, Oral		Not Reported
	Alcohol (Ethanol)			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2010	7723121	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2010173852		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Detoxification; Intentional Product Misuse; Lethargy; Overdose; Pain; Somnolence	Neurontin			S		600 Mg, (12 Pills)		Pfizer
	Morphine Sulfate			S		20 Mg/Ml		Unknown
	Oxycontin			S		80 Mg, Unk		Not Reported
	Diazepam			S		10 Mg, Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Soma			S		350 Mg, Unk		Not Reported
	Parafon Forte			S		Unk		Not Reported
	Zanaflex			S		4 Mg, Unk		Not Reported
	Klonopin			S		1 Mg, Unk		Not Reported
	Ativan			S		1 Mg, Unk		Not Reported
	Promethazine			S		Unk		Not Reported
	Lexapro			S		40 Mg, Unk		Not Reported
	Relafen			S		750 Mg, Unk		Not Reported

	Lidoderm	S	5 %	Not Reported
	Morphine Sulfate	C	Unk	Not Reported
	Reglan	C	10 Mg, Unk	Not Reported
	Msir	C	Unk	Not Reported
	Lovastatin	C	20 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2010	7619521	EXPEDITED (15-DAY)	Y	RI, OT	1000016319		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Personality Change	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Anxiolytics (Anxiolytics) (Anxiolytics)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2010	7753188	EXPEDITED (15-DAY)	Y	OT	2010SP062320		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Oedema Peripheral	Saphris			S	Sublingual	20 Mg; Hs; Sl		Not Reported
	Wellbutrin			S				Not Reported
	Lexapro			S				Not Reported
	Maxzide			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2010	7764961	EXPEDITED (15-DAY)	Y	RI, OT	1000017734			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Hypersensitivity; Tubulointerstitial Nephritis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Inexium (Esomeprazole Magnesium)			S				Not Reported
	Lexomil (Bromazepam)			C				Not Reported

(Bromazepam)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2010	7766111	DIRECT	N	HO			19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Balance Disorder; Confusional State; Overdose; Physical Assault; Suicidal Ideation	Lexapro			S	Oral	15mg Every Day Po		Walgreen
	Geodon			S	Oral	40mg Every Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2010	7794836	EXPEDITED (15-DAY)	Y	OT	AE-1210-401		44 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Lethargy; Overdose; Pain; Somnolence	Lidoderm			S				Not Reported
	Oxycontin			S		80 Mg		Not Reported
	Morphine Sulfate			S				Not Reported
	Diazepam			S				Not Reported
	Vicodin Es			S				Not Reported
	Soma			S				Not Reported
	Parafon Forte			S				Not Reported
	Zanaflex			S				Not Reported
	Klonopin			S				Not Reported
	Ativan			S				Not Reported
	Phenergan			S				Not Reported
	Lexapro			S				Not Reported
	Relafen			S				Not Reported
	Neurontin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2010	7629976	EXPEDITED (15-DAY)	Y	OT	1000016392		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Insomnia;	Escitalopram Oxalate			S		2.5 Mg (2.5 Mg, 1 In 1 D)		Not Reported

Logorrhoea; Paradoxical Drug Reaction	Escitalopram Oxalate	S	10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Levothyroxine Sodium	C			Not Reported
	Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine)	C			Not Reported
	Microval (Levonorgestrel) (Levonorgestrel)	C			Not Reported
	Myolastan (Tetrazepam) (Tetrazepam)	C			Not Reported
	Inexium (Esomeprazole Magnesium)	C			Not Reported
	Tramadol Hydrochloride And Acetaminophen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2010	7727985	EXPEDITED (15-DAY)	Y	HO, OT	FI-ASTRAZENECA-2010SE38024			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Leukopenia; Potentiating Drug Interaction; Psychotic Disorder	Seroquel			S	Oral			Zeneca
	Abilify			C				Not Reported
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2010	7730043	NON-EXPEDITED	N		US-PFIZER INC-2010176017		12 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejaculation Delayed	Zoloft			S	Oral	Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2010	7731189	EXPEDITED (15-DAY)	Y	HO	IN-MYLANLABS-2010S1022934		23 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dystonia; Temporomandibular Joint Syndrome	Escitalopram Oxalate			S	Unknown			Alphapharm
	Clonazepam			C	Unknown			Not Reported
	Aripiprazole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2010	7765225	EXPEDITED (15-DAY)		LT	1000017780			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2010	7765942	EXPEDITED (15-DAY)		OT	ACO_20790_2010		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Feeling Abnormal; Hemiparesis; Inappropriate Schedule Of Product Administration; Multiple Sclerosis; Vision Blurred	Ampyra			S	Oral	10 Mg, Qd, Oral, 10 Mg, Bid, Oral,		Not Reported
					Oral	10 Mg, Qd, Oral, 10 Mg, Bid, Oral,		
	Lexapro			S				Not Reported
	Valium /00017001/ (Diazepam)			C				Not Reported
	Antihypertensives			C				Not Reported
	Copaxone /03175301/ (Glatiramer Acetate, Mannitol			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2010	4170801	EXPEDITED (15-DAY)	Y	DS, RI, OT	S04-TUR-02785-01		38 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Corneal Opacity	Cipralex			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

	Sleeping Pills (Sleeping Pills) (Sleeping Pills)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2010	7676787	EXPEDITED (15-DAY)	N	RI, OT	1000016976		45 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Cataract Subcapsular; Dry Mouth; Fatigue; Glucose Tolerance Test Abnormal; Pollakiuria; Polydipsia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Supradyn (Supradyn) (Supradyn)			C				Not Reported
	Lansor (Lansoprazole) (Lansoprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2010	7766926	EXPEDITED (15-DAY)	Y	RI, OT	1000017582		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Agitation; Crying; Depersonalisation/Dereali sation Disorder; Discomfort; Disturbance In Attention; Dizziness; Drug Withdrawal Syndrome; Headache; Hyperhidrosis; Hypoaesthesia; Influenza Like Illness; Irritability; Muscle Tightness; Nausea; Overdose; Paraesthesia; Salivary Hypersecretion; Suicidal Ideation; Vertigo	Lexapro			S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Cymbalta			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported
	Propranolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2010	7768223	DIRECT	N	HO			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Loss Of Consciousness; Malaise; Nausea	Lexapro			S	Oral	5 Mg 1 Time Only Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2010	7768356	DIRECT		OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Balance Disorder; Decreased Appetite; Diarrhoea; Nausea; Urticaria; Vertigo; Vomiting	Lexapro			S	Oral	10 Mg Once Daily Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2010	7682181	EXPEDITED (15-DAY)	Y	HO	1000016997		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2010	7740337	EXPEDITED (15-DAY)	N	HO	IN-BRISTOL-MYERS SQUIBB COMPANY-15451370		23 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Joint Dislocation; Salivary Hypersecretion; Sedation	Clonazepam			S				Sandoz
	Aripiprazole			S				Not Reported
	Aripiprazole			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2010	7759853	EXPEDITED (15-DAY)	Y	HO	1000017714		52 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clavicle Fracture; Dizziness; Fall; Fatigue; Gastrointestinal Disorder; Generalised Tonic-Clonic Seizure; Somnolence; Spinal Column Injury; Temporal Lobe Epilepsy	Escitalopram Oxalate			S		15 Mg (15 Mg, 1 In 1 D)		Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2010	7766140	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000017833		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Sounds Abnormal; Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Tavor (Lorazepam)			S	Oral	50 Mg, Once, Oral		Not Reported
	Diazepam			S	Oral	250 Mg, Once, Oral		Not Reported
	Seroquel			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2010	7766764	EXPEDITED (15-DAY)	Y	RI, OT	1000017803			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2010	7767675	EXPEDITED (15-DAY)	Y	HO, OT	20100556		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Post Procedural	Methylene Blue			S				Not Reported

Complication; Renal Failure; Serotonin Syndrome	Escitalopram Oxalate		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2010	7770465	DIRECT	N	HO, LT, RI			16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt; Visual Impairment	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2010	7799038	EXPEDITED (15-DAY)	N	DE	1000017830		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Chest Pain; Drug Abuse; Incorrect Route Of Product Administration; Loss Of Consciousness; Wrong Technique In Product Usage Process	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Soma			S	Oral	1000 Mg (250 Mg, 4 In 1 D), Oral		Not Reported
	Percocet			S	Oral	5/325 Mg Tablets, Oral		Not Reported
	Valium			S				Not Reported
	Fentora			S	Buccal	400 Mg (400 Mg, 1 In 1 D), Bu		Not Reported
	Fentanyl Transdermal System			S	Transdermal	Transdermal		Not Reported
	Zipsor			S	Oral	(25 Mg), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2010	8538826	EXPEDITED (15-DAY)	Y	RI, OT	1000017835			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Transient	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2010	7742655	EXPEDITED (15-DAY)	Y	HO	CH-ASTRAZENECA-2010SE60174		50 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Seroquel Xr			S	Oral			Astrazeneca
	Oxazepam			C	Oral			Not Reported
	Oxazepam			C	Oral			Not Reported
	Campral			C	Oral			Not Reported
	Magnesium Carbonate\Potassium Iodide			C	Oral			Not Reported
	Thiamine Hydrochloride			C	Oral			Not Reported
	Ferrous Sulfate			C	Oral			Not Reported
	Allopurinol			C	Oral			Not Reported
	Seroquel Xr			S	Oral	1-4 X 50 Mg/Day In Reserve		Astrazeneca
	Seroquel Xr			S	Oral			Astrazeneca
	Seroquel Xr			S	Oral			Astrazeneca
	Seroquel Xr			S	Oral			Astrazeneca
	Remeron			S	Oral			Not Reported
	Remeron			S	Oral			Not Reported
	Remeron			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2010	7772864	EXPEDITED (15-DAY)	Y	HO	2010SP065684		50 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Convulsive Threshold Lowered; Drug Interaction; Generalised Tonic-Clonic Seizure	Remeron			S	Oral Oral	15 Mg; Qd;Po, 30 Mg; Qd;Po, 45 Mg; Qd; Po 15 Mg; Qd;Po, 30 Mg; Qd;Po, 45 Mg; Qd; Po		Not Reported

			Oral	15 Mg; Qd;Po, 30 Mg; Qd;Po, 45 Mg; Qd; Po	
	Seroquel Xr	S	Oral	300 Mg; Qd; Po, 500 Mg; Qd; Po, 600 Mg; Qd; Po, 200 Mg; Qd	Not Reported
			Oral	300 Mg; Qd; Po, 500 Mg; Qd; Po, 600 Mg; Qd; Po, 200 Mg; Qd	
			Oral	300 Mg; Qd; Po, 500 Mg; Qd; Po, 600 Mg; Qd; Po, 200 Mg; Qd	
			Oral	300 Mg; Qd; Po, 500 Mg; Qd; Po, 600 Mg; Qd; Po, 200 Mg; Qd	
	Cipralex	S	Oral	20 Mg; Qd; Po	Not Reported
	Oxazepam	S	Oral	15 Mg; Qid; Po, 15 Mg; Bid; Po	Not Reported
			Oral	15 Mg; Qid; Po, 15 Mg; Bid; Po	
	Campral	C			Not Reported
	Becozyme (Pyridoxine Hydrochloride/Biotin/Cyanocobalamin/Riboflavin)	C			Not Reported
	Benerva	C			Not Reported
	Ferr0 Gradumet	C			Not Reported
	Zyloric	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2010	7772938	EXPEDITED (15-DAY)	Y	OT	2010SP066041		69 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Varicophlebitis	Remeron			S		15 Mg; Qd, 30 Mg; Qd 15 Mg; Qd, 30 Mg; Qd		Not Reported
	Cipralex			S	Oral	10 Mg; Po, 10 Mg		Not Reported
					Oral	10 Mg; Po, 10 Mg		
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2010	7792255	EXPEDITED (15-DAY)	Y	HO	1000017678		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea; Menstruation Irregular	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 N 1 D),Oral		Not Reported
	Escitalopram Oxalate			C	Oral	Oral		Not Reported
	Strattera (Atomoxetine Hydrochloride)(Tablets)(Atomoxetine Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2010	7359111	EXPEDITED (15-DAY)	Y	CA, RI, OT	1000012796		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Abnormal; Cardiac Murmur; Maternal Drugs Affecting Foetus; Premature Baby; Transposition Of The Great Vessels; Ventricular Septal Defect	Lexapro			S	Transplacental	Transplacental		Not Reported
	Modafinil			S	Transplacental	200 Mg (200 Mg, 1 In 1 D),Transplacental		Not Reported
	Levothyroxine (Levothyroxine Sodium)(Levothyroxine Sodium)			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Buspar (Buspirone Hydrochloride)(Buspirone Hydrochloride)			C				Not Reported
	Nasonex (Mometasone Furoate) (Mometasone Furoate)			C				Not Reported
	Ob Natal (Ob Natal) (Ob Natal)			C				Not Reported
	Xyrem (Oxybate Sodium) (Oxybate Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2010	7744447	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-10P-163-0693390-00		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Overdose	Vicodin Es	S			Not Reported
	Lexapro	S			Not Reported
	Neurontin	S			Not Reported
	Oxycontin	C			Not Reported
	Morphine Sulfate	C			Not Reported
	Diazepam	C			Not Reported
	Soma	C			Not Reported
	Parafon Forte	C			Not Reported
	Zanaflex	C			Not Reported
	Klonopin	C			Not Reported
	Ativan	C			Not Reported
	Phenergan	C			Not Reported
	Lexapro	C			Not Reported
	Relafen	C			Not Reported
	Lidoderm	C	Patch		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2010	7771661	EXPEDITED (15-DAY)	N	DE	1000017884		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Depression	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2010	7388216	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2010056903		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Drug Ineffective; Insomnia; Meniscus Injury; Nausea; Panic Attack; Thoracic Vertebral Fracture; Thyroid Disorder	Celebrex			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Lexapro			S		20 Mg, 1x/Day		Not Reported
	Cymbalta			S		Unk		Not Reported
	Seroquel			S		600 Mg, 1x/Day		Not Reported
	Seroquel			S				Not Reported
	Tegretol			C		Unk		Not Reported

Lopresor	C	50 Mg, 2x/Day		Not Reported
Neurontin	C	300 Mg, 3x/Day		Not Reported
Glucophage	C	850 Mg, 2x/Day		Not Reported
Prilosec	C	20 Mg, 1x/Day		Not Reported
Dichloralphenazone\Isomethepte ne Mucate	C	Unk		Not Reported
Lorcet	C	10mg/650mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2011	6953712	EXPEDITED (15-DAY)	Y	HO	1000005134		89 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Acute Kidney Injury; Band Neutrophil Count Increased; Cheilitis; Inflammation; Leukocytosis; Lymphadenopathy; Rash	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Tetrazepam (Tetrazepam) (Tablets) (Tetrazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2011	7580319	EXPEDITED (15-DAY)	Y	RI, OT	1000015872		42 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Fatigue; Hypoaesthesia; Insomnia; Pollakiuria; Speech Disorder; Syncope; Thyroid Function Test Abnormal	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral; 25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
					Oral	30 Mg (30 Mg, 1 In 1 D), Oral; 25 Mg (25 Mg, 1 In 1 D), Oral		
					Oral	30 Mg (30 Mg, 1 In 1 D), Oral; 25 Mg (25 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D),		Not Reported

					Oral	Oral; 20 Mg (20 Mg, 1 In 1 D), Oral 15 Mg (15 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral				

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2011	7746856	EXPEDITED (15-DAY)	Y	HO, OT	CH-JNJFOC-20101208167		85 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Disorientation; Dysphagia; Gait Disturbance; General Physical Health Deterioration; Hypercalcaemia; Parkinsonism; Salivary Hypersecretion; Somnolence	Risperdal			S	Oral			Not Reported
	Calcimagon-D3			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown	Augmentation 5mg And 10mg		Not Reported
	Aspirin Cardio			C				Not Reported
	Fosamax			C	Oral			Not Reported
	Fluorometholone			C	Ophthalmic			Not Reported
	Omeprazole			C				Not Reported
	Perindopril Erbumine			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Dafalgan			C				Not Reported
	Magnesium Aspartate			C				Not Reported
	Unknown Medication			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2011	7774475	EXPEDITED (15-DAY)	Y	RI, OT	1000017915		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose	Escitalopram Oxalate			S	Oral	(60 Mg,Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2011	7774650	EXPEDITED (15-DAY)	Y	RI, OT	1000017921		86 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activated Partial Thromboplastin Time Prolonged; Haematuria; International Normalised Ratio Increased; Phimosis; Pulmonary Embolism; Urinary Tract Infection	Escitalopram Oxalate			S				Not Reported
	Fluindione			S	Oral	1 Dosage Form (1 Dosage Forms,1 In 1 D), Oral		Not Reported
	Fluindione			S	Oral	0.75 Dosage Form (0.75 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Lovenox			S	Subcutaneous	12000 Iu (6000 Iu,2 In 1 D),Subcutaneous, Subcutaneous		Not Reported
	Vastarel			C				Not Reported
	Tarka (Trandolapril, Verapamil) (Trandolapril, Verapamil)			C				Not Reported
	Lipanthyl (Fenofibrate) (Fenofibrate)			C				Not Reported
	Allopurinol			C				Not Reported
	Piascledine (Glycine Max Seed Oil, Persea Americana Oil)(Glycine Max Seed Oil, Persea Americana Oil)			C				Not Reported
	Chibro-Proscar (Finasteride) (Finasteride)			C				Not Reported
	Omexel (Tamsulosin Hydrochloride) (Tamsulosin Hydrochloride)			C				Not Reported
	Temesta (Lorazepam) (Lorazepam)			C				Not Reported
	Laroxyl (Amitriptyline Hydrochloride)(Amitriptyline Hydrochloride)			C				Not Reported
	Dafalgan (Paracetamol) (Paracetamol)			C				Not Reported
	Duphalac (Lactulose) (Lactulose)			C				Not Reported
	Peristaltine (Rhamnus Purshiana			C				Not Reported

Dry Extract) (Rhamnus Purshiana Dry Extract)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2011	7774710	EXPEDITED (15-DAY)	Y	RI, OT	1000017949		83 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Alopecia; Decreased Appetite; Dizziness; Dysgeusia; Insomnia; Lip Swelling; Myalgia; Optic Nerve Disorder; Oropharyngeal Blistering; Pruritus; Rash; Rhinorrhoea; Swollen Tongue; Weight Decreased	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2011	7550069	EXPEDITED (15-DAY)	Y	HO	IT-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2010-DE-04		68 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Peritoneal Disorder; Pyrexia	Telmisartan			S	Oral	80 Mg		Boehringer Ingelheim
	Cipralex			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2011	7747752	EXPEDITED (15-DAY)	Y	HO, OT	IN-ROXANE LABORATORIES, INC.-2010-RO-01730RO		62 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Dependence	Zolpidem			S		10 Mg		Roxane
	Zolpidem			S		40 Mg		Roxane
	Zolpidem			S				Roxane

	Escitalopram Oxalate	S	10 Mg		Not Reported
	Domperidone Maleate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2011	7748032	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2011SE00052		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Quetiapine			S	Oral			Zeneca
	Escitalopram Oxalate			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2011	7766498	EXPEDITED (15-DAY)	Y	RI, OT	1000011597			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Labour; Maternal Exposure During Pregnancy; Pregnancy; Prolonged Labour; Vacuum Extractor Delivery; Vaginal Perforation	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2011	7342962	EXPEDITED (15-DAY)	N	CA	US-ABBOTT-10P-163-0634234-00		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Maternal Exposure During Pregnancy; Transposition Of The Great Vessels; Ventricular Septal Defect	Lexapro			S	Transplacental			Not Reported
	Provigil			S	Transplacental			Not Reported
	Levothyroxine			C	Transplacental			Not Reported
	Metformin Hydrochloride			C	Transplacental			Not Reported

	Buspar	C	Transplacental		Not Reported
	Nasonex	C	Transplacental		Not Reported
	Ob Natal	C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2011	7747060	EXPEDITED (15-DAY)	Y	HO, OT	AU-ASTRAZENECA-2010SE54938		< 1 DAY	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal	Seroquel Xr			S	Transplacental	50 Mg Daily Started Pre-Pregnancy Stopped At 39/40 Weeks		Not Reported
	Lamotrigine			S	Transplacental	200 Mg Daily Started At 11/40 Week		Not Reported
	Lexapro			S	Transplacental	10 Mg Daily Started Pre-Pregnancy Stopped At 10/40 Week		Not Reported
	Valproate Sodium			S	Transplacental	1000 Mg Daily Started Pre-Pregnancy Stopped At 10/40 Week		Not Reported
	Ferrous Sulfate\Folic Acid			C	Transplacental	1 Tablet Daily From The First Trimester		Not Reported
	Ferrous Sulfate\Folic Acid			C	Transplacental	1 Tablet Daily From The First Trimester		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2011	7749342	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2011SE00267		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Quetiapine			S	Oral			Zeneca
	Metoprolol			S	Oral			Not Reported
	Duloxetine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

	Metoclopramide			S	Oral					Not Reported
	Clonazepam			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2011	7749381	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2011SE00275		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lisinopril			S	Oral			Zeneca
	Venlafaxine			S	Oral			Not Reported
	Cocaine			S	Oral			Not Reported
	Diphenhydramine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2011	7777527	EXPEDITED (15-DAY)	Y	RI, OT	1000017938		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Intraocular Pressure Increased	Escitalopram Oxalate			S				Not Reported
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2011	7777628	EXPEDITED (15-DAY)	Y	HO	1000017960		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Generalised Tonic-Clonic Seizure; Head Injury; Loss Of Consciousness	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Remeron			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral		Not Reported

				Oral	15 Mg (15 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral	
				Oral	15 Mg (15 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral	
	Seroquel Xr		S	Oral	See Image	Not Reported
				Oral	See Image	
				Oral	See Image	
				Oral	See Image	
	Anxiolit (Oxazepam) (Oxazepam)		C			Not Reported
	Acamprosate Calcium		C			Not Reported
	Becozyme (B-Complex) (B-Complex)		C			Not Reported
	Benerva (Thiamine Hydrochloride) (Thiamine Hydrochloride)		C			Not Reported
	Ferro Gradumet (Ferrous Sulfate) (Ferrous Sulfate)		C			Not Reported
	Allopurinol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2011	7777718	EXPEDITED (15-DAY)	Y	HO, LT	1000017961		81 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased; Intraventricular Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Phenprocoumon			S	Oral	Oral		Not Reported
	Sortis (Atorvastatin) (Atorvastatin)			C				Not Reported
	Coversum Combi (Bi Predonium) (Bi Predonium)			C				Not Reported
	Mephanol-100 (Allopurinol) (Allopurinol)			C				Not Reported
	Pradif (Tamsulosin Hydrochloride) (Tamsulosin			C				Not Reported

Hydrochloride)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2011	7777744	EXPEDITED (15-DAY)	Y	RI, OT	1000017962		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Overdose; Premature Menopause	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Mirena			S	Intra-uterine	(52 Mg), Intrauterine		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2011	7790027	EXPEDITED (15-DAY)	Y	CA, DS, HO	1000017906		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Withdrawal Syndrome; Macrosomia; Maternal Drugs Affecting Foetus; Overdose; Serotonin Syndrome; Talipes; Toxicity To Various Agents	Escitalopram Oxalate			S	Transplacental	40 Mg (40 Mg, 1 In 1 D), Transplacental		Not Reported
	Zyprexa			S	Transplacental	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Transplacental		Not Reported
	Depakote			S	Transplacental	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2011	7742699	EXPEDITED (15-DAY)	Y	DE, HO	1000017513		80 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arrhythmia; Atrial Fibrillation; Blood Loss Anaemia; Candida Infection; Cardiac Failure; Gastric Ulcer Haemorrhage; Gastric	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
	Olfen (Diclofenac Sodium)			S	Oral	150 Mg (75 Mg,2 In 1 D), Oral		Not Reported
	Aspirin			S	Oral	100 Mg (100mg,1 In 1 D), Oral		Not Reported

Ulcer Perforation; General Physical Health Deterioration; Melaena; Peritonitis; Procalcitonin Increased; Respiratory Failure; Sepsis	Sortis (Atorvastatin) (Tablets0 (Atorvastatin)		C		Not Reported
	Stilnox (Zolpidem) (Tabelts) (Zolpidem)		C		Not Reported
	Eltroxin (Levothyroxine Sodium) (Tablets) (Levothyroxine Sodium)		C		Not Reported
	Belco Zok (Metoprolol Succinate) (Tablets) (Metoprolol Succinate)		C		Not Reported
	Ramipril (Ramipril) (Tablets) (Ramipril)		C		Not Reported
	Norvasc (Amlodipine Besilate) (Tablets) (Amlodipine Besilate)		C		Not Reported
	Torem (Torasemide) (Tablets) (Torasemide)		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2011	7749975	EXPEDITED (15-DAY)	Y	OT	CH-BAYER-2010-007653		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Premature Menopause	Mirena			S	Intra-uterine	Unk	2141 DAY	Bayer
	Cipralex			S	Oral	Daily Dose 40 Mg		Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2011	7750536	EXPEDITED (15-DAY)	N	HO	B0691140A		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Coma; Hypotension; Hypothermia; Mydriasis; Rhabdomyolysis; Toxicity To Various Agents	Valacyclovir Hydrochloride			S	Unknown		1 DAY	Glaxosmithkline
	Aceprometazine Maleate\Meprobamate			S	Unknown	39tab Per Day	1 DAY	Unknown
	Zopiclone			S	Unknown	42tab Per Day	1 DAY	Unknown
	Inexium			S			1 DAY	Unknown
	Escitalopram Oxalate			S			1 DAY	Unknown

Depakote	S		1 DAY	Unknown
Tiapride	S		1 DAY	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2011	7750766	EXPEDITED (15-DAY)	Y	CA, DS, HO	FR-ABBOTT-10P-056-0694228-00			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macrosomia; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Overdose; Serotonin Syndrome; Talipes; Toxicity To Various Agents; Withdrawal Syndrome	Depakote			S	Transplacental			Not Reported
	Escitalopram Oxalate			S	Transplacental			Not Reported
	Zyprexa			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2011	7790733	EXPEDITED (15-DAY)	N	CA	1000018004		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Multiple Congenital Abnormalities; Patent Ductus Arteriosus; Ventricular Septal Defect	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2011	7792227	EXPEDITED (15-DAY)	Y	LT	1000018040		55 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Insomnia; Nausea; Restlessness; Suicidal Ideation	Escitalopram Oxalate			S	Oral	2.5 Mg (2.5 Mg, 1 In 1 D), Oral;3.75 Mg (3.75 Mg, 1 In 1 D),Oral; 5 Mg (5 Mg, 1 In 1 D),Oral		Not Reported
					Oral	2.5 Mg (2.5 Mg, 1 In 1 D),		

				Oral	Oral;3.75 Mg (3.75 Mg, 1 In 1 D),Oral; 5 Mg (5 Mg, 1 In 1 D),Oral	
	Sobril (Oxazepam) (Oxazepam)		C			Not Reported
	Propavan (Propiomazine Maleate) (Tablets) (Propiomazine Maleate)		C	Oral	2.5 Mg (2.5 Mg, 1 In 1 D), Oral;3.75 Mg (3.75 Mg, 1 In 1 D),Oral; 5 Mg (5 Mg, 1 In 1 D),Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2011	7795699	DIRECT	N	HO			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2011	7796929	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Lexapro			S	Oral	5 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2011	7299597	EXPEDITED (15-DAY)	Y	HO	1000011593		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Fibrosis; Hepatitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
	Furadantin			S	Oral	21.4286 Mg (50 Mg, 3 In 1 Wk), Oral		Not Reported
	Ibuprofen			S		0.25 Dosage Form (0.5 Dosage Forms, 1 In 2 D)		Not Reported

	Acetaminophen	S		0.25 Dosage Form (0.5 Dosage Forms,1 In 2 D)	Not Reported
	Crestor	S	Oral	10 Mg (10 Mg,1 In 1 D),Oral	Not Reported
	Prorofan (Propofan, Caffeine, Dextropropoxyphene)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2011	7752835	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-11P-056-0694770-00		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Coma; Hypotension; Hypothermia; Intentional Overdose; Mydriasis; Rhabdomyolysis; Toxicity To Various Agents	Depakote			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Aceprometazine Maleate\Meprobamate			S	Oral	400 Mg Coated		Not Reported
	Zopiclone			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Zelitrex			S	Oral			Not Reported
	Tiapridal			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2011	7756748	EXPEDITED (15-DAY)	Y	HO	1000017760		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Ataxia; Chest Discomfort; Chills; Confusional State; Drug Interaction; Electrocardiogram St-T Change; Hyperhidrosis; Mydriasis; Serotonin Syndrome; Tremor	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D)		Not Reported
	Selegiline			S		5 Mg (5 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2011	7788304	EXPEDITED (15-DAY)	Y	HO	1000015832		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Peritonitis; Pyrexia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D),Oral		Not Reported
	Telmisartan			S	Oral	80 Mg (80 Mg,1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2011	7789871	EXPEDITED (15-DAY)	Y	HO	1000017992		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Coma; Hypotension; Hypothermia; Mydriasis; Oxygen Saturation Decreased; Rhabdomyolysis; Toxicity To Various Agents	Escitalopram Oxalate			S		(Once)		Not Reported
	Aceprometazine\Meprobamate			S		(39 Dosage Forms,Once)		Not Reported
	Zopiclone			S		(42 Dosage Forms, Once)		Not Reported
	Inexium (Esomeprazole Magnesium)			S		(Once)		Not Reported
	Depakote			S		(Once)		Not Reported
	Valacyclovir Hydrochloride			S		(Once)		Not Reported
	Tiapride			S		(Once)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2011	7795437	DIRECT	Y	OT			11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depressive Symptom; Product Quality Issue; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qhs Po		Forest
	Abilify			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2011	7324758	EXPEDITED (15-DAY)	N	HO, OT	US-ROCHE-687974		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Bronchitis; Constipation; Decreased Appetite; Dyspnoea; Exostosis; Haemorrhage; Infection; Nerve Injury; Obstruction; Oedema Peripheral; Vascular Stent Insertion; White Blood Cell Count Decreased	Peginterferon Alfa-2a			S	Unknown	Form: Pre-Filled Syringe;		Roche
	Peginterferon Alfa-2a			S	Unknown			Roche
	Peginterferon Alfa-2a			S	Unknown			Roche
	Peginterferon Alfa-2a			S	Unknown	Patient In Week 30 Of Treatment		Roche
	Peginterferon Alfa-2a			S	Unknown	Week 33		Roche
	Peginterferon Alfa-2a			S	Unknown	Week 55		Roche
	Ribavarin			S	Unknown	Note: Divided Doses; Patient Received Ribasphere And Ribavirin (Par)		Not Reported
	Ribavarin			S	Unknown	Dosage Reduced. In Divided Doses; Week 55		Not Reported
	Lexapro			S	Oral			Not Reported
	Lyrica			C				Not Reported
	Fluticasone			C				Not Reported
	Seretide			C				Not Reported
	Skelaxin			C				Not Reported
	Vitamin B12			C				Not Reported
	Combivent			C				Not Reported
	Oxycodone			C				Not Reported
	Lamotrigine			C		Frequency: At Bedtime		Not Reported
	Morphine			C				Not Reported
	Trazodone			C		Frequency: At Bed Time		Not Reported
	Lisinopril			C				Not Reported
	Promethazine			C				Not Reported
	Fentanyl Patch			C				Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2011	7753716	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2011002893		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Venlafaxine Hcl			S	Oral			Pfizer
	Lisinopril			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Cocaine			S				Not Reported
	Diphenhydramine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2011	7753717	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2011002383		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate			S				Not Reported
	Alprazolam			S				Pfizer
	Cyclobenzaprine			S				Not Reported
	Zolpidem			S				Not Reported
	Desogestrel/Ethinylestradiol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2011	7790538	EXPEDITED (15-DAY)	Y	HO	1000018041		73 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Somnolence; Suicide Attempt	Escitalopram Oxalate			S				Not Reported
	Diazepam			S		(5 Mg)		Not Reported
	Xanax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2011	7755326	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20110101571		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Cyclobenzaprine Hydrochloride		S	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Not Reported
	Zolpidem		S	Oral	Not Reported
	Alprazolam		S	Oral	Not Reported
	Desogestrel\Ethinyl Estradiol		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2011	7755359	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20110101661		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse; Toxicity To Various Agents	Cyclobenzaprine Hydrochloride			S	Oral			Not Reported
	Verapamil Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Doxepin			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2011	7755740	EXPEDITED (15-DAY)	N	OT	A0904404A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Suicidal Ideation	Wellbutrin			S	Oral			Glaxosmithkline
	Tikosyn			S	Unknown			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2011	7755937	EXPEDITED (15-DAY)	N	DE, OT	US-CEPHALON-2011000113		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Chest Pain; Drug Abuse; Product Prescribing Error	Fentora			S	Buccal			Not Reported
	Fentora			S				Not Reported

	Lexapro	S		176 DAY	Not Reported
	Soma	S			Not Reported
	Soma	S			Not Reported
	Percocet	S			Not Reported
	Percocet	S			Not Reported
	Valium	S			Not Reported
	Fentanyl	S	Transdermal		Not Reported
	Fentanyl	S			Not Reported
	Zipsor	S			Not Reported
	Zipsor	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2011	7793802	EXPEDITED (15-DAY)	Y	RI, OT	1000018078			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain; Intraocular Pressure Increased	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Teralithe (Lithium Carbonate) (Lithium Carbonate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2011	5837874	EXPEDITED (15-DAY)	Y	RI, OT	S05-USA-03295-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Lexapro			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Clozapine			S	Oral	300 Mg (300 Mg, 1 In 1 D), Oral		Not Reported
	Clozapine			S	Oral	50 Mg, (150 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2011	7756565	NON-EXPEDITED	N		US-PFIZER INC-2011005057			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Sweats	Pristiq Extended Release			S	Oral	50 Mg, 1x/Day		Pfizer
	Zoloft			S	Oral	20 Mg, 1x/Day		Pfizer
	Zoloft			S				Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2011	7756604	NON-EXPEDITED	N		US-PFIZER INC-2011005070			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Increased Appetite; Weight Increased	Pristiq Extended Release			S	Oral	Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2011	7756655	NON-EXPEDITED	N		US-PFIZER INC-2011004027		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Panic Attack	Pristiq Extended Release			S	Oral	50 Mg, 1x/Day		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2011	7800580	DIRECT	N	HO			14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Insomnia; Irritability; Suicidal Ideation; Weight	Lexapro			S	Oral	10 Mg Once Daily Po		Not Reported

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2011	7759520	EXPEDITED (15-DAY)	N	OT	US-ROCHE-752271		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cerebral Disorder; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Hypophagia; Insomnia; Post-Traumatic Stress Disorder; Product Dose Omission; Psychomotor Hyperactivity; Suffocation Feeling; Wrong Technique In Product Usage Process	Valium			S	Oral	At Night		Roche
	Effexor			S	Oral	Other Indication: Panic Disorder; Form: Prolonged Release Capsule		Not Reported
	Effexor			S	Oral	Dose Increased		Not Reported
	Effexor			S	Oral			Not Reported
	Prozac			S	Oral			Not Reported
	Prozac			S	Oral	Dose Decreased		Not Reported
	Prozac			S	Oral	Dose Decreased		Not Reported
	Zyprexa			S	Oral		2 DAY	Not Reported
	Lexapro			S	Oral			Not Reported
	Calcium			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Niacinamide			C				Not Reported
	Panthenol			C				Not Reported
	Retinol			C				Not Reported
	Riboflavin			C				Not Reported
	Thiamine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2011	7759532	EXPEDITED (15-DAY)	Y	DE, HO	US-ROCHE-752292		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Chest Pain; Loss Of Consciousness	Valium			S	Unknown			Roche
	Percocet			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

	Soma	S	Oral	Not Reported
	Fentora	S	Unknown	Not Reported
	Fentanyl	S	Transdermal	Not Reported
	Zipsor	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2011	7759592	EXPEDITED (15-DAY)	Y	DE	US-PAR PHARMACEUTICAL, INC-2011SCPR002470		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Verapamil Hydrochloride			S	Oral	Unk		Par
	Doxepin			S	Oral	Unk		Par
	Alprazolam			S	Oral	Unk		Par
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2011	7759887	EXPEDITED (15-DAY)	N	CA, HO	US-ABBOTT-11P-163-0695775-00		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Congenital Abnormalities; Patent Ductus Arteriosus; Ventricular Septal Defect	Lexapro			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2011	7794355	EXPEDITED (15-DAY)	N	DE, HO	2011010001		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Chest Pain; Incorrect Route Of Product Administration; Intentional	Soma			S	Oral	1000 Mg 9250 Mg, 4 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D),		Not Reported

Product Misuse; Loss Of Consciousness				Oral	
	Percocet	S	Oral	5/325 Mg, Oral	Not Reported
	Valium	S			Not Reported
	Fentora	S		400 Mg (400 Mg, 1 In 1 D)	Not Reported
	Fentanyl (Fentanyl)	S	Transdermal	Transdermal	Not Reported
	Zipsor	S	Oral	(25 Mg) , Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2011	7794668	EXPEDITED (15-DAY)	Y	HO	1000018070		86 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Interaction; Hypomagnesaemia; Hyponatraemia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Omeprazole			S	Oral	Oral		Not Reported
	Perindopril Erbumine			C				Not Reported
	Imovane (Zopiclone) (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2011	7795783	EXPEDITED (15-DAY)	Y	RI, OT	1000018096			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thermal Burn	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2011	7757951	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2011SE00390		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Coma; Hypotension; Hypothermia; Mydriasis; Rhabdomyolysis; Toxicity To Various Agents	Inexium			S	Oral		1 DAY	Not Reported
	Acepromet azine\Meprobamate			S	Oral	Intake Of 39 Tablets Once	1 DAY	Not Reported
	Zopiclone			S	Oral	Intake Of 42 Tablets Once	1 DAY	Not Reported
	Escitalopram Oxalate			S	Oral		1 DAY	Not Reported
	Depakote			S			1 DAY	Not Reported

	Tiapride		S	Oral	1 DAY	Not Reported
	Valacyclovir		S	Oral	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2011	7761748	EXPEDITED (15-DAY)	N	HO, OT	US-PFIZER INC-2011006758		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Bipolar Disorder; Breast Cancer; Depressed Mood; Drug Ineffective; Drug Interaction; Endometrial Hypertrophy; Thyroid Neoplasm	Zoloft			S				Pfizer
	Lexapro			S				Not Reported
	Tamoxifen Citrate			S				Not Reported
	Cymbalta			S				Not Reported
	Femara			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2011	7813935	EXPEDITED (15-DAY)	Y	OT	DSA_44637_2011			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Suicidal Ideation	Bupropion Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Tikosyn			S				Not Reported
	Lexapro			S		(Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2011	7763410	EXPEDITED (15-DAY)	Y	DE	US-PAR PHARMACEUTICAL, INC-2011SCPR002501		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Diazepam			S	Oral	Unk		Par
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Acetaminophen\Hydrocodone			S	Oral	Unk		Not Reported
	Morphine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2011	7763482	EXPEDITED (15-DAY)	N		US-JNJFOC-20101202625			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction; Somnolence	Invega			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2011	7775896	EXPEDITED (15-DAY)	Y	RI, OT	1000017909		46 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Lactate Dehydrogenase Increased; Gamma-Glutamyltransferase Increased; Hepatic Function Abnormal; Pancytopenia	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Fotemustine			S	Intravenous (not otherwise specified)	10/5 Ml, Intravenous (Not Otherwise Specified		Not Reported
	Acetaminophen			S	Oral	3000 Mg (1000 Mg, 3in 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2011	7799568	EXPEDITED (15-DAY)	Y	HO	1000018126		1 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product By Child	Escitalopram Oxalate			S	Oral	(10 Mg,Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2011	7801141	EXPEDITED (15-DAY)	Y	HO	1000018127		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Blister; Cough; Haemoglobin Decreased; Haemoptysis; Immune Thrombocytopenic Purpura; Iron Deficiency; Oropharyngeal Blistering; White Blood Cell Count Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
	Lansoprazole (Lansoprazole)			S	Oral	1 Df (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Amoxicillin			C				Not Reported
	Solupred (Prednisolone Sodium Metazoate)			C				Not Reported
	Levothyrox (Levothyroxine Sodium) (Tablets) (Levothyroxine Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2011	7801144	EXPEDITED (15-DAY)	Y	RI, OT	1000018106		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Arterial Hypertension; Renal Failure; Systemic Lupus Erythematosus	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2011	7822472	EXPEDITED (15-DAY)	Y	RI, OT	1000018143		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Vein Thrombosis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2011	7449988	EXPEDITED (15-DAY)	Y	OT	1000014565		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Deafness Unilateral; Depression;	Lexapro			S	Oral	(10 Mg (10 Mg, 1 In 1 D), Oral) (5 Mg (5 Mg, 1 In 1		Not Reported

Dry Mouth; Exaggerated Startle Response; Night Sweats; Panic Attack; Paraesthesia; Temporomandibular Joint Syndrome; Tinnitus; Vision Blurred				D), Oral) (2.5 Mg (2.5 Mg, 1 In 1 D), Oral) (10	
			Oral	(10 Mg (10 Mg, 1 In 1 D), Oral) (5 Mg (5 Mg, 1 In 1 D), Oral) (2.5 Mg (2.5 Mg, 1 In 1 D), Oral) (10	
			Oral	(10 Mg (10 Mg, 1 In 1 D), Oral) (5 Mg (5 Mg, 1 In 1 D), Oral) (2.5 Mg (2.5 Mg, 1 In 1 D), Oral) (10	
			Oral	(10 Mg (10 Mg, 1 In 1 D), Oral) (5 Mg (5 Mg, 1 In 1 D), Oral) (2.5 Mg (2.5 Mg, 1 In 1 D), Oral) (10	
			Oral	(10 Mg (10 Mg, 1 In 1 D), Oral) (5 Mg (5 Mg, 1 In 1 D), Oral) (2.5 Mg (2.5 Mg, 1 In 1 D), Oral) (10	
			Oral	(10 Mg (10 Mg, 1 In 1 D), Oral) (5 Mg (5 Mg, 1 In 1 D), Oral) (2.5 Mg (2.5 Mg, 1 In 1 D), Oral) (10	
			Oral	(10 Mg (10 Mg, 1 In 1 D), Oral) (5 Mg (5 Mg, 1 In 1 D), Oral) (2.5 Mg (2.5 Mg, 1 In 1 D), Oral) (10	
	Lyrica	C			Not Reported
	Nasacort (Triamcinolone Acetonide) (Triamcinolone Acetonide)	C			Not Reported
	Prozac	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2011	7764972	EXPEDITED (15-DAY)	Y	DE	US-PAR PHARMACEUTICAL, INC-2011SCPR002547		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Death	Clonazepam		S	Oral	Unk	Par
	Quetiapine		S	Oral	Unk	Not Reported
	Escitalopram Oxalate		S	Oral	Unk	Not Reported
	Gabapentin		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2011	7764974	EXPEDITED (15-DAY)	Y	DE	US-PAR PHARMACEUTICAL, INC-2011SCPR002539		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Clonazepam			S	Oral	Unk		Par
	Quetiapine			S	Oral	Unk		Not Reported
	Metoclopramide			S	Oral	Unk		Not Reported
	Metoprolol			S	Oral	Unk		Not Reported
	Duloxetine			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2011	7765243	EXPEDITED (15-DAY)	Y	DE	US-JNJCH-2011000951		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Diphenhydramine			S	Oral	Text:Unknown		Not Reported
	Venlafaxine			S	Oral	Text:Unknown		Not Reported
	Cocaine			S	Oral	Text:Unknown		Not Reported
	Lisinopril			S	Oral	Text:Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	Text:Unknown		Not Reported
	Unspecified Ingredient			S	Oral	Text:Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2011	7805127	DIRECT	N	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Nightmare; Withdrawal Syndrome	Lexapro			S	Oral	10 Mg Daily Po	4 YR	Not Reported
	Lexapro			S	Oral	10 Mg Daily Po	5 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2011	7767631	EXPEDITED (15-DAY)	Y	OT	FR-PFIZER INC-2010159144		24 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Gamma-Glutamyltransferase Increased	Xanax			S		0.25 Mg, 4x/Day		Pfizer
	Stilnox			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Alcohol			S		Unknown; Excessive Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2011	7797290	EXPEDITED (15-DAY)	Y	RI, OT	1000018055		46 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Muscle Spasms; Nausea; Tonic Clonic Movements; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2011	7805762	DIRECT	N	HO			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Delusion; Euphoric Mood; Psychomotor Hyperactivity	Lexapro			S	Oral	20mg 1 Per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2011	7806657	DIRECT	N				47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2011	7806730	DIRECT	N	DS, OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2011	7825209	EXPEDITED (15-DAY)	N	DE, HO	2011S1000004		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Chest Pain; Drug Abuse; Incorrect Route Of Product Administration; Loss Of Consciousness	Zipsor			S		25 Mg		Not Reported
	Lexapro			S	Oral	20 Mg; Qd; Po		Not Reported
	Soma			S	Oral	250 Mg; Qid; Po		Not Reported
	Percocet			S	Oral	1625 Mg; Qd; Po		Not Reported
	Valium			S				Not Reported
	Fentora			S		400 Mg; Qd		Not Reported
	Fentanyl			S	Transdermal	400 Mg; Qd; Tder		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2011	7422233	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2010070738		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Attention Deficit/Hyperactivity Disorder; Bipolar Disorder; Blood Pressure Decreased; Blood Pressure Fluctuation; Major Depression; Personality Disorder	Geodon			S	Oral	20 Mg Daily		Pfizer
	Geodon			S		80 Mg, Unk		Pfizer
	Geodon			S		100 Mg, Unk		Pfizer
	Geodon			S		60 Mg, Unk		Pfizer
	Geodon			S		80 Mg, 3x/Day		Pfizer

Geodon	S		40 Mg, 2x/Day		Pfizer
Geodon	S		40 Mg, Unk		Pfizer
Geodon	S		60 Mg, Unk		Pfizer
Geodon	S		40 Mg, 2x/Day		Pfizer
Zoloft	S		Unk		Pfizer
Effexor	S	Oral	75 Mg, Daily		Pfizer
Effexor	S		37.5 Mg, In The Morning	7 DAY	Pfizer
Effexor	S		75 Mg, Unk		Pfizer
Effexor	S		150 Mg, In The Morning		Pfizer
Effexor	S		75 Mg, 2x/Day		Pfizer
Effexor	S		40 Mg, 2x/Day		Pfizer
Lithium	S		Unk		Not Reported
Klonopin	S		Unk		Not Reported
Klonopin	S		1 Mg, 2x/Day		Not Reported
Klonopin	S		0.5 Mg, 3x/Day		Not Reported
Klonopin	S		1 Mg, 3x/Day, As Needed		Not Reported
Klonopin	S		0.5 Mg, 3x/Day		Not Reported
Lexapro	S		Unk		Not Reported
Seroquel	S		100 Mg At Bedtime		Not Reported
Seroquel	S		50 Mg, At Bedtime As Needed		Not Reported
Seroquel	S		100 Mg, As Needed		Not Reported
Seroquel	S		200 Mg, At Night		Not Reported
Seroquel	S		300 Mg, Unk		Not Reported
Seroquel	S		200 Mg, At 6 And 9 At Night		Not Reported
Seroquel	S		200 Mg, At Night		Not Reported
Paxil	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2011	7769506	EXPEDITED (15-DAY)	Y	DE	US-PAR PHARMACEUTICAL, INC-2011SCPR002601		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Intentional Product Misuse; Toxicity To Various Agents	Alprazolam			S	Oral	Unk		Par
	Cyclobenzaprine			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported
	Desogestrel\Ethinyl Estradiol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2011	7769580	EXPEDITED (15-DAY)	Y	DE	US-ABBOTT-11P-163-0698445-00		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S		Ingestion		Not Reported
	Escitalopram Oxalate			S		Ingestion		Not Reported
	Tricyclic Antidepressants			S		Ingestion		Not Reported
	Alcohol			S		Ingestion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2011	7769731	EXPEDITED (15-DAY)	Y	DE	US-ABBOTT-11P-163-0698443-00		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S		Ingestion		Not Reported
	Escitalopram Oxalate			S		Ingestion		Not Reported
	Morphine			S		Ingestion		Not Reported
	Diazepam			S		Ingestion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2011	7807010	EXPEDITED (15-DAY)	Y	RI, OT	1000017503		46 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Hallucination; Hyperhidrosis; Pyrexia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Risperidone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2011	7807092	EXPEDITED (15-DAY)	Y	RI, OT	1000018214		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Arthralgia; Drug Interaction; Dysphagia; Dystonia; Irritability; Joint Dislocation; Muscle Spasms; Salivary Hypersecretion; Speech Disorder; Tremor	Escitalopram Oxalate			S		(10 Mg)		Not Reported
	Aripiprazole			S		(10 Mg,Once), (10 Mg)		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2011	7809468	DIRECT					45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Balance Disorder; Chest Discomfort; Confusional State; Fatigue; Feeling Abnormal; Hyperhidrosis; Memory Impairment; Pain; Palpitations; Panic Attack; Paraesthesia; Poor Quality Sleep; Rebound Effect	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2011	7771565	EXPEDITED (15-DAY)	N	DS, HO, LT, OT	B0693617A		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anterograde Amnesia; Clonus; Delirium; Disturbance In Attention; Drug Interaction; Echolalia; Epilepsy; Metabolic Encephalopathy; Myoclonus; Perseveration; Visual Acuity Reduced; Vomiting	Fortum			S	Intravenous (not otherwise specified)			Glaxosmithkline
	Amitriptyline Hydrochloride			S	Oral	10drop Per Day		Unknown
	Escitalopram Oxalate			S	Oral	10mg Per Day		Glaxosmithkline
	Primperan			S	Intravenous (not otherwise specified)	1unit Three Times Per Day		Unknown
	Ramipril			S	Oral	2.5mg Per Day		Glaxosmithkline
	Lasix			S	Oral			Glaxosmithkline
	Dalacine			C	Intravenous (not otherwise specified)	600mg Three Times Per Day	4 MTH	Not Reported
	Rifadine			C	Oral	200mg Three Times Per Day	4 MTH	Glaxosmithkline
	Lyrica			C	Oral	100mg Twice Per Day		Not Reported
	Inexium			C	Oral	20mg Per Day		Not Reported
	Kardegic			C	Oral	75mg Per Day		Not Reported
	Innohep			C	Subcutaneous	.6ml Per Day		Not Reported
	Doliprane			C	Oral	1g Four Times Per Day		Glaxosmithkline
	Bromazepam			C	Oral			Glaxosmithkline
	Bisoprolol Fumarate			C	Oral	1.25mg Per Day		Not Reported
	Tramadol Hydrochloride			C	Oral	50mg Four Times Per Day		Glaxosmithkline
	Pravastatin Sodium			C	Oral	20mg Per Day		Glaxosmithkline
	Bromazepam			C	Oral	.75tab Per Day		Glaxosmithkline
	Amikacin			C			3 DAY	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2011	7771783	EXPEDITED (15-DAY)	Y	HO, OT	GR-ASTRAZENECA-2011SE02761		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Blood Pressure Abnormal; Drug Interaction; Electrocardiogram Qt Prolonged; Ergot Poisoning; Prinzmetal Angina; Ventricular Tachycardia	Omeprazole			S	Oral			Not Reported
	Aspirin			C	Oral			Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)			Not Reported
	Escitalopram Oxalate			S		Chronic Use		Not Reported
	Dihydroergocristine			S		Chronic Use		Not Reported
	Carvedilol			S	Oral			Not Reported
	Carvedilol			S				Not Reported
	Carvedilol			S		Increased Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2011	7807960	EXPEDITED (15-DAY)	Y	RI, OT	1000018269		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cyst; Feeling Drunk; Muscle Contractions Involuntary; Myalgia; Nausea; Paraesthesia; Tachycardia; Tendon Pain; Tendonitis	Escitalopram Oxalate			S	Oral Oral Oral Oral	See Image, Oral See Image, Oral See Image, Oral See Image, Oral		Not Reported
	Escitalopram Oxalate			S	Oral Oral Oral	See Image, Oral See Image, Oral See Image, Oral		Not Reported
	Escitalopram Oxalate			S	Oral Oral	Oral, 3 Gtt (3 Gtt, 1 In 1 D) Oral, 3 Gtt (3 Gtt, 1 In 1 D)		Not Reported
	Zolpidem Tartrate			C				Not Reported
	Lexomil (Bromazepam) (Bromazepam)			C				Not Reported
	Nozinan (Levomepromazine) (Levome Promazine)			C				Not Reported
	Rivotril (Clonazepam) (Clonazepam)			C				Not Reported
	Renutryl (Renutryl) (Renutryl)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2011	7808404	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2011-00132		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lisinopril			S	Oral	Oral		Not Reported
	Venlafaxine			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Cocaine			S				Not Reported
	Diphenhydramine			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2011	7765595	EXPEDITED (15-DAY)	Y	CA, LT	1000017827		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermolysis; Hypoglycaemia Neonatal; Maternal Drugs Affecting Foetus; Traumatic Haematoma	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 N 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2011	7765766	NON-EXPEDITED	N		US-PFIZER INC-2011007677		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Insomnia	Cardura			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Lasix			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2011	7773452	EXPEDITED (15-DAY)	Y	OT	D0070046A		78 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Overdose; Hypotension; Intellectual Disability	Lamictal		S	Oral	50mg See Dosage Text	Glaxosmithkline
	Seroquel		S	Oral	350mg See Dosage Text	Glaxosmithkline
	Cipralex		S	Oral	20mg See Dosage Text	Not Reported
	Ramipril		S	Oral		Glaxosmithkline
	Spironolactone		S	Oral		Glaxosmithkline
	Madopar		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2011	7777061	EXPEDITED (15-DAY)	Y		1000017950		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Oedema; Lip Oedema	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2011	7809028	EXPEDITED (15-DAY)	Y	RI, OT	1000018218			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Paralysis	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Mirtazapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2011	7809789	EXPEDITED (15-DAY)	Y	HO	2011SP002123		61 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Deep Vein Thrombosis; Fatigue; Immobile; Peripheral Venous Disease	Remeron			S		15 Mg		Not Reported
	Depakine (Valproate Sodium)			S		(1000 Mg) (1500 Mg) (1000 Mg) (1000 Mg) (1500 Mg) (1000 Mg) (1000 Mg) (1500 Mg)		Not Reported

				(1000 Mg) (1000 Mg) (1500 Mg) (1000 Mg)	
	Cipralex	S	10 Mg		Not Reported
	Tamsulosin Hydrochloride	C			Not Reported
	Pantozol	C			Not Reported
	Ciproxine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2011	7809989	DIRECT	N				35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	10mg Once A Day Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2011	7810011	DIRECT	Y	OT			16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Dystonia	Lexapro			S	Oral	10mg Qam Po		Not Reported
	Haloperidol			S	Intravenous (not otherwise specified)	5mg, Stat,Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2011	7822218	EXPEDITED (15-DAY)	Y	DE	025450		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Alprazolam			S	Oral	Oral		Not Reported
	Cyclobenzaprine			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Zolpidem			S	Oral	Oral		Not Reported
	Desogestrel And Ethinyl Estradiol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2011	7831267	EXPEDITED (15-DAY)	Y	DE	025516		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S	Oral	(Oral)		Not Reported
	Verapamil Hydrochloride			S	Oral	(Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Oral)		Not Reported
	Cyclobenzaprine			S	Oral	(Oral)		Not Reported
	Doxepin			S	Oral	(Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2011	7294744	EXPEDITED (15-DAY)	Y	DE	1000011581		26 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D), 2 Or 3 Boxes (Once) 10 Mg (10 Mg, 1 In 1 D), 2 Or 3 Boxes (Once)		Not Reported
	Paroxetine Hydrochloride			S				Not Reported
	Morphine			S		(Once)		Not Reported
	Alcohol (Ethanol)			S		(Once)		Not Reported
	Xanax (Alprazolam) (0.5 Milligram) (Alprazolam)			C				Not Reported
	Olmifon (Adrafinil)(Adrafinil)			C				Not Reported
	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2011	7724624	EXPEDITED (15-DAY)	Y	DS, OT	FR-SANOFI-AVENTIS-2010SA075838		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Plaquenil			S	Oral			Not Reported

Plaquenil	S	Oral			Not Reported
Folic Acid	S	Oral	Every Day Excepted Monday		Not Reported
Cortancyl	S	Oral			Not Reported
Femara	S	Oral			Not Reported
Methotrexate	S		10 Mg Every Monday Dose:10 Milligram(S)/Millilitre		Not Reported
Inipomp	S	Oral			Not Reported
Calcium Carbonate	S	Oral			Not Reported
Fosamax	S	Oral	70 Mg On Friday		Not Reported
Valacyclovir Hydrochloride	S	Oral			Not Reported
Escitalopram Oxalate	S	Oral			Not Reported
Aprovel	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2011	7811044	EXPEDITED (15-DAY)	Y	RI, OT	1000018243			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Haematemesis	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1in 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2011	7417094	EXPEDITED (15-DAY)	Y	LT	DK-TEVA-236928ISR		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Drug Interaction	Mirtazapine			S	Oral			Teva
	Quetiapine			C	Oral			Not Reported
	Bendroflumethiazide			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2011	7776745	EXPEDITED (15-DAY)	Y	HO, OT	SE-PFIZER INC-2011016171		82 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer; Haemoglobin Decreased; Haemorrhoids	Prednisolone			S	Oral	2.5 Mg/24h, Unk		Pfizer
	Cipralex			S	Oral	10 Mg/24h, Unk		Not Reported
	Diclofenac			S	Oral	75 Mg/24h, Unk	68 DAY	Not Reported
	Heminevrin			C		300 Mg, Unk		Not Reported
	Vagifem			C		25 Ug, Unk		Not Reported
	Calcium Carbonate			C		500 Mg/400iu		Not Reported
	Omeprazole			C				Not Reported
	Metoprolol			C				Not Reported
	Calcium Phosphate\Folic Acid			C		5 Mg, Unk		Not Reported
	Acetaminophen			C		500 Mg, Unk		Not Reported
	Cyanocobalamin			C		1 Mg, Unk		Not Reported
	Nitromex			C	Sublingual	0.25 Mg, Unk		Not Reported
	Duphalac			C	Oral	670 Mg/Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2011	7730363	EXPEDITED (15-DAY)	N	OT	B0689678A		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Photophobia; Vision Blurred	Valacyclovir Hydrochloride			S	Oral			Glaxosmithkline
	Cortancyl			S	Oral	70mg Per Day		Unknown
	Femara			S	Oral	2.5mg Unknown		Unknown
	Plaquenil			S	Oral	200mg Twice Per Day		Unknown
	Methotrexate			S	Intravenous (not otherwise specified)	10mg Weekly		Unknown
	Folic Acid			S	Oral			Unknown
	Inipomp			S	Oral	40mg Per Day		Unknown

	Cacit Vitamine D3	S	Oral		Unknown
	Fosamax	S	Oral	70mg Weekly	Unknown
	Escitalopram Oxalate	S	Oral		Unknown
	Aprovel	S	Oral		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2011	7774466	EXPEDITED (15-DAY)	Y	DE	1000017910		76 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Arteriosclerosis; Azotaemia; Carotid Arteriosclerosis; Cerebral Atrophy; Cerebral Small Vessel Ischaemic Disease; Coma; Constipation; Electrocardiogram Qt Prolonged; Fatigue; Hypercreatinaemia; Hyperglycaemia; Hypernatraemia; Hyperosmolar State; Hypotension; Psychomotor Retardation; Tonic Clonic Movements; Vomiting	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Agomelatine			S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
	Lansoprazole			C				Not Reported
	Karvezide (Irbesartan, Hydrochlorothiazide) (Tablets) (Irbesartan, Hydrochlorothiazide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2011	7777965	NON-EXPEDITED	N		A0860715A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Panic Attack	Wellbutrin			S				Glaxosmithkline
	Lexapro			S			3 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2011	7777992	NON-EXPEDITED	N		A0866793A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Neoplasm Of Thyroid Gland; Goitre	Wellbutrin			S	Unknown			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2011	7778009	NON-EXPEDITED	Y		A0871968A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Wellbutrin			S				Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2011	7809598	EXPEDITED (15-DAY)	Y	HO	THQ2011A00194		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Gingival Bleeding; Haematoma; Haemoglobin Decreased; Haemoptysis; Immune Thrombocytopenic Purpura; Iron Deficiency; Oropharyngeal Blistering	Lansoprazole (Lansoprazole)			S	Oral	1 Df (1 Df, 1 In 1 D), Per Oral	1 MTH	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg 910 Mg, 1 In 1 D), Per Oral	2 MTH	Not Reported
	Amoxicillin Trihydrate			S	Oral	Per Oral		Not Reported
	Prednisolone			S	Oral	Per Oral		Not Reported
	Levothyroxine Sodium			S	Oral	12.5 Mcg (12.5 Mcg, 1 In 1 D), Per Oral		Not Reported
	Amoxicillin Trihydrate			C				Not Reported
	Prednisolone			C				Not Reported
	Levothyroxine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2011	7810940	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000018264		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased; Haemorrhage; Pallor; Pneumonia; Pulmonary Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Warfarin (Warfarin) (Tablets) (Warfarin)			C				Not Reported
	Digoxin (Digoxin) (0.25 Milligram, Tablets) (Digoxin)			C				Not Reported
	Clopidogrel (Clopidogrel) (Tablets) (Clopidogrel)			C				Not Reported
	Ramipril (Ramipril) (Tablets) (Ramipril)			C				Not Reported
	Carvedilol (Carvedilol) (Tablets) (Carvedilol)			C				Not Reported
	Furosemide (Furosemide) (Tablets) (Furosemide)			C				Not Reported
	Spironolakton (Spironolactone) (Tablets) (Spironolactone)			C				Not Reported
	Rosuvastatine (Rosuvastatin Calcium) (Tablets) (Rosuvastatin Calcium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2011	7814664	EXPEDITED (15-DAY)	Y	DE	2011VX000212		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Diazepam			S	Oral	Po		Not Reported
	Escitalopram Oxalate			S	Oral	Po		Not Reported
	Hydrocodone Bitartrate And Acetaminophen			S	Oral	Po		Not Reported
	Morphine			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2011	7817065	EXPEDITED (15-DAY)	Y	CA	1000018277			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Craniosynostosis; Maternal Drugs Affecting Foetus	Lexapro	S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental , 10 Mg (10 Mg,1 In 1 D),Transmammary		Not Reported
			Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental , 10 Mg (10 Mg,1 In 1 D),Transmammary		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2011	7817120	EXPEDITED (15-DAY)	N	RI, OT	1000018285		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Decreased Interest; Disturbance In Attention; Fall; Muscle Spasms; Upper Limb Fracture	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Trilipix (Fenofibric Acid) (Fenofibric Acid)			C				Not Reported
	Norvasc			C				Not Reported
	Lisinopril (Lisinopril)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2011	7822964	EXPEDITED (15-DAY)	Y	DE	NSR_00122_2011		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Metoclopramide Hydrochloride			S	Oral	Df Oral		Not Reported
	Metoprolol			S	Oral	Df Oral		Not Reported
	Quetiapine			S	Oral	Df Oral		Not Reported
	Duloxetine			S	Oral	Df Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df Oral		Not Reported
	Clonazepam			S	Oral	Df Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2011	7734967	EXPEDITED (15-DAY)	N	OT	FR-BRISTOL-MYERS SQUIBB COMPANY-15453160		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Aprovel			S	Oral			Bristol Myers Squibb
	Cortancyl			S		Initial Dose 70 Mg/D Then At Lower Dose From Jul-2009		Not Reported
	Femara			S	Oral			Not Reported
	Plaquenil			S	Oral	Rechallenged On 3dec10 At 2 Tab Daily		Sandoz
	Methotrexate Sodium			S		Every Monday		Bristol Myers Squibb
	Folic Acid			S	Oral	Every Day Except Monday		Not Reported
	Inipomp			S		From Prior To August 2009		Not Reported
	Calcium Carbonate			S	Oral	From Prior To August 2009		Not Reported
	Fosamax			S	Oral	Every Friday From Prior To August 2009		Not Reported
	Valacyclovir Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2011	7811204	DIRECT	N	OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Dyspnoea; Feeling Abnormal; Head Banging; Hyperhidrosis; Influenza Like Illness	Lexapro			S		One A Day		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2011	7813256	DIRECT	Y	HO			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Generalised Tonic-Clonic Seizure	Lexapro	S	Oral	Lexapro 10mg Po Qd	1 MTH		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2011	7821569	EXPEDITED (15-DAY)	Y	DE	IMP_05315_2011		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning	Oxymorphone Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Cyclobenzaprine			S	Oral	(Df Oral)		Not Reported
	Zolpidem			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Desogestrel\Ethinyl Estradiol			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2011	7834619	EXPEDITED (15-DAY)	Y	DE	1000018410		32 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate			S				Not Reported
	Cyclobenzaprine			S				Not Reported
	Alprazolam (Alprazolam)			S				Not Reported
	Desogestrel\Ethinyl Estradiol			S				Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2011	7420521	EXPEDITED (15-DAY)	Y	LT	2010AL003263		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Drug Interaction	Mirtazapine			S	Oral	15 Mg;Po		Not Reported
	Escitalopram Oxalate			S		5 Mg;Qd		Not Reported
	Bendroflumethiazide			S	Oral	Po		Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2011	7704273	EXPEDITED (15-DAY)	Y	DS, HO	1000017208		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Intentional Overdose; Somnolence	Escitalopram Oxalate			S	Oral	280 Mg, Once, Oral		Not Reported
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Cibadrex (Benazepril) (Tablets) (Benazepril)			C				Not Reported
	Seloken (Metoprolol Tartrate) (Tablets) (Metoprolol Tartrate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2011	7749944	EXPEDITED (15-DAY)	Y	HO	TW-RANBAXY-2010RR-40818		58 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Tardive Dyskinesia	Fluoxetine			S		20-40 Mg/Day		Ranbaxy
	Escitalopram Oxalate			S		10 Mg, Unk		Not Reported
	Mirtazapine			S		15 Mg, Unk		Not Reported
	Paroxetine Hydrochloride			S		10-40 Mg/Day		Not Reported
	Trazodone Hydrochloride			S		50-125 Mg/Day		Not Reported
	Venlafaxine			S		37.5-225 Mg/Day		Not Reported
	Duloxetine			S		30-60 Mg/Day		Not Reported
	Trazodone Hydrochloride			C		100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2011	7794822	EXPEDITED (15-DAY)	Y	HO	CH-ASTRAZENECA-2011SE04229		21 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Breast Discomfort; Breast Pain; Breast Swelling;	Seroquel Xr			S	Oral	350mg		Astrazeneca
	Seroquel Xr			S	Oral	100mg		Astrazeneca

Breast Tenderness; Galactorrhoea	Cipralex		S	Oral	20mg	Not Reported
	Cipralex		S	Oral	10mg	Not Reported
	Depakene		C	Oral	1500mg	Not Reported
	Lorazepam		C	Oral	1-10mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2011	7825473	EXPEDITED (15-DAY)	Y	LT	1000018533			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Withdrawal Syndrome	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2011	7844450	EXPEDITED (15-DAY)	Y	LT	2011SP004009			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Drug Interaction	Mirtazapine			S	Oral	15 Mg; Po		Not Reported
	Bendroflumethiazide\Potassium Chloride			S	Oral	Po		Not Reported
	Escitalopram Oxalate			S		5 Mg; Qd		Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2011	7801128	EXPEDITED (15-DAY)	Y	LT, RI, OT	1000018064		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Intentional Overdose; Seizure; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S	Oral	950 Mg, Once, Oral		Not Reported
	Cetirizine Hydrochloride			S	Oral	50 Mg, Once, Oral		Not Reported
	Lamotrigine			S	Oral	2500 Mg, Once, Oral		Not Reported
	Promethazine Hydrobromide			S	Oral	2000 Mg, Once, Oral		Not Reported
	Metamizole Sodium			S	Oral	5000 Mg, Once, Oral		Not Reported

	Unspecified Ingredient		S					Not Reported
	Alcohol (Ethanol)		S	Oral	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2011	7816747	DIRECT	N	OT			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Memory Impairment; Social Avoidant Behaviour	Lexapro			S				Not Reported
	Testim			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2011	7818269	DIRECT	Y	LT, OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Lexapro			S	Oral	5 Mg Po Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2011	7818307	DIRECT	Y	HO			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fluid Overload; Hyponatraemia; Nausea	Escitalopram Oxalate			S	Oral	10 Mg Daily Po		Not Reported
	Methimazole			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Ibandronate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2011	7829051	EXPEDITED (15-DAY)	Y	DS, HO, LT, RI, OT	1000018565		77 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anterograde Amnesia;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

Dialysis; Disturbance In Attention; Echolalia; Epilepsy; Metabolic Encephalopathy; Myoclonus	Ceftazidime	S	Intravenous (not otherwise specified)	6 G (6 Gm, 1 In 1 D), Intravenous	Not Reported
	Primperan	S	Oral	10 Gtt (10 Gtt, 1 In 1 D), Oral	Not Reported
	Primperan	S	Intravenous (not otherwise specified)	3 Dosafe Form (1 Dosage Forms, 3 In 1 D), Intravenous (Not Otherwise Specified)	Not Reported
	Dalacine (Clindamycin) (Solution) (Clindamycin)	C			Not Reported
	Rifampicine (Rifampicin) (Rifampicin)	C			Not Reported
	Lyrica (Pregabalin) (Capsules) (Pregabalin)	C			Not Reported
	Inexium (Esomeprazole Magnesium) (Tablets) (Esomeprazole Magnesium)	C			Not Reported
	Kardegic (Acetylsalicylate Lysine) (Powder) (Acetylsalicylate Lysine)	C			Not Reported
	Innohep (Heparin-Fraction, Sodium Salt) (Heparin-Fraction, Sodium Salt)	C			Not Reported
	Doliprane (Paracetamol) (Paracetamol)	C			Not Reported
	Lexomil (Bromazepam) (Tablets) (Bromazepam)	C			Not Reported
	Cardensiel (Bisoprolol Fumarate) (Bisoprolol Fumarate)	C			Not Reported
	Contramal (Tramadol Hydrochloride) (Tramadol Hydrochloride)	C			Not Reported
	Ramipril	C			Not Reported
	Lasilix (Furosemide) (Tablets) (Furosemide)	C			Not Reported
	Elisor (Pravastatin Sodium) (Tablets) (Pravastatin Sodium)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2011	7829064	EXPEDITED (15-DAY)	Y	HO	1000018589		53 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Small Intestinal Ulcer Haemorrhage	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2011	7831559	EXPEDITED (15-DAY)	N	OT	2011SP003919			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral; Swelling Face	Polyethylene Glycol 3350			S	Oral	17 Gm;Bid;Po		Not Reported
	Seroquel			S	Oral	50 Mg;Bid;Po		Not Reported
	Topamax			S	Oral	200 Mg; Qd; Po		Not Reported
	Escitalopram Oxalate			S	Oral	40 Mg, Qd, Po		Not Reported
	Neurontin			S	Oral	600 Mg; Tid; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2011	7798586	EXPEDITED (15-DAY)	Y	LT	DK-MYLANLABS-2011S1001547		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Mirtazapine			S	Oral			Not Reported
	Seroquel			C	Oral			Not Reported
	Bendroflumethiazide\Potassium Chloride			S	Oral		1240 DAY	Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2011	7820672	DIRECT	N				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Muscle Spasms; Temporomandibular Joint Syndrome	Trileptal			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2011	7852748	NON-EXPEDITED	N	OT	017873		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Dry Mouth; Feeling Abnormal; Pain; Suicidal Ideation; Thirst; Weight Increased	Keppra			S				Not Reported
	Lexapro			S	Oral	(10 Mg Qd Oral), (5 Mg Qd Oral), (2.5 Mg, Every Other Day Oral), (10 Mg Qd Oral)		Not Reported
					Oral	(10 Mg Qd Oral), (5 Mg Qd Oral), (2.5 Mg, Every Other Day Oral), (10 Mg Qd Oral)		
					Oral	(10 Mg Qd Oral), (5 Mg Qd Oral), (2.5 Mg, Every Other Day Oral), (10 Mg Qd Oral)		
					Oral	(10 Mg Qd Oral), (5 Mg Qd Oral), (2.5 Mg, Every Other Day Oral), (10 Mg Qd Oral)		
	Synthroid			C				Not Reported
	Baby Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2011	7774636	EXPEDITED (15-DAY)	Y	DS, RI, OT	1000017922		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Prednisone Acetate			S	Oral	70 Mg (70 Mg, 1 In 1 D), Oral; Oral		Not Reported
					Oral	70 Mg (70 Mg, 1 In 1 D), Oral; Oral		
	Femara			S	Oral	(2.5 Mg), Oral		Not Reported
	Plaquenil			S	Oral	400 Mg (200 Mg, 2 In 1 D), Oral		Not Reported

Plaquenil	S	Oral	Oral		Not Reported
Methotrexate Sodium	S		1,4286 Mg (10 Mg, 1 In 1 Wk)		Not Reported
Speciafoldine (Folic Acid)	S	Oral	Oral		Not Reported
Inipomp	S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
Calcium Carbonate\Cholecalciferol	S	Oral	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
Fosamax	S	Oral	10 Mg (70 Mg, 1 In 1 Wk), Oral		Not Reported
Valacyclovir Hydrochloride	S	Oral	Oral		Not Reported
Irbesartan	S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2011	7800453	EXPEDITED (15-DAY)	Y	HO	US-CEPHALON-2011000455		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiac Arrest; Coma; Confusional State; Hypotension; Hypoventilation; Hypoxia; Overdose; Respiratory Failure; Rhabdomyolysis; Seizure; Suicidal Ideation; Vomiting	Amrix			S	Oral			Not Reported
	Tanezumab			S			167 DAY	Not Reported
	Fioricet			S			167 DAY	Not Reported
	Phenergan			S				Not Reported
	Lexapro			S			2 YR	Not Reported
	Nortriptyline			S				Not Reported
	Lotrel			S				Not Reported
	Theragesic Creme			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2011	7836546	EXPEDITED (15-DAY)	Y	OT	2011SP003773			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Paralysis	Mirtazapine			S				Not Reported
	Cipralex			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2011	7836727	EXPEDITED (15-DAY)	Y	HO	1000018580		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder; Anxiety; Obsessive-Compulsive Disorder; Phobia; Sleep Disorder	Escitalopram Oxalate			S		15 Mg (15 Mg,1 In 1 D)		Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2011	7836800	EXPEDITED (15-DAY)	Y	RI, OT	1000018575		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Suicidal Ideation	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2011	7836803	EXPEDITED (15-DAY)	Y	RI, OT	1000018570		31 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Condition Aggravated; Obsessive-Compulsive Disorder; Overdose	Escitalopram Oxalate			S		(1 In 1 D) ; 40 Mg (40 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2011	7838284	EXPEDITED (15-DAY)	Y	RI, OT	1000018552		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Drunk; Loss Of Consciousness; Malaise; Mydriasis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2011	7838289	EXPEDITED (15-DAY)	Y	RI, OT	1000018560		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Hypomania	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Lithium			C				Not Reported
	Surmontil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2011	7838294	EXPEDITED (15-DAY)	Y	RI, OT	1000018554		94 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cognitive Disorder; Hyponatraemia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2011	7801541	EXPEDITED (15-DAY)	Y	HO, LT, OT	DE-ASTRAZENECA-2011SE05761		33 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Seroquel			S	Oral	100/200 Mg; 200-900 Mg Daily Per Os	185 DAY	Zeneca
	Cipralex			S	Oral	10-40 Mg Daily Per Os	98 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2011	7802733	EXPEDITED (15-DAY)	Y	HO	PHHO2011US01819			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiac Arrest; Coma; Confusional State; Hypotension; Hypoventilation; Hypoxia; Intentional Overdose; Respiratory Failure;	Lotrel			S	Oral	10/40		Novartis
	Fioricet			S		Unk	169 DAY	Not Reported
	Phenergan			S				Not Reported
	Lexapro			S		10 Mg, Qd		Not Reported

Rhabdomyolysis; Seizure; Suicidal Ideation; Suicide Attempt; Vomiting	Nortriptyline	S			Not Reported
	Amrix	S			Not Reported
	Theragesic Creme	C	Unk		Not Reported
	Hydrochlorothiazide	C	Unk		Not Reported
	Prozac	C	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2011	7824420	DIRECT	N	HO, LT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hypersensitivity; Paraesthesia; Refusal Of Treatment By Patient	Lexapro			S		20 Mg Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2011	7838162	EXPEDITED (15-DAY)	Y	CA	1000018566		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Caesarean Section; Carbon Dioxide Increased; Dyspnoea; Increased Bronchial Secretion; Maternal Drugs Affecting Foetus; Maternal Exposure During Breast Feeding	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental; 10 Mg (10 Mg, 1 In 1 D), Transmammary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2011	7838833	EXPEDITED (15-DAY)	Y	DE, HO	KADN20110016		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lethargy; Loss Of Consciousness;	Morphine			S	Oral	Per Oral		Not Reported

Myocardial Infarction; Respiratory Depression; Rhabdomyolysis	Escitalopram		S	Oral	Per Oral	Not Reported
	Hydrocodone Bitartrate & Acetaminophen		S	Oral	Per Oral	Not Reported
	Diazepam		S	Oral	Per Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2011	7841151	EXPEDITED (15-DAY)	Y	RI, OT	1000018608		42 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Restlessness; Sleep Disorder; Suicidal Behaviour	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2011	7849247	EXPEDITED (15-DAY)	Y	DE, HO	1000018649		87 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Organ Failure; Thrombocytopenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Calciparine			S	Subcutaneous	10,000 Iu/L 0.4 Ml, Subcutaneous		Not Reported
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	1 Gram (1 Gm, 1 In 1 D), Intravenous		Not Reported
	Inexium (Esomeprazole)			S	Intravenous (not otherwise specified)	40 Mg (40 Mg, 1 In 1 D), Intravenous		Not Reported
	Alizapride Hydrochloride			S	Intravenous (not otherwise specified)	2 Df (1 Dosage Forms, 2 In 1 D), Intravenous (Not Otherwise Specified)		Not Reported
	Acupan			S	Intravenous (not otherwise specified)	3 Df (1 Dosage Forms, 3 In 1 D), Intravenous (Not Otherwise Specified)		Not Reported
	Solu-Medrol			S	Intravenous (not otherwise specified)	1 Gram (1 Gm, 1 In 1 D), Intravenous (Not Otherwise Specified)		Not Reported

	Arixtra	S	Subcutaneous	Subcutaneous	Not Reported
	Lasilix (Furosemide)	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Casodex	C			Not Reported
	Forlax (Macrogl)	C			Not Reported
	Triatec (Ramipril)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2011	7738044	EXPEDITED (15-DAY)	Y	OT	FR-MERCK-1012FRA00127		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Fosamax			S	Oral			Merck
	Prednisone			S	Oral			Not Reported
	Letrozole			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate Sodium			S	Parenteral			Not Reported
	Folic Acid			S	Oral			Not Reported
	Pantoprazole Sodium			S	Oral			Not Reported
	Calcium Carbonate\Cholecalciferol			S	Oral			Not Reported
	Valacyclovir Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2011	7792630	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2011SE04819		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Inexium			S	Intravenous (not otherwise specified)		34 DAY	Astrazeneca
	Calciparine			S	Subcutaneous		10 DAY	Not Reported

	Ceftriaxone	S	Intravenous (not otherwise specified)	11 DAY	Not Reported
	Escitalopram Oxalate	S	Oral	15 DAY	Not Reported
	Alizapride Hydrochloride	S	Intravenous (not otherwise specified)	16 DAY	Not Reported
	Acupan	S		35 DAY	Not Reported
	Solu-Medrol	S	Intravenous (not otherwise specified)	12 DAY	Not Reported
	Arixtra	S	Subcutaneous		Not Reported
	Casodex	C			Not Reported
	Lasix	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Forlax	C			Not Reported
	Ramipril	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2011	7793447	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2011017087		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Solu-Medrol			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Pfizer
	Calciparin			S	Subcutaneous	1 Df, 2x/Day		Not Reported
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported
	Inexium			S	Intravenous (not otherwise specified)	40 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Plitican			S	Intravenous (not otherwise specified)	1 Df, 2x/Day		Not Reported
	Acupan			S		1 Df, 3x/Day		Not Reported
	Arixtra			S	Subcutaneous	Unk		Not Reported
	Lasilix			C				Not Reported
	Cardensiel			C				Not Reported
	Casodex			C				Not Reported

Forlax	C		Not Reported
Triatec (Ramipril)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2011	7799148	NON-EXPEDITED	N	OT	US-PFIZER INC-2011023117			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral; Swelling Face	Neurontin			S	Oral	600 Mg, 3x/Day		Pfizer
	Miralax			S	Oral	1 Capful At 1300, 1 Capful At 1830		Not Reported
	Seroquel			S	Oral	50 Mg, 2x/Day		Not Reported
	Topamax			S	Oral	200 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	40 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2011	7803393	NON-EXPEDITED	N		US-PFIZER INC-2011024094			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sinequan			S		Unk		Pfizer
	Lexapro			S				Not Reported
	Tofranil			S				Not Reported
	Wellbutrin			S				Not Reported
	Prozac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2011	7803794	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2011023899		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Hallucination, Visual	Lyrica			S	Oral	Unk		Pfizer
	Tramadol Hydrochloride And Acetaminophen			S	Oral	Unk	9 DAY	Not Reported
	Zolpidem			S	Oral	10 Mg, 1x/Day		Not Reported

	Escitalopram Oxalate	S	Oral	5 Mg, Alternate Day	Not Reported
	Propranolol	C			Not Reported
	Furosemide	C			Not Reported
	Diffu K	C			Not Reported
	Plavix	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2011	7794136	EXPEDITED (15-DAY)	N	HO	2010P1003456		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Potassium Decreased; Depression; Dizziness; Drug Ineffective; Fluid Retention; Ileus	Fentanyl Patch			S	Transdermal Transdermal	50 Mcg/Hr; Q 72 Hr; Tder, 50 Mcg/Hr; Q 72 Hr; Tder 50 Mcg/Hr; Q 72 Hr; Tder, 50 Mcg/Hr; Q 72 Hr; Tder		Not Reported
	Fentanyl Patch			S	Transdermal	75 Mcg/Jr; Q 72 Hr; Tder		Not Reported
	Furosemide			S	Oral	40 Mg; Qd; Po		Not Reported
	Lexapro			S	Oral	20 Mg; Po		Not Reported
	Sertraline			S		50 Mg; Qd		Not Reported
	Pantoprazole			C				Not Reported
	Diazyde			C				Not Reported
	Potassium Chloride			C				Not Reported
	Detrol La			C				Not Reported
	Re Dualvit Plus (Iron)			C				Not Reported
	Amlodipine			C				Not Reported
	Milk Of Magnesia			C				Not Reported
	Tylenol			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Prev Meds			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2011	7839583	EXPEDITED (15-DAY)	Y	HO	1000018620		82 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Gastric Ulcer; Haematochezia; Haemoglobin Decreased;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

Haemorrhoids	Prednisolone	S	Oral	2.5 Mg (12.5 Mg, 1 In 1 D), Oral	Not Reported
	Vagifem (Estradiol) (Estradiol)	C			Not Reported
	Heminevrin (Heminevrin) (Heminevrin)	C			Not Reported
	Kalcipos-D (Calcium, Vitamin D3 (Calcium, Vitamin D3)	C			Not Reported
	Omeprazole (Omeprazole) (Omperazole)	C			Not Reported
	Metoprolol Succinate	C			Not Reported
	Folacin (Folic Acid) (Folic Acid)	C			Not Reported
	Panodil (Paracetamol) (Paracetamol)	C			Not Reported
	Behepan (Cyanocobalamin) (Cyanocobalamin)	C			Not Reported
	Nitromex (Glyeryl Trinitrate) (Glyceryl Trinitrate)	C			Not Reported
	Duphalac (Lactulose) (Lactulose)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2011	7839692	EXPEDITED (15-DAY)	Y	HO	1000018680		80 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Asthenia; Decreased Appetite; Dementia; Diarrhoea; Disorientation; Drug Interaction; General Physical Health Deterioration; Logorrhoea; Oedema Peripheral; Pancreatic Cyst; Psychomotor Retardation; Renal Cyst; Vomiting; Weight Loss Poor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Digoxin			S	Oral	0.125 Mg (0.125 Mg, 1 In 1 D),Oral		Not Reported
	Digoxin			S				Not Reported
	Colchicine			S	Oral	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Previscan (Fluindione) (Fluindione)			S				Not Reported
	Adenuric (Febuxostat) (Tablets) (Febuxostat)			C				Not Reported
	Cordarone			C				Not Reported
	Coversyl (Perindopril) (Perindopril)			C				Not Reported
	Levothyrox (Levothyroxine)			C				Not Reported

	Carvedilol	C		Not Reported
	Transipeg (Macrogol)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2011	7845559	EXPEDITED (15-DAY)	Y	DE	2011S1000082		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Morphine Sulfate			S	Oral	;Po		Not Reported
	Escitalopram Oxalate			S	Oral	;Po		Not Reported
	Acetaminophen\Hydrocodone			S	Oral	;Po		Not Reported
	Diazepam			S	Oral	;Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2011	7807168	EXPEDITED (15-DAY)	Y	DE	CHPA2011US02089		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diphenhydramine		Y	S	Oral			Novartis
	Venlafaxine			S	Oral			Not Reported
	Cocaine			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2011	7831742	DIRECT	Y	DS			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Extrapyramidal Disorder; Therapeutic Product Effect Decreased	Lexapro			S	Oral	20 Mg Daily Po	4 MTH	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2011	7842339	EXPEDITED (15-DAY)	Y	DE	AE11-014-2		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Unspecified Ingredient			S				Not Reported
	Alcohol			S				Not Reported
	Lorcet			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2011	7842345	EXPEDITED (15-DAY)	Y	DE	AE11-014-1		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Lorcet			S				Not Reported
	Morphine			S				Not Reported
	Diazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2011	7843580	EXPEDITED (15-DAY)	Y	DE, HO	2011000494		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroduodenal Ulcer; Oesophagitis	Tarceva			S	Oral	(150 Mg,Qd), Oral		Not Reported
	Solu-Medrol			S	Intravenous (not otherwise specified)	(120 Mg,Qd), Intravenous		Not Reported
	Escitalopram Oxalate			S	Oral	(10 Mg,Qd), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2011	7855847	EXPEDITED (15-DAY)	Y	DE, HO	1000018686		64 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroduodenal Ulcer; Oesophagitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),		Not Reported

				Oral	
	Erlotinib	S	Oral	150 Mg (150 Mg, 1 In 1 D), Oral	Not Reported
	Solu-Medrol	S	Intravenous (not otherwise specified)	120 Mg (120 Mg, 1 In 1 D), Intravenous (Not Otherwise Specified)	Not Reported
	Mannitol	C			Not Reported
	Irbesartan	C			Not Reported
	Atarax	C			Not Reported
	Keppra	C			Not Reported
	Lasilix (Furosemide)	C			Not Reported
	Zofran	C			Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C			Not Reported
	Hypnovel (Midazolam)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2011	7679153	EXPEDITED (15-DAY)	Y	HO	PHHO2010US05532		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cerebrovascular Accident; Delirium; Encephalopathy; Fall; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Urinary Tract Infection Bacterial; White Blood Cell Count Increased	Zoledronic Acid			S	Intravenous (not otherwise specified)	Double Blind	1 DAY	Not Reported
	Unspecified Ingredient			S	Intravenous (not otherwise specified)	Double Blind	1 DAY	Not Reported
	Unspecified Ingredient			S	Intravenous (not otherwise specified)	Double Blind	1 DAY	Not Reported
	Methylphenidate			S				Not Reported
	Celexa			S				Not Reported
	Ditropan			S				Not Reported
	Wellbutrin			S				Not Reported
	Oxycodone			S				Not Reported
	Lexapro			S				Not Reported
	Zyrtec			S				Not Reported
	Clindamycin			S				Not Reported
	Calcium			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2011	7834561	DIRECT	Y	RI			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Aphasia	Lexapro			S	Oral	20mg At Night Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2011	7811071	EXPEDITED (15-DAY)	Y	HO	AT-ASTRAZENECA-2011SE06286		28 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged; Generalised Tonic-Clonic Seizure; Leukopenia	Seroquel			S	Oral		3 DAY	Zeneca
	Seroquel			S	Oral		45 DAY	Zeneca
	Seroquel			S	Oral			Zeneca
	Haldol			S			15 DAY	Not Reported
	Amisulpride			S			22 DAY	Not Reported
	Cipralex			S			19 DAY	Not Reported
	Cipralex			S			15 DAY	Not Reported
	Cipralex			S			52 DAY	Not Reported
	Topamax			C			2 DAY	Not Reported
	Topamax			C			35 DAY	Not Reported
	Lorazepam			C			8 DAY	Not Reported
	Lorazepam			C			11 DAY	Not Reported
	Lorazepam			C			10 DAY	Not Reported
	Lorazepam			C			57 DAY	Not Reported
	Lisinopril			C			86 DAY	Not Reported
	Amlodipine			C			86 DAY	Not Reported
	Abilify			C			11 DAY	Not Reported
	Abilify			C			52 DAY	Not Reported
	Kalium			C			86 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2011	7624610	NON-EXPEDITED	N		US-PFIZER INC-2010082389		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Somnolence; Weight Increased	Neurontin			S		Unk		Pfizer
	Pristiq Extended Release			S		Unk		Pfizer
	Pristiq Extended Release			S				Pfizer
	Effexor Xr			S		Unk		Pfizer
	Effexor Xr			S				Pfizer
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2011	7759412	EXPEDITED (15-DAY)	Y	HO	1000017706		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Fluctuation; Drug Ineffective; Drug Interaction; Epilepsy; Epistaxis; Excessive Eye Blinking; Intentional Product Misuse; Loss Of Consciousness; Muscle Rigidity; Overdose; Seizure; Toxicity To Various Agents; Tremor	Escitalopram Oxalate			S	Oral	40 Mg (20 Mg,2 In 1 D), Oral		Not Reported
	Flupentixol			S	Intramuscular	(40 Mg, 1 In 4 C), Intramuscular		Not Reported
	Levetiracetam (Levetiracetam) (Tablets) (Levetiracetam)			C				Not Reported
	Olanzapine			C				Not Reported
	Diazepam (Diazepam) (Tablets) (Diazepam)			C				Not Reported
	Metformin (Metformin) (Tablets) (Metformin)			C				Not Reported
	Atorvastatin (Atorvastatin) (Tablets) (Atorvastatin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2011	7812298	NON-EXPEDITED	N	OT	US-PFIZER INC-2011031442		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Mydriasis; Weight Increased	Pristiq Extended Release	S	Oral	50 Mg, 1x/Day	Pfizer
	Lexapro	S		Unk	Not Reported
	Xanax	C	Oral	0.25 Mg, As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2011	7841812	DIRECT	Y	RI, OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Coordination Abnormal; Disorientation; Dizziness; Palpitations; Restlessness	Abilify			S		10 Mg At Bedtime		Not Reported
	Lexapro			S		20 Mg In Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2011	7815709	EXPEDITED (15-DAY)	Y	HO	ES-JNJFOC-20110203842		70 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Parkinsonism	Risperdal			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Imipramine Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2011	7838311	DIRECT	Y	HO, LT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Anxiety; Autoimmune Disorder; Endocrine Disorder; Formication; Infection; Pruritus; Rash; Swollen Tongue; Thyroid Disorder; Urticaria	Lexapro			S	Oral	5mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2011	7859431	EXPEDITED (15-DAY)	N	OT	DSA_44928_2011		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Crying; Drug Ineffective; Suicidal Ideation	Wellbutrin			S		Df		Not Reported
	Lexapro			S	Oral	20 Mg, Qd, Oral		Not Reported
	Trazodone			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2011	7590370	NON-EXPEDITED	N		US-PFIZER INC-2010115950			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Ineffective; Headache; Hypersensitivity; Nausea; Therapeutic Response Unexpected; Wrong Technique In Product Usage Process	Zoloft			S		Unk		Pfizer
	Pristiq Extended Release			S		50 Mg, Each Morning		Pfizer
	Pristiq Extended Release			S				Pfizer
	Lexapro			S		Unk		Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2011	7749160	EXPEDITED (15-DAY)	Y	RI, OT	1000017604		35 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Oedema; Paraesthesia Oral	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Imovane (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2011	7749932	EXPEDITED (15-DAY)	Y	RI, OT	1000017607		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Eye Oedema; Face Oedema; Hypersensitivity	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Prazepam		C			Not Reported
	Amitriptyline Hydrochloride		C			Not Reported
	Imovane (Zopiclone)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2011	7766776	EXPEDITED (15-DAY)	Y	CA	1000017759		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankyloglossia Congenital; Apgar Score Low; Caesarean Section; Face Presentation; Maternal Drugs Affecting Foetus; Meconium In Amniotic Fluid; Selective Eating Disorder	Lexapro			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported
	Prenatal Vitamin (Prenatal Vitamin) (Prenatal Vitamin)			C				Not Reported
	Fish Oil (Fish Oil) (Fish Oil)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2011	7817328	EXPEDITED (15-DAY)	N	OT	A0913841A		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Ineffective; Product Quality Issue; Suicidal Ideation	Wellbutrin			S	Unknown			Glaxosmithkline
	Lexapro			S	Oral	20mg Per Day		Not Reported
	Trazodone			C		150mg Per Day		Not Reported
	Topamax			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2011	7829026	EXPEDITED (15-DAY)	Y	HO	1000018543		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Fluctuation; Drug Ineffective; Drug	Lexapro			S	Oral	40 Mg, Once, Oral		Not Reported
	Flupentixol Decanoate			S	Intramuscular	40 Mg, Intramuscular		Not Reported

Interaction; Epilepsy; Epistaxis; Loss Of Consciousness; Nephropathy Toxic; Overdose; Parkinsonism; Product Administration Error	Diazepam (Diazepam)	C	Not Reported
	Atorvastatin (Atorvastatin)	C	Not Reported
	Levetiracetam	C	Not Reported
	Metformin Hydrochloride	C	Not Reported
	Olanzapine (Olanzapine)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2011	7852484	EXPEDITED (15-DAY)	Y	HO	1000018791		81 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Hallucination, Visual	Escitalopram Oxalate			S	Oral	2.5 Mg (5 Mg, 1 In 2 D), Oral		Not Reported
	Zolpidem			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lyrica			S	Oral	Oral		Not Reported
	Tramadol Hydrochloride And Acetaminophen			S	Oral	Oral		Not Reported
	Tramadol Hydrochloride			S		150 Mg (50 Mg, 3 In 1 D)		Not Reported
	Avlocardyl (Propranolol)			C				Not Reported
	Furosemide (Furosemide)			C				Not Reported
	Potassium Chloride			C				Not Reported
	Plavix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2011	7853407	EXPEDITED (15-DAY)	Y	RI, OT	1000018790		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Oedema Peripheral; Pharyngeal Oedema	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2011	7853487	EXPEDITED (15-DAY)	Y	RI, OT	1000018822			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; Nausea; Thrombocytopenia; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2011	7853513	EXPEDITED (15-DAY)	Y	RI, OT	1000018821		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia; Fatigue; Female Orgasmic Disorder; Libido Decreased; Weight Increased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Lamotrigine (Lamotrigine) (Tablets) (Lamotrigine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2011	7854524	EXPEDITED (15-DAY)	Y	HO	2011SP000428		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Insomnia; Intentional Overdose; Suicide Attempt	Lunesta			S	Oral	2 Mg; Hs; Oral, 60 Mg; 1x, Oral		Not Reported
					Oral	2 Mg; Hs; Oral, 60 Mg; 1x, Oral		
	Ambien Cr			S		12.5 Mg; Hs;		Not Reported
	Xanax			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2011	7819544	EXPEDITED (15-DAY)	Y	HO	PHHY2008FR25786		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aphasia; Hyponatraemia; Seizure; Tremor	Tegretol		S	Oral	400 Mg, Tid	Novartis
	Inipomp		S	Oral	20 Mg, Qd	Not Reported
	Hydrochlorothiazide\Valsartan		S	Oral	1 Df, Qd	Not Reported
	Escitalopram Oxalate		S	Oral	20 Mg, Qd	Not Reported
	Actonel		C		35 Mg, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2011	7827165	EXPEDITED (15-DAY)	Y	HO	1000018154		33 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Hypothermia; Intentional Overdose; Poisoning Deliberate	Escitalopram Oxalate			S	Oral	10 Dosage Forms, Once, Oral		Not Reported
	Equanil			S	Oral	4000 Mg, Once, 800 Mg (400 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2011	7855836	EXPEDITED (15-DAY)	Y	RI, OT	1000018727			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Intentional Self-Injury; Papilloedema; Visual Field Defect	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2011	7860482	EXPEDITED (15-DAY)	Y	RI, OT	1000018813		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Tercian (Cyamemazine) (Cyamemazine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2011	7858905	EXPEDITED (15-DAY)	Y	RI, OT	1000018876		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Feeling Abnormal; Muscle Tightness	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2011	7637187	EXPEDITED (15-DAY)	N	HO	1000016393		89 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Hypersomnia; Insomnia; Lethargy; Staphylococcus Test Positive; Urinary Tract Infection	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Namenda			C				Not Reported
	Aricept			C				Not Reported
	Cozaar			C				Not Reported
	Clonidine Transdermal System			C				Not Reported
	Methylphenidate (Methylphenidate) (Methylphenidate)			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Omeprazole			C				Not Reported
	Oxytrol (Oxybutynin Transdermal)(Oxybutynin Transdermal)			C				Not Reported
	Seroquel (Quetiapine Fumarate) (Quetiapine Fumarate)			C				Not Reported
	Stalevo(Carbidopa, Levodopa, Entacapone)(Carbidopa, Levodopa, Entacapone)			C				Not Reported
	Fludrocortisone Acetate (Fludrocortisone Acetate)(Fludrocortisone Acetate)			C				Not Reported
	Finasteride (Finasteride)(Finasteride)			C				Not Reported

	Tpn (Tpn) (Liquid) (Tpn)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2011	7670642	EXPEDITED (15-DAY)	Y	HO, LT	GB-ROCHE-741254		87 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Naproxen			S	Oral			Roche
	Aspirin			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2011	7704327	EXPEDITED (15-DAY)	N	OT	DK-BRISTOL-MYERS SQUIBB COMPANY-15433980		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Initial Insomnia; Mania	Abilify			S		26jan09;2.5mg,Discontinued On 04nov09		Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2011	7810742	EXPEDITED (15-DAY)	Y	HO	1000018268		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; General Physical Health Deterioration; Pancytopenia; Purpura	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine)			C				Not Reported
	Temerit (Nebivolol) (Nebivolol)			C				Not Reported
	Atarax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2011	7856114	EXPEDITED (15-DAY)	Y	HO, LT	1000018877		76 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastric Ulcer; Haematocrit Decreased; International Normalised Ratio Decreased; Upper Gastrointestinal Haemorrhage	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Sintrom			S	Oral	Oral		Not Reported
	Ibuprofen (Ibuprofen)			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2011	7856142	EXPEDITED (15-DAY)	Y	HO	1000018879		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alexia; Aphasia; Blood Pressure Systolic Increased; Central Nervous System Vasculitis; Cerebral Haematoma; Cerebral Vasoconstriction; Meningorrhagia; Pupils Unequal	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Cardensiel (Bisoprolol Fumarate) (Bisoprolol Fumarate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2011	7861663	EXPEDITED (15-DAY)	Y	DE	1000018747			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Oedema	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2011	7826247	EXPEDITED (15-DAY)	Y	HO, LT	ZA-TEVA-245995ISR		83 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Dyskinesia;	Azilect			S	Oral			Teva

Hallucination, Visual; Hyperhidrosis; Hyperkalaemia; Hypertension; Psychotic Disorder; Pyrexia; Renal Failure; Rhabdomyolysis; Tachycardia	Tramadol Hydrochloride And Acetaminophen		S	Oral		Not Reported
	Fentanyl		S	Transdermal		Not Reported
	Stalevo		S	Oral		Not Reported
	Escitalopram Oxalate		S	Oral		Not Reported
	Escitalopram Oxalate		S			Not Reported
	Celecoxib		C	Oral		Not Reported
	Zopiclone		C	Oral		Not Reported
	Sinemet		C	Oral	50/200 Mg Od For Years	Not Reported
	Ergocalciferol		C	Oral		Not Reported
	Ocuvite Lutein		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2011	7826563	EXPEDITED (15-DAY)	N	HO	US-WATSON-2011-01859		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiac Arrest; Coma; Confusional State; Hypotension; Hypoventilation; Hypoxia; Overdose; Respiratory Failure; Rhabdomyolysis; Seizure; Suicide Attempt; Vomiting	Fioricet			S	Oral	25 Mg, Single	1 DAY	Watson
	Phenergan			S	Oral	Unk	1 DAY	Not Reported
	Lexapro			S	Oral	10 Mg 1x/Day	1 DAY	Not Reported
	Pamelor			S	Oral	25 Mg, 1x/Day	1 DAY	Not Reported
	Amrix			S	Oral	Unk	1 DAY	Not Reported
	Lotrel			S	Oral	10/40		Not Reported
	Unspecified Ingredient			S	Intravenous (not otherwise specified)	Every 8 Weeks	169 DAY	Not Reported
	Hydrochlorothiazide			C	Unknown	Unk		Not Reported
	Theragesic Creme			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2011	7873786	EXPEDITED (15-DAY)	Y	RI, OT	100017897		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrioventricular Block; Hyponatraemia	Escitalopram Oxalate		S	Oral	20 Mg (20 Mg,1 In 1 D), Oral	Not Reported
	Remeron		C			Not Reported
	Surmontil		C			Not Reported
	Fosicomp (Elidiur) (Elidiur)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2011	7774891	EXPEDITED (15-DAY)	Y	HO	CH-ABBOTT-11P-151-0700235-00		61 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombosis	Valproic Acid			S	Oral	150-600 Mg A Day		Not Reported
	Valproic Acid			S	Oral			Not Reported
	Valproic Acid			S	Oral			Not Reported
	Valproic Acid			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Remeron			S	Oral			Not Reported
	Pantozol			S				Not Reported
	Tamsulosin			C	Oral			Not Reported
	Ciprofloxacin			C	Oral			Not Reported
	Ciprofloxacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2011	7826175	EXPEDITED (15-DAY)	N	HO	A0914964A			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Ph Decreased; Depressed Level Of Consciousness; Endotracheal Intubation; Hypotension; Hypoxia; Overdose; Suicidal Ideation	Propafenone			S				Glaxosmithkline
	Metoprolol			S				Not Reported
	Clonazepam			S				Glaxosmithkline
	Lorazepam			S				Not Reported
	Escitalopram Oxalate			S				Glaxosmithkline
	Apixaban			C		5mg Twice Per Day		Not Reported
	Warfarin Sodium			C		7mg Per Day		Glaxosmithkline
	Metformin Hydrochloride			C				Glaxosmithkline
	Gliclazide			C				Not Reported

	Ezetrol			C						Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2011	7855990	DIRECT	N	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2011	7763368	EXPEDITED (15-DAY)	N	OT	FR-BRISTOL-MYERS SQUIBB COMPANY-15479660		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Disinhibition; Hypomania; Initial Insomnia; Libido Increased; Logorrhoea; Sexually Inappropriate Behaviour	Abilify			S	Oral	Morning		Not Reported
	Abilify			S	Oral	Morning		Not Reported
	Abilify			S	Oral	Morning		Not Reported
	Escitalopram Oxalate			S	Oral	Also 20mg/Day Reduced To 10mg/Day From 07oct10		Not Reported
	Escitalopram Oxalate			S	Oral	Also 20mg/Day Reduced To 10mg/Day From 07oct10		Not Reported
	Xanax			C	Oral	Before Jun10 Also :5mg Dosageg:1-3 Tabs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2011	7702698	EXPEDITED (15-DAY)	Y	RI, OT	1000017209		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Oropharyngeal Spasm; Overdose; Tongue Spasm	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D),Oral, 20 Mg (20 Mg, 1 In 1 D),Oral, 30 Mg (30 Mg, 1 In 1 D) Oral 10 Mg (10 Mg,1 In 1		Not Reported

D),Oral, 20 Mg (20 Mg, 1 In 1 D),Oral, 30 Mg (30 Mg, 1 In 1 D) Oral
10 Mg (10 Mg,1 In 1 D),Oral, 20 Mg (20 Mg, 1 In 1 D),Oral, 30 Mg (30 Mg, 1 In 1 D) Oral

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2011	7832163	NON-EXPEDITED	N		A0863154A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus	Lamictal			S	Oral			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Seroquel			S	Unknown			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2011	7833467	NON-EXPEDITED	Y		US-PFIZER INC-2010042881			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Geodon			S		20 Mg, Unk		Pfizer
	Mirtazapine			S		15 Mg, Unk		Not Reported
	Clonazepam			S		0.5 Mg, Unk		Not Reported
	Lexapro			S		20 Mg, Unk		Not Reported
	Bupropion			S		300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2011	7867342	EXPEDITED (15-DAY)	Y	RI, OT	1000018918		20 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Oedema Peripheral; Pain; Pain In Extremity	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral , 2.5 Mg (2.5 Mg, 1 In 1 D),		Not Reported

					Oral	Oral 5 Mg (5 Mg, 1 In 1 D), Oral , 2.5 Mg (2.5 Mg, 1 In 1 D), Oral				

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2011	7865643	EXPEDITED (15-DAY)	Y	HO	1000018920		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Poisoning Deliberate; Rhabdomyolysis	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Lexomil (Bromazepam)			S	Oral	Oral		Not Reported
	Tropatepine Hydrochloride			S	Oral	Oral		Not Reported
	Amisulpride			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2011	7793798	EXPEDITED (15-DAY)	Y	HO, OT	1000018075			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Disturbance In Attention; Electrocardiogram Qt Prolonged; Intentional Overdose; Suicide Attempt; Vomiting	Escitalopram Oxalate			S	Oral	(2500 Mg,Once),Oral		Not Reported
	Chlorprothixene			S	Oral	(1200 Mg,Once),Oral		Not Reported
	Seroquel			S	Oral	(4500 Mg,Once),Oral		Not Reported
	Alcohol (Ethanol)			S	Oral	(Once),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2011	7869874	EXPEDITED (15-DAY)	Y	RI, OT	1000019016			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Loss Of Consciousness	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2011	7775881	EXPEDITED (15-DAY)	Y	RI, OT	1000017897		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Hyponatraemia	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Remeron			C				Not Reported
	Surmontil			C				Not Reported
	Fosicomp (Elidiur)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2011	7839134	EXPEDITED (15-DAY)	Y	OT	PHHY2011FR03795		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Somnolence	Exelon Patch			S	Transdermal	4.6 Mg, Qd	1 DAY	Novartis
	Exelon Patch			S	Transdermal	4.6 Mg, Qd	1 DAY	Novartis
	Escitalopram Oxalate			S		10 Mg Daily		Not Reported
	Tramadol Hydrochloride And Acetaminophen			S		37.5 Mg Daily	3 DAY	Not Reported
	Levothyrox			C	Oral	50 Ug Daily		Not Reported
	Coumadin			C	Oral	4 Mg Daily		Not Reported
	Lasix			C	Oral	40 Mg Daily		Not Reported
	Ramipril			C	Oral	5 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2011	7865709	DIRECT	N	DS			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Fall; Nightmare	Lexapro			S	Oral	30mg 1 At Night Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2011	7840664	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-42358		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lisinopril			S	Oral	Unk		Ranbaxy
	Venlafaxine			S	Oral	Unk, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Cocaine			S	Oral	Unk		Not Reported
	Diphenhydramine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2011	7841423	EXPEDITED (15-DAY)	Y	OT	AU-PFIZER INC-2011045974			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased	Lipitor			S		80 Mg, Unk		Pfizer
	Dipyridamole			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2011	7841998	EXPEDITED (15-DAY)	Y	DE	CH-SANOFI-AVENTIS-2011SA011557		1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Cavity Infection; Foetal Death; Maternal Exposure During Pregnancy; Premature Baby	Stilnox			S	Transplacental			Not Reported
	Stilnox			S	Transplacental			Not Reported
	Abilify			S	Transplacental			Not Reported
	Abilify			S	Transplacental			Not Reported
	Escitalopram Oxalate			S	Transplacental			Not Reported
	Escitalopram Oxalate			S	Transplacental			Not Reported
	Lorazepam			S	Transplacental			Not Reported

	Zyprexa	S	Transplacental		Not Reported
	Zyprexa	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2011	7871221	EXPEDITED (15-DAY)	Y	RI, OT	1000019083		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Cavity Infection; Maternal Exposure During Pregnancy; Off Label Use; Pregnancy; Premature Rupture Of Membranes	Escitalopram Oxalate			S		20 Mg (20 Mg,2 In 1 D)		Not Reported
	Abilify			S		(15 Mg)		Not Reported
	Zolpidem			S		12.5 Mg (23.5 Mg,1 In 1 D)		Not Reported
	Lorazepam			S				Not Reported
	Zyprexa			S		7.5 Mg (7.5 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2011	7871479	EXPEDITED (15-DAY)	Y	DE	1000019084			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion; Maternal Drugs Affecting Foetus; Premature Baby; Premature Rupture Of Membranes	Escitalopram Oxalate			S	Transplacental	20 Mg (10 Mg,2 In 1 D), Transplacental		Not Reported
	Abilify			S	Transplacental	(15 Mg), Transplacental		Not Reported
	Lorazepam			S	Transplacental	Transplacental		Not Reported
	Zyprexa			S	Transplacental	7.5 Mg (7.5 Mg,1 In 1 D),Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2011	7842660	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-42564		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydrocodone Bitartrate And Acetaminophen			S	Oral	Unk, Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral			Not Reported

	Alcohol	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2011	7842666	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-42546		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydrocodone Bitartrate And Acetaminophen			S	Oral	Unk, Unk		Ranbaxy
	Diazepam			S	Oral	Unk, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk, Unk		Not Reported
	Morphine			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2011	6893896	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-FR-WYE-G02939109		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Effexor Xr			S	Oral	75 Mg, 1x/Day		Pfizer
	Lyrica			S	Oral	600 Mg, 1x/Day		Pfizer
	Tahor			S	Oral	Unk		Pfizer
	Rivotril			S	Oral	2 Mg, 1x/Day		Not Reported
	Anafranil			S	Oral	50 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, 1x/Day		Not Reported
	Levomepromazine			S	Oral	25 Mg, 1x/Day		Not Reported
	Lasix			S	Oral	20 Mg, 1x/Day		Not Reported
	Tranxene T-Tab			S	Oral	10 Mg, 1x/Day		Not Reported
	Tysabri			S	Intravenous (not otherwise specified)	300 Mg, 1x/Cyc		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2011	7775891	EXPEDITED (15-DAY)	Y	RI, OT	1000017902		45 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Physical Assault	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2011	7842813	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-42654		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Gabapentin			S	Oral	Unk		Ranbaxy
	Quetiapine			S	Oral	Unk, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2011	7842826	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-42722		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Cyclobenzaprine Hydrochloride			S	Oral	Unk, Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Zolpidem Tartrate			S	Oral	Unk		Ranbaxy
	Alprazolam			S	Oral	Unk		Not Reported
	Desogestrel\Ethinyl Estradiol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2011	7843088	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLINCKRODT-T201100434			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S	Oral			Tyco
	Morphine Sulfate			S	Oral			Tyco

	Escitalopram Oxalate	S	Oral		Not Reported
	Diazepam	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2011	7856140	EXPEDITED (15-DAY)	Y	HO	1000018889		19 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Contraceptives (Contraceptives) (Contraceptives)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2011	7877999	EXPEDITED (15-DAY)	Y	RI, OT	1000019076		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metrorrhagia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2011	7846089	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2011048172		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersomnia; Myalgia; Nephrolithiasis; Overdose	Lipitor			S		Unk		Pfizer
	Lexapro			S	Oral	10 Mg, Daily	7 DAY	Not Reported
	Lexapro			S	Oral	20 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	40 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	20 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	30 Mg, 1x/Day		Not Reported
	Nadolol			C		Unk		Not Reported

	Dexidrine	C	Unk	Not Reported
	Dexidrine	C	Unk	Not Reported
	Adderall	C	Unk	Not Reported
	Pravastatin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2011	7875978	EXPEDITED (15-DAY)	Y	RI, OT	1000019093		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hyperventilation; Suicide Attempt	Escitalopram Oxalate			S	Oral	15 Mg, Once, Oral		Not Reported
	Acetaminophen\Aspirin\Caffeine			S	Oral	1 Dosage Forms, Once, Oral		Not Reported
	Clonazepam			S	Oral	Once, Oral		Not Reported
	Opipramol Hydrochloride			S	Oral	Once, Oral		Not Reported
	Alcohol (Ethanol)			S	Oral	Once, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2011	7882894	EXPEDITED (15-DAY)	Y	RI, OT	1000019127		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Choking Sensation; Depression; Headache; Hyperhidrosis; Insomnia; Malaise; Skin Burning Sensation; Tachycardia; Tinnitus; Tremor; Vaginal Haemorrhage	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Alprazolam (Alprazolam) (Tablets) (Alprazolam)			C				Not Reported
	Atenolol			C				Not Reported
	Amlodipine			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2011	7871240	EXPEDITED (15-DAY)	Y	RI, OT	1000018755		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Generalised Tonic-Clonic Seizure; Hyponatraemia	Lexapro		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Hydrochlorothiazide		S	Oral	12.5 Mg (25 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2011	7871064	EXPEDITED (15-DAY)	Y	HO, OT	1000019043		16 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral	100 Mg, Once, Oral		Not Reported
	Codeine			S	Oral	240 Mg, Once, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2011	7852983	EXPEDITED (15-DAY)	Y	DE	US-TYCO HEALTHCARE/MALLINCKRODT-T201100437		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S	Oral			Tyco
	Unspecified Ingredient			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2011	7824147	EXPEDITED (15-DAY)	Y	HO	AT-ABBOTT-11P-009-0706350-00		29 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Leukopenia; Overdose	Escitalopram Oxalate			S		30 Mg Daily		Not Reported
	Escitalopram Oxalate			S		15 Mg Daily		Not Reported
	Escitalopram Oxalate			S		20 Mg Daily		Not Reported
	Amisulpride			S	Oral	1200 Mg Daily		Not Reported
	Seroquel			S		900 Mg Daily		Not Reported

	Seroquel	S		800 Mg Daily	Not Reported
	Seroquel	S		1000 Mg Daily	Not Reported
	Haldol	S		10 Mg Daily	Not Reported
	Topamax	C			Not Reported
	Topamax	C			Not Reported
	Lorazepam	C	Oral		Not Reported
	Lorazepam	C	Oral		Not Reported
	Lorazepam	C	Oral		Not Reported
	Lorazepam	C	Oral		Not Reported
	Kalium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2011	7878890	DIRECT	N	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Gambling Disorder; Mania	Lexapro			S	Oral	1 Tablet Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2011	7810079	EXPEDITED (15-DAY)	Y	HO	1000018273		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Osmolarity Decreased; Hypokalaemia; Hyponatraemia	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D),		Not Reported
	Lamictal			S				Not Reported
	Bumetanide			S		1 Mg (1 Mg, 1 In 1 D),		Not Reported
	Spironolactone			S		25 Mg (25 Mg, 1 In 1 D);		Not Reported
	Abilify			S		10 Mg (10 Mg, 1 In 1 D);		Not Reported
	Warfarin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2011	7857432	NON-EXPEDITED	N		US-PFIZER INC-2010150860		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Sedation; Somnolence	Pristiq Extended Release			S	Oral	50 Mg, 1x/Day		Pfizer
	Lexapro			S	Oral	5 Mg, 1x/Day		Not Reported
	Wellbutrin			S	Oral	100 Mg, 1x/Day	42 DAY	Not Reported
	Femara			C	Oral	Unk		Not Reported
	Tamoxifen			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2011	7702687	EXPEDITED (15-DAY)	Y	RI, OT	1000017193		62 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sleep-Related Event; Agitation; Nightmare; Violence-Related Symptom	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Atarax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2011	7860202	EXPEDITED (15-DAY)	Y	HO	FR-ROCHE-764501		22 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning; Somnolence	Rivotril			S	Oral	Frequency: Once		Roche
	Escitalopram Oxalate			S	Oral	Frequency: Once		Not Reported
	Valpromide			S	Oral	Frequency: Once		Not Reported
	Zyprexa			S	Oral	Frequency: At Once.		Not Reported
	Theralene			S	Oral			Not Reported
	Dafalgan			C	Oral	Frequency-Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2011	7860661	EXPEDITED (15-DAY)	Y	HO, OT	US-VIROPHARMA INCORPORATED-20110303CINRY1852		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Hereditary Angioedema; Inappropriate Schedule Of Product Administration; Infusion Related Reaction; Lip Swelling; Rash; Thyroid Disorder	Cinryze	S		Viropharma
	Lexapro	S		Not Reported
	Diazepam	S		Not Reported
	Atenolol	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2011	7875126	EXPEDITED (15-DAY)	Y	HO	1000019019		29 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Leukopenia; Overdose	Escitalopram Oxalate			S	Oral	30, 15 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
					Oral	30, 15 Mg (30 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel			S	Oral	900, 800, 1000 Mg (900 Mg, 1 In 1 D). Oral		Not Reported
					Oral	900, 800, 1000 Mg (900 Mg, 1 In 1 D). Oral		
	Amisulpride			S	Oral	1200 Mg (1200 Mg, 1 In 1 D), Oral		Not Reported
	Haldol			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Topamax			C				Not Reported
	Lorazepam			C				Not Reported
	Kalium (Potassium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2011	7768399	EXPEDITED (15-DAY)	Y	RI, OT	1000017778		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Bedridden; Cold Sweat;	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1		Not Reported

Diarrhoea; Disturbance In Attention; Dizziness; Heart Rate Increased; Increased Appetite; Paraesthesia; Presyncope; Sleep Disorder; Suicidal Ideation; Weight Decreased; Yawning	Oral	D),Oral 5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2011	7863081	EXPEDITED (15-DAY)	Y	HO, OT	CH-ASTRAZENECA-2011SE13676		21 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Galactorrhoea	Seroquel Xr			S	Oral			Astrazeneca
	Seroquel Xr			S	Oral		13 DAY	Astrazeneca
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral		9 DAY	Not Reported
	Depakene			C	Oral			Not Reported
	Lorazepam			C	Oral	1-10 Mg Daily	13 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2011	7763879	EXPEDITED (15-DAY)	N	HO	B0694112A		72 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Osmolarity Decreased; Hypokalaemia; Hyponatraemia	Lamictal			S	Unknown			Glaxosmithkline
	Abilify			S	Unknown			Not Reported
	Bumetanide			S	Unknown	1mg Per Day		Not Reported
	Spironolactone			S	Unknown	25mg Per Day		Glaxosmithkline
	Cipralex			S	Unknown	20mg Per Day		Not Reported
	Marevan			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2011	7860490	EXPEDITED (15-DAY)	Y	HO	1000018815		86 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Hypersensitivity; Malaise; Oedema Peripheral; Pollakiuria; Pruritus; Pseudomonas Infection; Rash; Thrombocytopenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Atorvastatin Calcium			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Kardegic (Acetylsalicylate Lysine)			C				Not Reported
	Modapar (Levodopa, Benzerazide)			C				Not Reported
	Seresta (Oxazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2011	7864931	EXPEDITED (15-DAY)	N	OT	GB-PFIZER INC-2011058581			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Burning Sensation; Drug Ineffective; Muscle Spasms; Muscle Twitching; Swollen Tongue	Lyrica			S		300 Mg, 3x/Day		Pfizer
	Lyrica			S				Pfizer
	Simvastatin			S		40 Mg, Unk		Not Reported
	Celebrex			S		200 Mg, Unk		Pfizer
	Omeprazole			S		20 Mg, Unk		Not Reported
	Xenical			S		120 Mg, Unk		Not Reported
	Dexamphetamine			S		5 Mg, Unk		Not Reported
	Cipralex			S		20 Mg, Unk		Not Reported
	Tramadol			S		100 Mg, Unk		Not Reported
	Calcium Carbonate\Calcium Glubionate\Sodium Bicarbonate			S		Unk		Not Reported
	Butrans			S	Transdermal	10 Ug/ Hr		Not Reported
	Oxybutynin Chloride			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2011	6792168	EXPEDITED (15-DAY)	N	HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-13944517		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Back Pain; Diplopia; Dyskinesia; Fibromyalgia; Mania; Spinal Stenosis; Teeth Brittle; Tooth Loss	Abilify			S		Started 7 Years Ago, Took For 5 Years	2 YR	Not Reported
	Lexapro			S				Not Reported
	Lasix			C				Not Reported
	Oxybutynin			C				Not Reported
	Metoprolol			C				Not Reported
	Elavil			C				Not Reported
	Flexeril			C				Not Reported
	Atarax			C				Not Reported
	Lipitor			C				Not Reported
	Neurontin			C				Not Reported
	Saphris			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2011	7742876	EXPEDITED (15-DAY)	Y	RI, OT	1000017504		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Triglycerides Increased; Feeling Cold; Hyperhidrosis; Weight Increased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Cortisone			S	Oral	Oral		Not Reported
	Magnetrans Extra (Magnesium Oxide) (Magnesium Oxide)			C				Not Reported
	Valette (Certostat)			C				Not Reported
	Rebif			C				Not Reported
	Vigantoletten (Colecalciferol) (1000 Iu (International Unit)) (Colecalciferol)			C				Not Reported
	Ibuprofen (Ibuprofen) (400 Milligram) (Ibuprofen)			C				Not Reported
	Pantoprazol (Pantoprazole Sodium) (20 Milligram) (Pantoprazol Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2011	7760194	EXPEDITED (15-DAY)	Y	CA, DE	1000017672			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Limb Reduction Defect; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy	Escitalopram Oxalate			S	Transplacental	Transplacental		Not Reported
	Diclectin			S				Not Reported
	Tamiflu			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2011	7867607	NON-EXPEDITED	N		US-PFIZER INC-2011061038			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Pristiq Extended Release			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2011	7867754	EXPEDITED (15-DAY)	Y	DE	US-ROCHE-766685		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Diazepam			S	Oral	Ongoing Status Unknown At The Time Of Death		Roche
	Escitalopram Oxalate			S	Oral	Ongoing Status Unknown At The Time Of Death		Not Reported
	Acetaminophen			S	Oral	Ongoing Status Unknown At The Time Of Death		Not Reported
	Hydrocodone			S	Oral	Ongoing Status Unknown At The Time Of Death		Not Reported
	Morphine			S	Oral	Ongoing Status Unknown At The Time Of Death		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2011	7868173	EXPEDITED (15-DAY)	Y	HO, OT	PHHY2011FR19942		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Disorientation; General Physical Health Deterioration; Hyponatraemia; Lower Limb Fracture; Pain	Hydrochlorothiazide\Valsartan			S		160mg Valsartan And 25mg Hydrochlorothiazide Qd		Novartis
	Escitalopram Oxalate			S		10 Mg, Qd		Not Reported
	Alprazolam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2011	7888821	DIRECT	N					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Tremor	Lexapro			S		Daily	5 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2011	7898987	EXPEDITED (15-DAY)	Y	RI, OT	1000019363		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Seizure	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg,1 In 1 D), Oral		Not Reported
	Trazodone (Trazodone) (Tablets) (Trazodone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2011	7899308	EXPEDITED (15-DAY)	Y	RI, OT	1000019305		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Hypertension	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported

	Alendronic Acid (Alendronic Acid) (Alendronic Acid)	C		Not Reported
	Antihypertensives (Antihypertensives) (Antihypertensives)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2011	7899376	EXPEDITED (15-DAY)	Y	RI, OT	1000019349		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Off Label Use	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
	Doxepin (Doxepin) (Doxepin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7760148	EXPEDITED (15-DAY)	Y	HO	1000017653			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Heart Rate Increased; Overdose; Suicidal Ideation; Suicide Attempt; Urticaria	Escitalopram Oxalate			S		20 Mg; 30 Mg; 20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7760154	EXPEDITED (15-DAY)	Y	RI, OT	1000017657		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Pain In Jaw; Tooth Injury	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D),Oral		Not Reported
					Oral	15 Mg (15 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D),Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7760192	EXPEDITED (15-DAY)	Y	RI, OT	1000017663		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea Haemorrhagic	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7856094	EXPEDITED (15-DAY)	Y	HO	US-PFIZER INC-2011055565		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Overdose; Suicide Attempt	Xanax			S		Unk		Pfizer
	Lunesta			S	Oral	2 Mg, At Hs		Not Reported
	Lunesta			S	Oral	60 Mg, Single		Not Reported
	Ambien Cr			S		12.5 Mg, At Hs		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7869443	EXPEDITED (15-DAY)	Y	DE	US-ROCHE-766630		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Clonazepam			S	Oral			Roche
	Quetiapine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7869567	EXPEDITED (15-DAY)	Y	DE	US-ROCHE-766936		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Toxicity To Various Agents	Clonazepam	S	Oral	Route: Ingestion, Ongoing Status Unknown At The Time Of Death	Roche
	Metoprolol	S	Oral	Route: Ingestion, Ongoing Status Unknown At The Time Of Death	Not Reported
	Quetiapine	S	Oral	Route: Ingestion, Ongoing Status Unknown At The Time Of Death	Not Reported
	Duloxetine	S	Oral	Route: Ingestion, Ongoing Status Unknown At The Time Of Death	Not Reported
	Escitalopram Oxalate	S	Oral	Route: Ingestion, Ongoing Status Unknown At The Time Of Death	Not Reported
	Metoclopramide	S	Oral	Route: Ingestion, Ongoing Status Unknown At The Time Of Death	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7869771	EXPEDITED (15-DAY)	Y	OT	D0070542A			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Insipidus; Polydipsia	Bupropion Hydrochloride			S	Oral	300mg Per Day		Glaxosmithkline
	Lamotrigine			S	Unknown	200mg Per Day		Unknown
	Quetiapine			S	Unknown	400mg Per Day		Glaxosmithkline
	Escitalopram Oxalate			S	Unknown	20mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7871193	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000019025		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Breast Cancer; Erythema; Haemorrhoids;	Lexapro			S	Oral	Oral		Not Reported

Rectal Haemorrhage; Skin Exfoliation; Tinnitus	Soliris		S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	600 Mg (600 Mg,1 In 1 1 Wk), Intravenous (Not Otherwise Specified); 900 Mg (1 In 2 Wk),Intravenous 600 Mg (600 Mg,1 In 1 1 Wk), Intravenous (Not Otherwise Specified); 900 Mg (1 In 2 Wk),Intravenous	Not Reported
	Tranlorazepate Potassium) (Clorazepate Dipotassium)		C			Not Reported
	Folic Acid		C			Not Reported
	Centrum (Multivitamin) (Multivitamin)		C			Not Reported
	Lipitor		C			Not Reported
	Arimidex (Anastrozole) (Anastrozole)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7890639	DIRECT	N	DE			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ambien			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7894380	DIRECT	N	OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Diarrhoea; Frequent Bowel Movements; Nausea	Lexapro			S	Oral	10mg 1x Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7898902	EXPEDITED (15-DAY)	Y	OT	1000019269		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperprolactinaemia; Pituitary Tumour Benign	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Vyvanse (Lisdexamfetamine) (Lisdexamfetamine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7901588	EXPEDITED (15-DAY)	Y	CA	1000019384		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Duodenal Atresia; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7901867	EXPEDITED (15-DAY)	N	RI, OT	1000019301		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bipolar Disorder; Bruxism; Dyskinesia; Dystonia; Grimacing; Initial Insomnia; Mania	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		
	Lexapro			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	15 Mg (15 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		

	Seroquel	S	Oral	25 Mg Qam, 50 Mg Qpm, Oral		Not Reported
	Seroquel	S	Oral	50 Mg Qam, 100 Mg Qpm, Oral		Not Reported
	Clonidine (Clonidine) (0.1 Milligram, Tablets) (Clonidine)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2011	7906534	EXPEDITED (15-DAY)	Y	HO	1000019387		29 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Confusional State; Hypotension; Loss Of Consciousness; Poisoning Deliberate	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Subutex			S	Oral	(2 Mg),Oral		Not Reported
	Zyprexa			S	Oral	Oral		Not Reported
	Acepromazine Maleate\Meprobamate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2011	7766516	EXPEDITED (15-DAY)	Y	RI, OT	1000017534		33 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infertility Male; Spermatozoa Abnormal	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Tranxene T-Tab			S	Oral	30 Mg (10 Mg,3 In 1 D,Oral) ; 10 Mg (5 Mg,2 In 1 D),Oral		Not Reported
					Oral	30 Mg (10 Mg,3 In 1 D,Oral) ; 10 Mg (5 Mg,2 In 1 D),Oral		
	Acepromazine Maleate			S	Oral	1 Dosage Form (1 Dosage Forms,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2011	7872077	EXPEDITED (15-DAY)	Y	HO, OT	PHHY2011FR21561		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Osmolarity Decreased; Cerebrovascular Accident; Dizziness; Fall; Feeling Abnormal; Gastroenteritis; Hemiparesis; Hyponatraemia	Aliskiren\Hydrochlorothiazide			S	Oral	1 Df, Qd	64 DAY	Novartis
	Aldactazine			S		1 Df, Qd	370 DAY	Not Reported
	Escitalopram Oxalate			S		1 Df, Qd	370 DAY	Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Levothyrox			C				Not Reported
	Plaquenil			C				Not Reported
	Piracetam			C				Not Reported
	Alprazolam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2011	7872929	EXPEDITED (15-DAY)	Y	HO	IT-ASTRAZENECA-2011SE15926		38 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sinus Tachycardia; Sopor	Nexium			S	Oral		1 DAY	Astrazeneca
	Cipralex			S	Oral			Not Reported
	Depakene			S	Oral		1 DAY	Not Reported
	Promazine Hydrochloride			S	Oral	4g/100 Ml Oral Drops, Solution Flacon 30 Ml, 20 Ml Once/Single Administration	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2011	7360520	EXPEDITED (15-DAY)	Y	HO	1000012910		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Bipolar I Disorder; Confusional State	Escitalopram Oxalate			S		(1 In 1 D)		Not Reported
	Unspecified Ingredient			S				Not Reported
	Clorazepate Dipotassium			C				Not Reported
	Insulin (Insulin) (Insulin)			C				Not Reported
	Enalapril Maleate			C				Not Reported
	Enalapril Maleate			C				Not Reported
	Adiro (Acetylsalicylic			C				Not Reported

Acid)(Acetylsalicylic Acid)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2011	7905228	EXPEDITED (15-DAY)	Y	HO	1000019381		22 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning Deliberate; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	(200 Mg,Once), Oral		Not Reported
	Valpromide			S	Oral	(6 Gm, Once),Oral		Not Reported
	Zyprexa			S	Oral	(110 Mg,Once), Oral		Not Reported
	Trimeprazine Tartrate			S	Oral	(Once),Oral		Not Reported
	Rivotril (Clonazepam)			C	Oral	(14 Mg,Once), Oral		Not Reported
	Dafalgan (Paracetamol) (Faracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2011	7905269	EXPEDITED (15-DAY)	Y	RI, OT	1000019382		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 N 1 D), Oral		Not Reported
	Pantoprazole			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral, 20 Mg (40 Mg, 1 In 2 D), Oral		Not Reported
	Valoron (Tilidine Hydrochloride, Naloxone)(Tilidine Hydrochloride, Naloxone)			C				Not Reported
	Lopresor (Metoprolol Tartrate) (Metoprolol Tartrate)			C				Not Reported
	Tavor (Lorazepam)			C				Not Reported
	Dipiperon (Pipamperone Hydrochloride) (40 Milligram)(Pipamperone Hydrochloride)			C				Not Reported
	Paracetamol (Paracetamol) (Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2011	7905281	EXPEDITED (15-DAY)	Y	RI, OT	1000019408		74 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Jaundice; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Athymil (Mianserin Hydrochloride)(Mianserin Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2011	7905315	EXPEDITED (15-DAY)	Y	HO	1000019413		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Eosinophilia Myalgia Syndrome; Pyrexia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tryptophan, Dl-			S	Oral	500 Mg (500 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2011	7908349	EXPEDITED (15-DAY)	Y	RI, OT	1000019372		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypochromic Anaemia	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2011	7908903	EXPEDITED (15-DAY)	Y	HO	1000019518		79 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Gastrointestinal Disorder; General Physical Health Deterioration;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

Hyperkalaemia; Hyponatraemia; Renal Failure	Bactrim		S	Oral	6 Dosage Forms (6 Dosage Forms, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2011	7878217	EXPEDITED (15-DAY)	N	HO	B0708135A		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Confusional State; Decreased Appetite; Dehydration; Hepatitis; Hypernatraemia; Thrombocytopenia	Augmentin			S	Oral	2g Per Day	5 DAY	Glaxosmithkline
	Allopurinol			S	Oral			Unknown
	Simvastatin			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral	15mg Per Day		Unknown
	Omeprazole			S	Oral			Unknown
	Memantine			S	Oral	20mg Per Day		Unknown
	Exelon			S	Transdermal	4.6mg Per Day		Unknown
	Isosorbide Dinitrate			C	Unknown	1unit Per Day		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2011	7878772	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011067304		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased; Mental Impairment; Tremor	Xanax			S	Oral	0.5 Mg, As Needed		Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2011	7888922	EXPEDITED (15-DAY)	Y	HO	2011SA007836		56 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pleural Effusion; Pneumonia; Sarcoidosis	Escitalopram Oxalate			S	Oral	10 Milligram (S);Daily; Po		Not Reported
	Ivy Dry (Isopropanol/Tannic Acid)			C				Not Reported

	Enzyme Preparations (Enzyme Preparations)	C	Not Reported
	Fusafungine (Fusafungine)	C	Not Reported
	Ibuprofen (Ibuprofen)	C	Not Reported
	Ofloxacin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2011	7879487	NON-EXPEDITED	N		US-PFIZER INC-2011069659			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Dry Mouth; Loss Of Libido; Malaise	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2011	7880616	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2011066571		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Xanax			S	Oral	0.5 Mg, 2x/Day		Pfizer
	Escitalopram Oxalate			S	Oral	20 Mg, 1x/Day		Not Reported
	Levothyrox			S	Oral	125 Ug, 1x/Day		Not Reported
	Lormetazepam			S	Oral	1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2011	7645673	NON-EXPEDITED	N		US-PFIZER INC-US-WYE-H14299410		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Ineffective; Tremor	Effexor			S	Oral	150.0 Mg, 2x/Day		Pfizer
	Zoloft			S	Oral	100.0 Mg, 1x/Day		Pfizer
	Zoloft			S	Unknown	50.0 Mg, 1x/Day		Pfizer
	Lexapro			S	Unknown	100.0 Mg, 1x/Day		Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Mg, 1x/Day		Not Reported

Lipitor	C	Unknown	30 Mg, 1x/Day		Not Reported
Fish Oil, Hydrogenated	C	Unknown	Unk		Not Reported
Gemfibrozil	C	Oral	600 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2011	7835700	NON-EXPEDITED	N	OT	US-PFIZER INC-2011038703			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicidal Ideation	Prozac			S		Unknown		Not Reported
	Prozac			S				Not Reported
	Cymbalta			S		1 Df, Single		Not Reported
	Cymbalta			S				Not Reported
	Lexapro			S		Unknown		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2011	7879117	EXPEDITED (15-DAY)	Y	HO	US-RB-024118-11		29 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Confusional State; Hypotension; Poisoning	Subutex			S	Nasal	Other Dosing Details Unknown		Reckitt Benckiser
	Escitalopram Oxalate			S	Nasal	Dosing Details Unknown		Not Reported
	Zyprexa			S	Nasal	Dosing Details Unknown		Not Reported
	Acepromet azine\Meprobamate			S	Nasal	Dosing Details Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2011	7880385	EXPEDITED (15-DAY)	Y	DS, HO	FR-ASTRAZENECA-2011SE16980		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Paracetamol			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Oral			Not Reported

	Cortancyl	S	Oral			Not Reported
	Omeprazole	S	Oral		11 MTH	Not Reported
	Escitalopram Oxalate	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2011	7910735	EXPEDITED (15-DAY)	Y	HO	1000019655		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Maternal Drugs Affecting Foetus; Neonatal Respiratory Distress Syndrome; Neonatal Seizure	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1d), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2011	7911271	EXPEDITED (15-DAY)	Y	OT	1000019390		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Navelbine (Vinorelbine) (Vinorelbine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2011	7913406	EXPEDITED (15-DAY)	Y	HO	1000019456		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction; Lip Swelling; Rash	Lexapro			S				Not Reported
	Cinryze			S		500 Unit (500 Units, 1 In 1 Wk)		Not Reported
	Diazepam			S				Not Reported
	Atenolol (Atenolol)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2011	7325793	EXPEDITED (15-DAY)	N	DE, OT	AU-PFIZER INC-2010031875		29 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Completed Suicide; Confusional State; Depression; Feeling Abnormal; Mood Altered; Nervousness; Restlessness	Zoloft			S		Unk		Pfizer
	Effexor			S		Unk		Not Reported
	Lexapro			S		5 Mg, 1x/Day		Not Reported
	Lexapro			S		10 Mg, 1x/Day		Not Reported
	Fish Oil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2011	7882958	NON-EXPEDITED	N		US-PFIZER INC-2010035994		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Ineffective; Tremor	Zoloft			S	Oral	100 Mg, 1x/Day		Pfizer
	Effexor			S	Oral	150 Mg, 2x/Day		Pfizer
	Lexapro			S		Unk		Not Reported
	Lipitor			C	Oral	30 Mg, 1x/Day		Not Reported
	Gemfibrozil			C	Oral	600 Mg, 2x/Day		Not Reported
	Acetylsalicylic Acid			C	Oral	81 Mg, 1x/Day		Not Reported
	Fish Oil			C		Unk, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2011	7883106	NON-EXPEDITED	N		US-PFIZER INC-2003037020		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Exostosis; Pain; Panic Attack; Paraesthesia; Plantar Fasciitis; Swelling; Tinnitus	Zoloft			S	Oral	50 Mg, 1x/Day		Pfizer
	Zoloft			S				Pfizer
	Zoloft			S				Pfizer
	Alprazolam			S	Oral	Unk		Pfizer

	Escitalopram Oxalate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2011	7883156	NON-EXPEDITED	N		US-PFIZER INC-2009284276		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Eye Pruritus; Food Allergy; Hypersensitivity; Ocular Hyperaemia; Reaction To Preservatives; Scleral Disorder; Thyroid Disorder	Zoloft			S	Oral	12.5 Mg, Unk		Pfizer
	Zoloft			S	Oral	12.5 Mg, Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Multivitamins			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Vitamin B12			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2011	7915285	EXPEDITED (15-DAY)	Y	HO	1000019702		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tramadol Hydrochloride			S	Oral	100 Mg (50 Mg, 2 In 1 D), Oral		Not Reported
	Seresta (Oxazepam) (Tablet) (Oxazepam)			C				Not Reported
	Nicobion (Nicotinamide) (Tablets) (Nicotinamide)			C				Not Reported
	Imovane (Zopiclone) (Tablets) (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2011	7871053	EXPEDITED (15-DAY)	Y	RI, OT	1000019047		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diabetes Insipidus; Polydipsia	Escitalopram Oxalate	S	Up To 20 Mg (1 In 1 D)		Not Reported
	Quetiapine Fumarate	S	Up To 400 Mg (1 In 1 D)		Not Reported
	Bupropion	S	Up To 300 Mg (1 In 1 D)		Not Reported
	Lamotrigine (Lamotrigine)	S	Up To 200 Mg (1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2011	7886079	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2010074098		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Insomnia; Tachycardia	Xanax Xr			S		Unk, As Needed Before Bedtime		Pfizer
	Effexor Xr			S		Unk, Once Daily		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2011	7886169	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2011069374		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Vasospasm	Xalatan			S	Ophthalmic	1 Gtt, 1x/Day		Pfizer
	Escitalopram Oxalate			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2011	7908921	EXPEDITED (15-DAY)	N	RI, OT	1000019453		17 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Erectile Dysfunction; Genital Hypoaesthesia; Sensory Loss	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2011	7914393	EXPEDITED (15-DAY)	Y	HO	1000018797		20 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hallucination, Auditory; Hallucination, Synaesthetic; Hallucination, Visual; Suicidal Behaviour; Suicidal Ideation	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D, Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Atarax			C				Not Reported
	Atarax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2011	7914938	EXPEDITED (15-DAY)	Y	HO	1000019637		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Epilepsy; Epistaxis; Fall; Goitre; Haematoma; Loss Of Consciousness; Rib Fracture; Tooth Fracture; Urinary Incontinence	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Zolpidem (Zolpidem) (Zolpidem)			C				Not Reported
	Tercian (Cyamemazine) (Cyamemazine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2011	7915000	EXPEDITED (15-DAY)	Y	RI, OT	1000019638		40 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2011	7916168	EXPEDITED (15-DAY)	Y	RI, OT	1000019641		38 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Compulsions; Intentional Self-Injury	Escitalopram Oxalate		S	Oral	Oral	Not Reported
	Seroquel (Quetiapine) (Quetiapine)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2011	7916171	EXPEDITED (15-DAY)	Y	HO	1000019635		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Formication; Malaise; Nausea; Sinus Tachycardia; Skin Burning Sensation	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Eutirox (Levothyroxine) (Levothyroxine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2011	7730283	EXPEDITED (15-DAY)	Y	OT	FR-PFIZER INC-2010176653		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Inipomp			S	Oral	40 Mg, 1x/Day		Pfizer
	Cortancyl			S	Oral	70 Mg, (Then Dose Reduced)		Not Reported
	Femara			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, 2x/Day	365 DAY	Not Reported
	Methotrexate			S		10 Mg, Every Monday		Not Reported
	Folic Acid			S	Oral	Everyday Except Mondays		Not Reported
	Calcium Carbonate			S	Oral	1 Dosage Forms		Not Reported
	Fosamax			S	Oral	1 Df, Weekly		Not Reported
	Valacyclovir Hydrochloride			S	Oral	Unk		Not Reported
	Aprovel			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2011	7808071	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2011025477		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Pollakiuria; Pruritus; Rash; Thrombocytopenia	Tahor			S	Oral	10 Mg, 1x/Day		Pfizer
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported
	Kardegic			C	Oral	160 Mg, 1x/Day		Not Reported
	Modopar			C	Oral	1 Df, 6x/Day		Not Reported
	Oxazepam			C	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2011	7887305	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2011SE18589		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Inexium			S	Oral			Astrazeneca
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Captopril			C	Oral			Not Reported
	Furosemide			C	Oral			Not Reported
	Framycetin Sulfate			C				Not Reported
	Tahor			C	Oral			Not Reported
	Tropatepine Hydrochloride			C	Oral		9 DAY	Not Reported
	Previscan (Fluindione)			C	Oral			Not Reported
	Escitalopram Oxalate			S	Oral		45 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2011	7908338	DIRECT	N	OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Dysuria; Gastrointestinal Disorder; Malaise; Pain; Tinnitus	Cymbalta			S		30 Mg. 1 A Day		Not Reported
	Lexapro			S		Lexapro 1 A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2011	7917846	EXPEDITED (15-DAY)	Y	HO	1000019629		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatic Steatosis; Hepatitis; Hepatitis B Core Antibody; Hepatocellular Injury; Hepatomegaly; Hiv Infection; Hyponatraemia; Oropharyngeal Candidiasis; Parvovirus B19 Test Positive; Pneumocystis Jirovecii Pneumonia; Pyrexia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Bactrim Forte			S	Oral	4800 Mg/ 960 Mg (2 Dosage Forms,3 In 1 D),Oral		Not Reported
	Bactrim			S	Intravenous (not otherwise specified)	2000 Mg/ 400 Mg,Intravenous (Not Otherwise Specified)		Not Reported
	Lederfoline (Calcium Folinate) (Calcium Folinate)			C				Not Reported
	Levothyroxine Sodium (Levothyroxine Sodium) (Levothyroxine Sodium)			C				Not Reported
	Gyno-Pevaryl (Econazole Nitrate) (Capsules) (Econazole Nitrate)			C				Not Reported
	Fungizone (Amphotericin B) (Amphotericin B)			C				Not Reported
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2011	6805354	EXPEDITED (15-DAY)	N	DE, OT	AU-PFIZER INC-AU-WYE-G02474308		17 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anhedonia; Anxiety; Bipolar Disorder; Bipolar Ii Disorder; Cognitive Disorder; Completed Suicide; Condition Aggravated; Confusional State; Crying; Depression; Distractibility;	Effexor			S		75.0 Mg, 1x/Day		Pfizer
	Effexor			S		75 Mg, Unk		Pfizer
	Effexor			S		112.5mg Daily		Pfizer
	Effexor			S		150 Mg, 1x/Day		Pfizer
	Effexor			S		75 Mg, 1x/Day		Pfizer
	Zoloft			S		Unk		Pfizer

Disturbance In Attention; Drug Ineffective; Drug Withdrawal Syndrome; Feeling Abnormal; Feeling Guilty; Feeling Of Despair; Frustration Tolerance Decreased; Impaired Driving Ability; Impulsive Behaviour; Insomnia; Intentional Product Misuse; Intentional Self-Injury; Malaise; Memory Impairment; Mental Status Changes; Mood Altered; Multiple Injuries; Nervousness; Nonspecific Reaction; Obsessive Thoughts; Panic Attack; Psychomotor Hyperactivity; Restlessness; Road Traffic Accident; Self Esteem Decreased; Sexual Dysfunction; Speech Disorder; Suicidal Ideation; Therapeutic Product Effect Decreased; Thinking Abnormal; Unevaluable Event	Lexapro	S	5 Mg, 1x/Day	3 DAY	Not Reported
	Lexapro	S	10 Mg, 1x/Day		Not Reported
	Erythromycin	C	20mg/G 2% Gel Daily		Not Reported
	Fish Oil	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2011	7777681	EXPEDITED (15-DAY)	Y	RI, OT	1000017936		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Electrocardiogram Qt Prolonged; Tachycardia	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
					Oral	20 Mg (20 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral		

	Metoprolol Succinate	C		Not Reported
	Trazodone (Trazodone) (Trazodone)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2011	7843548	EXPEDITED (15-DAY)	Y	DE, HO	US-CELGENEUS-163-21880-11022573		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Encephalopathy; Musculoskeletal Pain; Nausea; Plasma Cell Myeloma	Revlimid			S	Oral	25 Milligram		Celgene
	Revlimid			S	Oral	25 Milligram		Celgene
	Revlimid			S	Oral	25 Milligram		Not Reported
	Dexamethasone			S	Oral	40 Milligram		Not Reported
	Dexamethasone			S	Oral	40 Milligram		Not Reported
	Hydrocodone			S	Unknown			Not Reported
	Flexeril			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Dilaudid			S	Parenteral	.4 Milligram		Not Reported
	Xanax			S	Unknown			Not Reported
	Protonix			S	Unknown			Not Reported
	Rivastigmine			S	Unknown			Not Reported
	Aspirin			C	Oral	325 Milligram		Not Reported
	Antiviral			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2011	7905273	EXPEDITED (15-DAY)	Y	HO	029609		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Keppra			S	Oral	(2000 Mg, 20 Tablets Oral)		Not Reported
	Carvedilol (Carvedilol)			S	Oral	(12.5 Mg Oral)		Not Reported

	Ramipril	S	Oral	(10 Mg, 5 Mg Tablets; 14 Tablets Oral)	Not Reported
	Norvasc	S			Not Reported
	Cipralex	S			Not Reported
	Ticlopidine	C			Not Reported
	Metformin	C			Not Reported
	Allopurinol	C			Not Reported
	Actoplus Met	C			Not Reported
	Crestor	C			Not Reported
	Plavix	C			Not Reported
	Peptazol /01263202/)	C			Not Reported
	Xanax	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2011	7184808	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009296613			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Constipation; Decreased Appetite; Diarrhoea; Diverticulitis; Drug Ineffective; Dry Mouth; Dyskinesia; Muscle Twitching; Nightmare; Suicide Attempt; Therapeutic Product Effect Decreased; Tremor	Zoloft			S		Unk		Pfizer
	Trazodone Hydrochloride			S		Unk		Unknown
	Doxepin Hydrochloride			S		Unk		Pfizer
	Pristiq Extended Release			S	Oral	50 Mg, 1x/Day		Pfizer
	Effexor Xr			S	Oral	75 Mg, 1x/Day		Pfizer
	Mirtazapine			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported
	Seroquel			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paroxetine			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Depakote			S		Unk		Not Reported
	Vitamins			C		Unk		Not Reported

	Fish Oil	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2011	7676784	EXPEDITED (15-DAY)	Y	RI, OT	1000016972		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2011	7878017	EXPEDITED (15-DAY)	Y	HO	IT-ABBOTT-11P-083-0714762-00		38 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sinus Tachycardia; Sopor	Valproic Acid			S	Oral	Once		Not Reported
	Cipralex			S	Oral	Once		Not Reported
	Promazine			S	Oral	20ml Of 40mg/Ml Solution		Not Reported
	Esomeprazole			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2011	7891138	NON-EXPEDITED	N		US-PFIZER INC-2011073854			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Somnolence	Pristiq Extended Release			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2011	7901865	EXPEDITED (15-DAY)	Y	DE	1000019288		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Asthma; Bronchospasm;	Lexapro			S	Oral	Oral; 30 (30 Mg, 1 In 1 D), Oral;		Not Reported

Pneumonia; Toxicity To Various Agents	Nafazodone	C	Not Reported
	Trileptal	C	Not Reported
	Lamictal	C	Not Reported
	Xanax	C	Not Reported
	Campral	C	Not Reported
	Zyrtec (Ceitrizine)	C	Not Reported
	Flonase	C	Not Reported
	Robitussin Dm (Dextromethorphan, Guafenesin)	C	Not Reported
	Flovent Hfa	C	Not Reported
	Albuterol Hfa (Salbutamol)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2011	7906872	DIRECT		OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cheilitis; Gingival Disorder; Rash	Lexapro			S				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2011	7549719	EXPEDITED (15-DAY)	Y	HO, LT	ZA-JNJFOC-20100806521		83 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Dyskinesia; Hyperhidrosis; Hyperkalaemia; Hypertension; Psychotic Disorder; Pyrexia; Renal Failure; Rhabdomyolysis; Tachycardia	Duragesic			S	Transdermal			Not Reported
	Acetaminophen\Tramadol Hydrochloride			S	Oral			Not Reported
	Stalevo			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Azilect			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Sinemet Cr			C	Oral	50/200 Mg		Not Reported
	Ergocalciferol			C	Oral	50000 Iu Mg Mon/Wed/Fri		Not Reported

	Ocuvite Lutein			C	Unknown		Days			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2011	7893198	EXPEDITED (15-DAY)	Y	HO, LT, OT	CH-PFIZER INC-2011075727		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; C-Reactive Protein Increased; Diabetic Complication; Hyperkalaemia; Hyperthermia; Hypotension; Intentional Overdose; Loss Of Consciousness; Metabolic Acidosis; Mydriasis; Rhabdomyolysis; Tachycardia; Vomiting	Sortis			S	Oral	8 G, Single	1 DAY	Pfizer
	Sortis			S	Oral	Unk		Pfizer
	Lorazepam			S	Oral	50 Mg, Single	1 DAY	Pfizer
	Lorazepam			S	Oral	2.5 Mg, 3x/Day		Pfizer
	Lisinopril			S	Oral	350 Mg, Single	1 DAY	Not Reported
	Lisinopril			S	Oral			Not Reported
	Seroquel			S	Oral	52 G, Single	1 DAY	Not Reported
	Seroquel			S	Oral	1400 Mg, 1x/Day		Not Reported
	Cipralex			S	Oral	1.4 G, Single	1 DAY	Not Reported
	Cipralex			S	Oral	40 Mg, 1x/Day		Not Reported
	Flurazepam Hydrochloride			S	Oral	750 Mg, Single	1 DAY	Not Reported
	Flurazepam Hydrochloride			S	Oral	30 Mg, 1x/Day		Not Reported
	Potassium Chloride			S	Oral	470 Mmol, Single	1 DAY	Not Reported
	Potassium Chloride			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2011	7893670	EXPEDITED (15-DAY)	N	OT	US-ASTRAZENECA-2011SE18638		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Dystonia; Insomnia	Seroquel			S	Oral	25 Mg Qam And 50 Mg Qpm	0 YR	Zeneca
	Seroquel			S	Oral	25 Mg Qam And 50 Mg Qpm	0 YR	Zeneca

Seroquel	S	Oral	50 Mg Qam And 100 Mg Qpm	0 YR		Zeneca
Seroquel	S	Oral	50 Mg Qam And 100 Mg Qpm	0 YR		Zeneca
Lexapro	S	Oral				Not Reported
Lexapro	S	Oral				Not Reported
Lexapro	S	Oral				Not Reported
Lexapro	S	Oral				Not Reported
Lexapro	S	Oral		4 MTH		Not Reported
Lexapro	S	Oral		4 MTH		Not Reported
Lexapro	S	Oral				Not Reported
Lexapro	S	Oral				Not Reported
Clonidine	C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2011	7893864	EXPEDITED (15-DAY)	Y	HO, LT	CH-ASTRAZENECA-2011SE19337		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Complication; Hyperkalaemia; Hyperthermia; Hypotension; Intentional Overdose; Loss Of Consciousness; Metabolic Acidosis; Mydriasis; Rhabdomyolysis; Tachycardia; Vomiting	Lisinopril			S	Oral	350 Mgs Total	1 DAY	Zeneca
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral	1.4 Gms Total	1 DAY	Not Reported
	Potassium			S	Oral	470 Mmol	1 DAY	Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral	52 Gms Total	1 DAY	Not Reported
	Flurazepam Hydrochloride			S	Oral			Not Reported
	Flurazepam Hydrochloride			S	Oral	750 Mgs Total	1 DAY	Not Reported
	Sortis			S	Oral	8 Gms Total	1 DAY	Not Reported
	Lorazepam			S	Oral			Not Reported
	Lorazepam			S	Oral	50 Mgs Total	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2011	7928288	EXPEDITED (15-DAY)	Y	HO	1000019726		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Chest Discomfort; Dyspnoea; Hypoxia; Serotonin Syndrome	Lexapro			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2011	7931231	EXPEDITED (15-DAY)	Y	HO	1000019859		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatitis; Psychomotor Retardation; Somnolence	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Trileptal			S	Oral	600 Mg (300 Mg, 2 In 1 D), Oral		Not Reported
	Piracetam			S	Oral	800 Mg (800 Mg, 1 In 1 D), Oral		Not Reported
	Calcit (Calcium Carbonate)			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Inipomp			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2011	7674425	EXPEDITED (15-DAY)	Y	HO	1000016938		74 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Melaena; Peptic Ulcer	Lexapro			S	Oral	15 Mg (15 Mg,1 In 1 D), Oral		Not Reported
	Amlodipine			C				Not Reported
	Aspirin			C				Not Reported
	Zoton (Lansoprazole) (Tablets)			C				Not Reported

	(Lansoprfazole) Vit B12 (Cyanocobalamin) (Tablets) (Cyanocobalamin)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2011	7810436	EXPEDITED (15-DAY)	Y	HO	1000018242		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Hepatic Haematoma; Hepatitis Cholestatic; Incorrect Dose Administered; Vomiting; Weight Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
	Acetaminophen\Caffeine\Propoxyphene			S	Oral	6 Df (2 Dosage Forms,3 In 1 D), Oral		Not Reported
	Acetaminophen			S	Oral	Up To 6 Gm Daily (1 Gm,On Request), Oral		Not Reported
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2011	7840624	EXPEDITED (15-DAY)	Y	CA	GRT 2011-10388			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Arnold-Chiari Malformation; Maternal Drugs Affecting Foetus; Spina Bifida; Talipes	Lidoderm			S				Not Reported
	Atarax			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Folic Acid			C				Not Reported
	Tetrazepam			C				Not Reported
	Lyrica			C				Not Reported
	Propofan (Caffeine, Carbasalate Calcium, Chlorphenamine Maleate, Dextropropoxyphene, Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2011	7895425	EXPEDITED (15-DAY)	N	LT	B0712146A		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Inappropriate Antidiuretic Hormone Secretion	Lamictal			S	Oral	150mg Per Day	420 DAY	Glaxosmithkline
	Escitalopram Oxalate			S		10mgml Per Day	421 DAY	Glaxosmithkline
	Tavor (Lorazepam)			S	Oral	7.5mg Per Day	8 DAY	Not Reported
	Seretide			S				Glaxosmithkline
	Anafranil			C				Not Reported
	Bromazepam			C				Glaxosmithkline
	Pentetrazol			C				Not Reported
	Dihydrocodeine			C				Not Reported
	Lasix			C				Glaxosmithkline
	Tenormin			C				Not Reported
	Hydrochlorothiazide\Telmisartan			C				Glaxosmithkline
	Prednisone			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2011	7905366	EXPEDITED (15-DAY)	N	RI, OT	1000019459		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Asthenia; Butterfly Rash; Cervicobrachial Syndrome; Depression; Disturbance In Attention; Dyskinesia; Fall; Feeling Abnormal; Gait Disturbance; Headache; Hypersomnia; Insomnia; Nail Disorder; Neck Pain; Pain In Extremity; Paraesthesia; Posture Abnormal; Product Dose Omission; Psoriasis; Restless Legs Syndrome; Tinnitus; Tourette'S Disorder; Tremor; Visual Impairment	Lexapro			S	Oral	1.25 Mg (1.25 Mg,1 In 1 D),Oral		Not Reported
	Hyzaar (Hydrochlorothiazide, Losartan) (Hydrochlorothiazide, Losartan)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2011	7920164	EXPEDITED (15-DAY)	Y	HO, OT	1000019697		82 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Seizure	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
	Aricept			S	Oral	5 Mg (5 Mg, 1 In 1 U),Oral		Not Reported
	Alvedon (Paracetamol) (500 Milligram, Tablets) (Paracetamol)			C				Not Reported
	Simvastatin (Simvastatin) (40 Milligram, Tablets)(Simvastatin)			C				Not Reported
	Doxazosin (Doxazosin)(4 Milligram, Tablets)(Doxazosin)			C				Not Reported
	Furix (Furosemide)(40 Milligram, Tablets)(Furosemide)			C				Not Reported
	Nitromex (Glyceryl Trinitrate)(0.25 Milligram, Tablets)(Glyceryl Trinitrate)			C				Not Reported
	Allopurinol (Allopurinol) (100 Milligram, Tablets) (Allopurinol)			C				Not Reported
	Trombyl (Acetylsalicylic Acid)(160 Milligram, Tablets)(Acetylsalicylic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2011	7929088	EXPEDITED (15-DAY)	Y	HO	1000019862		59 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnestic Disorder; Dysgeusia; Dysphagia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
	Plavix (Clopidogrel) (Tablets) (Clopidogrel)			C				Not Reported
	Coversyl (Perindopril) (Tablets) (Perindopril)			C				Not Reported
	Kardegic (Acetylsalicylate			C				Not Reported

Lysine) (Powder) (Acetylsalicylate Lysine)			
Tahor (Atorvastatin Calcium) (Tablets) (Atorvastatin Calcium)	C		Not Reported
Procoralan (Ivabradine Hydrochloride) (Tablets) (Ivabradine Hydrochloride)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2011	7929559	EXPEDITED (15-DAY)	Y	HO	1000019866		82 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hallucination; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Nexium			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Captopril (Captopril) (Captopril)			C				Not Reported
	Furosemide			C				Not Reported
	Rhinotrophyl (Ethanolamine Tenate, Framycetin Sulfate) (Ethanolamine Tenoate, Framycetin Sulfate)			C				Not Reported
	Tahor (Atorvastatin Calcium) (Tablets) (Atorvastatin Calcium)			C				Not Reported
	Previscan (Fluindione)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2011	7930514	EXPEDITED (15-DAY)	Y	HO	1000019951		38 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Pressure Decreased; Intentional Overdose; Sinus Tachycardia; Sopor	Escitalopram Oxalate			S	Oral	(40 Mg,Once), Oral		Not Reported
	Valproic Acid			S	Oral	(2500 Mg,Once), Oral		Not Reported
	Promazine			S	Oral	(20 Ml,Once),Oral		Not Reported
	Esomeprazole			S	Oral	(80 Mg,Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2011	7931493	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2011-01128		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder	Metoprolol Tartrate			S		50mg-		Not Reported
	Lipitor			S		20mg-		Not Reported
	Cardizem La			S				Not Reported
	Lexapro			S		10mg-		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2011	7897499	EXPEDITED (15-DAY)	Y	HO	PHHY2011FR27356		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Purpura	Leponex			S		Unk		Novartis
	Plavix			S		75 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, Unk		Not Reported
	Modopar			C		100/25 Mg		Not Reported
	Xanax			C				Not Reported
	Lasix			C				Not Reported
	Potassium			C				Not Reported
	Debridat			C				Not Reported
	Symbicort			C				Not Reported
	Esomeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2011	7898020	NON-EXPEDITED	N		US-ASTRAZENECA-2010SE46008			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine	Atenolol			S				Zeneca
	Lexapro			S				Not Reported
	Topamax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2011	7759841	EXPEDITED (15-DAY)	Y	RI, OT	1000017769		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Feeling Abnormal; Myalgia; Tremor	Lexapro			S		10 Mg (10 Mg,1 In 1 D)		Not Reported
	Lexapro			S		5 Mg (5 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2011	7603967	EXPEDITED (15-DAY)	Y	RI, OT	1000016114		69 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Lorazepam			C				Not Reported
	Lexomil (Bromazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2011	7869374	EXPEDITED (15-DAY)	N	LT, OT	PHHY2011US22074			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Cold Sweat; Dizziness; Drug Dependence; Head Injury; Hot Flush; Hyperhidrosis; Insomnia; Precancerous Cells Present; Scar; Suicidal Behaviour; Visual Impairment	Vivelle Dot			S	Transdermal	0.0375, Twice Per Week		Novartis
	Flexeril			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Vicodin			S				Not Reported
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2011	7900571	EXPEDITED (15-DAY)	Y	OT	US-SANOFI-AVENTIS-2011SA021233		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flight Of Ideas; Hypomania; Inappropriate Affect; Overdose; Painful Erection; Priapism	Zolpidem			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Unknown	Reduced Dosage		Not Reported
	Quetiapine Fumarate			S	Unknown	Reduced Dosage		Not Reported
	Zolpidem			S	Unknown	Dose: 40-60 Mg Overdose		Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown	Returned To Baseline.		Not Reported
	Marijuana			S	Unknown			Not Reported
	Marijuana			S	Unknown	Taken Intermittently		Not Reported
	Cocaine			S	Unknown			Not Reported
	Unspecified Ingredient			S	Unknown			Not Reported
	Lamivudine & Zidovudine			C	Unknown			Not Reported
	Nevirapine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2011	7934544	EXPEDITED (15-DAY)	Y	HO	1000020067		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Communication Disorder; Hyponatraemia; Seizure; Unresponsive To Stimuli	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Xanax (Alprazolam) (Tablets) (Alprazolam)			C				Not Reported
	Nortem (Temazepam) (Tablets) (Temazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2011	7354086	EXPEDITED (15-DAY)	Y	RI, OT	1000012683		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spermatogenesis Abnormal	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2011	7379193	EXPEDITED (15-DAY)	Y	CA, OT	1000013413		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Floppy Infant; Hypertonia Neonatal; Hypotonia Neonatal; Maternal Drugs Affecting Foetus; Nervous System Disorder; Poor Sucking Reflex; Talipes	Lexapro			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental)		Not Reported
	Seroquel			S	Transplacental	200 Mg (100 Mg, 2 In 1 D), Transplacental		Not Reported
	Affex (Fluoxetine) (Capsules) (Fluoxetine)			C				Not Reported
	Ranitidine			C				Not Reported
	Amoxicillin			C				Not Reported
	Augmentin			C				Not Reported
	Cytamen (Cyanocobalamin) (Injection) (Cyanocobalamin)			C				Not Reported
	Galfer (Ferrous Fumarate) (Ferrous Fumarate)			C				Not Reported
	Solpadol (Paracetamol, Codeine Phosphate) (Paracetamol, Codeine Phosphate)			C				Not Reported
	Difene (Diclofenac Sodium) (Diclofenac Sodium)			C				Not Reported
	Zimovane (Zopiclone) (Tablets) (Zopiclone)			C				Not Reported
	Buscopan (Hyoscine Butylbromide) (Tablets) (Hyoscine Butylbromide)			C				Not Reported
	Fastum (Ketoperofen) (Gel)			C				Not Reported

	(Ketoperofen) Gertac (Ranitidine) (Ranitidine)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2011	7903521	NON-EXPEDITED	N		US-PFIZER INC-2011082157			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Ineffective; Drug Intolerance; Erectile Dysfunction; Headache	Pristiq Extended Release			S		Unk, 1 X/Day	2 DAY	Pfizer
	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Abilify			C		2 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2011	7924737	DIRECT	Y				20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hyperreflexia; Serotonin Syndrome; Suicidal Ideation; Tachycardia	Escitalopram Oxalate			S	Oral	1 Tab Qday Po > 3 Months		Not Reported
	Clomipramine Hydrochloride			S	Oral	1 Tab Qday Po > 3 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2011	7932654	EXPEDITED (15-DAY)	Y	HO	1000019988		90 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Purpura	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Plavix			S	Oral	(75 Mg), Oral		Not Reported
	Clozapine			S	Oral	Oral		Not Reported
	Modopar (Benserazide Hydrochloride, Levodopa)			C				Not Reported

(Benserazide Hydrochloride, Levodopa)			
Xanax	C		Not Reported
Lasilix (Furosemide) (Furosemide)	C		Not Reported
Diffu K (Potassium Chloride) (Potassium Chloride)	C		Not Reported
Transipeg (Macrogol)	C		Not Reported
Debridat (Trimebutine) (Trimebutine)	C		Not Reported
Symbicort (Budesonide, Formoterol Fumarate) (Budesonide, Formoterol Fumarate)	C		Not Reported
Inexium (Esomeprazole Magnesium)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2011	7932658	EXPEDITED (15-DAY)	Y	RI, OT	1000019992		64 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Asthenia; Diarrhoea; Feeling Cold; Heart Rate Irregular; Hypertension; Hypoaesthesia; Insomnia; Malaise; Nausea; Paraesthesia	Escitalopram Oxalate			S	Oral	(5 Mg, Once), Oral		Not Reported
	Alendronic Acid (Alendronic Acid) (Alendronic Acid)			C				Not Reported
	Aspirin			C				Not Reported
	Azathioprine			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Butran (Buprenorphine) (Buprenorphine)			C				Not Reported
	Lekovit Ca (Colecalciferol, Calcium Carbonate) (Colecalciferol, Calcium Carboante)			C				Not Reported
	Ciprofibrate (Ciprofibrate) (Ciprofibrate)			C				Not Reported
	Diazepam			C				Not Reported
	Lacri-Lube (Paraffin Liquid, Paraffin Soft White) (Paraffin Liquid, Paraffin Soft White)			C				Not Reported
	Metoclopramide			C				Not Reported

(Metoclopramide) (10 Milligram) (Metoclorpamide)			
Nitrolingual (Glyceryl Trinitrate) (Glyceryl Trinitrate)	C		Not Reported
Omeprazole	C		Not Reported
Paracetamol (Paracetamol) (500 Milligram) (Paracetamol)	C		Not Reported
Prednisolone	C		Not Reported
Ramipril	C		Not Reported
Tamsulosin Hydrochloride) (Tamsulosin Hydrochloride) (Tamsulosin Hydrochloride)	C		Not Reported
Tears Naturale (Dextran 70, Hypromellose) (Dextran 70, Hypromellose)	C		Not Reported
Temazepam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2011	7933110	EXPEDITED (15-DAY)	Y	LT	1000020120		67 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate			S	Oral	5 Gtt (5 Gtt,1 In 1 D),Oral		Not Reported
	Tavor (Lorazepam)			S	Oral	7.5 Mg (7.5 Mg,1 In 1 D),Oral		Not Reported
	Lamictal			S	Oral	150 Mg (150 Mg,1 In 1 D),Oral		Not Reported
	Cardiazol-Paracodina (Dihydrocdoeine, Pentetrazol) (Dihydrocodeine, Pentetrazol)			C				Not Reported
	Lasix			C				Not Reported
	Tenormin			C				Not Reported
	Pritorplus (Hydrochlorothiazide) (Hydrochlorothiazide)			C				Not Reported
	Seretide			C				Not Reported
	Deltacortene (Prednisone) (Prednisone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2011	7933652	EXPEDITED (15-DAY)	Y	DS, HO	1000020103		75 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervical Vertebral Fracture; Drug Interaction; Fall; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Mopral (Omeprazole)			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Contramal (Tramadol Hydrochloride) (Capsules) (Tramadol Hydrochloride)			C				Not Reported
	Acetaminophen			C				Not Reported
	Cortancyl (Prednisone) (Tablets) (Prednisone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2011	7933656	EXPEDITED (15-DAY)	Y	HO	IPC201104-000561		46 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Fall; Hypotension	Hydrochlorothiazide			S		12.5 Mg/D		Not Reported
	Irbesartan			S		300 Mg/D		Not Reported
	Quetiapine			S		50 Mg Bid		Not Reported
	Escitalopram Oxalate			S		10 Mg In The Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2011	7904565	EXPEDITED (15-DAY)	Y	OT	PL-PFIZER INC-2011082284		36 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities; Malaise; Somnolence	Venlafaxine Hydrochloride			S		150 Mg, 1x/Day		Pfizer
	Bupropion			S		300 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S		30 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2011	7907077	EXPEDITED (15-DAY)	N	OT	BR-PFIZER INC-2011083191		55 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting; Weight Decreased	Champix			S	Oral	0.5 Mg, 1x/Day		Pfizer
	Depakote			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2011	7907299	EXPEDITED (15-DAY)	Y	HO, OT	US-JNJFOC-20110406972		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cognitive Disorder; Drug Ineffective; Hallucination, Auditory; Suicidal Ideation	Haloperidol			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Rufinamide			S	Unknown			Not Reported
	Rufinamide			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Ziprasidone			S	Unknown			Not Reported
	Ziprasidone			S	Unknown			Not Reported
	Zolpidem			S	Unknown	As Needed		Not Reported
	Zolpidem			S	Unknown	As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2011	7760445	EXPEDITED (15-DAY)	Y	HO, OT	PHHY2010TW87821		58 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Depressed Mood; Dystonia; Insomnia;	Fluoxetine			S		20 To 40 Mg/Day		Novartis
	Escitalopram Oxalate			S		10 Mg, Qd		Not Reported

Tardive Dyskinesia; Trismus	Mirtazapine	S	15 Mg, Qd	Not Reported
	Paroxetine Hydrochloride	S	10 To 40 Mg/Day	Not Reported
	Trazodone Hydrochloride	S	15 To 125 Mg/Day	Not Reported
	Venlafaxine Hydrochloride	S	37.5 To 225 Mg/Day	Not Reported
	Duloxetine	S	30 To 60 Mg/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2011	7775880	EXPEDITED (15-DAY)	Y	RI, OT	1000017896		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vision Blurred; Visual Field Defect	Escitalopram Oxalate			S	Oral	5m (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2011	7909495	NON-EXPEDITED	N		US-ASTRAZENECA-2010SE10297		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Oedema Peripheral	Toprol Xl			S	Oral			Not Reported
	Synthroid			C				Not Reported
	Prevacid			C				Not Reported
	Aldactone			C				Not Reported
	Demadex			C				Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2011	7941597	EXPEDITED (15-DAY)	Y	RI, OT	1000020146		44 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyneuropathy	Lexapro			S	Oral	(10 Mg),Oral, Temporarily Dose Reduction, Oral		Not Reported
					Oral	(10 Mg),Oral, Temporarily Dose Reduction, Oral		
	Lexapro			S	Oral	Oral		Not Reported

Fluticasone Propionate	C		Not Reported
Montelukast	C		Not Reported
Pantozol (Pantoprazole Sodium)	C		Not Reported
Aerius (Desloratadine) (Tablets) (Desloratadine)	C		Not Reported
Spiriva	C		Not Reported
Symbicort(Budesonide, Formoterol Fumarate)(Budesonide, Formoterol Fumarate)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2011	7941688	EXPEDITED (15-DAY)	Y	HO	1000020108		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Blood Glucose Increased; Diabetic Complication; Haemodynamic Instability; Hyperkalaemia; Hyperthermia; Hypotension; Intentional Overdose; Loss Of Consciousness; Metabolic Acidosis; Mydriasis; Rhabdomyolysis; Tachycardia; Vomiting	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, 1 In 1d), Oral; 1.4 Gm, Once, Oral		Not Reported
	Seroquel			S	Oral	1400 Mg (1400 Mg, 1 In 1 D), Oral; (52 Gm, Once), Oral		Not Reported
	Lorazepam			S	Oral	7.5 Mg (2.5 Mg, 3 In 1 D), Oral; 50 Mg, Once, Oral		Not Reported
	Flurazepam Hydrochloride			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral; 750 Mg, Once, Oral		Not Reported
	Atorvastatin Calcium			S	Oral	Oral; 8 Gm, Once, Oral		Not Reported
	Lisinopril			S	Oral	Oral; 350 Mg, Once, Oral		Not Reported
	Potassium Chloride			S	Oral	Oral; 470 Milligram, Once, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2011	7941782	EXPEDITED (15-DAY)	Y	RI, OT	1000020143		76 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Feeling Abnormal;	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

Pneumonia; Syncope	Quetiapine (Quetiapine) (Quetiapine)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2011	7941804	EXPEDITED (15-DAY)	Y	RI, OT	1000020144		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Naratriptan Hydrochloride			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2011	7944593	EXPEDITED (15-DAY)	N	CA	1000020152		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Artery Anomaly; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2011	7816534	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000018510		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anaemia; Asthenia; Chronic Kidney Disease; Confusional State; Fall; Gastric Haemorrhage; Inappropriate Antidiuretic Hormone Secretion; Nausea; Pneumonia; Vomiting	Lexapro			S	Oral	Tablets (10 Mg,1 In 1 D),Oral		Not Reported
	Lisinopril			C				Not Reported
	Zetia			C				Not Reported
	Thyroid Meta Max (Thyroid Meta Max) (Thyroid Meta Max)			C				Not Reported
	Coreg Cr (Carvedilol) (Carvedilol)			C				Not Reported
	Avalide (Irbesartan, Hydrochlorothiazide) (Irbesartan, Hydrochlorothiazide)			C				Not Reported
	Protonix			C				Not Reported

	Requip (Ropinirole Hydrochloride) (Ropinirole Hydrochloride)	C		Not Reported
	Rozerem (Ramelteon) (Ramelteon)	C		Not Reported
	Wellbutrin Xl	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2011	7943623	EXPEDITED (15-DAY)	Y	HO	1000020249		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
	Seroquel (Quetiapine Fumarate) (Tablets-) (Quetiapine Fumarate)			C				Not Reported
	Cal-D-Vita (Colecalciferol, Calcium Carbonate) (Tablets) (Colecalciferol, Calcium Carbonate)			C				Not Reported
	Dominal Forte (Prothipendyl Hydrochloride)			C				Not Reported
	Dulcolax (Bisacodyl)			C				Not Reported
	Lantus			C				Not Reported
	Lasix (Furosemide) (Tablets) (Furosemide)			C				Not Reported
	Lisinopril			C				Not Reported
	Lisinopril Hct (Lisinopril Dihydrate, Hydochlorothiazide)			C				Not Reported
	Mexalen (Paracetamol) (Tablets) (Paracetamol)			C				Not Reported
	Novolog			C				Not Reported
	Oleovit D3 (Colecalciferol) (Tablets) (Colecalciferol)			C				Not Reported
	Aerius (Ebastine) (Ebastine)			C				Not Reported
	Aricept (Donepezil) (Tablets) (Donepezil)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2011	7340599	EXPEDITED (15-DAY)	Y	DE	1000012466		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis; Arteriosclerosis Coronary Artery; Body Fat Disorder; Cardiomyopathy; Cholelithiasis; Pleural Fibrosis; Pulmonary Congestion; Pulmonary Oedema; Uterine Mass	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2011	7947758	EXPEDITED (15-DAY)	Y	RI, OT	1000020281			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2011	7951647	EXPEDITED (15-DAY)	Y	DE, HO	030896		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Blood Cholesterol Increased; Blood Glucose Increased; Blood Potassium Decreased; Blood Triglycerides Increased; Cerebral Haemorrhage; Cognitive Disorder; Dementia; Depressed Level Of Consciousness; Dizziness; Fall; Hypotension; Hypotonia; Skin Laceration; Urinary Tract Infection; Vertigo	Keppra			S	Oral	(1000 Mg Oral)		Not Reported
	Cipralex			S	Oral	(5 Mg Oral), (10 Mg Oral), (20 Mg Oral) Depression		Not Reported
					Oral	(5 Mg Oral), (10 Mg Oral), (20 Mg Oral) Depression		
					Oral	(5 Mg Oral), (10 Mg Oral), (20 Mg Oral) Depression		
	Torsemide			S	Oral	Specified) (10 Mg Oral)		Not Reported
	Bisoprolol Fumarate			S	Oral	(5 Mg Oral)	6 DAY	Not Reported
	Pantozol			C				Not Reported
	Aspirin			C				Not Reported
	Mcp /00041901/			C				Not Reported
	Ferro-Sanol B			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2011	7916525	EXPEDITED (15-DAY)	Y	HO	PHHY2011FR32095		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticonvulsant Drug Level Above Therapeutic; Bradycardia; Clonus; Diplopia; Dizziness; Dysstasia; Fall; Headache; Motor Dysfunction; Mydriasis; Nausea; Periorbital Haematoma	Tegretol			S		100 Mg, Qd		Novartis
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2011	7917287	EXPEDITED (15-DAY)	Y	OT	US-ROXANE LABORATORIES, INC.-2011-RO-00546RO		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Thrombocytopenia	Levetiracetam			S		1000 Mg		Roxane
	Levetiracetam			S		2000 Mg		Roxane
	Levetiracetam			S		2250 Mg		Roxane
	Dexamethasone			S		8 Mg		Roxane
	Escitalopram Oxalate			S				Not Reported
	Advair Diskus			S				Not Reported
	Ranitidine			S				Not Reported
	Phenytoin			S		300 Mg		Not Reported
	Multivitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2011	7586957	EXPEDITED (15-DAY)	Y	OT	FI-TEVA-247872ISR		64 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Muscle Rupture; Myositis;	Azilect			S	Oral	1 Milligram;		Teva

Tendonitis	Levodopa W/Carbidopa	C	Oral	100/200mg Daily		Not Reported
	Ropinirole Hydrochloride	C	Oral			Not Reported
	Cabergoline	C	Oral			Not Reported
	Neupro	C	Topical			Not Reported
	Pramipexole Dihydrochloride	C	Oral			Not Reported
	Escitalopram Oxalate	S	Oral	5-10 Mg		Not Reported
	Atorvastatin Calcium	S	Oral	10 Milligram;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2011	7892806	EXPEDITED (15-DAY)	Y	HO, OT	AU-BRISTOL-MYERS SQUIBB COMPANY-15640170		46 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Depressed Mood; Drug Interaction; Fall; Hypotension; Liver Function Test Abnormal; Overdose; Renal Function Test Abnormal; Suicidal Ideation	Paracetamol			S				Cadence
	Codeine Phosphate			S				Not Reported
	Paroxetine Hydrochloride			S				Not Reported
	Irbesartan + Hctz			S	Unknown	1df=300/12.5mg(312.5mg)		Bristol Myers Squibb
	Quetiapine Fumarate			S	Unknown			Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2011	7840783	EXPEDITED (15-DAY)	Y	OT	US-ENDO PHARMACEUTICALS INC.-HCTZ20110002		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Hyponatraemia	Hydrochlorothiazide			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2011	7920178	EXPEDITED (15-DAY)	Y	HO	FR-BRISTOL-MYERS SQUIBB COMPANY-15695604		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Generalised Tonic-Clonic Seizure; Hypocalcaemia; International Normalised Ratio Increased; Urinary Tract Infection	Pravastatin Sodium			S	Oral	1 Df:1 Scored Tab/Day		Bristol Myers Squibb
	Escitalopram Oxalate			S	Oral	1 Df:1 Film Coated Score Tab Formulation:Seroplex 10mg		Not Reported
	Noroxin			S	Oral	1 Df:2 Coated Tabs/Day Formulation:400mg		Not Reported
	Previscan (Fluindione)			S	Oral	1 Df:3/4 Then 1/4 Scored Tablet Formulation:20 Mg		Not Reported
	Aspirin			S	Oral	1 Df:1 Oral Powder For Oral Soln Formulation:Kardegic 75 Mg		Not Reported
	Bisoprolol Fumarate			S	Oral	1 Df:1 Film-Coated Scored Tablet Formulation:Cardensiel 2.5 Mg		Not Reported
	Levothyrox			S	Oral	1 Df:1 Scored Tablet Formulation:Levothyrox 100 Mcg		Not Reported
	Inexium			C	Oral	1 Df:1 Enteric-Coated Tablet Formulation:Inexium 40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2011	7938570	DIRECT	N				29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Treatment Failure	Lexapro			S	Oral	20mg 1x Per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2011	7952906	EXPEDITED (15-DAY)	Y	HO	1000018276		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Galactorrhoea	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg) , Oral		Not Reported
	Seroquel			S	Oral	350 Mg (350 Mg,1 In 1 D), Oral		Not Reported
	Depakine (Valproic Acid) (Tablets) (Valproic Acid)			C				Not Reported
	Temesta (Lorazepam) (Tablets) (Lorazepam)			C				Not Reported
	Marvelon (Marvelon0 (Marvelon)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2011	7996286	NON-EXPEDITED	Y	HO	US-JNJFOC-20101005437		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Tylenol		Y	S	Oral	Oral		Not Reported
	Lexapro			S		20 Mg, 1 In 1 Day		Not Reported
	Study Medication (Investigational Drug)			C				Not Reported
	Prednisone			C				Not Reported
	Acyclovir			C				Not Reported
	Lisinopril (Lisinopril)			C				Not Reported
	Nexium (Esomeprazole Magnesium)			C				Not Reported
	Ativan			C				Not Reported
	Atenolol (Atenolol)			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2011	7923742	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-11P-056-0722455-00		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased; Melaena	Levothyroxine			S	Oral			Not Reported
	Levothyroxine			S				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

Noroxin	S	Oral		Not Reported
Fluindione	S			Not Reported
Aspirin	S	Oral		Not Reported
Bisoprolol Fumarate	S	Oral		Not Reported
Pravastatin Sodium	S	Oral		Not Reported
Inexium	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2011	7078920	EXPEDITED (15-DAY)	Y	DE	1000007846		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Blood Pressure Increased; Blood Sodium Decreased; Cardiac Failure; Chest Pain; Fall; Glycosylated Haemoglobin Increased; Headache	Escitalopram Oxalate			S		5 Mg (15 Mg,1 In 1 D)		Not Reported
	Flupentixol			S	Oral	0.5 Mg (0.5 Mg, 1 In 1 D), Oral		Not Reported
	Mianserin			S		10 Mg (10 Mg,1 In 1 D)		Not Reported
	Nuvaring			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Novorapid Flexpen (Insulin Aspart) (Solution) (Insulin Aspart)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2011	7856201	EXPEDITED (15-DAY)	Y	RI, OT	1000018805		17 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Off Label Use	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2011	7892721	EXPEDITED (15-DAY)	Y	HO	1000019336		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Pain; Breast Swelling; Galactorrhoea	Escitalopram Oxalate	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Seroquel Xr	S		350 Mg (350 Mg, 1 In 1 D), 100 Mg (100 Mg,1 In 1 D) 350 Mg (350 Mg, 1 In 1 D), 100 Mg (100 Mg,1 In 1 D)	Not Reported
	Depakine (Valproic Acid)(Tablets) (Valproic Acid)	C			Not Reported
	Temesta (Lorazepam) (Tablets) (Lorazepam)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2011	7900443	EXPEDITED (15-DAY)	N	HO, LT, OT	ZA-JNJFOC-20110404989		17 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Diplegia; Dizziness; Drug Interaction; Fall; Gait Inability; Gait Spastic; Loss Of Consciousness; Paralysis; Syncope; Visual Impairment	Acetaminophen\Tramadol Hydrochloride			S	Unknown	Prn		Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2011	7924289	NON-EXPEDITED	N		US-PFIZER INC-2011090956		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Insomnia; Therapeutic Response Unexpected	Xanax			S	Oral	0.5 Mg Daily As Needed		Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Lexapro			S				Not Reported
	Synthroid			C		Unk		Not Reported
	Imitrex			C		As Required		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2011	7951382	EXPEDITED (15-DAY)	N	RI, OT	1000020380		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Glaucoma	Lexapro			S	Oral	10 Mg (10 Mg,L In 1 D),0ral		Not Reported
	Aspirin (Acetylsalicylic Acid) (81 Milligram, Tablets) (Acetylsalicylic Acid)			C				Not Reported
	Coq10 (Ubidecarenone) (Ubide,Carenone)			C				Not Reported
	Folic Acid (Folic Acid)(1 Milligram, Tablets)(Folic Acid)			C				Not Reported
	Fish Oil (Fish Oil)(Fish Oil)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2011	7952280	EXPEDITED (15-DAY)	Y	RI, OT	1000020465		23 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokinesia; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	(1 Dosage Forms,Once), Oral		Not Reported
	Zopiclone			S	Oral	(150 Mg,Once),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2011	7905044	EXPEDITED (15-DAY)	Y	HO	CH-BRISTOL-MYERS SQUIBB COMPANY-15672900		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Restlessness; Withdrawal Syndrome	Abilify			S	Oral	Thereafter Dose Reduction To 5 Mg Daily (28sep10-30sep10) And 2.5 Mg Daily (01oct10-08oct10).		Not Reported
	Cipralex			S	Oral	22sep-14oct10 20mg		Not Reported

				15oct10-Ong 25mg	
	Seroquel	S	Oral	1df= 25-200 Mg Daily	Not Reported
	Heroin	S		Heroin 1 G On Two Occasions In A Period From 13sep10-20sep10	Not Reported
	Cocaine	S			Not Reported
	Methadone	S	Oral	22-23sep10 35mg 24-27sep10 50mg 28sep-6oct10 40mg 7oct10-Ong 35mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2011	7944446	EXPEDITED (15-DAY)	Y	RI, OT	1000020240		40 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Personality Change; Thinking Abnormal; Weight Increased	Lexapro			S		10 Mg (10 Mg,1 In 1 D)		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D) ; 20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg,1 In 1 D) ; 20 Mg (20 Mg,1 In 1 D),Oral		
	Simvastatin (Simvastatin, Simvastatin) (Simvastatin, Simvastatin)			C				Not Reported
	Cassia (Cinnamomum Verum) (Cinnamomum Verum)			C				Not Reported
	Panadol (Paracetaol) (Paracetamol)			C				Not Reported
	Persaic (Persaic) (Persaic)			C				Not Reported
	Norvasc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2011	7956981	EXPEDITED (15-DAY)	Y	DS	1000020618		44 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Birth Mark; Drug Interaction; Eye Pain; Hot Flush; Hypertension	Escitalopram Oxalate			S				Not Reported
	Tysabri			S		(300 Mg,Every 4-6 Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2011	7957041	EXPEDITED (15-DAY)	Y	RI, OT	1000020528			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Insomnia; Muscle Tightness	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2011	7371518	EXPEDITED (15-DAY)	Y	HO, LT	1000013252		79 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Depressed Level Of Consciousness; Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2011	7931955	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2011093619		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Xanax			S	Oral	Unk		Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Zopiclone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2011	7932007	EXPEDITED (15-DAY)	N	LT	FR-BRISTOL-MYERS SQUIBB COMPANY-15712201		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coma; Multiple Organ Dysfunction Syndrome; Neuroleptic Malignant Syndrome; Status Epilepticus	Abilify	S	Oral	Long Term-20mar11	Not Reported
	Escitalopram Oxalate	S	Oral	20mg 1 Df =2 Scored Film-Coated Tabs,Long Term To 20mar11	Not Reported
	Oxazepam	C	Oral	0.5-0.5-1 From Long Term To 20mar11	Not Reported
	Valpromide	C	Oral	(1-0-2) From Long Term To 20mar11	Not Reported
	Phenobarbital	C	Oral	1 Tab/D,100mg,Unk-28feb11,Then 50mg/D From 01mar11-18mar11	Not Reported
	Keppra	C		Film-Coated Tabs Bid From Long Term-20mar11	Not Reported
	Omix	C		Omix Lp Sr Caps	Not Reported
	Acepromazine\Aceprometazine\ Clorazepate Dipotassium	C	Oral	Scored Tab From Long Term To 20-Mar-2011	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2011	7947295	EXPEDITED (15-DAY)	Y	RI, OT	1000020276		19 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Weight Increased	Escitalopram Oxalate			S		30 Mg (10 Mg,3 In 1 D) ; 15 Mg (1 N 1 D) 30 Mg (10 Mg,3 In 1 D) ; 15 Mg (1 N 1 D)		Not Reported
	Depo-Provera			S	Intramuscular	1.6667 Mg (150 Mg,1 In 3 M),Intramuscular		Not Reported
	Risperidone			S	Oral	0.5 Mg (0.5 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2011	7932530	EXPEDITED (15-DAY)	Y	HO, OT	TR-PAR PHARMACEUTICAL, INC-2011SCPR002933		61 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Tardive Dyskinesia	Alprazolam	S	Unknown	1 Mg, Unknown		Par
	Risperidone	S	Unknown	2 Mg, Qd	365 DAY	Par
	Escitalopram Oxalate	S	Unknown	20 Mg, Per Day		Not Reported
	Venlafaxine	S	Unknown	300 Mg/D		Not Reported
	Olanzapine	S	Unknown	20 Mg/D		Not Reported
	Paroxetine Hydrochloride	S	Unknown	Unk, Unknown		Not Reported
	Mirtazapine	S	Unknown	15 G, Unknown		Not Reported
	Reboxetine	S	Unknown	8 Mg, Unknown		Not Reported
	Lamotrigine	S	Unknown	500 Mg, Unknown		Not Reported
	Tianeptine	S	Unknown	12.5 Mg, Unknown		Not Reported
	Sulpiride	S	Unknown	200 Mg, Unknown		Not Reported
	Clozapine	S	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2011	7949849	EXPEDITED (15-DAY)	N	RI, OT	1000020287		70 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deafness; Dysgeusia; Insomnia; Night Blindness; Tinnitus; Weight Decreased	Escitalopram Oxalate			S	Oral	5 Mg, Oral		Not Reported
	Ultrapreventivo X (Multivitamin)			C				Not Reported
	Mirtazepina Ratiopharma (Mirtazapine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2011	7959256	EXPEDITED (15-DAY)	Y	RI, OT	1000020574			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2011	7959695	EXPEDITED (15-DAY)	Y	HO	1000020611		79 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erosive Duodenitis; Gastrointestinal Haemorrhage; Generalised Tonic-Clonic Seizure; Haemoglobin Decreased; Hypocalcaemia; Hypoparathyroidism Secondary; International Normalised Ratio Increased; Red Blood Cell Count Decreased; Urinary Tract Infection	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Norfloxacin			S	Oral	800 Mg (400 Mg, 2 In 1 D), Oral		Not Reported
	Previscan (Fluindione)			S		20 Mg (20 Mg, 1 In 1 D),		Not Reported
	Aspirin			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Bisoprolol Fumarate			S	Oral	2.5 Mg (2.5 Mg, 1 In 1 D), Oral		Not Reported
	Pravastatin Sodium			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Levothyroxine Sodium			S	Oral	100 Ug (100 Mcg, 1 In 1 D), Oral		Not Reported
	Inexium (Esomeprazole Magnesium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2011	8348729	EXPEDITED (15-DAY)	Y	HO, OT	1000020139		20 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Intentional Overdose; Pallor; Suicide Attempt	Escitalopram Oxalate			S	Oral	Once, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2011	7696469	EXPEDITED (15-DAY)	Y	HO	1000017086		86 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Hyponatraemia; Malaise	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2011	7904963	EXPEDITED (15-DAY)	N	HO, RI, OT	S06-USA-01121-01		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Chronic Sinusitis; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Hypometabolism; Insomnia; Lethargy; Lung Carcinoma Cell Type Unspecified Stage Iv; Malaise; Pneumonia; Restlessness; Somnolence; Tension Headache; Tinnitus	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2011	7936184	EXPEDITED (15-DAY)	Y	DE, OT	US-ASTRAZENECA-2011SE26195		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Toxicity To Various Agents	Seroquel			S	Oral			Zeneca
	Cocaine			S				Not Reported
	Oxycodone			S				Not Reported
	Xanax			S				Not Reported
	Morphine			S				Not Reported
	Tch-Cooh (Tetrahydrocannabinol)			S				Not Reported
	Hydroxyzine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Ibuprofen			S				Not Reported
	Benzodiazepine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2011	7936915	EXPEDITED (15-DAY)	Y	HO	US-ALEXION-A201100045		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Asthenia; Haemorrhoids; Rectal Haemorrhage; Tinnitus	Soliris			S	Intravenous (not otherwise specified)	600 Mg, Qwx4		Alexion
	Soliris			S	Intravenous (not otherwise specified)	900 Mg, Q2w		Alexion
	Lexapro			S	Oral	Unk		Not Reported
	Tranxene T-Tab			C	Oral	7.5 Mg, Tid Prn		Not Reported
	Folic Acid			C	Oral	1 Mg, Qd		Not Reported
	Centrum /00554501/			C	Oral	Unk		Not Reported
	Lipitor			C	Oral	40 Mg, Qd		Not Reported
	Arimidex			C	Oral	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2011	7951869	DIRECT	N	OT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Disturbance In Attention; Euphoric Mood; Fatigue; Muscle Twitching; Serum Serotonin Increased; Tremor	Lexapro			S	Oral	One Per Day Po 2 Or 3 Weeks Twice		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2011	7952387	EXPEDITED (15-DAY)	Y	HO	1000020533		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Bladder Dilatation; Depression; Drug Interaction; Social Avoidant Behaviour; Urinary Retention	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported
	Abilify			S	Oral	5 Mg (5 Mg, 1 In 1 D) ,Oral		Not Reported
	Valdoxan (Agomelatin) (Tablets) (Agomelatin)			C				Not Reported
	Imovane			C				Not Reported

(Zopiclone)(Tabl.Ets)(Zopiclone)			
Xanax (Alprazolam)(Tablets)(Alprazolam)	C		Not Reported
Noctran (Noctran) (Tablets) (Noctran)	C		Not Reported
Tercian (Cyamemazine)(Tab Ets)(Cyamemazine)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2011	7960586	EXPEDITED (15-DAY)	Y	HO, OT	1000020424		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Electrocardiogram Qt Prolonged; Intentional Overdose; Lethargy; Mental Status Changes; Sinus Bradycardia; Suicide Attempt	Lexapro			S	Oral	(Once),Oral		Not Reported
	Lithium Carbonate			S	Oral	(Once),Oral		Not Reported
	Alcohol (Ethanol)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2011	7964232	EXPEDITED (15-DAY)	N	HO	1000020702			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Maternal Drugs Affecting Foetus; Ventricular Septal Defect	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2011	7964928	EXPEDITED (15-DAY)	N	RI, OT	1000020689			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Neonatal Respiratory Distress	Lexapro			S	Transplacental	Transplacental		Not Reported

Syndrome; Ventricular Septal Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2011	7964948	EXPEDITED (15-DAY)	N	CA	1000020694		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Exomphalos; Hernia; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2011	6728114	EXPEDITED (15-DAY)	Y	RI, OT	1000000353			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Apathy; Blood Electrolytes Decreased; Condition Aggravated; Crying; Depression; Disease Recurrence; Eczema; Eyelid Oedema; Fatigue; Feeling Abnormal; Feeling Cold; Food Craving; Hyperphagia; Hypersomnia; Insomnia; Mood Swings; Neutrophil Count Increased; Renal Impairment; Suicidal Ideation; Tear Discolouration; Vomiting; Weight Increased; White Blood Cell Count Increased	Escitalopram Oxalate			S	Oral	Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
	Topamax (Topiramate)			C				Not Reported
	(Topiramate)							
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2011	7940752	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20110501028		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Intentional Self-Injury	Invega			S	Oral	Unknown Dose Of 6 Mg Tablets		Not Reported
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2011	7941167	EXPEDITED (15-DAY)	Y	HO	PHHY2011ES38580		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Diovan			S	Oral	160 Mg, Unk		Novartis
	Cipralex			S	Oral	30 Mg Daily		Not Reported
	Hydrochlorothiazide			S	Oral	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2011	7954525	DIRECT	Y	OT			20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mydriasis	Cymbalta			S	Oral	1 Tab 30 Mg 1 Tab Qhs Po		Not Reported
	Lexapro			S	Oral	1/2 Tab 10 Mg -5 Mg- 1/2 Tab Qhs Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2011	7955307	DIRECT	N	HO			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Heart Rate Increased;	Lexapro			S	Oral	5 Mg To Be Increased To		Not Reported

Panic Attack; Psychotic Disorder	10 Mg 1 Per Day Po

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2011	7966092	EXPEDITED (15-DAY)	Y	RI, OT	1000020761		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Neonatal Respiratory Distress Syndrome	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported
	Zyprexa			S	Transplacental	2.5 Mg (2.5 Mg, 1 In 1 D), Transplacental		Not Reported
	Diazepam			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2011	7943934	NON-EXPEDITED	N		US-PFIZER INC-2010086429		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Headache; Hot Flush; Hyperhidrosis	Celebrex			S	Oral	Unk, 1x/Day		Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Zolpidem			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2011	7971165	EXPEDITED (15-DAY)	N	OT	1000020724		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Driving Ability; Sedation; Somnolence	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Norco (Vicodin) (Vicodin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2011	7675654	EXPEDITED (15-DAY)	N	HO, OT	PHHY2010BR75692			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Depression; Shock	Diovan Hct			S		320 Mg Valsartan /25mg Hydrochlorothiazide		Novartis
	Lexapro			S		10 Mg, Unk		Not Reported
	Trileptal			C		600 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2011	7960362	DIRECT	Y	OT			13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Suicidal Ideation	Lexapro			S	Oral	10 Mg Qd Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2011	7660983	EXPEDITED (15-DAY)	N	OT	US-RB-016370-10		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Dependence; Drug Withdrawal Syndrome; Insomnia; Overdose; Self-Injurious Ideation; Substance Abuse	Suboxone			S	Sublingual			Reckitt Benckiser
	Suboxone			S	Sublingual	Sublingual Film		Reckitt Benckiser
	Lexapro			S	Oral	Dosing Information Unknown		Not Reported
	Abilify			C	Unknown			Not Reported
	Metformin Hydrochloride			C	Unknown	Dosing Information Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2011	7948471	EXPEDITED (15-DAY)	Y	HO, OT	FR-SANOFI-AVENTIS-2011SA029640		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia; Somnolence	Fludex (Indapamide)			S	Oral			Not Reported
	Effexor			S	Oral			Not Reported

Escitalopram Oxalate	S	Oral		Not Reported
Escitalopram Oxalate	S	Oral		Not Reported
Esomeprazole Magnesium	S	Oral		Not Reported
Doxazosin	C			Not Reported
Pravastatin	C			Not Reported
Avodart	C			Not Reported
Trimetazidine Hydrochloride	C			Not Reported
Foradil	C			Not Reported
Spiriva	C			Not Reported
Domperidone	C			Not Reported
Mianserin Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2011	7975243	EXPEDITED (15-DAY)	Y	RI, OT	1000020817		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Calcium Decreased; Mouth Ulceration	Lexapro			S	Oral Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2011	7975259	EXPEDITED (15-DAY)	Y	RI, OT	1000020818		22 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Tendency To Bruise; Vaginal Haemorrhage	Escitalopram Oxalate Cox-2 Inhibitor (Cox-2) (-Cox-2)			S C				Not Reported Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2011	7975619	EXPEDITED (15-DAY)	Y	HO	1000020790		84 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Hyponatraemia	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Effexor	S	Oral	37.5 Mg (37.5 Mg, 1 In 1 D), Oral	Not Reported
	Fludex (Indapamide)	S	Oral	1.5 Mg (1.5 Mg, 1 In 1 D), Oral	Not Reported
	Inexium (Esomeprazole)	S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral	Not Reported
	Erythromycin	C			Not Reported
	Macrolides (Macrolides)	C			Not Reported
	Pravastatin	C			Not Reported
	Zoxan (Doxazosin Mesilate)	C			Not Reported
	Avodart	C			Not Reported
	Vastarel	C			Not Reported
	Foradil	C			Not Reported
	Spiriva	C			Not Reported
	Biperidys (Domperidone)	C			Not Reported
	Atorvastatin Calcium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2011	7976222	EXPEDITED (15-DAY)	Y	OT	2011SP020484		9 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Nasonex			S	Respiratory (inhalation)	Inh		Not Reported
	Asmanex			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2011	7865627	EXPEDITED (15-DAY)	Y	HO, OT	1000018954		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyclic Neutropenia	Lexapro			S	Oral	Oral		Not Reported

	Dianette (Cyproterone Acetate, Ethinylestradiol)(Cyproterone Acetate, Ethinylestradiol)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2011	7981377	EXPEDITED (15-DAY)	Y	HO	1000020921		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram Oxalate			S	Oral	30 Mg (15 Mg,2 In 1 D),Oral		Not Reported
	Hydrochlorothiazide			S	Oral	50 Mg (50 Mg, 1 In 1 D),Oral		Not Reported
	Diovan			S	Oral	160 Mg (160 Mg, 1 In 1 D),Oral		Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2011	7985424	EXPEDITED (15-DAY)	Y	DE, HO	2011SP021824		22 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Dehydration; Fluid Intake Reduced; Hyponatraemia; Hypophagia; Pericarditis	Mirtazapine			S	Oral	15 Mg Po		Not Reported
	Cipralex			S	Oral	5 Mg Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2011	7889089	EXPEDITED (15-DAY)	Y	DE	1000019160		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Depressed Level Of Consciousness; Dizziness; Drug Interaction; Fall; Hypotension; Nausea; Skin Laceration; Urinary	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In I1d),Oral, 20 Mg (20 Mg, 1 In I1d),Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In		

Tract Infection					
			Oral	I1d),Oral, 20 Mg (20 Mg, 1 In I1d),Oral 5 Mg (5 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In I1d),Oral, 20 Mg (20 Mg, 1 In I1d),Oral	
	Keppra	S	Oral	1000 Mg (1000 Mg,1 In 1 D),Oral	Not Reported
	Bisoprolol Fumarate	S	Oral	5 Mg (5 Mg, 1 In 1 D) , Oral, For A Long Time	Not Reported
	Torsemide	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, For A Long Time	Not Reported
	Aspirin	S		100 Mg (100 Mg,1 In 1 D),Oral For A Longer Time	Not Reported
	Pantozol (Pantoprazole Sodium)	C			Not Reported
	Mcp	C			Not Reported
	Ferro Sanol (Ferrous Sulfate) (Capsules) (Ferrous Sulfate)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2011	7966078	EXPEDITED (15-DAY)	Y	RI, OT	1000020767		30 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Hyperthyroidism; Weight Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Seroquel (Quetiapine Fumarate)(Tablets)(Quetiapine Fumarate)			C				Not Reported
	Camcolit (Lithium Carbonate) (Tablets)(Lithium Carbonate)			C				Not Reported
	Abilify (Aripiprazole)(Tablets)(Aripiprazole)			C				Not Reported
	Lithium (Lithium) (Tablets) (Lithium)			C				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2011	7891489	EXPEDITED (15-DAY)	Y	DS, HO, LT, OT	AU-PFIZER INC-2011068790		44 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Pristiq Extended Release			S	Oral	50 Mg, 1x/Day	16 DAY	Pfizer
	Lexapro			S	Oral	20 Mg, Unk	46 DAY	Not Reported
	Karvezide			C	Oral	12.5 Mg/150mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2011	7906599	EXPEDITED (15-DAY)	Y	HO, OT	HR-PFIZER INC-2011082006		41 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Flushing; Hypersensitivity; Suffocation Feeling; Tongue Oedema	Sertraline Hydrochloride			S		25 Mg, Single		Pfizer
	Sertraline Hydrochloride			S				Pfizer
	Escitalopram Oxalate			S		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2011	7955154	EXPEDITED (15-DAY)	Y	OT	IT-EISAI INC-E3810-04676-SPO-IT		69 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sopor	Pariet (Rabeprazole)			S	Oral	Unknown		Not Reported
	Cipralex			S	Oral			Not Reported
	Flurazepam Hydrochloride			S				Not Reported
	Promazine Hydrochloride			S	Oral			Not Reported
	Tavor (Lorazepam)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2011	7955737	EXPEDITED (15-DAY)	Y	HO	FR-MERCK-1105USA02948		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

International Normalised Ratio Increased; Melaena	Noroxin		S	Oral		4 DAY	Merck
	Escitalopram Oxalate		S	Oral			Not Reported
	Previscan (Fluindione)		S	Oral	3/4-1/4 (1 Dosage Form)		Not Reported
	Aspirin		S	Oral			Not Reported
	Bisoprolol Fumarate		S	Unknown			Not Reported
	Pravastatin Sodium		S	Oral			Not Reported
	Levothyrox		S	Oral			Not Reported
	Inexium		C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2011	7957223	EXPEDITED (15-DAY)	Y	HO	1000020580		69 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Pravastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2011	7986892	EXPEDITED (15-DAY)	Y	HO, LT, OT	2011MA005626		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Inversion; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Tramadol Hydrochloride			S		3 Gr;		Purepac
	Quetiapine Fumarate			S		15 G;		Not Reported
	Escitalopram Oxalate			S		560 Mg;		Not Reported
	Mirtazapine (Mirtazapine)			S		315 Mg;		Not Reported
	Fluoxetine			S		1.1 G;		Not Reported
	Risperidone (Risperidone)			S		120 Mg;		Not Reported
	Lithium (Lithium)			S		13 G;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2011	7997917	NON-EXPEDITED	N	OT	DSA_44810_2011		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Drug Interaction; Tinnitus; Tremor; Urinary Tract Infection	Aplenzin			S	Oral	(348 Mg Qd Oral)		Not Reported
	Lexapro			S	Oral	(40 Mg Qd Oral)		Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Oxycodone			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2011	7238457	EXPEDITED (15-DAY)	Y	HO, OT	AU-PFIZER INC-2009290743		29 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bradyphrenia; Crying; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Generalised Tonic-Clonic Seizure; Headache; Hyperreflexia; Nausea; Pain; Pyrexia; Respiratory Arrest; Seizure; Somnolence; Syncope; Tremor	Lyrica			S	Oral	300 Mg, 2x/Day		Pfizer
	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Tramadol Hydrochloride			S	Oral	150 Mg, 2x/Day		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, 1x/Day Nocte		Not Reported
	Oxycontin			C	Oral	20 Mg, 1x/Day Nocte		Not Reported
	Diazepam			C	Oral	5 Mg, 3x/Day		Not Reported
	Temazepam			C	Oral	10 Mg, Nocte As Needed		Not Reported
	Oxynorm			C	Oral	10 Mg, 2x/Day As Needed		Not Reported
	Codeine Phosphate			C		1 3x/Day		Not Reported
	Paracetamol			C		500 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2011	7843684	EXPEDITED (15-DAY)	Y	DE, HO, LT	CA-ROCHE-763039		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypotension; Hypoxia;	Clonazepam			S	Unknown			Roche

Intentional Overdose	Clonazepam	S	Unknown	Overdose	Roche
	Apixaban	S	Oral		Not Reported
	Warfarin Sodium	S	Oral		Not Reported
	Ativan	S	Unknown	As Necessary	Not Reported
	Ativan	S	Unknown	Overdose	Not Reported
	Cipralex	S	Unknown		Not Reported
	Metoprolol	S	Unknown		Not Reported
	Metoprolol	S	Unknown	Overdose	Not Reported
	Propafenone Hydrochloride	S	Unknown		Not Reported
	Propafenone Hydrochloride	S	Unknown	Overdose	Not Reported
	Metformin Hydrochloride	C			Not Reported
	Gliclazide	C			Not Reported
	Ezetrol	C			Not Reported
	Venlafaxine Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2011	7872047	EXPEDITED (15-DAY)	N	OT	BR-PFIZER INC-BR-WYE-H15150010		44 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Mass Index Increased; Fluid Retention; Swelling; Weight Decreased; Weight Fluctuation; Weight Increased; Weight Loss Poor	Pristiq Extended Release			S	Oral	50 Mg, 1x/Day		Pfizer
	Pristiq Extended Release			S				Pfizer
	Lexapro			S		10 Mg, 1x/Day	666 DAY	Not Reported
	Euthyrox			C	Oral	100 Ug, 1x/Day		Not Reported
	Pariet			C		20 Mg, 1x/Day	91 DAY	Not Reported
	Cellulase\Dehydrocholic Acid\Metoclopramide\Pancreatin\Pepsin			C		1 Df, 1x/Day	30 DAY	Not Reported
	Cellulase\Dehydrocholic Acid\Metoclopramide\Pancreatin\Pepsin			C				Not Reported
	Pantoprazole			C		40 Mg, 1x/Day	91 DAY	Not Reported
	Lorazepam			C		1 Mg, Weekly		Not Reported
	Fluconazole			C		150 Mg, 1x/Day		Not Reported

Celebrex	C	200 Mg, Occasionally		Not Reported
Levocetirizine	C	1 Df, 1x/Day	15 DAY	Not Reported
Biofenac (Diclofenac Diethylamine)	C	75 Mg, 1x/Day	7 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2011	7933763	EXPEDITED (15-DAY)	Y	HO	DE-WATSON-2011-06067		76 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Galantamine Hydrobromide			S	Unknown	8 -16 Mg, Then Increased To 16 Mg		Watson
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2011	7943440	NON-EXPEDITED	Y	DE	US-JNJFOC-20110505289		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Ibuprofen			S				Not Reported
	Oxycodone			S				Not Reported
	Cocaine			S				Not Reported
	Morphine			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Hydroxyzine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Quetiapine			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2011	7958842	EXPEDITED (15-DAY)	Y	HO, LT, OT	US-ROXANE LABORATORIES, INC.-2011-RO-00687RO		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Overdose; Suicide Attempt	Lithium Carbonate			S	Oral			Roxane
	Escitalopram Oxalate			S	Oral			Not Reported

	Alcohol			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2011	7977416	DIRECT	N	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug Ineffective; Gun Shot Wound; Insomnia; Product Substitution Issue	Lexapro			S	Oral	10 Mg 2 Per Day Oral		Forest
	Levaquin			S	Oral	500mg 1 Per Day Oral		Janssen
	Ciprofloxacin			S				Cobalt
	Bactrin			C				Not Reported
	Doxycycline			C				Not Reported
	Levaquin			C				Not Reported
	Zolpidem			C				Not Reported
	Flomax			C				Not Reported
	Actos			C				Not Reported
	Amlodipine			C				Not Reported
	Benazepril Hydrochloride			C				Not Reported
	Crestor			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Docusate Sodium			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2011	7987451	EXPEDITED (15-DAY)	Y	RI, OT	1000021021			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral; Oral		Not Reported
					Oral	15 Mg (15 Mg, 1 In 1 D), Oral; Oral	2 YR	
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2011	7987497	EXPEDITED (15-DAY)	Y	HO	1000021065		70 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tubulointerstitial Nephritis	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Tahor (Atorvastatin Calcium) (Tablets) (Atorvastatin Calcium)			C				Not Reported
	Prazepam			C				Not Reported
	Tardyferon (Ferrous Sulfate) (Ferrous Sulfate)			C				Not Reported
	1-Alpha (Alfacalcidol) (Alfacalcidol)			C				Not Reported
	Kenzen (Candesartan Cilexetil) (Candesartan Cilexetil)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2011	7989315	EXPEDITED (15-DAY)	Y	RI, OT	1000020974		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Drug Interaction; Suicidal Ideation	Lexapro			S	Oral	Oral		Not Reported
	Fentanyl Patches			S	Transdermal	Transdermal		Not Reported
	Oxycodone (Oxycodone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2011	7765575	EXPEDITED (15-DAY)	Y	HO	1000017837		87 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Pancytopenia	Escitalopram Oxalate			S	Oral	5 Mg, As Required, Oral		Not Reported
	Ramipril			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Nifedipine			S	Oral	30 Mg (3 Mg, 1 In 1 D), Oral		Not Reported
	Inipomp			S	Oral	40 Mg, Oral		Not Reported
	Acetaminophen			S	Oral	3 Gram (1 Gm, 3 In 1 D), Oral		Not Reported
	Diclofenac Sodium			S	Cutaneous	1 Dosage Forms, As Required), Cutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2011	7856111	EXPEDITED (15-DAY)	Y	DE, HO	1000018857		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder; Cardiac Arrest; Condition Aggravated; Decreased Appetite; Depressed Level Of Consciousness; Hypotension; Hypoxia; Intentional Overdose; Psychiatric Symptom; Restlessness; Stress; Suicide Attempt	Escitalopram Oxalate			S	Oral Oral	Oral; 30 Mg, Oral; Once, Oral Oral; 30 Mg, Oral; Once, Oral		Not Reported
	Apixaban			S	Oral Oral	Oral Oral		Not Reported
	Ativan			S		1 Mg, As Required); Once		Not Reported
	Clonazepam			S		1.5 Mg (0.5 Mg, 3 In 1 D); Once 1.5 Mg (0.5 Mg, 3 In 1 D); Once		Not Reported
	Metoprolol Tartrate			S		100 Mg (50 Mg, 2 In 1 D); Once		Not Reported
	Propafenone Hydrochloride			S		450 Mg (150 Mg, 3 In 1 D); Once 450 Mg (150 Mg, 3 In 1 D); Once		Not Reported
	Metformin Hydrochloride			C				Not Reported
	Gliclazide			C				Not Reported
	Effexor			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Warfarin Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2011	7942433	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2011SE27587		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Somnolence	Effexor			S	Oral		26 DAY	Not Reported
	Escitalopram Oxalate			S	Oral		3 DAY	Not Reported
	Escitalopram Oxalate			S	Oral		10 DAY	Not Reported

	Fludex (Indapamide)	S	Oral		19 DAY	Not Reported
	Ciprofloxacin	C				Not Reported
	Mianserin Hydrochloride	C				Not Reported
	Avodart	C				Not Reported
	Vastarel	C				Not Reported
	Foradil	C				Not Reported
	Spiriva	C				Not Reported
	Domperidone	C				Not Reported
	Pravastatin	C				Not Reported
	Inexium	S	Oral			Astrazeneca
	Erythromycin	S				Not Reported
	Tahor	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2011	7960557	EXPEDITED (15-DAY)	N	DS, HO, LT, OT	GR-BRISTOL-MYERS SQUIBB COMPANY-15750904		36 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Captopril And Hydrochlorothiazide			S	Oral	Tabs		Apothecon
	Cipralex			S	Oral	Tabs;1df=1/Litre		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2011	7975237	EXPEDITED (15-DAY)	Y	HO	1000020816		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Hepatic Steatosis; Hepatitis Cholestatic; Hepatosplenomegaly; Platelet Count Decreased	Escitalopram Oxalate			S	Oral	(10 Mg), Oral		Not Reported
	Chloramphenicol			S	Oral	Oral		Not Reported
	Neurontin			S		(300 Mg),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2011	7991529	EXPEDITED (15-DAY)	Y	LT	1000020992			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression; Anxiety; Decreased Appetite; Dysgeusia; Emotional Disorder; Feeling Abnormal; Insomnia; Suicidal Ideation; Weight Decreased	Escitalopram Oxalate	S	20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Propavan (Propiomazine Maleate)(Tablets)(Propiomazine Maleate)	C			Not Reported
	Stilnoct (Zolpidem Tartrate)(Tablets)(Zolpidem Tartrate)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2011	7991677	EXPEDITED (15-DAY)	Y	OT	1000021001		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental; 5 Mg (5 Mg, 1 In 1 D), Transplacental		Not Reported
					Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental; 5 Mg (5 Mg, 1 In 1 D), Transplacental		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2011	7743901	EXPEDITED (15-DAY)	Y	RI, OT	1000017482		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Oligohydramnios; Pregnancy	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Cymbalta			S	Oral	60 Mg (60 Mg,1 In 1 D),Oral		Not Reported
	Yasminelle (Drospirenone, Ethinyl Estradiol) (Tablets) (Drospirenone, Ethinyl Estradiol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2011	7743907	EXPEDITED (15-DAY)	Y	CA	1000017492			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Fluid Volume Decreased; Caesarean Section; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg,1 In 1 D),Transplacental		Not Reported
	Cymbalta			S	Transplacental	60 Mg (60 Mg, 1 In 1 D),Transplacental		Not Reported
	Yasminelle (Drospirenone, Ethinyl Estradiol) (Drospirenone, Ethinyl Estradiol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2011	7963155	NON-EXPEDITED	N		US-MYLANLABS-2010S1011986		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Headache; Hot Flush; Hyperhidrosis	Zolpidem Tartrate			S	Oral			Not Reported
	Lexapro			S	Oral			Alphapharm
	Celebrex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2011	7990247	EXPEDITED (15-DAY)	Y	LT	1000021067		64 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Methylene Blue			S				Not Reported
	Alendronic Acid (Alendronic Acid) (Alendronic Acid)			C				Not Reported
	Atorvastatin (Atorvastatin) (Atorvastatin)			C				Not Reported
	Dihydrocodeine (Dihydrocodeine) (Dihydrocodeine)			C				Not Reported
	Felodipine (Felodipine) (Felodipne)			C				Not Reported
	Gaviscon (Gaviscon /00237601/) (Gaviscon /00237601/)			C				Not Reported
	Losartin (Losartan Potassium)			C				Not Reported

(Losartan Potassium)			
Metformin Hydrochloride	C		Not Reported
Omeprazole	C		Not Reported
Paracetamol (Paracetamol) (Paracetamol)	C		Not Reported
Salbutamol (Salbutamol) (Salbutamol)	C		Not Reported
Seretide (Seretide /01420901/) (Seretide /01420901/)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2011	7993837	EXPEDITED (15-DAY)	Y	HO	DSA_46713_2011		82 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; General Physical Health Deterioration; Hyponatraemia	Enalapril Maleate			S	Oral	(5 Mg Qd Oral)		Not Reported
	Cipralex			S	Oral	(Df Oral)		Not Reported
	Pamol			C				Not Reported
	Acetylcysteine			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Ipramol			C				Not Reported
	Cocillana-Etyfin			C				Not Reported
	Diazepam			C				Not Reported
	Fenantoin			C				Not Reported
	Imovane			C				Not Reported
	Diazepan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2011	7815615	EXPEDITED (15-DAY)	N	DE, HO, LT, OT	B0699992A		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Decreased Appetite; Depressed Level Of Consciousness; Hypotension; Hypoxia; Mental Disorder; Mental Impairment; Overdose; Suicidal Ideation; Suicide Attempt	Rythmol			S	Unknown	150mg Three Times Per Day		Glaxosmithkline
	Cipralex			S	Oral	30mg Per Day		Not Reported
	Metoprolol Tartrate			S	Unknown	50mg Twice Per Day		Not Reported
	Clonazepam			S	Unknown	.5mg Three Times Per Day		Glaxosmithkline

	Ativan	S	Unknown	1mg As Required		Not Reported
	Placebo	S	Oral			Glaxosmithkline
	Warfarin Sodium	S	Oral	7mg Per Day		Glaxosmithkline
	Apixaban	S	Oral	5mg Twice Per Day	497 DAY	Not Reported
	Metformin Hydrochloride	C				Glaxosmithkline
	Gliclazide	C				Not Reported
	Ezetimibe	C				Glaxosmithkline
	Venlafaxine Hydrochloride	C				Glaxosmithkline
	Vitamin D Nos	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2011	7892725	EXPEDITED (15-DAY)	Y	RI, OT	1000019334		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anger; Anxiety; Bruxism; Depressed Mood; Dyskinesia; Emotional Disorder; Headache; Impulsive Behaviour; Insomnia; Irritability; Loss Of Libido; Paranoia; Sedation; Sexual Dysfunction; Suicidal Ideation; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Prozac (Fluoxetine) (Fluoxetine)			C				Not Reported
	Duloxetine (Duloxetine) (Duloxetine)			C				Not Reported
	Sertraline (Sertraline) (Sertraline)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2011	7924371	EXPEDITED (15-DAY)	Y	HO	1000019785		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence	Escitalopram Oxalate			S				Not Reported
	Dexfenfluramine Hydrochloride			S				Not Reported
	Benfluorex Hydrochloride			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2011	7944007	EXPEDITED (15-DAY)	N	RI, OT	1000020235			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D), Oral		Not Reported
	Tergretol Cr (Carbamazepine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2011	7964820	EXPEDITED (15-DAY)	Y	HO	TR-ASTRAZENECA-2011SE29706		54 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rhabdomyolysis	Quetiapine			S	Oral			Zeneca
	Metoprolol			C				Not Reported
	Olmesartan Medoxomil			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Quetiapine			S	Oral			Zeneca
	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2011	7970559	EXPEDITED (15-DAY)	Y	DE	1000020789		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Coma; Disseminated Intravascular Coagulation; Hepatic Cirrhosis; Hepatic Failure; Hepatic Neoplasm; Hyperthermia; Miosis; Neuroleptic Malignant Syndrome; Neuropathy Peripheral; Overdose; Poisoning Deliberate; Portal Hypertension; Product	Escitalopram Oxalate			S		20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Abilify			S		30 Mg (15 Mg,2 In 1 D)		Not Reported
	Gardenal (Phenobarbital) (Phenobarbital)			C				Not Reported
	Kepra (Levetiracetam) (Tablets) (Levetiracetam)			C				Not Reported

Dose Omission; Rhabdomyolysis; Status Epilepticus; Varices Oesophageal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2011	7987445	EXPEDITED (15-DAY)	Y	DE, HO	1000021008		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Blood Chloride Decreased; Blood Iron Decreased; Blood Magnesium Decreased; Cardiac Arrest; Dehydration; Gamma-Glutamyltransferase Increased; Haemoglobin Decreased; Hypophagia; International Normalised Ratio Increased; Oligodipsia; Pericarditis; Serum Ferritin Increased	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D), Oral		Not Reported
	Mirtazapine			S	Oral	15 Mg (15 Mg,1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2011	7644766	EXPEDITED (15-DAY)	Y	RI, OT	1000015683		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Colitis Ulcerative; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	2 YR	Not Reported
	Cortison (Cortisone Acetate) (Cortisone Acetate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2011	7964249	EXPEDITED (15-DAY)	Y	CA, DS, HO	1000020668		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Caesarean Section; Congenital Pulmonary Valve Disorder; Drug Withdrawal Syndrome Neonatal; Maternal Drugs Affecting Foetus; Renal Aplasia; Selective Eating Disorder; Small For Dates Baby; Temperature Regulation Disorder	Escitalopram Oxalate	S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported
	Cortisone (Cortisone) (Cortisone)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2011	7966455	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20110509701		42 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury	Topamax			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Tavor (Lorazepam)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2011	7967609	EXPEDITED (15-DAY)	Y	HO, OT	GXKR2011DE01832		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Maternal Exposure During Pregnancy; Oedema; Pre-Eclampsia; Premature Baby; Proteinuria	Mirtazapine			S	Oral	30 Mg/Day Until Gw 8.5, Rest Of Pregnancy 15 Mg/Day	255 DAY	Novartis
	Cipralex			S	Oral	10 Mg, Qd (Gw 0 To 8.5)	62 DAY	Not Reported
	Paracetamol			C	Oral	500 Mg, Qd (Gw 9.2 To 9.5)	4 DAY	Not Reported
	Amoxicillin\Clavulanate Potassium			C	Oral	1 Df, Bid (Gw 9.2 To 9.3)	2 DAY	Not Reported
	Folic Acid			C	Oral	0.8 Mg/Day (Gw 5 To 12.6)	52 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2011	7967677	EXPEDITED (15-DAY)	Y	HO, OT	GXKR2011DE01842		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Mirtazapine			S	Transplacental	Maternal Dose: 30 Mg/Day Until Gw 8.5 And 15 Mg/Day For The Rest Of Pregnancy		Novartis
	Cipralex			S	Transplacental	Maternal Dose: 10 Mg/Day, O To 8.5 Gw		Not Reported
	Paracetamol			C	Transplacental	Maternal Dose: 500 Mg/Day	4 DAY	Not Reported
	Amoxicillin\Clavulanate Potassium			C	Transplacental	Maternal Dose: 2 Df/Day	2 DAY	Not Reported
	Folic Acid			C	Transplacental	0.8 Mg/Day	52 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2011	7985669	DIRECT	N	CA, RI			< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Congenital; Maternal Drugs Affecting Foetus	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2011	7995960	EXPEDITED (15-DAY)	Y	HO	1000021155		23 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hyperhidrosis; Nausea; Sleep Disorder; Treatment Noncompliance; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Zyprexa			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2011	8029073	NON-EXPEDITED	Y	OT	US-001845		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Trazodone Hydrochloride			S	Oral	(Oral)		Not Reported
	Telavancin Hydrochloride			S	Intravenous (not otherwise specified)	(10 Mg/Kg, Total Dose Intravenous (Not Otherwise Specified))		Not Reported
	Lexapro			S	Oral	(Oral)		Not Reported
	Metoclopramide			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Novolin R			C				Not Reported
	Hydromorphone Hydrochloride			C				Not Reported
	Metoprolol			C				Not Reported
	Lisinopril			C				Not Reported
	Sitagliptin			C				Not Reported
	Imdur			C				Not Reported
	Lasix			C				Not Reported
	Cilostazol			C				Not Reported
	Colecalciferol			C				Not Reported
	Calcium Citrate			C				Not Reported
	Omeprazole			C				Not Reported
	Zolpidem			C				Not Reported
	Lipitor			C				Not Reported
	Fentanyl			C				Not Reported
	Lantus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2011	7969553	EXPEDITED (15-DAY)	Y	OT	DE-TEVA-283724GER			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pre-Eclampsia	Mirtazapine			S	Oral	30 Milligram;	255 DAY	Not Reported
	Mirtazapine			S	Oral		255 DAY	Not Reported
	Cipralex			S	Oral	10 Milligram;		Not Reported
	Paracetamol			C	Oral	500 Milligram;		Not Reported

	Amoxicillin\Clavulanate Potassium	C	Oral	250 Mg/D (2x125) Clavulanate + 1750 Mg /D (2x875) Amoxicillin		Not Reported
	Folio Forte	C	Oral	.8 Milligram;	52 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2011	7969556	EXPEDITED (15-DAY)	Y	CA, HO, OT	DE-TEVA-283726GER		< 1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemangioma Congenital; Hyperbilirubinaemia Neonatal; Premature Baby; Selective Eating Disorder	Mirtazapine			S	Transplacental		255 DAY	Teva
	Mirtazapine			S	Transplacental		255 DAY	Teva
	Cipralex			S	Transplacental	10 Milligram;		Not Reported
	Paracetamol			C	Transplacental	500 Milligram;		Not Reported
	Amoxicillin\Clavulanate Potassium			C	Transplacental	250 [Mg/D (2x125)] Clavulanate + 1750 [Mg/D (2x875)]Amoxicillin		Not Reported
	Folio Forte			C	Transplacental	.8 Milligram;	52 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2011	7969951	EXPEDITED (15-DAY)	Y	HO, OT	ES-PFIZER INC-2011112319		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gamma-Glutamyltransferase Increased; Hepatitis Cholestatic	Neurontin			S	Oral	Unk		Pfizer
	Calcium Carbimide			S	Oral	Unk		Not Reported
	Cipralex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2011	7969953	EXPEDITED (15-DAY)	N	OT	DE-PFIZER INC-2011116108			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Feeling Of Despair; Heart Rate Increased; Hypertension	Champix	S		Pfizer
	Doxepin Hydrochloride	S		Not Reported
	Cipralex	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2011	7986371	DIRECT	N	LT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Emotional Disorder; Suicidal Behaviour	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2011	7996116	EXPEDITED (15-DAY)	Y	HO	1000021229		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Fall; Hypotension	Lexapro			S	Oral	10 Mg (10 Mg, 1 I N 1 D), Oral		Not Reported
	Quetiapine Fumarate			S		100 Mg (100 Mg, 1 In 1 D)		Not Reported
	Hydrochlorothiazide\Irbesartan			S		1 Df (1 Dosage Forms, 1 I N1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2011	7996212	EXPEDITED (15-DAY)	N	HO	1000021195		55 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Dysstasia; Fall; Feeling Cold; Gait Disturbance; Headache; Hypoacusis; Ill-Defined Disorder; Malaise; Neck Pain; Restless Legs Syndrome; Sleep Disorder; Syncope; Visual Impairment; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg Mg, 1 In 1 D), Oral		Not Reported
	Xalatan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2011	7997197	EXPEDITED (15-DAY)	N	RI, OT	1000021166			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Hemiplegia; Migraine; Seizure; Speech Disorder	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2011	7952890	EXPEDITED (15-DAY)	Y	HO, LT, OT	DE-ABBOTT-11P-062-0725894-00		19 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Loss Of Consciousness; Somnolence; Suicide Attempt; Vomiting	Valproate Sodium			S	Oral	Overdose		Not Reported
	Cipralex			S	Oral			Not Reported
	Dimethindene			S	Oral	Overdose: 1 Bottle		Not Reported
	Alcohol			S	Other	Unknown Amount		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2011	7971737	EXPEDITED (15-DAY)	Y	OT	FR-BAXTER-2011BH017738		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2011	7971837	EXPEDITED (15-DAY)	Y	LT, OT	US-ROXANE LABORATORIES, INC.-2011-RO-00742RO		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest; Long Qt Syndrome	Ondansetron	S			Roxane
	Succinylcholine	S			Not Reported
	Nortriptyline Hydrochloride	S		25 Mg	Not Reported
	Atorvastatin	S		20 Mg	Not Reported
	Escitalopram Oxalate	S		10 Mg	Not Reported
	Topiramate	S		25 Mg	Not Reported
	Baby Aspirin	S			Not Reported
	Heparin	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2011	7989493	DIRECT	Y				65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Insomnia	Lexapro			S	Oral	10 Qd Po (Dates Of Use: Unknown, Several Months)		Not Reported
	Venlafaxine			S	Oral	37.5 Mg Bid Po (Dates Of Use: Unknown, Several Months)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2011	7998076	EXPEDITED (15-DAY)	Y	CA, HO, OT	2011SP024112		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Haemangioma Congenital; Hyperbilirubinaemia Neonatal; Maternal Death Affecting Foetus; Premature Baby; Selective Eating Disorder	Mirtazapine			S	Transplacental	Trpl		Not Reported
	Cipralex			S	Transplacental	Trpl		Not Reported
	Paracetamol			C				Not Reported
	Amoxicillin & Clavulanate Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2011	7962949	EXPEDITED (15-DAY)	Y	HO	1000020675		49 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Ketoacidotic Hyperglycaemic Coma; Rash Maculo-Papular	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolam			C				Not Reported
	Prazepam (Prazepam) (Prazepam)			C				Not Reported
	Neocodion (Codeine, Sulfogaiacol) (Tablets) (Codeine, Sulfogaiacol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2011	7982837	EXPEDITED (15-DAY)	Y	HO, LT, RI, OT	1000020940		19 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Overdose; Loss Of Consciousness; Somnolence; Suicide Attempt; Vomiting	Escitalopram Oxalate			S	Oral	30 Mg, Once, Oral		Not Reported
	Valproate Sodium			S	Oral	3300 Mg, Once, Oral		Not Reported
	Dimethindene Maleate			S	Oral	1 Bottle (Single Dosage), Oral		Not Reported
	Alcohol (Ethanol)			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2011	7987060	EXPEDITED (15-DAY)	Y	HO	1000020950		80 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Memantine			S		20 Mg (20 Mg, 1 In 1 D),		Not Reported
	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D),		Not Reported
	Fentanyl			S		1 Df (1 Dosage Forms, 1 In 1 D);		Not Reported
	Tamsulosine Hydrochloride			C				Not Reported
	Dutasteride			C				Not Reported
	Foline (Folic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2011	7976491	NON-EXPEDITED	N		US-BAYER-201028563NA		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Swelling Face; Swollen Tongue	Avelox			S	Oral	400 Mg, Qd	1 DAY	Bayer
	Ibuprofen			C		Unk Unk, Prn		Bayer
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Nicoderm Cq			S		Unk	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2011	8001462	EXPEDITED (15-DAY)	Y	HO, LT, OT	AUR-APL-2011-01870		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Ejection Fraction Decreased; Fibrosis; Incision Site Haemorrhage; Long Qt Syndrome; Procedural Haemorrhage; Sinus Bradycardia; Ventricular Fibrillation; Ventricular Tachycardia	Ondansetron			S				Not Reported
	Nortriptyline Hydrochloride			S		25mg		Not Reported
	Atorvastatin			S		20mg		Not Reported
	Escitalopram Oxalate			S		10 Mg		Not Reported
	Suxmethonium Chloride			C		25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2011	8006330	EXPEDITED (15-DAY)	Y	RI, OT	1000021410		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1), Oral		Not Reported
					Oral	40 Mg (40 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1), Oral		

	Cyclophosphamide	S	Intravenous (not otherwise specified)	1180 Mg (1180 Mg, 1 In 1 D), Intravenous (Not Otherwise Specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2011	8006336	EXPEDITED (15-DAY)	N	DE	1000021283		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Occlusion; Cardiac Ventricular Disorder; Heart Disease Congenital; Left Ventricular Failure; Maternal Drugs Affecting Foetus; Obstruction; Post Procedural Complication	Lexapro			S	Transplacental	Transplacental		Not Reported
	Zoloft			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2011	7934541	EXPEDITED (15-DAY)	Y	RI, OT	1000020064		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mastitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2011	7980181	NON-EXPEDITED	Y		US-PFIZER INC-2011121825		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery	Pristiq Extended Release			S		50 Mg		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2011	7980744	EXPEDITED (15-DAY)	Y	HO, OT	DE-MYLANLABS-2011S1010952		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Caesarean Section; Maternal Exposure During Pregnancy; Pre-Eclampsia	Mirtazapine	S	Oral	30 [Mg/D]/ Until Gw 8.5 30 Mg/D, Rest Of Pregnancy 15 Mg/D	255 DAY	Not Reported
	Mirtazapine	S	Oral	30 [Mg/D]/ Until Gw 8.5 30 Mg/D, Rest Of Pregnancy 15 Mg/D	255 DAY	Not Reported
	Cipralex	S	Oral	10 [Mg/D]	62 DAY	Not Reported
	Paracetamol	C	Oral	500 [Mg/D]		Not Reported
	Amoxicillin\Clavulanate Potassium	C	Oral	250 [Mg/D (2x125)] / 1750 [Mg/D (2x875)]	2 DAY	Not Reported
	Folic Acid	C	Oral	0.8 [Mg/D]	52 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2011	7980751	EXPEDITED (15-DAY)	Y	CA, HO, OT	DE-MYLANLABS-2011S1010960		< 1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemangioma Congenital; Hyperbilirubinaemia Neonatal; Maternal Exposure During Pregnancy; Premature Baby; Selective Eating Disorder	Mirtazapine			S	Transplacental	30 [Mg/D]/ Until Gw 8.5 30 Mg/D, Rest Of Pregnancy 15 Mg/D	255 DAY	Not Reported
	Cipralex			S	Transplacental	10 [Mg/D]	62 DAY	Not Reported
	Paracetamol			C	Transplacental	500 [Mg/D]	1 DAY	Not Reported
	Amoxicillin\Clavulanate Potassium			C	Transplacental	250 [Mg/D (2x125)] / 1750 [Mg/D (2x875)]	2 DAY	Not Reported
	Folic Acid\Potassium Iodide			C	Transplacental	0.8 [Mg/D]	52 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2011	8003834	EXPEDITED (15-DAY)	Y	CA, HO, RI, OT	1000021415		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Congenital Anomaly; Haemangioma Congenital; Hyperbilirubinaemia; Maternal Drugs Affecting	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D),Transplacental		Not Reported
	Mirtazapine			S	Transplacental	30 Mg (30 Mg, 1 In 1 D),Transplacenta, 15 Mg		Not Reported

Foetus; Premature Baby; Selective Eating Disorder			(15 Mg, 1 In 1 D),Transplacen		
	Paracetamol (Paracetamol)(Paracetamol)	C			Not Reported
	Amoxicillin\Clavulanate Potassium	C			Not Reported
	Folio Forte (Folic Acid) (Folic Acid)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2011	7904077	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20110403801		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Bradycardia; Hypotonia; Metabolic Acidosis; Respiratory Distress	Topamax			S	Transplacental			Not Reported
	Topamax			S	Transplacental	Start Date- 19-Oct		Not Reported
	Lexapro			S	Transplacental	On Therapy For 7 Weeks		Not Reported
	Elavil			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2011	7983512	EXPEDITED (15-DAY)	N	HO	B0723312A		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Cheilitis; Condition Aggravated; Conjunctivitis; Erythema Multiforme; Mouth Ulceration; Oropharyngeal Discomfort; Pharyngitis; Protein Total Abnormal; Pyrexia; Rash; Skin Lesion; Stevens-Johnson Syndrome	Lamictal			S	Oral	25mg Per Day	24 DAY	Glaxosmithkline
	Escitalopram Oxalate			S	Oral	20mg Per Day	24 DAY	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2011	7997433	DIRECT	Y				65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Insomnia	Lexapro			S	Oral	10 Qd Po		Not Reported
	Venlafaxine Hydrochloride			S	Oral	37.5mg Bid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2011	8007717	EXPEDITED (15-DAY)	N	CA	1000021289		1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Vascular Malformation	Lexapro			S	Transplacental	20 Mg (20 Mg,1 In 1 D),Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2011	8008406	EXPEDITED (15-DAY)	Y	LT	1000021428		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Road Traffic Accident; Somnolence	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Nisis			C				Not Reported
	Tranxene T-Tab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2011	8008590	EXPEDITED (15-DAY)	Y	RI, OT	1000021440		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		
	Trileptal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2011	8008608	EXPEDITED (15-DAY)	N	RI, OT	1000021438		2 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product By Child	Escitalopram Oxalate			S	Oral	1 Drop In A Small Amount Of Orange Juice, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2011	8009100	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000021439		31 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery; Urinary Tract Infection	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Mirtazapine			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
					Oral	30 Mg (30 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral		
	Folio Forte (Folic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2011	8009110	EXPEDITED (15-DAY)	Y	RI, OT	1000021443		14 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Contusion; Petechiae	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2011	8018388	EXPEDITED (15-DAY)	Y	HO	1000021420			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angina Pectoris; Balance Disorder; Extrasystoles; Fatigue; Vomiting	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg,1 In 1 D),Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2011	7869905	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20110307442		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Decreased Appetite; Hallucination; Headache; Incorrect Product Administration Duration; Occipital Neuralgia	Tylenol		Y	S	Oral			Not Reported
	Tylenol			S	Oral	1000mg 3-4 Times Day		Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral	8-10 Years		Not Reported
	Methylprednisolone			C	Oral			Not Reported
	Atenolol			C	Oral			Not Reported
	Levothyrox			C	Oral			Not Reported
	Valsartan W/ Hydrochlorothiazide			C	Oral	81mg/25mg, 8-10 Years		Not Reported
	Ocuvite Nos			C	Oral	6-7 Years		Not Reported
	Vitamins			C	Oral			Not Reported
	Bayer Aspirin			C	Oral			Not Reported
	Lovaza			C	Oral			Not Reported
	Vitamin D2			C	Oral			Not Reported
	Calcium Carbonate			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Ubidecarenone			C	Oral			Not Reported
	Fish Oil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2011	7986589	EXPEDITED (15-DAY)	Y	OT	DE-ABBOTT-11P-062-0730947-00		21 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Intentional Overdose; Suicide Attempt	Cipralex	S	Oral	7-20mg Tabs Once	Not Reported
	Ibuprofen	S	Oral	7-500mg Tabs Once	Not Reported
	Paracetamol	S	Oral		Not Reported
	Famotidine	S	Oral		Not Reported
	Prednisolone	S	Oral	10-20mg Tabs Once	Not Reported
	Methylphenidate Hydrochloride	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2011	8009709	EXPEDITED (15-DAY)	Y	RI, OT	1000021495		77 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Urea Increased; Drug Ineffective; Glomerular Filtration Rate Decreased	Lexapro			S				Not Reported
	Pristiq Extended Release			S				Not Reported
	Cartia (Diltiazem Hydrochloride) (Tablets) (Diltiazem Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2011	8009714	EXPEDITED (15-DAY)	Y	RI, OT	1000021510		69 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sopor	Escitalopram Oxalate			S	Oral	(560 Mg, Once), Oral		Not Reported
	Rabeprazole Sodium			S	Oral	(Once), Oral		Not Reported
	Flurazepam Hydrochloride			S		(900 Mg, Once)		Not Reported
	Promazine Hydrochloride			S	Oral	30 Ml (Once), Oral		Not Reported
	Tavor (Lorazepam)			S	Ophthalmic	(100 Mg, Once), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2011	8009722	EXPEDITED (15-DAY)	Y	HO	1000021521		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amyotrophic Lateral Sclerosis; Dysarthria; Dysphagia; Muscle Contractions Involuntary; Tongue Atrophy; Weight Decreased	Escitalopram Oxalate	S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral	Not Reported
	Influenza Virus Vaccine Nos	S	Other	(0.5 Ml), Other	Not Reported
	Almogran (Almotriptan Malate) (Tablets) (Almotriptan Malate)	C			Not Reported
	Levaxin (Levothyroxine Sodium) (Tablets) (Levothyroxine Sodium)	C			Not Reported
	Treo (Anacin /00141001/) (Tablets) (Anacin /00141001/)	C			Not Reported
	Citodon (Co-Dafalgan) (Tablets) (Co-Dafalgan)	C			Not Reported
	Imovane (Zopiclone) (Tablets) (Zopiclone)	C			Not Reported
	Naprosyn (Naproxen) (Tablets) (Naproxen)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2011	7963584	EXPEDITED (15-DAY)	N	RI, OT	1000020645			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D), Oral		Not Reported
	Carbamazepine			C				Not Reported
	Propranolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2011	7987761	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-15810377			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Sclerosis; Overdose; Suicide Attempt	Trazodone Hydrochloride			S		Half A Bottle		Apothecon
	Abilify			S		For A While But Not For Two Days		Not Reported
	Lexapro			S		Half A Bottle		Not Reported
	Copaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2011	7987972	EXPEDITED (15-DAY)	Y	OT	PHHY2011GB48979		21 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oculogyric Crisis	Risperidone			S				Novartis
	Cipralex			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2011	8012023	EXPEDITED (15-DAY)	Y	HO, OT	AUR-APL-2011-02107		31 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Oedema; Pre-Eclampsia; Proteinuria; Urinary Tract Infection	Mirtazapine			S	Oral	30mg-Daily-Oral		Not Reported
	Mirtazapine			S	Oral	15mg-Daily-Oral		Not Reported
	Cipralex			S	Oral	10mg-Daily-Oral		Not Reported
	Amoxicillin\Clavulanate Potassium			C				Not Reported
	Folio Forte (Folic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2011	8016386	EXPEDITED (15-DAY)	Y	CA, HO, OT	AUR-APL-2011-02111		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Haemangioma Congenital; Hyperbilirubinaemia Neonatal; Maternal Drugs Affecting Foetus; Pre-Eclampsia; Premature Baby; Selective Eating Disorder	Mirtazapine			S	Transplacental	30-15mg -Daily-Transpla		Not Reported
	Cipralex			S		10mg-Daily-Transplacent		Not Reported
	Paracetamol			C				Not Reported
	Amoxicillin\Clavulanate Potassium			C				Not Reported
	Folio Forte (Folic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2011	7794508	EXPEDITED (15-DAY)	Y	HO	1000017750		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Restlessness; Withdrawal Syndrome	Lexapro			S		15 Mg (15 Mg, 1 In 1 D) 10 Mg (10 Mg, 1 In 1 D) 5 Mg (5 Mg, 1 In 1 D) 15 Mg (15 Mg, 1 In 1 D) 10 Mg (10 Mg, 1 In 1 D) 5 Mg (5 Mg, 1 In 1 D) 15 Mg (15 Mg, 1 In 1 D) 10 Mg (10 Mg, 1 In 1 D) 5 Mg (5 Mg, 1 In 1 D)		Not Reported
	Lexapro			S		5 Mg (5 Mg, 1 In 1 D)		Not Reported
	Risperidone			C				Not Reported
	Seroquel (Quetiapine Fumarate) (Quetiapine Fumarate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2011	7990155	EXPEDITED (15-DAY)	N	HO, LT	CA-NAPPMUNDI-CAN-2011-0001971		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Oxycodone Hydrochloride			S		80 Mg, Qid		Purdue
	Cipralex			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2011	8014745	EXPEDITED (15-DAY)	Y	HO, LT	2011SP025896		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bradycardia; Device Related Infection; Diarrhoea; Disorientation; Dyspnoea; General Physical Health Deterioration; Hyperkalaemia; Hypotension; Lactic Acidosis; Pallor; Pyrexia;	Mirtazapine			S		15 Mg;Qd		Not Reported
	Candesartan Cilexetil\Hydrochlorothiazide			S	Oral	16 Mg;Qd;Po		Not Reported
	Metformin Hydrochloride			S	Oral	850 Mg;Tid;Po		Teva
	Acarbose			S	Oral	50 Mg;Tid;Po		Not Reported
	Urapidil			S	Oral	60 Mg;Tid;Po		Not Reported
	Atenolol			S	Oral	100 Mg;Qd;Po Po		Teva

Septic Shock; Staphylococcal Bacteraemia; Vomiting			Oral	100 Mg;Qd;Po Po		
	Verapamil Hydrochloride	S	Oral	240 Mg;Qd;Po		Teva
	Ciprofibrate	S	Oral	100 Mg;Qd;Po		Not Reported
	Escitalopram Oxalate	S		10 Mg;Qd;Po 10 Mg;Qd;Po		Not Reported
	Xanax	S	Oral	0.25 Mg;Tid;Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2011	7932653	EXPEDITED (15-DAY)	Y	HO, LT	1000019955		68 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Extradural Haematoma; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Fluindione			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
	Kardegic (Acetylsalicylate Lysine)			S	Oral	160 Mg (160 Mg, 1 In 1 D), Oral		Not Reported
	Urbanyl			C				Not Reported
	Lasilix (Furosemide) (Tablets) (Furosemide)			C				Not Reported
	Keppra (Levetiracetam) (Tablets) (Levetiracetam)			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2011	7942702	EXPEDITED (15-DAY)	N	RI, OT	1000020199		44 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Tremor	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2011	7945754	EXPEDITED (15-DAY)	N	DS	1000020196		75 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Pruritus; Arthralgia; Bursa Disorder; Gait Disturbance; Haemorrhoidal Haemorrhage; Myalgia; Product Quality Issue; Pruritus; Varicose Vein; Vision Blurred	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Calcium And Magnesium (Calcium, Magnesium) (Calcium, Magnesium)			C				Not Reported
	Eltroxin (Levothyroxine Sodium) (Tablets) (Levothyroxine Sodium)			C				Not Reported
	Lecithin (Lecithin) (Lecithin)			C				Not Reported
	Lipitac (Omega-3) (Omega-3)			C				Not Reported
	One A Day (Multivitamins) (Multivitamins)			C				Not Reported
	Vitamin B 50 (Thiamine Hydrochloride) (Thiamine Hydrochloride)			C				Not Reported
	Vitamin C (Ascorbic Acid) (Ascorbic Acid)			C				Not Reported
	Vitamin E (Tocopherol) (Tocopherol)			C				Not Reported
	Alcohol (Ethanol) (Ethanol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2011	7947753	EXPEDITED (15-DAY)	N	DS, HO, LT	1000020285		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Presyncope	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Asa (Acetylsalicylic Acid) (Acetylsalicylic Acid)			C				Not Reported
	Calcium (Calcium) (Calcium)			C				Not Reported
	Eltroxin (Levothyroxine Sodium) (Tablets) (Levothyroxine Sodium)			C				Not Reported
	Fosavance (Alendronic Acid,			C				Not Reported

Cholecalciferol) (Tablets) (Alendronic Acid, Cholecalciferol)				
Magnesium (Magnesium) (Magnesium)	C			Not Reported
Vitamin-D (Ergocalciferol) (Ergocalciferol)	C			Not Reported
Alcohol (Ethanol) (Ethanol)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2011	7981998	EXPEDITED (15-DAY)	Y	DS	FR-ABBOTT-11P-056-0730612-00		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Dyskinesia; Fall; Hypomania; Nuclear Magnetic Resonance Imaging Brain Abnormal	Depakote			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Lithium Carbonate			S	Oral			Not Reported
	Propranolol			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Ramipril			C				Not Reported
	Lasix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2011	7992956	EXPEDITED (15-DAY)	N	DE	US-ABBOTT-11P-163-0731364-00		4 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular Anomaly; Left Ventricular Failure; Maternal Exposure During Pregnancy	Lexapro			S	Transplacental			Not Reported
	Zoloft			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2011	7994598	EXPEDITED (15-DAY)	Y	HO	ES-MYLANLABS-2011S1011547		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tubulointerstitial Nephritis	Escitalopram Oxalate			S	Oral			Alphapharm
	Lioresal			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Oral			Not Reported
	Amlodipine Besylate\Olmesartan Medoxomil			S	Oral			Not Reported
	Cyanocobalamin\Folic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2011	8014531	EXPEDITED (15-DAY)	Y	HO, LT	1000021541		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Subdural Haematoma	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Roactemra (Tocilizumab) (Solution) (Tocilizumab)			C				Not Reported
	Methotrexate (Methotrexate) (Methotrexate)			C				Not Reported
	Cortancyl (Prednisone) (Tablets) (Prednisone)			C				Not Reported
	Kestin (Ebastine) (Tablets) (Ebastine)			C				Not Reported
	Adartrel (Ropinirole Hydrochloride) (Tablets) (Ropinirole Hydrochloride)			C				Not Reported
	Bonviva (Ibandronic Acid) (Tablets) (Ibandronic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2011	8014551	EXPEDITED (15-DAY)	Y	RI, OT	1000021543			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2011	8014698	EXPEDITED (15-DAY)	Y	DE	1000021538		48 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Abnormal Sleep-Related Event; Bipolar Disorder; Depression; Drowning; Hallucination, Auditory; Psychotic Disorder; Somnambulism	Lexapro			S		1 Df (1 Dosage Forms, 1 In 1 D)		Not Reported
	Codeine\Ibuprofen			S				Not Reported
	Acetaminophen\Codeine Phosphate			S				Not Reported
	Zolpidem Tartrate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2011	8134444	EXPEDITED (15-DAY)	Y	HO, OT	FR-PFIZER INC-2011123070		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Kidney Injury; Blood Bicarbonate Decreased; Blood Ph Decreased; Bradycardia; Diarrhoea; Disorientation; Drug Level Increased; Dyspnoea; General Physical Health Deterioration; Hyperkalaemia; Hypotension; Lactic Acidosis; Pallor; Pyrexia; Septic Shock; Staphylococcal Bacteraemia; Vomiting	Xanax			S	Oral	0.25 Mg, 3x/Day		Pfizer
	Candesartan Cilexetil And Hydrochlorothiazide			S	Oral	16/12.5mg Per Day		Not Reported
	Metformin Hydrochloride			S	Oral	850 Mg, 3x/Day		Not Reported
	Acarbose			S	Oral	50 Mg, 3x/Day		Not Reported
	Urapidil			S	Oral	60 Mg, 3x/Day		Not Reported
	Atenolol			S	Oral	100 Mg, 1x/Day		Not Reported
	Atenolol			S		Unk		Not Reported
	Verapamil Hydrochloride			S	Oral	240 Mg, 1x/Day		Not Reported
	Ciprofibrate			S	Oral	100 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Mirtazapine			S	Oral	15 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2011	7993930	NON-EXPEDITED	Y		US-PFIZER INC-2011131333			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Abnormal	Chantix			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2011	7994855	EXPEDITED (15-DAY)	Y	OT	PHHY2011HR50016		41 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asphyxia; Diarrhoea; Flushing; Hypersensitivity; Insomnia; Pruritus; Rash; Tongue Oedema; Urticaria; Weight Increased	Alprazolam			S		0.5 Mg, Unk		Novartis
	Escitalopram Oxalate			S				Not Reported
	Sertraline Hydrochloride			S		25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2011	8007556	DIRECT	N				49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Asthenia; Confusional State; Coordination Abnormal; Depression; Dizziness; Euphoric Mood; Fatigue; Heart Rate Increased; Hyperhidrosis; Impulsive Behaviour; Insomnia; Libido Decreased; Somnolence; Visual Impairment	Lexapro			S	Oral	1 Tablet Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2011	8007635	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Female Orgasmic Disorder; Libido Decreased; Sexual Dysfunction	Lexapro	S		Not Reported
	Zoloft	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2011	8017203	EXPEDITED (15-DAY)	N	CA	1000021589		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Craniosynostosis; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2011	8018429	EXPEDITED (15-DAY)	Y	HO	1000021575		67 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Kidney Injury; Bradycardia; Device Related Infection; Diarrhoea; Disorientation; Drug Level Increased; Dyspnoea; General Physical Health Deterioration; Hyperkalaemia; Hypotension; Lactic Acidosis; Septic Shock; Staphylococcal Bacteraemia; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Candesartan Cilexetil And Hydrochlorothiazide			S	Oral	16 Mg/12.5mg, Oral		Not Reported
	Metformin Hydrochloride			S	Oral	2550 Mg (850 Mg, 3 In 1 D), Oral		Not Reported
	Acarbose			S	Oral	150 Mg (50 Mg, 3 In 1 D), Oral		Not Reported
	Urapidil			S	Oral	180 Mg (60 Mg, 3 In 1 D), Oral		Not Reported
	Atenolol			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Verapamil Hydrochloride			S	Oral	240 Mg (240 Mg, 1 In 1 D), Oral		Not Reported
	Ciprofibrate			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Mirtazapine			S	Oral	15 Mg (15 Mg, 1 In 1 D),		Not Reported

	Xanax	S	Oral	Oral 0.75 Mg (0.25 Mg, 3 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2011	8134445	EXPEDITED (15-DAY)	Y	HO	JP-ASTRAZENECA-2011SE35982		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hyperkalaemia; Lactic Acidosis	Candesartan Cilexetil And Hydrochlorothiazide			S	Oral	Candesartan Cilexetil 16 Mg/Hydrochlorothiazide 12.5 Mg, 1 Df Daily		Astrazeneca
	Metformin Hydrochloride			S	Oral			Not Reported
	Acarbose			S	Oral			Not Reported
	Urapidil			S	Oral			Not Reported
	Atenolol			S	Oral			Not Reported
	Atenolol			S	Oral			Not Reported
	Verapamil Hydrochloride			S	Oral			Not Reported
	Ciprofibrate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2011	8348736	EXPEDITED (15-DAY)	N	CA, DE	1000021572		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly; Congenital Tricuspid Valve Atresia; Hypoplastic Right Heart Syndrome; Maternal	Lexapro			S	Transplacental	Transplacental		Not Reported

Drugs Affecting Foetus; Pulmonary Valve Stenosis; Ventricular Septal Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2011	7893206	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000019259			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Interaction; Dysphagia; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tremor	Lexapro			S		10 Mg (10 Mg,1 In 1 D)		Not Reported
	Omeprazole			S				Not Reported
	Amantadine (Amantadine) (Amantadine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2011	7967221	EXPEDITED (15-DAY)	Y	DE	1000020738		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Blood Chloride Increased; Blood Glucose Decreased; Blood Potassium Increased; Blood Sodium Decreased; Blood Urea Increased; Cardiomegaly; Pulmonary Congestion; Pulmonary Oedema; Toxicity To Various Agents	Escitalopram Oxalate			S				Not Reported
	Cocaine (Cocaine)			S				Not Reported
	Oxycodone (Oxycodone)			S				Not Reported
	Xanax			S				Not Reported
	Morphine			S				Not Reported
	Cannabis Sativa Subsp. Sativa Flowering Top			S				Not Reported
	Hydroxyzine			S				Not Reported
	Ibuprofen (Ibuprofen)			S				Not Reported
	Quetiapine Fumarate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2011	8022562	EXPEDITED (15-DAY)	Y	RI, OT	1000021626			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Vertigo; Withdrawal	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1		Not Reported

Syndrome

D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2011	7970877	EXPEDITED (15-DAY)	Y	HO, OT	US-PFIZER INC-2011117569		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Long Qt Syndrome; Sinus Bradycardia; Ventricular Tachycardia	Ondansetron			S		Unk		Pfizer
	Pantoprazole			S		20 Mg, 1x/Day		Pfizer
	Suxamethonium			S				Not Reported
	Nortriptyline Hydrochloride			S		25 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S		10 Mg, 1x/Day		Not Reported
	Acetylsalicylic Acid			C		81 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2011	7994183	EXPEDITED (15-DAY)	Y	HO	IT-ASTRAZENECA-2011SE35006		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sinus Bradycardia	Tenormin			S	Oral			Zeneca
	Cipralex			S	Oral			Not Reported
	Ramipril			C				Not Reported
	Adalat			C				Not Reported
	Tareg			C				Not Reported
	Lasix			C				Not Reported
	Catapresan			C				Not Reported
	Tavor (Lorazepam)			C				Not Reported
	Aldactone			C				Not Reported
	Cardioaspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2011	7997506	EXPEDITED (15-DAY)	Y	OT	ES-PFIZER INC-2011130671		19 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Weight Gain; Drug Interaction	Medroxyprogesterone Acetate		S	Intramuscular	150 Mg, Every 3 Months	Pfizer
	Cipralex		S	Oral	30 Mg, 1x/Day	Not Reported
	Risperidone		S	Oral	0.5 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2011	8021524	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000021629		81 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dyspnoea; Epilepsy; Normochromic Normocytic Anaemia; Seizure; Subileus	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Norfloxacin			S	Oral	800 Mg (400 Mg, 2 In 1 D), Oral		Not Reported
	Amitriptyline Hydrochloride			S	Oral	15 Drops (40 Mg/Ml), Oral		Not Reported
	Lovenox			C				Not Reported
	Diamicron (Gliclazide) (Gliclazide)			C				Not Reported
	Temesta (Lorazepam) (Lorazepam)			C				Not Reported
	Forlax (Macrogol) (Powder) (Macrogol)			C				Not Reported
	Debridat (Trimebutine) (Trimebutine)			C				Not Reported
	Spasfon /00765801/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2011	8021613	EXPEDITED (15-DAY)	Y	RI, OT	1000021630		45 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Hyperthermia; Hypotension; Loss Of Consciousness; Pain In Extremity; Tachycardia	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
	Tramadol Hydrochloride			S	Oral	300 Mg (150 Mg, 2 In 1 D), Oral		Not Reported
	Lexomil (Bromazepam) (Tablets) (Bromazepam)			C				Not Reported
	Tercian (Cyamemazine)			C				Not Reported

(Cyamemazine)			
Xylocaine Viscous	C		Not Reported
Dafalgan Codein (Panadeine Co) (Tablets) (Panadeine Co)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2011	7419086	EXPEDITED (15-DAY)	Y	OT	CH-PFIZER INC-CH-WYE-G06220510			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Respiratory Disorder Neonatal	Effexor Xr			S	Transplacental	75 Mg, 1x/Day		Pfizer
	Buspar			S	Transplacental	10 Mg, 3x/Day		Not Reported
	Cipralex			S	Transplacental	40 Mg, 1x/Day		Not Reported
	Cipralex			S	Transplacental	5 Mg, 1x/Day		Not Reported
	Oxazepam			S	Transplacental	15 Mg, 1x/Day		Not Reported
	Trazodone Hydrochloride			S	Transplacental	50 Mg, 1x/Prn		Not Reported
	Alcohol			S	Unknown	Occasionallly During Pregnancy		Not Reported
	Cannabis			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2011	7419093	EXPEDITED (15-DAY)	Y	OT	CH-PFIZER INC-CH-WYE-G06220410		34 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Postpartum Haemorrhage	Effexor Xr			S		75 Mg, 1x/Day		Pfizer
	Buspar			S		10 Mg, 3x/Day		Not Reported
	Cipralex			S	Unknown	10 Mg, 1x/Day		Not Reported
	Cipralex			S	Unknown	5 Mg, 1x/Day		Not Reported
	Oxazepam			S		15 Mg, 1x/Day		Not Reported
	Trazodone Hydrochloride			S		50 Mg, 1x/Prn		Not Reported
	Alcohol			S	Unknown	Episodically During The Pregnancy		Not Reported

	Cannabis			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2011	8001195	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2011133481		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Behaviour; Toxicity To Various Agents	Xanax			S	Oral	0.25 Mg, 1x/Day If Needed		Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2011	8014319	DIRECT	N	LT, RI			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Decreased Activity; Discomfort; Dyspnoea; Hyperphagia; Increased Appetite; Product Quality Issue; Weight Increased	Lexapro			S	Oral	Varied 10 Mg To 20mg Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2011	8014493	DIRECT	N	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Feeling Abnormal; Maternal Exposure During Pregnancy; Paraesthesia	Lexapro			S	Oral	10mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2011	7998113	EXPEDITED (15-DAY)	Y	HO, OT	2011SP024114		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Pain; Pre-Eclampsia; Premature Delivery; Urinary Tract Infection	Mirtazapine			S		30 Mg;Qd; 15 Mg;Qd 30 Mg;Qd; 15 Mg;Qd		Not Reported
	Cipralex			S	Oral	10 Mg;Qd;Po		Not Reported
	Paracetamol			C				Not Reported
	Amoxicillin\Clavulanate Potassium			C				Not Reported
	Folio Forte			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2011	8001832	EXPEDITED (15-DAY)	Y	RI, OT	1000020548		45 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Non-Hodgkin'S Lymphoma; Pancytopenia	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2011	8001908	EXPEDITED (15-DAY)	Y	LT	GB-JNJFOC-20110606702		38 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure; Syncope	Tramadol Hydrochloride			S	Oral		63 DAY	Not Reported
	Tramadol Hydrochloride			S	Oral		63 DAY	Not Reported
	Chlorpromazine			C				Not Reported
	Co-Codamol			C				Not Reported
	Nexium			C				Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2011	8018445	DIRECT	N	OT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Paraesthesia	Lexapro			S	Oral	20 Mg 1.5 Daily Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2011	8024840	EXPEDITED (15-DAY)	Y	RI, OT	1000021649		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Headache; Vertigo	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2011	8024938	EXPEDITED (15-DAY)	N	RI, OT	1000021654			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Long Qt Syndrome Congenital	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2011	8027929	EXPEDITED (15-DAY)	N	RI, OT	1000021585		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hypocapnia; Sexual Dysfunction; Weight Increased	Lexapro			S	Oral Oral	Oral Oral		Not Reported
	Venlafaxine Hydrochloride			S	Oral Oral	37.5 Mg (37.5 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D), Oral 37.5 Mg (37.5 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Prozac			S	Oral	(1 In 1 D), Oral		Not Reported
	Trazodone (Trazodone) (50 Milligram, Tablets) (Trazodone)			C				Not Reported
	Z-Dex 12d (Dextromethorphan, Chlorpheniramine, Phenylephrine) (Dextromethorphan, Chlorpheniramine, P			C				Not Reported

	Sominex (Methapyrilene Hydrochloride, Salicylamide, Scopolamine Aminoxide Hydrobromide) (Methapyrile	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2011	8027932	EXPEDITED (15-DAY)	N	RI, OT	1000021622		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Petit Mal Epilepsy; Weight Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2011	7984444	EXPEDITED (15-DAY)		OT	TW-PFIZER INC-2011123616		52 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Extrapyramidal Disorder; Multiple System Atrophy; Parkinsonism	Sertraline Hcl			S				Pfizer
	Escitalopram Oxalate			S				Not Reported
	Fluoxetine			S				Not Reported
	Duloxetine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2011	8003995	NON-EXPEDITED	Y	OT	US-PFIZER INC-2011133845			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2011	8006934	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2011131911		39 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Merycism; Suicidal Behaviour; Toxicity To Various Agents	Xanax			S		Unk	91 DAY	Pfizer
	Escitalopram Oxalate			S	Oral	Unk	91 DAY	Not Reported
	Ramipril			C				Not Reported
	Tramadol Hydrochloride And Acetaminophen			C		6 Df Unk		Not Reported
	Hydrochlorothiazide\Ramipril			C				Not Reported
	Ibuprofen			C				Not Reported
	Aerius (Desloratadine)			C				Not Reported
	Alcohol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2011	8028633	EXPEDITED (15-DAY)	Y	RI, OT	1000021652		42 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt; Unevaluable Event	Escitalopram Oxalate			S	Oral	1000 Mg, Once, Oral		Not Reported
	Nortriptyline Hydrochloride			S	Oral	2500 Mg, Once, Oral		Not Reported
	Lithium Carbonate			S	Oral	45000 Mg, Once, Oral;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2011	8028680	EXPEDITED (15-DAY)	Y	HO	1000021662		77 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cerebral Haemorrhage; Disorientation; Face Injury; Fall; Head Injury; Hemiparesis; Loss Of Consciousness	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Plavix			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Depakote			C				Not Reported
	Crestor (Rosuvastatin) (Tablets)			C				Not Reported
	Tercian (Cyamemazine) (Capsules)			C				Not Reported
	Urbanyl			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2011	8028782	EXPEDITED (15-DAY)	Y	HO	1000021680		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Nausea	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Aricept			C				Not Reported
	Langoran (Isosorbide Dinitrate)			C				Not Reported
	Zanidip (Lercanidipine)			C				Not Reported
	Candesartan Cilexetil			C				Not Reported
	Aspirin			C				Not Reported
	Lipanthyl (Fenofibrate) (Tablets)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2011	8009033	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2011134939		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Xanax			S	Oral	20 Tablets, Unk		Pfizer
	Escitalopram Oxalate			S	Oral	10 Tablets, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2011	7974258	EXPEDITED (15-DAY)		HO, OT	US-ASTRAZENECA-2011SE32305		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cataract Operation; Cerebrovascular Accident; Cervical Vertebral Fracture; Confusional State; Coronary Artery Disease; Dehydration; Dementia Alzheimer'S Type; Ejection Fraction Decreased; Fall; Hypersomnia;	Crestor			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

Incontinence; Loss Of Consciousness; Pneumonia; Presyncope; Radioisotope Scan; Spinal Fusion Surgery; Suicidal Ideation; Syncope; Urinary Bladder Suspension; Urinary Tract Infection; Ventricular Tachycardia; Vomiting; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2011	8010305	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2011136800			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Withdrawal Syndrome; Panic Attack	Geodon			S		60 Mg, Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2011	8033027	EXPEDITED (15-DAY)	Y	DS	1000021711		54 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Inability; Neuralgia; Pain In Extremity	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2011	8023459	DIRECT	N	LT, OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heat Exhaustion; Heat Stroke	Lexapro			S	Oral	10mg Daily Po	2 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2011	8033037	EXPEDITED (15-DAY)	Y	HO	1000021712		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Confusional State; Dyspnoea; Hyponatraemia; Pallor	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Lisinopril			C				Not Reported
	Lorazepam			C				Not Reported
	Mirtazapine			C				Not Reported
	Simvastatin (Simvastatin) (Simvasatin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2011	8036210	EXPEDITED (15-DAY)	Y	HO	1000021734			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukocytosis; Pancreatitis Acute	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2011	7807609	EXPEDITED (15-DAY)		CA, DE, OT	FR-PFIZER INC-2011029215			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arnold-Chiari Malformation; Congenital Foot Malformation; Foetal Exposure During Pregnancy; Spina Bifida	Atarax			S	Transplacental	25 Mg Or 50 Mg, Weekly		Pfizer
	Escitalopram Oxalate			S	Transplacental	Unknown		Not Reported
	Versatis			S	Transplacental	0.5 Df Qod, Drug Plaster		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2011	7951977	EXPEDITED (15-DAY)	Y	HO, LT	1000019289		44 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt; Trance	Escitalopram Oxalate			S		5 Mg (5 Mg,1 In 1 D)		Not Reported

	Effexor Xr (Venlafaxine Hydrochloride) (Capsules) (Venlafaxine Hydrochloride)	C		Not Reported
	Novo Venlafaxine Xr (Venlafaxine Hydrochloride) (Capsules) (Venlafaxine Hydrochloride)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2011	8014342	NON-EXPEDITED	N		A0859251A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Decreased	Zyban			S				Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2011	8014811	EXPEDITED (15-DAY)	Y	HO, LT	1000019332		44 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt; Trance	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Teva-Venlafaxine Xr (Venlafaxine) (Capsules) (Venlafaxine)			C				Not Reported
	Novo-Venlafaxine Xr (Venlafaxine) (Capsules) (Venlafaxine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2011	8024544	DIRECT	N	DS			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Discomfort; Tinnitus	Lexapro			S	Oral Oral Oral	2.5 Mg 3 Times Oral 2.5 Mg 3 Times Oral 2.5 Mg 3 Times Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2011	7749643	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2010182248		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Altered State Of Consciousness; Anxiety; Drug Ineffective; Drug Intolerance; Dysphagia; Insomnia; Mental Disorder; Nervous System Disorder; Post-Traumatic Stress Disorder; Sedation; Suffocation Feeling	Effexor Xr			S	Oral	75 Mg, Daily		Pfizer
	Effexor Xr			S	Oral	120 Mg, Unk		Pfizer
	Effexor Xr			S	Oral	150 Mg, Daily		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Prozac			S	Oral	20 Mg, Unk		Not Reported
	Valium			S	Oral	10 Mg, 1x/Day		Not Reported
	Zyprexa			S	Oral	1 Mg, 1x/Day		Not Reported
	Zyprexa			S		Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Calcium			C	Oral	Unk		Not Reported
	Multivitamins			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2011	7913139	EXPEDITED (15-DAY)	Y	DE, HO	FR-ROCHE-772674		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Rocephin			S	Intravenous (not otherwise specified)			Roche
	Humalog			C	Subcutaneous	Start Date : For A Long Time		Not Reported
	Lantus			C	Subcutaneous	Start Date : For A Long Time		Not Reported
	Aprovel			C	Oral	Start Date : For A Long Time		Not Reported
	Propranolol			C	Oral	Start Date : For A Long		Not Reported

				Time	
	Cortancyl	C	Oral		Not Reported
	Alendronic Acid	C	Oral		Not Reported
	Lercanidipine	C	Oral		Not Reported
	Omeprazole	C	Oral		Not Reported
	Previscan (Fluindione)	S	Oral	Start Date : For A Long Time	Not Reported
	Escitalopram Oxalate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2011	8036522	EXPEDITED (15-DAY)	Y	DE	1000021713			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Stillbirth	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2011	7916221	EXPEDITED (15-DAY)	Y	RI, OT	1000019741		51 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased	Escitalopram Oxalate			S	Oral Oral	5 Mg (5 Mg, 1 In 1 D), Oral 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral Oral	20 Mg (20 Mg, 1 In 1 D), Oral 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2011	8018819	EXPEDITED (15-DAY)	Y	OT	HR-WATSON-2011-09547		41 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Diarrhoea;	Alprazolam			S		0.5 Mg, Daily Once Or		Watson

Drug Ineffective; Urticaria				Twice A Week	
	Sertraline Hydrochloride		S	25 Mg, Unk	Watson
	Escitalopram Oxalate		S	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2011	8018897	EXPEDITED (15-DAY)	Y	HO	TW-MYLANLABS-2011S1013122		52 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple System Atrophy; Parkinsonism	Fluoxetine Hcl			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2011	8031408	DIRECT	Y	DE			3 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Cardio-Respiratory Arrest Neonatal; Death Neonatal; Foetal Hypokinesia; Hepatic Steatosis; Hypoperfusion; Maternal Drugs Affecting Foetus; Metabolic Acidosis; Vacuum Extractor Delivery	Lexapro			S	Oral	Po		Forest
	Ampicillin Sodium			C				Not Reported
	Ceftotaxime			C				Not Reported
	Lasix			C				Not Reported
	Gentamicin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Na Bicarb			C				Not Reported
	Midazolam			C				Not Reported
	Morphine			C				Not Reported
	Dobutamine Hydrochloride			C				Not Reported
	Dopamine			C				Not Reported
	Epinephrine			C				Not Reported
	Milrinone			C				Not Reported
	Tpn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2011	8044787	EXPEDITED (15-DAY)	Y	HO	1000021775		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Coma Scale Abnormal; Gamma-Glutamyltransferase Increased	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Xanax			S	Oral	Overdose, Oral		Not Reported
	Alcohol (Ethanol)			S				Not Reported
	Ramipril			C				Not Reported
	Tramadol Hydrochloride And Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2011	8044800	EXPEDITED (15-DAY)	Y	HO	1000021776		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Incorrect Dose Administered; Partner Stress	Escitalopram Oxalate			S	Oral	Oral Overdose Of Escitalopram		Not Reported
					Oral	Oral Overdose Of Escitalopram		
	Xanax			S		(0.25 Mg, If Necessary), Oral Overdose (Once)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2011	7947888	EXPEDITED (15-DAY)	Y	HO, OT	US-JNJFOC-20110506107			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Bradycardia; Hypotonia; Infantile Apnoea; Metabolic Acidosis	Topamax			S	Transplacental			Not Reported
	Topamax			S	Transplacental			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Omeprazole			S	Transplacental			Not Reported
	Ampicillin Sodium			S	Transplacental			Not Reported
	Gentamicin			S	Transplacental			Not Reported
	Clindamycin			S	Transplacental			Not Reported
	Elavil			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2011	8021800	EXPEDITED (15-DAY)	Y	HO	PHHY2011TW56904		52 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Balance Disorder; Extrapyramidal Disorder; Gait Disturbance; Multiple System Atrophy; Muscle Rigidity; Orthostatic Hypotension; Parkinsonism; Psychomotor Retardation; Tremor; Urinary Incontinence	Fluoxetine Hcl			S				Novartis
	Sertraline Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Duloxetine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2011	8041032	EXPEDITED (15-DAY)	N	HO	2011SP030151		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Panic Attack; Somnolence	Remeron			S	Oral	45 Mg;Qd;Po		Not Reported
	Lexapro			S		2.5 Mg ; 5 Mg		Not Reported
	Cymbalta			S				Not Reported
	Abilify			S				Not Reported
	Allopurinol			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2011	8024126	EXPEDITED (15-DAY)	Y	HO	1000021667		62 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Cardiac Arrest; Fibrosis; Gastric Bypass; Left Ventricular	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Nortriptyline Hydrochloride			S		25 Mg (25 Mg, 1 In 1 D)		Not Reported

Hypertrophy; Long Qt Syndrome; Sinus Bradycardia; Ventricular Tachycardia; Weight Increased	Succinylcholine Chloride		S	Not Reported
	Ondansetron		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2011	8044829	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000021905		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Congenital Hypotonia; Bradycardia; Cardiac Murmur; Congenital Anomaly; Congenital Choroid Plexus Cyst; Foetal Distress Syndrome; Maternal Drugs Affecting Foetus; Neonatal Respiratory Depression; Neural Tube Defect; Overdose; Premature Baby	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2011	8044863	EXPEDITED (15-DAY)	N	RI, OT	1000021824			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Oral; Weight Increased	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2011	8044970	EXPEDITED (15-DAY)	Y	HO	1000021937		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Headache; Hemiparesis; Muscular Weakness; Pain In	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

Extremity; Vertigo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2011	8730557	DIRECT	N	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Lymphadenopathy; Rash; Urticaria	Lexapro 10 Forest Laboratories			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2011	7957176	EXPEDITED (15-DAY)	Y	HO	1000020562		81 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Interaction; Gastrointestinal Haemorrhage; Haemoglobin Decreased; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	1 Dosage Form (1 Dosage Forms, 1 In 1 D),Oral		Not Reported
	Fluindione			S		Long-Standing Treatment - 03/16/2011		Not Reported
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	Intravenous (Not Otherwise Specified)		Not Reported
	Lantus			C				Not Reported
	Aprovel (Irbesartan) (150 Milligram) (Irbesartan)			C				Not Reported
	Avlocardyl (Propranolol)(Propranolol)			C				Not Reported
	Cortancyl (Prednisone) (20 Milligram) (Prednisone)			C				Not Reported
	Fosavance (Alendronic Acid, Colecalciferol)(Alendronic Acid, Colecalciferol)			C				Not Reported
	Lercan (Lercanidipine Hydrochloride) (Lercanidipine Hydrochloride)			C				Not Reported
	Mopral (Omeprazole) (Omeprazole)			C				Not Reported
	Humalog (Insulin) (Insulin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2011	7999365	EXPEDITED (15-DAY)	Y	RI, OT	1000021207		63 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy	Escitalopram Oxalate			S				Not Reported
	Fluoxetine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2011	8025943	EXPEDITED (15-DAY)	Y	DS	GB-EISAI INC-E2020-09407-SPO-GB		87 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Paralysis; Myoclonus; Tardive Dyskinesia	Aricept			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2011	8026810	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2011147693		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Xanax			S	Oral	0.25 Mg, Unk		Pfizer
	Xanax			S		0.25mg, (1/2-0-1/2)		Pfizer
	Zopiclone			S	Oral	7.5 Mg, 1x/Day		Not Reported
	Zopiclone			S		7.5 Mg, (0-0-1/2)		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Unk		Not Reported
	Tramadol Hydrochloride			S				Not Reported
	Actonel			C	Oral	75 Mg, 150mg Monthly		Not Reported
	Paracetamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2011	8027048	EXPEDITED (15-DAY)	Y	HO, OT	PHHY2011FR57394		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Leukopenia; Neutropenia	Zometa		S	4 Mg, Unk		Novartis
	Rocephin		S	1 G, Qd	16 DAY	Not Reported
	Lasix		S	20 Mg, Qd	31 DAY	Not Reported
	Escitalopram Oxalate		S			Not Reported
	Rivotril		C			Not Reported
	Xanax		C			Not Reported
	Aspirin		C			Not Reported
	Aprovel		C			Not Reported
	Esomeprazole		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2011	8031809	EXPEDITED (15-DAY)	Y	HO	1000021683		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Road Traffic Accident; Seizure	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Mirtazapine			S	Oral	15 Mg (15 Mg,1 In 1 D),Oral		Not Reported
	Theralen Oral Drops (Alimemazine Tartrate) (Drops(For Oral Use)) (Alimemazine Tartrate)			C				Not Reported
	Atarax (Hydroxyzine) (Tablets) (Hyroxyzine)			C				Not Reported
	Panocod (Acetaminophen, Codeine Phosphate) (Tablets) (Acetaminophen, Codeine Phosphate)			C				Not Reported
	Diklofenak (Diclofenac Sodium) (Tablets) (Diclofenac Sodium)			C				Not Reported
	Panodil Forte (Paracetamol) (Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2011	8046972	EXPEDITED (15-DAY)	Y	DE, HO	AUR-APL-2011-03696		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Antiphospholipid Antibodies Positive; Condition Aggravated; Deep Vein Thrombosis; Depression; International Normalised Ratio Abnormal; Pulmonary Embolism	Paroxetine Hydrochloride	S	(20 Mg)	Not Reported
	Sertraline Hydrochloride	S	(100 Mg)	Not Reported
	Mirtazapine (Mirtazapine)	S	(30 Mg)	Not Reported
	Venlafaxine	S	(225 Mg)	Not Reported
	Reboxetine	S	(4 Mg)	Not Reported
	Escitalopram Oxalate	S	(20 Mg)	Not Reported
	Quetiapine Fumarate	S	(100 Mg)	Not Reported
	Olanzapine (Olanzapine)	S	(5 Mg)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2011	8029110	EXPEDITED (15-DAY)	Y	DE	PHHY2011GB60248		60 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Pulmonary Valve Atresia; Maternal Exposure During Pregnancy	Citalopram			S	Transplacental	20 Mg, Qd		Novartis
	Escitalopram Oxalate			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2011	8029554	EXPEDITED (15-DAY)	Y	CA, DE	GB-TEVA-289675ISR		60 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia; Maternal Exposure During Pregnancy	Citalopram			S	Transplacental	20 Milligram;		Ivax
	Escitalopram Oxalate			S	Transplacental	20 Milligram;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2011	8049629	EXPEDITED (15-DAY)	Y	HO	1000021936		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Neutropenia	Escitalopram Oxalate			S	Oral	Oral		Not Reported

	Zometa	S	Intravenous (not otherwise specified)	4 Mg (4 Mg,1 In 1 D),Intravenous (Not Otherwise Specified)	Not Reported
	Furosemide	S	Oral	20 Mg (20 Mg,1 In 1 D),Oral	Not Reported
	Rocephin	S	Oral	1 Gram (1 Gm,1 In 1 D),Oral	Not Reported
	Rivotril (Clonazepam) (Clonazepam)	C			Not Reported
	Xanax	C			Not Reported
	Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine)	C			Not Reported
	Aprovel (Irbesartan) (Irbesartan)	C			Not Reported
	Inexium (Esomeprazole Magnesium)	C			Not Reported
	Transipeg (Macrogol)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2011	8050637	EXPEDITED (15-DAY)	Y	OT	DSA_47076_2011		28 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Photophobia; Vision Blurred	Wellbutrin Xl			S		(150 Mg Qd)		Not Reported
	Cipralex			S		(Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2011	8050729	EXPEDITED (15-DAY)	Y	HO, OT	2011MA008042		62 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Dependence; Incorrect Dose Administered; Withdrawal Syndrome	Zolpidem Tartrate			S		180 Mg, Qd;		Not Reported
	Escitalopram Oxalate			S		10 Mg, Qd;		Not Reported
	Acetaminophen\Domperidone			S		Qd;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2011	7987763	EXPEDITED (15-DAY)	N	HO, OT	AT-BRISTOL-MYERS SQUIBB COMPANY-		24 YR	Female	AUT

15812548

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Suicidal Ideation	Trazodone Hydrochloride			S				Apothecon
	Abilify			S	Oral			Not Reported
	Cipralex			S		10mg		Not Reported
	Chlorprothixene			S		30mg		Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2011	8026162	NON-EXPEDITED	N		US-PFIZER INC-2011152599			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Intervertebral Disc Disorder; Urticaria	Pristiq Extended Release			S	Oral	76 Mg, Daily	35 DAY	Pfizer
	Lexapro			S	Oral	10 Mg, Daily		Not Reported
	Klonopin			S	Oral	Unk		Not Reported
	Calcium			C		1200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2011	8032837	EXPEDITED (15-DAY)	Y	RI, OT	1000021710		33 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Muscle Twitching; Overdose; Weight Increased; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg,1 In 1 D),Oral,Dosage Reduced (Unknown Dosage),Oral		Not Reported
	Temesta Expidet (Astemizole)(Astemizole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2011	8053336	EXPEDITED (15-DAY)	Y	HO	1000021996		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Depression; Drug Interaction; Oedema Peripheral	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D),Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
	Mirtazapine			S	Oral	15 Mg (15 Mg, 1 In 1 D),Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral		Not Reported
					Oral	15 Mg (15 Mg, 1 In 1 D),Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral		
					Oral	15 Mg (15 Mg, 1 In 1 D),Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral		
	Atosil (Promethazine Hydrochloride) (Promethazine Hydrochloride)			C				Not Reported
	Marcumar (Phenprocoumon) (Phenprocoumon)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2011	8053838	EXPEDITED (15-DAY)	Y	RI, OT	1000021969		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Mitral Valve Incompetence	Escitalopram Oxalate			S	Oral	(10 Mg),Oral		Not Reported
	Benfluorex			S	Oral	(1 Dosage Forms),Oral, (2 Dosage Forms),Oral, (3 Dosage Forms),Oral		Not Reported
	Levothyroxine			S	Oral	(50 Mcg),Oral, (75 Mcg),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2011	6868092	EXPEDITED (15-DAY)	Y	DE, HO	US-PFIZER INC-2008153681		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Celecoxib			S	Oral	Unk		Pfizer
	Unspecified Ingredient			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Meloxicam			S	Oral	Unk		Not Reported
	Propoxyphene Hydrochloride And Acetaminophen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2011	7975195	EXPEDITED (15-DAY)	Y	HO	1000020821		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Aspirin			C				Not Reported
	Dipiridamol (Dipyridamole) (Dipyridamole)			C				Not Reported
	Metoprolo (Metoprolol) (Metoprolol)			C				Not Reported
	Pantoprazole (Pantoprazole) (Pantoprazole)			C				Not Reported
	Insulin (Insulin) (Insulin)			C				Not Reported
	Nitroglycerine (Glyceryl Trinitrate) (Poultice Or Patch) (Glyceryl Trinitrate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2011	7995783	EXPEDITED (15-DAY)	Y	DS, HO, LT, RI, OT	1000021094		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Toxicity To Various Agents	Escitalopram Oxalate			S		1 Dosage Form (1 Dosage		Not Reported

					Forms, 1 In D)	
	Hydroxycitric Acid		S			Not Reported
	Capozide		S	Oral	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2011	8046971	DIRECT	N	OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Delusion; Depersonalisation/Derealisation Disorder; Dry Mouth; Grandiosity; Hair Growth Abnormal; Imprisonment; Impulsive Behaviour; Irritability; Kleptomania; Mania; Mood Altered; Muscle Twitching; Nail Growth Abnormal; Onychoclasis; Somnolence; Weight Increased; Weight Loss Poor	Lexapro			S	Oral	20 Mg Lexapro 1x Daily Oral Tablet		Forest
	Naproxen Sodium			C				Not Reported
	Maxcide			C				Not Reported
	Celexa			C				Not Reported
	Thyroid Hormone Therapy			C				Not Reported
	Tahiti Trim Female Hormone Cream			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2011	8055022	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2011-03877		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse; Toxicity To Various Agents	Amlodipine			S	Oral	Oral		Not Reported
	Atenolol (Atenolol)			S	Oral	Oral		Not Reported
	Trazodone Hydrochloride			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Duloxetine			S	Oral	Oral		Not Reported
	Losartan Potassium			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2011	8056154	EXPEDITED (15-DAY)	Y	DE, HO	AUR-APL-2011-03797		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Product Misuse; Respiratory Arrest; Toxicity To Various Agents	Meloxicam			S	Oral	Oral		Not Reported
	Propoxyphene Hydrochloride And Acetaminophen			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Celecoxib			S	Oral	Oral		Not Reported
	Benzodiazepine			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2011	8056905	EXPEDITED (15-DAY)	Y	HO, LT	2011SP031846		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Autoimmune Hepatitis; Hepatic Steatosis; Hepatitis Acute; Reye'S Syndrome; Toxicity To Various Agents	Mirtazapine			S	Oral	15 Mg;Qd;Po ; 90 Mg;Once;Po		Not Reported
					Oral	15 Mg;Qd;Po ; 90 Mg;Once;Po		
	Xanax			S	Oral	0.5 Mg;Qd;Po ; 7.5 Mg;Once.Po		Not Reported
					Oral	0.5 Mg;Qd;Po ; 7.5 Mg;Once.Po		
	Propranolol			S	Oral	40 Mg;Qd;Po ; 320 Mg;Once;Po ; 40 Mg;Qd;Po		Not Reported
					Oral	40 Mg;Qd;Po ; 320 Mg;Once;Po ; 40 Mg;Qd;Po		
					Oral	40 Mg;Qd;Po ; 320 Mg;Once;Po ; 40 Mg;Qd;Po		
	Escitalopram Oxalate			S	Oral	20 Mg;Qd;Po ; 120 Mg;Once;Po		Not Reported

					Oral	20 Mg;Qd;Po ; 120 Mg;Once;Po				

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2011	8009773	EXPEDITED (15-DAY)	Y	RI, OT	1000021519		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Generalised Tonic-Clonic Seizure; Loss Of Consciousness	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Calcium D3 (Calcium D3 /01483701/) (Calcium D3 /01483701/)			C				Not Reported
	Atilnox (Zolpidem) (Tablets) (Zolpidem)			C				Not Reported
	Xanax (Alprazolam) (Tablets) (Alprazolam)			C				Not Reported
	Tercian (Cyamemazine) (Solution) (Cyamemazine)			C				Not Reported
	Sertraline (Sertraline) (Capsules) (Sertraline)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2011	8056539	EXPEDITED (15-DAY)	Y	RI, OT	1000022064		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neurogenic Bladder	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2011	8057222	EXPEDITED (15-DAY)	Y	HO	1000022028		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Alcohol Poisoning; Cardiac Failure; Somnolence; Syncope; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	(200 Mg,Once), Oral		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2011	8059297	EXPEDITED (15-DAY)	Y	HO, LT	IDA-00559		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis; Hepatitis Acute; Toxicity To Various Agents	Propranolol			S	Oral	8 Tablets Of 40mg Once Oral Formulation: Tablet/Oral	1 DAY	Not Reported
	Xanax			S	Oral	15 Tablets Of 0.5mg Oral Formulation: Tablet/ Oral Formulation: Tablet	4 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	6 Tablets Of 15mg Once Oral Formulation: Tablet/ Oral Formulation: Tablet	8 MTH	Not Reported
	Mirtazapine			S	Oral	Oral Formulation: Tablet/ Oral Formulation: Tablet	7 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2011	8032217	EXPEDITED (15-DAY)	Y	HO	1000021526		82 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Haemorrhage; Headache; Hyponatraemia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral		
	Zestril			S	Oral	20 Mg (20 Mg, 1 In 1d), Oral		Not Reported
	Stilnox (Zolpidem) (Tablets) (Zolpidem)			C				Not Reported
	Pravalotin (Pravastatin Sodium) (Tablets) (Pravastatin)			C				Not Reported
	Motilium (Domperidone Maleate) (Tablets) (Domperidone Maleate)			C				Not Reported

	Marcumar (Phenprocoumon) (Tablets) (Phenprocoumon)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2011	8037802	EXPEDITED (15-DAY)	Y	HO	FR-ALLERGAN-1109514US		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Dry Mouth; Fall; Memory Impairment	Trospium Chloride			S	Oral	20 Mg, Qd		Indevus
	Ditropan			S	Oral	1 Df, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Zopiclone			S	Oral	7.5 Mg, Qd		Not Reported
	Xanax			C		Unk		Not Reported
	Amlodipine Besylate			C				Not Reported
	Mianserin Hydrochloride			C				Not Reported
	Crestor			C				Not Reported
	Levothyrox			C				Not Reported
	Lovenox			C				Not Reported
	Alendronate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2011	8058148	EXPEDITED (15-DAY)	Y	HO	1000022091		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Loss Of Consciousness	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	L-Thyroxin (Levothyroxine Sodium) (Levothyroxine Sodium)			C				Not Reported
	Budesonid (Budesonide) (Budesonide)			C				Not Reported
	Omeprazol (Omeprazole) Omeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2011	8058692	EXPEDITED (15-DAY)	Y	DS	1000022088		87 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus; Tardive Dyskinesia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Aricept			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2011	8060650	EXPEDITED (15-DAY)	Y	RI, OT	1000022122		28 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Photophobia; Vision Blurred	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Wellbutrin Xl			S	Oral	150 Mg (150 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2011	8042836	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2011-BP-17		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Pradaxa			S	Oral	300 Mg		Boehringer Ingelheim
	Lexapro			S	Oral	10 Mg		Not Reported
	Coreg			C	Oral	25 Mg		Not Reported
	Lisinopril			C	Oral	20 Mg		Not Reported
	Lasix			C	Oral	40 Mg		Not Reported
	Amiodarone			C	Oral	200 Mg		Not Reported
	Aspirin			C	Oral	81 Mg		Not Reported
	Folic Acid			C	Oral	1 Mg		Not Reported
	Xanax			C	Oral			Not Reported
	Fosamax			C	Oral			Not Reported
	Calcium Carbonate			C	Oral	1000 Mg		Not Reported
	Synthroid			C	Oral	75 Mg		Not Reported

	Vitamin B12		C	Intramuscular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2011	8043845	EXPEDITED (15-DAY)	Y	OT	TW-WATSON-2011-10301		52 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Multiple System Atrophy	Fluoxetine Hcl			S	Unknown			Watson
	Sertraline Hydrochloride			S	Unknown			Watson
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2011	8043958	NON-EXPEDITED	N		US-KINGPHARMUSA00001-K201000880		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hyperthyroidism; Thyroxine Free Increased	Levoxyl			S	Oral	162 Mcg, Qd		King
	Levoxyl			S	Oral	137 Mcg, Qd		King
	Levoxyl			S	Oral	150 Mcg, Qd		King
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Lipitor			C		Unk		Not Reported
	Atenolol			C		Unk		Not Reported
	Ambien			C		Unk		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2011	8044030	NON-EXPEDITED	N		US-KINGPHARMUSA00001-K201001061			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Fatigue	Levoxyl			S	Oral	125 Mcg, Unk		King
	Lexapro			S		10 Mg, Unk		Not Reported
	Metformin Hydrochloride			C				Not Reported

	Byetta			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2011	7247068	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2010000996		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Phenytoin			S	Oral	Unk		Pfizer
	Pregabalin			S	Oral	Unk		Pfizer
	Metformin Hcl			S	Oral	Unk		Pfizer
	Ondansetron Hcl			S	Oral	Unk		Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Phenobarbital			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Trazodone			S	Oral	Unk		Not Reported
	Emtricitabine/Tenofovir			S	Oral	Unk		Not Reported
	Oxycodone			S	Oral	Unk		Not Reported
	Methylphenidate			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported
	Metoclopramide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2011	8045223	EXPEDITED (15-DAY)	Y	HO, OT	HR-JNJFOC-20110501972		29 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Schizophrenia; Substance Abuse; Toxicity To Various Agents	Rispolept Consta			S	Intramuscular			Not Reported
	Rispolept Consta			S	Intramuscular			Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown	1/2,0,1		Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported

Akineton	S	Unknown		Not Reported
Akineton	S	Unknown		Not Reported
Thioridazine Hydrochloride	S	Unknown	1,1,2	Not Reported
Leponex	S	Unknown		Not Reported
Leponex	S	Unknown	1/2,0,1	Not Reported
Cipralex	S	Unknown		Not Reported
Xanax	S	Unknown	3x1 Tablet	Not Reported
Xanax	S	Unknown	3x1/2 Tablet	Not Reported
Xanax	S	Unknown	3x1 Tablet	Not Reported
Xanax	S	Unknown	3x1/2 Tablet	Not Reported
Xanax	S	Unknown	3x1 Tablet	Not Reported
Xanax	S	Unknown	3x1/2 Tablet	Not Reported
Xanax	S	Unknown	3x1/2 Tablet	Not Reported
Xanax	S	Unknown	3x1 Tablet	Not Reported
Paroxetine Hydrochloride	S		1,0,0	Not Reported
Paroxetine Hydrochloride	S		1,0,0	Not Reported
Paroxetine Hydrochloride	S		1,0,0	Not Reported
Paroxetine Hydrochloride	S		1,0,0	Not Reported
Diazepam	S			Not Reported
Diazepam	S			Not Reported
Diazepam	S			Not Reported
Diazepam	S			Not Reported
Diazepam	S			Not Reported
Diazepam	S			Not Reported
Diazepam	S			Not Reported
Diazepam	S			Not Reported
Prazine (Promazine Hydrochloride)	S			Not Reported
Prazine (Promazine Hydrochloride)	S			Not Reported
Promazine Hydrochloride	S			Not Reported
Promazine Hydrochloride	S			Not Reported
Zolpidem Tartrate	S	Unknown		Not Reported

	Zolpidem Tartrate		S	Unknown	Not Reported
	Zolpidem Tartrate		S	Unknown	Not Reported
	Zolpidem Tartrate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2011	8045923	EXPEDITED (15-DAY)	N	HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-15898638		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Depression; Hyponatraemia; Overdose; Vomiting	Irbesartan And Hydrochlorothiazide			S	Oral			Bristol Myers Squibb
	Digoxin			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Acenocoumarol			C	Oral	Tablet		Not Reported
	Lansoprazole			C	Oral	Tablet		Not Reported
	Crestor			C	Oral	Tablet		Not Reported
	Amlodipine Besylate			C	Oral	It Is A Capsule		Not Reported
	Noroxin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2011	8046063	EXPEDITED (15-DAY)	Y	CA, DE	GB-MYLANLABS-2011S1013999		60 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia; Maternal Exposure During Pregnancy	Citalopram			S	Transplacental			Not Reported
	Escitalopram Oxalate			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2011	8062560	EXPEDITED (15-DAY)	Y	RI, OT	1000022237		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Paraesthesia; Sedation; Somnolence	Escitalopram Oxalate		S	10 Mg (10 Mg,1 In 1 D) ; 10 Mg (10 Mg,1 In 1 D),Oral 10 Mg (10 Mg,1 In 1 D) ; 10 Mg (10 Mg,1 In 1 D),Oral	Not Reported
	Methadone (Methadone) (Methadone)		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2011	8062607	EXPEDITED (15-DAY)	Y	RI, OT	1000022161			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Narrow Anterior Chamber Angle	Escitalopram Oxalate			S		20 Mg (20 Mg,1 In 1 D)		Not Reported
	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2011	8083231	EXPEDITED (15-DAY)	Y	DE, OT	2011AP001423		60 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia; Death Neonatal; Maternal Drugs Affecting Foetus	Citalopram Hydrobromide			S	Transplacental	20 Mg, Qd, Trpl		Not Reported
	Escitalopram Oxalate			S	Transplacental	20 Mg, Trpl, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2011	8034130	EXPEDITED (15-DAY)		OT	TW-PAR PHARMACEUTICAL, INC-2011SCPR003101			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple System Atrophy; Parkinsonism	Fluoxetine			S	Unknown	Unk, Unknown		Par
	Sertraline Hydrochloride			S	Unknown	Unk, Unknown		Not Reported
	Escitalopram Oxalate			S	Unknown	Unk, Unknown		Not Reported
	Duloxetine			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2011	8047238	EXPEDITED (15-DAY)	Y	HO	PHHY2011FR62540			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Attention Deficit/Hyperactivity Disorder; Craniocerebral Injury; Fall; Wound	Exelon			S	Transdermal	9.5 Mg, Unk		Novartis
	Leponex			S		Unk Ukn, Unk		Not Reported
	Leponex			S		Unk Ukn, Unk		Not Reported
	Escitalopram Oxalate			S		Unk Ukn, Unk		Not Reported
	Lormetazepam			S		Unk Ukn, Unk		Not Reported
	Sterogyl			C		Unk Ukn, Unk		Not Reported
	Lescol			C		Unk Ukn, Unk		Not Reported
	Movicol			C		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2011	8047503	EXPEDITED (15-DAY)	Y	DE	PL-GLAXOSMITHKLINE-B0734223A		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Antibodies; Embolism Venous; Pulmonary Embolism	Paroxetine Hydrochloride			S	Unknown			Glaxosmithkline
	Quetiapine			S	Unknown			Glaxosmithkline
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Glaxosmithkline
	Mirtazapine			S	Unknown			Not Reported
	Reboxetine			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Olanzapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2011	8048203	EXPEDITED (15-DAY)	Y	OT	TW-TYCO HEALTHCARE/MALLINCKRODT-T201101397		52 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Multiple System Atrophy; Parkinsonism; Therapy Non-Responder	Fluoxetine			S		Unk		Tyco
	Sertraline Hydrochloride			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2011	8063218	EXPEDITED (15-DAY)	Y	HO, LT	1000022188		38 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Hepatic Steatosis; Hepatitis Acute; Incorrect Dose Administered; Reye'S Syndrome; Unevaluable Event	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	(120 Mg, Once), Oral 20 Mg (20 Mg, 1 In 1 D), Oral		
						(120 Mg, Once), Oral		
	Xanax			S	Oral	Oral (7.5 Mg, Once), Oral		Not Reported
					Oral	Oral (7.5 Mg, Once), Oral		
	Propranolol			S	Oral	Oral (320 Mg, Once), Oral		Not Reported
					Oral	Oral (320 Mg, Once), Oral		
	Mirtazapine			S	Oral	Oral (90 Mg, Once), Oral		Not Reported
					Oral	Oral (90 Mg, Once), Oral		
	Alcohol (Ethanol)			S	Oral	(1 Lit), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2011	8063246	EXPEDITED (15-DAY)	Y	HO	1000022190		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Dry Mouth; Fall	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S		Reduced Dose, Oral		Not Reported
	Ditropan			S	Oral	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Trospium Chloride			S		1 Dosage Form (1 Dosage Forms, 1 In 1 D)		Not Reported

	Zopiclone	S	Oral	(7.5 Mg), Oral	Not Reported
	Zopiclone	S	Oral	Reduced Dose, Oral	Not Reported
	Levothyroxine Sodium	C			Not Reported
	Lovenox	C			Not Reported
	Crestor (Rosuvastatin0 (Rosuvastatin)	C			Not Reported
	Fosavance (Alendronate Sodium, Colecalciferol) (Alendronate Sodium, Colecalciferol)	C			Not Reported
	Amlodipine Besylate	C			Not Reported
	Xanax	C			Not Reported
	Athymil (Mianserin Hydrochloride) (Mianserin Hydrochloride)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2011	7995914	NON-EXPEDITED	N		US-PFIZER INC-2011131979		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Drug Ineffective; Malaise; Nausea; Product Residue Present; Stress	Effexor			S		Unk		Pfizer
	Effexor			S				Pfizer
	Xanax			S		0.5 Mg, Unk		Pfizer
	Xanax			S		1 Mg, 1x/Day		Pfizer
	Xanax			S		2 Mg, 2x/Day		Pfizer
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Prilosec			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2011	8048874	EXPEDITED (15-DAY)	Y	HO	FR-EISAI INC-E3810-04802-SPO-FR		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia; Jaundice	Aciphex			S	Oral			Not Reported

Cholestatic; Thrombocytopenia	Bactrim	S	Oral		Not Reported
	Amlodipine Besylate\Olmesartan Medoxomil	S	Oral		Not Reported
	Escitalopram Oxalate	S	Oral		Not Reported
	Aspirin	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2011	8060021	DIRECT		OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Follicle Stimulating Hormone Increased; Premature Menopause	Lexapro			S	Oral	20 Mg Qd Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2011	8065211	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2011-04202		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Product Misuse; Respiratory Arrest; Toxicity To Various Agents	Citalopram Hydrobromide			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Venlafaxine			S	Oral	Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2011	8066088	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2011-04210		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse	Zolpidem			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Duloxetine			S	Oral	Oral		Not Reported
	Temazepam			S	Oral	Oral		Not Reported

	Alcohol	S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2011	8066239	EXPEDITED (15-DAY)	Y	CA, DE	1000022223		60 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia; Death Neonatal; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported
	Citalopram			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2011	8066457	EXPEDITED (15-DAY)	Y	DE, HO	AUR-APL-2011-03987		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Product Misuse; Respiratory Arrest; Toxicity To Various Agents	Paroxetine Hydrochloride			S	Oral	Oral		Not Reported
	Tramadol Hydrochloride			S	Oral	Oral		Not Reported
	Diazepam (Diazepam)			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2011	8066528	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2011-04194		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse; Toxicity To Various Agents	Metoprolol Tartrate			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Carisoprodol			S	Oral	Oral		Not Reported
	Clopidogrel			S	Oral	Oral		Not Reported
	Diazepam (Diazepam)			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2011	8067890	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2011-04143		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse; Toxicity To Various Agents	Metformin Hydrochloride			S	Oral	Oral		Not Reported
	Zolpidem			S	Oral	Oral		Not Reported
	Ondansetron			S	Oral	Oral		Not Reported
	Phenytoin			S	Oral	Oral		Not Reported
	Phenobarbital (Phenobarbital)			S	Oral	Oral		Not Reported
	Quetiapine Fumarate			S	Oral	Oral		Not Reported
	Trazodone Hydrochloride			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Emtricitabine And Tenofovir Disoproxil Fumarate			S	Oral	Oral		Not Reported
	Oxycodone (Oxycodone)			S	Oral	Oral		Not Reported
	Methylphenidate			S	Oral	Oral		Not Reported
	Pregabalin			S	Oral	Oral		Not Reported
	Metoclopramide Hydrochloride			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2011	8067933	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2011-04204		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Arrest; Toxicity To Various Agents	Sertraline Hydrochloride			S	Oral	Oral		Not Reported
	Doxepin Hydrochloride			S	Oral	Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported
	Clonazepam			S	Oral	Oral		Not Reported
	Clonidine Transdermal System			S	Oral	Oral		Not Reported
	Diphenhydramine Hydrochloride			S	Oral	Oral		Not Reported

	Sildenafil Citrate		S	Oral	Oral	Not Reported
	Duloxetine		S	Oral	Oral	Not Reported
	Oxybutynin (Oxybutynin)		S	Oral	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2011	7755697	EXPEDITED (15-DAY)	Y	CA, DE, OT	AUR-APL-2010-03018		2 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital; Maternal Drugs Affecting Foetus; Pulmonary Artery Atresia	Citalopram Hydrobromide			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported
	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2011	8051993	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15362122		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Coumadin			S				Bristol Myers Squibb
	Coumadin			S				Bristol Myers Squibb
	Lexapro			S	Oral	Tabs		Not Reported
	Protonix			S	Oral	Tabs		Not Reported
	Multivitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2011	8069951	EXPEDITED (15-DAY)	Y	HO	1000022286		82 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia; Balanoposthitis; Blood Bilirubin Increased; Blood Thyroid Stimulating	Escitalopram Oxalate			S	Oral	1 In 1 D), Oral		Not Reported
	Bactrim			S		2 In 1 D		Not Reported
	Amlodipine Besylate\Olmesartan Medoxomil			S		1 Dosage Form (1 Dosage		Not Reported

Hormone Decreased; Gamma-Glutamyltransferase Increased; Jaundice Cholestatic; Platelet Count Decreased; Prostatic Specific Antigen Increased; Thrombocytopenia; Urinary Tract Infection Staphylococcal					Forms, 1 In 1 D)	
	Kardegic (Acetylsalicylate Lysine)		S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral	Not Reported
	Rabeprazole Sodium		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2011	8070002	EXPEDITED (15-DAY)	Y	RI, OT	1000022303		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Hyperhidrosis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral; 10 Mg(10 Mg, 1 In 1 D), Ora		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D),Oral; 10 Mg(10 Mg, 1 In 1 D), Ora		
	Trimipramine Maleate			S	Ophthalmic	100 Mg (100 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
					Ophthalmic	100 Mg (100 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D), Oral		
	Pantozol (Pantoprazole Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2011	8091295	EXPEDITED (15-DAY)	Y	HO	DSM-2011-00697		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia; Balanoposthitis; Bladder Dilatation; Blood Thyroid Stimulating	Amlodipine Besylate\Olmesartan Medoxomil			S	Oral	1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral		Not Reported

Hormone Decreased; Cholestasis; Complication Associated With Device; Depression; Prostatic Specific Antigen Increased; Streptococcal Urinary Tract Infection; Thrombocytopenia	Bactrim	S	Oral	2 Dosage Forms (1 Dosage Forms, 2 In 1 D),Oral	Not Reported
	Escitalopram Oxalate	S	Oral	1 Dosage Forms (1 Dosage Forms,1 In 1 D), Oral	Not Reported
	Kardegic (Acetylsalicylate Lysine)	S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral	Not Reported
	Rabeprazole Sodium	S		20 Mg (20 Mg, 1 In 1 D) Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2011	8057316	EXPEDITED (15-DAY)	Y	HO	PL-ARROW GEN-2011-10987		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Sertraline Hydrochloride			S		100 Mg, Daily	1095 DAY	Watson
	Mirtazapine			S		30 To 45 Mg, Daily	1095 DAY	Watson
	Paroxetine Hydrochloride			S		20 Mg, Daily	1095 DAY	Not Reported
	Venlafaxine Hydrochloride			S		225 Mg, Daily		Not Reported
	Quetiapine			S		100 To 300 Mg, Daily		Not Reported
	Olanzapine			S		5 Mg, Daily		Not Reported
	Reboxetine			S		4 Mg, Daily		Not Reported
	Escitalopram Oxalate			S		20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2011	8071930	EXPEDITED (15-DAY)	Y	HO	1000022336		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Aggression; Compulsive Shopping; Logorrhoea; Mania; Psychomotor Hyperactivity	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2011	8091427	EXPEDITED (15-DAY)	Y	HO	1000022288		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Drugs Affecting Foetus; Pulmonary Oedema Neonatal	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental; 5 Mg (5 Mg, 1 In 1 D), Transplacental		Not Reported
					Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental; 5 Mg (5 Mg, 1 In 1 D), Transplacental		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2011	8059586	NON-EXPEDITED	Y	OT	US-PFIZER INC-2011170545		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hyperhidrosis	Chantix			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2011	8079966	EXPEDITED (15-DAY)	Y	HO, LT	1000022395		89 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; Diarrhoea; Hyponatraemia	Escitalopram Oxalate			S		5 Mg (5 Mg, 1 In 1 D),		Not Reported
	Cordarone			C				Not Reported
	Cozaar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2011	8080246	EXPEDITED (15-DAY)	Y	HO	1000022404		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Blood Electrolytes Decreased; Creatinine Renal Clearance Decreased; Decreased Appetite; Dizziness; Hypokalaemia; Hyponatraemia; Vomiting	Escitalopram Oxalate	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported
	Alteis	S			Not Reported
	Acebutolol Hydrochloride	C			Not Reported
	Ikorel (Nicorandil) (Nicorandil)	C			Not Reported
	Seresta (Oxazepam) (Oxazepam)	C			Not Reported
	Transipeg (Macrogol)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2011	7952858	EXPEDITED (15-DAY)	Y	HO	1000020378		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akathisia; Bacteriuria; Blood Cholesterol Increased; Blood Thyroid Stimulating Hormone Increased; Drug Interaction; Drug Withdrawal Syndrome; High Density Lipoprotein Increased; Nitrite Urine Present; Overdose; Total Cholesterol/Hdl Ratio Decreased; Urine Analysis Abnormal	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 25 Mg (25 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 25 Mg (25 Mg, 1 In 1 D), Oral		
	Abilify			S	Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral, 2.5 Mg (2.5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral, 2.5 Mg (2.5 Mg, 1 In 1 D), Oral		
					Oral	7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral, 2.5 Mg (2.5 Mg, 1 In 1 D), Oral		
	Methadone Hydrochloride			S	Oral	See Image		Not Reported
					Oral	See Image		
					Oral	See Image		
					Oral	See Image		
	Seroquel			S	Oral	25-200 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2011	7960701	EXPEDITED (15-DAY)	Y	HO	1000020649		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parasomnia; Screaming	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 20 Mg (10 Mg, 2 In 1 D), Oral		
	Codiovan (Valsartan Hydrochlorothiazide) (Valsartan, Hydrochlorothiazide)			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Ass (Acetylsalicylic Acid) (Acetylsalicylic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2011	8060639	EXPEDITED (15-DAY)	N	RI, OT	1000022126		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nail Injury; Product Friable; Product Quality Issue; Restlessness	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2011	8060844	EXPEDITED (15-DAY)	N	HO, OT	BR-SANOFI-AVENTIS-2011SA047666			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Thyroid Stimulating Hormone Increased; Hypercholesterolaemia; Ischaemic Stroke	Lantus			S	Subcutaneous			Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Metformin Hydrochloride			S				Not Reported
	Lexapro			S				Not Reported
	Thiamine Hydrochloride			S				Not Reported
	Losartan Potassium			C				Not Reported

	Selozok	C		Not Reported
	Humalog	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2011	8061497	EXPEDITED (15-DAY)	N	DS	AU-PURDUE-USA-2011-0072359		49 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Decreased Appetite; Disturbance In Attention; Fatigue; Feeling Of Body Temperature Change; Insomnia; Myalgia; Somnolence; Urine Output Decreased	Oxynorm			S	Oral			Purdue
	Venlafaxine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Dothiepin /00160401/			C				Not Reported
	Lithium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2011	8085805	EXPEDITED (15-DAY)	Y	DS	1000022499		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Contractions Involuntary; Muscle Spasticity	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Xanax			C				Not Reported
	Atarax			C				Not Reported
	Baclofene (Baclofene) (Baclofene)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2011	7826813	EXPEDITED (15-DAY)	N	DS, HO, OT	2010SP040550		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amblyopia; Amenorrhoea; Arteriovenous Malformation; Back Pain; Blood Follicle Stimulating Hormone Increased; Blood Iron Decreased; Brain	Nuvaring			S				Not Reported
	Lexapro			S				Not Reported
	Dilantin			S				Not Reported
	Advil			C				Not Reported
	Marijuana			C				Not Reported

Midline Shift; Brain Oedema; Cerebral Haemorrhage; Cerebral Infarction; Cerebrovascular Accident; Cholecystitis; Cholelithiasis; Cyst; Depression; Diarrhoea; Disorientation; Dizziness; Drug Eruption; Encephalomalacia; Epilepsy; Eye Laser Surgery; Fatigue; Gallbladder Disorder; Heterophoria; Hormone Level Abnormal; Hot Flush; Hypercoagulation; Hyperhidrosis; Hyperlipidaemia; Hypoaesthesia; Hypobarism; Hypovitaminosis; Insomnia; Intracranial Venous Sinus Thrombosis; Jaw Disorder; Libido Decreased; Meniere'S Disease; Menstruation Irregular; Muscle Spasms; Muscle Tightness; Nausea; Nervousness; Night Sweats; Obstruction; Oligomenorrhoea; Panic Reaction; Parosmia; Post-Traumatic Stress Disorder; Pregnancy Test Positive; Seizure; Sinus Congestion; Stress; Temporomandibular Joint Syndrome; Therapy Non-Responder; Tinnitus; Toxicity To Various

Agents; Transaminases Increased; Transient Ischaemic Attack; Transverse Sinus Thrombosis; Urticaria; Vertigo; Visual Field Defect; Visual Field Defect; Vitamin D Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2011	7991688	EXPEDITED (15-DAY)	Y	HO, OT	1000021030		59 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Hyponatraemia; Toxic Skin Eruption	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Tegretol			S	Oral	400 Mg (200 Mg, 2 In 1 D), Oral		Not Reported
	Theralene (Alimemazine Tartrate) (Alimemazine Tartrate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2011	8056110	EXPEDITED (15-DAY)	Y	HO, LT	1000022004		26 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor; Suicide Attempt	Escitalopram Oxalate			S		Overdose : 14 Tablets At Once (14 Dosage Forms, Once)		Not Reported
	Risperidone			S		Overdose: 30 Tablets At Once (30 Dosage Forms, Once)		Not Reported
	Bromazepam			S		Overdose: 15 Tablets At Once (15 Dosage Forms, Once)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2011	8735273	DIRECT	N	OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2011	7744473	EXPEDITED (15-DAY)	Y	DE	1000017486		16 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Completed Suicide; Dizziness Postural; Ear Infection; Insomnia; Intentional Overdose; Multiple Injuries; Off Label Use; Product Dose Omission; Road Traffic Accident; Skin Laceration; Treatment Noncompliance	Escitalopram Oxalate			S		10 Mg (10 Mg, At Night) (80 Mg, Once) 10 Mg (10 Mg, At Night) (80 Mg, Once)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2011	8044830	EXPEDITED (15-DAY)	Y	CA, HO, RI, OT	1000021901		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Neonatal; Caesarean Section; Cardiac Murmur; Congenital Choroid Plexus Cyst; Foetal Acidosis; Foetal Distress Syndrome; Foetal Heart Rate Deceleration Abnormality; Hypotonia Neonatal; Maternal Drugs Affecting Foetus; Neonatal	Escitalopram Oxalate			S	Transplacental	40 Mg (40 Mg, 1 In 1 D) , Transplacental		Not Reported
	Methyldopa			S	Transplacental		18 DAY	Not Reported
	Folic Acid			C				Not Reported

Complications Of Substance Abuse; Neonatal Hypotension; Neonatal Respiratory Depression; Neonatal Tachycardia; Overdose; Pelvic Kidney; Premature Baby; Serotonin Syndrome; Small For Dates Baby

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2011	8063988	EXPEDITED (15-DAY)	Y	DE, HO	1000022192		90 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cerebral Haemorrhage; Fall; Hemianopia; Injury; Intraventricular Haemorrhage	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Aspirin			S		100 Mg (100 Mg,1 In 1 D)		Not Reported
	Seroquel (Quetiapine) (Quetiapine)			C				Not Reported
	Distraneurin (Clomethiazole) (Clomethiazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2011	8730903	DIRECT	N	DS			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Bone Disorder; Cerebrovascular Accident; Emotional Disorder; Feeling Abnormal; Homicidal Ideation; Influenza Like Illness; Mania; Panic Attack; Paraesthesia; Serotonin Syndrome; Suicidal Ideation; Tinnitus; Unevaluable Event; Visual	Lexapro			S	Oral	10mg Once Daily		Forest

Acuity Reduced

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2011	8068677	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2011SA046528		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Stilnox			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Bisoprolol Fumarate			C	Oral			Not Reported
	Aspirin			C	Oral			Not Reported
	Galantamine			C	Oral			Not Reported
	Calcium Carbonate			C				Not Reported
	Acetaminophen			C	Oral			Not Reported
	Aerius (Desloratadine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2011	8068961	EXPEDITED (15-DAY)	Y	HO, LT	FR-ROCHE-793994		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Rivotril			S	Oral	Dose: 2.5 Mg/Ml		Roche
	Bactrim Forte			S	Oral			Roche
	Tramadol Hydrochloride And Acetaminophen			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2011	8045149	EXPEDITED (15-DAY)	Y	DE	PHFR2011GB04264		61 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Neoplasm Malignant; Organ Failure; Respiratory Failure	Clozaril			S	Oral	450 Mg Daily		Novartis
	Sulpiride			S	Oral	600 Mg, Unk		Not Reported

	Escitalopram Oxalate	S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2011	8091309	EXPEDITED (15-DAY)	N	RI, OT	1000022560		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2011	8096110	EXPEDITED (15-DAY)	Y	DE	DSA_47315_2011		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Depression; Pulmonary Embolism	Venlafaxine Hydrochloride			S		(225 Mg)		Not Reported
	Quetiapine Fumarate			S		(100 Mg) ; (300 Mg)		Not Reported
	Paroxetine Hydrochloride			S		(20 Mg)		Not Reported
	Sertraline Hydrochloride			S		(100 Mg)		Not Reported
	Mirtazapine (Mirtazapine)			S		(30 Mg) ; (45 Mg)		Not Reported
	Reboxetine Mesylate			S		(4 Mg)		Not Reported
	Escitalopram Oxalate			S		(20 Mg)		Not Reported
	Olanzapine (Olanzapine)			S		(5 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2011	7750052	EXPEDITED (15-DAY)	Y	RI, OT	1000017594		60 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Drug Dependence; Ear Pain; Feeling Jittery; Gastrointestinal Disorder; Insomnia; Malaise; Nausea; Nightmare; Poor	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1in 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral Oral	See Image See Image		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),		Not Reported

Quality Sleep; Withdrawal Syndrome			Oral	
	Temesta (Lorazepam) (Tablets) (Lorazepam)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2011	8079432	NON-EXPEDITED	N		US-PFIZER INC-2011179842		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Headache; Malaise; Nausea	Advil			S	Oral	200 Mg Three To Four Tablets		Pfizer
	Advil			S	Oral	Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Alprazolam			C		2 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2011	8090086	EXPEDITED (15-DAY)	Y	DE	1000022583		96 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dehydration; Fall	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Bromazepam			S	Oral	Oral		Not Reported
	Isoptine (Verapamiil Hydrochloride)			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Tareg			C				Not Reported
	Aspirin			C				Not Reported
	Symbicort			C				Not Reported
	Singulair			C				Not Reported
	Desloratadine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2011	8081725	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20110802114			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Overdose	Tylenol	Y	S	Unknown		Not Reported
	Tylenol		S	Unknown	1 Bottle	Not Reported
	Depakote Er		S		500mg, 1-6 Hours	Not Reported
	Zolpidem Tartrate		S		10, Qh8ym	Not Reported
	Carisoprodol		S			Not Reported
	Escitalopram Oxalate		S		20, Qam	Not Reported
	Lamotrigine		S		200, Qms	Not Reported
	Sonata		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2011	8080135	EXPEDITED (15-DAY)	Y	RI, OT	1000022328		64 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Arteriosclerosis; Mitral Valve Incompetence	Escitalopram Oxalate			S			2 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2011	8094682	EXPEDITED (15-DAY)	N	RI, OT	1000022669		25 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haematochezia	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral		
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2011	8095670	EXPEDITED (15-DAY)	Y	RI, OT	1000020204		17 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2011	8097496	EXPEDITED (15-DAY)	Y	RI, OT	1000022709		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2011	8111198	EXPEDITED (15-DAY)	Y	RI, OT	1000022630			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2011	8046277	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2011SE41855		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Confusional State; Hyponatraemia	Candesartan Cilexetil And Hydrochlorothiazide			S	Oral	8 + 12.5 Mg Daily		Astrazeneca
	Escitalopram Oxalate			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Atenolol\Nifedipine			C	Oral			Not Reported
	Oxazepam			C	Oral			Not Reported

	Potassium Chloride	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2011	8083498	EXPEDITED (15-DAY)	Y	HO, OT	2011AP001528		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Bradykinesia; Condition Aggravated; Decreased Appetite; Depressed Mood; Drug Ineffective; Family Stress; Flat Affect; Gait Disturbance; Insomnia; Major Depression; Parkinsonism; Somatic Delusion; Suicidal Ideation	Risperidone			S		0.5 Mg;Qd; 0.5 Mg;Bid		Not Reported
	Paroxetine Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Rosuvastatin			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Lisinopril			C				Not Reported
	Duloxetine			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2011	8742829	DIRECT	Y				65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea	Lexapro			S		One Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2011	8088605	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011181339		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia; Anger; Drug Level Above Therapeutic; Homicide	Xanax			S		Unk		Pfizer
	Citalopram			S		Unk		Not Reported
	Zolpidem Tartrate			S	Oral	10 Mg, Unk		Not Reported
	Diphenhydramine			S		Unk		Not Reported
	Acetone			S		Unk		Not Reported
	Caffeine			S		Unk		Not Reported

Lexapro	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2011	8088895	EXPEDITED (15-DAY)	Y	HO, LT	US-ROXANE LABORATORIES, INC.-2011-RO-01129RO		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Distress; Staphylococcal Infection; Urosepsis	Lorazepam			S				Roxane
	Escitalopram Oxalate			S				Not Reported
	Benzodiazepine			S				Not Reported
	Methylphenidate			S				Not Reported
	Linezolid			S	Intravenous (not otherwise specified)			Not Reported
	Piperacillin And Tazobactam			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2011	7249213	EXPEDITED (15-DAY)	Y	HO	21323		84 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchoalveolar Lavage Abnormal; Cyanosis; Haemoptysis; International Normalised Ratio Increased; Overdose; Respiratory Distress	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Sintrom			S	Oral	2 To 4 Mg Daily According To Inr Value, Oral		Not Reported
	Lasilix (Furosemide) (Tablets) (Furosemide)			C				Not Reported
	Daonil (Glibenclamide) (Glibenclamide)			C				Not Reported
	Imovane (Zopiclone) (Zopiclone)			C				Not Reported
	Levothyrox (Levothyroxine Sodium) (Tablets) (Levothyroxine Sodium)			C				Not Reported
	Glucophage (Metformin Hydrochloride) (Tablets)			C				Not Reported

(Metformin Hydrochloride)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2011	8048669	EXPEDITED (15-DAY)	N	HO	1000021874			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Panic Attack	Viibryd			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2011	8068631	EXPEDITED (15-DAY)	Y	HO	1000022290		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Cerebellar Haematoma; Confusional State; Headache; Hypercoagulation; Hyponatraemia; Lung Disorder	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Candesartan Cilexetil And Hydrochlorothiazide			S		8 Mg/ 12.5 Mg (1 In 1 D)		Not Reported
	Aspirin			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Diffu K (Potassium Chloride) (Potassium Chloride)			C				Not Reported
	Tenordate (Nif-Ten) (Nif-Ten)			C				Not Reported
	Oxazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2011	8096990	DIRECT	N	OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Muscle Spasms	Lexapro			S		1 Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2011	7136909	EXPEDITED (15-DAY)	Y	HO, OT	CH-ASTRAZENECA-2009SE15253		30 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Endocarditis; Syncope; Ventricular Tachycardia; Weight Decreased	Seroquel			S	Oral		2 YR	Not Reported
	Seroquel			S	Oral			Not Reported
	Ritalin			S	Oral		2 YR	Not Reported
	Ritalin			S	Oral		3 DAY	Not Reported
	Methadone Hydrochloride			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Zopiclone			C	Oral		4 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2011	8108005	EXPEDITED (15-DAY)	N	OT	1000022824			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2011	8118144	EXPEDITED (15-DAY)	N	RI, OT	1000022248		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia; Anger; Homicide; Imprisonment; Loss Of Consciousness	Lexapro			S				Not Reported
	Ambien			S	Oral	10 Mg Prn (10 Mg,As Needed),Oral		Not Reported
	Xanax			S				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Acetone (Acetonie) (Acetone)			C				Not Reported
	Caffeine (Caffeine) (Caffeine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2011	8748927	DIRECT	N	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anhedonia; Depressed Mood; Depression; Feeling Abnormal; Feelings Of Worthlessness; Hypersomnia	Lexapro	S	Oral	1 & 1/2 Tablets, Daily, Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2011	8014704	EXPEDITED (15-DAY)	Y	RI, OT	1000021540		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Haemorrhage; Ecchymosis	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Spiriva			C				Not Reported
	Simvastatine (Simvastatin) (Tablets) (Simvastatin)			C				Not Reported
	Symbicort (Budesonie, Formoterol Fumarate) (Budesonide, Formoterol Fumarate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2011	8039382	EXPEDITED (15-DAY)	Y	DE	1000021787		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Poisoning; Unresponsive To Stimuli	Escitalopram Oxalate			S				Not Reported
	Oxycodone (Oxycodone)			S				Not Reported
	Diazepam (Diazepam)			S				Not Reported
	Nordazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2011	8093759	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2011SE47636		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Atacand	S	Oral	Daily			Not Reported
	Urapidil	C	Oral	Daily			Not Reported
	Escitalopram Oxalate	S	Oral	Daily		4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2011	8096137	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2011SE48064		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Partial Seizures	Zolmitriptan			S	Oral			Zeneca
	Transilane (Potassium Bicarbonate\Psyllium Husk)			C	Oral			Not Reported
	Oxazepam			C	Oral			Not Reported
	Lescol			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Bisoprolol Fumarate			C	Oral			Not Reported
	Actonel			C	Oral			Not Reported
	Valacyclovir Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Sanmigran			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2011	8111792	EXPEDITED (15-DAY)	Y	HO	2011MA010840		52 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Cerebral Atrophy; Extrapyramidal Disorder; Gait Disturbance; Muscle Rigidity; Orthostatic Hypotension; Psychomotor Hyperactivity; Treatment Noncompliance; Tremor;	Fluoxetine			S				Alphapharm
	Sertraline Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

Urinary Incontinence

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2011	8112142	EXPEDITED (15-DAY)	N	OT	AUR-APL-2011-04656		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia; Anger; Antidepressant Drug Level Above Therapeutic; Homicide; Imprisonment	Citalopram Hydrobromide			S				Not Reported
	Zolpidem			S	Oral	(10 Mg), Oral		Not Reported
	Xanax			S				Not Reported
	Diphenhydramine Hydrochloride			S				Not Reported
	Acetone			S	Oral			Not Reported
	Caffeine			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2011	8053744	EXPEDITED (15-DAY)	Y	RI, OT	1000021963		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased; Neutropenia; Red Blood Cell Count Decreased; White Blood Cell Count Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
					Oral	10 Mg (10 Mg 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral		
	Promethazine Hydrochloride			S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral; 50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported
					Oral	25 Mg (25 Mg, 1 In 1 D), Oral; 50 Mg (50 Mg, 1 In 1 D), Oral		

	Agomelatine	S	Oral	25 Mg (25 Mg, 1 In 1 D), Oral; 50 Mg (50 Mg, 1 In 1 D),Oral	Not Reported
			Oral	25 Mg (25 Mg, 1 In 1 D), Oral; 50 Mg (50 Mg, 1 In 1 D),Oral	
	Ximova (Zopiclone) (Zopiclone)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2011	8098343	EXPEDITED (15-DAY)	Y	HO	FR-GLAXOSMITHKLINE-B0738119A		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyspnoea; Loss Of Consciousness; Malaise; Partial Seizures	Valacyclovir Hydrochloride			S	Oral	500mg Per Day		Glaxosmithkline
	Escitalopram Oxalate			S	Oral	15mg Per Day		Unknown
	Zolmitriptan			S	Oral	2.5mg Per Day		Unknown
	Sanmigran			S	Oral	1mg Per Day		Unknown
	Potassium Bicarbonate\Psyllium Hemicellulose			C	Oral			Unknown
	Oxazepam			C	Oral	10mg Unknown		Unknown
	Lescol			C	Oral	20mg Per Day		Unknown
	Zopiclone			C	Oral	7.5mg Per Day		Unknown
	Bisoprolol Fumarate			C	Oral	3.75mg Per Day		Unknown
	Actonel			C	Oral	35mg Weekly		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2011	8113431	EXPEDITED (15-DAY)	Y	RI, OT	1000022865		64 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria	Escitalopram Oxalate			S	Oral	5mg - 10mg (1 In 1 D), Oral		Not Reported
	Corsodyl (Chlorhexidine Gluconate, Chlorhexidine Digluconate Solution)			C				Not Reported

	Fybogel	C	Not Reported
	Imipramine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2011	8099518	NON-EXPEDITED	N		US-PFIZER INC-2011190779		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Product Dose Omission; Strabismus; Vision Blurred	Pristiq Extended Release			S	Oral	50 Mg, Daily		Pfizer
	Lexapro			S	Oral	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2011	8116421	EXPEDITED (15-DAY)	Y	RI, OT	1000022928		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Lymphocytic Infiltration	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2011	8118195	EXPEDITED (15-DAY)	Y	HO	2011MA011405		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Parkinsonism; Somatic Delusion	Risperidone			S		0.5 Mg;Bid;		Actavis Totowa
	Clonazepam			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Paroxetine Hydrochloride			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Lisinopril			C				Not Reported
	Rosuvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2011	8128373	EXPEDITED (15-DAY)	Y	HO	1000022869		80 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gait Disturbance; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate	S	Oral	Oral		Not Reported
	Atacand	S		Oral		Not Reported
	Urapidil	S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2011	8142733	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000022847		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Disease; Ventricular Arrhythmia; Ventricular Extrasystoles; Ventricular Tachycardia	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Nadolol			C				Not Reported
	Crestor			C				Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported
	Micardis			C				Not Reported
	Janumet(Sitagliptin, Metformin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2011	7960789	EXPEDITED (15-DAY)	Y	HO	1000020671			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Blood Cholesterol Increased; Fatigue; Insomnia	Escitalopram Oxalate			S				Not Reported
	Atrovent			C				Not Reported
	Berodual (Fenoterol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2011	8088959	EXPEDITED (15-DAY)	Y	HO, OT	PHHY2011FR69793		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Glare; Joint Injury	Tramadol Hydrochloride			S	Oral	100 Mg, Bid		Novartis
	Nitroderm			S		Unk Ukn, Qd		Not Reported

	Furosemide	S	Oral	Unk Ukn, Qd	Not Reported
	Isosorbide Dinitrate	S	Oral	20 Mg, Bid	Not Reported
	Vastarel	S	Oral	Unk Ukn, Bid	Not Reported
	Escitalopram Oxalate	S		0.25 Df, Unk	Not Reported
	Dafalgan	C		6 Df, Unk	Not Reported
	Bromazepam	C		0.5 Df, Unk	Not Reported
	Seretide Diskus	C		Unk Ukn, Bid	Not Reported
	Trimebutine	C		100 Mg, Bid	Not Reported
	Ipratropium Bromide	C		Unk Ukn, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2011	8121017	EXPEDITED (15-DAY)	N	RI, OT	1000022976			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Constipation; Decreased Appetite; Depression; Drug Ineffective; Drug Withdrawal Syndrome; Faecal Volume Decreased; Gastrointestinal Disorder; Gastrointestinal Oedema; Micturition Disorder; Suicidal Ideation; Urine Output Decreased; Vaginal Abscess; Wrong Technique In Product Usage Process	Escitalopram Oxalate			S		(5 Mg)		Not Reported
	Escitalopram Oxalate			S		See Image		Not Reported
	Escitalopram Oxalate			S		10 Mg		Not Reported
	Escitalopram Oxalate			S		5 Mg		Not Reported
	Escitalopram Oxalate			S		10 Mg		Not Reported
	Escitalopram Oxalate			S		5 Mg		Not Reported
	Cymbalta			S	Oral	30 Mg, Oral		Not Reported
	Cymbalta			S	Oral	60 Mg, Oral		Not Reported
	Cymbalta			S	Oral	30 Mg, Oral		Not Reported
	Cymbalta			S	Oral	30 Mg, Oral		Not Reported
	Cymbalta			S	Oral	30 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2011	8100660	EXPEDITED (15-DAY)	Y	HO	IT-BAYER-2011-071714		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Myoclonus	Acetylsalicylic Acid(<=100 Mg)	S	Oral			Bayer
	Nitroglycerin	S	Transdermal			Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg, Qd		Not Reported
	Escitalopram Oxalate	S				Not Reported
	Dipyridamole	S				Not Reported
	Metoprolol	S	Oral			Not Reported
	Pantoprazole	S	Oral			Not Reported
	Insulin Nos	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2011	8104588	EXPEDITED (15-DAY)	Y	HO	PHHY2011FR73076			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Hydrochlorothiazide\Valsartan			S		160 Mg Valsartan/ 25 Mg Hydrochlorothiazide		Novartis
	Escitalopram Oxalate			S		Unk Ukn, Unk		Not Reported
	Methotrexate			C		Unk Ukn, Unk		Not Reported
	Metformin Hydrochloride			C		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2011	8118554	EXPEDITED (15-DAY)	N	CA	1000022942		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Hydrocephalus; Maternal Drugs Affecting Foetus; Spina Bifida	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2011	8120325	EXPEDITED (15-DAY)	Y	HO	1000023020			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dissociative Disorder; Nausea; Seizure	Escitalopram Oxalate	S	(10 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2011	8120845	EXPEDITED (15-DAY)	N	CA	1000022949		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoplastic Left Heart Syndrome; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2011	8123832	EXPEDITED (15-DAY)	Y	HO	1000023038		81 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Diverticulum; Haematochezia; Haematuria; Haemoglobin Decreased; Haemorrhage; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Sintrom			S	Oral	Oral		Not Reported
	Prozac			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Omeprazol (Omeprazole) (Omeprazole)			C				Not Reported
	Cardyl Comprimido Recubiertos Con Pelicula (Atorvastatin Calcium Trihydrate) (Atorvastatin Calcium T			C				Not Reported
	Trangorex Comprimidos (Amiodarone Hydrochloride) (Amiodarone Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2011	7898780	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000019325		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Disorientation;	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D) Oral		Not Reported

Fatigue; Platelet Count Increased; Seizure; Tongue Biting	Escitalopram Oxalate		S	Oral	10, 5 Mg (10, 5 Mg, 1 In 1 D), Oral	Not Reported
				Oral	10, 5 Mg (10, 5 Mg, 1 In 1 D), Oral	
	Viani		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2011	8006385	EXPEDITED (15-DAY)	Y	HO	1000021413		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Viani			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2011	8108082	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20110810240		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Jaundice	Haldol			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Cyamemazine			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2011	8108748	EXPEDITED (15-DAY)	Y	DS, OT	FR-PFIZER INC-2011198814		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Myalgia; Syncope; Vision Blurred	Atarax			S	Oral	25 Mg, Unk	28 DAY	Pfizer
	Escitalopram Oxalate			S	Oral	10 Mg, Unk	28 DAY	Not Reported
	Tavanic			C	Oral	500 Mg, 2x/Day		Not Reported
	Alendronate Sodium			C	Oral	1 Df, Weekly		Not Reported
	Domperidone			C	Oral	1 Df, 2x/Day		Not Reported

	Inipomp		C	Oral	40 Mg, Daily	Not Reported
	Dafalgan		C	Oral	2 To 4 Df Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2011	8126339	EXPEDITED (15-DAY)	Y	HO	1000023057		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Cerebral Atrophy; Cerebral Small Vessel Ischaemic Disease; Culture Urine Positive; Delirium; Electroencephalogram Abnormal; Escherichia Infection; Hyponatraemia	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D)		Not Reported
	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2011	8091586	EXPEDITED (15-DAY)	Y	DS	1000022621		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromaturia; Renal Pain	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2011	8096345	EXPEDITED (15-DAY)	Y	HO	1000022646		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Interstitial Lung Disease; Pulmonary Hypertension	Lexapro			S	Oral	10 Mg (10 Mg, In 1 D) Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Promocard Durette (Isosorbide Mononitrate) (Tablets)			C				Not Reported
	Albuterol			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported

	Esomeprazole Magnesium	C	Not Reported
	Oxazepam	C	Not Reported
	Risedronic Acid (Risedronate Sodium)	C	Not Reported
	Metoprolol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2011	8126415	EXPEDITED (15-DAY)	Y	RI, OT	1000023028		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral Oral	5 Mg (5 Mg, 1 In 1 D), Oral 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lamictal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2011	8126425	EXPEDITED (15-DAY)	N	HO	1000023030		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Back Pain; Bruxism; Chest Pain; Dizziness; Dry Mouth; Dyspnoea; Fatigue; Flatulence; Insomnia; Muscle Spasms; Myelodysplastic Syndrome; Night Sweats	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Oxycodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2011	8112698	EXPEDITED (15-DAY)	Y	HO, OT	FR-PFIZER INC-2011194543		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agranulocytosis; Anaemia; Febrile Neutropenia; Waldenstrom'S Macroglobulinaemia	Xanax		S	Oral	Unk	Pfizer
	Escitalopram Oxalate		S	Oral	Unk	Not Reported
	Tahor		C	Oral	10 Mg, 1x/Day	Not Reported
	Plavix		C	Oral	75 Mg, Unk	Not Reported
	Selokeen		C	Oral	100 Mg, Unk	Not Reported
	Ramipril		C	Oral	1.25 Mg, 1x/Day	Not Reported
	Aspirin		C	Oral	75 Mg, Unk	Not Reported
	Inexium		C		20 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2011	8129490	EXPEDITED (15-DAY)	Y	RI, OT	1000023103		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Sinusitis	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2011	8137453	EXPEDITED (15-DAY)	Y	DE	100023111		61 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Adenocarcinoma; Neoplasm Progression; Organ Failure; Respiratory Failure	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Clozaril			S	Oral	450 Mg (450 Mg, 1 In 1 D), Oral		Not Reported
	Sulpiride			S	Oral	600 Mg (600 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2011	8137533	EXPEDITED (15-DAY)	N	RI, OT	1000023135		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diplopia; Eye Pain; Halo Vision; Migraine; Photophobia; Pupils Unequal; Vitreous Floaters	Escitalopram Oxalate		S	Oral	Dose, Oral, (10 Mg, 1 In 1 D), Oral	Not Reported
				Oral	Dose, Oral, (10 Mg, 1 In 1 D), Oral	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2011	7987485	EXPEDITED (15-DAY)	Y	CA	1000020997		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Musculoskeletal Anomaly; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	20 Mg (20 Mg,1 In 1 D),Transplacental		Not Reported
	Oxazepam			S	Transplacental	60 Mg (60 Mg,1 In 1 D),Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2011	8117578	EXPEDITED (15-DAY)	Y	HO, LT	BR-PFIZER INC-2011203332		86 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Lyrica			S	Oral	75 Mg Daily		Pfizer
	Escitalopram Oxalate			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2011	8117702	EXPEDITED (15-DAY)	Y	OT	PL-MYLANLABS-2011S1017697		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Embolism Venous	Sertraline Hydrochloride			S	Unknown	Maximum Daily Dose Of 100mg		Not Reported
	Paroxetine Hydrochloride			S	Unknown	Maximum Daily Dose Of 20mg		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Maximum Daily Dose Of 225mg		Not Reported
	Mirtazapine			S	Unknown	Maximum Daily Dose Of 30mg		Not Reported

	Mirtazapine	S	Unknown	Maximum Daily Dose Of 45mg	Not Reported
	Reboxetine	S	Unknown	Maximum Daily Dose Of 4mg	Not Reported
	Quetiapine	S	Unknown	Maximum Daily Dose Of 100mg	Not Reported
	Escitalopram Oxalate	S	Unknown	Maximum Daily Dose Of 20mg	Not Reported
	Olanzapine	S	Unknown	Maximum Daily Dose Of 5mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2011	8062577	EXPEDITED (15-DAY)	Y	RI, OT	1000022227		35 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Labile Hypertension	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Doliprane (Paracetamol) (Paracetamol)			C				Not Reported
	Moxydar (Moxydar) (Moxydar)			C				Not Reported
	Gaviscon (Gaviscon) Gaviscon)			C				Not Reported
	Inexium (Esomeprazole Magnesium)			C				Not Reported
	Pariet (Rabeprazole Sodium) (Rabeprazole Sodium)			C				Not Reported
	Lexomil (Bromazepam (Bromazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2011	8080606	EXPEDITED (15-DAY)	Y	RI, OT	1000022411		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophil Count Increased; Leukopenia; Lymphocyte Percentage Increased; Neutropenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Seroquel Xr			S	Oral	300 Mg (300 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2011	8082775	EXPEDITED (15-DAY)	N	RI, OT	1000022350		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Lupus Erythematosus	Lexapro			S	Oral	10 Mg,Oral		Not Reported
	Lexapro			S	Oral	15 Mg,Oral		Not Reported
	Lexapro			S	Oral	10 Mg,Oral		Not Reported
	Lexapro			S	Oral	5 Mg,Oral		Not Reported
	Exelon (Rivastigmine) (Transdermal) (Rivastigmine)			C				Not Reported
	Levothyroxine (Levothyroxine Sodium) (Levothyroxine Sodium)			C				Not Reported
	Namenda			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2011	8111532	EXPEDITED (15-DAY)	Y	DE, HO	1000022848		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Fluid Intake Reduced; Hypophagia; Hypotension; Nausea; Pneumonia; Restlessness; Somnolence; Vomiting	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Prothipendyl Hydrochloride			S	Oral	80 Mg (80 Mg, 1 In 1 D), Oral		Not Reported
	Mirtazapine			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Pantozol			C				Not Reported
	Torsemide			C				Not Reported
	Ass (Acetylsalicylic Acid) (Acetylsalicylic Acid)			C				Not Reported

	Enalapril Maleate	C	Not Reported
	Allopurinol	C	Not Reported
	Bisoprolol Fumarate	C	Not Reported
	Limptar N (Quinine Sulfate) (Quinine Sulfate)	C	Not Reported
	Magnetrane (Magnesium Aspartate) (Magnesium Aspartate)	C	Not Reported
	Actraphane (Human Insulin) (Human Insulin)	C	Not Reported
	Exelon (Rivastigmine) (Rivastigmine)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2011	8119272	EXPEDITED (15-DAY)	Y	OT	FR-PFIZER INC-2011201348		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma Scale Abnormal; Miosis; Somnolence	Xanax			S	Oral	0.25 Mg, 3x/Day	4 DAY	Pfizer
	Morphine Sulfate			S	Oral	30 Mg, 2x/Day	4 DAY	Not Reported
	Morphine Sulfate			S	Oral	10 Mg, 6x/Day	4 DAY	Not Reported
	Durogesic			S	Transdermal	50ug/Hour	4 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2011	8135263	EXPEDITED (15-DAY)	Y	HO	1000023195		55 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Creatine	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 -In 1 D),Oral		Not Reported
	Haldol			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral		
	Cyamemazine			S	Oral	50 Mg (50 Mg, 1 In 1 D),Oral		Not Reported

Phosphokinase Increased; Depression; Gamma-Glutamyltransferase Increased; Jaundice	Zyprexa	S	Oral	50 Mg (50 Mg, 1 In 1 D),Oral		Not Reported
			Oral	20 Mg (20 Mg, 1in 1 D),Oral		
			Oral	20 Mg (20 Mg, 1in 1 D),Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2011	8135283	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000023186		64 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Thrombocytopenia; Yellow Skin	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2011	8135408	EXPEDITED (15-DAY)	Y	RI, OT	1000023314			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Small For Dates Baby	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2011	8006639	EXPEDITED (15-DAY)	Y	HO	CH-PFIZER INC-2011132053		36 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Cytarabine Syndrome; Hepatocellular Injury; Myalgia; Rash; Rhabdomyolysis; Serotonin Syndrome	Cytosar-U			S	Intravenous drip	1000 Mg/M2, 2x/Day (Day 1-6)	7 DAY	Pfizer
	Cytosar-U			S	Intravenous drip	1000 Mg/M2, 2x/Day (Day 1-6)	6 DAY	Pfizer
	Idarubicin Hydrochloride			S	Intravenous drip	12 Mg/M2, 1x/Day (Day 1-3)	3 DAY	Pfizer

	Cipralex	S	Oral	10 Mg, 1x/Day	45 DAY	Not Reported
	Amsidyl	S	Intravenous drip	120 Mg/M2, 1x/Day (Day 4-6)	3 DAY	Not Reported
	Famvir	S	Oral	500 Mg, 2x/Day	8 DAY	Not Reported
	Cancidas	S	Oral	70 Mg, 1x/Day	6 DAY	Not Reported
	Meropenem	S	Intravenous drip	1 G, 3x/Day	8 DAY	Not Reported
	Motilium	C	Sublingual	10 Mg, As Needed	10 DAY	Not Reported
	Motilium	C				Not Reported
	Piperacillin And Tazobactam	C		2.25 Mg, 3x/Day	12 DAY	Not Reported
	Piperacillin And Tazobactam	C		2.25 Mg, Once Per 3 Days	12 DAY	Not Reported
	Metoclopramide Hydrochloride	C	Oral	10 Mg, 3x/Day	35 DAY	Not Reported
	Metoclopramide Hydrochloride	C				Not Reported
	Nexium	C	Oral	40 Mg, 1x/Day		Not Reported
	Nexium	C				Not Reported
	Perfalgan	C	Intravenous bolus	500 Mg, As Needed	50 DAY	Not Reported
	Stilnox	C	Oral	10 Mg, As Needed	50 DAY	Not Reported
	Buscopan	C	Oral	10 Mg, As Needed	50 DAY	Not Reported
	Primolut-N	C	Oral	5 Mg, 4x/Day		Not Reported
	Dexamethasone	C	Oral	8 Mg, 3x/Day		Not Reported
	Vfend	C	Oral	1 G, 2x/Day	9 DAY	Not Reported
	Flagyl	C		500 Mg, 3x/Day	24 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2011	8096518	EXPEDITED (15-DAY)	Y	HO	FR-GLAXOSMITHKLINE-B0738591A		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cheilitis; Dermatitis Bullous; Genital Ulceration; Mucosal Erosion; Nikolsky'S Sign; Prurigo; Rash Morbilliform; Skin Lesion; Stevens-	Lamictal			S	Oral	100mg Twice Per Day	68 DAY	Glaxosmithkline
	Escitalopram Oxalate			S	Oral		68 DAY	Unknown
	Symbicort			C	Unknown			Unknown

Johnson Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2011	8120619	EXPEDITED (15-DAY)	Y	DE, OT	PL-TEVA-298803ISR		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Embolism Venous	Sertraline Hydrochloride			S		100 Milligram;		Not Reported
	Venlafaxine Hydrochloride			S		225 Milligram;		Not Reported
	Mirtazapine			S		30 Milligram;		Not Reported
	Mirtazapine			S		45 Milligram;		Not Reported
	Quetiapine			S		100 Milligram;		Not Reported
	Quetiapine			S		300 Milligram;		Not Reported
	Paroxetine Hydrochloride			S		20 Milligram;		Not Reported
	Reboxetine			S		4 Milligram;		Not Reported
	Escitalopram Oxalate			S		20 Milligram;		Not Reported
	Olanzapine			S		5 Milligram;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2011	8120916	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20110812827		49 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sluggishness	Topamax			S	Oral	6 Tablets		Not Reported
	Escitalopram Oxalate			S	Oral	8 Tablets		Not Reported
	Seroquel			S	Oral	12 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2011	8121533	EXPEDITED (15-DAY)	Y	HO, OT	BE-JNJFOC-20110900932		74 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Toxicity To Various Agents	Risperidone			S	Oral			Not Reported

	Furosemide	S	Unknown	Not Reported
	Spironolactone	S	Unknown	Not Reported
	Escitalopram Oxalate	S	Unknown	Not Reported
	Levomepromazine	S	Unknown	Not Reported
	Lormetazepam	C	Unknown	Not Reported
	Metformin Hydrochloride	C	Unknown	Not Reported
	Repaglinide	C	Unknown	Not Reported
	Dexetimide	C	Unknown	Not Reported
	Lisinopril	S	Unknown	Not Reported
	Lisinopril	S	Unknown	Not Reported
	Irbesartan	S	Unknown	Not Reported
	Lithium	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2011	8122171	EXPEDITED (15-DAY)	N	OT	US-WATSON-2011-13519			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Tremor	Fioricet			S	Oral	Unk		Watson
	Pristiq Extended Release			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Cymbalta			S	Unknown	4 Tabs In The Morning		Not Reported
	Klonopin			S	Unknown	Unk		Not Reported
	Reglan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2011	8122430	EXPEDITED (15-DAY)	Y	HO	PHHY2011FR77439		33 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spinal Cord Haematoma; Vomiting	Voltaren			S	Oral	1 Df, Qd	8 DAY	Novartis
	Klipal			S		1 Df, Tid	5 DAY	Not Reported

	Thiocolchicoside	S	Oral	Unk Ukn, Unk	8 DAY	Not Reported
	Dafalgan	S		1 Df, Tid	8 DAY	Not Reported
	Escitalopram Oxalate	S	Oral	5 Mg, Unk		Not Reported
	Escitalopram Oxalate	S	Oral	20 Mg, Daily	35 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2011	8010787	EXPEDITED (15-DAY)	Y	HO	CH-MERCK-1106USA02371		36 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Cytarabine Syndrome; Hepatocellular Injury; Myalgia; Rash; Rhabdomyolysis; Serotonin Syndrome	Cancidas			S	Unknown	Optimal Immunomodulating Dose	6 DAY	Merck
	Cipralex			S	Oral	Optimal Immunomodulating Dose	45 DAY	Not Reported
	Cipralex			S	Oral	Optimal Immunomodulating Dose	45 DAY	Not Reported
	Cytosar-U			S	Intravenous (not otherwise specified)		6 DAY	Not Reported
	Idarubicin Hydrochloride			S	Intravenous (not otherwise specified)	Optimal Immunomodulating Dose	3 DAY	Not Reported
	Famvir			S	Unknown		8 DAY	Not Reported
	Meropenem			S	Unknown		8 DAY	Not Reported
	Amsidyl			S	Unknown		3 DAY	Not Reported
	Motilium			C	Sublingual		10 DAY	Not Reported
	Motilium			C	Sublingual		10 DAY	Not Reported
	Piperacillin And Tazobactam			C	Unknown		12 DAY	Not Reported
	Metoclopramide Hydrochloride			C	Oral		35 DAY	Not Reported
	Metoclopramide Hydrochloride			C	Oral		35 DAY	Not Reported
	Nexium			C	Oral	Optimal Immunomodulating Dose		Not Reported
	Nexium			C	Oral	Optimal Immunomodulating Dose		Not Reported

	Perfalgan	C	Unknown		50 DAY	Not Reported
	Buscopan	C	Unknown	Optimal Immunomodulating Dose	50 DAY	Not Reported
	Stilnox	C	Unknown	Optimal Immunomodulating Dose	50 DAY	Not Reported
	Norethindrone Acetate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2011	8124279	EXPEDITED (15-DAY)	Y	HO	1000022955		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroduodenal Ulcer; Melaena; Oesophageal Ulcer	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Voltaren			S			2 WEEK	Not Reported
	Dalacin (Clindamycin) (Clindamycin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2011	8125058	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2011203843		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Dyspnoea; Eosinophilic Pneumonia	Xanax			S	Oral			Pfizer
	Trinordiol			S	Oral			Pfizer
	Escitalopram			S	Oral	10 Mg, 2x/Day		Not Reported
	Depakote			S	Oral	750 Mg, 1x/Day		Not Reported
	Stilnox			S	Oral	10 Mg, 1x/Day		Not Reported
	Tardyferon			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2011	8145127	EXPEDITED (15-DAY)	Y	RI, OT	1000023390		49 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Tinnitus	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2011	8749726	DIRECT	Y				16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Emotional Disorder; Erythema; Fall; Flushing; Hyperhidrosis; Insomnia; Nausea; Overdose; Pyrexia; Serotonin Syndrome; Tremor	Lexapro			S	Oral	Qday Am		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2011	8080087	NON-EXPEDITED	N	OT	US-PFIZER INC-2011177274		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Circumstance Or Information Capable Of Leading To Medication Error; Diarrhoea; Disturbance In Attention; Faeces Discoloured; Micturition Disorder; Nervousness; Pain; Personality Change; Weight Decreased	Pristiq Extended Release			S		50 Mg, 1x/Day	15 DAY	Pfizer
	Pristiq Extended Release			S				Pfizer
	Pristiq Extended Release			S				Pfizer
	Pristiq Extended Release			S				Pfizer
	Pristiq Extended Release			S				Pfizer
	Pristiq Extended Release			S				Pfizer
	Pristiq Extended Release			S				Pfizer
	Fioricet			S		Unk		Not Reported
	Cymbalta			S		4 Tablets In The Morning		Not Reported
	Cymbalta			S				Not Reported
	Cymbalta			S				Not Reported
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Klonopin			C		0.5 Mg, As Needed		Not Reported

Estradiol	C	0.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2011	8126842	EXPEDITED (15-DAY)		OT	PHHY2011BR77449		81 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Faeces Discoloured; Haematemesis; Haemorrhage; Pruritus; Ulcer	Losartan Potassium			S		50 Mg, Unk		Novartis
	Exelon			S	Oral	2 Mg, Unk		Not Reported
	Metformin Hydrochloride			S		500 Mg, Unk		Not Reported
	Memantine Hydrochloride			S		10 Mg, Unk		Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported
	Lipidil			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2011	8144919	EXPEDITED (15-DAY)	Y	HO	1000023429		86 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Affective Disorder; Agitation; Anxiety; Asthenia; Blood Potassium Decreased; Blood Sodium Decreased; Cognitive Disorder; Crying; Haemoglobin Decreased; Hepatitis; Hepatitis Acute; Hypokalaemia; Logorrhoea; Memory Impairment; Mental Disorder; Microalbuminuria; Muscle Spasms; Tachyphrenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zolpidem Tartrate			C				Not Reported
	Bipreterax (Indapamide Erbumine, Perindopril Erbumine)			C				Not Reported
	Inegy (Ezetimibe, Simvastatin)			C				Not Reported
	Aspirin			C				Not Reported
	Pantoprazole			C				Not Reported
	Meteospasmyl (Alverine Citrate, Methionine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2011	8008823	EXPEDITED (15-DAY)	Y	HO	CH-ASTRAZENECA-2011SE36772		36 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Cytarabine Syndrome; Hepatocellular Injury; Myalgia; Rash; Rhabdomyolysis; Serotonin Syndrome	Meropenem			S	Intravenous drip			Not Reported
	Cipralex			S	Oral		45 DAY	Not Reported
	Cipralex			S	Oral		45 DAY	Not Reported
	Cytosar-U			S	Intravenous drip		6 DAY	Not Reported
	Idarubicin Hydrochloride			S	Intravenous drip		3 DAY	Not Reported
	Amsidyl			S	Intravenous drip			Not Reported
	Famvir			S	Oral		8 DAY	Not Reported
	Cancidas			S	Oral		6 DAY	Not Reported
	Motilium			C	Sublingual		10 DAY	Not Reported
	Motilium			C	Sublingual		10 DAY	Not Reported
	Piperacillin And Tazobactam			C			12 DAY	Not Reported
	Metoclopramide Hydrochloride			C	Oral		35 DAY	Not Reported
	Metoclopramide Hydrochloride			C	Oral		35 DAY	Not Reported
	Nexium			C	Oral			Not Reported
	Nexium			C	Oral			Not Reported
	Perfalgan			C	Intravenous bolus		50 DAY	Not Reported
	Stilnox			C	Oral		50 DAY	Not Reported
	Buscopan			C	Oral		50 DAY	Not Reported
	Primolut N			C	Oral	One Per Four Days		Not Reported
	Dexamethasone			C	Oral		0 MTH	Not Reported
	Vfend			C	Oral	One Per Two Days	9 DAY	Not Reported
	Flagyl			C			24 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2011	8087096	EXPEDITED (15-DAY)	Y	RI, OT	1000022484		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Lexapro			S	Oral	10 Mg (10 M, 1 In 1 D), Oral; 10 Mg Bid (10 Mg, 2 In 1 D), Oral		Not Reported
	Loratadine (Loratadine) (Loratadine)			C				Not Reported
	Acetaminophen\Hydrocodone Bitartrate			C				Not Reported
	Zanaflex (Tizanidine Hydrochloride) (Tizanidine Hydrochloride)			C				Not Reported
	Motrin			C				Not Reported
	Methocarbamol (Methocarbamol) (Methacarbamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2011	8087811	EXPEDITED (15-DAY)	Y	RI, OT	1000022540		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Vertigo; Vomiting	Escitalopram Oxalate			S	Oral	1 Df (1 Dosage Forms, 1in 1 D), Oral		Not Reported
	Tegretol (Carbamazepine)(Tablets)(Carbamazepine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2011	8088804	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2011SA048936		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Vertigo	Furosemide			S	Oral			Not Reported
	Isosorbide Dinitrate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Trimetazidine Dihydrochloride			S	Oral			Not Reported

	Tramadol Hydrochloride	S	Oral	Not Reported
	Nitroderm	S	Transdermal	Not Reported
	Fenoterol Hydrobromide\Ipratropium Bromide	C	Unknown	Not Reported
	Dafalgan	C	Unknown	Not Reported
	Bromazepam	C	Unknown	Not Reported
	Fluticasone Propionate\Salmeterol Xinafoate	C	Unknown	Not Reported
	Trimebutine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2011	8144787	EXPEDITED (15-DAY)	N	RI, OT	1000023211		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Akathisia; Anxiety; Balance Disorder; Brain Injury; Burning Sensation; Depression; Derealisation; Dizziness; Emotional Disorder; Fear; Feeling Abnormal; Food Intolerance; Hallucination; Hallucination, Visual; Headache; Hypersensitivity; Influenza; Influenza Like Illness; Insomnia; Mania; Memory Impairment; Nausea; Night Blindness; Nightmare; Panic Attack; Paraesthesia; Screaming; Serotonin Syndrome; Tachyphrenia; Tinnitus; Tremor; Unevaluable Event; Violence-Related Symptom; Visual Impairment; Vitamin A	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2011	8145503	EXPEDITED (15-DAY)	Y	RI, OT	1000023474		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Menstrual Disorder; Metrorrhagia; Nausea	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2011	8130123	EXPEDITED (15-DAY)	Y	OT	FR-JNJFOC-20110901262		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Miosis; Overdose; Somnolence	Durogesic			S	Transdermal		4 DAY	Not Reported
	Morphine Sulfate			S	Oral		4 DAY	Not Reported
	Morphine Sulfate			S	Oral		4 DAY	Not Reported
	Xanax			S	Oral		4 DAY	Not Reported
	Escitalopram Oxalate			S	Oral		4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2011	8134551	EXPEDITED (15-DAY)	Y	HO	FR-MYLANLABS-2011S1018633		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Amitriptyline			S	Unknown			Not Reported
	Altizide			S	Unknown	Long Term		Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2011	8151999	EXPEDITED (15-DAY)	Y	RI, OT	1000023637		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Loss Of	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),		Not Reported

Consciousness | | | | | | | | | | Oral

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2011	8154138	EXPEDITED (15-DAY)	Y	LT	1000023645		87 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Interaction; Miosis; Respiratory Distress; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Morphine Sulfate			S	Oral	6 Df (1 Dosage Forms, 6 In 1 D), Oral		Not Reported
	Durogesic			S		0.3333 Df (1 Dosage Forms, 1 In 3 D), Other		Not Reported
	Xanax			S		(1 Dosage Forms, 3 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2011	8162872	EXPEDITED (15-DAY)	Y	HO	1000023640		99 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Fall; Skin Abrasion	Escitalopram Oxalate			S		1 In 1 D		Not Reported
	Aceprometazine\Meprobamate			S	Oral	1 Df (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Cyamemazine			S	Oral	6 Mg (6 Mg, 1 In 1 D), Oral		Not Reported
	Doliprane (Paracetamol) (Tablets) (Paracetamol)			C				Not Reported
	Ceris (Trospium Chloride) (Tablets) (Trospium Chloride)			C				Not Reported
	Lipanthyl (Fenofibrate) (Fenofibrate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2011	8155434	EXPEDITED (15-DAY)	Y	HO	1000023730			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Night Sweats; Pyrexia; Rash; Tremor	Lexapro	S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2011	8046573	EXPEDITED (15-DAY)	Y	HO	1000021902		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Apraxia; Coagulopathy; Confusional State; Coordination Abnormal; Cytarabine Syndrome; Dizziness; Febrile Neutropenia; Hepatic Enzyme Increased; Hepatocellular Injury; Hyperreflexia; International Normalised Ratio Decreased; Myalgia; Nausea; Nervous System Disorder; Rash; Rhabdomyolysis; Serotonin Syndrome; Sleep Disorder; Toxicity To Various Agents; Tremor; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Cytosar-U			S	Intravenous (not otherwise specified)	2000 Mg/M2 (1000 Mg/M2, 2 In 1 D), Intravenous (Not Otherwise Specified)		Not Reported
					Intravenous (not otherwise specified)	2000 Mg/M2 (1000 Mg/M2, 2 In 1 D), Intravenous (Not Otherwise Specified)		
	Idarubicin Hydrochloride			S	Intravenous (not otherwise specified)	12 M/M2 (12 Mg/M2, 1 In 1 D), Intravenous (Not Otherwise Specified)		Not Reported
	Amsidyl			S		120 Mg/M2 (120 Mg/M2, 1 In 1 D)		Not Reported
	Famvir			S	Oral	1000 Mg (500 Mg, 2 In 1 D), Oral		Not Reported
	Cancidas			S	Oral	70 Mg (70 Mg, 1 In 1 D), Oral		Not Reported
	Meropenem			S	Intravenous (not otherwise specified)	3 Gm (1 Gm, 3 In 1 D), Intravenous		Not Reported
	Motilium (Domperidone) (Tablets) (Domperidone)			C				Not Reported
	Tazobac (Pip/Tazo)-(Pip/Tazo)			C				Not Reported
	Paspertin (Metoclopramide Hydrochloride) (Tablets) (Metoclopramide Hydrochloride)			C				Not Reported
	Nexium (Esomerazole Magnesium) (Tablets) (Esomeprazole Magnesium)			C				Not Reported

Perfalgan	C		Not Reported
Stilnox (Zolpidem Tartrate) (Zolpidem Tartrate)	C		Not Reported
Buscopan (Hyoscine Butylbromide) (Hyoscine Butylbromide)	C		Not Reported
Primolut N (Norethisterone) (Norethisterone)	C		Not Reported
Dexamethason (Dexamethasone) (Dexamethasone)	C		Not Reported
Vfend	C		Not Reported
Flagyl (Metronidazole) (Metronidazole)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2011	8056540	EXPEDITED (15-DAY)	Y	RI, OT	1000022065		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Detensiel (Bisoprolol) (Bisoprolol)			C				Not Reported
	Exforge (Diovan Amlo) (Diovain Amlo)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2011	8159960	EXPEDITED (15-DAY)	N	RI, OT	1000023731			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Decreased Appetite; Drug Withdrawal Syndrome; Nausea; Nocturnal Fear; Suicidal Ideation; Tachycardia	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2011	8128866	EXPEDITED (15-DAY)	Y	HO, LT	CH-JNJFOC-20110812898		75 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Tramadol Hydrochloride			S	Oral	10 X 100 Mg		Not Reported
	Motilium			S	Unknown	6 X 10 Mg		Not Reported
	Motilium			S	Unknown	10 Mg Three Times A Day (1-1-1-0)		Not Reported
	Dafalgan			S	Oral	1 G 4 Times A Day (1-1-1-1)		Not Reported
	Dafalgan			S	Oral	32 G		Not Reported
	Atenolol\Nifedipine			S	Unknown	50/25 Once A Day (1-0-0-0)		Not Reported
	Atenolol\Nifedipine			S	Unknown	2 X 50/25		Not Reported
	Atorvastatin			S	Unknown	2 X 20 Mg		Not Reported
	Atorvastatin			S	Unknown	20 Mg Once A Day (0-0-1-0)		Not Reported
	Levothyroxine Sodium			S	Unknown	0.1 Mg Once A Day (1-0-0-0)		Not Reported
	Levothyroxine Sodium			S	Unknown	2 X 0.1 Mg		Not Reported
	Hydrochlorothiazide W/Irbesartan			S	Unknown	2 X 150/12.5		Not Reported
	Hydrochlorothiazide W/Irbesartan			S	Unknown	150/12.5 1/2 Per Day (1/2-0-0-0)		Not Reported
	Calcium Carbonate\Cholecalciferol			S	Unknown	4 Doses At A Time		Not Reported
	Calcium Carbonate\Cholecalciferol			S	Unknown	Twice A Day (1-1-0-0)		Not Reported
	Remeron			S	Unknown	15 Mg Once A Day (0-0-0-1)		Not Reported
	Remeron			S	Unknown	2 X 15 Mg		Not Reported
	Cipralex			S	Unknown	2 X 20 Mg		Not Reported
	Cipralex			S	Unknown	20 Mg (1-0-0-0)		Not Reported

Oxycontin	S	Unknown	10 Mg (1-0-0-2)		Not Reported
Oxycontin	S	Unknown	2 * 30 Mg		Not Reported
Xarelto	C	Oral	10 X 10 Mg		Not Reported
Xarelto	C	Oral	10 Mg Once A Day (0-0-1-0)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2011	8133985	EXPEDITED (15-DAY)	Y	HO, LT	1000023159		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilic Pneumonia; Rhinitis; Severe Acute Respiratory Syndrome	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
	Depakote			S	Oral	(750 Mg), Oral		Not Reported
	Zolpidem Tartrate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Ferrous Sulfate			S	Oral	Oral		Not Reported
	Xanax			S	Oral	Oral		Not Reported
	Levonorgestrel And Ethinyl Estradiol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2011	8144849	EXPEDITED (15-DAY)	N	RI, OT	1000023431		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcoholism; Apathy; Condition Aggravated; Depression; Hallucination; Insomnia; Mania; Nausea; Paranoia; Sexually Inappropriate Behaviour; Suicidal Ideation; Vomiting	Escitalopram Oxalate			S	Oral	Daily Dose Not Reported (20 Mg), Oral		Not Reported
	Clonazepam (Clonazepam) (Tablets) (Clonazepam)			C				Not Reported
	Cymbalta			C				Not Reported
	Topamax (Topiramate) (Topiramate)			C				Not Reported
	Lithium			C				Not Reported
	Risperdal			C				Not Reported
	Pantoprazole (Pantoprazole) (Tablets) (Pantoprazole)			C				Not Reported

	Pms-Procyclidine (Procyclidine)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2011	7201902	EXPEDITED (15-DAY)	Y	HO	1000010156		85 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Confusional State; Partial Seizures; Seizure; Status Epilepticus; Suicidal Ideation	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Exelon			S	Transdermal	9.5 Mg (9.5 Mg, 1 In 24 Hr), Trandermal		Not Reported
	Exelon			S	Transdermal	4.5 Mg (4.5 Mg, 1 In 1 D), Transdermal 4.6 Mg (4.6 Mg, 1 In 1 D), Transdermal		Not Reported
	Spironolactone			C				Not Reported
	Ginkor(Ginko Biloba, Troxirutin, Heptaminol)			C				Not Reported
	Meteospasmyl (Alverine Citrate, Simeticone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2011	8141289	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-47698		38 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Hydrocodone Bitartrate And Acetaminophen			S	Oral	Unk, Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral	Unk,Unk		Not Reported
	Clonazepam			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2011	8141875	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-47816		55 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Acetaminophen\Codeine Phosphate		S	Oral	Unk, Unk	Ranbaxy
	Hydrocodone Bitartrate And Acetaminophen		S	Oral	Unk	Ranbaxy
	Escitalopram Oxalate		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2011	8142240	EXPEDITED (15-DAY)	Y	HO	CH-JNJFOC-20110903406		46 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Hypertensive Heart Disease	Invega			S	Oral			Not Reported
	Pipamperone			S	Unknown			Not Reported
	Antabuse			S	Unknown			Not Reported
	Unspecified Ingredient			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2011	8144062	DIRECT	N	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Glucose Increased; Depression; Hypertension	Lexapro			S	Oral	10mg Or 5mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2011	7969782	EXPEDITED (15-DAY)	Y	HO	CH-MERCK-1105USA03810		20 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Metabolic Acidosis; Suicide Attempt	Janumet			S	Oral		1 DAY	Merck
	Cipralex			S	Unknown			Not Reported
	Amisulpride			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2011	8024804	EXPEDITED (15-DAY)	Y	HO	1000021650		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Papilloedema; Visual Acuity Reduced	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2011	8136179	EXPEDITED (15-DAY)	Y	DE	IT-ABBOTT-11P-083-0852392-00		64 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Depakene			S		Overdose: Unknown		Not Reported
	Cipralex			S		Overdose: Unknown		Not Reported
	Mirtazapine			S		Overdose: Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2011	8145608	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-47852		58 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lorazepam			S	Oral	Unk, Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral	Unk, Unk		Not Reported
	Valproic Acid			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2011	6766901	NON-EXPEDITED	Y	OT	US-ASTRAZENECA-2006UW27731		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Diabetes Mellitus; Erectile Dysfunction; Haemoglobin	Seroquel			S	Oral	25 Mg-200 Mg, 200 Mg 3 Pills A Day.		Not Reported
	Seroquel			S	Oral	25 Mg-200 Mg, 200 Mg 3		Not Reported

Decreased; Hypertriglyceridaemia; Liver Function Test Abnormal; Weight Increased				Pills A Day.		
	Seroquel	S	Oral	25 Mg-200 Mg, 200 Mg 3 Pills A Day.		Not Reported
	Seroquel	S	Oral	100 Mg-400 Mg	774 DAY	Not Reported
	Seroquel	S	Oral	100 Mg-400 Mg	774 DAY	Not Reported
	Seroquel	S	Oral	100 Mg-400 Mg	774 DAY	Not Reported
	Lexapro	S	Unknown			Not Reported
	Geodon	C	Oral		256 DAY	Not Reported
	Imipramine	C	Oral		4 MTH	Not Reported
	Invega	C			9 MTH	Not Reported
	Abilify	C			32 DAY	Not Reported
	Neurontin	C		300 Mg- 1800 Mg		Not Reported
	Vitamin E	C				Not Reported
	Clonazepam	C				Not Reported
	Nexium	C				Not Reported
	Trazodone Hydrochloride	C				Not Reported
	Paxil	C		20 Mg-40 Mg		Not Reported
	Remeron	C				Not Reported
	Viagra	C				Not Reported
	Niaspan	C				Not Reported
	Ranitidine	C				Not Reported
	Lipitor	C				Not Reported
	Androgel	C				Not Reported
	Ciprofloxacin	C				Not Reported
	Diovan	C				Not Reported
	Avandamet	C				Not Reported
	Topamax	C				Not Reported
	Protonix	C	Oral			Not Reported
	Risperdal	C	Oral	1 Mg - 3 Mg		Not Reported
	Klonopin	C		2 Mg 1 Bid 1 And 1/2 Hs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2011	8147310	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-48168		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxcarbazepine			S	Oral	Unk, Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral	Unk, Unk		Not Reported
	Bupropion			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2011	8148323	NON-EXPEDITED	N		US-ASTRAZENECA-2011SE09048			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive	Seroquel			S	Oral			Zeneca
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2011	8149084	NON-EXPEDITED	N		US-ASTRAZENECA-2011SE35740			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Decreased Appetite; Depression; Panic Attack; Phobia	Seroquel			S	Oral			Zeneca
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2011	8150101	NON-EXPEDITED	Y		US-ASTRAZENECA-2011SE12408		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Fatigue; Somnolence	Seroquel Xr			S	Oral		1 DAY	Astrazeneca
	Seroquel Xr			S	Oral		1 DAY	Astrazeneca
	Seroquel Xr			S	Oral		3 DAY	Astrazeneca
	Seroquel Xr			S	Oral		3 DAY	Astrazeneca
	Seroquel Xr			S	Oral			Astrazeneca
	Seroquel Xr			S	Oral			Astrazeneca

Lexapro	S	Oral		1 DAY	Not Reported
Lexapro	S	Oral		1 DAY	Not Reported
Lexapro	S	Oral			Not Reported
Lexapro	S	Oral			Not Reported
Xanax	C	Oral	Three Tablets A Day		Not Reported
Adderall	C	Oral	Two Tablets A Day		Not Reported
Vicodin Hp	C	Oral	10/660mg As Required		Not Reported
Depo-Provera	C	Intramuscular	One In Three Months		Not Reported
Methadone Hydrochloride	C	Oral			Not Reported
Motrin	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2011	8150707	NON-EXPEDITED	N		US-ASTRAZENECA-2010SE57629		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Dry Mouth; Dysuria; Vision Blurred	Seroquel			S	Oral			Zeneca
	Toviaz			S	Oral		5 DAY	Not Reported
	Xanax			S	Unknown			Not Reported
	Zocor			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Fish Oil			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Vitamin D2			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2011	8150825	NON-EXPEDITED	N	OT	US-ASTRAZENECA-2011SE41665		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca

	Ativan	S	Unknown	Not Reported
	Lexapro	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2011	8150967	NON-EXPEDITED	N	OT	US-ASTRAZENECA-2011SE06856			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral; Overdose; Swelling Face	Seroquel			S	Oral			Zeneca
	Miralax			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Neurontin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2011	8151387	NON-EXPEDITED		HO	US-ASTRAZENECA-2010SE59766		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Suicide Attempt	Seroquel Xr			S	Oral		31 DAY	Not Reported
	Lexapro			S	Unknown			Not Reported
	Xanax			S	Unknown			Not Reported
	Lisinopril			C	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported
	Oxycodone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2011	8151740	NON-EXPEDITED	N		US-ASTRAZENECA-2010SE38417		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction	Seroquel			S	Oral			Zeneca
	Doxepin			C				Not Reported

	Vitamin B12	C				Not Reported
	Colace	C				Not Reported
	Simethicone	C				Not Reported
	Lamictal	C				Not Reported
	Risperdal	C				Not Reported
	Gemfibrozil	C				Not Reported
	Aciphex	C				Not Reported
	Lexapro	S	Oral		4 DAY	Not Reported
	Lexapro	S	Oral			Not Reported
	Ativan	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2011	8157992	DIRECT	Y	CA, DS, HO			< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bicuspid Aortic Valve; Craniosynostosis; Dilatation Ventricular; Maternal Drugs Affecting Foetus	Lexapro			S	Oral	10mg 1 Po Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2011	7899008	EXPEDITED (15-DAY)	Y	RI, OT	1000019311		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infertility Male; Miscarriage Of Partner; Sperm Concentration Decreased; Spermatozoa Morphology Abnormal; Spermatozoa Progressive Motility Decreased	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Alprazolarm (Alprazolam) (Alprazolam)			C				Not Reported
	Zopiclone (Zopiclone) (Zopiclone)			C				Not Reported
	Pravastatine (Pravastatine) (Pravastatine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2011	8084511	EXPEDITED (15-DAY)	Y	DE, HO	1000022513		70 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Hypertension	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Simvastatin (Simvastatin) (Tablets) (Simvastatin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2011	8153371	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-48009		41 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Zolpidem Tartrate			S	Oral	Unk,Unk		Ranbaxy
	Atenolol			S	Oral	Unk,Unk		Ipca
	Escitalopram Oxalate			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2011	8153434	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-47954		39 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Topiramate			S	Oral	Unk, Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral	Unk, Unk		Not Reported
	Bupropion			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2011	8170165	EXPEDITED (15-DAY)	N	HO	1000024018		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Fatigue; Gastrointestinal Haemorrhage; Haemoglobin Decreased; Poor Quality Sleep	Lexapro			S	Oral Oral	5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

	Proscar	C	Not Reported
	Ferrous Sulfate	C	Not Reported
	Nexium (Esomeprazole)	C	Not Reported
	Stool Softener (Docusate Sodium)	C	Not Reported
	Centrum Silver Multivitamin	C	Not Reported
	Lisinopril	C	Not Reported
	Simvastatin	C	Not Reported
	Norvasc	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2011	8171029	EXPEDITED (15-DAY)	Y	HO	1000023881		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose	Escitalopram Oxalate			S	Oral	Oral; 30 Dosage Forms, Once, Oral		Not Reported
	Lorazepam			S	Oral	Oral; Oral		Not Reported
	Lorazepam			S	Oral	Oral; Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2011	8119449	EXPEDITED (15-DAY)	N	RI, OT	1000023023		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Articular Calcification; Cholelithiasis; Decreased Appetite; Fatigue; Nephrolithiasis; Photosensitivity Reaction; Polymyalgia Rheumatica; Weight Increased	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2011	8155412	EXPEDITED (15-DAY)	Y	HO	DK-MYLANLABS-2011S1019438			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coma; Intentional Overdose; Respiratory Rate Decreased; Seizure; Sinus Bradycardia; Suicide Attempt	Escitalopram Oxalate		S	160 Mg	Not Reported
	Baclofen		S	1850mg	Not Reported
	Baclofen		S	1850mg	Not Reported
	Baclofen		S	Up To 2500mg	Not Reported
	Baclofen		S	Up To 2500mg	Not Reported
	Mirtazapine		S	230 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2011	8155622	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-AUR-APL-2009-00008		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Cardiotoxicity; Coma; Hypotension; Overdose; Pulseless Electrical Activity; Respiratory Arrest; Seizure; Ventricular Arrhythmia; Ventricular Tachycardia	Citalopram			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Quinapril Hcl			S				Pfizer
	Venlafaxine Hcl			S				Pfizer
	Atenolol			S				Not Reported
	Enalapril			S				Not Reported
	Amitriptyline			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2011	8171229	EXPEDITED (15-DAY)	Y	HO	IMP_05435_2011			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma Scale Abnormal; Continuous Haemodiafiltration; Hypotonia; Loss Of Consciousness; Miosis; Overdose; Respiratory Acidosis; Respiratory Depression; Seizure; Sinus Bradycardia; Snoring; Toxicity To Various Agents	Baclofen			S		(1850 Mg, Once) ; (2500 Mg, Once) (1850 Mg, Once) ; (2500 Mg, Once)		Not Reported
	Mirtazapine (Mirtazapine)			S		(230 Mg, Once)		Not Reported
	Escitalopram Oxalate			S		(160 Mg, Once)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2011	8171488	EXPEDITED (15-DAY)	Y	RI, OT	1000023962			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dependent Personality Disorder; Depressed Mood; Hyperventilation; Listless; Panic Attack; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2011	8171491	EXPEDITED (15-DAY)	Y	RI, OT	1000023900		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ecchymosis; Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Rivotril (Clonazepam) (Clonazepam)			C				Not Reported
	Losartic (Losartan Potassium) (Losartan Potassium)			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Lacipil (Lacidipine) (Lacidipine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2011	8008831	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000021418		20 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Increased; Continuous Haemodiafiltration; Intentional Overdose; Metabolic Acidosis;	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Janumet			S	Oral	Overdose: 180 Tabs Once, Oral		Not Reported

Suicide Attempt; Vomiting	Solian (Amisulpride)(Amisulpride)	C		Not Reported
	Temesta (Lorazepam)(Lorazepam)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2011	8137119	EXPEDITED (15-DAY)	Y	HO	1000023270		91 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hyponatraemia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Coaprovel (Irbesartan, Hydrochlorothiazide)(Irbesartan, Hydrochlorothiazide)			C				Not Reported
	Lercan (Lercanidipine Hydrochloride) (Lercanidipine Hydrochloride)			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2011	8158152	NON-EXPEDITED			US-PFIZER INC-2011224017		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Penicillin G Benzathine/Penicillin G Procaine			S		Unk		Unknown
	Dilantin			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Lidocaine Hcl			S		Unk		Pfizer
	Baclofen			S		Unk		Not Reported
	Acetylsalicylic Acid			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Toradol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2011	8161270	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2011-05010		64 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Level Increased; Intentional Overdose; Toxicologic Test Abnormal	Mirtazapine (Mirtazapine)			S		(30 Mg)		Not Reported
	Escitalopram Oxalate			S		(10 Mg)		Not Reported
	Valproic Acid			S		(300 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2011	8160542	EXPEDITED (15-DAY)	Y	DE, OT	FR-SANOFI-AVENTIS-2011SA058947			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Irbesartan			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Telmisartan			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Paclitaxel			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Nitrendipine			S	Unknown			Not Reported
	Etoposide			S	Unknown			Not Reported
	Chlorpromazine			S	Unknown			Not Reported
	Metopimazine			S	Unknown			Not Reported
	Spironolactone			S	Unknown			Not Reported
	Glyceryl Trinitrate			S	Unknown			Not Reported
	Acebutolol Hydrochloride			S	Unknown			Not Reported
	Losartan Potassium			S	Unknown			Not Reported

Carbamazepine	S	Unknown	Not Reported
Furosemide	S	Unknown	Not Reported
Sertraline Hydrochloride	S	Unknown	Not Reported
Paroxetine Hydrochloride	S	Unknown	Not Reported
Escitalopram Oxalate	S	Unknown	Not Reported
Fluoxetine	S	Unknown	Not Reported
Omeprazole	S	Unknown	Not Reported
Oxcarbazepine	S	Unknown	Not Reported
Indapamide	S	Unknown	Not Reported
Rabeprazole Sodium	S	Unknown	Not Reported
Desmopressin Acetate	S	Unknown	Not Reported
Ramipril	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2011	8170879	EXPEDITED (15-DAY)	Y	RI, OT	1000024146			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2011	8162343	EXPEDITED (15-DAY)	N	OT	GXBR2011US04775		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Intervertebral Disc Compression; Intervertebral Disc Disorder; Transient Ischaemic Attack; Vitreous Floaters	Loratadine			S	Oral	10 Mg, Qd		Novartis
	Lexapro			S		5 Mg, Unk		Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2011	8176244	EXPEDITED (15-DAY)	Y	HO, OT	AUR-APL-2009-00008		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anoxia; Balance Disorder; Bradycardia; Cardiac Arrest; Cardiogenic Shock; Cardiotoxicity; Coma; Confusional State; General Physical Health Deterioration; Hypotension; Ischaemia; Left Ventricular Hypertrophy; Overdose; Poor Peripheral Circulation; Pulmonary Embolism; Pulseless Electrical Activity; Respiratory Arrest; Rhythm Idioventricular; Seizure; Urine Output Decreased; Ventricular Tachycardia	Atenolol (Atenolol)			S	Oral	Oral		Not Reported
	Citalopram Hydrobromide			S	Oral	Oral		Not Reported
	Venlafaxine			S	Oral	Oral		Not Reported
	Enalapril			S	Oral	Oral		Not Reported
	Amitriptyline Hydrochloride			S	Oral	Oral		Not Reported
	Quinapril Hydrochloride			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2011	8176590	EXPEDITED (15-DAY)	Y	HO, OT	AUR-APL-2009-00147		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Bradycardia; Cardiac Arrest; Cardiogenic Shock; Coma; Confusional State; Hypotension; Hypoxic-Ischaemic Encephalopathy; Mydriasis; Overdose; Pulseless Electrical Activity; Respiratory Arrest; Rhythm Idioventricular; Seizure; Toxicity To Various Agents; Unresponsive To	Atenolol (Atenolol)			S				Not Reported
	Citalopram Hydrobromide			S				Not Reported
	Venlafaxine			S				Not Reported
	Enalapril			S				Not Reported
	Amitriptyline Hydrochloride			S				Not Reported
	Quinapril Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

Stimuli; Ventricular Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2011	8170974	DIRECT	Y	CA, DS, HO			< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bicuspid Aortic Valve; Craniosynostosis; Left Ventricular Hypertrophy; Maternal Drugs Affecting Foetus	Lexapro			S	Oral	Lexapro 10mg 1 Po Daily 2004 Or 5 - 2009		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2011	8748963	DIRECT	N	DE, OT			35 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Sudden Infant Death Syndrome	Lexapro			S				Forest
	Lamictal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2011	8166053	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2011SE57655		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Fall; Hyponatraemia	Inexium			S	Oral			Astrazeneca
	Inexium			S	Oral			Astrazeneca
	Escitalopram Oxalate			S	Oral		12 DAY	Not Reported
	Zolpidem			S	Oral		12 DAY	Not Reported
	Prazepam			S	Oral			Not Reported
	Prazepam			S	Oral		12 DAY	Not Reported
	Tramadol Hydrochloride And Acetaminophen			S	Oral			Not Reported

	Gaviscon	S	Oral		Not Reported
	Debridat	C			Not Reported
	Spiriva	C			Not Reported
	Becotide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2011	8749569	DIRECT	Y	HO, LT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Escitalopram Oxalate			S	Oral	20 Mg Every Morning Po		Not Reported
	Valproate Sodium			S	Oral	500 Mg Tid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2011	8060637	EXPEDITED (15-DAY)	Y	HO, LT	1000022127		34 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Aggression; Anxiety; Dyspnoea; Epilepsy; Muscle Rigidity; Mydriasis; Trismus	Escitalopram Oxalate			S	Oral	10 Mg(10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2011	8166466	EXPEDITED (15-DAY)	Y	RI, OT	1000023779		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Overdose; Panic Attack	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D); 30 Mg (30 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2011	8182639	EXPEDITED (15-DAY)	Y	RI, OT	1000024244		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Drug Interaction; Fatigue; Fungal Infection; Mania; Palpitations	Lexapro	S	Oral	10 Mg (10 Mg,1 In 1 D),Oral	Not Reported
	Lexapro	S	Oral	20 Mg (20 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral	Not Reported
			Oral	20 Mg (20 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral	
	Fluconazole	S	Oral	Daily (1 In 1 D),Oral	Not Reported
	Deplin (Calcium Levomefolate) (Calcium Levomefolate)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2011	8184248	EXPEDITED (15-DAY)	Y	HO	1000024313			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Methadone Hydrochloride			S		180 Mg		Not Reported
	Quetiapine Fumarate			S	Oral	50 Mg, Oral		Not Reported
	Creon			C				Not Reported
	Esomeprazole Magnesium Trihydrate (Esomeprazole Magnesium) (Esomeprazole Magnesium)			C				Not Reported
	Vitaminorum B.P.C. (Kapsovit) (Kapsovit)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2011	8184283	EXPEDITED (15-DAY)	Y	HO	1000024341		74 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Contusion; Electrocardiogram Qt Prolonged; Fall	Lexapro			S		10 Mg (1 Time)		Not Reported
	Atenolol (Atenolol)			S	Oral	50 Mg (1 Time),Oral		Not Reported

	Aspirin	S	150 Mg (1 Time)		Not Reported
	Atorvastatin Calcium	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2011	6994733	EXPEDITED (15-DAY)	Y	DE	1000005980		7 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Completed Suicide; Impulsive Behaviour	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Symbyax			S		3mg/25mg (1 In 1 D),		Not Reported
	Vyvanse			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral; 50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported
					Oral	30 Mg (30 Mg, 1 In 1 D), Oral; 50 Mg (50 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2011	8170476	EXPEDITED (15-DAY)	Y	HO, LT, OT	AT-PFIZER INC-2011234765		30 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Triglycerides Increased; Depression; Gambling Disorder; Post-Traumatic Stress Disorder; Weight Increased	Effexor Xr			S	Oral	225 Mg, 1x/Day		Pfizer
	Cipralex			S	Oral	20 Mg, 1x/Day		Not Reported
	Seroquel			S	Oral	50 Mg, 1x/Day		Not Reported
	Prothipendyl			S	Oral	80 Mg, 1x/Day		Not Reported
	Abilify			C	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2011	8170659	EXPEDITED (15-DAY)	Y	OT	GXKR2011DE02966			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed; Maternal Exposure During Pregnancy	Trazodone Hydrochloride			S	Oral	12.5 Mg/Day		Novartis
	Cipralex			S	Oral	5 Mg/Day		Not Reported

	Folic Acid	C	Oral	0.8 Mg/Day	Not Reported
	Levothyroxine Sodium	C	Oral	137.5 Mg/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2011	8184729	EXPEDITED (15-DAY)	Y	DE	1000024359		81 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haematoma; Depressed Level Of Consciousness; Hemiplegia; Hypertension	Escitalopram Oxalate			S				Not Reported
	Coumadin			S	Oral	0.5 Df In Morning And 0.25 Df Alternately, Oral		Not Reported
	Ciprofibrate			S				Not Reported
	Digoxin			S				Not Reported
	Cardensiel (Bisoprolol Fumarate) (Bisoprolol Fumarate)			C				Not Reported
	Stablon (Tianeptine Sodium) (Tianeptine Sodium)			C				Not Reported
	Monotildiem (Diltiazem Hydrochloride) (Diltiazem)			C				Not Reported
	Modopar (Madopar) (Madopar)			C				Not Reported
	Diffu K (Potassium Chloride) (Potassium Chloride)			C				Not Reported
	Exelon (Rivastigmine) (Rivastigmine)			C				Not Reported
	Lioresal			C				Not Reported
	Mepronizine (Clindorm) (Clindorm)			C				Not Reported
	Mianserine (Mianserin Hydrochloride) (Mianserin Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2011	8184866	EXPEDITED (15-DAY)	Y	RI, OT	1000024338		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2011	8187484	EXPEDITED (15-DAY)	Y	OT	2011AP002179		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Gastrooesophageal Reflux Disease; Headache; Nausea; Salivary Hypersecretion	Citalopram Hydrobromide			S		10 Mg;Am;		Not Reported
	Escitalopram Oxalate			S		10 Mg;Am		Not Reported
	Vitamins With Minerals			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2011	7596043	EXPEDITED (15-DAY)	Y	RI, OT	1000016080			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Feeling Abnormal; Joint Lock; Serotonin Syndrome	Lexapro			S	Oral	Oral		Not Reported
	Zoloft			S				Not Reported
	Wellbutrin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2011	8160545	EXPEDITED (15-DAY)	Y		US-PURDUE-USA-2010-0048602		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Energy Increased; Inadequate Analgesia; Product Formulation Issue	Oxycontin			S		80 Mg, Q8h		Purdue
	Lexapro			S	Oral	10 Mg, Unk	11 DAY	Not Reported
	Zoloft			S	Oral	100 Mg, Unk	38 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2011	8172266	EXPEDITED (15-DAY)	N	DE, HO	FR-BRISTOL-MYERS SQUIBB COMPANY-16099350		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Blood	Coumadin			S		Coumadine 2 Mg, 0.5		Bristol Myers Squibb

Pressure Increased; Cerebellar Haematoma; Hemiplegia				Tablet Alternating With 0.25 Tablet Each Morning For Several Months	
	Escitalopram Oxalate	S	Oral		Not Reported
	Ciprofibrate	S	Oral		Not Reported
	Digoxin	S	Oral		Not Reported
	Mono-Tildiem	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Tianeptine	C			Not Reported
	Modopar	C			Not Reported
	Potassium Chloride	C			Not Reported
	Exelon	C			Not Reported
	Lioresal	C			Not Reported
	Meprobamate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2011	8186287	EXPEDITED (15-DAY)	N	CA	1000024402		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cardiac Murmur; Maternal Drugs Affecting Foetus; Patent Ductus Arteriosus; Ventricular Septal Defect	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2011	8173663	EXPEDITED (15-DAY)	Y	HO, OT	AT-PFIZER INC-2011235925		69 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Depression; Fall; Generalised Anxiety Disorder	Lyrica			S		Unk		Pfizer
	Cipralex			S		10-20 Mg Daily	36 DAY	Not Reported
	Trazodone Hydrochloride			S		100-150 Mg Daily	34 DAY	Not Reported
	Oxazepam			S		45-75 Mg Daily		Not Reported
	Mirtazapine			S		15mg Daily	2 DAY	Not Reported

Mirtazapine	S	30 Mg, Unk	7 DAY		Not Reported
Tenormin	C	50 Mg Daily			Not Reported
Pantoloc	C	40 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2011	7583384	EXPEDITED (15-DAY)	Y	RI, OT	1000015970		39 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Disturbance In Attention; Drooling; Fatigue; Feeling Of Despair; Feelings Of Worthlessness; Headache; Ischaemic Stroke; Speech Disorder; Supranuclear Palsy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2011	7877888	EXPEDITED (15-DAY)	Y	DE	1000019122		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D) Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2011	8168839	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20111000795		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Fall; Hyponatraemia	Tramadol Hydrochloride And Acetaminophen			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Prazepam			S	Oral			Not Reported

	Prazepam	S	Oral	Not Reported
	Inexium	S	Oral	Not Reported
	Inexium	S	Oral	Not Reported
	Gaviscon	S	Oral	Not Reported
	Gaviscon	S	Oral	Not Reported
	Debridat	C	Unknown	Not Reported
	Spiriva	C	Unknown	Not Reported
	Becotide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2011	8175876	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-16114514		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Glucose Increased; Fall; Hallucination; Musculoskeletal Chest Pain; Nausea	Glucophage			S			4 YR	Bristol Myers Squibb
	Lexapro			S				Not Reported
	Wellbutrin			C				Not Reported
	Xanax			C				Not Reported
	Fentanyl Patch			C		Started 5yrs Ago		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2011	8176229	EXPEDITED (15-DAY)		HO, OT	TR-PFIZER INC-2011235597		53 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Major Depression; Suicidal Behaviour	Escitalopram Oxalate			S		10 Mg, A Day		Not Reported
	Escitalopram Oxalate			S		20 Mg, A Day		Not Reported
	Alprazolam			S				Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2011	8176399	EXPEDITED (15-DAY)	Y	DE	TR-ASTRAZENECA-2011SE60399		50 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Failure	Arimidex		S	Oral	Zeneca
	Nexium		S	Oral	Not Reported
	Cipralex		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2011	8189188	EXPEDITED (15-DAY)	Y	HO	1000024478		45 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hepatitis; Incorrect Dose Administered; Pneumonia Aspiration; Prothrombin Time Prolonged; Psychomotor Retardation; Somnolence	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D) Oral		Not Reported
	Cyamemazine			S	Oral	100 Mg (25 Mg, 4 In 1 D), One Intake Of 105 Df, Oral		Not Reported
	Bromazepam			S	Oral	2 Df (0.5 Dosage Forms, 4 In 1 D), One Intake Of 30 Df, Oral		Not Reported
	Subutex (Buprfenorphine Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2011	8189238	EXPEDITED (15-DAY)	Y	RI, OT	1000024472		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Memory Impairment	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2011	8190109	EXPEDITED (15-DAY)	Y	OT	DSA_47766_2011		32 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Fear; Impaired Work Ability; Loss Of Personal Independence In Daily	Venlafaxine			S		(75 Mg Daily),(150 Mg Daily), (75 Mg Daily), (150 Mg Daily) (75 Mg Daily),(150 Mg	1 MTH 6 WEEK	Not Reported

Activities; Nausea; Persecutory Delusion				Daily), (75 Mg Daily), (150 Mg Daily)	
	Escitalopram Oxalate	S		(10 Mg Qd, (10 Mg Qd)	Not Reported
	Clonazepam	C			Not Reported
	Olanzapine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2011	8192663	EXPEDITED (15-DAY)	Y	HO	1000024439		49 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cerebral Haematoma	Escitalopram Oxalate			S	Oral	1 Df (1 Dosage Forms,1 In 1 D),Oral		Not Reported
	Abilify			S	Oral	1 Df (1 Dosage Forms,1 In 1 D),Oral		Not Reported
	Trihexyphenidyl Hydrochloride			S	Oral	1 Df (1 Dosage Forms,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2011	8192869	EXPEDITED (15-DAY)	Y	RI, OT	1000024407		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Speech Disorder	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2011	8176671	EXPEDITED (15-DAY)	Y	HO	US-JNJFOC-20111003969		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Screen False Positive; Intentional Overdose; Partial Seizures; Tachycardia	Tramadol Hydrochloride			S	Oral	600-800 Mg Daily		Not Reported
	Naproxen			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported

		Escitalopram Oxalate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2011	8177036	EXPEDITED (15-DAY)	N	HO, OT	AT-BRISTOL-MYERS SQUIBB COMPANY-16151151		30 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eating Disorder; Weight Increased	Abilify			S		Also 10mg On Feb2011(Dose Not Changed)		Not Reported
	Venlafaxine Hydrochloride			S				Not Reported
	Seroquel			S				Not Reported
	Cipralex			S				Not Reported
	Prothipendyl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2011	7987062	EXPEDITED (15-DAY)	Y		1000020959		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Bladder Sensation; Urinary Retention; Urine Flow Decreased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2011	8194913	EXPEDITED (15-DAY)	Y	RI, OT	1000024459			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Lexapro			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	7701166	NON-EXPEDITED	N	OT	1000014928		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Thyroid Stimulating Hormone Decreased; Syncope	Lexapro	S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Lexapro	S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Nexium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	7701205	NON-EXPEDITED	Y	DE	1000014986		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Mania	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral Oral	20 Mg (20 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D),Oral 20 Mg (20 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D),Oral		Not Reported
	Xanax			S	Oral	0.5 Mg Tid Prn, Oral		Not Reported
	Vicodin			S	Oral	Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported
	Seroquel Xr			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Trazodone Hydrochloride Ultram Imitrex Skelaxin			C C C C				Not Reported Not Reported Not Reported Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8181841	EXPEDITED (15-DAY)	N	OT	US-TEVA-304301USA		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Drug Interaction; Fatigue; Fungal Infection; Mania; Palpitations	Fluconazole		S	Oral		Not Reported
	Deplin (Calcium Levomefolate) (Calcium Levomefolate)		C			Not Reported
	Escitalopram Oxalate		S	Oral	10 Milligram;	Not Reported
	Escitalopram Oxalate		S	Oral	20 Milligram;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225598	NON-EXPEDITED	Y	RI	1000018065		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Crying; Drug Ineffective; Suicidal Ideation	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Wellbutrin			S				Not Reported
	Trazodone (Trazodone) (Tablets) (Trazodone)			C				Not Reported
	Topamax (Topiramate) (Topiramate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225618	NON-EXPEDITED	N	RI, OT	1000018159		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Mood Swings; Paranoia; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Alprazolam (Alprazolam) (1 Milligram, Tablets) (Alprazolam)			C				Not Reported
	Tramadol (Tramadol) (50 Milligram, Tablets) (Tramadol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225622	NON-EXPEDITED	Y	RI, OT	1000018260		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stomatitis; Suicidal	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1		Not Reported

Ideation						D),Oral				
	Xanax			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225647	NON-EXPEDITED	Y	RI, OT	1000018377		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersomnia; Myalgia; Nephrolithiasis; Overdose	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral		
	Lexapro			S	Oral	40 Mg (40 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral ; 30 Mg, (30 Mg,1 In 1 D),Oral		Not Reported
					Oral	40 Mg (40 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral ; 30 Mg, (30 Mg,1 In 1 D),Oral		
					Oral	40 Mg (40 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral ; 30 Mg, (30 Mg,1 In 1 D),Oral		
	Lipitor			S				Not Reported
	Nadolol (Nadolol) (Nadolol)			C				Not Reported
	Dexedrine (Dexamfetamine Sulfate) (Dexamfetamine Sulfate)			C				Not Reported
	Adderall (Amphetamine, Dextroamphetamine) (Amphetamine, Dextroamphetamine)			C				Not Reported
	Pravastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225668	NON-EXPEDITED	Y	RI, OT	1000018695		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 15 Mg (15 Mg,1 In 1 D),Oral		Not Reported
					Oral	10 Mg (10 Mg,1 In 1 D),Oral ; 15 Mg (15 Mg,1 In 1 D),Oral		
	Abilify (Aripiprazole) (5 Milligram, Tablets) (Aripiprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225669	NON-EXPEDITED	N	RI, OT	1000018998		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicidal Ideation	Lexapro			S	Oral	(1 In 1 D),Oral		Not Reported
	Vitamin B-12 (Cyanocobalamin) (Cyanocobalamin)			C				Not Reported
	Vicodin (Hydrocodone) (Hydrocodone)			C				Not Reported
	Lisinopril			C				Not Reported
	Simvastatin			C				Not Reported
	Omeprazole			C				Not Reported
	Nifedipine			C				Not Reported
	Carvedilol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225678	NON-EXPEDITED	Y	HO	1000019254		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt	Lexapro			S	Oral	Oral ; Oral		Not Reported
	Lunesta			S	Oral	2 Mg (2 Mg,1 In 1 D),Oral ; Oral		Not Reported
					Oral	2 Mg (2 Mg,1 In 1 D),Oral ; Oral		
	Ambien Cr			S	Oral	12.5 Mg (12.5 Mg,1 In 1		Not Reported

			Oral	D),Oral ; Oral 12.5 Mg (12.5 Mg,1 In 1 D),Oral ; Oral		
	Xanax	S	Oral	Oral ; Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225707	NON-EXPEDITED	N	HO	1000019281		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Oxycontin			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225711	NON-EXPEDITED	N	RI, OT	1000019386		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225715	NON-EXPEDITED	N	HO, OT	1000019477		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225763	NON-EXPEDITED	N	OT	1000015749		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Crying; Dry Mouth; Feeling Abnormal; Pain; Productive Cough; Suicidal Ideation; Thirst; Weight Increased	Lexapro	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral 5 Mg (5 Mg, 1 In 1 D), Oral 2.5 (2.5 Mg, Every Other Day), Oral	Not Reported
			Oral	10 Mg (10 Mg, 1 In 1 D), Oral 5 Mg (5 Mg, 1 In 1 D), Oral 2.5 (2.5 Mg, Every Other Day), Oral	
			Oral	10 Mg (10 Mg, 1 In 1 D), Oral 5 Mg (5 Mg, 1 In 1 D), Oral 2.5 (2.5 Mg, Every Other Day), Oral	
	Lexapro	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Keppra	S			Not Reported
	Synthroid	C			Not Reported
	Baby Aspirin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225768	NON-EXPEDITED	Y	DE	1000015826		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Klonopin (Clonazepam) (0.5 Milligram, Tablets) (Clonazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225780	NON-EXPEDITED	N	OT	1000015921			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225830	NON-EXPEDITED	N	OT	1000015938		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Fatigue; Mania; Suicidal Ideation	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral		
	Baclofen			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8225879	NON-EXPEDITED	Y	OT	1000016476		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226014	NON-EXPEDITED	N	OT	1000016592		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Trazodone (Trazodone) (Tablets) (Trazodone)			C				Not Reported
	Geodon (Ziprasidone) (Ziprasidone)			C				Not Reported
	Propranolol			C				Not Reported
	Focalin Xr (Dexmethylphenidate Hydrochloride) (Dexmethylphenidate Hydrochloride)			C				Not Reported
	Topamax (Topiramate)			C				Not Reported

(Topiramate)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226022	NON-EXPEDITED	N	HO	1000016758		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Electrocardiogram Change; Hyperhidrosis; Nausea; Paraesthesia; Tremor	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Azor (Amlodipine, Olmesartan) (Amlodipine, Olmesartan)			C				Not Reported
	Xyzal			C				Not Reported
	Prilosec (Omeprazole) (Omeprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226048	NON-EXPEDITED	Y	OT	1000016800			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226073	NON-EXPEDITED	Y	OT	1000016801			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226088	NON-EXPEDITED	Y	OT	1000016802			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226108	NON-EXPEDITED	N	DE	1000022739		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Completed Suicide; Suicidal Ideation	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226110	NON-EXPEDITED	Y	RI, OT	1000017219		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Overdose; Somnolence; Suicidal Ideation	Lexapro			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
	Zoloft			S	Oral	Oral		Not Reported
	Cymbalta			S	Oral	60 Mg (60 Mg, 1 In 1 D), Oral		Not Reported
	Wellbutrin			S	Oral	Oral		Not Reported
	Methadone (Methadone) (Methadone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226131	NON-EXPEDITED	N	HO	1000017235		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Pressure Decreased; Panic Attack; Suicidal Ideation; Supraventricular Tachycardia; Tremor	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Metoprolol (Metoprolol) (Tablets) (Metoprolol)			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Omeprazole			C				Not Reported
	Xanax (Alprazolam) (0.25 Milligram, Tablets) (Alprazolam)			C				Not Reported
	Decadron (Dexamethasone) (Tablets) (Dexamethasone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226132	NON-EXPEDITED	N	RI, OT	1000013431		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Glycosylated Haemoglobin Decreased; Glycosylated Haemoglobin Increased; Hypomania; Irritability; Somnolence; Type 2 Diabetes Mellitus	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Birth Control (Nos) (Contraceptives Nos) (Contraceptatives Nos)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226197	NON-EXPEDITED	Y	RI, OT	1000019506		38 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226199	NON-EXPEDITED	Y	HO	1000014465		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	10 Mg(10 Mg, 1 In 1 D), Oral		Not Reported
	Lisinopril			C				Not Reported
	Atenolol			C				Not Reported
	Simvastatin			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226202	NON-EXPEDITED	Y	RI, OT	1000017296			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Tachycardia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226215	NON-EXPEDITED	Y	RI, OT	1000021173		9 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Incorrect Route Of Product Administration	Lexapro			S				Not Reported
	Nasonex			S		Nasal		Not Reported
	Asmanex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226217	NON-EXPEDITED	N	RI, OT	1000021426			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Suicide Attempt	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226226	NON-EXPEDITED	Y	HO	1000017394		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed; Maternal Exposure During Pregnancy; Urinary Tract Infection	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Prenatal Vitamins With Dha (Prenatal Vitamins With Dha) (Prenatal Vitamins With Dha)			C				Not Reported
	Retin A Gel 0.1% (Tretinoin) (Tretinoin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226229	NON-EXPEDITED	N	RI, OT	1000021610		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226243	NON-EXPEDITED	N	OT	1000019507		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Night Sweats; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226244	NON-EXPEDITED	Y	HO	1000022068			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Lexapro			S				Not Reported
	Zoloft			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226245	NON-EXPEDITED	Y	HO	1000017468		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226247	NON-EXPEDITED	Y	OT	1000022296			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226252	NON-EXPEDITED	N	HO	1000019547		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Disturbance In Attention; Feeling Abnormal	Lexapro	S	Oral	20 Mg (20 Mg), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226256	NON-EXPEDITED	N	RI, OT	1000022437		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Amnesia; Food Craving; Headache; Insomnia; Mental Impairment; Suicidal Ideation	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	15 Mg (15 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral	1 DAY	
	Diovan			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Simvastatin			C				Not Reported
	Cilostazol (Cilostazol) (Cilostazol)			C				Not Reported
	Hydrocodone			C				Not Reported
	Losartan Hydrochlorothiazide (Losartan, Hydrochlorothiazide) (Losartan, Hydrochlorothiazide)			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Levothyroxine (Levothyroxine Sodium) (Levothyroxine Sodium)			C				Not Reported
	Prilosec (Omeprazole) (Omeprazole)			C				Not Reported
	Alka Seltzer (Sodium Bicarbonate, Citric Acid, Aspirin) (Sodium Bicarbonate, Citric Acid, Aspirin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226261	NON-EXPEDITED	Y	RI, OT	1000019668		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Lexapro			S	Oral	Oral		Not Reported
	Vibativ			S	Intravenous (not otherwise specified)	10 Mg/Kg Total Daily Dose, Intravenous (Not Otherwise Specified)		Not Reported
	Trazodone Hydrochloride			S	Oral	Oral		Not Reported
	Reglan			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Novolin R			C				Not Reported
	Hydromorphone Hydrochloride			C				Not Reported
	Metoprolol			C				Not Reported
	Lisinopril			C				Not Reported
	Sitagliptin			C				Not Reported
	Imdur			C				Not Reported
	Lasix			C				Not Reported
	Cilostazol			C				Not Reported
	Vitamin D (Colecalciferol)			C				Not Reported
	Calcium Citrate			C				Not Reported
	Omeprazole			C				Not Reported
	Zolpiderm			C				Not Reported
	Lipitor			C				Not Reported
	Fentanyl			C				Not Reported
	Lantus			C				Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226266	NON-EXPEDITED	N	LT	1000020040			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicidal Ideation	Lexapro			S	Oral	Oral		Not Reported
	Abilify			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226267	NON-EXPEDITED	N	RI, OT	1000017752		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypertension	Lexapro	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Synthroid (Levothyroxine Sodium) (50 Microgram, Tablets) (Levothyroxine Sodium)	C			Not Reported
	Alendronate (Alendronate Sodium) (Alendronate Sodium)	C			Not Reported
	Ambien (Zolpidem Tartrate) (5 Milligram, Tablets) (Zolpidem Tartrate)	C			Not Reported
	Simvastatin (Simvastatin) (20 Milligram, Tablets) (Simvastatin)	C			Not Reported
	Centrum Vitamins (Centrum Vitamins) (Centrum Vitamins)	C			Not Reported
	Calcium (Calcium) (Calcium)	C			Not Reported
	Vitamin D (Vitamin D) (Vitamin D)	C			Not Reported
	Viactiv (Calcium) (Calcium)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226271	NON-EXPEDITED	N	RI, OT	1000020557			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Overdose; Suicide Attempt	Lexapro			S	Oral			Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226272	NON-EXPEDITED	Y	HO	1000022690			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226273	NON-EXPEDITED	Y	OT	1000017836		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Overdose	Lexapro	S	Oral	Oral		Not Reported
	Neurontin	S	Oral	Oral		Not Reported
	Oxycontin (Oxycodone Hydrochloride) (Oxycodone Hydrochloride)	C				Not Reported
	Morphine Sulfate	C				Not Reported
	Diazepam	C				Not Reported
	Vicodin Er (Hydrocodone, Acetaminophen) (Hydrocodone, Acetaminophen)	C				Not Reported
	Soma (Carisoprodol) (Carisoprodol)	C				Not Reported
	Parafon Forte (Chlorzoxazone) (Chlorzoxazone)	C				Not Reported
	Zanaflex (Tizanidine Hydrochloride) (Tizanidine Hydrochloride)	C				Not Reported
	Klonopin	C				Not Reported
	Ativan	C				Not Reported
	Phenergan (Promethazine) (Promethazine)	C				Not Reported
	Relafen (Nabumetone) (Nabumetone)	C				Not Reported
	Lidoderm (Lidocaine) (Poultice Or Patch) (Lidocaine)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226301	NON-EXPEDITED	N	OT	1000020784		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Jittery; Suicidal Ideation	Lexapro			S		10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg Every Other Day (10 Mg, 1 In 2 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg Every Other Day (10 Mg, 1 In 2 D), Oral		Not Reported
	Seroquel			C				Not Reported

	Xanax			C						Not Reported
	Synthroid			C						Not Reported
	Coreg			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226302	NON-EXPEDITED	Y	RI, OT	1000018027			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Somnolence; Suicidal Ideation; Weight Increased	Lexapro			S				Not Reported
	Invega			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226314	NON-EXPEDITED	Y	HO	1000020983			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8226330	NON-EXPEDITED	Y	HO	1000020984		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Hyponatraemia	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Clonazepam			C				Not Reported
	Vytorin			C				Not Reported
	Aspirin			C				Not Reported
	Carbamazepine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8228485	NON-EXPEDITED	N	RI, OT	1000017454		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disturbance In Attention; Headache; Insomnia; Nervousness; Tremor; Weight Decreased	Lexapro		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Ambien		C			Not Reported
	Glyburide		C			Not Reported
	Vytorin (Inegy) (Inegy)		C			Not Reported
	Calcium (Calcium) (Calcium)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8228577	NON-EXPEDITED	N	RI, OT	1000021106		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 250 Mg, Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 250 Mg, Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8236433	NON-EXPEDITED	Y	RI, OT	10000015444		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Urticaria	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported
	Vesicare			C				Not Reported
	Simvastatin			C				Not Reported
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2011	8239074	NON-EXPEDITED	Y	HO	10000820982			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Hyponatraemia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2011	8182389	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2011SE60473		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Inexium			S	Oral		1 MTH	Astrazeneca
	Amoxicillin			S	Oral		1 MTH	Not Reported
	Clarithromycin			S	Oral		1 MTH	Not Reported
	Aricept			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Flagyl			S	Oral		1 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2011	7948744	EXPEDITED (15-DAY)	Y	DE	2011SP018390		34 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Mirtazapine			S	Oral	30 Mg;Qd;Po		Not Reported
	Cipralex			S	Oral	20 Mg;Qd;Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2011	8183271	DIRECT	N	DE			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asphyxia; Completed Suicide; Feeling Abnormal	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2011	8168441	EXPEDITED (15-DAY)	Y	HO	1000024066		17 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Priapism	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg,1 In 1 D),Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Oral	Not Reported
	Invega		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2011	8174969	EXPEDITED (15-DAY)	Y	RI, OT	1000024082		41 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Decreased Appetite; Dizziness; Fatigue; Headache; Hyperhidrosis; Nausea; Palpitations; Paraesthesia; Sinusitis; Suicidal Ideation; Tinnitus; Vomiting; Weight Decreased; Withdrawal Syndrome	Lexapro			S	Oral Oral Oral Oral	See Image See Image See Image See Image		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2011	8185810	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2011248798		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Loss Of Consciousness	Chantix			S	Oral	0.5 Mg, Daily		Pfizer
	Chantix			S	Oral	1 Mg, 2x/Day		Pfizer
	Lexapro			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2011	8186416	EXPEDITED (15-DAY)	N	HO, OT	FR-GLAXOSMITHKLINE-B0727777A		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Crying; Major Depression; Mental Disorder; Suicidal	Deroxat			S	Unknown			Glaxosmithkline
	Enbrel			S	Unknown	50mg Weekly		Unknown

Ideation; Tremor	Escitalopram Oxalate	S	Unknown		Unknown
	Anafranil	C	Intravenous (not otherwise specified)		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2011	8202109	EXPEDITED (15-DAY)	Y	RI, OT	1000022156		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Breast Discomfort; Breast Tenderness; Generalised Oedema; Nausea	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2011	8202173	EXPEDITED (15-DAY)	Y	RI, OT	1000024535			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oesophageal Achalasia	Lexapro			S		10 Mg (10 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2011	7995134	EXPEDITED (15-DAY)	Y	HO, OT	FR-AMGEN-FRASP2011030054		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Major Depression; Suicidal Ideation; Tremor	Enbrel			S		50 Mg, Weekly		Amgen
	Escitalopram Oxalate			S		Unk		Not Reported
	Deroxat			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2011	8120942	EXPEDITED (15-DAY)	Y	HO, LT	FR-SANOFI-AVENTIS-2011SA055863		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress	Stilnox			S	Oral		13 DAY	Not Reported

Syndrome; Dyspnoea; Eosinophilic Pneumonia	Depakote	S	Oral	5 DAY	Not Reported
	Escitalopram Oxalate	S	Oral	18 DAY	Not Reported
	Ferrous Sulfate	S	Oral		Not Reported
	Xanax	S	Oral		Not Reported
	Triphasil-21	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2011	8170912	EXPEDITED (15-DAY)	Y	CA	1000024030		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Disease; Aphasia; Bicuspid Aortic Valve; Craniosynostosis; Intellectual Disability; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	(10 Mg),Transplacental		Not Reported
	Prenatal Vitamins (Prenatal Vitamins) (Prenatal Vitamins)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2011	8189298	EXPEDITED (15-DAY)	Y	LT, OT	FR-SANOFI-AVENTIS-2011SA054192		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Dyspnoea; Eosinophilic Pneumonia	Stilnox			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Ferrous Sulfate			S				Not Reported
	Xanax			S				Not Reported
	Triphasil-21			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2011	8189740	EXPEDITED (15-DAY)	Y	HO	AU-PFIZER INC-2011245315			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Pristiq Extended Release			S				Pfizer

	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2011	8189948	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-2011245079			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Pain	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Oxycontin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2011	8192610	EXPEDITED (15-DAY)	Y	HO	1000024483		75 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Overdose; Suicide Attempt	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Methotrexate (Methotrexate) (Methotrexate)			C				Not Reported
	Pariet (Rabeprazole Sodium) (Tablets) (Rabeprazole Sodium)			C				Not Reported
	Mabthera (Rituximab) (Rituximab)			C				Not Reported
	Endoxan (Cyclophosphamide) (Cyclophosphamide)			C				Not Reported
	Doxorubicin Hydrochloride			C				Not Reported
	Vincristine Sulfate			C				Not Reported
	Cardiosaspirin (Acetylsalicylic Acid) (Tablets) (Acetylsalicylic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2011	8200410	EXPEDITED (15-DAY)	Y	HO	1000024628		69 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Delirium; Drug Ineffective; Withdrawal Syndrome	Escitalopram Oxalate	S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral	Not Reported
	Trazodone Hydrochloride	S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral	Not Reported
	Praxiten (Oxazepam) (Oxazepine)	C			Not Reported
	Mirtabene (Mirtazapine (Mirtazapine)	C			Not Reported
	Tenormin	C			Not Reported
	Pantoloc (Pantoprazole Sodium Sesquihydrate) (Pantoprazole Sodium Sesquihydrate)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2011	8211350	EXPEDITED (15-DAY)	Y	HO	1000024711		88 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Pruritus; Purpura; Rash Papular; Weight Decreased	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Co-Aprovel (Irbesartan, Hydrochlorothiazide) (Tablets) (Irbesartan, Hydrochlorothiazide)			C				Not Reported
	Redoxon (Ascorbic Acid) (Tablets) (Ascorbic Acid)			C				Not Reported
	Movicol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2011	8216895	EXPEDITED (15-DAY)	Y	RI, OT	1000024667		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Incorrect Dose Administered; Suicide Attempt	Escitalopram Oxalate			S		2 Boxes (Once)		Not Reported
	Lexomil (Bromazepam)			S		(Once)		Not Reported
	Voltaren			S		(Once)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2011	8164680	EXPEDITED (15-DAY)	Y	DE, HO	2011MA013053		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Antibodies Positive; Condition Aggravated; Depression; Embolism Venous; Pulmonary Embolism	Mirtazapine			S		45 Mg;Qd		Purepac
	Paroxetine Hydrochloride			S		20 Mg;Qd		Not Reported
	Sertraline Hydrochloride			S		100 Mg;Qd		Not Reported
	Venlafaxine			S		225 Mg;Qd		Not Reported
	Reboxetine			S		4 Mg;Qd		Not Reported
	Quetiapine Fumarate			S		300 Mg;Qd		Not Reported
	Escitalopram Oxalate			S		20 Mg;Qd		Not Reported
	Olanzapine (Olanzapine)			S		5 Mg;Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2011	8195052	DIRECT	N	RI, OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Inability; Hyperhidrosis; Skin Odour Abnormal; Vein Disorder; Weight Increased	Cymbalta			S		1 Pill @ Bedtime 1 - 1 1/2 Yrs	12 MTH	Not Reported
	Lexapro			S		1 Pill @ Bedtime	3 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2011	8187875	EXPEDITED (15-DAY)	Y	DE, HO	IE-ASTRAZENECA-2011SE61980		76 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Hepatitis	Seroquel			S	Oral			Not Reported
	Nexium			S	Oral			Not Reported
	Rifadin			S	Oral		5 DAY	Not Reported
	Fucidin (Fusidic Acid)			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Augmentin			S	Unknown	875/125 Mg		Not Reported
	Metronidazole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2011	8192572	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2011US-49338		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Fluoxetine			S	Oral	Unk, Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral	Unk, Unk		Not Reported
	Liothyronine Sodium			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2011	8192850	EXPEDITED (15-DAY)	N	HO	TR-US-EMD SERONO, INC.-7089068		26 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Thrombocytopenia	Rebif			S	Subcutaneous			Not Reported
	Lyrica			S	Oral		4 MTH	Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2011	8194074	NON-EXPEDITED	Y		US-PFIZER INC-2011252344			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased	Lipitor			S	Oral	10 Mg, 1x/Day		Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2011	8186357	EXPEDITED (15-DAY)	Y	HO	FR-ABBOTT-11P-056-0864075-00		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Clarithromycin			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

Amoxicillin		S	Oral		Not Reported
Aricept		S	Oral		Not Reported
Inexium		S	Oral		Not Reported
Flagyl		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2011	8111890	EXPEDITED (15-DAY)	Y	OT	2011SP038021		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Drug Interaction; Drug Level Decreased; Insomnia; Irritability; Loss Of Personal Independence In Daily Activities; Mood Altered; Myoclonus; Serotonin Syndrome; Tremor	Remeron			S	Oral	15 Mg;Qd;Po		Not Reported
	Cipralex			S	Oral	20 Mg;Qd;Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2011	8112759	EXPEDITED (15-DAY)	Y	HO, LT	FR-ABBOTT-11P-056-0849667-00		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Dyspnoea; Eosinophilic Pneumonia	Depakote			S	Oral	750mg Daily		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg Daily		Not Reported
	Stilnox			S	Oral			Not Reported
	Ferrous Sulfate			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported
	Triphasil-21			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2011	8194817	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20111008995			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Triglycerides Increased	Concerta			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2011	8195691	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Malaise; Withdrawal Syndrome	Lexapro			S	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2011	8215627	EXPEDITED (15-DAY)	Y	RI, OT	1000024769		60 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Restlessness	Escitalopram Oxalate			S	Transmammary	10 Mg (10 Mg, 1 In 1 D), Transmammary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2011	8216894	EXPEDITED (15-DAY)	N	CA	1000024784		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Talipes	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2011	7661231	EXPEDITED (15-DAY)		DS, HO, OT	PHHO2010IL16347		34 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Asthenia; Ataxia; Brain Oedema; Central	Fty 720			S	Oral	Dose Blinded		Novartis

Nervous System Lesion; Cerebral Atrophy; Colour Blindness; Constipation; Cyanosis; Depressed Mood; Disinhibition; Disorientation; Disturbance In Attention; Dysarthria; Dysmetria; Dysmetropsia; Dysphonia; Executive Dysfunction; Gait Disturbance; Gait Inability; Gamma-Glutamyltransferase Increased; Headache; Hemianopia Homonymous; Hypertension; Irritability; Joint Injury; Loss Of Consciousness; Memory Impairment; Metamorphopsia; Muscle Spasticity; Muscular Weakness; Nausea; Paresis; Peripheral Coldness; Pyramidal Tract Syndrome; Seizure; Status Epilepticus; Tongue Biting; Tonic Clonic Movements; Unresponsive To Stimuli; Urinary Incontinence; Vasospasm; Visual Impairment	Fty 720	S	Oral	0.5mg	Novartis
	Lioresal	S	Oral	Unk	Not Reported
	Escitalopram	S		Unk	Not Reported
	Cipralex	C			Not Reported
	Modafinil	C		Unk	Not Reported
	Ferrous Sulfate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2011	8163288	EXPEDITED (15-DAY)	Y	OT	US-SANOFI-AVENTIS-2011SA063852		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qt Prolonged; Ventricular	Multaq			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

Tachycardia	Aspirin	C		Not Reported
	Xanax	C		Not Reported
	Aciphex	C		Not Reported
	Dabigatran Etexilate	C		Not Reported
	Metoprolol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2011	8199520	DIRECT	N	OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Vertigo; Visual Impairment	Lexapro			S	Oral	10mg		Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2011	8040317	EXPEDITED (15-DAY)	Y	RI, OT	1000021853		46 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Crying; Drug Interaction; Suicidal Ideation; Tremor	Escitalopram Oxalate			S			2 DAY	Not Reported
	Enbrel			S		7.1429 Mg (50 Mg, 1 In 1 Wk);		Not Reported
	Paroxetine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2011	8200603	EXPEDITED (15-DAY)	Y	HO	FR-GLAXOSMITHKLINE-B0756543A		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vertigo; Vestibular Neuronitis	Avodart			S	Oral	.5mg Per Day		Glaxosmithkline
	Metformin Hydrochloride			S	Oral	700mg Three Times Per Day		Unknown
	Gliclazide			S	Oral	20mg Three Times Per Day		Unknown
	Indapamide			S	Oral			Unknown
	Bisoprolol Fumarate			S	Oral			Unknown

	Cordarone	S	Oral	200mg Per Day		Unknown
	Previscan (Fluindione)	S	Oral	20mg Per Day		Unknown
	Escitalopram Oxalate	S	Oral			Unknown
	Crestor	S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2011	8201174	EXPEDITED (15-DAY)	N	OT	BR-PFIZER INC-2011251253		42 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Lyrica			S	Oral	75 Mg, 1 Capsule Daily	7 DAY	Pfizer
	Lyrica			S	Oral	150mg (Two Capsules Of 75mg), Daily		Pfizer
	Alprazolam			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2011	8201413	EXPEDITED (15-DAY)	Y	OT	FR-WATSON-2011-17096		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Indapamide			S				Watson
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2011	8202048	EXPEDITED (15-DAY)	Y	HO	1000024656		80 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroduodenal Ulcer; Helicobacter Infection; Hepatitis	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Aricept			S	Oral	Oral		Not Reported
	Inexium (Esomeprazole)			S	Oral	Oral		Not Reported

	Amoxicillin		S	Oral	Oral	Not Reported
	Clarithromycin		S	Oral	Oral	Not Reported
	Flagyl		S	Oral	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2011	8222077	EXPEDITED (15-DAY)	Y	HO	1000024860		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Generalised Tonic-Clonic Seizure; Polydipsia; Suicide Attempt; Teething	Escitalopram Oxalate			S	Oral	1 Df (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Tramadol			S	Oral	100 Mg (50 Mg, 2 In 1 D), Oral		Not Reported
	Zyprexa			S		7.5 Mg (7.5 Mg, 1 In 1 D),		Not Reported
	Haldol			S		5 Mg (5 Mg, 1 In 1 D)		Not Reported
	Oxazepam			C				Not Reported
	Vitamin B1			C				Not Reported
	Vitamin B6			C				Not Reported
	Nicobion (Nicotinamide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2011	6549166	EXPEDITED (15-DAY)	N	RI, OT	S08-USA-00249-01		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Akathisia; Anxiety; Depression; Discomfort; Ejaculation Failure; Feeling Abnormal; Feeling Of Despair; Impulsive Behaviour; Irritability; Mania; Nervousness; Palpitations; Paranoia; Personality Change; Product Quality Issue; Suicide Attempt	Lexapro			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
	Sertraline Hydrochloride			S				Not Reported
	Hypericum			S		900 Mg (900 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2011	8060601	EXPEDITED (15-DAY)	N	HO	1000022129		69 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Mobility Decreased; Tremor	Escitalopram Oxalate			S	Oral	Daily Dose Not Reported, Oral		Not Reported
	Amiodarone Hydrochloride			S	Oral	200 Mg (200 Mg, 1 In 1 D), Oral		Not Reported
	Gluconorm (Repaglinide)			C				Not Reported
	Asa (Acetylsalicylic Acid)			C				Not Reported
	Ativan			C				Not Reported
	Lasix			C				Not Reported
	Lipitor			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Micardis			C				Not Reported
	Oxazepam			C				Not Reported
	Plavix			C				Not Reported
	Synthroid			C				Not Reported
	Vitamin D (Colecalciferol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2011	8228618	EXPEDITED (15-DAY)	N	CA	1000024864		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Maternal Drugs Affecting Foetus; Patent Ductus Arteriosus; Ventricular Septal Defect	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2011	8228703	EXPEDITED (15-DAY)	Y	DE, HO	1000024878		76 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure;	Lexapro			S	Oral	(15 Mg),Oral		Not Reported

Agitation; Bacterial Infection; Cardiac Failure; Confusional State; Dehydration; Escherichia Infection; Hepatitis; Skin Ulcer; Staphylococcal Infection	Nexium	S		(40 Mg)	Not Reported
	Seroquel	S		(25 Mg)	Not Reported
	Augmentin	S	Oral	Oral	Not Reported
	Metronidazole	S	Oral	400 Mg,Oral	Not Reported
	Fusidic Acid	S	Oral	500 Mg (250 Mg, 2 In 1 D),Oral	Not Reported
	Rifadin	S	Oral	600 Mg (300 Mg, 2 In 1 D),Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2011	8232509	EXPEDITED (15-DAY)	N	HO	1000024810		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive; Dysarthria; Encephalopathy; Impaired Driving Ability; Mental Status Changes; Off Label Use	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Iron (Iron) (Iron)			C				Not Reported
	Clonazepam			C				Not Reported
	Armour Thyroid (Thyroid) (Thyroid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2011	8233265	EXPEDITED (15-DAY)	N	RI, OT	1000022160		35 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dyspnoea; Haemorrhage; Hallucination; Heart Rate Increased; Muscle Spasms; Muscular Weakness; Nausea; Nervousness; Serotonin Syndrome; Syncope	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 Tatal), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2011	8233317	EXPEDITED (15-DAY)	Y	RI, OT	1000024976		20 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Depression; Feeling Abnormal; Generalised Tonic-Clonic Seizure	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zyprexa			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Flunitrazepam			S	Oral	2 Mg (2 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Brotizolam			S	Oral	0.25 Mg (0.25 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2011	8233376	EXPEDITED (15-DAY)	Y	RI, OT	1000024131			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Valium			C				Not Reported
	Depamide (Valpromide) (Valpromide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2011	8170834	EXPEDITED (15-DAY)	Y	RI, OT	1000024140			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2011	8202154	EXPEDITED (15-DAY)	N	RI, OT	1000024583		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Escitalopram Oxalate			S	Oral	Daily Dose Not Reported,Gradually Increased (1 In 1 D),Oral, 30 Mg (30 Mg 1 In 1 D) Oral		Not Reported
					Oral	Daily Dose Not Reported,Gradually Increased (1 In 1 D),Oral, 30 Mg (30 Mg 1 In 1 D) Oral		
	Wellbutrin (Bupropion Hydrochloride)(Tablets)(Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2011	8235913	EXPEDITED (15-DAY)	Y	HO	2011MA015283		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Autonomic Nervous System Imbalance; Bradykinesia; Decreased Appetite; Depressed Mood; Family Stress; Flat Affect; Insomnia; Parkinsonian Crisis; Psychotic Disorder; Reduced Facial Expression; Somatic Delusion; Suicidal Ideation; Thinking Abnormal	Risperidone			S		0.5 Mg;Bid;		Actavis Totowa
	Clonazepam			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Lisinopril And Hydrochlorothiazide			C				Not Reported
	Rosuvastatin			C				Not Reported
	Paroxetine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2011	8236845	NON-EXPEDITED	N	OT	DSA_44544_2010		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Overdose	Ativan	S	Not The Prescribed Amount	Not Reported
	Neurontin	S	Df	Not Reported
	Oxycontin	S	Df	Not Reported
	Morphine Sulfate	S	Df	Not Reported
	Diazepam	S	Df	Not Reported
	Vicodin	S	Df	Not Reported
	Soma	S	Df	Not Reported
	Parafon Forte	S	Df	Not Reported
	Zanaflex	S	Df	Not Reported
	Klonopin	S	Df	Not Reported
	Phenergan	S	Df	Not Reported
	Lexapro	S	Df	Not Reported
	Relafen	S	Df	Not Reported
	Lidoderm	S	Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2011	8170813	EXPEDITED (15-DAY)	Y	RI, OT	1000024137		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Narrow Anterior Chamber Angle	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2011	8171102	EXPEDITED (15-DAY)	Y	RI, OT	1000024130		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Narrow Anterior Chamber Angle; Ocular Hypertension	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2011	8200237	EXPEDITED (15-DAY)	Y	LT	1000024644		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Respiratory Depression	Lexapro			S	Transplacental	20 Mg (20 Mg, 1 In 1 D),Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2011	8200639	EXPEDITED (15-DAY)	Y	HO	1000024702			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injury; Victim Of Sexual Abuse	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2011	8237125	EXPEDITED (15-DAY)	Y	RI, OT	1000025019			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Loss Of Consciousness	Escitalopram Oxalate			S	Oral	Daily Dose Not Reported,Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2011	8242491	EXPEDITED (15-DAY)	Y	RI, OT	1000024135		64 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Narrow Anterior Chamber Angle	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Lexomil (Bromazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2011	8242417	EXPEDITED (15-DAY)	Y	HO	1000025048		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fatigue; Flashback; Movement Disorder; Musculoskeletal Stiffness; Obsessive Thoughts	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Atarax			C				Not Reported
	Opamox (Oxazepam) (Oxazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2011	8118922	EXPEDITED (15-DAY)	Y	HO	1000023006		78 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Lactic Acid Increased; Blood Ph Decreased; C-Reactive Protein Increased; Clonus; Convulsive Threshold Lowered; Drug Abuse; Dyspnoea; Flatulence; Headache; Infection; Loss Of Consciousness; Partial Seizures; Pco2 Increased; Pyrexia	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Valacyclovir Hydrochloride			S	Oral	500 Mg (500 Mg, 1 In 1 D), Oral, 500 Mg (500 Mg, 1 In 1 D), Oral		Not Reported
	Zolmitriptan			S	Oral	(2.5 Mg, On Request), Oral		Not Reported
	Unspecified Ingredient			S	Oral	1 Mg (0.5 Mg, 2 In 1 D), Oral		Not Reported
	Transilane (Herbals\Plantago Ovata Leaf)			C				Not Reported
	Seresta (Oxazepam) (Oxazepam)			C				Not Reported
	Lescol			C				Not Reported
	Imovane (Zopiclone) (Zopiclone)			C				Not Reported
	Cardensiel (Bisoprolol Fumarate) (Bisoprolol Fumarate)			C				Not Reported
	Actonel (Risedronate Sodium) (Risedronate Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2011	8176225	EXPEDITED (15-DAY)	Y	HO, OT	DK-WATSON-2011-15919			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coma; Mutism; Overdose; Respiratory Acidosis; Seizure; Sinus Bradycardia; Suicide Attempt	Baclofen		S	Oral	1850 Mg, Single	Watson
	Baclofen		S	Unknown	2500 Mg, Single	Watson
	Mirtazapine		S	Oral	230 Mg, Single	Watson
	Escitalopram Oxalate		S	Oral	160 Mg, Single	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2011	8179999	EXPEDITED (15-DAY)	Y	OT	1000024251		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Thalidomide			C				Not Reported
	Nivaquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2011	8190093	EXPEDITED (15-DAY)	Y	RI, OT	1000024312		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Zyprexa			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Trazodone Hydrochloride			S		300 Mg (300 Mg, 1 In 1 D);		Not Reported
	Pristiq Extended Release			S	Oral	(50 Mg, Every Other Dya), Oral		Not Reported
	Benicar			C				Not Reported
	Cymbalta			C				Not Reported
	Levothroid			C				Not Reported
	Omega 3 Fatty Acids			C				Not Reported
	Ativan			C				Not Reported
	Spectravite (Multivitamins)			C				Not Reported
	Viatmin D3 (Colecalciferol)			C				Not Reported
	Deplin (Calcium Levomefolate)			C				Not Reported
	Toprol Xl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2011	8202779	EXPEDITED (15-DAY)	Y	OT	AU-ABBOTT-11P-008-0866676-00		49 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack; Suicidal Ideation	Valproic Acid			S				Not Reported
	Lexapro			S				Not Reported
	Caffeine Citrate			S	Oral			Not Reported
	Effexor Xr			S				Not Reported
	Hypericum Perforatum			S				Not Reported
	Lithium			S				Not Reported
	Abilify			S				Not Reported
	Alvesco			S				Not Reported
	Somac			C				Not Reported
	Chondroitin Sulfate (Bovine)\Glucosamine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2011	8205552	EXPEDITED (15-DAY)	Y	HO, OT	FR-PFIZER INC-2011259894		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Vertigo; Vestibular Neuronitis	Cordarone			S	Oral	200 Mg, 1x/Day		Pfizer
	Metformin Hydrochloride			S	Oral	700 Mg, 3x/Day		Not Reported
	Gliclazide			S	Oral	20 Mg, 3x/Day		Not Reported
	Indapamide			S	Oral	1 Df, 1x/Day		Not Reported
	Bisoprolol Fumarate			S	Oral	2 Df, 1x/Day		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg, 1x/Day		Not Reported
	Avodart			S	Oral	0.5 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S	Oral	1 Df, 1x/Day		Not Reported
	Crestor			S	Oral	5 Mg, 1x/Day		Not Reported
	Crestor			S		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2011	8229641	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20111011928			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall	Durogesic			S	Transdermal	One 12.5 Patch And One 25 Patch		Not Reported
	Durogesic			S	Transdermal			Not Reported
	Durogesic			S	Transdermal			Not Reported
	Glucophage			S	Oral	Initiated A Long Time Ago		Not Reported
	Candesartan Cilexetil			S	Oral	Initiated A Long Time Ago		Not Reported
	Oramorph Sr Sustained Release			S	Oral			Not Reported
	Oramorph Sr Sustained Release			S	Oral	8 Doses Three Times A Day		Not Reported
	Colchicine			S	Oral	Initiated A Long Time Ago		Not Reported
	Prazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	Initiated A Long Time Ago		Not Reported
	Repaglinide			C		1-1-1		Not Reported
	Risperdal			C				Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C		1-1-1		Not Reported
	Betahistine Hydrochloride			C				Not Reported
	Betahistine Hydrochloride			C				Not Reported
	Atacand			C				Not Reported
	Acetaminophen			C				Not Reported
	Econazole			C				Not Reported
	Stilnox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2011	8239347	EXPEDITED (15-DAY)	N	CA	1000025091			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Spina Bifida Occulta	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2011	8239600	EXPEDITED (15-DAY)	Y	OT	1000025069			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gouty Arthritis	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2011	8240320	EXPEDITED (15-DAY)	Y	RI, OT	1000025063		77 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Valve Disease	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2011	8188449	EXPEDITED (15-DAY)	Y	HO	TR-PAR PHARMACEUTICAL, INC-2011SCPR003288			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Alprazolam			S	Unknown	0.5 Mg, Daily		Par
	Escitalopram Oxalate			S	Unknown	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2011	8232540	EXPEDITED (15-DAY)	Y	HO, LT, OT	FR-PFIZER INC-2011270641		94 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic	Ramipril			S	Oral	2.5 Mg, Daily		Pfizer

Shock	Escitalopram Oxalate	S	Oral	Unk	Not Reported
	Bisoprolol Fumarate	S	Oral	2.5 Mg, 2x/Day	Not Reported
	Digoxin	S	Oral	1 Df, Unk	Not Reported
	Aspirin	C		Unk	Not Reported
	Lasix	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2011	8232589	EXPEDITED (15-DAY)	Y	HO, OT	FR-PFIZER INC-2011269175		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hypotension; Loss Of Consciousness	Inipomp			S	Oral	Unk		Pfizer
	Urapidil			S	Oral	Unk		Not Reported
	Amlodipine Besylate\Perindopril			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Plavix			C	Oral	75 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2011	8233365	DIRECT	N	DE			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Toxicologic Test Abnormal	Lexapro			S				Forest
	Hydrochlorothiazide			C	Oral			Not Reported
	Neurontin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2011	8240719	EXPEDITED (15-DAY)	Y	HO	1000025196		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Haemorrhage; Seizure; Tongue Biting	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported

	Mianserin	S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2011	8240861	EXPEDITED (15-DAY)	Y	RI, OT	1000025118		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Seizure	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Amoxapine			C				Not Reported
	Meilax (Ethyl Loflazepate)			C				Not Reported
	Dogmatyl (Sulpiride)			C				Not Reported
	Amoban (Zopiclone)			C				Not Reported
	Gaster (Omeprazole)			C				Not Reported
	Metligine (Midodrine Hydrochloride)			C				Not Reported
	Inderal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2011	8242895	EXPEDITED (15-DAY)	Y	RI, OT	1000025142		64 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2011	8243059	EXPEDITED (15-DAY)	Y	HO	1000025140		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D)		Not Reported
	Durogesic			S	Transdermal	0.3333 Dosage Form (1 Dosage Forms,1 In 3 D),Transdermal		Not Reported
	Durogesic			S	Transdermal	Transdermal		Not Reported

	Morphine Sulfate	S	Oral	24 Dosage Form (8 Dosage Forms,3 In 1 D),Oral	Not Reported
	Morphine Sulfate	S	Oral	24 Dosage Form (8 Dosage Forms,3 In 1 D),Oral	Not Reported
	Colchicine	S	Oral	Oral	Not Reported
	Prazepam	S	Oral	3 Dosage Form (1 Dosage Form,3 In 1 D),Oral	Not Reported
	Glucophage (Metformin Hydrochloride) (850 Milligram, Tablets) (Metformin Hydrochloride)	C			Not Reported
	Candesartan (Candesartan Cilexetil) (4 Milligram, Tablets) (Candesartan Cilexetil)	C			Not Reported
	Novonorm (Repaglinide) (2 Milligram) (Repaglinide)	C			Not Reported
	Transipeg (Macrogol)	C			Not Reported
	Betaserc (Betahistine) (Betahistine)	C			Not Reported
	Doliprane (Paracetamol) (Paracetamol)	C			Not Reported
	Econazole (Econazole) (Econazole)	C			Not Reported
	Risperidone	C			Not Reported
	Stilnox (Zolpidem Tartrate) (Zolpidem Tartrate)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2011	8237385	EXPEDITED (15-DAY)	Y	OT	ES-UCBSA-044757		39 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea	Keppra			S	Oral			Not Reported
	Cipralex			S	Oral	Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2011	8242675	DIRECT	N	HO, RI, OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Dysgeusia; Hypertension; Pyrexia; Weight Increased	Lexapro			S		10mg 1x Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2011	8244797	EXPEDITED (15-DAY)	Y	HO	1000025246		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Dysphagia; Infection	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D)		Not Reported
	Rasagiline Mesylate			S	Oral	1 Mg (1 Mg,1 In 1 D),Oral		Not Reported
	Zolpidem (Zolpidem) (Tablets) (Zolpidem)			C				Not Reported
	Stalevo (Stalevo) (Tablets) (Stalevo)			C				Not Reported
	Movicol			C				Not Reported
	Acetylcystein Alternova (Acetylcysteine) (Acetylcysteine)			C				Not Reported
	Omeprazol Actavis (Omeprazole) (Tablets) (Omeprazole)			C				Not Reported
	Triobe (Hepagrisevit Forte-N /01079901/) (Tablets) (Hepagrisevit Forte-N /01079901/)			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Stesold (Diazepam) (Tablets) (Diazepam)			C				Not Reported
	Madopark (Madopar) (Tablets) (Madopar)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2011	8244812	EXPEDITED (15-DAY)	Y	DS, HO, RI, OT	1000025271		70 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Electrocardiogram Qt Prolonged; Fall; Progressive Supranuclear Palsy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Ramipril (Ramipril) (Capsules) (Ramipril)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2011	8244843	EXPEDITED (15-DAY)	Y	DE	1000025231		53 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Hyperhidrosis	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D) ; 10 Mg (10 Mg,1 In 1 D) 10 Mg (10 Mg,1 In 1 D) ; 10 Mg (10 Mg,1 In 1 D)		Not Reported
	Temesta (Lorazepam) (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2011	8244906	EXPEDITED (15-DAY)	Y	HO	1000025241		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hypotension; Iatrogenic Injury; Loss Of Consciousness	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Urapidil			S	Oral	Oral		Not Reported
	Coveram			S	Oral	Oral		Not Reported
	Pantoprazole			S	Oral	Oral		Not Reported
	Plavix (Clopidogrel Bisulfate) (75 Milligram, Tablets) (Clopidogrel Sulfate)			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2011	8244955	EXPEDITED (15-DAY)	Y	RI, OT	1000025238		54 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Impaired Work Ability; Joint Contracture; Memory Impairment; Migraine	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2011	8245024	EXPEDITED (15-DAY)	Y	RI, OT	1000025205		23 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2011	8245906	DIRECT	N	RI, OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation; Drug Ineffective; Mood Swings	Lexapro			S	Oral	20mg 1xd Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2011	8246219	EXPEDITED (15-DAY)	Y	OT	USA/USA/11/0021819			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Mania	Augmentin			S	Oral	875 Mg, 2 In 1 D, Oral		Not Reported
	Abilify			S				Not Reported
	Topamax			S				Not Reported
	Lexapro			S				Not Reported

	Seroquel	S		Not Reported
	Vimpat	C		Not Reported
	Metformin Hydrochloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2011	8239736	NON-EXPEDITED	N		US-ASTRAZENECA-2011SE51937		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Interaction	Lisinopril			S	Oral			Zeneca
	Toprol Xl			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Simvastatin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2011	8239933	EXPEDITED (15-DAY)	Y	HO	DE-GLAXOSMITHKLINE-D0073294A		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Sopor; Suicide Attempt; Vomiting	Lamictal			S	Oral		1 DAY	Glaxosmithkline
	Trimipramine Maleate			S	Oral		1 DAY	Not Reported
	Cipralex			S	Oral	20mg See Dosage Text	1 DAY	Not Reported
	Tavor (Lorazepam)			S	Oral		1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2011	8246236	EXPEDITED (15-DAY)	Y	LT	1000025167		94 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bradycardia; Cardioactive Drug Level Decreased; Cardiogenic Shock; Hyperkalaemia; Overdose	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Bisoprolol Fumarate			S	Oral	5 Mg (2.5 Mg, 2 In 1 D),Oral		Not Reported
	Digoxin			S	Oral	0.8571 Dosage Form (1 Dosage Forms,6 In 1		Not Reported

					Wk),Oral	
	Ramipril		S	Oral	1 Dosage Form (1 Dosage Forms, 1 In 1 D),Oral	Not Reported
	Kardegic (Acetylsalicylate Lysine)		C			Not Reported
	Furosemide		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2011	8241010	EXPEDITED (15-DAY)	Y	HO, OT	US-TEVA-308374USA		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Hypoglycaemia; Hypokalaemia; Overdose; Overdose	Atenolol			S				Not Reported
	Quinapril			S				Not Reported
	Venlafaxine			S				Not Reported
	Amitriptyline			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Insulin Nos			S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2011	7962169	EXPEDITED (15-DAY)	N	RI, OT	1000020555		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Gastric Dilatation; Haemorrhoids; Off Label Use	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2011	8053844	EXPEDITED (15-DAY)	Y	CA, DS	1000021972		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Attention Deficit/Hyperactivity Disorder; Developmental	Citalopram Hydrobromide			S	Transplacental	Transplacental		Not Reported
	Escitalopram Oxalate			S	Transplacental	See Image		Not Reported

Delay; Disturbance In Social Behaviour; Maternal Drugs Affecting Foetus; Speech Disorder Developmental	Transplacental	See Image
	Transplacental	See Image

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2011	8200250	EXPEDITED (15-DAY)	Y	RI, OT	1000024627		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed; Maternal Exposure During Pregnancy; Oligohydramnios	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Trazodone Hydrochloride			S	Oral	12.5 Mg (12.5 Mg, 1 In 1 D), Oral		Not Reported
	Folic Acid			C				Not Reported
	L-Thyroxin (Levothyroxine Sodium) (Levothyroxine Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2011	8202211	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000024629			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Pregnancy; Premature Baby	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2011	8210958	EXPEDITED (15-DAY)	Y	CA, HO	1000024638		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Developmental Hip Dysplasia; Foetal Growth Restriction; Maternal Drugs Affecting Foetus; Premature Baby	Escitalopram Oxalate			S	Transplacental	5 Mg (5 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2011	8224781	EXPEDITED (15-DAY)	Y	HO	1000024747		19 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Dysphagia; Neuroleptic Malignant Syndrome; Pneumothorax; Respiratory Distress	Escitalopram Oxalate			S				Not Reported
	Risperidone			S				Not Reported
	Olanzapine			S				Not Reported
	Lithium Carbonate			S				Not Reported
	Biperiden Hydrochloride			S				Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2011	8254323	EXPEDITED (15-DAY)	Y	RI, OT	1000025141		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qt Prolonged; Ventricular Tachycardia	Lexapro			S		(20 Dosage Forms)		Not Reported
	Multaq			S	Oral	800 Mg (400 Mg,2 In 1 D),Oral		Not Reported
	Aspirin			C				Not Reported
	Xanax			C				Not Reported
	Aciphex (Rabeprazole Sodium)(Rabeprazole Sodium)			C				Not Reported
	Dabigatran Etexilate (Dabigatran Etexilate)(Dabigatran Etexilate)			C				Not Reported
	Metoprolol Succinate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2011	8254608	EXPEDITED (15-DAY)	N	RI, OT	1000025257		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cellulitis; Constipation; Flatulence; Hyperhidrosis; Irritable Bowel Syndrome; Oedema; Vision Blurred;	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1		

Weight Decreased			D), Oral		
	Synthroid (Levothyrozine Sodium) (Levothyroxine Sodium)	C			Not Reported
	Wellbutrin (Bupropion Hydrochloride) (Bupropion Hydrochloride)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2011	8245223	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-16219719		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Head Injury; Increased Appetite; Logorrhoea; Loss Of Consciousness; Pollakiuria; Psychomotor Hyperactivity	Abilify			S	Oral	Continued In 2006; Stopped And Restarted On 07oct2011(10-15mg) Also Taken 30mg		Not Reported
	Abilify			S	Oral	Continued In 2006; Stopped And Restarted On 07oct2011(10-15mg) Also Taken 30mg		Not Reported
	Lexapro			S		Duration:7years Ago		Not Reported
	Lexapro			S		Duration:7years Ago		Not Reported
	Gabitril			S				Not Reported
	Gabitril			S				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2011	8245456	EXPEDITED (15-DAY)	N	HO, OT	PHEH2011US009069			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Dehydration; Fall; Infection; Migraine; Urinary Tract Infection	Loratadine			S		10 Mg, Unk		Novartis
	Gilenya			S	Oral	0.5 Mg, Qd		Not Reported
	Nitrofurantoin			S		100 Mg, Bid		Not Reported
	Lexapro			S		20 Mg, Qd		Not Reported

	Lyrica	S	100 Mg, Tid	Not Reported
	Adderall	S	10 Mg, Bid	Not Reported
	Ambien	S	5 Mg, Qd	Not Reported
	Singulair	S	10 Mg, Unk	Not Reported
	Mirapex	S	0.75 Mg, (0.25 Mg And 0.5 Mg)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2011	8257182	EXPEDITED (15-DAY)	Y	RI, OT	1000025452		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertonia; Hypervigilance; Respiratory Disorder; Seizure; Tachycardia	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Zoloft			S				Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2011	8201994	EXPEDITED (15-DAY)	Y	CA, HO	1000024659			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Foetal Distress Syndrome; Hyperinsulinism; Hypoglycaemia Neonatal; Macrocephaly; Maternal Drugs Affecting Foetus; Patent Ductus Arteriosus; Periventricular Leukomalacia; Premature Baby	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental 5 Mg (5 Mg, 1 In 1 D) Transplacental		Not Reported
					Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental 5 Mg (5 Mg, 1 In 1 D) Transplacental		
					Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental 5 Mg (5 Mg, 1 In 1 D) Transplacental		
	Bromazepam			S	Transplacental	3 Mg (1.5 Mg, 2 In 1 D), Transplacental 1.5 Mg (1.5 Mg, 1 In 1 D),		Not Reported

					Transplacental	Transplacental 3 Mg (1.5 Mg, 2 In 1 D), Transplacental 1.5 Mg (1.5 Mg, 1 In 1 D), Transplacental				

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2011	8237124	EXPEDITED (15-DAY)	Y	RI, OT	1000025051		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Energy Increased; Hypersexuality; Libido Increased; Middle Insomnia; Weight Decreased	Escitalopram Oxalate			S	Oral	5;10 Mg (5; 10 Mg,1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20;5 Mg (20;5 Mg, 1 In 1 D), Oral		Not Reported
	Zopiclone (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2011	8247068	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-16220139			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Anxiety; Menopausal Symptoms; Sjogren'S Syndrome; Swelling; Weight Increased	Abilify			S		Duration Of Therapy:About 5 Yrs Dose Reduced To 2.5mg/D Dose Increased To 15mg/D		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2011	8248000	EXPEDITED (15-DAY)	N	OT	CA-ASTRAZENECA-2011SE67517		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Depression; Dizziness; Dry Mouth; Erection Increased; Fatigue; Increased	Seroquel			S	Oral		2 YR	Zeneca
	Clonazepam			S	Oral		2 YR	Not Reported
	Cipralex			S	Oral			Not Reported

Appetite; Muscular Weakness; Nausea; Somnolence; Suicidal Ideation; Tinnitus; Tremor; Weight Increased	Wellbutrin Xl	S	Oral		3 YR	Not Reported
	Echinacea	C	Oral			Not Reported
	Horse Chestnut Extract	C	Oral			Not Reported
	Milk Thistle	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2011	8258391	EXPEDITED (15-DAY)	Y	RI, OT	1000025369		59 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Neoplasm; Aortic Valve Calcification; Aortic Valve Incompetence; Diarrhoea; Ejection Fraction Decreased; Hyperkinetic Heart Syndrome; Iatrogenic Injury; Left Atrial Dilatation; Left Ventricular Hypertrophy	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Benfluorex Hydrochloride			S	Oral	300 Mg (300 Mg, 1 In 1 D), Oral		Not Reported
	Fenfluramine			S	Oral	2 Dosage Form (2 Dosage Forms, 1 In 1 D). Oral		Not Reported
	Dexfenfluramine Hydrochloride			S		2 Dosage Form (2 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Dihydroergotamine Mesylate			S	Oral	Oral		Not Reported
	Boniva			C				Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported
	Biguanide (Biguanide)			C				Not Reported
	Beta Blocking Agents (Beta Blocking Agents)			C				Not Reported
	Sartan (Losartan Potassium)			C				Not Reported
	Diuretic (Diuretics)			C				Not Reported
	Januvia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2011	8258426	EXPEDITED (15-DAY)	Y	RI, OT	1000025368		39 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, In 1 D), Oral		Not Reported
	Levetiracetam			S	Oral	1000 Mg (500 Mg, 2 In 1		Not Reported

D), Oral

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2011	8258709	EXPEDITED (15-DAY)	N	CA	1000025339		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Stenosis; Bicuspid Aortic Valve; Congenital Hydrocephalus; Maternal Drugs Affecting Foetus; Patent Ductus Arteriosus; Spina Bifida; Ventricular Septal Defect	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2011	8258728	EXPEDITED (15-DAY)	N	CA	1000025347		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital; Maternal Drugs Affecting Foetus; Talipes	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2011	8259144	EXPEDITED (15-DAY)	Y	DS	1000025373		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Diarrhoea	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Betolvex (Cyanocobalamin) (Cyanocobalamin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2011	8169158	EXPEDITED (15-DAY)	Y	HO	1000023889		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Paxil			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Constan (Alprazolam) (Alprazolam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2011	8249189	EXPEDITED (15-DAY)	Y	OT	FR-PFIZER INC-2011277847		46 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Cardiac Murmur; Mitral Valve Incompetence; Tricuspid Valve Incompetence	Effexor			S	Oral	Unk		Pfizer
	Benfluorex Hydrochloride			S	Oral	150 Mg, 3x/Day		Not Reported
	Paroxetine Hydrochloride			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2011	8174965	EXPEDITED (15-DAY)	Y	RI, OT	1000024027			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Fall; Generalised Tonic-Clonic Seizure; Hyperlipidaemia; Hypertension; Nightmare; Red Blood Cell Count Decreased; Seizure	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Lisinopril			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Lovastatin (Lovastatin)(Lovastatin)			C				Not Reported
	Benadryl (Diphenhydramine)(Diphenhydramine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2011	8264038	EXPEDITED (15-DAY)	Y	DE	1000025527			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident At Work; Fall	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2011	8264066	EXPEDITED (15-DAY)	Y	RI, OT	1000025502			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Headache; Muscle Twitching	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Etizolam			S	Oral	Oral		Not Reported
	Tandospirone (Tandospirone) (Tandospirone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2011	8256930	EXPEDITED (15-DAY)	Y	HO	FR-GLAXOSMITHKLINE-B0708135A		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Confusional State; Decreased Appetite; Dehydration; Hepatitis; Hypernatraemia; Thrombocytopenia	Augmentin			S	Oral	2g Per Day	5 DAY	Glaxosmithkline
	Allopurinol			S	Oral			Unknown
	Simvastatin			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral	15mg Per Day		Unknown
	Omeprazole			S	Oral			Unknown
	Memantine			S	Oral	20mg Per Day		Unknown
	Exelon			S	Transdermal	4.6mg Per Day		Unknown
	Isosorbide Dinitrate			C	Unknown	1unit Per Day		Unknown
	Amlodipine Besylate			C	Unknown			Unknown
	Sectral			C	Unknown			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2011	8266280	EXPEDITED (15-DAY)	Y	HO, LT, OT	AMIT20110068		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anoxia; Cardiac Arrest; Cardiogenic Shock; Confusional State; Hypokalaemia; Hypoperfusion; Injury; Overdose; Pulseless Electrical Activity	Amitriptyline Hydrochloride			S	Oral	Oral		Not Reported
	Venlafaxine Hydrochloride			S	Oral	Oral		Not Reported
	Atenolol (Atenolol)			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Quinapril Hydrochloride			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2011	8266864	EXPEDITED (15-DAY)	Y	RI, OT	1000025501		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Laryngeal Oedema; Lichen Planus	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Lamictal			S	Oral Oral Oral Oral Oral	See Image Oral See Image Oral See Image Oral See Image Oral See Image Oral		Not Reported
	Valdoxan (Agomelatine) (Agomelatine)			C				Not Reported
	Multiple Vitamins (Multiple Vitamins) (Multiple Vitamins)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2011	8280047	NON-EXPEDITED	N		1000023867		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Agitation; Diarrhoea	Viibryd			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	20 Mg, (20 Mg, 1 In 1 D), Oral		Not Reported
	Ambien			S				Not Reported

Crestor	C		Not Reported
Gabapentin (Gabapentin)	C		Not Reported
Metformin Hydrochloride	C		Not Reported
Lorazepam	C		Not Reported
Benicar	C		Not Reported
Enalapril Maleate	C		Not Reported
Hydrochlorothiazide (Hydrochlorothiazide)	C		Not Reported
Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2011	7862861	EXPEDITED (15-DAY)	Y	DE, HO	PHHY2011FR21042		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Atrial Fibrillation; Confusional State; Decreased Appetite; Dehydration; Delirium; Diet Refusal; Hepatitis; Hypernatraemia; Leukocytosis; Pneumonia; Productive Cough; Psychomotor Hyperactivity; Pulmonary Embolism; Thrombocytopenia	Allopurinol			S		Unk		Novartis
	Exelon Patch			S	Transdermal	4.6 Mg, Qd		Not Reported
	Exelon Patch			S	Transdermal	4.6 Mg, Qd		Not Reported
	Omeprazole			S		Unk		Not Reported
	Simvastatin			S		Unk		Not Reported
	Simvastatin			S		Unk		Not Reported
	Augmentine			S		2 G, Daily	5 DAY	Not Reported
	Escitalopram Oxalate			S		15 Mg Daily		Not Reported
	Escitalopram Oxalate			S		15 Mg Daily		Not Reported
	Ebixa			S		20 Mg Daily		Not Reported
	Ebixa			S		20 Mg Daily		Not Reported
	Isosorbide Dinitrate			C	Oral	1 Df, Qd		Not Reported
	Isosorbide Dinitrate			C	Oral			Not Reported
	Sectral			C		Unk		Not Reported
	Amlodipine Besylate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2011	8192625	EXPEDITED (15-DAY)	Y	RI, OT	1000024486		32 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Amoxan (Amoxapine)(Amoxapine)			C				Not Reported
	Lexotan (Bromazepam) (Tablets) (Bromazepam)			C				Not Reported
	Flunitrazepam (Flunitrazepam) (Flunitrazepam)			C				Not Reported
	Irribow (Ramosetron Hydrochloride)(Ramosetron Hydrochloride)			C				Not Reported
	Benzalin (Nitrazepam)(Nitrazepam)			C				Not Reported
	Ravona (Pentobarbital Calcium)(Pentobarbital Calcium)			C				Not Reported
	Cymbalta			C				Not Reported
	Seniran (Bromazepam) (Bromazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2011	8193979	EXPEDITED (15-DAY)	Y	HO	1000024257		86 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Electrolytes Decreased; Blood Potassium Decreased; Blood Sodium Decreased; Diarrhoea; Fall; Nausea	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1in 1 D),Oral, 2.5 Mg (2.5 Mg, 1 ,In 1 D),Oral		Not Reported
					Oral	5 Mg (5 Mg, 1in 1 D),Oral, 2.5 Mg (2.5 Mg, 1 ,In 1 D),Oral		
	Indapamide			S	Oral	(1.25 Mg),Oral		Not Reported
	Ativan (Lorazepam) (Tablets) (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2011	8260189	EXPEDITED (15-DAY)		HO, LT	US-ARROW GEN-2011-19493		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiogenic Shock; Overdose; Pulseless Electrical Activity; Respiratory Arrest	Quinapril Hydrochloride	S	Unk	Watson
	Citalopram Hydrobromide	S	Unk	Watson
	Atenolol	S	Unk	Watson
	Venlafaxine Hydrochloride	S	Unk	Not Reported
	Amitriptyline	S	Unk	Not Reported
	Escitalopram Oxalate	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2011	8268868	EXPEDITED (15-DAY)	Y	RI, OT	1000025531		25 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Seizure	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2011	8269585	EXPEDITED (15-DAY)	Y	HO, OT	2011MA016244		77 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Decreased Appetite; Delusion; Depression; Drug Interaction; Essential Tremor; Gait Disturbance; General Physical Health Deterioration; Hypotonia; Insomnia; Irritability; Psychotic Disorder; Toxicity To Various Agents; Tremor	Carbamazepine			S		200 Mg;Q12hr		Purepac
	Escitalopram Oxalate			S		10 Mg;Qd		Not Reported
	Trazodone Hydrochloride			S		100 Mg;Qd		Not Reported
	Amiodarone			C				Not Reported
	Glibenclamide			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2011	8259909	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000025488		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Balance Disorder; Cardiac Arrest; Confusional State; Hypokalaemia; Hypoxic-Ischaemic Encephalopathy; Overdose; Pulseless Electrical Activity	Escitalopram Oxalate	S	Not Reported
	Amitriptyline Hydrochloride	S	Not Reported
	Atenolol (Atenolol)	S	Not Reported
	Venlafaxine	S	Not Reported
	Quinapril Hydrochloride	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2011	8262297	NON-EXPEDITED	Y	OT	US-PFIZER INC-2011283133		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis	Revatio			S		Unk		Pfizer
	Tyvaso			S		216 Mcg (54 Mcg, 4 In 1 D)		Not Reported
	Lexapro			S		Unk		Not Reported
	Tracleer			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2011	8270838	EXPEDITED (15-DAY)	Y	RI, OT	1000025583		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2011	8274010	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000025647		77 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Torsade De Pointes	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Digitoxin			S				Not Reported
	Loesnesium (Magnosolv) (Magnosolv)			C				Not Reported
	Beloc Zok Mite (Metoprolol			C				Not Reported

Succinate) (Metoprolol Succinate)			
Aldactone	C		Not Reported
Torem Cor (Torasemide) (Torasemide)	C		Not Reported
Enoxaparin Sodium	C		Not Reported
Cefuroxim (Cefuroxime Sodium) (Cefuroxime Sodium)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2011	8274138	EXPEDITED (15-DAY)	Y	RI	1000025643			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metrorrhagia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2011	8222200	EXPEDITED (15-DAY)	Y	RI, OT	1000024832			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Legal Problem; Road Traffic Accident	Escitalopram Oxalate			S	Oral	(10 Mg),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2011	8270159	EXPEDITED (15-DAY)	Y	RI, OT	1000025619		46 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Ejection Fraction Decreased; Mitral Valve Incompetence; Tricuspid Valve Incompetence	Escitalopram Oxalate			S	Oral	Oral	12 MTH	Not Reported
	Benfluorex Hydrochloride			S	Oral	3 Dosage Forms (1 Dosage Forms, 3 In 1 D), Oral		Not Reported

	Paroxetine Hydrochloride		S	Oral	Oral	Not Reported
	Effexor		S	Oral	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2011	8198861	EXPEDITED (15-DAY)	Y	DE, HO	IE-SANOFI-AVENTIS-2011SA067252		76 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Hepatitis; Jaundice; Vomiting	Rifadin			S	Oral		6 DAY	Not Reported
	Fusidic Acid			S	Oral		3 WEEK	Not Reported
	Metronidazole			S	Unknown		3 WEEK	Not Reported
	Augmentin			S	Unknown			Not Reported
	Seroquel			S	Oral		2 MTH	Not Reported
	Lexapro			S	Oral		2 MTH	Not Reported
	Esomeprazole			S	Oral		2 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2011	8264238	DIRECT	N	OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Gastrointestinal Disorder	Lexapro			S	Oral	7.5 Mg	2 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2011	8264832	EXPEDITED (15-DAY)	N	HO, OT	US-EISAI INC-E3810-05091-SPO-US		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Neoplasm Malignant; Pruritus	Aciphex			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Levothyroxine			C	Oral			Not Reported
	Pindolol			C	Oral			Not Reported

Diovan	C	Oral		Not Reported
Zantac	C	Oral		Not Reported
Prednisone	C	Oral		Not Reported
Xanax	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2011	8242422	EXPEDITED (15-DAY)	N	RI, OT	1000025057		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Crying; Depression; Nasal Congestion; Speech Disorder; Vomiting	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2011	8274775	EXPEDITED (15-DAY)	Y	HO	DSA_48207_2011		60 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Blood Chloride Decreased; Blood Osmolarity Decreased; Blood Urea Increased; Carcinoembryonic Antigen Increased; Fatigue; Hyponatraemia; Insomnia; Po2 Decreased; Secondary Adrenocortical Insufficiency; Weight Increased	Bupropion Hydrochloride			S		(Df), (Df)		Not Reported
	Escitalopram Oxalate			S		(10 Mg, Frequency Unknown), (Df)		Not Reported
	Mirtazapine			S		(15 Mg, Frequency Unknown), (Df)		Not Reported
	Alprazolam			S		(0.25 Mg Bid), (Df)		Not Reported
	Clonazepam			S		(0.5 Mg, Frequency Unknown)		Not Reported
	Aspirin			C				Not Reported
	Clopidogrel			C				Not Reported
	Simvastatin			C				Not Reported
	Telmisartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2011	8164852	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-		19 YR	Male	USA

16109340

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Suicide Attempt	Abilify			S		Started 6 Years Ago: Before 2005		Not Reported
	Abilify			S		Started 6 Years Ago: Before 2005		Not Reported
	Lexapro			S		Started 6 Years Ago		Not Reported
	Lexapro			S		Started 6 Years Ago		Not Reported
	Topamax			S				Not Reported
	Imitrex			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2011	7851686	EXPEDITED (15-DAY)	Y		1000018765			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Arnold-Chiari Malformation; Congenital Anomaly; Maternal Drugs Affecting Foetus; Spina Bifida; Talipes	Escitalopram Oxalate			S	Transplacental	Transplacental		Not Reported
	Lidocaine			S	Transplacental	0.25 Dosage For (0.5 Dosage Forms, 1in 2 D),Transplacenta, 0-22 Weeks Of Amenorrhea	22 WEEK	Not Reported
	Atarax			S	Transplacental	3.5714 Mg (25 Mg, 1 In 1 Wk),Transplacental,0-22 Weeks Of Amenorrhea	22 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2011	7927928	EXPEDITED (15-DAY)	Y	HO	1000019810		87 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Atrial Fibrillation; Bedridden; C-	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1		Not Reported

Reactive Protein Increased; Confusional State; Decreased Appetite; Dehydration; Delusion; Diet Refusal; Heart Rate Increased; Hepatitis; Hypernatraemia; Leukocytosis; Lung Disorder; Productive Cough; Psychomotor Hyperactivity; Pulmonary Embolism; Thrombocytopenia				D),Oral, Oral		
			Oral	15 Mg (15 Mg, 1 In 1 D),Oral, Oral		
	Memantine Hydrochloride	S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral, Oral		Not Reported
			Oral	20 Mg (20 Mg, 1 In 1 D),Oral, Oral		
	Augmentin	S	Oral	2 Gram (2 Gm, 1 In 1 D),Oral		Not Reported
	Allopurinol	S				Not Reported
	Simvastatin	S				Not Reported
	Omeprazole	S		(1 In 1 D)		Not Reported
	Exelon	S	Transdermal	(4.6 Milligram, Transdermal) (1 In 1 D),Transdermal, Transdermal		Not Reported
			Transdermal	(4.6 Milligram, Transdermal) (1 In 1 D),Transdermal, Transdermal		
	Lagoran (Isosorbide Dinitrate) (Isosorbide Dinitrate)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2011	8202020	EXPEDITED (15-DAY)	Y	CA, HO	1000024660			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Neonatal; Atrial Septal Defect; Caesarean Section; Congenital Hypoparathyroidism; Foetal Distress Syndrome; Hypocalcaemia; Maternal Drugs Affecting Foetus; Premature Baby	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental, 10 Mg (10 Mg, 1 In 1 D), Transplacental, 5 Mg (5 Mg, 1 In 1		Not Reported
					Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental, 10 Mg (10 Mg, 1 In 1 D), Transplacental, 5 Mg (5 Mg, 1 In 1		
					Transplacental	10 Mg (10 Mg, 1 In 1 D),		

	Lexatin (Bromazepam)		S	Transplacental	Transplacental, 10 Mg (10 Mg, 1 In 1 D), Transplacental, 5 Mg (5 Mg, 1 In 1		Not Reported
				Transplacental	3 Mg (1.5 Mg, 2 In 1 D), Transplacental, 1.5 Mg (1.5 Mg, 1 In 1 D), Transplacental		
				Transplacental	3 Mg (1.5 Mg, 2 In 1 D), Transplacental, 1.5 Mg (1.5 Mg, 1 In 1 D), Transplacental		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2011	8239934	EXPEDITED (15-DAY)	Y	HO	2011SP050759		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Dyskinesia; Dystonia; Heart Rate Increased; Stress; Tremor	Remeron			S	Oral	30 Mg;Qd;Po		Not Reported
	Cipralex			S	Oral	20 Mg;Qd;Po ; 10 Mg;Qd;Po		Not Reported
					Oral	20 Mg;Qd;Po ; 10 Mg;Qd;Po		
	Alvesco			C				Not Reported
	Spiriva			C				Not Reported
	Indacaterol			C				Not Reported
	Oxygen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2011	8257397	EXPEDITED (15-DAY)	Y	RI, OT	1000025390		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Feeling Hot; Hyperhidrosis; Insomnia; Peripheral Coldness	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Reflex (Picolamine Salicylate) (Picolamine Salicylate)			C				Not Reported
	Wypax (Lorazepam)			C				Not Reported

(Lorazepam)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2011	8277479	EXPEDITED (15-DAY)	Y	DE, HO	1000025742		83 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychiatric Decompensation; Pulmonary Embolism; Urinary Retention	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2011	8271866	NON-EXPEDITED			US-PFIZER INC-2011291102			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Pristiq			S		Unk		Pfizer
	Xanax			S		Unk		Pfizer
	Atenolol			S		Unk		Pfizer
	Zyprexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Zocor			S		Unk		Not Reported
	Levothroid			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2011	8281558	EXPEDITED (15-DAY)	Y	LT	1000025745		65 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2011	8283445	EXPEDITED (15-DAY)	Y	CA, HO	1000025785		< 1 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydronephrosis; Maternal Drugs Affecting Foetus; Urethral Valves	Escitalopram Oxalate			S	Transplacental	15 Mg (15 Mg, 1 In 1 D), Transplacental, 8 Mg (Temporarily Reduced Dosage) (8 Mg, 1 In 1 D), Transpl		Not Reported
					Transplacental	15 Mg (15 Mg, 1 In 1 D), Transplacental, 8 Mg (Temporarily Reduced Dosage) (8 Mg, 1 In 1 D), Transpl		
	Escitalopram Oxalate			S	Transplacental	15 Mg (15 Mg, 1 In 1 D), Transplacental		Not Reported
	Embolex			S	Transplacental	3000 Iu (3000 Iu, 1 In 1 D), Transplacental		Not Reported
	Amoxicillin			S	Transplacental	Transplacental		Not Reported
	Cotrim			S	Transplacental	Transplacental		Not Reported
	Acetaminophen			S	Transplacental	500 Mg, As Needed, Transplacental		Not Reported
	Femibion (Folic Acid) (Folic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2011	8283624	EXPEDITED (15-DAY)	Y	RI, OT	1000025218		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypokalaemia; Hypophagia	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Memantine Hydrochloride			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Risperidone (Risperidone)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2011	8284746	EXPEDITED (15-DAY)	Y	RI, OT	1000025783		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Campylobacter Infection; Induced Labour; Maternal Drugs Affecting Foetus; Pregnancy; Sinusitis	Escitalopram Oxalate			S	Oral Oral Oral	See Image See Image See Image		Not Reported
	Embolex			S	Subcutaneous	3000 Iu, Subcutaneous		Not Reported
	Acetaminophen			S	Oral	(500 Mg, As Needed), Oral		Not Reported
	Femibion (Folic Acid) (Folic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2011	8228540	EXPEDITED (15-DAY)	Y	HO, OT	DE-JNJFOC-20111012396		16 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Suicide Attempt	Risperdal			S	Oral	1-0-0		Not Reported
	Risperdal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral	1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2011	8246297	EXPEDITED (15-DAY)	Y	RI, OT	1000025239		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperventilation; Hypoaesthesia; Insomnia; Loss Of Consciousness; Muscle Contracture; Nausea; Palpitations	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2011	8282243	DIRECT	Y	OT			11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory	Lexapro			S	Oral	5mg Hs Po 047		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2011	8286160	EXPEDITED (15-DAY)	Y	CA, OT	1000025965			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Developmental Delay; Maternal Drugs Affecting Foetus; Motor Developmental Delay; Speech Disorder	Escitalopram Oxalate			S	Transplacental	20-30 Mg Daily (1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2011	8165769	EXPEDITED (15-DAY)	Y	RI, OT	1000023101		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased	Citalopram Hydrobromide			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Promethazine Hydrochloride			S	Oral	(12.5 Mg, Once), Oral, 1 Week Before Event		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2011	8182633	EXPEDITED (15-DAY)	Y	HO, OT	1000024269		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams;	Viibryd			S	Oral	10 Mg (10 Mg, 1 In 1 D),		Not Reported

Anxiety; Condition Aggravated; Depressed Mood; Dyspnoea; Eczema; Insomnia; Myoclonus; Panic Attack; Paraesthesia; Serotonin Syndrome; Tremor	Viibryd	S	Oral	Oral, 20 Mg (20 Mg, 1 In 1 D),Oral	Not Reported
			Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D),Oral	
			Oral	40 Mg (40 Mg, 1 In 1 D),Oral, 20 Mg (20 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D),Oral	
			Oral	40 Mg (40 Mg, 1 In 1 D),Oral, 20 Mg (20 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D),Oral	
			Oral	40 Mg (40 Mg, 1 In 1 D),Oral, 20 Mg (20 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D),Oral	
	Lexapro	S			Not Reported
	Adderall (Obetrol)-(Obetrol)	C			Not Reported
	Klonopin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2011	8194928	EXPEDITED (15-DAY)	Y	HO	1000024554		91 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Product Prescribing Error; Upper Gastrointestinal Haemorrhage	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Nexium			S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral, 40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
					Oral	40 Mg (40 Mg, 1 In 1 D), Oral, 40 Mg (40 Mg, 1 In 1 D), Oral		
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2011	8198322	EXPEDITED (15-DAY)	Y	HO	1000024555		90 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Neutropenia	Escitalopram Oxalate			S	Oral	(10 Milligram, Tablets) 5 Mg (5 Mg, 1 In 1 D),Oral		Not Reported
	Atrovent (Ipratropium Bromide)(20 Microgram, Tablets)			C				Not Reported
	Pulmicort Turbuhaler			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2011	8200305	EXPEDITED (15-DAY)	Y	CA, DE, HO	1000024563			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Congenital Bladder Anomaly; Congenital Renal Cyst; Congenital Spondylolysis; Maternal Drugs Affecting Foetus; Oligohydramnios; Renal Dysplasia; Renal Fusion Anomaly; Single Umbilical Artery	Escitalopram Oxalate			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental		Not Reported
	Ranitidine			C				Not Reported
	Alprazolam			C				Not Reported
	Doxylamine Succinate (Doxylamine Succinate) (Doxylamine Succinate)			C				Not Reported
	Materna (Materna) (Materna)			C				Not Reported
	Pyridoxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2011	8200371	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000024559		61 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Confusional State; Dizziness; Headache; Insomnia; Myalgia; Seizure; Suicidal Ideation; Visual Impairment	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg,2 In 1 D),Oral		Not Reported
	Ezetrol (Ezetimibe) (Tablets) (Ezetimibe)			C				Not Reported
	Losec (Omeprazole) (Omeprazole)			C				Not Reported
	Vasotec (Enalapril Maleate) (Enalapril Maleate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2011	8286281	EXPEDITED (15-DAY)	Y	RI, OT	1000025945			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Heart Rate Irregular; Malaise; Somnolence; Suicidal Ideation	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg,2 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2011	8182663	EXPEDITED (15-DAY)	Y	HO, LT	FR-JNJFOC-20111004931		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder; Pulmonary Embolism	Risperdal Consta			S	Intramuscular			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2011	8199906	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000024588		10 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Neutropenia; Off Label Use	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Atomoxetine (Atomoxetine) (Capsules) (Atomoxetine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2011	8200145	EXPEDITED (15-DAY)	Y	DE	1000024578		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level Above Therapeutic;	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

Toxicity To Various Agents	Elavil	S	Oral	150 Mg (50 Mg, 3 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2011	8292306	EXPEDITED (15-DAY)	N	CA	1000025955		2 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Spina Bifida	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2011	8292354	EXPEDITED (15-DAY)	Y	RI, OT	1000026001		55 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2011	8292746	EXPEDITED (15-DAY)	Y	RI, OT	1000025974			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Escitalopram Oxalate			S		0.5 Dosage Form (0.5 Dosage Forms, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2011	8341760	NON-EXPEDITED	N	OT	SPV1-2011-00627		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Decreased	Adderall Xr			S	Oral	15 Mg, 1x/Day: Qd, Oral		Not Reported
	Lexapro			S	Oral	10 Mg, 1x/Day: Qd, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2011	8283300	EXPEDITED (15-DAY)	Y	LT	NO-MYLANLABS-2011S1024476		44 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Confusional State; Eye Movement Disorder; Hyporeflexia; Hypoventilation; Muscle Rigidity; Mydriasis; Stupor; Suicide Attempt; Tachycardia	Baclofen			S	Oral	10mgx1 From 201102 = 4mths. Not Used 20110623-20110626 = 4 Days' Break		Mylan
	Cipralex			S	Oral	5 Mg X 1 First 2 Days	7 DAY	Not Reported
	Hiprex			C	Oral	Not Used 20110623-20110626 = 4 Days' Break		Not Reported
	Ascorbic Acid			C	Oral	Not Used 20110623-20110626 = 4 Days' Break		Not Reported
	Marevan			C	Oral	Not Used 20110623-20110626 = 4 Days Break		Not Reported
	Oxazepam			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2011	7724299	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2010175733		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Pancytopenia	Inipomp			S	Oral	40 Mg, 1x/Day		Pfizer
	Ramipril			S	Oral	10 Mg, Unk		Pfizer
	Nifedipine			S	Oral	30 Mg, Daily		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg, As Needed		Not Reported
	Acetaminophen			S	Oral	1 G, 3x/Day		Not Reported
	Diclofenac			S	Cutaneous	1 Df, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2011	8261210	NON-EXPEDITED	N	OT	US-PFIZER INC-2011285355		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Depression; Drug Ineffective; Emotional Disorder; Social Avoidant Behaviour	Zoloft			S	Oral	25 Mg, 1x/Day		Pfizer
	Zoloft			S				Pfizer
	Zoloft			S				Pfizer
	Lexapro			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Ativan			C		Unk		Not Reported
	Abilify			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2011	8263123	EXPEDITED (15-DAY)	Y	HO	PHHY2011IT100889		61 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug Level Increased; Feeling Abnormal; Intentional Overdose; Mood Altered; Self-Injurious Ideation; Sopor	Tegretol			S	Oral	200 Mg, Unk		Novartis
	Tegretol			S	Oral	9 Posological Units	1 DAY	Novartis
	Escitalopram Oxalate			S	Oral	20 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	14 Posological Units	1 DAY	Not Reported
	Prazepam			S	Oral	15 Posological Units	1 DAY	Not Reported
	Brotizolam			S	Oral	0.25 Mg, Unk		Not Reported
	Brotizolam			S	Oral	One Posological Unit	1 DAY	Not Reported
	Simvastatin			C				Not Reported
	Acetylsalicylic Acid			C	Oral	100 Mg, Unk		Not Reported
	Atenolol			C	Oral	100 Mg, Unk		Not Reported
	Metformin Hydrochloride			C				Not Reported
	Tavor (Lorazepam)			C	Oral	2 Posological Unit		Not Reported
	Isoptin			C	Oral	2 Posological Unit		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2011	8298304	EXPEDITED (15-DAY)	Y		1000026049		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Cough; Sleep Disorder	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2011	8301924	EXPEDITED (15-DAY)	Y	HO	1000025993		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Eczema; Feeling Hot; Hypersensitivity; Malaise; Nausea; Pharyngeal Oedema; Presyncope; Rash Pustular; Urticaria; Vision Blurred	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2011	8281392	EXPEDITED (15-DAY)	Y	HO, OT	CH-PFIZER INC-2011297228		18 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Drug Interaction; Extrapyramidal Disorder; Gait Disturbance; Nystagmus; Somnolence; Speech Disorder; Suicidal Ideation	Effexor Xr			S	Oral	75 Mg, 1x/Day		Pfizer
	Levomepromazine			S	Oral	30 Mg, Single	1 DAY	Not Reported
	Levomepromazine			S				Not Reported
	Seroquel			S	Oral	50 Mg, 1x/Day		Not Reported
	Cipralex			S		20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2011	8285495	NON-EXPEDITED	N		US-PFIZER INC-2011300006			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Nausea; Tremor	Diflucan			S		Unk		Pfizer
	Lexapro			S		5 Mg, 1x/Day (1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2011	8243040	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000025120			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported
	Methylphenidate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2011	8304998	EXPEDITED (15-DAY)	Y	HO	2011MA017469		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Emotional Distress; Fatigue; Overdose; Toxicity To Various Agents	Diazepam			S	Oral	Po		Not Reported
	Zyprexa			S	Oral	Po		Not Reported
	Cipralex			S	Oral	Po		Not Reported
	Lyrica			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2011	8306638	EXPEDITED (15-DAY)	Y	HO	1000026141		86 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Disorientation; Hyponatraemia	Escitalopram Oxalate			S	Oral	1 Df (1 Dosage Forms, 1 In 1 D),Oral		Not Reported
	Ofloxacin			S	Oral	2 Df (2 Dosage Forms, 1 In 1 D),Oral		Not Reported
	Flagyl			S	Oral	3 Df (3 Dosage Forms, 1 In 1 D),Oral		Not Reported
	Cordarone (Cordarone)			C				Not Reported
	Coaprovel (Irbesartan, Hydrochlorothiazide)(Irbesartan Hydrochlorothiazide)			C				Not Reported
	Lercan (Lercanidipine			C				Not Reported

Hydrochloride)(Lercanidipine Hydrochloride)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2011	8306800	EXPEDITED (15-DAY)	Y	HO	1000026104		53 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Aspirin			S	Oral	100 Mg (100 Mg, 1 In 1 D),Oral		Not Reported
	Isoptin (Verapamil Hydrochloride)(Tablets)(Verapamil Hydrochloride)			C				Not Reported
	Dancor (Nicorandil) (Tablets) (Nicorandil)			C				Not Reported
	Torem (Torasemide Sodium)(Tablets)(Torasemide Sodium)			C				Not Reported
	Pantozol			C				Not Reported
	Lyrica (Pregabalin) (Tablets) (Pregabalin)			C				Not Reported
	Levemir			C				Not Reported
	Novorapid (Insulin Aspart)(Insulin Aspart)			C				Not Reported
	Imovan (Zopiclone)(Tablets)(Zopiclone)			C				Not Reported
	Recormon (Epoetin Beta)(Epoetin Beta)			C				Not Reported
	Ferinject(Ferric Carboxymaltose)(Ferric Carboxymaltose)			C				Not Reported
	Calcitrol (Calcitriol)(Calcitriol)			C				Not Reported
	Vitamin D (Colecalciferol)(Colecalciferol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2011	8256730	EXPEDITED (15-DAY)	Y	HO	1000025275		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Uveitis	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2011	8306548	EXPEDITED (15-DAY)	N	RI, OT	1000025998			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Crying; Depression; Drug Ineffective; Emotional Disorder; Social Avoidant Behaviour	Lexapro			S				Not Reported
	Zoloft			S				Not Reported
	Cymbalta			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2011	8313175	EXPEDITED (15-DAY)	N	RI, OT	1000026154			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	7876122	EXPEDITED (15-DAY)	Y	RI, OT	1000019124		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Anti Factor X Antibody Positive; Antiphospholipid Antibodies Positive; Blood Immunoglobulin G Increased; Blood Immunoglobulin M Increased; Blood Uric Acid Increased; Drug Ineffective; Gamma-Glutamyltransferase	Escitalopram Oxalate			S	Oral	20 Mg, (20 Mg, 1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg Or 2.5 Mg, Oral		Not Reported
	Telfast (Fexofenadine) (Fexofenadine)			C				Not Reported
	Ranitidin (Ranitidine Hydrochloride) (Ranitidine Hydrocloride)			C				Not Reported
	Pentatop (Cromoglicate Sodium) (Cromoglicate Sodium)			C				Not Reported
	L-Thyroxin (Levothyroxine			C				Not Reported

Increased; Paraesthesia; Perichondritis; Plasmin Inhibitor Increased; Plasminogen Activator Inhibitor Decreased; Systemic Lupus Erythematosus; Urge Incontinence; Von Willebrand'S Factor Antigen Decreased	Sodium) (Levothyroxine Sodium) Tramadol Hydrochloride		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8254345	EXPEDITED (15-DAY)	N	OT	AUR-APL-2011-05774		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anger; Constipation; Deafness; Disturbance In Attention; Drug Ineffective; Erection Increased; Fatigue; Gastric Ulcer; Gynaecomastia; Head Injury; Headache; Influenza; Insomnia; Memory Impairment; Mood Altered; Muscle Spasms; Rash; Rectal Haemorrhage; Somnolence; Suicidal Ideation; Tinnitus; Weight Increased	Mirtazapine (Mirtazapine)			S				Not Reported
	Zoloft			S				Not Reported
	Skelaxin			S				Not Reported
	Effexor			S		3.75 Mg		Not Reported
	Effexor Xr			S				Not Reported
	Celebrex			S				Not Reported
	Geodon			S				Not Reported
	Depakote			S				Not Reported
	Zomig			S				Not Reported
	Imitrex (Sumatriptan)			S				Not Reported
	Soma			S				Not Reported
	Lithium (Lithium)			S				Not Reported
	Risperdal			S				Not Reported
	Seroquel			S				Not Reported
	Zyprexa			S				Not Reported
	Lexapro			S				Not Reported
	Lamictal			S				Not Reported
	Tegretol			S				Not Reported
	Wellbutrin			S				Not Reported
	Buspar			S				Not Reported
	Valium			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Paxil			S				Not Reported
	Cymbalta			S				Not Reported
	Elavil			S				Not Reported

	Klonopin			S						Not Reported
	Ritalin			S						Not Reported
	Pamelor			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295157	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15478886			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Abilify			S	Oral			Not Reported
	Lamictal			S				Not Reported
	Lexapro			S				Not Reported
	Ambien			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295309	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15867856		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms	Abilify			S		5mg Increased To 10 Mg Abt 6 Months Ago	6 MTH	Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295368	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15512361			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia	Abilify			S				Not Reported
	Lexapro			S				Not Reported
	Adderall			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295381	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-15878747		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S				Not Reported
	Lexapro			S		Started With 10 Mg, Increased To 20mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295490	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-15896525		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dizziness; Fatigue	Abilify			S	Oral	Restarted On 11mar2011		Not Reported
	Abilify			S	Oral	Restarted On 11mar2011		Not Reported
	Abilify			S	Oral	Restarted On 11mar2011		Not Reported
	Lexapro			S		10mg On 12aug10 Few Weeks Rest 20mg On 11mar11 Again 30mg 16may11.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295571	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15531163			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Abilify			S				Not Reported
	Zoloft			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295617	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15925662		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Thyroid Stimulating Hormone Decreased	Abilify			S	Oral	On 23may2011 Increased To 15mg		Not Reported

	Lexapro	S	Not Reported
	Wellbutrin	S	Not Reported
	Dexedrine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295670	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15536444		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Abilify			S				Not Reported
	Alcohol			S				Not Reported
	Lexapro			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295732	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-15962277		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295735	NON-EXPEDITED	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-15962616		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Depression; Extrapyramidal Disorder; Fall; Hypersensitivity	Abilify			S		Dose Increased:15mg 16dec2008		Not Reported
	Lexapro			S		Dose Reduced To 10 Mg		Not Reported
	Klonopin			C		As Necessary		Not Reported
	Spironolactone			C				Not Reported
	Simvastatin			C				Not Reported
	Ambien Cr			C				Not Reported
	Lanoxin			C				Not Reported
	Citalopram			C				Not Reported
	Seroquel			C				Not Reported

	Celexa			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295822	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-15568058			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295837	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15993371		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Seroquel			S				Not Reported
	Seroquel			S				Not Reported
	Seroquel			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8295928	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15583974		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8296064	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15603087		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome	Abilify			S				Not Reported

	Lexapro			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8296378	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-16172702		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Crying; Screaming	Abilify			S		2 Tablets At Bedtime.		Not Reported
	Abilify			S		2 Tablets At Bedtime.		Not Reported
	Lexapro			S				Not Reported
	Depakote			S				Not Reported
	Glyburide			C				Not Reported
	Insulin Nos			C				Not Reported
	Lexapro			C				Not Reported
	Celexa			C				Not Reported
	Blood Pressure Medication			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8296398	NON-EXPEDITED	Y		US-BRISTOL-MYERS SQUIBB COMPANY-16189060		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8296452	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15659600		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S		Then Increased To 5mg And Finally Increased To 7.5mg		Not Reported
	Lexapro			S		Maximum Dose		Not Reported
	Mirtazapine			S		Maximum Dose		Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8296459	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15662539			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Weight Increased	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8296663	NON-EXPEDITED	N	LT, OT	US-BRISTOL-MYERS SQUIBB COMPANY-15697436			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicidal Ideation	Abilify			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8296673	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15703598		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Abilify			S			9 MTH	Not Reported
	Lexapro			S			9 MTH	Not Reported
	Ritalin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8296738	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15368665		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sensation Of Foreign Body	Abilify			S		Initial Dose:2mg Dose Decreased From 5mg To 2mg		Not Reported

	Topamax	S		Not Reported
	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8296764	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15375462		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria	Abilify			S		Started From 2mg Increased To 5 Mg		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8296790	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15721988		62 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Weight Decreased	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8296925	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15750771		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Oedema Peripheral; Tremor	Abilify			S		Restart With 1 Mg Daily		Not Reported
	Lexapro			S		Initially 10mg Given,Then 5mg.		Not Reported
	Diazepam			C				Not Reported
	Premarin			C		But Not Sunday		Not Reported
	Prednisone			C				Not Reported
	Clonidine			C				Not Reported
	Albuterol Sulfate			C	Respiratory (inhalation)			Not Reported
	Percocet			C		1df=7.5/325mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8297036	NON-EXPEDITED	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-15797848		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Abnormal; Depression; Drug Ineffective; Fatigue; Food Craving; Insomnia; Weight Increased	Abilify			S		Taken As Conmed Past 3 Years		Not Reported
	Lexapro			S				Not Reported
	Dostinex			C			3 YR	Not Reported
	Quinapril			C			3 YR	Not Reported
	Revatio			C			3 YR	Not Reported
	Diltiazem Hydrochloride			C			3 YR	Not Reported
	Ritalin			C			3 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8297058	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15803414		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S			6 MTH	Not Reported
	Vyvanse			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2011	8297122	NON-EXPEDITED	N		US-BRISTOL-MYERS SQUIBB COMPANY-15432214		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia	Abilify			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Amlodipine			C	Oral			Not Reported
	Aspirin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2011	8082019	EXPEDITED (15-DAY)	Y	DS	1000022125		55 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Blood Pressure Increased; Depression; Macular Oedema; Retinal Vein Thrombosis; Visual Acuity Reduced	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Isradipine			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2011	8291856	EXPEDITED (15-DAY)	Y	RI, OT	1000025941		48 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Pressure Decreased; Diarrhoea; Feeling Abnormal; Peripheral Coldness	Lexapro			S	Oral	10 Mg (10 Mg , 1 In 1 D), Oral		Not Reported
	Dogmatyl (Sulpiride) (Tablets) (Sulipiride)			C				Not Reported
	Milnacipran Hydrochloride (Milnacipran Hydrochloride) (Tablets) (Milnacipran Hydrochloride)			C				Not Reported
	Wypax (Lorazepam (Tablets) (Lorazepam)			C				Not Reported
	Evamyl (Lormetazepam) (Tablets) (Lormetazepam)			C				Not Reported
	Halcion (Triazolam) (Tablets) (Triazolam)			C				Not Reported
	Luvox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2011	8298157	EXPEDITED (15-DAY)	Y	OT	GB-JNJFOC-20111206543			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Disorder	Methylphenidate Hydrochloride	S	Oral		Not Reported
	Cipralex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2011	8299688	EXPEDITED (15-DAY)	N	OT	DE-ASTRAZENECA-2011SE19881		35 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Maternal Exposure During Pregnancy	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Cipralex			S	Oral			Not Reported
	Insulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2011	8300489	EXPEDITED (15-DAY)	Y	HO	US-PFIZER INC-US-WYE-H07238408		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dysarthria; Hypertension; Hypokalaemia; Mental Status Changes; Multiple Drug Therapy	Desvenlafaxine			S	Oral	Blinded Therapy Daily	75 DAY	Pfizer
	Unspecified Ingredient			S	Oral	Blinded Therapy Daily	75 DAY	Pfizer
	Unspecified Ingredient			S	Oral	Blinded Therapy Daily	75 DAY	Pfizer
	Desvenlafaxine			S	Oral	Blinded Therapy Daily	26 DAY	Pfizer
	Unspecified Ingredient			S	Oral	Blinded Therapy Daily	26 DAY	Pfizer
	Unspecified Ingredient			S	Oral	Blinded Therapy Daily	26 DAY	Pfizer
	Ibuprofen			S	Unknown	800 Mg, 3x/Day		Pfizer
	Lyrica			S	Unknown	75 Mg, 1x/Day		Pfizer
	Clonazepam			S	Unknown	1 Mg, 2x/Day		Not Reported
	Loratadine			S	Unknown	10 Mg, 1x/Day		Pfizer
	Robaxin			S	Oral	750 Mg, 3x/Day		Pfizer
	Lexapro			S	Unknown	20 Mg, 1x/Day		Not Reported
	Abilify			S	Unknown	15 Mg, 2x/Day		Not Reported
	Fluticasone			S	Unknown	2 Sprays Daily		Not Reported

Vicodin	S	Unknown	5/500 Prn		Not Reported
Zestoretic	S	Unknown	20/12.5 Daily		Not Reported
Ambien	S	Oral	10 Mg, 1x/Day		Not Reported
Vivelle	S	Transdermal	0.1 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2011	8314939	EXPEDITED (15-DAY)	Y	HO	1000026208			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Neutropenia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Benzylpenicillinic Acid Ethoxyamide			S	Intravenous bolus	12 Gram (3 Gm, 4 In 1 D), Intravenous Bolus		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2011	8316107	EXPEDITED (15-DAY)	N	RI, OT	1000026121		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Off Label Use; Vomiting	Lexapro			S	Oral	10 Mg(10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2011	8316557	EXPEDITED (15-DAY)	N	RI, OT	1000026207			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Feeling Abnormal; Loss Of Consciousness; Speech Disorder; Thought Blocking	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2011	8316636	EXPEDITED (15-DAY)	N	DE	1000026205			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dissociative Identity Disorder; Irritability; Suicidal Ideation	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2011	8316654	EXPEDITED (15-DAY)	Y	RI, OT	1000026206			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Insomnia; Paraesthesia	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Escitalopram Oxalate			S	Oral	0.3333 Dosage Form (1 Dosage Forms, 1 In 3 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2011	7970533	EXPEDITED (15-DAY)	Y	RI, OT	1000020771		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anosmia; Cough; Nasal Obstruction; Oedema Mucosal; Rhinitis; Sinusitis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2011	8192657	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000024112		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pancreatitis Acute	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Truxal Dragees (Chlorprothixene Hydrochloride) (Tablets)			C				Not Reported

(Chlorprothixene Hydrochloride)			
Zolpidem Tartrate	C		Not Reported
Lorazepam	C		Not Reported
Remeron	C		Not Reported
Creon	C		Not Reported
Novothyral (Novothyral) (Tablets) (Novothyral)	C		Not Reported
Pantozol (Pantoprazole Sodium Sesquihydrate)	C		Not Reported
Novalgin (Metamizole Sodium)	C		Not Reported
Dafalgan (Paracetamol) (Tablets) (Paracetamol)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2011	8303058	NON-EXPEDITED	N		US-PFIZER INC-2011306325			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Inappropriate Schedule Of Product Administration; Neuralgia; Paraesthesia	Lyrica			S	Oral	75 Mg, Daily		Pfizer
	Lexapro			S		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2011	8316043	EXPEDITED (15-DAY)	Y	CA, HO	1000026311			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Bone Marrow Disorder; Caesarean Section; Congenital Anomaly; Infection; Maternal Drugs Affecting Foetus; Respiratory Disorder; Therapy Non-Responder	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8100072	EXPEDITED (15-DAY)	Y	LT	1000022516		44 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Asphyxia; Blood Creatine Phosphokinase Increased; Confusional State; Eye Movement Disorder; General Physical Health Deterioration; Hyporeflexia; Hypoventilation; Muscle Rigidity; Mydriasis; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Stupor; Suicide Attempt; Tachycardia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Baclofen			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Baclofen			S	Oral	25 Mg (25 Mg,1 In 1 D),Oral		Not Reported
	Hiprex (Methenamine Hippurate) (Methenamine Hippurate)			C				Not Reported
	Imovane (Zopiclone) (Zopiclone)			C				Not Reported
	Marevan			C				Not Reported
	Bio-C-Vitamin (Ascorbic Acid) (Ascorbic Acid)			C				Not Reported
	Alopam (Oxazepam) (Oxazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8170865	EXPEDITED (15-DAY)	Y	RI, OT	1000024145		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Optic Neuritis; Visual Field Defect	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8281540	EXPEDITED (15-DAY)	Y	RI, OT	1000025748		31 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Arterial Pressure Increased; Pulmonary Hypertension; Tricuspid Valve Incompetence	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Benfluorex Hydrochloride			S	Oral	Oral		Not Reported
	Levothyroxine Sodium			C				Not Reported
	Lantus (Insulin Glargine) (Insulin Glargine)			C				Not Reported
	Humalog			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8294525	EXPEDITED (15-DAY)	Y	HO	2011AP002854		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anoxia; Balance Disorder; Cardiac Arrest; Cardiogenic Shock; Confusional State; Hypokalaemia; Injury; Overdose	Quinapril Hydrochloride			S				Not Reported
	Venlafaxine			S				Not Reported
	Amitriptyline			S				Not Reported
	Atenolol			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Insulin Nos			S	Intravenous bolus	80 Iu;Ivbol		Not Reported
	Insulin Nos			S	Intravenous drip	Ivdrp		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8305676	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2011SE76852		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Quetiapine			S	Oral			Zeneca
	Escitalopram Oxalate			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8306241	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2011SE76936		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Atenolol			S	Oral			Zeneca
	Venlafaxine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Citalopram			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Hydroxyzine			S	Oral			Not Reported
	Alcohol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8306283	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2011SE76787		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Esomeprazole			S	Oral			Astrazeneca
	Metoprolol Succinate			S	Oral			Not Reported
	Metformin Hydrochloride			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported
	Acetaminophen\Unspecified Ingredient			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8306288	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2011SE76743		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lisinopril			S	Oral			Zeneca
	Carvedilol			S	Oral			Not Reported
	Diltiazem Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8306295	EXPEDITED (15-DAY)	Y	DE	US-ASTRAZENECA-2011SE76519		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Quetiapine			S	Oral			Zeneca
	Oxcarbazepine			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported

	Escitalopram Oxalate	S	Oral		Not Reported
	Zolpidem	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8316995	DIRECT	Y	RI			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Hyperpigmentation; Skin Lesion	Lexapro			S		10mg Po Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8318424	EXPEDITED (15-DAY)	Y	RI, OT	1000026421			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2011	8318469	EXPEDITED (15-DAY)	Y	HO	1000026358		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Agitation; Bladder Dilatation; Blood Glucose Increased; Blood Pressure Systolic Increased; Coma; Convulsive Threshold Lowered; Drug Interaction; Generalised Tonic-Clonic Seizure; Postictal State; Right Atrial Hypertrophy; Sinus Tachycardia; Treatment Noncompliance	Escitalopram Oxalate			S	Oral	1 Df (Dosage Forms, 1 In 1 D), Oral		Not Reported
	Baclofen			S	Oral	Oral		Not Reported
	Lithium Carbonate			S	Oral	2 Df (Dosage Forms, 1 In 1 D), Oral		Not Reported
	Amoxapine			S	Oral	2 Df (2 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Stilnox (Zolpidem Tartrate) (Zolpidem Tartrate)			C				Not Reported
	Avlocardyl (Propranolol) (Propranolol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2011	8278467	EXPEDITED (15-DAY)	N	DS	US-TEVA-311528USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Confusional State; Depression; Drug Interaction; Flat Affect; Loss Of Personal Independence In Daily Activities; Memory Impairment; Oedema Peripheral; Pain; Somnolence; Wrong Product Administered	Carbamazepine			S		200 Milligram;		Not Reported
	Docusate Sodium			C				Not Reported
	Ascorbic Acid			C		1000 Milligram;		Not Reported
	Allium Sativum			C		1000 Milligram;		Not Reported
	Calcium Citrate			C		1000 Unknown;		Not Reported
	Cyanocobalamin			C				Not Reported
	Fish Oil			C		1200 Unknown;		Not Reported
	Tocopherol			C				Not Reported
	Ergocalciferol			C		2000 Unknown;		Not Reported
	Chondroitin Sulfate (Bovine)\Glucosamine Sulfate			C		600/560		Not Reported
	Trazodone Hydrochloride			S		50 Milligram;		Not Reported
	Warfarin Sodium			S		1-7 Pills Evening		Not Reported
	Escitalopram Oxalate			S		20 Milligram;		Not Reported
	Levothyroxine Sodium			S		225 Microgram;		Not Reported
	Celecoxib			S		200 Milligram;		Not Reported
	Toviaz			S		8 Milligram;		Not Reported
	Omeprazole			S		1:00 Am		Not Reported
	Furosemide			S		80 Milligram;		Not Reported
	Bupropion Hydrochloride			S		300 Unknown;		Not Reported
	Potassium Chloride			S		20 Milliequivalents;		Not Reported
	Vicodin			S		10/325 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2011	8280449	EXPEDITED (15-DAY)	Y	HO	1000025759		61 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Level Increased; Intentional Overdose; Mood Altered; Social Avoidant Behaviour	Escitalopram Oxalate	S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 280 Mg, Once, Oral	Not Reported
			Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 280 Mg, Once, Oral	
	Tegretol	S	Oral	200 Mg (200 Mg, 1 In 1 D), Oral, 1800 Mg, Once, Oral	Not Reported
			Oral	200 Mg (200 Mg, 1 In 1 D), Oral, 1800 Mg, Once, Oral	
	Brotizolam	S	Oral	0.25 Mg (0.25 Mg, 1 In 1 D), Oral, Dose Ingested Not Reported (Once), Oral	Not Reported
			Oral	0.25 Mg (0.25 Mg, 1 In 1 D), Oral, Dose Ingested Not Reported (Once), Oral	
	Prazepam	S	Oral	150 Mg, Once, Oral	Not Reported
	Simvastatin	C			Not Reported
	Aspirin	C			Not Reported
	Atenolol	C			Not Reported
	Metforal (Metformin Hydrochloride) (Metformin Hydrochloride)	C			Not Reported
	Tavor (Lorazepam)	C			Not Reported
	Isoptin (Verapamil Hydrochloride) (Verapamil Hydrochloride)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2011	8292257	EXPEDITED (15-DAY)	N	HO	IT-BRISTOL-MYERS SQUIBB COMPANY-16274714		84 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Nausea; Vomiting	Irbesartan And Hydrochlorothiazide			S	Oral	1 Dosage Form = 1 Posological Unit	3 YR	Bristol Myers Squibb
	Escitalopram Oxalate			S	Oral	On 20-Sep-2011, Dose Reduced To 10mg		Not Reported
	Seroquel			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2011	8306177	NON-EXPEDITED	N		US-PFIZER INC-2010102880		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Incorrect Dose Administered	Viagra			S	Oral	Unk		Pfizer
	Naspro			C		Unk		Not Reported
	Naproxen			C		500 Mg, Daily		Not Reported
	Vitamin D2			C		Unk		Not Reported
	Viagra			S	Oral	Unk, As Needed		Pfizer
	Viagra			S	Oral	100mg Or 150mg, As Needed		Pfizer
	Viagra			S		100 Mg, Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2011	8323291	EXPEDITED (15-DAY)	Y	RI, OT	1000026322		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Daydreaming; Dizziness; Nausea; Panic Attack	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Yasmin (Drospirenone, Ethylestradiol) (Drospirenone, Ethinylestradiol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2011	8343368	EXPEDITED (15-DAY)	N	OT	DSA_48567_2011			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stress; Suicidal Ideation; Thinking Abnormal	Wellbutrin			S		300 Mg, Bid		Not Reported
	Effexor			S		Df		Not Reported
	Zyprexa			S		Df		Not Reported

Lexapro	S	Df	Not Reported
Adderall Xr	S	Df	Not Reported
Ambien	S	Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2011	8318853	DIRECT	N	DS, HO			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Insomnia; Pain; Personality Change; Social Avoidant Behaviour; Weight Decreased; Withdrawal Syndrome	Lexapro			S		10 Mg A Day 047		Forest
	Geodon			C				Not Reported
	Paxil			C				Not Reported
	Amadryl			C				Not Reported
	Seroquel			C				Not Reported
	Actos			C				Not Reported
	Naproxin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2011	8322839	EXPEDITED (15-DAY)	Y	RI, OT	1000026475		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Aggression; Agitation; Anger; Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Blood Lactate Dehydrogenase Increased; Personality Change	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Ethyl Loflazepate			S	Oral	8 Mg (4 Mg, 2 In 1 D), Oral		Not Reported
	Doral			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2011	8324710	EXPEDITED (15-DAY)	Y	OT	2011AP001167		21 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disturbance In Social Behaviour; Oculogyric Crisis	Risperidone (Risperidone)		S	Oral Oral	Po, 1.5 Mg;Po Po, 1.5 Mg;Po	Not Reported
	Cipralex		S	Oral	20 Mg;Po;Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2011	8270999	EXPEDITED (15-DAY)	Y	HO	1000025614		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Sluggishness; Suicide Attempt	Escitalopram Oxalate			S		Oral, Overdose: Unknown Amount (Once) Oral, Overdose: Unknown Amount (Once)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2011	8310053	EXPEDITED (15-DAY)	Y	HO	1000026159		89 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; International Normalised Ratio Increased; Lung Infection; Melaena; Small Intestinal Haemorrhage; Urinary Tract Infection	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Ketoprofen			S	Intravenous (not otherwise specified)	100 Mg (100 Mg, 1 In 1 D), Intravenous (Not Otherwise Specified)		Not Reported
	Fluindione			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
	Amlodipine Besylate			C				Not Reported
	Furosemide			C				Not Reported
	Zestril (Lisinopril (20 Milligram, Tablets) (Lisinopril)			C				Not Reported
	Tracleer (Bosentan) (125 Milligram, Tablets) (Bosentan)			C				Not Reported
	Stilnox (Zolpidem Tartrate) (10 Milligram, Tablets) (Zolpidem Tartrate)			C				Not Reported
	Eupantol			C				Not Reported
	Anafranil (Clomipramine Hydrochloride) (25 Milligram,			C				Not Reported

	Tablets) (Clomipramine Hydrochloride)			
	Adenuric (Febuxostat) (80 Milligram, Tablets) (Febuxostat)	C		Not Reported
	Mopral (Omeprazole) (Tablets) (Omeprazole)	C		Not Reported
	Aerius (Ebastine) (5 Milligram, Tablets) (Ebastine)	C		Not Reported
	Paracetamol (Paracetamol) (1 Gram) (Paracetamol)	C		Not Reported
	Durogesic	C		Not Reported
	Oxygen (Oxygen) (Gas For Inhalation) (Oxygen)	C		Not Reported
	Tavanic (Levofloxacin) (500 Milligram) (Levofloxacin)	C		Not Reported
	Rocephine (Ceftriaxone Sodium) (Ceftriaxone Sodium)	C		Not Reported
	Speciafoldine (Folic Acid) (Tablets) (Folic Acid)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2011	8325374	EXPEDITED (15-DAY)	Y	RI, OT	1000026483		63 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Ventricular Extrasystoles	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Lipitor (Atorvastatin Calcium) (Tablets) (Atorvastatin Calcium)			C				Not Reported
	Alprazolam (Alprazolam) (Tablets) (Alprazolam)			C				Not Reported
	Cetirizine (Cetirizine) (Tablets) (Cetirizine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2011	8325954	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Condition Aggravated; Confusional State; Depression; Insomnia; Suicidal Ideation	Paroxetine			S	Oral	30mg 1 Day Po		Cadila
	Lexapro			S	Oral	10mg 1 Day Po		Not Reported
	Benazepril Hcl And Hydrochlorothiazide			S				Not Reported
	Phenergan			C				Not Reported
	Premarin			C				Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2011	7935191	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2011096237		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Toxicity To Various Agents	Xanax			S				Pfizer
	Hydroxyzine Hcl			S				Pfizer
	Ibuprofen			S				Pfizer
	Morphine			S				Not Reported
	Cocaine			S				Not Reported
	Oxycontin			S				Not Reported
	Escitalopram			S				Not Reported
	Quetiapine			S				Not Reported
	Cannabis			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2011	8314938	EXPEDITED (15-DAY)	Y	HO, OT	GB-UCBSA-048375			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenomegaly	Metadate			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2011	8315143	EXPEDITED (15-DAY)	Y	HO, LT	DK-MYLANLABS-2011S1025955			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Muscle Spasms; Respiratory Acidosis; Seizure; Sinus Bradycardia; Suicide Attempt	Baclofen			S	Oral			Mylan
	Baclofen			S				Mylan
	Mirtazapine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2011	8315379	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2011310059		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product	Gabapentin			S				Pfizer
	Escitalopram Oxalate			S				Not Reported
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2011	8315587	EXPEDITED (15-DAY)	Y	RI, OT	1000026247		92 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Pressure Systolic Increased; Gastrooesophageal Reflux Disease; Loss Of Consciousness; Therapy Non-Responder	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Rasilez (Aliskiren Fumarate) (Aliskiren Fumarate)			C				Not Reported
	Aricept			C				Not Reported
	Carvedilol			C				Not Reported
	Risperdal			C				Not Reported
	Bup-4 (Propiverine Hydrochloride) (Propiverine Hydrochloride)			C				Not Reported
	Pariet (Rabeprazole Sodium) (Rabeprazole Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2011	8327595	EXPEDITED (15-DAY)	Y	RI, OT	1000026509		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Nerve Disorder	Lexapro			S	Oral	10-20 Mg/Day, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2011	8328682	EXPEDITED (15-DAY)	Y	RI, OT	1000026532		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Malaise; Sense Of Oppression; Suicidal Ideation	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	40 Mg (2 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Ixprim (Tramadol, Paracetamol) (Tramadol, Paracetamol)			C				Not Reported
	Seresta (Oxazepam) (Oxazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2011	8328977	EXPEDITED (15-DAY)	Y	HO	1000026524		67 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Muscular Weakness	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2011	8318047	EXPEDITED (15-DAY)	Y		1000026351			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dyspnoea; Fatigue; Swollen Tongue;	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S		15 Mg (15 Mg, 1 In 1 D),		Not Reported

Vomiting; Weight Increased	10 Mg (10 Mg, 1 In 1 D) 15 Mg (15 Mg, 1 In 1 D), 10 Mg (10 Mg, 1 In 1 D)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2011	8329430	EXPEDITED (15-DAY)	Y	HO	1000026569		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased; Excessive Exercise; Myalgia; Transaminases Increased	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Amisulpride			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2012	8263280	EXPEDITED (15-DAY)		OT	PHEH2011US009343			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Atrophy; Blood Pressure Inadequately Controlled; Drug Ineffective; Feeling Abnormal; Hepatic Enzyme Abnormal; Limb Discomfort; Malaise; Memory Impairment; Muscle Spasms; Nightmare; Ocular Discomfort; Sciatica; Sleep Disorder	Diovan Hct			S		1 Df, Qd		Not Reported
	Diovan Hct			S		1 Df (320/12.5mg), Qd		Not Reported
	Citalopram			S	Oral	20 Mg, Qd		Not Reported
	Oxycodone Hydrochloride			S		5 Mg, Unk		Not Reported
	Fexofenadine			S		180 Mg, Qd		Not Reported
	Gabapentin			S		Unk		Not Reported
	Morphine			S		30 Mg, Tid		Not Reported
	Oxycontin			S		30 Mg, Bid		Not Reported
	Cymbalta			S		30 Mg, Qd		Not Reported
	Cymbalta			S		60 Mg, Qd		Not Reported
	Lyrica			S		25 Mg, Qd		Not Reported
	Lexapro			S		10 Mg, Qd		Not Reported

	Effexor	S	Unk		Not Reported
	Percocet	S	1 Df (5/325mg), Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2012	8317895	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2011311409		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Alprazolam			S	Oral	Unk		Pfizer
	Carbamazepine			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2012	7150299	EXPEDITED (15-DAY)	Y	DS, HO	1000009122		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Aortic Arteriosclerosis; Aortic Valve Incompetence; Cerebral Artery Stenosis; Cerebral Haematoma; Hemiplegia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Citalopram (Citalopram Hydrobromide) (Citalopram Hydrobromide)			C				Not Reported
	Derinox (Naphazoline Nitrate\Prednisolone)			C				Not Reported
	Relpax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2012	8318159	NON-EXPEDITED	N		US-PFIZER INC-2011316017		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Amenorrhoea; Influenza Like Illness	Aldactone			S		100 Mg, 1x/Day (1 In 1 D)		Pfizer
	Lexapro			S	Oral	5 Mg, 1x/Day (1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2012	8318615	EXPEDITED (15-DAY)	Y	DE	FR-SANOFI-AVENTIS-2011SA083215		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Lasix			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Aspirin			C	Oral			Not Reported
	Inexium			C	Oral			Not Reported
	Levothyrox			C	Oral			Not Reported
	Perindopril			C	Oral			Not Reported
	Kaleorid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2012	8318991	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011315930		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Fatigue; Hallucination	Procardia Xl			S		Unk		Pfizer
	Lexapro			S	Oral	2.5 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	5 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	7.5 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	15 Mg, 1x/Day		Not Reported
	Remeron			S		15 Mg, 1x/Day	1 DAY	Not Reported
	Protonix			C		Unk		Not Reported
	Miralax			C		Unk		Not Reported
	Vitamin D2			C		Unk		Not Reported
	Multivitamins			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2012	8215374	EXPEDITED (15-DAY)	Y		1000024743		40 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disturbance In Attention; Dizziness; Nausea; Paraesthesia; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2012	8320266	EXPEDITED (15-DAY)	Y	DE	US-PAR PHARMACEUTICAL, INC-2011SCPR003799		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Death	Clonazepam			S	Oral	Unk, Unknown		Par
	Trazodone Hydrochloride			S	Oral	Unk, Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	Unk, Unknown		Not Reported
	Bupropion Hydrochloride			S	Oral	Unk, Unknown		Not Reported
	Lorazepam			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2012	8320372	EXPEDITED (15-DAY)	Y	DE	US-PAR PHARMACEUTICAL, INC-2011SCPR003872		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Diazepam			S	Oral	Unk, Unknown		Par
	Carvedilol			S	Oral	Unk, Unknown		Not Reported
	Diltiazem			S	Oral	Unk, Unknown		Not Reported
	Lisinopril			S	Oral	Unk, Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2012	8321510	EXPEDITED (15-DAY)	Y	HO	PHHY2011FR113222		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Confusional State; Drug Interaction; Extrapyramidal Disorder; Hyponatraemia	Tegretol Lp			S	Oral	400 Mg, Qd		Novartis
	Loprazolam Mesilate			C				Not Reported
	Bromazepam			C				Not Reported
	Omeprazole			C				Not Reported
	Symbicort			C				Not Reported
	Bronchodual			C				Not Reported
	Escitalopram Oxalate			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2012	8333773	EXPEDITED (15-DAY)	N	HO	1000026439		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hallucination; Joint Injury	Viibryd			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	2.5 Mg (2.5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral ; 7.5 Mg (7.5 Mg,1 In 1 D)		Not Reported
					Oral	2.5 Mg (2.5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral ; 7.5 Mg (7.5 Mg,1 In 1 D)		
					Oral	2.5 Mg (2.5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral ; 7.5 Mg (7.5 Mg,1 In 1 D)		
	Mirapex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2012	8333982	EXPEDITED (15-DAY)	Y	HO	2012SP000070		55 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anhedonia; Anxiety; Apathy; Depression; Disease Recurrence; Disturbance In Attention; Illness Anxiety Disorder; Insomnia; Memory Impairment; Psychotic Disorder; Refusal Of Treatment By Patient; Somatic Delusion; Tardive Dyskinesia; Therapy Non-Responder	Remeron			S		15 Mg/ Qd		Not Reported
	Escitalopram Oxalate			S		40 Mg; Qd		Not Reported
	Amitriptyline Hydrochloride			S		75 Mg; Qd, 25 Mg; Qd, 60 Mg; Qd 75 Mg; Qd, 25 Mg; Qd, 60 Mg; Qd 75 Mg; Qd, 25 Mg; Qd, 60 Mg; Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2012	8335665	EXPEDITED (15-DAY)	Y	DE	DSA_48633_2011		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse; Toxicity To Various Agents	Diltiazem Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Carvedilol			S		(Df)		Not Reported
	Diazepam			S		(Df)		Not Reported
	Escitalopram Oxalate			S		(Df)		Not Reported
	Lisinopril			S		(Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2012	8235024	NON-EXPEDITED	Y	OT	US-PFIZER INC-2011260551		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Lip Swelling; Swollen Tongue	Lisinopril			S		Unk		Not Reported
	Penicillin			S		Unk		Not Reported
	Prinzide			S	Oral	20-12.5 Daily		Not Reported
	Benadryl			S		Unk		Not Reported

	Lexapro	S	Unk	Not Reported
	Mobic	S	Unk	Not Reported
	Celebrex	C	Unk	Not Reported
	Allegra-D	C	Unk	Not Reported
	Amoxicillin	C	Unk	Not Reported
	Nasonex	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2012	8257154	EXPEDITED (15-DAY)	Y	RI, OT	1000025384		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Fluvoxamine			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported
	Losartan Potassium			C				Not Reported
	Goodmin (Britizolam)			C				Not Reported
	Selokeen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2012	8305898	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2011308670		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Hydroxyzine			S	Oral	Unk		Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Temazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2012	8306814	EXPEDITED (15-DAY)	Y	RI, OT	1000026095		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder;	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

Condition Aggravated; Diarrhoea; Drug Intolerance; Sleep Disorder	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2012	8322117	EXPEDITED (15-DAY)	Y	DE	US-PAR PHARMACEUTICAL, INC-2011SCPR003635		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Death	Alprazolam			S	Oral	Unk, Unknown		Par
	Carbamazepine			S	Oral	Unk, Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	Unk, Unknown		Not Reported
	Lamotrigine			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2012	8322966	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20111212473		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Paracetamol		Y	S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported
	Propoxyphene Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2012	8323359	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20120100839		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Facial Bones Fracture; Hallucination, Visual	Tramadol Hydrochloride And Acetaminophen			S	Oral		8 DAY	Not Reported
	Tahor			C	Unknown			Not Reported

Innohep	C	Unknown	Not Reported
Movicol	C	Unknown	Not Reported
Amlodipine Besylate	C	Unknown	Not Reported
Calcium Carbonate	C	Unknown	Not Reported
Allopurinol	C	Unknown	Not Reported
Singulair	C	Unknown	Not Reported
Seretide	C	Unknown	Not Reported
Coumadin	C	Unknown	Not Reported
Escitalopram Oxalate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2012	8323921	NON-EXPEDITED	N		US-ABBOTT-11P-163-0705117-00		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Dyspnoea; Fatigue; Hypothyroidism; Insomnia	Synthroid			S	Oral			Not Reported
	Synthroid			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2012	8336158	EXPEDITED (15-DAY)	Y	DE	1000026593		90 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; General Physical Health Deterioration; Haematoma; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Fluindione			S	Oral	Daily Dose Accroding To Inr, Oral		Not Reported
	Fosamax (Alendronate Sodium) (10 Milligram, Tablets) (Alendronate Sodium)			C				Not Reported
	Sterogyl (Ergocalciferol) (Drops) (Ergocalciferol)			C				Not Reported
	Cacit (Calcium Carbonate,			C				Not Reported

	Cholecalciferol0 (500 Milligram) (Calcium Carbonate, Cholecalciferol)			
	Aricept (Deonepezil Hydrochloride) (5 Milligram, Tablets) (Donepezil Hydrochloride)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2012	8336213	EXPEDITED (15-DAY)	Y	DE	1000026594		88 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Clonus; Hyponatraemia; Seizure	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lasix			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Kardegic (Acetylsalicylate Lysine)			C				Not Reported
	Inexium (Esomeprazole Magnesium) (40 Milligram, Tablets) (Esomeprazole Magnesium)			C				Not Reported
	Levothyrox (Levothyroxine Sodium) (25 Microgram, Tablets) (Levothyroxine Sodium)			C				Not Reported
	Coversyl (Perindopril Erbumine) (5 Milligram, Tablets) (Perinodpril Erbumine)			C				Not Reported
	Kaleorid (Potassium Chloride) (600 Milligram, Tablets) (Potassium Chloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2012	8336406	EXPEDITED (15-DAY)	Y	DS	1000026566		47 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoacusis; Tinnitus	Escitalopram Oxalate			S		20 Mg (20 Mg,1 In 1 D) : 15 Mg (15 Mg,1 In 1 D) :		Not Reported

					10 Mg (10 Mg,1 In 1 D)	
	Viread	C				Not Reported
	Kaletra	C				Not Reported
	Lexomil (Bromazepam)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2012	8324738	EXPEDITED (15-DAY)	N	HO	FR-BRISTOL-MYERS SQUIBB COMPANY-16325938		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerulonephritis Membranous	Orencia			S	Intravenous (not otherwise specified)	Interrupted On 17oct2011		Bristol Myers Squibb
	Atenolol			S	Oral			Sandoz
	Ezetrol			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Acetaminophen			S				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Tanakan			C				Not Reported
	Naftazone			C				Not Reported
	Domperidone			C				Not Reported
	Legalon			C				Not Reported
	Methotrexate			C		Resumed On 04aug2011		Not Reported
	Folic Acid			C		Resumed On 04aug2011		Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2012	8324786	EXPEDITED (15-DAY)	Y	DE	US-JNJFOC-20111212597		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Cyclobenzaprine Hydrochloride			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Salicylates Nos			S	Oral			Not Reported

	Unspecified Ingredient			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2012	8325637	EXPEDITED (15-DAY)	Y	DE	US-ABBOTT-11P-163-0888246-00		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Acetaminophen\Hydrocodone Bitartrate			S		Ingestion		Not Reported
	Escitalopram Oxalate			S		Ingestion		Not Reported
	Buprenorphine Hydrochloride And Naloxone Hydrochloride			S	Sublingual			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2012	8272276	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000024042		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bipolar I Disorder; Overdose; Pain; Psychotic Behaviour; Weight Increased	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D), Oral		Not Reported
	Seroquel			S		300 Mg (300 Mg,Qhs) : 100 Mg (100 Mg, Qam)		Not Reported
	Zyprexa			S				Not Reported
	Chantix			C				Not Reported
	Abilify			C				Not Reported
	Saphris			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2012	7063060	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2009245932		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Trazodone Hydrochloride			S	Unknown			Unknown
	Citalopram			S	Unknown			Not Reported
	Dilantin			S	Unknown			Pfizer
	Zyprexa			S	Unknown	10 Mg, 1x/Day		Not Reported

	Benadryl	S	Unknown	Not Reported
	Seroquel	S	Unknown	Not Reported
	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2012	8314195	EXPEDITED (15-DAY)	Y	HO, LT	DK-TEVA-314897ISR			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Muscle Spasms; Respiratory Acidosis; Seizure; Sinus Bradycardia; Suicide Attempt	Mirtazapine			S				Teva
	Baclofen			S	Oral			Not Reported
	Baclofen			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2012	8319323	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2011-05958		22 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disease Recurrence; Disturbance In Social Behaviour; Oculogyric Crisis	Risperidone (Risperidone)			S	Oral	(1.5 Mg), Oral		Not Reported
	Cipralex			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Orphenadrine Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2012	8328666	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000026580		23 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Delusion Of Reference; Depression; Dysarthria; Dyskinesia; Epilepsy; Hyporeflexia; Loss Of Consciousness; Muscular Weakness;	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Olanzapine			C				Not Reported
	Oxcarbazepine (Oxcarbazepine) (Tablets) (Oxcarbameipine)			C				Not Reported

Neurodegenerative Disorder; Regressive Behaviour; Schizophreniform Disorder; Suicide Attempt; Syncope; Tardive Dyskinesia; Tongue Biting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2012	8328793	DIRECT	Y	LT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Apathy; Decreased Appetite; Decreased Interest; Depressed Mood; Educational Problem; Fatigue; Feelings Of Worthlessness; Hypersomnia; Suicidal Ideation	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2012	8329202	EXPEDITED (15-DAY)	Y	LT	BE-GLAXOSMITHKLINE-B0774379A			Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bulimia Nervosa; Depression; Fatigue; Somnolence	Wellbutrin			S	Unknown			Glaxosmithkline
	Escitalopram Oxalate			S	Unknown			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2012	8329700	EXPEDITED (15-DAY)	Y	LT	FR-PFIZER INC-2012004088		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse;	Xanax			S	Oral	7.5 Mg		Pfizer

Coma; Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Xanax	S	Oral	7.5 Mg	Pfizer
	Propranolol	S	Oral	20 Mg, 1x/Day	Not Reported
	Propranolol	S	Oral	2 G	Not Reported
	Oxazepam	S	Oral	50 Mg, 4x/Day	Not Reported
	Oxazepam	S	Oral	1 G	Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg, 1x/Day	Not Reported
	Escitalopram Oxalate	S	Oral	140 Mg	Not Reported
	Prazepam	C		Unk	Not Reported
	Loprazolam Mesilate	C		1x/Day	Not Reported
	Topiramate	C		50 Mg, 1x/Day	Not Reported
	Atarax	C		3x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2012	8330206	EXPEDITED (15-DAY)	Y	HO	1000026586		63 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Cerebellar Atrophy; Cerebral Ischaemia; Dyskinesia; Gait Disturbance; Hypoaesthesia; Hyporeflexia; Sensory Loss; Slow Speech; Spur Cell Anaemia; Thinking Abnormal; Torticollis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Mirtazapine			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2012	8348985	EXPEDITED (15-DAY)	N	DS, HO	1000026716		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Inability; Neuralgia; Pain; Pain In Extremity; Somatic Symptom	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported

Disorder; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2012	7469255	EXPEDITED (15-DAY)	Y	OT	GB-PFIZER INC-2010082072		26 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death	Sertraline Hydrochloride			S		100 Mg, Daily		Pfizer
	Cipralex			S		20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2012	8277482	EXPEDITED (15-DAY)	Y	CA	1000025765			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Pulmonary Hypertension; Maternal Drugs Affecting Foetus; Ventricular Septal Defect	Escitalopram Oxalate			S	Transplacental	5 Mg (5 Mg, 1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2012	8326358	NON-EXPEDITED	N		US-PFIZER INC-2012002742		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Drug Ineffective; Hypertension; Joint Injury; Sleep Disorder	Pristiq Extended Release			S		50 Mg, 1x/Day		Pfizer
	Pristiq Extended Release			S				Pfizer
	Lipitor			S	Oral	20 Mg, 1x/Day		Pfizer
	Lorazepam			S		1mg Daily		Pfizer
	Lorazepam			S				Pfizer
	Lexapro			S		Unk		Not Reported
	Lunesta			S		3mg Daily		Not Reported
	Synthroid			S		0.125 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2012	8345680	EXPEDITED (15-DAY)	Y	DE	NSR_00366_2012		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning; Respiratory Arrest	Atenolol			S	Oral	Df Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df Oral		Not Reported
	Citalopram			S	Oral	Df Oral		Not Reported
	Lamotrigine			S	Oral	Df Oral		Not Reported
	Venlafaxine			S	Oral	Df Oral		Not Reported
	Hydroxyzine			S	Oral	Df Oral		Not Reported
	Alcohol			S	Oral	Df Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2012	8353240	EXPEDITED (15-DAY)	Y	DE	VAL_00679_2012		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning; Respiratory Arrest	Carbamazepine			S	Oral	(Df Oral)		Not Reported
	Alprazolam			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Lamotrigine			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8065721	EXPEDITED (15-DAY)	N	RI, OT	1000022183		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Transient Ischaemic Attack	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Ritonavir			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Truvada (Tenofovir,			C				Not Reported

	Emtricitabine) (Tablets) (Tenofovir, Emtricitabine)			
	Reyataz (Atazanavir Sulfate) (Capsules) (Atazanavir Sulfate)	C		Not Reported
	Alprazolam (Alprazolam) (0.5 Milligram, Tablets) (Alprazolam)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8286718	EXPEDITED (15-DAY)	Y	DE	1000025960		< 1 DAY	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death Neonatal; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	30 Mg (30 Mg, 1 In 1 D), Transplacental		Not Reported
	Ondansetron			C				Not Reported
	Phenergan (Promethazine) (Promethazine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8309038	EXPEDITED (15-DAY)	Y	DE, OT	US-PFIZER INC-2011310288		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents	Venlafaxine Hydrochloride			S	Oral	Unk		Pfizer
	Atenolol			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Citalopram			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Hydroxyzine			S	Oral	Unk		Not Reported
	Alcohol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8334272	EXPEDITED (15-DAY)	Y	DE	US-UCBSA-049095		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Alprazolam		S	Oral	Not Reported
	Carbamazepine		S	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Not Reported
	Lamotrigine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8334654	EXPEDITED (15-DAY)	Y	HO	PHHY2011FR34636		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Vestibular Syndrome; Arteriosclerosis; Dizziness; Dyskinesia; Epilepsy; Fall; Loss Of Consciousness; Malaise; Nystagmus; Urine Output Decreased; Vertigo; Vomiting	Exelon Patch			S	Transdermal	4.6 Mg/24h	3 DAY	Novartis
	Escitalopram Oxalate			S		5 Mg, Unk	3 DAY	Not Reported
	Aprovel			C		75 Mg, Daily		Not Reported
	Vastarel			C		20 Mg, Bid		Not Reported
	Betahistine Hydrochloride			C		24 Mg, Bid		Not Reported
	Tanakan			C		40 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8349280	EXPEDITED (15-DAY)	Y	DE	IMP_05520_2012		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Metformin Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Unspecified Ingredient			S	Oral	(Df Oral)		Not Reported
	Acetaminophen			S	Oral	(Df Oral)		Not Reported
	Metoprolol Succinate Extended-Release			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Esomeprazole			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8350524	EXPEDITED (15-DAY)	Y	DE	SAN_00012_2012		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Metformin Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Unspecified Ingredient			S	Oral	(Df Oral)		Not Reported
	Acetaminophen\Opium Alkaloids, Hydrochlorides			S	Oral	(Df Oral)		Not Reported
	Metoprolol			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Esomeprazole			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8350898	EXPEDITED (15-DAY)	Y	DE	NSR_00383_2012		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Hydroxyzine			S	Oral	(Df Oral)		Not Reported
	Temazepam			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8351900	EXPEDITED (15-DAY)	Y	DE	IMP_05586_2012		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Bupropion			S	Oral	(Df Oral)		Not Reported
	Heroin			S		(Df Unknown)		Not Reported
	Escitalopram Oxalate			S		(Df Unknown)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8351911	EXPEDITED (15-DAY)	Y	DE	IMP_05554_2012		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning;	Bupropion Hydrochloride			S	Oral	(Df Oral)		Not Reported

Respiratory Arrest	Trazodone Hydrochloride		S	Oral	(Df Oral)	Not Reported
	Escitalopram Oxalate		S	Oral	(Df Oral)	Not Reported
	Clonazepam		S	Oral	(Df Oral)	Not Reported
	Lorazepam		S	Oral	(Df Oral)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8351942	EXPEDITED (15-DAY)	Y	DE	IMP_05550_2012		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning; Respiratory Arrest	Bupropion Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Oxcarbazepine			S	Oral	(Df Oral)		Not Reported
	Lorazepam			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Zolpidem			S	Oral	(Df Oral)		Not Reported
	Quetiapine			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8353099	EXPEDITED (15-DAY)	Y	DE	IMP_05661_2012		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning; Respiratory Arrest	Alprazolam			S	Oral	(Df Oral)		Not Reported
	Carbamazepine			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Lamotrigine			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8353841	EXPEDITED (15-DAY)	Y	DE	DSA_48787_2012		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed	Bupropion			S	Oral	(Df Oral)		Not Reported

Suicide; Poisoning; Respiratory Arrest	Oxcarbazepine		S	Oral	(Df Oral)	Not Reported
	Lorazepam		S	Oral	(Df Oral)	Not Reported
	Escitalopram Oxalate		S	Oral	(Df Oral)	Not Reported
	Zolpidem		S	Oral	(Df Oral)	Not Reported
	Quetiapine		S	Oral	(Df Oral)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8354491	EXPEDITED (15-DAY)	Y	DE	1000026792		60 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Colitis Ulcerative; Electrocardiogram Qt Prolonged; Sepsis	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Ciprofloxacin			S		(600 Mg)		Not Reported
	Fluconazole			S		(200 Mg)		Not Reported
	Piperacillin Sodium\Tazobactam Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8354798	EXPEDITED (15-DAY)	Y	DE	DSA_48670_2011		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning; Respiratory Arrest	Lorazepam			S	Oral	Df Oral		Not Reported
	Escitalopram Oxalate			S	Oral	Df Oral		Not Reported
	Alcohol			S	Oral	Df Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8355046	EXPEDITED (15-DAY)	Y	DE	DSA_48803_2012		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Bupropion			S	Oral	(Df Oral)		Not Reported
	Heroin			S		(Df Unknown)		Not Reported

	Escitalopram Oxalate	S	(Df Unknown)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8355404	EXPEDITED (15-DAY)	Y	DE	DSA_48778_2012		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning; Respiratory Arrest	Bupropion			S	Oral	(Df Oral)		Not Reported
	Trazodone Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Escitalopram Oxalate			S	Oral	(Df Oral)		Not Reported
	Clonazepam			S	Oral	(Df Oral)		Not Reported
	Lorazepam			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8357704	EXPEDITED (15-DAY)	Y	HO	1000026774		83 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Loss Of Consciousness; Postictal State	Escitalopram Oxalate			S		Reduced Dose		Not Reported
	Reminyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2012	8358256	EXPEDITED (15-DAY)	Y	DE	1000026906		48 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate			S				Not Reported
	Hydrocodone Bitartrate And Acetaminophen			S				Not Reported
	Buprenorphine Hydrochloride And Naloxone Hydrochloride			S	Sublingual	Sublingual		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2012	6933684	NON-EXPEDITED	N		US-PFIZER INC-K200900063		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Blood Pressure Increased; Dyspepsia; Oedema Peripheral	Altace			S	Oral	5 Mg, Unk		Pfizer
	Xyrem			S	Oral	2 G, 2x/Day		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Duloxetine Hydrochloride			S		Unk		Not Reported
	Simvastatin			S		Unk		Not Reported
	Pregabalin			S		Unk		Not Reported
	Atenolol			S		Unk		Not Reported
	Hydrochlorothiazide\Triamterene			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2012	8335849	EXPEDITED (15-DAY)	N	HO	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2012-BP-00		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hallucination; Joint Injury	Mirapex			S				Boehringer Ingelheim
	Viibryd			S	Oral	10 Mg		Not Reported
	Lexapro			S	Oral	2.5 Mg	2 WEEK	Not Reported
	Lexapro			S	Oral	5 Mg	2 WEEK	Not Reported
	Lexapro			S		7.5 Mg	2 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2012	8354435	EXPEDITED (15-DAY)	Y	DE	1000027035		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Acetaminophen (Paracetamol)			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported
	Unspecified Ingredient			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2012	8354752	EXPEDITED (15-DAY)	Y	DE	1000027037		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Poisoning; Respiratory Arrest	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Trazodone Hydrochloride			S	Oral	Oral		Not Reported
	Bupropion Hydrochloride			S	Oral	Oral		Not Reported
	Clonazepam			S	Oral	Oral		Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2012	8354771	EXPEDITED (15-DAY)	Y	DE	1000027042		67 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Arrest	Escitalopram Oxalate			S				Not Reported
	Metoprolol Tartrate			S				Not Reported
	Amphetamine			S	Oral	Oral		Not Reported
	Dextroamphetamine			S	Oral	Oral		Not Reported
	Clozapine			S	Oral	Oral		Not Reported
	Solifenacin			S	Oral	Oral		Not Reported
	Simvastatin			S	Oral	Oral		Not Reported
	Memantine Hydrochloride			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2012	8354779	EXPEDITED (15-DAY)	Y	DE	1000027045		35 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Quetiapine Fumarate			S	Oral	Oral		Not Reported
	Gabapentin (Gabapentin)			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2012	8354788	EXPEDITED (15-DAY)	Y	DE	1000027018		62 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Diltiazem Hydrochloride			S	Oral	Oral		Not Reported
	Carvedilol (Carvedilol)			S	Oral	Oral		Not Reported
	Lisinopril (Lisinopril)			S	Oral	Oral		Not Reported
	Diazepam (Diazepam)			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2012	8355783	EXPEDITED (15-DAY)	Y	DE	09-AUR-09644		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Citalopram Hydrobromide			S		10 Mg (10 Mg, 1 In 1 D),		Not Reported
	Zyprexa			S				Not Reported
	Seroquel			S				Not Reported
	Benadryl			S				Not Reported
	Dilantin			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2012	8355890	EXPEDITED (15-DAY)	Y	LT	1000026898		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Circulatory Collapse; Coma; Heart Rate Decreased; Oxygen Saturation Decreased; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral; (140 Mg, Once), Oral		Not Reported
	Propranolol			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral; (2 Gm, Once), Oral		Not Reported
	Oxazepam			S	Oral	200 Mg (200 Mg, 1 In 1 D), Oral; (1 Gm, Once), Oral		Not Reported

			Oral	200 Mg (200 Mg, 1 In 1 D), Oral; (1 Gm, Once), Oral		
	Xanax	S	Oral	(7.5 Mg, Once), Oral		Not Reported
	Atarax	C				Not Reported
	Prazepam	C				Not Reported
	Topiramate	C				Not Reported
	Havlane (Loprazolam Mesilate)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2012	8357262	EXPEDITED (15-DAY)	Y	HO	1000026955		65 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Glomerulonephritis Membranous; Hypoalbuminaemia; Oedema Peripheral; Renal Cyst; Tubulointerstitial Nephritis	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Intravenous (Not Otherwise Specified)		Not Reported
	Ezetimibe			S				Not Reported
	Lansoprazole			S	Oral	Oral		Not Reported
	Caffeine\Opium			S	Oral	Oral		Not Reported
	Atenolol (Atenolol)			S	Oral	Oral		Not Reported
	Tanakan			C				Not Reported
	Etioven (Naftazone)			C				Not Reported
	Biperidys (Domperidone)			C				Not Reported
	Legalon (Silybum Marianum)			C				Not Reported
	Methotrexate			C				Not Reported
	Speciafoldine (Folic Acid)			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2012	8357273	EXPEDITED (15-DAY)	Y	HO	LTI2012A00005		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulum Oesophageal; Duodenitis; Gastritis; Glomerulonephritis	Lansoprazole			S	Oral	Oral (15 Mg,As Required)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg Intravenous	3 YR	Not Reported

Membranous; Oesophageal Disorder; Renal Cyst	Ezetimibe		S	Oral	Oral	Not Reported
	Acetaminophen\Atropa Belladonna\Caffeic Acid\Papaverine		S	Oral	Oral	Not Reported
	Atenolol (Atenolol)		S	Oral	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Oral	Not Reported
				Oral	Oral	
	Alprazolam		C			Not Reported
	Tanakan		C			Not Reported
	Etioven(Naftazone)		C			Not Reported
	Biperidys(Domperidone)		C			Not Reported
	Legalon(Silybum Marianum)		C			Not Reported
	Speciafoldine(Folic Acid)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8339347	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-11P-163-0841251-00		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Transient Ischaemic Attack	Norvir			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Truvada			C	Oral			Not Reported
	Reyataz			C	Oral			Not Reported
	Alprazolam			C	Oral	Twice A Day, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8340009	DIRECT	Y	HO, LT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Agitation; Conversion Disorder; Dyskinesia; General Physical Health Deterioration; Hallucinations, Mixed;	Lexapro			S				Not Reported
	Depakote			C	Oral			Not Reported
	Topamax			C				Not Reported
	Levothyroxine			C				Not Reported

Insomnia; Refusal Of Treatment By Patient; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8357635	EXPEDITED (15-DAY)	Y	HO	1000026789		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Epistaxis; Facial Bones Fracture; Haematoma; Hallucination, Visual	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Acetaminophen\Tramadol			S	Oral	2 To 3 Tablets (362.5 Mg, 1 In 1 D), Oral		Not Reported
	Seretide (Seretide) (Seretide)			C				Not Reported
	Singulair			C				Not Reported
	Atorvastatin Calcium			C				Not Reported
	Innohep (Tinzaparin Sodium) (Tinzaparin Sodium)			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Amlodipine Besylate			C				Not Reported
	Cacit D3 (Lekovit Ca) (Lekovit Ca)			C				Not Reported
	Allopurinol			C				Not Reported
	Movicol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8358151	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2012-00302		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Product Misuse; Respiratory Arrest; Toxicity To Various Agents	Zolpidem			S				Not Reported
	Oxcarbazepine (Oxcarbazepine)			S				Not Reported
	Bupropion Hydrochloride			S				Not Reported
	Lorazepam			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Quetiapine Fumarate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8359966	EXPEDITED (15-DAY)	Y	DE	1000027070		56 YR	Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Citalopram			S	Oral	Oral		Not Reported
	Atenolol (Atenolol)			S	Oral	Oral		Not Reported
	Lamotrigine (Lamotrigine)			S	Oral	Oral		Not Reported
	Venlafaxine			S	Oral	Oral		Not Reported
	Hydroxyzine			S		Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8360012	EXPEDITED (15-DAY)	Y	DE	1000027048		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Oxcarbazepine (Oxcarbazepine)			S	Oral	Oral		Not Reported
	Bupropion Hydrochloride			S	Oral	Oral		Not Reported
	Lorazepam			S	Oral	Oral		Not Reported
	Zolpidem			S	Oral	Oral		Not Reported
	Quetiapine Fumarate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8360032	EXPEDITED (15-DAY)	Y	DE	1000027040		46 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Lorazepam			S	Oral	Oral		Not Reported
	Alcohol			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8360078	EXPEDITED (15-DAY)	Y	HO	1000026942		49 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Musculoskeletal Pain; Tendonitis	Escitalopram Oxalate			S	Oral	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8360129	EXPEDITED (15-DAY)	Y	HO	1000026948		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Arteriosclerosis; Atrial Fibrillation; Condition Aggravated; Dizziness; Epilepsy; Fall; Loss Of Consciousness; Malaise; Nystagmus; Vomiting	Escitalopram Oxalate			S				Not Reported
	Exelon			S				Not Reported
	Betaserc (Betahistine) (24 Milligram, Tablets) (Betahistine)			C				Not Reported
	Aprovel (Irbesartan) (75 Milligram) (Irbesartan)			C				Not Reported
	Vastarel			C				Not Reported
	Tanakan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8360160	EXPEDITED (15-DAY)	Y	RI, OT	1000026950		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed; Foetal Death; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8360194	EXPEDITED (15-DAY)	Y	LT	DSA_48824_2012		18 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bulimia Nervosa; Depression; Disease Recurrence; Fatigue; Somnolence	Wellbutrin		S	Df, One Tablet Every Two Days, Dosage Unknown	Not Reported
	Escitalopram Oxalate		S	Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8362971	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2012-00230		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Carvedilol (Carvedilol)			S				Not Reported
	Lisinopril (Lisinopril)			S				Not Reported
	Diltiazem			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Diazepam (Diazepam)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8377596	EXPEDITED (15-DAY)	Y	DE, HO	AUR-APL-2012-00125		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional Product Misuse; Respiratory Arrest; Toxicity To Various Agents	Atenolol (Atenolol)			S				Not Reported
	Citalopram Hydrobromide			S				Not Reported
	Lamotrigine (Lamotrigine)			S				Not Reported
	Venlafaxine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Hydroxyzine			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8382858	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2012-00101		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Metformin Hydrochloride			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Acetaminophen\Unspecified Ingredient			S				Not Reported
	Metoprolol Tartrate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

	Esomeprazole (Esomeprazole)	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2012	8389226	EXPEDITED (15-DAY)	Y	DE	1000027240		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Alprazolam (Alprazolam)			S	Oral	Oral		Not Reported
	Carbamazepine			S	Oral	Oral		Not Reported
	Lamotrigine (Lamotrigine)			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2012	8281085	EXPEDITED (15-DAY)	Y	HO, OT	US-ASTRAZENECA-2011SE72130		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bipolar I Disorder; Overdose; Pain; Weight Increased	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral	100 Mg Every Morning, 300 Mg Every Night		Not Reported
	Lexapro			S	Oral			Not Reported
	Zyprexa			S				Not Reported
	Chantix			C				Not Reported
	Abilify			C				Not Reported
	Saphris			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2012	8328980	EXPEDITED (15-DAY)	Y	DE, RI, OT	1000026528		86 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Delusion; Hyponatraemia; Pneumonia	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg,1 In 1 D),Oral		Not Reported
	Haloperidol (Haloperidol) (Drops(For Oral Use)) (Haloperidol)			C				Not Reported
	Furosemid (Furosemide)			C				Not Reported

	(Tablets) (Furosemide)			
	Amiodaron Hydrochloride (Amiodarone Hydrochloride) (Tablets) (Amiodarone Hydrochloride)	C		Not Reported
	Digoxin	C		Not Reported
	Potassium Chloride (Potassium Chloride) (Tablets) (Potassium Chloride)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2012	8357734	EXPEDITED (15-DAY)	N	OT	DSA_48839_2012		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Condition Aggravated; Depressed Mood; Depression; Disturbance In Attention; Drug Ineffective; Drug Level Decreased; Hypersomnia; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Maternal Exposure During Pregnancy; Movement Disorder; Overdose; Pregnancy; Stress At Work	Wellbutrin			S	Oral	Df Oral		Not Reported
	Lamictal			S	Oral	300 Mg, Frequency Unknown Oral, Df Oral		Not Reported
					Oral	300 Mg, Frequency Unknown Oral, Df Oral		
	Lamotrigine			S		300 Mg Or 400 Mg A Day		Not Reported
	Microgestin 1/20			S		Df		Not Reported
	Geodon			S		Df		Not Reported
	Effexor			S		Df		Not Reported
	Lexapro			S		Df		Not Reported
	Lipitor			C				Not Reported
	Trileptal			C				Not Reported
	Nortriptyline Hydrochloride			C				Not Reported
	Folplex			C				Not Reported
	Prenatal Vitamins /01549301/			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2012	8382039	EXPEDITED (15-DAY)	Y	HO	1000027109		62 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Fatigue; Monoplegia; Somnolence; Vertigo	Escitalopram Oxalate	S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2012	7254482	EXPEDITED (15-DAY)	Y	HO	1000011010		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Hemianopia Homonymous	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Derinox (Naphazoline Nitrate\Prednisolone)			S	Nasal	3 Dosage Forms (1 Dosage Forms,3 In 1 D),Nasal		Not Reported
	Relpax			S	Oral	(40 Mg,As Required),Oral		Not Reported
	Flurbiprofen			S	Oral	(200 Mg,5 Days Per Month),Oral		Not Reported
	Euphon (Codeine, Erysimum) (Syrup) (Codeine, Erysimum)			C				Not Reported
	Cefuroxime			C				Not Reported
	Paracetamol (Paracetamol) (Capsules) (Paracetamol)			C				Not Reported
	Topalgic [Tramadol Hydrochloride]			C				Not Reported
	Seresta (Oxazepam) (Tablets) (Oxazepam)			C				Not Reported
	Havlane (Loprazolam Mesilate) (Tablets) (Loprazolam Mesilate)			C				Not Reported
	Propranolol (Propranolol) (Capsules) (Propranolol)			C				Not Reported
	Depakote (Valproate Semisodium) (Tablets) (Valproate Semisodium)			C				Not Reported
	Citalopram (Citalopram Hydrobromide) (Tablets) (Citalopram Hydrobromide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2012	8116486	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011197848			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anger; Anxiety; Breast Enlargement; Condition Aggravated; Constipation; Deafness; Dependence; Disturbance In Attention; Drug Ineffective; Ear Disorder; Erection Increased; Fatigue; Feeling Abnormal; Gastric Ulcer; Influenza Like Illness; Insomnia; Memory Impairment; Mood Swings; Muscle Spasms; Pain; Rash; Rectal Haemorrhage; Somnolence; Suicidal Ideation; Therapeutic Product Effect Increased; Unevaluable Event; Weight Increased	Zoloft			S		Unk		Pfizer
	Skelaxin			S		Unk		Pfizer
	Mirtazapine			S		Unk		Not Reported
	Effexor			S		37.5 Mg, Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Geodon			S		Unk		Pfizer
	Depakote			S		Unk		Not Reported
	Zomig			S		Unk		Not Reported
	Imitrex			S		Unk		Not Reported
	Soma			S		Unk		Not Reported
	Lithium			S		Unk		Not Reported
	Risperdal			S		Unk		Not Reported
	Seroquel			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lamictal			S		Unk		Not Reported
	Tegretol			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Buspar			S		Unk		Not Reported
	Valium			S		Unk		Not Reported
	Valium			S				Not Reported
	Valium			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Paxil			S		Unk		Not Reported
	Cymbalta			S				Not Reported
	Cymbalta			S				Not Reported
	Elavil			S		Unk		Not Reported
	Klonopin			S		Unk		Not Reported

	Ritalin	S		Not Reported
	Pamelor	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2012	8343926	EXPEDITED (15-DAY)	N		US-SANOFI-AVENTIS-2011SA002287		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Insomnia	Lasix			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Doxazosin Mesylate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2012	8353403	DIRECT	Y	HO, LT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Agitation; Conversion Disorder; Diet Refusal; Dyskinesia; General Physical Health Deterioration; Hallucinations, Mixed; Hypersomnia; Insomnia; Refusal Of Treatment By Patient; Regressive Behaviour; Stereotypy; Tremor	Lexapro			S	Oral	10mg Daily Oral		Forest
	Depakote			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2012	8354452	EXPEDITED (15-DAY)	Y	RI, OT	1000026818		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Angina Pectoris; Chest Discomfort; Gait Inability;	Lexapro			S		5 Mg (5 Mg, 1 In 1 D)		Not Reported
	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

Hypoglycaemia; Nausea; Pain In Extremity; Restlessness; Vomiting	Trazolan (Trazodone Hydrochloride)	C		Not Reported
	Omeprazol (Omeprazol)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2012	8359890	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2012-00257		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Cyclobenzaprine			S		Unknown		Not Reported
	Amitriptyline			S		Unknown		Not Reported
	Escitalopram Oxalate			S		Unknown		Not Reported
	Salicylate			S		Unknown		Not Reported
	Sennosides A And B			S		Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2012	8360175	EXPEDITED (15-DAY)	Y	RI, OT	1000027110		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroid Neoplasm	Escitalopram Oxalate			S	Oral	1 Df (1 Dosage Forms, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2012	8388600	EXPEDITED (15-DAY)	Y	HO	1000027127		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Amitriptyline Hydrochloride			S	Oral	Oral		Not Reported
	Trandolapril			S	Oral	Oral		Not Reported
	Laxatives (Laxatives)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2012	8388721	EXPEDITED (15-DAY)	Y	RI, OT	1000027141		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nervousness; Peripheral Coldness; Pruritus; Skin Burning Sensation	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Contraceptives (Contraceptives)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2012	8390830	EXPEDITED (15-DAY)	N	LT	1000027130		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Aggression; Confusional State; Decreased Appetite; Disturbance In Attention; Fatigue; Nervous System Disorder; Pollakiuria; Somnolence; Suicidal Ideation; Tinnitus	Escitalopram Oxalate			S	Oral	20 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2012	8346737	EXPEDITED (15-DAY)	Y	HO	FR-GLAXOSMITHKLINE-B0708151A		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria; Thrombocytopenia	Arixtra			S	Subcutaneous	2.5mg Per Day	28 DAY	Glaxosmithkline
	Escitalopram Oxalate			S	Oral	10mg Per Day	30 DAY	Unknown
	Ketoprofen			S	Oral		30 DAY	Unknown
	Sufentanyl			C	Unknown			Not Reported
	Hypnovel			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported
	Solu-Medrol			C	Unknown			Not Reported

	Chlorpromazine Hydrochloride	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2012	8349131	EXPEDITED (15-DAY)	Y	DE	US-MERCK-1201USA02191		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Cardiac Arrest; Respiratory Arrest	Zocor			S	Oral			Merck
	Solifenacin Succinate			S	Oral			Not Reported
	Memantine			S	Oral			Not Reported
	Clozapine			S	Oral			Not Reported
	Dextroamphet Saccharat, Amphet Aspartate, Dextroamphet Sulfate And Amphet Sulfat			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Metoprolol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2012	8349141	EXPEDITED (15-DAY)	Y	DE	US-MERCK-1201USA02206		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Prinivil			S	Oral			Merck
	Carvedilol			S	Oral			Not Reported
	Diltiazem Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2012	8360154	EXPEDITED (15-DAY)	Y	HO	1000026944		2 DAY	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation Neonatal; Dystonia; Flatulence; Hypertonia Neonatal; Maternal Drugs Affecting Foetus; Regurgitation; Retching	Escitalopram Oxalate	S	Transplacental	Transplacental	Not Reported
	Amitriptyline Hydrochloride	S	Transplacental	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Transplacental	Not Reported
	Chlorpromazine	S	Transplacental	75 Mg Daily Before Third Quarter Of Pregnancy (75 Mg, 1 In 1 D), Transplacental, Daily Dose Decrease	Not Reported
			Transplacental	75 Mg Daily Before Third Quarter Of Pregnancy (75 Mg, 1 In 1 D), Transplacental, Daily Dose Decrease	
	Oxazepam	S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental	Not Reported
	Prazepam	S	Transplacental	Switched To Oxazepam At The Third Quarter, Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2012	8390171	EXPEDITED (15-DAY)	N	CA	1000027180		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Torticollis; Maternal Drugs Affecting Foetus	Lexapro			S		Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2012	8390177	EXPEDITED (15-DAY)	N	CA	1000027181		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Maternal Drugs Affecting Foetus; Ventricular Septal	Lexapro			S		Transplacental		Not Reported

Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2012	8391062	EXPEDITED (15-DAY)	N	CA	1000027144		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Maternal Drugs Affecting Foetus; Ventricular Septal Defect	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2012	8391724	EXPEDITED (15-DAY)	Y	LT	1000027206		85 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Dyspnoea; Oedema Mouth; Oropharyngeal Pain; Swollen Tongue	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Irbesartan (Irbesartan) (Irbesartan)			C				Not Reported
	Hidroclorotiazida (Hydrochlorothiazide) (Tablets) (Hydrochlorothiazide)			C				Not Reported
	Lorazepam (Lorazepam) (Tablets) (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2012	6899368	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2009161616		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Blood Pressure Increased; Dyspepsia; Oedema Peripheral	Lyrica			S	Oral	225 Mg		Pfizer
	Atenolol			S		25 Mg, Unk		Pfizer
	Altace			S		5 Mg, Unk		Pfizer
	Simvastatin			S		20 Mg		Not Reported
	Lexapro			S		20 Mg, Unk		Not Reported

	Xyrem	S	Oral	2 G, 2x/Day	Not Reported
	Cymbalta	S		60 Mg	Not Reported
	Triamterene And Hydrochlorothiazide	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2012	8188669	EXPEDITED (15-DAY)	Y	HO, LT, OT	2011SP046144		37 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Increased; Coma; Continuous Haemodiafiltration; Intentional Overdose; Muscle Spasms; Respiratory Acidosis; Seizure; Sinus Bradycardia; Suicide Attempt	Mirtazapine (Mirtazapine)			S		230 Mg;		Not Reported
	Baclofen			S		1859 Mg;;Po, 2500 Mg;		Not Reported
	Escitalopram Oxalate			S		160 Mg;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2012	8305816	EXPEDITED (15-DAY)	Y	RI, OT	1000026059		15 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Haemorrhage; Condition Aggravated; Cushingoid; Eosinophilic Granulomatosis With Polyangiitis; Epistaxis; Nasal Congestion; Overweight; Rash Papular; Rash Pruritic; Scab	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, 20 Mg (20		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, 20 Mg (20		
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, 20 Mg (20		
					Oral	5 Mg (5 Mg, 1 In 1 D),		

		Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, 20 Mg (20	
Nexium (Esomeprazole Magnesium) (Tablets) (Esomeprazole Magnesium)	C		Not Reported
Kalcipos (Calcium Carbonate) (Tablets) (Calcium Carbonate)	C		Not Reported
Niferex (Ferroglycine Sulfate)	C		Not Reported
Folacin (Folic Acid) (Tablets) (Folic Acid)	C		Not Reported
Methotrexat (Methotrexate) (Tablets) (Methotrexate)	C		Not Reported
Prednisolon (Prednisolone) (Tablets) (Prednisolone)	C		Not Reported
Melatonin (Melatonin) (3 Milligram, Tablets) (Melatonin)	C		Not Reported
Theralen (Alimemazine Tartrate) (Tablets) (Alimemazine Tartrate)	C		Not Reported
Symbicort (Budesonide, Formoterol Fumarate) (Tablets) (Budesonide, Formoterol Fumarate)	C		Not Reported
Pulmicort (Budesonide, Formoterol Fumarate) (Tablets) (Budesonide, Formoterol Fumarate)	C		Not Reported
Singulair	C		Not Reported
Pulmozyme (Dornase Alfa) (Dornase Alfa)	C		Not Reported
Aerius (Ebastine) (Ebastine)	C		Not Reported
Tradolan (Tramadol Hydrochloride) (Tramadol Hydrochloride)	C		Not Reported
Stesolid (Diazepam) (Tablets) (Diazepam)	C		Not Reported
Propavan (Propiomazine Maleate) (Tablets) (Propiomazine Maleate)	C		Not Reported
Importal (Lactitol) (Lactitol)	C		Not Reported
Tavegyl (Clemastine Fumarate) (Clemastine Fumurate)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2012	8336334	EXPEDITED (15-DAY)	Y	HO	1000026336		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Albumin Decreased; Blood Bilirubin Increased; Blood Calcium Decreased; Blood Creatine Phosphokinase Increased; Blood Uric Acid Increased; Decreased Appetite; Dehydration; Feeling Abnormal; Insomnia; Lymphocyte Percentage Decreased; Seizure; Tremor; White Blood Cell Count Decreased	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		
	Amoxan (Amoxapine) (Amoxapine)			C				Not Reported
	Depas (Etizolam) (Etizolam)			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Rohypnol (Flunitrazepam) (Flunitrazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2012	8350477	EXPEDITED (15-DAY)	Y	DE	US-SHIRE-ALL1-2012-00264		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Carbamazepine			S	Oral	Unk, Unknown		Shire
	Alprazolam			S	Oral	Unk, Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	Unk, Unknown		Not Reported
	Lamotrigine			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2012	8351853	EXPEDITED (15-DAY)	N	DS, OT	US-TEVA-318288USA		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Spontaneous; Bedridden; Depressed Mood; Depression; Disability; Disturbance In Attention; Drug Level Decreased; Hypersomnia; Loss Of Personal Independence In Daily Activities; Maternal Exposure During Pregnancy; Overdose; Stress	Lamotrigine	S	Oral		Teva
	Lamictal	S	Oral		Not Reported
	Microgestin 1.5/30	S			Not Reported
	Ziprasidone Hydrochloride	S			Not Reported
	Bupropion	S	Oral		Not Reported
	Venlafaxine	S			Not Reported
	Escitalopram Oxalate	S			Not Reported
	Atorvastatin Calcium	C			Not Reported
	Oxcarbazepine	C			Not Reported
	Nortriptyline Hydrochloride	C			Not Reported
	Folplex	C			Not Reported
	Prenatal Vitamins	C			Not Reported
	Fish Oil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2012	8392061	EXPEDITED (15-DAY)	Y	DE, HO	1000027245		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchial Disorder; Cachexia; General Physical Health Deterioration; Lymphadenopathy Mediastinal; Psychomotor Retardation; Pulmonary Fibrosis; Tuberculosis	Escitalopram Oxalate			S	Oral	2 Dosage Form (2 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Dihydroergotamine Mesylate			S	Oral	Oral		Not Reported
	Levothyroxine Sodium			C				Not Reported
	Un-Alfa (Alfacalcidol) (Alfacalcidol)			C				Not Reported
	Tenormin			C				Not Reported
	Fortimel (Protein Supplements) (Protein Supplements)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2012	8392156	EXPEDITED (15-DAY)	Y	RI, OT	1000027319			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apallic Syndrome	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Zolpidem (Zolpidem) (Zolpidem)			C				Not Reported
	Spifen (Ibuprofen) (Ibuprofen)			C				Not Reported

	Dafalgan (Paracetamol) (Paracetamol)	C	Not Reported
	Derinox (Amoxicillin Trihydrate)	C	Not Reported
	Pinaverium (Pinaverium) (Pinaverium)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2012	7140416	EXPEDITED (15-DAY)	Y	DS	1000008839		44 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dyskinesia; Dysphagia; Dystonia; Mastication Disorder; Pain In Jaw; Speech Disorder; Tongue Biting	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Tamoxifen Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2012	8274535	EXPEDITED (15-DAY)	Y	CA, DE	1000025715			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Anencephaly; Maternal Drugs Affecting Foetus	Escitalopram Oxalate			S	Transplacental	10 Mg (10 Mg, 1 In 1 D), Transplacental		Not Reported
	Kenacutan			C				Not Reported
	Acetaminophen			C				Not Reported
	Vitamin (Vitamins Nos)			C				Not Reported
	Gravitamin (Vitamins Nos)			C				Not Reported
	Haemoglobin Iron (Iron)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2012	8353028	EXPEDITED (15-DAY)	N	HO, LT, OT	US-BRISTOL-MYERS SQUIBB COMPANY-16360927		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Dizziness; Drug Ineffective; Dry Mouth;	Abilify			S	Oral	Restarted In Jul,Dec11		Not Reported
	Abilify			S	Oral	Restarted In Jul,Dec11		Not Reported

Headache; Major Depression; Medication Error; Overdose; Paranoia; Suicidal Ideation	Lexapro	S	Not Reported
	Lexapro	S	Not Reported
	Wellbutrin	S	Not Reported
	Wellbutrin	S	Not Reported
	Prozac	S	Not Reported
	Prozac	S	Not Reported
	Seroquel	C	Not Reported
	Neurontin	C	Not Reported
	Topamax	C	Not Reported
	Misoprostol	C	Not Reported
	Actos	C	Not Reported
	Prilosec	C	Not Reported
	Diovan	C	Not Reported
	Glimepiride	C	Not Reported
	Welchol	C	Not Reported
	Celebrex	C	Not Reported
	Vesicare	C	Not Reported
	Singulair	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2012	8353701	DIRECT	Y	OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Deafness; Insomnia; Tinnitus	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2012	8392940	EXPEDITED (15-DAY)	Y	HO	1000027368		19 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Increased; Eye Swelling; Generalised Erythema; Pruritus Generalised; Urticaria; Visual Impairment; White Blood Cell Count Increased	Escitalopram Oxalate			S	Oral	(0.5 Dosage Forms), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	(1 Dosage Forms), Oral		Not Reported
	Macrobid			S	Oral	200 Mg (100 Mg, 2 In 1 D), Oral		Not Reported
	Tramadol Hydrochloride (Tramadol Hydrochloride) (Unknown) (Tramadol			C				Not Reported

	Hydrochloride) Marvelon (Marvelon) (Tablets) (Marvelon)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2012	8336082	EXPEDITED (15-DAY)	Y	HO, LT	1000026582			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Increased; Coma; Continuous Haemodiafiltration; Intentional Overdose; Miosis; Muscle Spasms; Poisoning; Respiratory Acidosis; Seizure; Sinus Bradycardia; Snoring; Suicide Attempt	Lexapro			S		Overdose: Unclear If 160mg Or 100 Mg (Once)		Not Reported
	Mirtazapine (Mirtazapine)			S		Overdose 230 Mg (Once)		Not Reported
	Baclofen			S		Overdose 1850 Mg (Once)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2012	8355189	EXPEDITED (15-DAY)	Y	DE	US-SHIRE-ALL1-2012-00257		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Dextroamphetamine			S	Oral	Unk, Unknown		Shire
	Metoprolol			S	Oral	Unk, Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	Unk, Unknown		Not Reported
	Clozapine			S	Oral	Unk, Unknown		Not Reported
	Memantine			S	Oral	Unk, Unknown		Not Reported
	Solifenacin Succinate			S	Oral	Unk, Unknown		Not Reported
	Simvastatin			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2012	8355689	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2012015409		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Bedridden; Depressed Mood; Depression; Disability; Disturbance In Attention; Drug Level Decreased; Hypersomnia; Loss Of Personal Independence In Daily Activities; Overdose; Stress	Effexor			S		Unk		Pfizer
	Geodon			S		Unk		Pfizer
	Lamictal			S	Oral	300 Mg, Unk		Not Reported
	Lamotrigine			S	Oral	300 Mg, Unk		Not Reported
	Microgestin 1.5/30			S		Unk		Not Reported
	Wellbutrin			S	Oral	Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lipitor			C		Unk		Not Reported
	Trileptal			C		Unk		Not Reported
	Nortriptyline			C		Unk		Not Reported
	Multivitamins			C		Unk		Not Reported
	Prenatal Vitamins			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2012	8356098	DIRECT	N	HO, OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Mental Impairment; Migraine; Speech Disorder; Tremor	Lexapro			S	Oral	1 Tab		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2012	8382052	EXPEDITED (15-DAY)	Y	LT, RI, OT	1000026517		35 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Asthenia; Bradycardia; Cough; Fall; Headache; Loss Of Consciousness; Parosmia; Tic	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported

	Drug For Headache (Drug For Headache) (Drug For Headache)	C	Not Reported
	Dogmatyl (Sulpiride) (Sulpiride)	C	Not Reported
	Wypax (Lorazepam) (Lorazepam)	C	Not Reported
	Zolpidem Tartrate	C	Not Reported
	Depas (Etizolam) (Etizolam)	C	Not Reported
	Lexotan (Bromazepam) (Bromazepam)	C	Not Reported
	Asmedin (Cimetidine) (Dimetidine)	C	Not Reported
	Kipres (Montelukast Sodium) (Montelukast Sodium)	C	Not Reported
	Lansoprazole	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2012	8394307	EXPEDITED (15-DAY)	Y	OT	2012MA000915		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oculogyric Crisis	Risperidone			S	Oral	Po		Not Reported
	Cipralex			S	Oral	20 Mg;Qd;Po		Not Reported
	Orphenadrine Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2012	7870817	EXPEDITED (15-DAY)	Y	HO	1000019020		25 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Encephalopathy; Hepatitis Toxic	Escitalopram Oxalate			S		10 Mg (10 Mg,1 In 1 D)		Not Reported
	Clozapine			S		400 Mg (400 Mg, 1 In 1 D)		Not Reported
	Risperidone			S	Intramuscular	(50 Mg), Intramuscular		Not Reported
	Topiramate			S		400 Mg (400 Mg,1 In 1 D)		Not Reported
	Omeprazole			S		20 Mg (20 Mg,1 In 1 D)		Not Reported
	Biperiden Hydrochloride			S		4 Mg (4 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2012	8357867	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0914299A		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction	Wellbutrin Xl			S	Oral	300mg Per Day		Glaxosmithkline
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2012	8357909	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0928630A		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Dyspepsia; Gastrooesophageal Reflux Disease; Sensation Of Foreign Body	Wellbutrin			S	Oral	160mg Per Day	28 DAY	Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day	26 DAY	Not Reported
	Lexapro			S	Oral	5mg Per Day	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2012	8358491	EXPEDITED (15-DAY)	Y	HO	FR-MERCK-1201USA02794		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerulonephritis Membranous	Zetia			S	Oral			Merck
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Acetaminophen\Caffeine\Opium			S	Oral			Not Reported
	Atenolol			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Tanakan			C	Unknown			Not Reported
	Naftazone			C	Unknown			Not Reported

	Domperidone	C	Unknown		Not Reported
	Legalon	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2012	8360108	NON-EXPEDITED	Y	OT	US-GLAXOSMITHKLINE-A0903029A		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Mania; Oedema Peripheral	Wellbutrin			S	Unknown			Glaxosmithkline
	Saphris			S	Sublingual	20mg At Night		Not Reported
	Lexapro			S	Unknown			Not Reported
	Alprazolam			C		4mg At Night		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2012	8394695	EXPEDITED (15-DAY)	Y	CA, DE	1000027276			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Drugs Affecting Foetus; Spina Bifida	Lexapro			S	Transplacental	20 Mg (20 Mg,1 In 1 D), Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2012	8394696	EXPEDITED (15-DAY)	N	CA	1000027413		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2012	8396430	EXPEDITED (15-DAY)	Y	HO	1000027402		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maternal Drugs Affecting Foetus; Neonatal Respiratory Depression	Lexapro		S	Transplacental	20 Mg (20 Mg,1 In 1 D), Transplacental	Not Reported
	Ferrofumaraat (Ferrous Fumarate)		C			Not Reported
	Omeprazole		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2012	8378738	NON-EXPEDITED	N		US-ABBOTT-11P-163-0860738-00		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Humira			S	Subcutaneous			Not Reported
	Lexapro			S		20 Mg Tablet Daily		Not Reported
	Simvastatin			C				Not Reported
	Fenofibrate			C				Not Reported
	Levothyroxine			C				Not Reported
	Lexapro			C				Not Reported
	Neocon			C		0.5-35-28 Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2012	7841882	EXPEDITED (15-DAY)	Y	HO	ES-ABBOTT-11P-144-0707957-00		25 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Encephalopathy; Hepatitis Toxic	Biperiden			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Clozapine			S				Not Reported
	Risperidone			S	Intramuscular			Not Reported
	Topiramate			S				Not Reported
	Omeprazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2012	8324463	NON-EXPEDITED	Y		US-PFIZER INC-2012002012			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug	Neurontin			S	Oral	300 Mg, 1x/Day	11 DAY	Pfizer

Hypersensitivity; Nausea	Lexapro	S	Unk		Not Reported
	Versed	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2012	8339776	EXPEDITED (15-DAY)		OT	PHHY2012US002247		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Liver Injury	Diclofenac			S		Unk Ukn, Unk		Novartis
	Nitrofurantoin			S		Unk Ukn, Unk		Not Reported
	Lexapro			S		10 Mg, Qd		Not Reported
	Lexapro			S		20 Mg, Qd		Not Reported
	Lisinopril			C		Unk Ukn, Unk		Not Reported
	Furosemide			C		Unk Ukn, Unk		Not Reported
	Loratadine			C		Unk Ukn, Unk		Not Reported
	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2012	8347928	NON-EXPEDITED	Y		US-PFIZER INC-2012013038			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Pristiq Extended Release			S		50 Mg, 1x/Day		Pfizer
	Lorazepam			S		0.5 Mg, 2x/Day		Pfizer
	Prozac			S		30 Mg, Unk	91 DAY	Not Reported
	Lexapro			S		20 Mg, Unk	91 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2012	8382074	EXPEDITED (15-DAY)	Y	HO, LT	1000027054		94 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Atrial Flutter; Chest Pain; Drug	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

Interaction; Dyspnoea; Electrocardiogram Qt Prolonged; Hypotension; Terminal State	Trazodone Hydrochloride		S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral	Not Reported
	Furosemide		C			Not Reported
	Memantine Hydrochloride		C			Not Reported
	Tramadol Hydrochloride		C			Not Reported
	Paracetamol		C			Not Reported
	Nitrofurantoin		C			Not Reported
	Losartan Potassium		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2012	8396425	EXPEDITED (15-DAY)	Y	RI, OT	1000027441		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrasystoles; Malaise	Escitalopram Oxalate			S	Oral	0.5 Dosage Form (0.5 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Prednisone			S		1 Dosage Form (1 Dosage Forms, 1 In 1 D)		Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2012	8242789	EXPEDITED (15-DAY)	Y	RI, OT	1000025018		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amylase Increased; Biliary Dilatation; Lipase Increased	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Truvada			S	Oral	Oral		Not Reported
	Isentress			S	Oral	Oral		Not Reported
	Cyamemazine			S	Oral	Oral		Not Reported
	Approvel(Irbesartan) (Irbesartan)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2012	8329447	EXPEDITED (15-DAY)	Y	RI, OT	1000026545		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Delirium; Drug Interaction; Tremor	Memantine Hydrochloride		S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral	Not Reported
	Escitalopram Oxalate		S	Oral	15 Mg (15 Mg,1 In 1 D),Oral	Not Reported
	Mepyramine Hydrochloride		S	Oral	30 Ml (30 Ml, 1 In 1 D),Oral	Not Reported
	Mepyramine Hydrochloride		S			Not Reported
	Tebetane Compuesto(Alanine, Glutamic Acid, Glycine Prunus Africana)(Capsules)		C		33 Df (3 Dosage Forms, 1 In 1	Not Reported
	Bonviva(Ibandronic Acid)(150 Milligram, Tablets)(Ibandronic Acid)		C			Not Reported
	Lekovit Ca(Calcium Carbonate, Colecalciferol)(Tablets)(Calcium Carbonate, Colecalciferoli)		C			Not Reported
	Pariet (Rabeprazole Sodium)(Tablets)(Rabeprazole Sodium)		C			Not Reported
	Pritor (Telmisartan)(Tablets)(Telmisartan)		C			Not Reported
	Sutril Neo (Torasemide)(Tablets)(Torasemide)		C			Not Reported
	Tardyferon (Ferrous Sulfate)(Ferrous Sulfate)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2012	8373108	NON-EXPEDITED	Y	OT	US-PFIZER INC-2012021057			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Serotonin Syndrome	Zyvox			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2012	8374498	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20120112411		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Tramadol Hydrochloride And Acetaminophen			S	Unknown	As Needed		Not Reported
	Levothyrox			C				Not Reported
	Fortimel			C				Not Reported
	Tareg			C				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2012	8391211	EXPEDITED (15-DAY)	N	OT	AUR-APL-2012-00505		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Blood Pressure Increased; Dyspepsia; Joint Swelling; Oedema Peripheral	Atenolol (Atenolol)			S		(25 Mg), Unknown		Not Reported
	Simvastatin			S		(20 Mg), Unknown		Not Reported
	Lyrica			S		(225 Mg), Unknown		Not Reported
	Altace			S	Oral	(5 Mg), Oral		Not Reported
	Lexapro			S		(20 Mg), Unknown		Not Reported
	Xyrem			S	Oral	4 Gm (2 Gm, 2 In 1 D), Oral		Not Reported
	Cymbalta			S		(60 Mg), Unknown		Not Reported
	Dyazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2012	8399412	EXPEDITED (15-DAY)	Y	HO	1000027365		56 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Asthenia; Blood Albumin Decreased; C-Reactive Protein Increased; Hyponatraemia; Seizure	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Remeron			S	Oral	45 Mg (45 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel			S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported
	Lorazepam			C				Not Reported

	Zolpidem Tartrate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2012	8400039	EXPEDITED (15-DAY)	Y	HO	1000027504			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Petit Mal Epilepsy	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2012	7995993	EXPEDITED (15-DAY)	Y	RI, OT	1000021144		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disease Recurrence; Disturbance In Social Behaviour; Oculogyric Crisis	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (10 Mg, 2 In 1 D), Oral		Not Reported
	Risperidone (Risperidone)			S	Oral	Variable Doses Between 0.25mg And 1 Mg Daily, Oral		Not Reported
	Risperidone (Risperidone)			S	Oral	1.5 Mg (1.5 Mg, 1 In 1 D), Oral		Not Reported
	Orphenadrine (Orphanedrine) (Orphenadrine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2012	8382506	EXPEDITED (15-DAY)	N	OT	US-WATSON-2012-00582		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Bedridden; Depression; Disability; Disturbance In Attention; Drug Level	Microgestin Fe 1.5/30			S	Unknown	Unk		Watson
	Lamictal			S	Oral	300 Mg		Not Reported
	Lamotrigine			S	Oral	300 Mg		Not Reported

Decreased; Hypersomnia; Loss Of Personal Independence In Daily Activities; Maternal Exposure During Pregnancy; Overdose; Stress	Ziprasidone Hydrochloride	S	Unknown	Unk	Not Reported
	Wellbutrin Xl	S	Oral	Unk	Not Reported
	Venlafaxine	S	Unknown	Unk	Not Reported
	Lexapro	S	Unknown	Unk	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported
	Oxcarbazepine	C	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Cyanocobalamin\Folic Acid\Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
	Ascorbic Acid\Biotin\Retinol\Tocopherol	C	Unknown	Unk	Not Reported
	Fish Oil	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2012	8382680	EXPEDITED (15-DAY)	Y	HO	DE-PFIZER INC-DE-WYE-G05122209		38 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Somnolence; Suicide Attempt	Tavor (Lorazepam)			S	Oral	Unk	1 DAY	Pfizer
	Ramipril			S	Oral	25 Mg, Unk	1 DAY	Pfizer
	Abilify			S	Oral	25 Mg, Unk	1 DAY	Not Reported
	Cipralex			S	Oral	50 Mg, Unk	1 DAY	Not Reported
	Pipamperone			S	Oral	100 Mg, Unk	1 DAY	Not Reported
	Levothyroxine Sodium			S	Oral	Unk	1 DAY	Not Reported
	Metformin Hydrochloride			S	Oral	Unk	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2012	8383724	EXPEDITED (15-DAY)	Y	HO	ES-ASTRAZENECA-2012SE05050		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Atacand Hct			S	Oral	32+25 Mg, 1 Df Daily		Astrazeneca
	Atenolol			C	Oral			Not Reported

Atorvastatin	C	Oral			Not Reported
Clopidogrel	C	Oral			Not Reported
Anagastra	C	Oral			Not Reported
Levemir	C	Subcutaneous	100u/Ml , 5 Prefilled Pens, 3 Ml Innolet , 24 Iu Daily		Not Reported
Insulin Aspart	C	Subcutaneous	100u/Ml Injectable Solution In A Prefilled Pen 5, 24 Iu Daily.		Not Reported
Agomelatine	C	Oral			Not Reported
Indapamide	C	Oral			Not Reported
Venlafaxine	C				Not Reported
Escitalopram Oxalate	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2012	8392019	EXPEDITED (15-DAY)	Y	HO	1000027243		69 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Chronic Obstructive Pulmonary Disease; Infection	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Surmontil (Trimipramine) (4 Percent, Drops) (Trimiipramine)			C				Not Reported
	Axotide			C				Not Reported
	Foradil Hfa (Formoterol Fumarate) (Formoterol Fumarate)			C				Not Reported
	Spiriva			C				Not Reported
	Ventolin (Salbutamol) (Salbutamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2012	8399982	EXPEDITED (15-DAY)	N	RI, OT	1000027356		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Heart Rate	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D),		Not Reported

Increased; Migraine; Palpitations				Oral	
	Fentanyl	C			Not Reported
	Soma	C			Not Reported
	Norco (Hydrocodone, Acetaminophen)	C			Not Reported
	Trazodone Hydrochloride	C			Not Reported
	Gabapentin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2012	8401367	EXPEDITED (15-DAY)	Y	HO	1000027494		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Galactorrhoea	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal			S	Oral	1 Mg (1 Mg, 1 In 1 D), Oral		Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2012	8402393	EXPEDITED (15-DAY)	Y	HO	1000027458		93 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Chronic Kidney Disease; Confusional State; Hemianopia Homonymous; Malaise; Refusal Of Treatment By Patient; Speech Disorder; Unevaluable Event	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Acetaminophen\Tramadol			S	Oral	(If Necessary), Oral		Not Reported
	Tareg (Valsartan) (Valsartan)			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Fortimel (Fortimel) (Fortimel)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2012	7522497	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000015081		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Flushing; Headache; Hypotension;	Escitalopram Oxalate			S	Oral	Oral		Not Reported

Loss Of Consciousness; Malaise; Pallor; Palpitations; Phaeochromocytoma; Photopsia; Syncope; Tachycardia; Vertigo; Vision Blurred	Escitalopram Oxalate		S	Oral	20 Mg (20 Mg,1 In 1 D),Oral	Not Reported
	Atarax		C			Not Reported
	Effortil (Etilefrine Hydrochloride) (Etilefrine Hydrochloride)		C			Not Reported
	Imigrane (Sumatriptan) (Sumatriptan)		C			Not Reported
	Levonogestrel W/ Ethinylestradiol (Levonorgestrel Ethinyl Estradiol) (Levonorgestrel, Ethinyl Estrad		C			Not Reported
	Tardyferon (Tardyferon) (Tardyferon)		C			Not Reported
	Tanganil (Acetylleucine) (Acetylleucine)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2012	8328330	EXPEDITED (15-DAY)	Y	HO	1000026561		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Asthenia; Atrioventricular Block First Degree; Cardiac Disorder; Cardiac Ventricular Disorder; Chest Discomfort; Dyspnoea; Electrocardiogram Normal; Electrocardiogram Qt Prolonged; Fatigue; Headache; Nightmare; Palpitations	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D), Oral		
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Mirzaten (Mirtazapine) (Tablets) (Mirtazapine)			C				Not Reported
	Helex (Alprazolam) (Tablets) (Alprazolam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2012	8405537	EXPEDITED (15-DAY)	N	RI, OT	1000027466			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Condition Aggravated; Depressed Mood; Drug Interaction; Feeling Abnormal; Gastrointestinal Infection; Serotonin Syndrome; Stress At Work	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D) Tapered Down From 20 Mg To 5 Mg In Steps Of 2.5 Mg		Not Reported
	Escitalopram Oxalate			S		15 Mg (15 Mg, 1 In 1 D)		Not Reported
	Escitalopram Oxalate			S		20 Mg (20 Mg, 1 In 1 D) 15 Mg (15 Mg, 1 In 1 D)		Not Reported
	Nystatin			S			2 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2012	8405642	EXPEDITED (15-DAY)	Y	HO, OT	UCM201201-000003		60 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Amnesia; Blood Pressure Increased; C-Reactive Protein Increased; Homicidal Ideation; Irritability; Leukocytosis; Major Depression; Neutrophil Count Decreased; Physical Assault; Rash; Rash Erythematous; Somnolence; Speech Disorder; Stress At Work; Suicidal Ideation; Thermal Burn	Meloxicam			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Zolpidem			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2012	8405964	EXPEDITED (15-DAY)	Y	DE	2012MA001183		64 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Incorrect Dose	Mirtazapine			S		30 Mg		Purepac

Administered; Toxicity To Various Agents	Mirtazapine		S	30 Mg	Actavis Totowa
	Escitalopram Oxalate		S	10 Mg	Not Reported
	Depakin Chrono		S	300 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2012	7055163	EXPEDITED (15-DAY)	Y	HO	1000007206		58 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Gastric Ulcer Haemorrhage	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Voltaren			S	Oral	(50 Mg), Oral		Not Reported
	Dafalgan (Paracetamol) (Tablets) (Paracetamol)			C				Not Reported
	Blopress (Candesartan Cilexetil) (Tablets) (Candesartan Cilexetil)			C				Not Reported
	Inderal (Propranolol) (Tablets) (Propranolol)			C				Not Reported
	Imigran (Sumatriptan) (Tablets) (Sumatriptan)			C				Not Reported
	Xanax (Alprazolam) (Tablets) (Alprazolam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2012	8286741	EXPEDITED (15-DAY)	Y	HO	1000025868		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Asthenia; Gastric Ulcer; Oesophageal Haemorrhage	Escitalopram Oxalate			S	Oral	Oral		Not Reported
	Voltaren			S	Oral	150 Mg (50 Mg, 3 In 1 D), Oral		Not Reported
	Xanax (Alprazolam) (Tablets) (Alprazolam)			C				Not Reported
	Inderal (Propranolol Hydrochloride) (Tablets) (Propranolol Hydrochloride)			C				Not Reported
	Imigran (Sumatriptan) (Tablets) (Sumatriptan)			C				Not Reported

	Dafalgan (Paracetamol) (Tablets) (Paracetamol)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2012	8314830	EXPEDITED (15-DAY)	N	RI, OT	1000026217		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Neoplasm Malignant	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2012	8388007	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0903725A		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Diarrhoea; Dizziness; Drug Interaction; Flushing; Headache; Malaise; Nausea	Lamictal			S	Oral			Glaxosmithkline
	Lexapro			S	Oral	5mg Per Day		Not Reported
	Imodium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2012	8394899	DIRECT	N	DS, HO				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Disturbance In Attention; Dyskinesia; Inappropriate Affect; Logorrhoea; Memory Impairment; Mental Status Changes; Panic Attack	Citalopram Hydrobromide			S	Oral	Citalopram 20 Mg Daily By Mouth		Not Reported
	Lexapro			S	Oral	Lexapro 10 Mg Daily By Mouth		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2012	8395431	DIRECT	Y				19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Trismus	Lexapro			S	Oral	Lexapro 5mg 1 Up To 2qd Po Starting Dose		Forest
	Lexapro			S	Oral	Lexapro 20mg 1qd Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2012	8403973	EXPEDITED (15-DAY)	Y	OT	2012AP000194		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Fibrosis; Hepatitis; Liver Injury	Loratadine			S				Not Reported
	Lisinopril			S				Not Reported
	Diclofenac			S				Not Reported
	Nitrofurantoin			S				Not Reported
	Furosemide			S				Not Reported
	Escitalopram Oxalate			S		10 Mg;Qd, 20 Mg;Qd		Not Reported
	Cymbalta			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2012	8406467	EXPEDITED (15-DAY)	Y	OT	1000027417		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage	Lexapro			S	Oral	15 Mg (15 Mg,1 In 1 D),Oral		Not Reported
	Dilantin			C				Not Reported
	Neurontin			C				Not Reported
	Avalide (Karvea Hct) (Karvea Hct)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2012	8406480	EXPEDITED (15-DAY)	N	CA	1000027562		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Aortic Stenosis; Hypoplastic Left Heart Syndrome; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2012	8406555	EXPEDITED (15-DAY)	Y		1000027384			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia	Lexapro			S				Not Reported
	Adderall			S				Not Reported
	Dexilant			S				Not Reported
	Zetia (Ezetimibe)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2012	8200520	EXPEDITED (15-DAY)	Y	RI, OT	1000024586			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Drugs Affecting Foetus; Supraventricular Extrasystoles	Lexapro			S		20 Mg (20 Mg, 1 In 1),		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2012	8410448	EXPEDITED (15-DAY)	N	RI, OT	1000027376		13 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Suicidal Ideation; Treatment Noncompliance	Escitalopram Oxalate			S	Oral	15 Mg (15 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg,1 In 1 D),Oral : 15 Mg (15 Mg,1 In 1 D),Oral		Not Reported
					Oral	20 Mg (20 Mg,1 In 1 D),Oral : 15 Mg (15 Mg,1		

In 1 D),Oral

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2012	8393837	DIRECT	N	DS			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Quality Of Life Decreased	Prozac			S	Oral	1-2 Per Day		Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2012	8412485	EXPEDITED (15-DAY)	Y	RI, OT	1000027592		57 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Syncope	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Thyrox (Levothyroxine Sodium) (Levothyroxine Sodium)			C				Not Reported
	Anastrozol (Anastrozole) (Anastrozole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2012	7508598	EXPEDITED (15-DAY)	Y	RI, OT	1000015043		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Blood Sodium Decreased; Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Miconazole			S		50 Mg (50 Mg, 1 In 1 D),		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2012	8356822	EXPEDITED (15-DAY)	Y	HO	JP-ABBOTT-12P-087-0897995-00		77 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hallucination, Visual; Hyponatraemia; Urinary Retention	Biperiden			S	Oral	(3 Milligrams)		Not Reported
	Lexapro			S		(10 Milligrams)		Not Reported
	Antihypertensives			C				Not Reported
	Hypnotics And Sedatives			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2012	8394038	EXPEDITED (15-DAY)	Y	RI, OT	1000027379		30 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2012	8395356	DIRECT	N	LT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Panic Reaction; Serotonin Syndrome	Lexapro			S	Oral	10 Mg	4 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2012	8395582	EXPEDITED (15-DAY)	Y	OT	IN-ROXANE LABORATORIES, INC.-2012-RO-00595RO		45 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Ineffective; Drug Withdrawal Syndrome; Medication Error	Zolpidem			S		10 Mg		Roxane
	Zolpidem			S		15 Mg		Roxane
	Zolpidem			S		20 Mg		Roxane
	Zolpidem			S		20 Mg		Roxane
	Zolpidem			S		45 Mg		Roxane
	Zolpidem			S		7.5 Mg		Roxane
	Lorazepam			S		8 Mg		Roxane

Escitalopram Oxalate	S	20 Mg		Not Reported
Propranolol	S	40 Mg		Not Reported
Propranolol	S	80 Mg		Not Reported
Propranolol	S	120 Mg		Not Reported
Mirtazapine	S	7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2012	8396219	EXPEDITED (15-DAY)	Y	OT	ZA-PFIZER INC-2012028757		50 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depersonalisation/Derealisation Disorder; Drug Interaction	Lyrica			S	Oral	75 Mg, 2x/Day		Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2012	8396517	NON-EXPEDITED	N		US-PFIZER INC-2012030008			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Prozac			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2012	8402410	EXPEDITED (15-DAY)	Y	RI, OT	1000027508		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Sodium Decreased; Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate	S	5 Mg (5 Mg, 1 In 1 D)		Not Reported
	Miconazole	S	50 Mg (50 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2012	8418953	EXPEDITED (15-DAY)	Y	HO	1000027666		88 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter	Escitalopram Oxalate			S	Oral	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Micardis (Telmisartan) (40) (Telmisartan)			C				Not Reported
	Levothyrox (Levothyroxine Sodium) (25) (Levothyroxine Sodium)			C				Not Reported
	Inexium (Esomeprazole Magnesium) (20) (Esomeprazole Magnesium)			C				Not Reported
	Voltarene (Diclofenac Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2012	8419225	EXPEDITED (15-DAY)	Y	OT	ZOLP20120002		45 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Blood Pressure Fluctuation; Delirium; Disorientation; Incontinence; Initial Insomnia; Overdose; Refusal Of Treatment By Patient; Withdrawal Syndrome	Zolpidem Tartrate			S		10-25 Mg Daily From Days 13-35,		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Lorazepam			C				Not Reported
	Mirtazapine			C				Not Reported
	Propranolol (Propanolol) (Propranolol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2012	8397790	EXPEDITED (15-DAY)	Y	HO, OT	DE-NAPPMUNDI-DEU-2012-0008587			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Neonatal Respiratory Distress Syndrome	Oxycodone Hydrochloride			S	Transplacental	70 Mg, Daily	270 DAY	Purdue
	Oxycodone Hydrochloride			S	Transplacental	10 Mg, See Text		Purdue
	Morphine Sulfate			S	Transplacental	Unk, See Text	40 DAY	Purdue
	Sertraline Hydrochloride			S	Transplacental	50 Mg, Daily	228 DAY	Not Reported
	Amitriptyline Hydrochloride			S	Transplacental	150 Mg, Daily	40 DAY	Not Reported
	Cymbalta			S	Transplacental	30 Mg, Bid	40 DAY	Not Reported
	Cipralex			S	Transplacental	30 Mg, Daily	40 DAY	Not Reported
	Chlorprothixene			S	Transplacental	50 Mg, Daily	40 DAY	Not Reported
	Dimenhydrinate			S	Transplacental	50 Mg, Tid	68 DAY	Not Reported
	Ferrous Succinate\Magnesium Hydroxide			S	Transplacental	0.4 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2012	7234096	EXPEDITED (15-DAY)	Y	OT	FR-PFIZER INC-K200901600		38 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Somnolence; Suicide Attempt	Altace			S	Oral	25 Mg, Single	1 DAY	Pfizer
	Levoxyl			S	Oral	5 Df, Single	1 DAY	Pfizer
	Metformin			S	Oral	5 Df, Single	1 DAY	Not Reported
	Abilify			S	Oral	25 Mg, Single	1 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	50 Mg, Single	1 DAY	Not Reported
	Pipamperone Hydrochloride			S	Oral	100 Mg, Single	1 DAY	Not Reported
	Tavor (Lorazepam)			S	Oral	30 Mg, Single	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2012	8235527	EXPEDITED (15-DAY)	Y	HO, OT	PHFR2011GB06215		50 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder;	Ritalin			S	Oral	Unk Ukn, Unk		Novartis

Adrenomegaly	Cipralex		S	Oral	20 Mg, Per Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2012	8399749	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0945641A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Attention Deficit/Hyperactivity Disorder; Hyperhidrosis; Libido Decreased; Loss Of Libido; Middle Insomnia; Night Sweats; Post-Traumatic Stress Disorder; Somnolence	Paxil			S	Unknown	40mg Per Day		Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2012	8399843	NON-EXPEDITED	Y		US-GLAXOSMITHKLINE-A0957158A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cortisol Increased; Gastritis Erosive; Insomnia; Palpitations; Tremor; Withdrawal Syndrome	Paxil Cr			S	Oral	12.5mg Per Day		Glaxosmithkline
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2012	8422602	EXPEDITED (15-DAY)	Y	DS	1000028049		21 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atonic Urinary Bladder; Overdose; Urinary Retention	Lexapro			S	Oral	Overdose: 10 - 30 Mg A Day (10 Mg), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2012	8422684	EXPEDITED (15-DAY)	Y	CA	1000027920		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoplastic Left Heart Syndrome; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2012	8422708	EXPEDITED (15-DAY)	N	CA	1000027890		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2012	8423089	EXPEDITED (15-DAY)	Y	RI, OT	1000028052		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Delirium; Depression; Sudden Onset Of Sleep; Weight Decreased	Escitalopram Oxalate			S	Oral	See Image		Not Reported
	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg,1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg,1 In 1 D),Oral		Not Reported
	Bipreterax (Perindopril) (Perindopril)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2012	8323254	EXPEDITED (15-DAY)	Y	RI, OT	1000026337		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Gastrointestinal Haemorrhage; Muscle Contracture; Oedema Peripheral; Torticollis	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral	Not Reported
	Topalgic [Tramadol Hydrochloride]		C			Not Reported
	Lexomil (Bromazepam) (Tablets) (Bromazepam)		C			Not Reported
	Piascledine (Piascledine /01305801/) (Tablets) (Piascledine /01305801/)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2012	8402522	EXPEDITED (15-DAY)	Y	DE	US-COVIDIEN/TYCO HEALTHCARE/MALLINCKRODT-T20120009		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Restoril			S	Oral			Tyco
	Hydroxyzine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2012	8403309	EXPEDITED (15-DAY)	Y	HO	PHHY2012FR010607		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block; Chest Pain; Oxygen Saturation Decreased; Pulmonary Embolism; Vertigo	Hydrochlorothiazide\Valsartan			S	Oral	1 Df, Daily		Novartis
	Ebixa			S	Oral	20 Mg, Unk		Not Reported
	Galantamine Hydrobromide			S	Oral	16 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg, Unk		Not Reported
	Atarax			S	Oral	25 Mg, Unk		Not Reported
	Caduet			S	Oral	1 Df, (5 Mg Amlod/ 10 Mg Atorvas)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2012	8422365	EXPEDITED (15-DAY)	N	CA	1000028169		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Coarctation Of The Aorta; Maternal Drugs Affecting Foetus; Ventricular Septal Defect	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2012	8422417	EXPEDITED (15-DAY)	N	CA	1000028153		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arnold-Chiari Malformation; Cerebral Ventricle Dilatation; Congenital Hydrocephalus; Maternal Drugs Affecting Foetus; Microcephaly; Spina Bifida	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2012	8422429	EXPEDITED (15-DAY)	N	CA	1000028145		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Tricuspid Valve Atresia; Foetal Exposure During Pregnancy; Pulmonary Artery Stenosis Congenital; Transposition Of The Great Vessels; Ventricular Septal Defect	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2012	8422438	EXPEDITED (15-DAY)	N	CA	1000028143		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Double Outlet Right Ventricle; Maternal Drugs Affecting Foetus; Ventricular Septal Defect	Lexapro		S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2012	8422449	EXPEDITED (15-DAY)	N	CA	1000028138		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arnold-Chiari Malformation; Foetal Exposure During Pregnancy; Spina Bifida	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2012	8422458	EXPEDITED (15-DAY)	N	CA	1000028126		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Ventricular Septal Defect	Lexapro			S	Transplacental	Translacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2012	8424625	EXPEDITED (15-DAY)	Y	OT	2012MA001568		92 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease Recurrence; Drug Ineffective	Citalopram Hydrobromide			S		20 Mg		Purepac
	Escitalopram Oxalate			S		10 Mg		Not Reported
	Cipralex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2012	8451364	NON-EXPEDITED	N		1000026361			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Dreams; Crying; Drug Ineffective; Energy Increased; Insomnia; Off Label Use	Savella	S	Oral	12.5 Mg (12.5 Mg, 1 In 1 D), Oral	Not Reported
	Lexapro	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Lexapro	S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2012	8273373	EXPEDITED (15-DAY)	Y	DS	FR-UCBSA-046521		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Keratitis	Neupro			S	Transdermal	Daily Dose:1 Patch.		Not Reported
	Escitalopram Oxalate			S	Oral	Daily Dose:1 Unit		Not Reported
	Dexamethasone			S	Intraocular	Collyrium		Not Reported
	Tamoxifen Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2012	8404649	EXPEDITED (15-DAY)	Y	HO, LT	FR-JNJFOC-20120205246		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Thrombocytopenia	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Ebixa			S	Oral			Not Reported
	Aricept			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Nicorandil			S	Oral			Not Reported
	Perindopril			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported
	Lovenox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2012	8405197	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2012021189			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Body Temperature Increased; Drug Withdrawal Syndrome Neonatal; Hyperhidrosis; Maternal Exposure Timing Unspecified; Neonatal Respiratory Distress Syndrome; Tachycardia; Tremor	Sertraline Hcl			S	Transplacental	50 Mg, 1x/Day, From Gw 6 To 38.3		Pfizer
	Oxycodone Hydrochloride			S	Transplacental	70 Mg/D (30-10-30)		Pfizer
	Oxycodone Hydrochloride			S	Transplacental	10 Mg/D		Pfizer
	Sevredol			S	Transplacental	40 Mg/D 3 To 4 Times Per Week, 2x 20mg/D Max, From Gw 0 To 5.4		Pfizer
	Saroten			S	Transplacental	150 Mg/D From Gw 0 To 5.4		Not Reported
	Cymbalta			S	Transplacental	30 Mg, 2x/Day From Gw 0 To 5.4		Not Reported
	Cipralex			S	Transplacental	30 Mg, 1x/Day		Not Reported
	Truxal			S	Transplacental	50 Mg, 1x/Day From Gw 0 To 5.4		Not Reported
	Vomex A			S	Transplacental	50 Mg, 3x/Day, From Gw 6 To 15.4		Not Reported
	Femibion [Minerals Nos;Vitamins Nos]			S	Transplacental	0.4 Mg, 1x/Day From Gw 5.4 To 12		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2012	8427029	EXPEDITED (15-DAY)	Y	RI, OT	1000028167		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dry Mouth; Feeling Abnormal; Nausea; Vision Blurred	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Inexium (Esomeprazole Magnesium)			C				Not Reported
	Crestor			C				Not Reported
	Stilnox (Zolpidem Tartrate)			C				Not Reported

	(Zolpidem Tartrate)			
	Lexomil (Bromazepam) (Bromazepam)	C		Not Reported
	Oestrogel (Estradiol) (Estradiol)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2012	8431624	EXPEDITED (15-DAY)	Y	HO	1000028150		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis; Malaise	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2012	8431639	EXPEDITED (15-DAY)	Y	HO	1000028151		79 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abnormal Behaviour; Aggression; Gastrointestinal Pain	Escitalopram Oxalate			S	Oral	1 Dosage Form (1 Dosage Forms,1 In 1 D), Oral		Not Reported
	Oxazepam			S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			S				Not Reported
	Tiapride			S				Not Reported
	Efferalgan (Paracetamol) (Paracetamol)			C				Not Reported
	Inexium (Esomeprazole Magnesium)			C				Not Reported
	Fosavance (Alendronate Sodium, Colecalciferol) (Alendronate Sodium, Colecalciferol)			C				Not Reported
	Aranesp (Darpepoetin Alfa) (Darbepoetin Alfa)			C				Not Reported
	Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine)			C				Not Reported
	Lantus (Insulin Glargine) (Insulin Glargine)			C				Not Reported
	Apidra (Insulin Glulisine) (Insulin Glulisine)			C				Not Reported

	Lactulose (Lactulose)(Lactulose)	C	Not Reported
	Eductyl	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2012	8431655	EXPEDITED (15-DAY)	Y	LT, RI, OT	1000028093		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Drugs Affecting Foetus; Neonatal Asphyxia; Neonatal Seizure	Lexapro			S		10 Mg (10 Mg, 1 In 1 D),Transplacental ; 20 Mg (20 Mg, 1 In 1 D),Transplacental		Not Reported
	Zoloft (Sertraline Hydrochloride) (Setraline Hydrochloride)			C				Not Reported
	Reflex (Mirtazapine) (Mirtazapine)			C				Not Reported
	Halrack (Triazolam) (Triazolam)			C				Not Reported
	Silece (Flunitrazepam) (Flunitrazepam)			C				Not Reported
	Levotomin (Levomepromazine Maleate) (Levomepromazine Maleate)			C				Not Reported
	Solanax (Alprazolam) (Alprazolam)			C				Not Reported
	Lexotan (Bromazepam) (Bromazepam)			C				Not Reported
	Risperidone			C				Not Reported
	Lekrica (Chlorphenamine Maleate) (Chlorphenamine Maleate)			C				Not Reported
	Goodmin (Brotizolam) (Brotizolam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2012	8406640	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20120204674		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Galantamine Hydrobromide			S	Oral	During Several Years		Not Reported

	Ebixa	S	Oral			Not Reported
	Escitalopram Oxalate	S	Unknown			Not Reported
	Atarax	S	Unknown			Not Reported
	Hydrochlorothiazide\Valsartan	S	Oral	80 Mg/12.5 Mg		Not Reported
	Caduet	S	Oral	5 Mg/10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2012	8407589	EXPEDITED (15-DAY)	Y	DE	US-COVIDIEN/TYCO HEALTHCARE/MALLIN CKRODT-T20120034		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Acetaminophen\Hydrocodone Bitartrate			S	Oral			Tyco
	Buprenorphine Hydrochloride And Naloxone Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2012	8292684	EXPEDITED (15-DAY)	Y	DS	1000025970		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Keratitis	Escitalopram Oxalate			S	Oral	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Rotigotine			S	Transdermal	1 Dosage Form (1 Dosage Forms, 1 In 1 D), Transdermal		Not Reported
	Dexamethasone Sodium Sulfate			S	Intraocular	Intraocular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2012	8429458	EXPEDITED (15-DAY)	Y	RI, OT	1000028374		26 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine	Escitalopram Oxalate			S	Oral	40 Mg (40 Mg, 1 In 1 D),		Not Reported

Phosphokinase Increased; Overdose	Oral

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2012	8430836	EXPEDITED (15-DAY)	Y	HO	1000028301		50 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Haemorrhoids; Malaise; Orthostatic Hypotension; Paraesthesia; Procedural Complication	Escitalopram Oxalate			S		10 Mg (10 Mg, 1 In 1 D) 20 Mg (20 Mg, 1 In 1 D) 5 Mg (10 Mg, 1 In 2 D) 10 Mg (10 Mg, 1 In 1 D) 20 Mg (20 Mg, 1 In 2 D) 10 Mg (10 Mg, 1 In 1 D) 20 Mg (20 Mg, 1 In 1 D) 5 Mg (10 Mg, 1 In 2 D)		Not Reported
	Lexomil (Bromazepam) (Bromazepam)			C				Not Reported
	Prazepam			C				Not Reported
	Magnesium (Magnesium) (Magnesium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2012	8286481	EXPEDITED (15-DAY)	Y	RI, OT	1000025959		33 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Overdose; Pregnancy; Premature Delivery	Lexapro			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported
	Ondansetron			C				Not Reported
	Phenergan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2012	8402564	EXPEDITED (15-DAY)	Y	HO	1000027473		24 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Activation Syndrome; Depression Suicidal; Nausea; Pyrexia; Suicidal Ideation; Suicide Attempt	Lexapro		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Risperidone (Risperidone)		C			Not Reported
	Tefmetin (Trimebutine Maleate)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2012	8410860	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2012039637		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Interaction; Dry Mouth; Dyspnoea; Feeling Abnormal; Myocardial Infarction; Nausea; Oral Discomfort; Pruritus Generalised; Seizure; Throat Tightness; Tremor	Dilantin-125			S		Unk		Pfizer
	Sumatriptan Succinate			S	Intrameningeal	6 Mg, Unk		Not Reported
	Lexapro			S	Oral	20 Mg, 1x/Day		Not Reported
	Sumatriptan			S		50 Mg, Unk		Not Reported
	Zonegran			C		Unk		Not Reported
	Neurontin			C		Unk		Not Reported
	Temazepam			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Multivitamins			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2012	8411312	EXPEDITED (15-DAY)	N	DS, OT	US-JNJFOC-20120205160			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Drug Ineffective; Drug Interaction; Epilepsy; Somnolence; Tremor	Topamax			S	Oral	100 Mg 1 Tablet In The Morning And 2 Tablets At Night		Not Reported
	Provera			S	Oral			Not Reported
	Premarin			S	Oral			Not Reported
	Lamictal			S	Oral			Not Reported
	Vimpat			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2012	8412649	EXPEDITED (15-DAY)	Y	OT	DK-WATSON-2012-02600		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Maternal Exposure During Pregnancy; Morbid Thoughts; Psychotic Disorder	Citalopram Hydrobromide			S	Oral	20 Mg Daily		Watson
	Risperidone			S	Oral	4 Mg Daily		Watson
	Escitalopram Oxalate			S				Not Reported
	Aripiprazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2012	8435587	EXPEDITED (15-DAY)	N	RI, OT	1000028376			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eating Disorder; Malaise; Off Label Use; Suicidal Ideation; Visual Impairment	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2012	8441669	EXPEDITED (15-DAY)	Y	HO	1000028421		58 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Glucose Increased; Blood Sodium Decreased; Depressed Level Of Consciousness; Diarrhoea; Dizziness; Drug Interaction; Hyponatraemia; Vision Blurred	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1d) Oral		Not Reported
	Atacand Hct			S	Oral	32 Mg/25 Mg (3 In 1 D) Oral		Not Reported
	Atenolol (Atenolol)			C				Not Reported
	Atorvastatin (Atorvastatin)			C				Not Reported
	Clopidogrel			C				Not Reported
	Pantoprazole			C				Not Reported
	Insulin Detemir (Insulin Detemir)			C				Not Reported
	Insulin Aspart (Insulin Aspart)			C				Not Reported
	Valdoxan (Agomelatine)			C				Not Reported
	Indapamide			C				Not Reported

	Venlafaxine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2012	8413733	NON-EXPEDITED	Y		US-ALLERGAN-1101265US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Ptosis	Botox			S	Intramuscular			Allergan
	Escitalopram Oxalate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2012	8218697	EXPEDITED (15-DAY)	Y	OT	FR-MERCK-1110FRA00094		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amylase Increased; Biliary Tract Disorder; Lipase Increased; Pancreatic Disorder	Isentress			S	Oral			Merck
	Isentress			S	Oral			Merck
	Emtricitabine And Tenofovir Disoproxil Fumarate			S	Unknown			Not Reported
	Emtricitabine And Tenofovir Disoproxil Fumarate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Oral		184 DAY	Not Reported
	Cyamemazine			S	Oral			Not Reported
	Irbesartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2012	8323221	EXPEDITED (15-DAY)	Y	HO	1000026327		19 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma Scale Abnormal; Depressed Level Of Consciousness; Dysarthria; Dysstasia; Extrapyramidal Disorder; Gait Disturbance;	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Levomepromazine			S	Oral	30 Mg (15 Mg, 2 In 1 D), Oral		Not Reported
	Seroquel			S	Oral	50 Mg (50 Mg, 1 In 1 D),		Not Reported

Nystagmus; Somnolence; Suicidal Ideation; Toxicity To Various Agents	Effexor		S	Oral	Oral 75 Mg (75 Mg, 1 In 1 D), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2012	8168185	EXPEDITED (15-DAY)	Y	HO	FR-GLAXOSMITHKLINE-B0751068A		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Nausea; Sleep Disorder; Tremor; Vomiting	Deroxat			S	Oral	20mg Unknown	141 DAY	Glaxosmithkline
	Modopar			S	Oral	62.5mg Three Times Per Day	141 DAY	Unknown
	Stresam			S	Oral		19 DAY	Unknown
	Bromazepam			S	Oral		19 DAY	Unknown
	Escitalopram Oxalate			S	Oral		19 DAY	Unknown
	Pariet			C	Unknown			Unknown
	Olmetec			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2012	8404017	EXPEDITED (15-DAY)	Y	HO	1000027461		46 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cough; Facial Paralysis; Seizure	Escitalopram Oxalate			S	Oral Oral	20 (20 Mg, 1 In1 D) Oral 20 (20 Mg, 1 In1 D) Oral		Not Reported
	Abilify			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Abilify			S		5 Mg (5 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2012	8431115	EXPEDITED (15-DAY)	Y	RI, OT	1000028375		65 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthyroidism	Escitalopram Oxalate			S				Not Reported

	Levothyroxine Sodium			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2012	8435299	EXPEDITED (15-DAY)	N	DS, RI, OT	1000028218		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Drug Ineffective; Drug Interaction; Epilepsy; Somnolence; Tremor	Lexapro			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Provera			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral, 20 Years Ago		Not Reported
	Premarin			S	Oral	0.625 Mg (0.625 Mg, 1 In 1 D), Oral		Not Reported
	Lamictal			S	Oral	300 Mg (150 Mg, 2 In 1 D), Oral		Not Reported
	Topamax			S	Oral	300 Mg (100 Mg Qam And 200 Mg Qpm),Oral		Not Reported
	Vimpat			S	Oral	400 Mg (100 Mg, 4 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2012	8436943	EXPEDITED (15-DAY)	N	CA	1000028280			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Maternal Drugs Affecting Foetus	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 7.5 Mg (7.5 Mg, 1 In 1 D), Oral		Not Reported
					Oral	5 Mg (5 Mg, 1 In 1 D), Oral, 7.5 Mg (7.5 Mg, 1 In 1 D), Oral		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2012	8438087	EXPEDITED (15-DAY)	Y	RI, OT	1000028407			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Self-Injury	Escitalopram Oxalate	S	Oral	Daily Dose Not Reported, Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2012	8438207	EXPEDITED (15-DAY)	N	RI, OT	1000028420		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Papilloedema	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2012	8454632	NON-EXPEDITED	N		1000025781		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Cystitis; Insomnia; Off Label Use	Viibryd			S	Oral	10 Mg (10 Mg, 1 I N1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Viibryd			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	30 Mg (30 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral		
	Lexapro			S				Not Reported
	Vyvanse (Lisdexamfetamine Mesilate) (Lisdexamfetamine Mesilate)			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2012	8382082	EXPEDITED (15-DAY)	Y	RI, OT	1000027107		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

Increased; Blood Lactate Dehydrogenase	Reflex (Mirtazapine) (Mirtazapine)	C	Not Reported
Increased; Gamma-Glutamyltransferase; Hepatic Function Abnormal	Gascon (Dimeticone) (Dimeticone)	C	Not Reported
	Gasmotin (Mosapride Citrate) (Mosapride Citrate)	C	Not Reported
	Magmitt (Magnesium Oxide) (Magnesium Oxide)	C	Not Reported
	Lorazepam	C	Not Reported
	Rohyphnol (Flunitrazepam) (Flunitrazepam)	C	Not Reported
	Risperdal	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2012	8412766	EXPEDITED (15-DAY)	Y	HO	1000027598		43 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Drunk; Incorrect Dose Administered; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral Overdose: 280 Mg Once, Oral		Not Reported
	Propranolol			S	Oral	Overdose: 2 G Once, Oral		Not Reported
	Tetrazepam			S	Oral	Overdose: 500 Mg Once, Oral		Not Reported
	Bromazepam			S	Oral	One Unique Intake (Unknown Dosage), Oral		Not Reported
	Alcohol (Ethanol)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2012	8420213	EXPEDITED (15-DAY)	Y	RI, OT	1000027825		91 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Off Label Use; Senile Dementia	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2012	8420895	DIRECT	N	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Anorgasmia; Depersonalisation/Dereali sation Disorder; Emotional Disorder; Hypoaesthesia; Libido Decreased; Maternal Exposure Before Pregnancy; Personality Change; Pregnancy; Sexual Dysfunction	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2012	8423103	EXPEDITED (15-DAY)	Y	RI, OT	1000028031		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Cholesterol Increased; Blood Triglycerides Increased; Gamma-Glutamyltransferase Increased; Liver Function Test Abnormal	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Trazodone Hydrochloride			S	Oral	100 Mg (100 Mg, 1 In 1 D), Oral		Not Reported
	Seroquel			S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral		Not Reported
	Zyprexa (Olanzapine)			C				Not Reported
	Tresleen (Sertraline Hydrochloride) (Tablets) (Sertraline Hydrochloride)			C				Not Reported
	Ixel (Milnacipran) (Tablets) (Milancipran)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2012	8427019	EXPEDITED (15-DAY)	Y	HO	1000028164		81 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Feeling Hot; Hyperhidrosis; Loss Of Consciousness; Presyncope	Escitalopram Oxalate		S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Betahistine Hydrochloride		S	Oral	32 Mg (16 Mg, 2 In 1 D), Oral	Not Reported
	Lyrica		S	Oral	150 Mg (75 Mg, 2 In 1 D), Oral	Not Reported
	Lansoprazolo (Lansoprazole) (Capsules) (Lansoprazole)		C			Not Reported
	Simvastatin (Simvastatin) (Tablets) (Simvastatin)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2012	8217915	EXPEDITED (15-DAY)	Y	RI, OT	1000024734		74 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea Haemorrhagic; Viral Infection	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Stagig (Metformin Embonate) (Metformin Embonate)			C				Not Reported
	Nisis (Valsartan) (Valsartan)			C				Not Reported
	Orocal D3 (Calcium Colecalciferol) (Calcium Colecaciferol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2012	8431291	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000028224		86 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Aggression; Anxiety; Atrial Fibrillation; Delirium; Fatigue; Fear; Gastrooesophageal Reflux Disease; Haemoglobin Decreased; Hallucination, Gustatory; Hallucination, Visual; Insomnia; Irregular	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D),Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, (10 Mg, 1 In 1 D) , Oral		Not Reported
	Distraneuran (Clomethiazole) (Clomethiazole)			C				Not Reported
	Litalir (Hydroxycarbamide) (Hydroxycarbamide)			C				Not Reported
	Aspirin			C				Not Reported

Sleep Wake Rhythm Disorder; Left Ventricular Failure; Lymphocyte Count Decreased; Restlessness; Suicide Attempt	Digoxin	C	Not Reported
	Carvedilol (Carvedilo) (Cavedilol)	C	Not Reported
	Pantoprazole (Pantoprazole) (Pantoprazole)	C	Not Reported
	Iron (Iii)-Hydroxide (Iron (Iii)-Hydroxide) (Iron (Iii)-Hyhydroxide)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2012	8431325	EXPEDITED (15-DAY)	Y	HO	1000028239		84 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Inappropriate Antidiuretic Hormone Secretion; Loss Of Consciousness; Seizure	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D),Oral		Not Reported
	Rheumatrex (Methotrexate) (Methotrexate)			C				Not Reported
	Remicade			C				Not Reported
	Durotep			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2012	8441123	EXPEDITED (15-DAY)	Y	CA, HO, RI, OT	1000028438			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Atrial Septal Defect; Infantile Apnoea; Maternal Drugs Affecting Foetus; Neonatal Respiratory Distress Syndrome; Patent Ductus Arteriosus; Pyelocaliectasis	Escitalopram Oxalate			S	Transplacental	40 Mg (40 Mg,L In 1 D),Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2012	8441466	EXPEDITED (15-DAY)	N	RI, OT	1000028475		16 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Withdrawal Syndrome; Dyskinesia; Muscle Twitching; Off Label Use; Tongue Disorder	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral ,(15 Mg,Instead Of 10 Mg, When Required),Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D),Oral ,(15 Mg,Instead Of 10 Mg, When Required),Oral		
	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2012	8443482	EXPEDITED (15-DAY)	Y	RI, OT	1000028437		30 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Maternal Exposure During Pregnancy; Overdose; Pregnancy	Escitalopram Oxalate			S		40 Mg (40 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2012	8444571	EXPEDITED (15-DAY)	Y	HO, RI, OT	1000028452			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Agitation; Conversion Disorder; Dyskinesia; Hallucination, Auditory; Insomnia; Tremor	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Depakote			C				Not Reported
	Topamax (Topiramate) (Topiramate)			C				Not Reported
	Levothyroxine (Levothyroxine Sodium) (Levothyroxine Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2012	8407648	EXPEDITED (15-DAY)	Y	HO, LT	FR-EISAI INC-E2020-10330-SPO-FR		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Aricept			S	Oral			Not Reported
	Perindopril			S	Oral			Not Reported
	Risperdal			S	Oral		10 DAY	Not Reported
	Risperdal			S	Oral		10 DAY	Not Reported
	Risperdal			S	Oral		10 DAY	Not Reported
	Aspirin			S	Oral			Not Reported
	Ebixa			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Nicorandil			S	Oral			Not Reported
	Xanax			S	Oral		7 DAY	Not Reported
	Lovenox			C		Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2012	8423864	NON-EXPEDITED	N		US-MYLANLABS-2011S1026036		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Throat Tightness	Lexapro			S				Mylan
	Unspecified Ingredient			S				Not Reported
	Perphenazine			S				Not Reported
	Alprazolam			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2012	8424706	NON-EXPEDITED	N		US-PFIZER INC-K201100732		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Dizziness	Altace			S		Unk		Pfizer

	Lexapro	S	Oral	5 Mg, 1x/Day	Not Reported
	Lexapro	S	Oral	10 Mg, 1x/Day	Not Reported
	Lexapro	S	Oral	20 Mg, 1x/Day	Not Reported
	Beta Blocking Agents	C		25 Mg, Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Niaspan	C		1 G, Unk	Not Reported
	Aspirin	C		Unk	Not Reported
	Prilosec	C		Unk	Not Reported
	B50	C		Unk	Not Reported
	Ubidecarenone	C		200 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2012	8425414	EXPEDITED (15-DAY)	Y	DE	US-UCBSA-049071		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Acetaminophen\Hydrocodone			S	Oral			Not Reported
	Buprenorphine Hydrochloride And Naloxone Hydrochloride			S	Sublingual			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2012	8436024	EXPEDITED (15-DAY)	Y	HO	1000028442		65 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Suicide Attempt	Lexapro			S	Oral	20 Mg (10 Mg, 1 In 2 D), Oral		Not Reported
	Dogmatyl (Sulpiride (Sulpiride)			C				Not Reported
	Anafranil			C				Not Reported
	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2012	8436881	EXPEDITED (15-DAY)	Y	HO	1000028406		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Lactate Dehydrogenase Increased; Condition Aggravated; Gamma-Glutamyltransferase Increased; Liver Disorder	Lexapro			S	Oral	10;20 Mg (10;20 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10;20 Mg (10;20 Mg, 1 In 1 D), Oral		
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal			S	Oral	1;0.5 Ml (1;0.5 Ml, 1 In 1 D), Oral		Not Reported
					Oral	1;0.5 Ml (1;0.5 Ml, 1 In 1 D), Oral		
					Oral	1;0.5 Ml (1;0.5 Ml, 1 In 1 D), Oral		
					Oral	1;0.5 Ml (1;0.5 Ml, 1 In 1 D), Oral		
	Gasmotin (Mosapride Citrate)			C				Not Reported
	Ensure Liquid (Ensure /06184901/)			C				Not Reported
	Jzoloft (Setrtraline Hydrochloride)			C				Not Reported
	Magmitt (Magnesium Oxide)			C				Not Reported
	Sennoside (Sennoside A+B)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2012	8442159	EXPEDITED (15-DAY)	Y	DE	1000028549		25 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Infection; Myocardial Infarction	Escitalopram Oxalate			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8257329	EXPEDITED (15-DAY)	Y	DE, HO, RI, OT	1000025398		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly; Constipation; Fall; Hepatic	Escitalopram Oxalate			S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral		Not Reported

Cirrhosis; Humerus Fracture; Hypertension; Hyperventilation; Internal Fixation Of Fracture; Lactic Acidosis; Lacunar Infarction; Multiple Organ Dysfunction Syndrome; Neuroleptic Malignant Syndrome; Renal Failure; Rhabdomyolysis; Serotonin Syndrome; Urinary Tract Infection	Ziprasidone Hydrochloride	S		80 Mg (40 Mg, 2 In 1 D)	Not Reported
	Lithium Citrate	S	Oral	Oral	Not Reported
	Mirtazapine (Mirtazapine)	S	Oral	30 Mg (30 Mg, 1 In 1 D), Oral	Not Reported
	Fragmin (Dalteparin Sodiuim)	C			Not Reported
	Ferro Dureter (Ferrous Sulfate)	C			Not Reported
	Centyl Med Kaliumklorid (Bendroflumethazide, Potassium Chloride)	C			Not Reported
	Furosemide	C			Not Reported
	Amlodipine	C			Not Reported
	Alprazolam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8260896	EXPEDITED (15-DAY)	Y	RI, OT	1000025428		51 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Thyroiditis; Blood Pressure Increased; Fatigue; Malaise; Myalgia; Restlessness; Serotonin Syndrome; Terminal Insomnia; Tremor	Escitalopram Oxalate			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram Oxalate			S	Oral	10; 5 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Mirtazapine (Mirtazapine)			C				Not Reported
	Lithium Carbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8345268	EXPEDITED (15-DAY)	Y	RI, OT	1000026666		52 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Blood Cholesterol Increased; Drug Ineffective; Electrocardiogram St Segment Abnormal	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Marevan			C				Not Reported
	Sanval (Zolpidem Tartrate)			C				Not Reported
	Trandolapril			C				Not Reported
	Diazepam (Diazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8420247	EXPEDITED (15-DAY)	Y	RI, OT	1000027806		18 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Bilirubin Increased; Blood Bilirubin Unconjugated Increased; C-Reactive Protein Increased; Drug Interaction; Fatigue; Gastrointestinal Disorder; Liver Injury; Nausea; Platelet Count Decreased; Treatment Noncompliance; Viral Infection	Escitalopram Oxalate			S	Oral	10 Mg (10 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D), Oral		
	Acetaminophen			S	Oral	2000 Mg (500 Mg, 4 In 1 D), Oral, 2000 Mg (500 Mg, 4 In 1 D), Oral		Not Reported
					Oral	2000 Mg (500 Mg, 4 In 1 D), Oral, 2000 Mg (500 Mg, 4 In 1 D), Oral		
	Drospirenone\Ethinyl Estradiol			S	Oral	1 Df (1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Desloratadine			C				Not Reported
	Mometasone Furoate Monohydrate			C				Not Reported
	Rubozinc (Zinc Gluconate) (Zinc Gluconate)			C				Not Reported
	Amoxicillin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8427057	EXPEDITED (15-DAY)	N	HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-16404576		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Haematoma; Haematuria; Haemorrhagic Stroke	Coumadin			S	Oral	1 Tablet In The Evening		Bristol Myers Squibb
	Paracetamol			S				Cadence
	Ramipril			S		One In The Morning And One In The Evening		Not Reported
	Cordarone			S		1df=One At Noon 5 Days/7 Days		Not Reported

Aspirin	S	At Noon	Not Reported
Tahor	S	In The Evening	Not Reported
Oxazepam	S	In The Evening	Not Reported
Escitalopram Oxalate	S	In The Morning	Not Reported
Topalgic (France)	S		Not Reported
Zopiclone	S	One At Bedtime	Not Reported
Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)	S	1df=1 Sachet In The Morning	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8428725	EXPEDITED (15-DAY)	Y	HO	FR-ROCHE-1042038		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Confusional State; Somnolence	Valium			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8441162	EXPEDITED (15-DAY)	Y	RI, OT	1000028552		25 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphangitis; Photosensitivity Reaction; Purpura; Skin Injury	Escitalopram Oxalate			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8441365	EXPEDITED (15-DAY)	Y	RI, OT	1000028513			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Dizziness; Intentional Self-Injury; Memory Impairment; Weight Increased	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8443536	EXPEDITED (15-DAY)	N	CA	1000028595		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8443550	EXPEDITED (15-DAY)		CA	1000028598		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Spina Bifida	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8443556	EXPEDITED (15-DAY)	N	CA	1000028593		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8444100	EXPEDITED (15-DAY)	Y	HO	1000028576			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatitis Cholestatic; International	Escitalopram Oxalate			S				Not Reported

Normalised Ratio Increased	Coumadin		S	Oral	10 Mg (10 Mg,1 In 1 D), Oral	Not Reported
	Tenormin		C			Not Reported
	Lercanidipine		C			Not Reported
	Atacand (Candesartan Cilexetil)		C			Not Reported
	Atorvastatin Calcium		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2012	8445074	EXPEDITED (15-DAY)	Y	RI, OT	1000028545		52 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Withdrawal Syndrome; Erectile Dysfunction; Paraesthesia; Tremor	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2012	8444005	EXPEDITED (15-DAY)	Y	RI, OT	1000028582		33 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Triglycerides Increased	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D),Oral		Not Reported
	Meilax (Ethyl Loflazepate)(Ethyl Loflazepate)			C				Not Reported
	Flunitrazepam (Flunitrazepam) (Flunitrazepam)			C				Not Reported
	Abilify(Aripiprazole)(Aripiprazole)			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2012	8444267	EXPEDITED (15-DAY)	Y	RI, OT	1000028492		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Viibryd			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2012	8423172	EXPEDITED (15-DAY)	Y	HO, OT	FR-PFIZER INC-2012042738		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Xanax			S	Oral	Unk		Pfizer
	Atarax			S	Oral	Unk		Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Aerius (Desloratadine)			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2012	8432205	DIRECT		HO			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Valve Disease; Depression; Diabetes Mellitus; Nausea; Night Sweats; Nightmare; Suicidal Ideation	Lexapro			S	Oral	250 Mg		Not Reported
	Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2012	8432666	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20120210107		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Balance Disorder; Confusional State; Drug Interaction; Somnolence	Risperdal			S	Oral			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Amlodipine Besylate			C	Unknown			Not Reported
	Coaprovel			C	Unknown			Not Reported
	Esidrex			C	Unknown			Not Reported
	Quetiapine			S	Oral		33 DAY	Not Reported
	Quetiapine			S	Oral		33 DAY	Not Reported
	Quetiapine			S	Oral		33 DAY	Not Reported

	Quetiapine	S	Oral		33 DAY	Not Reported
	Escitalopram Oxalate	S	Oral		33 DAY	Not Reported
	Valium	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2012	8432741	EXPEDITED (15-DAY)	Y	HO	FR-PFIZER INC-2012052630		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Eupantol			S	Oral	20 Mg, Unk	16 DAY	Pfizer
	Aspirin			S	Oral	75 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Unk		Not Reported
	Tareg			S	Oral	80 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2012	8433172	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000026774		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Escitalopram Oxalate			S	Oral			Forest
	Reminyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2012	8433188	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028138		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arnold-Chiari Malformation; Spina Bifida	Lexapro			S	Transplacental			Forest
	Folic Acid			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2012	8433928	EXPEDITED (15-DAY)	N	HO	US-FRI-1000028168		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Back Pain; Chest Pain; Dyspnoea; Electrocardiogram St Segment Abnormal; Limb Discomfort; Maternal Exposure During Pregnancy; Premature Rupture Of Membranes; Sinus Tachycardia	Lexapro	S	Oral	10 Mg		Forest
	Lexapro	S				Forest
	Allegra	C				Not Reported
	Buspar	C				Not Reported
	Skelaxin	C				Not Reported
	Imitrex	C				Not Reported
	Ortho Cyclen	C				Not Reported
	Ativan	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2012	8434018	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2012SE12534		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Confusional State; Somnolence	Quetiapine Fumarate			S	Oral		3 DAY	Astrazeneca
	Quetiapine Fumarate			S	Oral		17 DAY	Astrazeneca
	Quetiapine Fumarate			S	Oral		6 DAY	Astrazeneca
	Quetiapine Fumarate			S	Oral		7 DAY	Astrazeneca
	Escitalopram Oxalate			S	Oral		33 DAY	Not Reported
	Risperdal			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Bisoprolol			C	Oral			Not Reported
	Amlodipine Besylate			C	Oral			Not Reported
	Coaprovel			C	Oral			Not Reported
	Esidrex			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2012	8441366	DIRECT	N	OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Migraine; Nausea; Rash; Renal Pain; Tremor	Lexapro			S		10mgs Once Daily 7 Days		Forest
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2012	8406436	EXPEDITED (15-DAY)	Y	HO, LT, OT	FR-PFIZER INC-2012036442		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Dementia Alzheimer'S Type; Pulmonary Embolism; Thrombocytopenia	Xanax			S	Oral	0.25 Mg, 1x/Day	7 DAY	Pfizer
	Aricept			S	Oral	10 Mg, 1x/Day		Pfizer
	Risperdal			S	Oral	0.25 Mg, 2x/Day	2 DAY	Not Reported
	Risperdal			S	Oral	0.5 Mg, 2x/Day	4 DAY	Not Reported
	Risperdal			S	Oral	1 Mg, 2x/Day	4 DAY	Not Reported
	Ebixa			S	Oral	20 Mg, 1x/Day		Not Reported
	Aspirin			S	Oral	75 Mg, 1x/Day		Not Reported
	Nicorandil			S	Oral	10 Mg, 1x/Day		Not Reported
	Perindopril			S	Oral	4 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2012	8434787	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028280			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate	Lexapro			S	Transplacental	5 Mg		Forest
	Lexapro			S	Transplacental	7.5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2012	8435106	EXPEDITED (15-DAY)	N	CA, OT	US-FRI-1000028143			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Double Outlet Right Ventricle; Pyelocaliectasis; Transposition Of The Great Vessels; Ventricular Extrasystoles; Ventricular	Lexapro			S	Transplacental			Forest
	Prenatabs Fa			C	Transplacental			Not Reported
	Amoxicillin			C	Transplacental			Not Reported

Septal Defect	Folic Acid	C	Transplacental	Not Reported
	Vitamin B12	C	Transplacental	Not Reported
	Vitamin C	C	Transplacental	Not Reported
	Ferrous Sulfate	C	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2012	8436357	EXPEDITED (15-DAY)	Y	HO, OT	FR-FRI-1000028676		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram Oxalate			S	Oral			Forest
	Xanax			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Rivotril			C	Oral			Not Reported
	Aerius (Desloratadine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2012	8436408	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000028672		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Confusional State; Drug Interaction; Somnolence	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Quetiapine Fumarate			S	Oral	300 Mg	32 DAY	Not Reported
	Quetiapine Fumarate			S	Oral	600 Mg	32 DAY	Not Reported
	Quetiapine Fumarate			S	Oral	400 Mg	32 DAY	Not Reported
	Quetiapine Fumarate			S	Oral	600 Mg	32 DAY	Not Reported
	Risperdal			S	Oral	8 Mg		Not Reported
	Valium			S	Oral	10 Mg		Not Reported
	Bisoprolol			C				Not Reported
	Amlodipine Besylate			C				Not Reported
	Coaprovel			C				Not Reported
	Esidrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2012	8446215	EXPEDITED (15-DAY)	Y	OT	DKLU1066670		33 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infertility Male; Sperm Analysis Abnormal	Escitalopram Oxalate			S	Oral	10 Mg, 1 In 1 D, Oral		Not Reported
	Tranxene T-Tab			S	Oral	10;5 Mg, 3;2 In 1 D, Oral		Not Reported
	Acepromet azine\Meprobamate			S	Oral	1 Df Dosage Form, 1 In 1 D, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2012	8354946	EXPEDITED (15-DAY)	Y	DS, OT	US-PFIZER INC-2012017345			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Drug Ineffective; Drug Interaction; Epilepsy; Somnolence; Tremor	Provera			S	Oral	10 Mg, Daily		Pfizer
	Premarin			S	Oral	0.625 Mg, Daily		Pfizer
	Lamictal			S	Oral	150 Mg, 2x/Day		Not Reported
	Topamax			S	Oral	Unk,2x/Day		Not Reported
	Lacosamide			S		100 Mg, 4x/Day		Not Reported
	Lexapro			S		20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2012	8437024	EXPEDITED (15-DAY)	Y	DE, OT	CHPA2012US003762		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Acetaminophen (Paracetamol)		Y	S	Oral	Unk,Unk		Novartis
	Unspecified Ingredient			S	Oral	Unk,Unk		Not Reported
	Propoxyphene Hydrochloride			S	Oral	Unk,Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2012	8437082	EXPEDITED (15-DAY)	Y	OT	DE-JNJFOC-20120210508		24 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Somnolence; Suicide Attempt	Risperdal			S	Oral			Not Reported
	Paracetamol		Y	S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2012	8437664	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000027107		43 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal	Lexapro			S	Oral	20 Mg		Forest
	Mirtazapine			C	Oral	15 Mg		Not Reported
	Gascon			C	Oral	120 Mg		Not Reported
	Mosapride Citrate			C	Oral	15 Mg		Not Reported
	Magnesium Oxide			C	Oral	750 Mg		Not Reported
	Lorazepam			C	Oral	1.5 Mg		Not Reported
	Flunitrazepam			C	Oral	2 Mg		Not Reported
	Risperdal			C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2012	8438400	EXPEDITED (15-DAY)	N	OT	US-FRI-1000027356		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Heart Rate Increased; Migraine; Palpitations	Lexapro			S	Oral	20 Mg		Forest
	Fentanyl			C				Not Reported
	Soma			C				Not Reported
	Norco			C				Not Reported

	Trazodone Hydrochloride	C	Not Reported
	Gabapentin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2012	8438429	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2012052996		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Mood Swings; Paranoia; Suicidal Ideation	Pristiq Extended Release			S		50 Mg, Daily		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Seroquel			S		300 Mg, Daily		Not Reported
	Seroquel			S		600 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2012	8438619	EXPEDITED (15-DAY)	N	OT	US-FRI-1000028633			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Fall; Feeling Abnormal; Movement Disorder; Muscle Twitching; Paraesthesia; Visual Impairment	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2012	8436388	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000028689		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity Vasculitis; Vascular Purpura	Escitalopram Oxalate			S	Oral			Forest
	Influenza Virus Vaccine Nos			S	Intramuscular	Single Dose On 22-Nov-2011		Not Reported
	Clamoxyl (Amoxicillin)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2012	8438632	EXPEDITED (15-DAY)	Y	OT	DE-FRI-1000028710		59 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dizziness; Dysgeusia; Insomnia; Nausea; Nervousness; Panic Attack; Restlessness; Suicidal Ideation; Supraventricular Extrasystoles; Weight Decreased	Escitalopram Oxalate			S	Oral	5 Mg (5 Drops)		Forest
	Escitalopram Oxalate			S				Forest
	Escitalopram Oxalate			S	Oral	10 Mg (10 Drops)		Forest
	Escitalopram Oxalate			S	Oral	8 Mg (8 Drops)		Forest
	Doxepin Hydrochloride			C	Oral	15 - 80 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2012	8441525	EXPEDITED (15-DAY)	Y	HO	CH-ASTRAZENECA-2012SE13176		72 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Condition Aggravated; Confusional State; Dehydration	Seroquel Xr			S	Oral		5 DAY	Astrazeneca
	Cipralex			S	Oral		12 DAY	Not Reported
	Zuclopenthixol			S	Oral		8 DAY	Not Reported
	Clomethiazole			S	Oral		14 DAY	Not Reported
	Buprenorphine Hydrochloride			S	Oral		3 DAY	Not Reported
	Insulatard Nph Human			C	Subcutaneous			Not Reported
	Dafalgan			C	Oral			Not Reported
	Beloc-Zok			C	Oral			Not Reported
	Phosphonorm			C	Oral			Not Reported
	Levothyroxine Sodium			C	Oral			Not Reported
	Lasix			C	Oral			Not Reported
	Pramipexole Dihydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2012	8441812	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000028301		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Repolarisation Abnormality; Paraesthesia; Presyncope	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Escitalopram Oxalate			S	Oral	5 Mg		Not Reported
	Bromazepam			C	Oral	6 Mg		Not Reported
	Prazepam			C		Occasionally		Not Reported
	Magnesium			C		Occasionally		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2012	8456634	EXPEDITED (15-DAY)	Y	CA, OT	GER/GER/12/0023169			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Oesophageal Atresia	Zolpidem			S	Transplacental	Transplacental		Not Reported
	Mycophenolate Mofetil			S	Transplacental	0.5 Gm, Transplacental		Not Reported
	Lorazepam			S	Transplacental	Transplacental		Not Reported
	Escitalopram Oxalate			S	Transplacental	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2012	8359854	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2012-00252		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Arrest; Toxicity To Various Agents	Metoprolol Tartrate			S				Not Reported
	Simvastatin			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Amphetamine Aspartate And Amphetamine Sulfate And Dextroamphetamine Saccharate And Dextroamphetamine			S				Not Reported

	Clozapine	S	Not Reported
	Memantine Hydrochloride	S	Not Reported
	Solifenacin	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2012	8442601	DIRECT	N	DS, OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease Recurrence; Economic Problem; Hostility; Mania; Unemployment	Lexapro			S	Oral	10 Mg, 1 A Day, Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2012	8442851	EXPEDITED (15-DAY)	Y	CA	DE-SANOFI-AVENTIS-2012SA014787			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Oesophageal Atresia; Tracheal Atresia	Zolpidem Tartrate			S	Transplacental			Not Reported
	Escitalopram Oxalate			S	Transplacental			Not Reported
	Mycophenolate Mofetil			S	Transplacental			Not Reported
	Lorazepam			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2012	8442885	EXPEDITED (15-DAY)		HO	CH-FRI-1000027365			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Asthenia; Hyponatraemia; Seizure	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Remeron			S	Oral	45 Mg		Not Reported
	Remeron			S	Oral	45 Mg		Not Reported
	Remeron			S	Oral	30 Mg		Not Reported
	Seroquel			S	Oral	50 Mg		Not Reported
	Seroquel			S	Oral	50 Mg		Not Reported

Seroquel	S	Oral	100 Mg		Not Reported
Lorazepam	C	Oral	2.5 Mg		Not Reported
Lorazepam	C	Oral	1 Mg		Not Reported
Lorazepam	C	Oral	3 Mg		Not Reported
Lorazepam	C	Oral	2 Mg		Not Reported
Stilnox	C	Oral	12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2012	8443101	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-16415879		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Hypertension; Wrong Technique In Product Usage Process	Abilify			S			2 MTH	Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2012	8443818	EXPEDITED (15-DAY)	Y	OT	DE-FRI-1000028437		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Feeding; Gestational Diabetes; Meconium In Amniotic Fluid; Overdose; Pregnancy	Escitalopram Oxalate			S		40 Mg		Forest
	Escitalopram Oxalate			S		Unknown Dosage		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2012	8443819	EXPEDITED (15-DAY)	Y	OT	DE-FRI-1000028813			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Potentiating Drug Interaction; Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Pantozol			C		40 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg		Not Reported

	Seroquel Xr	S	Oral	200 Mg		Not Reported
	Seroquel Xr	S	Oral	100 Mg		Not Reported
	Seroquel Xr	S	Oral	200 Mg		Not Reported
	Seroquel Xr	S	Oral	300 Mg		Not Reported
	Remergil	S	Oral	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2012	8443922	EXPEDITED (15-DAY)	Y	HO	CH-FRI-1000028832		72 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Confusional State; Dehydration	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Not Reported
	Zuclopenthixol Acetate			S	Oral	40 Mg		Not Reported
	Zuclopenthixol Acetate			S	Oral	60 Mg		Not Reported
	Zuclopenthixol Acetate			S	Oral	50 Mg		Not Reported
	Seroquel Xr			S	Oral	50 Mg		Not Reported
	Seroquel Xr			S	Oral			Not Reported
	Seroquel Xr			S	Oral			Not Reported
	Seroquel Xr			S	Oral			Not Reported
	Clomethiazole			S	Oral	600 Mg		Not Reported
	Clomethiazole			S				Not Reported
	Buprenorphine Hydrochloride			S	Oral	0.1 Mg		Not Reported
	Dafalgan			C	Oral	3 G		Not Reported
	Insulatard Nph Human			C	Other	30 Iu		Not Reported
	Insulatard Nph Human			C		16 Iu		Not Reported
	Beloc-Zok			C	Oral	12.5 Mg		Not Reported
	Phosphonorm			C	Oral	900 Mg		Not Reported
	Levothyroxine Sodium			C	Oral	150 Mcg		Not Reported
	Lasix			C	Oral	500 Mg		Not Reported
	Lasix			C	Oral	250 Mg		Not Reported

	Pramipexole Dihydrochloride	C	Oral	0.075 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2012	8447947	EXPEDITED (15-DAY)	Y	HO	FR10S00054		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hyperreflexia; Hypertension; Hypertonia; Hyponatraemia; Overdose; Serotonin Syndrome; Somnolence; Tachycardia; Tremor	Loramyc			S		50 Mg Milligram (S) X		Not Reported
	Seroplex			S	Buccal	5 Mg Milligram (S) X 1 1 Per Days Buccal		Not Reported
	Levothyroxine Sodium			C				Not Reported
	Timolol Maleate			C				Not Reported
	Travoprost			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2012	8445413	EXPEDITED (15-DAY)	Y	CA, HO, OT	DE-FRI-1000028438		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Maternal Exposure During Breast Feeding; Neonatal Respiratory Distress Syndrome; Overdose; Patent Ductus Arteriosus; Pyelocaliectasis	Escitalopram Oxalate			S	Transplacental	40 Mg		Forest
	Escitalopram Oxalate			S	Transmammary			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2012	8430530	NON-EXPEDITED	N	OT	US-PFIZER INC-2012049897			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Insomnia; Mania; Weight Increased	Zoloft			S		Unk		Pfizer

	Celexa	S	Unk	Not Reported
	Paxil	S	5 Mg, Unk	Not Reported
	Prozac	S	Unk	Not Reported
	Ativan	S	0.5 Mg, 3x/Day	Not Reported
	Lexapro	S	Unk	Not Reported
	Brovana	C	15 Ug, 2x/Day	Not Reported
	Budesonide	C	0.25 Mg, 2x/Day	Not Reported
	Ipratropium Bromide	C	0.2 %, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2012	8447002	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-16422461			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombosis	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2012	8447531	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000028893		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Overdose; Respiratory Failure; Somnolence	Escitalopram Oxalate			S	Oral	1 Df		Forest
	Prazepam			S	Oral	2 Df		Not Reported
	Levothyrox			C				Not Reported
	Amisulpride			C				Not Reported
	Mirtazapine			C				Not Reported
	Pantoprazole			C				Not Reported
	Praxinor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2012	8455645	EXPEDITED (15-DAY)	Y	CA	2012020256			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maternal Drugs Affecting Foetus; Oesophageal Atresia; Premature Baby; Tracheal Atresia	Zolpidem		S	Transplacental	Transplacental	Not Reported
	Mycophenolate Mofetil		S	Transplacental	Transplacental	Not Reported
	Escitalopram Oxalate		S	Transplacental	Transplacental	Not Reported
	Lorazepam		S	Transplacental	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2012	8461083	EXPEDITED (15-DAY)	N	OT	DSA_55286_2012		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Wellbutrin Xl (Not Specified)			S		(300 Mg,)		Not Reported
	Viibryd			S		(Df)		Not Reported
	Lexapro			S		(Df)		Not Reported
	Ambien			S		(Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2012	8450335	EXPEDITED (15-DAY)	Y	LT, OT	DE-ROXANE LABORATORIES, INC.-2012-RO-00779RO		43 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Gambling Disorder; Nicotine Dependence; Suicide Attempt; Theft	Ropinirole			S		0.75 Mg		Roxane
	Ropinirole			S		2 Mg		Roxane
	Escitalopram Oxalate			S		30 Mg		Not Reported
	Escitalopram Oxalate			S		20 Mg		Not Reported
	Quetiapine			S		100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2012	8456200	DIRECT					29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Agitation; Alanine Aminotransferase	Escitalopram Oxalate			S				Not Reported
	Actigall			C				Not Reported

Increased; Anxiety; Aspartate Aminotransferase Increased; Autoimmune Hepatitis; Blood Bilirubin Increased; Chromaturia; Crying; Dyspnoea; Encephalopathy; Fatigue; Hallucination; Insomnia; International Normalised Ratio Increased; Jaundice; Liver Disorder; Liver Injury; Nausea; Pruritus; Rash	Prednisone	C	Not Reported
	Ativan	C	Not Reported
	Imuran	C	Not Reported
	Phenergan	C	Not Reported
	Zyprexa	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2012	8437815	EXPEDITED (15-DAY)	Y	OT	CY-FRI-1000028374		26 YR	Male	CYP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Overdose	Escitalopram Oxalate			S	Oral	40 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2012	8453640	NON-EXPEDITED	N		US-PFIZER INC-2012060644			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Apathy; Blood Pressure Decreased; Crying; Depression; Feeling Abnormal; Hunger; Nicotine Dependence; Obsessive Thoughts; Onychophagia; Weight Increased	Effexor Xr			S	Oral	150 Mg, 1x/Day (1 Cap Po Nightly)		Pfizer
	Effexor Xr			S	Oral	75 Mg, 1x/Day (1 Cap Po Nightly)		Pfizer
	Lexapro			S		Unk		Not Reported
	Lexapro			S		60 Mg, Daily		Not Reported
	Metoprolol Succinate			S		50 Mg, Daily		Not Reported
	Elavil			C		Unk		Not Reported

Nicoderm Cq	C	Unk	Not Reported
Dexidrine	C	Unk	Not Reported
Oxybutynin	C	5 Mg	Not Reported
Ativan	C	0.5 Mg 1 1/2/Day	Not Reported
Micronor	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2012	8454623	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028952		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2012	8454923	EXPEDITED (15-DAY)	Y	DE	NL-ASTRAZENECA-2012SE15410		26 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Seroquel			S	Oral			Zeneca
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2012	8455615	EXPEDITED (15-DAY)	Y	HO, LT	FR-FRI-1000028997		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Prazepam			C				Not Reported
	Varnoline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2012	8455647	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000029004		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Purpura	Escitalopram Oxalate	S	Oral	10 Mg		Forest
	Xanax	C	Oral	0.25 Mg		Not Reported
	Stilnox	C	Oral			Not Reported
	Isoptin	C				Not Reported
	Lescol	C				Not Reported
	Orocal D3	C				Not Reported
	Tramadol Hydrochloride	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2012	8456001	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028955		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Craniosynostosis; Foetal Exposure During Pregnancy	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2012	8456256	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028957		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip; Cleft Palate; Congenital Anomaly	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2012	8456664	EXPEDITED (15-DAY)	Y	OT	PHHY2012AU019801		25 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Akathisia; Depression; Drug Interaction; Ejaculation Failure; Feeling Of Despair; Homicidal Ideation; Impulsive Behaviour;	Sertraline Hydrochloride			S		Unk Ukn, Unk		Novartis
	Escitalopram Oxalate			S		Unk Ukn, Unk		Not Reported
	Hypericum Perforatum Extract			S		Unk Ukn, Unk		Not Reported

Mania; Paranoia;
Personality Change;
Serotonin Syndrome;
Suicide Attempt

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2012	8456804	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000011010		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Vasoconstriction; Cerebrovascular Accident	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Derinox (Naphazoline Nitrate\Prednisolone)			S	Nasal	3 Dosage Form		Not Reported
	Relpax			S	Oral			Not Reported
	Flurbiprofen			S	Oral			Not Reported
	Codeine			C	Oral	45 Ml		Not Reported
	Cefuroxime			C	Oral	500 Mg		Not Reported
	Paracetamol			C	Oral	1500 Mg		Not Reported
	Paracetamol			C	Oral	3 Gram		Not Reported
	Topalgic (France)			C	Oral	300 Mg		Not Reported
	Oxazepam			C	Oral	25 Mg		Not Reported
	Loprazolam Mesilate			C	Oral	1 Mg		Not Reported
	Propranolol			C	Oral	160 Mg		Not Reported
	Depakote			C	Oral	750 Mg		Not Reported
	Citalopram			C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2012	8456856	EXPEDITED (15-DAY)	Y	HO	SE-FRI-1000021521		48 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Influenza Virus Vaccine Nos			S	Other			Not Reported

Almogran	C	Oral		Not Reported
Levothyroxine Sodium	C	Oral		Not Reported
Treo	C	Oral		Not Reported
Acetaminophen And Codeine	C	Oral		Not Reported
Zopiclone	C	Oral		Not Reported
Naprosyn	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2012	8456912	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000019377		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Pregnancy; Premature Delivery	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2012	8457792	EXPEDITED (15-DAY)	N	HO, OT	US-US-EMD SERONO, INC.-7117365		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Fatigue; Self-Injurious Ideation	Rebif			S	Subcutaneous			Not Reported
	Lexapro			S				Not Reported
	Marijuana			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2012	8467440	DIRECT	Y	HO			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bundle Branch Block Right; Cardiomyopathy; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg/ Once Iv Recent		Not Reported
	Droperidol			S	Intravenous (not otherwise specified)	0.625 Once Iv Recent		Not Reported
	Escitalopram Oxalate			S	Oral	Po Chronic		Not Reported

Inversion; Electrolyte Imbalance; Post Procedural Complication	Alprazolam	C	Not Reported
	Lexapro	C	Not Reported
	M.V.I. Adult	C	Not Reported
	Aprepitant	C	Not Reported
	Dexamethasone	C	Not Reported
	Midazolam	C	Not Reported
	Ondansetron	C	Not Reported
	Scopalamine	C	Not Reported
	Clondomycin	C	Not Reported
	Magnesium Sulfate	C	Not Reported
	Hydromorphone Hydrochloride	C	Not Reported
	Promethazine	C	Not Reported
	Lr	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2012	8469179	DIRECT	Y	OT			22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Substitution Issue	Escitalopram Oxalate			S		20mg 1 Wk With Generic		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2012	8469474	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2012-01364		67 YR	Male	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Decreased Interest; Depressed Mood; Drug Interaction; Fatigue; Hypomania; Insomnia	Mirtazapine (Mirtazapine)			S		(7.5 Mg, 1 D), Unknown		Not Reported
	Escitalopram Oxalate (Escitalopram Oxalate)			S		(10 Mg, 1 D), Unknown		Not Reported
	Amlodipine			C				Not Reported
	Losartan Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2012	8487846	NON-EXPEDITED	N		PHHY2011US62097			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour;	Fanapt			S		8 Mg, Bid		Not Reported

Insomnia; Weight Increased	Saphris	S		Not Reported
	Lexapro	S		Not Reported
	Seroquel	S		Not Reported
	Risperdal	S		Not Reported
	Pristiq Extended Release	C		Not Reported
	Effexor Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2012	8221463	EXPEDITED (15-DAY)	Y	HO, LT, OT	FR-PFIZER INC-2011261856		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Oedema Peripheral; Pulmonary Embolism	Stediril [Ethinyl Estradiol\Norgestrel]			S	Oral	1 Df, Cyclic		Pfizer
	Alprazolam			S	Oral	0.25 Mg, 3x/Day		Pfizer
	Zyprexa			S	Oral	5 Mg, 1x/Day	28 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2012	8461833	EXPEDITED (15-DAY)	N	CA	US-FRI-1000028973			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2012	8438314	EXPEDITED (15-DAY)	Y		JP-FRI-1000028736		83 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Headache; Nausea; Vomiting	Lexapro			S	Oral	10 Mg		Forest
	Eperisone Hydrochloride			C	Oral	100 Mg		Not Reported
	Nexium			C	Oral	20 Mg		Not Reported
	Teprenone			C	Oral	180 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2012	8462981	EXPEDITED (15-DAY)	Y	OT	AU-MYLANLABS-2012S1005008		24 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Drug Interaction; Suicide Attempt	Sertraline Hydrochloride			S	Unknown			Mylan
	Escitalopram Oxalate			S	Unknown	10 Mg/Day		Not Reported
	Hypericum Perforatum			S	Unknown	900 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2012	8464189	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000029128		46 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Tetany	Escitalopram Oxalate			S		10 Mg		Forest
	Mirtazapine			C		15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2012	8464233	EXPEDITED (15-DAY)	Y	CA, HO	ES-FRI-1000024659		35 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Hyperinsulinism; Hypoglycaemia Neonatal; Macrocephaly; Patent Ductus Arteriosus; Periventricular Leukomalacia	Escitalopram Oxalate			S	Transplacental	10 Mg		Forest
	Escitalopram Oxalate			S	Transplacental	10 Mg		Not Reported
	Escitalopram Oxalate			S	Transplacental	5 Mg		Not Reported
	Bromazepam			S	Transplacental	3 Mg		Not Reported
	Bromazepam			S	Transplacental	1.5 Mg		Not Reported
	Lormetazepam			S	Transplacental	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2012	8464234	EXPEDITED (15-DAY)	Y	CA, HO	ES-FRI-1000024660		35 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Neonatal; Atrial Septal Defect; Foetal Exposure During Pregnancy; Hypocalcaemia; Hypoparathyroidism	Escitalopram Oxalate			S	Transplacental	10 Mg		Forest
	Escitalopram Oxalate			S	Transplacental	10 Mg		Not Reported
	Escitalopram Oxalate			S	Transplacental	5 Mg		Not Reported
	Bromazepam			S	Transplacental	3 Mg		Not Reported
	Bromazepam			S	Transplacental	1.5 Mg		Not Reported
	Lormetazepam			S	Transplacental	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2012	8430015	EXPEDITED (15-DAY)	N	OT	US-BRISTOL-MYERS SQUIBB COMPANY-16409419		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral	Abilify			S	Oral			Not Reported
	Lipitor			S				Not Reported
	Lexapro			S				Not Reported
	Xanax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2012	8465217	EXPEDITED (15-DAY)	Y	HO	BE-PFIZER INC-2012065935		88 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hypoglycaemia; Hypotonia; Muscular Weakness; Myoclonus; Paraesthesia	Lyrica			S	Oral	75 Mg, 1x/Day	9 DAY	Pfizer
	Piperacillin And Tazobactam			S	Intravenous (not otherwise specified)	4 G, 3x/Day	9 DAY	Pfizer
	Cipralex			S	Oral	10 Mg, 1x/Day	9 DAY	Not Reported
	Casodex			C	Oral	50 Mg, 1x/Day		Not Reported
	Leuprolide Acetate			C	Intramuscular	1 Unk, Cyclic		Not Reported
	Amlodipine Besylate			C	Oral	5 Mg, 1x/Day		Not Reported
	Tamsulosin Hydrochloride			C	Oral	4 Mg, 1x/Day		Not Reported
	Innohep			C		0.7 Ml, 1x/Day		Not Reported

Ferrous Sulfate	C	Oral	525 Mg, 1x/Day		Not Reported
Vitamin D2	C	Oral	Unk		Not Reported
Bumetanide	C	Oral	1 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2012	8466503	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000029154		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Drug Interaction; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Tavanic			S	Oral	250 Mg		Not Reported
	Previscan (Fluindione)			S	Oral	3 Or 4 Tablets Daily		Not Reported
	Rifadine			C				Not Reported
	Tildiem			C				Not Reported
	Plavix			C				Not Reported
	Xanax			C				Not Reported
	Levothyrox			C				Not Reported
	Aprovel			C				Not Reported
	Movicol			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2012	8468469	EXPEDITED (15-DAY)	N	HO	US-FRI-1000024018		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Diverticulitis; Fatigue; Gastrointestinal Haemorrhage; Poor Quality Sleep	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Proscar			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Nexium			C				Not Reported
	Docusate Sodium			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Lisinopril			C	Oral	5 Mg		Not Reported
	Simvastatin			C	Oral	10 Mg		Not Reported
	Norvasc			C	Oral	2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2012	8478928	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2012-01409		25 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Akathisia; Depression; Ejaculation Failure; Mania; Overdose; Paranoia; Personality Change; Substance Use; Suicide Attempt; Toxicity To Various Agents	Sertraline Hydrochloride			S		300 Mg (300 Mg, 1 In 1 D)		Not Reported
	Escitalopram Oxalate (Escitalopram Oxalate)			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Hypericum Perforatum Extract			S		900 Mg (900 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2012	8481359	EXPEDITED (15-DAY)	Y	OT	2012AP000685		25 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Akathisia; Depression; Drug Interaction; Ejaculation Failure; Feeling Of Despair; Imprisonment; Impulsive Behaviour; Mania; Paranoia; Personality Change; Physical Assault; Serotonin Syndrome; Suicide Attempt	Sertraline Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S		10 Mg;Qd		Not Reported
	Hypericum			S		900 Mg; Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2012	8471264	NON-EXPEDITED	N		US-PFIZER INC-2012069691		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus	Aldactone			S		Unk		Pfizer
	Furosemide			S		Unk		Not Reported

	Ativan	S	Unk	Not Reported
	Vitamin C	S	Unk	Not Reported
	Lexapro	S	10 Mg, 2x/Day	Not Reported
	Lexapro	S	10 Mg, 1x/Day	Not Reported
	Prilosec	S	Unk	Not Reported
	Fish Oil	S	Unk	Not Reported
	Toprol Xl	C	Unk	Not Reported
	Gabapentin	C	Unk	Not Reported
	Carafate	C	Unk	Not Reported
	Atarax	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2012	8471772	EXPEDITED (15-DAY)	Y	OT	PHHY2012CA023350		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Torsade De Pointes	Furosemide			S				Novartis
	Escitalopram Oxalate			S				Not Reported
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2012	8473900	DIRECT	N	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Physical Assault	Lexapro			S	Oral	10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2012	8476432	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Product Dispensing Error	Lexapro			S	Oral	Tablet By Mouth		Not Reported
	Lipitor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2012	8473129	EXPEDITED (15-DAY)	Y	OT	CA-MYLANLABS-2012S1005654		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Torsade De Pointes	Furosemide			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2012	8474018	EXPEDITED (15-DAY)	Y	OT	CA-TEVA-329059USA		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Torsade De Pointes	Furosemide			S	Unknown			Ivax
	Quetiapine			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2012	8474418	EXPEDITED (15-DAY)	Y	OT	AU-WATSON-2012-05131		25 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Akathisia; Depression; Drug Interaction; Ejaculation Failure; Paranoia; Physical Assault; Suicidal Ideation	Sertraline Hydrochloride			S	Oral			Watson
	Escitalopram Oxalate			S				Not Reported
	Hypericum Perforatum			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2012	8474655	EXPEDITED (15-DAY)	Y	HO	HU-ASTRAZENECA-2012SE17625		53 YR	Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Arrhythmia	Quetiapine			S	Oral			Zeneca

	Lithium Carbonate	S	Unknown		Not Reported
	Carbamazepine	S	Unknown		Not Reported
	Escitalopram Oxalate	S	Unknown		Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Amiloride	C			Not Reported
	Hydrochlorothiazide	C			Not Reported
	Levothyroxine	C			Not Reported
	Clonazepam	C		0.5-0.5-3 Mg	Not Reported
	Cinolazepam	C			Not Reported
	Ketoconazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2012	8475034	EXPEDITED (15-DAY)	Y	HO	NO-FRI-1000026208		69 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Neutropenia	Escitalopram Oxalate			S		10 Mg		Forest
	Penicillin			S	Intravenous bolus	12 G		Not Reported
	Ventolin			C	Respiratory (inhalation)	5 Mg/Ml Four Times Daily		Not Reported
	Aspirin\Dipyridamole			C	Oral	2 Df		Not Reported
	Theophylline			C	Oral	700 Mg		Not Reported
	Atrovent			C	Respiratory (inhalation)			Not Reported
	Simvastatin			C	Oral	20 Mg		Not Reported
	Prednisolone			C	Oral	40 Mg Daily Tapering		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2012	8463402	EXPEDITED (15-DAY)	Y	HO, OT	DE-FRI-1000029073			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Maternal Exposure During Breast	Escitalopram Oxalate			S	Transplacental			Forest
	Escitalopram Oxalate			S	Transmammary			Not Reported

Feeding; Neonatal Disorder; Restlessness; Selective Eating Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2012	8476923	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000029336		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spinal Cord Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Previscan (Fluindione)			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2012	8477002	EXPEDITED (15-DAY)	Y	HO, LT, OT	IT-FRI-1000014266		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Reaction With Eosinophilia And Systemic Symptoms; Myalgia; Nausea	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Lamotrigine			S	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2012	8479010	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000011613		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Xanax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2012	8504152	NON-EXPEDITED	Y	OT	PHEH2009US13124		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Insomnia	Gleevec			S	Oral	400 Mg, Qd, Oral		Not Reported

Lexapro	S		Not Reported
Cymbalta	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2012	8487516	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2012US-54276		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metformin Hydrochloride			S	Oral			Ranbaxy
	Escitalopram Oxalate			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Metoprolol			S	Oral	Unk, Unk		Ipca
	Acetaminophen\Unspecified Ingredient			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2012	8560148	NON-EXPEDITED	N	OT	PHHY2010US23539		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Inadequately Controlled	Valturna			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Valsartan			C				Not Reported
	Carvedilol			C				Not Reported
	Temazepam			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2012	8454267	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000028962		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Level Increased; Fall	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Acetaminophen			S				Not Reported
	Bromazepam			S		12 Mg		Not Reported
	Donormyl (Doxylamine Succinate)			S		15 Mg		Not Reported

	Levothyrox		C	Oral	75 Mcg	Not Reported
	Tanakan		C	Oral	120 Mg	Not Reported
	Ramipril		C	Oral		Not Reported
	Inexium		C	Oral	20 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2012	8481532	EXPEDITED (15-DAY)	Y	DE, HO	FR-JNJFOC-20120313231		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Drug Interaction; Serotonin Syndrome; Tachyphrenia	Tramadol Hydrochloride And Acetaminophen			S	Oral			Not Reported
	Baclofen			C	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Zolpidem			C	Unknown			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2012	8454317	EXPEDITED (15-DAY)	Y	OT	HU-FRI-1000028967		47 YR	Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Xanax			C	Oral	1 Mg		Not Reported
	Xanax			C	Oral	0.5 Mg		Not Reported
	Concor			C	Oral	1.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2012	8485694	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000029298			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasticity; Musculoskeletal Stiffness; Pain	Lexapro			S				Forest
	Wellbutrin			S				Not Reported
	Cymbalta			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2012	8496597	EXPEDITED (15-DAY)	Y	HO	2012SP016141		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Somnolence; Suicide Attempt; Vomiting	Remeron			S	Oral	30 Mg;Once;Po		Not Reported
	Cipralex			S	Oral	30 Mg;Once;Po		Not Reported
	Alcohol (Ethanol)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2012	8497597	DIRECT		DS, OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Eye Disorder; Glucose Tolerance Impaired; Macular Degeneration; Spinal Stenosis; Tinnitus	Losartan Potassium			S		100mg/ Cut To 50mg & Also To 75mg 1 Per Day		Not Reported
	Lexapro			S		5mg 1 X Per Nite		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2012	8555336	NON-EXPEDITED	Y	OT	PHHY2011US55324			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual	Exelon			S	Transdermal	1 Df, One Per Day (4.6 Mg), Transdermal		Not Reported
	Lexapro			S		5 Mg, Per Day		Not Reported
	Namenda			S		2 Df, 5 Mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2012	8449558	EXPEDITED (15-DAY)	Y	HO	AU-FRI-1000028619		44 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Electrocardiogram Qt Prolonged; Sinus Bradycardia	Escitalopram Oxalate			S		20 Mg		Forest
	Seroquel			S				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Pariet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2012	8486830	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2012US-54470		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Lorazepam			S	Oral	Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Oxcarbazepine			S	Oral	Unk		Ranbaxy
	Quetiapine			S	Oral	Unk		Not Reported
	Zolpidem Tartrate			S	Oral	Unk		Ranbaxy
	Bupropion			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2012	8487117	DIRECT	Y	HO			4 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Restlessness; Tachycardia; Therapy Non-Responder; Vomiting	Vyvanse 30mg Shire			S				Shire
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2012	8488078	EXPEDITED (15-DAY)	Y	OT	BR-FRI-1000029484		34 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Increased; Dyspepsia; Hyperhidrosis; Pain In Extremity; Vaginal Haemorrhage	Lexapro		S	Oral	20 Mg	Forest
	Lexapro		S	Oral	10 Mg	Forest
	Alprazolam		C	Oral	1 Mg	Not Reported
	Alprazolam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2012	8488079	EXPEDITED (15-DAY)	Y	CA	DK-FRI-1000025965		27 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Motor Developmental Delay; Speech Disorder Developmental	Escitalopram Oxalate			S	Transplacental	20 Mg Daily In First And Second Trimester		Forest
	Escitalopram Oxalate			S	Transplacental	30 Mg Daily In 3rd Trimester		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2012	8488237	EXPEDITED (15-DAY)	Y	OT	CA-FRI-1000029463		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Off Label Use; Seizure	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	Overdose: Escitalopram (50 Mg At Once)		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2012	8499850	EXPEDITED (15-DAY)	Y	HO	2012SP016422		23 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Overdose; Restlessness; Somnolence; Suicide Attempt; Tachycardia; Toxicity To Various Agents; Tremor	Remeron			S	Oral	Po		Not Reported
	Lorazepam			S	Oral	10 Mg;Once;Po		Not Reported
	Cipralex			S	Oral	Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2012	8500786	EXPEDITED (15-DAY)	Y	HO, OT	2012SP016446		15 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Epilepsy; Intentional Overdose; Poisoning; Somnolence; Suicide Attempt	Remeron			S	Oral	10 Df, Once, Po		Not Reported
	Cipralex			S	Oral	11 Df, Once, Po		Not Reported
	Cocaine (Cocaine)			S		Unk		Not Reported
	Cannabis Sativa Subsp. Sativa Flowering Top			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2012	8660606	NON-EXPEDITED	N	OT	PHHY2010US18795		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Burning Sensation; Chest Pain; Depression; Dizziness; Dyspnoea; Fatigue; Hyperhidrosis; Myocardial Depression; Pain In Extremity; Palpitations; Rash	Exforge			S		5/120 Mg		Not Reported
	Penicillin (Benzylpenicillin Sodium)			S				Not Reported
	Sulfamethoxazole			S				Not Reported
	Prozac			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Zoloft			S				Not Reported
	Atenolol (Atenolol)			C				Not Reported
	Premarin			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2012	8490835	EXPEDITED (15-DAY)	Y	OT	2012SP000518		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Latuda			S	Oral			Not Reported
	Metformin Hydrochloride			S				Not Reported
	Lexapro			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Aspirin			S				Not Reported

	Lovenox			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2012	8491296	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2012US-54535		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Lorazepam			S	Oral	Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Alcohol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2012	8491304	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2012US-54541		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Lorazepam			S	Oral			Ranbaxy
	Clonazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	Unk, Unk		Not Reported
	Bupropion Hydrochloride			S	Oral			Not Reported
	Trazodone Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2012	8491380	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2012US-54598		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cyclobenzaprine Hydrochloride			S	Oral	Unk		Ranbaxy
	Amitriptyline			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2012	8491766	EXPEDITED (15-DAY)	Y	LT	AU-FRI-1000029495		23 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Loss Of Libido; Memory Impairment; Suicidal Ideation	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2012	8492086	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20120400391			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasticity; Musculoskeletal Stiffness; Pain	Tramadol Hydrochloride			S	Unknown			Not Reported
	Unspecified Ingredient			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2012	8492306	EXPEDITED (15-DAY)	N	OT	US-GLAXOSMITHKLINE-A0972041A		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Insomnia; Mood Swings; Paranoia; Suicidal Ideation	Wellbutrin			S	Oral			Glaxosmithkline
	Seroquel			S	Unknown	300mgd Per Day	3 YR	Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Pristiq Extended Release			S	Unknown	50mgd Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2012	8501420	EXPEDITED (15-DAY)	Y	HO, OT	AUR-APL-2012-01601		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bradyarrhythmia; Syncope	Atenolol (Atenolol)			S	Oral	(100 Mg, 1 D), Oral		Not Reported

	Rivastigmine Tartrate	S	Oral	(1 Dosage Forms, 1 D), Oral	Not Reported
	Minitran	S	Transdermal	(1 Dosage Forms, 1 D0, Transdermal	Not Reported
	Amlodipine Besylate	S	Oral	(1 Dosage Forms), Oral	Not Reported
	Ramipril	S	Oral	(1 Dosage Forms), Oral	Not Reported
	Escitalopram Oxalate	S	Oral	(1 Dosage Forms), Oral	Not Reported
	Aspirin	S	Oral	91 Dosage Forms), Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2012	8502568	EXPEDITED (15-DAY)	Y	HO	2012SP016684		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Pneumonia Aspiration; Poisoning; Respiratory Failure; Suicide Attempt; Tachycardia	Remeron			S	Oral	30 Mg;Po		Not Reported
	Chlorprothixene			S	Oral	15 Mg;Po		Not Reported
	Lorazepam			S	Oral	1 Mg;Po		Not Reported
	Cipralex			S	Oral	10 Mg;Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8354887	EXPEDITED (15-DAY)	Y	HO	CH-ASTRAZENECA-2012SE04203		17 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Seroquel Xr			S	Oral			Not Reported
	Seroquel Xr			S	Oral		61 DAY	Not Reported
	Cipralex			S	Oral		10 DAY	Not Reported
	Cipralex			S	Oral			Not Reported
	Amisulpride			S	Oral			Not Reported
	Amisulpride			S	Oral		7 DAY	Not Reported
	Amisulpride			S	Oral		4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8411275	EXPEDITED (15-DAY)	Y	HO	JP-JNJFOC-20120205844		59 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal	Risperdal			S	Oral	0.5-2 Mg/Day		Not Reported
	Risperdal			S	Oral	0.5-2 Mg/Day		Not Reported
	Zoloft			S	Oral			Not Reported
	Zoloft			S	Oral	25-100/Day		Not Reported
	Zoloft			S	Oral	25-100/Day		Not Reported
	Zoloft			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral	10-20/Day		Not Reported
	Magnesium Oxide			C	Oral	100-600/Day		Not Reported
	Sennoside			C	Oral			Not Reported
	Sulpiride			C	Oral			Not Reported
	Brotizolam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8484636	EXPEDITED (15-DAY)	Y	HO	US-FRI-1000028430		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteraemia; Disorientation; Overdose; Serotonin Syndrome	Lexapro			S		40 Mg		Forest
	Zyvox			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8493334	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2012US-54660		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Carvedilol			S	Oral	Unk		Ranbaxy

	Diazepam	S	Oral		Not Reported
	Diltiazem Hydrochloride	S	Oral		Not Reported
	Escitalopram Oxalate	S	Oral		Not Reported
	Lisinopril	S	Oral		Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8493349	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2012US-54673		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Acetaminophen		Y	S	Oral	Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral			Not Reported
	Propoxyphene Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8493355	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2012US-54682		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Respiratory Arrest	Simvastatin			S	Oral			Ranbaxy
	Escitalopram Oxalate			S	Oral			Not Reported
	Memantine			S	Oral			Not Reported
	Metoprolol			S	Oral	Unk		Ipca
	Solifenacin Succinate			S	Oral			Not Reported
	Dextroamphet Saccharat, Amphet Aspartate, Dextroamphet Sulfate And Amphet Sulfat			S	Oral			Not Reported
	Clozapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8493386	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2012US-54736		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Overdose	Gabapentin		S	Oral	Unk	Ranbaxy
	Escitalopram Oxalate		S	Oral	Unk	Not Reported
	Quetiapine		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8493534	EXPEDITED (15-DAY)	Y	HO	ES-FRI-1000029528		74 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Amiloride Hcl W/ Hydrochlorothiazide			S		5 Mg/50 Mg		Not Reported
	Ferrous Sulfate			C	Oral			Not Reported
	Calcifediol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8493709	EXPEDITED (15-DAY)	Y	OT	SE-FRI-1000029532		39 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electric Shock	Escitalopram Oxalate			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8493713	EXPEDITED (15-DAY)	Y		DE-FRI-1000027466		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Feeling Abnormal; Restlessness	Escitalopram Oxalate			S		Changing Dosages		Forest
	Escitalopram Oxalate			S		20 Mg		Forest
	Escitalopram Oxalate			S		Decreased Dosage (Nos)		Forest
	Nystatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8493745	EXPEDITED (15-DAY)	Y	OT	IE-FRI-1000029534			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Vaginal Haemorrhage	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8494069	EXPEDITED (15-DAY)	N	CA	US-FRI-1000029479		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly; Respiratory Distress; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8494434	EXPEDITED (15-DAY)	Y	DE	US-ROXANE LABORATORIES, INC.-2012-RO-00949RO			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Methadone Hydrochloride			S				Roxane
	Alprazolam			S				Roxane
	Citalopram			S				Roxane
	Amlodipine			S				Roxane
	Naproxen			S				Roxane
	Promethazine			S				Not Reported
	Marijuana			S				Not Reported
	Pioglitazone Hydrochloride			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2012	8510434	DIRECT	Y				60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Disease Recurrence; Drug Ineffective; Product	Escitalopram Oxalate			S	Oral	20mg One Qd Oral		Mylan
	Lexapro			S				Not Reported

Substitution Issue

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2012	8432307	EXPEDITED (15-DAY)	N	CA, HO, OT	US-FRI-1000028126		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cardiomegaly; Hydronephrosis; Hypertension; Jaundice Neonatal; Nodal Rhythm; Urinary Tract Infection Neonatal; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2012	8432837	EXPEDITED (15-DAY)	N	CA, HO	US-FRI-1000028145			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Tricuspid Valve Atresia; Pleural Effusion; Pneumothorax; Pulmonary Valve Stenosis; Subdural Haemorrhage; Transposition Of The Great Vessels; Urinary Tract Infection; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest
	Prenatabs Fa			C				Not Reported
	Iron			C				Not Reported
	Pepcid			C				Not Reported
	Colace			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2012	8483734	EXPEDITED (15-DAY)	Y	LT, OT	DE-FRI-1000029424		23 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage Neonatal; Foetal Exposure During Pregnancy	Escitalopram Oxalate			S	Transplacental	10 Mg		Forest
	Escitalopram Oxalate			S	Transplacental	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2012	8495385	DIRECT	N	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Crying; Depression; Drug Withdrawal Syndrome; Product Substitution Issue; Tremor	Escitalopram Oxalate			S	Oral	20.0 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2012	8495886	EXPEDITED (15-DAY)	Y	DE	US-RANBAXY-2012US-55008		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Acetaminophen\Hydrocodone Bitartrate			S	Oral	Unk		Ranbaxy
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Buprenorphine\Naloxone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2012	8496058	EXPEDITED (15-DAY)	N	HO, OT	PHHY2010IN37440		46 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Anxiety; Blood Follicle Stimulating Hormone Increased; Depressed Mood; Drug Interaction; Galactorrhoea; Intracranial Mass; Sleep Disorder	Glyburide			S		5 Mg Per Day		Novartis
	Imipramine			S		75 Mg Per Day		Not Reported
	Escitalopram Oxalate			S		20 Mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2012	8496656	EXPEDITED (15-DAY)	Y	DE	GB-FRI-1000029577			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Respiratory Failure	Escitalopram Oxalate			S	Oral	50 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2012	8433984	EXPEDITED (15-DAY)	N	CA, HO, OT	US-FRI-1000028153			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arnold-Chiari Malformation; Dehydration; Dilatation Ventricular; Epilepsy; Hydrocele; Hydrocephalus; Hypoglycaemia; Hypotension; Microcephaly; Phimosis; Spina Bifida	Lexapro			S	Transplacental			Forest
	Prenate Elite			C	Transplacental			Not Reported
	Pepcid			C	Transplacental			Not Reported
	Prevacid			C	Transplacental			Not Reported
	Tums			C	Transplacental			Not Reported
	Rolaids			C	Transplacental			Not Reported
	Prilosec			C	Transplacental			Not Reported
	Tylenol			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2012	8497994	EXPEDITED (15-DAY)	Y	HO	ES-FRI-1000026524		67 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Myopathy	Escitalopram Oxalate			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2012	8498321	EXPEDITED (15-DAY)	Y	HO	JP-FRI-1000028442		65 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Lexapro			S	Oral	20 Mg		Forest
	Sulpiride			C	Oral			Not Reported
	Anafranil			C	Oral			Not Reported

	Cymbalta			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2012	8498407	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029453		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Feeling Abnormal; Homicidal Ideation; Nausea	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S			14 DAY	Forest
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2012	8339845	EXPEDITED (15-DAY)	Y	OT	2011SP060107		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Asthenia; Infection; Viral Upper Respiratory Tract Infection	Celestamine			S	Oral	1 Df;Qd;Po		Not Reported
	Disulfiram			S	Oral	500 Mg;Po		Not Reported
	Escitalopram Oxalate			S	Oral	Po		Not Reported
	Dienogest\Estradiol Valerate			S	Oral	1 Df;Qd;Po		Not Reported
	Aerius (Desloratadine)			C				Not Reported
	Augmentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2012	8485767	EXPEDITED (15-DAY)		HO	IE-FRI-1000029419		80 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Cardiac Failure; Condition Aggravated; Dysphagia; Fall; Fluid Intake Reduced; General Physical Health Deterioration; Pleural Effusion; Psychotic Disorder; Therapy Non-	Lexapro			S				Forest
	Unspecified Ingredient			S				Not Reported

Responder; Urinary Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2012	8491424	EXPEDITED (15-DAY)		OT	IE-FRI-1000029458		28 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Galactorrhoea; Headache	Escitalopram Oxalate			S				Forest
	Risperidone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2012	8499746	EXPEDITED (15-DAY)	Y	DE	US-ROXANE LABORATORIES, INC.-2012-RO-00964RO			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Methadone Hydrochloride			S				Roxane
	Diazepam			S				Roxane
	Quetiapine Fumarate			S				Roxane
	Topiramate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2012	8500148	DIRECT	N	DE			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Gun Shot Wound; Intentional Self-Injury; Partner Stress; Product Substitution Issue	Escitalopram 20 Mg Mylan			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2012	8500184	DIRECT	N	CA, DE, DS, HO, LT, RI, OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anger; Anxiety; Crying; Disturbance In Attention; Drug Ineffective; Emotional Disorder; Irritability; Mood Swings; Product Substitution Issue	Escitalopram 20 Mg Mylan		S	Oral	2 Tablets	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2012	8500430	EXPEDITED (15-DAY)	Y	DE	US-ROXANE LABORATORIES, INC.-2012-RO-00972RO			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Methadone Hydrochloride			S				Roxane
	Citalopram			S				Roxane
	Alprazolam			S				Roxane
	Promethazine			S				Not Reported
	Quinine Sulfate			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2012	8291269	EXPEDITED (15-DAY)	Y	DE	PHHY2011US108287		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metoprolol			S				Novartis
	Clonazepam			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Metoclopramide			S				Not Reported
	Duloxetine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2012	8478941	EXPEDITED (15-DAY)	Y	HO	NL-FRI-1000029362		81 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Feeling Of	Citalopram			S	Oral	20 Mg		Forest
	Citalopram			S				Forest

Despair; Malaise; Nausea; Nervousness; Tension	Citalopram		S	Oral	20 Mg		Forest
	Citalopram		S	Oral	10 Mg		Forest
	Citalopram		S	Oral	20 Mg		Forest
	Lexapro		S	Oral	10 Mg		Forest
	Lexapro		S				Forest
	Alprazolam		C	Oral			Not Reported
	Oxazepam		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2012	8498096	EXPEDITED (15-DAY)	Y	OT	US-GLAXOSMITHKLINE-A0972437A		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Hypertension; Muscle Spasticity; Musculoskeletal Stiffness; Pain	Wellbutrin			S	Oral			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Cymbalta			S	Oral			Glaxosmithkline
	Tramadol Hydrochloride			S	Unknown			Glaxosmithkline
	Unspecified Ingredient			S	Unknown		4 YR	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2012	8501324	EXPEDITED (15-DAY)	Y	OT	CA-SANOFI-AVENTIS-2012SA023308		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Furosemide			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2012	8501352	EXPEDITED (15-DAY)	N	HO	US-BRISTOL-MYERS SQUIBB COMPANY-16490807		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Loss Of Consciousness; Orthostatic Hypotension	Abilify		S	Initially Given 5 Mg Then Reduced To 2.5mg	Not Reported
	Lexapro		S	Dose:5mg	Not Reported
	Vitamins		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2012	8502037	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029593			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased; Nephrolithiasis; Suicidal Ideation	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2012	8502603	EXPEDITED (15-DAY)	Y	OT	CA-ARROW GEN-2012-05912		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Torsade De Pointes	Furosemide			S	Unknown	Unk		Watson
	Quetiapine			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2012	8693880	NON-EXPEDITED	Y	OT	AUR-APL-2011-05649		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Lip Swelling; Swollen Tongue	Lisinopril (Lisinopril)			S		Unknown		Not Reported
	Penicillin			S		Unknown		Not Reported
	Benadryl			S				Not Reported
	Lexapro			S				Not Reported
	Mobic			S	Oral	1 D, Oral		Not Reported
	Prinzide			S	Oral	1 D, Oral		Not Reported
	Celebrex			C				Not Reported
	Allegra-D (Allegra-D)			C				Not Reported

Amoxicillin	C		Not Reported
Nasonex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2012	8140357	EXPEDITED (15-DAY)	Y	HO, LT	FR-GLAXOSMITHKLINE-B0746122A		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Bacteraemia; Bone Marrow Failure; Cellulitis; Hyperthermia; Respiratory Disorder; Sepsis; Septic Shock	Betamethasone			S	Topical		49 DAY	Glaxosmithkline
	Escitalopram Oxalate			S	Oral	15mg Per Day	49 DAY	Unknown
	Cyamemazine			S	Oral	112.5mg Per Day	49 DAY	Unknown
	Tropatepine			S	Oral	10mg Per Day	28 DAY	Unknown
	Chlormadinone Acetate			S	Oral	10mg Per Day	42 DAY	Unknown
	Estradiol			S	Oral	2mg Per Day	42 DAY	Unknown
	Milnacipran Hydrochloride			C	Unknown			Unknown
	Xanax			C	Unknown			Unknown
	Lyrica			C	Unknown			Unknown
	Paracetamol			C	Unknown			Unknown
	Tegretol			C	Unknown			Unknown
	Mineral Oil			C	Unknown			Unknown
	Magnesium Lactate\Magnesium Pidolate\Pyridoxine Hydrochloride			C	Unknown			Unknown
	Lormetazepam			C	Unknown			Unknown
	Amorolfine Hydrochloride			C	Unknown			Unknown
	Aerius (Desloratadine)			C	Unknown			Unknown
	Crataegus			C	Unknown			Unknown
	Heptaminol Hydrochloride			C	Unknown			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2012	8476993	EXPEDITED (15-DAY)	Y	OT	BE-FRI-1000029299		44 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	15 Mg		Forest
	Lexapro			S	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2012	8503639	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000029687			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Agitation; Flat Affect; Irritability; Overdose	Escitalopram Oxalate			S	Oral	Overdose: 40 Mg Daily		Forest
	Escitalopram Oxalate			S	Oral	Overdose: 25 Mg Daily		Forest
	Escitalopram Oxalate			S	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2012	8525074	DIRECT	Y	OT			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Amnesia; Anxiety; Disturbance In Attention; Dyskinesia; Memory Impairment; Mental Status Changes; Panic Attack; Restlessness	Abilify			S	Oral	5mg Daily Oral		Not Reported
	Lexapro			S	Oral	10mg Daily Oral		Forest
	Citalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2012	8468680	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000029135		38 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Consciousness; Nausea; Photopsia	Lexapro			S	Oral	10 Mg		Forest
	Lithium Carbonate			C	Oral	400 Mg		Not Reported
	Ludiomil			C	Oral	20 Mg		Not Reported

Myslee	C	Oral	10 Mg		Not Reported
Brotizolam	C	Oral	0.25 Mg		Not Reported
Nizatidine	C	Oral	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2012	8483743	EXPEDITED (15-DAY)	Y	HO	IT-FRI-1000029398		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Bradyphrenia; Intentional Overdose; Sopor	Escitalopram Oxalate			S	Oral			Forest
	Escitalopram Oxalate			S	Oral	Overdose: 300 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2012	8505816	NON-EXPEDITED	Y		US-PFIZER INC-2012090048		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urine Odour Abnormal	Lipitor			S	Oral	40 Mg, Daily		Pfizer
	Lipitor			S	Oral	40 Mg, Daily		Pfizer
	Lexapro			S		10 Mg, Daily		Not Reported
	Lexapro			S		10 Mg, Daily		Not Reported
	Glucophage			C		1000 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2012	8507862	EXPEDITED (15-DAY)	N	CA	US-FRI-1000029638		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Atresia	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2012	8520425	EXPEDITED (15-DAY)	Y	RI, OT	FK201200929		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Torsade De Pointes	Furosemide			S				Not Reported
	Quetiapine Fumarate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2012	8445161	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000024586			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Supraventricular Extrasystoles	Lexapro			S	Transplacental	20 Mg		Forest
	Lexapro			S			8 MTH	Forest
	Valtrex			C	Transplacental	500 Mg		Not Reported
	Zofran			C	Transplacental	4 Mg Every 8 Hours As Needed		Not Reported
	Prenatabs Fa			C	Transplacental			Not Reported
	Zinc Sulfate			C	Transplacental			Not Reported
	Fish Oil			C	Transplacental			Not Reported
	Vitamin B12			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2012	8455927	EXPEDITED (15-DAY)	Y	HO, LT	ES-FRI-1000028966		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Furosemide			S	Oral	80 Mg		Not Reported
	Omeprazole			C	Oral	20 Mg		Not Reported
	Manidipine Hydrochloride			C	Oral	40 Mg		Not Reported
	Cardura			C	Oral	8 Mg		Not Reported
	Venlafaxine Hydrochloride			C	Oral	75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2012	8509553	NON-EXPEDITED			US-PFIZER INC-2012088013		55 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Sulfur			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2012	8510731	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029674		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Stress Fracture	Lexapro			S	Oral	10 Mg		Forest
	Multivitamins			C				Not Reported
	Calcium Carbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2012	8511027	NON-EXPEDITED	Y		US-PFIZER INC-2012089981			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Renal Pain; Urine Odour Abnormal	Lipitor			S	Oral	40 Mg, Daily		Pfizer
	Lipitor			S				Pfizer
	Lexapro			S		10 Mg, Daily		Not Reported
	Glucophage			C		1000 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2012	8522811	DIRECT	Y				3 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Substitution Issue; Urticaria	Escitalopram Oxalate	S	Oral	10 Mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2012	8523360	EXPEDITED (15-DAY)	N	OT	DSA_56063_2012			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Muscle Spasticity; Musculoskeletal Stiffness; Pain	Wellbutrin			S	Oral	(Df Oral)		Not Reported
	Tramadol Hydrochloride			S		(Df)		Not Reported
	Lexapro			S		(Df)		Not Reported
	Cymbalta			S	Oral	(Df Oral)		Not Reported
	Unspecified Ingredient			S		(Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2012	8530320	DIRECT	Y	HO			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Insomnia; Nausea; Pneumocephalus; Skull Fracture; Syncope	Lexapro			S				Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2012	8362554	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2012022337		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cerebrovascular Accident; Insomnia; Malaise; Mental Disorder; Nervous System Disorder; Stress	Geodon			S		40 Mg, Daily		Pfizer
	Geodon			S		80 Mg, Daily		Pfizer
	Risperdal			S		4 Mg, Daily		Not Reported
	Risperdal			S		3 Mg, Daily		Not Reported
	Risperdal			S		2 Mg, Daily		Not Reported
	Risperdal			S		Unk		Not Reported

	Lexapro	S	20 Mg, Daily	Not Reported
	Klonopin	C	1 Mg, 3x/Day	Not Reported
	Klonopin	C		Not Reported
	Wellbutrin	C	75 Mg, 2x/Day	Not Reported
	Zocor	C	40 Mg, Daily	Not Reported
	Coreg	C	6.25 Mg, Daily	Not Reported
	Altace	C	5 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2012	8494000	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000028669		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Disorientation; Hallucination; Impaired Driving Ability; Suicidal Ideation	Escitalopram Oxalate			S	Oral	5 Mg		Forest
	Celiprolol			C	Oral			Not Reported
	Prazepam			C	Oral	5 Mg If Necessary		Not Reported
	Zolpidem			C	Oral	0.5 Df If Necessary		Not Reported
	Avodart			C	Oral	1 Df If Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2012	8514036	DIRECT	N	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Emotional Disorder; Feeling Abnormal; Product Substitution Issue	Escitalopram Oxalate			S	Oral		2.5 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2012	8514353	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000029668			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Fluctuation	Escitalopram Oxalate	S	10 Mg		Forest
	Oral Hypoglycemic Agents (Nos)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2012	8514354	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000029669			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Fluctuation	Escitalopram Oxalate			S		10 Mg		Forest
	Oral Hypoglycemic Agents Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2012	8514676	EXPEDITED (15-DAY)	Y	HO, OT	DE-FRI-1000029755		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy; Pyelonephritis	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	20 Mg		Not Reported
	Femibion			C	Oral	0.4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2012	8514694	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000029759		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Drug Dependence; Renal Failure; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Escitalopram Oxalate			S	Oral	15 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2012	8514763	EXPEDITED (15-DAY)	Y	OT	CA-FRI-1000029769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Hypertonia; Poor Quality Sleep; Trismus	Escitalopram Oxalate		S	Transplacental		Forest
	Benztropine Mesylate		S			Not Reported
	Gabapentin		S		600 Mg	Not Reported
	Gabapentin		S		1200 Mg	Not Reported
	Methadone Hydrochloride		S			Not Reported
	Nortriptyline Hydrochloride		S			Not Reported
	Rabeprazole		S			Not Reported
	Seroquel		S	Transplacental	300 Mg	Not Reported
	Zopiclone		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2012	8514782	EXPEDITED (15-DAY)	Y	OT	FR-PFIZER INC-2012092328		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Status Epilepticus	Xanax			S		Unk		Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Acetaminophen\Codeine Phosphate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2012	8514822	EXPEDITED (15-DAY)	Y	CA	DE-FRI-1000029756		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Naevus Flammeus	Escitalopram Oxalate			S	Transplacental	10 Mg		Forest
	Escitalopram Oxalate			S	Transplacental	20 Mg		Not Reported
	Femibion			C	Transplacental	0.4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2012	8523961	DIRECT	Y	OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Dreams; Insomnia; Psychomotor Hyperactivity	Escitalopram Oxalate		S	Oral	10mg By Mouth Daily	Mylan
	Synthroid		C			Not Reported
	Prograf		C			Not Reported
	Lovaza		C			Not Reported
	Metoprolol Tartrate		C			Not Reported
	Ramipril		C			Not Reported
	Alprazolam		C			Not Reported
	Vivelle Dot		C			Not Reported
	Actos		C			Not Reported
	Crestor		C			Not Reported
	Furosemide		C			Not Reported
	Alendronate		C			Not Reported
	Prednisone		C			Not Reported
	Smz/Tmp Ds		C			Not Reported
	Azithromycin		C			Not Reported
	Acyclovir		C			Not Reported
	Allopurinol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2012	8494557	EXPEDITED (15-DAY)	Y	OT	IE-FRI-1000029585			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Abnormal	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Nexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2012	8515903	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000029790		50 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2012	8516762	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000029699		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Lexapro			S	Oral			Forest
	Latuda			S	Oral			Not Reported
	Metformin Hydrochloride			S				Not Reported
	Aspirin			S				Not Reported
	Lovenox			S				Not Reported
	Folic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2012	8516913	EXPEDITED (15-DAY)	Y	OT	JP-GLAXOSMITHKLINE-B0783764A		37 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Eruption; Erythema; Erythema Multiforme; Generalised Erythema; Malaise; Myalgia; Pyrexia; Rash; Rash Generalised; Swelling Face; Toxic Skin Eruption	Lamictal			S	Oral	25mg Alternate Days	2 WEEK	Glaxosmithkline
	Paxil			S	Oral	20mg Per Day		Glaxosmithkline
	Depakene			S	Oral	600mg Per Day	15 DAY	Not Reported
	Lexapro			S	Oral	10mg Per Day	8 WEEK	Not Reported
	Clotiazepam			S	Oral	15mg Per Day		Not Reported
	Mosapride Citrate			S	Oral	10mg Per Day		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2012	8517651	EXPEDITED (15-DAY)	Y	OT	TR-FRI-1000016976		45 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract Subcapsular	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Ferrous Carbonate			C	Oral			Not Reported
	Lansoprazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2012	8517653	EXPEDITED (15-DAY)	Y	HO, LT	CH-FRI-1000029792			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Anxiety; Electrocardiogram Qt Prolonged; Hallucination, Auditory; Hyperhidrosis; Intentional Overdose; Loss Of Consciousness; Muscle Rigidity; Myoclonus; Serotonin Syndrome; Sinus Tachycardia; Suicide Attempt; Tremor; Vomiting	Escitalopram Oxalate	S	Oral	10 Mg		Forest
	Paroxetine	S	Oral	80 Tabs		Not Reported
	Zolpidem	S	Oral	17 Tabs		Not Reported
	Lorazepam	S	Oral	5 Tabs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2012	8517664	EXPEDITED (15-DAY)	Y	DS, HO	CA-FRI-1000029794		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2012	8517689	EXPEDITED (15-DAY)	Y	LT	JP-FRI-1000029813			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Sepsis	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Cymbalta			C	Oral	50 Mg		Not Reported
	Amitriptyline Hydrochloride			C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2012	8503671	EXPEDITED (15-DAY)	Y	OT	AU-FRI-1000029684		72 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Fatigue; Hyperhidrosis; Transient Ischaemic	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Felodipine			C		5 Mg		Not Reported

Attack; Tremor	Olmetec		C	40/12.5	Not Reported
	Clopidogrel		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2012	8505670	EXPEDITED (15-DAY)	N	HO	PHHY2012FR030122		52 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholic Liver Disease; Ascites; Blood Albumin Decreased; Condition Aggravated; Hepatic Cirrhosis; Hepatic Failure; Hepatitis; Hepatosplenomegaly; Jaundice; Liver Injury; Prothrombin Level Decreased	Alprazolam			S	Oral	0.25 Mg, Tid		Novartis
	Anafranil			S	Oral	0.25 Mg, Tid		Not Reported
	Aliskiren\Hydrochlorothiazide			S	Oral	1 Df, Daily		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, Daily		Not Reported
	Zyprexa			S	Oral	5 Mg, Daily	44 DAY	Not Reported
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2012	8520518	EXPEDITED (15-DAY)	Y	OT	DE-FRI-1000029886			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis	Escitalopram Oxalate			S				Forest
	Mirtazapine			S				Not Reported
	Venlafaxine Hydrochloride			C				Not Reported
	Opipramol Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2012	8520670	DIRECT	Y	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Memory Impairment	Lexapro			S	Oral	20.0 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2012	8521189	EXPEDITED (15-DAY)	Y	OT	US-MYLANLABS-2012S1007501		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Metformin Hydrochloride			S				Mylan
	Latuda			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Aspirin			S				Not Reported
	Lovenox			S				Not Reported
	Pyridoxine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2012	8524101	EXPEDITED (15-DAY)	N	HO	FR-BRISTOL-MYERS SQUIBB COMPANY-16519340		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Hyponatraemic Encephalopathy	Inexium			S		Tabs		Not Reported
	Irbesartan And Hydrochlorothiazide			S	Oral	1df=1 Tab		Bristol Myers Squibb
	Escitalopram Oxalate			S		Tabs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2012	8524354	EXPEDITED (15-DAY)	N	HO	US-PURDUE-USA-2012-0085521		92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Sodium Decreased; Confusional State; Somnolence	Colace		Y	S				Purdue Pharma
	Tenormin			S				Not Reported
	Benicar			S				Not Reported
	Lexapro			S				Not Reported
	Namenda			S				Not Reported
	Xanax			S				Not Reported
	Travatan			S				Not Reported
	Synthroid			S				Not Reported
	Ascorbic Acid\Calcium Pantothenate\Ergocalciferol\Pyri			S				Not Reported

doxine Hydrochloride\Retinol\Riboflavin\ Thiamine Hydrochloride				
Ascorbic Acid	S			Not Reported
Calcium Carbonate	S			Not Reported
Aspirin	S			Not Reported
Lutein	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2012	8524404	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029729		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Oligohydramnios; Seizure	Lexapro			S	Oral	40 Mg		Forest
	Lasix			C				Not Reported
	Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2012	8524507	EXPEDITED (15-DAY)	N	CA, OT	US-FRI-1000029730		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Congenital Cardiovascular Anomaly; Unevaluable Event	Lexapro			S	Transplacental	40 Mg		Forest
	Lasix			C				Not Reported
	Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2012	8534240	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fear; Muscle Spasms; Tremor	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2012	8525561	EXPEDITED (15-DAY)	Y	OT	US-SANOFI-AVENTIS-2012SA024842		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Lovenox			S	Oral			Not Reported
	Unspecified Ingredient			S				Not Reported
	Metformin Hydrochloride			S				Not Reported
	Aspirin			S				Not Reported
	Unspecified Ingredient			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2012	8525933	EXPEDITED (15-DAY)	Y	HO, LT	ES-ASTRAZENECA-2012SE25563		27 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Depressed Level Of Consciousness; Drug Interaction; Intentional Overdose	Seroquel			S	Oral	6 Tablets	1 DAY	Zeneca
	Escitalopram Oxalate			S	Oral		1 DAY	Not Reported
	Akineton			S	Oral	20 Tablets	1 DAY	Not Reported
	Invega			S	Oral	281	1 DAY	Not Reported
	Rivotril			S	Oral	60 Tablets	1 DAY	Not Reported
	Zyprexa			S	Oral	28 Tablets	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2012	8526207	EXPEDITED (15-DAY)	Y	HO, LT	ES-JNJFOC-20120408242		27 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Depressed Level Of Consciousness; Drug Interaction; Intentional Overdose	Invega			S	Oral			Not Reported
	Akineton			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2012	8527601	DIRECT	Y	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Product Substitution Issue; Tinnitus	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2012	8527641	DIRECT	Y	HO			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Fall; Mental Status Changes; Unresponsive To Stimuli	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2012	8532815	DIRECT	Y				28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Escitalopram Oxalate			S	Oral	20 Mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2012	8529509	DIRECT	N				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anger; Muscle Spasms; Musculoskeletal Pain; Neck Pain; Product Substitution Issue	Escitalopram Oxalate			S	Oral	10mg		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2012	8529552	DIRECT	N	CA, DE, DS, HO, LT, RI, OT			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Paranoia	Lexapro			S	Oral	Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2012	8529556	EXPEDITED (15-DAY)	Y	HO	IT-ROCHE-1062041		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Sopor	Rivotril			S		Started More Or Less Two Months Ago		Not Reported
	Rivotril			S	Oral			Not Reported
	Acetaminophen\Codeine Phosphate			S		As Required		Not Reported
	Acetaminophen\Codeine Phosphate			S	Oral	Form Strength 500 Mg + 30 Mg		Not Reported
	Cipralex			S		Started More Or Less Two Months Ago		Not Reported
	Cipralex			S	Oral			Not Reported
	Xanax			S		Started More Or Less Two Months Ago		Not Reported
	Xanax			S	Oral			Not Reported
	Lormetazepam			S		Started More Or Less Two Months Ago		Not Reported
	Lormetazepam			S	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Duloxetine Hydrochloride			C		Started More Or Less Two Months Ago		Not Reported
	Duloxetine Hydrochloride			C				Not Reported
	Cardirene			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2012	8530524	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000026942		49 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Destruction; Tendonitis	Escitalopram Oxalate			S	Oral	15 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2012	8530626	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000030047		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Citalopram			S		20 Mg		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Myambutol			C	Oral	800 Mg		Not Reported
	Rimifon			C	Oral	150 Mg		Not Reported
	Rifadine			C	Oral	300 Mg		Not Reported
	Rifadine			C	Oral	150 Mg		Not Reported
	Pyrazinamide			C	Oral	1000 Mg		Not Reported
	Vitamin B1 B6			C	Oral	3 Df		Not Reported
	Ramipril			C	Oral	1.25 Mg		Not Reported
	Atarax			C	Oral	3 Df		Not Reported
	Foradil			C	Oral	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2012	8538061	DIRECT	N	OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Chest Discomfort; Influenza Like Illness; Insomnia; Product	Escitalopram Oxalate			S	Oral	10mg 1 Day Oral		Mylan

Substitution Issue;
Restlessness; Skin Warm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2012	8538082	DIRECT	N	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral; Pain In Extremity	Lexapro			S	Oral	5 Mg 1 X Day Oral		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2012	8588665	EXPEDITED (15-DAY)	Y	HO	FR-ASTRAZENECA-2012SE24175		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Hyponatraemic Encephalopathy	Inexium			S	Oral		4 DAY	Astrazeneca
	Inexium			S	Oral			Astrazeneca
	Escitalopram Oxalate			S	Oral		8 DAY	Not Reported
	Coaprovel			S	Oral	150 Mg / 12.5 Mg, 1 Dosage Form Daily	5 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2012	8422872	EXPEDITED (15-DAY)	N	OT	US-GLAXOSMITHKLINE-A0967017A		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Drug Ineffective; Drug Interaction; Epilepsy; Somnolence; Tremor	Lamictal			S	Oral	150mg Twice Per Day		Glaxosmithkline
	Provera			S	Oral	10mg Per Day	20 YR	Not Reported
	Premarin			S	Oral	.625mg Per Day		Not Reported
	Topamax			S	Oral	300mg Per Day		Glaxosmithkline
	Vimpat			S	Unknown	100mg Four Times Per Day		Glaxosmithkline
	Lexapro			S	Unknown	20mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2012	8531661	NON-EXPEDITED	N	OT	US-TEVA-US022005		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hallucination; Oral Candidiasis	Provigil			S	Oral	100 Milligram;		Not Reported
	Risperdal			S	Oral	1.25 Milligram;		Not Reported
	Risperdal			S	Oral	.25 Milligram;		Not Reported
	Lexapro			S	Oral	20 Milligram;		Not Reported
	Namenda			C	Oral	20 Milligram;		Not Reported
	Protonix			C	Oral	20 Milligram;		Not Reported
	Potassium			C	Oral			Not Reported
	Lasix			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2012	8531851	NON-EXPEDITED	N		US-PFIZER INC-2012101146		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Decreased	Cardura			S		Unk		Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day (10mg, 1 In 1 D)		Not Reported
	Lexapro			S		10 Mg, Daily		Not Reported
	Tamsulosin Hydrochloride			S		Unk		Not Reported
	Wellbutrin			C		Unk		Not Reported
	Tricor			C		Unk		Not Reported
	Lipitor			C		Unk		Not Reported
	Alphagan P			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2012	8532232	NON-EXPEDITED	Y	HO	US-TEVA-US025061		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Clonus; Delirium; Diarrhoea; Dry Mouth; Hyperhidrosis; Hypervigilance; Intentional Overdose; Suicide Attempt; Tachycardia	Provigil			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Depakote			C				Not Reported
	Amitriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2012	8540760	DIRECT	Y	OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Urticaria	Escitalopram Oxalate			S	Oral	Es-Citalopram One Qday Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2012	8444013	EXPEDITED (15-DAY)	Y	OT	SE-FRI-1000026059		15 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Haemorrhage; Epistaxis; Nasal Congestion; Off Label Use; Pruritus; Rash; Scab; Weight Increased	Escitalopram Oxalate			S	Oral	5 Mg		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Nexium			C	Oral	40 Mg		Not Reported
	Calcium Carbonate			C				Not Reported
	Niferex (Polysaccharide-Iron Complex)			C	Oral	100 Mg		Not Reported
	Folic Acid			C	Oral			Not Reported
	Methotrexate			C	Oral	1.4286 Mg		Not Reported
	Prednisolone			C	Oral	15 Mg		Not Reported
	Melatonin			C	Oral	6 Mg		Not Reported
	Theralen			C	Oral	35 Mg		Not Reported
	Symbicort			C				Not Reported

Pulmicort Flexhaler	C			Not Reported
Singulair	C	5 Mg		Not Reported
Aerius (Desloratadine)	C	10 Mg		Not Reported
Tramadol Hydrochloride	C			Not Reported
Diazepam	C			Not Reported
Propavan	C	1-2 Tablets		Not Reported
Lactitol	C			Not Reported
Clemastine Fumarate	C			Not Reported
Pulmozyme	C	5 Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2012	8533158	EXPEDITED (15-DAY)	Y	OT	ES-PFIZER INC-2012100960		44 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Vaginal Haemorrhage	Celebrex			S	Oral	200 Mg, 1x/Day	28 DAY	Pfizer
	Lorazepam			C	Oral	1 Mg, Unk		Not Reported
	Zonegran			C	Oral	25 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2012	8533800	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2012SA027941		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenitis; Oesophageal Stenosis	Stilnox			S	Oral	Long-Term Therapy.		Not Reported
	Atarax			S	Oral			Not Reported
	Galantamine			S	Oral			Not Reported
	Haldol			S	Oral	2 Mg/Ml.		Not Reported
	Alprazolam			S	Oral	Long-Term Therapy.		Not Reported
	Escitalopram Oxalate			S	Oral	Long-Term Therapy.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2012	8534008	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20120411208		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenitis; Gastritis; Oesophageal Stenosis	Reminyl			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2012	8534313	EXPEDITED (15-DAY)	Y	LT	CA-FRI-1000030087		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Somnambulism; Therapeutic Product Effect Decreased	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2012	8534784	EXPEDITED (15-DAY)	Y	DE	PHHY2012US035679		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Carbamazepine			S				Novartis
	Alprazolam			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Lamotrigine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2012	8535091	EXPEDITED (15-DAY)	Y	HO	CA-FRI-1000030099			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Heart Rate Irregular	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	20 Mg		Not Reported
	Naproxen			C		Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2012	8535104	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000030073		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Lyrica			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Klipal			S	Oral	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2012	8588666	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000030051		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Hyponatraemic Encephalopathy	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Inexium			S	Oral	20 Mg		Not Reported
	Coaprovel			S	Oral	150 Mg/12.5 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2012	8532522	EXPEDITED (15-DAY)	Y	HO	IT-PFIZER INC-2012099309		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradypnoea; Intentional Self-Injury; Sopor	Xanax	S	Oral	20 Tablets	1 DAY	Pfizer
	Acetaminophen\Codeine Phosphate	S	Oral	16 Tablets	1 DAY	Not Reported
	Rivotril	S	Oral	10 Tablets (2 Mg)	1 DAY	Not Reported
	Cipralex	S	Oral	28 Tablets (20 Mg)	1 DAY	Not Reported
	Lormetazepam	S	Oral	30 Tablets (1 Mg)	1 DAY	Not Reported
	Lyrica	C	Oral	150 Mg, 1x/Day		Not Reported
	Duloxetine Hydrochloride	C		60 Mg, Unk	61 DAY	Not Reported
	Cardirene	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2012	8534858	EXPEDITED (15-DAY)	Y	DE	PHHY2012US035391		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metoprolol			S				Novartis
	Metformin Hydrochloride			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Esomeprazole			S				Not Reported
	Acetaminophen\Codeine Phosphate			S				Not Reported
	Unspecified Ingredient			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2012	8534890	EXPEDITED (15-DAY)	Y	DE	PHHY2012US035360		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Metoprolol			S				Novartis
	Clozapine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Amphetamine Aspartate And Amphetamine Sulfate And Dextroamphetamine Saccharate And Dextroamphetamine			S				Not Reported
	Memantine Hydrochloride			S				Not Reported
	Simvastatin			S				Not Reported

	Solifenacin Succinate	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2012	8536244	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000030083		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Speech Disorder	Escitalopram Oxalate			S	Oral	1 Df		Forest
	Topiramate			S	Oral	50 Mg		Not Reported
	Stilnox			C				Not Reported
	Atarax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2012	8536276	EXPEDITED (15-DAY)	Y	DE, HO	FR-FRI-1000030089		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage Intracranial; Overdose	Escitalopram Oxalate			S	Oral	25 Mg		Forest
	Plavix			S	Oral	75 Mg		Not Reported
	Tareg			C	Oral	40 Mg		Not Reported
	Digoxine			C	Oral	0.7143 Df		Not Reported
	Omeprazole			C	Oral	20 Mg		Not Reported
	Sinemet			C	Oral	250 Mg/25 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2012	8536982	EXPEDITED (15-DAY)	Y	HO	ES-MERCK-1204ESP00036		87 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastric Haemorrhage	Zocor			S	Oral			Merck
	Escitalopram Oxalate			S	Oral			Not Reported
	Acenocoumarol			S	Oral			Not Reported
	Calcium Carbonate\Cholecalciferol			C	Oral			Not Reported

	Enalapril Maleate	C	Oral	Not Reported
	Formoterol Fumarate	C	Respiratory (inhalation)	Not Reported
	Budesonide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2012	8537384	EXPEDITED (15-DAY)	Y	OT	CH-FRI-1000030137			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Colitis; Melaena	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Acemetacin			S	Oral	180 Mg		Not Reported
	Trimethoprim			S				Not Reported
	Pantozol (Switzerland)			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2012	8283678	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011292301		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Agitation; Anxiety; Arteriosclerosis; Bipolar Ii Disorder; Cholelithiasis; Depression; Drug Ineffective; Feeling Abnormal; Folliculitis; Hysterectomy; Insomnia; Libido Decreased; Memory Impairment; Migraine; Obesity; Respiratory Tract Infection; Salpingo-Oophorectomy Bilateral; Seborrhoea; Sinusitis; Stress; Withdrawal Syndrome	Zoloft			S		25mg, A Day For Seven Days	7 DAY	Pfizer
	Zoloft			S		50mg, For Four Weeks		Pfizer
	Zoloft			S		75 Mg, 1x/Day		Pfizer
	Zoloft			S		20 Mg, 1x/Day For 4 Weeks		Pfizer
	Zoloft			S		50 Mg, 1x/Day		Pfizer
	Zoloft			S		100 Mg, 1x/Day		Pfizer
	Zoloft			S		50 Mg, 2x/Day		Pfizer
	Zoloft			S		75 Mg, Unk		Pfizer
	Zoloft			S	Oral	50 Mg, Unk		Pfizer
	Zoloft			S		100 Mg, For 6 Months		Pfizer
	Xanax			S		0.25 Mg, 2x/Day		Pfizer

Xanax	S		0.5 Mg, Every 8 Hours		Pfizer
Effexor	S		37.5 Mg, 1x/Day	7 DAY	Pfizer
Effexor	S		75 Mg, 1x/Day		Pfizer
Calan	S		Unk		Pfizer
Inderal La	S		60mg 1 At Night		Pfizer
Ultram	S		50 Mg, As Needed, Every 8 Hours		Not Reported
Elavil	S		Unk		Not Reported
Lexapro	S		10 Mg, Unk		Not Reported
Wellbutrin	S		200mg, One Daily	3 DAY	Not Reported
Wellbutrin	S		150 Mg, 1x/Day		Not Reported
Wellbutrin	S		300 Mg, Unk		Not Reported
Topamax	S		25, Twice A Day For Seven Days		Not Reported
Topamax	S		50 Mg And 25 Mg In The Morning For 7 Days		Not Reported
Topamax	S		25 Mg, X7days In The Morning		Not Reported
Topamax	S		25 Mg, At Night For 17 Days		Not Reported
Lortab	S		7.5/500 One Every 6-8 Hours As Needed		Not Reported
Lortab	S		5/500 One Every 8 Hours As Needed	16 DAY	Not Reported
Lunesta	S		Unk		Not Reported
Mirapex	S				Not Reported
Cymbalta	S		30 Mg, 1x/Day		Not Reported
Paxil	S	Oral	10 Mg, 1x/Day		Not Reported
Paxil	S		20 Mg, 1x/Day		Not Reported
Midrin	S		Two Capsules At Start Of Migraine		Not Reported
Motrin	S				Not Reported

	Excedrin Migraine	S			Not Reported
	Ortho-Novum	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2012	8538348	EXPEDITED (15-DAY)		HO	ES-FRI-1000030121		27 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose	Escitalopram Oxalate			S	Oral	None Reported		Forest
	Akineton			S	Oral	2 Mg In Total		Not Reported
	Paliperidone			S	Oral	3 Mg In Total		Not Reported
	Clonazepam			S	Oral	3 Mg In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8474807	NON-EXPEDITED	N		US-PFIZER INC-2012072681		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Feeling Abnormal; Headache; Nausea; Withdrawal Syndrome	Pristiq Extended Release			S	Oral	15 Mg, Daily		Pfizer
	Pristiq Extended Release			S				Pfizer
	Lexapro			S		10 Mg, Daily		Not Reported
	Lexapro			S				Not Reported
	Zyrtec			C		10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8506346	EXPEDITED (15-DAY)	Y	OT	US-BRISTOL-MYERS SQUIBB COMPANY-16504102		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Oedema Due To Cardiac Disease; Pericardial Effusion; Weight Increased	Abilify			S	Oral	Qam	3 MTH	Not Reported
	Celexa			S	Oral	Qam		Not Reported
	Lexapro			S				Not Reported
	Effexor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8510315	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029664		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Heart Rate Decreased; Legal Problem; Malaise; Myocardial Infarction	Lexapro			S		10 Mg		Forest
	Trazodone Hydrochloride			S		200 Mg Qhs		Not Reported
	Klonopin			C				Not Reported
	Neurontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8520162	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000024535		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oesophageal Achalasia	Lexapro			S		10 Mg		Forest
	Lexapro			S				Forest
	Lexapro			S				Forest
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8541628	EXPEDITED (15-DAY)	Y	DE, HO	CH-FRI-1000030205			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Marcumar			S	Oral			Not Reported
	Aricept			C				Not Reported
	Adalat			C				Not Reported
	Beloc-Zok			C				Not Reported
	Digoxin			C				Not Reported
	Seroquel			C				Not Reported
	Torsemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8541629	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000030174		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Homicidal Ideation; Suicidal Ideation	Escitalopram Oxalate			S	Oral			Forest
	Escitalopram Oxalate			S				Forest
	Citalopram Hydrobromide			S		1/2 Drop Daily		Forest
	Citalopram Hydrobromide			S		2 Drops Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8541726	EXPEDITED (15-DAY)	Y	HO	ES-FRI-1000030208		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Trileptal			S	Oral	1200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8541806	EXPEDITED (15-DAY)	Y	OT	DE-FRI-1000022480		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Pregnancy	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8541817	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000030183		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenitis; Oesophageal Stenosis	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Atarax			S	Oral	100 Mg		Not Reported
	Reminyl			S	Oral	8 Mg		Not Reported

	Haldol		S	Oral	24 Df	Not Reported
	Stilnox		S	Oral	10 Mg	Not Reported
	Alprazolam		S	Oral	1.5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8549461	DIRECT	Y	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Rash	Escitalopram Oxalate			S	Oral	Once Tab Po Qd		Not Reported
	Seroquel			C				Not Reported
	Depakote			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8553588	DIRECT	Y				45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Escitalopram Oxalate			S	Oral	20 Mg Qd Po @3/15/12 X 4/7		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8553782	DIRECT	Y	OT			8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Ineffective; Emotional Disorder; Product Substitution Issue	Escitalopram Oxalate			S	Oral	10mg One Qd Oral		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2012	8554654	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product	Lexapro			S	Oral	20mg One Qhs P.O.		Teva

Substitution Issue; Suicidal Ideation	Synthroid	C	Not Reported
	Wellbutrin Xl	C	Not Reported
	Zyprexa	C	Not Reported
	Glucophage	C	Not Reported
	Vesicare	C	Not Reported
	Lithobid 450 Mg	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2012	8544591	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000030091		99 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased	Escitalopram Oxalate			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2012	8544841	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030084		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2012	8545520	EXPEDITED (15-DAY)	N	OT	US-WATSON-2012-06804		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Heart Rate Decreased; Legal Problem; Myocardial Infarction	Trazodone Hydrochloride			S	Oral	200 Mg Qhs		Watson
	Lexapro			S	Oral	1 Tab Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2012	8545662	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030101		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Congenital Anomaly; Congenital Spinal Cord Anomaly; Microcephaly	Lexapro		S	Transplacental	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2012	8545680	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030171		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2012	8535138	EXPEDITED (15-DAY)	Y	HO	CN-FRI-1000030072		38 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer	Lexapro			S	Oral	10 Mg		Forest
	Mirtazapine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2012	8535547	EXPEDITED (15-DAY)	Y	HO, OT	FR-PFIZER INC-2012100726		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Interstitial Lung Disease; Raynaud'S Phenomenon	Lyrica			S	Oral	Unk		Pfizer
	Escitalopram Oxalate			S	Oral	Unk	218 DAY	Not Reported
	Bromazepam			S	Oral	Unk		Not Reported
	Klipal			S	Oral	Two Dosages Forms Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2012	8545996	EXPEDITED (15-DAY)	N	OT	US-SHIRE-ALL1-2012-02058		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chills; Depression; Disturbance In Attention; Drug Ineffective; Product Prescribing Error; Product Quality Issue; Pyrexia; Sluggishness; Tremor; Yawning	Vyvanse		S	Oral	50 Mg, 3-4 Times Per Week As Req'D	Shire
	Vyvanse		S	Oral	30 Mg, 1x/Day:Qd	Shire
	Amoxapine		S	Oral	Unk, 1x/Day:Qd	Not Reported
	Wellbutrin		S	Oral	Unk, 1x/Day:Qd	Not Reported
	Lexapro		S		Unk, 1x/Day:Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2012	8546029	NON-EXPEDITED	Y		US-PFIZER INC-2012107268			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Tramadol Hydrochloride			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Duragesic			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Compazine			S		Unk		Not Reported
	Droperidol			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2012	8547293	EXPEDITED (15-DAY)	Y	LT	MY-FRI-1000030253		56 YR	Male	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate			S	Oral	15 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2012	8547451	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030194		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Congenital Anomaly; Craniosynostosis	Lexapro		S	Transplacental		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2012	8547487	EXPEDITED (15-DAY)	N	OT	US-ABBOTT-12P-163-0929570-00		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Arthralgia; Burning Sensation; Choking Sensation; Dizziness; Drug Ineffective; Dyspnoea; Eye Swelling; Headache; Nausea; Neck Pain; Panic Attack; Pharyngeal Oedema; Pruritus; Psoriasis; Swelling Face; Swollen Tongue	Humira			S				Not Reported
	Lexapro			S		Daily Dose: 5mg		Not Reported
	Xanax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2012	8547757	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030207		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydrocephalus; Multiple Congenital Abnormalities; Spina Bifida	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2012	8547966	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000030256		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Encephalopathy	Escitalopram Oxalate			S	Oral			Forest
	Coumadin			S	Oral	2 Mg		Not Reported

Alprazolam	S	Oral			Not Reported
Ramipril	C	Oral	5 Mg		Not Reported
Aldactone	C	Oral	25 Mg		Not Reported
Tahor	C	Oral			Not Reported
Carvedilol	C	Oral	12.5 Mg		Not Reported
Furosemide	C	Oral	20 Mg		Not Reported
Omeprazole	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2012	8555533	DIRECT	Y	RI			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Intolerance; Feeling Abnormal; Insomnia; Mood Altered; Weight Increased	Escitalopram Oxalate			S	Oral	10mg Once Daily Oral Early 2012 X 1 Month		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2012	8541718	EXPEDITED (15-DAY)	N	OT	PHHY2012US034939			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous;	Bufferin		Y	S				Novartis
Blood Cholesterol	Morphine			S				Not Reported
Increased; Blood Glucose	Codeine			S				Not Reported
Increased; Blood Pressure	Maxalt			S				Not Reported
Increased; Crying; Drug	Topamax			S				Not Reported
Ineffective; Gastric	Effexor			S				Not Reported
Disorder; Incorrect Dose	Inderal			S				Not Reported
Administered; Incorrect	Prozac			S				Not Reported
Product Administration	Paxil			S				Not Reported
Duration; Maternal	Serzone			S				Not Reported
Exposure During	Lexapro			S				Not Reported
Pregnancy; Micturition	Zantac			S				Not Reported
Urgency; Migraine; Panic	Lortab			S				Not Reported
Attack; Suicidal Ideation;	Tylenol			S				Not Reported

Vomiting; Weight Increased	Advil	S		Not Reported
	Aleve	S		Not Reported
	Bayer Aspirin	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2012	8548503	EXPEDITED (15-DAY)	Y	DE	PHHY2012CH037631			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ritalin			S				Novartis
	Chantix			S	Oral			Not Reported
	Cipralex			S	Oral	10 Mg, Daily		Not Reported
	Remeron			S	Oral	15 Mg Oral Dose ¼ - ½ Tablet Per Day		Not Reported
	Lorazepam			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2012	8548627	NON-EXPEDITED	N		US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2012-BP-09		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Flomax			S	Oral			Boehringer Ingelheim
	Lexapro			S	Oral	10 Mg		Not Reported
	Lexapro			S				Not Reported
	Cardura			S				Not Reported
	Wellbutrin			C				Not Reported
	Tricor			C				Not Reported
	Lipitor			C				Not Reported
	Alphagan P			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2012	8549690	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20120412742		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Overdose; Intentional Self-Injury; Sopor	Haldol		S	Oral	Not Reported
	Delorazepam		S	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2012	8550211	EXPEDITED (15-DAY)	Y	CA	TR-FRI-1000030270			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Musculoskeletal Anomaly	Escitalopram Oxalate			S	Transplacental	10 Mg		Forest
	Remeron			S	Transplacental			Not Reported
	Medazepam			S	Transplacental			Not Reported
	Xanax			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2012	8559915	EXPEDITED (15-DAY)	Y	DE	2012SP023212		30 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression	Remeron			S	Oral	15 Mg;Qd;Po		Not Reported
	Chantix			S	Oral	Po		Not Reported
	Cipralex			S	Oral	10 Mg;Qid;Po		Not Reported
	Ritalin			S	Oral	Po		Not Reported
	Temesta (Lorazepam)			C				Not Reported
	Imovane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2012	8531100	EXPEDITED (15-DAY)	Y	HO, OT	MX-RANBAXY-2012RR-55804		76 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Lactic Acidosis	Metformin Hydrochloride			S	Unknown	850 Mg/ 8h		Ranbaxy
	Ibuprofen			S	Unknown	600 Mg, Tid		Ranbaxy

	Escitalopram Oxalate		S	Unknown	20 Mg/Day	Not Reported
	Mirtazapine		S	Unknown	30 Mg/Day	Not Reported
	Simvastatin		S	Unknown	40 Mg/Day	Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2012	8544862	EXPEDITED (15-DAY)	Y	OT	PHHY2012IN037006		67 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypomania	Clonazepam			S		0.5 Mg/ Day		Novartis
	Amlodipine			C		2.5 Mg/ Day		Not Reported
	Losartan Potassium			C		25 Mg/ Day		Not Reported
	Escitalopram Oxalate			S		10 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2012	8551122	EXPEDITED (15-DAY)	N	DE, HO	FR-BRISTOL-MYERS SQUIBB COMPANY-16558868		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Confusional State; Death; Disorientation; Encephalopathy; Urinary Retention	Coumadin			S	Oral			Bristol Myers Squibb
	Escitalopram Oxalate			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Ramipril			C				Not Reported
	Aldactone			C				Not Reported
	Tahor			C				Not Reported
	Carvedilol			C				Not Reported
	Furosemide			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2012	8552683	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000030169		44 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Deep Vein Thrombosis; Drug Intolerance	Escitalopram Oxalate	S	Oral	5 Mg	Forest
	Escitalopram Oxalate	S	Oral	20 Mg	Forest
	Escitalopram Oxalate	S	Oral	10 Mg	Forest
	Escitalopram Oxalate	S	Oral	5 Mg	Not Reported
	Agomelatine	S	Oral	25 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2012	8557493	DIRECT	Y	OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Feeling Abnormal; Product Dose Omission; Product Substitution Issue	Escitalopram Oxalate			S	Oral	20mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2012	8558857	DIRECT	N	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Influenza Like Illness; Paraesthesia	Lexapro			S	Oral	20mg 1/Day Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2012	8537016	EXPEDITED (15-DAY)	Y	HO, LT	FR-ABBOTT-12P-056-0928789-00		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asterixis; Encephalopathy; Hepatic Failure; Hepatitis Toxic; Jaundice; Liver Disorder	Progesterone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Disulfiram			S	Unknown			Not Reported
	Oxazepam			C	Oral			Not Reported

	Levothyroxine	C	Unknown	Not Reported
	Estradiol	C	Oral	Not Reported
	Milnacipran	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2012	8532701	EXPEDITED (15-DAY)	Y	HO	ES-ABBOTT-12P-144-0928203-00		27 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose	Akineton			S	Oral	Total		Not Reported
	Escitalopram Oxalate			S	Oral	Total		Not Reported
	Invega			S	Oral	Total		Not Reported
	Rivotril			S	Oral	Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2012	8556549	EXPEDITED (15-DAY)	Y	DE, HO	TR-FRI-1000030396		44 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Escitalopram Oxalate			S	Oral			Forest
	Moclobemide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2012	8192244	EXPEDITED (15-DAY)	Y	DS, HO, OT	2010SP063654		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Accident At Work; Acute Sinusitis; Adnexa Uteri Mass; Anger; Apathy; Arthralgia; Arthritis; Asthenia; Back Pain; Bacterial Vulvovaginitis; Bipolar Disorder; Blood 1,25-	Nuvaring			S				Not Reported
	Lexapro			S				Not Reported
	Reglan			S				Not Reported
	Coumadin			S				Not Reported

Dihydroxycholecalciferol Decreased; Blood Homocysteine Increased; Bradykinesia; Bruxism; Central Nervous System Lesion; Cerebellar Haemorrhage; Chest Discomfort; Constipation; Diplopia; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Dysgeusia; Dysmenorrhoea; Dyspnoea; Dysuria; Epstein-Barr Virus Infection; Eye Injury; Eye Pain; Fatigue; Feeling Jittery; Fibromyalgia; Flatulence; Folate Deficiency; Gastritis; Genital Discharge; Headache; Herpes Dermatitis; Hot Flush; Hypercoagulation; Hyperhidrosis; Hypersensitivity; Hypotension; Impaired Work Ability; Infectious Mononucleosis; Influenza Like Illness; Insomnia; International Normalised Ratio Decreased; International Normalised Ratio Increased; Iritis; Iron Deficiency Anaemia; Irritable Bowel Syndrome; Joint Swelling; Labyrinthitis; Listless; Loss Of Libido; Lower Respiratory Tract Infection Viral; Lymphadenopathy; Lymphoedema; Major

Depression; Malaise; Mastoptosis; Memory Impairment; Meniere'S Disease; Menorrhagia; Metrorrhagia; Micturition Urgency; Migraine; Migraine With Aura; Mood Swings; Multiple Injuries; Muscle Spasms; Muscle Strain; Musculoskeletal Chest Pain; Myositis; Nausea; Neck Pain; Nightmare; Oedema Peripheral; Onychoclasis; Osteoarthritis; Ovarian Cyst; Pain; Pain In Extremity; Paraesthesia; Pelvic Pain; Pharyngitis; Pollakiuria; Premenstrual Syndrome; Proctalgia; Protein C Decreased; Pulmonary Embolism; Rash; Sedation; Sleep Apnoea Syndrome; Sleep Disorder; Snoring; Somnolence; Suicidal Ideation; Systemic Lupus Erythematosus; Tension Headache; Thrombosis; Tinnitus; Treatment Noncompliance; Tricuspid Valve Incompetence; Urinary Tract Infection; Uterine Leiomyoma; Vertigo Positional; Viral Infection; Vitamin B12 Deficiency; Vitamin D Deficiency; Vomiting; Vulvovaginal Mycotic Infection; Weight Decreased; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2012	8558990	EXPEDITED (15-DAY)	Y	HO	CA-ROCHE-1064985		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autonomic Nervous System Imbalance; Clonus; Dizziness; Drug Interaction; Hyperreflexia; Mydriasis; Restlessness; Serotonin Syndrome; Tremor	Tamiflu			S	Oral			Not Reported
	Clonazepam			C	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2012	8559282	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030352		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spina Bifida	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2012	8441533	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2012054125			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Bipolar Disorder; Diarrhoea; Drug Intolerance; Eating Disorder; Headache; Hypersensitivity; Influenza Like Illness; Neck Pain; Pain In Extremity; Pyrexia; Weight Decreased	Lipitor			S		80 Mg, Daily		Pfizer
	Lipitor			S				Pfizer
	Nitrostat			S		Unk		Pfizer
	Xanax			S		Unk		Pfizer
	Alprazolam			S		Unk		Pfizer
	Carvedilol			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Nitrostat			C		Unk		Not Reported

	Aspirin	C	81 Mg, Unk	Not Reported
	Quinapril	C	Unk, Daily	Not Reported
	Xanax	C	2 Mg, 3x/Day	Not Reported
	Coreg	C	25 Mg, Unk	Not Reported
	Plavix	C	75 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2012	8475062	EXPEDITED (15-DAY)	N	CA, HO, OT	US-FRI-1000029169			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage Neonatal; Foetal Exposure During Pregnancy; Pyloric Stenosis; Transposition Of The Great Vessels	Lexapro			S	Transplacental			Forest
	Prozac			C				Not Reported
	Natachew			C				Not Reported
	Esgic-Plus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2012	8498399	EXPEDITED (15-DAY)	N	OT	US-FRI-1000029168		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Hypertension; Maternal Exposure During Pregnancy	Lexapro			S	Oral			Forest
	Prozac			C	Oral	10 Mg		Not Reported
	Natachew			C	Oral	1 Mg		Not Reported
	Esgic-Plus			C	Oral	500 Mg/50 Mg/40 Mg Q6h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2012	8560609	EXPEDITED (15-DAY)	Y	HO, LT	CH-ABBOTT-12P-151-0934037-00		46 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asterixis; Chills; Confusional State; Decreased Appetite; Drug Interaction; Drug Level	Norvir			S	Oral			Not Reported
	Truvada			C	Oral			Not Reported

Increased; Fatigue; Hepatic Pain; Hyperhidrosis; Hypertonia; Jaundice; Muscle Rigidity; Mydriasis; Myoclonus; Nausea; Psychomotor Skills Impaired; Serotonin Syndrome; Tremor; Vertigo; Vomiting	Morphine Sulfate		C	Oral	340 Am + 320 Pm	Not Reported
	Wellvone		C	Oral		Not Reported
	Noroxin		C	Oral		Not Reported
	Oxazepam		C	Oral		Not Reported
	Torsemide		C	Oral		Not Reported
	Lactitol		C	Oral		Not Reported
	Seretide		C	Respiratory (inhalation)		Not Reported
	Nasonex		C	Nasal		Not Reported
	Flunitrazepam		C	Oral		Not Reported
	Aldactone		C		Daily	Not Reported
	Lansoprazole		C		Daily	Not Reported
	Cipralex		S	Oral		Not Reported
	Prezista		S	Oral		Not Reported
	Nexium		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2012	8571405	DIRECT	Y				57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Product Quality Issue; Product Substitution Issue	Escitalopram Oxalate			S	Oral	1 Daily Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2012	8541753	EXPEDITED (15-DAY)	Y	HO	IT-FRI-1000030215		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Medication Error; Overdose; Sopor	Escitalopram Oxalate			S	Oral	Overdose: 28 Unit Dose (Frequency - Total)		Forest
	Acetaminophen\Codeine Phosphate			S	Oral	Overdose: 16 Unit Dose		Not Reported

				(Frequency - Total)	
	Rivotril	S	Oral	Overdose: 10 Unit Dose (Frequency - Total	Not Reported
	Xanax	S	Oral	Overdose: 20 Unit Dose (Frequency - Total)	Not Reported
	Lormetazepam	S	Oral	Overdose: 30 Unit Dose (Frequency - Total)	Not Reported
	Lyrica	C	Oral	150 Mg	Not Reported
	Duloxetine Hydrochloride	C	Oral	60 Mg	Not Reported
	Cardirene	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2012	8561453	EXPEDITED (15-DAY)		CA, OT	PHHY2012DE039585			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Oesophageal Atresia; Premature Baby; Tracheal Atresia	Escitalopram			S	Transplacental			Not Reported
	Lorazepam			S	Transplacental			Novartis
	Zolpidem			S	Transplacental			Not Reported
	Mycophenolate Mofetil			S	Transplacental	(Maternal Dose: 0.5 G/Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2012	8562106	EXPEDITED (15-DAY)	Y	HO	FR-SANOFI-AVENTIS-2012SA033040		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Fall	Stilnox			S	Oral			Not Reported
	Amisulpride			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2012	8562190	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000024137		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2012	8562746	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000030478		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Overdose	Escitalopram Oxalate			S	Oral	Overdose Of 30 Mg Daily		Forest
	Mirtazapine			S	Oral	15 Mg		Not Reported
	Risperdal			S	Oral	2 Mg		Not Reported
	Lovenox			C	Subcutaneous	120 Mg/1.26 Ml Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2012	8562748	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000030479		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Tramadol Hydrochloride And Acetaminophen			S	Oral			Not Reported
	Tenormin			C				Not Reported
	Hydrochlorothiazide\Valsartan			C				Not Reported
	Aspirin			C				Not Reported
	Crestor			C				Not Reported
	Cytomel			C				Not Reported
	Alendronate Sodium			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2012	8491744	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000029494			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal	Lexapro			S	Oral	10 Mg		Forest
	Pravastatin Sodium			S		1 Df		Not Reported
	Lansoprazole			C	Oral	30 Mg		Not Reported
	Brotizolam			C	Oral	0.25 Mg		Not Reported
	Flunitrazepam			C	Oral	4 Mg		Not Reported
	Nitrazepam			C	Oral	10 Mg		Not Reported
	Seroquel			C	Oral	700 Mg		Not Reported
	Lithium Carbonate			C	Oral	600 Mg		Not Reported
	Magtect			C	Oral	35 Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2012	8530636	EXPEDITED (15-DAY)	Y	HO	JP-FRI-1000030013		74 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Enterocolitis; Nausea; Pollakiuria	Lexapro			S		10 Mg		Forest
	Amlodipine			C	Oral	5 Mg		Not Reported
	Candesartan Cilexetil			C	Oral	4 Mg		Not Reported
	Amaryl			C	Oral	1 Mg		Not Reported
	Actos			C	Oral	15 Mg		Not Reported
	Biofermin			C	Oral	3 G		Not Reported
	Lac-B			C	Oral	3 G		Not Reported
	Rhubarb			C	Oral	0.5 G		Not Reported
	Seibule			C	Oral	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2012	8565762	EXPEDITED (15-DAY)		HO, LT	ES-ROCHE-1065964		27 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depressed Level Of Consciousness; Intentional Overdose	Clonazepam		S	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Not Reported
	Biperiden		S	Oral	Not Reported
	Paliperidone		S	Oral	Not Reported
	Quetiapine Fumarate		S	Oral	Not Reported
	Olanzapine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2012	8565831	EXPEDITED (15-DAY)	N	HO	US-FRI-1000030389		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Intentional Self-Injury	Escitalopram Oxalate			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2012	8573891	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Dizziness; Nausea; Product Substitution Issue; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	20 Mg Daily 047 (Oral)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2012	8574275	DIRECT	N	LT, OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Product Dispensing Error; Wrong Product Administered	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2012	8566665	EXPEDITED (15-DAY)	Y	DS, OT	AT-PFIZER INC-2012116612		22 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Depression; Psychotic Disorder; Spinal Pain; Weight Increased	Ziprasidone Hydrochloride			S		60 Mg Daily		Pfizer
	Cipralex			S		20 Mg Daily		Not Reported
	Lithium Carbonate			S		950 Mg Daily		Not Reported
	Seroquel			S		35 Mg Daily		Not Reported
	Abilify			S		15 Mg Daily		Not Reported
	Edronax			C		6 Mg, Unk		Not Reported
	Inderal			C		10 Mg Daily		Not Reported
	Euthyrox			C		50 Mg, Unk		Not Reported
	Euthyrox			C		75 Mg, Unk		Not Reported
	Euthyrox			C		100 Mg, Unk		Not Reported
	Trazodone Hydrochloride			C		200 Mg, Unk		Not Reported
	Trazodone Hydrochloride			C		150 Mg, Unk		Not Reported
	Sucralfate			C		3 G, Unk		Not Reported
	Pantoprazole Sodium			C		20 Mg, Unk		Not Reported
	Bisoprolol Fumarate			C		2.5 Mg, Unk		Not Reported
	Selokeen			C		95 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2012	8567205	NON-EXPEDITED	N		US-GLAXOSMITHKLINE-A0973648A		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Vomiting	Votrient			S	Oral	800mgd Per Day		Glaxosmithkline
	Lexapro			S				Not Reported
	Tums			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2012	7775716	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-US-WYE-H11674109		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ageusia; Constipation; Decreased Appetite; Diarrhoea; Drug Ineffective; Dry Mouth; Dyskinesia; Muscle Twitching; Nightmare; Suicidal Ideation; Suicide Attempt; Therapeutic Product Effect Decreased; Tremor	Effexor Xr	S	Oral	75 Mg, 1x/Day		Pfizer
	Pristiq Extended Release	S	Oral	50 Mg, 1x/Day		Pfizer
	Pristiq Extended Release	S	Oral	Half A Tablet		Pfizer
	Doxepin Hydrochloride	S		Unk		Pfizer
	Zoloft	S		Unk		Pfizer
	Mirtazapine	S		Unk		Not Reported
	Paroxetine	S		Unk		Unknown
	Trazodone	S		Unk		Not Reported
	Wellbutrin	S		Unk		Not Reported
	Zyprexa	S		Unk		Not Reported
	Seroquel	S		Unk		Not Reported
	Lexapro	S		Unk		Not Reported
	Cymbalta	S		Unk		Not Reported
	Paxil	S		Unk		Not Reported
	Prozac	S		Unk		Not Reported
	Depakote	S		Unk		Not Reported
	One-A-Day Nos	C				Not Reported
	Fish Oil, Hydrogenated	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2012	8483744	EXPEDITED (15-DAY)	Y		IT-FRI-1000029399			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Procedural Complication	Escitalopram Oxalate			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2012	8528501	EXPEDITED (15-DAY)	Y	HO, OT	FR-PFIZER INC-2012094513		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Meningitis	Sulfasalazine			S	Oral	Unk	4380 DAY	Pfizer

Aseptic; Paraesthesia; Vasculitis	Lansoprazole	S	Oral	Unk	Unknown
	Pravastatin Sodium	S	Oral	Unk	Not Reported
	Escitalopram Oxalate	S	Oral	Unk	Not Reported
	Mesalazine	C			Not Reported
	Azathioprine	C			Not Reported
	Solupred (Prednisolone Sodium Metazoate)	C			Not Reported
	Cirkan	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2012	8547195	EXPEDITED (15-DAY)	Y	OT	CA-FRI-1000028475		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Withdrawal Syndrome; Dyskinesia; Muscle Twitching; Off Label Use; Seizure; Tongue Paralysis; Urine Output Decreased	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	May Give 15 Mg Instead Of 10 Mg When Necessary		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2012	8562785	EXPEDITED (15-DAY)	Y	HO	IT-FRI-1000030453		65 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Psychomotor Hyperactivity	Escitalopram Oxalate			S	Oral	4 Df		Forest
	Ranitidine			C		150 Mg		Not Reported
	Ramipril			C		1 Df		Not Reported
	Plavix			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2012	8568713	EXPEDITED (15-DAY)	Y	HO, LT	CH-JNJFOC-20120510996		46 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Decreased Appetite; Dizziness; Fatigue; Hepatic Cirrhosis; Hyperhidrosis; Mydriasis; Myoclonus; Serotonin Syndrome; Tremor	Prezista			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Norvir			S	Oral			Not Reported
	Nexium			S	Oral			Not Reported
	Truvada			S	Oral			Not Reported
	Morphine Sulfate			C	Oral			Not Reported
	Wellvone			C	Oral			Not Reported
	Noroxin			C	Oral			Not Reported
	Oxazepam			C	Oral			Not Reported
	Torsemide			C	Oral			Not Reported
	Lactitol			C	Oral			Not Reported
	Seretide			C	Oral			Not Reported
	Nasonex			C	Nasal			Not Reported
	Flunitrazepam			C	Oral			Not Reported
	Lansoprazole			C	Oral			Not Reported
	Spironolactone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2012	8568986	EXPEDITED (15-DAY)	Y	CA, OT	DE-ROXANE LABORATORIES, INC.-2012-RO-01257RO			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oesophageal Atresia; Premature Baby; Tracheal Atresia	Mycophenolate Mofetil			S	Transplacental		10 WEEK	Roxane
	Lorazepam			S	Transplacental			Roxane
	Zolpidem			S	Transplacental			Roxane
	Escitalopram Oxalate			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2012	8569444	EXPEDITED (15-DAY)	N	HO	CH-BRISTOL-MYERS SQUIBB COMPANY-		28 YR	Male	CHE

16582520

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Abilify			S	Oral			Not Reported
	Seroquel			S				Not Reported
	Cipralex			S	Oral			Not Reported
	Lithium Carbonate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2012	8569700	EXPEDITED (15-DAY)	Y	HO	US-FRI-1000030433		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Mental Disorder	Lexapro			S		10 Mg		Forest
	Xanax Xr			S	Oral	3 Mg		Not Reported
	Xanax Xr			S				Not Reported
	Xanax Xr			S				Not Reported
	Lipitor			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2012	8578090	DIRECT	N	LT, OT			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Agitation; Anxiety; Drug Interaction; Insomnia; Nervousness; Product Substitution Issue	Escitalopram Oxalate			S	Oral	10 Mg 1 Per Night Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2012	8578105	DIRECT	N	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Substitution Issue	Escitalopram Oxalate			S		10 Mg Daily		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2012	8445218	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000028862		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles	Escitalopram Oxalate			S		10 Mg		Forest
	Escitalopram Oxalate			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2012	8560792	EXPEDITED (15-DAY)	Y	HO, LT	ES-FRI-1000030452		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Upper Gastrointestinal Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Gabapentin			C	Oral			Not Reported
	Atorvastatin Calcium			C	Oral	80 Mg		Not Reported
	Seroquel			C	Oral	25 Mg		Not Reported
	Acetylsalicylic Acid			S	Oral			Not Reported
	Warfarin Sodium			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2012	8572243	EXPEDITED (15-DAY)	Y	OT	AT-PFIZER INC-2012116700		41 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Lyrica			S	Oral	150 Mg, 1x/Day	7 DAY	Pfizer
	Cipralex			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2012	8572851	EXPEDITED (15-DAY)	N	DS	AT-BRISTOL-MYERS SQUIBB COMPANY-16590309		20 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spinal Disorder; Weight Increased	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Lithium Carbonate			S				Not Reported
	Lithium Carbonate			S				Not Reported
	Quetiapine Fumarate			S				Not Reported
	Quetiapine Fumarate			S				Not Reported
	Ziprasidone Hydrochloride			S				Not Reported
	Ziprasidone Hydrochloride			S				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Euthyrox			C		Dosage Form: 50mg From 2008-09,75 Mg From 2009-10,100mg Since 2010-Ong		Not Reported
	Pantoloc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2012	8573460	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000030636		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Risperdal			S	Oral	2 Mg		Not Reported
	Keppra			C				Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2012	8574653	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000030315			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Ventricular Fibrillation	Escitalopram Oxalate			S		20 Mg		Forest
	Quetiapine Fumarate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2012	8588899	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dry Mouth; Feeling Abnormal; Flatulence; Libido Decreased; Product Substitution Issue	Escitalopram Oxalate			S	Oral	20mg 2 Tabs Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2012	8574886	EXPEDITED (15-DAY)	Y	OT	IN-PAR PHARMACEUTICAL, INC-2012SCPR004388			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Clonazepam			S	Unknown	0.5 Mg/Day At Bed Time		Par
	Escitalopram Oxalate			S	Unknown	10 Mg, / Day		Not Reported
	Amlodipine			C	Unknown	2.5 Mg, / Day		Not Reported
	Losartan Potassium			C	Unknown	25 Mg, / Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2012	8575722	EXPEDITED (15-DAY)	Y	HO	CH-GLAXOSMITHKLINE-B0801815A		57 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Potassium Decreased; Blood Pressure Systolic Decreased; Dizziness; Drug Interaction; Electrocardiogram Qt Prolonged	Deroxat		S	Oral	20mg Per Day	Glaxosmithkline
	Pipamperone		S	Unknown		Not Reported
	Abilify		S	Unknown		Not Reported
	Risperdal		S	Oral	1mg Per Day	Glaxosmithkline
	Cipralex		S	Unknown		Glaxosmithkline
	Metoprolol		S	Oral	25mg Per Day	Not Reported
	Gliclazide		C	Oral	30mg Per Day	Glaxosmithkline
	Aspirin Cardio		C	Oral	100mg Per Day	Glaxosmithkline
	Allopurinol		C	Oral	300mg Per Day	Glaxosmithkline
	Lasix		C			Glaxosmithkline
	Torsemide		C		5mg Per Day	Not Reported
	Telmisartan		C	Oral	80mg Per Day	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2012	8576777	EXPEDITED (15-DAY)	Y	HO	TR-MYLANLABS-2012S1010028		54 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Mania; Psychotic Disorder	Escitalopram Oxalate			S	Unknown	20 Mg/Day		Mylan
	Modafinil			S	Unknown	200 Mg/Day In The 1st Week Of Treatment; Then Increased To 400 Mg/Day		Not Reported
	Modafinil			S	Unknown	400 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2012	8588009	EXPEDITED (15-DAY)	Y	HO	2012SP025259		30 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Hallucination; Headache; Intentional Overdose; Sluggishness; Somnolence; Suicide	Remeron			S	Oral	20 Df;Once;Po		Not Reported
	Levetiracetam			S	Oral	10 Df;Once;Po		Not Reported
	Escitalopram Oxalate			S	Oral	20 Df;Once;Po		Not Reported

Attempt; Vomiting	Methylphenidate Hydrochloride		S	Oral	8 Df;Once;Po	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2012	8588398	DIRECT	Y	OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Educational Problem; Product Substitution Issue; Suicidal Ideation	Escitalopram Oxalate			S	Oral	Escitalopram 20mg Once Daily Oral	2 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2012	8589139	DIRECT					80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dystonia; Product Substitution Issue; Tremor	Escitalopram Oxalate			S	Oral	10 Mg. Od Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	7932083	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2011-01248		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Muscle Twitching; Nightmare; Suicidal Ideation; Suicide Attempt; Therapeutic Product Effect Decreased; Tremor	Mirtazapine			S				Not Reported
	Paroxetine Hydrochloride			S				Not Reported
	Pristiq Extended Release			S	Oral	50 Mg (50 Mg, 1 In 1 D), Oral; Patient Tried Taking Half A Tablet, Oral		Not Reported
					Oral	50 Mg (50 Mg, 1 In 1 D), Oral; Patient Tried Taking Half A Tablet, Oral		
	Effexor Xr			S	Oral	75 Mg (75 Mg, 1 In 1 D), Oral		Not Reported
	Doxepin Hydrochloride			S				Not Reported
	Zoloft			S				Not Reported

	Trazodone Hydrochloride	S	Not Reported
	Wellbutrin	S	Not Reported
	Seroquel	S	Not Reported
	Lexapro	S	Not Reported
	Cymbalta	S	Not Reported
	Prozac	S	Not Reported
	Depakote	S	Not Reported
	Paxil	S	Not Reported
	Zyprexa	C	Not Reported
	One-A-Day	C	Not Reported
	Fish Oil, Hydrogenated	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	8545220	EXPEDITED (15-DAY)	N	OT	CN-JNJFOC-20110406144		16 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Influenza Like Illness; Myocardial Necrosis Marker Increased; Somnolence	Invega			S	Oral			Not Reported
	Risperdal			S	Oral	0.5 Mg In The Morning And 1 Mg At Night		Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	8554570	EXPEDITED (15-DAY)	Y	OT	AU-FRI-1000030359			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Sclerosis; Off Label Use	Lexapro			S	Oral	10 Mg		Forest
	Nasonex			C				Not Reported
	Panvax			C				Not Reported
	Cefaclor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	8577299	EXPEDITED (15-DAY)	Y	HO, LT	ES-JNJFOC-20120513868		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Hypercreatininaemia; Rhabdomyolysis	Tramadol Hydrochloride And Acetaminophen		S	Oral	Not Reported
	Tramadol Hydrochloride		S	Oral	Not Reported
	Pantoprazole		S	Oral	Not Reported
	Depakene		S	Oral	Not Reported
	Escitalopram Oxalate		S	Oral	Not Reported
	Lescol		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	8577436	EXPEDITED (15-DAY)	Y	DS, HO	CH-JNJFOC-20120509990		25 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Suicide Attempt	Risperdal			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	8578291	EXPEDITED (15-DAY)	Y	HO	FR-ROCHE-1067630		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Fall	Rivotril			S	Oral			Not Reported
	Amisulpride			S	Oral	200 Mg; 2 Tablets Daily		Not Reported
	Amisulpride			S	Oral			Not Reported
	Amisulpride			S	Oral			Not Reported
	Amisulpride			S				Not Reported
	Stilnox			S	Oral			Not Reported
	Trimeprazine Tartrate			S	Oral	Strength: 40 Mg/Ml		Not Reported
	Trimeprazine Tartrate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Inexium			C				Not Reported
	Amlodipine Besylate			C				Not Reported
	Folic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Fungizone			C				Not Reported

	Forlax (France)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	8578922	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000030712		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopia	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral			Not Reported
	Levothyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	8578923	EXPEDITED (15-DAY)	Y	HO	SE-FRI-1000030713		47 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Intentional Overdose; Mental Disorder	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Escitalopram Oxalate			S		Overdose: 120 Mg		Forest
	Escitalopram Oxalate			S		Overdose: 120 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	8578998	EXPEDITED (15-DAY)	Y	HO, LT, OT	ES-FRI-1000030744		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis; Off Label Use	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Azilect			S	Oral	1 Mg		Not Reported
	Quetiapine			S		50 Mg		Not Reported
	Risperidone			S	Oral	0.5 Mg		Not Reported
	Simvastatin			C	Oral	20 Mg		Not Reported
	Requip			C	Oral	8 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	8580157	EXPEDITED (15-DAY)	Y	OT	FR-JNJFOC-		59 YR	Male	FRA

20120515821

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia	Cetirizine Hydrochloride\Pseudoephedrine Hydrochloride		Y	S	Oral			Not Reported
	Cetirizine Hydrochloride\Pseudoephedrine Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	8590381	DIRECT	N	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Drug Ineffective; Dyspepsia; Flatulence; Headache; Hot Flush; Libido Decreased; Myalgia; Product Quality Issue; Product Substitution Issue; Social Avoidant Behaviour	Escitalopram Oxalate			S	Oral	1 Tab Bid Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2012	8590406	DIRECT	N				49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease Recurrence; Drug Ineffective; Product Substitution Issue; Withdrawal Syndrome	Lexapro			S		15mg/Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2012	8579720	EXPEDITED (15-DAY)	Y	OT	CH-JNJFOC-20120510051		34 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Labour; Premature Rupture Of Membranes	Topamax			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Xenical			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2012	8579721	EXPEDITED (15-DAY)	Y	OT	CH-JNJFOC-20120518094		< 1 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Premature Baby	Topamax			S	Transplacental			Not Reported
	Cipralex			S	Transplacental			Not Reported
	Xenical			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2012	8581445	EXPEDITED (15-DAY)	Y	DS	FR-FRI-1000030784		27 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Periodontal Disease	Escitalopram Oxalate			S	Oral	5 Mg		Forest
	Leponex			S	Oral	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2012	8602264	DIRECT	Y	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Drug Ineffective	Lexapro			S		20 Mg 1 Dly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2012	8505242	EXPEDITED (15-DAY)	N	OT	US-JNJFOC-20120404439			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Hypertension; Muscle Spasticity; Musculoskeletal Stiffness; Pain	Tramadol Hydrochloride			S	Unknown			Not Reported
	Wellbutrin			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Cymbalta			S	Oral			Not Reported
	Unspecified Ingredient			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2012	8583113	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20120515989		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Intentional Self-Injury; Tachycardia	Risperdal			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Metformin Hydrochloride			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Flurazepam Hydrochloride			S	Oral			Not Reported
	Levothyroxine Sodium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2012	8583594	EXPEDITED (15-DAY)	Y	HO, OT	AU-ASTRAZENECA-2012SE32165		< 1 DAY	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Meconium Abnormal	Seroquel Xr			S	Transplacental	75-100 Mg Daily Started Pre-Pregnancy And Stopped After Delivery		Astrazeneca
	Lexapro			S	Transplacental	20mg Daily Started At		Not Reported

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2012	8584787	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000030783		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Inflammation; Nausea; Vomiting	Lexapro			S		20 Mg		Forest
	Lexapro			S			10 YR	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2012	8584813	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000030819		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Middle Insomnia; Night Sweats	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Metformin Hydrochloride			C	Oral	1700 Mg		Not Reported
	Olmetec			C	Oral	10 Mg		Not Reported
	Fenofibrate			C	Oral	200 Gbq		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2012	8585901	EXPEDITED (15-DAY)	Y	HO	AU-FRI-1000030789		23 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Discharge; Breast Pain; Breast Swelling; Depression; Galactorrhoea; Psychomotor Hyperactivity	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2012	8600368	DIRECT	N				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia;	Escitalopram Oxalate			S	Oral	10 Mgs Bid Po		Mylan

Depression; Product Substitution Issue; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	7860434	EXPEDITED (15-DAY)	Y	OT	CA-FRI-1000022159			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Mood Swings; Overdose	Escitalopram Oxalate			S	Oral	30 Mg		Forest
	Remicade			S	Intravenous (not otherwise specified)	5.3571 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8569953	EXPEDITED (15-DAY)	Y	HO, LT	ES-FRI-1000030586		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypercreatinaemia; Rhabdomyolysis	Escitalopram Oxalate			S	Oral	5 Mg		Forest
	Depakene			S	Oral	400 Mg		Not Reported
	Pantoprazole			S	Oral	40 Mg		Not Reported
	Fluvastatin			S	Oral	80 Mg		Not Reported
	Tramadol Hydrochloride			S	Oral	150 Mg		Not Reported
	Ultracet			S	Oral	3 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8585914	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2010001738		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Citalopram			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Venlafaxine Hcl			S	Oral	Unk		Pfizer
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8588592	EXPEDITED (15-DAY)	Y	DE, HO, OT	US-GLAXOSMITHKLINE-B0803431A		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Areflexia; Completed Suicide; Gastrointestinal Sounds Abnormal; Hypotension; Hypoxic-Ischaemic Encephalopathy; Overdose; Peripheral Coldness; Pulseless Electrical Activity; Pupil Fixed; Sinus Tachycardia	Bupropion			S	Unknown			Glaxosmithkline
	Quetiapine			S	Unknown			Glaxosmithkline
	Escitalopram Oxalate			S	Unknown			Glaxosmithkline
	Ibuprofen			S	Unknown			Glaxosmithkline
	Desvenlafaxine Succinate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8588723	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030913		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8588777	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030911		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Patent Ductus Arteriosus	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8588813	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030909		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoplastic Left Heart	Lexapro			S	Transplacental			Forest

Syndrome

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder	Lexapro			S	Transplacental			Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoplastic Left Heart Syndrome; Maternal Drugs Affecting Foetus	Lexapro			S	Transplacental			Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoplastic Left Heart Syndrome	Lexapro			S	Transplacental			Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoplastic Left Heart Syndrome	Lexapro			S	Transplacental			Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Overdose; Photophobia; Vision Blurred	Escitalopram Oxalate			S	Oral	30 Mg		Forest
	Wellbutrin Xl			S	Oral	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8589269	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030899		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Prolapse; Congenital Aortic Valve Incompetence; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8589373	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030895		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Patent Ductus Arteriosus; Pulmonary Artery Stenosis Congenital	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8589448	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030877		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bicuspid Aortic Valve; Coarctation Of The Aorta; Hypoplastic Left Heart Syndrome; Patent Ductus Arteriosus	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8589483	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030865		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8589522	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030867		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8589549	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030869		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Fallot'S Tetralogy; Pulmonary Artery Stenosis Congenital; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8607666	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Chromatopsia; Dyspnoea; Hyperthermia; Loss Of Consciousness; Serotonin Syndrome; Urinary Incontinence	Trazodone Hydrochloride			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2012	8610405	DIRECT	Y				31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Insomnia; Product Substitution Issue; Restlessness	Escitalopram Oxalate			S		10mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8554387	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000030398		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Arthralgia; Burning Sensation; Choking Sensation; Dizziness; Drug Ineffective; Dyspnoea; Eye Swelling; Headache; Nausea; Neck Pain; Panic Attack; Pharyngeal Oedema; Pruritus; Psoriasis; Swelling Face; Swollen Tongue	Escitalopram Oxalate			S		5 Mg		Forest
	Humira			S		40 Mg/0.8 Ml Pen/2weeks		Not Reported
	Xanax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8590463	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030871		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8590486	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030873		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8590651	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030875		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Maternal Drugs Affecting Foetus; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8590756	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030879		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transposition Of The Great Vessels	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8590881	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030881		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8590950	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030883		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8590951	EXPEDITED (15-DAY)	N	DE	US-FRI-1000030885			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8590979	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030887		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Patent Ductus Arteriosus; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8591063	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030889		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transposition Of The Great Vessels	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8591174	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030891		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Double Outlet Right Ventricle; Fallot'S Tetralogy; Pulmonary Artery Stenosis Congenital; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8591214	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030893		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8591244	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030903		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Transposition Of The Great Vessels	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2012	8610741	DIRECT	Y	DE, OT			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Product Substitution Issue	Escitalopram Oxalate			S	Oral	20mg Qday Po	10 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2012	8447525	EXPEDITED (15-DAY)	Y	CA	FR-FRI-1000028867		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Gaze Palsy; Tremor	Escitalopram Oxalate			S	Transplacental	10 Mg		Forest
	Zoloft			C	Transmammary			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2012	8514716	EXPEDITED (15-DAY)	Y	HO, OT	CH-FRI-1000029760			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Myalgia; Paraesthesia; Visual Impairment	Escitalopram Oxalate			S		20 Mg		Forest
	Trazodone Hydrochloride			S				Not Reported
	Bactrim			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2012	8577075	NON-EXPEDITED	Y	HO	FR-JNJFOC-20120513760		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Tramadol Hydrochloride And Acetaminophen			S	Oral			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Cytomel			C	Unknown			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Hydrochlorothiazide\Valsartan			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2012	8595187	EXPEDITED (15-DAY)	Y	HO, LT	FR-FRI-1000030975		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardio-Respiratory Arrest; Generalised Tonic-Clonic Seizure; Hypokalaemia; Leukocytosis; Overdose; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S		Overdose With An Unknown Dose		Forest
	Valium			C	Oral			Not Reported
	Methadone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2012	8595289	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000030979		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition; Suicide Attempt	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Telmisartan			C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2012	7183450	EXPEDITED (15-DAY)	Y	OT	US-PFIZER INC-US-WYE-H11366009		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Constipation; Decreased Appetite; Diarrhoea; Drug Ineffective; Dry Mouth; Dyskinesia; Muscle Twitching; Nightmare; Suicidal Ideation; Suicide Attempt; Therapeutic Product Effect Decreased; Tremor	Effexor Xr			S	Oral	75 Mg, 1x/Day		Pfizer
	Pristiq Extended Release			S	Oral	50.0 Mg, 1x/Day		Pfizer
	Pristiq Extended Release			S	Oral	Patient Tried Taking Half A Tablet		Pfizer
	Doxepin Hydrochloride			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Mirtazapine			S		Unk		Not Reported
	Paroxetine			S		Unk		Unknown
	Trazodone Hydrochloride			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported
	Seroquel			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Depakote			S		Unk		Not Reported
	One-A-Day Nos			C				Not Reported
	Fish Oil, Hydrogenated			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2012	8557252	EXPEDITED (15-DAY)	Y	HO, LT	ES-ABBOTT-12P-144-0933953-00		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypercreatininaemia; Rhabdomyolysis	Depakene			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Fluvastatin			S	Oral			Not Reported
	Tramadol Hydrochloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Tramadol Hydrochloride And Acetaminophen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2012	8565703	EXPEDITED (15-DAY)	Y	HO	IT-PFIZER INC-2012117653		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Bradyphrenia; Hypotension; Intentional Overdose	Xanax			S	Oral	1 Mg, Unk		Pfizer
	Xanax			S		6 Df, Unk		Pfizer
	Escitalopram Oxalate			S	Oral	10 Mg, Unk		Not Reported
	Bromazepam			S	Oral	20 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2012	8598598	NON-EXPEDITED	Y	OT	US-FRI-1000030775		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection	Lexapro			S	Oral			Forest
	Bystolic			C				Not Reported
	Synthroid			C				Not Reported

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

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

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

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

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2012	8623471	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Agitation; Anger; Anxiety; Blood Pressure Increased; Hyperacusis; Insomnia; Product Substitution Issue; Pruritus Generalised; Stress	Lexapro			S				Teva
	Escitalopram Oxalate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2012	8603685	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030965		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2012	8603696	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030967			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2012	8603812	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030969			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2012	8622513	DIRECT	N				52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Dysstasia; Fungal Infection; Palpitations; Product Substitution Issue; Tremor	Escitalopram Oxalate			S		Am .5 1; Pm .10 1		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2012	8627732	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Libido; Product Substitution Issue	Escitalopram			S	Oral	1 Tab Daily By Mouth 1 Month	1 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2012	8635044	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Tremor	Citalopram			S	Oral	20 Mg Daily Oral		Forest
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2012	8578943	EXPEDITED (15-DAY)	Y	HO	IT-FRI-1000030682		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Bradyphrenia; Hypotension; Intentional Overdose	Escitalopram Oxalate			S	Oral			Forest
	Escitalopram Oxalate			S	Oral	28 Tablets		Forest
	Xanax			S	Oral			Not Reported
	Xanax			S	Oral	6 Tablets		Not Reported

	Bromazepam			S	Oral	20 Tablets			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2012	8605324	EXPEDITED (15-DAY)	N	HO	US-FRI-1000030988		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Physical Assault	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2012	8605803	EXPEDITED (15-DAY)	N	CA	US-FRI-1000030999		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2012	8606101	EXPEDITED (15-DAY)	N	CA	US-FRI-1000031051			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2012	8527423	EXPEDITED (15-DAY)	Y	HO, OT	JP-FRI-1000029975		67 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal; Jaundice	Lexapro			S	Oral	10 Mg		Forest
	Phenobarbital			C	Oral			Not Reported
	Bromisoval			C	Oral	0.3 Mg		Not Reported
	Alprazolam			C	Oral	1.2 Mg		Not Reported

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

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

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

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

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

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

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

At Once

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2012	8608989	EXPEDITED (15-DAY)	Y	DS	AU-FRI-1000031167		63 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Withdrawal Syndrome	Lexapro			S	Oral	Overdose 40 Mg - Downtitrated		Forest
	Prothiaden			C		100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2012	8609014	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000031168		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Encephalopathy	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Rocephin			C	Subcutaneous			Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Amitriptyline Hydrochloride			C				Not Reported
	Rivotril			C				Not Reported
	Tegretol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2012	7751556	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2011002730		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil Hcl			S				Pfizer
	Alprazolam			S				Pfizer
	Doxepin Hcl			S				Pfizer
	Escitalopram Oxalate			S				Not Reported
	Cyclobenzaprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2012	7772305	EXPEDITED (15-DAY)	Y	DE	US-PFIZER INC-2011US-41275		61 YR	Male	USA

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cardiac Aneurysm	Lexapro			S	Transplacental			Forest

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Homicide	Escitalopram Oxalate			S				Forest
	Xanax			S				Not Reported
	Bromazepam			S				Not Reported

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Lexapro			S	Oral	One Po Qd		Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2012	8618150	EXPEDITED (15-DAY)	Y	LT	CH-FRI-1000031397			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Disorder	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Ginseng, North American			S	Oral	60 Mg		Not Reported
	Calcimagon D3			C	Oral	1000 Mg		Not Reported
	Zopiclone			C	Oral	7.5 Mg		Not Reported
	Omeprazole			C	Oral	40 Mg		Not Reported
	Dafalgan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2012	8618228	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000031408			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impulsive Behaviour	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Oxazepam			C				Not Reported
	Baclofen			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2012	8636240	DIRECT	N	LT, OT			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Aggression; Anxiety; Asthenia; Blood Pressure Fluctuation; Chest Pain; Constipation; Crying; Dizziness; Eating Disorder; Fatigue; Gait Disturbance; Headache; Heart Rate Increased;	Escitalopram Oxalate			S	Oral	1 Pill 1 A Day Oral		Not Reported

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Craniosynostosis; Developmental Delay	Lexapro			S	Transplacental			Forest

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2012	8620544	EXPEDITED (15-DAY)	Y	OT	CA-FRI-1000027141		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nervousness; Peripheral Coldness; Pruritus; Skin Burning Sensation	Escitalopram Oxalate			S	Oral			Forest
	Escitalopram Oxalate			S				Forest
	Mirtazapine			S				Not Reported
	Mirtazapine			S				Not Reported
	Birth Control Pill			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2012	8620578	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000031432		47 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Tremor	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Lorazepam			C	Oral	1.5 Mg		Not Reported
	Ethyl Loflazepate			C	Oral	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2012	8622366	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000031238		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Glucose Increased; Blood Triglycerides Increased; Dizziness; Drug Ineffective; Fluid Retention; Hallucination; High Density Lipoprotein Increased; Low Density Lipoprotein Increased; Migraine; Nausea; Suicidal Ideation; Swelling;	Lexapro			S				Forest
	Pristiq Extended Release			S				Not Reported
	Pristiq Extended Release			S				Not Reported
	Pristiq Extended Release			S				Not Reported
	Effexor Xr			S				Not Reported
	Xanax			S				Not Reported
	Prozac			S				Not Reported
	Wellbutrin			S				Not Reported
	Cymbalta			S				Not Reported
	Lisinopril			C				Not Reported

Thinking Abnormal;
Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2012	8622672	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000031427		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemic Stroke	Escitalopram Oxalate			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2012	8622946	EXPEDITED (15-DAY)	Y	HO	CA-FRI-1000022231			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Swelling; Generalised Erythema; Pruritus Generalised; Urticaria; Visual Impairment	Escitalopram Oxalate			S	Oral	5 Mg		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Macrobid			S	Oral	200 Mg		Not Reported
	Desogestrel And Ethinyl Estradiol			C	Oral			Not Reported
	Tramadol Hydrochloride And Acetaminophen			C	Oral	325 Mg Acetaminophen, 37.5 Mg Tramadol		Not Reported
	Tylenol With Codeine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2012	8623043	EXPEDITED (15-DAY)	Y	HO	FR-MYLANLABS-2012S1011695		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Serotonin Syndrome	Escitalopram Oxalate			S	Unknown	5 Mg/Day		Mylan
	Levothyroxine Sodium			C	Unknown			Not Reported
	Travoprost			C	Unknown			Not Reported
	Timolol Maleate			C	Unknown			Not Reported
	Loramyc			S		50 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2012	8638068	DIRECT	Y				45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Disturbance In Attention; Fatigue; Initial Insomnia; Mood Altered; Pruritus; Sleep Disorder	Escitalopram Oxalate			S	Oral	1 1/2 Tablet Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2012	8474501	EXPEDITED (15-DAY)	Y	HO	BE-FRI-1000029132		62 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Dizziness; Tachycardia; Ventricular Tachycardia	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Flupentixol			S	Oral			Not Reported
	Prothiaden			C	Oral	75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2012	8488082	EXPEDITED (15-DAY)	Y	LT	FR-FRI-1000028584			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Escitalopram Oxalate			S				Forest
	Sotalol Hydrochloride			S	Oral	80 Mg		Not Reported
	Sotalol Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2012	8623987	EXPEDITED (15-DAY)	Y	HO	CA-FRI-1000027368		19 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate			S	Oral	10 Mg		Forest

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

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

Prilosec	C		Not Reported
Hydrochlorothizide	C		Not Reported
Amlodipine	C		Not Reported
Besylate	C		Not Reported

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2012	8541119	EXPEDITED (15-DAY)	Y	HO, OT	US-PFIZER INC-2012104183		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Malaise; Mental Disorder	Xanax Xr			S	Oral	1 Mg, 3x/Day		Pfizer
	Xanax Xr			S				Pfizer
	Xanax Xr			S				Pfizer
	Xanax Xr			S				Pfizer
	Lexapro			S		20 Mg, Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2012	8628946	EXPEDITED (15-DAY)	N	HO	US-FRI-1000031418		96 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicidal Ideation; Off Label Use; Suicidal Ideation	Lexapro			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2012	8629283	EXPEDITED (15-DAY)	N	CA	US-FRI-1000031368		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Bicuspid Aortic Valve; Congenital Anomaly; Pulmonary Artery Stenosis; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2012	8650703	DIRECT		OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Fluctuation; Confusional State; Disorientation; Headache; Muscular Weakness; Musculoskeletal Pain; Pain In Extremity	Escitalopram Oxalate			S	Oral	10mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2012	8630348	EXPEDITED (15-DAY)	Y	HO	JP-FRI-1000031510		69 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Aspiration; Vomiting	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Remeron			C	Oral	45 Mg		Not Reported
	Ethyl Loflazepate			C	Oral	45 Mg		Not Reported
	Lansoprazole			C	Oral	15 Mg		Not Reported
	Urapidil			C	Oral	60 Mg		Not Reported
	Magnesium Oxide			C	Oral	2640 Mg		Not Reported
	Estazolam			C	Oral	4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2012	8648194	DIRECT	Y	OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Heart Rate Increased; Hyperhidrosis; Hypertension; Musculoskeletal Stiffness; Product Substitution Issue; Tremor	Escitalopram Oxalate			S	Oral	10 Mg 1 Per Day Po	3 DAY	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2012	8647885	DIRECT	N	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dyspepsia; Insomnia; Product Substitution Issue	Escitalopram Oxalate			S	Oral	10 Mg Day Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2012	8648259	DIRECT	N	HO, LT, OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Blood Pressure Increased; Depression; Dizziness; Headache; Nausea; Product Quality Issue; Product Substitution Issue	Escitalopram Oxalate			S	Oral	1 Daily Po		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2012	8246434	EXPEDITED (15-DAY)	Y	DE, HO, OT	2011SP051883		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Hypertrophy; Depressed Level Of Consciousness; Fall; Hepatic Cirrhosis; Humerus Fracture; Hyperventilation; Internal Fixation Of Fracture; Lactic Acidosis; Lacunar Infarction; Multiple Organ Dysfunction Syndrome;	Mirtazapine			S	Oral	30 Mg;Qd;Po		Not Reported
	Cipralex			S	Oral	30 Mg;Qd;Po		Not Reported
	Lithium Citrate			S	Oral	Po		Not Reported
	Ziprasidone Hydrochloride			S	Oral	40 Mg;Bid;Po		Not Reported
	Alprazolam			C				Not Reported
	Potassium Chloride			C				Not Reported
	Ferro Duretter			C				Not Reported

Neuroleptic Malignant Syndrome; Organ Failure; Renal Failure; Rhabdomyolysis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2012	8346578	EXPEDITED (15-DAY)	Y	HO	CA-ABBOTT-12P-028-0893310-00		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Mavik			S	Oral	Daily Dose & Frequency Not Reported		Not Reported
	Cipralex			S	Oral	Daily Dose & Frequency Not Reported		Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Docusate Sodium			C		Daily Dose & Frequency Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2012	8634441	EXPEDITED (15-DAY)	Y	LT	CH-ASTRAZENECA-2012SE30626		25 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Injury; Suicide Attempt	Seroquel			S	Oral		1 DAY	Zeneca
	Risperdal			S	Oral		14 DAY	Not Reported
	Risperdal			S	Oral		9 DAY	Not Reported
	Risperdal			S	Oral		18 DAY	Not Reported
	Risperdal			S	Oral		13 DAY	Not Reported
	Risperdal			S	Oral		9 DAY	Not Reported
	Cipralex			S	Oral			Not Reported
	Lorazepam			S	Oral		1 DAY	Not Reported
	Lorazepam			S	Oral		1 DAY	Not Reported
	Lorazepam			S	Oral		1 DAY	Not Reported
	Lorazepam			S	Oral		20 DAY	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Acuity Reduced	Lexapro			S	Oral	20 Mg		Forest

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2012	8652497	DIRECT					27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Panic Attack; Product Substitution Issue	Escitalopram Oxalate			S		10 Mg, Daily, Oral 047 10 Mg, Daily, Oral 047	3 WEEK	Mylan
	Escitalopram Oxalate			S	Oral	20 Mg, Daily, Oral. 047	4 WEEK	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2012	8637779	EXPEDITED (15-DAY)	N	OT	US-TEVA-344867USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Head Injury; Hyperhidrosis; Joint Injury; Loss Of Consciousness; Muscular Weakness; Palpitations; Syncope	Escitalopram Oxalate			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2012	8638433	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000036602		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Rib Fracture; Speech Disorder; Vertigo	Escitalopram Oxalate			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2012	8639708	EXPEDITED (15-DAY)	N	OT	US-FRI-1000031555		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2012	8654794	DIRECT	N	HO, LT, OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Feeling Abnormal; Insomnia	Escitalopram Oxalate			S		1x Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2012	8654955	DIRECT					48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Product Substitution Issue	Escitalopram Oxalate			S	Oral	Escitalopram 20mg 1/D Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2012	8657794	DIRECT	N	OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Loss Of Personal Independence In Daily Activities; Product Substitution Issue; Suicidal Ideation	Escitalopram Oxalate			S	Oral	10mg Once A Day Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2012	8325434	EXPEDITED (15-DAY)	Y	DE	DK-WATSON-2011-22664		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Hypertrophy; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension; Internal Fixation Of	Mirtazapine			S	Oral	30 Mg, Daily		Watson
	Ziprasidone Hydrochloride			S	Oral	40 Mg, Bid		Not Reported
	Lithium Citrate			S	Oral	6 Mmol, Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2012	8591302	EXPEDITED (15-DAY)	Y	OT	IT-FRI-1000030456		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Bleeding	Escitalopram Oxalate			S	Oral	8 Df		Forest
	Lithium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2012	8640875	EXPEDITED (15-DAY)	N	CA	US-FRI-1000031557		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Maternal Drugs Affecting Foetus; Transposition Of The Great Vessels	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2012	8641063	EXPEDITED (15-DAY)	N	OT	US-FRI-1000031559		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Talipes	Lexapro			S	Transplacental			Forest

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

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

	Pipamperone Hydrochloride		S	Oral	40 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2012	8659613	DIRECT	Y				23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Product Substitution Issue; Sedation; Somnolence	Escitalopram Oxalate			S	Oral	20mg One Am Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2012	8661088	DIRECT		HO				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autonomic Nervous System Imbalance; Seizure	Lexapro			S		1 Pill 1 A Day For 4 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2012	8644075	EXPEDITED (15-DAY)	Y	LT	ID-BRISTOL-MYERS SQUIBB COMPANY-16713042		17 YR	Male	IDN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Abilify			S	Oral		3 DAY	Not Reported
	Abilify			S	Oral		3 DAY	Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2012	8646214	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000036776		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram Oxalate			S	Oral			Forest
	Abilify			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2012	8646519	EXPEDITED (15-DAY)	Y	DS, HO	FR-FRI-1000014090		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tolosa-Hunt Syndrome	Escitalopram Oxalate			S	Oral			Forest
	Influenza Virus Vaccine Nos			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2012	8646537	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000036710		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Ascites; Drug Interaction; Dyspnoea; Hyponatraemia; International Normalised Ratio Increased; Nausea; Oedema Peripheral; Weight Increased	Escitalopram Oxalate			S	Oral	5 Mg		Forest
	Coumadin			S				Not Reported
	Esidrex			C				Not Reported
	Tahor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2012	8646541	EXPEDITED (15-DAY)	Y	OT	TR-FRI-1000036773		92 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Insipidus; Fall	Escitalopram Oxalate			S	Oral	5 Mg		Forest
	Memantine			S	Oral	5 Mg		Forest
	Desyrel			C				Not Reported
	Sertraline Hydrochloride			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2012	8662826	DIRECT	N	LT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Suicidal Ideation	Escitalopram Oxalate			S	Oral	20 Mg 1 Day Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2012	8647879	EXPEDITED (15-DAY)	Y	LT	FR-FRI-1000036771		97 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	20 Mg		Not Reported
	Mianserin			S	Oral	10 Mg		Not Reported
	Crestor			C				Not Reported
	Ramipril			C				Not Reported
	Kardegic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2012	8647890	EXPEDITED (15-DAY)	Y	OT	CA-FRI-1000036772			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Escitalopram Oxalate			S	Oral	Daily Dose Not Reported		Forest
	Methadone Hydrochloride			C		Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2012	8648687	EXPEDITED (15-DAY)	Y	DE	FR-FRI-1000025231		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Hyperhidrosis	Escitalopram Oxalate			S		10 Mg		Forest
	Escitalopram Oxalate			S		10 Mg		Forest
	Alprazolam			C	Oral	0.375 Mg		Not Reported
	Theralene			C	Oral	10 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2012	8648757	EXPEDITED (15-DAY)	N	CA	US-FRI-1000036707		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydrocephalus; Spina Bifida	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2012	8664267	DIRECT	N	OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Mood Swings; Nausea; Panic Attack; Product Substitution Issue; Unevaluable Event; Vision Blurred	Escitalopram Oxalate			S	Oral	25 Mg 1/Day Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2012	8247522	EXPEDITED (15-DAY)	Y	DE, HO, OT	2011MA016018		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Hypertrophy; Constipation; Dialysis; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension; Infarction; Lactic Acidosis; Lacunar Infarction; Liver Disorder; Multiple Organ Dysfunction Syndrome; Myocardial Necrosis Marker Increased; Neuroleptic Malignant Syndrome; Polydipsia; Post Procedural	Mirtazapine			S	Oral	30 Mg;Qd;Po		Purepac
	Mirtazapine			S	Oral	30 Mg;Qd;Po		Actavis Totowa
	Ziprasidone Hydrochloride			S	Oral	40 Mg;Bid;Po		Not Reported
	Lithium Citrate			S	Oral	6 Mmol;Unk;Po		Not Reported
	Cipralex			S	Oral	30 Mg;Qd;Po		Not Reported
	Ferro Curetter			C				Not Reported
	Centyl Med			C				Not Reported
	Kalimklorid			C				Not Reported
	Alprazolam			C				Not Reported

Complication;
Rhabdomyolysis; Urinary
Tract Infection

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Drunk	Lyrica			S		Unk		Pfizer
	Hydroxyzine Hydrochloride			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2012	8650979	EXPEDITED (15-DAY)	N	CA	US-FRI-1000036768		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arnold-Chiari Malformation; Congenital Anomaly; Spina Bifida	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2012	8666057	DIRECT	Y	HO			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hyponatraemia; Wheezing	Lexapro			S	Oral	One Tablet Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2012	8667695	DIRECT		OT			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Condition Aggravated; Decreased Appetite; Depression; Dysphagia; Fatigue; Feeling Abnormal; Impaired Work Ability; Nausea; Product Substitution Issue; Visual Impairment	Escitalopram Oxalate			S	Oral	10mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2012	8597140	EXPEDITED (15-DAY)	Y	HO	BE-FRI-1000030976		38 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Seizure	Escitalopram Oxalate		S	Oral	5 Mg	Forest
	Escitalopram Oxalate		S			Forest
	Symbicort		C		2 Df	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Irritability; Paraesthesia	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Clonidine			C				Not Reported
	Potassium			C				Not Reported
	Vitamin B1			C				Not Reported
	Folic Acid			C				Not Reported
	Losartan Potassium			C				Not Reported
	Suboxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2012	8651886	NON-EXPEDITED	Y		US-FRI-1000036806			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery	Lexapro			S				Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Weight Decreased	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Victoza			S	Subcutaneous	3 Ml		Not Reported
	Simvastatin			S	Oral	20 Mg		Not Reported
	Gliclazide			S	Oral	60 Mg		Not Reported
	Metformin Hydrochloride			S	Oral	2550 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2012	8652038	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000026421			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2012	8652881	EXPEDITED (15-DAY)	Y	OT	IT-JNJFOC-20120700191		44 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sopor	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2012	8667589	DIRECT	N				44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Product Substitution Issue	Escitalopram Oxalate			S	Oral	2.5ml Once A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2012	8667693	DIRECT	Y				29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea; Product Substitution Issue	Escitalopram Oxalate			S	Oral	15 Mg Daily Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2012	8682058	EXPEDITED (15-DAY)	Y	OT	2012155287		67 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Bacterial	Methotrexate			S	Oral	1 Df, 1x/Day, Oral		Not Reported
	Fragmin			S	Subcutaneous	5000 Iu, 1x/Day, Subcutaneous		Not Reported
	Ibuprofen			S	Oral	1 Df Per Day, Oral		Not Reported
	Prednisone			S	Oral	10 Mg, 1x/Day, Oral		Not Reported
	Cipralex			S	Oral	10 Mg, 1x/Day, Oral		Not Reported
	Ramipril			C				Not Reported
	Pantozol (Pantoprazole Sodium)			C				Not Reported
	Calcimagon-D3 (Calcium Carbonate, Colecalciferol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2012	8654733	EXPEDITED (15-DAY)	Y	HO	IT-FRI-1000036861		84 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S			5 YR	Forest
	Zyprexa			S	Oral	2.5 Mg		Not Reported
	Zyprexa			S				Not Reported
	Bisoprolol Fumarate			C	Oral	2.5 Mg		Not Reported
	Diazepam			C	Oral	0.5		Not Reported
	Triatec Hct 5mg+25mg Compresse			C	Oral			Not Reported
	Triatec Compresse			C	Oral	5 Mg		Not Reported
	Pravastatin Sodium			C	Oral	20 Mg		Not Reported
	Clopidogrel Bisulfate			C	Oral	75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2012	8670084	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Fatigue; Feeling Abnormal; Movement Disorder	Lexapro			S				Forest
	Estradiol			C				Not Reported
	Vitamin B12 1000 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2012	8671705	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Lexapro			S	Oral	10 Mg Once Po Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2012	8671863	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram Oxalate			S	Oral	10 Mg Once Daily P.O (Oral)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2012	8673906	DIRECT					87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disorientation; Fall; Inappropriate Antidiuretic Hormone Secretion; Medication Error; Mental Status Changes	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2012	8673975	DIRECT					18 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Dispensing Error	Lisinopril			S		10 Mg		Not Reported
	Lexapro			S		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2012	9204308	NON-EXPEDITED			2012HGS-003392		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Hypotension; Nausea	Benlysta			S	Intravenous drip	1 In 28 D		Not Reported
	Hyzaar			C				Not Reported
	Losartan			C				Not Reported
	Clobetasol Propionate			C				Not Reported
	Plaquenil			C		2 In 1 D		Not Reported
	Prednisone			C				Not Reported
	Synthroid			C				Not Reported
	Vitamin D2 (Ergocalciferol)			C		1 In 1 Wk		Not Reported
	Amlodipine			C		Once		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2012	8648613	EXPEDITED (15-DAY)		HO	US-FRI-1000036747		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholecystitis; Cholelithiasis	Lexapro			S	Oral	20 Mg		Forest
	Unspecified Ingredient			S	Oral	3 Mg		Not Reported
	Yasmin			C				Not Reported
	Biotene			C				Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2012	8658180	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000036928			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Escitalopram Oxalate			S	Oral	20 Mg		Not Reported
	Amitriptyline Hydrochloride			S	Oral			Not Reported
	Effexor			S		150 Mg		Not Reported
	Prazepam			C	Oral	10 Mg As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2012	8658815	EXPEDITED (15-DAY)	Y	DE	JP-FRI-1000036917			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S	Oral			Forest
	Adalat			C	Oral			Not Reported
	Brotizolam			C	Oral			Not Reported
	Neurotropin Neurotropin(An Extract Obtained From Inflammatory Rabbit S			C	Oral			Not Reported
	Nicorandil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2012	8673970	DIRECT	Y				63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Lexapro			S	Oral	Lexapro 10mg Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2012	8674043	DIRECT	Y	OT			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hot Flush	Escitalopram Oxalate			S		20 Mg One Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2012	8660829	EXPEDITED (15-DAY)	Y	HO	AU-FRI-1000036940		< 1 DAY	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Lexapro			S	Transplacental	20 Mg		Forest
	Dexamphetamine			C	Transplacental	20 Mg		Not Reported
	Quetiapine			C	Transplacental	75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2012	8660837	EXPEDITED (15-DAY)	Y	DE	FR-FRI-1000036935		52 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction	Escitalopram Oxalate			S	Oral	5 Mg		Forest
	Tahor			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2012	8661061	EXPEDITED (15-DAY)	Y	HO	CH-ROCHE-1082216		67 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Enterocolitis Haemorrhagic; Lower Gastrointestinal Haemorrhage	Methotrexate			S	Oral	Drug Withdrawn		Not Reported
	Ramipril			C	Oral			Not Reported
	Pantozol (Pantoprazole Sodium)			C	Oral			Not Reported
	Calcimagon-D3			C	Oral			Not Reported

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anxiety; Depression; Drug	Imipramine Hydrochloride			S	Oral			Mutual

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2012	8662320	EXPEDITED (15-DAY)	Y	LT, OT	US-ASTRAZENECA-2012SE47031		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Cardiac Arrest; Haemodynamic Instability; Hypotension; Overdose; Sinus Tachycardia	Quetiapine			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported
	Desvenlafaxine			S				Not Reported
	Bupropion			S				Not Reported
	Ibuprofen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2012	8662900	EXPEDITED (15-DAY)	Y	LT	IT-FRI-1000006445		60 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Valsartan			S	Oral	80 Mg		Not Reported
	Rosuvastatin Calcium			C	Oral	10 Mg		Not Reported
	Levothyroxine			C	Oral	50 Mcg		Not Reported
	Phenobarbital			C	Oral	100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2012	8677612	DIRECT	N	DS			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Akathisia; Dysphemia; Gait Disturbance; Muscle Twitching; Speech Disorder; Tic	Abilify		S	Oral	Po Couple Months	Not Reported
	Lexapro		S	Oral	Po Couple Months	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2012	8677647	DIRECT	Y	OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Nausea	Escitalopram Oxalate			S	Oral	10 Mg, 1 Day, Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2012	8678001	DIRECT	N	HO			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Blood Pressure Increased; Chills; Feeling Of Body Temperature Change; Hyperhidrosis; Hypoaesthesia; Palpitations; Panic Attack; Somnolence	Escitalopram Oxalate			S	Oral	20 Mg Daily Po		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2012	8680557	DIRECT	N	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Decreased Interest; Disturbance In Attention; Dizziness; Fatigue; Feeling Abnormal; Feeling Hot; Heart Rate Increased; Nausea; Panic Attack; Product Substitution Issue;	Escitalopram Oxalate			S		5 Mg, Daily		Mylan

Therapeutic Product Effect Decreased; Treatment Noncompliance; Tremor

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

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

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

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

Ferrous Sulfate	C	Not Reported	Not Reported
Lantus	C	Not Reported	Not Reported
Cosopt	C	Not Reported	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2012	8683673	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Withdrawal Syndrome; Product Dose Omission; Product Substitution Issue; Tearfulness	Escitalopram Oxalate			S	Oral	1/2 Tab Bid Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2012	8324602	EXPEDITED (15-DAY)	Y	OT	GER/UKI/11/0018623		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disease Recurrence; Disturbance In Social Behaviour; Oculogyric Crisis	Risperidone (Risperidone)			S	Oral	Oral ; 1.5 Mg, 1 In 1 D, Oral ;1.5 Mg, 1 In 1 D, Oral	167 DAY	Not Reported
					Oral	Oral ; 1.5 Mg, 1 In 1 D, Oral ;1.5 Mg, 1 In 1 D, Oral		
					Oral	Oral ; 1.5 Mg, 1 In 1 D, Oral ;1.5 Mg, 1 In 1 D, Oral		
	Cipralex			S	Oral	10 Mg, 1 In 1 D, Oral ; 10 Mg, 2 In 1 D, Oral		Not Reported
					Oral	10 Mg, 1 In 1 D, Oral ; 10 Mg, 2 In 1 D, Oral		
	Orphenadrine Citrate			C				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyhydramnios; Pregnancy	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S				Forest

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2012	8670371	EXPEDITED (15-DAY)	N	OT	FR-ASTRAZENECA-2012SE48023		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Interaction; Tachycardia	Tenormin			S	Oral			Zeneca
	Hydrocortisone			C				Not Reported
	Flecainide Acetate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral		8 DAY	Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2012	8671443	EXPEDITED (15-DAY)	N	CA	US-FRI-1000036985		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip; Congenital Anomaly; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2012	8671753	EXPEDITED (15-DAY)	Y	OT	GB-FRI-1000021144		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Social Behaviour;	Escitalopram Oxalate			S	Oral	10 Mg		Forest

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appetite Disorder; Nausea; Product Substitution Issue; Sleep Disorder; Therapeutic Product Effect Decreased	Escitalopram Oxalate			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2012	8696607	DIRECT	Y				29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue; Tremor	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2012	8488077	EXPEDITED (15-DAY)	Y	HO	AU-FRI-1000029481		63 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Overdose	Lexapro			S	Oral	Prescribed Overdose: 50 Mg Daily		Forest
	Oxazepam			C				Not Reported
	Mirtazapine			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2012	8552600	EXPEDITED (15-DAY)	Y	OT	GB-FRI-1000030317			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Antibodies; Coagulation Time Prolonged; Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Aripiprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2012	8659035	EXPEDITED (15-DAY)	Y	HO	CH-ABBOTT-12P-151-0954432-00		68 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Enterocolitis Haemorrhagic; Gastrointestinal Haemorrhage	Klacid			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Cipralex			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rocephin			S	Intravenous (not otherwise specified)			Not Reported
	Calcium Carbonate			C	Oral			Not Reported
	Ramipril			C	Oral			Not Reported
	Pantozol (Switzerland)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2012	8661501	EXPEDITED (15-DAY)	Y	OT	JP-PFIZER INC-2012165348			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperventilation; Oxygen Saturation Decreased	Atarax			S	Intramuscular			Pfizer
	Zoloft			S	Oral			Pfizer
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2012	8672863	EXPEDITED (15-DAY)	Y	HO	NO-FRI-1000037139		78 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Headache; Hyponatraemia; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Losartan Potassium And Hydrochlorothiazide			S	Oral	50 Mg Losartan, 12.5 Mg Hydrochlorothiazide		Not Reported

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Nausea	Escitalopram Oxalate			S	Oral	10 Mg 1 Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2012	8675193	EXPEDITED (15-DAY)	Y	HO, LT	FR-ASTRAZENECA-2012SE49208		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction	Quetiapine Fumarate			S	Oral			Zeneca
	Cyamemazine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2012	8675657	EXPEDITED (15-DAY)	Y	HO	PHHY2012PL061187		75 YR	Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Ondansetron			S	Oral	24 Mg, Daily	19 DAY	Novartis
	Fentanyl			S	Transdermal	50 Ug, Daily	19 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Daily	19 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2012	8676162	EXPEDITED (15-DAY)	Y	HO	CH-FRI-1000037260			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Haematemesis; International Normalised Ratio Increased	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Aspirin Cardio			S	Oral	100 Mg		Not Reported
	Aspirin Cardio			S	Oral	100 Mg		Not Reported
	Plavix			S	Oral	75 Mg		Not Reported
	Plavix			S	Oral	75 Mg		Not Reported
	Torem			S	Oral	10 Mg		Not Reported
	Marcumar			S	Oral			Not Reported
	Pravastatin			C	Oral	20 Mg		Not Reported
	Beloc-Zok			C	Oral	50 Mg		Not Reported

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anxiety; Oculogyric Crisis	Risperidone			S	Oral			Not Reported
	Risperidone			S				Not Reported
	Risperidone			S				Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Orphenadrine Citrate			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Urogenital Haemorrhage	Escitalopram Oxalate			S				Forest
	Escitalopram Oxalate			S				Forest
	Diclofenac			C				Not Reported
	Ibuprofen			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Ibuprofen			S	Oral	1200 Milligram;		Ivax
	Omeprazole			S	Oral	40 Milligram;		Not Reported
	Cipralex			S	Oral	10 Milligram;		Not Reported

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Hyponatraemia;	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Fluoxetine Hcl			S	Oral			Not Reported

Inappropriate Antidiuretic Hormone Secretion

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Unexpected	Levitra			S		Unk		Jenapharm
	Lexapro			S		Unk		Not Reported
	Adderall Xr			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2012	8680426	EXPEDITED (15-DAY)	Y	OT	CA-ABBOTT-12P-028-0956883-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Foetal Exposure During Pregnancy; Normal Newborn	Cipralex			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2012	8680474	EXPEDITED (15-DAY)	Y	OT	GB-WATSON-2012-12432		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Social Behaviour; Oculogyric Crisis	Risperidone			S	Oral	1.5 Mg, Daily		Watson
	Risperidone			S	Oral	1.5 Mg, Daily	84 DAY	Watson
	Risperidone			S	Oral	0.25mg-1.5mg Daily, (Variable Dose)	85 DAY	Watson
	Cipralex			S	Oral	20mg Daily	142 DAY	Not Reported
	Cipralex			S	Oral	10 Mg, Daily	36 DAY	Not Reported
	Orphenadrine Citrate			C	Unknown	50 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2012	8708151	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hyperhidrosis; Malaise	Escitalopram Oxalate			S	Oral	Once Tab Qd Po		Teva

Coumadin	C		Not Reported
Inderal	C		Not Reported
Testoretic	C		Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depression; Paresis; Product Substitution Issue; Suicidal Ideation	Escitalopram Oxalate			S				Mylan

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Anxiety; Insomnia; Irritability; Panic Attack; Product Substitution Issue	Escitalopram Oxalate			S	Oral	10 Mg Once Q Afternoon Po		Teva
	Escitalopram Oxalate			S	Oral	20 Mg Once Q Hs Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2012	8687373	EXPEDITED (15-DAY)	Y	OT	US-FRI-1000037225			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Unevaluable Event	Lexapro			S				Forest
	Ramipril			C				Not Reported
	Estradiol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2012	8687590	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000037352		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyperreflexia; Tachycardia; Tremor	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral			Forest
	Tramadol Hydrochloride			S	Oral			Not Reported
	Haldol			S	Oral	20 Mg/Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2012	8688810	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000036862		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depersonalisation/Dereali sation Disorder; Depressed Mood; Flight Of Ideas; Logorrhoea; Restlessness; Suicidal Ideation; Tachyphrenia	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Plavix			C	Oral	75 Mg		Not Reported
	Oxazepam			C	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2012	8690526	NON-EXPEDITED	N	OT	US-ASTRAZENECA-2012SE18514		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Insomnia; Mood Swings; Paranoia; Suicidal Ideation	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Pristiq Extended Release			S				Not Reported
	Wellbutrin			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2012	8710335	DIRECT	Y				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Disease Recurrence; Drug Intolerance; Product Substitution Issue; Sedation	Lexapro			S	Oral	40 Mg Lexapro Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2012	8712867	DIRECT	N	LT, OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Suicidal Ideation; Thought Blocking; Vitamin D	Lexapro			S	Oral	10 Mg Once A Day, Po	1 WEEK	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2012	8714126	DIRECT	N	RI			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscular	Escitalopram Oxalate			S	Oral	40mg Daily Po		Teva

Weakness; Product Substitution Issue; Somnolence

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2012	8690801	EXPEDITED (15-DAY)		OT	GB-009507513-2011SP001131		35 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Paralysis	Zispin			S				Merck
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2012	8441197	EXPEDITED (15-DAY)	N	HO	US-FRI-1000028731		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Fatigue; Intentional Self-Injury; Off Label Use; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S		5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2012	8691054	EXPEDITED (15-DAY)	Y	HO	FR-JNJFOC-20120711229		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyperreflexia; Tachycardia; Tremor	Haldol			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Tramadol Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2012	8691445	NON-EXPEDITED	Y		US-PFIZER INC-2012180587			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2012	8569801	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000030544		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Haemorrhage	Escitalopram Oxalate			S	Oral	5 Mg		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2012	8651153	EXPEDITED (15-DAY)	N	CA	US-FRI-1000036740		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Double Outlet Right Ventricle; Pulmonary Valve Stenosis; Transposition Of The Great Vessels; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2012	8674205	EXPEDITED (15-DAY)	Y	OT	JP-FRI-1000037220		33 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Vegetamin-B			C	Oral	1 Df		Not Reported
	Flunitrazepam			C	Oral	2 Mg		Not Reported
	Etizolam			C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2012	8695221	EXPEDITED (15-DAY)	Y	HO	SE-FRI-1000037480		51 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Prolactin Increased; Gynaecomastia	Escitalopram Oxalate		S	Oral	10 Mg	Forest
	Inexium		C	Oral	40 Mg	Not Reported
	Prazepam		C	Oral	5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2012	8691538	EXPEDITED (15-DAY)	N	OT	US-PFIZER INC-2011102419			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Withdrawal Syndrome; Ejaculation Failure; Insomnia; Loss Of Libido; Pollakiuria; Suicidal Ideation; Thirst; Urinary Retention	Chantix			S		0.5 Mg, Daily		Pfizer
	Chantix			S		Unk		Pfizer
	Chantix			S		1 Mg, 2x/Day		Pfizer
	Geodon			S		40 Mg, 2x/Day		Pfizer
	Abilify			S		10 Mg, Daily		Not Reported
	Abilify			S		15 Mg, Daily		Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported
	Xanax			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2012	8696346	NON-EXPEDITED	N	OT	US-PFIZER INC-2012182500			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Fatigue; Hypersensitivity; Muscle Rigidity; Weight Increased	Geodon			S	Oral	40 Mg In Morning And 80 Mg At Night		Pfizer
	Geodon			S	Oral	80 Mg In Morning And 80 Mg At Night		Pfizer
	Geodon			S	Oral	80 Mg At Night And 20 Mg In Morning		Pfizer
	Lexapro			S		5 Mg, Daily		Not Reported
	Lexapro			S		10 Mg, Daily		Not Reported
	Lexapro			S		20 Mg, Daily		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2012	8696529	EXPEDITED (15-DAY)	Y	HO, LT	CH-BRISTOL-MYERS SQUIBB COMPANY-16802985		74 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Loss Anaemia; Drug Interaction; Lower Gastrointestinal Haemorrhage; Melaena	Glucophage			S	Oral			Bristol Myers Squibb
	Remeron			S	Oral			Not Reported
	Flector			S	Subcutaneous			Not Reported
	Concor			C	Oral			Not Reported
	Ramipril			C	Oral			Not Reported
	Sortis			C	Oral			Not Reported
	Seroquel			C				Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Tamsulosin Hydrochloride			C	Oral			Not Reported
	Haldol			C	Oral			Not Reported
	Plavix			S	Oral			Sanofi Aventis
	Aspirin Cardio			S	Oral	Interruoted:11may12 Resumed:21may12		Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2012	8697918	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000037516		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2012	8718188	DIRECT	N	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Feeling Of Despair; Irritable Bowel Syndrome; Product Substitution Issue; Therapeutic Product Effect Decreased	Escitalopram Oxalate			S	Oral	10 Mg Daily Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2012	8726010	DIRECT	Y				48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Screaming; Vomiting	Lexapro			S	Oral	20 Mg 1 Po Ad		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Abuse; Intentional Overdose	Escitalopram Oxalate			S	Oral	1 Posological Unit		Forest
	Lormetazepam			S	Oral	150 Posological Units		Not Reported
	Olanzapine			S	Oral	1 Posological Unit		Not Reported
	Brotizolam			S	Oral	1 Posological Unit		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2012	8707190	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000037217		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Injury; Off Label Use; Syncope	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	15 Mg		Forest
	Pantoprazole			C	Oral	20 Mg		Not Reported
	Simvastatin			C	Oral	40 Mg		Not Reported
	Zopiclone			C	Oral	7.5 Mg		Not Reported
	Cefpodoxime Proxetil			C	Oral			Not Reported
	Solupred (Prednisolone Sodium Metazoate)			C	Oral			Not Reported
	Derinox (Naphazoline Nitrate\Prednisolone)			C	Oral			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2012	8707202	EXPEDITED (15-DAY)	N	CA	US-FRI-1000037474		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydrocephalus; Maternal Drugs Affecting Foetus; Microcephaly; Oculoauriculovertebral Dysplasia	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2012	8728705	DIRECT	N	OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Crying; Depression; Disturbance In Attention; Feeling	Escitalopram Oxalate			S	Oral	20 Mg 1 X Day Po		Mylan

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2012	8634688	EXPEDITED (15-DAY)	Y	OT	PHHY2012CA044960		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Diclofenac			S		Unk Ukn, Prn		Novartis

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2012	8731369	DIRECT	N	HO			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Lexapro			S	Oral	10mg 1/Day Po		Not Reported
	Pristiq			S	Oral	50mg 1/Day Po		Not Reported
	Tenormin			C				Not Reported
	Pradaxa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2012	8736513	DIRECT	Y	OT			30 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Test Abnormal; Erythropenia; Neutropenia	Escitalopram Oxalate			S	Oral Oral	10mg 1per Day Po 10mg 1per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2012	8502751	EXPEDITED (15-DAY)	Y	DS, HO, LT	CA-FRI-1000029697		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Bipolar Disorder; Cardiac	Escitalopram Oxalate			S				Forest
	Cymbalta			S				Not Reported

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Asthenia; Balance Disorder; Diarrhoea; Disorientation; Disturbance In Attention; Dizziness; Drug Interaction; Dyspnoea; Euphoric Mood; Gait Disturbance; Hallucination; Headache; Hypopnoea; Muscle Spasms; Palpitations; Pulse Pressure Increased; Somnolence; Urinary Tract Infection; Vomiting	Escitalopram Oxalate	S	Oral	20 Mg		Forest
	Baclofen	S		60 Mg As Needed		Not Reported
	Butrans	S	Transdermal	480 Î¼G		Not Reported
	Butrans	S	Transdermal	360 Î¼G		Not Reported
	Butrans	S	Transdermal	240 Î¼G		Not Reported
	Butrans	S	Transdermal	120 Î¼G		Not Reported
	Butrans	S	Transdermal	480 Î¼G		Not Reported
	Cesamet	S	Oral	0.5 Mg		Not Reported
	Clonazepam	S	Oral	3 Mg		Not Reported
	Ciprofloxacin Extended-Release	C	Oral	1000 Mg		Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition; Intentional	Escitalopram Oxalate			S	Oral	10 Mg		Forest

Self-Injury; Off Label Use;
Suicidal Ideation

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

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

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

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

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

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

Sleep; Urinary Retention;
Weight Increased

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Enterocolitis Haemorrhagic; Gastrointestinal Haemorrhage	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Ibuprofen			S	Oral			Not Reported
	Prednisone			S	Oral	10 Mg		Not Reported
	Methotrexate			S	Oral			Not Reported
	Klacid			S	Oral	1000 Mg		Not Reported
	Rocephin			S	Intravenous (not otherwise specified)	2 G		Not Reported
	Fragmin			S	Subcutaneous	5000 Iu		Not Reported
	Calcimagon D3			C	Oral			Not Reported
	Ramipril			C	Oral	5 Mg		Not Reported
	Pantozol (Switzerland)			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2012	8678734	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000037257		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Panic Attack; Presyncope	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Previscan (Fluindione)			C				Not Reported
	Kerlone			C		1 Df		Not Reported
	Atacand			C		8 Mg		Not Reported
	Beta Blocking Agent			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2012	8696832	EXPEDITED (15-DAY)	Y	HO	CH-PFIZER INC-2012184320		73 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Loss Anaemia; Gastrointestinal Haemorrhage; Melaena	Flector			S	Topical	Unk		Pfizer
	Plavix			S	Oral	75 Mg, Daily	382 DAY	Not Reported
	Aspirin Cardio			S	Oral	100 Mg Daily	392 DAY	Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2012	8715439	EXPEDITED (15-DAY)	Y	HO	US-ASTRAZENECA-2012SE53980		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Product Misuse; Serotonin Syndrome	Quetiapine			S	Oral			Zeneca
	Quetiapine			S	Oral			Zeneca
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	Overdose		Not Reported
	Escitalopram Oxalate			S	Oral	Overdose		Not Reported
	Percocet			S				Not Reported
	Percocet			S				Not Reported
	Clonazepam			S				Not Reported
	Clonazepam			S				Not Reported
	Cocaine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2012	8652208	EXPEDITED (15-DAY)	Y	HO	CH-ABBOTT-12P-151-0950492-00		68 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate	Lexapro			S	Oral	10 Mg		Forest

Aminotransferase Increased; Jaundice	Jingwu Capsules		C	Oral	18 Capsules	Not Reported
	Tongtian Oral Solution		C	Oral	30 Ml	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Sopor	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Reminyl			S	Oral	12 Mg		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Escitalopram Oxalate			S				Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Depression; Dizziness; Dyspnoea Exertional; Fatigue; Fear; Headache; Hypersomnia; Hypokinesia; Muscular Weakness; Oedema Peripheral; Pain; Weight Increased	Zytiga			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Suicide Attempt	Seroquel			S	Oral		123 DAY	Zeneca
	Cipralex			S	Oral		123 DAY	Not Reported
	Depakene			S	Oral		123 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2012	8743022	DIRECT	N	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Cardiac Disorder; Chest Pain; Diarrhoea; Fatigue; Nausea; Product Substitution Issue; Somnolence	Escitalopram Oxalate			S	Oral	20 Mg Once Daily Po	8 DAY	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2012	7923108	EXPEDITED (15-DAY)		OT	US-ASTRAZENECA-2010SE21304		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Breast Cancer Female; Gastrooesophageal Reflux Disease; Meniscus Injury; Pain In Extremity; Panic Attack; Thyroid Disorder	Nexium			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Synthroid			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Arimidex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2012	8658256	EXPEDITED (15-DAY)	Y	HO, OT	JP-FRI-1000036745		68 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Blood Pressure Increased;	Lexapro			S	Oral	10 Mg		Forest
	Amoxapine			C				Not Reported

Hyperhidrosis;	Other Ssris		C			Not Reported
Palpitations; Tremor	Ludiomil		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2012	8723197	EXPEDITED (15-DAY)	Y	OT	GB-FRI-1000037739		40 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depersonalisation/Dereali sation Disorder; Depression; Derealisation; Dissociation	Escitalopram Oxalate			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2012	8723202	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000037746		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Overdose; Ventricular Extrasystoles	Escitalopram Oxalate			S	Oral	One Intake Of 10 Tab. Of 10 Mg		Forest
	Orap			S	Oral	One Intake Of 10 Tab. Of 1 Mg		Not Reported
	Paroxetine			S	Oral	One Intake Of 2 Tab. Of 20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2012	8723436	EXPEDITED (15-DAY)	N	OT	US-FRI-1000037812		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Interaction; Hallucination, Auditory; Hallucination, Visual; Somnolence; Toxicity To Various Agents	Lexapro			S	Oral	20 Mg		Forest
	Oxycontin			S				Not Reported
	Oxycontin			S		40 Mg Every 8 Hours As Needed		Not Reported
	Morphine			S				Not Reported

	Lunesta	S	3 Mg		Not Reported
	Vicodin	C	As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2012	8723492	EXPEDITED (15-DAY)	Y	OT	FR-GILEAD-2012-0059552		26 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Truvada			S	Oral	1 Df, Qd	27 DAY	Gilead
	Prezista			S	Oral	300 Mg, Qd	11 DAY	Not Reported
	Escitalopram Oxalate			S	Oral	1 Df, Qd		Not Reported
	Norvir			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2012	8739441	EXPEDITED (15-DAY)	Y	OT	2012AP002296		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Screen False Positive; Focal Dyscognitive Seizures; Intentional Overdose; Intentional Product Misuse; Postictal State; Tachycardia; Toxicity To Various Agents	Tramadol Hydrochloride			S				Not Reported
	Omeprazole			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Naproxen			S				Not Reported
	Cyclobenzaprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2012	8749139	DIRECT	N	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Lexapro			S	Oral	10 Mg, 1xday, Po	6 WEEK	Forest
	Pristiq Extended Release			C				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2012	8747201	DIRECT	Y				55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus Generalised	Escitalopram			S	Oral	20mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2012	8527753	EXPEDITED (15-DAY)	Y	HO, OT	DE-FRI-1000029976		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Chromaturia; Gamma-Glutamyltransferase Increased; Jaundice; Off Label Use; Protein Total Decreased; Serum Ferritin Increased; Transaminases Increased	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2012	8633890	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000031589		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Amlodipine Besylate			C	Oral	10 Mg		Not Reported
	Bisoprolol Fumarate			C	Oral	7.5 Mg		Not Reported
	Zocor			C	Oral	20 Mg		Not Reported
	Coaprovel			C	Oral	150 Mg		Not Reported

	Oxazepam		C	Oral	200 Mg	Not Reported
	Depakene		C	Oral	1000 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2012	8686829	NON-EXPEDITED	Y		US-PFIZER INC-2012181543		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Pristiq Extended Release			S	Oral	50 Mg, 1x/Day, At Bedtime		Pfizer
	Pristiq Extended Release			S	Oral	Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Effexor			C		Unk	14 DAY	Not Reported
	Levothyroxine			C		75 Ug, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2012	8698844	EXPEDITED (15-DAY)	Y	HO, OT	DE-FRI-1000037522			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Potentiating Drug Interaction	Escitalopram Oxalate			S	Oral	5 Mg		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Escitalopram Oxalate			S	Oral	10 Mg		Not Reported
	Remergil			S	Oral	30 Mg		Not Reported
	Remergil			S	Oral	45 Mg		Not Reported
	Remergil			S	Oral	30 Mg		Not Reported
	Nexium			S	Oral	20 Mg		Not Reported
	Seroquel			S	Oral	50 Mg		Not Reported
	Lamotrigine			C	Oral	25 Mg		Not Reported
	Lamotrigine			C	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2012	8727469	EXPEDITED (15-DAY)	Y	HO, OT	FR-FRI-1000037778			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Suicidal Ideation; Suicide Attempt; Swelling; Weight Increased	Escitalopram Oxalate			S	Oral	1 Df		Forest
	Escitalopram Oxalate			S		2 Df		Not Reported
	Questran			C				Not Reported
	Aldactazine			C				Not Reported
	Levothyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2012	8727630	EXPEDITED (15-DAY)	Y	OT	IT-FRI-1000037807		81 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Presyncope	Escitalopram Oxalate			S	Oral	1 Df		Forest
	Donepezil Hydrochloride			S	Oral	5 Mg		Not Reported
	Allopurinol			C				Not Reported
	Pantoprazole			C				Not Reported
	Peridon			C				Not Reported
	Cardioaspirin			C				Not Reported
	Esapent			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2012	8748166	DIRECT	N	OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Hypersomnia; Impaired Work Ability; Memory Impairment; Polydipsia; Product Substitution Issue; Suicidal Ideation	Escitalopram Oxalate			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2012	8749345	DIRECT	Y	OT			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease Recurrence; Product Substitution Issue	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2012	8695619	EXPEDITED (15-DAY)	Y	HO, LT	FR-FRI-1000037437		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Hyponatraemia; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	20 Mg		Forest
	Anafranil			S	Oral	75 Mg		Not Reported
	Lormetazepam			C	Oral	1 Df At Bedtime		Not Reported
	Pravastatin			C	Oral	20 Mg		Not Reported
	Lorazepam			C	Oral	2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2012	8732110	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000037846		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Aldactazine			S	Oral	1 Df		Not Reported
	Cordarone			C	Oral			Not Reported
	Levothyrox			C	Oral			Not Reported
	Vitamin B12			C	Oral			Not Reported
	Sterogyl			C				Not Reported
	Lercanidipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2012	8732303	EXPEDITED (15-DAY)	Y	OT	US-GLAXOSMITHKLINE-A0989918A		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blindness; Cardiac Disorder; Dizziness; Gait Inability; Palpitations; Vertigo; Withdrawal Syndrome	Paxil			S	Oral			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Alprazolam			S	Oral			Glaxosmithkline
	Sertraline Hydrochloride			S	Oral	50mg Per Day	3 WEEK	Not Reported
	Zoloft			S	Oral	50mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2012	8732629	EXPEDITED (15-DAY)	Y	HO	FR-FRI-1000037877		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemic Stroke	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Leponex			S	Oral	25 Mg		Not Reported
	Modopar			S	Oral	4 Df		Not Reported
	Modopar			S	Oral	100mg / 25mg		Not Reported
	Exelon			S	Other	1 Df		Not Reported
	Oxybutynin			S	Oral	2 Df		Not Reported
	Aspirin			C		1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2012	8732983	EXPEDITED (15-DAY)	Y	LT	FR-FRI-1000037894		26 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition	Escitalopram Oxalate			S				Forest
	Ludiomil			S	Oral	75 Mg		Not Reported
	Fentanyl			S	Oral			Not Reported

	Alcohol		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2012	8732984	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000037869		26 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Escitalopram Oxalate			S	Oral	1 Df		Forest
	Prezista			S	Oral	300 Mg		Not Reported
	Truvada			S	Oral	200 Mg/245 Mg		Not Reported
	Norvir			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2012	8749165	DIRECT	Y	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Tinnitus	Escitalopram Oxalate			S	Oral Oral	10 Mg Qd Po 5 Mg Qd Po 10 Mg Qd Po 5 Mg Qd Po		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2012	8721237	EXPEDITED (15-DAY)	Y	HO	IT-FRI-1000024740		35 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Suicide Attempt	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Seroquel			S	Oral	600 Mg		Not Reported
	Depakene			S	Oral	900 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2012	8734304	EXPEDITED (15-DAY)	N	CA, HO	US-FRI-1000037934		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular	Lexapro			S	Transplacental			Forest

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2012	8734576	EXPEDITED (15-DAY)	N	CA	US-FRI-1000037912		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cleft Palate; Congenital Anomaly; Lung Disorder	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2012	8734664	EXPEDITED (15-DAY)	N	HO	US-PURDUE-USA-2012-0091484			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Cardiac Disorder; Headache; Inadequate Analgesia; Nausea; Pain; Somnolence; Unevaluable Event	Oxycontin			S	Oral	80 Mg, Unk		Purdue
	Lexapro			S				Not Reported
	Alprazolam			S				Not Reported
	Roxicodone			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2012	8734673	EXPEDITED (15-DAY)	Y	HO	PHHY2012CA069982		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Hypotension; Intentional Overdose; Pulse Absent;	Amitriptyline			S				Novartis
	Fluoxetine Hcl			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Olanzapine			S				Not Reported
	Quetiapine			S				Not Reported
	Gabapentin			S				Not Reported

Suicide Attempt;
Tachycardia

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Malaise; Pruritus; Rash	Escitalopram Oxalate			S				Forest

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2012	8749192	DIRECT	N	DS, OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Economic Problem; Product Substitution Issue; Withdrawal Syndrome	Venlafaxine			S	Oral	450 Mg, Daily, Po		Teva
	Escitalopram Oxalate			S	Oral	40 Mg, Daily, Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2012	8749364	DIRECT		OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Drug Ineffective; Emotional Distress; Product Substitution Issue	Escitalopram Oxalate			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2012	8761637	EXPEDITED (15-DAY)		HO, OT	AUR-APL-2012-03481		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Depressed Mood; Incorrect Route Of Product Administration; Lethargy;	Escitalopram			S	Oral	1d		Not Reported
	Quetiapine			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported

Mental Status Changes; Oxygen Saturation Decreased; Respiratory Rate Decreased; Serotonin Syndrome	Cocaine (Cocaine)		S	Oral	Not Reported
	Percocet		S	Oral	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

	Sulfasalazine	S	Unknown		Not Reported
	Plavix	S	Unknown		Not Reported
	Simvastatin	S	Unknown		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Product Effect Decreased	Lexapro			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Nausea	Escitalopram Oxalate			S	Oral	20mg 1 Qd Oral		Teva

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S				Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Suicide Attempt	Valproic Acid			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

	Seroquel			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2012	8739793	EXPEDITED (15-DAY)	Y	OT	AU-AMGEN-AUSSP2012052346		53 YR	Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea; Orthostatic Hypotension	Cinacalcet Hydrochloride			S		Unk		Amgen
	Escitalopram Oxalate			S		10 Mg, Qd	3 DAY	Not Reported
	Lercanidipine			S		10 Mg, Qd		Not Reported
	Telmisartan			S		40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2012	8750210	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Dysphagia; Product Substitution Issue; Throat Tightness	Escitalopram Oxalate			S	Oral	1.5 Tabs, Daily, Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2012	8634243	EXPEDITED (15-DAY)	N	OT	TR-US-EMD SERONO, INC.-7122142			Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Cholelithiasis; Hepatic Enzyme Increased	Rebif			S	Subcutaneous			Not Reported
	Rebif			S				Not Reported
	Spasmex (Trospium Chloride)			S	Oral			Not Reported
	Famotidine			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Levothyroxine Sodium			S	Oral		4 YR	Not Reported

	Tegretol			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2012	8743441	EXPEDITED (15-DAY)	Y	OT	FR-FRI-1000038117		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	10 Mg		Forest
	Escitalopram Oxalate			S	Oral	5 Mg		Forest
	Escitalopram Oxalate			S	Oral			Not Reported
	Xanax			C	Oral	3 Df		Not Reported
	Stilnox			C	Oral	Not Regular Intake		Not Reported
	Theralene			C	Oral	15 To 20 Drops		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2012	8743446	EXPEDITED (15-DAY)	Y	CA	FR-FRI-1000038120		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias; Maternal Exposure During Pregnancy	Escitalopram Oxalate			S	Transplacental			Forest
	Aceprometazine Maleate\Meprobamate			S	Transplacental			Not Reported
	Prazepam			S	Transplacental			Not Reported
	Atarax			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2012	8750297	DIRECT	N	HO			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Coordination Abnormal; Disturbance In Attention; Dizziness; Dystonia; Headache; Heart Rate Increased; Hot	Lexapro			S	Oral	10 Mg Oral	12 HR	Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2012	8750456	DIRECT	Y	RI			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Irritability; Nausea; Product Substitution Issue; Tremor; Vomiting	Escitalopram Oxalate			S	Oral	20mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2012	8746431	EXPEDITED (15-DAY)	N	OT	2012SP002348		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Interaction; Hallucination, Auditory; Hallucination, Visual; Somnolence; Toxicity To Various Agents	Lunesta			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Oxycontin			S				Not Reported
	Oxycontin			S				Not Reported
	Morphine			S				Not Reported
	Vicodin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2012	8746685	EXPEDITED (15-DAY)	N	HO	US-PFIZER INC-2012207156			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Headache; Pain; Somnolence	Alprazolam			S				Pfizer
	Roxicodone			S				Not Reported
	Lexapro			S				Not Reported
	Oxycontin			S		80 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2012	8748741	EXPEDITED (15-DAY)	Y	OT	IT-FRI-1000038157		62 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Circulatory Collapse; Nausea; Vision Blurred	Escitalopram Oxalate			S	Oral			Forest
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2012	8683835	EXPEDITED (15-DAY)		DE	DE-FRI-1000037256		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Death; Overdose	Escitalopram			S	Oral	Suspected Overdose (260 Mg)		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2012	8757567	EXPEDITED (15-DAY)		HO	FR-FRI-1000038156		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; International Normalised Ratio Increased; Overdose; Subdural Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Previscan (Fluindione)			S	Oral	0.25 Df		Not Reported
	Previscan			S		Fluindione Overdose Nos		Not Reported
	Atorvastatine			C		10 Mg		Not Reported
	Mediatensyl			C				Not Reported
	Furosemide			C				Not Reported
	Coaprovel			C				Not Reported
	Celiprolol			C				Not Reported
	Forlax			C				Not Reported
	Ixprim			C				Not Reported
	Kaleorid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2012	8760251	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Intolerance; Dry Mouth; Headache; Nausea; Product Substitution Issue	Escitalopram			S	Oral			Not Reported
	Crestor			C				Not Reported
	Spironolactone			C				Not Reported
	Catapres			C				Not Reported
	Tumicelex			C				Not Reported
	Singulair			C				Not Reported
	Premarin			C				Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2012	8760603	DIRECT		OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Substitution Issue; Social Problem	Escitalopram			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2012	8780355	EXPEDITED (15-DAY)	Y	HO, OT	2012AP002523		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Coma; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haemodynamic Instability; Hypocalcaemia; Hypokalaemia; Hypotension; Intentional Overdose; Pulse Absent;	Amitriptyline			S				Not Reported
	Fluoxetine			S				Not Reported
	Olanzapine (Olanzapine)			S				Not Reported
	Quetiapine			S				Not Reported
	Gabapentin (Gabapentin)			S				Not Reported
	Escitalopram			S				Not Reported
	Fluoxetine (Fluoxetine)			C				Not Reported
	Escitalopram (Escitalopram)			C				Not Reported
	Olanzapine (Olanzapine)			C				Not Reported
	Quetiapine (Quetiapine)			C				Not Reported

Suicidal Ideation; Tachycardia	Gabapentin (Gabapentin)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2012	8345946	EXPEDITED (15-DAY)		DE, HO	BE-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2012-BL-00		94 YR	Male	BEL

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2012	8759582	EXPEDITED (15-DAY)		OT	US-FRI-1000038138			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Headache; Pain; Somnolence	Lexapro			S				Forest
	Oxycontin			S		80 Mg		Not Reported
	Alprazolam			S				Not Reported
	Roxicodone			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2012	8762410	NON-EXPEDITED			US-PFIZER INC-2012210339		77 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neosporin			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

	Monopril	S	Unk		Not Reported
	Zestoretic	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2012	8762503	NON-EXPEDITED			US-PFIZER INC-2012211188		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2012	8760934	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000038136		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Crying; Feeling	Lexapro			S				Forest
Abnormal; Impaired	Lexapro			S				Forest
Driving Ability;	Topamax			C				Not Reported
Somnolence; Suicidal	Soma			C				Not Reported
Ideation	Hydrocodone			C				Not Reported
	Detrol			C				Not Reported
	Provigil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2012	8761076	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000038192		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Hypoplastic Left Heart Syndrome	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2012	8762328	EXPEDITED (15-DAY)		DE, HO	BE-B.I. PHARMACEUTICALS,I		94 YR	Male	BEL

NC./RIDGEFIELD-2011-BL-00

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

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

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

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

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

Scratch; Therapy Cessation; Urticaria

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Scleroderma	Lexapro			S	Oral	2 Mg		Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spina Bifida	Lexapro			S	Transplacental	20 Mg		Forest
	Lexapro			S				Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Product Substitution Issue	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2012	8766833	EXPEDITED (15-DAY)		OT	DE-FRI-1000021654			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2012	8767559	EXPEDITED (15-DAY)		OT	NO-FRI-1000038256			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Balance Disorder; Burning Sensation; Decreased Appetite; Medication Error; Memory Impairment; Mobility Decreased; Neurological Symptom; Pain; Prescribed Overdose	Escitalopram			S		40 Mg		Forest
	Escitalopram			S		20 Mg		Forest
	Escitalopram			S		5 Mg		Not Reported
	Imovane			C				Not Reported
	Marevan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2012	8780208	DIRECT	Y				17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Product Substitution Issue	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2012	8768401	EXPEDITED (15-DAY)		OT	HU-ROCHE-1111384		53 YR	Female	HUN

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness	Escitalopram			S	Oral	5 Mg		Forest

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

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

onine)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2012	8784686	DIRECT		OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anger; Product Substitution Issue; Sleep Disorder; Sleep Terror	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2012	8773336	EXPEDITED (15-DAY)		DE	AU-FRI-1000038423		34 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Lexapro			S	Oral			Forest
	Lexapro			S	Oral	Overdose: Unknown Dose		Forest
	Olanzapine			C				Not Reported
	Olanzapine			C				Not Reported
	Oxazepam			C				Not Reported
	Oxazepam			C				Not Reported
	Temazepam			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2012	8789202	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Quality Issue	Escitalopram			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2012	7878648	EXPEDITED (15-DAY)		HO	US-ASTRAZENECA-2011SE11145		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Depression; Expired Product Administered; Feeling Jittery; Mania; Muscle Twitching; Wrong Technique In Product Usage Process	Abilify Tabs 10 Mg		S	Feb12:5mg/D,2d69670,Exp:Mr15;10mg:0f596898a,Expmy12;10mg:0f60008a.Expjl12,2.5mg 1df:1/2tabso(10mg)	Not Reported
	Lithium		S		Not Reported
	Escitalopram		S		Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haematoma; Menorrhagia; Metrorrhagia	Escitalopram		S	Oral	10 Mg	Forest
	Escitalopram		S	Oral	5 Mg	Forest
	Varnoline		C	Oral	1 Df	Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Gastrooesophageal Reflux Disease; Haematemesis; Hiatus Hernia; Hypochromic Anaemia; Intestinal Ulcer; Pneumonia	Sequase			S	Oral			Zeneca
	Cipralex			S	Oral			Not Reported
	Tilur			S	Oral			Not Reported
	Novalgine (Metamizole Sodium)			C	Oral			Not Reported
	Calcimagon D3			C	Oral			Not Reported
	Omezol			C	Oral			Not Reported
	Lithium Aspartate			C	Oral			Not Reported
	Neurontin			C	Oral			Not Reported

	Requip	C	Oral	Not Reported
	Madopar	C	Oral	Not Reported
	Detrusitol	C	Oral	Not Reported
	Motilium	C	Oral	Not Reported
	Euthyrox	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2012	8784319	EXPEDITED (15-DAY)		OT	JP-FRI-1000025531		25 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Seizure	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2012	8790925	DIRECT		OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Nausea; Unevaluable Event; Vomiting	Escitalopram			S	Oral	20mg Qd Po		Mylan
	Omeprazole			C				Not Reported
	Monelukast			C				Not Reported
	Loratidine			C				Not Reported
	Simvastatin			C				Not Reported
	Doxycycline			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2012	8790933	DIRECT		OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Maternal Exposure Timing Unspecified; Panic Attack; Pregnancy; Product Substitution Issue; Rash	Escitalopram			S	Oral			Teva
	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2012	8666160	EXPEDITED (15-DAY)		HO	JP-ASTRAZENECA-2012SE47527		39 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral; Nausea; Vertigo; Vertigo Positional	Atacand			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Aciclovir			C	Oral			Not Reported
	Estradiol			C	Oral			Not Reported
	Esomeprazole Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2012	8771772	EXPEDITED (15-DAY)		HO, OT	HU-ABBOTT-12P-076-0975861-00		53 YR	Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Atrial Tachycardia; Fatigue; Palpitations; Sinus Arrest; Sinus Bradycardia	Levothyroxine			S				Not Reported
	Escitalopram			S				Not Reported
	Quetiapine			S				Not Reported
	Amiloride			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Clonazepam			S		0.5-0.5-3 Mg		Not Reported
	Clonazepam			S		1-1-2 Mg		Not Reported
	Cinolazepam			S				Not Reported
	Ketoconazole			S		Intertrigo		Not Reported
	Lithium Carbonate			S				Not Reported
	Lithium Carbonate			S				Not Reported
	Carbamazepine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2012	8791346	DIRECT		LT, OT			89 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Adjustment Disorder With Depressed Mood; Confusional State; Imprisonment; Lethargy; Malaise; Nausea; Physical Assault; Suicidal Ideation; Weight Decreased	Lexapro			S	Oral	From May 1st To May 8th 1st Time From June 8th To June 30		Teva
	Namenda			C				Not Reported
	Aricept			C				Not Reported
	Axona Medical Food			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2012	8766627	EXPEDITED (15-DAY)		HO, OT	HU-FRI-1000038249		53 YR	Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Atrial Tachycardia; Fatigue; Palpitations; Sinus Arrest; Sinus Bradycardia	Escitalopram			S				Forest
	Lithium Carbonate			S		1000 Mg		Not Reported
	Quetiapine			S		200 Mg		Not Reported
	Amiloride			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Levothyroxin			S				Not Reported
	Clonazepam			S		0.5-0.5-3 Mg		Not Reported
	Cinolazepam			S				Not Reported
	Ketoconazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2012	8792741	EXPEDITED (15-DAY)		HO	FR-BAYER-2012-094203		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplasia; Dyspnoea; Ecchymosis; Haemorrhagic Disorder; Infection; Menorrhagia	Yaz			S	Oral	1 Df, Qd		Bayer
	Seroplex			S	Oral	Unk		Not Reported
	Xanax			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2012	8799217	DIRECT	Y	OT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Movement Disorder	Sertraline			S	Oral	50 - 100mg Daily Po 12/20/2011 - 8/20/12; 8/31/12 To Present But Tapering Off		Not Reported
					Oral	50 - 100mg Daily Po 12/20/2011 - 8/20/12; 8/31/12 To Present But Tapering Off		
	Escitalopram			S	Oral	10mg Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2012	8806331	DIRECT		DS, LT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2012	8709886	EXPEDITED (15-DAY)		OT	JP-FRI-1000037584		18 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Wound	Lexapro			S	Oral	20 Mg		Forest
	Cymbalta			C	Oral	40 Mg		Not Reported
	Lendormin D			C	Oral	0.25 Mg		Not Reported
	Evamyl			C	Oral	1 Mg		Not Reported
	Abilify			C	Oral	2 Mg		Not Reported
	Halcion			C	Oral			Not Reported
	Somelin			C	Oral			Not Reported

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2012	7916136	NON-EXPEDITED			US-PFIZER INC-2011089062		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Choking Sensation; Drug Ineffective; Drug Interaction; Energy Increased; Fatigue; Flatulence; Gastrooesophageal Reflux Disease; Insomnia; Malaise; Somnolence	Pristiq			S	Oral	50 Mg, 1x/Day		Pfizer
	Pristiq			S		Unk		Pfizer
	Zoloft			S	Oral	Unk		Pfizer
	Alprazolam			S				Pfizer
	Lexapro			S		Unk		Not Reported
	Restoril			S		Unk		Not Reported
	Suboxone			S				Not Reported
	Prilosec			C		20 (Units Unspecified), Qd		Not Reported
	Valium			C		10 Mg, 3x/Day		Not Reported
	Trazodone			C		50 Mg, Hs (At Bedtime)		Not Reported
	Xanax			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2012	8742064	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2012204441		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Suicidal Ideation	Xanax			S	Oral	0.5 Mg, Daily		Pfizer
	Xanax			S	Oral	1 Mg, Daily		Pfizer
	Cipralex			S	Oral	5 Mg, 1x/Day		Not Reported
	Cipralex			S	Oral	10 Mg, 1x/Day		Not Reported
	Cipralex			S	Oral	5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2012	8798385	EXPEDITED (15-DAY)		OT	SE-FRI-1000038717		18 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2012	8799281	EXPEDITED (15-DAY)		DS, HO, LT, OT	DE-FRI-1000038760		< 1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage Neonatal; Foetal Exposure During Pregnancy; Haemangioma Of Liver; Hypotonia; Seizure; Small For Dates Baby; Subdural Haemorrhage Neonatal	Escitalopram			S	Transplacental	20 Mg		Forest
	Escitalopram			S	Transplacental	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2012	8801187	NON-EXPEDITED			US-009507513-1209USA005724			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Insomnia; Weight Increased	Saphris			S	Oral			Merck
	Fanapt			S	Oral	8 Mg, Bid		Not Reported
	Lexapro			S				Not Reported
	Seroquel			S				Not Reported
	Risperidone			S				Not Reported
	Pristiq			C				Not Reported
	Effexor Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2012	8777756	EXPEDITED (15-DAY)		OT	PHHY2012FR078541		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Concomitant Disease Progression; Depression; Dyskinesia; Restless Legs Syndrome; Suicidal Ideation	Femara			S				Novartis
	Seroplex			S		5 Mg, Daily		Not Reported
	Fenofibrate			C				Not Reported
	Sevikar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2012	8801469	EXPEDITED (15-DAY)		HO	FR-FRI-1000038842		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2012	8801911	EXPEDITED (15-DAY)		HO	NL-FRI-1000038756		69 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Hyperhidrosis; Off Label Use; Panic Attack; Torticollis	Escitalopram			S	Oral	10 Mg		Forest
	Propranolol			C		80 Mg		Not Reported
	Salazopyrine			C		1000 Mg		Not Reported
	Ulcogant			C		3 Dosage Forms		Not Reported
	Ascal (Acetylsalicylate Calcium)			C		80 Mg		Not Reported
	Esomeprazol			C		80 Mg		Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2012	8808703	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Lexapro			S	Oral	Lexapro 5mg Once Daily Oral	<1 WK	Not Reported
	Lipitor			C				Not Reported
	Victoza			C				Not Reported
	Metformin			C				Not Reported
	Atenolol			C				Not Reported
	Norvasc			C				Not Reported
	Asa			C				Not Reported
	Temazepam			C				Not Reported
	Xolatan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2012	8809034	DIRECT		OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Feeling Abnormal; Headache; Nausea; Product Substitution Issue; Suicidal Ideation	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2012	8771504	EXPEDITED (15-DAY)		HO	FR-ABBOTT-12P-056-0932679-00			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia	Seroplex			S	Oral			Not Reported
	Domperidone			S	Oral			Not Reported
	Azilect			C	Oral			Not Reported
	Stalevo			C	Oral	100mg/25mg/200mg		Not Reported
	Requip			C	Oral			Not Reported
	Stalevo			C	Oral	50mg/12.5mg/200mg Tid		Not Reported
	Madopar			C	Oral	50mg/12.5mg		Not Reported
	Detensiel			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2012	8803948	EXPEDITED (15-DAY)		HO	FR-ABBOTT-12P-056-0970058-00		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; Drug Interaction; Dyspnoea; General Physical Health	Seroplex			S	Oral			Not Reported
	Altizide W/Spironolactone			S	Oral			Not Reported
	Cordarone			C	Oral			Not Reported

Deterioration; Hyponatraemia; Renal Failure; Vomiting	Levothyrox	C	Oral		Not Reported
	Vitamin B12	C	Oral		Not Reported
	Sterogyl	C			Not Reported
	Lercan	C			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral; Nausea; Vertigo; Vertigo Positional	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Atacand			S	Oral			Not Reported
	Aciclovir			C	Oral	A		Not Reported
	Progynova			C	Oral			Not Reported
	Nexium			C	Oral	A		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Suicide Attempt	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Depression; Drug Interaction; Extrapyramidal Disorder; Fall; General	Durogesic			S	Transdermal			Not Reported
	Seroplex			S	Oral	2 Tablets A Day		Not Reported

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Sipralexa			S	Oral			Not Reported

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

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

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Seizure	Escitalopram		S	Oral	20 Mg	Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hallucination	Risperdal			S	Oral			Not Reported
	Durogesic			S	Transdermal			Not Reported
	Seroplex			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Rivotril			S	Oral	2.5mg/Ml		Not Reported

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2012	8809793	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000038823			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Erythema; Off Label Use; Seizure; Weight Decreased	Lexapro			S	Subcutaneous			Forest
	Lexapro			S				Forest
	Rebif			S				Not Reported
	Alcohol			S				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2012	8809801	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000038989		19 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2012	8810323	NON-EXPEDITED			US-009507513-1209USA008841			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Back Pain; Drug Ineffective; Pain In Extremity	Cozaar			S	Oral			Merck
	Amlodipine			S				Not Reported
	Venlafaxine Hydrochloride			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2012	8811832	DIRECT	Y				31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Fatigue; Headache; Irritability; Nausea; Product Substitution Issue	Escitalopram			S	Oral	10mg 1 Po Qd		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2012	8814097	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Sluggishness	Escitalopram			S	Oral	30 Mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2012	8470559	EXPEDITED (15-DAY)		OT	JP-FRI-1000029225		42 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Excessive Eye Blinking; Facial Spasm; Fear; Musculoskeletal Stiffness; Nausea; Seizure; Tardive Dyskinesia; Tremor; Tremor; Vomiting	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Fluvoxamine Maleate			C	Oral	150 Mg		Not Reported
	Evamyl			C	Oral	2 Mg		Not Reported
	Brotizolam			C	Oral	0.25 Mg		Not Reported
	Estazolam			C	Oral	2 Mg		Not Reported
	Horizon			C	Oral	15 Mg		Not Reported
	Rilyfter			C	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2012	8738226	NON-EXPEDITED			US-PFIZER INC-2012205320			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nervousness	Pristiq			S	Oral	50 Mg, 1x/Day		Pfizer
	Lexapro			S		20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2012	8812492	EXPEDITED (15-DAY)		HO	US-TEVA-361271USA		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Serotonin Syndrome	Clonazepam			S	Nasal	Multiple Crushed Tablets		Teva
	Clonazepam			S	Unknown			Teva
	Escitalopram			S	Nasal	Multiple Crushed 20mg Tablets		Not Reported
	Escitalopram			S	Unknown	20 Mg/D		Not Reported
	Quetiapine			S	Nasal	Multiple Crushed 100mg Tablets		Not Reported
	Quetiapine			S	Unknown			Not Reported
	Percocet			S	Nasal	Multiple Crushed Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2012	8812528	EXPEDITED (15-DAY)		LT	FR-JNJFOC-20120908608		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Drug Interaction; Fall; Head Injury; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Vomiting	Risperdal			S	Oral			Not Reported
	Hytacand			S	Oral	8/12.5 Mg		Not Reported
	Seroplex			S	Oral			Not Reported
	Hemigoxine			C	Unknown			Not Reported
	Inipomp			C	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported
	Colchicine			C	Unknown			Not Reported
	Codoliprane			C	Unknown			Not Reported

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Escitalopram			S		20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2012	8816250	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Feeling Hot; Hyperhidrosis; Insomnia	Escitalopram			S	Oral	10mg 1 Per Day Po	7 DAY	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2012	8795815	EXPEDITED (15-DAY)		HO	FR-FRI-1000038611		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Lung Disorder; Overdose; Somnolence; Walking Disability	Escitalopram			S	Oral	15 Mg		Forest
	Escitalopram			S	Oral			Not Reported
	Lepticur			S	Oral	30 Df		Not Reported
	Lepticur			S		Overdose: Unknown Amount		Not Reported
	Levothyrox			C	Oral	75 Mcg		Not Reported
	Alprazolam			C	Oral	0.25 Mg		Not Reported
	Zyprexa			C	Oral	1 Df		Not Reported
	Inexium			C		40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2012	8814085	NON-EXPEDITED			US-PFIZER INC-2012237511		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Myalgia; Pain In Extremity	Amlodipine Besilate			S		Unk		Pfizer
	Venlafaxine Hydrochloride			S		Unk		Pfizer
	Losartan			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2012	8814860	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000038907		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Ebstein'S Anomaly	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2012	8815086	EXPEDITED (15-DAY)		CA	US-FRI-1000038912		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly; Fallot'S Tetralogy; Pulmonary Artery Stenosis Congenital; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2012	8712245	EXPEDITED (15-DAY)		HO, OT	FI-AMGEN-FINSP2012048488		67 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Lactate Dehydrogenase Increased; Thrombocytopenia	Xgeva			S	Subcutaneous	120 Mg, Q4wk		Amgen
	Xgeva			S				Amgen
	Cipralex			S	Oral	5 Mg, Qd		Not Reported
	Specicor			C	Oral	47.5 Mg, Bid		Not Reported
	Faslodex /01503001/			C	Intramuscular	500 Mg, Q4wk		Not Reported
	Faslodex /01503001/			C				Not Reported
	Oxycontin			C	Oral	10 Mg, Bid		Not Reported
	Lipcut			C	Oral	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2012	8817933	EXPEDITED (15-DAY)		DS, LT	FR-FRI-1000039067		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia; Osmotic Demyelination Syndrome	Escitalopram			S	Oral	10 Mg		Forest
	Olmetec			S	Oral	10 Mg		Not Reported
	Climaston			C				Not Reported
	Levothyrox			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Veratran			C				Not Reported
	Calciparine			C				Not Reported
	Volibris			C				Not Reported
	Revatio			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2012	8818572	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2012241917		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Decreased; Drug Ineffective; Infection Protozoal; Pain; Paralysis	Effexor			S		Unk		Pfizer
	Xanax			S		Unk, Daily As Needed		Pfizer
	Escitalopram Oxalate			S		40 Mg, Daily		Not Reported
	Klonopin			C		Half A Tablet Of 2mg Daily		Not Reported
	Klonopin			C				Not Reported
	Ritalin			C		20mg In Morning And 10mg At Noon		Not Reported
	Ritalin			C				Not Reported
	Oxyir			C		5 Mg, As Needed		Not Reported
	Oxyir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2012	8819692	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20120908635		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Hyponatraemia; Rhabdomyolysis	Durogesic		S	Transdermal	Not Reported
	Seroplex		S	Oral	Not Reported
	Lexomil		S	Oral	Not Reported
	Domperidone		C	Unknown	Not Reported
	Calcium Vitamine D3		C	Unknown	Not Reported
	Fosavance		C	Unknown	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cleft Palate; Congenital Anomaly; Diaphragmatic Hernia; Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2012	8816834	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Fatigue	Escitalopram			S	Oral	Escitalopram 20mg Once Daily Po		Not Reported
	Citalopram			S	Oral	Citalopram 40mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2012	8816835	DIRECT		OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hyperacusis; Migraine; Nausea; Photophobia; Unevaluable Event	Escitalopram			S	Oral	20 Mg 1 Tablet Daily By Mouth		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2012	8820534	EXPEDITED (15-DAY)		LT	FR-FRI-1000039069		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	10 Mg		Forest
	Hytacand			S	Oral	8 Mg/12.5 Mg		Not Reported
	Risperdal			S	Oral	1 Mg		Not Reported
	Colchicine			C				Not Reported
	Codoliprane			C				Not Reported

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

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

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

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

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

						Times A Day,15mg,10mg,Dosingtime Changed From Bedtime Morning On Mar 2012				
	Prilosec			C						Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Headache; Insomnia	Escitalopram Oxalate			S	Oral			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias; Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2012	8818829	DIRECT		OT			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease Recurrence; Irritability; Panic Attack; Product Substitution Issue	Escitalopram			S	Oral			Not Reported
	Lamotrigine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2012	8825195	EXPEDITED (15-DAY)		OT	US-TEVA-361072USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Dependence; Drug Intolerance; Drug Withdrawal Syndrome	Mirtazapine			S		15 Milligram Daily;		Teva
	Clonazepam			S		.125 Milligram Daily;		Not Reported
	Escitalopram Oxalate			S		10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2012	8829898	EXPEDITED (15-DAY)	Y	HO	2012AP003167		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depressed Mood; Incorrect Route Of Product Administration; Intentional Overdose; Serotonin Syndrome; Wrong Technique In Product Usage Process	Quetiapine Fumarate			S				Not Reported
	Clonazepam			S				Not Reported
	Escitalopram			S				Not Reported
	Percocet			S				Not Reported
	Cocaine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2012	9227449	NON-EXPEDITED		OT	PHEH2011US02520		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Burn; Application Site Irritation; Depression; Drug Ineffective; Hormone Level Abnormal; Pain In Extremity; Vaginal Haemorrhage	Estalis			S	Transdermal			Not Reported
	Climara (Estradiol)			S				Not Reported
	Lexapro (Escitalopram Oxalate)			S				Not Reported
	Diazepine (No Ingredients/Substances)			C				Not Reported
	Amlodipine (Amlodipine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2012	8771201	EXPEDITED (15-DAY)		DE, HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-16879645		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clavicle Fracture; Dysphagia; Fall; Parkinsonism; Pneumonia Aspiration	Abilify			S	Oral	Started Either 2 Or 5mg,Dose Increased To 10mg,Jul12		Not Reported
	Buspar			S				Bristol Myers Squibb
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Ambien			S		Qhs		Not Reported
	Lipitor			C				Not Reported
	Allegra			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2012	8823107	EXPEDITED (15-DAY)		CA	US-FRI-1000039056			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Artery Stenosis Congenital	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2012	8829424	DIRECT	Y				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2012	8772502	EXPEDITED (15-DAY)		OT	AU-FRI-1000038315		< 1 DAY	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress	Lexapro			S	Transplacental			Forest
	Aripiprazole			S	Transplacental	10 Mg		Not Reported
	Breast Feeding Support			C	Oral			Not Reported
	Fefol			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2012	8822409	EXPEDITED (15-DAY)		OT	US-FRI-1000039092		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cold Sweat; Dizziness; Drug Ineffective; Ecg P Wave Inverted; Electrocardiogram T Wave Inversion; Fatigue; Flushing; Insomnia; Left Atrial Enlargement; Lipoma; Myalgia; Palpitations; Panic Attack; Tachycardia	Escitalopram			S	Oral	10 Mg		Forest
	Klonopin			C		As Needed		Not Reported
	Aspirin			C	Oral	81 Mg		Not Reported
	Lipitor			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2012	8827698	NON-EXPEDITED			US-PFIZER INC-			Female	USA

2012244846

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Insomnia; Product Substitution Issue	Lexapro			S	Oral			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disturbance In Attention; Headache; Mood Swings	Escitalopram		S	Oral	1.5 Tablet Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2012	8164861	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-16113607		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cerebral Haematoma; Cerebrovascular Accident; Fall; Hemiplegia	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Seroplex			S	Oral	1 Dosage Form: Scored Film-Coated Tablet; Escitalopram Oxalate 10 Mg		Not Reported
	Parkinane			S	Oral	1 Dosage Form: Extended-Release Capsule; Trihexyphenidyl Hydrochlopride 5 Mg,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2012	8833954	DIRECT		OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Disease Recurrence; Drug Ineffective; Fatigue; Feeling Abnormal; Feeling Abnormal; Headache; Irritability; Lethargy; Premenstrual Syndrome; Product Substitution Issue	Escitalopram			S	Oral	5-10 Depends On Time Month.	3 MTH	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2012	8837031	EXPEDITED (15-DAY)		HO	USA/USA/12/0026136		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Bradycardia; Dizziness;	Nebivolol			S	Oral	2.5 Mg		Forest

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2012	8837262	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Diarrhoea; Headache; Hypersensitivity; Product Substitution Issue; Vomiting	Celexa			S	Oral	Celexa 20 Daily Po - Liquid		Not Reported
	Lexapro			S	Oral	Lexapro 20 Daily Po - Liquid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2012	8841714	EXPEDITED (15-DAY)	Y	HO	2012SUN00116		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Depressed Mood; Intentional Overdose; Intentional Product Use Issue; Serotonin Syndrome	Quetiapine Fumarate			S				Not Reported
	Escitalopram			S				Not Reported
	Clonazepam			S				Not Reported
	Percocet			S				Not Reported
	Cocaine (Cocaine)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	7701555	NON-EXPEDITED	N	HO	1000009544		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Sodium Decreased; Fatigue; Feeling Abnormal; Gait Disturbance	Lexapro			S	Oral	Oral		Not Reported
	High Blood Pressure Medication Nos (Antihypertensives)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	8225873	NON-EXPEDITED	Y	RI, OT	1000016212			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S				Not Reported
	Zoloft			S				Not Reported
	Wellbutrin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	8226225	NON-EXPEDITED	Y	RI, OT	1000021607		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplastic Anaemia	Lexapro			S		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	8226263	NON-EXPEDITED	N	RI, OT	1000022542		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral	1 DAY	Not Reported
	Prescription Pain Medications Nos (Prescription Pain Medications Nos)			S				Not Reported
	Haldol (Haloperidol)			C				Not Reported

	Nexium (Esomeprazole)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	8815447	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2012SE73307		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Urinary Retention	Xeroquel			S	Oral	Dose Progressively Increased To 300 Mg Per Day		Astrazeneca
	Seroplex			S	Oral			Not Reported
	Lexomil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	8837635	EXPEDITED (15-DAY)		HO, OT	IT-FRI-1000037407		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sopor; Suicide Attempt	Escitalopram			S	Oral	Overdose: 300 Mg		Forest
	Lexotan			C	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	8837885	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2012251930		80 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Blood Uric Acid Increased; Constipation; Diarrhoea; Flatulence; Haematocrit Decreased; Haemoglobin Decreased; Muscle Atrophy; Muscle Spasms; Myalgia; Nail Discolouration; Nitrite Urine Present; Red Blood Cell Count Decreased;	Tritace			S	Oral	2.5 Mg, 1x/Day		Pfizer
	Controloc			S	Oral	20 Mg, 1x/Day		Pfizer
	Aggrenox			S	Oral	1 Df, 2x/Day		Not Reported
	Teotard			S	Oral	200 Mg, 1x/Day		Not Reported
	Cipralex			S	Oral	5 Mg, 1x/Day		Not Reported
	Norprexanil			S	Oral	1 Df, 1x/Day		Not Reported
	Crestor			S	Oral	20 Mg, 1x/Day		Not Reported
	Lamisil			C	Topical	Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	8838284	EXPEDITED (15-DAY)		CA	US-FRI-1000039299		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Congenital Diaphragmatic Hernia; Neonatal Respiratory Distress	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	8838448	EXPEDITED (15-DAY)		CA	US-FRI-1000039305			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Stenosis; Atrial Septal Defect; Congenital Anomaly; Patent Ductus Arteriosus	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	8838655	EXPEDITED (15-DAY)		OT	HR-ASTRAZENECA-2012SE76972			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Blood Uric Acid Increased; Constipation; Diarrhoea; Flatulence; Haematocrit Decreased; Haemoglobin Decreased; Muscle Atrophy; Muscle Spasms; Myalgia; Nail Discolouration; Nitrite	Crestor			S	Oral			Astrazeneca
	Aggrenox			S	Oral	200 Mg Dypyridamole+ 25 Mg Acetylsalicylic Acid, 1 Df Two Times A Day		Not Reported
	Norprexanil			S	Oral	5 Mg Perindopril + 5 Mg Amlodipine Besilate 1 Df Every Day		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	8839336	DIRECT	Y	DS, OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Impaired Self-Care; Loss Of Personal Independence In Daily Activities; Pain; Product Substitution Issue	Escitalopram			S	Oral	Escitalopram 100mg T 1/2 Tablets P.O. Qam		Not Reported
	Escitalopram			S	Oral	Escitalopram 10mg Tablet Po Qam		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	8839429	DIRECT					69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Blood Pressure Increased; Fatigue; Formication; Gastrointestinal Pain; Hot Flush; Loss Of Consciousness; Product Substitution Issue; Skin Disorder	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227139	NON-EXPEDITED	Y	RI, OT	1000029076		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Rash	Lexapro (Escitalopram Oxalate) (10 Milligram, Tablets)			S	Oral	10 Mg (10mg, 1 In 1 D), Oral		Not Reported
	Amlodipine (Amlodipine) (Amlodipine)			C				Not Reported
	Zolpidem (Zolpidem) (Zolpidem)			C				Not Reported
	Hyzaar (Hyzaar) (Hyzaar)			C				Not Reported
	Premarin (Estrogen Conjugated) (Estrogens Conjugated)			C				Not Reported
	Toprol (Metoprolol Succinate) (Metoprolol Succinate)			C				Not Reported
	Trazodone (Trazodone) (Trazodone)			C				Not Reported
	Maxalt (Rizatriptan) (Rizatriptan)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227154	NON-EXPEDITED		HO	1000029116		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Crying; Social Avoidant Behaviour; Suicidal Behaviour; Suicidal Ideation	Lexapro (Escitalopram Oxalate)			S	Oral			Not Reported
	Lexapro (Escitalopram Oxalate)			S	Oral			Not Reported
	Loestrin Fe (Norethindrone, Ethinyl Estradiol) (Norethindrone, Ethinyl Estradiol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227158	NON-EXPEDITED		RI, OT	1000029147			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicide Attempt	Lexapro			S	Oral			Not Reported

Oral

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227160	NON-EXPEDITED		RI, OT	1000029221		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Fatigue; Suicidal Ideation	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227164	NON-EXPEDITED		RI, OT	1000029263		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Testosterone Decreased; Feeling Cold; Hyperhidrosis; Irritability; Libido Decreased; Suicidal Ideation; Tremor; Weight Increased	Lexapro			S				Not Reported
	Wellburtin (Bupropion Hydrochloride) (Bupropion Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227177	NON-EXPEDITED	Y		1000029279		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Fatigue; Self-Injurious Ideation	Lexapro			S	Oral			Not Reported
	Rebif			S	Subcutaneous	3 Doses In One Week.		Not Reported
	Marijuana			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227187	NON-EXPEDITED		RI, OT	1000029340		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

	Albuterol (Albuterol)(Albuterol)	C	Not Reported
	Symbicort (Budesonide, Formoterol)(Budesonide, Formoterol)	C	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Arrhythmia	Lexapro (Escitalopram Oxalate)			S				Not Reported

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227359	NON-EXPEDITED		HO	1000026846		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Lexapro			S	Oral	10mg (10mg, 1 In 1 D), Oral		Not Reported
	Keppra (Levetiracetam)			C				Not Reported
	Zonegran (Zonisamide)			C				Not Reported
	Vimpat (Lacosamide)			C				Not Reported
	Lorazepam (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227376	NON-EXPEDITED	Y	RI, OT	1000027216			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro (Escitalopram Oxalate)			S	Oral			Not Reported
	Sabril			S	Oral Oral			Not Reported
	Anti-Epileptic Drugs (Anti-Epileptic Drugs) (Anti-Epileptic Drugs)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227386	NON-EXPEDITED		RI, OT	1000027292			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Burning Sensation; Cold Sweat; Feeling Abnormal; Headache; Nausea	Lexapro (Escitalopram Oxalate)			S		5 Gm, 1 In 1 D		Not Reported
	Armour (Thyroid (Thyroid)			C				Armour
	Ativan (Lorazepam) (Lorazepam)			C				Not Reported
	Xanax			C				Not Reported
	Catapres (Clonidine) (Clonidine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227395	NON-EXPEDITED		DE	1000027438		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported
	Toprol Xl (Metoprolol) (Metoprolol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227404	NON-EXPEDITED	Y	RI, OT	1000028429			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Flutter; Hair Colour Changes; Tremor; Vision Blurred	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227413	NON-EXPEDITED		RI, OT	1000028448		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Diarrhoea; Feeling Abnormal; Insomnia; Neck Pain; Suicidal Ideation	Lexapro			S	Oral	(5 Mg, 1 In 1 D)		Not Reported
	Vitamin B 12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227420	NON-EXPEDITED		RI, OT	1000028865			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Mania	Lexapro			S		1 In 1 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227599	NON-EXPEDITED	Y	DE	1000030062			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Tachyphrenia; Unevaluable Event	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227611	NON-EXPEDITED		HO	1000030362		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Contusion; Dizziness; Fall; Fatigue	Lexapro			S				Forest
	Aspirin (Acetylsalicylic Acid)			C				Not Reported
	Warfarin (Warfarin)			C				Not Reported
	Diazepam (Diazepam)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227622	NON-EXPEDITED	Y	RI, OT	1000030447		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Insomnia; Panic Attack; Suicidal Ideation; Tachyphrenia	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227633	NON-EXPEDITED		RI, OT	1000030561		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Fatigue; Feeling Abnormal; Malaise	Lexapro			S		1 In 1 D		Not Reported
	Xanax Xr			S	Oral	1mg, 3 In 1 D		Not Reported
	Alprazolam			S	Oral	1 Mg, 3 In 1 D		Not Reported
	Lipitor (Atorvastatin Calcium) (Atorvastatin Calcium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227638	NON-EXPEDITED		RI, OT	100030625		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227646	NON-EXPEDITED		RI, OT	1000030827		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Pyrexia; Unevaluable Event	Lexapro			S				Not Reported
	Escitalopram			S				Not Reported
	Lipitor (Atorvastatin Calcium)			S		(80 Mg, 1 In 1 D)		Not Reported
	Alprazolam (Alprazolam)			S				Not Reported
	Carvedilol			S				Not Reported
	Unspecified			S				Not Reported
	Nitrostat(Nitroglycerin) (Nitroglycerin)			C				Not Reported
	Aspirin (Acetylsalicylic Acid) (Acetylsalicylic Acid)			C				Not Reported
	Quinapril (Quinapril) (Quinapril)			C				Not Reported
	Plavix (Clopidogrel Bisulfate) (Clopidogrel Bisulfate)			C				Not Reported
	Xanax			C				Not Reported
	Coreg (Carvedilol) (Carvedilol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227654	NON-EXPEDITED		RI, OT	1000031506		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Heart Rate Increased; Palpitations	Lexapro			S	Oral	10 Mg, 1 In 1 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227663	NON-EXPEDITED	Y	RI, OT	1000037036			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227666	NON-EXPEDITED		DE	1000031572			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective; Off Label Use	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227672	NON-EXPEDITED		RI, OT	1000037120		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hallucination; Hypoaesthesia; Nausea; Suicidal Ideation; Tachyphrenia	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227674	NON-EXPEDITED	Y	RI, OT	1000036640			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227680	NON-EXPEDITED		RI, OT	1000036719		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicidal Ideation	Lexapro			S	Oral Oral			Not Reported
	Clonazepam (Clonazepam) (Clonazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227693	NON-EXPEDITED		RI, OT	100023627		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicidal Ideation	Lexapro			S	Oral	20 Mg, 1 In 1 D		Not Reported
	Advair			C				Not Reported
	Metformin			C				Not Reported
	Glipizide			C				Not Reported
	Levothyroxine			C				Not Reported
	Zyprexa			C				Not Reported
	Lorazepam			C				Not Reported
	Digoxin			C				Not Reported
	Taztia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227707	NON-EXPEDITED	Y	RI, OT	1000023652		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Mood Swings; Suicidal Ideation	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral	Stopped		Not Reported
	Lexapro			S	Oral Oral			Not Reported
	Lexapro			S	Oral Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2012	9227719	NON-EXPEDITED	Y	RI, OT	1000024125		55 YR	Female	USA

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Insomnia; Suicidal Ideation	Escitalopram Oxalate			S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Lexapro			S				Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicidal Ideation	Escitalopram			S	Oral	Stopped		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Suicidal Ideation	Lexapro (Escitalopram Oxalate)			S				Not Reported
	Calan(Verapamil)(Verapamil)			C				Not Reported
	Coumadin(Warfarin)(Warfarin)			C				Not Reported
	Avapro(Irbesartan)(Irbesartan)			C				Not Reported
	Bystolic(Nebivolol Hydrochloride)(Nebivolol Hydrochloride)			C				Not Reported
	Allegra(Fexofenadine Hydrochloride)(Fexofenadine Hydrochloride)			C				Not Reported
	Anusol(Hydrocortisone)(Hydrocortisone)			C				Not Reported
	Calcium(Calcium)(Calcium)			C				Not Reported
	Vitamin D3(Colecalciferol)(Colecalciferol)			C				Not Reported
	Multivitamin(Multivitamin)(Moltivitamin)			C				Not Reported
	Vitamin C(Vitamin C)(Vitamin C)			C				Not Reported
	Super B Complex(Super B Complex)(Super B Complex)			C				Not Reported
	Xanax(Alprazolam)(0.25 Milligram)(Alprazolam)			C				Not Reported
	Lyrica(Pregabalin)(Pregabalin)			C				Not Reported
	Maxzide(Triamterene, Hydrochlorothiazide)(Triamteren Hydrochlorothiazide)			C				Not Reported
	Plaquenil(Hydrochloroquine)(Hydrochloroquine)			C				Not Reported
	Antivert(Meclizine)(Meclizine)			C				Not Reported
	Symal(Symal)(Symal)			C				Not Reported
	Macrobid(Nitrofurantoin)(Nitrofurantoin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2012	8838933	EXPEDITED (15-DAY)		HO, OT	US-PAR PHARMACEUTICAL, INC-2012SCPR004649			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction; Vascular Graft	Escitalopram			S				Forest
	Water Pill			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product	Escitalopram			S	Oral			Mylan

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2012	8842433	DIRECT					58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Incorrect Dose Administered; Product Substitution Issue	Escitalopram			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2012	8822499	EXPEDITED (15-DAY)		HO	FR-FRI-1000039110		26 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Infarction	Escitalopram			S	Oral	15 Mg		Forest
	Statin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2012	8829211	EXPEDITED (15-DAY)	Y	DS, HO, LT	DSM-2012-01036		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Confusional State; Disorientation; Hyponatraemia; Metabolic Disorder; Osmotic Demyelination Syndrome; Pulmonary Hypertension	Olmetec			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Seroplex			S	Oral			Not Reported
	Climaston (Estradiol, Dydrogesterone) (***) (Estradiol, Dydrogesterone)			C				Not Reported
	Levothyrox (Levothyroxine Sodium) (Levothyroxine Sodium)			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Veratran (Clotiazepam) (Clotiazepam)			C				Not Reported
	Calciparine (Heparin Calcium) (Heparin Calcium)			C				Not Reported
	Volibris (Ambrisentan) (Ambrisentan)			C				Not Reported

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Escitalopram			S				Forest

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol	Escitalopram			S	Oral	5 Mg		Forest

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Neutropenia	Lexapro			S	Oral	10 Mg		Forest

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Hyperhidrosis; Withdrawal Syndrome	Alprazolam			S	Oral			Mylan
	Citalopram Hydrobromide			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2012	8849593	DIRECT	Y	HO			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Malaise; Product Substitution Issue	Escitalopram			S	Oral	20mg One At Bedtime Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2012	8849634	DIRECT		OT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Apathy; Confusional State; Crying; Depressed Mood; Depressed Mood; Disturbance In Attention; Extraocular Muscle Disorder; Fatigue; Product Quality Issue; Product Substitution Issue; Sluggishness	Escitalopram			S	Oral	1 Tablet At Bedtime Po	5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2012	8851676	DIRECT		DS			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Drug Dependence; Paraesthesia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2012	8221973	EXPEDITED (15-DAY)	Y	HO, OT	DSA_47885_2011		60 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Aldosterone Increased; Blood Chloride Decreased; Blood Urea Increased; Carcinoembryonic Antigen Increased; Ejection Fraction Decreased; Hyponatraemia; Insomnia; Po2 Decreased; Secondary Adrenocortical Insufficiency; Weight Increased	Bupropion Hydrochloride			S		(Df) (Df)		Not Reported
	Escitalopram			S		Df		Not Reported
	Mirtazapine			S				Not Reported
	Alprazolam			S		Df		Not Reported
	Clonazepam			S				Not Reported
	Clopidogrel			C				Not Reported
	Simvastatin			C				Not Reported
	Telmisartan			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2012	8849732	EXPEDITED (15-DAY)		OT	GB-FRI-1000039605		57 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Oedema Peripheral; Swelling; Weight Increased	Escitalopram			S	Oral			Forest
	Venlalic Xl			C	Oral	150 Mg		Not Reported
	Venlalic Xl			C	Oral	75 Mg		Not Reported
	Zapain			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2012	8850742	EXPEDITED (15-DAY)		OT	CA-FRI-1000039604		15 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Muscle Contracture; Off Label Use; Seizure; Tremor	Escitalopram			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2012	8854082	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Thyroid Stimulating Hormone Decreased; Fatigue; Overdose; Product Substitution Issue; Serotonin Syndrome	Escitalopram			S	Oral			Mylan
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2012	9227912	NON-EXPEDITED	Y	RI, OT	1000037193		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Lexapro			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral		Not Reported
	Abilify (Aripiprazole) (Aripiprazole)			C				Not Reported
	Tegretal (Carbamazepine) (Carbamazepine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2012	8498406	EXPEDITED (15-DAY)			JP-FRI-1000029489		39 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Nausea	Lexapro			S	Oral	10 Mg		Forest
	Alprazolam			C	Oral	1.2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2012	8573027	EXPEDITED (15-DAY)			JP-FRI-1000030539		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2012	8857679	NON-EXPEDITED			US-PFIZER INC-2012263615			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Effexor			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2012	8877503	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2012228813			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Pharyngeal Swelling	Efexor Xr			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Cipramil [Citalopram Hydrobromide]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2012	9228387	NON-EXPEDITED		OT	DSA_56025_2012			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Insomnia; Mood Swings; Paranoia; Product Quality Issue; Suicidal Ideation	Wellbutrin			S				Not Reported
	Seroquel			S			3 YR	Not Reported
	Lexapro			S	Oral	(Df Oral)		Not Reported
	Pristiq 50 Mg (Not Specified)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2012	8861276	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Product Substitution Issue	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2012	8870122	DIRECT	Y	OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Attention; Product Substitution Issue	Escitalopram			S	Oral	1 Tab Daily Orally		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2012	9178207	EXPEDITED (15-DAY)		OT	US-RB-045963-12		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dacryostenosis Congenital; Foetal Exposure During Pregnancy; Gastrooesophageal Reflux Disease; Infantile Vomiting; Low Birth Weight Baby; Premature Baby; Rash Neonatal; Restlessness; Tremor Neonatal; Weight Decrease Neonatal	Subutex			S	Transplacental			Reckitt Benckiser
	Prenatal Vitamins			S	Transplacental	Dosing Details Unknown		Not Reported
	Lexapro			S	Transplacental	Before Bed Time		Not Reported
	Nicotine			S	Transplacental	Dosing Details Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2012	8863072	EXPEDITED (15-DAY)		DE, HO	FR-SANOFI-AVENTIS-2012SA075643		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Xatral			S	Oral			Not Reported
	Ilomedine			S	Intravenous (not otherwise specified)			Not Reported
	Aricept			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2012	8870308	DIRECT	Y				42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Product Effect Decreased	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2012	8878982	EXPEDITED (15-DAY)		DE, HO	FR-FRI-1000039790		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carotid Artery Stenosis; Cholelithiasis; Clostridium Difficile Colitis; Hepatitis Cholestatic; Lipase Increased; Melaena; Sepsis	Escitalopram			S	Oral	10 Mg		Forest
	Ilomedine			S	Intravenous (not otherwise specified)	0.5 Mg		Not Reported
	Aricept			S	Oral	10 Mg		Not Reported
	Previscan (Fluindione)			S	Oral	10 Mg		Not Reported
	Xatral			S	Oral	10 Mg		Not Reported
	Fluconazole			S	Oral	200 Mg		Not Reported
	Driptane			C				Not Reported
	Paracetamol			C				Not Reported
	Inexium			C				Not Reported
	Effizinc			C				Not Reported
	Diffu-K			C				Not Reported
	Vitamin D Nos			C				Not Reported

	Furosemide	C		Not Reported
	Vancomycin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2012	8845290	EXPEDITED (15-DAY)		HO	NO-FRI-1000039451		22 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Haematochezia	Escitalopram			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2012	8872517	EXPEDITED (15-DAY)		DE	US-ROXANE LABORATORIES, INC.-2012-RO-02130RO		29 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Methadone			S	Oral			Roxane
	Alprazolam Intensol [Oral Solution (Concentrate)] 1 Mg/Ml			S	Oral			Roxane
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2012	9179378	EXPEDITED (15-DAY)		OT	CH-FRI-1000039792			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Cancer	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2012	9179706	EXPEDITED (15-DAY)		OT	US-FRI-1000039700		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Lexapro			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2012	8872605	EXPEDITED (15-DAY)		DE	US-ROXANE LABORATORIES, INC.-2012-RO-02205RO		39 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam Intensol [Oral Solution (Concentrate)] 1 Mg/Ml			S	Oral			Roxane
	Escitalopram			S	Oral			Not Reported
	Chlorpheniramine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2012	8873064	EXPEDITED (15-DAY)		DE	US-ROXANE LABORATORIES, INC.-2012-RO-02214RO		34 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam Intensol [Oral Solution (Concentrate)] 1 Mg/Ml			S	Oral			Roxane
	Tricyclic Antidepressant			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2012	8877228	EXPEDITED (15-DAY)		HO	NL-FRI-1000039918			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental			Forest
	Escitalopram			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2012	9182726	EXPEDITED (15-DAY)		DE	US-ROXANE LABORATORIES, INC.-2012-RO-02190RO		35 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torsade De Pointes	Seroquel			S	Oral			Zeneca
	Cipralex			S	Oral			Not Reported
	Methadone			S	Oral			Not Reported
	Seresta			C	Oral			Not Reported
	Nexium			C	Oral			Not Reported
	Berodual			C	Respiratory (inhalation)			Not Reported
	Seretide			C	Respiratory (inhalation)			Not Reported
	Mst (Morphine Sulfate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2012	8879769	EXPEDITED (15-DAY)		CA	US-FRI-1000039883		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Aortic Anomaly	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2012	8853257	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2012262394		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Depression; Drug Ineffective; Suicidal Ideation	Pristiq			S	Oral	50 Mg, 1x/Day		Pfizer
	Pristiq			S	Oral	50 Mg, 1x/Day		Pfizer
	Venlafaxine Hydrochloride			S	Oral	75 Mg, 1x/Day		Pfizer
	Escitalopram			S		Unk		Not Reported
	Advair			C	Respiratory (inhalation)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2012	8880746	EXPEDITED (15-DAY)		HO	IT-FRI-1000039957		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sopor	Escitalopram			S	Oral	Intentional Overdose: 40 Tablets Of 10 Mg		Forest
	Largactil			S	Oral	Intentional Overdose: 19 Tablets Of 100 Mg		Not Reported
	Lendormin			S	Oral	Intentional Overdose: 19 Tablets Of 0.25 Mg		Not Reported
	Depakin Chrono			S	Oral	Intentional Overdose: 54 Tablets Of 500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2012	8887660	DIRECT					52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Irritation; Hyperaesthesia; Pain; Skin Burning Sensation	Escitalopram			S	Oral	1 Tablet Daily		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2012	8889330	DIRECT	Y	LT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Disease Recurrence; Suicidal Ideation	Lexapro			S	Oral	20 Mg One Daily Oral	3 WK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2012	8693720	EXPEDITED (15-DAY)		HO, OT	AT-BRISTOL-MYERS SQUIBB COMPANY-16807471		26 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Trittico			S		150mg		Apothecon
	Cipralex			S		10 Mg		Not Reported
	Temesta (Lorazepam)			S				Not Reported
	Truxal			S		2 Tabs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2012	8840313	EXPEDITED (15-DAY)		OT	FR-FRI-1000039422		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatocellular Injury	Escitalopram	S	Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2012	8884833	EXPEDITED (15-DAY)		DE, HO	FR-FRI-1000040014		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Depressed Level Of Consciousness; Disorientation	Escitalopram			S	Oral			Forest
	Avastin			S	Intravenous (not otherwise specified)	7.5 Mg/Kg		Not Reported
	Skenan			S	Oral	120 Mg		Not Reported
	Actiskenan			S	Oral			Not Reported
	Lexomil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2012	8891344	DIRECT	Y	HO			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder	Escitalopram			S	Oral	20 Mg Daily Po	15 DAY	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2012	8891356	DIRECT	Y				42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Product Effect Decreased	Lexapro			S	Oral	20 Mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2012	8886175	EXPEDITED (15-DAY)		DE, HO	FR-ROCHE-1148807		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2012	8891375	DIRECT	Y	OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Escitalopram Oxalate			S			2 WEEK 4 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2012	8896244	DIRECT	Y				18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Product Effect Decreased	Escitalopram			S	Oral Oral	5 Mg 1 Daily Po 10mg 1 Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2012	8889946	EXPEDITED (15-DAY)		HO	ES-ASTRAZENECA-2012SE82879		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyspnoea; Respiratory Depression; Somnolence	Atenolol			S	Oral			Zeneca
	Seroquel Prolong			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Noctamide			S	Oral			Not Reported
	Artane			S	Oral			Not Reported

	Hidrosaluretil	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2012	8890428	EXPEDITED (15-DAY)		OT	US-TEVA-368252USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Blood Pressure Increased; Fatigue; Formication; Gastrointestinal Pain; Hot Flush; Loss Of Consciousness; Paraesthesia; Thinking Abnormal	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2012	8891827	EXPEDITED (15-DAY)		OT	AUR-APL-2012-04592		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Depression; Suicidal Ideation; Therapy Non-Responder	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S				Not Reported
	Pristiq			S	Oral			Not Reported
	Advair			S	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2012	8896428	DIRECT	Y				25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Fatigue; Insomnia; Product Quality Issue; Product Substitution Issue; Restlessness	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2012	8896432	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Decreased Interest; Depressed Mood; Product Substitution Issue; Suicidal Ideation	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2012	8896471	DIRECT		LT			9 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Escitalopram			S	Oral			Mylan
	Amphetamine Salts			C				Not Reported
	Focalin			C				Not Reported
	Colace			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2012	8909232	EXPEDITED (15-DAY)	Y	HO, RI, OT	2012MA012717		26 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Constipation; Necrotising Colitis; Overdose; Toxicity To Various Agents	Lorazepam			S				Purepac
	Trazodone			S				Not Reported
	Clotiapine			S				Not Reported
	Lamotrigine (Lamotrigine)			S				Not Reported
	Escitalopram			S				Not Reported
	Quetiapine			S				Not Reported
	Zuclopenthixol			S		Q2w		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2012	8824908	EXPEDITED (15-DAY)		HO	JP-009507513-1208JPN006967		49 YR	Female	JPN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2012	8895316	EXPEDITED (15-DAY)		HO	CA-ASTRAZENECA-2012SE84094		91 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Prescribing Error; Upper Gastrointestinal Haemorrhage	Nexium			S	Oral			Astrazeneca
	Cipralex			S	Oral			Not Reported
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2012	8895479	EXPEDITED (15-DAY)		HO	FR-FRI-1000040197			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Homicidal Ideation	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2012	8895770	EXPEDITED (15-DAY)		CA, HO, OT	US-JNJFOC-20121101479			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Ear Infection	Topamax			S	Transplacental			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Tramadol			S	Transplacental			Not Reported
	Valacyclovir			S	Transplacental			Not Reported
	Prenatal Vitamins			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2012	8901171	EXPEDITED (15-DAY)		HO	FR-FRI-1000040250			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic	Escitalopram			S				Forest

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2012	8772506	EXPEDITED (15-DAY)		LT	AU-FRI-1000038314			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Hyperemesis Gravidarum; Pregnancy	Lexapro			S				Forest
	Aripiprazole			S		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2012	8819171	NON-EXPEDITED			US-PFIZER INC-2012241891		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Memory Impairment	Xanax			S	Oral	0.5 Mg, As Needed		Pfizer
	Benicar			S	Oral	20 Mg, Daily		Not Reported
	Lexapro			S	Oral	5 Mg, Daily		Not Reported
	Alprazolam			S	Oral	0.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2012	8843524	EXPEDITED (15-DAY)		OT	FR-FRI-1000026589		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma Muscle; Lymphoedema	Escitalopram			S	Oral	10 Mg		Forest
	Lexomil			C				Not Reported
	Plavix			C	Oral	1 Df		Not Reported
	Pravastatin			C	Oral	1df		Not Reported
	Triatec (Ramipril)			C	Oral	1 Df		Not Reported
	Amlor			C	Oral	1 Df		Not Reported
	Inipomp			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2012	8906374	DIRECT	Y				32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Substitution Issue	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2012	8903932	NON-EXPEDITED			US-ASTRAZENECA-2012SE82545		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Injury; Off Label Use	Seroquel			S	Oral			Zeneca
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2012	8906182	DIRECT		DS, OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Glossitis; Mastication Disorder	Escitalopram			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2012	8905499	NON-EXPEDITED			US-BAYER-2012-114386			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Unevaluable Event	Beyaz			S		Unk		Bayer
	Lexapro			S				Not Reported
	Unspecified Ingredient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2012	8905692	EXPEDITED (15-DAY)		HO	US-FRI-1000040353		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vith Nerve Paralysis	Lexapro			S	Oral	10 Mg		Forest
	Luaf41156			S	Oral	0.5 Mg		Not Reported
	Claritin			C				Not Reported
	Flonase			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2012	8906470	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Intolerance; Headache; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nausea; Panic Attack; Vomiting	Escitalopram			S	Oral	20mg 1qd Oral	5 DAY	Not Reported
	Escitalopram			S	Oral	20mg 1qd Oral	5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2012	8346249	EXPEDITED (15-DAY)		OT	US-JNJFOC-20120106642			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Topamax			S	Oral			Not Reported
	Clindamycin			S	Vaginal			Not Reported
	Terbutaline			S	Oral			Not Reported
	Prometrium			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lithium Carbonate			S	Oral			Not Reported
	Betamethasone			S	Unknown			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Zithromax			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2012	8910889	EXPEDITED (15-DAY)		OT	CH-ABBOTT-12P-151-0995317-00			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Chest Discomfort; Hyperhidrosis; Muscular Weakness; Nausea; Palpitations; Panic Reaction; Sleep Disorder; Suicidal Ideation; Tremor	Cipralex			S	Oral	5 Mg		Not Reported
	Cipralex			S	Oral			Not Reported
	Trittico			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2012	8913964	DIRECT					38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Blood Pressure Increased; Disturbance In Attention; Disturbance In Attention; Dizziness; Fatigue; Feeling Abnormal; Headache; Hot Flush; Nausea; Product Substitution Issue; Tremor; Visual Impairment	Escitalopram			S	Oral		4 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2012	8913971	DIRECT		OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Mental Disorder; Product Quality Issue; Product Substitution Issue	Escitalopram			S	Oral	1 Table Daily Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2012	8914006	DIRECT		HO, LT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Chest Discomfort; Crying; Heart Rate Increased; Hyperhidrosis; Hypersensitivity; Insomnia; Nausea; Nightmare; Product Substitution Issue	Lexapro			S	Oral	20mg 1 In Pm Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2012	8483536	EXPEDITED (15-DAY)		CA, OT	SI-GLAXOSMITHKLINE-B0791546A		182 DAY	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip; Foetal Exposure During Pregnancy; Ultrasound Scan Abnormal	Lamictal			S	Transplacental	75mg Per Day		Glaxosmithkline
	Cipralex			S	Transplacental	15mg Per Day		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2012	8786336	EXPEDITED (15-DAY)		HO	CH-FRI-1000038538			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2012	8910951	EXPEDITED (15-DAY)		DE	ES-SANOFI-AVENTIS-2012SA082354		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Seguril			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Spiriva			C	Respiratory (inhalation)			Not Reported
	Coversyl /Fra/			C	Oral			Not Reported
	Atorvastatin			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2012	8912643	EXPEDITED (15-DAY)		OT	ES-TEVA-359895ISR			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Azilect			S				Teva
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2012	8912660	EXPEDITED (15-DAY)		OT	FR-FRI-1000040410		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria; International Normalised Ratio Increased	Escitalopram			S	Oral			Forest
	Previscan (Fluindione)			S	Oral	10 Mg		Not Reported
	Calciparine			S	Subcutaneous	15 Kiu Iu (1000s)		Not Reported
	Olmetec			C				Not Reported
	Climaston			C				Not Reported
	Levothyrox			C				Not Reported
	Veratran			C				Not Reported
	Volibris			C				Not Reported
	Revatio			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2012	8914535	EXPEDITED (15-DAY)		OT	FR-FRI-1000040391		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Amnesia; Physical Assault	Escitalopram			S	Oral	1 Df		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2012	8915344	EXPEDITED (15-DAY)		HO	ES-GILEAD-2012-0064764		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Hyponatraemia; Nausea; Vomiting	Ranolazine			S		500 Mg, Unk		Gilead
	Eplerenone			C		Unk		Not Reported
	Ivabradine			C		Unk		Not Reported
	Glyceryl Trinitrate			C				Not Reported
	Ramipril			C				Not Reported
	Acenocoumarol			C				Not Reported
	Pantoprazole			C				Not Reported
	Clorazepate			C				Not Reported
	Carvedilol			C				Not Reported
	Torasemide			C				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2012	8914555	EXPEDITED (15-DAY)		DE	DE-FRI-1000040389			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide; Depression; Hypoxia; Pulse Absent	Escitalopram			S	Oral	5 Mg		Forest
	Citalopram			S		10 Mg		Forest
	Lyrica			S	Oral	50 Mg		Not Reported
	Oxazepam			S	Oral	15 Mg		Not Reported
	Oxazepam			S	Oral	25 Mg		Not Reported

	Zolpidem	S	Oral	5 Mg	Not Reported
	Medazepam	S			Not Reported
	Zopiclone	S			Not Reported
	Otc Sedatives	C			Not Reported
	Carbamazepine	C	Oral	400 Mg	Not Reported
	Carbamazepine	C	Oral	600 Mg	Not Reported
	Carbamazepine	C	Oral	800 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2012	8915807	EXPEDITED (15-DAY)		OT	IE-FRI-1000040464			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Increased	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2012	8916891	EXPEDITED (15-DAY)		LT	FR-FRI-1000040522		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke	Escitalopram			S	Oral			Forest
	Previscan (Fluindione)			S	Oral			Not Reported
	Lorazepam			C				Not Reported
	Akineton			C				Not Reported
	Micardis			C				Not Reported
	Xeroquel			C				Not Reported
	Ascofer			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2012	8918540	NON-EXPEDITED			US-ASTRAZENECA-2012SE18892		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Interaction; Feeling Abnormal	Nexium			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2012	8674250	EXPEDITED (15-DAY)		OT	JP-FRI-1000037216		64 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Selenica-R			S	Oral	400 Mg		Not Reported
	Selenica			S	Oral	600 Mg		Not Reported
	Zyprexa			S	Oral	5 Mg		Not Reported
	Zyprexa			S	Oral	10 Mg		Not Reported
	Zyprexa			S	Oral	15 Mg		Not Reported
	Zyprexa			S	Oral	10 Mg		Not Reported

	Dogmatyl	C	Oral	450 Mg		Not Reported
	Wintermin	C		30 Mg		Not Reported
	Nelbon	C	Oral	10 Mg		Not Reported
	Celecox	C	Oral	200 Mg		Not Reported
	Mucosta	C	Oral	200 Mg		Not Reported
	Magmitt	C	Oral			Not Reported
	Forsenid	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2012	8920235	EXPEDITED (15-DAY)		CA	US-FRI-1000040534		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Ectopic Kidney	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2012	8924265	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Headache; Lacrimation Increased; Product Substitution Issue	Escitalopram 20mg			S	Oral	Escitalopram 20mg Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2012	8902906	NON-EXPEDITED			US-PFIZER INC-2012279631		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Depression; Drug Ineffective; Weight Increased	Vistaril			S	Oral	50 Mg, 3x/Day As Necessary		Pfizer
	Lexapro			S	Oral	10 Mg, Daily		Not Reported
	Lexapro			S	Oral	20 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported

Klonopin	S	Oral	0.5 Mg, 2x/Day		Not Reported
Topamax	S		25 Mg, Daily		Not Reported
Cymbalta	S	Oral	20 Mg, Daily		Not Reported
Cymbalta	S				Not Reported
Adipex	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2012	8923401	EXPEDITED (15-DAY)		OT	PHHY2012BR105759			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Growth Hormone Decreased; Hypertension; Malaise; Nausea	Ludiomil			S	Oral	1 Df, Daily		Not Reported
	Calcium D3			S	Oral	1 Df, Daily		Not Reported
	Alendronate			S	Oral	1 Df, Weekly		Novartis
	Estradiol			S	Oral	1 Df, Daily		Not Reported
	Rivotril			S	Oral	1 Df, Daily		Not Reported
	Exodus//Escitalopram Oxalate			S		10 Mg, Unk		Not Reported
	Evista			S	Oral	1 Df, Daily		Not Reported
	Melatonin			S	Oral	1 Df, Daily		Not Reported
	Selozok			C	Oral	1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2012	8937140	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2012-04879			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Quetiapine			S				Not Reported
	Cipralex			S				Not Reported
	Methadone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2012	8880010	EXPEDITED (15-DAY)		OT	JP-FRI-1000039847		26 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Overdose; Suicide Attempt	Escitalopram	S	Oral	10 Mg		Forest
	Escitalopram	S	Oral			Forest
	Nitrazepam	S	Oral			Not Reported
	Nitrazepam	S	Oral			Not Reported
	Cercine	S	Oral			Not Reported
	Cercine	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2012	8922416	EXPEDITED (15-DAY)		DE	CH-JNJFOC-20121109166		84 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Fall; Spinal Fracture	Tramal			S	Oral			Not Reported
	Anxiolit			S	Unknown			Not Reported
	Cipralex			S	Oral			Not Reported
	Lexotanil			S	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported
	Amlodipine			C	Oral			Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Calcimagon D3			C	Oral			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2012	8925360	EXPEDITED (15-DAY)		HO	FR-FRI-1000040580		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Loss Of Consciousness	Escitalopram Oral Solution			S	Oral	7 Mg		Forest
	Urbanyl			C	Oral			Not Reported
	Lamictal			C	Oral			Not Reported
	Keppra			C				Not Reported
	Gardenal			C	Oral			Not Reported

	Dafalgan	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2012	8925400	DIRECT		OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Dizziness Postural; Drug Withdrawal Syndrome; Dry Mouth; Hypoaesthesia; Insomnia; Paraesthesia; Seizure; Vertigo	Escitolopram Normal			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2012	8925721	EXPEDITED (15-DAY)		LT, OT	BE-ROXANE LABORATORIES, INC.-2012-RO-02431RO		26 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Necrotising Colitis; Overdose	Lorazepam			S		5 Mg		Roxane
	Quetiapine Fumarate			S		900 Mg		Roxane
	Clotiapine			S		40 Mg		Not Reported
	Trazodone			S		200 Mg		Not Reported
	Lamotrigine			S		200 Mg		Not Reported
	Escitalopram			S		10 Mg		Not Reported
	Zuclopenthixol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2012	8927976	DIRECT	Y				57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2012	8927990	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Irritability; Product Substitution Issue; Restlessness	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2012	8932470	DIRECT	Y				39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Dizziness	Escitalopram 20 Mg Teva			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2012	8932478	DIRECT		DS			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Abnormal Dreams; Depression; Impaired Work Ability; Mental Disorder; Paraesthesia; Product Formulation Issue; Product Quality Issue; Suicidal Ideation	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2012	8932548	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Nausea	Escitalopram			S	Oral	10 Mg 1 Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2012	8876490	EXPEDITED (15-DAY)		OT	US-FRI-1000039482		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Cancer; Fall	Escitalopram			S		20mg		Forest
	Escitalopram			S				Forest
	Aspirin			C		325mg		Not Reported
	Clonazepam			C		1mg		Not Reported
	Meclozine			C		25mg As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2012	8923922	EXPEDITED (15-DAY)		DS	FI-SANOFI-AVENTIS-2012SA086280			Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury	Amaryl			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2012	8927359	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-17142068			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Abilify Tabs 5 Mg			S		5 Mg		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2012	8928958	EXPEDITED (15-DAY)		OT	CN-FRI-1000040641		16 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersomnia; Hypokinesia; Off Label	Lexapro			S	Oral	5 Mg		Forest

Use; Suicidal Ideation; Weight Increased	Lexapro	S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2012	8928967	EXPEDITED (15-DAY)		DE	ES-FRI-1000040637		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	20 Mg		Forest
	Seguril			S	Oral	40 Mg		Not Reported
	Omeprazole			C	Oral			Not Reported
	Atorvastatin			C	Oral			Not Reported
	Coversyl			C	Oral			Not Reported
	Spiriva			C	Nasal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2012	8935381	DIRECT					43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Anxiety; Coordination Abnormal; Crying; Dizziness; Eye Contusion; Loss Of Proprioception; Product Quality Issue; Product Substitution Issue	Escitalopram			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2012	8930217	EXPEDITED (15-DAY)		OT	CH-FRI-1000040625			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis; Platelet Adhesiveness Decreased; Prescribed Overdose	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	25 Mg		Forest
	Tramal			C	Oral	37.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2012	8930399	EXPEDITED (15-DAY)		DE	CH-FRI-1000040642			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Fall; Spinal Fracture	Escitalopram			S	Oral	10 Mg		Forest
	Tramal			S	Oral	50 Mg		Not Reported
	Anxiolit			S		15 Mg (Before Sleeping)		Not Reported
	Lexotanil			S		1.5 Mg		Not Reported
	Paracetamol			C		4000 Mg		Not Reported
	Amlodipine			C		5 Mg		Not Reported
	Atacand Plus			C				Not Reported
	Calcimagon D3			C				Not Reported
	Ibuprofen			C		800 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2012	8931768	EXPEDITED (15-DAY)		HO	FR-FRI-1000040620		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Incorrect Dose Administered	Escitalopram			S	Oral			Forest
	Lasilix			S	Oral	125 Mg		Not Reported
	Plavix			C	Oral	75 Mg		Not Reported
	Levothyrox			C		1 Df		Not Reported
	Triatec (Ramipril)			C	Oral	0.625		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2012	8937814	DIRECT	Y	OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Quality Issue; Product Substitution Issue; Treatment Failure	Escitalopram			S	Oral	1 Tablet Daily Po		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2012	8937996	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Irritability; Mood Swings; Product Substitution Issue	Lexapro			S	Oral			Not Reported
	Celexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2012	8938351	DIRECT	Y	OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Quality Issue; Product Substitution Issue; Treatment Failure	Escitalopram			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2012	8938364	DIRECT	Y	OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Quality Issue; Product Substitution Issue; Therapy Non-Responder	Escitalopram			S	Oral	1 Tablet Daily Po		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2012	8636995	EXPEDITED (15-DAY)		HO	IE-FRI-1000036597		41 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Hyponatraemia; Rhabdomyolysis	Escitalopram			S	Oral	15 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2012	8933972	EXPEDITED (15-DAY)		HO	FR-FRI-1000040633		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Overdose	Escitalopram			S	Oral	40 Mg		Forest
	Clopixol			S	Oral	20 Mg		Not Reported
	Loxapac			S	Oral	100 Mg		Not Reported
	Risperdal			S	Oral	12 Mg		Not Reported
	Parkinane			S	Oral	10 Mg		Not Reported
	Abilify			S	Oral	15 Mg		Not Reported
	Trivastal			C	Oral			Not Reported
	Valium			C	Oral	15 Mg		Not Reported
	Levothyrox			C	Oral	50 Mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2012	8942228	DIRECT	Y	HO			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Sepsis; Serotonin Syndrome	Wellbutrin Sr			S				Not Reported
	Lexapro			S				Not Reported
	Famotadine			C				Not Reported
	Protonix			C				Not Reported
	Plavix			C				Not Reported
	Furosemide			C				Not Reported
	Isosorbide			C				Not Reported
	Pletal			C				Not Reported
	Vytorin			C				Not Reported
	Metoprolam			C				Not Reported
	Singulair			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2012	8942236	DIRECT	Y				52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthenia; Depression; Product Substitution Issue; Weight Increased	Escitalopram 20mg			S	Oral	20 Mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2012	8879529	EXPEDITED (15-DAY)		HO	IT-ABBOTT-12P-083-1001620-00		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sopor	Depakin Chrono			S	Oral			Not Reported
	Cipralex			S	Oral	40 Tablets Of 10mg		Not Reported
	Largactil			S	Oral	19tablets Of 100mg		Not Reported
	Lendormin			S	Oral	19tablets Of 0.25mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2012	8935816	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY-17152265		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Abilify			S	Oral			Not Reported
	Loxapac			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Parkinane			S	Oral			Not Reported
	Clopixol			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Trivastal			C				Not Reported
	Valium			C				Not Reported
	Levothyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2012	8937585	EXPEDITED (15-DAY)		HO	FR-FRI-1000040712		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Vomiting	Escitalopram			S	Oral	10 Mg		Forest
	Colchimax (France)			S	Oral			Not Reported
	Pyostacine			S	Oral	3 G		Not Reported
	Omeprazole			S	Oral			Not Reported
	Xatral			C	Oral	10 Mg		Not Reported
	Kardegic			C	Oral	75 Mg		Not Reported
	Lasilix			C	Oral	40 Mg		Not Reported
	Plavix			C	Oral			Not Reported
	Doliprane			C	Oral	4 G		Not Reported
	Crestor			C	Oral	10 Mg		Not Reported
	Ezetrol			C	Oral	10 Mg		Not Reported
	Procoralan			C	Oral			Not Reported
	Inspra			C	Oral			Not Reported
	Amiodarone			C	Oral			Not Reported
	Losartan Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2012	8194175	EXPEDITED (15-DAY)		DS, HO, OT	CA-ASTRAZENECA-2011SE62178			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea Neonatal; Extrapyramidal Disorder; Foetal Exposure During Pregnancy; Hypertonia Neonatal; Neonatal Tachypnoea; Poor Quality Sleep; Selective Eating Disorder; Trismus	Seroquel			S	Transplacental			Not Reported
	Seroquel			S	Transplacental			Not Reported
	Cipralex			S	Transplacental			Not Reported
	Nortriptyline			S	Transplacental			Not Reported
	Gabapentin			S	Transplacental			Not Reported
	Benztropine			S	Transplacental			Not Reported
	Zopiclone			S	Transplacental			Not Reported
	Rabeprazole			S	Transplacental			Not Reported

	Methadone	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2012	8467544	EXPEDITED (15-DAY)		DS	FR-FRI-1000008839			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dyskinesia; Dysphagia; Dystonia; Speech Disorder	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest
	Citalopram			S	Oral	20 Mg		Forest
	Citalopram			S	Oral	30 Mg		Forest
	Tamoxifen			C	Oral	1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2012	8880281	EXPEDITED (15-DAY)		HO	AT-BRISTOL-MYERS SQUIBB COMPANY-16776973		71 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Parkinson'S Disease	Abilify			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Praxiten			S	Oral			Not Reported
	Simvastatin			C				Not Reported
	Acemin			C				Not Reported
	Laevolac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2012	8939078	NON-EXPEDITED			US-PFIZER INC-PRP-00036		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Dizziness; Fatigue; Fatigue; Feeling Abnormal; Feeling	Inderal			S	Oral	80 Mg, 1x/Day		Pfizer
	Inderal			S				Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day,Week 1		Not Reported

Abnormal; Heart Rate	Lexapro		S	5 Mg, Unk,Week 2	Not Reported
Abnormal; Malaise; Malaise	Lexapro		S	2.5 Mg, Unk,Week 3	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2012	8941294	NON-EXPEDITED			US-BAYER-2012-117104		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Sluggishness	Betaseron			S		Unk		Bayer
	Ampyra			S	Oral	10 Mg, Bid		Not Reported
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Metoprolol			C		50 Mg, Unk		Not Reported
	Aspirin			C		Unk		Not Reported
	Fosamax			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2012	8933714	EXPEDITED (15-DAY)		OT	GB-FRI-1000040628		33 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S		10 Mg		Forest
	Fluoxetine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2012	8942473	EXPEDITED (15-DAY)		OT	US-JNJFOC-20121111552		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Imprisonment; Obsessive-Compulsive Disorder	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2012	8945257	EXPEDITED (15-DAY)		OT	DE-FRI-1000040788			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Interaction; Hyperhidrosis; Malaise; Pyrexia; Respiratory Rate Increased	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S				Forest
	Pantoprazol			S	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2012	8945260	EXPEDITED (15-DAY)		DS	FI-FRI-1000040789			Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury	Escitalopram			S	Oral			Forest
	Amaryl			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2012	8947449	EXPEDITED (15-DAY)		HO	NZ-FRI-1000040816		94 YR	Female	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram			S		5 Mg		Forest
	Escitalopram			S		10 Mg		Not Reported
	Omeprazole			S		20 Mg		Not Reported
	Tiotropium			C				Not Reported
	Metoprolol			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Hydroxocobalamin			C				Not Reported
	Salbutamol			C				Not Reported
	Aspirin			C				Not Reported
	Zoledronic Acid			C				Not Reported
	Cefaclor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2012	8952534	EXPEDITED (15-DAY)		DS, LT, OT	GB-FRI-1000040791		29 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depersonalisation/Derealisation Disorder; Dissociation; Emotional Distress; Emotional Poverty; Nausea	Escitalopram			S	Oral	5 Mg		Forest
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2012	8952538	EXPEDITED (15-DAY)		DE	DK-FRI-1000040796		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S		20 Mg		Forest
	Sertindole			S	Oral	4 Mg		Not Reported
	Sertindole			S	Oral	8 Mg		Not Reported
	Sertindole			S	Oral	12 Mg		Not Reported
	Sertindole			S	Oral	16 Mg		Not Reported
	Sertindole			S	Oral	20 Mg		Not Reported
	Sertindole			S	Oral	24 Mg		Not Reported
	Zyprexa			S				Not Reported
	Corodil (Enalapril Maleate)			C	Oral	15 Mg		Not Reported
	Gestonette			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2012	8958516	DIRECT		OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Lexapro 20mg - Generic			S		20 Mg 1 Qam		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2012	8875980	EXPEDITED (15-DAY)		DE, HO	IT-FRI-1000014857		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Pneumonia; Torsade De Pointes	Escitalopram			S	Oral	10 Mg		Forest
	Rivastigmine			S	Oral	3 Mg		Not Reported
	Lidocaine			C	Topical			Not Reported
	Cortisone			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2012	8934443	EXPEDITED (15-DAY)		HO	FR-FRI-1000040676		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased; Off Label Use	Escitalopram			S	Oral			Forest
	Previscan (Fluindione)			S	Oral	15 To 20 Mg Daily In The Evening		Not Reported
	Ixprim			S	Oral			Not Reported
	Lipanthyl			C	Oral	1 Df		Not Reported
	Acebutolol			C	Oral	0.5 Df		Not Reported
	Vastarel			C	Oral	1 Df		Not Reported
	Biperidys			C				Not Reported
	Niflugel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2012	8948952	EXPEDITED (15-DAY)		DS	FR-FRI-1000040841		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Chest Pain; Hypokalaemia; Nausea; Paraesthesia;	Escitalopram			S	Oral	10 Mg		Forest

Presyncope; Syncope;
Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2012	8949855	EXPEDITED (15-DAY)		OT	FR-FRI-1000040848		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vaginal Haemorrhage	Escitalopram			S				Forest
	Lysanxia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2012	8953308	EXPEDITED (15-DAY)		OT	US-JNJFOC-20121112054			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dizziness; Dyspepsia; Extrapyramidal Disorder; Hyperhidrosis; Increased Appetite; Insomnia; Nausea; Somnolence; Vision Blurred; Weight Decreased	Risperidone			S	Unknown			Not Reported
	Concerta			S				Not Reported
	Adderall Xr			S	Unknown			Not Reported
	Daytrana			S	Unknown			Not Reported
	Vyvanse			S	Unknown			Not Reported
	Intuniv			S	Unknown			Not Reported
	Strattera			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Anafranil			S	Unknown			Not Reported
	Anafranil			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported

	Luvox	S	Unknown	Not Reported
	Luvox	S	Unknown	Not Reported
	Zoloft	S	Unknown	Not Reported
	Zoloft	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2012	8950687	EXPEDITED (15-DAY)		OT	TR-RANBAXY-2012RR-62394		5 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition	Escitalopram			S	Unknown	2-3 Mg/D;12 Wks		Not Reported
	Escitalopram			S				Not Reported
	Risperidone			S	Unknown	0.25-0.5 Mg/Day After Escitalopram Was Initiated		Ranbaxy
	Risperidone			S				Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2012	8951091	EXPEDITED (15-DAY)		OT	TR-RANBAXY-2012RR-62404		4 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition	Escitalopram			S	Unknown	2 Mg/D ; 2 Wks		Not Reported
	Risperidone			S	Unknown	0.25-0.5 Mg Before And During Escitalopram Treatment		Ranbaxy
	Risperidone			S				Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2012	8777494	EXPEDITED (15-DAY)		OT	FR-FRI-1000038454		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Haemorrhage; Vitreous Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Mycoster			C	Oral	3 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2012	8955917	EXPEDITED (15-DAY)		HO	US-FRI-1000040917		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Sciatica	Lexapro			S	Oral	10 Mg		Forest
	Luaf41156			S	Oral	3 Mg		Not Reported
	Lisinopril			S	Oral	20 Mg		Not Reported
	Baby Aspirin			C				Not Reported
	Lisinopril/Hctz			C				Not Reported
	Flexeril			C				Not Reported
	Oxycontin			C				Not Reported
	Oxycodone			C				Not Reported
	Neurontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2012	8956803	EXPEDITED (15-DAY)		DE	FR-FRI-1000040937		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Plavix			S	Oral	75 Mg		Not Reported
	Depakine Chrono			C	Oral	2250 Mg		Not Reported
	Lyrica			C	Oral	200 Mg		Not Reported
	Urbanyl			C	Oral	100 Mg		Not Reported
	Vimpat			C	Oral	100 Mg		Not Reported
	Kredex			C	Oral	12.5 Mg		Not Reported
	Tahor			C	Oral	80 Mg		Not Reported
	Lercan			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2012	8915777	EXPEDITED (15-DAY)		OT	JP-FRI-1000040465		73 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria; Urinary Retention	Lexapro			S	Oral	10 Mg		Forest
	Lendormin			C	Oral	0.25 Mg		Not Reported
	Magmitt			C	Oral	330 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2012	8960906	DIRECT	Y	OT			24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Unevaluable Event	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2012	8960924	DIRECT	Y				22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Ineffective; Impaired Work Ability; Vision Blurred	Citalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2012	7376665	EXPEDITED (15-DAY)		CA, DE, OT	US-ABBOTT-10P-163-0640912-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Stenosis; Atrial Septal Defect; Cerebrospinal Fluid Leakage; Coarctation Of The Aorta; Congenital Heart Valve Disorder; Cryptorchism; Cytogenetic Abnormality; Foetal Exposure During Pregnancy; Hemivertebra;	Humira 40 Mg/ 0.8 Ml Pre-Filled Syringe			S	Transplacental			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Trazodone			S	Transplacental			Not Reported
	Enbrel			S	Transplacental			Not Reported
	Mucinex			S	Transplacental			Not Reported
	Tums			S	Transplacental			Not Reported
	Tylenol			S	Transplacental			Not Reported

Hydrocephalus; Kidney Enlargement; Macrocephaly; Neurodegenerative Disorder; Patent Ductus Arteriosus; Tachypnoea

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2012	7523041	EXPEDITED (15-DAY)		HO	US-ABBOTT-10P-163-0640911-00		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Dyspepsia; Exposure During Pregnancy; Fall; Fungal Infection; Premature Delivery; Respiratory Tract Infection; Urinary Tract Infection	Humira 40 Mg/ 0.8 Ml Pre-Filled Syringe			S	Other			Not Reported
	Humira 40 Mg/ 0.8 Ml Pre-Filled Syringe			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Trazodone Hcl			C	Oral	4 In One Day As Needed		Not Reported
	Enbrel			C	Other			Not Reported
	Mucinex			C	Oral	1-2 Pills Qd		Not Reported
	Prenatal Vitamins			C		1 Pill Qd		Not Reported
	Caffeine			C	Oral	2.5 Servings Mountain Dew Daily		Not Reported
	Caffeine			C	Oral	5.67 Servings Mountain Dew Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2012	8959298	EXPEDITED (15-DAY)		HO	CH-ROCHE-1165319		70 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Fall; Hypokalaemia; Hyponatraemia; Muscular Weakness	Rivotril			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported
	Exforge Hct			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

Halcion	S	Oral		Not Reported
Temesta Expidet	S	Oral		Not Reported
Sirdalud	S	Oral		Not Reported
Seroquel	S	Oral		Not Reported
Movicol	C			Not Reported
Aspirin Cardio	C	Oral		Not Reported
Magnesium Carbonate	C	Oral		Not Reported
Omeprazole	C	Oral		Not Reported
Ceftriaxone	C	Intravenous (not otherwise specified)		Not Reported
Psychotropic Drug Nos	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2012	8965568	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Gait Disturbance; Seizure; Speech Disorder	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2012	8965575	DIRECT		DS, HO, LT, OT			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Mania; Overdose; Unevaluable Event	Lexapro			S	Oral	20mg Once Daily Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2012	8965589	DIRECT		OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blepharospasm;	Escitalopram			S	Oral	From The Time It Came		Not Reported

Dizziness; Jaw Disorder; Muscle Spasms; Product Substitution Issue	Out Until Mid November

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2012	8965609	DIRECT		DS, OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Dizziness; Headache; Irritability; Palpitations; Product Substitution Issue	Escitalopram			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2012	8963070	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2012313677		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Dermatitis; Headache; Hypertension; Hypoaesthesia; Rash	Pristiq			S		50 Mg, Daily		Pfizer
	Pristiq			S		100 Mg, Daily		Pfizer
	Prozac			S		Unk		Not Reported
	Prozac			S				Not Reported
	Paxil			S		Unk		Not Reported
	Paxil			S				Not Reported
	Celexa			S		Unk		Not Reported
	Celexa			S				Not Reported
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Wellbatrin			C		300 Mg, Daily		Not Reported
	Adderall			C		30 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2012	8662915	EXPEDITED (15-DAY)		HO, LT	CA-FRI-1000037012			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Sodium Decreased; Contusion; Delusional Disorder, Unspecified Type; Mental Disorder; Paranoia; Pelvic Fracture; Skin Injury	Escitalopram		S	Oral	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2012	8664746	EXPEDITED (15-DAY)		OT	CA-FRI-1000037010		21 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Erectile Dysfunction; Libido Decreased; Orgasmic Sensation Decreased; Premature Ejaculation; Suicidal Ideation	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S				Forest
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2012	8926068	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20121110202		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Intentional Self-Injury; Sluggishness	Haldol			S	Oral			Not Reported
	En			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2012	8962471	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20121114425		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased	Ixprim			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral	0.25 Of A Tablet		Not Reported
	Previscan (Fluindione)			S	Oral	15-20mg		Not Reported

	Previscan (Fluindione)	S	Oral	0.25 Of A Tablet	Not Reported
	Previscan (Fluindione)	S	Oral	Half Tab	Not Reported
	Seroplex	S	Unknown		Not Reported
	Biperidys	C	Oral		Not Reported
	Vastarel	C	Oral		Not Reported
	Niflugel	C	Topical		Not Reported
	Lipanthyl	C	Oral		Not Reported
	Acebutolol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2012	8964168	NON-EXPEDITED			US-PFIZER INC-2012300299		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Heart Rate Irregular; Somnolence	Oxycodone Hydrochloride			S	Oral	15 Mg, (Oral Every 4 Hrs As Needed)		Pfizer
	Oxycodone Hydrochloride			S	Oral	80 Mg, 2x/Day		Pfizer
	Ambien			S	Oral	12.5 Mg, (At Bedtime)		Not Reported
	Lexapro			S	Oral	20 Mg, Daily		Not Reported
	Oxycontin			S	Oral	60 Mg, 2x/Day		Not Reported
	Soma			S	Oral	350 Mg, 2x/Day		Not Reported
	Valium			S	Oral	10 Mg, Daily		Not Reported
	Xarelto			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2012	8964185	EXPEDITED (15-DAY)		OT	CA-FRI-1000036970		23 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Malaise; Sensory Loss	Escitalopram			S		10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2012	8965133	EXPEDITED (15-DAY)		CA	US-FRI-1000040942		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2012	8965776	EXPEDITED (15-DAY)		OT	IT-FRI-1000041047		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Intentional Self-Injury; Overdose	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	En			S	Oral			Not Reported
	En			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2012	8786369	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2012224870		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure	Xanax			S	Oral	Unk		Pfizer
	Seroplex			S	Oral	Unk		Not Reported
	Yaz			S	Oral	1 Df, 1x/Day		Not Reported
	Yaz			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2012	8966757	EXPEDITED (15-DAY)		HO	AU-SANOFI-AVENTIS-2012SA090914		81 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Hyponatraemia; Malaise; Urinary Retention; Urine Output Decreased	Lasix			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Fish Oil			C				Not Reported
	Coumadin			C				Not Reported
	Chondroitin Sulfate (Bovine)\Glucosamine Sulfate			C				Not Reported
	Lanoxin			C				Not Reported
	Losec			C				Not Reported
	Panadol			C				Not Reported
	Folic Acid/Vitamin B12 Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8918673	EXPEDITED (15-DAY)		HO	JP-FRI-1000040463		85 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femoral Neck Fracture	Escitalopram			S	Oral	10 Mg		Forest
	Zopicool			C	Oral	7.5 Mg		Not Reported
	Zestromin			C	Oral	0.25 Mg		Not Reported
	Paruleon			C	Oral	0.5 Mg		Not Reported
	Seniran			C	Oral	2 Mg		Not Reported
	Reflex			C	Oral	15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8946939	EXPEDITED (15-DAY)		OT	FR-009507513-1211FRA011526			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperprolactinaemia	Norset			S	Oral	Unk		Merck
	Seroplex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8968142	EXPEDITED (15-DAY)		HO, OT	CH-JNJFOC-20121206158		46 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Darunavir			S	Oral			Not Reported
	Ritonavir			S	Unknown			Not Reported
	Emtricitabine W/Tenofovir			S	Unknown	Emtricitabine 200 Mg; Tenofovir 245 Mg		Not Reported
	Esomeprazole			S	Unknown			Not Reported
	Escitalopram			S	Unknown	Had Been Taking For 5 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8968383	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16766909		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Mood Altered; Nightmare	Abilify			S		Ablify 20mg Cuts Them In Half For 10mg Daily Dose. Started With 5mg		Not Reported
	Lexapro			S				Not Reported
	Keppra			S				Not Reported
	Synthroid			C				Not Reported
	Clonazepam			C				Not Reported
	Paxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8968390	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16770547		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dystonia	Abilify			S				Not Reported
	Concerta			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8968927	EXPEDITED (15-DAY)		DS, LT, OT	GB-FRI-1000041096		26 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Iron Deficiency Anaemia	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral			Forest
	Flupentixol			C	Oral			Not Reported
	Valproate			C	Oral	750 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8968935	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16686867		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased	Abilify			S				Not Reported
	Lexapro			S				Not Reported
	Lamictal			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8968991	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16341877		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Malaise; Nausea	Abilify			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8969178	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16299679		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ammonia Increased; Swelling; Tremor	Abilify			S		5mg:Feb2011,Dose		Not Reported

							Increased:10mg,Mar2011, Decreased Later:2mg			
	Lexapro			S						Not Reported
	Keppra			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8969374	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16625220			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8969384	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16626129		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia	Abilify Tabs 5 Mg			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8969590	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16614141		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria	Abilify			S		Initially Given 5mg Then Increased To 10mg		Not Reported
	Lexapro			S				Not Reported
	Klonopin			S		1mg In Pm		Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8969838	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16537342		6 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Weight Increased	Abilify	S	Not Reported
	Lexapro	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8969864	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16544926		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8970001	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16525016		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify Tabs			S				Not Reported
	Lexapro			S				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8970083	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-16217523		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonic Convulsion	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8970231	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16487878		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8970392	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-17057035			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus	Abilify			S		1df: Upto 15mg		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8970506	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16502742		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Abilify			S				Not Reported
	Wellbutrin			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8970779	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2012305606		70 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Balance Disorder; Electrocardiogram Qt Prolonged; Fall; Hypokalaemia; Hyponatraemia; Muscular Weakness; Spinal Fracture	Xanax			S	Oral	1 Mg, 3x/Day		Pfizer
	Temesta Expidet			S	Oral	2.5 Mg, 4x/Day Maximal		Pfizer
	Halcion			S	Oral	0.25 Mg, 1x/Day		Pfizer
	Exforge Hct			S	Oral	5mg / 25mg / 160mg, 1x/Day		Not Reported
	Cipralex			S	Oral	2x 10mg 1x/Day		Not Reported
	Sirdalud			S	Oral	4 Mg, 1x/Day		Not Reported
	Rivotril			S	Oral	2x 2mg, 1x/Day		Not Reported
	Seroquel			S	Oral	1/2 300mg, 1x/Day		Not Reported
	Aspirin Cardio			C	Oral	100 Mg, Weekly (Monday)		Not Reported
	Mag 2 Forte			C	Oral	Unk , 2x/Day		Not Reported

Omeprazole	C	Oral	40 Mg, 2x/Day		Not Reported
Movicol	C		Unk, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8971303	EXPEDITED (15-DAY)		HO	AU-FRI-1000041094		46 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Chills; Diplopia; Dysarthria; Headache; Pyrexia; Syncope	Escitalopram			S		20 Mg		Forest
	Diazepam			S		5 Mg		Not Reported
	Mirtazapine			S	Oral	60 Mg		Not Reported
	Prazosin Hydrochloride			S		1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8972962	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16458515		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vertigo	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8972970	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16461436		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S				Not Reported
	Lexapro			S				Not Reported
	Klonopin			S				Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8973350	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16940629		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Dysarthria; Dyskinesia; Regurgitation; Swollen Tongue; Tremor	Abilify	S	Oral	From 06jun2012:5mg Increased To 10mg/Daily	Not Reported
	Abilify	S	Oral	From 06jun2012:5mg Increased To 10mg/Daily	Not Reported
	Abilify	S	Oral	From 06jun2012:5mg Increased To 10mg/Daily	Not Reported
	Lexapro	S		Reduced To 5 Mg	Not Reported
	Lexapro	S		Reduced To 5 Mg	Not Reported
	Lexapro	S		Reduced To 5 Mg	Not Reported
	Cogentin	S		On 07jun2012 Dose Decreased To 1 Mg/2/Day	Sandoz
	Depakote Er	C		250mg Qam, 750 Mg/2/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8973351	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16940884		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8973366	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16945958		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Viibryd			S				Not Reported

	Viibryd				S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8973439	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-16787723		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Triglycerides Increased; Constipation; Diarrhoea; Ejaculation Disorder; Libido Decreased; Muscle Spasms; Sleep Disorder; Suicidal Ideation; Thirst; Urinary Retention	Abilify			S	Oral	Increased To 15mg/Day		Not Reported
	Chantix			S		Restarted On 2011. Jul2012: 1mg		Not Reported
	Geodon			S				Not Reported
	Lexapro			S				Not Reported
	Xanax			C				Not Reported
	Lisinopril			C		1 Df = 20/25 Mg/Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8973471	NON-EXPEDITED		DE, OT	US-BRISTOL-MYERS SQUIBB COMPANY-16819112		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Completed Suicide	Abilify			S		Adjunctive Therapy,Dose Incd To 5mg Until 18apr12 Until 30apr2012		Not Reported
	Lexapro			S		Incr To 10mg-5nov07 20mg-28oct10 Until 30apr2012		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8973860	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16895484		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Dysarthria	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8973972	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16394827		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8978561	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Product Substitution Issue	Escalitalopram 10 Mg Teva			S	Oral	10 Daily Po	5 MTH	Teva
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2012	8983975	DIRECT		DS, HO, OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Prescribing Error; Seizure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2012	8975034	EXPEDITED (15-DAY)		OT	US-FRI-1000041039			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Depression; Mental Impairment; Paraesthesia; Suicidal Ideation; Therapeutic Product Effect Decreased	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2012	8975814	EXPEDITED (15-DAY)		OT	FR-FRI-1000041152			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2012	8976838	EXPEDITED (15-DAY)		HO	JP-FRI-1000041102		65 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Prostatic Hyperplasia; Condition Aggravated	Escitalopram			S	Oral	10mg		Forest
	Meilax			C	Oral			Not Reported
	Halcion			C	Oral			Not Reported
	Hirnamin			C	Oral			Not Reported
	Mucosta			C	Oral			Not Reported
	Crestor			C	Oral			Not Reported
	Maintate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2012	8977705	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20121208508		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema; Rash	Prezista			S	Oral			Not Reported
	Enfuvirtide			S	Unknown			Not Reported
	Tmc-125			S	Unknown			Not Reported
	Isentress			S	Oral			Not Reported
	Kivexa			S	Unknown			Not Reported
	Seroplex			S	Unknown			Not Reported
	Norvir			C	Oral			Not Reported

	Xanax	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2012	8977734	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA-2012SE93758		< 1 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypernatraemia; Metabolic Acidosis; Premature Baby; Respiratory Failure	Seroquel			S	Transplacental			Zeneca
	Cipralex			S	Transplacental			Not Reported
	Labetalol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2012	8977953	EXPEDITED (15-DAY)		HO	FR-FRI-1000026955		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerulonephritis Membranous	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			S	Oral			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Ezetrol			C				Not Reported
	Ogast			C	Oral			Not Reported
	Atenolol			C	Oral			Not Reported
	Tanakan			C				Not Reported
	Etioven			C				Not Reported
	Biperidys			C				Not Reported
	Legalon			C				Not Reported
	Methotrexate			C				Not Reported
	Speciafoldine			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2012	8986325	DIRECT	Y	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Nausea; Vomiting	Escitalopram Oxalate			S	Oral	10 Mg Qd Po		Mylan
	Seroquel			C				Not Reported
	Vistaril			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2012	8986775	DIRECT		OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Mental Status Changes; Mood Altered; Product Substitution Issue	Escitalopram			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8662959	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000037013		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram			S				Forest
	Furosemide			S				Not Reported
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8785989	EXPEDITED (15-DAY)		DE	GB-FRI-1000038584		31 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral			Forest
	Quetiapine			S	Oral	450 Mg Daily In Divided Doses		Not Reported
	Quetiapine			S	Oral			Not Reported
	Mirtazapine			S	Oral	45 Mg		Not Reported
	Mirtazapine			S	Oral			Not Reported
	Diazepam			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8796096	EXPEDITED (15-DAY)		HO	FR-FRI-1000038609		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure	Escitalopram			S	Oral			Forest
	Xanax			S	Oral			Not Reported
	Yaz			S	Oral	0.02 Mg/3 Mg		Not Reported
	Yaz			S	Oral	0.02 Mg/3 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8974685	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2012SE92958		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Hypotension	Symbicort			S	Respiratory (inhalation)	320/9 Ug Per Dose, One Inhalaltion Twice A Day		Astrazeneca
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Ixprim			S	Oral			Not Reported
	Coaprovel			S	Oral			Not Reported
	Coaprovel			S	Oral			Not Reported

	Xanax	C	Not Reported
	Imovane	C	Not Reported
	Abiraterone	C	Not Reported
	Doliprane	C	Not Reported
	Travatan	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8976036	EXPEDITED (15-DAY)		OT	FR-FRI-1000041150		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Fibrillation; Bradycardia; Tachycardia	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Spironolactone			C		50 Mg		Not Reported
	Furosemide			C		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8976057	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA-2012SE93761		< 1 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypernatraemia; Metabolic Acidosis; Premature Baby; Respiratory Failure	Seroquel			S	Transplacental			Zeneca
	Cipralex			S	Transplacental			Not Reported
	Labetalol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8976214	EXPEDITED (15-DAY)		HO, OT	PHHY2012BR116124		70 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Inadequately Controlled; Blood Viscosity Increased; Burning Sensation; Coronary Artery Occlusion; Depression; Drug Ineffective; Feeling	Trileptal			S	Oral	300 Mg, Unk		Not Reported
	Tofranil			S	Oral	1 Df, Tid		Not Reported
	Tofranil			S	Oral	1 Df, Tid		Not Reported
	Ludiomil			S	Oral	25 Mg, Unk		Not Reported
	Valdoxan			S	Oral	1 Df, Bid		Not Reported

Abnormal; Growth Retardation; Headache; Hyperhidrosis; Hypersensitivity; Hypertension; Tachycardia; Urticaria; Weight Increased	Glimepiride	S	Oral	1 Df, Bid	Not Reported
	Doxycycline	S	Oral	1 Df At Night	Novartis
	Sertraline Hydrochloride	S	Oral	50 Mg, Unk	Not Reported
	Amlodipine Besylate	S	Oral		Not Reported
	Topiramate	S	Oral	50 Mg, Unk	Not Reported
	Rivotril	S	Oral	4 Df At Night	Not Reported
	Respicil	S	Oral	400 Mg, Unk	Not Reported
	Socian	S	Oral	50 Mg, Unk	Not Reported
	Topamax	S	Oral	1 Df, Bid	Not Reported
	Duspatalin	S	Oral		Not Reported
	Prazol (Lansoprazole)	S	Oral	1 Df, Daily	Not Reported
	Tolvon	S	Oral	0.5 Df (Half Tablet At Night)	Not Reported
	Exodus//Escitalopram Oxalate	S	Oral		Not Reported
	Levoid	S	Oral		Not Reported
	Arflex	S	Oral		Not Reported
	Cebrin	S	Oral	20 Mg, Unk	Not Reported
	Remeron	S	Oral		Not Reported
	Tolrest	S	Oral		Not Reported
	Zetron (Bupropion Hydrochloride)	S	Oral	105 Mg, Unk	Not Reported
	Donaren	S	Oral	Unk	Not Reported
	Neurotrypt	S	Oral	Unk	Not Reported
	Buscopan	S		Unk	Not Reported
	Citta	S	Oral	1 Df, Daily	Not Reported
	Norvasc	S	Oral	Unk	Not Reported
	Cymbalta	S	Oral	30 Mg, Unk	Not Reported
	Selozok	S		Unk	Not Reported
	Tryptanol	S	Oral	1 Df, Bid	Not Reported
	Tamiram	S	Oral	1 Df, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8976399	EXPEDITED (15-DAY)		OT	DE-FRI-1000041156			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Muscle Spasms; Nausea; Tremor; Vomiting	Escitalopram			S				Forest
	Candesartan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8977083	EXPEDITED (15-DAY)		HO, LT	AU-FRI-1000041166			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Obsessive-Compulsive Disorder	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8977417	NON-EXPEDITED			US-PFIZER INC-2012321662		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Hytrin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8977926	EXPEDITED (15-DAY)		HO	FR-FRI-1000041148		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Hypotension	Escitalopram			S	Oral	15 Mg		Forest

	Coaprovel	S	Oral	150 Mg/12.5 Mg	Not Reported
	Symbicort	S	Other	800 Mg	Not Reported
	Ixprim	S	Oral		Not Reported
	Xanax	C			Not Reported
	Imovane	C			Not Reported
	Abiraterone Acetate	C			Not Reported
	Doliprane	C			Not Reported
	Travatan	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2012	8988340	DIRECT		LT, OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Homicidal Ideation; Suicidal Ideation	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2012	8979049	EXPEDITED (15-DAY)		HO, OT	CH-ASTRAZENECA-2011SE74604		35 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Exposure During Pregnancy	Seroquel			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Labetalol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2012	8979785	EXPEDITED (15-DAY)		OT	DE-FRI-1000041184			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Jaundice	Escitalopram Oral Solution			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2012	8980179	EXPEDITED (15-DAY)		DE	PHHY2012GB117786		31 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Overdose	Quetiapine			S	Oral	450 Mg, Qd In Divided Doses		Novartis
	Quetiapine			S	Oral	Overdose: Amount Unknown		Novartis
	Mirtazapine			S	Oral	45 Mg, Qd		Not Reported
	Mirtazapine			S	Oral	Overdose: Amount Unknown		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Cipralex			S	Oral	Overdose: Amount Unknown		Not Reported
	Diazepam			C	Oral	5 Mg,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2012	8980316	EXPEDITED (15-DAY)		HO	PHHY2012CH114419		70 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Balance Disorder; C-Reactive Protein Increased; Electrocardiogram Qt Prolonged; Fall; Hypokalaemia; Hyponatraemia; Inflammation; Leukocytosis; Muscular Weakness; Nitrite Urine Present; Spinal Compression Fracture; Spinal Cord Compression	Sirdalud			S	Oral	4 Mg, Qd		Not Reported
	Sirdalud			S		Unk Ukn, Unk		Not Reported
	Exforge Hct			S	Oral	1 Df (160 Mg Val/ 5 Mg Amlo/ 25 Mg Hct)		Novartis
	Rivotril			S	Oral	2 Mg Bid		Not Reported
	Cipralex			S	Oral	10 Mg Bid		Not Reported
	Cipralex			S		Unk Ukn, Unk		Not Reported
	Halcion			S	Oral	0.25 Mg Qd		Not Reported
	Halcion			S		Unk Ukn, Unk		Not Reported
	Xanax			S	Oral	1 Mg Tid		Not Reported
	Xanax			S		Unk Ukn, Unk		Not Reported
	Temesta (Lorazepam)			S	Oral	2.5 Mg Qid		Not Reported
	Temesta (Lorazepam)			S		Unk Ukn, Unk		Not Reported

	Seroquel	S	Oral	150 Mg Qd		Not Reported
	Seroquel	S		Unk Ukn, Unk		Not Reported
	Aspirin Cardio	C	Oral	100 Mg, Qw		Not Reported
	Mag 2	C	Oral			Not Reported
	Omeprazole	C	Oral	40 Mg Bid		Not Reported
	Movicol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2012	8980710	EXPEDITED (15-DAY)		OT	TR-FRI-1000041180		30 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Genital Haemorrhage; Somnolence	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2012	8997119	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2012-05443		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aphasia; Atrophy; Disease Progression	Citalopram (Citalopram)			S	Oral			Not Reported
	Paroxetine (Paroxetine)			S		5 And 10 Mg (1 D)		Not Reported
	Sertraline (Sertraline) (Sertraline)			S				Not Reported
	Olanzapine (Olanzapine)			S	Oral			Not Reported
	Quetiapine (Quetiapine) (Quetiapine)			S				Not Reported
	Escitalopram			S				Not Reported
	Haloperidol			S				Not Reported
	Clomipramine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2012	8983673	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY-17217183		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dehydration; Hypotension	Coaprovel Tabs 150mg/12.5mg		S	Oral	Bristol Myers Squibb
	Seroplex		S		Not Reported
	Symbicort		S	Respiratory (inhalation)	Not Reported
	Ixprim		S	Oral	Not Reported
	Xanax		C		Not Reported
	Imovane		C		Not Reported
	Doliprane		C		Not Reported
	Travatan		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2012	8984769	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20121210374		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Hypotension; Malaise	Ixprim			S	Oral			Not Reported
	Symbicort Turbohaler			S	Respiratory (inhalation)			Not Reported
	Coaprovel			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Abiraterone Acetate			C	Oral			Not Reported
	Doliprane			C	Oral			Not Reported
	Travatan			C	Ophthalmic			Not Reported
	Xanax			C	Oral			Not Reported
	Imovane			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2012	8905195	EXPEDITED (15-DAY)		DE, HO	JP-FRI-1000040282		93 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2012	8985342	EXPEDITED (15-DAY)		DE	GB-009507513-1212GBR009641		31 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Mirtazapine			S	Oral	45 Mg, Qd		Merck
	Mirtazapine			S	Oral	Unk		Merck
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Cipralex			S		Unk		Not Reported
	Quetiapine Fumarate			S	Oral	450 Mg, Qd		Not Reported
	Quetiapine Fumarate			S	Oral	Unk		Not Reported
	Diazepam			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2012	8985502	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2012324789		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Retroperitoneal Haematoma	Cordarone			S	Oral	200 Mg Daily		Pfizer
	Previscan (Fluindione)			S	Oral	20 Mg Daily		Not Reported
	Previscan			S				Not Reported
	Seroplex			S	Oral	10 Mg Daily		Not Reported
	Hyzaar			C		Unk		Not Reported
	Imovane			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2012	8985817	EXPEDITED (15-DAY)		DE	GB-ASTRAZENECA-2012SE95263		31 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Overdose	Quetiapine			S	Oral	450 Mg Daily, In Divided Doses		Zeneca
	Quetiapine			S	Oral			Zeneca

	Quetiapine	S	Oral	Zeneca
	Mirtazapine	S	Oral	Not Reported
	Mirtazapine	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Diazepam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2012	8986696	EXPEDITED (15-DAY)		HO	FR-ROCHE-1170221		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Hypertensive Angiopathy; Intracranial Haematoma	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Apranax			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Oroken			C	Oral			Not Reported
	Pantoprazole			C	Oral			Not Reported
	Doliprane			C	Oral			Not Reported
	Methotrexate			C				Not Reported
	Salazopyrine			C				Not Reported
	Plaquenil			C				Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported
	Remicade			C				Not Reported
	Naproxen			C				Not Reported
	Cefixime			C				Not Reported
	Pantoprazole			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2012	8494340	EXPEDITED (15-DAY)		OT	JP-FRI-1000029490		52 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Nausea	Lexapro	S	Oral	10mg		Forest
	Lexapro	S	Oral	10mg		Forest
	Mosapride Citrate Hydrate	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2012	8988114	EXPEDITED (15-DAY)		HO	FR-FRI-1000041246		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Hypertensive Angiopathy; Intracranial Haematoma	Escitalopram			S	Oral			Forest
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Apranax			S	Oral			Not Reported
	Cortancyl			S	Oral	20 Mg		Not Reported
	Oroken			C	Oral	100 Mg Qod		Not Reported
	Pantoprazole			C	Oral	20 Mg		Not Reported
	Doliprane			C	Oral	4000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2012	8989258	EXPEDITED (15-DAY)		HO	FR-009507513-1212FRA008585		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema; Rash	Isentress			S	Oral	400 Mg, Bid		Merck
	Study Drug (Unspecified)			S	Unknown	Unk		Not Reported
	Tmc-114			S	Oral	1200 Mg, Bid		Not Reported
	Tmc-125			S	Unknown	400 Mg, Qd		Not Reported
	Kivexa			S	Unknown	900 Mg, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Norvir			C	Oral	200 Mg, Bid		Not Reported

	Xanax	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2012	8990969	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritable Bowel Syndrome	Lexapro			S	Oral	5 Mg Od Po Before 11/19/12		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2012	8990971	DIRECT					62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram Oxalate			S	Oral	5mg 1 Daily Oral		Not Reported
	Sertraline Hcl			S	Oral	25mg 1 X Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2012	8991000	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Tremor	Escitalopram 20mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2012	8991002	DIRECT		OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Product Substitution Issue	Escitalopram 20mg			S	Buccal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2012	8879988	EXPEDITED (15-DAY)		OT	IE-FRI-1000039958		46 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Electrocardiogram Qt Prolonged	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2012	8988598	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2012331106		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Supraventricular Tachycardia	Xanax			S	Oral	3 Gtt, 1x/Day		Pfizer
	Cipralex			S	Oral	10 Gtt, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2012	8990335	EXPEDITED (15-DAY)		OT	CA-FRI-1000041283		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Seizure	Escitalopram			S	Oral	10 Mg		Forest
	Lexapro			C	Oral			Not Reported
	Lexapro			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2012	8990532	EXPEDITED (15-DAY)		HO	JP-FRI-1000028239			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	5 Mg		Forest
	Rheumatrex			C	Oral			Not Reported
	Remicade			C	Intravenous drip			Not Reported
	Durotep			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2012	8990654	EXPEDITED (15-DAY)		LT	JP-FRI-1000026517		35 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bradycardia; Headache; Loss Of Consciousness; Parosmia	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Dogmatyl			C	Oral	150 Mg		Not Reported
	Wypax			C	Oral	1.5 Mg		Not Reported
	Myslee			C	Oral	5 Mg		Not Reported
	Depas (Etizolam)			C	Oral	0.5 Mg		Not Reported
	Lexotan			C	Oral	12 Mg		Not Reported
	Asumeji			C	Oral			Not Reported
	Kipres			C	Oral	10 Mg		Not Reported
	Takepron			C	Oral	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2012	8990659	EXPEDITED (15-DAY)		OT	JP-FRI-1000025239		38 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperventilation	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2012	8990782	EXPEDITED (15-DAY)		HO	FR-FRI-1000041244		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retroperitoneal Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Previscan (Fluindione)			S	Oral	20 Mg		Not Reported
	Cordarone			S	Oral	200 Mg		Not Reported
	Hyzaar			C	Oral	50 Mg/12.5 Mg		Not Reported

	Imovane	C	Oral	7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2012	8992391	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20121213294		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akathisia; Choreoathetosis; Muscle Rigidity; Myoclonus; Nervousness; Reduced Facial Expression	Paliperidone			S	Oral			Not Reported
	Paliperidone			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2012	9013471	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2012-05538		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Overdose; Toxicity To Various Agents	Mirtazapine (Mirtazapine)			S	Oral Oral			Not Reported
	Quetiapine			S	Oral Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Diazepam (Diazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2013	8725431	EXPEDITED (15-DAY)		HO	JP-FRI-1000037747		77 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Cholestasis; Drug Eruption	Lexapro			S	Oral	10 Mg		Forest
	Paxil			S	Oral	10 Mg		Not Reported
	Paxil			S	Oral	20 Mg		Not Reported
	Paxil			S	Oral	10 Mg		Not Reported
	Tegretol			S	Oral	200 Mg		Not Reported

Cephadol	C	Oral	75 Mg		Not Reported
Depas (Etizolam)	C	Oral	0.5 Mg		Not Reported
Bayaspirin	C	Oral	100 Mg		Not Reported
Takepron	C	Oral	15 Mg		Not Reported
Pantosin	C	Oral	3 G		Not Reported
Magnesium Oxide	C	Oral	1.5 G		Not Reported
Aftach	C	Other	25 Mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2013	8993214	EXPEDITED (15-DAY)		HO, LT	CH-ROCHE-1175006		90 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Rocephin			S	Unknown			Not Reported
	Zaldiar			S	Oral	37.5 Mg Tramadol Hydrochloride And 325 Mg Paracetamol		Not Reported
	Paracetamol			S	Oral			Not Reported
	Xarelto			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Reminyl			S	Unknown			Not Reported
	Zolpidem			S	Unknown			Not Reported
	Inegy			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Flagyl			S	Unknown			Not Reported
	Esomeprazole			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Omeprazole			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Calciparin			C	Unknown			Not Reported
	Calcimagon-D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2013	8993300	NON-EXPEDITED			US-PFIZER INC-2012332632		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agoraphobia; Anxiety; Appetite Disorder; Cough; Depression; Diarrhoea; Drug Ineffective; Fatigue; Fear; Feeling Abnormal; Headache; Lethargy; Loss Of Libido; Nasopharyngitis; Nausea; Obsessive Thoughts; Paraesthesia; Weight Increased; Withdrawal Syndrome	Pristiq			S		100 Mg, Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2013	8996998	DIRECT	Y	HO			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Diastolic Increased; Confusional State; Heart Rate Abnormal; Nausea; Vision Blurred	Escitalopram Oxalate			S	Oral	10 Mg 1qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2013	9000189	EXPEDITED (15-DAY)		HO, LT	CH-SANOFI-AVENTIS-2012SA095627		90 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Zolpidem			S	Unknown			Not Reported
	Flagyl			S	Unknown			Not Reported
	Zaldiar			S	Oral			Not Reported

	Paracetamol	S	Oral	Not Reported
	Rocephin	S	Unknown	Not Reported
	Xarelto	S	Unknown	Not Reported
	Amlodipine	S	Unknown	Not Reported
	Esomeprazole	S	Unknown	Not Reported
	Galantamine Hydrobromide	S	Unknown	Not Reported
	Inegy	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Calciparin	C		Not Reported
	Omeprazole	C		Not Reported
	Ibuprofen	C		Not Reported
	Calcimagon-D3	C		Not Reported
	Prednisolone	C		Not Reported
	Asa	C		Not Reported
	Heparin	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2013	8930543	EXPEDITED (15-DAY)		OT	SI-FRI-1000040624		65 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bursitis; Fall; Off Label Use; Osteoarthritis	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Forest
	Crestor			C	Oral	5 Mg		Not Reported
	Aspirin Protect			C	Oral	100 Mg		Not Reported
	Micardis			C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2013	8990312	EXPEDITED (15-DAY)		OT	JP-FRI-1000041292			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Initial Insomnia; Loss Of Consciousness;	Lexapro			S	Oral			Forest

Malaise	Ganaton	C	Oral		Not Reported
	Lendormin	C	Oral		Not Reported
	Depas (Etizolam)	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2013	8995305	EXPEDITED (15-DAY)		LT	DE-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-DE-00		56 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Insufficiency; Hypotension; Incorrect Dose Administered; Poor Quality Sleep; Suicide Attempt; Vomiting	Micardis Hct			S	Oral	105 Anz		Boehringer Ingelheim
	Venlafaxin			S	Oral	50 Anz		Not Reported
	Amlodipin			S	Oral	150 Anz		Not Reported
	Cipralex			S	Oral	14 Anz		Not Reported
	Zopiclone			S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2013	8998650	EXPEDITED (15-DAY)		HO, LT	CH-009507513-1212CHE010780		90 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Inegy			S	Oral	10 Mg, Qd		Merck
	Zaldiar			S	Oral	325 Mg, Qid		Not Reported
	Acetaminophen			S	Oral	1000 Mg, Qid		Not Reported
	Rocephin			S		500 Mg, Tid		Not Reported
	Flagyl			S		2000 Mg, Qd		Not Reported
	Xarelto			S		10 Mg, Qd		Not Reported
	Amlodipine			S		5 Mg, Qd		Not Reported
	Esomeprazole			S		40 Mg, Qd		Not Reported
	Reminyl			S		16 Mg, Qd		Not Reported
	Zolpidem Tartrate			S		5 Mg, Qd		Not Reported
	Cipralex			S		10 Mg, Qd		Not Reported

	Calciparin	C	Unk, Bid	Not Reported
	Omeprazole	C	20 Mg, Qd	Not Reported
	Ibuprofen	C	400 Mg, Prn	Not Reported
	Calcimagon D3	C	500 Mg, Qd	Not Reported
	Prednisolone	C	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2013	9000553	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Escitalopram Oxalate			S	Oral	10mg 1 Daily By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2013	8916665	EXPEDITED (15-DAY)		CA	BE-FRI-1000040473			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Prader-Willi Syndrome	Escitalopram			S	Transplacental	10 Mg		Forest
	Xanax Retard			C		0.5 Mg		Not Reported
	Rivotril			C		1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2013	8997385	EXPEDITED (15-DAY)		LT	CH-FRI-1000041410			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Escitalopram			S		10 Mg		Forest
	Zaldiar			S	Oral	1300 Mg		Not Reported
	Paracetamol			S	Oral	4000 Mg		Not Reported
	Rocephin			S		1500 Mg		Not Reported
	Flagyl			S		2000 Mg		Not Reported
	Xarelto			S		10 Mg		Not Reported

	Amlodipine	S	5 Mg	Not Reported
	Esomeprazole	S	40 Mg	Not Reported
	Reminyl	S	16 Mg	Not Reported
	Zolpidem	S	5 Mg	Not Reported
	Inegy	S	10 Mg	Not Reported
	Omeprazol	C	20 Mg	Not Reported
	Ibuprofen	C		Not Reported
	Calcimagon D3	C	500 Mg	Not Reported
	Prednisolone	C	10 Mg	Not Reported
	Calciparin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2013	8997592	EXPEDITED (15-DAY)		DE	US-ASTRAZENECA-2013SE00362		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Quetiapine			S	Oral			Zeneca
	Escitalopram			S	Oral			Not Reported
	Acetaminophen/Codeine			S	Oral			Not Reported
	Metaxalone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2013	9005158	DIRECT	Y	OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Insomnia; Lethargy; Mood Swings; Product Substitution Issue; Psychomotor Hyperactivity	Escitalopram 10 Mg			S	Oral	1 Tab Qeve Po/047		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2013	9005180	DIRECT					33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Condition Aggravated; Drug Ineffective; Dyspnoea; Malaise; Panic Attack; Product Substitution Issue	Escitalopram			S	Oral	10 1 Po		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2013	9005202	DIRECT	Y				58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Tremor	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2013	9013252	DIRECT	Y	DS			16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Anxiety; Arthralgia; Back Pain; Blood Pressure Increased; Breast Disorder; Breast Tenderness; Chills; Decreased Appetite; Diarrhoea; Disinhibition; Disturbance In Attention; Dizziness; Dyspepsia; Eructation; Headache; Hyperacusis; Hyperaesthesia; Hyperhidrosis; Hypoaesthesia; Irritability; Memory Impairment; Mydriasis; Pain In Extremity; Pain In Extremity; Panic Attack; Photophobia; Pollakiuria;	Lexapro			S	Oral			Not Reported
	Medrol			C				Not Reported
	Kenalog			C				Not Reported
	Cymbalta			C				Not Reported

Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2013	9013403	DIRECT	Y				62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Restlessness; Tachyphrenia	Escitalopram			S	Oral	Escitalopram 10mg Daily (Po)		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2013	9132323	EXPEDITED (15-DAY)		HO	ES-FRI-1000041409		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardiogenic Shock; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram			S	Oral	20 Mg		Forest
	Paracetamol			C				Not Reported
	Lexatin (Bromazepam)			C	Oral	9 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2013	9500435	NON-EXPEDITED	Y	OT	PHEH2012US017443		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; White Blood Cell Count Decreased	Gilenya			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2013	8942866	EXPEDITED (15-DAY)		HO, OT	IT-FRI-1000040748		51 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Incorrect Dose Administered;	Escitalopram Oral Solution			S	Oral	8 Gtt		Forest
	Escitalopram Oral Solution			S	Oral			Forest

Overdose; Sopor	Tolep	C		Not Reported
	Lyrica	C		Not Reported
	Tavor (Lorazepam)	C		Not Reported
	Questran	C		Not Reported
	Eutirox	C		Not Reported
	Metformine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2013	9002831	EXPEDITED (15-DAY)		DE	US-BAYER-2013-002223		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Naproxen Sodium (<= 220 Mg)			S	Oral			Bayer
	Ciprofloxacin			S				Bayer
	Desipramine			S	Oral			Not Reported
	Diltiazem Er			S	Oral			Not Reported
	Venlafaxine			S				Not Reported
	Lamotrigine			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Armodafinil			S	Oral			Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Trifluoperazine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Thyroid Preparations			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Lansoprazole			S				Not Reported
	Rosuvastatin			S	Oral			Not Reported
	Nitrofurantoin			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Acetaminophen W/Hydrocodone			S	Oral			Not Reported
	Acetaminophen W/Propoxyphene			S	Oral			Not Reported
	Solifenacin			S	Oral			Not Reported
	Progestine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2013	9003045	EXPEDITED (15-DAY)		DE	US-ASTRAZENECA-2013SE00924		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Rosuvastatin			S	Oral			Astrazeneca
	Escitalopram			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Acetaminophen Hydrocodone			S	Oral			Not Reported
	Desipramine			S	Oral			Not Reported
	Diltiazem			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Armodafinil			S	Oral			Not Reported
	Trifluoperazine			S	Oral			Not Reported
	Acetaminophen\Propoxyphene			S	Oral			Not Reported
	Thyroid Preparations			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Nitrofurantoin			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Solifenacin			S	Oral			Not Reported
	Ciprofloxacin			S	Oral			Not Reported
	Progestin (Progesterone)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2013	9003454	EXPEDITED (15-DAY)		HO, OT	PHEH2013US000499			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cough; Depression; Dizziness; Fatigue; Feeling Abnormal; Heart Rate Decreased; Hyperhidrosis; Mental Impairment; Palpitations	Diovan			S	Oral	160 Mg, Qd		Novartis
	Losartan			S	Oral	100 Mg, Qd		Not Reported
	Escitalopram			S		10 Mg, Qd		Not Reported
	Alprazolam Er			S		1 Mg, Prn		Not Reported
	Accupril			S	Oral	20 Mg, Qd		Not Reported
	Metformin			C	Oral	1000 Mg, Qd		Not Reported
	Pravastatin			C		20 Mg, Qd		Not Reported
	Zoloft			C		Unk Ukn, Unk		Not Reported
	Byetta			C		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2013	9003663	NON-EXPEDITED			US-GLAXOSMITHKLINE-A0957113A		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Erectile Dysfunction; Taste Disorder	Lovaza			S	Oral	4cap Per Day		Glaxosmithkline
	Lexapro			S	Oral	1tab Per Day		Not Reported
	Androgel			C				Not Reported
	Zocor			C				Glaxosmithkline
	Hyzaar			C				Not Reported
	Niacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2013	9003947	EXPEDITED (15-DAY)		DE	US-BAYER-2013-001611		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Diphenhydramine Hydrochloride		Y	S				Bayer
	Lamotrigine			S				Not Reported
	Escitalopram			S				Not Reported
	Aripiprazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2013	9011495	EXPEDITED (15-DAY)		DE	2013SP000020		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Eszopiclone			S	Oral			Not Reported
	Metoprolol			S				Not Reported
	All Other Therapeutic Products			S				Not Reported
	Gabapentin			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported
	Acetaminophen W/Codeine			S				Not Reported
	Benzodiazepine			S				Not Reported
	Simvastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2013	9013766	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Condition Aggravated; Depression; Dizziness; Dizziness; Mental Impairment	Escitalopram			S	Oral	20 Mg Tab 1.5 Qd Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2013	9032414	EXPEDITED (15-DAY)	Y	HO, LT	DSA_61675_2013		90 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Hepatic Failure; Diarrhoea; Diverticulitis; Heparin-Induced Thrombocytopenia; Hepatocellular Injury; Pyrexia	Flagyl			S				Not Reported
	Zolpidem			S				Not Reported
	Zaldiar			S	Oral			Not Reported
	Paracetamol (Paracetamol)			S	Oral			Not Reported
	Rocephin			S				Not Reported
	Xarelto			S				Not Reported
	Amlodipine (Amlodipine)			S				Not Reported
	Esomeprazole (Esomeprazole)			S				Not Reported

	Reminyl	S	Not Reported
	Inegy	S	Not Reported
	Cipralex	S	Not Reported
	Calciparin	C	Not Reported
	Omeprazole	C	Not Reported
	Ibuprofen	C	Not Reported
	Calcimagon-D3	C	Not Reported
	Prednisolone	C	Not Reported
	Asa	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2013	9157403	DIRECT	Y				23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack; Product Substitution Issue	Escitalopram 20mg			S	Oral	20mg Daily By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2013	8993276	EXPEDITED (15-DAY)		HO	IT-FRI-1000041325		29 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Overdose	Escitalopram			S	Oral			Forest
	Trittico			S	Oral			Not Reported
	Tegretol			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Dulcolax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2013	9005570	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2013005790		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil Hcl			S		Unk		Pfizer

	Escitalopram			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2013	9005955	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2013006721		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Gabapentin			S				Pfizer
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2013	9010483	EXPEDITED (15-DAY)		DE	US-ASTRAZENECA-2013SE01317		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Metoprolol			S	Oral			Not Reported
	Quetiapine			S	Oral			Zeneca
	Escitalopram			S	Oral			Not Reported
	Unspecified Ingredient			S	Oral			Not Reported
	Acetaminophen And Codeine			S	Oral			Not Reported
	Benzodiazepine			S	Oral			Not Reported
	Eszopiclone			S	Oral			Not Reported
	Simvastatin			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2013	9010555	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2013004575		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone Hydrochloride			S		Unk		Pfizer
	Acetaminophen			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2013	9011178	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2013007454		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metaxalone			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported
	Quetiapine			S		Unk		Not Reported
	Acetaminophen W/Codeine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2013	9011197	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2013006081		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Gabapentin			S				Pfizer
	Metoprolol			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported
	Acetaminophen W/Codeine			S				Not Reported
	Eszopiclone			S				Not Reported
	Simvastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2013	8984956	EXPEDITED (15-DAY)		HO	PHHY2012IT118492			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury	Tegretol			S	Oral	10 Df, Unk		Novartis
	Trittico			S	Oral	10 Df, Unk		Not Reported
	Dulcolax			S	Oral	5 Df, Unk		Not Reported
	Rivotril			S	Oral	10 Df, Unk		Not Reported
	Zyprexa			S	Oral	2 Df, Unk		Not Reported
	Cipralex			S	Oral	10 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2013	9006679	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2013005800		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil Hcl			S	Oral			Pfizer
	Amitriptyline			S		Unk		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2013	9006879	EXPEDITED (15-DAY)		DE	US-ASTRAZENECA-2013SE01329		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Quetiapine			S	Oral			Zeneca
	Escitalopram			S	Oral			Not Reported
	Chlorpromazine			S	Oral			Not Reported
	Valproic Acid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2013	9006923	EXPEDITED (15-DAY)		DE	US-ASTRAZENECA-2013SE01748		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lisinopril			S	Oral			Zeneca
	Quetiapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2013	9006924	EXPEDITED (15-DAY)		DE	US-ASTRAZENECA-2013SE01709		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Quetiapine		S	Oral	Zeneca
	Escitalopram		S	Oral	Not Reported
	Gabapentin		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2013	9009591	EXPEDITED (15-DAY)		DE	US-ASTRAZENECA-2013SE01642		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Quetiapine			S	Oral			Zeneca
	Escitalopram			S	Oral			Not Reported
	Hydroxyzine			S	Oral			Not Reported
	Citalopram			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported
	Cyclobenzaprine			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2013	9009738	EXPEDITED (15-DAY)		CA	US-FRI-1000041471			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2013	9009957	EXPEDITED (15-DAY)		CA	US-FRI-1000028948		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bicuspid Aortic Valve; Congenital Anomaly; Patent Ductus Arteriosus; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2013	9009973	EXPEDITED (15-DAY)		CA	US-FRI-1000041469		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly; Limb Reduction Defect; Patent Ductus Arteriosus; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2013	8926768	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2012294611		48 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Asphyxia; Chest Pain; Confusional State; Dyspnoea; Feeling Abnormal; Feeling Abnormal; Heart Rate Increased; Mania; Panic Disorder; Suicidal Ideation; Uterine Disorder	Efexor Xr			S	Oral	1 Capsule (75 Mg), 1x/Day		Pfizer
	Efexor Xr			S		1 Capsule (75 Mg), 2x/Day		Pfizer
	Efexor Xr			S		1 Capsule (75mg) And 1 Capsule (37.5mg) A Day		Pfizer
	Efexor Xr			S	Oral	37.5 Mg, Unk		Pfizer
	Citalopram			S		Unk		Not Reported
	Lexapro			S		Half Tablet Of 10mg (5mg), 1x/Day		Not Reported
	Stilnox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2013	9008345	NON-EXPEDITED			US-PFIZER INC-2013011779			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Lyrica			S		50 Mg, 2x/Day		Pfizer
	Lyrica			S		100 Mg, 2x/Day		Pfizer
	Oxycodone Hydrochloride			S		Unk		Pfizer

	Lexapro			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2013	9008360	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2013SCPR004884		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Ibuprofen			S	Oral	Unk, Unknown		Par
	Valproic Acid			S	Oral	Unk, Unknown		Not Reported
	Hydroxyzine			S	Oral	Unk, Unknown		Not Reported
	Cyclobenzaprine			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2013	9008557	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2013007075		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Oxycodone Hydrochloride			S				Pfizer
	Triazolam			S				Pfizer
	Lithium			S				Not Reported
	Escitalopram			S				Not Reported
	Methylphenidate Hydrochloride			S		Unk		Not Reported
	Aripiprazole			S				Not Reported
	Simvastatin			S				Not Reported
	Valaciclovir			S		Unk		Not Reported
	Propoxyphene			S				Not Reported
	Hydrocodone			S				Not Reported
	Acetaminophen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2013	9009057	EXPEDITED (15-DAY)		HO	FR-FRI-1000041551		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Drug Interaction; Hypokalaemia; Hyponatraemia	Escitalopram		S	Oral	5 Mg	Forest
	Omeprazole		S	Oral	20 Mg	Not Reported
	Hytacand		S	Oral	1 Df	Not Reported
	Loxen (Nicardipine Hydrochloride)		C		100 Mg	Not Reported
	Tenormine		C		100 Mg	Not Reported
	Simvastatin		C		20 Mg	Not Reported
	Gliclazide		C		1 Df	Not Reported
	Seresta		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2013	9018186	DIRECT		OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Dizziness; Product Substitution Issue; Suicidal Ideation	Ic-Escitalopram			S	Oral	10 Mg Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2013	9018208	DIRECT	Y	RI			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Depressed Mood; Disease Recurrence; Insomnia; Loss Of Personal Independence In Daily Activities; Palpitations; Panic Attack; Product Substitution Issue; Visual Impairment	Lexapro			S	Oral	20mg 1/2 Tab. A Day Po	2 MTH	Not Reported
	Escitalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2013	9034378	EXPEDITED (15-DAY)	Y	DE, HO, OT	2013P1000002		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Depressed Level Of Consciousness; Drug Interaction; Haemodialysis; Hyperpyrexia; Leukocytosis; Muscle Rigidity; Neurotoxicity; Pyrexia; Rhabdomyolysis; Stupor; Tachypnoea	Lithium			S				Not Reported
	Amlodipine			S				Not Reported
	Escitalopram			S				Not Reported
	Buspirone			S				Not Reported
	Irbesartan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2013	9011963	EXPEDITED (15-DAY)		DE, HO, OT	US-UCBSA-074782		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Pantoprazole Sodium			S	Oral			Not Reported
	Acetaminophen\Hydrocodone			S	Oral			Not Reported
	Desipramine			S	Oral			Not Reported
	Diltiazem			S	Oral	Extended Release		Not Reported
	Venlafaxine			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Armodafinil			S	Oral			Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Trifluoperazine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Rovustatin			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported

	Nitrofurantoin	S	Oral	Not Reported
	Diclofenac	S	Oral	Not Reported
	Acetaminophen/Propoxyphene	S	Oral	Not Reported
	Solifenacin	S	Oral	Not Reported
	Ciprofloxacin	S	Oral	Not Reported
	Progestine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2013	9012666	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2013SE00789		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypokalaemia; Hyponatraemia; Polydipsia; Vomiting	Hytacand			S	Oral	16/12.5 Mg/D, 1df Daily		Astrazeneca
	Omeprazole			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Loxen (Nicardipine Hydrochloride)			C	Oral			Not Reported
	Tenormine			C	Oral			Not Reported
	Simvastatine			C	Oral			Not Reported
	Gliclazide			C	Oral			Not Reported
	Seresta			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2013	9012900	EXPEDITED (15-DAY)		OT	US-FRI-1000041546			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Atypical Pneumonia; Crying; Dizziness; Gait Disturbance; Gastritis; Headache; Paraesthesia; Wrong Product Administered	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Evista			S				Not Reported
	Synthroid			C				Not Reported
	Celebrex			C				Not Reported
	Remicade			C				Not Reported
	Sulfasalazine			C				Not Reported

	Simvastatin	C	Not Reported
	Diovan	C	Not Reported
	Toprol Xl	C	Not Reported
	Hydrochlorothiazide	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2013	9013046	EXPEDITED (15-DAY)		OT	US-009507513-1301USA001994			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apraxia; Foetal Exposure During Pregnancy	Singulair			S				Merck
	Ibuprofen			S				Not Reported
	Folsan			S				Not Reported
	Presinol			S				Not Reported
	Symbicort			S				Not Reported
	Berotec			S				Not Reported
	Thyronajod			S				Not Reported
	Cipralex			S				Not Reported
	Topamax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2013	9013047	NON-EXPEDITED			US-PFIZER INC-2013011896		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Burning Sensation; Insomnia	Lyrica			S	Oral	50 Mg, 2x/Day		Pfizer
	Lyrica			S	Oral	50 Mg, 2x/Day		Pfizer
	Lyrica			S	Oral	100 Mg, 2x/Day		Pfizer
	Lexapro			S		10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2013	9122062	EXPEDITED (15-DAY)		OT	GB-FRI-1000041593		24 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infertility Female	Escitalopram			S	Oral	20 Mg		Forest
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2013	8949339	EXPEDITED (15-DAY)		DE	PHHY2012DE112191		87 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Chest Pain; Dyspnoea; Faeces Discoloured; Gastrointestinal Haemorrhage; Myocardial Infarction; Pallor; Ventricular Hypokinesia	Acetylsalicylic Acid			S		100 Mg, Per Day		Not Reported
	Escitalopram			S				Not Reported
	Citalopram			S		20 Mg, Per Day		Novartis
	Olanzapine			C		5 Mg, Unk		Not Reported
	Zopiclone			C		7.5 Mg, Unk		Not Reported
	Nitrendipine			C		20 Mg, Unk		Not Reported
	Bisoprolol			C		5 Mg, Unk		Not Reported
	Lisinopril/Hydrochlorothiazide			C		20/12.5 Mg Per Day		Not Reported
	Buprenorphine			C		20 Ug/Hr, Unk		Not Reported
	Vitamin B12			C		1000 Ug, Weekly		Not Reported
	Pregabalin			C		150 Mg, Unk		Not Reported
	Lactulose			C		10 Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2013	9014427	EXPEDITED (15-DAY)		DE	US-JNJFOC-20130104870		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Risperidone			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Hydroxyzine			S	Oral			Not Reported
	Temazepam			S	Oral			Not Reported
	Benztropine			S	Oral			Not Reported

	Escitalopram	S	Oral	Not Reported
	Ondansetron	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2013	9015716	EXPEDITED (15-DAY)	Y	OT	20120779		32 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Early; Exposure During Pregnancy	Venofer			S	Intravenous drip	4 In 1 Total		Not Reported
	Cipralex			S				Not Reported
	Unspecified Medication			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2013	9034961	EXPEDITED (15-DAY)	Y	HO, LT	2013-00048		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Coma; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Hypotension; Intentional Overdose; Overdose; Pulse Absent; Suicide Attempt; Tachycardia	Fluoxetine Hydrochloride (Unknown) (Fluoxetine Hydrochloride) Unk, Unkunk			S				Not Reported
	Olanzapine			S				Not Reported
	Quetiapine Fumarate			S				Not Reported
	Gabapentin			S				Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Amitriptyline (Amitriptyline)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	7868619	EXPEDITED (15-DAY)		OT	US-RB-024190-11		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Suboxone Tablet			S	Sublingual			Reckitt Benckiser
	Subutex			S	Sublingual			Reckitt Benckiser
	Lexapro			S	Unknown	Dosage Information		Not Reported

							Unknown- 20 Milligrams Daily		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	7989798	EXPEDITED (15-DAY)	Y	HO	2011AP000994		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Interaction; Electrocardiogram Qt Prolonged; Intentional Overdose; Lethargy; Mental Status Changes; Sinus Bradycardia; Suicide Attempt; Toxicity To Various Agents	Lithium Carbonate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	9015132	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2013SCPR004966		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Verapamil			S	Oral	Unk, Unknown		Par
	Amitriptyline			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	9015706	EXPEDITED (15-DAY)		OT	GB-FRI-1000041627			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Fluctuation; Blood Pressure Fluctuation; Condition Aggravated; Hyperhidrosis; Migraine;	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Duloxetine			C		60 Mg		Not Reported

Sinusitis; Suicidal Ideation; Tinnitus; Vertigo	Duloxetine	C	30 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	9015979	EXPEDITED (15-DAY)		OT	US-FRI-1000041583		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Cough; Drug Interaction; Fall; Loss Of Consciousness; Oral Fungal Infection; Periorbital Haematoma; Skin Burning Sensation; Syncope; Urinary Incontinence	Lexapro			S				Forest
	Cymbalta			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	9016533	EXPEDITED (15-DAY)		HO, OT	US-009507513-1301USA003476			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Dehydration; Fall; Infection; Migraine; Urinary Tract Infection	Singulair			S		10 Mg, Unk		Merck
	Mirapex			S		0.75 Mg, (0.25 Mg And 0.5 Mg)		Not Reported
	Ambien			S		5 Mg, Qd		Not Reported
	Adderall Tablets			S		10 Mg, Bid		Not Reported
	Lyrica			S		100 Mg, Tid		Not Reported
	Lexapro			S		20 Mg, Qd		Not Reported
	Nitrofurantoin			S		100 Mg, Bid		Not Reported
	Loratadine			S		10 Mg, Unk		Not Reported
	Gilenya			S	Oral	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	9016765	EXPEDITED (15-DAY)		HO, OT	CH-009507513-1301CHE004817		22 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Hypokalaemia; Intentional Overdose; Suicide Attempt; Tachycardia	Remeron			S	Oral	90 Mg, Once		Merck
	Escitalopram			S	Oral	90 Mg, Once		Not Reported
	Quetiapine Fumarate			S	Oral	300 Mg, Once		Not Reported
	Topiramate			S	Oral	Unk, Once		Not Reported
	Methylenedioxymethamphetamine			S		1 Df, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	9034430	DIRECT		OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Fatigue; Hyperhidrosis; Nausea; Palpitations; Vomiting	Escitalopram			S	Oral	5 Mg 1 Pill/Day Oral		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	9123963	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2013SCPR004955		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Venlafaxine Hydrochloride			S	Oral	Unk, Unknown		Par
	Ciprofloxacin Er			S	Oral	Unk, Unknown		Par
	Desipramine			S	Oral	Unk, Unknown		Not Reported
	Diltiazem			S	Oral	Unk Unk, Unknown		Not Reported
	Lamotrigine			S	Oral	Unk, Unknown		Not Reported
	Hydrochlorothiazide			S	Oral	Unk Unk, Unknown		Not Reported
	Armodafinil			S	Oral	Unk, Unknown		Not Reported
	Potassium Chloride			S	Oral	Unk, Unknown		Not Reported
	Trifluoperazine			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported

	Thyroid Preparations	S	Oral	Unk, Unknown	Not Reported
	Pantoprazole	S	Oral	Unk, Unknown	Not Reported
	Lansoprazole	S	Oral	Unk, Unknown	Not Reported
	Rovustatin	S	Oral	Unk, Unknown	Not Reported
	Naproxen	S	Oral	Unk, Unknown	Not Reported
	Nitrofurantoin	S	Oral	Unk, Unknown	Not Reported
	Diclofenac	S	Oral	Unk, Unknown	Not Reported
	Acetaminophen W/Hydrocodone	S	Oral	Unk Unk, Unknown	Not Reported
	Acetaminophen W/Propoxyphene	S	Oral	Unk, Unknown	Not Reported
	Solifenacin	S	Oral	Unk, Unknown	Not Reported
	Progestin	S	Oral	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	9124090	EXPEDITED (15-DAY)		DE	FR-FRI-1000041667		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis	Escitalopram			S	Oral	1 Df		Forest
	Memantine			S	Oral			Forest
	Oxazepam			S	Oral			Not Reported
	Risperidone			S	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	9124308	NON-EXPEDITED			US-PFIZER INC-2013016923			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lyrica			S		Unk		Pfizer
	Lexapro			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	9124437	EXPEDITED (15-DAY)		HO	FR-FRI-1000041626		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervix Oedema; Dysphagia; Pharyngeal Oedema; Tongue Oedema	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2013	9124456	EXPEDITED (15-DAY)		DE, HO, OT	US-UCBSA-074690		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Methylphenidate			S	Oral			Not Reported
	Lithium			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Simvastatin			S	Oral			Not Reported
	Valacyclovir			S	Oral			Not Reported
	Propoxyphene			S	Oral			Not Reported
	Hydrocodone			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Triazolam			S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2013	8679002	EXPEDITED (15-DAY)		DS	FR-009507513-1207FRA000929		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder	Aerius (Desloratadine)			S	Oral	5 Mg, Prn		Merck
	Vidora			S	Oral	25 Mg, Unknown		Not Reported

	Seroplex	S	Oral	20 Mg, Qd	Not Reported
	Stagid	C	Oral	700 Mg, Tid	Not Reported
	Atenolol	C	Oral	50 Mg, Qd	Not Reported
	Tareg	C	Oral	40 Mg, Qd	Not Reported
	Lysanxia	C	Oral	1 Df, Tid	Not Reported
	Zolpidem Tartrate	C	Oral	1 Df, Qd	Not Reported
	Ixprim (Acetaminophen (+) Tramadol Hydrochloride)	C	Oral	Unk	Not Reported
	Paracetamol	C	Oral	Unk	Not Reported
	Ster-Dex	C	Ophthalmic	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2013	9017340	EXPEDITED (15-DAY)		HO	IT-FRI-1000041707		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; Hypotension; Intentional Self-Injury	Escitalopram			S	Oral	28 Df		Forest
	Etiltox			S		30 Df		Not Reported
	Cannabis			S				Not Reported
	Beer			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2013	9017400	EXPEDITED (15-DAY)		HO, LT	CA-NICOBRDEVP-2013-00048		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Coma; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Hypotension; Intentional Overdose; Overdose; Pulse Absent; Suicide	Fluoxetine Hydrochloride (Unknown)			S	Unknown	Unk, Unknown		Watson
	Olanzapine			S	Unknown	Unk, Unknown		Not Reported
	Quetiapine Fumarate			S	Unknown	Unk, Unknown		Not Reported
	Gabapentin (Unknown)			S	Unknown	Unk, Unknown		Watson
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported
	Amitriptyline			S	Oral	Unk, Unknown		Not Reported

Attempt; Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2013	9125199	EXPEDITED (15-DAY)		HO	FR-FRI-1000041706		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage	Escitalopram			S	Oral	20 Mg		Forest
	Pradaxa			S	Oral	220 Mg		Not Reported
	Pradaxa			S	Oral	220 Mg		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported
	Amiodarone			C				Not Reported
	Hemigoxine			C				Not Reported
	Simvastatine			C				Not Reported
	Tamsulosine			C				Not Reported
	Burinex			C				Not Reported
	Nozinan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	8554650	EXPEDITED (15-DAY)			JP-FRI-1000030371			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corneal Reflex Decreased; Excessive Eye Blinking; Headache; Muscle Rigidity; Paraesthesia; Seizure; Tremor	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	8949489	EXPEDITED (15-DAY)		HO	GB-FRI-1000040847		51 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Irritability;	Escitalopram			S	Oral	10 Mg		Forest

Psychotic Disorder; Sleep Disorder; Withdrawal Syndrome	Escitalopram	S	Oral	10 Mg		Forest
	Lyrica	S	Oral	50 Mg		Not Reported
	Lyrica	S	Oral	50 Mg		Not Reported
	Lorazepam	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	8972238	EXPEDITED (15-DAY)		HO	GB-PFIZER INC-2012317903		51 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Irritability; Paranoia; Sleep Disorder; Withdrawal Syndrome	Lyrica			S	Oral	50 Mg, 1x/Day		Pfizer
	Lyrica			S				Pfizer
	Cipralex			S	Oral	10 Mg, 1x/Day		Not Reported
	Cipralex			S				Not Reported
	Lorazepam			C	Oral	Nocturnal, As Needed. Rarely Taken.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9017758	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2013SCPR004992		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Verapamil			S	Oral	Unk, Unknown		Par
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9018010	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20130106571		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Cyclobenzaprine			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Hydroxyzine			S	Oral			Not Reported

	Citalopram	S	Oral		Not Reported
	Escitalopram	S	Oral		Not Reported
	Buspirone	S	Oral		Not Reported
	Levothyroxine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9019242	EXPEDITED (15-DAY)		DE	US-ABBOTT-13P-163-1037392-00		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Valproic Acid			S				Not Reported
	Escitalopram			S				Not Reported
	Chlorpromazine			S				Not Reported
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9019248	EXPEDITED (15-DAY)		DE	US-ABBOTT-13P-163-1037383-00		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Valproic Acid			S				Not Reported
	Ibuprofen			S				Not Reported
	Escitalopram			S				Not Reported
	Hydroxyzine			S				Not Reported
	Cyclobenzaprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9019292	EXPEDITED (15-DAY)		DE	US-ABBOTT-13P-163-1037188-00		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone			S				Not Reported
	Potassium Chloride			S				Not Reported
	Diltiazem			S				Not Reported
	Escitalopram			S				Not Reported
	Pantoprazole			S				Not Reported
	Lansoprazole			S				Not Reported
	Desipramine			S				Not Reported

	Venlafaxine	S	Not Reported
	Lamotrigine	S	Not Reported
	Hydrochlorothiazide	S	Not Reported
	Armodafinil	S	Not Reported
	Trifluoperazine	S	Not Reported
	Thyroid Preparations	S	Not Reported
	Rovustatin	S	Not Reported
	Naproxen	S	Not Reported
	Nitrofurantoin	S	Not Reported
	Diclofenac	S	Not Reported
	Acetaminophen/Propoxyphene	S	Not Reported
	Solifenacin	S	Not Reported
	Ciprofloxacin	S	Not Reported
	Progestin (Progesterone)	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9019592	EXPEDITED (15-DAY)		DE	US-SHIONOGI, INC-2013000066		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Nitrofurantoin			S		Unk		Shionogi
	Naproxen			S		Unk		Shionogi
	Desipramine Hcl			S		Unk		Not Reported
	Diltiazem Xr			S		Unk		Not Reported
	Venlafaxine			S		Unk		Not Reported
	Lamotrigine			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Armodafinil			S		Unk		Not Reported
	Potassium Chloride			S		Unk		Not Reported
	Trifluoperazine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Thyroid Preparations			S		Unk		Not Reported
	Pantoprazole			S		Unk		Not Reported
	Lansoprazole			S		Unk		Not Reported
	Rosuvastatin			S		Unk		Not Reported

	Diclofenac Potassium	S	Unk	Not Reported
	Acetaminophen\Hydrocodone Bitartrate	S	Unk	Not Reported
	Propoxyphene Hcl And Acetaminophen	S	Unk	Not Reported
	Solifenacin	S	Unk	Not Reported
	Ciprofloxacin	S	Unk	Not Reported
	Progestine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9019641	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16680480		6 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Vomiting	Abilify			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9021909	EXPEDITED (15-DAY)		OT	GB-FRI-1000041247		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Disorientation; Dizziness; Impaired Driving Ability; Malaise; Migraine	Escitalopram			S	Oral	10 Mg		Forest
	Cipralex			C	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9022039	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20130106004		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents	Methylphenidate			S	Oral			Not Reported
	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported

	Simvastatin	Y	S	Oral	Not Reported
	Lithium		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported
	Aripiprazole		S	Oral	Not Reported
	Valacyclovir		S	Oral	Not Reported
	Propoxyphene		S	Oral	Not Reported
	Hydrocodone		S	Oral	Not Reported
	Oxycodone		S	Oral	Not Reported
	Triazolam		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9022237	EXPEDITED (15-DAY)		DE	US-ABBOTT-13P-163-1037334-00		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levothyroxine			S				Not Reported
	Quetiapine			S				Not Reported
	Hydroxyzine			S				Not Reported
	Citalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Buspirone			S				Not Reported
	Cyclobenzaprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9036764	DIRECT	Y	OT			11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Product Substitution Issue	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9036800	DIRECT					70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Fall; Product Substitution Issue; Vertigo	Lexapro	S	Oral		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9059981	EXPEDITED (15-DAY)	Y	DE	TIR-01708		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levothyroxine			S				Not Reported
	Quetiapine			S				Not Reported
	Hydroxyzine			S				Not Reported
	Citalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Buspirone			S				Not Reported
	Cyclobenzaprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9060078	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2013-00555		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metoprolol			S	Oral			Not Reported
	Gabapentin (Gabapentin)			S				Not Reported
	Simvastatin			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported
	Acetaminophen/Codeine			S				Not Reported
	Eszopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2013	9060216	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2013-00456		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents	Risperidone			S				Not Reported
	Ondansetron			S				Not Reported
	Propranolol			S	Oral			Not Reported
	Oxycodone (Oxycodone)			S				Not Reported
	Trazodone			S				Not Reported

Clonazepam	S		Not Reported
Hydroxyzine	S		Not Reported
Temazepam	S		Not Reported
Benztropine	S		Not Reported
Escitalopram	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2013	8942890	EXPEDITED (15-DAY)		OT	CA-FRI-1000040753		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Sodium Decreased; Confusional State; Seizure; Skin Disorder; Urinary Retention	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Alcohol			S				Not Reported
	Acetylsalicylic Acid			C	Oral	Daily Dose Not Reported.		Not Reported
	Norvasc			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2013	9023954	EXPEDITED (15-DAY)		DE	US-JNJFOC-20130106624		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Diphenhydramine		Y	S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2013	9024339	EXPEDITED (15-DAY)		DE	US-JNJFOC-20130106461		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Acetaminophen/Codeine			S	Oral			Not Reported
	Metaxalone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

	Quetiapine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2013	9024458	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20130106398		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Incorrect Route Of Product Administration; Toxicity To Various Agents	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Benzodiazepine Nos			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2013	9025090	EXPEDITED (15-DAY)		DE	US-JNJFOC-20130106600		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Acetaminophen/Codeine			S	Oral			Not Reported
	Simvastatin		Y	S	Oral			Not Reported
	Metoprolol			S	Oral			Not Reported
	Calcium Antagonists			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Benzodiazepine Nos			S	Oral			Not Reported
	Eszopiclone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2013	8834171	EXPEDITED (15-DAY)		HO	US-TEVA-363380USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Blood Pressure Increased; Chest Discomfort; Confusional State; Dizziness	Escitalopram	S		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2013	9001511	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2013004413		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ibuprofen			S	Oral	Unk		Pfizer
	Hydroxyzine Pamoate			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Valproic Acid			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2013	9003258	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2013007285		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Propanolol Hcl			S	Oral	Unk		Unknown
	Oxycodone Hydrochloride			S	Oral	Unk		Pfizer
	Ondansetron			S	Oral	Unk		Pfizer
	Hydroxyzine Pamoate			S	Oral	Unk		Pfizer
	Trazodone			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Risperidone			S	Oral	Unk		Not Reported
	Temazepam			S	Oral	Unk		Not Reported
	Benztropine Mesylate			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2013	9006683	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2013006530		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levothyroxine Sodium			S	Oral	Unk		Pfizer
	Quetiapine			S	Oral	Unk		Not Reported
	Hydroxyzine			S	Oral	Unk		Not Reported
	Citalopram			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2013	9025252	EXPEDITED (15-DAY)		CA	US-FRI-1000041755		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2013	9061547	EXPEDITED (15-DAY)	Y	DE, OT	AUR-APL-2013-00565		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents	Simvastatin			S	Oral			Not Reported
	Valacyclovir			S				Not Reported
	Lithium (Lithium)			S				Not Reported
	Escitalopram			S				Not Reported
	Methylphenidate			S				Not Reported
	Aripiprazole (Aripiprazole)			S				Not Reported
	Propoxyphene			S				Not Reported
	Hydrocodone (Hydrocodone)			S				Not Reported
	Oxycodone (Oxycodone)			S				Not Reported
	Triazolam			S				Not Reported

	Acetaminophen (Paracetamol)	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2013	9061825	EXPEDITED (15-DAY)	Y	DE	2013POI058000041		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone Hcl			S				Not Reported
	Acetaminophen			S				Not Reported
	Escitalopram			S				Not Reported
	Benzodiazepine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2013	9093963	EXPEDITED (15-DAY)	Y	DE	2013POI077000003		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zipsor			S	Oral			Not Reported
	Desipramine			S	Oral			Not Reported
	Diltiazem			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Lamotrigine			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Armodafinil			S				Not Reported
	Potassium Chloride			S				Not Reported
	Trifluoperazine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Thyroid			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Rovustatin			S	Oral			Not Reported
	Naproxen			S				Not Reported
	Nitrofurantoin			S	Oral			Not Reported
	Acetaminophen\Hydrocodone			S	Oral			Not Reported
	Acetaminophen/Propoxyphene			S	Oral			Not Reported

	Solifenacin	S	Oral		Not Reported
	Ciprofloxacin	S			Not Reported
	Progestin	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2013	9094276	EXPEDITED (15-DAY)	Y	DE	2013POI058000060		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Oxycodone			S	Oral			Not Reported
	Lithium			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Methylphenidate			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Simvastatin			S	Oral			Not Reported
	Valacyclovir			S	Oral			Not Reported
	Propoxyphene			S	Oral			Not Reported
	Hydrocodone			S	Oral			Not Reported
	Triazolam			S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2013	9096389	EXPEDITED (15-DAY)	Y	DE	2013POI058000062		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Oxycodone Hcl			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Clonazepam			C	Oral			Not Reported
	Hydroxyzine			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported

	Temazepam	S	Oral	Not Reported
	Benztropine	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Ondansetron	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2013	9027318	EXPEDITED (15-DAY)		OT	DE-FRI-1000041935		50 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthmatic Crisis	Escitalopram			S		20 Mg		Forest
	Neuroleptics			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2013	9027365	EXPEDITED (15-DAY)		CA	US-FRI-1000041764		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arnold-Chiari Malformation; Cerebral Palsy; Congenital Hydrocephalus	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2013	9038823	DIRECT		DE			68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Cold Sweat; Completed Suicide; Feeling Cold; Hyperhidrosis; Insomnia; Sexual Dysfunction	Cipralex			S	Oral	20 Mg (For 2 Days) Am By Mouth Sept 5-19 / 12	2 DAY	Not Reported
	Quetiapine			S	Oral	25 Mg Pm By Mouth Sept. 11 - 19 / 12		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2013	9031585	EXPEDITED (15-DAY)		HO	AU-ROCHE-1182239		46 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Chills; Diplopia; Dysarthria; Headache; Pyrexia; Syncope	Diazepam			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Prazosin Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2013	9096392	EXPEDITED (15-DAY)	Y	DE	2013SP000332		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Diltiazem Hydrochloride			S				Not Reported
	Naproxen			S				Not Reported
	Diclofenac Sodium			S				Not Reported
	Ciprofloxacin			S				Not Reported
	Desipramine			S				Not Reported
	Venlafaxine			S				Not Reported
	Lamotrigine			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Armodafinil			S				Not Reported
	Potassium Chloride			S				Not Reported
	Trifluoperazine			S				Not Reported
	Escitalopram			S				Not Reported
	Pantoprazole			S				Not Reported
	Lansoprazole			S				Not Reported
	Rosuvastatin			S				Not Reported
	Nitrofurantoin			S				Not Reported
	Acetaminophen			S				Not Reported
	Hydrocodone			S				Not Reported
	Propoxyphene			S				Not Reported
	Progesterone			S				Not Reported
	Solifenacin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2013	9096721	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2013-00326		46 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebral Cyst; Galactorrhoea	Escitalopram (Escitalopram)	S			Not Reported
	Glibenclamide	S	Oral		Not Reported
	Imipramine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2013	8961243	EXPEDITED (15-DAY)		LT, OT	PHEH2012US024269			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Malaise; Malignant Melanoma; Thyroid Disorder	Vivelle Dot			S	Transdermal	0.025 Mg, Qw2 (Twice Weekly)		Novartis
	Cafergot			S				Not Reported
	Amoxapine			S				Not Reported
	Lexapro			S				Not Reported
	Codeine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2013	9029454	EXPEDITED (15-DAY)		DE	PHHY2013US006994		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diclofenac			S		Unk Ukn, Unk		Novartis
	Pantoprazole			S		Unk Ukn, Unk		Not Reported
	Potassium Chloride			S		Unk Ukn, Unk		Not Reported
	Desipramine			S		Unk Ukn, Unk		Not Reported
	Diltiazem			S		Unk Ukn, Unk		Not Reported
	Venlafaxine Hydrochloride			S		Unk Ukn, Unk		Not Reported
	Lamotrigine			S		Unk Ukn, Unk		Not Reported
	Hydrochlorothiazide			S		Unk Ukn, Unk		Not Reported
	Trifluoperazine			S		Unk Ukn, Unk		Not Reported
	Escitalopram			S		Unk Ukn, Unk		Not Reported
	Lansoprazole			S		Unk Ukn, Unk		Not Reported
	Rosuvastatin			S		Unk Ukn, Unk		Not Reported
	Naproxen			S		Unk Ukn, Unk		Not Reported

	Nitrofurantoin	S	Unk Ukn, Unk	Not Reported
	Solifenacin	S	Unk Ukn, Unk	Not Reported
	Ciprofloxacin	S	Unk Ukn, Unk	Not Reported
	Progestin	S	Unk Ukn, Unk	Not Reported
	Acetaminophen W/Propoxyphene	S	Unk Ukn, Unk	Not Reported
	Acetaminophen W/Hydrocodone	S		Not Reported
	Armodafinil	S	Unk Ukn, Unk	Not Reported
	Thyroid Preparations	S	Unk Ukn, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2013	9029669	EXPEDITED (15-DAY)		DE	PHHY2013US007176		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Methylphenidate			S				Novartis
	Paracetamol			S				Not Reported
	Escitalopram			S				Not Reported
	Aripiprazole			S				Not Reported
	Simvastatin			S				Not Reported
	Propoxyphene Hydrochloride			S				Not Reported
	Oxycodone Hydrochloride			S				Not Reported
	Triazolam			S				Not Reported
	Lithium			S				Not Reported
	Hydrocodone			S				Not Reported
	Valacyclovir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2013	9127089	EXPEDITED (15-DAY)		DE	PHHY2013US006979		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Valproic Acid			S				Novartis
	Chlorpromazine			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2013	9129121	EXPEDITED (15-DAY)		DE	US-FRI-1000041991		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Diltiazem			S				Forest
	Escitalopram			S				Forest
	Desipramine			S				Not Reported
	Venlafaxine			S				Not Reported
	Lamotrigine			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Armodafinil			S				Not Reported
	Potassium Chloride			S				Not Reported
	Trifluoperazine			S				Not Reported
	Thyroid Preparations			S				Not Reported
	Pantoprazole			S				Not Reported
	Lansoprazole			S				Not Reported
	Rovustatin			S				Not Reported
	Naproxen			S				Not Reported
	Nitrofurantoin			S				Not Reported
	Diclofenac			S				Not Reported
	Acetaminophen\Hydrocodone			S				Not Reported
	Acetaminophenpropoxyphene			S				Not Reported
	Solifenacin			S				Not Reported
	Ciprofloxacin			S				Not Reported
	Progestin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2013	9129402	EXPEDITED (15-DAY)		DE	US-FRI-1000041988		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Citalopram			S				Forest
	Escitalopram			S				Forest
	Levothroid			S				Forest
	Quetiapine			S				Not Reported
	Hydroxyzine			S				Not Reported
	Buspirone			S				Not Reported
	Cyclobenzaprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2013	9129477	EXPEDITED (15-DAY)		OT	IT-ROCHE-1180915		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury	Rivotril			S	Oral	2,5 Mg/Ml Oral Drops		Not Reported
	Entact			S	Oral	10 Mg		Not Reported
	Effexor			S	Oral	75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2013	9129684	EXPEDITED (15-DAY)		OT	IN-PFIZER INC-2013018091		46 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyst; Drug Interaction; Galactorrhoea	Escitalopram Oxalate			S	Unknown	20 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Glibenclamide			S	Oral	5 Mg, 1x/Day		Pfizer
	Imipramine			S	Unknown	75 Mg, 1x/Day		Not Reported
	Imipramine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2013	9133584	EXPEDITED (15-DAY)		DE	US-009507513-1301USA009945		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Simvastatin			S	Oral			Merck
	Acetaminophen (+) Codeine Phosphate			S	Oral			Not Reported
	Metoprolol			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Quetiapine Fumarate			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Eszopiclone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2013	9033553	EXPEDITED (15-DAY)		HO	FR-FRI-1000042164		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura; Thrombocytopenia	Escitalopram			S	Oral			Forest
	Evista			C	Oral			Not Reported
	Tanakan			C	Oral			Not Reported
	Uvedose			C	Oral			Not Reported
	Cacit [Calcium Carbonate]			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2013	9033571	EXPEDITED (15-DAY)		DE	PHHY2013US007397		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Level Increased	Valproic Acid			S				Novartis
	Hydroxyzine			S				Not Reported
	Cyclobenzaprine			S				Not Reported
	Escitalopram			S				Not Reported
	Ibuprofen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2013	9046479	DIRECT		OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Depression; Product Substitution Issue	Escitalopram			S	Oral	One A Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2013	9062555	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2013SCPR005495		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Completed Suicide; Death	Propranolol Hcl		S	Oral	Unk, Unknown	Par
	Clonazepam		S	Oral	Unk, Unknown	Par
	Risperidone		S	Oral	Unk, Unknown	Par
	Ondansetron		S	Oral	Unk, Unknown	Par
	Oxycodone		S	Oral	Unk, Unknown	Not Reported
	Trazodone		S	Oral	Unk, Unknown	Not Reported
	Hydroxyzine		S	Oral	Unk, Unknown	Not Reported
	Temazepam		S	Oral	Unk, Unknown	Not Reported
	Benztropine		S	Oral	Unk, Unknown	Not Reported
	Escitalopram		S	Oral	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2013	9067282	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2013SCPR005077		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Clonazepam			S	Oral	Unk, Unknown		Par
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Lamotrigine			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2013	9068452	EXPEDITED (15-DAY)		DE	PHHY2013US006687		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metoprolol			S		Unk Ukn, Unk		Novartis
	Acetaminophen (Paracetamol), Codeine Phosphate			S		Unk Ukn, Unk		Not Reported
	Gabapentin			S		Unk Ukn, Unk		Not Reported
	Quetiapine			S		Unk Ukn, Unk		Not Reported
	Escitalopram			S		Unk Ukn, Unk		Not Reported
	Simvastatin			S		Unk Ukn, Unk		Not Reported

	Eszopiclone			S	Unk Ukn, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2013	9068681	EXPEDITED (15-DAY)		OT	US-TEVA-382594USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	8891446	EXPEDITED (15-DAY)		OT	2012AP003451			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Decreased Appetite; Depression; Diarrhoea; Dizziness Postural; Drug Ineffective; Fatigue; Head Discomfort; Headache; Hypertension; Metamorphopsia; Myalgia; Nausea; Palpitations; Product Substitution Issue; Suicidal Ideation; Throat Irritation; Urticaria; Vision Blurred	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	8969971	EXPEDITED (15-DAY)		HO, OT	US-ELI_LILLY_AND_COMPANY-US201212003168			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Contusion; Cough; Drug Interaction; Eye Contusion; Fall; Loss Of Consciousness; Seizure;	Cymbalta			S		60 Mg, Qd		Eli Lilly And Co
	Lexapro			S		Unk, Unknown		Not Reported
	Hydrocodone			C		Unk, Unknown		Not Reported
	Klonopin			C		Unk, Unknown		Not Reported

Skin Abrasion; Syncope; Urinary Incontinence	Dexlansoprazole	C	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9038093	EXPEDITED (15-DAY)		DE	US-FRI-1000042145		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram			S				Forest
	Propranolol			S				Not Reported
	Oxycodone			S				Not Reported
	Trazodone			S				Not Reported
	Clonazepam			S				Not Reported
	Hydroxyzine			S				Not Reported
	Risperidone			S				Not Reported
	Temazepam			S				Not Reported
	Benztropine			S				Not Reported
	Ondansetron			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9038116	EXPEDITED (15-DAY)		DE	US-FRI-1000042148		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S				Forest
	Chlorpromazine			S				Not Reported
	Quetiapine			S				Not Reported
	Valproic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9038122	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-A0958320A		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Ill-Defined Disorder; Myocardial Infarction; Nasopharyngitis; Panic Attack; Stress; Suicidal	Wellbutrin			S		300mg Twice Per Day		Glaxosmithkline
	Effexor			S				Glaxosmithkline
	Ambien			S				Not Reported
	Zyprexa			S				Glaxosmithkline
	Lexapro			S				Not Reported

Ideation; Suicide Attempt	Adderall	S			Not Reported
	Concerta	S			Glaxosmithkline
	Ativan	S	Unknown		Not Reported
	Depakote	S	Unknown		Not Reported
	Trileptal	S	Unknown		Not Reported
	Lithium	S	Unknown		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9038131	NON-EXPEDITED			US-GLAXOSMITHKLINE-A0960858A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Wellbutrin			S	Unknown			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9038176	NON-EXPEDITED			US-GLAXOSMITHKLINE-A0975005A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Therapeutic Response Decreased; Weight Increased	Wellbutrin			S	Oral			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Crestor			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9038186	NON-EXPEDITED			US-GLAXOSMITHKLINE-A0977564A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Wellbutrin			S	Oral	150mg Per Day		Glaxosmithkline
	Lexapro			S	Oral	10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9038280	EXPEDITED (15-DAY)		DE	US-FRI-1000042149		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram			S				Forest
	Quetiapine			S				Not Reported
	Gabapentin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9038286	EXPEDITED (15-DAY)		HO, OT	CH-009507513-1301CHE011765		50 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Overdose; Suicide Attempt	Remeron			S	Oral	30 Mg; 60 Units Once		Merck
	Trimipramine			S	Oral	25 Mg; 50 Units, Once		Not Reported
	Escitalopram			S	Oral	10 Df, Once		Not Reported
	Alprazolam			S	Oral	Unk, Once		Not Reported
	Trospium Chloride			S	Unknown	40 Mg, Once		Not Reported
	Tramadol Hydrochloride			S	Unknown	Unk, Once		Not Reported
	Acetaminophen			S	Unknown	Unk, Once		Not Reported
	Esomeprazole			S	Unknown	Unk, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9041863	NON-EXPEDITED			US-ABBOTT-12P-163-0893986-00		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasopharyngitis; Rash; Rash; Skin Irritation; Skin Irritation	Humira 40 Mg/0.8 Ml Pen			S		80 Mg Once		Not Reported
	Humira 40 Mg/0.8 Ml Pen			S				Not Reported
	Humira 40 Mg/0.8 Ml Pen			S				Not Reported
	Lexapro			S				Not Reported
	Xanax			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9049033	DIRECT	Y	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pruritic	Escitalopram 10 Mg			S	Oral	10 Mg Orally Daily Aprox 3/20/12		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9049037	DIRECT	Y	OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Dizziness; Irritability; Product Substitution Issue	Escitalopram 5 Mg Daily			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9049040	DIRECT	Y				25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Fatigue; Headache; Product Substitution Issue	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9049044	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disturbance In Attention; Feeling Of Despair; Malaise; Panic Attack; Product Substitution Issue	Lexapro - Generic Escitalopram 20 Mg			S			8 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9049053	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Product Substitution Issue	Escitalopram 15 Mg			S	Oral	15 Mg Po Qdy 3 Mos Of Brand 6 Weeks Of Generic	3 MTH 6 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9049055	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Decreased; Product Substitution Issue	Escitalopram			S	Oral	1 Tab Daily 1 Month By Mouth	1 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9049058	DIRECT	Y				51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Depression; Feeling Abnormal; Middle Insomnia; Product Substitution Issue	Escitalopram 20 Mg Mylan			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9049061	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Insomnia; Product Substitution Issue; Therapeutic Response Changed	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9049072	DIRECT	Y	OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S		1 Tab 2 Day Ongoing		Not Reported
	Diltiazem			C				Not Reported
	Amitriptyline			C				Not Reported
	Lexose			C				Not Reported
	Crestor			C				Not Reported
	Flonase			C				Not Reported
	Beber Asa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9052001	DIRECT					27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Mood Altered; Product Substitution Issue	Lexapro			S		Lexapro 5 Mg Daily 6/12 - Current		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9052006	DIRECT	Y	OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Product Substitution Issue	Escitalopram			S	Oral	20 Mg Po Daily 08-15-12 To Present		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9052007	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease	Escitalopram			S	Oral			Not Reported

Recurrence; Product Substitution Issue

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9070248	EXPEDITED (15-DAY)		OT	IT-WATSON-2013-01078		53 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression	Alprazolam (Unknown)			S	Oral	1 Mg, Total		Watson
	Cipralex			S	Oral	60 Mg, Total		Not Reported
	Laroxyl			S	Oral	20 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9074746	EXPEDITED (15-DAY)		HO, OT	US-009507513-1301USA012773			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Singulair			S				Merck
	Quetiapine Fumarate			S				Not Reported
	Escitalopram			S				Not Reported
	Tolterodine			S				Not Reported
	Naproxen			S				Not Reported
	Pantoprazole			S				Not Reported
	Dicyclomine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9074899	EXPEDITED (15-DAY)		DE	US-FRI-1000042143		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram			S				Forest
	Lithium			S				Not Reported
	Methylphenidate			S				Not Reported
	Aripiprazole			S				Not Reported
	Simvastatin			S				Not Reported
	Valacyclovir			S				Not Reported
	Propoxyphene			S				Not Reported
	Hydrocodone			S				Not Reported

Oxycodone	S		Not Reported
Triazolam	S		Not Reported
Acetaminophen	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9076209	NON-EXPEDITED			US-ABBOTT-12P-163-0952017-00		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Injection Site Erythema; Injection Site Erythema; Injection Site Pruritus; Muscular Weakness; Pain; Pain; Pain In Extremity; Parkinsonism; Rash Papular; Rash Papular; Rash Papular; Rheumatoid Arthritis	Humira 40 Mg/0.8 Ml Pen			S				Not Reported
	Sinemet			S		25/100mg Tid To 25/100mg 2 Tab Tid To 1 Tab Tid		Not Reported
	Lexapro			S				Not Reported
	Proair			C	Respiratory (inhalation)			Not Reported
	Flovent Diskus			C				Not Reported
	Tylenol Extra Strength			C				Not Reported
	Calcium Nasal Spray			C		Daily		Not Reported
	Lasix			C		Daily		Not Reported
	Levothyroxin			C		Daily		Not Reported
	Metoprolol			C				Not Reported
	Estropipate			C		Daily		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2013	9077123	NON-EXPEDITED			US-ABBOTT-12P-163-0938654-00		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Injection Site Haemorrhage	Humira 40 Mg/0.8 Ml Pen			S				Not Reported
	Lexapro			S				Not Reported
	Zyrtec			C		Daily		Not Reported
	Benadryl			C		Daily		Not Reported
	Birth Control Pill			C				Not Reported
	Lexapro			C		10mg Daily		Not Reported

	Lexapro			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	8459297	EXPEDITED (15-DAY)		OT	JP-FRI-1000029057		53 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Acuity Reduced	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S		20 Mg		Forest
	Myslee			C	Oral			Not Reported
	Meilax			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	8986987	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-17226309		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Abilify Tabs 10 Mg			S	Oral			Not Reported
	Atacand			S	Oral	Scored Tabs		Not Reported
	Seroplex			S	Oral	Film Coated Tabs		Not Reported
	Depakote			S		250mg Gastro Resistant Tabs 6sep12,Incre To 1gm Daily, Decre To 500mg On 04oct12,250mg On 16oct12		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	9014152	EXPEDITED (15-DAY)		DE	US-JNJFOC-20130104191		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Ibuprofen			S	Oral			Not Reported
	Cyclobenzaprine			S	Oral			Not Reported
	Valproic Acid			S	Oral			Not Reported

	Hydroxyzine	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	9023595	EXPEDITED (15-DAY)		HO	FR-FRI-1000041769		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Enanthema; Eosinophilia; Pruritus; Rash Maculo-Papular	Escitalopram			S	Oral	20 Mg		Forest
	Valproate Sodium			S	Oral	600 Mg		Not Reported
	Valdoxan			S	Oral	25 Mg		Not Reported
	Rhinureflex			S	Oral	1 Df		Not Reported
	Claradol			S	Occlusive dressing technique	2 Df		Not Reported
	Spifen			S	Oral	1200 Mg		Not Reported
	Megamag			S	Oral	135 Mg		Not Reported
	Motilium			S	Oral			Not Reported
	Ideos			C	Oral			Not Reported
	Temesta (Lorazepam)			C	Oral	0.75 Mg		Not Reported
	Xyzall			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	9051964	DIRECT		OT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	9051970	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Palpitations; Skin Papilloma	Escitalopram	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	9051973	DIRECT	Y	RI, OT			16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Escitalopram 20 Mg Mylan			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	9078887	EXPEDITED (15-DAY)		OT	FR-TEVA-382409ISR		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Alprazolam			S	Unknown			Teva
	Etifoxine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	9079033	EXPEDITED (15-DAY)		CA	US-FRI-1000042154		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	9079055	EXPEDITED (15-DAY)		DE	US-FRI-1000042216		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S				Forest
	Hydrocodone			S				Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	9079181	EXPEDITED (15-DAY)		OT	BR-FRI-1000042213			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Chest Pain; Confusional State; Dyspnoea; Feeling Abnormal; Mania; Panic Attack; Suicidal Ideation; Tachycardia	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Not Reported
	Efexor Xr			C	Oral	75 Mg		Not Reported
	Stilnox			C				Not Reported
	Rivotril			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2013	9094042	EXPEDITED (15-DAY)	Y	DE	DSA_61931_2013		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse; Toxicity To Various Agents	Diltiazem Hydrochloride			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Ciprofloxacin			S	Oral			Not Reported
	Desipramine Hydrochloride			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Solifenacin Succinate			S	Oral			Not Reported
	Hydrocodone/Paracetamol			S	Oral			Not Reported
	Di-Gesic			S	Oral			Not Reported
	Trifluoperazine			S	Oral			Not Reported

	Diclofenac	S	Oral	Not Reported
	Progesterone	S	Oral	Not Reported
	All Other Therapeutic Products	S	Oral	Not Reported
	Nitrofurantoin	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2013	9045478	EXPEDITED (15-DAY)		HO	CH-FRI-1000042320			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Drug Abuse; Intentional Overdose; Suicide Attempt	Escitalopram			S	Oral	10 Mg		Forest
	Tranxilium			S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2013	9069545	EXPEDITED (15-DAY)		OT	FR-FRI-1000042322		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Behaviour Disorder; Product Dispensing Error	Escitalopram			S	Oral	15 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest
	Zolpidem			S	Oral	1 Df		Not Reported
	Alprazolam			S	Oral	0.25 Mg Bid Or Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2013	9088943	EXPEDITED (15-DAY)		HO, LT	PHHY2013ES008520		59 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Coma Scale Abnormal; Drug Interaction; Intentional Overdose; Long Qt Syndrome	Anafranil			S	Oral	12 Df, Daily		Not Reported
	Clotiapine			S	Oral	Unk Ukn, Unk		Not Reported
	Escitalopram			S	Oral	Unk Ukn, Unk		Not Reported
	Quetiapine			S	Oral	Unk Ukn, Unk		Novartis

	Flunitrazepam		S	Oral	Unk Ukn, Unk	Not Reported
	Levomepromazine Maleate		S	Oral	Unk Ukn, Unk	Not Reported
	Diazepam		C			Not Reported
	Calodis		C			Not Reported
	Loxifan		C			Not Reported
	Benadon		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2013	9089118	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2013034204		78 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria; Rectal Haemorrhage	Amiodarone Hcl			S	Oral	200 Mg, Daily		Pfizer
	Cipralex			S	Oral	10 Drops, Daily		Not Reported
	Sintrom			S	Oral	1 Mg, Daily		Not Reported
	Lanoxin			C		Unk		Not Reported
	Lansox			C		Unk		Not Reported
	Haldol			C		Unk		Not Reported
	Tavor (Lorazepam)			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2013	9091254	EXPEDITED (15-DAY)		HO, LT, OT	ES-ASTRAZENECA-2013SE06058		59 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Cerebral Ischaemia; Coma; Drug Interaction; Intentional Overdose; Long Qt Syndrome	Seroquel			S	Oral	6 Tablets Single Dose		Zeneca
	Escitalopram			S	Oral			Not Reported
	Anafranil			S	Oral	50 Dragees Single Dose		Not Reported
	Etumina			S	Oral	30 Tablets Single Dose		Not Reported
	Rohypnol			S	Oral	20 Tablets Single Dose		Not Reported
	Levomepromazine			S	Oral	20 Tablets Single Dose		Not Reported
	Diazepam			C				Not Reported

	Calodis	C	Not Reported
	Loxifan	C	Not Reported
	Benadon	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2013	8673159	EXPEDITED (15-DAY)		HO	FR-FRI-1000037145		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral	10 Mg		Forest
	Lovenox			C	Subcutaneous	4000 Iu		Not Reported
	Pravastatin Sodium			C	Oral	20 Mg		Not Reported
	Levothyrox			C	Oral	125 Mcg		Not Reported
	Cardensiel			C	Oral	2.5 Mg		Not Reported
	Inexium			C	Oral	20 Mg		Not Reported
	Kardegic			C	Oral	75 Mg		Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C	Oral	5.9 Mg		Not Reported
	Paracetamol			C	Oral			Not Reported
	Lantus			C	Other	18 Iu		Not Reported
	Lasilix			C	Oral	40 Mg		Not Reported
	Triatec (Ramipril)			C	Oral	2.5 Mg		Not Reported
	Rocephine			C	Other	1 G		Not Reported
	Adancor			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2013	9053939	DIRECT	Y				37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Decreased Appetite; Depression; Panic Attack	Escitalopram		S	Oral	4 WEEK	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2013	9087494	EXPEDITED (15-DAY)		HO	IT-FRI-1000042346		78 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria; Rectal Haemorrhage	Escitalopram Oral Solution			S	Oral	10 Mg		Forest
	Sintrom			S	Oral	1 Mg		Not Reported
	Cordarone			S	Oral	200 Mg		Not Reported
	Lansox			C	Oral	15 Mg		Not Reported
	Lanoxin			C	Oral			Not Reported
	Haldol			C	Oral	16 Drops Daily		Not Reported
	Tavor (Lorazepam)			C	Oral			Not Reported
	Calcium Sandoz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2013	8907373	EXPEDITED (15-DAY)		HO	AU-FRI-1000040355		81 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Hyponatraemia; Malaise; Urinary Retention; Urine Output Decreased	Lexapro			S	Oral	10 Mg		Forest
	Lasix			S				Not Reported
	Losec			C				Not Reported
	Blackmores Fish Oil			C				Not Reported
	Coumadin			C				Not Reported
	Chondroitin Sulfate (Bovine)\Glucosamine Sulfate			C				Not Reported
	Lanoxin			C				Not Reported
	Panadol Osteo			C				Not Reported
	Vitamin B12 Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2013	9049059	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-17316720		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fatigue; Mania	Abilify Tabs 5 Mg			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2013	9057377	EXPEDITED (15-DAY)		OT	PHHY2013BR001460		54 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depression; Dizziness; Headache; Hyperinsulinaemia; Hyperthyroidism; Hypothyroidism; Tachycardia	Ludiomil			S	Oral	2 Tablet (75 Mg) Daily		Not Reported
	Ludiomil			S	Oral	1 Tablet (75 Mg) Daily		Not Reported
	Ludiomil			S	Oral	1 Tablet (25 Mg) Daily		Not Reported
	Ludiomil			S	Oral	Half Tablet (25 Mg) Daily		Not Reported
	Ludiomil			S	Oral	1 Tablet (25 Mg) Daily		Not Reported
	Ludiomil			S	Oral	Half Tablet (25 Mg Daily		Not Reported
	Fluoxetine			S	Oral	20 Mg, Daily		Novartis
	Maprotilina			S	Oral	1 Df, Daily		Not Reported
	Espram			S	Oral	10 Mg, Daily		Not Reported
	Frontal			C	Oral	1 Tablet Daily (1mg)		Not Reported
	Aradois H			C	Oral	0.5 Tablet (50/12.5mg)		Not Reported
	Somalgin			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2013	9057505	DIRECT	Y				34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation;	Escitalopram			S	Oral			Teva

Feeling Jittery; Hallucination; Paranoia; Vocal Cord Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2013	9057942	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram Oxalate			S	Oral		5 MTH	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2013	9057944	DIRECT		OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Headache; Migraine; Product Complaint; Product Substitution Issue; Somnolence; Tremor; Vision Blurred	Escitalopram			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2013	9058160	DIRECT	Y	OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Panic Attack	Escitalopram			S	Oral		4 WEEK	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2013	9139494	EXPEDITED (15-DAY)	Y	DE	NSR_00832_2013		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydroxyzine			S	Oral	(Df Oral)		Not Reported

	Valproic Acid	S	Oral	(Df Oral)		Not Reported
	Ibuprofen	S	Oral	(Df Oral)		Not Reported
	Cyclobenzaprine	S	Oral	(Df Oral)		Not Reported
	Escitalopram	S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2013	9139955	EXPEDITED (15-DAY)	Y	DE	NSR_00843_2013		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Hydroxyzine			S	Oral	(Df Oral)		Not Reported
	Quetiapine			S	Oral	(Df Oral)		Not Reported
	Citalopram			S	Oral	(Df Oral)		Not Reported
	Escitalopram			S	Oral	(Df Oral)		Not Reported
	Buspirone			S	Oral	(Df Oral)		Not Reported
	Cyclobenzaprine			S	Oral	(Df Oral)		Not Reported
	Levothyroxine			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2013	9145551	EXPEDITED (15-DAY)	Y	DE	NSR_00906_2013		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning Deliberate; Respiratory Arrest	Propranolol			S	Oral	(Df)		Not Reported
	Hydroxyzine			S	Oral	(Df)		Not Reported
	Oxycodone			S	Oral	(Df)		Not Reported
	Trazodone			S	Oral	(Df)		Not Reported
	Clonazepam			S	Oral	(Df)		Not Reported
	Risperidone			S	Oral	(Df)		Not Reported
	Temazepam			S	Oral	(Df)		Not Reported
	Benztropine			S	Oral	(Df)		Not Reported
	Escitalopram			S	Oral	(Df)		Not Reported

	Ondansetron			S	Oral	(Df)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2013	9058351	DIRECT		LT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Dizziness; Hypertension; Product Substitution Issue	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2013	9139038	EXPEDITED (15-DAY)	Y	DE	DEP_00836_00836_2013		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Gabapentin			S				Not Reported
	Metoprolol			S	Oral			Not Reported
	Calcium Channel Blockers			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Acetaminophen W/Codeine			S	Oral			Not Reported
	Benzodiazepine Derivatives			S	Oral			Not Reported
	Eszopiclone			S	Oral			Not Reported
	Simvastatin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2013	9139133	EXPEDITED (15-DAY)	Y	DE	VAL_01340_2013		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metoprolol			S				Not Reported
	Acetaminophen W/Codeine			S				Not Reported
	Gabapentin			S				Not Reported
	Quetiapine			S				Not Reported

	Escitalopram	S		Not Reported
	Simvastatin	S		Not Reported
	Eszopiclone	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2013	9140566	EXPEDITED (15-DAY)	Y	DE	DEP_00841_2013		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning; Respiratory Arrest	Gabapentin			S		Df		Not Reported
	Quetiapine			S		Df Oral		Not Reported
	Escitalopram			S		Df Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2013	9059632	DIRECT	Y				15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Scratch	Escitalopram			S	Oral			Not Reported
	Pamelor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2013	9060253	DIRECT		DE			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lansoprazole			S	Oral			Takeda
	Diltiazem Hcl			S	Oral			Not Reported
	Venlafaxine Hcl			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Diclofenac Epolamine			S	Oral			Not Reported
	Ciprofloxacin			S				Not Reported
	Desipramine			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

	Hydrochlorothiazide		S	Oral		Not Reported
	Armodafinil		S	Oral		Not Reported
	Potassium Chloride		S	Oral		Not Reported
	Trifluoperazine		S	Oral		Not Reported
	Escitalopram		S	Oral		Not Reported
	Naproxen		S	Oral		Not Reported
	Nitrofurantoin		S	Oral		Not Reported
	Acetaminophen/Hydrocodone		S	Oral		Not Reported
	Acetaminophen/Propoxyphene		S	Oral		Not Reported
	Solifenacin		S	Oral		Not Reported
	Progestin (Progesterone)		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2013	9145921	EXPEDITED (15-DAY)	Y	DE	NSR_00894_2013		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Venlafaxine			S	Oral			Not Reported
	Desipramine			S	Oral			Not Reported
	Diltiazem			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Armodafinil			S	Oral			Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Trifluoperazine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Thyroid Preparations			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Rosuvastatin			S	Oral			Not Reported

	Naproxen		S	Oral			Not Reported
	Nitrofurantoin		S	Oral			Not Reported
	Diclofenac		S	Oral			Not Reported
	Acetaminophen W/Hydrocodone		S	Oral			Not Reported
	Acetaminophen W/Propoxyphene		S	Oral			Not Reported
	Solifenacin		S	Oral			Not Reported
	Ciprofloxacin		S	Oral			Not Reported
	Progestin		S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2013	9146062	EXPEDITED (15-DAY)	Y	DE	NSR_00855_2013		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Lamotrigine			S	Oral			Not Reported
	Diphenhydramine			S	Oral			Not Reported
	Escitalopram			S				Not Reported
	Aripiprazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2013	9146761	EXPEDITED (15-DAY)	Y	DE	NSR_00853_2013		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Lamotrigine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2013	9005360	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2013007612		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diltiazem Hcl			S	Oral	Unk		Unknown
	Venlafaxine Hydrochloride			S	Oral	Unk		Pfizer

Pantoprazole	S	Oral	Unk		Pfizer
Lansoprazole	S	Oral	Unk		Unknown
Diclofenac Epolamine	S	Oral	Unk		Unknown
Ciprofloxacin	S				Not Reported
Desipramine	S	Oral	Unk		Not Reported
Lamotrigine	S	Oral	Unk		Not Reported
Hydrochlorothiazide	S	Oral	Unk		Not Reported
Armodafinil	S	Oral	Unk		Not Reported
Potassium Chloride	S	Oral	Unk		Not Reported
Trifluoperazine	S	Oral	Unk		Not Reported
Escitalopram	S	Oral	Unk		Not Reported
Naproxen	S	Oral	Unk		Not Reported
Nitrofurantoin	S	Oral	Unk		Not Reported
Acetaminophen\Hydrocodone	S	Oral	Unk		Not Reported
Acetaminophen/Propoxyphene	S	Oral	Unk		Not Reported
Solifenacin	S	Oral	Unk		Not Reported
Progestin	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2013	9053250	EXPEDITED (15-DAY)		HO	FR-FRI-1000042490		44 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Hypertriglyceridaemia	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2013	9060067	DIRECT	Y	OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Substitution Issue;	Escitalopram			S	Oral			Mylan
	Geodon			C				Not Reported

Suicidal Ideation	Wellbutrin Generic	C		Not Reported
	Prozac Generic	C		Not Reported
	Lamictal Generic	C		Not Reported
	Spironolactone Genericm	C		Not Reported
	Lunesta	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2013	9096231	EXPEDITED (15-DAY)		LT	FR-FRI-1000042451		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Hyponatraemia; Respiratory Distress	Escitalopram			S	Oral	15 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2013	9096307	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20130114957		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Exposure During Pregnancy; Lung Infection; Melanocytic Naevus; Rheumatoid Factor Increased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tylenol With Codeine			S	Unknown			Not Reported
	Imodium			S	Unknown			Not Reported
	Ventolin			S	Unknown			Not Reported
	Tecta			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Multivitamins			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2013	9120032	EXPEDITED (15-DAY)		HO, OT	PHEH2013US002804			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Breast Cancer;	Femara			S		2.5 Mg, Qd		Novartis
	Zometa			S		Unk Ukn, Unk		Not Reported

Depression; Fatigue; Headache; Lymphoedema; Malignant Neoplasm Progression; Metastases To Bone; Nausea; Pallor; Renal Impairment; Suicide Attempt; Tardive Dyskinesia; Tooth Fracture	Arimidex	S	Unk Ukn, Unk	Not Reported
	Lexapro	S	Unk Ukn, Unk	Not Reported
	Tamoxifen	C	Unk Ukn, Unk	Not Reported
	Toremifene	C	Unk Ukn, Unk	Not Reported
	Wellbutrin Xr	C	Unk Ukn, Unk	Not Reported
	Taxol	C	Unk Ukn, Unk	Not Reported
	Gemcitabine	C	Unk Ukn, Unk	Not Reported
	Navelbine	C	Unk Ukn, Unk	Not Reported
	Vitamin D3	C	Unk Ukn, Unk	Not Reported
	Cozaar	C	Unk Ukn, Unk	Not Reported
	Metformin	C	Unk Ukn, Unk	Not Reported
	Omeprazole	C	Unk Ukn, Unk	Not Reported
	Senna	C	Unk Ukn, Unk	Not Reported
	Atenolol	C	Unk Ukn, Unk	Not Reported
	Zofran	C	Unk Ukn, Unk	Not Reported
	Naprosyn	C	Unk Ukn, Unk	Not Reported
	Compazine	C	Unk Ukn, Unk	Not Reported
	Trazodone	C	Unk Ukn, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2013	8895875	EXPEDITED (15-DAY)		HO	JP-FRI-1000040172		21 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Delirium; Hyperthyroidism; Overdose; Tachycardia	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2013	9010700	EXPEDITED (15-DAY)		HO	FR-FRI-1000041482		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Rectal Haemorrhage	Escitalopram		S	Oral		Forest
	Inexium		S	Oral	20 Mg	Not Reported
	Lantus		C			Not Reported
	Atenolol		C		50 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2013	9045327	EXPEDITED (15-DAY)		DE	FR-FRI-1000042328			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Diabetes Mellitus; Hyponatraemia; Nausea; Vomiting	Escitalopram			S	Oral	5 Mg		Forest
	Cordarone			C				Not Reported
	Plavix			C				Not Reported
	Burinex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2013	9054313	EXPEDITED (15-DAY)		DE	CHPA2013US002546		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diphenhydramine		Y	S	Oral	Unk, Unk		Novartis
	Lamotrigine			S	Oral	Unk, Unk		Not Reported
	Escitalopram			S	Oral	Unk, Unk		Not Reported
	Aripiprazole			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2013	9054507	NON-EXPEDITED			US-GLAXOSMITHKLINE-A0998441A		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Paxil			S		5mg Alternate Days		Glaxosmithkline
	Escitalopram			S		5mg Per Day		Mylan
	Xanax			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2013	9113640	EXPEDITED (15-DAY)		DE	CHPA2013US002527		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lansoprazole			S	Oral	Unk, Unk		Novartis
	Desipramine			S	Oral	Unk, Unk		Not Reported
	Diltiazem Er			S	Oral	Unk, Unk		Not Reported
	Venlafaxine			S	Oral	Unk, Unk		Not Reported
	Lamotrigine			S	Oral	Unk, Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk, Unk		Not Reported
	Armodafinil			S	Oral	Unk, Unk		Not Reported
	Potassium Chloride			S	Oral	Unk, Unk		Not Reported
	Trifluoperazine			S	Oral	Unk, Unk		Not Reported
	Escitalopram			S	Oral	Unk, Unk		Not Reported
	Thyroid Preparations			S	Oral	Unk, Unk		Not Reported
	Pantoprazole			S	Oral	Unk, Unk		Not Reported
	Naproxen			S	Oral	Unk, Unk		Not Reported
	Nitrofurantoin			S	Oral	Unk, Unk		Not Reported
	Diclofenac			S	Oral	Unk, Unk		Not Reported
	Acetaminophen W/Hydrocodone			S	Oral	Unk, Unk		Not Reported
	Acetaminophen W/Propoxyphene			S	Oral	Unk, Unk		Not Reported
	Solifenacin			S	Oral	Unk, Unk		Not Reported
	Ciprofloxacin			S	Oral	Unk, Unk		Not Reported
	Progestin			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2013	9113938	EXPEDITED (15-DAY)		DE, OT	CHPA2013US002528		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Completed Suicide	Acetaminophen (Paracetamol)	Y	S	Oral	Unk, Unk		Novartis
	Lithium		S	Oral	Unk, Unk		Not Reported
	Escitalopram		S	Oral	Unk, Unk		Not Reported
	Methylphenidate		S	Oral	Unk, Unk		Not Reported
	Aripiprazole		S	Oral	Unk, Unk		Not Reported
	Simvastatin		S	Oral	Unk, Unk		Not Reported
	Valaciclovir		S	Oral	Unk, Unk		Not Reported
	Propoxyphene		S	Oral	Unk, Unk		Not Reported
	Hydrocodone		S	Oral	Unk, Unk		Not Reported
	Oxycodone		S	Oral	Unk, Unk		Not Reported
	Triazolam		S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2013	9113984	EXPEDITED (15-DAY)		DE	CHPA2013US002435		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen (Paracetamol)		Y	S		Unk, Unk		Novartis
	Escitalopram			S		Unk, Unk		Not Reported
	Oxycodone			S		Unk, Unk		Not Reported
	Benzodiazepines			S		Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2013	9117247	EXPEDITED (15-DAY)		OT	US-FRI-1000042420		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2013	8988918	EXPEDITED (15-DAY)		OT	US-FRI-1000041249		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anal Haemorrhage; Gastric Dilatation; Off Label Use	Lexapro	S	Oral	10 Mg		Forest
	Lexapro	S	Oral	10 Mg Qod		Forest
	Aspirin	C				Not Reported
	Levothyroxine	C		50 Mcg		Not Reported
	Vitamin B12	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2013	9058949	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-16432361		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Metformin Hcl			S				Bristol Myers Squibb
	Plavix			S				Sanofi Aventis
	Plavix			S				Sanofi Aventis
	Ramipril			S				Not Reported
	Furosemide			S				Not Reported
	Simvastatin			S				Not Reported
	Lexapro			S				Not Reported
	Folic Acid			S				Not Reported
	Amlodipine			S				Not Reported
	Metoprolol Succinate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2013	9077164	EXPEDITED (15-DAY)		DE	US-RANBAXY-2013US-64449		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ciprofloxacin			S	Oral			Ranbaxy
	Pantoprazole			S	Oral			Ranbaxy
	Pantoprazole			S		Unk		Ranbaxy
	Acetaminophen\Hydrocodone Bitartrate			S	Oral			Ranbaxy
	Venlafaxin			S	Oral			Not Reported
	Rosuvastatin			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral			Not Reported

	Lamotrigina	S	Oral		Not Reported
	Diclofenac	S	Oral		Not Reported
	Lansoprazole	S	Oral		Not Reported
	Naproxen	S	Oral		Ranbaxy
	Nitrofurantoin	S	Oral		Ranbaxy
	Hydrochlorothiazide	S	Oral		Ipca
	Solifenacin	S	Oral		Not Reported
	Potassium Chloride	S	Oral		Not Reported
	Progesterone	S	Oral		Not Reported
	Diltiazem	S	Unknown	Unk	Not Reported
	Desipramine	S	Oral		Not Reported
	Armodafonil	S	Oral		Not Reported
	Trifluoperazine	S	Oral		Not Reported
	Acetaminophenpropoxyphene	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2013	9112803	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2013SE00665		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inhibitory Drug Interaction; Rectal Haemorrhage	Inexium			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Lantus			C				Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2013	9113118	EXPEDITED (15-DAY)		HO	DK-SANOFI-AVENTIS-2013SA010006			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Xatral			S	Unknown			Not Reported
	Quetiapine			S	Oral	Form: 245		Not Reported

	Escitalopram			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2013	9060413	EXPEDITED (15-DAY)		DE	US-BANPHARM-20130650		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Valproic Acid			S	Oral	Unk,		Not Reported
	Hydroxyzine			S				Not Reported
	Ibuprofen Unknown Product			S				Not Reported
	Cyclobenzaprine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2013	9060429	EXPEDITED (15-DAY)		DE	US-BANPHARM-20130666		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Valproic Acid			S	Oral	Unk,		Not Reported
	Chlorpromazine			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2013	9068530	DIRECT	Y				36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Headache; Muscle Twitching; Paraesthesia; Withdrawal Syndrome	Escitalopram			S	Oral	20 Mg Daily Po		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2013	9097244	EXPEDITED (15-DAY)		DE, OT	US-NOVEN-13US006165		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Completed Suicide	Lithium Carbonate	S	Oral	Unk		Noven
	Methylphenidate	S	Oral	Unk		Noven
	Escitalopram	S	Oral	Unk		Not Reported
	Aripiprazole	S	Oral	Unk		Not Reported
	Simvastatin	S	Oral	Unk		Not Reported
	Valacyclovir Hydrochloride	S	Oral	Unk		Not Reported
	Propoxyphene	S	Oral	Unk		Not Reported
	Hydrocodone	S	Oral	Unk		Not Reported
	Oxycodone	S	Oral	Unk		Not Reported
	Triazolam	S	Oral	Unk		Not Reported
	Acetaminophen	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2013	9097703	EXPEDITED (15-DAY)		OT	US-FRI-1000042506		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Coordination Abnormal; Haemorrhagic Stroke	Lexapro			S				Forest
	Lexapro			S				Forest
	Interferon Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2013	9092584	DIRECT		OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersomnia; Paraesthesia	Cymbalta			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2013	9093135	DIRECT	Y	OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Asthma; Headache; Heart Rate Irregular; Irritability; Product Substitution Issue; Weight Increased	Escitalopram		S	Oral	3 MTH	Not Reported
	Escitalopram		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2013	9098491	EXPEDITED (15-DAY)		OT	US-WATSON-2013-01825		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Trazodone Hydrochloride			S	Unknown	100 Mg, Daily		Watson
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported
	Methylthioninium Chloride			S	Unknown	1 Mg/Kg Bolus, Followed By 0.5 Mg/Kg/Hour Continous Infusion		Not Reported
	Phenylephrine			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2013	9098675	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2013SE09321		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Hyponatraemia; Nausea; Vomiting	Hytacand			S	Oral	16/12.5 Mg/D		Astrazeneca
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Plavix			C				Not Reported
	Foradil			C				Not Reported
	Stilnox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2013	9098726	EXPEDITED (15-DAY)		CA	US-FRI-1000042538		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Cardiac Defects	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2013	9098727	EXPEDITED (15-DAY)		CA	US-FRI-1000042516		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Developmental Delay; Heterotaxia; Pulmonary Artery Atresia; Transposition Of The Great Vessels; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2013	9060762	EXPEDITED (15-DAY)		HO	IT-FRI-1000042319		76 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Hyponatraemia	Escitalopram			S	Oral	20 Mg		Forest
	Pantoprazolo			C		40 Mg		Not Reported
	Halcion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2013	9066464	EXPEDITED (15-DAY)		HO	IE-FRI-1000042579			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Low Birth Weight Baby	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2013	9085369	EXPEDITED (15-DAY)		HO	FI-FRI-1000042315		14 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Off Label Use	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2013	9094909	DIRECT		DE, LT, OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Chest Pain; Confusional State; Disorientation; Unresponsive To Stimuli	Lexapro			S	Oral	10mg? Once Daily? Po		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2013	9099714	EXPEDITED (15-DAY)		HO	FR-FRI-1000042629			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vision Blurred; Vitreous Floaters	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2013	8164685	EXPEDITED (15-DAY)		HO, OT	PHHY2011FR82671		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Confusional State; Creatinine Renal Clearance Decreased; Renal Failure; Seizure; Status Epilepticus; Suicidal Ideation	Exelon Patch			S	Transdermal	9.5 Mg/24 Hr		Novartis
	Exelon Patch			S	Transdermal	4.6 Mg Daily		Novartis
	Seroplex			S		15 Mg (10 Mg In The Morning And 5 Mg In The Evening)		Not Reported
	Aldactazine			C		0.5 Df, Qd		Not Reported
	Neurontin			C		600 Mg Daily		Not Reported
	Neurontin			C		1200 Mg Daily		Not Reported
	Gardenal			C		10 Mg, Qd		Not Reported
	Tiapridal			C		100 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2013	8455433	EXPEDITED (15-DAY)		OT	JP-FRI-1000028582		33 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Hypertriglyceridaemia; Liver Disorder	Lexapro			S	Oral	20 Mg		Forest
	Tapizol			S	Oral	10 Mg		Not Reported
	Abilify			S	Oral	3 Mg		Not Reported
	Dogmatyl			S	Oral	100 Mg		Not Reported
	Meilax			C	Oral	2 Mg		Not Reported
	Flunitrazepam			C	Oral	1 Mg		Not Reported
	Rize			C	Oral			Not Reported
	Podonin-S			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2013	9012698	EXPEDITED (15-DAY)		DE	US-ABBOTT-13P-163-1035670-00		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Potassium Chloride			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Diltiazem			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Ciprofloxacin			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Armodafinil			S	Oral			Not Reported
	Trifluoperazine			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Diclofenac Sodium			S	Oral			Not Reported
	Desipramine			S	Oral			Not Reported

	Lamotrigine	S	Oral	Not Reported
	Hydrochlorothiazide	S	Oral	Not Reported
	Nitrofurantoin	S	Oral	Not Reported
	Acetaminophen W/Hydrocodone Bitartrate	S	Oral	Not Reported
	Solifenacin	S	Oral	Not Reported
	Progestin	S	Oral	Not Reported
	Procet [Hydrocodone,Paracetamol]	S	Oral	Not Reported
	Thyroid Preparations	S		Not Reported
	Rosuvastatin Calcium	S		Not Reported
	Dextropropoxyphene/Paracetamol	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2013	9064228	EXPEDITED (15-DAY)		HO	IT-FRI-1000042492		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Sopor	Escitalopram			S	Oral	40 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2013	9068936	EXPEDITED (15-DAY)		DE	US-BANPHARM-20130737		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Naproxen			S	Oral			Not Reported
	Desipramine			S	Oral			Not Reported
	Diltiazem Hydrochloride Extended Release			S				Not Reported
	Venlafaxine			S				Not Reported
	Lamotrigine			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Armodafinil			S				Not Reported
	Potassium Chloride			S				Not Reported
	Trifluoperazine			S				Not Reported
	Escitalopram			S				Not Reported

	Unspecified Ingredient	S	Not Reported
	Pantoprazole	S	Not Reported
	Lansoprazole	S	Not Reported
	Rovustatin	S	Not Reported
	Nitrofurantoin	S	Not Reported
	Diclofenac	S	Not Reported
	Acetaminophen\Hydrocodone	S	Not Reported
	Acetaminophen/Propoxyphene	S	Not Reported
	Solifenacin	S	Not Reported
	Ciprofloxacin	S	Not Reported
	Progestin	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2013	9069377	EXPEDITED (15-DAY)		DE	US-BANPHARM-20130820		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diphenhydramine Unknown Product			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2013	9101320	NON-EXPEDITED			US-BAYER-2013-004977		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Menorrhagia; Product Use In Unapproved Indication	Aleve			S	Oral	5 Mg, Unk		Bayer
	Bayer Genuine Aspirin Original Strength			S				Bayer
	Ibuprofen			S		Unk		Bayer
	Escitalopram			S	Oral	5 Mg, Unk		Not Reported
	Nyquil			S				Not Reported
	Dayquil [Dextromet Hbr,Guaif,Paracet,Pseudoeph Hcl]			S		Unk		Not Reported

Bc	S	Unk		Not Reported
Zantac	C	Unk		Not Reported
Nexium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2013	9093309	EXPEDITED (15-DAY)		HO, OT	CH-009507513-1302CHE006880		53 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Contusion; Fall; Hyperreflexia; Skin Laceration; Somnolence; Suicide Attempt	Remeron			S	Oral	10 Df, Once		Merck
	Zolpidem Tartrate			S	Oral	56 Df, Once		Not Reported
	Escitalopram			S	Oral	28 Df, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2013	9101058	EXPEDITED (15-DAY)		DE	US-COVIDIEN/TYCO HEALTHCARE/MALLINCKRODT-T20130069		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Roxicodone			S	Oral	Unk		Tyco
	Temazepam			S	Oral			Tyco
	Propranolol			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Hydroxyzine			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Benztropine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ondansetron			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2013	9101646	EXPEDITED (15-DAY)		DE	US-COVIDIEN/TYCO HEALTHCARE/MALLIN		23 YR	Female	USA

CKRODT-T20130042

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen/Codeine Tablets			S	Oral	Unk		Tyco
	Metaxalone			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Quetiapine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2013	9101852	EXPEDITED (15-DAY)		DE	US-COVIDIEN/TYCO HEALTHCARE/MALLIN CKRODT-T20130069		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen/Codeine Tablets			S	Oral	Unk		Tyco
	Metoprolol			S				Not Reported
	Calcium Antagonist			S				Not Reported
	Gabapentin			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported
	Benzodiazepine Derivatives			S				Not Reported
	Eszopiclone			S				Not Reported
	Simvastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2013	9101903	EXPEDITED (15-DAY)		DE	US-COVIDIEN/TYCO HEALTHCARE/MALLIN CKRODT-T20130058		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Roxicodone			S		Unk		Tyco
	Acetaminophen			S				Not Reported
	Escitalopram			S				Not Reported
	Benzodiazepine Derivatives			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2013	9102395	EXPEDITED (15-DAY)		DE	US-COVIDIEN/TYCO HEALTHCARE/MALLIN CKRODT-T20130067		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S	Oral	Unk		Tyco
	Pennsaid			S	Oral			Tyco
	Desipramine			S	Oral			Not Reported
	Diltiazem Er			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Armodafinil			S	Oral			Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Trifluoperazine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Thyroid Preparations			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Rosuvastatin			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Nitrofurantoin			S	Oral			Not Reported
	Acetaminophen W/Propoxyphene			S	Oral			Not Reported
	Solifenacin			S	Oral			Not Reported
	Ciprofloxacin			S	Oral			Not Reported
	Progestin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2013	9102421	EXPEDITED (15-DAY)		DE	US-COVIDIEN/TYCO HEALTHCARE/MALLIN		66 YR	Female	USA

CKRODT-T20130067

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Methylin			S	Oral	Unk		Tyco
	Roxicodone			S				Tyco
	Lithium			S				Not Reported
	Escitalopram			S				Not Reported
	Aripiprazole			S				Not Reported
	Simvastatin			S				Not Reported
	Valacyclovir Hydrochloride			S				Not Reported
	Propoxyphene			S				Not Reported
	Hydrocodone			S				Not Reported
	Triazolam			S				Not Reported
	Acetaminophen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2013	8990027	EXPEDITED (15-DAY)		OT	IT-ABBOTT-12P-083-1025461-00		17 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Disorder; Off Label Use; Syncope	Akineton			S	Oral			Not Reported
	Depakine Chrono			S	Oral			Not Reported
	Talofen			S	Oral	8 Drop Daily		Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S				Not Reported
	Abilify			S	Oral			Not Reported
	Abilify			S				Not Reported
	Evra			S	Transdermal	Every Other Day		Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2013	9051016	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2013044367		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Urinary Retention	Morphine Sulfate			S	Oral	30 Mg, Daily		Pfizer
	Pregabalin			S	Oropharingeal	25 Mg, Unk		Pfizer
	Esertia			S	Oral	20 Mg, 2x/Day		Not Reported
	Zomorph			S	Oral	60 Mg, Daily		Not Reported
	Humalog Mix Pen			C	Subcutaneous	Unk		Not Reported
	Lantus			C	Subcutaneous	32 Iu, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2013	9136945	EXPEDITED (15-DAY)		DS	FR-FRI-1000042711		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Memory Impairment	Escitalopram			S		15 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2013	9146396	EXPEDITED (15-DAY)	Y	DE	2013-00284		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lisinopril (Lisinopril)			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported
	Trazodone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2013	9312072	EXPEDITED (15-DAY)	Y	DE	THQ2013A00261		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lansoprazole (Lansoprazole)			S	Oral			Not Reported
	Diltiazem Hcl (Diltiazem Hydrochloride)			S	Oral			Not Reported
	Venlafaxine Hcl (Venlafaxine			S	Oral			Not Reported

Hydrochloride)			
Pantoprazole	S	Oral	Not Reported
Diclofenac Epolamine	S	Oral	Not Reported
Ciprofloxacin	S		Not Reported
Desipramine	S	Oral	Not Reported
Lamotrigine	S	Oral	Not Reported
Hydrochlorothiazide	S	Oral	Not Reported
Armodafinil	S	Oral	Not Reported
Potassium Chloride	S	Oral	Not Reported
Trifluoperazine	S	Oral	Not Reported
Escitalopram	S	Oral	Not Reported
Naproxen	S	Oral	Not Reported
Nitrofurantoin	S	Oral	Not Reported
Acetaminophen/Hydrocodone (Paracetamol, Hydrocodone)	S	Oral	Not Reported
Acetaminophen/Propoxyphene (Paracetamol, Dextropropoxyphene)	S	Oral	Not Reported
Solifenacin	S	Oral	Not Reported
Progestin (Progesterone)	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2013	8611165	EXPEDITED (15-DAY)		HO, OT	DE-FRI-1000031251		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2013	9061703	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2013-00516		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Venlafaxine	S		Unknown	Not Reported
	Nitrofurantoin	S		Unknown	Not Reported
	Diclofenac (Diclofenac)	S		Unknown	Not Reported
	Acetaminophen/ Hydrocodone	S		Unknown	Not Reported
	Acetaminophen/Propoxyphene	S		Unknown	Not Reported
	Solifenacin	S	Oral	Oral	Not Reported
	Lamotrigine (Lamotrigine)	S		Unknown	Not Reported
	Hydrochlorothiazide (Hydrochlorothiazide)	S		Unknown	Not Reported
	Ciprofloxacin (Ciprofloxacin)	S		Unknown	Not Reported
	Naproxen (Naproxen)	S		Unknown	Not Reported
	Escitalopram	S		Unknown	Not Reported
	Desipramine (Desipramine) (Desipramine)	S	Oral	Unknown	Not Reported
	Rosuvastatin (Rosuvastatin)	S		Unknown	Not Reported
	Diltiazem	S		Unknown	Not Reported
	Lansoprazole (Lansoprazole)	S		Unknown	Not Reported
	Armodafinil	S		Unknown	Not Reported
	Pantoprazole (Pantoprazole)	S		Unknown	Not Reported
	Unspecified Ingredient	S		Unknown	Not Reported
	Escitalopram (Escitalopram)	S		Unknown	Not Reported
	Trifluoperazine	S		Unknown	Not Reported
	Potassium Chloride (Potassium Chloride)	S		Unknown	Not Reported
	Progestin (Progesterone)	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2013	9101164	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dispensed To Wrong Patient; Medication Error	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2013	9105954	EXPEDITED (15-DAY)		HO, LT	AU-FRI-1000042748		25 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Obsessive-Compulsive Disorder	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2013	9106012	EXPEDITED (15-DAY)		HO	IT-FRI-1000042749		36 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Pain; Vomiting	Escitalopram Oral Solution			S	Oral	Overdose: Cipralex 20 Ml Total		Forest
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2013	9114892	DIRECT		OT			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Depression; Nausea; Panic Attack; Performance Status Decreased; Product Substitution Issue; Quality Of Life Decreased; Suicidal Ideation; Vomiting; Weight Decreased	Escitalopram			S	Oral		2 WEEK 2 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2013	9145310	EXPEDITED (15-DAY)	Y	DE	2013-00382		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Simvastatin			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported
	Metoprolol			S				Not Reported
	Gabapentin			S				Not Reported
	Acetaminophen/Codeine			S				Not Reported
	Eszopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2013	9075985	EXPEDITED (15-DAY)		CA, DE, OT	US-FRI-1000041995		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cleft Lip; Cleft Palate; Congenital Anomaly; Cytogenetic Abnormality; Deafness; Double Outlet Right Ventricle; Exomphalos; Lung Disorder; Multiple Cardiac Defects; Neural Tube Defect; Newborn Persistent Pulmonary Hypertension; Pulmonary Artery Stenosis Congenital; Talipes; Transposition Of The Great Vessels; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest
	Zoloft			S	Transplacental			Not Reported
	Prenatal Vitamin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2013	9115380	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Escitalopram 20mg Generic			S	Oral		30 DAY	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2013	9118815	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Citalopram 20 Mg			S				Not Reported
Palpitations	Escitatopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2013	9148345	EXPEDITED (15-DAY)	Y	DE	2013-00500		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Simvastatin (Unknown)			S				Not Reported
	Escitalopram			S				Not Reported
	Lithium			S				Not Reported
	Methylphenidate			S				Not Reported
	Aripiprazole			S				Not Reported
	Valacyclovir			S				Not Reported
	Propoxyphene			S				Not Reported
	Hydrocodone			S				Not Reported
	Oxycodone			S				Not Reported
	Triazolam			S				Not Reported
	Acetaminophen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2013	9101173	EXPEDITED (15-DAY)		OT	US-FRI-1000042670			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obesity	Escitalopram			S				Forest
	Escitalopram			S				Not Reported
	Clozaril			S	Oral	300 Mg		Not Reported
	Clozaril			S				Not Reported
	Clozaril			S				Not Reported
	Clozaril			S				Not Reported
	Eskalith Cr			C				Not Reported
	Eskalith Cr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2013	9108605	EXPEDITED (15-DAY)		CA	US-FRI-1000042856		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Gastrooesophageal Reflux Disease; Patent Ductus Arteriosus; Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2013	9119388	DIRECT	Y	OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Cognitive Disorder	Escitalopram			S		Lexapro 20 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2013	9119453	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Tension	Lexapro			S	Oral	10 Mg. Daily Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2013	8012810	EXPEDITED (15-DAY)		CA, DE, HO, OT	US-PFIZER INC-2011139942		2 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Stenosis; Aortic Valve Disease Mixed; Bicuspid Aortic Valve; Endocarditis; Foetal Exposure During Pregnancy; Intracranial Venous Sinus Thrombosis; Left	Zoloft			S	Transplacental	50 Mg, 1x/Day		Pfizer
	Lexapro			S	Transplacental	Unk		Not Reported
	Hydroxyzine			C	Transplacental	Unk		Not Reported
	Amoxil			C	Transplacental	Unk		Not Reported
	Chromagen Ob			C	Transplacental	Unk		Not Reported

Ventricular Dysfunction; Left Ventricular Failure; Lung Assist Device Therapy; Mediastinal Haemorrhage; Patent Ductus Arteriosus; Pulmonary Valve Incompetence; Pulmonary Valve Stenosis	Naproxen Sodium S	C	Transplacental	Unk		Not Reported
	Nistatin	C	Transplacental	Unk		Not Reported
	Dulcolax	C	Transplacental	Unk		Not Reported
	Serax	C	Transplacental	15 Mg, 1x/Day		Not Reported
	Promethazine	C	Transplacental	Unk		Not Reported
	Acetaminophen\Hydrocodone Bitartrate	C	Transplacental	Unk		Not Reported
	Ortho Tri Cyclen	C	Transplacental	Unk		Not Reported
	Palgic Ds	C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2013	8468684	EXPEDITED (15-DAY)			JP-FRI-1000029186		33 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased	Lexapro			S	Oral	20 Mg		Forest
	Myslee			C	Oral	10 Mg		Not Reported
	Rize			C	Oral	10 Mg		Not Reported
	Goodmin			C	Oral	0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2013	9121472	NON-EXPEDITED			US-PFIZER INC-2013065355		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia Oral; Taste Disorder	Protonix			S		Unk		Pfizer
	Benadryl			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Klonopin			S		Unk		Not Reported
	Vitamin D Nos			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2013	8934442	EXPEDITED (15-DAY)		OT	DE-FRI-1000040677		26 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Solar Dermatitis	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2013	9119626	EXPEDITED (15-DAY)		HO	FR-FRI-1000042915		92 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased	Escitalopram			S	Oral	5 Mg		Forest
	Previscan (Fluindione)			S	Oral	1 Df		Not Reported
	Paracetamol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2013	9119862	EXPEDITED (15-DAY)		DS, OT	BR-ASTRAZENECA-2013SE11396			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foot Fracture; Pulmonary Embolism	Seroquel			S	Oral			Zeneca
	Lexapro			S	Unknown			Not Reported
	Unspecified Ingredient			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2013	9120583	EXPEDITED (15-DAY)		DE	US-ROCHE-1194082		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Arrest; Toxicity To Various Agents	Clonazepam			S	Oral			Not Reported
	Clonazepam			S	Oral	Overdose		Not Reported
	Propranolol			S	Oral			Not Reported

Propranolol	S	Oral	Overdose		Not Reported
Oxycodone	S	Oral			Not Reported
Oxycodone	S	Oral	Overdose		Not Reported
Trazodone	S	Oral			Not Reported
Trazodone	S	Oral	Overdose		Not Reported
Hydroxyzine	S	Oral			Not Reported
Hydroxyzine	S	Oral	Overdose		Not Reported
Risperidone	S	Oral			Not Reported
Risperidone	S	Oral	Overdose		Not Reported
Temazepam	S	Oral			Not Reported
Temazepam	S	Oral	Overdose		Not Reported
Benztropine	S	Oral			Not Reported
Benztropine	S	Oral	Overdose		Not Reported
Escitalopram	S	Oral			Not Reported
Escitalopram	S	Oral	Overdose		Not Reported
Ondansetron	S	Oral			Not Reported
Ondansetron	S	Oral	Overdose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2013	9123227	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Supraventricular Extrasystoles	Escitalopram 10 Mg			S	Oral	I Dose, Once/Day, Po	5 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2013	9145510	DIRECT	Y	OT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Mood Altered; Product Substitution Issue	Escitalopram		S	Oral	Not Reported
	Loestrin 24 Fe Tabs (Norethin Ace-Eth Estrad-Fe Tabs)		C		Not Reported
	Lexapro 20 Mg Tabs (Escitalopram Oxalate)		C		Not Reported
	Trazodone Hcl 50 Mg Tabs (Trazodone Hcl)		C		Not Reported
	Adderall Xr 30 Mg Xr24h-Cap (Amphetamine-Dextroamphetamine)		C		Not Reported
	Anusol-Hc 25mg Supp (Hydrocortisone Acetate)		C		Not Reported
	Flexeril 10mg Tabs (Cyclobenzaprine Hcl)		C		Not Reported
	Naprosyn 375 Mg Tabs (Naproxen)		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2013	9123771	EXPEDITED (15-DAY)		DE	US-ROCHE-1194074		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Naproxen			S	Oral			Not Reported
	Naproxen			S	Oral	Overdose		Not Reported
	Desipramine			S	Oral			Not Reported
	Desipramine			S	Oral	Overdose		Not Reported
	Diltiazem			S	Oral			Not Reported
	Diltiazem			S	Oral	Overdose		Not Reported
	Venlafaxine			S	Oral			Not Reported
	Venlafaxine			S	Oral	Overdose		Not Reported
	Lamotrigine			S	Oral			Not Reported
	Lamotrigine			S	Oral	Overdose		Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral	Overdose		Not Reported
	Armodafinil			S	Oral			Not Reported

Armodafinil	S	Oral	Overdose	Not Reported
Potassium Chloride	S	Oral		Not Reported
Potassium Chloride	S	Oral	Overdose	Not Reported
Trifluoperazine	S	Oral		Not Reported
Trifluoperazine	S	Oral	Overdose	Not Reported
Escitalopram	S	Oral		Not Reported
Escitalopram	S	Oral	Overdose	Not Reported
Pantoprazole	S	Oral		Not Reported
Pantoprazole	S	Oral	Overdose	Not Reported
Lansoprazole	S	Oral		Not Reported
Lansoprazole	S	Oral	Overdose	Not Reported
Rosuvastatin	S	Oral		Not Reported
Rosuvastatin	S	Oral	Overdose	Not Reported
Nitrofurantoin	S	Oral		Not Reported
Nitrofurantoin	S	Oral	Overdose	Not Reported
Diclofenac	S	Oral		Not Reported
Diclofenac	S	Oral	Overdose	Not Reported
Acetaminophen\Hydrocodone	S	Oral		Not Reported
Acetaminophen\Hydrocodone	S	Oral	Overdose	Not Reported
Acetaminophen/Propoxyphene	S	Oral		Not Reported
Acetaminophen/Propoxyphene	S	Oral	Overdose	Not Reported
Solifenacin	S	Oral		Not Reported
Solifenacin	S	Oral	Overdose	Not Reported
Ciprofloxacin	S	Oral		Not Reported
Ciprofloxacin	S	Oral	Overdose	Not Reported
Progestin	S	Oral		Not Reported
Progestin	S	Oral	Overdose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2013	9124371	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2013GR019098		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Depressed Level Of Consciousness; Drug Interaction; Hyperpyrexia; Leukocytosis; Muscle Rigidity; Myoglobinuria; Neuroleptic Malignant Syndrome; Pyrexia; Rhabdomyolysis; Stupor; Tachypnoea	Escitalopram			S		20 Mg, Qd		Not Reported
	Buspirone Hydrochloride			S		10 Mg, Qd		Novartis
	Amlodipine Besylate			S		5 Mg, Qd		Not Reported
	Irbesartan			S		150 Mg, Qd		Not Reported
	Lithium Carbonate			S		300 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2013	9124950	EXPEDITED (15-DAY)		DE	US-ROCHE-1194060		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Clonazepam			S	Oral			Not Reported
	Clonazepam			S	Oral	Overdose		Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral	Overdose		Not Reported
	Lamotrigine			S	Oral			Not Reported
	Lamotrigine			S	Oral	Overdose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2013	9135981	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2013-00617		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Lisinopril (Lisinopril)	S		Not Reported
	Quetiapine (Quetiapine) (Quetiapine)	S		Not Reported
	Escitalopram	S		Not Reported
	Trazodone (Trazodone)	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2013	9136026	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2013-00461		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lamotrigine (Lamotrigine)			S				Not Reported
	Escitalopram (Escitalopram)			S	Oral			Not Reported
	Clonazepam (Clonazepam) (Clonazepam)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2013	9138986	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2013-00656		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Citalopram			S				Not Reported
	Cyclobenzaprine			S				Not Reported
	Quetiapine			S	Oral			Not Reported
	Hydroxyzine			S				Not Reported
	Escitalopram			S				Not Reported
	Buspirone			S				Not Reported
	Levothyroxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2013	9145365	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2013-00321		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lamotrigine (Lamotrigine)			S		Unknown		Not Reported
	Diphenhydramine (Diphenhydramine)			S	Oral	Oral		Not Reported
	Escitalopram			S		Unknown		Not Reported

	Aripiprazole (Aripiprazole)			S		Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2013	9145625	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2013	9145981	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hallucination; Nausea; Panic Attack; Vomiting	Celexa			S				Not Reported
	Paxil			S				Not Reported
	Lexapro			S				Not Reported
	Citalopram			S				Not Reported
	Sertraline			S				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2013	9148785	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2013-00600		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents	Gabapentin (Gabapentin)			S				Not Reported
	Escitalopram			S				Not Reported
	Quetiapine (Quetiapine) (Quetiapine)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2013	8174938	EXPEDITED (15-DAY)	Y	HO, OT	JPI-P-017046		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Fatigue	Xyrem			S	Oral	Nightly		Not Reported

Syndrome; Diarrhoea; Fibromyalgia; Hiatus Hernia; Intervertebral Disc Degeneration; Intervertebral Disc Protrusion; Oesophageal Disorder; Oral Herpes; Osteoarthritis; Pancreatic Enzyme Abnormality; Rectal Haemorrhage; Road Traffic Accident; Spinal Meningeal Cyst; Transient Ischaemic Attack; Weight Decreased				Oral	4.5 Gm (2.25 Gm, 2 In 1 D)	
	Alosetron		S			Not Reported
	Armodafinil		C			Not Reported
	Cyclobenzaprine		C			Not Reported
	Naproxen		C			Not Reported
	Hydrocodone		C		As Required	Not Reported
	Escitalopram		S			Not Reported
	Pantoprazole Sodium		S			Not Reported
	Valacyclovir		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2013	9050662	EXPEDITED (15-DAY)		HO, OT	JP-FRI-1000042409		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Lexapro			S	Oral	10 Mg		Forest
	Lithium Carbonate			S	Oral	800 Mg		Not Reported
	Amoxan			C	Oral	100 Mg		Not Reported
	Crestor			C	Oral	2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2013	9127846	NON-EXPEDITED			US-GLAXOSMITHKLINE-A1004740A			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Disturbance In Attention; Drug Ineffective; Tremor	Lamictal			S				Glaxosmithkline
	Escitalopram			S				Glaxosmithkline
	Vyvanse			S				Not Reported
	Abilify			S				Not Reported
	Flaxseed Oil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2013	9127973	EXPEDITED (15-DAY)		CA	US-FRI-1000042932		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Multiple Congenital Abnormalities; Patent Ductus Arteriosus; Transposition Of The Great Vessels	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2013	9128874	EXPEDITED (15-DAY)		HO	CH-ASTRAZENECA-2013SE11778		84 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Neck Pain; Pancytopenia; Pyrexia; Therapeutic Product Effect Incomplete; Viral Infection	Nexium			S	Oral			Astrazeneca
	Cipralex			S	Unknown			Not Reported
	Remeron			S	Oral			Not Reported
	De-Ursil			C	Oral			Not Reported
	Aspirin Cardio			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2013	9146768	DIRECT	Y	OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea	Escitalopram 20mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2013	9148269	DIRECT	Y				37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Substitution Issue; Unevaluable Event	Escitalopram 10 Mg	S	10mg 1/D / Pill For 2 Years	2 YR	Not Reported
	Prozac	S	20 Mg 1/ D/Pill		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2013	9131279	EXPEDITED (15-DAY)		DE	CA-FRI-1000043005		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2013	9149923	DIRECT		OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Product Substitution Issue; Suicidal Ideation	Escalipram -Lexapro Generic-20 Mf			S	Oral	20 Mg 1 Per Day Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2013	9153024	DIRECT		OT			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Chest Discomfort; Confusional State; Nausea; Nervousness	Escitalopram			S	Oral			Teva
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2013	9506225	NON-EXPEDITED		DE	RB-36229-2012		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Suboxone			S				Not Reported

Escitalopram	S		Not Reported
Acetaminophen W/ Hydrocodone	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2013	8562690	EXPEDITED (15-DAY)		HO, LT	CH-ASTRAZENECA-2012SE30117		46 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hyperhidrosis; Mydriasis; Myoclonus; Serotonin Syndrome; Tremor	Nexium			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Prezista			S	Oral			Not Reported
	Norvir			S	Oral			Not Reported
	Truvada			C	Oral	200/245 Mg Daily		Not Reported
	Kapanol			C	Oral			Not Reported
	Wellvone			C	Oral			Not Reported
	Noroxin			C	Oral			Not Reported
	Anxiolit			C	Oral			Not Reported
	Torasemid			C	Oral			Not Reported
	Importal			C	Oral			Not Reported
	Seretide			C	Respiratory (inhalation)			Not Reported
	Nasonex			C	Nasal			Not Reported
	Rohypnol			C	Oral			Not Reported
	Intelence			C				Not Reported
	Isentress			C				Not Reported
	3 Tc			C				Not Reported
	Aldactone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2013	9058845	EXPEDITED (15-DAY)		OT	US-FRI-1000042337		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disturbance In Attention; Dyspepsia; Dysphemia; Headache; Hemiparesis; Hypoaesthesia	Escitalopram	S	Oral	10 Mg		Forest
	Zyrtec	C	Oral	Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2013	9095660	EXPEDITED (15-DAY)		HO, LT	AT-PFIZER INC-2013054234		65 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles	Edronax			S		4 Mg, Unk		Pfizer
	Tritace			S	Oral	2.5 Mg, Daily		Pfizer
	Quilonorm			S	Unknown	225 Mg, Daily		Not Reported
	Quilonorm			S	Unknown	675 Mg, Daily		Not Reported
	Quilonorm			S	Unknown	450 Mg, Daily		Not Reported
	Cipralex			S		10 Mg, Unk		Not Reported
	Lamictal			S		50 Mg, Unk		Not Reported
	Risperdal			S	Unknown	3 Mg, Daily		Not Reported
	Risperdal			S	Unknown	2 Mg, Daily		Not Reported
	Euthyrox			S		75 Ug, Unk		Not Reported
	Pantoloc			S		40 Mg, Unk		Not Reported
	Seroquel			S	Oral	100 Mg, 1x/Day		Not Reported
	Venlafab			S	Oral	150 Mg, Daily		Not Reported
	Venlafab			S	Oral	300 Mg, Daily		Not Reported
	Escitalopram			C		Unk		Not Reported
	Lamotrigine			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2013	9135655	EXPEDITED (15-DAY)		OT	CH-MYLANLABS-2013S1004115		46 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Serotonin Syndrome	Darunavir	S	Unknown		Not Reported
	Ritonavir	S	Unknown		Not Reported
	Esomeprazole	S	Unknown	40mg Daily	Not Reported
	Escitalopram	S	Unknown		Mylan
	Truvada	C	Unknown	Emtricitabine 200/Tenofovir Disoproxil Fumarate 245mg Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2013	9137753	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-PERC20110027		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Panic Attack	Percocet			S	Oral	10/625 Mg		Not Reported
	Lexapro			S	Oral			Not Reported
	Lortab			C	Oral	Unk		Not Reported
	Dextroamphetamine			C		Unk		Not Reported
	Clonazepam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2013	9150052	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Economic Problem; Memory Impairment; Product Substitution Issue; Therapeutic Product Effect Decreased; Therapy Non-Responder	Escitalopram			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2013	9153345	DIRECT					40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Insomnia; Irritable Bowel Syndrome; Product Substitution Issue	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2013	9153399	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eructation; Food Intolerance; Nausea; Product Substitution Issue; Retching	Escitalopram Oxalate			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2013	9138775	NON-EXPEDITED		DE	US-ENDO PHARMACEUTICALS INC.-PERC20110001		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Chest Pain; Drug Abuse	Percocet-5			S	Oral	5/325 Mg		Not Reported
	Percocet-5			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Soma			S	Oral			Not Reported
	Soma			S				Not Reported
	Valium			S		Unk		Not Reported
	Fentora			S	Buccal			Not Reported
	Fentora			S				Not Reported
	Fentanyl			S	Transdermal	Unk		Not Reported
	Fentanyl			S				Not Reported
	Zipsor			S	Oral	25 Mg		Not Reported
	Zipsor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2013	9139672	NON-EXPEDITED			US-PFIZER INC-2013073565		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment; Psychiatric Symptom	Zoloft			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Trazodone			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2013	9150639	DIRECT		OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Headache; Hot Flush; Muscular Weakness; Nausea; Product Substitution Issue	Escitalopram 10mg Aurobiudo Pharma			S		Expiration 08-Feb-2014		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2013	9252320	NON-EXPEDITED	Y	DS	163-21880-12083000		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Oedema Peripheral	Revlimid			S	Oral Oral Oral Oral	5 Mg, 1 In 1 D, Po 10 Mg, 1 In 1 D, Po 5 Mg, 1 In 1 D, Po 5 Mg, 1 In 2 D, Po		Not Reported
	Dexamethasone			S				Not Reported

	(Dexamethasone)		
	Aspirin (Acetylsalicylic Acid)	S	Not Reported
	Lipitor (Atorvastatin) (40 Milligram, Tablets)	S	Not Reported
	Calcium (Calcium)	S	Not Reported
	Coreg (Carvedilol)	S	Not Reported
	Centrum (Centrum) (Tablets)	S	Not Reported
	Fragmin (Heparin-Fraction, Sodium Salt)	S	Not Reported
	Allopurinol	S	Not Reported
	Ergocalciferol (Ergocalciferol)	S	Not Reported
	Lexapro (Escitalopram Oxalate)	S	Not Reported
	Gemfibrozil (Gemfibrozil)	S	Not Reported
	Acetaminophen\Hydrocodone Bitartrate	S	Not Reported
	Hydroxyzine (Hydroxyzine)	S	Not Reported
	Keppra (Levetiracetam)	S	Not Reported
	Magnesium Oxide (Magnesium Oxide) (500 Milligram, Tablets)	S	Not Reported
	Ritalin	S	Not Reported
	Nortriptyline (Nortriptyline)	S	Not Reported
	Protonix	S	Not Reported
	Phenergan (Promethazine)	S	Not Reported
	Maxalt (Rizatriptan Benzoate)	S	Not Reported
	Valtrex (Valciclovir Hydrochloride)	S	Not Reported
	Vitamin D (Ergocalciferol) (Capsules)	S	Not Reported
	Platelets (Platelets)	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2013	9252440	NON-EXPEDITED	Y	HO, OT	163-21880-12083020		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Thrombosis	Revlimid			S	Oral Oral	25 Mg, 1 In 1 D, Po 10 Mg, 1 In 1 D, Po		Not Reported
	Valacyclovir			S				Not Reported
	Prochlorperazine			S				Not Reported
	Oxycontin (Oxycodone Hydrochloride)			S				Not Reported

Enoxaparin (Enoxaparin)	S		Not Reported
Oxycodone (Oxycodone)	S		Not Reported
Lexapro	S		Not Reported
Protonix	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2013	8442926	EXPEDITED (15-DAY)		DE, OT	JP-FRI-1000028810		79 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pneumonia Aspiration; Pneumothorax	Lexapro			S	Oral	10 Mg		Forest
	Keishi-Ka-Shakuyaku-To			S	Oral			Not Reported
	Ganaton			C	Oral			Not Reported
	Myslee			C	Oral			Not Reported
	Yodel-S			C	Oral			Not Reported
	Celecox			C	Oral	200 Mg		Not Reported
	Takepron			C	Oral	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2013	8554479	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000030395		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asterixis; Encephalopathy; Hepatic Failure; Hepatitis Acute; Jaundice; Liver Disorder	Escitalopram			S				Forest
	Esperal			S				Not Reported
	Utrogestan			S				Not Reported
	Seresta			C				Not Reported
	Levothyroxine			C		75 Mg		Not Reported
	Estreva			C	Oral			Not Reported
	Milnacipran			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2013	9030466	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013024458		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Crying; Depression; Drug Ineffective; Product Use In Unapproved Indication; Social Fear	Pristiq	S	Oral	Unk	Pfizer
	Pristiq	S	Oral	50 Mg, 2x/Day	Pfizer
	Pristiq	S	Oral	50 Mg, 3x/Day	Pfizer
	Pristiq	S	Oral	100 Mg, 2x/Day	Pfizer
	Pristiq	S	Oral	100mg Morning, 50mg Afternoon And 100mg Night	Pfizer
	Pristiq	S	Oral	50 Mg, Five Times Daily	Pfizer
	Zoloft	S		Unk	Pfizer
	Lithium Carbonate	S		300 Mg, 3x/Day	Pfizer
	Prozac	S		Unk	Not Reported
	Lamictal	S		Unk	Not Reported
	Wellbutrin	S		Unk	Not Reported
	Lexapro	S		Unk	Not Reported
	Abilify	S		10 Mg,Daily	Not Reported
	Topamax	S		Unk	Not Reported
	Klonopin	S		Unk	Not Reported
	Valium	S		Unk	Not Reported
	Paxil	S		Unk	Not Reported
	Celexa	S		Unk	Not Reported
	Cymbalta	S		Unk	Not Reported
	Anafranil	S		Unk	Not Reported
	Imipramine	S		Unk	Not Reported
	Tegretol	S		Unk	Not Reported
	Luvox	S		Unk	Not Reported
	Seroquel	S		Unk	Not Reported
	Depakote	S		Unk	Not Reported
	Seroquel Xr	C		250 Mg, Daily	Not Reported
	Xanax	C		0.5 Mg, As Needed	Not Reported
	Adderall	C		5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2013	9143244	EXPEDITED (15-DAY)		DE	US-ASTELLAS-2013JP003245		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Solifenacin			S	Oral			Astellas
	Desipramine			S	Oral	Unk		Not Reported
	Diltiazem			S	Oral			Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Armodafinil			S	Oral	Unk		Not Reported
	Potassium Chloride			S	Oral	Unk		Not Reported
	Trifluoperazine			S	Oral			Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Thyroid Preparations			S	Oral	Unk		Not Reported
	Pantoprazole			S	Oral	Unk		Not Reported
	Lansoprazole			S	Oral	Unk		Not Reported
	Rovustatin			C	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Nitrofurantoin			S	Oral	Unk		Not Reported
	Diclofenac			S	Oral	Unk		Not Reported
	Acetaminophen W/Hydrocodone			S	Oral	Unk		Not Reported
	Acetaminophen W/Propoxyphene			S	Oral	Unk		Not Reported
	Ciprofloxacin			S	Oral	Unk		Not Reported
	Progestin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2013	9143824	EXPEDITED (15-DAY)		HO	IT-ROCHE-1197897		20 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Suicide Attempt; Toxicity To Various Agents	Valium			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Minias			S	Oral			Not Reported
	Alcohol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2013	9144330	EXPEDITED (15-DAY)		OT	FR-FRI-1000043174			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Bleeding; Puncture Site Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Triatec (Ramipril)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2013	9144370	EXPEDITED (15-DAY)		HO	FR-FRI-1000043173		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram			S	Oral	10 Mg		Forest
	Micardiplus			C				Not Reported
	Modopar			C				Not Reported
	Spiriva			C				Not Reported
	Gliclazide			C				Not Reported
	Detrusitol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2013	9144656	EXPEDITED (15-DAY)		HO	DE-FRI-1000043083			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Potentiating Drug Interaction; Urinary Retention	Escitalopram			S	Oral	5 Mg		Forest
	Mirtazapin			S	Oral	15 Mg		Not Reported
	Metoprolol			S	Oral	95 Mg		Not Reported

Tafil	C	Oral	1.5 Mg		Not Reported
Tafil	C	Oral	2.5 Mg		Not Reported
Hct Hexal	C	Oral	12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2013	6679655	EXPEDITED (15-DAY)		CA, DE, HO, OT	US-PFIZER INC-2008049876			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Stenosis; Atrioventricular Septal Defect; Foetal Exposure During Pregnancy; Hepatic Congestion; Hypoplastic Left Heart Syndrome; Lung Disorder; Mitral Valve Hypoplasia; Multiple Congenital Abnormalities; Newborn Persistent Pulmonary Hypertension; Patent Ductus Arteriosus; Renal Tubular Necrosis; Right Ventricular Hypertrophy	Zoloft			S	Transplacental	50 Mg, 1x/Day		Pfizer
	Zoloft			S				Pfizer
	Lexapro			S	Transplacental	10 Mg, 1x/Day		Not Reported
	Prenatal Vitamins			C	Transplacental	Unk		Not Reported
	Reglan			C	Transplacental	10 Mg, Unk		Not Reported
	Zyrtec			C	Transplacental	10 Mg, Unk		Not Reported
	Benadryl			C	Transplacental	Unk		Not Reported
	Tylenol			C	Transplacental	Unk		Not Reported
	Robitussin "Robins"			C	Transplacental	Unk		Not Reported
	Z-Pack			C	Transplacental	Unk		Not Reported
	Kaopectate			C	Transplacental	Unk		Not Reported
	Darvocet			C	Transplacental	Unk		Not Reported
	Cephalexin			C	Transplacental	500 Mg, Unk		Not Reported
	Zithromax			C	Transplacental	250 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2013	9146841	EXPEDITED (15-DAY)		HO, LT	CH-PFIZER INC-2013077482		53 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Irfen			S	Oral	600 Mg, Up To 7x/Day		Not Reported
	Surmontil			S	Oral	75 Mg, 1x/Day		Not Reported

Cipralex	S	Oral	10 Mg, 1x/Day		Not Reported
Methadone	S	Oral	40 Mg, 2x/Day		Not Reported
Aspirin Cardio	C	Oral	100 Mg, 1x/Day		Not Reported
Triatec Comp	C	Oral	25mg/5mg, 1x/Day		Not Reported
Pantozol (Switzerland)	C	Oral	40 Mg, 1x/Day		Not Reported
Paracetamol	C		Unk		Not Reported
Ibuprofen	C		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2013	9147502	EXPEDITED (15-DAY)		OT	US-TEVA-389639USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Obesity; Tachycardia	Escitalopram			S				Ivax
	Escitalopram			S				Not Reported
	Clozaril			S	Oral	300 Milligram Daily;		Not Reported
	Eskalith			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2013	9147771	EXPEDITED (15-DAY)		HO, LT	ES-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-ES-00		89 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Micardisplus			S	Oral	1 Anz		Boehringer Ingelheim
	Escitalopram			S	Oral	15 Mg		Not Reported
	Captopril			C	Oral	50 Mg		Not Reported
	Orfidal Wyeth			C	Oral	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2013	9154998	DIRECT	Y				35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Depressed Mood; Disease Recurrence; Product Substitution Issue	Escitalopram 10mg Aurobiudo Pharma		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2013	9155005	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Oral	10 Mg Daily Oral (047)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2013	9148817	EXPEDITED (15-DAY)		OT	US-JNJFOC-20130216891			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Loss Of Weight; Alopecia; Depression; Hair Texture Abnormal; Influenza Like Illness; Memory Impairment; Migraine; Musculoskeletal Pain; Nausea; Neoplasm; Nephrolithiasis; Vomiting	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Synthroid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2013	9148819	EXPEDITED (15-DAY)		DE, HO	GR-MYLANLABS-2013S1004397		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Drug Interaction; Neuroleptic Malignant Syndrome;	Lithium			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Buspirone			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported

Rhabdomyolysis	Irbesartan	S	Unknown	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2013	9152543	EXPEDITED (15-DAY)		HO	JP-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-BI-05		82 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Micardis			S	Oral			Boehringer Ingelheim
	Lexapro			S	Oral			Not Reported
	Fluitran			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2013	9153963	DIRECT		HO			31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Feeling Abnormal; Headache; Palpitations; Product Substitution Issue; Suicidal Ideation	Escitalopram 20mg			S	Oral	15 Mg To 20 Mg		Mylan
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2013	9154175	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral	20mg Am Po Jan - March 2012		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2013	9157279	DIRECT		OT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disturbance In Attention; Dizziness; Feeling Abnormal; Hallucination	Lexapro		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2013	9157424	DIRECT		OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Blood Pressure Fluctuation; Blood Pressure Increased; Dizziness; Feeling Hot; Headache; Heart Rate Abnormal; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nausea; Paraesthesia	Lexapro / Forest Pharmace			S		Took 1/2 Tab 20 Mg 1x Day		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2013	8301396	EXPEDITED (15-DAY)		CA, OT	US-RB-035466-11			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Foetal Exposure During Pregnancy	Suboxone Film			S	Transplacental	Suboxone Film		Reckitt Benckiser
	Lexapro			S	Transplacental			Not Reported
	Marijuana			S	Transplacental	Dosing Details Unknown		Not Reported
	Benzodiazepines			S	Transplacental	Dosing Details Unknown		Not Reported
	Opiates			S	Transplacental	Dosing Details Unknown		Not Reported
	Nicotine			S	Transplacental	Dosing Details Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2013	9153466	EXPEDITED (15-DAY)		OT	GR-MYLANLABS-2013S1004298		84 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pseudodementia	Escitalopram	S	Oral		Mylan
	Ramipril	C	Oral		Not Reported
	Lexotanil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2013	9154780	EXPEDITED (15-DAY)		HO	FR-FRI-1000043239		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Urinary Retention	Escitalopram			S	Oral	5 Mg		Forest
	Aspegic [Acetylsalicylate Lysine]			C		100 Mg		Not Reported
	Triatec (Ramipril)			C		1.25 Mg		Not Reported
	Triatec (Ramipril)			C				Not Reported
	Bisoce			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2013	9154801	EXPEDITED (15-DAY)		DE, OT	GB-FRI-1000042718		20 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Dissociation; Dizziness; Feeling Abnormal; Feeling Abnormal; Insomnia; Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2013	9154925	NON-EXPEDITED			US-ABBOTT-12P-163-0967412-00		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Mood Altered; Off Label Use	Lupron Depot 11.25 Mg			S	Intramuscular			Not Reported
	Lexapro			S				Not Reported
	Depakote			C				Not Reported
	Toprol Xl			C				Not Reported
	Zonisamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2013	9155731	EXPEDITED (15-DAY)		HO	PHHY2013IT022172			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt; Toxicity To Various Agents	Diazepam			S				Novartis
	Lormetazepam			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2013	9155742	EXPEDITED (15-DAY)		HO	IT-FRI-1000043247		20 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt; Toxicity To Various Agents	Escitalopram Oral Solution			S	Oral	10 Df		Forest
	Minias			S	Oral			Not Reported
	Valium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2013	9157806	DIRECT		OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agoraphobia; Drug Ineffective; Hypertension; Panic Attack; Product Substitution Issue	Escitalopram 10mg Aurobiudo Pharma			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2013	9157351	EXPEDITED (15-DAY)		HO	FR-FRI-1000043245		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest
	Pegasys			S	Intravenous (not	180 Mcg Weekly		Not Reported

					otherwise specified)					
	Copegus			S	Oral	1000 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2013	9158371	EXPEDITED (15-DAY)		DE	GR-TEVA-390030ISR		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Drug Interaction; Neuroleptic Malignant Syndrome; Rhabdomyolysis	Amlodipine			S	Unknown	5 Milligram Daily;		Teva
	Lithium			S	Unknown	900 Milligram Daily;		Not Reported
	Escitalopram			S	Unknown	20 Milligram Daily;		Not Reported
	Buspirone			S	Unknown	10 Milligram Daily;		Not Reported
	Irbesartan			S	Unknown	150 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2013	9159273	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Myalgia	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2013	9162721	EXPEDITED (15-DAY)	Y	DE	AMLO20130006		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Antipsychotic Drug Level Increased; Blood Sodium Increased; Blood Uric Acid Increased; Cardio-Respiratory Arrest; Haemodialysis;	Amlodipine Besylate			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported
	Lithium Carbonate			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported
	Buspirone Hydrochloride			S	Oral			Not Reported

Neuroleptic Malignant Syndrome; Rhabdomyolysis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2013	7853856	NON-EXPEDITED			US-ABBOTT-10P-163-0640781-00		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Trismus; Trismus	Depakote			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Depakote			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Synthroid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2013	9002329	EXPEDITED (15-DAY)		OT	JP-FRI-1000040680		82 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome; Ventricular Extrasystoles	Lexapro			S	Oral	20 Mg		Forest
	Betamac			S	Oral	150 Mg		Not Reported
	Solanax			C	Oral	1.2 Mg		Not Reported
	Myslee			C	Oral	10 Mg		Not Reported
	Mexitil			C	Oral	150 Mg		Not Reported
	Diovan			C	Oral	40 Mg		Not Reported

	Actonel		C	Oral	2.5 Mg	Not Reported
	Magmitt		C	Oral	990 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2013	9109801	EXPEDITED (15-DAY)		HO	AT-FRI-1000042800			Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Atopic; Urticaria	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Stablon			S	Oral	37.5		Not Reported
	Cymbalta			S		60		Not Reported
	Trittico			C		200		Not Reported
	Dominal (Acetylsalicylic Acid)			C		80		Not Reported
	Valdoxan			C		25		Not Reported
	Valdoxan			C		50		Not Reported
	Valdoxan			C		50		Not Reported
	Cetirizin			C		20		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2013	9160372	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20130216988		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Risperdal			S	Oral			Not Reported
	Seroplex			S	Unknown			Not Reported
	Tercian			S	Unknown			Not Reported
	Depakote			S	Unknown			Not Reported
	Solian			S	Unknown			Not Reported
	Imovane			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2013	9161503	EXPEDITED (15-DAY)		CA	US-FRI-1000043263		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spina Bifida	Lexapro			S				Forest
	Celexa			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2013	9163059	DIRECT		OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chemical Poisoning; Dizziness; Feeling Abnormal; Impaired Driving Ability; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Product Quality Issue; Tremor; Tremor	Escitalopram			S	Oral			Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2013	9173436	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2013-02172		56 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Gastritis; Tardive Dyskinesia	Amisulpride			S			1 DAY 1 DAY	Not Reported
	Escitalopram (Escitalopram)			S			1 WEEK	Not Reported
	Fluvoxamine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2013	8916971	EXPEDITED (15-DAY)		HO	FR-FRI-1000040524		92 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cyanosis; Respiratory Distress	Escitalopram		S	Oral	10 Mg	Forest
	Tiapridal		S	Oral	75 Mg	Not Reported
	Imovane		S	Oral	3.75 Mg	Not Reported
	Seresta		S	Oral	10 Mg	Not Reported
	Coversyl		C			Not Reported
	Lasilix		C			Not Reported
	Inexium		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2013	9162307	EXPEDITED (15-DAY)		HO	PHHY2013ES023194		69 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Dafiro Hct			S	Oral	1 Df, Qd (160 Mg Vals, 10 Mg Amlo And 12.5 Mg Hydro)		Novartis
	Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Lorazepam Cinfa			C		1 Mg, Unk		Not Reported
	Dianben			C		850 Mg, Unk		Not Reported
	Simvastatin			C		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2013	9162933	EXPEDITED (15-DAY)		OT	ZA-FRI-1000043364		28 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome	Escitalopram			S	Oral	20 Mg		Forest
	Yasmin			C	Oral			Not Reported
	Trepiline			C	Oral	20 Mg		Not Reported
	Stilpane			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2013	9163501	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013084207		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Imprisonment; Myocardial Infarction; Nasopharyngitis; Panic Attack; Suicide Attempt	Effexor			S		Unk		Pfizer
	Ativan			S		Unk		Pfizer
	Lithium Carbonate			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Concerta			S		Unk		Not Reported
	Depakote			S		Unk		Not Reported
	Trileptal			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Ambien			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2013	9163649	EXPEDITED (15-DAY)		DE	GR-BRISTOL-MYERS SQUIBB COMPANY-17442690		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Neuroleptic Malignant Syndrome	Irbesartan			S				Bristol Myers Squibb
	Buspirone			S				Not Reported
	Lithium			S				Not Reported
	Amlodipine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2013	9163674	EXPEDITED (15-DAY)		CA	US-FRI-1000043278		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2013	9163692	EXPEDITED (15-DAY)		CA	US-FRI-1000043270		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Talipes	Lexapro	S	Transplacental		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2013	9163802	EXPEDITED (15-DAY)		CA	US-FRI-1000043280		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect	Lexapro			S	Transplacental			Forest
	Celexa			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2013	9163969	EXPEDITED (15-DAY)		CA	US-FRI-1000043291		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip; Cleft Palate	Lexapro			S				Forest
	Celexa			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2013	9167300	DIRECT	Y	LT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Escitalopram Oxalate			S		1 Tab Daily	3 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2013	8697780	EXPEDITED (15-DAY)		OT	US-ASTRAZENECA-2012SE47720		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Feeding Disorder; Gait Inability; Intentional Product Misuse; Neurological Procedural Complication; Product Dose Omission; Vomiting	Nexium			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Protonix			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2013	8957565	EXPEDITED (15-DAY)		OT	FR-FRI-1000040914		29 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicide; Road Traffic Accident; Suicide Attempt	Escitalopram			S	Oral	5 Mg		Forest
	Methadone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2013	9138280	EXPEDITED (15-DAY)		DE, HO, OT	GR-RANBAXY-2013RR-65730		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Drug Interaction; Neuroleptic Malignant Syndrome	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Lithium			S	Unknown	300 Mg, Tid		Not Reported
	Buspirone			S	Unknown	10 Mg, Qd		Not Reported
	Amlodipine			S	Unknown	5 Mg, Qd		Ranbaxy
	Irbesartan			S	Unknown	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2013	9161098	EXPEDITED (15-DAY)		OT	TR-FRI-1000043298		43 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S		20 Mg		Forest
	Isoniazid			S				Not Reported
	Corticosteroids			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2013	9164792	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013085507		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Loss Of Weight; Alopecia; Depression; Hair	Lyrica			S		Unk		Pfizer

Texture Abnormal; Influenza Like Illness; Memory Impairment; Migraine; Musculoskeletal Pain; Nausea; Neoplasm; Nephrolithiasis; Vomiting	Gabapentin	S		Unk	Pfizer
	Topamax	S	Oral	100 Mg, 1x/Day (50mg, 2 In 1 Day)	Not Reported
	Topamax	S			Not Reported
	Lexapro	S		Unk	Not Reported
	Synthroid	C		175 Ug, In 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2013	9166001	EXPEDITED (15-DAY)		DE	GR-ROXANE LABORATORIES, INC.-2013-RO-00374RO		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Neuroleptic Malignant Syndrome	Lithium Carbonate			S		900 Mg		Roxane
	Amlodipine			S		5 Mg		Roxane
	Irbesartan			S		150 Mg		Roxane
	Escitalopram Oxalate			S		20 Mg		Not Reported
	Buspirone Hydrochloride			S		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2013	9166997	EXPEDITED (15-DAY)		HO	FR-TEVA-390507ISR		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Kidney Injury; Bradycardia; Diarrhoea; Disorientation; Hyperkalaemia; Hypotension; Lactic Acidosis; Malaise; Pyrexia; Septic Shock; Staphylococcal Bacteraemia; Vomiting	Metformine			S	Oral	2550 Milligram Daily;		Goldline
	Atenolol			S	Oral	100 Milligram Daily;		Not Reported
	Atenolol			S	Oral	100 Milligram Daily;		Not Reported
	Verapamil			S	Oral	240 Milligram Daily;		Not Reported
	Cokenzen			S	Oral	1 Dosage Forms Daily; Candesartan Cilexetil 16mg/ Hydrochlorothiazide 12.5mg		Not Reported
	Glucor			S	Oral	150 Milligram Daily;		Not Reported
	Mediatensyl			S	Oral	180 Milligram Daily;		Not Reported

	Ciprofibrate	S	Oral	1 Dosage Forms Daily;	Not Reported
	Seroplex	S	Oral	10 Milligram Daily;	Not Reported
	Seroplex	S	Oral	10 Milligram Daily;	Not Reported
	Norset	S	Oral	15 Milligram Daily;	Not Reported
	Xanax	S	Oral	3 Dosage Forms Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2013	9167451	EXPEDITED (15-DAY)		OT	GR-ACCORD-016890		63 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Off Label Use	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2013	9168352	EXPEDITED (15-DAY)		HO	FR-FRI-1000043429		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Haemorrhage	Escitalopram			S	Oral	20 Mg		Forest
	Clopidogrel			S		1 Df		Not Reported
	Perindopril			C				Not Reported
	Verapamil			C				Not Reported
	Simvastatin			C				Not Reported
	Prednisone			C				Not Reported
	Esomeprazole			C				Not Reported
	Symbicort			C				Not Reported
	Alprazolam			C				Not Reported
	Doliprane			C				Not Reported
	Forlax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2013	9168770	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2013085553		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia;	Inspra			S	Oral	25 Mg, Daily		Pfizer

Thrombocytopenia	Calciparin	S	Subcutaneous	0.2 Ml, 2x/Day	Not Reported
	Clamoxyl (Amoxicillin)	S	Oral	1 G, 2x/Day	Not Reported
	Zeclar	S	Oral	500 Mg, 2x/Day	Not Reported
	Seroplex	S	Oral	10 Mg, Daily	Not Reported
	Paracetamol	S	Intravenous (not otherwise specified)	1 G, 4x/Day	Not Reported
	Crestor	S	Oral	5 Mg, Daily	Not Reported
	Plavix	S	Oral	75 Mg, Daily	Not Reported
	Kardegic	S	Oral	75 Mg, Daily	Not Reported
	Inexium	S	Oral	40 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2013	9169409	EXPEDITED (15-DAY)		HO, LT	CH-TEVA-390523ISR		53 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Overdose	Irfen			S	Oral	1800 Milligram Daily;		Ivax
	Irfen			S	Oral	Dosing Scheme Unclear, Up To 7 Tablets Per Day, Start Date Unknown		Ivax
	Surmontil			S	Oral	75 Milligram Daily; Start Date Unknown		Not Reported
	Cipralex			S	Oral	10 Milligram Daily; Start Date Unknown		Not Reported
	Methadon Streuli			S	Oral	80 Milligram Daily; Start Date Unknown		Not Reported
	Lyrica			S	Oral	300 Milligram Daily; Start Date Unknown		Not Reported
	Aspirin Cardio			C	Oral	100 Milligram Daily;		Not Reported
	Triatec Comp			C	Oral	1 Dosage Forms Daily; 1 Dosage Form = 25 Mg Hydrochlorothiazide/ 5 Mg Ramipril		Not Reported

	Pantozol (Switzerland)	C	Oral	40 Milligram Daily; Long-Term Therapy		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2013	9169636	EXPEDITED (15-DAY)		OT	AU-FRI-1000043491			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic Syndrome	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2013	9171271	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2013	9173481	DIRECT	Y				42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Feeling Abnormal; Thinking Abnormal	Escitalopram, 10 Mg, Teva			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2013	8990870	EXPEDITED (15-DAY)		HO	JP-009507513-1212JPN011109		27 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Fracture	Remeron			S	Oral	0.5 Df, Qd		Merck
	Remeron			S	Oral	1 Df, Qd		Merck
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Solanax			S	Oral	1.2 Mg, Qd		Not Reported

Loxonin	S	Oral	60 Mg, Qd		Not Reported
Mucosta	S	Oral	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2013	9024924	EXPEDITED (15-DAY)		HO, OT	US-MERCK-1001USA00361		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain; Depression; Gastritis; Suicidal Behaviour; Suicidal Ideation	Raltegravir Potassium			S	Oral	400 Mg, Bid		Merck
	Raltegravir Potassium			S	Oral	400 Mg, Bid		Merck
	Raltegravir Potassium			S	Oral	400 Mg, Bid		Merck
	Darunavir			C	Oral	600 Mg, Bid		Not Reported
	Darunavir			C	Oral	Unk Unk, Bid		Not Reported
	Ritonavir			C	Oral	100 Mg, Bid		Not Reported
	Ritonavir			C	Oral	Unk Unk, Bid		Not Reported
	Etravirine			C	Oral	200 Mg, Bid		Not Reported
	Bactrim Ds			C	Oral	On Monday, Tuesday And Wednesday		Not Reported
	Melatonin			C	Oral			Not Reported
	Lexapro			S	Oral	5 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Epzicom			S	Oral	600/300		Not Reported
	Epzicom			S	Oral	600/300		Not Reported
	Depo-Provera			C	Intramuscular	Unk Unk, Qm3		Not Reported
	Zoloft			C	Oral	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2013	9171973	EXPEDITED (15-DAY)		CA	US-FRI-1000043480		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly;	Lexapro			S	Transplacental			Forest

Craniosynostosis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2013	9171984	EXPEDITED (15-DAY)		CA	NO-FRI-1000043500			Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S	Transplacental	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2013	9172134	EXPEDITED (15-DAY)		HO	IT-FRI-1000043368		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypotension; Intentional Overdose; Intentional Self-Injury; Syncope	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S		70 Unit Dose		Forest
	Depakin Chrono			S	Oral	500 Mg		Not Reported
	Depakin Chrono			S		40 Unit Dose		Not Reported
	Torvast			S	Oral	20 Mg		Not Reported
	Torvast			S		35 Unit Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2013	9172223	EXPEDITED (15-DAY)		HO, OT	RS-FRI-1000043541		65 YR	Male	SRB

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastritis; Hepatitis Toxic; Nausea; Transaminases Increased; Vomiting	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Bromazepam			C	Oral	1.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2013	9173184	DIRECT	Y	HO			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dizziness; Dyspnoea	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2013	9173351	DIRECT		OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Headache; Muscle Spasms; Pain In Extremity	Escitalopram Oxalate			S			4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2013	6128914	EXPEDITED (15-DAY)		DE	US-JNJFOC-20060902622		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Blood Creatine Phosphokinase Increased; Completed Suicide; Hepatic Function Abnormal; Hypotension; Intentional Overdose; Myoglobin Blood Increased; Renal Impairment; Respiratory Failure; Subarachnoid Haemorrhage; Tachycardia; Urinary Retention	Cyclobenzaprine			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Pseudoephedrine Hydrochloride			S	Oral			Not Reported
	Aspirin		Y	S	Oral			Not Reported
	Acetaminophen & Codeine Phosphate			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2013	7924667	EXPEDITED (15-DAY)		DS, OT	US-PFIZER INC-2008067170		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Dissociation; Disturbance	Sertraline Hcl			S		Unk		Pfizer

In Sexual Arousal; Disturbance In Sexual Arousal; Emotional Disorder	Paroxetine	S	Unk	Unknown
	Venlafaxine Hydrochloride	S	Unk	Pfizer
	Fluoxetine Hcl	S	Unk	Pfizer
	Escitalopram Oxalate	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2013	9016040	EXPEDITED (15-DAY)		OT	CH-FRI-1000041665			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram			S				Forest
	Levaxin			C				Not Reported
	Augmentin			C				Not Reported
	Depakin			C				Not Reported
	Rivotril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2013	9174230	NON-EXPEDITED		DE	US-JNJFOC-2006111647		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Hepatic Function Abnormal; Intentional Overdose; Renal Impairment; Respiratory Failure; Subarachnoid Haemorrhage	Pseudoephedrine Hydrochloride		Y	S	Oral			Not Reported
	Pseudoephedrine Hydrochloride			S	Oral	Daily Dose Text: Unknown		Not Reported
	Ibuprofen			S	Oral	Daily Dose Text: Unknown		Not Reported
	Ibuprofen			S	Oral	Daily Dose Text: Unknown		Not Reported
	Acetylsalicylic Acid		Y	S	Oral	Daily Dose Text: Unknown		Not Reported
	Paracetamol+Codeine			S	Oral	Daily Dose Text: Unknown		Not Reported
	Naproxen			S	Oral	Daily Dose Text: Unknown		Not Reported
	Escitalopram			S	Oral	Daily Dose Text: Unknown		Not Reported
	Cyclobenzaprine Hydrochloride			S	Oral	Daily Dose Text: Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2013	9175273	EXPEDITED (15-DAY)		OT	SE-FRI-1000043509		55 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Almogran			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2013	9178020	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2013SE16980		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Neutropenia; Thrombocytopenia	Inexium			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Plavix			S	Oral			Not Reported
	Paracetamol Macopharma (Non Az Product)			S	Intravenous (not otherwise specified)			Not Reported
	Calciparine			S	Subcutaneous			Not Reported
	Clamoxyl (Amoxicillin)			S	Oral			Not Reported
	Zeclar			S	Oral			Not Reported
	Inspra			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2013	9182112	DIRECT		DS, OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Drug Ineffective; Feeding Disorder; Impaired Work Ability; Insomnia; Irritability; Loss Of Employment; Obsessive-Compulsive Disorder;	Lexapro			S	Oral			Teva

Product Substitution Issue; Tachyphrenia; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2013	9182286	DIRECT	Y	LT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Escitalopram Oxalate			S		1 Tab Daily	3 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2013	9189243	DIRECT		OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Drug Withdrawal Syndrome; Post Concussion Syndrome; Product Formulation Issue; Product Substitution Issue	Escitalopram			S	Oral	10 Mg 1x Day Po	1 WEEK 1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2013	9182787	EXPEDITED (15-DAY)		OT	US-FRI-1000043618			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Drug Hypersensitivity; Seizure	Lexapro Cymbalta			S S				Forest Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2013	9190001	EXPEDITED (15-DAY)	Y	OT	GR-MACLEODS PHARMA-000074		63 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Headache;	Escitalopram (Escitalopram)			S				Not Reported

Toothache

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2013	9190610	EXPEDITED (15-DAY)	Y	OT	2013P1003357		43 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State; Extensor Plantar Response; Hyperexplexia; Muscle Rigidity; Pyrexia; Serotonin Syndrome; Toxicity To Various Agents	Isoniazid			S			3 MTH	Not Reported
	Escitalopram			S				Not Reported
	Corticosteroids			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2013	9152330	EXPEDITED (15-DAY)		HO, LT, OT	AU-JNJFOC-20130215510		29 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Gestational Diabetes; Premature Labour; Respiratory Distress	Risperdal Consta			S	Intramuscular	The Start Date Was Pre-Pregnancy And Expsoure Time In Gestational Week Was 34/40 Weeks		Not Reported
	Quetiapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Novorapid			S	Subcutaneous			Not Reported
	Protaphane			S	Subcutaneous			Not Reported
	Oxycontin			S	Oral	20-30 Mg		Not Reported
	Oxynorm			S	Oral	5-10 Mg		Not Reported
	Elevit			C	Oral	X1		Not Reported
	Vitamin D Nos			C	Oral	X1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2013	9184843	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2006111647		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Hepatic Function Abnormal; Intentional Overdose; Intentional Overdose; Renal Impairment; Respiratory Failure; Subarachnoid Haemorrhage	Ibuprofen			S	Oral			Pfizer
	Naproxen Sodium			S	Oral			Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Acetaminophen W/Codeine			S	Oral	Unk		Not Reported
	Aspirin			S	Oral			Not Reported
	Cyclobenzaprine Hcl			S	Oral	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2013	9186197	EXPEDITED (15-DAY)		OT	FR-FRI-1000043633		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Urticaria	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Propanolol			C		0.25 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2013	9186288	EXPEDITED (15-DAY)		HO	SE-GLAXOSMITHKLINE-B0876936A		23 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Muscle Contractions Involuntary; Suicide Attempt	Alvedon		Y	S	Unknown			Glaxosmithkline
	Voxra			S	Unknown			Glaxosmithkline
	Lamotrigine			S	Unknown			Glaxosmithkline
	Zopiklon			S	Unknown			Glaxosmithkline
	Cipralex			S	Unknown			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2013	9187882	EXPEDITED (15-DAY)		HO	FR-FRI-1000043687		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bicytopenia; Labelled Drug-Drug Interaction Medication Error; Product Use Issue	Escitalopram			S	Oral	5 Mg		Forest
	Depakine			S	Oral	600 Mg		Not Reported
	Theralene			S	Oral	5 Mg		Not Reported
	Tercian			S	Oral	25 Mg		Not Reported
	Atarax			C	Oral	25 Mg		Not Reported
	Xanax			C	Oral	0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2013	9188155	EXPEDITED (15-DAY)		HO	CH-FRI-1000043627			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Bradycardia; Electrocardiogram Qt Interval Abnormal; Hypotension; Overdose; Suicide Attempt	Escitalopram			S	Oral	20 Mg		Forest
	Inderal La			S	Oral	800 Mg		Not Reported
	Zolpidem			S	Oral	40 Mg		Not Reported
	Cymbalta			S	Oral	Between 150 Mg To 300 Mg		Not Reported
	Laxoberon			C				Not Reported
	Isoptin			C	Oral	240 Mg		Not Reported
	Demetrin			C	Oral	10 Mg		Not Reported
	Calcimagon D3			C	Oral	1 Df		Not Reported
	Trittico			C	Oral	50 Mg		Not Reported
	Duphalac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2013	9193612	DIRECT		OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Depression; Headache; Insomnia; Mood Altered;	Escitalopram 5 Mg Teva			S	Oral Oral	5 Mg 1x Daily Po 2.5 Mg 1x Daily Po		Teva

Night Sweats; Palpitations;
Product Substitution Issue

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2013	9195715	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eructation; Nausea; Product Quality Issue; Product Substitution Issue; Retching	Escitalopram Oxalate			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2013	9195730	DIRECT	Y	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Lethargy; Product Quality Issue; Product Substitution Issue; Product Substitution Issue; Sedation	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2013	9188914	EXPEDITED (15-DAY)		OT	PHHY2013US027927		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Chills; Clonus; Hypertonia; Hypotension; Hypoxia; Mydriasis; Myoclonus; Nystagmus; Serotonin Syndrome	Methylene Blue			S		1 Mg/Kg Per Hour		Not Reported
	Methylene Blue			S		0.5 Mg/Kg Per Hour		Not Reported
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported
	Trazodone			S	Oral	100 Mg Daily		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2013	9191296	EXPEDITED (15-DAY)		OT	PHHY2013BR028434			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Decreased Interest; Depression; Panic Disorder; Post-Traumatic Stress Disorder; Sedation	Pamelor			S				Not Reported
	Clonazepam			S				Novartis
	Diazepam			S				Not Reported
	Rivotril			S				Not Reported
	Bromazepam			S				Not Reported
	Paroxetine			S				Not Reported
	Amitriptyline			S				Not Reported
	Pristiq			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2013	7711469	EXPEDITED (15-DAY)	Y	DE, HO	AUR-APL-2010-02726		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Cardiac Arrest; Coma; Electrocardiogram Qt Prolonged; Fall; Malaise; Neurological Decompensation; Sinus Tachycardia; Torsade De Pointes; Ventricular Fibrillation	Fluoxetine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Buspirone			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2013	8445397	EXPEDITED (15-DAY)		HO	JP-FRI-1000028406		59 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Liver Disorder	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Risperdal			S	Oral	1 Ml		Not Reported
	Risperdal			S	Oral	0.5 Ml		Not Reported
	Risperdal			S	Oral	1.5 Ml		Not Reported

	Risperdal	S	Oral	2 Ml		Not Reported
	Jzoloft	C				Not Reported
	Magmitt	C	Oral	1980 Mg		Not Reported
	Sennoside	C	Oral	24 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2013	9194353	EXPEDITED (15-DAY)		OT	US-RB-051453-13		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Suboxone Tablet			S	Transplacental			Reckitt Benckiser
	Clonazepam			S	Transplacental	Dosing Details Unknown, Dosing Frequency: Daily		Not Reported
	Lexapro			S	Transplacental	Dosing Details Unknown, Dosing Frequency: Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2013	9198703	DIRECT	Y	DS, RI			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro 20mg - Generic			S	Oral			Not Reported
	Wellbutrin Xl (Generic)			S	Oral			Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2013	9198758	DIRECT		OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Erectile Dysfunction; Product Substitution Issue; Weight Decreased	Escitalopram 10 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2013	9198792	DIRECT		OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Erectile Dysfunction; Product Substitution Issue; Weight Decreased	Escitalopram 10 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2013	9199691	DIRECT	Y	DS, RI			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Irritability; Social Avoidant Behaviour	Lexapro			S	Oral			Not Reported
	Wellbutrin Xl (Generic)			S	Oral	450mg Po Qam		Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2013	9199695	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Substitution Issue; Tremor	Lexapro			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2013	9203359	NON-EXPEDITED	Y	DE	2013-00634		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lamotrigine			S				Not Reported
	Venlafaxine			S				Not Reported
	Escitalopram (Unknown)			S				Not Reported
	Pantoprazole			S				Not Reported
	Ciprofloxacin			S				Not Reported

	Hydrochlorothizide	S	Not Reported
	Desipramine	S	Not Reported
	Diltiazem Extended Release	S	Not Reported
	Armodafinil	S	Not Reported
	Potassium Chloride	S	Not Reported
	Trifluoperazine	S	Not Reported
	Lansoprazole (Unknown)	S	Not Reported
	Rosuvastatin (Unknown)	S	Not Reported
	Naproxen (Unknown)	S	Not Reported
	Nitrofurantoin	S	Not Reported
	Diclofenac (Unknown)	S	Not Reported
	Acetaminophen/Hydrocodone	S	Not Reported
	Acetamiphen/Propoxyphene	S	Not Reported
	Solifenacin	S	Not Reported
	Progestin	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2013	9203376	NON-EXPEDITED	Y	DE	2013-00635		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lamotrigine (Lamotrigine)			S				Not Reported
	Escitalopram			S				Not Reported
	Diphenhydramine			S				Not Reported
	Aripiprazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2013	9055019	EXPEDITED (15-DAY)		OT	IE-FRI-1000042406		25 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Confusional State; Fatigue; Hyperhidrosis; Lethargy; Memory Impairment; Myalgia; Seizure Like Phenomena; Sleep Disorder	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	5 Mg		Forest
	Cilest			C	Oral			Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2013	9152332	EXPEDITED (15-DAY)		HO, LT, OT	AU-JNJFOC-20130215511		< 1 DAY	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Premature Baby; Respiratory Distress; Withdrawal Syndrome	Risperdal Consta			S	Transplacental			Not Reported
	Quetiapine			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Novorapid			S	Transplacental			Not Reported
	Protaphane			S	Transplacental			Not Reported
	Oxycontin			S	Transplacental			Not Reported
	Oxynorm			S	Transplacental			Not Reported
	Elevit			S	Transplacental			Not Reported
	Vitamin D Nos			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2013	9196528	EXPEDITED (15-DAY)		DE	FR-FRI-1000043767		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke	Escitalopram			S		15 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Memantine			C	Oral	20 Mg		Not Reported
	Cardensiel			C	Oral	1.5 Mg		Not Reported
	Hemigoxine Nativelle			C	Oral	0.125 Mg		Not Reported
	Crestor			C	Oral	5 Mg		Not Reported
	Chondrosulf			C	Oral	1200 Mg		Not Reported
	Cacit Vitamine D3			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2013	9196594	EXPEDITED (15-DAY)		DS	FR-FRI-1000043784		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Escitalopram			S	Oral	15 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2013	9197346	EXPEDITED (15-DAY)		DE	US-PFIZER INC-HQWYE305803NOV06		18 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Ibuprofen			S	Oral			Pfizer
	Escitalopram Oxalate			S	Oral	Unknown		Not Reported
	Pseudoephedrine Hydrochloride			S	Oral	Unknown		Not Reported
	Acetaminophen W/Codeine			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2013	9197859	EXPEDITED (15-DAY)		DS, LT	NO-FRI-1000043809		58 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Fatigue; General Physical Health Deterioration; Gingival Bleeding; Headache; Oropharyngeal Plaque; Pyrexia; Rash; Rash Vesicular; Serotonin Syndrome; Skin Haemorrhage; Swelling; Visual Impairment; Weight Increased	Escitalopram			S		10 Mg		Forest
	Escitalopram			S		20 Mg		Forest
	Escitalopram			S		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2013	9197865	EXPEDITED (15-DAY)		DE	US-FRI-1000043842		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death | Lexapro | S | Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2013	9199752	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Fatigue; Irritability; Product Substitution Issue; Therapeutic Response Decreased	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2013	9199756	DIRECT	Y	OT			14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Nausea; Product Substitution Issue	Escitalopram Oxalate			S	Oral	20 Mg 1/2 Qam Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2013	9202061	EXPEDITED (15-DAY)	Y	HO, RI	2013AP003859		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Trazodone Hydrochloride			S		Hs		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Methylthioninium Chloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2013	9203487	EXPEDITED (15-DAY)	Y	DS, OT	08-AUR-04980		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Female Sexual Arousal	Fluoxetine (Fluoxetine)			S				Not Reported
	Paroxetine (Paroxetine)			S				Not Reported

Disorder	Sertraline (Sertraline) (Sertraline)	S		Not Reported
	Escitalopram (Escitalopram)	S		Not Reported
	Venlafaxine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2013	8070524	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2011-04016		42 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Asthenia; Depressed Mood; Depression; Irritability; Logorrhoea; Mania; Pain; Pressure Of Speech; Psychomotor Hyperactivity; Speech Disorder; Suicidal Ideation	Mirtazapine (Mirtazapine)			S			1 DAY	Not Reported
	Fluoxetine			S				Not Reported
	Escitalopram Oxalate			S			1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2013	9171554	EXPEDITED (15-DAY)		OT	JP-FRI-1000025967		60 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neurogenic Bladder; Neuroleptic Malignant Syndrome	Lexapro			S	Oral	10 Mg		Forest
	Seroquel			C	Oral	150		Not Reported
	Blopress			C	Oral	8 Mg		Not Reported
	Thyradin			C	Oral			Not Reported
	Heberna			C	Oral	75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2013	9202332	DIRECT		OT			84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Lexapro			S				Not Reported
	Seroquel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2013	9203769	EXPEDITED (15-DAY)	Y	HO	SYM-2013-02122		23 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Incorrect Dose Administered; Muscle Contractions Involuntary; Suicide Attempt	Voxra			S	Oral			Not Reported
	Cipralex			S				Not Reported
	Paracetamol			S				Not Reported
	Lamotrigine (Lamotrigine) (Lamotrigine)			S				Not Reported
	Zopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2013	9203778	DIRECT	Y	OT			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Drug Ineffective; Hypotension; Product Substitution Issue	Escitalopram 10 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2013	9203418	EXPEDITED (15-DAY)		HO, OT	US-RANBAXY-2010US-40576		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Cholestasis; Coagulopathy; Drug Interaction; Encephalopathy; Hepatic Necrosis; Hepatitis; Hepatotoxicity; Liver Transplant; Portal Tract Inflammation; Therapeutic Response Decreased	Enalapril Maleate			S	Unknown	Unk		Ranbaxy
	Escitalopram			S	Unknown	Unk		Not Reported
	Simvastatin/ Ezetimibe			S	Unknown	10 Mg/40 Mg/Day		Not Reported
	Simvastatin/ Ezetimibe			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2013	9204387	EXPEDITED (15-DAY)		HO, LT, OT	CH-PFIZER INC-2013083426		31 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Cardiac Arrest; Drug Interaction; Generalised Tonic-Clonic Seizure; Hypokalaemia; Hypomagnesaemia; Long Qt Syndrome; Torsade De Pointes; Withdrawal Syndrome	Escitalopram Oxalate			S		Unk		Not Reported
	Ondansetron Hcl			S		Unk		Pfizer
	Methadone			S	Oral	50-60 Mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2013	9529849	NON-EXPEDITED		HO, OT	RB-48589-2013			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Suboxone			S	Transplacental	(16 Mg Suboxone Film Transplacental)		Not Reported
					Transplacental	(6 Mg, Suboxone Film Transplacental)		
	Lexapro (Not Specified)			S	Transplacental	(10 Mg Transplacental) (6 Mg, Suboxone Film Transplacental)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2013	8942431	EXPEDITED (15-DAY)		OT	GB-FRI-1000040757		58 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Asthenopia; Confusional State; Disturbance In Attention; Drug Interaction; Furuncle; Irritability; Malaise; Mental Fatigue; Metal Poisoning;	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S				Forest
	Aspirin			C		75 Mg		Not Reported
	Allopurinol			C		100 Mg		Not Reported

Tinnitus	Valaciclovir	C	500 Mg		Not Reported
	Diazepam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2013	8957416	EXPEDITED (15-DAY)		OT	DE-FRI-1000040974		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oral Solution			S	Oral	20 Mg		Forest
	Olanzapine			C	Oral	10 Mg		Not Reported
	Lyrica			C	Oral	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2013	9206846	EXPEDITED (15-DAY)		HO	FR-FRI-1000043956		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Loss Of Consciousness; Urinary Retention; Vomiting	Escitalopram			S	Oral	1 Df		Forest
	Lercapress (Enalapril Maleate\Lercanidipine Hydrochloride)			S	Oral	20 Mg/10 Mg		Not Reported
	Lexomil			S	Oral	0.75 Df		Not Reported
	Loxapac			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2013	9207066	EXPEDITED (15-DAY)		OT	PHEH2013US007262			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Disability; Myocardial Infarction; Nasopharyngitis; Panic Attack; Suicide Attempt	Trileptal			S		Unk Ukn, Unk		Novartis
	Concerta			S		Unk Ukn, Unk		Not Reported
	Effexor			S		Unk Ukn, Unk		Not Reported
	Lexapro			S		Unk Ukn, Unk		Not Reported
	Ambien			S		Unk Ukn, Unk		Not Reported

	Lithium	S	Unk Ukn, Unk	Not Reported
	Ativan	S	Unk Ukn, Unk	Not Reported
	Depakote	S	Unk Ukn, Unk	Not Reported
	Wellbutrin	S	Unk Ukn, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2013	9207722	EXPEDITED (15-DAY)		LT	US-BRISTOL-MYERS SQUIBB COMPANY-18713701		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Trazodone Hcl			S		At Bedtime		Apothecon
	Methylene Blue			S		0.5mg/Kg/Hrs		Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2013	9208266	EXPEDITED (15-DAY)		CA, OT	US-FRI-1000043878			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2013	9208293	EXPEDITED (15-DAY)		CA	US-FRI-1000043880		< 1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diaphragmatic Hernia	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2013	9209155	DIRECT	Y	DS			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Complaint;	Escitalopram 10 Mg			S				Not Reported

Therapeutic Response Changed

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2013	9209564	EXPEDITED (15-DAY)		HO	FR-FRI-1000043957		99 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Respiratory Distress	Escitalopram			S	Oral	5 Mg		Forest
	Seresta			S		25 Mg		Not Reported
	Furosemide			C				Not Reported
	Aldactone			C				Not Reported
	Bisoprolol			C				Not Reported
	Effexor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2013	9210854	EXPEDITED (15-DAY)		DS, OT	US-FRI-1000043890			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Intentional Self-Injury; Myocardial Infarction; Nasopharyngitis; Panic Attack; Unevaluable Event; Unevaluable Event; Unevaluable Event; Unevaluable Event; Unevaluable Event	Lexapro			S				Forest
	Effexor			S				Not Reported
	Wellbutrin			S		600 Mg		Not Reported
	Concerta			S				Not Reported
	Ativan			S				Not Reported
	Depakote			S				Not Reported
	Trileptal			S				Not Reported
	Ambien			S				Not Reported
	Lithium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2013	8495002	NON-EXPEDITED			US-PFIZER INC-2012084147		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Decreased Appetite; Drug Ineffective; Insomnia;	Xanax Xr			S		2 Mg, 1x/Day		Pfizer
	Zoloft			S		Unk		Pfizer

Nausea; Nervousness; Panic Attack	Lexapro	S	Unk	Not Reported
	Prozac	S	Unk	Not Reported
	Tenormin	C	25 Mg, Daily	Not Reported
	Captopril	C	25 Mg, 2x/Day	Not Reported
	Glyburide	C	1.25 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2013	9178396	EXPEDITED (15-DAY)		HO, OT	SE-FRI-1000043576			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Muscle Contractions Involuntary; Overdose; Suicide Attempt	Escitalopram			S		5-6 Daily Doses		Forest
	Alvedon			S		Some Tablets		Not Reported
	Lamotrigine			S		5-6 Daily Doses		Not Reported
	Zopiklon			S		5-6 Daily Doses		Not Reported
	Voxra			S		5-6 Daily Doses		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2013	9196554	EXPEDITED (15-DAY)		OT	GB-FRI-1000043781		21 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2013	9214237	EXPEDITED (15-DAY)		CA	US-FRI-1000044051		361 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arnold-Chiari Malformation; Conus Medullaris Syndrome; Lipoma; Spina Bifida Occulta; Spinal Disorder; Spine Malformation;	Lexapro			S	Transplacental			Forest

Syringomyelia; Tethered Cord Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2013	9215105	EXPEDITED (15-DAY)		OT	PL-FRI-1000044038		67 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Genital Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Betaloc Zok			C	Oral	50 Mg		Not Reported
	Prestarium			C	Oral	5 Mg		Not Reported
	Olicard			C	Oral	40 Mg		Not Reported
	Torasemide			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2013	9215276	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2013104582		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Intentional Overdose; Suicide Attempt	Sonata			S		10 Mg, As Needed		Pfizer
	Valium			S		5 Mg, As Needed		Not Reported
	Escitalopram			S	Oral	10 Mg, 1 In 1 Day (Daily)		Not Reported
	Escitalopram			S	Oral	20 Mg, 1 In 1 Day (Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2013	9218963	DIRECT	Y	OT			16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Product Substitution Issue	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2013	9219368	EXPEDITED (15-DAY)	Y	HO, LT	TRAZ20130001		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy; Serotonin Syndrome	Trazodone Hydrochloride			S	Oral	1 In 1 D		Not Reported
	Escitalopram			S	Oral	1 In 1 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2013	9131252	EXPEDITED (15-DAY)		HO	FR-FRI-1000043004		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis; Inflammation; Influenza Like Illness; Pyrexia	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Not Reported
	Escitalopram			S	Oral	10 Mg		Not Reported
	Escitalopram			S	Oral	5 Mg		Not Reported
	Oral Contraceptive Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2013	9216857	EXPEDITED (15-DAY)		DE, OT	ZA-FRI-1000044037		29 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Sudden Death	Escitalopram			S	Oral	10 Mg		Forest
	Femodene			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2013	9217079	EXPEDITED (15-DAY)		OT	FR-FRI-1000044070		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2013	9217086	EXPEDITED (15-DAY)		HO	FR-FRI-1000044067		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Duodenal Ulcer; Iron Deficiency Anaemia; Melaena	Escitalopram			S	Oral	5 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Temesta (Lorazepam)			C	Oral	5 Mg		Not Reported
	Hemigoxine Nativelle			C	Oral	0.0625 Mg		Not Reported
	Selokeen			C	Oral	200 Mg		Not Reported
	Lasilix			C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2013	9219322	DIRECT		DE			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Klonopin			S				Roche
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2013	9219476	DIRECT	Y	OT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea; Product Substitution Issue; Vomiting	Escitalopram Oxalate			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2013	9220585	EXPEDITED (15-DAY)		LT	FR-JNJFOC-20130401408		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete	Haldol			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2013	9058312	EXPEDITED (15-DAY)		OT	US-RB-044862-12		3 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Upper Limb Fracture	Suboxone Tablet			S	Transplacental			Reckitt Benckiser
	Suboxone Tablet			S	Transplacental			Reckitt Benckiser
	Suboxone Tablet			S	Transmammary			Reckitt Benckiser
	Seroquel			S	Transplacental			Not Reported
	Lexapril			S	Transplacental			Not Reported
	Nicotine			S	Transplacental	3 Packs Of Cigarettes Daily		Not Reported
	Nicotine			S	Transplacental	17 Cigarettes Daily		Not Reported
	Prenatal Vitamins			S	Transplacental	Dosing Details Unknown		Not Reported
	Pain Medication			S	Unknown	Dosing Details Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2013	9222505	EXPEDITED (15-DAY)		DS, HO, OT	US-SANOFI-AVENTIS-2013SA035501		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Atrial Fibrillation; Economic Problem; Legal Problem; Myocardial Infarction; Nasopharyngitis; Panic Attack; Suicide Attempt	Ambien			S				Not Reported
	Effexor			S				Not Reported
	Wellbutrin			S				Not Reported
	Concerta			S				Not Reported
	Ativan			S				Not Reported
	Depakote			S				Not Reported
	Trileptal			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2013	9222691	EXPEDITED (15-DAY)		HO	FR-FRI-1000044141		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Overdose; Poisoning	Escitalopram		S	Oral	1 Df	Forest
	Advil		S	Oral	3200 Mg	Not Reported
	Rhinadvil		S	Oral	1200 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2013	9222701	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2013104926		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning	Advil			S	Oral	16 Df, Single		Pfizer
	Rhinadvil			S	Oral	6 Df, Single		Pfizer
	Seroplex			S	Oral	1 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2013	9222749	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2013112801		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Intentional Self-Injury; Pain In Extremity; Tachycardia; Vomiting	Misofenac			S	Oral	9 Df, Daily		Pfizer
	Tachipirina			S	Oral	2000 Mg, Daily		Not Reported
	Escitalopram Oxalate			S	Oral	360 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2013	9222813	EXPEDITED (15-DAY)		OT	US-SHIRE-ALL1-2013-02055		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Irritability; Suicidal Ideation; Weight Decreased	Vyvanse			S	Oral	Unk, Unknown		Shire
	Escitalopram Oxalate			S	Oral	5 Mg, 1x/Day:Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2013	9223112	EXPEDITED (15-DAY)		OT	PHHY2013BR032414		28 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction; Norepinephrine Increased	Ritalina			S	Oral	1.5 Df (10 Mg), Daily		Novartis
	Ritalina			S	Oral	1 Df, Daily		Novartis
	Escitalopram			S	Oral	1 Df, Daily		Not Reported
	Antidepressants			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2013	9120802	EXPEDITED (15-DAY)		HO	IT-FRI-1000042946		23 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Serotonin Syndrome	Escitalopram Oral Solution			S	Oral	15 Drops		Forest
	Valium			C	Oral	30 Drops		Not Reported
	Growth Hormone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2013	9135109	NON-EXPEDITED			US-PFIZER INC-2013075067		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Somnolence	Lyrica			S	Oral	50 Mg, 2x/Day		Pfizer
	Lyrica			S				Pfizer
	Caffeine			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lantus			C		35 Iu, Daily At Night		Not Reported
	Novolog			C		9 Iu, After Each Meal		Not Reported
	Depakote			C		Unk		Not Reported
	Hydroxyzine			C		Unk		Not Reported
	Hydroxyzine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2013	9178217	EXPEDITED (15-DAY)		OT	US-RB-022557-11			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Exposure During Pregnancy; Fatigue; Hot Flush; Labour Pain; Panic Attack; Premature Delivery; Thirst	Subutex			S	Unknown			Reckitt Benckiser
	Lexapro			S	Unknown	Before Bed Time		Not Reported
	Nicotine			S	Respiratory (inhalation)	Smoking Throughout Pregnancy		Not Reported
	Prenatal Vitamins			C	Unknown	Dosing Details Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2013	9224559	EXPEDITED (15-DAY)		DS, HO, OT	US-JNJFOC-20130401623			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Disability; Hospitalisation; Imprisonment; Myocardial Infarction; Nasopharyngitis; Panic Attack; Suicide Attempt	Concerta			S	Oral			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Effexor			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lithium			S	Unknown			Not Reported
	Ativan			S	Unknown			Not Reported
	Ambien			S	Unknown			Not Reported
	Depakote			S	Unknown			Not Reported
	Trileptal			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2013	9225524	EXPEDITED (15-DAY)		HO	DE-FRI-1000044165		72 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Interaction; Prescribed Overdose; Toxicity To Various Agents	Escitalopram			S	Oral	40 Mg		Forest
	Tramal			S		100 Mg		Not Reported
	Tramal			S		150 Mg		Not Reported
	Tavor (Lorazepam)			C		0.5 Mg		Not Reported
	Ascotop			C				Not Reported

	Ass	C	100 Mg	Not Reported
	Bisoprolol	C	10 Mg	Not Reported
	Diclo Kd	C	75 Mg	Not Reported
	Pantoprazol	C	40 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2013	9226334	EXPEDITED (15-DAY)		OT	FR-FRI-1000044218		37 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation	Escitalopram			S	Oral	10 Mg		Forest
	Ibuprofene			C	Oral	1200 Mg		Not Reported
	Biocaliptol			C	Oral	4 Df		Not Reported
	Qlaira			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2013	9226377	EXPEDITED (15-DAY)		CA	US-FRI-1000044105		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Fallot'S Tetralogy; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2013	9226379	EXPEDITED (15-DAY)		CA	US-FRI-1000044107		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Patent Ductus Arteriosus; Talipes; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2013	9227653	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-18753988			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2013	9229864	DIRECT	Y				57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2013	9119639	EXPEDITED (15-DAY)		HO, LT, OT	AU-ASTRAZENECA-2013SE12519		29 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Gestational Diabetes; Respiratory Distress	Seroquel Xr			S	Oral	50 Mg/Day At 34/40 Wks P/N 10wks		Not Reported
	Risperdal Consta			S	Intramuscular	37.5 Mg, 2/52 Fortnightly Initiated Pre-Pregnancy And Ongoing		Not Reported
	Escitalopram			S	Oral	40 Mg/Day Pre-Pregnancy And Ongoing		Not Reported
	Oxycontin			S	Oral	20-30 Mg/Day Initiated At 27/40 Weeks And Stopped At Birth		Not Reported
	Oxynorm			S	Oral	5-10 Mg/Day Initiated At 27/40 Weeks And Stopped At Birth		Not Reported
	Elevit			C	Oral	1 Tablet/Day From First Trimester And Stopped At		Not Reported

				Birth	
	Vit D	C	Oral	1 Tablet/Day From First Trimester And Ongoing	Not Reported
	Novorapid	C	Subcutaneous	From 32/40 Weeks Until Birth, Three Tmes A Day	Not Reported
	Protophane	C	Subcutaneous	From 32/40 Weeks Until Birth, At Night	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2013	9119674	EXPEDITED (15-DAY)		DS, HO, LT, OT	AU-ASTRAZENECA-2013SE12513		< 1 DAY	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Premature Baby; Respiratory Distress	Seroquel Xr			S	Transplacental	50 Mg/Day Initiated At 34/40 Weeks And Stopped At Delivery		Not Reported
	Risperdal Consta			S	Transplacental	37.5 Mg, 2/52 Fortnightly Initiated Pre-Pregnancy And Ongoing		Not Reported
	Escitalopram			S	Transplacental	40 Mg/Day Initiated Pre-Pregnancy And Is Ongoing		Not Reported
	Oxynorm			S	Transplacental	20-30 Mg/Day, Fortnightly, Initiated At 27/40 Weeks Stopped At Birth		Not Reported
	Oxycontin			S	Transplacental	5-10 Mg/Day Initiated At 27/40 Weeks Stopped At Birth		Not Reported
	Elevit			C	Transplacental	1 Tablet/Day, Initiated Since 1 Trimester		Not Reported
	Vitamin D Nos			C	Transplacental	1 Tablet/Day, Initiated Since 1 Trimester		Not Reported
	Novorapid			C	Transplacental	1 Tablet/Day, Initiated Since 1 Trimester		Not Reported
	Protophane			C	Transplacental	1 Tablet/Day, Initiated Since 1 Trimester		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2013	9158600	EXPEDITED (15-DAY)		OT	US-FRI-1000043193		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Crying; Depressed Mood; Impatience	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	7.5 Mg		Forest
	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2013	9224839	EXPEDITED (15-DAY)	Y	HO	AUR-APL-2013-02849		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy; Hypotension; Hypoxia; Metabolic Disorder; Serotonin Syndrome; Toxicity To Various Agents	Escitalopram (Escitalopram)			S	Oral			Not Reported
	Trazodone (Trazodone)			S				Not Reported
	Methylthioninium Chloride			S				Not Reported
	Phenylephrine			S				Not Reported
	Methylthioninium Chloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2013	9230954	EXPEDITED (15-DAY)		LT	FR-FRI-1000044251		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete	Escitalopram			S	Oral	10 Mg		Forest
	Haldol			S	Oral	14 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2013	9231020	EXPEDITED (15-DAY)		HO, OT	US-ROCHE-1211783		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Drug Ineffective; Intentional Overdose; Suicide Attempt	Valium		S	Unknown	Not Reported
	Valium		S	Unknown	Not Reported
	Escitalopram		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported
	Sonata		S	Unknown	Not Reported
	Sonata		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2013	9231185	EXPEDITED (15-DAY)		OT	PHHY2013TR034975		43 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State; Drug Interaction; Hoffmann'S Sign; Hyperreflexia; Muscle Contractions Involuntary; Muscle Rigidity; Pyrexia; Serotonin Syndrome	Escitalopram			S		20 Mg, Daily		Not Reported
	Isoniazid			S				Novartis
	Corticosteroids			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2013	9232889	DIRECT		HO			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Food Interaction; Visual Impairment	Diovan			S	Oral	160mg Daily Po	5 YR	Novartis
	Lamotrigine			S	Oral	100mg Daily Po	5 YR	Cadila
	Escitalopram			S	Oral	7.5mg Daily Po	6 MTH	Forest
	Bupropion			S	Oral	50mg Daily Po		Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2013	9233343	DIRECT		OT			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Depressed Mood; Drug Withdrawal Syndrome; Fatigue; Headache; Nausea; Product Substitution Issue	Escitalopram		S	Oral	2 YR	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2013	9049613	EXPEDITED (15-DAY)		LT	JP-FRI-1000042415		69 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Fibrillation	Lexapro			S	Oral	10 Mg		Forest
	Eticalm			C	Oral	0.5 Mg		Not Reported
	Flunitrazepam			C	Oral	1 Mg		Not Reported
	Sediel			C	Oral	10 Mg		Not Reported
	Irbetan			C	Oral			Not Reported
	Allermist			C	Nasal			Not Reported
	Halcion			C	Oral			Not Reported
	Goodmin			C	Oral			Not Reported
	Tsumura			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2013	9071271	EXPEDITED (15-DAY)		HO	FR-FRI-1000042203		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning Deliberate; Suicide Attempt	Escitalopram			S	Oral			Forest
	Noctran			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2013	9236026	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Myalgia	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2013	9147444	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2013078839		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypotension; Intentional Overdose; Intentional Self-Injury; Syncope	Torvast			S	Oral	35 Df, Unit Doses Total		Pfizer
	Depakin Chrono			S	Oral	40 Df, Unit Doses Total		Not Reported
	Cipralex			S	Oral	70 Df, Unit Doses Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2013	9236098	EXPEDITED (15-DAY)		OT	PHHY2013IE036211		52 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compulsive Shopping; Depression; Hypersexuality; Impulse-Control Disorder; Libido Increased; Poisoning Deliberate; Sexually Inappropriate Behaviour	Stalevo			S		100 Mg, 6 Times Daily		Not Reported
	Amantadine			S		100 Mg, Tid		Not Reported
	Selegiline			S		5 Mg, Daily		Not Reported
	Pramipexole			S		0.18 Mg, Daily		Not Reported
	Alprazolam			S		0.5 Mg, Daily		Novartis
	Escitalopram			S		10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2013	9236657	EXPEDITED (15-DAY)		CA	US-FRI-1000044385		< 1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2013	9237313	EXPEDITED (15-DAY)		OT	TR-MYLANLABS-2013S1007783		43 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Electromyogram Abnormal; Serotonin Syndrome	Escitalopram		S	Unknown	20 Mg/Day	Mylan
	Isoniazid		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2013	9240301	EXPEDITED (15-DAY)	Y	HO	2013HINLIT0078		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Escitalopram (Escitalopram)			S	Oral	20 Mg/Day		Not Reported
	Methylthioninium Chloride			S	Intravenous bolus			Not Reported
					Intravenous bolus	0.5 Mg/Kg/Hour		
	Trazodone (Trazodone)			S		(Bed Time)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2013	9000246	EXPEDITED (15-DAY)		HO, LT	CH-JNJFOC-20130101511		90 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Zaldiar			S	Oral			Not Reported
	Zaldiar			S	Oral	325 Mg 4 Times A Day		Not Reported
	Xarelto			S	Oral	10 Mg Cumulative Dose		Not Reported
	Paracetamol		Y	S	Oral			Not Reported
	Paracetamol			S	Oral	4 Doses A Day		Not Reported
	Reminyl			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Flagyl			S	Oral	2000 Mg Once A Day		Not Reported
	Cipralex			S	Oral			Not Reported
	Inegy			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Rocephin			S	Oral	500 Mg 3 Times A Day		Not Reported
	Amlodipine			S	Oral			Not Reported

Ibuprofen	C	Oral	Not Reported
Omeprazole	C	Oral	Not Reported
Calciparin	C	Unknown	Not Reported
Calcimagon D3	C	Oral	Not Reported
Prednisolone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2013	9225536	EXPEDITED (15-DAY)		HO	IT-FRI-1000044164		16 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokinesia; Long Qt Syndrome; Off Label Use; Overdose; Tremor	Escitalopram			S	Oral	200 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2013	9238615	EXPEDITED (15-DAY)		DS	FR-ABBOTT-13P-056-1076954-00		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Myalgia; Neuropathy Peripheral	Norvir			S	Oral			Not Reported
	Intelence			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Isentress			C				Not Reported
	Prezista			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2013	9239278	EXPEDITED (15-DAY)		CA	US-FRI-1000044387		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2013	9240581	EXPEDITED (15-DAY)		OT	SE-NICOBRDEVP-2013-06702		23 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Muscle Contractions Involuntary; Suicide Attempt	Lamotrigine (Unknown)			S	Unknown	Unk		Watson
	Escitalopram (Unknown)			S	Unknown	Unk		Not Reported
	Paracetamol (Unknown)			S	Unknown	Unk		Actavis Mid Atlantic
	Zopiklon			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2013	9240681	EXPEDITED (15-DAY)		CA	US-FRI-1000044389			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Oesophageal Atresia	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2013	9240943	DIRECT	Y				11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2013	9100326	EXPEDITED (15-DAY)		OT	AT-PFIZER INC-2013058634		61 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Hyponatraemia	Halcion			S		0.25 Mg, 1x/Day		Pfizer
	Cipralex			S		5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2013	9104870	EXPEDITED (15-DAY)		DE, HO, OT	US-JNJFOC-20130206776		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Constipation; Death; Depression; Drug Ineffective; Drug Interaction; Failure To Thrive; Hallucination; Malignant Neoplasm Progression; Overdose; Pain	Nucynta Er			S	Oral	100 Mg- 3 Tablets -Twice A Day		Not Reported
	Nucynta Er			S	Oral	Twice Daily		Not Reported
	Nucynta			S	Oral	50 Mg, 3 Tablets Every 4-6 Hours As Needed		Not Reported
	Lexapro			S	Unknown	Once Daily		Not Reported
	Omeprazole			C	Unknown	Once A Day		Not Reported
	Oxazepam			C	Unknown	Once A Day		Not Reported
	Magic Mouthwash			C	Unknown	Unspecified -Tea Spoon-Every 4 Hours As Needed		Not Reported
	Magnesium Lactate			C	Unknown	Unspecified -Tea Spoon-Every 4 Hours As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2013	9243070	EXPEDITED (15-DAY)		CA	US-FRI-1000044432		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Valve Stenosis Congenital	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2013	9247772	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain; Diarrhoea; Discomfort; Loss Of Personal	Lexapro			S	Oral	10 Mg 1/2 8 Day Po		Forest

Independence In Daily Activities

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2013	8987631	EXPEDITED (15-DAY)		OT	CH-FRI-1000026462			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Generalised Oedema; Pregnancy; Uterine Contractions During Pregnancy	Escitalopram			S		20 Mg		Forest
	Seroquel			S		600 Mg		Not Reported
	Labetalol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2013	8988022	EXPEDITED (15-DAY)		HO, OT	CH-FRI-1000041216		1 DAY	Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypernatraemia; Metabolic Acidosis; Premature Baby; Respiratory Failure	Escitalopram			S	Transplacental			Forest
	Seroquel			S				Not Reported
	Labetalol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2013	8988137	EXPEDITED (15-DAY)		HO, OT	CH-FRI-1000041217		1 DAY	Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypernatraemia; Metabolic Acidosis; Premature Baby; Respiratory Failure	Escitalopram			S	Transplacental			Forest
	Seroquel			S				Not Reported
	Labetalol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2013	9244474	EXPEDITED (15-DAY)		HO	PHHY2013FR037331		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Hyponatraemia	Nisisco			S	Oral	1 Df (160mg Vals/12.5mg Hctz) Daily		Novartis
	Deroxat			S		0.5 Df, Daily		Not Reported
	Seroplex			S		Unk Ukn, Unk		Not Reported
	Seresta			C		50 Mg, Unk		Not Reported
	Seresta			C		Increased Dose		Not Reported
	Zocor			C		1 Df, Daily		Not Reported
	Stilnox			C		1 Df (10mg), Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2013	9246896	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-B0883792A		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Hyponatraemia	Deroxat			S	Oral	.5unit Per Day		Glaxosmithkline
	Seroplex			S	Oral			Unknown
	Nisisco			S	Oral	1unit Per Day		Unknown
	Seresta			C	Oral			Unknown
	Zocor			C	Oral	20mg Per Day		Unknown
	Stilnox			C	Oral	10mg Per Day		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2013	9253944	DIRECT		DS			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Lexapro			S	Oral	20 Mg. Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2013	9254454	DIRECT		OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Crying; Depression; Fatigue; Feeling Abnormal; Headache; Nausea; Sleep Disorder; Suicidal Ideation; Therapeutic Response Changed; Vomiting	Escitalopram			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2013	8261077	EXPEDITED (15-DAY)		CA	US-JNJFOC-20111107543			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Growth Retardation; Hypospadias	Topamax			S	Transplacental			Not Reported
	Topamax			S	Transplacental			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Zofran			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2013	9144600	EXPEDITED (15-DAY)		OT	GB-FRI-1000043176		65 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clavicle Fracture; Forearm Fracture	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg Daily		Forest
	Calcihew D3 Forte			C	Oral	Two Tablets Daily		Not Reported
	Alendronic Acid			C	Oral	70 Mg Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2013	9248822	EXPEDITED (15-DAY)		HO	FR-SANOFI-AVENTIS-2013SA038240		99 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia	Stilnox			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Furosemide			C	Oral			Not Reported
	Digoxine			C	Oral	0.125 Mg 1tablet 5 Days /7days		Not Reported
	Previscan (Fluindione)			C	Oral	1/2 Tablet = 10 Mg Every Day Except Three Fourth Tablet = 15 Mg On Tuesday And Friday		Not Reported
	Calcium/Colecalciferol			C		1 Bag On Tuesday And On Friday		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2013	9249551	EXPEDITED (15-DAY)		HO	AU-FRI-1000044541		44 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pleural Effusion	Lexapro			S	Oral	20 Mg		Forest
	Somac			S		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2013	9249632	EXPEDITED (15-DAY)		HO	FR-FRI-1000044547		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram			S	Oral	1 Df		Forest
	Cotriatec			C				Not Reported
	Bisoprolol			C				Not Reported
	Triatec (Ramipril)			C				Not Reported
	Amarel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2013	9255096	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue	Lexapro 20mg - Generic			S	Oral	1 Dose Po Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2013	8330966	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-A0960414A		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Bedridden; Depressed Mood; Depression; Disability; Disturbance In Attention; Drug Interaction; Drug Level Decreased; Exposure During Pregnancy; Hypersomnia; Loss Of Personal Independence In Daily Activities; Mood Altered; Prescribed Overdose; Stress	Lamictal			S	Oral	300mg Unknown		Glaxosmithkline
	Lamotrigine			S	Oral	300mg Unknown		Teva
	Microgestin			S	Unknown			Not Reported
	Geodon			S	Unknown			Not Reported
	Wellbutrin			S	Oral			Glaxosmithkline
	Effexor			S	Unknown			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Contraceptive			S				Not Reported
	Lipitor			C	Oral			Glaxosmithkline
	Trileptal			C				Not Reported
	Nortriptyline			C				Not Reported
	Folplex			C				Not Reported
	Prenatal Vitamins			C				Not Reported
	Fish Oil			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2013	9252933	EXPEDITED (15-DAY)		OT	US-FRI-S04-USA-08048-01		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Feeling Abnormal; Hallucination,	Lexapro			S	Oral			Forest
	Lexapro			S				Forest

Auditory; Homicide;
Irritability; Nervousness;
Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2013	9257764	DIRECT	Y				33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Irritability; Product Substitution Issue	Escitalopram Oxalate			S				Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	7685386	EXPEDITED (15-DAY)		HO	US-BAXTER-2010BH024940		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased	Lexapro			S	Oral			Not Reported
	Namenda			C	Oral			Not Reported
	Alendronate Sodium			C	Oral			Not Reported
	Aspirine			C	Oral			Not Reported
	Folic Acid W/Vitamin B12			C	Oral			Not Reported
	Loperamide Hydrochloride			C	Oral			Not Reported
	Calcium W/Vitamin D Nos			C	Oral			Not Reported
	Exelon			C	Transdermal			Not Reported
	Gammagard Liquid			S	Intravenous (not otherwise specified)	200 Mg/Ml Body Weight		Not Reported
	Gammagard Liquid			S	Intravenous (not otherwise specified)	200 Mg/Ml Body Weight		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9176089	EXPEDITED (15-DAY)		OT	CA-RB-046898-12		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Hepatitis C	Suboxone Tablet		S	Sublingual	Reckitt Benckiser
	Suboxone Tablet		S	Sublingual	Reckitt Benckiser
	Oxazepam		S	Oral	Not Reported
	Cipralex		S	Oral	Not Reported
	Valium		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9197745	EXPEDITED (15-DAY)		HO, OT	SI-FRI-1000043815			Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemic Stroke; Seizure	Escitalopram			S	Oral	10 Mg		Forest
	Amlessa			C	Oral	4 Mg		Not Reported
	Concor Cor			C	Oral	2.5 Mg		Not Reported
	Atorvastatin			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9233819	EXPEDITED (15-DAY)		OT	FI-PFIZER INC-2013112600		81 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Fibrillation; Contusion; Malaise; Mouth Swelling; Nausea; Swollen Tongue; Tremor	Xanor Depot			S		0.5 Mg, Unk		Pfizer
	Xanor Depot			S		1 Mg, Unk		Pfizer
	Xanor			S		Unk		Pfizer
	Xanor			S		0.5 Mg, 3x/Day		Pfizer
	Cipralex			S		Unk		Not Reported
	Norvasc			C				Not Reported
	Spirix			C				Not Reported
	Emconcor			C		2.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9253746	EXPEDITED (15-DAY)		DS, HO, LT	CA-BAYER-2013-048886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Mirena			S	Intra-uterine	20 Mcg/24hr, Cont		Bayer
	Cipralex			S	Oral	20mg 1 Tablet, Qd		Not Reported
	Pariet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9254079	EXPEDITED (15-DAY)		HO	FR-SANOFI-AVENTIS-2013SA041573		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia	Lasilix			S	Oral	Strength:40mg Dose:1 Unit(S)		Not Reported
	Perindopril			S	Oral	Strength:4mg Dose:1 Unit(S)		Not Reported
	Omeprazole			S	Oral	Strength:20mg Dose:1 Unit(S)		Not Reported
	Seroplex			S	Oral	Strength:5mg Dose:1 Unit(S)		Not Reported
	Crestor			S	Oral	Strength: 10mg Dose:1 Unit(S)		Not Reported
	Bisoce			C	Oral	Strength: 2.5mg Dose:2 Unit(S)		Not Reported
	Kardegic			C	Oral	Strength: 75mg Dose:1 Unit(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9254691	EXPEDITED (15-DAY)		OT	DE-FRI-1000044591			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Symmetrical Drug-Related Intertriginous And Flexural Exanthema	Escitalopram			S	Oral	5 Mg		Forest
	Quetiapin			C	Oral	50 Mg		Not Reported
	Quetiapin			C	Oral	100 Mg		Not Reported
	Quetiapin			C	Oral	150 Mg		Not Reported

	Quetiapin	C	Oral	300 Mg		Not Reported
	Quetiapin	C	Oral	100 Mg		Not Reported
	Xeplion	C	Intramuscular	0.8929 Mg		Not Reported
	Xeplion	C	Intramuscular	1.7857 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9255075	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000044672		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bicytopenia	Escitalopram			S	Oral	10 Mg		Forest
	Oflocet			S	Oral	400 Mg		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Oral	100 Mg		Not Reported
	Haldol			S	Oral	6 Df		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9255105	EXPEDITED (15-DAY)		HO	AU-FRI-1000044673		77 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hyperhidrosis; Polyuria; Serotonin Syndrome; Tremor	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Tramadol Hydrochloride			S	Oral	200 Mg		Not Reported
	Paracetamol			C		1995 Mg		Not Reported
	Vitamin B12 Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9255126	EXPEDITED (15-DAY)		HO	AU-FRI-1000044696		17 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Escitalopram			S		20 Mg		Forest

	Ethinyloestradiol-Levonorgestrol	C	Not Reported
	Ibuprofen	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9255169	EXPEDITED (15-DAY)		HO	FR-FRI-1000044675		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Hyponatraemia	Escitalopram			S	Oral			Forest
	Deroxat			S	Oral	0.5 Df		Not Reported
	Nisisco			S	Oral	160 Mg/12.5 Mg		Not Reported
	Seresta			C	Oral	Dose Increased		Not Reported
	Zocor			C	Oral	1 Df		Not Reported
	Stilnox			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9255193	EXPEDITED (15-DAY)		HO	CA-FRI-1000044697		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cold Sweat; Off Label Use; Palpitations	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9255997	EXPEDITED (15-DAY)		OT	FR-FRI-1000044681		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spontaneous Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Oxycontin			C		5 Mg		Not Reported
	Doliprane			C		3 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2013	9262431	DIRECT	Y	OT			30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Impaired Work Ability; Product Substitution Issue	Escitalopram			S	Oral	1		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2013	9256745	EXPEDITED (15-DAY)		HO, OT	IT-009507513-1304ITA015121		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hyperthermia Malignant; Hypertonia; Musculoskeletal Stiffness; Neuroleptic Malignant Syndrome; Rhabdomyolysis	Remeron			S	Oral	30 Mg, Qd		Merck
	Remeron			S				Merck
	Tolep			S	Oral	300 Mg, Qd		Not Reported
	Tolep			S				Not Reported
	Largactil			S	Intramuscular	50 Mg, Total		Not Reported
	Largactil			S				Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Cipralex			S				Not Reported
	Xeristar			S	Oral	60 Mg, Qd		Not Reported
	Xeristar			S				Not Reported
	Serenase (Haloperidol)			S	Intramuscular	5 Mg Taken As A Single Dose		Not Reported
	Serenase			S				Not Reported
	Dominans			S	Oral	10.5 Mg, Qd		Not Reported
	Dominans			S				Not Reported
	Lithium Carbonate			S	Oral	300 Mg, Qd		Not Reported
	Lithium Carbonate			S				Not Reported
	Lamotrigine			S	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2013	9262741	EXPEDITED (15-DAY)		HO	SYM-2013-03023		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation;	Wellbutrin			S	Oral			Not Reported

Imprisonment; Investigation; Myocardial Infarction; Nasopharyngitis; Panic Attack; Stress; Suicidal Ideation; Suicide Attempt	Ativan	S	Not Reported
	Effexor	S	Not Reported
	Ambien	S	Not Reported
	Adderall (Obetrol /01345401/)	S	Not Reported
	Concerta	S	Not Reported
	Trileptal	S	Not Reported
	Lithium Salt	S	Not Reported
	Depakote	S	Not Reported
	Zyprexa	S	Not Reported
	Lexapro	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2013	9531103	NON-EXPEDITED	Y	DE	2013-00615		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Quietiapine (Quetiapine Fumarate) (Unknown)			S		Unknown (Unknown, Unknown, Unknown), Unknown		Not Reported
	Escitalopram (Unknown)			S				Not Reported
	Gabapentin (Unknown)			S		Unknown (Unknown, Unknown, Unknown), Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2013	9531215	NON-EXPEDITED	Y	DE	2013-00321		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Quetiapine (Unknown)			S				Not Reported
	Escitalopram (Unknown)			S				Not Reported
	Acetaminophen/Codeine (Unknown)			S				Not Reported
	Metaxalone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2013	9531395	NON-EXPEDITED	Y	DE	2013-00598		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Quetiapine (Unknown)			S				Not Reported
	Escitalopram (Unknown)			S				Not Reported
	Valproic Acid			C				Not Reported
	Chlorpromazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2013	9531443	NON-EXPEDITED	Y	DE	2013-00609		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Quetiapine (Unknown)			S				Not Reported
	Escitalopram (Unknown)			S				Not Reported
	Citalopram (Unknown) (Citalopram)			S				Not Reported
	Hydroxyzine (Unknown)			S				Not Reported
	Buspirone			S				Not Reported
	Cyclobenzaprine (Unknown)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2013	8808036	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2012S1019037		66 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Circulatory Collapse; Condition Aggravated; Dizziness; Drug Interaction; Gait Disturbance; Headache; Malaise; Nausea; Speech Disorder; Tremor	Buspirone			S	Oral			Mylan
	Valium			S	Oral			Not Reported
	Escitalopram			S				Not Reported
	Lithium Carbonate			C	Oral			Not Reported
	Lofepramine			C	Oral			Not Reported
	Atorvastatin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2013	9261841	EXPEDITED (15-DAY)		OT	NZ-MYLANLABS-2013S1008327			Female	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hallucination, Auditory; Mood Altered; Personality Disorder; Somnolence	Loxalate	S	Oral	Mylan
	Epilim	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2013	9261943	EXPEDITED (15-DAY)		CA	US-FRI-1000044723		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Attention Deficit/Hyperactivity Disorder; Autism Spectrum Disorder; Craniosynostosis; Depression; Headache; Language Disorder; Nausea; Schizophrenia	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2013	9263883	DIRECT					62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Quality Issue; Product Substitution Issue	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2013	9248813	EXPEDITED (15-DAY)		OT	US-FRI-1000044644		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Chest Pain; Hypertension	Lexapro			S	Oral	20 Mg		Forest
	Opc-34712			S	Oral			Not Reported
	Opc-34712			S	Oral	1 Mg		Not Reported
	Lisinopril			C	Oral	20 Mg		Not Reported
	Coreg			C	Oral	6.25 Mg		Not Reported

	Acetaminophen	C	500 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2013	9264295	EXPEDITED (15-DAY)		CA	US-FRI-1000044725		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2013	9163993	EXPEDITED (15-DAY)		LT	JP-FRI-1000043367		47 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness	Lexapro			S	Oral	10 Mg		Forest
	Amoxan			C	Oral	100 Mg		Not Reported
	Tofranil			C	Oral	25 Mg		Not Reported
	Tofranil			C	Oral	150 Mg		Not Reported
	Tetramide			C	Oral	20 Mg		Not Reported
	Tryptanol			C	Oral	10 Mg		Not Reported
	Lithium Carbonate			C	Oral	100 Mg		Not Reported
	Dogmatyl			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2013	9265440	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2013SE28443		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia	Omeprazole			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Perindopril			S	Oral			Not Reported
	Perindopril			S	Oral			Not Reported

Lasilix	S	Oral		Not Reported
Bisoce	C	Oral		Not Reported
Kardegic	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2013	9274767	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Product Substitution Issue	Escitalopram			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2013	9274819	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Disease Recurrence; Drug Ineffective; Product Substitution Issue	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2013	9275390	DIRECT		HO, LT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chest Pain; Headache; Insomnia; Withdrawal Syndrome	Lexapro			S			1.5 YR	Not Reported
	Prempro			S			1 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2013	9276695	EXPEDITED (15-DAY)		OT	SYM-2013-03220		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous;	Wellbutrin (Bupropion			S	Oral			Not Reported

Biochemical Pregnancy; Depression; Disturbance In Attention; Drug Ineffective; Drug Interaction; Drug Level Decreased; Hypersomnia; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Maternal Exposure During Pregnancy; Mood Altered; Pregnancy; Prescribed Overdose; Product Substitution Issue; Stress	Hydrochloride) (Bupropion Hydrochloride)				
	Effexor (Venlafaxine Hydrochloride) Unknown	S			Not Reported
	Lamictal	S	Oral		Not Reported
	Lamotrigine (Lamotrigine) (Lamotrigine)	S	Oral		Not Reported
	Microgestin	S			Not Reported
	Ziprasidone Hcl	S			Not Reported
	Lexapro	S			Not Reported
	Contraceptives	S			Not Reported
	Atorvastatin Calcium (Atorvastatin Calcium) (Atorvastatin Calcium)	C			Not Reported
	Oxcarbazepine (Oxcarbazepine) (Oxcarbazepine)	C			Not Reported
	Nortriptyline (Nortriptyline) (Nortriptyline)	C			Not Reported
	Folplex (Hepagrisevit Forte-N /01079901/) (Pyridoxine Hydrochloride, Folic Acid, Cyanocobalamin)	C			Not Reported
	Prenatal Vitamins (Ascorbic Acid W/Biotin/Minerals Nos/Nicotinic) (Ascorbic Acid, Biotin, Tocopherol, Nicotinic Acid, Retinol, Minerals Nos, Vitamin B Nos, Vitamin D Nos)	C			Not Reported
	Fish Oil (Fish Oil) (Fish Oil)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2013	8940841	EXPEDITED (15-DAY)		OT	FR-FRI-1000040755		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Weight Decreased	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest
	Lexomil			C	Oral	0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2013	9267334	EXPEDITED (15-DAY)		HO	DE-BANPHARM-20131221		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Initial Insomnia; Middle Insomnia; Oedema Peripheral; Peripheral Swelling	Ibuprofen Unknown Product			S	Oral	1600 Mg Qd, Several Months,		Not Reported
	Remergil			S		15 Mg, Qd,		Not Reported
	Remergil			S		30 Mg,Qd		Not Reported
	Remergil			S	Oral	15 Mg, Qd,		Not Reported
	Cipralex			S	Oral	20 Mg Qd, Quite Some Time		Not Reported
	Pantozol			C	Oral	40 Mg, Qd,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2013	9268603	EXPEDITED (15-DAY)		CA	US-FRI-1000044727			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2013	9275636	DIRECT		DS			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenocortical Insufficiency Acute; Anxiety; Decreased Appetite; Dry Mouth; Fear; Flat Affect; Headache; Insomnia; Major Depression; Mood Altered; Muscle Twitching; Palpitations; Panic Attack	Lexapro			S	Oral	5 Milligrams Once Daily Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2013	9173341	EXPEDITED (15-DAY)		CA, HO, OT	US-JNJFOC-20130310413			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Audiogram Abnormal; Choanal Atresia; Deformity; Emotional Distress; Heart Valve Incompetence; Nasal Septum Deviation; Pain; Social Avoidant Behaviour	Topamax			S	Transplacental			Not Reported
	Focalin Xr			S	Transplacental			Not Reported
	Metoclopramide			S	Transplacental			Not Reported
	Clonazepam			S	Transplacental			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Klonopin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2013	9247366	EXPEDITED (15-DAY)		OT	US-JNJFOC-20130310412			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Exposure During Pregnancy	Topamax			S	Oral			Not Reported
	Focalin Xr			S	Oral			Not Reported
	Focalin Xr			S	Oral			Not Reported
	Metoclopramide			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Klonopin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2013	9269743	EXPEDITED (15-DAY)		OT	GB-FRI-1000044890		66 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Circulatory Collapse; Condition Aggravated;	Escitalopram			S	Oral			Forest
	Buspirone			S	Oral	15 Mg		Not Reported

Dizziness; Drug Interaction; Gait Disturbance; Headache; Malaise; Nausea; Speech Disorder; Tremor	Valium	S	Oral	10 Mg		Not Reported
	Atorvastatin	C	Oral			Not Reported
	Lithium Carbonate	C	Oral	400 Mg		Not Reported
	Lofepramine	C	Oral	70 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2013	9269892	EXPEDITED (15-DAY)		OT	SE-JNJFOC-20130411076		25 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blunted Affect; General Physical Condition Abnormal; Hypersomnia; Increased Appetite; Laziness; Sluggishness; Suicidal Ideation; Weight Increased	Xeplion			S	Intramuscular			Not Reported
	Xeplion			S	Intramuscular			Not Reported
	Xeplion			S	Intramuscular			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Haldol			S	Intramuscular			Not Reported
	Haldol			S	Intramuscular			Not Reported
	Haldol			S	Intramuscular			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Abilify			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported
	Cisordinol			S	Unknown			Not Reported
	Cisordinol			S	Unknown			Not Reported

	Cisordinol	S	Unknown	Not Reported
	Trilafon	S	Unknown	Not Reported
	Trilafon	S	Unknown	Not Reported
	Trilafon	S	Unknown	Not Reported
	Cipralex	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2013	9270561	EXPEDITED (15-DAY)		HO	PHHY2013IT041560			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Confusional State; Hyperpyrexia; Musculoskeletal Stiffness; Myoclonus; Psychomotor Hyperactivity; Rhabdomyolysis; Tremor; Vertigo	Tolep			S	Oral	300 Mg, Daily		Novartis
	Lamotrigine			S	Oral	100 Mg, Daily		Not Reported
	Carbolithium			S	Oral	300 Mg, Daily		Not Reported
	Dominans			S	Oral	10.5 Mg, Daily		Not Reported
	Serenase (Haloperidol)			S	Intramuscular	5 Mg, Total		Not Reported
	Xeristar			S	Oral	60 Mg, Daily		Not Reported
	Cipralex			S	Oral	10 Mg, Daily		Not Reported
	Largactil			S	Intramuscular	50 Mg, Total		Not Reported
	Remeron			S	Oral	30 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2013	9270850	EXPEDITED (15-DAY)		HO	IT-WATSON-2013-07481		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Confusional State; Hyperthermia Malignant; Hypertonia; Muscle Rigidity; Myoclonus; Neuroleptic Malignant Syndrome; Psychomotor Hyperactivity; Rhabdomyolysis; Tremor;	Lamotrigine (Unknown)			S	Oral	100 Mg, Daily		Watson
	Tolep			S	Oral	300 Mg, Daily		Not Reported
	Carbolithium			S	Oral	300 Mg, Daily		Not Reported
	Dominans			S	Oral	10.5 Mg, Daily		Not Reported
	Remeron			S	Oral	30 Mg, Daily		Not Reported
	Cipralex			S	Oral	10 Mg, Daily		Not Reported

Vertigo	Largactil /00011901/		S	Intramuscular	50 Mg, Unknown, Total	Not Reported
	Serenase /00015301/		S	Intramuscular	5 Mg Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2013	9277348	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Product Substitution Issue; Therapeutic Product Effect Decreased; Unevaluable Event	Escitalopram 10 Mg			S	Oral		1 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2013	9277410	DIRECT		OT			22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Product Formulation Issue; Product Substitution Issue	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2013	9271912	EXPEDITED (15-DAY)		HO	IT-TEVA-400688ISR		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Confusional State; Hyperpyrexia; Muscle Rigidity; Psychomotor Hyperactivity; Reduced Facial Expression; Rhabdomyolysis; Tremor; Vertigo	Carbolithium			S	Oral	300 Milligram Daily;		Barr
	Lamotrigina			S	Oral	100 Milligram Daily;		Not Reported
	Dominans			S	Oral	10.5 Milligram Daily;		Not Reported
	Serenase (Haloperidol)			S	Intramuscular	5 Milligram Daily;		Not Reported
	Xeristar			S	Oral	60 Milligram Daily;		Not Reported
	Cipralex			S	Oral	10 Milligram Daily;		Not Reported

Largactil	S	Intramuscular	50 Milligram Daily;		Not Reported
Tolep	S	Oral	300 Milligram Daily;		Not Reported
Remeron	S	Oral	30 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2013	9272084	EXPEDITED (15-DAY)		HO	IT-FRI-1000044935		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hyperthermia Malignant; Hypertonia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Rhabdomyolysis	Escitalopram			S	Oral	10 Mg		Forest
	Dominans			S	Oral	10.5 Mg		Not Reported
	Carbolithium			S	Oral	300 Mg		Not Reported
	Lamotrigina			S	Oral	100 Mg		Not Reported
	Serenase (Haloperidol)			S	Intramuscular	5 Mg		Not Reported
	Xeristar			S	Oral	60 Mg		Not Reported
	Largactil			S	Intramuscular	50 Mg		Not Reported
	Tolep			S	Oral	300 Mg		Not Reported
	Remeron			S	Oral	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2013	9272582	EXPEDITED (15-DAY)		HO	IT-GLAXOSMITHKLINE-B0889138A		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Confusional State; Dizziness; Hyperpyrexia; Muscle Rigidity; Myoclonus; Psychomotor Hyperactivity; Rhabdomyolysis; Tremor	Lamotrigine			S	Oral	100mg Per Day		Glaxosmithkline
	Carbolithium			S	Oral	300mg Per Day		Glaxosmithkline
	Escitalopram Oxalate			S	Oral	10mg Per Day		Glaxosmithkline
	Duloxetine Hydrochloride			S	Oral	60mg Per Day		Glaxosmithkline
	Fluphenazine + Nortriptyline			S	Oral	10.5mg Per Day		Glaxosmithkline
	Chlorpromazine Hydrochloride			S	Oral	10mg Per Day		Glaxosmithkline
	Mirtazapine			S	Oral	30mg Per Day		Not Reported
	Haloperidol			S	Intramuscular	5mg Per Day		Not Reported

	Oxcarbazepine	S	Oral	300mg Per Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2013	9287973	EXPEDITED (15-DAY)	Y	HO, LT, OT	2013P1005232		31 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; C-Reactive Protein Increased; Choking; Electrocardiogram T Wave Inversion; Faecaloma; Generalised Tonic-Clonic Seizure; Hypokalaemia; Hypomagnesaemia; Nausea; Stress Cardiomyopathy; Torsade De Pointes; Unresponsive To Stimuli; Ventricular Hypokinesia	Escitalopram			S				Not Reported
	Ondansetron			S	Intravenous (not otherwise specified)			Not Reported
	Methadone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2013	9194232	EXPEDITED (15-DAY)		LT	JP-FRI-1000043785		17 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Off Label Use	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2013	9249737	EXPEDITED (15-DAY)		OT	JP-FRI-1000044538		71 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg		Forest
	Selenica-R			C	Oral	400 Mg		Not Reported

	Lipitor	C	Oral	10 Mg		Not Reported
	Thyradin S	C	Oral	50 Mg		Not Reported
	Symbicort	C				Not Reported
	Mosapride	C	Oral	15 Mg		Not Reported
	Lac-B	C	Oral	30 Mg		Not Reported
	Maglax	C	Oral	990 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2013	9276034	NON-EXPEDITED		OT	US-PFIZER INC-2013139078			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Gait Disturbance; Glucose Tolerance Impaired; Increased Appetite; Muscle Spasms; Oedema Peripheral; Weight Increased	Zoloft			S	Oral	100 Mg, 1 In 1 D		Pfizer
	Lexapro			S	Oral	10 Mg, 1 In 1 D		Not Reported
	Amitriptyline			S	Oral	25 Mg, 1 In 1 D		Not Reported
	Warfarin			C	Oral	8 Mg, Tu, Wed, Fri, Sat, Sun, 1 In 1 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2013	9280125	DIRECT		DS, RI, OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Female Sexual Arousal Disorder; Product Substitution Issue; Vaginal Disorder	Escitalopram 10 Mg			S	Oral	1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2013	9298120	NON-EXPEDITED			PHEH2012US006354		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Acne; Blood Triglycerides	Afinitor (Rad)			S	Oral			Not Reported
	Carbatrol			S				Not Reported

Increased; Emotional Disorder; Mood Altered; Stomatitis	Vitamin C	S	Not Reported
	Lexapro	S	Not Reported
	Stress B (Minerals Nos, Vitamins Nos)	S	Not Reported
	Metformin	S	Not Reported
	Risperdal	S	Not Reported
	Seroquel	S	Not Reported
	Nasonex	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2013	9277906	EXPEDITED (15-DAY)		HO	PHEH2013US010017		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Crying; Drug Ineffective; Fatigue; Feeling Abnormal	Trileptal			S				Novartis
	Concerta			S		Unk Ukn, Unk		Not Reported
	Abilify			S		Unk Ukn, Unk		Not Reported
	Abilify			S		Unk Ukn, Unk		Not Reported
	Lexapro			S		Unk Ukn, Unk		Not Reported
	Saphris			S		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2013	9277967	EXPEDITED (15-DAY)		HO	IT-JNJFOC-20130415555		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hyperthermia Malignant; Hypertonia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Rhabdomyolysis	Serenase (Haloperidol)			S	Intramuscular			Not Reported
	Lamotrigina			S	Oral			Not Reported
	Carbolitium			S	Oral			Not Reported
	Dominans			S	Oral			Not Reported
	Xeristar			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Largactil			S	Intramuscular			Not Reported
	Tolep			S	Oral			Not Reported

	Remeron	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2013	9278582	EXPEDITED (15-DAY)		OT	FR-FRI-1000044966		27 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Malaise; Medication Error; Overdose; Vomiting	Escitalopram			S	Oral	Overdose: 60 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2013	9278875	EXPEDITED (15-DAY)		OT	PHHY2013IT043781			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Dysarthria; Facial Bones Fracture; Mydriasis; Sopor	Delorazepam			S	Oral	40 Ml, Unk		Not Reported
	Venlafaxine			S		2100 Mg, Unk		Novartis
	Lexotan			S	Oral	27 Mg, Unk		Not Reported
	Zoloft			S	Oral	750 Mg, Unk		Not Reported
	Xanax			S	Oral	2.5 Mg, Unk		Not Reported
	Entact			S	Oral	15 Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2013	9282197	DIRECT		OT			15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2013	9281323	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-18862946		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Mania; Pressure Of Speech	Abilify			S		Started On 2 Mg		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2013	9285628	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Product Substitution Issue	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2013	9269483	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2013136238		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hyponatraemia; Urinary Retention	Cordarone			S	Oral	5 Times Weekly (Dose: 0.7143 Df)		Pfizer
	Zofenil Duo			S	Oral	1 Df, 1x/Day		Not Reported
	Seroplex			S	Oral	10 Mg, Daily		Not Reported
	Mopral			S	Oral	20 Mg, Daily		Not Reported
	Kardegic			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2013	9285687	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013143980			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Drug Interaction; Malaise; Skin Odour Abnormal; Urinary Tract Infection	Amlodipine Besilate			S		Unk		Pfizer
	Levothyroxine			S		50 Ug, Five Days A Week		Not Reported
	Levothyroxine			S		75 Ug, Two Days In Weekend		Not Reported
	Lexapro			S		Unk		Not Reported

	Synthroid			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2013	9286004	EXPEDITED (15-DAY)		DE	CH-ASTRAZENECA-2013SE32263		40 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Seroquel			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Ritaline			C	Oral			Not Reported
	Zyprexa			C	Oral			Not Reported
	Temesta (Lorazepam)			C				Not Reported
	Nicotinell			C		14 Mg, 1 Per 24 Hours		Not Reported
	Irfen			C				Not Reported
	Prazine (Promazine Hydrochloride)			C				Not Reported
	Dafalgan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2013	9286427	EXPEDITED (15-DAY)		CA	US-FRI-1000045016		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2013	9288129	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20130500704		21 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Risperdal			S	Unknown			Not Reported
	Topamax			S	Unknown			Not Reported
	Atarax			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported

	Subutex	S	Unknown		Not Reported
	Trittico	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2013	9290095	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2013	9290676	DIRECT	Y				27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Tremor; Tremor	Escitalopram			S	Oral	(1-4 Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2013	8032500	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2011150703		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Inflammation; Reye'S Syndrome; Toxicity To Various Agents	Xanax			S	Oral	0.5 Mg, Unk		Pfizer
	Avlocardyl			S	Oral	40 Mg, Unk		Not Reported
	Seroplex			S	Oral	20 Mg, Unk		Not Reported
	Norset			S	Oral	15 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2013	9248875	EXPEDITED (15-DAY)		OT	FR-FRI-1000044495		29 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Incorrect Dose Administered; Incorrect	Escitalopram			S	Oral	Overdose: 90 Mg		Forest

Drug Administration Rate;
Medication Error;
Mydriasis; Off Label Use;
Tachycardia; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2013	9289994	EXPEDITED (15-DAY)		OT	US-ACCORD-017588		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Off Label Use; Sedation	Topiramate			S		Drug Started With 50 Mg/Day And Increased To 100 Mg/Day		Accord
	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2013	9290753	EXPEDITED (15-DAY)		OT	JP-FRI-1000044717		88 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypotension	Lexapro			S	Oral	10 Mg		Forest
	Clotiazepam			S	Oral	5 Mg		Not Reported
	Bayaspirin			C	Oral	100 Mg		Not Reported
	Irbetan			C	Oral	50 Mg		Not Reported
	Artist			C	Oral	2.5 Mg		Not Reported
	Towarat-Cr			C	Oral	20 Mg		Not Reported
	Mequitolide			C	Oral			Not Reported
	Vasolator			C	Other	27 Mg		Not Reported
	Crestor			C	Oral			Not Reported
	Glactiv			C	Oral	50 Mg		Not Reported
	Celecox			C	Oral	200 Mg		Not Reported
	Itopride Hydrochloride			C	Oral	150 Mg		Not Reported
	Pocevin			C	Intramuscular			Not Reported
	Nitroglycerin			C	Sublingual			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2013	9291118	EXPEDITED (15-DAY)		OT	US-NICOBRDEVP-2013-08103			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Bedridden; Decreased Activity; Depressed Mood; Depression; Disability; Disturbance In Attention; Drug Interaction; Drug Level Decreased; Hypersomnia; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Maternal Exposure During Pregnancy; Mood Altered; Overdose; Stress	Microgestin			S	Oral	Unk		Watson
	Lamotrigine (Watson Laboratories)			S	Oral	300 Mg, Unk		Watson
	Venlafaxine Hydrochloride (Unknown)			S	Unknown	Unk		Not Reported
	Lamictal			S	Oral	300 Mg, Unk		Not Reported
	Ziprasidone			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Oral	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Atorvastatin Calcium			C	Unknown	Unk		Not Reported
	Oxcarbazepine			C	Unknown	Unk		Not Reported
	Nortriptyline			C	Unknown	Unk		Not Reported
	Folplex			C	Unknown	Unk		Not Reported
	Prenatal Vitamins /01549301/			C	Unknown	Unk		Not Reported
	Fish Oil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2013	9292639	DIRECT					63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Escitalopram			S		10 Mg 1 Tab Daily 1g/250		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2013	9292703	DIRECT					65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Nightmare; Product Substitution Issue; Sleep Disorder	Escitalopram		S	Oral	10 Mg 1 Daily Oral	10 DAY	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2013	9197683	EXPEDITED (15-DAY)		OT	IE-FRI-1000043807		92 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Head Titubation; Tremor	Lexapro			S	Oral	5 Mg		Forest
	Amlodipine			C				Not Reported
	Statin			C				Not Reported
	Persantin Retard			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2013	9235077	EXPEDITED (15-DAY)		OT	DE-FRI-1000044249		19 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Condition Aggravated; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Inversion	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2013	9292023	NON-EXPEDITED			US-PFIZER INC-2013150301		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Middle Insomnia; Nausea; Somnolence	Lyrica			S		75 Mg, Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Xanax			C		Unk		Not Reported

	Elavil	C	Unk	Not Reported
	Vicodin	C	7.5mg/750mg	Not Reported
	Skelaxin	C	Unk	Not Reported
	Tramadol	C	Unk	Not Reported
	Tramadol	C		Not Reported
	Mobic	C	Unk	Not Reported
	Vitamin B12	C	1000mg Once A Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2013	9293718	EXPEDITED (15-DAY)		HO	ES-FRI-1000045182		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hyperprolactinaemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	20 Mg		Forest
	Enalapril			C				Not Reported
	Tesavel			C				Not Reported
	Tranxilium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2013	9241120	EXPEDITED (15-DAY)		LT, OT	JP-FRI-1000044481		80 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicide; Suicide Attempt	Lexapro			S	Oral	10 Mg		Forest
	Mevan			C	Oral	10 Mg		Not Reported
	Amlodipine Od			C	Oral	5 Mg		Not Reported
	Depas (Etizolam)			C	Oral	0.5 Mg		Not Reported
	Rebamipide			C	Oral	300 Mg		Not Reported
	Neurotropin			C	Oral	12 Ut		Not Reported
	Ringereaze			C	Oral	60 Mg		Not Reported
	Pa			C	Oral	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2013	9269673	EXPEDITED (15-DAY)		HO	JP-FRI-1000044889		63 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Lexapro			S	Oral	10 Mg		Forest
	Limas			S	Oral	200 Mg		Not Reported
	Amoxan			S	Oral	150 Mg		Not Reported
	Diovan			C	Oral			Not Reported
	Solanax			C	Oral			Not Reported
	Lendem			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2013	9279030	EXPEDITED (15-DAY)		OT	US-FRI-1000044954		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Impulsive Behaviour; Overdose	Daliresp			S	Oral	500 Mcg		Forest
	Prednisone			S				Not Reported
	Lexapro			S				Not Reported
	Xanax			S				Not Reported
	Morphine			S				Not Reported
	Oxycodone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2013	9295966	EXPEDITED (15-DAY)		OT	CA-FRI-1000045206			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Escitalopram			S	Oral			Forest
	Topamax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2013	9296708	NON-EXPEDITED		HO	JP-FRI-1000045247		61 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Seizure	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2013	9296781	EXPEDITED (15-DAY)		DE	CH-FRI-1000045207			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Escitalopram			S	Oral	10 Mg		Forest
	Seroquel			S	Oral	400 Mg		Not Reported
	Ritaline			C	Oral	20 Mg		Not Reported
	Zyprexa			C	Oral	10 Mg		Not Reported
	Temesta (Lorazepam)			C	Oral	3 Mg		Not Reported
	Nicotinell			C	Other	14 Mg		Not Reported
	Irfen			C	Oral	120 Mg		Not Reported
	Prazine (Promazine Hydrochloride)			C		200 Mg		Not Reported
	Dafalgan			C	Oral	4000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2013	9297658	DIRECT	Y	OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fear; Feeling Abnormal; Imprisonment; Incorrect Dose Administered; Separation Anxiety Disorder	Risperidone			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2013	9536631	NON-EXPEDITED	Y		1000042957		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Dizziness	Viibryd	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
	Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets)	S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral	Not Reported
			Oral	5 Mg (5 Mg, 1 In 1 D), Oral	
	Levothyroxine (Levothyroxine Sodium) (Levothyroxine Sodium)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2013	8664611	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20120703801		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Sopor; Wrong Product Administered	Reminyl			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2013	9155245	EXPEDITED (15-DAY)		DE	JP-FRI-1000043171		79 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Sudden Death	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Seniran			S	Oral	6 Mg		Not Reported
	Reflex			S	Oral	15mg		Not Reported
	Reflex			S	Oral	30mg		Not Reported
	Reflex			S	Oral	45mg		Not Reported
	Reflex			S	Oral	15mg		Not Reported
	Amaryl			S	Oral	1mg		Not Reported
	Rozerem			C	Oral	8mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2013	9256012	EXPEDITED (15-DAY)		LT	IT-FRI-1000044676		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Sopor	Escitalopram Oral Solution			S	Oral	Overdose: 15 Ml (300 Mg)		Forest
	Xanax			S	Oral	Overdose: 20 Tablets (60 Mg)		Not Reported
	Methadone Hydrochloride			S	Oral	90 Mg		Not Reported
	Depakin			S		Overdose: 6 Sachet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2013	9298579	EXPEDITED (15-DAY)		LT, OT	CA-ASTRAZENECA-2013SE34580		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Torsade De Pointes	Quetiapine			S	Oral			Zeneca
	Escitalopram			S				Not Reported
	Furosemide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2013	9301632	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear; Feeling Abnormal; Product Substitution Issue	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2013	9413172	EXPEDITED (15-DAY)	Y	HO, OT	AUR-APL-2013-03549		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hyperthermia Malignant; Hypertonia; Muscle Rigidity;	Lamotrigine (Lamotrigine)			S				Not Reported
	Remeron			S				Not Reported
	Tolep			S				Not Reported

Neuroleptic Malignant Syndrome; Rhabdomyolysis	Carbolithium	S	Not Reported
	Dominans	S	Not Reported
	Xeristar	S	Not Reported
	Cipralex	S	Not Reported
	Largactil	S	Not Reported
	Serenase (Haloperidol)	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2013	8666895	EXPEDITED (15-DAY)		OT	DE-FRI-1000037083		47 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Uveitis	Escitalopram			S	Oral	10 - 15 Mg		Forest
	Cymbalta			C	Oral	60 Mg		Not Reported
	Metoprolol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2013	9302950	EXPEDITED (15-DAY)		OT	DE-FRI-1000045262			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prostatic Specific Antigen Increased; Restlessness; Urinary Retention	Escitalopram Oral Solution			S	Oral	5 - 6 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2013	9302988	EXPEDITED (15-DAY)		HO	FR-FRI-1000045263		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Overdose; Oxygen Saturation Decreased	Escitalopram			S	Oral	Overdose: 60 Tablets		Forest
	Zopiclone			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Depamide			C				Not Reported
	Deroxat			C				Not Reported
	Inexium			C				Not Reported
	Valium			C				Not Reported

Sulfarlem	C		Not Reported
Noctamide	C		Not Reported
Risperdal	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2013	9303161	EXPEDITED (15-DAY)		HO	IT-FRI-1000045264		87 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Agitation; Confusional State; Dehydration; Erythema; Faecaloma; Haemorrhoids	Escitalopram Oral Solution			S	Oral	10 Mg		Forest
	Oxygen			S				Not Reported
	Lansoprazole			S		15 Mg		Not Reported
	Methylprednisolone			S		8 Mg		Not Reported
	Paracetamol			S		1500 Mg		Not Reported
	Acetylcysteine			S		2 Df		Not Reported
	Fluticasone Aerosol			S				Not Reported
	Allopurinol			S		300 Mg		Not Reported
	Furosemide			S		50 Mg		Not Reported
	Pregabalin			S		50 Mg		Not Reported
	Acetylsalicylic Acid			S		1 Df		Not Reported
	Calcium Levofolinate Pentahydrate			S		7.5 Mg		Not Reported
	Cyanocobalamin			S				Not Reported
	Calcitriol			S		0.25 Mg		Not Reported
	Promazine Hydrochloride			S		5-10 Drops		Not Reported
	Delorazepam			S		13 Drops		Not Reported
	Valerian			S				Not Reported
	Liquorice			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2013	9303355	EXPEDITED (15-DAY)		DE	FR-FRI-1000045294		92 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Subdural	Escitalopram			S	Oral	1 Df		Forest

Haematoma; Traumatic Intracranial Haemorrhage	Kardegic		S	Oral	1 Df	Not Reported
	Inexium		C	Oral	1 Df	Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)		C	Oral	2 Df	Not Reported
	Lasilix Faible		C	Oral	1 Df	Not Reported
	Seresta		C	Oral	2 Df	Not Reported
	Stilnox		C	Oral	1 Df	Not Reported
	Triatec (Ramipril)		C	Oral	1 Df	Not Reported
	Forlax		C	Oral	1 Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2013	9304397	EXPEDITED (15-DAY)		OT	PHHY2013GB050180		30 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased	Citalopram			S	Oral	20 Mg		Novartis
	Escitalopram			S	Oral	40 Mg		Not Reported
	Ventolin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2013	9033324	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000042165		1 DAY	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypotonia; Respiratory Depression	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2013	9044105	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000042207		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Decreased; Cardiotoxicity;	Escitalopram			S				Forest
	Amitriptyline			S				Not Reported

Coma; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haemodynamic Instability; Hypocalcaemia; Hypokalaemia; Hypotension; Intentional Overdose; Pulse Absent; Suicide Attempt; Tachycardia	Fluoxetine	S	Not Reported
	Gabapentin	S	Not Reported
	Olanzapine	S	Not Reported
	Quetiapine	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2013	9306271	EXPEDITED (15-DAY)		CA	US-FRI-1000045236		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Artery Stenosis Congenital; Transposition Of The Great Vessels; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2013	9033194	EXPEDITED (15-DAY)		LT	CA-FRI-1000042163		42 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Fatigue; Heart Rate Increased; Hyperhidrosis; Pallor; Somnolence; Yawning	Escitalopram			S				Forest
	Centrum			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2013	9033204	EXPEDITED (15-DAY)		OT	CA-FRI-1000042168		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Epistaxis; Haematoma; Impaired Healing; Menorrhagia;	Escitalopram			S	Oral	20 Mg		Forest

Nasal Disorder; Petechiae

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2013	9033313	EXPEDITED (15-DAY)		LT	CA-FRI-1000042167		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Dizziness; Hypersomnia; Hypoaesthesia; Loss Of Personal Independence In Daily Activities; Mental Impairment; Migraine	Escitalopram			S	Oral	5 Mg		Forest
	Concerta			S	Oral	54 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2013	9223204	EXPEDITED (15-DAY)		HO, OT	JP-009507513-1304JPN002734		65 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Extradural Haematoma; Fall; Pancytopenia; Pneumocephalus; Skull Fracture; White Blood Cell Count Decreased	Remeron			S	Oral	15 Mg, Qd		Merck
	Undepre			S	Oral	25 Mg, Tid		Not Reported
	Cymbalta			S	Oral	20 Mg, Bid		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Sulpiride			C	Oral	50 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2013	9307576	NON-EXPEDITED			US-PFIZER INC-2013154469		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction	Viagra			S		50 Mg, As Needed		Pfizer
	Lexapro			S		20 Mg Daily		Not Reported
	Wellbutrin			S		150 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2013	9308189	EXPEDITED (15-DAY)		OT	US-TEVA-406772USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Drug Interaction; Malaise; Parosmia; Urinary Tract Infection	Levothyroxine Sodium For Injection,200 Mcg/6 Ml Vial & 500 Mcg/6 Ml Vi			S		50 Mcg, Five Days A Week And 75mcg For Two Days In Weekend		Teva
	Levoxyl			S				Not Reported
	Lexapro			S				Not Reported
	Amlodipine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2013	9311586	NON-EXPEDITED			US-PFIZER INC-2013158678		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Penicillin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2013	9316489	DIRECT		HO			13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Psychotic Disorder; Refusal Of Treatment By Relative; Self-Injurious Ideation	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2013	9314807	EXPEDITED (15-DAY)		OT	GB-TEVA-407932ISR		30 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased	Citalopram		S	Oral	Ivax
	Escitalopram		S	Oral	Not Reported
	Ventolin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2013	9315338	NON-EXPEDITED			US-PFIZER INC-2013163389		45 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Abilify			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lunesta			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2013	9315660	EXPEDITED (15-DAY)		OT	CH-FRI-1000045444			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Restless Legs Syndrome; Sleep Disorder	Escitalopram			S	Oral			Forest
	Cymbalta			S	Oral	60 Mg		Not Reported
	Cymbalta			S				Not Reported
	Tramal			S	Oral	75 Mg		Not Reported
	Salazopyrin			C	Oral	1500 Mg		Not Reported
	Dafalgan			C	Oral	4000 Mg		Not Reported
	Tilur			C	Oral	180 Mg		Not Reported
	Esomeprazole			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2013	9144365	EXPEDITED (15-DAY)		HO, LT	SE-FRI-1000043130		21 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Personality Change; Suicidal Ideation; Suicide Attempt	Escitalopram		S	Oral	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2013	9173945	EXPEDITED (15-DAY)		DE, HO, OT	ES-CELGENEUS-144-21880-13031817		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Revlimid			S	Oral	10 Milligram		Celgene
	Dexamethasone			S	Oral	40 Milligram		Not Reported
	Metamizole			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Durogesic			S	Unknown			Not Reported
	Lactitol			S	Unknown			Not Reported
	Lactitol			S	Unknown			Not Reported
	Omeprazole			S	Unknown			Not Reported
	Zoledronic Acid			S	Unknown			Not Reported
	Zoledronic Acid			S	Unknown			Not Reported
	Aas			S	Unknown			Not Reported
	Salicylic Acid			S	Unknown			Not Reported
	Levofloxacine			S	Unknown			Not Reported
	Megestrol			S	Unknown			Not Reported
	Potassium			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2013	9192603	NON-EXPEDITED			US-PFIZER INC-2013095165		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Sensation In Eye; Drug Ineffective; Feeling Abnormal; Product Dose Omission; Sensory Disturbance; Tinnitus	Effexor Xr	S	150 Mg, Daily	Pfizer
	Effexor Xr	S	75 Mg, Daily	Pfizer
	Effexor Xr	S	37.5 Mg, Daily	Pfizer
	Effexor Xr	S	Unk	Pfizer
	Lexapro	S	Unk	Not Reported
	Trazodone	C	Unk	Not Reported
	Valaciclovir Hydrochloride	C	500 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2013	9280791	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2013143519			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bedridden; Brain Injury; Cognitive Disorder; Complex Regional Pain Syndrome; Concussion; Contusion; Diarrhoea; Dyskinesia; Dyspnoea; Eye Contusion; Feeding Disorder; Feeling Abnormal; Injury; Irritability; Loss Of Personal Independence In Daily Activities; Malaise; Memory Impairment; Pain; Pain; Swelling; Upper Limb Fracture; Vomiting; Weight Decreased; Withdrawal Syndrome	Gabapentin			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2013	9316477	EXPEDITED (15-DAY)		OT	GB-ACCORD-017761		30 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased	Escitalopram		S	Oral	Accord
	Citalopram		S	Oral	Accord
	Ventolin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2013	9320352	EXPEDITED (15-DAY)		OT	GB-FRI-1000045511		30 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased; Overdose	Escitalopram			S	Oral	Overdose: 40 Mg Daily		Forest
	Citalopram			C	Oral	20 Mg		Not Reported
	Ventolin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2013	9321085	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritable Bowel Syndrome; Product Substitution Issue	Lexapro			S	Oral	20mg Daily By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2013	9213902	EXPEDITED (15-DAY)		OT	IE-FRI-1000044030		30 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Visual Field Defect; Withdrawal Syndrome	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral	15 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2013	9213906	EXPEDITED (15-DAY)		OT	IE-FRI-1000044029			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Withdrawal Syndrome	Lexapro			S	Oral			Forest
	Lexapro			S		10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2013	9321389	EXPEDITED (15-DAY)		OT	US-FRI-1000045429			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Drug Ineffective; Haematochezia; Panic Attack	Celexa			S				Forest
	Lexapro			S		10 Mg		Forest
	Humira			S		40 Mg		Not Reported
	Lisinopril			C		10/12.5mg		Not Reported
	Lisinopril			C				Not Reported
	Cartia (Diltiazem Hydrochloride)			C		180 Mg		Forest
	Asacol			C		6 Dosage Forms		Not Reported
	Diphenhydramine			C		25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2013	9321544	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000045450			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bedridden; Complex Regional Pain Syndrome; Concussion; Contusion; Decreased Appetite; Diarrhoea; Drug Withdrawal Syndrome; Dyskinesia; Dysphagia;	Lexapro			S				Forest
	Lyrica			S				Not Reported
	Cymbalta			S				Not Reported
	Gabapentin			S				Not Reported

Dyspnoea; Eye Contusion; Fear Of Death; Irritability; Malaise; Memory Impairment; Mental Impairment; Movement Disorder; Negative Thoughts; Pain; Post-Traumatic Pain; Swelling; Unevaluable Event; Upper Limb Fracture; Vomiting; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2013	9322479	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2013S1011055		30 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased	Citalopram			S	Oral			Mylan
	Escitalopram			S	Oral			Not Reported
	Ventolin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2013	9325656	DIRECT					65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Depression; Disturbance In Attention; Irritability; Product Substitution Issue; Quality Of Life Decreased; Tachyphrenia	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2013	9194289	EXPEDITED (15-DAY)		HO	US-FRI-1000043679		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Drug Ineffective; Intentional Overdose; Suicide Attempt	Escitalopram	S	Oral	10mg	Forest
	Escitalopram	S	Oral	20mg	Forest
	Sonata	S		10mg As Needed	Not Reported
	Valium	S		5mg As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2013	9324904	EXPEDITED (15-DAY)		OT	GB-WATSON-2013-09631		30 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased	Citalopram Hydrobromide (Unknown)			S	Oral	20mg Daily		Watson
	Escitalopram			S	Oral	40 Mg, Daily		Not Reported
	Ventolin /00139502/			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2013	9324921	EXPEDITED (15-DAY)		HO	ES-TEVA-409397ISR		78 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Dysarthria; Hallucination	Azilect			S	Oral	1 Milligram Daily;		Teva
	Cipralex			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2013	9325837	DIRECT		OT			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Product Quality Issue; Product Substitution Issue; Therapeutic Product Effect Decreased; Thinking Abnormal	Escitalopram			S				Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2013	9326557	DIRECT	Y	HO			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash; Swelling Face	Lexapro			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2013	9278863	EXPEDITED (15-DAY)		OT	IT-FRI-1000044996		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Lethargy; Mydriasis; Nasal Injury; Overdose; Speech Disorder	Escitalopram Oral Solution			S	Oral			Forest
	Delorazepam			S	Oral	40 Ml		Not Reported
	Venlafaxine Hydrochloride			S	Oral	2100 Mg		Not Reported
	Lexotan			S	Oral	27 Mg		Not Reported
	Xanax			S	Oral	2.5 Mg		Not Reported
	Zoloft			S	Oral	750 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2013	9326190	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000045583		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Newborn Persistent Pulmonary Hypertension	Lexapro			S	Transplacental			Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2013	9327654	NON-EXPEDITED			US-PFIZER INC-2013167706		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Pristiq			S		Unk		Pfizer

	Flector	S	Unk	Pfizer
	Mirtazapine	S	Unk	Not Reported
	Ambien	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2013	9330734	DIRECT	Y	DS, OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Disorder; Product Substitution Issue	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2013	8541791	EXPEDITED (15-DAY)		LT	JP-FRI-1000030140		41 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia	Lexapro			S	Oral	20 Mg		Forest
	Reflex			C	Oral	15 Mg		Not Reported
	Reflex			C		45 Mg		Not Reported
	Gasmotin			C	Oral	5 Mg		Not Reported
	Rohypnol			C	Oral	2 Mg		Not Reported
	Reslin			C	Oral	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2013	9246597	EXPEDITED (15-DAY)		LT	IT-ABBOTT-13X-083-1079456-00		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Somnolence	Depakin			S	Oral			Not Reported

	Xanax	S	Oral	Tablet, Extended Release, 20 Dosage Form	Not Reported
	Methadone Hydrochloride	S	Oral		Not Reported
	Entact	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2013	9338257	DIRECT					67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mobility Decreased	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2013	9338584	DIRECT		OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral		3 DAY	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2013	9340490	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2013-04602		53 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Infection; Cerebral Atrophy; Cerebral Ventricle Dilatation; Cognitive Disorder; Diabetic Retinopathy; Gait Disturbance; Lethargy; Memory Impairment; Neurological Decompensation; Normal Pressure Hydrocephalus; Peripheral Sensorimotor Neuropathy; Speech	Escitalopram (Escitalopram)			S				Not Reported
	Pregabalin (Pregabalin)			S				Not Reported
	Carbamazepine (Carbamazepine)			S				Not Reported
	Amitriptyline (Amitriptyline)			S				Not Reported

Disorder; Urinary Incontinence

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2013	9335118	EXPEDITED (15-DAY)		OT	IN-FRI-1000045734		53 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Gait Disturbance; Lethargy	Escitalopram			S				Forest
	Amitriptyline			S				Not Reported
	Carbamazipine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2013	9339008	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Disease Recurrence; Irritability; Product Substitution Issue	Escitalopram			S	Oral	1 Tab Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2013	9342046	EXPEDITED (15-DAY)	Y	LT	2013AP005538		51 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicidal Ideation; Suicide Attempt	Escitalopram (Escitalopram)			S				Not Reported
	Fluoxetine Hydrochloride (Fluoxetine Hydrochloride)			S				Not Reported
	Esomeprazole Magnesium (Esomeprazole Magnesium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2013	9184552	EXPEDITED (15-DAY)		HO	FR-ABBOTT-13X-056-1065853-00		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Epistaxis; Neutropenia; Thrombocytopenia	Zeclar	S	Oral	500 Mg Twice		Not Reported
	Calciparine	S	Subcutaneous			Not Reported
	Clamoxyl (Amoxicillin)	S	Oral			Not Reported
	Seroplex	S	Oral			Not Reported
	Paracetamol	S	Oral			Not Reported
	Inspiral	S	Oral			Not Reported
	Crestor	S	Oral			Not Reported
	Plavix	S	Oral			Not Reported
	Kardegic	S	Oral			Not Reported
	Inexium	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2013	9187149	EXPEDITED (15-DAY)		HO	FR-FRI-1000043685		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Thrombocytopenia	Escitalopram			S	Oral	10 Mg		Forest
	Clamoxyl (Amoxicillin)			S	Oral	2 Gram		Not Reported
	Zeclar			S	Oral	1000 Mg		Not Reported
	Calciparine			C	Other	0.4 Ml		Not Reported
	Paracetamol Macopharma			C	Other	0.25 Gram		Not Reported
	Inspra			C	Oral	25 Mg		Not Reported
	Crestor			C	Oral	5 Mg		Not Reported
	Plavix			C	Oral	75 Mg		Not Reported
	Kardegic			C	Oral	75 Mg		Not Reported
	Inexium			C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2013	9200249	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2013094901		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Suicidal Ideation	Ziprasidone Hcl		S	Oral	60 Mg, 2x/Day	Pfizer
	Lexapro		S		Unk	Not Reported
	Trazodone		C	Oral	150 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2013	9247309	EXPEDITED (15-DAY)		HO, LT	FR-JNJFOC-20130408914		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Pyrexia	Haldol			S	Oral			Not Reported
	Oflocet			S	Oral			Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Oral			Not Reported
	Seroplex			S	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2013	9336724	EXPEDITED (15-DAY)		OT	FR-FRI-1000045740		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loose Tooth	Escitalopram			S	Oral			Forest
	Lexomil			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Oral			Not Reported
	Lysanxia			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2013	9336735	EXPEDITED (15-DAY)		LT	FR-FRI-1000045735		25 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Overdose	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose Of An Unknown Dose		Forest

	Imovane	S	Oral			Not Reported
	Imovane	S	Oral	Overdose Of An Unknown Dose		Not Reported
	Tercian	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2013	9336755	EXPEDITED (15-DAY)		HO	ES-FRI-1000045738		78 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Dysarthria; Hallucination	Escitalopram			S	Oral	10 Mg		Forest
	Rasagiline			S	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2013	9340447	EXPEDITED (15-DAY)		CA	DE-FRI-1000045758			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental			Forest
	Opipramol Dura			S	Transplacental	300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2013	9340541	DIRECT		HO			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack; Seizure	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2013	9341291	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Feeling Abnormal; Insomnia;	Escitalopram			S				Not Reported
	Lexapro			S	Oral	Strength: 10/20 1 Per Day		Forest

Product Quality Issue; Product Substitution Issue	Mouth

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2013	9236762	EXPEDITED (15-DAY)		HO, OT	US-TEVA-398025USA		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Cough; Dehydration; Dysphagia; Meningioma; Weight Decreased	Escitalopram			S		1/2 Tablet		Ivax
	Metformin			C				Not Reported
	Estropipate			C				Not Reported
	Robinal			C				Not Reported
	Lipitor			C				Not Reported
	Lamictal			C				Not Reported
	Effexor			C				Not Reported
	Neurontin			C				Not Reported
	Hyzaar			C				Not Reported
	Tramadol			C				Not Reported
	Deplin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2013	9260765	EXPEDITED (15-DAY)		OT	DK-FRI-1000044730		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fatigue; Illusion; Mania; Muscle Spasms; Palpitations; Restlessness; Sleep Disorder; Suicidal Ideation; Weight Increased	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2013	9343158	EXPEDITED (15-DAY)		OT	FR-FRI-1000045853		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Labelled Drug-Drug Interaction	Escitalopram			S		10 Mg		Forest
	Zyprexa			S				Not Reported

Medication Error	Xanax	C	Oral	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2013	9291364	EXPEDITED (15-DAY)		OT	US-FRI-1000045024		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Angina Pectoris; Depression; Hypothyroidism	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Viibryd			S	Oral	10 Mg		Forest
	Viibryd			S	Oral	20 Mg		Forest
	Coumadin			C				Not Reported
	Ibuprofen			C				Not Reported
	Lasix			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2013	9332718	EXPEDITED (15-DAY)		OT	AUR-APL-2013-04269		30 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Confusional State; Drug Abuse; Hyperhidrosis; Loss Of Libido; Partner Stress	Citalopram (Citalopram)			S	Oral			Not Reported
	Escitalopram (Escitalopram)			S	Oral			Not Reported
	Ventolin (Salbutamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2013	9345662	EXPEDITED (15-DAY)		OT	PHHY2013IN058944		53 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Dementia; Gait Disturbance; Lack Of Spontaneous Speech; Lethargy; Memory Impairment; Movement	Amitriptyline			S				Novartis
	Carbamazepine			S				Not Reported
	Pregabalin			S				Not Reported
	Escitalopram			S				Not Reported

Disorder; Normal Pressure Hydrocephalus; Peripheral Sensorimotor Neuropathy; Urinary Incontinence

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2013	9300530	EXPEDITED (15-DAY)		HO	JP-FRI-1000045210		41 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Dysarthria; Overdose; Peripheral Coldness; Toxicity To Various Agents	Lexapro			S	Oral	Overdose: 5 Tablets		Forest
	Depakene			S	Oral	Overdose: 13 Tablet Of Sodium Valproate 200 Mg		Not Reported
	Flunitrazepam			S	Oral	3 Mg		Not Reported
	Biofermin			C	Oral	4 Df		Not Reported
	Primperan			C	Oral	10 Mg		Not Reported
	Stomachics And Digestives			C	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2013	9323706	EXPEDITED (15-DAY)		OT	US-SHIRE-ALL1-2013-03472		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Oedema Peripheral	Blinded 489 (Lisdexamfetamine Dimesylate)			S	Oral	Unk Unk, 1x/Day:Qd		Shire
	Blinded Duloxetine Hydrochloride			S	Oral	Unk Unk, 1x/Day:Qd		Shire
	Blinded Escitalopram Oxalate			S	Oral	Unk Unk, 1x/Day:Qd		Shire
	Blinded Placebo			S	Oral	Unk Unk, 1x/Day:Qd		Shire
	Blinded Sertraline Hydrochloride			S	Oral	Unk Unk, 1x/Day:Qd		Shire
	Blinded Venlafaxine Hydrochloride			S	Oral	Unk Unk, 1x/Day:Qd		Shire
	Duloxetine Hydrochloride			S	Unknown	30 Mg, Unknown		Unknown
	Duloxetine Hydrochloride			S	Unknown	60 Mg, Unknown		Unknown
	Multivitamin /07504101/			C	Unknown	Unk Unk, Unknown		Not Reported

	Fish Oil	C	Unknown	Unk Unk, Unknown	Not Reported
	Biotin	C	Unknown	Unk Unk, Unknown	Not Reported
	B-12	C	Unknown	Unk Unk, Unknown	Not Reported
	Lutein /01638501/	C	Unknown	Unk Unk, Unknown	Not Reported
	Potassium	C	Unknown	Unk Unk, Unknown	Not Reported
	Probiotic /06395501/	C	Unknown	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2013	9347988	EXPEDITED (15-DAY)		DS, HO, OT	FR-ASTRAZENECA-2013SE41168		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metabolic Encephalopathy	Inexium			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Keal			S	Oral			Not Reported
	Seretide Diskus			C				Not Reported
	Spiriva			C				Not Reported
	Procoralan			C				Not Reported
	Amlor			C				Not Reported
	Gaviscon			C				Not Reported
	Tahor			C				Not Reported
	Kardegic			C				Not Reported
	Tardyferon B9 [Ferrous Sulfate;Folic Acid]			C				Not Reported
	Motilium			C				Not Reported
	Kaleorid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2013	9348935	EXPEDITED (15-DAY)		OT	PL-FRI-1000045925			Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunosuppression; Myalgia; Nasal Inflammation; Tendon Pain	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2013	9348943	EXPEDITED (15-DAY)		HO	FR-FRI-1000045926		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Escitalopram			S	Oral			Forest
	Coversyl			S	Oral			Not Reported
	Selokeen			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Lasilix			S				Not Reported
	Ogast			S				Not Reported
	Seresta			S	Oral			Not Reported
	Victan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2013	9348953	EXPEDITED (15-DAY)		DE	CH-FRI-1000045928		85 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Xarelto			S	Oral	20 Mg		Not Reported
	Xarelto			S				Not Reported
	Eltroxin			C	Oral	0.1 Mg		Not Reported
	Pantoprazol			C	Oral	40 Mg		Not Reported
	Symbicort			C	Other	200/6		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2013	9352984	DIRECT	Y				33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Diarrhoea; Product Substitution Issue	Escitalopram			S				Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2013	8586962	NON-EXPEDITED			US-ASTRAZENECA-2012SE31459		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hypertension; Hypothyroidism; Renal Impairment; Somnolence; Trismus	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Synthroid			C	Oral			Not Reported

Clomipramine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2013	9350591	EXPEDITED (15-DAY)		OT	US-ACCORD-018035		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Musculoskeletal Discomfort; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Tendonitis; Weight Increased	Escitalopram			S	Oral	Duration - 4-5 Months.		Accord
	Trazodone			C	Oral			Not Reported
	Adderall			C	Oral			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Concerta			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2013	9350663	EXPEDITED (15-DAY)		HO	PHHY2013NO059339		38 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis	Voltarol			S	Oral	25 Mg, 3-4 Times Daily		Novartis
	Escitalopram Actavis			S	Oral	15 Mg, Qd		Not Reported
	Imovane			C	Oral	7.5 Mg, Qd		Not Reported
	Paracet			C	Oral	500 Mg, (3-4 Times)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2013	9351102	EXPEDITED (15-DAY)		CA	US-FRI-1000045842		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2013	9353649	DIRECT	Y				60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Treatment Failure	Escitalopram			S	Oral			Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2013	9359154	EXPEDITED (15-DAY)	Y	HO	7215926		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplasia; Musculoskeletal Pain; Pyrexia	Levothyrox			S	Oral	From Long Term		Not Reported
	Taxotere			S	Intravenous (not otherwise specified)	180mg Per Cycle		Not Reported
	Seroplex			S	Oral	From Long Term		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2013	8584812	EXPEDITED (15-DAY)		DE	JP-FRI-1000030817		21 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Depression	Lexapro			S	Oral	10 Mg		Forest
	Medipeace			S	Oral	1 Mg		Not Reported
	Amoban			S	Oral	7.5 Mg		Not Reported
	Mucosta			C	Oral	200 Mg		Not Reported
	Goodmin			C	Oral	0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2013	9353660	EXPEDITED (15-DAY)		OT	FR-FRI-1000045957			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise; Product Dispensing Error	Escitalopram			S				Forest
	Modopar			C				Not Reported
	Cozaar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2013	9353856	EXPEDITED (15-DAY)		OT	US-TEVA-412705USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2013	9354900	DIRECT		DS, HO, LT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Asthenia; Decreased Appetite; Depression; Diarrhoea; Diplopia; Dizziness; Dry Mouth; Dyspepsia; Feeling Abnormal; Hallucination; Insomnia; Pollakiuria; Sinus Disorder; Sluggishness; Somnolence; Suicidal Ideation; Tinnitus	Escitalopram			S	Oral	1 And A Half Pills		Unknown
	Multi			C				Not Reported
	Calcium		Y	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2013	9355246	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Folliculitis; Scar; Skin Disorder	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2013	9272873	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2013138192		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Increased; Coma Scale; Drug Abuse; Fall; Lethargy; Mydriasis; Nasal Injury; Somnolence; Speech Disorder	Xanax	S	Oral	2.5 Mg, Total Dose	Pfizer
	Zoloft	S	Oral	750 Mg, Total Dose	Pfizer
	Venlafaxine Hcl	S	Oral	2100 Mg, Total Dose	Pfizer
	Lexotan	S	Oral	27 Mg, Total Dose	Not Reported
	Entact	S	Oral	15 Ml, Total Dose	Not Reported
	Delorazepam	S	Oral	40 Ml, Total Dose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2013	9354829	EXPEDITED (15-DAY)		HO	FR-ABBOTT-13X-056-1106176-00		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Bradycardia; Loss Of Consciousness; Malaise	Depakine			S	Oral	500 Milligram(S): Daily		Not Reported
	Seroplex			S	Oral	5 Milligram(S); Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2013	9355289	EXPEDITED (15-DAY)		OT	PL-ACCORD-018146		63 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort	Escitalopram			S				Accord
	Amlodipine			C				Not Reported
	Venlafaxine			S				Not Reported
	Bisoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2013	9355564	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2013182669		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Transaminases Increased; Urinary Retention	Cordarone			S	Oral	200 Mg Five Times A Week		Pfizer
	Zofenil Duo			S	Oral	1 Df, Daily		Not Reported
	Mopral			S	Oral	20 Mg, Daily		Not Reported

	Seroplex	S	Oral	10 Mg, Daily		Not Reported
	Kardegic	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2013	9355904	EXPEDITED (15-DAY)		OT	IN-MYLANLABS-2013S1012450		53 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Gait Disturbance; Multiple Drug Therapy; Normal Pressure Hydrocephalus	Escitalopram			S	Unknown			Mylan
	Pregabalin			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Carbamazepine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2013	9356543	EXPEDITED (15-DAY)		OT	NZ-MYLANLABS-2013S1012453		47 YR	Male	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Swelling Face	Escitalopram			S	Oral			Mylan
	Cipramil [Citalopram Hydrobromide]			C	Oral			Not Reported
	Lorazepam			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2013	9548455	NON-EXPEDITED	Y	OT	HYCA20100001		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dizziness	Hycodan [Hydrocodone Bitartrate]			S	Oral			Not Reported
	Lexapro (Escitalopram Oxalate) (10 Milligram, Tablets)			S	Oral Oral			Not Reported
	Inderal (Propranolol Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2013	8610171	EXPEDITED (15-DAY)		DE, LT	JP-FRI-1000031190		86 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lexapro			S	Oral	10 Mg		Forest
	Jzoloft			S	Oral	50 Mg		Not Reported
	Gascon			C	Oral	120 Mg		Not Reported
	Dogmatyl			C	Oral	100 Mg		Not Reported
	Takepron			C	Oral	15 Mg		Not Reported
	Predonine			C	Intravenous (not otherwise specified)	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2013	9308346	EXPEDITED (15-DAY)		OT	US-FRI-1000045324			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2013	9321663	EXPEDITED (15-DAY)		HO	JP-FRI-1000045486		57 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis	Lexapro			S	Oral	10 Mg		Forest
	Theodur			S	Oral			Not Reported
	Sekinarin			S	Oral			Not Reported
	Zyprexa			C	Oral	5 Mg		Not Reported
	Cymbalta			C	Oral	20 Mg		Not Reported
	Reflex			C	Oral	15 Mg		Not Reported
	Limas			C	Oral	400 Mg		Not Reported

Depakene-R	C	Oral	400 Mg		Not Reported
Horizon	C	Oral	10 Mg		Not Reported
Wypax	C	Oral	1 Mg		Not Reported
Amlodipine	C	Oral	10 Mg		Not Reported
Lipitor	C	Oral	5 Mg		Not Reported
Fluitran	C	Oral	2 Mg		Not Reported
Lamisil	C	Oral	125 Mg		Not Reported
Imidapril Hydrochloride	C	Oral	5 Mg		Not Reported
Cernilton	C	Oral	6 Df		Not Reported
Lansoprazole	C	Oral	15 Mg		Not Reported
Adetphos	C	Oral	300 Mg		Not Reported
Betahistine Mesilate	C	Oral	36 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2013	9357809	EXPEDITED (15-DAY)		OT	CH-FRI-1000046051			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest
	Lexotanil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2013	9360923	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Product Quality Issue	Lexapro			S	Oral	Lexapro 10 Mg Daily Oral	1 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2013	9272130	EXPEDITED (15-DAY)		HO, OT	FR-ASTRAZENECA-2013SE29259		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia; Transaminases Increased; Urinary Retention	Mopral			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Cordarone			S	Oral			Not Reported
	Zofenil Duo			S	Oral			Not Reported
	Kardegic			C		Long Lasting Treatment		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2013	9350659	EXPEDITED (15-DAY)		HO	PHHY2013FR059946		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer Haemorrhage	Sandostatin			S				Novartis
	Lovenox			S	Subcutaneous	0.4 Mg /12 Hours Bid		Not Reported
	Seroplex			S	Oral	20 Mg, Bid		Not Reported
	Aspegic [Acetylsalicylate Lysine]			S				Not Reported
	Tahor			C	Oral	10 Mg, Qd		Not Reported
	Domperidone			C		Unk Ukn, Unk		Not Reported
	Perindopril Arrow			C		4 Mg, Bid		Not Reported
	Pyostacine			C	Oral	1000 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2013	9368937	EXPEDITED (15-DAY)	Y	HO	2013000131		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Aceon (Perindopril Erbumine) Tablet			S	Oral			Not Reported
	Selokeen			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Paracetamol (Paracetamol)			S	Oral			Not Reported
	Lasilix (Furosemide)			S				Not Reported
	Ogast			S				Not Reported

	Seresta (Oxazepam)	S	Oral		Not Reported
	Victan	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2013	9364603	EXPEDITED (15-DAY)		OT	FR-FRI-1000046091		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Altered State Of Consciousness; Cardiac Arrest; Coma; Overdose; Respiratory Distress	Escitalopram			S	Oral			Forest
	Escitalopram			S		Overdose Of Unknown Dose		Not Reported
	Baclofene			S	Oral			Not Reported
	Baclofene			S	Oral	Overdose Of An Unknown Dose		Not Reported
	Seresta			S		Overdose Of An Unknown Dose		Not Reported
	Lexomil			S	Oral	Overdose Of Unknown Dose		Not Reported
	Tramadol			S	Oral	Overdose Of Unknown Dose		Not Reported
	Zolpidem			S	Oral	Overdose Of Unknown Dose		Not Reported
	Risperidone			S	Oral	Overdose Of Unknown Dose		Not Reported
	Anti-Vitamin K Nos			C		Dose According To Inr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2013	9365470	DIRECT		OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Withdrawal Syndrome; Feeling Abnormal; Headache; Irritability; Product Substitution Issue	Escitalopram			S	Oral			Camber
	Escitalopram 20 Mg Mylan			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2013	9194189	EXPEDITED (15-DAY)		OT	NO-FRI-1000043775		47 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2013	9365915	EXPEDITED (15-DAY)		HO	TR-FRI-1000046089		32 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder	Escitalopram			S		20 Mg		Forest
	Carbamazepine			C		100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2013	9366604	EXPEDITED (15-DAY)		OT	DK-FRI-1000046128		40 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2013	9366673	EXPEDITED (15-DAY)		OT	US-TEVA-405553USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chest Discomfort; Diarrhoea; Dizziness; Dyspnoea; Headache; Hip Arthroplasty; Hypothyroidism; Muscle Twitching; Myocardial Infarction; Osteoarthritis; Type V Hyperlipidaemia	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Levothyroxine Sodium			C	Oral	.1 Milligram Daily;		Not Reported
	Lansoprazole			C	Oral	30 Milligram Daily; Delayed Release		Not Reported
	Multivitamins And Iron			C				Not Reported
	Pyridoxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2013	9367352	EXPEDITED (15-DAY)		OT	FR-FRI-1000046132		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Petit Mal Epilepsy	Citalopram			S		10 Mg		Forest
	Citalopram			S				Forest
	Escitalopram			S		5 Mg		Forest
	Escitalopram			S				Forest
	Zyprexa			C		15 Mg		Not Reported
	Metformine			C				Not Reported
	Seresta			C				Not Reported
	Xelevia			C	Oral			Not Reported
	Novonorm			C	Oral			Not Reported
	Coversyl			C	Oral			Not Reported
	Fenofibrate			C				Not Reported
	Kardegic			C	Oral			Not Reported
	Havlane			C				Not Reported
	Cromedil			C				Not Reported
	Modopar			C	Oral			Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2013	9369394	DIRECT					67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral	1/Day	3 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2013	9378089	EXPEDITED (15-DAY)	Y	OT	2013P1008592		53 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Central Nervous System Infection; Cerebral Ventricle Dilatation; Cognitive Disorder; Dementia; Diabetic Retinopathy; Gait Disturbance; Gait Disturbance; Lack Of Spontaneous Speech; Lethargy; Memory Impairment; Mini Mental Status Examination Abnormal; Neurological Decompensation; Normal Pressure Hydrocephalus; Peripheral Sensorimotor Neuropathy; Urinary Incontinence	Escitalopram			S			3 MTH	Not Reported
	Pregabalin			S			3 MTH	Not Reported
	Amitryptiline			S				Not Reported
	Carbamazipine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2013	9291041	EXPEDITED (15-DAY)		OT	CH-FRI-1000045147			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2013	9315749	EXPEDITED (15-DAY)		OT	IN-PFIZER INC-2013159634		53 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Gait Disturbance; Lethargy	Escitalopram Oxalate			S		Unk		Not Reported
	Pregabalin			S		Unk		Pfizer
	Carbamazepine			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2013	9369522	EXPEDITED (15-DAY)		HO	DE-FRI-1000046084			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Dizziness; Nausea; Orthostatic Hypotension	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Not Reported
	Clozapine			S	Oral	25 Mg		Not Reported
	Clozapine			S	Oral	62.5 Mg		Not Reported
	Clozapine			S		Temporarily Dose Reduction; Thereafter Slow Dosage Increase To 150 Mg/Day		Not Reported
	Zeldox			S	Oral	160 Mg		Not Reported
	Enahexal			S	Oral	5 Mg		Not Reported
	Lamotrigin			C	Oral	100 Mg		Not Reported
	Ass			C	Oral	300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2013	9369884	EXPEDITED (15-DAY)		HO	JP-FRI-1000046217		31 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Overdose	Lexapro			S		Overdose: 29 Tablets		Forest
	Triazolam			S		Overdose: 40 Tablets		Not Reported
	Clonazepam			S		Overdose: 7 Tablets		Not Reported
	Flunitrazepam			S		Overdose: 61 Tablets		Not Reported
	Blonanserin			S		Overdose: Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2013	9370007	EXPEDITED (15-DAY)		CA, DS	BE-FRI-1000046207			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Microphthalmos; Visual Impairment	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2013	9370048	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013188156			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Depression; Dry Mouth; Fatigue; Nausea; Night Sweats; Urine Output Decreased	Premarin			S		Unk, (0.45)		Pfizer
	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2013	9370427	EXPEDITED (15-DAY)		LT, OT	FR-PFIZER INC-2013188318		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Blood Alcohol Increased; Coma; Disorientation; Extrapyramidal Disorder; Hallucination; Hypertension; Hypothermia; Muscle Spasticity; Sinus Bradycardia; Toxicity To Various Agents	Lyrica			S	Oral			Pfizer
	Lioresal			S	Oral	10 Mg, Unk		Not Reported
	Tranxene			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Tramadol Hydrochloride			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2013	9378664	EXPEDITED (15-DAY)	Y	HO	DSM-2013-00583		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Depression; Hyponatraemia	Axeler		S	Oral	40/5 Mg	Not Reported
	Seroplex		S	Oral	(10 Mg, 1 In 1 D)	Not Reported
	Fenofibrate		S	Oral	(67 Mg, 1 In 1 D)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2013	9548341	NON-EXPEDITED	Y	HO	299499		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Hypoaesthesia	Bupivacaine Hydrochloride			S				Not Reported
	Isovue			S		2 Ml, Epidural		Not Reported
	Lidocaine			C				Not Reported
	Kenalog-40			S		2 Ml, Epidural		Not Reported
	Aspirin			C				Not Reported
	Actos			C				Not Reported
	Lithium			C				Not Reported
	Metoprol			C				Not Reported
	Lyrica			C				Not Reported
	Namenda			C				Not Reported
	Lexapro			S				Not Reported
	Singulair			C				Not Reported
	Mag-Ox			C				Not Reported
	Kcl			C				Not Reported
	Ativan			C				Not Reported
	Lisinopril			C				Not Reported
	Simvastatin			C				Not Reported
	Lasix			C				Not Reported
	Isosorbide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2013	8830516	EXPEDITED (15-DAY)		DE, OT	JP-PFIZER INC-2012216483		52 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Breast Cancer; Device Occlusion; Dizziness; Myoclonus; Renal Failure;	Lyrica			S	Oral	75 Mg, 2x/Day		Pfizer
	Lyrica			S		75 Mg, 1x/Day		Pfizer
	Lyrica			S		25 Mg, 1x/Day		Pfizer

Somnolence	Lexapro	S	Oral	10 Mg, 1x/Day		Not Reported
	Lexapro	S	Oral	10 Mg, 1x/Day		Not Reported
	Fentos Tape	S	Transdermal	6 Mg, 1x/Day		Not Reported
	Takepron Od	C	Oral	15 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2013	9366802	EXPEDITED (15-DAY)		LT	FR-FRI-1000046092		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Bradycardia; Malaise; Product Use In Unapproved Indication; Torsade De Pointes	Escitalopram			S	Oral	1 Df		Forest
	Escitalopram			S		10 Mg		Forest
	Depakine			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2013	9371064	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-E2B_00000989		49 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Movement Disorder; Faeces Discoloured; Irritability; Neonatal Respiratory Distress; Somnolence	Escitalopram			S	Transmammary			Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2013	9371836	EXPEDITED (15-DAY)		OT	GB-FRI-1000046212		65 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Depression; Diarrhoea; Drug Ineffective; Malaise; Product Substitution Issue	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2013	9371973	EXPEDITED (15-DAY)		HO	FR-FRI-1000046214		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vaginal Haemorrhage	Escitalopram			S		15 Mg		Forest
	Antihypertensives			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2013	9372509	EXPEDITED (15-DAY)		OT	JP-FRI-1000046209		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granulocyte Count Decreased	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2013	9372760	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000046153		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anomalous Pulmonary Venous Connection; Atrial Septal Defect; Coarctation Of The Aorta; Congenital Anomaly; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2013	9372983	EXPEDITED (15-DAY)		HO	KR-FRI-1000046210		47 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Coma; Hyponatraemia; Respiration Abnormal; Seizure	Escitalopram			S		5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2013	9373561	EXPEDITED (15-DAY)		DS	CN-FRI-1000046278		71 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Escitalopram			S	Oral	10 Mg		Forest
	Mirtazapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2013	9321695	EXPEDITED (15-DAY)		OT	US-FRI-1000045527		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Asacol			C		4800 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2013	9375941	EXPEDITED (15-DAY)		OT	CA-RB-055443-13		3 DAY	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Hyperthermia	Suboxone Tablet			S	Transplacental			Reckitt Benckiser
	Subutex			S	Transplacental			Reckitt Benckiser
	Subutex			S	Transmammary			Reckitt Benckiser
	Cipralex			S	Transplacental			Not Reported
	Steroids			S	Transplacental	2 Doses		Not Reported
	Nicotine			S	Transplacental	<10 Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2013	9380169	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2013-05270		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion; Nocturia; Pollakiuria	Paroxetine (Paroxetine)			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2013	8844296	EXPEDITED (15-DAY)		HO, LT	AT-JNJFOC-20121002370		21 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Panic Attack; Paranoia; Suicidal Ideation	Concerta			S	Oral			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Nozinan			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2013	9286407	EXPEDITED (15-DAY)		OT	US-FRI-1000044974		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Attention Deficit/Hyperactivity Disorder; Premature Baby	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2013	9376350	EXPEDITED (15-DAY)		DE	FR-BRISTOL-MYERS SQUIBB COMPANY-19043017		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Intra-Abdominal Haematoma; Staphylococcal Sepsis	Coumadin Tabs 2 Mg			S	Oral	Took 4x1/D For 5 Days From 27feb2013 To 03mar2013		Bristol Myers Squibb
	Dafalgan			S		Capsules		Cadence
	Lovenox			S	Subcutaneous	1df-10000 Anti-Xa/1ml Soln For Inj In Prefilled		Not Reported

				Syringe	
	Seroplex	S		Tablets	Not Reported
	Topalgic (France)	S		Capsule	Not Reported
	Lasilix Retard	C	Oral		Not Reported
	Inegy	C		1 Df - 10mg/20mg Tablet	Not Reported
	Janumet	C		1 Df - 50mg/1000mg Tablet	Not Reported
	Pariet	C		Tablets	Not Reported
	Spiriva	C		1df - 18 Micro G, Powder For Inhalation In Hard Capsule	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2013	9376979	EXPEDITED (15-DAY)		HO	JP-FRI-1000046317		39 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Mouth Breathing; Overdose	Lexapro			S	Oral	Overdose 350 Mg		Forest
	Solanax			S	Oral	Overdose 210 Mg		Not Reported
	Dogmatyl			S	Oral	Overdose 190 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2013	9377040	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2013191013		19 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression; Dysphoria; Intentional Overdose; Intentional Self-Injury	Xanax			S	Oral	1mg (4 Df Of 0.25 Mg) Total		Pfizer
	Entact			S	Oral	20 Mg, 1x/Day (1df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2013	9095657	EXPEDITED (15-DAY)		HO, OT	FR-009507513-1302FRA006536		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Victrelis			S	Oral	2400 Mg, Qd		Merck
	Pegasys			S	Subcutaneous	1 Df, Qw		Not Reported
	Copegus			S		4 Df, Qd		Not Reported
	Zyprexa			S		Unk		Not Reported
	Methadone Hydrochloride			S		Unk		Not Reported
	Seroplex			S		1 Df, Qd		Not Reported
	Epoetin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2013	9379508	EXPEDITED (15-DAY)		CA	US-FRI-1000046300		74 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2013	9379530	EXPEDITED (15-DAY)		CA	US-FRI-1000046312		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Limb Reduction Defect; Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2013	9379538	EXPEDITED (15-DAY)		HO, OT	FR-009507513-1306FRA013521			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Victrelis			S	Oral	Unk		Merck
	Copegus			S	Oral	Unk		Not Reported
	Pegasys			S	Subcutaneous	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2013	9379573	EXPEDITED (15-DAY)		CA	US-FRI-1000046308		77 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2013	9380447	EXPEDITED (15-DAY)		OT	HU-FRI-1000045778		66 YR	Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hunger; Oedema; Weight Increased	Escitalopram			S	Oral	10 Mg		Forest
	Truxal Drazse			S	Oral	15 Mg		Not Reported
	Truxal Drazse			S				Not Reported
	Rivotril			C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2013	9380680	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20130616471		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury	Invega			S	Oral			Not Reported
	Lamictal			S	Oral			Not Reported
	Entact			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2013	9384169	DIRECT		OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hypertension; Nausea; Presyncope; Vertigo	Lexapro			S	Oral			Not Reported
	Victoza			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2013	9247008	EXPEDITED (15-DAY)		HO	US-AMGEN-USASP2013024370		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Interaction; Generalised Tonic-Clonic Seizure; Injection Site Erythema; Injection Site Pain; Injection Site Swelling; Injection Site Warmth; Migraine	Enbrel			S		50 Mg, Qwk		Amgen
	Enbrel			S				Amgen
	Enbrel			S				Amgen
	Tramadol /00599202/			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2013	9357832	EXPEDITED (15-DAY)		HO	FR-FRI-1000046030		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer Haemorrhage; Prescribed Overdose	Escitalopram			S	Oral	2 Df		Forest
	Lovenox			S	Other	2 Df		Not Reported
	Aspegic Enfant			S		1 Df		Not Reported
	Sandostatine			C	Oral			Not Reported
	Perindopril			C	Oral	2 Df		Not Reported
	Pyostacine			C	Oral	6 Df		Not Reported
	Tahor			C	Oral	1 Df		Not Reported
	Domperidone			C		3 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2013	9381605	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20130612059		61 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Diarrhoea; Nervousness;	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Tachycardia; Weight Increased	Cipralex		S	Unknown	Not Reported
	Cymbalta		S	Unknown	Not Reported
	Amineurin		S	Unknown	Not Reported
	Mirtazapin		S	Unknown	Not Reported
	Cortison		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2013	9382018	EXPEDITED (15-DAY)		HO	FR-FRI-1000046395		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Escitalopram			S	Oral			Forest
	Tercian			S	Oral			Not Reported
	Benzodiazepine			C				Not Reported
	Xeroquel			C	Oral			Not Reported
	Xeroquel			C	Oral	50 Mg		Not Reported
	Xeroquel			C	Oral	100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2013	9382036	EXPEDITED (15-DAY)		DE	FR-FRI-1000046394		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intra-Abdominal Haematoma	Escitalopram			S	Oral	2 Df		Forest
	Lovenox			S	Subcutaneous	20,000 Ui Anti-Xa/2 Ml		Not Reported
	Coumadine			S	Oral	4 Df		Not Reported
	Coumadine			S	Oral	4.5 Df		Not Reported
	Dafalgan			S	Oral	6 Df		Not Reported
	Topalgic (France)			S	Oral	2 Df		Not Reported
	Lasilix Retard			C	Oral	1 Df		Not Reported
	Inegy			C	Oral	10 Mg/ 20 Mg		Not Reported
	Janumet			C	Oral	50 Mg/1000 Mg Daily		Not Reported

	Spiriva	C	Respiratory (inhalation)	18 Mcg		Not Reported
	Pariet	C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2013	9382082	EXPEDITED (15-DAY)		DE	FR-GILEAD-2013-0078257		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prothrombin Level Decreased	Viread			S	Oral	245 Mg, Unk		Gilead
	Seroplex			S	Oral	10 Mg, Unk		Not Reported
	Aldactone /00006201/			S	Oral	25 Mg, Unk		Not Reported
	Noroxine			S	Oral	400 Mg, Unk		Not Reported
	Eupantol			S	Intravenous (not otherwise specified)	40 Mg, Bid		Not Reported
	Ceftriaxone Panpharma			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Avlocardyl /00030001/			C	Oral	80 Mg, Qd		Not Reported
	Vitamin B1			C	Oral	60 Mg, Unk		Not Reported
	Vitamin B6			C	Oral	500 Mg, Unk		Not Reported
	Phosphoneuros			C	Oral	50 Df, Tid		Not Reported
	Lovenox			C	Subcutaneous	4000 Iu, Unk		Not Reported
	Mag 2 /00454301/			C	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2013	9382439	EXPEDITED (15-DAY)		CA, HO	DE-FRI-1000046432			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Pyloric Stenosis	Escitalopram			S	Transplacental	5 Mg		Forest
	Neovin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2013	9350572	EXPEDITED (15-DAY)		HO	IE-ACCORD-018082		41 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Polydipsia; Rhabdomyolysis	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2013	9375238	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2013190760		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prothrombin Time Ratio Decreased	Aldactone			S	Oral	25 Mg, 1x/Day		Pfizer
	Eupantol			S	Intravenous (not otherwise specified)	40 Mg Daily		Pfizer
	Seroplex			S	Oral	10 Mg, Unk		Not Reported
	Viread			S	Oral	245 Mg, Daily		Not Reported
	Noroxin			S	Oral	400 Mg, Daily		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Avlocardyl			C	Oral	40 Mg, 2x/Day		Not Reported
	Thiamine Hydrochloride			C	Oral	60 Mg, Unk		Not Reported
	Pyridoxine Hydrochloride			C	Oral	500 Mg, Unk		Not Reported
	Phosphoneuros			C	Oral	50 Gtt, 3x/Day		Not Reported
	Lovenox			C	Subcutaneous	4000 Iu, Unk		Not Reported
	Mag 2			C	Oral	2 Df, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2013	9383438	EXPEDITED (15-DAY)		DE	FR-009507513-1306FRA013640		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Prothrombin Level Decreased	Noroxine		S	Oral	400 Mg, Qd	Merck
	Seroplex		S	Oral	10 Mg, Qd	Not Reported
	Viread		S	Oral	245 Mg, Qd	Not Reported
	Aldactone Tablets		S	Oral	25 Mg, Qd	Not Reported
	Eupantol		S	Intravenous (not otherwise specified)	40 Mg, Bid	Not Reported
	Ceftriaxone Sodium		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2013	9383784	EXPEDITED (15-DAY)		OT	CH-009507513-1306CHE004503		56 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Muscle Spasms; Myoclonus; Therapeutic Response Unexpected; Unevaluable Event	Remeron			S	Oral	Unk, Qd		Merck
	Cipralex			S	Oral	20 Mg, Qd		Not Reported
	Ritalin			S	Oral	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2013	7250828	EXPEDITED (15-DAY)	Y	DE, OT	AUR-APL-2009-01465		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Decreased; Apnoeic Attack; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Ph Decreased; Blood Potassium Increased; Hepatic Function Abnormal; Hypotension; Hypotonia; Intentional	Cyclobenzaprine			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Naproxen			S				Not Reported
	Escitalopram (Escitalopram)			S	Oral			Not Reported
	Pseudoephedrine Hydrochloride			S	Oral			Not Reported
	Aspirin			S				Not Reported
	Acetaminophen 325 Mg//Codeine 30 Mg			S	Oral			Not Reported

Overdose; International Normalised Ratio Decreased; Myoglobin Blood Increased; Pupillary Disorder; Renal Impairment; Respiratory Failure; Subarachnoid Haemorrhage; Suicide Attempt; Tachycardia; Thermometry Abnormal; Toxicologic Test Abnormal; Unresponsive To Stimuli; Urinary Retention

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2013	9388791	EXPEDITED (15-DAY)		DS, OT	GB-FRI-1000046467			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Migraine; Nausea; Withdrawal Syndrome	Escitalopram			S	Oral	15 Mg		Forest
	Escitalopram			S	Oral	12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2013	9322157	EXPEDITED (15-DAY)		HO	JP-FRI-1000045084		49 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Lexapro			S	Oral	10 Mg		Forest
	Methista			S	Oral	1500 Mg		Not Reported
	Huscode			S	Oral	6 Df		Not Reported
	Cefcapene Pivoxil Hydrochloride Hydrate			S	Oral	3 Df		Not Reported
	Pranlukast			S	Oral	4 Df		Not Reported
	Besastar Sr			C	Oral	400 Mg		Not Reported
	Depas (Etizolam)			C	Oral	3 Mg		Not Reported

Minzain	C	Oral	0.25 Mg		Not Reported
Amlodipine Od	C	Oral			Not Reported
Calonal	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2013	9391008	EXPEDITED (15-DAY)		DE	FR-FRI-1000046462		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prothrombin Time Ratio Decreased	Escitalopram			S	Oral	1 Df		Forest
	Viread			S	Oral	1 Df		Not Reported
	Aldactone			S	Oral	1 Df		Not Reported
	Noroxine			S	Oral	1 Df		Not Reported
	Eupantol			S	Other	2 Df		Not Reported
	Ceftriaxone Panpharma			S	Intravenous (not otherwise specified)			Not Reported
	Avlocardyl			C	Oral	2 Df		Not Reported
	Vitamin B1 And B6			C	Oral	60 Mg/500 Mg		Not Reported
	Phosphoneuros			C		150 Df		Not Reported
	Lovenox			C	Subcutaneous	40000 Iu		Not Reported
	Mag 2			C	Oral	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2013	9391546	EXPEDITED (15-DAY)		HO	FR-FRI-1000046396		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hyponatraemia	Escitalopram			S	Oral	1 Df		Forest
	Bipreterax			S	Oral	4 Mg/1.25 Mg		Not Reported
	Xanax			C	Oral	3 Df		Not Reported
	Actonel			C	Oral			Not Reported
	Glucor			C	Oral	1 Df		Not Reported

	Fixical Vitamin D3	C	Oral	1 Df	Not Reported
	Cosopt	C		20 Mg/5 Mg/Ml Ocular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2013	9391815	NON-EXPEDITED		LT, OT	US-ASTRAZENECA-2013SE51162			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Suicide Attempt	Seroquel			S	Oral			Zeneca
	Zoloft			S				Not Reported
	Lexapro			S				Not Reported
	Paxil			S				Not Reported
	Abilify			S				Not Reported
	Effexor			S				Not Reported
	Lamictal			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2013	9393406	DIRECT		OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Product Substitution Issue	Escitalopram			S	Oral			Camber
	Epa-Dha			C				Not Reported
	Vitamins S, D, & B			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2013	8681330	EXPEDITED (15-DAY)	Y	HO	2012153200		67 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Loss Anaemia; Cytomegalovirus Test Positive; Diverticulum; Drug Interaction; Enterocolitis Haemorrhagic; Fractured Sacrum; Haemorrhoids;	Methotrexate			S	Oral			Not Reported
	Fragmin			S	Subcutaneous			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Klacid			S	Oral			Not Reported

Lower Gastrointestinal Haemorrhage; Pneumonia Bacterial; Stress Fracture	Rocephin	S	Intravenous (not otherwise specified)	Not Reported
	Cipralex	S	Oral	Not Reported
	Ramipril	C		Not Reported
	Pantozol (Pantoprazole Sodium)	C		Not Reported
	Calcimagon-D3 (Calcium Carbonate, Colecalciferol)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2013	9342442	EXPEDITED (15-DAY)		LT	JP-FRI-1000045785		75 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Off Label Use; Ventricular Tachycardia	Lexapro			S	Nasal	10 Mg		Forest
	Lexapro			S	Nasal	10 Mg		Forest
	Lexapro			S	Nasal	20 Mg		Not Reported
	Aricept D			S	Nasal	2.5 Mg		Not Reported
	Aricept D			S	Nasal	5 Mg		Not Reported
	Daikenchuto			C	Oral			Not Reported
	Magmitt			C	Oral			Not Reported
	Zyprexa			C		2.5 Mg		Not Reported
	Zyprexa			C		5 Mg		Not Reported
	Zyprexa			C		2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2013	9393076	EXPEDITED (15-DAY)		HO	CA-FRI-1000046562		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticarial Vasculitis	Escitalopram			S	Oral	10 Mg		Forest
	Calcium And Vitamine D			C	Oral	500 Mg/400 Ui		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2013	9393114	EXPEDITED (15-DAY)		HO, LT	FR-JNJFOC-20130616728		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Disorientation; Extrapyramidal Disorder; Hallucination; Hypertension; Hypothermia; Sinus Bradycardia; Toxicity To Various Agents	Haldol			S	Oral			Not Reported
	Lioresal			S	Oral			Not Reported
	Tranxene			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2013	9393138	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000046565		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia	Escitalopram			S	Oral	2 Df		Forest
	Alprazolam			S	Oral	0.75 Mg		Not Reported
	Alprazolam			S	Oral	1.5 Mg		Not Reported
	Alprazolam			S	Oral	1.5 Mg		Not Reported
	Atarax			S	Oral	100 Mg		Not Reported
	Atarax			S	Oral	300 Mg		Not Reported
	Atarax			S	Oral	400 Mg		Not Reported
	Atarax			S	Oral	200 Df		Not Reported
	Atarax			S	Oral	300 Mg		Not Reported
	Atarax			S	Oral	250 Mg		Not Reported
	Atarax			S	Oral	200 Mg		Not Reported
	Tercian			S	Oral	40 Mg		Not Reported
	Tercian			S	Oral	80 Dosage Form		Not Reported
	Ciprofloxacine			S	Intravenous (not	3 Df		Not Reported

			otherwise specified)		
	Bactrim Forte	C		3 Df	Not Reported
	Fortum	C	Intravenous (not otherwise specified)	6500 Microgram	Not Reported
	Paracetamol	C	Intravenous (not otherwise specified)		Not Reported
	Diffu K	C			Not Reported
	Paroxetine	C		20 Mg	Not Reported
	Dafalgan	C			Not Reported
	Contramal	C			Not Reported
	Scopoderm	C		1 Mg / 72 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2013	9393827	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2013201064		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Lyrica			S	Oral	75 Mg, 2x/Day		Pfizer
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium			S	Oral	40 Mg Once Or Twice Daily		Not Reported
	Seroplex			S	Oral	15 Mg, 1x/Day		Not Reported
	Adepal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2013	9399790	EXPEDITED (15-DAY)	Y	HO, OT	AUR-APL-2013-05812		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dysphoria; Suicidal Ideation; Tearfulness	Escitalopram			S				Not Reported
	Ketamine			S				Not Reported
	Clomipramine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2013	9236494	EXPEDITED (15-DAY)		DS	FR-FRI-1000042316		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke; Macular Degeneration	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Kardegic			S	Oral	160 Mg		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported
	Crestor			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2013	9382255	EXPEDITED (15-DAY)		LT	FR-FRI-1000046428		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Extrapyramidal Disorder; Hallucination; Hypertension; Hypothermia; Intentional Overdose; Sinus Bradycardia	Escitalopram			S	Oral			Forest
	Lioresal			S	Oral			Not Reported
	Tranxene			S	Oral			Not Reported
	Monocrixo			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2013	9385898	EXPEDITED (15-DAY)		HO, LT, OT	TR-ASTRAZENECA-2013SE50641		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Depressed Level Of Consciousness; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose;	Quetiapine			S	Oral	9 Grams		Not Reported
	Escitalopram			S	Oral	280 Mg		Not Reported
	Ibuprofen			S	Oral	4 Grams		Not Reported

Sinus Tachycardia; Suicide Attempt	Amoxicillin	S	Oral	5 Grams		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2013	9396140	EXPEDITED (15-DAY)		HO	FR-FRI-1000046560		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Melaena	Escitalopram			S	Oral	2 Df		Forest
	Kardegic			S	Oral	1 Df		Not Reported
	Tareg			C				Not Reported
	Lasilix			C				Not Reported
	Xanax			C				Not Reported
	Tiapridal			C				Not Reported
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2013	9396144	EXPEDITED (15-DAY)		HO	AU-FRI-1000046615		54 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antipsychotic Drug Level Increased; Electrocardiogram Qt Prolonged	Escitalopram			S		5 Mg		Forest
	Clozapine			S	Oral	450 Mg		Not Reported
	Thyroxine Sodium			S		75 Mg		Not Reported
	Epilim			C		500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2013	8599926	EXPEDITED (15-DAY)		HO	JP-FRI-1000030944		63 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Epileptic Psychosis; Hallucination; Insomnia; Paranoia; Seizure	Lexapro		S	Oral	10 Mg	Forest
	Landsen		C	Oral	2 Mg	Not Reported
	Nizatidine		C	Oral	75 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2013	9397542	EXPEDITED (15-DAY)		CA, OT	US-PFIZER INC-2013202479			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Hypoplastic Left Heart Syndrome; Maternal Exposure During Pregnancy	Zoloft			S	Transplacental	Unk		Pfizer
	Sertraline Hcl			S	Transplacental	Unk		Pfizer
	Lexapro			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2013	9398346	EXPEDITED (15-DAY)		OT	NL-GLAXOSMITHKLINE-B0907519A		45 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Oral	10mg Per Day		Glaxosmithkline
	Sumatriptan			S	Oral	50mg Every Two Weeks		Glaxosmithkline
	Oxitriptan			S	Oral	50mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2013	9400447	DIRECT					63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Product Substitution Issue	Lexapro 10mg (Generic)			S	Oral	Strength: 10mg Quantity: 90 (3 Mo) Frequency: Daily Orally	90 DAY	Not Reported
	Synthroid			C				Not Reported
	Klonopin			C				Not Reported
	Restasis			C				Not Reported
	Gabapentin			C				Not Reported

	Cosamine Ds	C	Not Reported
	Tylenol	C	Not Reported
	Multivitamin	C	Not Reported
	L Lysine	C	Not Reported
	Vitamin D Nos	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2013	9400179	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000046578		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Hypoplastic Left Heart Syndrome; Pulmonary Hypertension	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2013	9400952	EXPEDITED (15-DAY)		OT	GR-ACTAVIS-2013-12052		63 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Headache; Toothache	Escitalopram (Unknown)			S	Unknown	60 Mg, Daily		Not Reported
	Escitalopram (Unknown)			S	Unknown	40 Mg, Daily		Not Reported
	Fluoxetine Hydrochloride (Unknown)			S	Unknown	40 Mg, Daily		Actavis Mid Atlantic
	Fluoxetine Hydrochloride (Unknown)			S	Unknown	60 Mg, Daily		Actavis Mid Atlantic

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2013	9402545	EXPEDITED (15-DAY)		HO	FR-FRI-1000046677		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia; Psychomotor Hyperactivity	Escitalopram			S		1 Df		Forest
	Kardegic			C		160 Mg		Not Reported
	Xanax			C				Not Reported
	Endotelon			C				Not Reported
	Tanakan			C				Not Reported

	Mianserin	C	1 Df	Not Reported
	Omeprazole	C		Not Reported
	Azantac	C	150 Mg	Not Reported
	Simvastatin	C	20 Mg	Not Reported
	Tareg	C	1 Df	Not Reported
	Hydrochlorothiazide\Valsartan	C	1 Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2013	9402584	EXPEDITED (15-DAY)		HO	FR-FRI-1000046680		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hepatocellular Injury; Neutropenia; Suicidal Ideation; Thrombocytopenia	Escitalopram			S	Oral			Forest
	Pegasys			S	Subcutaneous	90 Mcg Weekly		Not Reported
	Paracetamol			C				Not Reported
	Prozac			C				Not Reported
	Xanax			C				Not Reported
	Stilnox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2013	9402709	EXPEDITED (15-DAY)		HO	FR-FRI-1000046712		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram			S	Oral	15 Mg		Forest
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Inexium			S	Oral	40 To 80 Mg		Not Reported
	Lyrica			S	Oral	150 Mg		Not Reported
	Adepal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2013	9403260	EXPEDITED (15-DAY)		CA	US-FRI-1000046590		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Exomphalos; Hydrocephalus; Patent Ductus Arteriosus	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2013	9404082	DIRECT		OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hyponatraemia; Loss Of Consciousness; Pain; Painful Ejaculation; Seizure; Syncope	Escitalopram			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2013	9166364	EXPEDITED (15-DAY)		CA	US-JNJFOC-20111104297			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Dental Alveolar Anomaly; Dysarthria; Social Avoidant Behaviour	Topamax			S	Transplacental			Not Reported
	Zantac			S	Transplacental			Not Reported
	Keppra			S	Transplacental			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Azithromycin			S	Transplacental			Not Reported
	Sulphacetamide			S	Transplacental			Not Reported
	Phenergan			S	Transplacental			Not Reported
	Acebutolol			S	Transplacental			Not Reported
	Ferrous Sulfate			C	Transplacental			Not Reported
	Folic Acid			C	Transplacental			Not Reported
	Prenatal Vitamins			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2013	9404021	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20130706519		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Hepatitis Cholestatic	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Inexium			S	Oral	1 To 2 Df		Not Reported
	Lyrica			S	Oral	2 Df		Not Reported
	Seroplex			S	Oral	2 Df		Not Reported
	Adepal			C	Unknown	Started Approximately 4 Years Prior To The Report		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2013	9405343	EXPEDITED (15-DAY)		LT	AU-009507513-1307AUS004521		77 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Coma Scale Abnormal; Haemorrhage Intracranial; Pyrexia; Vomiting	Simvastatin			S	Oral	40 Mg, Daily		Merck
	Escitalopram			S		10 Mg, Daily		Not Reported
	Pradaxa			S		220 Mg, Daily		Not Reported
	Sotalol Hydrochloride			S		80 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2013	9406310	EXPEDITED (15-DAY)		HO	FR-ABBOTT-13X-056-1120237-00		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Fall	Depakote			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Kardegic			C				Not Reported
	Sotalex			C				Not Reported
	Coversyl			C				Not Reported

	Xalatan			C						Not Reported
	Azopt			C						Not Reported
	Dafalgan			C						Not Reported
	Pariet			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2013	9407919	EXPEDITED (15-DAY)		OT	US-FRI-1000046701		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2013	9361465	EXPEDITED (15-DAY)		DE, HO, OT	JP-FRI-1000043168		82 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Decubitus Ulcer; Pneumonia Aspiration; Poriomania; Serotonin Syndrome; Treatment Noncompliance; Urinary Incontinence	Lexapro			S	Oral	10 Mg		Forest
	Memary			C	Oral	5 Mg		Not Reported
	Memary			C	Oral	6 Df		Not Reported
	Memary			C	Oral	10 Mg		Not Reported
	Memary			C	Oral	5 Mg		Not Reported
	Desyrel			C	Oral	50 Mg		Not Reported
	Desyrel			C	Oral	6 Df		Not Reported
	Desyrel			C	Oral	25 Mg		Not Reported
	Rezaltas			C	Oral			Not Reported
	Selumito			C	Oral			Not Reported
	Loxoprofen			C				Not Reported
	Alesion			C	Oral			Not Reported
	Ointment Bases			C	Topical			Not Reported
	Vesicare			C	Oral			Not Reported
	Depas (Etizolam)			C	Oral			Not Reported
	Amoban			C	Oral			Not Reported

	Lendormin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2013	9372175	EXPEDITED (15-DAY)		LT, OT	FR-PFIZER INC-2013191199		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asterixis; Clonus; Toxic Encephalopathy	Zyvoxid			S	Intravenous drip	Unk		Pfizer
	Zyvoxid			S	Oral	600 Mg, 2x/Day		Pfizer
	Flagyl			S		500 Mg, 2x/Day		Pfizer
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Augmentin			C		Unk		Not Reported
	Lantus			C		10 Iu, 1x/Day (In The Morning)		Not Reported
	Previscan (Fluindione)			C	Oral	1 Tablet Daily		Not Reported
	Pravastatin			C		20 Mg, 1x/Day		Not Reported
	Cardensiel			C		2.5 Mg, 1x/Day		Not Reported
	Lasilix			C		40 Mg		Not Reported
	Inexium			C		20 Mg, 1x/Day		Not Reported
	Levothyrox			C		1 Df, Daily		Not Reported
	Econazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2013	9409209	EXPEDITED (15-DAY)		HO	AU-ACCORD-018533		21 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura Fulminans	Escitalopram			S				Accord
	Amoxicillin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2013	9409347	NON-EXPEDITED			US-PFIZER INC-2013211073		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Nefazodone			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Allegra			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Clarithromycin			S		Unk		Not Reported
	Acetaminophen			S		Unk		Not Reported
	Penicillin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2013	9410158	EXPEDITED (15-DAY)		OT	AT-ROXANE LABORATORIES, INC.-2013-RO-01178RO		49 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome	Lorazepam			S		3.5 Mg		Roxane
	Quetiapine Fumarate			S		100 Mg		Roxane
	Quetiapine Fumarate			S		200 Mg		Roxane
	Escitalopram			S		20 Mg		Not Reported
	Mirtazapine			S		15 Mg		Not Reported
	Mirtazapine			S		30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2013	9410429	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-B0907669A		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract Cortical; Diplopia; Discomfort; Headache; Headache; Periorbital Disorder; Visual Acuity	Lamictal			S	Oral	250mg Per Day		Glaxosmithkline
	Seroplex			S	Oral	10mg Per Day		Unknown

Reduced

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2013	9410450	EXPEDITED (15-DAY)		OT	TR-US-EMD SERONO, INC.-7224117			Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervical Dysplasia; Menstruation Irregular	Rebif			S	Subcutaneous			Not Reported
	Cipralex			S	Oral			Not Reported
	Beloc /00376902/			S	Oral			Not Reported
	Ecopirin			C	Oral			Not Reported
	Parol			C	Oral			Not Reported
	Parol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2013	9412235	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral	1 1/2 Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2013	9416691	EXPEDITED (15-DAY)	Y	LT, RI	TCI2013A04128		43 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Fibrillation	Lansoprazole (Lansoprazole)			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
					Oral			
	Acetylsalicylic Acid			C				Not Reported
	Clopidogrel Bisulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2013	9411575	EXPEDITED (15-DAY)		HO	FR-ROCHE-1250388		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall	Xeloda			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2013	9422452	EXPEDITED (15-DAY)	Y	HO	AU-MACLEODS PHARMA-000112		21 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Protein C Deficiency; Purpura Fulminans; Upper Respiratory Tract Infection	Escitalopram (Escitalopram)			S				Not Reported
	Amoxicillin (Amoxicillin)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2013	9414676	EXPEDITED (15-DAY)		OT	AU-FRI-1000046888		21 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura Fulminans	Escitalopram			S				Forest
	Amoxicillin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2013	9414821	EXPEDITED (15-DAY)		DE	NO-FRI-1000046890		39 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Escitalopram			S	Oral	10 Mg		Forest
	Xeplion			C	Oral	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2013	9414847	EXPEDITED (15-DAY)		CA	US-FRI-1000046814		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Palsy; Microcephaly	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2013	9416347	DIRECT		OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Drug Withdrawal Syndrome; Dyskinesia; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Nervousness; Product Substitution Issue; Shock; Therapeutic Response Changed; Thinking Abnormal; Weight Decreased	Lexapro			S	Oral	1, Daily, Po		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2013	9419259	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2013-05874		21 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Protein C Decreased; Purpura Fulminans; Thrombocytopenia	Amoxicillin (Amoxicillin)			S	Oral			Not Reported
	Escitalopram (Escitalopram)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2013	9404623	EXPEDITED (15-DAY)			DE-FRI-1000046639		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome	Escitalopram Oral Solution			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2013	9416997	EXPEDITED (15-DAY)		LT	FR-FRI-1000046975		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asterixis; Clonus; Toxic Encephalopathy	Escitalopram			S	Oral	1 Df		Forest
	Flagyl			S	Oral	1000 Mg		Not Reported
	Zyvoxid			S	Intravenous (not otherwise specified)	1200 Mg		Not Reported
	Lantus			C		10 Df In The Morning		Not Reported
	Previscan (Fluindione)			C		1 Df		Not Reported
	Pravastatine			C		20 Mg		Not Reported
	Cardensiel			C		2.5 Mg		Not Reported
	Lasilix			C				Not Reported
	Inexium			C		1 Df		Not Reported
	Levothyrox			C		1 Df		Not Reported
	Econazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2013	9419966	DIRECT		LT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Fatigue; Feeling Abnormal; Impaired Work Ability; Pain; Speech Disorder; Suicidal Ideation	Escitalopram 20mg			S				Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2013	9424813	EXPEDITED (15-DAY)		DS, HO	SYM-2013-06292		39 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Paraesthesia; Weight Decreased	Voxra			S				Not Reported
	Cipralex			S				Not Reported
	Antihistamines (Antihistamines)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2013	9137630	EXPEDITED (15-DAY)		OT	US-TEVA-389158USA		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Loss Of Consciousness; Skin Laceration; Syncope	Escitalopram			S				Ivax
	Terbinafine			C				Not Reported
	Lorazepam			C				Not Reported
	Bactrim Ds			C				Not Reported
	Bisacodyl			C				Not Reported
	Tramadol			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2013	9400183	EXPEDITED (15-DAY)		LT	AU-FRI-1000046638		77 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Coma Scale Abnormal; Haemorrhage Intracranial; Pyrexia; Vomiting	Escitalopram			S		10 Mg		Forest
	Pradaxa			S		220 Mg		Not Reported
	Simvastatin			S		40 Mg		Not Reported
	Simvastatin			S				Not Reported
	Sotalol Hydrochloride			S		80 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2013	9419115	EXPEDITED (15-DAY)		HO	FR-NOVOPROD-383411		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Novomix 30			S	Subcutaneous			Novo Nordisk
	Aldactone /00006201/			S	Oral	5 Mg, Qd		Not Reported
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Ursolvan-200			S	Oral	200 Mg, Qd		Not Reported
	Doliprane			S	Oral	2 G, Qd		Not Reported
	Previscan (Pentoxifylline)			C	Unknown	Unk		Not Reported
	Innohep			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2013	9420531	NON-EXPEDITED			US-ABBOTT-13P-163-1098937-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Drug Interaction; Malaise; Skin Odour Abnormal; Urinary Tract Infection	Synthroid			S				Not Reported
	Amlodipine			S				Not Reported
	Lexapro Film-Coated Tablets			S				Not Reported
	Levothyroxine			S		50mcg: 5 Days A Week And75mcg: 2 Days A Week		Not Reported
	Levoxyl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2013	9421306	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2013SE54261		91 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Syncope; Torsade De Pointes	Seroquel			S	Oral			Zeneca
	Cipralex			S	Oral			Not Reported
	Pantorc			C				Not Reported
	Tavor (Lorazepam)			C				Not Reported
	Enapren			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2013	9242065	EXPEDITED (15-DAY)		OT	BE-FRI-1000044480		41 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pituitary Tumour Benign	Escitalopram			S	Oral	10-15 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Forest
	Uni-Tranxene			C	Oral			Not Reported
	Nortrilen			C				Not Reported
	Sostilar			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2013	9416220	EXPEDITED (15-DAY)	Y	LT	SYM-2013-06427		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Clonus; Clostridium Test Positive; Confusional State; Encephalopathy; Hepatic Failure; Overdose; Thrombocytopenia; Tremor	Flagyl			S	Oral	2 Ut, Daily, Oral		Not Reported
	Zyvoxid			S	Intravenous (not otherwise specified) Oral	600mg 2 In 1 D Intravenous 600mg, 2 In 1 D, Oral		Not Reported
	Seroplex			S	Oral			Not Reported
	Augmentin			C				Not Reported
	Lantus (Insulin Glargine) (Insulin Glargine)			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Pravastatine)Pravastatin Sodium) (Pravastatin Sodium)			C				Not Reported
	Cardensiel (Bisoprolol Fumarate) (Bisoprolol Fumarate)			C				Not Reported
	Lasilix (Furosemide) (Furosemide)			C				Not Reported
	Inexium (Esomeprazole)			C				Not Reported
	Levothyrox (Levothyroxine Sodium) (Levothyroxine Sodium)			C				Not Reported
	Econazole (Econazole) (Econazole)			C				Not Reported
	Augmentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2013	9421768	EXPEDITED (15-DAY)		DE	AU-ASTRAZENECA-2013SE56043		152 DAY	Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Escherichia Sepsis; Foetal Exposure During Pregnancy; Microencephaly; Necrotising Enterocolitis Neonatal; Peritoneal Haemorrhage; Peritonitis; Premature Delivery	Seroquel			S	Transplacental			Zeneca
	Lexapro			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2013	9422714	EXPEDITED (15-DAY)		OT	CA-FRI-1000047223		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Escitalopram			S	Oral			Forest
	Saphris			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2013	9424225	DIRECT	Y	HO			< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Condition Aggravated; Drug-Induced Liver Injury; Fatigue; Influenza; Pain; Pyrexia	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2013	9423702	EXPEDITED (15-DAY)		HO, LT	PHHY2013TR078641		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Depressed Level Of Consciousness; Disorientation; Hypotension; Intentional Overdose; Sinus Tachycardia; Suicide Attempt	Quetiapine			S		9 G, Unk		Not Reported
	Escitalopram			S		280 Mg, Unk		Not Reported
	Amoxicillin			S		5 G, Unk		Novartis
	Ibuprofen			S		4 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2013	9424725	EXPEDITED (15-DAY)		OT	FR-ELI_LILLY_AND_COMPANY-FR201307006814		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Labelled Drug-Drug Interaction Medication Error	Zyprexa			S	Oral	5 Mg, Qd		Eli Lilly And Co
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2013	9426528	DIRECT		LT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Disturbance In Attention; Product Substitution Issue; Somnolence	Escitalopram			S	Oral	15ms		Unassigned

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2013	9426539	DIRECT		LT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Depression; Disturbance In Attention; Somnolence	Escitalopram		S	Oral	15ms	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2013	9429140	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20130716654		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epilepsy	Ixprim			S	Oral	1 Dose In The Morning And 1 Dose In The Evening		Not Reported
	Seroplex			S	Oral			Not Reported
	Dafalgan			C	Oral			Not Reported
	Botulinum Toxin			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2013	9431055	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2013222301		45 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Xanax			S	Oral	0.25 Mg, As Needed		Pfizer
	Xanax			S	Oral	5 Mg, Single		Pfizer
	Cipralex			S	Oral	20 Mg, Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2013	9431412	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2013S1016174		21 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Purpura Fulminans	Amoxicillin	S	Oral		Not Reported
	Escitalopram	S	Unknown		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2013	9431468	EXPEDITED (15-DAY)		CA	US-FRI-1000046970		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Fallot'S Tetralogy	Celexa			S	Transplacental			Forest
	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2013	9431514	EXPEDITED (15-DAY)		HO	TR-MYLANLABS-2013S1016336		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Intentional Overdose; Suicide Attempt; Tachycardia; Toxicity To Various Agents	Quetiapine			S	Oral	Estimated Ingestion Of 9g		Not Reported
	Amoxicillin			S	Oral	Estimated Ingestion Of 5g		Not Reported
	Escitalopram			S	Oral	Estimated Ingestion Of 280mg		Mylan
	Ibuprofen			S	Oral	Estimated Ingestion Of 4g		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2013	9435296	EXPEDITED (15-DAY)	Y	OT	2013AP006871		21 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermal Necrosis; Purpura Fulminans; Skin Haemorrhage	Amoxicillin (Amoxicillin)			S				Not Reported
	Escitalopram (Escitalopram)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2013	9432098	NON-EXPEDITED			US-PFIZER INC-2013221390		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Effexor	S	Unk	Pfizer
	Erythromycin	S	Unk	Not Reported
	Vicodin	S	Unk	Not Reported
	Biaxin	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Prozac	S	Unk	Not Reported
	Synthroid	S	Unk	Not Reported
	Paxil	S	Unk	Not Reported
	Bactrim	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2013	9433218	EXPEDITED (15-DAY)		OT	PHHY2013AU078535		21 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermal Necrosis; Purpura Fulminans; Rash; Skin Haemorrhage; Skin Lesion; Thrombosis	Amoxicillin			S	Oral			Novartis
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2013	9434809	DIRECT		OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Disease Recurrence; Product Substitution Issue	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2013	9272097	EXPEDITED (15-DAY)		HO	FR-FRI-1000044933		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Escitalopram			S	Oral	1 Df		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2013	9434754	EXPEDITED (15-DAY)		OT	FR-FRI-1000047325		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epilepsy	Escitalopram			S	Oral	1 Df		Forest
	Ixprim			S	Oral	2 Df		Not Reported
	Lyrica			C		150 Mg		Not Reported
	Lyrica			C				Not Reported
	Dafalgan			C		1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2013	9434756	EXPEDITED (15-DAY)		HO, OT	BE-FRI-1000047324		58 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Hyponatraemia; Weight Increased; Withdrawal Syndrome	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Not Reported
	Escitalopram			S	Oral	5 Mg		Not Reported
	Staurodorm			C	Oral			Not Reported
	Haldol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2013	9434825	EXPEDITED (15-DAY)		OT	DE-FRI-1000047363		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Pregnancy; Premature Rupture Of Membranes	Escitalopram			S	Oral	20 Mg		Forest
	Citalopram			S	Oral	10 Mg		Forest
	Citalopram			S	Oral	30 Mg		Forest
	Femibion [Minerals Nos;Vitamins Nos]			C		0.4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2013	9435117	EXPEDITED (15-DAY)		CA, HO	DE-FRI-1000047364		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect; Coarctation Of The Aorta; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 Mg		Forest
	Citalopram			S	Transplacental	10 Mg		Forest
	Citalopram			S	Transplacental	30 Mg		Forest
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental	0.4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2013	9436099	EXPEDITED (15-DAY)		HO	FR-FRI-1000047394		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Escitalopram			S	Oral	10 Mg		Forest
	Temesta (Lorazepam)			S	Oral	3 Mg		Not Reported
	Imovane			S	Oral	3.75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2013	9441937	EXPEDITED (15-DAY)	Y	HO	AXC-2013-000335		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Ascites; Myelodysplastic Syndrome; Neutrophil Count Decreased; Oedema; White Blood Cell Count Decreased	Ursodeoxycholic Acid			S	Oral			Not Reported
	Doliprane			S	Oral			Not Reported
	Aldactone			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Novomix			S	Subcutaneous			Not Reported
	Previscan (Fluindione)			C				Not Reported
	Innohep (Tinzaparin Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2013	9404701	EXPEDITED (15-DAY)		CA, DS	DK-FRI-1000046759			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Psychomotor Retardation	Escitalopram			S	Transplacental	20 Mg		Forest
	Citalopram			S	Transplacental	40 Mg		Forest
	Noritren			S	Transplacental	60 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2013	9437012	EXPEDITED (15-DAY)		OT	US-TEVA-422527USA		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Attention-Seeking Behaviour; Derealisation; Drug Interaction; Dysgeusia; Dysphoria; Illusion; Parosmia; Suicidal Ideation; Tearfulness; Trichotillomania	Clomipramine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Ketamine			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2013	9437544	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2013S1016531		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Amnesteem Capsules			S				Mylan
	Claravis			S				Mylan
	Latisse			S				Not Reported
	Lexapro			S				Not Reported
	Oral Contraceptive Nos			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2013	9437683	EXPEDITED (15-DAY)		OT	FR-FRI-1000047439		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram			S	Oral	1 Df		Forest
	Lioresal			S	Oral	Progressive Titration Up To 150 Mg Daily		Not Reported
	Lioresal			S	Oral	12 Df		Not Reported
	Seresta			C	Oral	3 Df		Not Reported
	Keppra			C		2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2013	9008251	EXPEDITED (15-DAY)	Y	HO, OT	THQ2012A11181		41 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Apathy; Blood Calcium Decreased; Blood Potassium Abnormal; Cardiac Failure; Coronary Artery Occlusion; Drug Interaction; Electrocardiogram R On T Phenomenon; Extrasystoles; Loss Of Consciousness; Torsade De Pointes; Ventricular Extrasystoles; Ventricular Fibrillation	Takepron (Lansoprazole)			S	Oral	15 Mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
					Oral	10 Mg (10 Mg, 1 In 1 D), Oral		
	Lamictal (Lamotrigine)			C				Not Reported
	Landsen (Clonazepam)			C				Not Reported
	Rivotril (Clonazepam)			C				Not Reported
	Plavix (Clopidogrel Bisulfate)			C				Not Reported
	Bayaspirin (Acetylsalicylic Acid) (Acetylsalicylic Acid)			C				Not Reported
	Crestor (Rosuvastatin Calcium)			C				Not Reported
	Nicorandis (Nicorandil)			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Solita (Sodium Lactate, Potassium Chloride, Calcium Chloride Dihydrate)			C				Not Reported
	Heparin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2013	9429239	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2013218206		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic; Hepatocellular Injury; Jaundice; Pruritus	Amlor			S	Oral	10 Mg, Daily		Pfizer
	Tahor			S	Oral	20 Mg, Daily		Pfizer
	Diamicron			S	Oral	60 Mg, Daily		Not Reported
	Eucreas			S	Oral	2 Df, Daily		Not Reported
	Coaprovel			S	Oral	1 Df Daily		Not Reported
	Levothyrox			S	Oral	125 Ng, Daily		Not Reported
	Seroplex			S	Oral	10 Mg, Daily		Not Reported
	Ixprim			S	Oral	Unk		Not Reported
	Doliprane			S	Oral	Unk		Not Reported
	Voltarene (Diclofenac Sodium)			S	Cutaneous	Unk		Not Reported
	Voltarene (Diclofenac Sodium)			S	Oral	Unk		Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2013	9439847	EXPEDITED (15-DAY)		HO, LT	TR-ROXANE LABORATORIES, INC.-2013-RO-01272RO		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Quetiapine Fumarate			S	Oral			Roxane
	Ibuprofen			S	Oral			Not Reported
	Amoxicillin			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2013	9441510	EXPEDITED (15-DAY)		HO	TR-PERRIGO-13TR007814		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Depressed Level	Ibuprofen 200 Mg 604			S	Oral	4 G, Unk		Perrigo

Of Consciousness; Disorientation; Hypotension; Intentional Overdose; Tachycardia	Quetiapine		S	Oral	9 G, Unk	Not Reported
	Escitalopram		S	Oral	280 Mg, Unk	Not Reported
	Amoxicillin		S	Oral	5 G, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2013	9442189	DIRECT		LT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Lexapro			S	Oral		1 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2013	9442450	DIRECT		DS			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Condition Aggravated; Drug Ineffective; Fatigue; Flatulence; Gastritis; Gastrointestinal Disorder; Nausea; Pain; Product Substitution Issue; Vomiting	Escitalopram Oxalate			S	Oral			Not Reported
	Metformin			C				Not Reported
	Lisinopril			C				Not Reported
	Multiple Vitamin			C				Not Reported
	Slo-Niacin			C				Not Reported
	Fish Oil			C				Not Reported
	Devil Claw			C				Not Reported
	Vitamin C			C				Not Reported
	Vo Q 10 Plus Read Yeast Rice			C				Not Reported
	Hyaluronic Acid			C				Not Reported
	Chrome-500			C				Not Reported
	Advil			C				Not Reported
	Aleve			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2013	9442964	DIRECT		LT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Dizziness;	Escitalopram			S	Oral	15 Mg 1 Per Day Pill By Mouth	3 DAY	Teva

Loss Of Consciousness; Product Substitution Issue; Syncope; Tremor	Escitalopram		S	Oral	One 20 Mg Pill Cut As Needed 1 Per Day Pill By Mouth	3 DAY	Mylan
	Singulair		C				Not Reported
	Lexapro		C				Not Reported
	Xanax		C				Not Reported
	Probiotic		C				Not Reported
	Vitamin D Nos		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2013	9444877	EXPEDITED (15-DAY)	Y	HO, OT	2013AP007020		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Attention-Seeking Behaviour; Derealisation; Drug Interaction; Dysphoria; Illusion; Parosmia; Suicidal Ideation; Taste Disorder; Tearfulness	Escitalopram			S				Not Reported
	Ketamine			S	Intravenous drip			Not Reported
	Clomipramine			S				Not Reported
	Selective Serotonin Reuptake Inhibitors			C				Not Reported
	Antipsychotics			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2013	9442261	EXPEDITED (15-DAY)		OT	TR-FRI-1000047502		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Hypotension; Intentional Overdose; Suicide Attempt; Tachycardia	Escitalopram			S		Estimated Ingested Dose		Forest
	Quetiapine			S		Estimated Ingested Dose		Not Reported
	Amoxicillin			S		Estimated Ingested Dose		Not Reported
	Ibuprofen			S		Estimated Ingested Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2013	9443417	EXPEDITED (15-DAY)		HO	ZA-GLAXOSMITHKLINE-B0912481A			Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Seizure; Tremor; Weight Increased	Lamictin		S	Unknown	100mg Twice Per Day	Glaxosmithkline
	Epilim		S	Unknown	600mg Twice Per Day	Not Reported
	Escitalopram		S	Unknown		Glaxosmithkline
	Levetiracetam		C	Unknown	500mg Twice Per Day	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2013	9444176	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Product Substitution Issue	Lexapro			S	Oral	20mg Daily Po		Not Reported
	Lexapro			S	Oral	10mg Daily Po		Not Reported
	Zyprexa			C				Not Reported
	Trazadone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2013	9444536	DIRECT		LT, OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feelings Of Worthlessness; Suicidal Ideation	Escitalopram			S	Oral	One Once Daily Taken By Mouth		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2013	9347064	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-B0872038A		71 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Euphoric Mood; Hyperkinesia; Logorrhoea; Mania	Lamictal			S	Oral	50mg Per Day		Glaxosmithkline
	Lamictal			S	Oral			Glaxosmithkline
	Lamictal			S	Oral	50mg Twice Per Day		Glaxosmithkline
	Lamictal			S	Oral	75mg Twice Per Day		Glaxosmithkline
	Lamictal			S	Oral	50mg Twice Per Day		Glaxosmithkline

Lexapro	S	Oral	10mg Per Day		Not Reported
Lithium Carbonate	S	Oral			Glaxosmithkline
Lithium Carbonate	S	Oral			Glaxosmithkline
Lithium Carbonate	S	Oral			Glaxosmithkline
Solanax	C	Oral	.4mg Twice Per Day		Glaxosmithkline
Palgin	C	Oral	1mg Per Day		Not Reported
Zolpidem Tartrate	C	Oral	10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2013	9434806	EXPEDITED (15-DAY)		HO	IT-FRI-1000047326		90 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Syncope; Torsade De Pointes	Escitalopram			S	Oral			Forest
	Seroquel			S	Oral	1 Df		Not Reported
	Pantorc			C				Not Reported
	Tavor (Lorazepam)			C				Not Reported
	Enapren			C	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2013	9444570	NON-EXPEDITED			US-PFIZER INC-2013228853		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Effexor			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2013	9444889	EXPEDITED (15-DAY)		HO	BE-FRI-1000047536		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Barrett'S Oesophagus; Gastric Ulcer; Rectal Haemorrhage	Escitalopram	S	Oral		Forest
	Motifene	S	Oral	150 Mg	Not Reported
	Asaflow	S	Oral		Not Reported
	Bisoprolol	C	Oral		Not Reported
	Perindopril	C	Oral		Not Reported
	Crestor	C	Oral		Not Reported
	Noctamid	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2013	9444901	EXPEDITED (15-DAY)		HO	SE-FRI-1000047568		75 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Electrocardiogram Qt Prolonged; Syncope	Escitalopram			S	Oral			Forest
	Simvastatin			C				Not Reported
	Zolpidem			C				Not Reported
	Enalapril			C				Not Reported
	Dentan Mouth Wash			C				Not Reported
	Trombyl			C				Not Reported
	Xanor			C				Not Reported
	Selokenzoc			C				Not Reported
	Atacand			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2013	9444912	EXPEDITED (15-DAY)		OT	PHHY2013US081971		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Anxiety; Decreased Appetite; Depressed Mood; Drug Interaction; Dysphoria; Sleep Disorder; Suicidal Ideation	Ketamine			S	Intravenous (not otherwise specified)			Not Reported
	Clomipramine			S				Novartis
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2013	9445106	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2013S1016805		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Attention-Seeking Behaviour; Derealisation; Drug Interaction; Dysgeusia; Dysphoria; Illusion; Parosmia; Suicidal Ideation; Tearfulness	Ketamine			S	Intravenous drip			Not Reported
	Clomipramine			S	Unknown			Mylan
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2013	9445201	EXPEDITED (15-DAY)		DE, HO	CH-GLAXOSMITHKLINE-B0891995A		44 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Sudden Death	Dabrafenib			S	Oral			Glaxosmithkline
	Trametinib			S	Oral			Glaxosmithkline
	Cipralex			S	Oral			Glaxosmithkline
	Keppra			S				Glaxosmithkline
	Novalgine (Metamizole Sodium)			S				Glaxosmithkline
	Dexamethasone			C	Oral			Glaxosmithkline
	Valproic Acid			C	Oral	600mg Twice Per Day		Not Reported
	Fortecortin			C				Not Reported
	Orfiril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2013	9432469	EXPEDITED (15-DAY)		HO, LT, OT	TR-RANBAXY-2013RR-71707		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Intentional Overdose; Suicide Attempt;	Quetiapine			S	Oral	9g, Estimated Dose		Not Reported
	Amoxicillin			S	Oral	5 G, Estimated Dose		Ranbaxy

Tachycardia	Escitalopram	S	Oral	280 Mg, Estimated Dose		Not Reported
	Ibuprofen	S	Oral	4 G, Estimated Dose		Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2013	9447893	EXPEDITED (15-DAY)		HO	PHHY2013FR082983		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Purpura; Thrombocytopenia	Ritaline			S	Oral	10 Mg, Qd		Novartis
	Carboplatin			S	Intravenous (not otherwise specified)	400 Mg, Per Course		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2013	9448225	EXPEDITED (15-DAY)		CA	US-FRI-1000047505		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Patent Ductus Arteriosus; Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2013	9448293	EXPEDITED (15-DAY)		CA	US-FRI-1000047524		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Patent Ductus Arteriosus; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2013	9448383	EXPEDITED (15-DAY)		CA	US-FRI-1000047527		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2013	8961910	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2012311529		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bradykinesia; Cogwheel Rigidity; Confusional State; Drug Ineffective; Drug Intolerance; Hyperhidrosis; Parkinsonism; Resting Tremor	Paroxetine			S		5 And 10 Mg Per Day		Unknown
	Sertraline Hcl			S		50 Mg, Unk		Pfizer
	Olanzapine			S	Oral	15 Mg Daily		Not Reported
	Quetiapine Fumarate			S		25 Mg Daily		Not Reported
	Citalopram Hbr			S	Oral	10 Mg, 2x/Day		Not Reported
	Escitalopram Oxalate			S		10 Mg Daily		Not Reported
	Haloperidol			S		1 Mg Daily		Pfizer
	Clomipramine			S	Oral	25 Mg, Daily		Not Reported
	Clomipramine			S	Oral	100 Mg		Not Reported
	Valproic Acid			S		Unk		Not Reported
	Trazodone			S		100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2013	9449387	EXPEDITED (15-DAY)		OT	AU-LUPIN PHARMACEUTICALS INC.-2013-01461			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal; Feeling Of Despair; Malaise; Nausea; Product Substitution Issue; Suicidal Ideation	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2013	9454318	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Chills; Nausea; Tremor; Vomiting	Lexapro 20mg - Generic	S		Not Reported
	Copaxone	C		Not Reported
	Badofu	C		Not Reported
	Glucosamine	C		Not Reported
	Vit D	C		Not Reported
	Percoet	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2013	9454325	DIRECT		OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Epistaxis	Escitalopram			S	Oral	Starting 1/2 Pill A Day 5mg 1 A Day - - Mouth		Apotex
	Omeprazole			C				Not Reported
	Advair			C				Not Reported
	Albuterol			C				Not Reported
	Multivitamin			C				Not Reported
	Vita D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2013	9025219	EXPEDITED (15-DAY)		HO	FR-ROCHE-1181866		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatitis Cholestatic	Rivotril			S	Unknown			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Solian			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2013	9417871	EXPEDITED (15-DAY)		OT	US-TEVA-420649USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Ranitidine			S				Teva
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2013	9452299	EXPEDITED (15-DAY)		OT	US-TEVA-424777USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dyskinesia; Gastrointestinal Disorder; Hypertension; Loss Of Personal Independence In Daily Activities; Morbid Thoughts; Negative Thoughts; Nervousness; Paraesthesia; Social Avoidant Behaviour; Suicidal Ideation; Weight Decreased; Withdrawal Syndrome	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2013	9457420	EXPEDITED (15-DAY)	Y	HO	2013000190		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly; Fall; Head Injury; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Aceon (Perindopril Erbumine) Tablet			S	Oral			Not Reported
	Temerit			S	Oral Oral			Not Reported
	Xatral			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Perindopril Arrow (Perindopril)			C				Not Reported
	Kardegic (Acetylsalicylate Lysine)			C				Not Reported
	Tahor (Atorvastatin Calcium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2013	9455512	EXPEDITED (15-DAY)		DS, HO, LT	FR-009507513-1308FRA001063		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Pulmonary Arterial Hypertension	Norset			S	Oral	Unk		Merck
	Prozac			S	Oral	20 Mg, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2013	9455706	EXPEDITED (15-DAY)		CA	US-FRI-1000047612		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Craniosynostosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	7568634	EXPEDITED (15-DAY)		HO, OT	PHHY2010FR55134		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Creatinine Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophil Count Increased; Purpura; Rash; Rash Erythematous; Vitamin D Decreased	Hydrochlorothiazide\Valsartan			S	Oral	1 Df, Qd		Novartis
	Previscan (Fluindione)			S		20 Mg, Unk		Not Reported
	Seroplex			S		Unk Ukn, Unk		Not Reported
	Imovane			S		1 Df, Qd		Not Reported
	Pariet			C		Unk Ukn, Unk		Not Reported
	Motilium			C		Unk Ukn, Unk		Not Reported
	Gaviscon			C		Unk Ukn, Unk		Not Reported
	Temerit			C		5 Mg, Unk		Not Reported
	Ditropan			C		Unk Ukn, Unk		Not Reported
	Dextropropoxyphene Hcl W/Paracetamol			C		Unk Ukn, Unk		Not Reported

	Tahor	C	Unk Ukn, Unk		Not Reported
	Amlor	C	Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	8932192	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20121107729		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatitis Cholestatic	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Tercian			S	Oral	Taken Occasionally If Needed		Not Reported
	Solian			S	Oral			Not Reported
	Seroplex			S	Oral	Reintroduction On An Unknown Date		Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

	Seroplex	S	Oral			Not Reported
	Seroplex	S	Oral			Not Reported
	Seroplex	S	Oral	Reintroduction On An Unknown Date		Not Reported
	Seroplex	S	Oral			Not Reported
	Seroplex	S	Oral			Not Reported
	Seroplex	S	Oral	Reintroduction On An Unknown Date		Not Reported
	Rivotril	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	9242891	EXPEDITED (15-DAY)		HO	JP-FRI-1000044443		81 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Ventricular Tachycardia	Lexapro			S	Oral	10 Mg		Forest
	Rasilez			C	Oral	150 Mg		Not Reported
	Norvasc			C	Oral	5 Mg		Not Reported
	Bup-4			C	Oral	20 Mg		Not Reported
	Protecadin			C	Oral	10 Mg		Not Reported
	Reminyl Od			C	Oral	16 Mg		Not Reported
	Nauzelin			C	Oral	20 Mg		Not Reported
	Amitiza			C	Oral	24 Mg		Not Reported
	Amlodipine			C	Oral	5 Mg		Not Reported
	Mohrus			C	Transdermal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	9431733	EXPEDITED (15-DAY)		OT	AU-RANBAXY-2013RR-71654		21 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura Fulminans	Amoxicillin			S	Oral	Unk		Ranbaxy

	Escitalopram			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	9444780	EXPEDITED (15-DAY)		OT	TW-RANBAXY-2013RR-71895			Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Nausea; Obsessive-Compulsive Disorder; Potentiating Drug Interaction	Sertraline			S	Unknown	300 Mg/Day		Ranbaxy
	Sertraline			S	Unknown	300 Mg/Day		Ranbaxy
	Clozapine			S	Unknown	400 Mg/Day		Not Reported
	Clozapine			S	Unknown	350 Mg/Day		Not Reported
	Escitalopram			S	Unknown	20 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	9458258	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013233349		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melanocytic Naevus; Panic Attack	Neurontin			S	Oral	600 Mg, 3x/Day		Pfizer
	Gabapentin			S	Oral	300 Mg, 3x/Day		Pfizer
	Lyrica			S		Unk		Pfizer
	Xanax			S		Once A Day		Pfizer
	Percocet			S	Oral	Oxycodone Hydrochloride 10 Mg, Paracetamol 325 Mg Take 1 Tab Every 4 Hours		Not Reported
	Lexapro			S	Oral	20 Mg, 1x/Day (Daily)		Not Reported
	Prozac			S		Unk		Not Reported
	Cymbalta			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	9458529	EXPEDITED (15-DAY)		CA	US-FRI-1000047717		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aorta Hypoplasia; Aortic Valve Incompetence; Arteriovenous Malformation; Congenital Hydrocephalus; Hypoplastic Left Heart Syndrome; Mitral Valve Hypoplasia; Pulmonary Artery Stenosis Congenital; Tricuspid Valve Incompetence	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	9458796	EXPEDITED (15-DAY)		DS, HO, LT	FR-FRI-1000047743		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Pulmonary Arterial Hypertension	Escitalopram			S	Oral	1 Df		Forest
	Prozac			S	Oral	1 Df		Not Reported
	Norset			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	9458967	EXPEDITED (15-DAY)		OT	FR-FRI-1000047770		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral	10 Mg		Forest
	Loxen (Nicardipine Hydrochloride)			S	Oral	2 Df		Not Reported
	Hyperium			S	Oral	2 Df		Not Reported
	Propranolol			S	Oral	40 Mg		Not Reported
	Solupred (Prednisolone)			S	Oral	160 Mg		Not Reported
	Atarax			S	Oral	25 Mg		Not Reported
	Paracetamol			C	Oral			Not Reported

	Nebivolol	C	Oral	5 Mg		Not Reported
	Esomeprazole	C	Oral	40 Mg		Not Reported
	Iperten	C		10 Mg		Not Reported
	Tahor	C		40 Mg		Not Reported
	Dafalgan	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	9459012	NON-EXPEDITED			US-PFIZER INC-2013235313		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Amoxil			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	9461393	DIRECT		OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Tremor	Escaitalopram 5 Mg Camber			S	Oral	5 Mg 1 Tablet A Bedtime By Mouth		Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2013	9462744	EXPEDITED (15-DAY)		HO	AUR-APL-2013-06606		45 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Akathisia; Blood Pressure Increased; Fall; Insomnia; Nausea; Palpitations; Panic Attack;	Escitalopram			S	Oral			Not Reported

Restlessness; Suicidal Ideation; Tremor; Tremor; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2013	9300903	EXPEDITED (15-DAY)		OT	BE-ELI_LILLY_AND_COMPANY-BE201305004233		75 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Drug Interaction; Fall	Cymbalta			S	Oral	60 Mg, Qd		Eli Lilly And Co
	Sipralexa /01588501/			S	Unknown	Unk, Unknown		Not Reported
	Emconcor			C	Unknown	Unk, Unknown		Not Reported
	Amlor			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2013	9379472	EXPEDITED (15-DAY)		CA, HO, OT	US-FRI-1000046302		266 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Atresia; Coarctation Of The Aorta; Failure To Thrive; Hypoplastic Left Heart Syndrome; Mitral Valve Stenosis; Necrotising Enterocolitis Neonatal	Lexapro			S	Transplacental	5 Mg		Forest
	Lexapro			S	Transplacental	10 Mg		Forest
	Zoloft			S	Transplacental	50 Mg		Not Reported
	Proventil Hfa			C		2 Puffs As Needed		Not Reported
	Cefdinir			C		30 Ml		Not Reported
	Nitrofurantoin			C		100 Mg Every 12 Hours		Not Reported
	Ibuprofen			C		600 Mg Four Times Daily As Needed		Not Reported
	Ondansetron			C		12 Mg		Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2013	9459325	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA-2012SE76410		21 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bezoar; Overdose	Quetiapine Xr			S	Oral			Astrazeneca
	Escitalopram			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Topiramate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2013	9459730	EXPEDITED (15-DAY)		HO, OT	FR-FRI-1000047623		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise; Orthostatic Hypotension	Nebivolol			S	Oral	5 Mg		Forest
	Nebivolol			S	Oral	2.5 Mg		Forest
	Xatral			S	Oral	10 Mg		Not Reported
	Coversyl			S	Oral	15 Mg		Not Reported
	Escitalopram			S	Oral	10 Mg		Forest
	Perindopril			C		12 Mg		Not Reported
	Kardegic			C	Oral	75 Mg		Not Reported
	Tahor			C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2013	9460371	EXPEDITED (15-DAY)		HO	AU-FRI-1000047798		65 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalitis Autoimmune; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	10 Mg		Forest
	Nitrazepam			S	Oral	5 Mg		Not Reported
	Sotalol Hydrochloride			C	Oral	320 Mg		Not Reported
	Candesartan Hydrochlorothiazide			C	Oral	32 Mg		Not Reported
	Lansoprazole			C	Oral	30 Mg		Not Reported
	Paracetamol-Codeine			C				Not Reported

	Phosphate Warfarin Sodium			C	Oral	6.5 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2013	9460489	EXPEDITED (15-DAY)		HO	AU-FRI-1000047851			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy; Premature Delivery	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S		200 Mg		Not Reported
	Seroquel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2013	9460520	EXPEDITED (15-DAY)		DE, HO	AU-FRI-1000047852		< 1 DAY	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Escherichia Sepsis; Foetal Exposure During Pregnancy; Microencephaly; Necrotising Colitis; Peritoneal Haemorrhage; Premature Delivery	Escitalopram			S	Transplacental	20 Mg		Forest
	Seroquel			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2013	9461368	EXPEDITED (15-DAY)		OT	US-ACCORD-018968			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2013	9461939	EXPEDITED (15-DAY)		HO	GB-FRI-1000047794		45 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Akathisia; Blood Pressure Increased; Condition Aggravated; Insomnia; Nausea; Palpitations; Panic Attack; Suicidal Ideation; Syncope; Tremor; Weight Decreased	Escitalopram	S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2013	9462742	EXPEDITED (15-DAY)		HO, OT	SI-ROXANE LABORATORIES, INC.-2013-RO-01336RO		79 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Neutropenia; Pancytopenia; Toxicity To Various Agents	Methotrexate			S				Roxane
	Trimethoprim-Sulfamethoxazole			S				Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Asasantin Retard			S				Not Reported
	Nifedipine			S				Not Reported
	Escitalopram			S				Not Reported
	Repaglinide			S				Not Reported
	Bisoprolol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2013	9462983	EXPEDITED (15-DAY)		HO	SE-ASTRAZENECA-2013SE63063		27 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Seizure	Seroquel			S	Oral			Zeneca
	Cipralex			S				Not Reported
	Ergenyl			S				Not Reported
	Temesta (Lorazepam)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2013	9463125	EXPEDITED (15-DAY)		HO, OT	SI-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-RO-01		79 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Neutropenia; Pancytopenia; Toxicity To Various Agents	Methotrexate			S				Roxane
	Trimethoprim-Sulfamethoxazole			S				Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Asasantin Retard			S				Boehringer Ingelheim
	Nifedipine			S				Not Reported
	Escitalopram			S				Not Reported
	Repaglinide			S				Not Reported
	Bisoprolol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2013	9471264	EXPEDITED (15-DAY)	Y	HO	1844252		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Anxiety; Decreased Appetite; Depressed Mood; Derealisation; Drug Interaction; Dysgeusia; Dysphoria; Hyperphagia; Hypersomnia; Illusion; Off Label Use; Parosmia; Poor Quality Sleep; Suicidal Ideation; Trichotillomania; Weight Increased	Ketamine Hydrochloride			S	Intravenous drip			Not Reported
	Clomipramine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2013	9464416	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000047788		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2013	9465124	EXPEDITED (15-DAY)		CA	US-FRI-1000047850		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Fallot'S Tetralogy	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2013	9467533	DIRECT	Y	HO			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematocrit Decreased;	Escitalopram			S				Not Reported
Haemoglobin Decreased;	Piperacillin/Tazobactam			C				Not Reported
Sepsis	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2013	9467610	DIRECT					43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dyspnoea; Irritability; Palpitations; Throat Tightness	Escitalopram			S	Oral	1 Tablet Once Daily Taken By Mouth		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2013	9467758	DIRECT		DS			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Dizziness; Hypokinesia; Hyporeflexia; Migraine	Escitalopram			S	Oral	10mg Once Daily Taken By Mouth 7 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2013	9556405	NON-EXPEDITED	Y	OT	13DE007279		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Inappropriate Antidiuretic Hormone Secretion; Nocturia; Pollakiuria	Paroxetine	S	Oral		Not Reported
	Cipralex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2013	9442435	EXPEDITED (15-DAY)		OT	JP-FRI-1000047441			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Memory Impairment; Suicide Attempt	Lexapro			S	Oral	10 Mg		Forest
	Paxil			C	Oral	3 Df		Not Reported
	Paxil			C	Oral	2 Df		Not Reported
	Paxil			C	Oral	1 Df		Not Reported
	Limas			C	Oral			Not Reported
	Lexotan			C	Oral			Not Reported
	Hypnotics And Sedatives, Antianxietics			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2013	9465988	EXPEDITED (15-DAY)		OT	US-FRI-1000030860		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Bronchitis; Cellulitis; Cubital Tunnel Syndrome; Drug Ineffective; Exposure During Pregnancy; Fall; Foot Fracture; Genital Herpes; Haematuria; Ligament Sprain; Menstruation Irregular; Migraine; Otitis Externa; Perinatal Depression; Upper Respiratory Tract Infection; Urinary Tract Infection; Uterine Spasm; Vaginal Abscess; Vaginal	Lexapro			S		10 Mg		Forest
	Lexapro			S		20 Mg		Forest
	Citalopram			S		40 Mg		Not Reported
	Lexapro			S		20 Mg		Forest
	Lexapro			S		10 Mg		Forest
	Lexapro			S		10 Mg		Forest
	Citalopram			S	Oral	40 Mg		Forest
	Lexapro			S		10 Mg		Forest
	Lexapro			S		20 Mg		Forest
	Aciphex			C		20 Mg		Not Reported

Haemorrhage	Trinessa	C			Not Reported
	Ortho Tri-Cyclen	C			Not Reported
	Advil	C		As Needed	Not Reported
	Vicodin	C		500/5 Mg Daily As Needed	Not Reported
	Nexium	C	Oral	20 Mg	Not Reported
	Prenatal Vitamin	C			Not Reported
	Percocet	C	Oral	5/325 Mg 1-2 Tabs As Needed	Not Reported
	Docusate	C	Oral	100 Mg	Not Reported
	Amitriptyline	C	Oral	10 Mg	Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2013	9466963	EXPEDITED (15-DAY)		HO	FR-FRI-1000047928		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Condition Aggravated	Escitalopram			S	Oral	1 Df		Forest
	Previscan (Fluindione)			S	Oral	10 Mg Even Days/5 Mg Odd Days		Not Reported
	Aerius (Desloratadine)			C		1 Df		Not Reported
	Hemigoxine			C		1 Df		Not Reported
	Inexium			C		1 Df		Not Reported
	Levemir			C		20 Units		Not Reported
	Novorapid			C		Depending On Capillary Glucose		Not Reported
	Lasilix			C		80 Mg On Morning And 40 Mg At Noon		Not Reported
	Nitriderm			C		1 Df		Not Reported
	Spasmine (Hawthorn Leaf With Flower\Valerian)			C		2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2013	9467131	EXPEDITED (15-DAY)		HO, OT	US-B.I.		10 YR	Male	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Long Qt Syndrome; Ventricular Tachycardia	Clonidine			S				Boehringer Ingelheim
	Methylphenidate			S				Not Reported
	Lithium			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2013	9469836	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Panic Attack; Therapeutic Product Effect Decreased	Lexapro			S	Oral	One Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2013	8589038	EXPEDITED (15-DAY)		DE, HO, OT	US-FRI-1000030861		313 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Atrial Septal Defect; Atrioventricular Block Complete; Brain Injury; Bronchiolitis; Cardiac Failure Congestive; Cardiogenic Shock; Cardiomegaly; Cerebrovascular Accident; Clostridium Difficile Infection; Coagulopathy; Conjunctivitis; Diarrhoea Haemorrhagic; Double Outlet Right Ventricle; Fallot'S Tetralogy;	Lexapro			S		10 Mg		Forest
	Lexapro			S		20 Mg		Forest
	Lexapro			S		20 Mg		Not Reported
	Lexapro			S		10 Mg		Not Reported
	Lexapro			S		10 Mg		Not Reported
	Lexapro			S		10 Mg		Not Reported
	Citalopram			C		40 Mg		Forest
	Citalopram			C		40 Mg		Forest
	Aciphex			C		20 Mg		Not Reported
	Trinessa			C				Not Reported
	Ortho Tri-Cyclen			C				Not Reported

Jaundice Neonatal; Multiple Organ Dysfunction Syndrome; Nodal Rhythm; Oral Candidiasis; Otitis Media; Pleural Effusion; Poor Feeding Infant; Pulmonary Hypertension; Serratia Infection; Skin Disorder; Urinary Tract Infection; Vomiting	Advil		C		As Needed	Not Reported
	Vicodin		C		500/5 Mg Daily As Needed	Not Reported
	Nexium		C	Oral	20 Mg	Not Reported
	Prenatal Vitamin		C			Not Reported
	Percocet		C	Oral	5/325 Mg 1-2 Tabs As Needed	Not Reported
	Docusate		C	Oral	100 Mg	Not Reported
	Amitriptyline		C	Oral	10 Mg	Not Reported
	Folic Acid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2013	8989355	EXPEDITED (15-DAY)		HO	IT-FRI-1000041218		23 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychomotor Hyperactivity; Tonic Clonic Movements	Escitalopram Oral Solution			S	Oral	15 Gtt		Forest
	Growth Hormone			C		0.4 Iu		Not Reported
	Valium			C		30 Gtt		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2013	9091737	EXPEDITED (15-DAY)		HO	FR-FRI-1000041624		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatitis Cholestatic; Off Label Use	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest
	Risperdal			S	Oral	4 Mg		Not Reported
	Risperdal			S	Oral	6 Mg		Not Reported
	Risperdal			S	Oral	8 Mg		Not Reported
	Risperdal			S	Oral	6 Mg		Not Reported
	Tercian			S	Oral			Not Reported
	Solian			S	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2013	9353671	EXPEDITED (15-DAY)		LT	FR-FRI-1000045962			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree	Escitalopram			S	Oral	1 Df		Forest
	Seresta			C				Not Reported
	Seresta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2013	9468337	NON-EXPEDITED			US-PFIZER INC-2013240669		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Dizziness; Fatigue; Heart Rate Decreased; Tremor	Xanax			S	Oral	0.125 Mg, 4x/Day		Pfizer
	Lexapro			S		2.5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2013	9472484	DIRECT	Y				16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Insomnia	Lexapro			S	Oral	1 Tab (10 Mg) Qhs/Bedtime Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2013	9470203	EXPEDITED (15-DAY)		CA	US-FRI-1000047893		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2013	9471298	EXPEDITED (15-DAY)		HO	FR-FRI-1000015887		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram			S	Oral	1 Df		Forest
	Previscan (Fluindione)			S	Oral			Not Reported
	Hydrochlorothiazide\Valsartan			S	Oral			Not Reported
	Imovane			S	Oral	7.5 Mg		Not Reported
	Tahor			C	Oral			Not Reported
	Amlor			C	Oral			Not Reported
	Temerit			C	Oral			Not Reported
	Diantalvic			C	Oral			Not Reported
	Ditropan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2013	9471534	EXPEDITED (15-DAY)		CA	US-FRI-1000047895		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Congenital Hydrocephalus; Spina Bifida	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2013	9471584	EXPEDITED (15-DAY)		CA	US-FRI-1000047901		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2013	9471586	EXPEDITED (15-DAY)		CA	US-FRI-1000047903		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syndactyly	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2013	9400383	EXPEDITED (15-DAY)		LT	JP-FRI-1000046637		23 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Altered State Of Consciousness; Hepatic Function Abnormal; Overdose	Lexapro			S	Oral	10 Mg		Forest
	Meilax			C	Oral	2 Mg		Not Reported
	Vegetamin-B			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2013	9473197	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-18753756		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fatigue	Sprycel (Cml) Tabs			S	Oral			Bristol Myers Squibb
	Lexapro			S				Not Reported
	Vitamin C			C				Not Reported
	Convallaria Majalis\Crataegus Laevigata Leaf\Proxyphylline			C				Not Reported
	Vitamin B			C				Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported
	Zinc			C				Not Reported
	Chlorella			C				Not Reported
	Zinc			C				Not Reported
	Zyrtec			C				Not Reported
	Tylenol			C				Not Reported
	Spirulina			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2013	9473613	EXPEDITED (15-DAY)		OT	US-TEVA-427810USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Dizziness; Drug Withdrawal	Escitalopram			S		10 Milligram Daily;		Ivax

Syndrome; Feeling Hot;
Malaise; Skin Burning
Sensation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2013	9474671	EXPEDITED (15-DAY)		OT	FR-FRI-1000048095		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotonic Urinary Bladder; Urinary Incontinence	Escitalopram			S				Forest
	Escitalopram			S		15 Mg		Not Reported
	Laroxyl			C				Not Reported
	Risperidone			C				Not Reported
	Alprazolam			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2013	9288161	EXPEDITED (15-DAY)			JP-FRI-1000045083		19 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Lexapro			S	Oral			Forest
	Lexapro			S	Oral	10 Mg		Forest
	Horizon			C	Oral	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2013	9477434	EXPEDITED (15-DAY)		HO, OT	DE-FRI-1000047498		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Urinary Retention	Escitalopram			S	Oral	20 Mg		Forest
	Amitriptylinoxide			S		120 Mg		Not Reported
	L-Thyroxin			C	Oral	Changing Dosages		Not Reported
	Ramipril			C	Oral			Not Reported
	Bisoprolol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2013	9460099	EXPEDITED (15-DAY)		OT	US-FRI-1000047736		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Parkinson'S Disease; Prescribed Overdose	Lexapro			S		20 Mg		Forest
	Viibryd			C	Oral	10 Mg		Not Reported
	Viibryd			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2013	9479488	EXPEDITED (15-DAY)			JP-FRI-1000048096		29 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	10 Mg		Forest
	Dogmatyl			S	Oral	200 Mg		Not Reported
	Dogmatyl			S	Oral	100 Mg		Not Reported
	Meilax			C	Oral	2 Mg		Not Reported
	Depas (Etizolam)			C	Oral	0.5 Mg		Not Reported
	Depas			C	Oral	1 Mg		Not Reported
	Wypax			C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2013	9485736	DIRECT					13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Oral	1/2 Tab/Day	1 MTH	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2013	9490541	DIRECT					23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Cold Sweat; Insomnia; Mydriasis; Palpitations; Product Substitution Issue; Suicidal Ideation	Escitalopram		S	Oral	30/Mo 10/Morning, 10/Night (Mg) Orally, Swallowed 01/01/2009 - N/A, Switched Back To Name Brand	Camber
	Chewable Daily Gummy-Vites		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2013	9395919	EXPEDITED (15-DAY)		OT	FR-FRI-1000046613		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spontaneous Haematoma	Escitalopram			S	Oral	1 Df		Forest
	Seresta			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2013	9482732	EXPEDITED (15-DAY)		CA, OT	US-FRI-1000048065		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta; Heart Disease Congenital	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2013	9485142	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2013246311		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Hypokalaemia; Hyponatraemia; Phlebotomy; Polydipsia; Suicide Attempt; Tendon Rupture; Withdrawal Syndrome	Effexor			S	Oral	Unk		Pfizer
	Seroplex			S	Oral	10 Mg, Daily		Not Reported
	Coversyl			C	Oral	2.5 Mg, Daily		Not Reported
	Stilnox			C	Oral	10 Mg, Daily		Not Reported
	Theralene			C	Oral	5 Mg, Daily		Not Reported
	Lysanxia			C	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2013	9458833	EXPEDITED (15-DAY)		DE, HO	CH-FRI-1000047683		44 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Sudden Death	Escitalopram			S	Oral	10 Mg		Forest
	Dabrafenib			S	Oral	300 Mg		Not Reported
	Trametinib			S	Oral	2 Mg		Not Reported
	Novalgine (Metamizole Sodium)			S	Oral	2000 Mg		Not Reported
	Keppra			S	Oral	1000 Mg		Not Reported
	Fortecortin			S	Oral	Lower Dose Than 12 Mg Daily		Not Reported
	Fortecortin			S	Oral	12 Mg		Not Reported
	Orfiril			S	Oral	1200 Mg		Not Reported
	Zelboraf			C				Not Reported
	Ipilimumab			C				Not Reported
	Cisplatin			C	Intravenous (not otherwise specified)			Not Reported
	Temodal			C		300 Mg		Not Reported
	Temodal			C		300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2013	9485662	EXPEDITED (15-DAY)		OT	CH-ROCHE-1265410		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction	Valium			S	Oral			Not Reported
	Valium			S	Oral	Dose Reduced		Not Reported
	Cipralex			S	Unknown	Form: Tablets, Tongue Soluble		Not Reported
	Lithiofor			S	Oral	Freq: Every 2 Days, Dose Increased		Not Reported
	Dipiperon			S	Oral	Freq: Every 3 Days		Not Reported

Clopin Eco	S	Oral			Not Reported
Psychopax	S	Oral			Not Reported
Pantozol (Switzerland)	C	Oral			Not Reported
Atropine Sulfate	C	Oral	Drug Name: 'Bellafit N'		Not Reported
Orfiril Long	C	Oral			Not Reported
Fragmin	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2013	9486638	EXPEDITED (15-DAY)		HO	FR-FRI-1000048147		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Escitalopram			S		2 Df		Forest
	Combivir			C	Oral	150 Mg / 300 Mg		Not Reported
	Norvir			C	Oral	2 Df		Not Reported
	Prezista			C	Oral	1200 Mg		Not Reported
	Gutron			C		3 Df		Not Reported
	Bactrim Forte			C	Oral	1 Df		Not Reported
	Depakote			C	Oral	2 Df		Not Reported
	Seresta			C	Oral	3 Df		Not Reported
	Mirtazapine			C	Oral	15 Mg		Not Reported
	Zoplicone			C	Oral			Not Reported
	Theralene			C	Oral	20 Gtt		Not Reported
	Gaviscon			C	Oral	3 Df		Not Reported
	Smecta			C	Oral	1 Df		Not Reported
	Clinutren			C				Not Reported
	Mouthwash			C		3 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9249057	EXPEDITED (15-DAY)		HO, LT	CA-FRI-1000044583		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Carpal Tunnel Syndrome; Generalised Oedema; Pain; Urticaria Chronic	Escitalopram			S	Oral	20 Mg		Forest
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9249377	EXPEDITED (15-DAY)		OT	CA-FRI-1000044575		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Drug Withdrawal Syndrome; Mood Altered; Paraesthesia	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9249559	EXPEDITED (15-DAY)		OT	CA-FRI-1000044579		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Heart Rate Irregular; Palpitations	Escitalopram			S	Oral	20 Mg		Forest
	Crestor			C	Oral	40 Mg		Not Reported
	Acetylsalicylic Acid			C	Oral	81 Mg		Not Reported
	Coversyl			C	Oral	4 Mg		Not Reported
	Doxepin			C	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9249797	EXPEDITED (15-DAY)		DS, OT	CA-FRI-1000044570		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prescribed Overdose; Urinary Incontinence	Escitalopram			S	Oral	30 Mg		Forest
	Celebrex			C	Oral	200 Mg		Not Reported

	Losec	C	Oral	40 Mg		Not Reported
	Tryptophan	C	Oral	6 Gram		Not Reported
	Tryptophan	C	Oral	3 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9249810	EXPEDITED (15-DAY)		HO	CA-FRI-1000044576		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Intentional Overdose; Vomiting	Escitalopram			S	Oral			Forest
	Arthrotec			S	Oral			Not Reported
	Ethanol			S	Oral	13 Alcoholic Drinks		Not Reported
	Rasberry Ketone Plus			S				Not Reported
	Gravol Naturals Certified Organic Ginger Tablet			S	Oral			Not Reported
	Oxycontin			C				Not Reported
	Seroquel			C				Not Reported
	Tylenol No.1 Caplets			C		300 Mg/8 Mg/15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9251661	EXPEDITED (15-DAY)		LT, OT	CA-FRI-1000044580		21 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Disturbance In Attention; Emotional Disorder; Fatigue; Feeling Of Despair; Irritability; Nausea; Suicidal Ideation	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest
	Zdxf			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9252065	EXPEDITED (15-DAY)		HO	CA-FRI-1000044589		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Asthenia; Chest Discomfort; Chills; Dyspnoea; Headache; Malaise; Palpitations; Tremor	Escitalopram		S	Oral	10 Mg	Forest
	Zopiclone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9252089	EXPEDITED (15-DAY)		OT	CA-FRI-1000044640		76 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dyspnoea; Glassy Eyes; Hallucination; Heart Rate Decreased; Incoherent; Loss Of Consciousness; Restlessness; Somnolence; Tachyphrenia; Tremor	Escitalopram			S	Oral	10 Mg		Forest
	Ativan			C	Oral	2-3 Times A Day		Not Reported
	Calcium			C	Oral			Not Reported
	Hyzaar			C	Oral	25 Mg		Not Reported
	Multivitamines			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9440489	EXPEDITED (15-DAY)		HO, LT, OT	PT-FRI-1000047440		70 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis; Gingival Bleeding; Haematuria; Melaena; Platelet Count Decreased; Thrombocytopenia	Escitalopram			S	Oral	10 Mg		Forest
	Selincro			S	Oral	18 Mg		Not Reported
	Topiramate			S	Oral	100 Mg		Not Reported
	Campral			C	Oral	1998 Mg		Not Reported
	Lyrica			C	Oral	100 Mg		Not Reported
	Simvastatin			C	Oral	20 Mg		Not Reported
	Naltrexone			C	Oral	50 Mg		Not Reported
	Naltrexone			C		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9490789	EXPEDITED (15-DAY)		HO, OT	FR-MERCK-1308FRA009978		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise; Vertigo	Aerius (Desloratadine)			S	Oral	1 Df, Qd		Merck
	Klipal			S	Oral			Not Reported
	Pariet			S	Oral	20 Mg, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Alteis			S	Oral	20 Mg, Qd		Not Reported
	Cacit Vitamine D3			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9491606	EXPEDITED (15-DAY)		HO	FR-NOVOPROD-386139		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Consciousness; Malaise	Victoza			S	Subcutaneous	0.6 Mg, Qd		Novo Nordisk
	Seroplex			S	Unknown	5 Mg, Qd		Not Reported
	Novorapid			C	Unknown	Unk		Novo Nordisk
	Kardegic			C				Not Reported
	Inexium /01479302/			C				Not Reported
	Glucophage			C		3000 Mg, Qd		Not Reported
	Tahor			C		40 Mg, Qd		Not Reported
	Triatec /00116401/			C		10 Mg, Qd		Not Reported
	Cardensiel			C		5 Mg, Qd		Not Reported
	Zyloric			C		300 Mg, Qd		Not Reported
	Amlor			C		10 Mg, Qd		Not Reported
	Colchimax /00728901/			C				Not Reported
	Tardyferon B9 /00023601/			C				Not Reported
	Laroxyl			C		19 Drops In The Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9492026	EXPEDITED (15-DAY)		OT	CH-FRI-1000048332			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depressed Level Of Consciousness	Escitalopram		S	Oral		Forest
	Escitalopram		S	Oral		Not Reported
	Valium		S	Oral		Not Reported
	Valium		S	Oral	5 Mg	Not Reported
	Lithiofor		S	Oral		Not Reported
	Lithiofor		S	Oral	1320 Mg	Not Reported
	Dipiperon		S	Oral		Not Reported
	Clopin Eco		S	Oral	300 Mg	Not Reported
	Psychopax		S	Oral		Not Reported
	Pantozol (Switzerland)		C	Oral	20 Mg	Not Reported
	Bellafit N		C	Oral	15 Drops	Not Reported
	Orfiril		C	Oral	2000 Mg	Not Reported
	Fragmin		C	Subcutaneous	5000 Iu	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9492172	EXPEDITED (15-DAY)		HO	FR-EISAI INC-E3810-06626-SPO-FR		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise; Vertigo	Pariet (Rabeprazole)			S	Oral			Not Reported
	Klipal			S	Oral	Unknown		Not Reported
	Seroplex			S	Oral			Not Reported
	Alteis			S	Oral			Not Reported
	Aerius (Desloratadine)			S	Oral	Unknown		Not Reported
	Cacit Vitamine D3			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2013	9492202	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA201305002094		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Dreams; Anxiety; Condition Aggravated; Depressed Mood; Hallucination; Hypervigilance; Injury; Tremor; Vomiting	Cymbalta	S	Oral	60 Mg, Qd		Eli Lilly And Co
	Cymbalta	S				Eli Lilly And Co
	Cipralex	S		10 Mg, Qd		Not Reported
	Cipralex	S				Not Reported
	Asa	C		325 Mg, Qd		Not Reported
	Atenolol	C	Oral	25 Mg, Qd		Not Reported
	Multaq	C	Oral			Not Reported
	Percocet	C	Oral	1 Df, Tid		Not Reported
	Synthroid	C		0.1 Mg, Qd		Not Reported
	Zopiclone	C		7.5 Mg, Each Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2013	8613008	EXPEDITED (15-DAY)		HO, LT	JP-FRI-1000031155		20 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Toxicity To Various Agents	Escitalopram			S	Oral	10 Mg		Forest
	Rohypnol			S	Oral	2 Mg		Not Reported
	Myslee			S	Oral	10 Mg		Not Reported
	Rize			S	Oral	15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2013	9251573	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000044584		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Blood Pressure Decreased; Diarrhoea; Drug Interaction; Hyperhidrosis; Influenza Like Illness; Pain; Serotonin Syndrome; Wound Infection	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Not Reported
	Fluconazole			S	Oral	400 Mg		Not Reported
	Mirtazapine			S	Oral	15 Mg		Not Reported
	Zyvoxam			S	Oral	1200 Mg		Not Reported

Hydromorphone	S	Subcutaneous	1-2 Mg Every 4 Hours		Not Reported
Hydromorphone	S	Oral	2-4mg Every 4 Hours		Not Reported
Acetaminophen	C	Oral			Not Reported
Atorvastatin Calcium	C	Oral	10 Mg		Not Reported
Clonazepam	C		1 Mg		Not Reported
Diazepam	C	Oral			Not Reported
Dimenhydrinate	C	Oral	25-50 Mg Every 4-6 Hours		Not Reported
Dimenhydrinate	C	Other	25-50 Mg Every 4-6 Hours As Needed		Not Reported
Ondansetron	C	Other	4 Mg Every 8 Hours As		Not Reported
Pantoprazole	C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2013	9440492	EXPEDITED (15-DAY)		HO, OT	JP-FRI-1000047438		92 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Interaction; Electrocardiogram Qt Prolonged; Malaise; Ventricular Fibrillation; Ventricular Tachycardia	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	5 Mg		Forest
	Lansoprazole-Od			S	Oral	15 Mg		Not Reported
	Sulpiride			S	Oral	50 Mg		Not Reported
	Cravit			S	Oral	1 Df		Not Reported
	Polyful			C	Oral	1 Gram		Not Reported
	Pollakisu			C	Oral	4 Mg		Not Reported
	Dopacol			C	Oral	100 Mg		Not Reported
	Arotinolol Hydrochloride			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2013	9451560	EXPEDITED (15-DAY)		HO, OT	US-SANOFI-AVENTIS-2013SA079081		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebrovascular Accident; Contusion; Fall; Loss Of Consciousness; Lung Disorder; Polyp	Plavix		S	Oral	Not Reported
	Plavix		S	Oral	Not Reported
	Lexapro		S	Unknown	Not Reported
	Xanax		S	Unknown	Not Reported
	Prilosec		C		Not Reported
	Oxygen		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2013	9495138	EXPEDITED (15-DAY)		DS	FR-FRI-1000048334		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Camptocormia; Overdose	Escitalopram			S	Oral	30 Mg		Forest
	Zyprexa			S	Oral	10 Mg		Not Reported
	Zyprexa			S	Oral	5 Mg		Not Reported
	Eupantol			C		20 Mg		Not Reported
	Art			C		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2013	9495769	EXPEDITED (15-DAY)		OT	IT-TEVA-421313ISR		64 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hallucination; Sleep-Related Eating Disorder; Somnambulism	Quetiapine			S	Oral			Teva
	Lamotrigine			S	Oral			Teva
	Stilnox			S	Oral	1 Dosage Forms Daily;		Not Reported
	Cipralex 20mg/Ml			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2013	9236248	EXPEDITED (15-DAY)		DS, OT	FR-ELI_LILLY_AND_COMPANY-FR201304001718		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Camptocormia	Zyprexa	S	Oral	10 Mg, Qd		Eli Lilly And Co
	Zyprexa	S		5 Mg, Qd		Eli Lilly And Co
	Seroplex	S	Oral	30 Mg, Qd		Not Reported
	Eupantol	C		20 Mg, Qd		Not Reported
	Art	C		50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2013	9466953	EXPEDITED (15-DAY)		CA	NL-FRI-1000047987			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Malformation; Foetal Exposure During Pregnancy	Lexapro			S	Transplacental	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2013	9496581	EXPEDITED (15-DAY)		HO	FR-FRI-1000048333		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Consciousness; Malaise	Escitalopram			S	Oral	5 Mg		Forest
	Victoza			S	Other	0.6 Mg		Not Reported
	Kardegic			C				Not Reported
	Inexium			C				Not Reported
	Glucophage			C		3 Df		Not Reported
	Tahor			C		1 Df		Not Reported
	Triatec (Ramipril)			C		1 Df		Not Reported
	Cardensiel			C		1 Df		Not Reported
	Zyloric			C		1 Df		Not Reported
	Amlor			C		1 Df		Not Reported
	Colchimax (France)			C		1 Df		Not Reported
	Tardyferon B9 [Ferrous Sulfate;Folic Acid]			C		1 Df		Not Reported
	Novorapid			C				Not Reported

	Laroxyl	C	19 Gtt	Not Reported
	Gliclazide	C	2 Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2013	9498492	EXPEDITED (15-DAY)		OT	BR-BRISTOL-MYERS SQUIBB COMPANY-19214568		41 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Interaction; Virologic Failure	Baraclude Tabs 0.5 Mg			S	Oral	Conmeds-Herbal Drugs		Bristol Myers Squibb
	Acetaminophen			S				Cadence
	Ketorolac Trometamol			S				Not Reported
	Pristiq			S				Not Reported
	Tramadol Hcl			S				Not Reported
	Cyclobenzaprine			S				Sandoz
	Prednisone			S				Not Reported
	Depakote			S				Not Reported
	Fluoxetine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Gabapentin			S				Not Reported
	Vitamin D Nos			C				Not Reported
	Pantoprazole			C				Not Reported
	Bisoprolol			C				Not Reported
	Lactulona			C				Not Reported
	Calcium Polycarbophil			C				Not Reported
	Macrogol 3350			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2013	9499855	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hot Flush; Mobility Decreased; Nausea; Unevaluable Event; Vertigo	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2013	9500469	DIRECT		DS			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Escitalopram			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2013	9506501	EXPEDITED (15-DAY)	Y	HO	DEM-2013-00786		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Glomerular Filtration Rate Decreased; Incorrect Dose Administered; Malaise; Syncope	Alteis			S	Oral			Not Reported
	Klipal Codeine			S	Oral			Not Reported
	Pariet			S	Oral	(20 Mg, 1 In 1 D), Oral		Not Reported
	Seroplex			S	Oral	(10 Mg, 1 In 1 D), Oral		Not Reported
	Aerius (Desloratadine)			S	Oral	(1 Dosage Forms, 1 In 1 D), Oral		Not Reported
	Cacit D3			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2013	9469377	EXPEDITED (15-DAY)		HO	SE-FRI-1000047980		27 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Seizure	Escitalopram			S				Forest
	Seroquel			C				Not Reported
	Temesta (Lorazepam)			C				Not Reported
	Ergenyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2013	9503857	DIRECT		OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dermatitis; Feeling Abnormal; Rash Pruritic	Escitalopram 10 Mg		S	Oral	Lexapro 10mg Once Daily Taken By Mouth	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2013	9240536	EXPEDITED (15-DAY)		HO	FR-FRI-1000044441		46 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Haematuria; Melaena	Escitalopram			S	Oral	1 Df		Forest
	Previscan (Fluindione)			S	Oral			Not Reported
	Imovane			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2013	9371821	EXPEDITED (15-DAY)		OT	DE-FRI-1000046213		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion; Nocturia; Pollakiuria	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest
	Paroxetin			S	Oral	20 Mg		Not Reported
	Paroxetin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2013	9465921	EXPEDITED (15-DAY)			BR-FRI-1000047934			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral			Forest
	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	5 Mg		Not Reported
	Pristiq			S	Oral	25 Mg		Not Reported
	Synthroid			C	Oral	100 Mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2013	9496658	EXPEDITED (15-DAY)		HO	FR-FRI-1000048356		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise; Vertigo	Escitalopram			S	Oral	1 Df		Forest
	Klipal Codein			S	Oral			Not Reported
	Pariet			S	Oral	1 Df		Not Reported
	Alteis			S	Oral	1 Df		Not Reported
	Aerius (Desloratadine)			S	Oral	1 Df		Not Reported
	Cacit Vitamine D3			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2013	9502421	EXPEDITED (15-DAY)		DE, HO	US-RANBAXY-2010US-38969		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Not Reported
	Fluoxetine			S	Unknown	Unk		Ranbaxy
	Trazodone			S	Unknown	Unk		Not Reported
	Buspirone			S	Unknown	Unk		Not Reported
	Temazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2013	9502987	EXPEDITED (15-DAY)		OT	IT-FRI-1000048462		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Parosmia	Escitalopram Oral Solution			S	Oral	1 Df		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2013	9503590	EXPEDITED (15-DAY)		CA	US-FRI-1000048376		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arnold-Chiari Malformation; Congenital Anomaly; Encephalocele; Klippel-Feil Syndrome; Renal Aplasia	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2013	9504443	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2013029204			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Maternal Exposure Timing Unspecified; Premature Baby	Xanax			S	Transplacental	Unk		Pfizer
	Methadone			S	Transplacental	26 Mg, 1x/Day		Not Reported
	Cipralex			S	Transplacental	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2013	9504446	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2013257763		24 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Uterine Haemorrhage	Xanax			S		Unk		Pfizer
	Methadone			S		26 Mg, 1x/Day		Not Reported
	Cipralex			S		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509051	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17375569		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Abilify			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509057	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17374935		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swollen Tongue	Abilify			S		Red To 2mg		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509059	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17370867		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Abilify			S		Also Taken 5 Mg		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509177	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17337718		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vision Blurred	Abilify Tabs 5 Mg			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509232	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-19005867		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Abilify			S				Not Reported
	Lexapro			S				Not Reported
	Remeron			S				Not Reported
	Cogentin			S				Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509234	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-19005388			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509251	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17329392		6 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Corrective Lens User; Depressive Symptom; Disturbance In Attention; Enuresis; Fatigue; Night Sweats; Somnolence; Tic; Weight Decreased	Abilify			S		Reduced To 5 Mg Twice A Day		Not Reported
	Lexapro			S				Not Reported
	Guanfacine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509426	NON-EXPEDITED		OT	US-BRISTOL-MYERS SQUIBB COMPANY-17293515		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Type 2 Diabetes Mellitus; Weight Increased	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509543	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17250200			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Lethargy	Abilify Tabs 5 Mg			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509645	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-18904946			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Abilify			S				Not Reported
	Concerta			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509702	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17170143		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fungal Infection	Abilify			S				Not Reported
	Armour Thyroid			S	Oral	Tablets; Aug-Oct2012 (30mg) Dose Increased To 60mg On Oct2012		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509704	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-17169525			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Disturbance In Attention; Drug Ineffective; Tremor	Abilify			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Vyvanse			S				Not Reported
	Lamictal			S				Not Reported
	Flaxseed Oil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9509958	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-18788067		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fatigue; Feeling Abnormal; Influenza Like Illness; Rash	Abilify Tabs 2 Mg		S	Oral	1-2mg Also	Not Reported
	Abilify Tabs 2 Mg		S	Oral	1-2mg Also	Not Reported
	Lexapro		S			Not Reported
	Carbamazepine		S			Not Reported
	Klonopin		S			Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2013	9510513	EXPEDITED (15-DAY)		HO, OT	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-BI-27			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Delusion; Drug Ineffective; Gambling Disorder; Hypersexuality; Impulsive Behaviour; Jealous Delusion; Paranoia; Psychotic Disorder	Amantadine			S				Not Reported
	Pramipexole			S		Up To 2.5 Mg		Boehringer Ingelheim
	Carbidopa-Levodopa			S		Levodopa-Equivalent Dose: 3140 Mg (Preoperatively)		Not Reported
	Carbidopa-Levodopa			S		Levodopa-Equivalent Dose: 1048 Mg (Postperatively)		Not Reported
	Entacapone			S				Not Reported
	Selegiline			S				Not Reported
	Baclofen			S				Not Reported
	Escitalopram			S				Not Reported
	Calcium Carbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2013	9462182	EXPEDITED (15-DAY)		HO	JP-FRI-1000047793		60 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal	Lexapro			S	Oral	10 Mg		Forest
	Myslee			C	Oral			Not Reported
	Solanax			C	Oral			Not Reported
	Dogmatyl			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2013	9492066	EXPEDITED (15-DAY)		HO	JP-FRI-1000048320		33 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Overdose	Lexapro			S	Oral	6 Tablets		Forest
	Isocline			C	Oral	15 Tablets		Not Reported
	Ravona			C	Oral	17 Tablets		Not Reported
	Lobu			C	Oral	2 Tablets		Not Reported
	Domperidone			C	Oral	8 Tablets		Not Reported
	Lansoprazole			C	Oral	4 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2013	9492096	EXPEDITED (15-DAY)		OT	DE-FRI-1000048319		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermolysis	Escitalopram Oral Solution			S	Oral	5 Mg		Forest
	Insulin			C				Not Reported
	Asthma-Spray			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2013	9511756	EXPEDITED (15-DAY)		HO	DE-FRI-1000048494		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Obstructed Labour; Pregnancy	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram Oral Solution			S	Oral	1 Mg		Forest
	Citadura			C	Oral	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2013	9513850	EXPEDITED (15-DAY)		OT	PHEH2013US018891			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Musculoskeletal Discomfort; Myocardial Infarction	Diovan			S		160 Mg, Unk		Novartis
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2013	9517438	EXPEDITED (15-DAY)		HO	IE-FRI-1000048686		20 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Hypotonia; Muscle Rigidity; Tachycardia	Escitalopram			S				Forest
	Fentanyl			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			C				Not Reported
	Co-Amoxiclav			C				Not Reported
	Ephedrine			C				Not Reported
	Sevoflurane			C				Not Reported
	Remifentanil			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2013	9519213	DIRECT		OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthma; Drug Ineffective; Panic Attack; Product Substitution Issue	Escitalopram			S	Oral		2 WEEK	Mylan
	Bupropion			C				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2013	9519289	DIRECT	Y				11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2013	9417834	EXPEDITED (15-DAY)		HO	IT-FRI-1000046991		7 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product By Child; Bradycardia; Medication Error	Escitalopram Oral Solution			S	Oral	Overdose: 10 Drops		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2013	9524117	DIRECT		HO, OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endometriosis; Fibromyalgia; Gait Disturbance; Speech Disorder	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2013	9438827	NON-EXPEDITED			US-PFIZER INC-2013222315		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dry Mouth; Enuresis; Urinary Incontinence	Lyrica			S	Oral	100 Mg, 3x/Day		Pfizer
	Lyrica			S				Pfizer
	Lyrica			S				Pfizer
	Omeprazole			S		40 Mg, 1x/Day		Not Reported
	Lexapro			S		10 Mg, 1x/Day		Not Reported
	Felodipine			S		2.5 Mg, 1x/Day		Not Reported
	Ambien			S		5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2013	9520530	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA-2013SE67811		56 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Condition Aggravated; Disturbance In Attention	Seroquel Xr			S	Oral			Zeneca
	Cipralex			S				Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Temesta (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2013	9531111	DIRECT		OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Heart Rate Irregular; Insomnia; Panic Attack; Product Substitution Issue; Suicidal Ideation	Escitalopram			S	Oral	1; Once Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	8626962	EXPEDITED (15-DAY)		LT	PT-FRI-1000027206		85 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Dizziness; Dyspnoea; Mouth Swelling; Oropharyngeal Pain; Swollen Tongue	Escitalopram			S	Oral	10 Mg		Forest
	Coaprovel			C				Not Reported
	Lorenin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	9458925	EXPEDITED (15-DAY)		HO	JP-FRI-1000047739		46 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Disturbance In Attention; Head Discomfort; Hyperhidrosis; Tension	Lexapro			S	Oral	10 Mg		Forest
	Flunitrazepam			C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	9459006	EXPEDITED (15-DAY)		HO	JP-FRI-1000047740		55 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Anxiety; Malaise; Suicide Attempt	Lexapro			S	Oral	10 Mg		Forest
	Rivotril			C	Oral	1 Mg		Not Reported
	Depas (Etizolam)			C	Oral	0.5 Mg		Not Reported
	Reslin			C	Oral	25 Mg		Not Reported
	Yokukansankachimpihange			C	Oral	7.5 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	9459101	EXPEDITED (15-DAY)		HO	JP-FRI-1000047742		52 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Activation Syndrome; Autonomic Nervous System Imbalance	Lexapro			S	Oral	10 Mg		Forest
	Remeron			C	Oral	15 Mg		Not Reported
	Lexotan			C	Oral	15 Mg		Not Reported
	Silece			C	Oral	4 Mg		Not Reported
	Seroquel			C	Oral	75 Mg		Not Reported
	Seroquel			C	Oral	100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	9493680	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20130814909		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Risperdal			S	Oral			Not Reported
	Entact			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	9529141	EXPEDITED (15-DAY)		OT	JP-FRI-1000024486		32 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S		10 Mg		Forest
	Amoxan			S	Oral	75 Mg		Not Reported
	Lexotan			C	Oral			Not Reported
	Flunitrazepam			C	Oral			Not Reported
	Irribow			C	Oral			Not Reported
	Benzalin (Nitrazepam)			C	Oral			Not Reported
	Ravona			C	Oral			Not Reported
	Cymbalta			C	Oral	60 Mg		Not Reported
	Seniran			C		6 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	9529968	EXPEDITED (15-DAY)		DE	US-FRI-1000048571		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Heart Disease Congenital	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	9529998	EXPEDITED (15-DAY)		HO	CH-FRI-1000042460			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Haemorrhage In Pregnancy; Pregnancy	Escitalopram			S		10 Mg		Forest
	Escitalopram			S		10 Mg		Forest
	Methadone			S		26 Mg		Not Reported
	Alprazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	9530043	EXPEDITED (15-DAY)		OT	CH-FRI-1000048804			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Condition Aggravated; Disturbance In Sexual Arousal	Escitalopram			S	Oral	15 Mg		Forest
	Escitalopram			S	Oral	25 Mg		Forest
	Escitalopram			S		10 Mg Qod		Not Reported
	Escitalopram			S		5 Mg Qod		Not Reported
	Seroquel Xr			S	Oral	50 Mg In The Evening		Not Reported
	Temesta (Lorazepam)			C		0.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	9530187	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2013263670		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dizziness; Pulmonary Embolism	Caduet			S	Oral	Amlodipine Besilate 5 Mg/Atorvastatin Calcium 10 Mg, 1 Df Daily		Pfizer
	Ebixa			S	Oral	20 Mg, Daily		Not Reported
	Reminyl			S	Oral	16 Mg, Daily		Not Reported
	Seroplex			S	Oral	5 Mg, Daily		Not Reported
	Atarax			S	Oral	25 Mg, Daily		Not Reported
	Nisisco			S	Oral	Valsartan 80 Mg/ Hydrochlorothiazide 12.5 Mg,1 Df Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	9531596	DIRECT	Y				14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Substitution Issue; Tremor	Lexapro	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2013	9536426	DIRECT		DS, HO			19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glucose Tolerance Impaired	Lexapro			S		10 Dose Once Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2013	9459007	EXPEDITED (15-DAY)		HO	US-FRI-1000047790		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Anxiety; Decreased Appetite; Depressed Mood; Derealisation; Drug Interaction; Hyperphagia; Hypersomnia; Illusion; Sleep Disorder; Suicidal Ideation; Therapeutic Product Effect Incomplete; Trichotillomania; Weight Increased	Lexapro			S				Forest
	Ketamine			S				Not Reported
	Clomipramine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2013	9531588	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20130907197		17 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack; Product Use In Unapproved Indication	Topiramate			S	Oral			Not Reported
	Topiramate			S	Oral			Not Reported
	Topiramate			S	Oral			Not Reported
	Topiramate			S	Oral			Not Reported

	Escitalopram		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2013	9532705	EXPEDITED (15-DAY)		HO, OT	CH-FRI-1000048921			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Premature Baby; Retroplacental Haematoma; Umbilical Cord Abnormality	Escitalopram			S	Transplacental	10 Mg		Forest
	Methadone			S	Transplacental	26 Mg		Not Reported
	Alprazolam			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2013	9533239	EXPEDITED (15-DAY)		OT	US-FRI-1000048699			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Schizophrenia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2013	9535078	EXPEDITED (15-DAY)		DE, HO	CH-UCBSA-098016		44 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Progression; Pyrexia	Keppra			S	Oral			Not Reported
	Dabrafenib			S	Oral	300 Mg/Day		Not Reported
	Trametinib			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Novalgine (Metamizole Sodium)			S	Oral	1500-2000 Mg/Day		Not Reported
	Fortecortin			S	Oral			Not Reported
	Fortecortin			S	Oral	12 Mg/Day		Not Reported
	Orfiril			S	Oral	1000-1200 Mg		Not Reported

Orfiril	S	Oral			Not Reported
Ipilimumab	C		Cycle		Not Reported
Cisplatin	C	Intravenous (not otherwise specified)	2 Cycles, 90 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2013	9536674	DIRECT	Y				14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Tremor	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2013	9537176	DIRECT					45 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Formulation Issue; Product Substitution Issue	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2013	9160718	NON-EXPEDITED		CA, DE, HO	US-JNJFOC-20130306472		94 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cardiac Failure Congestive; Chromosomal Deletion; Cytogenetic Abnormality; Double Outlet Right Ventricle; Factor V Leiden Mutation; Hypospadias; Lung Disorder; Necrotising Colitis; Patent Ductus Arteriosus; Periventricular	Topamax			S	Transplacental	200-500 Mg Every Day		Not Reported
	Lamictal			S	Transplacental			Not Reported
	Xanax			S	Transplacental			Not Reported
	Ambien			S	Transplacental			Not Reported
	Trazodone			S	Transplacental			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Zoloft			S	Transplacental			Not Reported
	Dilantin			S	Transplacental			Not Reported

Leukomalacia; Premature Baby; Respiratory Failure; Sepsis; Thrombocytopenia; Tracheitis; Transposition Of The Great Vessels; Vascular Skin Disorder; Ventricular Septal Defect	Z-Pack	S	Transplacental	Not Reported
	Metformin	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2013	9319286	EXPEDITED (15-DAY)		HO	FR-FRI-1000045448		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Escitalopram			S	Oral			Forest
	Citalopram			S	Oral	20 Mg		Forest
	Effexor			S	Oral	75 Mg		Not Reported
	Cerazette (Desogestrel)			C	Oral			Not Reported
	Lexomil			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2013	9517177	NON-EXPEDITED			US-PFIZER INC-2013260096		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Xanax			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Robaxin			S		Unk		Pfizer
	Etodolac			S		Unk		Pfizer
	Tramadol Hydrochloride			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported

	Flexeril	S	Unk	Not Reported
	Ambien	S	Unk	Not Reported
	Celexa	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Lunesta	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2013	9536586	NON-EXPEDITED		OT	US-JNJFOC-20130306471			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Exposure During Pregnancy; Perinatal Depression; Premature Labour	Topamax			S	Oral	200-500 Mg Every Day		Not Reported
	Lamictal			S	Oral	600-800 Mg Every Day		Not Reported
	Xanax			S	Oral	0.25 Mg To 1 Mg Every Day		Not Reported
	Ambien			S	Oral	50 Mg Every Day		Not Reported
	Trazodone			S	Oral	100-200 Mg Every Day		Not Reported
	Lexapro			S	Oral	25 Mg Every Day		Not Reported
	Lexapro			S	Oral	25 Mg Every Day		Not Reported
	Zoloft			S	Oral	2010 Till Present		Not Reported
	Zoloft			S	Oral	2010 Till Present		Not Reported
	Dilantin			S	Oral			Not Reported
	Z-Pack			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2013	9537405	EXPEDITED (15-DAY)		DS	FR-FRI-1000048942		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall;	Escitalopram			S	Oral	10 Mg		Forest

Hemianopia Homonymous; Hemiparesis; Ischaemic Stroke; Seizure	Furosemide		S	Oral	1 Df	Not Reported
	Alprazolam		S	Oral	1 Df	Not Reported
	Foradil		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2013	9541950	DIRECT					62 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Contamination Physical; Product Substitution Issue; Therapeutic Product Effect Decreased	Escitalopram			S		1.5, Once Daily, Taken By Mouth	10 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2013	9310380	EXPEDITED (15-DAY)		OT	FR-BRISTOL-MYERS SQUIBB COMPANY-18910620		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Rash; Sleep Apnoea Syndrome	Abilify			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Zyprexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2013	9539082	EXPEDITED (15-DAY)		DE	FR-FRI-1000048936		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S	Oral	1 Df		Forest
	Xarelto			S	Oral	1 Df		Not Reported
	Xanax			C	Oral	1 Df		Not Reported
	Flecaine			C	Oral	1 Df		Not Reported
	Inexium			C	Oral	1 Df		Not Reported

	Seresta	C	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2013	9539093	EXPEDITED (15-DAY)		HO	FR-FRI-1000048937		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral	1 Df		Forest
	Carboplatine			C				Not Reported
	Etoposide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2013	9543138	EXPEDITED (15-DAY)		HO, LT	FR-JHP PHARMACEUTICALS, LLC-JHP201300564		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Dantrium			S		Unk Unk, Single		Jhp
	Seroplex			S	Oral	20 Mg, Unk		Not Reported
	Laroxyl			S		50 Mg, Daily		Not Reported
	Lyrica			C		75 Mg, Bid		Not Reported
	Urbanyl			C		420 Mg, Tid		Not Reported
	Doliprane			C		1 G, Qid		Not Reported
	Rivotril			C		15 Df, Daily		Not Reported
	Baclofen			C		9 Df, Daily		Not Reported
	Ditropan			C		1.5 Df, Daily		Not Reported
	Neurontin			C		1200 Mg, Tid		Not Reported
	Xanax			C		0.5 Mg, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2013	9548777	DIRECT		DS, OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Disorder; Hypophagia; Insomnia; Intentional Self-Injury; Mental Disorder; Migraine; Nausea; Product Substitution Issue; Suicidal Ideation; Weight Decreased	Escitalopram	S	1 Pill; Once Daily		Not Reported
	Lexapro	C			Not Reported
	Propranolol	C			Not Reported
	Piroxicam	C			Not Reported
	Diazepam	C			Not Reported
	Tizanidine	C			Not Reported
	Ketorolac	C			Not Reported
	Sumatriptan	C			Not Reported
	Vitamin B2	C			Not Reported
	Magnesium	C			Not Reported
	Vitamins	C			Not Reported
	Coq10	C			Not Reported
	Acidophilus	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2013	9547495	EXPEDITED (15-DAY)		DE, HO	ES-SANOFI-AVENTIS-2013SA092934		92 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Blood Loss Anaemia; Coma	Clexane			S	Subcutaneous	40mg		Not Reported
	Escitalopram			S	Oral	10mg En Desayuno		Not Reported
	Dexketoprofen			S	Intravenous (not otherwise specified)	50mg/8h		Not Reported
	Haloperidol			C	Intravenous (not otherwise specified)	5mg/8h		Not Reported
	Risperidone			C	Oral	1mg En Cena		Not Reported
	Omeprazole			C	Oral	20mg		Not Reported
	Oxycodone			C	Oral	5mg/8h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2013	9549868	EXPEDITED (15-DAY)		DE, OT	US-ACTAVIS-2013-16626		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Toxicity To Various Agents	Cyproheptadine Hydrochloride (Amallc)			S	Unknown	Unk		Actavis Mid Atlantic

	Citalopram Hydrobromide (Watson Laboratories)	S	Unknown	Unk		Watson
	Lexapro	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2013	9553573	DIRECT		DS			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dizziness; Drug Withdrawal Syndrome; Impaired Driving Ability; Product Dose Omission; Wrong Technique In Product Usage Process	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2013	9100164	EXPEDITED (15-DAY)		HO	JP-FRI-1000042573		< 1 DAY	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Lexapro			S	Transplacental	20 Mg		Forest
	Remeron			C	Transplacental			Not Reported
	Rhythmy			C	Transplacental			Not Reported
	Myslee			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2013	9552970	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20130910076		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Orthostatic Hypotension	Haldol			S	Oral			Not Reported
	Lexomil			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2013	9553007	EXPEDITED (15-DAY)		HO	JP-FRI-1000042572			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy; Subchorionic Haematoma; Threatened Labour; Weight Increased	Lexapro			S	Oral	20 Mg		Forest
	Remeron			C	Oral			Not Reported
	Rhythmy			C	Oral			Not Reported
	Myslee			C	Oral	1 Df		Not Reported
	Cercine			C	Oral	3 Df		Not Reported
	Gasmotin			C	Oral	3 Df		Not Reported
	Silece			C	Oral	1 Df		Not Reported
	Vegetamin-B			C	Oral	1 Df		Not Reported
	Risperdal			C	Transdermal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2013	9553578	EXPEDITED (15-DAY)		HO	FR-FRI-1000048968		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Escitalopram			S	Oral			Forest
	Solian			C				Not Reported
	Metformine			C				Not Reported
	Repaglinide			C				Not Reported
	Parkinane			C				Not Reported
	Buspirone Hydrochloride			C				Not Reported
	Chondrosulf			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2013	9553950	EXPEDITED (15-DAY)		OT	IT-FRI-1000049036		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury;	Escitalopram			S				Forest

Sopor	Risperdal	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2013	9554325	EXPEDITED (15-DAY)		HO, OT	JP-FRI-1000048416		64 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; Hyponatraemia; Off Label Use; Urinary Retention	Lexapro			S	Oral	10 Mg		Forest
	Gasmotin			S	Oral	15 Mg		Not Reported
	Constan [Alprazolam]			S	Oral			Not Reported
	Lendormin			S	Oral			Not Reported
	Lendormin			S	Oral	0.25 Mg		Not Reported
	Olmetec			C	Oral	40 Mg		Not Reported
	Methycobal			C	Oral	1500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2013	9554375	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000047482		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Myocardial Infarction	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2013	9554404	EXPEDITED (15-DAY)		CA, HO	DE-FRI-1000049037		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Selective Eating Disorder; Urinary Tract Infection	Escitalopram			S	Transplacental	10 Mg		Forest
	Edronax			S	Transplacental	4 Mg		Not Reported
	Diclofenac			C	Transplacental			Not Reported
	Folic Acid			C	Transplacental	0.8 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2013	9554452	EXPEDITED (15-DAY)		CA	FR-FRI-1000049146			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Umbilical Hernia; Exposure During Pregnancy	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2013	8193189	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20111007241		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Generalised Tonic-Clonic Seizure; Hyponatraemia; Loss Of Consciousness	Haldol			S	Oral			Not Reported
	Contramal			S	Oral	Twice Daily		Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Seresta			C	Unknown			Not Reported
	Vitamin B1			C	Unknown			Not Reported
	Vitamin B6			C	Unknown			Not Reported
	Nicobion			C	Unknown			Not Reported
	Imovane			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2013	9585903	NON-EXPEDITED		DE	2013-00621		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Valproic Acid			S				Not Reported
	Escitalopram			S				Not Reported
	Hydroxyzine			S				Not Reported
	Ibuprofen			S				Not Reported

	Cyclobenzaprine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2013	8941819	EXPEDITED (15-DAY)		OT	CH-FRI-1000040751			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria; Renal Cyst	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2013	9530062	EXPEDITED (15-DAY)		OT	JP-FRI-1000045958		51 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Depression; Nausea; Off Label Use; Poor Quality Sleep; Thirst; Urine Output Decreased; Vision Blurred	Lexapro			S	Oral	10 Mg		Forest
	Lyrica			S	Oral	150 Mg		Not Reported
	Methycobal			S	Oral	3 Df		Not Reported
	Anplag			S	Oral	3 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2013	9554012	EXPEDITED (15-DAY)			JP-FRI-1000049043			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Hyperhidrosis; Palpitations	Lexapro			S	Oral			Forest
	Lunesta			C	Oral			Not Reported
	Etizolam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2013	9560372	EXPEDITED (15-DAY)		HO	CN-FRI-1000049264		53 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Back Pain; Blood Pressure Increased;	Lexapro			S	Oral	10 Mg		Forest

Chest Discomfort; Decreased Appetite; Discomfort; Insomnia; Palpitations; Tremor	Lexapro		S	Oral	1 Tab/2 Days To 1 Tab/5 Days		Forest
	Lexapro		S	Oral	1 Tab/5days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2013	9562285	EXPEDITED (15-DAY)		HO	FR-FRI-1000049272		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Orthostatic Hypotension	Escitalopram			S	Oral	1 Df		Forest
	Lexomil Roche			S	Oral	3 Df		Not Reported
	Haldol			S	Oral	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2013	9563034	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000049050		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect; Hypoplastic Left Heart Syndrome; Pulmonary Hypertension; Pulmonary Vein Stenosis; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2013	9563377	EXPEDITED (15-DAY)		OT	PHHY2013AU105976			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antipsychotic Drug Level Increased; Electrocardiogram Qt Prolonged	Clozapine			S		Unk		Novartis
	Escitalopram			S		Unk		Not Reported
	Thyroxin			S		Unk		Not Reported
	Epilim			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2013	9564996	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20130916638		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Somnolence	Contramal			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Trolamine			C	Topical			Not Reported
	Loperamide			C	Oral			Not Reported
	Atarax			C	Oral			Not Reported
	Lovenox			C	Parenteral			Not Reported
	Mopral			C	Oral			Not Reported
	Diprosone			C	Topical			Not Reported
	Diffu K			C	Oral			Not Reported
	Gutron			C	Oral			Not Reported
	Fludrocortisone			C	Oral			Not Reported
	Dafalgan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2013	9565958	EXPEDITED (15-DAY)		HO	FR-FRI-1000049245		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram			S	Oral	1 Df		Forest
	Fludex (Indapamide)			S	Oral	1 Df		Not Reported
	Valdoxan			S	Oral	2 Df		Not Reported
	Seresta			C	Oral	3 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2013	9566306	EXPEDITED (15-DAY)		HO, LT, OT	DE-ROXANE LABORATORIES, INC.-2013-RO-01596RO		31 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Electrocardiogram Qt Prolonged; Faecaloma; Generalised Tonic-Clonic Seizure; Hypokalaemia; Hypomagnesaemia; Pulse Absent; Torsade De Pointes; Ventricular Tachycardia	Methadone			S	Oral			Roxane
	Ondansetron			S	Intravenous (not otherwise specified)			Not Reported
	Escitalopram			S				Not Reported
	Esomeprazole			C	Intravenous (not otherwise specified)			Not Reported
	Butylscopolamine			C	Intravenous (not otherwise specified)			Not Reported
	Metamizole			C	Intravenous (not otherwise specified)			Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)			Not Reported
	Pethidine			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2013	9573331	DIRECT	Y	HO			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Torsade De Pointes	Lexapro			S	Oral	1 Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2013	9579977	DIRECT		OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease Recurrence; Panic Attack; Product Substitution Issue	Escitalopram			S	Oral	1 Pill		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2013	9580235	EXPEDITED (15-DAY)	Y	OT	2013P1019558			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Interaction	Escitalopram			S				Not Reported
	Furosemide			S				Not Reported
	Bromazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2013	9070945	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-B0845771A		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Decreased Appetite; Drug Eruption; Drug Interaction; Drug Reaction With Eosinophilia And Systemic Symptoms; Erythema Multiforme; Gait Disturbance; Generalised Erythema; Hypersensitivity; Inappropriate Schedule Of Product Administration; Malaise; Nasopharyngitis; Nausea; Ocular Hyperaemia; Oropharyngeal Pain; Pain In Extremity; Pruritus; Pyrexia; Rash; Rash Generalised; Red Blood Cell Count Decreased; Restlessness; Skin Disorder; Urticaria; Vomiting; White Blood Cell Count Decreased	Lamictal			S	Oral	25mg Per Day		Glaxosmithkline
	Lamictal			S	Oral	50mg Per Day		Glaxosmithkline
	Paxil			S	Oral	12.5mg Per Day		Glaxosmithkline
	Tramcet			S	Oral			Not Reported
	Tramcet			S	Oral			Not Reported
	Lexapro			S	Oral	10mg Per Day		Not Reported
	Lyrica			C	Oral	75mg Twice Per Day		Not Reported
	Milmag			C	Oral			Glaxosmithkline
	Gasrick D			C	Oral			Not Reported
	Meilax			C	Oral			Not Reported
	Lithium Carbonate			C	Oral	100mg Twice Per Day		Glaxosmithkline
	Rilmazafone Hydrochloride			C	Oral	2mg Per Day		Not Reported
	Thyradin S			C	Oral	75mcg Per Day		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2013	9499091	EXPEDITED (15-DAY)		HO, OT	US-RB-057907-13		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Depression; Drug Abuse; Drug Dependence; Insomnia; Overdose; Seizure; Suicidal Ideation	Suboxone Film			S	Sublingual	Suboxone Film		Reckitt Benckiser
	Suboxone Film			S	Sublingual	Suboxone Film		Reckitt Benckiser
	Xanax			S	Unknown	Dosing Details Unknown		Not Reported
	Ambien			S	Oral	Dosing Details Unknown; Daily		Not Reported
	Marijuana			S	Respiratory (inhalation)	Dosing Details Unknown		Not Reported
	Klonopin			S	Oral			Not Reported
	Prozac			S	Unknown	Dosing Details Unknown		Not Reported
	Lexapro			S	Unknown	Dosing Details Unknown		Not Reported
	Cymbalta			S	Unknown	Dosing Details Unknown		Not Reported
	Zoloft			S	Oral	Dosing Details Unknown;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2013	9510469	EXPEDITED (15-DAY)		HO	CH-TEVA-428982ISR		83 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Comilorid-Mepha			S	Oral	1 Dosage Forms Daily; Dosing Regimen: 1-0-0-0		Barr
	Remeron			S	Oral	45 Milligram Daily;		Not Reported
	Cipralex			S	Oral	20 Milligram Daily;		Not Reported
	Pantozol (Switzerland)			C	Unknown			Not Reported
	Pradif			C	Unknown	Pradif Was Discontinued During The Hospitalization		Not Reported
	Ciproxin			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

	Aspirin	C	Unknown	Not Reported
	Imovane	C	Unknown	Not Reported
	Calcium + D3	C	Unknown	Not Reported
	Paspertin [Metoclopramide Hydrochloride]	C	Unknown	Not Reported
	Perenterol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2013	9580214	DIRECT	Y				55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue	Escitalopram			S	Oral	1/2 Tabl	1 YR	Not Reported
	Oxycontin			C				Not Reported
	Ibuprofen			C				Not Reported
	Ranitidine			C				Not Reported
	Albuterol			C				Not Reported
	Vicodin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2013	9580904	DIRECT		OT			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Hallucination; Sleep Talking	Escitalopram			S		1 Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2013	9031974	EXPEDITED (15-DAY)		CA, DE, LT, OT	US-PFIZER INC-2013030509			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cleft Lip And Palate; Cytogenetic Abnormality;	Zoloft			S	Transplacental	Unk		Pfizer
	Lexapro			S	Transplacental	Unk		Not Reported

Double Outlet Right Ventricle; Exomphalos; Maternal Exposure Timing Unspecified; Neonatal Aspiration; Neural Tube Defect; Newborn Persistent Pulmonary Hypertension; Pulmonary Valve Stenosis; Talipes; Transposition Of The Great Vessels; Ventricular Septal Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2013	9507389	EXPEDITED (15-DAY)		OT	CA-FRI-1000048443		4 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product By Child	Escitalopram			S	Oral	Overdose: Escitalopram (Around 50 Mg)		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2013	9580161	EXPEDITED (15-DAY)		OT	PHHY2013US107278		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Drug Interaction; Dysstasia; Insomnia	Aripiprazole			S		25 Mg, Unk		Not Reported
	Quetiapine			S		450 Mg, Unk		Novartis
	Buspirone			S		30 Mg, Unk		Not Reported
	Clonazepam			S		3 Mg, Unk		Not Reported
	Lexapro			S		20 Mg, Unk		Not Reported
	Asenapine			S	Sublingual	5 Mg, Bid		Not Reported
	Asenapine			S		5 M Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2013	9581393	EXPEDITED (15-DAY)		OT	US-FRI-1000049275			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Vesicoureteric Reflux; Ectopic Kidney; Single Functional Kidney	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2013	9431470	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000046980		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Neonatal; Bradycardia; Bronchiolitis; Croup Infectious; Laryngomalacia; Metabolic Acidosis; Nasopharyngitis; Neurogenic Bladder; Spina Bifida; Talipes; Urinary Tract Infection	Lexapro			S				Forest
	Prilosec			C	Transplacental			Not Reported
	Macrobid			C	Transplacental			Not Reported
	Tylenol			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2013	9586383	EXPEDITED (15-DAY)		HO, OT	PHHY2013GR106282		42 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Confusional State; Depression; Fear; Generalised Tonic-Clonic Seizure; Hallucination, Auditory; Obsessive Thoughts; Obsessive-Compulsive Disorder; Persecutory Delusion; Self-Injurious Ideation; Suicidal Ideation; Suicide Attempt	Oxcarbazepine			S		Unk		Novartis
	Oxcarbazepine			S		1200 Mg, Unk		Novartis
	Clozapine			S		300 Mg, Unk		Not Reported
	Clomipramine			S		Unk		Not Reported
	Valproic Acid			S				Not Reported
	Maprotiline			S				Not Reported
	Paroxetine			S		Unk Ukn, Unk		Not Reported
	Venlafaxine			S				Not Reported
	Propranolol			S		20 Df, Unk		Not Reported
	Quetiapine			S		Unk 600 To 800 Mg For 2 Months		Not Reported

Lorazepam	S		Unk Ukn, Unk	Not Reported
Risperidone	S		Unk 2 To 4 Mg For Short Periods	Not Reported
Ziprasidone	S			Not Reported
Amitriptyline, Perphenazine	S		Unk	Not Reported
Escitalopram	S		Unk	Not Reported
Fluoxetine	S		Unk	Not Reported
Fluoxetine	S		40 Mg, Upto	Not Reported
Gabapentin	S		Unk	Not Reported
Pregabalin	S		Unk Ukn, Unk	Not Reported
Pregabalin	S		225 Mg, Upto	Not Reported
Pregabalin	S		300 Mg, Unk	Not Reported
Amisulpride	S		100 Mg, Unk	Not Reported
Sertraline	S		150 Mg, Unk	Not Reported
Sertraline	S		300 Mg, Unk	Not Reported
Mirtazapine	S		Unk	Not Reported
Topiramate	S		200 Mg, Unk	Not Reported
Alprazolam	S			Not Reported
Haloperidol	S		Unk	Not Reported
Diazepam	S		Unk	Not Reported
Thioridazine	S		Unk	Not Reported
Trifluoperazine	S		Unk Ukn, Unk	Not Reported
Nefazodone	S		Unk	Not Reported
Fluvoxamine	S		Unk	Not Reported
Olanzapine	S		Unk	Not Reported
Levomepromazine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Duloxetine	S		Unk	Not Reported
Zuclopenthixol	S		Unk	Not Reported
Biperiden	S		Unk	Not Reported

	Clorazepate			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2013	9586402	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2013SE72343		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoalbuminaemia; Hypogammaglobulinaemia; Pancreatitis Acute; Thrombocytosis	Entocort			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Imurel			S	Oral			Not Reported
	Pentasa			S	Oral			Not Reported
	Biprofenid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2013	9587645	EXPEDITED (15-DAY)		CA	US-FRI-1000049277		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Disease; Atrial Septal Defect; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2013	9587786	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000046979		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Presentation; Exposure During Pregnancy; Hypertension; Oligohydramnios	Lexapro			S				Forest
	Prilosec			C				Not Reported
	Macrobid			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2013	9565067	EXPEDITED (15-DAY)		OT	JP-FRI-1000049260		30 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Overdose; Physical Assault	Lexapro	S	Oral	210 Mg	Forest
	Depakene	C	Oral	Overdose: 800 Mg	Not Reported
	Silece	C		Overdose: 2 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2013	9596902	EXPEDITED (15-DAY)		OT	GB-FRI-1000049458		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Agitation; Confusional State; Dizziness; Hyperhidrosis; Mydriasis; Paraesthesia; Restlessness; Vaginal Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Depo-Provera			C	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2013	9601850	EXPEDITED (15-DAY)		OT	IT-ACCORD-019666			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Underweight	Alprazolam			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2013	9603363	EXPEDITED (15-DAY)		HO	FR-FRI-1000049608		29 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemic Stroke	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2013	9603374	EXPEDITED (15-DAY)		DE	FR-FRI-1000049609		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Labelled Drug-Drug Interaction Medication Error; Sudden Death	Escitalopram	S	Oral	20 Mg		Forest
	Kestine	S				Not Reported
	Psychotropic Agents Nos	C		Psychotropic Agent Overdose Nos		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2013	9170541	EXPEDITED (15-DAY)		CA, HO, OT	US-JNJFOC-20130310451			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chordee; Deformity; Developmental Delay; Drug Withdrawal Syndrome Neonatal; Emotional Distress; Encephalopathy; Eustachian Tube Dysfunction; Muscular Weakness; Otitis Media Acute; Pain; Penile Torsion; Periventricular Leukomalacia; Premature Baby; Prepuce Redundant; Skull Malformation; Social Avoidant Behaviour; Tachypnoea	Topamax			S	Transplacental			Not Reported
	Miralax			S	Transplacental			Not Reported
	Dulcolax			S	Transplacental			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Reglan			S	Transplacental			Not Reported
	Zofran			S	Transplacental			Not Reported
	Methadone			S	Transplacental			Not Reported
	Percocet			S	Transplacental			Not Reported
	Lortab			S	Transplacental			Not Reported
	Cymbalta			S	Transplacental			Not Reported
	Stadol			S	Transplacental			Not Reported
	Dilaudid			S	Transplacental			Not Reported
	Neurontin			S	Transplacental			Not Reported
	Protonix			S	Transplacental			Not Reported
	Bentyl			S	Transplacental			Not Reported
	Prenatal Vitamins			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2013	9499006	EXPEDITED (15-DAY)		LT	JP-FRI-1000048361		67 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Loss Of Consciousness; Respiratory Arrest	Lexapro	S	Oral	10 Mg		Forest
	Rize	C	Oral	15 Mg		Not Reported
	Crestor	C	Oral	2.5 Mg		Not Reported
	Co-Dio	C	Oral	1 Df		Not Reported
	Alinamin-F	C	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2013	9605677	EXPEDITED (15-DAY)		OT	BR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-BI-31		85 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sialocele; Suicide Attempt	Secotex			S	Oral			Boehringer Ingelheim
	Escitalopram			S	Oral	240 Mg		Not Reported
	Oxibutinina Hydrochloride			S	Oral			Not Reported
	Valsatana			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2013	9605928	EXPEDITED (15-DAY)		DS, HO	FI-FRI-1000049751		27 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Escitalopram			S	Oral	2.5 - 15 Mg Daily		Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2013	9607877	DIRECT		OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine; Product Substitution Issue	Escitalopram 20mg			S	Oral	45 Pills Once Daily Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2013	9611777	NON-EXPEDITED	Y	OT	2013-0007			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Triglycerides Increased	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2013	9612518	EXPEDITED (15-DAY)	Y	HO, OT	AUR-APL-2013-08321		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression	Escitalopram (Escitalopram)			S				Not Reported
	Topiramate (Topiramate)			C				Not Reported
	Valproate (Valproate Sodium)			C				Not Reported
	Flunarizine (Flunarizine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2013	9613517	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2013-08060		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Agitation; Confusional State; Dizziness; Erythema; Hyperhidrosis; Mydriasis; Restlessness; Tremor; Vaginal Haemorrhage	Escitalopram			S	Oral			Not Reported
	Depo-Provera (Medroxyprogesterone Acetate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2013	9609318	EXPEDITED (15-DAY)		HO	US-FRI-1000049715			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Limb; Cellulitis	Lexapro			S	Oral	10 Mg		Forest

	Sotalol	C	160 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2013	9610017	EXPEDITED (15-DAY)		OT	AU-FRI-1000049832			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S				Forest
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2013	9610642	EXPEDITED (15-DAY)		HO	PHHY2013FR111389		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Rash Maculo-Papular; Skin Exfoliation	Loxen (Nicardipine Hydrochloride)			S	Oral	20 Mg, Tid		Not Reported
	Paracetamol Sandoz			S	Oral	1 G, Tid		Not Reported
	Inexium//Esomeprazole Magnesium			S	Oral	20 Mg, Qd		Not Reported
	Lasilix			S	Oral	20 Mg, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Atarax			S	Oral	100 Mg, Qd		Not Reported
	Heparine			S	Intravenous (not otherwise specified)	170 Mg, Daily		Not Reported
	Umuline			S	Subcutaneous	Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2013	9610924	EXPEDITED (15-DAY)		OT	DE-FRI-1000049831			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Escitalopram			S	Oral	1 Df		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2013	9610960	EXPEDITED (15-DAY)		HO, OT	BR-FRI-1000049833		25 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hypothermia; Somnolence; Syncope; Tremor	Lexapro			S	Oral	5 Mg		Forest
	Diazepam			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2013	9614750	DIRECT					44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Affective Disorder; Anxiety; Gastrointestinal Disorder; Nausea; Night Sweats; Poor Quality Sleep; Product Substitution Issue; Vertigo	Escitalopram			S	Oral	1 Pill Once Daily Taken By Mouth		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2013	9617795	EXPEDITED (15-DAY)	Y	OT	IT-MACLEODS PHARMA-000143			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Low Birth Weight Baby; Maternal Drugs Affecting Foetus	Escitalopram (Escitalopram)			S	Transplacental			Macleods
	Alprazolam (Alprazolam)			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2013	7943324	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-624758		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Bevacizumab			S	Intravenous (not otherwise specified)	Form: Vial. Total Dose: 960 Mg. Date Of Last		Not Reported

			Dose Prior To Sae: 18 March 2009.	
Trastuzumab	S	Intravenous (not otherwise specified)	Form: Vial. Total Dose: 512 Mg. Date Of Last Dose Prior To Sae: 18 March 2009. Loading Dose.	Not Reported
Trastuzumab	S	Intravenous (not otherwise specified)		Not Reported
Docetaxel	S	Intravenous (not otherwise specified)	Form: Vial. Total Dose: 126.8 Mg. Date Of Last Dose Prior To Sae: 18 March 2009.	Not Reported
Docetaxel	S	Intravenous (not otherwise specified)		Not Reported
Carboplatin	S	Intravenous (not otherwise specified)	Dose: 6 Auc. Form:Vial. Total Dose: 852 Mg.Date Of Last Dose Prior To Sae:18 Mar 09.	Not Reported
Carboplatin	S	Intravenous (not otherwise specified)		Not Reported
Tylenol	S	Unknown		Not Reported
Morphine	S	Unknown	Frequency: Q 4 Hrs Prn	Not Reported
Cipralex	S	Unknown		Not Reported
Ciprofloxacin	S	Oral		Not Reported
Ammonium Chloride	C			Not Reported
Ceftazidime	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported
Trazodone	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Docusate	C	Unknown	Dose: 2 To 6	Not Reported
Senna	C	Unknown	Dose: 2to 6	Not Reported
Lactulose	C	Unknown	Dose: 15 To 30 Ml	Not Reported
Mouthwash Nos	C	Unknown	Drug Name: Cci Mouth	Not Reported

						Wash. Dosage: 30 Cc				
	Gravol			C	Unknown					Not Reported
	Codeine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2013	9537938	EXPEDITED (15-DAY)		OT	FR-FRI-1000048966		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemarthrosis; Haematoma; Inflammatory Marker Increased; International Normalised Ratio Increased; Oedema; Synovitis	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Previscan (Fluindione)			S	Oral	3 Or 4 Df Daily		Not Reported
	Previscan (Fluindione)			S				Not Reported
	Previscan (Fluindione)			S				Not Reported
	Solupred (Prednisolone)			S	Oral			Not Reported
	Sotalex			C		80 Mg		Not Reported
	Aldactone			C				Not Reported
	Sinemet			C	Oral	8 Df		Not Reported
	Modopar			C	Oral	1 Df		Not Reported
	Alprazolam			C	Oral	0.50 Mg		Not Reported
	Doliprane			C		4 Df		Not Reported
	Mianserin			C				Not Reported
	Zolpidem			C				Not Reported
	Aprovel			C				Not Reported
	Finasteride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2013	9611460	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2013SE73220		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Rash Maculo-Papular; Skin Exfoliation	Inexium			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported

	Contramal	S	Oral	Not Reported
	Lasilix	S	Oral	Not Reported
	Atarax	S	Oral	Not Reported
	Heparine Sodique	S	Intravenous (not otherwise specified)	Not Reported
	Loxen (Nicardipine Hydrochloride)	S	Oral	Not Reported
	Umuline	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2013	9612005	EXPEDITED (15-DAY)		HO	NO-FRI-1000049868		46 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Economic Problem; Mania	Escitalopram			S		10 Mg Daily, Dose Decreased /Jan/2013 And Discontinued /Feb/2013		Forest
	Remeron-S			S		0.25 Mg		Not Reported
	Remeron			S		15 Mg		Not Reported
	Remeron			S				Not Reported
	Triobe			C		1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2013	9612117	NON-EXPEDITED			US-ASTELLAS-2013US009593			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction	Myrbetriq			S	Oral	25 Mg, Unknown/D		Astellas
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2013	9432546	EXPEDITED (15-DAY)		HO	PHHY2013FR080067		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis Cholestatic; Jaundice; Pruritus	Eucreas		S	Oral	Unk Ukn, Bid	Not Reported
	Voltarene Lp		S	Oral	100 Mg	Novartis
	Voltarene Emulgel		S			Not Reported
	Diamicron		S	Oral	60 Mg, Bid	Not Reported
	Coaprovel		S	Oral	1 Df (300 Mg Irbe And 12.5 Mg Hydrochloro), Qd	Not Reported
	Amlor		S	Oral	10 Mg, Qd	Not Reported
	Tahor		S	Oral	20 Mg, Qd	Not Reported
	Levothyrox		S	Oral	125 Ug, Qd	Not Reported
	Levothyrox		S	Oral	100 Ug, Qd	Not Reported
	Seroplex		S	Oral	10 Mg, Qd	Not Reported
	Ixprim		S	Oral	10 Mg, Qd	Not Reported
	Doliprane		S	Oral	Unk Ukn, Unk	Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)		S		Unk Ukn, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2013	9454847	EXPEDITED (15-DAY)		HO	JP-MERCK-1308JPN003890		59 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinson'S Disease	Reflex			S	Oral	30mg Daily		Merck
	Reflex			S	Oral	15mg Daily		Merck
	Reflex			S	Oral	30mg Daily		Merck
	Remeron			S	Oral	Unk		Merck
	Lexapro			S	Oral	10 Mg Daily Dose		Not Reported
	Lexapro			S	Oral	5 Mg Daily Dose		Not Reported
	Lexapro			S	Oral	10 Mg Daily Dose		Not Reported
	Flunitrazepam			C	Oral	1mg		Not Reported
	Flunitrazepam			C				Not Reported
	Zolpidem Tartrate			C	Oral	10 Mg		Not Reported

Zolpidem Tartrate	C				Not Reported
Eszopiclone	C	Oral	3mg		Not Reported
Eszopiclone	C				Not Reported
Rabeprazole Sodium	C	Oral	10mg		Not Reported
Etizolam	C	Oral	0.5 Mg		Not Reported
Etizolam	C				Not Reported
Hydroxyzine	C	Oral	50mg		Not Reported
Hydroxyzine	C				Not Reported
Metformin Hydrochloride	C	Oral	750ng		Not Reported
Mosapride Citrate	C	Oral	15mg		Not Reported
Mecobalamin	C	Oral	1500 Microgram		Not Reported
Pregabalin	C	Oral	300 Mg		Not Reported
Sennosides	C	Oral	1.0g		Not Reported
Doxazosin Mesylate	C	Oral	4mg		Not Reported
Doxazosin Mesylate	C	Oral	2mg		Not Reported
Azilsartan	C	Oral	20mg		Not Reported
Dorzolamide Hydrochloride	C	Intraocular	3 Drops		Merck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2013	9474675	EXPEDITED (15-DAY)		HO	IT-FRI-1000048021		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oral Solution			S	Oral	Overdose: 300 Mg		Forest
	Lexotan			S	Oral	Overdose: 30 Mg		Not Reported
	Tavor (Lorazepam)			S	Oral	Overdose: 25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2013	9614662	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20131000223		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Fall	Risperdaloro			S	Oral			Not Reported

	Risperdaloro	S	Oral	Not Reported
	Risperdaloro	S	Oral	Not Reported
	Depakote	S	Oral	Not Reported
	Depakote	S	Oral	Not Reported
	Depakote	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Kardegic	C	Unknown	Not Reported
	Sotalex	C	Unknown	Not Reported
	Coversyl	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Azopt	C	Unknown	Not Reported
	Dafalgan	C	Unknown	Not Reported
	Pariet	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2013	9617225	DIRECT		DS			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Erectile Dysfunction; Genital Paraesthesia; Hypoaesthesia; Libido Decreased; Memory Impairment	Lexapro			S	Oral	1 Pill, Once Daily, Taken By Mouth	8 YR	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2013	9617774	EXPEDITED (15-DAY)		HO	FR-FRI-1000049926		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Rash Maculo-Papular; Skin Exfoliation	Escitalopram			S	Oral	10 Mg		Forest
	Contramal			S	Oral	150 Mg		Not Reported

	Inexium	S	Oral	20 Mg		Not Reported
	Lasilix	S	Oral	20 Mg		Not Reported
	Atarax	S	Oral	100 Mg		Not Reported
	Heparine Sodique	S	Intravenous (not otherwise specified)	170 Mg		Not Reported
	Loxen (Nicardipine Hydrochloride)	S	Oral	60 Mg		Not Reported
	Paracetamol	S	Oral	3 Gram		Not Reported
	Umuline	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2013	9618668	NON-EXPEDITED			US-PFIZER INC-2013293171		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Citalopram			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2013	9619548	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2013290004		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Disorder; Hypotension; Hypotonia; Left Ventricular Dysfunction; Overdose; Sinoatrial Block; Somnolence; Toxicity To Various Agents	Xanax			S	Oral	12 Mg, Single		Pfizer
	Theralene			S	Oral	135 Mg, Single		Not Reported
	Risperdal			S	Oral	20 Mg, Single		Not Reported
	Seroplex			S	Oral	420 Mg, Single		Not Reported
	Imovane			S	Oral	22.5 Mg, Single		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2013	9619765	EXPEDITED (15-DAY)		OT	FI-TEVA-2010R0503588			Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acute Sinusitis; Adjustment Disorder With Mixed Anxiety And Depressed Mood; Aggression; Anxiety; Blood Cholesterol Increased; Blood Glucose Increased; Confusional State; Depression; Dizziness; Drug Interaction; Dyspnoea; Erythema; Euphoric Mood; Fatigue; Fear; Feeling Abnormal; Hallucination; Hepatic Steatosis; Hypersensitivity; Hyposmia; Hypothyroidism; Increased Appetite; Infection; Influenza; Irritability; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Medication Error; Memory Impairment; Mood Swings; Musculoskeletal Discomfort; Nausea; Nightmare; Overweight; Palpitations; Panic Reaction; Personality Change; Restlessness; Sense Of Oppression; Sleep Disorder; Swelling; Tinnitus; Upper	Amoxin			S	Oral			Teva
	Amoxin			S				Teva
	Champix			S	Oral	.5 Milligram Daily;		Not Reported
	Champix			S	Oral	1 Milligram Daily;		Not Reported
	Champix			S	Oral	2 Milligram Daily;		Not Reported
	Nicorette Gum			S	Oral	2 Milligram Daily;		Not Reported
	Rinexin			S	Oral	50 Milligram Daily;		Not Reported
	Nicorette Patch			S	Transdermal			Not Reported
	Sertralin Orion			S	Oral	25 Milligram Daily;		Not Reported
	Cipralex			S				Not Reported
	Azithromycin			C				Not Reported
	Doximycin			C				Not Reported
	Klacid			C				Not Reported
	Havrix			C				Not Reported
	Toclase			C				Not Reported

Respiratory Tract Infection; Vasodilatation; Vertigo; Weight Increased; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2013	9619951	NON-EXPEDITED			US-PFIZER INC-2013292748			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Diarrhoea; Insomnia	Xanax			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2013	9535018	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2013264690		35 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash Generalised	Lyrica			S	Oral	25 Mg, 2x/Day		Pfizer
	Bactrim			S	Oral	2 G, 3x/Day		Not Reported
	Bactrim			S	Oral	800 Mg, Daily		Not Reported
	Seroplex			S	Oral	5 Mg, Daily		Not Reported
	Loxapac			S	Oral	25 Mg, Daily		Not Reported
	Truvada			C		Unk		Not Reported
	Prezista			C		Unk		Not Reported
	Norvir			C		Unk		Not Reported
	Rovalcyte			C				Not Reported
	Xanax			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2013	9625119	DIRECT	Y				30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Abdominal Pain Upper	Escitalopram 10 Mg	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2013	9626164	DIRECT					57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral	3 Pills Once Daily Taken By Mouth		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2013	9468437	EXPEDITED (15-DAY)		DE	IE-PFIZER INC-2013241955		65 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Product Use In Unapproved Indication	Lyrica			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2013	9627143	EXPEDITED (15-DAY)		HO	FR-FRI-1000049994		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Withdrawal Syndrome	Escitalopram			S	Oral	1 Df		Forest
	Hydrochlorothiazide\Valsartan			C				Not Reported
	Vastarel			C				Not Reported
	Kardegic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2013	9627965	EXPEDITED (15-DAY)		OT	PHHY2013AU113251			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Hypernatraemia; Partial Seizures; Sedation;	Valproic Acid			S				Novartis
	Escitalopram			S				Not Reported

Seizure	Quetiapine	S	Unk Ukn, Unk	Not Reported
	Quetiapine	S	Unk (Dose Increased)	Not Reported
	Mirtazapine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2013	9630616	DIRECT					64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dry Mouth; Electrolyte Imbalance; Hypertension; Paraesthesia; Syncope	Escitalopram			S	Oral	1 Dose		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2013	9442231	EXPEDITED (15-DAY)		HO	FR-FRI-1000047499		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic; Jaundice; Pruritus	Escitalopram			S	Oral	10 Mg		Forest
	Diamicron			S	Oral	120 Mg		Not Reported
	Eucreas			S	Oral	2 Df		Not Reported
	Coaprovel			S	Oral	300/12.5 Mg		Not Reported
	Amlor			S	Oral	1 Df		Not Reported
	Tahor			S	Oral	1 Df		Not Reported
	Levothyrox			S	Oral	125 Mcg		Not Reported
	Ixprim			S	Oral			Not Reported
	Doliprane			S	Oral			Not Reported
	Voltarene (Diclofenac Sodium)			S	Cutaneous			Not Reported
	Voltarene Lp			S	Oral			Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2013	9628526	EXPEDITED (15-DAY)		OT	US-ACCORD-019927		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Decreased Appetite; Depression; Disturbance In Attention; Drug Ineffective; Insomnia; Memory Impairment; Off Label Use; Suicidal Ideation; Weight Decreased	Topiramate			S				Accord
	Escitalopram			S				Accord
	Flunarizine			S	Oral			Not Reported
	Valproate			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2013	9628535	EXPEDITED (15-DAY)		OT	MX-SHIRE-ALL1-2013-06948			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Blinded 489 (Lisdexamfetamine Dimesylate)			S	Oral	Unk, 1x/Day:Qd		Shire
	Blinded Duloxetine Hydrochloride			S	Oral	Unk, 1x/Day:Qd		Shire
	Blinded Escitalopram Oxalate			S	Oral	Unk, 1x/Day:Qd		Shire
	Blinded Placebo			S	Oral	Unk, 1x/Day:Qd		Shire
	Blinded Sertraline Hydrochloride			S	Oral	Unk, 1x/Day:Qd		Shire
	Blinded Venlafaxine Hydrochloride			S	Oral	Unk, 1x/Day:Qd		Shire
	Duloxetine Hydrochloride			S	Oral	90 Mg, 2x/Day:Bid		Unknown
	Duloxetine Hydrochloride			S	Oral	60 Mg, 2x/Day:Bid		Unknown
	Ketorolac			C	Unknown	Unk, Unknown		Not Reported
	Neo Melubrina			C	Unknown	Unk, Unknown		Not Reported
	Neo Melubrina			C	Unknown	Unk, Unknown		Not Reported
	Neo Melubrina			C	Unknown	Unk, Unknown		Not Reported

Neo Melubrina	C	Unknown	Unk, Unknown		Not Reported
Neo Melubrina	C	Unknown	Unk, Unknown		Not Reported
Neo Melubrina	C	Unknown	Unk, Unknown		Not Reported
Neo Melubrina	C	Unknown	Unk, Unknown		Not Reported
Neo Melubrina	C	Unknown	Unk, Unknown		Not Reported
Neo Melubrina	C	Unknown	Unk Unk, Unknown		Not Reported
Neo Melubrina	C	Unknown	Unk, Unknown		Not Reported
Paracetamol	C	Unknown	Unk, Unknown		Not Reported
Nepafenac	C	Unknown	Unk, Unknown		Not Reported
Timolol	C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2013	9628756	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2013S1022622			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypernatraemia; Partial Seizures; Sedation	Escitalopram			S	Unknown			Not Reported
	Quetiapine			S	Unknown	Increasing Doses		Not Reported
	Sodium Valproate			S	Unknown			Mylan
	Mirtazapine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2013	9629933	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013293820		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Large Intestinal Haemorrhage; Off Label Use	Advil			S		Unk, As Needed		Pfizer
	Advil			S				Pfizer
	Lexapro			S		10 Mg, 1x/Day		Not Reported
	Synthroid			C		0.125 Mg, 2x/Day		Not Reported
	Benicar			C		40 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2013	9630999	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2013-08394		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Dysstasia; Initial Insomnia; Restlessness	Quetiapine			S				Not Reported
	Asenapine			S	Sublingual	10 Mg (5 Mg, 2 In 1 D)		Not Reported
	Aripiprazole			S				Not Reported
	Clonazepam			S				Not Reported
	Buspirone			S				Not Reported
	Lexapro (Escitalopram Oxalate)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2013	9633799	EXPEDITED (15-DAY)	Y	DE	2013AP008644		66 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Lithium Carbonate Capsules			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Methylphenidate			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Simvastatin			S	Oral			Not Reported
	Valaciclovir			S	Oral			Not Reported
	Propoxyphene			S	Oral			Not Reported
	Hydrocodone			S	Oral			Not Reported
	Triazolam			S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2013	8898735	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2012278694		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Dyspnoea; Respiratory Depression; Somnolence	Atenolol		S	Oral	50 Mg, Daily	Pfizer
	Escitalopram Oxalate		S		20 Mg, Daily	Not Reported
	Seroquel		S	Oral	400 Mg, 2x/Day	Not Reported
	Lormetazepam		S	Oral	2 Mg, Daily	Not Reported
	Artane		S	Oral	2 Mg, Daily	Not Reported
	Hidrosaluretil		C	Oral	25 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2013	9447463	EXPEDITED (15-DAY)	Y	HO	7226731		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cell Death; Headache; Hepatitis Cholestatic; Hepatotoxicity; Neck Pain; Self-Medication	Levothyrox			S	Oral	1 In 1 D		Not Reported
	Daimicron			S	Oral	2 Df In 1 D		Not Reported
	Eucreas			S	Oral	2 In 1 D		Not Reported
	Coaprovel			S	Oral			Not Reported
	Amlor			S	Oral			Not Reported
	Tahor			S	Oral			Not Reported
	Seroplex			S	Oral		4 MTH	Not Reported
	Ixprim			S	Oral			Not Reported
	Doliprane			S	Oral			Not Reported
	Voltarene (Diclofenac Sodium)			S		Cutaneous		Not Reported
	Voltarene (Diclofenac Sodium)			S	Oral			Not Reported
	Lamaline (Acetaminophen\Belladonna Leaf\Caffeine\Opium)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2013	9449735	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20130801355		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis Cholestatic; Jaundice; Overdose; Pruritus	Ixprim	S	Oral	Not Reported
	Diamicron	S	Oral	Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)	S	Oral	Not Reported
	Voltarene (Diclofenac Sodium)	S	Cutaneous	Not Reported
	Doliprane	S	Oral	Not Reported
	Coaprovel	S	Oral	Not Reported
	Amlor	S	Oral	Not Reported
	Tahor	S	Oral	Not Reported
	Levothyrox	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Voltarene (Diclofenac Sodium)	S	Oral	Not Reported
	Eucreas	S	Oral	Not Reported
	Tramadol	C	Unknown	Not Reported
	Humalog	C	Subcutaneous	Not Reported
	Questran	C	Oral	Not Reported
	Lantus	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2013	9631400	EXPEDITED (15-DAY)		DS	FR-FRI-1000050139			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Psychomotor Retardation	Escitalopram			S	Transplacental	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2013	9631604	NON-EXPEDITED			US-PFIZER INC-2013297318		96 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Drug Ineffective; Product Use In Unapproved Indication	Gabapentin		S	3x/Day, 300mg In Morning And Afternoon And 600mg At Night	Pfizer
	Effexor		S	75 Mg, Daily	Pfizer
	Effexor		S	150 Mg, Daily	Pfizer
	Effexor		S		Pfizer
	Lexapro		S	30 Mg, 1x/Day	Not Reported
	Maxalt		C	2.5 Mg, As Needed	Not Reported
	Lorazepam		C	1 Mg, As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2013	9632905	EXPEDITED (15-DAY)		HO	NO-FRI-1000050216		80 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Escitalopram			S		5 Mg		Forest
	Heminevrin			C		300 Mg		Not Reported
	Paracetamol			C	Oral	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2013	9633231	DIRECT					23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Headache; Insomnia; Panic Attack; Product Substitution Issue	Escitalopram			S	Oral	1 Pill		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2013	9633467	DIRECT		OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Withdrawal Syndrome;	Escitalopram			S	Oral			Mylan

Product Substitution Issue	Lexpro	C		Not Reported
	Albuterol Inhaler	C		Not Reported
	Lamictal	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2013	9633132	EXPEDITED (15-DAY)		HO	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-BI-33		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyponatraemia	Telmisartan + Hydrochlorothiazide			S	Oral	Daily Dose: 80/12.5 1 Df		Boehringer Ingelheim
	Lasilix			S	Oral	20 Mg		Not Reported
	Seroplex			S	Oral	5 Mg		Not Reported
	Minisintrom (Acenocoumarol)			C				Not Reported
	Ikorel (Nicorandil)			C				Not Reported
	Temerit (Nebivolol)			C				Not Reported
	Kaleorid (Potassium Chloride)			C				Not Reported
	Monuril (Fosfomycin Trometamol)			C				Not Reported
	Pentasa (Mesalazine)			C				Not Reported
	Requip (Ropinirole Hydrochloride)			C				Not Reported
	Oroken			C				Not Reported
	Lactulose (Lactulose)			C				Not Reported
	Dafalgan (Paracetamol)			C				Not Reported
	Lactulose (Lactulose)			C				Not Reported
	Aerius (Desloratadine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2013	9633434	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMPANY-FR201310001888		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Rash Maculo-Papular; Skin Exfoliation	Umuline			S	Subcutaneous	Unk		Eli Lilly And Co
	Contramal			S	Oral	50 Mg, Tid		Not Reported

	Inexium		S	Oral	20 Mg, Qd	Not Reported
	Lasilix		S	Oral	20 Mg, Qd	Not Reported
	Seroplex		S	Oral	10 Mg, Qd	Not Reported
	Atarax		S	Oral	100 Mg, Qd	Not Reported
	Heparina Sodica		S	Intravenous (not otherwise specified)	170 Mg, Qd	Not Reported
	Loxen (Nicardipine Hydrochloride)		S	Oral	20 Mg, Tid	Not Reported
	Paracetamol		S	Oral	1 G, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2013	9634326	EXPEDITED (15-DAY)		HO, LT	FR-JNJFOC-20131006399		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Hypotension; Hypotonia; Intentional Overdose; Somnolence	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	20 Tablets		Not Reported
	Theralene			S	Oral			Not Reported
	Theralene			S	Oral	27 Tablets		Not Reported
	Xanax			S	Oral	24 Tablets		Not Reported
	Xanax			S	Oral			Not Reported
	Seroplex			S	Oral	28 Tablets		Not Reported
	Seroplex			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Imovane			S	Oral	3 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2013	9636395	EXPEDITED (15-DAY)		DE	FR-FRI-1000050323		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Level Above Therapeutic	Escitalopram			S	Oral	1 Df		Forest

	Droleptan	S	Intravenous (not otherwise specified)	1 Mg At 03:00 A.M.	Not Reported
	Dexamethasone	S	Intravenous (not otherwise specified)	4 Mg	Not Reported
	Myolastan	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2013	9636480	EXPEDITED (15-DAY)		OT	GB-MALLINCKRODT-T201103057		60 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Increased; Drug Resistance; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Pennsaid			S	Unknown	Unk		Tyco
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	3 In 1 Week		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Risperidone			S	Unknown	1 Mg, Qd		Not Reported
	Aspirin			S	Unknown	75 Mg, Unk		Not Reported
	Simvastin			S	Unknown	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2013	9637181	EXPEDITED (15-DAY)		OT	US-JNJFOC-20131009794			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arrhythmia; Drug Interaction; Electrocardiogram Qt Prolonged	Levaquin			S	Unknown			Not Reported
	Zofran			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2013	9640128	NON-EXPEDITED			US-PFIZER INC-2013297291		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Effexor	S	Unk		Pfizer
	Zoloft	S	Unk		Pfizer
	Naproxen Sodium	S	Unk		Pfizer
	Prozac	S	Unk		Not Reported
	Lexapro	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2013	9641653	EXPEDITED (15-DAY)		HO	US-TAKEDA-TPA2013A07609		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression	Blinded Escitalopram Oxalate			S	Oral	Unk, Qd		Takeda
	Blinded Vortioxetine			S	Oral	Unk, Qd		Takeda
	Blinded Escitalopram Oxalate			S	Oral	Unk, Qd		Takeda
	Blinded Vortioxetine			S	Oral	Unk, Qd		Takeda
	Pariet			C	Oral	20 Mg, Qd		Not Reported
	Apo-Quinine			C	Oral	200 Mg, Qd		Not Reported
	Telmisartan			C	Oral	12.5 Mg, Qd		Not Reported
	Cipralex			C	Oral	10 Mg, Prn		Not Reported
	Cipralex			C	Oral	20 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2013	9642053	EXPEDITED (15-DAY)		OT	CA-ROCHE-1290749		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis	Rivotril			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Omega-3			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2013	9643913	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2013-08673			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Convulsive Threshold Lowered; Hallucination, Visual; Hypernatraemia; Partial Seizures; Sedation	Quetiapine			S				Not Reported
	Mirtazapine			S				Not Reported
	Escitalopram			S				Not Reported
	Sodium Valproate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2013	8774328	NON-EXPEDITED			US-PFIZER INC-2012215878		43 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Neurontin			S	Oral	600 Mg, 3x/Day		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Phenytoin			S		Unk		Pfizer
	Fexofenadine Hydrochloride			S		Unk		Not Reported
	Flurbiprofen			S		Unk		Pfizer
	Ketoprofen			S		Unk		Pfizer
	Ketorolac Tromethamine			S		Unk		Pfizer
	Lodine			S		Unk		Pfizer
	Meclofenamate Sodium			S		Unk		Pfizer
	Meclomen			S		Unk		Not Reported
	Mefenamic Acid			S		Unk		Pfizer
	Methocarbamol			S		Unk		Pfizer
	Momentum			S		Unk		Pfizer
	Motrin			S		Unk		Not Reported

Nabumetone		S	Unk	Pfizer
Naproxen Sodium		S	Unk	Pfizer
Omnicef		S	Unk	Pfizer
Ponstel		S	Unk	Pfizer
Pravastatin Sodium		S	Unk	Not Reported
Effexor Xr		S	Unk	Pfizer
Valerian Root		S	Unk	Unknown
Advil		S	Unk	Pfizer
Anacin		S	Unk	Pfizer
Ansaid		S	Unk	Pfizer
Celebrex		S	Unk	Pfizer
Diclofenac		S	Unk	Pfizer
Dimetapp Sinus		S	Unk	Pfizer
Cefadroxil		S	Unk	Not Reported
Dristan	Y	S	Unk	Pfizer
Daypro		S	Unk	Pfizer
Ceclor		S	Unk	Not Reported
Keflex		S	Unk	Not Reported
Aspirin		S	Unk	Not Reported
Lexapro		S	Unk	Not Reported
Augmentin		S	Unk	Not Reported
Quinidine		S	Unk	Not Reported
Pravachol		S	Unk	Not Reported
Tizanidine		S	Unk	Not Reported
Zanaflex		S	Unk	Not Reported
Cymbalta		S	Unk	Not Reported
Allegra		S	Unk	Not Reported
Maxzide		C	Unk	Not Reported
Acular		S	Unk	Not Reported

Aleve	S	Unk	Not Reported
Alka-Seltzer	S	Unk	Not Reported
Anaprox	S	Unk	Not Reported
Ascriptin	S	Unk	Not Reported
Aspirin "Bayer"	S	Unk	Not Reported
Bufferin	S	Unk	Not Reported
Cama	S	Unk	Not Reported
Cataflam	S	Unk	Not Reported
Cefaclor	S	Unk	Not Reported
Cephalexin	S	Unk	Not Reported
Feldine	S	Unk	Not Reported
Fenoprofen	S	Unk	Not Reported
Fiorinal	S	Unk	Not Reported
Haltran	S	Unk	Not Reported
Ibuprin	S	Unk	Not Reported
Indocin	S	Unk	Not Reported
Indomethacin	S	Unk	Not Reported
Medipren	S	Unk	Not Reported
Moxatag	S	Unk	Not Reported
Nalfon	S	Unk	Not Reported
Naprelan	S	Unk	Not Reported
Naprosyn	S	Unk	Not Reported
Naproxen	S	Unk	Not Reported
Norflex	S	Unk	Not Reported
Norgesic	S	Unk	Not Reported
Nuprin	S	Unk	Not Reported
Ocufen	S	Unk	Not Reported
Orphenadrine	S	Unk	Not Reported
Orudis	S	Unk	Not Reported

Oruvail	S	Unk	Not Reported
Pamprin	S	Unk	Not Reported
Pepto-Bismol	S	Unk	Not Reported
Percodan	S	Unk	Not Reported
Principen	S	Unk	Not Reported
Profenal	S	Unk	Not Reported
Propoxyphene	S	Unk	Not Reported
Equagesic	S	Unk	Not Reported
Ecotrin	S	Unk	Not Reported
Empirin	S	Unk	Not Reported
Clinoril	S	Unk	Not Reported
Ceftin	S	Unk	Not Reported
Aggrenox	S	Unk	Not Reported
Combunox	S	Unk	Not Reported
Congespirin	S	Unk	Not Reported
Darvon	S	Unk	Not Reported
Duloxetine	S	Unk	Not Reported
Nexium	C	Unk	Not Reported
Ventolin	C	Unk	Not Reported
Loratadine	C	Unk	Not Reported
Maxalt	C	Unk	Not Reported
Trazodone	C	Unk	Not Reported
Omeprazole	C	Unk	Not Reported
Advair	C	Unk	Not Reported
Fluoxetine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2013	9086045	EXPEDITED (15-DAY)		CA, OT	US-FRI-1000042156		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Hypoplastic Left Heart Syndrome; Patent Ductus Arteriosus; Pulmonary Hypertension; Ventricular Septal Defect	Lexapro	S	Transplacental		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2013	9524482	NON-EXPEDITED			US-PFIZER INC-2013265665		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective For Unapproved Indication; Drug Interaction; Fatigue; Gait Disturbance; Product Use In Unapproved Indication; Somnolence	Lyrica			S		Unknown Dose, 1x/Day		Pfizer
	Lyrica			S				Pfizer
	Lexapro			S		10 Mg, 1x/Day		Not Reported
	Dicyclomine			C		10 Mg, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2013	9642974	EXPEDITED (15-DAY)		HO	FR-SA-2013SA104942		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hepatocellular Injury; Hyperphosphataemia; Intentional Overdose; Lactic Acidosis	Paracetamol			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2013	9643034	EXPEDITED (15-DAY)		DE, OT	AT-JNJFOC-20131008865		24 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide;	Risperdal			S	Unknown			Not Reported

Hyperprolactinaemia; Hypophysitis	Risperdal	S	Unknown	Not Reported
	Risperdal	S	Unknown	Not Reported
	Risperdal	S	Unknown	Not Reported
	Risperdal	S	Unknown	Not Reported
	Risperdal	S	Unknown	Not Reported
	Risperdal	S	Unknown	Not Reported
	Risperdal	S	Unknown	Not Reported
	Risperdal	S	Unknown	Not Reported
	Zyprexa	S	Unknown	Not Reported
	Zyprexa	S	Unknown	Not Reported
	Zyprexa	S	Unknown	Not Reported
	Zyprexa	S	Unknown	Not Reported
	Temesta (Lorazepam)	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Temesta	S	Unknown	Not Reported
	Cipralex	S	Unknown	Not Reported
	Cipralex	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2013	9644221	EXPEDITED (15-DAY)		HO	CA-ROCHE-1292120		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Dizziness; Intentional Overdose; Prescribed Overdose; Suicide Attempt	Rivotril			S	Oral	Therapy Duration: 1.0 Days		Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral	Therapy Duration: 4.0 Months		Not Reported
	Ethanol			S	Oral	Therapy Duration: 1.0 Days		Not Reported
	Wellbutrin Sr			S	Oral	Therapy Duration: 4.0 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2013	9820228	NON-EXPEDITED	Y	HO, LT	2013-01691		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt; Toxicity To Various Agents	Quetiapine			S				Not Reported
	Escitalopram (Unknown)			S				Not Reported
	Ibuprofen (Unknown)			S				Not Reported
	Amoxicillin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2013	9517196	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC-2013255250		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Solu-Medrol			S	Intravenous (not otherwise specified)	140 Mg, 1x/Day		Pfizer
	Atarax			S	Oral	50 Mg, 1x/Day		Pfizer
	Fortum			S	Intravenous (not otherwise specified)	1 G, 4x/Day		Not Reported

Flagyl	S	Oral	500 Mg, 3x/Day	Not Reported
Gentamycin Pnapharma	S	Intravenous (not otherwise specified)	210 Mg, 1x/Day	Not Reported
Noxafil	S	Oral	200 Mg, 3x/Day	Not Reported
Cancidas	S	Intravenous (not otherwise specified)	Unk	Not Reported
Ambisome	S	Intravenous (not otherwise specified)	180 Mg, 1x/Day	Not Reported
Bactrim	S	Intravenous (not otherwise specified)	2 Df, 3 Times In Week	Not Reported
Folinic Acid	S	Intravenous (not otherwise specified)	50 Mg, 3 Times In Week	Not Reported
Zelitrex	S	Intravenous (not otherwise specified)	500 Mg, 2x/Day	Not Reported
Cymevene	S	Intravenous (not otherwise specified)	350 Mg, 2x/Day	Not Reported
Foscavir	S	Intravenous (not otherwise specified)	1 Df, 2x/Day	Not Reported
Clairyg	S	Intravenous (not otherwise specified)	Unk	Not Reported
Granocyte	S	Intravenous (not otherwise specified)	Unk	Not Reported
Heparin Sodium	S	Intravenous (not otherwise specified)	7000 Iu, 1x/Day	Not Reported
Inexium	S	Intravenous (not otherwise specified)	40 Mg, 1x/Day	Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	S	Intravenous (not otherwise specified)	2 Df, 3x/Day	Not Reported
Delursan	S	Oral	3 Df, 2x/Day	Not Reported
Defibrotide	S	Intravenous (not otherwise specified)	25 Mg/Kg, 1x/Day	Not Reported
Largactil	S	Intravenous (not otherwise specified)	1 Df, 1x/Day	Not Reported
Largactil	S	Intravenous (not	1 Df, 1x/Day	Not Reported

		otherwise specified)		
Tranxene	S	Oral	5 Mg, As Needed (1df 4)	Not Reported
Oxynorm	S	Intravenous (not otherwise specified)	Unk	Not Reported
Exacyl	S	Intravenous (not otherwise specified)	1 Df, 3x/Day	Not Reported
Perfalgan	S	Intravenous (not otherwise specified)	1 G, 3x/Day	Not Reported
Droleptan	S	Intravenous (not otherwise specified)	0.625 Mg, 4x/Day	Not Reported
Ultiva	S	Intravenous (not otherwise specified)	100 Gbq , 1 In 1 Hour	Not Reported
Lasilix	S	Intravenous (not otherwise specified)	40 Mg, 2x/Day	Not Reported
Seroplex	S	Oral	10 Mg, 1x/Day	Not Reported
Ceris	S	Oral	20 Mg, 2x/Day	Not Reported
Noctamide	S	Oral	2 Mg, 1x/Day	Not Reported
Noctamide	S	Oral	Scored Tablet, 1x/Day	Not Reported
Gentamycin	C		2 Df, 3x/Day	Not Reported
Colistimethate Sodium	C		2 Df, 3x/Day	Not Reported
Vancomycin Mylan	C		1 G, 1x/Day	Not Reported
Ciflox	C		400 Mg, 2x/Day	Not Reported
Targocid	C		400 Mg, 2x/Day	Not Reported
Mycostatine	C		2 Df, 1x/Day (Vials)	Not Reported
Triflucan	C		200 Mg, 1x/Day	Not Reported
Zovirax	C		250 Mg, 3x/Day	Not Reported
Methotrexate Mylan	C		18 Mg, 1x/Day	Not Reported
Elvorine	C		18.4 Mg, 1x/Day	Not Reported
Sandimmun	C		210 Mg, 1x/Day	Not Reported
Mopral	C		20 Mg, 1x/Day	Not Reported
Ogastro	C		30 Mg, 1x/Day	Not Reported

	Gelox	C	1 Df, 3x/Day	Not Reported
	Smecta	C	6 Bags/Day	Not Reported
	Luteran	C	Unk, One A Day	Not Reported
	Lexomil	C	0.5 Df, 1x/Day	Not Reported
	Zophren	C	2 Df, 1x/Day (Vials)	Not Reported
	Primperan	C	6 Df, 1x/Day (Vials)	Not Reported
	Acupan	C	6 Df, As Needed (Vials)	Not Reported
	Tiorfan	C	Unk	Not Reported
	Levocarnil	C	1 G, 3x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2013	9519934	EXPEDITED (15-DAY)		DE, HO, LT	FR-ASTRAZENECA-2013SE67508		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; General Physical Health Deterioration; Hepatitis Fulminant; Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis	Inexium			S	Intravenous (not otherwise specified)			Not Reported
	Seroplex			S	Oral			Not Reported
	Perfalgan			S	Intravenous (not otherwise specified)			Not Reported
	Ultiva			S	Intravenous (not otherwise specified)	2400 Gbq (100 Gbq Per Hour)		Not Reported
	Fortum			S	Intravenous (not otherwise specified)			Not Reported
	Flagyl			S	Oral			Not Reported
	Gentamicine Panpharma			S	Intravenous (not otherwise specified)			Not Reported
	Noxafil			S	Oral			Not Reported
	Cancidas			S	Intravenous (not otherwise specified)			Not Reported
	Ambisome			S	Intravenous (not otherwise specified)			Not Reported

Bactrim	S	Intravenous (not otherwise specified)		Not Reported
Acide Folinique	S	Intravenous (not otherwise specified)		Not Reported
Zelitrex	S	Intravenous (not otherwise specified)		Not Reported
Cymevene	S	Intravenous (not otherwise specified)		Not Reported
Foscavir	S	Intravenous (not otherwise specified)	6g/250ml, 1 Df Two Times A Day	Not Reported
Clairyg	S	Intravenous (not otherwise specified)		Not Reported
Granocyte	S	Intravenous (not otherwise specified)		Not Reported
Heparine Sodique	S	Intravenous (not otherwise specified)		Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	S	Intravenous (not otherwise specified)		Not Reported
Delursan	S	Oral		Not Reported
Defibrotide	S	Intravenous (not otherwise specified)	25 Mg/Kg Every Day	Not Reported
Largactil	S	Intravenous (not otherwise specified)		Not Reported
Tranxene	S	Oral	5 Mg Four Times A Day, On Demand	Not Reported
Oxynorm	S	Intravenous (not otherwise specified)		Not Reported
Exacyl	S	Intravenous (not otherwise specified)		Not Reported
Solumedrol	S	Intravenous (not otherwise specified)		Not Reported
Droleptan	S	Intravenous (not otherwise specified)		Not Reported
Atarax	S	Oral		Not Reported

Lasilix	S	Intravenous (not otherwise specified)		Not Reported
Ceris	S	Oral		Not Reported
Noctamide	S			Not Reported
Noctamide	S	Oral		Not Reported
Gentamicine + Colistine	C			Not Reported
Vancomycine Mylan	C			Not Reported
Ciflox	C			Not Reported
Targocid	C			Not Reported
Mycostatine	C		2 Flasks A Day	Not Reported
Triflucan	C			Not Reported
Zovirax	C			Not Reported
Methotrexate	C			Not Reported
Methotrexate	C		Mylan	Not Reported
Elvorine	C			Not Reported
Sandimmun	C			Not Reported
Mopral	C			Not Reported
Ogastoro	C			Not Reported
Gelox	C		1 Sachet Three Times A Day	Not Reported
Smecta	C		6 Sachets Every Day	Not Reported
Luteran	C			Not Reported
Lexomil	C			Not Reported
Zophren	C		2 Bulbs Every Day	Not Reported
Primperan	C		6 Bulbs Every Day	Not Reported
Acupan	C		6 Amps Every Day, On Demand	Not Reported
Tiorfan	C			Not Reported
Levocarnil	C			Not Reported
Endoxan	C			Not Reported
Busulvex	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2013	9644782	NON-EXPEDITED			US-PFIZER INC-2013302115			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Myalgia	Zoloft		S	Oral	100 Mg, 1x/Day	Pfizer
	Lexapro		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2013	9645293	EXPEDITED (15-DAY)		OT	US-FRI-1000050414			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Gastrointestinal Haemorrhage; Intestinal Haemorrhage	Lexapro			S				Forest
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2013	9646481	EXPEDITED (15-DAY)	Y	HO	FR-ABBVIE-13P-056-1161789-00		1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Crying; Foetal Exposure During Pregnancy; Portal Vein Thrombosis; Restlessness; Tachycardia Foetal	Depakote			S	Transplacental			Not Reported
	Theralite			S	Transplacental			Not Reported
	Seroplex			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2013	9648351	DIRECT					41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Withdrawal Syndrome; Product Substitution Issue	Escitalopram			S	Oral	1 Pill Once Daily		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2013	9648460	DIRECT					45 YR	Male	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Disturbance In Attention; Premature Ageing	Lexapro			S	Oral	1 Pill Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2013	9649623	EXPEDITED (15-DAY)	Y	OT	2013P1020261		1 DAY	Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Escitalopram			S	Intra-uterine		40 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2013	9820314	NON-EXPEDITED	Y	DE	2103-00321		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Quetiapine (Unknown)			S				Not Reported
	Escitalopram (Unknown)			S				Not Reported
	Acetaminophen/Codeine (Unknown)			S				Not Reported
	Metaxalone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2013	9521172	EXPEDITED (15-DAY)		HO, OT	FR-MERCK-1309FRA002229		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Cancidas			S	Intravenous (not otherwise specified)	Unk		Merck
	Fortum			S		1 Df, Qid		Not Reported
	Flagyl			S	Oral	1 Df, Tid		Not Reported
	Gentamicin			S	Intravenous (not otherwise specified)	210 Mg, Qd		Not Reported

Noxafil	S	Oral	200 Mg, Tid	Merck
Ambisome	S	Intravenous (not otherwise specified)	180 Mg, Qd	Not Reported
Bactrim	S	Intravenous (not otherwise specified)	2 Df, Tiw	Not Reported
Folic Acid	S	Intravenous (not otherwise specified)	50 Mg, Tiw	Not Reported
Zelitrex	S	Intravenous (not otherwise specified)	500 Mg, Bid	Not Reported
Cymevan Iv	S	Intravenous (not otherwise specified)	350 Mg, Bid	Not Reported
Foscavir	S	Intravenous (not otherwise specified)	1 Df, Bid	Not Reported
Clairyg	S	Intravenous (not otherwise specified)	Unk	Not Reported
Granocyte	S	Intravenous (not otherwise specified)	Unk	Not Reported
Heparin Sodium	S	Intravenous (not otherwise specified)	7000 Iu, Qd	Not Reported
Inexium	S	Intravenous (not otherwise specified)	1 Df, Qd	Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	S	Intravenous (not otherwise specified)	2 Df, Tid	Not Reported
Delursan	S	Oral	3 Df, Bid	Not Reported
Defibrotide	S	Intravenous (not otherwise specified)	25 Mg/Kg, Qd	Not Reported
Largactil	S	Intravenous (not otherwise specified)	1 Df, Qd	Not Reported
Tranxene	S	Oral	4 Df, Prn	Not Reported
Oxynorm	S	Intravenous (not otherwise specified)	Unk	Not Reported
Exacyl	S	Intravenous (not otherwise specified)	1 Df, Tid	Not Reported
Perfalgan	S	Intravenous (not	1 G, Tid	Not Reported

		otherwise specified)		
Solu-Medrol	S	Intravenous (not otherwise specified)	140 Mg, Qd	Not Reported
Droleptan	S	Intravenous (not otherwise specified)	0.625 Mg, Qid	Not Reported
Ultiva	S	Intravenous (not otherwise specified)	100 Gbq, Qh	Not Reported
Atarax (Alprazolam)	S	Oral	0.5 Df, Qd	Not Reported
Lasilix	S	Intravenous (not otherwise specified)	40 Mg, Bid	Not Reported
Seroplex	S	Oral	10 Mg, Qd	Not Reported
Ceris	S	Oral	2 Df, Qd	Not Reported
Noctamide	S	Oral	1 Df, Qd	Not Reported
Gentamicin	C		2 Df, Tid	Not Reported
Colistin	C		2 Df, Tid	Not Reported
Vancomycin Mylan	C		1 G, Qd	Not Reported
Ciflox (Ciprofloxacin Hydrochloride)	C		400 Mg, Bid	Not Reported
Targocid	C		400 Mg, Bid	Not Reported
Mycostatine	C		2 Df, Qd	Not Reported
Triflucan	C		200 Mg, Qd	Not Reported
Zovirax	C		250 Mg, Tid	Not Reported
Methotrexate	C		18 Mg, Qd	Not Reported
Elvorine	C		18.4 Mg, Qd	Not Reported
Sandimmun	C		210 Mg, Qd	Not Reported
Mopral (Omeprazole Sodium)	C		20 Mg, Qd	Not Reported
Ogastoro	C		30 Mg, Qd	Not Reported
Gelox (Aluminum Hydroxide)	C		1 Df, Tid	Not Reported
Smecta	C		6 Df, Qd	Not Reported
Luteran	C		1 Df, Qd	Not Reported
Lexomil	C		0.5 Df, Qd	Not Reported

Noctamide	C	1 Df, Qd		Not Reported
Zophren (Ondansetron)	C	2 Df, Qd		Not Reported
Primperan	C	6 Df, Qd		Not Reported
Acupan	C	6 Df, Prn		Not Reported
Tiorfan	C	Unk		Not Reported
Levocarnil	C	1 G, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2013	9649275	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-B0932294A		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaemia; Cholelithiasis; Flatulence; Gastric Haemorrhage; Gastrointestinal Haemorrhage; Haematemesis; Inflammation; Nephrolithiasis	Arixtra			S	Subcutaneous			Glaxosmithkline
	Pradaxa			S	Oral	110mg See Dosage Text		Unknown
	Seroplex			S	Oral	1unit Per Day		Unknown
	Ebixa			C				Glaxosmithkline
	Ramipril			C				Glaxosmithkline
	Dafalgan			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2013	9649643	EXPEDITED (15-DAY)		HO	FR-FRI-1000050540		30 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Intentional Overdose; Irregular Breathing	Escitalopram			S	Oral	Overdose Of 84 Tablets		Forest
	Theralene			S	Oral	Overdose Of 75 Tablets		Not Reported
	Diazepam			S	Oral	Overdose Of 20 Tablets		Not Reported
	Actiskenan			S	Oral	Overdose Of 7 Capsules		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2013	9631448	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000050158		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Hypotonia; Intentional Overdose; Somnolence	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose Of 28 Tablets		Not Reported
	Theralene			S	Oral			Not Reported
	Theralene			S	Oral	Overdose Of 27 Tablets		Not Reported
	Xanax			S	Oral			Not Reported
	Xanax			S	Oral	Overdose Of 24 Tablets		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	Overdose Of 20 Tablets		Not Reported
	Imovane			S	Oral			Not Reported
	Imovane			S	Oral	Overdose Of 3 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2013	9654961	EXPEDITED (15-DAY)		OT	US-NAPPMUNDI-USA-2012-0091804		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Hallucination, Auditory; Hallucination, Visual; Prescribed Overdose; Somnolence	Oxycontin (Nda 22-272)			S				Purdue
	Oxycontin (Nda 22-272)			S	Oral	40 Mg, Tid		Purdue
	Morphine /00036302/			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lexapro			S	Oral	20 Mg, Unk		Not Reported
	Lunesta			S		3 Mg, Hs		Not Reported
	Vicodin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2013	9519448	EXPEDITED (15-DAY)		DE, HO	FR-GLAXOSMITHKLINE-B0920180A		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haematuria; Hepatitis	Fortum			S	Intravenous (not otherwise specified)	1g Four Times Per Day		Glaxosmithkline

Fulminant; Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis	Flagyl	S	Oral	500mg Three Times Per Day	Unknown
	Gentamycine	S	Intravenous (not otherwise specified)	210mg Per Day	Unknown
	Noxafil	S	Oral	200mg Three Times Per Day	Unknown
	Cancidas	S	Intravenous (not otherwise specified)		Unknown
	Ambisome	S	Intravenous (not otherwise specified)	180mg Per Day	Unknown
	Bactrim	S	Intravenous (not otherwise specified)	2unit Three Times Per Week	Unknown
	Acid Folinic	S	Intravenous (not otherwise specified)	50mg Three Times Per Week	Unknown
	Zelitrex	S	Intravenous (not otherwise specified)	500mg Twice Per Day	Glaxosmithkline
	Cymevene	S	Intravenous (not otherwise specified)	350mg Twice Per Day	Unknown
	Foscavir	S	Intravenous (not otherwise specified)	1unit Twice Per Day	Otsuka
	Human Immunoglobulin A\Human Immunoglobulin G	S	Intravenous (not otherwise specified)		Unknown
	Granocyte	S	Intravenous (not otherwise specified)		Unknown
	Heparin	S	Intravenous (not otherwise specified)	7000iu Per Day	Unknown
	Inexium	S	Intravenous (not otherwise specified)	40mg Per Day	Unknown
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	S	Intravenous (not otherwise specified)	2unit Three Times Per Day	Unknown
	Delursan	S	Oral	3unit Twice Per Day	Unknown
	Defibrotide	S	Intravenous (not otherwise specified)	25mgk Per Day	Unknown
	Largactil	S	Intravenous (not	1unit Per Day	Unknown

			otherwise specified)		
Tranxene		S	Oral	4unit Per Day	Unknown
Oxynorm		S	Intravenous (not otherwise specified)		Unknown
Exacyl		S	Intravenous (not otherwise specified)	1unit Three Times Per Day	Unknown
Perfalgan	Y	S	Intravenous (not otherwise specified)	1g Three Times Per Day	Unknown
Solumedrol		S	Intravenous (not otherwise specified)	140mg Per Day	Unknown
Droleptan		S	Intravenous (not otherwise specified)	.625mg Four Times Per Day	Unknown
Ultiva		S			Unknown
Atarax		S	Oral	50mg Per Day	Unknown
Lasilix		S	Intravenous (not otherwise specified)	40mg Twice Per Day	Unknown
Seroplex		S	Oral	10mg Per Day	Unknown
Ceris		S	Oral	20mg Twice Per Day	Unknown
Noctamide		S	Oral	2mg Per Day	Unknown
Vancomycin		C	Unknown	1g Per Day	Unknown
Ciflox		C	Unknown	400mg Twice Per Day	Glaxosmithkline
Targocid		C	Unknown	400mg Twice Per Day	Not Reported
Mycostatine		C	Unknown	2bt Per Day	Glaxosmithkline
Triflucan		C	Unknown	200mg Per Day	Glaxosmithkline
Zovirax		C	Unknown	250mg Three Times Per Day	Glaxosmithkline
Methotrexate		C	Unknown	18mg Per Day	Glaxosmithkline
Elvorine		C	Unknown	18.4mg Per Day	Glaxosmithkline
Sandimmun		C	Unknown	210mg Per Day	Glaxosmithkline
Mopral		C	Unknown	20mg Per Day	Glaxosmithkline
Ogast		C	Oral	30mg Per Day	Glaxosmithkline
Gelox		C	Oral	1sac Three Times Per Day	Glaxosmithkline

	Smecta	C	Oral	6sac Per Day	Not Reported
	Luteran	C		1unit Per Day	Not Reported
	Lexomil	C		.5unit Per Day	Glaxosmithkline
	Zophren	C	Oral	2amp Per Day	Glaxosmithkline
	Primperan	C		6amp Per Day	Glaxosmithkline
	Acupan	C		6amp Per Day	Not Reported
	Tiorfan	C	Unknown		Glaxosmithkline
	Levocarnil	C	Unknown	1g Three Times Per Day	Glaxosmithkline
	Gentamicin	C	Oral	2cap Three Times Per Day	Glaxosmithkline
	Colistine	C	Oral	2cap Three Times Per Day	Not Reported
	Endoxan	C			Not Reported
	Busulfan	C			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2013	9523685	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1313978US		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis Fulminant; Organ Failure; Toxic Epidermal Necrolysis	Trospium Chloride Unk			S	Oral	1 Df, Bid		Indevus
	Clairyg			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Heparin Sodium			S	Intravenous (not otherwise specified)	1 X 1 Df / 1 Day(S)		Not Reported
	Delursan			S	Oral	2 Df, Tid		Not Reported
	Defibrotide			S	Intravenous (not otherwise specified)	25 Mg/Kg, Qd		Not Reported
	Noxafil			S	Oral	200 Mg, Tid		Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			S	Intravenous (not otherwise specified)	2 Df, Tid		Not Reported
	Largactil			S	Intravenous (not otherwise specified)	1 Df, Qd		Not Reported
	Oxynorm			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Fortum	S	Intravenous (not otherwise specified)	1 Df, Qid	Not Reported
Tranxene	S	Oral	4 X 1 Df, Prn	Not Reported
Cancidas	S	Intravenous (not otherwise specified)	Unk	Not Reported
Ambisome	S	Intravenous (not otherwise specified)	180 Mg, Qd	Not Reported
Zelitrex	S	Intravenous (not otherwise specified)	500 Mg, Bid	Not Reported
Inexium	S	Intravenous (not otherwise specified)	1 Df, Qd	Not Reported
Solumedrol	S	Intravenous (not otherwise specified)	140 Mg, Qd	Not Reported
Perfalgan	S	Intravenous (not otherwise specified)	1 G, Tid	Not Reported
Flagyl	S	Oral	500 Mg, Tid	Not Reported
Droleptan	S	Intravenous (not otherwise specified)	0.625 Mg, Qid	Not Reported
Ultiva	S	Intravenous (not otherwise specified)	100 Gbq, Q1hr	Not Reported
Atarax	S	Oral	0.5 Df, Qd	Not Reported
Lasilix	S	Intravenous (not otherwise specified)	40 Mg, Bid	Not Reported
Seroplex	S	Oral	10 Mg, Qd	Not Reported
Bactrim	S	Intravenous (not otherwise specified)	2 Df, Tid	Not Reported
Folinic Acid	S	Intravenous (not otherwise specified)	150 Mg, Q Week	Not Reported
Cymevene	S	Intravenous (not otherwise specified)	350 Mg, Bid	Not Reported
Exacyl	S	Intravenous (not otherwise specified)	1 Df, Tid	Not Reported
Granocyte	S	Intravenous (not otherwise specified)	Unk	Not Reported

Foscavir	S	Intravenous (not otherwise specified)	1 Df, Bid	Not Reported
Noctamide	S	Oral	2 Mg, Qd	Not Reported
Gentamicine Panpharma	S	Intravenous (not otherwise specified)	210 Mg, Qd	Not Reported
Gentamicin/Colistine	C		Unk	Not Reported
Vancomycin Mylan	C		Unk	Not Reported
Mycostatine	C		Unk	Not Reported
Triflucan	C		Unk	Not Reported
Zovirax	C		Unk	Not Reported
Methotrexate Mylan	C		Unk	Not Reported
Elvorine	C		Unk	Not Reported
Mopral	C		Unk	Not Reported
Gelox	C		Unk	Not Reported
Luteran	C		Unk	Not Reported
Lexomil	C		Unk	Not Reported
Noctamide	C		Unk	Not Reported
Zophren	C		Unk	Not Reported
Sandimmun	C		Unk	Not Reported
Ogastoro	C		Unk	Not Reported
Smecta	C		Unk	Not Reported
Primperan	C		Unk	Not Reported
Acupan	C		Unk	Not Reported
Tiorfan	C		Unk	Not Reported
Ciflox	C		Unk	Not Reported
Levocarnil	C		Unk	Not Reported
Targocid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2013	9614481	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC-2013291087		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Glomerular Filtration Rate Decreased; International Normalised Ratio Increased; Pneumonia Aspiration	Cordarone			S	Oral	200 Mg, Daily		Pfizer
	Amiodarone Hcl			S	Oral	400 Mg, Daily		Pfizer
	Doliprane			S	Oral	1 Unit, Daily		Not Reported
	Seroplex			S	Oral	15 Mg, Daily		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg, Daily		Not Reported
	Furosemide			C		Unk		Not Reported
	Lasilix			C		Unk		Not Reported
	Ebixa			C				Not Reported
	Mecir			C				Not Reported
	Debridat			C		Unk		Not Reported
	Lysanxia			C				Not Reported
	Kaleorid			C				Not Reported
	Permixon			C				Not Reported
	Xanax			C		Unk		Not Reported
	Valsartan			C				Not Reported
	Poly Karaya			C		Unk		Not Reported
	Movicol			C		Unk		Not Reported
	Tiapridal			C		Unk		Not Reported
	Augmentin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2013	9656147	EXPEDITED (15-DAY)		HO	US-JNJFOC-20131013655		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypotension; Lethargy; Overdose; Sinus Bradycardia; Skin Laceration; Syncope; Vomiting	Tramadol/Paracetamol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Acetaminophen\Hydrocodone Bitartrate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2013	9656528	EXPEDITED (15-DAY)		HO	FR-FRI-1000050554		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hepatocellular Injury; Hyperphosphataemia; Lactic Acidosis	Escitalopram			S	Oral	Overdose With 10 Tablets		Forest
	Paracetamol			S	Oral	Overdose With 50 Grams		Not Reported
	Zolpidem			S	Oral	Overdose With 14 Tablets		Not Reported
	Tercian			S	Oral	Overdose With 45 Tablets		Not Reported
	Venlafaxine			S	Oral	Overdose With 10 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2013	9657133	EXPEDITED (15-DAY)		CA	US-FRI-1000050548		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly; Heart Disease Congenital; Pulmonary Valve Stenosis; Right Atrial Enlargement; Right Ventricular Enlargement	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2013	9663776	DIRECT		HO			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Product Substitution Issue; Suicide Attempt	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2013	9663779	DIRECT		HO			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Response Changed	Bupropion Xl			S		Taken By Mouth		Teva
	Escitalopram			S		Taken By Mouth		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2013	9663793	DIRECT					45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Diarrhoea; Fatigue; Flatulence; Gastrointestinal Disorder; Headache; Insomnia; Weight Decreased	Escitalopram			S	Oral	1 Dose Once Daily Taken By Mouth		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2013	9664176	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapy Non-Responder	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2013	9664551	DIRECT					42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Product Substitution Issue; Restlessness; Stress	Escitalopram 10mg Aurobiudo Pharma			S	Oral			Not Reported
	Sertraline			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2013	8681116	EXPEDITED (15-DAY)		HO, LT, OT	CH-009507513-1207CHE007059		73 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Blood Loss Anaemia; Hypotonia; Lower Gastrointestinal Haemorrhage; Melaena	Remeron		S	Oral	30 Mg, Qd	Merck
	Plavix		S	Oral	75 Mg, Qd	Not Reported
	Aspirin Cardio		S	Oral	100 Mg, Qd	Not Reported
	Cipralex		S	Oral	10 Mg, Qd	Not Reported
	Glucophage		S		850 Mg, Qd	Not Reported
	Flector		S	Cutaneous	1 Df, Unk	Not Reported
	Concor		C	Oral	10 Mg, Qd	Not Reported
	Triatec Comp		C	Oral	2.5/12.5mg, Qd	Not Reported
	Sortis		C	Oral	40 Mg, Qd	Not Reported
	Seroquel		C		25 Mg, Qd	Not Reported
	Lantus		C	Subcutaneous	4 Iu	Not Reported
	Pradif		C		400 Microgram, Qd	Not Reported
	Haldol		C	Oral	Unk, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2013	8780945	EXPEDITED (15-DAY)		OT	US-009507513-1209USA003695		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amylase Increased; Biliary Dilatation; Lipase Increased	Isentress			S	Oral			Merck
	Escitalopram Oxalate			S	Oral			Not Reported
	Truvada			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Irbesartan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2013	8784739	EXPEDITED (15-DAY)		OT	ES-009507513-1209ESP005286		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis	Carbidopa (+) Levodopa			S	Oral			Merck
	Zyprexa			S	Oral			Not Reported

Deprax (Trazodone Hydrochloride)	S	Oral		Not Reported
Stelara	C	Oral		Not Reported
Escitalopram	S	Oral		Not Reported
Omeprazole	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2013	8795304	EXPEDITED (15-DAY)		DE, OT	US-009507513-1209USA006060		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Cardiomegaly; Completed Suicide; Left Ventricular Hypertrophy; Nephrosclerosis; Pneumoconiosis; Pulmonary Congestion; Self-Medication; Toxicity To Various Agents; Visceral Congestion	Saphris			S	Oral	5 Mg, Qd		Merck
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Xanax			S	Oral	1 Mg, Qd		Not Reported
	Vicodin			S	Oral	Unk		Not Reported
	Triamterene			C				Not Reported
	Atacand			C				Not Reported
	Simvastatin Tablets, Usp			C				Merck
	Famotidine			C				Merck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2013	9659155	EXPEDITED (15-DAY)		OT	CH-009507513-1310CHE011726		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Somnolence; Suicide Attempt; Tachycardia	Remeron			S	Oral	10 Dosage Units, Once		Merck
	Lorazepam			S	Oral	10 Dosage Units, Once		Not Reported
	Escitalopram			S	Oral	Number Of Units Unknown, Once		Not Reported
	Trimipramine			S	Oral	10 Dosage Units, Once		Not Reported
	Alcohol			S	Oral	2 Bottles, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2013	9660224	EXPEDITED (15-DAY)		DE	US-NAPPMUNDI-USA-2011-0066313		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Substance Abuse	Oxycontin Tablets			S				Purdue
	Morphine Sulfate (Similar To Nda 19-516)			S				Purdue
	Xanax			S				Not Reported
	Cocaine			S				Not Reported
	Cannabis			S				Not Reported
	Hydroxyzine			S				Not Reported
	Escitalopram			S				Not Reported
	Ibuprofen			S				Not Reported
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2013	9661103	EXPEDITED (15-DAY)		HO	FR-FRI-1000050681		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Portal Vein Thrombosis; Product Use In Unapproved Indication	Escitalopram			S	Transplacental	5 Mg		Forest
	Depakote			S	Transplacental	250 Mg		Not Reported
	Teralithe			S	Transplacental	125 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2013	9661259	EXPEDITED (15-DAY)		OT	US-FRI-1000050468			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Pressure Increased; Large Intestinal Haemorrhage	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S				Forest
	Advil			S		2-3 Times Daily Prn (Up To 6 Times Daily)		Not Reported
	Advil			S				Not Reported
	Synthroid			C		0.25 Mg		Not Reported

	Benicar	C	40 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2013	9665753	DIRECT					27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Condition Aggravated; Crying; Drug Ineffective; Product Substitution Issue	Escitalopram 20mg			S	Oral	1 Pill Once Daily Taken By Mouth	1 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2013	8818333	NON-EXPEDITED			US-009507513-1209USA004813			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Insomnia; Muscle Twitching	Januvia			S	Oral	50 Mg, Qd		Merck
	Lexapro			S		20 Mg, Unk		Not Reported
	Lexapro			S		10 Unk, Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Metformin			C		500 Mg, Bid		Not Reported
	Glyburide			C		5 Mg, Unk		Not Reported
	Trimethoprim			C		100 Mg, Unk		Not Reported
	Simvastatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2013	9531902	EXPEDITED (15-DAY)		DE, HO, OT	FR-SANOFI-AVENTIS-2013SA091919		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bladder Disorder; Blister; Graft Versus Host Disease In Gastrointestinal Tract; Haematuria; Hepatitis	Flagyl			S	Oral			Not Reported
	Heparin Sodium			S	Intravenous (not otherwise specified)			Not Reported

Fulminant; Multiple Organ Dysfunction Syndrome; Oedema; Skin Exfoliation; Skin Lesion; Toxic Epidermal Necrolysis	Largactil	S	Intravenous (not otherwise specified)	Form:Infusion	Not Reported
	Exacyl	S	Intravenous (not otherwise specified)	Form:Infusion	Not Reported
	Lasilix	S	Intravenous (not otherwise specified)		Not Reported
	Granocyte	S	Intravenous (not otherwise specified)	Form:Infusion	Not Reported
	Delursan	S	Oral		Not Reported
	Gentamicin	S	Intravenous (not otherwise specified)	Form:Infusion	Not Reported
	Noxafil	S	Oral		Not Reported
	Cancidas	S	Intravenous (not otherwise specified)	Form:Infusion	Not Reported
	Ambisome	S	Intravenous (not otherwise specified)	Form:Infusion	Not Reported
	Bactrim	S	Intravenous (not otherwise specified)		Not Reported
	Folinic Acid	S	Intravenous (not otherwise specified)		Not Reported
	Zelitrex	S	Intravenous (not otherwise specified)	Form:Infusion	Not Reported
	Cymevene	S	Intravenous (not otherwise specified)	Form:Infusion	Not Reported
	Foscavir	S	Intravenous (not otherwise specified)		Not Reported
	Clairyg	S	Intravenous (not otherwise specified)	Form:Infusion	Not Reported
	Inexium	S	Intravenous (not otherwise specified)		Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	S	Intravenous (not otherwise specified)		Not Reported
	Defibrotide	S	Intravenous (not otherwise specified)		Not Reported

Tranxene	S	Oral		Not Reported
Perfalgan	S	Intravenous (not otherwise specified)		Not Reported
Solumedrol	S	Intravenous (not otherwise specified)	Form:Infusion	Not Reported
Droleptan	S	Intravenous (not otherwise specified)		Not Reported
Ultiva	S	Intravenous (not otherwise specified)		Not Reported
Atarax	S	Oral		Not Reported
Seroplex	S	Oral		Not Reported
Ceris	S	Oral		Not Reported
Noctamide	S	Oral		Not Reported
Noctamide	S	Oral		Not Reported
Oxynorm	S	Intravenous (not otherwise specified)	Form:Infusion	Not Reported
Fortum	S	Intravenous (not otherwise specified)		Not Reported
Vancomycin Hydrochloride	C			Not Reported
Ciflox	C			Not Reported
Targocid	C			Not Reported
Mycostatin	C			Not Reported
Triflucan	C			Not Reported
Zovirax	C			Not Reported
Methotrexate	C			Not Reported
Elvorine	C			Not Reported
Sandimmune	C			Not Reported
Mopral	C			Not Reported
Ogastoro	C			Not Reported
Gelox	C			Not Reported
Smecta	C			Not Reported
Luteran	C			Not Reported
Lexomil	C			Not Reported
Primperan	C			Not Reported
Acupan	C			Not Reported
Tiorfan	C			Not Reported
Levocarnil	C			Not Reported

	Zophren			C						Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
01-Nov-2013	9549251	EXPEDITED (15-DAY)	Y	DE, HO, OT	AXC-2013-000466		41 YR	Female	FRA	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bladder Disorder; Graft Versus Host Disease In Gastrointestinal Tract; Haematuria; Hepatitis Fulminant; Oedema; Toxic Epidermal Necrolysis	Delursan (Ursodeoxycholic Acid) Tablet			S	Oral	3 Df, Bid, Oral		Not Reported
	Fortum			S	Intravenous (not otherwise specified)	1 Df, Qid, Intravenous		Not Reported
	Flagyl			S	Oral			Not Reported
	Gentamicine			S	Intravenous (not otherwise specified)			Not Reported
	Ambisome			S	Intravenous (not otherwise specified)			Not Reported
	Bactrim			S	Intravenous (not otherwise specified)	2 Df, 3x/Weekly, Itravenous		Not Reported
	Noxafil			S	Oral			Not Reported
	Cancidas			S	Intravenous (not otherwise specified)			Not Reported
	Folinic Acid			S	Intravenous (not otherwise specified)	50mg, 3x/Wk, Intravenous		Not Reported
	Zelitrex			S	Intravenous (not otherwise specified)			Not Reported
	Cymevene			S	Intravenous (not otherwise specified)			Not Reported
	Foscavir			S	Intravenous (not otherwise specified)	1 Df, Bid, Intravenous		Not Reported
	Clairyg			S	Intravenous (not otherwise specified)			Not Reported
	Granocyte			S				Not Reported
	Sodium Heparin			S	Intravenous (not otherwise specified)	7000 Lu, Qd, Intravenous		Not Reported
	Inexium (Esomeprazole Sodium)			S	Intravenous (not			Not Reported

		otherwise specified)		
Spasfon /00765801/	S		2 Df, Tid, Intravenous	Not Reported
Defibrotide	S	Intravenous (not otherwise specified)	25 Mg/Kg, Qd, Intravenous	Not Reported
Largactil	S	Intravenous (not otherwise specified)	1 Df, Qd, Intravenous	Not Reported
Tranxene	S	Oral	5 Mg, Qid Pm, Oral	Not Reported
Oxynorm	S	Intravenous (not otherwise specified)		Not Reported
Exacyl	S	Intravenous (not otherwise specified)	1 Df, Tid, Intravenous	Not Reported
Perfalgan	S	Intravenous (not otherwise specified)	1 G, Tid, Intravenous	Not Reported
Solumedrol	S	Intravenous (not otherwise specified)		Not Reported
Droleptan	S	Intravenous (not otherwise specified)	0.625 Mg, Qid, Intravensious	Not Reported
Ultiva	S	Intravenous (not otherwise specified)	100gbq, Q1h, Intravenous	Not Reported
Atarax	S	Oral		Not Reported
Lasilix	S	Intravenous (not otherwise specified)	40mg, Bid, Intravenous	Not Reported
Seroplex	S	Oral		Not Reported
Ceris	S	Oral		Not Reported
Noctamide	S	Oral	1 Df, Qd, Oral	Not Reported
Gentamicin +Colistin (Gentamicin + Colistin)	C			Not Reported
Vancomycine Mylan 9vancomycin Hydrochloride)	C			Not Reported
Ciflox/00697201/(Ciprofloxacin)	C			Not Reported
Targocid (Teicoplanin)	C			Not Reported
Mycostatin (Nystatin)	C			Not Reported
Triflucan (Teicoplanin)	C			Not Reported
Zovirax	C			Not Reported
Methotrexate Mylan	C			Not Reported

(Methotrexate Mylan)			
Elvorine (Calcium Levofolinate)	C		Not Reported
Sandimmun (Ciclosporin) Infusion	C		Not Reported
Mopral/006661201/(Omeprazole)	C		Not Reported
Ogastoro (Lansoprazole)	C		Not Reported
Gelox (Aluminum Hydroxide, Aluminum Silicate, Magnesium Hydroxide)	C		Not Reported
Smecta / 00837601/(Aluminum Hydroxide-Magnesium Carbonate Gel, Aluminum Magnesium Silicate, Glucose Monohydrate, Glycyrrhiza Glabra)	C		Not Reported
Magnesium Silicate, Glucose Monohydrate, Glycrrhiza Glabra)	C		Not Reported
Luteran (Chlormadinone Acetate)	C		Not Reported
Lexomil (Bromazepam)	C		Not Reported
Zophren / 00955301/ (Ondansetron)	C		Not Reported
Primperan (Metoclopramide Hydrochloride)	C		Not Reported
Acupan (Nefopam Hydrochloride)	C		Not Reported
Tiorfan (Acetorphan) Unknown	C		Not Reported
Levocarnil (Levocarnitine)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2013	9605857	EXPEDITED (15-DAY)		OT	FR-FRI-1000049746		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carotid Artery Dissection	Escitalopram			S	Oral	1 Df		Forest
	Levothyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2013	9636391	EXPEDITED (15-DAY)		OT	FR-FRI-1000050357		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Lip Swelling; Oropharyngeal Swelling; Swollen Tongue	Escitalopram			S	Oral	10 Mg		Forest
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2013	9636411	EXPEDITED (15-DAY)		CA, DE	IE-FRI-1000050219			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Heart Valve Disorder; Foetal Death; Foetal Exposure During Pregnancy; Hydrops Foetalis; Multiple Cardiac Defects	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2013	9645594	EXPEDITED (15-DAY)			CH-FRI-1000050248		25 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prescribed Overdose	Escitalopram			S	Oral	30 Mg		Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2013	9663503	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-LISI20110018		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment; Nausea	Lisinopril Tablets 5mg			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2013	9664360	EXPEDITED (15-DAY)		OT	US-TEVA-441709USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2013	9665305	EXPEDITED (15-DAY)		HO	FR-FRI-1000050116		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Dissociation; Bradycardia; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	1 Df		Forest
	Sifrol			C	Oral	1 Df		Not Reported
	Bactrim			C				Not Reported
	Zelitrex			C				Not Reported
	Loxan			C				Not Reported
	Lederfoline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2013	9566038	EXPEDITED (15-DAY)		OT	GB-ELI_LILLY_AND_COMPANY-GB201309007991			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chest Discomfort; Dyspepsia; Hypoaesthesia; Multiple Sclerosis Relapse; Product Dispensing Error; Product Name Confusion	Cialis			S	Oral	5 Mg, Qd		Eli Lilly And Co
	Cipralex			S	Unknown	5 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2013	9665168	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2013S1023812		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Overdose	Escitalopram			S	Oral	Df = 10mg		Mylan
	Paracetamol W/Tramadol Hydrochloride			S	Oral			Not Reported
	Procet /01554201/			S	Oral	Unknown Amount		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2013	9665171	EXPEDITED (15-DAY)		OT	TR-US-EMD SERONO, INC.-7246479			Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Toothache	Rebif			S	Subcutaneous			Not Reported
	Tamol			S	Oral			Not Reported
	Tamol			S				Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2013	9560190	EXPEDITED (15-DAY)	Y	DE, HO	2013CP000111		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bone Marrow Transplant; Graft Versus Host Disease In Gastrointestinal Tract; Haematuria; Hepatitis Fulminant; Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis	Perfalgan			S	Intravenous (not otherwise specified)			Not Reported
	Heparin Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Ceftazidime (Ceftazidime)			S	Intravenous (not otherwise specified)			Not Reported
	Gentamicine			S	Intravenous (not otherwise specified)			Not Reported
	Ambisome			S	Intravenous (not otherwise specified)			Not Reported
	Bactrim			S	Intravenous (not otherwise specified)			Not Reported
	Folinic Acid			S				Not Reported
	Zelitrex			S	Oral			Not Reported
	Cymevene			S				Not Reported
	Foscavir			S	Intravenous (not otherwise specified)			Not Reported
	Esomeprazole (Esomeprazole)			S				Not Reported
	Phloroglucinol (Phloroqlucinol)			S	Intravenous (not			Not Reported

		otherwise specified)		
Defibrotide	S	Intravenous (not otherwise specified)		Not Reported
Chlorpromazine Hydrochloride	S	Intravenous (not otherwise specified)		Not Reported
Tranexamic Acid	S	Intravenous (not otherwise specified)		Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)		Not Reported
Droperidol	S	Intravenous (not otherwise specified)		Not Reported
Ultiva	S	Intravenous (not otherwise specified)	100 Gbq; Qh; Iv	Not Reported
Furosemide	S	Intravenous (not otherwise specified)		Not Reported
Metronidazole	S	Oral		Not Reported
Noxafil	S	Oral		Not Reported
Delursan	S	Oral		Not Reported
Tranxene	S	Oral		Not Reported
Hydroxyzine	S	Oral		Not Reported
Seroplex	S	Oral		Not Reported
Ceris	S	Oral		Not Reported
Noctamide	S	Oral		Not Reported
Granocyte	S	Intravenous (not otherwise specified)		Not Reported
Oxynorm	S	Intravenous (not otherwise specified)		Not Reported
Gentamicine	C			Not Reported
Colistin	C			Not Reported
Vancomycin	C			Not Reported
Ciprofloxacin Hcl	C			Not Reported
Acyclovir	C			Not Reported
Cyclosporine	C			Not Reported
Ogastoro	C			Not Reported

	Smectite	C	Not Reported
	Luteran	C	Not Reported
	Lexomil	C	Not Reported
	Noctamide	C	Not Reported
	Ondansetron Hcl	C	Not Reported
	Primperan	C	Not Reported
	Acupan	C	Not Reported
	Levocarnil	C	Not Reported
	Racecadotril	C	Not Reported
	Targocid	C	Not Reported
	Gelox	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2013	9621143	EXPEDITED (15-DAY)		DE	FR-FRI-1000050027		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased	Escitalopram			S	Oral	1 Df		Forest
	Previscan (Fluindione)			S		0.75 Df		Not Reported
	Previscan (Fluindione)			S		Daily Dose Reduced Nos		Not Reported
	Cordarone			S	Oral	1 Df		Not Reported
	Doliprane			S	Oral	1 Df		Not Reported
	Lasilix			C	Oral	1 Df		Not Reported
	Lasilix			C	Oral	4 Df		Not Reported
	Lasilix			C	Oral	1 Df		Not Reported
	Ebixa			C	Oral	1.5 Df		Not Reported
	Mecir			C	Oral	1 Df		Not Reported
	Debridat			C		3 Df		Not Reported
	Lysanxia			C	Oral	1 Df		Not Reported
	Kaleorid			C	Oral	3 Df		Not Reported
	Permixon			C	Oral	2 Df		Not Reported
	Xanax			C	Oral			Not Reported
	Valsartan			C	Oral	1 Df		Not Reported
	Poly-Karaya			C				Not Reported

Movicol	C				Not Reported
Tiapridal	C	Oral	2 Df		Not Reported
Augmentin	C		3 Grams		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2013	9665631	EXPEDITED (15-DAY)		DE, HO	US-FRI-1000050704		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Posterior Reversible Encephalopathy Syndrome; Reversible Cerebral Vasoconstriction Syndrome; Serotonin Syndrome	Escitalopram			S		10 Mg		Forest
	Dihydroergotamine			S				Not Reported
	Hydrocodone			S				Not Reported
	Hydromorphone			S				Not Reported
	Tetrahydrocannabinol			S				Not Reported
	Anticoagulation			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2013	9665940	EXPEDITED (15-DAY)		OT	PHHY2013BR121015			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Dementia Alzheimer'S Type; Gait Disturbance; Hydrocephalus; Mood Altered; Parkinson'S Disease; Screaming; Speech Disorder; Thyroid Disorder; Tremor	Galvus Met			S	Oral	2 Df, (Metf 850 Mg/ Vild 50 Mg) Daily		Not Reported
	Metformin			S	Oral	850 Mg, Daily		Novartis
	Atenolol			S	Oral	2 Df, (25 Mg) Daily		Not Reported
	Lexapro			S	Oral	1 Df (15mg), Daily		Not Reported
	Diamicron			S	Oral	1 Df (60mg), Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2013	9665960	EXPEDITED (15-DAY)		DE, HO	FR-FRI-1000048785		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Escitalopram			S	Oral			Forest

Fortum	S	Intravenous (not otherwise specified)	4 Df	Not Reported
Flagyl	S	Oral	3 Df	Not Reported
Gentamicine Panpharma	S	Intravenous (not otherwise specified)	1 Df	Not Reported
Noxafil	S		3 Df	Not Reported
Cancidas	S	Intracavernous		Not Reported
Ambisome	S	Intravenous (not otherwise specified)	1 Df	Not Reported
Bactrim	S	Intravenous (not otherwise specified)	0.8571 Df	Not Reported
Acide Folinique	S	Intravenous (not otherwise specified)	21.4286 Mg	Not Reported
Zelitrex	S	Intravenous (not otherwise specified)	2 Df	Not Reported
Cymevene	S	Intravenous (not otherwise specified)	700 Mg	Not Reported
Foscavir	S	Intravenous (not otherwise specified)	12 Gram/500 Ml Daily	Not Reported
Clairyg	S	Intravenous (not otherwise specified)		Not Reported
Granocyte	S	Intravenous (not otherwise specified)		Not Reported
Heparin Sodique	S	Intravenous (not otherwise specified)	7000 Iu	Not Reported
Inexium	S	Intravenous (not otherwise specified)	1 Df	Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	S	Intravenous (not otherwise specified)	6 Df	Not Reported
Delursan	S	Oral	6 Df	Not Reported
Defibrotide	S	Intravenous (not otherwise specified)	25 Mg/Kg Daily	Not Reported
Largactil	S	Intravenous (not otherwise specified)	1 Df	Not Reported

Tranxene	S	Oral		Not Reported
Oxynorm	S	Intravenous (not otherwise specified)		Not Reported
Exacyl	S		3 Df	Not Reported
Perfalgan	S		3 Df	Not Reported
Solumedrol	S	Intravenous (not otherwise specified)	1 Df	Not Reported
Droleptan	S		4 Df	Not Reported
Ultiva	S	Endocervical	24 Df	Not Reported
Atarax	S	Oral	0.5 Df	Not Reported
Lasilix	S	Intravenous (not otherwise specified)	2 Df	Not Reported
Ceris	S	Oral	2 Df	Not Reported
Noctamide	S	Oral	1 Df	Not Reported
Gentamicine	C	Oral	6 Df	Not Reported
Colistine	C	Oral	6 Df	Not Reported
Vancomycine Mylan	C		1 Df	Not Reported
Ciflox	C		2 Df	Not Reported
Targocid	C		2 Df	Not Reported
Mycostatine	C		2 Bottles Daily	Not Reported
Triflucan	C		1 Df	Not Reported
Zovirax	C		3 Df	Not Reported
Methotrexate Mylan	C		1 Df	Not Reported
Elvorine	C		1 Df	Not Reported
Sandimmun	C		1 Df	Not Reported
Mopral	C		1 Df	Not Reported
Ogastoro	C		1 Df	Not Reported
Gelox	C		1 Packed Tid	Not Reported
Smecta	C		6 Packets Daily	Not Reported
Luteran	C		1 Df	Not Reported

	Lexomil	C	0.5 Df	Not Reported
	Noctamide	C	1 Df	Not Reported
	Zophren	C	2 Ampoules Daily	Not Reported
	Primperan	C	6 Ampoules Daily	Not Reported
	Acupan	C	6 Ampoules Daily On Request	Not Reported
	Tiorfan	C		Not Reported
	Levocarnil	C	3 Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2013	9667831	EXPEDITED (15-DAY)		HO, OT	US-TEVA-441607USA		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Overdose	Escitalopram			S	Oral	Df = 10mg		Ivax
	Tramadol + Paracetamol			S	Oral			Not Reported
	Hydrocodone + Paracetamol			S	Oral	Unknown Amount		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2013	9669615	DIRECT		HO			54 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Chest Pain; Chromaturia; Dyspepsia; Dysuria; Ulcer	Escitalopram			S	Oral	20 Mg 1 Pill At Bedtime Taken By Mouth		Camber
	Cyclobenzaprine			S	Oral			Cadista

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2013	9669920	EXPEDITED (15-DAY)	Y	HO	AUR-APL-2013-09110		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Bundle	Escitalopram (Escitalopram)			S	Oral			Not Reported
	Tramadol/Paracetamol			S				Not Reported

Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Intentional Overdose; Lethargy; Presyncope; Skin Laceration; Vomiting	Vicodin		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2013	8794234	EXPEDITED (15-DAY)		OT	US-MERCK-1209USA005725		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Mania; Oedema Peripheral	Saphris			S	Sublingual	20 Mg, Qpm		Merck
	Wellbutrin			S				Not Reported
	Lexapro			S				Not Reported
	Alprazolam			C		4 Mg, Qpm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2013	9648261	EXPEDITED (15-DAY)		OT	CA-FRI-1000050519		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis; Prescribed Overdose	Escitalopram			S	Oral	Overdose: (30 Mg Daily)		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2013	9668454	EXPEDITED (15-DAY)		HO	US-MICRO LABS LIMITED-BB2013-01089		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Interval; Lethargy; Overdose; Presyncope; Skin Laceration; Skin	Tramadol + Paracetamol			S	Oral	25 Tablets		Micro Labs
	Escitalopram			S	Unknown	50 Tablets		Not Reported
	Hydrocodone/Paracetamol			S	Unknown			Not Reported

Laceration; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2013	9669697	EXPEDITED (15-DAY)		HO	FR-FRI-1000050744		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction	Escitalopram			S	Oral	1 Df		Forest
	Xarelto			S	Oral	1 Df		Not Reported
	Tanakan			S	Oral	3 Df		Not Reported
	Doliprane			C	Oral			Not Reported
	Transilane (Potassium Bicarbonate\Psyllium Husk)			C	Oral			Not Reported
	Gutron			C	Oral	6 Df		Not Reported
	Flecaine			C	Oral	1 Df		Not Reported
	Seresta			C	Oral	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2013	9670122	EXPEDITED (15-DAY)		OT	FR-FRI-1000050742		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2013	9671316	DIRECT					52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Migraine With Aura	Escitalopram			S		Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2013	9676239	EXPEDITED (15-DAY)	Y	HO	2013AP009311		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Electrocardiogram Qt Prolonged; Overdose; Qrs Axis Abnormal	Escitalopram Oxalate			S	Oral			Apotex
	Paracetamol W/Tramadol Hydrochloride			S	Oral			Not Reported
	Acetaminophen\Hydrocodone			S	Oral			Not Reported
	Acetaminophen W/ Hydrocodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2013	9643352	EXPEDITED (15-DAY)		OT	JP-ELI_LILLY_AND_COMPANY-JP201310004590		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Cymbalta			S	Oral	20 Mg, Qd		Eli Lilly And Co
	Lexapro			S	Oral	10 Unk, Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Lonasen			C	Oral	4 Mg, Unk		Not Reported
	Levotomin /00038602/			C	Oral	75 Mg, Unk		Not Reported
	Depas (Etizolam)			C	Oral	3 Mg, Unk		Not Reported
	Flunitrazepam			C	Oral	Unk		Not Reported
	Goodmin			C	Oral	Unk		Not Reported
	Allorin			C	Oral	Unk		Not Reported
	Mucosta			C	Oral	Unk		Not Reported
	Loxonin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2013	9674688	DIRECT		OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Nausea; Presyncope; Product Substitution Issue	Escitalopram			S	Oral	1/2 Pill (About 5 Mg) Once Daily Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2013	9674696	DIRECT					42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Headache; Heart Rate Increased; Product Substitution Issue	Escitalopram			S	Oral	1 Pill; Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2013	9675097	DIRECT					58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Product Substitution Issue	Simvastatin			S				Not Reported
	Levothyroxine			S				Not Reported
	Irbesartan			S				Not Reported
	Escitalopram			S				Not Reported
	Novolog			S				Not Reported
	Multivitamin			C				Not Reported
	Calcium			C				Not Reported
	Zyrtec			C				Not Reported
	Apidra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2013	9675437	EXPEDITED (15-DAY)		OT	US-FRI-1000050828		12 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Failure To Thrive; Off Label Use	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2013	9676304	EXPEDITED (15-DAY)		LT	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-FF-02		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Inappropriate Antidiuretic Hormone Secretion	Spiriva		S	Respiratory (inhalation)	Boehringer Ingelheim
	Seroplex		S		Not Reported
	Haldol		C	Oral	Not Reported
	Sulfarlem		C	Oral	Not Reported
	Lepticur		C	Oral	Not Reported
	Miflonil		C	Respiratory (inhalation)	Not Reported
	Onbrez Breezhaler		C	Respiratory (inhalation)	Not Reported
	Onbrez Breezhaler		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2013	8774272	EXPEDITED (15-DAY)		HO	JP-009507513-2012SP014090		49 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness	Pegintron			S	Subcutaneous	1.3 Microgram Per Kilogram, Qw		Merck
	Pegintron			S	Subcutaneous	1.5 Microgram Per Kilogram, Qw		Merck
	Pegintron			S	Subcutaneous	1.5 Microgram Per Kilogram, Qw		Merck
	Pegintron			S	Subcutaneous	40 Microgram Per Kilogram, Qw		Merck
	Pegintron			S	Subcutaneous	60 Microgram Per Kilogram, Qw		Merck
	Pegintron			S	Subcutaneous	80 Microgram Per Kilogram, Qw		Merck
	Rebetol			S	Oral	800 Mg, Qd		Merck
	Rebetol			S	Oral	400 Mg, Qd		Merck
	Rebetol			S	Oral	800 Mg, Qd		Merck
	Telavic			S	Oral	2250 Mg, Qd		Not Reported

Telavic	S	Oral	1500 Mg, Qd	Not Reported
Telavic	S	Oral	Daily Dose Unknown	Not Reported
Desyrel	S	Oral	50 Mg, Qd, Formulation:Por	Not Reported
Lexapro	S	Oral	10 Mg, Qd, Formulation:Por	Not Reported
Mucosta	C	Oral	300 Mg, Qd	Not Reported
Loxonin	C	Oral	Prn, Formulation: Por	Not Reported
Aphtasolon	C	Parenteral	Prn, Formulation:Ext	Not Reported
Hachiazule Gargle	C	Parenteral	Prn, Formulation: Ext	Not Reported
Pursennid (Sennosides)	C	Oral	Prn, Formulation:Por	Not Reported
Celestoderm V	C	Topical	1 G, Qd	Not Reported
Fulmeta	C	Topical	Unk Unk, Prn	Not Reported
Nauzelin	C	Oral	3 Df, Qd	Not Reported
Lac-B	C	Oral	3 G, Qd, Formulation: Por	Not Reported
Primperan	C	Intravenous (not otherwise specified)	1 Df, Qd	Not Reported
Vitamedin Capsules	C		3 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2013	8995914	EXPEDITED (15-DAY)		DS, HO, OT	US-009507513-2010SP063654			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Sinusitis; Back Pain; Breast Disorder; Bursitis; Cerebellar Haemorrhage; Concussion; Depression; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Dystonia; Epstein-Barr Virus Infection; Fatigue; Feeling Jittery; Fibromyalgia; Folate Deficiency;	Nuvaring			S	Vaginal			Merck
	Nuvaring			S				Merck
	Nuvaring			S				Merck
	Nuvaring			S				Merck
	Lexapro			S				Not Reported
	Reglan			S				Not Reported
	Coumadin			S				Not Reported
	Coumadin			S				Not Reported

Gastrooesophageal Reflux Disease; Headache; Herpes Simplex; Hypercoagulation; Inappropriate Schedule Of Product Administration; Influenza Like Illness; Insomnia; Iron Deficiency Anaemia; Lichenoid Keratosis; Loss Of Consciousness; Lymphadenectomy; Mastoptosis; Metrorrhagia; Migraine; Muscle Strain; Off Label Use; Ovarian Cyst; Pain; Pelvic Pain; Pharyngitis; Pulmonary Embolism; Sleep Apnoea Syndrome; Sleep Apnoea Syndrome; Vaginal Discharge; Vertigo; Viral Infection; Vitamin B12 Deficiency

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2013	9678769	EXPEDITED (15-DAY)		DE, OT	US-TEVA-443306USA		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Cardiac Arrest; Haemodynamic Instability; Overdose	Bupropion			S	Unknown			Teva
	Escitalopram			S	Unknown			Ivax
	Quetiapine Fumarate			S	Unknown			Teva
	Desvenlafaxine			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2013	9678943	EXPEDITED (15-DAY)		OT	US-FRI-1000050941		12 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pleuritic Pain	Escitalopram			S		10 Or 20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2013	9680751	DIRECT					43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Loss Of Libido; Product Substitution Issue; Weight Increased	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2013	9684672	EXPEDITED (15-DAY)	Y	HO, LT, OT	2013HINLIT0216		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Electrocardiogram Abnormal; Lethargy; Overdose; Skin Laceration; Syncope	Escitalopram			S		500 Mg, Unk, Unknown		Not Reported
	Tramadol+Paracetamol (Tramadol+Paracetamol)			C				Not Reported
	Acetaminophen\Hydrocodone Bitartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2013	9619349	EXPEDITED (15-DAY)		OT	NZ-MYLANLABS-2013S1021874		17 YR	Female	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Depression; Exposure During Pregnancy; Off Label Use	Escitalopram			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2013	9671782	EXPEDITED (15-DAY)		OT	NO-PFIZER INC-2013315841		35 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Dependence; Epilepsy; Fatigue; Feeling Of Despair; Frustration Tolerance Decreased; Insomnia; Irritability; Malaise; Thinking Abnormal	Neurontin			S		300 Mg, Unk		Pfizer
	Sobril			S		10 Mg, Unk		Pfizer
	Paralgin Forte			S		30 Mg, Unk		Not Reported
	Imovane			S		7.5 Mg, Unk		Not Reported
	Vallergan			S		10 Mg, Unk		Not Reported
	Cipralex			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2013	9680370	EXPEDITED (15-DAY)		HO	CH-MERCK-1311CHE002410		72 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Hyponatraemia	Remeron			S	Oral	30 Mg, Qd		Merck
	Remeron			S	Oral	Unk		Merck
	Torem			S	Oral	5 Mg, Qd		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Cipralex			S	Oral	Unk		Not Reported
	Concor			C	Oral	1.25 Mg, Qd		Not Reported
	Norvasc			C	Oral	10 Mg, Qd		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
	Duphalac			C	Oral	20 Ml, Prn		Not Reported
	Benerva			C	Oral	100 Mg, Tid		Not Reported
	Becozym			C	Oral	1 Df, Qd		Not Reported
	Konakion			C	Intravenous bolus	10 Mg, Qd		Not Reported
	Nicotinell			C	Transdermal	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2013	9681257	EXPEDITED (15-DAY)		HO	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-FF-02		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Iron Deficiency Anaemia	Pradaxa			S	Oral			Boehringer Ingelheim
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2013	9681648	EXPEDITED (15-DAY)		HO	US-FRI-1000050818		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Hallucination, Auditory; Hallucination, Visual	Escitalopram			S	Oral	10 Mg		Forest
	Risperidone			C		6 Mg		Not Reported
	Benztropine			C		4 Mg		Not Reported
	Valium			C		5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2013	9684153	EXPEDITED (15-DAY)		CA, HO	FR-FRI-1000050999		1 DAY	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hypotonia Neonatal; Poor Feeding Infant; Ventricular Septal Defect	Escitalopram			S	Transplacental			Forest
	Largactil			S	Transplacental			Not Reported
	Atarax			S	Transplacental			Not Reported
	Lexomil			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2013	9685218	DIRECT					69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blepharospasm; Choking; Drooling; Facial Spasm; Lip Disorder; Nightmare; Product Substitution Issue	Escitalopram Tab 10mg			S	Oral	10 Mg 1 Tab Everyday By Mouth		Aurobindo
	Levothyroxin			C				Not Reported
	Metoprolol			C				Not Reported
	Lexapro			C				Not Reported

Vit D	C		Not Reported
Hydrocorothiazide	C		Not Reported
Compazine	C		Not Reported
Sirnethecone	C		Not Reported
Prilosec	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2013	9685423	DIRECT		LT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Irritability; Product Substitution Issue; Suicidal Ideation; Tic	Escitalopram			S	Oral	1 Dose Once Daily Taken By Mouth		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2013	9636353	EXPEDITED (15-DAY)		HO, LT	AU-FRI-1000050319		42 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Overdose	Lexapro			S	Oral	30 Mg		Forest
	Alprazolam			S	Oral	1 Mg		Not Reported
	Methylprednisolone			S	Other	40 Mg		Not Reported
	Sodium Valproate			S	Oral	1.5 Gram		Not Reported
	Mirtazapine			C	Oral	75 Mg		Not Reported
	Rabeprazole			C	Oral	20 Mg		Not Reported
	Salbutamol			C		6 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2013	9636367	EXPEDITED (15-DAY)		HO	AU-FRI-1000050324		57 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cogwheel Rigidity; Extrapyramidal Disorder;	Escitalopram			S				Forest
	Sodium Valproate			S				Not Reported

Petit Mal Epilepsy	Edronax	S	Oral	4 Mg		Not Reported
	Moduretic	C				Not Reported
	Nexium	C				Not Reported
	Aspirin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2013	9636409	EXPEDITED (15-DAY)		LT, OT	AU-FRI-1000050321		42 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression; Drug Interaction; Homicidal Ideation; Suicidal Behaviour	Escitalopram			S	Oral	30 Mg		Forest
	Methylprednisolone			S		40 Mg		Not Reported
	Champix			S	Oral	1 Df		Not Reported
	Sodium Valproate			S	Oral	1.5 Gram		Not Reported
	Alprazolam			C	Oral			Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2013	9671224	EXPEDITED (15-DAY)		DE	ES-JNJFOC-20131019370			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Infarction	Xeplion			S	Intramuscular			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2013	9685418	EXPEDITED (15-DAY)		OT	KR-ROXANE LABORATORIES, INC.-2013-RO-01798RO		57 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Limb Discomfort; Sleep-Related Eating Disorder	Diazepam			S		20 Mg		Roxane
	Zolpidem Tartrate			S		10 Mg		Roxane
	Quetiapine Fumarate			S		25 Mg		Roxane

	Lorazepam	S	2 Mg	Roxane
	Escitalopram	S	20 Mg	Not Reported
	Propylthiouracil	S	50 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2013	9686119	EXPEDITED (15-DAY)		OT	DE-FRI-1000051051			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Vasculitis	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2013	9686842	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2013323307		22 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Xanax			S	Oral	50 Gtt, Total		Pfizer
	Antabuse			S	Oral	800 Mg, Daily		Not Reported
	Cipralex			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2013	9176567	EXPEDITED (15-DAY)		DE	US-JNJFOC-20130306847			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Concerta			S	Oral			Not Reported
	Adderall			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Vyvanse			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2013	9181563	NON-EXPEDITED		OT	US-PFIZER INC-2013091534		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Glucose Tolerance Impaired; Increased Appetite; Muscle Spasms; Oedema Peripheral; Weight Increased	Zoloft	S	100 Mg, Unk	Pfizer
	Lexapro	S	10 Mg, Unk	Not Reported
	Amitriptyline	S	25 Mg, Unk	Not Reported
	Warfarin	C	8 Mg, Every Tuesday, Wednesday, Friday, Saturday And Sunday	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2013	9478493	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000047984		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicectomy; Depression; Drug Ineffective; Knee Arthroplasty; Prescribed Overdose	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	40 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Not Reported
	Levothyroxine			C		50 Mcg		Not Reported
	Insulin			C				Not Reported
	Simvastatin			C		20 Mg		Not Reported
	Omeprazole			C		20 Mg		Not Reported
	Diazepam			C		10 Mg		Not Reported
	Oxycontin			C		120 Mg		Not Reported
	Phenergan			C				Not Reported
	Lasix			C		40 Mg		Not Reported
	Potassium			C		20 Meq		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2013	9612008	EXPEDITED (15-DAY)		OT	GB-FRI-1000049869			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chest Discomfort; Dyspepsia; Hypoaesthesia; Multiple Sclerosis Relapse;	Escitalopram			S		5 Mg		Forest
	Cialis			S	Oral	5 Mg		Not Reported

Product Dispensing Error;
Product Name Confusion

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2013	9648169	EXPEDITED (15-DAY)		HO	PHEH2013US022324			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Thyroid Stimulating Hormone Decreased; Merycism; Speech Disorder; Tremor	Combipatch			S	Transdermal	Unk Ukn, Unk		Novartis
	Combipatch			S	Transdermal	Unk Ukn, Unk		Novartis
	Lexapro			S		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2013	9687969	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2013S1024797		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Cardiac Arrest; Haemodynamic Instability; Overdose	Bupropion			S	Unknown			Mylan
	Desvenlafaxine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2013	9688386	EXPEDITED (15-DAY)		HO	FR-FRI-1000051173		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Iron Deficiency Anaemia	Escitalopram			S	Oral	1 Df		Forest
	Pradaxa			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2013	9690123	DIRECT					43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Loss Of Libido; Product Substitution Issue; Weight Increased	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2013	9690182	DIRECT					33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Panic Attack; Product Substitution Issue	Escitalopram 20mg			S	Oral	1 Pill, Once Daily, Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2013	9690261	DIRECT		OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hyperhidrosis; Muscle Twitching; Panic Disorder; Product Substitution Issue; Withdrawal Syndrome	Escitalopram			S				Camber
	Zocor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2013	9526444	EXPEDITED (15-DAY)		DS, HO	US-TEVA-432072USA		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Cogwheel Rigidity; Drug Interaction; Obsessive-Compulsive Disorder; Parkinsonism; Toxicity To Various Agents	Clozapine			S				Ivax
	Luvox			S				Not Reported
	Lexapro			S				Not Reported
	Benzatropine Mesilate			C				Not Reported
	Depakote			C				Not Reported
	Prilosec			C				Not Reported
	Antidepressant			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2013	9632557	EXPEDITED (15-DAY)		HO, LT	IT-ABBVIE-13P-083-1159125-00		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Depakin			S	Oral			Not Reported
	Depakin			S				Not Reported
	Entact			S	Oral			Not Reported
	Entact			S				Not Reported
	Xanax			S	Oral			Not Reported
	Cardioaspirin			C				Not Reported
	Torvast			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2013	9691147	EXPEDITED (15-DAY)		DE, HO	FR-GLAXOSMITHKLINE-B0941072A		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Duodenal Ulcer Haemorrhage; Fall; Gastrointestinal Haemorrhage; Haematoma; Haematoma Muscle; Melaena; Shock Haemorrhagic	Arixtra			S	Subcutaneous	7.5mg Per Day		Glaxosmithkline
	Ibuprofen			S	Oral	400mg Three Times Per Day		Unknown
	Seroplex			S	Oral	15mg Per Day		Unknown
	Pyostacine			S	Oral	2g Per Day		Unknown
	Xanax			C				Glaxosmithkline
	Parlodel			C				Not Reported
	Vesicare			C				Not Reported
	Nuctalon			C				Not Reported
	Omeprazole			C				Glaxosmithkline
	Dafalgan			C				Glaxosmithkline
	Macrogol			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2013	9696009	EXPEDITED (15-DAY)	Y	HO, LT	2013P1020943		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Increased; Blood Potassium Decreased; Blood Pressure Decreased; Bundle Branch Block Right; Cardiotoxicity; Electrocardiogram Qrs Complex Prolonged; Lethargy; Overdose; Presyncope; Sinus Bradycardia; Vomiting	Escitalopram	S	Oral	500 Mg; Po	Not Reported
	Tramadol/Acetaminophen	S			Not Reported
	Acetaminophen\Hydrocodone Bitartrate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2013	9698514	EXPEDITED (15-DAY)	Y	DE, HO	2013P1020897		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased; Ischaemic Cerebral Infarction; Pyrexia; Reversible Cerebral Vasoconstriction Syndrome; Serotonin Syndrome; Subarachnoid Haemorrhage	Escitalopram			S				Not Reported
	Hydromorphone			S				Not Reported
	Dihydroergotamine			S	Intravenous (not otherwise specified)			Not Reported
	Hydrocodone			S				Not Reported
	Tetrahydrocannabinol			S				Not Reported
	Anticoagulant (S)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2013	9433007	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2013-06299		64 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hallucination; Sleep-Related Eating Disorder; Somnambulism	Lamotrigine (Lamotrigine)			S	Oral			Not Reported
	Quetiapine (Quetiapine)			S	Oral			Not Reported
	Stilnox			S	Oral	)1 Dosage Forms), Oral		Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2013	9693371	EXPEDITED (15-DAY)		OT	CA-ROCHE-1301791		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Depression; Dizziness; Dry Mouth; Erection Increased; Fatigue; Increased Appetite; Muscular Weakness; Nausea; Somnolence; Suicidal Ideation; Tinnitus; Tremor; Weight Increased	Clonazepam			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Wellbutrin Xl			S	Oral			Not Reported
	Echinacea			C	Oral			Not Reported
	Horse Chestnut Extract			C	Oral			Not Reported
	Milk Thistle			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2013	9693503	EXPEDITED (15-DAY)		OT	AU-ABBVIE-13P-008-1157517-00		57 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cogwheel Rigidity; Extrapyramidal Disorder; Petit Mal Epilepsy	Sodium Valproate			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Edronax			S				Not Reported
	Moduretic			C				Not Reported
	Nexium I.V.			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2013	9693779	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2013326671		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Alprazolam			S	Oral	1 Df, 1x/Day		Pfizer
	Control (Phenylpropanolamine)			S	Oral	2.5 Mg, 1x/Day		Not Reported
	Entact			S	Oral	10 Mg, 1x/Day		Not Reported

	Lormetazepam	S	Oral	1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2013	9694022	EXPEDITED (15-DAY)		OT	AU-ABBVIE-13P-008-1157813-00		42 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Overdose	Sodium Valproate			S				Not Reported
	Alprazolam			S				Not Reported
	Escitalopram			S				Not Reported
	Methylprednisolone			S				Not Reported
	Mirtazapine			C				Not Reported
	Rabeprazole Sodium			C				Not Reported
	Salbutamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2013	9695392	DIRECT		OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Hypersensitivity; Mood Swings; Product Substitution Issue; Sleep Disorder	Lexapro			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2013	9695818	DIRECT		OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dyspnoea; Hypertension; Palpitations; Product Substitution Issue	Escitalopram 20mg			S	Oral	1 Pill		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2013	9695850	DIRECT					37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Product Substitution Issue	Escitalopram 20mg	S	Oral	1 Pill 20mg Daily		Walmart

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2013	9698842	EXPEDITED (15-DAY)	Y	HO	2013110041		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Delirium; Disorientation; Disturbance In Attention; Drug Interaction; Hyponatraemia; Slow Response To Stimuli	Torem			S	Oral	1-0-0 (5 Mg, 1 In 1 D), Oral		Not Reported
	Remeron			S	Oral	0-0-1 (30 Mg, 1 In 1 D), Oral		Not Reported
	Cipralex			S	Oral	1-0-0 (10 Mg, 1 In 1 D), Oral		Not Reported
	Concor (Bisoprolol Fumarate)			C				Not Reported
	Norvasc (Amlodipine Besilate)			C				Not Reported
	Pantoprazol (Pantoprazole)			C				Not Reported
	Duphalac (Galactose, Lactulose, Lactose)			C				Not Reported
	Nicotinell			C				Not Reported
	Benerva (Thiamine Hydrochloride)			C				Not Reported
	Becozym Forte (Pyridoxine Hydrochloride, Biotin, Cyanocobalamin, Riboflavin, Thiamine Hydrochloride, Calcium Pantiothenate)			C				Not Reported
	Konakion (Phytomenadione)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2013	9648345	EXPEDITED (15-DAY)		HO, LT	IT-FRI-1000050520		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Sopor	Escitalopram			S	Oral	280 Mg At Once		Forest
	Depakin			S		Overdose: 60 Dosage Forms At Once		Not Reported
	Xanax			S		Overdose: 40 Dosage		Not Reported

						Forms At Once			
	Cardioaspirin			C	Oral				Not Reported
	Torvast			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2013	9670036	EXPEDITED (15-DAY)		HO	IT-FRI-1000050768		71 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Electrolyte Imbalance; Inappropriate Antidiuretic Hormone Secretion; Muscle Rigidity	Escitalopram			S	Oral	10 Mg		Forest
	Clonazepam			C	Oral	10 Drops		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2013	9696342	EXPEDITED (15-DAY)		DS, OT	GB-FRI-1000051460		73 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea	Escitalopram			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2013	9696377	EXPEDITED (15-DAY)		LT	ES-FRI-1000051462		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Ventricular Tachycardia	Escitalopram			S	Oral			Forest
	Ebastine			S	Oral			Not Reported
	Deprax (Trazodone Hydrochloride)			S				Not Reported
	Atarax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2013	9529797	EXPEDITED (15-DAY)		DE, HO	FR-ROCHE-1270915		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blister; Eschar; Graft Versus Host Disease In Gastrointestinal Tract; Haematuria; Hepatitis Fulminant; Mucosal Erosion; Multiple Organ Dysfunction Syndrome; Oedema; Skin Erosion; Skin Lesion; Toxic Epidermal Necrolysis	Bactrim			S	Intravenous drip			Not Reported
	Cymevene			S	Intravenous (not otherwise specified)			Not Reported
	Fortum			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Flagyl			S	Oral	500 Mg		Not Reported
	Zelitrex			S	Intravenous (not otherwise specified)			Not Reported
	Foscavir			S	Intravenous (not otherwise specified)			Not Reported
	Clairyg			S	Intravenous (not otherwise specified)			Not Reported
	Granocyte			S	Intravenous (not otherwise specified)			Not Reported
	Heparine Sodique			S	Intravenous (not otherwise specified)			Not Reported
	Inexium			S	Intravenous (not otherwise specified)	40 Mg Once Per Day		Not Reported
	Spasfon (France)			S	Intravenous (not otherwise specified)			Not Reported
	Delursan			S	Oral			Not Reported
	Defibrotide			S	Intravenous (not otherwise specified)			Not Reported
	Largactil			S	Intravenous (not otherwise specified)			Not Reported
	Tranxene			S	Oral	As Required		Not Reported
	Oxynorm			S	Intravenous (not otherwise specified)			Not Reported
	Exacyl			S	Intravenous (not otherwise specified)			Not Reported
	Perfalgan			S	Intravenous (not otherwise specified)			Not Reported

Solu-Medrol	S	Intravenous (not otherwise specified)		Not Reported
Droleptan	S	Intravenous (not otherwise specified)		Not Reported
Ultiva	S	Intravenous (not otherwise specified)		Not Reported
Atarax (France)	S	Oral	100 Mg	Not Reported
Lasilix	S	Intravenous (not otherwise specified)		Not Reported
Seroplex	S	Oral	Dose Increased On Unspecified Date	Not Reported
Ceris	S	Oral	20 Mg	Not Reported
Noctamide	S	Oral	2 Mg	Not Reported
Noctamide	S	Oral		Not Reported
Gentamicin	S	Intravenous (not otherwise specified)		Not Reported
Noxafil	S	Oral		Not Reported
Cancidas	S	Intravenous (not otherwise specified)		Not Reported
Folinic Acid	S	Intravenous (not otherwise specified)		Not Reported
Ambisome	S	Intravenous (not otherwise specified)		Not Reported
Endoxan	C			Not Reported
Busulfex	C			Not Reported
Methotrexate	C	Unknown		Not Reported
Vancomycine	C	Unknown		Not Reported
Ciflox (France)	C	Unknown		Not Reported
Targocid	C	Unknown		Not Reported
Mycostatine	C	Unknown	2 Vial	Not Reported
Triflucan	C	Unknown		Not Reported
Zovirax	C	Unknown		Not Reported

Elvorine	C	Unknown			Not Reported
Sandimmun	C	Unknown			Not Reported
Mopral (France)	C	Unknown			Not Reported
Ogastoro	C	Unknown			Not Reported
Gelox	C	Unknown			Not Reported
Smecta (France)	C	Unknown			Not Reported
Luteran	C	Unknown			Not Reported
Zophren	C	Unknown	One Tablet Per Day		Not Reported
Primperan (France)	C	Unknown			Not Reported
Acupan	C	Unknown	If Needed		Not Reported
Tiorfan	C	Unknown			Not Reported
Levocarnil	C	Unknown			Not Reported
Colistine	C	Unknown			Not Reported
Lexomil	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2013	9681870	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013320824		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chest Discomfort; Depression; Dyspnoea; Feeling Hot; Heart Rate Increased; Myalgia; Palpitations; Panic Attack; Product Use In Unapproved Indication; Vision Blurred	Lyrica			S		75 Mg, Daily		Pfizer
	Lyrica			S		50 Mg, 2x/Day		Pfizer
	Lyrica			S				Pfizer
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2013	9698023	EXPEDITED (15-DAY)		DE, HO	FR-FRI-1000051491		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gastrointestinal Haemorrhage; Haematoma Muscle; Overdose	Escitalopram	S	Oral	1 Df		Forest
	Arixtra	S	Subcutaneous	7.5 Mg/0.6 Ml		Not Reported
	Ibuprofen	S	Oral	3 Df		Not Reported
	Pyostacine	S	Oral	4 Df		Not Reported
	Xanax	C				Not Reported
	Parlodel	C				Not Reported
	Vesicare	C				Not Reported
	Nuctalon	C				Not Reported
	Omeprazole	C				Not Reported
	Dafalgan	C				Not Reported
	Macrogol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2013	9700959	DIRECT		OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Product Substitution Issue; Therapeutic Response Changed	Lexapro			S		Generic Lexapro Twice Daily	2 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2013	9701510	DIRECT					31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Impaired Work Ability	Escitalopram			S	Oral	1 Once Daily Taken By Mouth		Legacy Pharmaceutical Packaging

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2013	9701915	DIRECT	Y				16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product	Escitalopram			S	Oral			Not Reported

Substitution Issue

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2013	9701919	DIRECT		OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Night Sweats; Pain	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2013	9701999	EXPEDITED (15-DAY)	Y	OT	TR-MACLEODS PHARMA-000165		29 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Escitalopram			S		10.00-Mg-1.0days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2013	9826626	NON-EXPEDITED		OT	1000044743		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hot Flush; Insomnia	Viibryd			S	Oral	10 Mg, 1 In 1 D		Not Reported
	Lexapro (Escitalopram Oxalate) (10 Milligram, Tablets)			S	Oral	(10 Mg, 1 In 1 D)		Not Reported
	Alprazolam (Alprazolam) (Alprazolam)			C				Not Reported
	Lisinopril (Lisinopril) (Lisinopril)			C				Not Reported
	Amlodipine (Amlodipine) (Amlodipine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2013	9836662	NON-EXPEDITED			1000049313		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching	Viibryd (Vilazodone Hydrochloride)			S	Oral	10 Mg, 1 In1 D		Not Reported

			Oral	20 Mg, 1 In 1 D		
	Lexapro (Escitalopram Oxalate) Tablets	S	Oral	10 Mg, 1 In 1 D		Not Reported
	Crestor	C				Not Reported
	Vitamin D Nos	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2013	9382003	EXPEDITED (15-DAY)		CA, OT	JP-FRI-1000046398		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sperm Concentration Decreased; Spermatozoa Progressive Motility Decreased	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Meilax			C	Oral	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2013	9537936	EXPEDITED (15-DAY)		HO	IT-FRI-1000048938		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Sopor	Escitalopram			S	Oral	200 Mg		Forest
	Delorazepam			S	Oral	20 Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2013	9686102	EXPEDITED (15-DAY)		OT	CA-FRI-1000051049			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Escitalopram			S	Oral			Forest
	Escitalopram			S				Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S		10 Mg		Forest
	Metoprolol			C	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2013	9689326	EXPEDITED (15-DAY)		OT	NO-FRI-1000051375		35 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Dependence; Epilepsy; Fatigue; Feeling Of Despair; Frustration Tolerance Decreased; Insomnia; Irritability; Malaise; Thinking Abnormal	Escitalopram			S				Forest
	Vallergan			S		10 Mg		Not Reported
	Neurontin			S		300 Mg		Not Reported
	Paralgin Forte			S		30 Mg		Not Reported
	Sobril			S		10 Mg		Not Reported
	Imovane			S		7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2013	9700549	NON-EXPEDITED			US-PFIZER INC-2013331159		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2013	9701746	EXPEDITED (15-DAY)		OT	DK-ACTAVIS-2013-21289		36 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Diarrhoea; Dizziness; Drug Interaction; Hyperhidrosis; Malaise; Muscle Spasticity; Serotonin Syndrome	Tramadol Actavis			S	Unknown	Unk		Actavis Elizabeth
	Cipralex			S	Oral	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2013	9703303	EXPEDITED (15-DAY)		HO	US-JNJFOC-20131107934		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Product Use In Unapproved Indication; Tremor	Risperdal			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Abilify			S	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2013	9703970	EXPEDITED (15-DAY)		HO	FR-FRI-1000051629		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma	Escitalopram			S	Oral	1 Df		Forest
	Biprofenid			S	Oral			Not Reported
	Lyrica			C	Oral	2 Df		Not Reported
	Oxynorm			C	Oral			Not Reported
	Seresta			C		1 Df		Not Reported
	Baclofene			C		3 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2013	9705436	EXPEDITED (15-DAY)		OT	IT-ACTAVIS-2013-21216		64 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hallucination; Sleep-Related Eating Disorder; Somnambulism	Quetiapine (Unknown)			S	Oral	Unk		Actavis
	Lamotrigine (Unknown)			S	Oral	Unk		Watson
	Stilnox			S	Oral	1 Df, Qpm		Not Reported
	Cipralex			S	Oral	20 Mg/Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2013	9706810	DIRECT		LT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Hypersomnia; Product Substitution Issue	Lexapro 10mg (Generic)			S	Oral	1 Pill Once Daily Taken By Mouth	30 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2013	9690943	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013326280		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hip Fracture; Intentional Product Misuse; Mental Disorder	Xanax			S		0.5 Mg In The Morning And 1.5 Mg At Night		Pfizer
	Preparation H		Y	S		Unk, As Needed		Pfizer
	Remeron			S		30 Mg, Daily		Not Reported
	Lexapro			S		25 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2013	9708559	EXPEDITED (15-DAY)		HO	IT-FRI-1000051678		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Intentional Overdose; Poisoning; Sopor	Escitalopram			S	Oral	Overdose:560 Mg Once		Forest
	En			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2013	9708803	EXPEDITED (15-DAY)		OT	CH-FRI-1000051733		49 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoacusis; Nasal	Escitalopram			S	Oral	10 Mg		Forest

Obstruction	Trittico	C	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2013	9711819	DIRECT					49 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Drug Ineffective; Nasal Ulcer; Nightmare; Product Substitution Issue	Escitalopram			S	Oral	1 Pill Once Daily Taken By Mouth	6 MTH	Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2013	9716799	EXPEDITED (15-DAY)		OT	BR-TORRENT-00001828		69 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hemiparesis; Tremor	Espran (Inn:Escitalopram Oxalate)			S	Oral	Once Daily/Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2013	9718948	EXPEDITED (15-DAY)	Y	DE, HO	2013P1021126		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Cardiac Arrest; Circulatory Collapse; Overdose; Pulseless Electrical Activity; Sinus Tachycardia	Escitalopram			S		; X1;		Not Reported
	Bupropion			S		; X1 ;		Not Reported
	Quetiapine			S		; X1 ;		Not Reported
	Desvenlafaxine			S		; X1 ;		Not Reported
	Ibuprofen			S		; X 1 ;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2013	9537853	EXPEDITED (15-DAY)		HO, OT	JP-FRI-1000040028		68 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Dyspnoea; Feeling Hot; Nausea; Palpitations; Paraesthesia	Lexapro	S	Oral	10 Mg		Forest
	Adetphos	C	Oral	300 Mg		Not Reported
	Rebamipide	C	Oral	300 Mg		Not Reported
	Gasmotin	C	Oral	15 Mg		Not Reported
	Alositol	C	Oral	100 Mg		Not Reported
	Takepron	C	Oral	15 Mg		Not Reported
	Myslee	C	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2013	9665401	EXPEDITED (15-DAY)		DE, OT	US-JNJFOC-20131100280		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Areflexia; Brain Injury; Circulatory Collapse; Coma Scale Abnormal; Dry Skin; Gastrointestinal Sounds Abnormal; Hypotension; Overdose; Pulseless Electrical Activity; Pupil Fixed; Sinus Tachycardia	Ibuprofen			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Desvenlafaxine Succinate Monohydrate			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2013	9709415	EXPEDITED (15-DAY)		DE, HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2013SUN05051		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Cardiac Arrest; Circulatory Collapse; Intentional Overdose	Bupropion Hydrochloride Extended-Release Tablets, Usp (Sr) 100mg			S	Unknown			Not Reported
	Quetiapine Fumarate 25mg Tablets			S	Unknown			Not Reported
	Escitalopram 1mg/Ml Oral Solution			S	Unknown			Not Reported

	Desvenlafaxine	S	Unknown			Not Reported
	Ibuprofen	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2013	9714335	EXPEDITED (15-DAY)		OT	IT-FRI-1000041360			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Pregnancy	Escitalopram			S		10 Mg		Forest
	Escitalopram			S		20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2013	9715894	DIRECT		OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depression; Drug Ineffective	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2013	9722873	EXPEDITED (15-DAY)	Y	DE, HO	2013P1021124		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Circulatory Collapse; Hypotension; Overdose; Pulseless Electrical Activity; Sinus Tachycardia	Bupropion			S		X1		Not Reported
	Quetiapin			S		X1		Not Reported
	Desvenlafaxine			S		X1		Not Reported
	Escitalopram			S		X1		Not Reported
	Ibuprofen			S		X1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2013	9716625	NON-EXPEDITED			US-PFIZER INC-2013338910			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contusion	Zoloft	S	Unk	Pfizer
	Lexapro	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2013	9718723	EXPEDITED (15-DAY)		OT	CH-FRI-1000051795			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Serotonin Syndrome; Sleep Disorder; Tachycardia; Tremor	Escitalopram			S	Oral	5 Mg		Forest
	Trittico			C	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2013	9719242	EXPEDITED (15-DAY)		HO, OT	PHHY2013BE119304		32 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Depression; Hypokinesia; Increased Appetite; Multiple Sclerosis Relapse; Urine Output Decreased; Weight Increased	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Remergon			S				Not Reported
	Sipralexa			S				Not Reported
	Nitrofurantoin			C		150 Mg, Qd		Not Reported
	Zoplicone			C				Not Reported
	Lyrica			C		300 Mg, Bid		Not Reported
	Magnespasmyl			C				Not Reported
	Serlain			C		50 Mg, Unk		Not Reported
	Befact (Cyanocobalamin\Pyridoxine\Thiamine)			C				Not Reported
	Omnibionta			C				Not Reported
	Tri Minulet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2013	9601207	EXPEDITED (15-DAY)		OT	FI-JNJFOC-2010012535		46 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Acute Sinusitis; Adjustment Disorder With Mixed Anxiety And Depressed Mood; Aggression; Agitation; Anosmia; Anxiety; Blood Cholesterol Increased; Blood Glucose Increased; Confusional State; Confusional State; Depression; Dizziness; Drug Dependence; Drug Interaction; Dyspnoea; Dyspnoea; Erythema; Euphoric Mood; Fatigue; Fear; Feeling Abnormal; Hallucination; Hepatic Steatosis; Hypersensitivity; Hyposmia; Hypothyroidism; Increased Appetite; Infection; Influenza; Irritability; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Medication Error; Memory Impairment; Mood Swings; Musculoskeletal Discomfort; Nausea; Nightmare; Overdose; Overweight; Palpitations; Panic Reaction; Personality Change; Restlessness; Sense Of Oppression; Sleep Disorder; Swelling; Tinnitus; Upper Respiratory Tract Infection; Vasodilatation;	Nicorette Patch	Y	S	Transdermal		Not Reported
	Nicorette Patch		S	Transdermal	Daily Dose Text: Unknown 1/2 Tablet Daily;	Not Reported
	Nicorette Gum	Y	S	Oral	Daily Dose Text: 2mg And 4mg Unspecified	Not Reported
	Champix		S	Oral	Daily Dose Text: 1mg, 2x/ Day	Not Reported
	Champix		S	Oral	Daily Dose Text: 0.5mg, 1x/Day	Not Reported
	Champix		S	Oral	Daily Dose Text: 0.5mg, 2x/Day	Not Reported
	Amoxin		S	Oral		Not Reported
	Rinexin		S	Oral		Not Reported
	Cipralex		S	Unknown		Not Reported
	Pentoxyverine Citrate		C	Unknown		Not Reported
	Clarithromycin		C	Unknown		Not Reported
	Doximycin		C	Unknown		Not Reported
	Azithromycin		C	Unknown		Not Reported
	Havrix		C	Intramuscular	Daily Dose Text: Unknown	Not Reported

Vertigo; Weight Increased;
Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2013	9720141	EXPEDITED (15-DAY)		DE	US-INDICUS PHARMA-000181		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion	Metformin Hydrochloride			S	Oral			Indicus
	Metoprolol			S	Oral	Extended Release		Not Reported
	Escitalopram			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Acetaminophen/Opioid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2013	9720538	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20131118003		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Myoclonus	Ixprim			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Keppra			C	Oral			Not Reported
	Keppra			C	Oral			Not Reported
	Keppra			C	Oral			Not Reported
	Keppra			C	Oral			Not Reported
	Keppra			C	Oral			Not Reported
	Keppra			C	Oral			Not Reported
	Keppra			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Actonel			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Acide Folique			C	Oral			Not Reported

	Tahor	C	Oral	Not Reported
	Amlor	C	Oral	Not Reported
	Kardegic	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2013	9373064	EXPEDITED (15-DAY)			AT-FRI-1000046249			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenospermia; Oligospermia; Teratospermia	Escitalopram			S		10 Mg		Forest
	Escitalopram			S		20 Mg		Forest
	Escitalopram			S		2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2013	9659822	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2013308507		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Areflexia; Brain Injury; Cardiac Arrest; Circulatory Collapse; Coma Scale Abnormal; Dry Skin; Gastrointestinal Sounds Abnormal; Hypotension; Overdose; Pupil Fixed; Tachycardia	Quetiapine Fumarate			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Ibuprofen			S		Unk		Pfizer
	Desvenlafaxine Succinate Monohydrate			S		Unk		Pfizer
	Bupropion			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2013	9698558	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2013329226		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor; Toxicity To Various Agents	Xanax			S	Oral	1 Df, Daily		Pfizer
	Lormetazepam			S	Oropharingeal	1 Df, Unk		Pfizer
	Control (Phenylpropanolamine)			S	Oral	2.5 Mg, Daily		Not Reported

	Entact	S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2013	9725252	DIRECT					71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Muscle Twitching; Nightmare; Product Substitution Issue	Escitalopram			S	Oral	1 Once Daily Taken By Mouth	100 DAY	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2013	9725302	DIRECT		OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Depression; Panic Attack; Product Substitution Issue	Escitalopram			S		2 Pills, Once Daily, Taken By Mouth	2 MTH	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2013	9730459	EXPEDITED (15-DAY)		HO	JP-FRI-1000045325		77 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Bilirubin Increased; Blood Glucose Increased; Headache; Muscular Weakness; Nausea; Serotonin Syndrome; Thirst	Lexapro			S	Oral	10 Mg		Forest
	Opalmon			C	Oral			Not Reported
	Myslee			C	Oral			Not Reported
	Depas (Etizolam)			C	Oral			Not Reported
	Amlodin Od			C	Oral			Not Reported
	Onealfa			C	Oral			Not Reported
	Bayaspirin			C	Oral			Not Reported
	Crestor			C	Oral			Not Reported
	Omepral			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2013	9730739	EXPEDITED (15-DAY)		OT	FR-FRI-1000051810		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Myoclonus	Escitalopram			S	Oral	1 Df		Forest
	Ixprim			S	Oral	3 Df		Not Reported
	Amlor			C				Not Reported
	Tahor			C				Not Reported
	Kardegic			C				Not Reported
	Omeprazole			C				Not Reported
	Actonel			C				Not Reported
	Methotrexate			C				Not Reported
	Acide Folique			C				Not Reported
	Levetiracetam			C		500 Mg		Not Reported
	Levetiracetam			C		1000 Mg		Not Reported
	Levetiracetam			C		1500 Mg		Not Reported
	Levetiracetam			C		2000 Mg		Not Reported
	Levetiracetam			C		1000 Mg		Not Reported
	Levetiracetam			C		500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2013	9012610	EXPEDITED (15-DAY)		OT	DK-PFIZER INC-2013013843		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Coordination Abnormal; Drug Interaction; Dysstasia; Hot Flush; Laboratory Test Abnormal; Malaise	Relpax			S	Oral	1 Tablet Of 20mg Per Day For Migraine		Pfizer
	Relpax			S	Oral	40 Mg, In Case Of Migraine Attacks		Pfizer
	Cipralex			S	Oral	20 Mg, 1x/Day		Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2013	9726120	EXPEDITED (15-DAY)		HO	FI-FRI-1000051814		43 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Speech Disorder; Suicide Attempt	Escitalopram			S	Oral			Forest
	Citalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2013	9727542	EXPEDITED (15-DAY)		HO	FR-FRI-1000051819		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematemesis; Rectal Haemorrhage	Escitalopram			S	Oral	1 Df		Forest
	Eliquis			S	Oral	2 Df		Not Reported
	Levothyrox			C	Oral	37.5 Mcg		Not Reported
	Cokenzen			C	Oral	1 Df		Not Reported
	Omeprazole			C	Oral	1 Df		Not Reported
	Singulair			C	Oral	1 Df		Not Reported
	Seretide			C	Respiratory (inhalation)	2 Df		Not Reported
	Airomir Autohaler			C	Respiratory (inhalation)	2 Puffs		Not Reported
	Alprazolam			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2013	9727766	NON-EXPEDITED		OT	US-ENDO PHARMACEUTICALS INC.-AMIT20130011			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Gait Disturbance; Glucose Tolerance Impaired; Increased Appetite;	Amitriptyline Hcl 25mg			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Zoloft			S	Oral			Not Reported

Muscle Spasms; Oedema Peripheral; Weight Increased	Warfarin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2013	9732023	EXPEDITED (15-DAY)	Y	DE	US-ALKEM-000361		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Ingestion; Toxicity To Various Agents	Gabapentin			S	Oral	Oral		Not Reported
	Quetiapine			S	Oral	Oral		Not Reported
	Escitalopram			S	Oral	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2013	8504859	EXPEDITED (15-DAY)		HO	FR-FRI-1000029721		52 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatic Enzyme Increased; Hepatic Failure; Jaundice	Escitalopram			S	Oral	20 Mg		Forest
	Zyprexa			S	Oral	5 Mg		Not Reported
	Rasilez Hct			S	Oral	150 Mg/12.5 Mg		Not Reported
	Anafranil			S	Oral	37.5 Mg		Not Reported
	Alprazolam			S	Oral	0.75 Mg		Not Reported
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2013	9054756	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2013042222		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Respiratory Acidosis; Respiratory Depression; Sopor	Venlafaxine Hcl			S	Oral	21 Df, Total Dose		Pfizer
	Lexotan			S	Oral	51 Df, Total Dose		Not Reported
	Patrol			S	Oral	4 Df, Total Dose		Not Reported
	Moment 200			S	Oral	18 Df, Total Dose		Not Reported

	Cipralex	S	Oral	18 Mg, Total Dose	Not Reported
	Paracetamol	S	Oral	28 Df,Total Dose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2013	9540200	EXPEDITED (15-DAY)		HO	BE-FRI-1000049086		26 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Necrosis; Overdose	Escitalopram			S		10 Mg		Forest
	Escitalopram			S		Overdose Of Unknown Amount		Not Reported
	Clopixol			S		200 Mg Once Every 15th Day		Not Reported
	Clopixol			S		Overdose Of Unknown Amount		Not Reported
	Etumine			S		40 Mg		Not Reported
	Etumine			S		Overdose Of Unknown Amount		Not Reported
	Doctrazodone			S		200 Mg		Not Reported
	Doctrazodone			S		Overdose Of Unknown Amount		Not Reported
	Lambipol			S		200 Mg		Not Reported
	Lambipol			S		Overdose Of Unknown Amount		Not Reported
	Lorazepam			S		2.5 Mg		Not Reported
	Lorazepam			S		Overdose Of Unknown Amount		Not Reported
	Seroquel			S		600 Mg		Not Reported
	Seroquel			S		Overdose Of Unknown Amount (300 Mg Midday And At 17 Pm)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2013	9610959	EXPEDITED (15-DAY)		OT	FI-GLAXOSMITHKLINE-A1044399A		46 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acute Sinusitis; Adjustment Disorder With Mixed Anxiety And Depressed Mood; Aggression; Agitation; Anosmia; Anxiety; Blood Cholesterol Increased; Blood Glucose Increased; Confusional State; Confusional State; Depression; Dizziness; Drug Dependence; Drug Interaction; Dyspnoea; Dyspnoea; Erythema; Euphoric Mood; Fatigue; Fear; Feeling Abnormal; Hallucination; Hepatic Steatosis; Hypersensitivity; Hyposmia; Hypothyroidism; Increased Appetite; Infection; Influenza; Irritability; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Medication Error; Memory Impairment; Mood Swings; Musculoskeletal Discomfort; Nausea; Nightmare; Overdose; Overweight; Palpitations; Panic Reaction; Personality Change;	Nicorette Patch			S	Transdermal			Glaxosmithkline
	Nicorette Gum			S	Oral			Glaxosmithkline
	Champix			S	Oral			Not Reported
	Champix			S	Oral			Not Reported
	Champix			S	Oral			Not Reported
	Amoxin			S	Oral	.5mg Per Day		Glaxosmithkline
	Rinexin			S	Oral			Glaxosmithkline
	Cipralex			S	Unknown			Glaxosmithkline
	Pentoxyverine Citrate			C	Unknown			Glaxosmithkline
	Clarithromycin			C	Unknown			Glaxosmithkline
	Doximycin			C	Unknown			Glaxosmithkline
	Azithromycin			C	Unknown			Glaxosmithkline
	Havrix			C	Intramuscular			Glaxosmithkline

Restlessness; Sense Of Oppression; Sleep Disorder; Swelling; Tinnitus; Upper Respiratory Tract Infection; Vasodilatation; Vertigo; Weight Increased; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2013	9729276	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY-19864289		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematemesis; Rectal Haemorrhage	Eliquis			S	Oral	Eliquis 2.5 Mg Film-Coated Tablet		Bristol Myers Squibb
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Levothyrox			C	Oral	75 Micro G Scored Tablet. 1df= Half Tablet.		Not Reported
	Cokenzen			C	Oral	1df= 1 Tablet.		Not Reported
	Omeprazole			C	Oral	1df= 1 Tablet.		Not Reported
	Singulair			C	Oral	10 Mg Film-Coated Tablet		Not Reported
	Seretide			C	Respiratory (inhalation)	1df= 1 Puff		Not Reported
	Airomir			C		Autohaler 100 Micrograms/Dose.		Not Reported
	Salbutamol			C		Suspension For Pressurized Inhalation 1df= 2 Puff On Demand		Not Reported
	Alprazolam			C	Oral	0.25mg 1df= 1tablet.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2013	9730352	EXPEDITED (15-DAY)		OT	CA-ROCHE-1308075		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Asthenia; Balance Disorder; Diarrhoea; Disorientation; Disturbance In Attention; Dizziness; Drug Interaction; Dyspnoea; Euphoric Mood; Gait Disturbance; Hallucination; Headache; Hypopnoea; Muscle Spasms; Palpitations; Pulse Pressure Increased; Somnolence; Urinary Tract Infection; Vomiting	Clonazepam			S	Oral			Not Reported
	Baclofen			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Butrans			S	Transdermal	Therapy Duration: 7.0 Days		Not Reported
	Butrans			S	Transdermal			Not Reported
	Butrans			S	Transdermal			Not Reported
	Butrans			S	Transdermal			Not Reported
	Cesamet			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Cipro			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Wellbutrin Xl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2013	9731856	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Escitalopram			S	Oral	1 Tablet, Then Decreased To 1/4 Tablet--Symptoms Persisted ; Bedtime, Then Tried At Dinner		Camber
	Enalapril Maleate W/Hctz			C				Not Reported
	Zegrid			C				Not Reported
	Restasis			C				Not Reported
	Simvastatin			C				Not Reported
	Vivelle			C				Not Reported
	Progesterone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2013	9733096	EXPEDITED (15-DAY)		OT	FR-FRI-1000051866		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrasystoles	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2013	9735564	EXPEDITED (15-DAY)	Y	DE	US-ALKEM-000331		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Gabapentin (Gabapentin)			S	Oral	Oral		Not Reported
	Quetiapine (Quetiapine)			S	Oral	Oral		Not Reported
	Escitalopram (Escitalopram)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2013	9736341	EXPEDITED (15-DAY)	Y	DE	US-ALKEM-000302		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion; Overdose	Gabapentin			S	Oral			Not Reported
	Acetaminophen W/Codeine			S	Oral			Not Reported
	Metoprolol			S	Oral			Not Reported
	Simvastatin			S	Oral			Not Reported
	Escitalopram			S				Not Reported
	Quetiapine			S	Oral			Not Reported
	Eszopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2013	9580879	EXPEDITED (15-DAY)		HO	JP-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-BI-30		65 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Trazenta			S	Oral	5 Mg		Boehringer Ingelheim
	Xarelto / Rivaroxaban			S	Oral	10 Mg		Not Reported
	Plavix			S	Oral	75 Mg		Not Reported
	Diart			S	Oral	60 Mg		Not Reported
	Samsca			S	Oral	15 Mg		Not Reported
	Maintate			S	Oral	5 Mg		Not Reported
	Risperdal Od			S	Oral	1 Mg		Not Reported
	Lexapro			S	Oral	10 Mg		Not Reported
	Acinon / Nizatidine			C	Oral	300 Mg		Not Reported
	Vasolan / Verapamil Hydrochloride			C	Oral	80 Mg		Not Reported
	Predonine / Prednisolone			C	Oral	10 Mg		Not Reported
	Novorapid / Insulin Aspart(Genetical Recombination)			C	Subcutaneous	24 U		Not Reported
	Lantus			C	Subcutaneous	14 U		Not Reported
	Omnipaque 140 / Iohexol			C				Not Reported
	Nexium / Esomeprazole Magnesium Hydrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2013	9684631	EXPEDITED (15-DAY)	Y	DE, OT	AUR-APL-2013-09280		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Areflexia; Blood Lactic Acid Increased; Body Temperature Decreased; Brain Injury; Cardiac Arrest; Circulatory Collapse; Coma Scale Abnormal; Dry Skin; Gastrointestinal Sounds Abnormal; Heart Rate	Quetiapine			S				Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Ibuprofen (Ibuprofen)			S				Not Reported
	Desvenlafaxine Succinate			S				Not Reported
	Bupropion			S				Not Reported

Increased; Hypotension; Mydriasis; Overdose; Oxygen Saturation Increased; Peripheral Coldness; Ph Body Fluid Abnormal; Pulseless Electrical Activity; Sinus Tachycardia; Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2013	9699566	EXPEDITED (15-DAY)		HO	PHHY2013IT131932		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Lormetazepam			S	Oropharingeal	1 U, Qd		Not Reported
	Lormetazepam			S	Oropharingeal	1 Mg, Unk		Not Reported
	Entact			S	Oral	10 Mg, Qd		Not Reported
	Control (Lorazepam)			S	Oral	2.5 Mg, Qd		Not Reported
	Xanax			S	Oral	1 U, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2013	9721584	EXPEDITED (15-DAY)		OT	US-009507513-1311USA012141			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hip Fracture; Off Label Use; Unevaluable Event	Remeron			S	Oral	30 Mg, Qd		Merck
	Lexapro			S		25 Mg, Qd		Not Reported
	Xanax			S		Dose Of 0.5mg In The Morning And 1.5mg At Night , Bid		Not Reported
	Preparation H Hemorrhoidal Ointment			S		Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2013	9732655	EXPEDITED (15-DAY)		CA	US-FRI-1000051873		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2013	9734105	EXPEDITED (15-DAY)		CA	US-FRI-1000051854		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Atresia; Congenital Ectopic Bladder; Epispadias; Inguinal Hernia; Perineal Fistula; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2013	9627774	EXPEDITED (15-DAY)		DE	FR-FRI-1000050115		31 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Suicidal Behaviour	Escitalopram			S	Oral	1 Df		Forest
	Baclofene Zentiva			S	Oral	Progressive Titration To 60 Mg Daily		Not Reported
	Diazepam Ratiopharm			S	Oral	3 Df		Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2013	9708616	EXPEDITED (15-DAY)		HO	IT-FRI-1000051674		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Escitalopram			S	Oral	10 Mg		Forest
	Lormetazepam			S	Oropharingeal	1 Df		Not Reported
	Xanax			S	Oral	1 Df		Not Reported
	Control (Lorazepam)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2013	9052854	EXPEDITED (15-DAY)		HO	IT-FRI-1000042489		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Respiratory Acidosis; Respiratory Depression; Sopor	Escitalopram			S	Oral	18 Tablets Taken At Once As An Overdose.		Forest
	Paracetamol			S	Oral	28 Tablets Taken At Once As An Overdose.		Not Reported
	Venlafaxine			S	Oral	21 Tablets Taken At Once As An Overdose.		Not Reported
	Patrol			S	Oral	(37.5 Mg/325 Mg) 4 Tablets Taken At Once As An Overdose.		Not Reported
	Moment			S	Oral	18 Tablets Taken At Once As An Overdose.		Not Reported
	Lexotan			S	Oral	51 Tablets Taken At Once As An Overdose.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2013	9708787	EXPEDITED (15-DAY)		OT	JP-FRI-1000051631		70 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness Postural	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2013	9741177	EXPEDITED (15-DAY)		HO	FR-FRI-1000051979		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brief Psychotic Disorder With Marked Stressors; Chest Pain; Hallucination; Major Depression; Petit Mal Epilepsy	Escitalopram			S				Forest
	Contramal			S				Not Reported
	Epitomax			S				Not Reported
	Tercian			S		15 Drops Once		Not Reported

Modiodal	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2013	9746325	DIRECT					55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Disturbance In Attention; Dizziness; Memory Impairment; Nausea	Escitalopram			S	Oral		1 YR	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2013	9099878	EXPEDITED (15-DAY)		HO	IT-JNJFOC-20130203452		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyspnoea; Intentional Overdose; Loss Of Consciousness; Respiratory Acidosis; Respiratory Depression; Sopor; Suicidal Ideation; Toxicity To Various Agents	Patrol			S	Oral	150 Mg + 1300 Mg		Not Reported
	Lexotan			S	Oral	76.5 Mg		Not Reported
	Cipralex			S	Oral	180 Mg		Not Reported
	Moment 200			S	Oral	3600 Mg		Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2013	9632673	EXPEDITED (15-DAY)		HO, OT	ES-ELI_LILLY_AND_COMPANY-ES201310005292		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hyponatraemia; Suicidal Behaviour	Olanzapine			S	Unknown	5 Mg, Qd		Unknown
	Haloperidol			S	Unknown	20 Gtt, Qd		Not Reported
	Haloperidol			S		10 Gtt, Qd		Not Reported
	Clorazepate Dipotassium			C	Unknown	3 Df, Qd		Not Reported
	Clorazepate Dipotassium			C		10 Mg, Qd		Not Reported

	Enalapril	S	Unknown			Not Reported
	Escitalopram	S	Unknown	10 Mg, Qd		Not Reported
	Agomelatine	C	Unknown	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2013	9636031	EXPEDITED (15-DAY)		DE	FR-TEVA-437289ISR		31 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Suicidal Behaviour	Diazepam Ratiopharm 10mg			S	Oral	3 Dosage Forms Daily;		Barr
	Baclofene Zentiva 10mg			S	Oral	Progressive Increase To 60mg/D		Not Reported
	Seroplex 10mg			S	Oral	1 Dosage Forms Daily;		Not Reported
	Zopiclone Ratiopharm			C		1 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2013	9703299	EXPEDITED (15-DAY)		OT	US-ACCORD-020406		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Overdose	Dihydrocodeine/Paracetamol			C				Not Reported
	Escitalopram			S		Took Escitalopram Overdose		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2013	9735284	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2013345324		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Amlor			S	Oral	5 Mg, 1x/Day		Pfizer
	Furosemide			S	Oral	20 Mg, 1x/Day		Not Reported
	Previscan (Fluindione)			S	Oral	Unk		Not Reported
	Previscan			S	Oral	Unk		Not Reported

	Seroplex	S	Oral	10 Mg, 1x/Day		Not Reported
	Levothyrox	S	Oral	150 Ug, 1x/Day		Not Reported
	Contramal	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2013	9729924	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2013-09871			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Maternal Drugs Affecting Foetus	Paroxetine			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2013	9745755	EXPEDITED (15-DAY)		HO	FR-MERCK-1312FRA001020		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Zocor 20mg			S	Oral	20 Mg, Qd		Merck
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Previscan (Fluindione)			S	Oral	Unk		Not Reported
	Triatec (Ramipril)			C	Oral	5 Mg, Qd		Not Reported
	Triatec (Ramipril)			C	Oral	5 Mg, Qd		Not Reported
	Zanidip			C	Oral	10 Mg, Qd		Not Reported
	Betaserc			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2013	9746368	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2013351465		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Logorrhoea; Neck Injury	Xanax			S	Oral	0.5 Mg, Unk		Pfizer
	Xanax			S	Oral	0.25 Mg, Unk (Splitting It		Pfizer

				Into Half)	
	Effexor Xr		S	37.5 Mg, Unk	Pfizer
	Lexapro		S	40 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2013	9841712	NON-EXPEDITED		OT	ALL1-2012-02058		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Depression; Disturbance In Attention; Drug Ineffective; Product Prescribing Error; Product Quality Issue; Pyrexia; Sluggishness; Tremor; Yawning	Vyvanse (Lisdexamfetamine Dimesylate) Capsule			S	Oral	50 Mg, 3-4 Times Per Week As Req'D, Oral		Not Reported
					Oral			
	Amoxapine (Amoxapine)			S	Oral			Not Reported
	Wellbutrin (Bupropion Hydrochloride)			S	Oral			Not Reported
	Lexapro (Escitalopram Oxalate)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2013	8505660	EXPEDITED (15-DAY)		HO, OT	PHHY2012FR029732		52 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholic Liver Disease; Ascites; Condition Aggravated; Gynaecomastia; Hepatic Cirrhosis; Hepatic Enzyme Increased; Hepatic Failure; Hepatocellular Injury; Hepatomegaly; Jaundice; Liver Injury	Rasilez Hct			S	Oral	1 Df, (150 Mg Ali/ 12.5 Mg Hct)		Novartis
	Anafranil			S		37.5 Mg, Qd		Not Reported
	Alprazolam			S		0.25 Mg, Tid		Not Reported
	Seroplex			S		20 Mg, Qd		Not Reported
	Zyprexa			S		5 Mg, Qd		Not Reported
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2013	9059642	EXPEDITED (15-DAY)		HO	IT-RANBAXY-2013R1-65084		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Overdose; Respiratory Acidosis; Respiratory Depression; Somnolence	Venlafaxine		S	Oral	21 Dosage Units, Complete		Not Reported
	Paracetamol	Y	S	Oral	28 Dosage Units, Complete		Ohm Lab
	Cipralex		S	Oral	18 Dosage Units, Complete		Not Reported
	Patrol		S	Oral	4 Dosage Units, Complete		Not Reported
	Moment		S	Oral	18 Dosage Units, Complete		Not Reported
	Lexotan		S	Oral	51 Dosage Units, Complete		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2013	9249438	EXPEDITED (15-DAY)		DE	CA-FRI-1000044577		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Completed Suicide; Depression	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Seroquel			C	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2013	9698963	EXPEDITED (15-DAY)	Y	HO	AUR-APL-2013-08972		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Drug Interaction; Dysuria; International Normalised Ratio Fluctuation; Urinary Retention	Escitalopram			S				Not Reported
	Ipratropium Bromide			S	Respiratory (inhalation)	Nebulizer		Not Reported
	Cephalexin (Cefalexin)			C				Not Reported
	Metoprolol (Metoprolol)			C				Not Reported
	Amiodarone (Amiodarone)			C				Not Reported
	Ranitidine (Ranitidine)			C				Not Reported
	Furosemide (Furosemide)			C				Not Reported
	Digoxin (Digoxin)			C				Not Reported
	Lisinopril (Lisinopril)			C				Not Reported

	Nystop (Nystatin)	C	Not Reported
	Nystatin (Nystatin)	C	Not Reported
	Combivent (Combivent)	C	Not Reported
	Insulin Lispro (Insulin Lispro)	C	Not Reported
	Warfarin (Warfarin)	C	Not Reported
	Acetaminophen (Paracetamol)	C	Not Reported
	Milk Of Magnesia (Magnesium Hydroxide)	C	Not Reported
	Bisacodyl (Bisacodyl)	C	Not Reported
	Omeprazole (Omeprazole)	C	Not Reported
	Mucinex	C	Not Reported
	Diphenhydramine (Diphenhydramine)	C	Not Reported
	Docusate W/Senna (Docusate W/Senna)	C	Not Reported
	Triamcinolone (Triamcinolone)	C	Not Reported
	Fluticasone Propionate	C	Not Reported
	Ondansetron (Ondansetron)	C	Not Reported
	Albuterol (Salbutamol)	C	Not Reported
	Omeprazole (Omeprazole)	C	Not Reported
	Dimethicone (Dimeticone)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2013	9750336	EXPEDITED (15-DAY)		HO	FR-FRI-1000052172		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Subdural Haematoma	Escitalopram			S	Oral	1 Df		Forest
	Zocor			S	Oral	1 Df		Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Triatec (Ramipril)			C	Oral	1 Df		Not Reported
	Zanidip			C	Oral	1 Df		Not Reported
	Betaserc			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2013	9752020	DIRECT		OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Panic Reaction	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2013	9752167	DIRECT		OT			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Economic Problem; Product Substitution Issue	Escitalopram			S	Oral	1 1/2 Pills Once Daily Taken By Mouth	2 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2013	9752175	DIRECT		DS, OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Generalised Anxiety Disorder; Headache; Product Substitution Issue	Lexapro Generic 10mg			S		Lexapro/30		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2013	9252916	EXPEDITED (15-DAY)		DE, OT	CA-FRI-1000044638		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bradykinesia; Cogwheel Rigidity; Confusional State; Drug Ineffective; Drug Intolerance; Hyperhidrosis; Parkinsonism; Resting Tremor	Citalopram			S	Oral	10 Mg		Forest
	Citalopram			S	Oral	20 Mg		Not Reported
	Escitalopram			S		10 Mg		Forest
	Clomipramine			S	Oral	25 Mg		Not Reported
	Clomipramine			S	Oral			Not Reported
	Haloperidol			S		1 Mg		Not Reported
	Olanzapine			S	Oral	15 Mg		Not Reported
	Paroxetine			S		5 Mg		Not Reported

	Paroxetine	S	10 Mg	Not Reported
	Quetiapine	S	25 Mg	Not Reported
	Sertraline	S		Not Reported
	Trazodone	S		Not Reported
	Valproic Acid	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2013	9752609	EXPEDITED (15-DAY)		HO	IT-JNJFOC-20131204888		86 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Intentional Overdose; Psychomotor Hyperactivity; Sopor	Serenase (Haloperidol)			S	Oral			Not Reported
	Serenase			S	Oral	0.5 Unspecified Units Twice An Unspecified Period		Not Reported
	Serenase			S	Oral			Not Reported
	Serenase			S	Oral	0.5 Unspecified Units Twice An Unspecified Period		Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Metformina			S	Oral	Once An Unspecified Period		Not Reported
	Metformina			S	Oral			Not Reported
	Metformina			S	Oral	Once An Unspecified Period		Not Reported
	Metformina			S	Oral			Not Reported
	Bisoprolol			S	Oral			Not Reported
	Bisoprolol			S	Oral	2.5 Unspecified Units Twice An Unspecified Period		Not Reported
	Bisoprolol			S	Oral			Not Reported

Bisoprolol	S	Oral	2.5 Unspecified Units Twice An Unspecified Period		Not Reported
Tavor (Lorazepam)	S	Oral			Not Reported
Diamicron	S	Oral	30 Unspecified Units Thrice An Unspecified Period		Not Reported
Diamicron	S	Oral			Not Reported
Diamicron	S	Oral			Not Reported
Diamicron	S	Oral	30 Unspecified Units Thrice An Unspecified Period		Not Reported
Tachipirina	S	Oral			Not Reported
Coumadin	C	Unknown			Not Reported
Dibase	C	Unknown	100 Unspecified Units		Not Reported
Nexium	C	Unknown			Not Reported
Isoptin	C	Unknown			Not Reported
Macrogol	C	Unknown	20 Unspecified Units Once An Unspecified Period		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2013	9752725	EXPEDITED (15-DAY)		OT	CH-FRI-1000052207			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Withdrawal Syndrome	Escitalopram			S	Oral	3.75 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2013	9752760	EXPEDITED (15-DAY)		HO	FR-FRI-1000052209		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram			S	Oral	1 Df		Forest

	Previscan (Fluindione)	S	Oral			Not Reported
	Amlor	S	Oral	1 Df		Not Reported
	Furosemide	S	Oral	1 Df		Not Reported
	Levothyrox	S	Oral	150 Mcg		Not Reported
	Contramal	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2013	9752785	EXPEDITED (15-DAY)		HO	NL-FRI-1000052208		60 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S				Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2013	9756642	EXPEDITED (15-DAY)		OT	FR-FRI-1000052211			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dementia; Haemorrhage; Insomnia	Escitalopram			S				Forest
	Propranolol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2013	9756662	EXPEDITED (15-DAY)		HO	FR-FRI-1000052206		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Orthostatic Hypotension	Escitalopram			S	Oral	1 Df		Forest
	Fluanxol			S	Oral	120 Df		Not Reported
	Leponex			S	Oral	1 Df		Not Reported
	Xatral			S	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2013	9756668	EXPEDITED (15-DAY)		HO	FR-FRI-1000052210		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Escitalopram			S	Oral	1 Df		Forest
	Escitalopram			S				Forest
	Risperdal			S	Oral			Not Reported
	Risperdal			S				Not Reported
	Eucreas			S	Oral	100/1700 Mg		Not Reported
	Kardegic			C				Not Reported
	Ikorel			C				Not Reported
	Crestor			C				Not Reported
	Duphalac			C				Not Reported
	Cacit [Calcium Carbonate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2013	9756677	EXPEDITED (15-DAY)		HO	IT-ACTAVIS-2013-22321		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Respiratory Acidosis; Respiratory Depression; Sopor	Venlafaxine (Unknown)			S	Oral	21 Df, Single		Not Reported
	Paracetamol (Unknown)			S	Oral	28 Df, Single		Actavis Mid Atlantic
	Cipralex			S	Oral	18 Df, Single		Not Reported
	Lexotan			S	Oral	51 Df, Single		Not Reported
	Moment 200			S	Oral	18 Df, Single		Not Reported
	Patrol			S	Oral	4 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2013	10022181	EXPEDITED (15-DAY)		OT	BR-TORRENT-00001828-01		69 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hemiparesis; Tremor	Espran (Inn:Escitalopram Oxalate)			S	Oral	Once Daily/Oral		Not Reported

	Amato	C	Not Reported
	Glucovance	C	Not Reported
	Enalabal	C	Not Reported
	Simvastatin	C	Not Reported
	Stugeron	C	Not Reported
	Amiodarone	C	Not Reported
	Levothyroxine	C	Not Reported
	Bromazepam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2013	9757907	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20131207327		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Contramal			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Amlor			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2013	9757914	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20131202220		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Eucreas			S	Oral	50 Mg/850 Mg		Not Reported
	Kardegic			C	Unknown	160		Not Reported
	Ikorel			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported

	Duphalac	C	Unknown	Not Reported
	Cacit Nos	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2013	9759504	EXPEDITED (15-DAY)		LT	FR-FRI-1000052254		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mood Altered; Suicide Attempt	Escitalopram			S	Oral	1 Df		Forest
	Temesta (Lorazepam)			S	Oral			Not Reported
	Coaprovel			C				Not Reported
	Lercan			C				Not Reported
	Zyloric			C				Not Reported
	Praxilene			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2013	9759593	EXPEDITED (15-DAY)		HO	FR-FRI-1000052257		35 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Hypothermia; Intentional Overdose; Toxic Encephalopathy	Escitalopram			S	Oral	Overdose With One Intake Of 14 Tablets Of 20 Mg		Forest
	Baclofene			S	Oral	Overdose With One Intake Of 20 Df		Not Reported
	Seresta			S	Oral	Overdose With One Intake Of 100 Tablets Of 50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2013	9762023	EXPEDITED (15-DAY)		OT	US-FRI-1000052291		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Food Craving; Impaired Driving Ability; Inappropriate Affect; Obsessive-Compulsive	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	2.5 Mg		Not Reported

Disorder; Paraesthesia; Suicidal Ideation; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2013	9762785	EXPEDITED (15-DAY)		HO	IT-FRI-1000052282		86 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Intentional Overdose; Psychomotor Hyperactivity; Sopor	Escitalopram			S	Oral			Forest
	Metformin			S	Oral			Not Reported
	Bisoprolol Hemifumarate			S	Oral			Not Reported
	Tavor (Lorazepam)			S				Not Reported
	Diamicron			S	Oral			Not Reported
	Tachipirina			S	Oral			Not Reported
	Serenase (Haloperidol)			S	Oral			Not Reported
	Coumadin			C				Not Reported
	Dibase			C	Intramuscular	1 Vial / Month		Not Reported
	Nexium			C				Not Reported
	Isoptin			C				Not Reported
	Onligol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2013	9767710	EXPEDITED (15-DAY)		HO	PHHY2013IT145616			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Intentional Overdose; Psychomotor Hyperactivity; Somnolence	Metformin			S	Oral	1500 Mg, Once/Single		Novartis
	Bisoprolol			S	Oral	3 Df, Once/Single		Not Reported
	Tavor (Lorazepam)			S	Oral	6 Df, Once/Single		Not Reported
	Cipralex//Escitalopram			S	Oral	3 Df, Once/Single		Not Reported
	Diamicron			S	Oral	3 Df, Once/Single		Not Reported
	Tachipirina			S	Oral	3 Df, Once/Single		Not Reported
	Serenase (Haloperidol)			S	Oral	2 Df, Once/Single		Not Reported

	Coumadin//Warfarin Sodium	C			Not Reported
	Dibase	C	Intramuscular	1 Ukn, Qmo	Not Reported
	Nexium//Esomeprazole Sodium	C			Not Reported
	Isoptin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2013	9768251	EXPEDITED (15-DAY)		HO	FR-FRI-1000052313		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Overdose	Escitalopram			S	Oral	Titration Up To 35 Mg Daily		Forest
	Escitalopram			S	Oral	30 Mg		Not Reported
	Theralene			S	Oral	15 Df		Not Reported
	Mianserine			S		30 Mg		Not Reported
	Xeroquel			S	Oral	Progressive Titration Up To 200 Mg Daily		Not Reported
	Imovane			C	Oral	7.5 Mg		Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C	Oral	2 Df		Not Reported
	Seresta			C	Oral	3 Df		Not Reported
	Xarelto			C	Oral	1 Df		Not Reported
	Propranolol			C		80 Mg		Not Reported
	Inexium			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2013	9768274	EXPEDITED (15-DAY)		HO	FR-FRI-1000052284		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Subdural Haematoma	Escitalopram			S	Oral			Forest

	Aspegic [Acetylsalicylate Lysine]	S	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2013	9768295	EXPEDITED (15-DAY)		OT	CA-FRI-1000052285			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Diarrhoea; Diarrhoea Haemorrhagic; Emotional Disorder; Fatigue; Feeling Abnormal; Insomnia; Sexual Dysfunction	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2013	9768319	EXPEDITED (15-DAY)		HO	FR-FRI-1000052287		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperreflexia; Hypertonia; Hyponatraemia; Mydriasis; Prescribed Overdose	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	30 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Seresta			C	Oral	70 Mg		Not Reported
	Imovane			C	Oral	7.5 Mg		Not Reported
	Levothyrox			C	Oral	12.5 Mcg		Not Reported
	Vogalene			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2013	9768332	EXPEDITED (15-DAY)		HO	AU-FRI-1000052288		71 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S		15 Mg		Forest
	Progout			C		300 Mg		Not Reported
	Temaze			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2013	9769044	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicidal Behaviour	Lexapro			S	Oral	2 Tabs. Qd.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2013	9772505	EXPEDITED (15-DAY)	Y	HO	7255301		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Previscan (Fluindione) (Fluindione)			S	Oral Oral	Renewed As Home Discharge Treatment		Not Reported
	Levothroxine Sodium			S	Oral	150 Mcg (150 Mcg, 1 In 1 D), Oral Long Term		Not Reported
	Seroplex			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Amlor			S	Oral	5 Mg (5 Mg, 1 In 1 D), Oral		Not Reported
	Furosemide			S	Oral	20 Mg (20 Mg, 1 In 1 D), Oral, Ongoing (Long Term)		Not Reported
	Contramal			S	Oral	Ongoing (Long Term)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2013	8466572	EXPEDITED (15-DAY)		HO	AU-PFIZER INC-2012063736		40 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine	Varenicline Tartrate			S	Oral	0.5 Mg, 1x/Day		Pfizer
	Varenicline Tartrate			S	Oral	0.5 Mg, 2x/Day		Pfizer
	Varenicline Tartrate			S	Oral	0.5 Mg (2 Tablets) 2x/Day		Pfizer

	Depo-Provera	S	Intramuscular	Unk, Every 3 Months	Pfizer
	Lexapro	S	Oral	20 Mg, Daily	Not Reported
	Cymbalta	S	Oral	30 Mg, Daily	Not Reported
	Thyroxine	C	Oral	50 Mg, Daily	Not Reported
	Esomeprazole	C	Oral	20 Mg, As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2013	9769107	EXPEDITED (15-DAY)		HO	US-JNJFOC-20131207478		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Tremor	Risperdal			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Abilify			S	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2013	9770961	EXPEDITED (15-DAY)		OT	IT-FRI-1000041373			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pre-Eclampsia; Pregnancy	Escitalopram			S		10 Mg		Forest
	Escitalopram			S		10 Mg		Forest
	Alprazolam			C		0.25 Mg		Not Reported
	Levothyroxine			C		125 Mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2013	9771217	EXPEDITED (15-DAY)		HO	FR-FRI-1000052349		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Ataxia;	Escitalopram			S	Oral	10 Mg		Forest

Behaviour Disorder; Drug Interaction; Hallucination	Escitalopram		S	Oral	5 Mg	Not Reported
	Tramadol Biogaran		S	Oral	2 Df	Not Reported
	Paracetamol		C	Oral		Not Reported
	Kardegic		C	Oral	1 Df	Not Reported
	Amlor		C	Oral	1 Df	Not Reported
	Tahor		C	Oral	1 Df	Not Reported
	Xanax		C	Oral	1 Df	Not Reported
	Allopurinol		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2013	9772420	DIRECT	Y	HO			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Dyspnoea; Swollen Tongue	Lexapro			S	Oral	1 Tablet		Not Reported
	Lisinopril			S	Oral	Past 10 Years 1 Tablet Bid Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2013	9773150	EXPEDITED (15-DAY)		DS	US-BRISTOL-MYERS SQUIBB COMPANY-19828367		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nystagmus; Vision Blurred	Abilify			S	Oral	Dose Increased To 15 Mg Later Reduced To 5 Mg		Not Reported
	Lexapro			S	Oral			Not Reported
	Adderall Xr			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2013	9773604	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000052256		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Congenital Anomaly; Hypoplastic Left Heart Syndrome; Neonatal Multi-Organ Failure	Lexapro	S	Transplacental		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2013	9637906	EXPEDITED (15-DAY)			JP-ELI_LILLY_AND_COMPANY-JP201309008372		48 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperprolactinaemia	Cymbalta			S	Oral	20 Mg, Qd		Eli Lilly And Co
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Primperan			S	Oral	1 Df, Bid		Not Reported
	Sepazon			C	Oral	1 Mg, Bid		Not Reported
	Magmitt			C	Oral	660 Mg, Qd		Not Reported
	Cepharanthin			C	Oral	1 Mg, Bid		Not Reported
	Promac /01312301/			C	Oral	75 Mg, Bid		Not Reported
	Ferromia /00023520/			C	Oral	50 Mg, Bid		Not Reported
	Selbex			C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2013	9776270	EXPEDITED (15-DAY)		CA	US-FRI-1000052341		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2013	9776356	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-113AS20130478		86 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Abuse; Intentional Overdose; Psychomotor	Metformin			S	Oral	1500 Mg Total		Mylan
	Bisoprolol Hemifumarate			S	Oral	3 Df Total		Not Reported

Hyperactivity; Sopor	Tavor (Lorazepam)	S	Oral	6 Df Total		Not Reported
	Cipralex	S	Oral	3 Df Total		Not Reported
	Diamicron	S	Oral	3 Df Total		Not Reported
	Tachipirina	S	Oral	3 Df Total		Not Reported
	Serenase /00027401/	S	Oral	2 Df Total		Not Reported
	Coumadin - 5 Mg Compresse	C				Not Reported
	Dibase	C				Not Reported
	Nexium	C				Not Reported
	Isoptin - 80 Mg Compresse	C				Not Reported
	Rivestite Con Film Onligol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2013	8385704	NON-EXPEDITED			2012SP002852		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Interaction; Hypoaesthesia	Meloxicam			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2013	9779100	EXPEDITED (15-DAY)		LT, OT	GB-ELI_LILLY_AND_COMPANY-GB201312005528			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration	Zyprexa			S	Unknown	15 Mg, Unknown		Eli Lilly And Co
	Escitalopram			S	Unknown	30 Mg, Unknown		Not Reported
	Priadel /00033702/			S	Unknown	1000 G, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2013	9779455	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2013364530		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional	Lyrica			S	Oral	21 Df, Single		Pfizer

State; Depressed Level Of Consciousness; Drug Screen Positive; Intentional Overdose; Somnolence; Toxicity To Various Agents	Olanzapine		S	Oral	Unk	Not Reported
	Olanzapine		S	Oral	28 Df, Single 7.5 Mg	Not Reported
	Lexomil		S	Oral	Unk	Not Reported
	Lexomil		S	Oral	15 Df, Single	Not Reported
	Seroplex		S	Oral		Not Reported
	Seroplex		S	Oral	12 Df, Single 20 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2013	9781185	DIRECT		OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Blood Cholesterol Increased; Blood Triglycerides Increased; Dizziness; Drug Withdrawal Syndrome; Extrasystoles; Paraesthesia; Weight Increased	Lexapro			S	Oral	Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2013	9781233	DIRECT		OT			5 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2013	9783589	EXPEDITED (15-DAY)	Y	HO	2013AP010571		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Small Vessel Ischaemic Disease; Electroencephalogram	Gabapentin			S				Not Reported
	Trazodone Hydrochloride Tablets			S				Not Reported

Abnormal; Off Label Use; Thalamic Infarction	Escitalopram Oxalate	S	20 Mg, Am		Not Reported
	Levetiracetam	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2013	9780677	EXPEDITED (15-DAY)		OT	ES-RANBAXY-2013RR-74017		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Hyponatraemia	Venlafaxine			S	Unknown	150 Mg/D		Not Reported
	Escitalopram			S	Unknown	10 Mg/Day		Not Reported
	Olanzapine			S	Unknown	5 Mg/Day		Not Reported
	Haloperidol			S	Unknown	20 Drops/Day		Not Reported
	Haloperidol			S	Unknown	10 Drops/Day		Not Reported
	Enalapril			S	Unknown	Unk		Ranbaxy
	Amiloride Hydrochloride/Hydrochlorothiazide			S	Unknown	5/50 G (1c/D)		Not Reported
	Citalopram			C	Unknown	20 Mg/Day		Not Reported
	Agomelatine			C	Unknown	25 Mg/Day		Not Reported
	Clorazepate Dipotasium			C	Unknown	10mg (3c/D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2013	9848542	NON-EXPEDITED	Y	OT	PHEH2013US004433		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Tachycardia	Clozaril			S	Oral			Not Reported
	Lexapro (Escitalopram Oxalate)			S				Not Reported
	Eskalith Cr (Lithium Carbonate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2013	9525982	EXPEDITED (15-DAY)		DE, HO	FR-SANOFI-AVENTIS-2013SA090853		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Blister; Eschar; Graft Versus Host Disease In Gastrointestinal Tract; Haematuria; Hepatitis Acute; Mucosal Erosion; Multiple Organ Dysfunction Syndrome; Oedema; Skin Erosion; Skin Lesion; Toxic Epidermal Necrolysis	Granocyte	S	Intravenous (not otherwise specified)		Not Reported
	Heparin Sodium	S	Intravenous (not otherwise specified)	Dose:7000 Milliunit(S)	Not Reported
	Lasilix	S	Intravenous (not otherwise specified)		Not Reported
	Largactil	S	Intravenous (not otherwise specified)		Not Reported
	Exacyl	S	Intravenous (not otherwise specified)		Not Reported
	Flagyl	S	Oral		Not Reported
	Fortum	S	Intravenous (not otherwise specified)		Not Reported
	Gentamicin Sulfate	S	Intravenous (not otherwise specified)		Not Reported
	Noxafil	S	Oral		Not Reported
	Cancidas	S	Intravenous (not otherwise specified)		Not Reported
	Ambisome	S	Intravenous (not otherwise specified)		Not Reported
	Bactrim	S	Intravenous (not otherwise specified)		Not Reported
	Folinic Acid	S	Intravenous (not otherwise specified)		Not Reported
	Zelitrex	S	Intravenous (not otherwise specified)		Not Reported
	Cymevene	S	Intravenous (not otherwise specified)		Not Reported
	Foscavir	S	Intravenous (not otherwise specified)		Not Reported
	Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)		Not Reported
	Inexium	S	Intravenous (not otherwise specified)		Not Reported

Spasfon (Phloroglucinol, Trimethylphloroglucinol)	S	Intravenous (not otherwise specified)	Not Reported
Delursan	S	Oral	Not Reported
Defibrotide	S	Intravenous (not otherwise specified)	Not Reported
Tranxene	S	Oral	Not Reported
Oxynorm	S	Intravenous (not otherwise specified)	Not Reported
Perfalgan	S	Intravenous (not otherwise specified)	Not Reported
Solumedrol	S	Intravenous (not otherwise specified)	Not Reported
Droleptan	S	Intravenous (not otherwise specified)	Not Reported
Ultiva	S	Intravenous (not otherwise specified)	Not Reported
Atarax	S	Oral	Not Reported
Seroplex	S	Oral	Not Reported
Ceris	S	Oral	Not Reported
Noctamide	S	Oral	Not Reported
Colistin	C		Not Reported
Vancomycine	C		Not Reported
Ciflox	C		Not Reported
Targocid	C		Not Reported
Mycostatine	C		Not Reported
Triflucan	C		Not Reported
Zovirax	C		Not Reported
Methotrexate	C		Not Reported
Elvorine	C		Not Reported
Sandimmun	C		Not Reported
Mopral	C		Not Reported
Ogastoro	C		Not Reported
Gelox	C		Not Reported
Smecta	C		Not Reported
Luteran	C		Not Reported
Lexomil	C		Not Reported

Noctamide	C		Not Reported
Zophren	C		Not Reported
Primperan	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2013	9549603	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2013269020		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Fall; Inappropriate Antidiuretic Hormone Secretion; Nausea; Radius Fracture	Sertraline Hcl			S	Oral	25 Mg, Daily		Pfizer
	Luvox			S		Unk		Not Reported
	Luvox			S		50 Mg, Unk		Not Reported
	Luvox			S		75 Mg/Day		Not Reported
	Mirtazapine			S		7.5 Mg/Day		Not Reported
	Escitalopram Oxalate			S		15 Mg/Day		Not Reported
	Duloxetine			S		40 Mg/Day		Not Reported
	Benzalin (Nitrazepam)			S	Oral	25 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2013	9783971	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2013363260		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Xanax			S		0.5 Mg, 3x/Day		Pfizer
	Seroplex			S	Oral	40 Mg, 1x/Day		Not Reported
	Noctamide			S	Oral	2 Mg, 1x/Day		Not Reported
	Lovenox			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2013	9785223	DIRECT					38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Product	Lexapro 10mg (Generic)			S	Oral		1 MTH	Not Reported

Substitution Issue

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2013	9060917	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2013S1002558		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Intentional Overdose; Respiratory Acidosis; Respiratory Depression; Sopor	Venlafaxine			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Lexotan			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Patrol			S	Oral			Not Reported
	Moment			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2013	9785978	EXPEDITED (15-DAY)		DE	IE-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-BI-43		69 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis; Haematemesis; Haemoglobin Decreased	Persantin Retard			S		15 Ml		Boehringer Ingelheim
	Aspirin			S		75 Mg		Not Reported
	Lexapro			S		10 Mg		Not Reported
	Lansoprazole			C		30 Mg		Not Reported
	Sitagliptin			C		100 Mg		Not Reported
	Levetiracetam			C	Oral	1500 Mg		Not Reported
	Alprazolam			C		1 Ml		Not Reported
	Ondansetron			C		Route: Peg		Not Reported
	Zopiclone			C		Route: Peg		Not Reported
	Calogen			C		90 Ml		Not Reported
	Metoprolol Tartrate			C		25 Mg		Not Reported
	Cyclizine			C		150 Mg		Not Reported

	Gaviscon Liquid	C		Route: Peg, Dose: 10-25ml	Not Reported
	Lyrica	C		25 Mg	Not Reported
	Pharmaton Kiddi	C		15 Ml	Not Reported
	Perindopril	C	Oral	5 Mg	Not Reported
	Lactulose	C		30 Ml	Not Reported
	Paracetamol	C	Oral	4 G	Not Reported
	Risperidone	C		0.5 Mg	Not Reported
	Procal	C		90 Ml	Not Reported
	Nutrison	C		1000 Ml	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2013	9786047	EXPEDITED (15-DAY)		OT	FR-SA-2013SA132694		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Lovenox			S	Subcutaneous			Not Reported
	Xanax			S	Oral			Not Reported
	Noctamide			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2013	9786410	EXPEDITED (15-DAY)		HO	JP-FRI-1000052466		70 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal	Lexapro			S	Oral	10 Mg		Forest
	Contomin			C	Oral	50 Mg		Not Reported
	Contomin			C	Oral			Not Reported
	Contomin			C	Oral			Not Reported
	Contomin			C	Oral			Not Reported
	Risperdal			C	Oral	2 Mg		Not Reported

Risperidone	C	Oral	3 Mg		Not Reported
Tasmolin	C	Oral	3 Mg		Not Reported
Tasmolin	C	Oral	3 Mg		Not Reported
Tasmolin	C	Oral	6 Mg		Not Reported
Tasmolin	C	Oral	5 Mg		Not Reported
Tasmolin	C	Oral	4 Mg		Not Reported
Tasmolin	C	Oral	3 Mg		Not Reported
Tasmolin	C	Oral	2 Mg		Not Reported
Eurodin (Estazolam)	C	Oral	1 Mg		Not Reported
Eurodin (Estazolam)	C	Oral	2 Mg		Not Reported
Memary	C	Oral	20 Mg		Not Reported
Eticalm	C	Oral	0.5 Mg		Not Reported
Tsumura Yokukansan Extract Granules For Ethical Use	C	Oral	3 Df		Not Reported
Solita-T No.3	C		1000 Ml		Not Reported
Solita-T No.3	C		1500 Ml		Not Reported
Solita-T No.3	C		500 Ml		Not Reported
C-Para	C		2 Ml		Not Reported
Tarivid	C				Not Reported
Racol	C				Not Reported
Akineton	C	Oral	3 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2013	9786434	EXPEDITED (15-DAY)		DE	FR-FRI-1000052478		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged	Escitalopram			S				Forest
	Sotalol			S		2 Df		Not Reported
	Fludex (Indapamide)			S	Oral	1.5 Mg		Not Reported
	Hexaquine			S		1 Df		Not Reported
	Rilmenidine			C		2 Mg		Not Reported

	Praxilene	C	400 Mg	Not Reported
	Onglyza	C	5 Mg	Not Reported
	Previscan (Fluindione)	C	1.25 Df	Not Reported
	Coversyl	C		Not Reported
	Baclofene	C	30 Mg	Not Reported
	Lexomil	C	1 Df	Not Reported
	Doliprane Codeine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2013	9786532	EXPEDITED (15-DAY)		HO	FR-FRI-1000052434		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Labelled Drug-Drug Interaction Medication Error; Overdose; Urinary Retention	Escitalopram			S	Oral			Forest
	Stilnox			S				Not Reported
	Xeroquel			S				Not Reported
	Moclamine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2013	9786592	NON-EXPEDITED			US-PFIZER INC-2013368806			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Speech Disorder	Lipitor			S		Unk		Pfizer
	Ogen			S		Unk		Pfizer
	Provera			S		Unk		Pfizer
	Victoza			S		Unk		Not Reported
	Abilify			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Diovan			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Potassium			S		Unk		Not Reported
	Synthroid			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2013	9787855	DIRECT		OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Weight Decreased; Weight Gain Poor	Escitalopram Teva Ritecol May Have -301-267-2955			S	Oral	Ndc # 10mg-00093585101 20mg 0009358201 Strength:10 Mg 1 Week 20 Mg Quantity:1 Month Frequency:Once Ady How Was It Taken Or Used: Mouth		Teva
	Lorezepam			C				Not Reported
	Wellbutrin			C				Not Reported
	Geodon			C				Not Reported
	Famitodore			C				Not Reported
	Protonix			C				Not Reported
	Vit. K			C				Not Reported
	Fish Oil			C				Not Reported
	Multivitamins			C				Not Reported
	Calcium			C				Not Reported
	Antiosidents			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9274773	EXPEDITED (15-DAY)		CA, OT	US-JNJFOC-20130417571			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adhesion; Caesarean Section; Choking; Cleft Lip; Cleft Palate; Cough; Dacryostenosis Acquired; Dental Caries; Developmental Delay; Dysphagia; Jaundice Neonatal; Maternal Drugs Affecting Foetus; Nasal Disorder; Otitis Media Acute; Pilonidal Cyst;	Topamax			S	Transplacental			Not Reported
	Topamax			S	Transplacental			Not Reported
	Topamax			S	Transplacental			Not Reported
	Phenobarbital			S	Transplacental			Not Reported
	Depakote			S	Transplacental			Not Reported
	Neurontin			S	Unknown			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Lorazepam			S	Transplacental			Not Reported

Psychomotor Hyperactivity; Sensory Disturbance; Sleep Apnoea Syndrome; Sleep Terror; Snoring; Somnambulism; Spina Bifida; Umbilical Hernia	Promethazine		S	Transplacental	Not Reported
	Nitrofuran		S	Transplacental	Not Reported
	Cefaclor		S	Transplacental	Not Reported
	Fluconazole		S	Transplacental	Not Reported
	Fluoxetine		S	Transplacental	Not Reported
	Vitamin B2		C	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9773307	EXPEDITED (15-DAY)		HO	IT-FRI-1000052315		92 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Injury; Presyncope; Wound	Escitalopram			S	Oral	1 Df		Forest
	Coumadin 5 Mg Compresse			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9776253	EXPEDITED (15-DAY)		OT	DE-FRI-1000052396			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Pancreatic Failure; Prescribed Overdose	Escitalopram			S	Oral	Gradually Increased To 25 Mg/Day		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9787783	NON-EXPEDITED			US-PFIZER INC-2013368490		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Procardia			S		Unk		Pfizer
	Norvasc			S		Unk		Pfizer
	Vasotec			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9787841	NON-EXPEDITED			US-PFIZER INC-2013370940		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9788642	EXPEDITED (15-DAY)		OT	FR-FRI-1000052448			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocarditis	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9788646	EXPEDITED (15-DAY)		LT	FR-FRI-1000052458		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Shock Haemorrhagic	Escitalopram			S	Oral			Forest
	Plavix			S	Oral	75 Mg		Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Lovenox			S		14000 Iu		Not Reported
	Triatec (Ramipril)			C				Not Reported
	Amlor			C				Not Reported
	Depamide			C				Not Reported
	Inexium			C				Not Reported
	Cordarone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9788708	EXPEDITED (15-DAY)		OT	FR-FRI-1000052461		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Neutropenia; Overdose	Escitalopram		S	Oral	Overdose With 40 Mg Daily Of Escitalopram	Forest
	Noctamide		S	Oral	2 Mg	Not Reported
	Xanax		S	Oral	1.5 Mg	Not Reported
	Lovenox		S	Oral	Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9788735	EXPEDITED (15-DAY)		HO	IT-FRI-1000052490		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyperpyrexia; Off Label Use; Rhabdomyolysis; Tremor	Escitalopram Oral Solution			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9788747	EXPEDITED (15-DAY)		DE	FR-FRI-1000052455		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Escitalopram			S	Oral	1 Df		Forest
	Trazolan			S	Oral	1 Df		Not Reported
	Sectral			S	Oral	1 Df		Not Reported
	Ixprim			C	Oral	112.50/975 Mg Daily		Not Reported
	Ebixa			C	Oral			Not Reported
	Alprazolam			C	Oral	3 Df		Not Reported
	Calcium/Vitamin D3			C	Oral	500 Mg/400 Iu - 12 Tablets Weekly		Not Reported
	Azopt			C		10 Mg/Ml Twice Daily		Not Reported
	Ogastoro			C	Oral	1 Df		Not Reported
	Acide Alendronique			C	Oral	10 Mg		Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium			C	Oral	1 Df		Not Reported

Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9789186	EXPEDITED (15-DAY)		HO	FR-FRI-1000052492		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Depressed Level Of Consciousness; Overdose; Somnolence	Escitalopram			S	Oral	Drug Overdose Of 12 Tablets		Forest
	Lexomil			S	Oral	Drug Overdose Of 15 Tablets		Not Reported
	Lyrica			S	Oral	Drug Overdose Of Of 21 Df		Not Reported
	Olanzapine			S	Oral	Drug Overdose Of 28 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2013	9789995	DIRECT		DS			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Fracture; Impaired Work Ability	Lexapro			S	Oral		8 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2013	8471999	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20111109040			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Cavity Infection; Bipolar Disorder; Emotional Distress; Exposure During Pregnancy; Premature Delivery; Premature	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported

Rupture Of Membranes; Premature Separation Of Placenta	Clindamycin	S	Vaginal	Not Reported
	Terbutaline	S	Oral	Not Reported
	Prometrium	S	Oral	Not Reported
	Lexapro	S	Oral	Not Reported
	Lithium Carbonate	S	Oral	Not Reported
	Zithromax	S	Unknown	Not Reported
	Betamethasone	S	Unknown	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Ampicillin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2013	9603368	EXPEDITED (15-DAY)		HO	CH-FRI-1000049606			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; International Normalised Ratio Increased	Escitalopram Oral Solution			S	Oral	20 Mg		Forest
	Xarelto			S	Oral	20 Mg		Not Reported
	Xarelto			S	Oral	15 Mg		Not Reported
	Flector			S		1 Df		Not Reported
	Nebilet			C		5 Mg		Not Reported
	Mephanol			C		300 Mg		Not Reported
	Marcoumar			C		3 Mg		Not Reported
	Vitamin D3			C				Not Reported
	Trittico			C		100 Mg		Not Reported
	Atorvastatin			C				Not Reported
	Novalgine (Metamizole Sodium)			C		1000 Mg		Not Reported
	Traumanase			C	Oral	3 Df		Not Reported
	Nopil Forte			C	Oral	2 Df		Not Reported
	Glaupax			C	Oral			Not Reported
	Cosopt			C	Oral			Not Reported
	Kimzalplus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2013	9776777	EXPEDITED (15-DAY)		OT	US-ASTRAZENECA-2013SE89265		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Faeces; Adverse Drug Reaction; Agitation; Arthralgia; Asthenia; Back Pain; Bone Pain; Breast Cancer; Constipation; Cough; Decreased Appetite; Discomfort; Diverticulitis; Dizziness; Drug Hypersensitivity; Fatigue; Fatigue; Feeling Abnormal; Hepatic Steatosis; Hypoaesthesia; Hypothyroidism; Injection Site Pain; Injection Site Reaction; Intentional Product Misuse; Laryngitis; Lethargy; Limb Discomfort; Listless; Mental Impairment; Muscle Atrophy; Muscle Spasms; Musculoskeletal Stiffness; Myalgia; Nausea; Nerve Injury; Pain; Quality Of Life Decreased; Respiratory Tract Infection; Sedation; Skin Odour Abnormal; Urine Odour Abnormal; Vomiting; Weight Fluctuation	Faslodex			S	Intramuscular			Not Reported
	Faslodex			S	Intramuscular			Not Reported
	Lexapro			S	Unknown			Not Reported
	Letrozol			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Unspecified Steroid Type Medication			S	Unknown			Not Reported
	Xegva			C				Not Reported
	Another Unidentified Medication			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2013	9790140	EXPEDITED (15-DAY)		HO	CH-FRI-1000052484			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestatic Liver Injury; Jaundice	Escitalopram			S	Oral	10 Mg		Forest
	Urispas			S	Oral	200 Mg		Not Reported
	Urispas			S	Oral	400 Mg		Not Reported
	Tasmar			S	Oral	200 Mg		Not Reported
	Motilium			S	Oral	40 Mg		Not Reported
	Motilium			S				Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			S				Not Reported
	Becosym Forte			C				Not Reported
	Exelon Patch			C				Not Reported
	Gutron			C				Not Reported
	Madopar			C				Not Reported
	Remeron			C				Not Reported
	Rivotril			C				Not Reported
	Seroquel			C				Not Reported
	Sinemet Cr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2013	9790179	EXPEDITED (15-DAY)		HO	FR-FRI-1000052452		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma; Traumatic Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Xarelto			S	Oral	15 Mg		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported
	Inexium			C				Not Reported
	Mono-Tildiem			C				Not Reported
	Simvastatine			C				Not Reported
	Temesta (Lorazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2014	9785448	EXPEDITED (15-DAY)		HO, OT	CH-009507513-1312CHE010276		55 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Increased; Coma; Electrocardiogram Qt Prolonged; Rhabdomyolysis; Suicide Attempt	Remeron			S	Oral	Frequency: 39 Df At Once		Merck
	Lorazepam			S	Oral	37 Df At Once		Not Reported
	Quetiapine Fumarate			S	Oral	Dose: 1.8-18 Mg; Frequency 6-60 Df At One		Not Reported
	Janumet			S	Oral	Total Daily Dose: 1.25/25 G; Frequency 25 Df At One		Merck
	Escitalopram			S	Oral	700 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2014	9791547	EXPEDITED (15-DAY)		HO	TR-US-EMD SERONO, INC.-7259696		21 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Multiple Sclerosis Relapse; Nausea; Toxicity To Various Agents; Vomiting	Rebif			S	Subcutaneous			Not Reported
	Cipralex /01588501/			S	Oral			Not Reported
	Brufen /00109201/			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2014	9336706	EXPEDITED (15-DAY)		DS, OT	JP-FRI-1000045731		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Pancytopenia; Renal Impairment	Lexapro			S	Oral	20 Mg		Forest
	Meilax			C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2014	9779308	EXPEDITED (15-DAY)		DE	CH-FRI-1000052398		55 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Sudden Death	Escitalopram			S		Overdose 30 Mg Daily		Forest
	Methadone			S				Not Reported
	Atazanavir			S				Not Reported
	Levomepromazine			S		50 Mg		Not Reported
	Zidovudine			S		600 Mg		Not Reported
	Lamivudine			S		300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2014	9793261	EXPEDITED (15-DAY)		DE	IE-FRI-1000052610		69 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis; Haematemesis; Haemoglobin Decreased	Escitalopram			S	Oral			Forest
	Aspirin			S	Oral			Not Reported
	Persantin Retard			S	Oral			Not Reported
	Gaviscon			C				Not Reported
	Lansoprazole			C	Oral			Not Reported
	Sitagliptin			C	Oral			Not Reported
	Levetiracetam			C		1500 Mg		Not Reported
	Alprazolam			C		1000 Mcg		Not Reported
	Ondansetron			C				Not Reported
	Zopiclone			C				Not Reported
	Calogen			C		90 Ml		Not Reported
	Metoprolol Tartrate			C		25 Mg		Not Reported
	Cyclizine			C				Not Reported
	Lyrica			C		25 Mg		Not Reported
	Pharmaton Kiddi			C		15 Ml		Not Reported
	Perindopril			C	Oral	5 Mg		Not Reported
	Lactulose			C		30 Ml		Not Reported
	Paracetamol			C		0.5 Mg		Not Reported
	Risperidone			C		0.5 Mg		Not Reported

	Procal	C	90 Ml	Not Reported
	Nutrison	C	1000 Ml	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2014	9797486	DIRECT		OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hot Flush; Influenza; Neuralgia	Lexapro 10mg (Generic)			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2014	8563320	EXPEDITED (15-DAY)		HO, OT	FR-ELI_LILLY_AND_COMPANY-FR201205000922		52 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure	Zyprexa			S	Oral	5 Mg, Qd		Eli Lilly And Co
	Seroplex			S		20 Mg, Unk		Not Reported
	Rasilez Hct			S		Unk		Not Reported
	Anafranil			S		37.5 Mg, Qd		Not Reported
	Alprazolam			S		0.75 Mg, Qd		Not Reported
	Prazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2014	9798824	DIRECT	Y	OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Depression; Disturbance In Attention; Memory Impairment; Rash; Sexual Dysfunction; Suicidal Ideation	Escitalopram Oxalate			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2014	9798148	EXPEDITED (15-DAY)		DE, HO, OT	US-UCBSA-108005		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Alprazolam			S	Oral	Ingestion		Not Reported
	Escitalopram			S	Oral	Ingestion		Not Reported
	Zolpidem			S	Oral	Ingestion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2014	9799318	EXPEDITED (15-DAY)		OT	RS-FRI-1000052635			Female	SRB

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Sweats	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Forest
	Rivotril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2014	9802983	DIRECT					60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Substitution Issue	Escitalopram 10 Mg			S	Oral			Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2014	9720883	EXPEDITED (15-DAY)		HO	IT-ABBVIE-13P-083-1174304-00		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Nausea; Suicide Attempt; Tremor	Depakin Chrono			S	Oral	Extended-Release Tablet: 600 Mg Total		Not Reported
	Depakin (Valproate Sodium)			S	Oral			Not Reported

	Depakin (Valproate Sodium)	S	Oral	1000 Mg Total	Not Reported
	Cipralex	S	Oral	Solution: 20 Drops Total	Not Reported
	En	S	Oral	20 Drops Total	Not Reported
	En	S	Oral	Solution Drops: 24 Drops Total	Not Reported
	Sertraline Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2014	9803058	DIRECT		LT			31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Dyspnoea; Product Substitution Issue; Suicidal Ideation	Escitalopram			S	Oral	1/2 Pill Once Daily Taken By Mouth		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2014	9803220	DIRECT		OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Feeling Abnormal; Product Substitution Issue	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2014	9936775	NON-EXPEDITED		OT	E2B_00001438			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Heart Rate Irregular; Insomnia; Panic Attack; Product Substitution Issue; Suicidal Ideation	Escitalopram			S	Oral			Not Reported
	Atenolol			C	Oral			Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2014	9936776	NON-EXPEDITED	Y	HO, LT	2013-01953		65 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram (Unknown)			S				Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	1200 Mg (600 Mg, 2 In 1 D), Intravenous		Not Reported
	Clonazepam (Unknown)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2014	9547651	EXPEDITED (15-DAY)	Y	DE, HO, OT	SYM-2013-10767		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Graft Versus Host Disease In Gastrointestinal Tract; Hepatitis Fulminant; Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis	Flagyl			S	Intravenous (not otherwise specified)			Not Reported
	Largactil (Chlorpromazine) (Chlorpromazine)			S		1 Dosage Forms, Daily		Not Reported
	Exacyl (Tranexamic Acid) (Tranexamic Acid)			S		1 Dosage Forms, 3 In 1 D		Not Reported
	Fortum (Ceftazidime) (Injection) (Ceftazidime)			S		1 Dosage Forms, 4 In 1 D		Not Reported
	Gentamicin Sulfate (Gentamicin Sulfate) (Gentamicin Sulfate)			S	Intravenous (not otherwise specified)			Not Reported
	Noxafil (Posaconazole) (Posaconazole)			S	Oral			Not Reported
	Cancidas (Caspofungin Acetate) (Caspofungin Acetate)			S	Intravenous (not otherwise specified)	Iv (Not Otherwise Specified)		Not Reported
	Ambisome (Amphotericin B Liposome) (Amphotericin B, Liposome)			S	Intravenous (not otherwise specified)	1i80 Mg, Daily, Intravenous (Not Otherwise Specified)		Not Reported
	Bactrim (Bactrim) (Sulfamethoxazole, Trimethoprim)			S	Intravenous (not otherwise specified)	2 Dosage Forms, 3 In 1 Wk, Intravenous (Not Otherwise Specified)		Not Reported
	Folinic Acid (Folinic Acid) (Folinic Acid)			S	Intravenous (not otherwise specified)	50 Mg, 3 In 1 Wk, Intravenous (Not		Not Reported

			Otherwise Specified)	
Zelitrex (Valaciclovir Hydrochloride) (Valaciclovir Hydrochloride)	S	Intravenous (not otherwise specified)	500 Mg, 2 In 1 D, Intravenous (Not Otherwise Specified)	Not Reported
Cymevan (Ganciclovir Sodium) (Ganciclovir Sodium)	S	Intravenous (not otherwise specified)	350 Mg, 2 In 1 D, Intravenois (Not Otherwise Sepcified)	Not Reported
Foscavir (Foscarnet Sodium) (Solution For Infusion) (Foscarnet Sodium)	S		1 Dosage Forms, 2 In 1 D, Bid	Not Reported
Clairyg	S	Intravenous (not otherwise specified)	Intravaneous (Not Otherwise Specified)	Not Reported
Inexium (Esomeprazole Magnesium)	S	Intravenous (not otherwise specified)		Not Reported
Spasfon (Phloroglucinol)	S	Intravenous (not otherwise specified)	2 Dosages Forms, 3 In 1 D, Intravenous (Not Otherwise Specified)	Not Reported
Delursan (Ursodeoxycholic Acid) Tablet	S	Oral	3 Dosages Forms, 2 In 1 D, Oral	Not Reported
Defibrotide (Defibrotide) (Defibrotide)	S	Intravenous (not otherwise specified)		Not Reported
Tranxene (Clorazepate Dipotassium) (Capsules) (Clorazepate Dipotassium)	S	Oral		Not Reported
Oxynorm (Oxycodone Hydrochloride) (Oxycodone Hydrochloride)	S	Intravenous (not otherwise specified)	Intravenous (Not Otherwise Specified)	Not Reported
Perfalgan	S	Intravenous (not otherwise specified)		Not Reported
Solumedrol (Methylprednisolone Sodium Succinate) (Methylprednisolone Sodium Succinate)	S	Intravenous (not otherwise specified)	140 Mg, Daily, Intravenous (Not Otherwise Specified)	Not Reported
Ultiva (Remifentanil Hydrochloride) (Remifentanil Hydrochloride)	S			Not Reported
Noctamide	S	Oral Oral		Not Reported

Lasilix (Furosemide) (Furosemide)	S	Oral	Not Reported
Heparin Sodium (Heparin Sodium)	S	7000 Milliunit	Not Reported
Granocyte (Lenograstim) (Injection) (Lenograstime)	S	Intravenous (not otherwise specified)	Not Reported
Colistin	C		Not Reported
Vancomycin Hydrochloride	C		Not Reported
Ciflox (Ciprofloxacin) (Ciprofloxacin)	C		Not Reported
Targocid (Teicoplanin) (Teicoplanin)	C		Not Reported
Mycostatine (Nystatin) (Nystatin)	C		Not Reported
Triflucan (Fluconazole) (Fluconazole)	C		Not Reported
Zovirax (Aciclovir) (Aciclovir)	C		Not Reported
Methotrexate (Methotrexate) (Methotrexate)	C		Not Reported
Elvorine (Calcium Levofolinate) (Calcium Levofolinate)	C		Not Reported
Sandimmun (Ciclosporin) (Ciclosprin)	C		Not Reported
Mopral (Omeprazole) (Omeprazole)	C		Not Reported
Ogastoro (Lansoprazole) (Lansoprazole)	C		Not Reported
Gelox (Gelox) (Magnesium Hydroxide, Montmorillonite, Aluminium Hydroxide)	C		Not Reported
Smecta (Diosmectite) (Diosmectite)	C		Not Reported
Luteran (Chlormadinone Acetate) (Chlormadinone Acetate)	C		Not Reported
Lexomil (Bromazepam) (Bromazepam)	C		Not Reported
Zophren (Ondansetron Hydrochloride) (Ondansetron Hydrochloride)	C		Not Reported
Primperan (Metoclopramide Hydrochloride0 (Metoclopramide Hydrochloride)	C		Not Reported

	Acupan (Nefopam) (Nefopam)	C			Not Reported
	Tiorfan (Acetorphan) (Acetorphan)	C			Not Reported
	Levocarnil (Levocarniitine) (Levocarnitine)	C			Not Reported
	Atarax	S	Oral		Not Reported
	Seroplex (Escitalopram Oxalate) (Escitalopram Oxalate)	S	Oral		Not Reported
	Ceris	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2014	9805415	EXPEDITED (15-DAY)		DE, OT	US-UCBSA-108463		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen /Hydrocodone			S	Oral	Route: Ingestion		Not Reported
	Isosorbide Mononitrate			S	Oral	Route: Ingestion		Not Reported
	Amlodipine			S	Oral	Route: Ingestion		Not Reported
	Doxazosin			S	Oral	Route : Ingestion, Extended Release		Not Reported
	Escitalopram			S	Oral	Route: Ingestion		Not Reported
	Warfarin			S	Oral	Route: Ingestion		Not Reported
	Furosemide			S	Oral	Route: Ingestion		Not Reported
	Levothyroxine			S	Oral	Route: Ingestion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2014	9805882	EXPEDITED (15-DAY)		DE, OT	US-UCBSA-108321		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Hyperthermia	Alprazolam			S				Not Reported
	Vilazodone			S		Extended Release		Not Reported
	Salicylate			S		Extended Release		Not Reported
	Escitalopram			S				Not Reported
	Duloxetine			S				Not Reported

Clonazepam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2014	9690854	EXPEDITED (15-DAY)		OT	US-FRI-1000051153			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Depression; Dizziness; Emotional Disorder; Hallucination; Homicide; Hostility; Skin Burning Sensation; Suicidal Behaviour	Lexapro			S				Forest
	Xanax			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2014	9807748	EXPEDITED (15-DAY)		DE, OT	US-UCBSA-108245		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Acetaminophen/Hydrocodone			S				Not Reported
	Alprazolam			S				Not Reported
	Amlodipine			S				Not Reported
	Carvedilol			S				Not Reported
	Bupropion			S		Extended Release		Not Reported
	Citalopram			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2014	9808808	EXPEDITED (15-DAY)		DE	US-BAYER-2014-004062		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Paracetamol + Diphenhydramine		Y	S	Oral			Bayer
	Citalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2014	9813236	DIRECT		OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disease Recurrence; Feeling Abnormal; Insomnia; Product Substitution Issue	Escitalopram			S	Oral	1 Pill Once Daily Taken By Mouth	6 MTH	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2014	9812582	EXPEDITED (15-DAY)		OT	AU-ROCHE-1331759		46 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Hepatic Function Abnormal; Hepatic Steatosis; Renal Impairment; Weight Increased	Diazepam			S	Unknown			Not Reported
	Clopine			S	Oral			Not Reported
	Levetiracetam			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2014	9812959	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2014006713		93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2014	9813608	EXPEDITED (15-DAY)		CA	US-FRI-1000052769		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Congenital Anomaly; Congenital Hand Malformation	Lexapro		S	Transplacental	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2014	9814620	EXPEDITED (15-DAY)		HO	FR-FRI-1000052791		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Electrocardiogram Qt Prolonged; Overdose	Escitalopram			S	Oral	1 Df		Forest
	Escitalopram			S	Oral	Escitalopram 20 Mg Overdose: 42 Tablets Once.		Not Reported
	Zopiclone			S	Oral	1 Df		Not Reported
	Zopiclone			S	Oral	Zopiclone Overdose: 42 Tablets Once.		Not Reported
	Baclofen			S	Oral	1 Df		Not Reported
	Baclofen			S	Oral	Baclofen Overdose: 20 Tablets Once.		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2014	9814623	EXPEDITED (15-DAY)		HO	FR-FRI-1000052784		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased; Subdural Haematoma	Escitalopram			S	Oral	1 Df		Forest
	Minisintrom			S		1 Mg On Even Days And 2 Mg On Odd Days		Not Reported
	Actiskenan			C		5 Mg		Not Reported
	Triatec (Ramipril)			C		5 Mg		Not Reported
	Seresta			C		10 Mg		Not Reported
	Primperan			C		30 Mg		Not Reported
	Atarax			C		75 Mg		Not Reported

	Cacit D3	C	1 Df	Not Reported
	Cardensiel	C	3.75 Mg	Not Reported
	Dafalgan	C	3 Grams (Systematic)	Not Reported
	Lantus	C	600 Iu/Ml	Not Reported
	Lasilix	C	375 Mg	Not Reported
	Macrogol	C	2 Df (Systematic)	Not Reported
	Polaramine	C	6 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2014	9814642	EXPEDITED (15-DAY)		HO	FR-FRI-1000052785		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction	Escitalopram			S	Oral	1 Df		Forest
	Pradaxa			S	Oral	2 Df		Not Reported
	Meteospasmyl (Alverine Citrate\Dimethicone)			C	Oral	2 Df		Not Reported
	Forlax			C	Oral	4 Gram		Not Reported
	Furosemide			C	Oral	40 Mg		Not Reported
	Hemigoxine Nativelle			C	Oral			Not Reported
	Kaleorid			C	Oral	1 Df		Not Reported
	Zolpidem			C	Oral	1 Df		Not Reported
	Doliprane			C	Oral	3 Df		Not Reported
	Exelon			C	Transdermal	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2014	9814750	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2014006378		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Overdose; Respiratory Arrest	Alprazolam			S		Unk		Pfizer
	Vilazodone			S		Unk		Not Reported

	Salicylate	S	Unk		Not Reported
	Escitalopram	S	Unk		Not Reported
	Duloxetine	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2014	9815834	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2014006473		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Alprazolam			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2014	9816088	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2014006827		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Doxazosin Mesilate			S	Oral	Unk		Pfizer
	Furosemide			S	Oral	Unk		Unknown
	Levothyroxine Sodium			S	Oral	Unk		Pfizer
	Acetaminophen/ Hydrocodone			S	Oral	Unk		Not Reported
	Isosorbide Mononitrate			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Warfarin			S	Oral	Unk		Not Reported
	Potassium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2014	9816391	EXPEDITED (15-DAY)		HO	FR-ABBVIE-14P-056-1187902-00		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coma; Intentional Overdose; Seizure	Depakote	S	Oral		Not Reported
	Depakote	S	Oral		Not Reported
	Tercian	S	Oral		Not Reported
	Tercian	S	Oral		Not Reported
	Teralithe	S	Oral		Not Reported
	Teralithe	S	Oral		Not Reported
	Theralene	S	Oral		Not Reported
	Theralene	S	Oral		Not Reported
	Seroplex	S	Oral		Not Reported
	Seroplex	S	Oral		Not Reported
	Xanax	S	Oral		Not Reported
	Abilify	S	Oral		Not Reported
	Lysanxia	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2014	9816649	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMPANY-FR201401000023		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypocalcaemia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Nausea; Sleep Disorder; Thrombocytopenia; Vomiting	Cymbalta			S	Oral	Unk, Unknown		Eli Lilly And Co
	Seroplex			S	Oral	Unk, Unknown		Not Reported
	Atarax /00595201/			S	Oral	Unk, Unknown		Not Reported
	Diffu K			C	Unknown	Unk, Unknown		Not Reported
	Lamaline /01708901/			C	Unknown	Unk, Unknown		Not Reported
	Lercanidipine			C	Unknown	Unk, Unknown		Not Reported
	Esomeprazole			C	Unknown	Unk, Unknown		Not Reported
	Bisoprolol			C	Unknown	Unk, Unknown		Not Reported
	Aotal			C	Unknown	Unk, Unknown		Not Reported
	Alfuzosine L.P.			C	Unknown	Unk, Unknown		Not Reported
	Uvedose			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2014	9816731	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2014007226		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Alprazolam			S	Oral	Unk		Pfizer
	Carvedilol			S	Oral	Unk		Not Reported
	Bupropion			S	Oral	Unk		Not Reported
	Acetaminophen/ Hydrocodone			S	Oral	Unk		Not Reported
	Citalopram			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2014	9816917	EXPEDITED (15-DAY)		HO	FR-FRI-1000052854		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Seizure	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	Overdose :22 Tablets (220 Mg) Once		Forest
	Theralene			S	Oral	20 Drops On Evening		Not Reported
	Theralene			S	Oral	Overdose : 1 Bottle Once		Not Reported
	Tercian			S	Oral	20 Df		Not Reported
	Tercian			S	Oral	Overdose : 1 Bottle Once		Not Reported
	Depakote			S	Oral	1000 Mg		Not Reported
	Depakote			S	Oral	Overdose : 60 Tablets (30 Grams) Once		Not Reported
	Theralithe Lp			S	Oral			Not Reported
	Theralithe Lp			S	Oral	Overdose : 210 Tablets (84 Grams) Once		Not Reported
	Xanax			S	Oral	Overdose : 100 Df Once		Not Reported

	Abilify		S	Oral	Overdose : 14 Df	Not Reported
	Lysanxia		C		10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2014	9816935	EXPEDITED (15-DAY)		HO, OT	PHHY2014BR002544		74 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Depression; Dizziness; Haemorrhage Urinary Tract; Urinary Tract Infection	Exelon Patch			S	Transdermal	9.5 Mg, Daily		Not Reported
	Enalapril			S		Unk Ukn, Unk		Novartis
	Lexapro			S		1 Df, Qd (At Night)		Not Reported
	Prolopa			C		Unk Ukn, Unk		Not Reported
	Losartan			C		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2014	9820461	EXPEDITED (15-DAY)	Y	HO	2014HINLIT0002		65 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Pneumonitis; Serotonin Syndrome	Escitalopram			S				Not Reported
	Linezolid			S	Intravenous (not otherwise specified)			Not Reported
	Clonazepam (Clonazepam) (Clonazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2014	9818294	EXPEDITED (15-DAY)		LT, OT	GB-FRI-1000052810			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration	Escitalopram			S	Oral	30 Mg		Forest
	Priadel			S		1000 Mg		Not Reported
	Zyprexa			S		15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2014	9819598	EXPEDITED (15-DAY)		CA	US-FRI-1000052763		< 1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Gastroschisis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2014	9822192	EXPEDITED (15-DAY)	Y	HO	MAC2014000828		65 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hyperhidrosis; Hypoxia; Myoclonus; Pneumonitis; Serotonin Syndrome	Escitalopram Oxalate			S	Intravenous (not otherwise specified)			Not Reported
	Linezolid			S				Not Reported
	Clonazepam			C				Not Reported
	Etofylline			C				Not Reported
	Guaifenesin			C				Not Reported
	Ambroxol			C				Not Reported
	Amoxicillin			C				Not Reported
	Clavulanate Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2014	9825394	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Substitution Issue	Escitalopram			S			1 MTH	Not Reported
	Cymbalta			C				Not Reported
	Buspar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2014	9434810	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000047327		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haematoma; Subdural Haematoma	Escitalopram	S	Oral			Forest
	Plavix	S	Oral	1 Df		Not Reported
	Ramipril	C				Not Reported
	Furosemide	C				Not Reported
	Diffu K	C				Not Reported
	Norset	C				Not Reported
	Imovane	C				Not Reported
	Lexomil	C				Not Reported
	Tramadol	C				Not Reported
	Paracetamol	C				Not Reported
	Diclofenac	C				Not Reported
	Aranesp	C				Not Reported
	Movicol	C				Not Reported
	Uvedose	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2014	9814579	EXPEDITED (15-DAY)		HO	FR-FRI-1000052782		26 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Escitalopram Overdose: Unknown Amount.		Not Reported
	Bromazepam			S	Oral			Not Reported
	Bromazepam			S	Oral	Bromazepam Overdose: Unknown Amount.		Not Reported
	Zopiclone			S	Oral			Not Reported
	Zopiclone			S	Oral	Zopiclone Overdose: Unknown Amount.		Not Reported
	Tercian			S	Oral			Not Reported
	Tercian			S	Oral	Cyamemazine Overdose: Unknown Amount.		Not Reported
	Alcohol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2014	9821769	NON-EXPEDITED			US-PFIZER INC-2014012703		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Fosamax			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2014	9821899	EXPEDITED (15-DAY)		HO, OT	CA-ASTRAZENECA-2014SE02626			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Fibula Fracture; Syncope; Tibia Fracture	Seroquel			S	Oral			Zeneca
	Cipralex			S	Oral			Not Reported
	Ethanol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2014	9821923	EXPEDITED (15-DAY)		HO	FR-FRI-1000052856		46 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Suicide Attempt; Urinary Tract Disorder	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2014	9822088	EXPEDITED (15-DAY)		HO	PHHY2013CA149171		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Balance Disorder; Bradycardia; Dizziness; Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder	Metoprolol			S		50 Mg, Per Day		Novartis
	Metoprolol			S		25 Mg, Qd		Novartis
	Amlodipine			S		2.5 Mg, Bid		Not Reported
	Amlodipine			S		2.5 Mg, Daily		Not Reported
	Ramipril			S		5 Mg, Qd		Not Reported
	Glyceryl Trinitrate			S	Transdermal	0.4 Mg, Bid (Patch)		Not Reported

Glyceryl Trinitrate	S	0.4 Mg, Qd	Not Reported
Escitalopram	S	10 Mg, Qd	Not Reported
Escitalopram	S		Not Reported
Zopiclone	S	5 Mg, Qd	Not Reported
Zopiclone	S	2.5 Mg, Qd	Not Reported
Furosemide	S	40 Mg, Qd	Not Reported
Furosemide	S	20 Mg, Daily	Not Reported
Oxazepam	S	10 Mg, Bid	Not Reported
Codeine Phosphate	S	30 Mg, Bid	Not Reported
Codeine Phosphate	S	30 Mg, Tid	Not Reported
Clopidogrel	C	75 Mg, Qd	Not Reported
Clopidogrel	C		Not Reported
Clopidogrel	C		Not Reported
Atorvastatin	C	80 Mg, Qd	Not Reported
Atorvastatin	C		Not Reported
Vitamin D Nos	C	1000 Iu, Unk	Not Reported
Vitamin D	C	1000 Iu, Tid	Not Reported
Acetaminophen	C	500 Mg, Bid	Not Reported
Acetaminophen	C	500 Mg, Qid	Not Reported
Polyethylene Glycol	C		Not Reported
Pure Vitamin C	C		Not Reported
Rabeprazole	C	10 Mg, Per Day, For 2 Weeks	Not Reported
Pantoprazole	C	40 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2014	9822384	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000052761		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Atrial Septal Defect; Coarctation Of The Aorta; Left Ventricle Outflow Tract	Lexapro			S	Transplacental			Forest

Obstruction; Patent Ductus Arteriosus; Pulmonary Hypertension; Right Ventricle Outflow Tract Obstruction; Ventricular Septal Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2014	9822946	EXPEDITED (15-DAY)		DE, LT	NO-FRI-1000052849		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Self-Injury	Escitalopram			S				Forest
	Citalopram			S				Forest
	Nobligan			S		Strength: 50 Mg-200 Mg		Not Reported
	Imovane			S	Oral			Not Reported
	Lamictal			S		Strength: 25 Mg, 50 Mg, 100 Mg		Not Reported
	Pinex Forte			S		Strength: 500/30 Mg And Pandeine		Not Reported
	Seroquel			S				Not Reported
	Sobril			S				Not Reported
	Oxynorm			S		Strength: 5 Mg-10 Mg		Not Reported
	Remeron			S				Not Reported
	Sarotex			S				Not Reported
	Rivotril			S				Not Reported
	Orfiril			S		Strength: 600 Mg-1200 Mg		Not Reported
	Atarax			S				Not Reported
	Tramadol			S				Not Reported
	Vival			S				Not Reported
	Nozinan			S				Not Reported
	Truxal			S				Not Reported
	Catapresan			S		Strength: 25 Mg To 50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2014	9823240	EXPEDITED (15-DAY)		CA	US-FRI-1000052793		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Torticollis; Deafness; Heart Disease Congenital; Plagiocephaly; Spine Malformation	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2014	9824192	EXPEDITED (15-DAY)		CA	US-FRI-1000052795		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Transposition Of The Great Vessels	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2014	9825761	DIRECT		LT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Nausea	Lexapro Or Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2014	9809023	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-B0957260A		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Dyspnoea; Ecchymosis; Fatigue; Haematoma; Incorrect Dose Administered	Arixtra			S	Subcutaneous	5mg Per Day		Glaxosmithkline
	Plavix			S	Oral	75mg Per Day		Unknown
	Seroplex			S	Oral	10mg Per Day		Unknown
	Celluvisc			C	Ophthalmic			Not Reported
	Cordarone			C	Oral			Not Reported
	Tardyferon			C				Not Reported
	Alprazolam			C				Glaxosmithkline
	Amlor			C				Glaxosmithkline

	Cetirizine Dichlorhydrate			C					Glaxosmithkline
	Mestinon			C					Not Reported
	Ebixa			C					Glaxosmithkline
	Furadantine			C					Glaxosmithkline
	Dafalgan			C					Glaxosmithkline
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C					Not Reported
	Inexium			C	Oral				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2014	9827187	EXPEDITED (15-DAY)		DS	CA-009507513-1401CAN005496		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Orthostatic Hypotension	Nitro-Dur			S	Unknown	0.4 Mg Patch, 2 On At 9 Am And Off At 10 Pm, Rotating Site		Merck
	Nitro-Dur			S	Unknown	Single 0.4 Microgram Patch On For 12 H, Off For 12 H		Merck
	Metoprolol			S	Oral	Half A 50 Mg Tablet Twice Daily		Not Reported
	Metoprolol			S	Oral	25 Mg, Qd		Not Reported
	Metoprolol			S	Oral	12.5 Mg, Bid		Not Reported
	Amlodipine			S	Oral	Half A 5 Mg Tablet Twice Daily		Not Reported
	Amlodipine			S	Oral	2.5 Mg, Qd		Not Reported
	Furosemide			S	Oral	40 Mg Every Morning		Merck
	Furosemide			S	Oral	20 Mg/Daily For 1 Week		Merck
	Escitalopram			S	Unknown	10 Mg, Every Morning		Not Reported
	Escitalopram			S				Not Reported
	Zopiclone			S	Unknown	5 Mg At Bedtime		Not Reported

Zopiclone	S	Unknown	2.5 Mg,Every Night For 3 Weeks	Not Reported
Oxazepam	S	Oral	2, 10 Mg At Bedtime	Not Reported
Oxazepam	S	Oral	15 Mg, Every Night For 2}3 Weeks	Not Reported
Oxazepam	S	Oral	10 Mg, Every Night For 2}3 Weeks	Not Reported
Oxazepam	S	Oral	5 Mg, Every Night For 2}3 Weeks	Not Reported
Oxazepam	S	Oral	5 Mg, Every Other Day Or As Needed Nutil Able Stop	Not Reported
Ramipril	C	Unknown	5 Mg, Every Morning	Not Reported
Atorvastatin	C		80 Mg, At Bedtime	Not Reported
Atorvastatin	C			Not Reported
Atorvastatin	C			Not Reported
Vitamin D (Unspecified)	C	Unknown	1000 Iu, Qd	Not Reported
Vitamin D (Unspecified)	C	Unknown	3000 Iu, Qd	Not Reported
Clopidogrel	C	Unknown	75 Mg, Every Morning	Not Reported
Clopidogrel	C			Not Reported
Clopidogrel	C			Not Reported
Hydroxychloroquine Sulfate	C	Unknown	200 Mg, At Supper	Not Reported
Pantoprazole	C	Unknown	40 Mg, Every Morning	Not Reported
Pantoprazole	C	Unknown	40 Mg, Qd	Not Reported
Polyethylene Glycol	C	Unknown	Eye Drops As Needed	Not Reported
Acetaminophen (+) Codeine Phosphate	C	Unknown	30 Mg, Bid As Needed	Not Reported
Acetaminophen	C	Oral	500 Mg, 4 Times A Day	Not Reported
Acetaminophen	C		1000 Mg, Unk	Not Reported
Codeine	C	Unknown	30 Mg, 3 Times Daily As Needed	Not Reported
Codeine	C		30 Mg, 3 Times Daily Regularly	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2014	9837548	DIRECT		OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Heart Rate Increased; Hyperventilation; Panic Attack	Lexapro			S	Oral	1 Pill Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2014	9837618	DIRECT		OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Crying; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral	1 Once Daily Taken By Mouth		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2014	9828833	EXPEDITED (15-DAY)		DE	US-JNJFOC-20140108717		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Acetaminophen/Diphenhydramine		Y	S	Oral			Not Reported
	Citalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Tadalafil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2014	8260806	EXPEDITED (15-DAY)		CA, HO, OT	US-JNJFOC-20111107265			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cleft Palate; Conductive Deafness; Eustachian Tube Dysfunction; Feeding Disorder; Fistula; Infantile Apnoea; Jaundice Neonatal; Motor Developmental Delay; Otitis Media Chronic; Speech Disorder; Weight Decreased	Topamax			S	Transplacental			Not Reported
	Paracetamol		Y	S	Transplacental			Not Reported
	Paracetamol			S	Transplacental			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Levothyroxine			S	Transplacental			Not Reported
	Vicodin			S	Transplacental			Not Reported
	Suboxone			S	Transplacental			Not Reported
	Prenatal Vitamins			S	Transplacental			Not Reported
	Opioids Nos			S	Transplacental			Not Reported
	Subutex			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2014	9829728	EXPEDITED (15-DAY)		HO, OT	IN-ACCORD-021279		65 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome; Somnolence	Clonazepam			S				Accord
	Escitalopram			S				Accord
	Linezolid			S	Intravenous (not otherwise specified)			Not Reported
	Guaifenesin			C				Not Reported
	Paracetamol			C				Not Reported
	Ambroxol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2014	9830976	EXPEDITED (15-DAY)		OT	PHHY2014CH005599		43 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Cipralex			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2014	9628820	EXPEDITED (15-DAY)			JP-ELI_LILLY_AND_COMPANY-JP201310003334		40 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal; Hypertriglyceridaemia	Cymbalta			S	Oral	20 Mg, Qd		Eli Lilly And Co
	Lexapro			S	Oral	Unk		Not Reported
	Lipidil			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2014	9831486	EXPEDITED (15-DAY)		DE	US-JNJFOC-20140110556		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bradycardia; Completed Suicide; Hyperthermia; Hypotension; Overdose; Ventricular Tachycardia	Salicylate		Y	S	Unknown			Not Reported
	Vilazodone			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2014	9831801	EXPEDITED (15-DAY)		OT	BR-ELI_LILLY_AND_COMPANY-BR201401004836			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Panic Disorder; Visual Impairment	Fluoxetine Hydrochloride			S	Unknown	Unk, Unknown		Unknown
	Tranxilene			S	Unknown	Unk, Unknown		Not Reported
	Lorax//Lorazepam			S	Unknown	Unk, Unknown		Not Reported
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported
	Amitriptilina			S	Unknown	Unk, Unknown		Not Reported
	Venlafaxine			S	Unknown	Unk, Unknown		Not Reported

	Anafranil	S	Unknown	Unk, Unknown	Not Reported
	Tofranil	S	Unknown	Unk, Unknown	Not Reported
	Risperidona	S	Unknown	Unk, Unknown	Not Reported
	Rivotril	S	Unknown	2 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2014	9832922	EXPEDITED (15-DAY)		CA, DS, HO	BE-FRI-1000052946			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Megacolon; Foetal Exposure During Pregnancy; Sepsis	Escitalopram			S	Transplacental	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2014	9832997	EXPEDITED (15-DAY)		HO	FR-FRI-1000052950		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Tremor	Escitalopram			S				Forest
	Teralithe Lp			S	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2014	9523058	EXPEDITED (15-DAY)		DS, OT	CA-FRI-1000048781		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stress Fracture; Weight Increased	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2014	9523371	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000048783		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Intracranial	Escitalopram			S	Oral			Forest

Pressure Increased; Off Label Use; Papilloedema; Vision Blurred	Tetracycline	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2014	9834231	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY-20032579		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Baraclude Tabs 0.5 Mg			S	Oral			Bristol Myers Squibb
	Mabthera			S		03jul2007		Not Reported
	Tercian			S	Oral			Not Reported
	Noctran			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Durogesic			S	Transdermal	1df: 50mcg/Hour		Not Reported
	Dulcolax			C		1df: 1suppository		Not Reported
	Previscan (Fluindione)			C		1df: 0.5 Unit Nos		Not Reported
	Aerius (Desloratadine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2014	9835873	EXPEDITED (15-DAY)		OT	FR-FRI-1000052982		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2014	9844682	EXPEDITED (15-DAY)	Y	HO	VAL_02907_2014		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Fall; Headache; Hypotension; Mobility Decreased; Musculoskeletal Chest	Metoprolol Tartrate			S		50 Mg Day		Not Reported
	Amlodipine (Amlodipine)			S				Not Reported
	Ramipril (Ramipril)			S				Not Reported
	Glyceryl Trinitrate			S	Transdermal			Not Reported

Pain; Musculoskeletal	Escitalopram (Escitalopram)	S	Not Reported
Pain; Nausea; Neck Pain;	Zopiclone (Zopiclone)	S	Not Reported
Oedema Peripheral;	Furosemide (Furosemide)	S	Not Reported
Orthostatic Hypotension;	Praxiten Pliva (Oxazepam)	S	Not Reported
Serum Ferritin Decreased;	(Oxazepam)		
Sleep Disorder	Codeine Phosphate (Codeine Phosphate)	S	Not Reported
	Clopidogrel	C	Not Reported
	Atorvastatin	C	Not Reported
	Vitamin D2	C	Not Reported
	Acetaminophen	C	Not Reported
	Polyethylene Glycol	C	Not Reported
	Vitamin-C	C	Not Reported
	Rabeprazole	C	Not Reported
	Pantoprazole	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2014	9844719	EXPEDITED (15-DAY)		OT	7260901		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Levothyrox			S	Oral			Not Reported
	Alteis			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Nebivolol			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported
	Diffu K			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2014	9844840	EXPEDITED (15-DAY)	Y	HO, LT, OT	AUR-APL-2014-00197		65 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypoxia; Pneumonia; Serotonin Syndrome; Somnolence;	Escitalopram			S		1 D		Not Reported
	Linezolid			S		1 D		Not Reported

Therapy Non-Responder	Etophylline (Etofylline)	C	Not Reported
	Guaiphenesin (Guaifenesin)	C	Not Reported
	Ambroxol	C	Not Reported
	Amoxicillin (Amoxicillin)	C	Not Reported
	Clavulanic Acid (Clavulanci Acid)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2014	9845061	EXPEDITED (15-DAY)	Y	OT	DSM-2014-00019		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Alteis			S	Oral	40mg (40mg, 1 In 1 D) Oral		Not Reported
	Nebivolol			S	Oral	5mg (5mg, 1 In 1 D, Oral)		Not Reported
	Furosemide			S	Oral	40mg (40mg, 1 In 1d) Oral		Not Reported
	Seroplex			S	Oral	15mg, (15mg, 1 In 1 D) Oral		Not Reported
	Amlodipine			S	Oral	5mg (5mg, 1 In 1 D) Oral		Not Reported
	Levothyrox			S		125mcg, (125mcg, 1 In 1		Not Reported
	Zopiclone			S	Oral			Not Reported
	Diffu K			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2014	9523017	EXPEDITED (15-DAY)		OT	CA-FRI-1000048775		19 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Dizziness; Nausea; Unresponsive To Stimuli	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2014	9523060	EXPEDITED (15-DAY)		DE	CA-FRI-1000048780		20 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Completed Suicide; Irritability; Prescribed Overdose	Escitalopram	S	Oral	20 Mg	Forest
	Escitalopram	S	Oral	Overdose: Escitalopram 40 Mg Daily.	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2014	9530037	EXPEDITED (15-DAY)		OT	CA-FRI-1000048800		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Chest Pain; Depressed Mood; Diarrhoea; Dizziness; Dyspepsia; Dyspnoea; Emotional Disorder; Fatigue; Headache; Irritability; Nausea; Off Label Use; Pallor; Pharyngeal Swelling; Rash; Throat Irritation; Throat Tightness	Escitalopram			S	Oral	5 Mg		Forest
	Estrogel			C	Transdermal			Not Reported
	Lamisil			C	Oral			Not Reported
	Prometrium			C		100 Mg		Not Reported
	Zopiclone			C		0.5357 Mg		Not Reported
	Zopiclone			C		7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2014	9530052	EXPEDITED (15-DAY)		DS, HO, LT	CA-FRI-1000048778		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Arthralgia; Asthenia; Confusional State; Coordination Abnormal; Dyspnoea; Fatigue; Headache; Joint Stiffness; Loss Of Consciousness; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pharyngeal Disorder; Seizure; Urinary Incontinence; Urinary Retention; Wrist Fracture; Yellow Skin	Escitalopram			S	Oral	10 Mg		Forest
	Norvasc			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2014	9646375	EXPEDITED (15-DAY)		DE, LT	NO-WATSON-2013-19200		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Self-Injury	Vival			S	Unknown	Unk		Watson
	Pinex Forte			S	Unknown	Unk		Actavis Mid Atlantic
	Tramadol (Unknown)			S	Unknown	Unk		Actavis Elizabeth
	Rivotril			S	Unknown	Unk		Not Reported
	Sobril			S	Unknown	Unk		Not Reported
	Cipramil /00582602/			S	Unknown	Unk		Not Reported
	Nobligan			S	Unknown	Unk; Strength: 50 Mg-200 Mg		Not Reported
	Cipralex			S	Unknown	Unk		Not Reported
	Catapresan			S	Unknown	Unk; Strength: 25 Mg To 50 Mg		Not Reported
	Orfiril			S	Unknown	Unk; Strength: 600 Mg-1200 Mg		Not Reported
	Seroquel			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk; Strength: 25 Mg, 50 Mg, 100 Mg		Not Reported
	Nozinan /00038601/			S	Unknown	Unk		Not Reported
	Sarotex			S	Unknown	Unk		Not Reported
	Truxal			S	Unknown	Unk		Not Reported
	Atarax /00058402/			S	Unknown	Unk		Not Reported
	Imovane			S	Oral	Unk		Not Reported
	Oxynorm			S	Unknown	Unk; Strength: 5 Mg-10 Mg		Not Reported
	Remeron			S	Unknown	Unk		Not Reported
	Diamorphine			C	Unknown	Unk		Not Reported
	Cyanocobalamin			C	Unknown	Unk; According To Mah		Not Reported

Product Name Is "Forte"

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2014	9838821	EXPEDITED (15-DAY)		OT	IE-FRI-1000052983			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2014	9844395	EXPEDITED (15-DAY)	Y	HO	2014P1000227		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Back Pain; Drug Interaction; Gamma-Glutamyltransferase Increased; Haemorrhage; Hemianopia	Escitalopram			S		10 Mg; Qd;	2 YR	Not Reported
	Etoricoxib			S		90 Mg; Qd;	1 MTH	Not Reported
	Acetamyphen/Tramadol			S		;Tid;	1 MTH	Not Reported
	Tramadol			S		; Qd;	1 MTH	Not Reported
	Deflazacort			C				Not Reported
	Salbutamol			C				Not Reported
	Montelukast			C				Not Reported
	Atorvastatin			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2014	9845339	DIRECT		OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Mental Disorder; Panic Attack; Product Substitution Issue	Escitalopram 10 Mg			S	Oral	1 Pill Once Daily Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2014	9845418	DIRECT		DS			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Palpitations; Product Quality Issue; Product Substitution Issue	Escitalopram			S	Oral	1 Tab Daily Once Daily Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2014	9845946	DIRECT					39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression; Drug Ineffective; Insomnia; Product Substitution Issue	Escitalopram			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2014	9845965	DIRECT		OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral	2 Once Daily Taken By Mouth		Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2014	9530045	EXPEDITED (15-DAY)		OT	CA-FRI-1000048801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Lung Infection; Melanocytic Naevus; Pregnancy; Rheumatoid Factor Increased	Escitalopram			S		10 Mg		Forest
	Imodium			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5.3571 Mg		Not Reported
	Tecta			S		30 Mg		Not Reported
	Tylenol With Codeine No.3			S				Not Reported
	Ventolin			S				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2014	9840419	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2014SCPR008205		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Death	Bupropion Hcl Xl			S	Oral	Unk, Unknown		Par
	Clonazepam			S	Oral	Unk, Unknown		Par
	Citalopram			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Oral	Unk, Unknown		Not Reported
	Tadalafil			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2014	9840840	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2014SCPR008215		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Death	Bupropion Hcl Xl			S	Oral	Unk, Unknown		Par
	Alprazolam			S	Oral	Unk, Unknown		Par
	Amlodipine			S	Oral	Unk, Unknown		Not Reported
	Carvedilol			S	Oral	Unk, Unknown		Not Reported
	Acetaminophen/Hydrocodone			S	Oral	Unk, Unknown		Not Reported
	Citalopram			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2014	9842346	EXPEDITED (15-DAY)		CA	US-FRI-1000053015		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Congenital Pulmonary Valve Atresia; Congenital Tricuspid Valve Atresia; Ebstein'S Anomaly; Hypoplastic Right Heart Syndrome; Palatal Disorder; Pulmonary Valve Stenosis; Speech Disorder; Tricuspid Valve Incompetence	Lexapro	S	Transplacental		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2014	9842842	EXPEDITED (15-DAY)		OT	CA-FRI-1000053064		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bradycardia; Electrocardiogram Qt Prolonged; Palpitations	Escitalopram			S	Oral	10 Mg		Forest
	Zoloft			S	Oral	50 Mg		Not Reported
	Calcium			C		1000 Mg		Not Reported
	D-Tabs			C		10000 Iu Weekly		Not Reported
	Estrogel			C		1 Df		Not Reported
	Olmetec			C		20 Mg		Not Reported
	Prometrium			C		100 Mg		Not Reported
	Restoril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2014	9848038	DIRECT					53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Excitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2014	9848073	DIRECT		OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Medication Error	Escitalopram 20mg			S	Oral	60 Tablets, One Month,3 Refills 2 Pills Once Daily Taken By Mouth	1 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2014	9849397	DIRECT		OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Loss; Condition Aggravated; Osteoporosis; Product Substitution Issue	Lexapro			S	Oral			Aurobindo
	Escitalopram			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Fish Oil			C				Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2014	9849496	EXPEDITED (15-DAY)	Y	OT	2014P1000211		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Amnesia; Aphasia; Contusion; Diplopia; Dysgraphia; Headache; Mental Status Changes; Nausea; Night Sweats; Product Quality Issue; Product Substitution Issue; Reaction To Excipient; Sleep Terror; Somnambulism	Escitalopram Tablets Usp 20 Mg			S	Oral			Not Reported
	Adderall			C				Not Reported
	Clonazepam			C				Not Reported
	Percocet			C				Not Reported
	Soma			C				Not Reported
	Fioricet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2014	9850805	EXPEDITED (15-DAY)	Y	DE	2014AP000584		93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Amlodipine Besylate Tablets	S	Oral		Not Reported
	Escitalopram	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2014	9240913	EXPEDITED (15-DAY)		HO	FR-FRI-1000044442		17 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Product Use Issue	Escitalopram			S	Oral			Forest
	Atarax			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Candesartan Cilexetil			S	Oral			Not Reported
	Victoza			C				Not Reported
	Lantus			C				Not Reported
	Glucophage			C				Not Reported
	Novorapid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2014	9845080	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201400827		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S	Oral			Tyco
	Isosorbide Mononitrate			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Doxazosin			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Warfarin			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Potassium /00031402/			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2014	9845172	EXPEDITED (15-DAY)		HO, LT	CH-MYLANLABS-2014S1001207		31 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Interaction; Dyspepsia; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Product Administration Error; Stress Cardiomyopathy; Torsade De Pointes; Withdrawal Syndrome	Methadone			S	Oral	50-60mg Daily		Mylan
	Escitalopram			S	Unknown			Not Reported
	Ondansetron			S	Intravenous (not otherwise specified)			Not Reported
	Esomeprazole			C	Intravenous (not otherwise specified)			Not Reported
	Scopolamine Butylbromide			C	Intravenous (not otherwise specified)			Not Reported
	Dipyrone			C	Intravenous (not otherwise specified)			Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)			Not Reported
	Pethidine			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2014	9845751	NON-EXPEDITED			US-PFIZER INC-2014022770			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Efexor			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2014	9849018	DIRECT		OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Eczema	Lexapro	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2014	9856708	EXPEDITED (15-DAY)	Y	HO	E2B_7260692		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash Maculo-Papular	Eutirox (Levothyroxine Sodium)			S	Oral			Not Reported
	Lexatin (Bromazepam)			S	Oral		7 MTH	Not Reported
	Lorazepam (Lorazepam) (Lorazepam)			S	Oral		7 MTH	Not Reported
	Escitalopram (Escitalopram)			S	Oral		7 MTH	Not Reported
	Clopidogrel (Clopidogrel) (Clopidogrel)			C				Not Reported
	Atorvastatin (Atorvastatin) (Atorvastatin)			C				Not Reported
	Zamene (Deflazacort) (Deflazacort)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2014	9643092	EXPEDITED (15-DAY)		LT, OT	DE-FRI-1000050479			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2014	9696331	EXPEDITED (15-DAY)		OT	FR-FRI-1000051450		31 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Drug-Induced Liver Injury; Jaundice	Escitalopram			S		10 Mg		Forest
	Escitalopram			S		15 Mg		Forest
	Lexomil			C	Oral	1 Df		Not Reported

	Stilnox	C	Oral	1 Df		Not Reported
	Imovane	C	Oral	1 Df		Not Reported
	Aerius (Desloratadine)	C	Oral	1 Df		Not Reported
	Omeprazole	C	Oral	10 Mg		Not Reported
	Humalog	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2014	9828436	EXPEDITED (15-DAY)		HO	FR-FRI-1000052920		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke	Escitalopram			S	Oral	1 Df		Forest
	Kardegic			S	Oral	1 Df		Not Reported
	Plavix			S	Oral	1 Df		Not Reported
	Lasilix			C	Oral	1 Df		Not Reported
	Tahor			C	Oral	1 Df		Not Reported
	Zyloric			C	Oral	1 Df		Not Reported
	Risperdal			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2014	9848572	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20140109355		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Loss Of Weight; Adverse Event; Asthenia; Blood Pressure Diastolic Decreased; Fall; Feeling Abnormal; Inadequate Diet; Palpitations; Upper Respiratory Tract Infection; Urine Odour Abnormal	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	1/4 Tablet Daily Or One Tablet Every Other Day During Week 2		Not Reported
	Risperdal			S	Oral	1/2 Tablet		Not Reported
	Levothyroxine			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Ciprofloxacin			S	Oral			Not Reported

	Lexapro	S	Oral	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Aspirin	C	Oral	Not Reported
	Iron	C	Oral	Not Reported
	Amiodarone	C	Oral	Not Reported
	Multivitamins	C	Oral	Not Reported
	Atorvastatin	C	Oral	Not Reported
	Aricept	C	Oral	Not Reported
	Aricept	C	Oral	Not Reported
	Coumadin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2014	9849759	NON-EXPEDITED			US-PFIZER INC-2014024831		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Citalopram Hbr			S		Unk		Not Reported
	Codeine Sulfate			S		Unk		Not Reported
	Macrobid			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Wellbutrin Sr			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2014	9656674	EXPEDITED (15-DAY)		HO	FR-FRI-1000050591		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram			S	Oral	1 Df		Forest
	Ebixa			C				Not Reported
	Aricept			C				Not Reported
	Risperdal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2014	9852045	NON-EXPEDITED			US-PFIZER INC-2013295775		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Prava (Pravastatin Sodium)			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Savella			S		Unk		Not Reported
	Viibryd			S		Unk		Not Reported
	Wellbutrin Sr			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2014	9852914	EXPEDITED (15-DAY)		HO, LT	CH-TEVA-458122ISR		31 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Interaction; Dyspepsia; Electrocardiogram Qt Prolonged; Generalised Tonic-Clonic Seizure; Product Administration Error; Stress Cardiomyopathy; Torsade De Pointes; Withdrawal Syndrome	Ondansetron			S	Intravenous (not otherwise specified)			Teva
	Methadone			S	Oral	50-60mg Daily		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Esomeprazole			C	Intravenous (not otherwise specified)			Not Reported
	Scopolamine Butylbromide			C	Intravenous (not otherwise specified)			Not Reported

	Dipyrone	C	Intravenous (not otherwise specified)	Not Reported
	Paracetamol	C	Intravenous (not otherwise specified)	Not Reported
	Pethidine	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2014	9853494	EXPEDITED (15-DAY)		LT	CH-PERRIGO-14CH000577		55 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torsade De Pointes	Ibuprofen 200 Mg 604			S	Oral	1200 Mg, Unknown		Perrigo
	Acetaminophen 650mg Er 544			S	Oral	2 G, Unknown		Perrigo
	Methadone			S	Unknown	80 Mg, Unknown		Not Reported
	Escitalopram			S	Unknown	30 Mg, Unknown		Not Reported
	Olanzapine			S	Unknown	20 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2014	9853696	NON-EXPEDITED			US-GLAXOSMITHKLINE-A1007689A		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Drug Interaction; Fatigue; Fatigue; Influenza Like Illness; Therapeutic Response Decreased	Wellbutrin			S	Oral			Glaxosmithkline
	Paxil			S	Unknown			Glaxosmithkline
	Lamictal			S	Oral	25mg See Dosage Text		Glaxosmithkline
	Lexapro			S				Not Reported
	Simvastatin			C				Glaxosmithkline
	Iron Supplement			C				Not Reported
	Unknown Drug			C				Glaxosmithkline
	Cal-Mag			C				Not Reported
	Unknown Drug			C				Glaxosmithkline
	Vitamin D3			C				Glaxosmithkline
	Ester-C [Ascorbic Acid\Bioflavonoids]			C				Not Reported

	Methylfolate	C		Glaxosmithkline
	Tocopherol	C		Glaxosmithkline
	Unknown Drug	C		Glaxosmithkline
	Melatonin	C		Not Reported
	Synthroid	C		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2014	9853720	NON-EXPEDITED			US-GLAXOSMITHKLINE-A1012959A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Hyperphagia	Wellbutrin			S				Glaxosmithkline
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2014	9854042	EXPEDITED (15-DAY)		DS, HO	IE-FRI-1000053244		66 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Schizophrenia	Lexapro			S	Oral			Forest
	Unspecified Sleep Apnoea Drugs			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2014	9859103	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2014-00671		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Disturbance In Attention; Fear; Hyperhidrosis; Initial Insomnia; Irritability; Myalgia; Palpitations; Platelet Dysfunction; Social Anxiety Disorder	Citalopram			S		(20 Mg, 1 D), Unknown		Not Reported
	Escitalopram (Escitalopram)			S		(10 Mg, 1 D), Unknown		Not Reported
	Clomipramine (Clomipramine)			S		50 Mg (25 Mg, 2 In 1 D), Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2014	7953042	EXPEDITED (15-DAY)		HO, OT	US-RANBAXY-2011US-44443		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Long Qt Syndrome; Sinus Bradycardia; Ventricular Fibrillation	Nortriptyline Hydrochloride			S	Unknown	25 Mg, Daily		Ranbaxy
	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported
	Ondansetron			S	Unknown	Unk		Ranbaxy
	Succinylcholine			S	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Heparin			C	Subcutaneous			Not Reported
	Topiramate			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2014	9631596	NON-EXPEDITED			US-PFIZER INC-2013297160		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Penicillamine			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Ativan			C		Unk		Not Reported
	Wellbutrin			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Ambien			C		Unk		Not Reported

	Protonix	C	Unk	Not Reported
	Tramadol	C	Unk	Not Reported
	Flexeril	C	Unk	Not Reported
	Flonase	C	Unk	Not Reported
	Vitamin D3	C	Unk	Not Reported
	Omega 3	C	Unk	Not Reported
	Baby Aspirin	C	Unk	Not Reported
	Calcium	C	Unk	Not Reported
	Tessalon Perle	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2014	9776258	EXPEDITED (15-DAY)		OT	DE-FRI-1000052397			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Withdrawal Syndrome; Erythema; Pruritus	Escitalopram			S		5 Or 10 Mg/Day		Forest
	Escitalopram			S		1 Mg		Forest
	Escitalopram			S		5 Mg		Not Reported
	Citalopram			S		20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2014	9776807	EXPEDITED (15-DAY)		LT	FR-ROCHE-1320529		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Coma; Disturbance In Attention; Hypothermia	Valium			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Depakine			S	Oral			Not Reported
	Seroplex			S	Unknown			Not Reported
	Zyprexa			S	Oral			Not Reported
	Relpax			S	Oral			Not Reported
	Levomepromazine			S	Oral			Not Reported

	Tercian	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2014	9836203	EXPEDITED (15-DAY)		OT	PHHY2014BR004456			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Panic Disorder; Visual Impairment	Tofranil			S		Unk Ukn, Unk		Not Reported
	Anafranil			S		Unk Ukn, Unk		Not Reported
	Fluoxetine			S		Unk Ukn, Unk		Novartis
	Risperidone			S		Unk Ukn, Unk		Not Reported
	Tranxilene			S		Unk Ukn, Unk		Not Reported
	Lorax//Lorazepam			S		Unk Ukn, Unk		Not Reported
	Escitalopram			S		Unk Ukn, Unk		Not Reported
	Amitriptyline			S		Unk Ukn, Unk		Not Reported
	Venlafaxine			S		Unk Ukn, Unk		Not Reported
	Rivotril			S		2 Mg, Bid (Morning And Night)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2014	9855362	EXPEDITED (15-DAY)		HO	DE-FRI-1000053116			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Psoriasis	Escitalopram			S	Oral	20 Mg		Forest
	Luaf41156			S	Oral	1 Mg		Not Reported
	Micardis			C	Oral	40 Mg		Not Reported
	Torsemide			C	Oral	20 Mg		Not Reported
	Methotrexate Sodium			C	Oral	15 Mg		Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported
	Paracetamol			C	Oral	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2014	9856959	NON-EXPEDITED			NL-JNJFOC-20140113128			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Pipamperon			S	Unknown			Not Reported
	Pipamperon			S	Unknown			Not Reported
	Pipamperon			S	Unknown			Not Reported
	Pipamperon			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Fluvoxamine			S	Unknown			Not Reported
	Fluvoxamine			S	Unknown			Not Reported
	Fluvoxamine			S	Unknown			Not Reported
	Fluvoxamine			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported

Fluoxetine	S	Unknown	Not Reported
Fluoxetine	S	Unknown	Not Reported
Fluoxetine	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Venlafaxine	S	Unknown	Not Reported
Venlafaxine	S	Unknown	Not Reported
Venlafaxine	S	Unknown	Not Reported
Venlafaxine	S	Unknown	Not Reported
Mirtazapine	S	Unknown	Not Reported
Mirtazapine	S	Unknown	Not Reported
Mirtazapine	S	Unknown	Not Reported
Mirtazapine	S	Unknown	Not Reported
Clomipramine	S	Unknown	Not Reported
Clomipramine	S	Unknown	Not Reported
Clomipramine	S	Unknown	Not Reported
Clomipramine	S	Unknown	Not Reported
Amitriptyline	S	Unknown	Not Reported
Amitriptyline	S	Unknown	Not Reported
Amitriptyline	S	Unknown	Not Reported
Amitriptyline	S	Unknown	Not Reported
Bupropion	S	Unknown	Not Reported
Bupropion	S	Unknown	Not Reported

Bupropion	S	Unknown	Not Reported
Bupropion	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Olanzapine	S	Unknown	Not Reported
Olanzapine	S	Unknown	Not Reported
Olanzapine	S	Unknown	Not Reported
Olanzapine	S	Unknown	Not Reported
Aripiprazole	S	Unknown	Not Reported
Aripiprazole	S	Unknown	Not Reported
Aripiprazole	S	Unknown	Not Reported
Aripiprazole	S	Unknown	Not Reported
Lithium	S	Unknown	Not Reported
Lithium	S	Unknown	Not Reported
Lithium	S	Unknown	Not Reported
Lithium	S	Unknown	Not Reported
Valproic Acid	S	Unknown	Not Reported
Valproic Acid	S	Unknown	Not Reported
Valproic Acid	S	Unknown	Not Reported
Valproic Acid	S	Unknown	Not Reported
Levothyroxine	C	Unknown	Not Reported
Biperiden	C	Unknown	Not Reported
Insulin	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2014	9857164	EXPEDITED (15-DAY)		CA	US-FRI-1000053173		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Fallot'S Tetralogy; Hypospadias; Pulmonary Valve Incompetence	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9688460	EXPEDITED (15-DAY)		DE	DE-FRI-1000051147		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Sudden Death; Weight Increased	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest
	Escitalopram Oral Solution			S	Oral	Slow Dosage Increase		Forest
	Escitalopram Oral Solution			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9727493	EXPEDITED (15-DAY)		LT	FR-FRI-1000051816		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypokalaemia; Hyponatraemia; Seizure	Escitalopram			S	Oral	1 Df		Forest
	Fludex (Indapamide)			S	Oral	1 Df		Not Reported
	Xeroquel			C	Oral	1 Df		Not Reported
	Alprazolam			C	Oral	1 Df		Not Reported
	Zolpidem			C	Oral	5 Mg		Not Reported
	Vasten [Pravastatin Sodium]			C	Oral	1 Dr		Not Reported
	Doliprane			C	Oral	6 Df		Not Reported
	Domperidone			C	Oral	3 Df		Not Reported
	Tarka			C	Oral	180 Mg /2 Mg Daily		Not Reported
	Inexium			C	Oral	2 Df		Not Reported
	Levothyrox			C	Oral	1 Df		Not Reported
	Ostram Vitamine D3			C	Oral			Not Reported

	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)		C	Oral	2 Df				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9783378	EXPEDITED (15-DAY)		LT, OT	FR-SA-2013SA130931		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Coma; Disturbance In Attention; Hypothermia	Tercian			S	Oral			Not Reported
	Levomepromazine			S	Oral			Not Reported
	Depakine			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Relpax			S	Oral			Not Reported
	Ketum			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9842258	EXPEDITED (15-DAY)		LT, OT	FR-PFIZER INC-2014020668		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Coma; Disturbance In Attention; Hypothermia; Pneumonia Aspiration; Toxicity To Various Agents	Relpax			S	Oral	Unk		Pfizer
	Valium			S	Oral	Unk		Not Reported
	Stilnox			S	Oral	Unk		Not Reported
	Depakine			S	Oral	Unk		Not Reported
	Tercian			S	Oral	Unk		Not Reported
	Levomepromazine			S	Oral	Unk		Not Reported

	Seroplex	S		Unk	Not Reported
	Zyprexa	S	Oral	Unk	Not Reported
	Ketum	C		Unk	Not Reported
	Paracetamol	C		Unk	Not Reported
	Noctran	C			Not Reported
	Nordazepam	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9858138	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2014-00125		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Acetaminophen+Hydrocodone			S	Oral			Not Reported
	Isosorbide Mononitrate			S	Oral			Not Reported
	Doxazosin			S	Oral			Not Reported
	Warfarin			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9858145	EXPEDITED (15-DAY)		DE, HO	US-LUPIN PHARMACEUTICALS INC.-2014-00128		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Lupin
	Meloxicam			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9858729	EXPEDITED (15-DAY)		LT, OT	FR-ABBVIE-14P-056-1196584-00		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Coma; Disturbance In Attention; Hypothermia	Depakine			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Levomepromazine			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Relpax			S	Oral			Not Reported
	Ketum			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9858878	EXPEDITED (15-DAY)		OT	ES-TEVA-437945ISR		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Venlafaxine			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Teva
	Haloperidol			S	Unknown			Not Reported
	Enalapril			S	Unknown			Not Reported
	Unspecified Thiazide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9859275	EXPEDITED (15-DAY)		OT	NL-JNJFOC-20140113524			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Foetal Exposure During Pregnancy	Risperidone			S	Transplacental	Mother'S Dosing		Not Reported
	Haloperidol			S	Transplacental	Mother'S Dosing		Not Reported
	Pipamperon			S	Transplacental	Mother'S Dosing		Not Reported
	Citalopram			S	Transplacental	Mother'S Dosing		Not Reported
	Paroxetine			S	Transplacental	Mother'S Dosing		Not Reported
	Fluvoxamine			S	Transplacental	Mother'S Dosing		Not Reported
	Fluoxetine			S	Transplacental	Mother'S Dosing		Not Reported
	Escitalopram			S	Transplacental	Mother'S Dosing		Not Reported
	Sertraline			S	Transplacental	Mother'S Dosing		Not Reported
	Venlafaxine			S	Transplacental	Mother'S Dosing		Not Reported
	Mirtazapine			S	Transplacental	Mother'S Dosing		Not Reported
	Clomipramine			S	Transplacental	Mother'S Dosing		Not Reported
	Amitriptyline			S	Transplacental	Mother'S Dosing		Not Reported
	Bupropion			S	Transplacental	Mother'S Dosing		Not Reported
	Quetiapine			S	Transplacental	Mother'S Dosing		Not Reported
	Olanzapine			S	Transplacental	Mother'S Dosing		Not Reported
	Aripiprazole			S	Transplacental	Mother'S Dosing		Not Reported
	Lithium			S	Transplacental	Mother'S Dosing		Not Reported
	Valproic Acid			S	Transplacental	Mother'S Dosing		Not Reported
	Levothyroxine			C	Transplacental	Mother'S Dosing		Not Reported
	Biperiden			C	Transplacental	Mother'S Dosing		Not Reported
	Insulin			C	Transplacental	Mother'S Dosing		Not Reported
	Dexamethasone			C	Transplacental	Mother'S Dosing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9859678	EXPEDITED (15-DAY)		HO	FR-FRI-1000053329		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Electrocardiogram Qt Prolonged; Encephalitis; Extrapyramidal Disorder; Intentional Overdose	Escitalopram	S	Oral	1 Df	Forest
	Escitalopram	S		Overdose Of 13 Tablets Of 20 Mg	Not Reported
	Teralithe	S	Oral	1 Df	Not Reported
	Teralithe	S		Overdose Of 6 Or 7 Tablets Of 250 Mg	Not Reported
	Seresta	S	Oral		Not Reported
	Seresta	S	Oral	Overdose Of An Unknown Dose	Not Reported
	Havlane	S	Oral	1 Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9859705	EXPEDITED (15-DAY)		LT	FR-FRI-1000053300		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Coma; Disturbance In Attention; Hypothermia	Escitalopram			S				Forest
	Valium			S				Not Reported
	Stilnox			S				Not Reported
	Valproate De Sodium			S				Not Reported
	Tercian			S				Not Reported
	Levomepromazine			S				Not Reported
	Zyprexa			S				Not Reported
	Relpax			S				Not Reported
	Noctran			S				Not Reported
	Ketum			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9859721	EXPEDITED (15-DAY)		LT	FR-FRI-1000053299		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypercapnic Coma; Overdose; Respiratory Arrest	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose With 24 Tablets		Forest
	Victan			S	Oral			Not Reported

	Victan	S	Oral	Overdose With 30 Tablets	Not Reported
	Valdoxan	C			Not Reported
	Kardegic	C			Not Reported
	Flecaine	C			Not Reported
	Aldactazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9860971	DIRECT					53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Product Substitution Issue	Escitalopram 10 Mg			S	Oral	Q Daily Once Daily Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2014	9867261	EXPEDITED (15-DAY)	Y	DE	2014AP000499		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Citalopram Hydrobromide Tablets			S	Oral	; Po		Not Reported
	Escitalopram 20mg Generic			S	Oral	; Po		Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Oral	; Po		Not Reported
	Bupropion Hydrochloride Tablets			S	Oral	; Po		Not Reported
	Clonazepam Tablets, Usp			S	Oral	; Po		Not Reported
	Tadalafil			S	Oral	; Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2014	9860176	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2014-00184		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine			S	Oral			Not Reported

	Escitalopram	S	Oral	Not Reported
	Carvedilol	S	Oral	Not Reported
	Citalopram	S	Oral	Not Reported
	Alprazolam	S	Oral	Not Reported
	Bupropion (Extended Release)	S	Oral	Not Reported
	Acetaminophen/Hydrocodone	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2014	9657648	EXPEDITED (15-DAY)		HO	FR-SA-2013SA106956		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Hepatic Enzyme Increased; Pancreatitis Acute; Vomiting	Stilnox			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Seroplex			S	Oral	Strength: 10 Mg		Not Reported
	Seroplex			S	Oral			Not Reported
	Methadone			S	Oral			Not Reported
	Methadone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2014	9861807	EXPEDITED (15-DAY)		HO	FR-ROCHE-1342576		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Rocephine			S	Unknown			Not Reported
	Rocephine			S				Not Reported
	Seroplex			S	Oral	Coated-Film Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2014	9862826	EXPEDITED (15-DAY)		DE, OT	CHPA2014US001719		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Completed Suicide	Acetam/Diphen Citrate	Y	S	Oral		Novartis
	Citalopram		S	Oral		Not Reported
	Escitalopram		S	Oral		Not Reported
	Bupropion		S	Oral		Not Reported
	Clonazepam		S	Oral		Not Reported
	Tadalafil		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2014	9863160	EXPEDITED (15-DAY)		DE, HO	US-PAR PHARMACEUTICAL, INC-2014SCPR008744		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bradycardia; Cardio-Respiratory Arrest; Completed Suicide; Death; Hyperhidrosis; Hyperthermia; Hypotension; Muscle Rigidity; Nystagmus; Overdose; Pulmonary Oedema; Tremor	Alprazolam			S		Unk, Unknown, Ingst + Aspir		Par
	Vilazodone			S		Unk, Unknown, Ingst+ Aspir		Not Reported
	Salicylates Nos			S		Unk, Unknown, Ingst+ Aspir		Not Reported
	Escitalopram			S		Unk, Unknown, Ingst+ Aspir		Not Reported
	Duloxetine			S		Unk, Unknown, Ingst+ Aspir		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2014	9863176	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2014SCPR008742		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Death	Alprazolam			S	Oral	Unk, Unknown		Par
	Zolpidem Tartrate Er			S	Oral	Unk, Unknown		Par
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2014	9865170	EXPEDITED (15-DAY)		OT	PHHY2014IT011645			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Escitalopram			S	Transplacental	Maternal Dose: 10 Mg, Daily		Not Reported
	Alprazolam			S	Transplacental	Maternal Dose: 0.25 Mg Daily		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2014	9869660	DIRECT					44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2014	9880363	EXPEDITED (15-DAY)	Y	DE	ABR_01414_2014		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Lamotrigine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Meloxicam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2014	9735120	EXPEDITED (15-DAY)		DE	FR-FRI-1000051902		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Labelled Drug-Drug Interaction Medication Error; Sudden Death	Escitalopram			S	Oral	1 Df		Forest
	Methadone			S		1 Df		Not Reported

Tercian	C	Oral	6 Df		Not Reported
Valdoxan	C	Oral	1 Df		Not Reported
Noctamide	C	Oral	1 Df		Not Reported
Xanax	C	Oral	6 Df		Not Reported
Theralene	C	Oral	50 Df		Not Reported
Neuleptil	C		2 Df		Not Reported
Efexor	C		1 Df		Not Reported
Crestor	C		1 Df		Not Reported
Inexium	C		1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2014	9868972	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2014-00239		93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2014	9869240	EXPEDITED (15-DAY)		CA	DE-ASTRAZENECA-2014SE06138		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemangioma	Seroquel			S	Transplacental			Zeneca
	Cipralex			S	Transplacental			Not Reported
	Medikinet			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2014	9869941	EXPEDITED (15-DAY)		OT	CA-FRI-1000053375		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hip Fracture; Osteoporosis	Escitalopram		S	Oral	20 Mg	Forest
	Forteo		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2014	9880642	EXPEDITED (15-DAY)	Y	HO	AUR-APL-2013-10922		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Depressed Level Of Consciousness; Refusal Of Treatment By Patient; Self-Medication; Somnolence; Toxicity To Various Agents; Toxicologic Test Abnormal	Olanzapine (Olanzapine)			S	Oral			Not Reported
	Lyrica (Pregabalin)			S	Oral Oral	28 Df, Single 7.5 Mg, Oral		Not Reported
	Lexomil (Bromazepam)			S	Oral	Stopped		Not Reported
	Seroplex (Escitalopram Oxalate)			S	Oral Oral Oral	12 Df, Single 20 Mg, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2014	9881535	EXPEDITED (15-DAY)	Y	DE	IMP_07344_2014		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Alprazolam			S				Not Reported
	Escitalopram			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2014	9882075	EXPEDITED (15-DAY)	Y	DE	IMP_07445_2014		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Flutter; Bradycardia; Cardio-Respiratory Arrest; Completed Suicide; Exposure Via Ingestion;	Alprazolam			S		(~100 Df Oral)		Not Reported
	Vilazodone			S		(~21 Df Oral)		Not Reported
	Salizylates Nos			S		(Df Oral)		Not Reported
	Escitalopram			S		(Df Oral)		Not Reported

Exposure Via Inhalation; Haematemesis; Hyperhidrosis; Hyperthermia; Hypotension; Intentional Overdose; Livedo Reticularis; Lung Infiltration; Muscle Rigidity; Nystagmus; Pulmonary Oedema; Tremor; Unresponsive To Stimuli; Ventricular Tachycardia	Duloxetine	S		Not Reported
	Aripirazole	C		Not Reported
	Clonazepam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2014	9883112	EXPEDITED (15-DAY)	Y	DE	IMP_07159_2014		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning	Bupropion			S	Oral	(Df Oral)		Not Reported
	Citalopram			S	Oral	(Df Oral)		Not Reported
	Escitalopram			S	Oral	(Df Oral)		Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Oral	(Df Oral)		Not Reported
	Clonazepam			S	Oral	(Df Oral)		Not Reported
	Tadalafil			S	Oral	(Df Oral)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2014	9885768	EXPEDITED (15-DAY)	Y	DE	IMP_07169_2014		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Bupropion			S		(Df Oral) Unknown Until Not Continuing		Not Reported
	Alprazolam			S		(Df Oral) Unknown Until Not Continuing		Not Reported
	Amlodipine			S		(Df Oral) Unknown Until		Not Reported

			Not Continuing	
	Carvediol	S	(Df Oral) Unknown Until Not Continuing	Not Reported
	Acetaminophen W/Hydrocodone	S	(Df Oral) Unknown Until Not Continuing	Not Reported
	Citalopram	S	(Df Oral) Unknown Until Not Continuing	Not Reported
	Escitalopram	S	(Df Oral) Unknown Until Not Continuing	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2014	9615443	EXPEDITED (15-DAY)		OT	DE-FRI-1000049927		25 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Extremity Necrosis; Prescribed Overdose; Vasculitis	Escitalopram			S	Oral	30 Mg		Forest
	Escitalopram			S				Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2014	9704869	EXPEDITED (15-DAY)		HO	BR-ABBVIE-13P-020-1169600-00		54 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Coronary Artery Dissection; Pain In Extremity	Humira			S	Subcutaneous			Not Reported
	Escitalopram			S	Oral			Not Reported
	Pantoprazole			C	Oral			Not Reported
	Clopidogrel Bisulfate			C	Oral	1 Tablet After Lunch		Not Reported
	Aas			C	Oral	1 Tablet After Lunch		Not Reported
	Atorvastatin			C	Oral			Not Reported
	Atorvastatin			C	Oral	1 Tablet After Dinner		Not Reported
	Enalapril Maleate			C	Oral	1 Tablet In The Morning		Not Reported

				And 1 Tablet At Night.	
	Bromide Otilonio (Lonium)	C	Oral		Not Reported
	Bromide Otilonio (Lonium)	C			Not Reported
	Dipyrone	C	Oral		Not Reported
	Foraseq	C		Form Of Administration: Inhalant/Spray, Once A Day	Not Reported
	Nasonex	C	Nasal	Form Of Administration: Inhalant/Spray 2 Puffs In Each Nostril,Twice A Day	Not Reported
	Nasonex	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2014	9771156	EXPEDITED (15-DAY)		HO	AU-FRI-1000052319			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Partial Seizures	Escitalopram			S				Forest
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2014	9875861	NON-EXPEDITED			US-ACORDA-ACO_35712_2013			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Ampyra			S	Oral	10 Mg, Q 12 Hrs		Acorda
	Seroquel			S		25 Mg, Qd Hs		Not Reported
	Wellbutrin Xl			S		150 Mg, Qd		Not Reported
	Lexapro			S		30 Mg, Qd		Not Reported
	Provigil			S		100 Mg, Bid		Not Reported
	Strattera			C		40 Mg, Qd		Not Reported
	Baclofen			C		20 Mg, Tid		Not Reported
	Toviaz			C		8 Mg, Qd Hs		Not Reported
	Lisinopril			C		7.5 Unk, Qd		Not Reported

	Pravastatin	C	20 Mg, Qd	Not Reported
	Omeprazole	C	40 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2014	9877936	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000053243		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Product Misuse; Suicide Attempt	Escitalopram			S		20 Mg		Forest
	Lysanxia			C	Oral	10 Mg		Not Reported
	Lysanxia			C	Oral	Overdose Of 80 Tablets Of 10 Mg (800 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2014	9879282	EXPEDITED (15-DAY)		HO	CH-ASTRAZENECA-2014SE07160		61 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Haemorrhage; Blood Pressure Decreased; Drug Interaction; Haemoglobin Decreased	Brilique			S	Oral			Astrazeneca
	Klacid I.V.Infusionspraeparat			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Fragmin			S	Subcutaneous			Not Reported
	Sortis			C				Not Reported
	Seretide			C				Not Reported
	Ventolin			C				Not Reported
	Spiriva			C				Not Reported
	Lyrica			C				Not Reported
	Truxal			C				Not Reported
	Amaryl			C				Not Reported
	Tazobac			C				Not Reported
	Tamiflu			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2014	9879490	EXPEDITED (15-DAY)		OT	DE-FRI-1000053965		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Hellp Syndrome; Pre-Eclampsia	Escitalopram			S	Oral	20 Mg		Forest
	Seroquel			S	Oral	25 Mg		Not Reported
	Medikinet			S	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2014	9879609	EXPEDITED (15-DAY)		DE	FR-FRI-1000054021		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram			S	Oral			Forest
	Plavix			S	Oral	1 Df		Not Reported
	Diamicron			C				Not Reported
	Glucor			C				Not Reported
	Ikorel			C				Not Reported
	Pravastatin			C				Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C				Not Reported
	Triatec (Ramipril)			C				Not Reported
	Modopar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2014	9879667	EXPEDITED (15-DAY)		CA	DE-FRI-1000054006		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Haemangioma; Low Birth	Escitalopram			S	Transplacental	20 Mg		Forest
	Seroquel			S	Transplacental	25 Mg		Not Reported

Weight Baby; Neonatal Respiratory Distress; Premature Baby	Medikinet		S	Transplacental	20 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2014	9879742	EXPEDITED (15-DAY)		HO	IT-TEVA-384276ISR		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Respiratory Acidosis; Respiratory Depression; Sopor	Paracetamol			S	Oral	28 Dosage Forms Daily;		Not Reported
	Venlafaxine			S	Oral	21 Dosage Forms Daily;		Teva
	Lexotan			S	Oral	51 Dosage Forms Daily;		Not Reported
	Patrol 37.5mg/325mg			S	Oral	4 Dosage Forms Daily; 1 Dosage Form = Tramadol 37.5mg + Paracetamol 325mg		Not Reported
	Moment			S	Oral	18 Dosage Forms Daily;		Not Reported
	Cipralex			S	Oral	18 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2014	9885576	EXPEDITED (15-DAY)	Y	OT	2014HINLIT0093		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperglycaemia	Escitalopram			S			3 DAY 15 DAY	Not Reported
	Glibenclamide			C				Not Reported
	Enalapril + Hydrochlorotiazide			C				Not Reported
	Doxazosin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2014	8889958	NON-EXPEDITED			US-PFIZER INC-2012275999			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Norvasc			S		Unk		Pfizer

Oedema; Peripheral Swelling	Lexapro		S		Unk	Not Reported
	Celebrex		C	Oral	200 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2014	9859811	EXPEDITED (15-DAY)		DE, OT	NO-ABBVIE-14P-122-1195825-00		41 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level; Aortic Thrombosis; Arterial Disorder; Arterial Thrombosis; Arterial Thrombosis; Cardiac Ventricular Thrombosis; Cardiovascular Disorder; Cerebral Artery Occlusion; Cerebral Artery Stenosis; Cerebral Haemorrhage; Cerebral Infarction; Cerebral Infarction; Cerebrovascular Disorder; Circulatory Collapse; Connective Tissue Disorder; Coronary Artery Occlusion; Drug Screen Positive; Emphysema; Infarction; Myocardial Infarction; Renal Artery Thrombosis	Norvir			S	Oral			Not Reported
	Reyataz			S	Oral			Not Reported
	Truvada			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Cannabis			S				Not Reported
	Sarotex			S	Oral			Not Reported
	Neurontin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2014	9881157	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201400872		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S	Oral	Unk		Tyco
	Amlodipine			S	Oral	Unk		Not Reported
	Carvedilol			S	Oral	Unk		Not Reported

	Bupropion Hcl Er	S	Oral	Unk		Not Reported
	Citalopram	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Alprazolam	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2014	9882116	EXPEDITED (15-DAY)		OT	JP-FRI-1000053969		20 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased	Lexapro			S	Oral			Forest
	Abilify			S	Oral			Not Reported
	Abilit			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2014	9882673	EXPEDITED (15-DAY)		CA	US-FRI-1000053339		3 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arnold-Chiari Malformation; Congenital Anomaly; Spina Bifida; Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2014	9884464	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram 10 Mg			S	Oral	1 Pill Once Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2014	9884860	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2014	9888716	EXPEDITED (15-DAY)	Y	DE	SYM-2014-16251		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bicarbonate Decreased; Blood Chloride Increased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Lactic Acid Abnormal; Blood Ph Decreased; Blood Potassium Increased; Blood Urea Increased; Bradycardia; Cardio-Respiratory Arrest; Completed Suicide; Electrocardiogram Qrs Complex Prolonged; Exposure Via Ingestion; Haematemesis; Hyperhidrosis; Hyperthermia; Hypotension; Intentional Overdose; Livedo Reticularis; Muscle Rigidity; Nystagmus; Oxygen Saturation Decreased; Poisoning; Pulmonary Oedema; Respiratory Rate Decreased; Tremor;	Salicylate			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Vilazodone			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Duloxetine			S	Oral			Not Reported

Unresponsive To Stimuli;
Ventricular Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2014	9886199	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-PHEN20130002			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Increased	Phentermine Hcl Tablets			S	Oral	Unknown		Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2014	9890446	DIRECT					51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Atrial Fibrillation; Palpitations; Product Substitution Issue; Withdrawal Syndrome	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2014	9890974	EXPEDITED (15-DAY)	Y	OT	ADR-2014-00215		35 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Withdrawal Syndrome; Blood Pressure Increased; Confusional State; Drug Withdrawal Syndrome; Hallucination, Visual; Hepatocellular Injury; Hyperhidrosis; Leukocytosis; Neutrophilia; Sinus Tachycardia; Tremor	Baclofen			S		240 Mg/Day		Not Reported
	Alcohol (Ethanol)			S				Not Reported
	Alprazolam			S		2mg/Day		Not Reported
	Escitalopram			S		20mg/Day		Not Reported
	Amitriptyline			S		75mg/Day		Not Reported
	Cannabis			S				Not Reported
	Possible Other Benzodiazepine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2014	9891415	EXPEDITED (15-DAY)	Y	OT	2014030472		61 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction	Fragmin			S	Subcutaneous			Not Reported
	Cipralex			S	Oral			Not Reported
	Klacid			S	Intravenous (not otherwise specified)			Not Reported
	Seretide			C				Not Reported
	Ventolin(Salbutamol)			C				Not Reported
	Spiriva			C				Not Reported
	Lyrica(Pregabalin)			C				Not Reported
	Truxal(Chlorprothixene Hydrochloride)			C				Not Reported
	Amaryl(Glimepiride)			C				Not Reported
	Tazobac(Piperacillin Sodium, Tazobactam Sodium)			C				Not Reported
	Tamiful(Oseltamivir)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2014	9348609	EXPEDITED (15-DAY)		HO	US-SHIRE-ALL1-2013-03833		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Dizziness; Pain In Extremity	Blinded 489 (Lisdexamfetamine Dimesylate)			S	Oral	Unk, Unknown		Shire
	Blinded Escitalopram Oxalate			S	Oral	Unk, Unknown		Shire
	Blinded Placebo			S	Oral	Unk, Unknown		Shire
	Blinded Venlafaxine Hydrochloride			S	Oral	Unk, Unknown		Shire
	Escitalopram Oxalate			S	Oral	10 Mg, Unknown		Unknown
	Mirena			C	Vaginal	Unk Unk, Unknown		Not Reported
	Albuterol /00139501/			C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2014	9741190	EXPEDITED (15-DAY)		OT	FR-FRI-1000051969			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Initial Insomnia; Muscle Contracture; Off Label Use	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest
	Escitalopram			S				Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2014	9887664	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2013S1025458			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Hypoglycaemia	Escitalopram			S	Transplacental			Not Reported
	Paroxetine			S	Transplacental	20-40mg/Day		Not Reported
	Clonazepam			S	Transplacental			Not Reported
	Lorazepam			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2014	9888572	EXPEDITED (15-DAY)		HO	CH-FRI-1000054059			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Haemorrhage; Blood Pressure Decreased; Haemoglobin Decreased	Escitalopram			S	Oral	10 Mg		Forest
	Fragmin			S		5000 Iu		Not Reported
	Brilique			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Klacid			S	Intravenous (not otherwise specified)			Not Reported
	Tazobac			S				Not Reported
	Amaryl			S				Not Reported
	Lyrica			C				Not Reported

Seretide	C		Not Reported
Ventolin	C		Not Reported
Truxal	C		Not Reported
Amaryl	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2014	9889133	EXPEDITED (15-DAY)		HO	FR-FRI-1000054115		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction; Headache	Escitalopram			S	Oral	1 Df		Forest
	Kardegic			S	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2014	9889134	EXPEDITED (15-DAY)		OT	SE-FRI-1000054117		37 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuritis; Vision Blurred	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2014	9889339	EXPEDITED (15-DAY)		CA, OT	US-FRI-1000054042		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arnold-Chiari Malformation; Cerebral Dysgenesis; Cleft Lip And Palate; Congenital Anomaly; Congenital Central Nervous System Anomaly; Hydrocephalus; Seizure	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2014	9889669	NON-EXPEDITED			US-PFIZER INC-2014037604			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Viibryd			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2014	9904797	EXPEDITED (15-DAY)		OT	AUR-APL-2014-01264		35 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; No Therapeutic Response	Escitalopram			S		1 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2014	9908450	EXPEDITED (15-DAY)		DE	AUR-APL-2014-00967		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Exposure Via Ingestion; Respiratory Arrest; Toxicity To Various Agents	Lamotrigine (Lamotrigine)			S	Oral			Aurobindo
	Escitalopram (Escitalopram)			S				Not Reported
	Meloxicam (Meloxicam)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2014	9068661	EXPEDITED (15-DAY)		DE, HO, OT	US-009507513-1301USA009711		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Zocor			S	Oral			Merck
	Methylphenidate Hydrochloride			S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Lithium			S	Oral			Not Reported

	Escitalopram	S	Oral	Not Reported
	Aripiprazole	S	Oral	Not Reported
	Valacyclovir Hydrochloride	S	Oral	Not Reported
	Propoxyphene	S	Oral	Not Reported
	Hydrocodone	S	Oral	Not Reported
	Oxycodone	S	Oral	Not Reported
	Triazolam	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2014	9910175	EXPEDITED (15-DAY)		CA, DE	2014AP001191		1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip; Foetal Exposure During Pregnancy; Hernia; Hydrocele; Maternal Drugs Affecting Foetus	Paroxetine Hcl			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2014	9913063	EXPEDITED (15-DAY)	Y	HO	2014027812		61 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Application Site Haemorrhage; Blood Pressure Decreased; Chronic Obstructive Pulmonary Disease; Drug Interaction; Haemoglobin Decreased; Injection Site Pain; Pneumonia; Sepsis	Fragmin			S	Subcutaneous			Not Reported
	Brilique			S	Oral	1 Df 1x Day Oral		Not Reported
	Aspirin			S	Oral	1 Df 1x//Dayy, Oral		Bayer
	Cipralex			S	Oral			Not Reported
	Ventolin(Slbutamol)			C				Not Reported
	Spirivia(Tiotropium Bromide)			C				Not Reported
	Lyrica(Pregabalin)			C				Not Reported
	Truxal(Chlorprothixene Hydrochloride)			C				Not Reported
	Amaryl(Glimepiride)			C				Not Reported
	Tazobac(Piperacillin Sodium, Tazobactam Sodium)			C				Not Reported
	Tamiflu(Oseltamivir)			C				Not Reported

	Sortis(Atorvastatin)	C	Not Reported
	Seretide	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2014	9913965	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2014-01215		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Exposure Via Ingestion; Intentional Self-Injury; Respiratory Arrest; Toxicity To Various Agents	Citalopram (Citalopram)			S	Oral	Oral		Not Reported
	Escitalopram (Escitalopram)			S		Unknown		Not Reported
	Dozol			S		Unknown		Not Reported
	Bupropion (Bupropion)			S		Unknown		Not Reported
	Clonazepam (Clonazepam) (Clonazepam)			S		Unknown		Not Reported
	Tadalafil			S		Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2014	9342556	EXPEDITED (15-DAY)		OT	AT-PFIZER INC-2013170797		20 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Loss Of Consciousness; Sleep Disorder	Zeldox			S		40 Mg, 1x/Day		Pfizer
	Zeldox			S		60 Mg, 1x/Day		Pfizer
	Trittico Retard			S		150 Mg, 1x/Day		Not Reported
	Trittico Retard			S		300 Mg, 1x/Day		Not Reported
	Cipralex			S		10 Mg, 1x/Day		Not Reported
	Cipralex			S		10 Mg, 1x/Day		Not Reported
	Cipralex			S		20 Mg, Daily		Not Reported
	Risperdal			C		4 Mg, Daily		Not Reported
	Risperdal			C		3 Mg, Daily		Not Reported
	Risperdal			C		1 Mg, Daily		Not Reported
	Dominal Forte			C		80 Mg, Daily		Not Reported
	Nicorette Inhaler			C		Unk Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2014	9828461	EXPEDITED (15-DAY)		OT	AU-FRI-1000052922		46 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Hepatic Function Abnormal; Hepatic Steatosis; Renal Impairment; Weight Increased	Escitalopram			S	Oral	250 Mg		Forest
	Clopine			S				Not Reported
	Diazepam			S				Not Reported
	Levetiracetam			S				Not Reported
	Risperidone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2014	9866805	EXPEDITED (15-DAY)		OT	CH-009507513-1401CHE014395		43 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Intentional Overdose; Suicide Attempt	Remeron			S	Oral	12 Df, Once		Merck
	Ethanol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	5 Df, Once		Not Reported
	Lorazepam			S	Oral	2 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2014	9883838	EXPEDITED (15-DAY)		HO, LT, OT	FR-ELI_LILLY_AND_COMPANY-FR201401010987		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Coma; Disturbance In Attention; Drug Level Above Therapeutic; Hypothermia; Oxygen Saturation Decreased; Pneumonia Aspiration	Zyprexa			S	Oral	1 Df, Unknown		Eli Lilly And Co
	Valium /00017001/			S	Oral	1 Df, Unknown		Not Reported
	Stilnox			S	Oral	1 Df, Unknown		Not Reported
	Depakine /00228502/			S	Oral	1 Df, Unknown		Not Reported
	Tercian /00759301/			S	Oral	1 Df, Unknown		Not Reported
	Levomepromazine			S	Oral	1 Df, Unknown		Not Reported
	Seroplex			S	Oral	1 Df, Unknown		Not Reported

Relpax	S	Oral	1 Df, Unknown		Not Reported
Ketum	C	Unknown	1 Df, Prn		Not Reported
Paracetamol	C	Unknown	1 Df, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2014	9893811	EXPEDITED (15-DAY)		OT	BE-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2014-BI-05		81 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Food Interaction; Hallucination; Hypertonia; Parkinsonism Hyperpyrexia Syndrome; Pyrexia	Pramipexole			S	Oral	2.1 Mg		Boehringer Ingelheim
	Pramipexole			S		1.05 Mg		Boehringer Ingelheim
	Levodopa			S	Oral	250 Mg		Not Reported
	Levodopa			S		750 Mg		Not Reported
	Venlafaxine			S	Oral	150 Mg		Not Reported
	Escitalopram			S	Oral	10 Mg		Not Reported
	Isosource Energy			S		20 Ml/H (Protein Content: 6.1 G/100 Ml)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2014	9893837	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2014035238		76 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Aromasin			S	Oral	25 Mg, 1x/Day		Pfizer
	Cipralex			S	Oral	Unk		Not Reported
	Procoralan			S	Oral	Unk		Not Reported
	Bactrim			S	Oral	Unk		Not Reported
	Beloc-Zok			C	Oral	25 Mg, 1x/Day		Not Reported
	Cosaar Plus			C	Oral	1 Df (50/12.5 Mg), 1x/Day		Not Reported
	Aldactone			C	Oral	25 Mg, 1x/Day		Not Reported
	Prolia			C		Unk		Not Reported

	Potassium	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2014	9626159	EXPEDITED (15-DAY)		DE, HO, LT	FR-UCBSA-100212		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Thrombocytopenia	Keppra			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Vfend			S	Oral			Not Reported
	Vfend			S	Oral			Not Reported
	Noxafil			C				Not Reported
	Noxafil			C				Not Reported
	Itraconazole			C				Not Reported
	Itraconazole			C				Not Reported
	Cyclosporine			C				Not Reported
	Cellcept			C				Not Reported
	Zophren			C				Not Reported
	Amlor			C				Not Reported
	Methylprednisolone			C				Not Reported
	Domperidone			C				Not Reported
	Esomeprazole			C				Not Reported
	Effexor			C		Unknown Dose		Not Reported
	Vimpat			C		Unknown Dose		Not Reported
	Urbanyl			C		Unknown Dose		Not Reported
	Ogastoro			C		Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2014	9769130	EXPEDITED (15-DAY)	Y	HO	AUR-APL-2013-10493		86 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Abuse; Intentional Overdose; Psychomotor Hyperactivity; Sopor	Bisoprolol			S	Oral	(3 Dosage Forms,Total)		Not Reported
	Metformin			S	Oral	(1500 Mg,Total), Oral		Not Reported
	Tavor (Lorazepam)			S	Oral	(6 Dosage Forms,Total)		Not Reported

	Cipralex	S	Oral	(3 Dosage Forms,Total)	Not Reported
	Diamicron	S	Oral	(3 Dosage Forms,Total), Oral	Not Reported
	Tachipirina	S	Oral	(3 Dosage Forms,Total)	Not Reported
	Serenase (Haloperidol)	S	Oral	(2 Dosage Forms,Total)	Not Reported
	Coumadin (Warfarin Sodium)	C			Not Reported
	Dibase (Colecalciferol)	C			Not Reported
	Nexium (Esomeprazole Magnesium)	C			Not Reported
	Isoptin (Verapamil Hydrochloride)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2014	9897831	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/14/0038089		25 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Labour	Lamotrigine			S	Oral	150 [Mg/D]		Not Reported
	Escitalopram			S	Oral	20 [Mg/D]		Not Reported
	Femibion Schwangerschaft 1			C	Oral	0.8 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2014	9897833	EXPEDITED (15-DAY)		CA, OT	DE-DRREDDYS-GER/GER/14/0038082		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Hypotonia; Motor Developmental Delay; Premature Baby; Small For Dates Baby	Lamotrigine			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Femibion Schwangerschaft 1			C	Transplacental	0.8 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2014	9898034	EXPEDITED (15-DAY)		HO, OT	CH-ASTRAZENECA-2014SE09132		64 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Haematotoxicity; Hypokalaemia; Renal Failure; Toxicity To Various Agents; Urinary Tract Infection	Nexium			S	Oral			Astrazeneca
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Temgesic			S	Sublingual			Not Reported
	Transtec			S	Transdermal			Not Reported
	Afinitor			S	Oral			Not Reported
	Afinitor			S	Oral			Not Reported
	Afinitor			S	Oral	After The 22-Jan-2014 10mg/Day And Every 2nd Day+5 Mg/Day Addition		Not Reported
	Aromasin			C	Oral			Not Reported
	Xgeva			C		Per 2 Months		Not Reported
	Importal			C	Oral			Not Reported
	Xanax			C	Oral			Not Reported
	Seresta			C	Oral			Not Reported
	Dafalgan			C	Oral			Not Reported
	Irfen			C	Oral			Not Reported
	Magnesium			C	Oral			Not Reported
	Aranesp			C		3 Occasions (29-Aug-2013, 26-Sep-2013, 28-Nov-2013)		Not Reported
	Aranesp			C		To 10 Mg 1 Per Day And 5 Mg Every Second Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2014	9898858	EXPEDITED (15-DAY)		OT	CH-ROXANE LABORATORIES, INC.-2014-RO-00188RO		56 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Torsade De Pointes	Zidovudine	S	600 Mg	Roxane
	Methadone	S	80 Mg	Roxane
	Escitalopram	S	30 Mg	Not Reported
	Fluoxetine	S	20 Mg	Not Reported
	Zuclopenthixol	S	40 Mg	Not Reported
	Atazanavir	S	400 Mg	Not Reported
	Lamivudine	S	300 Mg	Not Reported
	Ritonavir	S	200 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2014	9898976	EXPEDITED (15-DAY)		DE, OT	CH-ROXANE LABORATORIES, INC.-2014-RO-00192RO		55 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sudden Cardiac Death	Methadone			S				Roxane
	Zidovudine			S		600 Mg		Roxane
	Escitalopram			S		30 Mg		Not Reported
	Atazanavir			S		400 Mg		Not Reported
	Levomepromazine			S		50 Mg		Not Reported
	Lamivudine			S		300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2014	9900075	EXPEDITED (15-DAY)		CA	US-FRI-1000054151		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Stenosis; Bicuspid Aortic Valve; Congenital Anomaly	Lexapro			S				Forest
	Zoloft			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2014	9913530	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2014-01183		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Exposure Via Ingestion; Respiratory Arrest; Toxicity To Various Agents	Amlodipine			S	Oral	Oral		Not Reported
	Carvedilol (Carvedilol)			S		Unknown		Not Reported
	Hydrocodone+Paracetamol(Vodocodin) (Unknown) (Paracetamol, Hydrocodone Bitartrate)			S		Unknown		Not Reported
	Citalopram (Citalopram)			S		Unknown		Not Reported
	Escitalopram (Escitalopram)			S		Unknown		Not Reported
	Alprazolam (Alprazolam)			S		Unknown		Not Reported
	Bupropion (Bupropion)			S		Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2014	9903000	EXPEDITED (15-DAY)		OT	PHHY2014BR018176		21 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Hallucination	Oxcarbazepine			S		600 Mg, Bid		Novartis
	Sertraline			S		100 Mg, Bid		Not Reported
	Lexapro			S		20 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Seroquel Xro			S		50 Mg, Qd		Not Reported
	Seroquel Xro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2014	9350925	EXPEDITED (15-DAY)		OT	AT-JNJFOC-20130604091		20 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Dysphagia; Fall; Loss Of Consciousness; Myalgia	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported

Cipralex	S	Unknown	Not Reported
Dominal Forte	S	Unknown	Not Reported
Dominal Forte	S	Unknown	Not Reported
Dominal Forte	S	Unknown	Not Reported
Trittico	S	Unknown	Not Reported
Trittico	S	Unknown	Not Reported
Nicotine	S	Unknown	Not Reported
Zeldox	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2014	9832944	EXPEDITED (15-DAY)		HO	AU-FRI-1000052948		36 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypotension; Seizure; Ventricular Tachycardia	Escitalopram			S	Oral	10 Mg		Forest
	Warfarin Sodium			S	Oral	4 Mg		Not Reported
	Amiodarone Hydrochloride			C		200 Mg		Not Reported
	Carvedilol Hydrochloride			C		12.5 Mg		Not Reported
	Frusemide			C		80 Mg		Not Reported
	Levetiracetam			C		1000 Mg		Not Reported
	Levetiracetam			C		2000 Mg		Not Reported
	Lisinopril			C		10 Mg		Not Reported
	Sodium Valproate			C		1000 Mg Mane/500 Mg Nocte		Not Reported
	Thyroxine Sodium			C	Oral	50 Mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2014	9873373	EXPEDITED (15-DAY)		HO, LT, OT	CH-RANBAXY-2014RR-77399		31 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Cipralex			S	Unknown	Unk		Not Reported

Drug Interaction; Electrocardiogram Qt Prolonged; Generalised Tonic-Clonic Seizure; Nausea; Torsade De Pointes	Zofran		S	Unknown	Unk	Not Reported
	Methadone		S	Oral	50-60 Mg/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2014	9879489	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2014032942		83 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus Inadequate Control; Drug Interaction; Hyperglycaemia	Escitalopram Oxalate			S	Unknown	5 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S	Unknown	10 Mg, Daily		Not Reported
	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Not Reported
	Glibenclamide			S	Unknown	7.5 Mg, 3x/Day		Not Reported
	Glibenclamide			S	Unknown	5 Mg, 3x/Day		Not Reported
	Glibenclamide			S	Unknown	2.5 Mg, 3x/Day		Not Reported
	Enap-Hl			C	Unknown	Unk		Not Reported
	Doxazosin			C	Unknown	2 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2014	9903755	EXPEDITED (15-DAY)		CA, OT	GXKR2014DE000894		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias; Motor Developmental Delay; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Lamotrigine			S	Transplacental	150 Mg/D		Novartis
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental	0.8 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2014	9907220	EXPEDITED (15-DAY)		HO	FR-FRI-1000053967		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Dizziness; Hyperhidrosis; Insomnia; Tremor; Withdrawal Syndrome	Escitalopram	S	Oral	1 Df	Forest
	Laroxyl	C			Not Reported
	Lexomil	C			Not Reported
	Actonel	C			Not Reported
	Skenan	C		20 Mg	Not Reported
	Prothiaden	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2014	9907358	EXPEDITED (15-DAY)		HO	CH-RB-063468-14		64 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Temgesic			S	Sublingual			Reckitt Benckiser
	Transtec			S	Transdermal			Reckitt Benckiser
	Afinitor			S	Oral			Not Reported
	Afinitor			S	Oral			Not Reported
	Afinitor			S	Oral	10 Mg/Daily + 5 Mg 1day/2		Not Reported
	Nexium			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Aromasin			C	Oral			Not Reported
	Xgeva			C	Oral	Dosing Details Unknown		Not Reported
	Importal			C	Oral			Not Reported
	Xanax			C	Oral			Not Reported
	Seresta			C	Oral			Not Reported
	Dafalgan			C	Oral			Not Reported
	Irfen			C	Oral			Not Reported
	Magnesium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2014	9995107	NON-EXPEDITED	Y	RI, OT	1000051657			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Medication Error; Serotonin Syndrome	Viibryd	S		7 D, 10 Mg (10 Mg, 1 In 1 D)	7 DAY	Not Reported
				20 Mg (20 Mg, 1 In 1 D)	7 DAY	
	Viibryd	S	Oral	40 Mg (40 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2014	9997303	NON-EXPEDITED		OT	1000051571		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Attention; Dizziness; Drug Ineffective; Menstruation Irregular; Nervousness; Night Sweats; Off Label Use; Tremor	Viibryd			S	Oral Oral Oral			Not Reported
	Viibryd			S	Oral			Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Wellbutrin (Bupropion Hydrochloride) (Bupropion Hydrochloride)			C				Not Reported
	Vitamin B12 (Vitamin B12) (Vitamin B12)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2014	8564445	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2012111563		35 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia; Transaminases Increased	Lyrica			S	Oral	150 Mg, 1x/Day		Pfizer
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Clonazepam			C	Oral	1.5 Mg, 1x/Day		Not Reported
	Fluoxetine			C		20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2014	9779994	EXPEDITED (15-DAY)		HO	IT-WATSON-2013-22917		86 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Abuse; Intentional Overdose; Psychomotor Hyperactivity; Sopor	Metformin (Unknown)			S	Oral	1500 Mg, Total		Watson
	Metformin (Unknown)			S	Oral	500 Mg, Daily		Watson
	Bisoprolol (Unknown)			S	Oral	3 Df, Total		Actavis Elizabeth
	Tavor /00273201/			S	Oral	6 Df, Total		Not Reported
	Cipralex			S	Oral	10 Mg, 3 Df, Total		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Diamicron			S	Oral	30 Mg, 3 Df, Total		Not Reported
	Diamicron			S	Oral	30 Df, Tid		Not Reported
	Tachipirina			S	Oral	3 Df, Total		Not Reported
	Serenase /00015301/			S	Oral	0.5 Mg, 2 Df, Total		Not Reported
	Coumadin /00014802/			C	Unknown	5 Mg, Unk		Not Reported
	Dibase			C	Intramuscular	100, 1 Vial/Month		Not Reported
	Nexium /01479302/			C	Unknown	Unk		Not Reported
	Isoptin /00014302/			C	Unknown	80 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2014	9908102	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2014000894			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Inhibitory Drug Interaction; Suicidal Ideation	Escitalopram			S	Unknown	Unk		Macleods
	Gliclazide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2014	9911639	EXPEDITED (15-DAY)		HO	PHHY2014CH015289		64 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Afinitor			S	Oral	10 Mg, Qd		Novartis

	Afinitor	S		5 Mg, Day	Novartis
	Afinitor	S		10 Mg 1 Per Day And 5 Mg Every Second Day	Novartis
	Cipralex	S	Oral	20 Mg, Qd	Not Reported
	Cipralex	S			Not Reported
	Temgesic	S	Sublingual	0.2 Mg	Not Reported
	Transtec	S	Transdermal	50 Ug, Qh	Not Reported
	Nexium//Esomeprazole Magnesium	S	Oral	40 Mg, Qd	Not Reported
	Xgeva	C	Unknown		Not Reported
	Aromasin	C	Oral	25 Mg, Qd	Not Reported
	Magnesium	C	Oral	5 Mmol, Qd	Not Reported
	Importal	C	Oral		Not Reported
	Xanax	C	Oral	1 Mg, Bid	Not Reported
	Seresta	C	Oral	50 Mg, Qd	Not Reported
	Dafalgan	C	Oral	1 G	Not Reported
	Irfen	C	Oral	400 Mg	Not Reported
	Aranesp	C			Not Reported
	Aranesp	C			Not Reported
	Aranesp	C			Not Reported
	Aranesp	C		10 Mg, Qd	Not Reported
	Aranesp	C		5 Mg,Every Second Day	Not Reported
	Zyprexa	C	Oral	2.5 Mg, Qd	Not Reported
	Zyprexa	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2014	9785666	EXPEDITED (15-DAY)		DE	CA-FRI-1000052465			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ovarian Cancer	Escitalopram			S	Oral	20 Mg		Forest
	Hydromorph Contin			C	Oral	42 Mg		Not Reported
	Taxol			C	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2014	9914059	EXPEDITED (15-DAY)		CA, OT	DE-GLAXOSMITHKLINE-D0082874A		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias; Hypotonia; Motor Developmental Delay; Premature Baby; Small For Dates Baby	Lamotrigine			S	Transplacental	150mg Per Day		Glaxosmithkline
	Escitalopram			S	Transplacental	20mg Per Day		Glaxosmithkline
	Vitamin With Folate			C	Transplacental	.8mg Per Day		Not Reported
	Iodine			C	Transplacental			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2014	9914734	EXPEDITED (15-DAY)		HO	NO-RB-063876-14		50 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Abuse; Drug Diversion; Hospitalisation; Intentional Product Misuse	Subutex			S	Unknown	At The Time When The Questionnaire Was Completed, Patient Had Been On Subutex 1 Year 7 Months		Reckitt Benckiser
	Cannabis			S	Respiratory (inhalation)	Details Unknown		Not Reported
	Cipralex			S	Unknown	Dosing Details Unknown		Not Reported
	Remeron			S	Unknown	Dosing Details Unknown		Not Reported
	Rivotril			S	Unknown	Dosing Details Unknown		Not Reported
	Benzodiazepine			S	Unknown	Takes On A Regular Basis. Specific Dosing Details Unknown.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2014	9916288	DIRECT		DS			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Depression; Diarrhoea; Drug Intolerance; Fatigue; Headache; Migraine; Nausea; Product Substitution Issue; Vomiting	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2014	8841664	EXPEDITED (15-DAY)		LT	CA-FRI-1000039397		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Panic Attack; Suicidal Ideation	Escitalopram			S	Oral	10 Mg		Forest
	Calcium			C				Not Reported
	Omeprazole			C	Oral	30 Mg		Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2014	9916807	EXPEDITED (15-DAY)		DE, HO, OT	US-ELI_LILLY_AND_COMPANY-US201402005391		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest; Completed Suicide; Haematemesis; Hyperhidrosis; Hyperthermia; Intentional Overdose; Livedo Reticularis; Muscle Rigidity; Nystagmus; Tremor; Unresponsive To Stimuli	Duloxetine Hydrochloride			S	Unknown			Unknown
	Alprazolam			S	Unknown	50 Mg, Single		Not Reported
	Salicylate Sodium			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Clonazepam			C				Not Reported
	Aripiprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2014	9917574	EXPEDITED (15-DAY)		HO	FR-FRI-1000054453		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition; Intentional Overdose; Suicide Attempt	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	Overdose With One Intake Of 140 Mg		Forest
	Escitalopram			S				Not Reported
	Imovane			C	Oral	Overdose With One Intake Of 105 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2014	9921844	DIRECT		OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia	Lexapro			S	Oral	10 Mg/1 Pill Once Daily Taken By Mouth	5 YR	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2014	9921920	DIRECT		OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Irritability; Product Substitution Issue	Escitalopram			S	Oral	1 Tab Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2014	9924827	EXPEDITED (15-DAY)		CA, DE	2014AP001344			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip; Congenital Anomaly; Hernia; Hydrocele; Maternal Drugs	Paroxetine Hcl Tablets			S				Not Reported
	Lexapro			S				Not Reported

Affecting Foetus; Multiple Injuries

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2014	9665219	EXPEDITED (15-DAY)		OT	DE-FRI-1000050702		78 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Intestinal Haemorrhage	Escitalopram Oral Solution			S	Oral	15 Mg		Forest
	Lyrica			S	Oral	25 Mg		Not Reported
	Lyrica			S				Not Reported
	Vasomotal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2014	9922332	DIRECT		OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Headache; Panic Attack; Product Substitution Issue; Therapeutic Product Effect Decreased	Escitalopram			S	Oral	1 Pill Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2014	9925633	EXPEDITED (15-DAY)	Y	DE	NL01PV14.35210		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Exposure Via Ingestion; Respiratory Arrest	Zolpidem Tablets			S	Oral			Not Reported
	Escitalopram Tablets Usp 20 Mg			S	Oral			Not Reported
	Alprazolam (Alprazolam)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2014	8838666	EXPEDITED (15-DAY)		OT	CA-FRI-1000039400		31 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2014	8842414	EXPEDITED (15-DAY)		OT	CA-FRI-1000039404			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Sensation In Eye; Drug Interaction; Dyspnoea; Eye Swelling; Fatigue; Headache; Lymphocyte Count Decreased; Multiple Sclerosis Relapse; Muscular Weakness; Nausea; Neutropenia; Pyrexia; Vision Blurred; White Blood Cell Count Decreased	Escitalopram			S				Forest
	Diclofenac			S				Not Reported
	Gilenya			S	Oral	0.5 Mg		Not Reported
	Amitriptyline			C				Not Reported
	Baclofen			C				Not Reported
	Clonazepam			C				Not Reported
	Gabapentin			C				Not Reported
	Nexium			C				Not Reported
	Tylenol Extra-Strength Ez			C				Not Reported
	Vesicare			C				Not Reported
	Water Pills			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2014	9921285	EXPEDITED (15-DAY)		HO	PHHY2014FR021234			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Tegretol			S	Oral	0.5 Df, Daily		Novartis
	Inexium//Esomeprazole Magnesium			S		Unk Ukn, Unk		Not Reported
	Seroplex			S		Unk		Not Reported
	Co-Aprovel			S		Unk Ukn, Unk		Not Reported
	Keppra			C		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2014	9921334	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2014SE11885		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Inexium			S	Oral			Astrazeneca
	Tegretol Sr			S	Oral			Not Reported
	Seroplex			S	Unknown			Not Reported
	Coaprovel			S	Unknown			Not Reported
	Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2014	9922822	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-462455GER		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias; Motor Developmental Delay; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental			Ivax
	Lamotrigine			S	Transplacental			Teva
	Femibion Schwangerschaft 1			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2014	9925260	DIRECT		OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Response Decreased	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2014	9290960	EXPEDITED (15-DAY)	Y	HO, OT	2013AP004963		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Face Injury; Fall; Lethargy; Mydriasis; Nasal Injury; Sedation; Speech Disorder	Venlafaxine Hydrochloride			S				Not Reported
	Sertraline Hydrochloride			S				Not Reported
	Delorazepam (Delorazepam)			S				Not Reported
	Bromazepam (Bromazepam)			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

(Escitalopram Oxalate)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2014	9819275	EXPEDITED (15-DAY)		LT, OT	JP-FRI-1000052779		14 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Off Label Use	Lexapro			S	Oral	2.5 Mg		Forest
	Lexapro			S	Oral	5 Mg		Forest
	Gasmotin			C	Oral	15 Mg		Not Reported
	Tsumura Shokenchuto Extract Granules For Ethical Use			C	Oral	5g		Not Reported
	Tsumura Shokenchuto Extract Granules For Ethical Use			C	Oral	2.5 G		Not Reported
	Tsumura Shokenchuto Extract Granules For Ethical Use			C	Oral	10g		Not Reported
	Tsumura Shokenchuto Extract Granules For Ethical Use			C	Oral	10g		Not Reported
	Lamictal			C	Oral	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2014	9925329	EXPEDITED (15-DAY)		HO	FR-SA-2014SA020616		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Coaprovel			S	Oral			Not Reported
	Tegretol			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2014	9925743	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000054610		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Patent Ductus Arteriosus; Ventricular Septal Defect	Lexapro		S	Transplacental	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2014	9926119	EXPEDITED (15-DAY)		CA, OT	DE-FRI-1000054597		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Hypotonia; Low Birth Weight Baby; Motor Developmental Delay; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	20 Mg		Forest
	Lamotrigin			S	Transplacental	150 Mg		Not Reported
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental	0.8 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2014	9926137	EXPEDITED (15-DAY)		HO	FR-FRI-1000054621		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Escitalopram			S				Forest
	Tegretol Lp			S	Oral	200 Mg		Not Reported
	Inexium			S				Not Reported
	Coaprovel			S				Not Reported
	Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2014	9926165	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2014S1003292		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hypospadias; Motor Developmental Delay; Premature Baby; Small For Dates Baby	Lamotrigin			S	Transplacental	150 [Mg/D]		Mylan
	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Folic Acid			C	Transplacental	0.8 [Mg/D] Femibion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2014	9928173	DIRECT		OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Insomnia; Night Sweats; Weight Increased	Escitalopram			S		1 Pill At Bedtime		Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2014	9931904	EXPEDITED (15-DAY)	Y	HO	IMP_07475_2014		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Areflexia; Brain Injury; Dry Skin; Gastrointestinal Sounds Abnormal; Hypotension; Overdose; Pulseless Electrical Activity; Pupil Fixed	Bupropion			S		(Df)		Not Reported
	Quetiapine			C		(Df)		Not Reported
	Desvenlafaxine			S		(Df)		Not Reported
	Escitalopram			S		(Df)		Not Reported
	Ibuprofen			S		(Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2014	9662179	EXPEDITED (15-DAY)		OT	PHHY2013US118929		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Paternal Exposure Timing Unspecified; Suicidal Ideation; Therapeutic Response Decreased	Fluoxetine			S				Not Reported
	Citalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Sertraline			S				Not Reported
	Bupropion			S				Not Reported
	Olanzapine			S				Not Reported
	Amitriptyline			S				Not Reported
	Valproic Acid			S				Not Reported
	Venlafaxine			S				Not Reported
	Risperidone			S				Novartis
	Zolpidem			S				Not Reported
	Quetiapine			S				Not Reported

Diphenhydramine	S		Not Reported
Trazodone	S		Not Reported
Prazosin	S		Not Reported
Eszopiclone	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2014	9853919	EXPEDITED (15-DAY)		HO	FR-FRI-1000053219		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysarthria; Speech Disorder	Escitalopram			S	Oral	1 Df		Forest
	Abilify			S	Oral	1 Df		Not Reported
	Valium			C		1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2014	9931101	EXPEDITED (15-DAY)		HO	NO-MERCK-1402NOR011979		50 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Abuse; Drug Diversion; Hospitalisation; Intentional Product Misuse	Remeron			S	Unknown	Dosing Details Unknown		Merck
	Subutex			S	Unknown	At The Time When The Questionnaire Was Completed, Patient Had Been On Subutex 1 Year 7 Months		Not Reported
	Hemp			S	Respiratory (inhalation)	Details Unknown		Not Reported
	Cipralex			S	Unknown	Dosing Details Unknown		Not Reported
	Rivotril			S	Unknown	Dosing Details Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2014	9931756	DIRECT		DS			22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In	Escitalopram			S	Oral			Not Reported

Attention; Dizziness; Emotional Disorder; Hypertension; Memory Impairment; Nausea; Tachycardia; Therapy Cessation; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9677807	EXPEDITED (15-DAY)		OT	FR-FRI-1000050878			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Pregnancy	Escitalopram			S		20 Mg		Forest
	Abilify			S		10 Mg		Not Reported
	Seresta			S		50 Mg		Not Reported
	Tercian			S		12.5 Mg		Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9677837	EXPEDITED (15-DAY)		HO	FR-FRI-1000050879		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Neonatal Hypoxia; Tremor	Escitalopram			S	Transplacental	20 Mg		Forest
	Abilify			S	Transplacental	10 Mg		Not Reported
	Seresta			S	Transplacental	50 Mg		Not Reported
	Tercian			S	Transplacental	12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9846811	EXPEDITED (15-DAY)		DE, HO	IE-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2014-BI-03		83 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Anaemia; Blood Creatinine Increased; Diarrhoea; Gastritis Haemorrhagic; Gastrointestinal Haemorrhage; Hypotension; Vomiting	Pradaxa	S	Oral	220 Mg		Boehringer Ingelheim
	Afinitor	S	Oral			Not Reported
	Escitalopram	S	Unknown	10 Mg		Not Reported
	Lorazepam	C	Unknown			Not Reported
	Lansoprazole	C	Unknown	30 Mg		Not Reported
	Perindopril	C	Unknown			Not Reported
	Atorvastatin	C	Unknown	10 Mg		Not Reported
	Lercanidipine	C	Unknown	10 Mg		Not Reported
	Zolpidem	C	Unknown	5 Mg		Not Reported
	Oxycontin	C	Unknown	20 Mg		Not Reported
	Aromasin	C	Unknown	25 Mg		Not Reported
	Zoledronic Acid	C	Unknown	0.0329 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9849216	EXPEDITED (15-DAY)		OT	US-FRI-1000053073		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9852292	EXPEDITED (15-DAY)		OT	AUR-APL-2014-00467			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Dyspnoea; Generalised Tonic-Clonic Seizure; Hallucination, Auditory; Hallucination, Visual; Muscle Rigidity; Muscle Spasms	Escitalopram			S				Not Reported
	Depakote (Valproate Semisodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9892037	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-			Unknown	ITA

2014038897

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Low Birth Weight Baby; Maternal Exposure During Pregnancy	Escitalopram Oxalate			S	Transplacental	10 Mg, Daily		Not Reported
	Alprazolam			S	Transplacental	0.25 Mg, Daily		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9907139	EXPEDITED (15-DAY)		HO	FR-FRI-1000054204		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise	Escitalopram			S	Oral	1 Df		Forest
	Oxycontin Lp			S	Oral	12 Df		Not Reported
	Oxynorm			S	Oral	Up To 8 Capsules Daily		Not Reported
	Depamide			S	Oral	4 Df		Not Reported
	Lyrica			S	Oral	2 Df		Not Reported
	Esomeprazole			C	Oral	20 Mg		Not Reported
	Gutron			C	Oral	2 Df		Not Reported
	Aerius (Desloratadine)			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9928442	EXPEDITED (15-DAY)	Y	CA, OT	AUR-APL-2014-01910		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Hypotonia; Motor Developmental Delay; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental			Not Reported
	Lamotrigine (Lamotrigine)			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9934161	EXPEDITED (15-DAY)		OT	US-SA-2014SA024126		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Renal Disorder; Stress; Wrong Technique In Product Usage Process	Multaq			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Coenzyme Q10			C				Not Reported
	Tryptophan, L-			C				Not Reported
	Aminogran Food Supplement			C				Not Reported
	Curcumen			C				Not Reported
	Acetylcysteine			C				Not Reported
	Alpha Lipoic Acid			C				Not Reported
	Vitamin C			C				Not Reported
	Melatonin			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9934527	EXPEDITED (15-DAY)		OT	JP-FRI-1000053970		70 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Ventricular Extrasystoles	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Amaryl			C	Oral	0.5 Mg		Not Reported
	Actos			C	Oral	30 Mg		Not Reported
	Nesina			C	Oral	25 Mg		Not Reported
	Nu-Lotan			C	Oral	50 Mg		Not Reported
	Reflex			C	Oral	15 Mg		Not Reported
	Reflex			C	Oral	30 Mg		Not Reported
	Myslee			C	Oral	10 Mg		Not Reported

	Myslee	C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9935288	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000054676		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	Overdose Of One Intake Of 7 Tablets (I.E. 70 Mg)		Not Reported
	Baclofene			S	Oral	40 Mg		Not Reported
	Baclofene			S	Oral	Overdose Of One Intake Of 8 Boxes (Unknown Strength)		Not Reported
	Chlormadinone			C		1 Df		Not Reported
	Chlormadinone			C		Overdose Of One Intake Of 9 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9935488	EXPEDITED (15-DAY)		HO	FR-FRI-1000054678			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Red Blood Cell Count Decreased	Escitalopram			S	Oral			Forest
	Kardegic			S	Oral			Not Reported
	Calcite			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2014	9935609	EXPEDITED (15-DAY)		OT	PHHY2014IT023596		36 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Therapeutic Product Effect Incomplete	Ribavirin			S		1000 Mg, Per Day		Novartis
	Escitalopram			S		10 Mg, Per Day		Not Reported

	Telaprevir	S	750 Mg, Tid	Not Reported
	Peginterferon Alfa-2a	S	180 Ug, Weekly	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2014	9474202	EXPEDITED (15-DAY)		OT	FR-FRI-1000048053		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Spontaneous Haematoma; Thrombocytopenia	Escitalopram			S	Oral			Forest
	Inipomp			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2014	9847362	EXPEDITED (15-DAY)		OT	JP-FRI-1000053113		55 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Paxil			C	Oral	10 Mg		Not Reported
	Paxil			C	Oral	40 Mg		Not Reported
	Paxil			C	Oral	20 Mg		Not Reported
	Paxil			C	Oral	10 Mg		Not Reported
	Anafranil			C	Oral	60 Mg		Not Reported
	Anafranil			C	Oral	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2014	9938631	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20140212451		45 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sluggishness	Risperdal			S	Oral	4 Tablets		Not Reported
	Cipralex			S	Oral			Not Reported

	Valium	S	Oral		Not Reported
	Tavor (Lorazepam)	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2014	9938841	NON-EXPEDITED			US-ABBVIE-12P-163-0952017-00		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Injection Site Erythema; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Muscular Weakness; Pain; Pain In Extremity; Parkinsonism; Rash Papular; Rash Papular; Rash Papular; Rheumatoid Arthritis; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Sinemet			S		25/100 Mg		Not Reported
	Lexapro			S				Not Reported
	Proair			C	Respiratory (inhalation)			Not Reported
	Flovent			C				Not Reported
	Tylenol Extra Strength			C				Not Reported
	Calcium Nasal Spray			C		Daily		Not Reported
	Lasix			C		Daily		Not Reported
	Levothyroxin			C		Daily		Not Reported
	Metoprolol			C				Not Reported
	Estropipate			C		Daily		Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2014	9940749	EXPEDITED (15-DAY)		DE, HO	PHHY2014IE010058			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia; Blood Creatinine Increased; Diarrhoea; Gastritis Haemorrhagic; Gastrointestinal Haemorrhage; Hypotension; Vomiting	Afinitor			S	Oral	10 Mg, Qd		Novartis
	Escitalopram			S		10 Mg		Not Reported
	Pradaxa			S		110 Mg, Bid		Not Reported
	Lorazepam			C		0.5 Mg, Daily		Not Reported
	Lansoprazole			C		30 Mg, Daily		Not Reported
	Perindopril			C				Not Reported
	Atorvastatin			C		10 Mg		Not Reported

Lercanidipine	C	10 Mg		Not Reported
Zolpidem	C	5 Mg		Not Reported
Oxycontin	C	2 Df, Qd		Not Reported
Aromasin	C	25 Mg		Not Reported
Zoledronic Acid	C	3 Mg, Q3mo		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2014	9942340	NON-EXPEDITED			US-PFIZER INC-2014059235		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Abilify			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2014	9942377	EXPEDITED (15-DAY)		CA, OT	DE-WATSON-2014-03195		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Motor Developmental Delay; Premature Baby; Small For Dates Baby	Escitalopram (Unknown)			S	Transplacental	20 Mg, Daily		Not Reported
	Lamotrigine (Unknown)			S	Transplacental	150 Mg, Daily		Watson
	Folic Acid			C	Transplacental	0.8 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2014	9943964	EXPEDITED (15-DAY)		HO	CH-FRI-1000054766		73 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Essential Tremor	Escitalopram			S	Oral	15 Mg		Forest

Risperdal	S	Oral	1 Mg		Not Reported
Temesta (Lorazepam)	S	Oral	1.5 Mg		Not Reported
Depakine Chrono	C	Oral	1200 Mg		Not Reported
Rivotril	C	Oral	0.5 Mg		Not Reported
Imovane	C	Oral	7.5 Mg		Not Reported
Inderal	C	Oral	80 Mg		Not Reported
Arimidex	C	Oral	1 Mg		Not Reported
Mysoline	C	Oral	125 Mg		Not Reported
Mysoline	C	Oral	250 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2014	9944022	EXPEDITED (15-DAY)		HO	FR-FRI-1000054765		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Photopsia	Escitalopram			S	Oral	1 Df		Forest
	Prazepam Biogaran			S	Oral	1 To 3 Tablets Daily		Not Reported
	Levothyrox			C				Not Reported
	Travatan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2014	6950747	NON-EXPEDITED	Y	HO, OT	RB-2644-2008		6 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Suboxone 8 Mg			S	Transplacental	32 Mg Transplacental		Not Reported
	Subutex			S	Transplacental	10 Mg Transplacental, 12 Mg Transplacental		Not Reported
					Transplacental	10 Mg Transplacental, 12 Mg Transplacental		
	Lexapro			S	Transplacental			Not Reported
	Clonazepam			S	Transplacental			Not Reported
					Transplacental			

Alcohol	S	Transplacental	Maternal Use In Early Pregnancy		Not Reported
Nicotine (None)	S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2014	9948728	EXPEDITED (15-DAY)		CA, OT	DE-LUPIN PHARMACEUTICALS INC.-E2B_00001725		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Motor Developmental Delay; Premature Baby; Small For Dates Baby	Lamotrigin			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Femibion Pregnancy 1			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	8655007	EXPEDITED (15-DAY)		HO, LT	PHHO2012DE009669		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Sclerosis Relapse; Organic Brain Syndrome; Personality Change	Risperidone			S		Unk		Novartis
	Fty 720			S	Oral	1 Df, 16 Wk Ws + Fty		Not Reported
	Tysabri			S	Intravenous drip	Unk		Not Reported
	Opipramol			S				Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	9788701	EXPEDITED (15-DAY)		HO	JP-FRI-1000052524		77 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	9917245	EXPEDITED (15-DAY)		HO	FR-FRI-1000054454		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypochloraemia; Hyponatraemia	Escitalopram			S	Oral	10 Mg		Forest
	Imovane			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	9961593	EXPEDITED (15-DAY)		DE	US-FRI-1000054885		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Citalopram			S				Forest
	Escitalopram			S				Forest
	Acetaminophen/Diphenhydramine			S				Not Reported
	Bupropion			S				Not Reported
	Clonazepam			S				Not Reported
	Tadalafil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	9963940	EXPEDITED (15-DAY)		HO	BE-PFIZER INC-2014059986			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Dizziness; Drug Interaction	Pantomed (Pantoprazole Sodium)			S		Unk		Pfizer
	Abilify			S		Unk		Not Reported
	Sipralexa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	9964250	EXPEDITED (15-DAY)		DE	US-BANPHARM-20142299		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Diphenhydramine And Acetaminophen Unknown Product			S	Oral			Not Reported
	Citalopram			S				Not Reported
	Escitalopram			S				Not Reported

Bupropion	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	9964933	EXPEDITED (15-DAY)		OT	PHHY2014US021139		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Implant Site Pain; Muscle Spasms; Muscle Tightness; Musculoskeletal Stiffness; Therapeutic Response Decreased; Urinary Tract Infection	Baclofen Intrathecal			S	Intrathecal	357.4 Ug/Day		Not Reported
	Baclofen			S	Oral	10 Mg, Bid		Not Reported
	Simvastatin			S		Unk Ukn, Unk		Novartis
	Duragesic			S		150 Ug/Hr, (1 Patch Every 48 Hours)		Not Reported
	Klonopin			S		0.5 Df, Bid (1 Mg)		Not Reported
	Levoxyl			S		200 Ug, Unk		Not Reported
	Lexapro			S		Unk Ukn, Unk		Not Reported
	Macrobid			S		Unk Ukn, Unk		Not Reported
	Neurontin			S		Unk Ukn, Unk		Not Reported
	Oxycodone			S		10/325		Not Reported
	Pepcid			S		Unk Ukn, Unk		Not Reported
	Probiotics			S		Unk Ukn, Unk		Not Reported
	Skelaxin			S		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	9967054	EXPEDITED (15-DAY)		DE	US-FRI-1000054855		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram			S				Forest
	Levothroid			S				Forest
	Acetaminophen/Hydrocodone			S				Not Reported
	Isosorbide Mononitrate			S				Not Reported
	Amlodipine			S				Not Reported
	Doxazosin			S				Not Reported
	Warfarin			S				Not Reported
	Furosemide			S				Not Reported

	Potassium	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	9967080	EXPEDITED (15-DAY)		DE	US-FRI-1000054875		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram			S				Forest
	Alprazolam			S				Not Reported
	Zolpidem			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	9967132	EXPEDITED (15-DAY)		DE	US-FRI-1000054857		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram			S				Forest
	Lamotrigine			S				Not Reported
	Meloxicam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	9971279	DIRECT					35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Ptosis; Peripheral Swelling; Swelling Face; Swelling Of Eyelid	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2014	9971321	DIRECT		DS			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Malignant; Pain; Peyronie'S Disease	Celexa			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2014	9904246	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2014-01467			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Low Birth Weight Baby; Maternal Drugs Affecting Foetus; Premature Baby	Escitalopram			S	Transplacental		1 DAY	Not Reported
	Alprazolam			S	Transplacental		1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2014	9926089	EXPEDITED (15-DAY)		HO	JP-FRI-1000054556		51 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Gaster			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2014	9969761	EXPEDITED (15-DAY)		HO	IT-TEVA-465961ISR		61 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Mydriasis; Sopor; Unresponsive To Stimuli	Alprazolam			S	Oral	1 Dosage Forms Daily;		Teva
	Cipralex - Compresse Rivestite Con Film - H. Lundbeck A/S			S	Oral	80 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2014	9970039	EXPEDITED (15-DAY)		OT	DE-TEVA-464641GER		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Isotretinoin			S	Oral			Barr

	Cipralex	S	Oral	10 Milligram Daily; Probably Longer		Not Reported
	Cymbalta	C	Oral			Not Reported
	Grippeimpfstoff	C	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2014	9971017	NON-EXPEDITED			US-ABBVIE-13P-163-1153315-00		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromaturia; Discomfort; Dizziness; Gastric Dilatation; Gastric Dilatation; Haematospermia; Haematuria; Injection Site Erythema; Injection Site Haemorrhage; Injection Site Pain; Lacrimation Increased; Malaise; Malaise	Humira			S	Subcutaneous	Loading Dose X 1		Not Reported
	Lexapro			S	Oral	20 Milligrams Daily		Not Reported
	Balsalazide			C	Oral			Not Reported
	Morphine			C	Oral			Not Reported
	Imuran			C	Oral	Three Tablets Daily		Not Reported
	Vitamin C			C	Oral			Not Reported
	Iron			C	Oral			Not Reported
	Zofran			C	Oral			Not Reported
	Kcl			C	Oral	Liquid, Twice A Day		Not Reported
	Marijuana			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2014	9975744	EXPEDITED (15-DAY)		DE	US-FRI-1000054884		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Overdose	Vilazodone			S				Forest
	Escitalopram			S				Forest
	Alprazolam			S				Not Reported
	Salicylate			S				Not Reported
	Duloxetine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2014	9976059	EXPEDITED (15-DAY)		CA, OT	US-FRI-1000054760			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder; Congenital Torticollis; Hydrocephalus; Speech Disorder Developmental	Lexapro			S	Transplacental			Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2014	9978283	EXPEDITED (15-DAY)		DE	US-FRI-1000054898		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Citalopram			S				Forest
	Escitalopram			S				Forest
	Amlodipine			S				Not Reported
	Carvedilol			S				Not Reported
	Bupropion			S				Not Reported
	Acetaminophen/Hydrocodone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2014	9980874	DIRECT					18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Anxiety; Constipation; Dyspepsia; Educational Problem; Gastrooesophageal Reflux Disease; Nausea; Product Substitution Issue	Escitalopram			S	Oral	1 Pill Once Daily Taken By Mouth		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2014	9980934	DIRECT		OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Depressed Mood; Drug	Escitalopram 10 Mg			S	Oral	1 Tablet Once Daily Taken		Aurobindo

Ineffective; Paradoxical Drug Reaction; Product Substitution Issue; Stress	By Mouth

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2014	9980431	EXPEDITED (15-DAY)		OT	DE-RANBAXY-2014R1-78638		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Isotretinoin			S	Oral	10 Mg, 2/Week		Ranbaxy
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Cymbalta			C	Oral	Unk		Not Reported
	Gippeimpfstoff			C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2014	9984712	EXPEDITED (15-DAY)		CA	US-FRI-1000054994		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip; Congenital Anomaly; Hernia Congenital; Hydrocele	Lexapro			S	Transplacental			Forest
	Paxil			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2014	9985108	NON-EXPEDITED			US-ABBVIE-13P-163-1184626-00		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dry Mouth; Insomnia; Pain In Extremity	Humira			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2014	9994859	DIRECT		DS, HO, LT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Generalised Tonic-Clonic Seizure; Stress	Escitalopram	S	Oral	1 Pill Once Daily Taken By Mouth	Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2014	9995779	EXPEDITED (15-DAY)		OT	BR-TORRENT-00001947		61 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Crying; Drug Ineffective; Fatigue; Fatigue; Malaise; Product Quality Issue; Product Substitution Issue; Productive Cough; Somnolence; Suicidal Ideation	Espran			S	Oral	Once Daily/Oral		Not Reported
	Atorvastatin			C				Not Reported
	Aas Infantil			C				Not Reported
	Olcadil			C				Not Reported
	Atenolol			C				Not Reported
	Losartan			C				Not Reported
	Benlcaranlo			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2014	9562106	EXPEDITED (15-DAY)		HO, OT	JP-009507513-1309JPN010149		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Reflex			S	Oral	3.75 Mg, Divided Dose, Frequency: Unknown		Merck
	Reflex			S	Oral	7.5 Mg, Divided Dose, Frequency: Unknown		Merck
	Reflex			S	Oral	15 Mg, Divided Dose, Frequency: Unknown		Merck
	Escitalopram Oxalate			S	Oral	20 Mg, Divided Dose, Frequency: Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	15 Mg, Divided Dose, Frequency: Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Divided Dose, Frequency: Unknown		Not Reported
	Duloxetine Hydrochloride			S	Oral	20 Mg, Divided Dose,		Not Reported

				Frequency: Unknown	
	Duloxetine Hydrochloride	S	Oral	40 Mg, Divided Dose, Frequency: Unknown	Not Reported
	Zolpidem Tartrate	C	Oral	Daily Dose 10 Mg	Not Reported
	Sulpiride	C	Oral	50 Mg, Divided Dose, Frequency: Unknown	Not Reported
	Amoxapine	C	Oral	10 Mg, Divided Dose, Frequency: Unknown	Not Reported
	Brotizolam	C	Oral	Daily Dose 0.25 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2014	9859513	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2014026592		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Delirium; Hallucination, Visual	Xanax			S		Unk		Pfizer
	Keppra			S		1 G, Daily		Not Reported
	Keppra			S		1 G, 2x/Day In The Morning And In The Evening		Not Reported
	Keppra			S		1.5 G, Daily		Not Reported
	Keppra			S		1 G, Daily		Not Reported
	Keppra			S		500 Mg, Daily		Not Reported
	Keppra			S		Unk		Not Reported
	Seroplex			S		Unk		Not Reported
	Tranxene			S		Unk		Not Reported
	Prodilantin			C		Unk		Not Reported
	Urbanyl			C		Unk		Not Reported
	Urbanyl			C		10 Unk, 3x/Day, 1 In The Morning, 1 At Noon And 2 In The Evening		Not Reported
	Temerit			C		2.5 In The Morning And 2.5 In The Evening		Not Reported

	Loxen Lp	C	50 Unk, 1x/Day In The Morning	Not Reported
	Diffu-K	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2014	9991759	EXPEDITED (15-DAY)		HO	NO-FRI-1000060417		50 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Abuse; Drug Diversion; Hospitalisation; Intentional Product Misuse	Escitalopram			S		Dosing Details Unknown		Forest
	Remeron			S		Dosing Details Unknown		Not Reported
	Rivotril			S		Dosing Details Unknown		Not Reported
	Cannabis			S		Details Unknown		Not Reported
	Subutex			S				Not Reported
	Benzodiazepine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2014	9904804	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2014-01433			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Exposure During Pregnancy; Hypoglycaemia; Hyporeflexia; Hypotonia; Lethargy; Therapy Non-Responder; Withdrawal Syndrome	Escitalopram (Escitalopram)			S	Transplacental			Not Reported
	Lorazepam (Lorazepam)			S	Transplacental			Not Reported
	Paroxetine			S	Transplacental			Not Reported
	Clonazepam (Clonazepam) (Clonazepam)			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2014	9958838	EXPEDITED (15-DAY)	Y	OT	KAD201402-000272		36 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Ribavirin (Ribavirin)			S				Not Reported
	Peginterferon Alfa-2a			S		180 Microg Weekly		Not Reported

	Telaprevir (Telaprevir)	S	750 Mg Three Times Per Day	Not Reported
	Escitalopram (Escitalopram)	S	10mg/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2014	9996243	EXPEDITED (15-DAY)		HO	IT-FRI-1000060438		61 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Mydriasis; Sopor; Unresponsive To Stimuli	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose: 80 Mg In One Dose		Forest
	Escitalopram			S	Oral			Forest
	Alprazolam			S	Oral			Not Reported
	Alprazolam			S	Oral	Overdose: One Bottle At Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2014	9996399	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-B0974540A			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Votrient			S	Unknown	600mg Per Day		Glaxosmithkline
	Propranolol			S	Unknown			Not Reported
	Seroplex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2014	9998955	DIRECT		OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Drug Ineffective; Loss Of Personal Independence In	Escitalopram Oxalate			S				Not Reported

Daily Activities

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2014	9999607	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Frustration Tolerance Decreased; Insomnia; Nervousness; Product Substitution Issue	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2014	9733772	EXPEDITED (15-DAY)		HO	IT-FRI-1000051937		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Escitalopram			S	Oral			Forest
	Delorazepam			S	Oral			Not Reported
	Ribavirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2014	9999156	EXPEDITED (15-DAY)		OT	CH-009507513-1403CHE001942		30 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Poisoning; Sopor; Suicide Attempt	Remeron			S	Oral	Dose 1050 Mg, Once		Merck
	Escitalopram			S	Oral	Dose 410 Mg, Once		Not Reported
	Aspirin			S	Oral	Dose 2800 Mg, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2014	10003687	NON-EXPEDITED			US-ABBVIE-13P-163-1084327-00		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Somnolence;	Depakote			S	Oral			Not Reported

Trismus	Depakote		S						Not Reported
	Depakote		S						Not Reported
	Lexapro		S	Oral					Not Reported
	Lexapro		S	Oral					Not Reported
	Lexapro		S	Oral					Not Reported
	Lexapro		S	Oral					Not Reported
	Seroquel		S	Oral					Not Reported
	Seroquel		S	Oral					Not Reported
	Seroquel		S	Oral					Not Reported
	Synthroid		C	Oral					Not Reported
	Clomipramine		C						Not Reported
	Metoprolol		C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2014	10003756	NON-EXPEDITED			US-ABBVIE-13P-163-1070735-00		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Drug Ineffective; Loss Of Personal Independence In Daily Activities	Depakote			S				Not Reported
	Lithium			S				Not Reported
	Lexapro Film-Coated Tablets			S				Not Reported
	Luvox			S				Not Reported
	Pristiq			S	Oral			Not Reported
	Pristiq			S	Oral			Not Reported
	Pristiq			S				Not Reported
	Pristiq			S		100mg In Morning, 50 Mg In The Afternoon, 100 Mg At Night		Not Reported
	Zoloft			S				Not Reported
	Prozac			S				Not Reported
	Lamictal			S				Not Reported
	Paxil			S				Not Reported
	Valium			S				Not Reported
	Klonopin			S				Not Reported
	Topamax			S				Not Reported
	Abilify			S		10 Mg Daily		Not Reported

Wellbutrin	S			Not Reported
Celexa	S			Not Reported
Cymbalta	S			Not Reported
Anafranil	S			Not Reported
Imipramine	S			Not Reported
Tegretol	S			Not Reported
Seroquel	S			Not Reported
Seroquel Xr	C	250mg Daily		Not Reported
Xanax	C			Not Reported
Adderall	C			Not Reported
Unspecified Medication	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2014	10004678	EXPEDITED (15-DAY)		HO	IT-ACTAVIS-2014-04311		61 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Mydriasis; Sopor; Unresponsive To Stimuli	Alprazolam (Unknown)			S	Oral	1 Df, Total		Watson
	Cipralex			S	Oral	80 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2014	10005385	EXPEDITED (15-DAY)		OT	US-RB-064444-14		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Depression; Drug Withdrawal Syndrome; Foetal Growth Restriction; Heart Rate Increased; Intentional Underdose; Lethargy; Maternal Exposure During Pregnancy; Nausea; Premature Delivery; Product Preparation Issue; Seizure; Vomiting	Buprenorphine Generic			S	Sublingual			Reckitt Benckiser
	Suboxone Film			S	Sublingual	Suboxone Film		Reckitt Benckiser
	Suboxone Film			S	Sublingual	Suboxone Film; Self Tapering And Cutting		Reckitt Benckiser
	Suboxone Film			S	Sublingual	Suboxone Film; Took One Piece Of Film		Reckitt Benckiser
	Wellbutrin			S	Oral	Dosing Details Unknown		Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2014	10018373	EXPEDITED (15-DAY)	Y	HO, OT	IMP_07498_2014		62 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Agitation; Confusional State; Constipation; Delirium; Disorientation; Drug Interaction; Dry Mouth; Dry Skin; Hallucination, Auditory; Hallucination, Visual; Insomnia	Bupropion			S		Day, Titration Up Performed), Mg/Day Mg/Day		Not Reported
	Quetiapine (Quetiapine)			S		Mg/D, Added On Day 8, Titration Up Performed Mg/D, Day 10		Not Reported
	Risperidone (Risperidone)			S		Mg/Day, Titration Up Performed Mg/Day Mg/Day		Not Reported
	Lamotrigine (Lamotrigine)			S		Mg/Day, Titration Up Performed Mg/Day		Not Reported
	Escitalopram (Escitalopram)			S		Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2014	9820498	EXPEDITED (15-DAY)		HO	HU-FRI-1000052875		36 YR	Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endometrial Hyperplasia; Metrorrhagia	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Frontin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2014	9851026	EXPEDITED (15-DAY)		LT	FR-FRI-1000053148		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coma; Electrocardiogram Qt Prolonged; Intentional Overdose	Escitalopram	S	Oral	Overdose Of 1 Intake Of Unknown Dose	Forest
	Tercian	S		Overdose Of 1 Intake Of Unknown Dose	Not Reported
	Seresta	S		Overdose Of 1 Intake Of Unknown Dose	Not Reported
	Stilnox	S		Overdose Of 1 Intake Of Unknown Dose	Not Reported
	Alcohol	S		Overdose Of 2 Bottles Of Wine	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2014	9914139	EXPEDITED (15-DAY)		CA, HO	NL-PFIZER INC-2014045751			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta; Foetal Exposure During Pregnancy; Respiratory Failure	Sertraline			S	Transplacental	50 Mg, 1x/Day		Pfizer
	Escitalopram Oxalate			S	Transplacental	10 Mg, 1x/Day		Not Reported
	Folic Acid			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2014	10006459	EXPEDITED (15-DAY)		OT	DE-FRI-1000064604		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage In Pregnancy; Nausea; Pregnancy	Escitalopram			S	Oral	10 Mg		Forest
	Amisulprid			S	Oral	50 Mg		Not Reported
	Mutagrip			C	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2014	10006478	EXPEDITED (15-DAY)		CA	DE-FRI-1000064605		< 1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Congenital Aural Fistula; Foetal Exposure During Pregnancy; Haemangioma	Escitalopram	S	Transplacental	10 Mg		Forest
	Amisulprid	S	Transplacental	50 Mg		Not Reported
	Mutagrip	C	Transplacental			Not Reported
	Omep	C	Transplacental	Only A Few Days In Third Trimester		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2014	10007303	EXPEDITED (15-DAY)		HO	FR-FRI-1000060525		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Partial Seizures With Secondary Generalisation	Escitalopram			S	Oral	15 Mg		Forest
	Zoloft			S	Oral	50 Mg		Not Reported
	Alprazolam			C				Not Reported
	Procoralan			C				Not Reported
	Tahor			C				Not Reported
	Doliprane			C				Not Reported
	Forlax			C				Not Reported
	Eductyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2014	10007365	EXPEDITED (15-DAY)		LT	US-ASTRAZENECA-2011SE65282		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Decreased; Coma Scale Abnormal; Heart Rate Decreased; Metabolic Acidosis; Overdose	Propranolol			S				Not Reported
	Quetiapine			S	Oral			Not Reported
	Escitalopram			S				Not Reported
	Atorvastatin			S				Not Reported
	Clonidine			S				Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2014	10008516	EXPEDITED (15-DAY)		OT	FR-FRI-1000064616			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatocellular Injury	Escitalopram	S	Forest
	Imovane	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2014	10008860	EXPEDITED (15-DAY)		HO	PHHY2014BE028151		81 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Drug Withdrawal Syndrome; Hyperthermia; Hypertonia; Neuroleptic Malignant Syndrome	Pramipexole			S		2.1 Mg Daily		Not Reported
	Pramipexole			S		0.350 Mg, Tid		Not Reported
	Venlafaxine			S		150 Mg		Novartis
	Escitalopram			S		10 Mg		Not Reported
	Levodopa			S		250 Mg Daily		Not Reported
	Levodopa			S		125 Mg, Q4h		Not Reported
	Levodopa			S		125 Mg, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2014	10017237	DIRECT		OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Product Substitution Issue	Escitalopram			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2014	10021298	EXPEDITED (15-DAY)	Y	OT	2014HINLIT0192		36 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Escitalopram			S				Not Reported
	Telaprevir (Telaprevir)			S				Not Reported
	Peginterferon +2a			S				Not Reported
	Ribavirin (Ribavirin)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2014	10011522	EXPEDITED (15-DAY)		LT	FR-SA-2014SA008103			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Intentional Overdose	Stilnox			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2014	10012953	EXPEDITED (15-DAY)		OT	IT-FRI-1000064618		45 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Somnolence	Escitalopram			S	Oral	3 Tablets Of Cipralex 5 Mg		Forest
	Risperdal			S	Oral	4 Tablets Of Risperdal 2mg		Not Reported
	Tavor (Lorazepam)			S		4 Tablets Of Tavor		Not Reported
	Valium			S		25 Drops Of Valium 0.5%		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2014	10018755	DIRECT		DS			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Depressed Mood; Depression; Drug Ineffective; Drug Withdrawal Syndrome; Impaired Work Ability; Irritability; Movement Disorder; Product Substitution Issue; Quality Of Life Decreased	Escitalopram			S	Oral	1 1/2 Pills Once Daily Taken By Mouth		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2014	10016077	EXPEDITED (15-DAY)		HO	BE-TEVA-468753ISR		81 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Food Interaction; Neuroleptic Malignant Syndrome; Withdrawal Syndrome	Venlafaxine			S	Oral	150 Milligram Daily;		Teva
	Levodopa			S	Oral	250 Milligram Daily;		Not Reported
	Levodopa			S	Other			Not Reported
	Pramipexole			S	Oral	2.1 Milligram Daily;		Not Reported
	Pramipexole			S	Other			Not Reported
	Escitalopram			S	Oral	10 Milligram Daily;		Not Reported
	Cefuroxime			C	Unknown			Not Reported
	Metronidazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2014	7271875	EXPEDITED (15-DAY)		OT	PHHY2010MX04920		80 YR	Male	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Contusion; Dyspnoea; Embolism; Fall; Groin Pain; Haemarthrosis; Vertigo	Exelon Patch			S	Transdermal	1 Df, Qd, 1 Patch (5 Cm2) Per Day		Novartis
	Stalevo			S		Unk Ukn, Unk		Not Reported
	Lexapro			S		Unk Ukn, Unk		Not Reported
	Norvas			C		Unk Ukn, Unk		Not Reported
	Spiriva			C		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2014	10016542	EXPEDITED (15-DAY)		OT	AT-PFIZER INC-2014074686		48 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Blood Prolactin	Lyrica			S		125 Mg, 1x/Day		Pfizer

Increased; Blood Triglycerides Increased; Body Mass Index Increased; Weight Increased	Lyrica	S		300 Mg, 1x/Day	Pfizer
	Lyrica	S		375 Mg, 1x/Day	Pfizer
	Lyrica	S		450 Mg, 1x/Day	Pfizer
	Doxazosin Mesilate	S		4 Mg, 1x/Day	Pfizer
	Doxazosin Mesilate	S		8 Mg, 1x/Day	Pfizer
	Mirtabene	S		45 Mg, 1x/Day	Not Reported
	Mirtabene	S		90 Mg, 1x/Day	Not Reported
	Mirtabene	S		60 Mg, 1x/Day	Not Reported
	Mirtabene	S		30 Mg, 1x/Day	Not Reported
	Cipralex	S		5 Mg, 1x/Day	Not Reported
	Cipralex	S		10 Mg, 1x/Day	Not Reported
	Cipralex	S		20 Mg, 1x/Day	Not Reported
	Cipralex	S		30 Mg, 1x/Day	Not Reported
	Risperdal	S	Oral	1 Mg, 1x/Day	Not Reported
	Risperdal	S	Oral	2 Mg, 1x/Day	Not Reported
	Sertraline	C		150 Mg, 1x/Day	Not Reported
	Sertraline	C		100 Mg, 1x/Day	Not Reported
	Lamictal	C		50 Mg, 1x/Day	Not Reported
	Lamictal	C		75 Mg, 1x/Day	Not Reported
	Lamictal	C		100 Mg, 1x/Day	Not Reported
	Lamictal	C		200 Mg, 1x/Day	Not Reported
	Rivotril	C		1.5 Mg, 1x/Day	Not Reported
	Exforge	C		1 Df, 1x/Day, 10 To 160 Mg	Not Reported
	Exforge	C		1 Df, 1x/Day, 5 To 160 Mg	Not Reported
	Folsan	C		10 Mg, 1x/Day	Not Reported
	Folsan	C		5 Mg, 1x/Day	Not Reported
	Fungoral	C		3, Three Times A Week	Not Reported
	Fungoral	S		1 Unk, 1x/Day	Not Reported

Ebrantil	C	60 Mg, 1x/Day	Not Reported
Nebivolol Hydrochloride	C	10 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2014	10019952	EXPEDITED (15-DAY)		HO	FR-FRI-1000064656		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Hepatic Encephalopathy	Escitalopram			S	Oral	10 Mg		Forest
	Temesta (Lorazepam)			S	Oral	1 Df		Not Reported
	Lexomil Roche			S	Oral	1 Df		Not Reported
	Avlocardyl			C	Oral	160 Mg		Not Reported
	Lantus			C		15 Iu		Not Reported
	Humalog			C		6 Df		Not Reported
	Sectral			C		400 Mg		Not Reported
	Esidrex			C	Oral	12.5 Mg		Not Reported
	Kardegic			C	Oral	75 Mg		Not Reported
	Creon			C		3 Df		Not Reported
	Inexium			C	Oral	20 Mg		Not Reported
	Speciafoldine			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2014	10020941	DIRECT		OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Drug Ineffective; Irritability; Product Substitution Issue	Escitalopram			S	Oral	1		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2014	10021066	DIRECT		OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Gastrointestinal Disorder; Product Substitution Issue	Escitalopram			S	Oral	1 Pill Once Daily Taken By Mouth		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2014	10021124	DIRECT		DS			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Ear Pain; Hot Flush; Insomnia; Tinnitus; Vitreous Floaters	Lexapro Generic 10mg			S	Oral	1 Tab		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2014	10021153	DIRECT		LT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Dependence; Gait Disturbance; Malaise; Suicidal Ideation; Thinking Abnormal	Lexapro			S	Oral	1 Tab		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2014	10025599	EXPEDITED (15-DAY)	Y	HO	AUR-APL-2014-02932		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Depressed Mood; Disturbance In Attention; Drug Ineffective; Fatigue; Feeling Guilty; Poor Quality Sleep; Suicidal Ideation	Escitalopram (Escitalopram)			S			1460 DAY	Aurobindo
	Oxycodone + Paracetamol (Paracetamol, Oxycodone)			S		1 Dosage Form 4 In 1 D		Not Reported
	Cyclobenzaprine (Cyclobenzaprine)			S		10 Mg 3 In 1 D	1095 DAY	Not Reported
	Celecoxib (Celecoxib)			S		200 Mg 2 In 1 D		Not Reported

	Diazepam (Diazepam)			S				1460 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2014	9889047	EXPEDITED (15-DAY)		HO, OT	FR-UCBSA-111596		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Delirium; Disorientation; Hallucination, Visual	Keppra			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Xanan			S	Oral	Benzodiazepines Doses Were Increased		Not Reported
	Xanan			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Tranxene			S	Oral	Benzodiazepines Doses Were Increased		Not Reported
	Tranxene			S	Oral			Not Reported
	Temerit			C		5 Mg		Not Reported
	Loxen (Nicardipine Hydrochloride)			C		50 Mg		Not Reported
	Diffu-K			C				Not Reported
	Prodilantin			C				Not Reported
	Urbanyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2014	9996315	EXPEDITED (15-DAY)		HO	FR-FRI-1000060416		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Confusional State	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	10 Mg		Forest

	Lysanxia	S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2014	10004632	EXPEDITED (15-DAY)		OT	CA-FRI-1000060440		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Escitalopram			S	Oral	20 Mg		Forest
	Wellbutrin Sr			C	Oral	100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2014	10021318	EXPEDITED (15-DAY)		HO	BE-MYLANLABS-2014S1005179		81 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Food Interaction; Neuroleptic Malignant Syndrome	Levodopa			S	Oral	250 Mg/Day		Not Reported
	Levodopa			S	Other			Not Reported
	Pramipexole			S	Oral	2.1 Mg/Day		Not Reported
	Pramipexole			S	Other			Not Reported
	Venlafaxine			S	Oral	150 Mg/Day		Not Reported
	Escitalopram			S	Oral	10 Mg/Day		Not Reported
	Cefuroxime			C	Unknown			Not Reported
	Metronidazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2014	10021399	EXPEDITED (15-DAY)		OT	DE-FRI-1000054626			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2014	10021428	EXPEDITED (15-DAY)		OT	CH-FRI-1000064778			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Escitalopram			S	Transplacental	20 Mg		Forest
	Escitalopram			S	Transplacental	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2014	10021450	EXPEDITED (15-DAY)		OT	CA-FRI-1000064767		46 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Stress; Suicidal Ideation	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Sleeping Aid Drug Nos			C		Daily Dose Not Reported.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2014	10022678	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2014074185		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Drug Interaction; Fall; Vertigo	Champix			S	Oral	0.5 Mg, 2x/Day (In The Morning And In The Afternoon)		Pfizer
	Escitalopram Oxalate			S		20 Mg, Unk		Not Reported
	Escitalopram Oxalate			S		10 Mg, Unk		Not Reported
	Diazepam			C		At Nights		Not Reported
	Halcion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2014	10024607	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Nausea	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2014	9856406	EXPEDITED (15-DAY)		HO, LT	JP-FRI-1000053218		58 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Lexapro			S	Oral	10 Mg		Forest
	U-Pan			S	Oral	3 Mg		Not Reported
	Depromel			S	Oral	150 Mg		Not Reported
	Foliamin			S	Oral	15 Mg		Not Reported
	Invega			S	Oral	6 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2014	9963949	EXPEDITED (15-DAY)		HO	JP-FRI-1000060237		83 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness	Lexapro			S	Oral	10 Mg		Forest
	Aricept			S	Oral	3 Mg		Not Reported
	Aricept			S	Oral	5 Mg		Not Reported
	Lotriga			C	Oral	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2014	10021254	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2014-02581		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electroencephalogram Abnormal; Seizure	Escitalopram			S				Not Reported
	Telaprevir (Telaprevir)			S		2250 Mg (750 Mg, 3 In 1 D), Unknown		Not Reported
	Peginterferon Alfa-2a			S				Not Reported
	Ribavirin (Ribavirin)			S		1000 Mg, 1 In 1 Day.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2014	10023997	EXPEDITED (15-DAY)		HO	FR-FRI-1000064771		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hallucinations, Mixed; Withdrawal Syndrome	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	2.5 Mg		Forest
	Tercian			S	Oral	0.5 Df		Not Reported
	Bisoce			C				Not Reported
	Furosemide			C				Not Reported
	Trivastal			C				Not Reported
	Zopiclone			C				Not Reported
	Micardis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2014	10025403	NON-EXPEDITED			US-PFIZER INC-2014072456			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance	Zoloft			S		50 Mg, Unk		Pfizer
	Protonix			S		40 Mg, Unk		Pfizer
	Metronidazole			S		750 Mg (250mg+ 500mg), Unk		Pfizer
	Cefuroxime Axetil			S		500 Mg, Unk		Not Reported
	Celebrex			S		100 Mg, Unk		Pfizer
	Detrol La			S		4 Mg, Unk		Pfizer
	Benzonatate			S		200 Mg, Unk		Pfizer
	Nadolol			S		20 Mg, Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Hydrochlorothiazide			S		25 Mg, Unk		Unknown
	Effexor Xr			S		75 Mg, Unk		Pfizer
	Requip			S		1 Mg, Unk		Not Reported
	Amitrip-Cdp			S		12.5-5, Unk		Not Reported

Micardis	S	80 Mg, Unk	Not Reported
Micardis Hct	S	80 Mg, Unk	Not Reported
Maxalt-Mlt	S	10 Mg, Unk	Not Reported
Topamax	S	25 Mg, Unk	Not Reported
Amitriptyline	S	25 Mg, Unk	Not Reported
Vioxx	S	25 Mg, Unk	Not Reported
Darvocet	S	100 Mg, Unk	Not Reported
Lexapro	S	Unk	Not Reported
Wellbutrin Sr	S	150 Mg, Unk	Not Reported
Chlorthalidone	S	50 Mg, Unk	Not Reported
Sucralfate	S	1 G, Unk	Not Reported
Guaifenex La	S	600 Mg, Unk	Not Reported
Naproxen Sodium	S	500 Mg, Unk	Not Reported
Ultrase	S	37.5 Mg, Unk	Not Reported
Cyclobenzaprine Hcl	S	Unk	Not Reported
Hyoscyamine	S	0.375 Mg, Unk	Not Reported
Flumadine	S	100 Mg, Unk	Not Reported
Allegra	S	180 Mg, Unk	Not Reported
Prilosec	S	Unk	Not Reported
Guaifenesin\Pseudoephedrine Hydrochloride	S	Unk	Not Reported
Bupropion Hcl	S	100 Mg, Unk	Not Reported
Cephalexin	S	500 Mg, Unk	Not Reported
Levaquin	S	500 Mg, Unk	Not Reported
Paxil	S	Unk	Not Reported
Baclofen	S	Unk	Not Reported
Citalopram Hydrobromide	S	Unk	Not Reported
Carvedilol	S	6.25 Mg, Unk	Not Reported
Antara	S	130 Mg, Unk	Not Reported
Guaifen-Pse	S	600 Mg, Unk	Not Reported

	Flexeril	S	5 Mg, Unk	Not Reported
	Biaxin	S	Unk	Not Reported
	Carisoprodol	S	350 Mg, Unk	Not Reported
	Tekturna	S	Unk	Not Reported
	Buspar	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2014	10026118	EXPEDITED (15-DAY)		OT	AT-TEVA-468026ISR		48 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombophlebitis	Mirtabene Filmtabletten Ratiopharm , 30 Mg, 45 Mg.			S	Unknown	Dosage Form: Unspecified		Teva
	Mirtabene Filmtabletten Ratiopharm , 30 Mg, 45 Mg.			S		Dosage Form: Unspecified		Teva
	Mirtabene Filmtabletten Ratiopharm , 30 Mg, 45 Mg.			S	Unknown	Dosage Form: Unspecified		Teva
	Mirtabene Filmtabletten Ratiopharm , 30 Mg, 45 Mg.			S	Unknown	Dosage Form: Unspecified, Started Since Months		Teva
	Cipralex			S	Unknown	Dosage Form: Unspecified		Not Reported
	Cipralex			S	Unknown	Dosage Form: Unspecified		Not Reported
	Cipralex			S	Unknown	Dosage Form: Unspecified		Not Reported
	Cipralex			S	Unknown	Dosage Form: Unspecified		Not Reported
	Risperdal			S	Oral	Dosage Form: Unspecified		Not Reported
	Risperdal			S	Oral	Dosage Form: Unspecified		Not Reported
	Lyrica			C	Unknown	Dosage Form: Unspecified		Not Reported
	Lyrica			C	Unknown	Dosage Form: Unspecified		Not Reported
	Lyrica			C	Unknown	Dosage Form: Unspecified		Not Reported
	Lyrica			C	Unknown	Dosage Form: Unspecified		Not Reported
	Sertraline			C	Unknown	Dosage Form: Unspecified		Not Reported
	Sertraline			C	Unknown	Dosaeg Form: Unspecified		Not Reported
	Lamictal			C	Unknown	Dosage Form: Unspecified		Not Reported

Lamictal	C	Unknown	Dosage Form: Unspecified	Not Reported
Lamictal	C	Unknown	Dosage Form: Unspecified	Not Reported
Lamictal	C	Unknown	Dosage Form: Unspecified	Not Reported
Rivotril	C			Not Reported
Doxazosin	C	Unknown	Dosage Form: Unspecified	Not Reported
Doxazosin	C	Unknown	Dosage Form: Unspecified	Not Reported
Folsan	C	Unknown	Dosage Form: Unspecified	Not Reported
Folsan	C	Unknown	Dosage Form: Unspecified, Started Since Months	Not Reported
Exforge	C	Unknown	Dosage Form: Unspecified, 10/160mg	Not Reported
Exforge	C	Unknown	Dosage Form: Unspecified, 5/160 Mg Since Months	Not Reported
Fungoral	C	Unknown		Not Reported
Fungoral	C	Unknown		Not Reported
Ebrantil	C	Unknown	Dosage Form: Unspecified, Started Since Months	Not Reported
Nomexor	C	Unknown	Dosage Form: Unsoecified, Started Since Months	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2014	10029633	DIRECT	Y	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Escitalopram			S	Oral			Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2014	10032422	EXPEDITED (15-DAY)	Y	HO	2014AP001856		81 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Food Interaction; Neuroleptic Malignant Syndrome	Venlafaxine (Venlafaxine)			S	Oral	150 Mg; Unknown; Po; Qd		Not Reported
	Escitalopram (Escitalopram)			S	Oral	10 Mg; Unknown; Po; Qd		Not Reported
	Levodopa			S	Oral Oral	250 Mg; Unknown; Po; Qd 125 Mg; Po; Q4h		Not Reported
	Pramipexole (Pramipexole)			S		2.1 Mg; Unknown; Qd 0.35 Mg; Unknown; Tid		Not Reported
	Cefuroxime (Cefuroxime)			C				Not Reported
	Metronidazole (Metronidazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2014	9893707	EXPEDITED (15-DAY)		HO	CA-FRI-1000054195		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Feeling Cold; Palpitations; Vision Blurred	Escitalopram			S	Oral	20 Mg		Forest
	Ativan			C	Oral	0.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2014	8960874	EXPEDITED (15-DAY)		OT	JP-ELI_LILLY_AND_COMPANY-JP201211003156		65 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rapid Eye Movements Sleep Abnormal; Sleep Talking	Cymbalta			S	Oral	20 Mg, Qd		Eli Lilly And Co
	Remeron			S	Oral	15 Mg, Qd		Not Reported
	Remeron			S	Oral	25 Mg, Unk		Not Reported
	Lexapro			S	Oral	5 Mg, Qd		Not Reported
	Reslin			S	Oral	12.5 Mg, Qd		Not Reported
	Rohypnol			C	Oral	2 Mg, Qd		Not Reported
	Lexotan			C	Oral	2 Mg, Qd		Not Reported
	Yokukan-San			C	Oral	5 G, Unk		Not Reported
	Yokukan-San			C	Oral	Unk		Not Reported

	Yokukan-San			C	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2014	9934417	EXPEDITED (15-DAY)		CA	NL-FRI-1000054749		< 1 DAY	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta	Lexapro			S	Transplacental			Forest
	Sertraline			S	Transplacental			Not Reported
	Folic Acid			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2014	9959102	EXPEDITED (15-DAY)	Y	CA, HO	AUR-APL-2014-02025		< 1 DAY	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta; Maternal Drugs Affecting Foetus; Respiratory Failure	Sertraline			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Folic Acid (Folic Acid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2014	10031673	NON-EXPEDITED			US-PFIZER INC-2014083631		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Flushing; Insomnia	Escitalopram Oxalate			S		Unk		Not Reported
	Lyrica			S		50 Mg, 3x/Day		Pfizer
	Metoprolol			C		50 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2014	10032848	EXPEDITED (15-DAY)		OT	AT-WATSON-2014-05102		48 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Weight Increased	Doxazosin (Unknown)	S	Unknown	4 Mg, Daily	Watson
	Doxazosin (Unknown)	S	Unknown	8 Mg, Daily	Watson
	Lyrica	S	Unknown	125 Mg, Daily	Not Reported
	Lyrica	S	Unknown	300 Mg, Daily	Not Reported
	Lyrica	S	Unknown	375 Mg, Daily	Not Reported
	Lyrica	S	Unknown	450 Mg, Daily	Not Reported
	Mirtabene	S	Unknown	90 Mg, Daily	Not Reported
	Mirtabene	S	Unknown	60 Mg, Daily	Not Reported
	Mirtabene	S	Unknown	30 Mg, Daily	Not Reported
	Mirtabene	S	Unknown	45 Mg, Daily	Not Reported
	Cipralex	S	Unknown	5 Mg, Daily	Not Reported
	Cipralex	S	Unknown	10 Mg, Daily	Not Reported
	Cipralex	S	Unknown	20 Mg, Daily	Not Reported
	Cipralex	S	Unknown	30 Mg, Daily	Not Reported
	Risperdal	S	Oral	1 Mg, Daily	Not Reported
	Risperdal	S	Oral	2 Mg, Daily	Not Reported
	Sertraline	C	Unknown	150 Mg, Daily	Not Reported
	Sertraline	C	Unknown	100 Mg, Daily	Not Reported
	Lamictal	C	Unknown	50 Mg, Daily	Not Reported
	Lamictal	C	Unknown	75 Mg, Daily	Not Reported
	Lamictal	C	Unknown	100 Mg, Daily	Not Reported
	Lamictal	C	Unknown	200 Mg, Daily	Not Reported
	Rivotril	C	Unknown	1.5 Mg, Daily	Not Reported
	Exforge	C	Unknown	10/160 Mg, Daily	Not Reported
	Exforge	C	Unknown	5/160 Mg, Daily	Not Reported
	Folsan	C	Unknown	5 Mg, Daily	Not Reported
	Folsan	C	Unknown	10 Mg, Daily	Not Reported
	Fungoral	C	Topical	1 Df, 3/Week [Shampoo]	Not Reported
	Fungoral	C	Topical	1 Df, 3/Week [Cream]	Not Reported

Ebrantil /00631801/	C	Unknown	60 Mg, Daily		Not Reported
Nomexor	C	Unknown	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2014	10034481	DIRECT		OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities; Neuropathy Peripheral; Product Substitution Issue	Escitalopram 20mg			S	Oral	I Pill		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2014	9844465	EXPEDITED (15-DAY)		HO	CA-SHIRE-ALL1-2014-00472		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	489 (Lisdexamfetamine Dimesylate)			S	Oral	30 Mg, 1x/Day:Qd		Shire
	Escitalopram Oxalate			S	Oral	Unk, Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2014	9912465	EXPEDITED (15-DAY)		OT	MX-ORION CORPORATION ORION PHARMA-ENTC2014-0068		80 YR	Male	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Embolism; Fall; Groin Pain; Traumatic Haemorrhage	Stalevo			S	Unknown			Not Reported
	Exelon			S	Transdermal	1 Patch (5 Cm2)		Not Reported
	Lexapro			S	Unknown			Not Reported
	Norvas			C	Unknown			Not Reported
	Spiriva			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2014	10034321	EXPEDITED (15-DAY)	Y	DE	US-ROCHE-1370652		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Arrest; Toxicity To Various Agents	Clonazepam			S	Oral			Not Reported
	Clonazepam			S	Oral	Overdose		Not Reported
	Citalopram			S	Oral			Not Reported
	Citalopram			S	Oral	Overdose		Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Acetaminophen/Diphenhydramine Hydrochloride			S	Oral			Not Reported
	Acetaminophen/Diphenhydramine Hydrochloride			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Tadalafil			S	Oral			Not Reported
	Tadalafil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2014	10035025	EXPEDITED (15-DAY)		DS, HO	NL-FRI-1000065727		56 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Pulmonary Embolism; Thrombosis	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2014	10035657	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2014SE19514		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dermatitis Bullous; Fall; General Physical Health Deterioration; Hyponatraemia	Inexium	S	Oral		Astrazeneca
	Seroplex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2014	10036334	EXPEDITED (15-DAY)		DS, HO	FI-FRI-1000065728		15 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Intentional Self-Injury; Off Label Use	Escitalopram			S	Oral			Forest
	Mirtazapine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2014	10036335	EXPEDITED (15-DAY)		OT	JP-FRI-1000065766		34 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Suicidal Ideation	Lexapro			S	Oral	10 Mg		Forest
	Zolpidem Tartrate			C	Oral	5 Mg		Not Reported
	Sorentmin (Brotizolam)			C	Oral	0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2014	10036336	EXPEDITED (15-DAY)		HO	FR-FRI-1000065767		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis; Traumatic Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported
	Hydrea			C	Oral	1 Capsule At Day 1 And 2 Capsules At Day 2		Not Reported
	Pariet			C	Oral	10 Mg		Not Reported
	Lysanxia			C	Oral			Not Reported

	Doliprane	C	Oral	1 To 3 Grams Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2014	10037339	DIRECT		DS			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Suicidal Ideation	Lexapro			S	Oral	Once A Day, Once Daily, Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2014	10032137	EXPEDITED (15-DAY)		OT	PHHY2014IT033223		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Fty 720			S	Oral			Not Reported
	Carbamazepine			S	Oral	800 Mg, Daily		Novartis
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Natalizumab			S		300 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2014	10038072	EXPEDITED (15-DAY)		CA	FR-FRI-1000065838		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Arterial Malformation; Exposure During Pregnancy; Urinary Tract Malformation	Escitalopram			S	Transplacental	10 Mg		Forest
	Escitalopram			S	Transplacental	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2014	10044284	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2014-03477		93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide;	Amlodipine			S	Oral			Not Reported

Exposure Via Ingestion; Toxicity To Various Agents	Escitalopram	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2014	10044438	EXPEDITED (15-DAY)	Y	HO, LT	2014/017		81 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Appendicitis Perforated; Hallucination; Hyperreflexia; Hypertonia; Ileus; Myoclonus; Peritonitis; Pneumonia; Pyrexia	Venlafaxine			S		150 Mg/Day, Unk & Unk		Not Reported
	Escitalopram			S		10 Mg/Day, Unk & Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2014	10044757	EXPEDITED (15-DAY)		OT	AUR-APL-2014-03752		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Drug Interaction; Dysstasia; Impaired Driving Ability; Impaired Work Ability; Vertigo	Escitalopram (Escitalopram)			S		(20 Mg), Unknown (10 Mg), Unknown		Not Reported
	Champix (Varenicline Tartrate)			S	Oral	1 Mg (0.5 Mg, 2 In 1 D), Oral		Not Reported
	Halcion (Triazolam)			C				Not Reported
	Diazepam (Diazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2014	10040320	EXPEDITED (15-DAY)		HO, LT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2014-BI-13		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Clonidine			S	Oral	2.8 Mg		Boehringer Ingelheim
	Propranolol			S	Oral	1120 Mg		Not Reported

	Escitalopram	S	Oral	400 Mg	Not Reported
	Lorazepam	S	Oral	28 Mg	Not Reported
	Atorvastatin	S	Oral	560 Mg	Not Reported
	Quetiapine	S	Oral	5600 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2014	10041052	EXPEDITED (15-DAY)		HO	FR-SA-2014SA034137		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningorrhagia	Plavix			S	Oral			Not Reported
	Seroplex			S	Oral	Strength:10 Mg Scored		Not Reported
	Stagid			C				Not Reported
	Tahor			C				Not Reported
	Diamicron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2014	10041156	EXPEDITED (15-DAY)		HO	FR-FRI-1000065850		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningorrhagia	Escitalopram			S	Oral	10 Mg		Forest
	Plavix			S	Oral	75 Mg		Not Reported
	Stagid			C				Not Reported
	Tahor			C				Not Reported
	Diamicron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2014	10048587	EXPEDITED (15-DAY)	Y	DE, HO, OT	AUR-APL-2014-03842		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Blood Chloride Decreased; Blood Potassium Decreased; Blood	Alprazolam (Alprazolam)			S				Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Duloxetine (Duloxetine)			S				Not Reported
	(Duloxetine)							

Pressure Decreased; Cardio-Respiratory Arrest; Completed Suicide; Haematemesis; Heart Rate Decreased; Hyperhidrosis; Muscle Rigidity; Nystagmus; Overdose; Oxygen Saturation Decreased; Pulmonary Oedema; Respiratory Rate Decreased; Toxicity To Various Agents; Tremor; Unresponsive To Stimuli	Vilazodone		S	Oral Respiratory (inhalation)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2014	9353713	EXPEDITED (15-DAY)		DS	FR-FRI-1000045959		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metabolic Encephalopathy	Escitalopram			S	Oral			Forest
	Keal			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Seretide Diskus			C				Not Reported
	Spiriva			C				Not Reported
	Procoralan			C				Not Reported
	Amlor			C				Not Reported
	Gaviscon			C				Not Reported
	Tahor			C				Not Reported
	Kardegic			C				Not Reported
	Tardyferon			C				Not Reported
	Motilium			C				Not Reported
	Kaleorid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2014	9595418	EXPEDITED (15-DAY)		DS	2013-US-001380		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disability	Xyrem	S	Oral		Not Reported
			Oral	3 G, Bid, Po	
			Oral		
	Klonopin (Clonazepam) (Tablets)	C			Not Reported
	Wellbutrin	C			Not Reported
	Lexapro (Escitalopram Oxalate)	S			Not Reported
	Adderall	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2014	10046877	DIRECT		HO			19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Paraesthesia; Seizure	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2014	10047676	DIRECT		OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram 10 Mg			S	Oral		6 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2014	10050385	EXPEDITED (15-DAY)	Y	DE	AUR-APL-2014-03693		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion; Toxicity To Various Agents	Hydrocodone+Paracetamol (Paracetamol, Hydrocodone)			S	Oral			Not Reported
	Amlodipine (Amlodipine)			S				Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Isosorbide Mononitrate			S				Not Reported
	Doxazocin			S				Not Reported
	Warfarin (Warfarin)			S				Not Reported
	Furosemide (Furosemide)			S				Not Reported
	Levothyroxine (Levothyroxine)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2014	9789616	EXPEDITED (15-DAY)		LT	FR-BRISTOL-MYERS SQUIBB COMPANY-19932425		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Liver Injury; Mydriasis; Rhabdomyolysis	Abilify			S				Not Reported
	Paracetamol			S				Cadence
	Zolpidem			S				Not Reported
	Paroxetine			S				Not Reported
	Hept-A-Myl			S				Not Reported
	Cymbalta			S				Not Reported
	Lamotrigine			S				Not Reported
	Escitalopram			S				Not Reported
	Agomelatine			S				Not Reported
	Avlocardyl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2014	10051578	EXPEDITED (15-DAY)	Y	DE, HO	2014P1002449		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Vasoconstriction; International Normalised Ratio Increased; Ischaemic Cerebral Infarction; Posterior Reversible Encephalopathy Syndrome; Serotonin Syndrome; Subarachnoid Haemorrhage	Escitalopram			S				Not Reported
	Hydromorphone			S				Not Reported
	Dihydroergotamine			S	Intravenous (not otherwise specified)			Not Reported
	Hydrocodone			S				Not Reported
	Tetrahydrocannabinol			S				Not Reported
	Unspecified Anticoagulant			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2014	9614700	EXPEDITED (15-DAY)		HO	FR-FRI-1000049925		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Haemoglobin	Escitalopram			S	Oral	1 Df		Forest

Decreased	Previscan (Fluindione)	S	Oral	15 Mg Daily D1 And D2	Not Reported
	Previscan (Fluindione)	S		20 Mg Daily On D3	Not Reported
	Furosemide	C		1 Df	Not Reported
	Cynomel	C		1 Df	Not Reported
	Sotalol	C		2 Df	Not Reported
	Amlodipine	C		2 Df	Not Reported
	Spironolactone	C		1 Df	Not Reported
	Neo-Mercazole	C		1 Df	Not Reported
	Levothyrox	C		150 Mcg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2014	9645438	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000050331		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Large Intestine Operation	Escitalopram			S	Oral	20 Mg		Forest
	Zeldox			S	Oral	40 Mg		Not Reported
	Zeldox			S	Oral	160 Mg		Not Reported
	Clonazepam			C	Oral	1 Mg		Not Reported
	Cogentin			C		Daily Dose Not Reported.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2014	9785835	EXPEDITED (15-DAY)		HO, LT	FR-SA-2013SA132873		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Intentional Overdose; Liver Injury; Mydriasis; Rhabdomyolysis	Zolpidem			S	Oral			Not Reported
	Paroxetine			S	Oral			Not Reported
	Hept A Myl			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported

Cymbalta	S	Oral		Not Reported
Lamotrigine	S	Oral		Not Reported
Agomelatine	S	Oral		Not Reported
Avlocardyl	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2014	9814292	EXPEDITED (15-DAY)		LT	FR-ELI_LILLY_AND_COMPANY-FR201401002011		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Liver Injury; Mydriasis; Rhabdomyolysis; Toxicity To Various Agents	Cymbalta			S	Oral	1 Df, Unknown		Eli Lilly And Co
	Zolpidem			S	Oral	1 Df, Unknown		Not Reported
	Paroxetine			S	Oral	1 Df, Unknown		Not Reported
	Heptamyl			S	Oral	1 Df, Unknown		Not Reported
	Abilify			S	Oral	1 Df, Unknown		Not Reported
	Lamotrigine			S	Oral	1 Df, Unknown		Not Reported
	Escitalopram			S	Oral	1 Df, Unknown		Not Reported
	Agomelatine			S	Oral	1 Df, Unknown		Not Reported
	Avlocardyl /00030001/			S	Oral	1 Df, Unknown		Not Reported
	Paracetamol			S	Oral	1 Df, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2014	9992616	NON-EXPEDITED			US-PFIZER INC-2014067494		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Dyskinesia; Tardive Dyskinesia	Gabapentin			S		Unk		Pfizer
	Neurontin			S	Oral	900 Mg, Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2014	10051231	EXPEDITED (15-DAY)		OT	FR-FRI-1000049998		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Labelled Drug-Drug Interaction Medication Error; Overdose	Escitalopram			S	Oral	30 Mg		Forest
	Escitalopram			S				Forest
	Tercian			S	Oral	50 Mg		Not Reported
	Teralithe			C	Oral	1400 Mg		Not Reported
	Zopiclone			C	Oral	7.5 Mg		Not Reported
	Temerit			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2014	10051376	EXPEDITED (15-DAY)		OT	FR-FRI-1000066023		23 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram			S	Oral	10 Mg		Forest
	Xeroquel			S	Oral	50 Mg		Not Reported
	Xeroquel			S	Oral	100 Mg		Not Reported
	Xeroquel			S	Oral	50 Mg		Not Reported
	Depamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2014	10052120	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Product Substitution Issue; Therapeutic Product Effect Decreased	Escitalopram Oxalate			S	Oral	10 Mg Once Daily, 10 Mg By Mouth Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2014	9550659	NON-EXPEDITED			US-SANOFI-AVENTIS-2013SA043992		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Blood Pressure Fluctuation; Blood Pressure Increased; Fatigue; Gait Disturbance; Heart Rate Increased; Nausea; Paraesthesia; Tremor	Aubagio			S	Oral			Not Reported
	Aubagio			S	Oral			Not Reported
	Aubagio			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2014	10018159	EXPEDITED (15-DAY)		OT	US-FRI-1000064678			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer; Drug Ineffective	Lexapro			S	Oral	20mg		Forest
	Temazepam			C		7.5mg		Not Reported
	Vitamins Nos			C		Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2014	10041155	EXPEDITED (15-DAY)		OT	DE-FRI-1000065729		66 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortitis	Escitalopram			S		10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2014	10054496	EXPEDITED (15-DAY)		HO, OT	BR-FRI-1000066085		62 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Bradycardia;	Lexapro			S	Oral	5 Mg		Forest

Hyperthermia	Lexapro	S	Oral	10 Mg		Forest
	Synthroid	C	Oral	75 Mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2014	8260674	NON-EXPEDITED		CA, HO, OT	US-JNJFOC-20111109043		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Asthma-Chronic Obstructive Pulmonary Disease Overlap Syndrome; Attention Deficit/Hyperactivity Disorder; Behaviour Disorder; Bronchopulmonary Dysplasia; Cleft Lip And Palate; Congenital Central Nervous System Anomaly; Developmental Delay; Emotional Disorder; Enlarged Clitoris; Gastrooesophageal Reflux Disease; Intraventricular Haemorrhage Neonatal; Lung Disorder; Malocclusion; Meningitis Neonatal; Nasal Septum Deviation; Patent Ductus Arteriosus; Pharyngotonsillitis; Premature Baby; Retinopathy Of Prematurity; Sepsis; Sleep Apnoea Syndrome; Strabismus	Topamax			S	Transplacental			Not Reported
	Clindamycin			S	Transplacental			Not Reported
	Terbutaline			S	Transplacental			Not Reported
	Prometrium			S	Transplacental			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Lithium Carbonate			S	Transplacental			Not Reported
	Zithromax			S	Transplacental			Not Reported
	Betamethasone			S	Transplacental			Not Reported
	Nifedipine			S	Transplacental			Not Reported
	Ampicillin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2014	9894472	EXPEDITED (15-DAY)		CA, OT	US-PFIZER INC-2014039954			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Bicuspid Aortic Valve; Congenital Aortic Stenosis; Maternal Exposure During Pregnancy; Ventricular Dysfunction	Zoloft			S	Transplacental	Unk		Pfizer
	Sertraline Hcl			S	Transplacental	Unk		Pfizer
	Lexapro			S	Transplacental	Unk		Not Reported
	Bupropion			C	Transplacental	Unk		Not Reported
	Trazodone			C	Transplacental	Unk		Not Reported
	Nuvaring			C	Transplacental	Unk		Not Reported
	Albuterol			C	Transplacental	Unk		Not Reported
	Acetaminophen			C	Transplacental	Unk		Not Reported
	Hydroxyzine			C	Transplacental	Unk		Not Reported
	Natelle			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2014	10060468	EXPEDITED (15-DAY)		HO	FR-SA-2014SA039866		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Zopiclone			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Lantus			S	Subcutaneous	Dose:15 Unit(S)		Not Reported
	Doliprane			S	Oral			Not Reported
	Victoza			S	Subcutaneous			Not Reported
	Celebrex			S	Oral	Frequency - 2 Days		Not Reported
	Crestor			S	Oral			Not Reported
	Athymil			S	Oral			Not Reported
	Amlor			S	Oral			Not Reported

Renitec [Enalapril Maleate]	S	Oral			Not Reported
Diamicron	S	Oral			Not Reported
Glucophage	S	Oral	Frequency - 2 Days		Not Reported
Seroplex	S	Oral			Not Reported
Ceris	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2014	10060893	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1406766US		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Trospium Chloride Unk			S	Oral	20 Mg, Unk		Indevus
	Lantus			S	Subcutaneous	15 Units, Unk		Not Reported
	Doliprane			S	Oral	500 Mg, Prn		Not Reported
	Celebrex			S	Oral	200 Mg, Qod		Not Reported
	Crestor			S	Oral	10 Mg, Unk		Not Reported
	Athymil			S	Oral	10 Mg, Unk		Not Reported
	Amlor			S	Oral	5 Mg, Unk		Not Reported
	Renitec /00574902/			S	Oral	10 Mg, Unk		Not Reported
	Diamicron			S	Oral	30 Mg, Unk		Not Reported
	Glucophage			S	Oral	8850 Mg, Unk		Not Reported
	Seroplex			S	Oral	10 Mg, Unk		Not Reported
	Zopiclone			S	Oral	Unk		Not Reported
	Kardegic			S	Oral	75 Mg, Unk		Not Reported
	Omeprazole			S		20 Mg, Unk		Not Reported
	Victoza			C	Subcutaneous	1.8 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	9412441	EXPEDITED (15-DAY)		HO, OT	CA-MERCK-1307CAN011138		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angle Closure Glaucoma; Inappropriate Schedule Of Product Administration; Underdose	Saphris		S	Oral	1.25 Mg, Unk	Merck
	Cipralex		S	Oral	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	9656456	EXPEDITED (15-DAY)		HO	CA-FRI-1000050614		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Heart Rate Increased; Heart Rate Irregular; Nausea	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	9656495	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000050619		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Fibula Fracture; Syncope; Tibia Fracture	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S				Forest
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	9656649	EXPEDITED (15-DAY)		DE	CA-FRI-1000050617		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Completed Suicide; Panic Attack; Product Dose Omission; Suicidal Behaviour	Escitalopram			S		10 Mg		Forest
	Trazodone			C		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	9656650	EXPEDITED (15-DAY)		OT	CA-FRI-1000050612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Pain; Depressed Mood; Disturbance In Sexual Arousal; Hypertonic Bladder; Insomnia; Muscle Spasms; Paraesthesia; Product Use In Unapproved Indication; Restless Legs Syndrome; Urethral Pain; Vulvovaginal Burning Sensation	Escitalopram			S	Oral	2.5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	10041153	EXPEDITED (15-DAY)		HO	NO-FRI-1000065848		78 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Dizziness; Executive Dysfunction; Syncope	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Zyprexa			S	Oral	20 Mg		Not Reported
	Norspan			C		240 Mcg		Not Reported
	Vallergan			C	Oral	30 Mg		Not Reported
	Zopiclone Actavis			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	10062568	EXPEDITED (15-DAY)		HO	IT-FRI-1000066196		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Haemolysis	Escitalopram Oral Solution			S	Oral	Overdose: Cipralex 30 Drops		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	10063235	EXPEDITED (15-DAY)		OT	CA-FRI-1000066178		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Aggression; Anger; Binge Drinking; Feeling Abnormal; Insomnia; Legal Problem	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Not Reported
	Escitalopram			S	Oral	Overdose: Escitalopram 40 Mg Once		Not Reported
	Blood Pressure Pills Nos			C		Daily Dose Not Reported		Not Reported
	Prostate Cancer Medication Nos			C		Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	10063444	EXPEDITED (15-DAY)		OT	US-FRI-1000066082			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Dissociative Disorder; Feeling Abnormal; Physical Assault	Lexapro			S				Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	10063486	EXPEDITED (15-DAY)		DE	FR-FRI-1000066199		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram			S	Oral	20 Mg		Forest
	Duoplavin			S	Oral	1 Df		Not Reported
	Coversyl			C				Not Reported
	Doliprane			C				Not Reported
	Eupantol			C				Not Reported
	Crestor			C				Not Reported
	Exelon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	10063724	EXPEDITED (15-DAY)		HO, LT	PHHY2014ES040668		77 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniocerebral Injury; Hyponatraemia; Subarachnoid Haemorrhage	Exforge			S	Oral	Unk Ukn, Unk		Novartis
	Heipram			S	Oral	Unk Ukn, Unk		Not Reported
	Adiro			C	Oral	100 Mg, Unk		Not Reported
	Inegy			C	Oral	1 Df (10 Mg Ezet/ 20 Mg Simv), Qd		Not Reported
	Orfidal			C	Oral	1 Mg, Qd		Not Reported
	Sevikar Hct			C	Oral	1 Df (5 Mg Amlo/ 12.5 Mg Hydr/ 40 Mg Olme), Unk		Not Reported
	Uniket Retard			C		50 Mg, Unk		Not Reported
	Vesicare			C	Oral	5 Mg, Unk		Not Reported
	Diuretics			C		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2014	10067451	EXPEDITED (15-DAY)	Y	HO	2014P1002744		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bicarbonate Decreased; Blood Glucose Increased; Blood Lactic Acid Increased; Blood Ph Decreased; Blood Pressure Systolic Decreased; Coma Scale Abnormal; Incorrect Dose Administered; Po2 Decreased; Toxicity To Various Agents; Treatment Failure	Clonidine			S	Oral			Not Reported
	Propanolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2014	9612065	NON-EXPEDITED		OT	US-ASTELLAS-2013US009182		87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Discomfort; Drug Ineffective; Drug Interaction; Inappropriate Schedule Of Product Administration; Urinary Retention	Myrbetriq			S	Oral	50 Mg, Unknown/D		Astellas
	Myrbetriq			S	Oral	50 Mg, Uid/Qd		Astellas
	Myrbetriq			S	Unknown	25 Mg, Unknown/D		Astellas
	Myrbetriq			S	Oral	Evry Other Day		Astellas
	Nexium /01479302/			S	Unknown	Unk		Not Reported
	Humalog			S	Unknown	Unk		Not Reported
	Lantus			S	Unknown	Unk		Not Reported
	Tiazac /00489702/			S	Unknown	Unk		Not Reported
	Losartan			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Buspar			S	Unknown	Unk		Not Reported
	Miralax /00754501/			C	Unknown	Unk		Not Reported
	Linaclotide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2014	9657922	EXPEDITED (15-DAY)		HO	CA-FRI-1000050623		18 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersomnia; Suicidal Behaviour; Suicidal Ideation	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2014	10064696	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2014SE23410		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pancreatitis Acute	Omeprazole	S	Oral	Not Reported
	Crestor	S	Oral	Not Reported
	Glucophage	S	Oral	Not Reported
	Doliprane	S	Oral	Not Reported
	Victoza	S	Subcutaneous	Not Reported
	Celebrex	S	Oral	Not Reported
	Athymil	S	Oral	Not Reported
	Amlor	S	Oral	Not Reported
	Renitec [Enalapril Maleate]	S	Oral	Not Reported
	Diamicron	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Zopiclone	S	Oral	Not Reported
	Kardegic	S	Oral	Not Reported
	Ceris	S	Oral	Not Reported
	Lantus	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2014	10065545	EXPEDITED (15-DAY)		HO, LT	ES-DSJP-DSE-2014-103973			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Head Injury; Hyponatraemia; Subarachnoid Haemorrhage	Sevikar Hct			S	Oral	1 Df, Qd		Not Reported
	Heipram			S	Oral	1-0-0		Not Reported
	Exforge			S	Oral	1 Df, Qd		Not Reported
	Uniket			C	Oral	50 Mg, Qd		Not Reported
	Inegy			C	Oral	10/20 Mg, Qd		Not Reported
	Orfidal			C	Oral	1-0-0		Not Reported
	Vesicare			C	Oral	5 Mg, Qd		Not Reported
	Adiro			C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2014	10066756	EXPEDITED (15-DAY)		OT	PHHY2014TW037744		43 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Erythema; Obsessive-Compulsive Disorder; Photosensitivity Reaction; Skin Hyperpigmentation; Sunburn; Therapeutic Product Cross-Reactivity	Escitalopram			S		20-30 Mg		Not Reported
	Fluvoxamine			S		100-150 Mg		Novartis
	Fluoxetine			S		40-60 Mg Per Day		Not Reported
	Clonazepam			C		1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2014	9656603	EXPEDITED (15-DAY)		OT	CA-FRI-1000050622		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2014	9661104	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000050683			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Hyperthermia	Escitalopram			S	Transplacental			Forest
	Corticosteroids			S	Transplacental			Not Reported
	Nicotine			S	Transplacental			Not Reported
	Suboxone			S	Transplacental	2 Mg		Not Reported
	Subutex			S	Transplacental	1 Df		Not Reported
	Subutex			S	Transmammary	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2014	9980812	EXPEDITED (15-DAY)		HO	NO-ROCHE-1355597		50 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Abuse; Drug Diversion; Hospitalisation; Intentional Product Misuse	Clonazepam			S	Unknown	Dosing Details Unknown		Not Reported
	Subutex			S	Unknown	At The Time When The Questionnaire Was Completed, Patient Had Been On Subutex 1 Year 7 Months		Not Reported
	Remeron			S	Unknown	Dosing Details Unknown		Not Reported
	Cannabis			S	Respiratory (inhalation)	Details Unknown		Not Reported
	Cipralex			S	Unknown	Dosing Details Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2014	10068044	EXPEDITED (15-DAY)		HO	US-FRI-1000066235		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tendon Rupture	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Luaf41156			S	Oral	Unk		Not Reported
	Blinded-Placebo			S	Oral			Not Reported
	Blinded Serequel Xr			S	Oral	Unk		Not Reported
	Prazosin Hydrochloride			C	Oral	6 Mg Milligram(S), Qpm		Not Reported
	Loratadine			C	Oral	10 Mg Milligram(S), Prn		Not Reported
	Flunisolide Acetate			C		0.025 % Percent, Unk		Not Reported
	Lisinopril/Hctz			C	Oral	20/25 Mg Milligram(S), Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2014	10068546	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY-20608998		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pancreatitis Acute	Glucophage	S	Oral	Bristol Myers Squibb
	Victoza	S	Subcutaneous	Not Reported
	Celebrex	S	Oral	Not Reported
	Crestor	S	Oral	Not Reported
	Athymil	S	Oral	Not Reported
	Amlor	S	Oral	Not Reported
	Renitec [Enalapril Maleate]	S	Oral	Not Reported
	Diamicron	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Zopiclone	S	Oral	Not Reported
	Kardegic	S	Oral	Not Reported
	Omeprazole	S	Oral	Not Reported
	Ceris	S	Oral	Not Reported
	Lantus	S	Subcutaneous	Not Reported
	Doliprane	S	Oral	Cadence

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2014	10068940	EXPEDITED (15-DAY)		HO	CA-FRI-1000066340		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Decreased; Coma Scale Abnormal; Overdose	Escitalopram			S		Overdose 400 Mg		Forest
	Clonidine			S		Overdose 2.8 Mg		Not Reported
	Propranolol			S		Overdose 1120 Mg		Not Reported
	Lorazepam			S		Overdose 28 Mg		Not Reported
	Atorvastatin			S		Overdose 560 Mg		Not Reported
	Quetiapine			S		Overdose 5600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2014	10085113	NON-EXPEDITED	Y	DE, HO	2014-00700		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram (Unknown)			S				Not Reported
	Zolpidem (Unknown)			S				Not Reported
	Alprazolam (Unknown)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2014	10085115	NON-EXPEDITED	Y	DE, HO	2014-00717		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S				Not Reported
	Duloxetine			S				Not Reported
	Alprazolam			S				Not Reported
	Vilazodone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2014	10085121	NON-EXPEDITED	Y	DE, HO	2014-00718		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram (Unknown)			S				Not Reported
	Citalopram (Unknown) (Citalopram)			S				Not Reported
	Bupropion (Unknown)			S				Not Reported
	Clonazepam (Unknown)			S				Not Reported
	Tadanafil (Unknown)			S				Not Reported
	Acetaminophen + Diphenhydramine (Unknown)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2014	10085130	NON-EXPEDITED		OT	E2B_00001718		54 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Inhibitory Drug Interaction; Suicidal Ideation	Escitalopram (Unknown)			S		10-20mg Daily	1 DAY	Not Reported
	Gliclazide (Unknown)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2014	9326083	EXPEDITED (15-DAY)		OT	JP-FRI-1000045596		68 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Supraventricular Extrasystoles; Ventricular Extrasystoles	Lexapro			S	Oral	10 Mg		Forest
	Takepron			S	Oral	15 Mg		Not Reported
	Paxil			S	Oral	40 Mg		Not Reported
	Predonine			S	Oral	20 Mg		Not Reported
	Predonine			S	Oral	15 Mg		Not Reported
	Prednisolone			S	Oral	3 Mg		Not Reported
	Risperdal			C	Oral	2 Mg		Not Reported
	Singulair			C	Oral	10 Mg		Not Reported
	Maglax			C	Oral	990 Mg		Not Reported
	Apidra			C	Subcutaneous	24 Ut		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2014	10062891	EXPEDITED (15-DAY)		OT	CH-FRI-1000066177		36 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Nodosum; Off Label Use	Escitalopram			S	Oral	10 Mg		Forest
	Tysabri			S	Other	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2014	10070561	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2014097539		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Heart Rate Increased; Hypertension; Intentional Overdose; Pneumonia Aspiration; Respiratory Failure	Xanax			S	Oral	0.50 Mg, Unk		Pfizer
	Methadone Ap-Hp			S	Oral	3 Tablets Of 20 Mg, Single		Not Reported
	Seroplex			S	Oral	11 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2014	10070906	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000066206			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Foetal Cardiac Disorder; Hypoplastic Left Heart Syndrome; Ventricular Fibrillation	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2014	10071061	EXPEDITED (15-DAY)		OT	CH-FRI-1000066208			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Loss Of Consciousness	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2014	10072145	DIRECT		DS, OT			20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Anorgasmia; Bulimia Nervosa; Condition Aggravated; Frustration Tolerance Decreased; Hypoaesthesia; Impaired Work Ability; Insomnia; Intentional Self-Injury; Orgasm Abnormal; Post-Traumatic Stress Disorder; Quality Of Life Decreased; Self-Injurious Ideation; Sexual Dysfunction; Vaginal Disorder	Lexapro			S	Oral	1 Pill Once Daily Taken By Mouth A Few Months (3-6 At Most)		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2014	10072195	DIRECT		DS			18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Crohn'S Disease; Gastritis; Helicobacter Gastritis; Mouth Ulceration; Weight Decreased	Escitalopram			S	Oral	1 Tablet, Once Daily Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2014	9875755	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2014-01098		83 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Depression; Diabetes Mellitus Inadequate Control; Drug Interaction; Glycosylated Haemoglobin Abnormal; Hyperglycaemia; Insomnia	Escitalopram			S		5 Mg, 1 In 1 D 1 D	3 DAY	Not Reported
	Glibenclamide			S		22.5 Mg (7.5 Mg, 3 In 1 D), Unknown 15 Mg (5 Mg, 3 In 1 D), Unknown 7.5 Mg (2.5 Mg, 3 In 1 D), Unknown		Not Reported
	Enalapril W/Hydrochlorothiazide (Enap -Hl/06436201/)			C				Not Reported
	Doxazosin (Doxazosin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2014	10041158	EXPEDITED (15-DAY)		HO	FR-FRI-1000065851		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Escitalopram			S		20 Mg		Forest
	Escitalopram			S				Forest
	Lexomil			C		0.5 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2014	10072697	NON-EXPEDITED			US-PFIZER INC-2014100824			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Disturbance In Attention; Drug Ineffective	Pristiq			S		Unk		Pfizer
	Effexor Xr			S		75 Mg, Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Xalatan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2014	10072802	EXPEDITED (15-DAY)		HO	FR-SA-2014SA040407		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral	Endotelon		Y	S	Oral	Dose:2 Unit(S)		Not Reported
	Rilmenidine			S	Oral	Dose:1 Unit(S)		Not Reported
	Lasilix			S	Oral	Dose:1 Unit(S)		Not Reported
	Sifrol			S	Oral	Dose:1 Unit(S)		Not Reported
	Seroplex			S	Oral	Dose:1 Unit(S)		Not Reported
	Previscan (Fluindione)			C	Oral			Not Reported
	Metformin			C	Oral			Not Reported
	Atenolol			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2014	10073589	EXPEDITED (15-DAY)		OT	CH-FRI-1000066374			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Blood Pressure Increased; Body	Escitalopram			S	Oral	5 Mg		Forest

Temperature Increased; Diarrhoea; Dizziness; Dysphoria; Dysstasia; Fatigue; Gait Disturbance; Headache; Heart Rate Increased; Hyperhidrosis; Hyperventilation; Impaired Work Ability; Insomnia; Listless; Nausea; Palpitations; Refusal Of Treatment By Patient; Serotonin Syndrome; Tachycardia; Tremor; Unresponsive To Stimuli; Vomiting	Concor	C	Oral	5 Mg	Not Reported
	Climen	C	Oral		Not Reported
	Halcion	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2014	10073602	EXPEDITED (15-DAY)		HO	FR-FRI-1000066334		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Interaction	Escitalopram			S	Oral			Forest
	Tercian			S	Intravenous (not otherwise specified)	50 Mg/5 Ml Daily		Not Reported
	Tercian			S	Oral	2 Df		Not Reported
	Noctamide			S	Oral	1 Df		Not Reported
	Valium			S	Intravenous (not otherwise specified)	10 Mg/2 Ml		Not Reported
	Anafranil			S	Oral	1 Df		Not Reported
	Seresta			S	Oral	30 Df		Not Reported
	Seresta			S	Oral	100 Mg		Not Reported
	Mianserine			S	Oral	1 Df		Not Reported
	Mianserine			S	Oral	2 Df		Not Reported
	Lescol			C				Not Reported
	Hydrochlorothiazide\Valsartan			C		80/12.5 Mg		Not Reported
	Lamaline			C	Oral	1 Df		Not Reported

(Acetaminophen\Caffeine\Opium
)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2014	10073604	EXPEDITED (15-DAY)		HO	FR-FRI-1000066335		16 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Product Use In Unapproved Indication	Escitalopram			S	Oral			Forest
	Escitalopram			S				Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest
	Alprazolam			C		0.25 Mg		Not Reported
	Alprazolam			C		0.75 Mg		Not Reported
	Alprazolam			C		0.5 Mg		Not Reported
	Alprazolam			C		0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2014	10075405	DIRECT		OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Hyperhidrosis	Escitalopram			S	Oral		1 MTH	Cadista

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2014	10076549	DIRECT		OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Diarrhoea; Feeling Abnormal; Insomnia	Escitalopram			S	Oral	1, Once Daily, Taken By Mouth		Walmart

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2014	10076559	DIRECT		OT			16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Product Substitution Issue	Escitalopram			S	Oral	1 Pill, Once Daily, Taken By Mouth		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2014	8052948	EXPEDITED (15-DAY)		OT	US-SANOFI-AVENTIS-2011SA046917		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia; Anger; Homicide	Zolpidem			S	Oral			Not Reported
	Citalopram			S	Unknown			Not Reported
	Diphenhydramine			S	Unknown			Not Reported
	Acetone			S	Unknown			Not Reported
	Caffeine			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Xanax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2014	10075095	EXPEDITED (15-DAY)		HO	FR-ROCHE-1376533		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Interaction	Valium			S	Intravenous (not otherwise specified)			Not Reported
	Tercian			S	Intravenous (not otherwise specified)	50mg/5ml		Not Reported
	Tercian			S	Oral	25mg		Not Reported
	Noctamide			S	Oral	2 Mg		Not Reported
	Anafranil			S	Oral	75mg		Not Reported

Seresta	S	Oral	50mg		Not Reported
Mianserine	S	Oral			Not Reported
Seroplex	S	Oral			Not Reported
Lescol	C	Unknown			Not Reported
Hydrochlorothiazide\Valsartan	C	Unknown	80/12.5mg		Not Reported
Xeroquel	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2014	10075628	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2014S1007973			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Nose Malformation; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 Mg/Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2014	10075634	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2014S1007974			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Necrotising Enterocolitis Neonatal	Escitalopram			S	Transplacental	20 Mg/Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2014	10075958	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000066377		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Altered State Of Consciousness; Overdose; Pneumonia Aspiration	Escitalopram			S	Oral	Unknown Dose		Forest
	Alprazolam			S	Oral	Overdose (Unknown Dose)		Not Reported
	Alcohol			S		Overdose Of Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2014	10077311	EXPEDITED (15-DAY)		HO	FR-FRI-1000066463		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Drug Interaction; Hyponatraemia	Escitalopram			S	Oral	5 Mg		Forest
	Bipreterax			S	Oral	5mg/ 1.25 Mg		Not Reported
	Sectral			C	Oral	100 Mg		Not Reported
	Previscan (Fluindione)			C	Oral	25 Mg		Not Reported
	Levothyrox			C	Oral	125 Mcg		Not Reported
	Exelon			C	Transdermal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2014	10077612	EXPEDITED (15-DAY)		HO	FR-FRI-1000066379		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Off Label Use; Transaminases Increased	Escitalopram			S	Oral			Forest
	Xeroquel			S	Oral	300 Mg		Not Reported
	Noctamide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2014	9818173	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2014SE01550		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Stevens-Johnson Syndrome; Toxic Skin Eruption	Esomeprazole			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Primperan			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Oxynorm			S	Oral			Not Reported

	Kardegic	C	Not Reported
	Plavix	C	Not Reported
	Lovenox	C	Not Reported
	Metoprolol	C	Not Reported
	Insuline	C	Not Reported
	Hexaspray	C	Not Reported
	Hydroxyzine	C	Not Reported
	Solumedrol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2014	10080114	EXPEDITED (15-DAY)		HO	FR-FRI-1000066503		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Product Dispensing Error	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose: 11 Tablets		Not Reported
	Methadone Ap Hp			S	Oral			Not Reported
	Methadone Ap Hp			S	Oral	Overdose: 3 Df		Not Reported
	Xanax			S	Oral			Not Reported
	Xanax			S	Oral	Overdose: Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2014	10081989	DIRECT	Y				58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Response Decreased	Lexapro Generic 10mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2014	10173072	NON-EXPEDITED	Y	OT	ALL1-2013-06454		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Vyvanse (Lisdexamfetamine Dimesylate) Capsule			S	Oral			Not Reported

	Remeron	S	Not Reported
	Lexapro (Escitalopram Oxalate)	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2014	10082250	EXPEDITED (15-DAY)		HO	PHHY2014FR044745		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged; Fall; Hypokalaemia; Malaise	Rasilez Hct			S	Oral	1 Df, Daily (Alis 300 Mg, Hctz 12.5 Mg)		Novartis
	Domperidone			S	Oral	Unk Ukn, Prn		Not Reported
	Cordarone			S	Oral	1 Df, Daily (200 Mg)		Not Reported
	Seroplex			S	Oral	1 Df, Daily (10 Mg)		Not Reported
	Xarelto			C		15 Mg, Unk		Not Reported
	Levothyrox			C		Unk Ukn, Unk		Not Reported
	Modopar			C		Unk Ukn, Unk		Not Reported
	Inexium//Esomeprazole Magnesium			C		40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2014	8961684	EXPEDITED (15-DAY)		HO	JP-FRI-1000040992		41 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Listless; Torsade De Pointes; Ventricular Fibrillation	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Takepron			S	Oral	15 Mg		Not Reported
	Lamictal			C	Oral	100 Mg		Not Reported
	Landsen			C	Oral	0.5 Mg		Not Reported
	Rivotril			C	Oral	0.5 Mg		Not Reported
	Plavix			C	Oral	75 Mg		Not Reported
	Bayaspirin			C	Oral	100 Mg		Not Reported
	Crestor			C	Oral	2.5 Mg		Not Reported

	Nicorandis		C	Oral	15 Mg	Not Reported
	Magnesium Oxide		C	Oral	1.5 G	Not Reported
	Solita-T No.1		C	Intravenous drip	500 Ml	Not Reported
	Heparin Sodium		C	Intravenous drip	12 Ku	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2014	10084580	EXPEDITED (15-DAY)		OT	US-FRI-1000066405		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hepatic Mass; Hepatic Steatosis	Lexapro			S	Oral	20 Mg		Forest
	Cymbalta			C	Oral	60 Mg		Not Reported
	Latuda			C	Oral	40 Mg		Not Reported
	Topiramate			C	Oral	50 Mg		Not Reported
	Quetiapine			C	Oral	50 Mg		Not Reported
	Benztropine			C	Oral	1 Mg		Not Reported
	Vitamin D3			C				Not Reported
	Skelaxin			C	Oral	100 Mg		Not Reported
	Astepro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2014	10089833	EXPEDITED (15-DAY)	Y	HO, OT	NSR_01541_2014		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Blood Pressure Systolic Decreased; Overdose; Toxicity To Various Agents; Treatment Failure	Propranolol (Propranolol)			S	Oral			Not Reported
	Clonidine (Clonidine)			S	Oral			Not Reported
	Escitalopram (Escitalopram)			S	Oral			Not Reported
	Lorazepam (Lorazepam)			S	Oral			Not Reported
	Atorvastatin (Atorvastatin)			S	Oral			Not Reported
	Quetiapine (Quetiapine)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2014	9760468	EXPEDITED (15-DAY)		DE, OT	US-BRISTOL-MYERS SQUIBB COMPANY-19885235		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Diplopia; Disturbance In Attention; Insomnia; Mania	Abilify			S	Oral	1/2 Tab. 12feb2013: 1mg. 14feb2013: 2mg. 26feb2013: 5mg. 04mar2013: 5mg 1/2 Tab		Not Reported
	Lexapro			S				Not Reported
	Topamax			C				Not Reported
	Risperidal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2014	9964120	EXPEDITED (15-DAY)		HO, OT	PHHY2014BR026048		86 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Drug Ineffective; Pneumonia; Urinary Tract Infection	Exelon Patch			S	Transdermal	1 Df, Daily		Novartis
	Fluoxetine			S		1 Df, Daily		Not Reported
	Lexapro			S		10 Drops		Not Reported
	Pantocal			C		Once A Day		Not Reported
	Verapamil Hydrochloride			C		Once A Day		Not Reported
	Vitamiin C			C		Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2014	10086542	EXPEDITED (15-DAY)		HO	FR-FRI-1000066608		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral			Forest
	Previscan (Fluindione)			S	Oral			Not Reported
	Sectral			C				Not Reported
	Esomeprazole			C				Not Reported

	Melaxose	C		Not Reported
	Ketum	C		Not Reported
	Lexomil	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2014	10089040	DIRECT		OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Diarrhoea; Disorientation; Dizziness; Fall; Headache; Nausea; Nightmare	Lexapro			S	Oral	1 Pill	1 DAY	Not Reported
	Prazosin			C				Not Reported
	Aspirin			C				Not Reported
	Zocor			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2014	10089107	DIRECT		OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Counterfeit; Seizure	Lexapro			S	Oral	1		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2014	10089498	DIRECT		OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Product Substitution Issue	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2014	9978173	NON-EXPEDITED		OT	US-PFIZER INC-2014065074		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Zoloft			S		Unk		Pfizer

Urinary Retention	Lexapro	S	Unk		Not Reported
	Requip	S	Unk		Not Reported
	Cymbalta	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2014	10080456	EXPEDITED (15-DAY)		OT	CA-ROCHE-1369728		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Accidental Overdose; Asthenia; Dizziness; Dyspnoea; Faeces Soft; Malignant Neoplasm Progression	Avastin			S	Intravenous (not otherwise specified)			Not Reported
	Avastin			S	Intravenous (not otherwise specified)			Not Reported
	Crestor			S	Unknown			Not Reported
	Frisium			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Avodart			C	Unknown			Not Reported
	Keppra			C				Not Reported
	Pantoprazole			C				Not Reported
	Decadron			C				Not Reported
	Docusate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2014	10090593	EXPEDITED (15-DAY)		HO	FR-FRI-1000066612		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Escitalopram			S				Forest
	Lexomil Roche			S	Oral	6 Mg		Not Reported
	Stablon			S				Not Reported
	Euphytose			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2014	10094453	DIRECT					37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Unexpected	Lexapro Generic 10mg			S	Oral	10 Mg, At Bedtime, Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2014	10098443	EXPEDITED (15-DAY)	Y	OT	2014HINLIT0363			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Necrotising Colitis	Escitalopram			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2014	10098463	EXPEDITED (15-DAY)	Y	CA, OT	2014HINLIT0364			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Nose Malformation; Maternal Drugs Affecting Foetus	Escitalopram			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2014	9689535	EXPEDITED (15-DAY)		OT	PHHY2013IT128638			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Hypoglycaemia; Hyporeflexia; Hypotonia; Lethargy; Slow Response To Stimuli	Paroxetine			S	Transplacental	Maternal Dose: 20-40 Mg Daily		Novartis
	Clonazepam			S	Transplacental	Maternal Dose: 0.5 Mg Daily		Not Reported
	Escitalopram			S	Transplacental	Maternal Dose: 10 Mg Daily		Not Reported

	Lorazepam	S	Transplacental	Maternal Dose: 1 Mg Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2014	9907251	EXPEDITED (15-DAY)		HO	IT-FRI-1000054291		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Nausea; Overdose; Sopor	Escitalopram			S	Oral	Overdose: 280 Mg		Forest
	Valeriana Alfa			S	Oral	Overdose: 3000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2014	10094049	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2014110315		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged; Fall; Hypokalaemia; Malaise; Vertigo	Cordarone			S	Oral	200 Mg (1 Tablet), Once Daily		Pfizer
	Domperidone			S	Oral	Unk, As Needed		Not Reported
	Seroplex			S	Oral	1 Df, Once Daily		Not Reported
	Rasilez Hct			S	Oral	1 Df, Once Daily		Not Reported
	Xarelto			C				Not Reported
	Levothyrox			C				Not Reported
	Modopar			C				Not Reported
	Inexium			C				Not Reported
	Vit K Antagonists			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2014	10094624	NON-EXPEDITED			US-PFIZER INC-2014110073			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Relpax			S		Unk		Pfizer
	Diclofenac Sodium			S		Unk		Pfizer

Celexa	S	Unk		Not Reported
Imitrex	S	Unk		Not Reported
Keppra	S	Unk		Not Reported
Lexapro	S	Unk		Not Reported
Reglan	S	Unk		Not Reported
Restoril	S	Unk		Not Reported
Synthroid	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2014	10094856	EXPEDITED (15-DAY)		DS	US-FRI-1000066625			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Learning Disorder	Lexapro			S	Transplacental			Forest
	Lovenox			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2014	10096705	EXPEDITED (15-DAY)		OT	PHHY2014IT042289		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Generalised Anxiety Disorder; Maternal Exposure During Pregnancy; Prolonged Pregnancy	Escitalopram			S		20 Mg, Unk		Not Reported
	Alprazolam			S		1.25 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2014	10096714	EXPEDITED (15-DAY)		CA	PHHY2014IT042322			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Escitalopram			S	Transplacental	Maternal Dose: 10 Mg/Day		Not Reported
	Alprazolam			S		Maternal Dose: 0.25		Novartis

Mg/Kg

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2014	10097122	EXPEDITED (15-DAY)		OT	CA-FRI-1000066736		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Totalis; Self Esteem Decreased	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2014	10098603	DIRECT	Y				17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depression; Irritability; Product Substitution Issue	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2014	10099926	DIRECT					35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Withdrawal Syndrome; Impaired Work Ability; Nausea; Tremor; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10mg At Bedtime Taken By Mouth	3 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2014	10101644	EXPEDITED (15-DAY)	Y	HO	IMP_07560_2014		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Blood Ph Decreased;	Clonidine (Clonidine)			S		(2.8 Mg, Once [Not The Prescribed Amount])	1 DAY	Not Reported

Blood Pressure Systolic Decreased; Coma Scale Abnormal; Overdose; Toxicity To Various Agents	Propranolol (Propranolol)	S	(1120 Mg, Once [Not The Prescribed Amount])	1 DAY	Not Reported
	Escitalopram (Escitalopram)	S	(400 Mg, Once [Not The Prescribed Amount])	1 DAY	Not Reported
	Lorazepam (Lorazepam)	S	928 Mg, Once [Not The Prescribed Amount])	1 DAY	Not Reported
	Atorvastatine /01326101/ (Atorvastatine) (Not Specified)	S	(560 Mg, Once [Not The Prescribed Amount])	1 DAY	Not Reported
	Quetiapine (Quetiapine)	S	(5600 Mg, Once [Not The Prescribed Amount])	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2014	9748558	EXPEDITED (15-DAY)		OT	CH-FRI-1000052184		1 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Escitalopram			S	Transplacental	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Abilify			S	Transplacental	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2014	9903768	EXPEDITED (15-DAY)		OT	IT-RANBAXY-2013RR-75219			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Hypoglycaemia; Hyporeflexia; Hyporesponsive To Stimuli; Hypotonia; Lethargy	Cipralex			S	Transplacental	10 Mg/Day, During 0-16 Gestational Weeks		Not Reported
	Sereupin			S	Transplacental	20-40 Mg/Day, During 16-38 Gestational Weeks		Not Reported
	Rivotril			S	Transplacental	0.5 Mg/Day, During 0-11 Gestational Weeks		Not Reported
	Lorazepam			S	Transplacental	1 Mg/Day, During 12-38 Gestational Weeks		Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2014	10016464	NON-EXPEDITED		OT	CH-FRI-1000052183		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oligohydramnios; Pregnancy	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Abilify			S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2014	10098482	NON-EXPEDITED			US-PFIZER INC-2014111166			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Geodon			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Creon			S		Unk		Not Reported
	Seroquel			S		Unk		Not Reported
	Tegretol			S		Unk		Not Reported
	Abilify			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2014	10041915	EXPEDITED (15-DAY)		DE	US-FRI-1000065785		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Viibryd			S	Oral	10 Mg		Forest
	Viibryd			S	Oral	20 Mg		Forest
	Viibryd			S	Oral	40 Mg		Not Reported
	Lexapro			S		10 Mg		Forest
	Seroquel Xr			C		50 Mg Qhs		Not Reported

Xanax	C	0.5 Mg		Not Reported
Crestor	C			Not Reported
Seroquel	C	50 Mg Qhs		Not Reported
Seroquel	C	100 Mg Qhs		Not Reported
Ambien	C	12.5 Mg		Not Reported
Ambien	C	12.5 Mg		Not Reported
Halcion	C	0.25 Mg Qhs		Not Reported
Xanax Xr	C	3 Mg		Not Reported
Zyprexa	C	10 Mg		Not Reported
Silenor	C	1 Tablet Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2014	10101988	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000066767		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Gastrointestinal Haemorrhage; Melaena	Escitalopram			S	Oral	1 Df		Forest
	Coumadine			S	Oral	1.5 Df		Not Reported
	Lasilix			C	Oral			Not Reported
	Perindopril			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Foradil			C				Not Reported
	Tardyferon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2014	10103707	EXPEDITED (15-DAY)		OT	FR-FRI-1000066768		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Myalgia; Overdose	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	40 Mg		Forest
	Escitalopram			S	Oral	60 Mg		Not Reported
	Levothyrox			C	Oral	0.5 Df		Not Reported

	Tranxene			C		10 To 15 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2014	10111066	DIRECT	Y				31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Drug Ineffective	Escitalopram			S	Oral	1 Tab		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2014	10128999	DIRECT	Y				31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral	1 Tab		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2014	9935070	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2014058009		61 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Mydriasis; Sopor; Unresponsive To Stimuli	Alprazolam			S	Oral	1 Df, Single		Pfizer
	Cipralex			S	Oral	80 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2014	10119316	NON-EXPEDITED			US-PFIZER INC-2014110807		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Hypervigilance; Immune System Disorder; Malaise; Nausea; Off Label Use;	Celebrex			S		Unk		Pfizer
	Lexapro			S	Oral	10 Mg, (1 In 1 D)		Not Reported
	Omega-3			C		Unk		Not Reported

Vertigo; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2014	10130316	DIRECT		DS, LT, OT			13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Attention Deficit/Hyperactivity Disorder; Dental Caries; Educational Problem; Gingival Disorder	Lexapro			S		20mgs Daily, Once Daily, Taken With Water		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2014	10016313	NON-EXPEDITED			US-PFIZER INC-2014075488			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S	Oral	Unk		Pfizer
	Reglan			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2014	10128419	EXPEDITED (15-DAY)		HO, LT	FR-BRISTOL-MYERS SQUIBB COMPANY-20654596		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia; Gastrointestinal Haemorrhage	Coumadin Tabs 2 Mg			S	Oral	1 Df:1.5 Tablet Unit Nos		Bristol Myers Squibb
	Seroplex			S	Oral	Scored Film-Coated Tablet		Not Reported
	Lasilix			C		Scored Tablet		Not Reported
	Perindopril			C				Not Reported
	Bisoprolol Hemifumarate			C				Not Reported
	Foradil			C				Not Reported
	Tardyferon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2014	10130063	NON-EXPEDITED			US-PFIZER INC-2014112297			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Doxepin Hcl			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2014	10137423	DIRECT					41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disease Recurrence; Product Substitution Issue	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2014	10138710	EXPEDITED (15-DAY)		HO, LT	IT-FRI-1000066854		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Loss Of Consciousness; Respiratory Arrest	Escitalopram			S	Oral	Overdose: 480 Mg		Forest
	Furosemide			S	Oral	Overdose: 750 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2014	10140139	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2014113357		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Fall; Hypokalaemia; Torsade De Pointes; Ventricular	Xanax			S	Oral	0.5 Mg, 1x/Day		Pfizer
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Plavix			C		Unk		Not Reported

Fibrillation	Stagid	C	Unk	Not Reported
	Pritor (Telmisartan)	C	Unk	Not Reported
	Aricept	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2014	10062252	EXPEDITED (15-DAY)		LT	JP-FRI-1000066194		52 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Altered State Of Consciousness; Suicide Attempt	Lexapro			S	Oral	10 Mg		Forest
	Limas			C	Oral	300 Mg		Not Reported
	Solanax			C	Oral	1.2 Mg		Not Reported
	Etizolam			C	Oral	1 Mg		Not Reported
	Brotizolam Od			C	Oral	0.25 Mg		Not Reported
	Flunitrazepam			C	Oral	2 Mg		Not Reported
	Phenobal			C	Oral	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2014	10143378	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000066881		197 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Tonic Convulsion; Vomiting	Escitalopram			S	Transmammary	10 Mg		Forest
	Bupropion Xl			S	Transmammary	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2014	10143443	EXPEDITED (15-DAY)		HO, LT, OT	JP-TAKEDA-THQ2012A11181		41 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Drug Interaction; Torsade De Pointes; Ventricular Fibrillation	Takepron Od Tablets 15			S	Oral	15 Mg, Qd		Takeda
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

Lamictal	C	Oral	50 Mg, Bid		Not Reported
Landsen	C	Oral	0.5 Mg, Qd		Not Reported
Rivotril	C	Oral	0.5 Mg, Qd		Not Reported
Plavix	C	Oral	75 Mg, Qd		Not Reported
Bayaspirin	C	Oral	100 Mg, Qd		Not Reported
Crestor	C	Oral	2.5 Mg, Qd		Not Reported
Nicorandis	C	Oral	5 Mg, Tid		Not Reported
Magnesium Oxide	C		0.5 Mg, Tid		Not Reported
Solita	C	Intravenous drip	500 Ml, Unk		Not Reported
Heparin Sodium	C	Intravenous drip	12 Kiu, Unk		Not Reported
Acetylsalicylic Acid	C	Oral	Unk		Not Reported
Clopidogrel Bisulfate	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2014	10144057	EXPEDITED (15-DAY)		DE, LT	FR-PFIZER INC-2014115848		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Snoring	Lyrica			S	Oral	300 Mg, Unk		Pfizer
	Durogesic			S	Transdermal	100 Ug Once Every 3 Days		Not Reported
	Oxynorm			S	Oral	10mg To 30mg Daily		Not Reported
	Topalgic (France)			S	Oral	1 To 3 Df Daily		Not Reported
	Tercian			S		50 Gtt, 1x/Day		Not Reported
	Imovane			S	Oral	7.5 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	15 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2014	10144078	EXPEDITED (15-DAY)		OT	AT-FRI-1000066855		38 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Focal Dyscognitive Seizures	Escitalopram		S	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2014	10144201	EXPEDITED (15-DAY)		OT	AT-FRI-1000066867		53 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Focal Dyscognitive Seizures	Escitalopram			S		10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2014	10144203	EXPEDITED (15-DAY)		OT	AT-FRI-1000066868		25 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram			S		10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2014	10144290	EXPEDITED (15-DAY)		DE	FR-FRI-1000066922			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Mood Altered	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2014	10090594	EXPEDITED (15-DAY)		HO	FR-FRI-1000066609		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Off Label Use; Seizure	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest
	Escitalopram			S	Oral	Dose Reduced (Nos)		Forest
	Temerit			C		5 Mg		Not Reported

	Hemigoxine	C	0.0625 Mg	Not Reported
	Xarelto	C	15 Mg	Not Reported
	Kardegic	C	75 Mg	Not Reported
	Galvus	C	50 Mg	Not Reported
	Lasilix	C	40 Mg	Not Reported
	Zyloric	C	50 Mg	Not Reported
	Inexium	C	20 Mg	Not Reported
	Calcium	C	500 Mg	Not Reported
	Lansoyl	C		Not Reported
	Eductyl	C		Not Reported
	Tobradex	C		Not Reported
	Ocufen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2014	10146772	EXPEDITED (15-DAY)		HO	FR-FRI-1000066942		4 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Nervousness; Tremor	Escitalopram			S	Transplacental	15 Mg		Forest
	Escitalopram			S	Transplacental	20 Mg		Not Reported
	Lexomil Roche			S	Transplacental			Not Reported
	Ritaline			C	Transplacental	60 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2014	9786820	EXPEDITED (15-DAY)		LT	IT-ABBVIE-13P-083-1183602-00		38 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Interaction	Depakin			S	Oral			Not Reported
	Tranquirit			S	Oral	Solution		Not Reported
	Paliperidone			S	Oral	Extended Release		Not Reported
	Venlafaxine			S	Oral			Not Reported
	Akineton			S	Oral	Extended Release		Not Reported

	Cipralex	S	Oral		Not Reported
	Lorazepam	C			Not Reported
	Alcohol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2014	9838827	EXPEDITED (15-DAY)		HO, OT	SE-FRI-1000052984		59 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Tachycardia	Escitalopram			S	Oral	5 Mg		Forest
	Trombyl			C		75 Mg		Not Reported
	Plavix			C		75 Mg		Not Reported
	Atacand			C		8 Mg		Not Reported
	Bisoprolol			C		10 Mg		Not Reported
	Spironolakton			C		25 Mg		Not Reported
	Simvastatin			C		20 Mg		Not Reported
	Mirtazapin			C		30 Mg		Not Reported
	Oxascand			C				Not Reported
	Cordarone			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2014	10149609	NON-EXPEDITED		OT	US-PFIZER INC-2014118074			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Amiodarone Hcl			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2014	10150001	EXPEDITED (15-DAY)		HO	TR-FRI-1000066926			Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Diarrhoea; Gastrointestinal Oedema	Escitalopram		S	Oral	10 Mg	Forest
	Norvasc		C	Oral		Not Reported
	Co-Diovan		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2014	10151064	EXPEDITED (15-DAY)		HO	FR-FRI-1000066974		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pleural Effusion	Escitalopram			S		10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2014	10151074	EXPEDITED (15-DAY)		DE	FR-FRI-1000067037		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Haematoma; Haemorrhagic Stroke	Escitalopram			S	Oral	1 Df		Forest
	Previscan (Fluindione)			S	Oral	15 Mg		Not Reported
	Previscan (Fluindione)			S	Oral	10 Mg		Not Reported
	Kardegic			S	Oral	1 Df		Not Reported
	Cordarone			C	Oral	200 Mg		Not Reported
	Tahor			C	Oral	10 Mg		Not Reported
	Stagid			C	Oral	280 Mg		Not Reported
	Diamicron			C	Oral	60 Mg		Not Reported
	Pariet			C	Oral	20 Mg		Not Reported
	Permixon			C	Oral	160 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2014	10152306	DIRECT		HO			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Delusion;	Lexapro			S	Oral	1 Pill		Forest

Feeling Abnormal; Myocardial Infarction; Nightmare; Panic Attack; Paranoia; Restlessness; Serotonin Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2014	10151493	EXPEDITED (15-DAY)		OT	IT-ACCORD-023421		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Anxiety; Bruxism; Hypomania	Escitalopram			S		Started Drug With 5mg/Day Dose		Accord
	Valproate			S		750 Mg/Day Dose Drug Was Started		Not Reported
	Lithium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2014	10151495	EXPEDITED (15-DAY)		HO	CA-MACLEODS PHARMACEUTICALS US LTD-MAC2014001052			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Tonic Convulsion; Vomiting	Escitalopram Oxalate			S	Oral	Unk		Macleods
	Bupropion Xl			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2014	10151836	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-023455		212 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Drug Interaction; Exposure Via Breast Milk; Hypertonia; Seizure Like Phenomena; Sleep Disorder; Somnolence;	Bupropion/Bupropion Hydrochloride			S	Transmammary			Not Reported
	Escitalopram			S	Transmammary			Accord

Unresponsive To Stimuli;
Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2014	10152476	EXPEDITED (15-DAY)		HO	FR-FRI-1000066977		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram			S	Oral	20 Mg		Forest
	Olanzapine Mylan			S		15 Mg		Not Reported
	Diffu K			C				Not Reported
	Keppra			C				Not Reported
	Lasilix			C				Not Reported
	Inexium			C				Not Reported
	Levothyrox			C				Not Reported
	Kardegic			C				Not Reported
	Bisoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2014	10155214	DIRECT					47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia	Lexapro 5 Mg			S	Oral		6 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2014	9323974	NON-EXPEDITED			US-PFIZER INC-2013166796		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Crying; Drug Ineffective; Fatigue; Feeling Abnormal; Hot Flush; Night Sweats	Pristiq			S		50 Mg, Daily		Pfizer
	Pristiq			S		100 Mg, Daily		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2014	9511374	NON-EXPEDITED		LT	IT-JNJFOC-20130902231		38 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Coma; Drug Interaction; Intentional Overdose; Intentional Self-Injury	Invega			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Depakin			S	Oral			Not Reported
	Tranquirit			S	Oral	0.5%		Not Reported
	Venlafaxine			S	Oral			Not Reported
	Akineton			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Ethanol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2014	9983355	EXPEDITED (15-DAY)		HO	US-SHIRE-US201400224		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	489 (Lisdexamfetamine Dimesylate)			S	Oral	70 Mg, 1x/Day:Qd		Shire
	489 (Lisdexamfetamine Dimesylate)			S	Oral	Unk, Unknown		Shire
	Escitalopram Oxalate			S	Oral	20 Mg, 1x/Day:Qd		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2014	10155023	EXPEDITED (15-DAY)		HO	JP-FRI-1000067064		50 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete	Lexapro			S	Oral	10 Mg		Forest
	Dogmatyl			S	Oral			Not Reported

	Meilax	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2014	10155084	EXPEDITED (15-DAY)		DE, LT	FR-FRI-1000067065		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Escitalopram			S	Oral	15 Mg		Forest
	Durogesic			S	Transdermal	33.3333 Mcg		Not Reported
	Oxynorm			S	Oral	1 To 3 Capsules Daily		Not Reported
	Topalgic (France)			S	Oral	1 To 3 Capsules Daily		Not Reported
	Imovane			S	Oral	7.5 Mg		Not Reported
	Lyrica			S	Oral			Not Reported
	Tercian			S	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2014	10155913	EXPEDITED (15-DAY)		HO	PHHY2014FR053072		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Behaviour Disorder; Confusional State	Stalevo			S	Oral	3 Df (100/25/200 Mg), Daily		Not Reported
	Stalevo			S	Oral	3 Df (50/12.5/200 Mg), Daily		Not Reported
	Tramadol			S	Oral	50 Mg, Bid		Novartis
	Seroplex			S	Oral	20 Mg, Daily		Not Reported
	Seroplex			S	Oral	10 Mg, Daily		Not Reported
	Seroplex			S	Oral	05 Mg, Daily		Not Reported
	Calcidose Vitamine D			C		1 Df (500 Mg/400 Iu), Bid		Not Reported
	Mopral			C		20 Mg, Qd		Not Reported
	Imovane			C		Unk Ukn, Unk		Not Reported
	Kardegic			C		160 Mg, Daily		Not Reported

Levothyrox	C	50 Ug, Qd	Not Reported
Seresta	C	10 Mg, Bid	Not Reported
Paracetamol	C	2 Df, Q8h, If Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2014	10157087	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack	Escitalopram 20mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2014	10159222	EXPEDITED (15-DAY)	Y	HO	2014HINLIT0418		195 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Exposure Via Breast Milk; Hypertonia; Maternal Drugs Affecting Foetus; Sleep Disorder; Somnolence; Vomiting	Escitalopram (Escitalopram) Unknown			S	Transmammary	10 Mg/Day		Not Reported
	Bupropion Xl (Bupropion) Unknown			S	Transmammary	150 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2014	10159886	EXPEDITED (15-DAY)	Y	OT	2014HINLIT0414		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Anger; Anhedonia; Anxiety; Apathy; Bruxism; Hypomania; Irritability; Middle Insomnia; Muscle Tightness; Nervousness; Nervousness; Tongue Biting; Tremor	Escitalopram			S				Not Reported
	Valproate (Valproate)			C				Not Reported
	Amisulpride (Amisulpride)			C				Not Reported
	Lithium (Lithium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2014	10159916	EXPEDITED (15-DAY)	Y	OT	2014HINLIT0416		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Depression; Dysphoria; Irritability; Migraine; Nervousness; Therapy Change; Tremor	Escitalopram			S				Not Reported
	Valproate (Valproate)			C				Not Reported
	Amisulpride (Amisulpride)			C				Not Reported
	Lithium (Lithium)			C				Not Reported
	Indomethacin+Caffeine+Prochlorperazine (Indomethacin+Caffeine+Prochlorperazine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2014	10156240	EXPEDITED (15-DAY)		HO	FR-ABBVIE-14K-056-1233693-00		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Overdose	Depakote			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Cyamemazine			S	Oral			Not Reported
	Cyamemazine			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Lepticur			C				Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2014	10157104	EXPEDITED (15-DAY)		HO	FR-SA-2014SA058636		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Nozinan			S	Oral	Daily Dose: 5 Drops Daily		Not Reported
	Plavix			S	Oral			Not Reported
	Zolpidem			S	Oral	Dose:1 Unit(S)		Not Reported
	Theralene			S	Oral	Daily Dose: 10 Drops Per Day		Not Reported
	Seroplex			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Pariet			S	Oral	Form - Gastrotab		Not Reported
	Seresta			S	Oral	Daily Dose 10 Mg Morning / 10 Mg Midday / 25 Mg Evening		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2014	10157238	EXPEDITED (15-DAY)		DE, LT	FR-JNJFOC-20140417838		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Durogesic			S	Transdermal			Not Reported
	Oxynorm			S	Oral	1-3 Capsules A Day		Not Reported
	Imovane			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Topalgic (France)			S	Oral	1-3 Capsusles		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2014	10158139	EXPEDITED (15-DAY)		HO	FR-EISAI INC-E3810-07077-SPO-FR		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Urinary Retention	Pariet	S	Oral		Not Reported
	Nozinan	S	Oral	5 Gtt	Not Reported
	Theralene	S	Oral	10 Gtt	Not Reported
	Seroplex	S	Oral		Not Reported
	Levothyrox	S	Oral	50 Ug	Not Reported
	Plavix	S	Oral		Not Reported
	Seresta	S	Oral	45 Mg In 1 Day	Not Reported
	Zolpidem	S	Oral	1 Dose(S)	Not Reported
	Loxen (Nicardipine Hydrochloride)	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2014	9788707	EXPEDITED (15-DAY)		LT	JP-FRI-1000052527		38 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure	Lexapro			S	Oral	5 Mg		Forest
	Meilax			C	Oral	4 Mg		Not Reported
	Depromel			C	Oral	150 Mg		Not Reported
	Seroquel			C	Oral	50 Mg		Not Reported
	Goodmin			C	Oral	0.5 Mg		Not Reported
	Lexotan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2014	10079095	EXPEDITED (15-DAY)		OT	PHEH2014US007142		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Nasal Congestion; Rhinorrhoea; Sinusitis; Sleep Apnoea Syndrome; Snoring	Tasigna			S	Oral	400 Mg, Bid		Novartis
	Tasigna			S	Oral	300 Mg, Unk		Novartis
	Morphine			S		15 Mg, Bid For 07 Days		Not Reported
	Lexapro			S	Oral	20 Mg, Unk		Not Reported

Oxycodone	C	Oral	5 Mg, Q4h		Not Reported
Mirtazapine	C	Oral	15 Mg, Unk		Not Reported
Neurontin	C	Oral	400 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2014	10160249	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2014-BI-20		93 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Asthenia; Balance Disorder; Decreased Appetite; Depressed Mood; Diarrhoea; Dizziness; Fall; Fatigue; Hyponatraemia; Hypotension; Orthostatic Hypotension; Osteoporosis; Skin Laceration; Somnolence; Vitamin B12 Deficiency; Vitamin D Deficiency; Weight Decreased	Telmisartan			S	Unknown	80 Mg		Boehringer Ingelheim
	Telmisartan			S				Boehringer Ingelheim
	Pantoprazole			S	Unknown	80 Mg		Not Reported
	Prednisone			S	Unknown	10 Mg		Not Reported
	Metoprolol			S	Unknown	50 Mg		Not Reported
	Metoprolol			S				Not Reported
	Escitalopram			S	Unknown	10 Mg		Not Reported
	Lorazepam			S	Unknown	1 Mg		Not Reported
	Tamsulosine			C	Unknown	0.4 Mg		Not Reported
	Loperamide			C	Unknown	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2014	9627504	EXPEDITED (15-DAY)		OT	IE-FRI-1000049997		50 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral			Forest
	Lithium			C				Not Reported
	Seroquel Xr			C				Not Reported
	Crestor			C				Not Reported

	Tritace	C	Not Reported
	Aspirin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2014	10163676	EXPEDITED (15-DAY)		CA, OT	DE-FRI-1000067099		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip; Foetal Exposure During Pregnancy; Small For Dates Baby; Syndactyly	Escitalopram Oral Solution			S	Transplacental	6 Mg		Forest
	Escitalopram Oral Solution			S	Transplacental	3 Mg		Not Reported
	L-Thyroxin			C	Transplacental	100 Mcg		Not Reported
	Folsaeure			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2014	10167516	DIRECT	Y	OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Product Substitution Issue	Escitalopram			S	Oral	Had Used Brand Lexapro In Past		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2014	10168724	EXPEDITED (15-DAY)	Y	HO	7290115		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Levothyrox (Levothyroxine Sodium) (50 Microgram, Tablet) (Levothyroxine Sodium)			S	Oral			Not Reported
	Nozinan /00038601/ (Levomepromazine) (4 Percent, Oral Solution) (Levomepromazine)			S	Oral			Not Reported
	Theralene (Alimemazine Tartrate) (4 Percent, Oral Solution) (Alimemazine Tartrate)			S	Oral			Not Reported
	Seroplex (Escitalopram Oxalate)			S	Oral			Not Reported

	(20 Mg, Film-Coated Tablet) (Escitalopram Oxalate)	S	Oral			Not Reported
	Pariet (Rabeprazole Sodium) (20 Mg, Gastro-Resistant Tablet) (Rabeprazole Sodium)	S	Oral			Not Reported
	Plavix /01220701/ (Clopidogrel) (75 Mg, Film-Coated Tablet) (Clopidogreal)	S	Oral			Not Reported
	Seresta (Oxazepam) (50 Mg, Tablet) (Oxazepam)	S	Oral	10 Mg, Morning, 10 Mg Noon, 25 Mg Evening		Not Reported
	Zolpidem (Zolpidem) (Zolpidem)	S	Oral			Not Reported
	Loxen (Nicardipine Hydrochloride)	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2014	10168966	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2014-05357		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Anger; Anhedonia; Anxiety; Apathy; Bruxism; Bruxism; Depression; Hypomania; Middle Insomnia; Myalgia; Nervousness; Sedation; Tongue Biting; Tremor	Escitalopram (Escitalopram)			S		10mg 1d) 5mg 1d		Not Reported
	Valproate Sodium (Valproate Sodium)			C				Not Reported
	Amisulpride (Amisulpride)			C				Not Reported
	Lithium (Lithium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2014	10168977	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2014-05366		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression; Drug Ineffective; Dysphoria; Headache; Irritability; Migraine; Musculoskeletal Pain; Neck Pain; Nervousness; Tooth Erosion; Tooth Fracture; Tremor; Trismus	Escitalopram			S		20mg 1d 4-10mg Day		Not Reported
	Valproate Sodium (Valproate Sodium)			C				Not Reported
	Lithium (Lithium)			C				Not Reported
	Indomethacin (Indometacin)			C				Not Reported
	Caffeine (Caffeine)			C				Not Reported

	Prochlorperazine (Prochlorperazine)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2014	10166458	EXPEDITED (15-DAY)		OT	AU-ELI_LILLY_AND_COMPANY-AU201404010013			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Dizziness; Hypothermia; Increased Upper Airway Secretion; Paraesthesia; Pollakiuria; Pyrexia; Serotonin Syndrome; Tinnitus	Cymbalta			S	Unknown	Unk, Unknown		Not Reported
	Zyprexa			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Aropax			S	Unknown	Unk, Unknown		Not Reported
	Celebrex			S	Unknown	Unk, Unknown		Not Reported
	Cipramil /00582602/			S	Unknown	Unk, Unknown		Not Reported
	Efexor			S	Unknown	Unk, Unknown		Not Reported
	Endep			S	Unknown	Unk, Unknown		Not Reported
	Endone			S	Unknown	Unk, Unknown		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Mogadon			S	Unknown	Unk, Unknown		Not Reported
	Naproxen			S	Unknown	Unk, Unknown		Not Reported
	Oxycontin			S	Unknown	Unk, Unknown		Not Reported
	Panadeine /00116401/			S	Unknown	Unk, Unknown		Not Reported
	Serepax			S	Unknown	Unk, Unknown		Not Reported
	Valium /00017001/			S	Unknown	Unk, Unknown		Not Reported
	Zoloft			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2014	10166513	EXPEDITED (15-DAY)		HO	FR-ORION CORPORATION ORION PHARMA-ENTC2014-0157		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety;	Stalevo			S	Oral	Strength: 100/25/200 Mg		Not Reported

Behaviour Disorder; Confusional State; Hallucination; Restlessness	Stalevo		S	Oral	Strength: 50/12.5/200 Mg	Not Reported
	Tramadol		S	Oral		Not Reported
	Seroplex		S	Oral		Not Reported
	Seroplex		S	Oral		Not Reported
	Seroplex		S	Oral		Not Reported
	Calcidose Vitamine D		C	Unknown		Not Reported
	Mopral		C	Unknown		Not Reported
	Imovane		C	Unknown		Not Reported
	Kardegic		C	Unknown		Not Reported
	Levothyrox		C	Unknown		Not Reported
	Seresta		C	Unknown		Not Reported
	Paracetamol		C	Unknown	Strength: 500 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2014	10166612	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20140419926		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Prescribed Overdose	Risperdal			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Lepticur			C	Unknown	10 (Units Unspecified) Once A Day		Not Reported
	Mirtazapine			C	Unknown	15 (Units Unspecified) Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2014	10167156	EXPEDITED (15-DAY)		HO	FR-FRI-1000067174		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Behaviour Disorder; Confusional State; Off Label Use	Escitalopram	S	Oral	20 Mg	Forest
	Escitalopram	S	Oral	10 Mg	Forest
	Escitalopram	S	Oral	5 Mg	Not Reported
	Tramadol	S	Oral	100 Mg	Not Reported
	Stalevo	S	Oral	3 Df	Not Reported
	Calcidose Vitamine D 500 Mg / 400 Iu	C		2 Df	Not Reported
	Mopral	C		40 Mg	Not Reported
	Imovane	C		7.5 Mg	Not Reported
	Kardegic	C		160 Mg	Not Reported
	Levothyrox	C		50 Mcg	Not Reported
	Seresta	C		20 Mg	Not Reported
	Paracetamol	C	Oral	2 Df Every 8 Hours, If Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2014	10167652	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-20697843		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2014	10135910	EXPEDITED (15-DAY)		HO, OT	PHHY2014US049565		92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adhesion; Anxiety; Arthralgia; Asthenia; Back Pain; Bursitis; Catatonia; Cerebrovascular Accident; Compression Fracture; Condition Aggravated; Confusional State;	Baclofen Intrathecal			S	Intrathecal	35.01 Ug/Day		Not Reported
	Amitriptyline Hcl Tablets Usp			S		1 Df, Qhs (1 Tablet Of 50 Mg, At Bedtime)		Novartis
	Lisinopril Tablets			S		1 Df/Daily (1 Tablet Of 20 Mg Daily)		Not Reported

Contusion; Conversion Disorder; Crepitations; Depression; Discomfort; Fall; Fluid Retention; Fractured Sacrum; Gait Disturbance; Gastrointestinal Sounds Abnormal; Headache; Hypoacusis; Hypoaesthesia; Hypopnoea; Hypotension; Injection Site Pain; Joint Swelling; Lethargy; Mental Status Changes; Mobility Decreased; Muscle Rigidity; Musculoskeletal Pain; Neuralgia; Oedema; Oedema Peripheral; Osteoarthritis; Overdose; Oxygen Saturation Decreased; Pain; Pain In Extremity; Pallor; Performance Status Decreased; Radicular Pain; Rash; Respiratory Depression; Rotator Cuff Syndrome; Sciatica; Sedation; Sleep Disorder; Swelling; Tenderness; Therapy Non-Responder; Withdrawal Syndrome; Wound	Simvastatin	S		1 Df, Daily (1 Tablet Of 40 Mg, Daily)	Not Reported
	Clonidine	S	Intrathecal	70.02 Ug/Day	Not Reported
	Bupivacaine	S	Intrathecal	2.626 Mg/Day	Not Reported
	Aspercream	S		Unk Ukn, Prn (As Directed On Tube As Needed)	Not Reported
	Clobetasol	S		Unk Ukn, Unk	Not Reported
	Imitrex	S	Subcutaneous	Unk Ukn, Prn (6 Mg/0.5 Injection As Needed)	Not Reported
	Lexapro	S		1 Df, Daily (1 Tablet Daily)	Not Reported
	Lidoderm	S		Unk Ukn, Unk (App Aa Daily)	Not Reported
	Toprol Xl	S		1 Df, Daily (1 Tablet Of 50 Mg, Daily)	Not Reported
	Tylenol	S		Unk Ukn, Prn (When Necessary)	Not Reported
	Valium	S		Unk Ukn, Prn (When Necessary)	Not Reported
	Zantac	S		1 Df, Qhs (One Df Of 150 Mg At Bedtime)	Not Reported
	Diuretics	S		Unk Ukn, Unk	Not Reported
	Sufentanil	S	Intrathecal	35.01 Ug, Daily	Not Reported
	Cymbalta	S		1 Df, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2014	10170184	EXPEDITED (15-DAY)		HO, LT, OT	TR-ACTAVIS-2014-09830		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Intentional Overdose; Suicide Attempt;	Quetiapine (Unknown)			S	Oral	Estimated Ingeste Amount Of 9 G		Actavis

Tachycardia	Escitalopram (Unknown)	S	Oral	Estimated Ingested Amount Of 280 Mg	Not Reported
	Ibuprofen (Unknown)	S	Oral	Estimated Ingested Amount Of 4g	Actavis Mid Atlantic
	Amoxicillin (Unknown)	S	Oral	Estimated Ingested Amount Of 5 G	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2014	10102192	EXPEDITED (15-DAY)	Y	CA, OT	AUR-APL-2014-04726			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Nose Malformation; Maternal Drugs Affecting Foetus	Escitalopram			S	Transplacental	20mg (20mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2014	10110272	EXPEDITED (15-DAY)	Y	CA, OT	AUR-APL-2014-04728			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Necrotising Colitis	Escitalopram			S	Transplacental	20 Mg (20 Mg, 1 In 1 D), Transplacental)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2014	10171180	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20140504229		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Vomiting	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Citalopram			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2014	10171330	EXPEDITED (15-DAY)		HO	BR-DRREDDYS-GPV/BRA/14/0040169		13 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Overdose; Poisoning; Suicidal Ideation; Suicide Attempt	Risperidone 3mg Tablet			S	Oral			Not Reported
	Paxil			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2014	10023648	EXPEDITED (15-DAY)	Y	OT	ADR-2013-02289		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Withdrawal Syndrome; Hyperhidrosis; Insomnia; Muscle Spasticity; Muscle Tightness; Nausea; Restlessness; Tremor; Vomiting	Baclofen	Y		S				Anazaohealth - Compounding
	Lipitor			S				Not Reported
	Celebrex			S				Not Reported
	Plavix			S				Not Reported
	Colace			S				Not Reported
	Lexapro			S				Not Reported
	Provigil			S				Not Reported
	Prilosec			S				Not Reported
	Flomax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2014	10174273	EXPEDITED (15-DAY)		DE	FR-FRI-1000067293		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Eye Haemorrhage	Escitalopram			S	Oral	0.5 Df		Forest
	Previscan (Fluindione)			S	Oral	1 Df		Not Reported
	Diffu K			C	Oral	1 Df		Not Reported
	Lasilix Faible			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2014	10179228	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2014-05526		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Withdrawal Convulsions; Drug Withdrawal Syndrome; Generalised Tonic-Clonic Seizure; Toxicity To Various Agents; Tremor	Ceftriaxone			S				Not Reported
	Escitalopram			S				Not Reported
	Tramadol			S				Not Reported
	Oxygen			S		30 Hbo2 At 2.4 Atm Abs For Two 45-Min		Not Reported
	Zolpidem (Zolpidem)			C				Not Reported
	Metronidazole (Metronidazole)			C				Not Reported
	Acetaminophen\Hydrocodone Bitartrate			C				Not Reported
	Hydromorphone (Hydromorphone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2014	10176124	NON-EXPEDITED			US-PFIZER INC-2014129421		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Food Allergy	Flagyl			S		Unk		Pfizer
	Amitriptyline			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2014	10176367	EXPEDITED (15-DAY)		HO	CH-NOVOPROD-409517		60 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypoglycaemia; Intentional Overdose; Nausea; Suicide Attempt; Vomiting	Novorapid			S	Subcutaneous	70 U		Novo Nordisk
	Co-Aprovel			S	Unknown	Unk		Not Reported
	Zanidip			S	Unknown	Unk		Not Reported
	Calcimagon D3			S	Unknown	Unk		Not Reported

	Cipralex /01588501/			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2014	10176655	EXPEDITED (15-DAY)		DE	CH-BAYER-2014-071390		83 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thalamus Haemorrhage	Aspirin Cardio			S		100 Mg, Qd		Bayer
	Cipralex			S	Oral	1 Df, Qd		Not Reported
	Pantozol (Switzerland)			C				Not Reported
	Sotalol			C				Not Reported
	Crestor			C				Not Reported
	Euthyrox			C				Not Reported
	Seroquel			C				Not Reported
	Trittico			C				Not Reported
	Zanidip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2014	10177310	EXPEDITED (15-DAY)		CA	US-FRI-1000067270		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Multiple Cardiac Defects; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2014	10177347	EXPEDITED (15-DAY)		CA	US-FRI-1000067302		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2014	10102378	EXPEDITED (15-DAY)		HO, LT	JP-ELI_LILLY_AND_COMPANY-JP201404002253		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Malaise; Neuroleptic Malignant Syndrome; Off Label Use	Zyprexa			S	Oral	5 Mg, Qd		Eli Lilly And Co
	Sulpiride			S	Oral	50 Mg, Tid		Not Reported
	Tandospirone Citrate			S	Oral	10 Mg, Tid		Not Reported
	Tandospirone Citrate			S				Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Granpam			C	Oral	1 Df, Tid		Not Reported
	Celecox			C	Oral	Unk		Not Reported
	Epenard			C	Oral	1 Df, Tid		Not Reported
	Cortril /00028601/			C	Oral			Not Reported
	Cortril /00028601/			C				Not Reported
	Bazedoxifene			C	Unknown	Unk		Not Reported
	Mohrus L			C	Transdermal	Unk		Not Reported
	Mohrus			C	Transdermal			Not Reported
	Amlodipine			C	Oral	Unk		Not Reported
	Pioglitazone			C	Oral	Unk		Not Reported
	Rabeprazole Sodium			C	Oral	Unk, Qd		Not Reported
	Ursodeoxycholic Acid			C	Oral	100 Mg, Tid		Not Reported
	Rebamipide			C		100 Mg, Tid		Not Reported
	Crestor			C	Oral	Unk		Not Reported
	Primperan			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2014	10178833	EXPEDITED (15-DAY)		OT	IT-UCBSA-121324			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus; Oculogyric Crisis; Therapeutic Response Unexpected	Rotigotine			S				Not Reported
	Rotigotine			S		Temporary Dosage Reduction		Not Reported
	Rotigotine			S		3 Months Later		Not Reported

	Escitalopram	S		Not Reported
	Pyridoxine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2014	10179328	EXPEDITED (15-DAY)		HO, LT	SE-FRI-1000067409		21 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness	Escitalopram			S	Oral	10-15 Mg Daily		Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2014	10182562	DIRECT		DS			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia	Celexa			S		1 Per Day		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2014	10185049	DIRECT		DS, LT, OT			13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Caries; Dry Mouth; Gingival Pain; Malaise; Tooth Fracture; Trismus	Escitalopram			S	Oral			Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2014	10184784	EXPEDITED (15-DAY)		OT	PHHY2013FR072299		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition; Hypersexuality	Exelon Patch			S	Transdermal	4.6 Mg, Qd		Novartis
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Pradaxa			S	Oral	110 Mg, Bid		Not Reported

	Doliprane	S	Oral	Unk Ukn, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2014	10185986	NON-EXPEDITED			US-PFIZER INC-2014135334		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Levothyroxine Sodium			S		Unk		Pfizer
	Lithium Carbonate			S		Unk		Pfizer
	Stadol			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Zofran			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lunesta			S		Unk		Not Reported
	Zyrtec			S		Unk		Not Reported
	Qvar			S		Unk		Not Reported
	Xopenex			S		Unk		Not Reported
	Klonopin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2014	10186247	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2014S1010701			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome	Loxalate			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2014	10186760	EXPEDITED (15-DAY)		OT	PHHY2014FR060953			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Weight Decreased	Gilenya	S	Oral		Novartis
	Seroplex	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2014	9676464	NON-EXPEDITED			US-PFIZER INC-2013314105		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Contact; Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Xanax			S		Unk		Pfizer
	Valium			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2014	10029195	EXPEDITED (15-DAY)		HO, LT, OT	FR-ASTRAZENECA-2014SE19205		44 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Epistaxis; Neuroleptic Malignant Syndrome; Renal Tubular Necrosis; Sinus Tachycardia; Thrombosis; Toxicity To Various Agents; Vomiting	Xeroquel			S	Oral			Not Reported
	Xeroquel			S	Oral	One Box		Not Reported
	Loxapac			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2014	10190241	EXPEDITED (15-DAY)		LT	FR-ASTRAZENECA-2014SE34862		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Status Epilepticus	Inexium			S	Oral			Astrazeneca
	Levofloxacine			S	Oral			Not Reported
	Domperidone			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

	Plavix	C	Oral		Not Reported
	Levothyrox	C	Oral		Not Reported
	Amlor	C	Oral		Not Reported
	Lovenox	C	Subcutaneous		Not Reported
	Alprazolam	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2014	9696139	EXPEDITED (15-DAY)		HO	CN-FRI-1000051458		63 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Decreased Appetite; Gastrooesophageal Reflux Disease; Muscle Tightness; Off Label Use; Parkinson'S Disease	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Zoloft			C	Oral	1 Df		Not Reported
	Omeprazole			C	Oral			Not Reported
	Metoprolol			C	Oral			Not Reported
	Ludingxin			C	Oral	1 Df		Not Reported
	Shenzhong			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2014	9928407	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2014-01871		54 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Depression; Drug Ineffective; Inhibitory Drug Interaction; Product Substitution Issue; Suicidal Ideation; Therapeutic Product Effect Decreased	Escitalopram			S				Not Reported
	Gliclazide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2014	10191336	EXPEDITED (15-DAY)		OT	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2014-BI-21		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition; Hypersexuality	Pradaxa			S	Oral	220 Mg		Boehringer Ingelheim
	Exelon			S	Transdermal	4.6 Mg		Not Reported
	Seroplex			S	Oral	5 Mg		Not Reported
	Doliprane			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2014	10197445	DIRECT		LT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro 10 Mg			S		1; One Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2014	10198443	DIRECT					76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Ear Pain; Headache; Ligament Pain; Muscle Spasms; Myalgia; Nausea; Pain	Escitalopram			S	Oral			Torrent
	Vitamin B3			C				Not Reported
	Red Yeast Rice			C				Not Reported
	Multivitamin			C				Not Reported
	Aromasin (Exemestane)			C				Not Reported
	Prilosec (Omeprazole)			C				Not Reported
	Mobic			C				Not Reported
	Tramadol (Ultram)			C				Not Reported
	Metaxalone (Skelaxin)			C				Not Reported
	Vitamin D3-1000			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2014	10198897	DIRECT					31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Panic Attack; Product Substitution Issue	Escitalopram 20 Mg Camber			S	Oral	1 Pill Once Daily Taken By Mouth		Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2014	9921150	EXPEDITED (15-DAY)		OT	GB-ACCORD-021970		54 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Inhibitory Drug Interaction; Suicidal Ideation	Escitalopram			S		10-20mg		Accord
	Gliclazide			S	Oral	Not Known (Prescribed By Gp)		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2014	10195573	EXPEDITED (15-DAY)		OT	PHHY2014US051377			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Musculoskeletal Stiffness	Lioresal Intratecal			S	Intrathecal	1400 Ug (Aprox.)/ Day		Not Reported
	Baclofen			S	Oral	Unk Ukn, Unk		Not Reported
	Gabapentin			S		Unk Ukn, Unk		Not Reported
	Omeprazole			S		Unk Ukn, Unk		Novartis
	Lexapro			S		Unk Ukn, Unk		Not Reported
	Crestor			S		Unk Ukn, Unk		Not Reported
	Seroquel			S		Unk Ukn, Unk		Not Reported
	Flomax			S		Unk Ukn, Unk		Not Reported
	Macrodantin			S		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2014	10196371	EXPEDITED (15-DAY)		OT	BE-JNJFOC-20140514817			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Memory Impairment; Musculoskeletal Stiffness; Poisoning; Product Use In Unapproved Indication; Somnolence; Tremor	Xeplion			S	Intramuscular			Not Reported
	Sipralexa			S	Unknown			Not Reported
	Trazolan			S	Unknown	100 Once A Day 0.5		Not Reported
	Maniprex			S	Unknown			Not Reported
	Depakine			S	Unknown			Not Reported
	L-Thyroxine			C	Unknown	0.0250 Unspecified Units		Not Reported
	Xanax Retard			C	Unknown	0.5 Unspecified Units		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2014	10196697	EXPEDITED (15-DAY)		OT	FR-FRI-1000067556		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition; Hypersexuality	Escitalopram			S	Oral	5 Mg		Forest
	Exelon 4.6 Mg/24 H			S	Transdermal	4.6 Mg		Not Reported
	Pradaxa			S	Oral	220 Mg		Not Reported
	Doliprane			S	Oral	If Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2014	10204595	DIRECT	Y	OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Product Substitution Issue; Therapeutic Response Decreased; Tremor	Escitalopram 20 Mg			S	Oral	One Daily, Qd, Oral		Not Reported
	Alprazolam			C				Not Reported
	B Complex + C			C				Not Reported
	Benicar			C				Not Reported
	Clindamycin			C				Not Reported
	Implanon			C				Not Reported

Lortab	C		Not Reported
Propranolol	C		Not Reported
Topiramate	C		Not Reported
Zetonna	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2014	10206004	DIRECT					24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Food Allergy; Headache; Irritability; Nausea; Neck Pain; Product Dose Omission; Rash Generalised; Urticaria; Varicose Vein; Weight Increased	Escitalopram			S	Oral	1 Pill/Day Once Daily Taken By Mouth	4 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2014	10206381	DIRECT		OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia; Transient Ischaemic Attack	Escitalopram			S	Oral	1 Pill		Teva
	Amitriptyline			C				Not Reported
	Prilosec			C				Not Reported
	Oxybuteron			C				Not Reported
	Vitamin B12			C				Not Reported
	81 Mg Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2014	10206422	DIRECT					56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral	One Tablet		Not Reported
	Xanax			C				Not Reported
	Protonix			C				Not Reported

	Ambien	C		Not Reported
	Brintellix	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2014	10206450	DIRECT		CA, DS, HO, LT			60 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Maternal Drugs Affecting Foetus; Premature Baby; Pulmonary Arterial Hypertension; Ventricular Septal Defect	Lexapro			S				Not Reported
	Flovent			C				Not Reported
	Flonase			C				Not Reported
	Albuterol			C				Not Reported
	Multivitamins		Y	C				Not Reported
	Allegra		Y	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10077132	EXPEDITED (15-DAY)		OT	US-FRI-1000066358		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Musculoskeletal Disorder	Lexapro			S	Oral	20 Mg		Forest
	Toprol Xl			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10172070	EXPEDITED (15-DAY)		HO, OT	PHEH2013US023761			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Blood Pressure Decreased; Blood Pressure Increased; Chest Pain; Concussion; Diarrhoea; Dizziness; Erythema; Feeding Disorder; Foot Deformity; Gait Disturbance; Gallbladder Disorder;	Diovan			S	Oral	325 Mg, Qd		Not Reported
	Diovan			S	Oral	160 Mg, Qd		Not Reported
	Diovan			S		80 Mg, Qd		Not Reported
	Diovan			S		1/3 Of A Tablet		Not Reported
	Diovan			S		Unk Ukn, Unk		Not Reported
	Lopresor			S	Oral	0.5 Df (Meto 50 Mg), Bid		Not Reported
	Diltiazem			S		Unk Ukn, Unk		Novartis

Gastric Disorder; Gastritis; Gastrointestinal Disorder; Hypotension; Lactose Intolerance; Limb Discomfort; Malaise; Muscle Spasms; Muscle Tightness; Myalgia; Nausea; Neuropathy Peripheral; Pain; Pain In Extremity; Palpitations; Rash; Road Traffic Accident; Skin Discolouration; Sleep Disorder; Somnolence; Spider Vein; Supraventricular Tachycardia; Taste Disorder; Tremor; Weight Decreased; Wrong Technique In Product Usage Process	Metoprolol	S		Unk Ukn, Unk	Not Reported
	Metoprolol	S		Unk Ukn, Unk	Not Reported
	Metoprolol	S		50 Mg, Unk	Not Reported
	Metoprolol	S		100 Mg, Unk	Not Reported
	Metoprolol	S		0.5 Df, (25 Mg Pill, Low Dose)	Not Reported
	Metoprolol	S		0.75 Df, (25 Mg) Bid	Not Reported
	Metoprolol	S		Unk Ukn, Unk	Not Reported
	Xanax	S		Unk Ukn, Unk	Not Reported
	Bystolic	S		Unk Ukn, Unk	Not Reported
	Lexapro	S		Unk Ukn, Unk	Not Reported
	Lexapro	S		0.5 Df, Bid (0.25 Mg)	Not Reported
	Kinevac	S	Intravenous (not otherwise specified)	(Over 60 Min)	Not Reported
	Kinevac	S		Unk Ukn, Unk	Not Reported
	Centrum	C		Unk Ukn, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10173685	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000067322		44 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Neuroleptic Malignant Syndrome; Renal Tubular Necrosis; Suicide Attempt	Escitalopram			S	Oral	20 Mg		Forest
	Xeroquel			S	Oral			Not Reported
	Xeroquel			S	Oral	Overdose Of 1 Box (Unknown Exact Dose)		Not Reported
	Loxapac			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10200434	EXPEDITED (15-DAY)		LT	FR-ROCHE-1404666		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Torsade De Pointes	Valium		S	Unknown	Not Reported
	Xatral		S	Unknown	Not Reported
	Seroplex		S	Unknown	Not Reported
	Primperan		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10201103	EXPEDITED (15-DAY)		OT	CN-FRI-1000067593		52 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Postmenopausal Haemorrhage	Lexapro			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10201106	EXPEDITED (15-DAY)		DE	CH-FRI-1000067596			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thalamus Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Aspirin Cardio			S	Oral	100 Mg		Not Reported
	Pantozol (Switzerland)			C				Not Reported
	Sotalol			C				Not Reported
	Crestor			C				Not Reported
	Euthyrox			C				Not Reported
	Seroquel			C				Not Reported
	Trittico			C				Not Reported
	Zanidip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10201236	EXPEDITED (15-DAY)		HO	CH-FRI-1000067594			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Disease; Drug Interaction; Epistaxis; Gingival	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported

Bleeding; Myocardial Ischaemia; Spontaneous Haematoma; Ventricular Hypokinesia	Dilzem	S	Oral	90 Mg		Not Reported
	Aspirin	S	Oral	100 Mg		Not Reported
	Efient	S	Oral	10 Mg		Not Reported
	Lexotanil	C	Oral	6 Mg		Not Reported
	Nitroderm	C	Topical	10 Mg		Not Reported
	Ulcogant	C	Oral	1000 Mg		Not Reported
	Laxoberon	C	Oral	10 Mg		Not Reported
	Isoket	C	Oral	1.25 Mg		Not Reported
	Beloc-Zok	C	Oral	25 Mg		Not Reported
	Dancor	C	Oral	20 Mg		Not Reported
	Diovan	C	Oral	80 Mg		Not Reported
	Nexium	C	Oral	40 Mg		Not Reported
	Ezetrol	C	Oral	10 Mg		Not Reported
	Ranexa	C	Oral	750 Mg		Not Reported
	Atorvastatine	C	Oral	80 Mg		Not Reported
	Lyrica	C	Oral	75 Mg		Not Reported
	Paracetamol/ Codein	C	Oral			Not Reported
	Nsaid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10201975	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-19800556		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased	Abilify Tabs 5 Mg			S				Not Reported
	Metformin Hcl			S				Bristol Myers Squibb
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10202507	EXPEDITED (15-DAY)		HO, OT	FR-ASTRAZENECA-2014SE35386		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hallucination; Oedema; Paralysis; Prostatitis	Xylocaine Jelly		S	Urethral		Not Reported
	Seroplex		S	Oral		Not Reported
	Seroplex		S	Oral		Not Reported
	Haldol		S	Oral	2mg/Ml 275 Drops Per Day	Not Reported
	Haldol		S	Oral		Not Reported
	Bactrim Forte		S	Oral		Not Reported
	Revatio		C	Oral		Not Reported
	Xatral		C	Oral		Not Reported
	Lasilix		C	Oral		Not Reported
	Lepticur		C	Oral		Not Reported
	Rivotril		C	Oral	2.5 Mg/Ml 40 Drops Per Day	Not Reported
	Seresta		C	Oral		Not Reported
	Tegretol		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10202576	EXPEDITED (15-DAY)		OT	IT-FRI-1000067655		79 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Sopor	Escitalopram			S				Forest
	Escitalopram			S		1/2 Tablet		Not Reported
	Perindopril			S	Oral	4 Mg		Not Reported
	Tachidol			S				Not Reported
	Amlodipine			C	Oral	10 Mg		Not Reported
	Ticlodipine			C				Not Reported
	Lasitone			C				Not Reported
	Megace			C				Not Reported
	Crestor			C	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10202706	EXPEDITED (15-DAY)		OT	US-FRI-1000067606		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Lexapro			S	Oral	10 Mg		Forest
	Mvi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2014	10207773	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Product Substitution Issue	Generic Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	9998226	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2014S1004708		61 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Mydriasis; Sopor; Unresponsive To Stimuli	Alprazolam			S	Oral	1 Df Total		Mylan
	Cipralex			S	Oral	80 Mg Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10070933	EXPEDITED (15-DAY)		CA	US-FRI-1000066305		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias; Premature Baby	Lexapro			S	Transplacental			Forest
	Acyclovir			C	Transplacental			Not Reported
	Insulin			C	Transplacental			Not Reported
	Betamethasone			C	Transplacental			Not Reported
	Erythromycin			C	Transplacental			Not Reported
	Ampicillin			C	Transplacental			Not Reported
	Morphine			C	Transplacental			Not Reported
	Nubain			C	Transplacental			Not Reported

	Vistaril	C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10204789	EXPEDITED (15-DAY)		OT	IT-TEVA-482916ISR		79 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Sopor	Perindopril			S	Oral	4 Milligram Daily;		Ivax
	Lasitone - 25 Mg + 37 Mg Capsule Rigide - Sanofi-Aventis S.P.A.			S				Not Reported
	Cipralex - Compresse Rivestite Con Film - H. Lundbeck A/S			S				Not Reported
	Crestor - Compresse Rivestite Con Film			C	Oral	10 Mg		Not Reported
	Megace - 160 Mg Compresse			C				Not Reported
	Tachidol - Adulti 500 Mg/30 Mg Granulato Effervescente			C				Not Reported
	Ticlopidine Hydrochloride			C				Not Reported
	Amlodipine Besylate			C	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10204884	NON-EXPEDITED		HO	US-FRI-1000066304		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery; Premature Rupture Of Membranes	Lexapro			S		20 Mg		Forest
	Acyclovir			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10204931	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20140510592		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Oedema; Paralysis	Haldol			S	Oral			Not Reported

Haldol	S	Oral			Not Reported
Haldol	S	Oral			Not Reported
Seroplex	S	Unknown	1 Tablets Per Day		Not Reported
Seroplex	S	Unknown	1 Tablet Per Day		Not Reported
Seroplex	S	Unknown			Not Reported
Bactrim Forte	S	Oral			Not Reported
Xylocaine	S	Intravenous (not otherwise specified)			Not Reported
Cymbalta	C	Unknown			Not Reported
Xatral	C	Unknown			Not Reported
Lasilix	C	Unknown			Not Reported
Rivotril	C	Unknown			Not Reported
Lepticur	C	Unknown			Not Reported
Dipiperon	C	Unknown			Not Reported
Seresta	C	Unknown	3.5 Tablets Per Day		Not Reported
Tegretol	C	Unknown			Not Reported
Revatio	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10205118	EXPEDITED (15-DAY)		LT	FR-FRI-1000067652			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Status Epilepticus	Escitalopram			S	Oral	10 Mg		Forest
	Levofloxacine			S	Oral	500 Mg		Not Reported
	Inexium			S	Oral	40 Mg		Not Reported
	Domperidone			S	Oral	10 Mg		Not Reported
	Plavix			C		1 Df		Not Reported
	Levothyrox			C		75 Mcg		Not Reported
	Amlor			C		5 Mg		Not Reported
	Lovenox			C	Other	40 Iu		Not Reported

Alprazolam	C	1 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10205121	EXPEDITED (15-DAY)		DE	CH-BAYER-2014-075430		75 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Aspirin Cardio			S	Oral	100 Mg, Qd		Bayer
	Cipralex			S	Oral	5 Mg, Qd		Not Reported
	Catapresan			C	Oral	Unk		Not Reported
	Beloc [Metoprolol]			C	Oral	50 Mg, Qd		Not Reported
	Triatec (Ramipril)			C	Oral	5 Mg, Qd		Not Reported
	Adalat Cr			C	Oral	60 Mg, Qd		Bayer
	Clonazepam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10205238	EXPEDITED (15-DAY)		HO	CA-FRI-1000067684			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Head Titubation; Suicidal Ideation	Escitalopram			S		15 Mg		Forest
	Escitalopram			S		20 Mg		Not Reported
	Escitalopram			S		5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10205251	EXPEDITED (15-DAY)		DE, HO, LT, OT	AU-FRI-1000066507		17 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Purpura; Thrombocytopenia	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10205253	EXPEDITED (15-DAY)		HO	FR-FRI-1000067096		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Muscle Rigidity	Escitalopram			S	Oral	10 Mg		Forest
	Loxapac			S	Oral	45 Df		Not Reported
	Atarax			S	Oral	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10205562	EXPEDITED (15-DAY)		HO	FR-FRI-1000067658		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema; Paralysis	Escitalopram			S	Oral	15 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Not Reported
	Haldol			S	Oral	275 Gtt		Not Reported
	Haldol			S	Oral	Dose Increased Nos		Not Reported
	Haldol			S				Not Reported
	Bactrim			S	Oral	2 Df		Not Reported
	Xylocaine			S	Urethral	2 Df		Not Reported
	Revatio			C	Oral	3 Df		Not Reported
	Xatral			C	Oral	1 Df		Not Reported
	Lasilix			C	Oral	1 Df		Not Reported
	Lepticur			C	Oral	1 Df		Not Reported
	Rivotril			C	Oral	40 Gtt		Not Reported
	Seresta			C	Oral	3.5 Df		Not Reported
	Tegretol			C	Oral	2 Df		Not Reported
	Cymbalta			C				Not Reported
	Dipiperon			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10205563	EXPEDITED (15-DAY)		DE	FR-FRI-1000067646		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; International Normalised Ratio Increased; Shock Haemorrhagic	Escitalopram			S	Oral			Forest
	Previscan (Fluindione)			S	Oral			Not Reported
	Furosemide			C				Not Reported
	Diamicron			C				Not Reported
	Coversyl			C				Not Reported
	Lercanidipine			C				Not Reported
	Eupressyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10205573	EXPEDITED (15-DAY)		OT	DE-FRI-1000067661		46 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Nausea; Pain	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S				Forest
	Tavor (Lorazepam)			C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2014	10207032	DIRECT		HO, OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Disturbance In Attention; Mental Status Changes; Seizure; Tremor; Vision Blurred	Viibryd			S		2 Tbl By Mouth		Forest
	Escitalopram			S				Mylan
	Imitrex			C				Not Reported
	Lido			C				Not Reported
	Prilocin			C				Not Reported
	Ibuprofen			C				Not Reported
	Ciprofloxacin			C				Not Reported
	Ciclobenzapine			C				Not Reported
	Meloxin			C				Not Reported
	Lexapro			C				Not Reported

	Flexeril	C	Not Reported
	Clindamycin	C	Not Reported
	Ibuprofen	C	Not Reported
	Vacinacion Afuria	C	Not Reported
	Xanax	C	Not Reported
	Vitamin D Nos	C	Not Reported
	Meloxicam	C	Not Reported
	Clonazepam	C	Not Reported
	Bactrim (Silfameth/Trimethoprim)	C	Not Reported
	Tramadol	C	Not Reported
	Keflex	C	Not Reported
	Sumatriptan	C	Not Reported
	Atorvastatin	C	Not Reported
	Sumatriptan	S	Not Reported
	Cyclobenzaprine	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2014	10207029	EXPEDITED (15-DAY)		OT	CN-FRI-1000022669			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haematochezia	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	15 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2014	10208455	NON-EXPEDITED			US-PFIZER INC-2014147321		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Lodine			S		Unk		Pfizer

	Indocin	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported
	Thorazine	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Vioxx	S	Unk	Not Reported
	Abilify	S	Unk	Not Reported
	Allopurinol	S	Unk	Not Reported
	Flexeril	S	Unk	Not Reported
	Clonazepam	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2014	10213727	EXPEDITED (15-DAY)	Y	OT	UCM201405-000087		32 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Protrusion Tongue	Divalproex Sodium			S		400 Mg Per Day In Divided Doses, 400 Mg Per Day In Divided Doses 900 Mg Per Day		Not Reported
	Sodium Phenytoin			S		300 Mg Per Day In Divided Doses, 300 Mg Per Day In Divided Doses 600 Mg Per Day		Not Reported
	Escitalopram			S		10 Mg Per Day, 10 Mg Per Day 15 Mg Per Day, 15 Mg Per Day 5 Mg Per Day, 5 Mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2014	10209512	EXPEDITED (15-DAY)		OT	TR-US-EMD SERONO, INC.-7294936			Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Diabetic Neuropathy	Rebif			S				Not Reported
	Beloc-Zok			S				Not Reported
	Escitalopram			S				Not Reported
	Thioctacid /00213801/			S				Not Reported
	Suprafen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2014	10211721	EXPEDITED (15-DAY)		CA	DE-FRI-1000067838		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arachnoid Cyst; Cerebellar Hypoplasia; Foetal Exposure During Pregnancy; Subdural Hygroma; Vith Nerve Disorder	Escitalopram			S	Transplacental	10-15 Mg		Forest
	Ibuprofen			C	Transplacental	800 Mg, If Required		Not Reported
	Meronem			C				Not Reported
	Folic Acid			C	Transplacental			Not Reported
	Dopegyt			C				Not Reported
	Anaesthetics			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2014	10211728	EXPEDITED (15-DAY)		HO	FR-FRI-1000067835		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poor Sucking Reflex; Poor Weight Gain Neonatal; Somnolence	Escitalopram			S	Transplacental	10 Mg		Forest
	Lexomil Roche			S	Transplacental	3 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2014	10211730	EXPEDITED (15-DAY)		OT	DE-FRI-1000067837		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Caesarean Section; Cervical Incompetence; Gestational Hypertension	Escitalopram			S	Oral	10-15 Mg		Forest
	Ibuprofen			C	Oral	800 Mg, If Required		Not Reported

	Folic Acid	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2014	9732485	EXPEDITED (15-DAY)		HO, OT	VAL_02842_2013			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Asthenia; Blood Pressure Increased; Chest Pain; Concussion; Diarrhoea; Dizziness; Dysgeusia; Eating Disorder; Erythema; Erythema; Feeling Abnormal; Gait Disturbance; Gallbladder Disorder; Gastric Disorder; Gastritis; Gastrointestinal Disorder; Hypotension; Hypotension; Lactose Intolerance; Malaise; Muscle Spasms; Muscle Tightness; Myalgia; Nausea; Neuropathy Peripheral; Pain; Pain In Extremity; Palpitations; Palpitations; Post Procedural Complication; Rash; Rash Erythematous; Reaction To Excipient; Road Traffic Accident; Sleep Disorder; Somnolence; Spider Vein; Supraventricular Tachycardia; Tremor; Weight Decreased; Weight Decreased; Wrong Technique In Product Usage Process	Lopressor			S		(25 Mg, Df)		Not Reported
	Diltiazem			S		(Df [Regimen 1])		Not Reported
	Xanax			S		Df		Not Reported
	Bystolic			S		(Df [Regimen 1]) Unknown Until Not Continuing		Not Reported
	Lexapro (Not Specified)			S		Df Regimen 1 0.5 Df Bid, [Regimen 2]		Not Reported
	Centrum / 07499601/			C				Not Reported
	Metoprolol			S		(Df) (Df [Regimen 2]) (50 Mg, Regimen 3]) (100 Mg, Regimen 4) (0.5 Df, Regimen 5) (0.75 Df Bid, [Regimen 6]) (0.25 Df Bid, [Regimen 7]) (0.5 Df Bid, [Regimen 8]) (1 Df Bid [Regimen 9])		Not Reported
	Diovan (Not Specified)			S	Oral Oral	([1/3 Tablet For 2-3 Weeks])		Not Reported
	Kinevac			S	Intravenous (not otherwise specified)	([Df Over 60 Min, Regimen 1])		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2014	9922660	EXPEDITED (15-DAY)		OT	GB-FRI-1000054530		54 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Inhibitory Drug Interaction; Off Label Use; Suicidal Ideation	Escitalopram			S	Oral			Forest
	Gliclazide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2014	10214132	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2014150650		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction	Trangorex			S	Oral	Unk		Pfizer
	Escitalopram Oxalate			S	Oral	20 Mg, Daily		Not Reported
	Sintrom			S	Oral	Unk		Not Reported
	Acetylsalicylic Acid			S	Oral	100 Mg, Daily		Not Reported
	Atenolol			C		Unk		Not Reported
	Lantus			C		Unk		Not Reported
	Seguril			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2014	10214981	EXPEDITED (15-DAY)		HO	DE-FRI-1000067781			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haemorrhage; Tachycardia	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Mirtazapin			S	Oral	30 Mg		Not Reported
	Mirtazapin			S	Oral	15 Mg		Not Reported
	Clexane			S	Other	0.6 Ml		Not Reported

Clexane	S	Other	1.2 Ml		Not Reported
Clexane	S	Other	0.6 Ml		Not Reported
Ebixa	C	Oral	10 Mg		Not Reported
Ebixa	C	Oral	15 Mg		Not Reported
Ebixa	C	Oral	20 Mg		Not Reported
Ebixa	C	Oral	15 Mg		Not Reported
Ebixa	C	Oral	10 Mg		Not Reported
Risperdal	C	Oral	1 Mg		Not Reported
Risperdal	C	Oral	0.5 Mg		Not Reported
Bisoprolol	C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2014	10215143	EXPEDITED (15-DAY)		HO	AU-FRI-1000067829		58 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Blood Potassium Decreased; Blood Pressure Decreased; Consciousness Fluctuating; Overdose; Respiratory Rate Decreased	Lexapro Oral Solution			S	Oral	900 Mg (90 Ml) Two Days		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2014	10215394	EXPEDITED (15-DAY)		HO, OT	CH-009507513-1105USA03810		20 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Increased; Continuous Haemodiafiltration; Intentional Overdose; Metabolic Acidosis; Off Label Use; Suicide	Janumet			S	Oral	180 Tablet Once		Merck
	Cipralex			S		20 Mg, Per Day		Not Reported
	Solian			C	Oral	400 Mg, Bid		Not Reported
	Temesta (Lorazepam)			C	Oral	1 Mg Daily		Not Reported

Attempt; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2014	10215771	EXPEDITED (15-DAY)		OT	GB-LUPIN PHARMACEUTICALS INC.-E2B_00001718		54 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Inhibitory Drug Interaction; Suicidal Ideation	Escitalopram			S	Unknown	10-20mg Daily		Not Reported
	Gliclazide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2014	10216310	EXPEDITED (15-DAY)		DE	FR-FRI-1000067827		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke; International Normalised Ratio Increased	Escitalopram			S	Oral			Forest
	Previscan (Fluindione)			S	Oral			Not Reported
	Lexomil			C				Not Reported
	Pantoprazole			C				Not Reported
	Coversyl			C				Not Reported
	Amiodarone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2014	10218869	DIRECT					29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Economic Problem; Feeling Jittery; Hyperhidrosis; Nausea; Nervousness; Product Substitution Issue	Escitolopram 20 Forest			S	Oral	3 Once Daily Taken By Mouth	3 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2014	10219134	DIRECT		HO			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Dizziness; Palpitations; Skin Discolouration; Syncope; White Blood Cell Count Increased	Lexapro			S	Oral	1 Pill Once Daily Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2014	10218377	EXPEDITED (15-DAY)		DE	ES-BAYER-2014-077955		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Adiro 100			S	Oral	100 Mg, Qd		Bayer
	Sintrom			S	Oral			Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Trangorex			S	Oral			Not Reported
	Atenolol			C	Oral	37.5 Mg, Bid		Not Reported
	Lantus			C	Subcutaneous	10 Iu, Qd		Not Reported
	Seguril			C	Oral	20 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2014	10219045	EXPEDITED (15-DAY)		OT	US-SA-2014SA073410		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Zolpidem Tartrate			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Acetaminophen\Hydrocodone Bitartrate			C				Not Reported
	Oxygen			C		30 Hyperbaric Oxygen Treatments		Not Reported

	Hydromorphone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2014	10220889	DIRECT		OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Tremor	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2014	10220254	EXPEDITED (15-DAY)		DE, OT	BR-ROCHE-1414343		85 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Neoplasm Of Unknown Primary Site; Overdose	Rivotril			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2014	10220260	EXPEDITED (15-DAY)		HO, LT	DE-DRREDDYS-GER/GER/14/0040829		26 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Olanzapine			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Quetiapine			S				Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Lorazepam			C	Oral			Not Reported
	Lorazepam			C	Oral			Not Reported
	Lorazepam			C	Oral			Not Reported

	Lorazepam			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2014	10221049	EXPEDITED (15-DAY)		OT	ZA-FRI-1000067895		16 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Seizure	Escitalopram			S				Forest
	Strattera			C				Not Reported
	Epitec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2014	10221050	EXPEDITED (15-DAY)		HO	FR-FRI-1000067878		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Loss Of Consciousness; Suicide Attempt	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	Overdose Of 28 Tablets (I.E. 280 Mg)		Forest
	Alprazolam			C				Not Reported
	Ixprim			C				Not Reported
	Doliprane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2014	10221531	EXPEDITED (15-DAY)		OT	CA-FRI-1000067974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Judgement Impaired; Mental Impairment; Stress	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2014	10222996	EXPEDITED (15-DAY)		HO	GXKR2014DE002161			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebellar Haemorrhage; Tachycardia	Mirtazapine	S	Oral	30 Mg, Unk		Novartis
	Mirtazapine	S	Oral	15 Mg, Unk		Novartis
	Cipralex /Den/	S	Oral	5 Mg, Unk		Not Reported
	Cipralex /Den/	S	Oral	10 Mg, Unk		Not Reported
	Clexane	S	Subcutaneous	0.6 Ml, Unk		Not Reported
	Clexane	S	Subcutaneous	1.2 Ml, Unk		Not Reported
	Clexane	S	Subcutaneous	0.6 Ml, Unk		Not Reported
	Ebixa	C	Oral	10 Mg, Unk		Not Reported
	Ebixa	C	Oral	15 Mg, Unk		Not Reported
	Ebixa	C	Oral	20 Mg, Unk		Not Reported
	Ebixa	C	Oral	15 Mg, Unk		Not Reported
	Ebixa	C	Oral	10 Mg, Unk		Not Reported
	Risperdal	C	Oral	1 Mg, Unk		Not Reported
	Risperdal	C	Oral	0.5 Mg, Unk		Not Reported
	Bisoprolol	C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2014	10204843	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2014144532		37 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mydriasis; Serotonin Syndrome; Somnolence; Suicide Attempt	Xanax			S	Oral	2 Mg, Single		Pfizer
	Lexomil Roche			S	Oral	180 Mg, Single		Not Reported
	Myolastan			S	Oral	600 Mg, Single		Not Reported
	Ixprim			S	Oral	Paracetamol 650 Mg/ Tramadol Hydrochloride 75 Mg, Single		Not Reported
	Seroplex			S	Oral	20 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2014	10225165	EXPEDITED (15-DAY)		HO	FR-FRI-1000068016		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Drug Interaction; Pneumonia Aspiration; Somnolence	Escitalopram			S	Oral	20 Mg		Forest
	Tranxene			S	Oral	Intake Of 40 Mg Once		Not Reported
	Deroxat			S	Oral	Intake Of 20 Mg Once		Not Reported
	Xanax			S		3 Df		Not Reported
	Zyprexa			S	Oral	Intake Of 7.5 Mg Once		Not Reported
	Tardyferon			C	Oral	1 Df		Not Reported
	Uvedose			C		100,000 Iu - 1 Ampoule / 3 Months		Not Reported
	Stilnox			C	Oral	0.5 Df		Not Reported
	Dafalgan			C	Oral	3 Df		Not Reported
	Movicol			C		2 Df		Not Reported
	Tanganil			C	Oral	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2014	10227182	EXPEDITED (15-DAY)		HO	ES-BAYER-2014-080798		87 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia	Adiro 100			S	Oral	100 Mg, Qd		Bayer
	Adiro 100			S				Bayer
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
	Orfidal			C	Oral			Not Reported
	Valdoxan			C	Oral	25 Mg, Qd		Not Reported
	Bicalutamide			C	Oral	50 Mg, Qd		Not Reported
	Eligard			C	Oral	45 Mg, Every 6 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2014	10227934	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2014SE39519		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Decreased Appetite; Diarrhoea; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Musculoskeletal Pain; Weight Decreased	Inexium		S	Oral	Astrazeneca
	Xarelto		S	Oral	Not Reported
	Lasilix		S	Oral	Not Reported
	Seroplex		S	Oral	Not Reported
	Befizal Sr		C	Oral	Not Reported
	Diffu K		C		Not Reported
	Sotalol		C	Oral	Not Reported
	Tardyferon		C	Oral	Not Reported
	Amlodipine		C	Oral	Not Reported
	Speciafoldine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2014	10228137	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20140603031		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Xarelto			S	Oral			Not Reported
	Lasilix			S	Unknown			Not Reported
	Seroplex			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Speciafoldine			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Tardyferon			C	Unknown			Not Reported
	Sotalol			C	Unknown			Not Reported
	Befizal			C	Unknown			Not Reported
	Diffu K			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2014	10228712	EXPEDITED (15-DAY)		HO	DE-009507513-1406DEU002103		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebellar Haemorrhage; Tachycardia	Mirtazapin Stada	S	Oral	30 Mg, Qd	Merck
	Mirtazapin Stada	S	Oral	15 Unk, Unk	Merck
	Cipralex	S	Oral	5 Mg, Qd	Not Reported
	Escitalopram	S	Oral	10 Mg, Qd	Not Reported
	Clexane (Enoxaparin Sodium)	S	Subcutaneous	1.2 Ml, Qd	Not Reported
	Clexane (Enoxaparin Sodium)	S	Subcutaneous	0.6 Ml, Qd	Not Reported
	Ebixa	C	Oral	10 Mg, Qd	Not Reported
	Ebixa	C	Oral	15 Mg, Qd	Not Reported
	Ebixa	C	Oral	20 Unk, Unk	Not Reported
	Ebixa	C	Oral	15 Unk, Unk	Not Reported
	Ebixa	C	Oral	10 Unk, Unk	Not Reported
	Risperdal	C	Oral	1 Mg, Qd	Not Reported
	Risperdal	C	Oral	0.5 Unk, Unk	Not Reported
	Bisoprolol	C	Oral	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2014	9395112	EXPEDITED (15-DAY)		OT	PHFR2013IE002986		71 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Cyanosis; Dizziness; Duodenal Ulcer; Electrocardiogram Qt Prolonged; Gout; Lower Respiratory Tract Infection; Parkinson'S Disease; Pneumonia	Clozaril			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Unk		Novartis
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Clarithromycin			S		Unk		Not Reported
	Donepezil Hydrochloride			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2014	10230375	EXPEDITED (15-DAY)		OT	JP-SA-2014SA076138			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Seizure	Myslee		S	Unknown	Not Reported
	Meilax		S	Oral	Not Reported
	Lexapro		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2014	10230946	EXPEDITED (15-DAY)		LT, OT	TR-FRI-1000068013		41 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Overdose; Somnolence; Speech Disorder; Suicide Attempt	Escitalopram			S	Oral			Forest
	Escitalopram			S		Overdose : Unknown Dose		Forest
	Sulpir			C				Not Reported
	Sulpir			C		Overdose : Unknown Dose		Not Reported
	Tegretol			C	Oral			Not Reported
	Tegretol			C		Overdose : Unknown Dose		Not Reported
	Irda			C				Not Reported
	Irda			C		Overdose : Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2014	10231327	EXPEDITED (15-DAY)		HO, LT	FR-ROCHE-1415029		49 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Vasoplegia Syndrome	Valium			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Simvastatine			S	Oral			Not Reported
	Coversyl			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10232548	NON-EXPEDITED			US-TEVA-456513USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Drug Hypersensitivity; Gait Disturbance; Hyperhidrosis; Musculoskeletal Stiffness; Palpitations	Escitalopram			S		10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10232549	NON-EXPEDITED			US-TEVA-474418USA		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Oral			Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10232550	NON-EXPEDITED			US-TEVA-466687USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Urticaria	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10232552	NON-EXPEDITED		OT	US-TEVA-458668USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Irritability; Suicidal Ideation; Therapeutic Response Changed; Tic	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10232555	NON-EXPEDITED			US-TEVA-467831USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Laryngitis	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Levothyroxine			C				Not Reported
	Zocor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10232557	NON-EXPEDITED			US-TEVA-476268USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10232558	NON-EXPEDITED			US-TEVA-468816USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Insomnia; Off Label Use	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10232563	NON-EXPEDITED			US-TEVA-476327USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10232564	NON-EXPEDITED			US-TEVA-481609USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10232565	NON-EXPEDITED			US-TEVA-479190USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Therapeutic Product Ineffective	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10233766	EXPEDITED (15-DAY)		OT	US-ACTAVIS-2014-12235		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Fluctuation; Urinary Retention	Escitalopram (Unknown)			S	Unknown	5 Mg, Daily		Not Reported
	Warfarin (Unknown)			S	Unknown	4 Mg, Daily		Not Reported
	Omeprazole (Watson Laboratories)			S	Unknown	20 Mg, Daily		Watson
	Furosemide			C	Unknown	40 Mg, Daily		Not Reported
	Metoprolol Tartrate			C	Unknown	50 Mg, Bid		Not Reported
	Amiodarone			C	Unknown	200 Mg, Daily		Not Reported
	Albuterol W/Ipratropium			C	Respiratory (inhalation)	3 Ml; Inhale Contents Of 1 Vial Every 2 Hours, As Needed (2.5 Mg/0.5 Mg)		Not Reported
	Docusate W/Senna			C	Oral	5/8.6 Mg Two Tablets Once A Day		Not Reported
	Humalog			C	Unknown	100 Units/Ml		Not Reported
	Nystop			C	Topical	100000 Units/G; Twice Daily To Bilateral Groin		Not Reported
	Acetaminophen			C	Unknown	650 Mg As Needed		Not Reported
	Bisacodyl			C	Unknown	Suppositories 10 Mg, Daily, As Needed		Not Reported
	Guaifenesin			C	Unknown	600 Mg, Bid		Not Reported
	Triamcinolone			C	Topical	0.1% Twice Daily		Not Reported

	Fluticasone Propionate	C	Unknown	220 Mg, Bid	Not Reported
	Ondansetron	C	Unknown	4 Mg, Q6h, As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2014	10233827	EXPEDITED (15-DAY)		HO	IT-BAYER-2014-083928		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Abuse; Psychomotor Hyperactivity	Aspirina			S	Oral	3 Df, Once		Bayer
	Xanax			S	Oral	20 Ml, Once		Not Reported
	Entact			S	Oral	15 Ml, Once		Not Reported
	Anafranil			S	Oral	3 Df, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2014	10179343	EXPEDITED (15-DAY)		OT	SE-FRI-1000067410		71 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arrhythmia; Breast Pain; Burning Sensation; Decreased Appetite; Derealisation; Eye Pain; Face Oedema; Heart Rate Increased; Lip Swelling; Localised Oedema; Muscle Spasms; Muscle Twitching; Nasal Congestion; Pain In Extremity; Paraesthesia; Pyrexia; Seizure; Sleep Disorder; Tinnitus; Vision Blurred; Weight Decreased; Withdrawal Syndrome	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram Oral Solution			S	Oral	1.5 Gtt		Forest
	Oxascand			C				Not Reported
	Imovane			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2014	10235075	NON-EXPEDITED			US-009507513-1406USA003372		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mirtazapine			S				Merck
	Diazepam			S				Not Reported
	Fluoxetine			S				Not Reported
	Phenelzine Sulfate			S				Not Reported
	Bupropion Hydrochloride			S				Not Reported
	Olanzapine			S				Not Reported
	Escitalopram			S				Not Reported
	Quetiapine Fumarate			S				Not Reported
	Selegiline			S				Not Reported
	Sertraline Hydrochloride			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Clonazepam			S				Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2014	10235617	EXPEDITED (15-DAY)		HO	TW-FRI-1000068132		24 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Prescribed Overdose; Sedation; Vision Blurred	Escitalopram			S		Overdose : 40 Mg		Forest
	Citalopram			S		Overdose: 60 Mg		Forest
	Aripiprazole			S		20 Mg		Not Reported
	Aripiprazole			S		30 Mg		Not Reported
	Sertraline			C		150 Mg		Not Reported
	Venlafaxine			C		225 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2014	10236972	EXPEDITED (15-DAY)		HO	DE-TEVA-486290GER		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebellar Haemorrhage; Tachycardia	Mirtazapin	S	Oral	30 Milligram Daily;	Teva
	Mirtazapin	S	Oral	15 Milligram Daily;	Teva
	Cipralex	S	Oral	5 Milligram Daily; 5 Mg	Not Reported
	Cipralex	S	Oral	10 Milligram Daily;	Not Reported
	Clexane	S	Subcutaneous	.6 Ml Daily;	Not Reported
	Clexane	S	Subcutaneous	1.2 Ml Daily;	Not Reported
	Clexane	S	Subcutaneous	.6 Ml Daily;	Not Reported
	Ebixa	C	Oral	10 Milligram Daily;	Not Reported
	Ebixa	C	Oral	15 Milligram Daily;	Not Reported
	Ebixa	C	Oral	20 Milligram Daily;	Not Reported
	Ebixa	C	Oral	15 Milligram Daily;	Not Reported
	Ebixa	C	Oral	10 Milligram Daily;	Not Reported
	Risperdal	C	Oral	1 Milligram Daily;	Not Reported
	Risperdal	C	Oral	.5 Milligram Daily;	Not Reported
	Bisoprolol	C	Oral	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2014	10238051	EXPEDITED (15-DAY)		HO	DE-ELI_LILLY_AND_COMPANY-DE201406001170		48 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Bladder Disorder; Constipation; Gastrointestinal Sounds Abnormal; Leukocytosis; Pain; Paruresis; Urinary Hesitation; Urinary Incontinence; Urinary Retention	Zyprexa			S	Oral	5 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Oral	7.5 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Oral	10 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Oral	12.5 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Oral	7.5 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Oral	5 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Oral	2.5 Mg, Qd		Eli Lilly And Co
	Tavor (Lorazepam)			S	Oral	1.5 Mg, Qd		Not Reported
	Tavor (Lorazepam)			S	Oral	1 Mg, Qd		Not Reported

Tavor (Lorazepam)	S	Oral	0.5 Mg, Qd		Not Reported
Tavor (Lorazepam)	S	Oral	0.25 Mg, Qd		Not Reported
Cipralex	S	Oral	5 Mg, Qd		Not Reported
Cipralex	S	Oral	10 Mg, Qd		Not Reported
Cipralex	S	Oral	15 Mg, Qd		Not Reported
Cipralex	S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2014	10238631	EXPEDITED (15-DAY)		HO	CA-FRI-1000068059		88 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Interaction; Dyspnoea; Fall; Nightmare	Memantine			S	Oral	10 Mg		Forest
	Memantine			S				Forest
	Escitalopram			S	Oral			Forest
	Dextromethorphan			S				Not Reported
	Vitamin B 12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2014	10239507	EXPEDITED (15-DAY)		DS, HO, OT	US-009507513-2010SP040550			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amblyopia; Blood Bicarbonate Decreased; Carotid Artery Thrombosis; Cerebral Haemorrhage; Depression; Dysmenorrhoea; Haemorrhagic Stroke; Hepatic Enzyme Increased; Insomnia; Intracranial Venous Sinus Thrombosis; Jaw Disorder; Jugular Vein Thrombosis; Libido Decreased;	Nuvaring			S	Vaginal	Every 3 Weeks		Merck
	Lexapro			S		Unk		Not Reported
	Dilantin			S				Not Reported
	Advil			C		400 Mg, Tid		Not Reported
	Hemp			C				Not Reported

Nausea; Parosmia; Post-Traumatic Stress Disorder; Premenstrual Syndrome; Seizure; Sinus Congestion; Transient Ischaemic Attack; Urticaria

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2014	10243822	EXPEDITED (15-DAY)	Y	OT	SYM-2014-21907		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Zolpidem Tartrate (Zolpidem Tartrate)			S				Not Reported
	Metronidazole (Metronidazole)			S				Not Reported
	Tramadol Hydrochloride (Tramadol Hydrochloride)			S				Not Reported
	Ceftriaxone (Ceftriaxone)			S				Not Reported
	Escitalopram Oxalate (Escitalopram Oxalate)			S				Not Reported
	Vicodin (Paracetamol, Hydrocodone Bitartrate)			C				Not Reported
	Oxygen (Oxygen)			C				Not Reported
	Hydromorphone (Hydromorphone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2014	10241297	NON-EXPEDITED			US-PFIZER INC-2014162099		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting	Aromasin			S	Oral	25 Mg, 1x/Day		Pfizer
	Lexapro			S	Oral	20 Mg, 1x/Day		Not Reported
	Compazine			C	Oral	5 Mg, Every 6 Hours As Needed		Not Reported
	Cardura			C	Oral	2 Mg, 1x/Day		Not Reported
	Advair			C		Fluticasone 500mcg, Salmeterol 50mcg, 1 Puffs		Not Reported

			Every 12 Hours	
Combivent	C	Respiratory (inhalation)	Ipratropium 18mcg, Albuterol 103mcg, 2 Puffs Every 6 Hours As Needed	Not Reported
Combivent	C	Respiratory (inhalation)	Ipratropium 20mcg, Albuterol 100mcg, 1 Puffs Every 6 Hours	Not Reported
Glucophage	C	Oral	500 Mg, 2x/Day	Not Reported
Singulair	C	Oral	10 Mg, 1x/Day	Not Reported
K-Dur	C	Oral	20 Meq, 1x/Day	Not Reported
Klor-Con	C	Oral	20 Meq, 1x/Day	Not Reported
Demadex	C	Oral	40 Mg, Daily	Not Reported
Diovan Hct	C	Oral	320mg, 12.5mg, 1df Once Daily	Not Reported
Calan-Sr	C	Oral	240 Mg, 2x/Day	Not Reported
Diclofenac Sodium	C	Oral	100 Mg, Daily	Not Reported
Catapres	C	Oral	0.3 Mg, 2x/Day	Not Reported
Catapres	C	Oral	0.3 Mg, Prn	Not Reported
Duoneb	C		Ipratropium 0.5mg, Salbutamol 3 Mg, Every 6 Hours As Needed	Not Reported
Theodur	C	Oral	200 Mg, 2x/Day	Not Reported
Hydrocortisone	C		2.5 %, 1x/Day	Not Reported
Penlac	C		8 %, Daily	Not Reported
Acetaminophen\Hydrocodone Bitartrate	C	Oral	Hydrocodone 5mg, Acetaminophen 300mg, 6 Hours As Needed	Not Reported
Proventil	C	Respiratory (inhalation)	90 Ug, 2 Puffs Every 6 Hours As Needed	Not Reported
Ventolin	C	Respiratory (inhalation)	90 Ug, 2 Puffs Every 6 Hours As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2014	10241582	EXPEDITED (15-DAY)		CA	CH-SA-2014SA078925			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Foot Malformation; Congenital Hand Malformation; Exposure During Pregnancy; Premature Baby; Syndactyly	Stilnox Cr			S	Transplacental			Not Reported
	Fluoxetine Hydrochloride			S	Transplacental			Not Reported
	Valdoxan			S	Transplacental			Not Reported
	Cipralex			S	Transplacental			Not Reported
	Cipralex			S	Transplacental			Not Reported
	Dalmadorm			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2014	10241683	EXPEDITED (15-DAY)		HO	DE-SA-2014SA074039		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haemorrhage; Cold Sweat; Disorientation; Restlessness; Tachycardia	Clexane			S	Subcutaneous			Not Reported
	Clexane			S	Subcutaneous			Not Reported
	Clexane			S	Subcutaneous			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Ebixa			C	Oral			Not Reported
	Ebixa			C	Oral			Not Reported
	Ebixa			C	Oral			Not Reported
	Ebixa			C	Oral			Not Reported
	Ebixa			C	Oral			Not Reported
	Risperidone			C	Oral			Not Reported
	Risperidone			C	Oral			Not Reported

	Bisoprolol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2014	10242186	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20140603034		88 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia	Haldol			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Physiotens			C	Unknown			Not Reported
	Aprovel			C	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2014	10242560	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2014S1013356		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haemorrhage; Tachycardia	Mirtazapin			S	Oral	30 Mg		Mylan
	Mirtazapin			S	Oral	15 Mg		Mylan
	Cipralex			S	Oral	5 Mg		Not Reported
	Cipralex			S	Oral	10 Mg		Not Reported
	Clexane			S	Subcutaneous	0.6 Ml		Not Reported
	Clexane			S	Subcutaneous	1.2 Ml		Not Reported
	Clexane			S	Subcutaneous	0.6 Ml		Not Reported
	Ebixa			C	Oral	10 Mg		Not Reported
	Ebixa			C	Oral	15 Mg		Not Reported
	Ebixa			C	Oral	20 Mg		Not Reported
	Ebixa			C	Oral	15 Mg		Not Reported

	Ebixa	C	Oral	10 Mg		Not Reported
	Risperdal	C	Oral	1 Mg		Not Reported
	Risperdal	C	Oral	0.5 Mg		Not Reported
	Bisoprolol	C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2014	10242706	EXPEDITED (15-DAY)		HO	US-ABBVIE-14P-163-1245250-00		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Dementia; Depression; Device Issue; Encephalopathy; Gait Inability; Headache; Loss Of Personal Independence In Daily Activities; Pseudodementia; Toxicity To Various Agents; Vomiting	Humira			S				Not Reported
	Topamax			S				Not Reported
	Lexapro			S				Not Reported
	Tramadol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2014	10246024	DIRECT		HO, LT			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Agitation; Anxiety; Depression; Overdose; Somnolence; Speech Disorder; Speech Disorder; Suicidal Ideation	Lexapro 5 Mg. Escitalopram Oxalate Q23624 Tablet Tev			S	Oral			Teva
	Heart Meds			C				Not Reported
	Aacex			C				Not Reported
	Potassium			C				Not Reported
	Vit D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2014	10246257	DIRECT		HO			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased;	Lexapro			S				Not Reported

Feeling Abnormal; Loss Of Consciousness; Pallor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2014	10214985	EXPEDITED (15-DAY)		HO	DE-FRI-1000067783			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Leukocytosis; Urinary Incontinence; Urinary Retention	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Escitalopram			S	Oral	15 Mg		Not Reported
	Escitalopram			S	Oral	20 Mg		Not Reported
	Zyprexa			S	Oral	5 Mg		Not Reported
	Zyprexa			S	Oral	7.5 Mg		Not Reported
	Zyprexa			S	Oral	10 Mg		Not Reported
	Zyprexa			S	Oral	12.5 Mg		Not Reported
	Zyprexa			S	Oral	7.5 Mg		Not Reported
	Zyprexa			S	Oral	5 Mg		Not Reported
	Zyprexa			S	Oral	2.5 Mg		Not Reported
	Tavor (Lorazepam)			S	Oral	1.5 Mg		Not Reported
	Tavor (Lorazepam)			S	Oral	1 Mg		Not Reported
	Tavor (Lorazepam)			S	Oral	0.5 Mg		Not Reported
	Tavor (Lorazepam)			S	Oral	0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2014	10219904	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2014151308		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Drug Interaction; Pneumonia Aspiration; Somnolence	Xanax			S	Oral	1 Df, 3x/Day		Pfizer
	Tranxene			S	Oral	40 Mg, Single		Not Reported
	Deroxat			S	Oral	20 Mg, Single		Not Reported

	Seroplex	S	Oral	20 Mg, 1x/Day In The Evening	Not Reported
	Zyprexa	S	Oral	7.5 Mg, Single	Not Reported
	Tareg	C		1 Df, Unk	Not Reported
	Kaleorid	C		1 Df, Unk	Not Reported
	Imurel	C		1 Df, Unk	Not Reported
	Chondrosulf	C		1 Df, Unk	Not Reported
	Tardyferon	C		1 Df, 1x/Day In The Morning	Not Reported
	Uvedose	C		100000 Iu, Every 3 Months	Not Reported
	Stilnox	C		0.5 Df, 1x/Day At Bedtime	Not Reported
	Dafalgan	C		1 Tablet In The Morning, At Noon And In The Evening	Not Reported
	Movicol	C		2 Df, 1x/Day In The Morning	Not Reported
	Tanganil	C		1 Tablet In The Morning And At Noon	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2014	10221033	EXPEDITED (15-DAY)		HO, LT	CA-PFIZER INC-2008062560		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Calcium Decreased; Blood Pressure Systolic Decreased; Bradycardia; Drug Interaction; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Hyperkalaemia; International Normalised Ratio Increased; Loss Of Consciousness; Nodal	Morphine Sulfate			S	Oral	30 Mg, Daily		Pfizer
	Morphine Sulfate			S		100 Mg, Unk		Pfizer
	Morphine Sulfate			S		15 Mg, Unk		Pfizer
	Lorazepam			S	Oral	1 Mg, Unk		Pfizer
	Zopiclone			S	Oral	15 Mg, Daily		Not Reported
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Diazepam			S	Oral	10 Mg, Unk		Not Reported
	Oxycodone			S	Oral			Not Reported

Rhythm; Overdose; Sinus Tachycardia	Oxycodone		S	Oral	20 Mg, Unk	Not Reported
	Oxycodone Extended Release		S	Oral	10 Mg, Unk	Not Reported
	Citalopram		S	Oral	Unk Mg, Unk	Not Reported
	Acetaminophen/Oxycodone		S	Oral	Acetaminophen 325mg, Oxycodone 5mg	Not Reported
	Altace		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2014	10221720	NON-EXPEDITED		HO	FR-JNJFOC-20140518574		37 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mydriasis; Somnolence; Toxicity To Various Agents	Ixprim			S	Oral			Not Reported
	Lexomil			S	Oral	180 Mg		Not Reported
	Myolastam			S	Oral	12 Tablets		Not Reported
	Xanax			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2014	10243763	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000068206		49 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Overdose; Vasoplegia Syndrome	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose Of 630 Mg Once		Not Reported
	Simvastatine			S	Oral			Not Reported
	Simvastatine			S	Oral	Overdose Of 400 Mg Once		Not Reported
	Zopiclone			S	Oral			Not Reported
	Zopiclone			S	Oral	Overdose Of 210 Mg Once		Not Reported
	Valium			S	Oral			Not Reported
	Valium			S	Oral	Overdose Between 40 To 200 Mg Once		Not Reported

	Coversyl	S	Oral			Not Reported
	Coversyl	S	Oral	Overdose Of 550 Mg Once		Not Reported
	Zolpidem	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2014	10243817	EXPEDITED (15-DAY)		OT	CA-FRI-1000068203		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Road Traffic Accident	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2014	10243828	EXPEDITED (15-DAY)		OT	CN-FRI-1000068204		28 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Mental Impairment; Poverty Of Thought Content	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2014	10248810	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Lexapro 20mg - Generic			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2014	10249031	EXPEDITED (15-DAY)	Y	OT	SYM-2014-22090		53 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain;	Voxra			S				Not Reported
Electrocardiogram T Wave	Duloxetine (Duloxetine)			S				Not Reported

Inversion; Headache; Sinus Bradycardia	(Duloxetine)		
	Escitalopram (Escitalopram)	S	Not Reported
	Micardis (Telmisartan)	C	Not Reported
	Thyroxin (Levothyroxine Sodium)	C	Not Reported
	Diformin (Metformin Hydrochloride)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2014	10247511	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2014165632		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disturbance In Attention; Eschar; Extensor Plantar Response; Extrapyramidal Disorder; Lung Infection; Mydriasis; Overdose; Renal Failure; Somnolence	Lyrica			S	Oral	1 Df, 2x/Day		Pfizer
	Contramal			S	Oral	1.5 Df, 2x/Day		Not Reported
	Laroxyl			S	Oral	6 Gtt, 3x/Day		Not Reported
	Seresta			S	Oral	1.5 Df, 1x/Day		Not Reported
	Stilnox			S	Oral	1.5 Df, 1x/Day		Not Reported
	Seroplex			S	Oral	1.5 Df, 1x/Day		Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C				Not Reported
	Doliprane			C				Not Reported
	Kardegic			C				Not Reported
	Modopar			C				Not Reported
	Olmetec			C				Not Reported
	Ostram			C				Not Reported
	Xagrid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2014	10247678	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2014166450		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Coma; Hypotension; Hypoxia; Intentional Overdose	Amlor	S	Oral	30 Mg, Unk		Pfizer
	Metformin Hcl	S	Oral	5 G, Unk		Pfizer
	Seroplex	S	Oral	40 Mg, Unk		Not Reported
	Temesta (Lorazepam)	S		35 Mg, Unk		Not Reported
	Bromazepam	S	Oral	Unk		Not Reported
	Tercian	C				Not Reported
	Micardis	C				Not Reported
	Bisoprolol	C		40 Mg, Unk		Not Reported
	Tahor	C		20 Mg, Unk		Not Reported
	Novonorm	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2014	10248977	DIRECT		DS, HO, LT, RI			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Autoimmune Hepatitis; Back Pain; Chromaturia; Contusion; Dyspepsia; Jaundice; Nausea; Pruritus	Cymbalta			S	Oral	40 Mg, Once Daily, Taken By Mouth		Not Reported
	Lexapro			S	Oral	10, Once Daily, Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2014	10252380	EXPEDITED (15-DAY)	Y	HO, LT, OT	2014000183		49 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bradycardia; Coma; Intentional Overdose; Vasoplegia Syndrome	Aceon			S	Oral Oral			Not Reported
	Seroplex			S	Oral Oral			Not Reported
	Simvastatin(Simvastatin)			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported

	Zopiclone	S	Oral		Not Reported
	Zolpidem	S	Oral Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2014	10248883	EXPEDITED (15-DAY)		CA	US-JNJFOC-20140612358			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cleft Lip; Cleft Lip And Palate; Foetal Exposure During Pregnancy; Ventricular Septal Defect	Topamax			S	Oral	Mother'S Dosing		Not Reported
	Phenobarbital			S	Transplacental	Mother'S Dosing		Not Reported
	Mysoline			S	Transplacental	Mother'S Dosing		Not Reported
	Lexapro			S	Transplacental	Mother'S Dosing		Not Reported
	Multivitamins			C	Transplacental	Mother'S Dosing		Not Reported
	Folic Acid			C	Transplacental	Mother'S Dosing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2014	10248890	EXPEDITED (15-DAY)		CA, OT	US-JNJFOC-20140611821			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Foetal Exposure During Pregnancy; Otitis Media Chronic	Topamax			S	Transplacental			Not Reported
	Lamictal			S	Transplacental			Not Reported
	Lexapro			S	Transplacental			Not Reported
	Prenatal Vitamins			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2014	10249510	EXPEDITED (15-DAY)		HO	FR-DSJP-DSE-2014-111942			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyponatraemia; Malaise	Coolmetec			S	Oral	1 Df, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported

	Lexomil	S	Oral	3 Mg, Qd		Not Reported
	Cordarone	C				Not Reported
	Coumadine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2014	10249808	EXPEDITED (15-DAY)		HO	DE-WATSON-2014-12956		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haemorrhage; Tachycardia	Mirtazapine (Unknown)			S	Oral	30 Mg, Daily		Watson
	Mirtazapine (Unknown)			S	Oral	15 Mg, Daily		Watson
	Cipralex /01588501/			S	Oral	5 Mg, Daily		Not Reported
	Cipralex /01588501/			S	Oral	10 Mg, Daily		Not Reported
	Clexane			S	Subcutaneous	0.6 Ml, Daily		Not Reported
	Clexane			S	Subcutaneous	1.2 Ml, Daily		Not Reported
	Clexane			S	Subcutaneous	0.6 Ml, Daily		Not Reported
	Ebixa			C	Oral	10 Mg, Daily		Not Reported
	Ebixa			C	Oral	15 Mg, Daily		Not Reported
	Ebixa			C	Oral	20 Mg, Daily		Not Reported
	Ebixa			C	Oral	15 Mg, Daily		Not Reported
	Ebixa			C	Oral	10 Mg, Daily		Not Reported
	Risperdal			C	Oral	1 Mg, Daily		Not Reported
	Risperdal			C	Oral	0.5 Mg, Daily		Not Reported
	Bisoprolol			C	Oral	5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2014	10250670	EXPEDITED (15-DAY)		HO, LT, OT	CH-GLAXOSMITHKLINE-B1005735A		31 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Depressed Level Of Consciousness; Drug	Ondansetron			S	Intravenous (not otherwise specified)			Glaxosmithkline

Interaction; Electrocardiogram Qt Prolonged; Electrocardiogram Repolarisation Abnormality; Generalised Tonic-Clonic Seizure; Hypokalaemia; Hypomagnesaemia; Loss Of Consciousness; Torsade De Pointes; Ventricular Hypokinesia; Ventricular Tachycardia	Methadone	S	Oral		Glaxosmithkline
	Escitalopram	S	Unknown		Glaxosmithkline
	Esomeprazole	C	Unknown		Glaxosmithkline
	Scopolamine Butylbromide	C	Unknown		Not Reported
	Dipyrone	C	Unknown		Glaxosmithkline
	Paracetamol (Acetaminophen)	C	Unknown		Glaxosmithkline
	Pethidine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2014	10252671	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Product Substitution Issue	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2014	10249224	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2014163529		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cheilitis; Cholestasis; Dyshidrotic Eczema; Eosinophilia; Erythema Multiforme; Face Oedema; Lichen Sclerosus; Vulval Oedema; Vulvovaginal Erythema	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Seroplex			S	Oral	5 Mg, 1x/Day		Not Reported
	Effexor Lp			C		Unk		Not Reported
	Bromazepam			C				Not Reported
	Singulair			C		Unk		Not Reported
	Telfast			C		Unk		Not Reported
	Esomeprazole			C		Unk		Not Reported
	Rinoclenil			C		Unk		Not Reported
	Colchicine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2014	10253627	EXPEDITED (15-DAY)		HO	PHHY2014FR076700		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Esidrex			S	Oral	12.5 Mg, Qd		Not Reported
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Seresta			C	Oral	10 Mg, Tid If Necessary		Not Reported
	Coumadine			C	Oral	4 Mg, Qd		Not Reported
	Doliprane			C		1000 Mg, Tid If Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2014	10257311	DIRECT		DS			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Chest Pain	Escitalopram			S	Oral			Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2014	10234204	NON-EXPEDITED		HO	US-FRI-1000068061		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Seizure; Tremor	Namenda Xr			S	Oral	28 Mg		Forest
	Namenda Xr			S				Forest
	Namenda Xr			S				Forest
	Namenda			S	Oral	5 Mg		Forest
	Namenda			S	Oral	10 Mg		Forest
	Namenda			S	Oral	10 Mg Am, 5 Mg Pm		Forest
	Namenda			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Not Reported
	Escitalopram			S				Not Reported
	Vimpat			S		50 Mg		Not Reported

	Vimpat	S	100 Mg	Not Reported
	Vimpat	S	50 Mg	Not Reported
	Vimpat	S	200 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2014	10256149	NON-EXPEDITED		LT, OT	US-ZOGENIX, INC.-2012ZX000043		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Interaction; Dyspnoea; Feeling Abnormal; Nausea; Oral Discomfort; Pruritus Generalised; Seizure; Throat Tightness; Tremor	Sumavel Dosepro			S				Zogenix
	Lexapro			S	Oral			Not Reported
	Zonegran			C	Oral			Not Reported
	Neurontin			C	Oral			Not Reported
	Neurontin			C				Not Reported
	Restoril			C				Not Reported
	Pepcid			C				Not Reported
	Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2014	10256639	EXPEDITED (15-DAY)		HO	FR-009507513-1406FRA010219		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Pyrexia; Rash Erythematous; Rash Maculo-Papular	Aerius (Desloratadine)			S	Oral	5 Mg, Qd		Merck
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Fucidine (Fusidate Sodium)			S	Oral	Unk		Not Reported
	Inexium (Esomeprazole Magnesium)			C	Oral	20 Mg, Qd		Not Reported
	Inexium (Esomeprazole Magnesium)			C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2014	10262149	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Product Substitution Issue; Therapeutic Response Changed	Escitalopram Oxalate		S	Oral	Not Reported
	Ibuprofen		S		Not Reported
	Cimetidine		S		Not Reported
	Pravastatin		S		Not Reported
	Lexapro		S		Not Reported
	Proair Hfa		S		Not Reported
	Trazodone		S		Not Reported
	Abilify		S		Not Reported
	Metformin		S		Not Reported
	Lisinopril		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2014	10264794	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Drug Ineffective; Product Substitution Issue; Unevaluable Event	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2014	10266439	DIRECT					38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Product Substitution Issue	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2014	10261537	EXPEDITED (15-DAY)		HO	FR-FRI-1000068478		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cheilitis; Dyshidrotic Eczema; Eosinophilia; Erythema Multiforme; Face Oedema; Vulval Oedema; Vulvovaginal Erythema	Escitalopram			S	Oral	5 Mg		Forest
	Lyrica			S	Oral	300 Mg		Not Reported
	Effexor			C				Not Reported
	Bromazepam			C				Not Reported
	Singulair			C				Not Reported

	Telfast	C	Not Reported
	Esomeprazole	C	Not Reported
	Rinoclenil	C	Not Reported
	Colchicine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2014	10261606	EXPEDITED (15-DAY)		HO	FR-FRI-1000068479		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disturbance In Attention; Off Label Use; Somnolence	Escitalopram			S	Oral	1.5 Df		Forest
	Contramal			S	Oral	3 Df		Not Reported
	Laroxyl			S	Oral	18 Gtt		Not Reported
	Lyrica			S	Oral	2 Df		Not Reported
	Seresta			S	Oral	1.5 Df		Not Reported
	Stilnox			S	Oral	1.5 Df		Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C				Not Reported
	Doliprane			C				Not Reported
	Kardegic			C				Not Reported
	Modopar			C				Not Reported
	Modopar Lp			C				Not Reported
	Olmetec			C				Not Reported
	Ostram			C				Not Reported
	Xagrid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2014	10261607	EXPEDITED (15-DAY)		DS, HO	FR-FRI-1000068481		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke	Escitalopram			S	Oral	10 Mg		Forest
	Lercan			C		10 Mg		Not Reported

Indapamide	C	1.5 Mg	Not Reported
Coversyl	C	10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2014	10261723	EXPEDITED (15-DAY)		HO	FR-FRI-1000068490		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram			S	Oral			Forest
	Paracetamol			S	Oral	3 Grams		Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			C				Not Reported
	Alprazolam			C				Not Reported
	Fentanyl			C				Not Reported
	Seretide			C				Not Reported
	Spiriva			C				Not Reported
	Lidocaine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2014	10263276	EXPEDITED (15-DAY)		HO	FR-FRI-1000068485		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension; Hypoxia; Intentional Overdose	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose Of 40 Mg Once		Not Reported
	Metformin			S	Oral			Not Reported
	Metformin			S	Oral	Overdose Of 5 G Once		Not Reported
	Amlor			S	Oral			Not Reported
	Amlor			S	Oral	Overdose Of 30 Mg Once		Not Reported
	Temesta (Lorazepam)			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Oral	Overdose Of 35 Mg Once		Not Reported
	Bromazepam			S	Oral			Not Reported
	Tercian			C				Not Reported
	Novonorm			C				Not Reported
	Micardis			C				Not Reported

Bisoprolol	C	Oral			Not Reported
Bisoprolol	C	Oral	Overdose Of 40 Mg Once		Not Reported
Tahor	C	Oral			Not Reported
Tahor	C	Oral	Overdose Of 20 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2014	10263369	EXPEDITED (15-DAY)		DE	FR-FRI-1000068498		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Congenital Diaphragmatic Hernia; Exposure During Pregnancy	Escitalopram			S	Transplacental	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2014	10272678	DIRECT	Y	HO			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Defaecation Urgency; Diarrhoea; Dizziness; Dry Mouth; Fall; Loss Of Consciousness; Nausea; Vomiting	Escitalopram			S	Oral	1, Qd, Oral		Mylan
	Metoprolol Tart			C				Not Reported
	Potassium Cl			C				Not Reported
	Lisinopril/Hctz			C				Not Reported
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2014	10238649	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMPANY-FR201406001243		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Hypertension; Pneumonia Aspiration; Sepsis; Somnolence;	Zyprexa			S	Oral	7.5 Mg, Single		Eli Lilly And Co
	Tranxene			S	Oral	40 Mg, Single		Not Reported

Urticaria; Wrong Patient Received Product	Deroxat	S	Oral	20 Mg, Single	Not Reported
	Seroplex	S	Oral	20 Mg, Qd	Not Reported
	Xanax	S	Oral	0.25 Mg, Tid	Not Reported
	Tardyferon	C		1 Df, Each Morning	Not Reported
	Uvedose	C	Unknown	100000 Iu, Every 3 Months	Not Reported
	Stilnox	C	Unknown	0.5 Df, Each Evening	Not Reported
	Dafalgan	C	Unknown	1 Df, Tid	Not Reported
	Movicol	C	Unknown	2 Df, Each Morning	Not Reported
	Tanganil	C		1 Df, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2014	10261990	EXPEDITED (15-DAY)		OT	LT-TEVA-489827ISR		32 YR	Unknown	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram Teva Ritecol May Have -301-267-2955			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2014	10267582	NON-EXPEDITED			US-PFIZER INC-2014179435			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Lyrica			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Savella			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2014	10268233	EXPEDITED (15-DAY)		DE	CH-BAYER-2014-094891		75 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebral Haematoma	Aspirin Cardio	S	Oral	100 Mg, Qd	Bayer
	Cipralex	S		5 Mg, Qd	Not Reported
	Catapresan	C	Oral	1 +0.5 Tablet In The Morning	Not Reported
	Beloc [Metoprolol]	C		50 Mg, Qd	Not Reported
	Triatec (Ramipril)	C		5 Mg, Qd	Not Reported
	Adalat	C	Oral	60 Mg, Qd	Not Reported
	Calcium Acetate	C	Oral	750 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2014	10268498	EXPEDITED (15-DAY)		HO	MY-FRI-1000068561		79 YR	Male	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Foaming At Mouth; Syncope	Lexapro			S	Oral			Forest
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2014	10273177	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Product Substitution Issue	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2014	10273693	EXPEDITED (15-DAY)	Y	HO	AUR-APL-2014-06748		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension; Hypoxia; Intentional Overdose	Metformin (Metformin) Unknown, Unknown			S	Oral	5 G, Total, Oral		Not Reported
	Amlor (Amlodipine Besilate)			S	Oral			Not Reported
	Seroplex (Escitalopram Oxalate)			S				Not Reported
	Temesta /00273201/			S				Not Reported

	Bromazepam (Bromazepam)	S	Oral	Not Reported
	Tercian /00759301/ (Cyamemazine)	C		Not Reported
	Micardis (Telmisartan)	C		Not Reported
	Bisoprolol (Bisoprolol)	C		Not Reported
	Tahor (Atorvastatin Calcium)	C		Not Reported
	Novonorm (Repaglinide)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2014	10271246	EXPEDITED (15-DAY)		OT	SE-FRI-1000068558		57 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Substitution Issue; Sleep Disorder	Escitalopram			S				Forest
	Escitalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2014	10271593	EXPEDITED (15-DAY)		CA	US-FRI-1000068508		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Talipes	Celexa			S	Transplacental			Forest
	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	9459793	EXPEDITED (15-DAY)		HO, LT	BE-ASTRAZENECA-2013SE62963		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Labelled Drug-Drug Interaction Medication Error; Long Qt Syndrome; Loss Of Consciousness; Torsade De Pointes; Vomiting	Omeprazole			S				Not Reported
	Escitalopram			S				Not Reported
	Tacrolimus			S				Not Reported
	Sotalol			S				Not Reported
	Bisoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10151098	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000066975		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Fall; Torsade De Pointes; Ventricular Fibrillation	Escitalopram			S	Oral	10 Mg		Forest
	Xanax			S	Oral	0.5 Mg		Not Reported
	Plavix			C				Not Reported
	Stagid			C				Not Reported
	Pritor (Telmisartan)			C				Not Reported
	Aricept			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10235311	NON-EXPEDITED			US-PFIZER INC-2014162043		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10272288	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002001			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Escitalopram Tablets Usp 10mg			S				Lupin
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10272616	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2014-00996		28 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Appetite	Stalopam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10272624	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00001879			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10272631	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002068			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Escitalopram Tablets Usp 20mg			S				Lupin
	Klonopin			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10272938	EXPEDITED (15-DAY)		HO	FR-FRI-1000068555		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Melaena	Escitalopram			S	Oral	5 Mg		Forest
	Arixtra			S	Subcutaneous	2.5 Mg / 0.5 Ml		Not Reported
	Plavix			S	Oral	1 Df		Not Reported
	Triatec (Ramipril)			C	Oral	2.5 Mg		Not Reported
	Seresta			C	Oral			Not Reported
	Risperdal			C	Oral	1 Mg		Not Reported
	Dafalgan			C				Not Reported
	Uvedose			C	Oral			Not Reported
	Durogesic			C	Transdermal	0.3333 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10272964	EXPEDITED (15-DAY)		DE	FR-FRI-1000068557		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Subdural Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Xarelto			S	Oral	15 Mg		Not Reported
	Xarelto			S				Not Reported
	Doliprane			C				Not Reported
	Fixical			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10273196	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2014S1014748		77 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuralgia	Escitalopram			S	Oral			Mylan
	Indapamide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10274089	EXPEDITED (15-DAY)		CA	DE-FRI-1000068656		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Atresia; Atrial Septal Defect; Ectopic Kidney; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Prescribed Overdose; Ventricular Septal Defect; Vitello-Intestinal Duct Remnant	Escitalopram			S	Transplacental	40 Mg		Forest
	Escitalopram			S	Transplacental	10 Mg		Not Reported
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10274090	EXPEDITED (15-DAY)		OT	DE-FRI-1000068655		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Foetal Distress Syndrome; Prescribed Overdose	Escitalopram			S	Oral	40 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Femibion [Minerals Nos;Vitamins Nos]			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10274418	EXPEDITED (15-DAY)		HO	FR-FRI-1000068626		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Pyrexia; Rash Erythematous; Rash Maculo-Papular	Escitalopram			S	Oral	10 Mg		Forest
	Fucidine (Fusidic Acid)			S	Oral			Not Reported
	Aerius (Desloratadine)			S	Oral	5 Mg		Not Reported
	Inexium			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2014	10280914	DIRECT		DS			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Myalgia	Escitalopram			S	Oral	1 Tablet Once Daily Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2014	10270778	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2014-06110		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Mania; Therapy Cessation	Escitalopram 20 Mg (Escitalopram) Unknown, 20mg			S			244 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2014	10275291	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002126		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Malaise; Mydriasis; Vomiting	Escitalopram Tablets Usp 10mg			S				Lupin
	Vitamin B			C	Unknown			Not Reported
	Ortho Tri-Cyclen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2014	10275294	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002036			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depersonalisation/Dereali sation Disorder; Disturbance In Attention; Memory Impairment	Escitalopram Tablets Usp 5mg			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2014	10275322	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2014-01116			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2014	10276216	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2014183671		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Natriuretic Peptide Increased; Dyspnoea; Electrocardiogram Qt Prolonged; Heart Rate	Cordarone			S	Oral	200 Mg, Daily		Pfizer
	Seroplex			S	Oral	10 Mg, Daily		Not Reported
	Isocard			C				Not Reported

Decreased; Malaise; Syncope; Torsade De Pointes	Vasten [Pravastatin Sodium]	C			Not Reported
	Tramadol	C			Not Reported
	Stilnox	C			Not Reported
	Levothyrox	C			Not Reported
	Inexium	C	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2014	10276394	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2014SE46538		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Ventricular Extrasystoles	Xeroquel			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Calcidose Vitamine D			C	Oral	500mg/400 Iu 2 Df Per Day		Not Reported
	Seresta			C	Oral	10 Mg, If Needed, Three Per Day Maximum		Not Reported
	Stilnox			C	Oral			Not Reported
	Talc Gifere			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2014	10235323	NON-EXPEDITED			US-PFIZER INC-2014162052		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Ambien			S		Unk		Not Reported
	Avelox			S		Unk		Not Reported
	Buspar			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Demerol			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported

Levaquin	S	Unk		Not Reported
Lorazepam	S	Unk		Not Reported
Lexapro	S	Unk		Not Reported
Remeron	S	Unk		Not Reported
Talc	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2014	10277706	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2014-00862		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Decreased Appetite; Dyspnoea; Feeling Jittery; Off Label Use; Palpitations; Weight Decreased	Viibryd			S	Oral			Not Reported
	Viibryd			S	Oral			Not Reported
	Viibryd			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Metformin			C	Unknown			Not Reported
	Zocor			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2014	10277708	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2014-00947			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2014	10277710	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS		16 YR	Male	USA

INC.-E2B_00001920

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Wrong Technique In Product Usage Process	Escitalopram Tablets Usp 5mg			S		Half Tablet Once A Day		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2014	10036004	EXPEDITED (15-DAY)		OT	AT-ELI_LILLY_AND_COMPANY-AT201403007233		43 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Drug Interaction; Dry Mouth; Vertigo	Cymbalta			S	Unknown	30 Mg, Unknown		Eli Lilly And Co
	Cymbalta			S	Unknown	60 Mg, Unknown		Eli Lilly And Co
	Cymbalta			S	Unknown	120 Mg, Unknown		Eli Lilly And Co
	Cipralex			S	Unknown	10mg		Not Reported
	Cipralex			S	Unknown	20mg		Not Reported
	Cipralex			S	Unknown	10mg		Not Reported
	Trittico Cr			S		100mg		Not Reported
	Trittico Cr			S		150mg		Not Reported
	Seroquel			S		100mg		Not Reported
	Seroquel			S		150mg		Not Reported
	Seroquel			S		200mg		Not Reported
	Seroquel Xr			S		200mg		Not Reported
	Seroquel Xr			S		300mg		Not Reported
	Seroquel Xr			S		400mg		Not Reported
	Lyrica			S	Unknown	150 Mg, Unknown		Not Reported
	Valdoxan			S	Unknown	1 Df, Unknown		Not Reported
	Rivotril			C		0.5mg		Not Reported

	Rivotril	C	1.0mg	Not Reported
	Rivotril	C	1.75mg	Not Reported
	Rivotril	C	1.25mg	Not Reported
	Rivotril	C	2.75mg	Not Reported
	Rivotril	C	2.5mg	Not Reported
	Sirdalud	C	2mg	Not Reported
	Thrombo Ass	C	100mg	Not Reported
	Dominal Forte	C	80mg	Not Reported
	Dominal Forte	C	40mg	Not Reported
	Zoldem	C	10mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2014	10244876	EXPEDITED (15-DAY)		HO	CN-FRI-1000068209		70 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Drug Ineffective; Fall; Fracture; Hyperhidrosis; Urine Output Decreased	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2014	10281839	EXPEDITED (15-DAY)		OT	TR-FRI-1000068704		16 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Off Label Use	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest
	Depakin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2014	10282438	EXPEDITED (15-DAY)		HO	FR-FRI-1000068671		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Brief Psychotic Disorder With Marked Stressors; Persecutory Delusion	Escitalopram	S	Oral	10 Mg		Forest
	Mirtazapine	C	Oral	1 Df		Not Reported
	Baclofene	C	Oral	70 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2014	10228640	EXPEDITED (15-DAY)		OT	US-ROXANE LABORATORIES, INC.-2014-RO-00881RO			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epilepsy; Feeling Abnormal; Product Commingling; Product Quality Issue	Morphine			S	Oral			Roxane
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Klonopin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2014	10283559	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20140618909		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Ventricular Extrasystoles	Risperdal			S	Oral			Not Reported
	Xeroquel			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Stilnox			C	Oral			Not Reported
	Calcidose Vitamin D			C	Oral	500 Mg/400iu (Oral Powder In Sachet-Dose) At 2 Sachets		Not Reported
	Seresta			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2014	10283687	EXPEDITED (15-DAY)		HO	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2014-BI-30		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Fall; Subdural Haematoma; Subdural Haematoma	Pradaxa		S	Oral		Boehringer Ingelheim
	Seroplex		S	Oral	5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2014	10284062	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2014186367		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Somnolence; Toxicity To Various Agents; Vomiting	Xanax			S	Oral	Unk		Pfizer
	Seroplex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2014	10296279	DIRECT					43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia	Lexapro 10mg Teva			S	Oral		2 YR	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2014	10216326	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2014146971		47 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Interaction; Irritability; Libido Decreased; Localised Infection; Obesity; Skin Infection; Weight Increased	Lyrica			S	Oral	75 Mg, 2x/Day		Pfizer
	Lyrica			S	Oral	Unk		Pfizer
	Cipralex			S	Oral	10 Mg, Daily		Not Reported
	Cipralex			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2014	10288854	EXPEDITED (15-DAY)		OT	FR-FRI-1000068695		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ventricular Extrasystoles	Escitalopram	S	Oral	15 Mg	Forest
	Xeroquel	S	Oral	50 Mg	Not Reported
	Risperdal	S	Oral	1 Mg	Not Reported
	Calcidose Vitamine D	C	Oral	2 Df	Not Reported
	Seresta	C	Oral	On Request, 30 Mg Daily Maximum	Not Reported
	Stilnox	C	Oral	10 Mg	Not Reported
	Talc De Venise	C		One Application Of 120 G Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2014	10288923	EXPEDITED (15-DAY)		CA	US-FRI-1000068667		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2014	10301807	EXPEDITED (15-DAY)	Y	LT	2014HINLIT0592		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Drug Interaction;	Escitalopram			S				Not Reported
Electrocardiogram Qt	Sotalol (Sotalol)			S				Not Reported
Prolonged; Hypokalaemia;	Tacrolimus (Tacrolimus)			S				Not Reported
Loss Of Consciousness;	Omeprazole (Omeprazole)			S				Not Reported
Pallor; Torsade De	Mgso4 (Mgso4)			C				Not Reported
Pointes; Vomiting								

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2014	10302056	DIRECT					56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Frequent Bowel Movements;	Lexapro			S	Oral		2 YR	Not Reported

Gastrointestinal Pain;
Head Discomfort;
Hyperhidrosis; Influenza;
Nausea

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2014	10132324	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2014S1009117		72 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Conduction Time Prolongation	Escitalopram Oxalate			S	Oral	20 Mg Daily		Not Reported
	Mirtazapine			S	Oral	30 Mg Daily		Not Reported
	Alprazolam			S	Oral	20 Gtt Daily		Mylan
	Moduretic			C	Oral			Not Reported
	Bisoprolol Hemifumarate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2014	10215149	EXPEDITED (15-DAY)		DE	CH-FRI-1000067825			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Aspirin Cardio			S	Oral	100 Mg		Not Reported
	Catapresan			C	Oral			Not Reported
	Beloc [Metoprolol]			C	Oral	50 Mg		Not Reported
	Triatec (Ramipril)			C	Oral	5 Mg		Not Reported
	Adalat			C	Oral	60 Mg		Not Reported
	Acetaphos			C	Oral	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2014	10280300	EXPEDITED (15-DAY)		OT	IT-ELI_LILLY_AND_COMPANY-IT201406009192		75 YR	Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Extrasystoles; Sopor; Syncope; Urinary Incontinence	Cymbalta		S	Oral	60 Mg, Qd	Eli Lilly And Co
	Entact		S	Unknown	10 Mg, Unknown	Not Reported
	Lacirex		C	Unknown	Unk, Unknown	Not Reported
	Provisacor		C	Unknown	Unk, Unknown	Not Reported
	Indapamide W/Perindopril		C	Unknown	Unk, Unknown	Not Reported
	Pantorc		C	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2014	10295636	EXPEDITED (15-DAY)		OT	US-TAKEDA-2014TUS005708		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease	Prevacid			S	Oral	15 Mg, Bid		Takeda
	Advair			S	Other	1 Puff		Not Reported
	Ventolin Hfa			S	Other	2 Puff As Required		Not Reported
	Ventolin Hfa			S	Other	2 Puff As Required		Not Reported
	Bupropion Hydrochloride			S	Oral	300 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Not Reported
	Hydroxyzine Hydrochloride			S	Oral	50 Mg, As Required		Not Reported
	Esterified Estrogens And Methyltestosterone			C		Unk		Not Reported
	Lisinopril			C		Unk		Not Reported
	Trazodone /00447702/			C		Unk		Not Reported
	Fluzone /01389801/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2014	10297559	EXPEDITED (15-DAY)		HO	AT-JNJFOC-20140700171		51 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Dyskinesia; Tongue Disorder	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported

Risperdal	S	Unknown			Not Reported
Risperdal	S	Unknown			Not Reported
Risperdal	S	Unknown	2-3 Mg		Not Reported
Cipralex	S	Unknown			Not Reported
Cipralex	S	Unknown			Not Reported
Trittico	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2014	10297695	EXPEDITED (15-DAY)		HO, OT	FR-FRI-1000068834		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Withdrawal Syndrome; Hyperhidrosis; Malaise; Overdose	Escitalopram			S	Oral	Overdose: 40 Mg Daily.		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Escitalopram			S	Oral	40 Mg		Not Reported
	Stilnox			S	Oral	40 Mg		Not Reported
	Stilnox			S	Oral	40 Mg		Not Reported
	Lysanxia			S	Oral	1 Mg		Not Reported
	Lysanxia			S	Oral	1 Mg		Not Reported
	Temesta (Lorazepam)			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Oral	3.75 Mg		Not Reported
	Temesta (Lorazepam)			S	Oral	7.5 Mg		Not Reported
	Tahor			C		40 Mg		Not Reported
	Levothyrox			C				Not Reported
	Esomeprazole			C		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2014	10298007	EXPEDITED (15-DAY)		OT	DE-RANBAXY-2012R1-56327			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly In	Mycophenolate Mofetil			S	Unknown	0.5 G, Daily		Not Reported

Offspring; Exposure During Pregnancy; Premature Delivery	Escitalopram		S	Unknown	Unk	Not Reported
	Lorazepam		S	Unknown	Unk	Ranbaxy
	Zolpidem		S	Unknown	Unk	Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2014	10298119	EXPEDITED (15-DAY)		CA	DE-RANBAXY-2012R1-56326			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Oesophageal Atresia; Premature Baby; Tracheal Atresia	Mycophenolate Mofetil			S	Transplacental	0.5 G, Daily		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported
	Lorazepam			S	Transplacental	Unk		Ranbaxy
	Zolpidem			S	Transplacental	Unk		Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2014	10298447	EXPEDITED (15-DAY)		CA, OT	US-FRI-1000068907		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Right Ventricular Dilatation	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2014	10302740	EXPEDITED (15-DAY)		OT	US-ABBVIE-13P-163-1108063-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Hallucination, Auditory; Hallucination, Visual; Hypoaesthesia; Nerve Injury; Pain In Extremity; Paraesthesia	Synthroid			S				Not Reported
	Protonix			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Detrol			S	Unknown			Not Reported
	Remeron			S	Unknown			Not Reported
	Abilify			S				Not Reported

Aldactone	S		Not Reported
Cymbalta	S		Not Reported
Lexapro	S		Not Reported
Zoloft	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2014	10211748	EXPEDITED (15-DAY)		HO, OT	2014IE004283		67 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Allergy To Arthropod Sting; Alopecia; Anaphylactic Reaction; Breast Mass; Breast Tenderness; Chills; Contusion; Depression; Disturbance In Attention; Drug Interaction; Dry Mouth; Fatigue; Feeling Drunk; Furuncle; Gait Disturbance; Gynaecomastia; Headache; Hordeolum; Hordeolum; Hyperhidrosis; Hypotonia; Hypotonia; Insomnia; Onychoclasis; Peripheral Swelling; Pruritus; Rash; Sinus Disorder; Skin Disorder; Stress; Urinary Tract Infection; Urinary Tract Infection; Weight Increased	Eligard			S	Other	45 Mg, Once In 6 Months, Other		Not Reported
	Lexapro (Escitalopram Oxalate)			S	Oral			Not Reported
	Solpadol (Codeine Phosphate, Paracetamol)			C				Not Reported
	Ibuprofen			C				Not Reported
	Elantan (Isosorbide Mononitrate)			C				Not Reported
	Caprin (Acetylsalicylic Acid)			C				Not Reported
	Boronex (Buspirone Hydrochloride)			C				Not Reported
	Stilnoct (Zolpidem Tartrate)			C				Not Reported
	Tamsulosin Hydrochloride (Tamsulosin Hydrochloride)			C				Not Reported
	Xenical (Orlistat)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2014	10306323	EXPEDITED (15-DAY)		LT, OT	BE-ACTAVIS-2014-15141		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt	Escitalopram (Unknown)			S	Unknown	Unk		Not Reported

Syndrome; Torsade De Pointes; Vomiting	Tacrolimus (Unknown)	S	Unknown	Unk		Watson
	Omeprazole (Unknown)	S	Unknown	Unk		Watson
	Sotalol (Unknown)	S	Unknown	Unk		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2014	10306452	EXPEDITED (15-DAY)		HO	US-FRI-1000068949		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Dementia; Depression; Encephalopathy; Gait Inability; Headache; Loss Of Personal Independence In Daily Activities; Pseudodementia; Toxicity To Various Agents; Vomiting	Lexapro			S				Forest
	Humira			S		40 Mg Every Other Week		Not Reported
	Topamax			S				Not Reported
	Tramadol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2014	10309920	DIRECT		DS, HO, LT, OT			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Agitation; Bipolar Disorder; Confusional State; Diarrhoea; Fear; Feeding Disorder; Hallucination; Heart Rate Increased; Heart Rate Irregular; Insomnia; Mania; Mental Impairment; Muscle Twitching; Schizophreniform Disorder; Seizure; Serotonin Syndrome; Vomiting; Withdrawal Syndrome	Lexapro			S	Oral	2 Pills Taken By Mouth	5 DAY	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2014	10309945	DIRECT					51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alcohol Use; Blood Alcohol Increased; Hostility; Imprisonment; Loss Of Consciousness; Memory Impairment; Road Traffic Accident; Stress	Escitalopram 20mg Lexapro			S	Oral	One Tablet At Bedtime Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2014	9798206	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2013374314		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Stevens-Johnson Syndrome; Toxic Skin Eruption	Lyrica			S	Oral	Unk		Pfizer
	Primperan			S		Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Esomeprazole Sodium			S	Oral	40 Mg, 1x/Day		Not Reported
	Oxynorm			S		10 Mg Every 6 Hours (40 Mg Daily)		Not Reported
	Crestor			C	Oral	20 Mg, 1x/Day		Not Reported
	Solumedrol			C		Unk		Not Reported
	Kardegic			C		75 Mg		Not Reported
	Plavix			C		75 Mg		Not Reported
	Lovenox			C		4000 Iu Anti-Xa/0.4 Ml		Not Reported
	Metoprolol Fumarate			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Hexaspray			C		Unk		Not Reported
	Hydroxyzine Hydrochloride			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2014	10261722	EXPEDITED (15-DAY)		OT	FR-FRI-1000068489		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Simple Partial Seizures	Escitalopram			S	Oral	1 Df		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2014	10308086	EXPEDITED (15-DAY)		HO	FR-FRI-1000068832		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Subdural Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Pradaxa			S	Oral			Not Reported
	Coaprovel 300 / 25 Mg			C				Not Reported
	Ezetrol			C				Not Reported
	Eucreas 50 / 1000 Mg			C				Not Reported
	Isoptine			C				Not Reported
	Lyrica			C				Not Reported
	Cystine B6 Bailleul			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2014	10308182	EXPEDITED (15-DAY)		OT	BE-FRI-1000068987		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Escitalopram			S				Forest
	Sotalol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2014	10308382	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC-2014192203		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma	Tahor			S	Oral	20 Mg, Daily		Pfizer
	Seroplex			S	Oral	5 Mg, Daily		Not Reported

	Kardegic	S	Oral	75 Mg, Daily	Not Reported
	Previscan (Fluindione)	S	Oral	0.75 Df On Even Days, 0.5 Df On Odd Days	Not Reported
	Previscan (Fluindione)	S	Oral	0.75 Df On Even Days, 0.25 Df On Odd Days	Not Reported
	Furosemide	C	Oral	40 Mg, Daily	Not Reported
	Detensiel	C	Oral	10 Mg, Daily	Not Reported
	Amlodipine	C	Oral	1 Df, Daily	Not Reported
	Ramipril	C	Oral	5 Mg, Daily	Not Reported
	Esomeprazole	C	Oral	Unk	Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)	C	Oral	5.9 G, Daily	Not Reported
	Doliprane	C	Oral	1000 Mg Tablet	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2014	10312661	DIRECT					20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Substitution Issue	Escitalopram			S	Oral	1 Pill Once Daily Taken By Mouth		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2014	10313409	EXPEDITED (15-DAY)		OT	SYM-2014-23210		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Depression; Dizziness; Dry Mouth; Erection Increased; Fatigue; Increased Appetite; Muscular	Wellbutrin Xl (Bupropion Hydrochloride) (Prolonged-Release Tablet) (Bupropion Hydrochloride)			S				Not Reported
	Clonazepam			S	Oral			Not Reported

Weakness; Nausea; Somnolence; Suicidal Ideation; Tinnitus; Tremor; Weight Increased	Escitalopram Oxalate (Escitalopram Oxalate)		S	Oral	Not Reported
	Quetiapine Fumarate (Quetiapine Fumarate)		S	Oral	Not Reported
	Echinacea Purpurea(Eschinacea Purpurea)		C		Not Reported
	Horse Chestnut Extract (Aesculus Hippocastanum Extract)(Aesculus Hippocastanum Extract)		C		Not Reported
	Milk Thistle		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2014	10152983	EXPEDITED (15-DAY)		HO, OT	PHHY2014FR052784		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Anxiety; Blood Pressure Increased; Confusional State; Drug Dependence; Drug Ineffective; Dyspepsia; Hallucination; Headache; Insomnia; Pain; Sleep Attacks; Somnolence; Vomiting; Withdrawal Syndrome	Baclofen			S		270 Mg, Per Day		Not Reported
	Baclofen			S		10 Mg, Unk		Not Reported
	Baclofen			S		30 Mg, Per Day		Not Reported
	Oxazepam			S		12.5 Mg, Per Day		Novartis
	Oxazepam			S		62.5 Mg, Per Day		Novartis
	Escitalopram			S		10 Mg, Per Day		Not Reported
	Zopiclone			C		7.5 Mg, Per Day		Not Reported
	Nicardipine			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2014	10310662	EXPEDITED (15-DAY)		HO	IT-FRI-1000068990		19 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Slow Speech; Sopor	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2014	10311384	EXPEDITED (15-DAY)		CA	DE-FRI-1000069051			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Escitalopram			S	Transplacental	20 Mg		Forest
	Escitalopram			S	Transplacental	10 Mg		Not Reported
	Thyronajod			C	Transplacental	0.05 Mg Levothyroxine / 0.15 Mg/Day Potassium Iodide Per Day Taken From Monday To Friday		Not Reported
	Mirtazapin			C	Transplacental	15 Mg/Day As Needed		Not Reported
	Mirtazapin			C	Transplacental	15 Mg		Not Reported
	Folio Jodfrei			C	Transplacental	0.4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2014	10311558	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-A1081440A		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Depression; Dizziness; Dry Mouth; Erection Increased; Fatigue; Increased Appetite; Muscular Weakness; Nausea; Somnolence; Suicidal Ideation; Tinnitus; Tremor; Weight Increased	Wellbutrin Xl			S	Oral	300mg Per Day		Glaxosmithkline
	Clonazepam			S	Oral	1mg Per Day		Glaxosmithkline
	Escitalopram Oxalate			S	Oral	10mg Per Day		Glaxosmithkline
	Quetiapine Fumarate			S	Oral	200mg Per Day		Glaxosmithkline
	Echinacea Purpurea			C				Not Reported
	Horse Chestnut Seed Extract			C				Not Reported
	Milk Thistle			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2014	10311862	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2014S1016022		94 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Delirium; Hallucination, Visual	Risperidone		S	Oral	Not Reported
	Seroplex		S	Oral	Not Reported
	Dihydan		C		Not Reported
	Alepsal /01606601/		C		Not Reported
	Xarelto		C		Not Reported
	Lasilix		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2014	10312770	DIRECT		OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cognitive Disorder; Feeling Abnormal; Impaired Work Ability	Lexapro Or Escitalopram			S	Oral	1 Pill; Once Daily		Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2014	6962634	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2009187922		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dysarthria; Hypertension; Hypokalaemia; Mental Status Changes; Multiple Drug Therapy	Desvenlafaxine Succinate Monohydrate			S	Oral	50 Mg, 1x/Day		Pfizer
	Desvenlafaxine Succinate Monohydrate			S	Oral	100 Mg, 1x/Day		Pfizer
	Lyrica			S	Oral	75 Mg, 1x/Day		Pfizer
	Lyrica			S				Pfizer
	Lyrica			S				Pfizer
	Ibuprofen			S	Oral	800 Mg, 3x/Day		Pfizer
	Loratadine			S	Oral	10 Mg, 1x/Day		Pfizer
	Robaxin			S	Oral	750 Mg, 3x/Day		Pfizer
	Robaxin			S		Unknown		Pfizer
	Robaxin			S				Pfizer
	Clonazepam			S	Oral	1 Mg, 2x/Day		Not Reported
	Clonazepam			S				Not Reported

Lexapro	S	Oral	20 Mg, 1x/Day		Not Reported
Lexapro	S				Not Reported
Abilify	S	Oral	15 Mg, 2x/Day		Not Reported
Abilify	S				Not Reported
Abilify	S				Not Reported
Fluticasone	S		2 Sprays Daily Route: In		Not Reported
Vicodin	S	Oral	5/500 Prn		Not Reported
Zestoretic	S	Oral	20/12.5 Daily		Not Reported
Ambien	S	Oral	10 Mg, 1x/Day		Not Reported
Vivelle	S	Transdermal	0.1 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2014	10313042	NON-EXPEDITED			US-PFIZER INC-2014201663		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Zofran			S		Unk		Not Reported
	Carafate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2014	10329320	DIRECT	Y				17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Economic Problem	Escitalopram 10mg Aurobiudo Pharma			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2014	10330663	DIRECT		OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Generic Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2014	9166696	EXPEDITED (15-DAY)		CA, OT	US-FRI-1000043320		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Aortic Dilatation; Heart Disease Congenital; Transposition Of The Great Vessels; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2014	10133555	EXPEDITED (15-DAY)		LT	IT-SA-2014SA050408		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Loss Of Consciousness; Respiratory Arrest	Lasix			S	Oral			Not Reported
	Entact			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2014	10308135	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20140706670		22 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Intentional Overdose; Seizure	Ixprim			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Baclofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2014	10329471	EXPEDITED (15-DAY)		OT	CA-FRI-1000068988		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Fall; Headache; Muscle Haemorrhage	Escitalopram			S		10 Mg		Forest
	Citalopram			S		20 Mg		Forest
	Clomipramine			S		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2014	10329569	EXPEDITED (15-DAY)		OT	AU-FRI-1000068993		74 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Confusional State; Hemiparesis; Syncope	Escitalopram			S				Forest
	Atorvastatin			S				Not Reported
	Carvedilol Hydrochloride			S				Not Reported
	Digoxin			S				Not Reported
	Irbesartan			S				Not Reported
	Pantoprazole			S				Not Reported
	Sitagliptin-Metformin			S				Not Reported
	Solifenacin Succinate			S				Not Reported
	Strontium Ranelate			S				Not Reported
	Warfarin Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2014	10334261	EXPEDITED (15-DAY)	Y	OT	US-ZYDUS-004131		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome; Serotonin Syndrome	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2014	10334525	EXPEDITED (15-DAY)	Y	OT	2014AP003615		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral	Escitalopram Oxalate			S				Not Reported

Vasoconstriction Syndrome; Subarachnoid Haemorrhage	(Escitalopram) Tablet

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2014	10338884	EXPEDITED (15-DAY)	Y	OT	2014JUB00050		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Delusion; Euphoric Mood; Insomnia; Logorrhoea; Mania; Psychomotor Hyperactivity; Refusal Of Treatment By Patient; Restlessness; Withdrawal Syndrome	Escitalopram (Escitalopram) Unknown			S	Oral		244 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2014	10089343	EXPEDITED (15-DAY)	Y	DS	AUR-APL-2014-04601		37 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disturbance In Attention; Paraesthesia; Product Use In Unapproved Indication; Sleep Disorder; Tremor	Auro-Quetipaine (Quetiapine) Film-Coated Tablet, 25mg			S	Oral	1 D		Not Reported
	Escitalopram Oxalate			S	Oral	1 D		Not Reported
	Esomeprazole Magnesium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2014	10288441	EXPEDITED (15-DAY)		DE	FR-FRI-1000068769		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Melaena; Rectal Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Xarelto			S	Oral	15 Mg		Not Reported
	Lasilix			C	Oral	1 Df		Not Reported
	Aldactone			C	Oral	1 Df On Even Days		Not Reported

Bisoprolol	C	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2014	10330963	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20140709019		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Tylenol			S	Unknown			Not Reported
	Avastin			S	Intravenous (not otherwise specified)			Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)			Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)			Not Reported
	Cipralex			S	Unknown			Not Reported
	Ciprofloxacin			S	Oral			Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)			Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)			Not Reported
	Herceptin			S	Intravenous (not otherwise specified)			Not Reported
	Herceptin			S	Intravenous (not otherwise specified)			Not Reported
	Morphine			S	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Docusate			C	Unknown			Not Reported
	Gravol			C	Unknown			Not Reported
	Unspecified Mouthwash			C	Unknown			Not Reported
	Senna			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Lactulose			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2014	10331577	EXPEDITED (15-DAY)		OT	JP-FRI-1000067650		67 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Bradycardia	Lexapro			S	Oral	10 Mg		Forest
	Meilax			C	Oral	1 Mg		Not Reported
	Amlodipine			C	Oral	5 Mg		Not Reported
	Coversyl			C	Oral	4 Mg		Not Reported
	Zyloric			C	Oral	100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2014	10332091	EXPEDITED (15-DAY)		HO	FR-FRI-1000069119		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Pradaxa			S	Oral	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2014	10332860	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2014FR088206		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Vasoplegia Syndrome	Loxen (Nicardipine Hydrochloride)			S	Oral	800 Mg, Single		Not Reported
	Loxen Lp			S	Oral	4000 Mg, Single		Not Reported
	Verapamil			S	Oral	1200 Mg, Single		Novartis
	Thyrozol			S	Oral	400 Mg, Single		Not Reported
	Seroplex			S	Oral	560 Mg, Single		Not Reported
	Noctamide			S	Oral	12 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2014	10333119	EXPEDITED (15-DAY)		HO	CA-ROCHE-1435428		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Avastin			S	Intravenous (not otherwise specified)	Therapy Duration: 18 Days		Not Reported
	Herceptin			S	Intravenous (not otherwise specified)			Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)			Not Reported
	Cipralex			S	Unknown			Not Reported
	Ciprofloxacin			S	Oral	Therapy Duration: 2 Days		Not Reported
	Ciprofloxacin			S	Intravenous (not otherwise specified)			Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)			Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)			Not Reported
	Morphine			S	Unknown	Therapy Duration: 3 Days		Not Reported
	Tylenol			S	Unknown			Not Reported
	Piperacillin Sodium/Tazobactam Sodium			S	Unknown			Not Reported
	Tylenol #1 (Canada)			S	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Docusate			C				Not Reported
	Gravol			C				Not Reported
	Lactulose			C	Unknown			Not Reported
	Senna			C				Not Reported
	Trazodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2014	10333221	EXPEDITED (15-DAY)		OT	DE-FRI-1000069118		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Obstructed Labour	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	5 Mg (Very Slow Dose Reduction During Pregnancy)		Forest
	Euthyrox			C	Oral	88 Mcg		Not Reported
	Gynvital			C	Oral	0.4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2014	10333350	EXPEDITED (15-DAY)		CA	US-FRI-1000069144		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Cardiac Defects; Truncus Arteriosus Persistent	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2014	10337953	DIRECT	Y	OT			18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Mood Swings; Product Substitution Issue; Tearfulness; Therapeutic Product Effect Decreased	Lexapro			S	Oral		6 MTH	Cvs Caremark

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2014	10305545	EXPEDITED (15-DAY)		LT	JP-FRI-1000068764		76 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Suicide Attempt	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2014	10335754	EXPEDITED (15-DAY)		HO	FR-FRI-1000069233		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Tahor			S	Oral	20 Mg		Not Reported
	Previscan (Fluindione)			S	Oral	0.5 Df		Not Reported
	Previscan (Fluindione)			S	Oral	0.25 Df		Not Reported
	Previscan (Fluindione)			S	Oral	3/4 On Even Days And 1/2 On Odd Days		Not Reported
	Furosemide			C	Oral	40 Mg		Not Reported
	Detensiel			C	Oral	10 Mg		Not Reported
	Amlodipine			C	Oral	1 Df		Not Reported
	Ramipril			C		5 Mg		Not Reported
	Esomeprazole			C	Oral			Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C	Oral	5.9 G		Not Reported
	Doliprane			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2014	10336200	EXPEDITED (15-DAY)		DE, HO, OT	FR-FRI-1000069174		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Overdose; Vasoplegia Syndrome	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose Of 560 Mg		Forest
	Loxen (Nicardipine Hydrochloride)			S	Oral			Not Reported

Loxen (Nicardipine Hydrochloride)	S		Overdose Of 4800 Mg		Not Reported
Verapamil	S	Oral			Not Reported
Verapamil	S	Oral	Overdose Of 1200 Mg		Not Reported
Thyrozol	S	Oral			Not Reported
Thyrozol	S		Overdose Of 400 Mg		Not Reported
Noctamide	S	Oral			Not Reported
Noctamide	S		Overdose Of 12 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2014	10336995	EXPEDITED (15-DAY)		CA	DE-FRI-1000069135		< 1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby; Ventricular Septal Defect	Escitalopram			S	Transplacental	20 Mg		Forest
	Escitalopram			S	Transplacental	5 Mg/Day (Very Slow Dose Reduction During Pregnancy)		Not Reported
	Euthyrox			C	Transplacental	88 Mcg		Not Reported
	Gynvital			C	Transplacental	0.4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2014	10337026	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2014204664		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Malaise; Parkinsonism	Efexor Er			S	Oral	1 Df, Daily		Pfizer
	Cipralex			S	Oral	1 Df, Daily		Not Reported
	Orap			S	Oral	1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2014	10337250	EXPEDITED (15-DAY)		HO	TR-MYLANLABS-2014S1016748		31 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anal Incontinence; Drug Interaction; Intentional Overdose; Suicide Attempt; Urinary Incontinence	Escitalopram		S	Oral	Df=10mg	Mylan
	Escitalopram		S	Oral	Df=10mg	Mylan
	Aripiprazole		S	Oral	Df=5mg	Not Reported
	Aripiprazole		S	Oral	Df=5mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2014	10344724	EXPEDITED (15-DAY)		OT	AUR-APL-2014-07749		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease	Escitalopram			S		20 Mg, Once A Day, Unknown		Not Reported
	Prevacid			S	Oral	15 Mg, Two Times A Day, Oral		Not Reported
	Hydroxyzine Hydrochloride			S	Oral			Not Reported
	Advair			S		1 Puff, Respiratory		Not Reported
	Ventolin Hfa			S		2 Puff, Respiratory		Not Reported
	Bupropion Hydrochloride			S	Oral	30 Mg, Once A Day, Oral		Not Reported
	Esterified Estrogens And Methyltestosterone (Estrogens Esterified, Methyltestosterone) Unknown			C				Not Reported
	Lisinopril (Lisinopril) Unknown			C				Not Reported
	Trazodone (Trazodone) Unknown			C				Not Reported
	Fluzone /00780601/ (Fluconazole) Unknown			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2014	10345348	EXPEDITED (15-DAY)	Y	HO	2014HINLIT0645		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Clonus; Diarrhoea; Drug Interaction; Dysmetria;	Escitalopram (Escitalopram) (Unknown)			S			244 DAY	Not Reported
	Mirtazapine (Mirtazapine)			S		At Bed Time		Not Reported

Hyperreflexia; Irritability; Persecutory Delusion; Serotonin Syndrome; Sleep Disorder; Toxicity To Various Agents; Tremor	Lorazepam (Lorazepam)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2014	10345362	EXPEDITED (15-DAY)	Y	OT	2014HINLIT0637		34 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism	Escitalopram			S		20 Mg/D		Not Reported
	Carbamazepine (Carbamazepine)			C				Not Reported
	Clonazepam (Clonazepam)			C				Not Reported
	Zopiclone (Zopiclone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2014	6956961	EXPEDITED (15-DAY)		HO	US-JNJFOC-20090307044		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dysarthria; Headache; Hypertension; Hypokalaemia; Mental Status Changes; Multiple Drug Therapy	Ibuprofen			S	Oral			Not Reported
	Desvenlafaxine Succinate Monohydrate			S	Oral			Not Reported
	Desvenlafaxine Succinate Monohydrate			S	Oral			Not Reported
	Desvenlafaxine Succinate Monohydrate			S	Oral			Not Reported
	Desvenlafaxine Succinate Monohydrate			S	Oral			Not Reported
	Desvenlafaxine Succinate Monohydrate			S	Oral			Not Reported
	Desvenlafaxine Succinate Monohydrate			S	Oral			Not Reported
	Desvenlafaxine Succinate Monohydrate			S	Oral			Not Reported
	Placebo			S	Oral			Not Reported

Placebo	S	Oral			Not Reported
Lexapro	S	Oral			Not Reported
Lexapro	S	Oral			Not Reported
Clonazepam	S	Oral			Not Reported
Clonazepam	S	Oral			Not Reported
Abilify	S	Oral			Not Reported
Abilify	S	Oral			Not Reported
Abilify	S	Oral			Not Reported
Fluticasone	S	Respiratory (inhalation)			Not Reported
Loratadine	S	Oral			Not Reported
Vicodin	S	Oral	5/500 As Needed		Not Reported
Zestoretic	S	Oral	20/12.5 Daily		Not Reported
Ambien	S	Oral			Not Reported
Vivelle	S	Transdermal			Not Reported
Robaxin	S	Oral			Not Reported
Robaxin	S	Oral			Not Reported
Robaxin	S	Oral			Not Reported
Lyrica	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2014	9804141	EXPEDITED (15-DAY)		HO	FR-NAPPMUNDI-GBR-2013-0016791		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Stevens-Johnson Syndrome; Toxic Skin Eruption	Oxynorm 10 Mg, Gelule			S		10 Mg, Qid		Purdue
	Primperan			S		Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Seroplex			S		Unk		Not Reported
	Esomeprazole			S	Oral	40 Mg, Daily		Not Reported
	Crestor			C		20 Mg, Daily		Not Reported

	Kardegic	C	75 Mg, Unk	Not Reported
	Plavix	C	75 Mg, Unk	Not Reported
	Lovenox	C	4000 Ui Anti-Xa/0.4 Ml	Not Reported
	Metoprolol	C		Not Reported
	Insulin	C		Not Reported
	Hexaspray	C		Not Reported
	Hydroxyzine	C		Not Reported
	Solumedrol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2014	9814573	EXPEDITED (15-DAY)		HO	FR-FRI-1000052781		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Stevens-Johnson Syndrome; Toxic Skin Eruption	Escitalopram			S	Oral			Forest
	Lyrica			S	Oral			Not Reported
	Esomeprazole			S	Oral	1 Df		Not Reported
	Oxynorm			S		4 Df		Not Reported
	Primperan			S				Not Reported
	Crestor			C	Oral	1 Df		Not Reported
	Kardegic			C	Oral			Not Reported
	Plavix			C	Oral			Not Reported
	Lovenox			C				Not Reported
	Metoprolol			C				Not Reported
	Insulin			C				Not Reported
	Hexaspray			C				Not Reported
	Hydroxyzine			C				Not Reported
	Solumedrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2014	10243990	EXPEDITED (15-DAY)		OT	JP-FRI-1000068205		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonic Convulsion; Seizure	Lexapro			S	Oral	10 Mg		Forest

	Lexapro		S	Oral	20 Mg		Forest
	Lexapro		S		20 Mg		Forest
	Myslee		S	Oral	10 Mg		Not Reported
	Myslee		S	Oral	10 Mg		Not Reported
	Meilax		S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2014	10337406	EXPEDITED (15-DAY)		HO	FR-ROCHE-1438872		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Valium			S	Oral	1%		Not Reported
	Seroplex			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Loxen (France)			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Eupantol			S	Oral			Not Reported
	Theralene (France)			S	Oral	4%		Not Reported
	Lepticur			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2014	10340791	EXPEDITED (15-DAY)		CA	US-FRI-1000069123		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Encephalocele	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2014	10340878	NON-EXPEDITED			US-MYLANLABS-2013S1012582			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Drug	Levothyroxine			S				Not Reported

Interaction; Malaise; Skin Odour Abnormal; Urinary Tract Infection	Levoxyl	S		Not Reported
	Amlodipine Besilate	S		Mylan
	Lexapro	S		Mylan
	Synthroid	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2014	10224073	EXPEDITED (15-DAY)		HO	CN-FRI-1000067949		< 1 DAY	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foaming At Mouth; Foetal Exposure During Pregnancy; Hand-Foot-And-Mouth Disease	Lexapro			S	Transplacental	10 Mg		Forest
	Alprazolam			C	Transplacental	1 Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2014	10342244	EXPEDITED (15-DAY)		HO	CH-ACCORD-024916		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S		Increased Progressively Upto 20 Mg/D During First 4 Months		Accord
	Mirtazapine			S		At Bedtime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2014	10343594	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-A1082704A		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lamictal			S	Unknown			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported
	Geodon			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2014	10347132	DIRECT		LT, OT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Blood Pressure Increased; Cardiac Murmur; Dizziness; Drug Withdrawal Syndrome; Dyspnoea; Heart Rate Increased; Hyperhidrosis; Irritability; Mood Swings; Muscle Rigidity; Muscle Spasms; Musculoskeletal Stiffness	Lexapro			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2014	8001511	EXPEDITED (15-DAY)		OT	US-RANBAXY-2011US-44588			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Withdrawal Syndrome	Lorazepam			S	Oral	1 Mg Tablet In Evening		Ranbaxy
	Lorazepam			S	Oral	0.5 Mg Tablet In Morning		Ranbaxy
	Tegretol			S	Unknown	600 Mg, Unk		Not Reported
	Lithium			S	Unknown	750 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2014	8403932	EXPEDITED (15-DAY)		OT	GB-RANBAXY-2011R1-45218		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Social Behaviour; Oculogyric Crisis; Oculogyric Crisis	Risperidone			S	Oral	1.5 Mg, Qd		Ranbaxy
	Risperidone			S	Oral	Unk		Ranbaxy
	Risperidone			S	Oral	1.5 Mg, Qd		Ranbaxy
	Cipralex			S	Oral	10 Mg, 1days		Not Reported
	Cipralex			S	Oral	10 Mg, Bid		Not Reported
	Orphenadrine			C	Unknown	50 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2014	10151060	EXPEDITED (15-DAY)		HO	DE-FRI-1000067036		38 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Limb Fracture	Lexapro			S		20 Mg		Forest
	Luaf41156			S		Unk		Not Reported
	Blinded Placebo			S		Unk		Not Reported
	Blinded Serequel Xr			S		Unk		Not Reported
	Nasic			C	Other	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2014	10267259	NON-EXPEDITED		HO	FR-JNJFOC-20140617353		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disturbance In Attention; Drug Interaction; Mydriasis; Somnolence	Contramal			S	Oral			Not Reported
	Laroxyl			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Doliprane			C	Oral			Not Reported
	Modopar			C	Oral			Not Reported
	Modopar			C	Oral			Not Reported
	Olmetec			C	Oral			Not Reported
	Calcium Phosphate			C	Oral			Not Reported
	Xagrid			C	Oral			Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium			C	Oral			Not Reported

	Chloride\Sodium Sulfate Anhydrous)				
	Kardegic	C	Oral		Not Reported
	Modopar	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2014	10344613	EXPEDITED (15-DAY)		OT	IL-ACCORD-024983		34 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism	Clonazepam			C				Not Reported
	Escitalopram			S				Accord
	Carbamazepine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2014	10345634	EXPEDITED (15-DAY)		OT	FR-FRI-1000069332			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2014	10345686	EXPEDITED (15-DAY)		HO	FR-FRI-1000069334		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Pneumonia Aspiration; Renal Failure; Suicide Attempt; Toxic Encephalopathy	Escitalopram			S	Oral	Overdose Of 840 Mg Once		Forest
	Laroxyl			S	Oral	Overdose Of 1 Gram Once		Not Reported
	Laroxyl			S	Oral	Overdose Of 1.325 Gram Once		Not Reported
	Alprazolam			S	Oral	Overdose Of 60 Mg Once		Not Reported
	Actiskenan			S	Oral	Overdose Of 280 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2014	10345811	EXPEDITED (15-DAY)		LT	US-PFIZER INC-2014208279		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Platelet Dysfunction; Serotonin Syndrome	Linezolid			S		Unk		Pfizer
	Escitalopram Oxalate			S		20 Mg, Unk		Not Reported
	Trazodone			S		Unk		Not Reported
	Fentanyl			S	Intravenous (not otherwise specified)	Intermittent		Not Reported
	Vancomycin			C		Unk		Not Reported
	Piperacillin/Tazobactam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2014	10346134	EXPEDITED (15-DAY)	Y	OT	CH-FRI-1000069329			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myofascial Pain Syndrome; Prescribed Overdose; Prurigo; Stress	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S		Dose Reduced		Not Reported
	Escitalopram			S		20 Mg		Not Reported
	Escitalopram			S		40 Mg		Not Reported
	Escitalopram			S		Dose Gradually Reduced		Not Reported
	St Johns Wort			S				Not Reported
	Interferon Nos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2014	10349590	EXPEDITED (15-DAY)		HO	2014AP003715		16 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2014	8025820	EXPEDITED (15-DAY)		OT	TW-RANBAXY-2011RR-45826		52 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Extrapyramidal Disorder; Gait Disturbance; Muscle Rigidity; Psychomotor Retardation; Tremor	Fluoxetine			S	Unknown	Unk		Ranbaxy
	Sertraline			S	Unknown	Unk		Ranbaxy
	Escitalopram			S	Unknown	Unk		Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2014	10271424	EXPEDITED (15-DAY)		CA, HO	IT-FRI-1000026311			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dermatitis; Foetal Exposure During Pregnancy; Gastrooesophageal Reflux Disease; Rhinitis	Escitalopram Oral Solution			S	Transplacental	10 Mg		Forest
	Xanax			S	Transplacental	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2014	10348108	EXPEDITED (15-DAY)		HO, OT	PHHY2014JP090827		46 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Interaction; Electrocardiogram Qt Prolonged; Sedation Complication; Ventricular Extrasystoles; Ventricular Fibrillation	Escitalopram			S				Not Reported
	Lansoprazole			S				Novartis
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Clopidogrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2014	10348265	EXPEDITED (15-DAY)		OT	IT-FRI-1000022085			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adnexal Torsion; Depression; Gestational	Escitalopram Oral Solution			S	Oral	10 Mg		Forest

Diabetes; Hypothyroidism; Infection; Pelvic Pain; Pregnancy	Xanax		C	Oral	5 Mg	Not Reported
	Progesterone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2014	10355205	EXPEDITED (15-DAY)	Y	OT	AUR-APL-2014-07976		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gastritis Erosive; Hiatus Hernia; Nausea; Product Use In Unapproved Indication	Escitalopram 5 Mg			S	Oral			Not Reported
	(Escitalopram) Unknown, 5mg				Oral			

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2014	10221047	EXPEDITED (15-DAY)		HO	CH-FRI-1000067893			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Irritability; Libido Decreased; Obesity; Weight Increased; Wound Infection	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Lyrica			S	Oral	150 Mg		Not Reported
	Lyrica			S	Oral	Dose Reduced By Half		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2014	10349103	EXPEDITED (15-DAY)		HO	PHHY2014CH091808		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Drug Interaction; Dyskinesia; Dysmetria; Irritability; Persecutory Delusion; Serotonin Syndrome; Suspiciousness; Tremor	Escitalopram			S		20 Mg/Day		Not Reported
	Escitalopram			S				Not Reported
	Mirtazapine			S		15 Mg/Day		Novartis
	Mirtazapine			S				Novartis
	Oral Contraceptive Nos			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2014	10349174	EXPEDITED (15-DAY)		OT	AE-ACCORD-025012		27 YR	Female	ARE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Escitalopram			S		Instructed To Increase The Dose Of Escitalopram To 10 Mg/Day After 4 Days.		Accord
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2014	10349577	EXPEDITED (15-DAY)		OT	CA-ROCHE-1441200		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatitis C; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Gamma-Glutamyltransferase Increased; Lymphocyte Morphology Abnormal	Diazepam			S	Oral			Not Reported
	Cipralex			S	Oral	Therapy Duration: 2 Month(S)		Not Reported
	Oxazepam			S	Sublingual			Not Reported
	Suboxone			S	Sublingual	Therapy Duration: 2 Day(S)		Not Reported
	Suboxone			S	Sublingual	Therapy Duration: 9 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2014	10350344	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2014210065		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Geodon			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Lamictal			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2014	10350990	EXPEDITED (15-DAY)		HO	IT-WATSON-2014-16262		20 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Lorazepam (Unknown)			S	Oral	20 Ml, Total		Watson
	Cipralex /01588501/			S	Oral	140 Mg, Total		Not Reported
	Talofen			S	Oral	40 Gtt Drop(S), Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2014	10353830	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2014-01389			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Escitalopram			S	Transplacental			Not Reported
	Alprazolam			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2014	10354609	EXPEDITED (15-DAY)		OT	JP-TEVA-498375ISR		46 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Lansoprazole			S	Unknown			Teva
	Escitalopram			S	Unknown			Not Reported
	Aspirin			C	Unknown	Controlled Release		Not Reported
	Clopidogrel			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2014	10354788	EXPEDITED (15-DAY)		OT	FR-FRI-1000069331		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Pain; Condition Aggravated	Escitalopram	S	Oral		Forest
	Verapamil	C		60 Mg In Morning And 120 Mg In Evening	Not Reported
	Aspegic [Acetylsalicylate Lysine]	C		100 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2014	10355557	EXPEDITED (15-DAY)		CA	US-FRI-1000069490		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Gastroschisis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2014	10361084	EXPEDITED (15-DAY)	Y	HO	2014HINLIT0672		31 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Drug Interaction; Overdose; Suicide Attempt; Urinary Incontinence	Escitalopram			S				Not Reported
	Aripiprazole			S				Not Reported
	Active Charcoal (Active Charcoal)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2014	9264778	EXPEDITED (15-DAY)		HO	DE-RANBAXY-2013RR-68254		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral; Peripheral Swelling	Ibuprofen		Y	S	Oral	1600 Mg, Daily		Ranbaxy
	Cipralex			S	Oral	20 Mg, Daily		Not Reported
	Remergil			S	Oral	15 Mg, Daily		Not Reported
	Remergil			S	Oral	30 Mg, Daily		Not Reported
	Remergil			S	Oral	15 Mg, Daily		Not Reported
	Pantozol			C	Oral	40 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2014	10196740	EXPEDITED (15-DAY)		DE	FR-FRI-1000067561		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S	Oral	1 Df		Forest
	Kardegic			S	Oral	1 Df		Not Reported
	Plavix			S	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2014	10282455	EXPEDITED (15-DAY)		HO	JP-FRI-1000068625		45 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg		Forest
	Diazepam			C	Oral	5 Mg		Not Reported
	Flunitrazepam			C	Oral	2 Mg		Not Reported
	Brotizolam			C	Oral	0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2014	10357006	EXPEDITED (15-DAY)		CA, HO, LT, OT	US-JNJFOC-20140716605			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Stenosis; Atrial Septal Defect; Cardiopulmonary Failure; Congenital Heart Valve Disorder; Foetal Exposure During Pregnancy; Hypoxia; Patent Ductus Arteriosus	Topamax			S	Transplacental			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2014	10357166	EXPEDITED (15-DAY)		HO	IT-TEVA-494423ISR		24 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nausea; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral	10 Df Daily		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2014	10357454	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2014213260		58 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Coordination Abnormal; Depression; Dizziness; Drug Ineffective; Drug Ineffective; Dysstasia; Ear Pain; Gait Disturbance; Major Depression; Memory Impairment	Frontal			S		Unk		Pfizer
	Frontal Xr			S		Unk		Pfizer
	Pristiq			S		Unk		Pfizer
	Efexor Xr			S		Unk		Pfizer
	Rivotril			S		Unk		Not Reported
	Lexotan			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Donaren			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2014	10357609	EXPEDITED (15-DAY)		HO	IT-TEVA-497664ISR		28 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Lorazepam Dorom			S	Oral	10 Ml Daily;		Ivax
	Entact 10 Mg			S	Oral	560 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2014	9972706	EXPEDITED (15-DAY)		HO	IT-FRI-1000060283		52 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Overdose; Sopor; Suicide Attempt	Escitalopram Oral Solution		S	Oral	Overdose : 7.5ml	Forest
	Alprazolam		S	Oral	Overdose: 1 Bottle	Not Reported
	Alprazolam		S	Oral	Overdose: About 10 Tablet	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2014	10347100	EXPEDITED (15-DAY)		HO	PHHY2014FR091196		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; International Normalised Ratio Increased	Tareg			S	Oral	40 Mg, Qd		Novartis
	Diffu K			S	Oral	3 Df, In One Hour		Not Reported
	Lasilix			S	Oral	60 Mg, Tid		Not Reported
	Tahor			S	Oral	10 Mg, Qd		Not Reported
	Cordarone			S	Oral	200 Mg, (5 Df In 7 Days)		Not Reported
	Doliprane			S	Oral	Unk Ukn, Unk		Not Reported
	Imovane			S		7.5 Mg, Qd		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg, (0.5 Df Qd)		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Seresta			C		Unk Ukn, Unk		Not Reported
	Lansoyl			C		Unk Ukn, Unk		Not Reported
	Transipeg /01618701/			C		Unk Ukn, Unk		Not Reported
	Voltarene//Diclofenac Sodium			C		Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2014	10351797	EXPEDITED (15-DAY)		HO	FR-FRI-1000069330		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Previscan (Fluindione)			S	Oral	10 Mg		Not Reported
	Novonorm			C	Oral	1 Df		Not Reported
	Cordarone			C	Oral	85.7143 Mg		Not Reported

	Lasilix	C	Oral			Not Reported
	Lercan	C	Oral	10 Mg		Not Reported
	Ideos	C	Oral			Not Reported
	Movicol	C	Oral			Not Reported
	Doliprane	C	Oral	3 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2014	10359740	EXPEDITED (15-DAY)		OT	CH-MERCK-2011SP038021		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Mirtazapine			S	Oral	15 Mg, Qd At Bedtime		Merck
	Mirtazapine			S				Merck
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2014	10360632	EXPEDITED (15-DAY)		HO	FR-FRI-1000069525		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Conduction Disorder; Confusional State; Overdose	Escitalopram			S	Oral	10 Mg		Forest
	Baclofene			S	Oral	Overdose Of 90 To 120 Mg Once		Not Reported
	Lexomil			S	Oral	6 Mg		Not Reported
	Lexomil			S	Oral	15 Mg		Not Reported
	Mianserin			S				Not Reported
	Xanax			C		On Request		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2014	10360636	EXPEDITED (15-DAY)		HO, OT	IN-FRI-1000069513		40 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drooling; Dysarthria; Extrapyramidal Disorder; Gaze Palsy; Hypokinesia	Escitalopram		S			Forest
	Clonazepam		S	0.5 Mg At Nighttime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2014	10361143	EXPEDITED (15-DAY)	Y	OT	JP-MYLAN-2014S1017594			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Lansoprazole			S	Unknown	Unk		Mylan
	Escitalopram			S	Unknown	Unk		Mylan
	Aspirin			C	Unknown	Unk		Not Reported
	Clopidogrel			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2014	10364359	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressive Symptom; Product Substitution Issue	Escitalopram			S		Lexapro 20mg Daily		Not Reported
	Cymbalta			C				Not Reported
	Lamictal			C				Not Reported
	Vyvanse			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2014	10364437	DIRECT					50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Condition Aggravated; Depression; Drug Ineffective; Panic Attack; Product Substitution Issue; Suicidal Ideation	Escitalopram			S	Oral	1 Plll Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2014	10365292	EXPEDITED (15-DAY)	Y	LT	AUR-APL-2014-08103		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Culture Positive; Cerebral Haemorrhage; Drug Interaction; Enterococcal Infection; Platelet Dysfunction; Serotonin Syndrome; Small Intestinal Obstruction; Unresponsive To Stimuli	Escitalopram 20 Mg (Escitalopram) Unknown, 20mg			S				Not Reported
	Fentanyl (Fentanyl)			S				Not Reported
	Linezolid (Linezolid)			S				Not Reported
	Trazodone (Trazodone)			S				Not Reported
	Piperacillina/Tazobactam (Piperacillin Sodium, Tazobactam Sodium)			C				Not Reported
	Vancomycin (Vancomycin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2014	10366156	EXPEDITED (15-DAY)	Y	HO, LT	JP2014K2966LIT		46 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Drug Interaction; Electrocardiogram Qt Prolonged; Sedation; Ventricular Fibrillation	Lansoprazole World (Lansoprazole) Unknown			S		Unknown Daily Dosage Unknown Rt Of Administration Unknown Therapy Date		Not Reported
	Escitalopram World (Escitalopram) Unknown			S		Unknown Daily Dosage (Route Of Administration Unknown Unknown Theraoy Dates		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2014	10280540	EXPEDITED (15-DAY)		OT	US-009507513-1407USA002407			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphoma; Nausea	Januvia			S	Oral	Dosage Form: 50 Mg, Bid		Merck
	Lorazepam			C				Not Reported
	Omeprazole			C				Merck
	Valacyclovir Hydrochloride			C				Not Reported

	Aspirin	C	Unk	Not Reported
	Lexapro	S	40	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2014	10338157	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20140710506			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Tramadol Hydrochloride			S	Unknown			Not Reported
	Fentanyl			S	Transdermal			Not Reported
	Citalopram			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Buspirone			S	Unknown			Not Reported
	Clomipramine			S	Unknown			Not Reported
	Ondansetron			S	Unknown			Not Reported
	Metoclopramide			S	Unknown			Not Reported
	Granisetron			S	Unknown			Not Reported
	Meperidine			S	Unknown			Not Reported
	Methadone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2014	10365206	EXPEDITED (15-DAY)		OT	PHHY2014KR093900		62 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Clonus; Depressed Level Of Consciousness; Dizziness; Drug Interaction; Gaze Palsy; Headache; Heart Rate Increased; Nausea; Seizure; Serotonin Syndrome; Tachycardia; Tremor; Unresponsive To Stimuli	Escitalopram	S			Not Reported
	Tramadol	S	Intramuscular	100 Mg, Unk	Not Reported
	Tramadol	S	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported
	Tramadol	S	Intravenous (not otherwise specified)	Tramadol 100 Mg And Normal Saline 100 Ml Over 10 Minutes	Not Reported
	Ketorolac	S			Novartis
	Fentanyl	S		1000 Ug, Unk	Not Reported
	Fentanyl	S	Intravenous drip	0.3 Ug/Kg/H	Not Reported
	Fentanyl	S	Intravenous bolus	0.15 Ug/Kg/H	Not Reported
	Remifentanil	C	Intravenous drip	200 Ug/Hr, Unk	Not Reported
	Propofol	C	Intravenous (not otherwise specified)	2 Mg/Kg, Unk	Not Reported
	Rocuronium	C	Intravenous (not otherwise specified)	0.8 Mg/Kg, Unk	Not Reported
	Rocuronium	C		15 Mg Was Injected Every Hour	Not Reported
	Sevoflurane	C			Not Reported
	Phenylephrine	C	Intravenous drip	80 Ug, Unk	Not Reported
	Ephedrine	C	Intravenous drip	10 Mg, Unk	Not Reported
	Normal Saline	C		950 Ml, Unk	Not Reported
	Pyridostigmine	C	Intravenous (not otherwise specified)	15 Mg, Unk	Not Reported
	Glycopyrrolate	C	Intravenous (not otherwise specified)	0.4 Mg, Unk	Not Reported
	Buspirone	C			Not Reported
	Quetiapine	C			Not Reported
	Clonazepam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2014	10365210	EXPEDITED (15-DAY)		HO, OT	CH-TEVA-498377ISR		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Sleep-Related Event; Drug Interaction; Persecutory Delusion; Serotonin Syndrome; Suspiciousness	Escitalopram	S	Unknown	[Progressively Increased]; Up To 20 Mg/Day	Ivax
	Escitalopram	S			Ivax
	Mirtazapine	S	Unknown	15 Mg/Day; At Bedtime	Teva
	Mirtazapine	S	Unknown	15 Mg/Day; At Bedtime	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2014	10365908	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000069544		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Renal Disorder; Encephalomalacia; Seizure	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2014	10365928	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000069549		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular Anomaly	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2014	10366639	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000069651		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Coma; Overdose; Thrombocytopenia	Escitalopram			S	Oral			Forest
	Topiramate			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Teralithe			S	Oral	Overdose Of An Unknown Dose Once		Not Reported
	Fluoxetine			S	Oral			Not Reported
	Clomipramine			S	Oral			Not Reported

	Alprazolam	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2014	10367596	DIRECT					35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Economic Problem; Product Substitution Issue; Therapeutic Product Effect Decreased	Lexapro			S	Oral	1 Pill Once Daily Taken By Mouth		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2014	9402596	EXPEDITED (15-DAY)		HO	FR-FRI-1000046678		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Escitalopram			S	Oral	10 Mg		Forest
	Lamictal			S	Oral	25 Mg		Not Reported
	Lamictal			S	Oral	150 Mg		Not Reported
	Kenzen			S	Oral	4 Mg		Not Reported
	Prozac			C				Not Reported
	Imovane			C	Oral	7.5 Mg		Not Reported
	Mopral			C	Oral	On Request		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2014	10367681	EXPEDITED (15-DAY)		HO	IT-FRI-1000069652		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug Interaction; Headache; Hypothyroidism; Toxicity To Various Agents;	Escitalopram			S	Oral	10 Mg		Forest
	Carbolithium			S	Oral	600 Mg		Not Reported
	Lamictal			C	Oral	25 Mg		Not Reported

Tremor	Novonorm	C	Oral	1 Mg		Not Reported
	Depakin-Chrono	C	Oral	300 Mg		Not Reported
	Lendormin	C	Oral	0.25 Mg		Not Reported
	Zocor	C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2014	10368328	NON-EXPEDITED			US-PFIZER INC-2014219225			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Headache; Nausea; Nervousness; Sluggishness	Chantix			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2014	10368782	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2014M1000121			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Platelet Dysfunction; Serotonin Syndrome	Escitalopram			S		20 Mg, Unk		Not Reported
	Trazodone			S				Not Reported
	Linezolid			S				Not Reported
	Fentanyl			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2014	10378253	EXPEDITED (15-DAY)	Y	OT	2014HINLIT0686		27 YR	Female	ARE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Engorgement; Galactorrhoea	Escitalopram (Escitalopram)			S				Not Reported
	Unknown							
	Clonazepam			C				Not Reported
	Agomelantine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2014	10374577	DIRECT					29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Activity; Depression; Loss Of Libido; Sexual Dysfunction; Suicidal Ideation	Escitalopram 20 Mg Teva			S	Oral	1 Pill Once Daily Taken By Mouth		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2014	10344942	EXPEDITED (15-DAY)	Y	DE, OT	AUR-APL-2014-07832		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Brain Oedema; Cerebral Infarction; Clonus; Coma; Condition Aggravated; Confusional State; Decerebrate Posture; Headache; Heart Rate Abnormal; Hyperreflexia; Muscle Rigidity; Posterior Reversible Encephalopathy Syndrome; Reversible Cerebral Vasoconstriction Syndrome; Subarachnoid Haemorrhage	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2014	10375654	EXPEDITED (15-DAY)		HO	IT-TEVA-499003ISR		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug Interaction; Headache;	Carbolithium 300mg			S	Oral	2 Dosage Forms Daily;		Barr

Hypothyroidism; Toxicity To Various Agents; Tremor	Cipralex 10 Mg		S	Oral	1 Dosage Forms Daily;	Not Reported
	Lamictal 25 Mg		C	Oral	1 Dosage Forms Daily;	Not Reported
	Novonorm 1 Mg		C	Oral	1 Dosage Forms Daily;	Not Reported
	Depakin Chrono 300 Mg		C	Oral	1 Dosage Forms Daily;	Not Reported
	Zocor 20 Mg		C	Oral	1 Dosage Forms Daily;	Not Reported
	Lendormin 0.25 Mg		C		1 Dosage Forms Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2014	10375689	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-LISI20140038		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Throat Irritation	Lisinopril Tablets			S	Unknown	Unk		Not Reported
	Escitalopram			S	Oral			Not Reported
	Trileptal			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2014	10376151	NON-EXPEDITED			US-ASTRAZENECA-2013SE63681		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Acne; Anxiety; Feeling Abnormal; Insomnia; Joint Swelling; Nasal Oedema; Seborrhoea	Arimidex			S	Oral			Zeneca
	Lexapro			S	Unknown			Not Reported
	Aromasin			S	Unknown			Not Reported
	Femara			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2014	10376597	NON-EXPEDITED		OT	US-FRI-1000069780		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Dizziness; Ear Discomfort;	Lexapro			S	Oral	10 Mg		Forest

Fatigue; Feeling Abnormal; Gait Disturbance; Tinnitus; Tunnel Vision

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2014	10379310	DIRECT					66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Personality Change; Product Substitution Issue	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2014	10381316	EXPEDITED (15-DAY)		OT	2014JUB00072		42 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Abuse; Anxiety; Impulsive Behaviour; Paranoia	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2014	10381331	EXPEDITED (15-DAY)	Y	LT, OT	2014JUB00071		41 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Alcoholism; Impaired Driving Ability; Imprisonment; Mania; Suicidal Ideation; Tremor	Escitalopram (Escitalopram) Unknown			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2014	10381350	EXPEDITED (15-DAY)	Y	OT	2014JUB00070		48 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcoholism; Behaviour Disorder; Decreased Interest; Disturbance In Social Behaviour	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2014	10382332	EXPEDITED (15-DAY)	Y	HO	2472796		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Enterococcal Infection; Intraventricular Haemorrhage; Pain; Platelet Count Decreased; Platelet Dysfunction; Serotonin Syndrome; Small Intestinal Obstruction	Fentanyl Citrate			S	Intravenous (not otherwise specified)	Not Otherwise Specified		Not Reported
	Linezolid			S				Not Reported
	Escitalopram			S				Not Reported
	Trazodone			S				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin And Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2014	10378719	EXPEDITED (15-DAY)			US-FRI-1000069785			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinson'S Disease	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2014	10379346	EXPEDITED (15-DAY)		HO	US-FRI-1000069797		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Platelet Dysfunction; Serotonin Syndrome	Escitalopram			S				Forest
	Linezolid			S				Not Reported
	Trazodone			S				Not Reported

	Fentanyl	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2014	10380375	DIRECT					48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Panic Attack; Product Substitution Issue	Lexapro			S	Oral	1 Pill Once Daily Taken By Mouth		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2014	10385722	EXPEDITED (15-DAY)	Y	LT, OT	2014JUB00078		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Electrocardiogram R On T Phenomenon; Hypokalaemia; Inhibitory Drug Interaction; Loss Of Consciousness; Pallor; Torsade De Pointes; Unevaluable Event; Vomiting	Escitalopram (Escitalopram)			S				Not Reported
	Tacrolimus (Tacrolimus)			S				Not Reported
	Omeprazole (Omeprazole)			S				Not Reported
	Sotalol (Sotalol)			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2014	10380954	EXPEDITED (15-DAY)		OT	JP-FRI-1000069791		72 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Lexapro			S	Oral	10 Mg		Forest
	Livalo			C	Oral	2 Mg		Not Reported
	Lipidil			C		80 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2014	10381898	EXPEDITED (15-DAY)		DS, HO, LT	NO-GLAXOSMITHKLINE-B1023176A		24 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Delusion; Depression; Incoherent; Mania; Psychotic Disorder; Substance-Induced Psychotic Disorder; Suicidal Ideation	Lamictal			S		25mg Per Day		Glaxosmithkline
	Lamictal			S	Unknown	50mg Per Day		Glaxosmithkline
	Cipralex			S		10mg Per Day		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2014	10382517	EXPEDITED (15-DAY)		OT	CA-FRI-1000069789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hallucination; Muscle Spasms; Muscle Tightness; Muscle Twitching; Nausea; Restlessness; Serotonin Syndrome; Skin Burning Sensation; Tremor; Vomiting	Escitalopram			S	Oral	5 Mg		Forest
	Effexor Xr			S	Oral	37.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2014	10382519	EXPEDITED (15-DAY)		HO	IT-FRI-1000069792		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Tachycardia	Escitalopram Oral Solution			S	Oral	Overdose: 15 Ml		Forest
	Mirtazapine			S	Oral	Overdose: 300 Mg		Not Reported
	Entact			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2014	10385004	DIRECT					26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Fat Disorder; Weight Increased	Escitalopram			S	Oral	1 Pill Once Daily Taken By Mouth		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2014	10351143	EXPEDITED (15-DAY)		DE, HO	FR-SA-2014SA100500		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; International Normalised Ratio Increased	Lasilix			S	Oral			Not Reported
	Cordarone			S	Oral	Start Date: Long Course, Dose: 1 Df, 5 In 7 Day		Not Reported
	Imovane			S	Oral	Start Date: Long Course, Dose: 1 Df, 1 In 1 Day		Not Reported
	Paracetamol			S	Oral	Start Date: Long Course		Not Reported
	Diffu K			S	Oral	Dose: 1 Df, 3 In 1 Hour		Not Reported
	Tahor			S	Oral	Start Date: Long Course, Tahor 10 Mg, Film Coated Tablet , 1 Df (1 Df , 1 In 1 Day)		Not Reported
	Previscan (Fluindione)			S	Oral	Previscan 20 Mg, Comprime Secable, Dose: 0.5 Df (0.5 Df, 1 In 1 Jour(S))		Not Reported
	Tareg			S	Oral	Start Date: Long Course		Not Reported
	Seroplex			S	Oral			Not Reported
	Oxazepam			C				Not Reported
	Oxazepam			C				Not Reported
	Lansoyl			C				Not Reported
	Doliprane			C				Not Reported
	Transipeg (Polyethylene Glycol			C				Not Reported

	3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)									
	Voltarene (Diclofenac Sodium)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2014	10384293	NON-EXPEDITED		OT	US-PFIZER INC-2014225920		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Fluconazole			S		Unk		Pfizer
	Ondansetron Hcl			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2014	10384486	EXPEDITED (15-DAY)		OT	CH-FRI-1000069788			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury; Off Label Use	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Zyprexa			S	Oral	2.5 Mg		Not Reported
	Zyprexa			S	Oral	1.25 Mg		Not Reported
	Co-Dafalgan			S	Oral	2000 Mg		Not Reported
	Voltaren			S	Oral	150 Mg		Not Reported
	Dalmadorm			C	Oral	30 Mg		Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported
	Tranxilium			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2014	10384681	EXPEDITED (15-DAY)		HO	PHHY2014IT096957		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Tachycardia	Mirtazapine			S	Oral	300 Mg, Once/Single		Novartis
	Escitalopram			S	Oral	15 Ml, Once/Single		Not Reported
	Entact			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2014	10385567	EXPEDITED (15-DAY)		DE, OT	US-BAXTER-2014BAX046552		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Culture Positive; Cerebral Haemorrhage	Vancomycin Injection, Usp			S	Unknown			Baxter
	Piperacillin-Tazobactam			S				Not Reported
	Linezolid			S	Unknown			Not Reported
	Fentanyl			S	Intravenous (not otherwise specified)			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2014	10386970	DIRECT					22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Nausea; Paraesthesia; Psychomotor Hyperactivity; Restlessness; Somnolence; Vomiting	Escitalopram			S	Oral	1 Pill Daily Once Daily Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2014	10390649	EXPEDITED (15-DAY)	Y	HO	AUR-APL-2014-08418		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Tachycardia	Mirtazapine (Mirtazapine)	S	Oral	300mg, Total, Oral		Not Reported
	Escitalopram (Escitalopram)	S	Oral	15ml, Single, Oral		Not Reported
	Entact (Escitalopram Oxalate)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2014	9931759	EXPEDITED (15-DAY)		OT	AT-JNJFOC-20140211497		48 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperprolactinaemia; Thrombophlebitis; Thrombosis; Weight Increased	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Mirtabene			S	Unknown			Not Reported
	Mirtabene			S	Unknown			Not Reported
	Mirtabene			S	Unknown	Started Since Months		Not Reported
	Mirtabene			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Doxazosin			S	Unknown			Not Reported
	Doxazosin			S	Unknown			Not Reported
	Lamictal			C	Unknown			Not Reported
	Lamictal			C	Unknown			Not Reported
	Lamictal			C	Unknown			Not Reported
	Lamictal			C	Unknown			Not Reported
	Sertraline			C	Unknown			Not Reported
	Sertraline			C	Unknown			Not Reported
	Cipralex			C	Unknown			Not Reported
	Cipralex			C	Unknown			Not Reported
	Cipralex			C	Unknown			Not Reported

Cipralex	C	Unknown			Not Reported
Rivotril	C	Unknown			Not Reported
Folsan	C	Unknown	Started Since Months		Not Reported
Folsan	C	Unknown			Not Reported
Nomexor	C	Unknown	Started Since Months		Not Reported
Ebrantil	C	Unknown	Started Since Months		Not Reported
Exforge	C	Unknown	5/160 Mg Since Months		Not Reported
Exforge	C	Unknown	10/160mg		Not Reported
Fungoral	C	Unknown			Not Reported
Fungoral	C	Unknown			Not Reported
Ultrabase	C	Unknown	If Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2014	10357085	EXPEDITED (15-DAY)		HO, OT	FR-FRI-1000069495			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2014	10362868	EXPEDITED (15-DAY)		HO, OT	CH-FRI-1000069579			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Overdose; Pregnancy	Escitalopram			S	Oral	Overdose: 25 Mg Daily		Forest
	Escitalopram			S	Oral	8 Mg Daily		Forest
	Tramal			S		450 Mg		Not Reported
	Tramal			S		220 Mg Daily		Not Reported
	Zaldiar			S	Oral			Not Reported
	Stilnox			C		10 Mg		Not Reported
	Heptaminol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2014	10387209	EXPEDITED (15-DAY)		HO	FR-FRI-1000069874		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypochloraemia; Hyponatraemia	Escitalopram			S	Oral	10 Mg		Forest
	Cotareg 80 Mg / 12.5 Mg			S	Oral	1 Df		Not Reported
	Glucophage			C	Oral	1700 Mg		Not Reported
	Coveram 10/10 Mg			C	Oral	1 Df		Not Reported
	Diffu K			C	Oral	1 Df		Not Reported
	Tiorfan			C	Oral	2 Df		Not Reported
	Mineral			C				Not Reported
	Multi Vitamin			C				Not Reported
	Lasilix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2014	10387415	EXPEDITED (15-DAY)		HO, LT, OT	FR-ELI_LILLY_AND_COMPANY-FR201408002852		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Coma; Hypernatraemia; Hypotension; Loss Of Consciousness; Miosis; Polyuria; Septic Shock; Thrombocytopenia	Zyprexa			S	Oral	Unk, Unknown		Unknown
	Fluoxetine Hydrochloride			S	Oral	Unk, Unknown		Not Reported
	Topiramate			S	Oral	Unk, Unknown		Not Reported
	Teralithe			S	Oral	Unk, Unknown		Not Reported
	Seroplex			S	Oral	Unk, Unknown		Not Reported
	Clomipramine Hydrochloride			S	Oral	Unk, Unknown		Not Reported
	Alprazolam			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2014	10388228	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-B1023874A		182 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cyanosis; Exposure Via Breast Milk; Sleep Disorder; Somnolence; Somnolence; Staring; Tonic Convulsion; Unresponsive To Stimuli; Vomiting	Bupropion		S	Unknown	150mg Per Day	Glaxosmithkline
	Escitalopram		S	Unknown	10mg Per Day	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2014	10393138	EXPEDITED (15-DAY)	Y	HO	2014HINLIT0696		46 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Myocardial Infarction; Ventricular Fibrillation	Escitalopram (Escitalopram) Unknown			S				Not Reported
	Lansoprazole (Lansoprazole)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2014	10395191	DIRECT		OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2014	10395819	DIRECT		OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased	Lexapro 10 Mg Accord Healthcare			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2014	10434732	NON-EXPEDITED	Y		2014TUS004560		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pruritus	Brintellix (Vortioxetine) Tablet		S	Oral	Not Reported
	Lexapro (Escitalopram Oxalate)		S	Oral	Not Reported
	Lamictal (Lamotrigine)		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2014	10434927	NON-EXPEDITED			2014TUS002630		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Disturbance In Attention; Feeling Of Despair; Headache	Brintellix (Vortioxetine) Tablet			S	Oral			Not Reported
	Escitalopram			S	Oral Oral Oral Oral			Not Reported
	Trazodone (Trazodone)			C				Not Reported
	Prempro (Estrogens Conjugated, Medroxyprogesterone Acetate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2014	10388776	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2014-01272			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2014	10142089	EXPEDITED (15-DAY)		HO	PHHY2014CA049304		93 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Fall; Fatigue; Hyponatraemia; Orthostatic Hypotension; Osteoporosis; Poor Quality Sleep	Metoprolol			S		50 Mg, Per Day		Novartis
	Metoprolol			S		25 Mg, Per Day		Novartis
	Metoprolol			S		12.5 Mg, Per Day		Novartis
	Pantoprazole			S		40 Mg, Bid		Not Reported
	Escitalopram			S		10 Mg, Per Day		Not Reported

	Escitalopram	S	5 Mg, Per Day	Not Reported
	Telmisartan	S	80 Mg, Per Day	Not Reported
	Telmisartan	S	40 Mg, Daily	Not Reported
	Telmisartan	S	20 Mg, Daily	Not Reported
	Prednisone	S	5 Mg, Bid	Not Reported
	Prednisone	S	7.5 Mg, Qd	Not Reported
	Lorazepam	S	1 Mg, At Bedtime	Not Reported
	Lorazepam	S	0.5 Mg, Unk	Not Reported
	Lorazepam	S	0.25 Mg, Unk	Not Reported
	Loperamide	C	1 Mg, As Needed	Not Reported
	Tamsulosin	C	0.4 Mg, At Bedtime	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2014	10391018	EXPEDITED (15-DAY)		HO	IT-WATSON-2014-17697		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Tachycardia	Mirtazapine (Unknown)			S	Oral	300 Mg, Unk		Watson
	Escitalopram (Unknown)			S	Oral	15 Ml, Unk		Not Reported
	Entact			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2014	10391479	EXPEDITED (15-DAY)		HO	IN-FRI-1000069919		63 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram			S		5 Mg		Forest
	Escitalopram			S		10 Mg		Forest
	Olanzapine			S		5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2014	10391480	EXPEDITED (15-DAY)		HO	CA-TEVA-502067USA			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Diarrhoea; Fall; Hyponatraemia; Orthostatic Hypotension; Sedation Complication; Skin Laceration; Vitamin B12 Deficiency; Vitamin D Deficiency	Pantoprazole			S	Unknown			Teva
	Metoprolol			S	Unknown	50mg/Day		Teva
	Telmisartan			S	Unknown	80mg/Day		Not Reported
	Lorazepam			S	Unknown	1mg At Bedtime As Needed		Not Reported
	Escitalopram			S				Not Reported
	Tamsulosin			C	Unknown	0.4mg At Bedtime		Not Reported
	Prednisone			C	Unknown			Not Reported
	Loperamide			C	Unknown	1mg As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2014	10391481	EXPEDITED (15-DAY)		OT	US-FRI-1000069859			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder	Lexapro Oral Solution			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2014	10391516	EXPEDITED (15-DAY)		DE	BE-FRI-1000069917		50 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2014	10391544	EXPEDITED (15-DAY)		DE	BE-FRI-1000069935		30 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2014	10395983	EXPEDITED (15-DAY)	Y	HO	2014AP003905		93 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Diarrhoea; Fall; Hyponatraemia; Orthostatic Hypotension; Skin Laceration; Somnolence; Vitamin D Deficiency	Pantoprazole (Pantoprazole) Unknown			S				Not Reported
	Apo-Telmisartan (Telmisartan) Tablet			S				Not Reported
	Apo-Metoprolol (Metoprolol) Tablet			S				Not Reported
	Apo-Lorazepam (Lorazepam) Tablet			S				Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Tamsulosin (Tamsulosin)			C				Not Reported
	Prednisone (Prednisone)			C				Not Reported
	Loperamide (Loperamide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2014	10396552	EXPEDITED (15-DAY)	Y	HO	2014JUB00087		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Drug Interaction; Serotonin Syndrome	Escitalopram (Escitalopram) Unknown			S			122 DAY	Not Reported
	Mirtazapine (Mirtazapine)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2014	10399250	DIRECT					68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Tinnitus	Escitalopram			S	Oral	1 Tablet Daily Once Daily Taken By Mouth		Pharmacy Benefits Manager (Pbm)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2014	10351390	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC-2014207726		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Cardiac Failure; Hepatitis; Incorrect Route Of Product Administration; Infection; International Normalised Ratio Increased; Overdose	Tahor			S	Oral	10 Mg, 1x/Day		Pfizer
	Cordarone			S	Oral	1000 Mg, Weekly (1 Df (200mg) 5 Times Weekly)		Pfizer
	Lasilix			S	Oral	60 Mg, 3x/Day		Not Reported
	Diffu K			S	Oral	1 Df, 3x/Day		Not Reported
	Paracetamol Arrow			S	Oral	1 G, As Needed (3 G Daily Maximum)		Not Reported
	Imovane			S	Oral	1 Df, Daily		Not Reported
	Previscan (Fluindione)			S	Oral	10 Mg, Daily		Not Reported
	Tareg			S	Oral	40 Mg, Daily		Not Reported
	Seroplex			S	Oral	10 Mg, Daily		Not Reported
	Seresta			C		Unk		Not Reported
	Lansoyl			C		Unk		Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C		Unk		Not Reported
	Voltarene (Diclofenac Sodium)			C		Unk		Not Reported
	Doliprane			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2014	10357099	EXPEDITED (15-DAY)		HO	FR-FRI-1000069499		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; International Normalised Ratio Increased	Escitalopram			S	Oral	10 Mg		Forest
	Lasilix			S	Oral	180 Mg		Not Reported
	Diffu K			S	Oral	72 Df		Not Reported
	Tahor			S	Oral	10 Mg		Not Reported

Cordarone	S	Oral	0.7143 Df		Not Reported
Paracetamol Arrow	S	Oral			Not Reported
Imovane	S	Oral	1 Df		Not Reported
Previscan (Fluindione)	S	Oral	0.5 Df		Not Reported
Tareg	S	Oral	40 Mg		Not Reported
Seresta	C				Not Reported
Lansoyl	C				Not Reported
Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)	C				Not Reported
Voltarene (Diclofenac Sodium)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2014	10393216	EXPEDITED (15-DAY)		HO	FR-FRI-1000069955		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction	Escitalopram			S	Oral	5 Mg		Forest
	Coumadine			S	Oral	9 Mg		Not Reported
	Lovenox			S	Subcutaneous	1.4 Ml		Not Reported
	Diltiazem Lp			C		300 Mg		Not Reported
	Xanax			C		0.75		Not Reported
	Omeprazole			C		20 Mg		Not Reported
	Digoxine			C		0.125 Mg		Not Reported
	Aprovel			C		150 Mg		Not Reported
	Temerit			C		5 Mg		Not Reported
	Doliprane			C		4 Gram		Not Reported
	Topalgic Lp			C		300 Mg		Not Reported
	Lasilix			C		60 Mg		Not Reported
	Diffu K			C		4800 Mg		Not Reported

Lyrica	C	50 Mg		Not Reported
Laroxyl	C	15 Gtt		Not Reported
Imovane	C	7.5 Mg		Not Reported
Gaviscon	C			Not Reported
Motilium	C			Not Reported
Econazole	C	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2014	10394086	EXPEDITED (15-DAY)		HO	FR-FRI-1000069958		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Pneumonia Aspiration	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	Overdose Nos.		Not Reported
	Alprazolam			S	Oral	0.75 Mg		Not Reported
	Alprazolam			S	Oral	Overdose Nos.		Not Reported
	Zopiclone			S	Oral	1 Df		Not Reported
	Zopiclone			S	Oral	Overdose Nos.		Not Reported
	Tercian			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2014	10398425	EXPEDITED (15-DAY)	Y	HO, OT	2014AP003976		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Suicide Attempt; Torsade De Pointes	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2014	10399370	EXPEDITED (15-DAY)	Y	HO, OT	AUR-APL-2014-08671		40 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradykinesia; Dysarthria; Dysarthria; Extrapyramidal Disorder; Hypokinesia; Oculogyric Crisis; Protrusion Tongue; Salivary Hypersecretion	Escitalopram	S	5 Mg, Once A Day, Unknown	Not Reported
	Clonazepam (Clonazepam)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2014	10035877	EXPEDITED (15-DAY)		OT	AT-FRI-1000060279			Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Dizziness; Dry Mouth	Escitalopram			S		10 Mg		Forest
	Escitalopram			S		20 Mg		Not Reported
	Escitalopram			S		10 Mg		Not Reported
	Valdoxan			S		25 Mg		Not Reported
	Valdoxan			S		50 Mg		Not Reported
	Valdoxan			S		25 Mg		Not Reported
	Lyrica			S		150 Mg		Not Reported
	Trittico			S		100 Mg		Not Reported
	Trittico			S		150 Mg		Not Reported
	Seroquel			S		100 Mg		Not Reported
	Seroquel			S		150 Mg		Not Reported
	Seroquel			S		200 Mg		Not Reported
	Seroquel			S		200 Mg		Not Reported
	Seroquel			S		300 Mg		Not Reported
	Seroquel			S		400 Mg		Not Reported
	Cymbalta			S		30 Mg		Not Reported
	Cymbalta			S		60 Mg		Not Reported
	Cymbalta			S		120 Mg		Not Reported
	Dominal (Prothipendyl Hydrochloride)			C		80 Mg		Not Reported
	Dominal (Prothipendyl			C		40 Mg		Not Reported

Hydrochloride)			
Zoldem	C	10 Mg	Not Reported
Zoldem	C	10 Mg	Not Reported
Rivotril	C	0.5 Mg	Not Reported
Rivotril	C	1 Mg	Not Reported
Rivotril	C	1.75 Mg	Not Reported
Rivotril	C	1.25 Mg	Not Reported
Rivotril	C	2.75 Mg	Not Reported
Rivotril	C	2.5 Mg	Not Reported
Sirdalud	C	2 Mg	Not Reported
Thromboass	C	100 Mg	Not Reported
Tolvon	C	60 Mg	Not Reported
Tolvon	C	30 Mg	Not Reported
Tolvon	C	60 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2014	10166903	EXPEDITED (15-DAY)	Y	HO	VAL_03094_2014		93 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Diarrhoea; Dizziness; Fall; Fatigue; Hyponatraemia; Mobility Decreased; Orthostatic Hypotension; Somnolence; Vitamin B12 Deficiency; Vitamin D Deficiency	Metoprolol Tartrate			S		2 Weeks 0 Days Not Continuing 1 Week 1 Cays Until Not Continuing		Not Reported
	Pantoprazole			S		Until Not Continuing		Not Reported
	Telmisartan			S				Not Reported
	Escitalopram			S		Until Not Continuing		Not Reported
	Lorazepam			S		Bedtime 0.5mg At Bedtime 2 Weeks 0 Days Until Not Continuig 0.25mg At Bedtime 2 Weeks 0 Days Until Not Continuing		Not Reported

Tamsulosin	C				Not Reported
Prednisolone	C				Not Reported
Loperamide	C				Not Reported
Prednisone	S	Unknown Until Not Continuing Unknown Util Cotinuing			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2014	10395489	EXPEDITED (15-DAY)	Y	HO	CA-MYLANLABS-2014M1001725			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Diarrhoea; Dizziness; Fall; Hyponatraemia; Orthostatic Hypotension; Sedation Complication; Skin Laceration; Vitamin B12 Deficiency; Vitamin D Deficiency	Escitalopram			S	Unknown	10mg/Day		Mylan
	Pantoprazole			S	Unknown			Not Reported
	Pantoprazole			S				Not Reported
	Telmisartan			S	Unknown	80mg/Day		Not Reported
	Metoprolol			S	Unknown	50mg/Day		Not Reported
	Lorazepam			S	Unknown	1mg At Bedtime As Needed		Mylan
	Tamsulosin			C	Unknown	0.4mg At Bedtime		Not Reported
	Prednisone			C	Unknown			Not Reported
	Loperamide			C	Unknown	1mg As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2014	10395790	EXPEDITED (15-DAY)		DE	MX-FRI-1000070012		75 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2014	10395917	EXPEDITED (15-DAY)		OT	CH-FRI-1000070017		< 1 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Foetal Macrosomia; Hypoglycaemia Neonatal	Escitalopram	S	Transplacental	20 Mg		Forest
	Abilify	S	Transplacental			Not Reported
	Topamax	S	Transplacental	100 Mg		Not Reported
	Temesta (Lorazepam)	S	Transplacental	3 Mg		Not Reported
	Seroquel	S	Transplacental	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2014	10395927	EXPEDITED (15-DAY)		OT	CH-FRI-1000070015			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Pregnancy	Escitalopram			S		10 Mg		Forest
	Abilify			S				Not Reported
	Topamax			S		100 Mg		Not Reported
	Temesta (Lorazepam)			S				Not Reported
	Seroquel			S		200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2014	10397144	EXPEDITED (15-DAY)		DE, LT	FR-FRI-1000070013		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhagic Stroke; International Normalised Ratio Increased	Escitalopram			S				Forest
	Previscan (Fluindione)			S				Not Reported
	Atorvastatin			S				Not Reported
	Kardegic			S				Not Reported
	Metoprolol			C				Not Reported
	Janumet			C				Not Reported
	Irbesartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2014	10397444	EXPEDITED (15-DAY)		CA	US-FRI-1000070004		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2014	10399066	EXPEDITED (15-DAY)		HO, LT, OT	US-ACTAVIS-2014-17801		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Intentional Overdose; Lethargy; Sinus Bradycardia; Vomiting	Escitalopram (Unknown)			S	Oral	500 Mg, Single		Not Reported
	Escitalopram (Unknown)			S				Not Reported
	Tramadol Hydrochloride And Acetaminophen 37.5/325mg (Watson) (Tramadol Hydrochloride Acetaminophen)			S	Oral	Unk, 25 Tablets		Watson
	Hydrocodone-Acetaminophen (Watson Laboratories)			S	Oral	Unk		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2014	10400950	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2014-0112476		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Sovaldi			S	Oral	400 Mg, Unk		Gilead
	Olysio			C		Unk		Not Reported
	Aspirin /00002701/			S	Oral	81 Mg, Unk		Not Reported
	Procardia /00340701/			S	Oral	10 Mg, Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Unk		Not Reported
	Prilosec /00661201/			S	Oral	40 Mg, Unk		Not Reported
	Multivitamin /07504101/			S	Unknown			Not Reported
	Miralax /00754501/			C				Not Reported
	Megaoxiod			C				Not Reported
	Valtrax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2014	8806652	EXPEDITED (15-DAY)		DE, HO	US-BRISTOL-MYERS SQUIBB COMPANY-15274749		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death; Deep Vein Thrombosis; Hyponatraemia	Ipilimumab	S	Intravenous (not otherwise specified)	No Of Courses: 02	Not Reported
	Lexapro	S			Not Reported
	Diovan Hct	C			Not Reported
	Enablex	C			Not Reported
	Flomax	C			Not Reported
	Aspirin	C			Not Reported
	Coreg	C			Not Reported
	Lanoxin	C			Not Reported
	Amaryl	C			Not Reported
	Lasix	C			Not Reported
	Ultram	C			Not Reported
	Zestril	C			Not Reported
	Nexium	C			Not Reported
	K-Dur	C			Not Reported
	Lortab	C			Not Reported
	Oxy-Ir	C			Not Reported
	Lipitor	C			Not Reported
	Losec	C			Not Reported
	Glyburide	C			Not Reported
	Fibercon	C			Not Reported
	Coumadin	C			Not Reported
	Lexapro	C			Not Reported
	Duragesic	C			Not Reported
	Lortab	C			Not Reported
	Digoxin	C			Not Reported
	Tramadol	C		Er	Not Reported
	Carvedilol	C			Not Reported
	Hydrochlorothiazide\Valsartan	C			Not Reported
	Darifenacin Hydrobromide	C			Not Reported
	Tamsulosin Hcl	C			Not Reported
	Glimepiride	C			Not Reported
	Furosemide	C			Not Reported
	Escitalopram Oxalate	C			Not Reported
	Apap	C		1df=500 Unit Not Given.	Not Reported
	Hydrocodone	C		1df=1df=7.5 Unit Not Given.	Not Reported
	Atorvastatin Calcium	C			Not Reported
	Lisinopril	C			Not Reported
	Oxycodone	C			Not Reported

	Potassium	C	Not Reported
	Warfarin Sodium	C	Not Reported
	Esomeprazole Magnesium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2014	10290501	NON-EXPEDITED		HO	US-JNJFOC-20140701713		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Dementia; Depression; Device Issue; Encephalopathy; Gait Inability; Headache; Loss Of Personal Independence In Daily Activities; Pseudodementia; Toxicity To Various Agents; Vomiting	Topamax			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2014	10401111	EXPEDITED (15-DAY)		OT	IN-ACCORD-025469		24 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Escitalopram			S				Accord
	Clonazepam			C		Drug Was Tapered Off Over 2 Weeks.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2014	10402513	NON-EXPEDITED			US-PFIZER INC-2014231984		70 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Tramadol Hcl			S		Unk		Pfizer
	Albuterol			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported

Dilaudid	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Paxil	S	Unk	Not Reported
Risperdal	S	Unk	Not Reported
Trazodone	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2014	10402680	EXPEDITED (15-DAY)		OT	AU-FRI-1000070041		68 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Periorbital Oedema; Rash Pruritic	Escitalopram			S		10 Mg		Forest
	Aspirin			C				Not Reported
	Atenolol			C				Not Reported
	Celecoxib			C				Not Reported
	Omeprazole			C				Not Reported
	Spironolactone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2014	10405830	DIRECT	Y				17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Product Substitution Issue	Escitalopram 10mg Aurobiudo Pharma			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2014	10409791	EXPEDITED (15-DAY)	Y	HO, OT	AUR-APL-2014-08808		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Electrocardiogram Qt Prolonged; Lethargy; Long Qt Syndrome Congenital; Overdose; Suicide	Escitalopram (Escitalopram) Unknown			S				Not Reported

Attempt; Torsade De Pointes

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2014	10405649	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002269			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Deformity	Escitalopram Tablets Usp 5mg			S				Lupin
	Escitalopram Tablets Usp 5mg			S				Lupin
	Vyvanse			C	Unknown			Not Reported
	Vyvanse			C				Not Reported
	Klonopin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2014	10405697	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002293			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Escitalopram Tablets Usp 10mg			S				Lupin
	Escitalopram Tablets Usp 10mg			S				Lupin
	Femring			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2014	10407152	EXPEDITED (15-DAY)		HO	US-GLAXOSMITHKLINE-A1086280A			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Ill-Defined Disorder	Lamictal			S	Unknown			Glaxosmithkline
	Lamotrigine			S	Unknown			Glaxosmithkline
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2014	10407620	NON-EXPEDITED			US-PFIZER INC-2014236167		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Lexapro.Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2014	10407954	EXPEDITED (15-DAY)		DE, OT	US-ASTRAZENECA-2014SE62905		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Headache	Prilosec			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Procardia Xl			S	Oral			Not Reported
	Sovaldi			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Multivitamin			S	Unknown			Not Reported
	Olysio			C				Not Reported
	Miralax			C				Not Reported
	Megaoxiod			C				Not Reported
	Valtrax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2014	10410321	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2014234493		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Headache	Procardia Xl			S	Oral	10 Mg, Unk		Pfizer
	Aspirin			S	Oral	81 Mg, Unk		Not Reported
	Sovaldi			S	Oral	400 Mg, Unk		Not Reported

	Lexapro	S	Oral	10 Mg, Unk		Not Reported
	Prilosec	S	Oral	40 Mg, Unk		Not Reported
	Olysio	C		Unk		Not Reported
	Miralax	C		Unk		Not Reported
	Valtrax	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2014	10416776	EXPEDITED (15-DAY)	Y	OT	US-H14001-14-00423		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Enterococcus Test Positive; Intraventricular Haemorrhage; Liver Transplant; Platelet Count Decreased; Platelet Dysfunction; Serotonin Syndrome; Small Intestinal Obstruction	Fentanyl (Fentanyl)			S	Intravenous (not otherwise specified)			Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Trazodone (Trazodone)			S				Not Reported
	Linezolid (Linezolid)			C				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin-Tazobactam (Pip/Tazo)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2014	10388123	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2014223785		76 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lyrica			S	Oral	75 Mg, 1x/Day		Pfizer
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported
	Carvedilol			C	Oral	12.5 Mg, 2x/Day		Not Reported
	Omeprazole			C	Oral	20 Mg, 1x/Day		Not Reported
	Atorvastatin			C	Oral	20 Mg, 1x/Day		Not Reported
	Tamsulosin			C	Oral	Unk		Not Reported
	Furosemide			C	Oral	40 Mg, 1x/Day		Not Reported
	Allopurinol			C	Oral	100 Mg, 1x/Day		Not Reported

	Losartan	C	Oral	50 Mg, 1x/Day		Not Reported
	Adiro	C		100 Mg, 1x/Day		Not Reported
	Orfidal	C	Oral	1 Mg, 1x/Day		Not Reported
	Sintrom	C	Oral	Unk		Not Reported
	Xalacom	C	Ophthalmic	1 Drop 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2014	10411430	NON-EXPEDITED		HO	IN-LUPIN PHARMACEUTICALS INC.-2014-01441		63 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Olanzapine			S	Unknown	5mg		Not Reported
	Escitalopram			S	Unknown	5mg		Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2014	10411662	EXPEDITED (15-DAY)		HO	FR-MERCK-1408FRA012897		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia; Poisoning Deliberate; Somnolence; Tachycardia	Norset			S	Oral	16 Df, Once		Merck
	Paracetamol			S	Oral	8000 Mg, Once		Not Reported
	Tercian			S	Oral	16 Df, Once		Not Reported
	Seroplex			S	Oral	4 Df, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2014	10412702	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2014SE62593		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Fall; Hyponatraemia	Inexium			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported

Furosemide	S	Oral		Not Reported
Coversyl	S	Oral		Not Reported
Amlor	C	Oral		Not Reported
Pravastatine	C	Oral		Not Reported
Stresam	C	Oral		Not Reported
Xanax	C	Oral		Not Reported
Zyprexa	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2014	10413251	EXPEDITED (15-DAY)		OT	SE-FRI-1000070207		25 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Personality Change; Suicidal Ideation	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	Dose Reduced		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2014	10413993	EXPEDITED (15-DAY)		HO	FR-FRI-1000070144		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pruritus; Rash Scarlatiniform	Escitalopram			S	Oral	5 Mg		Forest
	Alprazolam			S	Oral	0.25 Mg		Not Reported
	Atarax			S	Oral	25 Mg		Not Reported
	Kardegic			C	Oral			Not Reported
	Olmetec			C				Not Reported
	Tahor			C	Oral			Not Reported
	Imovane			C	Oral			Not Reported
	Lansoyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2014	10415930	DIRECT		OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery	Lexapro Generic 10mg			S	Oral			Mylan
	Lexapro Generic 10mg			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2014	10418427	EXPEDITED (15-DAY)	Y	DE, OT	2014JUB00090		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Platelet Disorder; Serotonin Syndrome	Escitalopram (Escitalopram)			S				Not Reported
	Unknown							
	Trazodone (Trazodone)			S				Not Reported
	Fentanyl (Fentanyl)			S	Intravenous (not otherwise specified)			Not Reported
	Linezolid (Linezolid)			S				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2014	10419495	EXPEDITED (15-DAY)	Y	OT	2014HINLIT0719		24 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea; Hyperprolactinaemia	Escitalopram (Escitalopram)			S				Not Reported
	Unknown							
	Clonazepam (Clonazepam)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2014	10419511	EXPEDITED (15-DAY)		OT	AUR-APL-2014-08982		62 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Balance Disorder; Condition Aggravated; Dizziness; Exposure During Pregnancy; Foetal Growth Restriction; Hypoglycaemia; Myalgia; Vertigo	Escitalopram 10 Mg (Escitalopram)Unknown, 10mg	S	Oral	Not Reported
	Fluoxetine (Fluoxetine)	C		Not Reported
	Glucosamine (Glucosamine)	C		Not Reported
	Lamotrigine (Lamotrigine)	C		Not Reported
	Trazodoone (Trazodone)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2014	8952274	EXPEDITED (15-DAY)		HO	US-009507513-1211USA011531		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urosepsis	Temozolomide			S	Oral	320 Mg, Days 1-5 Of Repeated 28 Day Cycles		Merck
	Study Drug (Unspecified)			S		0.8 Unk, Unk		Not Reported
	Pantoprazole			C				Not Reported
	Haloperidol			C				Not Reported
	Enoxaparin Sodium			C				Not Reported
	Ceftriaxone Sodium			C				Not Reported
	Vancomycin			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Celecoxib			C				Not Reported
	Citalopram			C				Not Reported
	Codeine			C				Not Reported
	Prednisone			C				Merck
	Alprazolam			C				Not Reported
	Fluconazole			C				Not Reported
	Acyclovir			C				Not Reported
	Clindamycin			C				Not Reported
	Gabapentin			C				Not Reported
	Levetiracetam			C				Not Reported
	Heparin			C				Not Reported
	Sodium Chloride			C				Not Reported
	Acetaminophen			C				Not Reported
	Nystatin			C				Not Reported
	Ondansetron			C				Not Reported
	Phenytoin			C				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2014	10416105	EXPEDITED (15-DAY)		HO	NL-FRI-1000070241			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrasystoles	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2014	10416184	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000070202		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delusion; Drug Interaction; Extrapyramidal Disorder; Hyperhidrosis; Hypertension; Myoclonus; Serotonin Syndrome	Escitalopram			S	Oral	5 Mg		Forest
	Effexor Lp			S	Oral	37.5 Mg		Not Reported
	Tramadol			S	Oral	200 Mg		Not Reported
	Anastrozole			C				Not Reported
	Noroxine			C				Not Reported
	Lexomil Roche			C	Oral			Not Reported
	Dafalgan			C				Not Reported
	Fumafer			C				Not Reported
	Speciafoldine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2014	10417036	EXPEDITED (15-DAY)		CA	US-FRI-1000070118		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Jaw Malformation; Talipes; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2014	10418087	EXPEDITED (15-DAY)		HO	AU-009507513-1408AUS015411		74 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aphasia; Confusional State; Hemiparesis; Syncope	Sitagliptin Phosphate (+) Metformin Hydrochloride	S	Oral	Unk		Merck
	Atorvastatin	S		Unk		Not Reported
	Digoxin	S		Unk		Not Reported
	Escitalopram	S		Unk		Not Reported
	Irbesartan	S		Unk		Not Reported
	Pantoprazole	S		Unk		Not Reported
	Solifenacin Succinate	S		Unk		Not Reported
	Strontium Ranelate	S		2 G, Daily		Not Reported
	Warfarin Sodium	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2014	10418104	EXPEDITED (15-DAY)		OT	GB-FRI-1000070286		62 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Balance Disorder; Condition Aggravated; Dizziness; Myalgia; Vertigo	Escitalopram			S	Oral	10 Mg Daily		Forest
	Fluoxetine			C				Not Reported
	Glucosamine			C				Not Reported
	Lamotrigine			C				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2014	10419314	EXPEDITED (15-DAY)		DE	US-BAYER-2014-126461		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Headache; Product Use In Unapproved Indication	Bayer Aspirin Regimen Adult Low Strength		Y	S	Oral	81 Mg Daily, Unk		Bayer
	Procardia			S	Oral	10 Mg, Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Unk		Not Reported
	Prilosec			S	Oral	40 Mg, Unk		Not Reported
	Multivitamins			S		Unknonwn		Not Reported
	Miralax			C				Not Reported
	Valtrax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2014	10421172	EXPEDITED (15-DAY)		HO, LT	FR-AUROBINDO-AUR-APL-2014-09124		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delusion; Drug Interaction; Extrapyramidal Disorder; Hyperhidrosis; Hypertension; Myoclonus; Serotonin Syndrome	Tramadol			S	Oral	100 Mg, Two Times A Day		Aurobindo
	Effexor			S	Oral	37.5 Mg, Once A Day		Not Reported
	Seroplex			S	Oral	5 Mg, Once A Day		Not Reported
	Anastrozole			C	Unknown	Unk		Not Reported
	Noroxin			C	Unknown	400 Mg, Unk		Not Reported
	Lexomil			C	Unknown	Unk		Not Reported
	Dafalgan			C	Unknown	Unk		Not Reported
	Fumafer			C	Unknown	Unk		Not Reported
	Speciafoldine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2014	10381446	NON-EXPEDITED			US-PFIZER INC-2014184988		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Pain; Pain In Extremity; Restless Legs Syndrome	Lyrica			S	Oral	200 Mg, 3x/Day		Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Mirapex			C		Unk		Not Reported
	Klonopin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2014	10426958	DIRECT		DS			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder	Escitalopram 10mg/20 Mg			S	Oral	1 10 Mg And 1 20 Mg Once Daily Taken By Mouth Duration: 1 1/2	1.5 YR	Not Reported

Years

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2014	10429852	DIRECT		HO, LT, OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Pulmonary Embolism	Lexapro			S	Oral	10 Mg Halved 1/2 Table/ 6 Days Once A Day By Mouth		Forest
	Vitamin D Nos			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Vitamin D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2014	10425844	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2014-09290		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Aurobindo
	Methylene Blue			S	Unknown	1 Mg/Kg, In 2 Consecutive Doses (Total Of 2mg/Kg)		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Lamotrigine			C	Unknown	Unk		Not Reported
	Salbutamol W/Ipratropium			C	Unknown	Unk		Not Reported
	Nitroglycerin			C	Sublingual	Unk, As Needed		Not Reported
	Lisinopril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2014	10427340	EXPEDITED (15-DAY)		DE	US-FRI-1000070255		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Headache	Lexapro			S	Oral	10 Mg		Forest
	Sovaldi			S	Oral	400 Mg		Not Reported
	Aspirin			S	Oral	81 Mg		Not Reported
	Procardia Xl			S	Oral	10 Mg		Not Reported
	Prilosec			S	Oral	40 Mg		Not Reported
	Multivitamin			S				Not Reported
	Olysio			C				Not Reported
	Miralax			C				Not Reported
	Megaoxiod			C				Not Reported
	Valtrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2014	10427864	EXPEDITED (15-DAY)		CA	US-FRI-1000070233		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly; Patent Ductus Arteriosus; Right Ventricular Hypertrophy; Supraventricular Tachycardia; Wolff-Parkinson-White Syndrome	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2014	10430636	DIRECT		OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Condition Aggravated; Depression; Disturbance In Attention; Dyskinesia; Feeling Abnormal; Impaired	Escitalopram 10 Mg Teva			S	Oral	1.5 Pills, Once Daily, Taken By Mouth		Teva

Driving Ability; Insomnia;
Product Substitution Issue;
Restless Legs Syndrome;
Restlessness

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2014	10154009	EXPEDITED (15-DAY)		HO	CA-RANBAXY-2014US-80901		93 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Fall; Fatigue; Hyponatraemia; Off Label Use; Orthostatic Hypotension; Osteoporosis; Poor Quality Sleep; Vitamin B12 Deficiency; Vitamin D Deficiency	Pantoprazole			S	Unknown	40 Mg, Bid		Ranbaxy
	Metoprolol			S	Unknown	Dose Decreased To 25 Mg, Qd		Ipca
	Metoprolol			S	Unknown	Dose Decreased To 12.5 Mg, Qd		Ipca
	Metoprolol			S	Unknown	12.5 Mg, Qd		Ipca
	Escitalopram (Ngx)			S	Unknown	Dose Decreased To 5 Mg, Qd		Not Reported
	Escitalopram (Ngx)			S	Unknown	5 Mg, Qd		Not Reported
	Lorazepam (Ngx) (Lorazepam) Unknown			S	Unknown	1 Mg At Bedtime; Dose Decreased To 0.5 Mg		Not Reported
	Lorazepam (Ngx) (Lorazepam) Unknown			S	Unknown	0.5 Mg; Dose Decreased To 0.25 Mg		Not Reported
	Lorazepam (Ngx) (Lorazepam) Unknown			S	Unknown	0.25 Mg		Not Reported
	Prednisone (Ngx) (Prednisone) Unknown			S	Unknown	Dose Decreased To 7.5 Mg, Qd		Not Reported
	Prednisone (Ngx) (Prednisone) Unknown			S	Unknown	Dose Increased To 5 Mg, Bid		Not Reported
	Telmisartan (Ngx)			S	Unknown	Dose Decreased To 40 Mg, Qd		Not Reported
	Telmisartan (Ngx)			S	Unknown	Dose Decreased To 20 Mg, Qd		Not Reported
	Telmisartan (Ngx)			S	Unknown	20 Mg, Qd		Not Reported
	Loperamide			C	Unknown	1 Mg, Prn		Not Reported

	Tamsulosin Cr		C	Unknown	0.4 Mg, Qd; At Bedtime	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2014	10429577	EXPEDITED (15-DAY)		HO	CA-EISAI INC-E3810-07388-SPO-CA		< 1 DAY	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Exposure During Pregnancy; Trismus	Rabeprazole			S	Transplacental	Unknown		Not Reported
	Quetiapine			S	Transplacental	Unknown		Not Reported
	Escitalopram			S	Transplacental	Unknown		Not Reported
	Nortriptyline			S	Transplacental	Unknown		Not Reported
	Gabapentin			S	Transplacental	Unknown		Not Reported
	Benztropine			S	Transplacental	Unknown		Not Reported
	Zopiclone			S	Transplacental	Unknown		Not Reported
	Methadone			S	Transplacental	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2014	10431042	EXPEDITED (15-DAY)		HO	FR-FRI-1000070382		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Paraesthesia; Poisoning Deliberate; Somnolence; Suicide Attempt; Tachycardia	Escitalopram			S	Oral	Overdose 4 Df Once Nos.		Forest
	Paracetamol			S	Oral	Overdose 8,000 Mg Once Nos.		Not Reported
	Tercian			S	Oral	Overdose 4,000 Mg Once Nos.		Not Reported
	Norset			S	Oral	Overdose 2,400 Mg Once Nos.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2014	10432409	DIRECT		DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Feeling Jittery; Product Substitution Issue	Generic Lexapro		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2014	10436062	EXPEDITED (15-DAY)	Y	HO, OT	US-ZYDUS-004433		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Long Qt Syndrome Congenital; Suicide Attempt; Torsade De Pointes	Escitalopram (Escitalopram)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2014	10436565	EXPEDITED (15-DAY)	Y	HO	TW-ZYDUS-004487		24 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sedation; Vision Blurred	Escitalopram (Escitalopram)			S		40.00mg - 1.0days		Not Reported
	Aripiprazole (Aripiprazole)			S		20.0mg 1.0days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2014	10432126	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-21347430		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gambling Disorder; Persistent Depressive Disorder; Suicidal Ideation	Abilify			S	Oral	May09-May10:15mg May10-Sep13:10mg Feb14-Jul14:15mg		Not Reported
	Lamictal			S	Oral	1df: 200 To 300mg		Not Reported
	Seroplex			S	Oral			Not Reported
	Nozinan			S	Oral			Not Reported
	Teralithe			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2014	10434404	EXPEDITED (15-DAY)	Y	HO	CH-FRI-1000070435			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Deep Vein Thrombosis; Electrocardiogram Qt Prolonged; Fall; Head Injury	Memantine			S	Oral	1 Df		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Fludex (Indapamide)			S	Oral	1.5 Mg		Not Reported
	Beloc [Metoprolol]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2014	10434426	EXPEDITED (15-DAY)		HO	US-ASTRAZENECA-2014SE64724			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotonia; Tachypnoea; Thrombocytopenia; Trismus	Quetiapine			S	Transplacental			Not Reported
	Quetiapine			S	Transplacental			Not Reported
	Quetiapine			S	Transplacental			Not Reported
	Quetiapine			S	Transplacental			Not Reported
	Quetiapine			S	Transplacental			Not Reported
	Quetiapine			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Benztropine			S	Transplacental			Not Reported
	Gabapentin			S	Transplacental			Not Reported
	Gabapentin			S	Transplacental			Not Reported
	Gabapentin			S	Transplacental			Not Reported
	Methadone			S	Transplacental			Not Reported
	Nortriptyline			S	Transplacental			Not Reported
	Nortriptyline			S	Transplacental			Not Reported

	Nortriptyline	S	Transplacental		Not Reported
	Rabeprazole	S	Transplacental		Not Reported
	Zopiclone	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2014	10434432	NON-EXPEDITED			US-PFIZER INC-2014246172		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Buspar			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2014	10434573	NON-EXPEDITED		HO	US-ASTRAZENECA-2014SE65729			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Drug Ineffective For Unapproved Indication; Flat Affect; Insomnia; Product Use In Unapproved Indication; Weight Decreased; Weight Increased	Quetiapine Fumurate			S	Oral	Dosage Being Reduced By 50 Mg Next Three Weeks, Then It Will Be Reduced By 25 Mg		Not Reported
	Lexapro			S	Unknown	Unknown Unk		Not Reported
	Geodon			S	Unknown	Unknown Unk		Not Reported
	Lamictal			C		Nr		Not Reported
	Xanax			C		Nr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10345693	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-A1081273A			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Bone Disorder; Chest	Advair			S	Respiratory (inhalation)			Glaxosmithkline

Discomfort; Cough; Cyanosis; Decreased Appetite; Depression; Diarrhoea; Dizziness; Drug Ineffective; Dyspnoea; Dyspnoea Exertional; Emphysema; Fall; Fatigue; Headache; Hiatus Hernia; Hypoaesthesia; Infection; Insomnia; Lung Infection; Malaise; Overdose; Pain; Panic Reaction; Pneumonia; Pruritus; Restlessness; Thinking Abnormal; Tremor	Ventolin	S	Unknown	Glaxosmithkline
	Spiriva	S	Unknown	Not Reported
	Clarithromycin	S	Unknown	Glaxosmithkline
	Atrovent	S	Unknown	Glaxosmithkline
	Seebri Breezhaler	S	Unknown	Glaxosmithkline
	Unknown Drug For Anxiety	S	Unknown	Not Reported
	Prednisone	S	Unknown	Glaxosmithkline
	Aerochamber	S	Unknown	Glaxosmithkline
	Cipralex	S		Glaxosmithkline
	Unknown Antihypertensive Agent	C	Unknown	Not Reported
	Gaba	C	Unknown	Not Reported
	Unknown Medication	C	Unknown	Glaxosmithkline
	Clonazepam	C		Glaxosmithkline
	Meloxicam	C		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10435383	EXPEDITED (15-DAY)		OT	NO-ACCORD-025647		36 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Disturbance In Attention; Dizziness; Drug Interaction; Dry Mouth; Headache; Heart Rate Irregular; Hyperhidrosis; Hypersomnia; Memory Impairment; Musculoskeletal Pain; Myalgia; Nausea; Paraesthesia; Paraesthesia; Pyrexia; Restlessness; Somnolence; Tinnitus; Vomiting	Escitalopram			S	Oral	Started On 10 Mg Daily From 14-Aug-2013 And Increase To 15 Mg Daily From 13-Nov-2013		Accord
	Montelukast			S	Oral	Seasonal		Accord
	Panodil			C	Oral			Not Reported
	Seretide Diskus			C	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10436788	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-19547744		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poor Quality Sleep	Abilify			S				Not Reported
	Lamictal			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10437165	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-20340592			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Abilify Tabs			S				Not Reported
	Remeron			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10437916	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-21075593			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Abilify			S				Not Reported
	Cipralex			S		1 Df= 20 Units Nos.		Not Reported
	Zeldox			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10438106	EXPEDITED (15-DAY)		OT	CA-MUNDIPHARMA DS AND PHARMACOVIGILANCE -CAN-2014-0		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Asthenia; Balance Disorder; Diarrhoea;	Butrans Transdermal Patch			S	Transdermal	10 Mcg, Q1h		Purdue
	Butrans Transdermal Patch			S	Transdermal	20 Mcg, Q1h		Purdue

Disorientation; Disturbance In Attention; Dizziness; Drug Interaction; Dyspnoea; Euphoric Mood; Gait Disturbance; Hallucination; Headache; Hypopnoea; Muscle Spasms; Palpitations; Pulse Pressure Increased; Somnolence; Urinary Tract Infection; Vomiting	Butrans Transdermal Patch	S	Transdermal	15 Mcg, Q1h		Purdue
	Butrans Transdermal Patch	S	Transdermal	5 Mcg, Q1h		Purdue
	Cesamet	S	Oral	0.25 Mg, Daily		Not Reported
	Baclofen	S	Unknown	20 Mg, Tid		Not Reported
	Baclofen	S	Unknown	10 Mg, Unk		Not Reported
	Clonazepam	S	Oral	1 Mg, Tid		Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg, Daily		Not Reported
	Escitalopram Oxalate	S	Oral	20 Mg, Unk		Not Reported
	Bisoprolol	C	Unknown	Unk		Not Reported
	Cipro /00697201/	C	Unknown	Unk		Not Reported
	Furosemide	C	Unknown	Unk		Not Reported
	Wellbutrin Xl	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10438329	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-19150010		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hunger	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Xarelto			C				Not Reported
	Atorvastatin			C				Not Reported
	Hctz			C				Not Reported
	Vitamin B Complex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10438510	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-20573317		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circumstance Or Information Capable Of	Abilify Tabs			S				Not Reported
	Abilify Tabs			S				Not Reported

Leading To Medication Error	Escitalopram		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10438714	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-19878776			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10439071	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-19911197			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify Tabs			S		Therapy Started With 2mg And Then Increased To 5mg And Then Stopped At 10mg		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10439087	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-19915842		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10439109	NON-EXPEDITED		HO	US-BRISTOL-MYERS SQUIBB COMPANY-19928027		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Tremor	Abilify	S				Not Reported
	Escitalopram	S	Oral	Dose Reduced To 10mg. Ongoing		Not Reported
	Risperdal	S	Oral			Not Reported
	Synthroid	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10439183	NON-EXPEDITED		HO	US-BRISTOL-MYERS SQUIBB COMPANY-21197223		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Memory Impairment; Myocardial Infarction; Off Label Use	Abilify Tabs			S	Oral	Ongoing 10mg Tabs Ndc-59148-008-13		Not Reported
	Abilify Tabs			S	Oral	Ongoing 10mg Tabs Ndc-59148-008-13		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10439224	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-21210414		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Dizziness; Myalgia; Reduced Facial Expression	Abilify			S				Not Reported
	Buspar			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10439949	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-19391846		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10440253	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-20698767		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Headache	Abilify			S				Not Reported
	Zoloft			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10441695	EXPEDITED (15-DAY)		HO, LT	GXKR2014DE003404			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus; Pyrexia; Serotonin Syndrome; Sinus Tachycardia	Mirtazapine			S	Oral	15 Mg, Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Amantadine			S	Oral	100 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2014	10445456	NON-EXPEDITED		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-19467513		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Dissociation; Feeling Abnormal; Myalgia; Panic Attack; Suicidal Ideation	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2014	9882581	EXPEDITED (15-DAY)		OT	JP-FRI-1000053960		29 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal	Lexapro			S	Oral	10 Mg		Forest
	Pariet			C	Oral	10 Mg		Not Reported

	Solanax	C	Oral	0.4 Mg	Not Reported
	Wypax	C	Oral	3 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2014	10416076	EXPEDITED (15-DAY)		OT	RS-FRI-1000070203			Female	SRB

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2014	10441421	EXPEDITED (15-DAY)		HO, OT	CH-ASTRAZENECA-2014SE65539		36 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Delusion; Drug Interaction; Hallucination, Visual; Psychiatric Symptom	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Coversum N			C	Oral			Not Reported
	Pantozol (Switzerland)			C				Not Reported
	Trittico			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2014	10442436	NON-EXPEDITED			US-PFIZER INC-2014248073		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Duragesic			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2014	10443151	EXPEDITED (15-DAY)		HO, LT, OT	CH-009507513-1409CHE001074		77 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardioversion; Long Qt Syndrome; Torsade De Pointes	Remeron			S	Oral	30 Mg, Qd		Merck
	Remeron			S	Oral	15 Mg, Qd		Merck
	Isentress			S	Oral	400 Mg, Bid		Merck
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Oral	0.25 Mg, Qd		Not Reported
	Pantozol (Pantoprazole Sodium)			S	Oral	40 Mg, Qd		Not Reported
	Prezista			S	Oral	600 Mg, Bid		Not Reported
	Norvir			S	Oral	100 Mg, Bid		Not Reported
	Kivexa			S	Oral	600/300 Mg, Once Daily		Not Reported
	Piperacillin Sodium (+) Tazobactam Sodium			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Madopar			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2014	10443749	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Product Substitution Issue	Escitalopram 20 Mg			S	Oral	1 Tab Daily Po 6 Months	6 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2014	10429887	EXPEDITED (15-DAY)		HO, OT	DE-JNJFOC-20140821976			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Activity; Foetal Exposure During Pregnancy; Respiratory	Risperdal Consta			S	Transplacental			Not Reported
	Cipralex			S	Transplacental			Not Reported

Rate Decreased	Clozapin		S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2014	10444450	EXPEDITED (15-DAY)		OT	NO-FRI-1000070487		36 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Disturbance In Attention; Dizziness; Headache; Heart Rate Irregular; Hyperhidrosis; Hypersomnia; Hypersomnia; Memory Impairment; Musculoskeletal Pain; Nausea; Paraesthesia; Paraesthesia; Pyrexia; Restlessness; Somnolence; Tinnitus; Vomiting	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest
	Montelukast			S	Oral	Seasonal (10 Mg)		Not Reported
	Montelukast			S				Not Reported
	Seretide Diskus			C		2 Df		Not Reported
	Panodil			C	Oral	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2014	10445835	EXPEDITED (15-DAY)		HO	US-ASTRAZENECA-2014SE67251		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia	Cokenzen			S	Oral	1 Df, Qd (16mg/12.5mg)		Astrazeneca
	Seroplex			S	Unknown	Unk		Not Reported
	Ogast			C	Oral			Not Reported
	Creon			C		Unk		Not Reported
	Sulfarlem			C		Unk		Not Reported
	Doliprane			C				Not Reported
	Azopt			C		Unk		Not Reported
	Crestor			C		Unk		Not Reported
	Amlor			C		Unk		Not Reported

	Ixprim			C	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10314580	NON-EXPEDITED			US-PFIZER INC-2014200494		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Diclofenac Epolamine			S		Unk		Unknown
	Wellbutrin			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10416063	EXPEDITED (15-DAY)		OT	RS-FRI-1000070205			Female	SRB

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Self-Injurious Ideation; Violence-Related Symptom	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest
	Bromazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10446435	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2014-01359		60 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Stalopam			S	Oral			Not Reported
	Amlodipine			C	Oral			Not Reported
	Deplatt			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10446462	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002324		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pruritus	Escitalopram Tablets Usp 10mg			S				Lupin
	Synthroid			C				Not Reported
	Hctz			C	Unknown			Not Reported
	Pepcid			C				Not Reported
	Estradiol Patch			C	Transdermal	1/2 Patch		Not Reported
	Aspirin			C				Not Reported
	Coq10			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10446908	EXPEDITED (15-DAY)		HO, LT, OT	HR-TEVA-506628ISR		61 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Cyst; Serum Ferritin Increased; Urinary Retention	Serpentil [Escitalopram Oxalate]			S	Oral	10 Milligram Daily;		Ivax
	Lunata			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10447046	EXPEDITED (15-DAY)		DE	FR-FRI-1000070449		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram			S		20 Mg		Forest
	Kardegic			S		75 Mg		Not Reported
	Previscan (Fluindione)			S		20 Mg		Not Reported
	Depamide			C		900 Mg		Not Reported
	Pulmicort Turbuhaler			C	Other	2 Df		Not Reported
	Nisis			C		80 Mg		Not Reported
	Furosemide Bayer			C		40 Mg		Not Reported

	Bisoprolol	C	10 Mg	Not Reported
	Metformine	C	2550 Mg	Not Reported
	Zopiclone Alter	C	5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10447650	EXPEDITED (15-DAY)		OT	AU-FRI-1000070557		37 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Product Use In Unapproved Indication; Suicidal Behaviour	Escitalopram			S				Forest
	Olanzapine			C		1250 Mcg		Not Reported
	Olanzapine			C		2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10448271	EXPEDITED (15-DAY)		HO	CH-FRI-1000070547			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Delusion; Hallucination, Visual; Psychiatric Symptom	Escitalopram			S	Oral	5 Mg Daily		Forest
	Escitalopram			S		10 Mg Daily		Forest
	Seroquel			S	Oral	300 Mg Daily		Not Reported
	Seroquel			S	Oral	200 Mg Daily		Not Reported
	Coversum N			C	Oral	2.5 Mg Daily		Not Reported
	Pantozol (Switzerland)			C	Oral	40 Mg Daily		Not Reported
	Trittico			C	Oral	25 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10448384	EXPEDITED (15-DAY)		HO, OT	DE-FRI-1000070535		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Clostridial Infection; Morning Sickness;	Escitalopram			S	Oral	15 Mg		Forest
	Escitalopram			S	Oral	Gradually Reduced To 1		Forest

Obstructed Labour; Pyelonephritis	Gynvital			C	Oral	Mg/Day 0.4 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10448404	EXPEDITED (15-DAY)		CA, OT	DE-FRI-1000070534		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hearing Disorder; Electrocardiogram Qt Prolonged; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	15 Mg		Forest
	Escitalopram			S	Transplacental	Gradually Reduced To 1 Mg/Day		Not Reported
	Neurobion			C	Transplacental			Not Reported
	Vitamins			C	Transplacental	0.4 Mg		Not Reported
	Cefuroxime			C	Transplacental			Not Reported
	Metronidazole			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10449552	DIRECT		OT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Dreams; Agitation; Dry Mouth; Irritability; Irritable Bowel Syndrome; Job Dissatisfaction; Nausea	Escitalopram 10 Mg Lupin Pharmaceu			S	Oral	1 Pill Once Daily Taken By Mouth		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2014	10452146	EXPEDITED (15-DAY)	Y	HO, LT	2014/062		63 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Dehydration; Depression;	Olanzapine			S		5mg/Day, Unk & Unk		Not Reported
	Escitalopram			S		10mg/Day Unk & Unk		Not Reported

Disorientation; Gait Disturbance; Hallucination, Auditory; Hyponatraemia; Lethargy; Muscle Spasms; Nausea; Pallor; Sleep Disorder; Tachycardia; Urinary Retention; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2014	10334974	EXPEDITED (15-DAY)		HO, LT	PHHY2014CA088425			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chest Discomfort; Chronic Obstructive Pulmonary Disease; Cough; Decreased Appetite; Depression; Diarrhoea; Drug Ineffective; Dyspnoea; Fatigue; Feeling Abnormal; Gait Disturbance; General Physical Health Deterioration; Hernia Pain; Hiatus Hernia; Hypoaesthesia; Insomnia; Lung Infection; Malaise; Moaning; Mobility Decreased; Pain; Panic Disorder; Poor Quality Sleep; Pruritus; Restlessness; Skin Discolouration	Seebri Breezhaler			S	Respiratory (inhalation)	Unk Ukn, Unk		Not Reported
	Clarithromycin			S		Unk Ukn, Unk		Novartis
	Cipralex//Escitalopram			S				Not Reported
	Prednisone			C		Unk Ukn, Unk		Not Reported
	Advair			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2014	10449563	EXPEDITED (15-DAY)		OT	DE-FRI-1000070544		45 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Depersonalisation/Dereali sation Disorder; Glycosylated Haemoglobin Increased; Hypercholesterolaemia; Hypertriglyceridaemia; Migraine With Aura; Weight Increased; Withdrawal Syndrome	Escitalopram Oral Solution			S	Oral	Changing Dosages		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2014	10450279	EXPEDITED (15-DAY)		OT	DE-FRI-1000070576			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Tachycardia Foetal	Escitalopram			S	Transplacental	10 Mg		Forest
	Folio			C	Transplacental	0.4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2014	10450971	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2014250545		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Fall; Head Injury; Hypotension; Hypotonia; Pneumonia Aspiration; Toxicity To Various Agents	Xanax			S	Oral	7.5 Mg (30 Df), Single		Pfizer
	Seroplex			S	Oral	280 Mg (28 Df), Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2014	10452152	DIRECT	Y				56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Depression; Somnolence	Escitalopram			S	Oral	1 Tablet, Qd, Oral		Bluepoint Laboratories

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2014	10453222	DIRECT		DS, HO, LT			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Crying; Economic Problem; Hallucination, Auditory; Product Dispensing Error	Lexapro			S	Oral		2 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2014	10455531	EXPEDITED (15-DAY)		LT, OT	2014JUB00131		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Encephalopathy; Metabolic Acidosis; Pulseless Electrical Activity; Serotonin Syndrome; Unresponsive To Stimuli	Escitalopram			S				Not Reported
	Methylene Blue			S		1 Mg/Kg Twice		Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported
	Metoprolol (Metoprolol)			C				Not Reported
	Lisinopril (Lisinopril)			C				Not Reported
	Atorvastatin (Atorvastatin)			C				Not Reported
	Furosemide (Furosemide)			C				Not Reported
	Insulin (Insulin)			C				Not Reported
	Lamotrigine (Lamotrigine)			C				Not Reported
	Ipratroprium-Albuterol (Ipratroprium And Albuterol			C				Not Reported
	Nitroglycerin (Nitroglycerin)			C				Not Reported
	Midazolam (Midazolam)			C				Not Reported
	Fentanyl (Fentanyl)			C				Not Reported
	Vecuronium (Vecuronium)			C				Not Reported
	Phenylephrine (Phenylephrine)			C				Not Reported
	Vasopressin (Vasopressin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2014	10456882	EXPEDITED (15-DAY)	Y	HO, OT	2014JUB00129		182 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Altered State Of Consciousness; Cyanosis; Drug Interaction; Drug Screen Positive; Hypertonia; Maternal Exposure During Breast Feeding; Seizure Like Phenomena; Sleep Disorder; Somnolence; Vomiting	Bupropion	S	Transmammary	Not Reported
	Escitalopram	S	Transmammary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2014	10470463	NON-EXPEDITED	Y	OT	2013AP009971		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram Oxalate			S			5 DAY	Not Reported
	Cefalexin			C				Not Reported
	Ranitidine			C				Not Reported
	Digoxin			C				Not Reported
	Lisinopril			C				Not Reported
	Nystatin			C				Not Reported
	Warfarin			C				Not Reported
	Diphenhydramine			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Amiodarone			C				Not Reported
	Furosemide			C				Not Reported
	Nystop			C				Not Reported
	Salbutamol W/Ipratropium			C				Not Reported
	Insulin Lispro			C				Not Reported
	Paracetamol			C				Not Reported
	Milk Of Magnesia			C				Not Reported
	Bisacodyl			C				Not Reported
	Omeprazole			C				Not Reported
	Guaifenesin			C				Not Reported
	Triamcinolone			S				Not Reported
	Fluticasone Propionate			C				Not Reported
	Warfarin			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2014	10451972	EXPEDITED (15-DAY)		HO, LT	DE-AUROBINDO-AUR-APL-2014-09510		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus; Procalcitonin Increased; Pyrexia; Serotonin Syndrome; Sinus Tachycardia	Mirtazapine 15mg			S	Oral	15 Mg, Unk		Aurobindo
	Escitalopram 10 Mg			S	Oral	10 Mg, Unk		Aurobindo
	Amantadin /00055901/			S	Oral	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2014	10452287	EXPEDITED (15-DAY)		HO, OT	IN-PAR PHARMACEUTICAL, INC-2014SCPR009380			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Gait Disturbance; Hyponatraemia; Leukocytosis; Pallor; Tachycardia; Urinary Retention	Olanzapine			S	Unknown	5 Mg, / Day		Par
	Olanzapine			S				Par
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2014	10452357	EXPEDITED (15-DAY)		OT	NL-RANBAXY-2014RR-85255			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression	Venlafaxine			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	Unk		Ranbaxy
	Paroxetine			S	Unknown	Unk		Not Reported
	Fluoxetine			S	Unknown	Unk		Ranbaxy
	Fluvoxamine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2014	10456609	DIRECT		OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Product Effect Decreased	Generic Lexapro			S	Oral		4 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2014	10459487	EXPEDITED (15-DAY)	Y	LT	US-H14001-14-00526		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Encephalopathy; Pulseless Electrical Activity; Serotonin Syndrome	Escitalopram (Escitalopram)			S				Not Reported
	Methylene Blue (Methylthioninium Chloride)			S		2 Mg/Kg (1 Mg/Kg,Two Consecutive Doses)		Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported
	Metoprolol (Metoprolol)			C				Not Reported
	Lisinopril (Lisinopril)			C				Not Reported
	Atorvastatin (Atorvastatin)			C				Not Reported
	Furosemide (Furosemide)			C				Not Reported
	Insulin (Insulin)			C				Not Reported
	Lamotrigine (Lamotrigine)			C				Not Reported
	Ipratropium-Albuterol (Combivent)			C				Not Reported
	Nitroglycerin (Glyceryl Trinitrate)			C				Not Reported
	Midazolam (Midazolam)			C				Not Reported
	Fentanyl (Fentanyl)			C				Not Reported
	Vecuronium (Vecuronium)			C				Not Reported
	Isoflurane (Isoflurane)			C				Not Reported
	Phenylephrine (Phenylephrine)			C				Not Reported
	Vasopressin (Vasopressin)			C				Not Reported
	Propofol (Propofol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2014	10507542	NON-EXPEDITED	Y	OT	2013-US-002139		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Insomnia; Intentional Product Misuse; Off Label Use; Ovarian Cyst Ruptured; Sedation; Vomiting	Xyrem (Sodium Oxybate) Oral Solution, 500mg/Ml			S	Oral Oral Oral Oral Oral			Not Reported
	Lexapro (Escitalopram Oxalate)			S				Not Reported
	Loratadine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2014	10507660	NON-EXPEDITED		OT	2013-US-002032		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Xyrem			S	Oral Oral Oral			Not Reported
	Escitalopram			S				Not Reported
	Lisinopril (Lisinopril)			C				Not Reported
	Tramadol (Tramadol Hydrochloride)			C				Not Reported
	Lanoxin (Digoxin)			C				Not Reported
	Maxalt (Rizatriptan Benzoate)			C				Not Reported
	Gemfibrozil (Gemfibrozil)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2014	10395289	EXPEDITED (15-DAY)		OT	PHHY2014BR103094		76 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cataract; Eye Swelling; Eyelash Discolouration; Fatigue; Nervousness; Panic Reaction; Tremor; Visual Impairment; Weight Decreased	Stalevo			S	Oral	100 Mg, Tid (Three Times A Day)		Orion
	Stalevo			S	Oral	100 Mg, Qid (Four Times A Day)		Orion
	Stalevo			S	Oral	150 Mg, Tid (Three Times A Day)		Orion
	Velija			S		Unk		Not Reported

	Exodus//Escitalopram Oxalate	S	Unk	Not Reported
	Rivotril	S	Unk	Not Reported
	Puran	S	1 Df, Daily (One Tablet Daily)	Not Reported
	Lansoprazole	S	1 Df, Daily (One Tablet Daily)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2014	10457610	EXPEDITED (15-DAY)		OT	GB-FRI-1000070642		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Mass; Liver Function Test Increased	Escitalopram			S	Oral	10 Mg Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2014	10460951	EXPEDITED (15-DAY)	Y	HO, OT	2014EDG00011		182 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Drug Interaction; Exposure Via Breast Milk; Hypertonia; Seizure; Sleep Disorder; Somnolence; Staring; Unresponsive To Stimuli; Vomiting	Bupropion			S	Transmammary			Not Reported
	Escitalopram			S	Transmammary			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2014	8970488	EXPEDITED (15-DAY)		OT	CN-FRI-1000041073		50 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral	15 Mg		Forest
	Lexapro			S	Oral	10 Mg		Not Reported

	Lexapro	S	Oral		Not Reported
	Buspirone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2014	10446192	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2014-09558		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome; Stomatitis	Ramipril			S	Unknown	Unk		Aurobindo
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported
	Forxiga			S	Oral	5 Mg, Daily		Not Reported
	Flucloxacillin			C	Unknown	Unk		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Fucibet			C	Unknown	Unk		Not Reported
	Humalog			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2014	10459676	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY-21396494		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pyrexia; Renal Failure; Rhabdomyolysis	Abilify			S				Not Reported
	Imovane			S	Oral			Not Reported
	Mianserin			S	Oral	1 Df = 120 Units Nos.		Not Reported
	Seroplex			S		In Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2014	10232571	NON-EXPEDITED			US-TEVA-483929USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Back Pain; Depressed Mood; Drug Ineffective; Hypersensitivity; Insomnia; Irritability; Respiratory Disorder; Therapeutic Response Changed; Thinking Abnormal	Escitalopram			S					Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2014	10461072	NON-EXPEDITED			US-TEVA-489121USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Gastrointestinal Disorder; Mood Altered	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2014	10461073	NON-EXPEDITED			US-TEVA-491718USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2014	10461075	NON-EXPEDITED			US-TEVA-497699USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Headache; Malaise; Pain	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2014	10461076	NON-EXPEDITED			US-TEVA-502664USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Malaise	Escitalopram	S	Unknown		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2014	10461078	NON-EXPEDITED			US-TEVA-504297USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Dizziness; Fatigue; Feeling Drunk; Headache; Paraesthesia; Somnolence; Speech Disorder	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2014	10461781	EXPEDITED (15-DAY)		OT	SI-FRI-1000070641			Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram			S	Oral			Forest
	Dabigatran			C				Not Reported
	Spironolactone			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2014	10461990	NON-EXPEDITED		HO	US-FRI-1000070610			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Ill-Defined Disorder	Lexapro			S				Forest
	Lamotrigine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2014	10462624	EXPEDITED (15-DAY)		OT	JP-FRI-1000070146		29 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased;	Lexapro			S	Oral	20 Mg		Forest

Blood Pressure Decreased; Depressed Level Of Consciousness; Overdose; Somnolence; Suicide Attempt	Lexapro		S	Oral	Overdose: 140 Mg	Forest
	Brotizolam		S	Oral	1.75 Mg	Not Reported
	Depakene-R		S	Oral	2800 Mg	Not Reported
	Tasmolin		S	Oral	7 Mg	Not Reported
	Seroquel		S	Oral	1400 Mg	Not Reported
	Seroquel		S	Oral	700 Mg	Not Reported
	Pantethine		C	Oral	700 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2014	10463870	DIRECT	Y				14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Product Substitution Issue	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2014	10466648	EXPEDITED (15-DAY)	Y	HO	2014JUB00135		63 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dehydration; Disorientation; Gait Disturbance; Hyponatraemia; Lethargy; Muscle Spasms; Muscle Spasms; Nausea; Pallor; Tachycardia; Urinary Retention	Olanzapine			S				Not Reported
	Escitalopram			S			730 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2014	10384484	EXPEDITED (15-DAY)		HO	FR-FRI-1000069787		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Confusional	Escitalopram			S	Oral			Forest

State; Incorrect Dose Administered; Medication Error	Escitalopram		S	Oral	2 Df	Not Reported
	Mono-Tildiem		S	Oral		Not Reported
	Mono-Tildiem		S	Oral	2 Df	Not Reported
	Coversyl		S	Oral		Not Reported
	Coversyl		S	Oral	2 Df	Not Reported
	Diamicron		S	Oral		Not Reported
	Diamicron		S	Oral	2 Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2014	10464261	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2014M1003863			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choking Sensation; Discomfort; Dyspnoea	Loxalate			S		0.5 Df, Hs		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2014	10464396	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2014256728		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Mydriasis; Overdose; Rhabdomyolysis; Somnolence; Suicide Attempt	Xanax			S	Oral	Unk		Pfizer
	Seroplex			S	Oral	Unk		Not Reported
	Noctamide			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2014	10465310	EXPEDITED (15-DAY)		HO, OT	GB-FRI-1000070779		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome; Stomatitis	Escitalopram			S	Oral			Forest
	Forxiga			S	Oral	5 Mg Once Daily		Not Reported
	Ramipril			S				Not Reported

	Codeine	C	Not Reported
	Flucloxacillin	C	Not Reported
	Fucibet	C	Not Reported
	Humalog	C	Not Reported
	Lantus	C	Not Reported
	Paracetamol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2014	10465368	EXPEDITED (15-DAY)		HO	AU-FRI-1000070835		22 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling; Swollen Tongue	Escitalopram			S				Forest
	Ketoprofen			C				Not Reported
	Panadeine Forte			C				Not Reported
	Zoladex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2014	10465627	EXPEDITED (15-DAY)		HO, OT	SI-FRI-1000028224		86 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Hallucination, Olfactory; Hallucination, Visual	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Quetiapine			C		500 Mg		Not Reported
	Lamotrigine			C		400 Mg		Not Reported
	Valproic Acid			C				Not Reported
	Distraneurin			C	Oral	400 Mg		Not Reported
	Litalir			C	Oral	2000 Mg		Not Reported
	Acetylsalicilic Acid			C	Oral	100 Mg		Not Reported
	Digoxin			C	Oral			Not Reported
	Carvedilol			C	Oral	3 Mg		Not Reported
	Pantoprazole			C	Oral	20 Mg		Not Reported
	Iron (Iii)-Hydroxide			C		200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2014	10465741	EXPEDITED (15-DAY)		HO	CH-FRI-1000070843			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S	Oral	10 Mg Daily		Forest
	Aspirin Cardio			S	Oral	100 Mg Daily		Not Reported
	Competact			C	Oral	1 Tablet Of 850 Mg Metformin Hci/15 Mg Pioglitazone Hci Daily		Not Reported
	Amaryl			C	Oral	2 Mg Daily		Not Reported
	Amaryl			C	Oral	1 Mg Daily		Not Reported
	Beloc-Zok			C	Oral	25 Mg Daily		Not Reported
	Zytiga			C	Oral	1000 Mg Daily		Not Reported
	Prednisone			C	Oral	10 Mg Daily		Not Reported
	Lucrin Depot			C	Subcutaneous	1 Pre-Filled Syringe Every 3 Months		Not Reported
	Xgeva			C	Subcutaneous	1 Single Subcutaneous Injection Every 3 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2014	10466201	DIRECT		HO, OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Muscle Twitching; Musculoskeletal Disorder; Myoclonus; Tic; Vision Blurred	Lexapro			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2014	10413136	EXPEDITED (15-DAY)		HO, OT	GB-BRISTOL-MYERS SQUIBB COMPANY-21313549		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome; Stomatitis	Forxiga			S	Oral			Bristol Myers Squibb
	Ramipril			S				Not Reported
	Escitalopram			S				Not Reported
	Flucloxacillin			C				Not Reported
	Codeine			C				Not Reported
	Fucibet			C				Not Reported
	Humalog			C				Not Reported
	Lantus			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	8664732	EXPEDITED (15-DAY)		DE	CA-FRI-1000037008		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Balance Disorder; Chest Pain; Confusional State; Crying; Drug Dependence; Fatigue; Hyperacusis; Hyponatraemia; Insomnia; Loss Of Personal Independence In Daily Activities; Myocardial Infarction; Pain In Extremity; Social Fear; Torsade De Pointes	Escitalopram			S	Oral			Forest
	Apo-Triazide			C		25 Mg/50 Mg		Not Reported
	Lorazepam			C	Oral	Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	10235471	EXPEDITED (15-DAY)		LT	JP-FRI-1000068010		75 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Hyponatraemia	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20 Mg		Forest
	Reflex			C	Oral	15 Mg		Not Reported

	Magmitt	C	Oral	1980 Mg	Not Reported
	Shinluck	C	Oral		Not Reported
	Halcion	C	Oral		Not Reported
	Amoban	C	Oral	7.5 Mg	Not Reported
	Depas (Etizolam)	C	Oral	0.5 Mg	Not Reported
	Ensure Liquid	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	10270923	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-A1079200A		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Dental Operation	Advair			S	Respiratory (inhalation)	1puff Twice Per Day		Glaxosmithkline
	Ventolin Hfa			S	Respiratory (inhalation)	2puff As Required		Glaxosmithkline
	Bupropion			S	Oral	300mg In The Morning		Unknown
	Escitalopram Oxalate			S	Oral	20mg Per Day		Unknown
	Hydroxyzine Hcl			S	Oral	50mg As Required		Unknown
	Proair Hfa			S	Respiratory (inhalation)	2puff As Required		Glaxosmithkline
	Prevacid			S	Oral	15mg Twice Per Day		Glaxosmithkline
	Esterified Estrogens + Methyltestosterone			C				Not Reported
	Lisinopril			C				Not Reported
	Trazodone Hcl			C				Not Reported
	Fluzone Vaccine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	10387857	EXPEDITED (15-DAY)	Y	HO, LT, OT	ADR-2014-01402		35 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of	Lioresal			S				Not Reported

Consciousness; Clonus; Device Connection Issue; Device Leakage; Disease Recurrence; Headache; Movement Disorder; Muscle Spasticity; Tonic Clonic Movements; Underdose	Cipralex Cp	S		Not Reported
	Dafalgan	S		Not Reported
	Importal Solution 30 Ml	S		Not Reported
	Clexane	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	10401120	EXPEDITED (15-DAY)		OT	BR-ORION CORPORATION ORION PHARMA-ENTC2014-0309		76 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Eye Swelling; Eyelash Discolouration; Fatigue; Nervousness; Panic Reaction; Tremor; Visual Impairment; Weight Decreased	Stalevo			S	Oral			Not Reported
	Stalevo			S	Oral			Not Reported
	Stalevo			S	Oral			Not Reported
	Velija			S	Unknown			Not Reported
	Exodus//Escitalopram Oxalate			S	Unknown			Not Reported
	Rivotril			S	Unknown			Not Reported
	Puran			S	Unknown			Not Reported
	Lansoprazole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	10457576	EXPEDITED (15-DAY)		HO	FR-FRI-1000070649		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Condition Aggravated; Melaena	Escitalopram			S	Oral	10 Mg		Forest
	Previscan (Fluindione)			S	Oral	20 Mg		Not Reported
	Plavix			S	Oral	75 Mg		Not Reported
	Orocald3			C				Not Reported
	Nebivolol			C				Not Reported
	Crestor			C				Not Reported

	Lasilix	C	Not Reported
	Uvedose	C	Not Reported
	Voltarene Actigo	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	10466780	NON-EXPEDITED			US-PFIZER INC-2014261730		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Buspar			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	10466988	EXPEDITED (15-DAY)		CA	FR-SA-2014SA128018		1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect; Exposure During Pregnancy	Zolpidem Tartrate			S	Transplacental			Not Reported
	Seroplex			S	Transplacental			Not Reported
	Lexomil			S	Transplacental			Not Reported
	Atarax			S	Transplacental			Not Reported
	Circadin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	10467106	EXPEDITED (15-DAY)		OT	SE-ACTAVIS-2014-20167		95 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dementia; Fatigue; Personality Change; Visual Impairment	Risperidon Actavis			S	Unknown	0.5 Mg, Daily		Watson
	Risperidon Actavis			S	Unknown	.025 Mg, Daily		Watson
	Cipralex /01588501/			S	Unknown	Unk		Not Reported

	Furosemide		C	Unknown	Unk	Not Reported
	Loratadine		C	Unknown	Unk	Not Reported
	Sobril		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	10467523	EXPEDITED (15-DAY)		HO	FR-FRI-1000070836		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hyponatraemia; Seizure	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	10467754	EXPEDITED (15-DAY)		HO, OT	GB-WATSON-2014-20216		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome; Stomatitis	Escitalopram (Unknown)			S	Unknown	Unk		Not Reported
	Ramipril (Unknown)			S	Unknown	Unk		Watson
	Forxiga			S	Oral	5 Mg, Daily		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Flucloxacillin			C	Unknown	Unk		Not Reported
	Fucibet			C	Unknown	Unk		Not Reported
	Humalog			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2014	10469861	DIRECT		OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Frustration Tolerance Decreased	Lexapro 20 Mg Camber			S	Oral	1 Tablet Once Daily Taken By Mouth		Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2014	10468842	EXPEDITED (15-DAY)		OT	SI-ACCORD-025938		85 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anxiety; Delirium; Disorientation; Fatigue; Hallucination; Hallucination, Olfactory; Hallucination, Visual; Insomnia; Restlessness	Clomethiazole/Clomethiazole Edisilate			S		In Single Evening Dose		Not Reported
	Lamotrigine			S				Not Reported
	Digoxin			C				Not Reported
	Escitalopram			S		Initially Received 5 Mg Daily Then Increased To 10mg Daily.		Accord
	Fluphenazine			S				Not Reported
	Hydroxycarbamide			C				Not Reported
	Carvedilol/Carvedilol Hydrochlodride			C				Not Reported
	Quetiapine			S				Accord
	Ferric Hydroxide Colloidal			C				Not Reported
	Valproic Acid			S				Not Reported
	Pantoprazole			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2014	10471595	EXPEDITED (15-DAY)		CA	US-FRI-1000070811		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Congenital Anomaly; Gastrointestinal Injury; Neural Tube Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2014	9166612	EXPEDITED (15-DAY)		CA	US-FRI-1000043307		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Developmental Delay;	Lexapro			S	Transplacental			Forest

Hypoplastic Right Heart Syndrome; Hypospadias

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2014	10403942	EXPEDITED (15-DAY)		HO	FR-BAUSCH-SYM-2014-24310		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Confusional State	Mono-Tildiem			S	Oral			Not Reported
	Mono-Tildiem			S	Oral			Not Reported
	Coversyl			S	Oral			Not Reported
	Coversyl			S	Oral			Not Reported
	Diamicron			S	Oral			Not Reported
	Diamicron			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2014	10472565	NON-EXPEDITED			US-PFIZER INC-2014260385		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Irritability; Potentiating Drug Interaction	Chantix			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2014	10473762	EXPEDITED (15-DAY)		CA	US-FRI-1000070809		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2014	10474404	EXPEDITED (15-DAY)		CA	US-FRI-1000070813		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Tricuspid Valve Atresia; Dextrocardia; Heart Injury; Pulmonary Artery Atresia; Univentricular Heart	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2014	10475171	DIRECT					14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2014	10156927	EXPEDITED (15-DAY)		DE, OT	FR-JNJFOC-20140419656		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Interaction; Drug Interaction	Topalgic (France)			S	Oral			Not Reported
	Durogesic			S	Transdermal			Not Reported
	Tercian			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Oxynorm			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2014	10476060	EXPEDITED (15-DAY)		OT	CA-FRI-1000070930			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer; Off Label Use	Escitalopram			S	Oral	5 Mg Daily; Started 4 Years Ago (Nos)		Forest
	Escitalopram			S	Oral	5 Mg Daily; Discontinued About A Year Ago (Nos)		Forest
	Crestor			S				Not Reported
	Metformin			C		Daily Dose Not Reported.		Not Reported
	Rosuvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2014	9166668	EXPEDITED (15-DAY)		CA	US-FRI-1000043318		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Fallot'S Tetralogy; Right Aortic Arch	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2014	10478940	EXPEDITED (15-DAY)		OT	AU-FRI-1000070931			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Somnolence	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2014	10483585	EXPEDITED (15-DAY)	Y	OT	2014HINLIT0819		86 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Anxiety; Atrial Fibrillation; Cardiac Failure; Cognitive Disorder; Delirium; Disorientation; Fear; Gastrooesophageal Reflux	Escitalopram			S				Not Reported
	Clomethiazole			C				Not Reported
	Hydroxyurea			C				Not Reported
	Acetylsalicilic Acid			C				Not Reported
	Digoxin			C				Not Reported
	Carvedilol			C				Not Reported
	Pantoprazole			C				Not Reported

Disease; Hallucination, Olfactory; Hallucination, Visual; Insomnia; Insomnia; Myeloproliferative Neoplasm; Restlessness; Thrombocytosis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2014	10480325	EXPEDITED (15-DAY)		DS, OT	US-ROCHE-1466189		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bladder Prolapse; Blood Pressure Increased; Drug Dependence; Drug Ineffective; Hypoaesthesia; Neuropathy Peripheral; Sciatica; Seizure	Klonopin			S	Oral	1 Pill		Not Reported
	Klonopin			S	Oral	Half A Pill		Not Reported
	Lexapro			S	Unknown			Not Reported
	Miralax			C				Not Reported
	Senna			C				Not Reported
	Neurontin (United States)			C	Unknown			Not Reported
	Colace			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2014	10480339	EXPEDITED (15-DAY)		DE, HO, OT	CH-JNJFOC-20140913506		84 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level Increased; Confusional State; Death; Dehydration; Dysphagia; Dyspnoea; General Physical Health Deterioration; Intestinal Obstruction; Parkinsonian Crisis; Psychomotor Hyperactivity; Urinary Retention; Urinary Tract Infection	Durogesic			S	Transdermal			Not Reported
	Durogesic			S	Transdermal			Not Reported
	Durogesic			S	Transdermal			Not Reported
	Durogesic			S	Transdermal			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

Madopar Liq 62.5	S	Oral	Not Reported
Madopar Liq 62.5	S	Oral	Not Reported
Madopar Liq 62.5	S	Oral	Not Reported
Haldol	C	Intravenous (not otherwise specified)	Not Reported
Aspirin	C	Oral	Not Reported
Temesta (Lorazepam)	C	Oral	Not Reported
Temesta (Lorazepam)	C	Oral	Not Reported
Temesta (Lorazepam)	C	Oral	Not Reported
Temesta (Lorazepam)	C	Oral	Not Reported
Temesta (Lorazepam)	C	Oral	Not Reported
Temesta (Lorazepam)	C	Oral	Not Reported
Temesta (Lorazepam)	C	Oral	Not Reported
Temesta (Lorazepam)	C	Oral	Not Reported
Temesta (Lorazepam)	C	Oral	Not Reported
Laxoberon	C	Oral	Not Reported
Morphine Hcl	C	Oral	Not Reported
Lyrica	C	Oral	Not Reported
Glucophage	C	Oral	Not Reported
Dafalgan	C	Oral	Not Reported
Amlodipine	C	Oral	Not Reported
Concor	C	Oral	Not Reported
Motilium	C	Oral	Not Reported
Zofran	C	Oral	Not Reported
Monuril	C	Oral	Not Reported
Anexate	C	Intravenous (not otherwise specified)	Not Reported
Midazolam	C	Intravenous (not otherwise specified)	Not Reported
Furadantine	C	Oral	Not Reported

	Quetiapine	C	Oral	Not Reported
	Nitroderm	C	Cutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2014	10481923	EXPEDITED (15-DAY)		HO, OT	PHHY2014US125461		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiomyopathy; Ejection Fraction Decreased; Paranoia; Suicide Attempt; Tachycardia; Treatment Failure	Clozapine			S		25 Mg, Per Day		Not Reported
	Clozapine			S		50 Mg, Per Day		Not Reported
	Clozapine			S		75 Mg, Per Day		Not Reported
	Clozapine			S		100 Mg, Per Day		Not Reported
	Clozapine			S		125 Mg, Per Day		Not Reported
	Clozapine			S		150 Mg, Per Day		Not Reported
	Clozapine			S		250 Mg, Per Day		Not Reported
	Risperidone			S		2 Mg, Per Day		Novartis
	Haloperidol			S		5 Mg, Per Day		Not Reported
	Haloperidol			S		10 Mg, Per Day		Not Reported
	Haloperidol			S		20 Mg, Per Day		Not Reported
	Escitalopram			S				Not Reported
	Citalopram			S				Not Reported
	Fluphenazine			S				Not Reported
	Lorazepam			S				Not Reported
	Quetiapine			S		50 Mg, Per Day		Not Reported
	Clonazepam			S		0.25 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2014	10482032	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-508148ISR		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome;	Ramipril			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Ivax

Stomatitis	Forxiga	S	Oral	5 Milligram Daily;	Not Reported
	Codeine	C			Not Reported
	Flucloxacillin	C			Not Reported
	Fucibet	C			Not Reported
	Humalog	C			Not Reported
	Lantus	C			Not Reported
	Paracetamol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2014	10482763	EXPEDITED (15-DAY)		HO	FR-FRI-1000071035		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cholestasis; Drug Reaction With Eosinophilia And Systemic Symptoms; International Normalised Ratio Increased	Escitalopram			S	Oral	10 Mg		Forest
	Allopurinol			S	Oral			Not Reported
	Colchimax (France)			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Celiprolol			C		200 Mg		Not Reported
	Furosemide			C		20 Mg		Not Reported
	Glucophage			C		500 Mg		Not Reported
	Tahor			C		10 Mg		Not Reported
	Coaprovel (Hydrochlorothiazide And Irbesartan)			C		300 / 25 Mg		Not Reported
	Noctamide			C		2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2014	10483871	DIRECT		DS, OT			38 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Activity; Depression; Headache; Palpitations; Tremor	Escitalopram 20mg			S	Oral	1 Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2014	10424296	EXPEDITED (15-DAY)		OT	PHHY2014BR110496			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Trileptal			S	Oral	1.5 Df, Bid		Novartis
	Trileptal			S				Novartis
	Reconter			S	Oral	1 Df, Daily		Not Reported
	Reconter			S				Not Reported
	Gardenal//Phenobarbital			S	Oral	1 Df, Daily		Not Reported
	Gardenal//Phenobarbital			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2014	10465075	EXPEDITED (15-DAY)		HO, OT	GB-MYLANLABS-2014M1004022			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome; Stomatitis	Escitalopram Oxalate			S	Unknown	Unk		Not Reported
	Forxiga			S	Oral	5 Mg, Qd		Not Reported
	Forxiga			S				Not Reported
	Ramipril			S	Unknown			Not Reported
	Codeine			C				Not Reported
	Flucloxacillin			C				Not Reported
	Fucibet			C				Not Reported
	Humalog			C				Not Reported
	Lantus			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2014	10484161	EXPEDITED (15-DAY)		OT	US-ROXANE LABORATORIES, INC.-2014-RO-01483RO		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Stereotypy	Ropinirole			S	Unknown			Roxane
	Quetiapine Fumarate			S	Unknown	25 Mg		Roxane

	Rasagiline	S	Unknown	1 Mg		Not Reported
	Clonazepam	S	Unknown	1 Mg		Not Reported
	Venlafaxine	S	Unknown	75 Mg		Not Reported
	Escitalopram	S	Unknown	10 Mg		Not Reported
	Carbidopa/Levodopa	S	Unknown	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2014	10484318	NON-EXPEDITED			US-PFIZER INC-2014268978		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Citalopram			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2014	10484587	EXPEDITED (15-DAY)		OT	ES-FRI-1000071081		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Depression; Hallucination; Insomnia; Nightmare; Psychomotor Hyperactivity; Suicidal Ideation; Suicide Attempt	Escitalopram			S				Forest
	Diazepam			C				Not Reported
	Clopidrogel			C				Not Reported
	Bisoprolol			C				Not Reported
	Ramipril			C				Not Reported
	Crestor			C				Not Reported
	Omeprazole			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2014	10485265	EXPEDITED (15-DAY)		OT	CH-FRI-1000071086			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Leukopenia; Monocytopenia; Neutropenia	Escitalopram		S	Oral	10 Mg Daily	Forest
	Remeron		S	Oral	30 Mg Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2014	10485268	EXPEDITED (15-DAY)		HO	FR-FRI-1000071033		26 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Escitalopram			S	Oral	20 Mg		Forest
	Olanzapine Mylan			S	Oral	10 Mg		Not Reported
	Valium Roche			C	Oral	Daily Dose Tapered For Withdrawal (40 Mg To 5 Mg Daily)		Not Reported
	Atarax			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2014	10223994	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2014153735		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Abuse; Dyspepsia; Psychomotor Hyperactivity	Xanax			S	Oral	20 Ml, Total		Pfizer
	Entact			S	Oral	15 Ml, Total		Not Reported
	Anafranil			S	Oral	3 Df, Total		Not Reported
	Aspirina			S	Oral	3 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2014	10306546	EXPEDITED (15-DAY)		OT	US-TEVA-493379USA		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Dental Operation	Proair Hfa			S	Respiratory (inhalation)	2 Puffs As Needed Eveery 4 Hours		Ivax
	Bupropion			S	Oral	300 Milligram Daily;		Teva
	Escitalopram			S	Oral	20 Milligram Daily;		Ivax

	Hydroxyzine	S	Oral	As Needed/X3/Day	Barr
	Lansoprazole	S	Oral	30 Milligram Daily;	Not Reported
	Ventolin Hfa-Cfc	S	Respiratory (inhalation)	2 Puffs As Needed Eveery 4 Hours	Not Reported
	Advair	S		1 Puff	Not Reported
	Est . Estrogen W/M.Testosterone	C			Not Reported
	Lisinopril	C			Not Reported
	Trazodone Hydrochloride	C			Not Reported
	Seasonal Influenza Vaccine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2014	10487655	EXPEDITED (15-DAY)		CA	FR-FRI-1000071153			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect; Exposure During Pregnancy	Escitalopram			S	Transplacental	10 Mg		Forest
	Stilnox			S	Transplacental	10 Mg		Not Reported
	Lexomil			S	Transplacental			Not Reported
	Atarax			S	Transplacental			Not Reported
	Circadin			S	Transplacental	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2014	10515970	NON-EXPEDITED		HO	2014005164		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Vimpat			S	Oral Oral			Not Reported
	Namenda			S	Oral Oral Oral Oral	10 Mg Am And 5mg P, Oral		Not Reported
	Namenda			S	Oral			Not Reported

	Escitalopram	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2014	10516492	NON-EXPEDITED	Y	HO	AUR-APL-2014-08330		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Escitalopram 10 Mg (Escitalopram) Unknown, 10 Mg			S	Oral			Not Reported
	Atorvastatin Calcium (Atorvastatin Calcium)			S	Oral			Not Reported
	Trazodone (Trazodone) Tablet			S	Oral			Not Reported
	Invega			C				Not Reported
	Bumetanide			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Lantus			C				Not Reported
	Labetalol			C				Not Reported
	Losartan			C				Not Reported
	Simvastatin			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2014	9790863	EXPEDITED (15-DAY)		LT	IT-FRI-1000052566		38 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Interaction	Escitalopram Oral Solution			S	Oral	5 Drops Daily		Forest
	Invega			S	Oral	9 Mg		Not Reported
	Venlafaxine			S	Oral	150 Mg		Not Reported
	Depakin			S	Oral	750 Mg		Not Reported
	Akineton			S	Oral	4 Mg		Not Reported
	Tranquirit 0,5%			S	Oral	20 Gtt		Not Reported
	Lorazepam Abc			S	Oral	7.5 Mg		Not Reported
	Ethanol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2014	10489433	EXPEDITED (15-DAY)		CA	US-FRI-1000071065		1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cardiac Murmur; Congenital Anomaly; Right Atrial Enlargement; Right Ventricular Enlargement	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2014	10489839	EXPEDITED (15-DAY)		HO	FR-FRI-1000048097		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion; Medication Error	Escitalopram			S	Oral	10 Mg		Forest
	Perindopril			S	Oral	2 Mg		Not Reported
	Indapamide			S	Oral	0.625 Mg		Not Reported
	Bisoprolol			C		5 Mg		Not Reported
	Kardegic			C		75 Mg		Not Reported
	Cacit Vitamine D3			C		1 Df		Not Reported
	Zopiclone			C		1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2014	10489989	EXPEDITED (15-DAY)		HO	IT-FRI-1000071178		3 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Vomiting	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2014	10490405	EXPEDITED (15-DAY)		CA	US-FRI-1000071073			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Low Set Ears; Patent Ductus Arteriosus; Pulmonary Hypoplasia; Right Aortic Arch; Umbilical Cord Abnormality; Ventricular Septal Defect	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2014	10490455	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2014-005784		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Dental Operation	Bupropion Hydrochloride			S	Oral			Not Reported
	Advair			S		250/50 Mcg, 1 Puff Bid		Not Reported
	Proair Hfa			S				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Hydroxyzine Hydrochloride			S	Oral	As Needed		Not Reported
	Ventolin			S				Not Reported
	Prevacid			S	Oral			Not Reported
	Methyltestosterone/Estrogens Esterified			C				Not Reported
	Methyltestosterone/Estrogens Esterified			C				Not Reported
	Lisinopril			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Fluzone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2014	10491001	EXPEDITED (15-DAY)		CA	US-FRI-1000071134		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly; Heart Disease Congenital	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2014	10495071	EXPEDITED (15-DAY)		OT	FR-ELI_LILLY_AND_COMPANY-FR201409007977		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Thrombocytopenia	Zyprexa			S	Oral	10 Mg, Qd		Eli Lilly And Co
	Seroplex			S	Oral	5 Mg, Unk		Not Reported
	Lovenox			S	Subcutaneous	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2014	10495078	EXPEDITED (15-DAY)		HO, OT	FR-ELI_LILLY_AND_COMPANY-FR201409007993		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Pallor; Syncope; Tachycardia; Ventricular Arrhythmia	Zyprexa			S	Oral	5 Mg, Qd		Eli Lilly And Co
	Seroplex			S	Unknown	10 Mg, Qd		Not Reported
	Trivastal /00397201/			C	Unknown	20 Mg, Qd		Not Reported
	Tadenan			C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2014	10497919	DIRECT	Y				14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Lexapro			S	Oral	20 Mg By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2014	10501412	DIRECT					21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression	Lexapro 10 Mg			S	Oral	1 Pill Once Daily Taken By		Not Reported

Mouth

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2014	10501321	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS INC.-2014-01353		42 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Drug Ineffective; Headache; Therapeutic Product Effect Decreased; Weight Increased	Escitalopram			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Tamoxifen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2014	10501325	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002341		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dyspnoea; Heart Rate Increased; Intentional Underdose; Panic Attack	Escitalopram Tablets Usp 20mg			S				Lupin
	Escitalopram Tablets Usp 20mg			S				Lupin
	Escitalopram Tablets Usp 20mg			S				Lupin
	Escitalopram Tablets Usp 20mg			S				Lupin
	Protonix			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported
	Zyrtec			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2014	10501348	NON-EXPEDITED		HO, LT	DE-LUPIN PHARMACEUTICALS INC.-E2B_00002465		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus; Pyrexia; Serotonin Syndrome;	Mirtazapin			S	Oral			Not Reported

Sinus Tachycardia	Escitalopram		S	Oral	Not Reported
	Amantadin		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2014	10501502	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS INC.-2014-01390		35 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Major Depression	Escitalopram			S	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2014	10503655	DIRECT		HO			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dry Mouth; Feeling Abnormal; Hyponatraemia; Hypovolaemia; Migraine; Myalgia; Nausea; Somnolence; Tremor; Urinary Tract Infection; Withdrawal Syndrome	Meloxicam 15mg			S	Oral			Not Reported
	Baby Aspirin			S				Not Reported
	Lexapro			S				Not Reported
	Lisinopril			S				Not Reported
	Ciproflaxin			S				Not Reported
	Crestor			S				Astrazeneca
	Remeron			S		15 Mg, 30, Once Daily, Mouth		Not Reported
	Xalatan			C				Not Reported
	Lexapro			C	Oral	10-20 Mg Through The Years 30 Once Daily Mouth		Not Reported
	Norvasc			C				Not Reported
	Apple Cider Vinegar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2014	10504544	DIRECT	Y	DS			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Label Issue; Tendon Rupture	Lexapro			S	Oral	1 Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2014	10086372	EXPEDITED (15-DAY)		HO	US-FRI-1000051980		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Pancreatitis; Toxicity To Various Agents	Escitalopram			S	Oral	20 Mg		Forest
	Luaf41156			S	Oral	3 Mg		Not Reported
	Luaf41156			S	Oral	3 Mg		Not Reported
	Luaf41156			S	Oral	.50 Unk, Daily Dose		Not Reported
	Luaf41156			S	Oral	1 Mg		Not Reported
	Luaf41156			S	Oral	2 Mg		Not Reported
	Tylenol			C	Oral	400 Mg		Not Reported
	Imitrex			C	Oral	50 Mg, Unk		Not Reported
	Ventolin			C		10 Mcg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2014	10465393	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2014256625		30 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia; Overdose; Serotonin Syndrome	Xanax			S	Oral	Unk		Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2014	10503899	EXPEDITED (15-DAY)		HO, LT, OT	AU-JNJFOC-20141001220			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Poisoning Deliberate	Paracetamol	S	Unknown	Not Reported
	Diazepam	S	Unknown	Not Reported
	Quetiapine	S	Unknown	Not Reported
	Temazepam	S		Not Reported
	Alprazolam	S	Unknown	Not Reported
	Opioids	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Sertraline	S	Unknown	Not Reported
	Venlafaxine	S	Unknown	Not Reported
	Desvenlafaxine	S	Unknown	Not Reported
	Duloxetine	S	Unknown	Not Reported
	Zolpidem	S	Unknown	Not Reported
	Zopiclone	S	Unknown	Not Reported
	Tricyclic Antidepressant Nos	S	Unknown	Not Reported
	Nsaids	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2014	10504856	EXPEDITED (15-DAY)		OT	GB-FRI-1000071227		41 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Mania; Suicidal Ideation; Tremor	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2014	10505062	EXPEDITED (15-DAY)		HO	FR-SA-2014SA136949		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Doliprane			S	Oral	Form: Powder For Oral Solution		Not Reported
	Tranxene			S	Oral			Not Reported
	Flagyl			S	Unknown			Not Reported

	Lovenox	S	Subcutaneous	Not Reported
	Inexium	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Ceftriaxone Panpharma	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2014	10505101	EXPEDITED (15-DAY)		HO	FR-FRI-1000071289		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Thrombocytopenia	Escitalopram			S	Oral	10 Mg		Forest
	Metoject			S	Subcutaneous	2.1429 Mg		Not Reported
	Orelox			S	Oral			Not Reported
	Cortancyl			S	Oral	0.5 Df		Not Reported
	Augmentin			S	Oral	3 G		Not Reported
	Kardegic			C				Not Reported
	Tahor			C				Not Reported
	Furosemide			C				Not Reported
	Ramipril			C				Not Reported
	Erythropoietin			C				Not Reported
	Inexium			C				Not Reported
	Methylprednisolone			C				Not Reported
	Speciafoldine			C				Not Reported
	Mag 2			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2014	10505673	EXPEDITED (15-DAY)		HO	FR-FRI-1000071291		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Drug Interaction; Haematuria; Rectal Haemorrhage	Escitalopram			S				Forest
	Pradaxa			S	Oral	Overdose 220 Mg/Day.		Not Reported
	Pradaxa			S				Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2014	10507291	DIRECT					46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Emotional Disorder; Migraine; Palpitations; Product Substitution Issue; Pyrexia	Escitalopram 10mg Lupin Pharmaceu			S	Oral	1 Pill, Once Daily, Taken By Mouth		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10259940	EXPEDITED (15-DAY)		HO	IT-FRI-1000068484		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Abuse; Psychomotor Hyperactivity	Escitalopram Oral Solution			S	Oral	15 Ml Of 20 Mg/Ml In 1 Single Dose		Forest
	Xanax			S	Oral	Overdose: 20 Ml Of 0.75 Mg/Ml		Not Reported
	Anafranil			S	Oral	Overdose: 225 Mg (3 Tablets Of 75 Mg)		Not Reported
	Aspirina			S	Oral	Overdose: 1500 Mg (3 Tablets Of 500 Mg)		Not Reported
	Baygon (Insecticides Substance)			S	Oral	Overdose: 3 Tablespoons		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10507783	EXPEDITED (15-DAY)		OT	DE-FRI-1000071344		76 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Transaminases Increased	Escitalopram			S	Transmammary	8 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10507844	EXPEDITED (15-DAY)		CA, DE, OT	US-MYLANLABS-2014M1006176			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Exposure During Pregnancy; Pulmonary Hypoplasia	Citalopram			S	Transplacental	Unk		Not Reported
	Lexapro			S	Transplacental	Unk		Not Reported
	Celexa /00582602/			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540480	NON-EXPEDITED		RI, OT	1000054686			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro (Escitalopram Oxalate)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540481	NON-EXPEDITED		RI, OT	1000060345			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Serotonin Syndrome	Lexapro (Escitalopram Oxalate)			S		- Stopped		Not Reported
	Triptans			S		- Stopped		Not Reported
	Yasmin (Drospirenone W/ Ethinylestradiol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540486	NON-EXPEDITED	Y	RI, OT	1000060443			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540501	NON-EXPEDITED	Y	RI, OT	1000064796		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Urinary Retention	Lexapro (Escitalopram Oxalate)	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540513	NON-EXPEDITED		RI, OT	1000067275		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Dizziness; Fatigue; Paraesthesia; Weight Increased	Lexapro			S	Oral Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540526	NON-EXPEDITED	Y	HO	1000067726		59 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets)			S	Oral			Not Reported
	Placebo (Placebo)			S	Oral			Not Reported
	Naprosyn (Naproxen)			C				Not Reported
	Atenolol			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Simvastatin			C				Not Reported
	Maalox (Magnesium Hydroxide, Aluminum Hydroxide)			C				Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported
	Prazosin Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540555	NON-EXPEDITED	Y	HO	1000068283		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Lexapro			S	Oral			Not Reported
	Prilosec (Omeprazole)			C				Not Reported
	Vitamin B12			C				Not Reported
	Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540568	NON-EXPEDITED	Y	RI, OT	1000068859		34 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Pregnancy	Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets)			S	Oral Oral			Not Reported
	Luaf41156			S	Oral			Not Reported
	Blinded Placebo			S	Oral			Not Reported
	Blinded Serequel Xr			S	Oral			Not Reported
	Tylenol Paracetamol (Paracetamol)			C				Not Reported
	Devils Claw			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540592	NON-EXPEDITED	Y	HO, RI, OT	1000068941		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro (Escitalopram Oxalate)			S				Not Reported
	Lamictal (Lamotrigine)			S				Not Reported
	Geodon			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540603	NON-EXPEDITED		RI, OT	1000069677		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Hyperhidrosis; Skin Laceration	Lexapro (Escitalopram Oxalate) (10 Milligram, Tablets)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540614	NON-EXPEDITED	Y	RI, OT	1000048132			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Delirium; Orthostatic Hypotension	Lexapro (Escitalopram Oxalate)			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540619	NON-EXPEDITED		RI, OT	1000049356		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicidal Ideation	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540642	NON-EXPEDITED	Y	HO	1000049954		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Testosterone Decreased; Crying; Depression; Mania; Sexual Dysfunction; Suicidal Ideation	Lexapro (Escitalopram Oxalate)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540672	NON-EXPEDITED		HO	1000050814		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Insomnia; Tremor	Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets)			S	Oral	15mg (15 Mg, 1 In 1 D), Oral		Not Reported
	Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets)			S	Oral	10 Mg (10 Mg, 1 In 1 D), Oral		Not Reported
	Risperdal (Risperidone)			S				Not Reported
	Abilify (Aripiprazole)			S				Not Reported
	Synthroid (Levothyroxine Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540694	NON-EXPEDITED		RI, OT	1000050921		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicidal Ideation	Escitalopram (Escitalopram Oxalate) (20 Milligram, Tablets)			S	Oral			Not Reported
	Percocet (Acetaminophen, Oxycodone) (Acetaminophen, Oxycodone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540710	NON-EXPEDITED		RI, OT	1000051465		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Ineffective; Headache; Muscle Twitching; Suicidal Ideation	Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540737	NON-EXPEDITED		RI, OT	1000051476		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Urinary Retention	Lexapro			S	Oral			Not Reported
	Xanax (Alprazolam)			C				Not Reported
	Metoprolol			C				Not Reported
	Atrovent (Ipratropium Bromide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540746	NON-EXPEDITED		HO, RI, OT	1000052137		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro (Escitalopram Oxalate) (20 Milligram, Tablets)			S				Not Reported
	Armour Thyroid (Thyroid)			C				Not Reported
	Levothyroxine (Levothyroxine Sodium)			C				Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540755	NON-EXPEDITED		DE	1000052528			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro (Escitalopram Oxalate)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2014	10540843	NON-EXPEDITED	Y	DE	1000052700		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2014	9675058	EXPEDITED (15-DAY)		HO	JP-FRI-1000050799		48 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block	Lexapro			S	Oral	20 Mg		Forest
	Reflex			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2014	10367670	EXPEDITED (15-DAY)		HO	CH-FRI-1000069654			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Gastrointestinal Haemorrhage; Normocytic Anaemia	Escitalopram			S	Oral	10 Mg		Forest
	Ponstan			S	Oral			Not Reported
	Magnesium			C				Not Reported
	Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2014	10468910	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2014-10095		26 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Confusional State; Hyponatraemia; Mydriasis; Overdose; Serotonin Syndrome; Tachycardia	Escitalopram			S	Oral	Unk		Aurobindo
	Xanax			S	Oral	0.25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2014	10510064	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2014-07749		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease	Escitalopram 20 Mg			S	Unknown	20 Mg, Once A Day		Aurobindo
	Prevacid			S	Oral	15 Mg, Two Times A Day		Not Reported
	Hydroxyzine Hydrochloride			S	Oral	50 Mg, As Necessary		Not Reported
	Advair			S	Respiratory (inhalation)	1 Puff		Not Reported
	Advair			S	Respiratory (inhalation)	1puff, Unk		Not Reported
	Ventolin Hfa			S	Respiratory (inhalation)	2 Puff		Not Reported
	Ventolin Hfa			S	Respiratory (inhalation)	2 Puff,		Not Reported
	Bupropion Hydrochloride			S	Oral	30 Mg, Once A Day		Not Reported
	Esterified Estrogens And Methyltestosterone			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Fluzone /00780601/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2014	10699864	EXPEDITED (15-DAY)		DE	US-APOTEX-2014AP003615		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Reversible Cerebral Vasoconstriction Syndrome; Serotonin Syndrome; Subarachnoid Haemorrhage	Escitalopram Oxalate		S	Unknown	10 Mg, Daily	Apotex
	Hydrocodone		S	Unknown		Not Reported
	Hydromorphone		S	Unknown		Not Reported
	Dihydroergotamine Mesilate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2014	10512941	EXPEDITED (15-DAY)		HO	IT-DRREDDYS-GER/ITL/14/0043465		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor	Quetiapine			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Prazene			S	Oral			Not Reported
	Paroxetine Hydrochloride			S	Oral			Not Reported
	Lasix			C				Not Reported
	Foster			C				Not Reported
	Stilnox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2014	10513167	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2014-10775		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor	Paroxetine Film-Coated Tablet			S	Oral	1.5 Df, Daily		Aurobindo
	Cipralex /01588501/			S	Oral	1 Df, Daily		Not Reported
	Prazene			S	Oral	1 Df, Daily		Not Reported
	Quetiapine Fumarate			S	Oral	300 Mg, Daily		Not Reported
	Foster /06206901/			C	Unknown	Unk		Not Reported
	Lasix /00032601/			C	Unknown	Unk		Not Reported
	Stilnox			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2014	10514626	EXPEDITED (15-DAY)		HO	FR-FRI-1000071462		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram			S				Forest
	Inexium			S	Oral	20 Mg		Not Reported
	Doliprane			S	Oral			Not Reported
	Tranxene			S	Oral			Not Reported
	Ceftriaxone Panpharma			S	Intravenous drip			Not Reported
	Flagyl			S		1500 Mg		Not Reported
	Lovenox			S	Subcutaneous	0.4 Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2014	10514969	EXPEDITED (15-DAY)		HO	PHHY2014AT130620		79 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Serotonin Syndrome	Tegretol			S	Unknown	200 Mg, Bid		Novartis
	Cipralex /Gfr/			S	Unknown	20 Mg, Qd		Not Reported
	Trittico			S	Unknown	75 Mg, Qd		Not Reported
	Lasix			S	Unknown	40 Mg, Qd		Not Reported
	Tramal			S	Unknown	1 Df, Bid		Not Reported
	Plavix			C		75 Mg, Qd		Not Reported
	Norvasc			C		5 Mg, Qd		Not Reported
	Dancor			C		10 Mg, Bid		Not Reported
	Glucophage			C		500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	9899050	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000054197			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Escitalopram			S		20 Mg		Forest
	Avapro			S		300 Mg		Not Reported

	Blinded Investigational Medicinal Product (Imp) Non-Partner	S	Oral	600 Mg	Not Reported
	Blinded Investigational Medicinal Product (Imp) Non-Partner	S	Oral	450 Mg	Not Reported
	Aspirin	C		Daily Dose Not Reported	Not Reported
	Hydrochlorothiazine	C		Daily Dose Not Reported	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10248729	EXPEDITED (15-DAY)		HO	B0997620A		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Areflexia; C-Reactive Protein Increased; Disturbance In Attention; Drug Interaction; Extensor Plantar Response; Hypertension; Lung Disorder; Medication Error; Rales; Red Blood Cell Count Decreased; Respiratory Tract Congestion; Sepsis; Somnolence; Urticaria; Wrong Patient Received Product	Paroxetine Hydrochloride			S	Oral	Single Dose		Not Reported
	Clorazepate Dipotassium			S	Oral	Single Dose		Not Reported
	Escitalopram Oxalate			S	Oral	At Night		Not Reported
	Alprazolam			S	Oral			Not Reported
	Olanzapine			S	Oral	Single Dose		Not Reported
	Valsartan			C				Not Reported
	Potassium Chloride			C				Not Reported
	Azathioprine			C				Not Reported
	Chondroitin Sulfate (Bovine)			C				Not Reported
	Tardyferon			C				Not Reported
	Colecalciferol			C				Not Reported
	Zolpidem			C				Not Reported
	Paracetamol			C				Not Reported
	Movicol			C				Not Reported
	Acetylleucine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10311974	EXPEDITED (15-DAY)	Y	OT	US-MYLANLABS-2014S1016336		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Coma; Reversible Cerebral Vasoconstriction Syndrome; Serotonin	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Hydrocodone			S	Unknown			Not Reported
	Hydromorphone			S	Unknown			Not Reported

Syndrome; Subarachnoid Haemorrhage	Dihydroergotamine Mesilate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10487994	EXPEDITED (15-DAY)		HO	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2014-BI-46		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Haematuria; Rectal Haemorrhage	Pradaxa			S	Oral	220 Mg		Boehringer Ingelheim
	Seroplex			S	Oral			Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10515434	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2014-07976		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gastritis Erosive; Hiatus Hernia; Nausea; Product Use In Unapproved Indication	Escitalopram 5 Mg (Escitalopram) Unknown, 5mg			S	Oral	5 Mg, Unk		Aurobindo
	Escitalopram 5 Mg (Escitalopram) Unknown, 5mg			S	Oral	10 Mg, Unk		Aurobindo
	Lexapro			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10516016	EXPEDITED (15-DAY)		HO	PHHY2014SI129440		86 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Acute Myocardial Infarction; Aggression; Angiopathy; Anxiety; Atrial Fibrillation; Cardiac Failure; Cognitive Disorder; Cyclothymic Disorder; Delirium;	Valproic Acid			S	Unknown	1000 Mg, Bid		Novartis
	Amitryptiline Hcl			S	Unknown			Not Reported
	Thioridazine			S	Unknown			Not Reported
	Citalopram			S	Unknown	60 Mg, Daily		Not Reported
	Quetiapine			S	Unknown	500 Mg, Daily		Not Reported
	Lamotrigine			S	Unknown	200 Mg, Bid		Not Reported

Depressed Mood; Disorientation; Drug Ineffective; Gastrooesophageal Reflux Disease; Hallucination, Olfactory; Hallucination, Visual; Hypomania; Insomnia; Mood Altered; Myeloproliferative Neoplasm; Psychomotor Hyperactivity; Restlessness; Suicide Attempt; Urinary Incontinence	Lamotrigine	S	Unknown	400 Mg, Bid	Not Reported
	Escitalopram	S	Unknown	5 Mg, Qd	Not Reported
	Escitalopram	S	Unknown	10 Mg, Daily	Not Reported
	Fluphenazine	S	Unknown	3 Mg, Daily	Not Reported
	Clomethiazole	S	Unknown	400 Mg, Qd	Not Reported
	Acetylsalicylic Acid	C	Unknown	100 Mg, Unk	Not Reported
	Pantoprazole	C	Unknown	20 Mg, Unk	Not Reported
	Carvedilol	C	Unknown	3 Mg, Unk	Not Reported
	Digoxin	C	Unknown	0.1 Mg, Unk	Not Reported
	Diazepam	C	Unknown	2 Mg, Daily	Not Reported
	Hydroxyurea	C	Unknown	1000 Mg, Bid	Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Carbamazepine	C	Unknown	800 Mg, Bid	Not Reported
	Olanzapine	C	Unknown	10 Mg, Unk	Not Reported
	Mianserin	C	Unknown	30 Mg, Unk	Not Reported
	Midazolam	C	Unknown	7.5 Mg, Unk	Not Reported
	Omeprazole	C	Unknown	20 Mg, Unk	Not Reported
	Ticlopidine	C	Unknown	250 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10516408	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2014SE75885		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Inexium			S	Oral			Not Reported
	Doliprane			S	Oral			Not Reported
	Tranxene			S	Oral			Not Reported
	Ceftriaxone Panpharma			S	Intravenous (not otherwise specified)			Not Reported
	Seroplex			S	Oral			Not Reported

	Lovenox	S	Subcutaneous	Not Reported
	Flagyl	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10516539	EXPEDITED (15-DAY)		HO	IT-TEVA-514322ISR		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor	Quetiapine			S	Oral	300 Mg Daily		Teva
	Paroxetine			S	Oral	1.5 Df Daily		Teva
	Cipralex - Compresse Rivestite Con Film Da 10 Mg - H.Lundbeck A/S			S	Oral	1 Df Daily		Not Reported
	Prazene - 20 Mg Compresse - Pfizer Italia S.R.L.			S	Oral	1 Df Daily		Not Reported
	Lasix - 25 Mg Compresse			C				Not Reported
	Foster - 100/6 Microgrammi - Soluzione Pressurizzata Per Inalazione			C				Not Reported
	Stilnox - 10 Mg Compresse Rivestite Con Film			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10516707	EXPEDITED (15-DAY)		OT	IT-TEVA-515090ISR		36 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Escitalopram			S	Unknown	10 Milligram Daily; 10 Mg/Day		Ivax
	Telaprevir			S	Unknown	2250 Milligram Daily;		Not Reported
	Peginterferon Alfa-2a			S	Unknown	180 Microg Weekly		Not Reported
	Ribavirin			C	Unknown	1000 Milligram Daily; 1000 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10517392	EXPEDITED (15-DAY)		HO	US-FRI-1000071499		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Albumin Increased; Drug Interaction; Gamma-Glutamyltransferase Increased; Liver Injury	Lexapro			S	Oral			Forest
	Cobimetinib			S	Oral			Not Reported
	Cobimetinib			S	Oral	60 Mg		Not Reported
	Vemurafenib			S	Oral	Dose Reduced, Most Recent Dose On 22/Jul/2013		Not Reported
	Vemurafenib			S	Oral	Dose Reduced (960 Mg)		Not Reported
	Claritin			C	Oral			Not Reported
	Benadryl			C	Oral			Not Reported
	Tylenol			C	Oral			Not Reported
	Tylenol			C				Not Reported
	Cymbalta			C	Oral			Not Reported
	Saline			C	Intravenous (not otherwise specified)			Not Reported
	Omeprazole			C	Oral			Not Reported
	Nitroglycerin			C	Sublingual			Not Reported
	Xanax			C	Oral			Not Reported
	Esomeprazole			C	Oral			Not Reported
	Ibuprofen			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10518902	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Product Quality Issue; Product Substitution Issue	Escitalopram			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10518908	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Malaise; Product Dispensing Error; Wrong Product Administered	Lexapro			S				Not Reported
	Enalapril Maleate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10519203	DIRECT	Y				34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Therapeutic Response Changed; Therapy Non-Responder	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10522622	EXPEDITED (15-DAY)	Y	OT	2014JUB00159		40 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Dysarthria; Extrapyramidal Disorder; Oculogyric Crisis; Protrusion Tongue	Escitalopram (Escitalopram) Unknown			S			1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2014	10522664	EXPEDITED (15-DAY)	Y	HO	2014HINLIT0913		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram (Escitalopram) Unknown			S				Not Reported
	Haloperidol (Haloperidol) (Haloperidol)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2014	10329823	EXPEDITED (15-DAY)		OT	US-TEVA-495453USA		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2014	10519046	EXPEDITED (15-DAY)		HO	JP-FRI-1000071464		86 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear; Musculoskeletal Stiffness; Tremor	Lexapro			S	Oral	10mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2014	10519213	EXPEDITED (15-DAY)		CA	FR-FRI-1000071544			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hand Malformation; Exposure During Pregnancy; Microcephaly; Psychomotor Retardation	Escitalopram			S	Transplacental			Forest
	Lamotrigine			S	Transplacental			Not Reported
	Bromazepam			S	Transplacental			Not Reported
	Dexeryl (Glycerol And White Soft Paraffin And Liquid Paraffin)			C				Not Reported
	Magne B6			C				Not Reported
	Acide Folique			C				Not Reported
	Ferrograd			C				Not Reported
	Fixical			C				Not Reported
	Metoclopramide			C				Not Reported
	Zymad			C				Not Reported
	Dosiseptine			C				Not Reported
	Diprosone			C				Not Reported
	Doliprane			C				Not Reported
	Doliprane			C				Not Reported
	Doliprane			C				Not Reported
	Doliprane			C				Not Reported
	Helicidine			C				Not Reported
	Pivalone /00803802/			C				Not Reported
	Pivalone /00803802/			C				Not Reported

Amoxicilline	C	Not Reported
Budesonide	C	Not Reported
Physiodose	C	Not Reported
Ventoline	C	Not Reported
Econazole	C	Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Not Reported
Gaviscon	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2014	10520010	EXPEDITED (15-DAY)		HO	PHHY2014IT131839			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Somnolence	Paroxetine Sandoz			S	Oral	1.5 Df, Qd		Novartis
	Quetiapine			S	Oral	300 Mg, Qd		Not Reported
	Cipralex//Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Prazene			S	Oral	1 Df, Qd		Not Reported
	Lasix			C	Unknown	Unk Ukn, Unk		Not Reported
	Foster			C	Unknown	Unk Ukn, Unk		Not Reported
	Stilnox			C	Unknown	Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2014	10520704	EXPEDITED (15-DAY)		DE, HO	US-NAPPMUNDI-GBR-2014-0022689		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebral Vasoconstriction; Serotonin Syndrome	Hydromorphone Hcl (Similar To 19-892)			S	Unknown	Unk, See Text		Purdue
	Hydromorphone Hcl (Similar To 19-892)			S				Purdue
	Escitalopram			S				Not Reported
	9-Tetrahydrocannabinol			S				Not Reported
	Anticoagulation Medication			C				Not Reported
	Dihydroergotamine			C	Intravenous (not otherwise specified)			Not Reported
	Dihydroergotamine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2014	10431912	EXPEDITED (15-DAY)		HO, OT	GB-PFIZER INC-2014246713		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome; Stomatitis	Ramipril			S	Unknown	Unk		Pfizer
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported
	Forxiga			S	Oral	5 Mg, 1x/Day		Not Reported
	Flucloxacillin			C		Unk		Not Reported
	Codeine			C		Unk		Not Reported
	Fucibet			C		Unk		Not Reported
	Humalog			C		Unk		Not Reported
	Lantus			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2014	10521882	EXPEDITED (15-DAY)		HO	PHHY2014ES134107		53 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Venlafaxine			S	Unknown	150 Mg, Qd		Not Reported
	Citalopram			S	Unknown	20 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Amiloride+Hydrochlorothiazide			S	Unknown	1 Df, Qd		Not Reported
	Enalapril			S	Unknown			Not Reported
	Olanzapine			S	Unknown	5 Mg, Qd		Novartis
	Haloperidol			S	Unknown	20 Drp, Qd		Not Reported
	Haloperidol			S	Unknown	10 Drp, Qd		Not Reported
	Agomelatine			C	Unknown	25 Mg, Qd		Not Reported
	Clorazepate Dipotassium			C	Unknown	10 Mg, Tid		Not Reported
	Clorazepate Dipotassium			C		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2014	10523166	EXPEDITED (15-DAY)		HO	CH-FRI-1000071524			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Hypochromic Anaemia	Escitalopram			S	Oral			Forest
	Marcoumar			S	Oral	3 Mg		Not Reported
	Pantozol (Switzerland)			C	Oral			Not Reported
	Torasemid			C	Oral	5 Mg		Not Reported
	Mirtazapin			C	Oral	30 Mg		Not Reported
	Quetiapin			C	Oral	25 Mg		Not Reported
	Vi-De 3			C	Oral			Not Reported
	Duphalac			C	Oral	5 Ml		Not Reported
	Vitarubin Superconc.			C	Intramuscular	11.111 Ug		Not Reported
	Dafalgan			C	Oral			Not Reported
	Fentanyl Matrix Transdermal System			C	Transdermal	4 Ug		Not Reported
	Dospir			C	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2014	10524826	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2014282449		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hip Fracture	Lyrica			S	Oral	Unk		Pfizer
	Tramadol Hcl			S	Oral	Unk		Pfizer
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Ebixa			S	Oral	10 Mg, 1x/Day		Not Reported
	Previscan (Fluindione)			C				Not Reported
	Insulin			C				Not Reported
	Furosemide			C				Not Reported
	Amlodipine			C				Not Reported
	Nebivolol			C				Not Reported

	Coaprovel	C	Not Reported
	Dafalgan	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2014	10525947	EXPEDITED (15-DAY)		DS	FR-FRI-1000071634		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral	15 Mg		Forest
	Previscan (Fluindione)			S	Oral	10 Mg		Not Reported
	Urbanyl			C				Not Reported
	Mopral			C				Not Reported
	Zamudol			C				Not Reported
	Fenofibrate			C				Not Reported
	Bisoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2014	10699994	EXPEDITED (15-DAY)		HO	IT-APOTEX-2014AP005103		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor	Paroxetine			S	Oral	1.5 Df, Daily		Apotex
	Quetiapine			S	Oral	300 Mg, Daily		Apotex
	Cipralex /01588502/			S	Oral	1 Df, Daily		Not Reported
	Prazene			S	Oral	1 Df, Unk		Not Reported
	Lasix /00032601/			C	Unknown			Not Reported
	Foster /06206901/			C	Unknown			Not Reported
	Stilnox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2014	9651872	EXPEDITED (15-DAY)		OT	CH-SA-2013SA107718		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Stilnox			S	Unknown			Not Reported

	Pristinamycin	S	Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Not Reported
	Ibuprofen	S	Unknown	Not Reported
	Ketoprofen	S	Unknown	Not Reported
	Zaldiar	S	Unknown	Not Reported
	Cipralex	S	Unknown	Not Reported
	Augmentin	C	Unknown	Not Reported
	Dafalgan	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2014	10527172	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2014-11054		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hip Fracture	Tramadol			S	Oral	Unk		Aurobindo
	Lyrica			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	10 Mg, Once A Day		Not Reported
	Ebixa			S	Oral	10 Mg, Once A Day		Not Reported
	Previscan (Fluindione)			C	Unknown	20 Mg, Unk		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Nebivolol			C	Unknown	Unk		Not Reported
	Coaprovel			C	Unknown	Unk		Not Reported
	Dafalgan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2014	10527724	EXPEDITED (15-DAY)		HO	CH-FRI-1000071632			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal	Escitalopram			S	Oral	10 Mg		Forest

Haemorrhage; Melaena; Shock Haemorrhagic	Clexane	S		40 Mg Daily		Not Reported
	Aspirin Cardio	S	Oral	100 Mg Daily		Not Reported
	Novalgine (Metamizole Sodium)	C				Not Reported
	Tazobac	C				Not Reported
	Piperacillin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2014	10527986	EXPEDITED (15-DAY)		HO	FR-FRI-1000071636		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus Generalised; Rash Vesicular; Urticaria	Escitalopram			S	Oral	20 Mg		Forest
	Lexomil			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2014	10528164	EXPEDITED (15-DAY)		HO, OT	SI-GLAXOSMITHKLINE-SI2014GSK004262		86 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Cognitive Disorder; Delirium; Disorientation; Fear; Hallucination, Visual; Insomnia; Insomnia; Psychomotor Hyperactivity; Restlessness; Restlessness	Escitalopram			S		10 Mg, Qd		Glaxosmithkline
	Clomethiazole			S				Not Reported
	Hydroxyurea			S		100 Mg, Bid		Not Reported
	Acetylsalicylic Acid			S		100 Mg, Unk		Not Reported
	Digoxin			S		0.1 Mg, Unk		Glaxosmithkline
	Carvedilol			S		3 Mg, Unk		Glaxosmithkline
	Pantoprazole			S		20 Mg, Unk		Not Reported
	Iron			S		200 Mg, Unk		Not Reported
	Citalopram			S		60 Mg, Unk		Glaxosmithkline
	Amitriptyline			C				Not Reported
	Thioridazine			C				Not Reported
	Haloperidol			C				Not Reported
	Carbamazepine			C		800 Mg, Bid		Glaxosmithkline
	Lamotrigine			C		400 Mg, Unk		Glaxosmithkline
	Olanzapine			C		10 Mg, Unk		Glaxosmithkline

	Mianserin	C	30 Mg, Unk	Not Reported
	Midazolam	C	7.5 Mg, Unk	Not Reported
	Omeprazole	C	20 Mg, Unk	Glaxosmithkline
	Ticlopidine	C	250 Mg, Unk	Not Reported
	Hydroxyurea	C		Glaxosmithkline
	Valproic Acid	C	1000 Mg, Bid	Not Reported
	Quetiapine	C	500 Mg, Unk	Glaxosmithkline
	Pantoprazole	S	20 Mg, Unk	Glaxosmithkline
	Flufenazine	C		Not Reported
	Folic Acid	C		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2014	10529980	DIRECT		OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejaculation Failure; Erectile Dysfunction	Escitalopram			S	Oral	1 Pill, Once Daily, Taken By Mouth		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2014	10530155	NON-EXPEDITED			US-PFIZER INC-2013337301			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Darvon			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Luvox			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2014	10530349	EXPEDITED (15-DAY)		OT	GB-DRREDDYS-GER/UKI/14/0043749		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Dyskinesia; Headache; Insomnia; Labelled Drug-Drug Interaction Medication Error; Mental Disorder; Serotonin Syndrome	Omeprazole			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2014	10530694	EXPEDITED (15-DAY)		HO	IT-ACTAVIS-2014-22184		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor	Quetiapine (Unknown)			S	Oral	300 Mg, Daily		Actavis
	Paroxetine (Unknown)			S	Oral	1.5 Dosage Unit Daily		Not Reported
	Cipralex /01588501/			S	Oral	1 Dosage Unit Daily		Not Reported
	Prazene			S	Oral	1 Dosage Unit Daily		Not Reported
	Lasix /00032601/			C	Unknown			Not Reported
	Foster /00500401/			C	Unknown			Not Reported
	Stilnox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2014	10532738	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2014M1007769			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Depression; Hyperkalaemia; Hyponatraemia; Mania; Psychomotor	Venlafaxine			S	Unknown	150mg/Day; Delayed Release		Not Reported
	Citalopram			S	Unknown	20mg/D		Not Reported

Hyperactivity; Suicidal Ideation	Olanzapine	S	Unknown	5mg/Day	Not Reported
	Enalapril	S	Unknown		Not Reported
	Escitalopram	S	Unknown	10mg/Day	Not Reported
	Haloperidol	S	Unknown	20 Drops /Day	Mylan
	Amiloride,Hydrochlorothiazide	S	Unknown	Amiloride/Hydroclorotiazide 5/50 G 1capsule/D	Mylan
	Agomelatine	C	Unknown	25mg/Day;	Not Reported
	Dipotassium Clorazepate	C	Unknown	10mg: 3 Capsule/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2014	10534491	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Depression; Nightmare; Product Substitution Issue	Generic Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2014	10699969	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2014AP005244		53 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hyperkalaemia; Hyponatraemia; Mania; Psychomotor Hyperactivity; Suicidal Behaviour	Venlafaxine			S	Unknown	150 Mg, Per Day; Delayed Release		Apotex
	Citalopram			S	Unknown	20 Mg, Per Day		Apotex
	Enalapril			S	Unknown			Apotex
	Escitalopram Apotex			S	Unknown	10 Mg, Per Day		Apotex
	Olanzapine			S	Unknown	5 Mg, Per Day		Apotex
	Haloperidol			S	Unknown	20 Gtt, Per Day		Not Reported
	Haloperidol			S		10 Gtt, Per Day		Not Reported
	Hydrochlorothiazide, Amiloride			S	Unknown	1 Df,		Not Reported
	Agomelatine			C	Unknown	25 Mg, Per Day		Not Reported

	Dipotassium Clorazepate	C	Unknown	3 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2014	10361185	EXPEDITED (15-DAY)	Y	DE, HO	2014HINLIT0673		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Cerebral Infarction; Cerebral Vasoconstriction; Coma; Posterior Reversible Encephalopathy Syndrome; Subarachnoid Haemorrhage	Escitalopram			S				Not Reported
	Dihydroergotamine Mesilate			C				Not Reported
	Hydromorphone			C				Not Reported
	Verapamil			C				Not Reported
	Nicardipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2014	10533927	EXPEDITED (15-DAY)		HO	FR-FRI-1000071670		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hip Fracture	Escitalopram			S	Oral	1 Df		Forest
	Memantine			S	Oral	1 Df		Forest
	Lyrica			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Previscan (Fluindione)			C	Oral			Not Reported
	Insuline			C				Not Reported
	Furosemide			C				Not Reported
	Amlodipine			C				Not Reported
	Nebivolol			C				Not Reported
	Coaprovel			C				Not Reported
	Dafalgan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2014	10535006	EXPEDITED (15-DAY)		OT	AT-PFIZER INC-2014288356		70 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Urinary Retention	Norvasc	S	5 Mg, Unk	Pfizer
	Norvasc	S	10 Mg, Unk	Pfizer
	Norvasc	S	7.5 Mg, Unk	Pfizer
	Norvasc	S	5 Mg, Unk	Pfizer
	Norvasc	S	7.5 Mg, Unk	Pfizer
	Norvasc	S	5 Mg, Unk	Pfizer
	Dominal Forte	S	80 Mg, Unk	Not Reported
	Dominal Forte	S	160 Mg, Unk	Not Reported
	Cipralex	S	15 Mg, Unk	Not Reported
	Cipralex	S	20 Mg, Unk	Not Reported
	Cipralex	S	30 Mg, Unk	Not Reported
	Temesta (Lorazepam)	C	1 Mg, Unk	Not Reported
	Temesta	C	2 Mg, Unk	Not Reported
	Temesta	C	2.5 Mg, Unk	Not Reported
	Temesta	C	1.75 Mg, Unk	Not Reported
	Temesta	C	1 Mg, Unk	Not Reported
	Temesta	C	0.5 Mg, Unk	Not Reported
	Temesta	C	1 Mg, Unk	Not Reported
	Temesta	C	0.5 Mg, Unk	Not Reported
	Sortis	C	40 Mg, Unk	Not Reported
	Finasteride	C	5 Mg, Unk	Not Reported
	Lyrica	C	100 Mg, Unk	Not Reported
	Lyrica	C	200 Mg, Unk	Not Reported
	Lyrica	C	300 Mg, Unk	Not Reported
	Lyrica	C	75 Mg, Unk	Not Reported
	Alna Retard	C	0.8 Mg, Unk	Not Reported
	Alna Retard	C	0.4 Mg, Unk	Not Reported
	Alna Retard	C	0.8 Mg, Unk	Not Reported
	Cal-D-Vita	C	1 Df, Unk	Not Reported

Zoldem	C	10 Mg, Unk	Not Reported
Zoldem	C	20 Mg, Unk	Not Reported
Zoldem	C	15 Mg, Unk	Not Reported
Zoldem	C	10 Mg, Unk	Not Reported
Mirtabene	C	45 Mg, Unk	Not Reported
Mirtabene	C	60 Mg, Unk	Not Reported
Mirtabene	C	30 Mg, Unk	Not Reported
Mirtabene	C	15 Mg, Unk	Not Reported
Bretaris Genuair	C	1 Df, 1x/Day	Not Reported
Tenormin	C	50 Mg, Unk	Not Reported
Tenormin	C	25 Mg, Unk	Not Reported
Oleovit-D3	C	50 Gtt, Weekly	Not Reported
Molaxole	C	1 Df, Unk	Not Reported
Maxi Kalz Vit D3	C	1 Df, Unk	Not Reported
Tritace	C	5 Mg, Unk	Not Reported
Tritace	C	10 Mg, Unk	Not Reported
Tritace	C	5 Mg, Unk	Not Reported
Circadin	C	2 Mg, Unk	Not Reported
Atorvalan	C	40 Mg, Unk	Not Reported
Sirdalud	C	8 Mg, Unk	Not Reported
Sirdalud	C	4 Mg, Unk	Not Reported
Sirdalud	C	2 Mg, Unk	Not Reported
Mogadon	C	1 Df, Unk	Not Reported
Tritazide	C	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2014	10536634	NON-EXPEDITED			US-RECKITT BENCKISER PHARMACEUTICAL, INC-RB-68632-			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Irritability; Paranoia; Self Esteem Inflated	Suboxone Film		S	Sublingual	Suboxone Film	Reckitt Benckiser
	Xanax		S	Oral	Dosing Details Unknown	Not Reported
	Lexapro		S	Oral	Dosing Details Unknown	Not Reported
	Serax		S	Oral	Dosing Details Unknown	Not Reported
	Motrin		S	Unknown	Dosing Details Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2014	10538061	DIRECT	Y				23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hypersomnia; Product Substitution Issue; Sedation; Somnolence	Escitalopram			S	Oral	1 Am		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2014	10538017	EXPEDITED (15-DAY)		HO	ES-TEVA-516544ISR		53 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Venlafaxine			S	Unknown	150 Milligram Daily; 150mg/Day; Delayed Release		Not Reported
	Citalopram			S	Unknown	20 Milligram Daily; 20mg/D		Not Reported
	Olanzapine			S	Unknown	5 Milligram Daily; 5mg/Day		Teva
	Enalapril			S	Unknown			Not Reported
	Escitalopram			S	Unknown	10 Milligram Daily; 10mg/Day		Not Reported
	Hydrochlorothiazide, Amiloride			S	Unknown	Amiloride/Hydroclorotiazide 5/50 G 1capsule/D		Not Reported
	Haloperidol			S	Unknown	20 Drops /Day		Not Reported
	Agomelatine			C	Unknown	25 Milligram Daily; 25mg/Day;		Not Reported
	Dipotassium Clorazepate			C	Unknown	10 Milligram Daily; 10mg:		Not Reported

3 Capsule/Day

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2014	10539484	NON-EXPEDITED		HO, LT	SE-JNJFOC-20141012166		23 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Electrocardiogram Abnormal; Muscle Twitching; Poisoning; Somnolence	Reactine (Cetirizine Hydrochloride)		Y	S	Oral			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Oral			Not Reported
	Postafen (Meclozine Hydrochloride)			S	Oral			Not Reported
	Tavegyl			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Loratadine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2014	10540825	DIRECT	Y				6 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Limb Deformity; Limb Reduction Defect	Lexapro			S	Oral			Not Reported
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2014	10554026	NON-EXPEDITED	Y		AP356-01251-SPO-US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Belviq			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2014	10567955	NON-EXPEDITED	Y	OT	AUR-APL-2014-08868		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Fluconazole (Fluconazole)			S				Not Reported
	Ondansetron (Ondansetron)			S				Not Reported
	Escitalopram (Escitalopram)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2014	10567960	NON-EXPEDITED		OT	AUR-APU-2014-07307		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Tremor	Escitalopram (Escitalopram)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2014	8434788	EXPEDITED (15-DAY)		CA, HO, OT	US-FRI-1000028169		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Atrioventricular Block Complete; Autism Spectrum Disorder; Coarctation Of The Aorta; Device Malfunction; Hypovolaemia; Inguinal Hernia; Premature Baby; Pulmonary Artery Stenosis; Respiratory Distress; Right Ventricular Hypertrophy; Umbilical Cord Abnormality; Ventricular Septal Defect	Lexapro			S	Transplacental	10 Mg		Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2014	8588850	EXPEDITED (15-DAY)		CA	US-FRI-1000030905		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Patent Ductus Arteriosus	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2014	8589308	EXPEDITED (15-DAY)		CA	US-FRI-1000030897		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Neonatal Cardiac Failure; Patent Ductus Arteriosus; Pulmonary Artery Stenosis Congenital; Transposition Of The Great Vessels; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2014	10303478	EXPEDITED (15-DAY)		OT	DK-FRI-1000068968		56 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Bundle Branch Block Right; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	10 Mg		Forest
	Cisordinol Tabletter			C		10mg+0+0+20mg		Not Reported
	Nozinan			C				Not Reported
	Cozaar Comp 100mg+12.5mg			C				Not Reported
	Cisordinol Depot Injektion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2014	10313515	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20140705319		46 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice Cholestatic	Concerta			S	Oral			Not Reported
	Augmentin			S	Oral	At The Beginning Of May For 8 Days.		Not Reported

	Augmentin		S	Oral		Not Reported
	Seroplex		S	Oral		Not Reported
	Lysanxia		S	Oral		Not Reported
	Coversyl		S	Oral		Not Reported
	Ibuprofene		S	Oral	1 Or 2 Tablet Per Month	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2014	10342773	EXPEDITED (15-DAY)		HO	IT-FRI-1000069305		20 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Product Use In Unapproved Indication; Sopor	Escitalopram			S	Oral	Overdose: 140 Mg		Forest
	Lorazepam			S	Oral	Overdose: 20 Ml		Not Reported
	Talofen			S	Oral	Overdose: 40		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2014	10382522	EXPEDITED (15-DAY)		OT	US-SA-2014SA068800		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Drug Interaction; Myalgia; Pain In Extremity; Pollakiuria; Polymyalgia Rheumatica; Productive Cough	Multaq			S	Oral			Not Reported
	Multaq			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2014	10444069	EXPEDITED (15-DAY)	Y	OT	ADR-2014-01569		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Increased; Device Power Source Issue; Drug Withdrawal Syndrome; Hot	Baclofen	Y		S		56.17 Mcg/Day		Not Reported
	Clonidine Intrathecal			S				Not Reported
	Dilaudid 0.9 Mg/Ml			S		0.9 Mg/Ml (0.22977		Not Reported

Flush; Muscle Spasms; Muscle Spasticity; Pain	Bupivacaine	S		Mg/Day 5.6 Mg/Ml (1.4297) Mg/Day)	Not Reported
	Flomax	S			Not Reported
	Lexapro	S		Day	Not Reported
	Copazone	S	Subcutaneous		Not Reported
	Vicodin	S			Not Reported
	Baclofen	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2014	10252646	EXPEDITED (15-DAY)		CA, OT	CH-FRI-1000068377		< 1 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Foot Malformation; Congenital Hand Malformation; Foetal Exposure During Pregnancy; Premature Baby; Syndactyly	Escitalopram			S	Transplacental	20 Mg		Forest
	Escitalopram			S	Transplacental	10 Mg, Decreased To 10 Mg At End Of Pregnancy		Forest
	Valdoxan			S	Transplacental	25 Mg		Not Reported
	Dalmadorm			S	Transplacental	15-30 Mg Daily		Not Reported
	Stilnox Cr			S	Transplacental	12.5 Mg		Not Reported
	Fluoxetin			S	Transplacental			Not Reported
	Aspirin			C	Transplacental	100 Mg		Not Reported
	Utrogestan			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2014	10485264	EXPEDITED (15-DAY)		HO	CH-FRI-1000071084			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antidepressant Drug Level Increased; Confusional State; Psychomotor Hyperactivity	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest

Escitalopram	S	Oral	10 Mg	Not Reported
Durogesic	S	Topical	12 Microg/H 1x/3 Days	Not Reported
Durogesic	S	Topical	25 Microg/H 1x/3 Days	Not Reported
Durogesic	S	Topical	50 Microg/H 1x/3days	Not Reported
Durogesic	S	Topical	25 Microg/H 1x/3 Days	Not Reported
Durogesic	S	Topical		Not Reported
Madopar	S	Oral	500 Mg	Not Reported
Madopar	S	Oral	1000 Mg	Not Reported
Madopar	S	Oral	500 Mg	Not Reported
Madopar	S	Oral		Not Reported
Aspirine	C	Oral	100 Mg	Not Reported
Temesta (Lorazepam)	C	Oral	0.5 Mg	Not Reported
Temesta (Lorazepam)	C	Other	1 Mg Daily, At The End Of Her Life, Increased Up To 3 Mg Daily	Not Reported
Temesta (Lorazepam)	C	Other	3 Mg	Not Reported
Laxoberon	C	Oral	5 Mg	Not Reported
Morphine Hcl	C	Oral	30 Mg	Not Reported
Lyrica	C	Oral	50 Mg	Not Reported
Glucophage	C	Oral	1000 Mg (In Addition: 500 Mg Daily)	Not Reported
Dafalgan	C	Oral	1500 Mg	Not Reported
Amlodipine	C	Oral	5 Mg	Not Reported
Concor	C	Oral	2.5 Mg	Not Reported
Motilium	C	Oral	30 Mg	Not Reported
Zofran	C	Oral	12 Mg	Not Reported
Monuril	C	Oral	3 G	Not Reported
Anexate	C	Other	0.4 Mg	Not Reported
Midazolam	C	Intravenous bolus	1.5 Mg	Not Reported
Furadantine	C	Oral	300 Mg	Not Reported

	Quetiapine	C	Oral	6 Mg		Not Reported
	Nitroderm	C	Cutaneous	10 Mg		Not Reported
	Haldol	C	Other	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2014	10542503	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2014-11120		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Dyskinesia; Headache; Insomnia; Labelled Drug-Drug Interaction Medication Error; Malaise; Mental Disorder; Serotonin Syndrome	Escitalopram 20 Mg			S	Unknown	20 Mg, Once A Day		Aurobindo
	Omeprazole 40mg			S	Unknown	40 Mg, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2014	10543508	NON-EXPEDITED			US-PFIZER INC-2014290750		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Somnolence	Lyrica			S		75 Mg, 1x/Day		Pfizer
	Lyrica			S				Pfizer
	Lexapro			S		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2014	10548653	DIRECT	Y	HO			18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypertension; Speech Disorder; Tachycardia; Tremor	Lexapro			S	Oral	1 Tablet		Unknown
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2014	10551100	EXPEDITED (15-DAY)		OT	IT-ZYDUS-003908		36 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Escitalopram (Escitalopram)			S				Not Reported
	Telaprevir (Telaprevir)			S				Not Reported
	Peginterferon Alfa 2a			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10547528	EXPEDITED (15-DAY)		OT	GB-ACCORD-026593		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Labelled Drug-Drug Interaction Medication Error; Serotonin Syndrome	Escitalopram			S				Accord
	Omeprazole			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10548402	EXPEDITED (15-DAY)		CA	US-FRI-1000071735		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect; Cleft Lip; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10548489	EXPEDITED (15-DAY)		CA	US-FRI-1000071745		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10548660	EXPEDITED (15-DAY)		HO, OT	FR-SHIRE-FR201407186		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemarthrosis	Xagrid			S	Oral	1 Mg, 1x/Day:Qd (2 Df, 0.5 Mg)		Shire
	Plavix			S	Oral	Unk, Unknown		Not Reported
	Plavix			S	Oral	Unk, Unknown		Not Reported
	Seroplex			S	Oral	1 Df, 1x/Day:Qd		Not Reported
	Loxen /00639802/			C	Unknown	20 Mg, 1x/Day:Qd		Not Reported
	Paracetamol			C	Unknown	1 To 3/Day, As Req'D		Not Reported
	Oxybutynin			C	Unknown	Unk, Unknown		Not Reported
	Lorazepam			C	Unknown	2.5 Mg, 1x/Day:Qd		Not Reported
	Uvedose			C	Unknown	1 Ampoule, Other (Once A Month)		Not Reported
	Econazole			C	Unknown	2 Applications, Other (Per Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10548860	EXPEDITED (15-DAY)		CA	US-FRI-1000071747		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10549028	EXPEDITED (15-DAY)		CA	US-FRI-1000071749		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Tricuspid Valve Atresia; Transposition Of The Great Vessels	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10549048	EXPEDITED (15-DAY)		CA	US-FRI-1000071792		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arachnoid Cyst; Arnold-Chiari Malformation; Growth Hormone Deficiency; Pineal Gland Cyst	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10549364	EXPEDITED (15-DAY)		CA	US-FRI-1000071751		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Limb Asymmetry; Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10549913	EXPEDITED (15-DAY)		CA	US-FRI-1000071753		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cardiac Failure Congestive; Congenital Pulmonary Valve Atresia; Hypoplastic Right Heart Syndrome; Patent Ductus Arteriosus; Tricuspid Valve Incompetence	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10550011	EXPEDITED (15-DAY)		CA	US-FRI-1000071755		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10550259	EXPEDITED (15-DAY)		OT	PHHY2014GB138178		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Dyskinesia; Headache; Insomnia; Labelled Drug-Drug Interaction Medication Error; Mental Disorder; Serotonin Syndrome	Omeprazole			S		40 Mg, Qd		Novartis
	Escitalopram			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2014	10554005	EXPEDITED (15-DAY)		OT	2014SA068800		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Drug Interaction; Macular Degeneration; Myalgia; Pollakiuria; Polymyalgia Rheumatica; Sputum Increased	Multaq			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2014	10551230	EXPEDITED (15-DAY)		CA	US-FRI-1000071757		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2014	10551594	NON-EXPEDITED			US-PFIZER INC-2014296998		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Metoprolol Tartrate			S		Unk		Not Reported

Potassium Citrate	S	Unk	Unknown
Singulair	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Lasix	S	Unk	Not Reported
Clinoril	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2014	10552469	EXPEDITED (15-DAY)		CA	US-FRI-1000071760		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniosynostosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2014	10552529	EXPEDITED (15-DAY)		CA	US-FRI-1000071762		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2014	10552572	EXPEDITED (15-DAY)		CA	US-FRI-1000071764		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Patent Ductus Arteriosus	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2014	10552656	EXPEDITED (15-DAY)		CA	US-FRI-1000071766		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10434647	NON-EXPEDITED		HO, OT	US-JNJFOC-20140803194		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extra Dose Administered; Liver Injury; Toxicity To Various Agents	Tylenol Extra Strength		Y	S	Unknown			Not Reported
	Tylenol Extra Strength			S	Unknown	6 To 8 Pills, Every 4 To 6 Hours		Not Reported
	Lexapro			S	Unknown			Not Reported
	Pamelor			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Acetaminophen\Hydrocodone Bitartrate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555830	EXPEDITED (15-DAY)		HO	CZ-FRI-1000071981		67 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypochloraemia; Hypokalaemia; Hyponatraemia; Presyncope	Escitalopram			S	Oral	10 Mg		Forest
	Cancombino 32 Mg/12.5 Mg			S				Not Reported
	Lexaurin			C				Not Reported
	Zocor 20 Mg			C				Not Reported
	Concor Cor 2.5 Mg			C				Not Reported
	Anopyrin 100 Mg			C				Not Reported
	Kapidin 10 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555831	EXPEDITED (15-DAY)		OT	GB-FRI-1000071979		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Dyskinesia; Headache; Insomnia; Labelled Drug-Drug	Escitalopram			S	Oral	20 Mg Once Daily		Forest
	Omeprazole			S		40 Mg Once Daily		Not Reported

Interaction Medication Error; Mental Disorder; Serotonin Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555857	EXPEDITED (15-DAY)		CA	US-FRI-1000071768		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555861	EXPEDITED (15-DAY)		CA	US-FRI-1000071776		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Stenosis; Bicuspid Aortic Valve	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555863	EXPEDITED (15-DAY)		CA	US-FRI-1000071770		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Patent Ductus Arteriosus; Transposition Of The Great Vessels	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555866	EXPEDITED (15-DAY)		CA	US-FRI-1000071778		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transposition Of The Great Vessels	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555869	EXPEDITED (15-DAY)		CA	US-FRI-1000071780		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Valve Stenosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555938	EXPEDITED (15-DAY)		CA	US-FRI-1000071782		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555942	EXPEDITED (15-DAY)		CA	US-FRI-1000071784		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Plagiocephaly; Scoliosis; Skull Malformation; Spina Bifida Occulta; Torticollis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555948	EXPEDITED (15-DAY)		CA	US-FRI-1000071786		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555949	EXPEDITED (15-DAY)		CA	US-FRI-1000071788		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cleft Palate	Lexapro	S	Transplacental		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10555956	EXPEDITED (15-DAY)		CA	US-FRI-1000071790		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydrocephalus; Spina Bifida	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2014	10559979	EXPEDITED (15-DAY)	Y	HO	2014JUB00177		53 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Decreased Appetite; Depressed Mood; Depression; Hyponatraemia; Insomnia; Suicidal Ideation	Olanzapine (Olanzapine) Unknown			S				Not Reported
	Escitalopram (Escitalopram) Unknown			S				Not Reported
	Enalapril (Enalapril)			S				Not Reported
	Clorazepate Dipotassium			C				Not Reported
	Agomelatine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2014	10248032	EXPEDITED (15-DAY)		CA	DK-FRI-1000068339		< 1 DAY	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Polydactyly	Escitalopram			S	Transplacental	5 Mg		Forest
	Eltroxin			C	Transplacental	242.8571 Mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2014	10549313	EXPEDITED (15-DAY)		HO	FR-FRI-1000070639		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Bacterial	Escitalopram			S	Oral	5 Mg		Forest

Sepsis	Mianserin	S	Oral	40 Mg		Not Reported
	Aricept	C		15 Mg		Not Reported
	Zopiclone	C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2014	10549833	EXPEDITED (15-DAY)		OT	GB-ASTRAZENECA-2014SE79413		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Mental Disorder; Serotonin Syndrome	Omeprazole			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2014	10558498	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2014GSK015491			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agoraphobia; Arthritis; Crying; Depression; Enuresis; Fatigue; Feeling Jittery; Peripheral Vascular Disorder; Personality Change; Vertigo	Wellbutrin			S	Oral			Glaxosmithkline
	Xyrem			S	Oral	4.5 G, Qd		Not Reported
	Xyrem			S				Not Reported
	Topamax			S				Not Reported
	Zanaflex			S				Not Reported
	Xanax			S				Not Reported
	Roxicodone			S				Not Reported
	Spiriva			S				Not Reported
	Lexapro			S				Not Reported
	Albuterol			S				Glaxosmithkline
	Elavil Tablet (Amitriptyline Hydrochloride)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2014	10558533	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2014296115		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Constipation; Fall; Gastrointestinal Sounds Abnormal; Major Depression; Malaise; Orthostatic Hypotension; Tachycardia; Treatment Failure	Xanax		S	Oral	0.5 Mg, 4x/Day	Pfizer
	Mirtazapine		S	Oral	30 Mg, 1x/Day	Not Reported
	Loxapac		S	Oral	20 Gtt, 3x/Day	Not Reported
	Loxapac		S	Oral	45 Gtt, Daily	Not Reported
	Risperdal		S	Oral	2 Mg, 1x/Day	Not Reported
	Risperdal		S	Oral	4 Mg, 1x/Day	Not Reported
	Noctamid		S	Oral	2 Mg, Daily	Not Reported
	Seroplex		S		Unk	Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)		C	Oral	5.9 G, Daily	Not Reported
	Lansoyl		C	Oral	Unk	Not Reported
	Fraxiparine		C	Subcutaneous	1 Df, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2014	10562216	EXPEDITED (15-DAY)	Y	OT	GB-DEXPHARM-20140675		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Omeprazole			S		3cp Dosages / Interval: 1 In 1 Days	48 DAY	Not Reported
	Escitalopram			S		Sep. Dosages / Interval: 1 In 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2014	10559418	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2014M1008220			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Dyskinesia; Headache; Insomnia;	Omeprazole			S		40 Mg, Qd		Not Reported
	Escitalopram			S		20 Mg, Qd		Not Reported

Labelled Drug-Drug Interaction Medication Error; Mental Disorder; Serotonin Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2014	10559717	NON-EXPEDITED			US-PFIZER INC-2014301466			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S		12.5 Mg, Unk		Pfizer
	Zoloft			S		50 Mg, Daily		Pfizer
	Effexor			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2014	10559751	NON-EXPEDITED			US-PFIZER INC-2014301389			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Eye; Fatigue; Insomnia; Loss Of Personal Independence In Daily Activities; Pain; Visual Acuity Reduced	Gabapentin			S		300 Mg, Unk		Pfizer
	Tramadol Hcl			S		1/2 Of A 50 Mg Tablet, 2x/Day		Unknown
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2014	10560059	EXPEDITED (15-DAY)		HO	US-SA-2014SA148250		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dysarthria; Hypertension; Hypokalaemia; Mental Status Changes; Multiple Drug Therapy	Ambien			S	Oral			Not Reported
	Desvenlafaxine Succinate			S	Oral			Not Reported
	Desvenlafaxine Succinate			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported

Ibuprofen	S	Oral			Not Reported
Lexapro	S	Oral			Not Reported
Clonazepam	S	Oral			Not Reported
Abilify	S	Oral			Not Reported
Vicodin	S	Oral	Dose:5/500		Not Reported
Fluticasone	S	Respiratory (inhalation)	Dose: 2 Sprays		Not Reported
Loratadine	S	Oral			Not Reported
Vivelle	S	Transdermal			Not Reported
Robaxin	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2014	10560980	EXPEDITED (15-DAY)		OT	GB-WATSON-2014-23239		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Dyskinesia; Headache; Insomnia; Labelled Drug-Drug Interaction Medication Error; Mental Disorder; Serotonin Syndrome	Omeprazole (Unknown)			S	Unknown	40 Mg, Daily		Watson
	Escitalopram (Unknown)			S	Unknown	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2014	10562522	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Oral	1 Tablet By Mouth Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2014	10561949	EXPEDITED (15-DAY)		OT	CH-RANBAXY-2014RR-86889		39 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Suicide Attempt	Fluoxetine		S	Unknown	20 Mg, Daily	Ranbaxy
	Escitalopram		S	Unknown	Unk	Not Reported
	Lorazepam		S	Unknown	10 Mg	Ranbaxy
	Quetiapine		S	Unknown	250 Mg	Not Reported
	Acemetacin		S	Unknown	90 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2014	10562093	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002586		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dizziness; Flushing; Headache; Palpitations; Product Substitution Issue; Pyrexia	Escitalopram Tablets Usp 20mg			S				Lupin
	Escitalopram Tablets Usp 20mg			S				Lupin
	Zyrted Otc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2014	10562987	EXPEDITED (15-DAY)		DE, HO	GB-FRI-1000071978		81 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anxiety; Hallucination	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2014	10357080	EXPEDITED (15-DAY)		DS	IT-FRI-1000069493		80 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prescribed Overdose; Visual Acuity Reduced	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	Overdose: 40 Mg Daily		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Tavor (Lorazepam)			S	Oral	1.5 Mg		Not Reported

	Tavor (Lorazepam)	S	Oral	2 Unit Dose Per Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2014	10530015	EXPEDITED (15-DAY)		OT	IN-AUROBINDO-AUR-APL-2014-11087		23 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisocial Behaviour; Anxiety; Crying; Decreased Appetite; Decreased Interest; Drug Ineffective; Dystonia; Mood Altered; Oculogyric Crisis	Escitalopram Oxalate Tablets 10 Mg			S	Unknown	10 Mg, Daily		Aurobindo
	Amisulpride Tablets			S	Unknown	Upto 1000 Mg, Unk		Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Aripiprazole			S	Unknown	30 Mg, Daily		Not Reported
	Aripiprazole			S	Unknown	30 Mg, Daily		Not Reported
	Olanzapine			S	Unknown	7.5 Mg, Daily		Not Reported
	Olanzapine			S	Unknown	15 Mg, Daily		Not Reported
	Olanzapine			S	Unknown	20 Mg, Daily		Not Reported
	Paliperidone			S	Unknown	3 Mg, Unk		Not Reported
	Propranolol			S	Unknown	40 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2014	10530112	NON-EXPEDITED			US-PFIZER INC-2014284792		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Meloxicam			S		Unk		Not Reported
	Theophylline			S		Unk		Pfizer
	Asa			S		Unk		Not Reported
	Cogentin			S		Unk		Not Reported
	Bactrim Ds			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Omega			S		Unk		Not Reported

Trazodone	S	Unk	Not Reported
Progesterone	S	Unk	Not Reported
Seroquel	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2014	10564757	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2014-11540		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Fall; Gastrointestinal Sounds Abnormal; Malaise; Orthostatic Hypotension; Tachycardia; Treatment Failure	Mirtazapine Film-Coated Tablet 15 Mg			S	Oral	2 Df, Daily		Aurobindo
	Risperdal			S	Oral	1 Df, Daily		Not Reported
	Risperdal			S	Oral	2 Df, Daily		Not Reported
	Xanax			S	Oral	4 Df, Unk		Not Reported
	Noctamide			S	Oral	1 Df, Unk		Not Reported
	Loxapac /00401801/			S	Oral	60 Gtt, Unk		Not Reported
	Loxapac /00401801/			S	Oral	45 Gtt, Daily		Not Reported
	Lansoyl			C	Oral			Not Reported
	Transipeg /00754501/			C	Unknown	1 Df, Daily		Not Reported
	Fraxiparine /01437702/			C	Subcutaneous	1 Df, Daily		Not Reported
	Seroplex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2014	10564787	EXPEDITED (15-DAY)		DE, HO	GB-ACCORD-026758		81 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anxiety; Hallucination	Escitalopram			S	Oral	Initially Given 5 Mg Then Dose Increased To 10 Mg Daily From Unknown Date.		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2014	10565035	EXPEDITED (15-DAY)		DE, HO	GB-AUROBINDO-AUR-APL-2014-11441		81 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anxiety; Death; Hallucination	Escitalopram			S	Oral	5 Mg, Daily		Aurobindo
	Escitalopram			S	Oral	Unk		Aurobindo
	Escitalopram			S	Oral	Unk		Aurobindo
	Escitalopram			S	Oral	10 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2014	10566406	EXPEDITED (15-DAY)		HO	FR-FRI-1000072053		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Somnolence	Escitalopram			S	Oral	1 Df		Forest
	Memantine			S	Oral	1 Df		Forest
	Tranxene			S	Oral	2 Df		Not Reported
	Lorazepam			S	Oral	0.5 Df		Not Reported
	Risperdal			C	Oral	0.5 Df		Not Reported
	Coumadine			C	Oral	1 Df		Not Reported
	Nicorandil			C	Oral	2 Df		Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			C		If Pain 4 Df Daily		Not Reported
	Lovenox			C	Subcutaneous	8000 Iu/0.8 Ml Daily		Not Reported
	Augmentin			C		2 Grams Then 3 Grams Daily		Not Reported
	Lasilix Retard			C	Oral	1 Df		Not Reported
	Allopurinol			C	Oral	1 Df		Not Reported
	Sotalol			C	Oral	0.5 Df		Not Reported
	Ramipril			C	Oral	1 Df		Not Reported
	Urapidil			C	Oral	2 Df		Not Reported
	Pantoprazole			C		1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2014	10567700	DIRECT		DS			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Ineffective; Hypersomnia; Living Alone; Product Substitution Issue	Escitalopram 10mg Teva			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2014	10704776	EXPEDITED (15-DAY)		OT	US-APOTEX-2014AP005482		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Encephalopathy; Serotonin Syndrome	Escitalopram Oxalate			S	Unknown	Unk		Apotex
	Methylthioninium Chloride			S	Unknown	1 Mg/Kg, Two Consecutive Doses		Not Reported
	Sodium Carbonate			S	Unknown	50 Meq, Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Lisinopril			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Lamotrigine			C	Unknown	Unk		Not Reported
	Ipratropium Bromide, Salbutamol			C	Unknown	Unk		Not Reported
	Nitroglycerin			C	Sublingual	Unk		Not Reported
	Midazolam			C	Unknown			Not Reported
	Fentanyl			C	Unknown			Not Reported
	Vecuronium Bromide			C	Unknown			Not Reported
	Isoflurane			C	Unknown			Not Reported

Phenylephrine	C	Unknown	40 Mg, Unk		Not Reported
Phenylephrine	C	Other	120mcg/Min		Not Reported
Vasopressin	C	Other	0.04 Units/Min		Not Reported
Propofol	C	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2014	10421171	EXPEDITED (15-DAY)		DS, HO	FR-AUROBINDO-AUR-APL-2014-09144		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Injury; Loss Of Consciousness; Malaise; Product Substitution Issue; Vertigo	Escitalopram Arrow 10 Mg			S	Oral	10 Mg, Once A Day		Aurobindo
	Escitalopram Arrow 10 Mg			S	Oral	7.5 Mg, Daily		Aurobindo
	Depakine Chrono			C	Unknown	2 Df, Once A Day		Not Reported
	Stablon			C	Unknown	Unk		Not Reported
	Seroplex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2014	10569145	EXPEDITED (15-DAY)		HO	PHHY2014CH142254		80 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea Haemorrhagic; Lower Gastrointestinal Haemorrhage	Exelon Patch			S	Transdermal	18 Mg, Unk		Novartis
	Aspirin Bayer			S	Oral	100 Mg, Qd		Not Reported
	Cipralex /Den/			S	Oral	0.5 Df, Qd		Not Reported
	Pantoprazol			C	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2014	10570178	DIRECT		OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Depression; Hypophagia; Impaired Work Ability;	Escitalopram			S	Oral	1 Pill, Once Daily, Taken By Mouth		Torrent

Mental Impairment;
Product Substitution Issue;
Social Problem;
Somnolence; Suicidal Ideation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2014	9665374	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20131019132		34 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Ibuprofen			S	Unknown			Not Reported
	Zaldiar			S	Unknown			Not Reported
	Ketoprofen			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Stilnox			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Pristinamycin			C	Unknown			Not Reported
	Augmentin			C	Unknown			Not Reported
	Dafalgan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2014	10571787	EXPEDITED (15-DAY)		HO	FR-FRI-1000072210		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Somnolence	Escitalopram			S	Oral	1 Df		Forest
	Loxapac			S	Oral	13 Df		Not Reported
	Loxapac			S	Oral	9 Df		Not Reported
	Alprazolam			S		0.75 Mg		Not Reported
	Alprazolam			S		1 Df		Not Reported
	Risperidone			S	Oral	1.5 Mg		Not Reported
	Risperidone			S		1 Mg		Not Reported

	Ebixa	C	1 Df	Not Reported
	Spironolactone	C	1 Df	Not Reported
	Uvedose	C	1 Ampoule (100,000 Iu) Every 3 Months	Not Reported
	Lumigan	C	1 Drop Daily In Each Eye	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2014	10572137	EXPEDITED (15-DAY)		HO	DE-ASTRAZENECA-2014SE83461		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Orthostatic Intolerance; Syncope	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ass			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2014	10573083	DIRECT		OT			18 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Alopecia	Escitalopram			S	Oral	1 Pill		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2014	10573215	DIRECT					27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Feeling Abnormal; Feeling Abnormal; Thought Blocking	Escitalopram			S	Oral	1 Pill		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2014	10366721	EXPEDITED (15-DAY)		HO	IT-MERCK-1408ITA001723		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Tachycardia	Mirtazapine			S	Oral	300 Mg, Once		Merck
	Mirtazapine			S				Merck
	Escitalopram Oxalate			S	Oral	15 Ml, Once		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Entact			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2014	10572871	EXPEDITED (15-DAY)		HO	CA-RANBAXY-2014US-77290		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Dizziness; Fall; Hypotension; Orthostatic Hypotension; Pain; Visual Impairment	Amlodipine			S	Unknown	2.5 Mg, Bid		Ranbaxy
	Furosemide			S	Unknown	40 Mg, Every Morning		Ipca
	Escitalopram			S	Unknown	10 Mg, Qd (Am)		Not Reported
	Escitalopram			S				Not Reported
	Metoprolol			S	Unknown	25 Mg, Bid		Ipca
	Metoprolol			S				Ipca
	Zopiclone			S	Unknown	5 Mg, Qd (Bed Time)		Not Reported
	Nitroglycerin			S	Transdermal	2 On At 9 Am And Off At 10 Pm, Rotating Site		Not Reported
	Oxazepam			S	Unknown	2 Df, Qd (Bed Time)		Not Reported
	Atorvastatin			C	Unknown	80 Mg (Bed Time)		Not Reported
	Atorvastatin			C				Not Reported
	Atorvastatin			C				Not Reported
	Acetaminophen			C	Unknown	500 Mg, Qid		Not Reported
	Clopidogrel			C	Unknown	75 Mg, Qd (Every Morning)		Not Reported
	Clopidogrel			C				Not Reported
	Clopidogrel			C				Not Reported

Codeine, Acetaminophen	C	Unknown	30 Mg, Twice Daily, Prn		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	200 Mg, Qd (Supper)		Not Reported
Pantoprazole	C	Unknown	40 Mg, Qd (Every Morning)		Not Reported
Polyethylene Glycol	C	Unknown	Unk, Prn		Not Reported
Ramipril	C	Unknown	5 Mg, Qd (Every Morning)		Not Reported
Nitroglycerin	C	Unknown	Unk, Prn		Not Reported
Vitamin D Nos	C	Unknown	1000 Iu (Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2014	10573461	EXPEDITED (15-DAY)		HO	IT-TEVA-519861ISR		69 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension	Lorazepam			S	Oral			Ivax
	Cipralex - H. Lundbeck A/S			S	Oral			Not Reported
	Olmesartan Medoxomil			S	Oral			Not Reported
	Eutirox			C				Not Reported
	Formistin (Cetirizine Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2014	10574334	EXPEDITED (15-DAY)		OT	US-TEVA-520232USA		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown			Ivax
	Methylthioninium Chloride			S	Unknown	1 Mg/Kg In 2 Consecutive Doses (Total 2 Mg/Kg)		Not Reported
	Aspirin			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

Furosemide	C	Unknown			Not Reported
Insulin	C	Unknown			Not Reported
Lamotrigine	C	Unknown			Not Reported
Ipratropium Bromide, Salbutamol	C	Unknown			Not Reported
Nitroglycerin	C	Sublingual	As Needed		Not Reported
Midazolam	C	Unknown			Not Reported
Fentanyl	C	Unknown			Not Reported
Vecuronium Bromide	C	Unknown			Not Reported
Isoflurane	C	Unknown			Not Reported
Phenylephrine	C	Unknown	40mg		Not Reported
Phenylephrine	C	Other	120mcg/Min		Not Reported
Vasopressin	C	Other	0.04 Units/Min		Not Reported
Propofol	C	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2014	10575766	DIRECT		LT, OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dizziness; Dysstasia; Hyperhidrosis; Nausea	Escitalopram			S	Oral	By Mouth At Bedtime		Teva
	Oxybutynin			C				Not Reported
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2014	10575978	DIRECT					40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Product Quality Issue; Product Substitution Issue; Sedation	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2014	9688343	EXPEDITED (15-DAY)		LT	US-DRREDDYS-USA/USA/13/0035516		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Cardiac Arrest; Coma Scale Abnormal; Hypotension; Overdose; Pulseless Electrical Activity; Tachycardia	Quetiapine Fumarate Tablets			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Desvenlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Bupropion			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2014	10574965	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2014-08418		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Tachycardia	Mirtazapine			S	Oral	300 Mg, Total		Aurobindo
	Escitalopram			S	Oral	15 Ml, Single		Aurobindo
	Entact			C	Unknown	28, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2014	10575035	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2014-11637		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Encephalopathy; Hyperthermia; Hypotension; Muscle Rigidity; Nystagmus; Pupillary Reflex Impaired; Serotonin Syndrome; Vasoplegia Syndrome	Escitalopram			S	Unknown	Unk		Aurobindo
	Methylene Blue			S	Unknown	1 Mg/Kg, (Total 2 Mg/Kg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2014	10577583	EXPEDITED (15-DAY)		HO, OT	DE-ASTRAZENECA-2014SE84162		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Interaction; Headache; Hyponatraemia; Hypotension; Vomiting	Seroquel Xr			S	Oral			Zeneca
	Seroquel Xr			S	Oral			Zeneca
	Seroquel Xr			S	Oral			Zeneca
	Seroquel Xr			S	Oral			Zeneca
	Tegretal			S	Oral			Not Reported
	Tegretal			S	Oral			Not Reported
	Tegretal			S	Oral			Not Reported
	Tegretal			S	Oral			Not Reported
	Tegretal			S	Oral			Not Reported
	Tegretal			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported
	Hydrochlorothiazid (Non Az)			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Simvastatin			C	Oral			Not Reported
	Metoprolol			C	Oral			Not Reported
	Vesikur			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2014	10578619	DIRECT		DS			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Irritability; Malaise	Escitalopram			S	Oral	Once Daily Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2014	10578678	DIRECT					60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Recurrence; Product Substitution Issue	Escitalopram			S		1 1/2		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2014	10578792	EXPEDITED (15-DAY)		DE, LT, OT	IE-JNJFOC-20141102841		89 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Gastrointestinal Haemorrhage; Pneumonia; Sepsis; Tachycardia	Xarelto			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Metoprolol Tartrate			C	Unknown			Not Reported
	Cordarone			C	Unknown			Not Reported
	Galfer			C	Unknown			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Cozaar			C	Unknown			Not Reported
	Protium			C	Unknown			Not Reported
	Protium			C	Unknown			Not Reported
	Zimovane			C	Unknown			Not Reported
	Lanoxin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2014	10579328	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20141101332		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Discomfort; Palpitations; Ventricular Extrasystoles	Risperdal		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2014	10704742	EXPEDITED (15-DAY)		HO	AU-APOTEX-2014AP003715		16 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour	Escitalopram			S		10 Mg Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2014	10103775	EXPEDITED (15-DAY)		DS	CA-FRI-1000066808		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Drug Interaction; Fatigue; Feeling Drunk; Haemochromatosis; Impaired Driving Ability	Escitalopram			S	Oral			Forest
	Escitalopram			S				Forest
	Alcohol			S	Oral	Took 5-6 Beers Of 33 Centiliters Each		Not Reported
	Vimovo			C		200mg /50 Mg		Not Reported
	Apo-Oxazepam			C		Dose Not Reported.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2014	10329288	EXPEDITED (15-DAY)		OT	CA-FRI-1000068980		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Dyskinesia; Serotonin Syndrome; Tachycardia; Toxicity To Various Agents	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2014	10329486	EXPEDITED (15-DAY)		HO, LT, OT	CA-FRI-1000068984		44 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Mobility Decreased	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2014	10329558	NON-EXPEDITED		DS	CA-FRI-1000068986		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Somnolence	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2014	10329911	EXPEDITED (15-DAY)		OT	CA-FRI-1000069031		32 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pericarditis	Escitalopram			S	Oral	10 Mg		Forest
	Colchicine			C		0.6 Mg (Frequency Not Reported)		Not Reported
	Tamsulosin Cr			C		0.4 Mg (Frequency Not Reported)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2014	10581811	EXPEDITED (15-DAY)		OT	DE-FRI-1000072302			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Diabetes Mellitus Inadequate Control; Therapeutic Product Effect Variable	Escitalopram Oral Solution			S	Oral			Forest
	Insulin Analogues			C	Intramuscular			Not Reported
	Antidepressants			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2014	10582223	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2014311285		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Dry Mouth; Oropharyngeal Pain; Type 2 Diabetes Mellitus; Visual Impairment	Lyrica			S		300 Mg, 2x/Day		Pfizer
	Effexor Xr			S		225 Mg, Daily (75mg Capsule And A 150mg Capsule Together)		Pfizer
	Ibuprofen			S		800mg In The Morning And 1200		Pfizer
	Metformin Hcl			S		100 Mg, Daily		Pfizer
	Simvastatin			S		40 Mg, Unk		Not Reported
	Valium			S		5 Mg, 3x/Day		Not Reported
	Aspirin			S		162 Mg, 1x/Day (81mg 2 Tablets At Night)		Not Reported
	Tizanidine			S		8 Mg, 3x/Day		Not Reported
	Seroquel			S		50mg Twice Daily In The Morning And Noon, And 200mg At Nightunk Unk, 3x/Day		Not Reported
	Seroquel			S				Not Reported
	Lexapro			S		20 Mg, 1x/Day		Not Reported
	Topamax			S		100 Mg, Daily (Daily In The Morning)		Not Reported
	Demadex			S		20 Mg, Daily		Not Reported
	Fentanyl			S		50 Mg, Every 48 Hours		Not Reported
	Oxycodone Apap			S		10/325mg 1 Of Them 3 Times Daily As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2014	10582443	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2014SE84611			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hypokalaemia; Hyponatraemia	Inexium			S	Oral			Astrazeneca
	Fortzaar			S	Oral			Not Reported

	Seroplex	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Logimax	C		Not Reported
	Paracetamol	C		Not Reported
	Pravastatin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2014	10582512	EXPEDITED (15-DAY)		OT	FR-FRI-1000072337		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Medication Error; Nausea; Product Dispensing Error	Escitalopram			S	Unknown	30 Mg		Forest
	Seresta			C	Unknown	30 Mg/ Day Plus 10 Mg If Needed		Not Reported
	Efferalgan Codeine			C	Unknown			Not Reported
	Imovane			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2014	10329543	EXPEDITED (15-DAY)		OT	CA-FRI-1000068985		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Insomnia; Somnolence; Suicidal Ideation; Tremor	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2014	10583878	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000072344		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Electrocardiogram Qt Prolonged; Malaise	Escitalopram			S	Oral	1 Df Dosage Form		Forest
	Cordarone			S	Oral	1 Df Dosage Form		Not Reported
	Zofenilduo			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2014	10585205	EXPEDITED (15-DAY)		OT	DE-FRI-1000072300			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Nocturia; Oedema Peripheral	Escitalopram			S	Oral	10 Mg		Forest
	Olanzapin			S	Oral	2.5 Mg		Not Reported
	Quilonum Retard			S	Oral	450 Mg		Not Reported
	Quilonum Retard			S	Oral	675 Mg		Not Reported
	Quilonum Retard			S	Oral	900 Mg		Not Reported
	Quilonum Retard			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2014	10585767	EXPEDITED (15-DAY)		DE, LT	IE-FRI-1000072258		89 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Gastrointestinal Haemorrhage; Pneumonia; Sepsis; Tachycardia	Lexapro			S	Sublingual	10 Mg		Forest
	Xarelto			S	Oral	15 Mg		Not Reported
	Lanoxin Pg			C		62.5 Mcg		Not Reported
	Metoprolol			C	Oral	50 Mg		Not Reported
	Cordarone X			C	Oral	100 Mg		Not Reported
	Paracetamol			C		4 Mg		Not Reported
	Atorvastatin			C		10 Mg		Not Reported
	Cozaar			C		25 Mg		Not Reported
	Protium			C		40 Mg		Not Reported
	Zimovane			C		3.75 Mg		Not Reported
	Galfer			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2014	10586872	DIRECT					52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Listless; Malaise; Malaise; Product Physical Issue; Product Quality Issue; Tremor	Escitalopram 10 Mg. Teva			S	Oral	1.5 Pills, Once Daily, Taken By Mouth		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2014	10589558	EXPEDITED (15-DAY)	Y	HO, OT	US-ZYDUS-005491		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Encephalopathy; Hypotension; Pulseless Electrical Activity; Serotonin Syndrome; Systemic Inflammatory Response Syndrome	Escitalopram (Escitalopram)			S				Not Reported
	Methylthioninium Chloride (Methylthioninium Chloride)			S			1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2014	10586019	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2014-12046		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Dry Mouth; Oropharyngeal Pain; Type 2 Diabetes Mellitus; Visual Impairment	Metformin			S	Unknown	100 Mg, Daily		Aurobindo
	Simvastatin 40mg			S	Unknown	40 Mg, Unk		Aurobindo
	Lyrica			S	Unknown	300 Mg, Two Times A Day		Not Reported
	Effexor Xr			S	Unknown	225 Mg (75mg Capsule And A 150mg Capsule Together), Daily		Not Reported
	Ibuprofen			S	Unknown	800mg In The Morning And 1200, Daily		Not Reported
	Valium /00017001/			S	Unknown	5 Mg, 3 Times A Day		Not Reported
	Aspirin			S	Unknown	162 Mg (81 Mg 2 Tablets At Night), Once A Day		Not Reported

Tizanidine	S	Unknown	8 Mg, 3 Times A Day		Not Reported
Seroquel	S	Unknown	300 Mg, Daily (50mg Twice Daily In The Morning And Noon 200mg At Night)		Not Reported
Seroquel	S				Not Reported
Lexapro	S	Unknown	20 Mg, Once A Day		Not Reported
Topamax	S	Unknown	100 Mg, Every Morning		Not Reported
Demadex /01036501/	S	Unknown	20 Mg, Daily		Not Reported
Fentanyl	S	Unknown	50 Unk, Every 48 Hours, Unk		Not Reported
Oxycodone /00045603/	S	Unknown	10/325mg 1 Of Them 3 Times Daily As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2014	9772468	EXPEDITED (15-DAY)	Y	OT	2013-US-003939		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Headache; Pain In Extremity; Serotonin Syndrome	Xyrem			S	Oral Oral Oral Oral	Dose Adjustments, Oral		Not Reported
	Lexapro			S	Oral Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Vyvanse (Lisdexamfetamine Mesilate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2014	10329093	EXPEDITED (15-DAY)		HO	CA-FRI-1000068971		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Balance Disorder;	Escitalopram			S		10 Mg		Forest
	Escitalopram			S				Forest

Bradycardia; Dizziness; Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder	Amlodipine	S		5 Mg	Not Reported
	Amlodipine	S		2.5 Mg	Not Reported
	Codeine Phosphate	S		90 Mg	Not Reported
	Codeine Phosphate	S		60 Mg	Not Reported
	Furosemide	S		40 Mg	Not Reported
	Furosemide	S		20 Mg	Not Reported
	Glyceryl Trinitrate	S	Transdermal	0.8 Mg	Not Reported
	Glyceryl Trinitrate	S	Transdermal	0.4 Mg	Not Reported
	Metoprolol	S		25 Mg	Not Reported
	Metoprolol	S		50 Mg	Not Reported
	Oxazepam	S		20 Mg	Not Reported
	Ramipril	S		5 Mg	Not Reported
	Zopiclone	S		5 Mg	Not Reported
	Zopiclone	S		2.5 Mg	Not Reported
	Vitamin C	C		Daily Dose Not Reported.	Not Reported
	Pantoprazole	C		Daily Dose Not Reported.	Not Reported
	Acetaminophen	C		Daily Dose Not Reported.	Not Reported
	Atorvastatin	C		Daily Dose Not Reported.	Not Reported
	Clopidogrel	C		Daily Dose Not Reported.	Not Reported
	Vitamin D Nos	C		Daily Dose Not Reported.	Not Reported
	Polyethylene Glycol	C		Daily Dose Not Reported.	Not Reported
	Rabeprazole	C		Daily Dose Not Reported.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2014	10329265	EXPEDITED (15-DAY)			CA-FRI-1000068977		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest
	Apo-Oxazepam			C		Daily Dose Not Reported.		Not Reported

	Vimovo			C	500/20 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2014	10586321	EXPEDITED (15-DAY)		LT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2014001463			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Hyperplasia; Lobular Breast Carcinoma In Situ	Escitalopram 10mg Tablet			S	Oral	10 Mg, Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2014	10586323	EXPEDITED (15-DAY)		CA	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2014001467			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Ventricular Septal Defect	Escitalopram 20mg Tablet			S	Transplacental	20 Mg, Unk		Macleods
	Escitalopram 20mg Tablet			S				Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2014	10586652	EXPEDITED (15-DAY)		LT	GB-AUROBINDO-AUR-APL-2014-11948		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Hyperplasia; Lobular Breast Carcinoma In Situ	Escitalopram 10 Mg			S	Oral	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2014	10588500	EXPEDITED (15-DAY)		HO	FR-SA-2014SA154059		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall	Lovenox			S	Sunconjunctival			Not Reported

Haematoma; Abdominal Wall Haematoma; Acute Kidney Injury; Anaemia	Kardegic	S	Oral		Not Reported
	Previscan (Fluindione)	S	Oral		Not Reported
	Seroplex	S	Oral		Not Reported
	Eupressyl	C		60 Mg	Not Reported
	Levothyrox	C		100 Mcg, Divisible Tablet	Not Reported
	Amlodipine	C			Not Reported
	Valsartan	C			Not Reported
	Esidrex	C			Not Reported
	Esomeprazole	C			Not Reported
	Haldol	C			Not Reported
	Seresta	C		50 Mg, Divisible Tablet	Not Reported
	Augmentin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2014	10588559	EXPEDITED (15-DAY)		LT	GB-TEVA-521895ISR		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Hyperplasia; Lobular Breast Carcinoma In Situ	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2014	10588675	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000072393		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis; Melaena; Shock Haemorrhagic; Spontaneous Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Pradaxa			S	Oral	220 Mg		Not Reported
	Mono-Tildiem			S	Oral	200 Mg		Not Reported
	Xanax			C	Oral	0.5 Mg		Not Reported
	Dafalgan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2014	10589900	DIRECT		OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Condition Aggravated; Dysstasia; Gait Disturbance; Gastrointestinal Haemorrhage; Haemoglobin Decreased; Product Substitution Issue; Withdrawal Syndrome	Escitalopram 20mg			S		1/Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2014	10589213	EXPEDITED (15-DAY)		LT	GB-ACCORD-027001		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lobular Breast Carcinoma In Situ	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2014	10590999	EXPEDITED (15-DAY)		OT	2014SP003637		334 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Baby	Latuda			S	Transplacental			Not Reported
	Abilify			S	Transplacental			Not Reported
	Cipralex			S	Transplacental			Not Reported
	Citalopram			S	Transplacental			Not Reported
	Edronax			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2014	10591571	NON-EXPEDITED			US-PFIZER INC-2014317245		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Tardive	Pristiq			S		50 Mg, 1x/Day		Pfizer

Dyskinesia; Tic	Escitalopram		S	10 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2014	10595248	EXPEDITED (15-DAY)	Y	HO	2014HINLIT0995		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Drug Interaction; Encephalopathy; Hyperthermia; Muscle Rigidity; Phaeochromocytoma; Serotonin Syndrome	Escitalopram (Escitalopram)			S				Not Reported
	Unknown							
	Methylthioninium Chloride			S				Not Reported
	Phenylephrine Unknown			C				Not Reported
	Vasopressin			C				Not Reported
	Propofol Infusion			C				Not Reported
	Sodium Bicarbonate Unknown			C				Not Reported
	Norepinephrine Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2014	10571983	EXPEDITED (15-DAY)		HO	CH-FRI-1000072214			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea Haemorrhagic; Lower Gastrointestinal Haemorrhage	Escitalopram			S	Oral	5 Mg		Forest
	Aspirin			S	Oral	100 Mg		Not Reported
	Exelon Patch			S	Transdermal			Not Reported
	Pantoprazol			C		40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2014	10593432	EXPEDITED (15-DAY)		DE, OT	FR-SA-2014SA156832		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypokalaemia; Hyponatraemia; International Normalised Ratio Increased; Torsade De Pointes; Ventricular	Prednisone			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Cordarone			S	Oral			Not Reported
	Bisoce			S	Oral			Not Reported

Fibrillation	Previscan (Fluindione)	S	Oral		Not Reported
	Co Olmetec	S	Oral		Not Reported
	Seroplex	S	Oral		Not Reported
	Lercan	C	Oral	Strength: 10mg	Not Reported
	Inexium	C	Oral	Strength: 40mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2014	10594145	EXPEDITED (15-DAY)		HO	US-FRI-1000072267		12 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Cyst; Drug Level Above Therapeutic; Headache; Mania; Off Label Use; Unevaluable Event; Weight Increased	Lexapro			S	Oral			Forest
	Abilify			S	Oral	3 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10391456	EXPEDITED (15-DAY)		HO	IT-MYLAN-2014M1001126			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Tachycardia	Mirtazapine			S	Oral	300 Mg, Total		Not Reported
	Escitalopram Oxalate			S	Oral	15 Ml, Total		Not Reported
	Entact			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10472699	EXPEDITED (15-DAY)		OT	US-FRI-1000070736		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Asthenia; Confusional State; Drug Ineffective; Dyspnoea; Dysstasia; Fatigue; Gait Disturbance; Hallucination;	Lexapro			S	Oral	5mg		Forest
	Lexapro			S	Oral	10mg		Forest
	Lexapro			S	Oral	5mg		Forest

Nightmare	Lexapro	S	Oral	10mg		Forest
	Lexapro	S	Oral	5mg		Forest
	Rapaflo	C				Not Reported
	Timolol	C				Not Reported
	Travatan	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10595147	EXPEDITED (15-DAY)		HO	FR-UCBSA-2014018762		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cholestasis; Hepatocellular Injury; Jaundice; Pyrexia	Keppra			S	Intravenous (not otherwise specified)	500 Mg, 2x/Day (Bid)		Ucb
	Augmentin			S	Intravenous (not otherwise specified)	1 G, 3x/Day (Tid)		Not Reported
	Seresta			S	Oral	50 Mg, 3x/Day (Tid)		Not Reported
	Seroplex			S	Oral	20 G, Once Daily (Qd)		Not Reported
	Nicobion			S	Oral	1 Df, 2x/Day (Bid)		Not Reported
	Tranxene			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10595796	EXPEDITED (15-DAY)		HO	FR-FRI-1000072518		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Hypotonia; Intentional Overdose; Suicide Attempt	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	Overdose: 400 Mg.		Forest
	Lamotrigine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10596022	EXPEDITED (15-DAY)		LT	GB-FRI-1000072505		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Hyperplasia; Lobular Breast Carcinoma In Situ	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10596374	EXPEDITED (15-DAY)		CA	US-FRI-1000072487		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10596375	EXPEDITED (15-DAY)		CA	US-FRI-1000072488		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Synostosis	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10596607	EXPEDITED (15-DAY)		HO, LT	FR-BAUSCH-BL-2014-008711		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis; Melaena; Shock Haemorrhagic; Spontaneous Haematoma	Mono-Tildiem			S	Oral			Not Reported
	Pradaxa			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Xanax			C				Not Reported
	Dafalgan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10596667	EXPEDITED (15-DAY)		DE, HO	FR-DSJP-DSE-2014-128994			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Hypokalaemia; Hyponatraemia; International Normalised Ratio Increased; Torsade De Pointes; Ventricular Fibrillation	Coolmetec 40 Mg/ 25 Mg	S	Oral	40/25 Mg, Qd	Not Reported
	Bisoprolol	S	Oral	2.5 Mg, Qd	Not Reported
	Previscan (Pentoxifylline)	S	Oral	20 Mg, Unk	Not Reported
	Prednisone	S	Oral		Not Reported
	Lasilix /00032601/	S	Oral	80 Mg, Qd	Not Reported
	Seroplex	S	Oral	10 Mg, Qd	Not Reported
	Cordarone	S	Oral	200 Mg, Qd	Not Reported
	Lercan	C	Oral	10 Mg, Qd	Not Reported
	Inexium /01479302/	C	Oral	40 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10597373	DIRECT	Y	RI			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Anticholinergic Syndrome; Condition Aggravated; Crying; Headache; Product Substitution Issue; Sleep Disorder; Therapeutic Product Effect Decreased	Escitalopram			S	Oral	20mg Qd Up To 1 1/2 Qd Po		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10597862	DIRECT					60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Insomnia; Product Substitution Issue	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10598046	DIRECT		OT			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Memory Impairment	Escitalopram			S	Oral	10mg 1 Per Day Mouth		Camber
	Oral Inhaler			C				Not Reported
	Lunesta			C				Not Reported
	Ativan			C				Not Reported
	Omnaris			C				Not Reported
	Lisinopril			C				Not Reported
	Wellbutrin			C				Not Reported
	Flonase			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Norvasc			C				Not Reported
	Advair Diskus			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10598071	DIRECT		HO			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Self-Injurious Ideation; Withdrawal Syndrome	Escitalopram 20mg			S	Oral	1 Pill, Once Daily, Taken By Mouth		Pharmacy Benefits Manager (Pbm)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2014	10601721	EXPEDITED (15-DAY)	Y	HO	IPC201411-000608		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Encephalopathy; Hyperthermia; Hypotension; Muscle Rigidity; Myocardial Infarction; Nystagmus; Pulseless Electrical Activity; Serotonin Syndrome	Furosemide			S				Not Reported
	Metoprolol Tartrate			S				Not Reported
	Aspirin (Acetylsalicylic Acid) (Acetylsalicylic Acid)			S				Not Reported
	Lisinopril (Lisinopril) (Lisinopril)			S				Not Reported
	Atorvastatin (Atorvastatin) (Atorvastatin)			S				Not Reported
	Insulin			S				Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Lamotrigine (Lamotrigine) (Lamotrigine)			S		Therapy - Stopped		Not Reported

	Ipratroprium/Albuterol	S		(As Needed)	Not Reported
	Nitroglycerin	S	Sublingual	(As Needed), Sublingual	Not Reported
	Methylene Blue	S		1mg/Kg In 2 Consecutive Doses	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10444589	EXPEDITED (15-DAY)		OT	US-FRI-1000070495		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Libido Decreased; Multiple Sclerosis Relapse; Optic Neuritis; Urinary Tract Infection	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S	Oral			Forest
	Lexapro			S	Oral	20 Mg		Not Reported
	Gilenya			C				Not Reported
	Sprintec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10597044	EXPEDITED (15-DAY)		DS	GB-ACCORD-027077		32 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Akathisia; Anxiety; Disturbance In Attention; Drug Withdrawal Syndrome; Insomnia; Muscle Twitching; Nasal Discomfort; Pain In Extremity; Psoriasis; Skin Irritation	Escitalopram			S	Oral			Accord
	Cerazette (Desogestrel)			C				Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10597078	EXPEDITED (15-DAY)		DS	GB-AUROBINDO-AUR-APL-2014-12034		32 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Aggression; Agitation;	Escitalopram 20 Mg			S	Oral	20 Mg, Unk		Aurobindo

Akathisia; Anxiety; Disturbance In Attention; Drug Withdrawal Syndrome; Insomnia; Muscle Spasms; Muscle Twitching; Nasal Discomfort; Pain In Extremity; Psoriasis; Restlessness; Skin Irritation	Cerazette (Desogestrel)	C	Unknown	Unk		Not Reported
	Thyroxine Sodium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10597082	EXPEDITED (15-DAY)		CA, OT	GB-AUROBINDO-AUR-APL-2014-12035			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram 20 Mg			S	Transplacental	20 Mg, Unk		Aurobindo
	Escitalopram 20 Mg			S				Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10597954	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC-2014319909		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypokalaemia; Hyponatraemia; International Normalised Ratio Increased; Torsade De Pointes; Ventricular Fibrillation	Cordarone			S	Oral	200 Mg, 1x/Day		Pfizer
	Coolmetec			S	Oral	1 Df, 1x/Day		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Lasilix			S	Oral	80 Mg, 1x/Day		Not Reported
	Bisoce			S	Oral	2.5 Mg, 1x/Day		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg, Unk		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Lercan			C		Unk		Not Reported
	Inexium			C		40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10598606	EXPEDITED (15-DAY)		HO	SE-PFIZER INC-2014320299		47 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Suicidal Ideation; Toxicity To Various Agents	Provera			S	Oral	20 Mg, Unk		Pfizer
	Fluanxol "Lundbeck"			S	Oral	2 Mg And 1000 Mg		Not Reported
	Seroquel			S	Oral	600 Mg, Unk		Not Reported
	Lergigan (Promethazine Hydrochloride)			S	Oral	50 Mg, Unk		Not Reported
	Cipralex			S	Oral	20 Mg, Unk		Not Reported
	Propavan			S	Oral	50 Mg, Unk		Not Reported
	Zopiclone			S	Oral	15 Mg, Unk		Not Reported
	Ergenyl			S	Oral	2000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10598626	EXPEDITED (15-DAY)		OT	AU-FRI-1000072582		60 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenopia; Depressed Level Of Consciousness; Nausea; Tremor; Vertigo	Escitalopram			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10598706	EXPEDITED (15-DAY)		OT	DE-FRI-1000072546		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy; Vaginal Infection	Escitalopram			S	Oral	10 Mg		Forest
	Citalopram			C	Oral			Not Reported
	L-Thyroxin			C	Oral	50 Mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10599534	EXPEDITED (15-DAY)		OT	DE-FRI-1000072551		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Meconium In Amniotic Fluid; Respiratory Disorder Neonatal	Escitalopram			S	Transplacental	10 Mg		Forest
	Citalopram			C	Transplacental			Not Reported
	L-Thyroxin			C	Transplacental	50 Mcg		Not Reported
	Cefaclor			C	Transplacental	Dosage Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10599829	EXPEDITED (15-DAY)		HO	FR-FRI-1000072584		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Abdominal Wall Haematoma; Acute Kidney Injury; Anaemia; Drug Interaction; Overdose	Escitalopram			S	Oral	20 Mg		Forest
	Previscan (Fluindione)			S	Oral	15 Mg		Not Reported
	Lovenox			S	Subcutaneous	16000 Iu		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported
	Eupressyl			C	Oral			Not Reported
	Levothyrox			C	Oral			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Esidrex			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Haldol			C	Unknown			Not Reported
	Seresta			C	Oral			Not Reported
	Augmentin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10599831	EXPEDITED (15-DAY)		HO	FR-FRI-1000072602		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Blood Loss Anaemia	Escitalopram			S	Oral	1 Df		Forest
	Previscan (Fluindione)			S	Oral	Inr Target 2 To 3		Not Reported
	Lasilix			C				Not Reported
	Hyperium			C				Not Reported
	Exforge			C				Not Reported
	Esidrex			C				Not Reported
	Tahor			C				Not Reported
	Modopar			C				Not Reported
	Ceris			C				Not Reported
	Tanganil			C				Not Reported
	Daflon (Diosmin/Hesperidin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10600868	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Product Substitution Issue; Vomiting	Escitalopram			S			18 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2014	10638673	NON-EXPEDITED	Y		163-10004-14082967		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Crying; Depression; Mood Swings	Otezla			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2014	10600280	EXPEDITED (15-DAY)		LT	GB-MYLANLABS-2014M1010836			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Hyperplasia; Lobular Breast Carcinoma In Situ	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2014	10236156	EXPEDITED (15-DAY)			FR-FRI-1000068089			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Nausea; Sinusitis	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2014	10600553	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2014-12312		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Venlafaxine Arrow Lp			S	Oral	37.5 Mg, Daily		Aurobindo
	Venlafaxine Arrow Lp			S	Oral	75 Mg, Daily		Aurobindo
	Venlafaxine Arrow Lp			S	Oral	150 Mg, Daily		Aurobindo
	Seroplex			S	Oral	1 Df, Unk		Not Reported
	Movicol /01749801/			C	Oral	1 Df, Daily		Not Reported
	Diffu K			C	Oral	4 Df, Daily		Not Reported
	Mecir			C	Oral	1 Df, Daily		Not Reported
	Previscan (Fluindione)			C	Oral	¼ Tablet Every 2 Days, ½ Tablet Every 2 Days		Not Reported
	Tahor			C	Oral	1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2014	10600557	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2014-12215		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Potassium Decreased; Drug Interaction; Hyponatraemia; Hypotension	Hydrochlorothiazide	S	Oral	5.75 Mg, Daily	Aurobindo
	Ramipril 2.5mg	S	Unknown	2.5 Mg, Daily	Aurobindo
	Seroquel Xr	S	Oral	200 Mg, Daily	Not Reported
	Seroquel Xr	S	Oral	300 Mg, Daily	Not Reported
	Seroquel Xr	S	Oral	400 Mg, Daily	Not Reported
	Seroquel Xr	S	Oral	500 Mg, Daily	Not Reported
	Tegretal	S	Oral	600 Mg, Daily	Not Reported
	Tegretal	S	Oral	500 Mg, Daily	Not Reported
	Tegretal	S	Oral	400 Mg, Daily	Not Reported
	Tegretal	S	Oral	300 Mg, Daily	Not Reported
	Tegretal	S	Oral	200 Mg, Daily	Not Reported
	Tegretal	S	Oral	100 Mg, Daily	Not Reported
	Cipralex /01588501/	S	Oral	10 Mg, Daily	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Solifenacin Succinate	C	Unknown	Unk	Not Reported
	Simvastatin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2014	10602134	EXPEDITED (15-DAY)		DS	GB-FRI-1000072606		32 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Akathisia; Anxiety; Disturbance In Attention; Drug Withdrawal Syndrome; Insomnia; Muscle Spasms; Muscle Twitching; Nasal Discomfort; Pain In Extremity; Psoriasis; Restlessness; Skin Irritation	Escitalopram			S	Oral	20 Mg Daily		Forest
	Cerazette (Desogestrel)			C				Not Reported
	Thyroxine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2014	10602307	EXPEDITED (15-DAY)		OT	PHHY2014CH148766		22 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Ritaline			S	Nasal			Not Reported
	Norlevo			S	Oral	1 Df, Unk		Not Reported
	Cocaine			S	Unknown			Not Reported
	Cipralex /Den/			S	Oral	10 Mg, Qd, At Irregular Intervals		Not Reported
	Ecstasy			S	Oral			Not Reported
	Cannabis Sativa Subsp. Sativa Flowering Top			S	Unknown			Not Reported
	Temesta (Lorazepam)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2014	10602443	EXPEDITED (15-DAY)		HO	FR-SA-2014SA160462		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Nausea; Seizure; Vomiting	Stilnox			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2014	10602760	EXPEDITED (15-DAY)		CA	GB-TEVA-522776ISR		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2014	10603173	EXPEDITED (15-DAY)		DS	GB-TEVA-522765ISR		32 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Akathisia; Anxiety; Disturbance In Attention; Drug Withdrawal Syndrome; Insomnia; Muscle Spasms; Muscle Twitching; Nasal Discomfort; Pain In Extremity; Psoriasis; Restlessness; Skin Irritation	Escitalopram			S	Oral			Ivax
	Cerazette (Desogestrel)			C				Not Reported
	Thyroxine Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2014	10618633	EXPEDITED (15-DAY)	Y	HO	IL-ZYDUS-005535		34 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism	Clonazepam			S				Not Reported
	Escitalopram (Escitalopram)			S		1.0 Days		Not Reported
	Carbamazepine (Carbamazepine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10519094	NON-EXPEDITED			US-PFIZER INC-2014282189		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Depressed Mood; Erectile Dysfunction; Male Sexual Dysfunction	Pristiq			S	Oral	50 Mg, 1x/Day		Pfizer
	Zoloft			S		Unk		Pfizer
	Prozac			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Simvastatin			C		40 Mg, 1x/Day		Not Reported
	Xanax			C	Oral	0.5 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10591590	EXPEDITED (15-DAY)		HO	IT-FRI-1000072432			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ureterolithiasis	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram Oral Solution			S	Oral	5 Gtt		Forest
	Depakin			C		150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10606318	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2014-12451		42 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Delusion; Depression; Feeling Guilty	Mirtazapine			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10606606	EXPEDITED (15-DAY)		HO	SE-ABBVIE-14P-150-1311868-00		47 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Toxicity To Various Agents	Ergenyl			S	Oral	2000 Mg Total		Not Reported
	Propavan			S	Oral	50 Mg Total		Not Reported
	Provera			S	Oral	20 Mg Total		Not Reported
	Fluanxol			S	Oral	2 Mg And 1000 Mg Total		Not Reported
	Seroquel			S	Oral	600 Mg Total		Not Reported
	Lergigan (Promethazine Hydrochloride)			S	Oral	50 Mg Total		Not Reported
	Zopiclone			S	Oral	15 Mg Total		Not Reported
	Cipralex			S	Oral	20 Mg Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10607195	EXPEDITED (15-DAY)		HO	NL-FRI-1000072625		26 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hiccups; Muscle Twitching	Escitalopram			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10607213	EXPEDITED (15-DAY)		HO	FR-FRI-1000072628		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Melaena	Escitalopram			S	Oral	10 Mg		Forest
	Xarelto			S	Oral	20 Mg		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported
	Lasilix			C	Oral	40 Mg		Not Reported
	Bisoce			C	Oral	3.75 Mg		Not Reported
	Paracetamol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10607266	EXPEDITED (15-DAY)		OT	FR-FRI-1000072652		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Optic Neuritis	Escitalopram			S		10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10608220	EXPEDITED (15-DAY)		HO	FR-FRI-1000072671		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastric Ulcer; Gastrointestinal Haemorrhage;	Escitalopram			S	Oral			Forest
	Kardegic			S	Oral	1 Df Dosage Form		Not Reported

Haematoma	Lantus	C	40 Iu In Evening	Not Reported
	Humalog	C	16 Iu In Morning, Noon And Evening	Not Reported
	Alprazolam	C	0.25 Mg In Evening	Not Reported
	Zolpidem	C	10 Mg In Evening	Not Reported
	Crestor	C	5 Mg In Evening	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10608342	EXPEDITED (15-DAY)		HO	FR-FRI-1000072638		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cell Death; Cholestasis; Jaundice; Pyrexia	Escitalopram			S	Oral	20 Mg		Forest
	Augmentin			S	Intravenous (not otherwise specified)	3 Gram		Not Reported
	Seresta			S	Oral	150 Mg		Not Reported
	Keppra			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Nicobion			S	Oral	2 Df		Not Reported
	Tranxene			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Tranxene			S	Intravenous (not otherwise specified)	250 Mg		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)			Not Reported
	Multivitamins			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10608421	EXPEDITED (15-DAY)		HO	DE-TEVA-523368GER		23 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Restlessness; Suicidal Ideation	Doxepin			S	Oral	25 Milligram Daily;		Teva

	Cipralex	S	Oral	20 Milligram Daily;		Not Reported
	Cipralex	S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10608474	NON-EXPEDITED			US-PFIZER INC-2014322366		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Effexor Xr			S		150 Mg, 1x/Day		Pfizer
	Effexor Xr			S				Pfizer
	Effexor Xr			S				Pfizer
	Effexor Xr			S				Pfizer
	Lyrica			S		150 Mg, Daily (50 Mg In Morning And 100 Mg At Night)		Pfizer
	Lyrica			S				Pfizer
	Lyrica			S				Pfizer
	Lexapro			S		20 Mg, 1x/Day		Not Reported
	Lexapro			S				Not Reported
	Prednisone			C		10 Mg, Daily		Not Reported
	Aspirin			C		325 Mg, Unk		Not Reported
	Clonazepam			C		1 Mg, 2x/Day		Not Reported
	Atarax			C		50 Mg, As Needed		Not Reported
	Zanaflex			C		4 Mg, As Needed		Not Reported
	Percocet			C		(10/325 Mg "Half To One" Every Six Hours As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10608961	EXPEDITED (15-DAY)		CA	GB-MYLANLABS-2014M1010884			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10608964	EXPEDITED (15-DAY)		DS	GB-MYLANLABS-2014M1010883			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Akathisia; Anxiety; Disturbance In Attention; Drug Withdrawal Syndrome; Insomnia; Muscle Spasms; Muscle Twitching; Nasal Discomfort; Pain In Extremity; Psoriasis; Restlessness; Skin Irritation	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Cerazette (Desogestrel)			C		Unk		Not Reported
	Thyroxine Sodium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2014	10615252	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro 20 Mg Camber			S	Oral	One		Not Reported
	Paxil 20 Mg Tablet Aurobindo			S	Oral	One		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2014	10434463	EXPEDITED (15-DAY)		HO	SE-FRI-1000070377		84 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree; Electrocardiogram Pq Interval Prolonged; Syncope	Escitalopram			S		10 Mg		Forest
	Behepan [Cyanocobalamin]			C				Not Reported
	Folacin [Folic Acid]			C				Not Reported
	Kalcipos-D Forte			C				Not Reported
	Norspan			C				Not Reported
	Waran			C				Not Reported
	Alvedon			C				Not Reported
	Importal Ex-Lax			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2014	10513752	EXPEDITED (15-DAY)		LT	RO-TEVA-514088ISR		68 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Hyperhidrosis; Irritability; Palpitations; Psychomotor Hyperactivity; Restlessness; Sleep Disorder; Tremor	Escitalopram Teva 10 Mg			S	Oral	10 Milligram Daily;		Ivax
	Escitalopram Teva 10 Mg			S	Oral	2 Milligram Daily;		Ivax
	Rivotril 2 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2014	10610565	EXPEDITED (15-DAY)		DE	FR-FRI-1000072631		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Interaction; Hypokalaemia; Hyponatraemia; International Normalised Ratio Increased; Torsade De Pointes; Ventricular Fibrillation	Escitalopram			S	Oral	10 Mg		Forest
	Bisoce			S	Oral	2.5 Mg		Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Lasilix			S	Oral	2 Df		Not Reported
	Coolmetec			S	Oral	40 Mg/25 Mg Daily		Not Reported
	Cordarone			S	Oral	1 Df		Not Reported
	Lercan			C	Oral	1 Df		Not Reported
	Inexium			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2014	10611105	EXPEDITED (15-DAY)		OT	RS-FRI-1000072689		61 YR	Female	SRB

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Escitalopram			S	Oral	10 Mg		Forest

	Indapres	C	Oral	0.75 Mg	Not Reported
	Corvitol	C	Oral	25 Mg	Not Reported
	Ksalol	C	Oral	0.5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2014	10611596	EXPEDITED (15-DAY)		HO, LT	BE-MYLANLABS-2014M1011840			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome; Torsade De Pointes	Escitalopram			S	Unknown			Not Reported
	Omeprazole			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Sotalol			S	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2014	10611726	EXPEDITED (15-DAY)		HO	SE-FRI-1000072715		47 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicidal Ideation; Toxicity To Various Agents	Escitalopram			S	Oral			Forest
	Fluanxol			S	Oral	Overdose: Unknown Dose		Not Reported
	Provera			S	Oral	Overdose: 20 Mg Once		Not Reported
	Seroquel			S	Oral	Overdose: 600 Mg Once		Not Reported
	Lergigan (Promethazine Hydrochloride)			S	Oral	Overdose: 50 Mg Once		Not Reported
	Propavan 25 Mg Tablett			S	Oral	Overdose: 50 Mg Once		Not Reported
	Zopiclone			S	Oral	Overdose: 15 Mg Once		Not Reported
	Ergenyl			S	Oral	Overdose: 2000 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2014	10619028	EXPEDITED (15-DAY)	Y	HO, OT	ADR-2014-02233		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anal Incontinence; Craniocerebral Injury; Fall; Loss Of Consciousness; Periorbital Haemorrhage; Urinary Incontinence; Wound Infection; Wound Necrosis	Lioresal			S				Not Reported
	Tercian			S				Not Reported
	Imovane (Zopiclone)			S	Oral			Not Reported
	Seroplex (Escitalopram Oxalate)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2014	10621529	DIRECT		HO			14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chest Pain; Fatigue; Feeling Abnormal; Feeling Abnormal; Feeling Abnormal; Hallucination; Headache; Heart Rate Increased; Hyperhidrosis; Hypertension; Insomnia; Mydriasis; Nausea; Panic Attack; Psychotic Behaviour	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2014	10612122	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2014-12470		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Parkinsonism; Persecutory Delusion; Rhabdomyolysis	Escitalopram			S	Oral	7.5 Mg, Once A Day		Aurobindo
	Mirtazapine 30mg			S	Oral	30 Mg, Once A Day		Aurobindo
	Orfidal			S	Oral	0.75 Mg, Two Times A Day		Not Reported
	Enalapril			C	Oral	10 Mg, Once A Day		Not Reported

	Duodart			C	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2014	10612849	EXPEDITED (15-DAY)		HO	SE-ASTRAZENECA-2014SE88302		47 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Toxicity To Various Agents	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Provera			S	Oral			Not Reported
	Provera			S	Oral			Not Reported
	Fluanxol			S	Oral			Not Reported
	Fluanxol			S	Oral			Not Reported
	Lergigan (Promethazine Hydrochloride)			S	Oral			Not Reported
	Lergigan (Promethazine Hydrochloride)			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Propavan			S	Oral			Not Reported
	Propavan			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported
	Ergenyl			S	Oral			Not Reported
	Ergenyl			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2014	10616033	EXPEDITED (15-DAY)		OT	IN-ROXANE LABORATORIES, INC.-2014-RO-01798RO		49 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Major Depression; Parkinsonism; Tardive	Propranolol			S	Unknown	10 Mg		Roxane

Dyskinesia; Torticollis	Amisulpride		S	Unknown	50 Mg	Not Reported
	Levosulpride		S	Unknown	100 Mg	Not Reported
	Escitalopram		S	Unknown		Not Reported
	Paroxetine		S	Unknown	12.5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2014	10617982	EXPEDITED (15-DAY)		HO, OT	PHHY2014CA154126		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Disorder; Chest Discomfort; Cough; Cyanosis; Decreased Appetite; Depression; Diarrhoea; Dizziness; Drug Ineffective; Dyspnoea Exertional; Emphysema; Fall; Fatigue; Headache; Hiatus Hernia; Hypoaesthesia; Insomnia; Malaise; Overdose; Pain; Panic Reaction; Pneumonia; Pruritus; Pulmonary Mass; Tremor	Seebri Breezhaler			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Novartis
	Atrovent			S	Unknown			Not Reported
	Advair Diskus			S	Respiratory (inhalation)	Unk Unk, Bid		Not Reported
	Advair Diskus			S	Respiratory (inhalation)	Unk		Not Reported
	Advair Diskus			S	Respiratory (inhalation)	Unk		Not Reported
	Ventolin Cr			S	Unknown			Not Reported
	Spiriva			S	Unknown			Not Reported
	Prednisone			S	Unknown	4 Df, Unk (4 Puffers Everyday)		Not Reported
	Cipralex//Escitalopram			S	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2014	10622205	DIRECT	Y				44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression;	Lexapro			S				Not Reported

Loss Of Personal Independence In Daily Activities	Lamictal	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2014	10361181	EXPEDITED (15-DAY)		HO	IT-FRI-1000069501		28 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Sopor	Escitalopram			S	Oral	Overdose: 560 Mg Once.		Forest
	Lorazepam Dorom			S	Oral	Overdose: 10 Ml Of Form Strength 20mg/10 Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2014	10591870	EXPEDITED (15-DAY)		CA, OT	GB-ACCORD-027058			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S	Transplacental			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2014	10619521	EXPEDITED (15-DAY)		HO	FR-FRI-1000072751		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Nausea; Seizure; Vomiting	Escitalopram			S	Oral	10 Mg		Forest
	Stilnox			S	Oral			Not Reported
	Alprazolam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2014	10620296	EXPEDITED (15-DAY)		CA	FR-ASTRAZENECA-2014SE91786		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Patent Ductus Arteriosus; Trisomy 21; Ventricular Septal Defect	Tenoretic	S	Transplacental	50 Mg/12.5 Mg Daily		Zeneca
	Abilify	S	Transplacental			Not Reported
	Seroplex	S	Transplacental			Not Reported
	Parkinane	S	Transplacental			Not Reported
	Tercian	S	Transplacental			Not Reported
	Loxen (Nicardipine Hydrochloride)	C	Transplacental			Not Reported
	Loxapac	C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2014	10620511	EXPEDITED (15-DAY)		OT	US-FRI-1000072761			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral Nerve Injury	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2014	10625371	EXPEDITED (15-DAY)	Y	OT	IPC201411-000637		49 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism; Tardive Dyskinesia; Torticollis	Propranolol Hydrochloride (Propranolol Hydrochloride) (Propranolol Hydrochloride)			S				Not Reported
	Amisulpride (Amisulpride)			S				Not Reported
	Levosulpiride (Levosulpiride)			S				Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Paroxetine (Paroxetine) (Paroxetine)			S				Not Reported
	Eltroxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2014	10554940	EXPEDITED (15-DAY)		HO	IT-DSJP-DSE-2014-127259			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Hypotension	Olmesartan Medoxomil		S	Oral	10 Mg, Qd	Not Reported
	Cipralex		S	Oral	10 Mg, Qd	Not Reported
	Lorazepam		S	Oral	1 Mg, Qd	Not Reported
	Eutirox		C		Unk	Not Reported
	Formistin		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2014	10605549	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2014-12252		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Crying; Depressed Mood; Hypersomnia; Middle Insomnia; Nausea; Parkinsonism	Escitalopram 20 Mg			S	Unknown	20 Mg, Daily		Aurobindo
	Escitalopram 20 Mg			S				Aurobindo
	Agomelatine			S	Unknown	25 Mg, Daily, At Bedtime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2014	10622450	EXPEDITED (15-DAY)		HO	FR-FRI-1000072793		17 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Analgesic Drug Level Increased; Hypotension; Hypothermia; Intentional Overdose; Overdose; Poisoning Deliberate; Tachycardia; Toxicity To Various Agents	Escitalopram			S	Oral	Overdose Of 5 Tablets Of 10 Mg Once		Forest
	Dafalgan Codein			S	Oral	Overdose Of 16 Grams Once		Not Reported
	Loxapac			S	Oral	Overdose Of 5 Df Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2014	10623067	EXPEDITED (15-DAY)		LT	SA-FRI-1000072777		70 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Neutropenia; Suicide Attempt	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2014	10623414	EXPEDITED (15-DAY)		CA	FR-FRI-1000072805		3 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Trisomy 21; Ventricular Septal Defect	Escitalopram			S	Transplacental	1 Df Dosage Form		Forest
	Abilify			S	Transplacental	15 Mg		Not Reported
	Parkinane			S	Transplacental	1 Df Dosage Form		Not Reported
	Tenoretic			S	Transplacental	50/12.5 Mg		Not Reported
	Tercian			S	Transplacental	1 Df Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2014	10631609	EXPEDITED (15-DAY)	Y	HO	BE-DEXPHARM-20140964		65 YR	Male	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Chloride Decreased; Blood Lactate Dehydrogenase Increased; Depression; Drug Interaction; Drug Intolerance; Haematocrit Decreased; Haemoglobin Decreased; Hypokalaemia; Long Qt Syndrome; Loss Of Consciousness; Platelet Count Increased; Protein Total Decreased; Red Blood Cell Count Decreased; Torsade De Pointes; Vomiting; White Blood Cell Count Increased	Escitalopram			S				Not Reported
	Omeprazole			S				Not Reported
	Sotalol			S				Not Reported
	Tacrolimus			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2014	10636609	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue; Therapeutic Response Changed	Lexapro 20mg - Generic			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2014	10587894	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2014314683		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Drug Interaction; Hyponatraemia; Hypotension	Ramipril			S	Oral	2.5 Mg, Daily		Pfizer
	Seroquel Xr			S	Oral	200 Mg, Daily		Not Reported
	Seroquel Xr			S	Oral	300 Mg, Daily		Not Reported
	Seroquel Xr			S	Oral	400 Mg, Daily		Not Reported
	Seroquel Xr			S	Oral	500 Mg, Daily		Not Reported
	Tegretal			S	Oral	600 Mg, Daily		Not Reported
	Tegretal			S	Oral	500 Mg, Daily		Not Reported
	Tegretal			S	Oral	400 Mg, Daily		Not Reported
	Tegretal			S	Oral	300 Mg, Daily		Not Reported
	Tegretal			S	Oral	200 Mg, Daily		Not Reported
	Tegretal			S	Oral	100 Mg, Daily		Not Reported
	Hydrochlorothiazid			S	Oral	5.75 Mg, Daily		Not Reported
	Cipralex			S	Oral	10 Mg, Daily		Not Reported
	Simvastatin			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Solifenacin Succinate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2014	10626333	EXPEDITED (15-DAY)		DE	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2014-BI-58		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Meloxicam			S	Oral			Boehringer Ingelheim
	Lamotrigine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2014	10626637	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2014SE93175			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Exposure During Pregnancy; Hypertension	Tenoretic			S	Oral	50 Mg/12.5 Mg Daily		Zeneca
	Abilify			S	Unknown			Not Reported
	Seroplex			S	Unknown			Not Reported
	Parkinane			S	Unknown			Not Reported
	Tercian			S	Unknown			Not Reported
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Loxapac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2014	10626935	NON-EXPEDITED			US-PFIZER INC-2014331104			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Neurontin			S		Taking Off And On		Pfizer
	Acetaminophen			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10561477	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000071722		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Haematocrit Decreased; Haemoglobin Decreased; Off Label Use	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S				Forest
	Ibuprofen			S		800 Mg 1-2 Times Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10627861	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-20845426		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Pravastatin Sodium			S	Oral			Bristol Myers Squibb
	Zoloft			S				Not Reported
	Methocarbamol			S				Not Reported
	Zocor			S				Not Reported
	Reglan			S				Sandoz
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10628654	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-21447321		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Abilify			S				Not Reported
	Lexapro			S				Not Reported
	Vyvanse			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10628662	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-21543871		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Akathisia	Abilify	S		Not Reported
	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10629283	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-21337001		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Vaginal Haemorrhage	Abilify			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10630319	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-21265541		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Abilify			S		Dose Increased From 2mg To 5 Mg		Not Reported
	Lamictal			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10631340	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-21497037			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Abilify			S				Not Reported
	Lexapro			S				Not Reported
	Inderal			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10633778	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-526260USA		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Hot Flush; Nausea;	Teva-Escitalopram			S	Oral	10 Milligram Daily;		Ivax

Paraesthesia Oral; Paraesthesia Oral; Pharyngeal Oedema; Pruritus; Urticaria; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10633976	EXPEDITED (15-DAY)		OT	BE-FRI-1000072858			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Interest; Diarrhoea; Fatigue; Weight Increased	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10635175	EXPEDITED (15-DAY)		OT	FR-FRI-1000072882			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Pre-Eclampsia; Pregnancy	Escitalopram			S	Oral	1 Df Dosage Form		Forest
	Imovane			S		1 Df Dosage Form		Not Reported
	Alprazolam			S		1 Df Dosage Form		Not Reported
	Progesterone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10635176	EXPEDITED (15-DAY)		CA	FR-FRI-1000072880		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Escitalopram			S		1 Df Dosage Form		Forest
	Imovane			S		1 Df Dosage Form		Not Reported
	Alprazolam			S		1 Df Dosage Form		Not Reported
	Progesterone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10635607	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1424561US		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Parathyroid Hormone Increased; Blood Phosphorus Decreased; Electrocardiogram Abnormal; Hallucination, Visual; Hypercalcaemia; Vomiting	Ganfort Eye Drops, Solution			S	Ophthalmic	300mg/Ml+5mg/Ml Qd		Allergan
	Tercian			S		3 Gtt, Unk		Not Reported
	Tercian			S		5 Gtt, Tid		Not Reported
	Teralhite			S		250 Mg, Unk		Not Reported
	Seroplex			S		0.5 Mg, Qd		Not Reported
	Seresta			S	Oral	40 Mg, Qd		Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			S		11.8 G, Qd		Not Reported
	Paracetamol			S		1 G, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10635970	EXPEDITED (15-DAY)		HO	FR-FRI-1000072914		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Parathyroid Hormone Increased; Blood Phosphorus Decreased; Electrocardiogram Abnormal; Hypercalcaemia	Escitalopram			S	Oral	5 Mg		Forest
	Teralithe			S	Oral	750 Mg		Not Reported
	Tercian			S	Oral	9 Gtt		Not Reported
	Tercian			S	Oral	15 Gtt		Not Reported
	Seresta			S	Oral	40 Mg		Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate			S	Oral	11.8 Mg		Not Reported

	Anhydrous)					
	Ganfort	S	Intraocular	300 Mg/Ml + 5 Mg/Ml		Not Reported
	Paracetamol	S	Oral	3 Gm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2014	10640586	EXPEDITED (15-DAY)	Y	HO, OT	BE-ZYDUS-005808		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Hypokalaemia;	Escitalopram (Escitalopram)			S				Not Reported
Long Qt Syndrome; Loss	Omeprazole (Omeprazole)			S				Not Reported
Of Consciousness; Pallor;	Sotalol (Sotalol)			S				Not Reported
Torsade De Pointes;	Tacrolimus (Tacrolimus)			S				Not Reported
Vomiting	Bisoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2014	10570863	EXPEDITED (15-DAY)		HO	PHHY2014IT142801		69 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension	Lorazepam			S	Oral	1 Mg, Qd		Novartis
	Cipralex /Den/			S	Oral	10 Mg, Qd		Not Reported
	Olmesartan Medoxomil			S	Oral	10 Mg, Qd		Not Reported
	Eutirox			C		125 Mg, Unk		Not Reported
	Formistin			C		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2014	10637636	EXPEDITED (15-DAY)		HO	FR-FRI-1000072883		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma Muscle	Escitalopram			S	Oral	5 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Lovenox			S	Unknown	2 Df Dosage Form		Not Reported
	Lovenox			S	Unknown	2 Df Dosage Form		Not Reported

Furosemide	C	Unknown	40 Mg		Not Reported
Crestor	C	Oral	10 Mg		Not Reported
Cordarone	C	Unknown	0.7143 Df Dosage Form		Not Reported
Kaleorid	C	Oral	1 Df Dosage Form		Not Reported
Tranxene	C	Oral	1 Df Dosage Form		Not Reported
Mecir	C	Oral	1 Df Dosage Form		Not Reported
Avodart	C	Oral	1 Df Dosage Form		Not Reported
Amoxicillin	C	Oral	6 Gram		Not Reported
Vancomycin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2014	10638446	EXPEDITED (15-DAY)		OT	TR-MYLANLABS-2014M1012253			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Papilloedema	Escitalopram			S	Unknown	20 Mg, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2014	10638822	EXPEDITED (15-DAY)		HO	CH-FRI-1000072918		87 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Loss Of Consciousness; Malaise	Escitalopram			S	Oral	10 Mg		Forest
	Iscador			S	Subcutaneous			Not Reported
	Femara			S	Oral	2.5 Mg		Not Reported
	Aspirin			C	Oral	100 Mg		Not Reported
	Importal			C	Oral	30 Ml		Not Reported
	Temesta (Lorazepam)			C	Oral	1 Mg		Not Reported
	Dafalgan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2014	10640133	DIRECT		OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Poor Quality Sleep	Lexapro			S	Oral	1	10 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2014	10640629	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Product Dispensing Error; Wrong Product Administered	Lexapro			S				Not Reported
	Celexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2014	10640637	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Selection Error	Celexa			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2014	10640927	DIRECT		DS, HO			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Delusion; Depressed Level Of Consciousness; Depression; Disturbance In Attention; Dyspnoea; Fall; Fatigue; Gait Disturbance; Hallucination;	Escitalopram 10 Mg			S	Oral	One Pill Once Daily Taken By Mouth		Not Reported
	Rapaflo			C				Not Reported
	Timolol			C				Not Reported
	Travatan			C				Not Reported
	Multivitamin		Y	C				Not Reported
	Astaxanthan			C				Not Reported
	Bili Berry			C				Not Reported

Hypersomnia; Influenza Like Illness; Memory Impairment; Muscular Weakness; Muscular Weakness; Nightmare; Speech Disorder; Unresponsive To Stimuli; Urinary Incontinence	Zeaxanthan	C	Not Reported
	Co Q10	C	Not Reported
	Probiotic	C	Not Reported
	Vitamin D3	C	Not Reported
	Omega 3	C	Not Reported
	Fish Oil	C	Not Reported
	Vitamin C	C	Not Reported
	Sam-E	C	Not Reported
	Prostate Formula	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2014	10642424	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Headache; Suicidal Ideation	Escitalopram			S	Oral	1 Pill, Once Daily, Taken By Mouth		Walmart

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2014	10525092	EXPEDITED (15-DAY)		HO	AT-ASTRAZENECA-2014SE77387		47 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Attention Deficit/Hyperactivity Disorder; Confusional State; Delirium; Disorientation; Gait Disturbance; Insomnia; Psychomotor Hyperactivity; Psychomotor Skills Impaired; Tremor	Seroquel Xr			S	Oral	400-800 Mg Daily		Not Reported
	Abilify			S	Oral	5		Not Reported
	Abilify			S	Oral	10		Not Reported
	Substitol (Non Az Product)			S	Oral			Not Reported
	Akineton			S	Oral			Not Reported
	Praxiten			S	Oral	150 Max 300		Not Reported
	Cipralex			S	Oral	10-30 Mg/Daily		Not Reported
	Trittico			C	Oral	150		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2014	10576506	EXPEDITED (15-DAY)		HO	CH-FRI-1000072209		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypovolaemic Shock; Intra-Abdominal Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Marcoumar			S	Oral			Not Reported
	Sortis			C	Oral	20 Mg		Not Reported
	Calcitriol Salmon Pharma			C	Oral	0.5 Mcg		Not Reported
	Ferrosanol			C	Oral	0.5 Df Dosage Form		Not Reported
	Tenormin			C	Oral	50 Mg		Not Reported
	Amlodipin-Mepha			C	Oral	5 Mg		Not Reported
	Nephrotrans			C	Oral	2000 Mg		Not Reported
	Pantozol (Switzerland)			C	Oral	40 Mg		Not Reported
	Cosaar			C	Oral	50 Mg		Not Reported
	Vi-De 3			C	Oral	8 Gtt		Not Reported
	Acidum Folicum Streuli			C	Oral	0.7143 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2014	10623121	EXPEDITED (15-DAY)		OT	CN-FRI-1000072762		50 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Lexapro			S	Oral	Overdose: 70 Mg		Forest
	Lexapro			S				Forest
	Alprazolam			C	Unknown			Not Reported
	Tandospirone			C	Unknown	10 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2014	10640374	EXPEDITED (15-DAY)		OT	US-FRI-1000072794			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Caries; Dry Mouth; Gingival Disorder; Nerve Injury	Lexapro			S		20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2014	10641530	EXPEDITED (15-DAY)		HO	FR-FRI-1000072973		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Post Procedural Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Pradaxa			S	Oral	110 Mg		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported
	Plavix			S	Oral	75 Mg		Not Reported
	Insulatard			C	Unknown			Not Reported
	Novonorm			C	Unknown			Not Reported
	Lasilix			C	Unknown	40 Mg		Not Reported
	Bisoprolol			C	Unknown	5 Mg		Not Reported
	Metformin			C	Unknown	850 Mg		Not Reported
	Diffu K			C	Unknown			Not Reported
	Aldactone			C	Unknown			Not Reported
	Perindopril			C	Unknown	8 Mg		Not Reported
	Crestor			C	Unknown	5 Mg		Not Reported
	Ikorel			C	Unknown	10 Mg		Not Reported
	Lovenox			C	Unknown	12000 Iu		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2014	10641925	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2014336460		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Overdose; Poisoning Deliberate	Xanax			S		1.25 Mg, Single		Pfizer
	Temerit			S		Unk		Not Reported
	Temerit			S		170 Mg, Single		Not Reported
	Procoralan			S		85 Mg, Single		Not Reported
	Tercian			S		Unk Unk, As Needed		Not Reported

	Tercian	S	625 To 2600 Mg As Single Dose		Not Reported
	Seroplex	S	Unk		Not Reported
	Seroplex	S	1100 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2014	10644220	EXPEDITED (15-DAY)		DE	AU-FRI-1000072904		62 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Unknown			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2014	10648957	EXPEDITED (15-DAY)	Y	HO, OT	ADR-2014-02298		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Fall; Head Injury; Infection; Loss Of Consciousness; Periorbital Haemorrhage; Skin Necrosis; Wound	Lioresal (Baclofen)			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Imovane (Zopiclone)			S	Oral			Not Reported
	Atarax (Hydroxyzine)			S	Oral		107 DAY	Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2014	10305485	EXPEDITED (15-DAY)		HO, LT	IT-MYLANLABS-2014S1016041			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Interaction	Lorazepam			S	Oral	7.5 Mg,Qd		Not Reported
	Venlafaxine			S	Oral	150 Mg,Qd		Not Reported
	Invega /05724801/			S	Oral	9 Mg,Qd		Not Reported
	Depakin			S	Oral	750 Mg,Qd		Not Reported
	Akineton /00079501/			S	Oral	4 Mg,Qd		Not Reported

	Tranquirit		S	Oral	20 Gtt,Qd	Not Reported
	Cipralex		S	Oral	5 Gtt,Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2014	10606854	EXPEDITED (15-DAY)		CA	GB-FRI-1000072622		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy	Escitalopram			S	Oral	20 Mg Daily		Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2014	10645620	EXPEDITED (15-DAY)		HO	AT-ASTRAZENECA-2014SE77489		47 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Gait Disturbance; Psychomotor Skills Impaired; Tremor	Seroquel Xr			S	Oral	400-800 Mg Daily		Not Reported
	Abilify			S	Unknown	5 Daily		Not Reported
	Abilify			S	Unknown	10 Daily		Not Reported
	Praxiten			S	Unknown	Max 300 Mg Daily		Not Reported
	Praxiten			S	Unknown			Not Reported
	Praxiten			S	Unknown			Not Reported
	Praxiten			S	Unknown			Not Reported
	Praxiten			S	Unknown	100-0 Mg, Daily		Not Reported
	Praxiten			S	Unknown	100-0 Mg, Daily		Not Reported
	Cipralex			S	Unknown	10-30mg Daily		Not Reported
	Substitol Ret			C				Not Reported
	Trittico Ret			C		150 Daily		Not Reported
	Akineton Ret			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2014	10645866	EXPEDITED (15-DAY)		CA	GB-FRI-1000072856			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S	Transplacental	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2014	10646814	EXPEDITED (15-DAY)		OT	GXBR2014US002574		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Dry Mouth; Oropharyngeal Pain; Type 2 Diabetes Mellitus; Visual Impairment	Tizanidine Sandoz			S	Unknown	8 Mg, Tid		Novartis
	Lyrica			S	Unknown	300 Mg, Bid		Not Reported
	Oxycodone And Acetaminophen			S	Unknown	10mg Oxycodone And 325 Mg Acetaminophen - 1 Df , Tid		Not Reported
	Seroquel			S	Unknown	50mg Twice Daily In The Morning And Noon, And 200mg At Night		Not Reported
	Seroquel			S				Not Reported
	Venlafaxine			S	Unknown	225 Mg, Qd		Not Reported
	Lexapro			S	Unknown	20 Mg, Qd		Not Reported
	Valium			S	Unknown	5 Mg, Tid		Not Reported
	Demadex			S	Unknown	20 Mg, Qd		Not Reported
	Aspirin			S	Unknown	162 Mg, Qhs		Not Reported
	Topamax			S	Unknown	100 Mg, Qd In The Morning		Not Reported
	Ibuprofen			S	Unknown	800 Mg, Unk		Not Reported
	Fentanyl			S	Unknown	50 Ug, Q48h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2014	10647544	EXPEDITED (15-DAY)		HO	IT-TEVA-527226ISR		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradykinesia; Drug Abuse; Sopor	Mirtazapine		S	Oral	600 Mg Total	Teva
	Periactin - 4 Mg Compresse - Avantgarde S.P.A.		S	Oral	10 Df Total	Not Reported
	Cipralex - Compresse Rivestite Con Film - H. Lundbeck A/S		S	Oral	14 Df Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2014	10584523	EXPEDITED (15-DAY)		HO	IT-WATSON-2014-24184		69 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Headache; Hypotension; Overdose	Lorazepam (Unknown)			S	Oral	1 Mg, Daily		Watson
	Olmesartan Medoxomil (Unknown)			S	Oral	10 Mg, Daily		Not Reported
	Cipralex /01588501/			S	Oral	10 Mg, Daily		Not Reported
	Formistin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2014	10650141	NON-EXPEDITED			US-ASTRAZENECA-2014SE95108		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Discomfort; Dyspepsia; Feeling Abnormal; Flatulence; Flatulence; Gait Disturbance; Gastric Disorder; Gastrooesophageal Reflux Disease; Hallucination; Intentional Product Misuse; Pain; Panic Attack; Scrotal Swelling; Testicular Pain	Nexium 24hr			S	Oral			Astrazeneca
	Prozac			S	Unknown			Not Reported
	Prozac			S	Unknown	20 Mg Ulternate Days		Not Reported
	Lexapro			S	Unknown	Generic		Not Reported
	Antidepressant			S	Unknown			Not Reported
	Lisinopril			C				Not Reported
	Atorvastatin			C				Not Reported
	Vitamin B12			C				Not Reported
	Vitamin B6			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2014	10576106	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2014M1009726			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Interval Abnormal; Headache; Hypotension; Overdose	Lorazepam			S	Oral	1 Mg, Qd		Not Reported
	Olmesartan Medoxomil			S	Oral	10 Mg, Qd		Not Reported
	Cipralex /01588502/			S	Oral	10 Mg, Qd		Not Reported
	Eutirox			C		125 Mg		Not Reported
	Formistin			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2014	10578272	EXPEDITED (15-DAY)		HO	IT-RANBAXY-2014RR-87839		69 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension	Lorazepam			S	Oral	1 Mg, Daily		Ranbaxy
	Olmesartan			S	Oral	10 Mg, Daily		Not Reported
	Cipralex			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2014	10651332	NON-EXPEDITED			US-TEVA-506850USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bradyphrenia; Crying; Depressed Mood; Depression; Drug Ineffective; Tearfulness	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2014	10651334	NON-EXPEDITED			US-TEVA-507343USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Agitation; Headache; Musculoskeletal Stiffness;	Escitalopram			S	Oral			Ivax
	Escitalopram			S				Ivax

Neck Pain; Nightmare

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2014	10651335	NON-EXPEDITED			US-TEVA-520403USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2014	10652397	EXPEDITED (15-DAY)		HO, LT	NL-FRI-1000073081		29 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Drug Interaction; Pulmonary Embolism	Escitalopram			S	Oral	10 Mg Daily		Forest
	Lithium Carbonate			S		400 Mg Daily		Not Reported
	Lithium Carbonate			S		100 Mg Daily		Not Reported
	Olanzapine			C		2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2014	10652621	EXPEDITED (15-DAY)		HO	IT-WATSON-2014-26473		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Drug Abuse; Sopor	Mirtazapine (Unknown)			S	Oral	600 Mg, Total		Actavis
	Cipralex /01588501/			S	Oral	14 Df, Total		Not Reported
	Periactin			S	Oral	10 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2014	10653048	EXPEDITED (15-DAY)		HO	FR-FRI-1000073075		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Gingival Bleeding	Escitalopram			S	Oral	10 Mg		Forest

	Arixtra	S	Subcutaneous	7.5 Mg/0.6 Ml	Not Reported
	Arixtra	S	Subcutaneous	7.5 Mg/0.6 Ml	Not Reported
	Uvedose	C	Oral	0.0111 Df	Not Reported
	Ramipril	C	Unknown	5 Mg	Not Reported
	Loxen Lp	C	Unknown	50 Mg	Not Reported
	Alprazolam	C	Unknown	0.5 Mg	Not Reported
	Macrogol Biogaran	C	Unknown	10 G	Not Reported
	Oracilline	C	Unknown	2000000 Iu	Not Reported
	Solupred (Prednisolone)	C	Unknown	20 Mg	Not Reported
	Bicarbonate De Sodium Lavoisier	C	Unknown	1500 Ml	Not Reported
	Esomeprazole	C	Unknown	20 Mg	Not Reported
	Lasilix	C	Unknown	60 Mg	Not Reported
	Paracetamol	C	Unknown	4 G	Not Reported
	Atrovent	C	Unknown	0.5 Mg	Not Reported
	Bricanyl	C	Unknown	5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2014	10653058	EXPEDITED (15-DAY)		HO	CH-FRI-1000073066		90 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestatic Liver Injury	Escitalopram			S	Oral	15 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Memantine			S	Oral	5 Mg		Forest
	Memantine			S	Oral	10 Mg		Forest
	Trittico			S	Oral	50 Mg		Not Reported
	Dexamethasone			C	Oral	4 Mg		Not Reported
	Sintrom			C	Oral			Not Reported
	Amlodipine			C	Oral	10 Mg		Not Reported
	Augmentin			C	Oral	500/125 Mg		Not Reported

Distraneurin	C	Oral	300 Mg		Not Reported
Nexium	C	Oral	20 Mg		Not Reported
Euthyrox	C	Oral	50 Mcg		Not Reported
Laxoberon	C	Oral	10 Mg		Not Reported
Torem	C	Oral	10 Mg		Not Reported
Calcimagon D3	C	Oral	2 Df		Not Reported
Zolpidem	C	Oral	5 Mg		Not Reported
Temesta (Lorazepam)	C	Oral	1 Mg		Not Reported
Dafalgan	C	Oral	3000 Mg		Not Reported
Quetiapine	C	Oral	12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2014	10654435	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicidal Ideation; Suicidal Ideation	Escitalopram 20mg Generic			S	Oral			Not Reported
	Prozac			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2014	10655237	DIRECT					57 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Head Discomfort; Insomnia; Negative Thoughts; Nervousness; Product Substitution Issue; Tearfulness	Generic Lexapro			S	Oral			Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2014	10576995	EXPEDITED (15-DAY)		HO	DE-FRI-1000072233		56 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Irregular; Palpitations; Prescribed Overdose; Restlessness	Escitalopram			S	Oral	Overdose: 30 Mg/Day		Forest
	Risperdal			S	Oral	1 Mg		Not Reported
	Risperdal			S	Oral	2 Mg		Not Reported
	Quilonum Retard			C	Oral	450 Mg		Not Reported
	Lyrica			C	Oral	100 Mg		Not Reported
	Pantozol			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2014	10654421	EXPEDITED (15-DAY)		HO	FR-FRI-1000073089		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S		75 Mg		Not Reported
	Ketoprofene			S				Not Reported
	Previscan (Fluindione)			S		10 Or 15 Mg Daily		Not Reported
	Rabeprazole			C		20 Mg		Not Reported
	Repaglinide			C		2 Mg		Not Reported
	Bisoce			C		25 Mg		Not Reported
	Crestor			C		5 Mg		Not Reported
	Amlor			C	Oral			Not Reported
	Coaprovel			C	Oral	300/25 Mg Daily		Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Novorapid			C	Subcutaneous	100 U/Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2014	10654954	NON-EXPEDITED			US-PFIZER INC-2014344394		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Oxaprozin	S	Unk		Pfizer
	Lexapro	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2014	10655045	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000073006		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Poisoning Deliberate	Nebivolol			S	Oral			Forest
	Nebivolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Not Reported
	Procoralan			S				Not Reported
	Procoralan			S				Not Reported
	Tercian			S	Oral			Not Reported
	Tercian			S	Oral	625 To 2600 Mg		Not Reported
	Xanax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2014	10659862	EXPEDITED (15-DAY)		HO	FR-FRI-1000073137		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retroperitoneal Haematoma	Escitalopram			S	Oral			Forest
	Innohep			S	Subcutaneous	1 Df		Not Reported
	Innohep			S	Subcutaneous	1 Df		Not Reported
	Previscan (Fluindione)			S	Oral	0.5 Df		Not Reported
	Previscan (Fluindione)			S	Oral	0.5 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2014	8607687	EXPEDITED (15-DAY)		DE, OT	AT-RANBAXY-2012R1-56859		41 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Shock; Toxicity To Various Agents; Unresponsive To Stimuli	Topamax		S	Unknown	Unk	Not Reported
	Cipralex		S	Unknown	Unk	Not Reported
	Somnubene		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2014	10667639	EXPEDITED (15-DAY)		OT	GB-TEVA-529059ISR		73 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Influenza Like Illness; Malaise; Nightmare; Pain; Product Substitution Issue; Withdrawal Syndrome	Clomipramine			S				Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2014	10669020	EXPEDITED (15-DAY)		DE	FR-FRI-1000073274		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S		1 Df		Forest
	Kardegic			S	Oral	7.5 Mg		Not Reported
	Tahor			C				Not Reported
	Coversyl			C				Not Reported
	Lyrica			C				Not Reported
	Topalgic (France)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2014	10669021	EXPEDITED (15-DAY)		OT	GB-FRI-1000073261		73 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Influenza Like Illness; Malaise; Nightmare; Pain; Withdrawal Syndrome	Escitalopram			S	Oral			Forest
	Clomipramine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2014	10669036	EXPEDITED (15-DAY)		HO	FR-FRI-1000073264		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Subileus	Escitalopram			S	Oral			Forest
	Zyprexa			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2014	10672306	DIRECT		OT			63 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S		1 Pill Daily Approx. 2-3 Years	2-3 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2014	10671402	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2014M1014313			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Influenza Like Illness; Malaise; Nightmare; Pain; Withdrawal Syndrome	Clomipramine			S				Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2014	10671467	EXPEDITED (15-DAY)		OT	CH-FRI-1000073226		15 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Muscle Spasms; Off Label Use; Tachycardia	Escitalopram Oral Solution			S	Oral	5 Gtt		Forest
	Risperdal			S	Oral	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2014	10671469	EXPEDITED (15-DAY)		OT	IE-FRI-1000073229		30 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Withdrawal Syndrome	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2014	10671496	EXPEDITED (15-DAY)		OT	PHFR2014GB008727		73 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Influenza Like Illness; Malaise; Nightmare; Pain; Withdrawal Syndrome	Clomipramine			S	Unknown			Novartis
	Cipralex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2014	10671704	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000073289		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged; Intentional Overdose; Poisoning Deliberate	Escitalopram			S	Oral	1 Df		Forest
	Sotalex			S	Oral			Not Reported
	Sotalex			S	Oral	Overdose Of 1920 Mg Once		Not Reported
	Laroxyl			S	Oral	50 Df		Not Reported
	Lexomil			C		1 Df		Not Reported
	Ceris			C		1 Df		Not Reported
	Topalgic (France)			C				Not Reported
	Mopral			C		1 Df		Not Reported
	Insulin			C				Not Reported
	Lovenox			C		2 Df		Not Reported
	Inexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2014	10441844	EXPEDITED (15-DAY)		DS, HO, LT	DE-009507513-1409DEU002402		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus; Pyrexia; Serotonin Syndrome; Sinus Tachycardia	Mirtazapin Stada			S	Oral	15 Mg, Qd		Merck
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Amantadine Hydrochloride			S	Oral	100 Mg, Unk		Not Reported
	Amantadine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2014	10649630	EXPEDITED (15-DAY)		OT	JP-FRI-1000073009		77 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome	Escitalopram			S	Oral	10 Mg		Forest
	Rize			C	Oral	10 Mg		Not Reported
	Zolpidem Tartrate			C	Oral	5 Mg		Not Reported
	Brotizolam			C	Oral	0.125 Mg		Not Reported
	Brotizolam			C	Oral	0.125 Mg		Not Reported
	Argamate			C	Oral	75 Mg		Not Reported
	Bayaspirin			C	Oral	100 Mg		Not Reported
	Halfdigoxin			C	Oral	0.125 Mg		Not Reported
	Benidipine			C	Oral	4 Mg		Not Reported
	Allopurinol			C	Oral	100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2014	10674610	EXPEDITED (15-DAY)		HO, OT	SI-ACTAVIS-2014-27229			Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium	Escitalopram (Unknown)			S		10 Mg, Daily		Not Reported

Escitalopram (Unknown)	S	Unknown	5 Mg, Daily		Not Reported
Lamotrigine (Unknown)	S		200 Mg, Bid		Watson
Quetiapine (Unknown)	S	Unknown	500 Mg, Daily		Actavis
Valproic Acid (Unknown)	S	Unknown	1000 Mg, Bid		Watson
Acetylsalicylic Acid	C	Unknown	100 Mg, Unknown		Not Reported
Digoxin	C	Unknown	0.1 Mg, Unknown		Not Reported
Carvedilol	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	20 Mg, Unknown		Not Reported
Hydroxyurea	C	Unknown	1000 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2014	10675008	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20141208555		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haematemesis; Pyrexia; Subileus	Risperdal			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2014	10624688	NON-EXPEDITED		OT	US-JNJFOC-20141119929		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Dry Mouth; Eye Disorder; Oropharyngeal Pain; Type 2 Diabetes Mellitus	Topamax			S	Oral			Not Reported
	Fentanyl			S	Transdermal			Not Reported
	Oxycodone/Apap			S	Unknown	10/325 Mg		Not Reported
	Ibuprofen			S	Unknown	800 Mg In The Morning And 1200 Mg		Not Reported
	Tizanidine			S	Unknown			Not Reported
	Seroquel			S	Unknown	50 Mg At Morning And Noon And 200 Mg At		Not Reported

				Night.	
	Seroquel	S	Unknown	50 Mg At Morning And Noon And 200 Mg At Night.	Not Reported
	Venlafaxine	S	Oral	75 Mg Capscule And A 150 Mg Capscule Together	Not Reported
	Lexapro	S	Unknown		Not Reported
	Valium	S	Unknown		Not Reported
	Demadex	S	Unknown		Not Reported
	Lyrica	S	Oral		Not Reported
	Metformin	C	Unknown		Not Reported
	Aspirin	C	Oral		Not Reported
	Simvastatin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2014	10676293	EXPEDITED (15-DAY)		HO, OT	DE-DRREDDYS-GER/GER/14/0045060		50 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Restlessness	Venlafaxine			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Remergil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2014	10163013	EXPEDITED (15-DAY)		OT	PHHY2014US054442		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Muscle Spasticity; Pain	Lioresal Intratecal			S	Intrathecal	2128 Ot, Qd, (2000 Ug/Ml)		Not Reported
	Lisinopril			S	Oral			Novartis
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2014	10533955	EXPEDITED (15-DAY)		HO, LT	SE-FRI-1000071629		23 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Electrocardiogram Abnormal; Muscle Twitching; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral			Forest
	Tavegyl			S	Oral			Not Reported
	Cetirizine			S	Oral			Not Reported
	Postafen (Buclizine Hydrochloride)			S	Oral			Not Reported
	Loratadine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2014	10571984	EXPEDITED (15-DAY)		HO	SE-FRI-1000072215		20 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dyspnoea; Overdose; Sinus Tachycardia; Toxicity To Various Agents; Vomiting	Escitalopram			S		Overdose: 14 Tablets (70 Mg)		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2014	10677628	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2014-13279		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blepharospasm; Impaired Driving Ability; Visual Impairment	Escitalopram 10 Mg			S	Oral	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2014	10677859	EXPEDITED (15-DAY)		OT	GB-ACCORD-027749		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blepharospasm	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2014	10679236	EXPEDITED (15-DAY)		OT	GB-TEVA-530455ISR		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blepharospasm	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2014	10577521	EXPEDITED (15-DAY)		HO, LT	SE-FRI-1000072237		55 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral	Overdose: 50 Tablets		Forest
	Citalopram			S	Oral	Overdose: 50 Tablets		Forest
	Atarax			S	Oral	25 Tabs		Not Reported
	Mirtazapine			S	Oral	Ca 50 St		Not Reported
	Esertia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2014	10583333	EXPEDITED (15-DAY)		OT	CHPA2014CA014906		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Arthritis; Breath Sounds Abnormal; Bronchitis; Chondropathy; Cough; Depression; Fall; Fatigue; Feeling Of Body Temperature Change; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Incorrect Product Administration Duration; Intervertebral Disc Disorder; Lymphoedema; Lymphoma; Mobility Decreased; Motor Dysfunction; Nausea; Pain; Panic Attack; Peripheral Swelling; Photopsia; Pneumonia; Respiratory Arrest; Therapeutic Response Decreased; Therapeutic Response Unexpected; Tremor	Voltaren Emulgel	S	Topical	3 Squeezes, Once Or Twice A Day And At Night	Not Reported
	Voltaren Emulgel	S	Topical	1 Squeeze, Unk	Not Reported
	Voltaren Emulgel	S			Not Reported
	Voltaren Emulgel	S			Not Reported
	Ibuprofen Sandoz	S	Unknown	100 Mg, Qd	Novartis
	Zopiclone	S	Unknown	15 Mg, At Night	Not Reported
	Gabapentin	S	Unknown	Unk, Tid	Not Reported
	Gabapentin	S	Unknown	Unk, Bid	Not Reported
	Trazodone	S	Unknown	50 Mg, Qd At Night	Not Reported
	Esomeprazole	S	Unknown	40 Mg, Qd	Not Reported
	Clorazepate	S	Oral	15 Mg, Tid	Not Reported
	Morphine	S	Unknown	Unk, Tid	Not Reported
	Cipralex//Escitalopram	S	Unknown	20 Mg, Hs	Not Reported
	Co Etidrocal	S	Unknown	500 Mg, Qd	Not Reported
	Bupropion Hcl Er	C	Oral	300 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2014	10683484	EXPEDITED (15-DAY)		OT	CH-FRI-1000073323		36 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Pregnancy	Escitalopram			S		20 Mg		Forest
	Zoldorm			S	Unknown			Not Reported
	Temesta (Lorazepam)			S	Unknown			Not Reported
	Tranxilium			S	Unknown			Not Reported
	Norlevo			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2014	10683508	EXPEDITED (15-DAY)		OT	US-FRI-1000073348			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Dementia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2014	10683677	EXPEDITED (15-DAY)			CA-FRI-1000073405		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Mydriasis; Seizure	Escitalopram			S		5 Mg		Forest
	Keppra			S		Daily Dose Not Reported.		Not Reported
	Keppra			S		Daily Dose Not Reported.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2014	10684025	EXPEDITED (15-DAY)		OT	US-SA-2014SA180072			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psychotic Disorder	Ambien			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported
	Klonopin			S	Unknown			Not Reported
	Percocet			C				Not Reported
	Oxy			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2014	10684053	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2014M1015171			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blepharospasm	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2014	10684508	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-E2B_00002994		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Asthenia; Confusional State; Drug Ineffective; Dysarthria; Dysstasia; Fatigue; Gait Disturbance; Hallucination; Hyperventilation; Incontinence; Intellectual Disability; Malaise; Muscular Weakness; Nightmare; Paranoia; Sleep Disorder; Somnolence; Speech Disorder; Treatment Noncompliance; Unresponsive To Stimuli; Withdrawal Syndrome	Escitalopram Tablets Usp 5mg			S				Lupin
	Escitalopram Tablets Usp 5mg			S				Lupin
	Escitalopram Tablets Usp 10mg			S				Lupin
	Travatan			C	Unknown			Not Reported
	Rapaflo			C	Unknown			Not Reported
	Same			C	Unknown			Not Reported
	Timolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2014	10686044	EXPEDITED (15-DAY)		OT	PHHY2014MX168543			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Discomfort; Feeling Abnormal; Nausea; Thanatophobia; Vision Blurred	Ultibro Breezhaler			S	Respiratory (inhalation)	1 Ot, At Morning		Not Reported
	Ultibro Breezhaler			S	Respiratory (inhalation)	Unk		Not Reported
	Lexapro			S	Unknown			Not Reported
	Spiriva			C	Unknown	At Morning		Not Reported
	Axis			C	Unknown	At Afternoon		Not Reported
	Dilacoran			C	Unknown	Unk		Not Reported
	Eutirox			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2015	10686862	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2014-13656			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Withdrawal Syndrome; Feeling Abnormal	Paroxetine Arrow 20 Mg Film-Coated Tablets			S	Oral	20 Mg, Daily		Aurobindo
	Seroplex			S	Oral	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2015	10687184	EXPEDITED (15-DAY)		OT	TR-ACCORD-027858		76 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Hyponatraemia; Urinary Incontinence	Escitalopram			S				Accord
	Rivastigmine/Rivastigmine Tartrate			C				Not Reported
	Sitagliptin/Sitagliptin Phosphate			C				Not Reported
	Memantine/Memantine Hydrochloride			C				Not Reported
	Losartan			C				Not Reported
	Trazodone/Trazodone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2015	10687808	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20141215320			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Pyelonephritis	Risperdal			S	Unknown			Not Reported
	Nordaz			S	Unknown			Not Reported
	Seroplex			S	Unknown			Not Reported
	Atarax			S	Unknown			Not Reported
	Imovane			S	Unknown			Not Reported
	Lepticur			S	Unknown	Lepticur Was Given A Twice A Day		Not Reported
	Avlocardyl			S	Unknown			Not Reported
	Augmentin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2015	10687809	EXPEDITED (15-DAY)		HO, OT	FR-JNJFOC-20141215360		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypotonia; Somnolence	Risperdal			S	Transplacental			Not Reported
	Nordaz			S	Transplacental			Not Reported
	Seroplex			S	Transplacental			Not Reported
	Atarax			S	Transplacental			Not Reported
	Imovane			S	Transplacental			Not Reported
	Augmentin			S	Transplacental			Not Reported
	Avlocardyl			S	Transplacental			Not Reported
	Lepticur			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2015	10687991	EXPEDITED (15-DAY)		HO	DE-FRI-1000073415		50 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Restlessness	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Escitalopram			S	Oral	10 Mg		Not Reported
	Escitalopram			S	Oral	20 Mg		Not Reported
	Abilify			S	Oral	5 Mg		Not Reported
	Abilify			S	Oral	10 Mg		Not Reported
	Venlafaxin Retard			S	Oral	150 Mg		Not Reported
	Venlafaxin Retard			S	Oral	75 Mg		Not Reported
	Remergil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2015	10688594	EXPEDITED (15-DAY)		CA, HO	FR-FRI-1000073416		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypotonia; Somnolence	Escitalopram			S	Transplacental	20 Mg		Forest
	Risperdal			S	Transplacental	2 Mg		Not Reported
	Nordaz			S	Transplacental	15 Mg		Not Reported
	Atarax			S	Transplacental	90 Mg		Not Reported
	Imovane			S	Transplacental	Not Specified		Not Reported
	Lepticur			C	Transplacental			Not Reported
	Avlocardyl			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2015	10688595	EXPEDITED (15-DAY)		OT	GB-FRI-1000073419		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blepharospasm	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2015	10688612	EXPEDITED (15-DAY)		HO	FR-FRI-1000073418		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Gingival Bleeding; International Normalised Ratio Increased; Melaena	Escitalopram			S	Oral	1 Dosage Forms		Forest
	Previscan (Fluindione)			S	Oral	1 And 3/4 Daily Alternately		Not Reported
	Kardegic			S	Oral	1 Dosage Forms		Not Reported
	Aprovel			C	Oral	300 Mg		Not Reported
	Amlor			C	Oral	10 Mg		Not Reported
	Bisoprolol			C	Oral	10 Mg		Not Reported
	Lasilix			C	Oral	40 Mg		Not Reported

Metformine	C	Oral	2550 Mg		Not Reported
Inexium	C	Oral	40 Mg		Not Reported
Doliprane	C	Oral	3000 Mg		Not Reported
Princi B (Pyridoxine\Thiamine)	C	Oral	6 Dosage Forms		Not Reported
Speciafoldine	C	Oral	5 Mg		Not Reported
Diffu K	C	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2015	10689400	DIRECT	Y	HO			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2015	10442364	EXPEDITED (15-DAY)		HO	IT-TEVA-506173ISR		72 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Balance Disorder; Disturbance In Attention; Tremor	Carbolithium 300 Mg			S	Oral	450 Milligram Daily;		Barr
	Entact 10 Mg			S	Oral	20 Milligram Daily;		Not Reported
	Eutirox 50 Mcg			C	Oral	1 Dosage Forms Daily;		Not Reported
	Anafranil 25 Mg			C	Oral	2 Dosage Forms Daily;		Not Reported
	Cardioapsirin 100 Mg			C	Oral	1 Dosage Forms Daily;		Not Reported
	Torvast			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2015	10689170	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2014-01765			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Headache; Insomnia;	Escitalopram			S	Unknown			Lupin

Irritability; Seizure; Vision Blurred

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2015	10689171	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2014-01822			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Gastric Disorder	Escitalopram Oxalate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2015	10689172	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-E2B_00002640		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Suicidal Ideation	Escitalopram Tablets Usp 10mg			S				Lupin
	Escitalopram Tablets Usp 10mg			S				Lupin
	Metoprolol Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2015	10689173	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002803		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Swelling; Mouth Swelling; Pharyngeal Swelling; Swelling Face	Escitalopram Tablets Usp 5mg			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2015	10689174	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002888			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Feeling Abnormal;	Escitalopram Tablets Usp 5mg			S				Lupin
	Escitalopram Tablets Usp 10mg			S				Lupin

Nephrolithiasis; Product Substitution Issue	Atenolol		C	Unknown	Not Reported
	Lisinopril		C	Unknown	Not Reported
	Synthroid		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2015	10692623	DIRECT					60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Substitution Issue	Escitalopram			S	Oral	One		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2015	10670657	EXPEDITED (15-DAY)	Y	DS	JP2014JPN033508		31 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Ejaculation Delayed; Erectile Dysfunction; Sexual Dysfunction	Paxil Cr			S	Oral Oral Oral		12 DAY 7 DAY 174 DAY 7 DAY	Not Reported
	Paxil			S	Oral Oral		13 DAY 7 DAY	Not Reported
	Lexapro			S	Oral Oral Oral		6 DAY 216 DAY 49 DAY	Not Reported
	Colonel (Polycarbophil Calcium)			C				Not Reported
	Traditional Chinese Medicine (Traditional Chinese Medicine)			C				Not Reported
	Depakene (Valproic Acid) Solution			C				Not Reported
	Desyrel (Trazodone Hydrochloride)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2015	10694884	DIRECT		OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Sweats; Poor Quality Sleep	Lexapro			S	Oral	1 Tablet Once Daily Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2015	10695683	DIRECT		OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Loss Of Personal Independence In Daily Activities; Product Substitution Issue; Suicidal Ideation; Weight Increased	Escitalopram 20 Mg			S	Oral	Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2015	10694308	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2014-01693		20 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Aripiprazole			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Paliperidone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2015	9844681	NON-EXPEDITED	Y	DE	2014AP000689		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Exposure Via Ingestion	Amlodipine Besylate			S	Oral			Not Reported
	Citalopram			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

	Carvedilol Tablets	S	Oral		Not Reported
	Bupropion Hydrochloride Tablets	S	Oral		Not Reported
	Acetaminophen/ Hydrocodone	S	Oral		Not Reported
	Alprazolam	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2015	9858781	NON-EXPEDITED	Y	DE	2014AP000472		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Zolpidem Tartrate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2015	9867119	NON-EXPEDITED	Y	DE	2014AP000420		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Lamotrigine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Meloxicam Tablets			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2015	10441429	EXPEDITED (15-DAY)		HO	IT-FRI-1000070485		72 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Balance Disorder; Disturbance In Attention; Tremor	Escitalopram			S	Oral	20 Mg		Forest
	Carbolithium			S	Oral	600 Mg		Not Reported
	Carbolithium			S	Oral	450 Mg		Not Reported
	Euritox			C	Oral	50 Ug		Not Reported
	Anafranil			C	Oral	50 Mg		Not Reported

	Cardioaspirin		C	Oral	100 Mg	Not Reported
	Torvast		C		10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2015	10635950	EXPEDITED (15-DAY)			JP-FRI-1000072891		54 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles	Lexapro			S	Oral	20 Mg		Forest
	Wypax			C	Oral	1.5 Mg		Not Reported
	Wypax			C	Oral	3 Mg		Not Reported
	Rohypnol			C	Oral	2 Mg		Not Reported
	Doral			C	Oral	30 Mg		Not Reported
	Loxonin			C	Oral	180 Mg		Not Reported
	Mucosta			C	Oral	300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2015	10697886	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20150101734		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Overdose	Risperdal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2015	10698207	EXPEDITED (15-DAY)		OT	CH-TEVA-527123ISR		69 YR	Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Merycism; Product Substitution Issue; Restlessness	Escitalopram-Mepha			S	Unknown	10 Mg		Ivax
	Escitalopram-Mepha			S				Ivax
	Zometa			C	Unknown	10-Aug: Start And End Date Not Known		Not Reported

Ponstan	C	Unknown			Not Reported
Vit D3/Ca	C				Not Reported
Bisoprolol	C	Unknown	2.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2015	10700998	DIRECT		HO			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Product Quality Issue; Product Substitution Issue; Vertigo	Lexapro			S	Oral			Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2015	10555755	EXPEDITED (15-DAY)		HO, LT	PHHY2014SE133389			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Electrocardiogram Abnormal; Muscle Twitching; Somnolence; Toxicity To Various Agents	Tavegyl			S	Oral			Not Reported
	Cetirizine			S	Oral			Novartis
	Loratadine			S	Oral			Not Reported
	Cipralex /Den/			S	Oral			Not Reported
	Postafen (Meclozine Hydrochloride)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2015	10568790	EXPEDITED (15-DAY)		HO	US-BRISTOL-MYERS SQUIBB COMPANY-21542436		12 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Cyst; Drug Level Above Therapeutic; Headache; Mania; Off Label Use; Unevaluable Event; Weight Increased	Abilify			S	Oral	L In 1 D		Bristol Myers Squibb
	Abilify			S				Bristol Myers Squibb
	Lexapro			S	Oral	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2015	10700955	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20150104515		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Topiramate			S	Oral			Not Reported
	Verapamil			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Codeine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2015	10700957	EXPEDITED (15-DAY)		DE	US-JNJFOC-20150104512		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Topiramate			S	Oral			Not Reported
	Promethazine			S	Oral			Not Reported
	Verapamil			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Acetaminophen/Hydrocodone			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2015	10701957	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2014M1000602			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akinesia; Confusional State; Tremor	Zolpidem 10 Mg			S	Oral	10 Mg, Hs		Mylan
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Seroplex			S	Oral	15 Mg, Qd		Not Reported

	Seroplex	S				Not Reported
	Seresta	S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2015	10705216	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015008459		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Sertraline Hcl			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Atomoxetine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2015	10706958	DIRECT					14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory; Therapy Change	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2015	10706988	DIRECT		DS			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Leukopenia	Lexapro 20 Mg Camber			S	Oral		7 YR	Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2015	10707062	DIRECT					64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Product Effect Decreased	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2015	10712901	DIRECT					49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Headache; Panic Attack; Product Substitution Issue	Escitalopram Oxalate			S	Oral	One Pill A Day Once Daily Taken By Mouth		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2015	9943979	EXPEDITED (15-DAY)		HO, LT, OT	JP-FRI-1000054770		23 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Fibrillation	Lexapro			S	Oral	20 Mg		Forest
	Amoxan			S	Oral	20 Mg		Not Reported
	Seroquel			S	Oral	20 Mg		Not Reported
	Bibittoace			S	Oral	1 Mg		Not Reported
	Landsen			S	Oral	0.5 Mg		Not Reported
	Allelock			S	Oral	10 Mg		Not Reported
	Kamishoyosan			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2015	10707242	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015006848		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Gabapentin			S	Oral	Unk		Pfizer
	Alprazolam			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Bupropion			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2015	10707973	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015007083		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Liothyronine Sodium			S	Oral	Unk		Pfizer
	Ondansetron Hcl			S	Oral	Unk		Pfizer
	Sertraline Hcl			S	Oral	Unk		Pfizer
	Gabapentin			S	Oral	Unk		Pfizer
	Amitriptyline			S	Oral	Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Acetaminophen/Hydrocodone			S	Oral	Unk		Not Reported
	Linaclotide			S	Oral	Unk		Not Reported
	Diclofenac			S	Oral	Unk		Not Reported
	Lubiprostone			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2015	10708638	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2015GSK002950		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S	Unknown			Glaxosmithkline
	Zonisamide			S	Unknown			Glaxosmithkline
	Escitalopram			S	Unknown			Glaxosmithkline
	Lorazepam			S	Unknown			Not Reported
	Lovastatin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2015	10710602	NON-EXPEDITED			US-ENDO		49 YR	Female	USA

PHARMACEUTICALS
INC.-OXYA20140010

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Hypercholesterolaemia; Oropharyngeal Pain; Type 2 Diabetes Mellitus; Visual Impairment	Oxycodone/Acetaminophen 10mg/325mg			S	Oral	30mg/975mg		Not Reported
	Aspirin Ec			S	Oral			Not Reported
	Ibuprofen Tablets			S	Oral	800mg In The Morning And 1200		Not Reported
	Lyrica			S	Oral			Not Reported
	Tizanidine			S	Oral			Not Reported
	Tizanidine			S				Not Reported
	Seroquel			S	Oral	50 Mg Twice Daily In The Morning And Noon, 200 Mg At Night		Not Reported
	Seroquel			S				Not Reported
	Lexapro			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Demadex			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Fentanyl			S	Transdermal			Not Reported
	Effexor			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2015	10710765	EXPEDITED (15-DAY)		DE	US-ASTRAZENECA-2015SE01496		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Esomeprazole			S	Oral			Astrazeneca
	Diazepam			S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

	Diclofenac	S	Oral	Not Reported
	Acetaminophen/Hydrocodone	S	Oral	Not Reported
	Promethazine	S	Oral	Not Reported
	Topiramate	S	Oral	Not Reported
	Verapamil	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2015	10711233	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015006869		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Respiratory Arrest	Nitroglycerin			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Doxycycline Calcium			S		Unk		Pfizer
	Methylprednisolone			S		Unk		Pfizer
	Oxycodone			S		Unk		Not Reported
	Cyclobenzaprine			S		Unk		Not Reported
	Metoprolol			S		Unk		Not Reported
	Clonidine			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Diclofenac			S		Unk		Not Reported
	Cephalexin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2015	10711248	EXPEDITED (15-DAY)		DE, HO	US-BAYER-2015-004010		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Toxicity To Various Agents	Acetylsalicylic Acid (> 100 Mg)		Y	S	Oral			Bayer
	Digoxin			S	Oral			Not Reported

	Clonazepam		S	Oral		Not Reported
	Trazodone		S	Oral		Not Reported
	Oxybutynin		S	Oral		Not Reported
	Quetiapine		S	Oral		Not Reported
	Lamotrigine		S			Not Reported
	Escitalopram		S	Oral		Not Reported
	Finasteride		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2015	10711576	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015008398		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil Hcl			S	Oral			Pfizer
	Promethazine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Acetaminophen W/Hydrocodone Bitartrate			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Topiramate			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2015	10711756	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015009066		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil Hcl			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Codeine			S	Oral	Unk		Not Reported
	Topiramate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2015	10712237	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2015GSK002968		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Bupropion			S	Oral			Glaxosmithkline
	Escitalopram			S	Oral			Glaxosmithkline
	Gabapentin			S	Oral			Glaxosmithkline
	Alprazolam			S	Oral			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2015	10366630	EXPEDITED (15-DAY)		HO	FR-FRI-1000069661		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction; Haemorrhagic Stroke	Escitalopram			S	Oral	1 Df		Forest
	Pradaxa			S	Oral	2 Df		Not Reported
	Allopurinol			C	Unknown	1 Df		Not Reported
	Atorvastatin			C	Unknown	1 Df		Not Reported
	Exelon			C	Transdermal	1 Df		Not Reported
	Loxapac			C	Oral	20 Df		Not Reported
	Sotalex			C	Unknown	2 Df		Not Reported
	Zopiclone			C	Unknown	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2015	10671740	EXPEDITED (15-DAY)		OT	SE-FRI-1000073221		38 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hypotension; Muscular Weakness; Tremor; Vision Blurred; Vision Blurred;	Escitalopram			S		10 Mg		Forest
	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Unknown			Not Reported

Withdrawal Syndrome	Escitalopram		S	Unknown	Not Reported
	Escitalopram		S	Unknown	Not Reported
	Escitalopram		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2015	10712306	EXPEDITED (15-DAY)		DE, HO	US-ASTRAZENECA-2015SE01512		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Quetiapine			S	Oral			Zeneca
	Clonazepam			S	Oral			Not Reported
	Digoxin			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Oxybutynin			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Finasteride			S	Oral			Not Reported
	Salicylate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2015	10713134	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS U.S.A., INC-2015SUN00130		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	20 Mg, Unk		Taro
	Garcinia Cambogia			S	Unknown	2 Df, Tid		Not Reported
	Sertraline			S	Unknown	50 Mg, Daily		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Oxycodone			C	Unknown	Unk		Not Reported

Silodosin	C	Unknown	Unk		Not Reported
Solifenacin	C	Unknown	Unk		Not Reported
Diphenhydramine	C	Unknown	Unk		Not Reported
Cannabinoids	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2015	10713692	EXPEDITED (15-DAY)		HO	FR-FRI-1000073596		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Upper Gastrointestinal Haemorrhage	Escitalopram			S	Oral			Forest
	Ketoprofene			S	Cutaneous			Not Reported
	Aldactazine			S	Oral	1 Df		Not Reported
	Eliquis			S	Oral	5 Mg		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported
	Temerit			C	Unknown			Not Reported
	Mediatensyl			C	Unknown			Not Reported
	Amiodarone			C	Unknown			Not Reported
	Eptavit			C	Unknown			Not Reported
	Doliprane			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2015	10713716	EXPEDITED (15-DAY)		HO	FR-FRI-1000073597		32 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Gingival Bleeding; Haematuria; Rectal Haemorrhage	Escitalopram			S	Oral	5mg		Forest
	Escitalopram			S	Oral	10mg		Forest
	Xanax			S	Oral	0.25mg		Not Reported
	Bilaska			C	Oral	20 Mg		Not Reported
	Tardyferon			C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2015	10714860	EXPEDITED (15-DAY)		DS	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-000821			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability	Abilify			S	Unknown	N/A		Bristol Myers Squibb
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2015	10715091	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2015GSK003131		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Quetiapine			S	Oral			Glaxosmithkline
	Cardiac Glycoside			S	Oral			Not Reported
	Clonazepam			S	Oral			Glaxosmithkline
	Trazodone			S	Oral			Not Reported
	Oxybutynin			S				Glaxosmithkline
	Lamotrigine			S	Oral			Glaxosmithkline
	Escitalopram			S	Oral			Glaxosmithkline
	Finasteride			S	Oral			Glaxosmithkline
	Salicylate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2015	10715098	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2015GSK003260		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Glaxosmithkline
	Lamotrigine			S	Oral			Glaxosmithkline
	Temazepam			S	Oral			Not Reported

	Lorazepam	S	Oral	Not Reported
	Primidone	S	Oral	Not Reported
	Benztropine	S	Oral	Not Reported
	Antihyperlipidemics (Nos)	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2015	10715158	EXPEDITED (15-DAY)		DE	US-JNJFOC-20150107004		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Acetaminophen/Diphenhydramine		Y	S	Oral			Not Reported
	Warfarin			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2015	10695069	EXPEDITED (15-DAY)		OT	US-ABBVIE-15K-163-1329058-00		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Gingival Pain; Gingival Swelling; Hyperhidrosis; Pneumonia; Seizure	Humira			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2015	10716258	EXPEDITED (15-DAY)		HO	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2014-004743		50 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Restlessness	Abilify			S	Oral	5 Mg/Day, Increased To 10 Mg/Day On 06-Mar-		Bristol Myers Squibb

					2013	
	Cipralex /01588501/		S	Oral	10 Mg/Day	Not Reported
	Venlafaxin		S	Oral	150 Mg/Day; 75mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2015	10716884	EXPEDITED (15-DAY)		OT	US-FRI-1000073598			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Dizziness; Irritability; Tinnitus	Escitalopram			S		10 Mg		Forest
	Escitalopram			S		1.25 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2015	10716932	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMPANY-FR201501001173		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haematemesis; Subileus	Zyprexa			S	Oral	Unk, Unknown		Eli Lilly And Co
	Risperdal			S	Unknown	Unk, Unknown		Not Reported
	Seroplex			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2015	10717614	EXPEDITED (15-DAY)		DE	US-BAYER-2015-005102		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Paracetamol + Diphenhydramine		Y	S	Oral	Unk		Bayer
	Paracetamol + Diphenhydramine		Y	S	Oral	Unk		Bayer
	Warfarin			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

	Prednisone			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2015	10724176	DIRECT					40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Anxiety; Drug Ineffective; Headache; Product Substitution Issue	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2015	10718227	NON-EXPEDITED			US-ASTRAZENECA-2014SE95702			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Erectile Dysfunction; Sexual Dysfunction; Somnolence	Seroquel Xr			S	Oral			Astrazeneca
	Seroquel Xr			S	Oral			Astrazeneca
	Pristiq (Non Az Product)			S	Oral			Not Reported
	Zoloft (Non Az Product)			S	Oral			Not Reported
	Wellbutrin (Non Az Product)			S	Oral			Not Reported
	Lexapro (Non Az Product)			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported
	Prozac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2015	10354792	EXPEDITED (15-DAY)		DS, HO, LT, OT	US-GLAXOSMITHKLINE-A1083024A		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Hypersensitivity; Ear Injury; Ear Swelling; Gait Disturbance;	Benlysta			S	Intravenous (not otherwise specified)	10 Mg/Kg, 850 Mg Per Month		Glaxosmithkline
	Benlysta			S	Unknown	150mg,25cc In 250ml, Cyc		Glaxosmithkline

Hospitalisation; Mobility Decreased; Otorrhoea; Pain; Peripheral Swelling; Suicidal Ideation; Swelling; Swelling Face	Benlysta	S		400 Mg, U	Glaxosmithkline
	Cymbalta	S		60 Mg, Qd	Glaxosmithkline
	Lexapro	S	Unknown	Unk, U	Not Reported
	Plaquenil	C			Not Reported
	Triamcinolone Cream	C			Not Reported
	Trazodone	C			Not Reported
	Gabapentin	C			Not Reported
	Lasix	C			Not Reported
	Cyanocobalamin	C			Not Reported
	Prenatal Vitamins	C			Not Reported
	Fentanyl Patch	C			Not Reported
	Solumedrol	C			Not Reported
	Benadryl	C			Glaxosmithkline
	Trazodone	C			Not Reported
	Lorazepam	C			Not Reported
	Ondansetron Hcl	C			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2015	10721283	EXPEDITED (15-DAY)		HO	FR-SA-2015SA005024		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Lasilix			S	Oral	40 Mg		Not Reported
	Lexomil			S	Oral			Not Reported
	Seresta			S	Oral	50 Mg; Tab		Not Reported
	Seroplex			S	Oral	10 Mg; Tab		Not Reported
	Preterax			S	Oral			Not Reported
	Tanganil			C	Oral			Not Reported
	Levothyrox			C	Oral	125 Mcg		Not Reported
	Doliprane			C	Oral			Not Reported
	Mopral			C	Oral			Not Reported
	Xanax			C		Strength: 0.25		Not Reported
	Diffu K			C	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2015	10722435	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-CA2015GSK006578		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Wellbutrin Xl			S	Oral	150 Mg, Bid		Glaxosmithkline
	Cipralex			S	Oral	20 Mg, U		Not Reported
	Clonazepam			S		0.5 Mg, Tid		Not Reported
	Domperidone			S		10 Mg, Bid		Not Reported
	Ferrous Sulphate			S	Oral	300 Mg, Tid		Not Reported
	Gabapentin			S	Oral	300 Mg, Qd		Not Reported
	Gabapentin			S		600 Mg, Bid		Not Reported
	Temazepam			S	Oral	30 Mg, 1d		Not Reported
	Tylenol With Codeine			S	Oral	2 Df, Tid		Not Reported
	Vitalux			S	Oral	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2015	10449781	NON-EXPEDITED			US-PFIZER INC-2014250872			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Doxycycline Monohydrate			S		Unk		Pfizer
	Bextra			S		Unk		Pfizer
	Septra			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Aspirin			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Ceclor			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

Symbyax	S	Unk		Not Reported
Lescol	S	Unk		Not Reported
Novocaine	S	Unk		Not Reported
Seroquel	S	Unk		Not Reported
Zocor	S	Unk		Not Reported
Topamax	S	Unk		Not Reported
Asa	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2015	10699229	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2014-001271			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psychotic Disorder	Abilify			S	Unknown	Unk Mg, Unk		Bristol Myers Squibb
	Abilify			S				Bristol Myers Squibb
	Abilify			S				Bristol Myers Squibb
	Lexapro			S	Unknown	20 Mg		Not Reported
	Klonopin			S	Unknown	Unk		Not Reported
	Ambien			S	Unknown	Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2015	10722672	EXPEDITED (15-DAY)		HO	CA-BAUSCH-BL-2015-000732		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Wellbutrin Xl			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Clonazepam			S				Not Reported
	Domperidone			S				Not Reported
	Ferrous Sulphate			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported

	Temazepam	S	Oral		Not Reported
	Tylenol With Codeine No. 3 - Tab	S	Oral		Not Reported
	Vitalux	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2015	10723046	EXPEDITED (15-DAY)		HO	US-DRREDDYS-USA/USA/15/0045446		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Hypertension; Hypokalaemia; Leukocytosis; Serotonin Syndrome; Toxicity To Various Agents	Sertraline Hydrochloride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	G. Cambogia			S	Unknown			Not Reported
	Baclofen			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Silodosin			C	Unknown			Not Reported
	Solifenacin			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2015	10724258	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2014SE98632		35 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyslipidaemia; Hyperphagia; Hypothyroidism; Weight Increased	Xeroquel			S	Oral			Zeneca
	Xeroquel			S	Oral			Zeneca
	Seroplex			S	Oral			Not Reported
	Alprazolam			C				Not Reported
	Atarax			C				Not Reported
	Theralene			C				Not Reported
	Zopiclone			C		1 To 2 Tablets Per Day		Not Reported

	Inhibitor Pump Of Proton	C	Not Reported
	Nicotine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2015	10724650	EXPEDITED (15-DAY)		HO	FR-FRI-1000073642		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carotid Artery Dissection; Cerebral Haemorrhage; Enuresis; Fall; Subarachnoid Haemorrhage	Escitalopram			S	Oral	5mg		Forest
	Xarelto			S	Oral	15mg		Not Reported
	Hemigoxine Nativelle			C	Oral	0.125mg		Not Reported
	Bisoprolol			C	Oral	5mg		Not Reported
	Pantoprazole			C	Oral	20mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2015	10724825	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20150105344		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Oxybutynin Hydrochloride			S	Oral			Not Reported
	Digoxin			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Finasteride			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2015	10725180	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2015GSK004487		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coma; Electrocardiogram Abnormal; Hypotension; Respiratory Failure	Lamictal		S	Oral	3 G, Single	Glaxosmithkline
	Tercian		S	Oral	375 Mg, Single	Not Reported
	Prazepam		S	Oral	600 Mg, Single	Not Reported
	Seroplex		S	Oral	600 Mg, Unk	Glaxosmithkline
	Levothyrox		C			Not Reported
	Sulfarlem		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2015	10727289	EXPEDITED (15-DAY)		HO	FR-FRI-1000073762		30 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Coma; Hepatocellular Injury; Hyperhidrosis; Mydriasis; Tachycardia	Escitalopram			S	Oral	20 Mg		Forest
	Depakote			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2015	10727298	EXPEDITED (15-DAY)		HO	FR-FRI-1000073724		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Melaena	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Triatec (Ramipril)			C	Oral	2.5 Mg		Not Reported
	Eupressyl			C	Oral	60 Mg		Not Reported
	Lasilix			C	Oral	60 Mg		Not Reported
	Diffu K			C	Oral	1800 Mg		Not Reported
	Amlor			C	Oral	10 Mg		Not Reported
	Natispray			C	Unknown			Not Reported
	Speciafoldine			C	Oral	5 Mg		Not Reported
	Laroscorbine			C	Oral	1000 Mg		Not Reported
	Seresta			C	Oral	60 Mg		Not Reported

	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Oral	480 Mg		Not Reported
	Forlax	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2015	10736108	EXPEDITED (15-DAY)	Y	HO	SE-001614		53 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Fluid Intake Reduced; Gastrointestinal Stoma Output Increased; Hypophagia; Ileal Stenosis; Urine Output Decreased	Revestive			S	Subcutaneous			Not Reported
	Morphine			C				Not Reported
	Escitalopram			S				Not Reported
	Mirtazapin			C				Not Reported
	Codeine			C				Not Reported
	Imodium			C				Not Reported
	Innohep			C				Not Reported
	Imovane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2015	10659795	EXPEDITED (15-DAY)		LT	JP-FRI-1000073111		27 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Electrocardiogram Abnormal; Hypothermia; Myocarditis; Overdose	Lexapro			S	Oral	30 Tablets		Forest
	Lexapro			S	Oral			Forest
	Rohypnol			S	Oral			Not Reported
	Rohypnol			S	Oral	120 Mg		Not Reported
	Myonal [Eperisone Hydrochloride]			S	Oral			Not Reported
	Myonal [Eperisone Hydrochloride]			S	Oral	4500 Mg		Not Reported
	Celecox			S	Oral			Not Reported
	Celecox			S	Oral	6000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2015	10678467	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2014356829		32 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Gingival Bleeding; Haematuria; Rectal Haemorrhage	Xanax			S	Oral	0.25 Mg, 1x/Day		Pfizer
	Seroplex			S	Oral	5 Mg, Unk		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Bilaska			C		20 Mg, Daily		Not Reported
	Tardyferon B9 [Ferrous Sulfate;Folic Acid]			C		1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2015	10695850	EXPEDITED (15-DAY)		HO	JP-FRI-1000073429			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compulsions; Condition Aggravated	Lexapro			S	Oral	20 Mg		Forest
	Cymbalta			C	Oral	60 Mg		Not Reported
	Lexotan			C	Oral	7.5 Mg		Not Reported
	Meilax			C	Oral	0.5 Mg		Not Reported
	Rohypnol			C	Oral	1 Mg		Not Reported
	Mevalotin			C	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2015	10728684	EXPEDITED (15-DAY)		DE, HO	US-ALVOGEN-2015AL000112		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Atenolol			S				Not Reported
	Escitalopram			S				Not Reported
	Primidone			S				Not Reported
	Anxiolytics			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2015	10728812	EXPEDITED (15-DAY)		HO, OT	FR-ASTRAZENECA-2015SE05270		99 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyponatraemia	Inexium			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Levothyrox			C	Oral			Not Reported
	Kardegic			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2015	10729394	EXPEDITED (15-DAY)		HO	FR-DSJP-DSE-2015-101752			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Miosis	Olmetec 10 Mg			S	Oral	10 Mg, Single		Not Reported
	Alprazolam			S		0.5 Mg, Single		Not Reported
	Seroplex			S	Oral	1 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2015	10729761	EXPEDITED (15-DAY)		DE, HO, OT	IS-MYLANLABS-2014M1009534			Unknown	ISL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Drug Abuse; Drug Dependence; Road Traffic Accident; Weight Decreased	Quetiapine			S				Not Reported
	Zopiclone			S				Not Reported
	Ketogan /00129101/			S				Not Reported
	Esopram			S				Not Reported
	Phenergan /00033001/			S				Not Reported
	Sobril			S				Not Reported
	Oxynorm			S				Not Reported
	Imovane			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2015	10730780	EXPEDITED (15-DAY)		DE, OT	US-UCBSA-2015002076		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Alprazolam			S	Oral			Schwartz
	Bupropion			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2015	10736838	EXPEDITED (15-DAY)	Y	DE	POI0573201500016		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxybutynin Chloride Extended-Release Tablets Usp 5mg, 10mg And And 15mg (Oxybutynin Hydrochloride) (Tablet)			S	Oral			Not Reported
	Cardiac Glycoside			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Finasteride			S	Oral			Not Reported
	Salicylate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2015	10513311	EXPEDITED (15-DAY)		HO	IT-ACCORD-026335		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor	Quetiapine			S	Oral			Accord
	Cipralex			S	Oral	1 Df Daily		Not Reported
	Paroxetine			S	Oral	1.5 Df Daily		Not Reported

	Prazene	S	Oral	1 Df Daily	Not Reported
	Stilnox	C			Not Reported
	Foster	C			Not Reported
	Lasix	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2015	10551850	EXPEDITED (15-DAY)		HO	FR-FRI-1000071857		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemarthrosis	Escitalopram			S	Oral	5mg		Forest
	Plavix			S	Oral	1df		Not Reported
	Xagrid			S	Oral	1 Mg		Not Reported
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Paracetamol			C		1 To 3/Day (If Needed)		Not Reported
	Oxybutynine			C		0.5 Df		Not Reported
	Lorazepam			C				Not Reported
	Uvedose			C	Oral	0.0333 Df		Not Reported
	Econazole			C	Transdermal	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2015	10582326	EXPEDITED (15-DAY)		HO, OT	US-ELI_LILLY_AND_COMPANY-US201411000653		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Interaction; Ear Injury; Ear Swelling; Off Label Use; Otorrhoea; Peripheral Swelling; Swelling Face	Cymbalta			S	Unknown	60 Mg, Qd		Eli Lilly And Co
	Belimumab			S	Unknown	850 Mg, Qd		Not Reported
	Belimumab			S	Unknown	150 Mg, Cyclical		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Triamcinolone /00031902/			C	Unknown	Unk, Unknown		Not Reported
	Trazodone			C	Unknown	Unk, Unknown		Not Reported
	Gabapentin			C	Unknown	Unk, Unknown		Not Reported

	Lasix /00032601/	C	Unknown	Unk, Unknown	Not Reported
	Cyanocobalamin	C	Unknown	Unk, Unknown	Not Reported
	Prenatal Vitamins /01549301/	C	Unknown	Unk, Unknown	Not Reported
	Fentanyl	C	Unknown	Unk, Unknown	Not Reported
	Plaquenil /00072602/	C	Unknown	Unk, Unknown	Not Reported
	Solumedrol	C			Not Reported
	Lorazepam	C			Not Reported
	Protonix	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2015	10683261	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2014360168		64 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Insomnia; Malaise; Nausea; Tremor	Zyvoxid			S	Oral	1200 Mg, Daily		Pfizer
	Cipralex			S	Oral	20 Mg, Daily		Not Reported
	Calcifediol			C				Not Reported
	Alendronic Acid			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2015	10683262	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2014360218		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Nausea; Tremor; Vomiting	Zyvoxid			S	Oral	1200 Mg, Daily		Pfizer
	Cipralex			S	Oral	20 Mg, Daily		Not Reported
	Lansoprazole			C	Oral	30 Mg, Unk		Not Reported
	Methylprednisolone			C		8 Mg, Unk		Not Reported
	Simvastatin			C	Oral	20 Mg, Unk		Not Reported
	Metformin Hydrochloride			C	Oral	1700 Mg, Unk		Not Reported
	Cardioaspirin			C	Oral	100 Mg, Unk		Not Reported
	Eutirox			C	Oral	0.025 Mg, Unk		Not Reported

	Oxycontin	C	40 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2015	10718365	EXPEDITED (15-DAY)		DE, OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2015001568			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug Interaction	Escitalopram Tablet			S	Oral	10 Mg, Unk		Macleods
	Escitalopram Tablet			S	Oral	15 Mg, Unk		Macleods
	Letrozole			S	Oral	Unk		Not Reported
	Adcal-D3			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2015	10731439	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2015-00281		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anxiety; Dizziness; Drug Ineffective; Drug Intolerance; Insomnia; Nausea; Vomiting	Citalopram			S	Unknown	Unk		Aurobindo
	Citalopram			S				Aurobindo
	Escitalopram			S	Unknown	2.5 Mg, Daily		Aurobindo
	Escitalopram			S				Aurobindo
	Fluoxetine 10 Mg			S	Unknown	10 Mg, Daily		Aurobindo
	Mirtazapine			S	Unknown	22.5 Mg, Daily		Aurobindo
	Mirtazapine			S				Aurobindo
	Paroxetine 10mg			S	Unknown	10 Mg, Daily		Aurobindo
	Paroxetine 10mg			S				Aurobindo
	Sertraline			S	Unknown	10 Mg, Daily		Aurobindo
	Sertraline			S				Aurobindo
	Venlafaxine			S	Unknown	Low Dose		Aurobindo
	Venlafaxine			S				Aurobindo
	Diazepam			S	Unknown	0.5 Mg, Daily		Not Reported
	Doxepin			S	Unknown	Unk		Not Reported
	Doxepin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2015	10735143	NON-EXPEDITED			US-ASTRAZENECA-2014SE90536		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Disorder; Depression; Dry Mouth; Fibromyalgia; Hypercholesterolaemia; Increased Appetite; Muscle Spasms; Oedema; Oropharyngeal Pain; Pain; Type 2 Diabetes Mellitus; Visual Impairment	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Lyrica			S	Oral			Not Reported
	Venlafaxine (Effesor)			S	Unknown			Not Reported
	Valium			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Ibuprofen			S	Unknown	800 Mg In Morning And 1200		Not Reported
	Fentanyl Patch			S	Unknown	50 Mcg Every 48 Hours		Not Reported
	Metformin(Non-Az Product)			S	Unknown			Not Reported
	Tizanidine			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Simvastin			S	Unknown			Not Reported
	Topamax			S	Unknown			Not Reported
	Demadex			S	Unknown			Not Reported
	Oxycodone			S	Unknown	10/325 Mg 1 Of Them 3 Times Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2015	10541372	EXPEDITED (15-DAY)		OT	US-TEVA-516808USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gastritis Erosive; Hiatus	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Bupropion			C				Not Reported

Hernia; Nausea	Levothyroxine	C	Not Reported
	Lyrica	C	Not Reported
	Zyrtec	C	Not Reported
	Hydrocodone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2015	10725194	EXPEDITED (15-DAY)		OT	AU-SYMPLMED PHARMACEUTICALS-2015SYM00009		67 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Blood Glucose Increased; Blood Triglycerides Increased; Blood Urea Decreased; Blood Urea Nitrogen/Creatinine Ratio Decreased; C-Reactive Protein Increased; Cardiac Aneurysm; Globulins Decreased; Left Atrial Dilatation; Mitral Valve Disease; Mitral Valve Incompetence; Pericardial Effusion; Pulmonary Valve Incompetence; Sedation; Tricuspid Valve Incompetence	Aceon			S		Unk		Symplmed Pharmaceuticals
	Escitalopram			S		Unk		Not Reported
	Amisulpride			S		Unk		Not Reported
	Atorvastatin			S		Unk		Not Reported
	Clozaril			S		Unk		Not Reported
	Clozaril			S		75 Mg, Unk		Not Reported
	Fenofibrate			S		Unk		Not Reported
	Metformin			S		Unk		Not Reported
	Olanzapine			S		Unk		Not Reported
	Oxazepam			S		Unk		Not Reported
	Thyroxine			S		Unk		Not Reported
	Warfarin			S		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2015	10736211	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2015AP005398		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Inappropriate Antidiuretic Hormone Secretion; Mania; Pneumonia Pseudomonal; Toxicity To Various Agents	Olanzapine			S	Unknown	10 Mg, Qd		Apotex
	Olanzapine			S	Unknown	7.5 Mg, Qd		Apotex
	Alprazolam			S	Unknown	Unk Unk, Prn		Apotex

Sertraline Hydrochloride	S	Unknown	50 Mg, Daily	Apotex
Fluticasone Propionate	S	Unknown		Apotex
Escitalopram Oxalate	S	Unknown	10 Mg, Qd	Apotex
Escitalopram Oxalate	S		20 Mg, Qd	Apotex
Prednisone	S	Unknown	10 Mg, Daily	Not Reported
Prednisone	S	Unknown	7.5mg Daily, Later Reduced	Not Reported
Prednisone	S	Unknown	2.5mg Daily, Later Reduced	Not Reported
Prednisone	S	Unknown	2mg Daily	Not Reported
Prednisone	S		1 Mg, Qd	Not Reported
Prednisone	S		5 Mg, Daily	Not Reported
Prednisone	S		20 Mg, Daily	Not Reported
Prednisone	S		Unk	Not Reported
Lorazepam	S	Intramuscular		Not Reported
Esomeprazole	C	Unknown		Not Reported
Tiotropium Bromide	C	Unknown		Not Reported
Haloperidol	C	Intramuscular		Not Reported
Buspirone	C	Unknown	15 Mg, Daily	Not Reported
Buspirone	C	Unknown	30 Mg, Daily	Not Reported
Lithium	C	Unknown	300 Mg, Daily	Not Reported
Lithium	C		600 Mg,Daily	Not Reported
Lithium	C		300 Mg, Daily	Not Reported
Ipratropium Bromide	C	Unknown		Not Reported
Risperidone	C		9 Mg, Qd	Not Reported
Risperidone	C	Unknown	1.5 Mg, Daily	Not Reported
Quetiapine	C		6.25 Mg, Qd	Not Reported
Quetiapine	C		100 Mg, Daily	Not Reported
Quetiapine	C		300 Mg, Daily	Not Reported
Quetiapine	C		200 Mg Daily	Not Reported

	Quetiapine	C		25 Mg, Daily	Not Reported
	Diltiazem	C	Unknown		Not Reported
	Trazodone	C	Unknown	25 Mg, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2015	10737387	EXPEDITED (15-DAY)		DE	US-LEHIGH_VALLEY-USA-POI0580201500027		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Poisoning Deliberate; Respiratory Arrest	Oxycodone Hcl Capsules			S				Lehigh Valley Tech
	Cyclobenzaprine			S				Not Reported
	Metoprolol			S				Not Reported
	Clonidine			S				Not Reported
	Nitroglycerin			S				Not Reported
	Lisinopril			S				Not Reported
	Escitalopram			S				Not Reported
	Ibuprofen			S				Not Reported
	Diclofenac			S				Not Reported
	Azithromycin			S				Not Reported
	Cephalexin			S				Not Reported
	Doxycycline			S				Not Reported
	Methylprednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2015	10738787	EXPEDITED (15-DAY)		HO	FR-FRI-1000073767		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Abnormal; Hypotension; Intentional Overdose; Respiratory Failure	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose: Estimated Dose Of 150 Mg On 04/Dec/2014		Forest
	Lamictal			S	Oral			Not Reported
	Lamictal			S	Oral	Overdose: Estimated Dose Of 3 G On 04/Dec/2014		Not Reported
	Tercian			S	Oral			Not Reported

	Tercian	S	Oral	Overdose: Estimated Dose Of 375 Mg On 04/Dec/2014	Not Reported
	Prazepam	S	Oral		Not Reported
	Prazepam	S	Oral	Overdose: Estimated Dose Of 600 Mg On 04/Dec/2014	Not Reported
	Levothyrox	C			Not Reported
	Sulfarlem	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2015	10739325	EXPEDITED (15-DAY)		DE, OT	US-009507513-1501USA007584		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Elavil (Made By Merck, Marketed By Zeneca)			S	Oral			Merck
	Tramadol Hydrochloride			S	Oral			Not Reported
	Tramadol Hydrochloride			S	Oral	Unk		Not Reported
	Acetaminophen (+) Hydrocodone Bitartrate			S	Oral			Not Reported
	Ondansetron Hydrochloride			S	Oral			Not Reported
	Linaclotide			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Lubiprostone			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Liothyronine Sodium			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Sertraline Hydrochloride			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2015	10725571	EXPEDITED (15-DAY)		DE, OT	GB-DRREDDYS-GER/UKI/15/0045450		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug Interaction	Letrozole			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Adcal-D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2015	10740057	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2015-001140		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion; Exposure Via Inhalation	Zolpidem			S				Valeant
	Ethanol			S				Not Reported
	Methamphetamine			S				Not Reported
	Carbon Monoxide			S				Not Reported
	Escitaopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2015	10740058	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1524943		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Potassium Increased; Blood Pressure Decreased; Bradycardia; Coma; Coma Scale Abnormal; Drug Interaction; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Heart Rate Decreased; Hyperkalaemia;	Diazepam			S	Unknown			Not Reported
	Diazepam			S	Oral	Frequency: Once; Therapy Duration: 1 Day		Not Reported
	Diazepam			S	Oral	Frequency And Therapy Duration: Once		Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown	Frequency: Once; Therapy Duration: 1 Day		Not Reported
	Cipralex			S	Oral	Frequency And Therapy Duration: Once		Not Reported
	Citalopram			S	Oral			Not Reported
	Lorazepam			S	Oral	Frequency: Once; Therapy Duration: 1 Day		Not Reported

Hypotension; Intentional Overdose; Loss Of Consciousness; Mechanical Ventilation; Opiates Positive; Overdose; Oxygen Saturation Decreased; Sinus Tachycardia; Suicide Attempt	Lorazepam		S	Oral	Frequency And Therapy Duration: Once	Not Reported
	Morphine Sulfate		S	Oral		Not Reported
	Morphine Sulfate		S	Unknown		Not Reported
	Morphine Sulfate		S	Unknown		Not Reported
	Oxycodone		S	Oral	Frequency: Once; Therapy Duration: 1 Day	Not Reported
	Oxycodone		S	Oral		Not Reported
	Oxycodone		S	Unknown		Not Reported
	Oxycodone		S	Unknown		Not Reported
	Oxycodone/Acetaminophen		S	Oral		Not Reported
	Zopiclone		S	Oral	Frequency: Once; Therapy Duration: 1 Day	Not Reported
	Zopiclone		S	Unknown		Not Reported
	Zopiclone		S	Oral	Frequency And Therapy Duration: Once	Not Reported
	Morphine		S	Oral		Not Reported
	Morphine		S	Oral	Frequency: Once; Therapy Duration: 1 Day	Not Reported
	Morphine		S	Unknown	Frequency And Therapy Duration: Once	Not Reported
	Morphine		S	Unknown	Frequency And Therapy Duration: Once	Not Reported
	Morphine		S	Unknown	Frequency And Therapy Duration: Once	Not Reported
	Altace		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2015	10740422	EXPEDITED (15-DAY)		DE, OT	US-009507513-1501USA007660		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Prinivil			S	Oral	Unk		Merck

	Acetaminophen	S	Oral	Unk		Not Reported
	Diphenhydramine Hydrochloride	S		Unk		Not Reported
	Warfarin	S		Unk		Not Reported
	Olanzapine	S		Unk		Not Reported
	Escitalopram	S		Unk		Not Reported
	Prednisone	S	Oral	Unk		Merck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2015	10740530	EXPEDITED (15-DAY)		DE	US-009507513-1501USA007661		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Toxicity To Various Agents	Prinivil			S	Oral	Unk		Merck
	Oxycodone			S		Unk		Not Reported
	Cyclobenzaprine Hydrochloride			S		Unk		Not Reported
	Metoprolol			S		Unk		Not Reported
	Clonidine			S		Unk		Not Reported
	Nitro-Dur			S	Transdermal	Unk		Merck
	Escitalopram			S		Unk		Not Reported
	Ibuprofen			S		Unk		Not Reported
	Diclofenac			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Cephalexin			S		Unk		Not Reported
	Doxycycline			S		Unk		Not Reported
	Methylprednisolone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2015	10740620	EXPEDITED (15-DAY)		DE, OT	US-009507513-1501USA007644		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide;	Mevacor Tablet			S	Oral	Unk		Merck

Toxicity To Various Agents	Lamotrigine		S	Oral	Not Reported
	Zonisamide		S	Oral	Not Reported
	Lorazepam		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2015	10740780	EXPEDITED (15-DAY)		DE, OT	US-009507513-1501USA007631		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Oxybutynin			S	Oral	Unk		Merck
	Finasteride			S	Oral	Unk		Merck
	Clonazepam			S	Oral	Unk		Not Reported
	Trazodone Hydrochloride			S	Oral	Unk		Not Reported
	Quetiapine Fumarate			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Salicylic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2015	10742821	EXPEDITED (15-DAY)		HO	CA-FRI-1000073830		93 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depressed Mood; Diarrhoea; Dizziness; Fall; Hyponatraemia; Hypotension; Hypovitaminosis; Poor Quality Sleep	Escitalopram			S	Unknown	10 Mg Daily.		Forest
	Lorazepam			S	Unknown			Not Reported
	Metoprolol			S	Unknown	50 Mg		Not Reported
	Metoprolol			S				Not Reported
	Pantoprazole			S	Unknown	80 Mg Daily.		Not Reported
	Telmisartan			S	Unknown	80 Mg Daily.		Not Reported
	Telmisartan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2015	10743314	EXPEDITED (15-DAY)		DE, OT	GB-MYLANLABS-2015M1001226			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug Interaction	Escitalopram			S	Oral	10 Increased To 15mg		Not Reported
	Letrozole			S	Oral	2.5 Mg, Unk		Not Reported
	Adcal-D3			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2015	10745343	DIRECT		OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Product Substitution Issue	Escitalopram 20 Mg			S	Oral		2 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2015	10745675	DIRECT		DS, OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Arthralgia; Arthralgia; Back Pain; Bone Pain; Disturbance In Attention; Economic Problem; Emotional Distress; Feelings Of Worthlessness; Incoherent; Insomnia; Loss Of Personal Independence In Daily Activities; Myalgia; Pain In Extremity; Product Substitution Issue; Somnolence	Escitalopram			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2015	10723011	EXPEDITED (15-DAY)		DE, OT	PHFR2015GB000795			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug Interaction	Letrozole			S	Oral	2.5 Mg, Qd		Novartis
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
	Adcal-D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2015	10731452	EXPEDITED (15-DAY)		DE, OT	GB-AUROBINDO-AUR-APL-2015-00326		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug Interaction	Escitalopram 10 Mg			S	Oral	10 Mg, Unk		Aurobindo
	Escitalopram 10 Mg			S	Oral	15 Mg, Unk		Aurobindo
	Letrozole			S	Oral	2.5 Mg, Unk		Not Reported
	Adcal D3			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2015	10743696	EXPEDITED (15-DAY)		DE, OT	US-BAUSCH-BL-2015-001156		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Bupropion			S				Not Reported
	Escitalopram			S				Not Reported
	Gabapentin			S				Not Reported
	Alprazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2015	10743807	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2015-00566		24 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Nausea; Withdrawal Syndrome	Escitalopram 10 Mg		S	Oral	10 Mg, Daily	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2015	10744232	EXPEDITED (15-DAY)		LT	SE-AUROBINDO-AUR-APL-2015-00707		23 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Electrocardiogram Abnormal; Muscle Twitching; Somnolence; Toxicity To Various Agents	Cetirizine			S	Unknown			Aurobindo
	Postafen /00060202/			S	Unknown			Not Reported
	Loratadine			S	Unknown			Not Reported
	Cipralex /01588501/			S	Unknown			Not Reported
	Tavegyl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2015	10746075	EXPEDITED (15-DAY)		DE	US-UPSHER-SMITH LABORATORIES, INC.-15000143		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Benztropine Mesylate			S	Oral	Unk, Unk		Upsher-Smith
	Temazepam			S	Oral	Unk, Unk		Not Reported
	Lorazepam			S	Oral	Unk, Unk		Not Reported
	Primidone			S	Oral	Unk, Unk		Not Reported
	Lamotrigine			S	Oral	Unk, Unk		Not Reported
	Escitalopram			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2015	10746353	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015029834		39 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Miosis; Suicide Attempt; Toxicity To Various Agents	Olmetec			S	Oral	10 Mg, Single		Not Reported
	Alprazolam			S	Unknown	0.5 Mg, Single		Pfizer

	Seroplex	S	Oral	1 Df, Single	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2015	10748843	DIRECT					64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Libido Decreased; Weight Increased	Escitalopram			S	Oral	10 Mg Once A Day, Once Daily, Taken By Mouth For A Year And Half	18 MTH	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2015	10932086	NON-EXPEDITED	Y	OT	2014TUS009803		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Brintellix (Vortioxetine) Tablet			S	Oral	10 Mg (Sample)		Not Reported
	Lexapro (Escitalopram Oxalate)			S		Low Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10516084	EXPEDITED (15-DAY)		HO	IT-FRI-1000071463		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor	Escitalopram			S	Oral	10 Mg		Forest
	Quetiapine			S	Oral	300 Mg		Not Reported
	Paroxetine Hydrochloride			S	Oral	1.5 Posological Units Daily		Not Reported
	Prazene			S	Oral	20 Mg		Not Reported
	Lasix			C				Not Reported
	Foster			C	Respiratory (inhalation)			Not Reported
	Stilnox			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10527966	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2014M1006954			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor	Quetiapine			S	Oral	300 Mg, Qd		Not Reported
	Paroxetine Hydrochloride			S	Oral	1.5 Df, Qd		Not Reported
	Prazene			S	Oral	1 Df, Qd		Not Reported
	Cipralex /01588501/			S	Oral	1 Df, Qd		Not Reported
	Lasix /00032601/			C	Unknown	Unk		Not Reported
	Foster /06206901/			C	Unknown	Unk		Not Reported
	Stilnox			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10533958	EXPEDITED (15-DAY)		DE	FR-FRI-1000071671		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Peritoneal Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Previscan (Fluindione)			S	Oral			Not Reported
	Bi-Tildiem			C		2 Dosage Forms		Not Reported
	Paracetamol			C				Not Reported
	Uvedose			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10659772	EXPEDITED (15-DAY)		HO	JP-FRI-1000073108		84 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage; Prothrombin Time Prolonged	Lexapro			S	Oral	10 Mg		Forest
	Warfarin			S	Oral	2.25 Mg		Not Reported
	Loxonin			S	Transdermal	50 Mg		Not Reported

Calonal	S	Oral	1200 Mg		Not Reported
Millis	C	Transdermal	5 Mg		Not Reported
Halcion	C	Oral	0.25 Mg		Not Reported
Fosamac 35mg	C	Oral			Not Reported
Maglax	C	Oral	1000 Mg		Not Reported
Pletaal Od	C	Oral	100 Mg		Not Reported
Methycobal	C	Oral	1000 Mcg		Not Reported
Incremin	C		5 Ml		Not Reported
Edirol	C	Oral	0.75 Mcg		Not Reported
Wypax	C	Oral	1 Mg		Not Reported
Lasix	C	Oral	20 Mg		Not Reported
Amlodin	C	Oral	10 Mg		Not Reported
Pariet	C	Oral	10 Mg		Not Reported
Tsumura Bukuryoingohangekobokuto Extract Granules For Ethical Use	C	Oral	5 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10660993	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2014-01824			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Crying; Depressed Mood; Dizziness; Feeling Abnormal; Paraesthesia; Restlessness; Withdrawal Syndrome	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10747080	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2015-001331		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diazepam			S				Not Reported

	Diclofenac	S	Bausch And Lomb
	Promethazine	S	Not Reported
	Verapamil	S	Not Reported
	Escitalopram	S	Not Reported
	Acetaminophen/Hydrocodone	S	Not Reported
	Topiramate	S	Not Reported
	Esomeprazole	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10747141	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00002976		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Chills; Diarrhoea; Migraine; Nausea	Escitalopram Tablets Usp 5mg			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10747773	EXPEDITED (15-DAY)		DE, OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2015SUN00251			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug Interaction	Letrozole Tabs 2.5mg			S	Oral	2.5mg		Sun
	Escitalopram			S	Oral	10mg		Not Reported
	Escitalopram			S	Oral	15 Mg, Unk		Not Reported
	Adcal-D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10748533	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2015US00587			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bradykinesia; Cerebral Disorder; Feeding Disorder; Gait Inability; Insomnia;	Donepezil			S		Unk		Cipla
	Donepezil			S				Cipla
	Escitalopram			S		Unk		Not Reported

Irritability; Muscle Rigidity; Nerve Degeneration; Parkinsonian Crisis; Parkinsonian Gait; Parkinsonian Gait; Tremor	Escitalopram	S			Not Reported
	Haloperidol	S	3.5 Mg, Qd		Not Reported
	Haloperidol	S	17.5 Unk, Unk		Not Reported
	Amisulpride	S	50 Mg, Unk		Not Reported
	Amisulpride	S	Unk		Not Reported
	Mirtazapine	S	15 Mg, Unk		Not Reported
	Mirtazapine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10748714	EXPEDITED (15-DAY)		HO	FR-FRI-1000073970		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemoglobin Decreased; Retroperitoneal Haematoma; Vessel Puncture Site Haematoma	Escitalopram			S	Oral	1 Df		Forest
	Kardegic			S	Oral	1 Df		Not Reported
	Plavix			S	Oral	1 Df		Not Reported
	Tahor			C		1 Df		Not Reported
	Nebivolol			C		1 Df		Not Reported
	Lansoprazole			C		1 Df		Not Reported
	Bipreterax			C		5 Mg/1.25 Mg Daily		Not Reported
	Alprazolam			C		1 Df		Not Reported
	Paracetamol			C				Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			C				Not Reported
	Avamys			C		2 Puffs On Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10748925	EXPEDITED (15-DAY)		HO	FR-FRI-1000073893		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Miosis; Suicide Attempt	Escitalopram			S	Oral	1 Df		Forest
	Escitalopram			S	Oral	Overdose Nos.		Forest

Olmetec	S	Oral	10 Mg		Not Reported
Olmetec	S	Oral	Overdose Nos.		Not Reported
Alprazolam	S	Oral	0.5 Mg		Not Reported
Alprazolam	S	Oral	Overdose Nos.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10750070	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000074015		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Aphonia; Decreased Appetite; Depression; Dyspnoea; Electrocardiogram Qt Prolonged; Insomnia; Irritability; Mania; Muscular Weakness; Nasal Congestion; Nausea; Nicotine Dependence; Thyroid Disorder; Tobacco User; Urinary Tract Infection; Weight Decreased	Lexapro			S		5 Mg		Forest
	Lexapro			S				Forest
	Lexapro			S				Not Reported
	Celexa			S		5 Mg		Forest
	Norvasc			S		2.5 Mg		Not Reported
	Levoxyl			C		125 Mcg		Not Reported
	Cytomel			C		5 Mcg		Not Reported
	Tums			C		One In Afternoon And One Later In Day		Not Reported
	Mylanta			C		1/2 Tsp At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10750164	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2015-001412		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lorazepam			S				Not Reported
	Lamotrigine			S				Not Reported
	Zonisamide			S				Not Reported
	Escitalopram			S				Not Reported
	Lovastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10750178	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2015-001419		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lorazepam			S				Not Reported
	Primidone			S				Not Reported
	Temazepam			S				Not Reported
	Lamotrigine			S				Not Reported
	Escitalopram			S				Not Reported
	Benztropine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10750210	EXPEDITED (15-DAY)		DE, OT	US-BAUSCH-BL-2015-001357		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Unevaluable Event	Nitroglycerin			S				Not Reported
	Diclofenac			S				Not Reported
	Doxycycline			S				Not Reported
	Oxycodone			S				Not Reported
	Cyclobenzaprine			S				Not Reported
	Metoprolol			S				Not Reported
	Clonidine			S				Not Reported
	Lisinopril			S				Not Reported
	Escitalopram			S				Not Reported
	Ibuprofen			S				Not Reported
	Azithromycin			S				Not Reported
	Cephalexin			S				Not Reported
	Methylprednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2015	10753583	DIRECT		OT			18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia	Lexapro			S	Oral	1 Pill Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2015	10750445	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2015-001560		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unevaluable Event	Primidone			S				Not Reported
	Atenolol			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2015	10750455	EXPEDITED (15-DAY)		DE, OT	US-BAUSCH-BL-2015-001402		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Abuse	Lorazepam			S				Not Reported
	Ethanol			S				Not Reported
	Escitalopram			S				Not Reported
	Methocarbamol			S				Not Reported
	Oxycodone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2015	10751958	NON-EXPEDITED			US-ELI_LILLY_AND_COMPANY-US201501005786		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Post-Traumatic Stress Disorder	Prozac			S	Unknown			Unknown
	Lexapro			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2015	10751959	EXPEDITED (15-DAY)		HO	FR-ABBVIE-15P-056-1339280-00		12 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Toxicity To Various Agents; Vomiting	Depakote			S	Oral	Gastro-Resistant		Not Reported

Alprazolam	S	Oral			Not Reported
Tetrazepam	S	Oral			Not Reported
Venlafaxine	S	Oral			Not Reported
Biprofenid	S	Oral	Modified-Release Tablet		Not Reported
Surgam	S	Oral			Not Reported
Seroplex	S	Oral	Film Coated		Not Reported
Diclofenac	S	Oral			Not Reported
Trazepam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2015	10754513	DIRECT					62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Quality Issue; Product Substitution Issue; Product Substitution Issue; Therapy Non-Responder	Escitalopram			S				Bluepoint Laboratories

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2015	10566245	EXPEDITED (15-DAY)		HO	IT-FRI-1000072061		102 DAY	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Vomiting; Wrong Product Administered	Escitalopram Oral Solution			S	Oral	3 Drops		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2015	10722802	EXPEDITED (15-DAY)		DE, OT	GB-ACCORD-028098		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug	Escitalopram			S	Oral			Accord
	Letrozole			S	Oral			Accord

Interaction	Adcal-D3	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2015	10754534	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201500503		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Roxicodone			S	Unknown	Unk		Tyco
	Cyclobenzaprine			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Clonidine			S	Unknown	Unk		Not Reported
	Nitroglycerin			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Cephalexin			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2015	10755776	EXPEDITED (15-DAY)		DE	US-APOTEX-2015AP005668		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Bupropion Hydrochloride			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Gabapentin			S	Oral			Apotex
	Alprazolam Tablets Usp			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2015	10758901	DIRECT		DS			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Amnesia; Confusional State; Depression; Disturbance In Attention; Female Orgasmic Disorder; Impaired Work Ability; Judgement Impaired; Libido Disorder; Tachyphrenia	Lexapro 10 Mg			S		1 Pill		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2015	10570606	EXPEDITED (15-DAY)		HO	IT-FRI-1000072171		91 DAY	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Vomiting; Wrong Product Administered	Escitalopram Oral Solution			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2015	10703941	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20150105117		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Tramadol			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Acetaminophen/Hydrocodone			S	Oral			Not Reported
	Ondansetron			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Liothyronine			S	Oral			Not Reported

Escitalopram	S	Oral	Not Reported
Sertraline	S	Oral	Not Reported
Gabapentin	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2015	10757326	EXPEDITED (15-DAY)		OT	NO-009507513-1501NOR012006		36 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Disturbance In Attention; Dizziness; Headache; Heart Rate Irregular; Hyperhidrosis; Hypersomnia; Memory Impairment; Musculoskeletal Pain; Nausea; Paraesthesia; Paraesthesia; Pyrexia; Restlessness; Somnolence; Tinnitus; Vomiting	Montelukast Sodium			S	Oral	Seasonal		Merck
	Escitalopram			S	Oral	Increased From 10 Mg Daily From 13-Nov-2013		Not Reported
	Seretide Diskus			C	Respiratory (inhalation)	1 Df, Bid		Not Reported
	Panodil			C	Oral	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2015	10759407	EXPEDITED (15-DAY)		DE	US-FRI-1000074206		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Linaclotide			S				Forest
	Escitalopram			S				Forest
	Amitriptyline			S				Not Reported
	Tramadol			S				Not Reported
	Acetaminophen/Hydrocodone			S				Not Reported
	Ondansetron			S				Not Reported
	Diclofenac			S				Not Reported
	Lubiprostone			S				Not Reported
	Zolpidem			S				Not Reported
	Liothyronine			S				Not Reported
	Sertraline			S				Not Reported

	Gabapentin	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2015	10759935	EXPEDITED (15-DAY)		DE	US-PERRIGO-15US000968		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lorazepam Concentrate Rx 2 Mg/Ml 1j9			S	Oral	Unk		Perrigo
	Ethanol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Methocarbamol			S	Oral	Unk		Not Reported
	Oxycodone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2015	10342331	EXPEDITED (15-DAY)		HO	IT-FRI-1000069028		24 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nausea; Withdrawal Syndrome	Escitalopram			S	Oral	10 Unit Dose Per Day		Forest
	Escitalopram			S		1/2 Tablet		Forest
	Escitalopram			S		1 Tablet Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2015	10732592	EXPEDITED (15-DAY)		DE, OT	GB-TEVA-534889ISR		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug Interaction	Escitalopram			S	Oral	10 Increased To 15mg		Ivax
	Escitalopram			S	Oral	10 Increased To 15mg		Ivax
	Letrozole			S	Oral	2.5mg		Teva
	Adcal-D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2015	10744734	EXPEDITED (15-DAY)		DE, OT	GB-ACTAVIS-2015-00705		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug Interaction	Escitalopram (Unknown)			S	Oral	10 Mg, Unknown		Not Reported
	Escitalopram (Unknown)			S	Oral	15 Mg, Unk		Not Reported
	Letrozole (Unknown)			S	Oral	2.5 Mg, Unknown		Actavis Totowa
	Adcal D3			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2015	10747758	EXPEDITED (15-DAY)	Y	DE, OT	FK201500348		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug Interaction	Letrozole			S	Oral			Not Reported
	Escitalopram			S	Oral Oral			Not Reported
	Adcal-D3 (Lekovit Ca)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2015	10760444	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2015AL000265		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lisinopril			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Acetaminophen/Diphenhydramine			S	Oral			Not Reported
	Warfarin			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2015	10760665	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015SUN00282			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alpha-1 Anti-Trypsin Deficiency; Delirium; Hypercapnia; Inappropriate Antidiuretic Hormone Secretion; Mania; Pneumonia Pseudomonal; Toxicity To Various Agents	Alprazolam			S	Unknown			Sun
	Alprazolam			S				Sun
	Olanzapine 10 Mg Tablets			S	Unknown	10 Mg, Daily		Sun
	Olanzapine 10 Mg Tablets			S				Sun
	Prednisone			S	Unknown	10 Mg, Daily		Not Reported
	Prednisone			S		7.5 Mg, Daily		Not Reported
	Prednisone			S		2.5 Mg, Daily		Not Reported
	Prednisone			S		2 Mg, Daily At Home		Not Reported
	Prednisone			S		1 Mg/Day, Unk		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Sertraline			S				Not Reported
	Fluticasone			C	Unknown			Not Reported
	Buspirone			C				Not Reported
	Buspirone			C				Not Reported
	Diltiazem			C				Not Reported
	Esomeprazole			C				Not Reported
	Ipratropium			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2015	10761704	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2015AP005838		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Cardio-Respiratory Arrest	Lisinopril			S				Apotex
	Escitalopram Oxalate			S				Apotex
	Diclofenac Potassium			S				Apotex
	Azithromycin			S				Apotex

	Oxycodone	S			Not Reported
	Cyclobenzaprine	S			Not Reported
	Metoprolol	S			Not Reported
	Nitroglycerin	S			Not Reported
	Ibuprofen	S			Not Reported
	Cephalexin /00145501/	S			Not Reported
	Doxycycline	S			Not Reported
	Methylprednisolone	S			Not Reported
	Clonidine	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2015	10762852	EXPEDITED (15-DAY)		DE, OT	US-ELI_LILLY_AND_COMPANY-US201502000707		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Olanzapine			S	Unknown			Unknown
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Lisinopril			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2015	10762941	EXPEDITED (15-DAY)		DE	US-PERRIGO-15US001164		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Loperamide Hydrochloride 0.2 Mg/Ml 377			S	Oral	Unk, Unk		Perrigo
	Escitalopram			S	Oral	Unk, Unk		Not Reported
	Meloxicam			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2015	10763217	EXPEDITED (15-DAY)		DE, HO, LT	FR-FRI-1000074141		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke	Escitalopram			S	Oral			Forest
	Pentasa			S	Oral	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2015	10763854	EXPEDITED (15-DAY)		DE	US-PERRIGO-15US001193		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lorazepam Concentrate Rx 2 Mg/Ml 1j9			S	Oral	Unknown, Unknown		Perrigo
	Lamotrigine			S	Oral	Unknown, Unknown		Not Reported
	Zonisamide			S	Oral	Unknown, Unknown		Not Reported
	Escitalopram			S	Oral	Unknown, Unknown		Not Reported
	Lovastatin			S	Oral	Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10489986	EXPEDITED (15-DAY)		LT	IE-FRI-1000071180		48 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Psychotic Disorder; Syncope	Escitalopram			S	Oral	10 Mg Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10522400	EXPEDITED (15-DAY)		HO	IT-FRI-1000071489		91 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastric	Escitalopram Oral Solution			S	Oral	20 Mg		Forest

Haemorrhage	Cardirene	S	Oral	160 Mg		Not Reported
	Solosa	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10667558	EXPEDITED (15-DAY)		OT	AU-FRI-1000073201			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Pulmonary Valve Incompetence; Tricuspid Valve Incompetence	Escitalopram			S	Unknown			Forest
	Clozaril			S	Oral			Not Reported
	Clozaril			S	Unknown			Not Reported
	Clozaril			S	Oral			Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Amisulpride			S	Unknown			Not Reported
	Fenofibrate			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Oxazepam			S	Unknown			Not Reported
	Perindopril			S	Unknown			Not Reported
	Thyroxine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10669648	NON-EXPEDITED			US-PFIZER INC-2014352780			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10749404	EXPEDITED (15-DAY)		DE, OT	GB-FRI-1000073936		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Drug Interaction	Escitalopram			S	Oral	10 Mg Daily		Forest
	Escitalopram			S	Oral	15 Mg Daily		Forest
	Letrozole			S	Oral	2.5 Mg Daily		Not Reported
	Adcal-D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10766240	EXPEDITED (15-DAY)		LT	FR-FRI-1000074191		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	1 Df		Forest
	Theralene			S	Oral	10 Df		Not Reported
	Imovane			C				Not Reported
	Mianserine			C				Not Reported
	Movicol			C				Not Reported
	Seresta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10766244	EXPEDITED (15-DAY)		OT	DE-FRI-1000074138		66 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Myalgia; Weight Increased	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10766246	EXPEDITED (15-DAY)		HO	FR-FRI-1000074192		12 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Overdose; Somnolence; Suicide Attempt; Toxicity To Various Agents; Vomiting	Escitalopram	S	Oral	Overdose: 140 Mg In One Intake.	Forest
	Alprazolam	S	Oral	Overdose: 12.25 Mg In One Intake.	Not Reported
	Tetrazepam	S	Oral	Overdose: 1,000 Mg In One Intake.	Not Reported
	Venlafaxine	S	Oral	Overdose: 1,500 Mg In One Intake.	Not Reported
	Depakote	S	Oral	Overdose: 2,000 Mg In One Intake.	Not Reported
	Biprofenid	S	Oral	Overdose: 3,000 Mg In One Intake.	Not Reported
	Diclofenac	S	Oral	Overdose: 3,000 Mg In One Intake.	Not Reported
	Surgam	S	Oral	Overdose: 15 Df Nos In One Intake.	Not Reported
	Trazepam	S	Oral	Overdose: 400 Mg In One Intake.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10767069	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-006843		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Testosterone Decreased; Feeling Abnormal; Mood Swings	Abilify			S	Unknown	Unk		Bristol Myers Squibb
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10767139	EXPEDITED (15-DAY)		DE, OT	US-ELI_LILLY_AND_COMPANY-US201502000757		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Atomoxetine Hydrochloride			S	Unknown			Unknown
	Sertraline			S	Unknown			Not Reported

	Escitalopram	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10961454	EXPEDITED (15-DAY)		DE, HO	US-APOTEX-2015AP005783		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Clonazepam Tablets Usp			S	Oral			Apotex
	Trazodone Hydrochloride			S	Oral			Apotex
	Quetiapine Fumarate			S	Oral			Apotex
	Lamotrigine			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Cardiac Glycosides			S	Oral			Not Reported
	Finasteride			S	Oral			Not Reported
	Salicylates Nos			S				Not Reported
	Oxybutynin Chloride Oral Solution Usp			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10961493	EXPEDITED (15-DAY)		DE	US-APOTEX-2015AP005834		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Abuse	Escitalopram Oxalate			S	Oral			Apotex
	Ethanol			S	Oral			Not Reported
	Methocarbamol			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10961506	EXPEDITED (15-DAY)		DE	US-APOTEX-2015AP005836		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Escitalopram Oxalate		S	Oral	Apotex
	Verapamil Hydrochloride		S	Oral	Apotex
	Topiramate		S	Oral	Apotex
	Diclofenac Potassium		S	Oral	Apotex
	Promethazine		S	Oral	Not Reported
	Acetaminophen W/Hydrocodone		S	Oral	Not Reported
	Diazepam		S	Oral	Not Reported
	Esomeprazole		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10961507	EXPEDITED (15-DAY)		DE, HO	US-APOTEX-2015AP005837		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate			S	Unknown			Apotex
	Atenolol			S	Unknown			Not Reported
	Benzodiazepine Derivatives			S	Unknown			Not Reported
	Primidone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10961508	EXPEDITED (15-DAY)		DE, HO	US-APOTEX-2015AP005839		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral			Apotex
	Meloxicam			S	Oral			Apotex
	Loperamide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10961604	EXPEDITED (15-DAY)		DE	US-APOTEX-2015AP005943		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aspiration; Completed Suicide; Exposure Via Ingestion	Lamotrigine	S	Unk		Apotex
	Zonisamide	S	Unk		Apotex
	Escitalopram Oxalate	S			Apotex
	Lovastatin Tablets Usp	S	Unk		Apotex
	Lorazepam	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10962902	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2015AP005947		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Temazepam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Primidone			S	Oral			Not Reported
	Benztropine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10962994	EXPEDITED (15-DAY)		DE	US-APOTEX-2015AP006006		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Olanzapine			S	Oral			Apotex
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Oral			Not Reported
	Warfarin			S				Not Reported
	Lisinopril			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10963091	EXPEDITED (15-DAY)		DE	US-APOTEX-2015AP006080		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Sertraline Hydrochloride			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Atomoxetine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10963160	EXPEDITED (15-DAY)		DE, HO	US-APOTEX-2015AP006141		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Tramadol Hydrochloride			S				Apotex
	Tramadol Hydrochloride			S				Apotex
	Escitalopram Oxalate			S				Apotex
	Gabapentin			S				Apotex
	Ondansetron Hydrochloride			S				Apotex
	Sertraline Hydrochloride			S				Apotex
	Zolpidem Tartrate			S				Apotex
	Amitriptyline			S				Not Reported
	Acetaminophen W/Hydrocodone			S				Not Reported
	Linaclotide			S				Not Reported
	Diclofenac			S				Not Reported
	Lubiprostone			S				Not Reported
	Liothyronine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10963240	EXPEDITED (15-DAY)		DE, HO	US-APOTEX-2015AP006196		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil Hydrochloride			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Topiramate			S	Oral			Apotex
	Codeine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2015	10963281	EXPEDITED (15-DAY)		DE	US-APOTEX-2015AP006235		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zolpidem Tartrate			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Ethanol			S				Not Reported
	Carbon Monoxide			S				Not Reported
	Methamphetamine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2015	10769462	EXPEDITED (15-DAY)		DE, OT	US-ELI_LILLY_AND_COMPANY-US201502000747		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Cephalexin Hydrochloride			S	Unknown			Unknown
	Oxycodone			S				Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Clonidine			S	Unknown			Not Reported
	Nitroglycerin			S	Unknown			Not Reported
	Lisinopril			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2015	10769497	EXPEDITED (15-DAY)		DE	US-PERRIGO-15US001376		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Lorazepam Concentrate Rx 2 Mg/Ml 1j9			S	Oral	Unknown, Unknown		Perrigo

	Temazepam	S	Oral	Unknown, Unknown	Not Reported
	Primidone	S	Oral	Unknown, Unknown	Not Reported
	Lamotrigine	S	Oral	Unknown, Unknown	Not Reported
	Escitalopram	S	Oral	Unknown, Unknown	Not Reported
	Benztropine	S	Oral	Unknown, Unknown	Not Reported
	Lipid Modifying Agents, Combinations	S	Oral	Unknown, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2015	10769876	EXPEDITED (15-DAY)		DE	US-PERRIGO-15US001241		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Ibuprofen 200 Mg 604			S	Unknown	Unknown, Unknown		Perrigo
	Nitroglycerin Rx 400 Mcg/Spray 8a5			S	Unknown	Unknown, Unknown		Perrigo
	Oxycodone			S	Unknown	Unknown, Unknown		Not Reported
	Cyclobenzaprine			S	Unknown	Unknown, Unknown		Not Reported
	Metoprolol			S	Unknown	Unknown, Unknown		Not Reported
	Clonidine			S	Unknown			Not Reported
	Lisinopril			S	Unknown	Unknown, Unknown		Not Reported
	Escitalopram			S	Unknown	Unknown, Unknown		Not Reported
	Diclofenac			S	Unknown	Unknown, Unknown		Not Reported
	Azithromycin			S	Unknown	Unknown, Unknown		Not Reported
	Cephalexin /00145501/			S	Unknown	Unknown, Unknown		Not Reported
	Doxycycline			S	Unknown	Unknown, Unknown		Not Reported
	Methylprednisolone			S	Unknown	Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2015	10771166	NON-EXPEDITED			US-ACORDA-ACO_104272_2014			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia	Ampyra	S	Unknown	10 Mg, Q 12 Hrs		Acorda
	Lexapro	S	Unknown			Not Reported
	Zoloft	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2015	10771526	EXPEDITED (15-DAY)		OT	US-ACTAVIS-2015-01217		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acanthosis Nigricans; Amenorrhoea; Weight Increased	Aripiprazole (Unknown)			S	Unknown	20 Mg, Unknown		Not Reported
	Aripiprazole (Unknown)			S	Unknown	15 Mg, Unknown		Not Reported
	Bupropion Hydrochloride (Actavis Laboratories Fl)			S	Unknown	100 Mg, Daily		Actavis
	Bupropion Hydrochloride (Actavis Laboratories Fl)			S				Actavis
	Escitalopram (Unknown)			S	Unknown	Unk		Not Reported
	Escitalopram (Unknown)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2015	10772379	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00102		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen/Diphenhydramine			S	Oral			Not Reported
	Warfarin			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2015	10772422	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00114		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Oxycodone			S				Not Reported
	Cyclobenzaprine			S				Not Reported
	Metoprolol			S				Not Reported
	Clonidine			S				Not Reported
	Nitroglycerin			S				Not Reported
	Lisinopril			S				Not Reported
	Escitalopram			S				Not Reported
	Ibuprofen			S				Not Reported
	Diclofenac			S				Not Reported
	Azithromycin			S				Not Reported
	Cephalexin			S				Not Reported
	Doxycycline			S				Not Reported
	Methylprednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2015	10772445	NON-EXPEDITED			US-ACORDA-ACO_105650_2014		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Gastrointestinal Disorder	Ampyra			S	Oral	10 Mg, Bid		Acorda
	Ampyra			S				Acorda
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Coq10			S	Oral	Unk		Not Reported
	Concerta			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10432127	EXPEDITED (15-DAY)		LT	FR-BRISTOL-MYERS SQUIBB COMPANY-21343223		52 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia; Atrial Fibrillation; Bacteraemia; Gastrointestinal Haemorrhage; Hypotension;	Coumadin			S	Oral	Last Dose On: 11aug14.		Bristol Myers Squibb
	Seroplex			S	Oral	Last Dose On: 11aug14.		Not Reported
	Efferalgan			C	Unknown			Bristol Myers Squibb
	Tramadol			C	Unknown			Not Reported

Hypothermia; International Normalised Ratio Increased; Ischaemic Hepatitis; Muscle Haemorrhage; Oedema Peripheral	Nasacor T	C	Unknown	Not Reported
	Seresta	C	Unknown	Not Reported
	Mopral	C	Unknown	Not Reported
	Arixtra	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10731660	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2015SCPR010195		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Zolpidem Tartrate Er			S		Unk, Unknown, Ingst+ Inhal		Par
	Ethanol			S		Unk, Unknown, Ingst+ Inhal		Not Reported
	Methamphetamine			S		Unk, Unknown, Ingst+ Inhal		Not Reported
	Carbon Monoxide			S		Unk, Unknown, Ingst+ Inhal		Not Reported
	Escitaopram			S		Unk, Unknown, Ingst+ Inhal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10774379	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00158		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lamotrigine			S				Not Reported
	Zonisamide			S				Not Reported
	Lorazepam			S				Not Reported
	Escitalopram			S				Not Reported
	Lovastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10774403	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS		34 YR	Female	USA

INC.-2015-00166

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amitriptyline			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Acetaminophen/Hydrocodone			S	Oral			Not Reported
	Ondansetron			S	Oral			Not Reported
	Linaclotide			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Lubiprostone			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Liothyronine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Sertraline			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10774410	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00170		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Sertraline			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Atomoxetine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10775790	EXPEDITED (15-DAY)		OT	NO-TEVA-538947ISR		37 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Febrile Neutrophilic Dermatosis	Escitalopram	S		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10777239	EXPEDITED (15-DAY)		DE	US-FRI-1000074240		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Abuse	Escitalopram			S				Forest
	Ethanol			S				Not Reported
	Metocarbamol			S				Not Reported
	Oxycodone			S				Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10777241	EXPEDITED (15-DAY)		DE	US-FRI-1000074253		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S				Forest
	Atenolol			S				Not Reported
	Benzodiazepine			S				Not Reported
	Primidone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10777243	EXPEDITED (15-DAY)		DE	US-FRI-1000074250		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S				Forest
	Sertraline			S				Not Reported
	Atomoxetine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10777248	EXPEDITED (15-DAY)		DE	US-FRI-1000074246		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest;	Escitalopram			S				Forest

Death	Oxycodone	S	Not Reported
	Cyclobenzaprine	S	Not Reported
	Metoprolol	S	Not Reported
	Clonidine	S	Not Reported
	Nitroglycerin	S	Not Reported
	Lisinopril	S	Not Reported
	Ibuprofen	S	Not Reported
	Diclofenac	S	Not Reported
	Azithromycin	S	Not Reported
	Cephalexin	S	Not Reported
	Doxycycline	S	Not Reported
	Methylprednisolone	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10777251	EXPEDITED (15-DAY)		DE	US-FRI-1000074248		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram			S				Forest
	Bupropion			S				Not Reported
	Gabapentin			S				Not Reported
	Alprazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2015	10779635	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Product Effect Decreased	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10512072	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000071385			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Accidental Overdose; Anxiety; Asthenia; Balance	Escitalopram			S		Overdose: Unknown Dose (Frequency Not Reported.)		Forest
	Clobazam			S				Not Reported

Disorder; Dizziness; Dyspnoea; Faeces Soft; Gait Inability; Genital Herpes; Malignant Neoplasm Progression; Mobility Decreased; Oral Herpes	Avastin	S	Intravenous (not otherwise specified)	Overdose: 680 Mg	Not Reported
	Avastin	S	Intravenous (not otherwise specified)	Overdose: 800 Mg	Not Reported
	Avastin	S	Intravenous (not otherwise specified)	Overdose: 850 Mg	Not Reported
	Rosuvastatin Calcium	S		Overdose: Unknown Dose	Not Reported
	Trazodone	S		Overdose: Unknown Dose	Not Reported
	Avodart	C			Not Reported
	Dexamethasone	C		Daily Dose Not Reported.	Not Reported
	Docusate	C		Daily Dose Not Reported.	Not Reported
	Keppra	C		Daily Dose Not Reported.	Not Reported
	Pantoprazole	C		Daily Dose Not Reported.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10512205	EXPEDITED (15-DAY)		HO	CA-FRI-1000071390			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Qrs Axis Abnormal; Sinus Tachycardia	Escitalopram			S		20 Mg		Forest
	Apo-Clozapine			S		450 Mg		Not Reported
	Haloperidol			S		5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10514654	EXPEDITED (15-DAY)		DS	CA-FRI-1000071384		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Off Label Use	Escitalopram			S	Oral			Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10514656	EXPEDITED (15-DAY)		LT	CA-FRI-1000071386		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Diarrhoea; Muscular Weakness; Nausea; Oxygen Saturation Decreased; Polyuria; Product Use In Unapproved Indication; Tremor; Vomiting	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S				Forest
	Apo Furosemide			C		40 Mg		Not Reported
	Apo Alpraz			C		3 Mg		Not Reported
	Euro K 20			C		1500 Mg		Not Reported
	Pms_Lisinopril			C		10 Mg		Not Reported
	Wellbutrin			C		300 Mg		Not Reported
	Lowpin			C		80 Mg		Not Reported
	Apo-Lansopraz			C		30 Mg		Not Reported
	Bricanyl			C		Daily Dose Not Reported		Not Reported
	Symbicort			C		Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10516407	EXPEDITED (15-DAY)		OT	CA-FRI-1000071392		19 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Generalised Tonic-Clonic Seizure; Product Use In Unapproved Indication; Simple Partial Seizures	Escitalopram			S	Oral	20 Mg		Forest
	Alysena 28			S	Oral	100/20 Mcg		Not Reported
	Lamotrigine			S	Oral	350 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10531795	EXPEDITED (15-DAY)		OT	JP-FRI-1000071522			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion; Pregnancy	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Lexotan			S	Oral	5 Mg		Not Reported
	Solanax			S	Oral	0.4 Mg		Not Reported

Solanax	S	Oral	1.2 Mg		Not Reported
Halcion	C	Oral	0.25 Mg		Not Reported
Seroquel	C	Oral	100 Mg		Not Reported
Seroquel	C	Oral	75 Mg		Not Reported
Seroquel	C	Oral	100 Mg		Not Reported
Silece	C	Oral	2 Mg		Not Reported
Landsen	C	Oral	3 Mg		Not Reported
Landsen	C	Oral	3 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10778570	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00259		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Loperamide			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Meloxicam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10778623	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00187		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Promethazine			S	Oral			Not Reported
	Verapamil			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Acetaminophen/Hydrocodone			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Topiramate			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10778975	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00247		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Atenolol			S	Unknown			Not Reported
	Benzodiazepine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Primidone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10779789	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-A0835418A		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Interaction; Fatigue; Feeling Abnormal; Nausea; Vomiting	Treximet Tablet			S	Oral	85/500 Mg. Single Dose.	1 DAY	Glaxosmithkline
	Treximet Tablet			S				Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10782133	EXPEDITED (15-DAY)		OT	GB-TEVA-517209ISR		152 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Insomnia	Escitalopram			S	Transmammary			Ivax
	Escitalopram			S	Transmammary	20 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10782796	EXPEDITED (15-DAY)		HO, LT	CA-FRI-1000071387		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Prescribed Overdose; Pulmonary Embolism	Escitalopram	S	Oral	10 Mg	Forest
	Escitalopram	S	Oral	20 Mg	Forest
	Escitalopram	S	Oral	Overdose: Escitalopram 30 Mg Daily	Forest
	Remeron	S	Oral	30 Mg	Not Reported
	Remeron	S	Oral	45 Mg	Not Reported
	Remeron	S	Oral	15 Mg	Not Reported
	Abilify	C		5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10782997	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-A1081750A			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Proventil Inhaler Inhalational Powder			S	Unknown			Glaxosmithkline
	Zoloft			S	Unknown			Glaxosmithkline
	Fluoxetine			S	Unknown			Glaxosmithkline
	Quetiapine Fumarate			S	Unknown			Glaxosmithkline
	Sertraline Hcl Tablet			S	Unknown			Glaxosmithkline
	Escitalopram Oxalate			S	Unknown			Glaxosmithkline
	Methadone			S	Unknown			Glaxosmithkline
	Morphine			S	Unknown			Glaxosmithkline
	Lidoderm			S	Unknown			Glaxosmithkline
	Spiriva			C				Not Reported
	Ventolin			C				Not Reported
	Tudorza			C				Not Reported
	Lexapro			C				Not Reported
	Viibryd			C				Not Reported
	Amitriptyline			C				Not Reported
	Fentanyl			C				Not Reported
	Oxycodone			C				Not Reported
	Avinza			C				Not Reported
	Trazodone			C				Not Reported

	Seroquel			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2015	10783672	EXPEDITED (15-DAY)		OT	DE-FRI-1000074405		71 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Intraocular Pressure Increased	Escitalopram			S	Oral			Forest
	Quetiapine			S	Unknown			Not Reported
	Tebonin			S	Unknown	240 Mg		Not Reported
	Euthyrox			C	Unknown	100 Mcg		Not Reported
	Ibuprofen			C	Unknown	1200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2015	10720029	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2015SCPR009604		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Lamotrigine			S		Unk, Unknown, Ingst+ Aspir		Par
	Zonisamide			S		Unk, Unknown, Ingst+ Aspir		Not Reported
	Lorazepam			S		Unk, Unknown, Ingst+ Aspir		Not Reported
	Escitalopram			S		Unk, Unknown, Ingst+ Aspir		Not Reported
	Lovastatin			S		Unk, Unknown, Ingst+ Aspir		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2015	10720441	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2015SCPR009609		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Death	Lamotrigine		S	Oral	Unk, Unknown	Par
	Temazepam		S	Oral	Unk, Unknown	Not Reported
	Lorazepam		S	Oral	Unk, Unknown	Not Reported
	Primidone		S	Oral	Unk, Unknown	Not Reported
	Escitalopram		S	Oral	Unk, Unknown	Not Reported
	Benztropine		S	Oral	Unk, Unknown	Not Reported
	Antihyperlipidemic		S	Oral	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2015	10722282	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2015SCPR009627		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Death; Toxicity To Various Agents	Clonidine			S		Unk, Unknown, Ingst+ Inhal		Par
	Ibuprofen			S		Unk, Unknown, Ingst+ Inhal		Par
	Doxycycline			S		Unk, Unknown, Ingst+ Inhal		Par
	Oxycodone			S		Unk, Unknown, Ingst+ Inhal		Not Reported
	Cyclobenzaprine			S		Unk, Unknown, Ingst+ Inhal		Not Reported
	Metoprolol			S		Unk, Unknown, Ingst+ Inhal		Not Reported
	Nitroglycerin			S		Unk, Unknown, Ingst+ Inhal		Not Reported
	Lisinopril			S		Unk, Unknown, Ingst+ Inhal		Not Reported
	Escitalopram			S		Unk, Unknown, Ingst+ Inhal		Not Reported
	Diclofenac			S		Unk, Unknown, Ingst+ Inhal		Not Reported

Azithromycin	S	Unk, Unknown, Ingst+ Inhal	Not Reported
Cephalexin /00145501/	S	Unk, Unknown, Ingst+ Inhal	Not Reported
Methylprednisolone	S	Unk, Unknown, Ingst+ Inhal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2015	10770819	EXPEDITED (15-DAY)		HO	IT-FRI-1000074099		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Escitalopram			S	Oral	10 Mg Daily		Forest
	Xanax			S	Oral	10 Drops Daily		Not Reported
	Metformine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2015	10784144	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00295		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Zolpidem			S	Oral			Not Reported
	Methamphetamine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2015	10784203	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00316		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Temazepam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Primidone			S	Oral			Not Reported

	Lamotrigine	S	Oral		Not Reported
	Escitalopram	S	Oral		Not Reported
	Benztropine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2015	10784263	EXPEDITED (15-DAY)		HO	CA-ROCHE-1536061		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Clonazepam			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Domperidone			S	Oral			Not Reported
	Ferrous Sulphate			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Temazepam			S	Oral			Not Reported
	Tylenol With Codeine			S	Oral			Not Reported
	Wellbutrin Xl			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2015	10784453	EXPEDITED (15-DAY)		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00050		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S	Oral			Not Reported
	Methocarbamol			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2015	10785752	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1002716			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Restlessness; Sleep Disorder	Escitalopram Oxalate			S		Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2015	10786351	EXPEDITED (15-DAY)		HO	CN-FRI-1000074354			Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Melaena; Upper Gastrointestinal Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Marcoumar			S	Oral			Not Reported
	Humalog			C				Not Reported
	Atorvastatin			C				Not Reported
	Beloc-Zok			C				Not Reported
	Spasmo-Canulase			C				Not Reported
	Stilnox			C				Not Reported
	Amlodipin			C				Not Reported
	Torem			C				Not Reported
	Esomep			C				Not Reported
	Kinzalplus			C				Not Reported
	Novalgine (Metamizole Sodium)			C				Not Reported
	Berocca Ca Mg			C				Not Reported
	Vi De3			C				Not Reported
	Paragol N			C				Not Reported
	Palladon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2015	10786683	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201500700		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen\Hydrocodone Bitartrate			S	Oral	Unk		Mallinckrodt
	Promethazine			S	Oral	Unk		Not Reported
	Verapamil			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

	Diazepam	S	Oral		Not Reported
	Topiramate	S	Oral		Not Reported
	Esomeprazole	S	Oral		Not Reported
	Diclofenac	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2015	10723238	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2015SCPR010142		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Olanzapine			S	Oral	Unk, Unknown		Par
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Oral	Unk, Unknown		Not Reported
	Warfarin			S	Oral	Unk, Unknown		Not Reported
	Lisinopril			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Prednisone /00044702/			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2015	10789564	EXPEDITED (15-DAY)		OT	NO-FRI-1000074391			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Delusion; Depression; Mania; Substance-Induced Psychotic Disorder; Suicidal Ideation	Escitalopram			S	Unknown			Forest
	Lamicta			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2015	9610901	EXPEDITED (15-DAY)		HO	FR-FRI-1000049829		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Neutropenia	Escitalopram		S	Oral		Forest
	Zyprexa		S	Oral	1 Df	Not Reported
	Lorazepam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2015	10792064	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201500738		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Temazepam			S	Oral	Unk		Tyco
	Lorazepam			S	Oral	Unk		Not Reported
	Primidone			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral			Not Reported
	Benztropine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2015	10792545	EXPEDITED (15-DAY)		HO	FR-FRI-1000074458		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Intentional Overdose	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	Overdose 280 Mg Once.		Forest
	Seresta			S	Oral	20 To 30 Mg		Not Reported
	Seresta			S	Oral	Overdose 600 Mg Once.		Not Reported
	Ethanol			S	Oral	Anise-Flavored Spirit, Half Bottle Of Gin And Wine		Not Reported
	Aotal			C	Oral	1998 Mg		Not Reported
	Aotal			C	Oral	Overdose: 6,660 Mg Once.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2015	10793374	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-01172		152 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Insomnia	Escitalopram Tablets			S	Transmammary	10 Mg, Once A Day		Aurobindo
	Escitalopram Tablets			S	Transmammary	20 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2015	10793491	EXPEDITED (15-DAY)		DE	CHPA2015US001885		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen, Diphenhydramine Citrate		Y	S	Oral	Unk		Novartis
	Warfarin			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2015	10794882	EXPEDITED (15-DAY)		DE	IT-FRI-1000074548			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oral Solution			S	Oral	5 Mg		Forest
	Escitalopram Oral Solution			S				Forest
	Minias			C	Oral	3 Dosage Forms		Not Reported
	Minias			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2015	10795539	EXPEDITED (15-DAY)		DE	US-WATSON-2015-01981		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Abuse; Drug Abuse; Toxicity To Various Agents	Oxycodone Hydrochloride (Aellc)			S	Oral	Unknown		Watson
	Lorazepam (Watson			S	Oral	Unk		Watson

	Laboratories)					
	Escitalopram (Unknown)	S	Oral	Unk		Not Reported
	Methocarbamol (Watson Laboratories)	S	Oral	Unk		Watson
	Ethanol	S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2015	10795724	EXPEDITED (15-DAY)		DE	US-WATSON-2015-02654		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Warfarin (Unknown)			S	Oral	Unk		Not Reported
	Olanzapine (Unknown)			S	Oral	Unk		Not Reported
	Lisinopril (Watson Laboratories)			S	Oral	Unk		Watson
	Escitalopram (Unknown)			S	Oral	Unk		Not Reported
	Prednisone (Watson Laboratories)			S	Oral	Unk		Watson
	Diphenhydramine Citrate W/Paracetamol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2015	10740509	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2015SCPR009642		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Verapamil			S	Oral	Unk, Unknown		Par
	Diazepam			S	Oral	Unk, Unknown		Par
	Promethazine			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Acetaminophen/Hydrocodone			S	Oral	Unk, Unknown		Not Reported
	Topiramate			S	Oral	Unk, Unknown		Not Reported
	Esomeprazole			S	Oral	Unk, Unknown		Not Reported
	Diclofenac			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2015	10740592	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2015SCPR009652		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Verapamil			S	Oral	Unk, Unknown		Par
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Codeine			S	Oral	Unk, Unknown		Not Reported
	Topiramate			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2015	10743566	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2015SCPR009684		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Death	Bupropion Hcl Xl			S	Oral	Unk, Unknown		Par
	Alprazolam			S	Oral	Unk, Unknown		Par
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Gabapentin			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2015	10750379	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2015SCPR010075		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Death	Tramadol			S	Oral	Unk, Unknown		Par
	Ondansetron			S	Oral	Unk, Unknown		Par
	Zolpidem Tartrate Er			S	Oral	Unk, Unknown		Par
	Amitriptyline			S	Oral	Unk, Unknown		Not Reported
	Acetaminophen/Hydrocodone			S	Oral	Unk, Unknown		Not Reported
	Linaclotide			S	Oral	Unk, Unknown		Not Reported

	Diclofenac	S	Oral	Unk, Unknown	Not Reported
	Lubiprostone	S	Oral	Unk, Unknown	Not Reported
	Liothyronine	S	Oral	Unk, Unknown	Not Reported
	Escitalopram	S	Oral	Unk, Unknown	Not Reported
	Sertraline	S	Oral	Unk, Unknown	Not Reported
	Gabapentin	S	Oral	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2015	10796137	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2015001598			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Maternal Exposure During Breast Feeding	Escitalopram			S	Transmammary	10 Mg, Qd		Macleods
	Escitalopram			S		20 Mg, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2015	10800694	EXPEDITED (15-DAY)		DE	US-WATSON-2015-02937		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Exposure Via Ingestion; Exposure Via Inhalation; Respiratory Arrest; Toxicity To Various Agents	Oxycodone Hydrochloride (Aellc)			S	Unknown	Unk		Watson
	Cyclobenzaprine Hydrochloride (Actavis Laboratories Fl)			S	Unknown	Unk		Actavis
	Metoprolol (Watson Laboratories)			S	Unknown	Unk		Watson
	Clonidine (Watson Laboratories)			S	Unknown	Unk		Watson
	Lisinopril (Watson Laboratories)			S	Unknown	Unk		Watson
	Escitalopram (Unknown)			S	Unknown	Unk		Not Reported
	Ibuprofen (Amallc)			S	Unknown	Unk		Actavis Mid Atlantic
	Diclofenac Sodium (Aellc)			S	Unknown	Unk		Watson
	Azithromycin (Unknown)			S	Unknown	Unk		Not Reported
	Cephalexin (Unknown)			S	Unknown	Unk		Not Reported

	Doxycycline (Watson Laboratories)	S	Unknown	Unk	Watson
	Methylprednisolone (Watson Laboratories)	S	Unknown	Unk	Watson
	Nitroglycerine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2015	10801414	EXPEDITED (15-DAY)		HO	CH-ACCORD-028657		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Imprisonment; Mania	Tramadol/Tramadol Hydrochloride			S		50 Mg Of Tramadol Twice A Day Was Prescribed		Accord
	Escitalopram			S				Accord
	Alfuzosin			C				Not Reported
	Metformin			C				Not Reported
	Zolpidem			C				Not Reported
	Cannabis Sativa			S				Not Reported
	Alprazolam			C				Not Reported
	Triamcinolone			S	Intramuscular	2 Im Injections Of 40 Mg Of Triamcinolone 1 Month Apart		Not Reported
	Ibuprofen			C				Not Reported
	Quetiapine/Quetiapine Fumarate			C		Increased Progressively Up To 1000 Mg/D		Not Reported
	Oxazepam			C		Increased Progressively Oxazepam Up To 180 Mg/D		Not Reported
	Paracetamol			C				Not Reported
	Baclofen			C				Not Reported
	Atorvastatin			C				Not Reported
	Trospium/Trospium Chloride			C				Not Reported
	Candesartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2015	10805748	NON-EXPEDITED			US-ABBVIE-14K-163-1246266-00		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Drug Ineffective	Humira	S	Not Reported
	Prozac	S	Not Reported
	Lexapro	S	Not Reported
	Trazodone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2015	10727279	EXPEDITED (15-DAY)		DE	FR-FRI-1000073733		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Aphasia; Cerebral Haematoma; Cerebral Haemorrhage; Cerebrovascular Accident; Epilepsy; Language Disorder	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg		Not Reported
	Esomeprazole			C	Oral	20 Mg		Not Reported
	Cordarone			C	Oral	50 Mg		Not Reported
	Furosemide			C	Oral	20 Mg		Not Reported
	Allopurinol			C	Oral	1 Dosage Form		Not Reported
	Stilnox			C	Oral	10 Mg		Not Reported
	Combodart 0.5 Mg/ 0.4 Mg			C	Oral	1 Dosage From		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2015	10792601	EXPEDITED (15-DAY)		DE, OT	CHPA2015US002022		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Diclofenac			S	Oral	Unk		Novartis
	Amitriptyline			S	Oral	Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Acetaminophen W/Hydrocodone			S	Oral	Unk		Not Reported
	Ondansetron			S	Oral	Unk		Not Reported
	Linaclotide			S	Oral	Unk		Not Reported
	Lubiprostone			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported

	Liothyronine	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Sertraline	S	Oral	Unk		Not Reported
	Gabapentin	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2015	10794257	EXPEDITED (15-DAY)		DE, OT	CHPA2015US001920		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Intentional Product Misuse	Diclofenac			S	Unknown	Unk		Novartis
	Ibuprofen			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Cyclobenzaprine			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Clonidine			S	Unknown	Unk		Not Reported
	Nitroglycerin			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Cephalexin			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2015	10816406	EXPEDITED (15-DAY)		DE, OT	US-009507513-1502USA006421		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Product Use Issue	Oxytrol For Women			S	Oral	Unk, Unknown		Merck
	Clonazepam			S	Oral	Unk, Unknown		Not Reported
	Trazodone Hydrochloride			S	Oral	Unk, Unknown		Not Reported

Quetiapine Fumarate	S	Oral	Unk, Unknown		Not Reported
Lamotrigine	S	Oral	Unk, Unknown		Not Reported
Escitalopram	S	Oral	Unk, Unknown		Not Reported
Finasteride	S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2015	10818509	EXPEDITED (15-DAY)		OT	FR-FRI-1000074581		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram			S	Oral	1 Dosage Form		Forest
	Erivedge			S	Oral	1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2015	10838004	EXPEDITED (15-DAY)	Y	OT	US-TORRENT-00000872		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Impaired Work Ability	Escitalopram			S		10mg Twice Da Day (Am An Pm)		Not Reported
	Lamictal (Lamotrigine)			C				Not Reported
	Clonazepam			C				Not Reported
	Furosemide			C				Not Reported
	Fexofenadine			C				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2015	10853501	EXPEDITED (15-DAY)		DE	NSR_01854_2015		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning	Atenolol			S	Oral	Df		Not Reported
	Benzodiazepine Related Drugs			S		Df		Not Reported
	Escitalopram			S		Df		Not Reported
	Primidone			S		(Df)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2015	10855442	DIRECT		OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Depression; Drug Ineffective; Product Substitution Issue; Self-Injurious Ideation	Lexapro			S	Oral	1 Pill	5 YR	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2015	10855677	DIRECT		LT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger	Escitalopram			S	Oral	1		Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2015	10855957	DIRECT		LT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Increased	Lexapro 20mg - Generic			S	Oral		9 MTH	Not Reported
	Xanax			C				Not Reported
	Percocet			C				Not Reported
	Adderall			C				Not Reported
	Effexor			C				Not Reported
	Vitamin C-B-D			C				Not Reported
	Citrucel			C				Not Reported
	Oscal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10562974	EXPEDITED (15-DAY)		HO	IT-FRI-1000071982		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Mydriasis;	Escitalopram Oral Solution			S	Oral			Forest

Sopor	En		S	Oral	Form Strength 1mg/Ml	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10591588	EXPEDITED (15-DAY)		DS	FR-FRI-1000072493		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage; Retinal Vein Thrombosis	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Lexomil			C	Oral			Not Reported
	Xanax			C	Oral			Not Reported
	Esberiven Fort			C	Oral			Not Reported
	Nurofenflash			C	Oral			Not Reported
	Doliprane			C	Oral	1 Gram		Not Reported
	Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10627562	EXPEDITED (15-DAY)		HO	IT-MERCK-1412ITA001286		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Drug Abuse; Sopor	Mirtazapine			S	Oral	600 Mg, Frequency Total		Merck
	Periactin Tablets			S	Oral	10 Df, Frequency Total		Not Reported
	Cipralex			S	Oral	14 Df, Frequency Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10792597	EXPEDITED (15-DAY)		DE	CHPA2015US002063		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diclofenac			S	Oral	Unk		Novartis
	Promethazine			S	Oral			Not Reported

Verapamil	S	Oral		Not Reported
Escitalopram	S	Oral		Not Reported
Hydrocodone/Apap	S	Oral		Not Reported
Diazepam	S	Oral		Not Reported
Topiramate	S	Oral		Not Reported
Esomeprazole	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10828646	NON-EXPEDITED			US-TARO-2015TAR00064		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram Oral Solution			S	Oral	2 Ml, 1x/Day		Taro
	Escitalopram Oral Solution			S				Taro

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10828650	NON-EXPEDITED			US-TARO-2015TAR00100			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oral Solution			S				Taro

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10831755	NON-EXPEDITED			US-ABBVIE-14P-163-1195142-00		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Pruritus; Rash Papular	Humira			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Unknown Lotion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10832054	EXPEDITED (15-DAY)		HO	US-GLAXOSMITHKLINE INC.-		48 YR	Female	USA

US2015GSK020027

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dysarthria; Headache; Hypertension; Hypokalaemia; Mental Status Changes; Multiple Drug Therapy	Fluticasone			S	Nasal	2 Df, Qd		Glaxosmithkline
	Desvenlafaxine Extended Release			S	Oral	Unk, Qd		Not Reported
	Lyrica			S		75 Mg, Qd		Not Reported
	Ibuprofen			S	Oral	800 Mg, Tid		Not Reported
	Loratadine			S	Oral	10 Mg, Qd		Not Reported
	Robaxin			S	Oral	750 Mg, Tid		Not Reported
	Clonazepam			S	Oral	1 Mg, Bid		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Abilify			S	Oral	15 Mg, Unk		Not Reported
	Vicodin			S	Oral	Unk, Prn		Not Reported
	Zestoretic			S	Oral	Unk, Qd		Not Reported
	Ambien			S	Oral	Unk		Not Reported
	Vivelle			S	Transdermal	0.1 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10832695	NON-EXPEDITED		OT	US-ABBVIE-14P-163-1196138-00		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Depressed Mood; Drug Ineffective; Drug Ineffective; Frequent Bowel Movements	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Lexapro			S				Not Reported
	Lipitor			C				Not Reported
	Toprol Xl			C				Not Reported
	Microzide			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

Imodium	C	4-6 Tabs Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10833531	EXPEDITED (15-DAY)		HO	US-FRI-1000074413		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Hypertension; Hypokalaemia; Mental Status Changes; Off Label Use	Lexapro			S	Oral	20 Mg		Forest
	Lexapro			S				Forest
	Ibuprofen			S	Oral	2400 Mg		Not Reported
	Ambien			S	Oral	10 Mg		Not Reported
	Vicodin			S	Oral	5/500 Prn		Not Reported
	Abilify			S	Oral	30 Mg		Not Reported
	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Lyrica			S	Oral	75 Mg		Not Reported
	Lyrica			S				Not Reported
	Clonazepam			S	Oral	2 Mg		Not Reported
	Clonazepam			S				Not Reported
	Robaxin			S	Oral	2250 Mg		Not Reported
	Robaxin			S				Not Reported
	Robaxin			S				Not Reported
	Zestoretic			S	Oral	20/12.5		Not Reported
	Fluticasone			S	Nasal	2 Df		Not Reported
	Loratadine			S	Oral	10 Mg		Not Reported
	Desvenlafaxine			S	Oral	50 Mg		Not Reported
	Desvenlafaxine			S	Oral	100 Mg		Not Reported
	Desvenlafaxine			S	Oral	100 Mg		Not Reported
	Desvenlafaxine			S	Oral	50 Mg		Not Reported
	Desvenlafaxine			S	Oral	25 Mg		Not Reported
	Vivelle			S	Transdermal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10834058	EXPEDITED (15-DAY)		HO	FR-FRI-1000074609		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Intentional Overdose; Malaise; Seizure; Suicide Attempt; Tetany; Torsade De Pointes; Toxicity To Various Agents; Ventricular Fibrillation	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	Escitalopram Overdose Nos.		Forest
	Xanax			S	Oral	0.25 Mg		Not Reported
	Xanax			S	Oral	Alprazolam Overdose Nos.		Not Reported
	Imovane			C		7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10834060	EXPEDITED (15-DAY)		HO	TW-FRI-1000074612		68 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Mania; Therapeutic Product Effect Incomplete	Escitalopram			S	Oral	10 Mg		Forest
	Estazolam			C	Unknown	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10861526	EXPEDITED (15-DAY)	Y	DE	DEP_02506_2015		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion	Diclofenac			S	Oral			Not Reported
	Promethazine			S	Oral			Not Reported
	Verapamil			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Apap W/Hydrocodone			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Topiramate			S	Oral			Not Reported

	Esomeprazole	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10861538	EXPEDITED (15-DAY)	Y	DE	DEP_02505_2015		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Poisoning Deliberate; Respiratory Arrest	Diclofenac			S	Oral	Df Oral		Not Reported
	Gabapentin			S	Oral	Df Oral		Not Reported
	Amitriptyline			S	Oral	Df Oral		Not Reported
	Tramadol			S	Oral	Df Oral		Not Reported
	Acetaminophen W/Hydrocodone			S	Oral	Df Oral		Not Reported
	Ondansetron			S	Oral	Df Oral		Not Reported
	Linaclotide			S	Oral	Df Oral		Not Reported
	Lubiprostone			S	Oral	Df Oral		Not Reported
	Zolpidem			S	Oral	Df Oral		Not Reported
	Liothyronine			S	Oral	Df Oral		Not Reported
	Escitalopram			S	Oral	Df Oral		Not Reported
	Sertraline			S	Oral	Df Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10861543	EXPEDITED (15-DAY)	Y	DE	DEP_02504_2015		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Poisoning; Respiratory Arrest	Diclofenac			S		Df		Not Reported
	Oxycodone			S		Df		Not Reported
	Cyclobenzaprine			S		Df		Not Reported
	Metoprolol			S		Df		Not Reported
	Clonidine			S		Df		Not Reported
	Nitroglycerin			S		Df		Not Reported
	Lisinopril			S		Df		Not Reported

Escitalopram	S	Df		Not Reported
Ibuprofen	S	Df		Not Reported
Azithromycin	S	Df		Not Reported
Cephalexin /00145501/	S	Df		Not Reported
Doxycycline	S	Df		Not Reported
Methylprednisolone	S	Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10861719	EXPEDITED (15-DAY)	Y	DE	DEP_02522_2015		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Gabapentin			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2015	10866377	DIRECT		DS			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Dyspnoea Exertional; Myocardial Infarction	Escitalopram 20mg			S	Oral	1 Pill Daily Once Daily Taken By Mouth	10 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2015	10838583	EXPEDITED (15-DAY)		HO, OT	PHHY2015US017395		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Dysarthria; Electrocardiogram St	Vivelle			S	Transdermal	0.1 Mg, Unk		Not Reported
	Desvenlafaxine Succinate			S	Oral	50 Mg, Qd		Not Reported

Segment Abnormal; Haemoglobin Increased; Headache; Hypertension; Hypokalaemia; Mental Status Changes; White Blood Cell Count Increased	Desvenlafaxine Succinate	S	Oral	100 Mg, Qd		Not Reported
	Desvenlafaxine Succinate	S	Unknown	50 Mg, Qd		Not Reported
	Desvenlafaxine Succinate	S	Unknown	Unk		Not Reported
	Desvenlafaxine Succinate	S	Oral	25 Mg, Qd		Not Reported
	Clonazepam	S	Oral	1 Mg, Bid		Not Reported
	Loratadine	S	Oral	10 Mg, Qd		Not Reported
	Lyrica	S	Oral	75 Mg, Qd		Not Reported
	Ibuprofen Sandoz	S	Oral	800 Mg, Tid		Novartis
	Robaxin	S	Oral	750 Mg, Tid		Not Reported
	Lexapro	S	Oral	20 Mg, Qd		Not Reported
	Lexapro	S				Not Reported
	Abilify	S	Oral	15 Mg, Bid		Not Reported
	Fluticasone	S	Respiratory (inhalation)	2 Df, Qd		Not Reported
	Vicodin	S	Oral	5 Ot, Prn (5/500)		Not Reported
	Zestoretic	S	Oral	20 Mg, Unk (20/12.5)		Not Reported
	Ambien	S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2015	10839280	NON-EXPEDITED			US-ABBVIE-14P-163-1232895-00		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anxiety; Anxiety; Arthralgia; Bronchitis; Condition Aggravated; Depression; Depression; Drug Ineffective; Fear Of Injection; Fibromyalgia; Headache; Inappropriate Schedule Of Product Administration; Infection; Inflammation; Inflammation; Influenza;	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Iud Nos			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			C	Oral	By Mouth As Needed		Not Reported

Injection Site Discomfort; Injection Site Pain; Musculoskeletal Stiffness; Nasopharyngitis; Pain; Pain In Extremity; Pain In Extremity; Pain In Extremity; Pain In Extremity; Psoriasis; Psoriasis; Sinus Congestion; Therapeutic Product Effect Incomplete; Thinking Abnormal; White Blood Cell Count Increased; Wrong Technique In Product Usage Process

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2015	10843650	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201500679		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Acetaminophen\Hydrocodone Bitartrate			S	Oral	Unk		Mallinckrodt
	Amitriptyline			S	Oral	Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Ondansetron			S	Oral	Unk		Not Reported
	Linaclotide			S	Oral	Unk		Not Reported
	Diclofenac			S	Oral	Unk		Not Reported
	Lubiprostone			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported
	Liothyronine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Sertraline			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2015	10844857	EXPEDITED (15-DAY)		OT	MY-FRI-1000074588		35 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2015	10866544	DIRECT		OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Dizziness; Drug Withdrawal Syndrome; Gastrointestinal Disorder; Haematochezia; Headache; Panic Attack; Product Substitution Issue; Somnolence	Escitalopram 10mg Aurobindo Pharm			S	Oral	1		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2015	10868505	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Migraine	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2015	10868667	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Generic Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2015	10624919	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2014-12751		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Drug Abuse; Sopor	Mirtazapine			S	Oral	600 Mg, Total		Aurobindo
	Periactin			S	Oral	10 Df, Total		Not Reported
	Cipralex /01588501/			S	Oral	14 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2015	10850118	EXPEDITED (15-DAY)		DE	US-BANPHARM-20153483		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion	Loperamide Unknown Product			S	Oral			Not Reported
	Escitalopram			S				Not Reported
	Meloxicam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2015	10850130	EXPEDITED (15-DAY)		OT	GB-TEVA-540958ACC		60 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Substitution Issue	Escitalopram Oxalate			S	Oral	5 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2015	10850334	EXPEDITED (15-DAY)		DE	US-WATSON-2015-03602		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion; Foreign Body Aspiration	Lamotrigine (Watson Laboratories)			S	Unknown	Unk		Watson
	Zonisamide (Watson Laboratories)			S	Unknown	Unk		Watson
	Lorazepam (Watson			S	Unknown	Unk		Watson

	Laboratories)					
	Escitalopram (Unknown)	S	Unknown	Unk		Not Reported
	Lovastatin (Aellc)	S	Oral	Unk		Actavis Elizabeth

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2015	9815686	EXPEDITED (15-DAY)		HO	FR-FRI-1000052812		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Ecchymosis; Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Plavix			S	Oral	75 Mg		Not Reported
	Arixtra			S	Subcutaneous	5 Mg		Not Reported
	Celluvisc			C	Ophthalmic	4 Mg/0.4 Ml		Not Reported
	Cordarone			C	Oral			Not Reported
	Tardyferon			C				Not Reported
	Alprazolam			C				Not Reported
	Amlor			C				Not Reported
	Dichlorhydrate De Cetirizine			C				Not Reported
	Mestinon			C				Not Reported
	Ebixa			C				Not Reported
	Furadantine			C				Not Reported
	Dafalgan			C				Not Reported
	Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous)			C				Not Reported
	Inexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2015	10562977	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2014M1008807			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Vomiting; Wrong Product	Escitalopram Oxalate			S	Oral	3 Gtt, Total		Not Reported

Administered

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2015	10574634	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2014M1009525			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Vomiting; Wrong Product Administered	Escitalopram Oxalate			S	Oral	3 Gtt, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2015	10864413	EXPEDITED (15-DAY)		OT	IN-ABBVIE-15P-078-1351193-00			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akathisia; Anxiety; Constipation; Diarrhoea; Dizziness; Dry Mouth; Dystonia; Fatigue; Gynaecomastia; Headache; Hypotension; Increased Appetite; Insomnia; Nausea; Orthostatic Hypotension; Parkinsonism; Pyrexia; Salivary Hypersecretion; Sedation; Seizure; Somnolence; Tachycardia; Tardive Dyskinesia; Tremor; Vision Blurred; Vomiting; Weight Increased	Divalproex Sodium			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Clozapine			S	Unknown			Not Reported
	Amisulpride			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported
	Chlorpromazine			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Fluphenazine Decanoate			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Trihexyphenidyl Hydrochloride			S	Unknown			Not Reported
	Zuclopenthixol Decanoate			S	Unknown			Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Trifluoperazine			S	Unknown			Not Reported
	Asenapine			S	Unknown			Not Reported
	Imipramine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2015	10870013	EXPEDITED (15-DAY)	Y	CA	UCM201502-000125			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cardiac Malposition; Congenital Diaphragmatic Eventration; Deformity Thorax; Maternal Drugs Affecting Foetus; Nipple Disorder; Patent Ductus Arteriosus; Rib Hypoplasia	Topiramate (Topiramate) (Topiramate)			S	Transplacental			Not Reported
	Tramadol (Tramadol) (Tramadol)			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Oxycodone/Acetaminophen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2015	10871494	DIRECT		OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Quality Issue; Product Substitution Issue; Suicidal Ideation	Escitalopram 10mg Camber			S	Oral	1		Camber
	Escitalopram 10mg Teva			S	Oral	1		Teva
	Vitamins - B Complex			C				Not Reported
	Calcium			C				Not Reported
	Glucosamine/Msm			C				Not Reported
	Escitalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2015	10874145	DIRECT	Y	DS			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Pain; Depression; Disturbance In Attention; Feelings Of Worthlessness; Insomnia; Loss Of Personal Independence In Daily Activities; Myalgia;	Escitalopram 20mg			S	Oral	20mg, 1 Qd, Po		Aurobindo
	Dextroamphetamine Er			C				Not Reported

Product Substitution Issue

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2015	10874295	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Migraine; Product Substitution Issue	Escitalopram			S	Oral	1-2 Months 2013 20 Mg Daily Oral		Not Reported
	Escitalopram			S	Oral	1/2 Months 2014 20 Mg Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2015	10598183	EXPEDITED (15-DAY)		OT	CH-FRI-1000072554		28 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metrorrhagia; Pregnancy; Premature Labour	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S				Forest
	Seropram (Citalopram Hydrobromide)			S		20 Mg		Not Reported
	Abilify			S	Oral	10 Mg		Not Reported
	Abilify			S				Not Reported
	Edronax			S	Oral	4 Mg		Not Reported
	Edronax			S				Not Reported
	Latuda			S		40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2015	10722809	EXPEDITED (15-DAY)		LT, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-001902		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Suicidal Ideation	Abilify			S	Oral	7.5 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Oral	15 Mg, Unk		Bristol Myers Squibb
	Wellbutrin			S	Unknown	300 Mg, Qd		Not Reported

	Wellbutrin	S			Not Reported
	Lexapro	S	Unknown	5 Mg, Unk	Not Reported
	Prozac	C	Unknown	Unk	Not Reported
	Montelukast	C	Unknown		Not Reported
	Zyrtec	C	Unknown		Not Reported
	Vitamin C /00008001/	C	Unknown		Not Reported
	Fish Oil	C	Unknown		Not Reported
	Multivitamin /00097801/	C	Unknown		Not Reported
	Minocycline\Minocycline Hydrochloride	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2015	10857240	NON-EXPEDITED		HO	FR-FRI-1000074646		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Haemorrhage; Fall; Subdural Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Atenolol			S	Oral	100 Mg		Not Reported
	Tahor			C	Oral	10 Mg		Not Reported
	Paracetamol			C	Oral	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2015	10857878	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2015M1005398			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Ecchymosis; Haematoma; Off Label Use	Fondaparinux			S	Subcutaneous	5 Mg/04.Ml, Qd		Not Reported
	Fondaparinux			S		Unk		Not Reported
	Fondaparinux			S	Subcutaneous	Unk		Not Reported
	Plavix			S	Oral	75 Mg, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported

	Celluvisc /00007002/	C	4 Mg, Unk	Not Reported
	Cordarone	C	200 Mg, Unk	Not Reported
	Tardyferon	C	Unk	Not Reported
	Alprazolam	C	Unk	Not Reported
	Amlor	C	Unk	Not Reported
	Cetirizine	C	Unk	Not Reported
	Mestinon	C	Unk	Not Reported
	Ebixa	C	Unk	Not Reported
	Furadantine	C	Unk	Not Reported
	Dafalgan	C	Unk	Not Reported
	Transipeg /00754501/	C	Unk	Not Reported
	Inexium /01479302/	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2015	10858250	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2015M1004187			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Insomnia	Escitalopram			S	Transmammary	10 Mg, Qd		Not Reported
	Escitalopram			S	Transmammary	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2015	10861268	EXPEDITED (15-DAY)		DE	US-BANPHARM-20153480		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zonisamide Unknown Product			S				Not Reported
	Lamotrigine			S				Not Reported
	Lorazepam			S				Not Reported
	Escitalopram			S				Not Reported
	Lovastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2015	10861322	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20150213608		94 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Ixprim			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported
	Permixon			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2015	10861845	EXPEDITED (15-DAY)		DE	US-BANPHARM-20153503		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Ibuprofen Unknown Product			S				Not Reported
	Oxycodone			S				Not Reported
	Cyclobenzaprine			S				Not Reported
	Metoprolol			S				Not Reported
	Clonidine			S				Not Reported
	Nitroglycerin			S				Not Reported
	Lisinopril			S				Not Reported
	Escitalopram			S				Not Reported
	Diclofenac			S				Not Reported
	Azithromycin			S				Not Reported
	Cephalexin			S				Not Reported
	Doxycycline			S				Not Reported
	Methylprednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2015	10863810	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015065264			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder; Bipolar Disorder;	Zoloft			S		Unk		Pfizer

Obsessive-Compulsive Disorder; Psychomotor Hyperactivity	Lexapro	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2015	10864411	EXPEDITED (15-DAY)		OT	PHHY2015FR020823			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Dihydroergotamine			S	Transplacental			Not Reported
	Aripiprazole			S	Transplacental	Maternal Dose (10 Mg/Day)		Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Oxazepam			S	Transplacental			Novartis
	Pipamperone			S	Transplacental			Not Reported
	Loprazolam			S	Transplacental			Not Reported
	Dipotassium Clorazepate			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2015	10865536	EXPEDITED (15-DAY)		DE, HO	2015SP000111		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Meloxicam			S	Oral			Not Reported
	Loperamide			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2015	10599532	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000072579			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Pulmonary Valve Disorder	Lexapro			S	Other	10 Mg		Forest
	Prenatal Plus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2015	10867498	EXPEDITED (15-DAY)		OT	SE-FRI-1000074684			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoacusis; Tinnitus	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Forest
	Quetiapine			C	Unknown			Not Reported
	Lamictal			C	Unknown			Not Reported
	Concerta			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2015	10867500	EXPEDITED (15-DAY)		CA, OT	US-JNJFOC-20150213245			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly; Congenital Diaphragmatic Eventration; Dextrocardia; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Supernumerary Nipple	Tramadol Hydrochloride			S	Transplacental			Not Reported
	Topiramate			S	Transplacental			Not Reported
	Oxycodone/Paracetamol			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2015	10867516	EXPEDITED (15-DAY)		OT	FR-FRI-1000074658		8 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder; Exposure During Pregnancy	Escitalopram			S	Transplacental			Forest
	Alprazolam			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2015	10868503	EXPEDITED (15-DAY)		HO, LT	ES-JNJFOC-20150209712		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Electrocardiogram Qt Prolonged	Risperdal			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lormetazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2015	10881865	DIRECT					57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Mental Disorder	Escitalopram			S	Oral			Teva
	Vitamin C			C				Not Reported
	Vitamin B Complex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2015	10813515	NON-EXPEDITED			US-PFIZER INC-2015061007		64 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash; Rubber Sensitivity	Etanercept			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Celecoxib			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Naproxen Sodium			S		Unk		Pfizer
	Voltaren			S		Unk		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

Leflunomide	S	Unk	Not Reported
Anaprox	S	Unk	Not Reported
Myochrysine	S	Unk	Not Reported
Gold Sodium Thiomalate	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Escitalopram Oxalate	S	Unk	Not Reported
Sulindac	S	Unk	Not Reported
Clinoril	S	Unk	Not Reported
Hydrocodone	S	Unk	Not Reported
Vicodin	S	Unk	Not Reported
Fluoxetine Hcl	S	Unk	Not Reported
Prozac	S	Unk	Not Reported
Acetaminophen	S	Unk	Not Reported
Etodolac	S	Unk	Not Reported
Lodine	S	Unk	Not Reported
Nabumetone	S	Unk	Not Reported
Relafen	S	Unk	Not Reported
Rofecoxib	S	Unk	Not Reported
Vioxx	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2015	10869980	NON-EXPEDITED			US-PFIZER INC-2015070729			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyskinesia; Dystonia; Extrapyramidal Disorder	Geodon			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Cogentin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2015	10881901	EXPEDITED (15-DAY)	Y	DE	ABR_02027_2015		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Lamotrigine			S		Df		Not Reported
	Zonisamide			S		Df		Not Reported
	Lorazepam			S		Df		Not Reported
	Escitalopram			S		Df		Not Reported
	Lovastatin			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2015	10881960	EXPEDITED (15-DAY)	Y	DE	ABR_02033_2015		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion; Poisoning	Lamotrigine			S	Oral	Df		Not Reported
	Cardiac Glycosides			S	Oral	Df		Not Reported
	Clonazepam			S	Oral	Df		Not Reported
	Trazodone			S	Oral	Df		Not Reported
	Oxybutynin			S	Oral	Df		Not Reported
	Quetiapine			S	Oral	Df		Not Reported
	Escitalopram			S	Oral	Df		Not Reported
	Finasteride			S	Oral	Df		Not Reported
	Salicylates Nos			S	Oral	Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2015	10882045	EXPEDITED (15-DAY)	Y	DE	ABR_02039_2015		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion;	Lamotrigine			S	Oral	Df		Not Reported

Poisoning	Temazepam	S	Oral	Df		Not Reported
	Lorazepam	S	Oral	Df		Not Reported
	Primidone	S	Oral	Df		Not Reported
	Escitalopram	S	Oral	Df		Not Reported
	Benztropine	S	Oral	Df		Not Reported
	Lipid Modifying Agents, Combinations	S	Oral	Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2015	10768978	EXPEDITED (15-DAY)		HO	AT-ELI_LILLY_AND_COMPANY-AT201502000978		33 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Anxiety Disorder; Major Depression	Cymbalta			S	Unknown	Unk		Eli Lilly And Co
	Cipralex /01588501/			S	Oral	10 Mg, Unknown		Not Reported
	Trittico			C				Not Reported
	Mogadon			C		Unk		Not Reported
	Nozinan /00038601/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2015	10794575	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015051201		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Hypokalaemia; Malaise; Seizure; Suicide Attempt; Tetany; Torsade De Pointes; Toxicity To Various Agents; Ventricular Fibrillation	Xanax			S	Oral	0.25 Mg, Daily		Pfizer
	Seroplex			S	Oral	10 Mg, Daily		Not Reported
	Imovane			C		7.5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2015	10872567	EXPEDITED (15-DAY)		OT	TW-CIPLA LTD.-2015TW01332			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Merycism	Sertraline			S		150 Mg, Per Day For 6 Months		Cipla
	Bupropion			S		300 Mg, Per Day For 3 Months		Not Reported
	Duloxetine			S		120 Mg, Per Day, For 6 Months		Not Reported
	Escitalopram			S		20 Mg, Per Day For 3 Months		Not Reported
	Venlafaxine			S		225 Mg, Per Day, For 6 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2015	10875217	EXPEDITED (15-DAY)		DE	US-ACTAVIS-2015-03951		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Bupropion Hydrochloride (Actavis Laboratories Fl)			S	Oral	Unknown		Actavis
	Escitalopram (Unknown)			S	Oral	Unknown		Not Reported
	Gabapentin (Aellc)			S	Oral	Unknown		Watson
	Alprazolam (Aellc)			S	Oral	Unknown		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2015	10641498	EXPEDITED (15-DAY)		HO	IT-FRI-1000072956		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Drug Abuse; Intentional Overdose; Overdose; Sopor	Escitalopram			S	Oral	Overdose: 140 Mg Daily		Forest
	Mirtazapine			S	Oral	600 Mg Daily		Not Reported
	Periactin			S	Oral	40 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2015	10652902	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2014M1013411			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Drug Abuse; Overdose; Sopor	Mirtazapine			S	Oral	600 Mg, Total		Not Reported
	Periactin			S	Oral	10 Df, Total		Not Reported
	Cipralex /01588502/			S	Oral	14 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2015	10904086	DIRECT		OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome; Vomiting	Rizatriptan			S	Oral	1 Pill		Not Reported
	Escitalopram Oxalate			S	Oral	1 Pill		Not Reported
	Yaz Birth Control Green Bayer			C				Not Reported
	Humira Syringe 40mg Abbvie			C				Not Reported
	Lexapro			C				Not Reported
	Provigil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2015	9777944	EXPEDITED (15-DAY)		HO	IT-BRISTOL-MYERS SQUIBB COMPANY-19923440		86 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Abuse; Intentional Overdose; Psychomotor Hyperactivity; Sopor	Metformin Hydrochloride			S	Oral	1500 Mg, Unk		Bristol Myers Squibb
	Tavor (Lorazepam)			S	Oral	6 Df, Unk		Not Reported
	Cipralex			S	Oral	3 Df, Unk		Not Reported
	Diamicron			S	Oral	30 Mg, Unk		Not Reported
	Tachipirina			S	Oral	3 Df, Unk		Not Reported
	Serenase (Haloperidol)			S	Oral	2 Df, Unk		Not Reported
	Bisoprolol Hemifumarate			S	Oral	3 Df, Unk		Not Reported

Macrogol	C	Unknown	1 Df, Unk		Not Reported
Coumadin	C	Unknown	5 Mg, Unk		Bristol Myers Squibb
Cholecalciferol	C	Intramuscular	1 Df, Qmo		Not Reported
Nexium	C	Unknown			Not Reported
Isoptin	C	Unknown	Film-Coated Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2015	10727677	EXPEDITED (15-DAY)		OT	PHHY2015FR006478		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Orthostatic Hypotension; Tachycardia	Cotareg			S	Oral	1 Df (Valsartan 80mg, Hydrochlorothiazide 12.5mg) Qd		Novartis
	Loxen (Nicardipine Hydrochloride)			S	Oral	20 Mg, Prn		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Oral	20 Mg, Prn (If Bp Greater Than 17/9)		Not Reported
	Norfloxacin			S	Oral	2 Df, Qd		Not Reported
	Seroplex			S	Oral	20 Mg, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2015	10885135	EXPEDITED (15-DAY)		HO	CH-FRI-1000074919		74 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hiccups; Laboratory Test Interference; Polymyalgia Rheumatica; Pyrexia; Respiratory Syncytial Virus Test Positive; Thrombocytopenia	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram Oral Solution			S	Oral	10 Mg		Forest
	Tolvon			S	Oral	15 Mg		Not Reported
	Augmentin			C	Intravenous (not otherwise specified)	3.6 Gram		Not Reported
	Tazobac			C	Intravenous (not otherwise specified)	13.5 Gram		Not Reported

Tavanic	C	Oral	500 Mg		Not Reported
Tienam	C	Unknown	2000 Mg		Not Reported
Dalfalgan	C	Oral	3 Gram		Not Reported
Prednisone Labatec	C	Oral	20 Mg		Not Reported
Enalapril Actavis	C	Oral	20 Mg		Not Reported
Nexium	C	Oral	40 Mg		Not Reported
Clexane	C	Oral	40 Mg		Not Reported
Morphine	C	Subcutaneous	8 Mg		Not Reported
Co-Amoxicillin	C	Unknown	3.9 Gram		Not Reported
Paracetamol	C		3 Gram		Not Reported
Paracetamol	C		1 Gram		Not Reported
Tienam	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2015	10885899	EXPEDITED (15-DAY)		DE	US-BANPHARM-20153551		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion	Diphenhydramine Unknown Product/Acetaminophen			S				Not Reported
	Warfarin			S				Not Reported
	Olanzapine			S				Not Reported
	Lisinopril			S				Not Reported
	Escitalopram			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2015	10886328	EXPEDITED (15-DAY)		DE	US-ACTAVIS-2015-03966		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amitriptyline			S	Oral	Unknown		Not Reported
	Tramadol Hydrochloride (Aellc)			S	Oral	Unknown		Actavis Elizabeth
	Hydrocodone-Acetaminophen			S	Oral	Unknown		Watson

(Watson Laboratories)					
Ondansetron (Unknown)	S	Oral	Unknown		Not Reported
Diclofenac Sodium (Aellc)	S	Oral	Unknown		Watson
Zolpidem Tartrate (Watson Laboratories)	S	Oral	Unknown		Watson
Escitalopram (Unknown)	S	Oral	Unknown		Not Reported
Sertraline Hydrochloride (Watson Laboratories)	S	Oral	Unknown		Watson
Gabapentin (Aellc)	S	Oral	Unknown		Watson
Lubiprostone	S	Oral	Unknown		Not Reported
Linaclotide	S	Oral	Unknown		Not Reported
Liothyronine	S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2015	10886337	EXPEDITED (15-DAY)		DE	US-WATSON-2015-03982		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Sertraline Hydrochloride (Watson Laboratories)			S	Oral	Unknown		Watson
	Escitalopram (Unknown)			S	Oral	Unknown		Not Reported
	Atomoxetine			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2015	10888964	EXPEDITED (15-DAY)		DE	US-WATSON-2015-04064		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion; Toxicity To Various Agents	Promethazine (Watson Laboratories)			S	Oral	Unknown		Watson
	Verapamil Hydrochloride (Watson Laboratories)			S	Oral	Unknown		Watson
	Escitalopram (Unknown)			S	Oral	Unknown		Not Reported
	Hydrocodone-Acetaminophen (Watson Laboratories)			S	Oral	Unknown		Watson
	Diazepam (Watson			S	Oral	Unknown		Watson

Laboratories)				
Topiramate (Watson Laboratories)	S	Oral	Unknown	Watson
Diclofenac (Watson Laboratories)	S	Oral	Unknown	Watson
Esomeprazole (Unknown)	S	Oral	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2015	10889272	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2015M1006720			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alcohol Abuse; Anxiety; Decreased Appetite; Impulsive Behaviour; Insomnia; Paranoia; Sexual Inhibition; Unevaluable Event	Escitalopram			S	Unknown	10-20mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2015	10889276	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2015M1006719			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Alcoholism; Imprisonment; Mania; Suicidal Behaviour; Tremor; Unevaluable Event	Escitalopram			S	Unknown	10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2015	10889281	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2015M1006718			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcoholism; Behaviour Disorder; Decreased Interest;	Escitalopram			S	Unknown	10mg		Not Reported

Emotional Disorder;
Unevaluable Event;
Unevaluable Event

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2015	10890264	EXPEDITED (15-DAY)		HO	CH-009507513-1502CHE010796		20 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Transaminases Increased	Remeron			S	Oral	15 Mg, Qd		Merck
	Quetiapine Fumarate			S	Oral	25 Mg, Qod		Not Reported
	Quetiapine Fumarate			S	Oral	50 Mg, Qd		Not Reported
	Quetiapine Fumarate			S	Oral	75 Mg, Qd		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2015	10891885	EXPEDITED (15-DAY)		HO	CH-FRI-1000075013			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Transaminases Increased	Escitalopram			S	Oral	10 Mg Daily		Forest
	Sequase			S	Oral	25 Mg Every Second Day		Not Reported
	Sequase			S	Oral	50 Mg Daily		Not Reported
	Sequase			S	Oral	75 Mg Daily		Not Reported
	Remeron			S	Oral	15 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2015	10892524	EXPEDITED (15-DAY)		CA	US-FRI-1000074907			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta; Congenital Anomaly	Lexapro			S				Forest
	Sertraline			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2015	10869461	EXPEDITED (15-DAY)		HO	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-010390		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Hypertension; Hypokalaemia; Mental Status Changes	Abilify			S	Oral	15 Mg, Bid		Bristol Myers Squibb
	Ibuprofen			S	Oral	800 Mg, Tid		Bristol Myers Squibb
	Desvenlafaxine			S	Oral	50 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Unk		Not Reported
	Fluticasone			S	Unknown	1 Df= 2 Sprays, Qd		Not Reported
	Vicodin			S	Oral	1 Df= 5/500 Units Nos, Prn		Not Reported
	Zestoretic			S	Oral	1 Df= 20/12.5 Units Nos, Qd		Not Reported
	Ambien			S	Oral	10 Mg, Qd		Not Reported
	Vivelle /00045401/			S	Transdermal	0.1 Mg, Unk		Not Reported
	Lyrica			S	Oral	75 Mg, Qd		Not Reported
	Loratadine			S	Oral	10 Mg, Qd		Not Reported
	Robaxin			S	Oral	750 Mg, Tid		Not Reported
	Clonazepam			S	Oral	1 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2015	10896590	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-E2B_00003236			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2015	10896746	EXPEDITED (15-DAY)		HO	ES-JNJFOC-20150220454		49 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Catatonia	Risperdal	S	Oral	Not Reported
	Trazodone Hydrochloride	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Etumina	S	Oral	Not Reported
	Orfidal	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2015	10899129	EXPEDITED (15-DAY)		LT	IE-TEVA-545414ISR		41 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Diarrhoea; Hyperhidrosis; Pyrexia; Tremor; Tremor	Escitalopram Teva			S	Oral	10 Milligram Daily;		Ivax
	Lansoprazole Teva Sante 15 Mg			S	Oral	30 Milligram Daily; Gastro-Resistant Capsule		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2015	10899754	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2015001628			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Product Substitution Issue	Escitalopram 10mg Tablet			S	Oral	10 Mg, Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2015	10899759	EXPEDITED (15-DAY)		HO	CH-FRI-1000075094			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Duodenal Ulcer; Haematemesis; International Normalised Ratio Increased; Melaena; Upper Gastrointestinal Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Marcoumar			S	Oral	1 Df Dosage Form		Not Reported
	Algifor			S	Oral	1600 Mg Daily		Not Reported
	Benerva			C	Unknown			Not Reported
	Becozym			C	Unknown			Not Reported

	Atorvastatin	C	Unknown	Not Reported
	Acidum Folicum	C	Unknown	Not Reported
	Amlodipin	C	Unknown	Not Reported
	Co Diovan	C	Unknown	Not Reported
	Remeron	C	Unknown	Not Reported
	Nizoral Creme	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2015	10899760	EXPEDITED (15-DAY)		HO	FR-FRI-1000075003		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased; Subdural Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Coumadine			S	Oral	7 Mg		Not Reported
	Procoralan			C	Unknown	5 Mg		Not Reported
	Crestor			C	Unknown	10 Mg		Not Reported
	Levothyrox			C	Unknown	175 Mcg		Not Reported
	Bromazepam			C	Unknown	6 Mg		Not Reported
	Spifen			C	Oral	1 Tablet If Headache		Not Reported
	Dafalgan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2015	10905274	DIRECT		OT			14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack; Screaming	Escitalopram			S		0.5		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2015	10906848	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Tinnitus	Escitalopram 10 Mg	S	Oral	1 Tablet Once Daily Taken By Mouth	Not Reported
	Clonzapam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2015	10906935	DIRECT					58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Erythema; Pruritus; Rash; Skin Exfoliation; Swelling; Urticaria	Lexapro			S	Oral	1 Pill		Camber
	Atenolol			C				Not Reported
	Lovastatin			C				Not Reported
	Acetaminophen\Hydrocodone Bitartrate			C				Not Reported
	Daily Multiple Vitamin			C				Not Reported
	Policosanol			C				Not Reported
	Vitamin D-3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2015	10693270	EXPEDITED (15-DAY)		OT	JP-FRI-1000073458		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Electrocardiogram Qt Prolonged; Sinus Arrest	Escitalopram			S	Oral	10 Mg		Forest
	Rize			C	Oral	10 Mg		Not Reported
	Spironolactone			C	Oral	25 Mg		Not Reported
	Lasix			C	Oral	20 Mg		Not Reported
	Allopurinol			C	Oral	100 Mg		Not Reported
	Blopress			C	Oral	2 Mg		Not Reported
	Warfarin			C	Oral	2.5 Mg		Not Reported
	Berasus La			C	Oral	120 Mg		Not Reported
	Aspenon			C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2015	10900183	EXPEDITED (15-DAY)		DS, OT	GB-AUROBINDO-AUR-APL-2015-01853		20 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Insomnia; Mood Altered	Escitalopram			S	Oral	5 Mg, Unk		Aurobindo
	Diphenhydramine			C	Unknown	Unk		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2015	10900243	EXPEDITED (15-DAY)		OT	GB-ACCORD-029067		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Product Substitution Issue	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2015	10900452	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-01876		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Product Substitution Issue	Escitalopram 10 Mg			S	Oral	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2015	10902971	EXPEDITED (15-DAY)		OT	GB-FRI-1000075129		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Mental Disorder; Product Substitution Issue	Escitalopram			S	Oral	10 Mg Daily		Forest
	Escitalopram			S	Oral	10 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10651333	NON-EXPEDITED		OT	US-TEVA-514401USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depressed Mood; Depression; Disturbance In Attention; Disturbance In Attention; Drug Ineffective; Dyskinesia; Insomnia; Product Substitution Issue; Restless Legs Syndrome; Restlessness; Suicidal Ideation	Escitalopram			S				Ivax
	Nexium			C		40 Milligram Daily;		Not Reported
	Dyazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10692687	EXPEDITED (15-DAY)		OT	CH-TEVA-527122ISR		37 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Activity; Fatigue; Malaise; Night Sweats; Product Substitution Issue; Sedation; Sexual Dysfunction; Therapeutic Product Effect Decreased	Escitalopram-Mepha			S	Unknown			Ivax
	Ass 100mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10903155	NON-EXPEDITED			US-TEVA-533916USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Urticaria	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10903156	NON-EXPEDITED			US-TEVA-529529USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depressed Mood; Drug Ineffective; Listless; Malaise; Malaise; Therapeutic Response Changed; Tremor	Escitalopram			S					Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10903157	NON-EXPEDITED			US-TEVA-541122USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dry Mouth	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10903158	NON-EXPEDITED		OT	US-TEVA-544459USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine; Suicidal Ideation	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10903159	NON-EXPEDITED			US-TEVA-530442USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10903160	NON-EXPEDITED			US-TEVA-533598USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dry Mouth; Muscular Weakness; Muscular Weakness; Thirst	Escitalopram			S	Oral	40 Milligram Daily;		Ivax
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Aciphex			C	Oral	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10903162	NON-EXPEDITED			US-TEVA-534526USA		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Back Pain; Bladder Disorder; Dysuria; Dysuria; Feeling Abnormal; Muscle Spasms; Penis Disorder; Pruritus	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10904659	NON-EXPEDITED			US-TEVA-530225USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Decreased Activity; Drug Ineffective; Hypersomnia; Product Substitution Issue; Psychiatric Symptom	Escitalopram			S				Ivax
	Escitalopram			S				Ivax
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10905212	EXPEDITED (15-DAY)		HO	FR-FRI-1000075088		22 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Overdose; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S		Overdose Of 15 Tablets Nos		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2015	10906110	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2015GSK028046			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Aggression; Cerebrovascular Accident; Drug Ineffective; Fatigue; Hallucination, Auditory; Hip Fracture; Insomnia; Weight Decreased	Wellbutrin Sr	S	Oral	100 Mg, 1d		Glaxosmithkline
	Wellbutrin Sr	S	Unknown	150 Mg, Qd		Glaxosmithkline
	Bupropion	S		Unk, U		Glaxosmithkline
	Lexapro	S	Unknown	10 Mg, U		Not Reported
	Cartia Xt	C				Not Reported
	Lovaza	C				Not Reported
	Plavix	C				Not Reported
	Protonix	C				Not Reported
	Aspirin (Baby)	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2015	10654817	NON-EXPEDITED		OT	US-PFIZER INC-2014343239		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Confusional State; Feeling Abnormal; Headache; Paraesthesia	Effexor Xr			S		150 Mg, 1x/Day		Pfizer
	Effexor Xr			S				Pfizer
	Effexor			S		150 Mg, 1x/Day		Pfizer
	Effexor			S				Pfizer
	Venlafaxine Hcl			S		150 Mg, 1x/Day		Pfizer
	Venlafaxine Hcl			S				Pfizer
	Escitalopram Oxalate			S		10 Mg, 1x/Day		Not Reported
	Vesicare			S		Unk Unk, 1x/Day		Not Reported
	Celebrex			C		200 Mg, 1x/Day		Not Reported
	Azathioprine			C		50, Unk		Not Reported
	Hydroxychloroquine			C		200, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2015	9721536	EXPEDITED (15-DAY)			JP-BRISTOL-MYERS SQUIBB COMPANY-19862523			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased	Abilify			S	Oral	Unk		Bristol Myers Squibb
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2015	10747658	EXPEDITED (15-DAY)		HO, LT	FR-JNJFOC-20150112509		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Coma; Electrocardiogram Qt Prolonged; Sinus Bradycardia; Suicide Attempt	Ixprim			S	Oral			Not Reported
	Domperidone			S	Oral			Not Reported
	Loperamide			S	Oral			Not Reported
	Paracetamol		Y	S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lexomil			S	Oral			Not Reported
	Seroplex			C	Oral			Not Reported
	Imovane			C	Oral			Not Reported
	Utrogestan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2015	10911591	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2015-02049			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure Timing Unspecified	Escitalopram			S	Oral	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2015	10803904	EXPEDITED (15-DAY)		OT	IE-FRI-1000074529		41 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cold Sweat; Dizziness; Dyskinesia; Hallucination,	Lexapro			S	Unknown			Forest

Visual; Hiccups; Palpitations; Product Use In Unapproved Indication; Seizure; Wheezing; Withdrawal Syndrome	Lexapro	S	Unknown	10 Mg		Forest
	Fucithalmic	S	Unknown			Not Reported
	Seretide	C	Unknown			Not Reported
	Antibiotics	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2015	10915912	EXPEDITED (15-DAY)		HO	IT-TEVA-546890ACC		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Abuse; Oxygen Saturation Decreased	Escitalopram			S	Oral	400 Mg Total		Ivax
	Cardioaspirin - 100 Mg Compresse Gastroresistenti			C		Gastro-Resistant Tablet		Not Reported
	En - 1 Mg/Ml Gocce Orali, Soluzione 20 Ml			C		Oral Drops, Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2015	10915972	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2015M1006667			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Product Substitution Issue	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2015	10916246	EXPEDITED (15-DAY)		HO	FR-FRI-1000075266		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral	1 Df		Forest
	Escitalopram			S	Oral	Overdose Of 1 Intake Of Unknown Dose		Forest
	Lexomil Roche			S	Oral	Overdose Of 1 Intake Of Unknown Dose		Not Reported
	Mopral			C		1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2015	10916259	EXPEDITED (15-DAY)		HO	FR-FRI-1000075214		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis; Musculoskeletal Pain	Escitalopram			S	Oral	1 Df		Forest
	Stilnox			C	Oral	1 Df		Not Reported
	Victan			C	Oral	1 Df		Not Reported
	Hept A Myl			C	Oral	30 Gtt		Not Reported
	Tardyferon			C		2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2015	10925060	DIRECT		HO			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Use; Intentional Self-Injury; Loss Of Consciousness; Memory Impairment; Skin Laceration	Bupropion Hcl			S	Oral	1 Pill	4 MTH	Mylan
	Escitalopram			S	Oral	1 Pills	9 MTH	Accord
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2015	10926532	EXPEDITED (15-DAY)	Y	OT	2015JUB00058		50 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypochloraemia; Hypokalaemia; Hyponatraemic Encephalopathy; Inappropriate Antidiuretic Hormone Secretion	Escitalopram (Escitalopram)			S				Not Reported
	Unknown							
	Telmisartan (Telmisartan)			C				Not Reported
	Acetyl Salicylate (Acetyl Salicylate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2015	10919987	EXPEDITED (15-DAY)		HO, OT	PHHY2015ES027626		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Blood Pressure Increased; Drug Interaction; Gamma-Glutamyltransferase Increased; Hemianopia	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
	Etoricoxib			S	Unknown	1 Df, Qd		Not Reported
	Tramadol			S	Unknown	1 Df, Qd		Not Reported
	Tramadol+Paracetamol			S	Unknown	1 Df, Tid		Not Reported
	Deflazacort			C	Unknown	1 Df, Qd		Not Reported
	Salbutamol			C	Unknown	1 Df, Prn		Not Reported
	Montelukast			C	Unknown			Not Reported
	Atorvastatin			C	Unknown	1 Df, Qd		Not Reported
	Omeprazole			C	Unknown	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2015	10920228	NON-EXPEDITED		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00418		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Codeine			S	Oral			Not Reported
	Topiramate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2015	10922470	EXPEDITED (15-DAY)		HO, OT	US-BAUSCH-BL-2015-009455		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Cerebrovascular Accident; Drug Ineffective; Fatigue; Fatigue; Hallucination, Auditory; Hip Fracture; Insomnia; Product	Bupropion			S	Unknown			Not Reported
	Wellbutrin Sr 150mg (Bupropion Hydrochloride) (Prolonged Release Tablet) (Bupropion Hydrochloride)			S	Oral			Not Reported
	Wellbutrin Sr 150mg (Bupropion Hydrochloride) (Prolonged			S	Unknown			Not Reported

Substitution Issue; Psychomotor Hyperactivity; Weight Decreased	Release Tablet) (Bupropion Hydrochloride)				
	Lexapro	S	Unknown		Not Reported
	Cartia Xt	C			Not Reported
	Lovaza	C			Not Reported
	Plavix	C			Not Reported
	Protonix	C			Not Reported
	Adult Low Dose Aspirin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2015	10927922	DIRECT		DS			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral	1 Pill	1 MTH	Lupin
	Omega 3			C				Not Reported
	Magnesium			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Multi Vitamin			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2015	10929250	EXPEDITED (15-DAY)	Y	OT	2015HINLIT0252		41 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Alcoholism; Mania; Suicidal Behaviour; Tremor	Escitalopram (Escitalopram) Unknown			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2015	10930638	EXPEDITED (15-DAY)	Y	OT	2015HINLIT0251		48 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Alcoholism; Decreased Interest;	Escitalopram (Escitalopram) Unknown			S				Not Reported

Feeling Abnormal; Partner Stress

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2015	10930679	EXPEDITED (15-DAY)	Y	OT	2015HINLIT0253		42 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Anxiety; Impulsive Behaviour; Paranoia	Escitalopram (Escitalopram)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2015	10930690	EXPEDITED (15-DAY)	Y	OT	2015HINLIT0254			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alcoholism; Decreased Appetite; Insomnia	Escitalopram (Escitalopram)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2015	10923722	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-02173		41 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Alcoholism; Impaired Driving Ability; Imprisonment; Mania; Suicidal Ideation; Tremor	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2015	10923913	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-02174		42 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation;	Escitalopram			S	Unknown	10-20 Mg		Aurobindo

Alcohol Abuse; Anxiety; Decreased Appetite; Depressed Mood; Impulsive Behaviour; Insomnia; Paranoia; Psychiatric Symptom; Sexual Inhibition

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2015	10924208	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-02172		48 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcoholism; Behaviour Disorder; Decreased Interest; Emotional Distress; Partner Stress	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2015	10929337	DIRECT					78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Gastrointestinal Disorder; Product Substitution Issue	Escitalopram 20 Mg Accord Healthca			S	Oral	1 Once Daily Taken By Mouth		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2015	10930691	DIRECT	Y				23 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered Visual Depth Perception; Balance Disorder; Diarrhoea; Disturbance In Attention; Feeling Hot; Loss Of Consciousness	Lexapro			S				Not Reported
	Propranolol			C				Not Reported
	Vyvance			C				Not Reported
	Yasmin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2015	10944137	EXPEDITED (15-DAY)	Y	OT	ES-ZYDUS-007190		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Drug Interaction; Hemianopia	Escitalopram			S		10.00 Dosage		Not Reported
	Etoricoxiib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2015	10694075	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2014-004150		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Gastric Ulcer; Prerenal Failure; Rectal Haemorrhage; Upper Gastrointestinal Haemorrhage; Vitamin B12 Deficiency	Eliquis			S	Oral	2.5 Mg, Bid		Bristol Myers Squibb
	Kardegic			S	Oral	75 Mg, Unk		Not Reported
	Ketoprofene /00032001/			S	Cutaneous	Unk		Not Reported
	Aldactazine			S	Oral	1 Df, Qd		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Temerit			C	Unknown	Unk		Not Reported
	Mediatensyl /00631801/			C	Unknown			Not Reported
	Amiodarone			C	Unknown	Unk		Not Reported
	Eptavit			C	Unknown			Not Reported
	Doliprane			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown			Not Reported
	Inexium /01479302/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2015	10888702	EXPEDITED (15-DAY)		OT	CH-TEVA-539615ISR		17 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Euphoric Mood; Fatigue; Feeling Abnormal;	Escitalopram Mepha 5 Mg			S	Oral	5 Milligram Daily;		Ivax

Inappropriate Affect; Insomnia; Logorrhoea; Mania; Memory Impairment; Tension; Tremor

Escitalopram Mepha Was Discontinued After About 1 Week

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2015	10921099	EXPEDITED (15-DAY)		HO	IT-FRI-1000075276		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Abuse; Overdose; Oxygen Saturation Decreased	Escitalopram			S	Oral	Escitalopram 400 Mg Once		Forest
	Cardioaspirin			C	Oral			Not Reported
	En			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2015	10930205	NON-EXPEDITED			US-PFIZER INC-2015093348		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2015	10932045	EXPEDITED (15-DAY)		HO	FR-FRI-1000075344		34 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Miosis; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral	Overdose: 280 Mg.		Forest
	Theralene			S	Oral	Overdose: 1 Bottle Of Alimemazine 4 % Nos.		Not Reported
	Zopiclone			S	Oral	Overdose: 105 Mg.		Not Reported
	Tetrazepam			S	Oral	Overdose: 950 Mg.		Not Reported
	Diazepam			S	Oral	100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2015	10932046	EXPEDITED (15-DAY)		DE	FR-FRI-1000075347		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Dyspnoea; Pericardial Effusion	Escitalopram			S	Oral			Forest
	Laroxyl			S	Intravenous (not otherwise specified)	50 Mg/2 Ml		Not Reported
	Foziretic			C	Oral	20 Mg/12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2015	10932566	DIRECT	Y				26 YR	Male	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2015	10932708	DIRECT		DS			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression Suicidal; Dizziness; Drug Ineffective; Drug Withdrawal Syndrome; Fall; Insomnia; Irritability; Tremor	Escitalopram Teva			S	Oral			Teva
	Liothyronine			C				Not Reported
	Levothyroxine			C				Not Reported
	Alprazolam			C				Not Reported
	Vitamin D Nos			C				Not Reported
	B12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2015	10854202	EXPEDITED (15-DAY)		DE, HO	FR-ABBVIE-15P-056-1350738-00		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Creon 25000 Iu			S	Oral			Not Reported

	Kardegic	S	Oral		Not Reported
	Atorvastatine	S	Oral		Not Reported
	Klipal Codeine	S	Oral		Not Reported
	Insulatard	S	Subcutaneous	22 Iu At Morning And 10 Iu At Evening	Not Reported
	Seroplex	S	Oral		Not Reported
	Ramipril	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2015	10874806	EXPEDITED (15-DAY)		CA	US-FRI-1000074713			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Anomaly; Congenital Diaphragmatic Eventration; Dextrocardia; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus	Escitalopram			S	Transplacental			Forest
	Topiramate			S	Transplacental			Not Reported
	Oxycodone/Acetominophen			S	Unknown			Not Reported
	Prenatal Multivitamins			S	Transplacental			Not Reported
	Tramadol			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2015	10932953	EXPEDITED (15-DAY)		HO	BR-PFIZER INC-2015092288		73 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Cerebrovascular Accident; Headache; Nausea; Somnolence	Atorvastatin Calcium			S	Oral	20 Mg, At Night		Pfizer
	Seroquel			S		Unk		Not Reported
	Exodus//Escitalopram Oxalate			S		Unk		Not Reported
	Vasopril [Enalapril Maleate]			C	Oral	25 Mg, Every Morning		Not Reported
	Citoneurin			C				Not Reported
	Aas			C		2 "Cp" (Unspecified Formulation) Of 100mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2015	10933774	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2015M1007825			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Abuse; Overdose; Oxygen Saturation Abnormal	Escitalopram Oxalate			S	Oral	400 Mg, Total		Not Reported
	Cardioaspirin			C				Not Reported
	En			C	Oral	Unk Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2015	10936076	EXPEDITED (15-DAY)		DE	US-WATSON-2015-04472		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Verapamil Hydrochloride (Watson Laboratories)			S	Oral	Unknown		Watson
	Escitalopram (Unknown)			S	Oral	Unknown		Not Reported
	Codeine (Unknown)			S	Oral	Unknown		Not Reported
	Topiramate (Watson Laboratories)			S	Oral	Unknown		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2015	10941775	EXPEDITED (15-DAY)		DE	US-ACTAVIS-2015-06119		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Temazepam (Aellc)			S	Oral	Unk		Watson
	Lorazepam (Watson Laboratories)			S	Oral	Unk		Watson
	Primidone (Watson Laboratories)			S	Oral	Unk		Watson
	Lamotrigine (Watson Laboratories)			S	Oral	Unk		Watson
	Escitalopram (Unknown)			S	Oral	Unk		Not Reported
	Benztropine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2015	10943336	EXPEDITED (15-DAY)		DE	US-WATSON-2015-05352		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Atenolol (Watson Laboratories)			S	Unknown	Unknown		Watson
	Primidone (Watson Laboratories)			S	Unknown	Unknown		Watson
	Escitalopram (Unknown)			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2015	10943341	EXPEDITED (15-DAY)		DE	US-ACTAVIS-2015-05346		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion; Toxicity To Various Agents	Clonazepam (Aellc)			S	Oral	Unknown		Watson
	Trazodone Hydrochloride (Watson Laboratories)			S	Oral	Unknown		Watson
	Oxybutynin Core			S	Oral	Unknown		Watson
	Quetiapine (Agptc)			S	Oral	Unknown		Actavis
	Lamotrigine (Watson Laboratories)			S	Oral	Unknown		Watson
	Finasteride (Atllc)			S	Oral	Unknown		Actavis Totowa
	Acetylsalicylic Acid (Unknown)			S	Oral	Unknown		Not Reported
	Escitalopram (Unknown)			S	Oral	Unknown		Not Reported
	Digoxin (Unknown)			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2015	10943421	EXPEDITED (15-DAY)		DE	US-WATSON-2015-05712		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zolpidem Tartrate (Watson Laboratories)			S	Unknown	Unk		Watson

	Escitalopram (Unknown)		S	Unknown	Unk	Not Reported
	Methamphetamine		S	Unknown	Unk	Not Reported
	Ethanol		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2015	10943961	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2015001656			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Micturition Urgency; Pollakiuria; Rash Generalised; Wheezing	Escitalopram 20mg Tablet			S	Oral	20 Mg, Unk		Macleods
	Nortriptyline			S	Oral	50 Mg, Tid		Not Reported
	Crestor			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2015	10949296	DIRECT					51 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyperhidrosis	Mucinex		Y	S	Oral			Reckitt Benckiser
	Lexapro			S	Oral			Not Reported
	Lisinopril			C				Not Reported
	Lunesta			C				Not Reported
	Tizandine (Tizandine Hydrochloride)			C				Not Reported
	Calcium			C				Not Reported
	Omega 3			C				Not Reported
	Vitamin B 12			C				Not Reported
	Pesudoephedrine			C				Not Reported
	Diphenhydramine			C				Not Reported
	Flonase Nasal Spray			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2015	10952894	EXPEDITED (15-DAY)	Y	OT	ADR-2015-00559		30 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Clonus; Condition Aggravated; Drug Eruption; Drug-Induced Liver Injury; Hyperreflexia; Hypertonia; Hyporeflexia; Muscle Rigidity; Muscle Spasms; Muscle Tightness; Musculoskeletal Stiffness; Pain In Extremity	Baclofen		N	S				Not Reported
	Pregabalin			S				Not Reported
	Carbamazepine			S				Not Reported
	Escitalopram			S				Not Reported
	Phenytoin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2015	10611809	EXPEDITED (15-DAY)		HO, LT	JP-FRI-1000072705		59 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Loss Of Consciousness; Nausea; Urinary Incontinence; Vomiting	Lexapro			S	Oral	10 Mg		Forest
	Gasmotin			C	Oral			Not Reported
	Frandol S			C	Transdermal	1 Mg		Not Reported
	Livalo Od			C	Oral	1 Mg		Not Reported
	Nifedipine Cr			C	Oral	40 Mg		Not Reported
	Nicorandil			C	Oral	15 Mg		Not Reported
	Rozerem			C	Oral	8 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2015	10905215	EXPEDITED (15-DAY)		HO	IT-FRI-1000075117		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplegia; Paralysis; Withdrawal Syndrome	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Seroquel Rp			S	Oral	50 Mg		Not Reported
	Seroquel Rp			S	Oral	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2015	10947959	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2015-02478		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Burning Sensation; Decreased Appetite; Hyperthermia; Pyrexia	Mirtazapine Arrow 15mg			S	Oral	15 Mg, Daily		Aurobindo
	Noctamide			S	Oral	2 Mg, Daily		Not Reported
	Seroplex			S	Unknown	20 Mg, Daily		Not Reported
	Tercian /00759301/			S	Oral	60 Gtt, Daily		Not Reported
	Theralene			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Lamaline /00764901/			C	Unknown	Unk		Not Reported
	Ibuprofene			C	Unknown	Unk		Not Reported
	Trimebutine Almus			C	Unknown	Unk		Not Reported
	Meteospasmyl /01017401/			C	Unknown	Unk		Not Reported
	Isoptine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2015	10948040	EXPEDITED (15-DAY)		OT	GB-ACCORD-029486		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Micturition Urgency; Pollakiuria; Rash Generalised; Urinary Incontinence; Wheezing	Escitalopram			S	Oral			Accord
	Nortriptyline			S	Oral			Not Reported
	Crestor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2015	10950740	EXPEDITED (15-DAY)		DE	NL-PFIZER INC-2015101655		56 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Alprazolam			S		0.5 Mg, 3x/Day As Needed		Pfizer

	Trazolan	S	100 Mg, 1x/Day As Needed	Unknown
	Medikinet	S	20 Mg, 1x/Day	Not Reported
	Medikinet	S	40 Mg, 1x/Day	Not Reported
	Medikinet	S	50 Mg, 1x/Day	Not Reported
	Lexapro	S	15 Mg, 1x/Day	Not Reported
	Zopiclon	S	15 Mg, 2x/Day As Needed	Not Reported
	Omeprazol	C	20 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2015	9631713	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMPANY-FR201310003041		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Zyprexa			S	Oral	5 Mg, Qd		Eli Lilly And Co
	Seroplex			S	Oral	1 Df, Unknown		Not Reported
	Lorazepam			C	Oral	1 Df, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2015	10952121	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-02494		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Micturition Urgency; Pollakiuria; Rash Generalised; Urinary Incontinence; Wheezing	Escitalopram 20 Mg			S	Oral	20 Mg, Unk		Aurobindo
	Nortriptyline			S	Oral	50 Mg, 3 Times A Day		Not Reported
	Crestor			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2015	10953073	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2015US02280			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S				Cipla

	Escitalopram	S		Teva
	Zonisamide	S		Not Reported
	Lorazepam	S		Not Reported
	Lovastatin	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2015	10953253	NON-EXPEDITED			US-PFIZER INC-2015092606			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer
	Bactrim			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Albuterol			S		Unk		Not Reported
	Advair			S		Unk		Not Reported
	Mobic			S		Unk		Not Reported
	Pravachol			S		Unk		Not Reported
	Dyazide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2015	10953676	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2015US02392			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zolpidem Tartarate			S				Cipla
	Ethanol			S				Not Reported
	Methamphetamine			S				Not Reported
	Escitaopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2015	10956620	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Product Substitution Issue	Escitalopram			S	Oral	1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2015	10573727	EXPEDITED (15-DAY)		HO	JP-FRI-1000072173		76 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Seizure	Lexapro			S	Oral	10 Mg		Forest
	Bayaspirin			C	Oral	100 Mg		Not Reported
	Zetia			C	Oral	10 Mg		Not Reported
	Crestor			C	Oral	2.5 Mg		Not Reported
	Fluitran			C	Oral	2 Mg		Not Reported
	Farom			C	Oral	100 Mg		Not Reported
	Artist			C	Oral	5 Mg		Not Reported
	Prazaxa			C	Oral	220 Mg		Not Reported
	Nexium			C	Oral	20 Mg		Not Reported
	Halcion			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2015	10707412	EXPEDITED (15-DAY)		OT	US-ASTELLAS-2015US000304		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Decreased Appetite; Feeling Abnormal; Headache; Herpes Virus Infection; Hypertension; Insomnia; Memory Impairment; Myalgia; Paraesthesia; Unevaluable Event; Weight Decreased	Vesicare			S	Unknown	Unk Unk, Once Daily		Astellas
	Effexor			S	Unknown			Not Reported
	Effexor			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Celebrex			C	Unknown	200 Unk, Unknown Freq.		Not Reported
	Azathioprin			C	Unknown	50 Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine			C	Unknown	200 Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2015	10750143	EXPEDITED (15-DAY)		HO, OT	PHHY2015ES009237		24 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Gilenya			S	Unknown			Novartis
	Gilenya			S	Oral	56 Tablets At One Time		Novartis
	Escitalopram			S	Oral	24 Tablets At One Time		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2015	10934637	NON-EXPEDITED		HO	ES-JNJFOC-20150307838		59 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Drug Interaction; Transplant Dysfunction	Simeprevir			S	Oral			Not Reported
	Sofosbuvir			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2015	10955497	EXPEDITED (15-DAY)		OT	US-ACCORD-029559		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exfoliative Rash; Subacute Cutaneous Lupus Erythematosus	Escitalopram			S				Accord
	Metoprolol			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Dipyridamole			S				Not Reported
	Levothyroxine			S				Not Reported
	Pravastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2015	10956131	EXPEDITED (15-DAY)		OT	GB-TEVA-549142ACC		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cough; Micturition Urgency; Pollakiuria; Rash Generalised; Wheezing	Escitalopram	S	Oral			Ivax
	Nortriptyline	S	Oral	150 Milligram Daily;		Not Reported
	Crestor	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2015	10957556	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20150318732		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Tramadol Hydrochloride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Triamcinolone			S	Intramuscular			Not Reported
	Triamcinolone			S	Intramuscular			Not Reported
	Triamcinolone			S	Intramuscular			Not Reported
	Triamcinolone			S	Intramuscular			Not Reported
	Baclofen			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Oxazepam			C	Unknown			Not Reported
	Oxazepam			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Alfuzosin			C	Unknown			Not Reported
	Trospium			C	Unknown			Not Reported
	Quetiapine			C	Unknown			Not Reported
	Quetiapine			C	Unknown			Not Reported
	Quetiapine			C	Unknown			Not Reported
	Zolpidem			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2015	10959295	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2015US02401			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S				Cipla
	Temazepam			S				Not Reported
	Lorazepam			S				Not Reported
	Primidone			S				Not Reported
	Escitalopram			S				Not Reported
	Benztropine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2015	10959317	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2015US02439			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Meloxicam			S				Cipla
	Escitalopram			S				Not Reported
	Loperamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2015	10959338	EXPEDITED (15-DAY)		DE, OT	US-CIPLA LTD.-2015US02291			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Zolpidem Tartarate			S				Cipla
	Sertraline			S				Cipla
	Amitriptyline			S				Not Reported
	Tramadol			S				Not Reported
	Acetaminophen/Hydrocodone			S				Not Reported
	Ondansetron			S				Not Reported
	Linaclotide			S				Not Reported
	Diclofenac			S				Not Reported
	Lubiprostone			S				Not Reported
	Liothyronine			S				Not Reported
	Escitalopram			S				Not Reported
	Gabapentin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2015	10959341	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2015US02296			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Sertraline			S				Cipla
	Atomoxetine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2015	10959863	EXPEDITED (15-DAY)		OT	US-ACCORD-029591			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Escitalopram Oxalate Accord			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2015	10961059	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2015US02315			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S				Teva
	Topiramate			S				Cipla
	Promethazine			S				Not Reported
	Verapamil			S				Not Reported
	Acetaminophen/Hydrocodone			S				Not Reported
	Diazepam			S				Not Reported
	Esomeprazole			S				Not Reported
	Diclofenac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2015	10961129	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2015US02328			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Topiramate			S				Cipla
	Verapamil			S				Not Reported
	Escitalopram			S				Not Reported

	Codeine		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2015	10963484	DIRECT					63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Drug Ineffective; Impaired Driving Ability; Insomnia; Memory Impairment	Gilenya			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2015	10966280	DIRECT					36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory	Escitalopram			S	Oral	1 Pill	3 DAY	International Labs

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2015	10557289	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2014300572		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder; Agitation; Anhedonia; Anxiety; Apathy; Depressed Mood; Derealisation; Disturbance In Attention; Eating Disorder; Feelings Of Worthlessness; Haematemesis; Headache; Impaired Work Ability; Insomnia; Lethargy; Mania; Mental Disorder; Mental Impairment; Nausea; Palpitations; Panic Attack;	Zoloft			S	Oral	25 Mg, 1x/Day		Pfizer
	Zoloft			S				Pfizer
	Zoloft			S				Pfizer
	Zoloft			S				Pfizer
	Celexa			S	Oral	10 Mg, 1x/Day		Not Reported
	Celexa			S				Not Reported
	Lexapro			S	Oral	5 Mg, Daily		Not Reported
	Lexapro			S		10mg, Unk		Not Reported
	Ambien			S	Oral	5 Mg, Unk		Not Reported
	Ambien			S	Oral	10 Mg, 1x/Day Before Sleep		Not Reported
	Multivitamins			C		Unk		Not Reported

Paranoia; Suicidal Ideation; Tachyphrenia; Tremor; Vomiting; Weight Decreased; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2015	10920518	EXPEDITED (15-DAY)		OT	PHHY2015BR030111			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Condition Aggravated; Depression; Disturbance In Attention; Feeling Abnormal; Headache; Nephrolithiasis; Osteoporosis	Deserila			S	Oral	1 Df, Qd		Not Reported
	Diclofenac			S	Unknown			Novartis
	Citalopram			S	Unknown			Not Reported
	Olcadil			S	Oral	1 Df, Qd		Not Reported
	Neosaldina			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Buscopan			S	Unknown			Not Reported
	Venlafaxine			C	Oral	1 Df, Qd		Not Reported
	Venlafaxine			C				Not Reported
	Depakote			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2015	10966082	NON-EXPEDITED			US-MYLANLABS-2014M1012235		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Oropharyngeal Pain	Fentanyl			S	Transdermal	50 Mg, Qh, Changed Q48h		Not Reported
	Lyrica			S		300 Mg, Bid		Not Reported
	Tizanidine			S		8 Mg, Tid		Not Reported
	Tizanidine			S				Not Reported
	Tizanidine			S				Not Reported
	Oxycodone And Acetaminophen			S		10 Mg, Tid		Not Reported

Seroquel	S	300 Mg, Qd	Not Reported
Seroquel	S		Not Reported
Seroquel	S		Not Reported
Metformin	S	1000 Mg, Qd	Not Reported
Venlafaxine	S	150 Mg, Qd	Not Reported
Venlafaxine	S	75 Mg, Qd	Not Reported
Lexapro	S	20 Mg, Qd	Not Reported
Valium	S	5 Mg, Tid	Not Reported
Aspirin /00002701/	S	162 Mg, Hs	Not Reported
Simvastatin	S	40 Mg, Unk	Not Reported
Topamax	S	100 Mg, Am	Not Reported
Ibuprofen	S	800 Mg, Am	Not Reported
Demadex /01036501/	S	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2015	10968354	EXPEDITED (15-DAY)		HO, OT	PHHY2015US035699		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Body Temperature Increased; Clonus; Hyperhidrosis; Hyperreflexia; Hypotonia; Muscle Rigidity; Mydriasis; Overdose; Serotonin Syndrome; Sinus Tachycardia	Metaxalone			S	Unknown	800 Mg, Qid		Novartis
	Escitalopram			S	Unknown	30 Mg, Qd		Not Reported
	Alpon//Alprazolam			C	Unknown	1 Mg, Qhs		Not Reported
	Clonazepam			C	Unknown	1 Mg, Tid		Not Reported
	Prazosin			C	Unknown	2 Mg, Qhs		Not Reported
	Propranolol			C	Unknown	80 Mg, Qd		Not Reported
	Quetiapine			C	Unknown	200 Mg, Qhs		Not Reported
	Butalbital, Acetaminophen And Caffeine			C	Unknown	415 Mg, Bid		Not Reported
	Mometasone			C	Nasal	50mcg/Act 2 Sprays Daily		Not Reported
	Apo Prednison			C	Oral	40 Mg, Qd		Not Reported
	Triamcinolone			C	Topical	0.1 %, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2015	10968725	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00003049			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Escitalopram Tablets Usp 10mg			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2015	10970407	DIRECT					52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Disturbance In Attention; Panic Reaction; Paraesthesia; Product Substitution Issue	Escitalopram Tab 10 Mg Torrent			S	Oral	1 Tablet Taken By Mouth		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2015	10257880	EXPEDITED (15-DAY)		HO, LT	AT-FRI-1000068460		43 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Brain Oedema; Coma; Constipation; Demyelination; Dysarthria; Extensor Plantar Response; Fatigue; Gait Disturbance; Gastrooesophageal Reflux Disease; Headache; Hiatus Hernia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Laryngospasm; Leukoencephalopathy;	Escitalopram			S	Oral	10 Mg		Forest

Mouth Swelling; Myopia;
Nasal Congestion;
Nystagmus; Seizure;
Syncope; Vocal Cord
Paralysis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2015	10970075	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2015-00343			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Condition Aggravated	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2015	10970136	NON-EXPEDITED		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00407		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2015	10970146	NON-EXPEDITED		DE	US-LUPIN PHARMACEUTICALS INC.-2015-00421		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Digoxin			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Oxybutynin			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported

	Lamotrigine	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Finasteride	S	Oral	Not Reported
	Salicylate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2015	10971357	NON-EXPEDITED			US-TEVA-550299USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Exposure Via Breast Milk; Nausea; Suppressed Lactation	Plan B One-Step			S	Oral	1.5 Milligram Daily;		Duramed
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2015	10972699	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2015M1008946			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Micturition Urgency; Pollakiuria; Rash Generalised; Wheezing	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Nortriptyline			S	Oral	50 Mg, Tid		Not Reported
	Crestor			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2015	10973764	DIRECT		OT			90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Depression; Dissociation; Gait Inability; Hallucinations, Mixed	Escitalopram 10mg Camber			S	Oral	1 Tab		Camber
	Nexum			C				Not Reported
	Lipator			C				Not Reported
	Prostate Drug			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2015	10990648	NON-EXPEDITED	Y	HO	2014000047		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Suicidal Ideation	Trazodone (Trazodone) Tablet			S	Oral			Not Reported
	Atorvastatin Calcium (Atorvastatin Calcium) Tablet			S	Oral			Not Reported
	Escitalopram Oxalate (Escitalopram Oxalate)			S	Oral			Not Reported
	Invega (Paliperidone Palmitate)			C				Not Reported
	Bumetanide			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Lantus (Insulin Glargine)			C				Not Reported
	Labetalol			C				Not Reported
	Losartan			C				Not Reported
	Simvastatin			C				Not Reported
	Aspirin (Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2015	10862628	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC-2015062451		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Dyspnoea; Haemoglobin Decreased; Neoplasm Malignant; Oedema Peripheral; Thrombocytopenia	Ramipril			S	Oral	10 Mg, Daily		Pfizer
	Atorvastatin Calcium			S	Oral	10 Mg, Daily		Pfizer
	Kardegic			S	Oral	1 Df, Daily		Not Reported
	Seroplex			S	Oral	1 Df, Daily		Not Reported
	Klipal Codeine			S	Oral	2 Df, Daily		Not Reported
	Creon			S	Oral	Unk		Not Reported
	Insulatard			S	Subcutaneous	Unk, 2x/Day (22 Iu In Morning And 10 Iu In The Evening)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2015	10863848	EXPEDITED (15-DAY)		DS	PT-TEVA-542519ISR		57 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dysgeusia; Fatigue; Headache; Malaise; Tinnitus; Tremor	Escitalopram Ratiopharm		S	Oral	Ivax
	Surmontil 25		C	Oral	Not Reported
	Unilan		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2015	10975279	EXPEDITED (15-DAY)		OT	GB-FRI-1000075553		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Micturition Urgency; Pollakiuria; Rash Generalised; Wheezing	Escitalopram			S	Oral	20 Mg		Forest
	Nortriptyline			S	Oral	150 Mg		Not Reported
	Crestor			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2015	10975281	EXPEDITED (15-DAY)		HO	FR-FRI-1000075531		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia	Escitalopram			S		20 Mg		Forest
	Mirtazapine Arrow			S	Oral	15 Mg		Arrow
	Noctamide			S	Oral	2 Mg		Not Reported
	Tercian			S		60 Df		Not Reported
	Theralene			S	Oral	30 Drops At Bed Time		Not Reported
	Diazepam Choay			S		1 Df		Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			C				Not Reported
	Ibuprofen Agi Pharma			C				Not Reported
	Trimebutine Almus			C				Not Reported
	Meteospasmyl (Alverine Citrate\Dimethicone)			C				Not Reported
	Isoptine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2015	10975282	EXPEDITED (15-DAY)		OT	FR-FRI-1000075579		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Morbid Thoughts	Escitalopram			S	Oral	1 Df		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2015	10052902	EXPEDITED (15-DAY)		HO	DK-TEVA-471831ISR			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Fatigue; Gait Disturbance; Hepatic Encephalopathy; Hepatic Failure; Hypoaesthesia; Lethargy; Motor Dysfunction; Muscle Contractions Involuntary; Muscle Spasms; Muscle Tightness; Musculoskeletal Stiffness; Myalgia; Restlessness; Serotonin Syndrome; Tremor	Modiodal			S	Unknown			Cephalon
	Cipralex			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Alopam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2015	10055775	EXPEDITED (15-DAY)		HO	DK-TEVA-472509ISR		54 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Fatigue; Hepatic Encephalopathy; Hepatic Failure; Hypoaesthesia; Hypokinesia; Hypokinesia;	Modiodal			S	Oral			Cephalon
	Cipralex			S	Oral	30 Milligram Daily;		Not Reported
	Cymbalta			S	Oral	120 Milligram Daily;		Not Reported
	Alopam			C	Oral			Not Reported

Lethargy; Motor Dysfunction; Muscle Contractions Involuntary; Muscle Spasms; Muscle Tightness; Musculoskeletal Stiffness; Myalgia; Restlessness; Serotonin Syndrome; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2015	10954463	EXPEDITED (15-DAY)		OT	CH-GLAXOSMITHKLINE-CH2015035840		41 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism	Lamictal			S	Oral	Unk		Glaxosmithkline
	Lamictal			S	Oral	200 Mg, Bid		Glaxosmithkline
	Tecfidera			S	Oral	240 Mg, Bid		Not Reported
	Escitalopram			S	Oral	10 Mg, Qod		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2015	10978658	EXPEDITED (15-DAY)		OT	GB-WATSON-2015-06935		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Micturition Urgency; Pollakiuria; Rash Generalised; Wheezing	Escitalopram (Unknown)			S	Oral	20 Mg, Unk		Not Reported
	Nortriptyline Hydrochloride (Watson Laboratories)			S	Oral	50 Mg, Tid		Watson
	Crestor			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2015	10981853	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000075516		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta;	Lexapro			S	Transplacental			Forest

Congenital Anomaly;
Foetal Exposure During
Pregnancy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2015	10215854	NON-EXPEDITED		HO, OT	CA-JNJFOC-20140517961		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Exposure During Pregnancy; Fall; Hidradenitis; Product Use In Unapproved Indication; Skin Laceration	Remicade			S	Intravenous (not otherwise specified)	15th Infusion		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Infusion Number 14		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Vials		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Metformin			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Gravol			S	Unknown			Not Reported
	Metamucil			S	Unknown			Not Reported
	Ativan			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Diclectin			S	Unknown	Started In Pregnancy With This		Not Reported
	Rabeprazole			S	Unknown			Not Reported
	Prenatal Vitamins			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2015	10985118	EXPEDITED (15-DAY)		HO	PHHY2015CH037482		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Affect Lability; Aggression; Disinhibition; Drug Interaction; Energy Increased; Euphoric Mood; Euphoric Mood; Flight Of Ideas; Grandiosity; Impulsive Behaviour; Irritability; Logorrhoea; Mania; Psychomotor Hyperactivity; Serotonin Syndrome; Sleep Disorder; Tachyphrenia; Weight Decreased	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Tramadol			S	Unknown	50 Mg, Bid		Novartis
	Triamcinolone			S	Intramuscular	40 Mg, Unk		Not Reported
	Cannabis			S	Unknown			Not Reported
	Quetiapine			C	Unknown	300 Mg, Qd		Not Reported
	Quetiapine			C	Unknown	1000 Mg, Qd		Not Reported
	Quetiapine			C	Unknown	800 Mg, Qd		Not Reported
	Oxazepam			C	Unknown	60 Mg, Qd		Not Reported
	Oxazepam			C	Unknown	180 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	2 Mg, Qd		Not Reported
	Zolpidem			C	Unknown	12.5 Mg, Qd		Not Reported
	Baclofen			C	Unknown	150 Mg, Qd		Not Reported
	Candesartan			C	Unknown	8 Mg, Qd		Not Reported
	Metformin			C	Unknown	500 Mg, Unk		Not Reported
	Atorvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Alfuzosin			C	Unknown	10 Mg, Qd		Not Reported
	Trospium Chloride			C	Unknown	20 Mg, Qd		Not Reported
	Acetaminophen			C	Unknown	4 G, Qd		Not Reported
	Ibuprofen			C	Unknown	1800 Mg, Qd		Not Reported
	Alcohol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2015	10054066	EXPEDITED (15-DAY)		HO	DK-FRI-1000066025		54 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Fatigue; Hepatic Encephalopathy; Hepatic Failure;	Escitalopram			S	Oral	30 Mg		Forest
	Modiodal			S	Oral	Styrke: 100 Mg.		Not Reported
	Cymbalta			S	Oral	120 Mg		Not Reported

Hypoaesthesia; Hypokinesia; Lethargy; Motor Dysfunction; Muscle Contractions Involuntary; Muscle Spasms; Muscle Tightness; Musculoskeletal Stiffness; Myalgia; Restlessness; Serotonin Syndrome; Tremor	Alopam		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2015	10576332	EXPEDITED (15-DAY)		HO, OT	US-SA-2014SA153437		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anhedonia; Anxiety; Apathy; Crying; Daydreaming; Decreased Appetite; Depressed Mood; Disturbance In Attention; Fear; Feeding Disorder; Feeling Of Despair; Haematemesis; Hallucination; Headache; Impaired Work Ability; Insomnia; Lethargy; Major Depression; Mania; Mental Impairment; Nausea; Palpitations; Palpitations; Paranoia; Suicidal Ideation; Tremor; Vomiting; Weight Decreased	Ambien			S	Oral			Not Reported
	Ambien			S	Oral			Not Reported
	Zoloft			S	Oral			Not Reported
	Zoloft			S	Oral			Not Reported
	Celexa			S	Oral			Not Reported
	Celexa			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Panthenol/Retinol/Thiamine Hydrochloride/Ascorbic Acid/Ergocalciferol/Folic Acid/Riboflavin/Nicotina			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2015	10683516	EXPEDITED (15-DAY)		HO	IT-FRI-1000073378		30 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Overdose; Nausea; Tremor	Escitalopram		S	Oral	Overdose:60 Mg Total In Single Day	Forest
	Escitalopram		S		5 Mg	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2015	10990453	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015114085		59 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia With Lewy Bodies; Depression; Drug Hypersensitivity; Parkinsonism	Jzoloft			S	Oral	25 Mg, Daily		Pfizer
	Risperidone			S		1 Mg, Daily		Not Reported
	Risperidone			S		2 Mg, Daily		Not Reported
	Flunitrazepam			S		1 Mg, Daily		Not Reported
	Escitalopram			S		10 Mg, Daily		Not Reported
	Mirtazapine			S		15 Mg, Daily		Not Reported
	Olanzapine			S		5 Mg, Daily		Not Reported
	Olanzapine			S		10 Mg, Daily		Not Reported
	Aripiprazole			S		6 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2015	10991704	EXPEDITED (15-DAY)		HO	PHHY2015CA037404		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Piperacillin+Tazobactam Sandoz			S	Unknown			Novartis
	Ciprofloxacin			S	Oral	1000 Mg, Unk		Not Reported
	Ciprofloxacin			S	Intravenous (not otherwise specified)			Not Reported
	Morphine			S	Unknown	2.5 Mg, Q4h		Not Reported
	Avastin			S	Intravenous (not otherwise specified)	15 Mg/Kg, Unk		Not Reported
	Trastuzumab			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported

Tylenol No.1 Forte	S	Unknown			Not Reported
Tylenol	S	Unknown			Not Reported
Carboplatin	S	Intravenous (not otherwise specified)			Not Reported
Cipralex	S	Unknown	10 Mg, Qd		Not Reported
Docetaxel	S	Intravenous (not otherwise specified)	75 Mg/M2, Unk		Not Reported
Docetaxel	S	Intravenous (not otherwise specified)	75 Mg/M2, Unk		Not Reported
Docusate	C	Unknown			Not Reported
Gravol	C	Unknown			Not Reported
Lactulose	C	Unknown			Not Reported
Codeine	C	Unknown			Not Reported
Senna	C	Unknown			Not Reported
Trazodone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2015	10994222	DIRECT	Y	OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Activity; Depression; Product Substitution Issue	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2015	10994825	DIRECT		OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Serotonin Syndrome	Lexapro			S	Oral	1 Pill, Taken By Mouth	8 YR	Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2015	10997629	EXPEDITED (15-DAY)	Y	HO	US-TORRENT-00000918			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack	Escitalopram Tablets			S			2 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2015	10050122	EXPEDITED (15-DAY)		HO, OT	DK-ELI_LILLY_AND_COMPANY-DK201403008928		54 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Coma Hepatic; Depressed Level Of Consciousness; Drug Interaction; Fatigue; Hepatic Cirrhosis; Hepatic Encephalopathy; Hepatic Failure; Hypoaesthesia; Hypokinesia; Incoherent; Lethargy; Motor Dysfunction; Muscle Contractions Involuntary; Muscle Spasms; Muscle Tightness; Muscle Twitching; Musculoskeletal Stiffness; Myalgia; Serotonin Syndrome; Tremor	Cymbalta			S	Oral	120 Mg, Unknown		Eli Lilly And Co
	Modiodal			S	Oral	200 Mg, Qd		Not Reported
	Modiodal			S	Oral	400 Mg, Qd		Not Reported
	Cipralex /01588502/			S	Oral	20 Mg, Unknown		Not Reported
	Cipralex /01588502/			S	Oral	30 Mg, Unknown		Not Reported
	Cipralex /01588502/			S	Oral	120 Mg, Unknown		Not Reported
	Alopam			C	Oral	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2015	10732731	EXPEDITED (15-DAY)		OT	CZ-FRI-1000073718		4 DAY	Unknown	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Neonatal Seizure	Escitalopram			S	Transmammary			Forest
	Fluvoxamin			S	Transmammary			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2015	10732733	EXPEDITED (15-DAY)		OT	CZ-FRI-1000073720		4 DAY	Unknown	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Breast Feeding; Neonatal Seizure	Escitalopram			S	Transmammary			Forest
	Fluvoxamin			S	Transmammary			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2015	10953873	EXPEDITED (15-DAY)		OT	CH-TEVA-549212ISR		42 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism; Serum Ferritin Decreased	Escitalopram Mepha 5 Mg			S	Oral	Continuing, 1 Tablet Every 2 Days		Ivax
	Tecfidera			S	Oral	480 Milligram Daily; Continuing		Not Reported
	Lamictal			S	Oral			Not Reported
	Lamictal			S	Oral	350 Milligram Daily; 150mg-0-200mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2015	10993184	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-E2B_00003193		24 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rash; Toxicity To Various Agents	Stalopam			S	Oral			Not Reported
	Lithium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2015	10995746	EXPEDITED (15-DAY)		OT	GB-FRI-1000075626		20 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Dreams; Abnormal Dreams; Anorgasmia; Anxiety; Confusional State; Derealisation; Dissociation; Flatulence; Genital Hypoaesthesia; Menorrhagia; Nausea; Paraesthesia; Restlessness	Escitalopram	S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2015	10995748	NON-EXPEDITED			US-PFIZER INC-2015119331			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Tetracycline Hcl			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Bleph-10			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2015	10996178	EXPEDITED (15-DAY)		HO, OT	CH-MYLANLABS-2015M1011175			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Mania	Tramadol			S	Unknown			Mylan
	Escitalopram			S	Unknown	20/Mg/Day		Mylan
	Triamcinolone			S	Intramuscular	40 Mg One Month Apart		Not Reported
	Quetiapine			C	Unknown	300 Mg/Day		Not Reported
	Oxazepam			C	Unknown	60 Mg/Day		Not Reported
	Alprazolam			C	Unknown	2 Mg/Day		Not Reported
	Zolpidem			C	Unknown	12.5 Mg/Day		Not Reported
	Baclofen			C	Unknown	150 Mg/Day		Not Reported
	Candesartan Cilexetil			C	Unknown	8 Mg/Day		Not Reported
	Metformin			C	Unknown	500 Mg/Day		Not Reported

Atorvastatin	C	Unknown	20 Mg/Day		Not Reported
Alfuzosin	C	Unknown	10 Mg/Day		Not Reported
Trospium Chloride	C	Unknown	20 Mg/Day		Not Reported
Ibuprofen	C	Unknown	1800 Mg/Day		Not Reported
Paracetamol	C	Unknown	4 Gm/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2015	10998089	DIRECT		OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Mental Disorder; Product Quality Issue; Product Substitution Issue	Escitalopram 10mg Walgreens			S	Oral			Walgreen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2015	10999059	EXPEDITED (15-DAY)		HO	CH-FRI-1000075675		78 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Pruritus; Rash Erythematous; Transaminases Increased	Escitalopram			S	Oral	20 Mg		Forest
	Irfen Lactab			S	Oral	800 Mg		Not Reported
	Dafalgan			C	Occlusive dressing technique	3000 Mg		Not Reported
	Anxiolit			C	Oral	7.5 Mg		Not Reported
	Clexane			C	Subcutaneous	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2015	11002052	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-022277		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Triamcinolone Acetonide			S	Intramuscular	40 Mg, Qmo		Bristol Myers Squibb

Triamcinolone Acetonide	S				Bristol Myers Squibb
Tramadol	S	Unknown	50 Mg, Bid		Not Reported
Escitalopram	S	Unknown	20 Mg, Qd		Not Reported
Paracetamol	C	Unknown	4 G, Qd		Bristol Myers Squibb
Paracetamol	C				Bristol Myers Squibb
Ibuprofen	C	Unknown	1800 Mg, Qd		Not Reported
Ibuprofen	C				Not Reported
Quetiapine	C	Unknown	300 Mg, Qd		Not Reported
Oxazepam	C	Unknown	60 Mg, Qd		Not Reported
Alprazolam	C	Unknown	2 Mg, Qd		Not Reported
Zolpidem	C	Unknown	12.5 Mg, Qd		Not Reported
Baclofen	C	Unknown	150 Mg, Qd		Not Reported
Candesartan	C	Unknown	8 Mg, Qd		Not Reported
Metformin	C	Unknown	500 Mg, Qd		Not Reported
Atorvastatin	C	Unknown	20 Mg, Qd		Not Reported
Alfuzosin	C	Unknown	10 Mg, Qd		Not Reported
Trospium	C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2015	11003289	DIRECT		DE			27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Headache; Hyperhidrosis; Insomnia	Escitalopram			S	Oral	1 1/2 To 2 Years, Once Daily, Taken By Mouth	2 YR	Cvs Caremark
	Synthroid			C				Not Reported
	Multi Vitamins			C				Not Reported
	Herbal Remedies			C				Not Reported
	Lexapro			S				Not Reported
	Citalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2015	10870056	EXPEDITED (15-DAY)	Y	OT	ADR-2015-00365		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diastolic Dysfunction; Dyspnoea; Mitral Valve Stenosis; Supraventricular Tachycardia	Baclofen			S	Intrathecal Intrathecal Intrathecal Intrathecal Intrathecal Intrathecal Intrathecal Intrathecal Intrathecal Intrathecal Intrathecal Intrathecal			Not Reported
	Norvasc (Amlodipine Besilate)			S				Not Reported
	Actos (Pioglitazone Hydrochloride)			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Diovan (Valsartan)			S				Not Reported
	Senna S			S				Not Reported
	Centrum Silver		Y	S				Not Reported
	Crestor (Rosuvastatin Calcium)			S				Not Reported
	Metformin Hydrochloride			S				Not Reported
	Aggrenox			S				Not Reported
	Foltx			S				Not Reported
	Folbee (Cyanocobalamin, Folic Acid, Pyridoxine Hydrochloride)			S				Not Reported
	Fish Oil			S				Not Reported
	Metoprolol Succinate			S				Not Reported
	Acetylsalicylic Acid (Acetylsalicylic Acid)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2015	11009463	EXPEDITED (15-DAY)		HO	FR-SA-2015SA042798		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Orthostatic Hypotension	Lasilix			S	Oral			Not Reported
	Bisoce			S	Unknown			Not Reported

	Epinitril	S	Transdermal		Not Reported
	Seroplex	S	Unknown		Not Reported
	Levothyrox	C		Strength: 100mcg	Not Reported
	Hemigoxine Nativelle	C		Strength: 0.125mg	Not Reported
	Inexium	C			Not Reported
	Previscan (Fluindione)	C		Strength: 20mg	Not Reported
	Valsartan	C			Not Reported
	Temesta (Lorazepam)	C			Not Reported
	Atorvastatin	C			Not Reported
	Digoxine Nativelle	C		Strength: 0.25 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2015	11010748	NON-EXPEDITED			US-PFIZER INC-2015124654		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2015	11011085	EXPEDITED (15-DAY)		HO	FR-SA-2015SA045137		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Stilnox			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2015	11011578	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2015SE32689		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Mania; Paralysis; Withdrawal Syndrome	Seroquel	S	Oral		Astrazeneca
	Seroquel	S	Oral		Astrazeneca
	Seroquel	S	Oral		Astrazeneca
	Cipralex	S	Oral		Not Reported
	Cipralex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2015	10791811	EXPEDITED (15-DAY)		OT	FR-ROCHE-1533897		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Drug Interaction; Eosinophilia; Hepatocellular Injury; Hyponatraemia	Erivedge			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2015	10995745	EXPEDITED (15-DAY)		HO	NL-FRI-1000075633		50 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Chest Pain; Chills; Dry Mouth; Hypertension; Malaise; Memory Impairment; Palpitations; Rash; Restlessness; Therapeutic Response Unexpected	Escitalopram Oral Solution			S	Oral			Forest
	Lexapro			S	Oral	15 Mg		Forest
	Lexapro			S	Unknown			Forest
	Escitalopram			S	Oral	15 Mg		Forest
	Seroplex			S	Oral			Not Reported
	Diazepam			C	Unknown			Not Reported
	Omeprazol			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2015	11021097	EXPEDITED (15-DAY)		HO	CH-TEVA-554600ISR		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Mania	Escitalopram	S	Unknown		Ivax
	Tramadol	S	Unknown	100 Milligram Daily;	Teva
	Triamcinolone	S	Intramuscular	40 Mg One Month Apart	Not Reported
	Quetiapine	C	Unknown	300 Milligram Daily;	Not Reported
	Oxazepam	C	Unknown	60 Milligram Daily;	Not Reported
	Alprazolam	C	Unknown	2 Milligram Daily;	Not Reported
	Zolpidem	C	Unknown	12.5 Milligram Daily;	Not Reported
	Baclofen	C	Unknown	150 Milligram Daily;	Not Reported
	Candesartan Cilexetil	C	Unknown	8 Milligram Daily;	Not Reported
	Metformin	C	Unknown		Not Reported
	Atorvastatin	C	Unknown	20 Milligram Daily;	Not Reported
	Alfuzosin	C	Unknown	10 Milligram Daily;	Not Reported
	Trospium Chloride	C	Unknown	20 Milligram Daily;	Not Reported
	Ibuprofen	C	Unknown	1800 Milligram Daily;	Not Reported
	Paracetamol	C	Unknown	4 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2015	11024103	EXPEDITED (15-DAY)		HO	BE-FRI-1000075831			Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain; Face Oedema	Escitalopram			S	Oral			Forest
	Zaldiar			C	Unknown	Zaldiar/Tramadol, Thydrochloride 37,5mg, Paracetamol 325mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2015	11025729	DIRECT		HO			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Gait Disturbance; Tremor	Lexapro			S	Oral			Mylan

Wellbutrin	C		Not Reported
Pravastatin	C		Not Reported
Tyenol	C		Not Reported
Calcium	C		Not Reported
B-12	C		Not Reported
Magnesium	C		Not Reported
D3	C		Not Reported
Centrum Silver	C		Not Reported
Aspirin	C		Not Reported
Lorazepam	C		Not Reported
Ambien	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2015	11026348	DIRECT		OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Flutter; Chest Discomfort; Dry Mouth; Fatigue; Feeling Abnormal; Feeling Abnormal; Heart Rate Increased; Hyperhidrosis; Mydriasis; Nausea; Ocular Hyperaemia; Palpitations; Vision Blurred	Lexapro			S	Oral	1 Pill		Not Reported
	Flonase			C				Not Reported
	Retina A (Topical)			C				Not Reported
	Omega 3'S			C				Not Reported
	Vitamin B,D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2015	11024502	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20131210845		55 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomagnesaemia; Torsade De Pointes	Ibuprofen			S	Unknown			Not Reported
	Acetaminophen		Y	S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Methadone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2015	11025956	EXPEDITED (15-DAY)		HO	FR-FRI-1000075833		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Hemianopia Homonymous; Neurologic Neglect Syndrome	Escitalopram			S	Oral	5 Mg		Forest
	Aspegic [Acetylsalicylate Lysine]			S	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2015	11026002	EXPEDITED (15-DAY)		OT	BE-FRI-1000075852			Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incision Site Haemorrhage; Post Procedural Haemorrhage	Escitalopram			S				Forest
	Nsaids			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2015	11026383	EXPEDITED (15-DAY)		HO, LT, OT	FR-APOTEX-2015AP008206		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Confusional State; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Paxil Tablets			S	Unknown	20 Mg, Daily		Apotex
	Seroplex			S	Oral	10 Mg, Daily		Not Reported
	Aldactazine			S	Oral	Unk		Not Reported
	Zoplicone			C	Unknown	Unk		Not Reported
	Cortancyl			C	Unknown	Unk		Not Reported
	Paracetamol+Codein			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2015	11030896	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Drug Ineffective; Suicidal Ideation	Escitalopram		S	Oral	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2015	11037038	EXPEDITED (15-DAY)		HO	2816258		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Morphine Sulphate			S		2.5 Mg Milligram(S), 1 Hour		Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)	1 Week Intravenous		Not Reported
	Ciprofloxacin			S	Intravenous (not otherwise specified)	1 Week Intravenous		Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)			Not Reported
					Intravenous (not otherwise specified)	75 Mg/M 2 Milligram(S)/Sq.Meter (1 Week)		
	Avastin /00848101/			S	Intravenous (not otherwise specified)	15 Mg/Kg Milligram(S), 1 Week		Not Reported
	Cipralex /01588501/			S		10 Mg Milligram(S), 1 Day		Not Reported
	Ciprofloxacin			S	Oral			Not Reported
	Piperacillin Sodium W/Tazobactam Sodium			S				Not Reported
	Trastuzumab			S	Intravenous (not otherwise specified)	8 Mg/Kg Milligram(S)/Kilogram, 1 Week		Not Reported
	Tylenol /00020001/			S				Not Reported
	Tylenol No. 1			S				Not Reported
	Codeine			C				Not Reported
	Docusate			C				Not Reported
	Gravol			C				Not Reported
	Lactulose			C				Not Reported
	Senna			C				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2015	10532723	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2014M1007047			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Pressure Systolic Decreased; Bundle Branch Block Right; Gastrointestinal Sounds Abnormal; Renal Failure; Rhabdomyolysis; Suicidal Behaviour; Tachycardia; Vomiting	Lamotrigin Dura			S	Oral	950 Mg, Total		Mylan
	Escitalopram			S	Oral	500 Mg, Total		Not Reported
	Anafranil			S	Oral	7500 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2015	10585403	EXPEDITED (15-DAY)		OT	US-FRI-1000072263		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anhedonia; Anxiety; Apathy; Crying; Depressed Mood; Disorientation; Fear; Feeding Disorder; Feelings Of Worthlessness; Haematemesis; Headache; Insomnia; Lethargy; Mania; Mental Impairment; Nausea; Palpitations; Paranoia; Suicidal Ideation; Tachyphrenia; Thought Blocking; Tremor; Tremor; Unevaluable Event; Vomiting; Weight Decreased	Celexa			S	Oral	10 Mg		Forest
	Celexa			S				Forest
	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest
	Ambien			S	Oral	10 Mg		Not Reported
	Ambien			S				Not Reported
	Zoloft			S	Oral	25 Mg		Not Reported
	Zoloft			S				Not Reported
	Zoloft			S				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2015	11030874	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000075866		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Confusional State; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	10 Mg		Forest
	Deroxat			S		20 Mg		Not Reported
	Aldactazine			S	Oral			Not Reported
	Zopiclone			C	Unknown			Not Reported
	Oxazepam			C	Unknown			Not Reported
	Cortancyl			C	Unknown	4 Mg		Not Reported
	Paracetamol+Codeine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2015	11038442	EXPEDITED (15-DAY)		HO	TR-ELI_LILLY_AND_COMPANY-TR201504004276		21 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Interaction	Olanzapine			S		5 Mg, Qd		Eli Lilly And Co
	Olanzapine			S				Eli Lilly And Co
	Escitalopram			S		20 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Cannabis			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2015	11038520	EXPEDITED (15-DAY)		OT	GXKR2015DE002012			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed	Mirtazapine			S	Oral	7.5 Mg, Unk		Novartis
	Cipralex /Den/			S	Oral	10 - 20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2015	11042456	EXPEDITED (15-DAY)		HO, OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2015-BI-19		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Disorder; Chest Discomfort; Cough; Cyanosis; Decreased Appetite; Depression; Diarrhoea; Dizziness; Drug Ineffective; Dyspnoea Exertional; Emphysema; Fall; Fatigue; Headache; Hiatus Hernia; Hypoaesthesia; Insomnia; Malaise; Overdose; Pain; Panic Reaction; Pneumonia; Pruritus; Pulmonary Mass; Tremor	Atrovent			S	Unknown			Boehringer Ingelheim
	Clarithromycin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Fluticasone Propionate			S	Respiratory (inhalation)			Not Reported
	Fluticasone Propionate			S	Respiratory (inhalation)			Not Reported
	Glycopyrronium Bromide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Tiotropium			S	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2015	10725008	EXPEDITED (15-DAY)		LT, OT	SE-009507513-1501SWE005841		55 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt; Toxicity To Various Agents	Mirtazapine			S	Oral			Merck
	Atarax (Hydroxyzine Hydrochloride)			S	Oral	Unk		Not Reported
	Citalopram			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2015	11007885	EXPEDITED (15-DAY)		OT	CA-FRI-1000075772		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Agitation; Asthenia; Blood Pressure Increased; Headache; Hypoaesthesia; Hypoaesthesia Oral; Insomnia; Loss Of Personal Independence In Daily Activities; Malaise; Palpitations; Paraesthesia; Paraesthesia Oral; Pruritus; Respiratory Rate Increased; Shock Symptom; Tinnitus	Escitalopram			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2015	11044483	EXPEDITED (15-DAY)		HO	FR-FRI-1000075965		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Fall	Escitalopram			S	Unknown	10 Mg		Forest
	Ditropan			S	Unknown	7.5 Mg		Not Reported
	Tiapridal			S	Oral	40 Gtt		Not Reported
	Alprazolam			S	Unknown	0.75 Mg		Not Reported
	Bisoce			C	Unknown	10 Mg		Not Reported
	Tamsulosine Lp			C	Unknown	0.4 Mg		Not Reported
	Seresta			C	Unknown	10 Mg		Not Reported
	Galantamine Lp			C	Unknown	8 Mg		Not Reported
	Kardegic			C	Unknown	75 Mg		Not Reported
	Levothyrox			C	Unknown	12.5 Mcg		Not Reported

	Movicol	C	Unknown	1 Df		Not Reported
	Zopiclone	C	Unknown	3.75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2015	11045889	EXPEDITED (15-DAY)		HO	PHHY2015TR045315		21 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Altered State Of Consciousness; Amnesia; Delirium; Drug Interaction; Hyperaesthesia; Somnolence; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Olanzapine			S	Unknown	5 Mg, Qd		Novartis
	Olanzapine			S				Novartis
	Cannabis			S	Unknown			Not Reported
	Cannabis			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2015	11047106	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2015IN02951			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Psychotic Disorder	Sertraline			S		Unk		Cipla
	Escitalopram			S				Not Reported
	Fluoxetine			S		Unk		Not Reported
	Fluvoxamine			S				Not Reported
	Clomipramine			S				Not Reported
	Paroxetine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2015	11048656	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2015AU02934			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Tactile; Hypomania	Lamotrigine			S	Unknown	100 Mg, Bid		Cipla
	Lamotrigine			S	Unknown	50 Mg, Bid		Cipla

	Lamotrigine	S	Unknown	25 Mg, Qd On Alternate Days	Cipla
	Lamotrigine	S	Unknown	50 Mg, Bid	Cipla
	Sertraline	S	Unknown		Cipla
	Citalopram	S	Unknown		Cipla
	Escitalopram	S		20 Mg, Qd	Not Reported
	Paroxetine	S	Unknown		Not Reported
	Sodium Valproate	S	Unknown	400 Mg, Bid	Not Reported
	Sodium Valproate	S	Unknown	500 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2015	11048913	EXPEDITED (15-DAY)		HO, OT	PHHY2015US045760		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Corneal Reflex Decreased; Embolic Stroke; Mental Disorder; Muscle Rigidity; Negativism; Pyrexia; Seizure; Verbigeration	Clozapin Hexal			S	Unknown	Unk		Novartis
	Clozapin Hexal			S				Novartis
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported
	Quetiapine			S	Unknown			Not Reported
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2015	11050707	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Dizziness; International Normalised Ratio Increased; Malaise; Tremor	Coumadin Warfarin			S	Oral			Not Reported
	Lexapro Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2015	11051597	DIRECT		DS, LT, OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Ineffective; Hyperhidrosis; Nausea; Product Substitution Issue	Lexapro			S	Oral			Not Reported
	Alprazolam			C				Not Reported
	Bupropion			C				Not Reported
	Lexapro			C				Not Reported
	Atenolol			C				Not Reported
	Lisinopril			C				Not Reported
	Vit. D			C				Not Reported
	Metformin			C				Not Reported
	Temazepam			C				Not Reported
	Tylenol			C				Not Reported
	Aleve			C				Not Reported
	Benadryl/Mucinex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2015	9744533	EXPEDITED (15-DAY)		DS	IE-FRI-1000052119			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depressed Mood; Drug Ineffective; Paranoia; Psychomotor Hyperactivity; Somnolence; Suicidal Ideation; Withdrawal Syndrome	Lexapro			S	Oral			Forest
	Quetiapine			C				Not Reported
	Librium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2015	10700814	EXPEDITED (15-DAY)		OT	CA-RB PHARMACEUTICALS LIMITED-RB-74673-2014		3 DAY	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation Neonatal; Drug Withdrawal Syndrome Neonatal; Exposure Via Breast Milk; Facial Asymmetry; Foetal Exposure During Pregnancy; Hyperbilirubinaemia Neonatal; Hypoglycaemia Neonatal; Jaundice Neonatal; Knee Deformity; Neonatal Respiratory Distress; Selective Eating Disorder; Talipes; Weight Decrease Neonatal	Suboxone	S	Transplacental	10 Mg, Daily		Reckitt Benckiser
	Suboxone	S	Transmammary	12 Mg, Daily		Reckitt Benckiser
	Subutex	S	Transplacental	10 Mg, Daily		Reckitt Benckiser
	Subutex	S	Transplacental	12 Mg, Daily		Reckitt Benckiser
	Nicotine	S	Transplacental	2-5 Cigarettes Daily		Not Reported
	Cipralex	S	Transplacental	30 Mg Dialy		Not Reported
	Cipralex	S				Not Reported
	Calcium	S	Transplacental	1000 Mg		Not Reported
	Vitamin D3	S	Transplacental	1000 Iu Daily		Not Reported
	Folic Acid	S	Transplacental	1000 Mg, Qd		Not Reported
	Prenatal Vitamins	C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2015	10741218	EXPEDITED (15-DAY)		LT	SE-AUROBINDO-AUR-APL-2015-00628		55 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt; Toxicity To Various Agents	Mirtazapine Od Tablets 30 Mg			S	Oral	30 Mg, Daily		Aurobindo
	Atarax /00058401/			S	Oral	25 Mg, Daily		Not Reported
	Citalopram			S	Oral	20 Mg, Daily		Not Reported
	Cipralex /01588501/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2015	10785976	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20150119966		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Muscle Rigidity; Overdose; Sopor	Serenase (Haloperidol)			S	Oral			Not Reported
	Serenase (Haloperidol)			S	Oral			Not Reported
	Serenase (Haloperidol)			S	Oral			Not Reported
	Tavor (Lorazepam)			S	Oral			Not Reported
	Tavor (Lorazepam)			S	Oral			Not Reported

	Cipralex	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Akineton	C	Unknown	Not Reported
	Triatec (Ramipril)	C	Oral	Not Reported
	Sequacor	C	Oral	Not Reported
	Cardioaspirin	C	Oral	Not Reported
	Pantopan	C	Oral	Not Reported
	Atorvastatin	C	Oral	Not Reported
	Nootropil	C		Not Reported
	Nootropil	C		Not Reported
	Citicolin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2015	11047786	NON-EXPEDITED			CN-FRI-1000075915			Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Herpes Virus Infection; Pruritus; Swelling Face	Escitalopram			S	Oral	10 Mg		Forest
	Clonazepam			C	Unknown			Not Reported
	Seroquel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2015	11052067	EXPEDITED (15-DAY)		DS, OT	SE-TEVA-555036ISR		25 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Gait Disturbance; Product Quality Issue; Product Substitution Issue; Product Substitution Issue; Product Substitution Issue; Somnolence; Stress	Escitalopram Teva 10 Mg Filmdragerad Tablett			S	Oral	10 Milligram Daily;		Ivax
	Propavan 25 Mg Tablett			C				Not Reported
	Concerta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2015	11053929	EXPEDITED (15-DAY)		OT	CA-FRI-1000075989		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Intestinal Haemorrhage	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Not Reported
	Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2015	9397437	EXPEDITED (15-DAY)		HO	IT-JNJFOC-20130705029		86 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hyponatraemia; Hypotension; Sopor	Serenase (Haloperidol)			S	Oral			Not Reported
	Serenase (Haloperidol)			S	Oral			Not Reported
	Serenase (Haloperidol)			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Metformine			C	Unknown			Not Reported
	Isoptin			C	Unknown			Not Reported
	Coumadin			C	Oral			Not Reported
	Dibase			C	Unknown			Not Reported
	Tavor (Lorazepam)			C	Oral			Not Reported
	Nexium			C	Unknown			Not Reported
	Diamicron			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2015	11054863	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2015US03274			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Hypotension; Overdose	Amlodipine			S	Unknown	5 Mg, Unk		Cipla
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Buspiron [Buspirone Hydrochloride]			S	Unknown	Unk		Not Reported
	Dexamfetamine			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Venlafexine			S	Unknown	Unk		Not Reported
	Prozac			S	Unknown	Unk		Not Reported
	Clonazepam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2015	11056074	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA-2015SE35217		26 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Obesity; Weight Increased	Seroquel Xr			S	Oral			Astrazeneca
	Seroquel Xr			S	Oral			Astrazeneca
	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Simvastatin			C	Oral			Not Reported
	Valium			C	Oral			Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2015	11056100	EXPEDITED (15-DAY)		HO	CA-ASTRAZENECA-2015SE35955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Seroquel			S	Oral			Zeneca
	Ativan			S	Oral			Not Reported
	Humalog			S	Subcutaneous			Not Reported
	Humalog			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Topiramate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2015	11056313	EXPEDITED (15-DAY)		HO	TR-MYLANLABS-2015M1013332			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium	Olanzapine			S	Oral	5mg/Day		Mylan
	Escitalopram			S	Unknown	20 Mg/Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2015	11058625	DIRECT					51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Serotonin Syndrome	Deplin			S	Oral	1 Pill Once Daily Taken By Mouth		Pamlab
	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2015	9402687	EXPEDITED (15-DAY)		HO	IT-FRI-1000046681		86 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged;	Escitalopram Oral Solution			S	Oral	17 Drops Daily		Forest

Hyponatraemia; Hypotension; Sopor	Serenase 1mg Compresse	S	Oral	1 Mg		Not Reported
	Bisprolol Fumarate	C	Unknown			Not Reported
	Metformin	C	Unknown			Not Reported
	Isoptin	C	Unknown			Not Reported
	Coumadin 5mg Compresse	C	Oral			Not Reported
	Dibase	C	Unknown			Not Reported
	Tavor (Lorazepam)	C	Oral			Not Reported
	Nexium	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2015	10025169	EXPEDITED (15-DAY)		HO	IT-FRI-1000064769		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Sopor; Vomiting	Escitalopram Oral Solution			S	Oral	10-15 Drops Daily		Forest
	Escitalopram Oral Solution			S	Oral	Overdose: 15 Ml		Forest
	Tachifludec			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2015	11046685	EXPEDITED (15-DAY)		OT	ES-ACCORD-030137		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram			S		Double The Drug Dose 20 Mg A Day		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2015	11057877	EXPEDITED (15-DAY)		DS	CA-ASTRAZENECA-2015SE35976		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Blood Pressure Increased; Depression; Heart Rate Increased; Mental	Seroquel			S	Oral			Zeneca
	Abilify			S	Oral			Not Reported

Impairment	Cipralex		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2015	11057936	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-95946		21 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Delirium; Drug Interaction	Olanzapine			S	Oral	5 Mg, Daily		Sun
	Olanzapine			S				Sun
	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2015	11058664	EXPEDITED (15-DAY)		HO	FR-FRI-1000075968		91 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma Muscle	Escitalopram			S	Oral	5 Mg		Forest
	Plavix			S	Oral	75 Mg		Not Reported
	Azilect			C	Unknown	1 Mg		Not Reported
	Pravastatine			C	Unknown	40 Mg		Not Reported
	Movicol			C	Oral	1 Df		Not Reported
	Modopar			C	Unknown	125 Mg		Not Reported
	Modopar			C	Unknown	187.5 Mg		Not Reported
	Modopar Lp			C	Unknown	125 Mg		Not Reported
	Tardyferon			C	Unknown	160 Mg		Not Reported
	Speciafoldine			C	Unknown	5 Mg		Not Reported
	Pantoprazole			C	Unknown	40 Mg		Not Reported
	Efferalgan Codeine			C	Unknown	3 Df		Not Reported
	Xolaam			C	Unknown	3 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2015	11059167	EXPEDITED (15-DAY)		OT	PHHY2015BR006746			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Balance Disorder; Decreased Activity; Fall; Hydrocephalus; Incontinence; Pain In Extremity	Galvus Met			S	Unknown	1 Df, Qd 1 Df (Tablet), Bid (In The Morning And At Night)		Not Reported
	Exelon Patch			S	Transdermal	18 Mg/ 10 Cm2 (9.5 Mg), Qd		Novartis
	Reconter			S	Unknown	1 Df, Qd		Not Reported
	Reconter			S				Not Reported
	Glifage			S	Unknown	2 Df, Qhs		Not Reported
	Aradois			C	Unknown	1 Df, Bid (In The Morning And At Night)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2015	11060779	EXPEDITED (15-DAY)		OT	DE-009507513-1504DEU014216		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed	Mirtazapine			S	Oral	7.5 Mg, Qd		Merck
	Cipralex			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2015	10525818	EXPEDITED (15-DAY)			PHHY2014BR129288		91 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Off Label Use; Renal Failure; Urinary Tract Infection	Exelon Patch			S	Transdermal	13.3 Mg, Qd (27mg/15cm2)		Not Reported
	Leponex			S	Unknown	15 Mg, Qd		Novartis
	Leponex			S	Unknown	50 Mg, Qd		Novartis
	Leponex			S	Unknown	75 Mg, Qd		Novartis

	Leponex	S	Unknown	100 Mg, Qd	Novartis
	Zider	S	Unknown	2 Df, Daily	Not Reported
	Exodus//Escitalopram Oxalate	S	Unknown	1 Df, Qd	Not Reported
	Vonau	S	Unknown	1 Df, Prn	Not Reported
	Donaren	C	Oral	1 Df, Qd	Not Reported
	Citalopram	C	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2015	11061092	EXPEDITED (15-DAY)		HO	FR-ROCHE-1567870		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Valium			S	Oral			Not Reported
	Tegretol			S	Oral			Not Reported
	Alepsal (France)			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Dificlir			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2015	11062485	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015141106		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Product Dispensing Error; Suicidal Ideation	Alprazolam			S		1 Mg, Qid As Needed (Prn)		Pfizer
	Alprazolam			S				Pfizer
	Alprazolam			S				Pfizer
	Alprazolam			S				Pfizer
	Lamotrigine			S		350 Mg, Daily (Qhs)		Not Reported
	Lamotrigine			S				Not Reported
	Lamotrigine			S				Not Reported
	Lamotrigine			S				Not Reported
	Escitalopram			S		25 Mg, 1x/Day		Not Reported
	Escitalopram			S				Not Reported

	Escitalopram	S			Not Reported
	Escitalopram	S			Not Reported
	Oxcarbazepine	S	300 Mg, 2x/Day		Not Reported
	Oxcarbazepine	S			Not Reported
	Oxcarbazepine	S			Not Reported
	Oxcarbazepine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2015	11062545	EXPEDITED (15-DAY)		OT	DE-TEVA-555246GER		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed	Mirtazapin			S	Oral			Teva
	Cipralex			S	Oral	10-20mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2015	11065745	EXPEDITED (15-DAY)		HO	TR-CIPLA LTD.-2015TR03365			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Incontinence; Major Depression; Muscle Rigidity	Risperidone			S	Oral	3 Mg, Unk		Cipla
	Lamivudine			S	Unknown	100 Mg, Unk		Cipla
	Interferon Alfa 2b			S	Unknown	30 Million Iu, Three Times A Week		Not Reported
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	15 Unk, Unk		Not Reported
	Escitalopram			S	Unknown	20 Unk, Unk		Not Reported
	Biperiden			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Olanzapine			S	Unknown	5 Mg, Unk		Not Reported
	Aripiprazole			S	Unknown	5 Mg, Unk		Not Reported
	Aripiprazole			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2015	11068648	NON-EXPEDITED			US-PFIZER INC-2015141073		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Xanax			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lovastatin			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2015	11069296	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2015US03366			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Anxiety; Blood Testosterone Decreased; Bone Development Abnormal; Decreased Appetite; Depressive Symptom; Disturbance In Attention; Drug Ineffective; Formication; Insomnia; Irritability; Loss Of Personal Independence In Daily Activities; Nail Picking; Panic Attack; Psychomotor Hyperactivity; Sensory Disturbance; Sinusitis; Stress	Citalopram			S		10 Mg		Cipla
	Citalopram			S		15 Mg		Cipla
	Citalopram			S		10 Mg		Cipla
	Citalopram			S		7.5 Mg		Cipla
	Lamotrigine			S		175 Mg		Cipla
	Fluvoxamine			S		75 Mg		Not Reported
	Risperidone			S		0.5 Mg		Cipla
	Aripiprazole			S		5-10 Mg		Not Reported
	Aripiprazole			S		2 Mg		Not Reported
	Aripiprazole			S		1 Mg		Not Reported
	Atomoxetine			S		18 Mg		Not Reported
	Dexamfetamine			S		30-60 Mg		Not Reported

	Dextroamphetamine	S	15 Mg	Not Reported
	Testosterone Cypionate	S	200 Mg/Ml	Not Reported
	Escitalopram	S	5 Mg	Not Reported
	Escitalopram	S	10 Mg	Not Reported
	Escitalopram	S	20 Mg	Not Reported
	Oxcarbazepine	S	Total 375 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2015	11070413	EXPEDITED (15-DAY)		HO	PHHY2015FR048960		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Leukopenia; Thrombocytopenia; Transaminases Increased	Exjade			S	Oral	1 Df, Qw3		Novartis
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Aranesp			C	Subcutaneous	1 Df, Qw		Not Reported
	Glucidion			C	Intravenous drip			Not Reported
	Bromazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2015	11071339	DIRECT					44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Dizziness; Headache; Insomnia; Irritability; Migraine; Nausea; Poor Quality Sleep; Product Substitution Issue	Escitalopram			S	Oral	1 Pill, Once Daily, Taken By Mouth		Lupin
	Multivitamin For Women			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2015	10732732	EXPEDITED (15-DAY)		HO	CH-FRI-1000073773		81 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Anaemia; Ecchymosis; Haematoma; Mouth Haemorrhage	Escitalopram	S	Oral	10 Mg Daily		Forest
	Sintrom	S	Oral			Not Reported
	Fraxiforte	S	Subcutaneous	1 Df		Not Reported
	Atacand	C	Oral	16 Mg Daily		Not Reported
	Dalacin C	C	Oral	3 Other Daily		Not Reported
	Nitroderm	C	Topical			Not Reported
	Tenormin	C	Oral	12.5 Mg		Not Reported
	Inegy	C	Oral	1 Other Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2015	10793045	EXPEDITED (15-DAY)		HO, OT	IT-FRI-1000074396		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Disorder; Muscle Rigidity; Overdose; Sopor; Speech Disorder	Escitalopram Oral Solution			S	Oral	20 Drops		Forest
	Escitalopram Oral Solution			S				Forest
	Serenase (Haloperidol)			S	Oral			Not Reported
	Serenase (Haloperidol)			S	Oral			Not Reported
	Serenase (Haloperidol)			S	Oral	25 Drops In The Evening		Not Reported
	Tavor (Lorazepam)			S	Oral			Not Reported
	Tavor (Lorazepam)			S	Oral	2 Mg		Not Reported
	Tavor (Lorazepam)			S	Oral	Overdose: 4 Mg		Not Reported
	Sequacor			C	Oral	5 Mg		Not Reported
	Cardioaspirin			C	Oral	100 Mg		Not Reported
	Triatec (Ramipril)			C	Oral	10 Mg		Not Reported
	Pantopan			C	Oral	20 Mg		Not Reported
	Nootropil			C	Oral	3000 Mg		Not Reported
	Atorvastatina			C	Oral	20 Mg		Not Reported
	Psycoton			C	Oral	3 G		Not Reported
	Citicolin			C	Oral	4000 Mg		Not Reported
	Hibiscus Sabdariffa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2015	10920576	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2015CH030129			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bradypnoea; Delusion; Depression; Drug Interaction; Electrocardiogram Qt Prolonged; Fear; Hallucination; Herpes Simplex Test Positive; Impulsive Behaviour; Loss Of Consciousness; Maternal Exposure During Pregnancy; Overdose; Prurigo; Psychotic Disorder; Restlessness; Somatic Delusion; Somnolence; Suicide Attempt; Toxicity To Various Agents	Ritalin			S	Unknown			Not Reported
	Ritalin			S	Unknown	80 Mg, Qd		Not Reported
	Ritalin			S	Unknown	10 Mg, Qd		Not Reported
	Ritalin La			S	Unknown	10 Mg, Qd		Not Reported
	Ritalin La			S	Unknown	30 Mg, Qd		Not Reported
	Ritalin-Sr			S	Unknown	20 Mg, Qd		Not Reported
	Cetirizine			S	Unknown	200 Mg, Unk		Novartis
	Cipralex//Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Cipralex//Escitalopram			S	Unknown	300 Mg, Unk		Not Reported
	Bilaxten			S	Oral			Not Reported
	Bilaxten			S	Unknown	400 Mg, Unk		Not Reported
	Seroquel			S	Unknown	2.5 G, Unk		Not Reported
	Rocuronium			C	Unknown	50 Mg, Unk		Not Reported
	Zyprexa			C	Oral	2.5 Ot, Qd		Not Reported
	Sequase			C	Oral	25 Mg, Qd		Not Reported
	Sequase			C	Unknown	50 Mg, Unk		Not Reported
	Concerta			C	Unknown			Not Reported
	Surmontil//Trimipramine			C	Unknown	100 Mg, (In The Evening)		Not Reported
	Relaxan			C	Unknown	3 Df, Bid		Not Reported
	Trittico			C	Unknown	50 Mg, (Night Medication)		Not Reported
	Mianserin			C	Unknown			Not Reported
	Mianserin			C	Unknown	60 M, Unk		Not Reported
	Redormin//Remifentanil Hydrochloride			C	Unknown	1 G, Unk		Not Reported
	Redormin//Remifentanil Hydrochloride			C	Unknown	2 Df, Qd (500 Mg)		Not Reported

	Valdoxan	C	Unknown	25 Mg, Qd		Not Reported
	Valdoxan	C				Not Reported
	Passiflora	C	Unknown			Not Reported
	Passiflora	C				Not Reported
	Bactrim Forte	C	Unknown			Not Reported
	Pantozol (Switzerland)	C	Unknown	20 Mg, Qd		Not Reported
	Etomidate	C	Unknown	12 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2015	10925717	EXPEDITED (15-DAY)		HO	SE-FRI-1000075321		30 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Enlargement	Escitalopram			S	Oral	20 Mg		Forest
	Imovane			C	Unknown			Not Reported
	Zolpidem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2015	11071096	EXPEDITED (15-DAY)		HO	US-ACCORD-030299		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drooling; Dysarthria; Hypoaesthesia; Pain	Escitalopram			S	Oral			Accord
	Hydrocodone			C				Not Reported
	Oxycodone/Oxycodone Hydrochloride/Oxycodone Pectinate/Oxycodone Terephthalate			C				Not Reported
	Topiramate			C				Not Reported
	Aciclovir			C				Not Reported
	Chlorhexidine			C		Mouth Rinse		Not Reported
	Clindamycin			C				Not Reported
	Betamethasone Dipropionate/Clotrimazole			C				Not Reported
	Sumatriptan			C				Not Reported
	Prednisone			C				Not Reported

	Rizatriptan	C	Not Reported
	Xanax	C	Not Reported
	Wellbutrin	C	Not Reported
	Valium	C	Not Reported
	Diltiazem	C	Not Reported
	Lantus	C	Not Reported
	Omeprazole	C	Not Reported
	Prazosin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2015	11071653	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-96247		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed	Mirtazapin			S	Oral	7.5 Mg		Sun
	Cipralex			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2015	11072196	EXPEDITED (15-DAY)		OT	CH-FRI-1000076058		27 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obesity; Weight Increased	Escitalopram			S	Oral	20 Mg		Forest
	Seroquel Xr			S	Oral	800 Mg		Not Reported
	Abilify			S	Oral	10 Mg		Not Reported
	Abilify			S	Oral	15 Mg		Not Reported
	Simvastatin			C	Oral	20 Mg		Not Reported
	Valium			C	Oral	5 Mg		Not Reported
	Temesta (Lorazepam)			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2015	11072703	EXPEDITED (15-DAY)		OT	DE-WATSON-2015-08834		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Missed; Exposure During Pregnancy	Mirtazapine (Unknown)		S	Oral	7.5 Mg, Unknown	Actavis
	Cipralex /01588501/		S	Oral	10 Mg, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2015	11073027	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2015SE37371		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer; Off Label Use	Crestor			S	Oral			Astrazeneca
	Cipralex			S	Oral			Not Reported
	Metformin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2015	11079170	EXPEDITED (15-DAY)	Y	HO	IPC201504-000225		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Imprisonment; Mania; Theft	Tramadol			S				Not Reported
	Escitalopram			S				Not Reported
	Triamcinolone			S	Intramuscular	40 Mg, 2 Intramuscular Injection, Intramuscular		Not Reported
	Oxazepam			C				Not Reported
	Alprazolam			C				Not Reported
	Zolpidem			C				Not Reported
	Baclofen			C				Not Reported
	Candesartan			C				Not Reported
	Metformin			C				Not Reported
	Atorvastatin			C				Not Reported
	Alfuzosin			C				Not Reported
	Trospium			S				Not Reported
	Acetaminophen			C				Not Reported
	Ibuprofen			C				Not Reported
	Quetiapine			C				Not Reported
	Trospium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2015	11047264	EXPEDITED (15-DAY)		HO	JP-BRISTOL-MYERS SQUIBB COMPANY-		57 YR	Male	JPN

BMS-2015-023996

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Mania; Tooth Fracture	Aripiprazole			S	Oral	3 Mg, Qd		Bristol Myers Squibb
	Aripiprazole			S	Oral	6 Mg, Qd		Bristol Myers Squibb
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	5 Mg, Qd		Not Reported
	Lexapro			S	Oral	15 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Cymbalta			S	Oral	20 Mg, Qd		Not Reported
	Cymbalta			S	Oral	40 Mg, Qd		Not Reported
	Cymbalta			S	Oral	20 Mg, Qd		Not Reported
	Cymbalta			S	Oral	40 Mg, Qd		Not Reported
	Cymbalta			S	Oral	20 Mg, Qd		Not Reported
	Lunesta			C	Unknown	Unk		Not Reported
	Estazolam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2015	11074478	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2015M1012853			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed; Exposure During Pregnancy	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Mirtazapin			S	Oral	7.5 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2015	11075572	NON-EXPEDITED			US-PFIZER INC-2015144489			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Vancomycin		S	Unk	Unknown
	Clindamycin Hcl		S	Unk	Pfizer
	Clarithromycin		S	Unk	Pfizer
	Zinacef		S	Unk	Not Reported
	Daptomycin		S	Unk	Not Reported
	Lexapro		S	10 Mg, Unk	Not Reported
	Nortriptyline		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2015	11075768	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000076073		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicidal Ideation	Escitalopram			S	Oral	1 Df		Forest
	Escitalopram			S	Oral	Overdose: 140 Mg Once		Forest
	Zolpidem			S	Oral	1 Df		Not Reported
	Zolpidem			S	Oral	Overdose: 140 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2015	11076307	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA-2015SE25417		34 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Depressed Mood; Aggression; Attention Deficit/Hyperactivity Disorder; Drug Abuse; Drug Interaction; Rash; Suicide Attempt; Weight Decreased	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Ritalin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Temesta (Lorazepam)			C		1mg Temesta With Each Sequase, 2.5mg For Severe Panic And 2.5mg For Sleeping		Not Reported
	Temesta			C		1mg Temesta With Each Sequase, 2.5mg For		Not Reported

			Severe Panic And 2.5mg For Sleeping	
	Stilnox	C		Not Reported
	Sirdalud	C	1-2x /4 Mg	Not Reported
	Dafalgan	C	1-2 G	Not Reported
	Centrum	C		Not Reported
	Lutein	C		Not Reported
	Calcimagon	C		Not Reported
	Magnesium	C		Not Reported
	Buscopan	C	Several Doses	Not Reported
	Tramal Drops	C	500 Mg Combined With 30 Mg Codeine	Not Reported
	Kreon	C	1000	Not Reported
	Vit B12	C		Not Reported
	Vit D3	C		Not Reported
	Ferritin	C		Not Reported
	Collusonol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2015	11082020	EXPEDITED (15-DAY)	Y	HO	NSR_02056_2015		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Use; Disinhibition; Family Stress; Irritability; Mania; Psychomotor Hyperactivity; Psychotic Disorder; Serotonin Syndrome; Substance Use; Theft	Tramadol			S		(Df)	1 MTH	Not Reported
	Escitalopram			S			6 MTH	Not Reported
	Quetiapine			C				Not Reported
	Oxazepam			C				Not Reported
	Alprazolam			C				Not Reported
	Zolpidem			C				Not Reported
	Metformin			C				Not Reported
	Atorvastatin			C				Not Reported
	Alfuzosin			C				Not Reported
	Trospium			C				Not Reported
	Acetaminophen			C				Not Reported
	Ibuprofen			C				Not Reported
	Triamcinolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2015	10656709	EXPEDITED (15-DAY)		OT	US-AMGEN-USASL2014096700		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chills; Condition Aggravated; Dizziness; Fall; Fatigue; Hyperhidrosis; Injection Site Bruising; Joint Swelling; Limb Injury; Mobility Decreased; Pain; Pain In Extremity; Rash	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Lexapro			S	Unknown	Unk		Not Reported
	Methotrexate			C		#4 2.5mg Pills Once Weekly		Not Reported
	Oxycodone			C		Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2015	10728743	EXPEDITED (15-DAY)		LT	SE-009507513-1501SWE005439		23 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Electrocardiogram Abnormal; Muscle Twitching; Somnolence; Toxicity To Various Agents	Loratadine			S	Oral			Merck
	Cipralex			S	Oral			Not Reported
	Tavegyl			S	Oral			Not Reported
	Postafen (Meclozine Hydrochloride)			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2015	11053111	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015GSK046104			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder	Wellbutrin Xl Tablet			S	Oral	450 Mg, Qd		Glaxosmithkline
	Lexapro			S	Oral	Unk, U		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2015	11080019	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2015AP008855		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Hypotension; Overdose; Shock	Amlodipine Besylate			S	Unknown	20-25 Tablets		Apotex
	Hydrochlorothiazide			S	Unknown			Apotex
	Buspiprone Hydrochloride Tablets Usp			S	Unknown			Apotex
	Clonazepam Tablets Usp			S	Unknown			Apotex
	Dexamfetamine			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2015	11080152	EXPEDITED (15-DAY)		HO	FR-FRI-1000076236		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Leukopenia; Thrombocytopenia; Transaminases Increased	Escitalopram			S	Oral	1 Df		Forest
	Exjade			S	Oral	0.4286 Df		Not Reported
	Aranesp			C	Subcutaneous	0.1429 Df		Not Reported
	Glucidion			C	Intravenous (not otherwise specified)			Not Reported
	Bromazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2015	11080153	EXPEDITED (15-DAY)		HO	FR-FRI-1000076209		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Epistaxis; International	Escitalopram			S	Oral	5 Mg		Forest

Normalised Ratio Increased	Previscan (Fluindione)	S	Oral	10 Mg		Not Reported
	Ramipril	C	Unknown	2.5 Mg		Not Reported
	Cardensiel	C	Unknown	2.5 Mg		Not Reported
	Furosemide	C	Unknown	40 Mg		Not Reported
	Levothyrox	C	Unknown	25 Mcg		Not Reported
	Dafalgan	C	Unknown	If Needed		Not Reported
	Oxybutynine	C	Unknown	1 Df		Not Reported
	Arestal	C	Unknown	1 Mg		Not Reported
	Noctamide	C	Unknown	1 Mg		Not Reported
	Uvedose	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2015	11080992	DIRECT					68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Quality Issue; Product Substitution Issue	Escitalopram			S	Oral	One		Aurobindo
	Lexapro			C				Not Reported
	Telmisartan			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Atenolol			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2015	11081430	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Response Decreased	Generic Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2015	11075733	EXPEDITED (15-DAY)		OT	PHHY2015US048685		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Product Dispensing Error; Product Use In Unapproved Indication; Suicidal Ideation	Oxcarbazepine			S	Unknown	300 Mg, Bid		Not Reported
	Lamotrigine			S	Unknown	350 Mg, Qhs		Novartis
	Escitalopram			S	Unknown	25 Mg, Qd		Not Reported
	Alprazolam			S	Unknown	1 Mg, Qd As Needed.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2015	11087577	DIRECT					28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Nausea; Tremor	Lexapro			S	Oral	5mg, Once Daily, Taken By Mouth		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2015	11086278	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1014178			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Staphylococcal Infection	Cytarabine			S		Unk		Mylan
	Nardil			S		15 Mg, Qid		Not Reported
	Nardil			S		15 Mg, Qd		Not Reported
	Nardil			S		30 Mg, Qd		Not Reported
	Nardil			S		45 Mg, Qd		Not Reported
	Xanax			S		0.5 Mg, Tid		Not Reported
	Xanax			S		1 Mg, Tid		Not Reported
	Klonopin			S		Unk		Not Reported
	Klonopin			S				Not Reported
	Escitalopram			S		10 Mg, Bid		Not Reported
	Escitalopram			S				Not Reported
	Antibiotic /00011701/			C		Unk		Not Reported
	Fluconazole			C		Unk		Not Reported

	Pepcid /00305201/	C	Unk	Not Reported
	Compazine /00013302/	C	Unk	Not Reported
	Acyclovir /00587301/	C	Unk	Not Reported
	Rituxan	S	Unk	Not Reported
	Bendamustine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2015	10646815	EXPEDITED (15-DAY)		OT	DE-FRI-1000073038		59 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Electrocardiogram Qt Prolonged; Extrasystoles	Escitalopram Oral Solution			S	Oral	Started With 1 Mg/Day, Increased By 1 Mg Every Three Days Up To 6 Mg/Day		Forest
	Diltahexal			C	Oral	180 Mg		Not Reported
	Imap			C	Intramuscular			Not Reported
	Imap			C	Intramuscular			Not Reported
	Alprazolam			C	Unknown	As Needed 0.5 To 1 Mg/Day		Not Reported
	Thyroxin			C	Oral	100 Micrograms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2015	10908164	EXPEDITED (15-DAY)		HO, LT	US-MERCK-1503USA003903		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Hypokalaemia; Lung Infection; Nausea	Vorinostat			S	Oral	500mg, Tid, On Days 1-3, Cycle 1		Merck
	Vorinostat			S	Oral	500mg, Tid, Total Dose Administered This Course 4500 Mg, On Days 1-3, Cycle 4		Merck
	Idarubicin			S	Intravenous (not	12 Mg/M2, Qd On Days 4-		Not Reported

			otherwise specified)	6, Cycle 1	
	Idarubicin	S	Intravenous (not otherwise specified)	8 Mg/M2, Qd On Days 4-5, Cycle 4, Total Dose Administered This Course 192.3 Mg	Not Reported
	Cytarabine	S	Intravenous (not otherwise specified)	1500 Mg/M2/Day On Days 4-7, Cycle 1	Not Reported
	Cytarabine	S	Intravenous (not otherwise specified)	750 Mg/M2/Day, On Days 4-6, Cycle 4	Not Reported
	Compazine	S		Unk	Not Reported
	Posaconazole	S	Oral	Unk	Merck
	Zofran	S		Unk	Not Reported
	Acyclovir	S		Unk	Not Reported
	Amlodipine	S		Unk	Not Reported
	Ciprofloxacin	S		Unk	Not Reported
	Fluconazole	S		Unk	Not Reported
	Lexapro	S		Unk	Not Reported
	Tramadol Hydrochloride	S		Unk	Not Reported
	Bupropion Hydrochloride	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2015	11046214	EXPEDITED (15-DAY)		HO, OT	CH-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-94738		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Serotonin Syndrome	Tramadol			S	Unknown	Exact Dose Not Known, 50mg Bid Was Prescribed		Sun
	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported
	Triamcinolone			S	Intramuscular	2 X 40 Mg, 1 Month Apart		Ranbaxy
	Cannabis			S	Unknown	Unk		Not Reported
	Quetiapine			C	Unknown	300 Mg, Daily		Not Reported

	Quetiapine	C	Unknown	Increased Progressively Up To1000 Mg, Daily	Not Reported
	Quetiapine	C	Unknown	800 Mg, Daily	Not Reported
	Alprazolam	C	Unknown	2 Mg, Daily	Not Reported
	Zolpidem	C	Unknown	12.5 Mg, Daily	Not Reported
	Baclofen	C	Unknown	150 Mg, Daily	Not Reported
	Oxazepam	C	Unknown	60 Mg, Daily	Not Reported
	Oxazepam	C	Unknown	Progressiveley Increased Tup To 180 Mg, Daily	Not Reported
	Candesartan	C	Unknown	8 Mg, Daily	Not Reported
	Metformin	C	Unknown	500 Mg, Daily	Not Reported
	Alfuzosin	C	Unknown	10 Mg, Daily	Not Reported
	Trospium	C	Unknown	20 Mg, Daily	Not Reported
	Acetaminophen	C	Unknown	4 G, Daily	Not Reported
	Ibuprofen	C	Unknown	1800 Mg, Daily	Not Reported
	Atorvastatin	C	Unknown	20 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2015	11086718	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/15/0047720		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Catatonia; Compartment Syndrome; Hypotension; Pyrexia; Respiratory Failure; Rhabdomyolysis; Seizure	Quetiapine Fumarate Tablets			S	Unknown			Not Reported
	Quetiapine Fumarate Tablets			S				Not Reported
	Clozapine			S				Not Reported
	Clozapine			S				Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2015	11087450	EXPEDITED (15-DAY)		OT	IN-AUROBINDO-AUR-APL-2015-03898		21 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Consciousness Fluctuating; Delirium; Drug Interaction; Dyskinesia; Hyperaesthesia; Poisoning; Soliloquy; Somnolence	Escitalopram 20 Mg		S	Unknown	20 Mg, Daily	Aurobindo
	Escitalopram 20 Mg		S			Aurobindo
	Olanzapine		S	Unknown	5 Mg, Daily	Not Reported
	Olanzapine		S			Not Reported
	Cannabis		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2015	11087480	EXPEDITED (15-DAY)		HO	IN-AUROBINDO-AUR-APL-2015-03952		71 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Oedema Peripheral	Escitalopram 10 Mg			S	Unknown	10 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2015	11087512	EXPEDITED (15-DAY)		HO	FR-FRI-1000076258		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Escitalopram			S	Oral	15 Mg		Forest
	Tegretol			S	Oral	2 Df		Not Reported
	Alepsal (Phenobarbital)			S	Unknown	100 Mg		Not Reported
	Alepsal (Phenobarbital)			S	Unknown	250 Mg		Not Reported
	Valium Roche			S	Oral	3 Df		Not Reported
	Dificlir			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2015	10834062	EXPEDITED (15-DAY)		OT	CA-FRI-1000074585		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities; Transient Ischaemic Attack; Vertigo	Escitalopram			S	Oral	Daily Dose Not Reported.		Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2015	11089298	EXPEDITED (15-DAY)		HO	TR-LUPIN PHARMACEUTICALS INC.-2015-01072		21 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Interaction	Escitalopram			S	Unknown	20 Mg/Day		Not Reported
	Escitalopram			S				Not Reported
	Olanzapine			S		5 Mg/Day		Not Reported
	Olanzapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2015	11089968	EXPEDITED (15-DAY)		HO, OT	CH-ELI_LILLY_AND_COMPANY-CH201504008853		82 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Biliary Dilatation; Blood Alkaline Phosphatase Increased; Blood Urea Increased; C-Reactive Protein Increased; Clavicle Fracture; Cogwheel Rigidity; Depressed Level Of Consciousness; Fall; Gallbladder Disorder; Gamma-Glutamyltransferase Increased; Hepatitis; Hyperammonaemia; Hyperbilirubinaemia; Lethargy; Psychomotor Retardation; Pyrexia; Somnolence; Ultrasound Abdomen Abnormal	Zyprexa			S	Oral	2.5 Mg, Bid		Eli Lilly And Co
	Zyprexa			S	Oral	2.5 Mg, Bid		Eli Lilly And Co
	Cipralex /01588501/			S	Oral	5 Mg, Qd		Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Prolia			C	Subcutaneous	60 Mg, Unk		Not Reported
	Prednisone			C	Oral	15 Mg, Qd		Not Reported
	Euthyrox			C	Oral	100 Ug, Qd		Not Reported
	Atacand			C	Oral	8 Mg, Qd		Not Reported
	Simcora			C	Oral	40 Mg, Qd		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Mg, Qd		Not Reported
	Tramadol			C	Oral	12.5 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2015	11092043	EXPEDITED (15-DAY)		OT	BR-FRI-1000076344		95 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Hallucination	Escitalopram Oral Solution			S	Oral			Forest
	Escitalopram Oral Solution			S	Oral			Forest
	Synthroid			C	Oral			Not Reported
	Aspirin Prevent			C	Oral	100 Mg		Not Reported
	Ictus			C	Oral	12 Mg		Not Reported
	Lasix			C	Oral			Not Reported
	Vasopril [Enalapril Maleate]			C	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2015	11096132	EXPEDITED (15-DAY)		HO	INS201504-000147		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Serotonin Syndrome	Subsys Sublingual Spray (Fentanyl)			S		Up To 4 Doses A Day		Not Reported
	Escitalopram (Escitalopram)			S		20 Mg, 1.5 Tablet Total Atleast 8 Years Ago		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2015	11094735	EXPEDITED (15-DAY)		OT	CN-FRI-1000076287		30 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Depressed Mood; Heart Rate Increased; Hypoaesthesia Oral; Incorrect Dose Administered; Mental Impairment	Lexapro			S	Oral			Forest
	Olanzapine			C	Oral			Not Reported
	Baishike			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2015	11095964	DIRECT		LT			8 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Aggression; Intentional Self-Injury; Product Quality Issue; Product Substitution Issue	Escitalopram			S	Oral	1 Pill		Camber
	Escitalopram			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2015	10853827	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2015-01440		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Pressure Abnormal; Clonus; Confusional State; Drug Level Above Therapeutic; Hyperhidrosis; Hyperreflexia; Hypotonia; Mental Status Changes; Muscle Rigidity; Myoclonus; Overdose; Serotonin Syndrome; Sinus Tachycardia; Skin Warm	Alprazolam 1mg			S	Unknown	1 Mg, At Bed Time		Aurobindo
	Escitalopram			S	Unknown	30 Mg, Daily		Aurobindo
	Quetiapine 200mg			S	Unknown	200 Mg, At Bed Time		Aurobindo
	Butalbital, Acetaminophen & Caffeine			S	Unknown	50/325/40 Mg, Two Times A Day		Not Reported
	Clonazepam			S	Unknown	1 Mg, 3 Times A Day		Not Reported
	Metaxalone			S	Unknown	Three Extra Tablets 7 H Earlier		Not Reported
	Mometasone			S	Unknown	50 Mcg/Act 2 Sprays Daily		Not Reported
	Prazosin			S	Unknown	2 Mg, At Bed Time		Not Reported
	Prednisone			S	Oral	40 Mg, Daily		Not Reported
	Propranolol			S	Unknown	80 Mg, Daily		Not Reported
	Triamcinolone			S	Unknown	0.1 %, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2015	11069826	EXPEDITED (15-DAY)		HO, OT	US-UCBSA-2015012258		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Spontaneous; Decreased Appetite; Dysphemia; Ectopic Pregnancy; Generalised Anxiety Disorder; Hypoaesthesia; Post-Traumatic Stress Disorder; Pregnancy; Pregnancy With Contraceptive Device; Sinus Tachycardia; Tremor; Vaginal Haemorrhage; Vision Blurred; Vomiting	Keppra Xr	S	Oral	1000 Mg, Once Daily (Qd)	Ucb
	Lexapro	S		5 Mg/2 Daily	Not Reported
	Nuvaring	S		Unk	Not Reported
	Buspar	S		Unk	Not Reported
	Vitamins Nos	C		Unk	Not Reported
	Jolessa	C		Unk	Not Reported
	Xanax	C	Oral	0.25 Mg, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2015	11098384	EXPEDITED (15-DAY)		DE	PHHY2015FR054613		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome; Torsade De Pointes	Rasilez			S	Oral	300 Mg, Qd		Novartis
	Nisis			S	Oral	160 Mg, Bid		Not Reported
	Atarax//Hydroxyzine Hydrochloride			S	Oral	2 Df, Qd		Not Reported
	Oflocet			S	Oral	200 Mg, Bid		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Seroplex			S	Oral	15 Mg, Qd		Not Reported
	Lexomil			S	Oral	0.5 Df, Tid		Not Reported
	Hyperium			S	Oral	1 Mg, Bid		Not Reported
	Hyperium			S	Oral	1 Mg, Qd		Not Reported
	Inexium//Esomeprazole Sodium			S	Oral	40 Mg, Qd		Not Reported
	Dafalgan			C	Oral	1 G, Tid		Not Reported
	Tardyferon			C	Oral	80 Mg, Bid		Not Reported
	Fumafer			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2015	11102244	EXPEDITED (15-DAY)	Y	HO, RI	US-H14001-15-00648		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Ejection Fraction Decreased; Heart Rate Decreased; Hypotension; Intentional Overdose; Lethargy; Shock	Amlodipine (Amlodipine) (5 Milligram, Tablets) (Amlodipine)			S		Unknown, 20-25 Tablets Of 5 Mg		Not Reported
	Hydrochlorothiazide (Hydrochlorothiazide) (Unknown) (Hydrochlorothiazide)			S				Not Reported
	Buspiron (Buspiron) (Hyoscine Butylbromide, Metamizole Sodium Monohydrate)			S				Not Reported
	Dexamfetamine (Dexamfetamine) (Unknown) (Dexamfetamine)			S				Not Reported
	Lexapro (Escitalopram Oxalate) (Escitalopram Oxalate)			S				Not Reported
	Venlafaxine (Venlafaxine) (Venlafaxine)			S				Not Reported
	Prozac (Fluoxetine Hydrochloride) (Fluoxetine Hydrochloride)			S				Not Reported
	Clonazepam (Clonazepam) (Clonazepam)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2015	11115108	NON-EXPEDITED	Y	HO, OT	2015AP005135		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Sertraline Hydrochloride (Sertraline) Tablet			S				Not Reported
	Escitalopram Oxalate (Escitalopram) Tablet			S			1 YR	Not Reported
	Garcinia Cambogia			S		1000 Mg; Two Capsules Three Times A Day For The Previous 2-3 Mo	2-3 MTH	Not Reported
	Baclofen			C				Not Reported

	Gabapentin	C	Not Reported
	Omeprazole	C	Not Reported
	Oxycodone	C	Not Reported
	Silodosin	C	Not Reported
	Solifenacin	C	Not Reported
	Diphenhydramine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2015	10877848	EXPEDITED (15-DAY)		CA, OT	US-PFIZER INC-2015073679			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta; Maternal Exposure During Pregnancy	Zoloft			S	Transplacental	Unk		Pfizer
	Sertraline Hcl			S	Transplacental	Unk		Pfizer
	Lexapro			S	Transplacental	Unk		Not Reported
	Prenatal Vitamins			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2015	11098898	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS EUROPE LIMITED-2015GMK		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Product Dispensing Error; Suicidal Ideation	Lamotrigine			S		350 Mg, Qhs		Glenmark
	Oxcarbazepine			S		300 Mg, Bid		Glenmark
	Escitalopram			S		25 Mg, Qd		Not Reported
	Alprazolam			S		1 Mg, Qid, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2015	11101828	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20150502122		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dysphagia; Pneumonia; Sepsis	Tylenol Extra Strength		Y	S	Unknown	2 Tabs In The Morning And At Noon		Not Reported

Tylenol Extra Strength		S	Unknown	2 Tabs In The Morning And At Noon	Not Reported
Tylenol		S	Unknown	1 To 2 Tabs As Needed Twice Daily)	Not Reported
Tylenol		S	Unknown		Not Reported
Tylenol	Y	S	Unknown		Not Reported
Tylenol		S	Unknown	1 To 2 Tabs As Needed Twice Daily)	Not Reported
Acetylsalicylic Acid	Y	S	Unknown		Not Reported
Amlodipine		S	Unknown		Not Reported
Levothyroxine		S	Unknown		Not Reported
Furosemide		S	Unknown		Not Reported
Lansoprazole		S	Unknown		Not Reported
Meloxicam		S	Unknown		Not Reported
Senokot		S	Unknown	At Bedtime	Not Reported
Quinapril		S	Unknown		Not Reported
Atenolol		S	Unknown		Not Reported
Docusate Sodium		S	Unknown		Not Reported
Nitro-Dur		S	Unknown	Daily	Not Reported
Potassium Chloride		S	Unknown	Daily	Not Reported
Humalog		S	Subcutaneous		Not Reported
Escitalopram		S	Unknown		Not Reported
Temazepam		S	Unknown	At Bedtime	Not Reported
Morphine		S	Oral		Not Reported
Vitamin		S	Unknown	Daily	Not Reported
Oxycodone-Acetaminophen		S	Unknown		Not Reported
Oxycodone-Acetaminophen		S	Unknown	5/325 Mg At Bed Time	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2015	10748021	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20150112085		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Respiratory Distress; Somnolence; Tremor	Risperdal			S	Transplacental			Not Reported
	Seroplex			S	Transplacental			Not Reported
	Theralene			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2015	10873667	EXPEDITED (15-DAY)		HO, LT	FR-JNJFOC-20150209628		20 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholecystitis Infective; Colitis Ischaemic; Colitis Ulcerative; Lactic Acidosis; Metabolic Acidosis	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Loxapac			S	Unknown			Not Reported
	Loxapac			S	Unknown			Not Reported
	Loxapac			S	Unknown			Not Reported
	Loxapac			S	Unknown			Not Reported
	Lepticur			S	Unknown			Not Reported
	Lepticur			S	Unknown			Not Reported
	Seroplex			S	Unknown			Not Reported
	Seroplex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2015	10913761	NON-EXPEDITED			US-PFIZER INC-2015087070		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Decreased Appetite; Drug Interaction; Electric Shock; Memory Impairment; Mental Disorder; Weight	Effexor Xr			S		Unk		Pfizer
	Effexor Xr			S		Unk, Alternate Day		Pfizer
	Tramadol			S		Unk		Not Reported
	Tramadol			S				Not Reported

Decreased	Lexapro	S	10 Mg, Daily		Not Reported
	Imuran	S	Unk		Not Reported
	Asa	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2015	11102689	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS U.S.A., INC-2015SUN01160		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Product Dispensing Error; Suicidal Ideation	Lamotrigine			S	Unknown	350 Mg, At Bed Time		Taro
	Escitalopram			S	Unknown	25 Mg, Qd		Taro
	Oxcarbazepine			S	Unknown	300 Mg, Bid		Not Reported
	Alprazolam			S	Unknown	1 Mg, Qid, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2015	11104312	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.-2015IT03616			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Binge Eating; Depressed Mood; Drug Ineffective; Food Craving; Frustration Tolerance Decreased; Gastrointestinal Disorder; Headache; Hyperhidrosis; Irritability; Tremor; Weight Loss Poor	Citalopram			S				Cipla
	Sertraline			S		100 Mg, Qd		Cipla
	Topiramate			S		50 Mg, Qd		Cipla
	Topiramate			S		400 Mg, Qd		Cipla
	Fluoxetine			S		20 Mg, Qd		Not Reported
	Venlafaxine			S				Not Reported
	Escitalopram			S				Not Reported
	Bupropion Xl			S		150 Mg Daily		Not Reported
	Bupropion Xl			S		300 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2015	11104352	EXPEDITED (15-DAY)		OT	JP-APOTEX-2015AP008495			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus; Paralysis	Paxil Cr Tablets			S	Oral	50 Mg, Qd		Apotex
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2015	11105857	DIRECT	Y	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Quality Issue; Product Substitution Issue	Escitalopram			S	Oral			Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2015	11029779	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2015-03224			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Depressed Mood; Flatulence; Product Substitution Issue; Suicidal Ideation	Escitalopram Aurobindo 20 Mg			S	Unknown	Unk		Aurobindo
	Microgynon 30			C	Unknown	Unk		Not Reported
	Valaciclovir			C	Unknown	500 M		Not Reported
	Quetiapine			S	Unknown	25 Mg, Unk Now And Then		Not Reported
	L-Lysine /00919901/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2015	11059057	EXPEDITED (15-DAY)		HO	TR-APOTEX-2015AP008472		21 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Interaction	Olanzapine			S	Oral	5 Mg, Daily		Apotex
	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported
	Cannabis			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2015	11106856	EXPEDITED (15-DAY)		HO	FR-FRI-1000076461		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disturbance In Attention; Fall; Haematoma	Escitalopram			S	Oral	1 Df		Forest
	Seresta			S	Oral	1 Df		Not Reported
	Theralene			S	Oral	0.5 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2015	11106919	EXPEDITED (15-DAY)		OT	GB-FRI-1000076345		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Headache; Joint Stiffness	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2015	11107409	EXPEDITED (15-DAY)		DE, HO, OT	FR-ASTRAZENECA-2015SE43144		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenomegaly; Hepatosplenomegaly; Phaeochromocytoma; Sedation; Serotonin Syndrome; Spleen Disorder; Torsade De Pointes	Inexium			S	Oral			Astrazeneca
	Lexomil Roche			S	Oral	Non Astrazeneca Product, 3 Mg, Three Times A Day		Not Reported
	Lexomil Roche			S	Oral	Non Astrazeneca Product, 1.5 Mg, At Night		Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Oflocet			S	Oral			Not Reported
	Rasilez			S	Oral			Not Reported
	Nisis			S	Oral			Not Reported

	Hyperium	S	Oral		Not Reported
	Hyperium	S			Not Reported
	Dafalgan	C	Oral		Not Reported
	Tardyferon	C	Oral		Not Reported
	Fumafer	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2015	11111787	DIRECT		HO, LT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Intentional Overdose; Suicide Attempt	Escitalopram			S	Oral	1 Pill, 10 Mg, Once Daily, Taken By Mouth		Not Reported
	Lexapro-Generic			C				Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2015	11111987	EXPEDITED (15-DAY)	Y	OT	US-H14001-15-00687		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Suicidal Ideation	Lamotrigine (Lamotrigine) (Lamotrigine)			S				Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Oxcarbazepine (Oxcarbazepine)			S				Not Reported
	Alprazolam (Alprazolam) (Alprazolam)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2015	11108822	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2015-04070		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Drug Ineffective; Expired Product Administered; Suicidal Ideation	Alprazolam 1mg			S	Unknown	1 Mg, Four Times/Day		Aurobindo
	Escitalopram			S	Unknown	25 Mg, Once A Day		Aurobindo
	Lamotrigine Tablet			S	Oral	25, Mg		Aurobindo

	Oxcarbazepine		S	Unknown	300 Mg, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2015	11109167	EXPEDITED (15-DAY)		HO	US-DRREDDYS-USA/USA/15/0047921		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Ejection Fraction Decreased; Hypotension; Overdose; Shock	Amlodipine Besylate			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Buspiron [Buspirone Hydrochloride]			S	Unknown			Not Reported
	Dexamfetamine			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2015	11109619	EXPEDITED (15-DAY)		CA	NL-FRI-1000076448		< 1 DAY	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dextrocardia; Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome	Escitalopram			S	Transplacental			Forest
	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2015	9773550	EXPEDITED (15-DAY)		HO	FR-FRI-1000052353		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus	Escitalopram			S	Oral	1 Df		Forest
	Cacit Vitamin D3			S	Oral	500 Mg/440 Iu Daily		Not Reported
	Speciafoldine			S	Oral	2 Df		Not Reported

	Aprovel	S	Oral	1 Df	Not Reported
	Doliprane	S		3 Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2015	11056346	EXPEDITED (15-DAY)		HO	TR-FRI-1000075967		64 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Embolism Venous; Pulmonary Embolism	Escitalopram			S		5 Mg		Forest
	Escitalopram			S		10 Mg		Forest
	Escitalopram			S		15 Mg		Not Reported
	Haloperidol			C		1 Mg		Not Reported
	Haloperidol			C	Unknown	3.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2015	11112029	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-97235		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Product Substitution Issue; Suicidal Ideation	Lamotrigine			S	Unknown	350 Mg, Qd (Every Night At Bedtime)		Taro
	Oxcarbazepine			S	Unknown	300 Mg, Bid		Ranbaxy
	Escitalopram			S	Unknown	25 Mg, Qd		Not Reported
	Alprazolam			S	Unknown	1 Mg, Qid		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2015	11113689	EXPEDITED (15-DAY)		DE, HO	FR-FRI-1000076600		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Serotonin Syndrome; Torsade De Pointes	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest

Atarax	S	Oral	2 Df		Not Reported
Oflocet	S	Oral	2 Df		Not Reported
Lexomil	S	Oral	0.25 Df		Not Reported
Lexomil	S	Oral	1.5 Df		Not Reported
Rasilez	S	Oral	1 Df		Not Reported
Nisis	S	Oral	2 Df		Not Reported
Hyperium	S	Oral	2 Df		Not Reported
Hyperium	S	Oral	1 Df		Not Reported
Inexium	S	Unknown	1 Df		Not Reported
Dafalgan	C	Oral	3 Df		Not Reported
Tardyferon	C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2015	11116062	DIRECT		OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease Recurrence; Gastrointestinal Disorder; Product Substitution Issue; Sleep Disorder	Escitalopram			S		1 20 Mg And 10 Mg		Accord
	Synthroid			C				Not Reported
	Klonopin			C				Not Reported
	Turmeric			C				Not Reported
	B Complete			C				Not Reported
	Vit C			C				Not Reported
	Vit D3			C				Not Reported
	Zinc			C				Not Reported
	Omegas			C				Not Reported
	Probiotics			C				Not Reported
	Magnesium			C				Not Reported
	Escitalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2015	11158166	NON-EXPEDITED	Y	DE	2015010067		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Completed Suicide	Zolpidem (Zolpidem)	S	Not Reported
	Amitriptyline (Amitriptyline)	S	Not Reported
	Tramadol (Tramadol)	S	Not Reported
	Hydrocodone W/Acetaminophen (Hydrocodone, Acetaminophen)	S	Not Reported
	Ondansetron (Ondansetron)	S	Not Reported
	Linaclotide (Linaclotide)	S	Not Reported
	Diclofenac (Diclofenac)	S	Not Reported
	Lubiprostone (Lubiprostone)	S	Not Reported
	Liothyronine (Liothyronine)	S	Not Reported
	Escitalopram (Escitalopram)	S	Not Reported
	Sertraline (Sertraline)	S	Not Reported
	Gabapentin (Gabapentin)	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2015	11008908	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2015-03091		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Detachment; Choroidal Effusion; Headache; Intraocular Pressure Increased; Visual Impairment	Escitalopram 20 Mg			S	Unknown	20 Mg, Daily		Aurobindo
	Escitalopram 20 Mg			S	Unknown	20 Mg, Two Times A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2015	11114407	EXPEDITED (15-DAY)		HO, LT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2015001747			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma	Escitalopram Tablet			S	Oral	15 Mg, Qd		Macleods
	Escitalopram Tablet			S		Unk		Macleods
	Amisulpride			S	Oral	400 Mg, Qd		Not Reported
	Clozapine			S	Oral	700 Mg,Per Day		Not Reported
	Aspirin			C	Unknown			Not Reported

Atorvastatin	C	Unknown		Not Reported
Esomeprazole	C	Unknown		Not Reported
Isotard Xl	C	Unknown		Not Reported
Metformin	C	Unknown		Not Reported
Paracetamol	C	Unknown		Not Reported
Procyclidine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2015	11116296	EXPEDITED (15-DAY)		OT	US-TAKEDA-2015TUS006437			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Brintellix			S	Oral	5 Mg, Qd		Takeda
	Brintellix			S	Oral	Unk		Takeda
	Brintellix			S	Oral	20 Mg, Qd		Takeda
	Lexapro			S	Oral	20 Mg, Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2015	11117203	NON-EXPEDITED			US-PFIZER INC-2015164804		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Condition Aggravated; Dizziness; Drug Ineffective; Tremor	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Xeljanz			S				Pfizer
	Tramadol			S		Unk, As Needed (4 Times A Day)		Not Reported
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2015	11117311	EXPEDITED (15-DAY)		HO, LT	PHFR2015GB003741		52 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma	Clozapine			S	Oral	200 Mg In The Morning And 500mg At Night		Novartis
	Amisulpride			S	Oral	400 Mg, Qhs		Not Reported
	Escitalopram			S	Oral	In The Morning		Not Reported
	Aspirin			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Isotard Xl			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Procyclidine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2015	11119346	DIRECT					61 YR	Male	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Headache; Product Substitution Issue	Escitalopram			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2015	11118031	EXPEDITED (15-DAY)		HO, LT	GB-AUROBINDO-AUR-APL-2015-04380		52 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma	Amisulpride 400 Mg			S	Oral	400 Mg, Once A Day At Night		Not Reported
	Escitalopram			S	Oral	15 Mg, Every Morning		Aurobindo
	Clozapine			S	Oral	700 Mg, Daily(200 Mg In The Morning And 500mg At Night)		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported

Atorvastatin	C	Unknown	Unk		Not Reported
Esomeprazole	C	Unknown	Unk		Not Reported
Isotard Xl	C	Unknown	Unk		Not Reported
Metformin	C	Unknown	Unk		Not Reported
Paracetamol	C	Unknown	Unk		Not Reported
Procyclidine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2015	11119638	EXPEDITED (15-DAY)		OT	DE-FRI-1000076637		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Head Titubation	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Not Reported
	Escitalopram			S	Oral	20 Mg		Not Reported
	Escitalopram			S	Oral	15 Mg		Not Reported
	Amisulpride			S	Oral	400 Mg		Not Reported
	Amisulpride			S	Oral	500 Mg		Not Reported
	Amisulpride			S	Oral	600 Mg		Not Reported
	Amisulpride			S	Oral	450 Mg		Not Reported
	Amisulpride			S	Oral	300 Mg		Not Reported
	Amisulpride			S	Oral	150 Mg		Not Reported
	Amisulpride			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2015	11119701	EXPEDITED (15-DAY)		OT	DE-FRI-1000076601		35 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Metrorrhagia	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest

	Gabapentin		C	Oral	1200 Mg	Not Reported
	Beloc-Zok		C	Oral	95 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	10758404	EXPEDITED (15-DAY)		HO	FR-FRI-1000074134		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Withdrawal Syndrome Neonatal; Exposure During Pregnancy; Respiratory Distress; Somnolence; Tremor	Escitalopram			S	Transplacental	15 Mg		Forest
	Theralene			S	Transplacental	10 Mg		Not Reported
	Risperdal			S	Transplacental	0.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	10867476	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000074726		20 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ischaemic; Colitis Ulcerative	Escitalopram			S	Oral	1 Df		Forest
	Risperdal			S	Oral			Not Reported
	Loxapac			S	Oral	4 Df		Not Reported
	Lepticur			S	Oral	2 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	11121648	EXPEDITED (15-DAY)		HO, LT	GB-TEVA-562768ACC		52 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma	Escitalopram			S	Oral	15 Milligram Daily; In The Morning		Ivax
	Amisulpride			S	Oral	400 Milligram Daily; At Night		Not Reported
	Clozapine			S	Oral	200 Mg In The Morning And 500mg At Night		Not Reported

	Aspirin	C	Not Reported
	Atorvastatin	C	Not Reported
	Esomeprazole	C	Not Reported
	Isotard Xl	C	Not Reported
	Metformin	C	Not Reported
	Paracetamol	C	Not Reported
	Procyclidine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	11122048	EXPEDITED (15-DAY)		HO, OT	FR-JNJFOC-20150504306		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Agitation; Atrophy; Behaviour Disorder; Benign Prostatic Hyperplasia; Extrapyramidal Disorder; General Physical Condition Abnormal; Hypercalcaemia; Hyperhidrosis; Hypertension; Inappropriate Schedule Of Product Administration; Insomnia; Myalgia; Pyrexia; Urinary Retention	Stelara			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Seroplex			S	Unknown			Not Reported
	Insulin			C				Not Reported
	Lithium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	11122235	EXPEDITED (15-DAY)		HO	CH-FRI-1000076597		72 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Loss Of Consciousness	Escitalopram			S	Oral	10 Mg		Forest
	Comilorid Mite			S	Oral			Not Reported
	Meto Zerok			C	Unknown			Not Reported
	Pantozol (Switzerland)			C	Unknown			Not Reported

	Calcimagon D3	C	Unknown	Not Reported
	Symbicort	C	Unknown	Not Reported
	Spiriva	C	Unknown	Not Reported
	Dafalgan	C	Unknown	Not Reported
	Zolpidem	C	Unknown	Not Reported
	Travatan	C	Unknown	Not Reported
	Novalgine (Metamizole Sodium)	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	11122346	EXPEDITED (15-DAY)		OT	NL-CIPLA LTD.-2015NL03866			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Intellectual Disability; Neutropenia; Seizure	Risperidone			S	Unknown			Cipla
	Haloperidol			S	Unknown			Not Reported
	Flupentixol			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Escitolapram			S	Unknown			Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Clozapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	11123564	EXPEDITED (15-DAY)		HO	FR-009507513-1505FRA001318		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Fidaxomicin			S	Oral	200 Mg, Unk		Merck
	Tegretol			S	Oral	400 Mg, Bid		Not Reported
	Alepsal (Caffeine\Phenobarbital)			S		250 Mg, Daily (50 Mg In The Morning And 100 Mg On Noon And 100 Mg In The Evening)		Not Reported

Valium	S	Oral	5 Mg, Tid		Not Reported
Seroplex	S	Oral	15 Mg, In The Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	11124252	DIRECT		DS, OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agoraphobia; Amnesia; Anxiety; Aphasia; Bruxism; Confusional State; Crying; Dyspepsia; Dyspnoea; Dysstasia; Heart Rate Abnormal; Hyperhidrosis; Insomnia; Mental Impairment; Migraine; Mood Swings; Nausea; Negative Thoughts; Orthostatic Hypotension; Suicidal Ideation; Syncope; Vertigo; Weight Increased	Escitalopram			S	Oral	1, Once Daily, Taken By Mouth		Not Reported
	Junel			C				Not Reported
	Multivitamin			C				Not Reported
	B Complex			C				Not Reported
	B12 Methylcobalamin			C				Not Reported
	Phosphatidyl Serine			C				Not Reported
	Ionic Magnesium			C				Not Reported
	Milk Thistle			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	11124498	DIRECT					29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Fatigue; Feeling Cold; Hypersomnia; Movement Disorder; Nausea; Nightmare; Product Quality Issue; Product Substitution Issue; Retching	Escitalopram			S	Oral	1 Pill Once Daily Taken By Mouth		Lupin
	Generic Lexapro			C				Not Reported
	Generic Adderal Xr			C				Not Reported
	Generic Ambien Cr			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2015	10637506	EXPEDITED (15-DAY)		HO, OT	CA-GSKJP-DK201416122002			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arterial Disorder; Asthenia; Biopsy Lung; Bone Disorder; Chest Discomfort; Cough; Cyanosis; Decreased Appetite; Depression; Diarrhoea; Dizziness; Drug Ineffective; Dyspnoea; Dyspnoea Exertional; Emphysema; Fall; Fatigue; Gait Disturbance; Headache; Hiatus Hernia; Hypoaesthesia; Infection; Insomnia; Limb Discomfort; Lung Infection; Malaise; Movement Disorder; Overdose; Pain; Panic Reaction; Pneumonia; Pruritus; Pulmonary Mass; Restlessness; Scar; Thinking Abnormal; Tremor	Advair Diskus			S	Respiratory (inhalation)	1 Df, Bid		Glaxosmithkline
	Ventolin			S	Unknown			Glaxosmithkline
	Spiriva			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Glaxosmithkline
	Atrovent			S	Unknown			Glaxosmithkline
	Seebri Breezhaler			S	Unknown			Glaxosmithkline
	Unknown Drug For Anxiety			S	Unknown	2 To 4 Tablets Die		Not Reported
	Prednisone			S	Unknown			Not Reported
	Cipralex			S				Glaxosmithkline
	Antihypertensive			C	Unknown			Not Reported
	Gaba			C	Unknown			Not Reported
	Unknown Medication			C	Unknown			Not Reported
	Clonazepam			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2015	10868726	EXPEDITED (15-DAY)		HO	IT-FRI-1000074712		63 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Escitalopram			S	Unknown			Forest
	Norvasc			S	Oral			Not Reported
	Blopress			S	Oral			Not Reported

	Lantanon (Mianserin Hydrochloride)	S	Unknown		Not Reported
	Cardioaspirin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2015	11125511	NON-EXPEDITED			US-PFIZER INC-2015167782			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Diflucan			S	Oral	150 Mg, Weekly (1 Df Weekly As Needed)		Pfizer
	Oxycodone			S		Unk		Pfizer
	Amoxil			S		Unk		Not Reported
	Benadryl Allergy /01454801/			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Ambien			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2015	11126442	NON-EXPEDITED			US-TEVA-562053USA		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Interaction; Feeling Abnormal; Feeling Abnormal; Fungal Infection; Insomnia; Rash; Restlessness; Somnolence; Tremor	Azilect			S	Unknown	4 Days A Week (Mon, Tues, Wed, And Thurs)		Teva
	Azilect			S	Unknown	1 Milligram Daily;		Teva
	Amantadine			S	Unknown			Not Reported
	Lexapro			S	Unknown	20 Milligram Daily;		Not Reported
	Invokana			C				Not Reported
	Mirapex Er			C				Not Reported
	Sinemet			C				Not Reported
	Metformin			C				Not Reported
	Victoza			C				Not Reported
	Lantus			C				Not Reported
	Plavix			C				Not Reported

	Diovan	C	Not Reported
	Crestor	C	Not Reported
	Dexamethasone Elixir	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2015	11128147	DIRECT					6 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Escitalopram 5mg Amneal			S	Oral	Liquid		Amneal
	Albuterol Puffer			C				Not Reported
	Singulair			C				Not Reported
	Loratidine			C				Not Reported
	Vitamins			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2015	10607240	EXPEDITED (15-DAY)		DS, HO, LT, OT	DE-FRI-1000072654		42 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Agranulocytosis; Ascites; Drug-Induced Liver Injury; Hepatic Cirrhosis; Splenomegaly; Thrombocytopenia; Urinary Tract Infection	Escitalopram			S	Oral	10 Mg		Forest
	Spironolactone			S	Unknown	50 Mg		Not Reported
	Spironolactone			S				Not Reported
	Torasemide			S	Unknown	10 Mg		Not Reported
	Torasemide			S				Not Reported
	Novalgine (Metamizole Sodium)			S	Oral	20 Drops As Needed		Not Reported
	Sertralin			C	Oral	50 Mg		Not Reported
	Mirtazapin			C	Oral	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2015	11109357	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2015162074		94 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction;	Trangorex			S	Oral	200 Mg, Daily		Pfizer

Hypocoagulable State	Amoxicillin/Clavulanic Acid	S	Intravenous (not otherwise specified)	1 G, 3x/Day	Not Reported
	Sintrom	S	Oral	Unk	Not Reported
	Esertia	S	Oral	15 Mg, Daily	Not Reported
	Enalapril	C		Unk	Not Reported
	Furosemide	C		Unk	Not Reported
	Paracetamol	C		Unk	Not Reported
	Omeprazole	C		Unk	Not Reported
	Eutirox	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2015	11127164	EXPEDITED (15-DAY)		HO, LT	GB-ACCORD-030786		52 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma; Off Label Use	Escitalopram			S	Oral	In The Morning		Accord
	Amisulpride			S	Oral	At Night		Not Reported
	Clozapine			S	Oral	200 Mg In The Morning And 500mg At Night		Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			C				Not Reported
	Isotard Xl			C				Not Reported
	Metformin			C				Not Reported
	Paracetamol			C				Not Reported
	Procyclidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2015	11128237	EXPEDITED (15-DAY)		CA	DK-FRI-1000076816			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Disease	Escitalopram			S	Transplacental			Forest

Congenital

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2015	11128624	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA-2015SE44954		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Drug Withdrawal Syndrome Neonatal	Seroquel			S	Transplacental			Zeneca
	Cipralex			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2015	11129284	NON-EXPEDITED			US-PFIZER INC-2015169291		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pain	Lyrica			S	Oral	300 Mg, 2x/Day , Daily		Pfizer
	Lidocaine Hcl			S	Topical	Unk (Apply Up To 3 Patches, Only Once For Up To 12 Hr Within A 24 Hr Period)		Pfizer
	Mirtazapine			S	Oral	Unk, 1x/Day (Take 1 Tab By Mouth At Dinnertime)		Not Reported
	Pantoprazole			S	Oral	40 Mg, Daily		Pfizer
	Escitalopram Oxalate			S	Oral	10 Mg, Daily		Not Reported
	Ranitidine Hcl			S		150 Mg, 2x/Day		Not Reported
	Hydrocortisone Acetate			S		Apply Small Amount To Rash Twice A Day		Pfizer
	Diltiazem Hcl			S	Oral	30 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2015	9255725	NON-EXPEDITED			US-009507513-1304USA014622			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anogenital Warts;	Propecia			S	Oral	1 Mg, Qd		Merck

Depression; Erectile Dysfunction; Joint Dislocation; Libido Decreased; Road Traffic Accident; Sexual Dysfunction; Skin Papilloma	Propecia		S	Oral	1 Mg, Qd	Merck
	Lexapro		S	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2015	9683959	EXPEDITED (15-DAY)		DE, HO	PHHY2013US125116		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Areflexia; Brain Injury; Cardiac Arrest; Circulatory Collapse; Corneal Reflex Decreased; Dry Skin; Gastrointestinal Sounds Abnormal; Hypotension; Overdose; Peripheral Coldness; Pulseless Electrical Activity; Pupil Fixed; Sinus Tachycardia; Unresponsive To Stimuli	Ibuprofen			S	Unknown			Novartis
	Bupropion			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Quetiapine			S				Not Reported
	Desvenlafaxine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2015	10815174	EXPEDITED (15-DAY)		HO	US-ASTRAZENECA-2015SE15149		64 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Blopress			S	Oral	Unk		Not Reported
	Norvasc			S	Unknown	Unk		Not Reported
	Lantanon (Mianserin Hydrochloride)			S	Unknown	Unk		Not Reported
	Entact			S	Unknown	Unk		Not Reported
	Cardioaspirin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2015	11131450	EXPEDITED (15-DAY)		DS	NL-FRI-1000076846		37 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Erectile Dysfunction; Genital Hypoaesthesia; Listless; Loss Of Libido; Partner Stress; Sexual Dysfunction	Lexapro			S	Oral	10 Mg		Forest
	Lamictal Dispersible Chew Tablet			C	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2015	11131662	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015169516			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Major Depression; Post-Traumatic Stress Disorder	Doxepin Hcl			S		Unk		Pfizer
	Pristiq			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Geodon			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Thorazine			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2015	11132712	EXPEDITED (15-DAY)		OT	AU-FRI-1000076826			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2015	11132757	EXPEDITED (15-DAY)		HO	ES-FRI-1000076841		94 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Hypocoagulable State	Escitalopram			S	Oral	15 Mg		Forest
	Sintrom 4 Mg Comprimidos , 20 Comprimidos			S	Oral			Not Reported
	Amoxicilina + Clavulanico			S	Intravenous (not otherwise specified)	3 G		Not Reported
	Trangorex 200 Mg Comprimidos , 30 Comprimidos			S	Oral	200 Mg		Not Reported
	Enalapril			C	Oral	5 Mg		Not Reported
	Furosemida			C	Oral	40 Mg		Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)	3 G		Not Reported
	Omeprazol			C	Oral	20 Mg		Not Reported
	Eutirox 112 Microgramos Comprimidos , 100 Comprimidos			C	Oral	112 Mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2015	10928772	NON-EXPEDITED			US-JNJFOC-20140514835			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Product Use In Unapproved Indication	Concerta			S	Oral			Not Reported
	Fetzima			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Viibryd			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2015	10928779	NON-EXPEDITED			US-JNJFOC-20140911403		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Concerta			S	Oral			Not Reported
	Fampridine			S	Oral			Not Reported
	Fampridine			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Ubidecarenone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	9255219	NON-EXPEDITED		HO	US-JNJFOC-20130310450			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Exposure During Pregnancy; Premature Labour	Topamax			S	Oral			Not Reported
	Miralax			S	Unknown			Not Reported
	Dulcolax			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Reglan			S	Unknown			Not Reported
	Zofran			S	Unknown			Not Reported
	Zofran			S	Unknown			Not Reported
	Methadone			S	Unknown			Not Reported
	Percocet			S	Unknown			Not Reported
	Lortab			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Stadol			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Neurontin			S	Unknown			Not Reported
	Protonix			S	Unknown			Not Reported

	Bentyl	S	Unknown	Not Reported
	Prenatal Vitamins	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	9661130	NON-EXPEDITED		OT	US-JNJFOC-20130606595			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Mass; Breast Pain; Emotional Distress; Gynaecomastia; Weight Increased	Risperdal Consta			S	Intramuscular			Not Reported
	Risperdal			S	Oral			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Tegretol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	10589297	NON-EXPEDITED		OT	US-JNJFOC-20141108501		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Dry Mouth; Oropharyngeal Pain; Type 2 Diabetes Mellitus; Visual Impairment	Ibuprofen			S	Unknown	800 Mg In The Morning And 1200		Not Reported
	Fentanyl			S	Unknown	50 Microgram, Every 48 Hours		Not Reported
	Oxycodone Paracetamol			S	Unknown	10/325 Mg, 1 Of Them 3 Times Daily, As Needed		Not Reported
	Topamax			S	Unknown	100 Mg, Daily (Daily In The Morning)		Not Reported
	Aspirin			S	Unknown	162 Mg, 1 Time Per Day (81mg, 2 Tablets At Night)		Not Reported
	Lyrica			S	Unknown			Not Reported
	Seroquel			S	Unknown	50 Mg Twice Daily In The		Not Reported

				Morning And Noon	
	Seroquel	S	Unknown	200 Mg At Night, Unk, Unk, 3 Times Per Day	Not Reported
	Seroquel	S	Unknown	200 Mg At Night, Unk, Unk, 3 Times Per Day	Not Reported
	Seroquel	S	Unknown	50 Mg Twice Daily In The Morning And Noon	Not Reported
	Lexapro	S	Unknown		Not Reported
	Demadex	S	Unknown		Not Reported
	Valium	S	Unknown		Not Reported
	Metformin Hcl	S	Unknown		Not Reported
	Effexor Xr	S	Unknown	225 Mg, Daily (75mg Capsule And A 150mg Capsule Together)	Not Reported
	Tizanidine	S	Unknown		Not Reported
	Simvastatin	S	Unknown	40 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	10937081	NON-EXPEDITED			US-JNJFOC-20130417562		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Exposure During Pregnancy	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Phenobarbital			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Neurontin			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lorazepam			S	Oral			Not Reported
	Promethazine			S	Oral			Not Reported

	Nitrofuran			S	Unknown				Not Reported
	Cefaclor			S	Unknown				Not Reported
	Fluconazole			S	Unknown				Not Reported
	Fluoxetine			S	Oral				Not Reported
	Vitamin B2			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	10937181	NON-EXPEDITED			US-JNJFOC-20130315736			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Topamax			S	Oral			Not Reported
	Depakote			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Klonopin			S	Unknown			Not Reported
	Valium			S	Unknown			Not Reported
	Paxil			S	Unknown			Not Reported
	Celexa			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Anafranil			S	Unknown			Not Reported
	Imipramine			S	Unknown			Not Reported
	Tegretol			S	Unknown			Not Reported
	Luvox			S	Unknown			Not Reported
	Pristiq			C	Unknown			Not Reported
	Lithium			C	Unknown			Not Reported

Seroquel Xr	C	Unknown		Not Reported
Xanax	C	Unknown		Not Reported
Adderall	C	Unknown		Not Reported
Abilify	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	10938290	NON-EXPEDITED			US-JNJFOC-20120706407			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction	Stelara			S	Subcutaneous	12th Week		Not Reported
	Topamax			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Klonopin			S	Unknown			Not Reported
	Klonopin			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	10972837	NON-EXPEDITED			US-JNJFOC-20140117180		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased	Risperdal Consta			S	Intramuscular			Not Reported
	Abilify			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Clonidine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	11014917	NON-EXPEDITED		OT	US-JNJFOC-20140111142		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Tramadol Hydrochloride			S	Unknown	Patients 2, 5		Not Reported
	Ceftriaxone			S	Unknown	Patient 2		Not Reported
	Escitalopram			S	Unknown	Patient 2		Not Reported
	Oxygen			S	Unknown	Patients 2, 5		Not Reported
	Metronidazole			C	Unknown	Patient 2		Not Reported
	Zolpidem			C	Unknown	Patient 2		Not Reported
	Acetaminophen\Hydrocodone Bitartrate			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	11020446	NON-EXPEDITED			US-JNJFOC-20140803303			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Levofloxacin			S	Unknown			Not Reported
	Effexor			S	Unknown			Not Reported
	Lamotrigine			S	Unknown			Not Reported
	Elavil			S	Unknown			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Amoxycillin Clavulanic Acid Sandoz			S				Not Reported
	Lexapro			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Dilantin			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Tioconazole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	11036478	NON-EXPEDITED			US-JNJFOC-20140518737			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Interaction; Headache	Xarelto			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	11065063	NON-EXPEDITED			US-JNJFOC-20111104649			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Exposure During Pregnancy; Stress	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Zantac			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Sulphacetamide			S	Unknown			Not Reported
	Phenergan			S	Unknown			Not Reported
	Acebutolol			S	Unknown			Not Reported
	Ferrous Sulfate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prenatal Vitamins			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	11096234	EXPEDITED (15-DAY)		OT	BR-ROCHE-1574283		75 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Rivotril			S	Oral			Not Reported

	Escitalopram	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	11141487	NON-EXPEDITED			US-JNJFOC-20120611062		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Risperdal			S	Oral	3 X/Morning And 4 X/Night		Not Reported
	Topamax			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2015	10700592	EXPEDITED (15-DAY)		CA, OT	CH-PFIZER INC-2015004043			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Maternal Exposure During Pregnancy; Premature Baby; Psychomotor Skills Impaired; Pulmonary Valve Stenosis	Xanax			S	Transplacental	0.5 Mg, Daily		Pfizer
	Xanax			S	Transplacental	1.5 Mg, Daily		Pfizer
	Xanax			S	Transplacental	0.125 Mg At Noon And 0.25 Mg In The Evening		Pfizer
	Cipralex			S	Transplacental	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2015	10923628	NON-EXPEDITED			US-JNJFOC-20141001642		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Paranoia	Risperidone			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Fluphenazine			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported

	Quetiapine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2015	11137071	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2015GSK071572		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Bupropion			S				Glaxosmithkline
	Escitalopram			S		3 Mg, 1d		Glaxosmithkline
	Quetiapine			S		400 Mg, 1d, At Night		Glaxosmithkline
	Lamotrigine			S		75 Mg, Bid		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2015	11137623	EXPEDITED (15-DAY)		HO, LT	GB-MYLANLABS-2015M1016329			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma	Escitalopram			S	Oral	15 Mg, Qd (In The Morning)		Not Reported
	Amisulpride			S	Oral	400 Mg, Qd (At Night)		Not Reported
	Clozapine			S	Oral	700 Mg Per Day, (200 Mg In The Morning And 500mg At Night)		Not Reported
	Aspirin /00002701/			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Esomeprazole			C		Unk		Not Reported
	Isotard Xl			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Procyclidine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	9833071	EXPEDITED (15-DAY)		LT, OT	PHHY2013CH155164		31 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Choking; Drug Interaction; Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; Electrocardiogram Repolarisation Abnormality; Generalised Tonic-Clonic Seizure; Hypokalaemia; Hypomagnesaemia; Loss Of Consciousness; Nausea; Product Administration Error; Pulse Absent; Respiration Abnormal; Stress Cardiomyopathy; Torsade De Pointes; Unresponsive To Stimuli; Ventricular Tachyarrhythmia; Ventricular Tachycardia	Escitalopram			S	Unknown			Not Reported
	Methadone			S	Oral	50-60 Mg, Daily		Novartis
	Ondansetron			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	10891883	EXPEDITED (15-DAY)		HO	IT-FRI-1000075007		37 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Product Administration Error; Sopor	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11138465	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2015-01030			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness	Escitalopram Generic Health 20mg Tablet	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11138466	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2015-01034			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Panic Attack	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11142199	EXPEDITED (15-DAY)		LT	FR-FRI-1000076943		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy	Escitalopram			S	Oral	5 Mg		Forest
	Tienam			S	Intravenous (not otherwise specified)	2 G		Not Reported
	Flagyl			C	Oral	1500 Mg		Not Reported
	Kardegic			C	Oral	75 Mg		Not Reported
	Chlorhydrate De Sotalol			C	Oral	160 Mg		Not Reported
	Oxycontin Lp			C		20 Mg On Morning And 30 Mg On Evening		Not Reported
	Oxynorm			C	Oral	40 Mg		Not Reported
	Amlor			C	Oral	5 Mg		Not Reported
	Xanax			C	Oral	0.25 Mg		Not Reported
	Eupantol			C	Oral	40 Mg		Not Reported
	Vancomycine			C	Intravenous (not otherwise specified)	2250 Mg		Not Reported
	Calciparine			C	Subcutaneous	0.4 Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11142202	EXPEDITED (15-DAY)		LT	FR-FRI-1000076952		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram			S	Oral	5 Mg		Forest
	Plaquenil			S	Oral	400 Mg		Not Reported
	Procoralan			S	Oral	10 Mg		Not Reported
	Atacand			C	Oral	4 Mg		Not Reported
	Aldactone			C	Oral	12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11144938	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro 20 Mg Camber			S	Oral			Not Reported
	Lexapro 5 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11148905	EXPEDITED (15-DAY)	Y	HO, LT, OT	2015COV00106		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Chest Pain; Diarrhoea; Drug Ineffective; Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Hyperlactacidaemia; Hypokalaemia; Loss Of Consciousness; Malaise; Metabolic Acidosis; Mydriasis; Nausea; Torsade De Pointes;	Plaquenil Tablet			S	Oral			Not Reported
	(Hydroxychloroquine) Tablet							
	Seroplex (Escitalopram Oxalate)			S	Oral			Not Reported
	Procoralan (Ivabradine Hydrochloride) Tablet			S	Oral			Not Reported
	Atacand (Candesartan Cilexetil)			C				Not Reported
	Aldactone (Spironolactone)			C				Not Reported

Vertigo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	7319573	EXPEDITED (15-DAY)		OT	ES-ASTRAZENECA-2010SE10022		67 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Seroquel			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Coaprovel			S	Oral	150/12.5 Mg 1 Df Daily		Not Reported
	Pantoprazole Alter			S	Oral			Not Reported
	Trialmin			S	Oral			Not Reported
	Alendronate (Alendronic Acid)			C	Oral			Not Reported
	Adartrel			C	Oral			Not Reported
	Bonesil D Flas			C	Oral	1500 Mg/400 Iu 1 Df Daily		Not Reported
	Simvastatin			C	Oral			Not Reported
	Torasemide			C	Oral			Not Reported
	Zolpidem			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	11142972	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2015-01472		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Suicidal Ideation	Lamotrigine			S	Unknown			Not Reported
	Oxcarbazepine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	11144071	EXPEDITED (15-DAY)		DE, HO	GR-SANOFI-AVENTIS-2012SA094260		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Antipsychotic Drug Level Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Pressure Decreased; Blood Sodium Increased; Blood Urea Increased; Blood Uric Acid Increased; Cardio-Respiratory Arrest; Depressed Level Of Consciousness; Drug Interaction; Hyperpyrexia; Leukocytosis; Muscle Rigidity; Myoglobinuria; Neuroleptic Malignant Syndrome; Rhabdomyolysis; Stupor; Tachypnoea	Lithium Carbonate			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Irbesartan			S	Unknown			Not Reported
	Amlodipine Besilate			S	Unknown			Not Reported
	Buspirone Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	11144707	EXPEDITED (15-DAY)		HO, LT	GB-FRI-1000076918		52 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma; Product Use In Unapproved Indication	Escitalopram			S	Oral	15 Mg		Forest
	Amisulpride			S	Oral	400 Mg		Not Reported
	Clozapine			S	Oral	700 Mg		Not Reported
	Aspirin			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

Esomeprazole	C	Unknown	Not Reported
Isotard Xl	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Paracetamol	C	Unknown	Not Reported
Procyclidine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	11144955	EXPEDITED (15-DAY)		OT	CH-FRI-1000076945		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental			Forest
	Seroquel			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	11146015	EXPEDITED (15-DAY)		OT	CH-GLAXOSMITHKLINE-CH2015GSK072869		34 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Labour; Premature Rupture Of Membranes	Xenical			S	Unknown	Unk		Glaxosmithkline
	Cipralex			S	Unknown			Glaxosmithkline
	Topamax			S	Oral	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	11146020	EXPEDITED (15-DAY)		OT	GB-GLAXOSMITHKLINE-GB2015GSK072855			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Burning Sensation; Drug Ineffective; Muscle Spasms; Muscle Twitching; Swollen	Xenical			S	Unknown	120 Mg, Unk		Glaxosmithkline
	Lyrica			S	Unknown	300 Mg, Tid		Not Reported
	Simvastatin			S	Unknown	40 Mg, Unk		Glaxosmithkline

Tongue	Celebrex	S	Unknown	200 Mg, Unk		Glaxosmithkline
	Omeprazole	S		20 Mg, Unk		Glaxosmithkline
	Dexamphetamine	S	Unknown	5 Mg, Unk		Glaxosmithkline
	Cipralex	S	Unknown	20 Mg, Unk		Glaxosmithkline
	Tramadol	S	Oral	100 Mg, Unk		Glaxosmithkline
	Butrans	S	Transdermal	10 Ug, Unk Per Hr.		Not Reported
	Oxybutynin Chloride	S	Unknown	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	11146028	EXPEDITED (15-DAY)		OT	CH-GLAXOSMITHKLINE-CH2015GSK072870		1 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Premature Baby	Xenical			S	Transplacental	Unk		Glaxosmithkline
	Cipralex			S	Transplacental	Unk		Glaxosmithkline
	Topamax			S	Transplacental	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	11148197	DIRECT					37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Escitalopram 20g			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2015	8574627	EXPEDITED (15-DAY)		HO, LT	ES-JNJFOC-20120513188		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis; Hypotension; Tachycardia	Risperdal Flas			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported

	Simvastatin		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2015	11095904	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2015-04005		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Catatonia; Condition Aggravated; Corneal Reflex Decreased; Hypokinesia; Hypotension; Mental Status Changes; Negativism; Pyrexia; Respiratory Failure; Rhabdomyolysis; Seizure; Verbigeration	Escitalopram			S	Unknown	Unk		Aurobindo
	Escitalopram			S				Aurobindo
	Quetiapine			S	Unknown	Unk		Aurobindo
	Quetiapine			S				Aurobindo
	Clozapine			S	Unknown	Unk		Not Reported
	Clozapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2015	11148230	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20150517740		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Xarelto			S	Oral	Unknown		Not Reported
	Xarelto			S	Oral	Unknown		Not Reported
	Seroplex			S	Oral	Unknown		Not Reported
	Lasilix			S	Oral	Unknown		Not Reported
	Crestor			S	Oral	Unknown		Not Reported
	Cardensiel			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2015	11148321	EXPEDITED (15-DAY)		OT	KP-CIPLA LTD.-2015KP04140			Unknown	PRK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mood Altered	Lamotrigine			S	Unknown			Cipla

	Sertraline	S	Unknown		Cipla
	Escitalopram	S			Not Reported
	Fluoxetine	S	Unknown		Not Reported
	Paroxetine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2015	11149412	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2015SE51969		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Crestor			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Cardensiel			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2015	11150420	EXPEDITED (15-DAY)		DE	GR-SA-BMS17442690		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Neuroleptic Malignant Syndrome	Irbesartan			S				Not Reported
	Buspirone			S				Not Reported
	Lithium			S				Not Reported
	Amlodipine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	8820028	EXPEDITED (15-DAY)		HO, OT	ES-ELI_LILLY_AND_COMPANY-ES201209006034		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Drug Interaction	Zyprexa			S	Oral	10 Mg, Unknown		Eli Lilly And Co
	Deprax /00447702/			S	Oral	20 Mg, Qd		Not Reported

Escitalopram	S	Oral	10 Mg, Qd		Not Reported
Sinemet-Plus	S	Oral	100 Mg, Qd		Not Reported
Omeprazol /00661201/	C	Oral	20 Mg, Qd		Not Reported
Stelara	C		1 Df, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	10717256	EXPEDITED (15-DAY)		CA	CH-FRI-1000073679			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby; Psychomotor Skills Impaired; Pulmonary Valve Stenosis	Escitalopram			S	Transplacental	10 Mg		Forest
	Xanax			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	10975277	EXPEDITED (15-DAY)		DE	NL-FRI-1000075554		56 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Lexapro			S	Oral	15 Mg Daily		Forest
	Medikinet			S	Unknown	20 Mg Daily		Not Reported
	Medikinet			S	Unknown	40 Mg Daily		Not Reported
	Medikinet			S	Unknown	50 Mg		Not Reported
	Trazolan			S	Unknown	100 Mg Daily		Not Reported
	Zopiclon			S	Unknown	15 Mg Daily		Not Reported
	Alprazolam			S	Unknown			Not Reported
	Omeprazol Actavis			C	Unknown	20 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	11076174	NON-EXPEDITED			US-PFIZER INC-2015138562		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xanax			S	Oral	0.5 Mg, 3x/Day		Pfizer
	Xanax			S				Pfizer
	Nardil			S	Oral	15 Mg, 1x/Day		Pfizer
	Nardil			S	Oral	15 Mg, 2x/Day		Pfizer
	Nardil			S	Oral	15 Mg, 3x/Day		Pfizer
	Nardil			S	Oral	15 Mg, 4x/Day		Pfizer
	Escitalopram			S	Oral	10 Mg, 2x/Day		Not Reported
	Escitalopram			S				Not Reported
	Klonopin			S	Oral	Unk		Not Reported
	Klonopin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	11150679	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-04742		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Pain	Escitalopram 20 Mg			S	Oral	20 Mg, Unk		Aurobindo
	Cetirizine			C	Unknown	Unk		Not Reported
	Desogestrel			C	Unknown	Unk		Not Reported
	Omeprazol /00661201/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	11151887	NON-EXPEDITED			US-PFIZER INC-2015181908		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2015	9656903	EXPEDITED (15-DAY)		OT	PHHY2013ES113758		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Olanzapine			S	Unknown			Novartis
	Enalapril			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2015	11155470	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015180829		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Fall; Hyponatraemia; Hypotension; Loss Of Consciousness; Wound	Xanax			S	Oral	0.25 Mg, 1x/Day		Pfizer
	Seroplex			S	Oral	5 Mg, 1x/Day		Not Reported
	Coveram			S	Oral	Perindopril Arginine: 5 Mg/ Amlodipine Besylate: 5 Mg; 1 Df, 1x/Day		Not Reported
	Novatrex			C		2.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2015	11157321	EXPEDITED (15-DAY)		OT	GB-LUPIN PHARMACEUTICALS INC.-2015-01556		41 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Alcoholism; Mania; Suicidal Ideation; Tremor	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2015	11163665	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapy Cessation; Tinnitus	Lexapro	S	Oral		2 WEEK	Not Reported
	Simvastatin	C				Not Reported
	Levothyroxine	C				Not Reported
	Allopurinol	C				Not Reported
	Wellbutrin	C				Not Reported
	Topamax	C				Not Reported
	Remeron	C				Not Reported
	Clonazepam	C				Not Reported
	Losartan	C				Not Reported
	Potassium	C				Not Reported
	Flexeril	C				Not Reported
	Hydrocodone	C				Not Reported
	Naproxen	C				Not Reported
	Vitamin D3	C				Not Reported
	Loratadine	C				Not Reported
	Magnesium	C				Not Reported
	Zinc	C				Not Reported
	Multivitamin	C				Not Reported
	Iron	C				Not Reported
	Orphenadrine Er	C				Not Reported
	Nora-Be	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2015	11163903	DIRECT					47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Headache; Incorrect Dose Administered; Product Dispensing Error; Product Quality Issue; Product Substitution Issue	Escitalopram			S	Oral	1/2 A Pill Once Daily Taken By Mouth		Mylan
	Trazadone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2015	11164243	DIRECT					53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Eye; Dry Mouth;	Escitalopram			S	Oral	1 Pill Once Daily Taken By		Camber

Headache; Insomnia; Product Substitution Issue; Suicidal Ideation — Mouth

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2015	11057637	EXPEDITED (15-DAY)		DS	PHEH2015US006748			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Recurrent Cancer	Sandostatin (Octreotide Acetate)			S	Unknown			Not Reported
	Sandostatin (Octreotide Acetate)			S	Unknown	Unk		Not Reported
	Metolazone			S	Unknown			Novartis
	Cymbalta			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Potassium			S	Unknown			Not Reported
	Magnesium			S	Unknown			Not Reported
	Zyrtec			S	Unknown			Not Reported
	Zantac			S	Unknown			Not Reported
	Fentanyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2015	11163223	EXPEDITED (15-DAY)		OT	CA-FRI-1000077154		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Prescribed Overdose; Rash; Vasculitis	Escitalopram			S	Oral	Overdose: Escitalopram 30 Mg Daily		Forest
	Escitalopram			S				Forest
	Trintellix			S	Oral	10 Mg		Not Reported
	Trintellix			S				Not Reported
	Terbinafine			S	Oral	250 Mg		Not Reported
	Amitriptyline			C	Oral	100 Mg		Not Reported

Clonazepam	C	Oral	3 Mg		Not Reported
Clonazepam	C				Not Reported
Nozinan	C	Oral	37.5 Mg		Not Reported
Nph Insulin	C	Subcutaneous	As Directed.		Not Reported
Crestor	C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2015	11164001	EXPEDITED (15-DAY)		OT	GB-ACCORD-031147		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Pain	Escitalopram			S	Oral			Accord
	Cetirizine			C				Not Reported
	Desogestrel			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2015	11165739	EXPEDITED (15-DAY)		HO, LT, OT	CH-ELI_LILLY_AND_COMPANY-CH201506001053		48 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Torsade De Pointes; Ventricular Fibrillation	Fluoxetine			S	Oral	Unk Unk, Unknown		Unknown
	Escitalopram			S	Oral	10 Mg, Bid		Not Reported
	Atacand			C	Oral	16 Mg, Bid		Not Reported
	Tranxilium			C		Unk Unk, Unknown		Not Reported
	Temesta /00273201/			C		Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2015	11170753	DIRECT		OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anorgasmia; Ejaculation Failure; Emotional	Escitalopram			S	Oral	1/2 Pill 5 Days -1 Pill 2 Days Twice Daily Taken	9 DAY	Not Reported

Disorder; Genital Hypoaesthesia; Mental Impairment; Nightmare; Premature Ejaculation				By Mouth	
	Amlodipine Besylate	C			Not Reported
	Levothyroxine	C			Not Reported
	Micardis	C			Not Reported
	Pravastatin	C			Not Reported
	Low Dose Aspirin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2015	11020319	EXPEDITED (15-DAY)		HO	JP-TEVA-554172USA		58 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	Unk, Cyclic		Cephalon
	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	Unk, Cyclic		Cephalon
	Placebo			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Placebo			S		Unk, Unknown Freq.		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk, Unknown Freq.		Not Reported
	Lithium Carbonate			S	Oral			Not Reported
	Lexapro /01588502/			S	Oral			Not Reported
	Cercine			S	Oral			Not Reported
	Feburic			C	Oral			Not Reported
	Takepron			C	Oral			Not Reported
	Baktar			C	Unknown			Not Reported
	Myonal /00287502/			C	Unknown			Not Reported
	Hirudoid /00723701/			C	Topical			Not Reported
	Miya Bm			C	Oral	Unk Unk, Thrice Daily		Not Reported
	Lulicon			C	Topical			Not Reported
	Antebate			C	Topical			Not Reported
	Zefnart			C	Topical			Not Reported
	Allegra			C	Oral			Not Reported

	Lamisil /00992601/	C	Topical	Not Reported
	Astat /01368101/	C	Topical	Not Reported
	Loperamide	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2015	11166890	EXPEDITED (15-DAY)		OT	GB-TEVA-566648ACC		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Pain	Escitalopram			S	Oral			Ivax
	Cetirizine			C				Not Reported
	Desogestrel			C				Not Reported
	Omeprazol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2015	11169437	EXPEDITED (15-DAY)		HO, OT	CA-ELI_LILLY_AND_COMPANY-CA201506000752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Humalog Lispro			S	Subcutaneous			Eli Lilly And Co
	Humalog Lispro			S	Oral	10 Df, Unk		Eli Lilly And Co
	Ativan			S	Oral	80 Df, Unk		Not Reported
	Cipralex /01588501/			S	Oral	20 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Oral	10 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Topiramate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2015	11171994	DIRECT		DS, LT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Back	Amitriptyline			S	Oral	2-4 At Bedtime Taken By		Not Reported

Pain; Chest Pain; Cognitive Disorder; Confusional State; Dementia; Dizziness Postural; Drug Monitoring Procedure Not Performed; Impaired Work Ability; Memory Impairment; Myalgia; Panic Reaction; Product Prescribing Error; Stress; Tachycardia; Vision Blurred	Escitalopram		S	Oral	M Outh 2 Twice Daily Taken By Mouth	Not Reported
	High Blood Pressure		C			Not Reported
	Heart Rate Medicine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2015	11110941	EXPEDITED (15-DAY)		HO	PL-FRI-1000076141		43 YR	Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Prescribed Overdose; Sexual Dysfunction	Escitalopram			S	Unknown	Overdose: 40 Mg Daily		Forest
	Divalproex			C	Unknown	1000 Mg		Not Reported
	Lithium			C	Unknown	750 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2015	11134417	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2015TJP008784			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Prescribed Overdose; Rash; Vasculitis	Trintellix			S	Oral	10 Mg, Qd		Takeda
	Trintellix			S				Takeda
	Terbinafine			S	Oral	250 Mg, Qd		Not Reported
	Cipralex Tablets			S	Oral	Overdose: Escitalopram 30 Mg, Qd		Not Reported
	Cipralex Tablets			S				Not Reported
	Amitriptyline			C	Oral	100 Mg, Qd		Not Reported
	Clonazepam			C	Oral	1 Mg, Tid		Not Reported
	Clonazepam			C				Not Reported

Nozinan /00038601/	C	Oral	37.5 Mg, Qd		Not Reported
Nph Insulin	C	Subcutaneous	As Directed.		Not Reported
Crestor	C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2015	11170510	EXPEDITED (15-DAY)		OT	FR-TEVA-568381ISR		20 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis; Sedation	Escitalopram			S	Unknown	Titrated From 5 To 20 Mg/D, Then Given 30mg		Ivax
	Escitalopram			S	Unknown	30 Mg		Ivax
	Aripiprazole			S	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2015	11172183	EXPEDITED (15-DAY)		OT	GB-FRI-1000077097		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Pain	Escitalopram			S	Oral	20 Mg Daily		Forest
	Escitalopram			S				Forest
	Cetirizine			C	Unknown			Not Reported
	Desogestrel			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2015	11172184	EXPEDITED (15-DAY)		HO	FR-FRI-1000077099		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Fall; Hyponatraemia; Hypotension; Loss Of Consciousness; Wound	Escitalopram			S	Oral	1 Df		Forest
	Coveram			S	Oral	5 Mg/5 Mg		Not Reported
	Xanax			S	Oral	1 Df		Not Reported

	Novatrex			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2015	11172233	EXPEDITED (15-DAY)		HO	FR-SYMPLMED PHARMACEUTICALS-2015SYMPLMED000019			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Fall; Hyponatraemia; Hypotension; Loss Of Consciousness; Wound; Wound Haemorrhage	Coveram			S	Oral	5mg/5mg Tablet Once Daily		Unknown
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Xanax			S	Oral	0.25 Mg, Qd		Not Reported
	Novatrex /00113801/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2015	10609022	EXPEDITED (15-DAY)		OT	PHHY2014US146215			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Pain; Sensory Disturbance; Therapeutic Response Decreased	Baclofen Intrathecal			S	Intrathecal	83 Ug, Per Day		Not Reported
	Baclofen Intrathecal			S				Not Reported
	Clonidine			S	Oral			Novartis
	Clonidine			S	Intrathecal	83 Ug, Per Day		Not Reported
	Lexapro			S	Oral			Not Reported
	Flexeril			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2015	11151277	EXPEDITED (15-DAY)		DE, HO	GR-PFIZER INC-2015181860		72 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Drug	Amlodipine Besilate			S		5 Mg, 1x/Day		Pfizer
	Lithium Carbonate			S		300 Mg, 3x/Day		Not Reported
	Escitalopram Oxalate			S		20 Mg, 1x/Day		Not Reported

Interaction; Neuroleptic Malignant Syndrome; Rhabdomyolysis	Irbesartan		S	150 Mg, 1x/Day	Not Reported
	Buspirone Hydrochloride		S	10 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2015	11174091	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2015-01026			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Insomnia	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2015	11177690	DIRECT		DE			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Completed Suicide; Headache; Social Avoidant Behaviour; Vision Blurred	Escitalopram 10 Mg			S			2 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2015	11169808	EXPEDITED (15-DAY)	Y	HO, OT	ADR-2015-01025		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Altered State Of Consciousness; Condition Aggravated; Confusional State; Constipation; Drug Withdrawal Syndrome; Hyperhidrosis; Hypertonia; Initial Insomnia; Muscle Spasticity; Musculoskeletal Stiffness; Pneumonia; Respiratory Tract Congestion; Screaming; Speech	Lioresal Intrathecal(Baclofen Injection) 2000 Mcg/Ml			S				Not Reported
	Ellura			S				Not Reported
	Microgestin 1.5/30			S				Not Reported
	Oxytrol			S	Topical	24 Hr Patch		Not Reported
	Lexapro			S				Not Reported
	Trazadone			S		50 Mg Tab 1-2 Tabs At Bedtime Prn		Not Reported
	Valium			S		5 Mg 1-2 Tab Prn		Not Reported

Disorder; Therapeutic Response Changed; Tooth Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2015	11178934	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2015M1017659			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Pain	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Cetirizine			C		Unk		Not Reported
	Desogestrel			C		Unk		Not Reported
	Omeprazol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2015	11183630	DIRECT					49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Feeling Abnormal; Insomnia; Mental Impairment; Product Substitution Issue; Tremor	Lexapro			S	Oral	1 /Day Once Daily Taken By Mouth		Accord
	Cpap			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2015	11184305	EXPEDITED (15-DAY)	Y	OT	2015HINLIT0479		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Depression; Disease Recurrence; Drug Ineffective; Headache; Hypomania; Migraine; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Therapy Change; Therapy Change	Escitalopram (Escitalopram) Unknown			S				Not Reported
	Lithium (Lithium) Unknown			S				Not Reported
	Valproate (Valproate)			C				Not Reported
	Indomethacin+Caffeine+Prochlorperazine (Indomethacin+Caffeine+Prochlorperazine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2015	11184322	EXPEDITED (15-DAY)	Y	OT	2015HINLIT0476		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Hypomania; Tongue Biting	Escitalopram (Escitalopram)			S				Not Reported
	Lithium (Lithium)			S				Not Reported
	Valproate (Valproate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2015	11184496	EXPEDITED (15-DAY)	Y	OT	2015HINLIT0477		35 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rabbit Syndrome	Escitalopram (Escitalopram)			S				Not Reported
	Unknown							
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2015	11189519	EXPEDITED (15-DAY)	Y	HO	NSR_02133_2015		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Drug Interaction; Hemianopia	Tramadol (Tramadol)			S		Df		Not Reported
	Tramadol And Acetaminophen			S		(1/1/1)		Not Reported
	Escitalopram (Escitalopram)			S		(10; 1/0/0)		Not Reported
	Etoricoxib (Etoricoxib)			S		(90; 1/0/0)		Not Reported
	Deflazacort			C				Not Reported
	Salbutamol			C				Not Reported
	Montelukast			C				Not Reported
	Atorvastatin			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2015	11184226	NON-EXPEDITED			US-PFIZER INC-2015193932			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspareunia	Duavee			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2015	11185070	EXPEDITED (15-DAY)		OT	US-ROXANE LABORATORIES, INC.-2015-RO-00946RO		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Suicidal Ideation	Oxcarbazepine			S	Unknown	600 Mg		Roxane
	Alprazolam Intensol [Oral Solution (Concentrate)] 1 Mg/Ml			S	Unknown			Roxane
	Lamotrigine			S	Unknown	350 Mg		Not Reported
	Escitalopram			S	Unknown	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2015	11188630	DIRECT		OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea; Somnolence	Escitalopram			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2015	11191265	EXPEDITED (15-DAY)		OT	KR-ROCHE-1593361		69 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Clonazepam			S	Unknown			Not Reported
	Clonazepam			S				Not Reported
	Haloperidol			S	Unknown			Not Reported
	Buspirone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

	Escitalopram	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2015	11195086	EXPEDITED (15-DAY)	Y	OT	ADR-2015-01121			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia;	Baclofen			S				Not Reported
Atrophy; Back Pain;	Dilaudid (Hydromorphone)			S	Intrathecal			Not Reported
Burning Sensation; Bursitis; Complex	Bupivacaine Intrathecal			S	Intrathecal			Not Reported
Regional Pain Syndrome;	Lorazepam			S				Not Reported
Depression; Diarrhoea;	Baclofen			S				Not Reported
Fall; Fractured Sacrum;	Tramadol			S				Not Reported
Haemangioma;	Mobic			S				Not Reported
Hallucination;	Zantac			S				Not Reported
Hyperaesthesia;	Zanaflex			S				Not Reported
Hypoaesthesia; Insomnia;	Valium			S				Not Reported
Joint Effusion; Mobility	Amitriptyline			S				Not Reported
Decreased; Mood Swings;	Naltrexone			S				Not Reported
Muscle Spasms; Muscle	Hydroxyzine			S				Not Reported
Spasms; Muscular	Lidocaine			S				Not Reported
Weakness;	Lithium			S				Not Reported
Musculoskeletal Stiffness;	Mathocarbamol			S				Not Reported
Myofascial Pain	Melatonin			S				Not Reported
Syndrome; Neuralgia;	Diclofenac			S				Not Reported
Osteoarthritis;	Miralax			S				Not Reported
Osteoporosis; Pain In	Ranitidine			S				Not Reported
Extremity; Panic Reaction;	Senna			S				Not Reported
Paraesthesia; Paralysis;	Docusate			S				Not Reported
Physical Deconditioning;	Vitamin B Complex With Vitamin C			S				Not Reported
Post Laminectomy Syndrome; Sacroiliitis;	Multivitamin			S				Not Reported
Scoliosis; Skin	Vitamin D3			S				Not Reported
Discolouration; Social	Acetaminophen			S				Not Reported
Avoidant Behaviour;	Topamax			S				Not Reported
Somatic Symptom	Heparin			S				Not Reported
Disorder; Stress Fracture;	Topiramate			S				Not Reported
Substance-Induced	Lorazepam			S				Not Reported
Psychotic Disorder;	Tramadol			S				Not Reported
Therapy Non-Responder;	Meloxicam			S				Not Reported

Urinary Incontinence; Urinary Retention	Diazepam	S		Not Reported
	Lidocaine	S	Topical	Not Reported
	Nortiptyline	S		Not Reported
	Olanzapine	S		Not Reported
	Hydroxyzine	S		Not Reported
	Fortco	S		Not Reported
	Savella	S		Not Reported
	Tizanidine	S		Not Reported
	Ketorolac	S		Not Reported
	Effexor	S		Not Reported
	Flexeril	S		Not Reported
	Lorazepam	S		Not Reported
	Vicodin	S		Not Reported
	Neuropathic Pain Compound 1	S		Not Reported
	Horizant	S		Not Reported
	Savella	S		Not Reported
	Medrol	S		Not Reported
	Celebrex	S		Not Reported
	Celexa	S		Not Reported
	Cymbalta	S		Not Reported
	Lodine	S		Not Reported
	Nexium	S		Not Reported
	Nucynta	S		Not Reported
	Pristiq	S		Not Reported
	Seroquel	S		Not Reported
	Skelaxin	S		Not Reported
	Vallium	S		Not Reported
	Piroxicam	S		Not Reported
	Hyoscyamine	S		Not Reported
	Librax	S		Not Reported
	Bextra	S		Not Reported
	Actonel	S		Not Reported
	Xanax	S		Not Reported
	Zoloft	S		Not Reported
	Lamictal	S		Not Reported
	Mobic	S		Not Reported
	Percocet	S		Not Reported
	Ultracet	S		Not Reported
	Butrans	S		Not Reported
	Toradol	S		Not Reported
	Depakote	S		Not Reported
	Ativan	S		Not Reported

Gabapentin	S	Not Reported
Abilify	S	Not Reported
Gabapentin	S	Not Reported
Osteoporosis Infusion	S	Not Reported
Hydromorphone	S	Not Reported
Toprol Xl	S	Not Reported
Plaquenil	S	Not Reported
Aspirin	S	Not Reported
Clonazepam	S	Not Reported
Venlaflaxine	S	Not Reported
Naproxen	S	Not Reported
Ondansetron	S	Not Reported
Tylenol	S	Not Reported
Roxicodone	S	Not Reported
Bisacodyl	S	Not Reported
Ketorolac	S	Not Reported
Carbamazepine	S	Not Reported
Cholecalciferol	S	Not Reported
Diclofenac Sodium	S	Not Reported
Enoxaparin	S	Not Reported
Nortriptyline	S	Not Reported
Olanzapine	S	Not Reported
Methocarbamol	S	Not Reported
Tranylcypromine	S	Not Reported
Divalproex	S	Not Reported
Ferrous Sulphate	S	Not Reported
Pantoprazole	S	Not Reported
Lactated Ringers	S	Not Reported
Magnesium Citrate	S	Not Reported
Pantoprazole	S	Not Reported
Milk Of Magnesia	S	Not Reported
Amitriptyline	S	Not Reported
Fluphenazine	S	Not Reported
Soma	S	Not Reported
Lithium	S	Not Reported
Phenergan	S	Not Reported
Benzoazepine	S	Not Reported
Amitriptyline	S	Not Reported
Prolixin	S	Not Reported
Bactrim	S	Not Reported
Macrobid	S	Not Reported
Melatonin	S	Not Reported

Ranitidine	S	Not Reported
Senna	S	Not Reported
Docusate	S	Not Reported
Prolixin	S	Not Reported
Pantoprazole	S	Not Reported
Naltrexone Hcl	S	Not Reported
Acetaminophen\Hydrocodone Bitartrate	S	Not Reported
Biaxin	S	Not Reported
Amoxicillin	S	Not Reported
Cyclobenzaprine	S	Not Reported
Alprazolam	S	Not Reported
Sertraline Hcl	S	Not Reported
Arthrotec	S	Not Reported
Methylprednisolone	S	Not Reported
Levaquin	S	Not Reported
Ibuprofen	S	Not Reported
Sulfamethoxazole	S	Not Reported
Ambien	S	Not Reported
Oxycodone	S	Not Reported
Propoxy-N/Apap	S	Not Reported
Lexapro	S	Not Reported
Metaxalone	S	Not Reported
Ciprofloxacin Hcl	S	Not Reported
Cephalexin	S	Not Reported
Limbrel	S	Not Reported
Alendronate Sodium	S	Not Reported
Valacyclovir	S	Not Reported
Nitrostat	S	Not Reported
Prednisone	S	Not Reported
Doxycycline Hyclate	S	Not Reported
Quetiapine Fumarate	S	Not Reported
Promethazine	S	Not Reported
Duloxetine Hcl	S	Not Reported
Namenda	S	Not Reported
Risperidone	S	Not Reported
Orphenadrine	S	Not Reported
Cimetidine	S	Not Reported
Mexiletine	S	Not Reported
Nuvigil	S	Not Reported
Trazodone	S	Not Reported
Zoloft	S	Not Reported

	Lidoderm Patch	S	Not Reported
	Fentora	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2015	11190477	EXPEDITED (15-DAY)		OT	US-BAYER-2015-316953		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Increased; Expired Product Administered; Intestinal Ulcer; Off Label Use; Red Blood Cell Count Abnormal	Bayer Aspirin Regimen Adult Low Strength			S	Oral	1 Df, Qd		Bayer
	Plavix			C		Unk		Not Reported
	Lipitor			C				Not Reported
	Ambien			C				Not Reported
	Seroquel			C				Not Reported
	Lexapro			S		Unk		Not Reported
	Vitamin D Nos			C				Not Reported
	Magnesium [Magnesium Oxide]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2015	11192055	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015195948		13 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Somnolence	Xanax			S	Oral	5 Mg (20-0.25 Mg, Tablets)		Pfizer
	Doliprane			S	Oral	2000 Mg (4-500mg Tablets)		Not Reported
	Paracetamol			S	Oral	4000 Mg, (8-500mg) Single		Not Reported
	Seroplex			S	Oral	90mg (18- 5mg Tablets)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2015	11193456	EXPEDITED (15-DAY)		HO, LT	FR-ASTRAZENECA-2015SE59233		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coma; Electrocardiogram Qrs Complex Prolonged; Shock; Status Epilepticus	Xeroquel	S	Oral		Astrazeneca
	Zolmitriptan	S	Oral		Not Reported
	Escitalopram	S	Oral		Not Reported
	Esperal	S	Oral		Not Reported
	Zyban	C			Not Reported
	Atarax	C			Not Reported
	Princi B (Cyanocobalamin\Pyridoxine Hydrochloride\Thiamine)	C			Not Reported
	Cernevit	C			Not Reported
	Decan (Minerals)	C			Not Reported
	Vitamin C	C			Not Reported
	Lovenox	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2015	11193884	EXPEDITED (15-DAY)		OT	FR-FRI-1000077320			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neurodevelopmental Disorder	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2015	11199720	DIRECT					27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Product Quality Issue; Product Quality Issue; Product Substitution Issue	Escitalopram 10 Mg			S	Oral	1 Pill		Accord
	Albuterol			C				Not Reported
	Allegra			C				Not Reported
	Flonase			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2015	11199792	DIRECT		OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Escitalopram			S	Oral			Torrent
	Zegerid			C				Not Reported
	Melatonin			C				Not Reported
	Allegra			C				Not Reported
	Ibuprofen			C				Not Reported
	Benadryl			C				Not Reported
	Epiduo Gel			C				Not Reported
	Triamcinolone Ointment			C				Not Reported
	Ketoconazole			C				Not Reported
	Seborrheic Dermatitis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11175143	EXPEDITED (15-DAY)		HO	JP-FRI-1000077171		24 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Seizure	Lexapro			S	Oral	10 Mg		Forest
	Amoxan			S	Oral	50 Mg		Not Reported
	Meilax			C	Oral			Not Reported
	Saikokaryukotsuboreito			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11182082	EXPEDITED (15-DAY)		HO	PHHY2015ES066883		88 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Hyponatraemia; Slow Speech	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Esidrex			S	Oral	25 Mg, Qd		Novartis
	Enalapril			C	Oral	20 Mg, Qd		Not Reported
	Coropres			C	Oral	25 Mg, Bid		Not Reported
	Eucreas			C	Oral	10 Mg, Qd		Not Reported
	Lantus			C	Subcutaneous	11 Iu, Qd		Not Reported
	Optivite			C	Oral			Not Reported

	Zaldiar	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11195884	NON-EXPEDITED			US-DRREDDYS-USA/USA/15/0045394		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Vomiting	Sertraline Hydrochloride			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Low Dose		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Paroxetine			S				Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Fluoxetine Tablets			C	Unknown			Not Reported
	Diazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11197407	EXPEDITED (15-DAY)		HO	CH-FRI-1000077441		48 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	20 Mg		Forest
	Fluoxetin			S	Oral	Treated For 12 Years With Unknown Dosage		Not Reported
	Atacand			C	Oral	32 Mg		Not Reported
	Tranxilium			C	Oral			Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11197408	EXPEDITED (15-DAY)		OT	JP-FRI-1000077437			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased;	Lexapro			S	Oral			Forest

Hepatic Function Abnormal	Depas (Etizolam)	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11197409	EXPEDITED (15-DAY)		HO	US-FRI-1000076071		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Kidney Infection; Urinary Tract Infection	Escitalopram			S	Oral	20 Mg Milligram(S), Unk		Forest
	Blinded Investigational Medicinal Product (Imp) Non-Partner			S	Oral	Unk		Not Reported
	Lisinopril			C	Oral	10 Mg Milligram(S), Unk		Not Reported
	Levothyroxine			C	Oral	100 Mcg, Unk		Not Reported
	Azelastine			C	Ophthalmic	1 Gtt Drop(S), Unk		Not Reported
	Benadryl			C	Oral	25 Mcg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11143373	EXPEDITED (15-DAY)		OT	ES-UCBSA-2015016384			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Vimpat			S		200 Mg, 2x/Day (Bid)		Ucb
	Omeprazole			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Phenobarbital			C		Unk		Not Reported
	Phenytoin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11156885	EXPEDITED (15-DAY)		HO	ES-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2015-BI-28		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Micardisplus			S	Oral	1 Anz		Boehringer Ingelheim

Escitalopram	S	Oral	10 Mg		Not Reported
Tryptizol	S	Oral	25 Mg		Not Reported
Metformina	C	Unknown	Dose Per Application: 50mg /850 Mg; Daily Dose: 100mg/1700 Mg		Not Reported
Glimepirida	C	Unknown	4 Mg		Not Reported
Paracetamol	C	Unknown	1000 Mg		Not Reported
Zarator	C	Unknown	10 Mg		Not Reported
Adiro	C	Unknown	100 Mg		Not Reported
Atenolol Alter	C	Unknown	25 Mg		Not Reported
Omeprazol	C	Unknown	40 Mg		Not Reported
Sintrom	C	Unknown	4 Mg		Not Reported
Xumadol	C	Unknown	2 G		Not Reported
Plusvent	C	Unknown	100 Mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11169927	EXPEDITED (15-DAY)		DE, OT	CA-TAKEDA-2015TJP010080		46 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective	Trintellix			S	Oral	5 Mg, Qd		Takeda
	Cipralex /01588501/			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11198315	EXPEDITED (15-DAY)			US-STRIDES ARCOLAB LIMITED-2014SP004427			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Levofloxacin			S		Unk		Not Reported
	Vancomycin			S		Unk		Strides
	Amoxicillin And Clavulanate Potassium			S		Unk		Not Reported

	Meloxicam	S	Unk	Strides
	Effexor	S	Unk	Not Reported
	Lamotrigine	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Sulfonamide	S	Unk	Not Reported
	Celebrex	S	Unk	Not Reported
	Phenytoin	S	Unk	Not Reported
	Amitriptyline	S	Unk	Not Reported
	Tioconazole	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11200493	EXPEDITED (15-DAY)		DE	FR-FRI-1000077500		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral			Forest
	Plavix			S	Oral			Not Reported
	Hyperium			C	Unknown			Not Reported
	Lercan			C	Unknown			Not Reported
	Insulin Basal Bolus			C				Not Reported
	Simvastatine			C	Unknown			Not Reported
	Lasilix			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11200906	EXPEDITED (15-DAY)		LT	FR-FRI-1000077463		39 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Condition Aggravated; Suicidal Ideation; Suicide Attempt	Escitalopram			S	Oral			Forest
	Selincro			S	Oral			Not Reported
	Naltrexone			S	Oral			Not Reported
	Venlafaxine			S	Oral	225 Mg		Not Reported

	Atarax	C	Oral		Not Reported
	Temesta (Lorazepam)	C	Oral	2.5 Mg	Not Reported
	Inexium	C	Oral		Not Reported
	Seresta	C	Unknown		Not Reported
	Bevitine	C	Unknown		Not Reported
	Lansoprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11200931	EXPEDITED (15-DAY)		CA	US-FRI-1000077480			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11200934	EXPEDITED (15-DAY)		CA	US-FRI-1000077531			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11200935	EXPEDITED (15-DAY)		CA	US-FRI-1000077455			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11206424	DIRECT		HO			16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro 20 Mg Camber			S	Oral	1 Pill		Not Reported
	Buspar			C				Not Reported
	Deplin			C				Not Reported

	Ativan			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11203271	EXPEDITED (15-DAY)		CA, DE	US-FRI-1000077459		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Septal Defect	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11203322	EXPEDITED (15-DAY)		CA	US-FRI-1000077523			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11203468	EXPEDITED (15-DAY)		CA	US-FRI-1000077528			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11203536	EXPEDITED (15-DAY)		CA	US-FRI-1000077526			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11203577	EXPEDITED (15-DAY)		CA, DE, OT	US-FRI-1000077461			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoplastic Left Heart Syndrome	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11203662	EXPEDITED (15-DAY)		CA	US-FRI-1000077510			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11203686	EXPEDITED (15-DAY)		CA	US-FRI-1000077514			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Disease Congenital	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11211333	DIRECT		DS			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Fear	Lexapro			S	Oral	1 Once Daily Taken By Mouth		Walmart

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2015	11178866	EXPEDITED (15-DAY)		DE, OT	CA-FRI-1000077199		46 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective	Escitalopram			S	Oral	10 Mg		Forest
	Trintellix			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2015	11204764	EXPEDITED (15-DAY)		OT	ES-JUBILANT GENERICS LIMITED-1040095		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Psychosis	Olanzapine		S	Oral	Jubilant
	Escitalopram		S		Not Reported
	Trazodone		S		Not Reported
	Carbidopa And Levodopa		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2015	11205850	EXPEDITED (15-DAY)		OT	ES-SA-2015SA084359		67 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Quetiapine Fumarate			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Gemfibrozil			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Irbesartan			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Ropinirole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2015	11206620	EXPEDITED (15-DAY)	Y	OT	PHHY2014US174191		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Arthralgia; Asthenia; Atrophy; Back Pain; Bursitis; Contusion; Depression; Fall; Insomnia; Joint Effusion; Muscle Spasms; Myofascial Pain Syndrome; Osteoporosis; Panic Reaction; Social Avoidant Behaviour; Somatic Symptom Disorder; Substance-Induced Psychotic	Baclofen Intrathecal			S	Intrathecal	10 Mg, Tid Prn		Not Reported
	Baclofen			S	Oral	10 Mg, Tid Prn		Not Reported
	Nortriptyline			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Bid		Not Reported
	Carbamazepine			S	Unknown	Unk		Novartis
	Ibuprofen			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			S	Unknown	Unk		Not Reported

Disorder; Therapy Non-Responder	Tramadol	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Naltrexon Hcl	S	Unknown	Unk	Not Reported
	Hydroxyzine	S	Unknown	Unk	Not Reported
	Lidocaine	S	Unknown	Unk	Not Reported
	Ranitidine	S	Unknown	Unk	Not Reported
	Heparin	S	Unknown	Unk	Not Reported
	Topiramate	S	Unknown	Unk	Not Reported
	Lorazepam	S	Unknown	Unk	Not Reported
	Meloxicam	S	Unknown	Unk	Not Reported
	Olanzapine	S	Unknown	Unk	Not Reported
	Tizanidine	S	Unknown	Unk	Not Reported
	Ketorolac	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Enoxaparin Sodium	S	Unknown	Unk	Not Reported
	Fluphenazine	S	Unknown	Unk	Not Reported
	Ondansetron	S	Unknown	Unk	Not Reported
	Trazodone	S	Unknown	Unk	Not Reported
	Amoxicillin	S	Unknown	Unk	Not Reported
	Alprazolam	S	Unknown	Unk	Not Reported
	Cyclobenzaprine	S	Unknown	Unk	Not Reported
	Sulfamethoxazole	S	Unknown	Unk	Not Reported
	Sertraline Hydrochloride	S	Unknown	Unk	Not Reported
	Ciprofloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Valaciclovir	S	Unknown	Unk	Not Reported
	Metaxalone	S	Unknown	Unk	Not Reported
	Quetiapine	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Promethazine	S	Unknown	Unk	Not Reported

Risperidone	S	Unknown	Unk	Not Reported
Orphenadrine	S	Unknown	Unk	Not Reported
Cimetidine	S	Unknown	Unk	Not Reported
Gabapentin	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Effexor	S	Unknown	150 Mg, Qd	Not Reported
Zantac	S	Unknown	Unk	Not Reported
Flexeril	S	Endocervical	Unk	Not Reported
Vicodin	S	Unknown	Unk	Not Reported
Horizant	S	Unknown	Unk	Not Reported
Medrol	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Lithium	S	Unknown	Unk	Not Reported
Celexa	S	Unknown	Unk	Not Reported
Valium	S	Unknown	Unk	Not Reported
Cymbalta	S	Unknown	Unk	Not Reported
Lodine	S	Unknown	Unk	Not Reported
Nexium//Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Nucynta	S	Unknown	Unk	Not Reported
Seroquel	S	Unknown	Unk	Not Reported
Skelaxin	S	Unknown	Unk	Not Reported
Piroxicam	S	Unknown	Unk	Not Reported
Vitamin B Complex With Vitamin C /02146701/	S	Unknown	Unk	Not Reported
Hyoscyamine	S	Unknown	Unk	Not Reported
Melatonin	S	Unknown	Unk	Not Reported
Vitamin B3	S	Unknown	Unk	Not Reported
Savella	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported

Librax	S	Unknown	Unk	Not Reported
Senna	S	Unknown	Unk	Not Reported
Docusate	S	Unknown	Unk	Not Reported
Topamax	S	Unknown	Unk	Not Reported
Miralax	S	Unknown	Unk	Not Reported
Multi Vitamin	S	Unknown	Unk	Not Reported
Dilaudid	S	Intrathecal		Not Reported
Dilaudid	S	Intrathecal	5.996 Mg, 20.0 Mg/Ml (Dose Was Decreased 14 Percent) Per Day	Not Reported
Dilaudid	S		Unk, 10 Mg/Ml Minimum Rate	Not Reported
Zanaflex	S	Unknown	Unk	Not Reported
Mobic	S	Unknown	Unk	Not Reported
Methocarbamol	S	Unknown	Unk	Not Reported
Bextra	S	Unknown	Unk	Not Reported
Actonel	S	Endocervical	Unk	Not Reported
Xanax	S	Unknown	Unk	Not Reported
Zoloft	S	Unknown	Unk	Not Reported
Lamictal	S	Unknown	Unk	Not Reported
Percocet	S	Unknown	Unk	Not Reported
Ultracet	S	Unknown	Unk	Not Reported
Butrans	S	Unknown	Unk	Not Reported
Toradol	S	Unknown	Unk	Not Reported
Depakote	S	Unknown	Unk	Not Reported
Ativan	S	Unknown	Unk	Not Reported
Namenda	S	Unknown	Unk	Not Reported
Abilify	S	Unknown	Unk	Not Reported
Hydromorphone	S	Unknown	Unk	Not Reported
Toprol Xl	S	Unknown	Unk	Not Reported

Plaquenil	S	Unknown	Unk	Not Reported
Aspirin	S	Unknown	Unk	Not Reported
Venlafaxin	S	Unknown	Unk	Not Reported
Tylenol	S	Unknown	Unk	Not Reported
Roxicodone	S	Unknown	Unk	Not Reported
Bisacodyl	S	Unknown	Unk	Not Reported
Tranylcypromine	S	Unknown	Unk	Not Reported
Divalproex	S	Unknown	Unk	Not Reported
Ferrous Sulphate	S	Unknown	Unk	Not Reported
Lactated Ringers	S	Unknown	Unk	Not Reported
Magnesium Citrate Enteral	S	Unknown	Unk	Not Reported
Milk Of Magnesia	S	Unknown	Unk	Not Reported
Sona	S	Unknown	Unk	Not Reported
Phenergan /00488301/	S	Unknown	Unk	Not Reported
Benzodiazepines	S	Unknown	Unk	Not Reported
Prolixin	S	Unknown	Unk	Not Reported
Bactrim	S	Unknown	Unk	Not Reported
Macrobid	S			Not Reported
Acetaminophen\Hydrocodone Bitartrate	S	Unknown	Unk	Not Reported
Biaxin	S	Unknown	Unk	Not Reported
Arthrotec	S	Endocervical	Unk	Not Reported
Levaquin	S	Unknown	Unk	Not Reported
Ambien	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	Unk	Not Reported
Propoxyphene N/Apap	S	Unknown	Unk	Not Reported
Lexapro	S	Unknown	Unk	Not Reported
Cephalexin	S	Unknown	Unk	Not Reported
Limbrel	S	Unknown	Unk	Not Reported
Nitrostat	S	Unknown	Unk	Not Reported

Doxycycline Hyclate	S	Unknown	Unk		Not Reported
Duloxetine Hcl	S	Unknown	Unk		Not Reported
Mexiletine	S	Unknown	Unk		Not Reported
Nuvigil	S	Unknown	150 Mg, Qd		Not Reported
Lidoderm	S	Unknown	Unk		Not Reported
Bupivacaine	S	Intrathecal	Unk		Not Reported
Fentora	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2015	11212785	DIRECT					46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bruxism; Diarrhoea; Incorrect Dose Administered; Malaise; Muscle Spasms; Musculoskeletal Stiffness; Mydriasis; Nausea; Toxicity To Various Agents; Tremor	Escitalopram 10mg			S	Oral	Half A Pill (5mg) Once Daily Taken By Mouth		Not Reported
	Bisoprolol			C				Not Reported
	B Complex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2015	11214907	DIRECT		LT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Personality Change; Product Substitution Issue; Suicidal Ideation	Escitalopram 20mg			S				Not Reported
	Synthroid			C				Not Reported
	Folic Acid Vitamins			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Biotin Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2015	11214961	DIRECT		DS			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue; Withdrawal Syndrome	Escitalopram 20 Mg Mylan			S	Oral			Mylan
	Daily Multi-Vitamin			C				Not Reported
	B12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11173165	EXPEDITED (15-DAY)		OT	US-FRI-1000077222		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree; Dizziness; Presyncope	Escitalopram			S		10 Mg		Forest
	Memantine			S		10 Mg		Forest
	Aspirin			C		81 Mg		Not Reported
	Clopidogrel			C		37.5 Mg		Not Reported
	Seroquel			C		25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11211165	EXPEDITED (15-DAY)	Y	HO, OT	IT-ASTRAZENECA-2015SE60008		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Intentional Self-Injury	Seroquel			S	Oral			Zeneca
	Entact			S	Oral			Not Reported
	Gestodiol			S	Oral	30 Mcg +75 Mcg, Unknown		Not Reported
	Depakin Chrono			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11211475	EXPEDITED (15-DAY)		OT	PHHY2015BR031566			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Emotional Disorder; Headache; Hip Fracture; Memory	Exelon Patch			S	Transdermal	1 Df, Qd (After Dinner)		Novartis
	Meloxicam			S	Unknown	15 Mg, Qd (After Lunch)		Not Reported

Impairment; Off Label Use; Rib Fracture; Upper Limb Fracture	Escitalopram	S	Unknown	1 Df, Qd (After Breakfast)	Not Reported
	Assert	S	Unknown	1 Df, Qhs (At Night)	Not Reported
	Assert	S			Not Reported
	Assert	S			Not Reported
	Prebictal	C	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11211657	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2015-05333			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Cardiac Failure Congestive; Cough; Disorientation; Dyspnoea; Dyspnoea Exertional; Malaise; Obesity; Pulmonary Arterial Hypertension; Pulmonary Hypertension; Rales; Sleep Apnoea Syndrome; Weight Decreased; Wheezing	Metformin 500mg			S	Unknown	500 Mg, Two Times A Day		Aurobindo
	Abilify			S	Unknown	2 Mg, Once A Day		Not Reported
	Aspirin			S	Unknown	81 Mg, Once A Day		Not Reported
	Cymbalta			S	Unknown	60 Mg, Once A Day		Not Reported
	Digoxin			S	Oral	250 Mcg, Unk		Not Reported
	Flomax /00889901/			S	Unknown	0.4 Mg, Once A Day		Not Reported
	Furosemide			S	Unknown	40 Mg, Once A Day		Not Reported
	Lexapro			S	Unknown	10 Mg, Once A Day		Not Reported
	Potassium Chloride			S	Unknown	10 Meq, Two Times A Day		Not Reported
	Revatio			S	Unknown	20 Mg, 3 Times A Day		Not Reported
	Tracleer /01587701/			S	Unknown	125 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11212571	EXPEDITED (15-DAY)		HO	FR-FRI-1000077627			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Bipolar I Disorder; Irritability; Logorrhoea	Escitalopram			S		10 Mg		Forest
	Tercian			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported
	Augmentin			C	Unknown			Not Reported

	Kardegic			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	10459479	EXPEDITED (15-DAY)		HO	FR-FRI-1000070707		91 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma Muscle; International Normalised Ratio Increased	Escitalopram			S	Oral			Forest
	Previscan (Fluindione)			S	Oral			Not Reported
	Tavanic			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	11214261	EXPEDITED (15-DAY)		HO	PHHY2015IT072832		51 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrocardiogram St Segment Elevation	Lorazepam			S	Oral	20 Mg, Once/Single		Novartis
	Cipralex 10 Mg			S	Oral	280 Mg, Once/Single		Not Reported
	Benexol			S	Oral	6 Df, Once/Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	11215669	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2015M1021301			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Product Substitution Issue; Withdrawal Syndrome	Loxalate			S		1 Df, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	11216874	EXPEDITED (15-DAY)		OT	FR-FRI-1000077704			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Decreased Appetite; Eye Swelling;	Escitalopram			S	Oral	10 Mg		Forest

Malaise; Nausea; Ocular Hyperaemia; Urinary Retention; Vertigo	Omeprazole		S	Oral	10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	10369476	EXPEDITED (15-DAY)		LT	FR-FRI-1000069719		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Encephalopathy	Escitalopram			S	Oral	10 Mg		Forest
	Renitec [Enalapril Maleate]			C				Not Reported
	Dafalgan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	10867558	EXPEDITED (15-DAY)		OT	IT-FRI-1000074744		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Abuse; Electrocardiogram Qt Prolonged; Overdose	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose: 10 Units		Forest
	Talofen			S	Oral			Not Reported
	Talofen			S	Oral	Overdose: 30 Ml.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	11217343	EXPEDITED (15-DAY)		OT	DE-TAKEDA-2015TJP011331		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Scleral Haemorrhage	Brintellix			S	Oral	5 Mg, Qd		Takeda
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Mirtazapin			C	Oral	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	11218295	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000077670		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Shock; Status Epilepticus	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Oral	Overdose: 1,800 Mg		Forest
	Esperal			S	Unknown			Not Reported
	Esperal			S	Oral	Overdose: 30 Grams		Not Reported
	Xeroquel			S	Oral			Not Reported
	Xeroquel			S		Overdose: 48 Grams		Not Reported
	Zolmitriptan			S	Oral	Overdose: 45 Mg		Not Reported
	Zyban			C	Unknown			Not Reported
	Atarax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	11218300	EXPEDITED (15-DAY)		OT	CN-FRI-1000077660		45 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphoria; Intracranial Aneurysm	Escitalopram			S	Unknown	In The Morning		Forest
	Trazodone Hydrochloride			C	Oral	0.5 - 1 Tablet Per Day Before Sleeping, Intermittently		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	11218771	EXPEDITED (15-DAY)		HO	FR-FRI-1000077672		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Forest
	Indapamide			S	Oral			Not Reported
	Stilnox			C				Not Reported
	Alprazolam			C				Not Reported
	Dafalgan			C				Not Reported
	Uvedose			C				Not Reported

	Euphytose	C	Not Reported
	Clinutren	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	11218786	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2015GSK090062		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorganised Speech; Echolalia; Logorrhoea; Reduced Facial Expression; Staring	Lamictal			S	Oral	25 Mg, Bid		Glaxosmithkline
	Imovane			S	Oral	Unk		Glaxosmithkline
	Artane			S	Oral	2 Mg, Tid		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Glaxosmithkline
	Risperdal			C	Oral	2 Mg, Bid		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	11218823	EXPEDITED (15-DAY)		OT	JP-SA-2015SA089352		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Arthralgia; Asthenia; Atrophy; Back Pain; Bursitis; Contusion; Depression; Fall; Insomnia; Joint Effusion; Muscle Spasms; Myofascial Pain Syndrome; Osteoporosis; Panic Reaction; Social Avoidant Behaviour; Somatic Symptom Disorder; Substance-Induced Psychotic Disorder; Therapy Non-Responder	Levaquin			S	Unknown			Not Reported
	Ambien			S	Unknown			Not Reported
	Baclofen			S	Intrathecal			Not Reported
	Baclofen			S	Oral			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Bupivacaine			S	Intrathecal			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported
	Zantac			S	Unknown			Not Reported
	Zanaflex			S	Unknown			Not Reported
	Zanaflex			S	Unknown			Not Reported

Valium	S	Unknown		Not Reported
Amitriptyline	S	Unknown		Not Reported
Hydroxyzine	S	Unknown		Not Reported
Lidocaine	S	Topical	Form-Patch	Not Reported
Lithium	S	Unknown		Not Reported
Methocarbamol	S	Unknown		Not Reported
Melatonin	S	Unknown		Not Reported
Diclofenac	S	Unknown		Not Reported
Miralax	S	Unknown	Form-Powder	Not Reported
Ranitidine	S	Unknown		Not Reported
Senna	S	Unknown		Not Reported
Docusate	S	Unknown		Not Reported
Panthenol/Retinol/Thiamine Hydrochloride/Ascorbic Acid/Ergocalciferol/Folic Acid/Riboflavin/Nicotina Vitamin D3	S	Unknown		Not Reported
Acetaminophen	S	Unknown		Not Reported
Topamax	S	Unknown		Not Reported
Heparin	S	Unknown		Not Reported
Topiramate	S	Unknown		Not Reported
Meloxicam	S	Unknown		Not Reported
Diazepam	S	Unknown		Not Reported
Nortriptyline	S	Unknown		Not Reported
Olanzapine	S	Unknown		Not Reported
Savella	S	Unknown		Not Reported
Tizanidine	S	Unknown		Not Reported
Ketorolac	S	Unknown		Not Reported
Effexor	S	Unknown		Not Reported
Flexeril	S	Unknown		Not Reported

Vicodin	S	Unknown	Not Reported
Medrol	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Celexa	S	Unknown	Not Reported
Cymbalta	S	Unknown	Not Reported
Lodine	S	Unknown	Not Reported
Nexium	S	Unknown	Not Reported
Nucynta	S	Unknown	Not Reported
Pristiq	S	Unknown	Not Reported
Seroquel	S	Unknown	Not Reported
Skelaxin	S	Unknown	Not Reported
Piroxicam	S	Unknown	Not Reported
Hyoscyamine	S	Unknown	Not Reported
Librax	S	Unknown	Not Reported
Bextra	S	Unknown	Not Reported
Actonel	S	Unknown	Not Reported
Xanax	S	Unknown	Not Reported
Zoloft	S	Unknown	Not Reported
Zoloft	S	Unknown	Not Reported
Lamictal	S	Unknown	Not Reported
Mobic	S	Unknown	Not Reported
Percocet	S	Unknown	Not Reported
Ultracet	S	Unknown	Not Reported
Toradol	S	Unknown	Not Reported
Depakote	S	Unknown	Not Reported
Ativan	S	Unknown	Not Reported
Abilify	S	Unknown	Not Reported
Gabapentin	S	Unknown	Not Reported
Hydromorphone	S	Unknown	Not Reported

Toprol Xl	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Aspirin	S	Unknown	Not Reported
Clonazepam	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Ondansetron	S	Unknown	Not Reported
Tylenol	S	Unknown	Not Reported
Roxicodone	S	Unknown	Not Reported
Bisacodyl	S	Oral	Not Reported
Enoxaparin	S	Unknown	Not Reported
Methocarbamol	S	Unknown	Not Reported
Tranylcypromine	S	Unknown	Not Reported
Divalproex Sodium	S	Unknown	Not Reported
Ferrous Sulphate	S	Unknown	Not Reported
Pantoprazole	S	Unknown	Not Reported
Magnesium Citrate	S	Oral	Not Reported
Milk Of Magnesia	S	Unknown	Not Reported
Fluphenazine	S	Unknown	Not Reported
Phenergan	S	Unknown	Not Reported
Prolixin	S	Unknown	Not Reported
Bactrim	S	Unknown	Not Reported
Macrobid	S	Unknown	Not Reported
Acetaminophen\Hydrocodone Bitartrate	S	Unknown	Not Reported
Biaxin	S	Unknown	Not Reported
Amoxicillin	S	Unknown	Not Reported
Cyclobenzaprine	S	Unknown	Not Reported
Alprazolam	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Arthrotec	S	Unknown	Not Reported

Methylprednisolone	S	Unknown	Not Reported
Ibuprofen	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Lexapro	S	Unknown	Not Reported
Metaxalone	S	Unknown	Not Reported
Ciprofloxacin Hydrochloride	S	Unknown	Not Reported
Cephalexin	S	Unknown	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Valaciclovir	S	Unknown	Not Reported
Nitrostat	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Doxycycline Hyclate	S	Unknown	Not Reported
Quetiapine Fumarate	S	Unknown	Not Reported
Promethazine	S	Unknown	Not Reported
Duloxetine	S	Unknown	Not Reported
Namenda	S	Unknown	Not Reported
Risperidone	S	Unknown	Not Reported
Orphenadrine	S	Unknown	Not Reported
Cimetidine	S	Unknown	Not Reported
Mexiletine	S	Unknown	Not Reported
Nuvigil	S	Unknown	Not Reported
Trazodone	S	Unknown	Not Reported
Lidoderm	S	Unknown	Not Reported
Carbamazepine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	11223961	EXPEDITED (15-DAY)	Y	HO	8030627		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pulmonary Arterial Hypertension	Levothyrox		S	Oral	Not Reported
	Xagrid		S	Oral	Not Reported
	Hydrea		S	Oral	Not Reported
	Exjade		S	Oral	Not Reported
	Aspegic [Acetylsalicylate Lysine]		S	Oral	Not Reported
	Seroplex (Escitalopram Oxalate) (Escitalopram Oxalate)		S	Oral	Not Reported
	Nebilox		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2015	11163221	EXPEDITED (15-DAY)		HO	FR-FRI-1000077138		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	2.1429 Mg		Not Reported
	Exforge			C	Unknown	1 Df		Not Reported
	Reminyl			C	Unknown			Not Reported
	Cacit D3			C	Unknown			Not Reported
	Dafalgan			C	Unknown			Not Reported
	Forlax			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			C	Unknown			Not Reported
	Tardyferon			C	Unknown			Not Reported
	Ursolvan			C	Unknown			Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2015	11220978	EXPEDITED (15-DAY)		OT	ES-009507513-1506ESP012420		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis	Carbidopa (+) Levodopa			S	Oral			Merck
	Trazodone Hydrochloride			S	Oral			Not Reported
	Escitalopram			S				Not Reported
	Olanzapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2015	11221177	EXPEDITED (15-DAY)		DS, OT	ES-JUBILANT GENERICS LIMITED-1040195		67 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Quetiapine Fumarate			S				Jubilant
	Escitalopram			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Irbesartan			S				Not Reported
	Pantoprazole			S				Not Reported
	Gemfibrozil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2015	11222097	EXPEDITED (15-DAY)		OT	FR-FRI-1000077701		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Eye Swelling; Product Use In Unapproved Indication; Renal Disorder; Visual Impairment	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2015	11224624	DIRECT	Y				29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2015	11225563	DIRECT					33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Product Quality Issue	Escitalopram 10mg Unknown			S	Oral	1 Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2015	11223378	NON-EXPEDITED			US-ACCORD-029818			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea	Escitalopram Accord			S		For About A Month And A Half		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2015	11223379	NON-EXPEDITED		OT	US-ACCORD-030197		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Gastrointestinal Pain; Gastrointestinal Sounds Abnormal; Gastrooesophageal Reflux Disease; Off Label Use	Escitalopram Accord			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2015	11223380	NON-EXPEDITED			US-ACCORD-030657		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Accord Escitalopram			S	Oral	Started 3 Or 4 Days Ago		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2015	11223396	EXPEDITED (15-DAY)		DS, HO	DK-TEVA-572173ISR		68 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Fall; Hemiparesis; Hypoaesthesia; Hypoaesthesia	Escitalopram "Teva"			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2015	11054871	EXPEDITED (15-DAY)	Y	HO, OT	ADR-2015-00735		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcohol Abuse; Disinhibition; Drug Abuse; Euphoric Mood; Grandiosity; Impulsive Behaviour; Irritability; Legal Problem; Mania; Negativism; Psychomotor Hyperactivity; Theft; Weight Decreased	Baclofen			S	Oral			Not Reported
	Tramadol			S				Not Reported
	Escitalopram			S				Not Reported
	Quetiapine			S				Not Reported
	Oxazepam			S				Not Reported
	Alprazolam			S				Not Reported
	Zolpidem			S				Not Reported
	Candesartan			S				Not Reported
	Metformin			S				Not Reported
	Atorvastatin			S				Not Reported
	Alfuzosin			S				Not Reported
	Trospium			S				Not Reported
	Acetaminophen			S				Not Reported
	Ibuprofen			S				Not Reported
	Triamcinolone			S	Intramuscular Intramuscular			Not Reported
	Cannabis			S				Not Reported
	Alcohol (Ethanol)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2015	11225250	EXPEDITED (15-DAY)		CA, OT	US-PFIZER INC-2015214359			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maternal Exposure During Pregnancy; Multiple Congenital Abnormalities	Zoloft		S	Transplacental	Unk	Pfizer
	Lexapro		S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2015	11226417	EXPEDITED (15-DAY)		HO, OT	PHHY2015BR074404		60 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Hallucination; Irritability; Pyrexia; Pyrexia; Viral Infection	Exelon Patch			S	Transdermal	Patch 10 (Cm2), Each 24 Hours		Novartis
	Exelon Patch			S	Transdermal	Patch 10 (Cm2), Each 24 Hours		Novartis
	Depakene			S	Unknown	2 Tablets, Qd		Not Reported
	Olanzapine			S	Unknown	2 Tablets, Qd		Not Reported
	Olanzapine			S	Unknown	2 Tablets, Qd		Not Reported
	Olanzapine			S				Not Reported
	Escitalopram			S	Unknown	2 Tablets, Qd		Not Reported
	Escitalopram			S	Unknown	2 Tablets, Qd		Not Reported
	Mirtazapine			S	Unknown	1 Tablet, Qd		Not Reported
	Mirtazapine			S	Unknown	1 Tablet, Qd		Not Reported
	Stilnox			S	Unknown	1 Tablet, Qd		Not Reported
	Stilnox			S	Unknown	1 Tablet, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2015	11230864	DIRECT		LT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Decreased Activity; Impaired Work Ability; Product Substitution Issue; Suicidal Ideation	Lexapro			S	Oral	1		Forest
	Lamictal			C				Not Reported
	Welbutrin			C				Not Reported
	Klonapin			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2015	11231000	EXPEDITED (15-DAY)	Y	HO	2015RR-99288		51 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Electrocardiogram St Segment Elevation	Lorazepam (Lorazepam)			S	Oral	20 Mg, Total		Not Reported
	Cipralex			S	Oral	280 Mg, Total		Not Reported
	Benexol			S	Oral	6 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11229281	EXPEDITED (15-DAY)		HO	FR-009507513-1506FRA013786		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Daptomycin			S	Intravenous (not otherwise specified)	700 Mg, Qd		Merck
	Omeprazole			S	Oral	20 Mg, Qd		Merck
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Simvastatin			C				Merck
	Desloratadine			C				Merck
	Olmetec			C				Not Reported
	Rifampin			C				Not Reported
	Cardensiel			C				Not Reported
	Kardegic			C				Not Reported
	Exemestane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11229886	EXPEDITED (15-DAY)		OT	DE-FRI-1000077636		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Scleral Haemorrhage	Escitalopram			S	Oral	5 Milligram		Forest
	Brintellix			S	Oral	5 Milligram		Not Reported
	Mirtazapin			C	Oral	7.5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2015	11211094	EXPEDITED (15-DAY)		HO, LT, OT	CA-ROCHE-1596624		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Asthenia; Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Diarrhoea; Fatigue; Nephritic Syndrome; Shock	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Myfortic			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Ranitidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2015	11230407	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2015SE63144		20 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Constipation; Dysuria; Sleep Disorder; Urinary Retention	Xeroquel			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Lysanxia			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2015	11231051	EXPEDITED (15-DAY)		OT	IT-WATSON-2015-12805		66 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Mirtazapine			S	Oral	30 Mg, Daily		Actavis
	Escitalopram			S	Oral	7 Gtt Drop(S), Daily		Not Reported
	Control /00273201/			S	Oral	1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2015	11232174	EXPEDITED (15-DAY)		OT	SE-FRI-1000077802		22 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury; Product Use In Unapproved Indication	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2015	11232619	EXPEDITED (15-DAY)		OT	JP-FRI-1000077775		42 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome	Lexapro			S	Oral			Forest
	Depromel (Fluvoxamine Maleate)			C	Oral			Not Reported
	Depromel (Fluvoxamine Maleate)			C	Oral			Not Reported
	Evamyl (Lormetazepam)			C	Oral			Not Reported
	Meilax (Ethyl Loflazepate)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2015	11232768	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2015214785		67 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Gemfibrozil			S		Unk		Pfizer
	Pantoprazole			S		Unk		Pfizer
	Irbesartan			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Quetiapine Fumarate			S	Oral	100 Mg, Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2015	11233025	EXPEDITED (15-DAY)		HO	PHHY2015FR075958		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Cubicin			S	Intravenous (not otherwise specified)	700 Mg, Qd		Not Reported
	Omeprazole			S	Oral	20 Mg, Qd		Novartis
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Rifampicine			C	Unknown	1800 Mg, Qd		Not Reported
	Cardensiel			C	Unknown			Not Reported
	Kardegic			C	Unknown			Not Reported
	Simvastatine			C	Unknown			Not Reported
	Desloratadine			C	Unknown			Not Reported
	Olmetec			C	Unknown			Not Reported
	Exemestane			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2015	11136738	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2015-04483		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Product Substitution Issue; Suicidal Ideation	Alprazolam 1mg			S	Unknown	1 Mg, Once A Day		Aurobindo
	Escitalopram			S	Unknown	25 Mg, Once A Day		Aurobindo
	Lamotrigine			S	Unknown	350 Mg, Once A Day		Aurobindo
	Oxcarbazepine			S	Unknown	300 Mg, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2015	11186029	EXPEDITED (15-DAY)		HO	SE-FRI-1000077322			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Seizure	Escitalopram	S	Oral	10 Mg		Forest
	Escitalopram	S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2015	11234892	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2015SE64194		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Cubicin			S	Intravenous (not otherwise specified)			Not Reported
	Omeprazole			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Simvastatin			C				Not Reported
	Desloratadine			C				Not Reported
	Olmetec			C				Not Reported
	Rifampin			C				Not Reported
	Cardensiel			C				Not Reported
	Kardegic			C				Not Reported
	Exemestane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2015	11235671	EXPEDITED (15-DAY)		OT	AU-MUNDIPHARMA DS AND PHARMACOVIGILANCE -GBR-2014-0		55 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Drug Administration Rate; Serotonin Syndrome	Oxycontin Tablets (Nf)			S	Oral	15mg Bid + 10mg		Purdue
	Oxycontin Tablets (Nf)			S	Oral	15 Mg, Bid		Purdue
	Maxalt /01406501/			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Daily		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Verapamil			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Panadol Osteo			C	Oral	3990 Mg, Unk		Not Reported

	Panadol Osteo	C			Not Reported
	Endone	C	Unknown		Not Reported
	Imovane	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2015	11236009	EXPEDITED (15-DAY)		OT	FI-FRI-1000077808			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Iron Deficiency Anaemia	Escitalopram			S	Oral	5 Mg		Forest
	Aerius (Desloratadine)			C	Oral	5 Mg		Not Reported
	Hipeksal			C	Oral	2 G		Not Reported
	Lyrica			C	Oral	25 Mg		Not Reported
	Melatonin			C	Oral	3 Mg		Not Reported
	Thyroxin			C	Oral	0.1 Mg		Not Reported
	Tenox (Temazepam)			C	Oral	20 Mg		Not Reported
	Norspan			C	Transdermal	5 Ug/H Microgram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2015	11243282	DIRECT		DS			18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Insomnia; Insomnia	Proctofoam Hc			S				Not Reported
	Ibuprofen 800mg			S				Not Reported
	Escitalopram 5mg Amneal			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11080666	EXPEDITED (15-DAY)		OT	JP-ELI_LILLY_AND_COMPANY-JP201504007225		43 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glycosylated Haemoglobin Increased; Hyperglycaemia;	Cymbalta			S	Oral	60 Mg, Qd		Eli Lilly And Co
	Solanax			S	Oral	Unk		Not Reported

Polydipsia; Polyuria; Thirst	Lexapro	S	Oral	Unk	Not Reported
	Hangekobokuto /07984801/	C	Oral	Unk	Not Reported
	Depas (Etizolam)	C	Oral	1 Mg, Prn	Not Reported
	Actos	C	Oral	15 Mg, Each Morning	Not Reported
	Premarin	C	Oral	0.625 Mg, Bid	Not Reported
	Duphaston	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239664	NON-EXPEDITED		HO	TR-LUPIN PHARMACEUTICALS INC.-2015-01080		64 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Escitalopram			S	Unknown	5 Mg		Not Reported
	Escitalopram			S	Unknown	10 Mg		Not Reported
	Escitalopram			S	Unknown	15 Mg		Not Reported
	Haloperidol			S	Unknown	1 Mg		Not Reported
	Haloperidol			S	Unknown	3.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239730	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2015-01112		69 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral	Escitalopram			S	Unknown	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239737	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2015-01113		71 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral	Escitalopram			S	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239777	NON-EXPEDITED		HO	US-LUPIN PHARMACEUTICALS INC.-2015-01420		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Methylene Blue			S	Intravenous (not otherwise specified)	1-Mg/Kg Bolus Followed By Continuous Infusion Of 0.5 Mg/Kg Per Hour		Not Reported
	Escitalopram			S	Oral	20mg		Not Reported
	Trazodone			S	Oral	100mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239778	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2015-01555		48 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alcoholism; Behaviour Disorder	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239796	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2015-01557		42 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alcohol Abuse; Anxiety; Decreased Appetite; Impulsive Behaviour; Insomnia; Paranoia	Escitalopram			S	Unknown	10-20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239797	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2015-01558			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alcohol Use	Escitalopram		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239800	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS INC.-2015-01597		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism	Escitalopram			S	Unknown	20mg		Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported
	Escitalopram			S	Unknown	20mg		Not Reported
	Escitalopram			S	Unknown	15mg		Not Reported
	Escitalopram			S	Unknown	Upto 15mg		Not Reported
	Escitalopram			S	Unknown	5mg		Not Reported
	Escitalopram			S	Unknown	4-10 Mg		Not Reported
	Indomethacin + Caffeine + Prochlorperazine			C	Unknown			Not Reported
	Valproate			C	Unknown	900mg		Not Reported
	Valproate			C	Unknown	600mg		Not Reported
	Valproate			C	Unknown	150mg		Not Reported
	Lithium			C	Unknown			Not Reported
	Lithium			C	Unknown	300-450mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239801	NON-EXPEDITED		HO	US-LUPIN PHARMACEUTICALS INC.-2015-01606		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Metaxalone			S	Unknown			Not Reported
	Metaxalone			S	Unknown			Not Reported
	Metaxalone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

	Alprazolam	C	Unknown		Not Reported
	Prazosin	C	Unknown		Not Reported
	Propranolol	C	Unknown		Not Reported
	Quetiapine	C	Unknown		Not Reported
	Clonazepam	C	Unknown		Not Reported
	Butalbital + Acetaminophen + Caffeine	C	Unknown		Not Reported
	Mometasone	C	Unknown	50 Mcg/Act 2 Sprays	Not Reported
	Prednisone	C			Not Reported
	Triamcinolone	C	Topical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239803	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS INC.-2015-01595		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism	Escitalopram			S	Unknown	5mg		Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported
	Escitalopram			S	Unknown	5mg		Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported
	Valproate			C	Unknown	750mg		Not Reported
	Valproate			C	Unknown	500 Mg		Not Reported
	Amisulpride			C	Unknown	50 Mg		Not Reported
	Lithium			C	Unknown			Not Reported
	Lithium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239815	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2015-01607		35 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rabbit Syndrome	Escitalopram			S	Unknown			Not Reported

	Clonazepam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239818	NON-EXPEDITED			BR-LUPIN PHARMACEUTICALS INC.-2015-01763		52 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Indifference; Yawning	Venlafaxine Xr			S	Unknown	75 Mg		Not Reported
	Escitalopram			S	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11239881	NON-EXPEDITED			US-PFIZER INC-2015218253		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Phenergan			S		Unk		Not Reported
	Elavil			S				Not Reported
	Protamine Sulfate			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Advair			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Sotalol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11241784	EXPEDITED (15-DAY)		HO, OT	PHHY2015US070353		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Hernia; Abdominal Wound Dehiscence; Asthenia; Hernia Pain; Hypertonia;	Lioresal Intratecal			S	Intrathecal	618.6 Ug, Qd		Not Reported
	Lioresal Intratecal			S	Intrathecal	479.4 Ug, Qd (23 Percent Decrease)		Not Reported

Implant Site Infection; Medical Device Site Erythema; Medical Device Site Pain; Medical Device Site Swelling; Pain; Pocket Erosion; Pyrexia; Staphylococcal Infection; White Blood Cell Count Increased; Wound Infection; Wound Secretion	Lioresal Intratecal	S	Intrathecal	199.8 Ug, Qd	Not Reported
	Lioresal	S	Oral	10 Mg, Qid (Four Times Daily)	Not Reported
	Voltaren	S	Topical	2 G, Qd (As Needed)	Novartis
	Gentamicin	S	Unknown	30 G, (Compounded Capsule)	Not Reported
	Gentamicin	S	Unknown	(30 -15 Mg) (Powder)	Not Reported
	Ferrous Sulfate	S	Oral	325 Mg, Bid	Not Reported
	Wellbutrin Sr	S	Oral	150 Mg, Bid	Not Reported
	Vit D	S	Oral	1200 Ot, Qd	Not Reported
	Restasis	S	Ophthalmic	1 Drp, Bid	Not Reported
	Lomotil	S	Oral	1 Df, Qid	Not Reported
	Lexapro	S	Oral	20 Mg, Qd	Not Reported
	Estrace	S	Oral	1.5 Mg, Qd	Not Reported
	Synthroid	S	Oral	100 Ug, Qd	Not Reported
	Claritin	S	Oral	10 Mg, Qd	Not Reported
	Silica	S	Oral		Not Reported
	Fish Oil	S	Oral	1 Df, Qd	Not Reported
	Ditropan	S	Oral	5 Mg, Tid	Not Reported
	Mylicon	S	Oral	250 Mg, Qid (Every 6 (Six) Hours As Needed)	Not Reported
	Trivitamin	S	Oral	Unk Unk, Qd	Not Reported
	Maalox /00416501/	S	Oral	Unk, Qid	Not Reported
	Cranberry Berco	S	Oral	125 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11241958	EXPEDITED (15-DAY)		DE	ZA-MYLANLABS-2015M1021543			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Malignant	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported

Symbicord	C	Unknown	Unk Unk, Qd (120 Dose)	Not Reported
Symbicord	C			Not Reported
Fendermal	C	Unknown	100 Mg, Qd	Not Reported
Xalatan	C	Unknown	50 Mg, Qd	Not Reported
Purata	C	Unknown	30 Mg, Qd	Not Reported
Vasomil	C	Unknown	80 Mg, Qd	Not Reported
Arycor	C	Unknown	200 Mg, Qd	Not Reported
Zofer	C	Unknown	4 Mg, Qd	Not Reported
Zofer	C			Not Reported
Covocort	C	Unknown	10 Mg, Qd	Not Reported
Ecotrin	C	Unknown	81 Mg, Qd	Not Reported
Euphyllin /00012201/	C	Unknown	250 Mg, Qd	Not Reported
Acetaminophen\Tramadol Hydrochloride	C	Unknown	325 Mg, Qd	Not Reported
Adco-Zolpidem	C	Unknown	10 Mg, Qd	Not Reported
Be-Tabs Folic Acid	C	Unknown	5 Mg, Qd	Not Reported
Lancap	C	Unknown	30 Mg, Qd	Not Reported
Evorel	C	Unknown	503.2 Mg, Qd	Not Reported
Forvent	C	Unknown	18 Mg, Qd	Not Reported
Clopamon	C	Unknown	10 Mg, Qd	Not Reported
Lanoxin	C	Unknown	0.25 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11242620	DIRECT		DE			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Completed Suicide; Gun Shot Wound; Head Injury; Intentional Self-Injury	Lexapro			S	Oral			Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11246396	DIRECT		DS			19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Libido Decreased	Lexapro			S	Oral	1		Not Reported
	Buspirone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2015	11169210	EXPEDITED (15-DAY)		HO, OT	PHHY2015US062853			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Altered State Of Consciousness; Confusional State; Constipation; Hyperhidrosis; Hypertonia; Initial Insomnia; Muscle Spasticity; Musculoskeletal Stiffness; Pneumonia; Respiratory Tract Congestion; Tooth Disorder; Withdrawal Syndrome	Lioresal Intratecal			S	Intrathecal	1173.4 Mcg/Day		Not Reported
	Lioresal Intratecal			S	Intrathecal	1223.3 Ug, Qd		Not Reported
	Lioresal Intratecal			S	Intrathecal	1223 Ug, Qd		Not Reported
	Lioresal Intratecal			S		100 Ug, Unk (Bolous)		Not Reported
	Lioresal Intratecal			S	Intrathecal	720 Ug, Qd		Not Reported
	Trazodone			S	Unknown	2 Df, Prn (1 To 2 Tabs At Bedtime)		Novartis
	Microgestin			S	Unknown	Unk		Not Reported
	Oxytrol			S	Unknown	1 Df, Qw2 (24 Hour Patch, 2 Times Week)		Not Reported
	Lexapro			S	Unknown	20 Mg, Qd (Daily)		Not Reported
	Valium			S	Unknown	2 Df, Prn (1 To 2 Tablets)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2015	11243004	EXPEDITED (15-DAY)		HO	FR-MUNDIPHARMA DS AND PHARMACOVIGILANCE -GBR-2015-0		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Extrapyramidal Disorder; Fall; Gait	Oxycontin Lp 5 Mg, Comprime Pellicule A Liberation Prolongee			S	Oral	1 Df, Bid		Purdue

Disturbance	Seroplex	S	Oral	0.5 Df, Daily	Not Reported
	Seresta	S	Oral	1 Df, Bid	Not Reported
	Dafalgan	C			Not Reported
	Econazole	C			Not Reported
	Inexium /01479302/	C			Not Reported
	Zymad	C			Not Reported
	Ketum	C			Not Reported
	Melaxose	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2015	11245350	EXPEDITED (15-DAY)		CA	US-FRI-1000077700			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly	Lexapro			S	Transplacental			Forest
	Zoloft			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11026530	EXPEDITED (15-DAY)		HO	IT-FRI-1000075858		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Overdose; Sopor	Escitalopram Oral Solution			S	Oral	Overdose: 100 Mg		Forest
	Escitalopram Oral Solution			S	Unknown	10 Gtt		Forest
	Stilnox 10mg Compresse Riv Con Film-30 Compresse			S	Oral			Not Reported
	Stilnox 10mg Compresse Riv Con Film-30 Compresse			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11239951	EXPEDITED (15-DAY)		OT	IE-FRI-1000076538		9 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Accidental Exposure To Product By Child;	Escitalopram			S	Oral			Forest
	Buscopan			C	Unknown			Not Reported

Agitation; Anxiety; Body Temperature Increased; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11246239	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2015US05293			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Topiramate			S	Oral	Unk		Cipla
	Bupropion			S	Oral			Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11246314	EXPEDITED (15-DAY)		DE, OT	US-CIPLA LTD.-2015US05299			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Zolpidem Tartarate			S	Oral	Unk		Cipla
	Escitalopram			S	Oral	Unk		Not Reported
	Atenolol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11247113	NON-EXPEDITED			US-PFIZER INC-2015224442		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11247288	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015223630		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Somnolence; Suicide Attempt; Toxicity To Various Agents	Xanax			S	Oral	20 Df, Single		Pfizer
	Dioalgo			S	Oral	1200 Mg, Single		Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			S	Oral	25.6 G, Single		Not Reported
	Seroplex			S	Oral	> 100 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11247992	EXPEDITED (15-DAY)		HO	FR-FRI-1000077968		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorganised Speech; Echolalia; Logorrhoea; Reduced Facial Expression; Staring	Escitalopram			S	Oral	10 Mg		Forest
	Imovane			S	Oral	1 Dosage Form		Not Reported
	Artane			S	Oral	6 Mg		Not Reported
	Lamictal			S	Oral	50 Mg		Not Reported
	Risperdal			C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	10785720	EXPEDITED (15-DAY)		HO	AT-ELI_LILLY_AND_COMPANY-AT201502000323		48 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Delirium; Disorientation; Fatigue; Insomnia	Zyprexa			S	Unknown	10 Mg, Unknown		Eli Lilly And Co
	Zyprexa			S	Unknown	15 Mg, Unknown		Eli Lilly And Co
	Zyprexa			S	Unknown	20 Mg, Unknown		Eli Lilly And Co
	Zyprexa			S	Unknown	10 Mg, Unknown		Eli Lilly And Co
	Substitol			S	Unknown	600 Mg, Unknown		Not Reported
	Substitol			S	Unknown	480 Mg, Unknown		Not Reported
	Substitol			S	Unknown	360 Mg, Qd		Not Reported
	Rivotril			S	Unknown	2 Mg, Unknown		Not Reported

	Rivotril	S	Unknown	1 Mg, Unknown	Not Reported
	Depakine /00228501/	S	Oral	1000 Mg, Unknown	Not Reported
	Depakine /00228501/	S	Oral	1.5 G, Qd	Not Reported
	Cipralex /01588501/	S	Oral	10-20 Mg, Unknown	Not Reported
	Cipralex /01588501/	S	Oral	30 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11253077	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-E2B_00003046		32 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Product Dose Omission	Stalopam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11253087	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2015-01199		33 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram			S	Unknown	5mg		Not Reported
	Escitalopram			S	Unknown	20mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11254898	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2015SE65027		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Fall; Product Prescribing Error; Somnolence	Symbicort Turbuhaler			S	Respiratory (inhalation)	80/4.5 Ug Per Dose, Twice Per Day		Astrazeneca
	Potassium			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Baclofene			S	Oral			Not Reported

Bisoprolol	S	Oral		Not Reported
Escitalopram	S	Oral		Not Reported
Lormetazepam	S	Oral		Not Reported
Oxazepam	S	Oral		Not Reported
Nebivolol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11258952	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Lexapro 20 Mg Camber			S	Oral	1.5 Tabs, Qd, Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11258967	DIRECT		OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dysphagia; Dyspnoea; Insomnia; Muscle Spasms; Product Quality Issue; Product Substitution Issue; Thyroid Disorder	Escitalopram 10 Mg Accord Health			S	Oral	1 Tablet, Once Daily, Taken By Mouth		Accord
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11264051	EXPEDITED (15-DAY)	Y	HO, OT	ADR-2015-01228		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoinflammatory Disease; Balance Disorder; Coordination Abnormal; Fall; Fatigue; Gait Disturbance; Hypoaesthesia; Inflammation; Intestinal	Baclofen Intrathecal			S				Not Reported
	Tazarotene (Ta20rac)			S				Not Reported
	Baclofen (Lioresal)			S				Not Reported
	Duloxetine (Cymbalta) 60mg			S				Not Reported
	Ketoconazole (Nizoral) 2%			S				Not Reported
	Escitalopram Oxalate (Lexapro Po)			S				Not Reported

Obstruction; Muscular Weakness; Muscular Weakness; Neurogenic Bladder; Neurological Symptom; Nuclear Magnetic Resonance Imaging Brain Abnormal; Paraesthesia; Pneumonia; Urinary Tract Infection	Cleocin T	S	Not Reported
	Tacrolimus (Protopic) 0.1%	S	Not Reported
	Tysabri (Natalizumab)	S	Not Reported
	Levetiracetam (Keppra) 1000 Mg	S	Not Reported
	Potassium Chloride (Klor-Con)	S	Not Reported
	Cranberry Vitamin C	S	Not Reported
	Furosemide (Lasix)	S	Not Reported
	Guaifenesin Er 12 Hr (Mucinex) 600 Mg	S	Not Reported
	Tizanidine (Zanaflex)	S	Not Reported
	Ascorbic Acide (Vitamin C) 1000 Mg	S	Not Reported
	Xanax (Alprazolam)	S	Not Reported
	Acetaminophen (Tylenol) 325 Mg Tab	S	Not Reported
	Zolpidem (Ambien) 10 Mg	S	Not Reported
	Boniva (Bandronate Sodium)	S	Not Reported
	Polyethylene Glycol 3350 (Miralax)	S	Not Reported
	Norvasc (Amlodipine)	S	Not Reported
	Levothyroxine (Synthroid)	S	Not Reported
	Solifenacin	S	Not Reported
	Cyanocobalamin (Vitamin B-12) 50 Mcg	S	Not Reported
	Ciclopirox (Loprox) 1%	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11264863	EXPEDITED (15-DAY)		OT	BR-TORRENT-00002997		57 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Dizziness Postural; Dry Mouth; Dysphagia; Dyspnoea; Gastrointestinal Haemorrhage; Haematochezia; Haematochezia; Hyperhidrosis; Initial Insomnia; Myalgia; Nasal	Espran			S	Oral			Not Reported
	Rivotril			C				Not Reported
	Diovan Amio			C				Not Reported

Congestion; Nausea;
Pollakiuria; Pyrexia;
Somnolence; Tachycardia;
Urticaria

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2015	11259121	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2015223572		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Reaction With Eosinophilia And Systemic Symptoms	Lyrica			S	Oral	25 Mg, 3x/Day		Pfizer
	Abilify			S	Oral	5 Mg, 1x/Day In The Morning		Not Reported
	Seroplex			S	Oral	30mg, 1x/Day In The Morning		Not Reported
	Imovane			S	Oral	7.5 Mg, 1x/Day At Bedtime		Not Reported
	Seresta			S	Oral	10 Mg, 3x/Day		Not Reported
	Loxapac /00401801/			C		"10-0-10-20 Mg", 3x/Day		Not Reported
	Esomeprazole			C		20 Mg, 1x/Day In The Evening		Not Reported
	Thiopental			C		Unk		Not Reported
	Suxamethonium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2015	11259915	EXPEDITED (15-DAY)		HO	CA-HOSPIRA-2752327		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Docetaxel			S	Intravenous (not otherwise specified)			Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)	Not Reported		Not Reported
	Morphine Sulphate			S	Intravenous (not otherwise specified)			Not Reported
	Ciprofloxacin			S	Intravenous (not	Not Reported		Not Reported

			otherwise specified)		
	Avastin /00848101/	S	Intravenous (not otherwise specified)		Not Reported
	Piperacillin/Tazobactam	S	Unknown	Not Reported	Not Reported
	Cipralex /01588501/	S	Intravenous (not otherwise specified)		Not Reported
	Herceptin	S	Unknown		Not Reported
	Herceptin	S	Intravenous (not otherwise specified)		Not Reported
	Lactulose	C		Not Reported	Not Reported
	Tylenol No.1	S	Unknown	Not Reported	Not Reported
	Docusate	C		Not Reported	Not Reported
	Stomatological Preparations	C		Not Reported	Not Reported
	Senna /00142201/	C		Not Reported	Not Reported
	Trazodone	C		Not Reported	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2015	11260862	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2015098324		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Escitalopram			S				Glaxosmithkline
	Atorvastatin			C				Glaxosmithkline
	Risperidone			S				Glaxosmithkline
	Bupropion			S				Glaxosmithkline
	Valproic Acid			S				Not Reported
	Fentanyl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2015	11261735	EXPEDITED (15-DAY)		HO	IT-WATSON-2015-12408		51 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt	Lorazepam			S	Oral	20 Mg, Total (20 Tablets)		Watson

Prolonged; Electrocardiogram St Segment Elevation; Overdose	Cipralex /01588502/	S	Oral	280 Mg, Total (28 Tablets)	Not Reported
	Benexol /00176001/	S	Oral	6 Df, Total (6 Tablets)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2015	11263008	EXPEDITED (15-DAY)		LT	FR-FRI-1000077985		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Diarrhoea; Hypokalaemia	Escitalopram			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	10973730	NON-EXPEDITED		OT	US-JNJFOC-20150313241			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Depression; Galactorrhoea; Gynaecomastia; Hyperprolactinaemia; Tardive Dyskinesia	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Adderall			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported
	Geodon			C	Unknown			Not Reported
	Concerta			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11264748	EXPEDITED (15-DAY)		HO, LT	NO-FRI-1000077978			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Escitalopram			S	Oral			Forest
	Polaramin			C	Oral	4 Mg		Not Reported
	Lipitor			C	Oral	20 Mg Every Other Day		Not Reported

Lipitor	C		40 Mg Every Other Day		Not Reported
Selozok	C	Oral	50 Mg		Not Reported
Aprovel	C	Oral	150 Mg		Not Reported
Stesolid	C	Oral	15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11264749	EXPEDITED (15-DAY)		HO	FR-FRI-1000077982		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hallucination	Escitalopram			S	Oral	10 Mg		Forest
	Codoliprane			S	Oral			Not Reported
	Calcium Vitamin D			C	Unknown			Not Reported
	Qvar			C	Unknown			Not Reported
	Ventoline			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11266397	EXPEDITED (15-DAY)		OT	CN-FRI-1000078039		58 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Logorrhoea; Mania; Product Use In Unapproved Indication; Sleep Disorder	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Unknown			Forest
	Ebixa			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11272042	DIRECT		DS			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack; Tremor; Vertigo	Lexapro 10mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11272045	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Attention; Withdrawal Syndrome	Escitalopram Tabs 10mg Torrent			S				Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	10811907	EXPEDITED (15-DAY)		HO, OT	AT-FRI-1000074547		32 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder	Escitalopram			S	Oral	10 Mg In The Morning		Forest
	Trittico			C	Unknown	200 Mg		Not Reported
	Mogadon			C	Unknown	10 Milligram		Not Reported
	Nozinan			C	Unknown	15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	11064246	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-025489		27 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obesity; Weight Increased	Abilify			S	Oral	10 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Oral	15 Mg, Qd		Bristol Myers Squibb
	Seroquel			S	Oral	800 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Oral	20 Mg, Qd		Not Reported
	Simvastatin			C	Oral	20 Mg, Qd		Not Reported
	Valium			C	Oral	5 Mg, Qd		Not Reported
	Temesta /00273201/			C	Oral	2.5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	11214461	EXPEDITED (15-DAY)		HO	IT-TEVA-571084ACC		51 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Electrocardiogram St Segment Elevation; Suicide Attempt	Lorazepam			S	Oral	20 Mg Total		Ivax
	Cipralex - 10 Mg Compresse Rivestite Con Film			S	Oral	280 Mg Total		Not Reported
	Benexol - Compresse Gastroresistenti - Bayer S.P.A.			S	Oral	6 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	11269625	EXPEDITED (15-DAY)		HO, OT	US-ACTAVIS-2015-14366		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Escitalopram (Unknown)			S	Unknown	Unknown		Not Reported
	Risperidone (Watson Laboratories)			S	Unknown	Unknown		Watson
	Bupropion Hydrochloride (Actavis Laboratories Fl)			S	Unknown	Unknown		Actavis
	Divalproex Sodium Dr (Actavis Laboratories Fl)			S	Unknown	Unknown		Scherer
	Fentanyl Patch			S	Unknown	Unknown		Watson
	Atorvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	11270860	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015230365			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Emotional Disorder; Self Esteem Decreased; Suicidal Ideation; Weight Increased	Gabapentin			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	11270884	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000067098		19 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Serotonin Syndrome; Suicide Attempt	Escitalopram			S	Oral			Forest
	Escitalopram			S		Overdose: 14 Tablets (Estimated Dose)		Forest
	Trimipramine Base			S	Oral	Overdose: Dose Unknown		Not Reported
	Imipramine			S	Oral	Overdose: Dose Unknown		Not Reported
	Zolpidem			S	Oral			Not Reported
	Zolpidem			S	Oral	Overdose: 5 Tablets (Estimated Dose)		Not Reported
	Alprazolam			S	Oral			Not Reported
	Alprazolam			S	Oral	Overdose: 25 Tablets (Estimated Dose)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	11275360	EXPEDITED (15-DAY)	Y	HO	US-H14001-15-01161		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Creatine Phosphokinase Increased; Flushing; Hyperhidrosis; Hypernatraemia; Hypertension; Hyperthermia Malignant; Hypocalcaemia; Hyporeflexia; Lipase Increased; Muscle Rigidity; Neuroleptic Malignant Syndrome; Respiratory Failure; Seizure; Serotonin Syndrome; Tachycardia;	Valproate			S				Not Reported
	Fentanyl (Fentanyl) (Fentanyl)			S		Day 11 - Day 12		Not Reported
	Escitalopram			S				Not Reported
	Risperidone			S				Not Reported
	Bupropion (Bupropion) (Unknown) (Bupropion)			S				Not Reported
	Lorazepam			C				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin-Tazobactam (Pip.Tazo) (Piperacillin Sodium, Tazobactam Sodium)			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

Transaminases Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	10685125	NON-EXPEDITED			US-PFIZER INC-2014351122			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Ativan			S		Unk		Pfizer
	Seroquel			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Norco			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	11228494	EXPEDITED (15-DAY)		HO	IT-FRI-1000077773		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Intentional Overdose	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose: 14 Df		Forest
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral	Overdose: 60 Df		Not Reported
	Gestodiol 30 Mcg/75 Mcg Compresse Rivestite/Ethinylestradiol+Gestodene			S		Overdose: 21 Df		Not Reported
	Depakin Chrono			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	11271802	EXPEDITED (15-DAY)		HO	US-MACLEODS PHARMACEUTICALS US LTD-MAC2015001860			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Neuroleptic Malignant Syndrome	Escitalopram Oxalate	S	Unknown	Macleods
	Risperidone	S	Unknown	Not Reported
	Bupropion	S	Unknown	Not Reported
	Valproic Acid	S	Unknown	Not Reported
	Fentanyl	S	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	11273027	EXPEDITED (15-DAY)		HO	US-ABBVIE-15P-163-1425737-00		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Valproic Acid			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Vancomycin			C	Unknown			Not Reported
	Vancomycin			C				Not Reported
	Piperacillin / Tazobactam			C	Unknown			Not Reported
	Piperacillin / Tazobactam			C				Not Reported
	Azithromycin			C	Unknown			Not Reported
	Azithromycin			C				Not Reported
	Lorazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	11274543	EXPEDITED (15-DAY)		HO, OT	US-IMPAX LABORATORIES, INC-2015-IPXL-00755		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Bupropion Hydrochloride Sr			S	Unknown	Unk		Impax

Divalproex Sodium Er	S	Unknown	Unk		Impax
Escitalopram	S	Unknown	Unk		Not Reported
Risperidone	S	Unknown	Unk		Not Reported
Vancomycin	C	Unknown	Unk		Not Reported
Vancomycin	C				Not Reported
Piperacillin/Tazobactam	C	Unknown	Unk		Not Reported
Piperacillin/Tazobactam	C				Not Reported
Azithromycin	C	Unknown	Unk		Not Reported
Azithromycin	C				Not Reported
Ceftriaxone	C	Unknown	Unk		Not Reported
Ceftriaxone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	11276205	DIRECT		LT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Diarrhoea; Muscle Spasms; Muscle Spasms; Muscle Twitching; Pollakiuria	Escitalopram 5 Mg			S	Oral			Camber
	Lisinopril			C				Not Reported
	Synthroid			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Furosemide			C				Not Reported
	Ecotrin			C				Not Reported
	Calcium+ Vita D3			C				Not Reported
	Potassijum Cl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	11276872	DIRECT		DS			16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Fatigue Syndrome; Educational Problem; Impaired Work Ability; Orthostatic Intolerance; Postural Orthostatic Tachycardia	Escitalopram			S	Oral			Not Reported
	Florinef Seasonique			C				Not Reported
	Ana-Histamine			C				Not Reported
	L-Glutathione			C				Not Reported

Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	10570755	EXPEDITED (15-DAY)		DS	CN-FRI-1000072126		85 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blindness Unilateral; Discomfort; Dizziness; Incorrect Dose Administered; Nausea; Optic Atrophy; Somnolence; Vision Blurred; Visual Impairment; Vitreous Opacities	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	40 Mg		Not Reported
	Escitalopram			S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	10731205	EXPEDITED (15-DAY)		OT	GR-MYLANLABS-2015M1000874			Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Generics 10mg Film-Coated Tablet			S	Oral	1 Tablet, Qd		Mylan
	Escitalopram Generics 10mg Film-Coated Tablet			S	Unknown	1.5 Df, Unk		Mylan
	Xanax			C	Oral	1 Tablet Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11227511	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20150619548		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Intentional Self-Injury	Haldol			S	Oral			Not Reported
	Lendormin			S	Oral			Not Reported
	Entact			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11275249	EXPEDITED (15-DAY)		DS, OT	GB-ACCORD-032196		42 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Chest Pain; Fatigue; Male Sexual Dysfunction; Memory Impairment; Oropharyngeal Pain; Somnolence; Yawning	Escitalopram			S	Oral			Accord
	Diltiazem			C				Not Reported
	Lipitor			C				Not Reported
	Nicorandil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11275951	EXPEDITED (15-DAY)		HO, LT	US-LUPIN PHARMACEUTICALS INC.-2015-02126		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Serotonin Syndrome	Escitalopram			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Valproate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11276027	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-100310			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Escitalopram			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Ranbaxy
	Bupropion			S	Unknown	Unk		Sun
	Valproic Acid			S	Unknown	Unk		Sun
	Fentanyl			S	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11276827	EXPEDITED (15-DAY)		HO	FR-FRI-1000078154		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Toxicity To Various Agents	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Forest
	Paracetamol			S	Oral			Not Reported
	Spiramycine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11276830	EXPEDITED (15-DAY)		HO	FR-FRI-1000078150		93 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Craniocerebral Injury; Fall	Escitalopram			S	Oral	20 Mg		Forest
	Bromazepam			S	Oral	4.5 Mg		Not Reported
	Cordarone			C	Oral	142.8571 Mg		Not Reported
	Previscan (Fluindione)			C	Oral	5 Mg		Not Reported
	Moduretic			C	Oral	1 Df		Not Reported
	Bisoprolol			C	Oral	10 Mg		Not Reported
	Zocor			C	Oral	20 Mg		Not Reported
	Permixon			C	Oral	320 Mg		Not Reported
	Pariet			C	Oral	20 Mg		Not Reported
	Vitabact			C	Ophthalmic	4 Gtt		Not Reported
	Motilium			C	Oral	3 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11276917	EXPEDITED (15-DAY)		OT	SE-FRI-1000078084			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blindness; Visual Impairment	Escitalopram		S	Unknown	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2015	11278982	EXPEDITED (15-DAY)		HO	US-FRESENIUS KABI-FK201503386		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Valproate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Escitalopram			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2015	11279277	NON-EXPEDITED			US-PFIZER INC-2015236314		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2015	11279602	EXPEDITED (15-DAY)		OT	BR-FRI-1000078230		52 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Slow Response To Stimuli; Unresponsive To Stimuli; Yawning	Escitalopram			S	Unknown	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2015	11279665	EXPEDITED (15-DAY)		HO	FR-FRI-1000078172		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Overdose	Escitalopram			S	Oral	30 Mg		Forest
	Abilify			S	Oral	5 Mg		Not Reported
	Imovane			S	Oral	7.5 Mg		Not Reported
	Lyrica			S	Oral	75 Mg		Not Reported
	Seresta			S	Oral	30 Mg		Not Reported
	Loxapac			C		40 Mg		Not Reported
	Esomeprazole			C		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2015	11280997	EXPEDITED (15-DAY)		HO	FR-FRI-1000078148		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral	Overdose: >100 Mg		Forest
	Dioalgo			S	Oral	Overdose: 1,200 Mg		Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			S	Oral	Overdose: 25.6 Mg		Not Reported
	Xanax			S	Oral	Overdose: 20 Df.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2015	11282996	EXPEDITED (15-DAY)		DS, OT	GB-TEVA-576831ACC		42 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Chest Pain; Fatigue; Male Sexual Dysfunction; Memory Impairment; Oropharyngeal Pain; Somnolence; Yawning	Escitalopram			S	Oral			Ivax
	Diltiazem			C				Not Reported
	Lipitor			C				Not Reported
	Nicorandil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2015	11284999	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2015194358		44 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased; Chest Pain; Headache	Lyrica			S	Oral	Unk, As Needed		Pfizer
	Livalo			S	Oral	2 Mg, 1x/Day		Not Reported
	Actos			S	Oral	15 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Depas (Etizolam)			S	Oral	0.5 Mg, 3x/Day		Not Reported
	Depas (Etizolam)			S	Oral	1.0 Mg, 3x/Day		Not Reported
	Amoxan			C				Not Reported
	Solanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11218733	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2015M1020030			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Abuse; Electrocardiogram Qt Prolonged; Electrocardiogram St Segment Elevation; Intentional Overdose; Suicide Attempt	Lorazepam			S	Oral	20 Mg, Total		Mylan
	Cipralex /01588502/			S	Oral	280 Mg, Total		Not Reported
	Benexol /00176001/			S	Oral	6 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11221025	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-99288			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged;	Lorazepam			S	Oral	20 Mg Total		Ranbaxy
	Cipralex			S	Oral	280 Mg Total		Not Reported

Electrocardiogram St Segment Elevation; Suicide Attempt	Benexol		S	Oral	6 Df Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11226338	EXPEDITED (15-DAY)		HO	IT-FRI-1000077776		51 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Electrocardiogram St Segment Elevation; Intentional Overdose; Suicide Attempt	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose: 280 Mg Once		Forest
	Lorazepam 1 Mg			S	Oral			Not Reported
	Lorazepam 1 Mg			S	Oral	Overdose: 20 Mg Once		Not Reported
	Benexol Compresse Gastroresistenti/Vitamin B Complex			S	Oral			Not Reported
	Benexol Compresse Gastroresistenti/Vitamin B Complex			S	Oral	Overdose: 6 Dosage Forms Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11285927	EXPEDITED (15-DAY)		HO, OT	US-PAR PHARMACEUTICAL, INC-2015SCPR014149			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Serotonin Syndrome	Bupropion Hcl Xl			S	Unknown	Unk Unk, Unknown		Par
	Risperidone			S	Unknown	Unk Unk, Unknown		Par
	Valproate			S	Unknown	Unk Unk, Unknown		Not Reported
	Escitalopram			S	Unknown	Unk Unk, Unknown		Not Reported
	Fentanyl			S	Intravenous (not otherwise specified)	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11286017	EXPEDITED (15-DAY)		HO	US-ACCORD-032379		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypernatraemia; Hypocalcaemia; Neuroleptic Malignant Syndrome; Pneumonia; Respiratory Failure; Sepsis; Streptococcus Test Positive	Escitalopram			S		Discontinued Around Day 5 Of Hospitalization.		Accord
	Risperidone			S		Discontinued Around Day 5 Of Hospitalization.		Not Reported
	Bupropion/Bupropion Hydrochloride			S		Discontinued Around Day 5 Of Hospitalization.		Not Reported
	Valproic Acid			S		Discontinued Around Day 7 Of Hospitalization.		Not Reported
	Fentanyl			S		Continuous Infusion Discontinued Around Day 5 Of Hospitalization. Restarted On Day 11.		Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11287702	NON-EXPEDITED		OT	US-PFIZER INC-2015242684		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11289805	NON-EXPEDITED			US-PFIZER INC-2015238792		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11289854	NON-EXPEDITED			US-PFIZER INC-2015238418			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction; Weight Increased	Venlafaxine Hcl			S		Unk		Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11289904	EXPEDITED (15-DAY)		DS, OT	GB-MYLANLABS-2015M1023090			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Chest Pain; Fatigue; Male Sexual Dysfunction; Memory Impairment; Oropharyngeal Pain; Somnolence; Yawning	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Lipitor			C		Unk		Not Reported
	Nicorandil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11289972	NON-EXPEDITED			PHHY2015US076973		84 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Lioresal Intratecal			S	Intrathecal	39.95 Ug, Qd (Per Day)		Not Reported
	Benazepril			S	Oral			Novartis
	Magnesium			S	Oral			Not Reported
	Pravastatin			S	Oral			Not Reported
	Warfarin			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Tylenol			S	Oral			Not Reported
	Vitamin D3			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

	Insulin Glargine	S	Unknown	Not Reported
	Insulin Lispro	S	Unknown	Not Reported
	Levothyroxine	S	Oral	Not Reported
	Aspirin	S	Oral	Not Reported
	Lotrisone	S	Topical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2015	11291362	EXPEDITED (15-DAY)		DS, OT	GB-AUROBINDO-AUR-APL-2015-06422		42 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Chest Pain; Fatigue; Male Sexual Dysfunction; Memory Impairment; Oropharyngeal Pain; Somnolence; Yawning	Escitalopram 20 Mg			S	Oral	20 Mg		Aurobindo
	Diltiazem			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Nicorandil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2015	11292453	NON-EXPEDITED		HO	DE-EISAI MEDICAL RESEARCH-EC-2015-008613			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Loss Of Personal Independence In Daily Activities	Donepezil			S	Oral	Unknown		Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2015	11293066	EXPEDITED (15-DAY)		OT	BE-FRI-1000078321			Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Breast Cancer; Drug Interaction	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Unknown			Forest
	Tamoxifen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2015	9871087	NON-EXPEDITED			US-GILEAD-2013-0073443		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Resting Tremor	Stribild			S		Unk		Gilead
	Wellbutrin			S		200 Mg, Qd		Not Reported
	Abilify			S		15 Mg, Qd		Not Reported
	Lexapro			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2015	9871102	NON-EXPEDITED			US-GILEAD-2013-0075220		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Diarrhoea; Drug Interaction	Stribild			S		1 Df, Qd		Gilead
	Pantoprazole			S		40 Mg, Unk		Not Reported
	Lexapro			S		5 Mg, Qd		Not Reported
	Xanax			S		0.5 Mg, Prn		Not Reported
	Tylenol /00020001/			S				Not Reported
	Vitamin C /00008001/			S				Not Reported
	Vitamin B			S				Not Reported
	Vitamin D /00107901/			S				Not Reported
	Multivitamin /00097801/			S				Not Reported
	Saw Palmetto /00833501/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2015	11306548	EXPEDITED (15-DAY)		DS, OT	GB-FRI-1000078220		42 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Chest Pain; Fatigue; Male Sexual Dysfunction; Memory Impairment;	Escitalopram			S	Oral	20 Mg Daily		Forest
	Diltiazem			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported

Oropharyngeal Pain; Somnolence; Yawning	Nicorandil		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2015	11307195	EXPEDITED (15-DAY)		OT	FR-009507513-1507FRA010147		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Norset			S	Oral			Merck
	Seroplex			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Kardegic			C				Not Reported
	Inipomp			C				Not Reported
	Aprovel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	10308211	EXPEDITED (15-DAY)		OT	DK-FRI-1000069027		46 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris	Escitalopram			S	Oral	5 Mg		Forest
	Hjertemagnyl [Acetylsalicylic Acid\Magnesium Oxide]			C				Not Reported
	Hjertemagnyl [Acetylsalicylic Acid\Magnesium Oxide]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11183245	EXPEDITED (15-DAY)		OT	PHHY2015US069564			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Therapeutic Response Decreased	Lioresal Intratecal			S	Unknown	160 Ug, Qd		Not Reported
	Lisinopril			S	Unknown			Novartis
	Albuterol			S	Unknown			Not Reported
	Vitamin D Nos			S	Unknown			Not Reported
	Allegra			S	Unknown			Not Reported

	Lexapro	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11307704	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2015-01865		30 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania; Product Use In Unapproved Indication	Memantine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11308207	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2015-02208		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Overdose; Restlessness; Suicide Attempt	Fluoxetine			S	Unknown	10 Mg		Not Reported
	Fluoxetine			S	Unknown	20 Mg		Not Reported
	Doxycycline			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lamotrigine			C	Unknown			Not Reported
	Methylphenidate			C	Unknown	27 Mg		Not Reported
	Methylphenidate			C	Unknown	54 Mg		Not Reported
	Methylphenidate			C	Unknown	45 Mg		Not Reported
	Propranolol			C	Unknown	30 Mg		Not Reported
	Clonazepam			C	Unknown			Not Reported
	Risperidone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11308307	EXPEDITED (15-DAY)		DE	CA-FRESENIUS KABI-FK201503530		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Sudden Cardiac Death	Diphenhydramine Injection (Manufacturer Unknown) (Diphenhydramine	S	Unknown		Fresenius Medical Care
	Cipralex	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11308654	EXPEDITED (15-DAY)		HO	FR-NOVOPROD-457306		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Novonorm			S	Oral	3 Df, Qd		Novo Nordisk
	Insulatard			S	Subcutaneous	42 Iu, Bid		Novo Nordisk
	Januvia			S	Oral	100 Mg, Qd		Not Reported
	Risperdal			S	Oral	4 Mg, Qd		Not Reported
	Depakote			S	Oral	250 Mg, Bid		Not Reported
	Inegy			S	Oral	1 Df, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Celiprolol			S	Unknown	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11308793	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2015US06100			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Decreased Appetite; Drug Ineffective; Weight Decreased	Citalopram			S	Unknown			Cipla
	Risperidone			S	Unknown			Cipla
	Topiramate			S	Unknown	25 Mg, Qd		Cipla
	Topiramate			S	Unknown	25 Mg, Bid		Cipla
	Topiramate			S	Unknown	75 Mg, Bid		Cipla
	Atomoxetine			S	Unknown	Unk		Not Reported
	Methylphenidate Extended-Release (Er)			S	Unknown	36 Mg, Qd		Not Reported
	Methylphenidate Extended-Release (Er)			S				Not Reported

	Lisdexamfetamine Dimesylate	S	Unknown	Unk	Not Reported
	Guanfacine	S	Unknown	2 Mg, Qd	Not Reported
	Escitalopram	S	Unknown	Unk	Not Reported
	Clomipramine	S	Unknown	Unk	Not Reported
	Mirtazapine	S	Unknown	Unk	Not Reported
	Aripiprazole	S	Unknown	Unk	Not Reported
	Lithium	S	Unknown	Unk	Not Reported
	Bupropion	S		75 Mg, Bid	Not Reported
	Fluvoxamine	S	Unknown	200 Mg, Qd	Not Reported
	Divalproex Sodium	S	Unknown	1500 Mg, Qd	Not Reported
	Quetiapine	S	Unknown	200 Mg, Qd	Not Reported
	Quetiapine	S	Unknown	400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11312387	DIRECT		OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Condition Aggravated; Dyspnoea; Emotional Disorder; Hypoaesthesia; Mental Disorder; Palpitations; Panic Attack; Product Substitution Issue	Escitalopram 20mg Aur			S	Oral			Aurobindo
	Lexapro			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Clairitan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2015	11267041	NON-EXPEDITED		HO	US-JNJFOC-20150705870		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Risperidone			S				Not Reported
	Fentanyl Citrate			S				Not Reported
	Bupropion			S				Not Reported
	Valproic Acid			S				Not Reported

	Escitalopram	S	Not Reported
	Atorvastatin	C	Not Reported
	Vancomycin	C	Not Reported
	Vancomycin	C	Not Reported
	Piperacillin-Tazobactam	C	Not Reported
	Piperacillin-Tazobactam	C	Not Reported
	Azithromycin	C	Not Reported
	Azithromycin	C	Not Reported
	Lorazepam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2015	11312191	EXPEDITED (15-DAY)		HO	FR-FRI-1000078486		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Headache; Subdural Haematoma	Escitalopram			S				Forest
	Arixtra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2015	11319408	EXPEDITED (15-DAY)	Y	HO, OT	US-ZYDUS-008656		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Attention Deficit/Hyperactivity Disorder; Chest Discomfort; Hallucinations, Mixed; Hypertension; Hypophagia; Insomnia; Intentional Overdose; Panic Reaction; Paranoia; Psychotic Disorder; Restlessness; Suicide Attempt; Tachycardia; Tachyphrenia; Therapy Cessation	Lamotrigine			S		12.50mg 2.00 Times Per-1days		Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Fluoxetine (Fluoxetine)			S				Not Reported
	Methylphenidate (Methylphenidate)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2015	10867565	EXPEDITED (15-DAY)		HO	IT-FRI-1000074691		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Sopor; Sopor	Escitalopram Oral Solution			S		Overdose: 30 Ml		Forest
	Lexotan			S		Overdose: 30 Ml		Not Reported
	Quetipine			S		Overdose: 40 Dosage Form		Not Reported
	Mirtazapine			S		Overdose: 12 Dosage Form		Not Reported
	Xanax			S		Overdose: 46 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2015	11317339	EXPEDITED (15-DAY)		OT	TR-FRI-1000078556		75 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Bradycardia	Escitalopram			S		5 Mg		Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2015	11317340	EXPEDITED (15-DAY)		OT	TR-FRI-1000078558		70 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hypotension; Presyncope; Sinus Bradycardia	Escitalopram			S		5 Mg		Forest
	Escitalopram			S		10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2015	11317342	EXPEDITED (15-DAY)		OT	CN-FRI-1000067890		76 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Overdose; Serotonin Syndrome	Lexapro		S	5 Mg	Forest
	Olanzapine		S	Overdose Olanzapine (Amount Unknown) The Dosage Under Physician Prescription Was 1/4 Tablet Per Day,	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2015	11320834	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram 20mg			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2015	11233930	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-040874		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Abilify			S	Oral	2 Mg, Unk		Bristol Myers Squibb
	Cipralex /01588501/			S	Unknown	20 Mg, Qd		Not Reported
	Serax /00040901/			C	Unknown	45 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2015	11321828	EXPEDITED (15-DAY)		CA	CH-PFIZER INC-2015248041			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Oesophageal Atresia	Xanax			S	Transplacental	0.25 Mg, Occasionally		Pfizer
	Cipralex /01588501/			S	Transplacental	15 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2015	11291892	EXPEDITED (15-DAY)		OT	FR-TEVA-577520ISR		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Haematoma; Monoplegia; Nausea; Paraesthesia; Platelet Count Decreased; Swollen Tongue	Escitalopram Teva			S	Unknown			Ivax
	Escitalopram Teva			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2015	11323226	NON-EXPEDITED			US-MYLANLABS-2014M1012605			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Levothyroxine Sodium Tablets, Usp			S		Unk		Mylan
	Escitalopram			S		Unk		Forest
	Aciphex			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2015	11323760	NON-EXPEDITED			US-MYLANLABS-2014M1008490			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Drug Interaction; Libido Decreased; Prescribed Overdose; Somnolence	Tramadol			S				Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Lexapro			S	Oral	40 Mg, Qd		Not Reported
	Lexapro			S	Oral	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2015	11325600	EXPEDITED (15-DAY)		OT	SG-JUBILANT GENERICS LIMITED-1040872		66 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Mania	Escitalopram Oxalate			S				Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2015	11327892	EXPEDITED (15-DAY)		OT	SE-FRI-1000078676		< 1 DAY	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Infantile Apnoea	Escitalopram			S	Transplacental	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2015	11327893	EXPEDITED (15-DAY)		DE	FR-FRI-1000078568		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction	Escitalopram			S	Oral			Forest
	Previscan (Fluindione)			S	Oral			Not Reported
	Diffu-K			C				Not Reported
	Duphalac			C				Not Reported
	Enalapril			C				Not Reported
	Speciafoldine			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2015	11327895	EXPEDITED (15-DAY)		HO, LT	CN-FRI-1000074349		19 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	10538570	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-A0966434A		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident At Work; Application Site Burn;	Androderm			S	Transdermal	1 Df, Qd		Glaxosmithkline

Application Site Pain; Application Site Pruritus; Asthma; Ataxia; Back Injury; Disability; Drug Ineffective; Dyspnoea; Fluid Retention; Hypoaesthesia; Ill-Defined Disorder; Intervertebral Disc Protrusion; Joint Swelling; Migraine; Oral Infection; Overdose; Pain; Pulmonary Congestion; Spinal Operation; Spinal Operation; Visual Impairment; Wheezing	Advair	S	Respiratory (inhalation)	1 Puff(S), Bid	Glaxosmithkline
	Advair	S		500/50 Mcg, U	Glaxosmithkline
	Ventolin	S	Respiratory (inhalation)	2-6 Puffs Prn	Glaxosmithkline
	Ventolin	S		Unk, U	Glaxosmithkline
	Biotene Oral Balance Gel (2013 Formulation)	S		Unk, U	Glaxosmithkline
	Escitalopram	S	Unknown	Unk, U	Glaxosmithkline
	Oxycontin	C			Not Reported
	Oxycodone	C			Not Reported
	Valium	C			Glaxosmithkline
	Gabapentin	C			Glaxosmithkline
	Duexis	C			Not Reported
	Singulair	C			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11132798	NON-EXPEDITED			US-PFIZER INC-2015169445			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Doxepin Hcl			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Geodon			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Thorazine /00011901/			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11238741	NON-EXPEDITED		HO	PHEH2014US021471		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Leukocytosis;	Clozaril			S	Oral	250 Mg, Qhs		Novartis

Neutrophil Count Increased; Psychotic Disorder; Schizophrenia; Suicide Attempt	Risperidone	S	Oral	2 Ug, Bid	Not Reported
	Latuda	S	Oral	80 Ug, Qd	Not Reported
	Lexapro	S	Oral	40 Ug, Bid	Not Reported
	Klonopin	S	Oral	1 Ug, Bid	Not Reported
	Haldol	C	Oral		Not Reported
	Prolixin	C	Oral		Not Reported
	Zyprexa	C	Oral		Not Reported
	Metformin	C	Unknown		Not Reported
	Mobic	C	Unknown		Not Reported
	Oxycodone	C	Unknown		Not Reported
	Topamax	C	Unknown		Not Reported
	Zocor	C	Unknown		Not Reported
	Vivelle	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11330304	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APU-2015-06273			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Haematochezia; Product Substitution Issue; Withdrawal Syndrome	Escitalopram Tablets Usp 10mg			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11330359	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APU-2015-06215			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dyspnoea; Hypertension; Palpitations; Product Substitution Issue	Escitalopram Tablets Usp 20mg			S	Unknown	20 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11330388	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APU-2015-06205			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depressed Mood; Fatigue; Headache; Nausea; Product Substitution Issue; Withdrawal Syndrome	Escitalopram Tablets Usp 20mg			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11330402	EXPEDITED (15-DAY)		DS, OT	US-AUROBINDO-AUR-APU-2015-06225			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Interest; Depressed Mood; Depressive Symptom; Drug Withdrawal Syndrome; Irritability; Loss Of Personal Independence In Daily Activities; Product Substitution Issue	Escitalopram Tablets Usp 20mg			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11330404	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APU-2015-06275			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Pain; Depression; Disturbance In Attention; Feelings Of Worthlessness; Insomnia; Loss Of Personal Independence In Daily Activities; Myalgia; Product Substitution Issue;	Escitalopram Tablets Usp 20mg			S	Unknown	20 Mg, Unk		Aurobindo
	Escitalopram Tablets Usp 20mg			S	Unknown	20 Mg, Unk		Aurobindo

Regressive Behaviour

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11331005	EXPEDITED (15-DAY)		HO	GXKR2015DE003571			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Metoprolol			S	Unknown	100 Mg, Qd		Novartis
	Hydrochlorothiazide			S	Unknown	25 Mg, Qd		Not Reported
	Quetiapine			S	Unknown	400 Mg, Qd		Not Reported
	Cipralex /Den/			S	Unknown	5 Mg, Qd		Not Reported
	Remergil			S	Unknown	45 Mg, Qd		Not Reported
	Lorazepam			C	Unknown	1 Mg, Qd		Not Reported
	Evista			C	Unknown	60 Mg, Unk		Not Reported
	Calcium Carbonate			C	Unknown	1500 Mg, Qd		Not Reported
	L-Thyroxine//Levothyroxine			C	Oral	75 Ug, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11331006	EXPEDITED (15-DAY)		DE, OT	PHHY2015US090321		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Depressed Level Of Consciousness; Overdose; Respiratory Depression; Serotonin Syndrome; Skin Abrasion	Amitriptyline Sandoz			S	Oral	1 Df, Qd		Novartis
	Nucynta			S	Oral	1 Df, Tid		Not Reported
	Lexapro			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11333674	EXPEDITED (15-DAY)		OT	US-009507513-1507USA011466		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicidal Ideation; Suicide Attempt	Remeron			S	Oral	Unk		Merck
	Buspar			S	Oral	Unk		Not Reported

	Lexapro			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11334069	EXPEDITED (15-DAY)		OT	IE-FRI-1000078684		36 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dysgeusia; Fatigue; Increased Appetite; Overdose; Paraesthesia; Unresponsive To Stimuli; Vertigo	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	Overdose: 5/6 Times Per Day		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2015	11334676	NON-EXPEDITED			US-TEVA-507703USA		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Laziness	Venlafaxine			S	Unknown			Teva
	Lexapro			S	Oral	20 Milligram Daily;		Not Reported
	Lexapro			S	Oral	20 Milligram Daily;		Not Reported
	Synthroid			C				Not Reported
	Protonix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2015	11335738	NON-EXPEDITED			US-TEVA-582296USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Somnolence	Nuvigil			S	Oral			Cephalon
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2015	11336266	EXPEDITED (15-DAY)		HO, OT	AU-DRREDDYS-USA/AUS/15/0049782		44 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Body Dysmorphic Disorder; Delusional Disorder, Unspecified Type; Depression; Drug Ineffective; Dyskinesia; Obsessive-Compulsive Disorder; Schizoaffective Disorder	Olanzapine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Citalopram			S				Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Clomipramine			S	Unknown			Not Reported
	Clozapine			S	Unknown			Not Reported
	Phenelzine			S	Unknown	Above 60 Mg A Day		Not Reported
	Aripiprazole			S	Unknown	Up To 45 Mg		Not Reported
	Amisulpride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2015	11337100	EXPEDITED (15-DAY)		OT	PHHY2015BR046464		44 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Central Nervous System Lesion; Discomfort; Drug Ineffective; Headache; Lymphocyte Count Decreased; Urinary Tract Infection; White Blood Cell Count Decreased	Gilenya			S	Oral	1 Df, Qd		Novartis
	Lexapro			S	Oral	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2015	11398864	NON-EXPEDITED		HO	1000068061		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Seizure; Tremor	Namenda Xr			S	Oral			Not Reported

	Namenda	S	Oral		Not Reported
			Oral	10 Mg (5 Mg 2 In 1 D), Oral	
			Oral	10 Mg Am, 5 Mg Pm	
			Oral		
	Escitalopram	S	Oral		Not Reported
	Vimpat	S		100 Mg (50 Mg, 2 In 1 D)	Not Reported
	Vimpat	S		200 Mg (100 Mg, 2 In 1 D)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2015	11340763	NON-EXPEDITED			US-PFIZER INC-2015258619		56 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Bactrim			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Sulfamethoxazole			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2015	11342246	EXPEDITED (15-DAY)		CA	NL-FRI-1000078754			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Single Umbilical Artery	Escitalopram			S	Transplacental			Forest
	Ritalin			S	Transplacental			Not Reported
	Ritalin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2015	11342521	EXPEDITED (15-DAY)		HO	DE-TEVA-582738GER		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dystonia	Quetiapin Retard			S		400 Dosage Forms Daily;		Teva
	Metoprolol			S		100 Dosage Forms Daily;		Teva
	Hct			S		25 Dosage Forms Daily;		Ivax
	Cipralex			S		5 Dosage Forms Daily;		Not Reported
	Remergil			S		45 Dosage Forms Daily;		Not Reported
	Lorazepam			C		1 Dosage Forms Daily;		Not Reported
	Evista			C		60 Dosage Forms Daily;		Not Reported
	Calcium Carbonate			C		1500 Dosage Forms Daily;		Not Reported
	L-Thyroxin			C		.075 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2015	11342570	EXPEDITED (15-DAY)		HO	CH-FRI-1000078694		50 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral			Forest
	Trittico (Trazodone Hydrochloride)			S	Oral	50 Mg		Not Reported
	Coversum N (Perindopril Arginine)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2015	11343077	EXPEDITED (15-DAY)		HO	DE-ASTRAZENECA-2015SE74286		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dystonia; Fall	Metoprolol			S				Not Reported
	Seroquel			S	Oral			Zeneca
	Mirtazapine			S	Unknown			Not Reported
	Hydrochlorothiazide			S		25 Df Daily, Non Astrazeneca Product		Not Reported

	Cipralex	S	Unknown	Not Reported
	Lorazepam	C		Not Reported
	Raloxifene Hydrochloride	C		Not Reported
	Calcium Carbonate	C		Not Reported
	L-Thyroxin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2015	11344482	DIRECT		OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Activity; Depression; Disease Recurrence; Fatigue; Obsessive-Compulsive Disorder; Product Substitution Issue; Sedation	Escitalopram			S		1 Pill Per Day		Accord
	Vitamin B			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2015	11349475	EXPEDITED (15-DAY)	Y	HO, OT	2015HINLIT0634		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Cough; Dyspnoea; Hypernatraemia; Hyperthermia Malignant; Hypocalcaemia; Leukocytosis; Lipase Increased; Neuroleptic Malignant Syndrome; Respiratory Disorder; Seizure; Serotonin Syndrome; Transaminases Increased	Escitalopram (Escitalopram) Unknown			S				Not Reported
	Bupropion (Bupropion) Unknown			S				Not Reported
	Valproate (Valproate)			S				Not Reported
	Risperidone (Risperidone)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	10741522	EXPEDITED (15-DAY)		DE, OT	CA-FRI-1000073811		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Delusion; Homicidal Ideation; Paranoia	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	10741968	EXPEDITED (15-DAY)		HO	CA-FRI-1000073807		31 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Effusion; Seizure; Suicide Attempt	Escitalopram			S	Unknown	Daily Dose Not Reported		Forest
	Ativan			S	Unknown	Daily Dose Not Reported		Not Reported
	Ativan			S	Unknown	Overdose: Dose Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5.5357 Mg		Not Reported
	Seroquel			S	Unknown	Daily Dose Not Reported		Not Reported
	Seroquel			S	Unknown	Overdose: Unknown Dose		Not Reported
	Imuran			C		Daily Dose Not Reported.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	10742613	EXPEDITED (15-DAY)		OT	CA-FRI-1000073814		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Suicidal Ideation	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	10742819	EXPEDITED (15-DAY)		DS	CA-FRI-1000073821		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Blood Pressure Increased;	Escitalopram			S		Dose Not Reported		Forest
	Abilify			S		Dose Not Reported		Not Reported

Depression; Heart Rate Increased; Mental Impairment; Product Use In Unapproved Indication	Seroquel		S	Unknown	Dose Not Reported	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	10742854	EXPEDITED (15-DAY)		OT	CA-FRI-1000073854		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysuria; Hypotension; Urinary Retention	Escitalopram			S	Oral	20 Mg Daily		Forest
	Mirena			C		Daily Dose Not Reported.		Not Reported
	Modafinil			C				Not Reported
	Pantoprazole			C		80 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	10742895	EXPEDITED (15-DAY)		OT	CA-FRI-1000073826		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Flushing; Headache; Hyperhidrosis; Nausea; Nervousness; Pain; Serotonin Syndrome; Tremor	Escitalopram			S	Oral	20 Mg		Forest
	Effexor			S	Oral	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	10856161	EXPEDITED (15-DAY)		DE	CA-FRI-1000073823		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Chest Pain; Completed Suicide; Depression; Hallucination, Visual; Hyperhidrosis; Intentional Overdose; Mood Swings; Musculoskeletal Chest	Escitalopram			S	Unknown	Overdose: Dose Unknown		Forest
	Zopiclone			S	Unknown	Overdose: Dose Unknown		Not Reported
	Rosuvastatin			C	Oral	10 Mg		Not Reported
	Senna Plus			C	Oral	8.6 Mg/50 Mg		Not Reported

Pain; Suicidal Ideation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11030562	EXPEDITED (15-DAY)		OT	ES-FRI-1000075850		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Ameride (Amiloride Hydrochloride\Hydrochlorothiazide)			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported
	Adiro			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11294134	EXPEDITED (15-DAY)		HO	US-FRI-1000078323		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Escitalopram			S	Unknown			Forest
	Risperidone			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11343235	EXPEDITED (15-DAY)		HO, OT	DE-DRREDDYS-GER/GER/15/0049688		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Delusion; Depression;	Metoprolol			S				Not Reported
	Hydrochlorothiazide			S				Not Reported

Drug Interaction; Dystonia; Impaired Driving Ability	Quetiapine Retard	S	Not Reported
	Remergil	S	Not Reported
	Cipralex	S	Not Reported
	Lorazepam	C	Not Reported
	Evista	C	Not Reported
	Calcium Carbonate	C	Not Reported
	Levothyroxine Sodium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11344007	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/15/0049871		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Pneumonia; Sepsis; Serotonin Syndrome	Risperidone			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Valproate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11345637	EXPEDITED (15-DAY)		HO, OT	JP-KOWA-15JP001007		44 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased; Chest Pain; Headache	Livalo			S	Oral	2 Mg, Qd		Kowa Pharm
	Lyrica			S	Oral	Unk, Prn		Not Reported
	Actos			S	Oral	15 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Depas (Etizolam)			S	Oral	1.0 Mg, Tid		Not Reported
	Depas			S	Oral	0.5 Mg, Tid		Not Reported
	Amoxan			C	Oral	Unk, Unk		Not Reported
	Solanax			C	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11345809	EXPEDITED (15-DAY)		OT	FR-FRI-1000078780			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuritis	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11348427	EXPEDITED (15-DAY)		OT	PHHY2015TR091650		43 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome; Therapeutic Response Decreased	Escitalopram			S	Unknown			Not Reported
	Citalopram			S	Unknown			Novartis
	Levothyroxine			C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11350172	DIRECT		OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Loss Of Consciousness	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11350475	DIRECT					43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Apathy; Apathy; Diarrhoea; Somnolence; Somnolence	Escitalopram Lexapro 10 Mg Torrent Pharma			S	Oral	2 Daily Once Daily Taken By Mouth		Torrent
	Vitamin D3			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11358702	EXPEDITED (15-DAY)	Y	HO	DE-2015VAL000504		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Metoprolol Tartrate			S				Not Reported

Hydrochlorothiazide (Hydrochlorothiazide) 25mg	S			Not Reported
Quetiapine (Quetiapine) 400mg	S	Extended Release Tablet, 400 Mg, Qd		Not Reported
Cipralex /01588501/ (Escitalopram) 5mg	S			Not Reported
Remergil (Mirtazapine) 45mg	S			Not Reported
Lorazepam	C			Not Reported
Evista (Raloxifene Hydrochloride)	C			Not Reported
Calcium Carbonate	C			Not Reported
L-Thyroxine /00068001/ (Levothyroxine)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	9824319	NON-EXPEDITED			US-GILEAD-2011-0037286		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Headache; Nausea; Palpitations; Vomiting	Letairis			S	Oral			Gilead
	Letairis			S				Gilead
	Lexapro			S				Not Reported
	Adcirca			C				Not Reported
	Coumadin			C				Not Reported
	Oxygen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	10741610	EXPEDITED (15-DAY)		OT	CA-FRI-1000073816		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hallucination; Muscle Spasms; Muscle Tightness; Muscle Twitching; Nausea; Restlessness; Serotonin Syndrome; Skin Burning Sensation; Tachycardia; Tremor; Vomiting	Escitalopram			S	Unknown	5 Mg		Forest
	Effexor Xr			S	Oral	1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	10742765	EXPEDITED (15-DAY)		HO	CA-FRI-1000073825		< 1 DAY	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Trismus	Escitalopram			S	Transplacental	20 Mg		Forest
	Benztropine Mesylate			S	Transplacental	1.5 Mg		Not Reported
	Gabapentin			S	Transplacental	1800 Mg		Not Reported
	Methadone			S	Transplacental	70 Mg		Not Reported
	Nortriptyline			S	Transplacental	20 Mg		Not Reported
	Quetiapine			S	Transplacental	600 Mg		Not Reported
	Rabeprazole			S	Transplacental	Daily Dose Not Reported		Not Reported
	Zopiclone			S	Transplacental	Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11226469	EXPEDITED (15-DAY)		OT	DE-GILEAD-2015-0152211		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Depression; Drug Dependence; Dyspnoea; Fatigue	Ledipasvir/Sofosbuvir			S	Oral	1 Df, Qd		Gilead
	Ribavirin			S	Oral	1200 Mg, Qd		Not Reported
	Ribavirin			S	Oral	800 Mg, Qd		Not Reported
	Ribavirin			S	Oral	600 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Methadon			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11349157	EXPEDITED (15-DAY)		HO, OT	TW-MACLEODS PHARMACEUTICALS US LTD-MAC2015001907			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Agitation; Delirium; Disturbance In Attention; Drug Interaction; Hallucinations, Mixed; Incoherent	Escitalopram Oxalate	S	Unknown	10 Mg/Day		Macleods
	Disulfiram	S	Unknown	200 Mg, Qd		Not Reported
	Griseofulvin	S	Unknown	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11350440	EXPEDITED (15-DAY)		OT	CA-FRI-1000078697			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11350546	EXPEDITED (15-DAY)		HO	US-FRI-1000078784			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Ineffective; Psychiatric Symptom	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11353311	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2015-06734			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dystonia; Fall	Hydrochlorothiazide			S	Unknown	25 Df, Daily		Aurobindo
	Metoprolol			S	Unknown	100 Df, Daily		Aurobindo
	Quetiapine			S		400 Df, Daily		Aurobindo
	Cipralex /01588501/			S		5 Df, Daily		Not Reported
	Remergil			S	Unknown	45 Df, Daily		Not Reported
	Lorazepam			C	Unknown	1 Df, Daily		Not Reported
	Evista			C	Unknown	60 Df, Daily		Not Reported
	Calcium Carbonate			C	Unknown	1500 Df, Daily		Not Reported

	Thyroxin	C	Unknown	0.075 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11354825	NON-EXPEDITED			US-JNJFOC-20150103411		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Drug Ineffective; Post-Traumatic Stress Disorder	Risperdal			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Prozac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11355280	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-050789		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Post Procedural Haemorrhage; Renal Haematoma; Renal Stone Removal	Coumadine			S	Oral	1 Df, Qd		Bristol Myers Squibb
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Inexium /01479302/			C	Unknown	20 Mg, Qd		Not Reported
	Rythmol /00546301/			C	Unknown	1 Df, Bid		Not Reported
	Esidrex			C	Unknown	25 Mg, Qd		Not Reported
	Temesta /00273201/			C	Unknown	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2015	10756584	EXPEDITED (15-DAY)		OT	PHHY2015BR010479			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Body Height Decreased; Dementia Alzheimer'S Type; Dry Mouth; Dysphagia; Fatigue; Gait Disturbance; Malaise; Memory Impairment; Pain;	Exelon Patch			S	Transdermal	Patch 10 (Cm2)		Novartis
	Exelon Patch			S	Transdermal	Patch 10 (Cm2), In Morning		Novartis
	Neotiapim			S	Oral	2 Df, Qd		Not Reported
	Citoneurin			S	Unknown	Unk		Not Reported

Somnolence; Speech Disorder; Spinal Deformity; Tremor; Weight Decreased; Weight Increased	Lexapro	S	Unknown	15 Mg, Unk	Not Reported
	Oscal	S	Unknown	400 Iu, Unk	Not Reported
	Alois	S	Oral	2 Df, Qd	Not Reported
	Vitersol D	S	Oral	Unk	Not Reported
	Actonel	S	Unknown	150 Ot, Unk	Not Reported
	Rivotril	S	Oral	5 Gtt, Qhs	Not Reported
	Lyrica	S	Oral	2 Df, Qd	Not Reported
	Lyrica	S	Unknown	75 Mg, Unk	Not Reported
	Dramin B6	C	Oral	Unk	Not Reported
	Lescol	C	Oral	Unk	Not Reported
	Lexotan	C	Oral	1.5 Df, Qhs	Not Reported
	Ocuguard Plus	C	Oral	2 Df, Qd	Not Reported
	Harpagophytum Procumbens	C	Oral	Unk	Not Reported
	Ensure	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2015	11302483	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2015US05893			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Pneumonia; Respiratory Failure; Sepsis; Serotonin Syndrome	Risperidone			S	Oral	1 Mg, Qhs		Cipla
	Bupropion			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Valproate			S	Unknown	Unk		Not Reported
	Fentanyl			S		Unk		Not Reported
	Lorazepam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2015	11319381	EXPEDITED (15-DAY)		CA	PHHY2015NL087692			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Single Umbilical Artery	Ritalin		S	Unknown	1 Df, Unk	Novartis
	Lexapro		S	Unknown	1 Df, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2015	11359911	EXPEDITED (15-DAY)		DE	FR-NOVEN PHARMACEUTICALS, INC.-FR2015000643			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Paroxetine			S	Oral	20 Mg, Qd		Noven
	Escitalopram Mylan Pharma			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram Mylan Pharma			S	Oral	10 Mg, Qd		Not Reported
	Seroplex			S	Oral	15 Mg, Qd		Not Reported
	Alprazolam			C		.25 Mg, Unk		Not Reported
	Alprazolam			C		0.25 Mg, Qd		Not Reported
	Kardegic			C	Oral	1 Df, Qd		Not Reported
	Valaciclovir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2015	11363077	EXPEDITED (15-DAY)		CA, OT	CH-FRI-1000078893			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Oesophageal Atresia	Escitalopram			S	Transplacental			Forest
	Xanax			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2015	11310192	EXPEDITED (15-DAY)		DE	FR-FRI-1000078320		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke	Escitalopram			S	Oral	10 Mg		Forest
	Previscan (Fluindione)			S	Oral	40 Mg		Not Reported
	Doliprane			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2015	11364380	NON-EXPEDITED			US-PFIZER INC-2015255380		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Norvasc			S		Unk		Pfizer
	Synthroid			S		Unk		Not Reported
	Omeprazole			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Labetalol			S		Unk		Not Reported
	Ferrous Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2015	11364961	EXPEDITED (15-DAY)		OT	FR-FRI-1000078887		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Cognitive Disorder; Condition Aggravated; Off Label Use	Escitalopram			S	Oral	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2015	11365876	EXPEDITED (15-DAY)		HO	FR-FRI-1000078882		31 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Escitalopram			S	Oral	10 Mg		Forest
	Atarax			S	Oral	50 Mg		Not Reported
	Tercian			S	Oral			Not Reported
	Deroxat			S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2015	11366148	EXPEDITED (15-DAY)		HO	FR-FRI-1000078863		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose: 210 Mg Once.		Forest
	Klipal			S	Oral	Overdose: 7.2 G Of Paracetamol And 600 Mg Of Codeine		Not Reported
	Seresta			S	Oral			Not Reported
	Seresta			S	Oral	Overdose: 300 Mg Once.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2015	11368207	DIRECT					22 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Bipolar I Disorder; Panic Attack; Suicidal Ideation	Lexapro			S	Oral	Taken By Mouth	2.5 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2015	11368714	EXPEDITED (15-DAY)		HO	CA-ROCHE-1618703			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Clonazepam			S	Unknown			Not Reported
	Cipralex			S	Oral			Not Reported
	Domperidone			S	Unknown			Not Reported
	Ferrous Sulphate			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Temazepam Capsules			S	Oral			Not Reported

	Tylenol With Codeine #3 (United States)	S	Oral	Not Reported
	Vitalex (Unk Ingredients)	S	Oral	Not Reported
	Wellbutrin Xl	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2015	11368736	EXPEDITED (15-DAY)		OT	US-JUBILANT GENERICS LIMITED-1041045		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Serotonin Syndrome	Bupropion			S				Jubilant
	Escitalopram			S				Not Reported
	Valproate Sodium			S				Not Reported
	Fentanyl			S				Not Reported
	Risperidone			S				Not Reported
	Vancomycin Hcl			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Azithromycin			C				Not Reported
	Lorazepam			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2015	11369345	NON-EXPEDITED			US-JNJFOC-20150506351			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy	Stelara			S	Subcutaneous			Not Reported
	Adderall			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2015	11371743	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2015M1026348			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Metoprolol			S		100 Df, Unk		Not Reported

	Hct	S	25 Df, Unk	Mylan
	Cipralex	S	5 Df, Unk	Not Reported
	Quetiapin Retard	S	400 Df, Unk	Not Reported
	Remergil	S	45 Df, Unk	Not Reported
	Lorazepam	C	1 Df, Unk	Not Reported
	Evista	C	60 Df, Unk	Not Reported
	Calcium Carbonate	C	1500 Df, Unk	Not Reported
	L-Thyroxin	C	0.075 Df, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2015	11378910	EXPEDITED (15-DAY)	Y	HO	2015EDG00030		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Serotonin Syndrome	Bupropion (Bupropion)			S				Not Reported
	Escitalopram (Escitalopram)			S				Not Reported
	Valproate (Valproate)			S				Not Reported
	Fentanyl (Fentanyl) Injection			S				Not Reported
	Risperidone (Risperidone)			S				Not Reported
	Vancomycin (Vancomycin)			C				Not Reported
	Piperacillin-Tazobactam (Piperacillin-Tazobactam)			C				Not Reported
	Azithromycin (Azithromycin)			C				Not Reported
	Lorazepam (Lorazepam)			C				Not Reported
	Ceftriaxone (Ceftriaxone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2015	11341581	EXPEDITED (15-DAY)		HO	FR-FRI-1000078748		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Post Procedural Haemorrhage	Escitalopram			S	Oral	15 Mg		Forest
	Coumadine			S	Oral	1 Mg		Not Reported
	Inexium			C	Oral	20 Mg		Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported

Rythmol	C	Oral	300 Mg		Not Reported
Esidrex	C	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2015	11375931	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015265255		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Paraesthesia	Xanax			S	Oral	0.25 Mg, Unk		Pfizer
	Xeloda			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	10 Mg, Unk		Not Reported
	Oxycontin Lp			S	Oral	20 Mg (10mg X 2), 1x/Day		Not Reported
	Paracetamol			C		Unk		Not Reported
	Ixprim			C		Unk		Not Reported
	Imodium			C		Unk		Not Reported
	Primperan			C		Unk		Not Reported
	Dexeryl /00557601/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2015	11375980	EXPEDITED (15-DAY)		HO	KR-MYLANLABS-2015M1026954			Unknown	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Tardive Dyskinesia	Amitriptyline			S		10 Mg, Qd		Mylan
	Escitalopram			S		5 Mg, Qd		Mylan
	Trazodone			S		25 Mg, Qd		Mylan
	Benztropine			C		2mg Qd		Not Reported
	Lorazepam			C		2 Mg, Qd		Not Reported
	Clonazepam			C		1.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2015	11377207	NON-EXPEDITED			US-TAKEDA-2015TUS010567		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Labelled Drug-Drug Interaction Medication Error; Panic Disorder	Contrave			S	Oral	8mg/90mg, Qd		Takeda
	Lexapro			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2015	10390117	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2014223572		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Pyrexia; Tachycardia; Tremor	Zyvoxid			S	Oral	1200 Mg, 1x/Day		Pfizer
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Flecaine Lp			C				Not Reported
	Imovane			C				Not Reported
	Fraxodi			C				Not Reported
	Decontractyl (Mephenesin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2015	11198413	EXPEDITED (15-DAY)		OT	TR-ACCORD-031442		18 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2015	11328915	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2015-06458		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Attention Deficit/Hyperactivity Disorder; Chest Discomfort; Depressive Symptom; Feeling Abnormal; Generalised Anxiety Disorder; Hallucination, Auditory; Hypertension;	Escitalopram 10 Mg			S	Unknown	10 Mg, Daily		Aurobindo
	Fluoxetine			S	Unknown	20 Mg, Daily		Not Reported
	Fluoxetine			S	Unknown	10 Mg, Daily		Not Reported
	Methylphenidate			S	Unknown	945 Mg, Unk		Not Reported
	Methylphenidate			S	Unknown	54 Mg, Daily		Not Reported
	Methylphenidate			S	Unknown	27 Mg, Daily		Not Reported

Hypophagia; Insomnia; Mood Altered; Overdose; Panic Reaction; Paranoia; Restlessness; Suicide Attempt; Tachycardia; Tachyphrenia; Toxicity To Various Agents	Lamotrigine	C	Oral	12.5 Mg, Every Week	Not Reported
	Lamotrigine	C	Oral	12.5 Mg, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2015	11379669	EXPEDITED (15-DAY)		HO, OT	TW-ACCORD-033033		38 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Interaction	Escitalopram			S				Accord
	Disulfiram			S				Not Reported
	Griseofulvin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2015	11381625	EXPEDITED (15-DAY)		HO	FR-FRI-1000078931		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome	Escitalopram			S	Transplacental	10 Mg		Forest
	Skenan			S	Transplacental	40 Mg		Not Reported
	Actiskenan			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2015	11381953	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2015M1026139			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Escitalopram Mylan Génériques 5 Mg, Comprimé Pelliculé Sécable			S	Oral	5 Mg, Qd		Mylan
	Escitalopram Mylan Génériques 5 Mg, Comprimé Pelliculé Sécable			S	Oral	10 Mg, Qd		Mylan

Alprazolam 0.25 Mg	S	Oral	Unk		Mylan
Alprazolam 0.25 Mg	S	Oral	Unk		Mylan
Seroplex	S	Oral	15 Mg, Qd		Not Reported
Divarius	S	Oral	20 Mg, Qd		Not Reported
Kardegic	C	Oral	1 Df, Qd		Not Reported
Valaciclovir	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2015	11383586	NON-EXPEDITED			US-PFIZER INC-2015269930			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Crying; Drug Ineffective	Sertraline Hcl			S		100 Mg, Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2015	11387206	NON-EXPEDITED			US-TEVA-586742USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Provigil			S				Cephalon
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2015	11387843	EXPEDITED (15-DAY)		OT	TR-PFIZER INC-2015262903		26 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Rectal Haemorrhage	Efexor Xr			S		75 Mg, 1x/Day		Pfizer
	Cipralex			S		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2015	11388217	EXPEDITED (15-DAY)		OT	FR-APOTEX-2015AP011348			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Paxil Tablets			S	Oral	Unk		Apotex
	Atarax /00058401/			S	Oral	25 Mg, Bid		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Tercian /00759301/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2015	11389618	EXPEDITED (15-DAY)		CA	FR-FRI-1000078989		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Congenital Foot Malformation; Foetal Exposure During Pregnancy; Talipes; Tremor	Escitalopram			S	Transplacental	20 Mg One Day / 10 Mg The Other Day		Forest
	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2015	11395198	DIRECT					45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypertension; Weight Increased	Lexapro			S		One 20mg Pill A Day -- --		Not Reported
	Lebetalol			C				Not Reported
	Vitamin C			C				Not Reported
	Vsl #3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2015	11395441	DIRECT		OT			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Contact; Product Formulation Issue; Product	Escitalopram 20 Mg Intas Pharmaceuticals Limited			S	Oral			Intas
	Restasis			C				Not Reported

Formulation Issue; Product Substitution Issue; Rash	Vitamin D2 (Vegan)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	10527783	EXPEDITED (15-DAY)		HO	FR-FRI-1000071633		95 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S	Oral			Not Reported
	Tahor			C				Not Reported
	Burinex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	10671821	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2014351850		50 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Drug Interaction; Restlessness	Venlafaxine Hcl			S	Oral	75 Mg, 1x/Day		Pfizer
	Venlafaxine Hcl			S	Oral	150 Mg, 1x/Day		Pfizer
	Venlafaxine Hcl			S	Oral	75 Mg, 1x/Day		Pfizer
	Cipralex			S	Oral	10 Mg, 1x/Day		Not Reported
	Cipralex			S	Oral	20 Mg, 1x/Day		Not Reported
	Cipralex			S	Oral	10 Mg, 1x/Day		Not Reported
	Cipralex			S	Oral	10 Mg, 1x/Day		Not Reported
	Cipralex			S	Oral	20 Mg, 1x/Day		Not Reported
	Abilify			S	Oral	50 Mg, 1x/Day		Not Reported
	Abilify			S	Oral	10 Mg, 1x/Day		Not Reported
	Remergil			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	11389952	EXPEDITED (15-DAY)		HO, OT	PHHY2015KR096217		56 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dystonia; Excessive Eye Blinking; Tardive Dyskinesia; Torticollis	Amitriptyline			S	Unknown	10 Mg, Qd		Novartis
	Trazodone			S	Unknown	25 Mg, Qd		Not Reported
	Flurazepam			S	Unknown	15-30 Mg Qd		Not Reported
	Lorazepam			S	Unknown	2 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	5 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	1.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	11392269	EXPEDITED (15-DAY)			NO-JNJFOC-20150804485		38 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Incorrect Product Administration Duration; Product Complaint; Wrong Technique In Product Usage Process	Durogesic			S	Transdermal			Not Reported
	Durogesic			S	Transdermal			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	11392811	EXPEDITED (15-DAY)		HO	IT-FRI-1000079016		22 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Abuse; Intentional	Escitalopram Oral Solution			S	Oral	Overdose: 15ml		Forest

Overdose; Intentional Self-Injury	Lexotan		S	Oral	10 Ml	Not Reported
	Alcohol		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	11398420	EXPEDITED (15-DAY)	Y	OT	ABR_02339_2015		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Product Dispensing Error; Suicidal Ideation	Lamotrigine			S		350 Mg Qhs		Not Reported
	Oxcarbazepine			S				Not Reported
	Escitalopram			S				Not Reported
	Alprazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	11399043	DIRECT		HO			1 DAY	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis Neonatal; Foetal Exposure During Pregnancy; Infantile Apnoea; Neonatal Respiratory Distress	Escitalopram 10mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2015	11215867	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0159460		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Ambrisentan			S	Unknown	10 Mg, Qd		Gilead
	Ambrisentan			S				Gilead
	Sildenafil			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2015	11247180	NON-EXPEDITED			US-PFIZER INC-2015225503		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Lyrica			S	Oral	75 Mg, 3x/Day		Pfizer
	Effexor			S		Unk		Pfizer
	Advair			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Penicillin G			S		Unk		Not Reported
	Valium			S		Unk		Not Reported
	Doxycycline			S		Unk		Not Reported
	Fluticasone			S				Not Reported
	Salmeterol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2015	11198510	EXPEDITED (15-DAY)		HO	FR-009507513-1506FRA006659		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photosensitivity Reaction; Rash Erythematous	Proglicem			S	Oral	175 Mg, Qd		Merck
	Proglicem			S	Oral	550 Mg, Qd		Merck
	Lexomil			S		3 Mg, If Needed At Bedtime		Not Reported
	Theralene			S	Oral	10 Drops In The Evening(At Bedtime) If Needed		Not Reported
	Acetaminophen			S	Oral	Unk, Frequency Reported As "If Pain"		Not Reported
	Seroplex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2015	11263363	EXPEDITED (15-DAY)		HO	US-TEVA-577245USA		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Escitalopram			S	Unknown			Ivax
	Risperidone			S	Unknown			Pliva
	Fentanyl			S	Unknown			Cephalon
	Bupropion			S	Unknown			Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2015	11317341	EXPEDITED (15-DAY)		OT	IT-FRI-1000078436		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury	Escitalopram Oral Solution			S	Oral	Overdose: 15 Ml		Forest
	Haldol "10 Mg/Ml Gocce Orali, Soluzione"/Haloperidol			S	Oral	Overdose:30 Mls		Not Reported
	Lendormin "0,25 Mg Compresse"/Brotizolam			S	Oral	Overdose: 10 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2015	11398102	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2015001928			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Escitalopram Oxalate			S				Macleods
	Sertraline			S	Unknown	Unk		Not Reported
	Sertraline			S				Not Reported
	Venlafaxime			S	Unknown	225 Mg/Day, Qd		Not Reported
	Venlafaxime			S				Not Reported
	Risperidone			S	Unknown	2 Mg/Day		Not Reported
	Risperidone			S				Not Reported
	Paroxetine			S	Unknown	Unk		Not Reported

	Paroxetine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2015	11398607	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2015-07365		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Depressed Mood; Drug Interaction; Insomnia	Escitalopram			S	Oral			Aurobindo
	Alprazolam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2015	11400579	EXPEDITED (15-DAY)		HO	CA-BAUSCH-BL-2015-019696		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Wellbutrin Xl			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Domperidone			S	Oral			Not Reported
	Ferrous Sulfate			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Temazepam			S	Oral			Not Reported
	Tylenol With Codeine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2015	11400998	EXPEDITED (15-DAY)		HO	PHHY2015CH096926		77 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Carboplatin			S	Intravenous drip			Novartis
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported
	Cipralex//Escitalopram			S	Oral			Not Reported

	Paclitaxel		C	Intravenous drip	Unk	Not Reported
	Nexium//Esomeprazole Magnesium		C	Oral	20 Mg, Qd	Not Reported
	Omeprazole		C	Oral	40 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2015	11401609	EXPEDITED (15-DAY)		HO, OT	FR-NOVEN PHARMACEUTICALS, INC.-FR2015000721			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Paroxetine			S	Unknown	Unk, Unknown		Noven
	Paroxetine			S	Unknown	40 Mg, Qd		Noven
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported
	Escitalopram			S				Not Reported
	Sertraline			S	Unknown	Unk, Unknown		Not Reported
	Sertraline			S				Not Reported
	Venlafaxine			S	Unknown	Until The Dosage Of 225mg, Qd		Not Reported
	Venlafaxine			S				Not Reported
	Risperidone			S	Unknown	2 Mg, Qd		Not Reported
	Risperidone			S	Unknown	2 Mg, Qd		Not Reported
	Diazepam			S	Unknown	20 Mg, Qd		Not Reported
	Diazepam			S				Not Reported
	Quetiapine			S	Unknown	100 Mg, Qd		Not Reported
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2015	11403586	NON-EXPEDITED		HO, OT	US-TEVA-578833USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Somnolence; Somnolence; Suicidal Ideation; Suicidal Ideation	Fluoxetine			S	Unknown			Barr
	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2015	11403940	EXPEDITED (15-DAY)		HO	CH-TEVA-586072ISR		78 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Mirtazapin			S	Oral	15 Milligram Daily;		Teva
	Carboplatin			S	Intravenous drip			Not Reported
	Cipralex			S	Oral	Dosage Unknown		Not Reported
	Paclitaxel			C	Intravenous drip			Not Reported
	Nexium			C	Oral	20 Milligram Daily;		Not Reported
	Omeprazole			C	Oral	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2015	10654394	EXPEDITED (15-DAY)		HO	FR-FRI-1000073103		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Modopar			C	Unknown	6 Df		Not Reported
	Axeler			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported
	Atarax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2015	10930265	NON-EXPEDITED			US-PFIZER INC-2015096140			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Doxycycline Calcium			S				Pfizer
	Septra Ds			S		Unk		Pfizer
	Penicillin G Benzathine/Penicillin G Procaine			S		Unk		Unknown

Haloperidol	S	Unk	Pfizer
Zolpidem Tartrate	S	Unk	Pfizer
Metoclopramide Hcl	S	Unk	Pfizer
Depakote	S	Unk	Not Reported
Keflex	S	Unk	Not Reported
Cipro	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported
Baclofen	S	Unk	Not Reported
Bupropion	S	Unk	Not Reported
Toradol	S	Unk	Not Reported
Amitriptyline	S	Unk	Not Reported
Cephalexin	S	Unk	Not Reported
Divalproex	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Maxalt	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported
Methadone	S	Unk	Not Reported
Phenazopyridine	S	Unk	Not Reported
Prochlorperazine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2015	11408908	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2015IN06733			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Phobia; Urticaria	Cetirizine Hydrochloride Allergy			S	Oral	10 Mg, Unk		Cipla
	Cetirizine Hydrochloride Allergy			S				Cipla
	Cetirizine Hydrochloride Allergy			S				Cipla
	Cetirizine Hydrochloride Allergy			S				Cipla
	Cetirizine Hydrochloride Allergy			S				Cipla
	Cetirizine Hydrochloride Allergy			S				Cipla

Paracetamol	S	Unknown		Not Reported
Diclofenac	S	Oral	25 Mg, Unk	Not Reported
Fexofenadine	S	Oral	180 Mg, Unk	Not Reported
Levocetirizine	S	Unknown		Not Reported
Hydroxyzine	S	Unknown		Not Reported
Ebastine	S	Unknown		Not Reported
Cyproheptadine	S	Unknown		Not Reported
Omeprazole	S	Unknown		Not Reported
Esomeprazole	S	Unknown		Not Reported
Cefixime	S	Unknown		Not Reported
Ivermectin	S	Unknown		Not Reported
Escitalopram	S	Unknown		Not Reported
Clonazepam	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2015	11409245	EXPEDITED (15-DAY)		HO, OT	CA-HOSPIRA-2974807		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Exposure During Pregnancy; Fall; Hidradenitis; Off Label Use; Product Use Issue; Skin Laceration	Prenatal Vitamins /02014401/			C				Not Reported
	Metamucil /00029101/			S	Unknown			Not Reported
	Morphine Sulphate			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Cipralex /01588501/			S	Unknown			Not Reported
	Ativan			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Diclectin			S	Unknown			Not Reported
	Gravol			S	Unknown			Not Reported
	Rabeprazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2015	11410928	EXPEDITED (15-DAY)		HO	FR-FRI-1000079073		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photosensitivity Reaction; Rash Erythematous	Escitalopram			S	Oral			Forest
	Proglicem			S	Oral	175 Mcg		Not Reported
	Proglicem			S	Oral	550 Mcg		Not Reported
	Proglicem			S	Oral	175 Mg		Not Reported
	Lexomil Roche			S	Unknown	3 Mg/Day If Needed (At Bedtime)		Not Reported
	Theralene			S	Oral	10 Drops/Day If Needed (At Bedtime)		Not Reported
	Paracetamol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2015	11413931	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-CA2015GSK120565		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Inappropriate Schedule Of Product Administration; Mental Disorder	Wellbutrin Xl			S	Oral	150 Mg, Bid		Glaxosmithkline
	Clonazepam			S	Oral	.5 Mg, Tid		Glaxosmithkline
	Cipralex			S	Oral	20 Mg, 1d		Glaxosmithkline
	Domperidone			S	Oral	10 Mg, Bid		Glaxosmithkline
	Ferrous Sulfate			S	Oral	300 Mg, Tid		Glaxosmithkline
	Gabapentin			S	Oral	300 Mg, 1d		Glaxosmithkline
	Gabapentin			S	Oral	600 Mg, Bid		Glaxosmithkline
	Temazepam			S	Oral	30 Mg, 1d		Not Reported
	Tylenol With Codeine			S	Oral	1 Df, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2015	11178600	EXPEDITED (15-DAY)		HO	JP-ASTRAZENECA-2015SE55183		44 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased	Nexium			S	Oral			Not Reported
	Solanax			S	Oral	Dose Unknown		Not Reported
	Amoxan			S	Oral	Dose Unknown		Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Depas (Etizolam)			S	Oral			Not Reported
	Depas			S	Oral			Not Reported
	Livalo Od			S	Oral			Not Reported
	Actos			S	Oral			Not Reported
	Selbex			C	Oral			Not Reported
	Statin			C				Not Reported
	Anti-Diabetic			C				Not Reported
	Anti-Psychotic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2015	11414992	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-033247		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Infarction; Treatment Failure	Escitalopram			S				Accord
	Sertraline			S				Accord
	Venlafaxine/Venlafaxine Hydrochloride			S				Not Reported
	Risperidone			S				Not Reported
	Paroxetine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2015	11420118	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Hypervigilance; Irritability; Polydipsia; Product Substitution Issue	Escitalopram 20mg Mylan And Invagen Pharm			S	Oral	One Pill		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2015	11421206	EXPEDITED (15-DAY)		OT	FR-FRI-1000079089		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Withdrawal Syndrome	Escitalopram			S	Unknown	5 Mg		Forest
	Paracetamol			S	Unknown	3 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2015	11421367	EXPEDITED (15-DAY)		HO	US-SA-2015SA125492		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy; Hyponatraemia	Ambien			S	Oral	Frequency: Prn, Qhs		Not Reported
	Blinded Therapy			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Apixaban			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Chondroitin Sulfate/Glucosamine Hydrochloride			C	Unknown			Not Reported
	Psyllium Husk			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Carvedilol			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Lactobacillus Acidophilus			C	Unknown			Not Reported

Vitamin C	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2015	6526659	EXPEDITED (15-DAY)		HO, LT, OT	AU-PFIZER INC-2007105903		42 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Depression; Homicidal Ideation; Intentional Overdose; Poor Quality Sleep; Suicidal Behaviour; Suicide Attempt	Champix			S	Oral	1 Df, Daily		Pfizer
	Methylprednisolone			S		40 Mg, Daily		Pfizer
	Escitalopram			S	Oral	30 Mg, Daily		Not Reported
	Valproate Sodium			S	Oral	200 Mg Three Daily And 500 Mg At Night		Not Reported
	Valproate Sodium			S	Oral	1.5 G, Daily		Not Reported
	Efexor			C		150 Mg, Daily		Not Reported
	Seroquel			C		800 Mg, Daily		Not Reported
	Valium			C		5 Mg, Daily		Not Reported
	Valium			C		10 Mg, Daily		Not Reported
	Kalma (Tryptophan)			C		As Required		Not Reported
	Alprazolam			C	Oral	1 Mg, Daily		Not Reported
	Avanza			C	Oral	30 Mg, 1x/Day		Not Reported
	Lexapro			C	Oral	10 Mg, One And A Half, Daily		Not Reported
	Atrovent			C		Unk		Not Reported
	Mobic			C		Unk		Not Reported
	Nystatin			C		Unk		Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2015	11422412	NON-EXPEDITED			US-PFIZER INC-2015283091		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disease Progression; Fatigue; Hyperhidrosis; Insomnia; Somnolence; Tremor	Effexor Xr			S	Oral	75 Mg, 1x/Day		Pfizer
	Lexapro			S	Oral	20 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2015	11424553	EXPEDITED (15-DAY)		HO	US-FRI-1000079129		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy; Hyponatraemia	Lexapro			S	Oral	20mg		Forest
	Tafamidis Meglumine (Double-Blind)			S				Not Reported
	Ambien			S	Oral			Not Reported
	Apixaban			C				Not Reported
	Acetaminophen			C				Not Reported
	Bupropion			C				Not Reported
	Glucosamine Chondroitin			C				Not Reported
	Psyllium Husk			C				Not Reported
	Loratadine			C				Not Reported
	Carvedilol			C				Not Reported
	Celebrex			C				Not Reported
	Trazodone			C				Not Reported
	Lactobacillus Acidophilus			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D3			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2015	11318556	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2015-06291		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Body Temperature Increased; Confusional State; Cough; Crepitations; Dyspnoea;	Escitalopram			S	Unknown			Aurobindo
	Risperidone			S	Unknown			Aurobindo
	Bupropion			S	Unknown			Not Reported

Flushing; Hyperhidrosis; Hypernatraemia; Hypocalcaemia; Leukocytosis; Lipase Increased; Muscle Rigidity; Neuroleptic Malignant Syndrome; Respiratory Failure; Transaminases Increased	Valproate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2015	11432665	EXPEDITED (15-DAY)		OT	DE-FRI-1000078228		59 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaesthetic Complication; Arrhythmia; Differential White Blood Cell Count Abnormal; Enuresis; Influenza Like Illness; Nightmare; Oxygen Saturation Decreased; Prescribed Overdose; Pyrexia; Serotonin Syndrome	Escitalopram			S	Unknown	5 Mg		Forest
	Escitalopram			S	Unknown	10 Mg		Forest
	Escitalopram			S	Unknown	20 Mg		Not Reported
	Escitalopram			S	Unknown	Overdose: 30 Mg/Day		Not Reported
	Escitalopram			S	Unknown	Overdose: 40 Mg/Day		Not Reported
	Escitalopram			S	Unknown	Overdose: 30 Mg/Day		Not Reported
	Escitalopram			S	Unknown	Overdose: 40 Mg/Day		Not Reported
	Escitalopram			S	Unknown	20 Mg		Not Reported
	Anaesthetics			S	Unknown	Succinylcholine 100 / Methohexital Sodium 90		Not Reported
	Anaesthetics			S	Unknown	Succinylcholine 100 / Methohexital Sodium 90		Not Reported
	Anaesthetics			S	Unknown	Succinylcholine 90 / Methohexital Sodium 90		Not Reported
	Anaesthetics			S	Unknown	Succinylcholine 90 / Methohexital Sodium 90		Not Reported
	Anaesthetics			S	Unknown	Succinylcholine 90 / Methohexital Sodium 90		Not Reported
	Anaesthetics			S	Unknown	Succinylcholine 90 / Methohexital Sodium 90		Not Reported

Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported
Anaesthetics	S	Unknown	Succinylcholine 90 / Methohexital Sodium 90	Not Reported

Mirtazapine	S	Unknown	15 Mg	Not Reported
Mirtazapine	S	Unknown	30 Mg	Not Reported
Mirtazapine	S	Unknown	45 Mg	Not Reported
Mirtazapine	S	Unknown	30 Mg	Not Reported
Mirtazapine	S	Unknown	15 Mg	Not Reported
Mirtazapine	S	Unknown	30 Mg	Not Reported
Mirtazapine	S	Unknown	15 Mg	Not Reported
Mirtazapine	S	Unknown	30 Mg	Not Reported
Mirtazapine	S	Unknown	45 Mg	Not Reported
Mirtazapine	S	Unknown	60 Mg	Not Reported
Beloc Zok (Metoprolol Succinate)	C	Unknown	23.75 Mg	Not Reported
Beloc Zok (Metoprolol Succinate)	C	Unknown	47.5 Mg	Not Reported
Beloc Zok (Metoprolol Succinate)	C	Unknown	23.75 Mg	Not Reported
Thyroxin	C	Unknown	150 Mcg	Not Reported
Ass	C	Unknown	100 Mg	Not Reported
Seroquel	C	Unknown	100 Mg	Not Reported
Seroquel	C	Unknown	200 Mg	Not Reported
Seroquel	C	Unknown	250 Mg	Not Reported
Seroquel	C	Unknown	300 Mg	Not Reported
Seroquel	C	Unknown	400 Mg	Not Reported
Seroquel	C	Unknown	600 Mg	Not Reported
Seroquel	C	Unknown	800 Mg	Not Reported
Seroquel	C	Unknown	400 Mg	Not Reported
Seroquel	C	Unknown	600 Mg	Not Reported
Seroquel	C	Unknown	800 Mg	Not Reported
Seroquel	C	Unknown	400 Mg	Not Reported
Seroquel	C	Unknown	600 Mg	Not Reported
Rivotril	C	Unknown	1 Mg	Not Reported

Rivotril	C	Unknown	0.5 Mg	Not Reported
Rivotril	C	Unknown	0.25 Mg	Not Reported
Rivotril	C	Unknown	0.75 Mg	Not Reported
Rivotril	C	Unknown	0.5 Mg	Not Reported
Tavor (Lorazepam)	C	Unknown	1 Mg	Not Reported
Clexane	C	Unknown	0.3 Mg	Not Reported
Clexane	C	Unknown	0.6 Mg	Not Reported
Kalinor Brause (Potassium Bicarbonate\Potassium Citrate)	C	Oral	1 Df	Not Reported
Kalinor Brause (Potassium Bicarbonate\Potassium Citrate)	C	Oral	2 Df	Not Reported
Kalinor Brause (Potassium Bicarbonate\Potassium Citrate)	C	Oral	1 Df	Not Reported
Cotrim	C	Unknown	960 Mg	Not Reported
Cotrim	C	Unknown	1920 Mg	Not Reported
Cotrim	C	Unknown	960 Mg	Not Reported
Cotrim	C	Unknown	1920 Mg	Not Reported
Sterofundin	C	Unknown	500 Ml	Not Reported
Sterofundin	C	Unknown	500 Ml	Not Reported
Sterofundin	C	Unknown	500 Ml	Not Reported
Acc Long	C	Unknown	600 Mg	Not Reported
Acc Long	C	Unknown	800 Mg	Not Reported
Paracetamol	C	Unknown	500 Mg	Not Reported
Paracetamol	C	Unknown	500 Mg	Not Reported
Cefuroxim	C	Intravenous (not otherwise specified)	1 Df	Not Reported
Cefuroxim	C	Intravenous (not otherwise specified)	0.5 Df	Not Reported
Cefuroxim	C	Unknown	500 Mg	Not Reported
Ibuprofen	C	Unknown	800 Mg	Not Reported
Ranitidin	C	Unknown	300 Mg	Not Reported
Ranitidin	C	Unknown	300 Mg	Not Reported

Ranitidin	C	Unknown	300 Mg		Not Reported
Ranitidin	C	Unknown	300 Mg		Not Reported
Ranitidin	C	Unknown	300 Mg		Not Reported
Ranitidin	C	Unknown	300 Mg		Not Reported
Ranitidin	C	Unknown	300 Mg		Not Reported
Ranitidin	C	Unknown	300 Mg		Not Reported
Aricept	C	Unknown	5 Mg		Not Reported
Ciprobay	C	Unknown	500 Mg		Not Reported
Atropin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2015	11441050	DIRECT					46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Fatigue; Feeling Abnormal; Headache; Myalgia; Withdrawal Syndrome	Lexapro 10 Mg			S		Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2015	11444748	DIRECT		DS			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Bruxism; Coordination Abnormal; Dizziness; Dizziness; Feeling Jittery; Headache; Malaise; Nausea; Somnolence; Vertigo	Escitalopram			S	Oral			Accord
	Tylenol			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2015	11316592	EXPEDITED (15-DAY)		HO, LT, OT	FR-ELI_LILLY_AND_COMP		35 YR	Female	FRA

ANY-FR201507006507

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Cardiogenic Shock; Cell Death; Coagulopathy; Hepatitis; Intentional Overdose; Renal Failure; Rhabdomyolysis	Cymbalta			S	Oral	180 Mg, Single		Eli Lilly And Co
	Paracetamol			S	Oral	64 G, Single		Not Reported
	Seroplex			S	Oral	560 Mg, Single		Not Reported
	Nocertone			S	Oral	1.8 G, Single		Not Reported
	Xanax			S	Oral	7.5 Mg, Single		Not Reported
	Selokeen			S	Oral	3 G, Single		Not Reported
	Depamine			S	Oral	4.8 G, Single		Not Reported
	Ketum			S	Oral	3 G, Single		Not Reported
	Myolastan			S	Oral	20 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2015	11389268	EXPEDITED (15-DAY)		HO, OT	TW-FRI-1000079044		38 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Interaction	Escitalopram			S	Unknown	10 Mg		Forest
	Disulfiram			S	Unknown	200 Mg		Not Reported
	Griseofulvin			S	Unknown	500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2015	11442990	EXPEDITED (15-DAY)		OT	IT-FRI-1000079188		16 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Product Use Issue	Escitalopram			S	Oral			Forest
	Aircort 200 Microgrammi/Erogazione Sospensione Pressurizzata Per			C	Respiratory (inhalation)			Not Reported

	Inal Montegen Compresse Masticabili 5 Mg/ Montelukast	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2015	11443352	EXPEDITED (15-DAY)		HO	FR-FRI-1000079238		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Speech Disorder	Escitalopram			S	Oral	10 Mg		Forest
	Exelon			S	Transdermal	4.6 Mg		Not Reported
	Prazepam			S	Oral			Not Reported
	Tamoxifene Base			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2015	11273935	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015232652		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Orthostatic Hypotension	Epinitril			S	Transdermal	5 Mg, 1x/Day		Not Reported
	Bisoce			S		5 Mg, 1x/Day		Not Reported
	Lasilix /00032601/			S	Oral	40 Mg, 1x/Day		Not Reported
	Seroplex			S		5 Mg, 1x/Day		Not Reported
	Inexium /01479303/			C		Unk		Not Reported
	Previscan /00789001/			C		20 Mg, Unk		Not Reported
	Digoxine Nativelle			C		0.25 Mg, Unk		Not Reported
	Valsartan			C		Unk		Not Reported
	Temesta /00273201/			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Levothyrox			C		100 Mg, Unk		Not Reported
	Hemigoxine Nativelle			C		0.125 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2015	11445156	EXPEDITED (15-DAY)		HO, OT	PHHY2012US121340		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Decreased Activity; Pain; Therapy Non-Responder; Unevaluable Event	Baclofen Intrathecal			S	Intrathecal	780 Mg, Qd		Not Reported
	Transderm-Scop			S	Transdermal	1.5 Mg, Prn (Pt72)		Novartis
	Robaxin			S	Unknown	2 Df, Qd		Not Reported
	Robaxin			S				Not Reported
	Robaxin			S				Not Reported
	Symbicort			S	Unknown	160 To 4.5 Mcg Per Auction		Not Reported
	Imitrex//Sumatriptan			S	Unknown	20 Mg, Per Auction		Not Reported
	Neurotin//Gabapentin			S	Unknown	400 Mg, Tid		Not Reported
	Flexeril			S	Unknown	10 Mg, Prn		Not Reported
	Vesicare			S	Unknown	5 Mg, Unk		Not Reported
	Lortab			S	Unknown	1 Df, (One Tab 3 To 4 Times Daily As Needed)		Not Reported
	Flector			S	Unknown	1.3 % For Left Knee Every 12 Hours		Not Reported
	Nasonex			S	Unknown	50 Ug, Per Auction		Not Reported
	Albuterol			S	Unknown	90 Ug, Per Auction		Not Reported
	Medrol			S	Unknown	4 Mg, Use As Directed (Pak)		Not Reported
	Lexapro			S	Unknown	Unk, 10 Mg Tabs 1.5 Tabs Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2015	11448432	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2015AP011517		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Pneumonia	Escitalopram Oxalate			S	Unknown			Apotex

Risperidone	S	Unknown			Apotex
Bupropion Hydrochloride	S	Unknown			Apotex
Valproic Acid Oral Solution Usp	S	Unknown			Apotex
Fentanyl /00174602/	S	Intravenous (not otherwise specified)	Unk		Not Reported
Fentanyl /00174602/	S	Unknown	Unk		Not Reported
Atorvastan	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2015	11451710	DIRECT		HO			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Blood Glucose Decreased; Blood Potassium Decreased; Chest Discomfort; Chest Pain; Hypertension	Escitalopram			S	Oral		9 MTH	Torrent
	Alprazolam			C				Not Reported
	Chlorzoxazone			C				Not Reported
	Levothyroxine			C				Not Reported
	Metoprolol			C				Not Reported
	Melatonin			C				Not Reported
	Ibuprofen			C				Not Reported
	Docusate Sodium			C				Not Reported
	Nasocort			C				Not Reported
	Chloropheniramine Maleate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2015	11473572	NON-EXPEDITED		RI, OT	1000078190			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Suicidal Ideation; Weight Increased	Celexa (Citalopram Hydrobromide)			S				Not Reported
	Lexapro (Escitalopram Oxalate)			S				Not Reported
	Gabapentin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	10751855	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2015018669		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug Abuse; Drug Abuse; Dyslalia; Intentional Overdose; Poisoning Deliberate; Somnolence; Suicide Attempt; Toxicity To Various Agents	Xanax			S	Oral	0.75 Mg/Ml A Bottle (20 Ml, Total)		Pfizer
	Lexotan			S	Oral	37.5 Mg, Total		Not Reported
	Cipralex			S	Oral	Unk		Not Reported
	Cipralex			S	Oral	280 Mg, Total		Not Reported
	Nurofen			S	Oral	12 Tablets, Total		Not Reported
	Enantyum			S	Oral	25 Mg Tablets, 10 Tablets, Total		Not Reported
	Sereupin			S	Oral	280 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11276918	EXPEDITED (15-DAY)			AT-FRI-1000078063		53 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vitreous Opacities	Escitalopram			S	Oral	5 Milligram		Forest
	Escitalopram			S	Oral	2.5 Milligram		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11309078	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015242297		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Hepatitis; Neutropenia; Rhabdomyolysis; Toxicity To Various Agents	Xanax			S	Oral	7.5 Mg, Single		Pfizer
	Paracetamol			S	Oral	64 G, Single		Not Reported
	Seroplex			S	Oral	560 Mg, Single		Not Reported
	Nocertone			S	Oral	1.8 G, Single		Not Reported
	Selokeen			S	Oral	300 Mg, Single		Not Reported
	Depamide			S	Oral	4.8 G, Single		Not Reported
	Ketum			S	Oral	3 G, Single		Not Reported
	Cymbalta			S	Oral	180 Mg, Single		Not Reported

	Myolastan	S	Oral	20 Df, Single	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11455176	EXPEDITED (15-DAY)		HO	ES-FRI-1000079179		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Post Procedural Haemorrhage; Procedural Haemorrhage	Escitalopram			S	Oral			Forest
	Green Tea			S	Unknown			Not Reported
	Phenylephrine			C	Unknown			Not Reported
	Atropine			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Ephedrine			C	Unknown			Not Reported
	Augmentine			C	Unknown			Not Reported
	Emconcor Cor			C	Unknown			Not Reported
	Enema Casen			C	Unknown			Not Reported
	Esmeron			C	Unknown			Not Reported
	Fentanest			C	Unknown			Not Reported
	Propofol Lipuro			C	Unknown			Not Reported
	Solu-Moderin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11526694	NON-EXPEDITED		OT	US-ELI_LILLY_AND_COMPANY-US201403005514			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Disturbance In Attention; Drug Ineffective; Dysphonia; Off Label Use; Suicidal Ideation; Tinnitus; Tremor	Cymbalta			S	Unknown	60 Mg, Unknown		Eli Lilly And Co
	Cymbalta			S	Unknown	90 Mg, Qd		Eli Lilly And Co
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Clonazepam			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11526975	NON-EXPEDITED			US-ELI_LILLY_AND_COMPANY-US201312007589			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisocial Behaviour; Cold Sweat; Decreased Appetite; Diarrhoea; Drug Withdrawal Syndrome; Fatigue; Feeling Abnormal; Nausea; Paraesthesia; Tinnitus; Urinary Retention; Vomiting	Cymbalta			S	Unknown	30 Mg, Qd		Eli Lilly And Co
	Cymbalta			S		60 Mg, Qd		Eli Lilly And Co
	Cymbalta			S				Eli Lilly And Co
	Lexapro			S				Not Reported
	Welchol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	9227349	NON-EXPEDITED	Y	RI, OT	1000026745		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Dysphagia	Lexapro			S	Oral	5 Mg (5mg, 1 In 1 D), Oral		Not Reported
	Lexapro			S	Oral	2.5mg (2.5mg, 1 In 1 D), Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	10540471	NON-EXPEDITED	Y	DS, HO, LT, RI, OT	1000069740		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Swelling	Lexapro			S				Not Reported
	Benlysta			S		850mg (850mg, 1 In 1m)		Not Reported
	Prenatal Vitamins (Mineral Nos, Vitamins Nos))			S				Not Reported
	Hydroxychloroquine			C				Not Reported
	Triamcinolone Acetonide (Triamcinolone Acetonide)			C				Not Reported
	Trazodone			C				Not Reported

Gabapentin	C		Not Reported
Furosemide	C		Not Reported
Cyanocobalamin	C		Not Reported
Fentanyl	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11460803	NON-EXPEDITED			PHEH2015US008142			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Fatigue; Headache; Hot Flush; Hypermetropia; Photophobia	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Lexapro			S	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Lamictal			C	Unknown			Not Reported
	Aciphex			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported
	Probiotic /07343501/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11473226	DIRECT					43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Product Substitution Issue	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11483860	NON-EXPEDITED	Y	RI, OT	1000069618		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Lexapro			S	Oral			Not Reported
	Gilenya (Fingolimod Hydrochloride) (0.5 Milligram, Capsules)			S	Oral Oral			Not Reported
	Vitamin D (Vitamin D) (Vitamin			C				Not Reported

	D) Ampyra (Fampridine) (Fampridine)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11483877	NON-EXPEDITED		RI, OT	1000070687		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Autophobia; Erectile Dysfunction; Feeling Abnormal; Libido Decreased; Paraesthesia; Paranoia; Suicidal Ideation; Thinking Abnormal; Tremor; Violence-Related Symptom	Lexapro			S	Oral Oral Oral			Not Reported
	Valium (Diazepam) (Diazepam)			C				Not Reported
	Zubsolv (Buprenorphine, Naloxone) (Buprenorphine, Naloxone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11483917	NON-EXPEDITED		RI, OT	1000071668			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Drug Ineffective; Irritability; Suicidal Ideation	Lexapro			S				Not Reported
	Pristiq (Desvenlafaxine Succinate)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11483953	NON-EXPEDITED	Y	RI, OT	1000072460		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Father; Miscarriage Of Partner; Pregnancy Of Partner	Lexapro			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Enalapril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11483976	NON-EXPEDITED		DE	1000073948		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro (Escitalopram Oxalate) (Tablets)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11483998	NON-EXPEDITED		RI, OT	1000074180			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11484018	NON-EXPEDITED		HO	1000075398			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism; Suicidal Ideation; Suicide Attempt	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11484036	NON-EXPEDITED		RI, OT	1000076473			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Irritability; Suicidal Ideation	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11484513	NON-EXPEDITED	Y	RI, OT	1000078670			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11484536	NON-EXPEDITED	Y	RI, OT	1000078727			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro (Escitalopram Oxalate)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11484561	NON-EXPEDITED		RI, OT	1000078816		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Depression; Drug Ineffective; Insomnia; Suicidal Ideation	Lexapro			S	Oral	10 Mg 1 In 1 D 10 Yeaars Ago		Not Reported
	Losartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2015	11465529	EXPEDITED (15-DAY)		HO	FR-UCBSA-2015027976		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Aspiration	Keppra			S	Oral	500 Mg, Once Daily (Qd)		Ucb
	Seroquel			S	Oral	150 Mg, Once Daily (Qd)		Not Reported
	Loxapac			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	10 Mg, 3x/Day (Tid)		Not Reported
	Noctamide			S	Oral	2 Mg, Once Daily (Qd) In The Evening		Not Reported
	Imovane			S	Oral	7.5 Mg, Once Daily (Qd)		Not Reported
	Laroxyl			S	Oral	50 Mg, Once Daily (Qd)		Not Reported
	Effexor			S	Oral	75 Mg, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2015	11466276	EXPEDITED (15-DAY)		HO, LT	FR-ASTRAZENECA-2015SE86252		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Pneumonia Aspiration; Respiratory Arrest	Xeroquel			S	Oral			Astrazeneca
	Xeroquel			S	Oral			Astrazeneca
	Effexor			S	Oral			Not Reported
	Laroxyl			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Loxapac			S	Oral			Not Reported
	Loxapac			S	Oral			Not Reported
	Noctamide			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2015	11235398	EXPEDITED (15-DAY)		DE, HO, OT	FR-GILEAD-2015-0160844		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Interaction; Vertigo; Vomiting	Harvoni			S	Unknown	Unk Df, Unk		Gilead
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Cordarone			S	Oral	200 Mg, Qd		Not Reported
	Bisoprolol			C	Oral	1.25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2015	11434028	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20150818250			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Zyrtec		Y	S	Oral			Not Reported
	Zyrtec			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

	Atarax	S	Oral	As Needed		Not Reported
	Nutritional Supplement	C	Unknown			Not Reported
	Sedatif Pc	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2015	11467150	EXPEDITED (15-DAY)		HO, LT	FR-AUROBINDO-AUR-APL-2015-07783		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Bedridden; Dehydration; General Physical Health Deterioration; Neutrophil Count Decreased	Escitalopram			S	Unknown			Aurobindo
	Pantoprazole Arrow			S	Oral			Aurobindo
	Tercian /00759301/			S	Oral			Not Reported
	Memantine			C	Unknown	Unk		Not Reported
	Exelon			C	Unknown			Not Reported
	Nebivolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2015	11472951	EXPEDITED (15-DAY)		OT	US-JAZZ-2013-US-003619			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthma; Depression; Enuresis; Fatigue; Feeling Jittery; Peripheral Vascular Disorder; Personality Change; Vertigo	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Topamax			S		Unknown Dose		Not Reported
	Zanaflex			S		Unknown Dose		Not Reported
	Xanax			S		Unknown Dose		Not Reported
	Roxicodone			S		Unknown Dose		Not Reported
	Wellbutrin			S		Unknown Dose		Not Reported
	Spiriva			S		Unknown Dose		Not Reported
	Lexapro			S		Unknown Dose		Not Reported
	Albuterol			S		Unknown Dose		Not Reported

	Elavil	S	Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2015	11473165	EXPEDITED (15-DAY)		OT	US-JAZZ-2014-US-012146			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataplexy	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2015	11474169	NON-EXPEDITED			US-JAZZ-2013-US-004362		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Muscular Weakness	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Unknown Dose		Jazz
	Xyrem			S	Oral	4.5 G, Total Dose		Jazz
	Xyrem			S		6 G, Total Dose		Jazz
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11457008	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-058624			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Myalgia; Pain In Extremity; Weight Increased; Wrong	Abilify			S	Unknown	2 Mg, Unk		Bristol Myers Squibb
	Abilify			S	Unknown	0.5 Df, Qd		Bristol Myers Squibb
	Abilify			S				Bristol Myers Squibb

Technique In Product Usage Process	Lexapro	S	Unknown	Unk		Not Reported
	Lexapro	S				Not Reported
	Lexapro	S				Not Reported
	Ativan	S	Unknown	Unk		Not Reported
	Ativan	S				Not Reported
	Ativan	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11476090	NON-EXPEDITED			US-JAZZ-2015-US-007057			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	5.5 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported
	Sonata			C		Unk		Not Reported
	Adderall			C		Unk		Not Reported
	Amitriptyline Hcl			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11476804	NON-EXPEDITED			US-JAZZ-2014-US-010886		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11478260	NON-EXPEDITED			US-JAZZ-2014-US-011599		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradyphrenia; Feeling Abnormal; Hot Flush; Memory Impairment; Performance Status Decreased	Xyrem	S	Oral	2.25 G, Bid		Jazz
	Xyrem	S				Jazz
	Ambien	S		Unk		Not Reported
	Lexapro	S		Unk		Not Reported
	All Other Therapeutic Products	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11479126	EXPEDITED (15-DAY)		HO	FR-SA-2015SA133621		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Inappropriate Antidiuretic Hormone Secretion	Coaprovel			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported
	Dafalgan Codeine			C				Not Reported
	Mono-Tildiem			C				Not Reported
	Fractal			C		Strength: 40mg		Not Reported
	Ganfort			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11479358	NON-EXPEDITED			US-JAZZ-2015-US-010477		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Bruxism; Hypertension; Swelling	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Norvasc			S		Unk		Not Reported
	Effexor			S		Unk		Not Reported
	Effexor			S				Not Reported
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Nuvigil			C		Unk		Not Reported

Ammonium Lactate	C	Unk	Not Reported
Ciclopirox	C	Unk	Not Reported
Fluorometholone	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Halobetasol Prop	C	Unk	Not Reported
Hydrocortisone	C	Unk	Not Reported
Kenalog	C	Unk	Not Reported
Levothyroxine	C	Unk	Not Reported
Medroxyprogesterone	C	Unk	Not Reported
Mometasone Furoate	C	Unk	Not Reported
Montelukast Sodium	C	Unk	Not Reported
Omeprazole	C	Unk	Not Reported
Premarin	C	Unk	Not Reported
Triamcinolone	C	Unk	Not Reported
Valtrex	C	Unk	Not Reported
Ventolin Hfa	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11479410	NON-EXPEDITED			US-JAZZ-2014-US-012354		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Fatigue; Feeling Abnormal; Malaise; Pain; Product Use In Unapproved Indication	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	3.75 G, Bid		Jazz
	Xyrem			S	Oral	2.75 G, Bid		Jazz
	Xyrem			S	Oral	3.75 G,First Dose		Jazz
	Xyrem			S	Oral	4.5 G, Second Dose		Jazz
	Lexapro			S				Not Reported
	Amitriptyline			S				Not Reported
	Neurontin			S				Not Reported

	Pristiq	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11482159	EXPEDITED (15-DAY)		HO	PHHY2015FR107756		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise	Exelon			S	Unknown	9.5 Mg, Qd		Novartis
	Zyprexa			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	10 Mg, Qd		Not Reported
	Coumadine			C	Unknown	Unk		Not Reported
	Tahor			C	Unknown	Unk		Not Reported
	Diffu K			C	Unknown			Not Reported
	Tareg			C	Unknown			Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Transipeg//Macrogol			C	Unknown	Unk		Not Reported
	Tardyferon			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11484940	DIRECT					72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Ineffective; Haematochezia; Product Shape Issue; Product Substitution Issue	Escitalopram			S	Oral	1 Pill		Aurobindo
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11485178	DIRECT					59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Depression; Insomnia; Panic Attack	Escitalopram 5 Mg	S	Oral	Taken By Mouth	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11486209	NON-EXPEDITED			US-JAZZ-2014-US-016810			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Product Use Issue	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S	Oral	Unk		Not Reported
	Junel			C	Oral	Unk		Not Reported
	Allegra			C		Unk		Not Reported
	Adderall			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11490313	EXPEDITED (15-DAY)		HO	FR-FRI-1000079392		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Henoch-Schonlein Purpura	Escitalopram			S	Oral	10 Mg		Forest
	Loxapac			S	Oral	400 Mg		Not Reported
	Sulfarlem S 25 Mg			S	Oral	6 Df		Not Reported
	Kardegic			C	Oral			Not Reported
	Ramipril			C				Not Reported
	Metformine			C				Not Reported
	Noctamide			C				Not Reported
	Atarax			C				Not Reported
	Crestor			C				Not Reported
	Levemir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2015	8438787	NON-EXPEDITED			US-PFIZER INC-2012049389		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ibuprofen			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Oxycodone Hydrochloride			S		Unk		Pfizer
	Morphine Sulfate			S				Pfizer
	Prednisone			S		Unk		Not Reported
	Cipro "Bayer"			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Zetia			S		Unk		Not Reported
	Percocet			S		Unk		Not Reported
	Tylox			S		Unk		Not Reported
	Reglan			S		Unk		Not Reported
	Demerol			S		Unk		Not Reported
	Darvocet-N			S		Unk		Not Reported
	Codeine			S				Not Reported
	Naproxen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2015	11383598	NON-EXPEDITED			US-PFIZER INC-2015270158			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Dry Mouth; Insomnia	Zoloft			S		Unk		Pfizer
	Sertraline Hcl			S		(25 For 5days,50,75,100 For Three Weeks)		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2015	11419481	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-102083			Unknown	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dry Mouth; Dystonia; Nausea; Tardive Dyskinesia; Vision Blurred	Etravil			S	Unknown	10 Mg, Daily		Not Reported
	Trittico			S	Unknown	25 Mg, Daily		Not Reported
	Benztropine			S	Unknown	1-2 Mg/Day		Not Reported
	Benztropine			S	Unknown	2 Mg, Daily		Not Reported
	Lexapro			S	Unknown	5 Mg, Daily		Not Reported
	Trittico			S	Unknown	25 Mg, Daily		Not Reported
	Benztropine			S	Unknown	2 Mg, Daily		Not Reported
	Benztropine			S	Unknown	2 Mg, Daily		Not Reported
	Trihexin			S	Unknown	2 Mg, Daily		Not Reported
	Perkin			S	Unknown	50/200 Mg/Day		Not Reported
	Ativan			S	Unknown	2 Mg, Daily		Not Reported
	Baclofen			C	Unknown	20 Mg, Daily		Not Reported
	Flurazepam			C	Unknown	15-30 Mg/Day		Not Reported
	Procyclidine			C	Unknown	5 Mg, Daily		Not Reported
	Clonazepam			C	Unknown	1.5 Mg, Daily		Not Reported
	Clonazepam			C	Unknown	1.5 Mg, Daily		Not Reported
	Aripiprazole			C	Unknown	0.5 Mg, Daily		Not Reported
	Aripiprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2015	11492002	EXPEDITED (15-DAY)		HO	SE-GLAXOSMITHKLINE-SE2015GSK130135			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Foetal	Voxra			S	Transplacental			Glaxosmithkline

Exposure During Pregnancy	Cipralex	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2015	11492441	EXPEDITED (15-DAY)		OT	CN-FRI-1000079534		17 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue; Tongue Paralysis; Torticollis	Lexapro			S	Oral	10 Mg		Forest
	Paliperidone			S	Oral	6 Mg		Not Reported
	Paliperidone			S	Oral	3 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2015	11334070	EXPEDITED (15-DAY)		HO	FR-FRI-1000078664		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Intentional Overdose; Neutropenia; Suicide Attempt	Escitalopram			S	Oral	Overdose 560 Mg.		Forest
	Paracetamol			S	Oral	Overdose 64 G.		Not Reported
	Nocertone			S	Oral	Overdose 1.8 G.		Not Reported
	Xanax			S	Oral	Overdose 7.5 Mg.		Not Reported
	Selokeen			S	Oral	Overdose 3 G.		Not Reported
	Depamide			S	Oral	Overdose 4.8 G.		Not Reported
	Ketum			S	Oral	Overdose 3 G.		Not Reported
	Cymbalta			S	Oral	Overdose 180 Mg.		Not Reported
	Myolastan			S	Oral	Overdose 20 Df.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2015	11495073	EXPEDITED (15-DAY)		OT	FR-009507513-1509FRA004878		52 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Januvia			S	Oral	1 Tablet Per Day		Merck

Metformin	S	Oral	2 To 3 Tablets Per Day		Not Reported
Glimepiride	S	Oral	1 Mg, Qd (1 Tablet Per Day)		Not Reported
Risperidone	S	Oral	4 Mg, Qd (1 Tablet Per Day)		Not Reported
Seroplex	S	Oral	1 Tablet Per Day		Not Reported
Depamide	C	Oral	2 Tablets (600 Mg) Per Day		Not Reported
Doliprane	C	Oral	2 Tablets (2 G) Per Day If Needed		Not Reported
Kardegic	C	Oral	1 Sachet (75 Mg) Per Day		Not Reported
Lipanthyl	C	Oral	1 Tablet (160 Mg) Per Day		Not Reported
Lormetazepam	C	Oral	1 Tablet (2 Mg) Per Day If Needed		Not Reported
Loxapac (Loxapine Succinate)	C	Oral	2 To 3 Tablets Per Day		Not Reported
Saw Palmetto	C	Oral	1 Capsule (160 Mg) Per Day		Not Reported
Tenordate	C	Oral	1 Capsule Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2015	11496239	EXPEDITED (15-DAY)			JP-FRI-1000079460		23 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Convulsions Local; Liver Function Test Abnormal; Nausea; Vomiting	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2015	11496283	EXPEDITED (15-DAY)		LT	CH-PFIZER INC-2015302804		30 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Neurontin			S	Oral	400 Mg, 4x/Day		Pfizer

Temesta Expidet	S	Oral	2.5 Mg, Unk		Pfizer
Abilify	S	Oral	10 Mg, 1x/Day		Not Reported
Cipralex	S	Oral	30 Mg, 1x/Day		Not Reported
Truxal	C	Oral	50 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2015	11497522	NON-EXPEDITED			PHEH2015US014885		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Aggression; Anger; Anxiety; Asthenia; Depression; Diplopia; Dysphemia; Fall; Feeling Abnormal; Frustration Tolerance Decreased; General Physical Health Deterioration; Headache; Hypoaesthesia; Insomnia; Limb Discomfort; Malaise; Memory Impairment; Muscle Spasms; Pain; Pain In Extremity; Relapsing-Remitting Multiple Sclerosis; Vision Blurred; Vitamin D Deficiency	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Solumedrol			S	Unknown			Not Reported
	Acthar			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Valium			S	Unknown			Not Reported
	Flomax "Boehringer Ingelheim"			S	Unknown			Not Reported
	Neurontin			C	Unknown			Not Reported
	Magnesium			C	Unknown			Not Reported
	B12-Vitamin			C	Unknown			Not Reported
	Co Q-10			C	Unknown			Not Reported
	Fish Oil			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported
	Oxycodon			C	Unknown			Not Reported
	Zanaflex			C	Unknown			Not Reported
	Gabantin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ultram /01573601/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2015	10776843	EXPEDITED (15-DAY)		HO	IT-APOTEX-2015AP006335		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychomotor Retardation; Toxicity To Various Agents	Paxil Tablets			S	Oral	280 Mg, Daily		Apotex
	Lexotan			S	Oral	15 Ml, Single		Not Reported
	Xanax			S	Oral	20 Ml, Single		Not Reported
	Cipralex /01588501/			S	Unknown	280 Mg, Single		Not Reported
	Nurofen			S	Unknown			Not Reported
	Enantyum			S		250 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2015	11500553	NON-EXPEDITED			US-PFIZER INC-2015295347			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Cleocin			S		Unk		Pfizer
	Cipra Pro			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2015	11420380	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-CA2015GSK121189			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Complaint	Paxil			S				Glaxosmithkline
	Lexapro			S				Not Reported
	Celexa			S				Not Reported
	Wellbutrin			S				Glaxosmithkline
	Prozac			S				Not Reported
	Remeron			S				Not Reported
	Pristiq			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2015	11448470	EXPEDITED (15-DAY)		HO	CN-FRI-1000079244		25 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Discomfort; Dizziness; Glassy Eyes; Head Discomfort; Intentional Self-Injury; Memory Impairment	Lexapro		S	Oral	5 Mg	Forest
	Lexapro		S	Oral	10 Mg	Forest
	Lexapro		S	Oral	5 Mg	Not Reported
	Lorazepam		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2015	11500594	NON-EXPEDITED			US-PFIZER INC-2015306330		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Pristiq			S		50 Mg, Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2015	11507513	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2015305913		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Extrasystoles	Cordarone			S	Oral	1 Df, Daily		Pfizer
	Seroplex			S	Oral	1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2015	11509231	EXPEDITED (15-DAY)		HO	FR-FRI-1000079454		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Aspiration; Prescribed Overdose	Escitalopram			S	Oral	30 Mg		Forest
	Xeroquel			S	Oral			Not Reported
	Loxapac			S	Oral			Not Reported
	Laroxyl			S	Oral	50 Mg		Not Reported
	Noctamide			S	Oral	2 Mg		Not Reported
	Keppra			S	Oral	500 Mg		Not Reported

	Imovane		S	Oral	7.5 Mg	Not Reported
	Effexor		S	Oral	150 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2015	11510036	NON-EXPEDITED			US-JNJFOC-20150811632		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anxiety; Crying; General Physical Health Deterioration; Mania; Product Dose Omission; Tearfulness	Invega			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2015	11510828	EXPEDITED (15-DAY)		HO, LT, OT	CA-JNJFOC-20150905060		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Body Temperature Increased; Diarrhoea; Flushing; Hallucination, Auditory; Hallucination, Visual; Insomnia; Rash; Serotonin Syndrome	Concerta			S	Oral			Not Reported
	Atasol (Acetaminophen)			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Meperidine			S	Oral			Not Reported
	Morphine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Diprosone			C	Unknown			Not Reported
	Docusate Sodium			C	Unknown			Not Reported
	Glucagon			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Metformin			C	Unknown			Not Reported
	Phisohex (Hexachlorophene)			C	Unknown			Not Reported
	Proctodan-Hc			C	Rectal			Not Reported
	Hydrocortisone			C	Unknown			Not Reported

	Ramipril	C	Unknown	Not Reported
	Simvastatin	C	Unknown	Not Reported
	Tecta	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2015	11443210	EXPEDITED (15-DAY)		HO, OT	FR-APOTEX-2015AP012437		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Paxil Tablets			S	Unknown			Apotex
	Paxil Tablets			S	Unknown	40 Mg, Qd		Apotex
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported
	Risperidone			S	Unknown	2 Mg, Qd		Not Reported
	Risperidone			S				Not Reported
	Venlafaxine			S	Unknown	225 Mg, Qd		Not Reported
	Venlafaxine			S				Not Reported
	Sertraline			S	Unknown	Unk		Not Reported
	Sertraline			S				Not Reported
	Diazepam			S	Unknown	20 Mg, Qd		Not Reported
	Diazepam			S				Not Reported
	Quetiapine			S	Unknown	100 Mg, Qd		Not Reported
	Quetiapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2015	11514457	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2015AP012609		37 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Hypersensitivity	Apo-Escitalopram			S	Unknown	10 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2015	11515395	EXPEDITED (15-DAY)		DS	CA-FRI-1000079544		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Lethargy; Sedation	Escitalopram			S	Oral	5 Mg		Forest
	Magnesium Citrate			C	Unknown	Daily Dose Not Reported		Not Reported
	Riboflavin			C	Unknown	Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2015	11515476	EXPEDITED (15-DAY)		HO	CH-FRI-1000079448			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Muscle Twitching; Prescribed Overdose	Escitalopram			S	Unknown	Overdose: 30 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2015	11516972	DIRECT					37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Aphasia; Cerebral Disorder; Memory Impairment; Weight Increased	Lexapro 10 Mg			S	Oral			Not Reported
	Beyaz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11288199	EXPEDITED (15-DAY)		HO	CH-TEVA-579477ISR		37 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Hemiparesis; Speech Disorder	Irfen			S	Oral	As Required, For Several Weeks, Sometimes Taken Up To 4 X/Day		Ivax
	Cipralex			S	Oral	20 Milligram Daily;		Not Reported
	Risperdal			C	Oral	2 Milligram Daily; Taken For Months		Not Reported
	Xanax			C	Oral	Long Term, 6 Mg In The		Not Reported

Morning, 6 Mg At Midday, 6 Mg In The Evening

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11518623	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMPANY-FR201509001096		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Areflexia; Bradycardia; Disorientation; Dyskinesia; Electrocardiogram Qrs Complex Shortened; Loss Of Consciousness; Malaise; Tremor; Urinary Incontinence; Ventricular Extrasystoles	Zyprexa			S	Unknown	Unk, Unknown		Unknown
	Exelon			S	Unknown	9.5 Mg, Qd		Not Reported
	Seroplex			S	Unknown	10 Mg, Qd		Not Reported
	Coumadine			C	Unknown	Unk, Unknown		Not Reported
	Tahor			C	Unknown	Unk, Unknown		Not Reported
	Diffu K			C	Unknown	Unk, Unknown		Not Reported
	Tareg			C	Unknown	Unk, Unknown		Not Reported
	Lantus			C	Unknown	Unk, Unknown		Not Reported
	Transipeg /00754501/			C	Unknown	Unk, Unknown		Not Reported
	Tardyferon			C	Unknown	Unk, Unknown		Not Reported
	Paracetamol			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11518794	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2015M1031038			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Laryngeal Haemorrhage; Overdose; Self-Medication	Warfarin			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11518820	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000079642		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Shock	Escitalopram	S	Unknown	Forest
	Esmeron	S	Unknown	Not Reported
	Diprivan	S	Unknown	Not Reported
	Sufentanil	S	Unknown	Not Reported
	Hypnovel	S	Unknown	Not Reported
	Atenolol	S	Unknown	Not Reported
	Inexium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11519209	EXPEDITED (15-DAY)		OT	IT-FRI-1000079476		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Presyncope	Escitalopram			S	Oral	10 Gtt		Forest
	Olanzapina Zentiva			S	Oral	5 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11519210	EXPEDITED (15-DAY)		OT	FR-FRI-1000079563		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Extrasystoles	Escitalopram			S	Oral	10 Mg		Forest
	Cordarone			S	Oral	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11519924	DIRECT		CA, DE			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Foetal Growth Restriction; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy	Escitalopram			S	Oral			Not Reported
	Prenatal Vitamins			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11520768	DIRECT		OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Product Quality Issue	Escitalopram 20mg Torrent			S	Oral	1 Qd Oral		Torrent
	Bactrim Ds (Generic) 800mg Rx#6564016			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2015	10743587	EXPEDITED (15-DAY)		LT, OT	JP-TAKEDA-2015TJP000989AA		68 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Tachycardia	Takepron Od Tablets 15			S	Oral	15 Mg, Qd		Takeda
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Toledomin			C	Oral	15 Mg, Qd		Not Reported
	Maglax			C	Oral	330 Mg, Tid		Not Reported
	Singulair			C	Oral	10 Mg, Qd		Not Reported
	Predonine /00016201/			C	Oral	20 Mg, Qd		Not Reported
	Mucodyne			C	Oral	250 Mg, Tid		Not Reported
	Foipan			C	Oral	200 Mg, Tid		Not Reported
	Baktar			C	Oral	1 Df, Qd		Not Reported
	Jzoloft			C	Oral	25 Mg, Qd		Not Reported
	Paxil /00830802/			C		10 Mg, Qd		Not Reported
	Paxil /00830802/			C	Oral	20 Mg, Qd		Not Reported
	Paxil /00830802/			C	Oral	30 Mg, Qd		Not Reported
	Paxil /00830802/			C	Oral	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2015	10746990	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL, INC-2015SCPR009917		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Clonazepam			S	Oral	Unk, Unknown		Par
	Lamotrigine			S	Oral	Unk, Unknown		Par
	Cardiac Glycosides			S	Oral	Unk, Unknown		Not Reported
	Trazodone			S	Oral	Unk, Unknown		Not Reported
	Oxybutynin			S	Oral	Unk, Unknown		Not Reported
	Quetiapine			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Finasteride			S	Oral	Unk, Unknown		Not Reported
	Salicylates Nos			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2015	11247268	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC-2015225889		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Dizziness; Drug Interaction; Sinus Bradycardia; Vomiting	Cordarone			S	Oral	1 Df, Daily		Pfizer
	Seroplex			S	Oral	5 Mg, Daily		Not Reported
	Harvoni			S	Unknown	Unk		Not Reported
	Bisoprolol			S		1.25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2015	11519421	EXPEDITED (15-DAY)		HO	FR-ROCHE-1635621		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Somnolence	Valium			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Speciafoldine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2015	11521426	NON-EXPEDITED			US-ROCHE-729199		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Asthenia; Depression; Feeling Abnormal; Headache; Nausea; Pain; Platelet Count Decreased; Pyrexia; Toxicity To Various Agents; Viral Load Increased; Weight Decreased	Pegasys			S	Subcutaneous			Not Reported
	Copegus			S	Oral			Not Reported
	Copegus			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Phenergan			C	Unknown			Not Reported
	Hctz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2015	11522469	EXPEDITED (15-DAY)		HO	FR-FRI-1000079580		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2015	11523168	NON-EXPEDITED			US-MEDA-2014110053		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Hypercholesterolaemia; Oropharyngeal Pain; Type 2 Diabetes Mellitus; Visual Impairment	Demadex			S				Meda
	Lyrica			S				Not Reported
	Tizanidine			S				Not Reported
	Tizanidine			S				Not Reported
	Oxycodone Apap 10/325 Mg			S		10/325 Mg		Not Reported
	Seroquel			S		50 Mg In The Morning And Noon		Not Reported
	Seroquel			S		200 Mg At Night		Not Reported
	Seroquel			S		50 Mg In The Morning And Noon		Not Reported
	Seroquel			S		200 Mg At Night		Not Reported
	Metformin			S				Not Reported

	Effexor	S	75 Mg + 150 Mg Together	Not Reported
	Lexapro	S		Not Reported
	Valium	S		Not Reported
	Aspirin	S		Not Reported
	Simvastatin	S		Not Reported
	Topamax	S		Not Reported
	Ibuprofen	S	800 Mg In The Morning	Not Reported
	Ibuprofen	S		Not Reported
	Fentanyl Patch	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2015	11523486	NON-EXPEDITED			US-ROCHE-713835		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Dizziness; Nausea; Procedural Complication; Rash	Pegasys			S	Subcutaneous	Form: Pre-Filled Syringe		Not Reported
	Ribavirin			S	Oral	Taken In Divided Doses		Not Reported
	Ribavirin			S	Oral	Dosage Decreased		Not Reported
	Ribavirin			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2015	11525687	EXPEDITED (15-DAY)		DE, OT	CH-CIPLA LTD.-2015CH07453			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Sudden Death	Zidovudine			S	Unknown	600 Mg, Unk		Cipla
	Lamivudine			S	Unknown	300 Mg, Unk		Cipla
	Methadone			S	Unknown			Not Reported
	Escitalopram			S	Unknown	30 Mg, Unk		Not Reported
	Atazanavir			S	Unknown	400 Mg, Unk		Not Reported
	Levomepromazine			S	Unknown	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2015	10915678	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2015-02198		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Abuse; Oxygen Saturation Decreased	Escitalopram			S	Oral	400 Mg Total, Unk		Aurobindo
	Cardioaspirin			C	Unknown	Unk		Not Reported
	En			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2015	11526230	EXPEDITED (15-DAY)		OT	CH-CIPLA LTD.-2015CH07445			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Torsade De Pointes	Zidovudine			S	Unknown	600 Mg, Unk		Cipla
	Ritonavir			S	Unknown	200 Mg, Unk		Cipla
	Lamivudine			S	Unknown	300 Mg, Unk		Cipla
	Atazanavir			S	Unknown	400 Mg, Unk		Not Reported
	Methadone			S	Unknown	80 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	30 Mg, Unk		Not Reported
	Fluoxetine			S	Unknown	20 Mg, Unk		Not Reported
	Zuclopenthixol			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2015	11082134	EXPEDITED (15-DAY)		HO	PHHY2015FR049879		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemarthrosis; International Normalised Ratio Increased	Sintrom			S	Oral	(According To Inr)		Not Reported
	Ibuprofen			S	Oral	Unk		Novartis
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Acenocoumarol			C	Unknown	Unk Unk, Prn (According		Not Reported

				To Inr)	
	Acenocoumarol	C	Unknown	3 Mg, Qd (In Evening)	Not Reported
	Acenocoumarol	C	Unknown	0.5 Df For 3 Days, Unk	Not Reported
	Acenocoumarol	C	Unknown	0.75 Df On 4th Day, Unk	Not Reported
	Potassium Chloride	C	Unknown	2 Df, Bid	Not Reported
	Furosemide	C	Unknown	40 Mg, Qd	Not Reported
	Amlodipine	C	Unknown	10 Mg, Qd	Not Reported
	Perindopril Tert-Butylamine	C	Unknown	4 Mg, Qd	Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)	C	Unknown	4 Daily	Not Reported
	Paracetamol	C	Unknown	500 Mg, Bid	Not Reported
	Zolpidem	C	Unknown	10 Mg, Qd	Not Reported
	Cholecalciferol	C	Unknown	1 Df, Unk	Not Reported
	Magne B6	C	Unknown	Unk Unk, Qd	Not Reported
	Alprazolam	C	Unknown	1.5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2015	11311713	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20150709120		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Melaena; Multiple Organ Dysfunction Syndrome; Toxicity To Various Agents	Risperdal			S	Oral			Not Reported
	Propranolol			S	Oral	1-0-0		Not Reported
	Temesta (Lorazepam)			S	Oral	1-1-1		Not Reported
	Atarax			S	Oral			Not Reported
	Seroplex			S	Oral	0-0-1		Not Reported
	Mogadon			C	Unknown	1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2015	11530621	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015GSK129374			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Wellbutrin Xl Tablet			S				Glaxosmithkline
	Lexapro			S				Not Reported
	Celexa			S				Not Reported
	Wellbutrin			S				Glaxosmithkline
	Cymbalta			S				Not Reported
	Paxil			S				Not Reported
	Prozac			S				Not Reported
	Remeron			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2015	11532944	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2013-000029		< 1 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby	Abilify			S	Transplacental	10 Mg, Qd		Bristol Myers Squibb
	Cipralex /01588501/			S	Transplacental	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2015	11533101	EXPEDITED (15-DAY)		HO	IT-BAYER-2015-422486		66 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amylase Increased; Lipase Increased	Cardioaspirin			S	Oral	100 Mg, Unk		Bayer
	Metformin Hydrochloride			S	Oral	3 Mg, Unk		Not Reported
	Entact			S	Oral	10 Mg, Unk		Not Reported
	Pramipexole			C	Oral			Not Reported
	Deursil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2015	11533117	NON-EXPEDITED			PHEH2015US017619			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Erythema; Pruritus; Skin Reaction	Exelon Patch	S	Unknown	Unk	Novartis
	Exelon Patch	S	Unknown	9.5 Mg/24hours (Patch 10 Cm2, 18 Mg Daily Rivastigmine Base)	Novartis
	Exelon Patch	S	Unknown	4.6 Mg(Patch 5 Cm2, 09 Mg Daily Rivastigmine Base) For 2 Days	Novartis
	Lexapro	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2015	11535410	DIRECT		OT			4 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; General Physical Health Deterioration; Reaction To Excipient	Lexipro 20 Mg Aurobindo/Teva			S	Oral		6 YR	Aurobindo
	Buspirone 5 Mg Teva			S	Oral			Teva
	Atenolol			C				Not Reported
	Klonopin			C				Not Reported
	Multiple Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2015	11536909	DIRECT		OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Escitalopram			S		Taken By Mouth		Not Reported
	Pramipexole			S		At Bedtime, Taken By Mouth		Walmart
	Tramadol			C				Not Reported
	Loestrin			C				Not Reported
	Iron			C				Not Reported
	Multivitamin			C				Not Reported
	Vit. B Complex			C				Not Reported
	Motrin			C				Not Reported
	Tylenol			C				Not Reported
	Generic Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11325297	EXPEDITED (15-DAY)		HO	CH-FRI-1000078635		37 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Hemiparesis	Escitalopram			S	Oral	20 Mg		Forest
	Irfen			S	Oral	As Needed: Treatment In Reserve Since Several Weeks, Taken Sometimes Up To 4x/Day		Not Reported
	Risperdal			C	Oral	2 Mg		Not Reported
	Xanax			C	Oral	3x/Day: 6 Mg In The Morning, 6 Mg Midday, 9 Mg In The Evening.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11533775	EXPEDITED (15-DAY)		CA, DE, OT	PHHY2015GB110755		2 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia	Citalopram			S	Transplacental	20 Mg, 1x/Day		Novartis
	Escitalopram			S	Transplacental	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11534297	EXPEDITED (15-DAY)		HO, LT, OT	FR-ALVOGEN-2015AL003689		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Hilar Lymphadenopathy; Lung Disorder; Lymphadenopathy Mediastinal	Atenolol			S				Not Reported
	Esmeron			S				Not Reported
	Diprivan			S	Intravenous (not otherwise specified)			Not Reported
	Sufentanil			S				Not Reported
	Midazolam Hydrochloride			S				Not Reported
	Seroplex			S				Not Reported
	Esomeprazole Magnesium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11535401	EXPEDITED (15-DAY)		CA, DE, OT	GB-TEVA-593542ACC			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia	Citalopram			S	Transplacental	20 Milligram Daily; 20 Mg, 1x/Day		Pliva
	Escitalopram Oxalate			S	Transplacental	20 Milligram Daily; 20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11537141	EXPEDITED (15-DAY)		OT	PHHY2015AT112208			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Gabapentin			S	Unknown	300 Mg, Unk		Novartis
	Gabapentin			S				Novartis
	Tramadol			S	Unknown	450 Mg, Unk		Not Reported
	Tramadol			S	Unknown	20-60 Ggt/Day		Not Reported
	Hydromorphone			S	Unknown	18 Mg, Bid		Not Reported
	Hydromorphone			S				Not Reported
	Naproxen			S	Unknown	500 Mg, Bid		Not Reported
	Cipralex			S	Unknown	15 Mg, Qd		Not Reported
	Cipralex			S				Not Reported
	Midazolam			C	Unknown	2 Df, Unk		Not Reported
	Midazolam			C				Not Reported
	Mirtazapine			C	Unknown	15 Mg, Unk		Not Reported
	Spironolacton			C	Unknown			Not Reported
	Doxazosin			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Levothyroxin			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11537655	NON-EXPEDITED			US-ELI_LILLY_AND_COMPANY-US201509006738		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Screaming	Prozac			S	Unknown	Unk		Eli Lilly And Co
	Xanax			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	8049653	EXPEDITED (15-DAY)		CA, DE, OT	GB-ARROW GEN-2011-10568			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia; Foetal Exposure During Pregnancy	Citalopram			S	Transplacental	20 Mg, Daily		Watson
	Escitalopram (Unknown)			S	Transplacental	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11266398	EXPEDITED (15-DAY)		DE	FR-FRI-1000078060		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Dizziness; Drug Interaction; Vomiting	Escitalopram			S	Oral	1 Df		Forest
	Harvoni			S				Not Reported
	Cordarone			S	Oral	1 Df		Not Reported
	Bisoprolol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11325311	EXPEDITED (15-DAY)		HO	FR-FRI-1000078484		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Multiple Organ Dysfunction Syndrome; Overdose; Toxicity To Various Agents	Escitalopram	S	Oral	15 Mg	Forest
	Escitalopram	S	Oral	Overdose: Dose Unknown.	Forest
	Propranolol	S	Oral	40 Mg	Not Reported
	Propranolol	S	Oral	Overdose: Dose Unknown.	Not Reported
	Temesta (Lorazepam)	S	Oral	7.5 Mg	Not Reported
	Temesta (Lorazepam)	S	Oral	Overdose: Dose Unknown.	Not Reported
	Atarax	S	Oral		Not Reported
	Atarax	S	Oral	Overdose: Dose Unknown.	Not Reported
	Risperdal	S	Oral		Not Reported
	Risperdal	S	Oral	Overdose: Dose Unknown.	Not Reported
	Mogadon	C	Unknown	1 Dosage Form	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11449057	EXPEDITED (15-DAY)			DE-FRI-1000079315		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Blood Thyroid Stimulating Hormone Increased; Diarrhoea; Dizziness; Drug Interaction; Dysstasia; Fatigue; Gait Disturbance; Nausea; Tremor	Escitalopram			S	Unknown	5 Milligram		Forest
	Escitalopram			S	Unknown	5 Milligram		Forest
	Euthyrox			S	Unknown	50 Microgram		Not Reported
	Euthyrox			S	Unknown	25 Microgram		Not Reported
	Metoprolol			C	Oral	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11538773	EXPEDITED (15-DAY)		CA, DE, OT	GB-CIPLA LTD.-2015GB07526			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia	Citalopram			S	Transplacental	20 Mg, Qd		Cipla
	Escitalopram Oxalate			S	Transplacental	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11539169	EXPEDITED (15-DAY)		OT	US-ACCORD-033930		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne Cystic; Aggression; Crying; Depression; Fear; Hypokinesia; Panic Attack; Restlessness; Suicidal Ideation	Escitalopram Accord			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11540033	EXPEDITED (15-DAY)		LT	FR-FRI-1000079640		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke; Overdose	Escitalopram			S	Unknown	20 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Tahor			C	Unknown			Not Reported
	Azantac			C	Unknown			Not Reported
	Bi-Tildiem			C	Unknown	180 Mg		Not Reported
	Zestril			C	Unknown			Not Reported
	Lioresal			C	Unknown			Not Reported
	Keppra			C	Unknown	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11541221	NON-EXPEDITED			US-APOTEX-2015AP005186		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Treatment Failure; Vomiting	Paroxetine Hydrochloride			S	Unknown	10 Mg, Daily		Apotex
	Sertraline Hydrochloride			S	Unknown	10 Mg, Daily		Apotex
	Mirtazapine			S	Unknown	22.5 Mg, Daily		Apotex
	Citalopram			S	Unknown			Apotex

Venlafaxine	S	Unknown	At Low Dose		Not Reported
Escitalopram Oxalate	S	Unknown	2.5 Mg, Daily		Apotex
Doxepin	S	Unknown			Not Reported
Fluoxetine /00724402/	C	Unknown	10 Mg, Daily		Not Reported
Diazepam	C	Unknown	0.5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11544411	DIRECT					72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Depression; Mood Swings; Product Substitution Issue	Escitalopram			S	Oral	1 Pill		Torrent
	Clopidogrel			C				Not Reported
	Microzide			C				Not Reported
	Atorvastatin			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Vitamin C			C				Not Reported
	Beta Prostate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11213840	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2015SE60505		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Inexium			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Kardegic			C	Oral			Not Reported
	Seresta			C	Oral			Not Reported
	Sinemet			C	Oral			Not Reported
	Tahor			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Tardyferon			C	Oral			Not Reported
	Uvedose			C	Oral			Not Reported

	Doliprane	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11397335	EXPEDITED (15-DAY)		OT	DE-ABBVIE-15P-062-1445305-00		77 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hernia; Hyperkinesia	Duodopa			S	Other	Md 5.0 Ml, Crd 2.3 Ml/Hr, Ed 1.0 Ml		Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11544256	EXPEDITED (15-DAY)		HO	IT-ACCORD-033792		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Abuse; Oxygen Saturation Decreased	Escitalopram			S	Oral			Accord
	Cardioaspirin			C				Not Reported
	En			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11544586	EXPEDITED (15-DAY)		HO	CH-FRI-1000079584		83 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastric Ulcer; Melaena; Upper Gastrointestinal Haemorrhage	Escitalopram			S	Oral	15 Mg		Forest
	Voltaren Retard			S	Oral	100 Mg		Not Reported
	Aspirin Cardio			S	Oral	100 Mg		Not Reported
	Pantozol			C	Unknown	20 Mg		Not Reported
	Aricept			C	Unknown			Not Reported
	Haldol			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Remeron			C	Unknown			Not Reported
	Seroquel			C	Unknown			Not Reported

	Dafalgan	C	Unknown	Not Reported
	Oxycontin	C	Unknown	Not Reported
	Pradif Retard	C	Unknown	Not Reported
	Torem	C	Unknown	Not Reported
	Vi De3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11544771	EXPEDITED (15-DAY)		OT	US-FRI-1000079618			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11545198	NON-EXPEDITED			US-TAKEDA-2015TUS012847		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Diarrhoea; Headache; Labelled Drug-Drug Interaction Medication Error; Nausea; Vomiting	Contrave			S	Oral	8mg/90mg, Qd		Takeda
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Pantoprazole			C	Oral	40 Mg, Unk		Not Reported
	Singulair			C	Oral	10 Mg, Unk		Not Reported
	Simvastatin			C	Oral	20 Mg, Unk		Not Reported
	Fluticasone W/Salmeterol			C	Other	Unk		Not Reported
	Lisinopril/Hctz			C	Oral	Unk		Not Reported
	Metformin			C	Oral	1000 Mg, Unk		Not Reported
	Liraglutide			C	Subcutaneous	1.2 Mg, Unk		Not Reported
	Amaryl			C	Oral	2 Mg, Unk		Not Reported
	Albuterol /00139501/			C	Other	Unk		Not Reported
	Mvi /07504101/			C	Oral	Unk		Not Reported
	B12 /00056201/			C	Oral	Unk		Not Reported
	Vitamin D3			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11547203	EXPEDITED (15-DAY)		CA, DE, OT	GB-MYLANLABS-2015M1031304			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pulmonary Valve Atresia; Foetal Exposure During Pregnancy	Citalopram			S	Transplacental	20 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S	Transplacental	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11548647	EXPEDITED (15-DAY)		DE, HO	CH-FRI-1000079686		87 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Delirium; International Normalised Ratio Increased; Subdural Haematoma	Escitalopram			S	Oral	Half A Tablet Taken In The Mornings		Forest
	Marcoumar			S	Oral			Not Reported
	Mirtazapin			C	Oral	1 Dosage Form		Not Reported
	Pantoprazol			C	Unknown			Not Reported
	Amlodipin			C	Unknown			Not Reported
	Bilol			C	Unknown			Not Reported
	Eltroxin			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Novalgine (Metamizole Sodium)			C	Unknown			Not Reported
	Dipiperon			C	Unknown			Not Reported
	Torem			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported
	Haldol			C	Unknown			Not Reported
	Vi De3			C	Unknown			Not Reported
	Fentanyl			C	Unknown	25mg Patch, A New Patch Applied Every 72 Hours		Not Reported
	Candesartan			C	Unknown			Not Reported

	Solmucalm			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	9924619	NON-EXPEDITED			US-PFIZER INC-2014053762		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Chantix			S		Unk		Pfizer
	Pristiq			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Penicillin Vk			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11553207	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2015SE91859		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Blood Pressure Decreased; Face Injury; Fall; Hepatic Cirrhosis; Hyponatraemia; Limb Injury	Inexium			S	Oral			Astrazeneca
	Inexium			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11567639	EXPEDITED (15-DAY)	Y	OT	2015HINLIT0690		70 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Dizziness; Hypotension; Presyncope; Sinus Bradycardia	Escitalopram (Escitalopram) Unknown			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2015	10933796	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1007993			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Labelled Drug-Drug Interaction Medication Error	Escitalopram Mylan Pharma			S		20 Mg Daily		Mylan
	Anafranil			S	Oral	112.5 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2015	11521908	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2015311876		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Hilar Lymphadenopathy; Lung Disorder; Lymphadenopathy Mediastinal	Atenolol			S		Unk		Pfizer
	Diprivan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Esmeron			S		Unk		Not Reported
	Sufentanil			S		Unk		Not Reported
	Hypnovel			S		Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Inexium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2015	11558620	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2015-05280		66 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Withdrawal Syndrome; Hallucination, Visual	Escitalopram			S	Oral	7 Gtt, Daily		Aurobindo
	Escitalopram			S	Oral	7 Gtt Daily		Aurobindo
	Mirtazapine Aurobindo Pharma Italia 30mg Film-Coated Tablets			S	Oral	30 Mg, Daily		Aurobindo
	Control /00273201/			S	Oral	1 Df Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2015	11559736	EXPEDITED (15-DAY)		OT	PHHY2015US113970		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Orthostatic Hypotension	Clopidogrel			S	Unknown	75 Mg, Qod		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Memantine Hydrochloride			S	Unknown	10 Mg, Qd		Not Reported
	Acetylsalicylic Acid		Y	S	Unknown	81 Mg, Qd		Novartis
	Seroquel			S	Unknown	75 Mg, Qod		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2015	11561275	EXPEDITED (15-DAY)		DS	LT-JNJFOC-20150913521		21 YR	Male	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Gynaecomastia; Neuropathy Peripheral; Product Use In Unapproved Indication; Sexual Dysfunction; Weight Increased	Rispolet			S	Oral			Not Reported
	Parkopan			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2015	11555478	EXPEDITED (15-DAY)		HO, LT	CH-ASTRAZENECA-2015SE91810		32 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Colitis; Disseminated Intravascular Coagulation; Hepatic Necrosis; Jaundice; Klebsiella Sepsis	Quetiapine			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Euthyrox			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2015	11568109	EXPEDITED (15-DAY)		HO, LT, OT	CH-ELI_LILLY_AND_COMPANY-CH201509008422			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Ascites; Benign Hepatic Neoplasm; Colitis; Disseminated Intravascular Coagulation; Gastrointestinal Oedema; Hepatic Necrosis; Jaundice; Klebsiella Sepsis; Pleural Effusion	Zyprexa			S	Oral	2.5 Mg, Qd		Eli Lilly And Co
	Quetiapin			S	Oral	50 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Oral	10 Mg, Qd		Not Reported
	Euthyrox			C	Oral	50 Ug, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2015	11568944	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2015AP013094		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Piperacillin & Tazobactam			S	Unknown	Unk		Hospira
	Apo-Ciproflox			S	Oral	1000 Mg, Unk		Apotex
	Apo-Ciproflox			S	Intravenous (not otherwise specified)	One Every Three Weeks		Apotex
	Avastin /00848101/			S	Intravenous (not otherwise specified)	15 Mg/Kg, One Every Three Weeks		Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)	One Every Three Weeks		Not Reported
	Cipralex /01588501/			S	Unknown	10 Mg, Qd		Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)	75 Mg/M2, Unk		Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)	75 Mg/Kg, One Every Three Weeks		Not Reported
	Morphine			S	Unknown	2.5 Mg, Q.4h.		Not Reported
	Trastuzumab			S	Intravenous (not	8 Mg/Kg, One Every Three		Not Reported

			otherwise specified)	Weeks	
	Tylenol /00020001/	S	Unknown	Unk	Not Reported
	Tylenol No.1	S	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Docusate	C	Unknown	Unk	Not Reported
	Gravol	C	Unknown	Unk	Not Reported
	Lactulose	C	Oral	Unk	Not Reported
	Senna /00142201/	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2015	11569144	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2015316594		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Product Prescribing Error	Triflucan			S	Buccal	200 Mg, 3x/Day		Pfizer
	Atarax /00058401/			S	Oral	25 Mg, 2x/Day As Needed		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Primperan			S	Oral	10 Mg, 3x/Day As Needed		Not Reported
	Eupantol			C	Oral	40 Mg, 2x/Day		Not Reported
	Creon			C	Oral	75000 Iu, 3x/Day		Not Reported
	Allopurinol			C	Oral	100 Mg, Alternate Day		Not Reported
	Carbosylane /00814601/			C	Oral	1 Df, 3x/Day		Not Reported
	Amlodipine			C	Oral	5 Mg, 1x/Day		Not Reported
	Spasfon /00765801/			C	Oral	2 Df, 3x/Day		Not Reported
	Oxycontin Lp			C	Oral	10 Mg, 2x/Day		Not Reported
	Oxynorm			C	Oral	5 Mg, 6x/Day As Needed		Not Reported
	Smecta /07327601/			C	Oral	1 Df, 3x/Day As Needed		Not Reported
	Imodium Enfants			C	Oral	2 Mg, 3x/Day As Needed		Not Reported
	Doliprane			C	Oral	1 G, 3x/Day		Not Reported

	Augmentin /00756801/	C	Intravenous (not otherwise specified)	1 G, Single	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2015	11570189	EXPEDITED (15-DAY)		HO	FR-FRI-1000079788		99 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyphaema	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Zolpidem			C	Unknown			Not Reported
	Tahor			C	Unknown			Not Reported
	Macrogol			C	Unknown			Not Reported
	Heptamyl			C	Unknown			Not Reported
	Educyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	8771784	EXPEDITED (15-DAY)		OT	DE-ROCHE-611106			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Neoplasm; Drug Abuse; Glioblastoma; Intentional Self-Injury; Jaundice; Major Depression; Mania; Renal Failure; Retinopathy	Peg-Interferon Alfa 2a			S	Subcutaneous			Not Reported
	Ribavirin			S	Oral	Tdd: 800 Mg To 1200 Mg		Not Reported
	Blinded Escitalopram			S	Unknown	Started 2 Weeks Prior To Hepatitis C Therapy		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	10828641	EXPEDITED (15-DAY)		HO	US-ROCHE-1539040		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

Tramadol	S	Oral	As Needed		Not Reported
Risperidone	S	Oral			Not Reported
Simvastatin	S	Oral			Not Reported
Blinded Bococizumab	S	Subcutaneous			Not Reported
Ambien	C				Not Reported
Proair Hfa	C				Not Reported
Vitamin D2	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	11575184	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-103831			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Seizure; Therapeutic	Escitalopram			S	Transmammary	Unk, Daily For Several Months		Not Reported
Agent Urine Positive; Vomiting	Bupropion			S	Transmammary	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	11575707	NON-EXPEDITED			US-TORRENT-00000947		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram Oxalate-Escitalopram Oxalate Tablet			S		Twice A Day		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	11575710	NON-EXPEDITED			US-TORRENT-00000956			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Product Substitution Issue	Escitalopram Oxalate-Escitalopram Oxalate Tablet			S				Torrent
	Allegra			C				Unknown
	Zegerid			C				Bayer
	Vitamin D Nos			C				Unknown

	Melatonin				C					Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	11575727	NON-EXPEDITED			US-TORRENT-00000962			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Product Substitution Issue; Withdrawal Syndrome	Escitalopram Oxalate-Escitalopram Oxalate Tablet			S				Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	11576978	EXPEDITED (15-DAY)		DS, OT	NO-FRI-1000079838		25 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Withdrawal Syndrome; Headache; Hypoacusis; Nausea; Panic Attack; Paraesthesia; Tinnitus; Visual Impairment; Vomiting	Escitalopram			S	Unknown	10 Mg		Forest
	Escitalopram			S	Unknown	5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	11578211	EXPEDITED (15-DAY)		OT	IT-FRI-1000079779		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Paraesthesia; Vertigo; Withdrawal Syndrome	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Forest
	Lorazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	11583253	DIRECT		OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Memory Impairment; Product Quality Issue	Escitalopram 10 Mg Teva	S	Oral	1 Pill		Teva
	Water Pill	C				Not Reported
	High Blood Pressure Pill	C				Not Reported
	Diabetes Pill	C				Not Reported
	Iron	C				Not Reported
	Vitamin D Nos	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11581793	NON-EXPEDITED			US-ROCHE-679322		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Decreased Appetite; Dyspepsia; Dyspnoea; Haemoptysis	Pegasys			S	Unknown	Form: Pfs		Not Reported
	Ribavirin			S	Unknown	Divided Doses		Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11582578	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2015-02429		43 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Restless Legs Syndrome	Fluoxetine			S	Unknown	20 Mg		Not Reported
	Citalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Gabapentin			C	Unknown	150 Mg		Not Reported
	Gabapentin			C	Unknown	300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11582632	NON-EXPEDITED		HO	TR-LUPIN PHARMACEUTICALS INC.-2015-02489		65 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia;	Escitalopram			S	Unknown	10mg		Not Reported

Electrocardiogram Qt Prolonged

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11582867	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2015-02500		75 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Escitalopram			S	Unknown	5mg		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11582869	NON-EXPEDITED		HO	KR-LUPIN PHARMACEUTICALS INC.-2015-02524		56 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Tardive Dyskinesia	Escitalopram			S	Unknown	5 Mg/ Day		Not Reported
	Amitriptyline			S	Unknown	10 Mg /Day		Not Reported
	Amitriptyline			S	Unknown	10 Mg /Day		Not Reported
	Trazodone			S	Unknown	25 Mg /Day		Not Reported
	Trazodone			S	Unknown	25 Mg /Day		Not Reported
	Clonazepam			S	Unknown	1.5 Mg /Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11582873	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-E2B_00003916		45 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Muscular Weakness	Stalopam 10			S	Oral			Not Reported
	Lelock Dsr			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11582874	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS		22 YR	Female	USA

INC.-E2B_00004042

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Pruritus Generalised; Rash; Urticaria	Escitalopram Tablets Usp 20mg			S				Lupin
	Gildess			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11582929	NON-EXPEDITED			US-TORRENT-00000958			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Heart Rate Increased; Hyperventilation	Escitalopram Oxalate-Escitalopram Oxalate Tablet			S		Once A Day		Torrent
	Jolessa			C		Levonorgestrel 0.15mg And Ethinylestradiol 0.03mg		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11583194	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2015-02506		70 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dizziness; Hypotension	Escitalopram			S	Unknown	5mg		Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11583219	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2015-02336		18 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

	Escitalopram	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11583246	NON-EXPEDITED			SG-LUPIN PHARMACEUTICALS INC.-2015-02388		66 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Escitalopram			S	Unknown	10 Mg		Not Reported
	Escitalopram			S	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11584099	NON-EXPEDITED			US-ROCHE-665152		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Pain; Choking; Depression; Dry Mouth; Dyspepsia; Fatigue; Hair Texture Abnormal; Increased Appetite; Injection Site Erythema; Pruritus; Vomiting	Pegasys			S	Subcutaneous	Form:Pre Filled Syringe		Not Reported
	Copegus			S	Oral	2 In Morning And 3 At Night		Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11585500	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2015323159		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Valve Incompetence	Zoloft			S	Oral	1 Df, 1x/Day		Pfizer
	Effexor			S	Oral	1 Df, 1x/Day		Pfizer
	Seroplex			S	Oral	1 Df, 1x/Day		Not Reported
	Deroxat			S	Oral	1 Df, 1x/Day		Not Reported
	Cymbalta			S	Oral	30 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11585713	EXPEDITED (15-DAY)		DS	LT-FRI-1000079830		21 YR	Male	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Gynaecomastia; Neuropathy Peripheral; Sexual Dysfunction; Weight Increased	Escitalopram			S	Oral	10 Mg		Forest
	Rispolept			S	Unknown	3 Mg		Not Reported
	Parkopan			S	Oral	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11223381	NON-EXPEDITED			US-ACCORD-030696		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appetite Disorder; Drug Ineffective	Escitalopram			S		Strength: 5 Mg, 10 Mg,15mg,20 Mg, Initially Received 5 Mg Daily For 2 Weeks, Then 10mg For 2 Weeks.		Accord
	Klonopin			C				Not Reported
	Xanax			C		0.25 Mg Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11471806	NON-EXPEDITED		OT	US-AMGEN-USASP2015090677		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Disorder; Colitis; Irritable Bowel Syndrome; Rash	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Zoloft			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Ditropan			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			C		Unk		Not Reported
	Pepcid /00305201/			C		Unk		Not Reported

Protonix /00661201/	C	Unk		Not Reported
Tramadol	C	50 Mg, Unk		Not Reported
Norco	C	Unk 5/325		Not Reported
Baclofen	C	Unk		Not Reported
Lyrica	C	Unk		Not Reported
Baby Aspirin	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11588371	NON-EXPEDITED			US-ACCORD-031468			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Weight Decreased	Escitalopram			S		Started 5 Mg Once Daily, Increase To 2 Tab Daily After 2 Weeks, And Then 3 Tab Daily(15mg) 2 Week		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11588372	NON-EXPEDITED			US-ACCORD-031951		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability	Escitalopram Accord			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11588373	NON-EXPEDITED			US-ACCORD-032322		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram Accord			S	Oral			Accord
	Premarin			C				Not Reported
	Spironolactone			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11588377	NON-EXPEDITED			US-ACCORD-032560		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Arthralgia; Crying; Fatigue; Feeling Abnormal; Irritability; Myalgia; Pain; Product Substitution Issue; Therapy Non-Responder	Escitalopram Accord			S				Accord
	Amlodipine			C				Not Reported
	Camrese			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11588378	NON-EXPEDITED			US-ACCORD-032859		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Condition Aggravated; Depression; Drug Ineffective; Fatigue; Fear; Product Substitution Issue	Escitalopram Accord			S		Pill		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11588382	EXPEDITED (15-DAY)		OT	US-ACCORD-033413		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Confusional State; Decreased Appetite; Dizziness; Dry Mouth; Dyspnoea; Feeling Cold; Frustration Tolerance Decreased; Headache; Joint Stiffness; Lip Swelling; Malaise; Mouth Swelling; Nausea; Suicidal Ideation; Swelling Face;	Escitalopram			S	Oral			Accord
	Ergocalciferol			C	Oral			Not Reported
	Tenormin			C		Strength: 25 Mg		Not Reported
	Ativan			C				Not Reported

Swollen Tongue; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11588383	NON-EXPEDITED			US-ACCORD-033757		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Urticaria	Escitalopram Accord			S	Oral			Accord
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11590065	NON-EXPEDITED			US-TAKEDA-2015TUS013382		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Labelled Drug-Drug Interaction Medication Error; Tremor	Contrave			S	Oral	8mg/90mg, Qd		Takeda
	Contrave			S	Oral	8mg/90mg, Bid		Takeda
	Contrave			S	Oral	8mg/90mg, Tid		Takeda
	Contrave			S	Oral	8mg/90mg, Qid		Takeda
	Escitalopram			S	Oral	Unk		Not Reported
	Synthroid			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11592908	DIRECT					39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Escitalopram 10mg			S	Oral	1/2 Pill Once Daily Taken By Mouth		Not Reported
	5 Htp [Oxitriptan]			C				Not Reported
	Multivitamin			C				Not Reported
	Calcium			C				Not Reported
	B6 Supplement			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11610703	NON-EXPEDITED		HO	AUR-APU-2015-06145			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder	Escitalopram Tablets Usp 20mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2015	11591152	NON-EXPEDITED			US-INVAGEN PHARMACEUTICALS, INC.-1042536		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Fatigue; Malaise	Escitalopram			S	Oral			Invagen
	Ramipril			C				Not Reported
	Synthroid			C				Not Reported
	Vitamins A And D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11592219	EXPEDITED (15-DAY)		HO, OT	AU-MACLEODS PHARMACEUTICALS US LTD-MAC2015002028			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate			S	Unknown	30 Mg, Daily		Macleods
	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Bupropion			S	Oral	75 Mg, Unk		Not Reported
	Dothiepin			S	Unknown	Unk		Not Reported
	Dothiepin			S	Unknown	225 Mg, Unk		Not Reported
	Dothiepin			S	Unknown	175 Mg, Unk		Not Reported
	Quetiapine			S	Unknown	400 Mg,At Night		Not Reported
	Lamotrogine			C	Unknown	75 Mg, Bid		Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Oestradiol			C	Unknown			Not Reported

Ramipril	C	Unknown			Not Reported
Glipizide	C	Unknown			Not Reported
Metformin	C	Unknown	Unk		Not Reported
Lantus Insulin	C	Unknown			Not Reported
Aspirin	C	Unknown			Not Reported
Norfloxacin	C		400 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11594559	NON-EXPEDITED			US-INVAGEN PHARMACEUTICALS, INC.-1042578		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Decreased Appetite; Diarrhoea; Hyperhidrosis; Weight Decreased	Escitalopram			S	Oral			Invagen
	Celebrex			S	Oral			Not Reported
	Nexium			C				Not Reported
	Kombiglyze Xr			C				Not Reported
	Jardiance			C				Not Reported
	Votrient			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11594584	EXPEDITED (15-DAY)		OT	FR-FRI-1000079976		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	10 Mg		Forest
	Atarax			S	Oral	50 Mg		Not Reported
	Triflucan			S	Buccal			Not Reported
	Primperan			S	Oral	30 Mg		Not Reported
	Eupantol			C	Oral	80 Mg		Not Reported
	Creon			C	Oral	225000 Iu (International Unit)		Not Reported
	Allopurinol			C	Oral			Not Reported
	Carbosylane			C	Oral	3 Dosage Forms		Not Reported

Amlodipine	C	Oral	5 Mg		Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Oral	6 Dosage Forms		Not Reported
Oxycontin	C	Oral	20 Mg		Not Reported
Oxynorm	C	Oral	30 Mg		Not Reported
Smecta	C	Oral	3 Dosage Forms		Not Reported
Imodium	C	Oral	1.2 Mg		Not Reported
Doliprane	C	Oral	3000 Mg		Not Reported
Augmentin	C	Intravenous (not otherwise specified)	Only Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11594600	NON-EXPEDITED			US-INVAGEN PHARMACEUTICALS, INC.-1042580		8 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Aggression; Aggression	Escitalopram			S	Oral			Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11594623	NON-EXPEDITED			US-INVAGEN PHARMACEUTICALS, INC.-1042583		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; Product Substitution Issue	Escitalopram			S	Oral			Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11594630	NON-EXPEDITED			US-APOTEX-2015AP010618		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome	Escitalopram Oxalate			S	Unknown	10 Mg/Day		Apotex
	Cefalexin			C	Oral			Not Reported

	Propranolol		C	Unknown	30 Mg, Qd	Not Reported
	Clonazepam		C	Unknown	0.25 Mg, Bid	Not Reported
	Clonazepam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11594648	NON-EXPEDITED			US-INVAGEN PHARMACEUTICALS, INC.-1042585			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral			Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11594670	NON-EXPEDITED			US-INVAGEN PHARMACEUTICALS, INC.-1042587		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Escitalopram			S	Oral			Invagen
	Synthroid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11597059	DIRECT		DS			59 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Disturbance In Attention; Eye Pain; Impaired Work Ability; Impatience; Insomnia; Learning Disorder	Escitalopram 10 Mg Lupin			S	Oral			Lupin
	Xanax			C				Not Reported
	Conazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11603151	DIRECT		OT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hallucination; Homicidal Ideation; Mania; Thinking Abnormal	Lexapro	S	Oral	1 Pill	1 MTH	Not Reported
	St. John'S Wart	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2015	11569860	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2015323123		69 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spinocerebellar Ataxia	Cipralex			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2015	11599108	EXPEDITED (15-DAY)		HO	FR-FRI-1000079983		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Haematoma Muscle	Escitalopram			S	Oral			Forest
	Calciparine			S	Subcutaneous	30000 Iu (International Unit)		Not Reported
	Perindopril			C	Unknown			Not Reported
	Trivastal			C	Unknown			Not Reported
	Seresta			C	Oral			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11134544	EXPEDITED (15-DAY)		HO, OT	US-MERCK-1505USA009221		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Zocor			S	Oral	40 Mg, Qd		Merck
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported
	Tramadol Hydrochloride			S	Oral	50 Mg, Bid, As Needed		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Daily		Not Reported

	Risperidone	S	Oral	0.5 Mg, Daily	Not Reported
	Ambien	C			Not Reported
	Proair (Albuterol Sulfate)	C			Not Reported
	Ergocalciferol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11459104	EXPEDITED (15-DAY)		OT	DE-FRI-1000079321		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Decreased Appetite; Intentional Self-Injury; Irritability	Escitalopram			S	Oral	10 Milligram		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11576976	EXPEDITED (15-DAY)		OT	JP-FRI-1000079607		64 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Feeling Abnormal; Nausea	Lexapro			S	Oral	5 Mg		Forest
	Meilax			C	Oral	1 Mg		Not Reported
	Reflex			C	Oral	7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11597264	EXPEDITED (15-DAY)		HO	CH-ASTRAZENECA-2015SE94069		69 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypertonia; Psychomotor Retardation; Pyrexia; Renal Impairment; Tremor; Weight Increased	Quetiapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Temgesic			S	Sublingual			Not Reported
	Sifrol			C	Oral			Not Reported
	Flector (Diclofenac Epolamine)			C	Topical			Not Reported

	Lasix	C	Intravenous drip	Not Reported
	Amlodipin	C	Oral	Not Reported
	Beloc-Zok	C	Oral	Not Reported
	Aprovel	C	Oral	Not Reported
	Lantus	C	Subcutaneous	Not Reported
	Novorapid	C	Subcutaneous	Not Reported
	Vitamin B 6	C	Oral	Not Reported
	Vi-De 3	C	Oral	Not Reported
	Laxoberon	C	Oral	Not Reported
	Movicol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11604758	EXPEDITED (15-DAY)		HO	CH-FRI-1000080045		32 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Hepatic Necrosis; Jaundice; Liver Transplant	Escitalopram			S	Oral	10 Mg		Forest
	Zyprexa			S	Oral	2.5 Mg		Not Reported
	Quetiapin			S	Oral	25 Mg		Not Reported
	Quetiapin			S	Oral	50 Mg		Not Reported
	Euthyrox			C	Oral	0.15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11605685	NON-EXPEDITED			US-TORRENT-00000996			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Agitation; Irritability; Product Substitution Issue	Escitalopram Oxalate Tablets 10 Mg			S				Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	10660021	EXPEDITED (15-DAY)		OT	CH-GLAXOSMITHKLINE-			Unknown	CHE

CH2014034392

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy	Cipralex			S	Transplacental	5 Mg, Qd		Glaxosmithkline
	Lamictal			S	Transplacental			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11184732	EXPEDITED (15-DAY)		HO	US-JNJFOC-20150608944		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Tramadol Hydrochloride			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Placebo			S	Subcutaneous			Not Reported
	Simvastatin			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Ambien			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported
	Proair Hfa			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11610124	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2015-02347		11 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown	Dose Reduced		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11610168	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2015-02288		45 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus	Escitalopram			S	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11611845	EXPEDITED (15-DAY)		OT	FR-APOTEX-2015AP013361		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Valve Incompetence	Paxil Tablets			S	Oral	1 Df, Qd		Apotex
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Zoloft			S	Oral	1 Df, Qd		Not Reported
	Effexor			S	Oral	1 Df, Qd		Not Reported
	Cymbalta			S	Oral	30 Mg, Qd		Not Reported
	Norepinephrine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11613704	EXPEDITED (15-DAY)		OT	DE-FRI-1000080080		81 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Escitalopram			S	Unknown	10 Milligram		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11613926	EXPEDITED (15-DAY)		HO	US-ASTRAZENECA-2015SE96280		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Orthostatic Hypotension	Kenzen			S	Oral	8 Mg, Qd		Astrazeneca
	Bisoprolol			S	Oral	5 Mg, Qd		Not Reported

	Seroplex	S	Unknown		Not Reported
	Umuline Profil	C			Not Reported
	Umuline Profil	C			Not Reported
	Clopidogrel	C	Oral		Not Reported
	Levothyrox	C	Oral	1 Tablet Of 75 Mcg In Morning Alternating With One Tablet Of 100 Mcg	Not Reported
	Inexium	C	Oral		Not Reported
	Tanakan	C	Oral		Not Reported
	Vasten [Pravastatin Sodium]	C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11614234	EXPEDITED (15-DAY)		HO	FR-FRI-1000080138		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Subdural Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Clopidogrel Base			S	Oral	75 Mg		Not Reported
	Indapamide			C	Oral	1.5 Mg		Not Reported
	Candesartan Cilexetil			C	Oral	8 Mg		Not Reported
	Diffu K			C	Oral			Not Reported
	Simvastatine			C	Oral	200 Mg		Not Reported
	Allopurinol			C	Oral	300 Mg		Not Reported
	Alprazolam			C	Oral	0.25 Mg		Not Reported
	Oxazepam			C	Oral	10 Mg		Not Reported
	Silodosine			C	Oral	8 Mg		Not Reported
	Pantoprazole			C	Unknown	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11614236	EXPEDITED (15-DAY)		HO	DE-FRI-1000080041		22 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dermatitis Allergic; Rash	Escitalopram		S	Oral	5 Milligram	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11614237	EXPEDITED (15-DAY)		OT	FR-FRI-1000080066		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Valve Incompetence	Escitalopram			S	Oral	1 Df		Forest
	Zoloft			S	Oral	1 Df		Not Reported
	Effexor			S	Oral	1 Df		Not Reported
	Deroxat			S	Oral	1 Df		Not Reported
	Cymbalta			S	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11614246	EXPEDITED (15-DAY)		OT	DE-FRI-1000080062		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Foetal Death; Oligohydramnios; Pregnancy; Retroplacental Haematoma; Uterine Leiomyoma	Escitalopram			S	Oral	20 Milligram (Temporarily Discontinued For 4 Days In Gestational Week 4)		Forest
	Folsaeure			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11615443	DIRECT		OT			13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Swelling; Pyrexia; Swelling Face; Urticaria	Generic Lexapro 2.5 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11498243	NON-EXPEDITED		OT	US-PFIZER INC-2015301664		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Disorder; Colitis; Condition Aggravated; Irritable Bowel Syndrome; Rash	Enbrel			S	Unknown	50 Mg, Qwk		Unknown
	Zoloft			S	Unknown	Unk		Pfizer
	Lexapro			S	Unknown	Unk		Not Reported
	Ditropan			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			C		Unk		Not Reported
	Pepcid /00305201/			C		Unk		Not Reported
	Protonix /00661201/			C		Unk		Not Reported
	Tramadol			C		50 Mg, Unk		Not Reported
	Norco			C		Unk 5/325		Not Reported
	Baclofen			C		Unk		Not Reported
	Lyrica			C		Unk		Not Reported
	Baby Aspirin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11614703	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-069032			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Abilify			S	Unknown			Bristol Myers Squibb
	Xyrem			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11616570	EXPEDITED (15-DAY)		CA	US-FRI-1000080067			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11617096	EXPEDITED (15-DAY)		HO	US-JNJFOC-20151001967		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Treatment Noncompliance	Xarelto			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Paxil			S	Oral			Not Reported
	Tricor			S	Oral			Not Reported
	Estradiol			S	Oral			Not Reported
	Dicyclomine			C	Oral			Not Reported
	Advair Diskus			C	Respiratory (inhalation)	250-50 Mcg/Dose Inhalation, 1 Puff Twice A Day Approximately 12 Hours Apart Morning And Evening		Not Reported
	Albuterol Sulfate			C	Respiratory (inhalation)	90 Mcg, Every 4 Hours As Needed For 30 Days		Not Reported
	Aldactone			C	Oral			Not Reported
	Apidra			C	Subcutaneous	100 Unit/Ml		Not Reported
	Benzonatate			C	Oral			Not Reported
	Clonidine Hcl			C	Oral			Not Reported
	Elocon			C	Topical	A Thin Layer To Be Applied Topically To Affected Area		Not Reported
	Ferrous Sulfate			C	Oral	After Meals		Not Reported
	Humalog Mix			C	Subcutaneous	40 Units In The Morning And 20 Units In The Evening		Not Reported

Hydroxyzine Hcl	C	Oral	As Needed	Not Reported
Hyzaar	C	Oral	100-25 Mg	Not Reported
Ibuprofen	C	Oral		Not Reported
Imitrex	C	Oral		Not Reported
Klor-Con	C	Oral		Not Reported
Lipitor	C	Oral	At Bedtime	Not Reported
Nexium	C	Oral	For 90 Days	Not Reported
Prilosec	C	Oral		Not Reported
Proair Hfa	C	Respiratory (inhalation)	2 Puffs Every 4 Hours As Needed	Not Reported
Promethazine Dm	C	Oral	6.25-15 Mg/5ml, One Teaspoonful 4 Times A Day As Needed For 5 Days	Not Reported
Reglan	C	Oral	30 Minutes Before Meals And At Bedtime For 30 Days	Not Reported
Remeron	C	Oral	At Bedtime	Not Reported
Soma	C	Oral	As Needed	Not Reported
Sumatriptan	C	Oral		Not Reported
Synthroid	C	Oral		Not Reported
Zolpidem	C	Oral	At Bed Time As Needed For 90 Days	Not Reported
Ultram	C	Oral	As Needed For 30 Days	Not Reported
Folic Acid	C	Unknown		Not Reported
Toprol Xl	C	Oral		Not Reported
Xyzal	C	Oral	Every Evening	Not Reported
Insulin	C	Unknown	250 (Units Uspecified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11617147	EXPEDITED (15-DAY)		HO	CH-TEVA-551226ISR		79 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Fall; Transaminases Increased	Irfen-400 Lactab			S	Oral			Ivax
	Dafalgan 1 G Filmtabletten			S	Oral	3 Gram Daily; Taken Inconstantly Since The Beginning Of Feb-2015, On Average: On 2 Out Of 3 Days		Not Reported
	Cipralex Meltz			S	Oral	20 Milligram Daily;		Not Reported
	Anxiolit			C	Oral	7.5 Milligram Daily;		Not Reported
	Clexane 100 Mg/Ml			C	Subcutaneous	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11617577	NON-EXPEDITED		OT	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2015-BI-55		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Intraventricular Haemorrhage; Medication Error; Subdural Haematoma	Pradaxa			S	Oral	300 Mg		Boehringer Ingelheim
	Dronedarone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Mirtazapine			C	Unknown			Not Reported
	Digoxin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11622474	DIRECT					61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Coordination Abnormal; Drug Ineffective; Myalgia;	Escitalopram			S	Oral			Aurobindo
	Lexapro			C				Not Reported
	Snorepin Nose Insert			C				Not Reported

Product Quality Issue; Tremor; Withdrawal Syndrome	Cpap	C	Not Reported
	Ca	C	Not Reported
	Mg	C	Not Reported
	K	C	Not Reported
	Zn	C	Not Reported
	Vitamins C	C	Not Reported
	Vitamin B	C	Not Reported
	Vitamin D Nos	C	Not Reported
	Naproxen Sodium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2015	11501917	EXPEDITED (15-DAY)		CA, OT	US-PFIZER INC-2015303448			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aorta Hypoplasia; Bicuspid Aortic Valve; Coarctation Of The Aorta; Heart Disease Congenital; Maternal Exposure During Pregnancy; Shone Complex	Zoloft			S	Transplacental	Unk		Pfizer
	Zoloft			S	Transplacental	50 Mg, Daily (100 Mg Half Tablet)		Pfizer
	Zoloft			S				Pfizer
	Lexapro			S	Transplacental	Unk		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Cefzil			C	Transplacental	500 Mg, 2x/Day		Not Reported
	Phenergan			C	Transplacental	25 Mg, As Needed (Every 4 To 6 Times)		Not Reported
	Zantac			C	Transplacental	150 Mg, 2x/Day (As Needed)		Not Reported
	Maxifed Dm			C	Transplacental	Unk, 2x/Day (As Needed)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2015	11619045	EXPEDITED (15-DAY)		OT	FR-ELI_LILLY_AND_COMPANY-FR201509009335		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Valve Incompetence	Cymbalta			S	Oral	30 Mg, Qd		Eli Lilly And Co
	Seroplex			S	Oral	1 Df, Qd		Not Reported

	Zoloft	S	Oral	1 Df, Unk	Not Reported
	Effexor	S	Oral	1 Df, Qd	Not Reported
	Deroxat	S	Oral	1 Df, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2015	11620608	EXPEDITED (15-DAY)		HO	TR-MYLANLABS-2015M1034258			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Drug Interaction	Escitalopram			S	Unknown	10 Mg/Day		Mylan
	Dabigatran Etexilate			S	Unknown	110 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2015	11621391	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3031961		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Breath Sounds Abnormal; Bronchitis; Chondropathy; Cough; Depression; Fall; Fatigue; Feeling Of Body Temperature Change; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Incorrect Product Administration Duration; Intervertebral Disc Disorder; Lymphoedema; Lymphoma; Mobility Decreased; Motor Dysfunction; Nausea; Pain; Panic Attack; Peripheral Swelling; Photopsia; Pneumonia; Respiratory Arrest; Therapeutic Response	Ibuprofen			S	Unknown			Not Reported
	Bupropion Hcl Er			C	Oral			Not Reported
	Morphine Sulphate			S	Unknown			Not Reported
	Cipralex /01588501/			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Voltaren			S	Topical			Not Reported
	Voltaren			S	Topical			Not Reported
	Voltaren			S	Topical			Not Reported
	Voltaren			S	Topical			Not Reported
	Zopiclone			S	Unknown			Not Reported
	Clorazepate			S	Oral			Not Reported
	Co Etidrocal			S	Unknown			Not Reported
	Esomeprazole			S	Unknown			Not Reported

Decreased; Therapeutic Response Unexpected; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2015	11306183	NON-EXPEDITED			US-PFIZER INC-2015139513		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Vision Blurred	Norpace Cr			S	Oral	100 Mg, 2x/Day		Pfizer
	Norpace Cr			S				Pfizer
	Norpace Cr			S				Pfizer
	Zoloft			S		100 Mg, 1x/Day		Pfizer
	Zoloft			S		150 Mg, 1x/Day		Pfizer
	Zoloft			S		200 Mg, 1x/Day		Pfizer
	Zoloft			S		100 Mg, 1x/Day		Pfizer
	Lexapro			S		Unk		Not Reported
	Tenormin			C		50 Mg, 1x/Day		Not Reported
	Sular Er			C		8.5 Mg, 1x/Day (In The Evening)		Not Reported
	Xanax			C		As Needed (At 12pm And 8pm)		Not Reported
	Acidophilus			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2015	11625630	NON-EXPEDITED		HO	US-JNJFOC-20150914983			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Affect Lability; Depression; Disturbance In Social Behaviour; Dysphonia; Feeling Abnormal; Neoplasm; Off Label Use; Product Use In	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	2 Mg In The Morning And 3 Mg At Night		Not Reported

Unapproved Indication; Psychotic Disorder	Risperdal	S	Oral	2 Mg In The Morning And 3 Mg At Night.	Not Reported
	Risperdal	S	Oral		Not Reported
	Lexapro	S	Oral		Not Reported
	Lexapro	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2015	11629356	DIRECT		OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral			Cvs Caremark
	Lexapro			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2015	7574741	EXPEDITED (15-DAY)		DE, OT	FR-JNJFOC-20100809281		27 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Insomnia; Intentional Overdose	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tercian			S	Oral			Not Reported
	Seroplex			S		1 Df Qd		Not Reported
	Stilnox			S				Not Reported
	Voltarene (Diclofenac Sodium)			C				Not Reported
	Ventoline Inhaler			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2015	11628161	EXPEDITED (15-DAY)		DE	GB-MHRA-ADR 20652148		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Intentional Overdose	Fluoxetine (Unknown)		S	Oral	Overdose: Small Amount	Watson
	Ibuprofen (Unknown)		S	Oral	Overdose: Small Amount	Watson
	Nortriptyline Hydrochloride (Watson Laboratories)		S	Oral	Unk	Watson
	Oxazepam (Unknown)		S	Oral	Overdose: Small Amount	Watson
	Temazepam (Unknown)		S	Oral	Overdose: Small Amount	Watson
	Cipralex		S	Oral	Unk	Not Reported
	Cipralex		S	Oral	Unk	Not Reported
	Cipralex		S	Oral	Overdose: 22 X 10mg Tablets (220mg)	Not Reported
	Alcohol		S	Oral	5x Driving Limit	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2015	11630152	EXPEDITED (15-DAY)		HO	CH-FRI-1000080158		69 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychomotor Retardation; Pyrexia; Tremor	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest
	Quetiapin			S	Oral	6 Mg		Not Reported
	Tramadol			S	Oral	300 Mg		Not Reported
	Temgesic			S	Sublingual	0.9 Mg		Not Reported
	Sifrol			C	Oral	0.125 Mg		Not Reported
	Flector (Diclofenac Epolamine)			C	Topical	2 Df		Not Reported
	Lasix			C	Intravenous drip	20 Mg		Not Reported
	Amlodipin			C	Oral	10 Mg		Not Reported
	Beloc [Metoprolol]			C	Oral	100 Mg		Not Reported
	Aprovel			C	Oral	75 Mg		Not Reported
	Lantus			C	Subcutaneous	28 Iu		Not Reported
	Novorapid			C	Subcutaneous			Not Reported
	Vitamin B6			C	Oral	20 Mg		Not Reported

	Vi-De 3	C	Oral	800 Iu		Not Reported
	Laxoberon	C	Oral	10 Mg		Not Reported
	Movicol	C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2015	11630733	EXPEDITED (15-DAY)		OT	DK-GLAXOSMITHKLINE-DK2015144569		59 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Fatigue; Haemoptysis; Mouth Haemorrhage; Muscle Spasms; Nightmare; Prescribed Overdose; Restlessness; Seizure; Tremor	Lamictal			S				Glaxosmithkline
	Cipralex			S				Glaxosmithkline
	Escitalopram Sandoz			S				Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2015	11631391	EXPEDITED (15-DAY)		HO	ES-AMGEN-ESPSP2015106111		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paresis Cranial Nerve	Prolia			S	Unknown			Amgen
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2015	11632418	DIRECT		LT			65 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Product Substitution Issue; Quality Of Life Decreased; Suicidal Ideation	Escitalopram Mylan			S	Oral	1 Once Daily Taken By Mouth	6 MTH	Mylan
	Ritalin			C				Not Reported
	Eltroxin			C				Not Reported
	Lansoprazole			C				Not Reported
	Estrofem [Estradiol]			C				Not Reported

	Alprazolam	C	Not Reported
	Stilnox	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2015	11633081	DIRECT		OT			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Presyncope; Product Dose Omission; Product Substitution Issue	Lexapro 10 Mg			S	Oral	1 Pill		Not Reported
	Lexapro			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	7575250	EXPEDITED (15-DAY)		DE	CHPA2010GB13592		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Ibuprofen			S	Oral	Unk, Unk		Not Reported
	Temazepam			S	Oral	Unk, Unk		Novartis
	Fluoxetine			S	Oral	Unk, Unk		Not Reported
	Nortriptyline			S	Oral	Unk, Unk		Not Reported
	Oxazepam			S	Oral	Unk, Unk		Not Reported
	Cipralex /Den/			S	Oral	10 Mg, Qd		Not Reported
	Cipralex /Den/			S	Oral	10 Mg, Qd		Not Reported
	Cipralex /Den/			S	Oral	220 Mg, Once/Single		Not Reported
	Alcohol			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	11631721	NON-EXPEDITED			IT-GLENMARK PHARMACEUTICALS INC, USA.-2015GMK01496		76 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For	Gabapentin			S	Unknown	Unk		Glenmark

Unapproved Indication; Off Label Use; Therapeutic Response Unexpected	Quetiapine		S		25 Mg, Unk	Not Reported
	Escitalopram Oxalate 10mg Accord Hlthcare		S		10 Mg, Unk	Not Reported
	Benzodiazepine Derivatives		C	Unknown	Unk	Not Reported
	Amitriptyline		C	Unknown	Unk	Not Reported
	Mirtazapine		C	Unknown	Unk	Not Reported
	Promazine		C	Unknown	Unk	Not Reported
	Trazodone		C		50 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	11631912	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2015002054			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Faecaloma; Rash	Escitalopram			S	Oral	10 Mg, Qd		Macleods
	Amitriptylin			C	Oral	50 Mg, Qd Application For Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	11632311	EXPEDITED (15-DAY)		DS	GB-WATSON-2015-22020			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching	Citalopram (Unknown)			S	Oral	10mg Once A Day Increasing To 20mg Once A Day Then 30mg Once A Day		Watson
	Citalopram (Unknown)			S	Oral	20 Mg, Daily		Watson
	Citalopram (Unknown)			S	Oral	30 Mg, Daily		Watson
	Escitalopram (Unknown)			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	11632720	EXPEDITED (15-DAY)		HO	FR-JNJFOC-		95 YR	Female	FRA

20151005617

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Hallucination; Mania	Risperdal			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Xanax			S	Unknown			Not Reported
	Xanax			S	Unknown	Dose: 0.25 Mg, ½ Tablet 3 Times Per Day		Not Reported
	Imovane			S	Oral			Not Reported
	Imovane			S	Oral	Dose: ½ Tablet Of 7.5 Mg Per Day		Not Reported
	Monuril			C	Unknown			Not Reported
	Cardensiel			C	Unknown			Not Reported
	Hyperium			C	Unknown			Not Reported
	Lercan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	11633327	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2015342231		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Extrapyramidal Disorder; Rhabdomyolysis	Lipitor			S		10 Mg, Daily		Pfizer
	Lexapro			S		15 Mg, Daily		Not Reported
	Mirtazapine			S		15 Mg, Daily		Not Reported
	Seroquel			S		Unk		Not Reported
	Depakote			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	11633748	NON-EXPEDITED			US-INDIVIOR-RB-		25 YR	Male	USA

73546-2014

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Prescribing Error; Tremor	Suboxone 8mg Film			S	Unknown	8 Mg, Tid		Reckitt Benckiser
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11635446	EXPEDITED (15-DAY)		HO	US-ZYDUS-009227		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torticollis	Escitalopram			S				Not Reported
	Clonazepam			C				Not Reported
	Ibuprofen			C				Not Reported
	Amlodipine			C				Not Reported
	Celecoxib			C				Not Reported
	Tamsulosin/Tamsulosin Hydrochloride			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11635592	NON-EXPEDITED			US-PFIZER INC-2015312465			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ativan			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Ceclor			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Prevacid			S		Unk		Not Reported

	Lisinopril	S	Unk	Not Reported
	Compazine	S	Unk	Not Reported
	Zantac	S	Unk	Not Reported
	Divalproex Sodium	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11635728	EXPEDITED (15-DAY)		OT	AU-HETERO LABS LTD-1043025		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hyponatraemia	Escitalopram			S	Unknown			Hetero
	Bupropion Hydrochloride			S	Oral			Not Reported
	Dothiepin			S	Unknown			Not Reported
	Quetiapine Fumarate			C	Unknown			Not Reported
	Lamotrigine			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Glipizide			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Lantus			C	Unknown			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11636203	EXPEDITED (15-DAY)		DS	GB-TEVA-600246ACC			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching	Citalopram			S	Oral	10 Milligram Daily; 10mg Once A Day Increasing To 20mg Once A Day Then 30mg Once A Day		Pliva

	Citalopram	S	Oral	30 Milligram Daily;	Pliva
	Citalopram	S	Oral	20 Milligram Daily;	Pliva
	Escitalopram	S	Oral	Unknown	Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11636660	EXPEDITED (15-DAY)		DE	GB-BANPHARM-20154308		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Ibuprofen Unknown Product			S	Oral	Overdose: Small Amount		Not Reported
	Alcohol			S	Oral	5x Driving Limit		Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral	Overdose: 22 X 10mg Tablets (220mg)		Not Reported
	Fluoxetine			S	Oral	Overdose: Small Amount		Not Reported
	Oxazepam			S	Oral	Overdose: Small Amount		Not Reported
	Temazepam			S	Oral	Overdose: Small Amount		Not Reported
	Nortriptyline			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11637253	NON-EXPEDITED			US-TORRENT-00000984			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Product Substitution Issue	Escitalopram Oxalate-Escitalopram Oxalate Tablet			S				Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11637315	EXPEDITED (15-DAY)		CA	US-FRI-1000080206			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Cardiac Defects	Lexapro			S	Transplacental			Forest

	Zoloft	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11637720	EXPEDITED (15-DAY)		OT	GB-FRI-1000080285		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Insomnia; Paranoia; Product Use In Unapproved Indication; Tachyphrenia; Withdrawal Syndrome	Escitalopram			S	Oral			Forest
	Propranolol			S	Unknown			Not Reported
	Selincro			C	Oral	One Tablet Daily As Required		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11638526	NON-EXPEDITED			US-PFIZER INC-2015348475			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Remeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11638774	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA-2015SE97586		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Drug Interaction; Photopsia	Seroquel Xr			S	Oral			Astrazeneca
	Seroquel Xr			S	Oral			Astrazeneca
	Cipralex			S	Oral			Not Reported

	Cipralex	S	Oral		Not Reported
	Zolpidem	C	Oral		Not Reported
	Temesta (Lorazepam)	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	7553830	EXPEDITED (15-DAY)		DE	GB-PFIZER INC-GB-WYE-G06578910		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Ibuprofen			S	Oral	Unk		Pfizer
	Ethanol			S	Oral	5 Times Over The Driving Limit		Not Reported
	Cipralex			S	Oral	10.0 Mg, 22x/Tot		Not Reported
	Cipralex			S				Not Reported
	Fluoxetine			S	Oral	Unk		Not Reported
	Nortriptyline			S	Oral	Unk		Not Reported
	Oxazepam			S	Oral	Unk		Not Reported
	Temazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	7573969	EXPEDITED (15-DAY)		DE	GB-RANBAXY-2010RR-35516			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Nortriptyline			S	Oral	Unk		Taro
	Ibuprofen		Y	S	Oral	Unk		Ranbaxy
	Cipralex			S	Oral	Unk		Not Reported
	Cipralex			S	Oral	Unk		Not Reported
	Cipralex			S	Oral	22 X 10mg Tablets (220mg)		Not Reported
	Fluoxetine			S	Oral	Overdose: Small Amount		Sun
	Alcohol			S	Oral	5x Driving Limit		Not Reported

	Oxazepam	S	Oral	Overdose: Small Amount	Mutual
	Temazepam	S	Oral	Unk	Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	7575286	EXPEDITED (15-DAY)		DE	GB-MYLANLABS-2010S1015525			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Fluoxetine			S	Oral	Overdose: Small Amount		Not Reported
	Temazepam			S	Oral	Overdose: Small Amount		Not Reported
	Alcohol			S	Oral	5x Driving Limit		Not Reported
	Cipralex			S	Oral	220 Mg,Once		Not Reported
	Cipralex			S	Oral	10 Mg,Qd		Not Reported
	Cipralex			S	Oral	Overdose: 22 X 10mg Tablets		Not Reported
	Ibuprofen			S	Oral	Overdose: Small Amount		Not Reported
	Nortriptyline			S	Oral	5x Driving Limit		Not Reported
	Oxazepam			S	Oral	Overdose: Small Amount		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	9420228	NON-EXPEDITED			US-PFIZER INC-2013216441		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Relpax			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Topamax			S		Unk		Not Reported
	Diovan			S		Unk		Not Reported

	Lexapro	S	Unk	Not Reported
	Bonna	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	11613655	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2015AP013089		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torticollis	Escitalopram Oxalate			S	Unknown	5 Mg, Daily		Apotex
	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Apotex
	Escitalopram Oxalate			S	Unknown	15 Mg, Unk		Apotex
	Clonazepam Ic			C	Unknown	0.25 Mg, Q.H.S.		Not Reported
	Clonazepam Ic			C	Unknown	0.25- 0.5 Mg, Prn		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Celecoxib			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Tamsulosin			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	11639144	EXPEDITED (15-DAY)		DS	GB-AUROBINDO-AUR-APL-2015-09075			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching	Citalopram Film-Coated Tablets 10mg			S	Oral	10 Mg, Daily (10mg Once A Day Increasing To 20mg Once A Day Then 30mg Once A Day)		Aurobindo
	Citalopram Film-Coated Tablets 10mg			S	Oral	20 Mg, Once A Day		Aurobindo
	Citalopram Film-Coated Tablets 10mg			S	Oral	30 Mg, Once A Day		Aurobindo
	Escitalopram			S	Oral	Unknown		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	11639181	EXPEDITED (15-DAY)		OT	US-JUBILANT GENERICS LIMITED-1043080		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torticollis	Escitalopram Oxalate			S				Jubilant
	Clonazepam			C				Not Reported
	Ibuprofen			C				Not Reported
	Amlodipine			C				Not Reported
	Celecoxib			C				Not Reported
	Tamsulosin Hydrochloride			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	11640086	EXPEDITED (15-DAY)		HO, OT	CH-ACTAVIS-2015-21836		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Mirtazapine (Unknown)			S	Unknown	15 Mg, Qhs		Actavis
	Mirtazapine (Unknown)			S				Actavis
	Escitalopram (Unknown)			S	Unknown	20 Mg, Daily		Not Reported
	Escitalopram (Unknown)			S	Unknown	Unk (Doses Increasing Progressively Up To 20mg/D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	11643551	DIRECT					21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Crying; Feeling Abnormal; Nausea; Palpitations; Somnolence; Tremor	Escitalopram 5mg Walmart			S	Oral	1 Pill Once Daily		Walmart
	Essential Oils			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	11643632	DIRECT					35 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Work Ability; Product Quality Issue; Product Substitution Issue	Escitalopram			S	Oral			Ranbaxy
	Omega-3 Fish Oil			C				Not Reported
	Omega-6 Primrose Oil			C				Not Reported
	Zinc			C				Not Reported
	Siemens Light Therapy			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	11643673	DIRECT	Y				31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Product Substitution Issue	Escitalopram 20 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	10637299	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20140503666		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Exposure During Pregnancy	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cipralex			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Domperidone			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11639165	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2015-09345		42 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Faecaloma; Rash	Escitalopram 10 Mg			S	Oral	10 Mg, Daily		Aurobindo
	Amitriptylin			C	Oral	50 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11642548	EXPEDITED (15-DAY)		HO, LT, OT	CA-HOSPIRA-3038091		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Body Temperature Increased; Diarrhoea; Flushing; Hallucination, Auditory; Hallucination, Visual; Insomnia; Rash; Serotonin Syndrome	Morphine Sulphate			S	Intravenous (not otherwise specified)			Not Reported
	Metformin			C				Not Reported
	Tecta			C				Not Reported
	Atasol 30			S	Oral			Not Reported
	Lantus			C				Not Reported
	Phisohex /00107601/			C				Not Reported
	Cipralex /01588501/			S	Oral			Not Reported
	Proctodan-Hc			C				Not Reported
	Ramipril			C				Not Reported
	Simvastatin			C				Not Reported
	Diprosone /00008502/			C				Not Reported
	Docusate Sodium			C				Not Reported
	Concerta			S	Oral			Not Reported
	Meperidine			S	Oral			Not Reported
	Glucagon			C				Not Reported
	Proctol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11643821	EXPEDITED (15-DAY)		LT	NL-JNJFOC-20151013775		46 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Suicide Attempt	Zaldiar			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	All Other Therapeutic Products			C	Unknown			Not Reported

	Symbicort	C	Respiratory (inhalation)		Not Reported
	Paracetamol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11644151	EXPEDITED (15-DAY)		OT	CH-FRI-1000080222		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	20 Mg		Forest
	Escitalopram			S				Forest
	Mirtazapine			S	Unknown	15 Mg At Bedtime		Not Reported
	Mirtazapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11644218	EXPEDITED (15-DAY)		OT	CH-FRI-1000080349		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Photopsia	Escitalopram			S	Oral	10 Mg		Forest
	Seroquel Xr			S	Oral	300 Mg		Not Reported
	Zolpidem			C	Oral	10 Mg		Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11644554	EXPEDITED (15-DAY)		OT	CA-ROXANE LABORATORIES, INC.-2015-RO-01708RO		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Libido Decreased	Ramipril			S	Unknown	5 Mg		Roxane
	Escitalopram			S	Unknown	20 Mg		Not Reported
	Pregabalin			S	Unknown	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2015	11647683	EXPEDITED (15-DAY)		OT	FR-009507513-1510FRA008413		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Cancidas			S	Intravenous (not otherwise specified)	1 Df, Qd		Merck
	Ancotil			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imipenem			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium (Esomeprazole Magnesium)			S	Oral	1 Df, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Fluconazole			S	Intravenous (not otherwise specified)	800 Mg, Qd		Not Reported
	Zyvoxid			C				Not Reported
	Seroplex			C				Not Reported
	Rifadin			C				Not Reported
	Amikacin			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2015	11647686	EXPEDITED (15-DAY)		HO	TR-LUPIN PHARMACEUTICALS INC.-2015-03242		68 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Therapeutic Product Effect Decreased	Dabigatran			S	Unknown	110mg		Not Reported
	Dabigatran			S	Unknown	110mg		Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2015	11651068	NON-EXPEDITED		OT	US-BAUSCH-SYM-2013-13500		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Asthma; Depression; Enuresis; Fatigue; Feeling Jittery; Peripheral Vascular Disorder; Personality Change; Vertigo	Wellbutrin	S	Unknown		Not Reported
	Xyrem	S	Oral		Not Reported
	Xyrem	S	Oral	Dose Adjustments	Not Reported
	Xyrem	S	Oral		Not Reported
	Topamax	S	Unknown		Not Reported
	Zanaflex	S	Unknown		Not Reported
	Xanax	S	Unknown		Not Reported
	Roxicodone	S	Unknown		Not Reported
	Spiriva	S	Unknown		Not Reported
	Lexapro	S	Unknown		Not Reported
	Albuterol	S	Unknown		Not Reported
	Elavil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2015	11651131	NON-EXPEDITED			US-BAUSCH-BL-2015-009250			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder	Wellbutrin Xl			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2015	11327894	EXPEDITED (15-DAY)		HO	IT-FRI-1000078566		21 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Dissociation; Euphoric Mood; Intentional Overdose; Intentional Self-Injury	Escitalopram			S	Oral	Overdose: 120 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2015	11653382	EXPEDITED (15-DAY)		OT	FR-FRI-1000080373		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral	5 Mg		Forest
	Ancotil			S	Intravenous (not otherwise specified)	1900 Mg		Not Reported
	Imipenem Cilastatine Panpharma			S	Intravenous (not otherwise specified)			Not Reported
	Inexium			S	Oral	20 Mg		Not Reported
	Cancidas			S	Intravenous (not otherwise specified)	1 Dosage Form		Not Reported
	Fluconazole Kabi			S	Intravenous (not otherwise specified)	800 Mg		Not Reported
	Zyvoxid			C	Unknown			Not Reported
	Rifadine			C	Unknown			Not Reported
	Amikacine			C	Unknown			Not Reported
	Vancomycine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2015	11653430	EXPEDITED (15-DAY)		OT	GB-FRI-1000080359		49 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased	Escitalopram			S	Oral			Forest
	Amlodipine			C	Unknown	1 Df		Not Reported
	Bisoprolol			C	Unknown	1 Df		Not Reported
	Candesartan			C	Unknown	1 Df		Not Reported
	Doxazosin			C	Unknown	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2015	11653937	EXPEDITED (15-DAY)		OT	DE-TEVA-601076GER		42 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Faecaloma; Rash	Escitalopram		S	Oral	10 Milligram Daily;	Ivax
	Amitriptylin		C	Oral	50 Milligram Daily; Has Been Used For Months	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11418852	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APU-2015-07313		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cerebrovascular Accident; Dysarthria	Escitalopram 20 Mg			S	Oral	20 Mg, Daily		Aurobindo
	Risperidone 0.5mg			S	Oral	0.5 Mg, Daily		Aurobindo
	Simvastatin 40mg			S	Oral	40 Mg, Daily		Aurobindo
	Tramadol 50mg			S	Oral	50 Mg, Two Times A Day		Aurobindo
	Clonazepam			S	Oral	0.5 Mg, Daily		Not Reported
	Ambien			C	Unknown			Not Reported
	Vitamin D /00107901/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11630185	EXPEDITED (15-DAY)		OT	DK-FRI-1000080081			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Dizziness; Fatigue; Haemoptysis; Nightmare; Prescribed Overdose; Restlessness; Seizure; Tremor	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Unknown	Prescribed Overdose Of 30 Mg		Forest
	Lamictal			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11654783	EXPEDITED (15-DAY)		HO	TR-HETERO LABS LTD-1043318		68 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Drug Interaction	Escitalopram			S				Hetero

	Dabigatran	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11654844	EXPEDITED (15-DAY)		OT	TR-HETERO LABS LTD-1043320		21 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metrorrhagia	Escitalopram			S	Unknown			Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11655088	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015351006		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Amlor			S	Oral	5 Mg, 1x/Day		Pfizer
	Forlax			S	Oral	10 G, 1x/Day		Not Reported
	Furosemide			S	Oral	20 Mg, 1x/Day		Not Reported
	Gaviscon /00237601/			S	Oral	10 Ml, 1x/Day		Not Reported
	Kardegic			S	Oral	75 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11655277	EXPEDITED (15-DAY)		DE	CH-JNJFOC-20151015487		90 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Circulatory Collapse	Risperdal			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Diovan			C	Oral			Not Reported
	Ginkgo Biloba			C	Oral			Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11655279	EXPEDITED (15-DAY)		DE	CH-JNJFOC-20151015568		89 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; General Physical Health Deterioration	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Coversum			C	Unknown	10 Mg/Day From 21-May-2015 To 28-May-2015.		Not Reported
	Aspirin Cardio			C	Unknown			Not Reported
	Euthyrox			C	Unknown			Not Reported
	Temesta (Lorazepam)			C	Unknown	13/05/15, 15/05/15, 16/05/15, 21/05/15, 27/05/15		Not Reported
	Morphine			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Novalgine (Metamizole Sodium)			C	Unknown			Not Reported
	Adalat			C	Unknown			Not Reported
	Ringer Lactate			C	Transdermal			Not Reported
	Rivastigmine			C	Unknown	Once Daily.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11656096	EXPEDITED (15-DAY)		DS	GB-FRI-1000080347			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching	Citalopram			S	Oral	10 Mg		Forest
	Citalopram			S	Oral	20 Mg		Forest
	Citalopram			S	Oral	30 Mg		Not Reported

	Escitalopram			S	Oral				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11656620	NON-EXPEDITED			US-ELI_LILLY_AND_COMPANY-US201510002626			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Somnolence	Cymbalta			S	Unknown			Eli Lilly And Co
	Prozac			S	Unknown			Not Reported
	Xyrem			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11657059	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2015M1035173			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Faecaloma; Rash	Escitalopram			S	Oral	10 Mg, Qd (10 Mg Millgram(S) Every Days)		Not Reported
	Amitriptylin			C	Oral	50 Mg, Qd (50 Mg Millgram(S) Every Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11657547	EXPEDITED (15-DAY)		OT	DK-FRI-1000080385		59 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Dizziness; Fatigue; Haemoptysis; Mouth Haemorrhage; Muscle Spasms; Nightmare; Prescribed Overdose; Restlessness; Restlessness; Seizure; Tremor; Tremor	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Unknown	Overdose: 30 Mg		Not Reported
	Lamictal			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2015	11656629	EXPEDITED (15-DAY)		DE, OT	CH-ASTRAZENECA-2015SF02068		89 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Drug Interaction; General Physical Health Deterioration	Seroquel			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Coversum			C	Oral			Not Reported
	Coversum			C	Oral			Not Reported
	Coversum			C	Oral			Not Reported
	Aspirin Cardio			C	Oral			Not Reported
	Euthyrox			C	Oral			Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported
	Temesta (Lorazepam)			C	Oral			Not Reported
	Morphine			C	Oral			Not Reported
	Atorvastatin			C	Oral			Not Reported
	Novalgine (Metamizole Sodium)			C	Oral			Not Reported
	Adalat			C	Oral			Not Reported
	Ringer Lactat			C	Intravenous (not otherwise specified)			Not Reported
	Exelon Patch			C	Transdermal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2015	11658954	NON-EXPEDITED			US-JUBILANT GENERICS LIMITED-		70 YR	Male	USA

1043365

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Escitalopram Oxalate			S				Jubilant
Blood Pressure Increased;	Allopurinol			C				Not Reported
Diarrhoea; Heart Rate	Lovastatin			C				Not Reported
Decreased; Rhinorrhoea	Xanax			C				Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2015	11661283	EXPEDITED (15-DAY)		OT	IT-FRI-1000080362			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spinocerebellar Ataxia	Escitalopram			S	Unknown			Forest
	Fosicombi			C	Unknown			Not Reported
	Plavix			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2015	11662082	EXPEDITED (15-DAY)		OT	TR-MYLANLABS-2015M1035911			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S	Unknown	He Received Three Doses Of 2.5mg		Mylan
	Valproate			S	Unknown	30 Mg/Kg		Mylan
	Topiramate			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2015	11665226	DIRECT		OT			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Migraine; Product Formulation Issue; Product Quality Issue	Escitalopram Oxalate 10mg Accord Hlthcare	S	Oral	1 Pill		Accord
	Gnc Multivitamin	C				Not Reported
	Cla	C				Not Reported
	Magnesium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2015	11665436	DIRECT					58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Product Quality Issue; Product Substitution Issue	Lexapro			S		2 Pills Twice Daily		Teva
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2015	11665499	DIRECT					37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram 20 Mg			S	Oral	Alternating Name Brand	1 YR	Not Reported
	Armour Thyroid			C				Not Reported
	Lexapro			C				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2015	11658861	EXPEDITED (15-DAY)		DE, OT	PHHY2015US095132			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Healing; Pneumonia; Respiratory Disorder; Wound Infection	Baclofen Intrathecal			S	Intrathecal			Not Reported
	Baclofen			S	Oral	Unk		Not Reported
	Tizanidine			S	Unknown			Novartis
	Valium			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

	Lyrica	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2015	11669853	EXPEDITED (15-DAY)		HO	FR-FRI-1000080487		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Escitalopram			S	Oral			Forest
	Speciafoldine			S	Oral	0.4 Mg		Not Reported
	Iomeron			S	Intravenous (not otherwise specified)			Not Reported
	Atenolol			C		1 Dosage Form		Not Reported
	Alimta			C	Unknown			Not Reported
	Carboplatine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2015	11669855	EXPEDITED (15-DAY)		HO	FR-FRI-1000080447		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma Scale Abnormal; Hypotension; Intentional Overdose; Somnolence; Suicide Attempt	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral			Forest
	Zolpidem			S	Oral	1 Dosage Form		Not Reported
	Zolpidem			S	Oral	Intentional Overdose Of 280 Mg.		Not Reported
	Lercanidipine			C	Oral	10 Mg		Not Reported
	Alprazolam			C	Oral	1.5 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	8057314	EXPEDITED (15-DAY)		CA, DE, OT	GB-ARROW GEN-2011-10896			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Congenital Pulmonary Valve Atresia	Citalopram Hydrobromide (Unknown)		S	Transplacental	20 Mg, Daily	Watson
	Escitalopram		S	Transplacental	20 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11657043	EXPEDITED (15-DAY)		HO	US-ABBVIE-15P-163-1483119-00		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis; Unevaluable Event	Depakote			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11672645	EXPEDITED (15-DAY)		HO, OT	JP-MACLEODS PHARMACEUTICALS US LTD-MAC2015002087			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Confusional State; Dehydration; Hyperreflexia; Insomnia; Loss Of Consciousness; Myoclonus; Oxygen Saturation Decreased; Pyrexia; Seizure; Serotonin Syndrome; Somnolence; Urinary Tract Infection	Escitalopram Oxalate			S	Unknown	10 Mg Per Day		Macleods
	Escitalopram Oxalate			S	Unknown	10 Mg Per Day		Macleods
	Mirtazapine			C	Unknown	30 Mg Per Day		Not Reported
	Nitrazepam			C	Unknown	5 Mg Per Day		Not Reported
	Risperidone			C	Unknown	1 Mg Per Day		Not Reported
	Risperidone			C				Not Reported
	Risperidone			C				Not Reported
	Levofloxacin			C	Unknown	500 Mg, Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11673926	EXPEDITED (15-DAY)		HO, OT	US-ACTAVIS-2015-22651		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Extrapyramidal Disorder; Rhabdomyolysis	Mirtazapine (Aellc)		S	Unknown	15 Mg Daily	Actavis Elizabeth
	Lipitor		S	Unknown	10 Mg Daily	Not Reported
	Lexapro /01588501/		S	Unknown	15 Mg Daily	Not Reported
	Seroquel		S	Unknown	Unknown	Not Reported
	Depakote		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11674625	EXPEDITED (15-DAY)		OT	TR-APOTEX-2015AP013691		4 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paresis; Rebound Effect; Seizure	Topiramate			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	2.5 Mg, 2 Hours Before Each Session		Not Reported
	Valproate			S	Unknown	30 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11676804	EXPEDITED (15-DAY)		HO	FR-FRI-1000080508		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral	5 Mg		Forest
	Amlor			S	Oral			Not Reported
	Forlax			S	Oral	10 Gram		Not Reported
	Furosemide Arrow			S	Oral	20 Mg		Not Reported
	Gaviscon			S	Oral	10 Ml		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11676852	EXPEDITED (15-DAY)		OT	TR-FRESENIUS KABI-FK201505273		4 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Paresis; Seizure; Therapy Change; Viral Infection	Valproate (Manufacturer Unknown)	S	Unknown	Fresenius Medical Care
	Valproate (Manufacturer Unknown)	S	Unknown	Fresenius Medical Care
	Topiramate (Manufacturer Unknown)	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11677086	EXPEDITED (15-DAY)		DE, HO	PE-TEVA-602402ISR		79 YR	Female	PER

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Intestinal Obstruction; Pulmonary Infarction	Prolide			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11682000	DIRECT		HO, RI			55 YR	Male	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia; Anxiety; Decreased Activity; Histrionic Personality Disorder; Loss Of Employment; Personality Change; Psychiatric Symptom; Restlessness; Social Anxiety Disorder	Lexapro 20mg - Generic			S				Not Reported
	Remeron			S				Not Reported
	Olanzapine			C				Not Reported
	Britellix			C				Not Reported
	Valium			C				Not Reported
	Benzos (Xanax)			C				Not Reported
	Magnesium			C				Not Reported
	Fish Oil			C				Not Reported
	Vit C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2015	11682362	NON-EXPEDITED			US-PFIZER INC-2015364446		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Drug Ineffective; Screaming	Xanax			S		Unk		Pfizer

	Prozac	S	Unk		Not Reported
	Lexapro	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2015	11682705	EXPEDITED (15-DAY)		OT	FR-FRI-1000080479		22 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury; Transaminases Increased	Escitalopram			S	Oral			Forest
	Xanax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2015	11684230	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP013977			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Escitalopram Oxalate			S	Unknown			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2015	11685360	DIRECT					46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Intolerance; Product Substitution Issue	Escitalopram 10mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2015	11624674	EXPEDITED (15-DAY)		HO	AT-TEVA-600394ISR		34 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Epilepsy; General Physical Health Deterioration;	Pantoprazol 40mg			S		1-0-0		Teva
	Cipralex 10 Mg			S		1-0-0		Not Reported
	Deanxit			S		1-0-0, Neuroleptica And		Not Reported

Generalised Tonic-Clonic Seizure; Hepatic Function Abnormal; Seizure; Thrombocytopenia			Antidepressive Combination: Flupentixol 0.5mg And Melitracen 10mg		
	Acemin 5mg	S	1/2-0-0		Not Reported
	Legalon 70 Mg	S	1-0-0		Not Reported
	Ursofalk 250 Mg	S	1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2015	11686722	NON-EXPEDITED			US-PFIZER INC-2015364759			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Metoclopramide Hcl			S		Unk		Unknown
	Venlafaxine Hcl			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Flonase			S		Unk		Not Reported
	Mometasone Furoate			S		Unk		Not Reported
	Clavulanate Potassium			S		Unk		Not Reported
	Advair			S		Unk		Not Reported
	Augmentin			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Omnicef			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2015	11687369	EXPEDITED (15-DAY)		HO	AU-APOTEX-2015AP013818		55 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dyspnoea; Feeling Jittery; Panic Attack	Escitalopram			S	Unknown	10 Mg, Unk		Apotex
	Panadol /00020001/			C	Unknown			Not Reported

	Vitamin D /00107901/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2015	11687977	EXPEDITED (15-DAY)		HO	US-ABBVIE-15P-163-1487615-00		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Treatment Noncompliance	Tricor			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Paxil			S	Oral			Not Reported
	Estradiol			S	Oral			Not Reported
	Dicyclomine			C	Oral			Not Reported
	Advair			C	Respiratory (inhalation)			Not Reported
	Albuterol Sulfate			C	Respiratory (inhalation)			Not Reported
	Aldactone			C	Oral			Not Reported
	Apidra			C	Subcutaneous	100 Unit/Ml		Not Reported
	Benzonatate			C	Oral			Not Reported
	Clonidine Hcl			C	Oral			Not Reported
	Elocon			C	Topical			Not Reported
	Ferrous Sulfate			C	Oral			Not Reported
	Humalog Mix			C	Subcutaneous	In The Morning		Not Reported
	Humalog Mix			C	Subcutaneous	In The Evening		Not Reported
	Hydroxyzine Hcl			C	Oral			Not Reported
	Hyzaar			C	Oral			Not Reported
	Ibuprofen			C	Oral			Not Reported

Imitrex	C	Oral	Once Daily		Not Reported
Klor-Con	C	Oral			Not Reported
Lipitor	C	Oral			Not Reported
Nexium	C	Oral			Not Reported
Prilosec	C	Oral			Not Reported
Proair Hfa	C	Respiratory (inhalation)			Not Reported
Promethazine Dm	C	Oral			Not Reported
Reglan	C	Oral			Not Reported
Remeron	C	Oral			Not Reported
Soma	C	Oral			Not Reported
Sumatriptan	C	Oral			Not Reported
Synthroid	C	Oral			Not Reported
Zolpidem	C	Oral			Not Reported
Ultram	C	Oral			Not Reported
Folic Acid	C	Unknown			Not Reported
Toprol Xl	C	Oral			Not Reported
Xyzal	C	Oral			Not Reported
Insulin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2015	11688303	EXPEDITED (15-DAY)		HO, OT	JP-ACCORD-034911		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Dehydration; Insomnia; Serotonin Syndrome; Somnolence; Urinary Tract Infection	Escitalopram			S		For More Than 6 Months		Accord
	Nitrazepam			S				Not Reported
	Risperidone			S				Not Reported
	Mirtazapine			C				Not Reported
	Levofloxacin/Levofloxacin Mesylate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11692151	EXPEDITED (15-DAY)		OT	US-ACCORD-034966		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejaculation Failure; Gastrooesophageal Reflux Disease; Insomnia; Off Label Use; Peptic Ulcer	Escitalopram			S	Oral	Strength: 10 Mg		Accord
	Fenofibrate			C				Not Reported
	Crestor			C				Not Reported
	Levothyroxine			C				Not Reported
	Metoprolol Succ Er			C				Not Reported
	Aspirin			C				Not Reported
	Lisinopril			C				Not Reported
	Effient			C				Not Reported
	Fluticasone			C				Not Reported
	Ambient			C				Not Reported
	Nitro Stat			C		Only When Needed		Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11692486	NON-EXPEDITED			US-PFIZER INC-2015354371		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Lopid			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Iodine			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Vytorin			S		Unk		Not Reported
	Zanaflex			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11693794	EXPEDITED (15-DAY)		HO, OT	JP-MYLANLABS-2015M1037409			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Serotonin Syndrome	Escitalopram			S	Unknown	10 Mg, Qd		Mylan
	Escitalopram			S	Unknown	10 Mg, Qd		Mylan
	Mirtazapine			S	Unknown	30 Mg, Qd		Mylan
	Risperidone			S	Unknown	1 Mg, Qd		Not Reported
	Nitrazepam			S	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11695763	DIRECT					47 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Tinnitus; Vertigo	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2015	11696043	EXPEDITED (15-DAY)		DS, HO	US-WATSON-2015-17592		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident At Work; Asthma; Ataxia; Back Injury; Disability; Drug Ineffective; Dyspnoea; Fluid Retention; Hypoaesthesia; Ill-Defined Disorder; Intervertebral Disc Protrusion; Joint Swelling; Migraine; Oral Infection; Pain; Pulmonary Congestion; Visual Impairment; Wheezing	Androderm (Actavis Laboratories Ut)			S	Transdermal	1 Df, Daily		Actavis
	Advair			S	Respiratory (inhalation)	1 Puff Twice Daily		Not Reported
	Ventolin /00139501/			S	Respiratory (inhalation)	2-6 Puffs As Needed		Not Reported
	Biotene Oral Balance			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Oxycontin			C				Not Reported
	Oxycodone			C				Not Reported
	Valium			C				Not Reported

	Gabapentin	C	Not Reported
	Duexis	C	Not Reported
	Singulair	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2015	11697413	EXPEDITED (15-DAY)		DE	CH-FRI-1000080660		90 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Circulatory Collapse	Escitalopram			S	Oral	5 Mg		Forest
	Risperdal 2 Mg Film-Coated Tablets			S	Oral	2 Mg		Not Reported
	Diovan			C	Oral	80 Mg		Not Reported
	Symfona (Ginkgo Biloba)			C	Oral			Not Reported
	Temesta (Lorazepam)			C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2015	11698409	EXPEDITED (15-DAY)		OT	US-FRI-1000080677			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Stimulation	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2015	11673916	EXPEDITED (15-DAY)		HO, OT	JP-WATSON-2015-23017		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia	Escitalopram (Unknown)			S	Unknown	10 Mg, Daily		Not Reported
	Nitrazepam (Unknown)			S	Unknown	5 Mg, Daily		Not Reported
	Risperidone (Unknown)			S	Unknown	1 Mg, Daily		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2015	11700353	NON-EXPEDITED			US-PFIZER INC-2015370867		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache	Sertraline Hcl			S		Unk		Pfizer
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2015	11702254	NON-EXPEDITED		OT	BR-TORRENT-00003180		68 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Disorder; Contusion; Drug Ineffective For Unapproved Indication; Fall; Intracardiac Thrombus; Off Label Use; Osteopenia; Petechiae; Spinal Pain; Stress Cardiomyopathy	Neblock			S	Oral	Once Every 12 Hours/ Oral		Torrent
	Espran			S	Oral	Once Daily/ Oral		Torrent
	Rivotril			C	Oral	Dose Number Is Unknown/ Once Daily/ Oral		Roche
	Aradois			C	Oral	Dose Number Is Unknown/ Once Every 12 Hours/ Oral		Not Reported
	Puran T4			C	Oral	Once Daily/ Oral		Aventis
	Marevan			C	Oral	Marevan 5 Mg Half Of A Tablet Daily/ Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2015	11443351	EXPEDITED (15-DAY)		HO	IT-FRI-1000079228		90 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Melaena	Escitalopram			S	Oral	1 Df		Forest
	Pradaxa			S	Oral	2 Df		Not Reported
	Selokeen			C	Oral			Not Reported
	Lucen			C	Oral			Not Reported
	Lasix			C	Oral			Not Reported
	Enapren			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2015	11704487	NON-EXPEDITED			US-PFIZER INC-2015374347		72 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Hydrocodone			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil /00830802/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2015	10874084	EXPEDITED (15-DAY)		HO	JP-FRI-1000074472		< 1 DAY	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypotonia; Neonatal Oversedation; Respiratory Disorder Neonatal	Lexapro			S	Transplacental	10 Mg		Forest
	Lexapro			S	Transplacental	10 Mg		Forest
	Meilax			S	Transplacental	1 Mg		Not Reported
	Meilax			S	Transplacental	1 Mg		Not Reported
	Sodium Rabeprazole			C	Transplacental	10 Mg		Not Reported
	Sodium Rabeprazole			C	Transplacental	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2015	11667976	EXPEDITED (15-DAY)		HO	JP-FRI-1000080477		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Serotonin Syndrome	Escitalopram			S	Unknown	10 Mg		Forest
	Mirtazapine			C	Unknown	30 Mg		Not Reported
	Nitrazepam			C	Unknown	5 Mg		Not Reported
	Risperidone			C	Unknown	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2015	11713392	EXPEDITED (15-DAY)		OT	MY-ACCORD-035142		17 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Amenorrhoea; Condition Aggravated; Delusion; Delusion Of Reference; Extrapyramidal Disorder; Fear; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Obsessive-Compulsive Disorder; Psychotic Disorder; Salivary Hypersecretion; Schizophrenia; Tachycardia; Thinking Abnormal; Tongue Disorder; Treatment Failure; Weight Increased	Quetiapine			S		Initially Started At The Dose 50 Mg, Then Increased To 100 Mg, And Subsequently Increased To 200 Mg.		Accord
	Risperidone			S				Accord
	Olanzapine			S				Not Reported
	Haloperidol			S				Not Reported
	Lexapro			S		Dose: 10 Mg Nocte Dose Was Increased To 30 Mg Daily Over The Period Of Two Months		Not Reported
	Aripiprazole			S		Started At 5mg/Day, Then Gradually Increased In Two Weeks Up To 30 Mg Daily.		Not Reported
	Clozapine			S		Started At 12.5mg Daily And Gradually Increased Up To 300 Mg Daily Over The Period Of 2 Months		Not Reported
	Paliperidone/Paliperidone Palmitate			S		Gradually Increased To 12 Mg Daily Over The Period Of 4 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2015	11713910	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-09923		26 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Quality Of Life Decreased	Escitalopram			S	Oral	15 Mg, Daily		Aurobindo
	Escitalopram			S	Oral	10 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2015	11715911	EXPEDITED (15-DAY)		CA	FR-FRI-1000080786		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2015	11718264	DIRECT					35 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blepharospasm; Drug Withdrawal Syndrome; Fatigue	Lexapro			S	Oral		10 YR	Teva
	Omega-3 Fish Oil			C				Not Reported
	Prenatal Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2015	11717498	EXPEDITED (15-DAY)		HO	GB-DEXPHARM-20152092			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal	Azathioprine			S	Transplacental			Not Reported
	Co-Dydramol			S	Transplacental	Strength: 10/500		Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Omeprazole			S	Transplacental			Not Reported
	Oramorph			S	Transplacental			Not Reported
	Oramorph			S	Unknown			Not Reported
	Tapentadol			S	Transplacental	100 Mg		Not Reported
	Daktarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2015	11720338	EXPEDITED (15-DAY)		OT	GB-TEVA-606510ACC		26 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Emotional Distress; Impaired Work Ability	Escitalopram			S	Oral	15 Mg Daily		Ivax
	Escitalopram			S	Oral	10 Mg Daily		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2015	11720359	EXPEDITED (15-DAY)		HO	AU-FRI-1000080693			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S	Unknown			Forest
	"Ice" / Methamphetamine			C	Unknown			Not Reported
	Cocaine			C	Unknown			Not Reported
	Marijuana			C	Unknown			Not Reported
	Valium / Diazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2015	11722416	DIRECT	Y	HO, LT			11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory; Intentional Self-Injury; Memory Impairment; Mood Altered; Skin Laceration; Staring; Suicidal Ideation	Escitalopram 10 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2015	11723191	DIRECT		DS, HO, LT, OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Headache; Product Substitution Issue; Product	Escitalopram			S	Oral			Accord
	Clonozepam (Generic For Klonopin)			C				Not Reported

Substitution Issue;
Therapy Cessation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2015	11722440	EXPEDITED (15-DAY)		DS, OT	US-ACTAVIS-2015-24090			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Neuromyopathy; Sedation; Suicidal Ideation	Escitalopram (Unknown)			S	Unknown	20 Mg, Unknown		Not Reported
	Escitalopram (Unknown)			S	Unknown	10 Mg, Unknown		Not Reported
	Escitalopram (Unknown)			S	Unknown	Titrated To 20 Mg		Not Reported
	Fluoxetine (Watson Laboratories)			S	Unknown	Unk		Watson
	Olanzapine (Unknown)			S	Unknown	Unk		Not Reported
	Sertraline			C	Unknown	25 Mg, Unknown		Not Reported
	Sertraline			C				Not Reported
	Mirtazapine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2015	11723055	EXPEDITED (15-DAY)		HO, OT	JP-TEVA-603552ISR		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Bradykinesia; Delusion; Hallucination; Pyrexia; Serotonin Syndrome; Somnolence	Nitrazepam			S		5 Milligram Daily; For More Than 6 Months		Not Reported
	Risperidone			S		1 Milligram Daily; For More Than 6 Months		Pliva
	Escitalopram			S		10 Milligram Daily; For More Than 6 Months		Not Reported
	Mirtazapine			C		30 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2015	11723082	NON-EXPEDITED			US-TORRENT-00001013			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Escitalopram Oxalate Tablet	S	Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11734616	EXPEDITED (15-DAY)		HO	CA-PURDUE PHARMA-CAN-2015-0006235		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Morphine Sulfate			S	Unknown	2.5 Mg, Q4h		Purdue
	Avastin /01555201/			S	Intravenous (not otherwise specified)	15 Mg/Kg, See Text		Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)	Unk Unk, See Text		Not Reported
	Cipralex			S	Unknown	10 Mg, Daily		Not Reported
	Ciprofloxacin			S	Intravenous (not otherwise specified)	Unk, See Text		Not Reported
	Ciprofloxacin			S	Oral	1000 Mg, Unk		Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)	75 Mg/M2, See Text		Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)	75 Mg/M2, Unk		Not Reported
	Piperacillin Sodium W/Tazobactam Sodium			S	Unknown	Unk		Not Reported
	Trastuzumab			S	Intravenous (not otherwise specified)	8 Mg/Kg, See Text		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Tylenol No.1			S	Unknown	Unk		Not Reported
	Codeine			C	Unknown	Unk		Purdue
	Docusate			C	Unknown	Unk		Not Reported
	Gravol			C	Unknown	Unk		Not Reported
	Lactulose			C	Unknown	Unk		Not Reported
	Senna /00142201/			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11734944	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2015-0006248		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Breath Sounds Abnormal; Bronchitis; Chondropathy; Cough; Depression; Fall; Fatigue; Feeling Of Body Temperature Change; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Incorrect Product Administration Duration; Intervertebral Disc Disorder; Lymphoedema; Lymphoma; Mobility Decreased; Motor Dysfunction; Nausea; Pain; Panic Attack; Peripheral Swelling; Photopsia; Pneumonia; Respiratory Arrest; Therapeutic Response Decreased; Therapeutic Response Unexpected; Tremor	Morphine Sulfate			S	Unknown	Unk, Tid		Purdue
	Cipralex			S	Unknown	20 Mg, Unk		Not Reported
	Clorazepate			S	Oral	15 Mg, Tid		Not Reported
	Co Etidrocal			S	Unknown	500 Mg, Daily		Not Reported
	Esomeprazole			S	Unknown	40 Mg, Daily		Not Reported
	Gabapentin			S	Unknown	Unk, Bid		Not Reported
	Gabapentin			S	Unknown	Unk, Tid		Not Reported
	Ibuprofen			S	Unknown	100 Mg, Daily		Not Reported
	Trazodone			S	Unknown	50 Mg, Unk		Not Reported
	Voltaren Emulgel			S	Topical	Unk		Not Reported
	Voltaren Emulgel			S				Not Reported
	Voltaren Emulgel			S				Not Reported
	Voltaren Emulgel			S				Not Reported
	Zopiclone			S	Unknown	15 Mg, Unk		Not Reported
	Bupropion Hcl Er			C	Oral	300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11737010	EXPEDITED (15-DAY)		HO	FR-FRI-1000080903		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Tachycardia; Confusional State; Hallucination, Auditory; Hallucination, Visual	Escitalopram			S	Oral			Forest
	Digoxine Nativelle			S	Oral			Not Reported
	Tiapridal			S	Oral			Not Reported

	Coumadine	C	Not Reported
	Lasilix	C	Not Reported
	Doliprane	C	Not Reported
	Speciafoldine	C	Not Reported
	Tardyferon B9 [Ferrous Sulfate;Folic Acid]	C	Not Reported
	Levothyrox	C	Not Reported
	Triatec (Ramipril)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11737978	EXPEDITED (15-DAY)		HO	US-SA-2015SA177570		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pulmonary Embolism; Treatment Noncompliance	Lasix			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Paxil			S	Oral			Not Reported
	Tricor			S	Oral			Not Reported
	Estradiol			S	Oral			Not Reported
	Dicyclomine			C	Oral			Not Reported
	Advair Diskus			C	Respiratory (inhalation)			Not Reported
	Albuterol Sulfate			C	Respiratory (inhalation)			Not Reported
	Aldactone			C	Oral			Not Reported
	Apidra			C	Subcutaneous	100 Unit/Ml		Not Reported
	Benzonatate			C	Oral			Not Reported
	Clonidine Hydrochloride			C	Oral			Not Reported
	Elocon			C	Topical			Not Reported
	Ferrous Sulfate			C	Oral			Not Reported
	Humalog Mix			C	Subcutaneous			Not Reported

Hydroxyzine Hydrochloride	C	Oral	Not Reported
Hyzaar	C	Oral	Not Reported
Ibuprofen	C	Oral	Not Reported
Imitrex	C	Oral	Not Reported
Klor-Con	C	Oral	Not Reported
Lipitor	C	Oral	Not Reported
Nexium	C	Oral	Not Reported
Prilosec	C	Oral	Not Reported
Proair Hfa	C	Respiratory (inhalation)	Not Reported
Promethazine Dm	C	Oral	Not Reported
Reglan	C	Oral	Not Reported
Remeron	C	Oral	Not Reported
Soma	C	Oral	Not Reported
Sumatriptan	C	Oral	Not Reported
Synthroid	C	Oral	Not Reported
Zolpidem	C	Oral	Not Reported
Ultram	C	Oral	Not Reported
Folic Acid	C		Not Reported
Toprol Xl	C	Oral	Not Reported
Xyzal	C	Oral	Not Reported
Insulin	C		Not Reported
Amitiza	C		Not Reported
Seretide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11741830	DIRECT		OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Aura; Hallucination, Visual; Heart Rate Irregular;	Lexapro 10 Mg. Forest Labs			S	Oral	1 Pill		Forest
	Synthroid			C				Not Reported

Hypersensitivity; Mania; Panic Attack; Product Complaint; Restlessness	Vitamin D Nos	C	Not Reported
	Calcium	C	Not Reported
	Fish Oil	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2015	11382937	NON-EXPEDITED			US-PFIZER INC-2015260924		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache	Tikosyn			S	Oral	250 Mg, 2x/Day		Pfizer
	Tikosyn			S				Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Pradaxa			C	Oral	150 Mg, 2x/Day		Not Reported
	Metoprolol			C	Oral	100 Mg, 2x/Day		Not Reported
	Diltiazem			C	Oral	360 Mg, 1x/Day		Not Reported
	Coenzyme Q10			C	Oral	100 Mg, Liquid, Unk		Not Reported
	Vitamin D Nos			C	Oral	1000 Iu, 1x/Day		Not Reported
	Calcium Magnesium Zinc /01320801/			C	Oral	500 Mg, 2x/Day		Not Reported
	Aspirin Low			C	Oral	81 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2015	11741272	EXPEDITED (15-DAY)		OT	US-ORION CORPORATION ORION PHARMA-SERO2015-0026			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Motor Dysfunction; Psychiatric Decompensation; Sedation; Suicidal Ideation; Treatment Failure	Fluoxetine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2015	11746401	DIRECT		DS, HO			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Urinary Retention	Lexapro			S		One In The Morning		Not Reported
	Inderal			C				Not Reported
	Potassium			C				Not Reported
	Flomax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2015	11687444	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000080481			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome	Escitalopram			S	Transplacental	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2015	11745712	EXPEDITED (15-DAY)		HO	FR-ACTAVIS-2015-24417		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Confusional State; Encephalopathy; Incoherent; Platelet Count Decreased; Uraemic Encephalopathy	Zolpidem (Unknown)			S	Oral	1 Df, Daily In Evening		Watson
	Pantoprazole (Unknown)			S	Oral	1 Df, Daily In Morning		Actavis Totowa
	Pravastatine Arrow			S	Oral	1 Df, Daily In Evening		Not Reported
	Escitalopram			S	Oral	1 Df, Daily In Evening		Not Reported
	Bromazepam			S	Oral	0.25 Df, Daily In Evening		Not Reported
	Cefepime Mylan			S	Intravenous (not otherwise specified)	2 G, Bid Every 12 Hours		Not Reported
	Lasilix /00032601/			S	Oral	0.5 Df, Daily At Noon		Not Reported
	Ferograd			S	Oral	1 Df, Bid Morning And Evening		Not Reported

	Calciparine	S	Subcutaneous	1 Df, Bid Morning And Evening	Not Reported
	Kardegic	S	Oral	1 Df, Daily	Not Reported
	Ezetrol	S	Oral	1 Df, Daily In Evening	Not Reported
	Ikorel	C	Unknown	Unk Unk, Unknown	Not Reported
	Aldactone /00006201/	C	Unknown	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2015	11745799	EXPEDITED (15-DAY)		OT	JP-JUBILANT GENERICS LIMITED-1044269		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Haematuria; Oxygen Saturation Decreased; Protein Urine Present; Serotonin Syndrome; Urine Leukocyte Esterase Positive; Withdrawal Syndrome	Escitalopram Oxalate			S				Jubilant
	Risperidone			C				Not Reported
	Nitrazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2015	11746468	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1039650			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Motor Neurone Disease	Fluoxetine			S	Unknown			Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2015	11746470	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1039654			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Motor Neurone Disease	Escitalopram			S	Unknown			Not Reported

	Sertraline	S	Unknown		Not Reported
	Bupropion	C	Unknown	300mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2015	11748609	EXPEDITED (15-DAY)		HO	FR-FRI-1000080952		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Wound Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	Daily Dose Increased On 10/Aug/2015 (Unknown Dose)		Forest
	Escitalopram			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg		Not Reported
	Levothyrox			C	Unknown	112.5 Mcg		Not Reported
	Crestor			C	Unknown	10 Mg		Not Reported
	Atenolol			C	Unknown	50 Mg		Not Reported
	Triatec (Ramipril)			C	Unknown	1.25 Mg		Not Reported
	Zolpidem			C	Unknown	5 Mg		Not Reported
	Lamictal			C	Unknown	100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2015	11740981	EXPEDITED (15-DAY)		HO, OT	FR-009507513-1511FRA005269		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Encephalopathy; Incoherent	Ezetrol			S	Oral	10 Mg, Qpm		Merck
	Cefepime			S	Intravenous (not otherwise specified)	2 G, Q12h		Not Reported
	Escitalopram			S		1 Tablet, Qpm		Not Reported
	Bromazepam			S		0.25 Tablet, Qpm		Not Reported
	Zolpidem			S		1 Tablet, Qpm		Not Reported

	Lasilix	S	Oral	20 Mg, At Midday (Daily)	Not Reported
	Lasilix	S	Oral	Unk	Not Reported
	Ferrograd C (Ascorbic Acid (+) Ferrous Sulfate)	S		1 Tablet Qam And 1 Tablet Qpm	Not Reported
	Ferrograd C (Ascorbic Acid (+) Ferrous Sulfate)	S		Unk	Not Reported
	Calciparine	S	Subcutaneous	1 Injection In The Morning And Evening	Not Reported
	Kardegic	S		1 Bag At Midday	Not Reported
	Pantoprazole	S		1 Tablet, Qam	Not Reported
	Pravastatin	S		40 Mg, Qpm	Not Reported
	Ikorel	C		0.5 Tablet Qam	Not Reported
	Ikorel	C		0.75 Tablet , Qpm	Not Reported
	Aldactone (Spironolactone)	C		1 Tablet, At Midday (Daily)	Not Reported
	Pyridoxine (+) Thiamine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2015	11748883	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2015-10171		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cognitive Disorder; Confusional State; Disorientation; Hypercreatininaemia; Hypoalbuminaemia; Hypochloraemia; Hypokalaemia; Hyponatraemia; Hypoproteinaemia; Leukoencephalopathy; Renal Failure; Tachycardia	Escitalopram Arrow Film-Coated Tablet 5mg			S	Oral	5 Mg, Daily		Aurobindo
	Perindopril Actavis			S	Oral	8 Mg, Daily		Not Reported
	Esidrex			S	Oral	12.5 Mg, Daily		Not Reported
	Esomeprazole			S	Oral	40 Mg, Daily		Not Reported
	Aerius /01009701/			C	Oral	5 Mg, Daily		Not Reported
	Movicol /01625101/			C	Oral	1 Df, Daily		Not Reported
	Seresta			C	Oral	10 Mg, Daily		Not Reported
	Dexeryl /00557601/			C	Subcutaneous	Unk		Not Reported
	Monazol			C	Subcutaneous	Unk		Not Reported
	Avamys			C	Respiratory (inhalation)	Unk		Not Reported

Uvedose	C	Oral	0.0333 Once Monthly		Not Reported
Lercan	C	Oral	20 Mg, Daily		Not Reported
Aerius /01009701/	C	Oral	5 Mg, Daily		Not Reported
Proctolog /01026901/	C	Unknown	3 Applications Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2015	11749762	EXPEDITED (15-DAY)		OT	CH-FRI-1000080850		64 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronotropic Incompetence	Escitalopram			S	Oral	20 Mg		Forest
	Aspirin (Acetylsalicylic Acid)			C	Oral	100 Mg		Not Reported
	Lisitril Comp. (Hydrochlorithiazide/Lisinopril)			C	Oral			Not Reported
	Crestor (Rosuvastatin Calcium)			C	Oral	10 Mg		Not Reported
	Brilique (Ticagrelor)			C	Oral	180 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2015	11751171	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014530		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Headache; Movement Disorder; Pain In Jaw; Rapid Eye Movements Sleep Abnormal; Restlessness	Escitalopram Oxalate			S	Unknown			Apotex
	Sertraline Hydrochloride			S	Unknown			Apotex
	Bupropion			C	Unknown	300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2015	11751994	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2015GSK160733			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Chronic	Lamictal			S	Unknown	Unk		Glaxosmithkline

Obstructive Pulmonary Disease; Depression; Glucose Tolerance Impaired; Rash	Spironolactone		S	Unknown	Unk	Glaxosmithkline
	Lexapro		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2015	11752280	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014529		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Jittery; Movement Disorder; Neurological Decompensation; Suicidal Ideation	Fluoxetine Oral Solution Usp			S	Unknown	Unk		Apotex
	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Apotex
	Escitalopram Oxalate			S	Unknown	20 Mg, Unk		Apotex
	Sertraline Hydrochloride			S	Unknown	25 Mg, Unk		Apotex
	Sertraline Hydrochloride			S				Apotex
	Zyprexa			C				Not Reported
	Mirtazapine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2015	11753628	EXPEDITED (15-DAY)		HO	PHHY2015ES148840		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia; Syncope	Co-Diovan Forte			S	Oral	Unk		Novartis
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2015	11754230	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2015-10291		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Agitation; Blood Creatinine Increased; Blood Urea Increased; C-Reactive	Bromazepam Tablet			S	Oral	0.25 Df, Once A Dayin Evening		Not Reported
	Escitalopram Arrow Film-Coated Tablets			S	Oral	1 Df, Once A Day In		Aurobindo

Protein Increased; Clonus; Condition Aggravated; Confusional State; Dysphagia; Encephalopathy; Incoherent; Platelet Count Decreased; Uraemic Encephalopathy				Evening	
	Pantoprazole Arrow Gastro-Resistant Tablet	S	Oral	1 Df, Once A Day, In Morning	Aurobindo
	Pravastatin Arrow Tablets 40mg	S	Oral	1 Df, Once A Day In Evening	Not Reported
	Zolpidem Film-Coated Tablet	S	Oral	1 Df, Once A Day In Evening	Aurobindo
	Cefipime	S	Intravenous (not otherwise specified)	2 G, Every 12 Hours	Not Reported
	Lasilix /00032601/	S	Oral	0.5 Df, Once A Day	Not Reported
	Ferograd	S	Oral	1 Df, In The Morning And Evening	Not Reported
	Calciparine	S	Subcutaneous	1 Df, In The Morning And Evening	Not Reported
	Kardegic	S		1 Sachet At Noon	Not Reported
	Ezetrol	S	Oral	1 Df, In Evening	Not Reported
	Ikorel	C		0.5 Tablet Morning, And 0.75 Tablet Evening	Not Reported
	Aldactone /00006201/	C		I Tablet At Noon	Not Reported
	Vitamin B	C		1 Tablet Morning	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2015	11755199	EXPEDITED (15-DAY)		HO	FR-FRI-1000081012		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Encephalopathy; Incoherent	Escitalopram			S	Oral	10 Mg		Forest
	Cefepime Mylan			S	Intravenous (not otherwise specified)	4 G		Not Reported
	Bromazepam			S	Oral	0.25 Mg		Not Reported
	Zolpidem			S	Oral	10 Mg		Not Reported
	Lasilix			S	Oral	20 Mg		Not Reported
	Ferograd			S	Oral	1000 Mg		Not Reported

Calciparine	S	Subcutaneous	0.4 Ml		Not Reported
Kardegic	S	Oral	75 Mg		Not Reported
Pantoprazole	S	Oral	20 Mg		Not Reported
Ezetrol	S	Oral	10 Mg		Not Reported
Pravastatin Arrow	S	Oral	40 Mg		Not Reported
Ikorel	C	Oral	20 Mg		Not Reported
Aldactone	C	Oral	25 Mg		Not Reported
Vitamin B1 And B6	C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11756837	EXPEDITED (15-DAY)		OT	US-ACCORD-035293		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Diarrhoea; Hypoaesthesia; Malaise; Vomiting	Escitalopram Accord			S	Oral	Strength: 5 Mg 2 Tablets Daily		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11757002	EXPEDITED (15-DAY)		OT	US-ZYDUS-009521		10 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Neuromyopathy; Sedation; Sleep Disorder; Suicidal Ideation; Therapeutic Product Effect Incomplete	Escitalopram			S				Not Reported
	Fluoxetine/Fluoxetine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11757307	EXPEDITED (15-DAY)		DE, OT	PHHY2015US151881		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Level Increased	Metoprolol			S	Unknown			Not Reported

	Diclofenac	S	Unknown			Novartis
	Ibuprofeno	S	Unknown			Not Reported
	Oxycodone Hydrochloride	S	Unknown			Not Reported
	Cyclobenzaprine	S	Unknown			Not Reported
	Nitroglycerin Sandoz	S	Unknown	Unk		Not Reported
	Clonidine	S	Unknown			Not Reported
	Lisinopril	S	Unknown			Not Reported
	Escitalopram	S	Unknown			Not Reported
	Azithromycin	S	Unknown			Not Reported
	Methylprednisolone	S	Unknown			Not Reported
	Doxycycline	S	Unknown			Not Reported
	Cefalexin	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11757362	EXPEDITED (15-DAY)		DE	PHHY2015US151883		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diclofenac			S	Oral			Novartis
	Ondansetron			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Liothyronine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Sertraline			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Acetaminophen W/Hydrocodone			S	Oral			Not Reported
	Linaclotide			S	Oral			Not Reported
	Lubiprostone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11760980	EXPEDITED (15-DAY)		HO	FR-SA-2015SA180120		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Encephalopathy; Incoherent	Bromazepam			S	Unknown			Not Reported
	Zolpidem			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Calciparine			S	Subcutaneous			Not Reported
	Kardegic			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Cefepime			S	Intravenous (not otherwise specified)			Not Reported
	Fero Grad Vitamine C			S	Unknown			Not Reported
	Ezetrol			S	Unknown			Not Reported
	Pravastatine			S	Unknown			Not Reported
	Ikorel			C	Unknown	0,5 Df Morning, 0,75 Df Evening		Not Reported
	Aldactone			C	Unknown			Not Reported
	Vitamin B1 And B6			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11761478	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2015GSK165203		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alanine Aminotransferase Increased; Aphasia; Aphasia; Appetite Disorder; Aspartate	Clonazepam			S				Glaxosmithkline
	Lamotrigine			S				Glaxosmithkline
	Lithium Carbonate			S				Glaxosmithkline
	Escitalopram			S				Glaxosmithkline
	Bupropion			S				Glaxosmithkline

Aminotransferase Increased; Blood Insulin Increased; Body Mass Index Increased; Distractibility; Exercise Lack Of; Fibrosis; Food Craving; Hepatic Steatosis; Hyperphagia; Liver Function Test Increased; Mania; Mental Impairment; Non-Alcoholic Steatohepatitis; Obesity; Restlessness; Sleep Disorder; Splenomegaly; Steatohepatitis; Stress; Weight Increased	Diphenhydramine Hcl	S			Glaxosmithkline
	Quetiapine	S			Glaxosmithkline
	Minocycline\Minocycline Hydrochloride	S			Glaxosmithkline
	Metformin	S			Glaxosmithkline
	Sertraline	S	50 Mg, Qd		Not Reported
	Cetirizine	S	Unk		Not Reported
	Naproxen	S	Unk		Not Reported
	Cyclobenzaprine	S			Not Reported
	Lorazepam	S	0.5 Mg, Unk		Not Reported
	Oxcarbazepine	S			Not Reported
	Aripiprazole	S			Not Reported
	Docusate Sodium	S			Not Reported
	Acetylcysteine	S			Not Reported
	Methylphenidate	S			Not Reported
	Clonidine	S			Not Reported
	Pregabalin	S			Not Reported
	Levothyroxine	S			Not Reported
	Vitamin B Complex	S	Unk		Not Reported
	Cholecalciferol	S	Unk		Not Reported
	Melatonin	S			Not Reported
	Tizanidine	S	Unk		Not Reported
	Ondansetron	S			Not Reported
	Amphetamine	S			Not Reported
	Dextroamphetamine	S			Not Reported
	Norgestimate And Ethinyl Estradiol	S			Not Reported
	Lurasidone	S			Not Reported
	Polyethylene Glycol	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11762768	EXPEDITED (15-DAY)		OT	FR-SYMPLMED PHARMACEUTICALS-2014SYM00055		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Confusional State; Incorrect Dose Administered; Medication	Aceon			S	Oral	10 Mg, Qd		Symplmed Pharmaceuticals

Error	Aceon		S	Oral	10 Mg, Bid	Symplmed Pharmaceuticals
	Diamicron Nos		S	Oral	1 Df, Qd	Not Reported
	Diamicron Nos		S	Oral	1 Df, Bid	Not Reported
	Mono-Tildiem		S	Oral	300 Mg, Qd	Not Reported
	Mono-Tildiem		S	Oral	300 Mg, Bid	Not Reported
	Seroplex		S	Oral	10 Mg, Qd	Not Reported
	Seroplex		S	Oral	10 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2015	11768075	NON-EXPEDITED			US-JNJFOC-20151019552			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error	Zyrtec		Y	S	Unknown			Not Reported
	Zyrtec			S	Unknown			Not Reported
	Zantac		Y	S	Unknown			Not Reported
	Advil			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2015	11768786	NON-EXPEDITED			US-PFIZER INC-2015389789			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Lyrica			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2015	11770774	EXPEDITED (15-DAY)		DE, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2015VAL000770		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death; Drug Level Increased	Metoprolol Tartrate	S	Unk	Validus
	Diclofenac	S	Unk	Not Reported
	Ibuprofeno (Ngx)	S	Unk	Not Reported
	Oxycodone Hydrochloride (Ngx)	S	Unk	Not Reported
	Cyclobenzaprine (Ngx)	S	Unk	Not Reported
	Nitroglycerin Sandoz (Ngx)	S	Unk	Not Reported
	Clonidine (Ngx)	S	Unk	Not Reported
	Lisinopril (Ngx)	S	Unk	Not Reported
	Escitalopram (Ngx)	S	Unk	Not Reported
	Azithromycin (Ngx)	S	Unk	Not Reported
	Methylprednisolone (Ngx)	S	Unk	Not Reported
	Doxycycline (Ngx)	S	Unk	Not Reported
	Cefalexin (Ngx)	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11699112	EXPEDITED (15-DAY)		HO, LT, OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-076260		66 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Pain; Delirium; Disorientation; Psychotic Disorder	Nivolumab			S	Intravenous (not otherwise specified)	Unk Mg, Unk		Bristol Myers Squibb
	Morphine Sulfate			S	Unknown			Bristol Myers Squibb
	Cipralex /01588501/			S	Unknown	20 Mg/Ml, Unk		Not Reported
	Palladon			S	Unknown	4 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	5 Mg, Unk		Not Reported
	Novalgin /00169801/			S	Unknown	500 Mg, Unk		Not Reported
	Stilnox			S	Unknown	12.5 Mg, Unk		Not Reported
	Palexia			S	Unknown	100 Mg, Unk		Not Reported
	Motilium /00498201/			C	Unknown	10 Mg, Tid		Not Reported
	Ponstan			C	Unknown	500 Mg, Tid		Not Reported

Dafalgan	C	Unknown	1 G, Unk		Not Reported
Neupogen	C	Unknown			Not Reported
Paspertin /00041902/	C	Unknown	10 Mg, Unk		Not Reported
Folvite /00024201/	C	Unknown	1 Mg, Qd		Not Reported
Pantozol /01263204/	C	Unknown	40 Mg, Unk		Not Reported
Emend /01627301/	C	Unknown			Not Reported
Prednison	C	Unknown	20 Mg, Unk		Not Reported
Transipeg /00754501/	C	Unknown			Not Reported
Imodium	C	Unknown	2 Mg, Unk		Not Reported
Zofran /00955301/	C	Unknown	4 Mg, Unk		Not Reported
Alopexy	C	Unknown	60 Ml, Unk		Not Reported
Pantoprazol	C	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772212	EXPEDITED (15-DAY)		HO	TR-FRI-1000081105		68 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Drug Interaction	Escitalopram			S	Unknown	10 Mg		Forest
	Dabigatran			S	Unknown	110 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772953	NON-EXPEDITED			US-PFIZER INC-2015394302			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Nexium			S		Unk		Unknown
	Erythromycin			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported
	Hctz			S		Unk		Not Reported
	Toprol Xl			S		Unk		Not Reported

	Ventolin	S	Unk	Not Reported
	Crestor	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11774506	EXPEDITED (15-DAY)		HO, OT	DE-FRI-1000081180		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Diarrhoea; Electrolyte Imbalance; Fall; Muscle Spasms; Product Use In Unapproved Indication	Escitalopram			S	Unknown	10 Mg		Forest
	Escitalopram			S	Unknown	15 Mg		Forest
	Atarax			C	Unknown			Not Reported
	Cetirizin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2015	11777504	EXPEDITED (15-DAY)		HO	KR-FRI-1000081118		76 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haemorrhage	Escitalopram			S	Oral	10 Mg		Forest
	Xanax			C	Oral	0.25 Mg		Not Reported
	Xanax			C	Oral			Not Reported
	Mirapex			C	Oral	0.125 Mg		Not Reported
	Harnal-D			C	Oral	0.2 Mg		Not Reported
	Motilium-M			C	Oral	30 Mg		Not Reported
	Sinemet 25/100			C	Oral	25/100 Mg		Not Reported
	Synthyroid			C	Oral	0.1 Mg		Not Reported
	Solondo			C	Oral	10 Mg		Not Reported
	Minirin			C	Oral	120 Mcg		Not Reported
	Vytorin 10/10			C	Oral			Not Reported
	Superpirin			C	Oral			Not Reported
	Vastinan			C	Oral	35 Mg		Not Reported
	Nexium			C	Oral	20 Mg		Not Reported

	Azilect			C	Oral	1 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2015	11777576	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03800			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Neuromyopathy; Psychiatric Decompensation; Sedation; Suicidal Ideation	Fluoxetine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Sertraline			C	Unknown			Not Reported
	Sertraline			C				Not Reported
	Mirtazapine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2015	11777625	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-15-01			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuromyopathy; Psychiatric Decompensation; Suicidal Ideation	Escitalopram			S	Unknown			Hikma
	Escitalopram			S	Unknown			Hikma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2015	11778169	NON-EXPEDITED			US-ASTRAZENECA-2015SF17951			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus	Lexapro			S	Unknown			Not Reported
	Seroquel			S	Oral			Zeneca

	Suboxone	S	Unknown		Not Reported
	Lunesta	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2015	11779395	NON-EXPEDITED			US-PFIZER INC-2015399794			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Pristiq			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2015	11784968	DIRECT		DS, HO			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nightmare; Paranoia; Psychotic Disorder	Lexapro 20 Mg Camber			S	Oral	1 Pill		Not Reported
	Acarbose			C				Not Reported
	Norvasc			C				Not Reported
	Calcium 600mg + D3			C				Not Reported
	Vitamin D3			C				Not Reported
	Lexapro			C				Not Reported
	Vagifem			C				Not Reported
	Prenatal Vitamins			C				Not Reported
	Ambien			C				Not Reported
	Systane			C				Not Reported
	Vitamin E			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2015	11780540	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-082450			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S	Unknown	Unk		Bristol Myers Squibb
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2015	11780979	NON-EXPEDITED			US-JNJFOC-20151113302		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Psychomotor Hyperactivity	Zyrtec 10mg Ir Tablet		Y	S	Oral			Not Reported
	Zyrtec 10mg Ir Tablet			S	Oral	1 Tablet, 1x Per Day		Not Reported
	Focalin			S	Unknown	1 Tab Once Every Morning For 2+Years		Not Reported
	Lexapro			S	Unknown	1 Tab Once Qd Am For 2 Years		Not Reported
	Singulair			S	Unknown	1 Tab/1x Qd Hs 3-4 Years		Not Reported
	Ritalin			S	Unknown	1 Tab/1x Qd Afternoon (1 Years)		Not Reported
	Melatonin			S	Unknown	2 Tabs/1x Qd Hs 1 Year		Not Reported
	Nasonex			S	Unknown	1 Sq/1x Qd Bilat As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2015	11780981	EXPEDITED (15-DAY)		OT	US-HETERO LABS LTD-1044689		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuromyopathy; Suicidal Ideation	Escitalopram			S	Unknown			Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2015	11762447	NON-EXPEDITED		OT	PHEH2015US024125			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apnoea; Asthenopia; Cd4 Lymphocytes Decreased; Cd8 Lymphocytes	Gilenya			S	Oral	0.5 Mg, Qod		Novartis
	Nuedexta /07198301/			S	Unknown			Not Reported
	Nuedexta /07198301/			S				Not Reported

Decreased; Cervical Radiculopathy; Cognitive Disorder; Constipation; Contusion; Coordination Abnormal; Depression; Disturbance In Attention; Dizziness; Dry Eye; Fatigue; Headache; Herpes Zoster; Macular Oedema; Malaise; Middle Insomnia; Migraine; Multiple Sclerosis Relapse; Muscle Spasms; Neck Pain; Neuralgia; Pain; Prescribed Underdose; Restlessness; Snoring; Stress; Vision Blurred; Vitamin B12 Deficiency; Vitamin D Deficiency; White Blood Cell Count Decreased	Lexapro	S	Oral	20 Mg, (0.5 Tablet) For 7 Days	Not Reported
	Lexapro	S	Oral	20 Mg, Qd	Not Reported
	Alprazolam	C	Oral	0.5 Mg, Tid	Not Reported
	Calcium + Vit D	C	Unknown	500 Mg, Unk	Not Reported
	Crestor	C	Oral	10 Mg, (At Bed Time)	Not Reported
	Escitalopram Oxalate	C	Unknown	20 Mg, Unk	Not Reported
	Bupropion Hcl	C	Oral	100 Mg, (In Morning)	Not Reported
	Levetiracetam	C	Oral	500 Mg, (1 In The Am And 2 In Qhs)	Not Reported
	Nexum	C	Oral	40 Mg, Qd	Not Reported
	Tizanidine Hcl	C	Oral	4 Mg, Qd (At Bed)	Not Reported
	Tysabri	C	Unknown		Not Reported
	Copaxone	C	Unknown		Not Reported
	Tamsulosin Hcl	C	Unknown	0.4 Mg, (1 Daily As Needed)	Not Reported
	Carbamazepine	C	Unknown	200 Mg, (1 Tablet At Bed Time)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2015	11787247	EXPEDITED (15-DAY)		HO, OT	TW-ACTAVIS-2015-16624		38 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Delirium; Drug Interaction; Refusal Of Treatment By Patient	Disulfiram (Unknown)			S	Unknown	200 Mg, Daily		Watson
	Griseofulvin (Unknown)			S	Unknown	500 Mg, Daily		Actavis Mid Atlantic
	Escitalopram (Unknown)			S	Unknown	10 Mg/D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2015	11787849	NON-EXPEDITED			GXBR2015US000936		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension; Rash	Nadolol		S	Oral	10 Mg Am / 30 Mg Hs	Novartis
	Escitalopram		S	Unknown	5 Mg, Unk	Not Reported
	Mirtazapine		C	Oral	15 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11519211	EXPEDITED (15-DAY)		HO	IT-FRI-1000079608		66 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amylase Increased; Lipase Increased	Escitalopram			S	Oral			Forest
	Metfonorm 1000mg Compresse Rivestite Con Film/Metformin			S	Oral	3 Gram		Not Reported
	Cardio Aspirin			S	Oral			Not Reported
	Pramipexolo Eg 0,18mg Compresse/Pramipexole			C	Oral			Not Reported
	Deursil 450mg Capsule Rigide A Rilascio Prolungato/Ursodeoxycholic Aci			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11784017	EXPEDITED (15-DAY)		OT	PHHY2015SI152993		87 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Dizziness; Fall; Hypotonia; Insomnia; Musculoskeletal Pain; Pain In Extremity; Spinal Pain; Tachycardia; Urinary Incontinence; Vision Blurred	Quetiapine			S	Unknown	100 Mg, Qd (In Evening)		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd (In Morning)		Not Reported
	Acetylsalicylic Acid			S	Unknown	100 Mg, Qd (At Noon)		Not Reported
	Furosemide			S	Unknown	40 Mg, Qd (3 Days)		Not Reported
	Bisoprolol			S	Unknown	1.25 Mg, Qd (In Morning)		Not Reported
	Omeprazole			S	Unknown	20 Mg, Qd (In Morning)		Not Reported
	Rivastigmine Sandoz			S	Unknown	13.3 Mg, Qd (24 Hour)		Not Reported
	Metformin Hydrochloride Sandoz			S	Unknown	1000 Mg, Bid		Not Reported
	Gliclazide			S	Unknown	60 Mg, Qd		Not Reported
	Atorvastatin			S	Unknown	40 Mg, Qd		Not Reported

	Atorvastatin		S	Unknown	20 Mg, Unk	Not Reported
	Tramadol+Paracetamol		S	Unknown	Unk	Not Reported
	Butylscopolamine		S	Unknown	10 Mg, Tid	Not Reported
	Nitrazepam		S	Unknown	5 Mg, Qd (In Evening)	Not Reported
	Bisacodyl		S	Unknown	When Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11788440	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-082369			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Abilify			S	Unknown			Bristol Myers Squibb
	Clonopin			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11788863	EXPEDITED (15-DAY)		OT	FR-WATSON-2015-17253			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram (Unknown)			S	Unknown	Unk		Not Reported
	Escitalopram (Unknown)			S				Not Reported
	Sertraline (Unknown)			S	Unknown	Unk		Watson
	Sertraline (Unknown)			S				Watson
	Venlafaxine (Unknown)			S	Unknown	225 Mg, Daily		Not Reported
	Risperidone (Unknown)			S	Unknown	2 Mg/Day		Watson
	Risperidone (Unknown)			S		2 Mg/Day		Watson
	Paroxetine (Unknown)			S	Unknown	40 Mg, Daily		Not Reported
	Paroxetine (Unknown)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11789353	EXPEDITED (15-DAY)		HO, LT, OT	FR-ELI_LILLY_AND_COMPANY-FR201511008927		< 1 DAY	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Foetal Distress Syndrome; Foetal Heart Rate Decreased; Hypotonia Neonatal; Infantile Apnoea; Large For Dates Baby; Meconium In Amniotic Fluid; Neonatal Respiratory Distress Syndrome; Neurological Symptom; Tremor; Withdrawal Syndrome	Prozac			S	Transplacental	Unk, Unknown		Eli Lilly And Co
	Anafranil			S	Transplacental	75 Mg, Bid		Not Reported
	Seroplex			S	Transplacental	10 Mg, Qd		Not Reported
	Seresta			S	Transplacental	10 Mg, Qid		Not Reported
	Seresta			S	Transplacental	10 Mg, Qid		Not Reported
	Valium			S	Transplacental	Unk, Unknown		Not Reported
	Tegeline			C	Transplacental	2 Courses, Unknown		Not Reported
	Prednisolone			C	Transplacental	1mg/Kg/24hour		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11789725	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1041487			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Condition Aggravated; Reaction To Excipient	Clonazepam Tablets, Usp			S		Unk		Mylan
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11792232	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-081236			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Disturbance In Attention; Dizziness; Fatigue; Gait Disturbance; Hyperhidrosis; Hypotension; Pruritus Generalised	Abilify			S	Oral	10 Mg, Qd		Bristol Myers Squibb
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Trihexyphenidyl			S	Oral	2 Mg, Qd		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Quetiapine Fumarate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11792254	EXPEDITED (15-DAY)		OT	IL-MUNDIPHARMA DS AND		83 YR	Male	ISR

PHARMACOVIGILANCE
-GBR-2015-0

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Euphoric Mood; Hypervigilance; Insomnia; Restlessness	Targin 10/5 Mg Cr Tablet			S	Unknown	10 Mg, Bid		Purdue
	Targin 10/5 Mg Cr Tablet			S	Unknown	10 Mg, Bid		Purdue
	Cipralex			S	Unknown	15 Mg, Unk		Not Reported
	Cipralex			S	Unknown	10 Mg, Unk		Not Reported
	Lyrica			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11793195	DIRECT	Y				67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Product Quality Issue; Product Substitution Issue	Escitalopram 20mg Accord			S	Oral	1 Tab Qd Oral		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11793744	DIRECT		OT			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Pregnancy	Lexapro			S	Oral	Po Qam		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11553113	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015GSK136512			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity;	Paxil			S		Unk, U		Glaxosmithkline

Drug Ineffective; Product Complaint	Seroquel		S	Unk Unk, U	Glaxosmithkline
	Effexor		S	Unk, U	Glaxosmithkline
	Cymbalta		S	Unk, U	Glaxosmithkline
	Lexapro		S	Unk, U	Not Reported
	Prozac		S	Unk, U	Not Reported
	Zoloft		S	Unk, U	Not Reported
	Remeron		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11794534	NON-EXPEDITED			US-WARNER CHILCOTT, LLC-1044942		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia	Lo Loestrin Fe			S	Oral			Warner Chilcott
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11795133	EXPEDITED (15-DAY)		OT	DE-FRI-1000081344		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Exposure During Pregnancy; Hypoglycaemia Neonatal	Escitalopram			S	Transplacental	20 Mg		Forest
	Euthyrox			C	Unknown	100 Microgram		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11795299	EXPEDITED (15-DAY)		CA, DS	FR-PFIZER INC-2015413184			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Malnutrition; Low Birth Weight Baby; Maternal Drugs Affecting	Xanax			S	Transplacental	Unk		Pfizer
	Baclofen Zentiva			S	Transplacental	21 Df, Daily		Not Reported
	Baclofen Zentiva			S		12 Df, Daily		Not Reported

Foetus; Maternal Exposure During Pregnancy	Seresta		S	Transplacental	Unk	Not Reported
	Seroplex		S	Transplacental	1 Df, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11796973	DIRECT		DS, OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia; Paraesthesia	Lexapro			S	Oral	1 Pill		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2015	11796384	NON-EXPEDITED			US-PFIZER INC-2015407924		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Benzylpenicillin Potassium			S		Unk		Pfizer
	Sulfa /00076401/			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2015	11798517	NON-EXPEDITED			US-REGENERON PHARMACEUTICALS, INC.-2015-11719			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia; Erythema Of Eyelid; Foreign Body Sensation In Eyes; Hordeolum; Metamorphopsia; Swelling Of Eyelid; Vision Blurred	Eylea			S	Intraocular	Every 4 Weeks, Od		Regeneron
	Eylea			S	Intraocular	Every 4 Weeks, Od		Regeneron
	Eylea			S	Intraocular	Every 4-5 Weeks, Od		Regeneron
	Eylea			S		Every 4-5 Weeks, Od		Regeneron
	Lexapro			S		Unk		Not Reported

	Synthroid	C	Unk	Not Reported
	Potassium	C	Unk	Not Reported
	Furosemide	C	Unk	Not Reported
	Metoprolol	C	Unk	Not Reported
	Lisinopril	C	Unk	Not Reported
	Aspirin /00002701/	C	Unk	Not Reported
	Vitamins /00067501/	C	Unk	Not Reported
	Reclast	C	Unk, Once A Year	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2015	11801593	DIRECT		OT			64 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Product Quality Issue; Product Substitution Issue	Escitalopram 20mg Camber			S	Oral		1 WEEK	Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2015	11771941	EXPEDITED (15-DAY)		HO	FR-WATSON-2015-25450			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drop Attacks	Zolpidem (Unknown)			S	Oral	1 Df, Daily		Watson
	Gabapentine			S	Oral	100 Mg, Tid		Not Reported
	Esidrex			S	Oral	12.5 Mg, Daily		Not Reported
	Irbesartan Arrow			S	Oral	300 Mg, Daily		Not Reported
	Plavix			S	Oral	75 Mg, Daily		Not Reported
	Valium			S	Oral	5 Mg, Bid		Not Reported
	Seroplex			S	Oral	15 Mg, Daily		Not Reported
	Seroplex			S	Oral	10 Mg, Daily		Not Reported
	Levothyrox			S	Oral	150 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2015	11802687	EXPEDITED (15-DAY)		OT	DE-FRI-1000081349		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Microcephaly; Small For Dates Baby	Escitalopram			S	Transplacental	10 Mg		Forest
	Haes-Steril			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2015	11803440	EXPEDITED (15-DAY)		OT	DE-FRI-1000081347		< 1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	20 Mg		Forest
	Escitalopram			S	Transplacental	15 Mg		Forest
	Escitalopram			S	Transplacental	10 Mg		Not Reported
	Thyronajod			C	Transplacental	100 Mcg/150 Mcg		Not Reported
	Utrogest			C	Transplacental	600 Mg		Not Reported
	Vitaverlan			C	Transplacental	.4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11786567	EXPEDITED (15-DAY)		OT	DE-TAKEDA-2015TUS017087		23 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Liver Injury	Brintellix			S	Oral	10 Mg, Qd		Takeda
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Seroquel			S	Unknown	75 Mg, Qd		Not Reported
	Quilonum			C	Oral	62.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11795100	EXPEDITED (15-DAY)		OT	KR-JNJFOC-20151122831		66 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Delirium; Pneumonia; Tremor	Velcade			S	Subcutaneous	Cycle 6		Not Reported
	Velcade			S	Subcutaneous	Cycle 7		Not Reported
	Velcade			S	Subcutaneous	Cycle 5		Not Reported
	Velcade			S	Subcutaneous	Cycle 4		Not Reported
	Velcade			S	Subcutaneous	Cycle 3 Day 1 To Day 50		Not Reported
	Velcade			S	Subcutaneous	Cycle 2 Day 1 To Day 50		Not Reported
	Velcade			S	Subcutaneous	Cycle 1 Day 1 To Day 43		Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Melphalan			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Etravil			S	Unknown			Not Reported
	Lamotrigine			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11806205	NON-EXPEDITED			US-ASTRAZENECA-2015SF18971			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Nexium		S	Oral	Unk	Not Reported
	Toprol Xl		S	Oral	Unk	Not Reported
	Crestor		S	Oral	Unk	Not Reported
	Hctz		S	Unknown	Unk	Not Reported
	Celebrex		S	Unknown	Unk	Not Reported
	Escitalopram		S	Unknown	Unk	Not Reported
	Ventolin		S	Unknown	Unk	Not Reported
	Erythromycin		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11808339	NON-EXPEDITED			US-ROCHE-1494235		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oropharyngeal Pain; Visual Acuity Reduced	Valium			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Tizanidine			S	Nasal			Not Reported
	Oxycodone			S	Unknown	10/325 Mg One Of Them		Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown	Night		Not Reported
	Effexor			S	Unknown	75mg Capsule And A 150mg Capsule Together		Not Reported
	Lexapro			S	Unknown			Not Reported
	Aspirin			S	Unknown	2 Tablet At Night		Not Reported
	Simvastin			S	Unknown			Not Reported
	Topamax			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Fentanyl Patch			S	Unknown			Not Reported
	Demadex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11808405	NON-EXPEDITED			US-ROCHE-1645581			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Fatigue; Insomnia	Valium			S	Unknown	2 Ml At Night		Not Reported
	Valium			S	Unknown	2 And Half Ml In The Morning		Not Reported
	Lexapro			S	Unknown	2 Ml At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11810143	DIRECT	Y	HO			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bipolar Disorder; Dementia; Mania; Suicidal Ideation	Escitalopram 20 Mg			S	Oral			Not Reported
	Metformin			C				Not Reported
	Januvia			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Glimepride			C				Not Reported
	Lexapro			C				Not Reported
	Xarelto			C				Not Reported
	Diltiazem			C				Not Reported
	Tamsulosin			C				Not Reported
	Simvastatin			C				Not Reported
	Oxybutynin			C				Not Reported
	Temazepam			C				Not Reported
	Irbesartan			C				Not Reported
	Doxepin			C				Not Reported
	Trazodone			C				Not Reported
	Glyburide			C				Not Reported
	Enalapril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11810173	DIRECT		HO			19 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Vomiting	Zoloft	S	Oral	1 Pill	1 DAY	Not Reported
	Lexapro	S	Oral	1 Pill	2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11810177	DIRECT					33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Dysphagia; Gastrooesophageal Reflux Disease; Maternal Exposure During Pregnancy; Pregnancy; Vomiting	Cirpalex			S	Oral	1 Pill	6 YR	Lundbeck
	Cipralex Diclectin			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11810681	DIRECT					48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Product Substitution Issue	Escitalopram 20 Mg Mylan			S	Oral			Mylan
	Lorazepam			C				Not Reported
	Sam-E			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2015	11627978	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2015-08982		57 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug Abuse; Presyncope	Mirtazapine			S	Oral	60 Mg Total		Aurobindo
	Mirtazapine			S	Oral	30 Mg, Daily		Aurobindo
	Olanzapine			S	Oral	20 Mg Total		Aurobindo
	Olanzapine			S	Oral	10 Mg, Daily		Aurobindo
	Cipralex /01588501/			S	Oral	2 Df Total		Not Reported
	Cipralex /01588501/			S	Oral	20 Mg, Daily		Not Reported

Lyrica	C	Unknown	75 Mg, Unk		Not Reported
Folina /00024201/	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2015	11652680	EXPEDITED (15-DAY)		CA, LT, OT	JP-ASTRAZENECA-2015SF01971			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Dyspnoea; Infantile Apnoea; Neonatal Asphyxia; Transient Tachypnoea Of The Newborn	Seroquel			S	Transplacental	25-50 Mg, Once Daily		Not Reported
	Lexapro			S	Transplacental			Not Reported
	Utemerin			S	Transplacental			Not Reported
	Selbex			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2015	11771088	EXPEDITED (15-DAY)		HO, OT	FR-ROCHE-1662324			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drop Attacks; Fall; Muscular Weakness	Valium			S	Oral			Not Reported
	Esidrex			S	Oral			Not Reported
	Irbesartan Arrow			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Plavix			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2015	11809692	EXPEDITED (15-DAY)		HO	FR-009507513-1512FRA001916		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Psoriasis	Inegy	S	Oral	Unk		Merck
	Chibro-Proscar	S	Oral	Unk		Merck
	Seroplex	S	Oral	Unk		Not Reported
	Amiodarone	S	Oral	Unk		Not Reported
	Previscan (Fluindione)	S	Oral	Unk		Not Reported
	Bisoprolol Fumarate	S	Oral	Unk		Not Reported
	Tareg	S	Oral	Unk		Not Reported
	Lasilix	S	Oral	Unk		Not Reported
	Novo-Norm	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2015	11810850	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015424373		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Respiratory Arrest	Alprazolam			S	Oral	Unk		Pfizer
	Gabapentin			S	Oral	Unk		Pfizer
	Oxycodone			S	Oral	Unk		Not Reported
	Oxymorphone			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Trazodone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11801311	EXPEDITED (15-DAY)		OT	KR-TAKEDA-2015MPI008137			Unknown	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Delirium; Pneumonia; Tremor	Velcade			S	Subcutaneous	1.3 Mg/M2, Unk		Takeda
	Velcade			S	Subcutaneous	1.3 Mg/M2, Unk		Takeda
	Velcade			S	Subcutaneous	1.3 Mg/M2, Unk		Takeda
	Velcade			S	Subcutaneous	1.3 Mg/M2, Unk		Takeda
	Velcade			S	Subcutaneous	1.3 Mg/M2, Unk		Takeda

	Velcade	S	Subcutaneous	1.3 Mg/M2, Unk	Takeda
	Velcade	S	Subcutaneous	1.3 Mg/M2, Unk	Takeda
	Risperidone	S	Unknown	0.25 Mg, Unk	Not Reported
	Risperidone	S	Unknown	0.5 Mg, Unk	Not Reported
	Tramadol	S	Unknown	150 Mg, Unk	Not Reported
	Prednisone	S	Unknown	7.5 Mg/M2, Unk	Not Reported
	Gabapentin	S	Unknown	100 Mg, Tid	Not Reported
	Gabapentin	S	Unknown	300 Mg, Bid	Not Reported
	Melphalan	S	Unknown	60 Mg/M2, Unk	Not Reported
	Pregabalin	S	Unknown	75 Mg, Qd	Not Reported
	Pregabalin	S	Unknown	150 Mg, Qd	Not Reported
	Etravil	S	Unknown	10 Mg, Qd	Not Reported
	Lamotrigine	S	Unknown	Unk	Not Reported
	Aripiprazole	S	Unknown	2.5 Mg, Unk	Not Reported
	Escitalopram	S	Unknown	2.5 Mg, Unk	Not Reported
	Escitalopram	S	Unknown	5 Mg, Unk	Not Reported
	Morphine	S	Unknown	5 Mg, Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11814084	EXPEDITED (15-DAY)		HO	FR-SA-2015SA205511			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Amiodarone			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Tareg			S	Oral			Not Reported

	Inegy	S	Oral	Not Reported
	Novonorm	S	Oral	Not Reported
	Chibro-Proscar	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11814324	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20151202286		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Intentional Self-Injury; Sleep Disorder; Treatment Noncompliance; Weight Decreased	Risperdal			S	Unknown	Half A Tablet 4 Times Per Day		Not Reported
	Seroplex			S	Unknown			Not Reported
	Stilnox			S	Unknown			Not Reported
	Anafranil			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Lysanxia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11815422	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015428978		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Propanolol Hcl			S				Unknown
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11815594	EXPEDITED (15-DAY)		HO	DE-FRI-1000081547		53 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	5 Mg		Not Reported
	Bupropion			C	Oral	150 Mg		Not Reported

Bupropion	C	Oral	300 Mg		Not Reported
Bisoprolol	C	Oral	5 Mg		Not Reported
Ramipril	C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11815912	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015429533		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Sertraline Hcl			S	Oral			Pfizer
	Acetaminophen			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11815915	EXPEDITED (15-DAY)		HO, OT	US-SUNOVION-2015SUN001182			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Suicidal Behaviour; Suicidal Ideation	Latuda			S	Oral	Unk		Sunovion
	Latuda			S	Oral	Unk		Sunovion
	Lexapro			S		30 Mg, Unk		Not Reported
	Lexapro			S		20 Mg, Unk		Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported
	Lexapro			S		5 Mg, Unk		Not Reported
	Xanax			C		0.25 Mg, About Once Weekly		Not Reported
	Effexor			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11815949	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015425860		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Respiratory Arrest	Morphine Sulfate			S	Oral			Pfizer
	Hydrocodone/Acetaminophen /00607101/			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Cyclobenzaprine			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11818846	DIRECT	Y	HO			91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Oesophagitis Ulcerative; Upper Gastrointestinal Haemorrhage; Vitamin K Deficiency	Xarelto			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Xanax			C				Not Reported
	Norvasc			C				Not Reported
	Vit. B12			C				Not Reported
	Folvite			C				Not Reported
	Norco			C				Not Reported
	Mvi			C				Not Reported
	Zegerid			C				Not Reported
	Zofran			C				Not Reported
	Exelon			C				Not Reported
	Restoril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11839405	NON-EXPEDITED	Y	HO	AUR-APL-2015-06984			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Torasemide 20mg (Torasemide) Unknown, 20mg			S	Oral			Not Reported
	Ascorbic Acid (Ascorbic Acid)			S	Oral			Not Reported
	Lexapro (Escitalopram Oxalate)			S				Not Reported
	Magnesium Oxide (Magnesium			C				Not Reported

	Oxide)				
	Vasotec /00574902/ (Enalapril Maleate)	C	Oral		Not Reported
	Vitamin D3 (Colecalciferol)	S	Oral		Not Reported
	Glucosamine	C			Not Reported
	Fish Oil	C			Not Reported
	Aspirin (Acetylsalicylic Acid)	C			Not Reported
	Mvi (Vitamins Nos)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2015	10738702	EXPEDITED (15-DAY)		DS, OT	NO-PFIZER INC-2015028989		19 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Spasm; Limb Injury; Loss Of Personal Independence In Daily Activities; Muscle Twitching	Zeldox			S		80-40 Mg Per Day		Pfizer
	Cipralex			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2015	11802665	EXPEDITED (15-DAY)		HO, LT	NO-FRI-1000081334		< 1 DAY	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Respiratory Failure; Seizure	Escitalopram			S	Transplacental	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2015	11806069	EXPEDITED (15-DAY)		HO	PHHY2015FR158941		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Tareg			S	Oral	Unk		Not Reported
	Amiodarone			S	Oral	Unk		Novartis

	Bisoprolol	S	Oral	Unk		Not Reported
	Seroplex	S	Oral	Unk		Not Reported
	Previscan (Fluindione)	S	Oral	Unk		Not Reported
	Inegy	S	Oral	Unk		Not Reported
	Lasilix	S	Oral	Unk		Not Reported
	Novonorm	S	Oral	Unk		Not Reported
	Chibro-Proscar	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2015	11821263	EXPEDITED (15-DAY)		DE, HO	US-ASTRAZENECA-2015SF23051		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Quetiapine			S	Oral			Not Reported
	Sertraline			S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2015	11823045	EXPEDITED (15-DAY)		HO	FR-NOVOPROD-472830		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Novonorm			S	Oral	Unk		Novo Nordisk
	Seroplex			S	Unknown	Unk		Not Reported
	Amiodarone			S	Oral	Unk		Not Reported
	Previscan /00261401/			S	Oral	Unk		Not Reported
	Bisoprolol			S	Oral	Unk		Not Reported
	Tareg			S	Oral	Unk		Not Reported
	Inegy			S	Oral	Unk		Not Reported
	Lasilix /00032601/			S	Oral	Unk		Not Reported

	Chibro-Proscar			S	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2015	11823232	EXPEDITED (15-DAY)		HO	AU-FRI-1000081461		14 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Product Use Issue; Psychotic Disorder; Suicidal Ideation	Escitalopram			S	Unknown	20 Mg		Forest
	Escitalopram			S				Forest
	Escitalopram			S				Forest
	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2015	11824333	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015427277		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2015	11825346	DIRECT	Y	HO			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Torsade De Pointes	Methadone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11790775	EXPEDITED (15-DAY)		HO	FR-FRI-1000081179			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drop Attacks; Fall	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest

Esidrex	S	Oral	12.5 Mg		Not Reported
Irbesartan Arrow	S	Oral	300 Mg		Not Reported
Gabapentine	S	Oral	300 Mg		Not Reported
Plavix	S	Oral	75 Mg		Not Reported
Valium Roche	S	Oral	10 Mg		Not Reported
Zolpidem	S	Oral	10 Mg		Not Reported
Levothyrox	S	Oral	150 Microgram		Not Reported
Oxazepam	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11826549	EXPEDITED (15-DAY)		HO	FR-FRI-1000081464		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage Intracranial; Prescribed Overdose; Subarachnoid Haematoma; Subdural Haematoma	Escitalopram			S	Oral	30 Mg		Forest
	Xarelto			S	Oral	20 Mg		Not Reported
	Xarelto			S				Not Reported
	Xarelto			S				Not Reported
	Lasilix			C	Oral	40 Mg		Not Reported
	Cordarone			C	Oral	142.8571 Mg		Not Reported
	Atacand			C	Oral	16 Mg		Not Reported
	Lercan			C	Oral	20 Mg		Not Reported
	Urbanyl			C	Oral	30 Mg		Not Reported
	Revia			C	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11826550	EXPEDITED (15-DAY)		CA	FR-FRI-1000081462		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malnutrition; Low Birth	Escitalopram			S	Transplacental	1 Dosage Form		Forest
	Baclofen Zentiva			S	Transplacental	21 Dosage Forms		Not Reported

Weight Baby	Baclofen Zentiva		S	Transplacental	12 Dosage Forms	Not Reported
	Seresta		S	Transplacental		Not Reported
	Xanax		S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11827315	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20151204139		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Topiramate			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Dextromethorphan			S	Oral			Not Reported
	Cyclobenzaprine			S	Oral			Not Reported
	Chlorpheniramine			S	Oral			Not Reported
	Meloxicam			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Sumatriptan			S	Oral			Not Reported
	Benzonatate			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11828046	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015439100		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Psoriasis	Amiodarone Hcl			S	Oral	Unk		Pfizer
	Bisoprolol Fumarate			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Tareg			S	Oral	Unk		Not Reported
	Lasilix			S	Oral	Unk		Not Reported
	Previscan (Fluindione)			S	Oral	Unk		Not Reported

	Inegy	S	Oral	Unk		Not Reported
	Novonorm	S	Oral	Unk		Not Reported
	Chibro-Proscar	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11645622	EXPEDITED (15-DAY)			JP-FRI-1000080327		56 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hyperkalaemia; Nausea	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	2.5 Mg		Forest
	Sepazon			C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11653375	EXPEDITED (15-DAY)		OT	DE-FRI-1000080357		42 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Faecaloma; Rash	Escitalopram			S	Oral	10 Mg		Forest
	Amitriptyline-Form Unknown			C	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11770485	EXPEDITED (15-DAY)		HO	FR-SA-2015SA186473		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drop Attacks	Gabapentin			S	Oral			Not Reported
	Plavix			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Irbesartan			S	Oral	Long Standing Treatment		Not Reported

	Esidrex	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11787727	NON-EXPEDITED			US-GILEAD-2015-0184903		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Lethargy; Nausea; Somnolence	Harvoni			S	Unknown	Unk		Gilead
	Harvoni			S	Unknown	Unk		Gilead
	Adderall			S	Oral	30 Mg, Unk		Not Reported
	Bupropion			S	Oral	150 Mg, Unk		Not Reported
	Clonazepam			S	Oral	1 Mg, Unk		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Lamotrigine			S	Oral	200 Mg, Unk		Not Reported
	Dandelion Root			C		Unk		Not Reported
	Excedrin /00110301/			C		Unk		Not Reported
	Fiber			C		Unk		Not Reported
	Gas-X			C		Unk		Not Reported
	Protein Powder			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11831410	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014583		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Death; Toxicity To Various Agents	Oxymorphone Hcl			S	Oral	Unk, Unknown		Par
	Alprazolam			S	Oral	Unk, Unknown		Par
	Oxycodone			S	Oral	Unk, Unknown		Not Reported
	Gabapentin			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

	Trazodone		S	Oral	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11831704	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014601		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Lamotrigine			S	Oral	Unk Unk, Unknown		Par
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Atenolol			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11831718	EXPEDITED (15-DAY)		OT	CH-ELI_LILLY_AND_COMPANY-CH201512003636		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Gestational Diabetes; Placental Insufficiency	Zyprexa			S	Oral	10 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Unknown	2.5 Mg, Qd		Eli Lilly And Co
	Cipralex /01588501/			S	Oral	10 Mg, Qd		Not Reported
	Tegretol			S	Oral	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11831721	EXPEDITED (15-DAY)		OT	CH-ELI_LILLY_AND_COMPANY-CH201512001460		< 1 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alloimmunisation; Breech Presentation; False Positive Investigation Result; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Hypoglycaemia Neonatal; Petechiae	Zyprexa			S	Transplacental	10 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Transplacental	10 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Unknown	2.5 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Unknown	2.5 Mg, Qd		Eli Lilly And Co
	Cipralex /01588501/			S	Transplacental	10 Mg, Qd		Not Reported

Cipralex /01588501/	S	Transplacental	10 Mg, Qd		Not Reported
Tegretol	S	Transplacental			Not Reported
Tegretol	S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11832299	EXPEDITED (15-DAY)		CA, HO, OT	BR-FRI-1000081530		1 DAY	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Foetal Exposure During Pregnancy	Lexapro			S	Transplacental	10 Mg		Forest
	Omega-3 Fatty Acid			C	Transplacental			Not Reported
	Folic Acid			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2015	11838852	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014637		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardio-Respiratory Arrest; Completed Suicide; Death; Poisoning Deliberate; Respiratory Arrest	Propranolol Hcl			S	Oral	Unk Unk, Unknown		Par
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2015	11783032	EXPEDITED (15-DAY)		HO	PHHY2015FR152634			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drop Attacks	Esidrex			S	Oral	12.5 Mg, Qd		Not Reported
	Zolpidem			S	Oral	10 Mg, Qd, In Evening		Novartis
	Irbesartan			S	Oral	300 Mg, Qd		Not Reported
	Gabapentin			S	Oral	100 Mg, Tid		Not Reported

Plavix	S	Oral	75 Mg, Qd		Not Reported
Valium	S	Unknown	5 Mg, Bid		Not Reported
Seroplex	S	Oral	15 Mg, Qd		Not Reported
Seroplex	S	Oral	10 Mg, Qd		Not Reported
Levothyrox	S	Oral	150 Ug, Qd		Not Reported
Oxazepam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2015	11839326	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00004298		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Dry Eye; Dyspnoea; Feeling Hot; Memory Impairment; Palpitations; Panic Attack; Sleep Disorder	Escitalopram Tablets Usp 10mg			S	Unknown			Lupin
	Escitalopram Tablets Usp 10mg			S	Unknown			Lupin
	Lisinopril			C	Oral			Not Reported
	Xanax			C	Oral	0.5mg		Not Reported
	Clonazepam			C	Oral			Not Reported
	Vagifem			C	Vaginal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2015	11839358	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014618		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death; Poisoning Deliberate	Olanzapine			S	Oral	Unk Unk, Unknown		Par
	Sumatriptan Succinate			S	Oral	Unk, Unknown		Par
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Dextromethorphan			S	Oral	Unk, Unknown		Not Reported
	Cyclobenzaprine			S	Oral	Unk, Unknown		Not Reported
	Topiramate			S	Oral	Unk, Unknown		Not Reported

	Chlorpheniramine /00072501/	S	Oral	Unk, Unknown	Not Reported
	Meloxicam	S	Oral	Unk, Unknown	Not Reported
	Trazodone	S	Oral	Unk, Unknown	Not Reported
	Benzonatate	S	Oral	Unk Unk, Unknown	Not Reported
	Buspirone	S	Oral	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2015	11839653	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20151205946		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Ingestion; Toxicity To Various Agents	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported
	Sertraline			S				Not Reported
	Buspirone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11471954	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015291119		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metabolic Encephalopathy; Toxicity To Various Agents	Lyrica			S	Oral	50 Mg, Daily		Pfizer
	Lyrica			S	Oral	600 Mg, Daily		Pfizer
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Dafalgan Codeine			S	Oral	Maximum 6 Tablets Daily		Not Reported
	Seresta			S	Oral	25 Mg, 1x/Day		Not Reported
	Victoza			C	Subcutaneous	1.8 Ml, 1x/Day		Not Reported
	Lantus			C	Subcutaneous	36 Iu, 1x/Day		Not Reported
	Avlocardyl /00030001/			C	Oral	40 Mg, 1x/Day		Not Reported
	Aprovel			C	Oral	300 Mg, 1x/Day		Not Reported
	Fluvastatin			C	Oral	40 Mg, 1x/Day		Not Reported

Glucophage	C	Oral	500 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11503970	EXPEDITED (15-DAY)		HO	FR-FRI-1000079450		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metabolic Encephalopathy	Escitalopram			S	Oral	10 Mg/Kg		Forest
	Lyrica			S	Oral	50 Mg		Not Reported
	Lyrica			S	Oral	600 Mg		Not Reported
	Dafalgan Codeine			S	Oral			Not Reported
	Seresta			S	Oral	25 Mg		Not Reported
	Victoza			C	Subcutaneous	1.8 Ml		Not Reported
	Lantus			C	Subcutaneous	36 Iu		Not Reported
	Avlocardyl			C	Oral	1 Dosage Form		Not Reported
	Approvel			C	Oral	300 Mg		Not Reported
	Fluvastatine Base			C	Oral	40 Mg		Not Reported
	Glucophage			C	Oral	1500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11696675	EXPEDITED (15-DAY)		HO	JP-FRI-1000080573		74 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Ventricular Tachycardia	Lexapro			S	Oral	10 Mg		Forest
	Trazenta			C	Oral			Not Reported
	Enalapril Maleate			C	Oral			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Mobic			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Basen			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11794347	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2015-10871			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drop Attacks	Zolpidem			S	Oral	Unk, Once A Day		Aurobindo
	Irbesartan Arrow Lab 300 Mg Film-Coated Tablets			S	Oral	300 Mg, Once A Day		Aurobindo
	Gabapentin			S	Oral	100 Mg, 3 Times A Day		Aurobindo
	Plavix			S	Oral	75 Mg, Once A Day		Not Reported
	Esidrex			S	Oral	12.5 Mg, Once A Day		Not Reported
	Valium /00017001/			S	Oral	5 Mg, Two Times A Day		Not Reported
	Seroplex			S	Oral	10 Mg, Once A Day		Not Reported
	Seroplex			S	Oral	15 Mg, Daily		Not Reported
	Levothyrox			S	Oral	150 Mg, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11814757	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015424768		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Dextromethorphan Hbr		Y	S	Oral	Unk		Unknown
	Sumatriptan Succinate			S	Oral	Unk		Pfizer
	Benzonatate			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported
	Topiramate			S	Oral	Unk		Not Reported
	Chlorphenamine			S	Oral	Unk		Not Reported
	Meloxicam			S	Oral	Unk		Not Reported
	Trazodone			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Not Reported

	Buspirone		S	Oral	Unk	Not Reported
	Citalopram		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11822273	EXPEDITED (15-DAY)		LT	IT-TEVA-614657ACC		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Ventricular Fibrillation	Escitalopram Oxalate			S	Oral	5 Gtt Daily; 5 Gtt Daily, Oral Drops, Solution		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11843755	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014859		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Bupropion Hcl Xl			S		Unk, Unknown, Ingst + Aspir		Par
	Lamotrigine			S		Unk, Unknown, Ingst + Aspir		Par
	Clonazepam			S		Unk, Unknown Ingst + Aspir		Par
	Escitalopram			S		Unk, Unknown, Ingst + Aspir		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11843843	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014877		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Bupropion Hcl Xl			S	Oral	Unk Unk, Unknown		Par
	Metoprolol			S	Oral	Unk, Unknown		Not Reported

	Escitalopram	S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11845567	NON-EXPEDITED			US-FRI-1000077918			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Hyposmia; Sinusitis	Lexapro Oral Solution			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11845568	NON-EXPEDITED			US-FRI-1000080266			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Fatigue; Insomnia	Lexapro Oral Solution			S	Oral	2.5ml		Forest
	Lexapro Oral Solution			S	Oral	2ml		Forest
	Valium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11845569	NON-EXPEDITED			US-FRI-1000079831			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Muscle Spasms	Lexapro Oral Solution			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11845570	NON-EXPEDITED			US-FRI-1000078381			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dry Eye; Myopia	Lexapro Oral Solution			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11846466	EXPEDITED (15-DAY)		HO	FR-FRI-1000081528		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Escitalopram			S	Oral			Forest
	Amiodarone			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Bisoprolol			S	Oral			Not Reported
	Tareg			S	Oral			Not Reported
	Inegy			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Novonorm			S	Oral			Not Reported
	Chibro Proscar			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11847672	EXPEDITED (15-DAY)		OT	CH-FRI-1000081605			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
False Positive Investigation Result; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Hypoglycaemia Neonatal; Petechiae	Escitalopram			S	Transplacental	10 Mg		Forest
	Tegretol (Carbamazepine)			S	Transplacental	Unknown		Not Reported
	Zyprexa (Olanzapine)			S	Transplacental	10 Mg		Not Reported
	Zyprexa (Olanzapine)			S	Transplacental	2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11847682	NON-EXPEDITED			US-SHIRE-US201516489		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Lethargy; Nausea; Prescribed Overdose; Product Use In Unapproved Indication; Somnolence	Adderall Xr			S	Oral	30 Mg, Unknown		Shire
	Harvoni			S	Unknown	Unk, Unknown		Not Reported
	Bupropion			S	Oral	150 Mg, Unknown		Not Reported
	Clonazepam			S	Oral	1 Mg, Unknown		Not Reported

	Escitalopram	S	Oral	20 Mg, Unknown	Not Reported
	Lamotrigine	S	Oral	200 Mg, Unknown	Not Reported
	Excedrin /00110301/	C	Unknown	Unk, Unknown	Not Reported
	Fiber	C	Unknown	Unk, Unknown	Not Reported
	Gas-X	C	Unknown	Unk, Unknown	Not Reported
	Vitamin D /00107901/	C	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11847838	EXPEDITED (15-DAY)		HO, OT	AT-ASTRAZENECA-2015SE56435		56 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Delirium; Pruritus	Seroquel			S	Oral			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Dibondrin			S	Unknown			Not Reported
	Cipralex			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Temesta (Lorazepam)			C	Unknown			Not Reported
	Temesta (Lorazepam)			C	Unknown			Not Reported
	Temesta (Lorazepam)			C	Unknown			Not Reported
	Temesta (Lorazepam)			C	Unknown			Not Reported
	Temesta (Lorazepam)			C	Unknown			Not Reported
	Naproxen			C				Not Reported
	Pantoloc			C				Not Reported
	Seractil			C				Not Reported

	Omega 3	C	1x1, Daily		Not Reported
	Aqua Tears	C	Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11611736	EXPEDITED (15-DAY)		HO, LT	AT-ASTRAZENECA-2015SE96346		44 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt	Seroquel			S	Oral	10 G Seroquel (50 Tablets 200 Mg)		Not Reported
	Cipralex			S	Unknown			Not Reported
	Trittico			S	Oral	About 20 Tablets Of 150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11824324	EXPEDITED (15-DAY)		HO, LT	IT-MYLANLABS-2015M1043429			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Ventricular Fibrillation	Escitalopram			S	Oral	5 Gtt, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11830883	EXPEDITED (15-DAY)		LT	IT-ACCORD-036304		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Ventricular Fibrillation	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11848513	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014758		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Death; Poisoning Deliberate	Zolpidem Tartrate Er		S	Oral	Unk Unk, Unknown	Par
	Diazepam		S	Oral	Unk Unk, Unknown	Par
	Metoprolol		S	Oral	Unk Unk, Unknown	Not Reported
	Oxycodone		S	Oral	Unk Unk, Unknown	Not Reported
	Escitalopram		S	Oral	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11848658	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014893		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death; Poisoning Deliberate	Clonazepam			S	Oral	Unk, Unknown		Par
	Duloxetine			S	Oral	Unk, Unknown		Not Reported
	Baclofen			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Thyroid Preparations			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11848710	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014897		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Clonazepam			S	Oral	Unk, Unknown		Par
	Beta Blocker			S	Oral	Unk, Unknown		Not Reported
	Lisinopril			S	Oral	Unk, Unknown		Not Reported
	Escitaopram			S	Oral	Unk, Unknown		Not Reported
	Trazodone			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11851887	EXPEDITED (15-DAY)		CA, DE	FR-FRI-1000081670		1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Holoprosencephaly	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11853044	EXPEDITED (15-DAY)		DE	US-DEP_13242_2015		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Citalopram			S		Df		Not Reported
	Metaxalone			S		Df		Not Reported
	Phenytoin			S		Df		Not Reported
	Indomethacin			S		Df		Not Reported
	Allopurinol			S		Df		Not Reported
	Lamictal			S		Df		Unknown
	Lexapro			S		Df		Unknown
	Altace			S		Df		Unknown
	Prilosec			S		Df		Unknown
	Gabapentin			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11855468	DIRECT					62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Quality Issue	Escitalopram 10mg Mylan			S	Oral	8 Tabs		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2015	11854274	EXPEDITED (15-DAY)		HO	FR-009507513-1512FRA009294		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dermatomyositis	Januvia	S	Oral	Unk		Merck
	Lasilix	S	Oral	Unk		Not Reported
	Seroplex	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2015	11786488	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2015405930		84 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Abuse; Overdose; Sopor	Alprazolam			S		Unk, One Bottle		Pfizer
	Cardioaspirin			S		Unk		Not Reported
	Triatec (Ramipril)			S		Unk		Not Reported
	Entact			S		Unk, One Box		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2015	11827851	EXPEDITED (15-DAY)		HO, LT	IT-FRI-1000081424		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Ventricular Fibrillation	Escitalopram Oral Solution			S	Oral	5 Gtt		Forest
	Alpivigor (Food Supplement)/Mg, Guarana, Caffeine, Royal Jelly, Fe, Ar			C	Oral	1 Vial Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2015	11854409	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014781		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Death; Poisoning; Poisoning Deliberate	Diazepam			S	Oral	Unk Unk, Unknown		Par
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2015	11854481	EXPEDITED (15-DAY)		HO, OT	CH-009507513-1512CHE009253		47 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Coma; Intentional Overdose	Remeron			S	Oral	75 Mg, Once		Merck
	Quetiapine Fumarate			S	Oral	125 Mg, Once		Not Reported
	Escitalopram			S	Oral	100 Mg, Once		Not Reported
	Alcohol			S	Oral	One Glass Of Wine, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2015	11854953	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014917		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Death; Poisoning Deliberate; Toxicity To Various Agents	Morphine Sulfate			S	Oral	Unk Unk, Unknown		Par
	Acetaminophen W/Hydrocodone			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Cyclobenzaprine			S	Oral	Unk, Unknown		Not Reported
	Aripiprazole			S	Oral	Unk, Unknown		Not Reported
	Drug, Unknown			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2015	11856714	EXPEDITED (15-DAY)		HO	SE-FRI-1000081801		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Intentional Overdose; Nausea; Poisoning	Escitalopram			S	Unknown	Overdose: Took 20 Tables A 20 Mg Of Cipralex		Forest
	Atenolol			S	Unknown	Took 14 Tables A 50 Mg Of Atenolol		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2015	11856715	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000081821		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral	Intentional Overdose Of 220 Mg Of Escitralopram.		Forest
	Escitalopram			S				Forest
	Lexomil Roche			S	Oral	Intentional Overdose Of 30 Df Of Bromazepam.		Not Reported
	Lexomil Roche			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2015	11856813	DIRECT		CA, DE			34 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Stillbirth	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2015	11856949	EXPEDITED (15-DAY)		HO, LT	CH-TEVA-617760ISR		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hyperhidrosis; Serotonin Syndrome; Tachycardia	Fentanyl-Mepha Matrixpflaster 50mcg/Hr			S	Topical			Cephalon
	Cipralex			S	Oral			Not Reported
	Targin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	10783009	EXPEDITED (15-DAY)		OT	NO-FRI-1000074346		19 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Facial Spasm; Limb Injury; Loss Of Personal Independence In Daily Activities; Muscle Twitching	Escitalopram	S	Unknown	Unk	Forest
	Zeldox	S	Unknown	80-40 Mg Per Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11185436	EXPEDITED (15-DAY)		HO	AT-FRI-1000077314		87 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decubitus Ulcer; Parkinson'S Disease	Escitalopram			S	Unknown	10 Mg		Forest
	Risperdal			S	Unknown	0.5 Mg		Not Reported
	Memantine-Form-Unknown			C	Oral	20 Mg		Not Reported
	Zoldem			C	Oral	10 Mg		Not Reported
	Akineton Retard			C	Oral	2 Mg		Not Reported
	Mirtabene			C	Unknown	30 Mg		Not Reported
	Dominal Forte			C	Oral	40 Mg		Not Reported
	Exelon			C	Transdermal	9.5 Mg Per 24 Hours		Not Reported
	Thrombo Ass			C	Oral	50 Mg		Not Reported
	Durotiv			C	Unknown	20 Mg		Not Reported
	Cal-D-Vita			C	Unknown	1 Tablet		Not Reported
	Cerebokan			C	Oral	240 Mg		Not Reported
	Esomep			C	Unknown	Unit Dose: 20		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11858169	NON-EXPEDITED			US-TEVA-608643USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Trazodone			S	Unknown			Barr
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11858477	EXPEDITED (15-DAY)		HO	PHEH2015US026307		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Pain; Lymphadenopathy; Mania; Multiple Sclerosis; Pain In Extremity; Weight Decreased	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11858923	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2015-ALVOGEN-020454		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion	Oxycodone			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Atenolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11860894	EXPEDITED (15-DAY)		OT	FR-FRI-1000081796		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Coma; Product Use In Unapproved Indication; Speech Disorder; Syncope; Vertigo; Walking Disability	Escitalopram			S	Oral	5 Mg		Forest
	Lyrica			C	Unknown	25 Mg		Not Reported
	Tramadol			C	Unknown			Not Reported
	Versatis			C	Transdermal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11860897	EXPEDITED (15-DAY)		DE	FR-FRI-1000081830		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypoglycaemia	Escitalopram			S	Oral	5 Mg		Forest
	Tramadol Base			S	Oral	100 Mg		Not Reported
	Glimepiride			S	Oral	1 Mg		Not Reported
	Previscan (Fluindione)			C				Not Reported
	Movicol			C				Not Reported
	Sotalex			C				Not Reported
	Propylex			C				Not Reported
	Discotrine			C				Not Reported
	Clopidogrel			C				Not Reported
	Coversyl			C				Not Reported
	Crestor			C				Not Reported
	Fumafer			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11861503	EXPEDITED (15-DAY)		DE, HO, OT	CH-JNJFOC-20151217801		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Nausea; Transaminases Increased	Xarelto			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Remeron			S	Unknown			Not Reported
	Cipralex			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Lorazepam			C	Oral			Not Reported
	Metamizole Sodium			C	Oral			Not Reported
	Lisinopril			C	Oral			Not Reported
	Metoclopramide			C	Unknown			Not Reported
	Torasemid			C	Unknown			Not Reported
	Nebivolol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11862593	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2015-ALVOGEN-020372		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lisinopril			S	Oral			Not Reported
	Atenolol			S	Oral			Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Escitalopram			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11863841	EXPEDITED (15-DAY)		HO	FR-FRI-1000081826		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Hyponatraemia; Renal Failure	Escitalopram			S	Oral			Forest
	Lasilix			S	Oral			Not Reported
	Inspra			S	Oral			Not Reported
	Tavanic			S	Oral			Not Reported
	Triatec (Ramipril)			S	Oral			Not Reported
	Previscan (Fluindione)			C	Unknown			Not Reported
	Mediatensyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11865271	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2015454470		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Suicide Attempt; Toxicity To Various Agents	Xanax			S	Oral	0.5 Mg, 4 Dosage Forms (Df) A Day		Pfizer
	Xanax			S	Oral	Unk, Single		Pfizer
	Xanax			S	Oral	Unk		Pfizer

	Tercian	S	Oral	25 Mg 1 Df Daily (Evening)	Not Reported
	Tercian	S	Oral	Unk; Single Dose	Not Reported
	Tercian	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	20 Mg 1 Df Daily (Morning)	Not Reported
	Seroplex	S	Oral	Unk Single Dose	Not Reported
	Seroplex	S	Oral	Unk	Not Reported
	Imovane	S	Oral	1 Df Daily (At Bedtime)	Not Reported
	Imovane	S	Oral	Unk, Single	Not Reported
	Imovane	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11865581	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2015M1046622			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Quetiapine			S	Oral	100mg		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Irbesartan			S	Unknown			Not Reported
	Gemfibrozil			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Ropinirole			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11865846	EXPEDITED (15-DAY)		OT	JP-SA-2015SA216953		18 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness	Myslee			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Nauzelin			S	Oral			Not Reported
	Gasmotin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2015	11866452	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2015-ALVOGEN-020462		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone			S	Oral			Not Reported
	Metoprolol			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2015	11866738	EXPEDITED (15-DAY)		OT	ES-APOTEX-2015AP015455		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis	Olanzapine			S	Oral	Unk		Apotex
	Escitalopram Apotex			S	Unknown	Unk		Apotex
	Trazodone			S	Unknown	Unk		Not Reported
	Levodopa/Carbidopa			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2015	11866823	EXPEDITED (15-DAY)		OT	ES-APOTEX-2015AP015457		67 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Quetiapine			S	Oral	100 Mg, Unk		Apotex
	Pantoprazole			S	Unknown			Apotex
	Escitalopram			S	Unknown			Not Reported
	Hydrochloorthiazide			S	Unknown			Not Reported
	Gemfibrozil			S	Unknown			Not Reported
	Irbesartan			S	Unknown			Not Reported

	Ropinirole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2015	11867191	EXPEDITED (15-DAY)		DE, HO	FR-JNJFOC-20151215498		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Risperdal			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Tramadol			S	Unknown			Not Reported
	Paracetamol			C				Not Reported
	Macrogol 3350			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported
	Kardegic			C	Unknown			Not Reported
	Tahor			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported
	Seresta			C	Unknown	A Half Tablet A Day.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2015	11868373	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015451565			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Hyponatraemia; Renal Failure	Inspra			S	Oral	Unk		Pfizer
	Triatec (Ramipril)			S	Oral	Unk		Pfizer
	Lasilix /00032601/			S	Oral	Unk		Not Reported
	Tavanic			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Previscan /00789001/			C				Not Reported

	Mediatensyl /00631801/	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2015	11871009	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Palpitations	Lexapro			S		Anxiety		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2015	11871104	DIRECT	Y	HO			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Psychotic Disorder; Serotonin Syndrome	Escitalopram			S	Oral			Not Reported
	Clonazepam			C				Not Reported
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2015	11869170	EXPEDITED (15-DAY)		HO	US-ACCORD-036441		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Diarrhoea; Malaise; Pancreatitis; Vomiting; Weight Decreased	Escitalopram			S	Oral			Accord
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2015	11869843	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2015-ALVOGEN-020509		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Exposure Via Ingestion	Oxycodone			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Oxycodone			S	Oral			Not Reported

Alprazolam	S	Oral		Not Reported
Trazodone Hydrochloride	S	Oral		Not Reported
Gabapentin	S	Oral		Not Reported
Escitalopram	S	Oral		Not Reported
Oxymorphone	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2015	11871712	EXPEDITED (15-DAY)		DE	US-NSR_02299_2015		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Loss Of Consciousness; Overdose; Toxicity To Various Agents	Allopurinol			S		Df		Not Reported
	Prilosec			S		Df		Unknown
	Lexapro			S		Df		Unknown
	Altace			S		Df		Unknown
	Gabapentin			S		Df		Not Reported
	Indomethacin			S		Df		Not Reported
	Skelaxin			S		Df		Unknown
	Citalopram			S		Df		Not Reported
	Phenytoin			S		Df		Not Reported
	Lamictal			S		Df		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2015	11872486	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015467333		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Desvenlafaxine Succinate Monohydrate			S		Unk, 1x/Day		Pfizer
	Cymbalta			S		Unk		Not Reported
	Viibryd			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11734630	EXPEDITED (15-DAY)		DE, OT	CA-FRI-1000080852		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Citalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral			Forest
	Clonazepam			C	Oral			Not Reported
	Flomax			C				Not Reported
	Crestor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11775029	EXPEDITED (15-DAY)		DE	GB-TEVA-609795ACC		51 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Ivax
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11874204	NON-EXPEDITED			CA-LUPIN PHARMACEUTICALS INC.-2015-02878		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Libido Disorder	Escitalopram			S	Unknown	20mg		Not Reported
	Pregabalin			S	Unknown	150mg		Not Reported
	Pregabalin			S	Unknown	50mg		Not Reported
	Ramipril			C	Unknown	5mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11874212	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2015-03265		71 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Oedema Peripheral	Escitalopram		S	Unknown	10 Mg	Not Reported
	Clonazepam		C	Unknown	0.75 Mg	Not Reported
	Clonazepam		C	Unknown	0.5 Mg	Not Reported
	Warfarin		C	Unknown		Not Reported
	Warfarin		C			Not Reported
	Bisoprolol		C	Unknown		Not Reported
	Bisoprolol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11874219	NON-EXPEDITED		OT	TR-LUPIN PHARMACEUTICALS INC.-2015-03305		4 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S	Unknown			Not Reported
	Valproate			C	Unknown			Not Reported
	Valproate			C	Unknown			Not Reported
	Acth			C	Unknown			Not Reported
	Topiramate			C	Unknown			Not Reported
	Topiramate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11874239	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2015-03817			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Pain In Jaw	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Pramipexole			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11874240	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS INC.-2015-03869		81 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Telangiectasia	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11875885	EXPEDITED (15-DAY)		HO	FR-SA-2015SA217259		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis	Lasilix			S	Oral			Not Reported
	Januvia			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11876211	EXPEDITED (15-DAY)		OT	ES-TEVA-621387ISR		67 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Quetiapine			S	Oral	100mg		Teva
	Escitalopram			S	Unknown			Ivax
	Pantoprazole			S	Unknown			Teva
	Irbesartan			S	Unknown			Teva
	Gemfibrozil			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Ropinirole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11876536	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20151219889		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis	Risperdal			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Colprone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11876936	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201505784		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue	Morphine			S	Oral	Unk		Mallinckrodt
	Acetaminophen\Hydrocodone Bitartrate			S	Oral	Unk		Mallinckrodt
	Escitalopram			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported
	Aripiprazole			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	6884855	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-14390819			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Large For Dates Baby	Abilify			S	Transplacental	10 Mg, Qd		Bristol Myers Squibb
	Lexapro			S	Transplacental	20 Mg, Qd		Not Reported
	Tylenol			C	Transplacental	Unk Unk, Prn		Not Reported
	Proventil Inhaler			C	Transplacental	Unk Unk, Prn		Not Reported
	Prenatal Vitamin			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	10868697	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC-2015067198		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Head Injury	Aldactone	S	Oral		Pfizer
	Avlocardyl	S		10 Mg, 3x/Day	Pfizer
	Lantus	S	Subcutaneous	10 Iu, 1x/Day In The Evening	Not Reported
	Humalog	S	Subcutaneous	6 Iu, 2x/Day	Not Reported
	Seroplex	S	Oral	10 Mg, 1x/Day	Not Reported
	Heptaminol	C	Oral	1 Df, 3x/Day	Not Reported
	Gaviscon	C	Oral	1 Df, Daily	Not Reported
	Duphalac	C	Oral	1 Df, 3x/Day	Not Reported
	Dafalgan	C	Oral	500 Mg, 3x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	10873630	EXPEDITED (15-DAY)		DE, HO	FR-SA-2015SA022450		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Lantus			S	Subcutaneous			Not Reported
	Lantus			S	Subcutaneous			Not Reported
	Avlocardyl			S	Unknown	Strength: 40 Mg		Not Reported
	Humalog			S	Subcutaneous			Not Reported
	Seroplex			S	Oral	Strength: 10 Mg		Not Reported
	Aldactone			S	Oral			Not Reported
	Heptaminol			C	Oral			Not Reported
	Gaviscon			C	Oral			Not Reported
	Duphalac			C	Oral			Not Reported
	Dafalgan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11633113	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015338533		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Hallucination; Mania	Xanax	S		0.25 Mg, 1x/Day	Pfizer
	Xanax	S		0.125 Mg, 1x/Day	Pfizer
	Seroplex	S	Oral	10 Mg, Daily	Not Reported
	Seroplex	S	Oral	20 Mg, Daily	Not Reported
	Imovane	S	Oral	7.5 Mg, Daily	Not Reported
	Imovane	S	Oral	3.75 Mg, Daily	Not Reported
	Risperdal	S	Oral	0.25 Ml, 2x/Day	Not Reported
	Monuril	C		Unk	Not Reported
	Cardensiel	C		Unk	Not Reported
	Hyperium	C		Unk	Not Reported
	Lercan	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11727794	EXPEDITED (15-DAY)			BR-PFIZER INC-2015384003		13 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Lexapro			S		Unk		Not Reported
	Tegretol			C		1 Tablet, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11777755	EXPEDITED (15-DAY)		OT	CH-TEVA-610945ISR		46 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Decreased; C-Reactive Protein Increased; Conduction Disorder; Drug Interaction; Hyponatraemia	Escitalopram			S	Unknown	20 Milligram Daily;		Ivax
	Olanzapine			S	Unknown	12.5 Milligram Daily;		Teva
	Pantoprazole			S	Unknown	40 Milligram Daily;		Teva
	Valproic Acid			C	Unknown	1000 Milligram Daily;		Not Reported
	Levothyroxine			C	Unknown	.125 Milligram Daily;		Not Reported
	Vitamin D3			C	Unknown	1000 Iu (International Unit) Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11860893	EXPEDITED (15-DAY)		OT	JP-FRI-1000081817		70 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depressive Symptom; Tremor	Lexapro			S	Oral	10 Mg		Forest
	Dopacol			S	Oral	200 Mg		Not Reported
	Flunitrazepam			C	Oral	Unknown		Not Reported
	Rebamipide			C	Oral	Unknown		Not Reported
	Amlodipine			C	Oral	Unknown		Not Reported
	Etizolam			C	Oral	Unknown		Not Reported
	Verapamil Hydrochloride			C	Oral	Unknown		Not Reported
	Magmitt			C	Oral	Unknown		Not Reported
	Famotidine			C	Oral	Unknown		Not Reported
	Tasmolin			C	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11877708	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-02966		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Insomnia; Nausea; Torticollis	Citalopram			S	Unknown	10mg		Not Reported
	Escitalopram			S	Unknown	5mg		Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported
	Escitalopram			S	Unknown	15mg		Not Reported
	Clonazepam			C	Unknown	0.25mg		Not Reported
	Clonazepam			C	Unknown	0.25-0.5mg		Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Celecoxib			C	Unknown			Not Reported

	Tamsulosin	C	Unknown		Not Reported
	Omeprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11877709	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2015-03284		21 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vaginal Haemorrhage	Escitalopram			S	Unknown	5mg		Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported
	Escitalopram			S	Unknown	5mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11877738	NON-EXPEDITED			KP-LUPIN PHARMACEUTICALS INC.-2015-03288		24 YR	Male	PRK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown	40 Mg		Not Reported
	Valproic Acid			S	Unknown	250 Mg		Not Reported
	Alprazolam			S	Unknown	0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11877741	NON-EXPEDITED			KP-LUPIN PHARMACEUTICALS INC.-2015-03289		29 YR	Male	PRK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown	30 Mg		Not Reported
	Fluoxetine			S	Unknown	80 Mg		Not Reported
	Buspirone			S	Unknown	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11877742	NON-EXPEDITED		HO	JP-LUPIN PHARMACEUTICALS		78 YR	Female	JPN

INC.-2015-03307

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Escitalopram			S	Unknown	10mg		Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported
	Mirtazapine			C	Unknown	30mg		Not Reported
	Nitrazepam			C	Unknown	5mg		Not Reported
	Risperidone			C	Unknown	1mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11878972	EXPEDITED (15-DAY)		HO	FR-FRI-1000081888		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis	Escitalopram			S	Oral			Forest
	Januvia			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11879906	EXPEDITED (15-DAY)		CA	FR-FRI-1000081827		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Spine Malformation; Talipes; Urinary Incontinence	Escitalopram			S	Transplacental	20 Mg		Forest
	Escitalopram			S	Transplacental	10 Mg		Forest
	Seresta			S	Transplacental			Not Reported
	Omeprazole			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11880240	EXPEDITED (15-DAY)		HO	FR-FRI-1000081909		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Subdural Haematoma	Escitalopram			S	Oral	20 Mg		Forest
	Previscan (Fluindione)			S	Oral	12.8571 Mg		Not Reported
	Esomeprazole			C	Oral	20 Mg		Not Reported
	Bisoprolol			C	Oral	5 Mg		Not Reported
	Furosemide			C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11880695	EXPEDITED (15-DAY)		DE	FR-FRI-1000081926		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Forest
	Risperdal			S				Not Reported
	Tramadol Base			S	Oral			Not Reported
	Bisoprolol			C		1.25 Mg		Not Reported
	Perindopril			C		4 Mg		Not Reported
	Kardegic			C		75 Mg		Not Reported
	Tahor			C		10 Mg		Not Reported
	Paracetamol			C		3 Gram		Not Reported
	Macrogol			C		1 Dosage Form If Necessary		Not Reported
	Inexium			C		20 Mg		Not Reported
	Seresta			C		7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11880718	EXPEDITED (15-DAY)		HO, OT	CH-FRI-1000081890		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite;	Escitalopram			S	Oral	20 Mg		Forest

Nausea; Transaminases Increased	Xarelto	S	Oral	20 Mg		Not Reported
	Pantoprazol	S	Oral	40 Mg		Not Reported
	Remeron	S	Oral	15 Mg		Not Reported
	Torasemid	C	Oral	2.5 Mg		Not Reported
	Lisinopril	C	Oral	5 Mg		Not Reported
	Nebivolol	C	Oral	2.5 Mg		Not Reported
	Novalgine (Metamizole Sodium)	C	Oral			Not Reported
	Temesta (Lorazepam)	C	Oral			Not Reported
	Paspertin [Metoclopramide Hydrochloride]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11880747	EXPEDITED (15-DAY)		HO	FR-FRI-1000081921			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Mitral Valve Incompetence	Escitalopram			S				Forest
	Mediator			S	Oral			Not Reported
	Isomeride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11880765	EXPEDITED (15-DAY)		HO	FR-FRI-1000081925		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Toxicity To Various Agents	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	Overdose On An Unknown Dose Once		Forest
	Tercian			S	Oral	25 Mg		Not Reported
	Tercian			S	Oral	Overdose On An Unknown Dose Once		Not Reported
	Imovane			S	Oral	1 Dosage Form		Not Reported
	Imovane			S	Oral	Overdose On An Unknown Dose Once		Not Reported

Xanax	S	Oral	8 Mg		Not Reported
Xanax	S	Oral	Overdose Of An Unknown Dose Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11881979	DIRECT					44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dizziness; Drug Ineffective; Paraesthesia; Post-Traumatic Stress Disorder; Product Quality Issue; Product Substitution Issue; Withdrawal Syndrome	Lexapro 20			S	Oral	1 Pill		Not Reported
	Lamotrigine			C				Not Reported
	Multi Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2015	11881425	EXPEDITED (15-DAY)		OT	TW-ACCORD-036667		37 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Gastrointestinal Disorder	Escitalopram			S				Accord
	Sertraline			S				Accord
	Bupropion/Bupropion Hydrochloride			S				Not Reported
	Duloxetine			S				Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2015	11881891	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2015-04469		67 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Quetiapine			S	Oral	100 Mg		Not Reported

Escitalopram	S	Unknown		Not Reported
Irbesartan	S	Unknown		Not Reported
Gemfibrozil	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported
Hydrochlorothiazide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2015	11884520	DIRECT	Y	HO			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Hyperreflexia; Mental Status Changes; Serotonin Syndrome; Tachycardia; Tremor	Escitalopram 20 Mg			S	Oral	Years, 40 Mg, Qd, Oral		Not Reported
	Nuvigil 150 Mg Teva/Cephalon			S	Oral		3 WEEK	Not Reported
	Acetaminophen			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Nuvigil			C				Not Reported
	Pepto-Bismol			C				Not Reported
	Celecoxib			C				Not Reported
	Cetirizine			C				Not Reported
	Escitalopram			C				Not Reported
	Fish Oil			C				Not Reported
	Fluticasone Propionate			C				Not Reported
	Fluocinonide Ointment			C				Not Reported
	Gabapentin			C				Not Reported
	Ginger Root			C				Not Reported
	Ibuprofen			C				Not Reported
	Lamotrigine			C				Not Reported
	Lotemax			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2015	11885478	DIRECT	Y				45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2016	11590932	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2015-08060			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Contraindicated Product Administered; Drug Interaction	Allopurinol Arrow Tablets			S	Oral	200 Mg, Unk		Not Reported
	Escitalopram Arrow Film-Coated Tablets			S	Oral	10 Mg, Unk		Aurobindo
	Escitalopram Arrow Film-Coated Tablets			S	Oral	5 Unk, Unk		Aurobindo
	Hydroxyzine Arrow Film-Coated Tablet			S	Oral	25 Mg, Unk		Not Reported
	Ketoprofen Arrow Lp 100 Mg Scored Tablet Extended Release			S	Oral	Unk		Not Reported
	Tercian /00759301/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2016	11883916	EXPEDITED (15-DAY)		HO	US-HETERO LABS LTD-1046070		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt; Treatment Failure	Escitalopram			S				Hetero
	Olanzapine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2016	11790680	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2015397613		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chills; Crying; Depression; Diplopia; Disturbance In Attention; Fatigue; Feeling Abnormal; Feeling Hot; Hyperhidrosis; Impaired Driving Ability; Nasopharyngitis; Rash;	Lyrica			S		75 Mg, 3x/Day		Pfizer
	Lyrica			S		50 Mg, 1x/Day		Pfizer
	Lexapro			S		20 Mg, Unk		Not Reported
	Amitriptyline Hcl			S		10 Mg, (1 Or 2 A Day)		Not Reported
	Gabapentin			C		300 Mg, 1x/Day		Not Reported

Tremor; Vision Blurred;
Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2016	11888663	DIRECT		OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Agitation; Anxiety; Asthenia; Crying; Depression; Diarrhoea; Feeling Abnormal; Insomnia; Nausea; Suicidal Ideation	Lexapro 10mg			S	Oral	1 Pill Once Daily		Not Reported
	Multi-Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2016	7216270	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-14684997		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Normal Newborn	Abilify			S	Oral	5 Mg, Unk		Bristol Myers Squibb
	Desyrel			S	Oral	1 Df, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2016	8296669	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-15703317		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Feeding; Live Birth; Maternal Exposure During Pregnancy; Stress; Suppressed Lactation	Abilify			S	Oral	2.5 Mg, Qd		Bristol Myers Squibb
	Abilify			S				Bristol Myers Squibb
	Abilify			S				Bristol Myers Squibb
	Lexapro			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2016	9467456	EXPEDITED (15-DAY)		HO, OT	PHHY2013IL076818		53 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Alopecia; Amnesia; Blood Bilirubin Increased; Blood Cholesterol Increased; Blood Glucose Increased; Chills; Constipation; Diarrhoea; Fatigue; Feeling Abnormal; Gastroenteritis; Hypersomnia; Hypothermia; Immune System Disorder; Insomnia; Low Density Lipoprotein Increased; Myalgia; Nausea; Pain; Somnolence; Vomiting; Weight Increased	Tasigna			S	Oral	150 Mg, Bid		Novartis
	Cipralex			S	Unknown			Not Reported
	Bondormin			C	Unknown			Not Reported
	Multi Vit			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2016	11837311	NON-EXPEDITED			US-PFIZER INC-2015443708		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack	Pristiq			S	Oral	50 Mg,		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2016	11890732	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2015-04523		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug	Escitalopram			S	Unknown	10 Mg		Not Reported

Interaction; Rhabdomyolysis	Escitalopram		S			Not Reported
	Mirtazapine		S	Unknown	At Night	Not Reported
	Mirtazapine		S			Not Reported
	Risperidone		S	Unknown	At Night	Not Reported
	Risperidone		S	Unknown	At Night	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11688686	EXPEDITED (15-DAY)		HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2015002126			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal	Escitalopram			S	Transplacental	Unk		Macleods
	Azathioprine			S	Transplacental			Not Reported
	Co-Dydramol			S	Transplacental	10/500, Qid		Not Reported
	Omeprazole			S	Transplacental	Unk		Not Reported
	Oramorph			S	Transplacental	15 Mg, 3-6 Times Per Day As Required		Not Reported
	Oramorph			S	Transplacental	Unk		Not Reported
	Tapentadol			S	Transplacental	100 Mg		Not Reported
	Daktarin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11826419	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20151202331		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Muscle Spasms; Myalgia	Durogesic			S	Transdermal			Not Reported
	Xarelto			S	Oral			Not Reported
	Votrient			S	Oral			Not Reported
	Actiskenan			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported

	Laroxyl	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11880497	EXPEDITED (15-DAY)		HO	US-FRI-1000081875		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Confusional State; Fall; Feeling Abnormal; Seizure; Transient Ischaemic Attack	Escitalopram			S	Oral	10mg		Forest
	Lasix			C				Not Reported
	Plavix			C				Not Reported
	Welchol			C				Not Reported
	Zetia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11890904	EXPEDITED (15-DAY)		OT	US-PAR PHARMACEUTICAL COMPANIES-2016SCPR015056			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rhabdomyolysis	Risperidone			S	Unknown	0.5 Mg, Qhs		Par
	Risperidone			S	Unknown	1 Mg, Qhs		Par
	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported
	Escitalopram			S				Not Reported
	Mirtazapine			C	Unknown	15 Mg, Qhs		Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11892142	EXPEDITED (15-DAY)		DS, OT	GB-FRI-1000081932			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Blindness; Disorientation; Feeling Abnormal; Homicidal Ideation; Libido	Escitalopram			S	Oral	10 Mg Daily		Forest
	Diazepam			C	Unknown	5 Mg As Necessary		Not Reported

Decreased; Mood Swings;
Paraesthesia;
Photosensitivity Reaction

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11893215	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1046936			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt; Treatment Failure	Escitalopram			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Lithium			S	Unknown			Not Reported
	Liothyronine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11893279	EXPEDITED (15-DAY)		HO	JP-FRI-1000081939		52 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug-Induced Liver Injury	Lexapro			S	Oral			Forest
	Paxil Cr			S	Oral	25 Mg		Not Reported
	Paxil Cr			S	Oral	37.5 Mg		Not Reported
	Brotizolam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11894248	DIRECT		OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Homicidal Ideation; Suicidal Ideation	Escitalopram 20mg Generic			S	Oral			Not Reported
	Prozac 10 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2016	6001673	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-		< 1 DAY	Unknown	USA

13297247

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Sedation; Selective Eating Disorder	Abilify			S	Transplacental	Unk		Bristol Myers Squibb
	Topamax			S	Transplacental	Unk		Not Reported
	Lexapro			S	Transplacental	Unk		Not Reported
	Remeron			S	Transplacental	Unk		Not Reported
	Zyprexa			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2016	11723525	EXPEDITED (15-DAY)		HO	GB-FRI-1000080783			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal	Escitalopram			S	Transplacental			Forest
	Azathioprine			S	Transplacental			Not Reported
	Co-Dydramol			S	Transplacental	(10/500) Four Times Daily As Required		Not Reported
	Omeprazole			S	Transplacental			Not Reported
	Oramorph			S	Transplacental	1 Mg 3-6 Times Daily As Required		Not Reported
	Tapentadol			S	Transplacental	100 Mg Once Daily		Not Reported
	Daktarin			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2016	11895147	NON-EXPEDITED			US-PFIZER INC-2015436814		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

	Klonopin	S	Unk	Not Reported
	Robaxin	S	Unk	Not Reported
	Methadone	S	Unk	Not Reported
	Oxycodone	S	Unk	Not Reported
	Metformin	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2016	11897904	DIRECT		DS, OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appetite Disorder; Asthenia; Balance Disorder; Dizziness; Drug Ineffective; Drug Withdrawal Syndrome; Fatigue; Head Discomfort; Hypoaesthesia; Hypoaesthesia; Insomnia; Nausea; Weight Decreased	Viibryd - Vilazodone Hcl Tablets Forest Pharmaceuticals Inc.			S		By Mouth; 30 Tablets		Forest
	Escitalopram 5 Mg Tab. Teva			S				Teva
	Multiple Vitamin			C				Not Reported
	Triamterene			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2016	11232172	EXPEDITED (15-DAY)		HO	FR-FRI-1000077780		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhagic Stroke	Escitalopram			S	Oral	10 Mg		Forest
	Lovenox			S	Subcutaneous	12000 Iu		Not Reported
	Lasilix			C				Not Reported
	Morphin			C				Not Reported
	Oxazepam			C				Not Reported
	Doliprane			C				Not Reported
	Calcium			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Qvar			C				Not Reported
	Ventoline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2016	11700557	EXPEDITED (15-DAY)		HO	GB-WATSON-2015-23608		121 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal	Azathioprine (Unknown)			S	Transplacental	Unk		Not Reported
	Co-Dydramol			S	Transplacental	Unk Unk, Qid (Strength: 10/500)		Not Reported
	Escitalopram (Unknown)			S	Transplacental	Unk		Not Reported
	Omeprazole (Unknown)			S	Transplacental	Unk		Actavis
	Oramorph			S	Transplacental	15 Mg, 3-6 Per Day		Not Reported
	Oramorph			S	Unknown	Unk		Not Reported
	Tapentadol			S	Transplacental	100 Mg, Daily		Not Reported
	Daktarin /00310801/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2016	11898672	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2016GSK000903		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Metoprolol			S	Oral	Unk		Not Reported
	Bupropion			S	Oral	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2016	11898689	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2016GSK000808		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	Unk		Glaxosmithkline
	Lamotrigine			S	Unknown	Unk		Glaxosmithkline

	Clonazepam	S	Unknown	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2016	11904677	NON-EXPEDITED			US-ROCHE-1571782		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Staphylococcal Infection; Therapeutic Response Decreased	Rituxan			S	Unknown			Not Reported
	Nardil			S	Oral			Not Reported
	Nardil			S				Not Reported
	Xanax			S	Oral			Not Reported
	Xanax			S				Not Reported
	Klonopin			S	Unknown			Not Reported
	Klonopin			S				Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S				Not Reported
	Fluconazole			C				Not Reported
	Pepcid			C				Not Reported
	Compazine			C				Not Reported
	Acyclovir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2016	4122627	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-12493342		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Pregnancy	Abilify			S	Oral	5 Mg, Qd		Bristol Myers Squibb
	Seroquel			S	Unknown	25 Mg, Qd		Not Reported
	Klonopin			S	Unknown	.5 Mg, Bid		Not Reported
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported
	Wellbutrin			S	Unknown	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2016	11905199	NON-EXPEDITED		HO, OT	US-JNJFOC-20151222951		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Off Label Use; Product Use In Unapproved Indication; Rhabdomyolysis	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown	Initial Dose Of 0.5 Mg Qhs, Titrated Upto 1 Mg		Not Reported
	Risperidone			S	Unknown	Initial Dose Of 0.5 Mg Qhs, Titrated Upto 1 Mg		Not Reported
	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			C	Unknown	15 Mg Qhs		Not Reported
	Mirtazapine			C	Unknown	15 Mg Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2016	11905386	NON-EXPEDITED		HO	US-JNJFOC-20151208764		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Risperdal			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Hydroxizine			S	Unknown			Not Reported
	Elvitegravir			S	Oral	1 Df (Dose Factor).		Not Reported
	Cobicistat			S	Oral	1 Df (Dose Factor).		Not Reported
	Emtricitabine			S	Oral	1 Df (Dosage Factor)		Not Reported
	Tenofovir Alafenamide			S	Oral	1 Df (Dosage Factor).		Not Reported
	Tenofovir Disoproxil Fumarate			S	Oral	1 Df (Dosage Factor).		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2016	11905555	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-092977		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Axonal Neuropathy; Cyanosis; Livedo Reticularis; Raynaud'S Phenomenon	Abilify	S	Oral	15 Mg, Qd		Bristol Myers Squibb
	Abilify	S				Bristol Myers Squibb
	Abilify	S				Bristol Myers Squibb
	Lepticur	S	Unknown	15 Mg, Unk		Not Reported
	Lepticur	S				Not Reported
	Lepticur	S				Not Reported
	Ritaline	S	Oral	100 Mg, Unk		Not Reported
	Ritaline	S	Oral	110 Mg, Qd		Not Reported
	Ritaline	S				Not Reported
	Xeroquel	S	Oral	400 Mg, Qd		Not Reported
	Xeroquel	S				Not Reported
	Xeroquel	S				Not Reported
	Seroplex	S	Oral	10 Mg, Qd		Not Reported
	Seroplex	S				Not Reported
	Seroplex	S				Not Reported
	Laroxyl	S	Unknown	Unk		Not Reported
	Laroxyl	S				Not Reported
	Laroxyl	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2016	11903149	EXPEDITED (15-DAY)		HO	PHHY2015US172500		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rhabdomyolysis	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Risperidone			S	Unknown	0.5 Mg, Qhs		Novartis
	Risperidone			S	Unknown	1 Mg, Unk		Novartis
	Mirtazapine			C	Unknown	15 Mg, Qhs		Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	10648647	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2014GSK034688			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Adverse Drug Reaction; Back Injury; Back Pain; Bipolar Disorder; Confusional State; Deep Brain Stimulation; Dependence; Depression; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Encephalopathy; Essential Tremor; Fall; Hostility; Hypersensitivity; Hypersensitivity; Ill-Defined Disorder; Impulsive Behaviour; Lethargy; Loss Of Personal Independence In Daily Activities; Oedema; Road Traffic Accident; Speech Disorder; Spinal Operation; Swelling; Therapeutic Response Decreased	Lamictal	S	Oral	200 Mg, Qd	Glaxosmithkline
	Lamictal	S		Unk	Glaxosmithkline
	Lamictal	S		100 Unk, Unk	Glaxosmithkline
	Lamotrigine	S		200 Mg, Qd	Glaxosmithkline
	Atenolol	S	Unknown	Unk, U	Glaxosmithkline
	Atenolol	S			Glaxosmithkline
	Aldactone	S	Unknown	Unk, U	Glaxosmithkline
	Lasix	S	Unknown	Unk, U	Glaxosmithkline
	Effexor	S	Unknown	Unk, Qd	Glaxosmithkline
	Lithium	S		450 Mg, Qd	Glaxosmithkline
	Flagyl	S	Unknown	Unk, U	Glaxosmithkline
	Prozac	S	Unknown	Unk, U	Not Reported
	Lexapro	S	Unknown	Unk, U	Not Reported
	Serotonin	S	Unknown	2 Df, Qd	Not Reported
	Bioflex	C			Not Reported
	Potassium	C			Not Reported
	Pepcid	C			Not Reported
	Theodur	C			Not Reported
	Melatonin	C			Not Reported
	Omeprazol	C			Not Reported
	Doxycycline	C			Not Reported
	Oxycodone	C			Not Reported
	Norco	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11442606	EXPEDITED (15-DAY)		OT	FR-FRI-1000079240		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Gamma-Glutamyltransferase Increased; Overdose; Transaminases Increased	Escitalopram			S	Oral	Overdose: 30 Mg/Day		Forest
	Depamide			S	Oral			Not Reported
	Zyvoxid			C	Unknown	1200 Mg		Not Reported
	Mirtazapine			C	Oral	30 Mg		Not Reported

	Mysoline	C	Oral	500 Mg		Not Reported
	Paracetamol	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11699778	EXPEDITED (15-DAY)		HO, OT	GB-DRREDDYS-GER/UKI/15/0053704		121 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal	Omeprazole			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Co-Dydramol			S	Transplacental	Strength: 10/500		Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Oramorph			S	Transplacental			Not Reported
	Oramorph			S	Unknown			Not Reported
	Tapentadol			S	Transplacental			Not Reported
	Daktarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11903167	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2016GSK000816		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Dextromethorphan			S	Oral	Unk		Glaxosmithkline
	Chlorpheniramine			S	Oral	Unk		Glaxosmithkline
	Buspirone Hcl			S	Oral	Unk		Glaxosmithkline
	Olanzapine			S	Oral	Unk		Glaxosmithkline
	Sumatriptan			S	Oral	Unk		Glaxosmithkline
	Trazodone			S	Oral	Unk		Not Reported
	Meloxicam			S	Oral	Unk		Glaxosmithkline
	Benzonatate			S	Oral	Unk		Not Reported

	Topiramate	S	Oral	Unk		Glaxosmithkline
	Cyclobenzaprine	S	Oral	Unk		Not Reported
	Cyclobenzaprine	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11906677	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2016002730		87 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Labyrinthitis; Nausea; Pneumonia; Vomiting	Cordarone			S	Oral	200 Mg, 3x/Day		Pfizer
	Cordarone			S	Oral	200 Mg, 1x/Day		Pfizer
	Cordarone			S	Oral	100 Mg, 1x/Day		Pfizer
	Cipralex			S	Oral	10 Mg, 2x/Day		Not Reported
	Nexium			C		Unk		Not Reported
	Enalapril			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11906808	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2016M1000126			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Incorrect Dose Administered; Muscle Spasms; Product Packaging Issue; Serotonin Syndrome; Tremor; Withdrawal Syndrome	Escitalopram			S		10 Mg, Unk		Not Reported
	Escitalopram			S		15 Mg, Unk		Not Reported
	Escitalopram			S		20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11907504	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2016GSK000847		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Escitalopram	S	Oral	Unk		Glaxosmithkline
	Lamotrigine	S	Oral	Unk		Glaxosmithkline
	Atenolol	S	Oral	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11908004	EXPEDITED (15-DAY)		HO	PHHY2016FR001625		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Guillain-Barre Syndrome	Neoral			S	Oral	20 Mg, Qd		Novartis
	Neoral			S	Oral	80 Mg, Bid		Novartis
	Speciafoldine			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Noxafil			S	Oral	200 Mg, Unk		Not Reported
	Mecir			S	Oral	Unk		Not Reported
	Zelitrex			S	Oral	Unk		Not Reported
	Alprazolam			S	Unknown			Not Reported
	Oracilline			S	Oral	Unk		Not Reported
	Bactrim Forte			S	Oral	Long Term		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11908571	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2016M1000727			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Rhabdomyolysis	Escitalopram			S	Unknown	10mg Daily		Not Reported
	Risperidone			S	Unknown	At Night		Not Reported
	Mirtazapine			S		At Night		Not Reported
	Mirtazapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11910659	DIRECT		DS, OT			40 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Nausea; Panic Attack; Product Substitution Issue	Escitalopram			S				Not Reported
	Lexapro			C				Not Reported
	Zanex			C				Not Reported
	Fish Oil			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Vitamin B			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	6929432	EXPEDITED (15-DAY)		CA, OT	US-BRISTOL-MYERS SQUIBB COMPANY-14530828			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Foetal Exposure During Pregnancy	Abilify			S	Transplacental	20 Mg, Unk		Bristol Myers Squibb
	Lexapro			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	7215369	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-14529184			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Maternal Exposure During Pregnancy	Abilify			S	Unknown	20 Mg, Unk		Bristol Myers Squibb
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	7995648	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-15705049			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Failure To Thrive; Foetal Exposure During Pregnancy; Gastrooesophageal Reflux Disease; Menstrual	Abilify			S	Transplacental	2.5 Mg, Qd		Bristol Myers Squibb
	Lexapro			S	Transplacental	20 Mg, Qd		Not Reported

Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	11031559	EXPEDITED (15-DAY)		DE, HO	FR-ELI_LILLY_AND_COMPANY-FR201504002011		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Glucose Decreased; Death; Fall	Humalog Lispro			S	Subcutaneous	6 Iu, Bid		Eli Lilly And Co
	Avlocardyl /00030001/			S	Unknown	0.25 Df, Tid		Not Reported
	Lantus			S	Subcutaneous	10 Iu, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Aldactone /00006201/			S	Oral			Not Reported
	Heptaminol			C		1 Df, Tid		Not Reported
	Gaviscon /00237601/			C		1 Df, Qd		Not Reported
	Duphalac /00163401/			C		1 Df, Tid		Not Reported
	Dafalgan			C		500 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	11695645	EXPEDITED (15-DAY)		HO	GB-AUROBINDO-AUR-APL-2015-09841		121 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal	Escitalopram			S	Transplacental			Aurobindo
	Escitalopram			S				Aurobindo
	Omeprazole			S	Transplacental			Aurobindo
	Omeprazole			S				Aurobindo
	Azathioprine			S	Transplacental			Not Reported
	Azathioprine			S				Not Reported
	Co-Dydramol			S	Transplacental	Strength: 10/500		Not Reported
	Co-Dydramol			S				Not Reported
	Oramorph			S	Transplacental	15 Mg, Unk		Not Reported
	Oramorph			S	Unknown	Unk		Not Reported
	Tapentadol			S	Transplacental	100 Mg, Once A Day		Not Reported

	Tapentadol	S				Not Reported
	Daktarin /00310801/	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	11704053	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-035084		121 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal	Escitalopram			S	Transplacental			Accord
	Omeprazole			S	Transplacental			Accord
	Azathioprine			S	Transplacental			Not Reported
	Co-Dydramol			S	Transplacental	Strength: 10/500		Not Reported
	Oramorph			S	Transplacental	Exposed To Oramorph 15 Mg, 3-6 Times Per Day Via Transplacental As Required.		Not Reported
	Tapentadol			S	Transplacental	100 Mg		Not Reported
	Daktarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	11909775	NON-EXPEDITED		OT	US-ELI_LILLY_AND_COMPANY-US201601001649		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Behaviour	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Viibryd			S	Unknown	Unk, Unknown		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	11911968	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2016-000620		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diazepam			S	Oral			Not Reported

Zolpidem	S	Oral		Not Reported
Metoprolol	S	Oral		Not Reported
Oxycodone	S	Oral		Not Reported
Escitalopram	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	11912129	NON-EXPEDITED			US-APOTEX-2015AP014860		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Product Use In Unapproved Indication	Sertraline Hydrochloride			S	Unknown	Unk		Apotex
	Fluoxetine Oral Solution Usp			S	Unknown	Unk		Apotex
	Paroxetine Hydrochloride			S	Unknown	Unk		Apotex
	Citalopram			S	Unknown	Unk		Apotex
	Escitalopram Oxalate			S	Unknown	Unk		Apotex
	Venlafaxine			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Imipramine			S	Unknown	Unk		Not Reported
	Carbamazepine			C	Unknown	600-1400mg Daily		Not Reported
	Lamotrigine			C	Unknown	300-600mg Daily		Not Reported
	Clonazepam			C	Unknown	1 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	11912736	DIRECT		DS, OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Balance Disorder; Decreased Appetite; Dizziness; Drug Ineffective; Ear Disorder; Fatigue; Feeling Abnormal; Head Discomfort;	Viibryd Vilazodone Hcl Tablets 20mg			S	Oral	30 Tabs 1 Daily By Mouth		Forest
	Escitalopram 5 Mg Tab Tev			S				Walmart
	Triamterene Hctz			C				Not Reported
	Multiple Vitamin			C				Not Reported

Hypoaesthesia;
Hypoaesthesia;
Hypoaesthesia Oral;
Insomnia; Nausea;
Vertigo; Withdrawal
Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2016	11653421	EXPEDITED (15-DAY)		HO, OT	FR-FRI-1000080386		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Hallucination, Visual; Mania; Product Use In Unapproved Indication	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Xanax			S	Oral	0.25 Mg		Not Reported
	Imovane			S	Oral	7.5 Mg		Not Reported
	Risperdal			S	Oral	0.5 Ml		Not Reported
	Monuril			C	Unknown			Not Reported
	Cardensiel			C	Unknown			Not Reported
	Hyperium			C	Unknown			Not Reported
	Lercan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2016	11913354	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201505823		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue	Roxicodone			S	Oral	Unk		Mallinckrodt
	Oxymorphone Hydrochloride			S	Oral	Unk		Mallinckrodt
	Alprazolam			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Trazodone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2016	11913940	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201505975		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Roxicodone			S	Oral	Unk		Mallinckrodt
	Metoprolol			S				Not Reported
	Zolpidem			S				Not Reported
	Diazepam			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2016	11914318	EXPEDITED (15-DAY)		OT	US-APOTEX-2016AP005086		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis	Escitalopram Oxalate			S	Unknown	10mg Daily		Apotex
	Escitalopram Oxalate			S				Apotex
	Risperidone			S	Unknown	At Night		Apotex
	Risperidone			S	Unknown	1 Mg, Unk		Apotex
	Mirtazapine			C	Unknown	At Night		Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2016	11698292	EXPEDITED (15-DAY)		HO	GB-ASTRAZENECA-2015SF04612		121 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Sepsis Neonatal	Omeprazole			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Oramorph			S	Transplacental	15 Mg, 3-6 Times Per Day As Required		Not Reported
	Oramorph			S	Transplacental	15 Mg, 3-6 Times Per Day As Required		Not Reported

	Oramorph	S	Unknown		Not Reported
	Co-Dydramol	S	Transplacental	Strength: 10/500, Four Times A Day As Required	Not Reported
	Escitalopram	S	Transplacental		Not Reported
	Tapentadol	S	Transplacental		Not Reported
	Daktarin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2016	11917137	EXPEDITED (15-DAY)		HO	FR-FRI-1000082053		32 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Chest Pain; Coronary Arterial Stent Insertion; Hypercholesterolaemia	Escitalopram			S	Oral	5 Mg		Forest
	Xeroquel			S	Oral	50 Mg		Not Reported
	Xeroquel			S				Not Reported
	Melatonine			C	Unknown			Not Reported
	Alimemazine			C	Unknown			Not Reported
	Digoxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2016	11917539	EXPEDITED (15-DAY)		HO	FR-FRI-1000082072		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Angina Pectoris; Cholestasis; Coronary Arterial Stent Insertion; Hepatocellular Injury	Escitalopram			S	Oral	5 Mg		Forest
	Xeroquel			S	Oral	50 Mg		Not Reported
	Xeroquel			S				Not Reported
	Kardegic			C	Unknown			Not Reported
	Brilique			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Tenormine			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported

	Theralene	C	Unknown		Not Reported
	Atarax	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2016	11917725	EXPEDITED (15-DAY)		OT	ES-NSR_02305_2016		67 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Hydrochlorothiazide			S		Df		Not Reported
	Pantoprazole			S		Df		Not Reported
	Irbesartan			S		Df		Not Reported
	Quetiapine			S	Oral	100 Mg, Unk		Not Reported
	Quetiapine			S	Oral	100 Mg, Unk		Not Reported
	Escitalopram			S		Df		Not Reported
	Gemfibrozil			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2016	11918830	DIRECT					58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dizziness; Feeling Abnormal; Presyncope; Respiratory Rate Increased; Speech Disorder; Tremor	Risperidone Walmart - Pharmacy			S	Oral			Walmart
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2016	11919421	NON-EXPEDITED			US-JNJFOC-20151219273			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Xarelto			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported

	Escitalopram	S	Unknown	Not Reported
	Donepezil	S	Unknown	Not Reported
	Pravastatin	C	Oral	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Citracal Plus	C	Unknown	Not Reported
	Glucosamine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2016	11926802	DIRECT		OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Escitalopram			S	Oral	1 1/2 At Bedtime		Not Reported
	Adderall Xr			C				Not Reported
	Xanax			C				Not Reported
	Lipitor			C				Not Reported
	Trazodone			C				Not Reported
	Topamax			C				Not Reported
	Colace			C				Not Reported
	Ditopan			C				Not Reported
	Prilosec			C				Not Reported
	Flexeril			C				Not Reported
	Folic Acid			C				Not Reported
	Percocet			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11910630	EXPEDITED (15-DAY)		HO, LT	FR-ASTRAZENECA-2016SE01934		33 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Angina Pectoris; Aortic Valve Incompetence; Cholestasis; Coronary Artery Stenosis;	Xeroquel Sr			S	Oral			Not Reported
	Xeroquel Sr			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported

Hepatocellular Injury; Hypercholesterolaemia; Myalgia; Product Use In Unapproved Indication	Seroplex		S	Oral	Not Reported
	Melatonin		C	Oral	Not Reported
	Theralene		C		Not Reported
	Atarax		C		Not Reported
	Kardegic		C		Not Reported
	Brilique		C		Not Reported
	Tenormine		C		Not Reported
	Inexium		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11923418	NON-EXPEDITED			IL-LUPIN PHARMACEUTICALS INC.-2015-04247		28 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram			S	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11925503	EXPEDITED (15-DAY)		HO	SE-TEVA-625739ISR		29 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Self-Injury; Toxicity To Various Agents	Escitalopram			S				Ivax
	Propavan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	9638581	EXPEDITED (15-DAY)		OT	AU-BRISTOL-MYERS SQUIBB COMPANY-16034886		40 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Abilify			S	Unknown	20 Mg, Qd		Bristol Myers Squibb
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	11723832	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-2015M1037488			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Exposure During Pregnancy; Sepsis Neonatal	Azathioprine			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported
	Omeprazole			S	Transplacental	Unk		Not Reported
	Co-Dydramol			S	Transplacental	Unk		Mylan
	Oramorph			S	Transplacental	15 Mg, (3 - 6 Per Day)		Mylan
	Oramorph			S	Unknown	Unk		Mylan
	Tapentadol			S	Transplacental	100 Mg		Mylan
	Daktarin /00310801/			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	11777505	EXPEDITED (15-DAY)		HO	FR-FRI-1000081157		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Persecutory Delusion	Escitalopram			S	Oral			Forest
	Preterax			C	Oral	2.5 Mg		Not Reported
	Seresta			C	Oral			Not Reported
	Movicol			C	Oral	Per Needed		Not Reported
	Effexor			C	Oral	18.75 Mg		Not Reported
	Uvedose			C	Oral	0.2143 Df		Not Reported
	Doliprane			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	11925915	EXPEDITED (15-DAY)		HO	CA-ROCHE-1695785		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Clonazepam		S	Oral	Not Reported
	Cipralex		S	Oral	Not Reported
	Domperidone		S	Oral	Not Reported
	Ferrous Sulfate		S	Oral	Not Reported
	Gabapentin		S	Oral	Not Reported
	Gabapentin		S	Oral	Not Reported
	Temazepam		S	Oral	Not Reported
	Tylenol With Codeine		S	Oral	Not Reported
	Wellbutrin Xl		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	11927844	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005275		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Escitalopram Oxalate			S				Apotex
	Aripiprazole Tablets			S	Oral			Apotex
	Morphine			S	Oral			Not Reported
	Acetaminophen W/Hydrocodone			S	Oral			Not Reported
	Cyclobenzaprine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	11927862	EXPEDITED (15-DAY)		OT	FR-FRI-1000082202		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alveolar Lung Disease; Interstitial Lung Disease; Muscle Spasms	Escitalopram			S		7.5 Mg		Forest
	Escitalopram			S		7.5 Mg		Not Reported
	Amiodarone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	11929468	DIRECT					48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Dizziness; Product Substitution Issue	Escitalopram			S	Oral	1xday		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	7835256	EXPEDITED (15-DAY)		DE, OT	CH-BRISTOL-MYERS SQUIBB COMPANY-15565690		1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death Neonatal; Foetal Exposure During Pregnancy	Abilify			S	Transplacental	15 Mg, Qd		Bristol Myers Squibb
	Cipralex			S	Transplacental	10 Mg, Bid		Not Reported
	Stilnox			S	Transplacental	12.5 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Transplacental	Unk		Not Reported
	Zyprexa			S	Transplacental	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11929580	EXPEDITED (15-DAY)		OT	CA-TEVA-627236ACC		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Obsessive Thoughts; Psychomotor Retardation; Somnolence	Citalopram			S	Oral	50 Milligram Daily;		Pliva
	Citalopram			S				Pliva
	Escitalopram			S		10 Milligram Daily;		Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11929802	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005332		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Death	Alprazolam Tablets Usp			S	Oral			Apotex
	Gabapentin			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex

	Trazodone Hydrochloride	S	Oral		Apotex
	Oxycodone	S	Oral		Not Reported
	Oxymorphone	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11930426	DIRECT	Y	LT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Suicidal Ideation	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11931462	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA-2016SE03115		37 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Vomiting	Inderal			S	Oral	1-1-0-0, I.E. 10 Mg In The Morning And 10 Mg At Midday With Nothing Else After That		Not Reported
	Sequase			S	Oral	0-1-0-2 Tablets, I.E. 200 Mg At Midday And 400 Mg Before Going To Sleep		Not Reported
	Escitalopram			S	Oral			Not Reported
	Lyrica			S	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11932137	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005385		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral			Apotex
	Bupropion Hydrochloride			S	Oral			Apotex
	Metoprolol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11932145	EXPEDITED (15-DAY)		HO	FR-FRI-1000082203		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antipsychotic Drug Level Above Therapeutic; Intentional Overdose; Tremor	Escitalopram			S	Oral	Overdose Of Unknown Number Of Tablets Once		Forest
	Escitalopram			S	Oral	Overdose Of Unknown Tablets Once		Forest
	Teralithe Lp			S	Oral			Not Reported
	Teralithe Lp			S	Oral	Overdose Of Unknown Number Of Tablets Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11932253	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005672		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral			Apotex
	Amlodipine Besylate			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11932254	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005673		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral			Apotex
	Citalopram			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11934824	DIRECT		OT			49 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Drug Ineffective; Product Substitution Issue	Lexapro 10 Mg		S	Oral	1 Pill Daily	Not Reported
	Lexapro		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11937767	DIRECT	Y	DS				Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Feeling Abnormal; Memory Impairment	Nexito 10mg Sun Pharma			S	Oral		20 DAY	Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	7832893	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-15571714		32 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Cavity Infection; Maternal Exposure During Pregnancy; Premature Delivery	Abilify			S	Unknown	15 Mg, Qd		Bristol Myers Squibb
	Cipralex			S	Unknown	10 Mg, Bid		Not Reported
	Stilnox			S	Unknown	12.5 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11714074	NON-EXPEDITED			US-PFIZER INC-2015375920			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive	Amoxicillin			S		Unk		Pfizer
	Chantix			S		Unk		Pfizer
	Xanax			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11933812	EXPEDITED (15-DAY)		DE, HO	US-APOTEX-2016AP005366		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Quetiapine Fumarate			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Sertraline Hydrochloride			S	Oral			Apotex
	Buspiprone Hydrochloride Tablets Usp			S	Oral			Apotex
	Acetaminophen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11934178	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005576		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S	Oral			Apotex
	Bupropion Hydrochloride			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Clonazepam Tablets Usp			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11934183	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005580		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Atenolol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11934584	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005416		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram Oxalate			S	Oral			Apotex
	Propranolol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11934837	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005425		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lisinopril			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Clonazepam Tablets Usp			S	Oral			Apotex
	Trazodone Hydrochloride			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11936414	EXPEDITED (15-DAY)		DE, OT	US-BAUSCH-BL-2016-000900		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Diazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11964484	DIRECT					38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Thinking Abnormal	Lexapro 10mg			S	Oral			Not Reported
	Straterra			C				Not Reported
	Vit B12			C				Not Reported
	Multi Vitamin			C				Not Reported
	B Complex			C				Not Reported
	L-Arginine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11833010	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-085903			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Abilify			S	Unknown	Unk, Qd		Bristol Myers Squibb
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11842716	EXPEDITED (15-DAY)		HO, OT	ES-ROCHE-1664023			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Disorientation; Drug Interaction; Psychomotor Hyperactivity; Toxicity To Various Agents	Cobimetinib			S	Oral			Not Reported
	Vemurafenib			S	Unknown	240 Mg Per Tablet		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Pristiq			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11865954	EXPEDITED (15-DAY)		OT	CA-APOTEX-2015AP015290		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nipple Pain; Product Contamination; Weight Increased	Apo-Escitalopram			S	Unknown	10 Mg, Qd		Apotex
	Tylenol With Codeine No.3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11938284	EXPEDITED (15-DAY)		DE	US-ROCHE-1698294		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Clonazepam			S	Oral			Not Reported
	Duloxetine			S	Oral			Not Reported

	Baclofen	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11939066	EXPEDITED (15-DAY)		HO	FR-FRI-1000082224		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Escitalopram			S	Oral	Overdose:15 Tablets Once		Forest
	Valium			S	Oral	Overdose: 1 Bottle Once		Not Reported
	Theralene			S	Oral	Overdose: 1 Bottle Once		Not Reported
	Theralene			S	Oral	Overdose: 50 Tablets Once		Not Reported
	Abilify			S	Oral	Overdose: 7 Tablets Once		Not Reported
	Stilnox			S	Oral	Overdose: 30 Tablets Once		Not Reported
	Seresta			S	Oral	Overdose: 80 Tablets Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11939089	EXPEDITED (15-DAY)		LT	FR-FRI-1000082208		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhagic Stroke	Escitalopram			S	Oral	10 Mg		Forest
	Xarelto			S	Oral	10 Mg		Not Reported
	Metformine			C		1700 Mg		Not Reported
	Cyanocobalamine			C				Not Reported
	Folic Acid			C		10 Mg		Not Reported
	Diffu K			C		1800 Mg		Not Reported
	Sotalol			C		40 Mg		Not Reported
	Furosemide			C		40 Mg		Not Reported
	Esomeprazole			C				Not Reported

Prednisone	C	7 Mg	Not Reported
Simvastatine	C	10 Mg	Not Reported
Tardyferon	C	160 Mg	Not Reported
Zopiclone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11939159	EXPEDITED (15-DAY)		HO	FR-FRI-1000082218		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral			Forest
	Cordarone			S	Unknown			Not Reported
	Eliquis			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11939693	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2016AP005636		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram Oxalate			S	Oral			Apotex
	Diazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11939694	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005640		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral			Apotex
	Topiramate			S	Oral			Apotex
	Meloxicam			S	Oral			Apotex
	Trazodone Hydrochloride			S	Oral			Apotex
	Olanzapine			S	Oral			Apotex
	Sumatriptan Tablets Usp			S	Oral			Apotex

	Buspiprone Hydrochloride Tablets Usp	S	Oral	Apotex
	Dextromethorfan	S	Oral	Not Reported
	Cyclobenzaprine	S	Oral	Not Reported
	Chlorpheniramine /00072501/	S	Oral	Not Reported
	Benzonatate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11939824	EXPEDITED (15-DAY)		HO	FR-FRI-1000082212		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Diarrhoea; Overdose; Prothrombin Time Ratio Decreased	Escitalopram			S	Oral	Intentional Overdose Of 140 Mg Of Escitalopram.		Forest
	Colchicine			S	Oral	Intentional Overdose Of 20 Mg Of Colchicine.		Not Reported
	Truvada			C	Unknown			Not Reported
	Reyataz			C	Unknown			Not Reported
	Norvir			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11939890	EXPEDITED (15-DAY)		HO	SE-TEVA-627544ISR		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Nausea; Toxicity To Various Agents	Atenolol			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11939999	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005444		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zolpidem Tartrate			S	Oral			Apotex

	Escitalopram Oxalate	S	Oral	Apotex
	Metoprolol	S		Not Reported
	Oxycodone	S		Not Reported
	Diazepam	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11963352	DIRECT		OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Aphasia; Fatigue; Feeling Abnormal; Headache; Mood Altered	Escitalopram 5 Mg Teva			S	Oral	1 Per Day		Teva
	Zyrtec			C				Not Reported
	Tums			C				Not Reported
	Pepto Bismol			C				Not Reported
	Biotin			C				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2016	7228610	EXPEDITED (15-DAY)		CA, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-14901060		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Abilify			S	Transplacental	10 Mg, Unk		Bristol Myers Squibb
	Seroplex			S	Transplacental	20 Mg, Unk		Not Reported
	Dipiperon			S	Transplacental	1 Df, Qd		Not Reported
	Ikaran			S	Transplacental	10 Mg, Unk		Not Reported
	Seresta			S	Transplacental	75 Mg, Unk		Not Reported
	Havlane			S	Transplacental	Unk Unk, Qd		Not Reported
	Tranxene			S	Transplacental	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2016	11941685	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005661		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Duloxetine Hydrochloride Delayed-Release Capsules		S	Oral	Apotex
	Clonazepam Tablets Usp		S	Oral	Apotex
	Escitalopram Oxalate		S	Oral	Apotex
	Baclofen		S	Oral	Not Reported
	Thyroid Preparations		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2016	11942071	EXPEDITED (15-DAY)		DE	US-ROCHE-1698285		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Clonazepam			S	Oral			Not Reported
	Bupropion Er			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2016	11942077	EXPEDITED (15-DAY)		DE	US-ROCHE-1698353		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Clonazepam			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	7643314	EXPEDITED (15-DAY)		OT	AU-BRISTOL-MYERS SQUIBB COMPANY-15352784		1 DAY	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Foetal Exposure During	Abilify			S	Transplacental	30 Mg, Qd		Bristol Myers Squibb

Pregnancy; Premature Baby	Lexapro		S	Transplacental	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	10390937	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-21291208			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Macrosomia; Hypoglycaemia Neonatal	Abilify			S	Transplacental	Unk		Bristol Myers Squibb
	Temesta (Lorazepam)			S	Transplacental	Unk		Not Reported
	Cipralex			S	Transplacental	Unk		Not Reported
	Topamax			S	Transplacental	Unk		Not Reported
	Seroquel			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	11706565	EXPEDITED (15-DAY)		HO	IT-JNJFOC-20151100729		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Dysarthria; Intentional Product Misuse; Self-Medication; Somnolence; Sopor; Speech Disorder	Haldol			S	Oral			Not Reported
	Biperiden Hydrochloride			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Clonidine Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	11942187	EXPEDITED (15-DAY)		DE	US-ROCHE-1698283		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Arrest; Toxicity To Various Agents	Diazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	11942309	EXPEDITED (15-DAY)		DE	US-ROCHE-1698299		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Diazepam			S	Oral			Not Reported
	Metoprolol			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	11943173	EXPEDITED (15-DAY)		OT	GB-ACCORD-037114		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Face Oedema; Fatigue; Oedema Peripheral	Escitalopram			S	Oral			Accord
	Atorvastatin			C				Not Reported
	Diclofenac			C				Not Reported
	Ezetimibe			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	11950071	EXPEDITED (15-DAY)		DE	US-LEHIGH_VALLEY-USA-POI0580201600017		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Poisoning Deliberate; Respiratory Arrest	Oxycodone Hcl Capsules			S				Lehigh Valley Tech
	Oxymorphone			S				Not Reported
	Alprazolam			S				Not Reported
	Gabapentin			S				Not Reported
	Escitalopram			S				Not Reported
	Trazodone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	11950139	EXPEDITED (15-DAY)		DE	US-LEHIGH_VALLEY-		42 YR	Female	USA

USA-
POI0580201600062

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone Hcl Capsules			S				Lehigh Valley Tech
	Metoprolol			S				Not Reported
	Zolpidem			S				Not Reported
	Diazepam			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11793716	EXPEDITED (15-DAY)		HO, OT	PHHY2015IT153835		84 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Abuse; Fall; Injury; Sopor	Alprazolam			S	Unknown			Novartis
	Cardioaspirin			S	Unknown			Not Reported
	Triatec (Ramipril)			S	Unknown			Not Reported
	Entact			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11957436	EXPEDITED (15-DAY)		HO	PHHY2016FR006565		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Medication Error; Somnolence	Baclofen			S	Oral	8 Df, Qd		Not Reported
	Amlodipine			S	Oral	10 Mg, Once/Single		Novartis
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Bisoprolol			S	Oral	5 Mg, Bid (10 Mg)		Not Reported
	Amitriptyline			S	Oral	10 Drp, Single Intake		Not Reported
	Symbicort			S	Unknown	1 Df, Bid (2 Df), 100/6/ Day		Not Reported
	Lormetazepam			S	Oral	1 Mg, Once/Single		Not Reported

Oxazepam	S	Oral	50 Mg, Bid (100 Mg)		Not Reported
Potassium	S	Oral	600 Mg, Bid (1200 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	7975924	EXPEDITED (15-DAY)		HO	DE-BRISTOL-MYERS SQUIBB COMPANY-15152879			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy; Premature Rupture Of Membranes	Abilify			S	Unknown	10 Mg, Qd		Bristol Myers Squibb
	Cipralex			S	Unknown	10 Mg, Unk		Not Reported
	Neuroleptic Agent			C	Unknown			Not Reported
	Folsan			C	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	10881233	EXPEDITED (15-DAY)		HO	HR-JNJFOC-20150211176			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Foetal Exposure During Pregnancy	Rispolept Consta			S	Transplacental			Not Reported
	Xeplion			S	Transplacental			Not Reported
	Risperidone			S	Transplacental			Not Reported
	Elicea			S	Transplacental			Not Reported
	Zoloft			S	Transplacental			Not Reported
	Lithium			S	Transplacental			Not Reported
	Normabel			S	Transplacental			Not Reported
	Seroquel Xr			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11787651	EXPEDITED (15-DAY)		HO	IT-BAYER-2015-474612		84 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug	Cardioaspirin			S				Bayer

Abuse; Sopor	Alprazolam	S		Not Reported
	Entact	S		Not Reported
	Triatec (Ramipril)	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11951078	EXPEDITED (15-DAY)		OT	GB-TEVA-603612ISR		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Quetiapine			S	Unknown	300 Milligram Daily;		Teva
	Citalopram			S	Unknown	20 Milligram Daily;		Pliva
	Escitalopram			S	Unknown			Ivax
	Dothieapin			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Lofepramine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11965198	EXPEDITED (15-DAY)		OT	US-ACCORD-037198			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depersonalisation/Dereali sation Disorder; Disorientation; Headache; Hyperacusis; Impaired Work Ability; Malaise; Migraine; Paraesthesia; Photophobia; Product Substitution Issue; Withdrawal Syndrome	Escitalopram			S		Took The Medication For 3 Weeks Daily		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11965437	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2016-00430		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Face Oedema; Fatigue; Oedema Peripheral	Escitalopram	S	Oral	5 Mg, Unk		Aurobindo
	Atorvastatin	C	Unknown			Not Reported
	Diclofenac	C	Unknown			Not Reported
	Ezetimibe	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11965528	EXPEDITED (15-DAY)		HO	IT-ROCHE-1699910		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Intentional Product Misuse; Language Disorder; Self-Medication; Somnolence; Sopor	Valium			S	Oral	2 Mg Hard Capsules 30 Capsules		Not Reported
	Haldol			S	Oral	1 Mg Tablets 30 Tablets		Not Reported
	Akineton			S	Oral	2 Mg Tablets 60 Tablets		Not Reported
	Cipralex			S	Oral	28 X 20 Mg Tablets In A White Pvc/Pe/Pvdc/Al Blis		Not Reported
	Catapresan			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11966718	EXPEDITED (15-DAY)		DE, LT	FR-FRI-1000082310		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Lovenox			S	Subcutaneous	16000 Iu		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11966719	EXPEDITED (15-DAY)		OT	NL-FRI-1000082178			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S	Unknown			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11968853	DIRECT					22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Skin Burning Sensation; Skin Warm	Lexapro Generic 10mg			S	Oral			Accord
	Lorazepam (Ativan)			C				Not Reported
	Bupap			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	8167342	EXPEDITED (15-DAY)		CA, HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-16113003		4 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysmorphism; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Large For Dates Baby; Respiratory Distress	Abilify			S	Transplacental	Unk		Bristol Myers Squibb
	Tercian			S	Transplacental	Unk		Not Reported
	Imovane			S	Transplacental	Unk		Not Reported
	Seroplex			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11059319	EXPEDITED (15-DAY)		DS	CA-FRI-1000076062		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Dreams; Antiandrogen Therapy; Arthralgia; Cold Sweat; Confusional State; Diarrhoea; Flatulence; Hunger; Hyperhidrosis; Prescribed Overdose; Rhinorrhoea; Sleep Disorder; Urinary Incontinence	Escitalopram			S	Oral	Overdose: Escitalopram 30 Mg Daily		Forest
	Zeldox			C	Unknown	Daily Dose Not Reported.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11885011	EXPEDITED (15-DAY)		HO	US-ACTAVIS-2015-28715		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Rhabdomyolysis	Risperidone (Watson Laboratories)			S	Unknown	1 Mg, Daily		Watson
	Risperidone (Watson Laboratories)			S	Unknown	0.5 Mg Qhs		Watson
	Escitalopram (Unknown)			S	Unknown	10 Mg, Daily		Not Reported
	Escitalopram (Unknown)			S				Not Reported
	Mirtazapine (Actavis Laboratories Fl)			S	Unknown	15 Mg Qhs		Actavis
	Mirtazapine (Actavis Laboratories Fl)			S				Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11944448	EXPEDITED (15-DAY)		HO, OT	CN-GLAXOSMITHKLINE-CN2015113537		56 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Escitalopram Oxalate			S		Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11968828	EXPEDITED (15-DAY)		OT	GB-DRREDDYS-USA/UKI/15/0053339		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Quetiapine			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Dothiepin			S	Unknown			Not Reported
	Lofepramine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11969517	EXPEDITED (15-DAY)		OT	GB-ACTAVIS-2016-01616		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Quetiapine (Unknown)			S	Unknown			Actavis
	Escitalopram (Unknown)			S	Unknown	Unknown		Not Reported
	Dosulepin			S	Unknown	Unknown		Not Reported
	Fluoxetine (Unknown)			S	Unknown	Unknown		Watson
	Lofepramine (Unknown)			S	Unknown	Unknown		Not Reported
	Citalopram			C	Unknown	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11969913	EXPEDITED (15-DAY)		OT	GB-FRI-1000082216		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Face Oedema; Fatigue; Oedema Peripheral	Escitalopram			S	Oral	5 Mg Daily		Forest
	Atorvastatin			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Ezetimibe			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11971729	EXPEDITED (15-DAY)		OT	KR-BRISTOL-MYERS SQUIBB COMPANY-15908783			Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy; Pregnancy On Contraceptive; Uterine Dilation And Curettage	Aripiprazole			S	Oral	Unk		Bristol Myers Squibb
	External-Escitalopram			S	Oral	1 Df, Qd		Unknown
	Mefenamic Acid			C	Unknown	Unk		Not Reported
	Phazyme			C	Unknown	Unk		Not Reported
	Domperidone			C	Unknown	Unk		Not Reported

Almagate	C	Unknown	Unk		Not Reported
Ibudilast	C	Unknown	Unk		Not Reported
Talniflumate	C	Unknown			Not Reported
Diastase	C	Unknown	Unk		Not Reported
Lipase	C	Unknown	Unk		Not Reported
Ursodeoxycholic Acid	C	Unknown	Unk		Not Reported
Itopride Hcl	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11973020	EXPEDITED (15-DAY)		OT	CA-TEVA-629523USA			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alcohol Use; Dissociation; Dizziness; Emotional Disorder; Emotional Distress; Emotional Poverty; Feeling Abnormal; General Physical Health Deterioration; Hyperhidrosis; Impulsive Behaviour; Insomnia; Job Dissatisfaction; Pain; Paraesthesia; Personality Change; Quality Of Life Decreased; Therapeutic Response Unexpected; Withdrawal Syndrome	Teva-Escitalopram			S		Started Taking Product Approximately A Year Ago		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11977287	DIRECT					64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Libido	Escitalopram 10 Mg Accord			S	Oral		1.5 YR	Accord

Decreased; Weight Increased	Health			
	Zanax	C		Not Reported
	Vit B Complex With C	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	6754770	EXPEDITED (15-DAY)		CA, OT	CH-BRISTOL-MYERS SQUIBB COMPANY-14326458		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Presentation; Dysmorphism; Ear Malformation; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Multiple Congenital Abnormalities; Selective Eating Disorder	Abilify			S	Transplacental	30 Mg, Qd		Bristol Myers Squibb
	Cipralex			S	Transplacental	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11059709	EXPEDITED (15-DAY)		OT	CA-FRI-1000076063		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Breath Sounds Abnormal; Bronchitis; Chondropathy; Cough; Depression; Fall; Fatigue; Feeling Of Body Temperature Change; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Incorrect Product Administration Duration; Intervertebral Disc Disorder; Lymphoedema; Lymphoma; Motor Dysfunction; Nausea; Oedema Peripheral; Pain; Panic Attack; Photopsia;	Escitalopram			S	Unknown	20 Mg Once Daily At Bedtime		Forest
	Clorazepate			S	Oral	45 Mg		Not Reported
	Co Etidrocal			S	Unknown	500 Mg		Not Reported
	Esomeprazole			S	Unknown	40 Mg		Not Reported
	Gabapentin			S	Unknown	Dose Not Reported.		Not Reported
	Gabapentin			S	Unknown	Dose Not Reported.		Not Reported
	Ibuprofen			S	Unknown	100 Mg		Not Reported
	Morphine			S	Unknown	Dose Not Reported.		Not Reported
	Trazodone			S	Unknown	50 Mg Once Daily At Bedtime		Not Reported
	Voltaren Emulgel			S	Topical	3 Squeezes Once Or		Not Reported

Pneumonia; Respiratory Arrest; Therapeutic Response Changed; Therapeutic Response Decreased; Tremor; Walking Disability					Twice A Day And At Night	
	Voltaren Emulgel		S			Not Reported
	Voltaren Emulgel		S			Not Reported
	Zopiclone		S	Unknown	15 Mg Once Daily At Night	Not Reported
	Bupropion Hcl		C	Unknown	Dose Not Reported.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11069102	EXPEDITED (15-DAY)		LT	CA-FRI-1000076042		24 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Prescribed Overdose	Escitalopram			S	Oral	Overdose: Escitalopram 40 Mg Daily		Forest
	Adderall Xr			S	Oral	10 Mg		Not Reported
	Adderall Xr			S	Oral	20 Mg		Not Reported
	Dantrium			S	Oral			Not Reported
	Temazepam			S	Oral	15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11771268	EXPEDITED (15-DAY)		HO, OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-080558		93 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Encephalopathy; Enterococcus Test Positive; Extrapyramidal Disorder; Loss Of Consciousness; Malaise; Renal Failure; Rhabdomyolysis; Urinary Tract Infection	Abilify			S	Oral	Unk		Bristol Myers Squibb
	Cipralex /01588501/			S	Oral	20 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Oral	10 Mg, Qd		Not Reported
	Keppra			S	Oral	250 Mg, Bid		Not Reported
	Keppra			S	Oral	250 Mg, Qd		Not Reported
	Amoxicillin Sodium			S	Oral	500 Mg, Bid		Not Reported
	Valdoxan			C	Oral	25 Mg, Qd		Not Reported
	Xanax			C	Oral	0.25 Mg, Qd		Not Reported
	Xanax			C	Oral	0.125 Mg, Qd		Not Reported

Temesta /00273201/	C	Oral	0.5 Mg, Qd		Not Reported
Aspirin Cardio	C	Unknown	100 Mg, Unk		Not Reported
Nexium /01479302/	C	Oral	20 Mg, Qd		Not Reported
Anxiolit	C	Oral	15 Mg, Qid		Not Reported
Anxiolit	C	Oral	15 Mg, Qid		Not Reported
Anxiolit	C	Oral	7.5 Mg, Qid		Not Reported
Prednisone	C	Oral	2.5 Mg, Qd		Not Reported
Prednisone	C	Oral	5 Mg, Qd		Not Reported
Valtrex	C	Oral	500 Mg, Qd		Not Reported
Vitamine B6	C	Oral	40 Mg, Qd		Not Reported
Metoject	C	Subcutaneous	15 Mg, Qwk		Not Reported
Laxoberon	C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11803534	EXPEDITED (15-DAY)		HO	IT-TEVA-613107ACC		84 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Abuse; Fall; Head Injury; Overdose; Sopor	Alprazolam			S		1 Bottle		Teva
	Cardioaspirin - 100 Mg Compresse Gastroresistenti - Bayer S.P.A.			S				Not Reported
	Triatec - 2.5 Mg Compresse - Programmi Sanitari Integrati S.R.L.			S				Not Reported
	Entact - Compresse Rivestite Con Film - H. Lundbeck A/S			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11977844	EXPEDITED (15-DAY)		OT	FR-BRISTOL-MYERS SQUIBB COMPANY-21650262			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section;	Abilify			S	Unknown	15 Mg, Unk		Bristol Myers Squibb

Delirium; Hypertension; Maternal Exposure During Pregnancy; Off Label Use	Seroplex		S	Unknown	Unk	Not Reported
	Parkinane		S	Unknown	Unk	Not Reported
	Tenoretic		S	Unknown	1 Df, Qd	Not Reported
	Tercian		S	Unknown	1 Df, Qd	Not Reported
	Loxen (Nicardipine Hydrochloride)		C	Unknown	Unk	Not Reported
	Loxapac		C	Unknown	Unk Unk, Intermittent	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11980648	EXPEDITED (15-DAY)		OT	US-JNJFOC-20160116550			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Domperidone			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Itraconazole			S	Unknown			Not Reported
	Ketoconazole			S	Unknown			Not Reported
	Miconazole		Y	S	Unknown			Not Reported
	Miconazole			S	Unknown			Not Reported
	Droperidol			S	Unknown			Not Reported
	Desipramine			S	Unknown			Not Reported
	Doxepin			S	Unknown			Not Reported
	Dronedarone			S	Unknown			Not Reported
	Clomipramine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Flecainide			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported

Amitriptyline	S	Unknown	Not Reported
Ibutilide	S	Unknown	Not Reported
Imipramine	S	Unknown	Not Reported
Methadone	S	Unknown	Not Reported
Moxifloxacin	S	Unknown	Not Reported
Norfloxacin	S	Unknown	Not Reported
Nortriptyline	S	Unknown	Not Reported
Octreotide	S	Unknown	Not Reported
Ondansetron	S	Unknown	Not Reported
Perflutren	S	Unknown	Not Reported
Propafenone	S	Unknown	Not Reported
Ranolazine	S	Unknown	Not Reported
Ciprofloxacin	S	Unknown	Not Reported
Sotalol	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Voriconazole	S	Unknown	Not Reported
Aprepitant	S	Unknown	Not Reported
Cyclosporine	S	Unknown	Not Reported
Diltiazem	S	Unknown	Not Reported
Isoniazid	S	Unknown	Not Reported
Citalopram	S	Unknown	Not Reported
Clarithromycin	S	Unknown	Not Reported
Metronidazole	S	Unknown	Not Reported
Nicardipine	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Tetracaine	S	Unknown	Not Reported
Tetracycline	S	Unknown	Not Reported
Verapamil	S	Unknown	Not Reported
Tacrolimus	S	Unknown	Not Reported

Amidarone	S	Unknown	Not Reported
Clindamycin	S	Unknown	Not Reported
Fluconazole	S	Unknown	Not Reported
Clotrimazole	S	Unknown	Not Reported
Lidocaine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11981096	EXPEDITED (15-DAY)		HO	IT-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2016-BI-04		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Intentional Product Misuse; Language Disorder; Somnolence; Sopor	Catapresan			S	Oral			Boehringer Ingelheim
	Haldol			S	Oral	Strength: 1 Mg		Not Reported
	Akineton			S	Oral	Strength: 2 Mg		Not Reported
	Valium			S	Oral	Strength: 2 Mg		Not Reported
	Cipralex			S	Oral	Strength: 20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11982681	DIRECT		DS, OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Agitation; Anal Incontinence; Defaecation Urgency; Depression; Discomfort; Emotional Disorder; Eructation; Feeling Abnormal; Flatulence; Flatulence; Gastrointestinal Motility Disorder; Hallucination, Auditory; Hallucination, Visual; Hyperhidrosis;	Escitalopram 10 Mg			S		Taken By Mouth		Not Reported
	Spironolactone			C				Not Reported
	Nattokinase			C				Not Reported

Hypoaesthesia; Irritability; Lethargy; Nervousness; Overdose; Pain; Paraesthesia; Pruritus; Somnolence; Tremor; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2016	11981447	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2016-00527		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury	Escitalopram			S	Oral	190 Mg, Unk		Aurobindo
	Olanzapine			S	Oral	22.5 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11714569	EXPEDITED (15-DAY)		HO	GB-TEVA-605523ACC		121 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal	Azathioprine			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Ivax
	Omeprazole			S	Transplacental			Not Reported
	Co-Dydramol			S	Transplacental	Strength: 10/500		Not Reported
	Oramorph			S	Transplacental	3-6 Per Day		Not Reported
	Oramorph			S	Unknown			Not Reported
	Tapentadol			S	Transplacental	100 Milligram Daily;		Not Reported
	Daktarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11801512	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-107113			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Abuse; Somnolence	Alprazolam			S	Unknown			Sun
	Cardioasprin			S	Unknown			Not Reported
	Triatec (Ramipril)			S	Unknown			Not Reported
	Entact			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11805233	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2015M1042207			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Abuse; Fall; Head Injury; Overdose; Sopor	Alprazolam			S		1 Bottle		Not Reported
	Cardioaspirin			S		Unk		Mylan
	Triatec /00885601/			S		Unk		Mylan
	Entact			S		1 Bottle		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11982399	EXPEDITED (15-DAY)		OT	GB-ALKEM-001067		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Quetiapine/Quetiapine Fumarate			S				Alkem
	Escitalopram			S				Not Reported
	Dosulepin			S				Not Reported
	Fluoxetine			S				Not Reported
	Lofepramine			S				Not Reported
	Citalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11982942	NON-EXPEDITED			US-APOTEX-2015AP013833		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Therapy Non-Responder	Trazodone Hydrochloride			S	Unknown	100 Mg, Unk		Apotex

	Escitalopram Oxalate	S	Unknown	40 Mg, Unk	Apotex
	Bupropion Hydrochloride	S		Up To 375mg/Day	Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11983812	EXPEDITED (15-DAY)		HO	FR-SA-2016SA015041		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Cyamemazine			S	Oral	Form Drops		Not Reported
	Cyamemazine			S	Oral	Form Unknown		Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Oral	Form Divisable Tablet		Not Reported
	Temesta (Lorazepam)			S	Oral	Form Divisable Tablet		Not Reported
	Olanzapine			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral	Film-Coated Divisible Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	7414202	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-15135338		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Respiratory Disorder Neonatal	Buspar			S	Transplacental	10 Mg, Tid		Bristol Myers Squibb
	Trittico			S	Transplacental	50 Mg, Qd		Not Reported
	Cipralex			S	Transplacental	5 Mg, Qd		Not Reported
	Effexor			S	Transplacental	75 Mg, Qd		Not Reported
	Seresta			S	Transplacental	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	8662921	EXPEDITED (15-DAY)		OT	IT-FRI-1000037024			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Escitalopram			S	Transplacental	10 Mg		Forest
	Pasaden [Etizolam]			C	Transplacental	0.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	11796894	EXPEDITED (15-DAY)		HO, OT	IT-FRI-1000081294		84 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Abuse; Overdose; Sopor	Escitalopram			S	Unknown	Unknown		Forest
	Escitalopram			S	Unknown	Overdose: One Package		Forest
	Triatec (Ramipril)			S	Unknown	Unknown		Not Reported
	Triatec			S	Unknown	Overdose: Unknown Dose		Not Reported
	Cardioaspirin			S	Unknown	Unknown		Not Reported
	Cardioaspirin			S	Unknown	Overdose: Unknown Dose		Not Reported
	Alprazolam			S	Unknown	Unknown		Not Reported
	Alprazolam			S	Unknown	Overdose: A Flacon		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	11891852	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-108711		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rhabdomyolysis	Risperidone			S	Unknown	Titrated Upto 1 Mg		Ranbaxy
	Risperidone			S	Unknown	0.5 Mg, Qd (Qhs)		Ranbaxy
	Escilatopram			S	Unknown	10 Mg, Daily		Not Reported
	Escilatopram			S				Not Reported
	Mirtazapine			C	Unknown	15 Mg, Qd(Qhs)		Not Reported
	Mirtazapine			C		15 Mg Qhs		Not Reported
	Mirtazapine			C		15 Mg Qhs		Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	11957821	NON-EXPEDITED			US-ABBVIE-15K-163-1343478-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Irregular; Middle Insomnia; Nervousness; Panic Reaction	Humira			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown	Dose Decreased		Not Reported
	Xanax			C		Wean Off		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	11991024	EXPEDITED (15-DAY)		HO	NL-ASTRAZENECA-2016SE09175		55 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Pulmonary Embolism	Seroquel Xr			S	Oral			Astrazeneca
	Seroquel Xr			S	Oral			Astrazeneca
	Seroquel Xr			S	Oral	Dose Reduced		Astrazeneca
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	11992660	DIRECT					47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Nausea	Lexapro 10 Mg			S	Oral	1 Pill, Once Daily, Taken By Mouth		Not Reported
	Cozaar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	9749853	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-19873413		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Oligohydramnios; Vomiting	Abilify			S	Unknown	10 Mg, Qd		Bristol Myers Squibb
	Cipralex /01588501/			S	Unknown	29jan13 29jan13		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11996053	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-630183GER		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby	Dominal (Prothipendyl Hydrochloride)			S	Transplacental	240 Mg /Day / Dosage Reduction To 40mg/D Step By Step		Not Reported
	Escitalopram			S	Transplacental	10 Milligram Daily;		Ivax
	Tavor (Lorazepam)			C	Transplacental			Not Reported
	Lyrica			C	Transplacental	300 Milligram Daily;		Not Reported
	Metamizol			C	Transplacental	500 Milligram Daily;		Not Reported
	Femaform Natal			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11998301	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2016NSR000296		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Baclofen			S	Oral	Unk Df, Unk		Northstar
	Duloxetine			S	Oral	Unk Df, Unk		Not Reported
	Clonazepam			S	Oral	Unk Df, Unk		Not Reported
	Escitalopram			S	Oral	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11999434	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Medication Error; Product Dispensing Error	Escitalopram Oxalate (Escitalopram) Tablet			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2016	11951240	EXPEDITED (15-DAY)		HO	PHHY2016IT006036		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury	Olanzapine			S	Oral	22.5 Mg, Qd		Novartis
	Escitalopram			S	Oral	190 Mg, Once/Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2016	11999264	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2014002387			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby	Escitalopram			S	Transplacental	10 Mg ,Qd (0.0- 38.4. Gestational Week)		Macleods
	Dominal (Prothipendyl Hydrochloride)			S	Transplacental	240 Mg, Qd (0.0 - 38.4. Gestational Week)		Not Reported
	Dominal (Prothipendyl Hydrochloride)			S	Transplacental	40 Mg, Qd (0.-38.4. Gestational Week)		Not Reported
	Dominal (Prothipendyl Hydrochloride)			S		Unk		Not Reported
	Tavor (Lorazepam)			C	Transplacental	On Demand (0.0 - 38.4. Gestational Week)		Not Reported
	Lyrica			C	Transplacental	300 Mg, Qd (0.0 - 7. Gestational Week)		Not Reported
	Metamizol			C	Transplacental	500 Mg, Qd / On Demand (0.0 -38.4. Gestational Week)		Not Reported

	Femaform Natal	C	Transplacental	Unk, (5.0 -38.5. Gestatiaonal Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2016	12000711	NON-EXPEDITED			US-PFIZER INC-2016007250			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Vistaril			S		Unk		Pfizer
	Spiriva			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Advair			S		Unk		Not Reported
	Proair			S		Unk		Not Reported
	Prilosec			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Zyloprim			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Colace			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2016	12004144	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2016NSR000284		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Atenolol			S	Oral	Unk Df, Unk		Northstar
	Escitalopram			S	Oral	Unk Df, Unk		Not Reported
	Lamotrigine			S	Oral	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2016	12007719	EXPEDITED (15-DAY)		HO	JP-FRI-1000081929		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg		Forest
	Edirol (Eldecalcitol)			C	Oral	Unknown		Not Reported
	Arimidex (Anastrozole)			C	Oral	Unknown		Not Reported
	Mevalotin (Pravastatin Sodium)			C	Oral	Unknown		Not Reported
	Trazenta (Linagliptin)			C	Oral	Unknown		Not Reported
	Depas (Etizolam)			C	Oral	Unknown		Not Reported
	Mohrus Tape (Ketoprofen)			C	Cutaneous	Unknown		Not Reported
	Naboal (Diclofenac Sodium)			C	Unknown	Unknown		Not Reported
	Ruefrien (Sodium Gualenate Hydrate/L-Glutamine)			C	Oral	Unknown		Not Reported
	Claritin (Loratadine)			C	Oral	Unknown		Not Reported
	Hirudoid (Heparinoid)			C	Cutaneous	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	8793808	EXPEDITED (15-DAY)		OT	BE-BRISTOL-MYERS SQUIBB COMPANY-16699746		28 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Systemic Lupus Erythematosus	Abilify			S	Unknown	2.5 Mg, Unk		Bristol Myers Squibb
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	11442989	EXPEDITED (15-DAY)		HO	RU-FRI-1000079224		43 YR	Male	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome	Escitalopram			S	Oral	20 Mg, Qd		Forest
	Escitalopram			S	Oral	10 Mg, Qd		Forest
	Escitalopram			S	Oral	20 Mg, In The Morning		Not Reported
	Luaf41156			S	Oral	1 Mg, Qd (At Night)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	11616157	EXPEDITED (15-DAY)		HO, OT	PHEH2015US020054		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Arthralgia; Back Pain; Bone Pain; Burning Sensation; Chills; Cytogenetic Abnormality; Decreased Appetite; Diarrhoea; Dry Mouth; Dysgeusia; Facial Pain; Fatigue; Feeling Abnormal; Halo Vision; Headache; Hypometabolism; Hypotension; Immunoglobulins Increased; Influenza; Influenza Like Illness; Myalgia; Nervousness; Pain; Pain In Jaw; Palpitations; Photophobia; Spinal Pain; Tongue Dry; Toxicity To Various Agents; Urinary Tract Infection; Vision Blurred; White Blood Cell Count Decreased	Gilenya			S	Oral	0.5 Mg, Qd		Not Reported
	Prednisone			S	Unknown			Novartis
	Lexapro			S	Unknown	Unk		Not Reported
	Vit D			S	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	11702902	EXPEDITED (15-DAY)		DE, HO	PA-FRI-1000080649		89 YR	Female	PAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Asthenia; Drug-Induced Liver Injury; Hepatomegaly; Intestinal	Escitalopram			S	Oral			Forest

Haemorrhage; Jaundice;
Nausea

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	11977318	EXPEDITED (15-DAY)		HO, OT	IT-ELI_LILLY_AND_COMPANY-IT201601006788		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Malaise; Off Label Use	Olanzapine			S	Oral	2.5 Mg, Qd		Eli Lilly And Co
	Olanzapine			S	Oral	22.5 Mg, Single		Eli Lilly And Co
	Escitalopram Eg			S	Oral	Unk, Unknown		Not Reported
	Escitalopram Eg			S	Oral	190 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	12010008	EXPEDITED (15-DAY)		DE	US-DEP_13495_2016		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Abuse; Toxicity To Various Agents	Gabapentin			S	Oral	Df		Not Reported
	Alprazolam			S	Oral	Df		Not Reported
	Oxycodone			S	Oral	Df		Not Reported
	Oxymorphone			S	Oral	Df		Not Reported
	Escitalopram			S	Oral	Df		Not Reported
	Trazodone			S	Oral	Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	12010629	EXPEDITED (15-DAY)		HO	FR-FRI-1000082429		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence	Escitalopram			S	Oral	20 Mg		Forest
	Dafalgan			S	Oral	Overdose: 18 Grams Once		Not Reported
	Spifen			S	Oral	Overdose: 8 Grams Once		Not Reported

Lysanxia	S	Oral	30 Mg		Not Reported
Noctamide	S	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2016	11952593	EXPEDITED (15-DAY)		HO	IT-TEVA-627470ACC		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Malaise	Olanzapine			S	Oral	2.5 Milligram Daily; 2.5 Mg Daily		Teva
	Escitalopram			S	Oral	10 Mg Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2016	12034572	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2016NSR000325		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk Df, Unk		Northstar
	Escitalopram			S	Oral	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	11987850	EXPEDITED (15-DAY)		DS, HO	IT-ACCORD-037393		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Malaise	Escitalopram			S	Oral			Accord
	Olanzapine			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12036827	EXPEDITED (15-DAY)		OT	DE-ROCHE-1706615		36 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Myalgia; Rhabdomyolysis	Cellcept		S	Oral	750-0-500 Mg	Not Reported
	Cipralex		S	Oral		Not Reported
	Cipralex		S	Oral		Not Reported
	Ramipril		C	Oral		Not Reported
	Amlodipin		C	Oral		Not Reported
	Pantoprazol		C	Oral		Not Reported
	Colecalciferol		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12037351	NON-EXPEDITED			US-APOTEX-2015AP006456			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Exfoliation; Swelling Face	Paxil Tablets			S	Unknown			Apotex
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12037630	NON-EXPEDITED			US-APOTEX-2015AP011279		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Paxil Tablets			S	Unknown	Unk		Apotex
	Lexapro			S	Unknown	Unk		Not Reported
	Celexa /00582602/			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	Unk		Not Reported
	Prozac			S	Unknown	Unk		Not Reported
	Remeron			S	Unknown	Unk		Not Reported
	Pristiq			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12039859	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2016-00961		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby	Escitalopram 10 Mg			S	Transplacental	10 Mg, Daily		Aurobindo
	Dominal /00002701/			S	Transplacental	240 Mg, Daily		Not Reported
	Dominal /00002701/			S	Transplacental	40 Mg, Daily Step To Step		Not Reported
	Tavor /00273201/			C	Transplacental	On Demand		Not Reported
	Lyrica			C	Transplacental	300 Mg, Daily		Not Reported
	Metamizol /06276702/			C	Transplacental	500 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12040373	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2016012009		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Hypertension; Insulin Resistance; Labelled Drug-Drug Interaction Medication Error	Lamotrigine Tablet			S	Oral	100 Mg, 1d		Glaxosmithkline
	Lamotrigine Tablet			S	Oral	50 Mg, Qd		Glaxosmithkline
	Lexapro			S		100 Mg, Qd		Not Reported
	Hydroxyz Pam			S	Oral	25 Mg, Unk		Not Reported
	Levothyroxin			C				Not Reported
	Doxepine			C		Unk		Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12041717	NON-EXPEDITED			US-APOTEX-2015AP013620			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Paxil Tablets			S	Unknown			Apotex
	Lexapro			S	Unknown			Not Reported
	Effexor			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported

	Zoloft	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12042548	EXPEDITED (15-DAY)		DE	US-ARBOR PHARMACEUTICALS, LLC-US-2016ARB000059		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lamotrigine			S		Unk Df, Unk		Arbor
	Bupropion (Extended Release)			S		Unk Df, Unk		Not Reported
	Escitalopram			S		Unk Df, Unk		Not Reported
	Clonazepam			S		Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12042562	EXPEDITED (15-DAY)		DE	US-ARBOR PHARMACEUTICALS, LLC-US-2016ARB000063		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lamotrigine			S	Oral	Unk Df, Unk		Arbor
	Escitalopram			S	Oral	Unk Df, Unk		Not Reported
	Atenolol			S	Oral	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	11515477	EXPEDITED (15-DAY)		HO	CA-FRI-1000079541		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Escitalopram			S	Oral			Forest
	Clonazepam			S	Oral	1.5 Mg		Not Reported
	Domperidone			S	Oral	20 Mg		Not Reported
	Ferrous Sulphate			S	Oral	900 Mg		Not Reported
	Gabapentin			S	Oral	1200 Mg		Not Reported

Gabapentin	S	Oral	300 Mg		Not Reported
Temazepam	S	Oral	30 Mg		Not Reported
Tylenol/Codeine No.3	S	Oral	6 Df		Not Reported
Vitalux	S	Oral	Daily Dose Not Reported		Not Reported
Wellbutrin Xl	S	Oral	300 Mg		Not Reported
Acetaminophen/Codeine Phosphate	S	Oral	6 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	11831792	EXPEDITED (15-DAY)		LT	JP-FRI-1000081115		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury	Lexapro			S	Oral	10 Mg		Forest
	Lunesta			C	Oral	1 Mg		Not Reported
	Myslee			C	Oral	10 Mg		Not Reported
	Rohypnol			C	Oral	1 Mg		Not Reported
	Amlodipine			C	Oral	5 Mg		Not Reported
	Reminyl			C	Oral	16 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	11938747	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2016M1002890			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Malaise	Olanzapine			S		Unk		Not Reported
	Olanzapine			S	Oral	22.5 Mg, Qd		Not Reported
	Escitalopram Mylan			S		Unk		Mylan
	Escitalopram Mylan			S	Oral	190 Mg, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	11994845	EXPEDITED (15-DAY)		HO	IT-FRI-1000082405		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Intentional Product Misuse; Medication Error; Somnolence; Sopor; Speech Disorder	Escitalopram			S	Oral			Forest
	Catapresan			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Akineton			S	Oral			Not Reported
	Valium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12052909	EXPEDITED (15-DAY)		HO, OT	US-ELI_LILLY_AND_COMPANY-US200602005208		1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Exposure Via Breast Milk; Sedation; Selective Eating Disorder	Zyprexa			S	Transplacental			Eli Lilly And Co
	Topamax			S	Transplacental			Not Reported
	Lexapro /Usa/			S	Transplacental			Not Reported
	Abilify			S	Transplacental			Not Reported
	Remeron /Net/			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12055842	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-15298680			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pre-Eclampsia; Pregnancy On Oral Contraceptive; Premature Delivery	Abatacept			S	Intravenous (not otherwise specified)	10 Mg/Kg, Q4wk		Bristol Myers Squibb
	Metformin Hydrochloride			S	Oral	500 Mg, Bid		Bristol Myers Squibb
	External-Mycophenolate Mofetil			S	Oral	1000 Mg, Qd		Unknown
	External-Prednisone			S	Oral	5 Mg, Qd		Unknown
	External-Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Unknown
	External-Ethinylestradiol+Desogestrel			S	Oral	20 Mg, Qd		Not Reported

	External-Levothyroxine	S	Oral	150 Mg, Qd	Not Reported
	External-Iron	S	Oral	1 Df, Qd	Not Reported
	External-Esomeprazole	S	Oral	40 Mg, Qd	Not Reported
	External-Escitalopram Oxalate	S	Oral	10 Mg, Qd	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12058429	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Fatigue	Escitalopram Oxalate			S	Oral	20mg 90 One Po Qd By Mouth		Not Reported
	Lexapro			C				Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12059163	DIRECT		OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease Recurrence; Product Substitution Issue	Escitalopram 20mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12059201	DIRECT		OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Crying; Depression; Nightmare; Product Substitution Issue	Escitalopram 20mg Unknown			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12059555	DIRECT		LT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Suicidal Ideation	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	11969912	EXPEDITED (15-DAY)		HO	IT-FRI-1000082343		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Product Use Issue	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	Overdose: 20 Tablets Of 10 Mg		Forest
	Olanzapine			S	Oral	2.5 Mg		Not Reported
	Olanzapine			S	Oral	Overdose: 9 Tablets Of 2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	11975681	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-110257			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury	Olanzapine			S	Oral	22.5 Mg, Daily		Sun
	Escitalopram			S	Oral	190 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12057395	EXPEDITED (15-DAY)		OT	AT-PFIZER INC-2016065418		33 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Disturbance In Attention; Eye Pain; Gait Disturbance; Headache; Impaired Work Ability;	Lyrica			S		125 Mg, Daily (25-25-25-50)		Pfizer
	Lyrica			S				Pfizer
	Lyrica			S				Pfizer

Intentional Product Use Issue; Mental Impairment; Migraine; Nausea; Neck Pain; Night Sweats; Peripheral Coldness; Pruritus Generalised; Rash; Tremor; Vertigo; Vision Blurred; Weight Increased	Escitalopram Oxalate	S	5 Mg, Unk		Not Reported
	Escitalopram Oxalate	S			Not Reported
	Escitalopram Oxalate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12059537	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2016M1004610			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby	Escitalopram			S	Transplacental	10 [Mg/D]		Not Reported
	Dominal /00018902/			S	Transplacental	240 [Mg/D]/ Dosage Reduction To 40mg/D Step By Step		Mylan
	Tavor /00273201/			C	Transplacental	On Demand		Mylan
	Lyrica			C	Transplacental	300 [Mg/D]		Mylan
	Metamizol			C	Transplacental	500 [Mg/D]/ On Demand		Mylan
	Folic Acid			C	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12060148	EXPEDITED (15-DAY)		DE	US-EGALET US INC-US-2016EGA000033		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Abuse; Toxicity To Various Agents	Oxycodone Hydrochloride			S	Oral	Unk Df, Unk		Egalet
	Oxymorphone			S	Oral	Unk Df, Unk		Not Reported
	Alprazolam			S	Oral	Unk Df, Unk		Not Reported
	Gabapentin			S	Oral	Unk Df, Unk		Not Reported
	Escitalopram			S	Oral	Unk Df, Unk		Not Reported
	Trazodone			S	Oral	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12060391	EXPEDITED (15-DAY)		DE	US-EGALET US INC-US-2016EGA000079		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Oxycodone Hydrochloride			S	Oral	Unk Df, Unk		Egalet
	Metoprolol			S	Oral	Unk Df, Unk		Not Reported
	Zolpidem			S	Oral	Unk Df, Unk		Not Reported
	Diazepam			S	Oral	Unk Df, Unk		Not Reported
	Escitalopram			S	Oral	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12061097	EXPEDITED (15-DAY)		DE	US-PERRIGO-16US001189		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Morphine Sulfate 20 Mg/Ml 0l8			S	Oral	Unk		Perrigo
	Acetaminophen W/Hydrocodone			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported
	Aripiprazole			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12066354	DIRECT	Y				60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Tremor	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2016	11792317	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Weight Increased	Abilify			S	Unknown	Unk		Bristol Myers Squibb
	Lexapro			S	Unknown	Unk		Not Reported
	Remeron			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2016	12065940	EXPEDITED (15-DAY)		HO	US-ASTRAZENECA-2016SE12105		46 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Quetiapine			S	Oral			Zeneca
	Escitalopram			S	Unknown			Not Reported
	Lithium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2016	12070328	EXPEDITED (15-DAY)		OT	CA-SA-2016SA021353		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Torsade De Pointes	Furosemide			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2016	12070476	EXPEDITED (15-DAY)		HO	CA-SA-2016SA021401		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Depressed Mood; Dizziness; Fall; Hypotension; Orthostatic Hypotension; Pain; Visual Acuity Reduced	Furosemide	S	Unknown	Not Reported
	Amlodipine	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Metoprolol	S	Unknown	Not Reported
	Metoprolol	S	Unknown	Not Reported
	Oxazepam	S	Unknown	Not Reported
	Nitroglycerine	S	Transdermal	Not Reported
	Zopiclone	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Acetaminophen W/Codeine	C		Not Reported
	Atorvastatin Calcium	C		Not Reported
	Clopidogrel	C		Not Reported
	Hydroxychloroquine	C		Not Reported
	Nitroglycerine	C		Not Reported
	Pantoprazole	C		Not Reported
	Polyethylene Glycol	C		Not Reported
	Ramipril	C		Not Reported
	Vitamin D Nos	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2016	12070683	EXPEDITED (15-DAY)		OT	AT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-010026		47 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Abilify			S	Unknown	2.5 Mg, Unk		Bristol Myers Squibb
	Abilify			S	Unknown	5 Mg, Unk		Bristol Myers Squibb
	Risperdal			S	Unknown	1 Mg, Qd		Not Reported
	Gewacalm			S	Unknown	30 Mg, Qd		Not Reported
	Gewacalm			S	Unknown	20 Mg, Qd		Not Reported
	Gewacalm			S	Unknown	10 Mg, Qd		Not Reported
	Gewacalm			S	Unknown	5 Mg, Qd		Not Reported
	Seroquel			S	Unknown	50 Mg, Qd		Not Reported

Seroquel	S	Unknown	1 Df, Qd	Not Reported
Seroquel	S	Unknown	100 Mg, Qd	Not Reported
Seroquel	S	Unknown	75 Mg, Qd	Not Reported
Seroquel	S	Unknown	50 Mg, Qd	Not Reported
Seroquel	S	Unknown	25 Mg, Qd	Not Reported
Anafranil	S	Unknown	75 Mg, Qd	Not Reported
Cipralex /01588501/	S	Unknown	20 Mg, Qd	Not Reported
Cipralex /01588501/	S	Unknown	30 Mg, Qd	Not Reported
Trittico	S	Unknown	150 Mg, Qd	Not Reported
Trittico	S	Unknown	150 Mg, Qd	Not Reported
Trittico	S	Unknown	300 Mg, Qd	Not Reported
Trittico	S	Unknown	200 Mg, Qd	Not Reported
Trittico	S	Unknown	300 Mg, Qd	Not Reported
Trittico	S	Unknown	250 Mg, Qd	Not Reported
Trittico	S	Unknown	200 Mg, Qd	Not Reported
Trittico	S	Unknown	250 Mg, Qd	Not Reported
Rivotril	S	Unknown	2 Mg, Qd	Not Reported
Rivotril	S	Unknown	2.5 Mg, Qd	Not Reported
Rivotril	S	Unknown	1.5 Mg, Qd	Not Reported
Rivotril	S	Unknown	1.25 Mg, Qd	Not Reported
Rivotril	S	Unknown	1 Mg, Qd	Not Reported
Rivotril	S	Unknown	0.5 Mg, Qd	Not Reported
Cymbalta	S	Unknown	60 Mg, Qd	Not Reported
Ixel	S	Unknown	50 Mg, Qd	Not Reported
Ixel	S	Unknown	100 Mg, Qd	Not Reported
Ixel	S	Unknown	150 Mg, Qd	Not Reported
Ixel	S	Unknown	200 Mg, Qd	Not Reported
Paroxetin /00830801/	S	Unknown	40 Mg, Qd	Not Reported
Molaxole	S	Unknown	Unk	Not Reported

	Oleovit D3	S	Unknown	30 G, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2016	12071067	EXPEDITED (15-DAY)		OT	AT-FRI-1000082623		47 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea; Prescribed Overdose	Escitalopram			S	Unknown	20 Mg		Forest
	Escitalopram			S	Unknown	Overdose: 30 Mg Daily		Forest
	Rivotril			S	Unknown	2 Mg		Not Reported
	Rivotril			S	Unknown	2.5 Mg		Not Reported
	Rivotril			S	Unknown	1.5 Mg		Not Reported
	Rivotril			S	Unknown	1.25 Mg		Not Reported
	Rivotril			S	Unknown	1 Mg		Not Reported
	Rivotril			S	Unknown	0.5 Mg		Not Reported
	Cymbalta			S	Unknown	60 Mg		Not Reported
	Risperdal			S	Unknown	1 Mg		Not Reported
	Oleovit D3			S	Unknown	4.2857 Df		Not Reported
	Seroquel			S	Unknown	50 Mg		Not Reported
	Seroquel			S	Unknown	50 Mg		Not Reported
	Seroquel			S	Unknown	Unit Dose: 100-200 Milligram		Not Reported
	Seroquel			S	Unknown	100 Mg		Not Reported
	Seroquel			S	Unknown	75 Mg		Not Reported
	Seroquel			S	Unknown	50 Mg		Not Reported
	Seroquel			S	Unknown	25 Mg		Not Reported
	Gewacalm			C	Unknown	30 Mg		Not Reported
	Gewacalm			C	Unknown	20 Mg		Not Reported
	Gewacalm			C	Unknown	10 Mg		Not Reported
	Gewacalm			C	Unknown	5 Mg		Not Reported
	Anafranil Retard			C	Unknown	75 Mg		Not Reported

Trittico Retard	C	Unknown	150 Mg		Not Reported
Trittico Retard	C	Unknown	150 Mg		Not Reported
Trittico Retard	C	Unknown	300 Mg		Not Reported
Trittico Retard	C	Unknown	200 Mg		Not Reported
Trittico Retard	C	Unknown	300 Mg		Not Reported
Trittico Retard	C	Unknown	250 Mg		Not Reported
Trittico Retard	C	Unknown	200 Mg		Not Reported
Trittico Retard	C	Unknown	250 Mg		Not Reported
Ixel	C	Unknown	50 Mg		Not Reported
Ixel	C	Unknown	100 Mg		Not Reported
Ixel	C	Unknown	150 Mg		Not Reported
Ixel	C	Unknown	200 Mg		Not Reported
Abilify	C	Unknown	2.5 Mg		Not Reported
Abilify	C	Unknown	5 Mg		Not Reported
Seroquel Xr	C	Unknown	200 Mg		Not Reported
Paroxetine	C	Unknown	40 Mg		Not Reported
Molaxole	C	Unknown	3 Df		Not Reported
Molaxole	C	Unknown	4 Df		Not Reported
Molaxole	C	Unknown	2 Df		Not Reported
Molaxole	C	Unknown	3 Df		Not Reported
Molaxole	C	Unknown	2 Df		Not Reported
Molaxole	C	Unknown	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2016	10233287	NON-EXPEDITED			US-PFIZER INC-2014160718		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Pristiq			S	Oral	100 Mg, 2x/Day (100 Mg In The Morning And 100 Mg In The Evening)		Pfizer

Pristiq	S	Oral	25 Mg, 1x/Day	Pfizer
Effexor	S		Unk	Pfizer
Zoloft	S		Unk	Pfizer
Prozac	S		Unk	Not Reported
Citalopram	S		Unk	Not Reported
Lexapro	S		Unk	Not Reported
Wellbutrin	S		Unk	Not Reported
Tegretol	C		Unk	Not Reported
Klonopin	C		Unk	Not Reported
Levothyroxine	C		Unk	Not Reported
Lidocaine	C		Unk	Not Reported
Lidocaine	C		Unk	Not Reported
Zofran	C		Unk	Not Reported
Oxycodone	C		Unk	Not Reported
Benztropine Mesilate	C		Unk	Not Reported
Vicoprofen	C		Unk	Not Reported
Ibuprofen	C		Unk, As Needed	Not Reported
Tylenol	C		Unk	Not Reported
Botox	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2016	11940126	EXPEDITED (15-DAY)		OT	IT-ELI_LILLY_AND_COMPANY-IT201601008195		26 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depression; Drug Ineffective	Fluoxetine Hydrochloride			S	Unknown	40 Mg, Qd		Unknown
	Clomipramine			S	Unknown	75 Mg, Qd		Not Reported
	Amitriptine			S	Unknown	25 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	75 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2016	12071616	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016077466		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Lower Respiratory Tract Infection; Sinusitis	Lyrica			S		200 Mg, 2x/Day		Pfizer
	Duloxetine			S		60 Mg, 1x/Day		Not Reported
	Escitalopram			S		20 Mg, 1x/Day		Not Reported
	Benadryl			S		25 Mg, 1x/Day		Not Reported
	Celexa			S		40 Mg, 1x/Day		Not Reported
	Ginger Root/Vitamin B6			S		150 Mg, 1x/Day		Not Reported
	Turmeric			S		500 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2016	12073194	EXPEDITED (15-DAY)		CA, OT	DE-FRI-1000082466		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby	Escitalopram			S	Transplacental	10 Mg		Forest
	Tavor (Lorazepam)			S	Transplacental			Not Reported
	Lyrica			S	Transplacental	300 Mg		Not Reported
	Metamizol			S	Transplacental	500 Mg		Not Reported
	Dominal (Prothipendyl Hydrochloride)			S	Transplacental	240 Mg		Not Reported
	Femaform Natal			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2016	12073883	EXPEDITED (15-DAY)		DE	US-PERRIGO-16US001328		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Acetaminophen			S	Oral	Unknown, Unknown		Perrigo
	Quetiapine			S	Oral	Unknown, Unknown		Not Reported

	Escitalopram	S	Oral	Unknown, Unknown	Not Reported
	Sertraline	S	Oral	Unknown, Unknown	Not Reported
	Buspirone	S	Oral	Unknown, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2016	12077091	EXPEDITED (15-DAY)		HO	FR-FRI-1000082587		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma Muscle	Escitalopram			S	Oral			Forest
	Xarelto			S	Oral			Not Reported
	Modopar			C				Not Reported
	Levothyrox			C				Not Reported
	Zestoretic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2016	12077390	EXPEDITED (15-DAY)		OT	ZA-FRI-1000081546			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Inadequately Controlled	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12078701	EXPEDITED (15-DAY)		OT	US-ACCORD-037691		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Hot Flush; Myalgia; Nausea; Night Sweats; Pain	Escitalopram			S	Oral	Strength: 10 Mg		Accord
	Ativan			C		Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12078982	NON-EXPEDITED			US-PFIZER INC-2016028112		38 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Zoloft	S	Unk	Pfizer
	Effexor Xr	S	Unk	Pfizer
	Paxil	S	Unk	Not Reported
	Prozac	S	Unk	Not Reported
	Demerol	S	Unk	Not Reported
	Bactrim	S	Unk	Not Reported
	Viibryd	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12080654	EXPEDITED (15-DAY)		OT	FR-ASTELLAS-2016US004941		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Pancytopenia; Splenomegaly	Advagraf			S	Oral			Astellas
	Mecir Lp			S	Unknown	0.4 Mg, Unknown Freq.		Not Reported
	Imurel /00001501/			S	Oral			Not Reported
	Seroplex			S	Unknown			Not Reported
	Kardegic			C	Unknown			Not Reported
	Lantus			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Imodium			C	Unknown			Not Reported
	Aprovel			C	Unknown			Not Reported
	Lercan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12080668	EXPEDITED (15-DAY)		HO	FR-SA-2016SA024952		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Aprovel			S	Oral			Not Reported
	Seroplex			S	Oral	10 Mg		Not Reported
	Plavix			C	Oral	Strength: 75 Mg		Not Reported

	Lipanthyl	C	Oral	Strength: 160 Mg	Not Reported
	Tenormin	C	Oral	Strength: 50 Mg, Divisible Tablet	Not Reported
	Amlor	C	Oral	Strength: 5 Mg	Not Reported
	Atarax	C	Oral	Strength: 25 Mg, Divisible	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12080943	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2016-01098		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Divalproex			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Risperidone			S	Unknown	Unk		Aurobindo
	Fentanyl			S	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Bupropion			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12082815	DIRECT		OT			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Headache; Product Substitution Issue	Lexapro 10mg Tablet Aurobindo			S	Oral			Aurobindo
	Vyvanse			C				Not Reported
	Fish Oil			C				Not Reported
	Vit D			C				Not Reported
	Multivitamin			C				Not Reported
	Lexapro 10mg Tablet Aurobindo (Generic)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12083698	DIRECT					58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Bones Fracture; Fall; Syncope	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12084156	DIRECT		OT			57 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Alopecia	Escitalopram			S	Oral	1 Daily Once Daily		Mylan
	Lostratan			C				Not Reported
	Norvasc			C				Not Reported
	Hydrochlorizide			C				Not Reported
	D3			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12084207	DIRECT		LT, OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Depression; Drug Withdrawal Syndrome; Headache; Muscle Twitching; Nausea; Panic Attack; Product Substitution Issue; Vomiting	Escitalopram 20 Mg			S	Oral		12 DAY	Not Reported
	Lexapro			C				Not Reported
	Alprazolam Extended Release			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12084244	DIRECT		DS			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Eye Irritation; Headache; Nausea; Panic Attack; Product Substitution Issue	Escitalopram 5mg Accord Healthcare			S	Oral	1 Pill Once Daily Taken By Mouth		Accord
	Synthroid			C				Not Reported
	Vit. D3			C				Not Reported

	Probiotic			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2016	12082529	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-010535		89 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia	Eliquis			S	Oral	2.5 Mg, Unk		Bristol Myers Squibb
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Atenolol			C	Unknown	20 Mg, Unk		Not Reported
	Coversyl /00790702/			C	Unknown	5 Mg, Unk		Not Reported
	Adenuric			C	Unknown	80 Mg, Unk		Not Reported
	Lescol			C	Unknown	80 Mg, Unk		Not Reported
	Seresta			C	Unknown	10 Mg, Unk		Not Reported
	Betaserc /00141801/			C	Unknown			Not Reported
	Mecir			C	Unknown	0.4 Mg, Unk		Not Reported
	Inexium /01479302/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2016	12083882	EXPEDITED (15-DAY)		HO	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-111707			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome	Quetiapine			S	Unknown	100 Mg, Daily		Sun
	Quetiapine			S				Sun
	Quetiapine			S	Unknown	150 Mg, Daily		Sun
	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported
	Lithium			S	Unknown	600 Mg, Daily		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2016	12084644	EXPEDITED (15-DAY)		HO	PHHY2016FR019470		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Metabolic Acidosis	Eucreas			S	Oral	1 Df, Bid (Morning And Evening)		Not Reported
	Enalapril			S	Oral	20 Mg, Qd (In Morning)		Novartis
	Escitalopram			S	Oral	20 Mg, Qd (In Morning)		Not Reported
	Zolpidem			S	Oral	Unk, Prn (In Evening)		Not Reported
	Alprazolam			S	Oral	0.5 Mg, Bid (In Morning And Evening)		Not Reported
	Amarel			S	Oral	2 Mg, Qd (In Morning)		Not Reported
	Trimebutine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2016	12085547	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016064354			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Malaise	Robitussin		Y	S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2016	12087835	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2014-12673			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Contusion; Cough; Drug Hypersensitivity; Memory Impairment; Myalgia; Psychomotor Hyperactivity; Rash; Urticaria	Penicillin V Potassium			S	Unknown			Aurobindo
	Amoxicillin			S	Unknown			Aurobindo
	Atenolol			S	Unknown			Aurobindo
	Simvastatin			S	Unknown			Aurobindo
	Celexa /00582602/			S	Unknown			Not Reported
	Cipro /00697201/			S	Unknown			Not Reported
	Keflex /00145501/			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

Lipitor	S	Unknown		Not Reported
Paxil /00500401/	S	Unknown		Not Reported
Trazodone Hcl	S	Unknown		Not Reported
Vicodin	S	Unknown		Not Reported
Metoprolol	C	Oral	Unk, Once A Day	Not Reported
Lasix /00032601/	C	Oral	1 Df, Two Times A Day	Not Reported
Aldactone /00006201/	C	Oral	1 Df, Once A Day	Not Reported
Digoxin	C	Oral	1 Tablet On Monday, Wednesday And Friday	Not Reported
Amiodarone	C	Oral	Half Tablets Once A Day	Not Reported
Pravastatin Sodium	C	Oral	1 Df, Once A Day	Not Reported
Omeprazole	C	Oral	1 Df, Once A Day	Not Reported
Lyrica	C	Unknown	1 Df, 3 Times A Day	Not Reported
Lorazepam	C	Oral	1 Df, As Necessary	Not Reported
Aspirin	C	Oral	1 Df, Once A Day	Not Reported
Flonase	C	Nasal	50 Mcg/Act 2 Puffs, Twice A Day	Not Reported
Warfarin Sodium	C	Unknown	2 Tablets On Friday, 1 Tablet The Rest Of The Week	Not Reported
Vitamin B-12	C	Oral	1 Df, Once A Day	Not Reported
Nortriptyline	C	Unknown	1 At Bed Time	Not Reported
Spironolactone	C	Unknown	25 Mg, Once A Day	Not Reported
Sulfa /00076401/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2016	12089178	DIRECT		DS, LT			29 YR	Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anhedonia; Apathy; Asthenia;	Escitalopram 10 Mg Richter Gedeon Nyrt.			S	Oral			Gedeon Richter

Cognitive Disorder; Decreased Appetite; Depression; Diffuse Alopecia; Disturbance In Attention; Drug Withdrawal Syndrome; Emotional Disorder; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Genital Hypoaesthesia; Genital Paraesthesia; Head Discomfort; Hypotension; Influenza Like Illness; Insomnia; Loss Of Employment; Loss Of Libido; Memory Impairment; Menstruation Irregular; Palpitations; Peripheral Coldness; Sexual Dysfunction; Sleep Disorder; Tremor; Weight Decreased	Omega 3	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2016	12092362	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Product Substitution Issue	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	9232851	EXPEDITED (15-DAY)		DS	FR-JNJFOC-20130404027		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Creatine Phosphokinase Increased; Drug Interaction; Myalgia;	Intelence			S	Oral			Not Reported
	Norvir			S	Oral			Not Reported

Neuropathy Peripheral	Seroplex	S	Oral		Not Reported
	Prezista	C	Oral		Not Reported
	Isentress	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	11154636	EXPEDITED (15-DAY)		HO, LT, OT	FR-AMGEN-FRASP2015051933		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardio-Respiratory Arrest; Chest Pain; Diarrhoea; Electrocardiogram Qt Prolonged; Hypokalaemia; Lactic Acidosis; Malaise; Nausea; Torsade De Pointes; Ventricular Dyssynchrony	Procoralan			S	Oral	5 Mg, Bid		Amgen
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Atacand			C		4 Mg, Daily		Not Reported
	Aldactone /00006201/			C		25 Mg, Unkevery Other Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	11669235	EXPEDITED (15-DAY)		CA, DE, HO, OT	US-FRI-1000080399		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Aqueductal Stenosis; Atrial Septal Defect; Bradycardia; Cardiomegaly; Cerebral Ventricle Dilatation; Congenital Hydrocephalus; Congenital Hydronephrosis; Congenital Spinal Fusion; Hemivertebra; Hyponatraemia; Hypotension; Irritability; Limb Malformation; Macrocephaly;	Lexapro			S	Transplacental	10mg		Forest

Malnutrition; Maternal Condition Affecting Foetus; Microtia; Multiple Congenital Abnormalities; Neonatal Respiratory Distress Syndrome; Premature Baby; Pulmonary Oedema; Pulmonary Vascular Disorder; Renal Failure; Seizure; Sepsis; Sepsis Neonatal; Shock; Tachypnoea; Truncus Arteriosus Persistent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	11889844	EXPEDITED (15-DAY)		HO	JP-FRI-1000081968		57 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome	Lexapro			S	Oral	10 Mg		Forest
	Myslee			C	Oral	5 Mg		Not Reported
	Saikokaryukotsuboreito			C	Oral			Not Reported
	Melex			C	Oral	0.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	11917151	EXPEDITED (15-DAY)		HO	FR-UCBSA-2016000712		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Arrhythmia	Cimzia			S		Unk		Ucb
	Seroplex			S	Oral	10 Mg, Once Daily (Qd)		Not Reported
	Havlane			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	12089126	EXPEDITED (15-DAY)		OT	FR-FRI-1000082646		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral			Forest
	Imurel			S	Oral			Not Reported
	Advagraf			S	Oral	1.5 Mg		Not Reported
	Kardegic			C	Oral			Not Reported
	Lantus			C	Unknown			Not Reported
	Imodium			C	Oral			Not Reported
	Aprovel			C	Oral			Not Reported
	Lercan			C	Oral			Not Reported
	Mecir			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	12091544	EXPEDITED (15-DAY)		OT	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2016-BI-09		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Pancytopenia; Splenomegaly	Mecir			S	Unknown	0.4 Mg		Boehringer Ingelheim
	Advagraf			S	Oral	1.5 Mg		Not Reported
	Imurel			S	Oral	50 Mg		Not Reported
	Seroplex			S	Unknown	5 Mg		Not Reported
	Kardegic			C	Unknown	75 Mg		Not Reported
	Lantus			C	Unknown			Not Reported
	Imodium			C	Unknown	2 Mg		Not Reported
	Aprovel			C	Unknown	300 Mg		Not Reported
	Lercan			C	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	12091775	EXPEDITED (15-DAY)		HO	US-FRI-1000080395		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Complication Of Pregnancy; Cough; Diabetes Mellitus Inadequate Control; Diabetic Ketoacidosis; Exposure During Pregnancy; Menstruation Delayed; Nausea; Oropharyngeal Pain; Rhinorrhoea; Urinary Tract Infection; Vaginal Haemorrhage; Vomiting	Lexapro	S	Oral	10mg		Forest
	Relion	C				Not Reported
	Relion	C				Not Reported
	Novolog	C		30 Units		Not Reported
	Neurontin	C	Oral	600mg		Not Reported
	Zofran	C	Oral	24mg		Not Reported
	Ultram	C	Oral			Not Reported
	Albuterol	C				Not Reported
	Albuterol	C				Not Reported
	Zithromax	C	Oral	500mg		Not Reported
	Zithromax	C	Oral	250mg		Not Reported
	Mucinex	C	Oral			Not Reported
	Concept Dha	C	Oral			Not Reported
	Rocephin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	12092721	DIRECT		OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Substitution Issue	Lexapro Generic 20mg Generic---I Do Not Know More			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12095152	EXPEDITED (15-DAY)		DS	FR-ABBVIE-13P-056-1076954-00		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Myalgia; Neuropathy Peripheral	Norvir			S	Oral			Not Reported
	Intelence			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Isentress			C				Not Reported
	Prezista			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12099596	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Insomnia; Product Dispensing Error	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	10480274	EXPEDITED (15-DAY)		HO	FR-009507513-1409FRA009458		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Body Temperature Abnormal; C-Reactive Protein Increased; Diarrhoea; Duodenitis; Gastritis; General Physical Condition Abnormal; Nausea; Oesophagitis	Victrelis			S	Unknown	800 Mg, Tid		Merck
	Ribavirin			S	Unknown	400 Mg, Bid		Merck
	Norfloxacin			S	Oral	Unk		Merck
	Peginterferon Alfa-2a			S	Unknown	180 Microgram, Qw		Not Reported
	Inexium (Esomeprazole Sodium)			S	Unknown	40 Mg, Qd		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Unknown	Unk		Not Reported
	Esomeprazole			S	Unknown	Unk		Not Reported
	Kardegic			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12055656	EXPEDITED (15-DAY)		OT	SI-FRI-1000082430		49 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Impaired Work Ability; Malaise; Nerve Conduction Studies Abnormal; Radiculopathy	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12099241	NON-EXPEDITED			US-PFIZER INC-2016102369		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Irritability; Mood Altered; Nausea; Withdrawal Syndrome	Effexor			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12100989	EXPEDITED (15-DAY)		HO	FR-FRI-1000082674		22 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Escitalopram			S	Oral			Forest
	Temesta (Lorazepam)			S	Oral	6 Mg		Not Reported
	Loxapac			S	Oral	50 Mg		Not Reported
	Loxapac			S	Oral	100 Mg		Not Reported
	Olanzapine			S	Oral			Not Reported
	Olanzapine			S	Oral	20 Mg		Not Reported
	Xeroquel			C	Oral			Not Reported
	Seresta			C	Oral			Not Reported
	Risperdal			C	Oral	2 Mg		Not Reported
	Risperdal			C	Oral	6 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12101463	EXPEDITED (15-DAY)		HO	FR-SA-2016SA029056		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury	Enalapril Maleate		S	Oral		Not Reported
	Amarel		S	Oral	Morning	Not Reported
	Alprazolam		S	Oral	Morning And Evening	Not Reported
	Zolpidem		S	Oral	If Necessary On Evening	Not Reported
	Escitalopram		S	Oral		Not Reported
	Eucreas		S	Oral	Morning End Evening	Not Reported
	Trimebutine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12102313	EXPEDITED (15-DAY)		HO, OT	ALCN2016CA001392		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Vitalux			S	Oral	2 Tablets, Qd		Not Reported
	Wellbutrin			S	Oral	150 Mg, Bid		Not Reported
	Tylenol With Codeine No.3			S	Oral	2 Tablets, Tid		Not Reported
	Temazepam			S	Oral	30 Mg, Qd		Not Reported
	Gabapentin			S	Oral	600 Mg, Bid		Not Reported
	Gabapentin			S	Oral	300 Mg, Qd		Not Reported
	Ferrous Sulphate			S	Unknown	300 Mg, Tid		Not Reported
	Domperidone			S	Oral	10 Mg, Bid		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Tid		Not Reported
	Cipralex//Escitalopram			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12102866	NON-EXPEDITED			US-ACORDA-ACO_112554_2015			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Energy Increased; Inappropriate Schedule Of Product Administration; Insomnia; Logorrhoea;	Ampyra			S	Oral	10 Mg, Bid		Acorda
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Gilenya			C		0.5 Mg, Unk		Not Reported

Psychomotor Hyperactivity; Weight Increased	Amantadine	C	100 Mg, Unk	Not Reported
	Vitamin D Nos	C	4000 Iu, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12103098	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2016M1006967			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Confusional State; Drug Interaction; Hyponatraemia	Escitalopram			S	Unknown	30 Mg Daily		Not Reported
	Dosulepin			S	Unknown	225mg		Not Reported
	Dosulepin			S	Unknown	175mg		Not Reported
	Bupropion			S	Oral	75mg		Not Reported
	Quetiapine			C	Unknown	At Night		Mylan
	Lamotrigine			C	Unknown			Mylan
	Estradiol			C	Unknown			Mylan
	Ramipril			C	Unknown			Mylan
	Glipizide			C	Unknown			Mylan
	Metformin			C	Unknown			Mylan
	Lantus			C	Unknown			Mylan
	Atorvastatin			C	Unknown			Mylan
	Aspirin /00002701/			C	Unknown			Mylan
	Norfloxacin			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12108815	DIRECT					35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Lexapro 5 Mg			S	Oral	Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12109193	DIRECT	Y	OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram 20 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12104455	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2016-01806		54 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Product Substitution Issue	Escitalopram			S	Unknown			Aurobindo
	Cipralex /01588501/			C	Unknown	Use As Directed		Not Reported
	Diazepam			C	Unknown	1 Df, Unk		Not Reported
	Dihydrocodeine			C	Unknown	1 Df, Unk		Not Reported
	Lansoprazole			C	Unknown	1 Df, Once A Day		Not Reported
	Loperamide			C	Unknown	Use As Directed		Not Reported
	Metronidazole			C	Unknown	5 Ml, 3 Times A Day		Not Reported
	Oramorph			C	Unknown	5mls To Be Taken Four Times Daily When Required		Not Reported
	Paracetamol			C	Unknown	2 Df, Four Times/Day		Not Reported
	Zopiclone			C	Unknown	1 Df, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12105091	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20160215328			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Product Use In Unapproved Indication	Risperdal			S	Oral	One Tablet Per Day		Not Reported
	Depakote			S	Oral			Not Reported
	Tercian			S	Oral	Dose Strength 25 Mg Frequency Half A Tablet Per Day If Needed		Not Reported
	Seresta			S	Oral	One Tablet Per Day		Not Reported

	Seropam	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12105092	EXPEDITED (15-DAY)		CA, DE	FR-JNJFOC-20160215490			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Maternal Drugs Affecting Foetus; Spina Bifida	Risperdal			S	Transplacental	Mother'S Dose, 1 Tablet Per Day, On Demand		Not Reported
	Depakote			S	Transplacental	Mother'S Dose 500 Mg 2 Tablets Per Day		Not Reported
	Tercian			S	Transplacental	Mother'S Dose Strength 25 Mgfrequency Half A Tablet Per Day If Needed		Not Reported
	Seresta			S	Transplacental	Mother'S Dose, Frequency One Tablet Per Day On Demand		Not Reported
	Seropam			S	Transplacental	Mother'S Dose,Strength 20 Mg Frequency Half A Tablet Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12107292	EXPEDITED (15-DAY)		DE	CA-TEVA-637120ACC		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Death	Quetiapine			S	Unknown	100 Milligram Daily;		Teva
	Cipralex			S	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12109389	DIRECT					37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Dizziness; Fatigue; Feeling	Lexapro 10 Mg			S	Oral	1 Pill A Day, Once Daily, Taken By Mouth		Not Reported

Abnormal; Headache; Impaired Work Ability; Libido Decreased; Nausea; Night Sweats; Sleep Disorder; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12109454	DIRECT					44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Headache; Product Quality Issue	Escitalopram 20mg Teva			S	Oral			Teva
	Lunesta			C				Not Reported
	Welchol			C				Not Reported
	Omeprazole			C				Not Reported
	Amlodipine			C				Not Reported
	Motrin			C				Not Reported
	Melatonin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12109464	DIRECT					33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Paraesthesia; Product Formulation Issue; Withdrawal Syndrome	Escitalopram 20 Mg Camber			S	Oral	1 Pill Once Daily Taken By Mouth		Camber
	Adderall			C				Not Reported
	Magnesium			C				Not Reported
	Escitalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12109488	DIRECT		DS, OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Panic Attack; Product Substitution Issue	Escitalopram			S	Oral	1 Pill		Accord
	Escitalopram			S				Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2016	10097131	EXPEDITED (15-DAY)		OT	CA-FRI-1000066734		38 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Impulsive Behaviour	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2016	12094795	EXPEDITED (15-DAY)		OT	FI-FRI-1000082667			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage In Pregnancy; Pregnancy	Escitalopram			S	Oral	7.5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2016	12108789	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2016US01305			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Chest Discomfort; Dizziness; Drug Interaction; Palpitations; Rhabdomyolysis	Risperidone			S	Unknown	0.5 Mg, Qhs		Cipla
	Risperidone			S	Unknown	1 Mg, Qhs		Cipla
	Escitalopram			S	Unknown	10 Mg, Qd		Teva
	Escitalopram			S				Teva
	Mirtazapine			S	Unknown	15 Mg, Qhs		Not Reported
	Mirtazapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2016	12110397	EXPEDITED (15-DAY)		LT	FR-FRI-1000082737		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Distress;	Escitalopram			S		20 Mg		Forest

Sudden Death	Nebivolol	S	5 Mg	Forest
	Flecaine	S	200 Mg	Not Reported
	Atarax	S		Not Reported
	Paroxetine	C		Not Reported
	Lexomil	C		Not Reported
	Lexomil	C		Not Reported
	Mianserine	C		Not Reported
	Valium	C		Not Reported
	Subutex	C		Not Reported
	Suboxone	C		Not Reported
	Inexium	C		Not Reported
	Thiocolchicoside	C		Not Reported
	Tiorfan	C		Not Reported
	Doliprane	C		Not Reported
	Ibuprofene	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2016	12110398	EXPEDITED (15-DAY)		OT	GB-FRI-1000082757		54 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Product Substitution Issue	Escitalopram			S	Unknown			Forest
	Cipralex Film-Coated Tablets			C	Unknown			Not Reported
	Diazepam			C	Unknown	One Dosage Form As Necessary		Not Reported
	Dihydrocodeine			C	Unknown	One Dosage Form Daily		Not Reported
	Lansoprazole			C	Unknown	One Dosage Form Daily		Not Reported
	Loperamide			C	Unknown			Not Reported
	Metronidazole			C	Unknown	5 Ml Three Times Daily		Not Reported
	Oramorph			C	Unknown	5ml As Necessary		Not Reported
	Paracetamol			C	Unknown	Two Dosage Forms Four Times Daily		Not Reported
	Zopiclone			C	Unknown	One Dosage Form Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2016	12110406	EXPEDITED (15-DAY)		OT	SE-FRI-1000082759		22 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Intentional Overdose; Lethargy; Nausea; Toxicity To Various Agents	Escitalopram			S	Unknown	100 Mg		Forest
	Atarax			S	Unknown	150 Mg		Not Reported
	Sertraline			S	Unknown	1 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2016	12111283	EXPEDITED (15-DAY)		OT	US-FRI-1000082763			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Choking; Confusional State; Dysphagia; Muscle Spasms; Rib Fracture; Transient Ischaemic Attack; Tremor; Urinary Tract Infection	Lexapro			S				Forest
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2016	12111737	EXPEDITED (15-DAY)		OT	US-TAKEDA-2016TUS002961		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome; Serotonin Syndrome; Sinus Operation; Tachycardia	Brintellix			S	Unknown	Unk		Takeda
	Lexapro			S	Unknown	40 Mg, Unk		Not Reported
	Buspar			S	Unknown	60 Mg, Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported
	Requip			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	9240596	EXPEDITED (15-DAY)		DS	FR-FRI-1000044444		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Drug Interaction; Myalgia; Neuropathy Peripheral	Escitalopram			S	Oral			Forest
	Intelence			S	Oral	400 Mg		Not Reported
	Norvir			S	Oral	200 Mg		Not Reported
	Isentress			C		400 Mg		Not Reported
	Prezista			C		1200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	9880262	EXPEDITED (15-DAY)		OT	JP-BRISTOL-MYERS SQUIBB COMPANY-19068535		36 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Live Birth; Maternal Exposure During Pregnancy; Off Label Use	Abilify			S	Oral	3 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Oral	6 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Oral	9 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Oral	15 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Oral	12 Mg, Qd		Bristol Myers Squibb
	Lexapro			S	Oral	Tabs		Not Reported
	Silece			S	Oral	Tabs.		Not Reported
	Contomin			S	Oral	25 Mg, Bid		Not Reported
	Seroquel			S	Oral	25 Mg, Qd		Not Reported
	Cymbalta			S	Oral	Capsule.		Not Reported
	Pyrethia /00033002/			C	Unknown	25 Mg, Unk		Not Reported
	Tasmolin /00079501/			C	Unknown	1 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	10097126	EXPEDITED (15-DAY)		OT	CA-FRI-1000066732		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Crying; Dizziness; Dizziness Postural; Halo Vision; Insomnia; Muscle Spasms; Muscle Tightness; Myalgia; Panic Attack; Paraesthesia; Paraesthesia Oral; Photophobia; Sleep Disorder	Escitalopram			S	Oral	10 Mg		Forest
	Cymbalta			S	Oral			Not Reported
	Zomig			C		Daily Dose Not Reported.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12113578	EXPEDITED (15-DAY)		OT	GB-ACCORD-037987		54 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Product Substitution Issue	Escitalopram			S				Accord
	Cipralex			C		Use As Directed		Not Reported
	Diazepam			C		Take One As Needed		Not Reported
	Dihydrocodeine			C		Take One Every 4-6 Hrs		Not Reported
	Lansoprazole			C				Not Reported
	Loperamide			C		Use As Directed		Not Reported
	Metronidazole			C				Not Reported
	Oramorph			C		5mls To Be Taken Four Times Daily When Required		Not Reported
	Paracetamol			C				Not Reported
	Zopiclone			C		At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12114448	EXPEDITED (15-DAY)		HO	FR-FRI-1000082756		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Escitalopram			S	Oral	20 Mg		Forest

Enalapril	S	Oral	20 Mg		Not Reported
Eucreas	S	Oral	1 Df		Not Reported
Amarel	S	Oral	2 Mg		Not Reported
Alprazolam	S	Oral	0.5 Mg		Not Reported
Zolpidem	S	Oral	On Evening		Not Reported
Trimebutine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12114577	EXPEDITED (15-DAY)		HO	FR-FRI-1000082791		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Subcutaneous Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Previscan (Fluindione)			S	Oral	20 Mg		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported
	Olmesartan			C	Unknown	10 Mg		Not Reported
	Sotalol			C	Unknown	180 Mg		Not Reported
	Amlodipine			C	Unknown	10 Mg		Not Reported
	Befizal Lp			C	Unknown	400 Mg		Not Reported
	Forlax			C	Unknown			Not Reported
	Lumigan			C	Unknown			Not Reported
	Azarga			C	Unknown			Not Reported
	Iopidine			C	Unknown			Not Reported
	Celluvisc			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12114741	EXPEDITED (15-DAY)		OT	CH-SA-2016SA034629		32 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Synaesthetic; Hallucination, Visual	Zolpidem			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported

	Escitalopram	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12115669	NON-EXPEDITED			US-TORRENT-00001101			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation	Escitalopram Tablets, Usp			S				Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12116494	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2016M1006909			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Product Substitution Issue	Escitalopram			S		Unk		Not Reported
	Cipralex /01588501/			C		Use As Directed		Mylan
	Diazepam			C		1 Df, (Take One As Needed)		Mylan
	Dihydrocodeine			C		1 Df, (Take One Every 4-6 Hrs)		Mylan
	Lansoprazole			C		1 Df, Qd		Mylan
	Loperamide			C		Use As Directed		Mylan
	Metronidazole			C		5 Ml, Tid		Mylan
	Oramorph			C		5 Ml, (5mls To Be Taken Four Times Daily When Required)		Mylan
	Paracetamol			C		2 Df, Qid		Mylan
	Zopiclone			C		1 Df, Qd (At Night)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2016	10094557	EXPEDITED (15-DAY)		OT	CA-FRI-1000066660		85 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Potassium Decreased; Gastrointestinal Disorder	Escitalopram	S	Oral	10mg	Forest
	Losartan/Hydrochlorothiazide	C		100/25mg Daily	Not Reported
	Nifedipine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2016	10097135	EXPEDITED (15-DAY)		HO	CA-FRI-1000066738		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Drug Interaction; Electrocardiogram Qt Interval; Loss Of Consciousness; Nausea; Presyncope; Vomiting	Escitalopram			S	Oral	20 Mg In The Morning		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Pms-Methylphenidate			S	Oral	20 Mg		Not Reported
	Ethanol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2016	12118092	EXPEDITED (15-DAY)		HO	AU-LUPIN PHARMACEUTICALS INC.-2016-00766		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram			S	Unknown	30 Mg		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Bupropion			S	Oral			Not Reported
	Bupropion			S	Unknown			Not Reported
	Dothiepin			S	Unknown			Not Reported
	Dothiepin			S	Unknown			Not Reported
	Oestradiol			C	Unknown			Not Reported
	Glipizide			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Lantus Insulin			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Quetiapine			C	Unknown	At Night		Not Reported

	Lamotrigine	C	Unknown	Not Reported
	Aspirin	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2016	12120470	EXPEDITED (15-DAY)		DE	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2016-BI-11		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Pradaxa			S	Oral			Boehringer Ingelheim
	Seroplex			S	Oral			Not Reported
	Irbesartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2016	12120774	EXPEDITED (15-DAY)		OT	KR-FRI-1000082812		82 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Nervousness; Sleep Disorder	Escitalopram			S	Oral			Forest
	Clonazepam			C	Oral			Not Reported
	Donepezil			C	Oral			Not Reported
	Zolpidem			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2016	12121183	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-636413GER		< 1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Developmental Hip Dysplasia; Foetal Exposure During Pregnancy; Hypotonia; Seizure	Escitalopram			S	Transplacental	15 Milligram Daily;		Ivax
	Venlafaxin Retard			C	Transplacental	225 Milligram Daily;		Not Reported
	Euthyrox			C	Transplacental	100 Microgram Daily;		Not Reported
	Cyanocobalamin			C	Transplacental			Not Reported

	Folsaeure	C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2016	12121341	EXPEDITED (15-DAY)		OT	US-TEVA-636955USA		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Lower Respiratory Tract Infection; Sinusitis	Escitalopram			S	Unknown	20 Milligram Daily;		Ivax
	Duloxetine			S	Unknown			Teva
	Probiotic			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Celexa			S	Unknown	40 Milligram Daily;		Not Reported
	Ginger Root/Vitamin B6			S	Unknown	150 Milligram Daily;		Not Reported
	Turmeric			S	Unknown	500 Milligram Daily;		Not Reported
	Benadryl			S	Unknown	25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2016	12124060	EXPEDITED (15-DAY)		OT	CA-TEVA-637991ACC		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Chills; Condition Aggravated; Dizziness; Dyspnoea; Fatigue; Heart Rate Increased; Heart Rate Irregular; Hyperhidrosis; Loss Of Consciousness; Nausea; Photophobia	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Dayquil			C				Not Reported
	Diclofenac Sodium			C				Not Reported
	Ferrous Sulphate			C				Not Reported
	Misoprostol			C				Not Reported
	Multivitamine(S)			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2016	12124063	EXPEDITED (15-DAY)		OT	CA-TEVA-638431ACC		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Product Substitution Issue; Restlessness; Therapeutic Product Effect Decreased	Escitalopram	S	Oral		Ivax
	Lorazepam	C			Not Reported
	Olanzapine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2016	12124064	EXPEDITED (15-DAY)		LT	CA-TEVA-638487ACC		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Suicidal Ideation	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2016	12124066	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-637986ACC		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Feeling Hot; Flushing; Nausea; Paraesthesia Oral; Pharyngeal Oedema; Pruritus; Rash Generalised; Urticaria; Vomiting	Teva-Escitalopram			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2016	12124173	EXPEDITED (15-DAY)		OT	CA-TEVA-638457ACC		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Emotional Distress; Palpitations; Panic Reaction; Product Substitution Issue	Teva-Escitalopram			S	Unknown	25 Milligram Daily;		Ivax
	Clonazepam			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2016	12124174	EXPEDITED (15-DAY)		OT	CA-TEVA-638464ACC		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Headache; Hot Flush; Lymph Node Pain; Musculoskeletal Pain; Nausea; Neck Pain; Suicidal Ideation; Tinnitus	Teva-Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	10097134	EXPEDITED (15-DAY)		DE	CA-FRI-1000066735		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Completed Suicide; Product Use In Unapproved Indication; Tinnitus	Escitalopram			S	Oral	1 Df		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12124947	EXPEDITED (15-DAY)		CA, HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2014002444			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Developmental Hip Dysplasia; Dyspnoea; Foetal Exposure During Pregnancy; Hypotonia; Muscle Rigidity; Seizure; Tremor	Escitalopram			S	Transplacental	15 Mg, Qd (8 - 38.5 Gestational Week)		Macleods
	Euthyrox			C	Transplacental	100 Mg, Qd (0 -38.5 Gestational Week)		Not Reported
	Venlafaxin Retard			C	Transplacental	225 Mg, Qd (0- 8 Gestational Week)		Not Reported
	Cyanocobalamin			C	Transplacental	Unk (0-38.5gestational Week)		Not Reported

	Folsaure			C	Transplacental	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12126297	NON-EXPEDITED			US-FRI-1000079270			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Drug Ineffective; Intentional Product Misuse; Nausea; Off Label Use; Sexual Dysfunction	Viibryd			S				Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12126665	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2016GSK028175			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Ineffective; Emotional Disorder; Tremor	Wellbutrin			S				Glaxosmithkline
	Pristiq			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12126945	EXPEDITED (15-DAY)		OT	US-FRI-1000082886		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prescribed Overdose; Restless Legs Syndrome; Serotonin Syndrome; Sinus Operation; Tachycardia	Escitalopram			S	Unknown	40 Mg, Unk		Forest
	Brintellix			S	Unknown	Unk		Not Reported
	Buspar			S	Unknown	60 Mg, Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported
	Requip			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12126969	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2016M1007997			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Asthenia; Confusional State; Death Of Relative; Decreased Appetite; Depression; Diet Refusal; Expired Product Administered; Gait Disturbance; Insomnia	Escitalopram 10 Mg Film-Coated Tablets			S	Unknown	10 Mg, Qd		Mylan
	Concor			C		Unk		Mylan
	Lorazepam			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12127237	EXPEDITED (15-DAY)		HO	FR-FRI-1000082874			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased; Muscle Haemorrhage	Escitalopram			S	Oral			Forest
	Previscan (Fluindione)			S	Oral	15 Mg		Not Reported
	Amoxicillin Clavulanic Acid			C	Unknown			Not Reported
	Diffu K			C	Unknown			Not Reported
	Fumafer			C	Unknown			Not Reported
	Lasilix			C	Unknown			Not Reported
	Loxapac			C	Unknown			Not Reported
	Mecir			C	Unknown			Not Reported
	Movicol			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Mirtazapine			C	Unknown			Not Reported
	Risperidone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12128141	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016116979		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine	Lyrica			S		Unk		Pfizer

	Paxil /00830802/	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Prozac	S	Unk	Not Reported
	Naltrexone	S	Unk	Not Reported
	Savella	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12129964	DIRECT					35 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Paraesthesia; Product Substitution Issue; Vision Blurred; Withdrawal Syndrome	Escitalopram 10mg			S	Oral	1 1/2 Pills Once Daily Taken By Mouth		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12130677	DIRECT	Y	LT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Suicidal Ideation	Escitalopram 10mg			S	Oral	1/2 Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12132904	DIRECT					53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching; Myoclonus	Escitalopram 10 Mg			S	Oral	10 Mg (1 Pill) Once Daily Taken By Mouth		Not Reported
	Red Yeast Rice			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2016	10094552	EXPEDITED (15-DAY)		OT	CA-FRI-1000066659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Depressed Level Of Consciousness; Dizziness; Drug Withdrawal Syndrome; Sleep Disorder	Escitalopram			S				Forest
	Gilenya			S	Oral	0.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2016	10096741	EXPEDITED (15-DAY)		HO	CA-FRI-1000066733		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Large Intestine Operation	Escitalopram			S	Oral	20mg Every Dinner		Forest
	Zeldox			S	Oral	5.7143 Mg		Not Reported
	Zeldox			S	Oral	160 Mg		Not Reported
	Clonazepam			C		Daily Dose Not Reported		Not Reported
	Cogentin			C		Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2016	11920341	EXPEDITED (15-DAY)		HO	JP-FRI-1000082118		< 1 DAY	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Lexapro			S	Transplacental	10 Mg		Forest
	Depas (Etizolam)			S	Transplacental	1.5 Mg		Not Reported
	Magmitt			C	Transplacental	1500 Mg		Not Reported
	Famotidine			C	Transplacental			Not Reported
	Ritodrine			C	Transplacental	Unknown		Not Reported
	Racol			C	Transplacental	Unknown		Not Reported
	Medicon			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2016	12131243	NON-EXPEDITED			US-PFIZER INC-2015389052		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Piperacillin And Tazobactam			S		Unk		Unknown
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2016	12138879	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2016M1008247			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Developmental Hip Dysplasia; Foetal Exposure During Pregnancy; Hypotonia; Seizure	Escitalopram			S	Transplacental	15 Mg, Qd		Not Reported
	Venlafaxin			C	Transplacental	225 Mg, Qd (225 [Mg/D])		Mylan
	Euthyrox			C	Transplacental	100 Mg, Qd (100 [Mg/D])		Mylan
	Cyanocobalamin			C	Transplacental	Unk		Mylan
	Folsaeure			C	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2016	11915171	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-085896			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Feeding; Live Birth; Maternal Exposure During Pregnancy	Abilify			S	Unknown	Unk		Bristol Myers Squibb
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2016	12126995	EXPEDITED (15-DAY)		OT	US-JNJFOC-20160217307			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Lower	Benadryl		Y	S	Unknown	Taking For Years		Not Reported

Respiratory Tract Infection; Sinusitis	Lyrica	S	Unknown	Started Taking 4 Months Ago.	Not Reported
	Duloxetine	S	Unknown	Started Taking 4 Months Ago.	Not Reported
	Celexa	S	Unknown	Started Taking 3 Weeks Ago.	Not Reported
	Escitalopram	S	Unknown		Not Reported
	Ginger	S	Unknown	Started Taking 3 Months Ago.	Not Reported
	Turmeric	S	Unknown	Started Taking 3 Months Ago.	Not Reported
	Probiotics Nos	S	Unknown	Started Taking About Two Months Ago.	Not Reported
	All Other Therapeutic Products	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2016	12142036	EXPEDITED (15-DAY)		HO	CH-ASTRAZENECA-2016SE19681		94 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure Acute; Cholestatic Liver Injury; Escherichia Sepsis; Pancreatitis; Respiratory Failure	Nexium			S	Oral			Not Reported
	Beloc-Zok			S	Oral			Not Reported
	Ceftriaxon			S	Intravenous bolus			Not Reported
	Lasix			S	Intravenous bolus			Not Reported
	Amlodipin			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Metronidazole			S	Intravenous bolus			Not Reported
	Calciparine			S	Subcutaneous			Not Reported
	Propycil			S	Oral			Not Reported
	Ipramol			C	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2016	12142050	EXPEDITED (15-DAY)		OT	US-FRI-1000082888			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Intentional Product Misuse; Intentional Product Misuse; Pneumonia; Serotonin Syndrome	Viibryd			S	Oral			Forest
	Lexapro			S	Oral			Forest
	Tramadol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2016	12142769	EXPEDITED (15-DAY)		HO, OT	ES-FRI-1000082915			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Interaction; Psychomotor Hyperactivity; Toxicity To Various Agents	Escitalopram			S	Unknown	20mg		Forest
	Vemurafenib			S	Unknown	1920mg		Not Reported
	Cobimetinib			S	Oral	60mg		Not Reported
	Cobimetinib			S	Oral			Not Reported
	Pristiq			S	Unknown	50mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2016	12153256	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2016-02032			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Developmental Hip Dysplasia; Foetal Exposure During Pregnancy; Hypotonia; Seizure	Escitalopram			S	Transplacental	15 Mg, Daily		Aurobindo
	Venlafaxine			C	Transplacental	225 Mg, Daily		Not Reported
	Euthyrox			C	Transplacental	100 Mcg, Daily		Not Reported
	Cyanocobalamin			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2016	12153260	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2016-02033		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Haemorrhoids Thrombosed	Escitalopram			S	Oral	15 Mg, Daily		Aurobindo
	Venlafaxine			C	Oral	225 Mg, Daily		Not Reported
	Euthyrox			C	Oral	100 Mcg, Daily		Not Reported
	Cyanocobalamin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2016	12153315	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2016-02095		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Abuse; Respiratory Arrest	Escitalopram			S	Unknown			Aurobindo
	Oxycodone			S	Unknown			Aurobindo
	Ethanol			S	Unknown			Not Reported
	Methocarbamol			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2016	11885634	EXPEDITED (15-DAY)		HO	US-APOTEX-2015AP011284			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Aggression; Condition Aggravated; Drug Ineffective; Product Complaint; Psychiatric Symptom	Paxil Tablets			S	Unknown			Apotex
	Lexapro			S	Unknown	Unk		Not Reported
	Serzone			S	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Pristiq			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2016	12041724	EXPEDITED (15-DAY)		OT	US-JNJFOC-20160105241		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Gynaecomastia; Hyperinsulinaemia; Obesity	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	In Varying Doses Of 0.5 Mg And 1 Mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	In Varying Doses Of 0.5 Mg And 1 Mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	In Varying Doses Of 0.5 Mg And 1 Mg		Not Reported
	Risperdal			S	Oral	In Varying Doses Of 0.5 Mg And 1 Mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Zoloft			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Focalin			S	Unknown			Not Reported
	Focalin			S	Unknown			Not Reported
	Sertraline			C				Not Reported
	Abilify			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2016	12154311	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2016-02690		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Respiratory Arrest	Cyclobenzaprine			S	Unknown			Aurobindo

	Escitalopram	S	Unknown	Aurobindo
	Lisinopril	S	Unknown	Aurobindo
	Metoprolol	S	Unknown	Aurobindo
	Oxycodone	S	Unknown	Aurobindo
	Cephalexin /00145501/	S	Unknown	Not Reported
	Clonidine	S	Unknown	Not Reported
	Nitroglycerin	S	Unknown	Not Reported
	Ibuprofen	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Methylprednisolone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2016	12154351	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-02737		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Meloxicam			S	Oral			Aurobindo
	Loperamide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2016	12156306	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2016AP005594		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Blunted Affect; Drug Ineffective; Gastrointestinal Disorder; Homicidal Ideation; Intentional Overdose; Pre-Existing Condition	Fluoxetine Oral Solution Usp			S	Unknown	10 Mg, Unknown		Apotex
	Escitalopram Oxalate			S	Unknown	Unk Unk, Unknown		Apotex
	Aripiprazole Tablets			S	Unknown	2 Mg, Unknown		Apotex
	Aripiprazole Tablets			S	Unknown	5 Mg, Unk		Apotex
	Risperidone			S	Unknown	0.5 Mg, Bid		Apotex

Improved; Suicidal Ideation	Lamotrigine	S	Unknown	25mg Daily		Apotex
	Paracetamol	C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2016	12158143	DIRECT		HO, OT			17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Paraesthesia; Suicidal Ideation	Lexapro			S	Oral		3 MTH	Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2016	11421202	EXPEDITED (15-DAY)		HO	FR-FRI-1000079090		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Delirium	Escitalopram			S	Oral	5 Mg		Forest
	Tecfidera			S	Oral	480 Mg		Not Reported
	Bromazepam			S	Oral	0.5 Dosage Forms		Not Reported
	Kardegic			C	Unknown	160 Mg		Not Reported
	Levothyrox			C	Unknown	75 Microgram		Not Reported
	Tardyferon			C	Unknown	80 Mg		Not Reported
	Avlocardyl			C	Unknown	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2016	12142429	EXPEDITED (15-DAY)		CA, OT	DE-FRI-1000082865			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Developmental Hip Dysplasia; Foetal Exposure During Pregnancy; Hypotonia; Seizure	Escitalopram			S	Transplacental	15 Mg		Forest
	Venlafaxin Retard			C	Transplacental	225 Mg		Not Reported
	Euthyrox			C	Transplacental	100 Mcg		Not Reported
	Cyanocobalamin			C	Transplacental			Not Reported

	Folic Acid	C	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2016	12157381	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2016-00917			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Lower Respiratory Tract Infection; Sinusitis	Duloxetine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Celexa			S	Unknown			Not Reported
	Turmeric			S	Unknown			Not Reported
	Benadryl			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2016	12157434	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-02717		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Carbon Monoxide			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported
	Methamphetamine			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2016	12159586	EXPEDITED (15-DAY)		OT	CA-FRI-1000082962			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Negative Thoughts; Suicide Attempt	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2016	12160995	EXPEDITED (15-DAY)		DE	FR-FRI-1000083022		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Subdural Haematoma	Escitalopram			S	Oral			Forest
	Pradaxa			S	Oral			Not Reported
	Irbesartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2016	9880259	EXPEDITED (15-DAY)		HO, OT	JP-BRISTOL-MYERS SQUIBB COMPANY-20161428		< 1 DAY	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Neonatal Asphyxia; Tremor Neonatal	Abilify			S	Transplacental	3 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Transplacental	6 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Transplacental	9 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Transplacental	15 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Transplacental	12 Mg, Qd		Bristol Myers Squibb
	Lexapro			S	Transplacental	10 Mg, Bid		Not Reported
	Silece			S	Transplacental	Tabs		Not Reported
	Contomin			S	Transplacental	25 Mg, Bid		Not Reported
	Seroquel			S	Transplacental	25 Mg, Qd		Not Reported
	Cymbalta			S	Transplacental	Caps		Not Reported
	Pyrethia /00033002/			C	Transplacental	25 Mg, Unk		Not Reported
	Tasmolin /00079501/			C	Transplacental	1 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2016	12165417	NON-EXPEDITED			US-009507513-1602USA011844		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gynaecomastia	Proscar		S	Oral	5 Mg, Unk	Merck
	Lexapro		S	Oral	5 Mg, Qd	Not Reported
	Lexapro		S	Oral	10 Mg, Qd	Not Reported
	Lexapro		S	Oral	5 Mg, Qd	Not Reported
	Spironolactone		S	Oral	25 Mg, Qd	Not Reported
	Cholecalciferol		C			Not Reported
	Lisinopril		C		2.5 Mg, Q12h	Merck
	Imdur		C	Oral	30 Mg, Qd	Merck
	Lasix (Furosemide)		C	Oral	20 Mg, Qid	Not Reported
	Metoprolol		C	Oral	100 Mg, Qd	Not Reported
	Digoxin		C	Oral	125 Microgram, Qd	Not Reported
	Loratadine		C	Oral	10 Mg, Unk	Merck
	Vytorin		C	Oral	20 Mg, Qd	Merck
	Tamsulosin Hydrochloride		C	Oral	0.4 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2016	12167043	DIRECT		DE			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Partner Stress; Prescribed Overdose; Thinking Abnormal	Escitalopram (Generic For Lexapro) 1st Presciption 10mg. 7/15/15 Doubled To 20 Mg. 8/25/15 .			S	Oral	10mg 7/10/15 15mg 8/25/2015		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2016	11118739	EXPEDITED (15-DAY)		OT	IE-TEVA-563141ISR		38 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Escitalopram Teva			S	Oral	Increased From 5mg Daily Initially		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2016	12167540	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2016GSK032154		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disturbance In Sexual Arousal; Ejaculation Disorder; Erectile Dysfunction; Erection Increased; Loss Of Libido; Prescription Drug Used Without A Prescription	Lamictal Tablet			S	Oral	Two 200 Mg Tablets Once Daily By Mouth		Glaxosmithkline
	Viagra			S	Oral	1 Tablet Once By Mouth At Night		Not Reported
	Viagra			S				Not Reported
	Latuda			S	Oral	120 Mg Tablet 1d Orally		Not Reported
	Risperdal			S	Oral	0.5 Mg, 1d Orally		Not Reported
	Lithium			S	Oral	30 Mg, 1d		Not Reported
	Lithium			S				Not Reported
	Lexapro			S		40 Mg 1d At Night		Not Reported
	Nicotine			S		1 Pack Per Day Of E-Cigarettes		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2016	12168575	NON-EXPEDITED			US-ROXANE LABORATORIES, INC.-2016-RO-00496RO			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Loss Of Libido	Lithium Carbonate Capsules Usp, 150 Mg			S	Oral	30 Mg		Roxane
	Lithium Carbonate Capsules Usp, 150 Mg			S				Roxane
	Lamictal			S	Oral	400 Mg		Not Reported
	Latuda			S	Oral	120 Mg		Not Reported
	Risperdal			S	Oral	0.5 Mg		Not Reported
	Lexapro			S	Unknown	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2016	12168793	EXPEDITED (15-DAY)		CA, OT	CH-SA-2016SA043387			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Ureteric Anomaly; Exposure During Pregnancy	Cipralex			S	Transplacental			Not Reported
	Tranxilium			S	Transplacental			Not Reported
	Zolpidem			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2016	12169014	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000083118		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Asthenia; Asthenia; Chest Pain; Diarrhoea; Ecg Signs Of Myocardial Ischaemia; Electrocardiogram Abnormal; Fatigue; Fear; Gastrointestinal Disorder; Limb Discomfort; Muscle Spasms; Nausea; Paraesthesia; Unevaluable Event; Vomiting; Weight Decreased	Lexapro			S	Oral	20mg		Forest
	Lexapro			S	Oral	10mg		Forest
	Lexapro			S	Oral	5mg		Not Reported
	Lexapro			S		One Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2016	12170991	DIRECT					36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Activity; Depression; Dizziness; Drug Dependence; Nausea; Withdrawal	Lexapro 20mg - Generic Celexa 20mg Forest Laboratories/ Meijer#205			S				Not Reported
				S				Not Reported
	Apap			C				Not Reported

Syndrome	Cetirizine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2016	12170917	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-02416		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Benzatropine			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Primidone			S	Oral			Not Reported
	Temazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2016	12171612	EXPEDITED (15-DAY)		OT	AU-EDGEMONT-2016EDG00007		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Bupropion			S	Oral	75 Mg, "Po Mane"		Edgemont
	Dothiepin			S	Unknown	Unk		Not Reported
	Dothiepin			S	Unknown	225 Mg, Unk		Not Reported
	Dothiepin			S	Unknown	175 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	30 Mg, 1x/Day		Not Reported
	Ramipril			S	Unknown			Not Reported
	Quetiapine			C	Unknown	400 Mg, At Night		Not Reported
	Lamotrigine			C	Unknown	75 Mg, 2x/Day		Not Reported
	Estradiol			C				Not Reported
	Glipizide			C				Not Reported
	Metformin			C				Not Reported
	Lantus			C				Not Reported
	Atorvastatin			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2016	12173174	EXPEDITED (15-DAY)		OT	AU-PRINSTON PHARMACEUTICAL INC.-2016PRN00038		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Bupropion Hydrochloride			S	Oral	75 Mg, “Po Mane”		Prinston Pharmaceutical
	Escitalopram			S	Unknown	30 Mg, 1x/Day		Prinston Pharmaceutical
	Dothiepin			S	Unknown			Not Reported
	Dothiepin			S	Unknown	225 Mg, Unk		Not Reported
	Dothiepin			S	Unknown	175 Mg, Unk		Not Reported
	Ramipril			S	Unknown			Not Reported
	Quetiapine			C		400 Mg, At Night		Not Reported
	Lamotrigine			C	Unknown	75 Mg, 2x/Day		Not Reported
	Estradiol			C				Not Reported
	Glipizide			C				Not Reported
	Metformin			C				Not Reported
	Lantus			C				Not Reported
	Atorvastatin			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2016	12174574	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-03284		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Unknown			Aurobindo
	Topiramate			S	Unknown			Aurobindo
	Verapamil			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2016	12174442	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02266			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Citalopram			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Not Reported
	Promethazine			S	Unknown	Unk		Not Reported
	Desmethylpromethazine			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Nordiazepam			S	Unknown	Unk		Not Reported
	Hydroxyzine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	11983931	EXPEDITED (15-DAY)		OT	FR-GILEAD-2016-0194053		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Eviplera			S	Unknown	Unk		Gilead
	Seroplex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12174800	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2016002506			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Dermatitis; Erythema; Pemphigoid; Pruritus	Escitalopram			S	Unknown	10 Mg, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12176866	EXPEDITED (15-DAY)		HO	FR-SYMPLMED PHARMACEUTICALS-2016SYMPLMED000169			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Overdose; Amnesia; Asthenia; Bradycardia; Coma Scale Abnormal; Confusional State; Disorientation; Ejection Fraction Decreased; Electrocardiogram Qt Prolonged; Fall; Hypotonia; International Normalised Ratio Increased; Medication Error; Mydriasis; Somnolence	Perindopril		S	Oral	2.5 Mg, Unk	Unknown
	Perindopril		S	Oral	10 Mg-17.5 Mg, Single	Unknown
	Procoralan		S	Oral	5 Mg, Unk	Not Reported
	Procoralan		S	Oral	70 Mg, Single	Not Reported
	Zopiclone		S	Oral	7.5 Mg, Unk	Not Reported
	Zopiclone		S	Oral	37.5 Mg, Single	Not Reported
	Coumadine		S	Oral	10 Mg, Unk	Not Reported
	Coumadine		S	Oral	100 Mg-140 Mg, Single	Not Reported
	Escitalopram		S	Oral	10 Mg, Unk	Not Reported
	Escitalopram		S	Oral	70 Mg, Single	Not Reported
	Montelukast		S	Oral	10 Mg, Unk	Not Reported
	Montelukast		S	Oral	40 Mg-70 Mg, Single	Not Reported
	Cetirizine		S	Oral	10 Mg, Unk	Not Reported
	Cetirizine		S	Oral	40 Mg-70 Mg, Single	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12176933	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02277			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Fibrosis	Citalopram			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Cipla
	Nortriptyline			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Nordiazepam			S	Unknown	Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported
	O-Desmethyltramadol			S	Unknown	Unk		Not Reported
	Caffeine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12176935	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02275			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Myocardial Fibrosis	Citalopram			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12176942	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02276			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Citalopram			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12176958	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02274			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Citalopram			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12177068	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02278			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Citalopram			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12177080	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02279			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Citalopram			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Not Reported
	Nortriptyline			S	Unknown	Unk		Not Reported
	7-Aminonitrazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12177119	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02298			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Poisoning	Citalopram			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Not Reported
	Ethanol			S	Unknown	Unk		Not Reported
	Carbon Monoxide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12177224	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02301			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder	Citalopram			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Not Reported
	Ethanol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12177229	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02307			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accident; Poisoning	Citalopram		S	Unknown	Unk	Cipla
	Escitalopram		S	Unknown	Unk	Not Reported
	Zopiclone		S	Unknown	Unk	Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12177237	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02320			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning	Citalopram			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Not Reported
	Ethanol			S	Unknown	Unk		Not Reported
	Alimemazine			S	Unknown	Unk		Not Reported
	Desmethylalimemazine			S	Unknown	Unk		Not Reported
	Carbamazepin			S	Unknown	Unk		Not Reported
	Hydroxyzine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12178830	DIRECT		OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Hypertension; Sensory Disturbance	Escitalopram Oxalate 10 Mg Aurobindo Pharma			S	Oral			Aurobindo
	Baby Aspirin			C				Not Reported
	Effexor			C				Not Reported
	Pravastatin			C				Not Reported
	Centrum Silver			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12179818	EXPEDITED (15-DAY)		HO	SE-TAKEDA-2016TUS004248		37 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain;	Brintellix			S	Unknown	5 Mg, Qd		Takeda

Diarrhoea; Drug Interaction; Feeling Abnormal; Vomiting	Escitalopram-Form_Unknown	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	12177202	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2016-00013		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Imitrex			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported
	Suprax (Cefixime)			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Augmentin			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	12177486	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-02540		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Olanzapine			S	Unknown			Aurobindo
	Lisinopril			S	Unknown			Aurobindo
	Escitalopram			S	Unknown			Aurobindo
	Prednisone			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	12177722	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02322			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Myocardial Infarction	Citalopram	S	Unknown	Unk		Cipla
	Escitalopram	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	12178099	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02306			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Cold Exposure Injury	Citalopram			S	Unknown			Cipla
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	12178215	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2016-03185		24 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata	Escitalopram			S	Oral	15 Mg		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	12178365	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2016SE02321			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Fat Embolism	Citalopram			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	12178785	EXPEDITED (15-DAY)		OT	AU-JUBILANT GENERICS LIMITED-1049038		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Bupropion			S				Jubilant
	Escitalopram			S				Not Reported
	Dothiepin			S				Not Reported
	Ramipril			S				Not Reported

	Quetiapine Fumarate	C	Not Reported
	Lamotrogine	C	Not Reported
	Oestradiol	C	Not Reported
	Glipizide	C	Not Reported
	Metformin	C	Not Reported
	Lantus Brand Insulin	C	Not Reported
	Atorvastatin Calcium	C	Not Reported
	Aspirin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	11893805	EXPEDITED (15-DAY)		HO	TR-FRI-1000081967		59 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Dyspnoea; Hallucination; Hypercapnia; Hyponatraemia; Hypoxia; Somnolence	Escitalopram			S	Unknown	10 Mg Qd		Forest
	Acetylsalicylic Acid			C	Unknown	300 Mg		Not Reported
	Metoprolol			C	Unknown	25 Mg		Not Reported
	Perindopril			C	Unknown	5 Mg		Not Reported
	Amiodarone			C	Unknown	200 Mg		Not Reported
	Spironolactone			C	Unknown	50 Mg		Not Reported
	Aldactazide			C	Unknown	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12175431	EXPEDITED (15-DAY)		OT	GB-FRI-1000083125		24 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata	Escitalopram			S	Oral	15 Mg Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12182326	EXPEDITED (15-DAY)		OT	CZ-CIPLA LTD.-2016CZ02380			Unknown	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Stillbirth	Sertraline			S	Unknown	Unk		Cipla

	Citalopram	S	Unknown	Unk		Cipla
	Escitalopram	S	Unknown	Unk		Not Reported
	Fluoxetine	S	Unknown	Unk		Cipla
	Paroxetin	S	Unknown	Unk		Not Reported
	Fluvoxamin	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12182731	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-02834		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Atenolol			S	Unknown			Aurobindo
	Escitalopram			S	Unknown			Aurobindo
	Primidone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12182875	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-02839		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Finasteride			S	Oral			Aurobindo
	Lamotrigine			S	Oral			Aurobindo
	Quetiapine			S				Aurobindo
	Clonazepam			S	Oral			Not Reported
	Oxybutynin			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12183015	EXPEDITED (15-DAY)		CA, OT	DE-HETERO LABS LTD-1049139		10 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby	Escitalopram	S	Transplacental	Hetero
	Prothipendyl Hydrochloride	S	Transplacental	Not Reported
	Lorazepam	C	Transplacental	Not Reported
	Magnesium Chloride	C	Transplacental	Not Reported
	Pregabalin	C	Transplacental	Not Reported
	Folic Acid	C	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12183129	EXPEDITED (15-DAY)		OT	JP-XENOPORT, INC.-2016JP002362		80 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Blood Pressure Decreased; Depressive Symptom; Malaise; Nausea; Oedema Peripheral	Regnite			S	Oral	Unk		Xenoport
	Neupro			S	Transdermal	2.25 Mg, Once Daily		Not Reported
	Neupro			S	Transdermal	2.25 Mg, Once Daily		Not Reported
	Neupro			S	Transdermal	2.25 Mg, Once Daily		Not Reported
	Neupro			S	Transdermal	4.5 Mg, Once Daily		Not Reported
	Neupro			S	Transdermal	9 Mg, Once Daily		Not Reported
	Mohrus			S				Not Reported
	Irbetan			S				Not Reported
	Amlodin			S				Not Reported
	Urief			S				Not Reported
	Lantus			S				Not Reported
	Novorapid			S				Not Reported
	Opalmon			S				Not Reported
	Lexapro			S				Not Reported
	Meilax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12184826	EXPEDITED (15-DAY)		HO	SE-FRI-1000083207		37 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Drug	Escitalopram			S	Unknown			Forest

Interaction; Vomiting	Brintellix	S	Unknown	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12187563	DIRECT		OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Dyspnoea; Madarosis; Madarosis; Panic Attack; Product Substitution Issue	Excitalopram Oxalate			S	Oral			Not Reported
	Ocella (Birth Control)			C				Not Reported
	Diazepam			C				Not Reported
	Lexapro			C				Not Reported
	Fish Oil			C				Not Reported
	Multi Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12063207	EXPEDITED (15-DAY)		HO	FR-SA-2016SA019940		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disorientation; Hyponatraemia	Coaprovel			S	Unknown			Not Reported
	Seroplex			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Monocrixo			S	Oral			Not Reported
	Lexomil			S	Oral			Not Reported
	Levothyrox			C		50 Mcg Tablets		Not Reported
	Avlocardyl			C		40 Mg Tablets		Not Reported
	Dedrogyl			C				Not Reported
	Calcidose [Calcium Carbonate]			C				Not Reported
	Trophigil			C				Not Reported
	Flector			C		1% Gel		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12185907	EXPEDITED (15-DAY)		CA, OT	DE-HETERO LABS LTD-1049230			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Developmental Hip Dysplasia; Hypotonia; Seizure	Escitalopram			S	Transplacental			Hetero
	Venlafaxine Hydrochloride			C	Transplacental			Not Reported
	Levothyroxine Sodium			C	Transplacental			Not Reported
	Cyanocobalamin			C	Transplacental			Not Reported
	Folic Acid			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12186291	EXPEDITED (15-DAY)		OT	IT-ACCORD-038883		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12186477	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-03105		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S	Unknown			Aurobindo
	Escitalopram			S	Unknown			Aurobindo
	Zonisamide			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Lovastatin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12186572	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2016-03145		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Hydrocodone Bitartrate And Acetaminophen			S	Unknown			Aurobindo
	Gabapentin			S	Unknown			Aurobindo

	Escitalopram	S	Unknown	Aurobindo
	Ondansetron	S	Unknown	Aurobindo
	Zolpidem	S	Unknown	Aurobindo
	Amitriptyline	S	Unknown	Not Reported
	Tramadol	S	Unknown	Not Reported
	Linaclotide	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Lubiprostone	S	Unknown	Not Reported
	Liothyronine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12186652	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-03162		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S	Unknown			Aurobindo
	Sertraline			S	Unknown			Aurobindo
	Atomoxetine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12187326	NON-EXPEDITED			US-PFIZER INC-2016108272		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Spironolactone			S	Oral	25 Mg, 1x/Day		Pfizer
	Lexapro			S	Oral	5 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	5 Mg, 1x/Day		Not Reported
	Finasteride			S	Oral	5 Mg, Unk		Not Reported
	Vitamin D3			C				Not Reported
	Lisinopril			C		2.5 Mg, 2x/Day		Not Reported
	Imdur			C	Oral	30 Mg, 1x/Day		Not Reported

Lasix	C	Oral	20 Mg, 4x/Day		Not Reported
Metoprolol	C	Oral	100 Mg, 1x/Day		Not Reported
Digoxin	C	Oral	125 Ug, 1x/Day		Not Reported
Loratadine	C	Oral	10 Mg, Daily		Not Reported
Simvastatin	C	Oral	20 Mg, 1x/Day		Not Reported
Tamsulosin	C	Oral	0.4 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12188306	EXPEDITED (15-DAY)		CA, OT	CH-FRI-1000083227			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Ureteric Anomaly; Foetal Exposure During Pregnancy; Maternal Drugs Affecting Foetus	Escitalopram			S	Transplacental			Forest
	Tranxilium (Clorazepate Dipotassium)			S	Transplacental	10 Mg		Not Reported
	Zolpidem (Zolpidem)			S	Transplacental	0.5 Cp Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12188399	EXPEDITED (15-DAY)		HO, OT	FR-AMGEN-FRASP2016031851		46 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Asthenia; Bradycardia; Coma Scale Abnormal; Confusional State; Disorientation; Ejection Fraction Decreased; Electrocardiogram Qt Prolonged; Fall; Hypotonia; International Normalised Ratio Increased; Medication Error; Mydriasis; Overdose; Somnolence	Procoralan			S	Oral	Unk		Amgen
	Procoralan			S	Oral	70 Mg, Qd		Amgen
	Perindopril			S	Oral	Unk		Not Reported
	Perindopril			S	Oral	10 Mg - 17.5 Mg,, Qd		Not Reported
	Zopiclone			S	Oral	Unk		Not Reported
	Zopiclone			S	Oral	37.5 Mg, Qd		Not Reported
	Coumadine			S	Oral	Unk		Not Reported
	Coumadine			S	Oral	100 Mg - 140 Mg, Qd		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	70 Mg, Qd		Not Reported

Montelukast	S	Oral	Unk		Not Reported
Montelukast	S	Oral	40 Mg - 70 Mg, Qd		Not Reported
Cetirizine	S	Oral	Unk		Not Reported
Cetirizine	S	Oral	40 Mg - 70 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12189324	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-017428		46 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Confusional State; Disorientation; Fall; Hypotonia; International Normalised Ratio Increased; Medication Error; Mydriasis; Overdose	Coumadine			S	Unknown	10 Tab, Unk		Bristol Myers Squibb
	Zopiclone			S	Oral	5 Tab, Unk		Not Reported
	Procoralan			S	Unknown	5 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	7 Tab, Unk		Not Reported
	Perindopril			S	Unknown	1 Df, Unk		Not Reported
	Montelukast			S	Unknown	10 Mg, Unk		Not Reported
	Cetirizine			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12190534	DIRECT		HO, LT, OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Confusional State; Dyspnoea; Feeling Abnormal; Hyperhidrosis; Palpitations	Escitalopram 10 Mg Generic/Cvs			S	Oral	1 10 Mg Once Daily Taken By Mouth		Cvs Caremark

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12190969	DIRECT	Y	OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Suicidal Ideation; Urticaria	Escitalopram 20mg Unknown			S	Oral			Unknown
	Metformin			C				Not Reported
	Singulair			C				Not Reported
	Zofran			C				Not Reported
	Xoponex Neb			C				Not Reported
	Lantus			C				Not Reported
	Ibuprofen			C				Not Reported
	Loratadine			C				Not Reported
	Januvia			C				Not Reported
	Requip			C				Not Reported
	Amaryl			C				Not Reported
	Trilipex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12056824	EXPEDITED (15-DAY)		HO, OT	FR-ASTRAZENECA-2016SE12531		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Depressed Level Of Consciousness; Disorientation; Faecal Vomiting; Fall; Hypertension; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Productive Cough	Inexium			S	Oral			Not Reported
	Lexomil			S	Oral	(Roche) 1 Tablet Per Day		Not Reported
	Seroplex			S	Oral			Not Reported
	Coaprovel			S	Unknown	300 Mg + 12.5 Mg Daily		Not Reported
	Temesta (Lorazepam)			S	Oral			Not Reported
	Monocrixo			S	Oral			Not Reported
	Levothyrox			C				Not Reported
	Avlocardyl			C				Not Reported
	Dedrogyl			C				Not Reported
	Calcidose [Calcium Carbonate]			C		500		Not Reported
	Trophigil			C				Not Reported
	Flector			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12167913	NON-EXPEDITED			PHHY2016US028926		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Tremor	Lioresal Intratecal	S	Intrathecal	128.78 Ug, Qd		Not Reported
	Lioresal Intratecal	S	Intrathecal	183.77 Ug, Qd		Not Reported
	Simvastatin	S	Unknown			Novartis
	Lexapro	S	Unknown	Unk		Not Reported
	Keppra	S	Unknown	Unk		Not Reported
	Plavix	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12189651	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-03256		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Unknown			Aurobindo
	Hydrocodone Bitartrate And Acetaminophen			S	Unknown			Aurobindo
	Topiramate			S	Unknown			Aurobindo
	Promethazine			S	Unknown			Not Reported
	Verapamil			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Esomeprazole			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12189694	EXPEDITED (15-DAY)		LT	FR-009507513-1603FRA007070		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Lung Disorder	Sinemet 250 Mg/25 Mg Comprime Secable			S	Oral	Currently 5 Tablets Per Day		Merck
	Apomorphine Hydrochloride			S	Subcutaneous	Unk		Not Reported
	Mantadix			S	Oral	100 Mg, Qd		Not Reported
	Modopar			S	Oral	If Required		Not Reported

	Seroplex	S	Oral	15 Mg, Qd		Not Reported
	Imovane	S	Oral	7.5 Mg, Qd		Not Reported
	Sifrol	S	Oral	1.05 Mg, Qd		Not Reported
	Azilect	S	Oral	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12194504	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypoaesthesia; Hypoaesthesia; Nausea; Product Substitution Issue; Rash; Throat Tightness; Vision Blurred; Vomiting	Lexapro			S	Oral			Not Reported
	Topamax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12093822	EXPEDITED (15-DAY)		OT	DE-GLAXOSMITHKLINE-DE2016GSK023831		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Haemorrhage	Omacor			S	Oral	1000 Mg, Bid		Glaxosmithkline
	Cipralex			S	Oral	10 Mg, 1d		Glaxosmithkline
	Concor Cor			C		Unk		Not Reported
	Xanef			C		Unk		Not Reported
	Tromcardin Complex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12126947	EXPEDITED (15-DAY)		HO	JP-FRI-1000082856		72 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Inappropriate Antidiuretic	Lexapro			S	Oral	5 Mg		Forest

Hormone Secretion	Lexapro	S	Oral	10 Mg	Forest
	Nexium	S	Oral	20 Mg	Not Reported
	Mecobalamin	C	Oral	2 Tablets Divided Into 2 Doses/Day	Not Reported
	Juvela	C	Oral	400 Mg	Not Reported
	Depas (Etizolam)	C	Oral	0.5 Mg	Not Reported
	Limaprost Alfadex	C	Oral	15 Mcg	Not Reported
	Cravit	C	Oral	(Prescribed 1 Tablet At Night) 2 Tablets Was Taken For Symptom Of Suspected Cystitis From The Second	Not Reported
	Kallidinogenase	C	Oral	50 Units, 1 Tablet, 1 Dose/Day	Not Reported
	Loxonin	C	Transdermal		Not Reported
	Fluvastatin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12194426	EXPEDITED (15-DAY)		HO	FR-LUPIN PHARMACEUTICALS INC.-2016-01015		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Neuroleptic Malignant Syndrome	Risperdalconsta			S	Intramuscular			Not Reported
	Risperdalconsta			S	Intramuscular			Not Reported
	Risperdalconsta			S				Not Reported
	Escitalopram			S	Intramuscular	20 Mg		Not Reported
	Escitalopram			S				Not Reported
	Theralene			C	Intramuscular	20 Drops At Night If Need		Not Reported
	Theralene			C				Not Reported
	Siresta			C	Intramuscular	10 Mg		Not Reported
	Siresta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195061	NON-EXPEDITED			US-TEVA-640507USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195062	NON-EXPEDITED			US-TEVA-572570USA		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195064	NON-EXPEDITED			US-TEVA-554096USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Drug Ineffective; Mental Disorder; Product Substitution Issue; Urinary Hesitation	Escitalopram			S	Unknown	Frequency Not Provided		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195065	NON-EXPEDITED			US-TEVA-558205USA		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Generic Lexapro			S	Unknown	20 Milligram Daily;		Ivax
	Generic Lexapro			S				Ivax
	Nardil			S	Unknown	60 Milligram Daily;		Not Reported
	Nardil			S	Unknown	60 Milligram Daily;		Not Reported

	Xanax	S	Unknown	1.5 Milligram Daily;	Not Reported
	Xanax	S	Unknown	3 Milligram Daily;	Not Reported
	Klonopin	S	Unknown		Not Reported
	Klonopin	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195067	NON-EXPEDITED			US-TEVA-578801USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Energy Increased; Inappropriate Schedule Of Product Administration; Insomnia; Logorrhoea; Psychomotor Hyperactivity; Weight Increased	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Ampyra			S	Oral	20 Milligram Daily;		Not Reported
	Gilenya			C				Not Reported
	Amantadine			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195068	NON-EXPEDITED			US-TEVA-568938USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Somnolence	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195069	NON-EXPEDITED			US-TEVA-630736USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Nausea; Panic Attack; Product Substitution Issue; Retching; Vomiting	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195070	NON-EXPEDITED			US-TEVA-630086USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia	Escitalopram			S	Unknown	5 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195071	NON-EXPEDITED			US-TEVA-610345USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Crying; Feeling Abnormal; Heart Rate Increased; Nausea; Panic Attack; Product Substitution Issue; Somnolence; Tremor; Vomiting	Escitalopram			S	Unknown			Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195072	NON-EXPEDITED			US-TEVA-591715USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195073	NON-EXPEDITED			US-TEVA-569593USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195074	NON-EXPEDITED			US-TEVA-623213USA		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dyspnoea; Movement Disorder	Escitalopram			S	Oral	40 Milligram Daily;		Ivax
	Escitalopram			S				Ivax
	Buspar			C		10 Mg In Am, 5 Mg In Pm		Not Reported
	Phentermine			C		1/2 Daily		Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195075	NON-EXPEDITED			US-TEVA-593199USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195076	NON-EXPEDITED			US-TEVA-553201USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195077	NON-EXPEDITED			US-TEVA-564394USA		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Depressed Mood; Depression; Fatigue; Irritability; Menopausal Symptoms; Negative Thoughts; Off Label Use; Poor Quality Sleep;	Escitalopram			S	Oral			Ivax

Product Substitution Issue;
Product Use In
Unapproved Indication

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195088	NON-EXPEDITED		HO	US-TEVA-584675USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Generic Lexapro			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195089	NON-EXPEDITED			US-TEVA-611022USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195090	NON-EXPEDITED			US-TEVA-610420USA		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Salivary Hypersecretion	Escitalopram			S	Unknown			Ivax
	Abilify			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195091	NON-EXPEDITED			US-TEVA-586053USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sleep Disorder	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195092	NON-EXPEDITED			US-TEVA-614233USA		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Feeling Abnormal; Intentional Product Use Issue; Product Dispensing Error; Product Dose Omission; Product Substitution Issue	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Escitalopram			S				Ivax
	Diazepam			C	Oral	Take 1/2 When Needed		Not Reported
	Atenolol			C	Oral	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195093	NON-EXPEDITED			US-TEVA-631831USA		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Pain; Intentional Product Use Issue; Vulvovaginal Dryness; Wrong Technique In Product Usage Process	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12195094	NON-EXPEDITED			US-TEVA-591113USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction	Escitalopram			S	Unknown	20 Milligram Daily;		Ivax
	Lisinopril			S	Unknown	40 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12196017	EXPEDITED (15-DAY)		HO	FR-EISAI MEDICAL RESEARCH-EC-2016-015399		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Pariet			S	Oral	Unknown		Not Reported
	Seroplex			S	Oral	Unknown		Not Reported
	Ogastoro			S	Oral	Unknown		Not Reported

Coaprovel	C	Oral	Unknown		Not Reported
Lercan	C	Oral	Unknown		Not Reported
Ideos	C	Oral	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12072825	NON-EXPEDITED			US-PFIZER INC-2016021554			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer
	Effexor			S				Pfizer
	Lithium			S		Unk		Not Reported
	Risperdal			S		Unk		Not Reported
	Topamax			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12197811	NON-EXPEDITED			US-JNJFOC-20160305018			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Off Label Use; Product Use In Unapproved Indication	Risperdal			S	Oral	Started It 5 Years Ago		Not Reported
	Lamictal			S	Oral	Two Tablets Of 200 Mg Once A Day (Since 5 Years Ago)		Not Reported
	Latuda			S	Oral	Started It 4 Years		Not Reported
	Lithium			S	Oral	Started It 2 Months Ago		Not Reported
	Lithium			S	Oral	Started It 2 Months Ago		Not Reported

Lexapro	S	Unknown	Once At Night, Started 2 Years Ago		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12200159	EXPEDITED (15-DAY)		OT	CN-FRI-1000083331		63 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cerebral Atrophy; Chromaturia; Cold Sweat; Dry Mouth; Dysgeusia; Liver Function Test Abnormal	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral			Forest
	Lexapro			S	Oral	10 Mg		Not Reported
	Citalopram			S	Unknown	40 Mg		Forest
	Citalopram			S	Unknown			Forest
	Citalopram			S	Unknown	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	10101748	EXPEDITED (15-DAY)		OT	SE-FRI-1000066765		35 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Decreased Appetite; Dizziness; Nausea; Paranoia; Sleep Disorder; Tremor	Escitalopram			S	Unknown	1 Tablet Daily At Ovulation		Forest
	Propavan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12075341	EXPEDITED (15-DAY)		HO	FR-FRI-1000082561		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disorientation; Hyponatraemia	Escitalopram			S	Oral	10 Mg		Forest
	Coaprovel			S	Oral	300 Mg		Not Reported
	Temesta (Lorazepam)			S	Oral	1 Mg		Not Reported
	Inexium			S	Oral	20 Mg		Not Reported

	Monocrixo	S	Oral	100 Mg	Not Reported
	Lexomil Roche	S	Oral	1 Df	Not Reported
	Levothyrox	C			Not Reported
	Avlocardyl	C			Not Reported
	Dedrogyl	C			Not Reported
	Calcidose [Calcium Carbonate]	C			Not Reported
	Trophigil	C			Not Reported
	Flector	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12184496	EXPEDITED (15-DAY)		OT	US-ASTRAZENECA-2016SE26666			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choking; Depression; Drug Ineffective; Oesophageal Pain; Sensory Disturbance	Nexium			S	Oral			Not Reported
	Nexium			S	Oral			Not Reported
	Nexium			S	Oral			Not Reported
	Nexium			S	Oral			Not Reported
	Escitalopram Oxalate			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204247	EXPEDITED (15-DAY)		HO	BE-FRI-1000083428			Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Not Reported
	Abilify/Aripiprazole			C	Oral	(1/2 Of Tablet Of 10mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204661	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000083453		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coma; Depressed Level Of Consciousness; Intentional Overdose; Somnolence	Escitalopram		S	Oral	Overdose Of 280 Mg Once	Forest
	Tranxene		S	Oral	Overdose Of 560 Mg Once	Not Reported
	Laroxyl		S	Oral		Not Reported
	Meteospasmyl (Alverine Citrate\Dimethicone)		S	Oral	Overdose Of 3 Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204765	EXPEDITED (15-DAY)		OT	GB-ASTRAZENECA-2016SE30930			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Suicidal Ideation; Tinnitus	Quetiapine Fumarate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204800	EXPEDITED (15-DAY)		HO	FR-FRI-1000083408		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Pneumonia Aspiration	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Seresta			S	Oral	40 Mg		Not Reported
	Risperdal			S	Oral	1 Mg		Not Reported
	Plavix			C	Oral	75 Mg		Not Reported
	Pravastatine Sodique			C	Oral	1 Df		Not Reported
	Amlor			C	Oral	10 Mg		Not Reported
	Vogalene			C	Oral			Not Reported
	Duphalac			C	Oral	1 Df		Not Reported
	Pantoprazole			C	Oral	1 Df		Not Reported
	Spasfon Lyoc			C	Oral	1 To 3 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12207359	DIRECT	Y	HO			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hyponatraemia; Nausea; Vomiting	Escitalopram			S	Oral			Not Reported
	Aspirin			C				Not Reported
	Fluticasone			C				Not Reported
	Metoprolol			C				Not Reported
	Omeprazole			C				Not Reported
	Tiotropium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2016	10621751	NON-EXPEDITED			US-PFIZER INC-2014328455			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Vitamin D Nos			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2016	12206514	NON-EXPEDITED			US-PFIZER INC-2016143628		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer
	Crestor			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	E-Mycin			S		Unk		Not Reported
	Fenofibrate			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

Livalo	S	Unk	Not Reported
Lovastatin	S	Unk	Not Reported
Niacin	S	Unk	Not Reported
Paxil	S	Unk	Not Reported
Pravastatin Sodium	S	Unk	Not Reported
Zetia	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2016	12206605	EXPEDITED (15-DAY)		HO	TR-SCIEGEN PHARMACEUTICALS INC-2016SCILIT00045		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dyspnoea; Hallucination; Hypercapnia; Hyponatraemia; Hypoxia; Inappropriate Antidiuretic Hormone Secretion; Somnolence	Hydrochlorothiazide Tablets			S	Unknown	50 Mg, Unk		Sciegen
	Spironolactone			S	Unknown	50 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2016	12209031	EXPEDITED (15-DAY)		LT	FR-TEVA-644762ISR		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Lung Disorder	Azilect			S	Oral	1 Milligram Daily;		Teva
	Apokinon			S	Subcutaneous			Not Reported
	Mantadix 100 Mg			S	Oral	100 Milligram Daily;		Not Reported
	Sinemet 250 Mg/25 Mg			S	Oral	Carbidopa 25 Mg + Levodopa 250 Mg		Not Reported
	Sinemet 250 Mg/25 Mg Comprime Secable			S	Oral	5 Dosage Forms Daily; Carbidopa 25 Mg + Levodopa 250 Mg		Not Reported
	Modopar 125 (100 Mg/25 Mg)			S	Oral	Benserazide 25 Mg + Levodopa 100 Mg		Not Reported

	Seroplex	S	Oral	Not Reported
	Imovane 7.5 Mg	S	Oral	Not Reported
	Sifrol Lp 1.05 Mg	S	Oral	Not Reported
	Alprazolam	C		Not Reported
	Apomorphine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2016	12210570	DIRECT					34 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Rigidity; Myoclonus; Nausea; Restlessness; Stress; Weight Decreased	Hydromorphone Contin 3mg & 6mg			S	Oral	One 3mg & 6mg Capsule Twice Daily Taken By Mouth		Not Reported
	Cipralex 20 Mg			S	Oral	20mg / One Tablet Hs Once Daily Taken By Mouth		Not Reported
	Sodium Oxybate			C				Not Reported
	Celebrex			C				Not Reported
	Hydromorphone			C				Not Reported
	Lansoprazole			C				Not Reported
	Ciprolex			C				Not Reported
	Clonazepam			C				Not Reported
	Lactulose			C				Not Reported
	Dexedrine			C				Not Reported
	Lorazepam			C				Not Reported
	Vitamin B Complex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	11865333	EXPEDITED (15-DAY)		OT	FR-SA-2015SA212838		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Depressed Level Of Consciousness; Disorientation; Hypotension; Somnolence	Mianserin Hydrochloride			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported

Tramadol Base	S	Unknown		Not Reported
Valsartan	S	Unknown		Not Reported
Lasilix	S	Unknown		Not Reported
Seroplex	S	Unknown		Not Reported
Pantoprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	12210818	EXPEDITED (15-DAY)		OT	FR-FRI-1000083426		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aneurysm; Arrhythmia; Cardiac Arrest; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	12211277	EXPEDITED (15-DAY)		CA	US-FRI-1000083382			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Atresia; Congenital Pulmonary Hypertension; Kidney Malformation; Patent Ductus Arteriosus; Tethered Cord Syndrome; Vaginal Fistula; Ventricular Septal Defect	Lexapro			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	12212053	EXPEDITED (15-DAY)		HO	CH-ASTRAZENECA-2016SE30259		93 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Normochromic Normocytic Anaemia	Nexium			S	Oral			Astrazeneca
	Cipralex			S	Oral			Not Reported

Co Irbesan	S	Oral		Not Reported
Amlodipin	C	Oral		Not Reported
Seresta	C	Oral		Not Reported
Venoruton	C			Not Reported
Aspirin Cardio	C	Oral		Not Reported
Novalgine (Metamizole Sodium)	C			Not Reported
Celecoxib	C	Oral		Not Reported
Furadantin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	12212370	EXPEDITED (15-DAY)		HO	CA-TAKEDA-2016TUS002433AA			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Suicidal Ideation	Trintellix			S	Oral	10 Mg, Unk		Takeda
	Escitalopram			S	Unknown	Unk		Not Reported
	Clonazepam			C		Unk		Not Reported
	Amitriptyline			C		Unk		Not Reported
	Seroquel			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2016	12207624	NON-EXPEDITED		HO, LT, OT	US-MDT-ADR-2016-00550		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sedation Complication	Compounded Baclofen			S	Intrathecal	195.14 Mcg/Day		Not Reported
	Dilaudid (Hydromorphone)			S	Intrathecal	9.006 Mg/Day		Not Reported
	Dilaudid (Hydromorphone)			S	Intrathecal	12.008mg/Day		Not Reported
	Cymbalta			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Baclofen			S	Oral			Not Reported

Norco	S	Oral			Not Reported
Lasix	S	Oral			Not Reported
Ondansetron	S	Oral			Not Reported
Compounded Baclofen	S	Intrathecal	360.18mcg/Day		Not Reported
Gabapentin	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2016	12213929	EXPEDITED (15-DAY)		OT	GB-ACTAVIS-2016-06247			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Suicidal Ideation; Tinnitus	Escitalopram (Unknown)			S	Unknown	Unk		Not Reported
	Quetiapine Fumarate (Unknown)			S	Unknown	Unk		Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2016	12213932	EXPEDITED (15-DAY)		LT, OT	ES-WATSON-2016-06488		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes	Metoclopramide (Unknown)			S	Unknown	Unk		Watson
	Metoclopramide (Unknown)			S				Watson
	Amiodarone (Unknown)			S	Unknown	Unk		Not Reported
	Escitalopram (Unknown)			S	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported
	Betahistine			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Acenocoumarol			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Ferrous Sulfate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2016	12214228	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2016M1012543			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug Abuse; Intentional Overdose; Sopor	Escitalopram			S		100 Mg, Total		Not Reported
	Flurazepam			S	Oral	150 Mg, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2016	12214389	EXPEDITED (15-DAY)		LT, OT	ES-TEVA-647343ISR		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram			S				Ivax
	Metoclopramide			S				Not Reported
	Metoclopramide			S				Not Reported
	Amiodarone			S				Not Reported
	Losartan			C				Not Reported
	Betahistine			C				Not Reported
	Simvastatin			C				Not Reported
	Bisoprolol			C				Not Reported
	Acenocoumarol			C				Not Reported
	Metformin			C				Not Reported
	Ferrous Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2016	12217878	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nightmare	Escitalopram			S	Oral			Camber
	Victoza			C				Not Reported
	Tizanidine			C				Not Reported
	Pioglitazone			C				Not Reported
	Montelukast			C				Not Reported
	Metformin			C				Not Reported
	Levemir			C				Not Reported

	Latanoprost	C	Not Reported
	Advair	C	Not Reported
	Baclofen	C	Not Reported
	Coreg	C	Not Reported
	Crestor	C	Not Reported
	Docusate	C	Not Reported
	Fluticasone	C	Not Reported
	Furosemide	C	Not Reported
	Gabapentin	C	Not Reported
	Glimepiride	C	Not Reported
	Norco	C	Not Reported
	Invokana	C	Not Reported
	Januvia	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12194788	EXPEDITED (15-DAY)		HO, LT, OT	ZA-GLAXOSMITHKLINE-ZA2016GSK039240		47 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt	Wellbutrin Xl			S	Oral	300 Mg, Daily For The Past 3 Years		Glaxosmithkline
	Trazadona			S	Oral	150 Mg, Daily For The Past 3 Years		Not Reported
	Lexamil			S	Oral	10 Mg, Daily For The Past 3 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12216289	EXPEDITED (15-DAY)		HO, LT, OT	ES-HOSPIRA-3228942		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Solifenacin			S	Intravenous (not otherwise specified)			Not Reported
	Furosemide			C				Not Reported
	Digoxin			S				Not Reported
	Levofloxacin			S				Not Reported
	Amiodarone			S				Not Reported
	Sulpiride			S				Not Reported

	Escitalopram	S		Not Reported
	Candesartan	C		Not Reported
	Acenocoumarol	C		Not Reported
	Simvastatin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12218007	EXPEDITED (15-DAY)		HO	IT-TEVA-646318ACC		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug Abuse; Product Administration Error; Sopor	Escitalopram Oxalate			S		100 Mg Total		Ivax
	Flurazepam Monohydrochloride			S	Oral	150 Mg Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12218180	EXPEDITED (15-DAY)		HO	FR-TAKEDA-2016TEU002081		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Ogastoro			S	Oral	Unk		Takeda
	Ideos			S	Unknown	Unk		Not Reported
	Pariet			S	Unknown	Unk		Not Reported
	Coaprovel			S	Unknown	Unk		Not Reported
	Lercan			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Temesta /00273201/			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12219079	EXPEDITED (15-DAY)		HO	AU-IMPAX LABORATORIES, INC-2016-IPXL-00179		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Bupropion Hydrochloride Sr			S	Oral	75 Mg, Unk		Impax
	Dothiepin Hydrochloride			S	Unknown	Unk		Not Reported

	Dothiepin Hydrochloride	S	Unknown	225 Mg, Unk	Not Reported
	Dothiepin Hydrochloride	S	Unknown	175 Mg, Unk	Not Reported
	Escitalopram	S	Unknown	30 Mg, Daily	Not Reported
	Lamotrigine	C	Unknown	75 Mg, 2 /Day	Not Reported
	Oestradiol	C	Unknown	Unk	Not Reported
	Ramipril	C	Unknown	Unk	Not Reported
	Glipizide	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Lantus	C	Unknown	Unk	Not Reported
	Aspirin	C	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	400 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12219339	EXPEDITED (15-DAY)		LT, OT	ES-BAUSCH-BL-2016-007173		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Metoclopramide			S	Unknown			Valeant
	Metoclopramide			S				Valeant
	Escitalopram			S	Unknown			Not Reported
	Amiodarone			S	Unknown			Not Reported
	Losartan			C				Not Reported
	Betahistine			C				Not Reported
	Simvastatin			C				Not Reported
	Bisoprolol			C				Not Reported
	Acenocoumarol			C				Not Reported
	Metformin			C				Not Reported
	Ferrous Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	11812043	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20151205280		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyskinesia; Muscle Spasms; Myalgia	Xarelto	S	Oral			Not Reported
	Pazopanib	S	Oral			Not Reported
	Durogesic	S	Transdermal	200		Not Reported
	Actiskenan	S	Oral			Not Reported
	Lyrica	S	Oral			Not Reported
	Laroxyl	S	Oral			Not Reported
	Seroplex	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	11859339	EXPEDITED (15-DAY)		OT	FR-FRI-1000081819		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Depressed Level Of Consciousness; Disorientation; Hypotension; Somnolence	Escitalopram			S		Daily Dose Not Reported		Forest
	Mianserine			S		Daily Dose Not Reported		Not Reported
	Alprazolam			S		Daily Dose Not Reported		Not Reported
	Pregabaline			S		Daily Dose Not Reported		Not Reported
	Tramadol Base			S		Daily Dose Not Reported		Not Reported
	Valsartan			S		Daily Dose Not Reported		Not Reported
	Lasilix			S		Daily Dose Not Reported		Not Reported
	Pantoprazole			C		Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	11893342	EXPEDITED (15-DAY)		HO	JP-FRI-1000082049		60 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Electrocardiogram Qt Prolonged; Hepatic Steatosis; Parkinsonism; Rhabdomyolysis	Lexapro			S	Oral	10 Mg		Forest
	Amoxan			C	Oral	30 Mg		Not Reported
	Meilax			C	Oral	3 Mg		Not Reported
	Magnesium Oxide			C	Oral	1980 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	11895922	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2015423120		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Tumour Cell Infiltration; Dyskinesia; Muscle Spasms; Myalgia; Paraplegia; Phlebitis; Pulmonary Embolism; Renal Failure; Ureteric Obstruction	Lyrica			S	Oral	Unk		Pfizer
	Votrient			S	Oral	400 Mg, 1x/Day		Not Reported
	Durogesic			S	Transdermal	200 Daily		Not Reported
	Actiskenan			S	Oral	Unk		Not Reported
	Laroxyl			S	Oral	Unk		Not Reported
	Xarelto			S	Oral	10 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12159787	EXPEDITED (15-DAY)		HO, LT	JP-FRI-1000082992		47 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Overdose; Suicide Attempt	Lexapro			S	Oral			Forest
	Lexapro			S	Oral	Overdose: 300 Mg		Forest
	Flunitrazepam			S	Oral	2 Mg		Not Reported
	Flunitrazepam			S	Oral	Overdose: 36 Mg		Not Reported
	Ethyl Loflazepate			S	Oral	2 Mg		Not Reported
	Ethyl Loflazepate			S	Oral	Overdose: 34 Mg		Not Reported
	Gasmotin			S	Oral	5 Mg		Not Reported
	Gasmotin			S	Oral	Overdose: 150 Mg		Not Reported
	Podonin-S			S	Oral	0.5 Mg		Not Reported
	Podonin-S			S	Oral	Overdose: 15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12193452	EXPEDITED (15-DAY)		LT	FR-B.I. PHARMACEUTICALS,I		65 YR	Female	FRA

NC./RIDGEFIELD-2016-BI-16

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Lung Disorder	Sifrol			S	Oral	1.05 Mg		Boehringer Ingelheim
	Apokinon			S	Subcutaneous			Not Reported
	Mantadix			S	Oral	100 Mg		Not Reported
	Sinemet			S	Oral	1250 Anz		Not Reported
	Modopar			S	Oral	Strength: 125		Not Reported
	Seroplex			S	Oral	15 Mg		Not Reported
	Imovane			S	Oral	7.5 Mg		Not Reported
	Azilect			S	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12213258	NON-EXPEDITED		DE, OT	US-JNJFOC-20160314012			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acidosis; Anion Gap Increased; Arrhythmia; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Bradycardia; Cardiac Arrest; Cardiac Arrest; Coma; Conduction Disorder; Confusional State; Cyanosis; Diarrhoea; Dizziness; Electrocardiogram Change; Hyperglycaemia; Hyperhidrosis; Hypertension; Hyperventilation;	Tylenol		Y	S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Benadryl		Y	S	Unknown			Not Reported
	Motrin		Y	S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride		Y	S	Unknown			Not Reported
	Ibuprofen		Y	S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Adderall			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported

Hypotension; Intentional Self-Injury; Lethargy; Liver Function Test Abnormal; Mydriasis; Nausea; Non-Cardiac Chest Pain; Respiratory Arrest; Respiratory Depression; Seizure; Somnolence; Syncope; Tachycardia; Tachypnoea; Tinnitus; Vomiting; X-Ray Abnormal	Anafranil	S	Unknown	Not Reported
	Benicar	S	Unknown	Not Reported
	Cartia Xt	S	Unknown	Not Reported
	Depakote	S	Unknown	Not Reported
	Effexor	S	Unknown	Not Reported
	All Other Therapeutic Products	S	Unknown	Not Reported
	Flecainide	S	Unknown	Not Reported
	Flexeril	S	Unknown	Not Reported
	Geodon	S	Unknown	Not Reported
	Lamictal	S	Unknown	Not Reported
	Lexapro	S	Unknown	Not Reported
	Methadone	S	Unknown	Not Reported
	Methamphetamine	S	Unknown	Not Reported
	Opioids	S	Unknown	Not Reported
	Paxil	S	Unknown	Not Reported
	Potassium	S	Unknown	Not Reported
	Trazodone	S	Unknown	Not Reported
	Strattera	S	Unknown	Not Reported
	Wellbutrin	S	Unknown	Not Reported
	Vicodin	S	Unknown	Not Reported
	Xanax	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12220119	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2015-04518			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Hypersomnia	Duloxetine Delayed-Release 30 Mg Capsules Usp			S	Oral			Not Reported
	Duloxetine Delayed-Release 30 Mg Capsules Usp			S	Oral			Not Reported

	Lexapro	S	Unknown	Not Reported
	Women'S Centrum Silver	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12220254	EXPEDITED (15-DAY)		LT, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2016002563			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Metoclopramide			S	Unknown	Unk		Not Reported
	Metoclopramide			S				Not Reported
	Amiodarone			S	Unknown			Not Reported
	Metformin Hydrochloride			C	Unknown			Not Reported
	Losartan Potassium			C	Unknown			Macleods
	Betahistine			C	Unknown			Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Acenocoumarol			C	Unknown			Not Reported
	Ferrous Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12220426	EXPEDITED (15-DAY)		HO, LT, OT	ES-MACLEODS PHARMA UK LTD-MAC2016002564			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Haemodynamic Instability; Hypokalaemia; Hypomagnesaemia; Syncope; Torsade De Pointes; Ventricular Tachycardia	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Levofloxacin			S	Unknown	Unk		Macleods
	Sulpiride			S	Unknown	Unk		Not Reported
	Solifenacin			S	Unknown	Unk		Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Digoxin	S	Unknown	Unk		Not Reported
	Candesartan	C	Unknown	Unk		Not Reported
	Furosemide	C	Unknown	Unk		Not Reported
	Acenocoumarol	C	Unknown	Unk		Not Reported
	Simvastatin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12220979	EXPEDITED (15-DAY)		OT	US-ACTAVIS-2016-06695		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Condition Aggravated; Dystonia; Hallucinations, Mixed; Therapeutic Response Unexpected; Unevaluable Event	Escitalopram (Unknown)			S	Unknown	Unk		Not Reported
	Duloxetine Hydrochloride (Aellc)			S	Unknown	Unk		Actavis Elizabeth
	Fluoxetine Hydrochloride (Watson Laboratories)			S	Unknown	30 Mg, Unk		Watson
	Fluvoxamine Maleate (Aellc)			S	Unknown	25 Mg, Daily		Watson
	Venlafaxine (Unknown)			S	Unknown	Unk		Not Reported
	Quetiapine (Agptc)			S	Unknown	Unk		Actavis
	Donepezil Hydrochloride (Apmpl)			S	Unknown	Unk		Actavis
	Olanzapine (Unknown)			S	Unknown	Unk		Not Reported
	Sertraline			C	Unknown	Unk		Not Reported
	Memantine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12222083	EXPEDITED (15-DAY)		HO	FR-FRI-1000083522		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Suicide Attempt; Tonic Clonic Movements; Toxicity To Various Agents	Escitalopram			S	Oral	Only One Intake (Doses Unknown).		Forest
	Baclofene			S	Oral	Only One Intake (Doses Unknown).		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12223662	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2016M1012322			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Suicidal Ideation; Tinnitus	Escitalopram			S		Unk		Not Reported
	Quetiapine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12224196	EXPEDITED (15-DAY)		DS	NO-FRI-1000083461		35 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Insomnia; Nausea; Pain; Sleep Disorder; Yellow Skin	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Unknown	180 G		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12228415	DIRECT	Y	HO			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure; Toxicity To Various Agents	Vancomycin			S	Intravenous (not otherwise specified)	2 G Bid Intravenous (Not Otherwise Specified)	11 DAY	Not Reported
	Atorvastatin			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Enalpril			C				Not Reported
	Escitalopram			S				Not Reported
	Acetaminophen\Hydrocodone Bitartrate			C				Not Reported
	Mydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	10554493	NON-EXPEDITED			US-PFIZER INC-2014298019			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Ativan			S		Unk		Pfizer
	Keflex			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	10950824	EXPEDITED (15-DAY)		HO	FR-FRI-1000075415		94 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram			S	Oral	1 Df		Forest
	Previscan (Fluindione)			S		0.5 Mg		Not Reported
	Tahor			C	Oral	1 Df		Not Reported
	Seresta			C	Oral	1 Df		Not Reported
	Dafalgan			C	Oral	On Request (Up To 4 Tab. Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	12223681	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2016M1013042			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Tachypnoea	Lorazepam			S	Transplacental	0.25 Mg, Qd		Not Reported
	Escitalopram			S	Transplacental	5 Gtt, Qd		Not Reported
	Adalat			S	Transplacental	60 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	12224564	EXPEDITED (15-DAY)		OT	GB-ACCORD-039210			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Emotional Distress; Suicidal Ideation; Tinnitus	Escitalopram	S		Accord
	Quetiapine	S		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	12224577	EXPEDITED (15-DAY)		OT	GB-ALKEM-001550			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Suicidal Ideation; Tinnitus	Quetiapine/Quetiapine Fumarate			S				Alkem
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	12225897	EXPEDITED (15-DAY)		HO	FR-FRI-1000083618		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tonic Convulsion	Escitalopram			S	Oral	5 Mg		Forest
	Atarax			S	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	12226316	EXPEDITED (15-DAY)		HO	FR-FRI-1000083616		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypertonia; Tremor	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	12226378	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMPANY-US201603007950		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Occlusion; Gingival Bleeding; Intervertebral Disc Protrusion; Myocardial Infarction; Platelet Count Decreased;	Effient			S	Unknown	10 Mg, Qd		Eli Lilly And Co
	Aspirin /00002701/			S	Unknown	Unk, Unknown		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported

Platelet Function Test Abnormal	Buspar	S	Unknown	Unk, Unknown	Not Reported
	Janumet	C			Not Reported
	Carvedilol	C			Not Reported
	Potassium	C			Not Reported
	Lyrica	C			Not Reported
	Isosorbide Mononitrate	C			Not Reported
	Lasix /00032601/	C			Not Reported
	Clonidine	C			Not Reported
	Losartan	C			Not Reported
	Lantus	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	12226885	NON-EXPEDITED			US-ELI_LILLY_AND_COMPANY-US201603010762		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Agitation; Chest Pain; Diarrhoea; Dizziness; Dyspepsia; Euphoric Mood; Fatigue; Headache; Hypersensitivity; Pain; Sedation; Therapeutic Reaction Time Decreased	Zyprexa			S	Unknown	Unk, Unknown		Unknown
	Baclofen			S	Unknown	Unk, Unknown		Not Reported
	Carbatrol			S	Unknown	Unk, Unknown		Not Reported
	Daypro			S	Unknown	Unk, Unknown		Not Reported
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported
	Eszopiclone			S	Unknown	Unk, Unknown		Not Reported
	Levoxyl			S	Unknown	Unk, Unknown		Not Reported
	Oxycodone			S	Unknown	Unk, Unknown		Not Reported
	Seroquel			S	Unknown	Unk, Unknown		Not Reported
	Ultram /00599202/			S	Unknown	Unk, Unknown		Not Reported
	Vicodin			S	Unknown	Unk, Unknown		Not Reported
	Wellbutrin			S	Unknown	Unk, Unknown		Not Reported
	Zantac			S	Unknown	Unk, Unknown		Not Reported
	Zithromax			S	Unknown	Unk, Unknown		Not Reported
	Zolpidem			S	Unknown	Unk, Unknown		Not Reported
	Sertraline			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	12227556	EXPEDITED (15-DAY)		HO	FR-FRI-1000083615		17 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Behaviour; Toxicity To Various Agents	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Not Reported
	Escitalopram			S	Oral	Overdose Of 600 Mg Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	11822952	EXPEDITED (15-DAY)		HO	PHHY2015FR160511		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Muscle Spasms; Myalgia	Votrient			S	Oral	400 Mg, Qd		Novartis
	Durogesic			S	Transdermal	200 Ot, Unk		Not Reported
	Actiskenan			S	Oral	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Laroxyl			S	Oral			Not Reported
	Xarelto			S	Oral	10 Mg, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	11930502	EXPEDITED (15-DAY)			BE-FRI-1000082116			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	12227952	NON-EXPEDITED			US-TORRENT-00001141			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Tinnitus	Escitalopram Tablets, Usp			S	Oral			Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	12227983	EXPEDITED (15-DAY)		OT	GB-DRREDDYS-GER/UKI/16/0078246			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress;	Quetiapine			S				Not Reported
Suicidal Ideation; Tinnitus	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	12228098	EXPEDITED (15-DAY)		HO	IT-ACCORD-039277		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Sopor	Escitalopram			S				Accord
	Flurazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	12231045	NON-EXPEDITED			US-009507513-1603USA011907			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Remeron			S	Oral	Unk		Merck
	Trazodone Hydrochloride			S				Not Reported
	Escitalopram			S		Unk		Not Reported
	Bupropion Hydrochloride			S		Unk		Not Reported
	Lamotrigine			S				Not Reported
	Aripiprazole			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	12232613	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2016VAL000680		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Depressed Level Of Consciousness; Disorientation; Hypotension; Somnolence	Furosemide			S		Unk		Validus
	Mianserin Hydrochloride			S		Unk		Not Reported
	Alprazolam			S		Unk		Not Reported
	Pregabalin			S		Unk		Not Reported
	Tramadol Hydrochloride			S		Unk		Not Reported
	Valsartan			S		Unk		Not Reported
	Seroplex			S		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	10238976	EXPEDITED (15-DAY)		OT	US-009507513-1406USA006221			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Sinusitis; Arthralgia; Attention Deficit/Hyperactivity Disorder; Carpal Tunnel Syndrome; Cholecystectomy; Conjunctivitis; Dermatitis Contact; Diarrhoea; Epididymitis; Erectile Dysfunction; Essential Hypertension; Generalised Anxiety Disorder; Hair Disorder; Headache; Hypertriglyceridaemia; Insomnia; Liver Function Test Abnormal; Loss Of Libido; Lyme Disease; Major Depression; Migraine; Obesity; Orchitis; Osteoarthritis; Palpitations; Panic Disorder; Plantar Fascial	Propecia			S	Oral	1 Mg, Qd		Merck
	Lexapro			S	Unknown	Unk		Not Reported

Fibromatosis; Pruritus; Rash; Sexual Dysfunction; Sexually Transmitted Disease; Skin Texture Abnormal; Tachycardia; Vitamin D Deficiency

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12233465	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2016-03998			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Suicidal Ideation; Tinnitus	Escitalopram			S	Unknown	Unk		Aurobindo
	Quetiapine			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12233589	EXPEDITED (15-DAY)		OT	ES-PAR PHARMACEUTICAL COMPANIES-2016SCPR015307			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardio-Respiratory Arrest; Torsade De Pointes	Metoclopramide			S	Unknown	Unk Unk, Unknown		Par
	Metoclopramide			S				Par
	Losartan			S	Unknown	Unk, Unknown		Not Reported
	Betahistine			S	Unknown	Unk, Unknown		Not Reported
	Simvastatin			S	Unknown	Unk, Unknown		Not Reported
	Amiodarone			S	Unknown	Unk, Unknown		Not Reported
	Bisoprolol			S	Unknown	Unk Unk, Unknown		Not Reported
	Acenocoumarol			S	Unknown	Unk, Unknown		Not Reported
	Metformin			S	Unknown	Unk, Unknown		Not Reported
	Iron Sulfate			S	Unknown	Unk, Unknown		Not Reported
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12233671	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2016-04100		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug Abuse; Sopor	Escitalopram			S	Unknown	100 Mg, Unk		Aurobindo
	Flurazepam			S	Oral	150 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12234006	EXPEDITED (15-DAY)		OT	GB-LUPIN PHARMACEUTICALS INC.-E2B_00005183			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Suicidal Ideation; Tinnitus	Escitalopram			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12235739	EXPEDITED (15-DAY)		OT	GB-FRI-1000083625			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Suicidal Ideation; Tinnitus	Escitalopram			S	Oral			Forest
	Quetiapine Fumarate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12237389	DIRECT					32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Substitution Issue	Escitalopram: Oral Tablet (10mg), 10 Mg			S	Oral			Teva
	Lexapro			C				Not Reported
	Welbutrin			C				Not Reported
	Lamictal			C				Not Reported
	Buspirone			C				Not Reported

	Vitamin D Nos			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2016	12237003	EXPEDITED (15-DAY)		HO, LT, OT	ES-ACCORD-039374		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Sulpiride/Sulpiride			S				Not Reported
	Adamantanecarboxylat							
	Escitalopram			S				Accord
	Levofloxacin/Levofloxacin Mesylate			S				Accord
	Solifenacin/Solifenacin Succinate			S				Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)			Not Reported
	Digoxin			S				Not Reported
	Candesartan			C				Not Reported
	Furosemide			C				Not Reported
	Acenocoumarol			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2016	12237004	EXPEDITED (15-DAY)		HO, LT, OT	ES-ACCORD-039376		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Metoclopramide			S				Accord
	Escitalopram			S				Accord
	Amiodarone			S				Not Reported
	Losartan			C				Not Reported
	Betahistine			C				Not Reported
	Simvastatin			C				Not Reported
	Bisoprolol			C				Not Reported
	Acenocoumarol			C				Not Reported
	Metformin			C				Not Reported
	Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2016	12237023	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2016-02458			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macule; Papule; Skin Lesion; Telangiectasia	Escitalopram 10 Mg			S	Oral	10 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2016	12237907	EXPEDITED (15-DAY)		OT	CN-FRI-1000083735		67 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Leukaemia	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2016	12241340	DIRECT		HO, LT, RI, OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anion Gap Decreased; Blood Creatinine Decreased; Blood Potassium Decreased; Blood Urine Present; Chromaturia; Dehydration; Platelet Count Decreased; Seizure; White Blood Cells Urine Positive	Haldol			S		Misdiagnosis/Drug Forced On Me		Unknown
	Trazodone			S				Not Reported
	Escitalopram			S				Not Reported
	Bupropion			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2016	9555126	NON-EXPEDITED		HO, OT	ADR-2012-02307		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis;	Compounded Baclofen			S				Not Reported

Decreased Activity; Device Defective; Pain; Therapy Non-Responder; Unevaluable Event	Symbicort	S	160-4.5mcg/Act Aero	Not Reported
	Imitrex	S	20mg/Act Soln	Not Reported
	Transderm-Scop	S	1.5mg Pt72 As Needed	Not Reported
	Flector	S	1.3% Patch To Left Knee For Pain Flare Up Every 12 Hours	Not Reported
	Nasonex	S	50mcg/Act Susp	Not Reported
	Medrol Pak	S	4mg Tabs - Use As Directed	Not Reported
	Robaxin	S	500mg Twice Daily As Needed For Spasms	Not Reported
	Neurotin	S	400mg 3 Times Daily	Not Reported
	Flexeril	S	10mg Tabs As Needed For Spasms	Not Reported
	Vesicare	S	5mg Tabs	Not Reported
	Lortab	S	7.5-500mg Tabs; 1 Tab 3-4 Times Daily As Needed For Pain	Not Reported
	Albuterol	S	90mcg/Act Aers	Not Reported
	Lexapro	S	1.5 Tabs Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2016	12171456	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2016125599		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Euphoric Mood; Intervertebral Disc Protrusion; Nerve Injury; Pain In Extremity	Lyrica			S		75 Mg, Daily		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2016	12240815	EXPEDITED (15-DAY)		HO, OT	TH-ACCORD-039246		77 YR	Male	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Interaction; Haemodialysis; Serotonin Syndrome	Escitalopram			S				Accord
	Rasagiline/Rasagiline Mesylate			S				Not Reported
	Ticlopidine			C				Not Reported
	Atorvastatin			C				Not Reported
	Gemfibrozil			C				Not Reported
	Piribedil/Piribedil Monomethanesulfonate			C				Not Reported
	Rivastigmine/Rivastigmine Tartrate			C		Patch 10 Cm2		Not Reported
	Stalevo			C		Levodopa 100 Mg, Carbidopa 25 Mg, And Entacapone 200 Mg		Not Reported
	Pramipexole/Pramipexole Dihydrochloride			C				Not Reported
	Melatonin			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2016	12241619	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2016-04247		< 1 DAY	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Tachypnoea	Lorazepam			S	Transplacental	Unk		Not Reported
	Escitalopram 5 Mg			S	Transplacental	5 Gtt, Unk		Aurobindo
	Adalat			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2016	12191790	NON-EXPEDITED			US-PFIZER INC-2016143391		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Zoloft			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Paxil			S		Unk		Not Reported
	Buspar			S		Unk		Not Reported

	Wellbutrin	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Prozac	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2016	12247668	EXPEDITED (15-DAY)		HO	US-ABBVIE-16K-163-1597728-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Limb Discomfort; Liver Disorder; Pruritus Generalised	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Advair			S	Unknown			Not Reported
	Albuterol			S	Unknown			Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported
	Amoxicillin And Clavulanate Potassium			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Lisinopril			S	Unknown			Not Reported
	Lovastatin			S	Unknown			Not Reported
	Losartan Potassium			S	Unknown			Not Reported
	Meclizine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Norco			S	Unknown			Not Reported
	Pantoprazole Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Ranitidine			S	Unknown			Not Reported
	Ventolin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2016	12249979	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2016AP007532		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Haemodynamic Instability; Hypokalaemia; Hypomagnesaemia; Multiple Drug Therapy; Respiratory Tract Infection; Torsade De Pointes; Ventricular Extrasystoles; Ventricular Tachycardia	Escitalopram Apotex			S	Unknown	Unk Unk, Unknown		Apotex
	Levofloxacin			S	Unknown	Unk Unk, Unknown		Apotex
	Sulpiride			S	Unknown	Unk, Unknown		Not Reported
	Solifenacin			S	Unknown	Unk, Unknown		Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)	Unk Unk, Unknown		Not Reported
	Furosemide			C	Unknown	Unk, Unknown		Not Reported
	Acenocoumarol			C	Unknown	Unk, Unknown		Not Reported
	Candesartan			C	Unknown	Unk, Unknown		Not Reported
	Digoxin			C	Unknown	Unk, Unknown		Not Reported
	Simvastatin			C	Unknown	Unk, Unknown		Not Reported
	Magnesium Sulphate /01097001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2016	12252606	DIRECT		OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chest Discomfort; Confusional State; Dizziness; Fatigue; Feeling Abnormal; Quality Of Life Decreased	Lexapro, 20 Mg			S	Oral	30 Tablet(S) At Bedtime Taken By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	11717283	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-077201			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Conjunctival Haemorrhage	Eliquis	S	Unknown	5 Mg, Unk		Bristol Myers Squibb
	Lipitor	S	Unknown	20 Mg, Qd		Not Reported
	Hydrochlorothiazide	S	Unknown	25 Mg, Qd		Not Reported
	Losartan	S	Unknown	100 Mg, Qd		Not Reported
	Lexapro	S	Unknown	10 Mg, Qd		Not Reported
	Acetyl-L-Carnitine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	12216780	NON-EXPEDITED			US-PFIZER INC-2016179799		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Pristiq			S	Oral	50 Mg, 1x/Day		Pfizer
	Lexapro			S	Oral	30 Mg, 1x/Day		Not Reported
	Benicar			C		10 Mg		Not Reported
	Zocor			C		40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	12253804	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-027591			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Labelled Drug-Drug Interaction Medication Error	Warfarin Sodium			S	Unknown			Bristol Myers Squibb
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	12254462	EXPEDITED (15-DAY)		OT	CZ-MYLANLABS-2016M1014465			Unknown	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis	Lamotrigine			S		Unk		Not Reported
	Olanzapine			S		20 Mg, Unk		Not Reported

	Escitalopram	S	10 Mg, Unk	Not Reported
	Trazodone	S	150 Mg, Unk	Not Reported
	Oxazepam	C	15 Mg, Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	12254505	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-027592			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Labelled Drug-Drug Interaction Medication Error	Warfarin Sodium			S	Unknown			Bristol Myers Squibb
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	12256862	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Cessation; Tinnitus	Escitalopram, 5 Mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12088145	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2014-07108			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Metformin			S	Unknown			Aurobindo
	Amoxicillin			S	Unknown			Aurobindo
	Zoloft			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Advil /00044201/			S	Unknown			Not Reported
	Pristiq			S	Unknown			Not Reported
	Pce			S	Unknown			Not Reported
	Biaxin			S	Unknown	Unk		Not Reported

Benadryl /00000402/	S	Unknown			Not Reported
Tylenol With Codeine	S				Not Reported
Novocain	S	Unknown			Not Reported
Actos	S				Not Reported
Cipro /00697201/	S	Unknown			Not Reported
Macrodantin	S	Unknown	Unk		Not Reported
Albuterol /00139501/	S	Unknown	Unk		Not Reported
Elavil /00002202/	S	Unknown	Unk		Not Reported
Prozac	S	Unknown			Not Reported
Lexapro	S	Unknown			Not Reported
Lithobid	S	Unknown	Unk		Not Reported
Remeron	S	Unknown	Unk		Not Reported
Risperdal	S	Unknown	Unk		Not Reported
Xylocaine /00033401/	S	Unknown	Unk		Not Reported
Paxil /00500401/	S	Unknown	Unk		Not Reported
St. John'S Wort /01166801/	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12205506	EXPEDITED (15-DAY)		DS, HO	GXKR2016DE001457		43 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Stress Disorder; Akathisia; Dyskinesia; Impaired Work Ability; Nervousness; Restless Legs Syndrome	Quetiapin Hexal			S	Oral	50 Mg In The Morning And 200 Mg In The Evening		Novartis
	Quetiapin Hexal			S	Oral	50 Mg, Bid		Novartis
	Risperidone			S		Unk Ukn, Unk		Not Reported
	Mirtazapine			S	Oral	Unk Ukn, Unk		Not Reported
	Melperone			S	Oral	Unk Ukn, Unk		Not Reported
	Melneurin			S	Oral	Variable Dosages		Not Reported
	Zyprexa			S	Oral	Variable Dosages		Not Reported
	Risperidon Atid			S	Oral	Unk Ukn, Unk		Not Reported

	Escitalopram Basics	S	Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12215354	EXPEDITED (15-DAY)		HO, OT	CZ-TEVA-644392ISR		82 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Wall Haematoma; Dehydration; Fall; Fall; Hyponatraemia	Atorvastatin			S	Oral	10 Milligram Daily;		Teva
	Escitalopram 10 Mg			S	Oral	10 Milligram Daily;		Ivax
	Levothyroxin 75 Mcg Unknown			S	Oral	75 Microgram Daily;		Not Reported
	Furosemid 40 Mg			S	Oral	40 Milligram Daily;		Ivax
	Omeprazol 20 Mg			S	Oral	20 Milligram Daily;		Not Reported
	Nitrendipin 10 Mg			S	Oral	10 Milligram Daily;		Not Reported
	Perindopril 5 Mg			S	Oral	10 Milligram Daily;		Not Reported
	Isosorbid 20 Mg			S	Oral	40 Milligram Daily;		Not Reported
	Tiaprid 100 Mg			S	Oral	100 Milligram Daily;		Not Reported
	Fentanyl 25 Mcg/H Actavis			S	Transdermal			Cephalon
	Metamizol 500 Mg			S	Oral	3000 Milligram Daily;		Not Reported
	Tramadol 150 Mg Sr			S	Oral	300 Milligram Daily;		Not Reported
	Rivoxaban 20 Mg			S	Oral	20 Milligram Daily;		Not Reported
	Bromazepam 3 Mg			S	Oral	.5 Dosage Forms Daily;		Not Reported
	Chlortalidon/Amilorid 25 Mg/2.5 Mg			S	Oral	2 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12255809	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-02405			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Metformin			S	Unknown	Unk		Aurobindo
	Oxycodone			S	Unknown	Unk		Aurobindo
	Tramadol			S	Unknown	Unk		Aurobindo

	Cymbalta	S	Unknown	Unk	Not Reported
	Neurontin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Dilantin /00017401/	S	Unknown	Unk	Not Reported
	Lexapro	S	Unknown	Unk	Not Reported
	Methadone	S	Unknown	Unk	Not Reported
	Stadol	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12256432	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-07526			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Metformin Hydrochloride Tablets Usp 500 Mg			S	Unknown	500 Mg, Two Times A Day		Aurobindo
	Benazepril 10 Mg			S	Unknown	10 Mg, Once A Day		Aurobindo
	Tramadol Hydrochloride Tablets Usp 50 Mg			S	Unknown	50 Mg, Every 8 Hours		Aurobindo
	Abilify			S	Unknown	2 Mg, Every Morning		Not Reported
	Ativan			S	Unknown	1 Mg, Two Times A Day		Not Reported
	Lasix /00032601/			S	Unknown	40 Mg, Two Times A Day		Not Reported
	Lexapro			S	Unknown	20 Mg, Every Morning		Not Reported
	Nitro /00003201/			S	Unknown	0.4 Mg, Unk		Not Reported
	Proair Hfa			S	Unknown	90 Mcg, Two Times A Day		Not Reported
	Proventil /00139501/			S	Unknown			Not Reported
	Spiriva			S	Unknown	1 Df, Daily		Not Reported
	Zocor			S	Unknown	40 Mg, At Bed Time		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12257137	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20160406024			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Insomnia; Restless Legs Syndrome	Serenase (Haloperidol)		S	Oral	Not Reported
	Rivotril		S	Oral	Not Reported
	Cipralex		S	Oral	Not Reported
	Cipralex		S	Oral	Not Reported
	Insulin		C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12257823	NON-EXPEDITED		HO	TH-FRI-1000083761		77 YR	Male	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Escitalopram			S	Unknown	Unknown		Forest
	Rasagiline			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2016	12231820	EXPEDITED (15-DAY)		HO	PHHY2016IT040639		< 1 DAY	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Tachypnoea	Escitalopram			S	Transplacental	5 Drp, Qd		Not Reported
	Lorazepam			S	Transplacental	Mother Took 2.5 Mg, Qd		Novartis
	Adalat			S	Transplacental	Mother Took 60mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2016	12262487	EXPEDITED (15-DAY)		OT	US-ACCORD-039534		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective	Escitalopram			S	Oral	Strength: 20 Mg Initially Received 10 Mg.		Accord
	Melatonin			C		Otc Melatonin		Not Reported
	Ibuprofen			C		Frequently		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2016	12263383	EXPEDITED (15-DAY)		HO	CH-SA-2016SA069553		74 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Tamponade; Haematuria; Potentiating Drug Interaction	Plavix			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Xarelto			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Sequase			C	Unknown			Not Reported
	Prograf			C	Unknown			Not Reported
	Torem			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Concor			C	Unknown			Not Reported
	Triatec (Ramipril)			C	Unknown			Not Reported
	Aldactone			C	Unknown			Not Reported
	Pantozol			C	Unknown			Not Reported
	Zyloric			C	Unknown			Not Reported
	Euthyrox			C	Unknown			Not Reported
	Levemir			C	Unknown			Not Reported
	Movicol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2016	12265407	EXPEDITED (15-DAY)		HO	CH-BAYER-2016-064710		74 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Tamponade; Haematuria; Potentiating Drug Interaction	Xarelto			S		10 Mg, Qd		Unknown
	Acetylsalicylic Acid(<=100 Mg)		Y	S		100 Mg, Qd		Bayer
	Plavix			S		75 Mg, Qd		Not Reported
	Escitalopram			S		20 Mg, Qd		Not Reported

	Quetiapine Fumarate	C	50 Mg, Qd	Not Reported
	Prograf	C	1 Mg, Bid	Not Reported
	Torem	C	10 Mg, Qd	Not Reported
	Atorvastatin	C	10 Mg, Qd	Not Reported
	Concor	C	2.5 Mg, Qd	Not Reported
	Triatec (Ramipril)	C	2.5 Mg, Qd	Not Reported
	Aldactone A	C	25 Mg, Qd	Not Reported
	Pantozol	C	40 Mg, Qd	Not Reported
	Zyloric	C	300 Mg, Qd	Not Reported
	Euthyrox	C	0.075 Mg, Qd	Not Reported
	Levemir	C	6 Iu, Qd	Not Reported
	Movicol	C	1 Df, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2016	12266165	DIRECT	Y				54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Generic Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12088526	EXPEDITED (15-DAY)		HO	US-BAUSCH-BL-2016-003730		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Drug Ineffective; Tremor; Weight Decreased	Wellbutrin Xl			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Lorazepam			S	Oral	½ Tablet In The Morning And 1 Tablet At Night		Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12257026	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015376027		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctival Haemorrhage	Eliquis			S	Unknown	5 Mg, 2x/Day		Not Reported
	Lipitor			S	Unknown	20 Mg, 1x/Day		Pfizer
	Losartan			S		100 Mg, 1x/Day		Not Reported
	Hydrochloorthiazide			S		25 Mg, 1x/Day		Not Reported
	Lexapro			S		10 Mg, Daily		Not Reported
	Acetyl L Carnitin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12266937	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2016-04437			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram			S	Unknown	Unk		Aurobindo
	Escitalopram			S				Aurobindo
	Sertraline			S	Unknown	Unk		Aurobindo
	Sertraline			S				Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo
	Venlafaxine			S				Aurobindo
	Risperidone			S	Unknown	2 Mg/Day		Aurobindo
	Risperidone			S		2 Mg/Day		Aurobindo
	Paroxetine			S				Aurobindo
	Paroxetine			S				Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12269586	EXPEDITED (15-DAY)		HO	SE-TEVA-651584ISR		37 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain;	Escitalopram			S				Ivax

Diarrhoea; Drug Interaction; Vomiting	Brintellix	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12270415	DIRECT		OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Therapy Change	Escitalopram			S	Oral			Mylan
	Omeprazole			C				Not Reported
	Fenofibrate			C				Not Reported
	Lopo-Flavonoid			C				Not Reported
	Omega 3 Fish Oil			C				Not Reported
	Fibercon			C				Not Reported
	Glucosamine Chondroitin			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12270580	DIRECT		OT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chest Pain; Chills; Dehydration; Heart Rate Irregular; Hypertension	Escitalopram	Y		S	Oral		1 DAY	Not Reported
	Atenolol			C				Not Reported
	Lexapro			C				Not Reported
	Extra Strength Tylenol			C				Not Reported
	Pepcid Ac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12109629	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2016GSK025468		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Drug Ineffective; Tremor; Weight Decreased	Wellbutrin Xl			S	Oral	300 Mg, Qd		Glaxosmithkline
	Bupropion			S	Oral	600 Mg, Qd		Glaxosmithkline
	Lorazepam			S	Oral	0.5 Df, Qd		Not Reported

Lorazepam	S	Oral	1 Df, Qd		Not Reported
Lexapro	S	Oral	Unk		Not Reported
Lexapro	S	Oral	3 Df, 1d		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12227503	EXPEDITED (15-DAY)		HO	ES-FRI-1000083691		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biliary Colic; Bundle Branch Block Left; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram			S	Unknown	Unknown		Forest
	Amiodarone			S	Unknown			Not Reported
	Metoclopramide			S	Unknown			Not Reported
	Metoclopramide			S				Not Reported
	Losartan			C	Unknown			Not Reported
	Betahistine			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Acenocoumarol			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Iron Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12256057	EXPEDITED (15-DAY)		OT	IT-ROCHE-1738422		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Restless Legs Syndrome	Rivotril			S	Oral	'2.5 Mg/Ml Oral Drops, Solution' 10 Ml Bottle		Not Reported
	Serenase (Italy)			S	Oral	'2 Mg/Ml Oral Drops, Solution' 1 X 15 Ml Bottle		Not Reported
	Cipralex			S	Oral	28 X 20 Mg Tablets		Not Reported
	Insulin			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12270239	EXPEDITED (15-DAY)		HO	SE-TEVA-650536ISR		22 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Lethargy; Nausea; Toxicity To Various Agents	Sertralin			S				Not Reported
	Atarax			S				Not Reported
	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12273368	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20160410963		74 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Tamponade; Haematuria; Potentiating Drug Interaction	Xarelto			S	Oral			Not Reported
	Plavix			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Prograf			C	Unknown			Not Reported
	Aldactone A			C	Unknown			Not Reported
	Pantozol			C	Unknown			Not Reported
	Zyloric			C	Unknown			Not Reported
	Euthyrox			C	Unknown			Not Reported
	Levemir			C	Unknown			Not Reported
	Triatec (Ramipril)			C	Unknown			Not Reported
	Movicol			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Torem			C	Unknown			Not Reported
	Quetiapine Fumarate			C	Unknown			Not Reported
	Concor			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12273619	EXPEDITED (15-DAY)		OT	DE-FRI-1000083829			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Decreased Appetite; Fatigue; Insomnia; Mental Impairment	Escitalopram			S	Unknown	10-25 Milligram Daily For 10 Years		Forest
	Escitalopram			S	Unknown	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12273731	NON-EXPEDITED			ADR-2015-01197		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Lioresal			S	Intrathecal	39.95 Mc/Gday		Not Reported
	Percocet			S				Not Reported
	Tylenol			S				Not Reported
	Aspirin			S				Not Reported
	Insulin Lispro			S				Not Reported
	Levothyroxine			S				Not Reported
	Magneisum Hydroxide			S				Not Reported
	Metformin			S				Not Reported
	Pravastatin			S				Not Reported
	Warfarin			S				Not Reported
	Lotrisine Topical			S	Topical			Not Reported
	Benazepril			S				Not Reported
	Vitaqmin D3			S				Not Reported
	Lexapro			S				Not Reported
	Insulin Glargine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12274844	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-028691		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Off Label Use;	Abilify			S	Oral	5 Mg, Qd		Bristol Myers Squibb

Respiratory Distress; Somnolence	Temesta /00273201/	S	Unknown	2.5 Mg, Unk	Not Reported
	Seroplex	S	Oral	20 Mg, Qd	Not Reported
	Kardegic	C	Unknown	75 Mg, Unk	Not Reported
	Flodil /00641902/	C	Unknown	5 Mg, Unk	Not Reported
	Tegretol	C	Unknown	400 Mg, Unk	Not Reported
	Gardenal /00023201/	C	Unknown	100 Mg, Unk	Not Reported
	Inegy	C	Unknown	1 Df, Unk	Not Reported
	Bisoce	C	Unknown	2.5 Mg, Unk	Not Reported
	Omexel	C	Unknown	0.4 Mg, Unk	Not Reported
	Uvedose	C	Unknown	100000 U, Unk	Not Reported
	Dafalgan	C	Unknown	1 G, Unk	Not Reported
	Avodart	C	Unknown	0.5 Mg, Unk	Not Reported
	Vesicare	C	Unknown	10 Mg, Unk	Not Reported
	Topalgic /00599202/	C	Unknown	150 Mg, Unk	Not Reported
	Allopurinol	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Domperidone	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Spasfon /00765801/	C	Unknown		Not Reported
	Ventoline /00139501/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2016	12090135	NON-EXPEDITED		OT	US-ACTAVIS-2015-25380		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Increased; Cough; Decreased Appetite; Dyspnoea; Ear Pain; Haemoptysis; Headache; Lung Cancer Metastatic;	Benazepril Hydrochloride (Actavis Laboratories Fl)			S	Oral	10 Mg, Daily		Actavis
	Lexapro /01588501/			S	Oral	10 Mg, Daily		Not Reported
	Boniva			C	Oral	1 Tablet, Once A Month		Not Reported

Night Sweats; Pain;
Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2016	12222084	EXPEDITED (15-DAY)		OT	FR-FRI-1000083491		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Vertigo; Withdrawal Syndrome	Escitalopram			S	Oral	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2016	12279983	EXPEDITED (15-DAY)		HO	FR-FRI-1000083870		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Traumatic Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Previscan (Fluindione)			S	Oral	10 Mg		Not Reported
	Lasilix			C	Oral	40 Mg		Not Reported
	Lasilix Retard			C	Oral	60 Mg		Not Reported
	Nebivolol			C	Oral	5 Mg		Not Reported
	Bromazepam			C	Oral	3 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2016	12281298	DIRECT		HO			17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Mental Disorder; Suicidal Ideation	Escitalopram, 10 Mg, Teva			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2016	12280631	EXPEDITED (15-DAY)		HO	SE-AUROBINDO-AUR-APL-2016-04869			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Lethargy; Nausea; Toxicity To Various Agents	Sertraline		S	Unknown	Unk	Aurobindo
	Atarax /00058401/		S	Unknown	25 Mg, Unk	Not Reported
	Cipralex /01588501/		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2016	12285044	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Nightmare; Rash	Escitalopram Oxalate, 20mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2016	12287835	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2016M1016181			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypokinesia; Intentional Overdose; Speech Disorder; Toxicity To Various Agents	Escitalopram			S	Oral	1 Df, Total		Not Reported
	Escitalopram			S	Oral	28 Df Total		Not Reported
	Xanax			S	Oral	2 Df, Total		Mylan
	Xanax			S	Oral	60 Df Total		Mylan
	Neurontin			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2016	12288278	NON-EXPEDITED			ADR-2015-01442		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Muscle Spasms; Nerve Compression	Lioresal			S	Intrathecal	257.4 Mcg/Day		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2016	12290330	DIRECT	Y	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Malaise; Product Substitution Issue	Escitalopram Oxalate 10mg Accord Hlthcare			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2016	12289450	NON-EXPEDITED			US-ELI_LILLY_AND_COMPANY-US201604005259			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retrograde Ejaculation	Strattera			S	Oral	Unk, Unknown		Eli Lilly And Co
	Lexapro			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	12238414	EXPEDITED (15-DAY)		LT, OT	ES-PFIZER INC-2016174192		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardio-Respiratory Arrest; Contraindicated Product Administered; Electrocardiogram Qt Prolonged; Torsade De Pointes	Amiodarone Hcl			S	Unknown	Unk		Pfizer
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported
	Metoclopramide			S	Unknown	Unk		Not Reported
	Metoclopramide			S				Not Reported
	Losartan			C		Unk		Not Reported
	Betahistine			C		Unk		Not Reported
	Simvastatin			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported
	Acenocoumarol			C		Unk		Not Reported
	Acenocoumarol			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Ferrous Sulfate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	12245363	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL		< 1 DAY	Male	ITA

INDUSTRIES LTD-
2016RR-114544

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Tachypnoea	Lorazepam			S	Transplacental	0.25 Mg Daily		Sun
	Escitalopram			S	Transplacental	5 Gtt Daily		Not Reported
	Adalat			S	Transplacental	60 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	12247383	EXPEDITED (15-DAY)		HO, OT	IT-FRI-1000083756		< 1 DAY	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Tachypnoea	Escitalopram Oral Solution			S	Transplacental	5 Gtt		Forest
	Adalat/ Nifedipine			S	Transplacental	60 Mg		Not Reported
	Lorazepam			S	Transplacental	0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	12294796	NON-EXPEDITED			US-PFIZER INC-2016212046			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Effexor			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	12295637	EXPEDITED (15-DAY)		HO	IT-TEVA-653750ACC		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypokinesia; Speech Disorder; Toxicity	Escitalopram			S	Oral	28 Df Total		Ivax

To Various Agents	Xanax - 0.25 Mg Compresse - 4pharma S.R.L.	S	Oral	60 Df Total		Not Reported
	Neurontin	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	12296114	EXPEDITED (15-DAY)		HO	FR-FRI-1000084003		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Escitalopram			S	Oral	10 Mg		Forest
	Tramadol			S	Oral			Not Reported
	Iperten			C				Not Reported
	Lamictal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2016	12298633	EXPEDITED (15-DAY)		HO, OT	FR-AMGEN-FRASP2016049782		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholecystitis Infective; Colitis	Xgeva			S	Subcutaneous	120 Mg, Q4wk		Amgen
	Coversyl /00790702/			S	Oral	10 Mg, Qd		Not Reported
	Fenofibrate			S	Oral	100 Mg, Qd		Not Reported
	Previscan (Fluindione)			S	Oral	20 Mg, Dividable Pill		Not Reported
	Cortancyl			S	Oral	20 Mg, Qd		Not Reported
	Monuril			S	Oral	3 G, Granules For Oral Solution In Sachet		Not Reported
	Inexium			S	Oral	20 Mg, Gastro-Resistant Pill Qd		Not Reported
	Amlor			S	Oral	50 Mg, Qd		Not Reported
	Zopiclone			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	10 Mg, Dividable Coated Pill		Not Reported
	Levothyrox			S	Oral	125 Mug, Dividable, Pill		Not Reported
	Dafalgan			S	Oral	Unk		Not Reported

	Tramadol Basi			S	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2016	12300173	NON-EXPEDITED		HO, OT	ADR-2015-00661		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autonomic Dysreflexia; Blood Pressure Increased; Blood Test Abnormal; Device Breakage; Drug Withdrawal Syndrome; Headache; Heart Rate Increased; Hypertonia; Muscle Spasms; Muscle Spasticity; Pyrexia; Rash; Tremor; Urine Analysis Abnormal; Urticaria	Ascorbic Acid			S	Oral			Not Reported
	Escitalopram Lexapro			S	Oral			Not Reported
	Ketoconazole 2 Percent Topical Cream			S	Topical			Not Reported
	Detrol La			S	Oral			Not Reported
	Hydrocortisone 2.5% Ointment			S	Topical			Not Reported
	Potassium			S	Oral			Not Reported
	Normal Saline			S	Topical			Not Reported
	Minocycline (Minocin)			S	Oral			Not Reported
	Rifampin			S	Oral			Not Reported
	Docusate Sodium			S	Oral			Not Reported
	Clonidine Transdermal Patch			S	Transdermal	0.2 Mg/24 Hr Weekly Transdermal Patch One Patch Every Week		Not Reported
	Clonidine Hcl			S	Oral	0.1 Mg Tablet One Tablet By Mouth Every Other Day		Not Reported
	Dakins 0.025% Solution			S	Unknown			Not Reported
	Citrucel Fiber			S	Oral			Not Reported
	Lioresal Intrathecal (Baclofen Injection)			S	Intrathecal	879.8mcg/Day		Not Reported
	Baclofen			S	Intrathecal			Not Reported
	Baclofen			S	Intrathecal			Not Reported
	Levothyroxine Synthroid			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Nystatin 100,00 Unit/Gram Topical Powder			S	Topical			Not Reported

	Tolterodine Detrol La	S	Oral		Not Reported
	Imipramine	S	Oral		Not Reported
	Ciclopirox	S	Topical	Apply To Scalp Every Other Day	Not Reported
	Betamethasone Dipropionate 0.05% Lotion	S	Topical		Not Reported
	Juven	S	Oral		Not Reported
	Gentamicin 0.1% Topical Ointment	S	Topical		Not Reported
	Clindamycin Phosphate 1% Topical	S	Topical		Not Reported
	Sulfamethoxazole Trimethoprim (Bactrim Ds)	S	Oral	Sulfamethoxazole 800 Mg Trimethoprim 160 Mg Tablet One Tablet By Mouth Daily	Not Reported
	Sulfacetamide Sodium-Sulfur 10%-5% Topical Cleanser	S	Topical		Not Reported
	Baclofen	S	Oral		Not Reported
	Diazepam (Valium)	S	Oral		Not Reported
	Acetaminophen\Hydrocodone Bitartrate	S	Oral	Hydrocodone 10 Mg Acetaminophen 325 Mg Tablet One Tablet By Mouth Every Six Hours As Needed	Not Reported
	Escitalopram Lexapro	S	Oral		Not Reported
	Baclofen	S	Intrathecal	900.2 Mcg/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2016	12300464	NON-EXPEDITED			US-PFIZER INC-2016203303		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S		Unk		Pfizer
	Alprazolam			S		Unk		Pfizer
	Lorazepam			S		Unk		Pfizer

Clonazepam	S	Unk		Not Reported
Wellbutrin	S	Unk		Not Reported
Lexapro	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2016	12301195	EXPEDITED (15-DAY)		HO	IT-WATSON-2016-06928		< 1 DAY	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Tachypnoea	Lorazepam (Unknown)			S	Transplacental	Unk		Watson
	Escitalopram (Unknown)			S	Transplacental	Unk		Not Reported
	Adalat			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2016	12304237	DIRECT		OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dysgeusia; Fall; Feeling Hot; Flushing; Head Injury; Headache; Nausea	Escitalopram Oxalate, 5mg			S	Oral			Not Reported
	Sumatriptan			C				Not Reported
	Fluticasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2016	12304378	DIRECT		HO			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Pain In Jaw; Serotonin Syndrome; Suicidal Ideation	Escitalopram 10mg Aurobindo Pharm			S	Oral	10mg 1 Tablet 1 A Day In Morning Mouth		Aurobindo
	Prilosec			C				Not Reported
	Motrin			C				Not Reported
	Xanax			C				Not Reported
	Benadryl			C				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2016	12304677	DIRECT		DS, HO			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthralgia; Dyspnoea; Erectile Dysfunction; Malaise; Myalgia; Nausea; Tinnitus; Vision Blurred; Weight Decreased	Escitalopram - Lexipro			S	Oral	1 Pill 1 Time Daily Mouth		Camber
	Metformin			C				Not Reported
	Previcid			C				Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12253858	EXPEDITED (15-DAY)		OT	US-MDT-ADR-2016-00648		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catheter Site Swelling; Drug Withdrawal Syndrome; Fall; Loss Of Consciousness; Malaise; Post Lumbar Puncture Syndrome; Toxicity To Various Agents	Bupivacaine			S	Intrathecal	7.6 Mg/Day		Not Reported
	Compounded Baclofen			S	Intrathecal	70 Mcg/Day		Not Reported
	Dilaudid (Hydromorphone)			S	Intrathecal	3.78 Mg/Day		Not Reported
	Fentanyl			S	Intrathecal	630 Mg/Day		Not Reported
	Tizanidine			S		2 Mg		Not Reported
	Baclofen			S		10 Mg		Not Reported
	Topamax			S		100 Mg		Not Reported
	Remeron			S		115 Mg		Not Reported
	Synthroid			S		200 Mcg		Not Reported
	Midrin			S				Not Reported
	Adderall			S		10 Mg		Not Reported
	Lexapro			S		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12304456	EXPEDITED (15-DAY)		HO	TH-LUPIN PHARMACEUTICALS INC.-2016-01613		77 YR	Male	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown			Not Reported
	Rasagiline			S	Unknown			Not Reported
	Ticlopidine			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Gemfibrozil			C	Unknown			Not Reported
	Piribidil			C	Unknown			Not Reported
	Rivastigmine Patch			C	Unknown	10 Cm2		Not Reported
	Stalevo 100			C	Unknown			Not Reported
	Pramiprexole			C	Unknown			Not Reported
	Melatonin			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12306899	EXPEDITED (15-DAY)		DS	AU-FRI-1000084025		45 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Depression; Dizziness; Food Intolerance; Histamine Intolerance; Suicidal Ideation; Tachycardia; Urticaria	Escitalopram			S	Unknown	20 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12308243	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2016SE43033		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chemical Peritonitis; Cholecystitis Infective; Colitis; Lung Disorder; Melaena; Sciatica	Inexium			S	Oral			Not Reported
	Cortancyl			S	Oral	From 20mg To 60mg Once In The Morning		Not Reported

Xgeva	S	Subcutaneous	Not Reported
Fenofibrate	S	Oral	Not Reported
Previscan (Fluindione)	S	Oral	Not Reported
Monuril	S	Oral	Not Reported
Amlor	S	Oral	Not Reported
Coversyl	S	Oral	Not Reported
Zopiclone	S	Oral	Not Reported
Seroplex	S	Oral	Not Reported
Levothyrox	S	Unknown	Not Reported
Dafalgan	S	Oral	Not Reported
Tramadol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12308919	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Product Substitution Issue	Escitalopram			S	Oral	Prior To Up To 7/14/15		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12309189	DIRECT					58 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Somnolence	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12309217	DIRECT		OT			24 YR	Male	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Food Interaction; Headache	Lexapro Lamotragine			S C				Not Reported Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	10991392	NON-EXPEDITED			US-PFIZER INC-2015117628		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Depakote			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Trileptal			S		Unk		Not Reported
	Bee Venom, Standard			S		Unk		Not Reported
	Losartan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12188498	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20160226890		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Breast Enlargement; Confusional State; Headache; Hospitalisation	Risperdal Consta			S	Intramuscular			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Risperidone			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12204477	EXPEDITED (15-DAY)		CA, HO	FR-FRI-1000083392			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Growth Restriction	Escitalopram			S	Transplacental	Not Specified		Forest
	Baclofene			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12308861	EXPEDITED (15-DAY)		OT	BR-SHIRE-BR201604799		13 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cardiac Arrest; Condition Aggravated; Depression; Oxygen Consumption Decreased; Panic Disorder; Poor Venous Access; Pulse Abnormal; Social Avoidant Behaviour; Tooth Disorder; Vascular Access Complication; Vein Disorder	Elaprase			S	Intravenous drip	18 Mg (3 Vials), 1x/Week		Shire
	Escitalopram Oxalate			S	Unknown	20 Mg (10 Mg, 2 Tablets), 1x/Day:Qd (In The Morning)		Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12309331	EXPEDITED (15-DAY)		HO	IT-ACCORD-039984		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypokinesia; Speech Disorder; Toxicity To Various Agents	Escitalopram			S	Oral			Accord
	Xanax			S	Oral	Strength: 0.25 Mg Mah: 4pharma S.R.L.		Not Reported
	Neurontin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12310423	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016220488		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholecystitis Infective; Colitis	Amlor			S	Oral	5 Mg, 1x/Day		Pfizer
	Inexium			S	Oral	20 Mg, 1x/Day		Unknown
	Xgeva			S	Subcutaneous	120 Mg Every 4 Weeks		Not Reported
	Fenofibrate			S	Oral	100 Mg, 1x/Day		Not Reported

Previscan /00789001/	S	Oral	Strenght 20 Mg		Not Reported
Cortancyl	S	Oral	20 Mg, 1x/Day		Not Reported
Monuril Adultes	S	Oral	3 G, Single		Not Reported
Coversyl /00790703/	S	Oral	10 Mg, 1x/Day		Not Reported
Zopiclone	S	Oral	1 Df, 1x/Day		Not Reported
Seroplex	S	Oral	10 Mg, 2x/Day		Not Reported
Levothyrox	S	Oral	62.5 Ug, 1x/Day		Not Reported
Dafalgan	S	Oral	Unk		Not Reported
Tramadol Hydrochloride	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12311398	EXPEDITED (15-DAY)		HO	FR-SYMPLMED PHARMACEUTICALS-2016SYMPLMED000202			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chemical Peritonitis; Cholecystitis Infective; Colitis; Diarrhoea; Enterobacter Infection; Melaena; Pneumonia; Pyrexia; Sciatica; Septic Shock; Tachycardia; Urinary Tract Infection; Vomiting	Coversyl			S	Oral	10 Mg, Qd		Unknown
	Xgeva			S	Subcutaneous	120 Mg, Every 4 Weeks		Not Reported
	Fenofibrate			S	Oral	100 Mg, Qd		Not Reported
	Previscan /00789001/			S	Oral	20 Mg, Unk		Not Reported
	Cortancyl			S	Oral	20 Mg, Qd		Not Reported
	Monuril			S	Oral	3 Gram, Once		Not Reported
	Inexium /01479302/			S	Oral	20 Mg, Qd		Not Reported
	Amlor			S	Oral	5 Mg, Qd		Not Reported
	Zopiclone			S	Oral	1 Df, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Bid		Not Reported
	Levothyrox			S	Oral	62.5 Mg, Qd		Not Reported
	Dafalgan			S	Oral	Unk		Not Reported
	Tramadol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12311620	EXPEDITED (15-DAY)		HO	FR-FRI-1000084148		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Jaundice; Product Use Issue	Escitalopram			S	Oral	5 Mg		Forest
	Zelitrex			C				Not Reported
	Wellvone			C				Not Reported
	Alprazolam			C				Not Reported
	Cortancyl			C				Not Reported
	Nasonex			C				Not Reported
	Movicol			C				Not Reported
	Gaviscon			C				Not Reported
	Tercian			C				Not Reported
	Permixon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12311716	EXPEDITED (15-DAY)		OT	FR-UCBSA-2016014716		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Xyzall			S	Oral	Unk Unk, As Needed (Prn)		Ucb
	Istodax			S		Unk		Not Reported
	Istodax			S	Intravenous (not otherwise specified)	24 Mg, Unk		Not Reported
	Inexium			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Gaviscon			S	Oral	1 Df, 3x/Day (Tid)		Not Reported
	Seroplex			S	Oral	10 Mg, Once Daily (Qd)		Not Reported
	Bactrim			C		Unk		Not Reported
	Zelitrex			C				Not Reported
	Neorecormon			C				Not Reported
	Granocyte			C				Not Reported
	Dexamethasone			C		Unk		Not Reported
	Bendamustine			C		Unk		Not Reported
	Brentuximab			C		Unk		Not Reported

Revlimid	C	Unk		Not Reported
Endoxan	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12313522	DIRECT		OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity	Escitalopram (Subet For Lexapro) 10 Mg Tablet Accord Healthca (Lblr.)			S	Oral	10 Mg Tab 30 1 X Day By Mouth		Accord
	Losartan			C				Not Reported
	Saphris			C				Not Reported
	50 + Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12314260	DIRECT	Y	CA			< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Alveolar Anomaly; Gingival Disorder; Maternal Drugs Affecting Foetus	Lexapro			S				Not Reported
	Marijuana			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2016	12217176	EXPEDITED (15-DAY)		LT	FR-FRI-1000083489		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Lung Disorder	Escitalopram			S	Oral	15 Mg		Forest
	Apokinon			S	Subcutaneous			Not Reported
	Mantadix			S	Oral	100 Mg		Not Reported
	Sinemet			S	Oral	1250 Mg		Not Reported
	Modopar			S	Oral			Not Reported
	Imovane			S	Oral	7.5 Mg		Not Reported

	Sifrol	S	Oral	1.05 Mg		Not Reported
	Azilect	S	Oral	1 Mg		Not Reported
	Alprazolam	S				Not Reported
	Apomorphine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2016	12312735	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2016IT03999			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypokinesia; Speech Disorder; Toxicity To Various Agents	Escitalopram			S	Oral	28 Df Total		Invagen
	Xanax			S	Oral	60 Df, Total		Not Reported
	Neurontin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2016	12313139	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2016-05070		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypokinesia; Speech Disorder; Toxicity To Various Agents	Escitalopram Film-Coated Tablets			S	Oral	28 Df, Total		Aurobindo
	Xanax			S	Oral	60 Df, Total		Not Reported
	Neurontin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2016	12314561	EXPEDITED (15-DAY)		OT	IE-FRI-1000084107		62 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Headache; Heart Rate Increased; Insomnia	Lexapro			S	Oral	5 Mg		Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2016	12314566	EXPEDITED (15-DAY)		HO	IT-FRI-1000084116		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypokinesia; Intentional Overdose; Intentional Overdose; Speech Disorder; Toxicity To Various Agents	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	Overdose: 28 Df (10 Mg X 28 = 280mg)		Forest
	Xanax "0,25mg Compresse			S	Oral			Not Reported
	Xanax "0,25mg Compresse			S	Oral	Overdose: 60 Df ((0.25 Mg X 60= 15 Mg)		Not Reported
	Neurontin/ Gabapentin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2016	12315298	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2016SE44029		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Neoplasm Progression; Thrombocytopenia	Inexium			S	Oral			Astrazeneca
	Xyzall			S	Oral	If Needed		Not Reported
	Istodax			S	Intravenous (not otherwise specified)			Not Reported
	Istodax			S	Intravenous (not otherwise specified)			Not Reported
	Gaviscon			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Bactrim			C				Not Reported
	Zelitrex			C				Not Reported
	Neorecormon			C				Not Reported
	Granocyte			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2016	12217185	EXPEDITED (15-DAY)		OT	FR-FRI-1000083487		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejaculation Failure; Product Use In	Escitalopram			S	Oral	5 Mg		Forest

Unapproved Indication	Escitalopram	S	Oral	10 Mg		Forest
	Bromazepam	C	Unknown			Not Reported
	Meteoxane	C	Unknown			Not Reported
	Pantoprazole	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2016	12317145	EXPEDITED (15-DAY)		OT	SE-ACCORD-039976		51 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Product Substitution Issue	Escitalopram Accord			S	Oral			Accord
	Propavan Sanofi Ab			C		Propavan 25 Mg Tablet		Not Reported
	Oxascand			C		Oxascand 10 Mg Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2016	12317457	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2016US03823			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Fatigue; Myocardial Infarction; Ventricular Tachycardia	Gemcitabine			S		1000 Mg/M2 On 2 Weeks On, 1 Week Off Schedule		Cipla
	Gemcitabine			S		1000 Mg/M2, Infused Over 30 Mins		Cipla
	Gabapentin			S	Unknown	600 Mg, Qd		Invagen
	Escitalopram			S	Unknown	10 Mg, Qd		Invagen
	Docetaxel			S		40 Mg/M2, Unk		Cipla
	Nifedipine			S	Unknown	10 Mg, Qd		Cipla
	Digoxin			S	Unknown	0.25 Mg, Qd		Not Reported
	Spironolactone			S	Unknown	25 Mg, Qd		Not Reported
	Rabeprazole			S	Unknown	20 Mg, Qd		Not Reported
	Rofecoxib			S	Unknown	25 Mg, Qd		Not Reported
	Aspirin			S	Unknown	81 Mg, Qd		Not Reported

	Nitroglycerin	S	Unknown	0.4 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2016	12318687	EXPEDITED (15-DAY)		OT	TR-FRI-1000084337			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cold Sweat; Dizziness; Drug Ineffective; Hypoaesthesia; Hypoaesthesia; Nausea; Seizure	Escitalopram			S	Unknown			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2016	12321152	DIRECT					32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pollakiuria	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2016	12321162	DIRECT		OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Burning Sensation; Burning Sensation; Discomfort; Disturbance In Attention; Dry Skin; Dry Skin; Flank Pain; Gait Disturbance; Oedema; Oedema Peripheral; Pain In Extremity; Pruritus; Rash; Rash; Rash Erythematous; Swelling; Withdrawal Syndrome	Escitalopram, 20 Mg Teva Usa			S	Oral	1 Tablet(S) Once A Day Taken By Mouth		Teva
	Levothyroxine			C				Not Reported
	Warfarin			C				Not Reported
	Multi Vit/Mineral			C				Not Reported
	Calc			C				Not Reported
	D3			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2016	12321864	DIRECT	Y	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal	Escitalopram Oxalate 10mg Accord Hlthcare			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2016	12268590	EXPEDITED (15-DAY)		HO	CN-FRI-1000083840		53 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Lexapro			S	Unknown	10 Mg		Forest
	Mirtazapine			C	Unknown			Not Reported
	Dexzopiclone Tablets			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2016	12321675	EXPEDITED (15-DAY)		OT	US-TORRENT-00001202			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Emotional Distress; Nasopharyngitis; Surgery; Tension; Tremor	Escitalopram Tablets, Usp			S		1/2 Tablet Daily (20mg)		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2016	12326856	EXPEDITED (15-DAY)		OT	FR-FRI-1000084321		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Behaviour; Toxicity To Various Agents	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Not Reported

	Bromazepam	S	Oral	Not Reported
	Bromazepam	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2016	12329334	EXPEDITED (15-DAY)		OT	US-INDIVIOR LIMITED-INDV-090134-2016		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Premature Baby; Psychomotor Hyperactivity	Suboxone			S	Transplacental	8 Mg, Qd		Reckitt Benckiser
	Subutex			S	Transplacental	Unk		Reckitt Benckiser
	Lexapro			S	Transplacental	10 Mg, Qd		Not Reported
	Clonidine			S	Transplacental	0.1 Mg, Tid		Not Reported
	Ativan			S	Transplacental	0.5 Mg Two Times A Day And When Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2016	12329723	EXPEDITED (15-DAY)		HO	BR-TAKEDA-2016TUS007550		30 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Diarrhoea; Headache; Vomiting	Brintellix			S	Oral	5 Mg, Qd		Takeda
	Escitalopram			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2016	12331411	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	12266408	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2016AP007534		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram Apotex		S	Unknown	Apotex
	Amiodarone		S	Unknown	Not Reported
	Metoclopramide /00041902/		S	Unknown	Not Reported
	Metoclopramide /00041902/		S		Not Reported
	Losartan		C	Unknown	Not Reported
	Betahistine		C	Unknown	Not Reported
	Simvastatin		C	Unknown	Not Reported
	Bisoprolol		C	Unknown	Not Reported
	Acenocoumarol		C	Unknown	Not Reported
	Metformin		C	Unknown	Not Reported
	Iron Sulfate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	12330992	EXPEDITED (15-DAY)		OT	US-ASTELLAS-2016US017094		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Disease; Tremor	Prograf			S	Unknown			Astellas
	Cellcept /01275102/			S	Unknown	Unk, Unknown Freq.		Not Reported
	Sirolimus			S	Unknown	0.5 Mg, Unknown Freq.		Not Reported
	Lexapro /01588501/			S	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	12331205	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-2016-001887			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Road Traffic Accident	Diazepam 5mg			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	12336314	DIRECT		OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Ineffective; Haemorrhage; Pruritus Generalised; Scratch	Escitalopram, 10mg Walmart			S	Oral			Walmart
	Prozac			C				Not Reported
	Clonazepam			C				Not Reported
	Skelaxin			C				Not Reported
	Suboxone			C				Not Reported
	Tylenol			C				Not Reported
	Excedrin			C				Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12242569	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000083662			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Balance Disorder; Blindness Unilateral; Blood Pressure Increased; Dehydration; Depressed Mood; Diarrhoea; Eye Swelling; Fatigue; Furuncle; Hair Colour Changes; Hair Texture Abnormal; Headache; Infection; Intestinal Obstruction; Liver Abscess; Muscular Weakness; Nausea; Neovascular Age-Related Macular Degeneration; Nervousness; Oral Pain; Pruritus; Swelling Face; Vision Blurred; Vomiting; Weight Fluctuation	Escitalopram			S				Not Reported
	Sutent			S				Not Reported
	Levothyroxine			S		100 Mcg		Not Reported
	Losartan			S				Not Reported
	Amlodipine Besylate			S				Not Reported
	Trazodone			S				Not Reported
	Vitamin D3			S				Not Reported
	Probiotic			S				Not Reported
	Ergocalciferol			C				Not Reported
	Cyclobenzaprine Hydrochloride			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12336785	EXPEDITED (15-DAY)		LT	CH-ACTAVIS-2016-08978		86 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Clonus; Drug Interaction; Hyperhidrosis; Hyperreflexia; Hypertonia; Pyrexia; Serotonin Syndrome; Tremor	Escitalopram (Unknown)		S	Oral	10 Mg, Daily	Not Reported
	Mirtazapine		S	Oral	15 Mg, Daily	Actavis
	Fentanyl (Unknown)		S	Intravenous drip	12 Mg, Daily	Watson
	Oxycodone (Unknown)		S	Oral	20 Mg, Daily	Watson
	Pethidine		S	Intravenous drip	768 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12337345	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2016237608		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Movement Disorder; Myoclonus; Tinnitus; Tremor; Vertigo	Effexor			S	Oral	37.5 Mg, Unk		Pfizer
	Effexor			S	Oral	75 Mg, Unk		Pfizer
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Escitalopram			S	Oral	5 Mg, Daily		Not Reported
	Tranxene			C	Oral	Unk		Not Reported
	Plavix			C		Unk		Not Reported
	Zocor			C		Unk		Not Reported
	Cotareg			C		Unk		Not Reported
	Levothyrox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12339229	EXPEDITED (15-DAY)		HO	US-FRI-1000084339			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenopia; Asthenopia; Headache; Headache; Influenza Like Illness; Influenza Like Illness; Product Administration Error; Pyrexia; Streptococcal Infection; Streptococcal Sepsis	Lexapro			S	Oral			Forest
	Lexapro			S	Oral			Forest
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12339233	EXPEDITED (15-DAY)		HO	US-ASTRAZENECA-2016SE45931		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chemical Peritonitis; Cholecystitis Infective; Colitis; Enterobacter Infection; Large Intestinal Obstruction; Large Intestine Perforation; Pneumonia; Septic Shock	Inexium			S	Oral			Not Reported
	Amlor			S	Oral			Not Reported
	Xgeva			S	Subcutaneous			Not Reported
	Fenofibrate			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Monuril Adultes			S	Oral			Not Reported
	Coversyl			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Dafalgan			S	Oral			Not Reported
	Tramadol Hydrochloride			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12340970	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prozac			S				Not Reported
	Zoloft			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12341010	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12333239	EXPEDITED (15-DAY)		OT	CN-FRI-1000084324		35 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Dependence; Drug Ineffective; Exposure During Pregnancy; Feeling Abnormal	Escitalopram			S	Unknown	0.5 Tablet, 1 Tablet, 1.5 Tablets And 2 Tablets (Step Increased For 2 Months). Then Step Decreased F		Forest
	Escitalopram			S	Unknown	Step Increased To 1.5 Tablets		Forest
	Escitalopram			S	Unknown	1 Tablet Per Day		Not Reported
	Elevit Vitamin Complex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12340046	EXPEDITED (15-DAY)		OT	US-ACCORD-040129		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Depression; Drug Ineffective; Fatigue; Feeling Abnormal; Frustration Tolerance Decreased	Accord Escitalopram			S	Oral	Pt. Took 5 Mg (Half Tablet) For A Month Then Dose Was Increased To 10 Mg (Whole Tablet)		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12341362	EXPEDITED (15-DAY)		CA, DE	FR-FRI-1000084377			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Central Nervous System Anomaly; Foetal Exposure During Pregnancy; Microcephaly	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12341745	EXPEDITED (15-DAY)		HO, LT	FR-JNJFOC-20160503132		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Toxicity To Various Agents	Risperdal			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Subutex			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported
	Valium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12343416	EXPEDITED (15-DAY)		OT	US-ABBVIE-16K-163-1620631-00		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Generalised Tonic-Clonic Seizure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12343640	EXPEDITED (15-DAY)		HO	FR-TAKEDA-2016TUS007740		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting	Adenuric			S	Oral	Unk		Takeda
	Adenuric			S	Oral	80 Mg, Qd		Takeda
	Nebivolol			S	Oral	Unk		Not Reported
	Nebivolol			S	Oral	5 Mg, Qd		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Atarax /00058401/			S	Oral	Unk		Not Reported
	Atarax /00058401/			S	Oral	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12346057	DIRECT					58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Product Substitution Issue	Escitalopram Oxalate 20mg, 20 Mg			S	Oral	30 Tablet(S) In The Morning Taken By Mouth		Lupin
	Lexapro			C				Not Reported
	Trazodone			C				Not Reported
	Clonazepam			C				Not Reported
	Vitamin D3			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2016	12224877	NON-EXPEDITED			US-PFIZER INC-2016186319		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Head Discomfort	Zoloft			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2016	12348694	EXPEDITED (15-DAY)		HO	FR-SA-2016SA089512			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; Malaise; Torsade De Pointes	Lasilix			S	Oral			Not Reported
	Cordarone			S	Oral	Dose And Frequency:1/2 In The Morning Except On Weekends		Not Reported
	Seroplex			S	Oral			Not Reported

	Temesta (Lorazepam)	S	Oral		Not Reported
	Previscan (Fluindione)	S	Oral	Dose:1/4 In The Evening	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2016	12348729	EXPEDITED (15-DAY)		HO, LT	FR-INDIVIOR LIMITED-INDV-090262-2016		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Atrioventricular Block First Degree; Bradycardia; Intentional Product Use Issue; Poisoning Deliberate; Toxicity To Various Agents	Subutex			S	Oral	Unk		Reckitt Benckiser
	Seroplex			S	Oral	Unk		Not Reported
	Risperdal			S	Oral	Unk		Not Reported
	Seresta			S	Oral	Unk		Not Reported
	Alcohol			S	Oral	Unk		Not Reported
	Valium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2016	12351412	DIRECT	Y				36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral			Not Reported
	Tylenol			C				Not Reported
	Depakote Er			C				Not Reported
	Ativan			C				Not Reported
	Seroquel			C				Not Reported
	Clonidin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2016	12225106	EXPEDITED (15-DAY)		LT, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-114116		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardio-Respiratory Arrest;	Metoclopramide			S	Unknown			Mutual
	Metoclopramide			S				Mutual

Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Amiodarone	S	Unknown	Taro
	Escitalopram	S	Unknown	Not Reported
	Losartan	C	Unknown	Not Reported
	Betahistine	C	Unknown	Not Reported
	Simvastatin	C	Unknown	Not Reported
	Bisoprolol	C	Unknown	Not Reported
	Acenocoumarol	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Ferrous Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2016	12277938	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20160414366		24 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sluggishness; Tachycardia	Risperdal			S	Oral			Not Reported
	Invega			S	Oral			Not Reported
	Depakin			S	Oral			Not Reported
	Neoduplamox			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2016	12351182	EXPEDITED (15-DAY)		HO	US-PURDUE PHARMA-CAN-2016-0006668		94 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective For Unapproved Indication; Off Label Use	Methylphenidate Hcl (Similar To 205831)			S	Unknown	Unk		Rhodes
	Sertraline			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Venlafaxine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported

	Bupropion			S	Unknown	Unk			Not Reported
	Trazodone			S	Unknown	Unk			Not Reported
	Lorazepam			S	Unknown	Unk			Not Reported
	Clonazepam			S	Unknown	Unk			Not Reported
	Donepezil			S	Unknown	Unk			Not Reported
	Memantine			S	Unknown	Unk			Not Reported
	Lamotrigine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2016	12352739	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20160503256		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Nausea; Vomiting	Durogesic			S	Transdermal			Not Reported
	Lyrica			S	Oral			Not Reported
	Seroplex			S	Oral	0.5 Tablet		Not Reported
	Lasilix			C	Oral			Not Reported
	Kardegic			C	Oral			Not Reported
	Pravastatin Sodium			C	Oral			Not Reported
	Lercan			C	Oral			Not Reported
	Renitec [Enalapril Maleate]			C	Oral			Not Reported
	Cardensiel			C	Oral			Not Reported
	Lantus			C	Subcutaneous	12 To 14 Iu In The Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	12218019	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/16/0078135		57 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Cipralex 40 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	12354187	EXPEDITED (15-DAY)		HO	CZ-CIPLA LTD.-2016CZ04875			Unknown	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Wall Haematoma; Dehydration; Fall; Hyponatraemia; Syncope	Escitalopram			S	Unknown	10 Mg, Qd		Invagen
	Perindopril			S	Unknown	5 Mg, Bid		Not Reported
	Omeprazole			S	Unknown	20 Mg, Qd		Cipla
	Atorvastatin			S	Unknown	10 Mg, 1/2 Once Daily		Not Reported
	Chlorthalidone/Amiloride			S	Unknown	25 Mg / 2.5 Mg, Bid		Not Reported
	Levothyroxine			S	Unknown	75 Mcg, Qd		Not Reported
	Furosemide			S	Unknown	40 Mg, Qd		Not Reported
	Bromazepam			S	Unknown	3 Mg, 1/2 Once Daily		Not Reported
	Nitrendipine			S	Unknown	10 Mg, Qd		Not Reported
	Isosorbide Dinitrate			S	Unknown	20 Mg, Bid		Not Reported
	Tramadol			S	Unknown	150 Mg, Bid		Not Reported
	Tiapride			S	Unknown	100 Mg, Qd		Not Reported
	Rivaroxaban			S	Unknown	20 Mg, Qd		Not Reported
	Fentanyl			S	Unknown	25 Mcg/H		Not Reported
	Metamizole			S	Unknown	500 Mg, Two Doses, Thrice Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	12354217	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-116210		26 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Exposure During Pregnancy	Thiocolchicoside			S	Oral	16 Mg, Daily		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Dexketoprofen			S	Unknown			Not Reported

Etodolac	S	Unknown		Ranbaxy
Desloratadine	S	Unknown		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	12355802	NON-EXPEDITED			US-FRI-1000083115		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Libido Decreased; Off Label Use; Urinary Retention	Fetzima			S	Oral	40mg		Forest
	Fetzima			S	Oral	20mg		Forest
	Lexapro			S	Oral	20mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	12357417	NON-EXPEDITED			US-TEVA-653051ACC		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Menstruation Delayed	Paragard 380a			S				Duramed
	Lexapro			S	Unknown			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	12358862	DIRECT		DS, HO			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Dizziness; Head Discomfort; Headache; Heart Rate Increased; Impaired Work Ability; Pain; Paraesthesia	Lexapro			S	Oral			Forest
	Multi Vitamin			C				Not Reported
	Omega 3			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin E			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2016	12351863	NON-EXPEDITED		OT	US-PFIZER INC-2016241950		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Rash Erythematous; Rash Papular; Rash Pruritic	Geodon			S		40 Unk, Unk		Pfizer
	Geodon			S		60 Unk, Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Lexapro			S		30 Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2016	12362285	EXPEDITED (15-DAY)		OT	IT-ABBVIE-16P-083-1624323-00		24 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sluggishness; Tachycardia	Depakin			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Invega			S	Oral	Tablet, Extended Release		Not Reported
	Neoduplamox			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2016	12364703	EXPEDITED (15-DAY)		OT	ES-ANIPHARMA-2016-ES-000006		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes	Metoclopramide (Non-Specific)			S	Unknown	Unknown		Ani
	Iron Sulfate			C				Not Reported
	Amiodarone			S	Unknown	Unknown		Not Reported
	Escitalopram			S	Unknown	Unknown		Not Reported
	Losartan			C				Not Reported
	Betahistine			C				Not Reported
	Simvastatin			C				Not Reported
	Bisoprolol			C				Not Reported
	Acenocoumarol			C				Not Reported
	Metformin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2016	12365375	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016251966			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; International Normalised Ratio Increased; Malaise; Torsade De Pointes	Cordarone			S	Oral	At A Dose Of Half In The Morning Except On Weekends		Pfizer
	Temesta (Lorazepam)			S	Oral	Unk, Daily		Pfizer
	Lasilix			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Previscan (Fluindione)			S	Oral	At A Dose Of One-Fourth In The Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2016	12367789	EXPEDITED (15-DAY)		OT	FR-FRI-1000084556		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Erythema; Prescribed Overdose; Product Use Issue; Pruritus; Pyrexia; Rash Pustular; Tachycardia	Escitalopram			S	Oral	Overdose: Escitalopram 30 Mg Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2016	12368265	EXPEDITED (15-DAY)		HO	FR-FRI-1000084572		94 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Iron Deficiency Anaemia; Oesophageal Ulcer	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S	Oral	1 Df		Not Reported
	Rivastigmine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2016	12368708	EXPEDITED (15-DAY)		HO	FR-FRI-1000084504		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting	Nebivolol			S	Oral	30 To 40 Mg		Forest
	Nebivolol			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	40 To 50 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Adenuric			S	Oral	320 To 480 Mg		Not Reported
	Adenuric			S	Oral	80 Mg		Not Reported
	Atarax			S	Oral	5 To 6 Tablets		Not Reported
	Atarax			S	Oral	1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2016	12369137	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2016-05963		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram			S	Unknown			Aurobindo
	Amiodarone			S	Unknown			Not Reported
	Metoclopramide			S	Unknown			Not Reported
	Metoclopramide			S				Not Reported
	Losartan			C	Unknown			Not Reported
	Betahistine			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Acenocoumarol			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Iron Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2016	12351870	NON-EXPEDITED			US-PFIZER INC-2016224051		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Food Allergy; Hypersensitivity	Celebrex			S		Unk		Pfizer
	Tessalon			S		Unk		Pfizer
	Aleve			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Lortab			S		Unk (Hydrocodone Bitartrate 7.5/Paracetamol 7.5)		Not Reported
	Ultram			S		Unk		Not Reported
	Isosorbide Mononitrate			S		Unk		Not Reported
	Parafon Forte			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Ultracet			S		Unk		Not Reported
	Darvon			S		Unk		Not Reported
	Duragesic			S		Unk		Not Reported
	Hydrocodone\Ibuprofen			S		Unk		Not Reported
	Gluten			S		Unk		Not Reported
	Nitrofurantoin			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2016	12369555	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2016-05849			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Tachycardia	Escitalopram Aurobindo Film-Coated Tablets 10mg			S	Oral	20 Df, Total		Aurobindo
	Depakin			S	Oral	3 Df, Total		Not Reported

	Invega /05724801/	S	Oral	Unk	Not Reported
	Neoduplamox	S	Oral	3 Df, Total	Not Reported
	Risperdal	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2016	12371202	NON-EXPEDITED			US-PFIZER INC-2016224646			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Diflucan			S		Unk		Pfizer
	Prednisolone			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2016	12371595	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP008324		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Loss Of Consciousness; Seizure	Apo-Escitalopram			S	Oral	5 Mg, Qd		Apotex
	Dayquil Sinus			S	Unknown	2 Df, Single		Not Reported
	Dalacin /00166002/			S	Unknown	Unk		Not Reported
	Stieva-A			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2016	12373090	EXPEDITED (15-DAY)		HO	TW-SIGMAPHARM LABORATORIES, LLC-2016SIG00014		38 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Interaction	Disulfiram			S	Unknown	200 Mg, 1x/Day		Sigmapharm
	Griseofulvin			S	Oral	500 Mg, 1x/Day		Sigmapharm
	Escitalopram			S	Unknown	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2016	12373369	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20160511203		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Balance Disorder; Sinus Bradycardia	Reminyl			S	Oral			Not Reported
	Seroplex			S	Unknown			Not Reported
	Seroplex			S	Unknown			Not Reported
	Diacerein			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2016	12373519	EXPEDITED (15-DAY)		HO	ES-IPCA LABORATORIES LIMITED-IPC201605-000412		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Metoclopramide Hydrochloride			S				Ipca
	Metoclopramide Hydrochloride			S				Ipca
	Amiodarone			S				Not Reported
	Escitalopram			S				Not Reported
	Losartan			C				Not Reported
	Betahistine			C				Not Reported
	Simvastatin			C				Not Reported
	Bisoprolol			C				Not Reported
	Acenocoumarol			C				Not Reported
	Metformin			C				Not Reported
	Iron Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2016	12374272	DIRECT					39 YR	Male	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome; Sleep Disorder Due To General Medical Condition, Insomnia Type	Escitalopram			S	Oral			Camber
	Lamictal			C				Not Reported
	Clonazepam			C				Not Reported

	Vit-D				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2016	12375428	DIRECT		DS, HO, LT				Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Transient Ischaemic Attack; Vaginal Haemorrhage	Cipralex			S				Not Reported
	Celexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	10680921	EXPEDITED (15-DAY)		HO	TR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2014-BI-62		68 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Sleep Disorder; Social Avoidant Behaviour	Pradaxa			S	Unknown	110 Mg		Boehringer Ingelheim
	Escitalopram			S	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	11698410	EXPEDITED (15-DAY)		DE	CH-FRI-1000080610		89 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; General Physical Health Deterioration	Escitalopram			S	Oral	5 Mg		Forest
	Seroquel			S	Other			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	1 Mg		Not Reported
	Risperdal			S	Oral	0.5 Mg		Not Reported
	Coversum			C	Oral			Not Reported
	Coversum			C	Oral			Not Reported
	Aspirin Cardio			C	Oral	100 Mg		Not Reported

Euthyrox	C	Oral			Not Reported
Temesta (Lorazepam)	C	Oral			Not Reported
Temesta (Lorazepam)	C	Oral			Not Reported
Temesta (Lorazepam)	C	Oral			Not Reported
Morphin	C	Oral			Not Reported
Atorvastatin	C	Oral	10 Mg		Not Reported
Novalgine (Metamizole Sodium)	C	Oral	0.5 Mg		Not Reported
Adalat	C	Oral	20 Mg		Not Reported
Ringer Lactat	C	Intravenous (not otherwise specified)	1000 Ml		Not Reported
Exelon	C	Transdermal	4.6 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12195283	EXPEDITED (15-DAY)		HO	FR-FRI-1000083361		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Exposure During Pregnancy; Hypotonia Neonatal; Supraventricular Tachycardia	Escitalopram			S	Transplacental	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12370525	EXPEDITED (15-DAY)		HO	PHHY2016FR065744		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Fall; Gait Disturbance; Hyponatraemia	Voltarene (Diclofenac Sodium)			S	Parenteral	1 Df, Bid		Not Reported
	Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Perindopril			S	Oral	1 Df, Qd		Not Reported
	Alprazolam			S	Oral	1.5 Df, Qd		Novartis
	Nebivolol			S	Oral	1 Df, Qd		Not Reported

	Acupan	S	Parenteral	1 Df, Bid	Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)	S	Oral		Not Reported
	Lyrica	S	Oral		Not Reported
	Lantus	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Pravastatine	C	Unknown		Not Reported
	Kardegic	C	Unknown		Not Reported
	Vesicare	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12374341	EXPEDITED (15-DAY)		OT	US-ROCHE-1757972		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Disease; Tremor	Cellcept			S	Unknown			Not Reported
	Prograf			S	Unknown	1mg In The Morning And 1mg At Night		Not Reported
	Sirolimus			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12375196	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-036910			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Eliquis			S	Unknown	5 Mg, Bid		Bristol Myers Squibb
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12375863	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2016GSK069619		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Fall; Gait Disturbance; Hyponatraemia	Voltarene (Diclofenac Sodium)			S	Parenteral	1 Df, Bid		Glaxosmithkline
	Escitalopram			S		1 Df, Qd		Glaxosmithkline
	Alprazolam			S	Oral	1.5 Df, Qd		Glaxosmithkline
	Nebivolol			S	Oral	1 Df, Qd		Glaxosmithkline
	Perindopril			S	Oral	1 Df, Qd		Not Reported
	Acupan			S	Parenteral	1 Df, Bid		Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			S	Oral	Unk		Not Reported
	Lyrica			S	Oral			Not Reported
	Lantus			C				Not Reported
	Metformin			C				Glaxosmithkline
	Pravastatine			C				Not Reported
	Kardegic			C				Not Reported
	Vesicare			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12376016	NON-EXPEDITED			US-JAZZ-2015-US-014265		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Sensation Of Foreign Body	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustements		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Provigil			C		Unk		Not Reported
	Adderall			C		Unk		Not Reported
	Aspirin			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported
	Multivitamins			C		Unk		Not Reported

	Methylphenidate Hcl	C	Unk	Not Reported
	Modafinil	C	Unk	Not Reported
	Meloxicam	C	Unk	Not Reported
	Escitalopram	C	Unk	Not Reported
	Tizanidine Hydrochloride	C	Unk	Not Reported
	Xanax	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12376100	EXPEDITED (15-DAY)		LT	ES-ELI_LILLY_AND_COMPANY-ES201605004547		35 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blastic Plasmacytoid Dendritic Cell Neoplasia; Cough	Zyprexa			S	Oral	10 Mg, Unknown		Eli Lilly And Co
	Escitalopram			S	Unknown	15 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12377614	NON-EXPEDITED			US-JNJFOC-20140611274		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Benadryl		Y	S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported
	Tylenol With Codeine			S	Unknown			Not Reported
	Pristiq			S	Unknown			Not Reported
	Metformin Hcl			S	Unknown			Not Reported
	Amoxicillin			S	Unknown			Not Reported
	Pce			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported
	Novocain			S	Unknown			Not Reported
	Actos			S	Unknown			Not Reported

	Cipro	S	Unknown	Not Reported
	Macrodantin	S	Unknown	Not Reported
	Albuterol	S	Unknown	Not Reported
	Elavil	S	Unknown	Not Reported
	Prozac	S	Unknown	Not Reported
	Lexapro	S	Unknown	Not Reported
	Paxil	S	Unknown	Not Reported
	Xylocaine	S	Unknown	Not Reported
	Glucotrol Xl	S	Unknown	Not Reported
	St. John'S Wort	S	Unknown	Not Reported
	Lithobid	S	Unknown	Not Reported
	Remeron	S	Unknown	Not Reported
	Zoloft	S	Unknown	Not Reported
	Advil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12377642	EXPEDITED (15-DAY)		HO, OT	ES-NORTHSTAR HEALTHCARE HOLDINGS-ES-2016NSR001398			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardiac Disorder; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Metoclopramide Hydrochloride			S		Unk		Northstar
	Metoclopramide Hydrochloride			S				Northstar
	Amiodarone			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Betahistine			C		Unk		Not Reported
	Simvastatin			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported
	Acenocoumarol			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported

	Iron Sulfate			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12378432	EXPEDITED (15-DAY)		HO	FR-FRI-1000084607		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria	Escitalopram			S	Oral	1 Df		Forest
	Kardegic			S	Oral	1 Df		Not Reported
	Atarax			C				Not Reported
	Melaxose			C				Not Reported
	Celluvisc			C				Not Reported
	Crestor			C				Not Reported
	Triatec (Ramipril)			C				Not Reported
	Levothyrox			C				Not Reported
	Trimebutine			C				Not Reported
	Baclofene			C				Not Reported
	Noctamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12378590	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-2016VAL001543			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; Malaise; Torsade De Pointes	Furosemide			S	Oral	Unk		Validus
	Cordarone			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Temesta /00273201/			S	Oral	Unk		Not Reported
	Previscan /00789001/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12378659	EXPEDITED (15-DAY)			CA-PERNIX THERAPEUTICS-2016PT000017			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Interaction; Incoherent; Somnambulism; Speech Disorder	Silenor	S	Oral	3 Mg, At Bedtime	Pernix
	Cipralex /01588501/	S			Not Reported
	Warfarin	C		4 Mg, Unk	Not Reported
	Simvastatin	C		20 Mg, Unk	Not Reported
	Ursodiol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12378863	EXPEDITED (15-DAY)		HO	BE-FRI-1000083903			Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Insipidus; Hypophysitis; Langerhans' Cell Histiocytosis; Rash	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12378899	EXPEDITED (15-DAY)		OT	TR-FRI-1000084335		34 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arrhythmia; Chest Discomfort; Dizziness; Dizziness; Hypoaesthesia; Nightmare; Panic Attack	Escitalopram			S	Oral			Forest
	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Oral			Forest
	Depakin			C	Unknown			Not Reported
	Depakin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12378900	EXPEDITED (15-DAY)		DS	FR-FRI-1000084614		37 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12379012	EXPEDITED (15-DAY)		HO	FR-FRI-1000084611			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Malaise; Torsade De Pointes	Escitalopram			S	Oral			Forest
	Temesta (Lorazepam)			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Cordarone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	11626629	NON-EXPEDITED		OT	ADR-2015-01093		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Dislocation; Device Inversion; Device Kink; Pain; Therapeutic Response Decreased	Lioresal			S	Intrathecal			Not Reported
	Albuterol			S				Not Reported
	Lexapro			S				Not Reported
	Els Ii			S				Not Reported
	Vitamin D Nos			S				Not Reported
	Allegra			S				Not Reported
	Lisinopril			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12380682	NON-EXPEDITED		OT	ADR-2015-01116		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Muscle Spasticity; Pain; Therapeutic Response Decreased	Baclofen			S	Intrathecal			Not Reported
	Lexapro			S				Not Reported
	Ortho Evra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12380940	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016254939		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Disorientation; Fall; Gait Disturbance; Hyponatraemia; Mixed Dementia	Perindopril		S	Oral	1 Df, 1x/Day	Not Reported
	Alprazolam		S	Oral	1.5 Df, 1x/Day	Pfizer
	Lyrica		S	Oral	Unk	Pfizer
	Escitalopram		S	Oral	1 Df, 1x/Day	Not Reported
	Acupan		S	Parenteral	1 Df, 2x/Day	Not Reported
	Lamaline (France)		S	Oral	Unk	Not Reported
	Voltarene (Diclofenac Sodium)		S	Parenteral	1 Df, 2x/Day	Not Reported
	Nebivolol		S	Oral	1 Df, 1x/Day	Not Reported
	Lantus		C		Unk	Not Reported
	Metformin		C		Unk	Not Reported
	Pravastatin Sodium		C		Unk	Not Reported
	Kardegic		C		Unk	Not Reported
	Vesicare		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12381278	EXPEDITED (15-DAY)		HO	FR-FRI-1000084660		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Nausea; Vomiting	Escitalopram			S	Oral	5 Mg		Forest
	Lyrica			S	Oral	150 Mg		Not Reported
	Durogesic			S	Transdermal	25 Mcg/Hour (4.2 Mg/10.5 Cm2)		Not Reported
	Lantus			C	Subcutaneous	12 To 14 Iu		Not Reported
	Cardensiel			C	Oral			Not Reported
	Kardegic			C	Oral			Not Reported
	Lasilix			C	Oral	80 Mg		Not Reported
	Pravastatine			C	Oral			Not Reported
	Renitec [Enalapril Maleate]			C	Oral			Not Reported
	Lercan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12381475	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016254823		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Disease; Product Use In Unapproved Indication; Tremor	Sirolimus			S		0.5 Mg, Unk		Pfizer
	Prograf			S		1 Mg, 2x/Day (1 Mg In The Morning And 1 Mg Night)		Not Reported
	Prograf			S				Not Reported
	Cellcept			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12381854	EXPEDITED (15-DAY)		HO	FR-FRI-1000084618		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Hallucination; Hypertonia	Escitalopram			S	Oral			Forest
	Veratran			S	Oral			Not Reported
	Temerit			C				Not Reported
	Esomeprazole			C				Not Reported
	Pravastatine			C				Not Reported
	Cetornan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12381855	EXPEDITED (15-DAY)		HO	FR-FRI-1000084656		24 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Delirium; Disease Recurrence; Hallucination; Loss Of Consciousness; Malaise; Tonic Clonic Movements; Tremor	Escitalopram			S	Oral	1 Df		Forest
	Zyprexa			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Haldol			S	Oral	6 Df		Not Reported
	Clozapine			S	Oral	400 Mg		Not Reported

	Tercian	S	Oral	200 Mg		Not Reported
	Theralene 4%	S	Oral			Not Reported
	Noctamide	C		1 Df		Not Reported
	Parkinane	C		3 Df		Not Reported
	Hept A Myl	C	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12381856	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000084662		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Poisoning Deliberate; Toxicity To Various Agents	Escitalopram			S	Oral			Forest
	Risperdal			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Subutex			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported
	Valium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12382022	EXPEDITED (15-DAY)		LT	FR-FRI-1000084617		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock	Escitalopram			S	Oral	10 Mg		Forest
	Flecaine Lp			S	Oral	50 Mg		Not Reported
	Bisoprolol			S	Oral			Not Reported
	Inexium			C				Not Reported
	Valsartan			C				Not Reported
	Previscan (Fluindione)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12384789	DIRECT	Y	OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Decreased Appetite; Diarrhoea; Dyspnoea; Feeling Abnormal; Headache; Nausea; Restlessness; Suicidal Ideation; Tachyphrenia	Escitalopram 5mg			S	Oral	1/2 Tablet Daily Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2016	11788931	EXPEDITED (15-DAY)		HO, OT	KR-WATSON-2015-18655		56 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dystonia; Nausea; Tardive Dyskinesia; Vision Blurred	Amitriptyline			S	Unknown	10 Mg, Daily		Not Reported
	Amitriptyline			S		10 Mg, Daily		Not Reported
	Trazodone Hydrochloride (Watson Laboratories)			S	Unknown	25 Mg, Daily		Watson
	Escitalopram (Unknown)			S	Unknown	5 Mg, Daily		Not Reported
	Trihexyphenidyl Hydrochloride (Watson Laboratories)			S	Unknown	2 Mg, Daily		Watson
	Carbidopa/Levodopa (Aellc)			S	Unknown	Unk, 50/200mg/Day		Actavis Elizabeth
	Benztropine			S	Unknown	2 Mg, Daily		Not Reported
	Benztropine			S	Unknown	2 Mg, Daily		Not Reported
	Benztropine			S		Unk		Not Reported
	Baclofen			C	Unknown	20 Mg, Daily		Not Reported
	Flurazepam			C	Unknown	Unk, 15-30mg/Day		Not Reported
	Lorazepam			C	Unknown	2 Mg, Daily		Not Reported
	Clonazepam			C	Unknown	1.5 Mg, Daily		Not Reported
	Clonazepam			C		1.5 Mg, Daily		Not Reported
	Vitamin E /00110501/			C	Unknown	1000 Iu, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2016	12289866	NON-EXPEDITED			PHEH2016US009725		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Fatigue; Hypotension; Malaise; Product Use In Unapproved Indication; Vision Blurred	Entresto			S	Oral	24/26 Mg, Bid		Novartis
	Lexapro			S	Unknown			Not Reported
	Oxybutin			C	Unknown			Not Reported
	Coreg			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Senna			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Razadyne			C	Unknown			Not Reported
	Pradaxa//Dabigatran Etexilate			C	Unknown			Not Reported
	Tambocor			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Multi Vitamin			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2016	12384648	NON-EXPEDITED			US-PFIZER INC-2016242377		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Amitriptyline			S		Unk		Not Reported
	Ditropan			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

	Spectracef			S	Unk					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2016	12385568	EXPEDITED (15-DAY)		DS	IT-ASTRAZENECA-2016SE53153		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dysgraphia; Dyskinesia; Therapeutic Product Effect Decreased; Tremor	Quetiapine Fumarate			S	Oral			Zeneca
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2016	12386126	EXPEDITED (15-DAY)		DE	SK-ELI_LILLY_AND_COMPANY-SK201605005622		31 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Parent-Child Problem	Zypadhera			S	Intramuscular	405 Mg,Unknown		Eli Lilly And Co
	Zalasta			S	Unknown	10 Mg, Unknown		Not Reported
	Elicea /01588501/			S	Unknown	10 Mg, Unknown		Not Reported
	Stilnox			S	Unknown	10 Mg, Unknown		Not Reported
	Rivotril			S	Unknown	0.5 Mg, Unknown		Not Reported
	Alcohol			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2016	12386127	EXPEDITED (15-DAY)		HO, OT	FR-ELI_LILLY_AND_COMPANY-FR201605004133			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Delirium; Electroencephalogram Abnormal; Hallucination; Hyporeflexia; Loss Of Consciousness; Malaise; Seizure; Tonic Clonic Movements; Tremor	Zyprexa		S	Oral	Unk Unk, Unknown	Eli Lilly And Co
	Zyprexa		S	Oral	10 Mg, Qd	Eli Lilly And Co
	Seroplex		S	Oral	10 Mg, Each Morning	Not Reported
	Haldol /00027401/		S	Oral	5 Mg, Other	Not Reported
	Clozapine		S	Oral	100 Mg, Qid	Not Reported
	Clozapine		S	Oral	300 Mg, Qd	Not Reported
	Clozapine		S	Oral	400 Mg, Qd	Not Reported
	Clozapine		S	Oral	Unk, Unknown	Not Reported
	Theralene		S	Oral	20 Df, Prn	Not Reported
	Tercian /00759301/		S	Oral	50 Mg, Qid	Not Reported
	Noctamide		C	Oral	2 Mg, Unknown	Not Reported
	Parkinane		C	Oral	5 Mg, Tid	Not Reported
	Hept-A-Myl		C	Oral	184.8 Mg, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2016	12386952	EXPEDITED (15-DAY)		OT	DK-MYLANLABS-2016M1019746			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Caries; Dry Mouth; Periodontitis; Tooth Loss	Clomipramine Mylan `			S	Oral	Unk		Mylan
	Citalopram "Orion"			S	Oral	Unk		Mylan
	Mirtazapin Hexal			S	Oral	Unk		Mylan
	Lyrica			S	Oral	Unk		Mylan
	Stadaquel			S	Oral	Unk		Mylan
	Olanzapin Sandoz			S	Oral	Unk		Mylan
	Risperidon Krka			S	Oral	Unk		Mylan
	Zonoct			S	Oral	Unk		Mylan
	Escitalopram Glenmark			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	11658950	EXPEDITED (15-DAY)		HO	FR-ROCHE-1649277		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hemiparesis	Roactemra			S	Intravenous drip			Not Reported
	Metoject			S	Unknown			Not Reported
	Tercian			S	Unknown			Not Reported
	Seroplex			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Haldol			S	Unknown			Not Reported
	Speciafoldine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12373455	EXPEDITED (15-DAY)		OT	SE-JNJFOC-20160503099		37 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Breast Neoplasm	Xeplion			S	Intramuscular			Not Reported
	Xeplion			S	Intramuscular			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Singulair			S	Unknown			Not Reported
	Innovair			S	Respiratory (inhalation)			Not Reported
	Dymista			S	Nasal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12388056	EXPEDITED (15-DAY)		HO	TN-ACCORD-040741		33 YR	Male	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram			S		Received As Anti-Depressive Treatments		Accord

Clomipramine	S	Received As Anti-Depressive Treatments	Not Reported
Sertraline	S	Received As Anti-Depressive Treatments	Not Reported
Venlafaxine/Venlafaxine Hydrochloride	S	Received As Anti-Depressive Treatments	Not Reported
Paroxetine	S	Received As Anti-Depressive Treatments	Not Reported
Lithium	S	Received As Mood Stabilizers	Not Reported
Lamotrigine	S	Received As Mood Stabilizers	Not Reported
Olanzapine	S	Received As Mood Stabilizers	Not Reported
Risperidone	S	Received As Mood Stabilizers	Not Reported
Amisulpride	S	Received As Mood Stabilizers	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12389861	EXPEDITED (15-DAY)		LT	SI-FRI-1000084621			Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Cheyne-Stokes Respiration; Epilepsy; Hyponatraemia	Escitalopram			S	Oral	1 Df		Forest
	Insulin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12391121	NON-EXPEDITED			US-PFIZER INC-2016260848		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Toviaz			S		Unk		Pfizer

	Bextra	S	Unk	Pfizer
	Amoxicillin	S	Unk	Pfizer
	Boniva	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Fosamax	S	Unk	Not Reported
	Mobic	S	Unk	Not Reported
	Enablex	S	Unk	Not Reported
	Bactrim	S	Unk	Not Reported
	Oxybutynin	S	Unk	Not Reported
	Mirtazapine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2016	11683573	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20151016961		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hemiparesis	Haldol			S	Oral			Not Reported
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Tercian			S	Unknown			Not Reported
	Seroplex			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Speciafoldine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2016	11693564	EXPEDITED (15-DAY)		HO	IT-FRI-1000080518		37 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Ineffective	Escitalopram Oral Solution			S	Oral	15 Ml		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2016	12392086	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-10733			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram			S	Unknown			Aurobindo
	Hydrochlorothiazide			S	Unknown			Aurobindo
	Celebrex			S	Unknown			Not Reported
	Crestor			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Nexium /01479302/			S	Unknown			Not Reported
	Toprol Xl			S	Unknown			Not Reported
	Ventolin /00139501/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2016	12393278	NON-EXPEDITED			US-PFIZER INC-2016244212			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2016	12395442	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1020768			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Escitalopram			S				Not Reported
	Quetiapine			S				Not Reported
	Venlafaxine			S				Not Reported
	Valproic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2016	12398298	DIRECT	Y	LT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Blood Glucose Increased; Electrocardiogram Qt Prolonged; Lymphocyte Count Decreased; Protein Total Decreased	Risperidone, 0.5 Mg			S	Oral			Not Reported
	Escitalopram, 10 Mg, Teva			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2016	12073734	EXPEDITED (15-DAY)		CA	IT-TEVA-633360ACC			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Univentricular Heart	Carbolithium - Teva Italia S.R.L.			S	Transplacental	750 Milligram Daily; 750 Mg Daily		Barr
	Tasigna - Novartis Europharm Ltd			S	Transplacental	400 Milligram Daily; 400 Mg Daily		Not Reported
	Cipralex - H. Lundbeck A/S			S	Transplacental	1 Dosage Forms Daily; 1 Df Daily		Not Reported
	Tavor - Pfizer Italia S.R.L.			S	Transplacental	1 Dosage Forms Daily; 1 Df Daily		Not Reported
	Tirosint - Ibsa Farmaceutici Italia S.R.L.			S	Transplacental	150 Microgram Daily; 150 Ug Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2016	12329735	EXPEDITED (15-DAY)		HO	FR-FRI-1000084341		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholecystitis Infective; Colitis	Escitalopram			S	Oral	2 Df		Forest
	Monurol			S	Oral			Forest

	Xgeva	S	Subcutaneous	0.0013 Df	Not Reported
	Xgeva	S	Subcutaneous		Not Reported
	Fenofibrate	S	Oral	100 Mg	Not Reported
	Previscan (Fluindione)	S	Oral		Not Reported
	Cortancyl	S	Oral	1 Df	Not Reported
	Inexium	S	Oral	1 Df	Not Reported
	Amlor	S	Oral	1 Df	Not Reported
	Coversyl	S	Oral	1 Df	Not Reported
	Zopiclone	S	Oral	1 Df	Not Reported
	Levothyrox	S	Oral	62.5 Mcg	Not Reported
	Dafalgan	S	Oral		Not Reported
	Tramadol Base	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2016	12396441	EXPEDITED (15-DAY)		HO	FR-ROCHE-1761805		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus	Cellcept			S	Oral			Not Reported
	Laroxyl			S	Intravenous (not otherwise specified)			Not Reported
	Seroplex			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Tramadol			S	Intravenous (not otherwise specified)			Not Reported
	Novorapid			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2016	12398250	EXPEDITED (15-DAY)		OT	DE-FRI-1000084805		41 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dermatitis Allergic; Rash	Escitalopram	S	Oral			Forest
	Escitalopram	S	Oral			Forest
	Escitalopram	S	Oral			Not Reported
	Escitalopram	S	Oral			Not Reported
	Escitalopram	S	Oral			Not Reported
	Escitalopram	S	Oral			Not Reported
	Mirtazapin / Mirtazapine	C	Oral			Not Reported
	Mirtazapin / Mirtazapine	C	Oral			Not Reported
	Mirtazapin / Mirtazapine	C	Oral	3.75 Mg		Not Reported
	Mirtazapin / Mirtazapine	C	Oral			Not Reported
	Mirtazapin / Mirtazapine	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2016	12398251	EXPEDITED (15-DAY)		OT	DE-FRI-1000084806		29 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Rash	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Vitamine B1			C	Oral	600 Mg		Not Reported
	Tavor (Lorazepam)			C	Oral	4 Mg		Not Reported
	Tavor / Lorazepam			C	Oral	3 Mg		Not Reported
	Tavor / Lorazepam			C	Oral	2 Mg		Not Reported
	Tavor / Lorazepam			C	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2016	12398999	EXPEDITED (15-DAY)		HO	AU-FRI-1000084743		26 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Nausea;	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Unknown			Forest

Serotonin Syndrome; Tachycardia; Vomiting	Escitalopram		S	Unknown	Forest
	Escitalopram		S	Unknown	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2016	12316610	EXPEDITED (15-DAY)		OT	PHHY2014US122251		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decubitus Ulcer; Diastolic Dysfunction; Headache; Incision Site Pain; Mitral Valve Stenosis; Myalgia; Myoclonus; Pain; Peripheral Swelling; Procedural Pain; Supraventricular Tachycardia	Baclofen			S		100 Ug, Qd (2000 Ug/Ml)		Not Reported
	Diovan			S	Unknown			Not Reported
	Metformin Hydrochloride Sandoz			S	Unknown			Novartis
	Escitalopram Oxalate			S	Unknown			Not Reported
	Amlodipine Besylate			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Foltx			S	Unknown			Not Reported
	Norvasc /Grc/			S	Unknown			Not Reported
	Pioglitazone Hcl			S	Unknown			Not Reported
	Centrum Silver			S	Unknown			Not Reported
	Senna S			S	Unknown			Not Reported
	Crestor			S	Unknown			Not Reported
	Aggrenox			S	Unknown			Not Reported
	Folbee			S	Unknown			Not Reported
	Fish Oil			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Sensi Care Protective Barrier			S	Unknown			Not Reported
	Toprol			S	Unknown			Not Reported
	Baby Aspirin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2016	12404564	NON-EXPEDITED			US-PFIZER INC-2016275535		19 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Premarin			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Norco			S		Unk		Not Reported
	Klonopin			S		Unk		Not Reported
	Synthroid			S		Unk		Not Reported
	Pravastatin			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2016	12404766	EXPEDITED (15-DAY)		HO	FR-FRI-1000084897		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Balance Disorder; Sinus Bradycardia	Escitalopram			S	Oral	1 Dosage Form		Forest
	Reminyl			S	Oral	1 Dosage Forms		Not Reported
	Art			C	Unknown	50		Not Reported
	Piascledine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2016	12405522	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-E2B_00005450		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Insomnia; Mania; Sinusitis; Sleep Paralysis; Tachyphrenia	Escitalopram Tablets Usp 10mg			S	Oral			Not Reported
	Escitalopram Tablets Usp 10mg			S	Oral			Not Reported

	Escitalopram Tablets Usp 10mg	S	Oral	Not Reported
	Escitalopram Tablets Usp 10mg	S	Oral	Not Reported
	Virtprex	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2016	12091271	EXPEDITED (15-DAY)		CA	IT-FRI-1000082656			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Univentricular Heart	Escitalopram			S	Transplacental	1 Df		Forest
	Tasigna			S	Transplacental	400mg		Not Reported
	Carbolithium			S	Transplacental	750mg		Not Reported
	Tavor [Lorazepam]			S	Transplacental	1 Df		Not Reported
	Tirosint			S	Transplacental	150mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2016	12406009	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-06668		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Quetiapine			S				Aurobindo
	Escitalopram			S	Oral	Unk		Aurobindo
	Sertraline			S	Oral	Unk		Aurobindo
	Acetaminophen			S	Oral	Unk		Not Reported
	Buspirone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2016	12407235	EXPEDITED (15-DAY)		DE, HO, OT	FR-JNJFOC-20160522458		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Death; Intentional Overdose; Overdose	Tramadol Hydrochloride			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Xatral	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Baclofene	S	Oral	Not Reported
	Dafalgan	S	Oral	Not Reported
	Folic Acid	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2016	12408043	EXPEDITED (15-DAY)			DE-UCBSA-2016016292		33 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product	Vimpat			S	Oral	150 Mg, Total		Ucb
	Valproic Acid			S	Oral	600 Mg, Total		Not Reported
	Oxcarbazepine			S	Oral	1050mg, Total (600 Mg 1 Tablet + 300 Mg 1.5 Tablet)		Not Reported
	Escitalopram			S	Oral	20 Mg, Total		Not Reported
	Salt			S	Oral	4000 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2016	12408975	EXPEDITED (15-DAY)		DE, HO, OT	FR-MDT-ADR-2016-00955		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Coma; Drug Screen Positive; Toxicity To Various Agents	Paracetamol (Ngx)			S				Not Reported
	Seroplex (Escitaloprm Oxalate)			S				Not Reported
	Depamide (Valpromide)			S				Not Reported
	Dextropropoxyphene			S				Not Reported
	Baclofen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2016	12409335	EXPEDITED (15-DAY)		DE, HO, OT	FR-MDT-ADR-2016-00958		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest; Coma; Drug Screen Positive; Toxicity To Various Agents	Lopressor (Metoprolol Tartrate)	S	Not Reported
	Seroplex (Escitalopram Oxalate)	S	Not Reported
	Baclofen	S	Not Reported
	Coversyl (Peridopril Arginine)	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2016	12411161	DIRECT					60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disturbance In Attention; Irritability; Loss Of Dreaming; Rapid Eye Movements Sleep Abnormal; Sleep Disorder	Lexapro			S	Oral	One Pill Once, Daily Orally		Not Reported
	Concerta (Methylphenidate)			C				Not Reported
	Klonopin (Clonazepam)			C				Not Reported
	Alprazolam (Xanax)			C				Not Reported
	Crestor (Rosuvastatin)			C				Not Reported
	Zetia (Ezetimibe)			C				Not Reported
	Riboflavin (B2)			C				Not Reported
	Trintellix (Vortioxetine)			C				Not Reported
	Androgel (Testosterone)			C				Not Reported
	Synthroid (Levothyoxine)			C				Not Reported
	Vit D3			C				Not Reported
	Meclizine			C				Not Reported
	Afo Brace			C				Not Reported
	Flonase			C				Not Reported
	Ibuprofen			C				Not Reported
	Metamucil			C				Not Reported
	Glucosamine Condroitin			C				Not Reported
	Saline Nasal Rinse			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2016	12409756	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2016-06706		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Respiratory Arrest	Cyclobenzaprine			S	Unknown			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Hydrocodone Bitartrate And Acetaminophen			S	Oral			Aurobindo
	Aripiprazol			S	Oral			Not Reported

	Morphine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2016	12410069	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-06833		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Escitalopram			S		Unk		Aurobindo
	Lamotrigine			S	Oral			Aurobindo
	Lamotrigine			S		Unk		Aurobindo
	Bupropion			S	Oral			Not Reported
	Bupropion			S		Unk		Not Reported
	Clonazepam			S	Oral			Not Reported
	Clonazepam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2016	12410452	EXPEDITED (15-DAY)		OT	CA-SHIRE-CA201606199			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Vyvanse			S	Oral	Unk, Unknown		Shire
	Cipralex /01588501/			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2016	12412660	EXPEDITED (15-DAY)		HO, OT	FR-NOVOPROD-493493		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus	Novorapid			S	Unknown	Unk		Novo Nordisk
	Cellcept /01275102/			S	Oral	500 Mg, Qd		Not Reported
	Laroxyl			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Seroplex	S	Oral	1 Df, Qd		Not Reported
	Rivotril	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2016	12414150	NON-EXPEDITED			US-MDT-ADR-2016-00407		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Lioresal			S	Intrathecal	183.77mcg/Day		Not Reported
	Lioresal			S	Intrathecal	128.78mcg/Day		Not Reported
	Lexapro			S				Not Reported
	Keppra			S				Not Reported
	Plavix			S				Not Reported
	Simvastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12350156	EXPEDITED (15-DAY)		HO, OT	ES-ZYDUS-010988		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biliary Colic; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram			S	Unknown			Zydus Pharm
	Losartan			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Amiodarone			S	Unknown			Not Reported
	Metoclopramide			S	Unknown			Not Reported
	Betahistine			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Acenocoumarol			C	Unknown			Not Reported
	Iron			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12350178	EXPEDITED (15-DAY)		HO, OT	ES-ZYDUS-010987		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Syncope; Torsade De Pointes; Ventricular Tachycardia	Escitalopram			S	Unknown			Zydus Pharm
	Levofloxacin			S	Unknown			Zydus Pharm
	Solifenacin/Solifenacin Succinate			S	Unknown			Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)			Not Reported
	Sulpiride/Sulpiride Adamantanecarboxylat			S	Unknown			Not Reported
	Acenocoumarol			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Digoxin			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414243	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-06920		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414320	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2016-06832		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Respiratory Arrest	Alprazolam			S	Oral	Unk		Aurobindo
	Escitalopram			S	Oral	Unk		Aurobindo

	Gabapentin	S	Oral	Unk		Aurobindo
	Oxycodone	S	Oral	Unk		Aurobindo
	Trazodone	S	Oral	Unk		Aurobindo
	Oxymorphone	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414353	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-06939		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Bupropion			S	Oral			Not Reported
	Metoprolol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414414	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-07022		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Citalopram			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414416	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-07067		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram			S	Oral			Aurobindo
	Propranolol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414419	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-07012		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Cyclobenzaprine			S	Oral					Aurobindo
	Chlorpheniramine			S	Oral					Aurobindo
	Escitalopram			S	Oral					Aurobindo
	Meloxicam			S	Oral					Aurobindo
	Olanzapine			S	Oral					Aurobindo
	Sumatriptan			S	Oral					Aurobindo
	Trazodone			S	Oral					Aurobindo
	Topiramate			S	Oral					Aurobindo
	Venlafaxine			S	Oral					Aurobindo
	Buspirone			S	Oral					Not Reported
	Benzonatate			S	Oral					Not Reported
	Dextromethorphan			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414428	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-07092		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lisinopril			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Trazodone			S	Oral			Aurobindo
	Clonazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414440	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-07084		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Atenolol			S	Oral	Unk		Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Lamotrigine			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414482	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-07110		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metoprolol			S	Oral			Aurobindo
	Oxycodone			S	Oral			Aurobindo
	Zolpidem			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Diazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414562	EXPEDITED (15-DAY)		OT	KR-ACCORD-041012		56 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Escitalopram			S				Accord
	Clonazepam			S				Accord
	Benzatropine			S				Not Reported
	Trazodone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2016	12416678	EXPEDITED (15-DAY)		HO, OT	FR-JNJFOC-20140711999		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Frontotemporal Dementia; Tremor	Risperdal			S	Oral			Not Reported
	Seroplex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2016	12416788	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016276555		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gene Mutation; Product	Xanax			S				Pfizer

Use Issue; Serotonin Syndrome; Suicidal Behaviour	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2016	10364762	EXPEDITED (15-DAY)		OT	US-JNJFOC-20140800604			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Homicidal Ideation; Suicidal Ideation	Risperdal			S	Oral			Not Reported
	Invega			S	Oral			Not Reported
	Concerta			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Clonidine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2016	11129464	EXPEDITED (15-DAY)		DE	CH-FRI-1000076821			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exomphalos; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2016	11643342	EXPEDITED (15-DAY)			JP-ELI_LILLY_AND_COMPANY-JP201510005334		22 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour	Strattera			S	Oral	80 Mg, Qd		Eli Lilly And Co
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Sulpiride			C	Oral	50 Mg, Qd		Not Reported
	Merislon			C	Oral	18 Mg, Qd		Not Reported
	Seroquel			C	Oral	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2016	12421914	NON-EXPEDITED		OT	US-MDT-ADR-2016-00220		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Rigidity	Lioresal			S	Intrathecal			Not Reported
	Wellbutrin Xr			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Glucose			S	Oral	4 G Chew Tab; 8 Tablets By Mouth As Needed		Not Reported
	Hiprex			S	Oral	1 G Tab		Not Reported
	Zantac			S				Not Reported
	Cialis			S				Not Reported
	Baclofen			S	Intrathecal	500.5 Mcg/Day		Not Reported
	Baclofen			S	Intrathecal	549.5 Mcg/Day		Not Reported
	Lioresal			S	Oral	10 Mg Tab; 1-2 Tabs By Mouth Every 4 Hours As Needed		Not Reported
	Albuterol Hfa			S				Not Reported
	Eliquis			S				Not Reported
	Valium			S				Not Reported
	Glucophage			S	Oral			Not Reported
	Dilaudid			S				Not Reported
	Baclofen			S	Intrathecal	99.9 Mcg/Day		Not Reported
	Baclofen			S	Intrathecal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2016	11697429	EXPEDITED (15-DAY)		HO	FR-FRI-1000080654		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hemiparesis	Escitalopram			S	Unknown			Forest
	Roactemra			S	Intravenous (not otherwise specified)	16 Mg		Not Reported

	Metoject	S	Subcutaneous	10 Mg	Not Reported
	Tercian	S	Unknown		Not Reported
	Alprazolam	S	Unknown		Not Reported
	Haldol	S	Unknown		Not Reported
	Gutron	C	Unknown		Not Reported
	Speciafoldine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2016	12422201	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.-2016IT06035			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Sertraline			S	Unknown	50 Mg, Qd		Invagen
	Sertraline			S	Unknown	200 Mg, Qd		Invagen
	Sertraline			S	Unknown	50 Mg, Qd		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Quetiapine			S	Oral	Unk		Not Reported
	Venlafaxine			S	Unknown	Unk		Cipla
	Valproic Acid			S	Unknown	Unk		Cipla
	Mirtazapine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2016	12424923	EXPEDITED (15-DAY)		OT	IT-FRI-1000084954		21 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S	Oral	Overdose: 14 Dosage Forms		Forest
	Zoloft "50mg Compresse Rivestite Con Film"/Sertraline			C	Oral			Not Reported
	Abilify "5mg Compresse"/ Aripiprazole			C	Oral			Not Reported
	Abilify "5mg Compresse"/ Aripiprazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2016	12425677	EXPEDITED (15-DAY)		DS	NL-FRI-1000085034			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Product Use In Unapproved Indication; Therapeutic Response Unexpected; Tooth Disorder	Citalopram			S	Oral	1 Times Per Day 1 Piece		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Omeprazol Rp Capsule Msr 10mg - Non-Current Drug			C	Oral	Extra Info: Only When I Am Taking For Example Antibiotics		Not Reported
	Paracetamol/Ascorbinezuur Poeder V Drank 500/50mg			C	Oral	Extra Info: Now And Then For (Head)Ache		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2016	12426105	EXPEDITED (15-DAY)		DE, HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-2016VAL001623		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Coma; Toxicity To Various Agents	Lopressor			S		Unk		Validus
	Baclofen			S		Unk		Not Reported
	Seroplex			S		Unk		Not Reported
	Coversyl /00790702/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2016	12427809	DIRECT		DS, OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Depression; Fatigue; Infection; Loss Of Consciousness; Product Packaging Quantity Issue; Suicidal Ideation; Tremor;	Escitalopram 10 Mg Tablet, 10 Mg Lupin Pharmaceuticals			S				Lupin
	Lexapro			C				Not Reported
	Clonazepam			C				Not Reported
	Estrace			C				Not Reported
	Losartan			C				Not Reported

Viral Infection	Nexium	S				Not Reported
	Singular	C				Not Reported
	Myrbetriq Er	C				Not Reported
	Fosamax	C				Not Reported
	Flonase	C				Not Reported
	Xopenex Prn	C				Not Reported
	Hydrocodone	C				Not Reported
	Alleve	C				Not Reported
	Colace	C				Not Reported
	Centrum Silver Womens 50 Plus (Pfizer)	C				Not Reported
	Tylenol Prn	C				Not Reported
	Magnesium Prn	C	Oral	90 Tablets Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2016	12428606	DIRECT	Y				38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Headache	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2016	12429052	EXPEDITED (15-DAY)		HO	FR-FRI-1000085035		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spontaneous Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S	Oral	160 Mg		Not Reported
	Calciparine			S	Subcutaneous			Not Reported
	Inexium			C				Not Reported
	Nefopam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2016	12429706	NON-EXPEDITED			US-TARO-2016TAR00178		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Nausea	Escitalopram Oral Solution	S	Oral	1 Mg, 1x/Day		Taro
	Escitalopram Oral Solution	S	Oral	2.5 Mg, 1x/Day		Taro
	Probiotic	C				Not Reported
	Vitamin D Nos	C				Not Reported
	Unspecified Digestive Enzyme	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2016	12433879	EXPEDITED (15-DAY)		LT	FR-B. BRAUN MEDICAL INC.-1053209		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Metronidazole			S	Intravenous (not otherwise specified)			B Braun
	Rifadine (Rifampicin)			S	Intravenous (not otherwise specified)			Not Reported
	Simvastatin			C				Not Reported
	Cubicin			S	Intravenous (not otherwise specified)			Not Reported
	Azactam			S	Intravenous (not otherwise specified)			Not Reported
	Pravastatin			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Allopurinol			S	Oral			Not Reported
	Calciparine (Heparin Calcium)			S	Subcutaneous			Not Reported
	Nebivolol			S	Oral			Not Reported
	Irbesartan And Hydrochlorothiazide			S	Oral			Not Reported
	Seresta (Oxazepam)			C				Not Reported
	Inexium (Esomeprazole)			C				Not Reported
	Voltarene (Diclofenac Sodium)			C				Not Reported
	Rimactan (Rifampicin)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2016	12240158	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2016187117		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Blood Alcohol Increased; Fatigue; Loss Of Consciousness; Muscle Twitching; Neuroleptic Malignant Syndrome; Overdose; Pain; Seizure	Geodon			S	Oral	20 Mg At Dinner		Pfizer
	Geodon			S	Oral	60 Mg Per Day (20 Mg In The Morning And 40 Mg At Dinner)		Pfizer
	Geodon			S	Oral	420 Mg, Single		Pfizer
	Alprazolam			S	Oral	0.5 Mg Tablets, 3 Times Per Day, As Needed		Pfizer
	Zolpidem Tartrate			S	Oral	10 Mg Tablets Per Day		Not Reported
	Lexapro			S	Oral	20 Mg Tablet, Once Per Day		Not Reported
	Lexapro			S	Oral	140 Mg, Single		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	150 Mg Tablets Once Per Day In The Morning		Not Reported
	Lamotrigine			S	Oral	1050 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2016	12437441	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-07094		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Duloxetine			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Baclofen			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2016	12439931	EXPEDITED (15-DAY)		HO	CA-IPCA LABORATORIES LIMITED-IPC201605-000479		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Hydrochlorothiazide	S		Ipca
	Escitalopram	S		Not Reported
	Gliclazide	C		Not Reported
	Insulin	C		Not Reported
	L-Thyroxine	C		Not Reported
	Telmisartan	C		Not Reported
	Trazadone	C		Not Reported
	Metformin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2016	12442878	DIRECT		DS, HO, LT, OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree	Bupropn Hcl			S	Oral	1 Tablet(S) In The Morning Taken By Mouth		Not Reported
	Escitalopram			S	Oral	1 Tablet(S) In The Morning Taken By Mouth		Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Epsom			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2016	12227568	EXPEDITED (15-DAY)		HO	IT-FRI-1000083529		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Intentional Overdose; Sopor	Escitalopram			S	Unknown	Overdose: 100 Mg		Forest
	Flurazepam Monohydrochloride			S	Oral	Overdose: 150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2016	12302245	EXPEDITED (15-DAY)		HO	JP-FRI-1000084103		33 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic	Lexapro			S	Oral	15 Mg		Forest

Symptoms	Lexapro	S	Oral	Forest
	Cyanamide	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2016	12356433	EXPEDITED (15-DAY)		OT	JP-FRI-1000084393		42 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Lexapro			S	Oral	5 Mg		Forest
	Paxil			C	Oral			Not Reported
	Lexotan			C	Oral			Not Reported
	Benzalin (Nitrazepam)			C	Oral			Not Reported
	Keishikaryukotsuboreito			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2016	12441313	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-043165			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dissociation; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Daklinza			S	Oral	60 Mg, Qd		Bristol Myers Squibb
	Sovaldi			S	Oral	400 Mg, Qd		Not Reported
	Seroplex			S	Oral	Unk, Qd		Not Reported
	Xanax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2016	12443682	NON-EXPEDITED			US-PFIZER INC-2016274697			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Skelaxin			S				Pfizer
	Pristiq			S				Pfizer
	Lexapro			S				Not Reported
	Ambien			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2016	12445076	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2016-012785		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Weight Increased	Xenazine			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12074823	EXPEDITED (15-DAY)		HO, OT	AT-ELI_LILLY_AND_COMPANY-AT201602000133		47 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hepatic Enzyme Increased; Hepatic Steato-Fibrosis; Hyperprolactinaemia; Leiomyoma; Renal Cyst	Cymbalta			S	Oral	60 Mg, Unknown		Eli Lilly And Co
	Cymbalta			S				Eli Lilly And Co
	Risperdal			S	Unknown	1 Mg, Unk		Not Reported
	Seroquel			S	Unknown	50 Mg, Qd		Not Reported
	Seroquel			S		Unk		Not Reported
	Seroquel			S	Oral	100 Mg, Qd		Not Reported
	Seroquel			S	Unknown	75 Mg, Qd		Not Reported
	Seroquel			S	Unknown	50 Mg, Qd		Not Reported
	Seroquel			S	Unknown	25 Mg, Qd		Not Reported
	Trittico			S	Unknown	150 Mg, Qd		Not Reported
	Trittico			S	Unknown	150 Mg, Qd		Not Reported
	Trittico			S	Oral	300 Mg, Qd		Not Reported
	Trittico			S	Unknown	300 Mg, Qd		Not Reported
	Trittico			S	Unknown	250 Mg, Qd		Not Reported
	Trittico			S	Unknown	200 Mg, Qd		Not Reported
	Trittico			S	Unknown	150 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Unknown	20 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Unknown	30 Mg, Unknown		Not Reported

Gewacalm	S	Unknown	30 Mg, Qd		Not Reported
Gewacalm	S	Unknown	20 Mg, Qd		Not Reported
Gewacalm	S	Unknown	10 Mg, Qd		Not Reported
Gewacalm	S	Unknown	5 Mg, Qd		Not Reported
Rivotril	C	Unknown	2 Mg, Qd		Not Reported
Rivotril	C	Unknown	2.5 Mg, Qd		Not Reported
Rivotril	C	Unknown	1.5 Mg, Qd		Not Reported
Rivotril	C	Unknown	1.25 Mg, Qd		Not Reported
Rivotril	C	Unknown	1 Mg, Qd		Not Reported
Rivotril	C	Unknown	0.5 Mg, Qd		Not Reported
Molaxole	C	Unknown	Unk, Unknown		Not Reported
Oleovit D3	C	Unknown	30 Gtt, Weekly (1/W)		Not Reported
Cevitol /00008001/	C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2016	12450010	EXPEDITED (15-DAY)		DE, HO, OT	US-STRIDES ARCOLAB LIMITED-2016SP004432			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents	Meloxicam			S	Oral	Unk		Strides
	Meloxicam			S	Oral	Unk		Strides
	Lamotrigine			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2016	12453096	EXPEDITED (15-DAY)		HO	FR-FRI-1000085203		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haematemesis	Escitalopram	S	Oral	10 Mg		Forest
	Previscan (Fluindione)	S	Oral			Not Reported
	Ebixa Film-Coated Tablets	C				Not Reported
	Zymad	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2016	12455659	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Transcription Medication Error; Wrong Product Administered	Lexapro			S	Oral			Not Reported
	Enalapril Maleate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2016	12455523	NON-EXPEDITED		HO	FR-EISAI MEDICAL RESEARCH-EC-2016-017555		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Aricept			S	Oral	Unknown		Not Reported
	Desloratadine			S	Oral	5 Mg		Not Reported
	Pantoprazole			S	Oral	20 Mg		Not Reported
	Escitalopram			S	Oral	10 Mg		Not Reported
	Furosemide			S	Oral	40 Mg		Not Reported
	Alteis			S	Oral	40 Mg		Not Reported
	Aspegic [Acetylsalicylate Lysine]			C		Unknown		Not Reported
	Nebivolol			C		Unknown		Not Reported
	Levothyrox			C		Unknown		Not Reported
	Alepsal (Caffeine\Phenobarbital)			C		Unknown		Not Reported
	Nerisone			C		Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2016	12456239	EXPEDITED (15-DAY)		HO	FR-FRI-1000085209		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram			S	Oral			Forest
	Zeclar			S	Oral	500 Mg		Not Reported
	Josacine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Mucothiol			S	Oral			Not Reported
	Polery (Aconite Tincture\Belladonna Leaf\Codeine\Ethylmorphine Hydrochloride\Polygala Tenuifolia Root\Sodium Benzoate\Sodium Bromide)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2016	12279906	EXPEDITED (15-DAY)		HO, OT	US-TEVA-652224USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia; Decreased Appetite; Haemorrhage; Hallucination; Intentional Self-Injury; Loss Of Consciousness; Malaise; Nausea; Treatment Noncompliance; Urinary Incontinence	Clonazepam			S	Unknown			Teva
	Escitalopram			S	Unknown			Ivax
	Tramadol			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12313299	NON-EXPEDITED			US-PFIZER INC-2016219314		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Chantix	S	Unk		Pfizer
	Colestid	S	Unk		Pfizer
	Codeine	S	Unk		Not Reported
	Hydrocodone	S	Unk		Not Reported
	Citalopram	S	Unk		Not Reported
	Zocor	S	Unk		Not Reported
	Lexapro	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12458987	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/16/0080267		53 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejaculation Disorder; Erectile Dysfunction; Fatigue; Urinary Retention; Urinary Straining	Venlafaxine			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S				Not Reported
	Pantoprazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460139	NON-EXPEDITED			US-PFIZER INC-2016291495			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Crying; Drug Ineffective	Zoloft			S	Unk			Pfizer
	Lexapro			S	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460206	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-00		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Drug Interaction; Mental Status Changes;	Doxycycline			S	Unknown			Hikma

Nephrogenic Diabetes Insipidus; Renal Impairment; Toxicity To Various Agents; Tremor	Lithium		S	Unknown	Roxane
	Aripiprazole		S	Unknown	Not Reported
	Escitalopram		S	Unknown	Not Reported
	Klonopin		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12464119	DIRECT		HO, LT, OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Hallucination, Auditory; Product Substitution Issue; Suicidal Behaviour	Escitalopram			S	Oral	In The Morning Taken By Mouth		Not Reported
	Lamotrigine			C				Not Reported
	Norethindrone			C				Not Reported
	Nifedipine			C				Not Reported
	Aripiprazole			C				Not Reported
	Levothyroxine			C				Not Reported
	Gabapentin			C				Not Reported
	Nortriptyline			C				Not Reported
	Trazodone			C				Not Reported
	Vistaril			C				Not Reported
	Proair			C				Not Reported
	Hyoscyamine			C				Not Reported
	B12			C				Not Reported
	Ferrix			C				Not Reported
	Vitamin With Iron			C				Not Reported
	Calcium Citrate With Zinc And Magnesium			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2016	12463468	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/16/0080426		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Long Qt Syndrome	Levofloxacin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2016	12463701	NON-EXPEDITED			US-PFIZER INC-2016295155			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Malaise; Nausea; Tremor	Zoloft			S		Unk, Less Than Four Doses		Pfizer
	Escitalopram			S		Unk, Less Than Four Doses		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2016	12463809	NON-EXPEDITED			US-PFIZER INC-2016289950			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2016	12464719	NON-EXPEDITED			US-TORRENT-00001195			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram Tablets, Usp			S				Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2016	12465512	EXPEDITED (15-DAY)		HO	FR-SA-2016SA108290		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Hypercapnia; Respiratory Acidosis; Somnolence	Stilnox			S	Oral			Not Reported
	Skenan			S	Oral	70 Mg In Morning And 50 Mg In Evening		Not Reported
	Actiskenan			S	Oral			Not Reported

	Domperidone Arrow	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Lysanxia	S	Oral	Not Reported
	Clamoxyl (Amoxicillin)	C	Unknown	Not Reported
	Novorapid	C	Unknown	Not Reported
	Lantus	C	Unknown	Not Reported
	Lovenox	C	Unknown	Not Reported
	Macrogol	C	Unknown	Not Reported
	Eupantol	C	Unknown	Not Reported
	Adrovance	C	Unknown	Not Reported
	Amoxicillin	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2016	12465904	EXPEDITED (15-DAY)		OT	IT-ABBVIE-16P-083-1650601-00		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor; Toxicity To Various Agents	Depakin			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2016	12009330	EXPEDITED (15-DAY)		OT	IT-ACCORD-037384		51 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus	Escitalopram			S		Dose Reduced To 10mg		Accord
	Eutirox			C	Oral			Not Reported
	Cardioaspirin			C	Oral			Not Reported
	Tavor [Lorazepam]			C				Not Reported
	Surmontil			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2016	12456802	EXPEDITED (15-DAY)		HO	FR-FRI-1000085204		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	1 Df		Forest
	Prozac			C	Unknown			Not Reported
	Imovane			C	Unknown			Not Reported
	Athymil			C	Unknown			Not Reported
	Euthyral			C	Unknown	0.75 Df		Not Reported
	Mianserine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2016	12468676	EXPEDITED (15-DAY)		HO	FR-FRI-1000085290			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Heart Rate Disorder	Escitalopram			S	Transplacental	10 Mg		Forest
	Leponex			S	Transplacental	250 Mg		Not Reported
	Seresta			S	Transplacental	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2016	12468756	EXPEDITED (15-DAY)		HO, LT	FR-DSJP-DSE-2016-119929			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemic Stroke	Alteis 20 Mg			S	Oral	20 Mg, Qd		Daiichi
	Raloxifene Biogaran			S	Oral	60 Mg, Qd		Not Reported
	Candesartan Biogaran (Non-Az Product)			S	Oral	4 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Not Reported
	Bromazepam Biogaran			S	Oral	6 Mg, Unk		Not Reported
	Lamaline /01708901/			S	Oral	3 Df, Qd As Needed		Not Reported

Sulfarlem S 25 Mg	S	Oral	25 Mg, Unk		Not Reported
Omeprazole Biogaran	S	Oral	20 Mg, Unk		Not Reported
Urbanyl	S	Oral	10 Mg, Unk		Not Reported
Nebivolol Biogaran	C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2016	12468860	EXPEDITED (15-DAY)		DS	NL-MYLANLABS-2016M1024023			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Therapeutic Response Unexpected; Tooth Disorder	Escitalopram Mylan 10 Mg Filmomhulde Tabletten			S	Oral	10 Mg, Qd (1 Keer Per Dag 1 Stuk(S))		Mylan
	Cipramil /00582602/			S	Oral	Unk (1 Keer Per Dag 1 Stuk(S))		Mylan
	Resure			C		Unk		Mylan
	Omeprazol /00661201/			C	Oral	Extra Info: Alleen Als Ik Bv Antibiotica Krijg		Mylan
	Ascorbinezuur			C	Oral	Extra Info: Af En Toe Bij (Hoofd)Pijn		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2016	12471723	DIRECT	Y	HO			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Condition Aggravated; Drug Interaction; Dyspnoea; Electrocardiogram Qt Prolonged	Flecainidide			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Coreg			C				Not Reported
	Zyrtec			C				Not Reported
	Coenzyme Q10			C				Not Reported
	Toviaz			C				Not Reported
	Tambicor			C				Not Reported
	Folvite			C				Not Reported
	Novolog			C				Not Reported
	Lantus			C				Not Reported
	Calciu			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12077720	EXPEDITED (15-DAY)		OT	PHHY2016IT016600		42 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Stenosis; Concomitant Disease Aggravated; Maternal Exposure During Pregnancy; Thrombophlebitis Superficial	Tasigna			S	Oral	400 Mg, Qd		Novartis
	Cipralex//Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Carbolithium			S	Oral	750 Mg, Qd		Not Reported
	Tavor (Lorazepam)			S	Oral	1 Df, Qd		Not Reported
	Tirosint			S	Oral	150 Ug, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12077731	EXPEDITED (15-DAY)		OT	PHHY2016IT016208			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aorta Hypoplasia; Foetal Exposure During Pregnancy; Foetal Malformation; Mitral Valve Atresia; Univentricular Heart	Tasigna			S	Transplacental	Mother Dose:400 Mg, Qd		Novartis
	Cipralex//Escitalopram			S	Transplacental	Mother Dose:1 Df, Qd (One Posologic Unit) For 11 Years		Not Reported
	Carbolithium			S	Transplacental	Mother Dose:750 Mg, Qd (For 11 Years)		Not Reported
	Tavor//Lorazepam			S	Transplacental	Mother Dose:1 Df, Qd (One Posologic Unit) (For 11 Years)		Not Reported
	Tirosint			S	Transplacental	Mother Dose:150 Ug, Qd (For 17 Years)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12470397	EXPEDITED (15-DAY)		DE, HO	US-STRIDES ARCOLAB LIMITED-2016SP006874			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Meloxicam	S	Oral	Unk		Strides
	Buspirone Hydrochloride	S		Unk		Strides
	Benzonatate	S	Oral	Unk		Unknown
	Escitalopram	S	Oral	Unk		Not Reported
	Topiramate	S	Oral	Unk		Not Reported
	Sumatriptan	S	Oral	Unk		Not Reported
	Chlorphenamine	S	Oral	Unk		Not Reported
	Dextromethorphan	S	Oral	Unk		Not Reported
	Cyclobenzaprine	S	Oral	Unk		Not Reported
	Olanzapine	S	Oral	Unk		Not Reported
	Trazodone	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12472861	NON-EXPEDITED			US-JAZZ-2015-US-019723			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Loss Of Personal Independence In Daily Activities	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported
	Adderall			C		Unk		Not Reported
	Amoxicillin Trihydrate			C		Unk		Not Reported
	Amphetamine Salts			C		Unk		Not Reported
	Flonase Allergy Rlf			C		Unk		Not Reported
	Imitrex			C		Unk		Not Reported
	Lamictal			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Mucinex Allergy			C		Unk		Not Reported
	Naltrexone Hcl			C		Unk		Not Reported
	Plaquenil			C		Unk		Not Reported

Proair Hfa	C	Unk	Not Reported
Qvar	C	Unk	Not Reported
Temazepam	C	Unk	Not Reported
Trazodone	C	Unk	Not Reported
Viibryd	C	Unk	Not Reported
Xanax	C	Unk	Not Reported
Xyzal	C	Unk	Not Reported
Zofran Odt	C	Unk	Not Reported
Dexedrine Spansule	C	Unk	Not Reported
Horizant Er	C	Unk	Not Reported
Edluar	C	Unk	Not Reported
Advil	C	Unk	Not Reported
Aleve	C	Unk	Not Reported
Flonase	C	Unk	Not Reported
Folic Acid	C	Unk	Not Reported
Vitamin B12	C	Unk	Not Reported
Vitamin D Nos	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12473898	EXPEDITED (15-DAY)		HO	FR-009507513-1606FRA007732		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Olmesartan Medoxomil			S	Oral	40 Mg, Qd		Not Reported
	Aricept			S	Oral	Unk		Not Reported
	Nebivolol Hydrochloride			C				Not Reported
	Levothyrox			C				Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported
	Alepsal (Caffeine (+) Phenobarbital)			C				Not Reported
	Nerisone			C		Unk		Not Reported
	Desloratadine			S	Oral	5 Mg, Qd		Not Reported

Pantoprazole	S	Oral	20 Mg, Qd		Not Reported
Escitalopram	S	Oral	10 Mg, Qd		Not Reported
Furosemide	S	Oral	40 Mg, Qd		Merck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2016	12256544	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2016203813		48 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Blood Glucose Increased; Blood Triglycerides Increased; Insomnia; Low Density Lipoprotein Increased; Mania; Somnolence; Suicidal Ideation	Effexor			S	Oral	37.5 Mg, 1x/Day		Pfizer
	Effexor			S	Oral	75 Mg, 1x/Day		Pfizer
	Effexor			S	Oral	112.5 Mg, 1x/Day		Pfizer
	Effexor			S	Oral	150 Mg, 1x/Day		Pfizer
	Effexor			S	Oral	112.5 Mg, 2x/Day		Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Seniran			C	Oral	2 Mg, 3x/Day		Not Reported
	Vegetamin B			C	Oral	1 Df, 1x/Day		Not Reported
	Sorentmin (Brotizolam)			C	Oral	0.25 Mg, 1x/Day		Not Reported
	Flunitrazepam			C	Oral	4 Mg, 1x/Day		Not Reported
	Quetiapine			C	Oral	100 Mg, 1x/Day		Not Reported
	Cystanin			C	Oral	100 Mg, 3x/Day		Not Reported
	Alosenn /00476901/			C	Oral	0.5 G, 3x/Day		Not Reported
	Pantosin			C	Oral	1 G, 3x/Day		Not Reported
	Vemas			C	Oral	2 Df, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2016	12399251	EXPEDITED (15-DAY)		HO	CN-FRI-1000084845		16 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Drug-Induced Liver Injury;	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral			Forest

Product Use In
Unapproved Indication;
Product Use Issue

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2016	12465237	EXPEDITED (15-DAY)		HO	FR-DSJP-DSE-2016-119943			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Alteis 40 Mg			S	Oral	40 Mg, Qd		Daiichi
	Aricept			S	Oral	Unk		Not Reported
	Desloratadine			S	Oral	5 Mg, Qd		Not Reported
	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Furosemide			S	Oral	40 Mg, Qd		Not Reported
	Nebivolol Hydrochloride			C	Oral	Unk		Not Reported
	Levothyrox			C	Oral	Unk		Not Reported
	Aspegic /00002703/			C		Unk		Not Reported
	Alepsal /01606601/			C	Oral	Unk		Not Reported
	Nerisone			C	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2016	12474608	EXPEDITED (15-DAY)		OT	KR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-048797		40 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Facial Paralysis; Palpitations	Abilify			S	Unknown	2 Mg, Unk		Bristol Myers Squibb
	Alprazolam			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Valproic Acid			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2016	12474715	EXPEDITED (15-DAY)		LT	FR-ASTRAZENECA-2016SE65737		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Diarrhoea; Inappropriate Antidiuretic Hormone Secretion; Urticaria	Inexium			S	Oral	40.0mg Unknown		Astrazeneca
	Seroplex			S	Oral			Not Reported
	Xarelto			C		20.0mg Unknown		Not Reported
	Co-Kenzen			C				Not Reported
	Tahor			C		40.0mg Unknown		Not Reported
	Diamicron			C				Not Reported
	Stagid			C				Not Reported
	Detensiel			C				Not Reported
	Lyrica			C				Not Reported
	Victoza			C				Not Reported
	Allopurinol			C				Not Reported
	Doliprane			C				Not Reported
	Ixprim			C				Not Reported
	Xatral			C				Not Reported
	Seresta			C				Not Reported
	Betagan			C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2016	12475170	NON-EXPEDITED			US-PFIZER INC-2016285810		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Xanax			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Phenergan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2016	12477134	EXPEDITED (15-DAY)		OT	CN-FRI-1000085286			Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Induced	Escitalopram		S	Unknown	Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2016	12477890	EXPEDITED (15-DAY)		LT	FR-LUNDBECK-DKLU2015242		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemic Stroke	Urbanyl			S	Oral			Lundbeck
	Escitalopram			S	Oral			Not Reported
	Candesartan			S	Oral			Not Reported
	Alteis			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			S	Oral	Prn		Not Reported
	Raloxifene			S	Oral			Not Reported
	Sulfarlem			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Nebivolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2016	12436159	EXPEDITED (15-DAY)		DS, OT	IT-TEVA-664792ACC		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dysgraphia; Dyskinesia; Product Use In Unapproved Indication; Therapeutic Product Effect Decreased; Tremor	Quetiapine Fumarate			S	Oral			Teva
	Quetiapine Fumarate			S				Teva
	Sertraline Hydrochloride			S		50 Milligram Daily;		Not Reported
	Sertraline Hydrochloride			S		200 Milligram Daily;		Not Reported
	Mirtazapine			S				Teva
	Mirtazapine			S				Teva
	Venlafaxine			S				Teva
	Venlafaxine			S				Teva
	Valproic Acid			S				Not Reported
	Valproic Acid			S				Not Reported

	Escitalopram	S		Ivax
	Escitalopram	S		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2016	12479877	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.-2016IT06662			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor; Toxicity To Various Agents	Escitalopram			S	Oral	27 Df Total		Invagen
	Depakin "200 Mg Compresse Gastroresistenti"40 Compresse - (Sanofi S.P)			S	Oral	20 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2016	12480322	EXPEDITED (15-DAY)		OT	IT-FRI-1000085373		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor; Toxicity To Various Agents	Escitalopram			S	Oral	Overdose: 27 Dosage Forms.		Forest
	Depakin "200mg Compresse Gastroresistenti"			S	Oral	20 Dosage Forms.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	11928376	EXPEDITED (15-DAY)		HO, LT, OT	JP-FRI-1000082094		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Haemolytic Anaemia	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral			Forest
	Wypax			C	Oral	3 Mg		Not Reported
	Aricept			C	Oral			Not Reported
	Norvasc			C	Oral	10 Mg		Not Reported
	Selectol			C	Oral	100 Mg		Not Reported
	Diovan			C	Oral	20 Mg		Not Reported

	Sermion		C	Oral	15 Mg	Not Reported
	Nexium		C	Oral	Unknown	Not Reported
	Desyrel		C	Oral	25 Mg	Not Reported
	Lexotan		C	Oral	1 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12392962	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP008468		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Fatigue; Product Substitution Issue	Apo-Escitalopram			S	Oral	10 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12434723	EXPEDITED (15-DAY)		HO	US-FRI-1000085083		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Intentional Overdose; Loss Of Consciousness; Neuroleptic Malignant Syndrome	Escitalopram			S	Oral	20mg		Forest
	Escitalopram			S				Forest
	Geodon			S	Oral	20mg		Not Reported
	Geodon			S	Oral	20mg Qam And 40mg Q Dinner		Not Reported
	Geodon			S		420 Mg		Not Reported
	Lamotrigine			S	Oral	150mg		Not Reported
	Lamotrigine			S		1050 Mg		Not Reported
	Alprazolam			S	Oral	1.5mg		Not Reported
	Zolpidem			S	Oral	10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12483269	EXPEDITED (15-DAY)		DE, HO	US-STRIDES ARCOLAB LIMITED-2016SP006890			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Buspirone Hydrochloride			S	Oral	Unk		Strides
	Paracetamol			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Sertraline			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12483609	EXPEDITED (15-DAY)		OT	IT-ACCORD-041588		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor; Toxicity To Various Agents	Depakin			S	Oral	Strength: 200 Mg		Not Reported
	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12484033	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2016-02747		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Drug Interaction; Galactorrhoea; Libido Increased; Vision Blurred	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported
	Venlafaxine			S	Unknown	75 Mg		Not Reported
	Venlafaxine			S	Unknown	37.5 Mg		Not Reported
	Omeprazole			S	Unknown			Not Reported
	Paroxetine			C	Unknown			Not Reported
	Paroxetine			C				Not Reported
	Buspirone			C	Unknown			Not Reported
	Buspirone			C				Not Reported
	Sertraline			C	Unknown			Not Reported
	Sertraline			C	Unknown	Increased To Maximum Dose		Not Reported

Clonazepam	C	Unknown		Not Reported
Fexofenadine	C	Unknown		Not Reported
Pseudoephedrine Hydrochloride	C	Unknown		Not Reported
Fluticasone	C	Unknown		Not Reported
Albuterol	C	Unknown		Not Reported
Budesonide/Formoterol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12484410	EXPEDITED (15-DAY)		OT	IT-TEVA-668084ACC		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor; Toxicity To Various Agents	Escitalopram			S	Oral	27 Df Total		Ivax
	Depakin - 200 Mg Compresse Gastroresistenti - Sanofi S.P.A.			S	Oral	20 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12484788	NON-EXPEDITED			US-ACTAVIS-2015-15463			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Drug Ineffective	Bupropion Hydrochloride Xl (Actavis Laboratories Fl)			S	Oral	Unknown		Actavis
	Escitalopram			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12484794	EXPEDITED (15-DAY)		DE	US-NOVOPROD-496470			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Seizure	Levemir			S	Subcutaneous			Novo Nordisk
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12485321	EXPEDITED (15-DAY)		HO	GB-FRI-1000084664			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 Mg Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12486178	EXPEDITED (15-DAY)		HO	JP-FRI-1000082013		83 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Polydipsia	Lexapro			S	Oral	10 Mg		Forest
	Bisoprolol			C	Oral	2.5 Mg		Not Reported
	Inhibace			C	Oral	0.25 Mg		Not Reported
	Livalo			C	Oral	2 Mg		Not Reported
	Uritos			C	Oral	0.2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12486506	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000085478		52 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardiovascular Insufficiency; Drug Interaction; Electrocardiogram Qt Interval; Product Use In Unapproved Indication; Torsade De Pointes	Escitalopram			S	Oral	10 Mg		Forest
	Clopixol Comprimés Enrobés			S	Oral			Not Reported
	Solian			S	Oral	66.6667 Mg		Not Reported
	Theralene			S	Unknown	100 Mg		Not Reported
	Parkinane			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12213939	EXPEDITED (15-DAY)		HO, LT, OT	ES-WATSON-2016-		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram (Unknown)			S	Unknown	Unk		Not Reported
	Levofloxacin (Unknown)			S	Unknown	Unk		Watson
	Solifenacin (Unknown)			S	Unknown	Unk		Not Reported
	Digoxin (Unknown)			S	Unknown	Unk		Not Reported
	Amiodarone /00133102/			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Candesartan			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Acenocoumarol			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12214362	EXPEDITED (15-DAY)		HO, LT, OT	ES-TEVA-647341ISR		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Levofloxacin			S				Teva
	Escitalopram			S				Ivax
	Sulpiride			S				Not Reported
	Solifenacin			S				Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)			Not Reported
	Digoxin			S				Not Reported
	Candesartan			C				Not Reported
	Furosemide			C				Not Reported
	Acenocoumarol			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12487949	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2016-07792		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor; Toxicity To Various Agents	Escitalopram Film-Coated Tablets			S	Oral	27 Df, Unk		Aurobindo
	Depakin			S	Oral	20 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12488914	EXPEDITED (15-DAY)		HO	US-NOVEN PHARMACEUTICALS, INC.-US2016001543			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Gait Disturbance	485 (Methylphenidate)			S	Unknown	Unknown		Noven
	Sertraline			S	Unknown	Unk, Unknown		Not Reported
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported
	Venlafaxine			S	Unknown	Unk, Unknown		Not Reported
	Mirtazapine			S	Unknown	Unk, Unknown		Not Reported
	Bupropion			S	Unknown	Unk, Unknown		Not Reported
	Trazodone Hcl			S	Unknown	Unk, Unknown		Not Reported
	Lamotrigine			S	Unknown	Unk, Unknown		Not Reported
	Lorazepam			S	Unknown	Unk, Unknown		Not Reported
	Clonazepam			S	Unknown	Unk, Unknown		Not Reported
	Donepezil			S	Unknown	Unk, Unknown		Not Reported
	Memantine			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12490002	EXPEDITED (15-DAY)		CA	DE-TEVA-668672GER		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cleft Lip And Palate; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram		S	Transplacental	10 Milligram Daily; From 0-6 And 23-30+6.	Ivax
	L-Thyrox		C	Transplacental	50 Microgram Daily;	Not Reported
	Folsäure		C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12490206	EXPEDITED (15-DAY)		OT	FR-FRI-1000085534		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Homicide; Impulsive Behaviour; Irritability	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S				Forest
	Amlor			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12490207	EXPEDITED (15-DAY)		LT	FR-FRI-1000085532		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction	Escitalopram			S	Oral	10 Mg		Forest
	Lovenox			S	Subcutaneous	4000 Ui Anti-Xa/0,4 Ml		Not Reported
	Lamictal			C		300 Mg		Not Reported
	Lamictal			C				Not Reported
	Omeprazole			C		20 Mg		Not Reported
	Xatral Lp			C		10 Mg		Not Reported
	Sectral			C		200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12490557	NON-EXPEDITED			US-JAZZ-2015-US-020674		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Feeling Abnormal; Heart Rate Increased; Hypersensitivity; Peripheral Swelling; Serum Serotonin Increased; Somnolence; Unevaluable Event; Vertigo; Vomiting; Weight Decreased	Xyrem	S	Oral	2.25 G, Bid	Jazz
	Xyrem	S	Oral	Dose Adjustments	Jazz
	Xyrem	S	Oral	3 G, Bid	Jazz
	Chantix	S		Unk	Not Reported
	Chantix	S		Unk	Not Reported
	Lexapro	S			Not Reported
	Atenolol	S			Not Reported
	Zolpidem Tartrate	C		Unk	Not Reported
	Calcium + Vitamin D	C		Unk	Not Reported
	Clonazepam	C		Unk	Not Reported
	Proair Hfa	C		Unk	Not Reported
	Veramyst	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12492057	DIRECT		HO			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza; Middle Insomnia; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Toothache; Vasodilatation; Weight Decreased	Escitalopram 10mg Tablet Accord			S	Oral			Accord
	Combivent			C				Not Reported
	Qvar			C				Not Reported
	Hydrocide			C				Not Reported
	Previd			C				Not Reported
	Milk Thistle			C				Not Reported
	Vit D3			C				Not Reported
	Vit A&D Ointment			C				Not Reported
	Magnesium			C				Not Reported
	C			C				Not Reported
	B6			C				Not Reported
	Blink Gel Eye Drops			C				Not Reported
	Gas X			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	11552918	EXPEDITED (15-DAY)		HO, OT	PHHY2015CA113466		182 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Seizure	Bupropion			S	Transmammary			Novartis
	Escitalopram			S	Transmammary			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	11669861	EXPEDITED (15-DAY)		DE	CA-FRI-1000080408		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Death	Escitalopram			S	Oral	20 Mg		Forest
	Quetiapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	11669862	EXPEDITED (15-DAY)		OT	CA-FRI-1000080406		9 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Gastrointestinal Haemorrhage; Haematemesis; Nausea; Product Use Issue; Vomiting	Escitalopram			S	Unknown	Daily Dose Not Reported.		Forest
	Methylphenidate Hydrochloride			S	Unknown	Daily Dose Not Reported.		Not Reported
	Risperidone			S	Unknown	Daily Dose Not Reported.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	12491100	EXPEDITED (15-DAY)		CA, HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2016002832			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	10 Mg, Qd (From 0-6 And 23-30+6 Weeek)		Macleods
	L-Thyroxine Sodium			C	Transplacental	50 Mg, Qd (30.6-30.6 Gestational Week)		Not Reported
	Folsäure			C	Transplacental	Unk (0. - 30.6. Gestational Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	12491915	EXPEDITED (15-DAY)		HO, LT, OT	ES-CIPLA LTD.-2016ES07759			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Haemodynamic Instability; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Levofloxacin			S				Cipla
	Escitalopram			S	Unknown	Unk		Invagen
	Sulpiride			S				Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)			Not Reported
	Digoxin			S				Not Reported
	Solifenacin			S				Not Reported
	Acenocoumarol			C				Not Reported
	Simvastatin			C				Not Reported
	Furosemide			C				Not Reported
	Candesartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	12493339	EXPEDITED (15-DAY)		HO, LT, OT	ES-PFIZER INC-2016307403		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bundle Branch Block Left; Contraindicated Product Administered; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Tachycardia; Torsade De Pointes; Ventricular Extrasystoles	Amiodarone Hcl			S				Pfizer
	Levofloxacin			S	Unknown	Unk		Pfizer
	Amiodarone Hcl			S	Intravenous (not otherwise specified)			Not Reported
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported
	Digoxin			S	Unknown	Unk		Not Reported
	Sulpiride			S	Unknown	Unk		Not Reported
	Solifenacin Succinate			S	Unknown	Unk		Not Reported
	Candesartan			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Acenocoumarol			C		Unk		Not Reported
	Simvastatin			C		Unk		Not Reported

	Magnesium Sulfate			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	12493558	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2016M1025223			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram Mylan			S	Transplacental	10 Mg, Qd (10 [Mg/D]/ From 0-6 And 23-30+6.)		Mylan
	L-Thyrox			C	Transplacental	50 Mg, Qd (50 [Mg/D]/ Since When And Until When?)		Mylan
	Folsaeure			C	Transplacental			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	12494003	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20160616374		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Coma; Lung Infection; Respiratory Depression; Sensorimotor Disorder	Topalgic (France)			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Lexomil			S	Oral			Not Reported
	Xarelto			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Esidrex			C	Unknown			Not Reported
	Losartan			C	Unknown			Not Reported
	Movicol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	12494086	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2016PRN00078			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersensitivity	Escitalopram	S	Unk		Prinston Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2016	12220589	EXPEDITED (15-DAY)		HO, LT, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-113916		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Sulpiride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Ranbaxy
	Solifenacin			S	Unknown			Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)			Not Reported
	Digoxin			S	Unknown			Sun
	Candesartan			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Acenocoumarol			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2016	12495464	EXPEDITED (15-DAY)		OT	US-009507513-1606USA008092			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctival Haemorrhage	Cozaar			S	Oral	100 Mg, Qd		Merck
	Hydrochlorothiazide			S	Oral	25 Mg, Qd		Not Reported
	Eliquis			S		5 Mg, Bid		Not Reported
	Lipitor			S		20 Mg, Qd		Not Reported
	Lexapro			S		10 Mg, Qd		Not Reported
	Acetylcarnitine Hydrochloride			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2016	12495689	EXPEDITED (15-DAY)		OT	DE-CIPLA LTD.-2016DE08041			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Tachycardia	Escitalopram			S	Oral	Unk		Invagen
	Quetiapine			S	Oral	Unk		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2016	12497302	EXPEDITED (15-DAY)		DE	JP-PFIZER INC-2016312225		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Circulatory Collapse; Completed Suicide; Overdose; Pulmonary Oedema	Alprazolam			S	Oral	Unk		Pfizer
	Levomepromazine			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Duloxetine Hydrochloride W/Mecobalamin			S		Unk		Not Reported
	Escitalopram Oxalate W/Etizolam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2016	12499536	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram 20 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2016	12484260	EXPEDITED (15-DAY)		DS	GXKR2016DE002799		88 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cognitive Disorder; Decreased	Ramipril			S	Oral	5 Mg, Bid		Novartis

Appetite; General Physical Health Deterioration; Hypotension; Impaired Self-Care; Mobility Decreased; Somnolence; Urinary Incontinence; Weight Decreased	Candesartan Cilexetil	S	Oral	16 Mg, Qd	Not Reported
	Isosorbide Dinitrate	S	Oral	20 Mg, Bid	Not Reported
	Metoprolol	S	Oral	47.5 Mg, Bid	Not Reported
	Furosemide	S	Oral	40 Mg, Bid	Not Reported
	Hydrochlorothiazide	S	Oral	25 Mg, Qd	Not Reported
	Moxonidine	S	Oral	0.4 Mg, Qd	Not Reported
	Metformin	S	Oral	850 Mg, Bid	Not Reported
	Glimepiride	S	Oral	1 Mg, Qd	Not Reported
	Allopurinol	S	Oral	300 Mg, Qd	Not Reported
	Escitalopram	S	Oral	20 Mg, Qd	Not Reported
	Pantoprazol	S	Oral	40 Mg, Qd	Not Reported
	Tilidine+Naloxone	S	Oral	1 Df, Tid	Not Reported
	Trospium	S	Oral	15 Mg, Qd	Not Reported
	Digitoxin	S		0.07 Mg, Once Daily	Not Reported
	Insulin	S		26-0-16	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2016	12503494	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal; Feeling Jittery; Nervousness	Lexapro			S				Not Reported
	Prozac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	11665135	EXPEDITED (15-DAY)		OT	CA-FRI-1000080431		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Noise; Pain In Jaw; Product Use Issue	Celexa			S	Oral			Forest
	Escitalopram			S	Oral			Forest
	Abilify			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12504120	EXPEDITED (15-DAY)		DE, OT	JP-ELI_LILLY_AND_COMPANY-JP201606009024		25 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Circulatory Collapse; Completed Suicide; Depressed Level Of Consciousness; Pulmonary Oedema	Cymbalta			S	Oral			Eli Lilly And Co
	Alprazolam			S	Oral			Not Reported
	Levomepromazine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12504346	EXPEDITED (15-DAY)		DS	DE-VALIDUS PHARMACEUTICALS LLC-DE-2016VAL002174		88 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cognitive Disorder; Decreased Appetite; General Physical Health Deterioration; Hypotension; Impaired Self-Care; Mobility Decreased; Somnolence; Urinary Incontinence; Weight Decreased	Metoprolol Tartrate			S	Oral	47.5 Mg, Bid		Validus
	Furosemide			S	Oral	40 Mg, Bid		Validus
	Ramipril			S	Oral	5 Mg, Bid		Not Reported
	Candesartan Cilexetil			S	Oral	16 Mg, Qd		Not Reported
	Isosorbide Dinitrate			S		20 Mg, Bid		Not Reported
	Hydrochlorothiazide			S	Oral	25 Mg, Qd		Not Reported
	Moxonidine			S	Oral	0.4 Mg, Qd		Not Reported
	Metformin			S	Oral	850 Mg, Bid		Not Reported
	Glimepiride			S	Oral	1 Mg, Qd		Not Reported
	Allopurinol			S	Oral	300 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported
	Naloxone W/Tilidine			S	Oral	1 Df, Tid (4/50mg)		Not Reported

	Trospium	S	Oral	15 Mg, Qd	Not Reported
	Digitoxin	S		0.07 Mg, Qd	Not Reported
	Insulin	S		30/70 Iu, 26-0-16	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12504436	EXPEDITED (15-DAY)		CA	DE-FRI-1000085671		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	10 Mg		Forest
	L-Thyrox			C	Transplacental	50 Mcg		Not Reported
	Folsaeure			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12505181	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2016GSK090584		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Pyrexia; Rash Erythematous; Rash Pruritic; Rash Pustular; Toxic Skin Eruption	Lamisil			S	Topical	Unk		Glaxosmithkline
	Lamisil			S	Oral	Unk		Glaxosmithkline
	Seroplex			S	Oral	Unk		Not Reported
	Tiapridal			S	Oral	Unk		Not Reported
	Econazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12505544	EXPEDITED (15-DAY)		HO	PHHY2016FR086751		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash Erythematous; Rash Pruritic; Rash Pustular; Toxic Skin Eruption	Lamisil			S	Oral	Unk		Novartis
	Lamisil			S	Topical	1 %, Unk		Not Reported
	Seroplex			S	Unknown	0.5 Ml, Qd		Not Reported

Tiapridal	S	Unknown	10 Drops Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12506126	EXPEDITED (15-DAY)		HO	FR-FRI-1000085622		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Sensorimotor Disorder	Escitalopram			S	Unknown	15 Mg		Forest
	Lexomil Roche			S	Oral			Not Reported
	Topalgic (France)			S	Oral			Not Reported
	Xarelto			C	Unknown	20 Mg		Not Reported
	Bisoprolol			C	Unknown	10 Mg		Not Reported
	Esidrex			C	Unknown	12.5 Mg		Not Reported
	Losartan			C	Unknown	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12480321	EXPEDITED (15-DAY)		HO	FR-FRI-1000085405		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Hypercapnia; Prescribed Overdose; Respiratory Acidosis; Somnolence	Escitalopram			S	Oral	Overdose: Escitalopram 30 Mg Daily		Forest
	Skenan			S	Oral			Not Reported
	Actiskenan			S	Oral			Not Reported
	Domperidone Arrow			S	Oral	6.6667 Mg		Not Reported
	Stilnox			S	Oral	10 Mg		Not Reported
	Lysanxia			S	Oral	3.3333 Mg		Not Reported
	Novorapid			C				Not Reported
	Lantus			C				Not Reported
	Lovenox			C				Not Reported
	Macrogols			C				Not Reported
	Eupantol			C				Not Reported
	Adrovance			C				Not Reported
	Amoxicillin			C				Not Reported

	Vitamin D3			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12507679	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2016-08107		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram 10 Mg			S	Transplacental	10 Mg, Daily		Aurobindo
	L-Thyrox			C	Transplacental	50 Mcg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12508924	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1026869			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Escitalopram			S	Unknown	10 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518628	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2016GSK092261		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash Erythematous; Rash Pruritic; Rash Pustular; Toxic Skin Eruption	Lamisil			S	Oral	Unk		Glaxosmithkline
	Lamisil			S	Topical	1 %, Unk		Glaxosmithkline
	Seroplex			S		0.5 Ml, Qd		Glaxosmithkline
	Tiapridal			S		10 Df, Unk (10 Drops Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12521218	DIRECT		OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Balance Disorder; Vertigo	Escitalopram Tablet 20mg	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2016	12521778	EXPEDITED (15-DAY)		DS	DE-SA-2016SA120271		88 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Sodium Decreased; Cognitive Disorder; Decreased Appetite; Dysstasia; Gait Inability; General Physical Health Deterioration; Haemoglobin Decreased; Hypotension; Impaired Self-Care; Multiple Drug Therapy; Somnolence; Urinary Incontinence; Weight Decreased	Furosemide			S	Oral			Not Reported
	Metoprolol Tartrate			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported
	Candesartan Cilexetil			S	Oral			Not Reported
	Isosorbide Dinitrate			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Glimepiride			S	Oral			Not Reported
	Allopurinol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Naloxone Hydrochloride/Tilidine Phosphate			S	Oral	4/50 Mg		Not Reported
	Trospium			S	Oral			Not Reported
	Digitoxin			S	Unknown			Not Reported
	Insulin			S	Unknown	30/70 Iu; At A Dose Of 26-0-16 Iu		Not Reported
	Moxonidine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2016	12522767	NON-EXPEDITED		HO, LT	ZA-FRI-1000084412		83 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Dyskinesia; Hallucination, Visual;	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest

Hyperhidrosis; Hyperkalaemia; Hypertension; Psychotic Disorder; Pyrexia; Renal Failure; Rhabdomyolysis; Tachycardia	Rasagiline	S	Oral	1 Mg	Not Reported
	Paracetamol W/Tramadol Hydrochloride	S	Oral	18.75 Mg	Not Reported
	Fentanyl	S	Transdermal	12.5 Microgram Per Hour	Not Reported
	Stalevo	S	Oral	500 Mg	Not Reported
	Celecoxib	C	Oral	100 Mg	Not Reported
	Zopiclone	C	Oral	Nocte Day	Not Reported
	Sinemet	C	Oral	50/200 Mg Od For Years Nocte Day	Not Reported
	Ergocalciferol	C	Oral	Monday, Wednesday And Friday	Not Reported
	Ocuvite Lutein	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2016	12522771	EXPEDITED (15-DAY)		CA, HO	NL-FRI-1000085834		< 1 DAY	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choanal Atresia; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental			Forest
	Omeprazol Capsule Msr 40mg			C	Transplacental	40 Mg		Not Reported
	Folic Acid			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2016	12522772	EXPEDITED (15-DAY)		OT	GB-FRI-1000085740		20 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Narcolepsy	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2016	12525417	EXPEDITED (15-DAY)		DS	DE-BAUSCH-BL-2016-015760		88 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Decreased Appetite; General Physical Health Deterioration; Hypotension; Mobility Decreased; Somnolence; Urinary Incontinence; Weight Decreased	Isosorbide Dinitrate	S	Unknown	Not Reported
	Metformin	S	Oral	Santarus
	Ramipril	S	Oral	Not Reported
	Ramipril	S	Oral	Not Reported
	Allopurinol	S	Oral	Not Reported
	Pantoprazole	S	Oral	Not Reported
	Furosemide	S	Oral	Not Reported
	Furosemide	S	Oral	Not Reported
	Metoprolol Tartrate	S	Oral	Not Reported
	Metoprolol Tartrate	S	Oral	Not Reported
	Candesartan Cilexetil	S	Oral	Not Reported
	Hydrochlorothiazide	S	Oral	Not Reported
	Glimepiride	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Naloxone Hydrochloride/Tilidine Phosphate	S	Oral	Not Reported
	Trospium	S	Oral	Not Reported
	Digitoxin	S	Unknown	Not Reported
	Insulin	S	Unknown	Not Reported
	Moxonidine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2016	12525438	EXPEDITED (15-DAY)		DE	CA-ASTRAZENECA-2016SE71737		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Ineffective; Feelings Of Worthlessness; Insomnia; Suicidal Ideation	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Cipralex			S	Oral			Not Reported

	Cipralex	S	Oral		Not Reported
	Trazodone	C	Oral		Not Reported
	Vitamin B12	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	9695780	NON-EXPEDITED		DS, OT	JP-FRI-1000051453		29 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Hyperhidrosis; Intentional Overdose; Off Label Use; Pyrexia; Rhabdomyolysis; Suicide Attempt; Tachycardia	Lexapro			S	Oral			Forest
	Lexapro			S	Oral			Forest
	Meilax			C	Oral			Not Reported
	Allegra			C	Oral	60 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12511133	EXPEDITED (15-DAY)		DE	AU-FRI-1000085661			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Pulmonary Hypertension	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12526419	EXPEDITED (15-DAY)			IT-HETERO LABS LTD-1054612		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Escitalopram			S	Unknown			Hetero
	Betamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12529266	EXPEDITED (15-DAY)		HO	ES-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2016-		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Micardisplus			S	Oral	80 Mg		Boehringer Ingelheim
	Escitalopram			S	Oral	15 Mg		Not Reported
	Sertraline			S	Oral	50 Mg		Not Reported
	Carduran Neo			C	Unknown	4 Mg		Not Reported
	Sumial			C	Unknown	60 Mg		Not Reported
	Atorvastatin			C	Unknown	20 Mg		Not Reported
	Diazepam			C	Unknown	10 Mg		Not Reported
	Sinemet Plus			C	Unknown			Not Reported
	Azilect			C	Unknown	1 Mg		Not Reported
	Exelon			C	Unknown	9.5 Mg		Not Reported
	Clopidogrel			C	Unknown	75 Mg		Not Reported
	Quetiapine			C	Unknown	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2016	12529690	EXPEDITED (15-DAY)			US-MACLEODS PHARMACEUTICALS US LTD-MAC2016002693			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram Oxalate 10mg Tablet			S	Oral	10 Mg		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2016	12530856	EXPEDITED (15-DAY)		HO	FR-FRI-1000085794		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash	Escitalopram Oral Solution			S	Oral	0.5 Ml		Forest

Erythematous; Rash Pruritic; Rash Pustular; Toxic Skin Eruption	Lamisil		S	Oral		Not Reported
	Lamisil		S	Topical		Not Reported
	Tiapridal		S	Oral	10 Gtt	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2016	12530874	EXPEDITED (15-DAY)		HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-054412		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypotonia; Miosis	Abilify			S	Oral	5 Mg, Qd		Bristol Myers Squibb
	Zopiclone			S	Oral	210 Mg, Qd		Not Reported
	Zyprexa			S	Oral	1 Df, Unk		Not Reported
	Lysanxia			S	Oral	1440 Mg, Unk		Not Reported
	Seroplex			S	Oral	140 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2016	12532241	EXPEDITED (15-DAY)		DE	JP-FRI-1000085843			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Escitalopram			S	Oral			Forest
	Levomepromazine			S	Oral			Not Reported
	Mirtazapine			C	Oral			Not Reported
	Duloxetine Hydrochloride			C	Oral			Not Reported
	Alprazolam			C	Oral			Not Reported
	Risperidone			C	Oral			Not Reported
	Paroxetine Hydrochloride Hydrate			C	Oral			Not Reported
	Flunitrazepam			C	Oral			Not Reported
	Quazepam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2016	11389271	EXPEDITED (15-DAY)		OT	TR-FRI-1000079024		18 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal	Escitalopram			S	Unknown	5 Mg		Forest
	Escitalopram			S	Unknown	10 Mg		Forest
	Escitalopram			S	Unknown	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2016	12488693	EXPEDITED (15-DAY)		HO, LT, OT	ES-CONCORDIA PHARMACEUTICALS INC.-E2B_00007764		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Digoxin			S				Concordia
	Sulpiride			S				Not Reported
	Escitalopram			S				Not Reported
	Levofloxacin			S				Not Reported
	Solifenacin			S				Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)			Not Reported
	Candesartan			C				Not Reported
	Furosemide			C				Not Reported
	Acenocoumarol			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2016	12535028	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2016US08328			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Laboratory Test Abnormal	Escitalopram			S	Oral	10 Mg, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2016	12537869	EXPEDITED (15-DAY)		OT	SE-FRI-1000085896		37 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Derealisation; Dizziness; Fatigue; Headache; Muscle Twitching; Nausea; Vision Blurred	Escitalopram			S	Unknown			Forest
	Escitalopram			S				Forest
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Yaz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2016	12537957	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2016M1027346			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Neonatal; Congenital Hydronephrosis; Foetal Exposure During Pregnancy; Kidney Duplex; Respiratory Disorder Neonatal	Escitalopram			S	Transplacental	10 [Mg/D]/ Intermittently 7.5 Mg/D For A Short Time Period.		Not Reported
	Decortin-H /00016201/			S	Transplacental	5.5 [Mg/D]/ Minimum Dosage 5 Mg/D		Mylan
	L-Thyroxin			C	Transplacental	75 [Mg/D]		Mylan
	Dekristol			C	Transplacental	1000 [Ie/D]/ Probably Taken Longer. Reduction To 500 Ie/D, Stopped During The 1st Trimester		Mylan
	Cytotec			C	Transplacental			Mylan
	Femibion 1			C	Transplacental	0.8 [Mg/D]		Mylan
	Ampicillin			C	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2016	12538046	EXPEDITED (15-DAY)		OT	ZA-FRI-1000085886			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; White Blood Cell Count Decreased	Escitalopram			S	Unknown			Forest
	Tetralysal [Tetracycline]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2016	12538221	EXPEDITED (15-DAY)		HO	NL-FRI-1000085837			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Abnormal; Poisoning	Escitalopram			S	Unknown			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2016	11021240	EXPEDITED (15-DAY)		OT	US-009507513-1504USA005235			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Asthenia; Attention Deficit/Hyperactivity Disorder; Back Pain; Blood Testosterone Decreased; Cardiac Arrest; Colon Adenoma; Cough; Cough; Depressed Level Of Consciousness; Depression; Dizziness; Dysphonia; Erectile Dysfunction; Fall; Fall; Fatigue; Fatigue; Gastrooesophageal Reflux Disease; Hypersensitivity; Hypogonadism Male; Hypotension; Joint Dislocation; Libido Decreased; Ligament Rupture; Lipids Increased; Malaise; Meningioma; Meniscus Injury; Musculoskeletal Chest Pain; Neck Pain; Nocturia; Orgasm Abnormal; Osteoarthritis; Plantar Fasciitis; Pollakiuria;	Propecia			S	Oral	1 Mg, Qd		Merck
	Metoprolol			S	Unknown	Unk, Unknown		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Wellbutrin			S	Unknown	Unk, Unknown		Not Reported

Psychosexual Disorder; Rib Fracture; Rotator Cuff Syndrome; Rotator Cuff Syndrome; Skin Abrasion; Sperm Concentration Decreased; Stress At Work; Tendonitis; Tendonitis; Ventricular Extrasystoles; Ventricular Fibrillation; Viral Myocarditis; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2016	12538711	EXPEDITED (15-DAY)		HO, OT	CA-SCIEGEN PHARMACEUTICALS INC-2016SCILIT00291		182 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Breast Feeding; Seizure; Vomiting	Bupropion Hydrochloride			S	Transmammary	Unk		Sciegen
	Escitalopram			S	Transmammary	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2016	12539799	EXPEDITED (15-DAY)		HO, OT	ES-CIPLA LTD.-2016ES08290			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biliary Colic; Cardio-Respiratory Arrest; Drug Interaction; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram			S	Unknown	Unk		Invagen
	Losartan			S	Unknown	Unk		Not Reported
	Simvastatin			S	Unknown	Unk		Cipla
	Amiodarone			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Iron Sulfate			S	Unknown	Unk		Not Reported
	Betahistine			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Acenocoumarol			S	Unknown	Unk		Not Reported

	Metoclopramide		S	Unknown	Unk	Not Reported
	Metoclopramide		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2016	12541535	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-672270GER		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Neonatal; Congenital Hydronephrosis; Foetal Exposure During Pregnancy; Kidney Duplex; Respiratory Disorder Neonatal	Escitalopram			S	Transplacental	10mg/Day; Intermittently 7.5 Mg/D For A Short Time Period; 0. - 36.2. Gestational Week		Ivax
	Decortin-H			S	Transplacental	5.5mg/Day; Minimum Dosage 5 Mg/D; 0. - 36.2. Gestational Week		Not Reported
	L-Thyroxin			C	Transplacental	75 Microgram Daily; 0. - 36.2. Gestational Week		Not Reported
	Dekristol			C	Transplacental			Not Reported
	Cytotec			C	Transplacental	36.2. - 36.2. Gestational Week		Not Reported
	Femibion Schwangerschaft 1			C	Transplacental	.8 Milligram Daily;		Not Reported
	Ampicillin			C	Transplacental	36.2. - 36.2. Gestational Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12298439	NON-EXPEDITED			US-009507513-1604USA004800			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Zetia			S	Oral	Unk		Merck
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12543832	NON-EXPEDITED		OT	US-JAZZ-JPI-P-022332		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Anxiety; Arthralgia; Cataplexy; Dysphagia; Muscle Contractions Involuntary; Muscle Discomfort; Musculoskeletal Stiffness	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S				Not Reported
	Nuvigil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12544289	EXPEDITED (15-DAY)		HO	IT-LUPIN PHARMACEUTICALS INC.-2016-03033		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12544574	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2016-09014		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Fluid Volume Increased; Exposure During Pregnancy; Premature Rupture Of Membranes	Escitalopram 10 Mg			S	Oral	10 Mg, Daily		Aurobindo
	Decortin-H /00016201/			S	Oral	5.5 Mg, Daily		Not Reported
	L-Thyroxin			C	Oral	75 Mcg, Daily		Not Reported
	Dekristol			C	Oral	Unk		Not Reported
	Cytotec			C	Unknown	Unk		Not Reported
	Ampicillin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12544656	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2016-08582		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Neonatal; Congenital Hydronephrosis;	Escitalopram 10 Mg			S	Transplacental	10 Mg, Daily		Aurobindo
	Decortin-H /00016201/			S	Transplacental	5.5 Mg, Daily		Not Reported

Hypotonia Neonatal; Kidney Duplex; Respiratory Disorder Neonatal	L-Thyroxin	C	Transplacental	75 Mcg, Daily		Not Reported
	Dekristol	C	Transplacental	1000 Iu, Daily		Not Reported
	Cytotec	C	Transplacental	Unk		Not Reported
	Ampicillin	C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12546801	EXPEDITED (15-DAY)		DE	FR-SA-2016SA124957		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Intentional Overdose	Stilnox			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Propafenone Hydrochloride			S	Unknown			Not Reported
	Stagid			S	Oral			Not Reported
	Diamicron			S	Oral			Not Reported
	Noctamide			S	Oral			Not Reported
	Lexomil			S	Oral			Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			C	Unknown			Not Reported
	Dafalgan			C	Unknown			Not Reported
	Meteoxane			C	Unknown			Not Reported
	Fortum			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12547164	EXPEDITED (15-DAY)		CA, OT	DE-FRI-1000085908		< 1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Neonatal; Congenital Hydronephrosis; Foetal Exposure During Pregnancy; Kidney Duplex; Respiratory	Escitalopram			S	Transplacental	10 Mg		Forest
	Decortin-H / Prednisolone			S	Transplacental	5.5 Mg		Not Reported
	Decortin-H / Prednisolone			S	Transplacental			Not Reported
	L-Thyroxin / Levothyroxine Sodium			C	Transplacental	75 Mg		Not Reported

Disorder Neonatal	Dekristol / Colecalciferol	C	Transplacental	1000 Iu		Not Reported
	Dekristol / Colecalciferol	C	Transplacental			Not Reported
	Cytotec / Misoprostol	C	Transplacental			Not Reported
	Femibion Schwangerschaft 1 / Folic Acid	C	Transplacental	0.8 Mg		Not Reported
	Ampicillin / Ampicillin	C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12547176	EXPEDITED (15-DAY)		HO	CH-FRI-1000085894		25 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Supraventricular Tachycardia	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	11705407	EXPEDITED (15-DAY)		HO	PHHY2015GB140223		121 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal	Omeprazole			S	Transplacental			Novartis
	Omeprazole			S	Transplacental			Novartis
	Omeprazole			S	Transplacental			Novartis
	Azathioprine			S	Transplacental			Not Reported
	Co-Dydramol			S	Transplacental	Strength: 10/500		Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Oramorph			S	Transplacental	15 Mg, Unk		Not Reported
	Oramorph			S	Unknown	Unk		Not Reported
	Tapentadol			S	Transplacental	100 Mg		Not Reported
	Daktarin//Miconazole Nitrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12549982	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2016M1028499			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Abuse	Escitalopram			S	Oral	300 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12550266	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000086042		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Hypoglycaemia; Hypokalaemia; Intentional Overdose; Miosis; Sinus Bradycardia	Escitalopram			S	Oral	14 Tablets At Once		Forest
	Corgard			S	Oral	28 Tablets At Once		Not Reported
	Alprazolam			S	Oral	30 Tablets At Once		Not Reported
	Levothyrox			S	Oral	30 Tablets At Once		Not Reported
	Esomeprazole			S	Oral	4 Tablets At Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12550272	EXPEDITED (15-DAY)		HO	FR-FRI-1000086012		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Iron Deficiency Anaemia	Escitalopram			S	Oral	20 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Clopidogrel			S	Oral	1 Df		Not Reported
	Ebixa Film-Coated Tablets			C	Unknown			Not Reported
	Levothyrox			C				Not Reported
	Eupantol			C				Not Reported
	Lasilix			C				Not Reported
	Diffu K			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12550406	EXPEDITED (15-DAY)		HO	FR-FRI-1000085949		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Haemorrhage	Escitalopram			S	Unknown			Forest

Coumadine	S	Oral	4 Mg		Not Reported
Kardegic	S	Oral	75 Mg		Not Reported
Bisoprolol	C	Unknown			Not Reported
Stilnox	C	Unknown			Not Reported
Oxycontin Lp	C	Unknown			Not Reported
Oxynormoro	C	Unknown			Not Reported
Inexium	C	Unknown			Not Reported
Triatec (Ramipril)	C	Unknown			Not Reported
Tahor	C	Unknown			Not Reported
Hydrocortisone Roussel	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12550608	EXPEDITED (15-DAY)		HO	IT-FRI-1000086090		40 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Abuse	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2016	12521680	EXPEDITED (15-DAY)		HO, OT	US-TEVA-673427USA		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S				Ivax
	Estrogen Nos			S				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2016	12526479	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2016US08452			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown	Unk		Invagen
	Estrogen Nos			S	Unknown	Unk, Supplementation		Not Reported

	Trazodone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2016	12552745	EXPEDITED (15-DAY)		OT	FR-FRI-1000086062		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Escitalopram			S	Unknown	10 Mg		Forest
	Chlorpromazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2016	12553050	EXPEDITED (15-DAY)		OT	ES-JNJFOC-20160706142		49 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Xeplion			S	Intramuscular			Not Reported
	Escitalopram Oxalate			S	Oral	28 Tablets		Not Reported
	Trileptal			S	Oral	50 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2016	12553769	EXPEDITED (15-DAY)		OT	US-JNJFOC-20160704609			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Pneumonia; Serotonin Syndrome	Ultram			S	Oral	As Necessary		Not Reported
	Viibryd			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2016	11038727	EXPEDITED (15-DAY)		HO, OT	US-009507513-1504USA013052			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Depression; Depression; Ejaculation	Propecia			S	Oral	1 Mg, Qd		Merck

Disorder; Endocrine Disorder; Erectile Dysfunction; Essential Hypertension; Gastrooesophageal Reflux Disease; Generalised Anxiety Disorder; Haemorrhoidal Haemorrhage; Hand Fracture; Hormone Level Abnormal; Insomnia; Loss Of Libido; Nocturia; Organic Erectile Dysfunction; Painful Ejaculation; Penile Size Reduced; Penis Injury; Sexual Dysfunction; Skin Lesion; Sunburn; Testicular Atrophy	Lexapro	S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2016	12556099	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2016M1028896			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Drug Interaction; Somnambulism	Zolpidem			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2016	12556345	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016335220		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hyponatraemia	Xanax			S	Oral	0.5 Mg, 2x/Day		Pfizer
	Indapamide W/Perindopril			S	Oral	0.5 Df, 1x/Day		Not Reported
	Zopiclone			S	Oral	3.75 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	5 Mg, 1x/Day		Not Reported

Clopidogrel	C	Oral	75 Mg, 1x/Day		Not Reported
Nebivolol	C	Oral	5 Mg, 1x/Day		Not Reported
Movicol	C		20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2016	12557791	EXPEDITED (15-DAY)		OT	FR-FRI-1000084831			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	15 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2016	12560260	DIRECT		DS			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Pain; Rash	Escitalopram/Lexapro 10mg, 10mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2016	10332632	EXPEDITED (15-DAY)		HO, LT, OT	TR-BRISTOL-MYERS SQUIBB COMPANY-21204250		31 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Drug Interaction; Overdose; Suicide Attempt; Urinary Incontinence	Aripiprazole			S	Oral	14 Tabs		Bristol Myers Squibb
	Escitalopram			S	Oral	20 Tabs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2016	12550607	EXPEDITED (15-DAY)		HO	DK-FRI-1000085955			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression; Confusional State; Drug Ineffective; Feeling Abnormal; Limb Discomfort; Muscle Spasms	Escitalopram		S	Unknown	Forest
	Brintellix		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2016	12562625	EXPEDITED (15-DAY)		OT	IT-PRINSTON PHARMACEUTICAL INC.-2016PRN00173		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Escitalopram			S	Unknown	10 Mg, 1x/Day		Prinston Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2016	12563336	EXPEDITED (15-DAY)		OT	PHHY2016AU096166		34 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hallucination; Sleep-Related Eating Disorder	Zolpidem			S	Unknown			Novartis
	Escitalopram			S	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2016	12562212	EXPEDITED (15-DAY)		HO, OT	AU-ACTAVIS PTY LTD-2016-15379		66 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning	Escitalopram (Unknown)			S	Unknown	10 Mg, Daily		Not Reported
	Perindopril (Unknown)			S	Unknown	Unk		Not Reported
	Atenolol (Unknown)			S	Unknown	Unk		Watson
	Rosuvastatin (Unknown)			S	Unknown	Unk		Watson
	Pantoprazole (Unknown)			S	Unknown	Unk		Actavis Totowa
	Lercanidipine (Unknown)			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2016	12563716	EXPEDITED (15-DAY)		CA, OT	DE-HETERO LABS LTD-1055129		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Neonatal; Congenital Hydronephrosis; Exposure During Pregnancy; Kidney Duplex; Premature Baby; Respiratory Disorder Neonatal	Escitalopram			S	Transplacental			Hetero
	Decortin-H			S	Transplacental			Not Reported
	L-Thyroxin			C	Transplacental			Not Reported
	Dekristol			C				Not Reported
	Cytotec			C				Not Reported
	Femibion [Minerals Nos;Vitamins Nos]			C				Not Reported
	Ampicillin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2016	12563795	EXPEDITED (15-DAY)		HO, OT	AU-MACLEODS PHARMACEUTICALS US LTD-MAC2016002905			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Macleods
	Pantoprazole			S	Unknown	Unk		Macleods
	Rosuvastatin			S	Unknown	Unk		Not Reported
	Atenolol			S	Unknown	Unk		Not Reported
	Lercanidipine			S	Unknown	Unk		Not Reported
	Perindopril			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	11841133	EXPEDITED (15-DAY)		DE, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-087890		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Paracetamol			S	Unknown			Bristol Myers Squibb

	Hydrocodone	S	Unknown	Bristol Myers Squibb
	Aripiprazole	S	Unknown	Bristol Myers Squibb
	Escitalopram	S	Unknown	Not Reported
	Cyclobenzaprine	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12520705	EXPEDITED (15-DAY)		HO	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-01		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown			Hikma
	Estrogen Nos			S	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12546509	EXPEDITED (15-DAY)		HO	DK-TAKEDA-2016TUS011790		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Confusional State; Drug Ineffective; Feeling Abnormal; Limb Discomfort; Muscle Spasms	Brintellix			S	Unknown	5 Mg, Unk		Takeda
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12554768	EXPEDITED (15-DAY)			CA-TAKEDA-2016TUS012216		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Trintellix			S	Oral	10 Mg, Qd		Takeda
	Cipralex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12564976	EXPEDITED (15-DAY)		HO	IT-ACCORD-042357		40 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Abuse	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12565022	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2016-09314		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12565399	EXPEDITED (15-DAY)		OT	PHHY2016AU096174		35 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Drug Interaction; Somnambulism	Zolpidem			S	Unknown			Novartis
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12567220	EXPEDITED (15-DAY)		OT	SE-TEVA-675678ISR		52 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia Oral; Pharyngeal Oedema	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12567222	EXPEDITED (15-DAY)		OT	SE-TEVA-675733ISR		77 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypoacusis	Escitalopram	S	Oral		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12570116	DIRECT		HO			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Calcium Decreased; Blood Potassium Decreased; Contusion; Foot Fracture; Impaired Driving Ability; Lip Injury; Road Traffic Accident; Seizure; Skin Laceration	Omeprazole, 20 Mg			S	Oral	90 Capsule(S) In The Morning Taken By Mouth		Not Reported
	Escitalopram, 10mg			S	Oral	90 Tablet(S) In The Morning Taken By Mouth		Not Reported
	Lexapro			C				Not Reported
	Omepresole			C				Not Reported
	Vitamin C			C				Not Reported
	D3			C				Not Reported
	Bcompex			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12336751	EXPEDITED (15-DAY)		OT	CA-FRI-1000084380			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Diarrhoea; Haematochezia; Haematochezia	Escitalopram			S		20 Mg		Forest
	Flurazepam			C		7.5 Mg		Not Reported
	Omega 3			C				Not Reported
	Vitamin C			C		250 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12520109	EXPEDITED (15-DAY)		HO, OT	US-FRI-1000085735		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown			Forest
	Estrogens			S	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12546261	EXPEDITED (15-DAY)		OT	IT-TEVA-674867ISR		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Escitalopram			S		10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12568499	EXPEDITED (15-DAY)		OT	IT-JUBILANT GENERICS LIMITED-1055224		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Escitalopram Oxalate			S				Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12569923	EXPEDITED (15-DAY)		OT	FR-FRI-1000086190			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram			S	Oral			Forest
	Inexium			S	Unknown			Not Reported
	Lysanxia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12571397	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1029817			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Sopor	Mirtazapine			S	Oral	20 Df, Total		Not Reported
	Sertraline			S	Oral	25 Df, Total		Not Reported
	Escitalopram			S	Oral	10 Gtt, Total		Not Reported
	Samyr /00882301/			S	Oral	1 Df, Total		Mylan
	Zolpidem			S	Oral	20 Df, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12573225	DIRECT		OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Product Measured Potency Issue; Product Size Issue	Escitalopram			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12549764	EXPEDITED (15-DAY)		DE, HO	AR-BAXTER-2016BAX035857		80 YR	Male	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Death; Decreased Appetite; Diarrhoea; Fall; Gait Disturbance; Hypotension; Peritonitis; Urinary Incontinence	Dianeal Pd2 / Solución Para Diálisis Peritoneal, Dextrosa, Cloruro De			S	Intraperitoneal			Baxter
	Dianeal Pd2 / Solución Para Diálisis Peritoneal, Dextrosa, Cloruro De			S				Baxter
	Escitalopram			S	Oral			Not Reported
	Amiodarone			S	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	B Complex			C	Oral			Not Reported
	Rosuvastatin			C	Oral			Not Reported
	Trimebutine			C	Oral			Not Reported
	Simethicone			C	Oral			Not Reported
	Amiodarone			C	Oral			Not Reported
	Aspirin			C	Oral			Not Reported
	Escitalopram			C	Oral			Not Reported
	Leuprolide			C	Unknown			Not Reported
	Ranitidine			C	Oral			Not Reported
	Erythropoietin			C	Subcutaneous			Not Reported

	Red Blood Cells	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12572879	EXPEDITED (15-DAY)		HO, OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2016002908			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Liver Function Test Increased; Ocular Icterus	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Zolpidem			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12573058	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2016-09017		40 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Abuse	Escitalopram Film-Coated Tablets			S	Oral	300 Mg, Total		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12577815	DIRECT	Y	OT			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Behaviour Disorder; Product Substitution Issue	Escitalopram, 10mg Accord Healthcare			S	Oral			Accord
	Risperidone			C				Not Reported
	Dexmethylphenidate			C				Not Reported
	Methylphenidate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12578070	DIRECT					53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fatigue; Hallucination, Auditory; Nervousness; Restless Legs Syndrome	Escitalopram Tab 20mg, 20 Mg			S	Oral	30 Tablet(S) In The Morning Taken By Mouth	6 WEEK	Camber
	Norvir			C				Not Reported
	Truvada			C				Not Reported
	Prezista			C				Not Reported
	Wellbutrin Sr			C				Not Reported
	Escitalopram			C				Not Reported
	Cpap			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Pre-Biotic			C				Not Reported
	Pro-Biotic			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12017039	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-009165			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Abilify			S	Unknown			Bristol Myers Squibb
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12184833	EXPEDITED (15-DAY)		HO	IT-FRI-1000083124		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Escitalopram			S	Unknown	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12379063	EXPEDITED (15-DAY)		OT	CA-FRI-1000084615			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hot Flush; Seizure	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12568944	EXPEDITED (15-DAY)		HO	DK-ACCORD-042319		73 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Confusional State; Drug Ineffective; Feeling Abnormal; Limb Discomfort; Muscle Spasms	Escitalopram			S				Accord
	Brintellix			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12579600	EXPEDITED (15-DAY)		HO	JP-FRI-1000082182		32 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pregnancy; Premature Labour	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S				Forest
	Depas (Etizolam)			S	Oral	4.5 Mg		Not Reported
	Magmitt			C		1500 Mg		Not Reported
	Famotidine			C	Oral	20 Mg		Not Reported
	Ritodrine			C	Intravenous drip			Not Reported
	Racol			C	Unknown			Not Reported
	Medicon			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12579608	EXPEDITED (15-DAY)		DE	FR-FRI-1000086164		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Intentional	Escitalopram			S	Oral			Forest
	Stilnox			S	Unknown			Not Reported

Overdose	Propafenone Hydrochloride	S	Unknown	Not Reported
	Stagid	S	Oral	Not Reported
	Diamicron	S	Oral	Not Reported
	Noctamide	S	Oral	Not Reported
	Lexomil	S	Oral	Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Unknown	Not Reported
	Dafalgan	C	Unknown	Not Reported
	Meteoxane	C	Unknown	Not Reported
	Fortum	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12579617	EXPEDITED (15-DAY)		OT	JP-FRI-1000086249		56 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eructation	Lexapro			S	Oral			Forest
	Reflex			S	Oral			Not Reported
	Peroric			C	Oral	9 Df		Not Reported
	Famotidine			C	Unknown			Not Reported
	Lyrica			C	Oral	4 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12580160	EXPEDITED (15-DAY)		HO	FR-FRI-1000086240		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral	1 Df		Forest
	Xarelto			S	Oral	20 Mg		Not Reported
	Kardegic			S	Oral	75 Mg		Not Reported
	Lasilix			S	Oral	40 Mg		Not Reported
	Spiriva			C	Unknown			Not Reported

Cordarone	C	Unknown	Not Reported
Bisoprolol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12580283	EXPEDITED (15-DAY)		HO, LT	CA-ASTRAZENECA-2016SE78065		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Potentiating Drug Interaction; Serotonin Syndrome	Quetiapine			S	Oral			Zeneca
	Bupropion			S				Not Reported
	Escitalopram			S				Not Reported
	Olanzapine			S				Not Reported
	Primidone			S				Not Reported
	Phenytoin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12580822	EXPEDITED (15-DAY)		HO	FR-FRI-1000086239		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria	Escitalopram			S	Oral	10 Mg		Forest
	Xarelto			S	Oral	20 Mg		Not Reported
	Kardegic			S	Oral	1 Dosage Forms		Not Reported
	Cardensiel			C	Unknown			Not Reported
	Lasilix			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported
	Spiriva			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Cordarone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12581177	EXPEDITED (15-DAY)		HO	FR-FRI-1000086241		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Hemianopia; Hemiparesis	Escitalopram			S	Oral	5 Mg		Forest
	Kardegic			S	Oral	160 Mg		Not Reported
	Tahor			C	Oral	40 Mg		Not Reported
	Temerit			C	Oral	2.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12582280	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Occlusive Disease; Drug Resistance; Palpitations; Sleep Terror	Escitalopram 20 Mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12424587	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016277695		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dehydration; Diarrhoea; Fatigue; Hyponatraemia; Renal Failure; Vomiting	Paclitaxel Hospira			S	Intravenous (not otherwise specified)	60 Mg/M2, Cyclic		Pfizer
	Hydrochlorothiazide			S	Oral	1 Df, 1x/Day		Not Reported
	Telmisartan			S	Oral	1 Df, 1x/Day		Not Reported
	Heptamyl			S	Oral	187.8 Mg, 3x/Day		Not Reported
	Escitalopram			S	Oral	5 Mg, 1x/Day		Not Reported
	Zopiclone			C		Unk		Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12535474	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-042141		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Reversible Cerebral Vasoconstriction Syndrome	Escitalopram	S		Accord
	Estrogen Nos	S		Not Reported
	Trazodone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12549093	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2016-08931		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown	Unk		Aurobindo
	Estrogen Nos			S	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12583109	EXPEDITED (15-DAY)		OT	AU-APOTEX-2016AP009798		35 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Drug Interaction; Sleep-Related Eating Disorder; Somnambulism	Chemmart Zolpidem			S	Unknown			Apotex
	Escitalopram			S	Unknown			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12586233	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Nausea; Swelling	Escitalopram, 10mg			S	Oral			Not Reported
	Escitalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2016	12585103	EXPEDITED (15-DAY)		HO	US-ACCORD-042599		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S		In May-2015, Her		Accord

				Psychiatrist Restarted Antidepressant Treatment With Escitalopram 10 Mg For 5 Days	
	Diazepam	C			Not Reported
	Lorazepam	C			Not Reported
	Zolpidem	C			Not Reported
	Fexofenadine/Fexofenadine Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12572182	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2016347528		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Somnolence; Sopor	Sertraline Hcl			S	Oral	25 Df, Total		Pfizer
	Samyr /00882301/			S	Oral	1 Df, Total		Not Reported
	Zolpidem			S	Oral	20 Df, Total		Not Reported
	Mirtazapine			S	Oral	20 Df, Total		Not Reported
	Escitalopram			S	Oral	10 Drops, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12581809	EXPEDITED (15-DAY)		OT	IT-009507513-1607ITA008429		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Mirtazapine			S	Oral	Total: 20 Dose Unit		Merck
	Samyr			S	Oral	400 Mg, Total: 1 Dose Unit		Not Reported
	Zolpidem			S	Oral	Total: 20 Dose Units		Not Reported
	Sertraline Hydrochloride			S	Oral	Total: 25 Dose Units		Not Reported
	Escitalopram			S	Oral	Total: 10 Drops, Formulation: Drops		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12585906	NON-EXPEDITED		OT	US-TAKEDA-2016TUS012732			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Serotonin Syndrome	Trintellix			S	Oral	5 Mg, Qd		Takeda
	Lexapro			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12585936	EXPEDITED (15-DAY)		OT	IT-ACCORD-042650		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram			S	Oral			Accord
	Sertraline			S	Oral			Accord
	Samyr Bgp Products			S	Oral	Strength: 400 Mg		Not Reported
	Zolpidem			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12585953	EXPEDITED (15-DAY)		OT	SA-ACCORD-042607		28 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Gastrointestinal Disorder	Escitalopram			S		Escitalopram Up To 10 Mg/ Day		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12586258	NON-EXPEDITED			US-JAZZ-2016-US-002302			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Feeling Abnormal	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz

Xyrem	S	3.75 G, Bid	Jazz
Wellbutrin	S		Not Reported
Lexapro	S		Not Reported
Ramipril	C	Unk	Not Reported
Synthroid	C	Unk	Not Reported
Citracal + D	C	Unk	Not Reported
Multivitamins	C	Unk	Not Reported
Vitamin C	C	Unk	Not Reported
Allegra Allergy	C	Unk	Not Reported
Delsym	C	Unk	Not Reported
Claritin	C	Unk	Not Reported
Cod Liver Oil	C	Unk	Not Reported
Mucinex Dm	C	1200-60 Mg	Not Reported
Losartan Potassium	C	Unk	Not Reported
Vitamin B-12	C	Unk	Not Reported
Bupropion Hcl	C	Unk	Not Reported
Potassium Cl	C	Unk	Not Reported
Escitalopram	C	Unk	Not Reported
Nuvigil	C	Unk	Not Reported
Spironolactone	C	Unk	Not Reported
Vitamin D3	C	Unk	Not Reported
Amlodipine Besylate	C	Unk	Not Reported
Fenofibrate	C	Unk	Not Reported
Hydroxychloroquine	C	Unk	Not Reported
Welchol	C	Unk	Not Reported
Hydrocortisone	C	10 Mg, Unk	Not Reported
Hydrocortisone	C	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12586528	NON-EXPEDITED			US-PFIZER INC-2016322725		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Fibromyalgia	Menest			S		0.3 Mg		Pfizer
	Menest			S				Pfizer
	Menest			S				Pfizer
	Oxycodone			S		5-325 Tab Half In The Morning, Half At Night As Needed		Not Reported
	Escitalopram			S		30mg A Day		Not Reported
	Xanax			C		Unk		Not Reported
	Alprazolam			C	Oral	0.25 Mg, 2x/Day		Not Reported
	Naproxen			C	Oral	500 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12589337	EXPEDITED (15-DAY)		HO, OT	AU-MYLANLABS-2016M1030517			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Heart Rate Increased; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning	Lercanidipine			S		Unk		Not Reported
	Rosuvastatin			S		Unk		Not Reported
	Perindopril			S		Unk		Not Reported
	Escitalopram			S		10 Mg, Qd		Not Reported
	Pantoprazole			S		Unk		Not Reported
	Atenolol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12590266	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-2016VAL002302		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Furosemide			S	Oral	1 Df, Qd		Validus
	Kardegic			S	Oral	1 Df, Qd		Not Reported

Xarelto	S	Oral	1 Df, Qd		Not Reported
Seroplex	S	Oral	1 Df, Qd		Not Reported
Spiriva	C		Unk		Not Reported
Cordarone	C		Unk		Not Reported
Bisoprolol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12590603	NON-EXPEDITED		HO	ES-LUPIN PHARMACEUTICALS INC.-2016-01164		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Torsade De Pointes	Amiodarone			S	Intravenous (not otherwise specified)			Not Reported
	Sulpiride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Solifenacin			S	Unknown			Not Reported
	Acenocoumarol			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Digoxin			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Magnesium Sulfate			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	10576664	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-21581913		28 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During	Abilify			S	Oral	10 Mg, Qd		Bristol Myers Squibb
	Abilify			S				Bristol Myers Squibb

Pregnancy; Metrorrhagia; Off Label Use; Premature Delivery; Premature Rupture Of Membranes	Latuda	S	Unknown	40 Mg, Qd		Not Reported
	Latuda	S				Not Reported
	Cipralex	S	Oral	20 Mg, Qd		Not Reported
	Cipralex	S				Not Reported
	Seropram /00582602/	S	Unknown	20 Mg, Qd		Not Reported
	Seropram /00582602/	S				Not Reported
	Edronax	S	Oral	4 Mg, Qd		Not Reported
	Edronax	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12089311	EXPEDITED (15-DAY)		OT	AU-ACTAVIS PTY LTD-2016-03199		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram (Unknown)			S	Unknown	30 Mg, Daily		Not Reported
	Bupropion Hydrochloride (Unknown)			S	Oral	75 Mg Po Mane		Actavis
	Dothiepin /00160401/			S	Unknown	Increased To 225 Mg, Unk		Not Reported
	Dothiepin /00160401/			S	Unknown	Decreased To 175 Mg, Unk		Not Reported
	Ramipril (Unknown)			S	Unknown	Unk		Watson
	Norfloxacin			C	Unknown	400 Mg, Bid		Not Reported
	Quetiapine			C	Unknown	400 Mg, Qhs		Not Reported
	Lamotrigine			C	Unknown	75 Mg, Bid		Not Reported
	Oestradiol /00045401/			C	Unknown	Unk		Not Reported
	Glipizide			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12380456	NON-EXPEDITED			US-PFIZER INC-2016247753			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Benzylpenicillin Potassium			S				Pfizer
	Levofloxacin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Influenza			S				Not Reported
	Baclofen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12535473	EXPEDITED (15-DAY)		DE	PHHY2016TR092498		81 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Lung Infection; Product Use In Unapproved Indication	Rivastigmine			S	Transdermal	5-10 Cm2/Day		Not Reported
	Quetiapine			S	Unknown	150 Mg (50-150 Mg), Qd		Novartis
	Escitalopram			S	Oral	15 Mg (10-15 Mg), Qd		Not Reported
	Melatonin			S	Unknown	3 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12589106	EXPEDITED (15-DAY)		OT	PHHY2016IT098237		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Sertraline			S	Oral	25 Df, Once/Single		Novartis
	Zolpidem			S	Oral	20 Df, Once/Single		Not Reported
	Mirtazapina			S	Oral	20 Df, Once/Single		Not Reported
	Escitalopram			S	Oral	10 Gtt, Once/Single		Not Reported
	Samyr (Ademetionine)			S	Oral	400 Mg, Once/Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12593793	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016349243		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Hyponatraemia; Vertigo	Zithromax		S	Oral	1 Df, 3x/Week	Pfizer
	Seroplex		S	Oral	5 Mg, 1x/Day	Not Reported
	Tenstaten		S	Oral	50 Mg, 1x/Day	Not Reported
	Kardegic		C		Unk	Not Reported
	Temerit		C		Unk	Not Reported
	Fenofibrate		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12597130	EXPEDITED (15-DAY)		OT	IT-FRI-1000086349		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram Oral Solution			S	Oral			Forest
	Sertraline			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Samyr 400mg Compresse Gastroresistenti			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12598115	EXPEDITED (15-DAY)		HO, LT, OT	CA-ELI_LILLY_AND_COMPANY-CA201607010050		39 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Withdrawal Syndrome; Arrhythmia; Drug Interaction; Hyperthermia; Major Depression; Overdose; Pneumonia; Sepsis; Serotonin Syndrome	Olanzapine			S	Unknown	Unk, Unknown		Unknown
	Olanzapine			S	Unknown	Unk, Unknown		Unknown
	Primidone			S	Unknown	Unk, Unknown		Not Reported
	Primidone			S	Unknown	Unk, Unknown		Not Reported
	Quetiapine			S	Unknown	Unk, Unknown		Not Reported
	Quetiapine			S	Unknown	Unk, Unknown		Not Reported
	Bupropion			S	Unknown	Unk, Unknown		Not Reported

	Citalopram	S	Unknown	Unk, Unknown	Not Reported
	Citalopram	S	Unknown	Unk, Unknown	Not Reported
	Phenytoin	S	Unknown	Unk, Unknown	Not Reported
	Phenytoin	S	Unknown	Unk, Unknown	Not Reported
	Escitalopram	S	Unknown	Unk, Unknown	Not Reported
	Escitalopram	S	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12598339	EXPEDITED (15-DAY)		OT	IT-APOTEX-2016AP009909		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Zolpidem Doc Generici			S	Oral	20 Df, Total		Apotex
	Sertraline			S	Oral	25 Df, Total		Apotex
	Mirtazapine			S	Oral	20 Df, Total		Not Reported
	Escitalopram			S	Oral	10 Gtt, Total		Not Reported
	Samyr /00882301/			S	Oral	1 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12598443	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1663708US		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Limb Discomfort; Liver Disorder; Pruritus Generalised	Norco 5/325			S	Oral			Allergan
	Humira			S	Subcutaneous	40mg/0.8ml		Not Reported
	Advair			S				Not Reported
	Albuterol			S				Not Reported
	Cyclobenzaprine			S				Not Reported
	Amoxicillin Clavulanic Acid			S				Not Reported
	Escitalopram			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Lisinopril			S				Not Reported
	Lovastatin			S				Not Reported
	Losartan Potassium			S				Not Reported
	Meclizine			S				Not Reported

Methotrexate	S		Not Reported
Pantoprazole Sodium	S		Not Reported
Prednisone	S		Not Reported
Tramadol	S		Not Reported
Ranitidine	S		Not Reported
Ventolin	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12231895	EXPEDITED (15-DAY)		HO, LT, OT	ES-ASTELLAS-2016US011929		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bundle Branch Block Left; Cardiac Disorder; Contraindicated Product Administered; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Tachycardia; Torsade De Pointes; Ventricular Extrasystoles	Solifenacin			S	Unknown	Unk, Unknown Freq.		Astellas
	Escitalopram /01588502/			S	Unknown	Unk, Unknown Freq.		Not Reported
	Sulpiride Gd Ulcer			S	Unknown	Unk, Unknown Freq.		Not Reported
	Levofloxacin			S	Unknown	Unk, Unknown Freq.		Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)	Unk, Unknown Freq.		Not Reported
	Digoxin			S	Unknown	Unk, Unknown Freq.		Not Reported
	Candesartan			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Furosemide			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Acenocoumarol			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Simvastatin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12450253	EXPEDITED (15-DAY)		OT	US-ACCORD-041125		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Arthritis; Carpal Tunnel Syndrome; Constipation; Dyspnoea; Grandiosity; Headache; Hyperhidrosis; Hypertension; Influenza Like Illness; Insomnia;	Escitalopram			S	Oral			Accord
	Armor Thyroid			C				Not Reported
	Combivent			C		Combivent Inhaler 2 Puffs		Not Reported
	Klor-Con			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Prevacid Solo			C	Sublingual			Not Reported

Myalgia; Nausea; Neck Pain; Paraesthesia; Peripheral Swelling; Sinusitis; Skin Odour Abnormal; Tachyphrenia; Toothache; Vascular Pain; Weight Decreased; Yawning	Lasix	C	Not Reported
	Lidoderm	C	Not Reported
	Prednisone	C	Not Reported
	Acetylsalicylic Acid	C	Not Reported
	Colecalciferol	C	Not Reported
	Retinol	C	Not Reported
	Pyridoxine	C	Not Reported
	Biotin	C	Not Reported
	Magnesium Hydroxide	C	Not Reported
	Milk Thistle	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12540725	EXPEDITED (15-DAY)		HO	US-FRI-1000085879		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Unknown	10 Mg		Forest
	Diazepam			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Zolpidem			C	Unknown			Not Reported
	Fexofenadine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12598612	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2016GSK106386		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Jaundice	Voltarene Lp			S	Oral	75 Mg, Unk		Glaxosmithkline
	Voltarene Lp			S	Oral	1 Df, Bid		Glaxosmithkline
	Sipralexa			S		1 Df, Qd		Glaxosmithkline
	Seresta			S		0.5 Df, Unk		Glaxosmithkline
	Naprosyne			S	Oral	Unk		Glaxosmithkline
	Altim//Cortivazol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12600187	EXPEDITED (15-DAY)		OT	IT-EISAI MEDICAL RESEARCH-EC-2016-018837		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury	Pariet			S	Oral	Unknown		Not Reported
	Levosulpiride			S	Oral	Unknown		Not Reported
	En			S	Oral	Unknown		Not Reported
	Entact			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12600700	EXPEDITED (15-DAY)		HO	IT-FRI-1000086344		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor; Toxicity To Various Agents	Escitalopram			S	Oral			Forest
	Delorazepam			S	Oral			Not Reported
	Coumadin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12600705	EXPEDITED (15-DAY)		DS, HO	CA-FRI-1000086485		30 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Chills; Hyperhidrosis; Nightmare	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12601721	DIRECT		OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease;	Escitalopram, Blue Point			S	Oral			Not Reported
	Nebulizer			C				Not Reported

Feeling Abnormal; Seizure	Inhaler	C		Not Reported
	Risperdone	C		Not Reported
	Lorazepam	C		Not Reported
	Lexapro	C		Not Reported
	Ranitidine	C		Not Reported
	Vitamins One-A-Day	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12599178	EXPEDITED (15-DAY)		OT	IT-TEVA-679245ACC		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Zolpidem			S	Oral	20 Df Total		Teva
	Mirtazapine			S	Oral	20 Df Total		Not Reported
	Sertraline			S	Oral	25 Df Total		Not Reported
	Escitalopram			S	Oral	10 Gtt Total		Not Reported
	Samyr - 400 Mg Compresse Gastroresistenti			S	Oral	1 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12601626	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2016-09564		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Mirtazapine			S	Oral	20 Df, Total		Aurobindo
	Sertraline			S	Oral	25 Df,Total		Aurobindo
	Escitalopram			S	Oral	10 Gtt,Drops Total		Aurobindo
	Samyr /00882301/			S	Oral	1 Df, Total		Not Reported
	Zolpidem			S	Oral	20 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12601933	EXPEDITED (15-DAY)		OT	RO-JNJFOC-20160721392		20 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Erectile Dysfunction; Mental Impairment; Muscle Spasms; Off Label Use; Panic Disorder; Product Use In Unapproved Indication	Rispolept		S	Unknown	3 Weeks Ago From The Time Of Report.	Not Reported
	Valproic Acid		S	Unknown	3 Weeks Ago From The Time Of Report.	Not Reported
	Cipralex		S	Unknown	3 Weeks Ago From The Time Of Report.	Not Reported
	Neuromultivit		S	Unknown	3 Weeks Ago From The Time Of Report.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12602861	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016355784		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Overdose; Toxicity To Various Agents	Xanax			S	Oral	15 Mg, Single		Pfizer
	Seroplex			S	Oral	20 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12603297	EXPEDITED (15-DAY)		OT	IT-WATSON-2016-15833		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Zolpidem (Unknown)			S	Oral	20 Df, Total		Watson
	Mirtazapine (Unknown)			S	Oral	20 Df, Total		Actavis
	Sertraline (Unknown)			S	Oral	25 Df, Total		Watson
	Escitalopram (Unknown)			S	Oral	10 Gtt Drop(S), Total		Not Reported
	Samyr /00882301/			S	Oral	1 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12604738	EXPEDITED (15-DAY)		HO	FR-FRI-1000086499		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Jaundice	Escitalopram			S	Oral	10 Mg		Forest

	Voltaren Lp	S	Oral	150 Mg		Not Reported
	Seresta	S	Oral	25 Mg		Not Reported
	Altim//Cortivazol	S	Intra-articular	Daily Dose Not Reported		Not Reported
	Naprosyne	S	Oral	Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12604781	EXPEDITED (15-DAY)		HO	FR-FRI-1000086500		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Persecutory Delusion	Escitalopram			S	Oral			Forest
	Kardegic			C	Unknown	Daily Dose Not Reported		Not Reported
	Ramipril			C	Unknown	Daily Dose Not Reported		Not Reported
	Nebivolol			C	Unknown	Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	9786252	EXPEDITED (15-DAY)		OT	US-FRI-S03-USA-03330-01		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Back Pain; Balance Disorder; Blindness Unilateral; Chills; Corneal Oedema; Corneal Opacity; Diarrhoea; Diplopia; Drooling; Dyskinesia; Ecchymosis; Fall; Flatulence; Gastrooesophageal Reflux Disease; Hallucination, Visual; Headache; Hyperhidrosis; Hypoaesthesia Oral; Joint Swelling; Nausea; Neuralgia; Nightmare; Off	Lexapro			S	Oral	10mg		Forest
	Lexapro			S				Forest
	Inderal			C		60mg		Not Reported
	Premarin			C		0.3mg		Not Reported
	Valium			C		5mg		Not Reported
	Tylenol			C				Not Reported

Label Use; Ophthalmoplegia; Pain In Extremity; Palpitations; Paraesthesia; Pruritus Generalised; Restless Legs Syndrome; Retinal Aneurysm; Skin Lesion; Visual Impairment; Vitreous Floaters

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12579615	EXPEDITED (15-DAY)		OT	US-FRI-1000086160			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Chills; Decubitus Ulcer; Diplopia; Dyskinesia; Headache; Pain In Extremity; Palpitations; Retinal Aneurysm; Vision Blurred	Lexapro			S	Oral	10mg		Forest
	Inderal			C				Not Reported
	Valium			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12605774	EXPEDITED (15-DAY)		OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-121003		34 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Drug Interaction; Sleep-Related Eating Disorder	Zolpidem			S	Unknown	Unk		Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12605863	EXPEDITED (15-DAY)		OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-121048		35 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Drug Interaction; Sleep-Related Eating Disorder; Somnambulism	Zolpidem			S	Unknown	Unk		Sun
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12606368	EXPEDITED (15-DAY)		OT	HR-CIPLA LTD.-2016HR09985			Unknown	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; No Adverse Event; Suicide Attempt	Escitalopram			S	Oral	140 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12608565	EXPEDITED (15-DAY)		HO, OT	CA-BAUSCH-BL-2016-018256		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Bupropion			S	Unknown			Not Reported
	Primidone			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Phenytoin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12609579	DIRECT	Y	OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hypersomnia; Increased Appetite; Product Substitution Issue	Escitalopram 10 Mg Unknown			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12609617	DIRECT		HO			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Driving Ability; Road Traffic Accident; Seizure	Escitalopram 10 Mg, 10 Mg Lupin Pharmacy			S	Oral	90 Tablet(S) In The Morning Taken By Mouth		Lupin
	Omeprazole, 20 Mg Zydus			S	Oral	90 Capsule(S) In The Morning Taken By Mouth		Zydus Pharm
	Multi Vitamin			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Vitamin B3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12610410	DIRECT		OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Eye; Eye Pain; Vitreous Floaters	Escitalopram 10mg			S	Oral	10 Mg 90 Tablets Once A Day Taken By Mouth		Not Reported
	Bisoprl/Hctz			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Nabumetone			C				Not Reported
	Progesterone			C				Not Reported
	Estradiol			C				Not Reported
	Zantac			C				Not Reported
	Testosterone Cream 2%			C				Not Reported
	Melatonin			C				Not Reported
	Vit D3			C				Not Reported
	Multi Vitamin			C				Not Reported
	B-12			C				Not Reported
	Proomega			C				Not Reported
	Efa			C				Not Reported
	Epa			C				Not Reported
	Dha			C				Not Reported
	Probiotic			C				Not Reported
	Cranberry			C				Not Reported
	Coq10			C				Not Reported

	Calcium	C	Not Reported
	Milk Thistle	C	Not Reported
	Slo-Niacin	C	Not Reported
	Aspirin	C	Not Reported
	Dhea	C	Not Reported
	Lutein	C	Not Reported
	Selenium	C	Not Reported
	Folic Acid	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12083021	NON-EXPEDITED			US-PFIZER INC-2016078048		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Promethazine Hcl			S		Unk		Unknown
	Cortisone			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Methotrexate			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Leucovorin Calcium			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Aciphex			S		Unk		Not Reported
	Carafate			S		Unk		Not Reported
	Ambien			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Hctz			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

	Mobic	S	Unk	Not Reported
	Buspar	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported
	Paxil	S	Unk	Not Reported
	Prilosec	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported
	Keflex	S	Unk	Not Reported
	Amitiza	S	Unk	Not Reported
	Align	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12591776	EXPEDITED (15-DAY)		OT	AU-LUPIN PHARMACEUTICALS INC.-2016-03261		35 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Drug Interaction; Sleep-Related Eating Disorder; Somnambulism	Zolpidem			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Zolpidem			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12609272	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2016M1030836			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S	Unknown			Not Reported
	Diazepam			C	Unknown			Mylan
	Lorazepam			C	Unknown			Mylan
	Zolpidem			C	Unknown			Mylan
	Fexofenadine			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12609938	EXPEDITED (15-DAY)		HO, LT	CA-LUPIN PHARMACEUTICALS INC.-2016-03331		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Serotonin Syndrome	Bupropion			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Phenytoin			S	Unknown			Not Reported
	Primidone			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12610580	EXPEDITED (15-DAY)		HO, OT	CA-ACTAVIS-2016-16766		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Bupropion Hydrochloride (Unknown)			S	Unknown	Unk		Actavis
	Escitalopram (Unknown)			S	Unknown	Unk		Not Reported
	Olanzapine (Unknown)			S	Unknown	Unk		Not Reported
	Phenytoin (Amallc)			S	Unknown	Unk		Actavis Mid Atlantic
	Primidone (Watson Laboratories)			S	Unknown	Unk		Watson
	Quetiapine (Unknown)			S	Unknown	Unk		Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611266	EXPEDITED (15-DAY)		HO, OT	CN-FRI-1000086531		15 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue; Systemic Lupus Erythematosus; Tic	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12614442	DIRECT	Y				152 DAY	Male	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Product Substitution Issue	Escitalopram, 20mg Cipla			S	Oral			Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12456801	EXPEDITED (15-DAY)		HO	FR-FRI-1000085207		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dehydration; Diarrhoea; Fatigue; Hyponatraemia; Renal Failure; Vomiting	Escitalopram			S	Oral	5 Mg		Forest
	Paclitaxel Hospira			S	Intravenous (not otherwise specified)	60 Mg/M2		Not Reported
	Hydrochlorothiazide			S	Oral	1 Df		Not Reported
	Telmisartan			S	Oral	1 Df		Not Reported
	Hept A Myl			S	Oral	3 Df		Not Reported
	Zopiclone			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12605571	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-121005		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Zolpidem			S	Oral	20 Df Total		Sun
	Mirtazapine			S	Oral	20 Df Total		Sun
	Sertraline			S	Oral	25 Df Total		Sun
	Escitalopram			S	Oral	10 Gtt Total		Not Reported
	Samyr 400 Mg			S	Oral	1 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12612893	EXPEDITED (15-DAY)		HO, OT	CA-ALEMBIC PHARMACUETICALS LIMITED-2016SCAL000621			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Quetiapine Fumarate			S		Unk		Alembic
	Olanzapine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Phenytoin			S		Unk		Not Reported
	Primidone			S		Unk		Not Reported
	Bupropion			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12613166	EXPEDITED (15-DAY)		HO, OT	CA-PAR PHARMACEUTICAL COMPANIES-2016SCPR015669			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Drug Interaction; Overdose; Serotonin Syndrome	Bupropion Hcl Xl			S	Unknown	Unk, Unknown		Par
	Olanzapine			S	Unknown	Unk, Unknown		Par
	Cyproheptadine			S	Unknown	Unk, Unknown		Par
	Clonidine			S	Unknown	Unk Unk, Unknown		Par
	Dexmedetomidine Hydrochloride			S	Unknown	Unk Unk, Unknown		Par
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported
	Phenytoin			S	Unknown	Unk, Unknown		Not Reported
	Primidone			S	Unknown	Unk, Unknown		Not Reported
	Quetiapine			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12613451	EXPEDITED (15-DAY)		HO, LT, OT	CA-MACLEODS PHARMACEUTICALS			Unknown	CAN

US LTD-
MAC2016002958

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Arrhythmia; Communication Disorder; Condition Aggravated; Confusional State; Delirium; Drug Interaction; Hyperhidrosis; Hyperreflexia; Hyperthermia; Mental Status Changes; Muscle Rigidity; Myoclonus; Overdose; Serotonin Syndrome; Toxicity To Various Agents; Tremor	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Olanzapine			S	Unknown	Unk		Macleods
	Quetiapine			S	Unknown	Unk		Macleods
	Phenytoin			S	Unknown	Unk		Not Reported
	Primidone			S	Unknown	Unk		Not Reported
	Bupropion			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12614114	EXPEDITED (15-DAY)		OT	SK-FRI-1000086553		74 YR	Unknown	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Haemorrhage	Escitalopram			S	Unknown			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12614118	EXPEDITED (15-DAY)		HO	FR-FRI-1000086580		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Toxicity To Various Agents	Escitalopram			S	Oral			Forest
	Xanax			S	Oral	30 Tablets Taken At Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12616703	EXPEDITED (15-DAY)		OT	DE-FRI-1000086532		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Bruxism; Derealisation; Dizziness; Feeling Of Despair; Insomnia; Muscle Twitching; Nausea; Panic Reaction; Withdrawal Syndrome	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral			Forest
	Elontril			C	Unknown			Not Reported
	Zopiclin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12617186	EXPEDITED (15-DAY)		OT	FR-ZYDUS-011751		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Interaction; Drug-Induced Liver Injury; Eosinophilia; Hepatocellular Injury; Influenza Like Illness; Liver Function Test Abnormal	Escitalopram			S	Unknown			Zydus Pharm
	Chlorpromazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12617219	EXPEDITED (15-DAY)		OT	FR-ROCHE-1807062		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Rivotril			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported
	Adepal			S	Oral			Not Reported
	Noctamide			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12618451	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2016GSK109401		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Arrhythmia; Clonus; Cognitive Disorder; Condition Aggravated; Confusional State; Delirium; Device Related Sepsis; Drug Interaction; Hyperhidrosis; Hyperreflexia; Hyperthermia; Incoherent; Muscle Rigidity; Myoclonus; Overdose; Pneumonia; Serotonin Syndrome; Tachycardia; Toxicity To Various Agents; Tremor	Bupropion			S				Glaxosmithkline
	Escitalopram			S				Glaxosmithkline
	Olanzapine			S				Glaxosmithkline
	Phenytoin			S				Glaxosmithkline
	Quetiapine			S				Glaxosmithkline
	Primidone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12619452	EXPEDITED (15-DAY)		HO	CA-UNICHEM LABORATORIES LIMITED-UCM201608-000167		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Intentional Overdose; Potentiating Drug Interaction; Serotonin Syndrome; Toxicity To Various Agents	Quetiapine			S				Unichem
	Bupropion			S				Not Reported
	Escitalopram			S				Not Reported
	Olanzapine			S				Not Reported
	Phenytoin			S				Not Reported
	Primidone			S				Not Reported
	Dexmedetomidine			C				Not Reported
	Clonidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12619812	EXPEDITED (15-DAY)		HO	CH-FRI-1000086637		61 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenal Ulcer; Haematemesis	Escitalopram Oral Solution			S	Oral			Forest
	Marcourmar/Phenprocoumon			S	Oral	3 Mg		Not Reported
	Bilol/Bisoprolol Fumarate			C	Oral			Not Reported
	Bioflorin/Enterococcus Faecalis			C	Unknown			Not Reported
	Amlodipin Actavis/Amlodipine Besilate			C	Unknown			Not Reported
	Imodium Akut/Loperamide Hydrochlorid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12619818	EXPEDITED (15-DAY)		HO	IL-FRI-1000086581		79 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hepatic Function Abnormal	Escitalopram			S	Unknown			Forest
	Eliquis 5mg (Apixaban)			S		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12621200	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Feeling Abnormal; Product Formulation Issue; Product Substitution Issue; Toxicity To Various Agents	Escitalopram, 10 Mg			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12554652	EXPEDITED (15-DAY)		OT	CH-FRI-1000086040		75 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebral Ischaemia; Extrapyramidal Disorder; Tremor	Escitalopram Oral Solution		S	Oral	5 Mg	Forest
	Surmontil		S	Oral	12 Mg	Not Reported
	Zolpidem		C	Unknown	5 Mg Per Os/Each 1 - 2 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12622936	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20160800910		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Risperdal			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported
	Adepal			S	Oral	1 During The Menstrual Cycle, For Contraception		Not Reported
	Noctamide			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12623494	EXPEDITED (15-DAY)		HO	CN-FRI-1000086558		45 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Abnormal; Product Use In Unapproved Indication	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral			Forest
	Risperdal			S	Oral	4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12623514	EXPEDITED (15-DAY)		OT	IT-ECLAT PHARMACEUTICALS-2016ECL00019		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Product Misuse; Intentional Self-Injury	Pariet	S	Oral	Unk		Eclat
	Levosulpiride	S	Oral	Unk		Not Reported
	En	S	Oral	Unk		Not Reported
	Entact	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12627119	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2016369507		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Adepal			S	Oral	1 Df, Daily		Pfizer
	Theralene			S	Oral	20 Mg, 1x/Day		Not Reported
	Noctamide			S	Oral	1 Mg, 1x/Day		Not Reported
	Risperdal			S	Oral	4 Mg, 1x/Day		Not Reported
	Seresta			S	Oral	50 Mg, 1x/Day		Not Reported
	Rivotril			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12627212	EXPEDITED (15-DAY)		HO	FR-SA-2016SA139032		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Epistaxis; Melaena	Kardegic			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Clopidogrel Bisulfate			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Bisoprolol			C				Not Reported
	Amlodipine			C				Not Reported
	Furosemide			C				Not Reported
	Simvastatin			C				Not Reported
	Lansoprazole			C				Not Reported
	Xatral Lp			C				Not Reported
	Doliprane			C				Not Reported

	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12627214	EXPEDITED (15-DAY)		HO	FR-SA-2016SA139036		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Epistaxis; Melaena	Kardegic			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Clopidogrel Bisulfate			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Lansoprazole			C	Unknown			Not Reported
	Xatral Lp			C	Unknown			Not Reported
	Doliprane			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12628642	DIRECT		HO			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia	Escitalopram, 10 Mg			S	Oral			Not Reported
	Caffeine			C				Not Reported
	Gabapentin			C				Not Reported
	Pyidostigmine			C				Not Reported
	Ranitidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12628933	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depression; Drug Ineffective; Insomnia; Product Substitution Issue	Escitalopram, 20mg Cipla			S	Oral			Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12628451	EXPEDITED (15-DAY)		CA, OT	US-CIPLA LTD.-2016US16994			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12628509	EXPEDITED (15-DAY)		CA, OT	US-CIPLA LTD.-2016US16993			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12628746	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-042925		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome	Escitalopram			S				Accord
	Quetiapine			S				Accord
	Bupropion/Bupropion Hydrochloride			S				Not Reported
	Olanzapine			S				Not Reported
	Phenytoin			S				Not Reported
	Primidone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12629618	EXPEDITED (15-DAY)		HO	FR-FRI-1000086672		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram			S	Oral	5 Mg		Forest
	Previscan (Fluindione)			S	Oral	10 Mg		Not Reported
	Cardensiel			C	Unknown	1.25 Mg		Not Reported
	Lasilix			C	Unknown	80 Mg		Not Reported
	Lasilix			C	Unknown	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12629826	EXPEDITED (15-DAY)		LT	FR-FRI-1000086697		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke	Escitalopram			S	Oral			Forest
	Eliquis			S	Oral	10 Mg		Not Reported
	Crestor			C	Unknown			Not Reported
	Beta-2 Mimetic			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12635272	NON-EXPEDITED		OT	US-FRI-1000086747			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Seizure	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12635274	EXPEDITED (15-DAY)		HO	FR-FRI-1000086694			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction;	Escitalopram			S	Oral	10 Mg		Forest

Epistaxis; Melaena	Kardegic	S	Oral	75 Mg	Not Reported
	Clopidogrel Base	S	Oral	75 Mg	Not Reported
	Bisoprolol	C		1 Df	Not Reported
	Amlodipine	C		1 Df	Not Reported
	Furosemide	C		1 Df	Not Reported
	Simvastatin	C		1 Df	Not Reported
	Lansoprazole	C		1 Df	Not Reported
	Xatral Lp	C		1 Df	Not Reported
	Doliprane	C			Not Reported
	Methotrexate	C		5.71 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12473368	EXPEDITED (15-DAY)		DS	IT-FRI-1000085347		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Escitalopram			S	Unknown			Forest
	Quetiapine			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Sertraline			S	Unknown	50 Mg		Not Reported
	Sertraline			S	Unknown	200 Mg		Not Reported
	Sertraline			S	Unknown	50 Mg		Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12612603	EXPEDITED (15-DAY)		OT	US-JAZZ-2016-US-013950			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Exostosis;	Xyrem			S	Oral	2.25 G, Bid		Jazz

Fatigue; Weight Increased	Xyrem	S	Oral	Dose Adjustments		Jazz
	Xyrem	S	Oral	4.5 G, Bid		Jazz
	Lexapro	S				Not Reported
	Nuvigil	C		Unk		Not Reported
	Hydrocodone/Acetaminophen	C		Unk		Not Reported
	Levothyroxine	C		Unk		Not Reported
	Phentermine	C		Unk		Not Reported
	Advil	C		Unk		Not Reported
	Escitalopram	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12629800	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2016371590		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Nausea; Nervous System Disorder; Respiratory Distress; Vertigo; Wrong Product Administered	Lyrica			S	Oral	50 Mg, Unk		Pfizer
	Laroxyl			S	Oral	50 Drops		Not Reported
	Imurel			S	Oral	Unk		Not Reported
	Lansoprazole Mylan			S	Oral	15 Mg, Unk		Not Reported
	Calcidose Vitamine D			S	Oral	Unk		Not Reported
	Escitalopram Arrow			S	Oral	10 Mg, Unk		Not Reported
	Mytelase			S	Oral	Unk		Not Reported
	Clairyg			C	Intravenous (not otherwise specified)	0.4 G/Kg, Daily		Not Reported
	Lovenox			C	Subcutaneous	0.4 Ml, 1x/Day (In The Evening)		Not Reported
	Magnevie B6			C		2 Tablets, 3x/Day		Not Reported
	Folic Acid			C		5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12634222	EXPEDITED (15-DAY)		HO	CA-IMPAX LABORATORIES, INC-2016-IPXL-00838		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Intentional Overdose; Serotonin Syndrome	Bupropion Hydrochloride Sr			S	Unknown	Unk		Impax
	Phenytoin Chewable			S	Unknown	Unk		Corepharma
	Escitalopram			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Not Reported
	Primidone			S	Unknown	Unk		Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12636093	EXPEDITED (15-DAY)		CA, OT	US-CIPLA LTD.-2016US16987			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12636109	EXPEDITED (15-DAY)		CA, OT	US-CIPLA LTD.-2016US16980			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12636111	EXPEDITED (15-DAY)		CA, OT	US-CIPLA LTD.-2016US16989			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12636119	EXPEDITED (15-DAY)		CA, OT	US-CIPLA LTD.-2016US16999			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12636120	EXPEDITED (15-DAY)		CA, OT	US-CIPLA LTD.-2016US16995			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12636125	EXPEDITED (15-DAY)		CA, OT	US-CIPLA LTD.-2016US16998			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12636129	EXPEDITED (15-DAY)		CA, OT	US-CIPLA LTD.-2016US16996			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12636131	EXPEDITED (15-DAY)		CA, OT	US-CIPLA LTD.-2016US16992			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Escitalopram			S	Transplacental			Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12636718	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC-2016SUN00387		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Drug-Induced Liver Injury	Escitalopram			S	Unknown	10 Mg, Daily		Taro
	Diazepam			C				Not Reported
	Lorazepam			C				Not Reported
	Zolpidem			C				Not Reported
	Fexofenadine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12637031	EXPEDITED (15-DAY)		OT	FR-FRI-1000086761		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Nodosum	Escitalopram			S	Oral	1 Df		Forest
	Stresam			S	Oral	1 Df		Not Reported
	Leeloo			S	Oral	0.1 Mg/0.02 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12638798	EXPEDITED (15-DAY)		HO	FR-FRI-1000086763		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delusion; Hyponatraemia; Somnolence	Escitalopram			S	Oral	5 Mg		Forest
	Risperidone			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2016	9687412	EXPEDITED (15-DAY)		DE, HO	US-RANBAXY-2013US-75060		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Cardiac Arrest; Circulatory Collapse; Overdose; Pulseless Electrical Activity	Ibuprofen		Y	S	Unknown	Unk		Ranbaxy
	Escitalopram			S	Unknown	Unk		Not Reported
	Quetiapine			S	Unknown	Unk		Sun
	Bupropion			S	Unknown	Unk		Not Reported
	Desvenlafaxine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2016	12640082	EXPEDITED (15-DAY)		OT	US-FRI-1000086664		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Lexapro			S	Oral			Forest
	Humira			S	Subcutaneous	40mg/0.8ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2016	12640730	EXPEDITED (15-DAY)		OT	FR-TEVA-681668ISR		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Nodosum	Leeloo 0,1 Mg/0,02 Mg			S	Oral	1 Dosage Form= 0.02 Mg Ethinylestradiol + 0.1 Mg Levonorgestrel		Duramed
	Stresam			S	Oral	1 Dosage Forms Daily;		Not Reported
	Seroplex			S	Oral	1 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2016	12641024	EXPEDITED (15-DAY)		HO, OT	CA-ALKEM LABORATORIES LIMITED-CA-ALKEM-		39 YR	Male	CAN

2016-00110

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Quetiapine Fumarate			S		Unknown		Alkem
	Olanzapine			S		Unknown		Alkem
	Bupropion			S		Unknown		Not Reported
	Escitalopram			S		Unknown		Not Reported
	Phenytoin			S		Unknown		Not Reported
	Primidone			S		Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2016	12641689	NON-EXPEDITED			US-ELI_LILLY_AND_COMPANY-US201608005099			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Nausea; Respiratory Tract Congestion; Throat Irritation; Vomiting	Zyprexa			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Humira			S	Subcutaneous	2 In 1 Once		Not Reported
	Trintellix			S	Unknown	Unk Unk, Unknown		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Lamictal			S	Unknown	Unk, Unknown		Not Reported
	Ativan			C	Unknown	Unk, Unknown		Not Reported
	Prilosec /00661201/			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2016	12642456	EXPEDITED (15-DAY)		DE, HO	FR-PFM-FR-2016-2359		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Death; Prinzmetal Angina	Navelbine			S	Intravenous (not otherwise specified)	Unk		Pierre Fabre Medicament

Carboplatine	S	Intravenous (not otherwise specified)	Unk		Not Reported
Amlodipine	S	Oral	Unk		Not Reported
Bi-Tildiem	S	Oral	Unk		Not Reported
Cortancyl	S	Oral	Unk		Not Reported
Eupantol	S	Oral			Not Reported
Hydroxyzine	S	Oral	Unk		Not Reported
Zophren	S	Oral	Unk		Not Reported
Oxycodone	S	Oral			Not Reported
Seroplex	S	Oral			Not Reported
Colchicine	C	Unknown			Not Reported
Natispray	C	Unknown			Not Reported
Morphine	C	Unknown			Not Reported
Inexium	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2016	12504427	EXPEDITED (15-DAY)		OT	JP-FRI-1000085659		45 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Erythema; Pain In Extremity	Lexapro			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2016	12622013	EXPEDITED (15-DAY)		HO	FR-FRI-1000086555		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Multiple Fractures; Pneumothorax Traumatic; Road Traffic Accident; Subcutaneous Emphysema	Escitalopram			S	Oral			Forest
	Lysanxia			S	Oral			Not Reported
	Levothyrox			C	Unknown	125 Mcg		Not Reported
	Inexium			C	Unknown	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2016	12644638	EXPEDITED (15-DAY)		HO, OT	DE-IMPAX LABORATORIES, INC-2016-IPXL-00847		76 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Galantamine Hydrobromide Er			S	Unknown	8 Mg, Unk		Impax
	Galantamine Hydrobromide Er			S	Unknown	16 Mg, Unk		Impax
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2016	12648767	NON-EXPEDITED			US-PFIZER INC-2016379981			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Citalopram			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Oxybutynin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2016	12648971	EXPEDITED (15-DAY)		HO	CH-BAYER-2016-149753		82 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pyrexia; Serotonin Syndrome	Ciprofloxacin			S	Oral	Unk, Every Week		Bayer
	Cipralex			S	Oral	20 Mg, Qd		Not Reported
	Duodart			C	Oral	1 Df, Qd		Not Reported
	Enalapril			C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2016	12649338	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2016M1032982			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Medication Error; Nausea; Respiratory Distress; Vertigo	Mylan-Lansoprazole			S	Oral	15 Mg, Unk		Mylan
	Laroxyl			S	Oral	50 Gtt, Unk		Mylan
	Lyrica			S	Oral	50 Mg, Unk		Mylan
	Imurel /00001501/			S	Oral	Unk		Mylan
	Calcidose /07357001/			S	Oral	Unk		Mylan
	Escitalopram Arrow			S	Oral	10 Mg, Unk		Mylan
	Mytelase			S	Oral	Unk		Mylan
	Vitamin D3			S	Oral	Unk		Mylan
	Clairyg			C	Intravenous (not otherwise specified)	Unk Unk, Qd		Mylan
	Lovenox			C	Subcutaneous	0.4 Ml, Qd		Mylan
	Magnevie B6			C		2 Df, Tid		Mylan
	Folic Acid			C		5 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2016	12448146	EXPEDITED (15-DAY)		HO, OT	US-TEVA-664092USA		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Muscle Twitching; Neuroleptic Malignant Syndrome; Overdose	Lamotrigine			S	Oral	150 Milligram Daily;		Teva
	Geodon			S	Oral			Not Reported
	Lexapro			S	Oral	20 Milligram Daily;		Not Reported
	Lexapro			S				Not Reported
	Alprazolam			S	Oral	1.5 Milligram Daily; As Needed		Not Reported
	Zolpidem			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2016	12650435	EXPEDITED (15-DAY)		OT	FR-ROCHE-1810975		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Thrombocytopenia	Rivotril	S	Intravenous (not otherwise specified)		Not Reported
	Valium	S	Oral		Not Reported
	Xeroquel	S	Oral		Not Reported
	Xeroquel	S	Oral		Not Reported
	Loxapac	S	Intravenous (not otherwise specified)		Not Reported
	Seroplex	S	Oral		Not Reported
	Lepticur	S	Oral		Not Reported
	Seresta	S	Oral		Not Reported
	Aotal	S	Oral		Not Reported
	Temesta (France)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2016	12651151	NON-EXPEDITED		OT	US-JAZZ-2016-US-005360		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Paraesthesia; Somnolence	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S				Not Reported
	Zoloft			S				Not Reported
	Neurontin			C		Unk		Not Reported
	Nordette-28			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2016	12654153	DIRECT		DS			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Asthenia; Balance Disorder; Dizziness; Ear Pain;	Escitalopram, 10 Mg			S	Oral			Forest
	Estrogens			C				Not Reported
	Fish Oil			C				Not Reported

Fatigue; Feeling Abnormal; Gait Disturbance; Headache; Hypoaesthesia; Impaired Work Ability; Memory Impairment; Nerve Injury; Paraesthesia; Paraesthesia; Paraesthesia; Paraesthesia Oral; Paraesthesia Oral; Pharyngeal Paraesthesia; Tremor; Vision Blurred	Women'S Multi-Vitamin	C		Not Reported
	Magnesium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2016	12654688	DIRECT		LT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Menorrhagia	Lexapro (Escitalopram)			S	Oral	1 Pill Once A Day By Mouth		Costco
	Metoprolol			C				Not Reported
	Hectorol			C				Not Reported
	Epogen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12629921	EXPEDITED (15-DAY)		OT	DE-FRI-1000086680		42 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dysuria; Increased Appetite; Malaise; Micturition Disorder; Micturition Urgency; Muscular Weakness; Nausea; Paraesthesia; Product Use In Unapproved Indication; Pruritus; Sexual Dysfunction; Somnolence;	Escitalopram			S	Oral	10 Mg		Forest

Tremor; Urinary Retention; Urticaria; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12654020	EXPEDITED (15-DAY)		OT	US-ACCORD-043050		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Somnolence; Violence-Related Symptom	Escitalopram			S		Started At 10 Mg, 20 Mg Pill To Reach Prescribed Doses		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12654445	EXPEDITED (15-DAY)		OT	GB-FRI-1000086835			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Diarrhoea	Escitalopram			S	Oral	5 Mg Daily		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12656508	NON-EXPEDITED			US-TAKEDA-2016TUS013973			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Respiratory Tract Congestion; Throat Irritation; Vomiting	Trintellix			S	Unknown	Unk		Takeda
	Humira			S	Subcutaneous	Unk Unk, Qd		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Ativan			C		Unk		Not Reported
	Prilosec /00661201/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12657164	EXPEDITED (15-DAY)		HO, OT	FR-ASTRAZENECA-2016SE87089		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Thrombocytopenia	Xeroquel			S	Oral	1.0df Once/Single Administration		Astrazeneca
	Xeroquel			S	Oral	Once/Single Administration		Astrazeneca
	Rivotril			S	Intravenous (not otherwise specified)	1.0df Once/Single Administration		Not Reported
	Valium			S	Oral			Not Reported
	Loxapac			S	Intravenous (not otherwise specified)	2.0df Once/Single Administration		Not Reported
	Seroplex			S	Oral			Not Reported
	Lepticur			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Aotal			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2016	12474968	EXPEDITED (15-DAY)		HO, OT	AU-ACCORD-041674		66 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning	Escitalopram			S				Accord
	Perindopril/Perindopril Erbumine			S				Not Reported
	Atenolol/Atenolol Hydrochloride			S				Not Reported
	Rosuvastatin/Rosuvastatin Calcium			S				Not Reported
	Lercanidipine			S				Not Reported
	Pantoprazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2016	12658186	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2016-03496			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Malaise	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2016	12660266	NON-EXPEDITED			US-FRI-1000078695		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Celexa			S				Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	10742763	EXPEDITED (15-DAY)		OT	CA-FRI-1000073858		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatitis C; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Gamma-Glutamyltransferase Increased; Lymphocyte Morphology Abnormal	Escitalopram			S	Oral			Forest
	Buprenorphine Hydrochloride/Naloxone Hydrochloride			S	Sublingual	8 Mg		Not Reported
	Buprenorphine Hydrochloride/Naloxone Hydrochloride			S	Sublingual	12 Mg		Not Reported
	Diazepam			S	Oral			Not Reported
	Oxazepam			S	Sublingual			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12405467	EXPEDITED (15-DAY)		HO	JP-FRI-1000084906		60 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Loss Of Consciousness	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral			Forest
	Ecard			S	Oral			Not Reported

Atorvastatin	C	Oral		Not Reported
Myslee	C	Oral		Not Reported
Depas (Etizolam)	C	Oral		Not Reported
Rize	C	Oral		Not Reported
Zolpidem Tartrate	C	Oral		Not Reported
Lexotan	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12505288	EXPEDITED (15-DAY)		OT	JP-FRI-1000085688		50 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sinus Bradycardia	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	20 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Not Reported
	Escitalopram			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12662945	NON-EXPEDITED			US-TAKEDA-2016TUS014280			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Libido Decreased	Brintellix			S	Unknown	Unk		Takeda
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12665672	NON-EXPEDITED			US-FRI-1000085631			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celexa			S				Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12666033	NON-EXPEDITED			US-JAZZ-JPI-P-006566		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Blood Pressure Increased; Depression; Insomnia; Somnolence; Weight Increased	Xyrem			S	Oral	2.5 G, Bid		Jazz
	Xyrem			S	Oral	3.5 G, Qd		Jazz
	Xyrem			S	Oral	3 G, Qd		Jazz
	Xyrem			S	Oral	4 G, Bid		Jazz
	Aripiprazole			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Ciclesonide			C	Respiratory (inhalation)			Not Reported
	Dextroamphetamine			C				Not Reported
	Dextroamphetamine			C				Not Reported
	Pramipexole			C				Not Reported
	Pramipexole			C				Not Reported
	Citalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12666409	EXPEDITED (15-DAY)		OT	ZA-FRI-1000086853		3 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder; Facial Paralysis; Foetal Exposure During Pregnancy; Muscle Contractions Involuntary	Escitalopram			S	Transplacental			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12666410	EXPEDITED (15-DAY)		DS, HO, LT	SE-FRI-1000086893		41 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Epilepsy; Muscle Spasms	Escitalopram	S	Unknown	High Dose Which Was Decreased Last Year	Forest
	Perphenazine	C	Unknown		Not Reported
	Haldol	C	Unknown		Not Reported
	Abilify	C	Unknown		Not Reported
	Stesolid	C	Unknown		Not Reported
	Risperdal	C	Unknown		Not Reported
	Voxra	C	Unknown		Not Reported
	Sobril	C	Unknown		Not Reported
	Nozinan	C	Unknown		Not Reported
	Zyprexa	C	Unknown		Not Reported
	Atarax	C	Unknown		Not Reported
	Xanor	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12666412	EXPEDITED (15-DAY)		HO	KR-FRI-1000086892		33 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Product Use In Unapproved Indication	Escitalopram			S	Oral	2.5 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12667262	DIRECT		DS			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Disease Recurrence; Drug Ineffective; Product Substitution Issue	Escitalopram Oxalate Oral Sol'N, 5 Mg Camber Pharmaceuticals, Inc			S	Oral	2 Teaspoon		Camber
	Centrum Silver Multivitamin			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12666498	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2016US08309			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Condition Aggravated; Drug Ineffective; Galactorrhoea; Hypersexuality; Vision Blurred	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen
	Sertraline			S	Unknown	Unk		Invagen
	Sertraline			S				Invagen
	Venlafaxine			S	Unknown	75 Mg, Qd		Cipla
	Venlafaxine			S	Unknown	37.5 Mg, Qd		Cipla
	Buspirone			S	Unknown	Unk		Not Reported
	Buspirone			S				Not Reported
	Paroxetine			S	Unknown	Unk		Not Reported
	Paroxetine			S				Not Reported
	Clonazepam			C	Unknown	0.25 Mg, Prn		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			C	Unknown	Unk		Not Reported
	Fluticasone			C	Unknown	Unk		Not Reported
	Albuterol			C	Unknown	Unk		Not Reported
	Budesonide/Formoterol			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12666719	NON-EXPEDITED			US-TAKEDA-2016TUS014194			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Off Label Use; Paraesthesia	Brintellix			S	Unknown	10 Mg, Unk		Takeda
	Elicea /01588501/			S	Unknown	2.5 Mg, Unk		Not Reported
	Elicea /01588501/			S	Unknown	5 Mg, Unk		Not Reported
	Elicea /01588501/			S	Unknown	7.5 Mg, Unk		Not Reported

	Elicea /01588501/		S	Unknown	10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12667569	NON-EXPEDITED			US-TAKEDA-2016TUS014274			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Dysstasia; Feeling Abnormal; Speech Disorder; Tremor	Brintellix			S	Unknown	5 Mg, Unk		Takeda
	Brintellix			S	Unknown	10 Mg, Unk		Takeda
	Brintellix			S	Unknown	20 Mg, Unk		Takeda
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12669861	EXPEDITED (15-DAY)		HO, LT	ZA-FRI-1000015964		83 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Hyperhidrosis; Hyperkalaemia; Hypertension; Psychotic Disorder; Pyrexia; Renal Failure; Rhabdomyolysis; Tachycardia	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S				Forest
	Rasagiline			S	Oral			Not Reported
	Tramacet			S	Oral	300 Mg		Not Reported
	Duragesic			S	Other	4.1667 Mcg		Not Reported
	Stalevo			S	Oral	500 Mg		Not Reported
	Celebrex			C	Oral	100 Mg		Not Reported
	Immovane			C	Oral	7.5 Mg		Not Reported
	Sinemet Cr			C	Oral	50/200 Mg A Day		Not Reported
	Calciferol [Ergocalciferol]			C		50,000 Iu/Mg Every Mon/Wed/Fri.		Not Reported
	Ocuvite Lutein			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12671153	DIRECT		HO, LT, OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Lexapro, 20 Mg			S	Oral	At Bedtime		Not Reported
	Multiple Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2016	12671512	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2016-10372		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Respiratory Distress; Vertigo; Wrong Patient Received Product	Escitalopram Arrow			S	Oral	10 Mg, Unk		Aurobindo
	Laroxyl			S	Oral	50 Drops		Not Reported
	Imurel /00001501/			S	Unknown	Unk		Not Reported
	Lansoprazole Mylan			S	Oral	15 Mg, Unk		Not Reported
	Calcidose Vitamine D			S	Oral	Unk		Not Reported
	Mytelase			S	Oral	Unk		Not Reported
	Lyrica			S	Oral	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2016	12672075	EXPEDITED (15-DAY)		DE, HO, LT	CH-JNJFOC-20160813272		60 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Drug Level Increased; Inhibitory Drug Interaction; Sinus Node Dysfunction; Upper Gastrointestinal Haemorrhage	Imbruvica			S	Oral			Not Reported
	Amiodarone			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Nebivolol			C	Oral			Not Reported
	Ramipril			C	Oral			Not Reported
	Eplerenone			C	Oral			Not Reported
	Atorvastatin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2016	12673653	EXPEDITED (15-DAY)		HO, OT	AU-TEVA-2016-15379		66 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning	Escitalopram (Unknown)			S	Unknown	10 Milligram Daily;		Ivax
	Atenolol			S	Unknown			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Pantoprazole (Unknown)			S	Unknown			Teva
	Perindopril (Unknown)			S	Unknown			Not Reported
	Lercanidipine (Unknown)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	10892989	EXPEDITED (15-DAY)		CA, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-013971		238 DAY	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Aortic Anomaly; Foetal Exposure During Pregnancy; Premature Baby; Pulmonary Valve Stenosis; Ventricular Septal Defect	Abilify			S	Transplacental	Unk Unk, Qd		Bristol Myers Squibb
	Dihydroergotamine			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported
	Oxazepam			S	Transplacental	Unk		Not Reported
	Pipamperone			S	Transplacental	Unk		Not Reported
	Loprazolam			S	Transplacental	Unk		Not Reported
	Dipotassium Clorazepate			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	11968404	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-17035734			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Presentation; Foetal Exposure During	Abilify			S	Transplacental	15 Mg, Qd		Bristol Myers Squibb

Pregnancy	Cipralex	S	Transplacental	20 Mg, Qd		Not Reported
	Temesta (Lorazepam)	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12046834	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2012-000050		28 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Live Birth; Maternal Exposure During Pregnancy; Off Label Use	Abilify			S	Oral	15 Mg, Qd		Bristol Myers Squibb
	Cipralex			S	Oral	20 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12675086	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2016003009			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Diarrhoea	Escitalopram 5mg Tablet			S	Oral	5 Mg, Qd (Daily)		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12675771	NON-EXPEDITED		OT	US-JAZZ-2016-US-006684		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Plaquenil			C		Unk		Not Reported
	Mirtazapine			C		Unk		Not Reported
	Quasense			C		Unk		Not Reported
	Xanax			C		Unk		Not Reported

Probiotic	C	Unk	Not Reported
Olux	C	Unk	Not Reported
Desonide	C	Unk	Not Reported
Cyclobenzaprine	C	Unk	Not Reported
Synthroid	C	Unk	Not Reported
Ambien	C	Unk	Not Reported
Ferrous Gluconate	C		Not Reported
Lexapro	S		Not Reported
Mirapex	C	Unk	Not Reported
Multivitamins Plus Iron	C	Unk	Not Reported
Nuvigil	C		Not Reported
Relpax	C		Not Reported
Seasonique	C	0.15-0.03-0.01	Not Reported
Valpax	C		Not Reported
Iron	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12676448	EXPEDITED (15-DAY)		OT	IE-TEVA-684431ACC			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Feeling Abnormal; Headache; Lethargy; Slow Speech; Somnolence; Speech Disorder; Thinking Abnormal; Thirst	Escitalopram Teva			S	Oral			Ivax
	Eltroxin			C		50mg Mon-Fri, 100mg Sat-Sun		Not Reported
	Eltroxin			C		50mg Mon-Fri, 100mg Sat-Sun		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12676480	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2016GSK115859			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Nausea; Respiratory Tract Congestion; Throat	Lamictal			S		Unk Unk, U		Glaxosmithkline
	Humira Solution For Injection			S	Subcutaneous	2 In 1 Once		Not Reported

Irritation; Vomiting	Trintellix	S	Unk Unk, U		Not Reported
	Lexapro	S	Unk Unk, U		Not Reported
	Zyprexa	S	Unk Unk, U		Not Reported
	Ativan	C	Unk Unk, U		Not Reported
	Prilosec	C	Unk Unk, U		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12677222	NON-EXPEDITED			US-TAKEDA-2016TUS014301			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Nausea; Vomiting; Withdrawal Syndrome; Wrong Technique In Product Usage Process	Trintellix			S	Unknown	5 Mg, Unk		Takeda
	Trintellix			S	Unknown	20 Mg, Unk		Takeda
	Trintellix			S	Unknown	5 Mg, Unk		Takeda
	Trintellix			S	Unknown	2 Mg, Unk		Takeda
	Celexa /00582602/			S	Unknown	5 Mg, Unk		Not Reported
	Lexapro			S	Unknown	5 Mg, Unk		Not Reported
	Lexapro			S	Unknown	7 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12679239	DIRECT					49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Product Formulation Issue; Product Substitution Issue; Somnolence; Weight Increased	Escitalopram 10 Mg Tab, 10 Mg			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12679489	DIRECT	Y	RI			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Suicidal Ideation; Thinking Abnormal	Escitalopram	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	11876537	EXPEDITED (15-DAY)		OT	RO-JNJFOC-20151219642		71 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Drug Ineffective For Unapproved Indication; Extrapyramidal Disorder; Hallucination; Off Label Use	Risperdal			S	Unknown	For 2 Weeks		Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown	For 2 Weeks		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Diosminum			C	Unknown			Not Reported
	Betahistinum			C	Unknown			Not Reported
	Ginkgo Biloba			C	Unknown			Not Reported
	Acidum Valproicum			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12678995	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2016US17472			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12679935	NON-EXPEDITED		HO, OT	US-FRI-1000080356		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Rhabdomyolysis	Lexapro			S		15mg		Forest
	Mirtazapine			S		15mg		Not Reported
	Lipitor			C		10mg		Not Reported
	Seroquel			C				Not Reported
	Depakote			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680017	NON-EXPEDITED		HO	US-FRI-1000080537		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Suicidal Ideation	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680019	NON-EXPEDITED		OT	US-FRI-1000080427		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depression; Drug Ineffective; Fatigue; Gait Disturbance; Headache; Suicidal Ideation; Tremor	Lexapro			S	Oral			Forest
	Lexapro			S	Oral			Forest
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680020	NON-EXPEDITED		HO	US-FRI-1000080810		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S				Forest
	Blinded Ruxolitinib Or Placebo			S	Oral			Not Reported
	Capecitabine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680096	NON-EXPEDITED		OT	US-FRI-1000086227		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	0.5mg		Forest
	Rexulti			S				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680102	NON-EXPEDITED		OT	US-FRI-1000083654		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Intentional Self-Injury; Morbid Thoughts; Suicidal Behaviour; Unevaluable Event	Lexapro			S				Forest
	Rexulti			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680103	NON-EXPEDITED		OT	US-FRI-1000083578			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Intentional Product Misuse; Suicidal Ideation	Lexapro			S		20mg		Forest
	Lexapro			S		40mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680105	NON-EXPEDITED		HO	US-FRI-1000085455		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Depressed Mood; Headache; Off Label Use	Lexapro			S		10mg		Forest
	Flonase			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680120	EXPEDITED (15-DAY)		OT	US-FRI-1000086504			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Serotonin Syndrome	Escitalopram			S	Oral	10 Mg, Unk		Forest
	Trintellix			S	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680190	NON-EXPEDITED		HO	US-FRI-1000084522		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Intentional Overdose; Suicidal Ideation; Suicide Attempt	Lexapro			S	Oral			Forest
	Lexapro			S	Oral	50 Mg		Forest
	Lexapro			S		20 Mg		Not Reported
	Sertraline			S	Oral	100mg		Not Reported
	Seroquel			C		150mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680434	NON-EXPEDITED			US-FRI-1000079160		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Malaise; Mydriasis; Nausea	Lexapro			S	Oral	5mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680436	NON-EXPEDITED			US-FRI-1000079170			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral			Forest
	Lexapro			S				Forest

	Mirtazapine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680437	NON-EXPEDITED			US-FRI-1000079180			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680438	NON-EXPEDITED		HO	US-FRI-1000077975		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral			Forest
	Ipatasertib			S	Oral	Once A Day, 3 Weeks On, 1 Week Off		Not Reported
	Paclitaxel			S	Intravenous (not otherwise specified)	80 Mg/M2,Days 1, 8, And 15 Of 28 Day Cycle		Not Reported
	Baclofen			C	Oral			Not Reported
	Sinemet			C	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported
	Ergocalciferol			C	Oral			Not Reported
	Oxcarbazepine			C	Oral	Oxtellar Xr (Oxcarbazepine Extended-Release) (900 Mg)		Not Reported
	Oxycodone Hcl			C	Oral			Not Reported
	Famotidine			C	Oral			Not Reported
	Simvastatin			C	Oral			Not Reported
	Synthroid(Levothyroxine Sodium)			C	Oral			Not Reported
	Torsemide			C	Oral			Not Reported
	Triamterene			C	Oral			Not Reported
	Xanax			C	Oral			Not Reported

	Potassium Chloride			C	Oral	Other				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680479	NON-EXPEDITED			US-FRI-1000079202			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Insomnia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680480	NON-EXPEDITED			US-FRI-1000079388			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680504	NON-EXPEDITED			US-FRI-1000079503			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680578	NON-EXPEDITED			US-FRI-1000079524			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680583	NON-EXPEDITED			US-FRI-1000079504			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680649	NON-EXPEDITED			US-FRI-1000080063			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680650	NON-EXPEDITED			US-FRI-1000080057			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Somnolence	Lexapro			S		30mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680700	NON-EXPEDITED			US-FRI-1000080085			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Lexapro			S				Forest
	Xyrem			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680701	NON-EXPEDITED			US-FRI-1000080017			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myalgia; Off Label Use	Lexapro			S				Forest
	Lexapro			S				Forest
	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Ativan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680713	NON-EXPEDITED			US-FRI-1000079437			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Malaise	Escitalopram			S	Oral	20mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680714	NON-EXPEDITED			US-FRI-1000080234		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Oral	15mg		Forest
	Lexapro			S				Forest
	Tamoxifen			C	Oral			Not Reported
	Singulair			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681029	NON-EXPEDITED			US-FRI-1000081218		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681032	NON-EXPEDITED			US-FRI-1000080287			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681033	NON-EXPEDITED			US-FRI-1000080398			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Generalised; Urticaria	Lexapro			S		10mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681034	NON-EXPEDITED			US-FRI-1000080331			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681035	NON-EXPEDITED			US-FRI-1000080205			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Lexapro			S				Forest
	Lexapro			S				Forest
	Lexapro			S				Forest
	Zoloft			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681036	NON-EXPEDITED			US-FRI-1000080253			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681037	NON-EXPEDITED			US-FRI-1000080480		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Drug Ineffective; Headache; Malaise; Off Label Use; Withdrawal Syndrome	Lexapro			S	Oral	20mg		Forest
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681081	NON-EXPEDITED			US-TAKEDA-2016TUS014356			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cognitive Disorder; Drug Ineffective; Drug Tolerance; Emotional Poverty; Gait Disturbance; Lethargy; Limb Discomfort; Withdrawal Syndrome	Trintellix			S	Unknown	10 Mg, Unk		Takeda
	Trintellix			S	Unknown	20 Mg, Unk		Takeda
	Zoloft			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk		Not Reported
	Valium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681108	NON-EXPEDITED			US-FRI-1000081735		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Alopecia; Restless Legs Syndrome; Restlessness	Lexapro			S	Oral	20mg		Forest
	Lexapro			S				Forest
	Lexapro			S				Forest
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681109	NON-EXPEDITED			US-FRI-1000081656			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Headache; Paraesthesia; Product Dose Omission	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681138	NON-EXPEDITED			US-FRI-1000081772			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Insomnia	Lexapro	S		Forest
	Lexapro	S		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681139	NON-EXPEDITED			US-FRI-1000081757		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack	Lexapro			S				Forest
	Pristiq			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681140	NON-EXPEDITED			US-FRI-1000081811			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Decreased Appetite; Feeling Hot; Nausea	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681151	NON-EXPEDITED			US-FRI-1000082021			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral	20mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681157	NON-EXPEDITED			US-FRI-1000082154			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Dizziness; Nausea	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681165	NON-EXPEDITED			US-FRI-1000082002			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Libido Decreased	Lexapro			S		10mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681447	NON-EXPEDITED			US-FRI-1000080020			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Paranoia	Lexapro			S				Forest
	Xyrem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681448	NON-EXPEDITED			US-FRI-1000080095			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681449	NON-EXPEDITED			US-FRI-1000081858			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Intentional Product Misuse; Nightmare	Lexapro			S				Forest
	Lexapro			S				Forest
	Lexapro			S				Forest
	Lexapro			S				Forest
	Levothyroxine			C		50mcg		Not Reported
	Finasteride			C		5mg		Not Reported
	Prilosec			C				Not Reported
	Flomax			C		0.8mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681450	NON-EXPEDITED			US-FRI-1000079414			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Dizziness; Dry Mouth; Nausea; Product Dose Omission	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681451	NON-EXPEDITED			US-FRI-1000082529			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nightmare	Lexapro			S		15mg		Forest
	Lexapro			S		20mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681452	NON-EXPEDITED			US-FRI-1000080387			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681453	NON-EXPEDITED			US-FRI-1000080706			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681454	NON-EXPEDITED			US-FRI-1000079982			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Agitation;	Lexapro			S				Forest
Depression;	Lexapro			S				Not Reported
Hyperhidrosis; Insomnia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681455	NON-EXPEDITED			US-FRI-1000080879		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction	Lexapro			S	Oral	20mg		Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681456	NON-EXPEDITED			US-FRI-1000080267			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Sweats	Lexapro			S	Oral			Forest
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681457	NON-EXPEDITED			US-FRI-1000080462			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681458	NON-EXPEDITED			US-FRI-1000079567			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain; Eye Swelling; Insomnia; Swelling Face	Lexapro			S	Oral	10mg		Forest
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681459	NON-EXPEDITED			US-FRI-1000079946			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Lexapro			S					Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681464	NON-EXPEDITED			US-FRI-1000080578		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Lexapro			S				Forest
Feeling Abnormal;	Imuran			C				Not Reported
Intentional Product	Cimzia			C				Not Reported
Misuse; Pregnancy	Vitamin B12			C				Not Reported
	Entocort			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681467	NON-EXPEDITED			US-FRI-1000082320			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal;	Lexapro			S				Forest
Intentional Product Misuse	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681469	NON-EXPEDITED			US-FRI-1000082356			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681470	NON-EXPEDITED			US-FRI-1000081358			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nightmare	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681479	NON-EXPEDITED			US-FRI-1000082078		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Oral	10mg		Forest
	Lexapro			S	Oral	20mg		Forest
	Accutane			S				Not Reported
	Vyvanse			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681480	NON-EXPEDITED			US-FRI-1000081447		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681732	NON-EXPEDITED			US-FRI-1000081190			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Escitalopram			S	Oral	10mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681739	NON-EXPEDITED			US-FRI-1000081610			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Muscle Spasms; Palpitations; Tremor	Lexapro			S	Oral	10mg		Forest
	Lexapro			S	Oral	20mg		Forest
	Trazodone			C	Oral	100mg		Not Reported
	Trazodone			C				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681741	NON-EXPEDITED			US-FRI-1000082970			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Paraesthesia; Product Quality Issue; Product Quality Issue	Lexapro	S	Oral	20mg		Forest
	Lexapro	S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681742	NON-EXPEDITED			US-FRI-1000082790		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lexapro			S	Oral	10mg		Forest
	Birth Control Pill (Unspecified)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681743	NON-EXPEDITED			US-FRI-1000083097		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681744	NON-EXPEDITED			US-FRI-1000082938			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Somnolence	Lexapro			S		5mg		Forest
	Lexapro			S		10mg		Not Reported
	Lexapro			S		5mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681745	NON-EXPEDITED			US-FRI-1000083013		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Lexapro			S	Oral	5mg		Forest
	Nitrofurantoin			C				Not Reported

	Unspecified Statin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681746	NON-EXPEDITED			US-FRI-1000082195		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Weight Increased	Lexapro			S	Oral	10mg		Forest
	Lexapro			S	Oral	20mg		Forest
	Lexapro			S	Oral	30mg		Not Reported
	Lexapro			S	Oral	40mg		Not Reported
	Lithium			C	Oral			Not Reported
	Unspecified Vitamins			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681748	NON-EXPEDITED			US-FRI-1000083195		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vision Blurred	Lexapro			S	Oral	20mg		Forest
	Lexapro			S	Oral	10mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681751	NON-EXPEDITED			US-FRI-1000082878			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral	5mg		Forest
	Lunesta			C				Not Reported
	Otc Allergy Medications			C				Not Reported
	Nexium			C				Not Reported
	Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681752	NON-EXPEDITED			US-FRI-1000083363			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersomnia	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681753	NON-EXPEDITED			US-FRI-1000083383			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681754	NON-EXPEDITED			US-FRI-1000083442			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681760	NON-EXPEDITED			US-FRI-1000083046			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia; Visual Impairment	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681761	NON-EXPEDITED			US-FRI-1000083152			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pyrexia	Lexapro			S		10mg		Forest

Lexapro	S		Forest
Atorvastatin	C		Not Reported
Hydralazine	C		Not Reported
Glipizide	C		Not Reported
Levothyroxine	C		Not Reported
Clopidogrel	C		Not Reported
Losartan	C		Not Reported
Metoprolol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681763	NON-EXPEDITED			US-FRI-1000082614			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681764	NON-EXPEDITED			US-FRI-1000082966			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681898	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2016M1034545			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Diarrhoea	Escitalopram			S	Oral	Unk (5 Mg Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12682316	NON-EXPEDITED			US-FRI-1000083457			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12682317	NON-EXPEDITED			US-FRI-1000083565			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12682318	NON-EXPEDITED			US-FRI-1000083049			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12682321	NON-EXPEDITED			US-FRI-1000083263			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12682329	NON-EXPEDITED			US-FRI-1000079266			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12682333	NON-EXPEDITED			US-FRI-1000083359			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral	1.5 Tablets Daily		Forest
	Estradiol			C	Oral	1 Mg		Not Reported
	Metoprolol Succinate Er			C	Oral	50 Mg		Not Reported

Amlodipine Besylate	C	Oral	5 Mg		Not Reported
Prednisone	C	Oral	30 Mg (3 Tablets Once Daily)		Not Reported
Prednisone	C	Oral	20 Mg (2 Tablets Once Daily)		Not Reported
Prednisone	C	Oral	10 Mg		Not Reported
Prednisone	C	Oral	10mg Tablet, 1/2 Tablet Daily		Not Reported
Tizanidine Hcl	C	Oral	12 Mg		Not Reported
Pristiq	C		50 Mg		Not Reported
Omeprazole	C	Oral	40 Mg		Not Reported
Dapsone	C	Oral	100mg Tabletand 25mg Tablet Once Daily		Not Reported
Synthroid	C	Oral	50 Mcg		Not Reported
Lisinopril	C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12682334	NON-EXPEDITED			US-FRI-1000083106			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest
	Celexa			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12682335	NON-EXPEDITED			US-FRI-1000082280			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Lexapro			S				Forest
	Xyrem			S				Not Reported
	Nuvigil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12682336	NON-EXPEDITED			US-FRI-1000079348			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12682338	NON-EXPEDITED			US-FRI-1000079406		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hyperhidrosis; Menstrual Disorder; Product Dose Omission	Lexapro			S	Oral	10mg		Forest
	Lactose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12682961	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Nervousness	Prozac			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	10619674	EXPEDITED (15-DAY)		CA, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-21634787		3 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Trisomy 21; Ventricular Septal Defect	Abilify			S	Transplacental	15 Mg, Qd		Bristol Myers Squibb
	Seroplex			S	Transplacental	1 Df, Qd		Not Reported
	Parkinane			S	Transplacental	1 Df, Unk		Not Reported
	Tenoretic			S	Transplacental	1 Df, Qd		Not Reported
	Tercian			S	Transplacental	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	11211478	EXPEDITED (15-DAY)		HO	PHHY2015FR074700		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Exjade			S	Oral			Novartis
	Xagrid			S	Unknown	0.5 Mg, Unk		Not Reported
	Hydrea			S	Oral	500 Mg, Unk		Not Reported
	Levothyrox			S	Oral			Not Reported
	Aspergic			S	Oral			Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Nebilox			S	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	11229858	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-040936		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Off Label Use; Pulmonary Arterial Hypertension	Hydrea			S	Oral	500 Mg, Unk		Bristol Myers Squibb
	Xagrid			S	Oral	0.5 Mg, Unk		Not Reported
	Exjade			S	Oral	Unk		Not Reported
	Aspegic /00002703/			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Levothyrox			S	Oral			Not Reported
	Nebilox			S	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12528050	EXPEDITED (15-DAY)		DS	DE-PFIZER INC-2016329176		88 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased	Candesartan Cilexetil			S	Oral	16 Mg, 1x/Day		Not Reported

Appetite; General Physical Health Deterioration; Hypotension; Somnolence; Urinary Incontinence; Weight Decreased	Escitalopram Oxalate	S	Oral	20 Mg, 1x/Day	Not Reported
	Escitalopram Oxalate	S		Unk (2 Weeks At Half-Dosage)	Not Reported
	Glimepiride	S	Oral	1 Mg, 1x/Day	Not Reported
	Metformin Hcl	S	Oral	850 Mg, 2x/Day	Pfizer
	Ramipril	S	Oral	5 Mg, 2x/Day	Pfizer
	Ramipril	S		Unk (In 1/2 Dosage)	Pfizer
	Allopurinol	S	Oral	300 Mg, 1x/Day	Not Reported
	Digitoxin	S		0.07 Mg, 1x/Day	Not Reported
	Furosemide	S	Oral	40 Mg, 2x/Day	Not Reported
	Furosemide	S		Unk (At Half Dosage)	Not Reported
	Hydrochlorothiazide	S	Oral	25 Mg, 1x/Day	Not Reported
	Insulin	S	Unknown	30/70 Iu, 26-0-16 (Continue But Adjust The Dose)	Not Reported
	Isosorbide Dinitrate	S	Oral	20 Mg, 2x/Day (Taper The Drug Within A Week)	Not Reported
	Metoprolol Tartrate	S	Oral	47.5 Mg, 2x/Day	Not Reported
	Metoprolol Tartrate	S		Unk (At Half Dosage)	Not Reported
	Moxonidine	S	Oral	0.4 Mg, 1x/Day (Taper Over One Week)	Not Reported
	Tilidin	S	Oral	1 Df, 3x/Day (50/4mg)	Not Reported
	Pantoprazole	S	Oral	40 Mg, 1x/Day (2 Weeks At Half-Dosage, Then Stop)	Not Reported
	Trospium	S	Oral	15 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12617350	EXPEDITED (15-DAY)		OT	US-APOTEX-2016AP010098		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Autoimmune Hepatitis	Escitalopram Oxalate	S	Unknown	Unk		Apotex
	Diazepam	C	Unknown	Unk		Not Reported
	Lorazepam	C	Unknown	Unk		Not Reported
	Zolpidem	C	Unknown	Unk		Not Reported
	Fexofenadine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12683826	NON-EXPEDITED			US-FRI-1000084095			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12683828	NON-EXPEDITED			US-FRI-1000084139			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12683830	NON-EXPEDITED			US-FRI-1000084023			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Insomnia	Lexapro			S				Forest
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12683831	NON-EXPEDITED			US-FRI-1000085064			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Decreased	Lexapro			S	Oral	40mg		Forest
	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12683832	NON-EXPEDITED			US-FRI-1000083646		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12683833	NON-EXPEDITED			US-FRI-1000083915			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12683834	NON-EXPEDITED			US-FRI-1000084007			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Nausea	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12683846	NON-EXPEDITED			US-FRI-1000084315			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12683847	NON-EXPEDITED			US-FRI-1000084573			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Intentional Product Misuse	Lexapro			S		20mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684360	NON-EXPEDITED			US-FRI-1000085871			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684367	NON-EXPEDITED			US-FRI-1000084163			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Lexapro			S		Full Dose		Forest
	Lexapro			S		Half Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684371	NON-EXPEDITED			US-FRI-1000086044		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Heart Rate Increased; Weight Increased	Lexapro			S				Forest
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684382	NON-EXPEDITED			US-FRI-1000085766			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Heart Rate Increased; Intentional Product Misuse	Lexapro			S		1.25mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684383	NON-EXPEDITED			US-FRI-1000086018			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684384	NON-EXPEDITED			US-FRI-1000085576		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Lexapro			S				Forest
	Celexa			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684516	NON-EXPEDITED			US-FRI-1000086659			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S				Forest
	Rexulti			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684668	EXPEDITED (15-DAY)		DS	PHHY2016DK114561		63 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphemia	Sertralin Hexal			S	Oral	50 Mg, Qd		Novartis
	Escitalopram Stada			S	Oral	10 Mg, Qd		Not Reported
	Doltard			C	Unknown			Not Reported
	Hjertemagnyl//Acetylsalicylic Acid			C	Unknown			Not Reported
	Paracetamol Sandoz			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684673	EXPEDITED (15-DAY)		OT	FR-FRI-1000087005		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Balance Disorder; Confusional State; Dysstasia; Time Perception Altered	Escitalopram			S	Oral	10 Mg		Forest
	Lantus			C	Subcutaneous			Not Reported
	Novorapid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684892	NON-EXPEDITED			US-FRI-1000079074		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Pressure Fluctuation; Confusional State; Contusion; Eye Swelling; Intentional Product Misuse; Ocular Icterus; Off Label Use; Pain In Extremity; Syncope	Lexapro			S	Oral	15 Mg		Forest
	Lexapro			S				Forest
	Klonopin			C	Oral	4mg		Not Reported
	Aloe			C	Oral			Not Reported
	Nexium			C				Not Reported
	Tums			C	Oral			Not Reported
	Vitamin C			C				Not Reported
	Centrum Silver			C				Not Reported
	Magnesium			C				Not Reported
	Vitamin B12			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684893	NON-EXPEDITED			US-FRI-1000086667		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685029	NON-EXPEDITED			US-FRI-1000080392		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pruritic	Lexapro			S	Oral			Forest

	Vitamins	C		Not Reported
	Norvasc	C		Not Reported
	Aspirin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685031	NON-EXPEDITED			US-FRI-1000080466			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685042	NON-EXPEDITED			US-FRI-1000079578			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Anxiety; Depression; Hypervigilance; Irritability	Escitalopram			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685043	NON-EXPEDITED			US-FRI-1000086662			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Dizziness; Vertigo	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685044	NON-EXPEDITED			US-FRI-1000079662		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteoporosis	Lexapro			S	Oral	10mg		Forest
	Atenolol			C	Oral	50mg		Not Reported
	Atorvastatin			C	Oral	10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685112	NON-EXPEDITED			US-FRI-1000086181		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Oral			Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685550	NON-EXPEDITED			US-FRI-1000084405			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685555	NON-EXPEDITED			US-FRI-1000081866			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Feeling Abnormal; Hypersomnia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685556	NON-EXPEDITED			US-FRI-1000085316		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased	Lexapro			S	Oral	10mg		Forest
	Lexapro			S	Oral	5mg		Forest
	Baclofen			C				Not Reported
	Ambien			C				Not Reported
	Ativan			C				Not Reported
	Xarelto			C				Not Reported
	Vit D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685557	NON-EXPEDITED			US-FRI-1000080882			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Morbid Thoughts	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685558	NON-EXPEDITED			US-FRI-1000081886		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Off Label Use	Lexapro			S	Oral	25mg		Forest
	Multivitamin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685572	NON-EXPEDITED			US-FRI-1000081998		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Dizziness; Feeling Abnormal; Hypoaesthesia; Impaired Work Ability; Pruritus; Throat Tightness	Lexapro			S	Oral			Forest
	Xanax			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685575	NON-EXPEDITED			US-FRI-1000082152			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Flushing; Frustration Tolerance Decreased; Heart Rate Increased; Helplessness; Hypertension; Irritability;	Lexapro			S		10mg		Forest

Stress

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685581	NON-EXPEDITED			US-FRI-1000081444		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meibomian Gland Dysfunction; Nasal Dryness	Lexapro			S	Oral	10mg		Forest
	Lexapro			S	Oral	5mg		Forest
	Avapro			C	Oral	300mg		Not Reported
	Tekturna			C	Oral	150mg		Not Reported
	Toprol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685582	NON-EXPEDITED			US-FRI-1000080827			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glucose Tolerance Impaired	Lexapro			S				Forest
	Spironolactone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685905	NON-EXPEDITED			US-FRI-1000082441			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Intolerance; Emotional Disorder; Tremor	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685906	NON-EXPEDITED			US-FRI-1000082871		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Pain; Feeling Hot;	Lexapro			S	Oral	10mg		Forest

Neck Pain; Pain In Jaw; Pigmentation Disorder; Tenderness	Relion	C		100 Unit/Ml (20 Units At Breakfast And 12 Units At Supper)	Not Reported
	Relion	C			Not Reported
	Novolog	C			Not Reported
	Neurontin	C	Oral	600mg	Not Reported
	Zofran	C	Oral	24mg	Not Reported
	Zofran	C			Not Reported
	Ultram	C	Oral	200mg	Not Reported
	Albuterol	C		90 Mcg/Act 1-2 Puffs Q4-6h Wheezes And Sob	Not Reported
	Albuterol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685932	NON-EXPEDITED			US-FRI-1000082576		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Joint Stiffness; Muscle Spasms; Musculoskeletal Stiffness; Neck Pain	Lexapro			S	Oral	10mg		Forest
	Vitamin D Nos			C				Not Reported
	Vitamin B12			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685933	NON-EXPEDITED			US-FRI-1000082612			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685937	NON-EXPEDITED			US-FRI-1000082227		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Lexapro			S	Oral	5mg		Forest

Lexapro	S	Oral	10mg		Forest
Lexapro	S	Oral	5mg		Forest
Finasteride	S	Oral			Not Reported
Spironolactone	S	Oral	25mg		Not Reported
Vitamin D3	C				Not Reported
Lisinopril	C		5mg		Not Reported
Imdur	C	Oral	30mg		Not Reported
Lasix	C	Oral	80mg		Not Reported
Metoprolol	C	Oral	100mg		Not Reported
Digoxin	C	Oral	125mcg		Not Reported
Loratadine	C	Oral			Not Reported
Simvastatin	C	Oral	20mg		Not Reported
Tamsulosin	C	Oral	0.4mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685940	NON-EXPEDITED			US-FRI-1000082336		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Dizziness; Flatulence; Nausea; Nausea; Somnolence; Thinking Abnormal	Lexapro			S	Oral			Forest
	Lipitor			C	Oral	40mg		Not Reported
	Asa			C	Oral	81mg		Not Reported
	Dymista			C				Not Reported
	Potassium Citrate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685942	NON-EXPEDITED			US-FRI-1000082164			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12686032	NON-EXPEDITED			US-FRI-1000082986			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Depressed Mood; Irritability; Nausea; Social Avoidant Behaviour	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12686069	NON-EXPEDITED			US-FRI-1000082820			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12687568	EXPEDITED (15-DAY)		DE	DE-FRI-1000087011		32 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Asphyxia; Completed Suicide	Escitalopram			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688907	NON-EXPEDITED			US-FRI-1000082916			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688908	NON-EXPEDITED			US-FRI-1000086116		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Lexapro			S	Oral	20mg			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688909	NON-EXPEDITED			US-FRI-1000085273			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688910	NON-EXPEDITED			US-FRI-1000084521			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688911	NON-EXPEDITED			US-FRI-1000086631			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688912	NON-EXPEDITED			US-FRI-1000085082			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S		10mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688918	NON-EXPEDITED			US-FRI-1000085214			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Withdrawal	Lexapro			S	Oral	20mg		Forest

Syndrome	Clonazepam	C		Not Reported
	Lamictal	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688919	NON-EXPEDITED			US-FRI-1000082912			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Lexapro			S	Oral	10mg		Forest
	Depakote			S	Oral	1000 Mg		Not Reported
	Depakote			S	Oral	500 Mg		Not Reported
	Depakote			S	Oral	125 Mg		Not Reported
	Levothyroxine			C	Oral	50mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688920	NON-EXPEDITED			US-FRI-1000086045		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688921	NON-EXPEDITED			US-FRI-1000080988		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Decreased Appetite; Dizziness; Dry Mouth; Feeling Abnormal	Lexapro			S	Oral	20mg		Forest
	Coumadin			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688923	NON-EXPEDITED			US-FRI-1000080277			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hot Flush; Libido Decreased; Paraesthesia Oral; Withdrawal Syndrome	Lexapro		S	Oral	10mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688924	NON-EXPEDITED			US-FRI-1000086653			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Paranoia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688925	NON-EXPEDITED			US-FRI-1000079480			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Dissociation; Fatigue; Fatigue; Insomnia; Nausea; Paraesthesia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688926	NON-EXPEDITED			US-FRI-1000086650			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688927	NON-EXPEDITED			US-FRI-1000080679		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Auditory Disorder; Intentional Product Misuse; Libido Decreased; Libido Decreased	Lexapro			S	Oral	10mg		Forest
	Lexapro			S	Oral	10mg		Forest

	Lexapro	S	Oral			Not Reported
	Lexapro	S	Oral			Not Reported
	Viagra	C	Oral			Not Reported
	Xanax	C	Oral	2mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688928	NON-EXPEDITED			US-FRI-1000085491			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Tinnitus	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688929	NON-EXPEDITED			US-FRI-1000085443			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Appetite; Weight Increased	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688930	NON-EXPEDITED			US-FRI-1000081659		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688933	NON-EXPEDITED			US-FRI-1000079545		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Increased; Cough; Dyspnoea; Ear Pain; Haemoptysis; Headache; Night Sweats; Pain;	Lexapro			S	Oral			Forest
	Benazepril			S	Oral			Not Reported
	Vitamins			C				Not Reported

Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688934	NON-EXPEDITED			US-FRI-1000080363		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Food Craving; Weight Increased	Lexapro			S	Oral	20mg		Forest
	Melatonin			C	Oral	10mg		Not Reported
	Folic Acid			C		15mg		Not Reported
	Pristiq			C	Oral	50mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688936	NON-EXPEDITED			US-FRI-1000080750			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Skin Disorder	Lexapro			S	Oral	20mg		Forest
	Lexapro			S				Forest
	Xanax			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688937	NON-EXPEDITED			US-FRI-1000085626			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro			S		20mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688938	NON-EXPEDITED			US-FRI-1000082095			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Disturbance In Attention; Impaired Driving Ability; Rash; Tremor;	Lexapro			S				Forest
	Lyrica			S				Not Reported
	Anti-Depressant			S				Not Reported

Unevaluable Event;
Unevaluable Event;
Unevaluable Event; Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688939	NON-EXPEDITED			US-FRI-1000085663			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S		10mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688940	NON-EXPEDITED			US-FRI-1000085699			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688941	NON-EXPEDITED			US-FRI-1000079817			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Lexapro			S				Forest
Screaming; Unevaluable	Prozac			S				Not Reported
Event	Xanax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688942	NON-EXPEDITED			US-FRI-1000085560		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Panic Attack	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688943	NON-EXPEDITED			US-FRI-1000079548		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Swelling	Lexapro			S	Oral	Either 10 Or 20mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688944	NON-EXPEDITED			US-FRI-1000086799			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688945	NON-EXPEDITED			US-FRI-1000081187			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Dose Titration Not Performed; Irritability	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688946	NON-EXPEDITED			US-FRI-1000079481			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Malaise; Nausea	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688947	NON-EXPEDITED			US-FRI-1000080579		32 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Disorder	Lexapro			S				Forest
	Keppra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688948	NON-EXPEDITED			US-FRI-1000080335		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Heart Rate Increased; Listless; Sleep Disorder	Lexapro			S	Oral	7.5mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688959	NON-EXPEDITED			US-FRI-1000080422			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Motion Sickness; Nausea; Unevaluable Event	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12688960	NON-EXPEDITED			US-FRI-1000080420		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Dizziness; Dizziness; Fatigue; Feeling Abnormal; Paraesthesia; Weight Increased	Lexapro			S	Oral	10mg		Forest
	Lexapro			S				Forest
	Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12500722	EXPEDITED (15-DAY)		HO	IT-FRI-1000085538		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Hyperhidrosis; Hypotension; Product Use In Unapproved Indication;	Escitalopram			S	Oral	5 Mg		Forest
	Escitalopram			S	Oral	10 Mg		Forest
	Buscopan			C	Oral			Not Reported

Syncope; Vomiting	Prednisone	C	Oral	20 Mg	Not Reported
	Rivotril	C	Oral	Unit Dose: 10-15 Drops (Prn)	Not Reported
	Fortimel Creme	C	Oral	2 Dfs	Not Reported
	Calcitriol	C	Oral	.25 Mg	Not Reported
	Optalidon [Butalbital;Caffeine;Propyphenazone]	C	Oral	1 Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12689083	EXPEDITED (15-DAY)		OT	GB-ACCORD-043435			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12689928	NON-EXPEDITED			US-FRI-1000082302		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dizziness; Erythema; Flushing; Nausea; Panic Reaction; Paraesthesia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12689932	NON-EXPEDITED			US-FRI-1000079365			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unevaluable Event	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12689998	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016397146		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning Deliberate; Toxicity To Various Agents	Advil			S	Oral	2 Df, Single		Pfizer
	Escitalopram Oxalate			S	Oral	14 Df, Single		Not Reported
	Seresta			S	Oral	26 Df, Single		Not Reported
	Tercian			S	Oral	12 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690365	NON-EXPEDITED			US-FRI-1000084414			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Caries; Toothache	Lexapro			S				Forest
	Sertraline			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690366	NON-EXPEDITED			US-FRI-1000084730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram			S				Forest
	Tysabri			C				Not Reported
	Fampyra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690373	NON-EXPEDITED			US-FRI-1000084780			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Pruritus; Rash; Rash	Lexapro			S				Forest
	Geodon			S		40		Not Reported
	Geodon			S		60		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690382	NON-EXPEDITED			US-FRI-1000083757			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Irritability	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690384	NON-EXPEDITED			US-FRI-1000084109		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dysphonia; Ejaculation Delayed; Night Sweats	Lexapro			S	Oral	5mg		Forest
	Lexapro			S				Forest
	Vimpat			C	Oral	25mg		Not Reported
	Klonopin			C	Oral			Not Reported
	Ativan			C	Oral			Not Reported
	Aspirin			C	Oral	81mg		Not Reported
	Vitamin B			C	Oral			Not Reported
	Vitamin C			C	Oral			Not Reported
	Vitamin D3			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690386	NON-EXPEDITED			US-FRI-1000084137			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Mood; Social Avoidant Behaviour	Lexapro			S				Forest
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690389	NON-EXPEDITED			US-FRI-1000084213			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690393	NON-EXPEDITED			US-FRI-1000083683		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Defaecation Urgency; Diarrhoea; Disturbance In Attention; Gastrointestinal Sounds Abnormal; Intentional Product Use Issue; Irritability; Nausea; Restlessness; Sleep Disorder	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	7.5 Mg		Forest
	Lexapro			S	Oral	5 Mg		Not Reported
	Lexapro			S	Oral	2.5 Mg		Not Reported
	Lexapro			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690394	NON-EXPEDITED			US-FRI-1000083703		10 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Fatigue; Headache; Intentional Product Misuse; Nausea; Pain In Extremity; Paraesthesia; Photosensitivity Reaction; Weight Increased	Lexapro			S	Oral	2.5mg		Forest
	Lexapro			S	Oral	5mg		Forest
	Lexapro			S	Oral	7.5mg		Not Reported
	Lexapro			S	Oral	10mg		Not Reported
	Lexapro			S	Oral	7.5mg		Not Reported
	Tylenol			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690395	NON-EXPEDITED			US-FRI-1000083738			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690397	NON-EXPEDITED			US-FRI-1000084343			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Erythema; Erythema; Flushing; Intentional Product Misuse	Lexapro			S	Oral			Forest
	Topamax			C	Oral	300mg		Not Reported
	Klonopin			C	Oral	0.01mg		Not Reported
	Vitamins			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690398	NON-EXPEDITED			US-FRI-1000084220			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Hot Flush	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690404	NON-EXPEDITED			US-FRI-1000084799			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Hypersensitivity; Headache	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690405	NON-EXPEDITED			US-FRI-1000084153			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal; Unevaluable Event	Lexapro			S	Oral	10mg		Forest
	Protonix			C	Oral	40mg		Not Reported
	Gabapentin			C	Oral			Not Reported

Tramadol	C	Oral	150mg		Not Reported
Oxycontin	C	Oral			Not Reported
Xanax	C	Oral			Not Reported
Tizanidine	C	Oral	6mg		Not Reported
Adipex	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690411	NON-EXPEDITED			US-FRI-1000086537		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Headache; Insomnia; Nausea	Lexapro			S	Oral	10mg		Forest
	Lisinopril			C		40mg Am		Not Reported
	Amlodipine			C		2.5mg		Not Reported
	Fenofibrate			C		48mg		Not Reported
	Humira			C		30mg Q 2 Weeks		Not Reported
	Omega 3 Fish Oil			C				Not Reported
	Probiotics			C				Not Reported
	Vit D			C		2000 Iu		Not Reported
	Vit C			C		1000 Mg		Not Reported
	Coq 10			C		200mg		Not Reported
	Bayer Aspirin			C		325mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690412	NON-EXPEDITED			US-FRI-1000082997		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoacusis	Lexapro			S	Oral	10mg		Forest
	Lexapro			S				Forest
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690413	NON-EXPEDITED			US-FRI-1000083148		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lacrimation Increased; Product Dose Omission; Vision Blurred; Visual Impairment	Lexapro			S	Oral	10mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690414	NON-EXPEDITED			US-FRI-1000083087		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Ejaculation Failure; Erectile Dysfunction; Erection Increased; Prescribed Overdose	Lexapro			S		40mg		Forest
	Lamictal			S	Oral	400mg		Not Reported
	Latuda			S	Oral	120mg		Not Reported
	Risperdal			S	Oral	0.5mg		Not Reported
	Lithium			S	Oral	30mg		Not Reported
	Lithium			S				Not Reported
	E-Cigs			C		1 Pack A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690415	NON-EXPEDITED			US-FRI-1000083260			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690416	NON-EXPEDITED			US-FRI-1000083090			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pruritus	Lexapro			S						Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690417	NON-EXPEDITED			US-FRI-1000083099			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690418	NON-EXPEDITED			US-FRI-1000083364			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Product Difficult To Remove	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690419	NON-EXPEDITED			US-FRI-1000083144		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying	Lexapro			S				Forest
	Nerve Pill			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690420	NON-EXPEDITED			US-FRI-1000083255			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Weight Increased	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690790	EXPEDITED (15-DAY)		OT	GB-TEVA-687245ACC			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Diarrhoea	Escitalopram			S	Oral	5 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690799	NON-EXPEDITED			US-FRI-1000085420			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unevaluable Event	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690800	NON-EXPEDITED			US-FRI-1000085475			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690801	NON-EXPEDITED			US-FRI-1000085423			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Unevaluable Event	Lexapro			S				Forest
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690802	NON-EXPEDITED			US-FRI-1000085479		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Feeling Abnormal; Memory Impairment; Off Label Use; Therapeutic Response Unexpected	Lexapro			S				Forest
	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690803	NON-EXPEDITED			US-FRI-1000086226			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual;	Lexapro			S				Forest
Hyperhidrosis;	Lexapro			S				Not Reported
Hypnagogic Hallucination;	Lexapro			S				Not Reported
Migraine; Nausea; Vertigo;	Rexulti			S				Not Reported
Withdrawal Syndrome	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690805	NON-EXPEDITED			US-FRI-1000086719			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Female Orgasmic	Lexapro			S				Forest
Disorder; Paraesthesia	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690808	NON-EXPEDITED			US-FRI-1000086630			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain; Headache; Photopsia; Visual Impairment	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690809	NON-EXPEDITED			US-FRI-1000086352			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Condition Aggravated	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690810	NON-EXPEDITED			US-FRI-1000086356			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Enlargement; Breast Pain	Lexapro			S	Oral	10mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690811	NON-EXPEDITED			US-FRI-1000086821			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Respiratory Tract Congestion; Throat Irritation; Vomiting	Lexapro			S	Subcutaneous	40mg/0.8ml		Forest
	Humira			S				Not Reported
	Trintellix			S				Not Reported
	Lamictal			S				Not Reported
	Zyprexa			S				Not Reported
	Ativan			C				Not Reported
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12690814	NON-EXPEDITED			US-FRI-1000086564			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Irritation; Ocular Hyperaemia; Vision Blurred; Visual Impairment	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12691058	NON-EXPEDITED			US-FRI-1000042781			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Blood Pressure Increased; Decreased Appetite;	Lexapro			S	Oral	10 Mg		Forest
	Lexapro			S	Oral	20mg		Forest

Dizziness; Nausea; Panic Attack; Somnolence; Weight Increased	Synthroid	C				Not Reported
	Metformin	C	Oral	500 Mg		Not Reported
	Hormone Replacement Therapy Nos	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12691068	NON-EXPEDITED			US-FRI-1000086858			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12691069	NON-EXPEDITED			US-FRI-1000086159		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Tenderness	Lexapro			S	Oral	5mg		Forest
	Klonopin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12691070	NON-EXPEDITED			US-FRI-1000086717		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12691071	NON-EXPEDITED			US-FRI-1000086001		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Lexapro			S	Oral	10mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12691252	EXPEDITED (15-DAY)		DE	DE-MYLANLABS-2016M1035212			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2016	12692085	NON-EXPEDITED			US-SHIRE-US201610467			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug Ineffective; Inappropriate Schedule Of Product Administration; Prescribed Overdose; Vision Blurred	Adderall Xr			S	Oral	25 Mg, Other (Take For 4 Days, Then Does Not Take For 3 Days		Shire
	Lexapro			S	Unknown	2.5 Mg, Unknown		Not Reported
	Zyrtec			C	Unknown	Unk, Unknown		Not Reported
	Flonase /00908302/			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2016	10667374	EXPEDITED (15-DAY)		DS	US-009507513-1110USA04072			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Anxiety; Basilar Migraine; Blood Pressure Increased; Cholelithiasis; Cognitive Disorder; Dependence; Depression; Dry Skin; Ear Operation; Erectile Dysfunction; Exposure To Toxic Agent; Fatigue; Flatulence; Fracture; Frustration Tolerance Decreased; Hypogonadism; Hypopituitarism; Injury; Irritability; Libido Decreased; Memory Impairment; Migraine;	Propecia			S	Oral	1 Mg, Qd		Merck
	Lexapro			S	Oral	Unk, Unknown		Not Reported

Muscle Fatigue; Muscular Weakness; Nasal Congestion; Nasopharyngitis; Palpitations; Premature Ejaculation; Prostatic Specific Antigen Increased; Sedation Complication; Semen Volume Decreased; Sexual Dysfunction; Skin Lesion; Somnolence; Stress; Testicular Pain; Vision Blurred; Visual Impairment; Wheezing

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2016	12620604	EXPEDITED (15-DAY)		OT	ZA-CIPLA LTD.-2016ZA10134			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Heart Rate Irregular	Lexamil			S	Unknown	10 Mg, Qd In The Morning Started Just Over 2 Months Ago		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2016	12693953	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP010671		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glossodynia	Apo-Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Pantoloc /01263204/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2016	12695159	EXPEDITED (15-DAY)		HO	CA-MYLANLABS-2016M1035922			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Overdose; Serotonin Syndrome	Bupropion		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported
	Olanzapine		S	Oral	Not Reported
	Phenytoin		S	Oral	Not Reported
	Quetiapine		S	Oral	Not Reported
	Primidone		S	Oral	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2016	12696192	EXPEDITED (15-DAY)		HO, OT	JP-FRI-1000087131		48 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Blood Glucose Increased; Blood Triglycerides Increased; Insomnia; Low Density Lipoprotein Increased; Mania; Somnolence; Suicidal Ideation	Escitalopram			S	Oral	10 Mg		Forest
	Effexor			S	Oral	37.5 Mg		Not Reported
	Effexor			S	Oral	75 Mg		Not Reported
	Effexor			S	Oral	112.5 Mg		Not Reported
	Effexor			S	Oral	150 Mg		Not Reported
	Effexor			S	Oral	112.5 Mg 2 Times Per Day		Not Reported
	Seniran			C	Oral	6 Mg		Not Reported
	Vegetamin-B			C	Oral	1 Df		Not Reported
	Sorentmin (Brotizolam)			C	Oral	0.25 Mg		Not Reported
	Flunitrazepam			C	Oral	4 Mg		Not Reported
	Quetiapine			C	Oral	100 Mg		Not Reported
	Cystanin			C	Oral	900 Mg		Not Reported
	Alosenn (Senna)			C	Oral	4.5 Gram		Not Reported
	Pantethine			C	Oral	9 Gram		Not Reported
	Vemas			C	Oral	2 Tablets Three Times Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12527607	NON-EXPEDITED			US-SHIRE-US201607043		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Product Quality Issue; Therapeutic Response Unexpected; Weight Decreased; Weight Increased	Vyvanse			S	Oral	50 Mg, 1x/Day:Qd		Shire
	Lexapro			S	Oral	20 Mg, 1x/Day:Qd		Not Reported
	Losartan			C	Oral	50 Mg, 1x/Day:Qd		Not Reported
	Pravastatin			C	Oral	40 Mg, 1x/Day:Qd		Not Reported
	Aspirin /00002701/			C	Oral	81 Mg, 1x/Day:Qd		Not Reported
	Vitamin B12 /00056201/			C	Oral	5000 Mg, 1x/Day:Qd		Not Reported
	Ferro-Sequels			C	Oral	50 Mg, 1x/Day:Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12645968	NON-EXPEDITED			US-PFIZER INC-2016158220			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12690182	EXPEDITED (15-DAY)		HO	CH-TEVA-686883ISR		76 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder	Escitalopram Actavis			S	Oral	10 Milligram Daily;		Ivax
	Lithiofor			S	Oral	1 Dosage Forms Daily; 0.5 Dosage Forms Each In The Morning And In The Evening		Not Reported
	Lithiofor			S	Oral	.5 Dosage Forms Daily; 0.5 Dosage Forms In The Evening		Not Reported
	Lithiofor			S	Oral	1320 Milligram Daily; 2 Dosage Forms Of 660 Mg Each At Lunch Time		Not Reported

	Lithiofor	S	Oral	Dosage And Start Date Unknown, Long-Term Therapy	Not Reported
	Tenoretic Mite	C	Oral	1 Df = 50 Mg Atenolol And 12,5 Mg Chlortalidone	Not Reported
	Kcl	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12696408	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2016-10662			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Diarrhoea	Escitalopram Tablets			S	Oral	5 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12696441	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2016GB17739			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Diarrhoea	Escitalopram			S	Oral	5 Mg, Daily		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12696657	EXPEDITED (15-DAY)		DE, OT	CA-APOTEX-2016AP010670		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Apo-Escitalopram			S	Unknown			Apotex
	Apo-Temazepam			S	Unknown			Not Reported
	Tylenol With Codeine No.3			S	Unknown			Not Reported
	Advair			C	Unknown			Not Reported
	Atrovent			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

	Ranitidine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12696817	EXPEDITED (15-DAY)		LT, OT	CA-APOTEX-2016AP010674			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Apo-Escitalopram			S	Unknown	10 Mg, Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12696963	EXPEDITED (15-DAY)		LT, OT	CA-APOTEX-2016AP010672		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Decreased Appetite; Diarrhoea; Drug Hypersensitivity; Fatigue; Headache; Hypersensitivity; Rhinitis; Urticaria	Apo-Escitalopram			S	Oral	20 Mg, Bid		Apotex
	Apo-Escitalopram			S				Apotex
	Clobazam			C	Unknown			Not Reported
	Tegretol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12699133	EXPEDITED (15-DAY)		HO	PHHY2016CA116225		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Product Misuse; Serotonin Syndrome; Tachycardia	Quetiapine			S	Unknown			Novartis
	Bupropion			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Phenytoin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Primidone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12699567	EXPEDITED (15-DAY)		HO	FR-FRI-1000087142		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning Deliberate; Toxicity To Various Agents	Escitalopram			S	Oral			Forest
	Tercian			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Advil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12699573	EXPEDITED (15-DAY)		DS, HO	FR-FRI-1000087148		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Extradural Haematoma; Subdural Haematoma	Escitalopram			S	Oral	10 Mg		Forest
	Kardegic			S	Oral	160 Mg		Not Reported
	Alepsal (Phenobarbital)			C		150 Mg		Not Reported
	Atorvastatine			C		40 Mg		Not Reported
	Forlax			C				Not Reported
	Ramipril			C		5 Mg		Not Reported
	Tegretol Lp			C		800 Mg		Not Reported
	Travatan			C				Not Reported
	Uvedose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12699974	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20160825817		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State	Ixprim			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Diffu K			C	Unknown			Not Reported

	Tanakan	C	Unknown	Not Reported
	Imovane	C	Unknown	Not Reported
	Doliprane	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12700187	NON-EXPEDITED			US-SHIRE-US201611231			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Dizziness; Headache; Incorrect Dose Administered; Malaise; Nausea; Negative Thoughts; Nervousness; Performance Status Decreased; Tinnitus; Vomiting	Vyvanse			S	Oral	40 Mg, Unknown		Shire
	Vyvanse			S	Oral	60 Unk, Unk		Shire
	Vyvanse			S	Oral	40 Mg, 1x/Day:Qd (In The Morning)		Shire
	Vyvanse			S	Oral	20 Mg, Unknown		Shire
	Lexapro			S	Unknown	0.5 Df, Unknown		Not Reported
	Cymbalta			S	Unknown	30 Mg, 1x/Day:Qd		Not Reported
	Abilify			S	Unknown	1 Mg (Half Of A 2 Mg), 1x/Day:Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12701928	NON-EXPEDITED			US-JAZZ-2016-US-007450		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cataplexy	Xyrem			S	Oral	1.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported
	Focalin			C				Not Reported
	Focalin Xr			C				Not Reported
	Penicillin Vk			C				Not Reported
	Tamiflu			C				Not Reported
	Acetaminophen W/Codeine			C				Not Reported
	Amitriptyline Hcl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12702184	EXPEDITED (15-DAY)		DE	DE-AUROBINDO-AUR-APL-2016-10812		32 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Completed Suicide	Escitalopram 10 Mg			S	Oral	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12702980	EXPEDITED (15-DAY)		HO	PHHY2016DK116646			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Intentional Overdose; Restlessness; Sedation; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Weight Increased	Oxapax			S	Oral			Novartis
	Cipralex /Den/			S	Oral	10 Mg, Unk		Not Reported
	Imoclone			S	Oral	7.5 Mg, Unk		Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral	200 Mg, Unk		Not Reported
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Truxal			S	Oral	265 Mg, Unk		Not Reported
	Zeldox//Ziprasidone Hydrochloride			S	Oral	80 Mg Stigende Til 160 Mg		Not Reported
	Solian			S	Oral			Not Reported
	Risperidon Krka			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12703318	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-117351		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence	Escitalopram			S	Unknown	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Sun

	Carbidopa/Levodopa	S	Unknown	Unk		Ranbaxy
	Trazodone	S	Unknown	Unk		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12703940	EXPEDITED (15-DAY)		HO	CH-TEVA-677634ISR		47 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Epistaxis; Furuncle; Myalgia	Escitalopram-Mepha			S	Unknown			Ivax
	Escitalopram-Mepha			S	Unknown	10 Milligram Daily;		Ivax
	Quetiapine Xr			C	Unknown	800 Milligram Daily; Two Dose Forms Taken In The Evening		Not Reported
	Cymbalta			C	Unknown	60 Milligram Daily; Take In The Morning		Not Reported
	Pantozol			C		40 Milligram Daily; Taken In The Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12704122	EXPEDITED (15-DAY)		OT	BR-009507513-1608BRA014438		39 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Anxiety; Anxiety; Disturbance In Attention; Dysgraphia; Hypothyroidism; Insomnia; Panic Disorder; Pregnancy On Contraceptive; Reading Disorder; Therapeutic Product Effect Decreased; Unintended Pregnancy	Nuvaring			S		Unk, 3 Weeks With The Vaginal Ring And One Week Free		Merck
	Nuvaring			S	Vaginal	Unk,3 Weeks With The Vaginal Ring And One Week Free		Merck
	Nuvaring			S	Vaginal	Unk,3 Weeks With The Vaginal Ring And One Week Free		Merck
	Pristiq			S		Unk		Not Reported
	Pristiq			S				Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

Ritalin	S	Oral	80mg, 2 Tablets Daily		Not Reported
Frontal	S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12704326	EXPEDITED (15-DAY)		OT	BR-009507513-1608BRA014429			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy On Contraceptive; Therapeutic Product Effect Decreased; Unintended Pregnancy	Nuvaring			S	Vaginal			Merck
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12704660	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2016SE91376		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Hepatitis Cholestatic; Ischaemic Stroke	Inexium			S	Oral			Astrazeneca
	Advagraf			S	Oral			Not Reported
	Advagraf			S	Oral			Not Reported
	Advagraf			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported
	Tahor			S	Oral	10.0mg Unknown		Not Reported
	Bisoprolol			C				Not Reported
	Triatec (Ramipril)			C				Not Reported
	Kayexalate			C				Not Reported
	Cellcept			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12704854	EXPEDITED (15-DAY)		HO	CH-MEDA-2016080104		90 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall	Torem	S		½-0-0-0	Meda
	Cipralex	S		1-0-0-0	Not Reported
	Madopar	S		200/50 Mg; ½-½-½-0	Not Reported
	Lyrica	S	Oral	0-0-0-½	Not Reported
	Lyrica	S	Oral	0-0-0-1	Not Reported
	Temesta (Lorazepam)	S	Oral	0-0-0-½	Not Reported
	Acidum Folicum Streuli	C		1-0-0-0	Not Reported
	Vitamin D3 Streuli	C		Every Tuesday	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12705058	DIRECT	Y				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Pruritus; Rash	Escitalopram, 10 Mg			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12705079	DIRECT					33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chills; Dizziness; Nausea; Presyncope	Escitalopram			S	Oral	1 Tablet(S) Once A Day Taken By Mouth		Lupin
	Magnesium			C				Not Reported
	Probiotic			C				Not Reported
	Multi Vitamin			C				Not Reported
	Coenzyme Q 10			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	10684237	EXPEDITED (15-DAY)			PL-JNJFOC-20141213366			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Paracetamol			S	Unknown			Not Reported

Paracetamol		S	Unknown	Not Reported
Fluconazole	Y	S	Unknown	Not Reported
Acetyl Salicylic Acid	Y	S	Unknown	Not Reported
Ibuprofen		S	Unknown	Not Reported
Ketoprofen		S	Unknown	Not Reported
Erythromycin		S	Unknown	Not Reported
Domperidone		S	Unknown	Not Reported
Haloperidol		S	Unknown	Not Reported
Clonazepam		S	Unknown	Not Reported
Midazolam		S	Unknown	Not Reported
Zopiclone		S	Unknown	Not Reported
Zolpidem		S	Unknown	Not Reported
Amitriptyline		S	Unknown	Not Reported
Citalopram		S	Unknown	Not Reported
Mirtazapine		S	Unknown	Not Reported
Escitalopram		S	Unknown	Not Reported
Sertraline		S	Unknown	Not Reported
Paroxetine		S	Unknown	Not Reported
Venlafaxine		S	Unknown	Not Reported
Fluoxetine		S	Unknown	Not Reported
Methylphenidate		S	Unknown	Not Reported
Gabapentin		S	Unknown	Not Reported
Pregabalin		S	Unknown	Not Reported
Carbamazepine		S	Unknown	Not Reported
Phenytoin		S	Unknown	Not Reported
Oxcarbazepine		S	Unknown	Not Reported
Levomepromazine		S	Unknown	Not Reported
Chlorpromazine		S	Unknown	Not Reported
Metoclopramide		S	Unknown	Not Reported

Ondansetron	S	Unknown	Not Reported
Granisetron	S	Unknown	Not Reported
Tropisetron	S	Unknown	Not Reported
Cyclizine	S	Unknown	Not Reported
Dimenhydrinate	S	Unknown	Not Reported
Hyoscine	S	Unknown	Not Reported
Lansoprazole	S	Unknown	Not Reported
Esomeprazole	S	Unknown	Not Reported
Pantoprazole	S	Unknown	Not Reported
Omeprazole	S	Unknown	Not Reported
Ranitidine	S	Unknown	Not Reported
Cimetidine	S	Unknown	Not Reported
Tramadol	S	Unknown	Not Reported
Penicillin	S	Unknown	Not Reported
Cephalosporins	S	Unknown	Not Reported
Ciprofloxacin	S	Unknown	Not Reported
Metronidazole	S	Unknown	Not Reported
Clarithromycin	S	Unknown	Not Reported
Acyclovir	S	Unknown	Not Reported
Heparin	S	Unknown	Not Reported
Warfarin	S	Unknown	Not Reported
Codeine	S	Unknown	Not Reported
Tranexamic Acid	S	Unknown	Not Reported
Statins	S	Unknown	Not Reported
Calcium Channel Blockers	S	Unknown	Not Reported
Beta Adrenergic Receptor Antagonists	S	Unknown	Not Reported
Amiodarone	S	Unknown	Not Reported
Loop Diuretics	S	Unknown	Not Reported
Potassium-Sparing Agents	S	Unknown	Not Reported

Thiazides	S	Unknown	Not Reported
Allopurinol	S	Unknown	Not Reported
Oral Hypoglycemic Agents	S	Unknown	Not Reported
Insulin	S	Unknown	Not Reported
Thyroxin	S	Unknown	Not Reported
Hormone Replacement Therapy	S	Unknown	Not Reported
Vitamins	S	Unknown	Not Reported
Herbal Medicines	S	Unknown	Not Reported
Metamizole	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Megestrol Acetate	S	Unknown	Not Reported
Oxazepam	S	Unknown	Not Reported
Dexamethasone	S	Unknown	Not Reported
Prednisolone	S	Unknown	Not Reported
Methylprednisolone	S	Unknown	Not Reported
Betamethasone	S	Unknown	Not Reported
Gabapentin	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Amitriptyline	S	Unknown	Not Reported
Antiemetics	S		Not Reported
Laxatives	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Morphine	S	Unknown	Not Reported
Fentanyl	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Hydromorphone	S	Unknown	Not Reported
Methadone	S	Unknown	Not Reported
Buprenorphine	S	Unknown	Not Reported
Levomethadone	S	Unknown	Not Reported

	Alprazolam	S	Unknown		Not Reported
	Lorazepam	S	Unknown		Not Reported
	Diazepam	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	11218377	EXPEDITED (15-DAY)		HO	FR-FRI-1000077696		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Nebivolol			S	Oral			Forest
	Escitalopram			S	Oral			Forest
	Xagrid			S	Oral			Not Reported
	Hydrea			S	Oral			Not Reported
	Exjade			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	11227938	EXPEDITED (15-DAY)		HO	FR-FRI-1000077785		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Escitalopram			S	Oral			Forest
	Nebilox			S	Oral			Not Reported
	Xagrid			S	Oral			Not Reported
	Hydrea			S	Oral			Not Reported
	Exjade			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12627526	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2016-US-014280			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Interaction; Lung Disorder; Malaise	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	3.75 G, Bid		Jazz
	Lexapro			S		20 Mg, Unk		Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Prozac			C		Unk		Not Reported
	Levofloxacin			C		Unk		Not Reported
	Xanax			C		0.5 Mg, Unk		Not Reported
	Xanax			C		0.25 Mg, Unk		Not Reported
	Adderall			C		Unk		Not Reported
	Advair			C		Unk		Not Reported
	Budesonide			C		Unk		Not Reported
	Celexa			C		Unk		Not Reported
	Celexa			C		Unk		Not Reported
	Claritin			C		Unk		Not Reported
	Modafinil			C		Unk		Not Reported
	Singulair			C		Unk		Not Reported
	Ventolin Hfa			C		Unk		Not Reported
	Medrol			C		Unk		Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12696619	EXPEDITED (15-DAY)		DE	CN-BAUSCH-BL-2016-020482		36 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression Suicidal	Bupropion			S	Oral			Not Reported
	Eszopiclone			C				Not Reported

Escitalopram	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12707170	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016399448		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Cerebral Ischaemia; Gamma-Glutamyltransferase Increased; Hepatitis Cholestatic	Xanax			S	Oral	Unk		Pfizer
	Xanax			S	Oral	Increased Dose		Pfizer
	Tahor			S	Oral	10 Mg, 1x/Day		Pfizer
	Advagraf			S	Oral	Unk		Not Reported
	Advagraf			S	Oral	2.5 Mg, 1x/Day		Not Reported
	Advagraf			S	Oral	Unk		Not Reported
	Inexium			S	Oral	Unk		Not Reported
	Inexium			S	Oral	40 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Increased Dose		Not Reported
	Bisoprolol			C		Unk		Not Reported
	Triatec (Ramipril)			C		Unk		Not Reported
	Kayexalate			C		Unk		Not Reported
	Cellcept			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12707242	EXPEDITED (15-DAY)		HO	DK-PFIZER INC-2016403435		35 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Intentional Overdose; Restlessness; Sedation; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Weight Increased	Zeldox			S	Oral	80 Mg, Unk		Pfizer
	Zeldox			S	Oral	160 Mg, Unk		Pfizer
	Cipralex /01588501/			S	Oral	Strength: 10 Mg		Not Reported
	Imoclone			S	Oral	Strength: 7.5 Mg		Not Reported
	Imoclone			S	Oral	Strenght: 7.5mg		Not Reported

Oxapax	S	Oral	Unk		Not Reported
Oxapax	S		Unk		Not Reported
Seroquel	S	Oral	Unk		Not Reported
Seroquel	S	Oral	Strength: 200 Mg		Not Reported
Abilify	S	Oral	Strength: 10 Mg.		Not Reported
Truxal /00012101/	S	Oral	265 Mg, Unk		Not Reported
Solian	S	Oral	Unk		Not Reported
Risperidon Krka	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12707452	EXPEDITED (15-DAY)		HO, LT, OT	DK-ASTRAZENECA-2016SE91020			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Restlessness; Sedation; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Weight Increased	Seroquel			S	Oral	100.0mg Unknown		Zeneca
	Seroquel			S	Oral	300.0mg Unknown		Zeneca
	Seroquel			S	Oral	200.0mg Unknown		Zeneca
	Abilify			S	Oral	10.0mg Unknown		Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Imoclone			S	Oral			Not Reported
	Imoclone			S	Oral	7.5mg Unknown		Not Reported
	Oxapax			S	Oral			Not Reported
	Truxal			S	Oral	265.0mg Unknown		Not Reported
	Zeldox			S	Oral	80 Mg Increasing To 160 Mg		Not Reported
	Solian			S	Oral			Not Reported
	Risperidon			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12708938	NON-EXPEDITED			US-JAZZ-2016-US-008482			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Paranoia; Stress	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported
	Adderall			C				Not Reported
	Lorazepam			C				Not Reported
	Clonazepam			C				Not Reported
	Vyvanse			C				Not Reported
	Effexor			C				Not Reported
	Provigil			C				Not Reported
	Escitalopram			C				Not Reported
	Pristiq			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12708959	EXPEDITED (15-DAY)		HO	CH-ASTRAZENECA-2016SE90924		96 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contusion; Craniocerebral Injury; Dizziness; Dizziness Postural; Face Injury; Fall; Gait Disturbance; Haemorrhage Intracranial; Hyponatraemia; Skin Injury; Skin Laceration	Ass Cardio			S	Unknown			Not Reported
	Beloc Zok			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Torem			S	Unknown			Not Reported
	Amiodaron-Mepha			S	Unknown			Not Reported
	Polystyrene Sulfonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12710552	DIRECT	Y				42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Vomiting	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2016	11717721	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2015SF07761		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Crestor			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Cardensiel			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Seroplex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2016	12342733	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2016242078		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anger; Condition Aggravated; Crying; Depression; Drug Ineffective; Loss Of Consciousness; Nervousness; Weight Increased; Weight Loss Poor	Effexor Xr			S	Oral	75 Mg, 1x/Day		Pfizer
	Effexor Xr			S	Oral	10 Mg, 2x/Day		Pfizer
	Effexor Xr			S				Pfizer
	Effexor Xr			S				Pfizer
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported
	Escitalopram			S	Oral	10 Mg, 2x/Day		Not Reported
	Diazepam			C		10 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2016	12696194	EXPEDITED (15-DAY)		OT	IT-FRI-1000087125		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Nausea; Neck Pain	Escitalopram			S	Oral	10 Mg		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2016	12711001	EXPEDITED (15-DAY)		HO	DK-FRI-1000087230			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Intentional Overdose; Restlessness; Sedation; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Weight Increased	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Oral			Forest
	Imoclone			S	Unknown			Not Reported
	Imoclone			S	Oral			Not Reported
	Oxapax			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel Prolong			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Truxal			S	Oral			Not Reported
	Zeldox			S	Oral	Dose: 80 Mg Increasing To 160 Mg		Not Reported
	Solian			S	Oral			Not Reported
	Risperidon "Krka"			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2016	12711205	EXPEDITED (15-DAY)		DS	DK-FRI-1000087231			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Photopsia; Pollakiuria; Visual Impairment	Escitalopram			S	Oral			Forest
	Escitalopram			S	Unknown			Forest
	Mianserin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2016	12572421	EXPEDITED (15-DAY)		HO	IL-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-057808		79 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hepatic Function Abnormal	Eliquis			S	Unknown	5 Mg, Bid		Bristol Myers Squibb
	Cipralex /01588501/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2016	12636499	EXPEDITED (15-DAY)		HO, OT	US-BAUSCH-BL-2016-018916			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Interaction; Lung Disorder; Malaise	Wellbutrin			S	Unknown			Not Reported
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral	Dose Adjustments		Not Reported
	Xyrem			S	Oral			Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Prozac			C				Not Reported
	Prozac			C				Not Reported
	Levofloxacin			C				Not Reported
	Xanax			C				Not Reported
	Xanax			C				Not Reported
	Adderall			C				Not Reported
	Advair			C				Not Reported
	Budesonide			C				Not Reported
	Celexa			C				Not Reported
	Celexa			C				Not Reported
	Claritin			C				Not Reported
	Modafinil			C				Not Reported
	Singulair			C				Not Reported
	Ventolin Hfa			C				Not Reported
	Medrol			C				Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2016	12714485	NON-EXPEDITED		OT	US-JAZZ-2016-US-008898			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Nausea; Vomiting	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	5.5 G, Tid		Jazz
	Zoloft			S		Unk		Not Reported
	Lexapro			S		Unknown Dose		Not Reported
	Boost Calorie Smart			C		Unk		Not Reported
	Warfarin Sodium			C		1 Mg, Unk		Not Reported
	Warfarin Sodium			C		5 Mg, Unk		Not Reported
	Warfarin Sodium			C		4 Mg, Unk		Not Reported
	Warfarin Sodium			C		2 Mg, Unk		Not Reported
	Amlodipine Besylate			C		Unk		Not Reported
	Zofran			C		Unk		Not Reported
	Lisinopril			C		Unk		Not Reported
	Lovenox			C		Unk		Not Reported
	Miralax			C		Unk		Not Reported
	Prilosec			C		Unk		Not Reported
	Amitiza			C		8 Mg, Unk		Not Reported
	Amitiza			C		24 Mg, Unk		Not Reported
	Methadone Hcl			C		Unk		Not Reported
	Ambien Cr			C		Unk		Not Reported
	Duragesic			C		Unk		Not Reported
	Librax			C		Unk		Not Reported
	Lipitor			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported
	Percocet			C		Unk		Not Reported
	Remeron			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2016	12714906	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20160902036		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Petit Mal Epilepsy	Durogesic			S	Transdermal			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2016	12715148	EXPEDITED (15-DAY)		HO, LT, OT	TR-MYLANLABS-2016M1037242			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Intentional Overdose; Serotonin Syndrome; Suicide Attempt	Escitalopram			S	Unknown	1400mg		Not Reported
	Moclobemide			S	Unknown	6000mg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	6365722	EXPEDITED (15-DAY)		OT	FR-BRISTOL-MYERS SQUIBB COMPANY-13853411		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Abilify			S	Transplacental	15 Mg, Qd		Bristol Myers Squibb
	Seroplex			S	Transplacental	10 Mg, Qd		Not Reported
	Depamide			S	Transplacental	1200 Mg, Qd		Not Reported
	Seresta			S	Transplacental	Unk		Not Reported
	Largactil			S	Transplacental	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	6366492	EXPEDITED (15-DAY)		OT	FR-BRISTOL-MYERS SQUIBB COMPANY-13853429		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Abilify			S	Transplacental	15 Mg, Qd		Bristol Myers Squibb
	Seroplex			S	Transplacental	10 Mg, Qd		Not Reported
	Depamide			S	Transplacental	1200 Mg, Qd		Not Reported
	Seresta			S	Transplacental	Unk		Not Reported
	Largactil			S	Transplacental	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12715998	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP010733		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome	Apo-Escitalopram			S	Oral	Unk		Apotex
	Apo-Olanzapine Odt			S	Oral	Unk		Apotex
	Apo-Quetiapine			S	Oral	Unk		Apotex
	Primidone			S	Oral	Unk		Not Reported
	Phenytoin			S	Oral	Unk		Not Reported
	Bupropion			S	Oral	Unk		Not Reported
	Clonidine			C	Unknown	Unk		Not Reported
	Dexmedetomidine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12716942	EXPEDITED (15-DAY)		HO	CH-MEDA-2016080110		96 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Torem			S				Meda
	Cipralex			S				Not Reported
	Ass Cardio			S				Not Reported

	Beloc Zok	S	Not Reported
	Amiodaron-Mepha	S	Not Reported
	Sodium Polystyrene Sulfonate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12717274	EXPEDITED (15-DAY)		HO	CH-TEVA-688424ISR		96 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Ass Cardio Actavis			S	Unknown			Not Reported
	Amiodaron-Mepha			S	Unknown			Teva
	Torem			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Beloc Zok			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12717570	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20160901173		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Self-Medication	Haldol			S	Oral	12 Drops Morning And Midday And 13 Drops Evening		Not Reported
	Tarka			S	Unknown	In Evening		Not Reported
	Aldactazine			S	Unknown	Morning		Not Reported
	Seroplex			S	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Spaglumic Acid			C	Unknown	19.6 Mg/0.4 Ml 1 Instillation 2 To 6 Times Daily		Not Reported
	Lantus			C	Unknown	Evening		Not Reported
	Xanax			C	Unknown	Half Tablet 1 To 3 Times Daily		Not Reported
	Stagid			C	Unknown	1.5 Tab		Not Reported

Stagid	C	Unknown			Not Reported
Parkinane	C	Unknown	Morning		Not Reported
Atorvastatin	C	Unknown	Evening		Not Reported
Levothyrox	C	Unknown	Morning On An Empty Stomach		Not Reported
Levothyrox	C	Unknown	Half Tablet In Morning On An Empty Stomach		Not Reported
Omeprazole	C	Unknown			Not Reported
Allergodil	C	Nasal	1 Spritz In Each Nostril		Not Reported
Cetirizine	C	Unknown	Evening For 3 Months		Not Reported
Uvedose	C	Unknown	1 Vial		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12724460	DIRECT		OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia; Vision Blurred	Escitalpram			S	Oral	30 Tablets Daily Oral		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	9663411	EXPEDITED (15-DAY)		HO	US-RANBAXY-2013US-74750		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Intentional Overdose	Escitalopram			S	Oral	50 Df, Single		Not Reported
	Hydrocodone And Acetaminophen			S	Oral	Unk Unk, Single		Sun
	Tramadol/Acetaminophen			S	Oral	25 Df, Single		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	12623311	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-681942USA		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Escitalopram	S	Ivax
	Quetiapine	S	Teva
	Olanzapine	S	Teva
	Phenytoin	S	Not Reported
	Primidone	S	Not Reported
	Bupropion	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	12640939	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2016GSK115302			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Asthma; Drug Interaction; Lung Disorder; Malaise	Wellbutrin			S		Unk		Glaxosmithkline
	Xyrem			S	Oral	2.25 G, Bid		Not Reported
	Xyrem			S	Oral	2.25 G, Bid		Not Reported
	Xyrem			S	Oral	Unk		Not Reported
	Xyrem			S	Oral	3.75 G, Bid		Not Reported
	Lexapro			S		20 Mg, Unk		Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported
	Prozac			C		Unk		Not Reported
	Levofloxacin			C		Unk		Not Reported
	Xanax			C		0.5 Mg, Unk		Not Reported
	Xanax			C		0.25 Mg, Unk		Not Reported
	Adderall			C		Unk		Not Reported
	Advair			C		Unk		Glaxosmithkline
	Budesonide			C		Unk		Not Reported
	Celexa			C		Unk		Not Reported
	Celexa			C		Unk		Not Reported
	Claritin Tablet (Loratadine)			C		Unk		Not Reported
	Modafinil			C		Unk		Not Reported
	Singulair			C		Unk		Not Reported
	Ventolin Hfa			C		Unk		Glaxosmithkline

Medrol	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	12720725	EXPEDITED (15-DAY)		HO	FR-FRI-1000087377		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Escitalopram			S	Oral	Daily Dose Not Reported		Forest
	Cardensiel			S	Oral	Daily Dose Not Reported		Not Reported
	Kardegic			S	Oral	Daily Dose Not Reported		Not Reported
	Levothyrox			S	Oral	Daily Dose Not Reported		Not Reported
	Crestor			S	Oral	Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	12720748	EXPEDITED (15-DAY)		HO, OT	CA-SCIEGEN PHARMACEUTICALS INC-2016SCILIT00402		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Arrhythmia; Confusional State; Delirium; Device Related Sepsis; Hyperhidrosis; Hyperreflexia; Hyperthermia; Incoherent; Major Depression; Muscle Rigidity; Myoclonus; Neuroleptic Malignant Syndrome; Overdose; Pneumonia; Seizure; Serotonin Syndrome; Tachycardia; Tremor	Bupropion Hydrochloride			S	Unknown	Unk		Sciegen
	Escitalopram			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Not Reported
	Phenytoin			S	Unknown	Unk		Not Reported
	Primidone			S	Unknown	Unk		Not Reported
	Quetapine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	12720824	EXPEDITED (15-DAY)		HO, OT	CA-SCIEGEN PHARMACEUTICALS INC-2016SCILIT00404		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Arrhythmia; Confusional State; Delirium; Device Related Sepsis; Hyperhidrosis; Hyperreflexia; Hyperthermia; Incoherent; Major Depression; Muscle Rigidity; Myoclonus; Neuroleptic Malignant Syndrome; Overdose; Pneumonia; Seizure; Serotonin Syndrome; Tachycardia; Tremor	Bupropion Hydrochloride Extended-Release Tablets Usp, 150 Mg	S	Unknown	Unk	Sciegen
	Escitalopram	S	Unknown	Unk	Not Reported
	Olanzapine	S	Unknown	Unk	Not Reported
	Phenytoin	S	Unknown	Unk	Not Reported
	Primidone	S	Unknown	Unk	Not Reported
	Quetapine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	12721751	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2016M1037675			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Blood Sodium Increased; Dehydration; General Physical Health Deterioration; Hypokalaemia; Parotitis; Renal Failure	Alprazolam Mylan 0.25 Mg, Comprimé Sécable			S	Oral	0.5 Df, Qd		Mylan
	Escitalopram Arrow			S	Oral	10 Mg, Qd		Mylan
	Cordarone			C				Mylan
	Lasilix /00032601/			C				Mylan
	Doliprane			C				Mylan
	Kardegic			C				Mylan
	Seresta			C				Mylan
	Levothyrox			C				Mylan
	Discotrine			C				Mylan
	Eupantol			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	12721800	NON-EXPEDITED			US-TORRENT-00001244			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eczema	Escitalopram Tablets, Usp			S		1 Daily		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	12722413	EXPEDITED (15-DAY)		HO	FR-FRI-1000087242		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Hepatitis Cholestatic	Escitalopram			S	Oral			Forest
	Advagraf			S	Oral	2.5 Mg		Not Reported
	Inexium			S	Oral	40 Mg		Not Reported
	Xanax			S	Oral			Not Reported
	Tahor			S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12649114	EXPEDITED (15-DAY)		DS, HO, OT	US-SAOL THERAPEUTICS-2016SAO00367		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bedridden; Cardiac Disorder; Catheter Site Swelling; Chest Discomfort; Chest Pain; Chills; Cognitive Disorder; Disturbance In Attention; Drug Withdrawal Syndrome; Dry Skin; Dyspnoea; Fall; Fatigue; General Physical Condition Abnormal; Headache; Heart Rate Increased; Hyperhidrosis; Influenza; Loss Of Consciousness; Malaise; Muscle Spasms; Muscle Spasticity; Muscular Weakness; Nasopharyngitis;	Baclofen			S	Intrathecal	70 Mg, \Day		Saol Therapeutics
	Baclofen			S		Unk Mg, Unk		Not Reported
	Compounded Baclofen			S		70 Mg, \Day		Saol Therapeutics
	Dilaudid			S	Intrathecal	3.78 Mg, \Day		Not Reported
	Fentanyl			S	Intrathecal	630 Mg, \Day		Not Reported
	Bupivacaine			S	Intrathecal	7.6 Mg, \Day		Not Reported
	Tizanidine			S		Unk		Not Reported
	Remeron			S		Unk		Not Reported
	Topamax			S				Not Reported
	Synthroid			S				Not Reported
	Midrin			S				Not Reported
	Lexapro			S				Not Reported
	Adderall			S				Not Reported
	Diazepam			C	Oral	20 Mg, \Day		Not Reported

Nightmare; Off Label Use; Overdose; Pain; Paraesthesia; Performance Status Decreased; Post Lumbar Puncture Syndrome; Pruritus; Road Traffic Accident; Toxicity To Various Agents; Tremor; Vomiting	Percocet	C	Oral	40 Mg, \Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12709618	EXPEDITED (15-DAY)		OT	DK-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-071524			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Intentional Overdose; Restlessness; Sedation; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Weight Increased	Abilify			S	Oral	10 Mg, Unk		Bristol Myers Squibb
	Cipralex /01588501/			S	Oral	10 Mg, Unk		Not Reported
	Imoclone			S	Oral	7.5 Mg, Unk		Not Reported
	Oxapax			S	Oral	Unk		Not Reported
	Seroquel			S	Oral	100 Mg, Unk		Not Reported
	Seroquel			S	Unknown	300 Mg, Unk		Not Reported
	Seroquel Prolong			S	Oral	200 Mg, Unk		Not Reported
	Truxal /00012101/			S	Oral	265 Mg, Unk		Not Reported
	Zeldox /01487002/			S	Oral	1 Df, Unk		Not Reported
	Solian			S	Oral	1 Df, Unk		Not Reported
	Solian			S	Unknown	50 Mg, Unk		Not Reported
	Risperidon			S	Oral	Unk, 1/2 Mg At Night		Not Reported
	Risperidon			S	Oral	1 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12712018	EXPEDITED (15-DAY)		DS, HO, OT	JP-FRI-1000087076		50 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Oculogyric Crisis; Protrusion Tongue; Seizure; Vomiting	Asenapine	S	Sublingual	10 Mg		Forest
	Lexapro	S	Oral	20 Mg		Forest
	Quetiapine Fumarate	S	Oral	100 Mg		Not Reported
	Quetiapine Fumarate	S	Oral	175 Mg		Not Reported
	Quetiapine Fumarate	S	Oral	300 Mg		Not Reported
	Tandospirone Citrate	C				Not Reported
	Brotizolam	C				Not Reported
	Suvorexant	C				Not Reported
	Yoku-Kan-San	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12723407	EXPEDITED (15-DAY)		HO	CA-ROCHE-1827187		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Clonazepam			S	Oral			Not Reported
	Acetaminophen/Codeine Phosphate			S	Oral			Not Reported
	Domperidone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ferrous Sulfate			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Temazepam			S	Oral			Not Reported
	Wellbutrin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12724251	EXPEDITED (15-DAY)		HO, LT	ES-PFIZER INC-2016417483		69 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Upper Gastrointestinal Haemorrhage	Trangorex			S	Oral	200 Mg, Daily		Pfizer
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported

Omeprazole		S	Unknown	Unk	Not Reported
Aldocumar		S	Oral	Unk	Not Reported
Secalip		S	Unknown	Unk	Not Reported
Efferalgan /00020001/		S	Unknown	Unk	Not Reported
Tramadol		S		Unk	Not Reported
Nebivolol		C		Unk	Not Reported
Furosemide		C		Unk	Not Reported
Amlodipine		C		Unk	Not Reported
Metformin Hydrochloride/Sitagliptin Phosphate		C		Unk	Not Reported
Fluticasone/Salmeterol		C		Unk	Not Reported
Tiotropium		C		Unk	Not Reported
Salbutamol		C		Unk	Not Reported
Lormetazepam		C		Unk	Not Reported
Metamizole		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12726075	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2016M1036998			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastric Ulcer; Haematocrit Decreased; International Normalised Ratio Increased; Upper Gastrointestinal Haemorrhage	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Omeprazole			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported
	Secalip			S		Unk		Mylan
	Aldocumar			S	Oral	Unk		Mylan
	Trangorex			S	Oral	200 Mg, Qd		Mylan
	Efferalgan /00020001/			S		Unk		Mylan
	Nebivolol			C				Mylan
	Furosemide			C				Mylan
	Amlodipine			C				Mylan

	Metformin Hydrochloride W/Sitagliptin	C	Mylan
	Salmeterol/Fluticasonpropionaat	C	Mylan
	Tiotropium	C	Mylan
	Salbutamol	C	Mylan
	Lormetazepam	C	Mylan
	Metamizole	C	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12726656	NON-EXPEDITED			US-TAKEDA-2016TUS015852			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Trintellix			S	Unknown	Unk		Takeda
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12729608	DIRECT	Y	OT			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Ineffective	Generic Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2016	12695234	EXPEDITED (15-DAY)		DE, HO, LT	CH-JNJFOC-20160819529		60 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Cardiac Arrest; Inhibitory Drug Interaction; Potentiating Drug Interaction; Sinus Node Dysfunction; Upper Gastrointestinal Haemorrhage	Xarelto			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Ibrutinib			S	Oral			Not Reported
	Amiodarone			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Nebivolol			C	Oral			Not Reported
	Atorvastatin			C	Oral			Not Reported

	Ramipril	C	Oral	Not Reported
	Eplerenone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2016	12729087	EXPEDITED (15-DAY)		HO	FR-ABBVIE-16P-056-1722133-00		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Tarka Er 4 Mg/240 Mg			S	Oral	Daily Dose: 1 Df Once Daily In The Evening		Not Reported
	Aldactazine			S	Oral	Daily Dose: 1 Df Once Daily In The Morning		Not Reported
	Haldol			S	Oral	12 Drops Morning And Noon, 13 Drops Evening		Not Reported
	Seroplex			S	Oral	Daily Dose: 1 Df Daily In The Morning		Not Reported
	Stagid			C				Not Reported
	Lantus			C		22 Units In The Evening		Not Reported
	Parkinane			C		1 Fial Morning		Not Reported
	Atorvastatin			C		10 Mg Evening		Not Reported
	Levothyrox			C		1 Df Morning		Not Reported
	Levothyrox			C		1/2 Df Morning		Not Reported
	Omeprazole			C				Not Reported
	Loperamide			C				Not Reported
	Proctolog			C		1df; 1 Or 2 Times Daily		Not Reported
	Cetirizine			C		1 Df Evening For 3 Months		Not Reported
	Allergodil			C		1 Puff In Each Nostril 2 Times Daily		Not Reported
	Naabak (Spaglumic Acid)			C		Instillation, 2 Or 6 Times Daily		Not Reported
	Uvedose			C				Not Reported
	Xanax			C		1/2 Df 1 To 3 Times Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2016	12729363	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20160906098		37 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Intentional Overdose; Intentional Self-Injury	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2016	12732182	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Depression; Irritability; Nervousness; Obsessive-Compulsive Disorder	Escitalopram Oxalate 20mg, 20 Mg			S	Oral			Bluepoint Laboratories

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2016	9564677	NON-EXPEDITED			US-PFIZER INC-2013278375		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Phenytoin			S		Unk		Pfizer
	Lamotrigine			S		Unk		Not Reported
	Levetiracetam			S		Unk		Unknown
	Sertraline Hcl			S		Unk		Pfizer
	Phenobarbital			S		Unk		Not Reported
	Valproic Acid			S		Unk		Not Reported
	Carbamazepine			S		Unk		Not Reported
	Oxcarbazepine			S		Unk		Not Reported

	Escitalopram	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2016	12696191	EXPEDITED (15-DAY)		OT	MY-FRI-1000086877		45 YR	Male	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Drug Ineffective; Sexual Dysfunction	Citalopram			S	Unknown	20 Mg		Forest
	Escitalopram			S	Unknown	20 Mg		Forest
	Hypoglycemic Agent			C	Oral			Not Reported
	Sodium Valproate			C	Unknown			Not Reported
	Mirtazapine			C	Oral			Not Reported
	Olanzapine			C	Unknown			Not Reported
	Quetiapine Xr			C	Unknown	Uptitrated To 400 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2016	12731534	NON-EXPEDITED			US-APOTEX-2016AP008293		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Bupropion Hydrochloride			S				Apotex
	Citalopram			S				Apotex
	Paroxetine Hydrochloride			S				Apotex
	Sertraline Hydrochloride			S				Apotex
	Mirtazapine			S				Apotex
	Escitalopram Oxalate			S				Apotex
	Venlafaxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2016	12731883	DIRECT		LT, OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Reaction To Excipient	Escitalopram			S	Oral			Torrent
	Lexapro			C				Not Reported
	Atenolol			C				Not Reported

	Estradiol	C	Not Reported
	Vitamin C	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2016	12738638	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neck Pain	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2016	12739302	EXPEDITED (15-DAY)		DS, HO, OT	PHHY2016US048902			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bedridden; Cardiac Disorder; Catheter Site Swelling; Chest Discomfort; Chest Pain; Chills; Cognitive Disorder; Disturbance In Attention; Drug Withdrawal Syndrome; Dry Skin; Dyspnoea; Fall; Fatigue; General Physical Condition Abnormal; Headache; Heart Rate Increased; Hyperhidrosis; Influenza; Loss Of Consciousness; Malaise; Muscle Spasms; Muscle Spasticity; Muscular Weakness; Nasopharyngitis; Nightmare; Off Label Use; Overdose; Pain; Paraesthesia; Performance Status Decreased; Post Lumbar Puncture Syndrome;	Baclofen Intrathecal			S	Intrathecal	70 Ug, Qd		Not Reported
	Baclofen			S	Unknown	Unk Mg, Unk		Not Reported
	Baclofen Intrathecal			S	Intrathecal	70 Ug, Qd		Not Reported
	Tizanidine			S	Unknown	, Unk		Novartis
	Dilaudid			S	Intrathecal	3.78 Mg, Qd		Not Reported
	Fentanyl			S	Intrathecal	630 Mg, Qd		Not Reported
	Bupivacaine			S	Intrathecal	7.6 Mg, Qd		Not Reported
	Remeron			S	Unknown	Unk, Unk		Not Reported
	Topamax			S	Unknown	, Unk		Not Reported
	Midrin			S	Unknown			Not Reported
	Synthroid			S	Unknown	, Unk		Not Reported
	Lexapro			S	Unknown			Not Reported
	Adderall			S	Unknown	, Unk		Not Reported
	Diazepam			C	Unknown			Not Reported
	Percocet			C	Unknown			Not Reported

Pruritus; Road Traffic Accident; Toxicity To Various Agents; Tremor; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2016	12484432	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2016300987		23 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Hyponatraemia; Status Epilepticus	Temesta (Lorazepam)			S	Oral	1 Mg, As Needed (Max 2/24h)		Pfizer
	Leponex			S	Oral	100 Mg, 3x/Day		Not Reported
	Leponex			S	Oral	100 Mg, 4x/Day		Not Reported
	Cipralex /01588501/			S	Oral	20 Mg, 1x/Day (1-0-0-0)		Not Reported
	Humulus Lupulus Extract/Valerian Root			C	Oral	1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2016	12722862	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2016SE85801		65 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Gingival Bleeding; Petechiae; Thrombocytopenia	Crestor			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Stiliden			S	Oral	10 Mg/Ml Oral Drops, Daily		Not Reported
	Stiliden			S	Oral			Not Reported
	Cipralex			S	Oral	20 Mg/Ml Oral Drops, Daily		Not Reported
	Diamox			S	Oral			Not Reported
	Omeprazole			C	Oral	20.0mg Unknown		Not Reported
	Glucophage			C	Oral	1000.0mg Unknown		Not Reported
	Metformin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2016	12740933	EXPEDITED (15-DAY)		HO	TW-MACLEODS PHARMACEUTICALS US LTD-MAC2016003099			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Disturbance In Attention; Drug Interaction; Euphoric Mood; Insomnia; Mania; Psychomotor Hyperactivity	Escitalopram Oxalate			S	Unknown	15 Mg, Qd		Macleods
	Dextromethorphan			S	Oral	30 Mg, Qid (Every 6 Hourly In A Day)		Not Reported
	Paracetamol			C	Unknown	325 Mg, Tid		Not Reported
	Ambroxol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2016	12746119	DIRECT		DS			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Lactose Intolerance; Malaise; Reaction To Excipient	Escitalopram			S	Oral			Camber
	Escitalopram			S	Oral			Aurobindo
	Fentanyl Hydromorphone			C				Not Reported
	Valium			C				Not Reported
	Lexapro			C				Not Reported
	Tylenol			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2016	12549259	EXPEDITED (15-DAY)		HO	CA-IMPAX LABORATORIES, INC-2016-IPXL-00708		182 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Drug Interaction; Exposure Via Breast Milk; Hypertonia; Seizure Like Phenomena; Sleep Disorder;	Bupropion Xl			S	Transmammary	Unk		Impax
	Escitalopram			S	Transmammary	Unk		Not Reported

Somnolence; Staring;
Unresponsive To Stimuli;
Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2016	12746558	DIRECT		OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Constipation; Haemorrhage; Haemorrhoids; Insomnia	Escitalopram			S	Oral	1 Tablet Oral		Cipla
	Hydroxyzine			C				Not Reported
	Viorele			C				Not Reported
	Loratidine			C				Not Reported
	Calcium			C				Not Reported
	Flonase			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2016	12747509	NON-EXPEDITED			US-ASTELLAS-2016US031700		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Xtandi			S	Oral			Astellas
	Escitalopram			S	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2016	12747952	EXPEDITED (15-DAY)		OT	DK-PFIZER INC-2016429406		17 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anger; Anxiety; Asthenia; Asthenia; Bronchitis; Decreased Immune Responsiveness; Delusion; Depressed Mood; Derealisation; Diarrhoea; Disturbance In Sexual Arousal; Drug	Lyrica			S	Oral	Unk		Pfizer
	Abilify			S		Unk		Not Reported
	Cipralex /01588501/			S	Oral	Unk		Not Reported
	Circadin			S	Oral	Unk		Not Reported
	Serdolect			S	Oral	Strength: 4 - 12 - 16 Mg.		Not Reported
	Seroquel Prolong			S	Oral	Unk		Not Reported

Ineffective; Fatigue; Fungal Infection; Gastrointestinal Disorder; Hallucination, Auditory; Hallucination, Visual; Hypersomnia; Impaired Reasoning; Impulsive Behaviour; Insomnia; Irritable Bowel Syndrome; Lung Infection; Nasopharyngitis; Nausea; Nightmare; Otitis Media; Pain; Personality Change; Restlessness; Sleep Disorder; Sleep Paralysis; Suicidal Ideation; Violence-Related Symptom; Weight Fluctuation; Weight Increased	Solian	S	Oral	Unk		Not Reported
	Truxal /00012102/	S	Oral	Unk, As Needed		Not Reported
	Seroquel	S	Oral	Unk, As Needed		Not Reported
	Zyprexa	S	Oral	Unk, As Needed		Not Reported
	Venlafaxin Actavis	S	Oral	Unk		Not Reported
	Pulmicort	C		Unk		Not Reported
	Bricanyl Turbuhaler	C		Unk		Not Reported
	Seretide	C		Unk		Not Reported
	Canesten	C		Unk		Not Reported
	Brentan /00310801/	C		Unk		Not Reported
	Nizoral	C		Unk		Not Reported
	Cetirizin Actavis	C		Unk		Not Reported
	Telfast	C		Unk		Not Reported
	Depo-Medrol	C		Unk		Not Reported
	Depo-Provera	C		Unk		Not Reported
	Tradolan	C	Oral	Unk		Not Reported
	Dolol /00020001/	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2016	12717468	EXPEDITED (15-DAY)		DS	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-122221		50 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inhibitory Drug Interaction; Off Label Use; Therapeutic Product Ineffective; Therapeutic Response Unexpected; Urinary Incontinence	Paroxetine			S	Unknown	40 Mg, Daily		Sun
	Sertraline			S	Unknown	100 Mg, Daily		Sun
	Clomipramine			S	Unknown	150 Mg, Daily		Taro
	Luvox			S	Unknown	100 Mg, Daily		Not Reported
	Luvox			S	Unknown	25 Mg, Daily		Not Reported
	Lexapro			S	Unknown	Dose Increased By 10 Mg/Day Every 4 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2016	12750358	EXPEDITED (15-DAY)		OT	CA-CIPLA LTD.-2016CA18458			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Invagen
	Haloperidol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2016	12750748	EXPEDITED (15-DAY)		OT	CA-CIPLA LTD.-2016CA18456			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Invagen
	Fluconazole			S	Unknown	Unk		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2016	12756791	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2016-11710		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Psychomotor Hyperactivity; Vomiting	Lorazepam			S	Oral	Total		Not Reported
	Quetiapine			S	Oral	Total		Aurobindo
	Entact			S	Oral	Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2016	11833977	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-084958		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Abilify			S	Oral	2 Mg, Qd		Bristol Myers Squibb
	Cipralex /01588501/			S	Unknown	30 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	10729012	NON-EXPEDITED			US-PFIZER INC-2015026350		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Zyrtec			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Penicillin Nos			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported
	Acyclovir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12401577	EXPEDITED (15-DAY)		HO, LT	FR-SA-2016SA098601		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Rifadine			S	Intravenous (not otherwise specified)			Not Reported
	Calciparine			S	Subcutaneous			Not Reported
	Azactam			S	Intravenous (not otherwise specified)			Not Reported
	Cubicin			S	Intravenous (not otherwise specified)			Not Reported
	Metronidazole			S	Intravenous (not otherwise specified)			Not Reported
	Pravastatine			S	Unknown			Not Reported
	Pravastatine			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported

	Escitalopram	S	Oral		Not Reported
	Allopurinol	S	Unknown		Not Reported
	Allopurinol	S	Oral		Not Reported
	Allopurinol	S	Oral		Not Reported
	Nebivolol	S	Oral		Not Reported
	Hydrochlorothiazide/Irbesartan	S	Oral	300/12.5mg	Not Reported
	Hydrochlorothiazide/Irbesartan	S	Oral	150/12.5 Mg	Not Reported
	Simvastatin	C			Not Reported
	Seresta	C			Not Reported
	Inexium	C			Not Reported
	Voltarene (Diclofenac Sodium)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12704283	EXPEDITED (15-DAY)		HO	FR-ASTELLAS-2016US033394		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Cerebral Ischaemia; Gamma-Glutamyltransferase Increased; Hepatitis Cholestatic	Advagraf			S	Oral	Unk Unk, Unknown Freq.		Astellas
	Advagraf			S	Oral			Astellas
	Advagraf			S	Oral	Unk Unk, Unknown Freq.		Astellas
	Atorvastatin			S	Oral			Not Reported
	Xanax			S	Oral	Unk, Unknown Freq.		Not Reported
	Xanax			S	Oral	Increased Dose, Unknown Freq.		Not Reported
	Inexium /01479302/			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Inexium /01479302/			S	Oral			Not Reported
	Seroplex			S	Oral	Unk, Unknown Freq.		Not Reported
	Seroplex			S	Oral	Increased Dose, Unknown Freq.		Not Reported
	Bisoprolol			C	Unknown	Unk, Unknown Freq.		Not Reported
	Triatec /00885601/			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Kayexalate			C	Unknown	Unk, Unknown Freq.		Not Reported

	Cellcept /01275104/	C	Unknown	Unk, Unknown Freq.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12761048	EXPEDITED (15-DAY)		HO	HR-ROCHE-1831565			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Poisoning; Suicide Attempt	Rivotril			S	Oral	30-40 Tbl, Once, Strength Unknown		Not Reported
	Nozinan			S	Oral	10 Tbl, Once, Strength Unknown		Not Reported
	Sanval			S	Oral	30 Tbl, Once, Strength Unknown		Not Reported
	Citram			S	Oral	Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12761665	EXPEDITED (15-DAY)		HO, OT	FR-ASTRAZENECA-2016SE97384		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bile Duct Stone; Drug-Induced Liver Injury; Hepatic Mass; Hepatitis	Inexium			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12762553	EXPEDITED (15-DAY)		HO	FR-FRI-1000087570		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S	Oral	5 Mg		Forest
	Loperamide			S	Oral	6 Mg		Not Reported
	Tanganil			S	Oral	1500 Mg		Not Reported
	Doliprane			S	Oral	Daily Dose Not Reported		Not Reported
	Kenacort			S	Unknown	Daily Dose Not Reported		Not Reported
	Lemoxil Roche			S	Oral	Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12762899	EXPEDITED (15-DAY)		HO, LT	CH-JNJFOC-20160919838		90 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Haematemesis; Potentiating Drug Interaction; Shock	Xarelto			S	Oral			Not Reported
	Torem			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12763258	EXPEDITED (15-DAY)		HO	FR-FRI-1000087601		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Muscle Haemorrhage	Escitalopram			S	Oral	Daily Dose Not Reported		Forest
	Previscan (Fluindione)			S	Oral	Daily Dose Not Reported		Not Reported
	Lansoprazole			C	Unknown	Daily Dose Not Reported		Not Reported
	Levocetirizine			C	Unknown	Daily Dose Not Reported		Not Reported
	Lorazepam			C	Unknown	Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12763259	EXPEDITED (15-DAY)		HO	FR-FRI-1000087602		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Petit Mal Epilepsy	Escitalopram			S	Oral	10 Mg		Forest
	Durogesic			S	Transdermal	Daily Dose Not Reported		Not Reported
	Alprazolam			C	Unknown	Daily Dose Not Reported		Not Reported
	Zopiclone			C	Unknown	Daily Dose Not Reported		Not Reported
	Pantoprazole			C	Unknown	Daily Dose Not Reported		Not Reported
	Meteospasmyl (Alverine Citrate\Dimethicone)			C	Unknown	Daily Dose Not Reported		Not Reported
	Paracetamol			C	Unknown	Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12764358	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2016PRN00147			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Somnolence	Escitalopram			S				Prinston Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12764523	EXPEDITED (15-DAY)		OT	DK-ASTRAZENECA-2016SE97037		17 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anger; Anxiety; Asthenia; Asthenia; Bronchitis; Decreased Immune Responsiveness; Depressed Mood; Derealisation; Diarrhoea; Disturbance In Sexual Arousal; Drug Ineffective; Fatigue; Fungal Infection; Gastrointestinal Disorder; Hallucination; Hallucination, Auditory; Hallucination, Visual; Hypersomnia; Impaired Reasoning; Impulsive Behaviour; Insomnia; Irritable Bowel Syndrome; Lung Infection; Nasopharyngitis; Nausea; Nightmare; Otitis Media; Pain; Personality Change; Restlessness; Sleep Disorder; Sleep Paralysis; Suicidal Ideation; Violence-Related	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Abilify			S	Unknown			Not Reported
	Venlafaxin			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Circadin			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Serdolect			S	Oral	4 - 12 -16 Mg.		Not Reported
	Solian			S	Oral			Not Reported
	Truxal			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Pulmicort			C				Not Reported
	Bricanyl Turbuhaler			C				Not Reported
	Seretide			C				Not Reported
	Canesten			C				Not Reported
	Brentan			C				Not Reported
	Nizoral			C				Not Reported
	Cetirizin			C				Not Reported
	Telfast			C				Not Reported
	Depo-Medrol			C				Not Reported

Symptom; Weight Fluctuation; Weight Increased	Depo-Provera	C			Not Reported
	Tradolan	C	Oral		Not Reported
	Dolol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12764607	EXPEDITED (15-DAY)		OT	DK-ELI_LILLY_AND_COMPANY-DK201609005087		17 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anger; Anxiety; Asthenia; Bronchitis; Decreased Immune Responsiveness; Depressed Mood; Derealisation; Diarrhoea; Disturbance In Sexual Arousal; Drug Ineffective; Fatigue; Fungal Skin Infection; Gastrointestinal Disorder; General Physical Condition Abnormal; Genital Infection Fungal; Hallucination; Hallucination, Auditory; Hallucination, Visual; Hypersomnia; Impaired Reasoning; Impulse-Control Disorder; Impulsive Behaviour; Insomnia; Irritable Bowel Syndrome; Libido Disorder; Lung Infection; Nasopharyngitis; Nausea; Nightmare; Otitis Media; Pain; Personality Change; Restlessness; Sleep Disorder; Sleep Paralysis; Suicidal Ideation; Violence-Related Symptom; Weight	Zyprexa			S	Oral	Unk Unk, Prn		Eli Lilly And Co
	Seroquel			S	Oral	Unk, Prn		Not Reported
	Truxal /00012101/			S	Oral	Unk, Prn		Not Reported
	Serdolect			S	Oral	Unk, Prn		Not Reported
	Serdolect			S	Oral	12 Mg, Prn		Not Reported
	Serdolect			S	Oral	16 Mg, Prn		Not Reported
	Solian			S	Oral	Unk, Unknown		Not Reported
	Abilify			S	Unknown	Unk, Unknown		Not Reported
	Cipralex /01588501/			S	Oral	Unk, Unknown		Not Reported
	Circadin			S	Oral	Unk, Unknown		Not Reported
	Lyrica			S	Oral	Unk, Unknown		Not Reported
	Seroquel			S	Oral	Unk, Prn		Not Reported
	Venlafaxin Actavis			S	Oral	Unk, Unknown		Not Reported
	Pulmicort			C	Unknown	Unk, Unknown		Not Reported
	Bricanyl Turbuhaler			C	Unknown	Unk, Unknown		Not Reported
	Seretide			C	Unknown	Unk, Unknown		Not Reported
	Canesten			C	Unknown	Unk, Unknown		Not Reported
	Brentan /00310801/			C	Unknown	Unk, Unknown		Not Reported
	Nizoral			C	Unknown	Unk, Unknown		Not Reported
	Cetirizin Actavis			C	Unknown	Unk, Unknown		Not Reported
	Telfast			C	Unknown	Unk, Unknown		Not Reported

Fluctuation; Weight Increased	Depo-Medrol	C	Unknown	Unk, Unknown	Not Reported
	Depo-Provera	C	Unknown	Unk, Unknown	Not Reported
	Tradolan	C	Oral	Unk, Unknown	Not Reported
	Dolol /00020001/	C	Oral	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12771537	DIRECT	Y				67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	10467701	EXPEDITED (15-DAY)		LT	FR-FRI-1000070838		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hallucination; Intentional Overdose; Neuroleptic Malignant Syndrome	Escitalopram			S		Overdose Of 20 Df Once		Forest
	Baclofene			S	Oral	Overdose Of 140 Df Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	11239649	EXPEDITED (15-DAY)		HO	FR-FRI-1000077877		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Gastric Ulcer; Gastrointestinal Haemorrhage	Escitalopram			S	Oral	5 Mg		Forest
	Kardegic			S	Oral	75 Mg		Not Reported
	Fosamax			C	Oral	70 Mg		Not Reported
	Levothyrox			C	Oral	50 Microgram		Not Reported
	Candesartan Mylan			C	Oral	8 Mg		Not Reported
	Bisoprolol Arrow			C	Oral	10 Mg		Not Reported

	Seresta	C	Oral	10 Mg		Not Reported
	Loxen (Nicardipine Hydrochloride)	C	Oral	40 Mg		Not Reported
	Inexium	C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12365448	EXPEDITED (15-DAY)		HO, LT	JP-FRI-1000083337		82 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Escitalopram			S	Oral	10 Mg		Forest
	Olmetec			S	Oral	20 Mg		Not Reported
	Myslee			S	Oral	10 Mg		Not Reported
	Depas (Etizolam)			S	Oral	0.5 Mg		Not Reported
	Kakkonto			C	Oral			Not Reported
	Calonal			C	Oral			Not Reported
	Mohrus Tape			C	Transdermal			Not Reported
	Neurotropin			C	Intravenous (not otherwise specified)	Unit Dose: 3.6 Ut		Not Reported
	Claritin			C	Oral			Not Reported
	Yokukansan			C	Oral			Not Reported
	Meilax			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12627186	EXPEDITED (15-DAY)		HO	FR-FRI-1000086671		22 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Miosis; Somnolence	Escitalopram			S	Oral	10 Mg		Forest
	Escitalopram			S	Oral	Overdose: Escitalopram 280 Mg At Once.		Forest
	Doxylamine			S	Oral			Not Reported
	Nocertone			S	Oral			Not Reported

	Codeine	S	Oral			Not Reported
	Paracetamol	C	Oral			Not Reported
	Ketoprofene	C	Oral			Not Reported
	Ketoprofene	C	Oral	Overdose: Ketoprofene 700 Mg At Once.		Not Reported
	Jasminelle	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12765260	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2016-03254		34 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Drug Interaction; Sleep-Related Eating Disorder	Zolpidem			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Zolpidem			S	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12766661	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2016431183		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Psychomotor Hyperactivity; Vomiting	Lorazepam			S	Oral	Total		Pfizer
	Quetiapine Fumarate			S	Oral	Total		Not Reported
	Entact			S	Oral	Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12767770	EXPEDITED (15-DAY)		HO, LT	CZ-JNJFOC-20160811600		82 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Wall Haematoma; Dehydration; Fall; Hyponatraemia; Syncope	Fentanyl			S	Transdermal			Not Reported
	Tramadol			S	Unknown	1-0-1		Not Reported

Tiaprid	S	Unknown	0-0-0-1		Not Reported
Metamizole	S	Unknown	2-2-2		Not Reported
Nitrendipin	S	Unknown	1-0-0		Not Reported
Bromazepam	S	Unknown	1/2-0-0		Not Reported
Omeprazole	S	Unknown	1-0-0		Not Reported
Furosemide	S	Unknown	1-0-0		Not Reported
Levothyroxine	S	Unknown	1-0-0		Not Reported
Escitalopram	S	Unknown	1-0-0		Not Reported
Atorvastatin	S	Unknown	0-0-1/2		Not Reported
Perindopril	S	Unknown	1-0-1		Not Reported
Isosorbid Dinitrate	S	Unknown			Not Reported
Amiloride Hydrochloride W/Chlortalidone	S	Unknown	25 Mg/2.5 Mg (1-0-1)		Not Reported
Rivaroxaban	C	Unknown	1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12767789	EXPEDITED (15-DAY)		HO	FR-FRI-1000087628		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hypochloraemia; Hyponatraemia	Escitalopram			S	Oral	10 Mg		Forest
	Valsartan			S	Oral	Daily Dose Not Reported		Not Reported
	Eupantol			S	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12767873	EXPEDITED (15-DAY)		HO	IT-FRI-1000087606		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Intentional Overdose; Suicide Attempt	Escitalopram			S	Oral			Forest
	Escitalopram			S	Oral	Overdose: 560 Mg		Forest
	Minias 2.5 Mg/Ml Gocce Orali, Soluzione			S	Oral			Not Reported

	Minias 2.5 Mg/Ml Gocce Orali, Soluzione	S	Oral	Overdose: 50 Mg	Not Reported
	Trittico 150 Mg Compresse Rivestite Con Film A Rilascio Prolungato	S	Oral		Not Reported
	Trittico 150 Mg Compresse Rivestite Con Film A Rilascio Prolungato	S	Oral	Overdose: 2100 Mg	Not Reported
	Solian 200 Mg Compresse	C	Oral		Not Reported
	Solian 200 Mg Compresse	C	Oral		Not Reported
	Levopraid 25 Mg/Ml Gocce Orali Soluzione	C	Oral		Not Reported
	Vantavo 70 Mg/5600 Ui Compresse	C	Oral		Not Reported
	Vantavo 70 Mg/5600 Ui Compresse	C	Oral		Not Reported
	Tolep 300 Mg Compresse	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12767874	EXPEDITED (15-DAY)		OT	SE-FRI-1000087590			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inhibitory Drug Interaction	Escitalopram			S	Unknown	20 Mg		Forest
	Corsodyl			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12768237	EXPEDITED (15-DAY)		HO, OT	HR-TEVA-692643ACC			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Suicide Attempt	Ladiomil			S	Oral			Actavis
	Normabel			S	Oral			Not Reported
	Elicea			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12768360	EXPEDITED (15-DAY)		HO	FR-FRI-1000087642		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning Deliberate; Somnolence	Escitalopram			S	Oral			Forest
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12768610	EXPEDITED (15-DAY)		OT	US-FRI-1000080935			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuromyopathy; Suicidal Ideation	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Unknown			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12768614	EXPEDITED (15-DAY)			JP-FRI-1000080680		80 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lexapro			S	Oral	10 Mg		Forest
	Depas (Etizolam)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12414641	EXPEDITED (15-DAY)		HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-040279		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Renal Impairment	Azactam			S	Intravenous (not otherwise specified)	500 Mg, Tid		Bristol Myers Squibb
	Rifadine /00146901/			S	Intravenous (not otherwise specified)	600 Mg, Bid		Not Reported

Calciparine	S	Subcutaneous	0.2 Ml, Bid		Not Reported
Cubicin	S	Intravenous (not otherwise specified)	Unk		Not Reported
Metronidazole B Braun	S	Intravenous (not otherwise specified)	500 Mg, Tid		Not Reported
Pravastatin Arrow	S	Oral	20 Mg, Qd		Not Reported
Escitalopram Arrow	S	Oral	10 Mg, Qd		Not Reported
Allopurinol Arrow	S	Oral	200 Mg, Qd		Not Reported
Allopurinol Arrow	S	Oral	100 Mg, Qd		Not Reported
Nebivolol Arrow	S	Oral	2.5 Mg, Qd		Not Reported
Simvastatine	C	Unknown	20 Mg, Qd		Not Reported
Seresta	C	Unknown	10 Mg, Qd		Not Reported
Inexium /01479302/	C	Unknown	20 Mg, Qd		Not Reported
Voltarene /00372302/	C	Unknown	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12439178	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-ELI_LILLY_AND_COMPANY-NO201606000159		28 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Shoulder Deformity; Weight Increased	Zyprexa Velotab			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Abilify			S	Unknown	Unk, Unknown		Not Reported
	Xeplion			S	Unknown	Unk, Unknown		Not Reported
	Cipralex /01588501/			S	Unknown	Unk, Unknown		Not Reported
	Risperdal			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12502305	EXPEDITED (15-DAY)		HO	CH-FRI-1000085630		23 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Hyponatraemia	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Unknown			Forest
	Escitalopram			S	Oral	20 Mg		Not Reported
	Temesta (Lorazepam)			S	Oral	2/24 H, As Required		Not Reported
	Leponex (Clozapine)			S	Oral	300 Mg		Not Reported
	Leponex (Clozapine)			S	Unknown	400 Mg		Not Reported
	Linomed (Senna Alexandria/Linum Usitatissimum Seed/Rhamnus Frangula Ba			C	Oral			Not Reported
	Redormin (Valeriana Officinalis Root/Humulus Lupulus Hops)			C	Oral	1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12745011	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2016US05060			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anger; Crying; Depression; Drug Ineffective; Emotional Disorder; Fatigue; Feeling Abnormal; Loss Of Consciousness; Nervousness; Pain; Sedation; Weight Increased; Weight Loss Poor	Escitalopram			S	Oral	Unk, Bid, 10 Mid		Invagen
	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Cyclobenzaprine			S	Unknown	Unk, Prn		Invagen
	Lyrica			S	Unknown	75 Mg, Bid, Two Capsules		Not Reported
	Lyrica			S	Unknown	10 Mg, Bid		Not Reported
	Propranolol			S	Oral	10 Mg, Qd At Night		Not Reported
	Diazepam			S	Oral	10 Mg, Tid		Not Reported
	Singulair			S	Unknown	Unk		Not Reported
	Synthroid			S	Oral	Unk, 1 Tablet, Qd		Not Reported
	Tramadol			S	Oral	50 Mg, 6 Hourly, Prn		Not Reported
	Effexor			S	Oral	10 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12769634	EXPEDITED (15-DAY)		HO, LT	CA-ORCHID HEALTHCARE-1057560		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Device Related Sepsis; Overdose; Pneumonia; Serotonin Syndrome	Olanzapine			S	Unknown			Orchid
	Bupropion			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported
	Phenytoin			S	Unknown			Not Reported
	Primidone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12769953	EXPEDITED (15-DAY)		HO	TW-ACCORD-044138		22 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Mania	Escitalopram			S				Accord
	Dextromethorphan			S	Oral			Not Reported
	Ambroxol/Ambroxol Acefyllinate/Ambroxol Hydrochloride			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12772029	EXPEDITED (15-DAY)		OT	DK-TEVA-693414ACC		17 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anger; Anxiety; Asthenia; Asthenia; Bronchitis; Decreased Immune Responsiveness; Delusion; Depressed Mood; Derealisation; Diarrhoea; Disturbance In Sexual Arousal; Drug Ineffective; Fatigue; Fungal Infection;	Venlafaxin "Actavis"			S	Oral			Teva
	Abilify			S				Not Reported
	Cipralex			S	Oral			Not Reported
	Circadin			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Serdolect			S	Oral	Styrke: 4 - 12 -16 Mg.		Not Reported
	Seroquel Prolong			S	Oral			Not Reported
	Solian			S	Oral			Not Reported

Gastrointestinal Disorder; Hallucination; Hallucination, Auditory; Hallucination, Visual; Hypersomnia; Impaired Reasoning; Impulsive Behaviour; Insomnia; Irritable Bowel Syndrome; Lung Infection; Nasopharyngitis; Nausea; Nightmare; Otitis Media; Pain; Personality Change; Restlessness; Sleep Disorder; Sleep Paralysis; Suicidal Ideation; Violence-Related Symptom; Weight Fluctuation; Weight Increased	Truxal	S	Oral	Dosis: Ved Behov	Not Reported
	Seroquel	S	Oral	Dosis: Ved Behov	Not Reported
	Zyprexa	S	Oral	Dosis: Ved Behov	Not Reported
	Pulmicort	C			Not Reported
	Bricanyl Turbuhaler	C			Not Reported
	Seretide	C			Not Reported
	Canesten	C			Not Reported
	Brentan	C			Not Reported
	Nizoral	C			Not Reported
	Cetirizin "Actavis"	C			Not Reported
	Telfast	C			Not Reported
	Depo-Medrol	C			Not Reported
	Depo-Provera	C			Not Reported
	Tradolan	C	Oral		Not Reported
	Dolol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12772352	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2016M1039648			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Psychomotor Hyperactivity; Vomiting	Quetiapine			S	Oral	Unk Unk, Total		Not Reported
	Lorazepam			S	Oral	Unk Unk, Total		Not Reported
	Entact			S	Oral	Unk Unk, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2016	12413228	EXPEDITED (15-DAY)		LT	FR-009507513-1605FRA011514		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Daptomycin			S	Intravenous (not otherwise specified)	1000 Mg, Biw (Every Two Weeks)		Merck
	Daptomycin			S	Intravenous (not otherwise specified)	1000 Mg, Qd		Merck

Rifadin	S	Intravenous (not otherwise specified)	600 Mg, (4 Capsules, Daily For Two Days), Bid	Not Reported
Metronidazole	S	Intravenous (not otherwise specified)	500 Mg, Tid	Not Reported
Azactam	S	Intravenous (not otherwise specified)	1000 Mg, Once/Single	Not Reported
Azactam	S	Intravenous (not otherwise specified)	500 Mg, Tid	Not Reported
Pravastatin	S	Oral	20 Mg, Qd	Not Reported
Pravastatin	S	Oral	Unk	Not Reported
Escitalopram Oxalate	S	Oral	10 Mg, Qd	Not Reported
Escitalopram Oxalate	S	Oral	Unk	Not Reported
Allopurinol	S	Oral	200 Mg, Qd	Not Reported
Allopurinol	S	Oral	100 Mg, Qd	Not Reported
Allopurinol	S	Oral	Unk	Not Reported
Nebivolol Hydrochloride	S	Oral	2.5 Mg, Qd	Not Reported
Calciparine	S	Subcutaneous	0.2 Ml, Bid	Not Reported
Calciparine	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide (+) Irbesartan	S	Oral	300/12.5 Mg, Qd	Not Reported
Hydrochlorothiazide (+) Irbesartan	S	Oral	150/2.5 Mg, Qd	Not Reported
Seresta	C			Not Reported
Inexium (Esomeprazole Sodium)	C			Not Reported
Voltarene (Diclofenac Sodium)	C			Not Reported
Simvastatin	C			Merck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2016	12774380	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-077166			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Cardiac Flutter; Feeling Abnormal; Major Depression; Sleep	Abilify			S	Unknown			Bristol Myers Squibb
	Wellbutrin			S	Unknown			Not Reported

Disorder; Suicidal Ideation; Therapeutic Response Decreased	Lexapro	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2016	12775355	EXPEDITED (15-DAY)		HO	IT-TEVA-693889ACC		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Psychomotor Hyperactivity; Vomiting	Quetiapine			S	Oral			Teva
	Lorazepam			S	Oral			Actavis
	Entact - 10 Mg Compresse Rivestite Con Film - H. Lundbeck A/S			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2016	12775573	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016439554		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hypochloraemia; Hyponatraemia	Eupantol			S	Oral	40 Mg, Qd		Pfizer
	Valsartan			S	Oral	Unk, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Lyrica			C		Unk		Not Reported
	Loxen /00639802/			C		Unk		Not Reported
	Celiprolol			C		Unk		Not Reported
	Atarax /00058402/			C		Unk		Not Reported
	Foradil			C		Unk		Not Reported
	Ceris			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2016	12759768	EXPEDITED (15-DAY)		CA, DE	PHHY2016US128692		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Failure; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Multiple Organ Dysfunction Syndrome	Ondansetron	S	Transplacental		Not Reported
	Sertraline	S	Transplacental		Novartis
	Escitalopram	S	Transplacental		Not Reported
	Progesterone	S	Transplacental	Maternal Dose: High Dsoe	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2016	12777254	EXPEDITED (15-DAY)		HO	IT-ACCORD-044189		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Psychomotor Hyperactivity; Vomiting	Quetiapine			S	Oral			Accord
	Entact			S	Oral	Strength 10 Mg Dose: Total Oral		Not Reported
	Lorazepam			S	Oral	Dose: Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2016	12780046	EXPEDITED (15-DAY)		HO, LT	TR-MYLANLABS-2016M1040862			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Coma; General Physical Health Deterioration; Hypernatraemia; Hypocalcaemia; Leukopenia; Loss Of Consciousness; Respiratory Depression; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Valproic Acid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2016	12780578	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2016441329		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bradycardia; Coma; Intentional Overdose; Pneumonia Aspiration; Toxicity To Various Agents	Amlor			S	Oral	Unk Unk, Single		Pfizer
	Amlor			S				Pfizer
	Lyrica			S	Oral	Unk, Single		Pfizer
	Lyrica			S				Pfizer
	Sectral			S	Oral	Unk, Single		Not Reported
	Sectral			S				Not Reported
	Seroplex			S	Oral	Unk, Single		Not Reported
	Seroplex			S				Not Reported
	Actiskenan			S	Oral	Unk, Single		Not Reported
	Actiskenan			S				Not Reported
	Plavix			C				Not Reported
	Crestor			C				Not Reported
	Pariet			C				Not Reported
	Doliprane			C				Not Reported
	Spasfon /00765801/			C				Not Reported
	Movicol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2016	12781267	EXPEDITED (15-DAY)		OT	AU-SA-2016SA171157		34 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Eating Disorder; Hallucination	Zolpidem			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12761992	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-124180		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Psychomotor Hyperactivity; Vomiting	Quetiapine			S	Oral	1 Dosage Total		Sun
	Lorazepam			S	Oral	Total		Sun

	Entact	S	Oral	Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12782000	NON-EXPEDITED		DE	JP-LUPIN PHARMACEUTICALS INC.-2016-03180		20 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Mirtazapine			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12782852	DIRECT		OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dizziness; Fall; Fatigue; Product Substitution Issue; Scratch; Similar Reaction On Previous Exposure To Drug; Withdrawal Syndrome	Escitalopram Oxalate			S	Oral			Aurobindo
	Generic Lexapro			C				Not Reported
	Prevacid			C				Not Reported
	Allegra			C				Not Reported
	Digestive Advantage Daily Probiotic			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12783031	NON-EXPEDITED			US-PFIZER INC-2016449593		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Rexulti			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12783922	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1000087630		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Psychomotor Hyperactivity; Refusal Of Treatment By Patient; Self-Medication; Vomiting	Escitalopram Oxalate Unk			S	Oral	10 Mg, Unk		Allergan
	Quetiapine			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12784826	EXPEDITED (15-DAY)		HO, LT	CH-MEDA-2016090062		90 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Haematemesis; Potentiating Drug Interaction; Shock	Torem 5 Mg			S	Oral	1-0-0		Meda
	Xarelto 20 Mg			S	Oral	1-0-0		Not Reported
	Escitalopram			S	Oral	1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12786865	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1669878US		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abnormal Dreams; Acne; Arthralgia; Breast Swelling; Decreased Appetite; Diarrhoea; Dry Mouth; Insomnia; Myalgia; Nausea; Nightmare; Ocular Discomfort; Pruritus; Suicidal Ideation; Throat Irritation; Tinnitus; Tremor; Vertigo; Weight Decreased	Seroplex Tablets			S	Unknown			Allergan
	Mylan-Risperidone			S	Unknown	Unk		Not Reported
	Permixon			C	Unknown			Not Reported
	Nebivolol			C	Unknown			Not Reported
	Kardegic			C	Unknown			Not Reported
	Doliprane			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12786972	EXPEDITED (15-DAY)		OT	DK-ALLERGAN-1000087643		17 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anger; Anxiety; Asthenia; Asthenia; Bronchitis; Decreased Immune Responsiveness; Depressed Mood; Derealisation; Diarrhoea; Disturbance In Sexual Arousal; Drug Ineffective; Fatigue; Fungal Infection; Gastrointestinal Disorder; Hallucination; Hallucination, Auditory; Hallucination, Visual; Hypersomnia; Impaired Reasoning; Impulsive Behaviour; Insomnia; Irritable Bowel Syndrome; Lung Infection; Nasopharyngitis; Nausea; Nightmare; Otitis Media; Pain; Personality Change; Product Use Issue; Restlessness; Sleep Disorder; Sleep Paralysis; Suicidal Ideation; Violence-Related Symptom; Weight Fluctuation; Weight Increased	Cipralex Tablets			S	Oral	Unk		Allergan
	Abilify			S	Unknown	Unk		Not Reported
	Circadin			S	Oral	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Serdolect			S	Oral	Strength: 4 - 12 -16 Mg		Not Reported
	Seroquel Prolong			S	Oral	Unk		Not Reported
	Solian			S	Oral	Unk		Not Reported
	Truxal			S	Oral	Unk Unk, Prn		Not Reported
	Seroquel			S	Oral	Unk, Prn		Not Reported
	Zyprexa			S	Oral	Unk, Prn		Not Reported
	Venlafaxin "Actavis"			S	Oral	Unk		Not Reported
	Pulmicort			C	Unknown	Unk		Not Reported
	Bricanyl Turbuhaler			C	Unknown	Unk		Not Reported
	Seretide			C	Unknown	Unk		Not Reported
	Canesten			C	Unknown	Unk		Not Reported
	Brentan			C	Unknown	Unk		Not Reported
	Nizoral			C	Unknown	Unk		Not Reported
	Cetirizin "Actavis"			C	Unknown	Unk		Not Reported
	Telfast			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Unknown	Unk		Not Reported
	Depo-Provera			C	Unknown	Unk		Not Reported
	Tradolan			C	Oral	Unk		Not Reported
	Dolol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12788687	DIRECT		HO, LT			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Seizure	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12790093	EXPEDITED (15-DAY)		OT	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2016-BI-62		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Sifrol			S	Oral	0.7 Mg		Boehringer Ingelheim
	Arava			S	Oral	1 Anz		Not Reported
	Seroplex			S	Oral	10 Mg		Not Reported
	Femara			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12790250	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1000087634		45 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abdominal Pain Upper; Abnormal Dreams; Abnormal Dreams; Confusional State; Diarrhoea; Dizziness; Fatigue; Feeling Abnormal; Headache; Hyperhidrosis; Insomnia; Lethargy; Memory Impairment; Muscle Disorder; Yawning	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S				Allergan
	Escitalopram Oxalate Unk			S				Allergan
	Alepam / Oxazepam			C	Unknown	15 Mg, Unk		Not Reported
	Panadol / Paracetamol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	12431684	EXPEDITED (15-DAY)		LT	FR-AUROBINDO-AUR-APL-2016-06519		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Allopurinol Arrow			S	Oral	100 Mg, Once A Day		Not Reported
	Escitalopram Arrow 10 Mg			S	Oral	10 Mg, Once A Day		Aurobindo
	Nebivolol Arrow			S	Oral	2.5 Mg, Once A Day		Not Reported
	Pravastatin Arrow 20mg			S	Oral	20 Mg, Once A Day		Not Reported
	Azactam			S	Intravenous (not otherwise specified)	500 Mg, 3 Times A Day		Not Reported
	Cubicin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Irbesartan And Hydrochlorothiazide			S	Oral	Unk, Once A Day		Not Reported
	Metronidazole B Braun			S	Intravenous (not otherwise specified)	500 Mg, 3 Times A Day		Not Reported
	Rifadine /00146901/			S	Intravenous (not otherwise specified)	600 Mg, Two Times A Day		Not Reported
	Heparin Calcium			S	Subcutaneous	0.2 Ml, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	12525609	NON-EXPEDITED		OT	US-JNJFOC-20160615361		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Irritability; Mood Swings	Invega			S	Oral			Not Reported
	Invega			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	12791492	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2016US18916			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contact Lens Acute Red Eye; Disturbance In Attention; Feeling Abnormal; Headache; Insomnia; Ocular Discomfort	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Tylenol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	12791753	EXPEDITED (15-DAY)		OT	PHHY2016FR131308		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatitis Cholestatic	Femara			S	Oral	Unk		Novartis
	Arava			S	Oral	1 Df, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Unk		Not Reported
	Sifrol			S	Unknown	0.7 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	12795769	EXPEDITED (15-DAY)		DE	PHHY2016CH133717		75 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Drug Interaction	Voltaren Retard			S	Oral	75 Mg, Bid		Novartis
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Symfona N (Ginkgo Biloba Extract)			S	Oral	120 Mg, Bid		Not Reported
	Marcoumar			S	Oral	Unk		Not Reported
	Omeprazole			C	Oral	20 Mg, Bid		Not Reported
	Novalgine (Metamizole Sodium)			C	Oral	500 Mg, Qid		Not Reported

	Lexotanil	C	Oral	1.5 Mg, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	12797000	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1670193US		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Overdose; Pneumonia Aspiration	Escitalopram Oxalate Unk			S	Oral	50 Df, Single		Allergan
	Seresta			S	Oral	30 Df, Single		Not Reported
	Moclamine			S	Oral	50 Df, Single		Not Reported
	Teralithe			S	Oral	3 Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	12797016	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1670190US		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eructation; Platelet Disorder; Post Procedural Haemorrhage; Procedural Haemorrhage; Withdrawal Syndrome	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Unknown	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2016	12660404	EXPEDITED (15-DAY)		HO, LT, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2016VAL002418		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Body Temperature Increased; Diarrhoea; Flushing; Hallucination, Auditory; Hallucination, Visual; Insomnia; Rash; Serotonin Syndrome	Meperidine Hydrochloride			S	Oral	Unk		Validus
	Atasol (Acetaminophen)			S	Oral	Unk		Not Reported
	Cipralex			S	Oral	1.5 Df, Qd		Not Reported
	Cipralex			S	Unknown	Unk		Not Reported
	Cipralex			S		Unk		Not Reported

Concerta	S	Oral	18 Mg, Qd		Not Reported
Morphine Sulfate	S	Intravenous (not otherwise specified)	Unk		Not Reported
Diprosone	C	Unknown	Unk		Not Reported
Docusate Sodium	C	Unknown	Unk		Not Reported
Glucagon	C	Unknown	Unk		Not Reported
Lantus	C	Unknown	Unk		Not Reported
Metformin	C	Unknown	Unk		Not Reported
Phisohex	C	Unknown	Unk		Not Reported
Proctodan Hc	C	Unknown	Unk		Not Reported
Proctosol Hc	C	Unknown	Unk		Not Reported
Ramipril	C	Unknown	Unk		Not Reported
Simvastatin	C	Unknown	Unk		Not Reported
Tecta	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2016	12780888	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2016AP011948		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Psychomotor Hyperactivity; Vomiting	Quetiapina Doc Generici Compresse Rivestite Con Film			S	Oral	Unk		Apotex
	Lorazepam			S	Oral	Unk		Not Reported
	Entact			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2016	12797986	EXPEDITED (15-DAY)		OT	SA-MACLEODS PHARMACEUTICALS US LTD-MAC2016003164			Unknown	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Drug Withdrawal	Escitalopram Oxalate			S	Unknown	Unk		Macleods

Syndrome; Headache; Photophobia; Vision Blurred; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2016	12798325	EXPEDITED (15-DAY)		OT	FR-ACCORD-044399		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Hepatocellular Injury; Influenza Like Illness	Escitalopram			S				Accord
	Chlorpromazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2016	12799027	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20160929410		35 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2016	12800021	EXPEDITED (15-DAY)		OT	FR-SA-2016SA178461		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Arava			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Sifrol			S	Unknown			Not Reported
	Femara			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2016	12801921	DIRECT					91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Escitalopram Oxalate 5 Mg Tab Ac			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Vitamin C			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Unspecified Ingredient			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2016	12805631	DIRECT		LT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Substitution Issue; Suicidal Ideation	Lexapro			S	Oral	Quantity:90 Tablet(S);		Not Reported
	Levothyroxin			C				Not Reported
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12643483	EXPEDITED (15-DAY)		DS	IT-FRI-1000086765		59 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Complex Regional Pain Syndrome; Complex Regional Pain Syndrome; Hyperhidrosis; Nausea; Night Sweats; Weight Increased	Entact Oral Drops			S	Oral	20 Mg, Qd		Allergan
	Cipralex Tablets			S	Oral	10 Mg, Qd		Allergan
	Cipralex Tablets			S		Unk		Allergan
	Inderal			C	Oral	40 Mg, Qd		Not Reported
	Inderal			C				Not Reported
	Deursil			C	Oral	450 Mg, Bid		Not Reported
	Tavor [Lorazepam]			C	Oral	1 Mg, Qd		Not Reported
	Tavor			C	Oral	1 Mg, Prn		Not Reported
	Diclofenac			C	Intramuscular	Unk Unk, Unk		Not Reported
	Diclofenac			C	Unknown	50 Mg, Prn		Not Reported
	Muscoril			C	Intramuscular	As Reuired		Not Reported
	Aciclovir			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Oral	20 Mg, Unk		Not Reported

	Didrogyl	C	Oral	3 Gtt, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12802851	EXPEDITED (15-DAY)		DE, OT	CH-GLAXOSMITHKLINE-CH2016GSK143660		75 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Drug Interaction	Voltaren Retard			S	Oral	75 Mg, Bid		Glaxosmithkline
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Symfona N (Ginkgo Biloba Extract)			S	Oral	120 Mg, Bid		Not Reported
	Marcoumar			S	Oral	Unk		Not Reported
	Omeprazole			C				Not Reported
	Novalgine (Metamizole Sodium)			C		Unk		Not Reported
	Lexotanil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12802877	NON-EXPEDITED			US-DRREDDYS-USA/USA/15/0053042			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Peripheral Swelling	Augmentin			S	Unknown			Not Reported
	Prevnar 13			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12803276	EXPEDITED (15-DAY)		HO, OT	PHHY2016HR134895		53 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Drug Interaction; Electrocardiogram Abnormal	Quetiapine			S	Unknown	800 Mg, Qd		Novartis
	Quetiapine			S	Unknown	400 Mg, Qd		Novartis
	Quetiapine			S	Unknown	100 Mg, Qd		Novartis
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported

Valproate	C	Unknown	1500 Mg, Qd		Not Reported
Valproate	C				Not Reported
Diazepam	C	Unknown	30 Mg, Qd		Not Reported
Diazepam	C				Not Reported
Zolpidem	C	Unknown	10 Mg, Qd		Not Reported
Zolpidem	C				Not Reported
Biperiden	C	Unknown	1 Mg, Qd		Not Reported
Biperiden	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12804570	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1670490US		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bradycardia; Coma; Pneumonia Aspiration	Seroplex Tablets			S	Oral	Unk		Allergan
	Sectral			S	Oral	Unk		Not Reported
	Amlor			S	Oral	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Actiskenan			S	Oral	Unk		Not Reported
	Plavix			C		Unk		Not Reported
	Crestor			C		Unk		Not Reported
	Pariet			C		Unk		Not Reported
	Doliprane			C	Unknown			Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			C		Unk		Not Reported
	Movicol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12804581	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1670499US		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Interaction; Haematemesis; Rectal	Seroplex Tablets			S	Oral	10 Mg, Qd		Allergan

Haemorrhage	Kardegic	S	Oral	75 Mg, Qd	Not Reported
	Coaprovel	C		150 Mg/12.5 Mg, Qam	Not Reported
	Imovane	C		7.5 Mg, Qhs	Not Reported
	Transipeg (Macrogol 3350)	C	Oral	Unk, Bid (Morning And Night)	Not Reported
	Inofer	C		2 Df, Qam	Not Reported
	Paracetamol	C		1g, Prn (Morning And Night If Pain)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12628056	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2016-09895		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Interaction; Eosinophilia; Hepatocellular Injury; Influenza Like Illness; Liver Function Test Abnormal	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo
	Chlorpromazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12805247	NON-EXPEDITED			US-TAKEDA-2016TUS017023		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Abdominal Pain Upper; Diarrhoea; Nausea	Trintellix			S	Oral	10 Mg, Qd		Takeda
	Trintellix			S	Oral	20 Mg, Qd		Takeda
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Verapamil Er			C	Oral	180 Mg, Qd		Not Reported
	Hydrochlorothiazide			C	Oral	25 Mg, Qd		Not Reported
	Trazodone			C	Oral	100 Mg, Qd		Not Reported

Alprazolam	C	Oral	2 Mg, Qd		Not Reported
Carisoprodol	C	Oral	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12808367	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1670486US		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Acne; Anaemia; Decreased Appetite; Diastolic Dysfunction; Epistaxis; Haemorrhagic Pneumonia; Hypertension; Hypotension; Nausea; Oliguria; Peripheral Swelling; Thrombocytopenia	Lexapro			S				Allergan
	Sirolimus			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12808537	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2016M1042404			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abnormal Dreams; Acne; Breast Swelling; Decreased Appetite; Diarrhoea; Dizziness; Dry Mouth; Dyspepsia; Erectile Dysfunction; Gynaecomastia; Insomnia; Nausea; Nightmare; Paraesthesia; Pruritus; Rash; Suicidal Ideation; Throat Irritation; Tinnitus; Tremor; Weight Decreased	Mylan-Risperidone			S		Unk		Mylan
	Seroplex			S		Unk		Mylan
	Permixon			C				Mylan
	Nebivolol			C				Mylan
	Kardegic			C				Mylan
	Doliprane			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12809117	EXPEDITED (15-DAY)		DS	FR-ALLERGAN-1670503US		4 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder; Autism Spectrum Disorder; Foetal Exposure During Pregnancy	Seroplex Tablets			S	Transplacental	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12809141	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1670893US			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appetite Disorder; Cognitive Disorder; Decreased Interest; Depressed Mood; Disturbance In Attention; Fatigue; Feelings Of Worthlessness; Intentional Self-Injury; Irritability; Suicidal Behaviour; Weight Fluctuation	Escitalopram Oxalate Unk			S	Unknown	Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12680461	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2016389753		90 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Temesta (Lorazepam)			S	Oral	0.5 Mg, 1x/Day (1mg, 0-0-0-1/2)		Pfizer
	Lyrica			S	Oral	62.5 Mg, 1x/Day		Pfizer
	Madopar			S		100mg/25mg, 3x/Day (200mg/50mg, 1/2-1/2-1/2-0)		Not Reported

	Cipralex /01588501/	S	10 Mg, 1x/Day (1-0-0-0)	Not Reported
	Torem /01036501/	S	2.5 Mg, 1x/Day (5 Mg, 1/2-0-0-0)	Not Reported
	Acidum Folicum Streuli	C	5 Mg, 1x/Day	Not Reported
	Vitamin D3 Streuli	C	Gtt, Every Tuesday	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12809966	EXPEDITED (15-DAY)		HO, LT	TR-LUPIN PHARMACEUTICALS INC.-2016-04424		24 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypernatraemia; Hypocalcaemia; Leukopenia; Respiratory Depression; Somnolence; Suicide Attempt; Toxicity To Various Agents	Valproic Acid			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12810100	NON-EXPEDITED			US-PFIZER INC-2016461280		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disease Progression; Menopausal Symptoms	Effexor			S	Oral	75 Mg, 1x/Day		Pfizer
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12818168	EXPEDITED (15-DAY)		OT	TW-ALLERGAN-1000087611		27 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12818197	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1670899US			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Interest; Depressed Mood; Fatigue; Intentional Self-Injury; Irritability; Negative Thoughts; Suicidal Behaviour	Escitalopram Oxalate Unk			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2016	12818023	DIRECT		DE			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Therapy Change	Escitalopram 20mg Tablet (Lexapro)			S	Oral	Quantity:1 Tablet(S);		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2016	12818102	NON-EXPEDITED			US-PFIZER INC-2016463328		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2016	12821713	EXPEDITED (15-DAY)		LT, OT	PHHY2016TR134298		24 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Suicide Attempt	Olanzapine			S	Unknown			Novartis
	Valproic Acid			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2016	12823392	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMPANY-US201609009641			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis; Hepatomegaly; Pancytopenia; Splenomegaly	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Qudexy			S	Unknown	200 Df, Qd		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Cyclobenzaprine			S	Unknown	Unk, Unknown		Not Reported
	Tazetol			S	Unknown	Unk, Unknown		Not Reported
	Proton /00661201/			S	Unknown	Unk, Unknown		Not Reported
	Calcium			C	Unknown	Unk, Unknown		Not Reported
	Bentyl			C	Unknown	Unk, Unknown		Not Reported
	Vitamin D /00107901/			C	Unknown	Unk, Unknown		Not Reported
	Prevacid			C	Unknown	Unk, Unknown		Not Reported
	Trazodone			C	Unknown	Unk, Unknown		Not Reported
	Zofran /00955301/			C	Unknown	Unk, Unknown		Not Reported
	Ativan			C	Unknown	Unk, Unknown		Not Reported
	Norco			C	Unknown	Unk, Unknown		Not Reported
	Lyrica			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2016	12510191	EXPEDITED (15-DAY)		LT	FR-FRI-1000085621		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Drug Interaction; Loss Of Consciousness; Lung Disorder; Subarachnoid Haemorrhage	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Eliquis			S	Oral	5 Mg, Bid		Not Reported
	Cordarone			S	Oral	200 Mg, Qd		Not Reported
	Micardis			C	Oral	1 Df, Qd		Not Reported

Pariet	C	Oral	20 Mg, Qd		Not Reported
Singulair	C	Oral	10 Mg, Qd		Not Reported
Symbicort Turbuhaler	C	Respiratory (inhalation)	1 Df, Bid		Not Reported
Lasilix Faible	C	Oral	20 Mg, Qd		Not Reported
Euphylline L.A.	C	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2016	12633613	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2016-10217		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Autonomic Nervous System Imbalance; Body Temperature Increased; Clonus; Condition Aggravated; Confusional State; Drug Interaction; Hyperhidrosis; Hyperreflexia; Hyperthermia; Mental Status Changes; Muscle Rigidity; Myoclonus; Overdose; Serotonin Syndrome; Tachycardia; Tachycardia; Toxicity To Various Agents; Tremor	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Olanzapine Oraldispersible Tablet			S	Unknown	Unk		Aurobindo
	Quetiapine Film-Coated Tablet			S	Unknown	Unk		Aurobindo
	Phenytoin			S	Unknown	Unk		Not Reported
	Bupropion			S	Unknown	Unk		Not Reported
	Primidone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2016	12661665	NON-EXPEDITED			US-PFIZER INC-2016388581		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Headache; Vomiting	Effexor Xr			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2016	12770805	EXPEDITED (15-DAY)			DK-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076151		26 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Product Prescribing Error	Abilify			S	Oral	30 Mg, Qd		Bristol Myers Squibb
	Propranolol			S	Oral	80 Mg, Qd		Not Reported
	Citalopram			S	Oral	40 Mg, Qd		Not Reported
	Escitalopram			S	Oral	30 Mg, Qd		Not Reported
	Olanzapine			S	Oral	10 Mg, Qd		Not Reported
	Quetiapine			S	Oral	900 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2016	12831747	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2016US19165			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lactose Intolerance; Product Substitution Issue	Escitalopram			S	Unknown	20 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2016	12834303	EXPEDITED (15-DAY)		OT	NO-ALLERGAN-1671499US			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Decreased Interest; Depressed Mood; Disturbance In Attention; Drug Ineffective; Fatigue; Feelings Of Worthlessness; Negative Thoughts; Suicidal Behaviour	Escitalopram Oxalate Unk			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2016	12763280	EXPEDITED (15-DAY)		HO, OT	US-SAOL THERAPEUTICS-2016SAO00659		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anxiety; Aphasia; Confusional State; Disturbance In Attention; Dysarthria; Gait Inability; Malaise; Memory Impairment; Migraine; Multiple Sclerosis Relapse; Muscle Tightness; Seizure; Sepsis; Substance-Induced Psychotic Disorder; Ulcer Haemorrhage; Urinary Tract Infection; Withdrawal Syndrome	Lioresal			S	Intrathecal	101.78 Mg, \Day		Saol Therapeutics
	Lioresal			S		Unk		Saol Therapeutics
	"Steroids"			S				Not Reported
	Intravenous Immunoglobulin			S				Not Reported
	Lexapro			S				Not Reported
	Topamax			S				Not Reported
	Rebif			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2016	12768350	EXPEDITED (15-DAY)		HO	FR-FRI-1000087639		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatitis; Jaundice; Pyrexia	Escitalopram Oxalate Unk			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2016	12835583	NON-EXPEDITED			US-TAKEDA-2016TUS018355			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Respiratory Tract Congestion; Throat Irritation; Vomiting	Trintellix			S	Unknown	Unk		Takeda
	Escitalopram			S	Unknown	Unk		Not Reported

	Humira	S	Subcutaneous	40mg/0.8ml	Not Reported
	Lamictal	S	Unknown	Unk	Not Reported
	Zyprexa	S	Unknown		Not Reported
	Ativan	C	Unknown	Unk	Not Reported
	Prilosec /00661201/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2016	12837321	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1671483US		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Drug Dependence; Hepatitis Cholestatic	Seroplex Tablets			S	Unknown			Allergan
	Codeine			S	Unknown			Not Reported
	Paracetamol			S				Not Reported
	Ursodesoxycholic Acid			C		Unk		Not Reported
	Atarax			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2016	12837323	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1671481US		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Overuse Headache	Cipralex Tablets			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2016	12830867	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1671247US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy; Premature Labour	Seroplex Tablets			S	Transplacental			Allergan
	Abilify			S	Transplacental			Not Reported
	Depamide			S	Transplacental			Not Reported
	Seresta			S	Transplacental			Not Reported

	Largactil	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2016	12838173	EXPEDITED (15-DAY)		HO, OT	PHHY2016BR028121		53 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Lower; Anxiety; Asthenia; Back Pain; Bacteriuria; Central Nervous System Lesion; Concomitant Disease Aggravated; Crying; Decreased Activity; Decreased Interest; Depression; Headache; Hemiparesis; Hypoaesthesia; Limb Injury; Memory Impairment; Micturition Urgency; Mobility Decreased; Musculoskeletal Discomfort; Neck Pain; Pain; Paraesthesia; Peripheral Swelling; Sensory Disturbance; Urinary Incontinence; Urinary Tract Infection; Weight Increased; White Blood Cell Count Decreased	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Folic Acid			C	Unknown	1 Df, Qd		Not Reported
	Amitriptilina			C	Oral	1 Df, Qd		Not Reported
	Glifage			C	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2016	12838182	EXPEDITED (15-DAY)		HO, OT	TR-HETERO LABS LTD-1058246		24 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt; Toxicity	Escitalopram			S	Unknown			Hetero

To Various Agents	Valproic Acid	S		Not Reported
	Olanzapine	S		Not Reported
	Olanzapine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2016	12839155	EXPEDITED (15-DAY)		HO	CH-SA-2016SA184754		81 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Syncope	Triatec (Ramipril)			S	Unknown			Not Reported
	Plavix			S	Oral			Not Reported
	Torem			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Temesta (Lorazepam)			S	Oral			Not Reported
	Pantozol (Pantoprazole Sodium)			S	Unknown			Not Reported
	Aspirin Cardio			S	Unknown			Not Reported
	Haldol			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Circadin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2016	12839970	EXPEDITED (15-DAY)		DE, OT	CH-ALLERGAN-1671466US		75 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Drug Interaction	Escitalopram Oxalate Unk			S	Oral			Allergan
	Symfona N (Ginkgo Biloba Extract)			S	Oral			Not Reported
	Voltaren			S	Oral			Not Reported
	Marcoumar			S	Oral			Not Reported
	Omeprazol			C	Oral			Not Reported
	Novalgine (Metamizole Sodium)			C	Oral			Not Reported
	Lexotanil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2016	12237183	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2015-11354		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macule; Papule; Skin Lesion; Telangiectasia	Escitalopram 10 Mg			S	Oral	10 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2016	12836741	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1671473US			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Decreased Interest; Depressed Mood; Fatigue; Irritability; Negative Thoughts; Suicidal Behaviour	Escitalopram Oxalate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2016	12843081	EXPEDITED (15-DAY)		HO	CH-BAYER-2016-192809		81 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Haematoma; Syncope	Aspirin Cardio			S		100 Mg, Qd		Bayer
	Hydromorphoni Hydrochloridum Streuli			S		10 Ml, Qid		Not Reported
	Circadin			S	Oral	10 Mg, Qd		Not Reported
	Torem			S	Oral	200 Mg, Qd		Not Reported
	Cipralex			S		10 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Oral	1 Mg, Bid		Not Reported
	Pantozol (Pantoprazole Sodium)			S		20 Mg, Qd		Not Reported
	Triatec (Ramipril)			S		2.5 Mg, Qd		Not Reported
	Plavix			S	Oral	75 Mg, Qd		Not Reported

	Haldol	S		Not Reported
	Insulin Novomix	S	28 -0 -14-0	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2016	12845076	EXPEDITED (15-DAY)		HO, OT	TR-SCIEGEN PHARMACEUTICALS INC-2016SCILIT00451		24 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Clonus; Coma; General Physical Health Deterioration; Hypercapnia; Hypernatraemia; Hypocalcaemia; Leukopenia; Loss Of Consciousness; Respiratory Depression; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Fluoxetine Capsules, Usp			S	Oral	Unk		Sciegen
	Valproic Acid			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2016	12495991	EXPEDITED (15-DAY)		HO	JP-FRI-1000085481		49 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Electrocardiogram Qt Prolonged; Syncope; Ventricular Tachycardia	Lexapro Tablets			S	Oral	10 Mg, Qd		Allergan
	Lexapro Tablets			S	Oral	15 Mg, Qd		Allergan
	Lexapro Tablets			S	Oral	20 Mg, Qd		Allergan
	Lexapro Tablets			S	Oral	5 Mg, Qd		Allergan
	Tryptanol			S	Oral	75 Mg, Unk		Not Reported
	Wypax			C	Oral	115 Mg		Not Reported
	Rohypnol			C	Oral	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2016	12561805	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2016343305		66 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia	Escitalopram			S		10 Mg, 1x/Day		Not Reported
	Atenolol			C				Not Reported
	Lercanidipine Hydrochloride			C				Not Reported
	Pantoprazole			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Perindopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2016	12847559	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1671948US		49 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Suicide Attempt; Tachycardia; Toxicity To Various Agents	Seroplex Tablets			S	Oral	30 Df, Single		Allergan
	Efferalgan Codeine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2016	12850790	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1672118US		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Chest Pain; Hyponatraemia; Long Qt Syndrome	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2016	12850915	EXPEDITED (15-DAY)		HO, LT, OT	PL-TEVA-699054ISR			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Toxicity To Various Agents	Sulpiride			S	Unknown			Not Reported

Olanzapine	S	Unknown	Teva
Risperidone	S	Unknown	Pliva
Hydroxyzine	S	Unknown	Barr
Zolpidem	S	Unknown	Teva
Sertraline	S	Unknown	Not Reported
Escitalopram	S	Unknown	Ivax
Venlafaxine	S	Unknown	Teva
Carbamazepine	S	Unknown	Not Reported
Lamotrigine	S	Unknown	Teva
Topiramate	S	Unknown	Teva
Donepezil	S	Unknown	Barr
Paracetamol	S	Unknown	Not Reported
Ibuprofen	S	Unknown	Ivax
Acetylsalicylic Acid	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Morphine	S	Unknown	Not Reported
Bisoprolol	S	Unknown	Duramed
Metoprolol	S	Unknown	Teva
Amlodipine	S	Unknown	Teva
Ramipril	S	Unknown	Teva
Indapamide	S	Unknown	Ivax
Valsartan	S	Unknown	Teva
Simvastatin	S	Unknown	Ivax
Atorvastatin	S	Unknown	Teva
Rosuvastatin	S	Unknown	Teva
Dextromethorphan	S	Unknown	Not Reported
Metformin	S	Unknown	Not Reported
Omeprazole	S	Unknown	Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2016	12780860	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-078321		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Dyskinesia; Memory Impairment; Tardive Dyskinesia; Weight Increased	Abilify			S	Unknown	Unk		Bristol Myers Squibb
	Lexapro			S	Unknown			Not Reported
	Depakote			C	Unknown			Not Reported
	Klonopin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2016	12852581	DIRECT					27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness	Escitalopram 10 Mg			S	Oral	Quantity:30 Tablet(S);		Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12556768	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-01		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Drug-Induced Liver Injury	Escitalopram			S	Unknown			Hikma
	Diazepam			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Zolpidem			C	Unknown			Not Reported
	Fexofenadine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12837711	EXPEDITED (15-DAY)		OT	US-GILEAD-2016-0224117		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Epistaxis; Gingival Bleeding; Melaena; Rectal Haemorrhage; Skin Haemorrhage	Ambrisentan			S	Unknown	10 Mg, Qd		Gilead
	Lexapro			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Revatio			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12853020	EXPEDITED (15-DAY)		OT	NO-ALLERGAN-1672502US		20 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Interest; Depressed Mood; Disturbance In Attention; Fatigue; Feelings Of Worthlessness; Negative Thoughts; Sleep Disorder; Suicidal Behaviour; Weight Fluctuation	Escitalopram Oxalate - Bp			S	Unknown	Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12855211	EXPEDITED (15-DAY)		OT	NO-MYLANLABS-2016M1043614			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Decreased Interest; Depressed Mood; Disturbance In Attention; Drug Ineffective; Fatigue; Feelings Of Worthlessness; Negative Thoughts; Suicidal Behaviour	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12855348	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1672433US		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Cognitive Disorder	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Crestor			C	Unknown	5 Mg, Unk		Not Reported
	Rivastigmine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2016	12612177	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-060580		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Product Use In Unapproved Indication	Eliquis			S	Oral	5 Mg, Bid		Bristol Myers Squibb
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12576853	NON-EXPEDITED			US-OTSUKA-2016_011586		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Off Label Use; Panic Attack	Rexulti			S	Oral	0.5 Mg, Qd		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported
	Xanax			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	Unk, Qd (At Bedtime)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12576947	NON-EXPEDITED			US-OTSUKA-2016_016047		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hallucination; Hallucination, Visual; Hyperhidrosis; Migraine; Nausea; Vertigo; Withdrawal Syndrome	Rexulti		S	Oral	0.5 Mg, Qd	Otsuka
	Lexapro		S	Unknown	60 Mg, Unk	Not Reported
	Lexapro		S	Unknown	0.5 Mg, Unk	Not Reported
	Lexapro		S	Oral	20 Mg, Unk	Not Reported
	Lexapro		S	Unknown	15 Mg, Unk	Not Reported
	Cymbalta		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12577049	NON-EXPEDITED			US-OTSUKA-2016_014948		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Feeling Abnormal; Laziness; Off Label Use; Pollakiuria; Weight Decreased	Rexulti			S	Oral	0.5 Mg, Qd		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported
	Xanax			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12843567	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2016466511		81 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Haematoma; Syncope	Temesta (Lorazepam)			S	Oral	1 Mg, 2x/Day (1-0-1-0)		Pfizer
	Triatec (Ramipril)			S	Unknown	2.5 Mg, Daily (1/2-0-1/2-0)		Pfizer
	Hydromorphoni Hydrochloridum Streuli			S	Unknown	10 Ml, 4x/Day		Not Reported
	Circadin			S	Oral	10 Mg, Daily		Not Reported
	Torem /01036501/			S	Oral	200 Mg, Daily (1/4-0-0-0)		Not Reported
	Cipralex /01588501/			S	Unknown	10 Mg, Daily (1-0-0-0)		Not Reported
	Pantozol /01263204/			S	Unknown	20 Mg, Daily (1-0-0-0)		Not Reported
	Aspirin Cardio			S	Unknown	100 Mg, Daily (1-0-0-0)		Not Reported
	Plavix			S	Oral	75 Mg, Daily (1-0-0-0)		Not Reported
	Haldol			S	Unknown	5 Gtt, 2x/Day (1gtt= 2.0		Not Reported

	Insulin			C		Mg/Ml) Unk, 2x/Day				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12860858	EXPEDITED (15-DAY)		HO	US-SUNOVION-2016SUN002559			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Mania; Withdrawal Syndrome	Latuda			S	Oral	20 Mg, Unk		Sunovion
	Latuda			S	Oral	60 Mg, Qd		Sunovion
	Lexapro			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12862811	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1672780US		29 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Tongue Biting	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12862841	EXPEDITED (15-DAY)		HO	SG-ALLERGAN-1672786US		49 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photosensitivity Reaction	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12863045	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1672793US		19 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oculogyric Crisis	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12863242	EXPEDITED (15-DAY)		HO	SG-ALLERGAN-1672795US		39 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Seizure	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12863251	NON-EXPEDITED			US-OTSUKA-2016_017508			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Rexulti			S	Unknown	Unk		Otsuka
	Rexulti			S				Otsuka
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12865590	DIRECT	Y	LT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2016	12488540	EXPEDITED (15-DAY)		HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-048646		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aneurysm Repair; Carotid Artery Aneurysm; Labelled Drug-Drug Interaction Medication Error; Pneumonia Aspiration; Subarachnoid Haemorrhage	Eliquis			S	Oral	5 Mg, Bid		Bristol Myers Squibb
	Cordarone			S	Oral	200 Mg, Daily		Not Reported
	Seroplex			S	Oral	20 Mg, Daily		Not Reported
	Micardis			C	Oral	1 Df, Qd		Not Reported
	Pariet			C	Oral	20 Mg, Qd		Not Reported

Singulair	C	Oral	1 Df, Qd		Not Reported
Symbicort	C	Respiratory (inhalation)	200 Mg, Bid		Not Reported
Lasilix Faible	C	Oral	1 Df, Qd		Not Reported
Euphylline L.A.	C	Oral	1 Df, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2016	12685028	EXPEDITED (15-DAY)		OT	US-FRI-1000086663		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Epistaxis; Gingival Bleeding; Melaena; Off Label Use; Rectal Haemorrhage; Skin Haemorrhage	Lexapro			S		Unk		Allergan
	Ambrisentan			S		10 Mg, Qd		Not Reported
	Zoloft			S				Not Reported
	Revatio			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2016	12834239	EXPEDITED (15-DAY)			NL-ALLERGAN-1671494US		20 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2016	12867383	EXPEDITED (15-DAY)		HO, OT	AT-MYLANLABS-2016M1044373			Unknown	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Depression; Dysphoria; Insomnia; Mania; Paranoia; Psychomotor Hyperactivity; Social Avoidant Behaviour	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12476328	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2016298678		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obsessive-Compulsive Disorder	Xanax			S	Oral	0.5 Mg, Unk		Pfizer
	Lamictal			S	Oral	Unk		Not Reported
	Lamictal			S	Oral	200 Mg, Daily		Not Reported
	Theralene			S	Oral	Unk		Not Reported
	Imovane			S	Oral	1 Df, 1x/Day		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Optilova			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12492419	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2016312120		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aneurysm Repair; Carotid Artery Aneurysm; Labelled Drug-Drug Interaction Medication Error; Pneumonia Aspiration; Subarachnoid Haemorrhage	Cordarone			S	Oral	200 Mg, 1x/Day		Pfizer
	Eliquis			S	Oral	5 Mg, 2x/Day		Not Reported
	Eliquis			S				Not Reported
	Seroplex			S	Oral	20 Mg, 1x/Day		Not Reported
	Micardis			C	Oral	1 Df, 1x/Day		Not Reported
	Pariet			C	Oral	20 Mg, 1x/Day		Not Reported
	Singulair			C	Oral	1 Df, 1x/Day		Not Reported
	Symbicort			C	Respiratory (inhalation)	200 Mg, 2x/Day		Not Reported
	Lasilix Faible			C	Oral	1 Df, 1x/Day		Not Reported
	Euphylline L.A.			C	Oral	1 Df, 2x/Day		Not Reported
	Lasilix /00032601/			C				Not Reported
	Euphylline /00003701/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12691382	EXPEDITED (15-DAY)		OT	CA-VERTEX PHARMACEUTICALS-2016-004943		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Increased Appetite; Nausea; Suicidal Ideation	Orkambi			S	Oral	400-250 Mg, Bid		Vertex
	Cipralex			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12827017	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1000087604		1 DAY	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Lexapro Tablets			S	Transplacental	10 Mg, Single		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12855084	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016478596		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Epistaxis; Gingival Bleeding; Melaena; Rectal Haemorrhage; Skin Haemorrhage	Zoloft			S		Unk		Pfizer
	Ambrisentan			S		10 Mg, 1x/Day		Not Reported
	Lexapro			S		Unk		Not Reported
	Revatio			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12870487	EXPEDITED (15-DAY)		CA, HO	NL-AUROBINDO-AUR-APL-2014-02025			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta;	Sertraline Aurobindo			S	Transplacental	50 Mg,Once A Day,		Aurobindo

Foetal Exposure During Pregnancy; Respiratory Failure	Filmomhulde Tabletten 50mg Escitalopram Aurobindo Filmomhulde Tabletten 10mg	S	Transplacental	10 Mg,Once A Day,		Aurobindo
	Folic Acid	C	Unknown	Unk Unk,Unk,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12871536	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Physical Product Label Issue; Product Dispensing Error	Escitalopram Oxalate Escitalopram			S				Not Reported
	Enalapril Maleate Enalaprilat			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12871670	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Product Selection Error	Atorvastatin Calcium Atorvastatin			S	Oral			Not Reported
	Escitalopram Oxalate Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12874213	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1672886US		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Crying; Hallucination; Mood Swings; Muscle Spasms; Staphylococcal Infection; Suicidal Ideation; Tremor	Lexapro			S	Oral	20 Mg, Unk		Allergan
	Lexapro			S	Oral	40 Mg, Unk		Allergan
	Norco			C	Oral	Unk, Prn		Not Reported
	Gabapentin			C	Oral	Unk, Tid		Not Reported
	Lisinopril			C	Oral	20 Mg, Qd		Not Reported
	Lisinopril			C				Not Reported
	Topiramate			C	Oral	Unk Unk, Bid		Not Reported

Clonopin	C	Oral	0.1 Mg, Prn		Not Reported
Memantine Hydrochloride	C	Oral	10 (Units Not Provided), Qd		Not Reported
Atorvastatin	C	Oral	40 Mg, Qd		Not Reported
Ms Contin	C	Oral	Unk, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12874485	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1673150US		17 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Overdose; Poisoning; Product Use Issue; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S		50 Mg, Single		Allergan
	Paracetamol			S	Unknown	Overdose 15 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12874645	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1000087584		32 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Exposure During Pregnancy; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Zoloft			S	Oral	25 Mg, Qd		Not Reported
	Seresta			S	Oral	15 Mg, Bid		Not Reported
	Seresta			S	Oral	30 Mg, Qd		Not Reported
	Seroquel			S	Unknown	100 Mg, Qd		Not Reported
	Anxiolit			S	Unknown	60 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Unknown	2.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12473452	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2016GSK085431		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Obsessive-Compulsive Disorder; Product Use In Unapproved Indication	Lamictal		S	Oral	Unk	Glaxosmithkline
	Xanax		S	Oral	0.5 Mg, Unk	Glaxosmithkline
	Imovane		S	Oral	1 Df, Qd	Glaxosmithkline
	Seroplex		S	Oral	Unk	Glaxosmithkline
	Theralene		S	Oral	Unk	Not Reported
	Optilova		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12875612	EXPEDITED (15-DAY)		OT	DK-ACCORD-045043		26 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Medication Error; Overdose	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12875823	NON-EXPEDITED			US-JAZZ-2016-US-014878		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Initial Insomnia	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S		Unknown Dose		Not Reported
	Alvesco			C				Not Reported
	Nuvigil			C				Not Reported
	Veramyst			C				Not Reported
	Zyrtec			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12877651	EXPEDITED (15-DAY)		HO, LT, OT	PL-SA-2016SA193820			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Overdose; Toxicity To Various Agents	Ramipril	S	Unknown	Not Reported
	Metformin	S	Unknown	Not Reported
	Diclofenac Salt Not Specified	S	Unknown	Not Reported
	Risperidone	S	Unknown	Not Reported
	Hydroxyzine	S	Unknown	Not Reported
	Zolpidem	S	Unknown	Not Reported
	Topiramate	S	Unknown	Not Reported
	Donepezil Hydrochloride	S	Unknown	Not Reported
	Bisoprolol Fumarate	S	Unknown	Not Reported
	Metoprolol Salt Not Specified	S	Unknown	Not Reported
	Amlodipine (Salt Not Specified)	S	Unknown	Not Reported
	Simvastatin	S	Unknown	Not Reported
	Atorvastatin	S	Unknown	Not Reported
	Rosuvastatin	S	Unknown	Not Reported
	Dextromethorphan Hydrobromide	S	Unknown	Not Reported
	Omeprazole	S	Unknown	Not Reported
	Lamotrigine	S	Unknown	Not Reported
	Valsartan	S	Unknown	Not Reported
	Venlafaxine	S	Unknown	Not Reported
	Olanzapine	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Indapamide	S	Unknown	Not Reported
	Morphine Hydrochloride	S	Unknown	Not Reported
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Carbamazepine	S	Unknown	Not Reported
	Sertraline	S	Unknown	Not Reported
	Sulpiride	S	Unknown	Not Reported
	Ibuprofen	S	Unknown	Not Reported
	Paracetamol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12877921	EXPEDITED (15-DAY)		DE	AT-ALLERGAN-1673371US		70 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Marcumar / Phenprocoumon			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12878331	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1673364US		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Fall; Haematoma	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Arixtra			S	Subcutaneous	7.5mg/0.6ml		Not Reported
	Exelon			C	Unknown			Not Reported
	Cibadrex			C	Unknown			Not Reported
	Tahor			C				Not Reported
	Lactulose			C	Unknown			Not Reported
	Doliprane			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12878401	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1673370US		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Eyelid Haematoma; Periorbital Haematoma	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Kardegic			S	Oral			Not Reported
	Clopidogrel			S	Oral	75 Mg, Qd		Not Reported
	Atorvastatin Arrow			C	Unknown			Not Reported
	Perindopril Arginine Servier			C	Unknown			Not Reported

Nebivolol Actavis	C	Unknown			Not Reported
Seretide	C	Unknown	250/25µg		Not Reported
Fosavance	C	Unknown	70mg/28000 Ui		Not Reported
Uvedose	C	Unknown			Not Reported
Doliprane	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12878611	EXPEDITED (15-DAY)		OT	NO-MYLANLABS-2016M1044639			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Interest; Depressed Mood; Disturbance In Attention; Fatigue; Feelings Of Worthlessness; Negative Thoughts; Sleep Disorder; Suicidal Behaviour; Weight Fluctuation	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12878661	EXPEDITED (15-DAY)		DE	PHHY2016US144408		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metoprolol			S	Oral			Novartis
	Oxycodone Hydrochloride			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12878906	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2016M1045674			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Fall; Haematoma	Fondaparinux	S	Subcutaneous	7.5 Mg, Qd	Not Reported
	Seroplex	S	Oral	20 Mg, Qd	Mylan
	Exelon /01383201/	C		4.6 Mg, Qd	Mylan
	Cibadrex	C		Unk	Mylan
	Tahor	C		Unk	Mylan
	Lactulose	C		Unk	Mylan
	Doliprane	C		Unk	Mylan
	Esomeprazole	C		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	10971154	NON-EXPEDITED			US-JNJFOC-20150313235		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Gynaecomastia; Obesity	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Catapres			S	Oral			Not Reported
	Depakote Er			C	Oral			Not Reported
	Zoloft			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	11020901	NON-EXPEDITED			US-JNJFOC-20150404210			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Galactorrhoea; Gynaecomastia; Hyperprolactinaemia; Off Label Use; Product Use In Unapproved Indication	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	11880691	EXPEDITED (15-DAY)		HO, LT	JP-FRI-1000081924		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Haemolytic Anaemia	Lexapro Tablets			S	Oral	1/2 Tablet Daily		Allergan
	Lexapro Tablets			S	Oral	10mg Daily		Allergan
	Trazodone Hydrochloride			C	Oral	25 Mg, Qd		Not Reported
	Lexotan (Bromazepam)			C	Oral	1 Mg, Qd		Not Reported
	Wypax			C	Oral	Unknown		Not Reported
	Norvasc			C				Not Reported
	Selectol			C				Not Reported
	Diovan			C				Not Reported
	Sermion			C				Not Reported
	Aricept			C				Not Reported
	Nexium			C				Not Reported
	Desyrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12449865	NON-EXPEDITED			US-JNJFOC-20160505909		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Gynaecomastia; Off Label Use; Overweight; Product Use In Unapproved Indication	Risperdal			S	Oral	0.5 (Unit Not Specified)		Not Reported
	Risperdal			S	Oral	0.5 (Unit Not Specified)		Not Reported
	Abilify			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Strattera			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879422	EXPEDITED (15-DAY)		OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-088348		34 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Alopecia; Bronchitis; Depression; Gastrointestinal Infection; General Physical Health Deterioration; Haematoma; Insomnia; Nausea; Sinusitis; Vomiting	Entecavir			S	Unknown			Bristol Myers Squibb
	Peginterferon Alfa-2a			S	Subcutaneous	180 Mg, Qwk		Not Reported
	Cipralex /01588501/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879447	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US07014			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Palpitations	Escitalopram			S	Oral	20 Mg, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879453	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US04595			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram			S		10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879454	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US07024			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Swelling	Escitalopram			S	Oral	10 Mg, Qd, 3 Weeks		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879560	EXPEDITED (15-DAY)		OT	DK-ACCORD-045045		26 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Medication Error; Potentiating Drug Interaction	Escitalopram			S	Oral			Accord
	Olanzapine			S	Oral			Accord
	Propranolol			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879585	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US07038			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Escitalopram			S				Invagen
	Aricept			C	Unknown	10 Mg, Qd		Not Reported
	Actonel			C	Unknown	35 Mg, Once A Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879588	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US07031			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Sleep Disorder	Escitalopram			S	Oral	10 Mg, Every Other Day, Since 10 Years		Invagen
	Verapamil			C	Unknown	80 Mg, Qd		Not Reported
	Zyrtec			C	Unknown	10 Mg, Qd		Not Reported
	Multi Vitamins			C	Unknown	Unk, Qd		Not Reported
	Chantix			C	Unknown	1 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879590	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US07059			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Escitalopram			S	Oral	5 Mg, Qd		Invagen
	Metoprolol			C	Unknown	Half Tablet Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879591	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US07042			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia; Erythema; Headache; Swelling Of Eyelid; Vision Blurred	Escitalopram			S		5 Mg, Qd		Invagen
	Escitalopram			S				Invagen
	Aspirin			C	Unknown	81 Mg, Unk		Not Reported
	Potassium Chloride			C	Unknown	10 Meq, Bid		Not Reported
	Synthroid			C	Unknown	100 Mcg, Unk		Not Reported
	Metaprolol			C	Unknown	50 Mg, Unk		Not Reported
	Furosemide			C	Unknown	20 Mg, Unk		Not Reported
	Lisinopril			C	Unknown	5 Mg, Unk		Not Reported
	Allegra			C	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879592	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US07032			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Escitalopram			S	Oral	5 Mg, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879594	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US06577			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Hallucination; Nausea	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Escitalopram			S	Oral	2 More Pills,Unk		Invagen
	Escitalopram			S	Oral	2 More Pills, Unk		Invagen
	Pravacid 24 Hrs			C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879605	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US07081			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash; Urticaria	Escitalopram			S	Oral	20 Mg, Qd		Invagen
	Lipitor			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879612	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US09590			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown	20 Mg, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879747	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US17365			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown	5 Mg, Qd, (10mg Tablet Broken Into 5mg Half Consumed Every Morning)		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879757	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US17837			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Escitalopram			S	Oral	5 Mg, Unk		Invagen
	Escitalopram			S	Oral	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879760	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US18095			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Provera			S	Unknown	100 Mg, Qd		Not Reported
	Minivelle Estrogen Patch			S	Unknown	0.025 Mg, Twice A Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879768	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US18225			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown	20 Mg, Qd		Invagen
	Escitalopram			S				Invagen
	Nature Thyroid			C	Unknown	65 Mg, 1 Grain		Not Reported
	Xolair			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879775	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US17000			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective	Escitalopram			S	Unknown	20 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12882417	EXPEDITED (15-DAY)		DE	PHHY2016US144437		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metoprolol			S	Oral			Novartis
	Escitalopram			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12882652	EXPEDITED (15-DAY)		DE	PHHY2016US144568		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Baclofen			S	Oral	Unk		Not Reported
	Duloxetine			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral			Novartis
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12883279	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1673372US		34 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Eating Disorder; Hallucination	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Zolpidem			S	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12883304	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1673519US		31 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Normal Foetus	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2016	12227357	EXPEDITED (15-DAY)		HO, LT	ES-FRI-1000083688		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Digoxin			S	Unknown	Unk		Not Reported
	Simvastatin			S	Unknown	Unk		Not Reported
	Sulpiride			S	Unknown	Unk		Not Reported
	Solifenacin			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Amiodarone			S	Unknown	Unk		Not Reported
	Acenocoumarol			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Candesartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2016	12798920	EXPEDITED (15-DAY)		HO, LT, OT	TR-APOTEX-2016AP012422		24 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Coma; Depressed Level Of Consciousness; General Physical Health Deterioration; Hypernatraemia; Hypocalcaemia; Leukopenia; Loss Of Consciousness; Respiratory Depression; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Olanzapine			S	Oral	Unk		Apotex
	Valproic Acid			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Fluoxetine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2016	12865899	EXPEDITED (15-DAY)		DE	CH-JNJFOC-20161016796		89 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Basal Ganglia Haemorrhage; Dysphagia; Hemiparesis	Xarelto			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Candesartan			C	Oral			Not Reported
	Espasmo Canulase			C	Oral			Not Reported
	Sirdalud			C	Oral			Not Reported
	Tamsulosin			C	Oral			Not Reported
	Magnesiocard			C	Oral			Not Reported
	Vitamin D3			C	Oral			Not Reported
	Povidone			C				Not Reported
	Amlodipine			C	Oral			Not Reported
	Metoprolol Succinate			C	Oral			Not Reported
	Atorvastatin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2016	12886261	EXPEDITED (15-DAY)		DE	US-VALIDUS PHARMACEUTICALS LLC-US-2016VAL002873		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metoprolol Tartrate			S	Oral	Unk		Validus
	Oxycodone Hydrochloride			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported
	Diazepam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12509968	EXPEDITED (15-DAY)		OT	FR-FRI-1000085623		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obsessive-Compulsive Disorder	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Lamictal			S	Oral	200 Mg, Unk		Not Reported
	Theralene			S	Oral	Unk		Not Reported
	Xanax			S	Oral	Unk		Not Reported
	Imovane			S	Oral	1 Df, Qd		Not Reported
	Optilova			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12888332	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US07078			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypertension; Nausea; Polyuria; Weight Decreased	Escitalopram			S	Oral	5 Mg, Unknown Date Since 5 Years To Ongoing		Invagen
	Escitalopram			S				Invagen
	Metoprolol			C	Unknown	25 Mg, Qd		Not Reported
	Vitamin-D			C	Unknown	400 Iu, Bid		Not Reported
	Aspirin			C	Unknown	81 Mg, Qd		Not Reported
	Crestor			C	Unknown	Unk, Qd		Not Reported
	Xanax			C	Unknown	0.25 Mg, Tid		Not Reported
	Tylenol			C	Unknown	1000 Mg, Qd		Not Reported
	Restasis			C	Unknown	0.5 Mg, Bid		Not Reported
	Oxycodone			C	Unknown	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12889682	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1673732US		54 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12889987	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1673890US			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12890339	EXPEDITED (15-DAY)		HO, OT	HR-MYLANLABS-2016M1046323			Unknown	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Suicide Attempt	Leponex			S	Oral	Unk		Mylan
	Elicea /01588501/			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12890696	NON-EXPEDITED		OT	US-JAZZ-2016-US-015788		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Depression; Weight Decreased	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Ritalin			C		Unk		Not Reported
	Adderall			C		Unk		Not Reported
	Nuvigil			C		150 Mg, Unk		Not Reported

	Nuvigil	C	250 Mg, Unk	Not Reported
	Robaxin	C	Unk	Not Reported
	5 Hour Energy	C	Unk	Not Reported
	Ibuprofen	C	Unk	Not Reported
	Nyquil Cold & Flu	C	Unk	Not Reported
	Tylenol Extra-Strength	C	Unk	Not Reported
	Epipen 2-Pak	C	Unk	Not Reported
	Modafinil	C	Unk	Not Reported
	Vitamin B Complex	C	Unk	Not Reported
	Theraflu Cold & Cough [Dextromethorphan Hydrobromide\Pheniramine Maleate\Phenylephrine Hydrochloride]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12893553	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Suicidal Ideation	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12892262	EXPEDITED (15-DAY)		DE	US-VALIDUS PHARMACEUTICALS LLC-US-2016VAL002881		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metoprolol Tartrate			S	Oral	Unk		Validus
	Escitalopram			S	Oral	Unk		Not Reported
	Bupropion			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12892782	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1673906US			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dependence	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12893124	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016493027		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Fragmine			S	Subcutaneous	5000 Iu, Daily		Pfizer
	Ceftriaxone Panpharma			S	Intravenous (not otherwise specified)	1 G, Daily		Not Reported
	Ceftriaxone Panpharma			S	Intravenous (not otherwise specified)	2 G, Daily		Not Reported
	Esidrex			S	Oral	12.5 Mg, Daily		Not Reported
	Esidrex			S	Oral	25 Mg, Daily		Not Reported
	Escitalopram Arrow			S	Oral	20 Mg, Daily		Not Reported
	Oxazepam			C		10 Mg, 3x/Day		Not Reported
	Amlodipine			C		10 Mg, Daily		Not Reported
	Simvastatin			C		10 Mg, Daily		Not Reported
	Paracetamol			C		Unk Unk, As Needed		Not Reported
	Phloroglucinol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12894062	EXPEDITED (15-DAY)		HO	HR-LANNETT COMPANY, INC.-HR-2016LAN001716		53 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Electrocardiogram	Escitalopram Oxalate			S		20 Mg, Qd		Lannett
	Quetiapine Xr			S		800 Mg, Qd		Not Reported

Qt Prolonged	Quetiapine Xr	S	400 Mg, Qd		Not Reported
	Quetiapine Xr	S	100 Mg, Qd		Not Reported
	Valproate	C	1500 Mg, Qd		Not Reported
	Diazepam	C	30 Mg, Qd		Not Reported
	Zolpidem	C	10 Mg, Qd		Not Reported
	Biperiden	C	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12894799	EXPEDITED (15-DAY)		OT	TR-MYLANLABS-2016M1046438			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Escitalopram			S	Unknown	10 Mg/Day (In 4-6 Gestation Weeks)		Not Reported
	Levothyroxine			S	Unknown	1000 Mcg/Day		Not Reported
	Cefprozil			S	Unknown	1000 Mg/Day (In 4-6 Gestation Weeks)		Mylan
	Dexketoprofen			S	Unknown	25 Mg/Day (In 4-6 Gestation Weeks)		Mylan
	Trimetazidine			S	Unknown	40 Mg/Day (In 4-6 Gestation Weeks)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12894800	EXPEDITED (15-DAY)		OT	TR-MYLANLABS-2016M1046441			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Escitalopram			S	Unknown	10 Mg/Day (In 0-5 Gestation Weeks)		Not Reported
	Nifedipine			S	Unknown	30 Mg/Day (In 0-5 Gestation Weeks)		Not Reported
	Zofenopril			S	Unknown	30 Mg/Day (In 0-5 Gestation Weeks)		Mylan
	Trimetazidine			S	Unknown	40 Mg/Day (In 0-5		Mylan

Gestation Weeks)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12894835	EXPEDITED (15-DAY)		DE, OT	CH-ALLERGAN-1674040US		89 YR	Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Basal Ganglia Haemorrhage; Dysphagia; Dyspnoea; Hemiparesis; Hypertonia; Tachycardia	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Xarelto (Rivaroxaban)			S	Oral			Not Reported
	Meto Zerok (Metoprolol Succinate)			C	Oral	25 Mg, Qd		Not Reported
	Amlodipin (Amlodipine)			C	Oral	5 Mg, Qd		Not Reported
	Candesartan (Candesartan)			C	Oral	8 Mg, Qd		Not Reported
	Atorvastatin (Atorvastatin)			C	Oral	40 Mg, Qd		Not Reported
	Sirdalud (Tizanidine Hydrochloride)			C	Oral	4 Mg, Qd		Not Reported
	Tamsulosin (Tamsulosin)			C	Oral	4 Mg, Qd		Not Reported
	Magnesioncard (Magnesium Aspartate Hydrochloride)			C	Oral	5 Mmol, Qd		Not Reported
	Vitamin D3 (Colecalciferol)			C	Oral	1 Df, Qd		Not Reported
	Oculac (Povidone)			C				Not Reported
	Spasmo Canulase (Glutamic Acid Hydrochloride)			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2016	12091208	EXPEDITED (15-DAY)		HO, OT	AU-BAUSCH-BL-2016-004085		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Inappropriate Antidiuretic Hormone Secretion	Bupropion			S	Oral			Not Reported
	Ramipril			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Dothiepin			S	Unknown			Not Reported
	Dothiepin			S	Unknown			Not Reported
	Quetiapine			C				Not Reported

	Lamotrigine	C	Not Reported
	Oestradiol	C	Not Reported
	Glipizide	C	Not Reported
	Metformin	C	Not Reported
	Lantus	C	Not Reported
	Atorvastatin	C	Not Reported
	Aspirin	C	Not Reported
	Norfloxacin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2016	12896268	EXPEDITED (15-DAY)		DE	BR-TORRENT-00003640			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Off Label Use; Off Label Use; Parkinson'S Disease	Menelat			S	Oral	Once Daily/ Oral		Torrent
	Espran			S	Oral	Once Daily/ Oral		Torrent
	Clomenac			C	Oral	Number Of Units In Interval Is Unknown/ Oral		Actavis
	Kitapen			C	Oral	Number Of Units In Interval Is Unknown/ Oral		Actavis
	Prolopa			C	Oral	Unk/ Oral		Roche

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2016	12896763	EXPEDITED (15-DAY)		OT	AU-GLAXOSMITHKLINE-AU2016158851		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Toxicity To Various Agents	Escitalopram			S				Glaxosmithkline
	Bupropion			S		75 Mg Po Mane		Glaxosmithkline
	Ramipril			S				Glaxosmithkline
	Norfloxacin			C				Not Reported
	Dothiepin Hydrochloride			S				Not Reported
	Dothiepin Hydrochloride			S				Not Reported
	Dothiepin Hydrochloride			S				Not Reported
	Quetiapine			C		400 Mg At Night		Not Reported
	Lamotrigine			C				Not Reported
	Oestradiol			C				Not Reported

	Glipizide	C	Not Reported
	Metformin	C	Not Reported
	Insulin Lantus	C	Not Reported
	Atorvastatin	C	Not Reported
	Acetylsalicylic Acid	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2016	12897718	EXPEDITED (15-DAY)		OT	US-LUNDBECK-DKLU2021900		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Product Dose Omission; Suicidal Ideation	Lexapro Film-Coated Tablets			S	Unknown			Forest
	Abilify			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2016	12897958	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1674208US		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nausea; Pancreatitis	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2016	12522017	EXPEDITED (15-DAY)		OT	JP-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-053742		26 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothermia; Malaise	Abilify			S	Oral	1.5 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Oral	0.75 Mg, Qd		Bristol Myers Squibb
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Lendormin			C	Oral	0.25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2016	12900339	EXPEDITED (15-DAY)		HO	PHHY2016HR147687			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Trileptal			S	Oral	30 Df, Once/Single		Novartis
	Elicea			S	Oral	20 Df, Once/Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2016	12900350	EXPEDITED (15-DAY)		OT	PHHY2016TR149408			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Delivery	Escitalopram			S	Transplacental	Maternal Dose: 10 Mg/Day		Not Reported
	Levofloxacin			S	Transplacental	Maternal Dose: 500 Mg/Day		Novartis
	Cefprozil			S	Transplacental	Maternal Dose: 1000 Mg/Day		Not Reported
	Etodolac			S	Transplacental	Maternal Dose: 300 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2016	12900352	EXPEDITED (15-DAY)		OT	PHHY2016TR149407		21 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Levofloxacin			S	Unknown	500 Mg, Qd		Novartis
	Cefprozil			S	Unknown	1000 Mg, Qd		Not Reported
	Etodolac			S	Unknown	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12083886	EXPEDITED (15-DAY)		OT	AU-SUN PHARMACEUTICAL			Unknown	AUS

INDUSTRIES LTD-
2016RR-111658

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Toxicity To Various Agents	Escitalopram			S	Unknown	30 Mg, Daily		Not Reported
	Bupropion			S	Oral	75 Mg Po Mane		Sun
	Ramipril			S	Unknown	Unk		Ranbaxy
	Dothiepin Hydrochloride			S	Unknown	225 Mg, Unk		Not Reported
	Dothiepin Hydrochloride			S	Unknown	175 Mg, Unk		Not Reported
	Dothiepin Hydrochloride			S	Unknown	175 Mg, Unk		Not Reported
	Norfloxacin			C	Oral	400 Mg, Bid		Not Reported
	Quetiapine			C	Unknown	400 Mg At Night		Not Reported
	Lamotrigine			C	Unknown	75 Mg, Bid		Not Reported
	Oestradiol			C	Unknown	Unk		Not Reported
	Glipizide			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Lantus Insulin			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12903850	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1000087249		96 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contusion; Craniocerebral Injury; Dizziness; Face Injury; Fall; Gait Disturbance; Hyponatraemia; Skin Lesion	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Ass Cardio			S	Unknown	Unk		Not Reported
	Beloc Zok			S	Unknown	Unk		Not Reported
	Amiodaron-Mepha			S	Unknown	Unk		Not Reported
	Torem			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12904636	EXPEDITED (15-DAY)		OT	JP-TEVA-2016-JP-002282J		35 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Eurodin 2mg. Tablets			S	Oral			Actavis
	Risperdal			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Primperan			C	Unknown			Not Reported
	Laxoberon			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12916593	DIRECT		DS			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Jolessa			C				Not Reported
	Prednisone			C				Not Reported
	Hydroxyzine Hcl			C				Not Reported
	Multi Vitamin			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Biotin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12939595	DIRECT	Y				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Intolerance; Treatment Failure	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2016	12906818	EXPEDITED (15-DAY)		DS	GB-ALLERGAN-1674520US		26 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Female Orgasmic Disorder; Female Sexual Dysfunction; Libido Decreased; Vulvovaginal Dryness	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Cetirizine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2016	12907990	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2016M1046624			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Food Craving; Hepatic Fibrosis; Non-Alcoholic Steatohepatitis; Weight Increased	Sertraline			S	Unknown	50mg Daily		Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Lorazepam			S	Unknown	0.5mg As Needed		Not Reported
	Lithium			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Methylphenidate			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Mylan
	Aripiprazole			S	Unknown			Mylan
	Lamotrigine			C	Unknown			Mylan
	Oxcarbazepine			C	Unknown			Mylan
	Docusate Sodium			C	Unknown			Mylan
	Acetylcysteine			C	Unknown			Mylan

	Clonidine	C	Unknown	Mylan
	Levothyroxine Sodium	C	Unknown	Mylan
	Diphenhydramine	C	Unknown	Mylan
	Topiramate	C	Unknown	Mylan
	Ondansetron	C	Unknown	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2016	12908376	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1674403US		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	14 Df, Unk		Allergan
	Temesta (Lorazepam)			S	Oral	Unk Unk, Single		Not Reported
	Temesta			S	Oral			Not Reported
	Alprazolam			S	Oral	14 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2016	12916258	DIRECT					48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Food Interaction; Rash Erythematous	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Aurobindo
	Vitamin B			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin E			C				Not Reported
	Calcium			C				Not Reported
	Baby Aspirin			C				Not Reported
	Generic Claritin			C				Not Reported
	Fish Oil			C				Not Reported
	Methyl Folate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2016	12283472	EXPEDITED (15-DAY)		OT	US-SA-2015SA177732		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Balance Disorder; Balance Disorder; Blood Pressure Increased; Cd4 Lymphocytes Decreased; Chest Discomfort; Chills; Cognitive Disorder; Cold Sweat; Condition Aggravated; Condition Aggravated; Condition Aggravated; Cough; Crystal Urine; Decreased Immune Responsiveness; Depression; Dermatitis; Dizziness; Dysphagia; Emotional Disorder; Fatigue; Fatigue; Gait Disturbance; Gait Disturbance; Headache; Hemiparesis; Influenza Like Illness; Laboratory Test Abnormal; Malaise; Multiple Sclerosis Relapse; Muscle Spasticity; Muscular Weakness; Musculoskeletal Disorder; Nasopharyngitis; Nausea; Oral Mucosal Exfoliation; Oral Pain; Pruritus; Pyrexia; Seizure; Skin Discolouration; Skin Disorder; Somnolence; Stomatitis; T-Lymphocyte Count Abnormal; Temperature Intolerance; Tremor; Tremor; Visual Impairment	Lemtrada	S	Intravenous drip	Not Reported
	Solumedrol	S	Intravenous drip	Not Reported
	Solumedrol	S	Intravenous drip	Not Reported
	Lexapro	S	Unknown	Not Reported
	Lexapro	S	Unknown	Not Reported
	Acyclovir	C		Not Reported
	Symmetrel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2016	12912969	EXPEDITED (15-DAY)		HO	US-GLENMARK PHARMACEUTICALS		50 YR	Female	USA

EUROPE LIMITED-2016GMK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Reaction With Eosinophilia And Systemic Symptoms; Viral Infection	Lamotrigine			S	Unknown	Unk		Glenmark
	Cyclobenzaprine			S	Unknown	10 Mg, Tid		Not Reported
	Escitalopram			S	Unknown	10 Mg, Od		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2016	12913645	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093614		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Suicidal Ideation; Treatment Noncompliance	Abilify			S	Unknown	10 Mg, Qd		Bristol Myers Squibb
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2016	12913816	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2015-08341			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2016	12913823	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2016-05874		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension	Escitalopram Tablets Usp 10mg			S	Unknown	One Tablet Daily		Aurobindo
	Valsartan			C	Unknown			Not Reported
	Metoprolol			C	Unknown	75 Mg, Unk		Not Reported
	Bupropion			C	Unknown			Not Reported

	Clarityn /00082102/			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2016	12913828	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2015-10219			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Escitalopram Tablets Usp 10mg			S	Oral	1 Df, Once A Day		Aurobindo
	Trazodone			C	Unknown			Not Reported
	Folic Acid			C	Unknown	1 Mg, Unk		Not Reported
	Mono Linyah			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2016	12913841	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2015-07954		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Hypoaesthesia; Medication Error	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Daily		Aurobindo
	Escitalopram Tablets Usp 10mg			S				Aurobindo
	Escitalopram Tablets Usp 10mg			S				Aurobindo
	Escitalopram Tablets Usp 10mg			S				Aurobindo
	Stalevo			C	Unknown	200 Mg, Unk		Not Reported
	Metoprolol			C	Unknown			Not Reported
	Parcopa			C	Unknown			Not Reported
	Clonazepam			C	Unknown	0.5 Mg, Unk		Not Reported
	Ropinirole			C	Unknown			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2016	12914075	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2016-02306		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In	Escitalopram Tablets			S	Unknown	10 Mg, Once A Day		Aurobindo

Attention; Somnolence	Escitalopram Tablets	S	Unknown	20 Mg, Once A Day	Aurobindo
	Bupropion	C	Unknown		Not Reported
	Wellbutrin Xl	C	Unknown	300 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2016	12920304	DIRECT		DS, HO			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Confusional State; Dizziness; Fall; Motor Dysfunction; Rib Fracture	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2016	12915764	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2016-09706			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea	Escitalopram Tablets Usp 20mg			S	Unknown	1/2 Tab		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2016	12915767	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2016-08536			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Feeling Abnormal; Headache	Escitalopram Tablets Usp 5mg			S	Unknown	5 Mg, Once A Day		Aurobindo
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2016	12915773	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2016-09758			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Reaction	Escitalopram Tablets Usp 20mg	S	Unknown	20 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	11618608	EXPEDITED (15-DAY)		HO, OT	AU-ACCORD-034376		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Escherichia Urinary Tract Infection; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Toxicity To Various Agents	Escitalopram			S				Accord
	Ramipril			S				Accord
	Bupropion/Bupropion Hydrochloride			S	Oral	In The Mroning		Not Reported
	Dosulepin			S		Previously Received 225 Mg		Not Reported
	Quetiapine/Quetiapine Fumarate			C		At Night		Not Reported
	Lamotrigine			C				Not Reported
	Estradiol			C				Not Reported
	Glipizide			C				Not Reported
	Metformin			C				Not Reported
	Lantus			C				Not Reported
	Atorvastatin			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Norfloxacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12253083	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2016138816		66 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Carotid Arteriosclerosis; Insomnia; Intentional Product Misuse; Nightmare; Poor Quality Sleep; Visual Impairment	Xanax Xr			S	Oral	1 Mg, 2x/Day		Pfizer
	Xanax Xr			S	Oral	0.5 Mg, Daily		Pfizer
	Xanax Xr			S	Oral	0.25 Mg, Daily		Pfizer
	Cipralex			S		Unk		Not Reported
	Aspirina			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915873	NON-EXPEDITED			US-ACCORD-034742			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Accord			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915874	NON-EXPEDITED			US-ACCORD-034750		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Insomnia; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Product Complaint	Escitalopram Accord			S	Oral			Accord
	Dicycloverine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915875	NON-EXPEDITED			US-ACCORD-035136		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective	Escitalopram Accord			S	Oral			Accord
	Pristiq			S	Oral	35mg Orally By Mouth, Once A Day. Then Dose Increased To 50mg,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915877	NON-EXPEDITED			US-ACCORD-035306		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue; Withdrawal Syndrome	Escitalopram Accord			S	Oral	Strength: 10 Mg. 30 Tablets		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915880	NON-EXPEDITED		DS, HO, OT	US-ACCORD-035307		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebrovascular Accident; Depression; Headache; Hypertension	Escitalopram	S	Oral	Strength: 10 Mg	Accord
	Lexapro	S		5 Tablets	Not Reported
	Meloxicam	C			Not Reported
	Clonazepam	C			Not Reported
	Paxil	C			Not Reported
	Terbinafine/Terbinafine Hydrochloride	C		250	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915885	NON-EXPEDITED			US-ACCORD-037013			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Product Substitution Issue; Withdrawal Syndrome	Escitalopram Accord			S		Strength: 5 Mg		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915893	NON-EXPEDITED			US-ACCORD-037425			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Weight Decreased	Escitalopram Accord			S		Strength: 5 Mg		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915927	NON-EXPEDITED		OT	US-ACCORD-037743		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Escitalopram Accord			S	Oral	Strenght: 20 Mg Previously Received 10 Mg In Oct-2015 Or Nov-2015		Accord
	Ibuprofen			C		Ibuprofen Prn		Not Reported
	Ergocalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915941	NON-EXPEDITED			US-ACCORD-040130			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram			S		Strength: 10 Mg		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915943	NON-EXPEDITED			US-ACCORD-040413		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Hypopnoea; Nasopharyngitis	Escitalopram			S	Oral	Strength: 10 Mg 2.5 Mg Once Daily At Bed Time, Then Increased To 5 Mg, 10 Mg And Then 15 Mg		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915945	NON-EXPEDITED			US-ACCORD-041977			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram Accord			S		Pills		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915953	NON-EXPEDITED			US-ACCORD-041978		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Thinking Abnormal	Escitalopram			S	Oral	20 Mg Once Daily 7 Weeks Ago		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915966	NON-EXPEDITED			US-ACCORD-043051			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Drug Ineffective; Headache	Escitalopram			S		Started At 10 Mg, 20 Mg Pill To Reach Prescribed Doses		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915974	NON-EXPEDITED		OT	US-ACCORD-043111		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Menorrhagia	Escitalopram			S	Oral	Strength: 10 Mg		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915977	NON-EXPEDITED			US-ACCORD-042500		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Oral	Dose/Strength: 10 Mg		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915980	NON-EXPEDITED			US-ACCORD-043574		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Insomnia; Weight Decreased	Escitalopram			S	Oral	Strength 10 Mg		Accord
	Ergocalciferol			C				Not Reported
	Chondroitin Sulfate Sodium/Glucosamine Hydrochloride			C				Not Reported
	Chondroitin/Glucosamine			C				Not Reported
	Calcium Gluconate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12916435	EXPEDITED (15-DAY)		OT	US-ZYDUS-012665		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aphasia; Aphasia; Aspartate Aminotransferase Increased; Body Mass Index Increased; Hepatic Fibrosis; Hepatic Steatosis; Non-Alcoholic Steatohepatitis; Weight Increased	Bupropion/Bupropion Hydrochloride	S	Unknown	Zydus Pharm
	Escitalopram	S	Unknown	Zydus Pharm
	Sertraline	S	Unknown	Zydus Pharm
	Lorazepam	S	Unknown	Not Reported
	Cyclobenzaprine	S	Unknown	Not Reported
	Clonazepam	S	Unknown	Not Reported
	Aripiprazole	S	Unknown	Not Reported
	Lithium	S	Unknown	Not Reported
	Methylphenidate	S	Unknown	Not Reported
	Pregabalin	S	Unknown	Not Reported
	Quetiapine/Quetiapine Fumarate	S	Unknown	Not Reported
	Topiramate	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Lamotrigine	C	Unknown	Not Reported
	Oxcarbazepine	C	Unknown	Not Reported
	Docusate	C	Unknown	Not Reported
	Acetylcysteine	C	Unknown	Not Reported
	Clonidine	C	Unknown	Not Reported
	Levothyroxine	C	Unknown	Not Reported
	Melatonin	C	Unknown	Not Reported
	Ondansetron	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Dexamfetamine	C	Unknown	Not Reported
	Minocycline	C	Unknown	Not Reported
	Ethinylestradiol/Norgestimate	C	Unknown	Not Reported
	Lurasidone	C	Unknown	Not Reported
	Polyethylene Glycol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12917338	EXPEDITED (15-DAY)		DS, HO	JP-ALLERGAN-1675036US		67 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Nausea; Serotonin Syndrome; Therapeutic Response Decreased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Linezolid			S	Oral	1200 Mg, Qd		Not Reported
	Sulpiride			C	Unknown	100 Mg, Qd		Not Reported
	Etizolam			C	Oral	2 Mg, Qd		Not Reported
	Trazodone Hydrochloride			C	Oral	50 Mg, Qd		Not Reported
	Mirtazapine			C	Oral	3.75 Mg, Qd		Not Reported
	Mirtazapine			C		45 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12917342	EXPEDITED (15-DAY)		OT	US-TEVA-709629USA		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Food Craving; Hepatic Fibrosis; Non-Alcoholic Steatohepatitis; Weight Increased	Clonazepam			S	Unknown			Teva
	Lorazepam			S	Unknown	0.5mg As Needed		Actavis
	Aripiprazole			S	Unknown			Teva
	Bupropion Extended Release Xl			S	Unknown			Actavis
	Escitalopram			S	Unknown			Ivax
	Methylphenidate Hydrochloride			S	Unknown			Barr
	Quetiapine Fumarate			S	Unknown			Teva
	Sertraline			S	Unknown	50mg Daily		Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported
	Lithium			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported

	Metformin	S	Unknown	Not Reported
	Lamotrigine	C	Unknown	Not Reported
	Oxcarbazepine	C	Unknown	Not Reported
	Docusate Sodium	C	Unknown	Not Reported
	Acetylcysteine	C	Unknown	Not Reported
	Clonidine	C	Unknown	Not Reported
	Levothyroxine Sodium	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Topiramate	C	Unknown	Not Reported
	Ondansetron	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12917441	NON-EXPEDITED			US-PFIZER INC-2016517517			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Alprazolam			S				Pfizer
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12917490	EXPEDITED (15-DAY)		OT	PT-ALLERGAN-1674843US		71 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Eyelid Oedema; Oedema Peripheral; Polydipsia	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Somazina			S	Unknown			Not Reported
	Acutil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12918308	NON-EXPEDITED			US-APOTEX-2016AP008106			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersensitivity	Escitalopram Oxalate	S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12918367	NON-EXPEDITED			US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2016-BI-07		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torticollis	Busco Ibuprofen			S	Unknown			Not Reported
	Busco Omeprazole			S	Unknown			Not Reported
	Tamsulosin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Celecoxib			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12918509	EXPEDITED (15-DAY)		OT	ZA-ELI_LILLY_AND_COMPANY-ZA201610009040			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia	Prozac			S	Oral	20 Mg, Qd		Eli Lilly And Co
	Prozac			S	Oral	20 Mg, Qd		Eli Lilly And Co
	Lexamil			S	Oral	5 Mg, Qd		Not Reported
	Lexamil			S				Not Reported
	Cortisone			C	Other	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12827020	EXPEDITED (15-DAY)		HO	TW-ALLERGAN-1000087603		22 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Interaction; Mania	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Daily		Allergan
	Dextromethorphan			S	Oral	30 Mg, Q6hr		Not Reported
	Ambroxol			C	Unknown	30 Mg, Unk		Not Reported
	Paracetamol			C		325 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12889421	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1673902US		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraventricular Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Kardegic			S	Oral	160 Mg, Qd		Not Reported
	Glucophage			C	Unknown	Daily Dose Not Reported		Not Reported
	Novonorm			C	Unknown	Daily Dose Not Reported		Not Reported
	Modopar			C	Unknown	Daily Dose Not Reported		Not Reported
	Zaldiar			C	Unknown	Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12919372	EXPEDITED (15-DAY)		OT	US-APOTEX-2016AP014063		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Food Craving; Hepatic Fibrosis; Non-Alcoholic Steatohepatitis; Weight Increased	Sertraline Hydrochloride			S	Unknown	50 Mg, Qd		Apotex
	Clonazepam Tablets Usp			S	Unknown			Apotex
	Aripiprazole Tablets			S	Unknown			Apotex
	Escitalopram Oxalate			S	Unknown			Apotex
	Bupropion Hydrochloride			S	Unknown			Apotex
	Metformin Hydrochloride			S	Unknown			Apotex
	Quetiapine Fumarate			S	Unknown			Apotex
	Lithium Carbonate			S	Unknown			Apotex

Lorazepam	S	Unknown	0.5 Mg As Needed		Not Reported
Methylphenidate	S	Unknown			Not Reported
Pregabalin	S	Unknown			Not Reported
Cyclobenzaprine	C	Unknown			Not Reported
Lamotrigine	C	Unknown			Not Reported
Oxcarbazepine	C	Unknown			Not Reported
Docusate Sodium	C	Unknown			Not Reported
Acetylcysteine	C	Unknown			Not Reported
Clonidine	C	Unknown			Not Reported
Levothyroxine Sodium	C	Unknown			Not Reported
Diphenhydramine	C	Unknown			Not Reported
Topiramate	C	Unknown			Not Reported
Ondansetron	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12919431	EXPEDITED (15-DAY)		OT	SE-SHIRE-SE201615905		28 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Serotonin Syndrome	Elvanse			S	Oral	30 Mg, 1x/Day:Qd		Shire
	Cipralex /01588501/			S	Unknown	Unk, Unknown		Not Reported
	Mirtazapine			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12926994	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2016US04757			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram			S	Oral	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12886454	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1673736US		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akinesia; Tremor	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Kardegic			C	Unknown	75 Mg, Unk		Not Reported
	Temerit			C	Unknown	Unk, Unknown		Not Reported
	Fumafer			C	Unknown	Unk, Unknown		Not Reported
	Xanax			C	Unknown	Unk, Unknown		Not Reported
	Inexium			C	Unknown	Unk, Unknown		Not Reported
	Perindopril			C	Unknown	Unk, Unknown		Not Reported
	Eliquis			C	Unknown	Unk, Unknown		Not Reported
	Repaglinide			C	Unknown	Unk, Unknown		Not Reported
	Daonil			C	Unknown	Unk, Unknown		Not Reported
	Seresta			C	Unknown	Unk Unk, Unknown		Not Reported
	Lasilix			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12894851	EXPEDITED (15-DAY)		OT	NL-ALLERGAN-1673908US		57 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Product Use Issue; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12922545	EXPEDITED (15-DAY)		OT	US-CIPLA-2016US04490			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Tremor	Escitalopram			S	Oral	30 Mg, Qd, Tablet		Invagen

	Pristiq	S	Oral	50 Mg, Qd, Tablet	Not Reported
	Benicar	C		10 Mg, Unk	Not Reported
	Zocor	C		40 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12923633	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2016511426		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardiogenic Shock; Hepatic Failure; Hypovolaemic Shock; Inflammation; Multiple Organ Dysfunction Syndrome; Rhabdomyolysis	Tahor			S	Oral	Unk		Pfizer
	Alprazolam			S	Oral	Unk		Pfizer
	Atenolol			S	Oral	10 Mg, 1x/Day		Not Reported
	Bipreterax /01421201/			S	Oral	Unk		Not Reported
	Kardegic			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12925608	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1675082US		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Abuser; Drug Dependence; Hypokalaemia; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Cannabis And Resin			S	Unknown			Not Reported
	Tobacco Powder			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12926611	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1675192US		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Coma; Inappropriate Schedule Of Product Administration	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Alprazolam			S	Oral			Not Reported
	Abilify			C	Unknown	5 Mg, Unk		Not Reported

	Atarax	C	Unknown	25 Mg, Tid		Not Reported
	Revia	C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12927093	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1675031US		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropsychiatric Lupus; Photosensitivity Reaction	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Levothyrox			C	Unknown			Not Reported
	Kardegic			C	Unknown			Not Reported
	Novopulm			C	Unknown			Not Reported
	Orocal D3			C	Unknown			Not Reported
	Preservision			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12168487	NON-EXPEDITED			US-PFIZER INC-2016139951		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Xanax			S		Unk		Pfizer
	Norvasc			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Calcium Carbonate			S		600 Mg, Unk		Pfizer
	Homatropine Methylbromide/Hydrocodone Bitartrate			S		Unk		Pfizer
	Naproxen Sodium			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Sonata			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer

Furosemide	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported
Trazodone Hcl	S	Unk	Not Reported
Aspirin	S	Unk	Not Reported
Cefuroxime Sodium	S	Unk	Not Reported
Diovan	S	Unk	Not Reported
Dyrenium	S	Unk	Not Reported
Ketek	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Proventil	S	Unk	Not Reported
Prozac	S	Unk	Not Reported
Qvar	S	Unk	Not Reported
Rhinocort Aqua	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported
Triamterene And Hydrochlorothiazide	S	Unk	Not Reported
Ultram	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Biaxin	S	Unk	Not Reported
Lisinopril	S	Unk	Not Reported
Toprol Xl	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12172063	NON-EXPEDITED		OT	US-GLAXOSMITHKLINE-US2016GSK033600		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Accidental Exposure To Product; Blood Glucose Increased; Device Leakage; Device Use	Tanzeum Solution For Injection In Pre-Filled Pen			S	Intravenous (not otherwise specified)	30 Mg, We		Glaxosmithkline
	Tanzeum Solution For Injection In Pre-Filled Pen			S	Intravenous (not otherwise specified)	30 Mg, We		Glaxosmithkline

Error; Dry Mouth; Headache; Hypophagia; Ill-Defined Disorder; Increased Appetite; Labelled Drug-Disease Interaction Medication Error; Limb Operation; Product Preparation Issue; Pruritus; Skin Burning Sensation; Squamous Cell Carcinoma Of Skin; Stress; Urinary Tract Infection; Weight Increased	Tanzeum Solution For Injection In Pre-Filled Pen		S	Intravenous (not otherwise specified)	30 Mg, We	Glaxosmithkline
	Escitalopram		S		Unk	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12928743	EXPEDITED (15-DAY)		HO, LT, OT	ES-ELI_LILLY_AND_COMPANY-ES201611002272		42 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Interaction; Hepatomegaly; Neuroleptic Malignant Syndrome; Overdose; Pleural Effusion; Suicide Attempt	Zyprexa			S	Oral	10 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Oral	140 Mg, Qd		Eli Lilly And Co
	Haloperidol			S	Oral	5 Mg, Tid		Not Reported
	Haloperidol			S	Oral	150 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Escitalopram			S	Oral	400 Mg, Qd		Not Reported
	Xeplion			C	Intramuscular	150 Mg, Monthly (1/M)		Not Reported
	Alcohol			C	Unknown	2 Beers A Day		Not Reported
	Cocaine			C	Respiratory (inhalation)	Unk, Unknown		Not Reported
	Cocaine			C	Intravenous (not otherwise specified)	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12930595	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1675324US		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Contraindicated Product Administered; Overdose; Poisoning Deliberate	Escitalopram Oxalate - Bp			S	Oral	240 Mg, Single		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12930808	EXPEDITED (15-DAY)		OT	CN-JNJFOC-20161104369		43 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Suicidal Ideation; Thinking Abnormal	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown	2 Tablets Per Morning		Not Reported
	Lexapro			S	Unknown	2 Tablets Per Morning, 2 Tablets Per Noon, 1 Tablet At Every 16:00 Pm		Not Reported
	Clonazepam			C	Oral			Not Reported
	Clonazepam			C	Oral	Half Dosage Currently Compared With Before		Not Reported
	Stilnox			C	Unknown			Not Reported
	Stilnox			C	Unknown	Half Dosage Currently Compared With Before		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12931209	NON-EXPEDITED			US-JAZZ-2016-US-018025			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Sweats; Unevaluable Event; Weight Increased	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	Unknown Dose		Jazz
	Escitalopram			S				Not Reported

	Buspirone Hcl	C	Not Reported
	Ceftina	C	Not Reported
	Minastrin 24 Fe	C	Not Reported
	Nuvigil	C	Not Reported
	Excedrin Extra Strength	C	Not Reported
	Ibuprofen	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12931433	EXPEDITED (15-DAY)		HO	GXKR2016DE005071			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Metoprolol			S	Oral	23.75 Mg, Qd		Novartis
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	L-Thyroxine			C	Oral	37.5 Ug, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12932561	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2016-04995		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Food Craving; Non-Alcoholic Steatohepatitis; Weight Increased	Sertraline			S	Unknown	50 Mg		Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Lithium			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Methylphenidate			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12934429	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1675512US		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Hypovolaemic Shock; Multiple Organ Dysfunction Syndrome	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Atenolol			S	Oral	10 Mg, Qd		Not Reported
	Bipreterax			S	Oral	5mg/1.25mg		Not Reported
	Kardegic			S	Oral	75 Mg, Unk		Not Reported
	Tahor			S	Oral	80 Mg, Unk		Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12629078	EXPEDITED (15-DAY)		HO, OT	FR-ALEMBIC PHARMACUETICALS LIMITED-2016SCAL000635			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Electrocardiogram Qt Prolonged; Hypoglycaemia; Nystagmus; Overdose; Toxicity To Various Agents	Venlafaxine Hydrochloride			S		7875 Mg, Unk		Alembic
	Escitalopram			S		840 Mg, Unk		Not Reported
	Bromazepam			S		180 Mg, Unk		Not Reported
	Lormetazepam			S		14 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12791120	NON-EXPEDITED			US-PFIZER INC-2016455897		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Wrong Dose	Lyrica			S		50 Mg, Unk		Pfizer
	Clonazepam			S		4 Mg, Unk		Not Reported
	Clonazepam			S	Oral	0.5 Mg, 1x/Day At Night		Not Reported
	Escitalopram			S	Oral	20 Mg, 1x/Day At Night		Not Reported

	Seroquel	S		100 Mg, Unk		Not Reported
	Seroquel	S	Oral	50 Mg, 1x/Day At Night		Not Reported
	Klonopin	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12893951	EXPEDITED (15-DAY)		HO	FR-IPSEN BIOPHARMACEUTICALS, INC.-2016-09150			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Faecal Vomiting; Intestinal Obstruction; Muscular Weakness; Neuromuscular Toxicity; Respiratory Failure; Urinary Retention; Vomiting	Dysport			S	Intramuscular	100 Iu		Not Reported
	Dysport			S				Not Reported
	Gutron			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported
	Gaviscon			S	Oral			Not Reported
	Inipomp			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12935726	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2016US20958			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S		More Than 20 Mg, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12935811	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2016US20959			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S	Unknown	More Than 20mg Daily		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12935977	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2016US20986			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Cardiac Death	Escitalopram			S	Unknown	Unk, >20 Mg		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12937475	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2016-05064		12 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Irritability; Restlessness; Sleep Disorder	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12939519	DIRECT		HO			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Abnormal Dreams; Delirium; Hallucination; Thinking Abnormal	Citalopram			S	Oral	Quantity:1 Tablet(S); Daily; Oral		Not Reported
	Escitalopram			S				Not Reported
	Pravastatin			C				Not Reported
	Ramipril			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12940388	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/16/0084703		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Non-Alcoholic Steatohepatitis	Sertraline Hydrochloride			S	Unknown			Not Reported
	Quetiapine Fumarate Tablets			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Lithium Carbonate			S	Unknown			Not Reported

Escitalopram	S	Unknown	Not Reported
Aripiprazole	S	Unknown	Not Reported
Bupropion	S		Not Reported
Methylphenidate	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Cetirizine	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Paracetamol	C	Unknown	Not Reported
Vitamin B Complex	C	Unknown	Not Reported
Cholecalciferol	C	Unknown	Not Reported
Melatonin	C	Unknown	Not Reported
Tizanidine	C	Unknown	Not Reported
Lamotrigine	C	Unknown	Not Reported
Oxcarbazepine	C	Unknown	Not Reported
Levothyroxine	C	Unknown	Not Reported
Ondansetron	C	Unknown	Not Reported
Clonidine	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Docusate Sodium	C	Unknown	Not Reported
Acetylcysteine	C	Unknown	Not Reported
Minocycline	C	Unknown	Not Reported
Lurasidone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12943136	EXPEDITED (15-DAY)		DE, HO, OT	US-PFIZER INC-2016522408			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Drug Withdrawal Syndrome Neonatal; Irritability; Maternal Exposure During	Vistaril			S	Transplacental	50 Mg, 2x/Day		Pfizer
	Gabapentin			S	Transplacental	Unk Unk, 1x/Day (Qd)		Pfizer
	Suboxone			S	Transplacental	10 Mg, Daily		Not Reported

Pregnancy; Neonatal Aspiration; Oral Candidiasis; Poor Feeding Infant	Buprenorphine		S	Transplacental	Various Doses	Not Reported
	Lexapro		S	Transplacental	20 Mg, 1x/Day (Qd)	Not Reported
	Buprenorphine		S	Transplacental	10 Mg, 1x/Day (Qd)	Not Reported
	Nicotine		S	Transplacental	40 Cigarettes, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12944206	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1675831US		43 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Overdose; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown	2 Df, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	2 Tablets Per Morning, 2 Tablets Per Noon And 1 Tablet At Every 16:00		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown	0.5 Df, Qd		Not Reported
	Clonazepam			C	Unknown	Half Dosage Compared With Before.		Not Reported
	Stilnox			C	Unknown	Half Dosage Currently Compared With Before.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12484991	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2016GSK087253			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Back Pain; Exostosis; Fall; Hypoaesthesia; Musculoskeletal Pain; Nausea; Pain In Extremity; Spinal Disorder	Wellbutrin			S		150 Mg, Bid		Glaxosmithkline
	Methadone			S		5 Mg, Bid		Glaxosmithkline
	Lexapro			S		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12944717	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2016US20987			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Cardiac Death	Escitalopram			S	Unknown	Unk, > 20 Mg		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12944746	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2016US20989			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Cardiac Death	Escitalopram			S	Unknown	Unk, > 20 Mg		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12944780	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2016US20988			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Cardiac Death	Escitalopram			S	Unknown	Unk, >20 Mg		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12944843	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2016US20991			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Escitalopram			S	Unknown	Unk, >20 Mg		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12944846	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2016US20992			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Escitalopram			S	Unknown	Unk, > 20 Mg		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12944850	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2016US20990			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Escitalopram			S	Unknown	Unk, > 20 Mg		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12945856	EXPEDITED (15-DAY)		HO, OT	RO-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-127636		38 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Treatment Noncompliance; Tremor	Amisulpride			S	Unknown	600 Mg, Daily		Not Reported
	Valproic Acid			S	Unknown	1200 Mg, Daily		Sun
	Valproic Acid			S	Unknown	1000 Mg, Daily		Sun
	Diazepam			S	Unknown	20 Mg, Daily		Not Reported
	Quetiapine			S	Unknown	400 Mg, Daily		Sun
	Quetiapine			S	Unknown	600 Mg, Daily		Sun
	Quetiapine			S	Unknown	400 Mg, Daily		Sun
	Levomepromazine			S	Unknown	50 Mg, Daily		Not Reported
	Clonazepam			S	Unknown	2 Mg, Daily		Sun
	Bromazepam			S	Unknown	6 Mg, Daily		Not Reported
	Zopiclone			S	Unknown	7.5 Mg, Daily		Not Reported
	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported
	Zolpidem			S	Unknown	10 Mg, Daily		Sun
	Risperidone			S	Unknown	4 Ml, Daily		Not Reported
	Siofor			C	Unknown	1000 Mg, Bid (1-0-1)		Not Reported
	Mixtard			C	Subcutaneous	100 Ui/Ml, 18u-0-10ui, Before Meals		Not Reported
	Metoprolol			C	Unknown	50 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12947282	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2016M1048921			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Metoprolol			S	Oral	23.75 Mg, Qd (Daily Dose: 23.75 Mg Milligram(S) Every Day)		Not Reported
	Cipralex			S	Oral	10 Mg, Qd (Daily Dose: 10 Mg Milligram(S) Every Day)		Mylan
	L-Thyroxin			C	Oral	37.5 Mg, Qd (Daily Dose: 37.5 Mg Microgram(S) Every Day)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12950144	EXPEDITED (15-DAY)		HO	CN-ALLERGAN-1676420US		47 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; White Blood Cell Count Decreased	Escitalopram Oxalate - Bp			S	Oral	5-10 Mg Daily		Allergan
	Seroquel			S	Oral	12.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12950975	EXPEDITED (15-DAY)		CA	FR-ASTRAZENECA-2016SF19499			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Talipes	Xeroquel			S	Transplacental			Not Reported
	Xeroquel			S	Transplacental			Not Reported
	Seroplex			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12951674	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMP		38 YR	Female	FRA

ANY-FR201611005693

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedematous Pancreatitis	Prozac			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Seroplex			S	Unknown	Unk, Unknown		Not Reported
	Dafalgan Codein			S	Oral	Unk, Unknown		Not Reported
	Xanax			C	Unknown	Unk, Unknown		Not Reported
	Stilnox			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12953484	EXPEDITED (15-DAY)		DE	CH-ALLERGAN-1676655US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Zolpidem			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Varenicline			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Phenylephrine			S	Unknown			Not Reported
	Dimetindene			S	Unknown			Not Reported
	Bisacodyl			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12954776	DIRECT	Y				10 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation	Lexapro			S	Oral	5 Mg At Bedtime Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2016	12438133	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-043148		28 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication; Shoulder Deformity; Weight Increased	Abilify			S	Unknown			Bristol Myers Squibb
	Cipralex /01588501/			S	Unknown			Not Reported
	Xeplion			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2016	12918414	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1674813US		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal; Hypertension; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Ferromia			C	Oral			Not Reported
	Edirol			C	Oral			Not Reported
	Alfacalcidol			C	Oral			Not Reported
	Mucosta			C	Oral			Not Reported
	Rozerem			C	Oral			Not Reported
	Chlomy			C	Vaginal			Not Reported
	Belsomra			C	Oral	Unk		Not Reported
	Seroquel			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2016	12925630	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1675029US		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dysphagia; Faecal Vomiting; Hypercapnia; Hypoxia; Intestinal Obstruction; Malaise; Respiratory Disorder; Speech Disorder; Urinary Retention; Vomiting	Escitalopram Oxalate - Bp			S		10 Mg, Qd		Allergan
	Dysport			S	Intramuscular	100 Iu, Single		Not Reported
	Gutron			S		10 Mg, Qd		Not Reported
	Xanax			S		0.5 Mg, Bid		Not Reported
	Gaviscon			S				Not Reported
	Inipomp			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2016	12954436	NON-EXPEDITED			US-PFIZER INC-2016534207		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Paxil			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2016	12954964	EXPEDITED (15-DAY)		OT	SA-LUPIN PHARMACEUTICALS INC.-2016-05098		45 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Drug Withdrawal Syndrome	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2016	12955676	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2016M1049838			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypoglycaemia; Hyponatraemia; Lactic Acidosis	Escitalopram	S	Unknown		Not Reported
	Gliclazide	S	Unknown		Not Reported
	Metformin	S	Unknown	Initial Dose Not Stated; Eventually The Dose Was Increased To 1gram Twice A Day	Not Reported
	Hydrochlorothiazide	S	Unknown		Not Reported
	Insulin	S	Unknown		Mylan
	Levothyroxine Sodium	C	Unknown		Mylan
	Telmisartan	C	Unknown		Mylan
	Trazodone	C	Unknown		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2016	12957616	EXPEDITED (15-DAY)		CA	FR-ALLERGAN-1676709US			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Escitalopram Oxalate - Bp			S	Transplacental			Allergan
	Xeroquel			S	Transplacental	300 Mg, Unk		Not Reported
	Xeroquel			S	Transplacental	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12579610	EXPEDITED (15-DAY)		HO	JP-FRI-1000086131		31 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Hepatic Function Abnormal	Lexapro Tablets			S	Oral	10 Mg, Qd		Allergan
	Meilax			S	Oral	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12619335	EXPEDITED (15-DAY)		HO, OT	AU-SYMPLMED PHARMACEUTICALS-2016SYMPLMED000284			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning	Perindopril			S	Unknown	10 Mg, Qd		Unknown
	Rosuvastatin Calcium			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Not Reported
	Lercanidipine Hydrochloride			S	Unknown	Unk		Not Reported
	Pantoprazole Sodium Sesquihydrate			S	Unknown	Unk		Not Reported
	Atenolol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12649964	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2016-10491		23 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Carcinoid Syndrome; Flushing; Metastases To Liver; Nausea; Pancreatic Neuroendocrine Tumour; Tachycardia; Vomiting	Escitalopram 10 Mg Film-Coated Tablet			S	Unknown	10 Mg, One 10 Mg Tablet		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12825508	EXPEDITED (15-DAY)		DE, HO	SI-JNJFOC-20161004315		79 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Condition Aggravated; Confusional State; Fear; Insomnia; Pain; Personality Change	Durogesic			S	Transdermal			Not Reported
	Haldol			S	Intramuscular			Not Reported
	Cipralex			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Kventiax			S	Oral			Not Reported
	Arcoxia			S	Oral			Not Reported
	Triptorelin			C	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12958544	EXPEDITED (15-DAY)		CA	GB-CIPLA LTD.-2016GB21705			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12958765	EXPEDITED (15-DAY)		CA	GB-CIPLA LTD.-2016GB21935			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12958776	EXPEDITED (15-DAY)		CA	GB-CIPLA LTD.-2016GB21934			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12958787	EXPEDITED (15-DAY)		CA	GB-CIPLA LTD.-2016GB21933			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12958814	EXPEDITED (15-DAY)		CA	DK-CIPLA LTD.-2016DK21718			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Disease Congenital	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12958841	EXPEDITED (15-DAY)		CA	DK-CIPLA LTD.-2016DK21655			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12959284	EXPEDITED (15-DAY)		CA	DK-CIPLA LTD.-2016DK21890			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12959285	EXPEDITED (15-DAY)		CA	DK-CIPLA LTD.-2016DK21891			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12959309	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2016-14294		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Metoprolol			S	Oral	23.75 Mg, Unk		Aurobindo
	Cipralex /01588501/			S	Oral	10 Mg, Daily		Not Reported
	L-Thyroxin			C	Oral	37.5 Mcg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12959539	EXPEDITED (15-DAY)		HO	US-ABBVIE-16P-163-1737590-00		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Cellulitis; Depression; Electrolyte Imbalance; Hypertension; Hyponatraemia	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12961407	EXPEDITED (15-DAY)		HO	DE-VALIDUS PHARMACEUTICALS LLC-DE-2016VAL002982		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Metoprolol Tartrate			S	Oral	23.75 Mg, Qd		Validus
	Cipralex /01588502/			S	Oral	10 Mg, Qd		Not Reported
	L-Thyroxine /00068001/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12961835	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016538154		76 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Decreased Appetite; Suicide Attempt	Effexor		S	Oral	75 Mg, Daily	Pfizer
	Lexapro		S	Oral	Unk	Not Reported
	Limas		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12962138	EXPEDITED (15-DAY)		DS	IT-ALLERGAN-1676907US		22 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Disturbance In Attention; Erectile Dysfunction	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12801525	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-080352		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Treatment Noncompliance	Abilify			S	Unknown	10 Mg, Qd		Bristol Myers Squibb
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12918407	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016500352		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Faecal Vomiting; Fatigue; General Physical Health Deterioration; Hypercapnia; Hypoxia; Intestinal Obstruction; Miosis; Respiratory Disorder; Urinary Incontinence; Urinary Retention; Vomiting	Xanax			S		0.25 Mg Per Two Tablet Daily		Pfizer
	Inipomp			S		40 Mg Per Two Dosage Form Daily		Pfizer
	Gutron			S	Other	2.5 Mg Per Four Tablet Daily		Not Reported
	Dysport /01136801/			S	Intramuscular	100 Iu, Single		Not Reported
	Seroplex			S		10 Mg, Qd		Not Reported

	Gaviscon /00237601/	S	1 Df, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12963093	EXPEDITED (15-DAY)		CA	NO-CIPLA LTD.-2016NO21684			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12963095	EXPEDITED (15-DAY)		CA	NO-CIPLA LTD.-2016NO21919			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12963166	EXPEDITED (15-DAY)		CA	NO-CIPLA LTD.-2016NO21920			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12963172	EXPEDITED (15-DAY)		CA	NO-CIPLA LTD.-2016NO21921			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12963360	EXPEDITED (15-DAY)		CA	DK-CIPLA LTD.-2016DK21959			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Disease Congenital	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12963367	EXPEDITED (15-DAY)		CA	DK-CIPLA LTD.-2016DK21958			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Disease Congenital	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12963370	EXPEDITED (15-DAY)		CA	DK-CIPLA LTD.-2016DK21889			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12965489	EXPEDITED (15-DAY)		HO	CA-UNICHEM LABORATORIES LIMITED-UCM201611-000259		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Hydrochlorothiazide			S				Unichem
	Escitalopram			S				Not Reported
	L-Thyroxine			C				Not Reported
	Telmisartan			C				Not Reported
	Trazadone			C				Not Reported

	Gliclazide Mr	C		Not Reported
	Metformin	C		Not Reported
	Insulin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12970104	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	11482534	NON-EXPEDITED			US-JAZZ-2014-US-014545			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hunger; Hyperhidrosis; Hyperphagia; Hypersensitivity; Night Sweats; Pruritus; Scratch; Weight Increased; Wrong Technique In Product Usage Process	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Cymbalta			S				Not Reported
	Lexapro			S		20 G, Qd		Not Reported
	Brintellix			S		10mg, Qd		Not Reported
	Brintellix			S	Oral	20 Mg, Qd		Not Reported
	Clonazepam			C				Not Reported
	Propranolol			C				Not Reported
	Propranolol			C				Not Reported
	Claritin			C				Not Reported
	Flixonase			C				Not Reported
	Fetzima			C				Not Reported
	Vitamin D3			C				Not Reported
	Deplin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	11655276	EXPEDITED (15-DAY)		HO	JP-JNJFOC-20151015732		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradykinesia; Dehydration; Somnolence; Urinary Tract Infection	Risperidone	S	Unknown	Not Reported
	Risperidone	S	Unknown	Not Reported
	Risperidone	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Mirtazapine	C	Unknown	Not Reported
	Nitrazepam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12164036	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2016GSK033637		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Anxiety; Depression; Drug Ineffective; Ejaculation Failure; Emotional Disorder; Emotional Distress; Feeling Abnormal; Headache; Hypertension; Potentiating Drug Interaction; Sexual Dysfunction; Tinnitus; Unevaluable Event	Paxil			S				Glaxosmithkline
	Paxil			S				Glaxosmithkline
	Wellbutrin			S		150 Mg, Qd		Glaxosmithkline
	Wellbutrin			S				Glaxosmithkline
	Cymbalta			S		60 Mg, Unk		Glaxosmithkline
	Cymbalta			S				Glaxosmithkline
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12967745	EXPEDITED (15-DAY)		CA	FI-CIPLA LTD.-2016FI21819			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During	Escitalopram			S	Transplacental	Unk		Invagen

Pregnancy; Ventricular Septal Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12968699	DIRECT					75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Fatigue	Lexapro			S	Oral			Mylan
	Levothyroxine			C				Not Reported
	Pantoprazole			C				Not Reported
	Cranberry			C				Not Reported
	Zinc			C				Not Reported
	Vitamin D3			C				Not Reported
	Lactaid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12970517	EXPEDITED (15-DAY)		HO	DE-TEVA-711295GER		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Metoprolol			S	Oral	23.75 Milligram Daily;		Not Reported
	Cipralex			S	Oral	10 Milligram Daily;		Not Reported
	L-Thyroxin			C	Oral	37.5 Microgram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12970625	EXPEDITED (15-DAY)		HO	GR-PRINSTON PHARMACEUTICAL INC.-2016PRN00322		76 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prostatectomy; Urinary Retention	Escitalopram			S		10 Mg, 1x/Day		Prinston Pharmaceutical
	Escitalopram			S		20 Mg, 1x/Day		Prinston Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12970979	NON-EXPEDITED			US-JAZZ-2015-US-003581		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Anxiety; Fatigue; Feeling Abnormal	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S	Oral	Unk		Not Reported
	Nuvigil			C	Oral	Unk		Not Reported
	Latuda			C	Oral	Unk		Not Reported
	Adderall			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12971500	NON-EXPEDITED		OT	US-JAZZ-2016-US-019629			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cataplexy; Headache; Hepatic Enzyme Increased; Hypersensitivity; Sinus Disorder	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Lexapro			S				Not Reported
	Excedrin /00110301/			S				Not Reported
	Flonase /00908302/			C		Unk		Not Reported
	Imitrex /01044801/			C		Unk		Not Reported
	Pramipexole			C		Unk		Not Reported
	Prevacid			C		15 Mg, Unk		Not Reported
	Prevacid			C		30 Mg, Unk		Not Reported
	Provent			C		Unk		Not Reported
	Provigil /01265601/			C		Unk		Not Reported
	Singulair			C				Not Reported

Sudafed /00076302/	C	Unk		Not Reported
Vitamin C /00008001/	C	Unk		Not Reported
Vitamin D /00107901/	C	Unk		Not Reported
Nyquil Cold & Flu	C	Unk		Not Reported
Hydrocodone/Acetaminophen /00607101/	C	Unk		Not Reported
Colon Herbal Cleanser	C			Not Reported
Multivitamins /00116001/	C			Not Reported
Vitamin D3	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12975185	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Balance Disorder; Blood Thyroid Stimulating Hormone Increased; Delusion Of Grandeur; Derealisation; Electrocardiogram Qt Prolonged; Head Injury; Restless Legs Syndrome; Victim Of Crime	Lexapro			S	Oral		9 MTH	Not Reported
	Abilify			S	Oral		1 YR	Torrent
	Aripiprazole			C				Not Reported
	Escitalopram			C				Not Reported
	Meloxicam			C				Not Reported
	Cefdinir			C				Not Reported
	Levothyroxine			C				Not Reported
	Mupirocin			C				Not Reported
	Calcium Citrate With Vitamin D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2016	12971964	EXPEDITED (15-DAY)		CA	FI-CIPLA LTD.-2016FI21817			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Left Ventricle Outflow Tract Obstruction	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2016	12972112	EXPEDITED (15-DAY)		DE, HO	FR-ACCORD-045762		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Psychiatric Symptom	Clonazepam			S		Reintroduced 0.6 Mg/D In Jun-2015		Accord
	Escitalopram			S				Accord
	Tetrabenazine			S		25 Mg/D Was Finally Reintroduced Mar-2015		Not Reported
	Baclofen			S				Not Reported
	Mianserin			C				Not Reported
	Hydroxycarbamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2016	12972288	EXPEDITED (15-DAY)		HO, LT	FR-ZYDUS-012780		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyspnoea; Fall; Serotonin Syndrome	Escitalopram			S	Unknown			Not Reported
	Tramadol			S	Unknown			Zydus Pharm
	Fluindione			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Perindopril/Perindopril Erbumine			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Spironolactone			S	Unknown			Not Reported
	Rosuvastatin/Rosuvastatin Calcium			S	Unknown			Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)			Not Reported
	Furosemide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2016	12974220	EXPEDITED (15-DAY)		CA	FI-CIPLA LTD.-2016FI22168			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular	Escitalopram			S	Transplacental	Unk		Invagen

Septal Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2016	12974231	EXPEDITED (15-DAY)		CA	FI-CIPLA LTD.-2016FI22167			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2016	12974246	EXPEDITED (15-DAY)		CA	FI-CIPLA LTD.-2016FI22166			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2016	12974809	EXPEDITED (15-DAY)		HO	FR-LUPIN PHARMACEUTICALS INC.-2016-05181		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Fluindione			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Spironolactone			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2016	12474882	EXPEDITED (15-DAY)		HO, OT	FR-PAR PHARMACEUTICAL COMPANIES-2016SCPR015544			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State; Electrocardiogram Qt Prolonged; Hypoglycaemia; Loss Of Consciousness; Nystagmus; Overdose; Psychomotor Retardation; Suicide Attempt; Toxicity To Various Agents	Venlafaxine Hydrochloride			S	Oral	7875 Mg, Unknown		Par
	Escitalopram			S	Oral	840 Mg, Unknown		Not Reported
	Bromazepam			S	Oral	180 Mg, Unknown		Not Reported
	Lormetazepam			S	Oral	14 Mg, Unknown		Not Reported
	Alcohol			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2016	12976052	EXPEDITED (15-DAY)		DS, HO	GXKR2016DE005290			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Olanzapin			S	Oral			Not Reported
	Olanzapin			S	Oral			Not Reported
	Mirtazapine			S	Oral			Novartis
	Escitalopram Lundbeck			S	Oral			Not Reported
	Escitalopram Lundbeck			S	Oral			Not Reported
	Tavor (Lorazepam)			S	Oral			Not Reported
	Tavor (Lorazepam)			S	Oral			Not Reported
	Tavor (Lorazepam)			S	Oral			Not Reported
	L-Thyroxine			C	Oral			Not Reported
	Aprovel			C	Oral			Not Reported
	Urivesc			C	Oral			Not Reported
	Felodipin			C	Oral			Not Reported
	Kalium-Duriles			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2016	12978075	DIRECT		LT, OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Dizziness; Dysarthria; Feeling Drunk; Heart Rate Increased; Multi-Organ Disorder; Muscular Weakness; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Nausea; Paraesthesia; Paraesthesia; Respiratory Rate Increased; Syncope; Tremor; Vision Blurred; Vomiting	Etalopro 5mg Escitalopram Oxalate			S	Oral	Quantity:1 Tablet(S);		Clonmel
	Methylphenidate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2016	12978186	DIRECT		OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Gastrointestinal Disorder; Muscle Rigidity; Mydriasis; Palpitations; Product Substitution Issue; Serotonin Syndrome	Lexapro 10mg	Y		S	Oral	Quantity:1 Tablet(S);		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2016	12976629	EXPEDITED (15-DAY)		HO	GR-JUBILANT GENERICS LIMITED-1060074		76 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prostatectomy; Urinary	Escitalopram Oxalate			S				Jubilant

Retention

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12834903	EXPEDITED (15-DAY)		HO, LT	CN-ALLERGAN-1671476US			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Shock; Suspected Counterfeit Product	Lexapro Tablets			S	Oral	Unk		Allergan
	Lexapro Tablets			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12885642	EXPEDITED (15-DAY)		OT	ZA-ALLERGAN-1673737US			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Bypass; Prescribed Overdose; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Qd		Allergan
	Fluanxol			S	Unknown	05. Mg, Twice A Day Or When Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12959137	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2016-14063		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Body Mass Index Increased; Fibrosis; Non-Alcoholic Steatohepatitis; Weight Increased	Aripiprazole			S	Unknown	2.5 Mg, At Night		Aurobindo
	Cyclobenzaprine			S	Unknown			Aurobindo
	Escitalopram			S				Aurobindo
	Quetiapine			S	Unknown			Aurobindo
	Sertraline 50mg			S	Unknown	50 Mg, Daily		Aurobindo
	Bupropion			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Lithium			S	Unknown			Not Reported
	Lorazepam			S	Unknown	0.5 Mg, Unk		Not Reported
	Methylphenidate			S	Unknown			Not Reported

	Pregabalin		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12963400	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/16/0084876			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt; Thinking Abnormal	Zenatane			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12976894	EXPEDITED (15-DAY)		CA	NO-CIPLA LTD.-2016NO21850			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy	Citalopram			S	Transplacental	Unk		Invagen
	Escitalopram			S	Transplacental	Unk		Invagen
	Folic Acid			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12976997	EXPEDITED (15-DAY)		CA	NO-CIPLA LTD.-2016NO21851			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy	Citalopram			S	Transplacental	Unk		Invagen
	Escitalopram			S	Transplacental	Unk		Invagen
	Folic Acid			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12977006	EXPEDITED (15-DAY)		CA	NO-CIPLA LTD.-2016NO21858			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During	Citalopram			S	Transplacental	Unk		Invagen

Pregnancy	Escitalopram		S	Transplacental	Unk		Invagen
	Folic Acid		S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12977478	EXPEDITED (15-DAY)		CA	SE-CIPLA LTD.-2016SE22073			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12977494	EXPEDITED (15-DAY)		CA	SE-CIPLA LTD.-2016SE22074			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12977510	EXPEDITED (15-DAY)		CA	SE-CIPLA LTD.-2016SE22076			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12977651	EXPEDITED (15-DAY)		CA	NO-CIPLA LTD.-2016NO21857			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Citalopram			S	Transplacental	Unk		Invagen
	Escitalopram			S	Transplacental	Unk		Invagen

	Folic Acid		S	Transplacental	Unk	Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12977983	EXPEDITED (15-DAY)		DS, HO	DE-009507513-1611DEU010185		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Mirtazapine			S	Oral	30 Mg, Qd		Merck
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Olanzapine			S	Oral	2.5 Mg, Qd		Not Reported
	Olanzapine			S	Oral	5 Mg, Qd		Not Reported
	Tavor (Lorazepam)			S	Oral	3 Mg, Qd		Not Reported
	Tavor (Lorazepam)			S	Oral	2 Mg, Qd		Not Reported
	Tavor (Lorazepam)			S	Oral	1.5 Mg, Qd		Not Reported
	L-Thyroxin			C	Oral	100 Microgram, Qd		Not Reported
	Aprovel			C	Oral	300 Mg, Qd		Not Reported
	Urivesc			C	Oral	60 Mg, Qd		Not Reported
	Felodipine			C	Oral	10 Mg, Qd		Not Reported
	Kalium-Duriles			C	Oral	3 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12978376	NON-EXPEDITED			US-PFIZER INC-2016543031		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Zoloft			S		Unk		Pfizer
	Desyrel			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12980468	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1677990US		78 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lethargy; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Mirtazapin Actavis			S	Oral	Unk		Not Reported
	Sobril			S	Oral	Unk		Not Reported
	Imovane			S	Oral	Unk		Not Reported
	Metoprolol Gea Retard			C	Unknown			Not Reported
	Inderal			C	Unknown			Not Reported
	Oralovite			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12980492	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1677986US		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Incorrect Dose Administered; Medication Error	Escitalopram Oxalate - Bp			S	Oral	2 Df, Once		Allergan
	Temesta (Lorazepam)			S	Oral	2 Df, Once		Not Reported
	Zolpidem			S	Oral	2 Df, Once		Not Reported
	Piracetam			S	Oral	2 Df, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12827338	EXPEDITED (15-DAY)		HO	TR-TEVA-698138ISR		24 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; General Physical Health Deterioration; Hypernatraemia; Hypocalcaemia; Leukopenia; Loss Of Consciousness;	Fluoxetine			S	Oral			Barr
	Valproic Acid			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

Respiratory Depression; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12900878	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-1000086346		72 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrooesophageal Reflux Disease; Long Qt Syndrome; Off Label Use; Serotonin Syndrome; Transient Ischaemic Attack	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Mystan			S	Oral	5 Mg, Bid		Not Reported
	Lendormin			S	Oral	.25 Mg, Qd		Not Reported
	Belsomra			S	Oral	20 Mg, Qd		Not Reported
	Milmag			C	Oral	300 Mg, Unk		Not Reported
	Malfa			C	Oral	Unk		Not Reported
	Micardis			C	Oral	1 Df, Unk		Not Reported
	Madopar			C				Not Reported
	Pariet			C				Not Reported
	Gasmotin			C				Not Reported
	Hangekobokuto			C				Not Reported
	Micamlo			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12962570	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1676995US		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Pregnancy	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Cefprozil			C		1000 Mg, Qd		Not Reported
	Dexketoprofen			C		25 Mg, Qd		Not Reported
	Trimetazidine			C		40 Mg, Qd		Not Reported
	Levothyroxine			C		1000 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12962579	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1676996US		39 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Pregnancy	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Zofenopril			C		30 Mg, Qd		Not Reported
	Trimetazidine			C		40 Mg, Qd		Not Reported
	Nifedipine			C		30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12967159	EXPEDITED (15-DAY)		OT	PT-ACCORD-045639		23 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metastases To Liver	Escitalopram			S		One 10 Mg Tablet		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12981863	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2016-14850		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Olanzapine 2.5mg			S	Oral	2.5 Mg, Once A Day		Aurobindo
	Olanzapine 2.5mg			S	Oral	5 Mg, Once A Day		Aurobindo
	Mirtazapine 30mg			S	Oral	30 Mg, Unk		Aurobindo
	Escitalopram Lundbeck			S	Oral	10 Mg, Once A Day		Not Reported
	Escitalopram Lundbeck			S	Oral	20 Mg, Once A Day		Not Reported
	Tavor /00273201/			S	Oral	3 Mg, Once A Day		Not Reported
	Tavor /00273201/			S	Oral	2 Mg, Once A Day		Not Reported
	Tavor /00273201/			S	Oral	1.5 Mg, Once A Day		Not Reported
	Thyroxin			C	Oral	100 Mcg, Once A Day		Not Reported
	Aprovel			C	Oral	300 Mg, Once A Day		Not Reported

	Urisec	C	Oral	60 Mg, Once A Day		Not Reported
	Felodin	C	Oral	10 Mg, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12982129	EXPEDITED (15-DAY)		DE, OT	CN-ALLERGAN-1677971US			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Heart Rate Abnormal	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan
	Propylthiouracil			C	Transplacental			Not Reported
	Alprazolam			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12982548	EXPEDITED (15-DAY)		DS, HO	DE-PFIZER INC-2016544022		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervical Vertebral Fracture; Dizziness; Fall	Tavor [Lorazepam]			S	Oral	3 Mg, 1x/Day		Pfizer
	Tavor			S	Oral	2 Mg, 1x/Day		Pfizer
	Tavor			S	Oral	1.5 Mg, 1x/Day		Pfizer
	Escitalopram Lundbeck			S	Oral	10 Mg, 1x/Day		Not Reported
	Escitalopram Lundbeck			S	Oral	20 Mg, 1x/Day		Not Reported
	Olanzapin			S	Oral	2.5 Mg, 1x/Day		Not Reported
	Olanzapin			S	Oral	5 Mg, 1x/Day		Not Reported
	Mirtazapin			S	Oral	30 Mg, 1x/Day		Not Reported
	L-Thyroxin			C	Oral	100 Ug, 1x/Day		Not Reported
	Aprovel			C	Oral	300 Mg, 1x/Day		Not Reported
	Urivesc			C	Oral	60 Mg, 1x/Day		Not Reported
	Felodipin			C	Oral	10 Mg, 1x/Day		Not Reported

	Kalium Durule	C	Oral	3 Df, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12982826	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2016553276		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting	Lorazepam			S	Oral	5 Df, Total		Pfizer
	Escitalopram			S	Oral	10 Df, Total		Not Reported
	Sodium Valproate			S	Oral	2 Df, Total		Not Reported
	Eutirox			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12982851	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1677977US		39 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion; Drug Ineffective; Exposure During Pregnancy; Feeling Abnormal; Heart Rate Increased; Nasopharyngitis; Restlessness; Sensation Of Blood Flow; Tremor	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Propylthiouracil			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12983065	NON-EXPEDITED			US-MALLINCKRODT-T201602641		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Weight Increased	Fentanyl Transdermal System			S	Transdermal	50 Mcg/Hl, One Patch Every 72 Hours		Mallinckrodt

	Lexapro	S	Unknown	30 Mg (Unknown Frequency)	Not Reported
	Lexapro	S	Unknown	40 Mg (Unknown Frequency)	Not Reported
	Fentanyl	C		37 Mcg/Hr (One 25 Mcg/Hr Plus One 12 Mcg/Hr)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12983282	EXPEDITED (15-DAY)		DS, HO	DE-MYLANLABS-2016M1051301			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Olanzapine			S	Oral	2.5 Mg, Qd		Not Reported
	Olanzapine			S	Oral	5 Mg, Qd		Not Reported
	Mirtazapine			S	Oral	30 Mg, Qd		Not Reported
	Tavor /00273201/			S	Oral	3 Mg, Qd		Mylan
	Tavor /00273201/			S	Oral	2 Mg, Qd		Mylan
	Tavor /00273201/			S	Oral	1.5 Mg, Qd		Mylan
	L-Thyroxin			C	Oral	100 Mg, Qd		Mylan
	Aprovel			C	Oral	300 Mg, Qd		Mylan
	Urivesc			C	Oral	60 Mg, Qd		Mylan
	Felodipin			C	Oral	10 Mg, Qd		Mylan
	Kalium Durule			C	Oral	3 Df, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12985212	NON-EXPEDITED			US-ALEMBIC PHARMACUETICALS LIMITED-2015SCAL000843			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Fall; Fatigue; Feeling Abnormal; Tremor	Modafinil	S	Oral	200 Mg, Bid, At 6am And One Tablet At Noon Daily	Qualitest
	Modafinil	S			Qualitest
	Modafinil	S			Qualitest
	Modafinil	S			Qualitest
	Lexapro	S	Oral	10 Mg, Unk	Not Reported
	Benadryl /00000402/	C		Unk	Not Reported
	Allegra	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12271646	EXPEDITED (15-DAY)		DE, HO, OT	IE-PFIZER INC-2016209765		63 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Altered State Of Consciousness; Blood Test Abnormal; Coagulopathy; Completed Suicide; Contusion; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Electrocardiogram St Segment Elevation; Fall; Fall; Fear; Fear Of Death; Haemorrhage; Head Injury; Hepatic Enzyme Abnormal; Hyponatraemia; Liver Function Test Abnormal; Negative Thoughts; Panic Reaction; Withdrawal Syndrome	Sertraline Hcl			S		50 Mg, Unk		Pfizer
	Sertraline Hcl			S		100 Mg, Unk		Pfizer
	Sertraline Hcl			S		50 Mg, Unk		Pfizer
	Zispin			S		15 Mg, Unk		Not Reported
	Zispin			S		30 Mg, Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Diazepam			C		5 Mg, Unk		Not Reported
	Diazepam			C		2 Mg, Unk		Not Reported
	Temazepam			C		20 Mg At Night		Not Reported
	Solpadeine /00154101/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12938396	EXPEDITED (15-DAY)		HO, OT	PT-TEVA-711070ISR		23 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Carcinoid Syndrome; Metastases To Liver; Pancreatic Neuroendocrine Tumour	Escitalopram 10 Mg Film-Coated Tablet	S	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12977380	EXPEDITED (15-DAY)		CA	NO-CIPLA LTD.-2016NO21852			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy	Citalopram			S	Transplacental	Unk		Invagen
	Escitalopram			S	Transplacental	Unk		Invagen
	Folic Acid			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12977633	EXPEDITED (15-DAY)		CA	NO-CIPLA LTD.-2016NO21856			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Citalopram			S	Transplacental	Unk		Invagen
	Escitalopram			S	Transplacental	Unk		Invagen
	Folic Acid			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12977642	EXPEDITED (15-DAY)		CA	NO-CIPLA LTD.-2016NO21855			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy	Citalopram			S	Transplacental	Unk		Invagen
	Escitalopram			S	Transplacental	Unk		Invagen
	Folic Acid			S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12985361	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2016US22254			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Product Substitution Issue	Escitalopram			S	Oral	10 Mg, Unk, Camber Distributed		Invagen
	Escitalopram			S	Oral	10 Mg, Unk, Cipla Distributed		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12985672	EXPEDITED (15-DAY)		HO, LT, OT	FR-ACCORD-045909		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Tramadol/Tramadol Hydrochloride			S		January 19th: Prescription And Administration Of One Dose Of Tramadol Extended Release 100 Mg		Accord
	Escitalopram			S				Accord
	Fluindione			C				Not Reported
	Pantoprazole			C				Not Reported
	Perindopril/Perindopril Erbumine			C				Not Reported
	Bisoprolol			C				Not Reported
	Spironolactone			C				Not Reported
	Rosuvastatin/Rosuvastatin Calcium			C				Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)			Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12986091	EXPEDITED (15-DAY)		HO, OT	IT-009507513-1611ITA012807		45 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sopor	Lortaan 12,5 Mg Compresse Rivestite Con Film			S	Oral	28 Dose Unit, Total, Oral		Merck
	Escitalopram Oxalate			S	Oral	30 Ml, Total, Oral Drops		Not Reported
	Zolpidem Tartrate			S	Oral	30 Ml, Total, Oral Drops		Not Reported

Anafranil	S	Oral	20 Dose Unit, Total Oral		Not Reported
Levoxacin	S	Oral	5 Dose Unit, Total, Oral		Not Reported
Bentelan	S	Oral	10 Mg Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12987265	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1677804US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Fall; Spinal Fracture	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12987272	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1677801US		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12988673	EXPEDITED (15-DAY)		HO	DE-ASTRAZENECA-2016SF25665		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse	Quetiapine			S	Oral	50.0mg As Required		Zeneca
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	11786950	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20151123767		17 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced;	Topamax			S	Oral	25-0-50mg/ Day		Not Reported

Exposure During Pregnancy; Off Label Use; Product Use In Unapproved Indication	Lyrica	S	Oral		Not Reported
	Cipralex	S	Oral		Not Reported
	Aspirin	S	Oral		Not Reported
	Omeprazole	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12968064	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2016AP014926		65 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Bleeding; Immune Thrombocytopenic Purpura; Petechiae; Tinnitus	Paxil Tablets			S	Unknown	20 Mg, Qd		Apotex
	Glucophage			S	Unknown	500 Mg, Qd		Not Reported
	Crestor			S	Unknown	10 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Unknown	4 Mg, Qd		Not Reported
	Esopral /01479302/			S	Unknown	20 Mg, Qd		Not Reported
	Esopral /01479302/			S				Not Reported
	Diamox /00016901/			S	Unknown	250 Mg, Qd		Not Reported
	Muscoril			S	Unknown	4 Mg, Qd		Not Reported
	Sereupin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12979613	EXPEDITED (15-DAY)		HO	IN-JNJFOC-20161124242			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Drug Interaction	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12989233	EXPEDITED (15-DAY)		OT	TR-ACCORD-045926		21 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maternal Exposure During Pregnancy; Premature Delivery	Escitalopram	S		Accord
	Levofloxacin/Levofloxacin Mesylate	C		Not Reported
	Cefprozil	C		Not Reported
	Etodolac	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12990748	EXPEDITED (15-DAY)		OT	AU-APOTEX-2015AP007370		43 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Depressed Level Of Consciousness; Disturbance In Attention; Feeling Abnormal; Memory Impairment	Escitalopram			S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12991346	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2016M1051660			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12991670	EXPEDITED (15-DAY)		OT	ZA-ALLERGAN-1678356US			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12991683	EXPEDITED (15-DAY)		DS	FR-ALLERGAN-1678557US		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Haematoma; Haemothorax; Muscle Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Xarelto			S	Oral	20 Mg, Qd		Not Reported
	Valsartan			C	Unknown			Not Reported
	Betahistine			C	Unknown			Not Reported
	Tanganil			C	Unknown			Not Reported
	Cordarone			C	Unknown			Not Reported
	Metformine			C	Unknown			Not Reported
	Tahor			C	Unknown			Not Reported
	Lexomil			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12992061	EXPEDITED (15-DAY)		HO	DE-009507513-1611DEU013996		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium	Nacom 100 Mg/25 Mg Tabletten			S	Oral	100/25 Mg Daily		Merck
	Nacom 100 Mg/25 Mg Tabletten			S	Oral	400/100 Mg Daily		Merck
	Nacom 100 Mg/25 Mg Tabletten			S	Oral	600/150 Mg Daily		Merck
	Nacom 100 Mg/25 Mg Tabletten			S	Oral	300/75 Mg Daily		Merck
	Nacom 100 Mg/25 Mg Tabletten			S	Oral	150/37.5 Mg Daily		Merck
	Amitriptyline Hydrochloride			S	Oral	25 Mg, Qd		Merck
	Amitriptyline Hydrochloride			S	Oral	50 Mg, Qd		Merck
	Amitriptyline Hydrochloride			S	Oral	75 Mg, Qd		Merck
	Amitriptyline Hydrochloride			S	Oral	50 Mg, Qd		Merck
	Amitriptyline Hydrochloride			S	Oral	25 Mg, Qd		Merck
	Escitalopram			S	Oral	5 Mg, 1 Day		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported

Eliquis	C	Oral	5 Mg, Qd		Not Reported
Metformin	C	Oral	2 G, Unk		Not Reported
Lorazepam	C	Oral	1 Mg, Qd		Not Reported
Lorazepam	C	Oral	1.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12993500	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Nausea; Vomiting	Generic Escitalopram 10.5			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12325817	EXPEDITED (15-DAY)		OT	US-CIPLA-2016US04333			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Intentional Product Misuse; Overdose	Warfarin			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Comet Cleaner			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12933440	EXPEDITED (15-DAY)		HO, OT	PT-ALLERGAN-1000084606		23 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metastases To Liver; Metastasis; Pancreatic Neuroendocrine Tumour; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S		10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12970711	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1677579US		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Abuse; Overdose	Escitalopram Oxalate Unk			S	Oral			Allergan
	Escitalopram Oxalate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12993971	EXPEDITED (15-DAY)		OT	AU-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-101489		40 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Product Use Issue	Abilify			S	Oral	20 Mg, Qd		Bristol Myers Squibb
	Escitalopram /01588502/			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12994254	EXPEDITED (15-DAY)		DS, HO	DE-TEVA-714641GER		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Olanzapin			S	Oral			Not Reported
	Olanzapin			S	Oral			Not Reported
	Mirtazapine			S	Oral			Teva
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Tavor [Lorazepam]			S	Oral			Not Reported
	Tavor			S	Oral			Not Reported
	Tavor			S	Oral			Not Reported
	L-Thyroxin			C	Oral			Not Reported
	Aprovel			C	Oral			Not Reported
	Urivesc			C	Oral			Not Reported
	Felodipin			C	Oral			Not Reported
	Kalium Duriles			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12994458	EXPEDITED (15-DAY)		HO	DE-TEVA-714916GER		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Quetiapine			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12995011	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1000081643		17 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Aspirin Cardio			S	Oral	100 Mg, Qd		Not Reported
	Omeprazole			S	Oral	20 Mg, Qd		Not Reported
	Topamax Migraene			S	Oral	25 Mg, Tid		Not Reported
	Lyrica			S	Oral	100 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12995466	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1678838US		56 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choking; Cough; Nausea; Off Label Use; Throat Irritation	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Cibadrex (5 Mg Benazepril Hidroklorür Ve 6,25 Mg Hidroklorotiyazid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12995553	EXPEDITED (15-DAY)		HO	SE-TEVA-714655ACC		78 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Lethargy; Suicide Attempt; Toxicity To Various Agents	Mirtazapin Actavis	S	Oral		Teva
	Imovane	S	Oral		Not Reported
	Cipralex	S	Oral		Not Reported
	Sobril	S	Oral		Not Reported
	Metoprolol Gea Retard	C			Not Reported
	Inderal	C			Not Reported
	Oralovite	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12995904	EXPEDITED (15-DAY)		DS, HO	DE-ELI_LILLY_AND_COMPANY-DE201611007882		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervical Vertebral Fracture; Dizziness; Drug Interaction; Fall; Subgaleal Haematoma; Syncope	Olanzapine			S	Oral	2.5 Mg, Qd		Eli Lilly And Co
	Olanzapine			S	Oral	5 Mg, Qd		Eli Lilly And Co
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Mirtazapin			S	Oral	30 Mg, Qd		Not Reported
	Tavor /00273201/			S	Oral	3 Mg, Qd		Not Reported
	Tavor /00273201/			S	Oral	2 Mg, Qd		Not Reported
	Tavor /00273201/			S	Oral	1.5 Mg, Unknown		Not Reported
	L-Thyroxin			C	Oral	100 Ug, Qd		Not Reported
	Aprovel			C	Oral	300 Mg, Qd		Not Reported
	Urivesc			C	Oral	60 Mg, Qd		Not Reported
	Felodipin			C	Oral	10 Mg, Qd		Not Reported
	Kalium Durule			C	Oral	3 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12995954	EXPEDITED (15-DAY)		LT	AU-ALLERGAN-1678833US		37 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Feeding; Gestational Diabetes; Maternal Exposure During Pregnancy; Overdose; Pregnancy	Escitalopram Oxalate - Bp		S	Unknown	Allergan
	Seroquel Xr / Quetiapine		S	Unknown	Not Reported
	Elevit		C	Unknown	Not Reported
	Vitamin C		C	Endocervical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12995963	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1679032US		45 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Overdose; Sopor	Escitalopram Oxalate - Bp			S	Oral	30 Ml, Unk		Allergan
	Zolpidem Tartrate			S	Oral	30 Ml, Unk		Not Reported
	Anafranil			S	Oral	20 Df, Unk		Not Reported
	Levoxacin			S	Oral	5 Df, Unk		Not Reported
	Bentelan			S	Oral	10 Mg, Unk		Not Reported
	Lortaan			S	Oral	28 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12995968	EXPEDITED (15-DAY)		HO	IT-ABBVIE-16P-083-1799096-00		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypertension; Myoclonus; Somnolence; Tremor; Vomiting	Valproate Sodium			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Eutirox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12996021	EXPEDITED (15-DAY)		HO	PT-PRINSTON PHARMACEUTICAL INC.-2016PRN00328		23 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Syndrome	Escitalopram			S	Oral	10 Mg, Unk		Prinston

	Anti-Inflammatories		C	Unknown		Pharmaceutical Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12996051	EXPEDITED (15-DAY)		HO	AU-ALLERGAN-1679015US		1 DAY	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Caesarean Section; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Hyperreflexia; Maternal Drugs Affecting Foetus; Maternal Exposure During Breast Feeding; Neonatal Respiratory Distress; Respiratory Distress; Somnolence; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Transplacental			Allergan
	Seroquel Xr / Quetiapine			S	Transplacental			Not Reported
	Elevit			C	Transplacental			Not Reported
	Vitamin C			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12997387	DIRECT		OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2016	12893781	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2016GSK158285			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder	Wellbutrin			S		Unk		Glaxosmithkline
	Escitalopram Oxalate Tablet			S		20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2016	12998035	EXPEDITED (15-DAY)		HO, LT	CA-NAPPMUNDI-CAN-2016-0007237		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Potassium Increased; Blood Pressure Decreased; Bradycardia; Coma; Coma Scale Abnormal; Drug Interaction; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Heart Rate Decreased; Hyperkalaemia; Hypotension; Intentional Overdose; Loss Of Consciousness; Mechanical Ventilation; Opiates Positive; Overdose; Oxygen Saturation Decreased; Sinus Tachycardia; Suicide Attempt	Oxycodone Hydrochloride			S	Unknown	Unk		Purdue
	Oxycodone Hydrochloride			S	Oral	20 Mg, Unk		Purdue
	Oxycodone Hydrochloride			S	Oral	Unk		Purdue
	Oxycodone Hydrochloride			S	Unknown	10 Mg, Unk		Purdue
	Morphine Sulfate			S	Unknown	9500 Mg, Unk		Purdue
	Morphine Sulfate			S	Unknown	420 Mg, Unk		Purdue
	Morphine Sulfate			S	Unknown	2640 Mg, Unk		Purdue
	Morphine Sulfate			S	Oral	30 Mg, Unk		Purdue
	Morphine Sulfate			S	Oral	Unk		Purdue
	Morphine Sulfate			S	Oral	30 Mg, Daily		Purdue
	Morphine Sulfate			S	Unknown	15 Mg, Unk		Purdue
	Morphine Sulfate			S	Unknown	100 Mg, Unk		Purdue
	Altace			C	Unknown	Unk		Not Reported
	Cipralex			S	Unknown	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	140 Mg, Unk		Not Reported
	Cipralex			S	Unknown	10 Mg, Daily		Not Reported
	Citalopram			S	Oral	Unk		Not Reported
	Diazepam			S	Unknown	10 Mg, Unk		Not Reported
	Diazepam			S	Oral	1800 Mg, Unk		Not Reported
	Diazepam			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	30 Mg, Unk		Not Reported
	Lorazepam			S	Oral	10 Unk, Unk		Not Reported
	Oxycodone / Acetaminophen			S	Oral	Unk		Not Reported
	Zopiclone			S	Unknown	7.5 Mg, Unk		Not Reported
	Zopiclone			S	Oral	187.5 Mg, Unk		Not Reported

	Zopiclone	S	Oral	15 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2016	12998412	EXPEDITED (15-DAY)		DS, HO, OT	DE-DRREDDYS-GER/GER/16/0085045		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Dizziness; Fall; Liver Function Test Abnormal	Olanzapine			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Tavor [Lorazepam]			S	Oral			Not Reported
	Tavor			S	Oral			Not Reported
	Tavor			S	Oral			Not Reported
	Levothyroxine Sodium			C	Oral			Not Reported
	Aprovel			C	Oral			Not Reported
	Urivesc			C	Oral			Not Reported
	Felodipin			C	Oral			Not Reported
	Potassium Chloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2016	12999380	EXPEDITED (15-DAY)		HO, OT	DE-DRREDDYS-GER/GER/16/0085106		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Discomfort; Palpitations	Quetiapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	9837009	NON-EXPEDITED			US-PFIZER INC-2014018541		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Product Use In Unapproved Indication	Neurontin			S	Oral	Unk, Daily		Pfizer
	Amitriptyline			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	Unk, 1x/Day		Not Reported
	Prozac			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	12984442	EXPEDITED (15-DAY)		DE, HO, LT	FR-DSJP-DSE-2016-139401			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bezoar; Completed Suicide; Intestinal Ischaemia; Skin Necrosis; Toxicity To Various Agents	Sevikar			S	Oral	129 Df (5.16 G/1.29 G), Single		Daiichi
	Atarax /00058401/			S	Oral	700 Mg, Single		Not Reported
	Lysanxia			S	Oral	420 Mg, Single		Not Reported
	Seroplex			S	Oral	280 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13000324	NON-EXPEDITED		HO	SG-LUNDBECK-DKLU2021199		27 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Escitalopram-Form-Unknown			S	Unknown			Not Reported
	Clobazam			S	Unknown			Lundbeck
	Sertraline			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13000629	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2016US22315			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Angioedema;	Lisinopril			S	Oral	5 Mg, At 11 Am In The		Invagen

Concussion; Disease Recurrence; Syncope					Morning	
	Carvedilol		S	Oral	6.25 Mg At 11 Am In The Morning	Cipla
	Levetiracetam		S	Oral	Unk	Invagen
	Escitalopram		S	Oral	10 Mg, Qd	Invagen
	Aspirin		C	Unknown	Unk	Not Reported
	Rosuvastatin		C	Unknown	Unk	Not Reported
	Lorazepam		C	Unknown	Unk	Not Reported
	Hydromorphone		C	Unknown	Unk, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13000662	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2016003617			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S	Transplacental	10 Mg, Qd (0.-38.5.Gestational Week)		Macleods
	Paracetamol			C	Transplacental	500 Mg, Qd (14.0 - 17.0 Gestational Week)		Not Reported
	Thyronajod			C	Transplacental	(50 ?G/D) And (150 ?G/D)Qd		Not Reported
	Folio Forte (Jodfrei)			C	Transplacental	0.8 Mg, Qd		Not Reported
	Ibuprofen Lysinate			C	Transplacental	Unk, Bid (Twice, Dosage)		Not Reported
	Korodin			C	Transplacental	Unk,1-3x Per Week		Not Reported
	Opipramol			C	Transplacental	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13000931	EXPEDITED (15-DAY)		DS, HO	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-128647		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall	Mirtazapine	S	Oral	30 Mg, Daily		Sun
	Olanzapine	S	Oral	2.5 Mg, Daily		Sun
	Olanzapine	S	Oral	5 Mg, Daily		Sun
	Escitalopram Lundbeck	S	Oral	10 Mg, Daily		Not Reported
	Escitalopram Lundbeck	S	Oral	20 Mg, Daily		Not Reported
	Tavor [Lorazepam]	S	Oral	3 Mg, Daily		Not Reported
	Tavor	S	Oral	2 Mg, Daily		Not Reported
	Tavor	S	Oral	1.5 Mg, Daily		Not Reported
	I-Thyroxin	C	Oral	100 Mg, Daily		Not Reported
	Aprovel	C	Oral	60 Mg, Daily		Not Reported
	Felodipin	C	Oral	10 Mg, Daily		Not Reported
	Kalium Duriles	C	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13000952	EXPEDITED (15-DAY)		HO	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-128570		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Escitalopram			S	Oral	5 Mg, Daily		Not Reported
	Quetiapine			S	Oral	50 Mg, Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13000986	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2016-14659		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Circulatory Collapse; Electrocardiogram Qt Prolonged; Palpitations; Restlessness	Escitalopram 10 Mg			S	Oral	10 Mg, Once A Day		Aurobindo
	Escitalopram 10 Mg			S	Oral	5 Mg, Once A Day		Aurobindo
	Quetiapine			S	Oral	50 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13001028	EXPEDITED (15-DAY)		HO	DE-ACCORD-046312		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse	Escitalopram			S	Oral	Dose Reduced To 5 Mg/Day From 30-May-2016 To 04-May-2016		Not Reported
	Quetiapine			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13003034	EXPEDITED (15-DAY)		HO, OT	JP-LUNDBECK-DKLU2016560		71 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrooesophageal Reflux Disease; Long Qt Syndrome; Serotonin Syndrome	Lexapro Film-Coated Tablets			S	Oral			Not Reported
	Mystan			S	Oral			Lundbeck
	Lendormin			S	Oral			Not Reported
	Belsomra			S	Oral			Not Reported
	Milmag			C	Oral			Not Reported
	Malfa			C	Oral			Not Reported
	Micardis			C	Oral			Not Reported
	Madopar			C	Oral			Not Reported
	Pariet			C	Oral			Not Reported
	Gasmotin			C	Oral			Not Reported
	Hangekobokuto			C	Oral			Not Reported
	Micamlo			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13003113	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2016M1052809			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Product Misuse; Intentional Self-Injury; Overdose; Sopor	Escitalopram		S	Oral	30 Ml, Total	Not Reported
	Bentelan		S	Oral	10 Mg, Total	Mylan
	Anafranil		S	Oral	20 Df, Total	Mylan
	Levoxacin		S	Oral	5 Df, Total	Mylan
	Lortaan		S	Oral	28 Df, Total	Mylan
	Zolpidem Tartrate		S	Oral	30 Ml, Total	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13003119	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1052817			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram			S	Oral	Unk		Not Reported
	Delorazepam			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13003120	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2016M1052800			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting	Escitalopram			S	Oral	10 Df, Total		Not Reported
	Lorazepam			S	Oral	5 Df, Total		Not Reported
	Valproate Sodium			S	Oral	2 Df, Total		Mylan
	Eutirox			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13003336	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2016M1052932			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Septal Defect	Escitalopram			S	Transplacental	10 [Mg/D]		Not Reported
	Thyronajod			C	Transplacental	50/150		Mylan
	Folio Forte			C	Transplacental	0.8 [Mg/D]		Mylan

Ibuprofen Lysinate	C	Transplacental	Twice, Dosage Unknown		Mylan
Paracetamol	C	Transplacental	500 [Mg/D]/ 2-3 Times, If Necessary		Mylan
Korodin /08256501/	C	Transplacental	Unk Unk, 3xw		Mylan
Opipramol	C	Transplacental	50 [Mg/D]		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13003357	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1679280US		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram Oxalate Unk			S	Oral	Unk		Allergan
	Delorazepam			S	Oral	Overdose: Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2016	13006748	EXPEDITED (15-DAY)		HO	JP-ELI_LILLY_AND_COMPANY-JP201611003204		85 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Off Label Use; Off Label Use; Portal Vein Flow Decreased	Zyprexa			S	Oral	10 Mg, Qd		Eli Lilly And Co
	Zyprexa			S	Oral	2.5mg Tab In The Morning; 5mg Tab In The Evening		Eli Lilly And Co
	Tramcet			S	Unknown	2 Df, Bid (Morning And Evening)		Not Reported
	Reminyl			S		12 Mg, Qd (Morning)		Not Reported
	Lexapro			S	Unknown	10 Mg, Qd (Evening)		Not Reported
	Desyrel			S	Unknown	25 Mg, Qd (Before Bedtime)		Not Reported
	Lunesta			S	Unknown	1 Mg, Qd (Before Bedtime)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2016	13007335	EXPEDITED (15-DAY)		HO	PHHY2016IT164398		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting	Escitalopram			S	Oral	10 Df, Once/Single		Not Reported
	Lorazepam			S	Oral	5 Df, Once/Single		Novartis
	Sodium Valproate			S	Oral	2 Df, Once/Single		Not Reported
	Eutirox			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2016	13010299	DIRECT		OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia	Lexapro			S	Oral	Quantity:1 Tablet(S);		Cipla
	Evista			C				Not Reported
	Magnesium Trace Minerals			C				Not Reported
	D3			C				Not Reported
	B12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	12874215	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1672915US		53 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Hyposmosis; Blood Osmolarity Increased; Blood Sodium Increased; Dizziness; Feeling Abnormal; Inappropriate Antidiuretic Hormone Secretion; Muscular Weakness; Nausea	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan
	Risperdal			S	Oral	5 Mg, Bid		Not Reported
	Anafranil			S	Oral	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	12928183	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-095103		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Product Use In Unapproved Indication	Abilify		S	Unknown	Unk	Bristol Myers Squibb
	Abilify		S	Unknown		Bristol Myers Squibb
	Aripiprazole		S	Unknown	Unk	Not Reported
	Lexapro		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13008367	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2016-15010		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Psychomotor Hyperactivity; Sopor	Delorazepam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13008487	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2016-15016		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting	Escitalopram Film-Coated Tablets			S	Oral	10 Df, Total		Aurobindo
	Lorazepam Tablets			S	Oral	5 Df, Total		Not Reported
	Sodium Valproate			S	Oral	2 Df, Total		Not Reported
	Eutirox			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13008744	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1679373US		62 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Hyperhidrosis; Seizure	Escitalopram Oxalate - Bp			S		1 Tab		Allergan
	Clonazepam			S		1 Tab		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13008832	EXPEDITED (15-DAY)		OT	TW-RECKITT		22 YR	Female	TWN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Distractibility; Euphoric Mood; Mania; Product Use In Unapproved Indication; Psychomotor Hyperactivity; Sleep Disorder	Unspecified Dextromethorphan Hydrobromide			S	Oral	30 Mg, Every 6 Hours		Not Reported
	Unspecified Dextromethorphan Hydrobromide			S				Not Reported
	Escitalopram			S	Unknown	15 Mg, Qd (A Day)		Not Reported
	Ambroxol			C	Unknown	30 Mg, Tid		Not Reported
	Acetaminophen			C	Unknown	325 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13009123	EXPEDITED (15-DAY)		HO	CA-SCIEGEN PHARMACEUTICALS INC-2016SCILIT00608		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Fall; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Lethargy	Hydrochlorothiazide Tablets			S	Unknown	Unk		Sciegen
	Escitalopram			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Gliclazide			S	Unknown	Unk		Not Reported
	Insulin			S	Unknown	Unk		Not Reported
	L-Thyroxine			S	Unknown	Unk		Not Reported
	Telmisartan			S	Unknown	Unk		Not Reported
	Trazadone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13009837	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1679560US		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Fall	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

	Zolpidem		S	Oral	0.5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13009838	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1679564US		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Overdose; Product Administration Error	Escitalopram Oxalate - Bp			S	Oral	Overdose: Escitalopram 40 Mg Daily		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13010863	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2016M1053925			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Diarrhoea	Escitalopram			S	Oral	10 Mg Daily		Not Reported
	Cardioaspirin			C	Oral			Mylan
	Serenase (Haloperidol)			C	Oral			Mylan
	Quetiapine			C	Oral	25 Mg		Mylan
	Enalapril			C	Oral	20 Mg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13010933	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1679750US		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Abuse; Hyperventilation; Overdose; Product Use In Unapproved Indication	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13012961	DIRECT					23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain Upper; Bedridden; Dizziness; Facial Paralysis; Influenza; Loss Of Personal Independence In Daily Activities; Nausea; Paraesthesia	Escitalopram		S	Oral	Quantity:1 Tablet(S);	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13017028	DIRECT		DS, HO, RI, OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Eating Disorder; Impaired Work Ability; Mental Disorder; Panic Attack; Product Substitution Issue; Weight Decreased	Paxil			S				Not Reported
	Fluoxetine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	12980664	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1677983US		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Osmolarity Decreased; Confusional State; General Physical Health Deterioration; Hyponatraemia; Off Label Use; Somnolence	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Moducren			S	Oral			Not Reported
	Laroxyl			S	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Alprazolam			C	Oral			Not Reported
	Theralene			C	Oral			Not Reported
	Atarax			C	Oral	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	13011314	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.-2016IT22782			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram			S	Oral	Unk		Invagen
	Delorazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	13011691	EXPEDITED (15-DAY)		HO	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-129032		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Escitalopram			S	Oral	15 Mg, Daily		Not Reported
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported
	Amitriptyline			S	Oral	25 Mg, Daily		Sun
	Amitriptyline			S	Oral	50 Mg, Daily		Sun
	Amitriptyline			S	Oral	75 Mg, Daily		Sun
	Amitriptyline			S	Oral	50 Mg, Daily		Sun
	Amitriptyline			S	Oral	25 Mg, Daily		Sun
	Amitriptyline			S		Unk		Sun
	Tramadol			S	Oral	50 Mg, Daily		Sun
	Eliquis			C	Oral	5 Mg, Daily		Not Reported
	Metformin			C	Oral	2 G, Daily		Not Reported
	Lorazepam			C	Oral	1 Mg, Daily		Not Reported
	Lorazepam			C	Oral	1.5 Mg, Daily		Not Reported
	Diclofenac			C	Unknown	150 Mg, Daily		Not Reported
	Ibuprofen			C	Oral	1200 Mg, Daily		Not Reported
	Ramipril			C	Oral	5 Mg, Daily		Not Reported
	Escitalopram			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	13011723	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-128750		45 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	30 Ml Total		Not Reported
	Zolpidem			S	Oral	30 Ml Total		Sun
	Bentelan 1 Mg			S	Oral	10 Mg Total		Not Reported
	Anafranil			S	Oral	20 Df Total		Not Reported
	Levoxacin			S	Oral	5 Df Total		Not Reported
	Lortaan			S	Oral	28 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	13011755	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2016003615			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delirium; Depressed Level Of Consciousness; Disorientation	Tramadol Hydrochloride			S	Oral	50 Mg, Qd		Macleods
	Escitalopram			S	Oral	5 Mg, Qd		Macleods
	Escitalopram			S	Oral	10 Mg, Qd		Macleods
	Escitalopram			S	Oral	15 Mg, Qd		Macleods
	Escitalopram			S	Oral	20 Mg, Qd		Macleods
	Amitriptylin			S	Oral	25 Mg, Qd		Not Reported
	Amitriptylin			S	Oral	50 Mg, Qd		Not Reported
	Amitriptylin			S	Oral	75 Mg, Qd		Not Reported
	Amitriptylin			S	Oral	50 Mg, Qd		Not Reported
	Amitriptylin			S	Oral	25 Mg, Qd		Not Reported
	Metformin Hydrochloride			C	Unknown	2 G, Qd (For Year - B.A.W.)		Not Reported

Eliquis	C	Oral	5 Mg, Qd		Not Reported
Lorazepam	C	Oral	1 Mg, Unk (For Months)		Not Reported
Lorazepam	C	Oral	1.5 Mg, Qd		Not Reported
Diclofenac	C	Unknown	150 Mg, Qd		Not Reported
Ramipril	C	Oral	5 Mg, Qd (B.A.W)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	13011762	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2016IT22727			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting	Escitalopram			S	Oral	10 Df Total		Invagen
	Sodium Valproate			S	Oral	2 Df Total		Not Reported
	Lorazepam			S	Oral	5 Df Total		Not Reported
	Eutirox			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	13011942	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-128940		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting	Escitalopram			S	Oral	10 Df Total		Not Reported
	Lorazepam			S	Oral	5 Df Total		Sun
	Sodium Valproate			S	Oral	2 Df Total		Not Reported
	Eutirox			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	13014235	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1679723US		87 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	13014366	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1679742US		79 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Diarrhoea	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Cardioaspirin			C	Oral			Not Reported
	Serenzase			C				Not Reported
	Quetiapine			C	Oral			Not Reported
	Enalapril			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	13014371	EXPEDITED (15-DAY)		HO	GR-ALLERGAN-1674405US		76 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Prostatic Hyperplasia; Urinary Retention	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	13014377	EXPEDITED (15-DAY)		CA, HO	DE-ALLERGAN-1679730US		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Thyronajod			C	Transplacental	50 Mg, Unk		Not Reported
	Thyronajod			C	Transplacental	150 Mg, Unk		Not Reported
	Folio Forte			C	Transplacental			Not Reported
	Ibuprofen Lysinate			C	Transplacental			Not Reported
	Paracetamol			C	Transplacental			Not Reported
	Korodin			C	Transplacental			Not Reported
	Opipramol			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2016	13015006	EXPEDITED (15-DAY)		CA, OT	DE-STRIDES ARCOLAB LIMITED-2016SP019063			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Oesophageal Atresia; Premature Baby	Mycophenolate Mofetil			S	Transplacental	Unk		Strides
	Escitalopram			S	Transplacental	Unk		Not Reported
	Zolpidem			S	Transplacental	Unk		Not Reported
	Lorazepam			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2016	13015151	NON-EXPEDITED		OT	US-ELI_LILLY_AND_COMPANY-US201612001349			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Fatigue; Seizure; Tremor; Vision Blurred	Cymbalta			S	Oral	20 Mg, Qd		Eli Lilly And Co
	Cymbalta			S	Oral	30 Mg, Qd		Eli Lilly And Co
	Duloxetine Hydrochloride			S	Oral	20 Mg, Qd		Eli Lilly And Co
	Duloxetine Hydrochloride			S	Oral	30 Mg, Qd		Eli Lilly And Co
	Lexapro			S	Unknown	Unk Unk, Unknown		Not Reported
	Nefazodone			S	Unknown	Unk Unk, Unknown		Not Reported
	Ventolin /00139501/			C	Unknown	Unk Unk, Unknown		Not Reported
	Flovent			C	Unknown	Unk Unk, Unknown		Not Reported
	Seasonique			C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12554596	EXPEDITED (15-DAY)		HO	PHHY2016FR094517		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Reaction With	Tegretol			S	Oral	200 Mg, Qd		Novartis

Eosinophilia And Systemic Symptoms; Eosinophilia; Lymphadenopathy; Lymphocyte Morphology Abnormal; Pruritus; Pyrexia; Rash Maculo-Papular; Transaminases Increased; Vulvovaginal Erythema	Seroplex	S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12680104	EXPEDITED (15-DAY)		OT	US-FRI-1000083397		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia; Serotonin Syndrome; Wrong Patient Received Product	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S				Allergan
	Benazepril			S		20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12681747	NON-EXPEDITED			US-FRI-1000082596		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Disorder; Nausea; Off Label Use; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S		10 Mg, Unk		Allergan
	Cozaar			C		Unk		Not Reported
	Hydrochlorothiazide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12681762	NON-EXPEDITED			US-FRI-1000082609			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal	Escitalopram Oxalate Unk			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12682319	NON-EXPEDITED			US-FRI-1000083598			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Escitalopram Oxalate Unk			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12682320	NON-EXPEDITED			US-FRI-1000083184			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Off Label Use	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12682337	NON-EXPEDITED			US-FRI-1000082292			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation	Lexapro			S		Unk		Allergan
	Lexapro			S		Unk		Allergan
	Escitalopram Oxalate Unk			S		Unk		Allergan
	Escitalopram Oxalate Unk			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12683825	NON-EXPEDITED			US-FRI-1000083914			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain	Escitalopram Oxalate Unk			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12683827	NON-EXPEDITED			US-FRI-1000084123			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Therapy Cessation	Lexapro Tablets			S		10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12684357	NON-EXPEDITED			US-FRI-1000085417			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Panic Attack	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Lorazepam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12684358	NON-EXPEDITED			US-FRI-1000084567			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia	Lexapro Tablets			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12684359	NON-EXPEDITED			US-FRI-1000084381			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Sinemet			C	Oral	Unk Unk, Qd		Not Reported
	Sinemet			C	Oral	Unk Unk, Frequency 2,Freq_Time 4,Freq Unit Hours		Not Reported
	Lorazepam			C		"Takes Carefully"		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12684366	NON-EXPEDITED			US-FRI-1000085354			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro Tablets			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12684517	NON-EXPEDITED			US-FRI-1000085774			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12685939	NON-EXPEDITED			US-FRI-1000082799			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Weight Gain Poor	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12688931	NON-EXPEDITED			US-FRI-1000081812		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Hostility	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Baby Aspirin			C	Oral	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12688935	NON-EXPEDITED			US-FRI-1000081996		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anxiety; Depression; Dizziness; Drug Ineffective;	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S				Allergan

Dyssomnia; Energy Increased; Insomnia; Irritability; Mental Disorder; Mental Disorder; Paraesthesia; Photophobia; Post-Traumatic Stress Disorder; Psychotic Behaviour; Tremor; Withdrawal Syndrome	Lamotrigine	C	Oral	100 Mg, Qd	Not Reported
	Multivitamins	C	Oral	Unk	Not Reported
	Mepron	C	Oral	Unk	Not Reported
	Mepron	C			Not Reported
	Nystatin	C	Oral	Unk	Not Reported
	Nystatin	C			Not Reported
	Tindamax	C	Oral	Unk	Not Reported
	Tindamax	C			Not Reported
	Biaxin	C	Oral	Unk	Not Reported
	Biaxin	C			Not Reported
	Advil	C	Oral	Unk	Not Reported
	Cetirizine	C	Oral	10 Mg, Qd	Not Reported
	Deplin	C	Oral	7 Mg, Qd	Not Reported
	Diflucan	C	Oral	Unk	Not Reported
	Diflucan	C			Not Reported
	Methylcobalamin	C	Sublingual	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12690374	NON-EXPEDITED			US-FRI-1000084376			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram Oxalate Unk			S		10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12690381	NON-EXPEDITED			US-FRI-1000084013		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticholinergic Syndrome; Anxiety; Confusional State; Drug Withdrawal Syndrome; Flushing; Headache; Hyperacusis; Insomnia; Intentional	Lexapro Tablets			S	Oral	10 Mg, Qd		Allergan
	Lexapro Tablets			S	Oral	5 Mg, Qd		Allergan
	Lexapro Tablets			S	Oral	7.5 Mg, Qd		Allergan
	Lexapro Tablets			S	Oral	5 Mg, Qd		Allergan

Product Misuse; Nausea; Off Label Use; Pyrexia; Tinnitus; Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12690383	NON-EXPEDITED			US-FRI-1000084092			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Headache; Off Label Use; Pollakiuria; Snoring; Somnolence	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12690388	NON-EXPEDITED			US-FRI-1000084100			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Depressed Mood; Mood Altered	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Bid		Allergan
	Lexapro			S	Oral	10 Mg, Bid		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Bid		Allergan
	Escitalopram Oxalate Unk			S	Oral	10 Mg, Unk		Allergan
	Escitalopram Oxalate Unk			S	Oral	20 Mg, Unk		Allergan
	Steroids			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12690396	NON-EXPEDITED			US-FRI-1000084236			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Titration Error; Dry Mouth; Fatigue; Feeling Abnormal; Paraesthesia; Product Dose Omission; Taste Disorder	Lexapro Tablets	S	10 Mg, Unk		Allergan
	Lexapro Tablets	S	5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12690406	NON-EXPEDITED			US-FRI-1000083433		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lacrimation Increased	Escitalopram Oxalate Unk			S	Oral	10 Mg, Unk		Allergan
	Asa			C	Oral	Prn		Not Reported
	Ibuprofen			C	Oral	Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12690428	NON-EXPEDITED			US-FRI-1000085136		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anal Incontinence; Bladder Disorder; Influenza Like Illness; Intentional Product Use Issue; Muscle Spasms; Pain In Extremity; Urinary Retention	Lexapro Tablets			S	Oral	10 Mg, Qd		Allergan
	Alprazolam			C	Oral	1 Mg, Qid		Not Reported
	Bupropion			C	Oral	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12690804	NON-EXPEDITED			US-FRI-1000085579		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Feeling Abnormal; Paraesthesia; Peripheral Coldness; Therapy Cessation;	Lexapro			S	Oral	5 Mg, Unk		Allergan
	Lexapro			S				Allergan
	Lexapro			S	Oral	5 Mg, Unk		Allergan

Withdrawal Syndrome	Lexapro	S				Allergan
	Escitalopram Oxalate Unk	S		Unk		Allergan
	Verapamil	C	Oral	40 Mg, Bid		Not Reported
	Verapamil	C				Not Reported
	Verapamil	C				Not Reported
	Lorazepam	C	Oral	0.2-1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12981772	EXPEDITED (15-DAY)		HO	LT-ORION CORPORATION ORION PHARMA-ESCI2016-0002			Male	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Gait Disturbance; Nausea; Product Dispensing Error; Wrong Product Administered	Escitalopram Orion			S	Oral	Not Used		Not Reported
	Entacapone (Trade Name Unknown)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13015724	EXPEDITED (15-DAY)		OT	TR-MACLEODS PHARMACEUTICALS US LTD-MAC2016004015			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoembryonic Antigen Increased	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Escitalopram Oxalate			S				Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13015775	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2016-14497		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonic Convulsion; Drug Interaction; Dyspnoea; Extensor Plantar Response; Fall;	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo
	Tramadol 100mg			S	Unknown	100 Mg, Extended Release		Aurobindo

Musculoskeletal Stiffness; Myoclonic Epilepsy; Postictal State; Pyrexia; Serotonin Syndrome; Somnolence	Fluindione	C	Unknown	Unk	Not Reported
	Pantoprazole	C			Not Reported
	Perindopril	C			Not Reported
	Bisoprolol	C			Not Reported
	Spironolactone	C			Not Reported
	Rosuvastatin	C			Not Reported
	Paracetamol	C	Intravenous (not otherwise specified)		Not Reported
	Furosemide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13015822	EXPEDITED (15-DAY)		HO	IT-ACCORD-046284		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting	Escitalopram			S	Oral	10 Df Total		Accord
	Valproic Acid			S	Oral	2 Df Total		Not Reported
	Lorazepam			S	Oral	5 Df Total		Not Reported
	Eutirox			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13016669	EXPEDITED (15-DAY)		HO	DE-LUPIN PHARMACEUTICALS INC.-E2B_00006748		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13016679	EXPEDITED (15-DAY)		DS, HO	DE-LUPIN PHARMACEUTICALS INC.-E2B_00006756		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Loss Of Consciousness	Escitalopram	S	Oral		Not Reported
	Escitalopram	S	Oral		Not Reported
	Olanzapine	S	Oral		Not Reported
	Olanzapine	S	Oral		Not Reported
	Mirtazapine	S	Oral		Not Reported
	Tavor [Lorazepam]	S	Oral		Not Reported
	Tavor [Lorazepam]	S	Oral		Not Reported
	Tavor	S	Oral		Not Reported
	L-Thyroxin	C	Oral		Not Reported
	Aprovel	C	Oral		Not Reported
	Urivesc	C	Oral		Not Reported
	Felodipine	C	Oral		Not Reported
	Kalium Duriles	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13016897	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2016-15136		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram 10 Mg			S	Transplacental	10 Mg, Once A Day		Aurobindo
	Thyronajod			C	Transplacental	150 Unk, Once A Day		Not Reported
	Folio Forte			C	Transplacental	0.8 Mg, Once A Day		Not Reported
	Ibuprofen Lysinate			C	Transplacental			Not Reported
	Paracetamol			C	Transplacental	500 Mg, Once A Day		Not Reported
	Korodin /00642501/			C	Transplacental			Not Reported
	Opipramol			C	Transplacental	50 Mg, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13017964	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20161207503		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebellar Haemorrhage; Craniocerebral Injury; Dizziness; Fall; Orthostatic Hypotension	Imbruvica		S	Oral	Not Reported
	Pantoprazole		S	Oral	Not Reported
	Losartan Potassium		S	Oral	Not Reported
	Seroplex		S	Oral	Not Reported
	Cordarone		S	Oral	Not Reported
	Zelitrex		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13018188	EXPEDITED (15-DAY)		HO	IT-TEVA-717784ACC		45 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sopor	Escitalopram Oxalate			S	Oral	30 Ml Total		Ivax
	Bentelan -1 Mg Compresse Effervescenti			S	Oral	10 Mg Total		Not Reported
	Anafranil - Sigma-Tau Industrie Farmaceutiche Riunite Spa			S	Oral	20 Df Total		Not Reported
	Levoxacin - Glaxosmithkline S.P.A.			S	Oral	5 Df Total		Not Reported
	Lortaan - Msd Italia S.R.L.			S	Oral	28 Df Total		Not Reported
	Zolpidem Tartrate			S	Oral	30 Ml Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13018985	EXPEDITED (15-DAY)		HO	IT-TEVA-717792ACC		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting	Valproate Sodium			S	Oral	2 Df Total		Not Reported
	Lorazepam			S	Oral	5 Df Total		Actavis
	Escitalopram			S	Oral	10 Df Total		Not Reported
	Eutirox			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020187	EXPEDITED (15-DAY)		CA	DE-TEVA-716197GER		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S	Transplacental	10 Milligram Daily;		Ivax
	Thyronajod			C	Transplacental	50 (Microg/D) 150 (Microg/D)		Not Reported
	Folio Forte (Iodine-Free)			C	Transplacental	.8 Milligram Daily;		Not Reported
	Ibuprofen Lysinate			C	Transplacental	Twice, Dosage Unknown		Not Reported
	Paracetamol			C	Transplacental	500 (Mg/D)/ 2-3 Times, If Necessary		Not Reported
	Korodin			C	Transplacental	1-3x Per Week		Not Reported
	Opipramol			C	Transplacental	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020247	EXPEDITED (15-DAY)		DE, HO	CA-ALLERGAN-1679977US		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020259	EXPEDITED (15-DAY)		OT	IN-ELI_LILLY_AND_COMPANY-IN201612001739		37 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Gastric Ph Decreased; Gastritis	Fluoxetine Hydrochloride			S	Unknown	Unk, Unknown		Not Reported
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020626	NON-EXPEDITED			US-ALLERGAN-1669901US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejaculation Disorder	Lexapro			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020627	NON-EXPEDITED			US-ALLERGAN-1677976US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020630	NON-EXPEDITED			US-ALLERGAN-1674900US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Nausea	Escitalopram Oxalate Unk			S		5 Mg, Qhs		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020631	NON-EXPEDITED			US-ALLERGAN-1677930US		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020632	EXPEDITED (15-DAY)		OT	DK-ALLERGAN-1000085293		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Weight Increased	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Xenazine			S	Oral	25 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020637	NON-EXPEDITED			US-FRI-1000085575			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020638	NON-EXPEDITED			US-ALLERGAN-1000085040		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Insomnia; Musculoskeletal Pain; Off Label Use; Pain; Pain In Jaw	Armour Thyroid 15 Mg			S	Oral	30 Mg, Qod		Allergan
	Armour Thyroid 15 Mg			S	Oral	60 Mg, Qod		Allergan
	Escitalopram Oxalate Unk			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020639	NON-EXPEDITED			US-ALLERGAN-1000087482			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Expired Product Administered; Nervousness	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020640	EXPEDITED (15-DAY)		OT	DK-ALLERGAN-1000086504			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Serotonin Syndrome	Escitalopram Oxalate Unk			S	Oral	10 Mg, Unk		Allergan
	Trintellix			S	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020641	NON-EXPEDITED			US-ALLERGAN-1674005US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Metabolising Enzyme Decreased; Off Label Use	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Pristiq			C	Oral	25 Mg, Qd		Not Reported
	Pristiq			C	Oral	50 Mg, Qd		Not Reported

Methylphenidate	C	Unknown	5 Mg, Qam		Not Reported
Methylphenidate	C	Unknown	36 Mg, Qam		Not Reported
Hgh	C	Unknown	1.4 Unspecified, Qd		Not Reported
Trazodone	C	Unknown	50 Mg, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020643	NON-EXPEDITED			US-FRI-1000082821			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Drug Ineffective; Irritability; Restlessness	Lexapro			S	Oral	1mg/Ml		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020644	EXPEDITED (15-DAY)		HO	DK-ALLERGAN-1000079019		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Lexapro Tablets			S	Oral	20 Mg, Unk		Allergan
	Luaf41156			S	Oral	3 Mg, Qd		Not Reported
	Estradiol Unk			C	Oral	2 Mg, Unk		Allergan
	Maxzide			C	Oral	37.5/25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020875	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1679953US		60 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Vomiting	Escitalopram Oxalate - Bp			S	Unknown	49 Df, Unk		Allergan
	Co Efferalgan/ Paracetamol + Codeine Phosphate			S	Unknown	24 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	11916951	NON-EXPEDITED			US-PFIZER INC-2015465806		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Lipitor			S		Unk		Pfizer
	Nifedipine			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Toprol			S		Unk		Not Reported
	Fish Oil			S		Unk		Not Reported
	Iberet			S		Unk		Not Reported
	Teva Alendronate/Cholecalciferol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	12550663	EXPEDITED (15-DAY)		OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-053945		27 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Suicidal Ideation; Weight Increased	Abilify			S	Oral	15 Mg, Unk		Bristol Myers Squibb
	Escitalopram			S	Unknown	Unk		Not Reported
	Zuclopenthixol			S	Intramuscular	Unk		Not Reported
	Zuclopenthixol			S	Intramuscular	Unk		Not Reported
	Abilify Maintena			S	Intramuscular	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Olanzapine			S	Intramuscular	Unk		Not Reported
	Haloperidol			S	Intramuscular	Unk		Not Reported

Paliperidone	S	Oral	Unk		Not Reported
Paliperidone	S	Unknown			Not Reported
Paliperidone	S	Unknown	Unk		Not Reported
Clozapine	S	Unknown	100 Mg, Bid		Not Reported
Fluvoxamine	S	Unknown	50 Mg, Unk		Not Reported
Lorazepam	C	Unknown	4 Mg, Unk		Not Reported
Lorazepam	C	Unknown	2 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	12923023	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1675185US		1 DAY	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Hair Colour Changes	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan
	Wypax			C	Transplacental	1.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	12989941	EXPEDITED (15-DAY)		HO	PHHY2016LT164547			Male	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Gait Disturbance; Nausea; Product Dispensing Error; Wrong Product Administered	Entacapone			S	Unknown	200 Mg, Qd,For Some Time		Novartis
	Escitalopram			S	Oral	Not Used		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13021400	EXPEDITED (15-DAY)		OT	IT-ACCORD-046272		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram			S	Oral			Accord

	Delorazepam		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13021421	EXPEDITED (15-DAY)		HO	IT-ACCORD-046276		45 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Product Misuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	30 Ml Total		Accord
	Bentelan			S	Oral	10 Mg Total Strength: 1 Mg Effervescent Tablets		Not Reported
	Anafranil Sigma-Tau Industrie Farmaceutiche Riunite Spa			S	Oral	20 Df Total		Sigma Tau
	Levoxacin - Glaxosmithkline S.P.A.			S	Oral	5 Df Total		Not Reported
	Lortaan - Msd Italia S.R.L.			S	Oral	28 Df Total		Not Reported
	Zolpidem			S	Oral	30 Ml Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13021458	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2016-05442		37 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dyspepsia; Gastritis	Escitalopram			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023308	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1680129US		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Escitalopram Oxalate - Bp			S	Oral	3 Mg, Single		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2016	13025797	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2016-15216		79 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Diarrhoea	Escitalopram Film-Coated Tablets			S	Oral	10 Mg, Daily		Aurobindo
	Cardioaspirin			C	Oral	Unk		Not Reported
	Serenase /00027401/			C	Oral	Unk		Not Reported
	Quetiapine			C	Oral	25 Mg, Unk		Not Reported
	Enalapril			C	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2016	13026811	DIRECT	Y	LT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2016	13027158	EXPEDITED (15-DAY)		HO	IT-TEVA-718854ACC		79 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Diarrhoea	Escitalopram Oxalate			S	Oral			Ivax
	Cardioaspirin			C	Oral			Not Reported
	Serenase (Haloperidol)			C	Oral			Not Reported
	Quetiapine			C	Oral			Not Reported
	Enalapril			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13029471	EXPEDITED (15-DAY)		HO	IT-ACCORD-046410		79 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Diarrhoea	Escitalopram			S	Oral	Escitalopram Oxalate		Accord
	Cardioaspirin			C	Oral			Not Reported

	Serenase (Haloperidol)	C	Oral	Not Reported
	Quetiapine/Quetiapine Fumarate	C	Oral	Not Reported
	Enalapril	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13030120	EXPEDITED (15-DAY)		HO	PHHY2016FR170380		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Confusional State	Stalevo			S	Oral	3 Df, Qd (Entacapone 100 Mg, Levodopa 25 Mg, Carbidopa 200 Mg)		Novartis
	Mantadix			S	Oral	1 Df, Qd		Not Reported
	Azilect			S	Oral	1 Df, Qd		Not Reported
	Escitalopram			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13031218	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2016GSK182461		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haemorrhage; Craniocerebral Injury; Dizziness; Fall; Orthostatic Hypotension	Zelitrex			S	Oral	1000 Mg, Qd		Glaxosmithkline
	Pantoprazole			S	Oral	40 Mg, Qd		Glaxosmithkline
	Losartan			S	Oral	50 Mg, Qd		Glaxosmithkline
	Seroplex			S	Oral	20 Mg, Qd		Glaxosmithkline
	Cordarone			S	Oral	200 Mg, Qd		Not Reported
	Imbruvica			S	Oral	420 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	12569926	EXPEDITED (15-DAY)		HO	FR-FRI-1000086191		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Lymphadenopathy; Lymphocyte Morphology Abnormal; Pruritus; Pyrexia; Rash Maculo-Papular; Transaminases Increased; Vulvovaginal Erythema	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd		Allergan
	Tegretol	S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	12994718	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1678850US		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Tamoxifene			S	Oral			Not Reported
	Femara			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13013440	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2016569034			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiopulmonary Failure; Cervix Cancer Metastatic	Pantoprazole			S	Unknown	Unk		Pfizer
	Estradiol			S	Unknown	Unk		Pfizer
	Metoclopramide Hcl			S	Unknown	Unk		Pfizer
	Ondansetron			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Pfizer
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported
	Oxycodone Hcl			S	Unknown	Unk		Not Reported
	Pembrolizumab			S	Intravenous (not otherwise specified)	200 Mg, Q3weeks		Not Reported

	Buspirone	S	Unknown	Unk		Not Reported
	Polyethylene Glycol	S	Unknown	Unk		Not Reported
	Hyoscyamine Sulfate	S	Unknown	Unk		Not Reported
	Carboplatin W/Gemcitabine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13033940	EXPEDITED (15-DAY)		HO, OT	DE-HETERO LABS LTD-1060895		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse	Escitalopram			S	Oral			Hetero
	Quetiapine Fumarate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13034030	EXPEDITED (15-DAY)		DE, HO, LT	FR-LUPIN PHARMACEUTICALS INC.-2016-05547		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bezoar; Overdose; Toxicity To Various Agents	Sevikar			S	Unknown	129 Units		Not Reported
	Atarax			S	Unknown	28 Tablets		Not Reported
	Lysanxia			S	Unknown	42 Tablets		Not Reported
	Escitalopram			S	Unknown	28 Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13035234	EXPEDITED (15-DAY)		HO, OT	FR-009507513-1612FRA006256		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haemorrhage; Craniocerebral Injury; Dizziness; Fall; Orthostatic Hypotension	Losartan Zentiva 50mg, Comprimé Pelliculé Sécable			S	Oral	50 Mg, Qd		Merck
	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported
	Cordarone			S	Oral	200 Mg, Qd		Not Reported
	Seroplex			S	Oral	20 Mg, Qd		Not Reported

	Zelitrex	S	Oral	Unk Unk, Qd		Not Reported
	Imbruvica	S	Oral	420 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13035903	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1680890US		94 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased; Upper Gastrointestinal Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Xarelto			S	Unknown			Not Reported
	Xarelto			S				Not Reported
	Aspirin Cardio 100			S	Unknown			Not Reported
	Casodex			S	Unknown			Not Reported
	Casodex			S				Not Reported
	Novalgine (Metamizole Sodium)			S	Unknown			Not Reported
	Pantoprazol			C	Oral			Not Reported
	Macrogol			C	Oral			Not Reported
	Calcium D3			C	Oral			Not Reported
	Torem			C	Oral			Not Reported
	Micardis			C	Oral			Not Reported
	Dafalgan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13036405	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1680694US		35 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Somnolence; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Overdose		Allergan
	Alprazolam			S	Oral	Overdose		Not Reported
	Norvasc			S	Oral	Overdose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13036433	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1680897US		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haemorrhage; Craniocerebral Injury; Dizziness; Face Injury; Fall; Orthostatic Hypotension	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported
	Losartan Potassique			S	Oral	50 Mg, Qd		Not Reported
	Cordarone			S	Oral	200 Mg, Qd		Not Reported
	Zelitrex			S	Oral	1000 Mg, Qd		Not Reported
	Imbruvica			S	Oral	420 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13036479	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1680900US		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Escitalopram Oxalate - Bp			S		20 Mg, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2016	13037505	EXPEDITED (15-DAY)		CA	DE-HETERO LABS LTD-1060935		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S				Hetero
	Thyronajod			C				Not Reported
	Folio Forte			C	Transplacental			Not Reported
	Ibuprofen Lysinate			C	Transplacental			Not Reported
	Paracetamol			C				Not Reported
	Korodin			C	Transplacental			Not Reported
	Opipramol			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2016	13037733	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2016PRN00278			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Intentional Product Use Issue; Therapeutic Product Effect Incomplete	Escitalopram			S		10 Mg, Unk		Prinston Pharmaceutical
	Escitalopram			S		20 Mg, Unk		Prinston Pharmaceutical
	Escitalopram			S		30 Mg, Unk		Prinston Pharmaceutical
	Wellbutrin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2016	13040315	DIRECT	Y	HO, RI			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Depression; Diarrhoea; Dizziness; Headache; Hot Flush; Hypertension; Irritability; Nausea; Serotonin Syndrome; Vision Blurred; Vision Blurred; Vomiting	Tramadol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2016	13038223	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2016-02692			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Finasteride 5mg			S	Oral	Unk		Aurobindo
	Lexapro			S	Oral	5 Mg, Once A Day		Not Reported
	Lexapro			S	Oral	10 Mg, Once A Day		Not Reported
	Lexapro			S	Oral	5 Mg, Once A Day		Not Reported

Spironolactone	S	Oral	25 Mg, Once A Day		Not Reported
Vitamin D3	C	Unknown			Not Reported
Lisinopril	C	Oral	2.5 Mg, Every 12 Hours		Not Reported
Imdur	C	Oral	30 Mg, Unk		Not Reported
Lasix /00032601/	C	Oral	20 Mg, Four Times/Day		Not Reported
Metorpololtartraat A	C	Oral	100 Mg, Once A Day		Not Reported
Digoxin	C	Oral	125 Mcg, Once A Day		Not Reported
Loratadin	C	Oral	10 Mg, Unk		Not Reported
Simvastatin	C	Oral	20 Mg, Once A Day		Not Reported
Tamsulosin	C	Oral	0.4 Mg, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2016	13038691	EXPEDITED (15-DAY)		HO	FR-ORION CORPORATION ORION PHARMA-ENTC2016-0742		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Confusional State	Stalevo			S	Oral	Strength: 25/100/200 Mg		Not Reported
	Sifrol			S	Oral	Strength: 0.52 Mg		Not Reported
	Mantadix			S	Oral	Strength: 100 Mg		Not Reported
	Escitalopram			S	Oral	Strength: 5 Mg		Not Reported
	Azilect			S	Oral	Strength: 1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2016	13042213	NON-EXPEDITED			US-PFIZER INC-2016587067		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Libido Decreased	Zoloft			S		Three Tablets In The Morning		Pfizer
	Lexapro			S	Oral	Unk, 1x/Day		Not Reported
	Oxcarbazepine			S		Unk		Not Reported

	Seroquel	S	100 Mg Or 200 Mg Once At Night Time		Not Reported
	Benadryl	C	Unk, Once At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2016	13042336	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1681367US		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Kardegic			S	Oral	75 Mg, Qd		Not Reported
	Tahor			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2016	13046053	NON-EXPEDITED		HO	US-DRREDDYS-USA/USA/15/0055105		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Olanzapine Film-Coated Tablet			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2016	13048168	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1056273			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Poisoning; Sopor	Simvastatin			S	Oral	14 Df, Total		Not Reported
	Rivotril			S	Oral	10 Ml, Total		Mylan
	Entact			S	Oral	28 Df, Total		Mylan
	Torvast			S	Oral	8 Df, Total		Mylan
	Deursil			S	Oral	10 Df, Total		Mylan
	Igroton			S	Oral	15 Df, Total		Mylan
	Acetylsalicylic Acid			S	Oral	20 Df, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	11291680	NON-EXPEDITED			US-PFIZER INC-2015242014		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Drug Ineffective; Pruritus	Effexor			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Diclofenac Epolamine			S		Unk		Unknown
	Venlafaxine Hcl			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Methadone			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	12636816	EXPEDITED (15-DAY)		HO, OT	FR-ELI_LILLY_AND_COMPANY-FR201608001055		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatitis; Hepatocellular Carcinoma	Trulicity			S	Subcutaneous	Unk, Weekly (1/W)		Eli Lilly And Co
	Okimus			S	Oral	Unk, Unknown		Not Reported
	Mysoline			S	Oral	125 Mg, Bid		Not Reported
	Repaglinide			S	Oral	7 Mg, Qd		Not Reported
	Perindopril			S	Oral	2.5 Mg, Qd		Not Reported
	Tranxene			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported
	Stagid			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	12738629	NON-EXPEDITED		HO	US-PFIZER INC-2016422933		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sleep Disorder; Suicidal Ideation	Zoloft			S		Unk		Pfizer
	Zoloft			S				Pfizer
	Ativan			S		1 Mg, 1x/Day		Pfizer
	Ativan			S				Pfizer
	Buspar			S		Unk		Not Reported
	Quetiapine Fumarate			S		Unk		Not Reported
	Quetiapine Fumarate			S				Not Reported
	Mirtazapine			S		7.5 Mg, Unk		Not Reported
	Mirtazapine			S		30 Mg, 1x/Day		Not Reported
	Fluoxetine Hydrochloride			S		25 Mg, 1x/Day		Not Reported
	Fluoxetine Hydrochloride			S		40 Mg, 1x/Day		Not Reported
	Fluoxetine Hydrochloride			S				Not Reported
	Cymbalta			S		Unk		Not Reported
	Cymbalta			S				Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported
	Lexapro			S		20 Mg, Unk		Not Reported
	Lexapro			S		30 Unk, Unk		Not Reported
	Trazodone			C		25 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13014865	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2016FR165138		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anuria; Bezoar; Cardiogenic Shock; Gastrointestinal Necrosis; Hyperlactacidaemia;	Zolpidem			S	Unknown			Novartis
	Sevikar			S	Unknown	129 Df, Unk		Not Reported
	Atarax			S	Unknown	28 Df, Unk		Not Reported

Intestinal Ischaemia; Multiple Organ Dysfunction Syndrome; Toxicity To Various Agents; Vasoplegia Syndrome	Lysanxia	S	Unknown	42 Df, Unk	Not Reported
	Seroplex	S	Unknown	28 Df, Unk	Not Reported
	Nordiazepam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13030555	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016579642		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haemorrhage; Craniocerebral Injury; Dizziness; Fall; Orthostatic Hypotension	Cordarone			S	Oral	200 Mg, 1x/Day		Pfizer
	Pantoprazole			S	Oral	40 Mg, 1x/Day		Pfizer
	Losartan Potassium			S	Oral	50 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	20 Mg, 1x/Day		Not Reported
	Zelitrex			S	Oral	1000 Mg, 1x/Day		Not Reported
	Imbruvica			S	Oral	420 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13047381	EXPEDITED (15-DAY)		HO, LT	US-ALLERGAN-1681483US		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate Unk			S	Unknown			Allergan
	Methylene Blue			S	Unknown	7.5 Mg/Kg, Unk		Not Reported
	Isoflurane			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13048706	NON-EXPEDITED		DE, HO, LT	MX-TORRENT-00000083		81 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peptic Ulcer Haemorrhage; Thrombocytopenia	Memantine			S	Oral	One 10 Mg Tablet Per Day		Torrent
	Donepezil			S	Oral	One 10 Mg Tablet Per Day		Torrent

	Escitalopram	S	Oral	One 10 Mg Tablet Per Day	Torrent
	Aspirin Protect	C		One 100 Mg Tablet Per Day	Bayer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13048755	EXPEDITED (15-DAY)		OT	CH-AMGEN-CHESP2016177394		74 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Decreased; Pelvic Fracture; Rebound Effect; Spinal Fracture	Prolia			S	Unknown	60 Mg, Q6mo		Amgen
	Prolia			S	Unknown	Unk		Amgen
	Pantoprazole Actavis			S	Unknown	20 Mg, Qd		Not Reported
	Cipralex			S	Unknown	10 Mg, Unk		Not Reported
	Bekunis Bisacodyl			C		Unk Unk, Bid		Not Reported
	Kalcipos D3			C		Unk Unk, Qd		Not Reported
	Lexotanil			C		3 Mg, Qd		Not Reported
	Losartan			C		50 Mg, Unk		Not Reported
	Metoprolol			C		50 Mg, Qd		Not Reported
	Ponstan			C		Unk Unk, As Necessary		Not Reported
	Simvastatin			C				Not Reported
	Targin			C		Unk Unk, Bid		Not Reported
	Vi-De 3			C		50 Drops/Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13049216	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1680849US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Mania; Withdrawal Syndrome	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan
	Latuda			S	Oral	20 Mg, Unknown		Not Reported
	Latuda			S	Oral	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13049703	NON-EXPEDITED		HO, OT	US-DRREDDYS-USA/USA/15/0055081		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Palpitations; Rhabdomyolysis	Risperidone			S		0.5 Mg Qhs		Not Reported
	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported
	Mirtazapine			C		15 Mg Qhs		Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13051380	DIRECT		DS			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Orgasm Abnormal; Orgasm Abnormal	Escitalopram 10 Mg			S	Oral	Quantity:1 Tablet(S);		Camber
	D3			C				Not Reported
	Multi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13051862	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1681765US			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Disorientation; Dizziness; Irritability; Nervousness; Thinking Abnormal; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13052316	EXPEDITED (15-DAY)		OT	CH-TEVA-720748ISR		74 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Decreased; Pelvic Fracture; Rebound Effect; Spinal Fracture	Pantoprazol-Actavis			S	Oral	20 Milligram Daily; Enteric, Strength: 20mg, Start Date Unknown, Continous		Teva
	Prolia			S	Subcutaneous			Not Reported
	Prolia			S	Subcutaneous	Continous- Last Injection In Oct 2016)		Not Reported
	Cipralex			S	Oral	5 Milligram Daily; Strength: 10mg, Start Date Unknown, Therapy Ongoing		Not Reported
	Bekunis Bisacodyl			C	Oral	6 Dosage Forms Daily; No Details Available		Not Reported
	Kalcipos D3			C	Oral	1 Dosage Forms Daily; No Details Available		Not Reported
	Lexotanil			C	Oral	3 Milligram Daily; Strength: 3mg, No Details Available		Not Reported
	Losartan			C	Oral	25 Milligram Daily; No Details Available, Strength 50 Mg		Not Reported
	Metoprolol			C	Oral	50 Milligram Daily; No Details Available		Not Reported
	Ponstan			C	Oral	1 Dosage Forms Daily; No Details Available		Not Reported
	Simvastatin			C	Oral	.5 Dosage Forms Daily; No Details Available		Not Reported
	Targin			C	Oral	2 Dosage Forms Daily; No Details Available		Not Reported
	Vi-De 3			C	Oral	No Details Available		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	12194581	NON-EXPEDITED			US-PFIZER INC-2016153668		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Neurontin	S	Unk		Pfizer
	Atenolol	S	Unk		Pfizer
	Levofloxacin	S	Unk		Pfizer
	Levaquin	S	Unk		Not Reported
	Avelox	S	Unk		Not Reported
	Paxil	S	Unk		Not Reported
	Prozac	S	Unk		Not Reported
	Lisinopril	S	Unk		Not Reported
	Prednisone	S	Unk		Not Reported
	Lexapro	S	Unk		Not Reported
	Cymbalta	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	12962580	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1676965US		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate Unk			S	Oral	10 Mg, Unk		Allergan
	Tramadol			S	Oral	100 Mg, Unk		Not Reported
	Fluindione			C				Not Reported
	Pantoprazole			C				Not Reported
	Perindopril			C				Not Reported
	Bisoprolol			C				Not Reported
	Spironolactone			C				Not Reported
	Rosuvastatin			C				Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)			Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13054057	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Dispensing Error	Latuda Latuda 160	S		Not Reported
	Lexapro Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13054570	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1681780US		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fall; Injury; Malaise	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13054719	DIRECT		OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Attention; Feeling Abnormal; Insomnia	Escitalopram			S	Oral	Quantity:90 Tablet(S);		Torrent
	Ramipril			C				Not Reported
	Lexapro			C				Not Reported
	Vit D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13055498	EXPEDITED (15-DAY)		OT	IT-TEVA-722519ACC		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Poisoning; Sopor	Simvastatin			S	Oral			Ivax
	Acetylsalicylic Acid			S	Oral			Not Reported
	Rivotril - 2,5mg/Ml Gocce Orali Soluzione - Roche S.P.A.			S	Oral	10 Ml Total		Not Reported
	Entact - H. Lundbeck A/S			S	Oral			Not Reported
	Torvast - Pfizer Limited			S	Oral			Not Reported
	Deursil - Cheplapharm Arzneimittel Gmbh			S	Oral			Not Reported
	Igroton - Amdipharm Ltd			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13055594	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1682076US		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Poisoning; Product Use In Unapproved Indication; Sopor	Escitalopram Oxalate Unk			S	Oral	28 Df, Unk		Allergan
	Acetylsalicylic Acid			S	Oral	Unk Df, Unk		Not Reported
	Rivotril			S	Oral	10 Ml, Unk		Not Reported
	Simvastatin			S	Oral			Not Reported
	Torvast			S	Oral			Not Reported
	Deursil			S	Oral			Not Reported
	Igroton			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13056427	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1681761US		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Biken Ha			S	Subcutaneous	0.5 Ml, Single		Not Reported
	Triazolam			C	Unknown	0.25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13056464	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1681776US		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Interstitial Lung Disease	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Detensiel			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Amlor			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13056484	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1681773US		29 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Poisoning; Drug Dependence; Wrong Product Administered	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Tobacco Powder			S	Respiratory (inhalation)	5 Packs/Year		Not Reported
	Alcohol			S	Oral	1 Beer A Day		Not Reported
	Methadone			S	Oral			Not Reported
	Subutex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13057068	EXPEDITED (15-DAY)		OT	PHHY2016IT173643		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor; Toxicity To Various Agents	Simvastatin			S	Oral	14 Df, Once/Single		Novartis
	Acetylsalicylic Acid Sandoz			S	Oral	20 Df, Once/Single		Not Reported
	Igroton			S	Oral	15 Df, Once/Single		Not Reported
	Rivotril			S	Oral	10 Ml, Once/Single		Not Reported
	Deursil			S	Oral	10 Df, Once/Single		Not Reported
	Torvast			S	Oral	8 Df, Once/Single		Not Reported
	Entact			S	Oral	28 Df, Once/Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13057833	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2016US23663			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Escitalopram			S	Unknown	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13058123	DIRECT	Y				50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Iritis; Scleritis	Fluoxetine			S	Oral		4 MTH	Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13059736	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2016578939		26 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Malaise; Palpitations; Withdrawal Syndrome	Temesta (Lorazepam)			S	Oral	1 Mg, As Needed		Pfizer
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Escitalopram			S		5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13060065	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1682050US		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Plavix			S	Oral	1 Df, Qd		Not Reported
	Tahor			C	Oral			Not Reported
	Lamictal			C	Oral			Not Reported
	Renitec [Enalapril Maleate]			C	Oral			Not Reported
	Diffu K			C	Oral			Not Reported
	Movicol			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13060171	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2016GSK190288		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Feeling Abnormal	Wellbutrin			S		Unk		Glaxosmithkline
	Wellbutrin			S				Glaxosmithkline
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Flax Seed Oil			C				Not Reported
	Tramadol			C				Not Reported
	Melatonin			C				Not Reported
	Zyrtec-D			C				Not Reported
	Theraflu - Unknown			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13060245	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1682055US		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Haematoma Muscle	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Coumadine			S	Oral			Not Reported
	Letrozole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2016	8920401	EXPEDITED (15-DAY)		HO	DE-JNJFOC-20121103783		22 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Drug Diversion; Dysarthria; Electrocardiogram Qt Prolonged; Overdose; Seizure; Somnolence; Staring; Suicide Attempt; Systolic Hypertension;	Dipiperon			S	Oral			Not Reported
	Diphenhydramine			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Sycrest			S	Oral			Not Reported
	Dominal (Prothipendyl			S	Oral			Not Reported

Tachycardia; Vomiting	Hydrochloride)				
	Buscopan	S	Oral		Not Reported
	Paracetamol	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2016	13061466	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2016-15586		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Poisoning; Sopor	Simvastatin Tablet			S	Oral	14 Df, Unk		Aurobindo
	Acetylsalicylic Acid			S	Oral	20 Df, Unk		Not Reported
	Entact			S	Oral	28 Df, Unk		Not Reported
	Torvast			S	Oral	8 Df, Unk		Not Reported
	Deursil			S	Oral	10 Df, Unk		Not Reported
	Igroton			S	Oral	15 Df, Unk		Not Reported
	Rivotril			S	Oral	10 Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2016	13061753	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-129702		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Poisoning; Sopor	Simvastatin			S	Oral	14 Df Total		Sun
	Acetylsalicylic Acid			S	Oral	20 Df Total		Sun
	Rivotril 2,5mg/Ml			S	Oral	10 Ml Total		Not Reported
	Igroton			S	Oral	15 Df Total		Not Reported
	Deursil			S	Oral	10 Df Total		Not Reported
	Torvast			S	Oral	8 Df Total		Not Reported
	Entact			S	Oral	28 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2016	13062432	EXPEDITED (15-DAY)		HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-108889		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Haemorrhagic Stroke	Eliquis			S	Oral	2.5 Mg, Bid		Bristol Myers Squibb
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Tanakan			C	Unknown			Not Reported
	Levothyrox			C	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported
	Cordarone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2016	13062513	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1682180US		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Olanzapine			C	Unknown	10 Mg, Qd		Not Reported
	Olanzapine			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2016	13062718	EXPEDITED (15-DAY)		HO	PHHY2016FR175977		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Torsade De Pointes	Cotareg			S	Oral	Unk Unk, Qd		Novartis
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Stagid			S	Oral	700 Mg, Tid		Not Reported
	Mediatensyl			S	Oral	60 Mg, Qd		Not Reported
	Symbicort			C	Unknown	(400/12), Bid		Not Reported
	Levothyrox			C	Unknown	75 Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	12967024	EXPEDITED (15-DAY)		HO, LT, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-127980		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Tramadol			S	Unknown	Extended Release		Sun
	Perindopril			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported
	Spironolactone			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Fluindione			C	Unknown	Unk		Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13063042	EXPEDITED (15-DAY)		OT	IT-ROCHE-1871356		46 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Abuse; Psychomotor Retardation	Valium			S	Oral	5 Mg/Ml Oral Drops, Solution' Bottle Containing 20 Oral Drops, Solution		Not Reported
	Cipralex			S	Oral	14 X 5 Mg Film-Coated Tablets		Not Reported
	Tavor (Italy)			S	Oral	2.5 Mg Tablets' 20 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13066889	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1682353US		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Coma Scale Abnormal; Hypokalaemia; Mydriasis; Pco2 Increased; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	28 Df, Single		Allergan
	Stilnox			S	Oral	12 Df, Single		Not Reported
	Raloxifene Base			S	Oral	60 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13066891	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1682357US		14 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Miosis; Off Label Use; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	4 Df, Single		Allergan
	Lysanxia			S	Oral	10 Df, Single		Not Reported
	Largactil			S	Oral	6 Df, Single		Not Reported
	Atarax			S	Oral	10 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13066892	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1682359US		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Eliquis			S	Oral	5 Mg, Qd		Not Reported
	Tanakan			C	Unknown			Not Reported
	Levothyrox			C	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported
	Cordarone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13066897	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1682355US		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Tonic Clonic Movements	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp	S	Oral	Unk		Allergan
	Crestor	C	Unknown			Not Reported
	Depakine Chrono	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13066898	EXPEDITED (15-DAY)		HO	NL-ALLERGAN-1682335US		60 DAY	Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Premature Baby	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13066899	EXPEDITED (15-DAY)		OT	NL-ALLERGAN-1682189US		37 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Labour	Escitalopram Oxalate - Bp			S	Oral	09-2016 -> 5mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13067238	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2016IT23831			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Suicidal Ideation	Escitalopram			S	Unknown	20 Mg, Total		Invagen
	Valproic Acid			S	Unknown	300 Mg, Total		Cipla
	Venlafaxine			S	Unknown	300 Mg, Total		Cipla
	Quetiapine			S	Unknown	Unk, Total		Not Reported
	Alprazolam			S	Unknown	1.5 Mg, Total		Cipla
	Trazodone Hydrochloride			S	Unknown	75 Mg, Total		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2016	10882280	EXPEDITED (15-DAY)		DS	FR-ABBVIE-15P-056-1354299-00		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Action Tremor; Dementia; Parkinsonism	Depakote			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Crestor			C				Not Reported
	Lasilix			C				Not Reported
	Kardegic			C				Not Reported
	Plaquenil			C				Not Reported
	Preterax			C				Not Reported
	Abufene			C				Not Reported
	Inexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2016	13000493	EXPEDITED (15-DAY)		DE, HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-128854		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bezoar; Gastrointestinal Ischaemia; Shock; Skin Necrosis; Toxicity To Various Agents	Sevikar			S	Unknown	10 Mg, 129 Tablets		Not Reported
	Atarax			S	Unknown	25 Mg, 28 Tablets		Not Reported
	Lysanxia			S	Unknown	420 Mg, 42 Tablets		Not Reported
	Seroplex			S	Unknown	280 Mg, 28 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2016	13067650	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2016004103			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Premature Baby; Respiratory Disorder Neonatal; Small For Dates Baby	Escitalopram		S	Transplacental	10 Mg, Qd (0-35.5 Gestational Week)	Macleods
	Folsaure		C	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2016	13069042	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2016SF35403		65 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenic Purpura; Tinnitus	Crestor			S	Oral			Not Reported
	Glucophage Unidie			S	Oral			Not Reported
	Eutimil			S	Oral			Not Reported
	Eutimil			S	Unknown	Sereupin		Not Reported
	Cipralex			S	Unknown			Not Reported
	Esopral			C	Oral	20.0mg Unknown		Not Reported
	Diamox			C	Oral	250.0mg Unknown		Not Reported
	Muscoril			C	Oral	4.0mg Unknown		Not Reported
	Stiliden			C	Oral	10 Mg/Ml Oral Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2016	13069826	EXPEDITED (15-DAY)		HO, LT	PHHY2016IN174860		19 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hypoglycaemia; Suicide Attempt	Clonazepam			S	Unknown	Unk Unk, Qd		Novartis
	Clonazepam			S	Oral	Ingested 10-15 Tablets		Novartis
	Escitalopram			S	Unknown	Unk Unk, Qd		Not Reported
	Escitalopram			S	Oral	Ingested 10-15 Tablets		Not Reported
	Venlafaxine			S	Unknown	1 Df, Qd		Not Reported
	Venlafaxine			S	Oral	Ingested 10-15 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2016	11120390	NON-EXPEDITED			US-PFIZER INC-2015167081		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Omnicef			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2016	12389853	EXPEDITED (15-DAY)		DE, HO, OT	IE-FRI-1000071177		63 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Blood Test Abnormal; Coagulopathy; Completed Suicide; Contusion; Electrocardiogram Abnormal; Electrocardiogram St Segment Elevation; Fall; Fear; Fear Of Death; Haemorrhage; Head Injury; Hepatic Enzyme Abnormal; Hyponatraemia; Negative Thoughts; Panic Reaction; Psychotic Disorder; Withdrawal Syndrome	Lexapro Tablets			S	Oral	Unk		Allergan
	Zispin			S	Unknown	30 Mg, Unk		Not Reported
	Zispin			S	Unknown	30 Mg, Unk		Not Reported
	Sertraline			S	Unknown	100 Mg, Unk		Not Reported
	Sertraline			S	Unknown	100 Mg		Not Reported
	Sertraline			S	Unknown	50 Mg, Unk		Not Reported
	Sertraline			S	Unknown	50 Mg, Unk		Not Reported
	Temazepam			C	Unknown	20 Mg, Unk		Not Reported
	Solpadeine (Acetaminophen\Caffeine\Codeine Phosphate)			C				Not Reported
	Solpadeine (Acetaminophen\Caffeine\Codeine Phosphate)			C				Not Reported
	Paracetamol			C				Not Reported
	Diazepam			C		Unk		Not Reported
	Diazepam			C		Unk		Not Reported

	Sudafed	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2016	12649667	EXPEDITED (15-DAY)		HO	IT-FRI-1000086792		65 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Bleeding; Immune Thrombocytopenic Purpura; Petechiae; Tinnitus	Escitalopram Oxalate - Bp			S	Oral	4 Gtt, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Gtt, Qd		Allergan
	Crestor			S	Oral	10 Mg, Qd		Not Reported
	Eutimil			S	Oral	20 Mg, Unk		Not Reported
	Sereupin			S	Oral	Unk		Not Reported
	Glucophage			S	Oral	500 Mg, Bid		Not Reported
	Stiliden			C	Oral	40 Gtt, Qd		Not Reported
	Stiliden			C	Oral	35 Gtt, Qd		Not Reported
	Stiliden			C	Oral	30 Gtt, Qd		Not Reported
	Muscoril			C	Oral	1 Df, Bid		Not Reported
	Muscoril			C				Not Reported
	Diamox			C	Oral	1 Df, Qd		Not Reported
	Paroxetine			C	Oral	20 Mg, Qd		Not Reported
	Esopral			C		20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2016	13049284	EXPEDITED (15-DAY)		HO	LB-APOTEX-2016AP015906		50 YR	Female	LBN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysgeusia; Nausea; Polyuria; Salivary Hypersecretion; Toxicity To Various Agents; Vomiting	Valsartan 160			S	Unknown	160 Mg, Qd		Not Reported
	Valsartan 160			S				Not Reported
	Apo-Olanzapine			S	Unknown	15 Mg, Qd		Apotex
	Apo-Olanzapine			S	Unknown	5 Mg, Qd		Apotex
	Fluoxetine			S	Unknown	20 Mg, Qd		Apotex

Diazepam	S	Unknown	10 Mg, Qd		Not Reported
Diazepam	S	Unknown	15 Mg, Qd		Not Reported
Lithium Carbonate	S	Unknown	400 Mg, Qd		Not Reported
Lithium Carbonate	S	Unknown	600 Mg, Qd		Not Reported
Lithium Carbonate	S	Unknown	400 Mg, Bid		Not Reported
Lithium Carbonate	S	Unknown	800 Mg, Qd		Not Reported
Escitalopram /01588502/	S	Unknown	10 Mg, Qd		Not Reported
Quetiapine /01270902/	S	Unknown	100 Mg, Qd		Not Reported
Quetiapine /01270902/	S	Unknown	300 Mg, Qd		Not Reported
Levothyroxine Sodium	C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2016	13071263	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-108894		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adenocarcinoma; Blood Loss Anaemia; Haematoma Muscle	Coumadine			S	Oral	3 Mg, Qd		Bristol Myers Squibb
	Seroplex			S	Oral	5 Mg, Unk		Not Reported
	Letrozole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2016	13075489	DIRECT		HO			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Product Substitution Issue; Suicidal Behaviour; Suicide Attempt	Lexapro			S	Oral	Quantity:30 Tablet(S); At Bedtime; Oral		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	10891769	EXPEDITED (15-DAY)		DS	FR-FRI-1000075006		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Action Tremor; Dementia; Parkinsonism	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Depakote			S	Oral	1500 Mg, Qd		Not Reported
	Depakote			S	Oral	1000 Mg, Unk		Not Reported
	Depakote			S	Oral	500 Mg, Unk		Not Reported
	Crestor			C	Oral	5 Mg, Unk		Not Reported
	Lasilix			C	Oral	40 Mg, Unk		Not Reported
	Kardegic			C	Oral	75 Mg, Unk		Not Reported
	Plaquenil			C	Oral	200 Mg, Unk		Not Reported
	Preterax			C		Unk		Not Reported
	Abufene			C	Oral	400 Mg, Unk		Not Reported
	Inexium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	12772303	EXPEDITED (15-DAY)		HO, OT	JP-FRI-1000087629		74 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Loss Of Consciousness; Sinus Node Dysfunction; Syncope	Escitalopram Oxalate Unk			S	Oral	Unk		Allergan
	Donepezil Hydrochloride			C	Oral	5 Mg, Qd		Not Reported
	Zopiclone			C	Oral	7.5 Mg, Qd		Not Reported
	Yokukansan			C	Oral	2.5 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13034180	EXPEDITED (15-DAY)		OT	IT-009507513-1612ITA007161		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Poisoning; Sopor	Simvastatin			S	Oral	14 Dose Units, Total		Merck
	Aspirin			S	Oral	20 Dose Units, Total		Not Reported
	Rivotril			S	Oral	Strength: 2.5 Mg/Ml, 10 Ml		Not Reported

				Total		
	Entact	S	Oral	28 Dose Units, Total		Not Reported
	Torvast	S	Oral	8 Dose Units, Total		Not Reported
	Deursil	S	Oral	10 Dose Units, Total		Not Reported
	Igroton	S	Oral	15 Dose Units, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13037708	EXPEDITED (15-DAY)		HO, OT	FR-ASTRAZENECA-2016SF31955		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Cutaneous Lupus Erythematosus; Anaemia; Lymphopenia; Toxic Epidermal Necrolysis	Inexium			S	Oral			Not Reported
	Aprovel			S	Oral			Not Reported
	Aerius (Desloratadine)			S	Oral			Not Reported
	Aerius (Desloratadine)			S	Oral	Doubled Dose		Not Reported
	Gaviscon			S	Oral			Not Reported
	Eliquis			S	Oral			Not Reported
	Eliquis			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Hemigoxine Nativelle			S	Oral	0.125mg Unknown		Not Reported
	Loperamide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13074408	EXPEDITED (15-DAY)		HO	IT-APOTEX-2016AP016119		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Venlafaxina Doc Generici			S	Unknown	300 Mg, Total		Apotex
	Quetiapina Doc Generici			S	Unknown	200 Mg/Kg, Total		Apotex
	Compresse Rivestite Con Film Trazodone Hydrochloride			S	Unknown	75 Mg, Total		Not Reported
	Escitalopram			S	Unknown	20 Mg, Total		Not Reported

	Clonazepam		S	Unknown	0.5 Mg, Total	Not Reported
	Valproic Acid		S	Unknown	300 Mg, Total	Not Reported
	Alprazolam		S	Unknown	1.5 Mg, Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13074612	EXPEDITED (15-DAY)		OT	PT-LUPIN PHARMACEUTICALS INC.-2016-05799		23 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Syndrome	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13076078	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error	Buspar			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13076769	EXPEDITED (15-DAY)		HO, LT, OT	JP-ALLERGAN-1680117US		16 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Intentional Self-Injury; Suicidal Behaviour	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13076773	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1682568US		34 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13076782	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1682626US		46 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Abuse; Psychomotor Retardation	Escitalopram Oxalate - Bp			S	Oral	Unk Gtt, Unk		Allergan
	Valium			S	Oral	Unk Gtt, Unk		Not Reported
	Tavor [Lorazepam]			S	Oral	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13077318	EXPEDITED (15-DAY)		DE, OT	US-JNJFOC-20161225121			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Loperamide		Y	S	Unknown			Not Reported
	Loperamide			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13088725	DIRECT					41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sensation In Eye; Balance Disorder; Dizziness; Feeling Abnormal; Headache; Muscle Spasticity; Nausea; Paraesthesia; Tinnitus; Withdrawal Syndrome	Escitalopram			S				Not Reported
	Synthroid			C				Not Reported
	B-Complex			C				Not Reported
	Vitd			C				Not Reported
	Fish Oil			C				Not Reported
	Digestive Advantage Probiotic			C				Not Reported
	Metamucil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2017	13084248	DIRECT		HO			30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Risperdal			S	Oral	Quantity:30 Tablet(S);		Not Reported
	Lexapro			S	Oral	Quantity:30 Tablet(S);		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2017	13033368	EXPEDITED (15-DAY)		OT	IT-ROCHE-1867275		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Poisoning; Sopor	Rivotril			S	Oral	2.5 Mg/Ml Oral Drops, Solution' 10 Ml Bottle		Not Reported
	Simvastatin			S	Oral			Not Reported
	Simvastatin			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Entact			S	Oral			Not Reported
	Torvast			S	Oral			Not Reported
	Deursil			S	Oral			Not Reported
	Igroton			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2017	13078433	EXPEDITED (15-DAY)		LT	IT-TEVA-725220ACC		63 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Labelled Drug-Drug Interaction Medication Error; Musculoskeletal Stiffness; Rhabdomyolysis; Tremor	Escitalopram Oxalate			S				Ivax
	Lithium			S				Barr

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	10903110	EXPEDITED (15-DAY)		OT	IN-AUROBINDO-AUR-APL-2015-01872		50 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Electroencephalogram Abnormal; Hypochloraemia; Hypokalaemia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Metabolic Encephalopathy; Urine Sodium Abnormal; Vomiting	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo
	Telmisartan			C	Unknown	80 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13042576	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1680921US		52 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoembryonic Antigen Increased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13060246	EXPEDITED (15-DAY)		HO, LT, OT	IN-ALLERGAN-1682186US		19 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hypoglycaemia; Intentional Overdose; Respiratory Rate Increased; Suicidal Ideation; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Venlafaxine			S	Oral	1 Df, Qd		Not Reported
	Venlafaxine			S	Oral	10-15 Tablets		Not Reported
	Clonazepam			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13060254	EXPEDITED (15-DAY)		HO, LT, OT	IN-BAUSCH-BL-2016-032279		19 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hypoglycaemia; Intentional Overdose; Respiratory Rate Increased; Suicidal Ideation; Suicide Attempt	Venlafaxine			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13082165	EXPEDITED (15-DAY)		OT	DE-TEVA-723599GER		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Respiratory Disorder Neonatal; Small For Dates Baby	Escitalopram			S	Transplacental	10 Milligram Daily;		Ivax
	Folsaeure			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13082345	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2016M1058599			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Premature Baby; Respiratory Disorder Neonatal; Small For Dates Baby	Escitalopram			S	Transplacental	10 Mg, Qd		Not Reported
	Folsaeure			C	Transplacental			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13085506	DIRECT		OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Depression; Dizziness;	Escitalopram 10 Mg Tablet - Oval Aurobindo Pharm			S	Oral	Quantity:1 Tablet(S);		Aurobindo

Mood Swings; Product Substitution Issue; Pruritus Generalised; Therapy Cessation	Synthroid	C	Not Reported
	Varapamil	C	Not Reported
	Creon	C	Not Reported
	Protonix	C	Not Reported
	B-12	C	Not Reported
	Levocetirizine	C	Not Reported
	Biotin	C	Not Reported
	Vitamin D Nos	C	Not Reported
	Benedril	C	Not Reported
	Baby Aspirin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	10777637	NON-EXPEDITED			US-PFIZER INC-2015047139		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Xanax			S		Unk		Pfizer
	Estradiol			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13083159	EXPEDITED (15-DAY)		DS, HO, LT	SE-CIPLA LTD.-2016SE24278			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Muscle Spasms	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13083342	EXPEDITED (15-DAY)		OT	SE-CIPLA LTD.-2016SE24326			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inhibitory Drug Interaction	Escitalopram			S	Unknown	Unk		Invagen
	Corsodyl 1 %			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13083893	EXPEDITED (15-DAY)		OT	FR-ROCHE-1873603		4 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Developmental Delay; Foetal Exposure During Pregnancy; Speech Disorder	Rivotril			S	Transplacental			Not Reported
	Seroplex			S	Transplacental			Not Reported
	Stilnox			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13084314	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2016GSK193561		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Ethanol			S	Oral			Glaxosmithkline
	Clonazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13084318	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2016GSK194052		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Duloxetine			S	Oral			Glaxosmithkline
	Bupropion			S	Oral			Glaxosmithkline
	Escitalopram			S	Oral			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13084805	EXPEDITED (15-DAY)		HO, LT	IT-TEVA-2010005656		63 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depressed Level Of Consciousness; Musculoskeletal Stiffness; Rhabdomyolysis; Tremor	Carbolithium	S	Oral	900 Milligram Daily;		Barr
	Carbolithium	S	Oral			Barr
	Zyprexa	S	Oral	10 Milligram Daily;		Not Reported
	Zyprexa	S				Not Reported
	Cipralex	S	Oral	15 Milligram Daily;		Not Reported
	Lorazepam	C				Not Reported
	Bisoprololo	C				Not Reported
	Lansoprazolo	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13084886	EXPEDITED (15-DAY)		OT	FR-SA-2017SA000752		4 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Developmental Delay; Foetal Exposure During Pregnancy; Speech Disorder	Stilnox			S	Transplacental			Not Reported
	Seroplex			S	Transplacental			Not Reported
	Rivotril			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13085394	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20170100166		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Tramadol			S	Oral			Not Reported
	Baclofen			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Hydrocodone/Acetaminophen			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13086088	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1700119US		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Overdose; Pregnancy; Premature Labour	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Qd		Allergan
	Bupropion			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13086151	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2016M1058974			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolysis; Self-Medication	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2017	13087577	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2016-16141		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Respiratory Disorder Neonatal; Small For Dates Baby	Escitalopram 10 Mg			S	Transplacental	10 Mg, Once A Day		Aurobindo
	Folsaeure			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2017	13088860	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2016M1058714			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Metformin			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Vildagliptin			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2017	13088897	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1700292US		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Premature Baby; Respiratory Disorder Neonatal; Small For Dates Baby	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Folsaeure			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2017	13089156	EXPEDITED (15-DAY)		HO	IT-TEVA-725022ACC		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolysis; Self-Medication	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2017	13089791	EXPEDITED (15-DAY)		HO, LT, OT	US-ALLERGAN-1700298US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; C-Reactive Protein Increased; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Necrosis; Haematochezia; Hypertonia; Hypocalcaemia; Hypoglycaemia; Hyponatraemia; Hypothermia; Irritability; Leukopenia; Necrotising Colitis; Pneumatosis; Polycythaemia; Thrombocytopenia; Tremor; Vomiting	Escitalopram Oxalate - Bp			S	Transplacental	30 Mg, Qd		Allergan
	Bupropion			S	Transplacental	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2017	13090186	EXPEDITED (15-DAY)		OT	FR-ANIPHARMA-2017-FR-000002		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Risperidone (Non-Specific)			S	Unknown			Not Reported
	Vildagliptin			S				Not Reported
	Escitalopram			S				Not Reported
	Metformin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13070960	EXPEDITED (15-DAY)		HO, LT, OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-130339		19 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hypoglycaemia; Intentional Overdose; Respiratory Rate Increased; Suicidal Ideation; Suicide Attempt	Clonazepam			S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram And Tablet Clonazepam		Sun
	Clonazepam			S	Oral	Unk Unk, Qd		Sun
	Escitalopram			S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam		Not Reported
	Escitalopram			S	Oral	Unk Unk, Qd		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Venlafaxine			S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13083902	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20161226465		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Famotidine		Y	S	Oral			Not Reported
	Famotidine			S	Oral			Not Reported
	Cetirizine		Y	S	Oral			Not Reported
	Cetirizine			S	Oral			Not Reported
	Doxepin			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Hydrocodone			S	Oral			Not Reported
	Olmesartan			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13091877	EXPEDITED (15-DAY)		OT	IT-TEVA-726426ACC		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Poisoning; Sopor	Simvastatin			S	Oral			Ivax
	Simvastatin			S	Oral			Ivax
	Aspirina - Bayer S.P.A.			S				Not Reported
	Rivotril - Roche S.P.A.			S	Oral			Not Reported
	Rivotril - Roche S.P.A.			S				Not Reported
	Igroton - Amdipharm Ltd			S	Oral			Not Reported
	Igroton - Amdipharm Ltd			S				Not Reported
	Deursil - Cheplapharm Arzneimittel Gmbh			S	Oral			Not Reported
	Deursil - Cheplapharm Arzneimittel Gmbh			S				Not Reported
	Torvast - Pfizer Limited			S	Oral			Not Reported
	Torvast - Pfizer Limited			S				Not Reported
	Entact - H. Lundbeck A/S			S	Oral			Not Reported
	Entact - H. Lundbeck A/S			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13091999	EXPEDITED (15-DAY)		DE	US-JNJFOC-20161226353		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Ibuprofen		Y	S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13092219	EXPEDITED (15-DAY)		DE	US-JNJFOC-20161226577		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Diphenhydramine		Y	S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13092284	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20161226578		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Diphenhydramine		Y	S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13093578	EXPEDITED (15-DAY)		DE, OT	US-JNJFOC-20170100749			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest; Cardiac Disorder; Death; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Domperidone		S	Unknown	Not Reported
	Domperidone		S	Unknown	Not Reported
	Domperidone		S	Unknown	Not Reported
	Domperidone		S	Unknown	Not Reported
	Domperidone		S	Unknown	Not Reported
	Domperidone		S	Unknown	Not Reported
	Domperidone		S	Unknown	Not Reported
	Domperidone		S	Unknown	Not Reported
	Domperidone		S	Unknown	Not Reported
	Levofloxacin		S	Unknown	Not Reported
	Risperidone		S	Unknown	Not Reported
	Droperidol		S	Unknown	Not Reported
	Itraconazole		S	Unknown	Not Reported
	Ketoconazole		S	Unknown	Not Reported
	Miconazole	Y	S	Unknown	Not Reported
	Miconazole	Y	S	Unknown	Not Reported
	Tetracycline		S	Unknown	Not Reported
	Fluconazole	Y	S	Unknown	Not Reported
	Haloperidol		S	Unknown	Not Reported
	Lapatinib		S	Unknown	Not Reported
	Diltiazem		S	Unknown	Not Reported
	Metronidazole		S	Unknown	Not Reported
	Aprepitant		S	Unknown	Not Reported
	Nicardipine		S	Unknown	Not Reported
	Norfloxacin		S	Unknown	Not Reported
	Sertraline		S	Unknown	Not Reported
	Verapamil		S	Unknown	Not Reported
	Voriconazole		S	Unknown	Not Reported
	Clarithromycin		S	Unknown	Not Reported

Amiodarone	S	Unknown	Not Reported
Isoniazid	S	Unknown	Not Reported
Cyclosporine	S	Unknown	Not Reported
Erythromycin	S	Unknown	Not Reported
Desipramine	S	Unknown	Not Reported
Clotrimazole	S	Unknown	Not Reported
Lidocaine	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Ibutilide	S	Unknown	Not Reported
Fluoxetine	S	Unknown	Not Reported
Imipramine	S	Unknown	Not Reported
Azithromycin	S	Unknown	Not Reported
Methadone	S	Unknown	Not Reported
Moxifloxacin	S	Unknown	Not Reported
Nortriptyline	S	Unknown	Not Reported
Octreotide	S	Unknown	Not Reported
Ondansetron	S	Unknown	Not Reported
Perflutren	S	Unknown	Not Reported
Propafenone	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Ranolazine	S	Unknown	Not Reported
Citalopram	S	Unknown	Not Reported
Sotalol	S	Unknown	Not Reported
Clindamycin	S	Unknown	Not Reported
Desipramine	S	Unknown	Not Reported
Ciprofloxacin	S	Unknown	Not Reported
Doxepin	S	Unknown	Not Reported
Dronedarone	S	Unknown	Not Reported
Tacrolimus	S	Unknown	Not Reported

	Flecainide	S	Unknown	Not Reported
	Amitriptyline	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13093854	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1700386US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Crying; Electrocardiogram Qt Prolonged; Foetal Exposure During Pregnancy; High-Pitched Crying; Hypertonia; Hypopnoea; Irritability; Lethargy; Meconium Aspiration Syndrome; Posturing; Seizure; Tachycardia; Toxicity To Various Agents; Umbilical Cord Around Neck	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13096987	DIRECT		OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Condition Aggravated; Depression; Drug Ineffective; Product Substitution Issue	Escitalopram 10 Mg			S	Oral	Quantity:1 Tablet(S); Daily; Oral		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2017	13095154	EXPEDITED (15-DAY)		OT	FR-ZYDUS-013270		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Metformin			S	Unknown			Zydus Pharm

	Risperidone	S	Unknown	Zydus Pharm
	Escitalopram	S	Unknown	Zydus Pharm
	Vildagliptin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	13096153	EXPEDITED (15-DAY)		DS, HO, OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-121894			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Dystonia; Restlessness; Tardive Dyskinesia	Escitalopram Basics 10 Mg Filmtabletten			S	Unknown	1/2-0-1/2		Not Reported
	Escitalopram Basics 10 Mg Filmtabletten			S	Unknown	1-0-1/2		Not Reported
	Escitalopram Basics 10 Mg Filmtabletten			S	Unknown	1-0-0		Not Reported
	Citalopram Basics			S	Oral	15 Mg		Sun
	Risperidon Atid Fta			S	Unknown	Up To 4 Mg		Not Reported
	Melperon Aristo			S	Unknown	Unk		Not Reported
	Quetiapine			C	Unknown	Unk		Not Reported
	Olanzapine			C	Unknown	Unk		Not Reported
	Mirtazapine			C	Unknown	Unk		Not Reported
	Akineton			C	Unknown	Unk		Not Reported
	Parkopan			C	Unknown	Unk		Not Reported
	Dociton			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Folgamma			C	Unknown	Unk		Not Reported
	Tetmodis			C	Unknown	Unk		Not Reported
	Biolin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	13097987	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017GSK001151			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Wellbutrin			S				Glaxosmithkline
	Lexapro			S				Not Reported
	Zoloft			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	9893763	EXPEDITED (15-DAY)		OT	CA-FRI-1000054196		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anxiety; Feeling Jittery; Hallucination; Hyperhidrosis; Hypervigilance; Injury; Middle Insomnia; Mood Altered; Restlessness; Tremor; Vomiting	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S				Allergan
	Cymbalta			S	Oral	60 Mg, Qd		Not Reported
	Cymbalta			S				Not Reported
	Asa			C		325 Mg, Qd		Not Reported
	Atenolol			C		25 Mg, Qd		Not Reported
	Dronedarone			C		400 Mg, Qd		Not Reported
	Percocet			C		Unk Unk, Tid		Not Reported
	Synthroid			C		.1 Mg, Qd		Not Reported
	Zopiclone			C		7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	11850406	EXPEDITED (15-DAY)		HO	FR-FRI-1000081668		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemarthrosis	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Plavix			S	Oral	75 Mg, Qd		Not Reported
	Atorvastatin			C	Unknown	50 Mg, Bid		Not Reported
	Atacand			C	Unknown	8 Mg, Qd		Not Reported
	Stresam			C	Unknown	1 Df, Bid		Not Reported
	Lyrica			C	Unknown	25 Mg, Tid		Not Reported
	Zyprexa			C	Unknown	5 Mg, Qd		Not Reported

	Levothyrox	C	Unknown	50 Mg, Qd	Not Reported
	Theralene	C	Unknown	5 Mg, Qd	Not Reported
	Zymad	C	Oral	80000 Iu, Q Month	Not Reported
	Dafalgan	C	Unknown	500 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	12496097	EXPEDITED (15-DAY)		OT	DE-CIPLA LTD.-2016DE08123			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Gambling; Nicotine Dependence; Suicide Attempt; Theft	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Quetiapine			S	Unknown	Unk		Not Reported
	Ropinirole			S	Unknown	Unk		Not Reported
	Ropinirole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	12918075	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1674835US		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Plavix			S	Oral	75 Mg, Qd		Not Reported
	Kardegic			S	Oral	Unk		Not Reported
	Seresta			C		10 Mg, Bid		Not Reported
	Pantoprazole			C		20 Mg, Qd		Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Folinoral			C		5 Mg, Qd		Not Reported
	Duphalac			C		Unk		Not Reported
	Dexeryl (Glycerol And White Soft Paraffin And Liquid Paraffin)			C		Unk		Not Reported
	Simvastatin			C		40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	13086153	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1058947			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Poisoning; Sopor	Simvastatin			S	Oral	14 Df, Once		Not Reported
	Simvastatin			S		20 Df, Once		Not Reported
	Acetylsalicylic Acid			S		Unk		Not Reported
	Rivotril			S	Oral	10 Ml, Total		Mylan
	Igroton			S	Oral	15 Df, Total		Mylan
	Deursil			S	Oral	10 Df, Total		Mylan
	Torvast			S	Oral	8 Df, Total		Mylan
	Entact			S	Oral	28 Df, Total		Mylan
	Aspirina			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	13091008	EXPEDITED (15-DAY)		HO, LT, OT	IN-ACCORD-047140		19 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hypoglycaemia; Intentional Overdose; Respiratory Rate Increased; Suicidal Ideation; Suicide Attempt	Clonazepam			S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam		Accord
	Escitalopram			S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam		Accord
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	13100986	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2017SE00880		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Quetiapine			S	Oral			Zeneca
	Venlafaxine			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Sodium Valproate			S	Unknown			Not Reported
	Sodium Valproate			S	Unknown	Doubled Dose		Not Reported
	Trazodone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	13101079	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2017008938		43 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Intentional Overdose; Somnolence; Suicide Attempt	Alprazolam			S	Oral	Unknown		Pfizer
	Mirtazapine			S	Oral	Unknown		Not Reported
	Lamotrigin			S	Oral	Unknown		Not Reported
	Escitalopram			S	Oral	Unknown		Not Reported
	Ergometrin Lek			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	13102985	EXPEDITED (15-DAY)		HO	FR-SA-2017SA002932		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Allopurinol			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported

	Stilnox	S	Oral	Not Reported
	Xatral	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Levothyrox	S	Oral	Not Reported
	Keppra	S	Oral	Not Reported
	Acetylcysteine	S	Oral	Not Reported
	Solumedrol	S	Intravenous (not otherwise specified)	Not Reported
	Erbitux	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	12390763	EXPEDITED (15-DAY)		HO	BR-DSJP-DSE-2016-116525			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Face Injury; Facial Bones Fracture; Fall; Insomnia; Rib Fracture; Sciatic Nerve Injury; Somnolence; Spinal Pain; Urinary Incontinence; Urinary Tract Infection; Weight Increased	Benicar 40 Mg Com Rev Ct Bl Al/Al X 30			S	Oral	40 Mg, Qd		Daiichi
	Scitalax 10 Mg Com Rev Ct Bl Al Plas Inc X 28			S	Oral	10 Mg, Qd		Not Reported
	Scitalax 10 Mg Com Rev Ct Bl Al Plas Inc X 28			S				Not Reported
	Lantus			C		Unk, Bid		Not Reported
	Janumet			C	Oral	50/1000 Mg, Bid		Not Reported
	Higroton			C	Oral	0.5 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13027806	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2016578809		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Poisoning; Sopor	Torvast			S	Oral	8 Df, Total		Pfizer
	Aspirina			S	Oral	20 Df, Total		Not Reported
	Simvastatin			S	Oral	14 Df, Total		Not Reported

Rivotril	S	Oral	10 Ml, Total		Not Reported
Entact	S	Oral	28 Df, Total		Not Reported
Deursil	S	Oral	10 Df, Total		Not Reported
Igroton	S	Oral	15 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13031019	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1680300US		32 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Pregnancy	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13087461	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-130777		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Poisoning; Sopor	Simvastatin			S	Unknown	14 Df, Total		Sun
	Aspirina			S	Unknown			Not Reported
	Rivotril			S	Oral	10 Ml, Total		Not Reported
	Entact			S	Oral	28 Df, Total		Not Reported
	Torvast			S	Oral	8 Df, Total		Not Reported
	Deursil			S	Oral	10 Df, Total		Not Reported
	Igroton			S	Oral	15 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13103684	EXPEDITED (15-DAY)		HO	US-ACCORD-047274			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Hypertonia; Hypoglycaemia; Hypothermia; Irritability; Maternal Drugs Affecting Foetus; Necrotising Enterocolitis Neonatal; Tremor	Escitalopram		S	Transplacental	Accord
	Bupropion/Bupropion Hydrochloride		S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13104115	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP005411		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besylate			S	Oral	Unk		Apotex
	Amlodipine Besylate			S	Parenteral	Unk		Apotex
	Enalapril			S	Oral	Unk		Apotex
	Enalapril			S	Parenteral	Unk		Apotex
	Escitalopram Oxalate			S	Oral	Unk		Apotex
	Escitalopram Oxalate			S	Parenteral	Unk		Apotex
	Tamsulosin			S	Oral	Unk		Not Reported
	Tamsulosin			S	Parenteral	Unk		Not Reported
	Insulin			S	Oral	Unk		Not Reported
	Insulin			S	Parenteral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13104305	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US000192		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Ibuprofen			S	Oral	Unknown, Unknown		Perrigo
	Oxycodone			S	Oral	Unknown, Unknown		Not Reported
	Escitalopram			S	Oral	Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13104469	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP005252		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Tramadol Hydrochloride			S	Oral			Apotex
	Clonazepam Tablets Usp			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Alprazolam			S	Oral			Apotex
	Baclofen			S	Oral			Not Reported
	Acetaminophen W/Hydrocodone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13105880	EXPEDITED (15-DAY)		HO, OT	FR-UCBSA-2017001177			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Keppra			S	Oral	500 Mg, 2x/Day (Bid), 500 Mg In The Morning And In The Evening		Ucb
	Erbitux			S	Intravenous (not otherwise specified)	Unk Unk, Ev 2 Weeks(Qow)		Not Reported
	Solumedrol			S	Intravenous (not otherwise specified)	Unk Unk, Ev 2 Weeks(Qow)		Not Reported
	Acetylcysteine			S	Oral	200 Mg, 2x/Day (Bid)		Not Reported
	Allopurinol			S	Oral	200 Mg, Once Daily (Qd)		Not Reported
	Levothyrox			S	Oral	50 Mg, Once Daily (Qd)		Not Reported
	Metformine			S	Oral	500 Mg, 2x/Day (Bid)		Not Reported
	Seroplex			S	Oral	10 Mg In The Morning, 10 Mg, Once Daily (Qd)		Not Reported
	Stilnox			S	Oral	10 Mg In The Evening, 10 Mg, Once Daily (Qd)		Not Reported
	Alfuzosin Hydrochloride			S	Oral	Strength-10 Mg, 10 Mg,		Not Reported

	Omeprazole			C		Once Daily (Qd) Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13106149	NON-EXPEDITED			US-PFIZER INC-2017008850		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Insomnia; Pain; Peripheral Swelling; Weight Increased	Lyrica			S		50 Mg, Once Daily		Pfizer
	Lyrica			S		75 Mg, Unk		Pfizer
	Lyrica			S		100 Mg, Unk		Pfizer
	Klonopin			S	Oral	1 Mg, 3x/Day		Not Reported
	Klonopin			S				Not Reported
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported
	Osphena			C		60 Mg, Unk		Not Reported
	Nortriptyline			C		25 Mg, Once A Day (At Night)		Not Reported
	Flexeril			C		Unk		Not Reported
	Treximet			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13106516	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1701047US		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Respiratory Distress; Toxicity To Various Agents	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	9 Df, Single		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13106517	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1701048US		4 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Behaviour Disorder; Developmental Delay; Speech Disorder	Escitalopram Oxalate Unk		S	Transplacental	Allergan
	Rivotril		S	Transplacental	Not Reported
	Stilnox		S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13106640	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1701049US		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning Deliberate; Toxicity To Various Agents	Escitalopram Oxalate Unk			S	Oral	28 Df, Single		Allergan
	Bromazepam			S	Oral	30 Df, Single		Not Reported
	Metformine			S	Oral	15 Df, Single		Not Reported
	Diamicron			C	Unknown	Unk, Tid		Not Reported
	Stilnox			C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13106670	EXPEDITED (15-DAY)		DE	IE-ALLERGAN-1701058US		32 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Stillbirth	Escitalopram Oxalate Unk			S	Transplacental	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13106699	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1701077US		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Erbitux			S	Intravenous (not otherwise specified)			Not Reported
	Solumedrol			S	Intravenous (not otherwise specified)			Not Reported
	Acetylcysteine			S	Oral			Not Reported

	Allopurinol	S	Oral		Not Reported
	Keppra	S	Oral		Not Reported
	Levothyrox	S	Oral		Not Reported
	Metformine	S	Oral		Not Reported
	Stilnox	S	Oral		Not Reported
	Xatral Lp	S	Oral		Not Reported
	Omeprazole	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13106739	EXPEDITED (15-DAY)		DE	US-ABBVIE-17P-163-1836436-00		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen/Hydrocodone			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Baclofen			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13107449	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2016004162			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolysis; Self-Medication	Escitalopram			S	Unknown	Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13107637	EXPEDITED (15-DAY)		HO	US-ACCORD-047272			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Foetal Exposure During Pregnancy; High-Pitched Crying; Hypertonia; Irritability; Pupil Fixed; Seizure	Escitalopram		S	Transplacental	20 Mg Throughout Pregnancy	Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13108836	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1701171US		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Prazepam			S	Oral	10 Mg, Qd		Not Reported
	Seresta			S	Oral	Unk		Not Reported
	Ipraalox			S	Oral	Unk		Not Reported
	Ginkgo			S	Oral	Unk		Not Reported
	Alcool			S	Oral	Unk		Not Reported
	Menophytes			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13109170	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2017LAN000027		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Baclofen (20mg) Lannett Company, Inc.			S	Oral	Unk		Lannett
	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Tramadol			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Acetaminophen W/Hydrocodone			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13109172	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP005290		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besylate			S	Oral	Ingestion + Unknown		Apotex
	Escitalopram Oxalate			S	Oral	Ingestion + Unknown		Apotex
	Ethanol			S	Oral	Ingestion + Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13109227	EXPEDITED (15-DAY)		OT	FR-TEVA-728019ISR		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Risperidone			S	Unknown			Pliva
	Escitalopram			S	Unknown			Ivax
	Metformin			S	Unknown			Not Reported
	Vildagliptin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13110327	DIRECT					22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Cetrizine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13111183	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US000379		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Famotidine			S	Oral	Unk		Perrigo
	Cetirizine Hydrochloride			S	Oral	Unk		Perrigo

Doxepin	S	Oral	Unk		Not Reported
Escitalopram	S	Oral	Unk		Not Reported
Hydrocodone	S	Oral	Unk		Not Reported
Olmesartan	S	Oral	Unk		Not Reported
Alprazolam	S	Oral	Unk		Not Reported
Hydrochlorothiazide	S	Oral	Unk		Not Reported
Pregabalin	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	12285930	EXPEDITED (15-DAY)		DE, HO, OT	IE-009507513-1604IRL011222		63 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Blood Test Abnormal; Coagulopathy; Completed Suicide; Contusion; Contusion; Electrocardiogram Abnormal; Electrocardiogram St Segment Elevation; Fall; Fall; Fear; Fear Of Death; Haemorrhage; Head Injury; Hepatic Enzyme Abnormal; Hyponatraemia; Negative Thoughts; Panic Reaction; Withdrawal Syndrome	Zispin			S	Unknown	15 Mg, Unknown		Merck
	Zispin			S	Unknown	Total Daily Dose 30 Mg		Merck
	Lexapro			S		Unk		Not Reported
	Sertraline Hydrochloride			S		100 Mg		Not Reported
	Sertraline Hydrochloride			S		100 Mg		Not Reported
	Sertraline Hydrochloride			S		50 Mg		Not Reported
	Solpadeine (Acetaminophen\Caffeine\Codeine Phosphate)			C		Paracetamol 500mg, Cod 500/30/8 Milligram		Not Reported
	Temazepam			C		20 Mg		Not Reported
	Diazepam			C		5 Mg, Reducing Dose		Not Reported
	Diazepam			C		2 Mg		Not Reported
	Sudafed			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	12941895	EXPEDITED (15-DAY)		DS, HO	PT-ALLERGAN-1675711US		64 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

Increased; Chronic Kidney Disease; Flight Of Ideas; Gamma-Glutamyltransferase Increased; Hallucination, Visual; Insomnia; Major Depression; Mania; Psychomotor Hyperactivity; Tachyphrenia	Adt (Amitriptyline)	S		25 Mg, Qd	Not Reported
	Levofloxacina	S	Oral		Not Reported
	Zilpen	S	Oral		Not Reported
	Zyloric	C	Oral	300 Mg, Qd	Not Reported
	Zyloric	C	Oral		Not Reported
	Kainever	C	Oral	2 Mg, Qd	Not Reported
	Amlodipina	C	Oral	5 Mg, Qd	Not Reported
	Amlodipina	C	Oral		Not Reported
	Enalapril	C	Oral	20 Mg, Qd	Not Reported
	Enalapril	C	Oral		Not Reported
	Propranolol	C	Oral	80 Mg, Qd	Not Reported
	Furosemida	C	Oral	20 Mg, Qd	Not Reported
	Furosemida	C	Oral		Not Reported
	Adalgur N	C	Oral	1 Df, Q8hr	Not Reported
	Domperidona	C	Oral		Not Reported
	Cipralex Film-Coated Tablets	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13107524	EXPEDITED (15-DAY)		HO	IT-ACCORD-047287		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Retching	Escitalopram			S	Oral	10 Mg 10 Dosage Form		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13112371	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2017-00205		33 YR	Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Retching	Escitalopram Film-Coated Tablets 10mg			S	Oral	100 Mg, Total		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13114380	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1701270US		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Aneurysm; Asthenia; Cytomegalovirus Infection; Decreased Appetite; Epstein-Barr Virus Infection; Febrile Bone Marrow Aplasia; General Physical Condition Abnormal; Lung Disorder; Pancytopenia; Systemic Inflammatory Response Syndrome	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Tavanic			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Ofloxacine			C		Unk		Not Reported
	Norfloxacine			C		Unk		Not Reported
	Amoxicilline			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13115024	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1701423US		20 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Off Label Use; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Ingested 18 Tablets		Allergan
	Insulin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13115048	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1701484US		29 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Extrapyramidal Disorder	Escitalopram Oxalate Unk			S	Oral	10 Mg, Unk		Allergan
	Clopixol			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Temesta Expidet			C	Unknown			Not Reported

	Valium			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13115176	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2017GSK003970		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Electrocardiogram Qt Prolonged; Therapy Non-Responder	Olanzapine			S				Glaxosmithkline
	Iloperidone			S				Not Reported
	Bupropion			S				Glaxosmithkline
	Escitalopram			S				Glaxosmithkline
	Amitriptyline			S				Glaxosmithkline
	Mirtazapine			S				Not Reported
	Lorazepam			S				Glaxosmithkline
	Alprazolam			S				Not Reported
	Quetiapine			C		50 Mg, At Bedtime		Not Reported
	Clonazepam			C		1 Mg, Bid		Not Reported
	Trazodone			C		50 Mg, At Bedtime		Not Reported
	Warfarin			C		6 Mg, Qd		Not Reported
	Propranolol			C		160 Mg, Qd		Not Reported
	Methimazole			C		30 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2017	13115961	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-091052		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	12940920	NON-EXPEDITED			US-JNJFOC-20161103436			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Dry Mouth; Gynaecomastia; Increased Appetite; Off Label Use; Product Use In Unapproved Indication; Somnolence	Risperdal			S	Oral	0.5 Mg To 1 Mg		Not Reported
	Risperdal			S	Oral	0.5 Mg To 1 Mg		Not Reported
	Abilify			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13056525	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1681965US		73 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Decreased; Pelvic Fracture; Rebound Effect; Spinal Fracture	Escitalopram Oxalate - Bp			S	Oral	0.5-0-0		Allergan
	Prolia			S	Subcutaneous	60 Mg, Q Month		Not Reported
	Prolia			S	Subcutaneous			Not Reported
	Pantoprazol Actavis			S	Oral			Not Reported
	Bekunis Bisacodyl			C	Oral	Unk Unk, Unknown		Not Reported
	Metoprolol			C	Oral			Not Reported
	Ponstan			C	Oral	Unk Unk, Unknown		Not Reported
	Ponstan			C		As Needed		Not Reported
	Simvastatin			C	Oral	Unk Unk, Unknown		Not Reported
	Targin			C	Oral	Unk Unk, Unknown		Not Reported
	Vi-De 3			C	Oral	Unk Unk, Unknown		Not Reported
	Vi-De 3			C	Oral			Not Reported
	Losartan			C	Oral	50 Mg, Unknown		Not Reported
	Lexotanil			C	Oral			Not Reported
	Lexotanil			C	Oral			Not Reported
	Kalcipos-D3			C	Oral	Unk Unk, Unknown		Not Reported
	Cipralex Tablets			S	Oral	0.5-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13116280	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-091154		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral			Not Reported
	Duloxetine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13116475	EXPEDITED (15-DAY)		HO	US-HETERO LABS LTD-1062035			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Necrotising Enterocolitis Neonatal	Escitalopram			S	Transplacental			Hetero
	Bupropion			C	Transplacental			Not Reported
	Ampicillin Sodium			C	Transplacental			Not Reported
	Gentamicin			C	Transplacental			Not Reported
	Vancomycin Hcl			C	Transplacental			Not Reported
	Metronidazole			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13116609	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-091173		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported
	Dexamfetamine			S	Oral			Not Reported
	Amfetamine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13117226	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2017LAN000309		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S		Unk		Lannett
	Amlodipine			S		Unk		Not Reported
	Ethanol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13117229	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2017LAN000308		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Diphenhydramine Hydrochloride			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13117232	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2017LAN000307		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Duloxetine			S	Oral	Unk		Not Reported
	Bupropion			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13117240	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2017LAN000310		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate	S	Unk	Lannett
	Amlodipine	S	Unk	Not Reported
	Enalapril	S	Unk	Not Reported
	Tamsulosin	S	Unk	Not Reported
	Insulin	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13117654	EXPEDITED (15-DAY)		OT	HR-GLAXOSMITHKLINE-HR2017002042		43 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Intentional Overdose; Somnolence; Suicide Attempt	Lamotrigine			S	Oral	Unknown		Glaxosmithkline
	Escitalopram			S	Oral	Unknown		Glaxosmithkline
	Mirtazapine			S	Oral	Unknown		Not Reported
	Ergometrin (Ergometrine Maleate)			S	Oral	Unknown		Not Reported
	Alprazolam			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13118877	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1701650US		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hospitalisation	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13119277	EXPEDITED (15-DAY)		DE	US-LEHIGH_VALLEY-USA-POI0580201700028		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone Hcl Capsules			S				Lehigh Valley Tech
	Escitalopram			S				Not Reported
	Ibuprofen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13119461	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-001857			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Metformin Hydrochloride			S	Oral	500 Mg, Bid		Bristol Myers Squibb
	Erbitux			S	Intravenous (not otherwise specified)	Unk, Q2wk		Not Reported
	Levothyrox			S	Oral	50 Mg, Qd		Not Reported
	Solumedrol			S	Intravenous (not otherwise specified)	Unk, Q2wk		Not Reported
	Acetylcysteine			S	Oral	200 Mg, Bid		Not Reported
	Allopurinol			S	Oral	200 Mg, Qd		Not Reported
	Keppra			S	Oral	500 Mg, Bid		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Stilnox			S	Oral	10 Mg, Unk		Not Reported
	Xatral			S	Oral	10 Mg, Qd		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	12771571	EXPEDITED (15-DAY)		DE, HO	FR-FRI-1000087591		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Anuria; Bradycardia; Cardiogenic Shock; Intentional Overdose; Multiple Organ Dysfunction Syndrome	Escitalopram Oxalate Unk			S	Oral	70 Tablets		Allergan
	Propranolol Hcl Unk			S	Oral	110 Tablets		Allergan
	Doliprane			S	Oral	7 G, Unk		Not Reported
	Alprazolam			S	Oral	100 Tablets		Not Reported
	Prazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13087349	EXPEDITED (15-DAY)		HO	IN-CIPLA LTD.-2016IN24348			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hypoglycaemia; Intentional Overdose; Suicidal Ideation; Suicide Attempt	Escitalopram			S	Unknown	Unk Unk, Qd		Invagen
	Escitalopram			S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam		Invagen
	Venlafaxine			S	Unknown	Unk, Qd		Not Reported
	Venlafaxine			S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam		Not Reported
	Clonazepam			S	Unknown	Unk, Qd		Not Reported
	Clonazepam			S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13119980	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP005124		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion Hydrochloride			S	Oral			Apotex
	Clonazepam Tablets Usp			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex
	Amfetamine W/Dexamfetamine			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13120073	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP005360		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral			Apotex
	Oxycodone			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13120096	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000292		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Alfuzosin Extended-Release Tablet 10 Mg			S	Oral			Concordia
	Allopurinol			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Acetylcysteine			S	Oral			Not Reported
	Solumedrol			S	Intravenous (not otherwise specified)	Every Cycle		Not Reported
	Erbitux			S	Intravenous (not otherwise specified)	Every Cycle		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13120141	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP005487		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral			Apotex
	Alprazolam			S	Oral			Apotex

Hydrochlorothiazide	S	Oral		Apotex
Famotidine Tablets Usp	S	Oral		Apotex
Cetirizine Hydrochloride Tablets	S	Oral		Apotex
Doxepin	S	Oral		Not Reported
Hydrocodone	S	Oral		Not Reported
Olmesartan	S	Oral		Not Reported
Pregabalin	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13120145	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP005466		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Duloxetine Hydrochloride Delayed-Release Capsules			S	Oral			Apotex
	Bupropion Hydrochloride			S	Oral			Apotex
	Escitalopram Oxalate			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13120149	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP005458		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S	Oral			Apotex
	Amitriptyline			S	Oral			Not Reported
	Diphenhydramine			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13122332	EXPEDITED (15-DAY)		DE, OT	US-MYLANLABS-2017M1002100			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Failure; Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Ondansetron		S	Transplacental	Not Reported
	Sertraline		S	Transplacental	Not Reported
	Escitalopram		S	Transplacental	Not Reported
	Progesterone		S	Transplacental	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13122333	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2017M1002099			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Human Herpesvirus 6 Infection; Maternal Exposure During Pregnancy	Ondansetron			S	Unknown			Not Reported
	Sertraline			S	Unknown	Drug Was Administered For First Two Trimesters.		Not Reported
	Escitalopram			S	Unknown	Was Administered In The Last Trimester		Not Reported
	Progesterone			S	Unknown	Initiated From Week 16		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13123156	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1701795US		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby; Temperature Regulation Disorder	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg/D Until Week 24+3 And From Unknown Date Then 10mg/D Untildelivery		Allergan
	Fluoxetine			C	Transplacental			Not Reported
	Elevit			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13123625	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017004203			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby; Temperature Regulation Disorder	Escitalopram			S	Transplacental	10 Mg, Qd (From Gw18.6 Until Week 24+3 (2 Trimester)		Macleods
	Escitalopram			S	Transplacental	5 Mg, Qd		Macleods
	Escitalopram			S	Transplacental	10 Mg, Qd (Until Delivery At Gw 39)		Macleods
	Fluoxetin			C	Transplacental	20 Mg, Qd (First Trimester)(0- 14.6 Gw)		Not Reported
	Eelvit			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	12696443	EXPEDITED (15-DAY)		HO	FR-UCBSA-2016032839		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Xyzall			S	Oral	Unk		Ucb
	Seroplex			S	Oral	5 Mg, Once Daily (Qd)		Not Reported
	Esomeprazole			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Alprazolam			S	Oral	0.5 Mg, Once Daily (Qd)		Not Reported
	Amlor			C	Oral	5 Mg, Once Daily (Qd)		Not Reported
	Aprovel			C	Oral	300 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13124042	EXPEDITED (15-DAY)		OT	CZ-ACCORD-047482		54 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sexual Dysfunction	Escitalopram			S				Accord
	Sertraline			S				Accord
	Warfarin			C				Not Reported
	Zolpidem			C				Not Reported
	Agomelatine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13124578	EXPEDITED (15-DAY)		CA, DE	PHHY2017US004336		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Hypersensitivity; Multiple Organ Dysfunction Syndrome	Ondansetron			S	Transplacental			Novartis
	Sertraline			S	Transplacental			Not Reported
	Progesterone			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13125508	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2017LAN000138		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Oxycodone Hydrochloride			S	Oral	Unk		Lannett
	Escitalopram			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13125586	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2017LAN000298		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Doxepin Hydrochloride			S	Oral	Unk		Lannett
	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Hydrochlorothiazide (50mg)			S	Oral	Unk		Lannett
	Cetirizine Hydrochloride			S	Oral	Unk		Lannett
	Hydrocodone			S	Oral	Unk		Not Reported

Olmesartan	S	Oral	Unk		Not Reported
Alprazolam	S	Oral	Unk		Not Reported
Famotidine	S	Oral	Unk		Not Reported
Pregabalin	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13126990	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1701941US		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antipsychotic Drug Level Increased; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	2 Blister Packs		Allergan
	Teralithe			S	Oral	2 Blister Packs		Not Reported
	Teralithe			S	Oral	400 Mg, Tid		Not Reported
	Tercian			C	Unknown	25 Mg, Prn		Not Reported
	Alprazolam			C	Unknown	0.25 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13127043	EXPEDITED (15-DAY)		OT	DE-TEVA-728609GER		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby; Temperature Regulation Disorder	Escitalopram			S	Transplacental	10 (Mg/D)/ Until Week 24 And 3: 5mg/D, Then 10mg/D Until Delivery		Ivax
	Fluoxetin			C	Transplacental	20 Milligram Daily;		Not Reported
	Elevit			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13127656	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1701942US		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Chills; Drug Intolerance; Serotonin	Escitalopram Oxalate - Bp			S	Oral			Allergan

Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13128331	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1701890US		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Cellulitis; Depression; Electrolyte Imbalance; Hypertension; Hyponatraemia	Lexapro			S	Unknown			Allergan
	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported
	Humira			S				Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13128430	EXPEDITED (15-DAY)		DE	US-ARBOR PHARMACEUTICALS, LLC-US-2017ARB000013		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amphetamine Sulfate			S	Oral	Unk		Arbor
	Bupropion			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13128857	EXPEDITED (15-DAY)		HO	SE-CIPLA LTD.-2017SE00693			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lethargy; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Sobril			S	Oral	Unk		Not Reported
	Imovane			S	Oral	Unk		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13129618	EXPEDITED (15-DAY)		OT	PHHY2017HR003566		43 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Intentional Overdose; Somnolence; Suicide Attempt	Ergometrin Lek			S	Oral			Not Reported
	Lamotrigine			S	Oral			Novartis
	Escitalopram			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13130312	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017GSK006759			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Depressed Mood; Diarrhoea; Drug Ineffective; Insomnia; Partner Stress; Psychomotor Hyperactivity	Wellbutrin Tablet			S		10 Mg, Qd		Glaxosmithkline
	Paxil Capsule			S		50 Mg, Qd		Glaxosmithkline
	Lexapro			S		10 Mg, Qd		Not Reported
	Zoloft			S		20 Mg, Unk		Not Reported
	Omeprazole			C		40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13130337	EXPEDITED (15-DAY)		DE, HO	US-TARO PHARMACEUTICALS USA.,INC-2017SUN00012		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congestive Cardiomyopathy; Drug Hypersensitivity; Foetal Exposure During Pregnancy; Human	Escitalopram			S	Transplacental	Unk		Taro
	Ondansetron Hydrochloride			S	Transplacental	Unk		Taro
	Progesterone			S	Transplacental	Unk		Not Reported
	Progesterone			S				Not Reported

Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Sertraline		S	Transplacental	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13131371	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1002775			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Small For Dates Baby; Temperature Regulation Disorder	Escitalopram			S	Transplacental	10 Mg, Qd		Not Reported
	Escitalopram			S	Transplacental	5 Mg, Unk		Not Reported
	Escitalopram			S		10 Mg, Qd		Not Reported
	Fluoxetin			C	Transplacental	20 Mg, Qd		Mylan
	Elevit /01730301/			C	Transplacental			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13131773	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2017NSR000065		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Tramadol Hydrochloride			S	Oral	Unk		Northstar
	Baclofen			S	Oral	Unk		Northstar
	Clonazepam			S	Oral	Unk		Not Reported
	Acetaminophen W/Hydrocodone			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13132873	DIRECT					25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort;	Generic Bactrim			S	Oral			Not Reported

Delusion; Drug Interaction; Headache; Night Sweats; Nightmare	Generic Lexapro		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13133217	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Product Substitution Issue	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	13132918	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP005886			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Exposure During Pregnancy; Human Herpesvirus 6 Infection	Ondansetron Hydrochloride Tablets Usp			S	Unknown	Unk		Apotex
	Sertraline Hydrochloride			S	Unknown	Unk		Apotex
	Escitalopram Oxalate			S	Unknown	Unk		Apotex
	Progesterone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	13132957	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP005888		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Ondansetron Hydrochloride Tablets Usp			S	Transplacental	Unk		Apotex
	Sertraline Hydrochloride			S	Transplacental	Unk		Apotex
	Escitalopram Oxalate			S	Transplacental	Unk		Apotex
	Progesterone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	13132988	EXPEDITED (15-DAY)		OT	HR-TEVA-729235ACC		43 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Intentional Overdose; Somnolence; Suicide Attempt	Mirtazapine			S	Oral	Unknown		Teva
	Escitalopram			S	Oral	Unknown		Not Reported
	Lamotrigin			S	Oral	Unknown		Not Reported
	Ergometrin Lek			S	Oral	Unknown		Not Reported
	Alprazolam			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	13133101	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201700552			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Human Herpesvirus 6 Infection; Product Use In Unapproved Indication	Progesterone Injection (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Ondansetron (Manufacturer Unknown)			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	13134124	EXPEDITED (15-DAY)		DE	US-EGALET US INC-US-2017EGA000051		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Oxycodone Hydrochloride			S	Oral	Unk		Egalet
	Escitalopram			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	13134648	EXPEDITED (15-DAY)		CA, DE, OT	US-FRESENIUS KABI-FK201700554		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congenital Cardiovascular Anomaly; Congestive Cardiomyopathy; Human Herpesvirus 6 Infection; Maternal Drugs Affecting Foetus; Multiple Organ Dysfunction Syndrome; Vertical Infection Transmission	Progesterone Injection (Manufacturer Unknown)			S	Transplacental			Fresenius Medical Care
	Ondansetron (Manufacturer Unknown)			S	Transplacental			Not Reported
	Sertraline			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	13135876	EXPEDITED (15-DAY)		HO, OT	FR-NORTHSTAR HEALTHCARE HOLDINGS-FR-2017NSR000093		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Anxiety; Depressive Symptom; Fatigue; Feeling Abnormal; Grandiosity; Insomnia; Logorrhoea; Mania; Prescribed Overdose; Psychomotor Hyperactivity; Tachyphrenia	Baclofen			S		60 Mg, Qd		Northstar
	Baclofen			S		Gradual Increase		Northstar
	Baclofen			S		270 Mg, Qd		Northstar
	Baclofen			S		240 Mg, Unk		Northstar
	Baclofen			S		210 Mg, Unk		Northstar
	Baclofen			S		180 Mg, Unk		Northstar
	Baclofen			S		150 Mg, Unk		Northstar
	Escitalopram			S		10 Mg, Unk		Not Reported
	Escitalopram			S		20 Mg, Unk		Not Reported
	Escitalopram			S		Decreased		Not Reported
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	9132152	EXPEDITED (15-DAY)		HO	DE-FRI-1000043006		47 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arrhythmia; Asthenia; Atrial Fibrillation; Blood Testosterone Decreased; Coronary Artery Disease; Depressed Level Of Consciousness; Diabetes Mellitus; Diffuse Alopecia; Disturbance In Attention; Dyslipidaemia; Glycosylated Haemoglobin Increased; Hormone Level Abnormal; Hyperhidrosis; Libido Disorder; Lipid Metabolism Disorder; Lipoprotein (A) Increased; Migraine; Mood Swings; Obesity; Restlessness; Seborrhoeic Dermatitis; Supraventricular Extrasystoles; Ventricular Extrasystoles; Weight Increased	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	2.5 Mg, Qd		Allergan
	Bisoprolol			C				Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Nebivolol			C				Not Reported
	Nebivolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	13136707	EXPEDITED (15-DAY)		OT	IN-CIPLA (EU) LIMITED-2017IN00837			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder	Escitalopram			S		5 Mg, Daily		Invagen
	Clonazepam			C		0.5 Mg, Nighttime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	13137210	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2017-01366		1 DAY	Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby; Temperature Regulation Disorder	Escitalopram			S	Transplacental	10 [Mg/D]I Until Week 24+3: 5mg/D, Then 10mg/D Until Delivery		Aurobindo
	Fluoxetine 20 Mg			S	Transplacental	20 Mg, Daily		Aurobindo
	Elevit /01730301/			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	13138992	EXPEDITED (15-DAY)		OT	US-TEVA-731851USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Human Herpesvirus 6 Infection	Ondansetron			S	Unknown			Teva
	Progesterone			S	Unknown	Initiated From Week 16		Teva
	Sertraline			S	Unknown	Drug Was Administered For First Two Trimesters.		Not Reported
	Escitalopram			S	Unknown	Was Administered In The Last Trimester		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	13139022	EXPEDITED (15-DAY)		CA, DE, OT	US-TEVA-731852USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Ondansetron			S	Transplacental			Teva
	Progesterone			S	Transplacental			Teva
	Sertraline			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	13140499	EXPEDITED (15-DAY)		HO, OT	IN-MYLANLABS-2017M1003268			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hypoglycaemia; Overdose; Suicidal Ideation; Suicide Attempt	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral	Once A Day		Not Reported
	Clonazepam			S	Oral	Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	13141327	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1702573US		37 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperchlorhydria; Nausea; Palpitations; Strangury	Escitalopram Oxalate Unk			S	Oral	10 Gtt, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	13142134	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017026209		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besilate			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13099496	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2017M1000774			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Overdose; Retching	Escitalopram			S	Oral	100 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13143862	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US01061			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Apathy; Drug Ineffective; Enuresis; Fatigue; Impulse-Control Disorder; Insomnia; Loss Of Consciousness; Memory Impairment; Substance Abuse; Treatment Noncompliance	Sertraline			S	Unknown	25 Mg, Qd, Every Morning		Invagen
	Sertraline			S	Unknown	25 Mg, Bid		Invagen
	Escitalopram			S	Unknown	20 Mg, Qd		Invagen
	Escitalopram			S				Invagen
	Bupropion			S	Unknown	Unk		Invagen
	Bupropion			S				Invagen
	Effexor Xr			S	Unknown	37.5 Mg, Qd		Not Reported
	Effexor Xr			S	Unknown	75 Mg, Qd		Not Reported
	Effexor Xr			S	Unknown	150 Mg, Qd		Not Reported
	Prozac			S	Unknown	Unk		Not Reported
	Prozac			S				Not Reported
	Alcohol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13144160	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017026230		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S	Oral	Unk		Pfizer
	Tramadol			S	Oral	Unk		Not Reported
	Baclofen			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Hydrocodone/Paracetamol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13144381	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017029270		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Propanolol Hcl			S	Oral	Unk		Unknown
	Gabapentin			S	Oral	Unk		Pfizer
	Ibuprofen			S	Oral	Unk		Pfizer
	Quetiapine			S	Oral	Unk		Not Reported
	Citalopram			S	Oral	Unk		Not Reported
	Acetaminophen			S	Oral	Unk		Not Reported
	Benztropine			S	Oral	Unk		Not Reported
	Trazodone			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13145340	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017028849		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Doxepin Hcl			S	Oral	Unk		Pfizer
	Alprazolam			S	Oral	Unk		Pfizer
	Pregabalin			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Hydrocodone			S	Oral	Unk		Not Reported
	Olmesartan			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Cetirizine			S	Oral	Unk		Not Reported
	Famotidine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13145589	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017026211		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Amlodipine Besilate	S	Unk		Pfizer
	Enalapril	S	Unk		Not Reported
	Escitalopram	S	Unk		Not Reported
	Tamsulosin	S	Unk		Not Reported
	Insulin	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13157693	DIRECT		DS			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Rash; Rash; Skin Lesion; Vulvovaginal Rash	Lexapro			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13089979	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1700416US		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Retching	Escitalopram Oxalate Unk			S	Oral	10 Mg, 10 Tablets		Allergan
	Escitalopram Tablets			S	Oral	The Patient Took 10 Tablets Of Escitalopram 10 Mg.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13146299	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2017-13213		22 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Overdose; Sopor	Escitalopram Film-Coated Tablets			S	Oral	400 Mg, Total		Aurobindo
	Depakin			S	Oral	3 G, Total		Not Reported
	Lexotan			S	Oral	25 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13147965	EXPEDITED (15-DAY)		CA, DE, OT	DE-LUPIN PHARMACEUTICALS INC.-2017-00390		4 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Infection; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Maternal Drugs Affecting Foetus; Neonatal Multi-Organ Failure	Escitalopram			S	Transplacental			Not Reported
	Sertraline			S	Transplacental			Not Reported
	Progesterone			S	Transplacental			Not Reported
	Ondansteron			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13147994	EXPEDITED (15-DAY)		OT	DE-LUPIN PHARMACEUTICALS INC.-2017-00391			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Human Herpesvirus 6 Infection	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Progesterone			S	Unknown			Not Reported
	Ondansetron			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13151969	EXPEDITED (15-DAY)		HO, OT	TR-MYLANLABS-2017M1003934			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Drug Interaction	Mirtazapine			S	Unknown	15 Mg/Day		Not Reported
	Escitalopram			S	Unknown	10 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13152439	EXPEDITED (15-DAY)		OT	US-MIDATECHPHARMA-2017-US-000785			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Ondansetron (Non-Specific)			S	Unknown			Not Reported
	Escitalopram			S	Unknown	Used In Final Trimester Of Pregnancy		Not Reported
	Sertraline			S	Unknown	Used In Initial Two Trimesters Of Pregnancy		Not Reported
	Progesterone			S	Unknown	Used From 16th Week Of Pregnancy		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13152440	EXPEDITED (15-DAY)		DE	US-MIDATECHPHARMA-2017-US-000687		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congenital Cardiovascular Anomaly; Congenital Infection; Congestive Cardiomyopathy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Ondansetron (Non-Specific)			S	Intra-uterine			Not Reported
	Escitalopram			S	Intra-uterine	Maternal Use In Final Trimester Of Pregnancy		Not Reported
	Sertraline			S	Intra-uterine	Maternal Use In Initial Two Trimesters Of Pregnancy		Not Reported
	Progesterone			S	Intra-uterine	Maternal Use From 16th Week Of Pregnancy		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13152712	EXPEDITED (15-DAY)		OT	FR-009507513-1701FRA011329		63 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Keytruda			S	Parenteral	150 Mg, Every 3 Weeks		Merck
	Perfalgan			S	Parenteral	Unk		Not Reported

	Propofol	S		Unk	Not Reported
	Sufentanil	S		Unk	Not Reported
	Sevorane	S		Unk	Not Reported
	Ketamine	S		Unk	Not Reported
	Xylocaine (Lidocaine)	S		Unk	Not Reported
	Acupan	S		Unk	Not Reported
	Cefazolin	S	Parenteral	2 G, Unk	Not Reported
	Escitalopram	S		Unk, If Needed	Not Reported
	Xanax	C		Unk, If Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	12676784	NON-EXPEDITED			US-VALIDUS PHARMACEUTICALS LLC-US-2015VAL000481			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Benazepril Hydrochloride			S	Oral	Unk		Validus
	Lioresal Intratecal			S	Intrathecal	39.95 Mg, Qd		Not Reported
	Magnesium (Nch)			S	Oral	Unk		Not Reported
	Pravastatin (Ngx)			S	Oral	Unk		Not Reported
	Warfarin (Ngx)			S	Oral	Unk		Not Reported
	Metformin /00082702/			S	Oral	Unk		Not Reported
	Tylenol /00020001/			S	Oral	Unk		Not Reported
	Vitamin D3			S	Oral			Not Reported
	Lexapro			S		Unk		Not Reported
	Insulin Glargine			S		Unk		Not Reported
	Insulin Lispro			S		Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Aspirin (E.C.)			S	Oral	Unk		Not Reported
	Lotrisone			S	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	12824198	EXPEDITED (15-DAY)		HO	AT-ALLERGAN-1670884US		40 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Intentional Overdose; Toxicity To Various Agents	Cipralex Tablets			S	Oral	21 Tablets At Once		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13014234	EXPEDITED (15-DAY)		LT, OT	HR-ALLERGAN-1679736US			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Serotonin Syndrome; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Deanxit/Flupentixol + Melitracen			C	Unknown	Unk		Not Reported
	Cymbalta /Duloxetine			C	Unknown			Not Reported
	Cymbalta /Duloxetine			C				Not Reported
	Clonazepam			C	Unknown	20 Mg, Unk		Not Reported
	Fluoxetine			C	Unknown	Unk Mg, Unk		Not Reported
	Benadryl/Diphenhydramine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13153302	NON-EXPEDITED			US-TORRENT-00001320			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Taste Abnormal	Escitalopram Tablets, Usp			S				Torrent
	Loestrin 24 Fe			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13154182	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2017028947		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Ibuprofen	S	Oral	Unk		Pfizer
	Oxycodone	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13156463	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1703044US			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Trintellix			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13156569	EXPEDITED (15-DAY)		DE, HO	CH-ALLERGAN-1703063US		84 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Pradaxa /Dabigatran			C	Unknown	110 Mg, Bid		Not Reported
	Tebokan /Gingki Biloba			C	Unknown	80 Mg, Qd		Not Reported
	Beloc Zok / Metoprolol Succinate			C	Oral	25 Mg, Qd		Not Reported
	Digoxin / Digoxin			C	Oral	0.125 Mg, Unk		Not Reported
	Tirosint / Levothyroxine Sodium			C	Oral	50 Mg, Qd		Not Reported
	Calcimagon D3 / Colecalciferol			C	Oral			Not Reported
	Omeprazole / Omeprazole			C	Oral	20 Mg, Qd		Not Reported
	Estradot / Estradiol			C	Transdermal	50 Mg, Unk		Not Reported
	Madipar /Levodopa			C	Unknown	125 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	12194537	NON-EXPEDITED			US-APOTEX-2016AP007117		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Anxiety; Depression; Drug Ineffective; Ejaculation Failure; Emotional Distress; Feeling Abnormal; Headache; Hypertension; Potentiating Drug Interaction; Sexual Dysfunction; Tinnitus; Unevaluable Event	Paxil Tablets			S		Unk		Apotex
	Paxil Tablets			S				Apotex
	Wellbutrin			S		150 Mg, Once Daily		Not Reported
	Wellbutrin			S				Not Reported
	Cymbalta			S		60 Mg, Unk		Not Reported
	Cymbalta			S				Not Reported
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13067596	EXPEDITED (15-DAY)		HO	IT-TEVA-723434ACC		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Affective Disorder; Anhedonia; Anxiety; Depressed Mood; Drug Ineffective; Feeling Abnormal; Insomnia; Labelled Drug-Drug Interaction Medication Error; Social Avoidant Behaviour; Suicidal Ideation; Tension	Quetiapine			S	Oral	200 Milligram Daily;		Teva
	Venlafaxine			S	Oral	300 Milligram Daily;		Teva
	Valproic Acid			S	Oral	300 Milligram Daily;		Not Reported
	Valproic Acid			S	Oral	600 Milligram Daily;		Not Reported
	Alprazolam			S	Oral	1.5 Milligram Daily;		Actavis
	Trazodone Hydrochloride			S	Oral	75 Milligram Daily;		Not Reported
	Trazodone Hydrochloride			S	Oral	150 Milligram Daily;		Not Reported
	Escitalopram			S	Oral	20 Milligram Daily;		Not Reported
	Clonazepam			S	Oral	.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13109234	EXPEDITED (15-DAY)		HO	IT-TEVA-727838ACC		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retching	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13157214	EXPEDITED (15-DAY)		OT	CA-TEVA-734119ACC		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Escitalopram			S	Oral	5 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13157243	EXPEDITED (15-DAY)		OT	CA-TEVA-734123ACC		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Negative Thoughts; Paranoia	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Ibuprofen			C				Not Reported
	Lorazepam			C				Not Reported
	Metformin			C				Not Reported
	Rosuvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13157505	NON-EXPEDITED		DE	MX-TORRENT-00000084		6 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemic Stroke; Off Label Use	Olanzapine			S				Torrent
	Escitalopram			S				Torrent
	Losartan			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13158327	EXPEDITED (15-DAY)		DS, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-117747		67 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Glaucoma	Escitalopram			S	Unknown	Unk		Not Reported
	Gemfibrozil			S	Unknown	Unk		Sun

	Hydrochlorothiazide	S	Unknown	Unk		Sun
	Irbesartan	S	Unknown	Unk		Not Reported
	Pantoprazole	S	Unknown	Unk		Sun
	Quetiapine	S	Oral	Unk		Sun
	Ropinirole	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13160403	EXPEDITED (15-DAY)		OT	PHHY2017AU009436			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Hepatic Function Abnormal	Olanzapine			S	Unknown	20 Mg, Unk		Novartis
	Escitalopram			S	Unknown	40 Mg, Unk		Not Reported
	Paliperidone			S	Unknown	150 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	12398808	NON-EXPEDITED			US-PFIZER INC-2016270731		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Spiriva			S		Unk		Not Reported
	Protonix			S		Unk		Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Doxycycline Hyclate			S		Unk		Pfizer
	Pristiq			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer
	Theo-Dur			S		Unk		Not Reported
	Lortab			S		Unk		Not Reported
	Reglan			S		Unk		Not Reported

Topamax	S	Unk	Not Reported
Vioxx	S	Unk	Not Reported
Paxil	S	Unk	Not Reported
Vasotec	S	Unk	Not Reported
Buspar	S	Unk	Not Reported
Cipro	S	Unk	Not Reported
Prozac	S	Unk	Not Reported
Singulair	S	Unk	Not Reported
K-Dur	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Micardis	S	Unk	Not Reported
Levaquin	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported
Bystolic	S	Unk	Not Reported
Lisinopril	S	Unk	Not Reported
Simvastatin	S	Unk	Not Reported
Ultracet	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	12464482	NON-EXPEDITED			US-APOTEX-2016AP006769		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Product Complaint; Withdrawal Syndrome	Paxil Tablets			S	Unknown	Unk		Apotex
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	12921321	EXPEDITED (15-DAY)		HO	GB-TEVA-704386ACC		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Feeling Jittery; Hot Flush; Loss Of Consciousness; Palpitations; Psoriasis	Propranolol	S	Oral	40 Milligram Daily;		Actavis
	Escitalopram	S	Unknown			Ivax
	Amlodipine	C	Unknown	10 Milligram Daily;		Not Reported
	Capasal Therapeutic Shampoo	C	Unknown			Not Reported
	Cetraben Cream	C	Unknown			Not Reported
	Dermol 200 Shower Emollient	C	Unknown			Not Reported
	Dovobet Gel	C	Unknown			Not Reported
	Loratadine	C	Unknown			Not Reported
	Crepe Bandage Bp	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13160974	EXPEDITED (15-DAY)		DE	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-131864			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Loperamide			S	Unknown	Unk		Ranbaxy
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13161006	EXPEDITED (15-DAY)		OT	CA-TEVA-734134ACC		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glossodynia	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Pantoloc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13161047	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2017-28389		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Duloxetine			S	Oral			Aurobindo

	Escitalopram		S	Oral		Aurobindo
	Bupropion		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13161129	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2017-28480		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Tamsulosin			S	Oral			Aurobindo
	Amlodipine			S	Oral			Aurobindo
	Enalapril			S	Oral			Not Reported
	Insulin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13161610	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2017-28397		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Oxycodone			S	Oral			Aurobindo
	Ibuprofen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13162510	EXPEDITED (15-DAY)		DE	CA-TEVA-734132ACC		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S	Unknown			Ivax
	Temazepam			S	Unknown			Not Reported
	Tylenol With Codeine No. 3 - Tab			S	Unknown			Not Reported
	Advair			C				Not Reported
	Atrovent			C				Not Reported
	Gabapentin			C				Not Reported

Naproxen	C		Not Reported
Ranitidine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13162658	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2017033644		17 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Suicide Attempt	Xanax			S	Oral	Unk		Pfizer
	Citram			S	Oral	Unk		Not Reported
	Seroquel			S	Oral	Unk		Not Reported
	Risset			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13163792	NON-EXPEDITED		OT	US-STI PHARMA LLC-1062511			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram			S	Oral			Sti Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13163926	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201607018		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydrocodone/Acetaminophen			S	Oral			Mallinckrodt
	Tramadol			S	Oral			Not Reported
	Baclofen			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13165079	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-734146ACC		18 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Aggression; Crying; Intentional Self-Injury; Psychotic Disorder	Teva-Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Teva-Escitalopram			S				Ivax
	Abilify			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13145670	EXPEDITED (15-DAY)		HO, OT	TR-ALLERGAN-1702566US		54 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Drug Ineffective; Intentional Overdose; Serotonin Syndrome; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	80 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	40 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Trazodone			S	Oral	200-300 Mg Daily Irregularly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13165583	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2017-28683		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Diphenhydramine			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13165641	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2017-28844		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Alprazolam	S	Oral	Aurobindo
	Escitalopram	S	Oral	Aurobindo
	Hydrochlorothiazide	S	Oral	Aurobindo
	Doxepin	S	Oral	Not Reported
	Olmesartan	S	Oral	Not Reported
	Famotidine	S	Oral	Not Reported
	Cetirizine	S	Oral	Not Reported
	Pregabalin	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13165826	EXPEDITED (15-DAY)		OT	US-HETERO LABS LTD-1062551			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Human Herpesvirus 6 Infection	Escitalopram			S	Unknown			Hetero
	Ondansetron			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Progesterone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13165937	EXPEDITED (15-DAY)		DE, HO, OT	US-HETERO LABS LTD-1062552		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Escitalopram			S	Transplacental			Hetero
	Ondansetron			S				Not Reported
	Sertraline			S	Transplacental			Not Reported
	Progesterone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13165982	EXPEDITED (15-DAY)		OT	NL-ASTRAZENECA-2017SE09134		58 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Blood Cholesterol Increased; Blood Glucose Increased	Quetiapine			S	Oral			Zeneca
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13166022	EXPEDITED (15-DAY)		OT	DE-HETERO LABS LTD-1062554			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby; Temperature Regulation Disorder	Escitalopram			S	Transplacental			Hetero
	Fluoxetine			C	Transplacental			Not Reported
	Elevit			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13166094	EXPEDITED (15-DAY)		DE, OT	US-ZYDUS-013463		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy Neonatal; Dilatation Ventricular; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome; Systolic Dysfunction	Escitalopram			S	Transplacental			Zydus Pharm
	Sertraline			S	Transplacental			Zydus Pharm
	Ondansetron			S	Transplacental			Not Reported
	Progesterone			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13166110	EXPEDITED (15-DAY)		OT	US-ZYDUS-013465			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy; Human Herpesvirus 6 Infection; Hypersensitivity	Escitalopram		S	Unknown	Zydus Pharm
	Sertraline		S	Unknown	Zydus Pharm
	Ondansetron		S	Unknown	Not Reported
	Progesterone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13166420	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2017-28604		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13166522	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2017-28829		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Diphenhydramine			S	Oral			Aurobindo
	Amitriptyline			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13167014	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2017-29108		41 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Tramadol			S	Oral			Aurobindo
	Hydrocodone Bitartrate And Acetaminophen			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo

	Alprazolam	S	Oral		Aurobindo
	Clonazepam	S	Oral		Not Reported
	Baclofen	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13167373	EXPEDITED (15-DAY)		HO, OT	NL-GLAXOSMITHKLINE-TW2017GSK012770		66 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Dyspnoea; Lethargy; Pulmonary Embolism	Olanzapine			S		Unk		Glaxosmithkline
	Mirtazapine			S		Unk		Not Reported
	Escitalopram			S		Unk		Glaxosmithkline
	Bupropion			S		Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13170079	EXPEDITED (15-DAY)		HO, OT	CA-PURDUE PHARMA-CAN-2017-0007368		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Exposure During Pregnancy; Fall; Hidradenitis; Off Label Use; Product Use Issue; Skin Laceration	Morphine Sulfate			S	Unknown			Purdue
	Ativan			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Diclectin			S	Unknown			Not Reported
	Gravol			S	Unknown			Not Reported
	Metamucil /00091301/			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Rabeprazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	500 Mg, Q 6 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q 6 Weeks		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	500 Mg, Q 6 Weeks		Not Reported
	Prenatal Vitamins /01549301/	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13170235	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1703561US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Open Angle Glaucoma	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Lumigan			C	Ophthalmic			Not Reported
	Larmabak			C	Ophthalmic			Not Reported
	Valdoxan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13170600	EXPEDITED (15-DAY)		OT	FR-ABBVIE-17P-056-1852908-00		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Ultane			S	Intrathecal			Not Reported
	Pembrolizumab			S	Intrathecal	2 Mg/ Kg (150 Mg) With Well Being Tolerance		Not Reported
	Propofol			S	Unknown			Not Reported
	Citrate Sufentanil			S	Unknown			Not Reported
	Lidocaine Chlrohydrate Monohydrate			S	Unknown			Not Reported
	Chlorhydrate Nefopam			S	Unknown			Not Reported
	Oxalate Escitalopram			S	Unknown			Not Reported
	Paracetamol			S	Intrathecal			Not Reported
	Sodium Cefazoline			S	Intrathecal			Not Reported
	Ketamine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13170773	NON-EXPEDITED			US-ABBVIE-16K-163-			Female	USA

1676768-00

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Respiratory Tract Congestion; Throat Irritation; Vomiting	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Trintellix			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Ativan			C				Not Reported
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	12957376	EXPEDITED (15-DAY)		DS, HO, OT	US-ALLERGAN-1676612US		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective; Gait Inability; Off Label Use; Oxygen Saturation Decreased; Weight Increased	Lexapro			S	Unknown	Unk		Allergan
	Lexapro			S				Allergan
	Antivert			C				Not Reported
	Antivert			C				Not Reported
	Revert			C				Not Reported
	Revert			C				Not Reported
	Medrol			C				Not Reported
	Medrol			C				Not Reported
	Vicodin			C				Not Reported
	Vicodin			C				Not Reported
	Lyrica			C				Not Reported
	Lyrica			C				Not Reported
	Xanax			C		0.5 Mg, Tid		Not Reported
	Xanax			C				Not Reported
	Alprazolam			C				Not Reported
	Hydrocodone			C		7.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	13159110	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017GSK010485			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bradyphrenia; Decreased Interest; Depressive Symptom; Distractibility; Disturbance In Attention; Feelings Of Worthlessness; Impaired Work Ability; Irritability; Memory Impairment; Performance Status Decreased; Social Avoidant Behaviour; Social Fear	Wellbutrin			S		Unk		Glaxosmithkline
	Wellbutrin			S		Unk		Glaxosmithkline
	Lexapro			S		10 Mg, Unk		Not Reported
	Lexapro			S		20 Mg, Unk		Not Reported
	Lexapro			S		30 Mg, Unk		Not Reported
	Lexapro			S		20 Mg, Unk		Not Reported
	Chantix			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	13172716	EXPEDITED (15-DAY)		HO	PHHY2017SE013739		34 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Poisoning; Anxiety; Tachycardia; Toxicity To Various Agents	Tegretol Retard			S	Unknown			Novartis
	Cipralex			S	Unknown	Unk		Not Reported
	Seroquel			S	Unknown	Unk		Not Reported
	Theralen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	13175433	EXPEDITED (15-DAY)		HO, LT	US-PFIZER INC-2017044567		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Focal Dyscognitive Seizures; Incorrect Dose	Doxepin Hcl			S	Oral	2 Df, Single		Pfizer
	Rebif			S	Subcutaneous	44 Ug, Three Times A Week		Not Reported

Administered; Influenza; Insomnia; Memory Impairment; Overdose; Seizure; Speech Disorder; Therapy Non-Responder	Lexapro	S	Oral	10 Mg, 1x/Day		Not Reported
	Lexapro	S	Oral	20 Mg, Single		Not Reported
	Lexapro	S	Oral	10 Mg, 1x/Day		Not Reported
	Dilantin	C				Not Reported
	Depakote	C				Not Reported
	Ambien	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	13175743	EXPEDITED (15-DAY)		OT	AU-LUPIN PHARMACEUTICALS INC.-2017-00465			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Hepatic Function Abnormal	Olanzapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Paliperidone			S	Unknown			Not Reported
	Clozapine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	13176434	EXPEDITED (15-DAY)		LT	US-PFIZER INC-2017044432		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Ineffective; Focal Dyscognitive Seizures; Generalised Tonic-Clonic Seizure; Incoherent; Incorrect Dose Administered; Insomnia; Memory Impairment; Mobility Decreased; Speech Disorder; Suicidal Ideation; Viral Infection	Doxepin Hcl			S	Oral			Pfizer
	Rebif			S		Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Dalmane			C				Not Reported
	Depakote			C				Not Reported
	Ambien			C				Not Reported
	Dilantin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	12325801	NON-EXPEDITED			ES-LUPIN PHARMACEUTICALS INC.-2015-04500		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis	Quetiapine			S	Oral			Not Reported
	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180032	NON-EXPEDITED			IL-LUPIN PHARMACEUTICALS INC.-2015-04270		25 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram			S	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180038	NON-EXPEDITED			IL-LUPIN PHARMACEUTICALS INC.-2015-04282		39 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram			S	Unknown	40 Mg		Not Reported
	Simvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180041	NON-EXPEDITED			IL-LUPIN PHARMACEUTICALS INC.-2015-04285		41 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180052	NON-EXPEDITED			IL-LUPIN PHARMACEUTICALS INC.-2015-04291		32 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180055	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2016-00482		32 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Escitalopram			S	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180057	NON-EXPEDITED		OT	ES-LUPIN PHARMACEUTICALS INC.-2015-04498		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis	Olanzapine			S	Oral			Not Reported
	Trazodone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Levodopa + Carbidopa			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180058	NON-EXPEDITED		HO	FR-LUPIN PHARMACEUTICALS INC.-2016-00881		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180059	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2016-01711			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram Tablets Usp 10mg			S	Unknown			Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180067	NON-EXPEDITED		OT	CN-LUPIN PHARMACEUTICALS INC.-2016-02183		70 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180071	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2016-02169		44 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180080	NON-EXPEDITED		OT	CN-LUPIN PHARMACEUTICALS INC.-2016-02185		41 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180086	NON-EXPEDITED		OT	CN-LUPIN PHARMACEUTICALS INC.-2016-02199		67 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180088	NON-EXPEDITED		OT	CN-LUPIN PHARMACEUTICALS INC.-2016-02200		61 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180091	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2016-02417			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Major Depression	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180094	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2016-02426			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Chills; Headache	Escitalopram 5 Mg			S	Oral			Not Reported
	Escitalopram 5 Mg			S	Oral			Not Reported
	Escitalopram 5 Mg			S	Oral			Not Reported
	Valium			C	Oral	At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180116	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2016-03298		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug-Induced Liver Injury	Escitalopram		S	Unknown	10 Mg	Not Reported
	Chlorpromazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180117	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2016-03432		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Diazepam			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Zolpidem			C	Unknown			Not Reported
	Fexofenadine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180120	NON-EXPEDITED			SA-LUPIN PHARMACEUTICALS INC.-2016-03556		28 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Gastrointestinal Disorder	Escitalopram			S	Unknown	Up To 10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180121	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2016-03861		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Madarosis	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180125	NON-EXPEDITED		OT	HR-LUPIN PHARMACEUTICALS		53 YR	Male	HRV

INC.-2016-04011

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Quetiapine			S	Unknown	800 Mg		Not Reported
	Quetiapine			S	Unknown	400mg		Not Reported
	Quetiapine			S	Unknown	200mg		Not Reported
	Quetiapine			S	Unknown	100mg		Not Reported
	Escitalopram			S	Unknown	20mg		Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported
	Escitalopram			S	Unknown	5mg		Not Reported
	Valproate			C	Unknown	1500 Mg		Not Reported
	Valproate			C				Not Reported
	Diazepam			C	Unknown	30 Mg		Not Reported
	Diazepam			C				Not Reported
	Zolpidem			C	Unknown	10 Mg		Not Reported
	Zolpidem			C				Not Reported
	Biperiden			C	Unknown	1 Mg		Not Reported
	Biperiden			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180128	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2016-04034		21 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Sleep Disorder; Urinary Incontinence	Mirtazapine			S	Unknown	30 Mg		Not Reported
	Escitalopram			S	Unknown	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180136	NON-EXPEDITED			TW-LUPIN PHARMACEUTICALS INC.-2016-04219		27 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13180677	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1703912US		47 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Sopor	Escitalopram Oxalate - Bp			S	Oral	120 Ml, Single		Allergan
	Lorazepam			S	Oral	30 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	11825505	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00004503		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Nausea; Wrong Technique In Product Usage Process	Escitalopram			S	Oral			Not Reported
	Keppra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13168811	EXPEDITED (15-DAY)		HO	SE-ASTRAZENECA-2017SE10264		34 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Poisoning; Anxiety; Gastrointestinal Motility Disorder; Tachycardia; Toxicity To Various Agents	Seroquel			S	Oral			Not Reported
	Tegretol Retard			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Theralen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13182454	NON-EXPEDITED			US-PFIZER INC-2017044844		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Celebrex	S	Unk	Pfizer
	Effexor Xr	S	Unk	Pfizer
	Flagyl	S	Unk	Pfizer
	Gabapentin	S	Unk	Pfizer
	Zoloft	S	Unk	Pfizer
	Ciprofloxacin	S	Unk	Unknown
	Bupropion	S	Unk	Not Reported
	Amoxicillin	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Lamictal	S	Unk	Not Reported
	Iodine	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Plavix	S	Unk	Not Reported
	Remeron	S	Unk	Not Reported
	Vioxx	S	Unk	Not Reported
	Wellbutrin Sr	S	Unk	Not Reported
	Zocor	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183076	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2016-05394		19 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Muscle Spasms	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Flunitrazepam			S	Unknown			Not Reported
	Zolpidem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183081	NON-EXPEDITED			MY-LUPIN PHARMACEUTICALS		45 YR	Male	MYS

INC.-2016-04347

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183084	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS INC.-2016-05244		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Telangiectasia	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183112	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00004684		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Depressed Mood; Diarrhoea; Drug Ineffective; Fear; Feeling Of Body Temperature Change; Flatulence; Nausea	Escitalopram Tablets Usp 10mg			S	Oral			Lupin
	Metoprolol			C	Oral			Not Reported
	Ramipril			C	Oral			Not Reported
	Gabapentin			C	Oral			Not Reported
	Atorvastatin			C	Oral			Not Reported
	Allopurinol			C	Oral			Not Reported
	Xarelto			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183119	NON-EXPEDITED			DE-LUPIN PHARMACEUTICALS INC.-E2B_00005128		61 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gamma-Glutamyltransferase Increased	Citalopram 10 Mg	S	Oral	10/20 Mg Tabletten	Not Reported
	Escitalopram	S	Oral	10 Mg Tropfen	Not Reported
	Citalopram 20 Mg	S	Oral	10/20 Mg Tabletten	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183123	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00005766		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Tablets Usp 10mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183129	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00005777		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Tablets Usp 10mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183131	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00005825			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Dizziness; Gluten Sensitivity; Myalgia	Escitalopram Tablets Usp 10mg			S	Oral			Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183132	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00005900			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram Tablets Usp 20mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183135	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-E2B_00006241		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Tablets Usp 10mg			S	Oral	20mg		Not Reported
	Bupropion			C	Oral			Not Reported
	Opdivo			C	Unknown			Not Reported
	Primodone			C	Oral			Not Reported
	Keppra			C	Oral			Not Reported
	Ibuprofen			C	Oral			Not Reported
	Lorazepam			C	Oral			Not Reported
	Biotin			C	Oral			Not Reported
	Melatonin			C	Oral			Not Reported
	Hydrocodone/Ibuprofen			C	Oral			Not Reported
	Vitamin D3			C	Oral			Not Reported
	Fish Oil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13184119	NON-EXPEDITED			KR-LUPIN PHARMACEUTICALS INC.-2015-04460		69 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Haloperidol			S	Unknown	1.5mg		Not Reported
	Clonazepam			S	Unknown	0.5mg		Not Reported
	Buspirone			S	Unknown	10mg		Not Reported
	Escitalopram			S	Unknown	10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13184683	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1006324			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Overdose; Sopor	Lorazepam			S	Oral	30 Df, Total		Not Reported
	Escitalopram			S	Oral	120 Ml, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13185487	NON-EXPEDITED			US-PFIZER INC-2017045101			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Bacitracin			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13185565	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1704085US		34 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Poisoning; Anxiety; Constipation; Tachycardia; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Tegretol Retard			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Theralen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2017	13139320	EXPEDITED (15-DAY)		DE, HO	FR-LANNETT COMPANY, INC.-FR-2017LAN000403		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Acute Kidney Injury; Cardiogenic Shock;	Escitalopram Oxalate			S	Oral	280 Mg, Single (Seroplex Tablets)		Lannett

Hyperlactacidaemia; Intentional Overdose; Left Ventricular Dysfunction; Loss Of Consciousness; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Skin Necrosis; Toxicity To Various Agents; Vasoplegia Syndrome	Hydroxyzine Hydrochloride	S	Oral	700 Mg, Single (Atarax Tablets)	Lannett
	Sevikar	S	Oral	1290 Mg Of Amlodipine And 5160 Mg Of Olmesartan, Single	Not Reported
	Zolpidem	S		Unk	Not Reported
	Lysanxia	S	Oral	420 Mg, Single	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2017	13188128	EXPEDITED (15-DAY)		HO	CA-GLENMARK PHARMACEUTICALS-2017GMK026179			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Gabapentin			S	Oral	600 Mg, Bid		Glenmark
	Gabapentin			S	Oral	300 Mg, Od		Glenmark
	Acetaminophen & Cod. Phosp.			S	Oral	2 Df, Tid		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Tid		Not Reported
	Domperidone			S	Oral	10 Mg, Bid		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Ferrous Sulfate			S	Unknown	300 Mg, Tid		Not Reported
	Temazepam			S	Oral	30 Mg, Od		Not Reported
	Wellbutrin			S	Oral	150 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2017	13190574	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2017GSK014787			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Resistance; Hypomania; Suicide Attempt; Therapy Cessation	Lithium			S				Glaxosmithkline
	Aripiprazole			S				Not Reported
	Clozapine			S				Glaxosmithkline
	Haloperidol			S				Not Reported

Risperidone	S	Not Reported
Bupropion	S	Not Reported
Duloxetine	S	Glaxosmithkline
Lamotrigine	S	Glaxosmithkline
Carbamazepine	S	Glaxosmithkline
Lorazepam	S	Glaxosmithkline
Quetiapine	S	Glaxosmithkline
Ziprasidone	S	Not Reported
Chlorpromazine	S	Not Reported
Loxapine	S	Not Reported
Nefazodone	S	Not Reported
Citalopram	S	Glaxosmithkline
Escitalopram	S	Glaxosmithkline
Doxepine	S	Not Reported
Paroxetine	S	Glaxosmithkline
Venlafaxine	S	Glaxosmithkline
Trazodone	S	Not Reported
Trihexyphenidyl	S	Not Reported
Benztropine	S	Not Reported
Divalproex	S	Not Reported
Oxcarbazepine	S	Not Reported
Topiramate	S	Glaxosmithkline
Chloral Hydrate	S	Not Reported
Clonazepam	S	Not Reported
Diazepam	S	Glaxosmithkline
Phenobarbital	S	Glaxosmithkline
Temazepam	S	Not Reported
Triazolam	S	Not Reported
Alprazolam	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13125630	EXPEDITED (15-DAY)		HO, OT	FR-TAKEDA-2017TUS001249		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Suicide Attempt	Brintellix			S	Oral	10 Mg, Unk		Takeda
	Seroplex			S	Oral	20 Mg, Qd		Not Reported
	Lexomil			C	Oral	6 Mg, Qd		Not Reported
	Doliprane			C	Oral	Unk, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13192177	EXPEDITED (15-DAY)		DS	CA-TEVA-736094ACC		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Mental Status Changes	Lorazepam			S	Unknown			Actavis
	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13192736	EXPEDITED (15-DAY)		HO	IT-TEVA-737059ACC		46 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Lorazepam			S	Oral			Actavis
	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13193470	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201607182		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Roxicodone			S	Oral			Mallinckrodt
	Escitalopram			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13195204	DIRECT	Y	OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Heart Rate Increased; Panic Attack; Product Substitution Issue	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13195840	DIRECT	Y	HO			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lexapro			S	Oral			Not Reported
	Albuterol			C				Not Reported
	Aspirin			C				Not Reported
	Carvedilol			C				Not Reported
	Warfarin			C				Not Reported
	Tiotropium			C				Not Reported
	Lactobacillus			C				Not Reported
	Bupropion			C				Not Reported
	Clonazepam			C				Not Reported
	Diaepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13205558	DIRECT		OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Product Substitution Issue; Therapeutic Response Changed; Withdrawal Syndrome	Escitalopram			S	Oral	Quantity:3 Tablet(S);		Unknown
	Celexa			C				Not Reported
	Lisinipril			C				Not Reported
	Multi Vitamin			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	12914090	EXPEDITED (15-DAY)		OT	AU-APOTEX-2016AP013845		38 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Abnormal; Product Substitution Issue	Apo-Escitalopram			S	Oral	20 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	13042163	NON-EXPEDITED			US-PFIZER INC-2016586661		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S	Oral	50 Mg, Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	13195188	NON-EXPEDITED			US-BAXTER-2017BAX003346		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibromyalgia; Gastrooesophageal Reflux Disease; Neuropathy Peripheral; Osteoarthritis; Weight Increased	Fluconazole Injection, Usp			S	Unknown	As Needed		Baxter
	Pristiq			S	Unknown			Not Reported
	Pristiq			S	Unknown			Not Reported
	Pristiq			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Buspirone			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Tramadol			S	Unknown	1/2 To 2 Needed Per Day		Not Reported
	Meloxicam			S	Unknown	1 Per Day At Night		Not Reported
	Protonix			S	Unknown			Not Reported
	Ativan			S	Unknown	Dose: 1.0		Not Reported
	Robaxin			S	Unknown	1 To 3 Daily		Not Reported
	Trazodone			S	Unknown	1 To 2		Not Reported
	Celexa			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported

	Doxycycline			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	13197136	EXPEDITED (15-DAY)		DE	TR-ELI_LILLY_AND_COMPANY-TR201702001961		51 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Embolism Venous; Haemorrhage; Toxicity To Various Agents	Olanzapine			S	Unknown			Eli Lilly And Co
	Citalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	13205998	DIRECT		OT			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Depressed Mood; Dyspnoea; Heart Rate Increased; Speech Disorder	Lexapro	Y		S	Oral	Quantity:60 Tablet(S);		Cadista

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13065208	EXPEDITED (15-DAY)		HO, LT, OT	IN-PFIZER INC-2016596876		19 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hypoglycaemia; Intentional Overdose; Respiratory Rate Increased; Suicidal Ideation; Suicide Attempt	Venlafaxine Hcl			S	Oral	37.5 Mg, Od Orally		Pfizer
	Venlafaxine Hcl			S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam		Pfizer
	Clonazepam			S	Oral	1 Df, 1x/Day		Not Reported
	Clonazepam			S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet		Not Reported

					Escitalopram, And Tablet Clonazepam	
	Escitalopram		S	Oral	1 Df, 1x/Day	Not Reported
	Escitalopram		S	Oral	10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13202059	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-132698		46 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Lorazepam			S	Oral	30 Df Total		Sun
	Escitalopram			S	Oral	120 Ml Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13208050	EXPEDITED (15-DAY)		DE, HO	US-ALLERGAN-1680857US		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Intentional Self-Injury; Mood Swings; Multiple Injuries; Stress; Suicidal Ideation	Lexapro			S		20 Mg, Qam		Allergan
	Metformin			C		500 Mg, Bid		Not Reported
	Iron Sulfate			C		325 Mg, Bid		Not Reported
	Topamax			C		50 Mg, Bid		Not Reported
	Amoxicillin			C		500 Mg, Unk		Not Reported
	Doxycycline Hyclate			C		100 Mg, Unk		Not Reported
	Escitalopram			C		20 Mg, Unk		Not Reported
	Alprazolam			C		.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13209306	NON-EXPEDITED			US-PFIZER INC-2017049684		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported
	Lamictal			S		Unk		Not Reported
	Keppra			S		Unk		Not Reported
	Montelukast			S		Unk		Not Reported
	Penicillin G			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13089478	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016604616		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hernia	Xeljanz			S		5 Mg, Unk		Pfizer
	Xeljanz			S		10 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S		Unk, 1x/Day (2.5)		Pfizer
	Meloxicam			S		15 Mg, 1x/Day		Not Reported
	Anastrozole			S		1 Mg, 1x/Day		Not Reported
	Omeprazole			S		20 Mg, 1x/Day		Not Reported
	Escitalopram			S		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13156344	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1703047US		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Ineffective; Overdose; Pneumonia; Pneumonia Aspiration	Escitalopram Oxalate - Bp			S	Oral	Overdose: 1 Box (Presumed Quantity)		Allergan
	Ketamine Panpharma			S	Unknown	4 Ampoules, Qd		Not Reported
	Ketamine Panpharma			S	Oral	Overdose: 23 Boxes Of 5 Ampoules Of 50mg/5ml		Not Reported

	Laroxyl		S	Oral	Unk, Single	Not Reported
	Laroxyl		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13210024	EXPEDITED (15-DAY)		HO	PT-JNJFOC-20170204655		47 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Off Label Use; Product Use In Unapproved Indication	Haloperidol			S	Unknown	5-15 Mg		Not Reported
	Pregabalin			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lorazepam			S	Unknown	Up To 30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13212563	EXPEDITED (15-DAY)		DE	CA-ALLERGAN-1704890US		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13212614	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1704889US		96 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate - Bp			S	Oral	3 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	2 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13213966	EXPEDITED (15-DAY)		DE	CA-ALLERGAN-1705046US		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Escitalopram Oxalate - Bp	S	Unknown	Unk Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13214465	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1671455US		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Brexpiprazole			S		1 Mg, Qd		Not Reported
	Luaf41156			S	Oral	1 Mg, Qd		Not Reported
	Oxycodone			C	Oral	10/325 Mg, Unk		Not Reported
	Oxycodone			C				Not Reported
	Lisinopril			C	Oral	5 Mg, Unk		Not Reported
	Albuterol			C	Oral	Unk, 2 Puffs		Not Reported
	Symbicort			C	Oral	Unk, 2 Puffs		Not Reported
	Amlodipine			C	Oral	2.5 Mg, Unk		Not Reported
	Fentanyl Patch			C				Not Reported
	Endocet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13219188	EXPEDITED (15-DAY)		HO	IT-ACCORD-048053		47 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Accord
	Lorazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13220110	EXPEDITED (15-DAY)		OT	AU-TORRENT-00000041		24 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Hepatic Function Abnormal	Olanzapine			S				Unknown
	Escitalopram			S				Unknown
	Paliperidone			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2017	10715561	EXPEDITED (15-DAY)		DE	US-JNJFOC-20150105346		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Loperamide		Y	S	Oral			Not Reported
	Loperamide			S	Oral	2 Mg Loperamide (10 Caplets)		Not Reported
	Escitalopram			S	Oral	20 Mg Escitalopram (30 Tablets Missing)		Not Reported
	Meloxicam			S	Oral	15 Mg Meloxicam (13 Tablets Missing)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	12866268	EXPEDITED (15-DAY)			BR-TAKEDA-2016TUS018860			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Vortioxetine			S	Unknown	10 Mg, Qd		Takeda
	Vortioxetine			S	Unknown	10 Mg, Bid		Takeda
	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	13226134	EXPEDITED (15-DAY)		OT	US-ACORDA-ACO_133605_2017			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Amnesia; Cognitive Disorder; Condition Aggravated; Confusional State; Deafness; Gallbladder Operation; Hemiparesis; Hemiplegia; Irritability; Lip Swelling; Somnolence; Tinnitus; Urticaria; Uterine	Ampyra			S	Unknown	Unk		Acorda
	Tysabri			S	Intravenous (not otherwise specified)	300 Mg, Infused Over One Hour Every 4 Weeks		Not Reported
	Gilenya			S	Unknown	Unk		Not Reported
	Copaxone			S	Unknown	Unk		Not Reported
	Solumedrol			S	Unknown	Unk		Not Reported

Operation	Acthar	S	Unknown	Unk		Not Reported
	Lexapro	S	Unknown	Unk		Not Reported
	Cymbalta	S	Unknown	Unk		Not Reported
	Nuvigil	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	13226442	EXPEDITED (15-DAY)		OT	HR-JNJFOC-20170210805		26 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sopor; Suicide Attempt; Vomiting	Tramal			S	Oral			Not Reported
	Q Pin			S	Oral			Not Reported
	Elicea			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Sulpirid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2017	13232361	NON-EXPEDITED			US-009507513-1702USA000340		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Remeron			S	Oral	Unk		Merck
	Fluoxetine			S				Not Reported
	Citalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Venlafaxine Hydrochloride			S				Not Reported
	Bupropion Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	13236973	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1705798US		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis; Oesophagitis	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan

	Kardegic	S	Oral	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	13237178	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1705801US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13134348	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2016M1058466			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Hypersensitivity	Escitalopram Mylan 5 Mg			S		1 Df, Qd		Mylan
	Escitalopram Mylan 5 Mg			S		Unk		Mylan
	Citalopram			S		5 Mg, Unk		Not Reported
	Monoprost			C		1 Gtt, Tid		Mylan
	Optive			C		1 Gtt, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13241035	EXPEDITED (15-DAY)		OT	PT-JNJFOC-20170209058			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Interaction; Fatigue; Gastrointestinal Infection; Haematotoxicity; Haemorrhage; Hypertension; Myalgia; Pneumonitis Chemical; Respiratory Tract Infection	Ibrutinib			S	Oral			Not Reported
	Ibrutinib			S	Oral			Not Reported
	Ibrutinib			S	Oral			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Amiodarone			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Not Reported
	Aliskiren			S	Unknown			Not Reported

Voriconazole	S	Unknown	Not Reported
Fluconazole	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Paroxetine	S	Unknown	Not Reported
Enoxaparin	S	Unknown	Not Reported
Ibuprofen	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13243195	DIRECT		DS, HO, LT, OT			31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acoustic Neuroma	Escitalopram			S	Oral	Quantity:1 Capsule(S);		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13248138	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1705782US		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Aortic Aneurysm; Apathy; Blood Urine Present; Drug Ineffective; Dysuria; Malaise; Rash	Lexapro			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	9885323	NON-EXPEDITED			US-PFIZER INC-2014036696		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Insomnia	Celebrex			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13250805	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US01995			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13251111	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US01951			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Palpitations; Panic Attack; Suicidal Ideation	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Clopidogrel			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13252931	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1705956US		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cognitive Disorder; Condition Aggravated; Confusional State; Deafness; Drug Ineffective; Gallbladder Operation; Hemiparesis; Hemiplegia; Irritability; Lip Swelling; Somnolence; Tinnitus; Urticaria; Uterine Operation	Lexapro			S				Allergan
	Ampyra			S				Not Reported
	Tysabri			S	Intravenous (not otherwise specified)	300 Mg, Q4weeks		Not Reported
	Gilenya			S				Not Reported
	Copaxone			S				Not Reported
	Solumedrol			S				Not Reported
	Acthar			S				Not Reported
	Cymbalta			S				Not Reported
	Nuvigil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13253483	NON-EXPEDITED			US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001857		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Dizziness; Drug Interaction	Nuplazid			S	Oral	34 Mg, Qd		Acadia Pharmaceuticals
	Lexapro			S				Not Reported
	Azilect			C	Unknown	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13256689	DIRECT		OT			20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Confusional State; Energy Increased; Feeling Jittery; Formication; Hypomania; Impulsive Behaviour; Mania; Restlessness; Sleep Disorder	Aripiprazole (Generic Abilify)			S	Oral			Not Reported
	Escitalopram (Generic Lexapro)			S	Oral			Not Reported
	Fluoxetine (Generic For Prozac)			C				Not Reported
	Gabapentin (Generic For Neurontin)			C				Not Reported
	Dexmethylphenidate (Generic For Focalin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	9688626	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2013314534		63 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bradycardia; Confusional State; Drug Ineffective; Dry Mouth; Extrasystoles; Fear; Feeling Abnormal; Headache; Loss Of Consciousness; Migraine; Orthostatic Hypotension; Palpitations; Photopsia; Retinal Tear; Somnolence; Vitreous Disorder	Frontal			S	Oral	1.5 Mg, Daily		Pfizer
	Frontal			S	Oral	1mg, Daily (Half Tablet (0.5mg) At Lunch Time And Another Half Tablet (0.5mg) At Night)		Pfizer
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13135562	EXPEDITED (15-DAY)		HO	IT-ABBVIE-17P-083-1847855-00		22 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Overdose; Sopor	Depakine Chrono			S	Oral			Not Reported
	Depakine Chrono			S				Not Reported
	Depakine Chrono			S				Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Lexotan (Bromazepam) Oral Drops, Solution			S	Oral			Not Reported
	Lexotan (Bromazepam) Oral Drops, Solution			S				Not Reported
	Lexotan (Bromazepam) Oral Drops, Solution			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13255508	EXPEDITED (15-DAY)		HO, LT, OT	TR-ELI_LILLY_AND_COMPANY-TR201702007439		24 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Coma; Hypercapnia; Hypernatraemia; Hypocalcaemia; Intentional Overdose; Leukopenia; Respiratory Depression; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Olanzapine			S	Oral	Unk, Unknown		Eli Lilly And Co
	Fluoxetine Hydrochloride			S	Oral	Unk, Unknown		Eli Lilly And Co
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Valproic Acid			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13255728	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2017SE18910		31 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compulsive Shopping; Diffuse Alopecia; Erection Increased; Hypersexuality	Xeroquel			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13256325	DIRECT	Y	HO, RI				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematocrit Decreased; Haemoglobin Decreased; International Normalised Ratio Increased	Warfarin			S				Not Reported
	Escitalopram			S				Not Reported
	Atorvastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13257020	EXPEDITED (15-DAY)		DE	CA-ALLERGAN-1706365US		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate - Bp			S	Unknown	20 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13257775	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1706543US			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Overdose; Pyrexia; Somnolence	Escitalopram Oxalate - Bp			S	Oral	28 Df, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13257896	EXPEDITED (15-DAY)		OT	PHEH2017US004537			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cognitive Disorder; Condition	Gilenya			S	Unknown			Novartis

Aggravated; Confusional State; Deafness; Hemiparesis; Hemiplegia; Irritability; Lip Swelling; Somnolence; Tinnitus; Urticaria	Ampyra	S	Unknown		Not Reported
	Tysabri	S	Intravenous (not otherwise specified)	300 Mg Infused Over One Hour Every 4 Weeks (Qw4)	Not Reported
	Copaxone	S	Unknown		Not Reported
	Solumedrol	S	Unknown		Not Reported
	Acthar	S	Unknown		Not Reported
	Lexapro	S	Unknown		Not Reported
	Cymbalta	S	Unknown		Not Reported
	Nuvigil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13258104	EXPEDITED (15-DAY)		HO	FI-ALLERGAN-1706362US		45 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hereditary Angioedema; Swelling; Swelling Face; Swelling Of Eyelid; Swollen Tongue	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13262995	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Product Substitution Issue	Escitalopram 20mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	10453352	NON-EXPEDITED			US-PFIZER INC-2014255004		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Skin;	Pristiq			S		50 Mg, Unk		Pfizer

Feeling Abnormal; Fibromyalgia; Gastrooesophageal Reflux Disease; Inflammation; Intentional Product Misuse; Neuropathy Peripheral; Osteoarthritis; Skin Lesion; Weight Increased	Pristiq	S	100 Mg, Unk	Pfizer
	Pristiq	S	100 Mg, 1x/Day	Pfizer
	Fluconazole	S	100 Mg, As Needed (1 In 1 As Required)	Pfizer
	Gabapentin	S	100 Mg, 3x/Day	Pfizer
	Protonix	S	40 Mg, 1x/Day	Pfizer
	Zoloft	S	Unk	Pfizer
	Lexapro	S	10 Mg, Unk	Not Reported
	Lexapro	S	20 Mg, 1x/Day	Not Reported
	Buspirone	S	7.5 Mg, 2x/Day	Not Reported
	Ativan	S	Unk, As Needed (1.0 (Units Not Reported) As Needed)	Not Reported
	Robaxin	S	Unk, Daily 500 Mg (Muscles)	Not Reported
	Robaxin	S	500 Mg, Unk (1 To 3 Daily)	Not Reported
	Trazodone	S	50 Mg, Unk (1 To 2)	Not Reported
	Celexa	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Tramadol	S	50 Mg, As Needed (1/2 To 2 Needed Per Day)	Not Reported
	Meloxicam	S	15 Mg, 1x/Day (1 Per Day At Night) (1 In 1 Pm)	Not Reported
	Doxycycline	C	100 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	13259302	NON-EXPEDITED			US-PFIZER INC-2017071143		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer

Vancomycin Hcl	S	Unk		Pfizer
Daptomycin	S	Unk		Unknown
Clarithromycin	S	Unk		Not Reported
Zinacef /00454601/	S	Unk		Not Reported
Lexapro	S	Unk		Not Reported
Nortriptyline	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2017	13264505	DIRECT		OT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abnormal Behaviour; Drug Ineffective; Feeding Disorder; Feeling Abnormal; Gastrointestinal Disorder; Hallucination; Hyperhidrosis; Hyperphagia; Hypoaesthesia; Malaise; Muscle Twitching; Mydriasis; Nightmare; Palpitations; Vomiting; Weight Increased	Zoloft			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Lexapro			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Probiotic			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2017	13266097	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017073739		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Decreased Appetite; Hypokinesia; Loss Of Personal Independence In Daily Activities; Morose; Mutism; Nausea; Overdose; Psychomotor	Xanax			S	Oral	0.25 Mg, 1x/Day		Pfizer
	Seroplex			S		Unk		Not Reported
	Anexate			S				Not Reported
	Digoxin			S				Not Reported

Skills Impaired

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2017	13267118	DIRECT		LT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyspnoea; Gait Inability; Hyperhidrosis; Muscle Twitching; Mydriasis; Paraesthesia; Tremor; Visual Impairment	Lexapro			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Buspar			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2017	13269120	EXPEDITED (15-DAY)		DE	US-LPDUSPRD-20170195		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Progesterone Injection (0750-01)			S	Transplacental	Dose Unknown		Luitpold
	Ondansetron Injection (4420-01)			S	Transplacental	Dose Unknown		Luitpold
	Sertraline			S	Transplacental	Dose Unknown		Not Reported
	Escitalopram			S	Transplacental	Dose Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2017	13269457	EXPEDITED (15-DAY)		OT	US-LPDUSPRD-20170198			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Human Herpesvirus 6 Infection	Progesterone Injection (0750-01)			S	Unknown	Dose Unknown		Luitpold
	Ondansetron Injection (4420-01)			S	Unknown	Dose Unknown		Luitpold
	Sertraline			S	Unknown	Dose Unknown		Not Reported
	Escitalopram			S	Unknown	Dose Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2017	13269944	NON-EXPEDITED			US-IMPAX LABORATORIES, INC-2016-IPXL-01976		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Burning Sensation; Drug Hypersensitivity; Fatigue; Fatigue; Headache; Headache; Rash	Mirtazapine Odt			S	Unknown			Impax
	Baclofen			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Eszopiclone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Penicillin (Benzylpenicillin)			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Zolpidem			S	Unknown			Not Reported
	Lyrica			S	Unknown	200 Milligram Daily;		Not Reported
	Daypro			S	Unknown			Not Reported
	Levoxyl			S	Unknown			Not Reported
	Protonix /01263204/			S	Unknown			Not Reported
	Zithromax			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Tegretol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2017	13272574	DIRECT					52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pollakiuria; Somnolence; Tinnitus; Vision Blurred	Escitalopram - 20mg			S	Oral	Quantity:30 Tablet(S);		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	11941084	EXPEDITED (15-DAY)		OT	US-ABBVIE-16K-163-1543592-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abdominal Pain Upper; Fatigue; Fatigue; Gastrointestinal Inflammation; Headache; Pseudopolyp; Rectal Haemorrhage	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported
	Cyproheptadine			C				Not Reported
	Wellbutrin			C				Not Reported
	Wellbutrin			C				Not Reported
	Vitamin B12			C				Not Reported
	Culturelle			C				Not Reported
	Vitamin D3			C				Not Reported
	Melatonin			C				Not Reported
	Multivitamin			C				Not Reported
	Probiotic			C				Not Reported
	Cyproheptad			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	12925498	EXPEDITED (15-DAY)		HO	US-SA-2016SA159206		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Chronic Obstructive Pulmonary Disease; Panic Attack; Product Dose Omission; Renal Disorder; Tremor	Praluent			S	Unknown			Not Reported
	Praluent			S	Unknown			Not Reported
	Praluent			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Alirocumab Prefilled Pen			C	Unknown			Not Reported
	Alirocumab Prefilled Pen			C	Unknown			Not Reported
	Alirocumab Prefilled Pen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13110634	EXPEDITED (15-DAY)		OT	IT-TEVA-728395ACC			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Speech Disorder	Fluoxetine			S				Barr
	Citalopram			S				Pliva
	Sertraline			S				Not Reported
	Paroxetine			S				Not Reported
	Fluvoxamine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13145570	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1702569US		22 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Overdose; Sopor	Escitalopram Oxalate - Bp			S	Oral	Overdose: Unknown Dose		Allergan
	Depakin Chrono 300mg Compresse Rivestite/ Valproic Acid			S	Oral	Overdose: Unknown Dose.		Not Reported
	Lexotan/ Bromazepam			S	Oral	Overdose: Unknown Dose.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13151170	EXPEDITED (15-DAY)		HO	IT-TEVA-732876ACC		22 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Overdose; Sopor	Escitalopram Oxalate			S	Oral	400 Mg Total		Ivax
	Depakin Chrono - 300 Mg Compresse Rivestite - Sanofi S.P.A.			S	Oral	3 G Total		Not Reported
	Lexotan - Roche S.P.A.			S	Oral	25 Mg Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13180332	EXPEDITED (15-DAY)		HO	ES-ALLERGAN-1703894US		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Oculogyric Crisis;	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

Partial Seizures; Systemic Infection	Carbamazepine		S	Unknown	Unk	Not Reported
	Diazepam		S	Unknown	Unk	Not Reported
	Topiramate		S	Unknown	Unk	Not Reported
	Haloperidol		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13208137	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1704684US			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Seizure; Tremor	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Irinotecan Hydrochloride			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13272270	EXPEDITED (15-DAY)		DS	CN-ALLERGAN-1706771US			Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Spinal Fracture	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13273494	EXPEDITED (15-DAY)		OT	ES-TAKEDA-2017TUS004259		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Motor Dysfunction; Therapy Non-Responder	Brintellix			S	Oral	5 Mg, Qd		Takeda
	Brintellix			S	Oral	10 Mg, Qd		Takeda
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13273611	NON-EXPEDITED		HO	DE-TORRENT-00006232		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Serotonin Syndrome	Quetiapine	S		Unknown
	Lithium Carbonate	S		Unknown
	Escitalopram	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13273992	EXPEDITED (15-DAY)		OT	NL-ALLERGAN-1706968US			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Derealisation; Electrocardiogram Abnormal	Escitalopram Oxalate - Bp			S	Oral	Unk Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13274537	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMPANY-US201702005908			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cognitive Disorder; Condition Aggravated; Confusional State; Deafness; Hemiparesis; Hemiplegia; Irritability; Lip Swelling; Somnolence; Tinnitus; Urticaria	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Ampyra			S	Unknown	Unk, Unknown		Not Reported
	Tysabri			S	Intravenous (not otherwise specified)	300 Mg, Monthly (1/M)		Not Reported
	Gilenya			S	Unknown	Unk, Unknown		Not Reported
	Copaxone			S	Unknown	Unk, Unknown		Not Reported
	Solumedrol			S	Unknown	Unk, Unknown		Not Reported
	Acthar /00005501/			S	Unknown	Unk, Unknown		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Nuvigil			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13275843	DIRECT					57 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Faeces;	Escitalopram 5 Mg			S	Oral	Quantity:30 Tablet(S);		Lupin

Contusion; Faeces Discoloured; Feeling Abnormal; Gingival Bleeding; Middle Insomnia; Pain In Extremity; Pain In Extremity; Product Substitution Issue	Multivitamins	C	Not Reported
	Vitamin B	C	Not Reported
	Vitamin C	C	Not Reported
	Vitamin E	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	12611322	EXPEDITED (15-DAY)		OT	CA-FRI-1000086501		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain; Headache; Pain In Jaw	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Zopiclone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	13119912	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2017US00593			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Drug Ineffective; Loss Of Consciousness	Bupropion			S	Unknown	Unk, Far Farm		Invagen
	Bupropion			S	Oral	150 Mg, Qd		Invagen
	Escitalopram			S	Unknown	10 Mg, Qd		Invagen
	Losartan			S	Unknown	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	13266444	EXPEDITED (15-DAY)		DS	IT-MYLANLABS-2017M1011711			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Quality Issue; Product Substitution Issue	Escitalopram Mylan Pharma			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	13276939	NON-EXPEDITED		OT	DE-TORRENT-00006251		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Behaviour	Escitalopram			S				Unknown
	Mirtazapine			S				Unknown
	Quetiapine			S				Unknown
	Lorazepam			S				Unknown
	Ethanol			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	13278455	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1707196US		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Motor Dysfunction	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Vortioxetine			S	Oral	10 Mg, Qd		Not Reported
	Vortioxetine			S	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	13278458	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1707215US		37 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Night Sweats; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Seroquel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	13278519	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2017M1011599			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sialoadenitis	Ondansetron			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

	Temozolomide	C	Unknown	Mylan
	Levetiracetam	C	Unknown	Mylan
	Dexamethasone	C	Unknown	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	13278695	EXPEDITED (15-DAY)		HO, OT	IT-ABBVIE-17P-083-1890789-00		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Lactic Acidosis; Metabolic Disorder; Neurological Decompensation	Depakin Chrono			S	Oral	Extended Release		Not Reported
	Tegretol			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	13280026	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Panic Attack; Therapy Non-Responder	Escitalopram 10mg			S	Oral			Not Reported
	Celexa 20mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	12600703	EXPEDITED (15-DAY)			CA-FRI-1000086484		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Irregular; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Trazodone			C	Unknown	25 Mg, Qhs		Not Reported
	Valtrex			C	Unknown	1000 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13082369	EXPEDITED (15-DAY)		LT	IT-MYLANLABS-2016M1058666			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Labelled Drug-Drug Interaction Medication Error; Musculoskeletal Stiffness; Rhabdomyolysis; Tremor	Escitalopram			S		Unk		Not Reported
	Lithium			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13160933	EXPEDITED (15-DAY)		HO	IT-ACCORD-047632		22 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Overdose; Sopor	Escitalopram			S	Oral			Accord
	Depakin Chrono			S	Oral	Strength: 300 Mg		Not Reported
	Lexotan Roche			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13282175	EXPEDITED (15-DAY)		OT	BR-ROCHE-1899600		18 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Of Despair; Loss Of Consciousness; Mood Swings; Overdose; Suicide Attempt	Rivotril			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13286337	EXPEDITED (15-DAY)		OT	PHHY2017BR027679			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Fatigue; Incorrect Dose Administered; Pain; Tremor; Vertigo	Razapina			S	Unknown	15 Mg, Unk		Novartis
	Citalopram			S	Unknown			Not Reported
	Amitriptyline			S	Unknown	75 Mg, Unk		Not Reported

	Exodus//Escitalopram Oxalate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	12600704	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000086487		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Fluid Volume Decreased; Drug Hypersensitivity; Gestational Diabetes; Gestational Hypertension; Haematochezia; Mucous Stools; Nausea; Pregnancy; Sinusitis; Vomiting	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Remicade			S	Intravenous (not otherwise specified)	400 Mg, Every Six Weeks		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Progesterone			C	Unknown	Unk		Not Reported
	Vitamin B12			C	Other	Unk		Not Reported
	Prometrium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13285819	NON-EXPEDITED			US-FRI-1000085998		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective	Viibryd			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Paxil			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13285886	NON-EXPEDITED			US-FRI-1000086173		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Pruritus Generalised; Pruritus Generalised	Viibryd			S	Oral	20 Mg, Qd		Allergan
	Viibryd			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan

Synthroid	C	Oral	.1 Mg, Qd		Not Reported
Verapamil	C	Oral	120 Mg, Qd		Not Reported
Vitamin D Nos	C	Oral	Unk Unk, Qd		Not Reported
Iron	C	Oral	Unk Unk, Qd		Not Reported
Metrx	C		Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13285938	NON-EXPEDITED			US-FRI-1000087560			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fatigue; Hallucination; Hypokinesia; Influenza Like Illness; Limb Discomfort; Night Sweats; Off Label Use; Pain; Paralysis; Sleep Terror	Viibryd			S	Oral	5 Mg - Tapered Dose		Allergan
	Lexapro			S	Oral	Unk		Allergan
	Gabapentin			C	Ophthalmic	Unk		Not Reported
	Synthroid			C	Oral	Unk Unk, Qd		Not Reported
	Lidoderm			C	Topical	Unk, Prn		Not Reported
	Oxycontin			C	Oral	Unk		Not Reported
	Vicodin			C	Oral	Unk Unk, Prn		Not Reported
	Accufex			C	Unknown	Unk		Not Reported
	Patanase			C	Nasal	Unk		Not Reported
	Warfarin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13287901	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1707583US		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Disorder; Breast Cancer; Hernia	Escitalopram Oxalate - Bp			S		10 Mg, Qd		Allergan
	Omeprazole			S		20 Mg, Qd		Not Reported
	Methotrexate			S		2.5 Mg, Qd		Not Reported
	Meloxicam			S		15 Mg, Qd		Not Reported
	Xeljanz			S		10 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13287906	EXPEDITED (15-DAY)		OT	ES-IPCA LABORATORIES LIMITED-IPC201702-000085		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Salivary Gland Calculus; Sialoadenitis	Ondansetron			S				Ipca
	Temozolomide			S				Not Reported
	Dexamethasone			S				Not Reported
	Escitalopram			S				Not Reported
	Dexamethasone			C				Not Reported
	Levetiracetam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13288410	EXPEDITED (15-DAY)		OT	US-MALLINCKRODT-T201700673			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Amnesia; Cognitive Disorder; Condition Aggravated; Confusional State; Deafness; Gallbladder Operation; Hemiparesis; Hemiplegia; Irritability; Lip Swelling; Somnolence; Tinnitus; Urticaria; Uterine Operation	H P Acthar			S				Mallinckrodt
	Ampyra			S				Not Reported
	Tysabri			S	Unknown	300 Mg Infused Over One Hour Every 4 Week, Concentrate For Solution For Infused		Not Reported
	Gilenya			S	Unknown	Unk		Not Reported
	Copaxone			S				Not Reported
	Solumedrol			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Nuvigil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13291192	DIRECT		OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Burning Sensation; Chest Discomfort; Hypertension; Palpitations; Serotonin Syndrome	Escitalopram 10 Mg	S	Oral	Quantity:30 Tablet(S);	Unknown
	Metaprolol	C			Not Reported
	Fosonopril	C			Not Reported
	Aspirin	C			Not Reported
	Multi Vitamin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	12980497	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1677704US		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Cerebral Disorder; Seizure; Weight Decreased	Lexapro			S	Unknown	5 Mg, Qd		Allergan
	Lexapro			S	Unknown	10 Mg, Qd		Allergan
	Lexapro			S	Unknown	20 Mg, Qd		Allergan
	Vesicare			C		10 Mg, Qd		Not Reported
	Sertraline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13048172	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2016M1056321			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Syndrome	Escitalopram			S	Unknown	10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13277269	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2017SE20183		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Lactic Acidosis; Metabolic Disorder; Neurological Decompensation	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Tegretol			S	Oral			Not Reported

	Tegretol	S	Oral		Not Reported
	Tegretol	S	Oral		Not Reported
	Tegretol	S	Oral		Not Reported
	Cipralex	S	Oral		Not Reported
	Cipralex	S	Oral		Not Reported
	Depakin	S	Oral		Not Reported
	Depakin	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13289954	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2017029638		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Intentional Product Misuse; Nausea	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Lexapro			S	Unknown	Unk		Not Reported
	Advair			C				Not Reported
	Proair			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13293955	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2017LAN000601		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Drug Hypersensitivity; Foetal Exposure During Pregnancy; Multiple Organ Dysfunction Syndrome	Ondansetron			S	Transplacental	Unk		Lannett
	Escitalopram Oxalate			S	Transplacental	Unk		Lannett
	Sertraline			S	Transplacental	Unk		Not Reported
	Progesterone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294120	EXPEDITED (15-DAY)		OT	US-LANNETT COMPANY, INC.-US-			Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Exposure During Pregnancy; Herpes Simplex	Ondansetron			S		Unk		Lannett
	Escitalopram Oxalate			S		Unk		Lannett
	Sertraline			S		Unk		Not Reported
	Progesterone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294389	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1707980US		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematemesis; Melaena; Overdose	Escitalopram Oxalate Unk			S	Oral	15 Mg, Qd		Allergan
	Previscan (Fluindione)			S	Oral	15 Mg, Qd		Not Reported
	Econazole			S	Topical			Not Reported
	Daivonex			C	Unknown			Not Reported
	Diffu K			C	Unknown			Not Reported
	Doliprane			C	Unknown			Not Reported
	Eludril (Chlorhexidine Gluconate\Chlorobutanol)			C	Oral			Not Reported
	Lasilix			C	Unknown			Not Reported
	Lorazepam			C	Oral			Not Reported
	Lysanxia			C	Oral			Not Reported
	Montelukast			C	Oral			Not Reported
	Oxycontin Lp			C	Oral			Not Reported
	Oxynormoro			C	Oral	5 Mg, Bid		Not Reported
	Seretide Discus			C	Respiratory (inhalation)	500µg/50µg/Dose		Not Reported
	Soriatane			C	Oral			Not Reported

Theralene	C	Oral			Not Reported
Valaciclovir	C	Oral			Not Reported
Ventoline	C	Respiratory (inhalation)	2 Puffs Every 6 Hours As Needed		Not Reported
Xylocaine	C	Cutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13295483	EXPEDITED (15-DAY)		HO, LT, OT	DE-ALLERGAN-1708010US		50 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Ventricular Fibrillation	Escitalopram Oxalate Unk			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13295491	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1708068US		59 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Delusion Of Grandeur; Euphoric Mood; Hostility; Mania; Sleep Disorder	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Trittico			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2017	13296138	EXPEDITED (15-DAY)		OT	US-ACCORD-048633		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Pregnancy Test False Positive	Escitalopram			S		Started On Escitalopram 10 Mg Daily		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	13194202	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1704394US		23 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Function Abnormal; Off Label Use; Serotonin Syndrome	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd		Allergan
	Yaz	C	Oral			Not Reported
	Tsumura Yokukansan Extract Granules For Ethical Use	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	13298962	EXPEDITED (15-DAY)		HO	DE-TEVA-743323GER			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Galactorrhoea	Risperidon			S				Teva
	Risperidon			S				Teva
	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Aripiprazol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	13301310	DIRECT		HO			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Contusion; Dry Skin; Dry Skin; Respiratory Failure; Seizure; Skin Exfoliation; Thinking Abnormal; Tongue Injury; Tremor; Visual Impairment; Weight Decreased	Escitalopram			S	Oral			Lundbeck
	Amlodipine			C				Not Reported
	Vitamin B Complex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	12261822	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-09576			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Metformin			S	Unknown			Aurobindo
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13061928	EXPEDITED (15-DAY)		HO, OT	PT-APOTEX-2016AP016121		23 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Syndrome; Metastases To Liver	Escitalopram Apotex Comprimidos Orodispersiveis			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13282251	EXPEDITED (15-DAY)		HO	PHHY2017IT029673		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Lactic Acidosis; Metabolic Disorder; Neurological Decompensation	Tegretol			S	Oral	90 Df, Unk (Total)		Novartis
	Depakin			S	Oral	20 Df, Unk (Total)		Not Reported
	Cipralex			S	Oral	10 Df, Unk (Total)		Not Reported
	Seroquel			S	Oral	50 Df, Unk(Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13301464	EXPEDITED (15-DAY)		HO	FR-009507513-1703FRA002661		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Sevikar			S	Oral	Unk		Not Reported
	Furosemide			S	Oral	Unk		Merck
	Acetaminophen			S	Oral	Unk		Not Reported
	Simvastatin			S	Oral	Unk		Merck
	Esomeprazole Magnesium			S	Oral	20 Mg, Qd		Merck
	Esomeprazole Magnesium			S	Oral	20 Mg, In The Morning		Merck
	Metformin			S	Oral	Unk		Not Reported
	Amlodipine			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Naproxen			S	Oral	Unk		Not Reported

Pregabalin	S	Oral	Unk		Not Reported
Escitalopram	S	Oral	10 Mg, Qd		Not Reported
Escitalopram	S	Oral	10 Mg, In The Evening		Not Reported
Lantus	C	Subcutaneous	Unk		Not Reported
Lantus	C	Subcutaneous	30 Iu, In The Evening		Not Reported
Loprazolam	C		Unk		Not Reported
Lumirelax (Methocarbamol)	C		Unk		Not Reported
Desloratadine	C		Unk		Merck
Levothyrox	C		Unk		Not Reported
Levothyrox	C		100 Microgram, In The Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13302146	EXPEDITED (15-DAY)		DS, OT	US-ARALEZ PHARMACEUTICALS RD INC.-ARA-TP-US-2017-9		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Dysarthria; Hemiplegia	Metoprolol Succinate			S	Oral			Aralez Pharmaceuticals
	Metoprolol Succinate			S				Aralez Pharmaceuticals
	Lisinopril			S	Oral			Not Reported
	Onglyza			S				Not Reported
	Escitalopram			S	Oral			Not Reported
	Diltiazem			C	Oral			Not Reported
	Digoxin			C	Oral			Not Reported
	Furosemide			C	Oral			Not Reported
	Gabapentin			C	Oral			Not Reported
	Glimepiride			C	Oral			Not Reported
	Levothyroxine			C	Oral			Not Reported
	Metformin			C	Oral			Not Reported

	Pradaxa	C	Oral	Not Reported
	Pravastatin	C	Oral	Not Reported
	Tramadol	C	Oral	Not Reported
	Potassium Chloride	C	Oral	Not Reported
	Levemir Flex Insulin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13142898	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2017M1003749			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Overdose; Sopor	Escitalopram			S	Oral	400 Mg, Total		Not Reported
	Depakin Chrono			S	Oral	3 G, Total		Mylan
	Lexotan			S	Oral	25 Mg, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13305988	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2017-30649			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Galactorrhoea	Risperidone 4mg			S	Oral	4 Mg, Daily		Aurobindo
	Risperidone 4mg			S	Oral	2 Mg, Daily		Aurobindo
	Cipralex /01588501/			S	Oral	20 Mg, Daily		Not Reported
	Cipralex /01588501/			S	Oral	25 Mg, Daily		Not Reported
	Aripiprazol			C	Unknown	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13307308	EXPEDITED (15-DAY)		DE	ZA-MYLANLABS-2017M1013957			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Mylan Oxybutynin 5 Mg			S	Oral	5 Mg, Unk		Mylan
	Purgoxin			S	Oral	0.25 Mg, Unk		Mylan

Renitec [Enalapril Maleate]	S	Oral	5 Mg, Unk		Mylan
Carbilev	S	Oral	Unk		Mylan
Ecotrin	S	Oral	81 Mg, Unk		Mylan
Celebrex	S	Oral	200 Mg, Unk		Mylan
Puricos	S	Oral	100 Mg, Unk		Mylan
Vesicare	S	Oral	5 Mg, Unk		Mylan
Lexamil	S	Oral	5 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13307515	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1708877US		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Rash Maculo-Papular	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Dalacine			S	Oral	1800 Mg, Qd		Not Reported
	Fucidine (Fusidic Acid)			S	Oral	1500 Mg, Qd		Not Reported
	Antivitamin-K			C	Unknown			Not Reported
	Discotrine			C	Unknown			Not Reported
	Amlor			C	Unknown			Not Reported
	Tahor			C	Unknown			Not Reported
	Inexium			C	Unknown	Unk		Not Reported
	Triatec (Codeine Phosphate/Paracetamol)			C	Unknown			Not Reported
	Lasilix			C	Unknown			Not Reported
	Amiodarone			C	Unknown			Not Reported
	Acupan			C	Unknown	Unk		Not Reported
	Alprazolam			C	Unknown			Not Reported
	Keppra			C	Unknown			Not Reported
	Diffu-K			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown			Not Reported
	Speciafoldine			C	Unknown			Not Reported

	Paracetamol	C	Unknown	Not Reported
	Lovenox	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13326236	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1014024			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Skin Exfoliation; Skin Fissures	Escitalopram			S				Not Reported
	Canesten			C				Mylan
	Citalopram			C				Mylan
	Clobetasone Butyrate			C		Apply 1-2 Times/Day.		Mylan
	Clotrimazole			C		Use As Directed.		Mylan
	Hydrocortisone			C				Mylan
	Lactulose			C				Mylan
	Naproxen			C		Maximum Three Times Daily.		Mylan
	Omeprazole			C				Mylan
	Paracetamol			C		One To Two To Be Taken Four Times A Day.		Mylan
	Quetiapine			C		Night.		Mylan
	Zerobase			C		Apply Liberally.		Mylan
	Zopiclone			C		Take Half To One Tablet At Night.		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	10340742	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-B1016879A		182 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Increased; Exposure Via Breast Milk; Seizure; Vomiting	Bupropion			S	Transmammary			Glaxosmithkline
	Escitalopram Oxalate			S	Transmammary			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	12698099	NON-EXPEDITED			US-JNJFOC-20160709705			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Insomnia; Lethargy; Memory Impairment; Off Label Use; Product Use In Unapproved Indication	Risperdal			S	Oral			Not Reported
	Invega			S				Not Reported
	Lexapro			S	Unknown			Not Reported
	Strattera			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13243668	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1706000US		84 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea; Product Administration Error; Syncope	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Citalopram Sandoz			S	Oral			Not Reported
	Normorix Mite			C	Unknown			Not Reported
	Artrotec			C	Unknown			Not Reported
	Stesolid			C	Unknown			Not Reported
	Alvedon			C	Unknown			Not Reported
	Trombyl			C	Unknown			Not Reported
	Metoprolol Orion			C	Unknown			Not Reported
	Ovesterin			C	Unknown			Not Reported
	Daktacort			C	Unknown			Not Reported
	Loceryl			C	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13301946	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017098062		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradyphrenia; Drug Abuse; Movement Disorder	Efexor Er		S	Oral	3 Df, Total	Pfizer
	Tavor [Lorazepam]		S	Oral	2 Df, Total	Pfizer
	Cipralex /01588501/		S	Oral	60 Df, Total	Not Reported
	Abilify		S	Oral	0.5 Df, Total	Not Reported
	Talofen		S	Oral	5 Gtt, Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13309679	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2017-30476		42 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Vomiting	Escitalopram Aurovitas Film-Coated Tablets			S	Oral	5 Mg, Once A Day		Aurobindo
	Bupropiom			S	Oral	150 Mg, Once A Day		Not Reported
	Levodopa-Carbidopa			C	Unknown	Unk		Not Reported
	Levodopa-Carbidopa			C		Medicação Concomitante Sem Dados Adicionais		Not Reported
	Tizanidina			C	Unknown	Terapêutica Concomitante Sem Oura Informação		Not Reported
	Tizanidina			C		Terapêutica Concomitante Sem Oura Informação		Not Reported
	Ropinirol			C	Unknown	Unk		Not Reported
	Ropinirol			C		Terapêutica Concomitante Sem Outra Informação		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13312894	EXPEDITED (15-DAY)		OT	BE-ALLERGAN-1708915US		29 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Anxiety; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13312932	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1708907US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy; Premature Labour; Premature Rupture Of Membranes; Streptococcal Infection	Escitalopram Oxalate - Bp			S	Unknown	10 Gtt, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13312935	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1708912US		16 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Off Label Use; Syncope	Escitalopram Oxalate - Bp			S		20 Mg, Qam		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13313294	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-019754		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis; Surgery	Abilify			S	Oral	Unk		Bristol Myers Squibb
	Seroplex			S	Oral	Unk		Not Reported
	Innohep			C	Unknown	0.8 Ml, Qd		Not Reported
	Gaviscon /00237601/			C	Unknown	Unk, Tid		Not Reported
	Ogastoro			C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13313317	EXPEDITED (15-DAY)		CA, HO, OT	FR-ALLERGAN-1708884US		1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Nose	Escitalopram Oxalate - Bp			S	Transplacental	10 Gtt, Qd		Allergan

Malformation; Premature Baby

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13313330	EXPEDITED (15-DAY)		HO	GB-ALLERGAN-1708936US		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Hot Flush; Loss Of Consciousness; Palpitations; Psoriasis	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Propranolol			S	Oral	40 Milligram Daily;		Not Reported
	Amlodipine			C	Unknown	10 Milligram Daily;		Not Reported
	Capasal			C	Unknown			Not Reported
	Cetraben Emollient Cream			C	Unknown			Not Reported
	Dermol Shampoo			C	Unknown			Not Reported
	Dovobet			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13313341	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1708895US		83 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Parkinson'S Disease; Somnolence; Spinal Pain	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Qd		Allergan
	Diazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13313414	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1709117US		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aptyalism; Drug Ineffective; Off Label Use; Overdose; Panic Disorder	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Unknown		Allergan

Amitriptyline	S	Oral	20 Mg, Qd		Not Reported
Buspirone	S	Oral	5 Mg, Qd		Not Reported
Zyprexa	S	Oral	2.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13319974	EXPEDITED (15-DAY)			US-LUNDBECK-DKLU2026430		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenopia; Dry Mouth; Feeling Abnormal; Feeling Jittery; Malaise; Nervousness; Palpitations; Visual Impairment	Escitalopram Oral Drops			S	Oral	20 Mg, Unk		Not Reported
	Escitalopram Oral Drops			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	12666411	EXPEDITED (15-DAY)		LT	JP-FRI-1000086879		31 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13094784	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1700384US		88 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Rozerem			C	Oral			Not Reported
	Belsomra			C	Oral	15 Mg, Unk		Not Reported
	Selenica R			C		200 Mg, Unk		Not Reported
	Reminyl			C	Oral	8 Mg, Unk		Not Reported
	Risperidone			C	Oral	0.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13106469	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1700966US		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Fall; Loss Of Consciousness; Upper Limb Fracture	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Clorazepate			C	Oral	7.5 Mg, Qd		Not Reported
	Uloric			C	Oral	80 Mg, Qd		Not Reported
	Probenecid			C	Oral	500 Mg, Qid		Not Reported
	Colcrys			C	Oral	0.6 Mg, Bid		Not Reported
	Flexeril			C		10 Mg, Unk		Not Reported
	Topamax			C	Oral	200 Mg, Bid		Not Reported
	Glucotrol			C	Oral	5 Mg, Unk		Not Reported
	Welchol			C	Oral	625 Mg, Bid		Not Reported
	Prevacid			C	Oral	15 Mg, Qid		Not Reported
	Prevacid			C				Not Reported
	Prevacid			C				Not Reported
	K-Dur			C	Oral	25 Meq, Unk		Not Reported
	Lasix			C	Oral	40 Mg, Unk		Not Reported
	Coreg			C	Oral	25 Mg, Bid		Not Reported
	Hydralazine			C	Oral	25 Mg, Unk		Not Reported
	Synthroid			C	Oral	125 Mg, Unk		Not Reported
	Premarin			C	Oral	0.625 Mg, Unk		Not Reported
	Pataday			C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13301475	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2017-30326		49 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Depression; Dyspnoea; Headache;	Escitalopram			S	Unknown	5 Mg, Daily		Aurobindo

Hyperhidrosis;
Hyponatraemia;
Inappropriate Antidiuretic
Hormone Secretion;
Nausea; Pancreatitis
Chronic; Paraesthesia;
Respiratory Alkalosis;
Tremor; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13315808	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2017GB02799			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Skin Exfoliation; Skin Fissures	Escitalopram			S	Unknown	Unk		Invagen
	Canesten			C	Unknown	1 Df, Bid		Not Reported
	Citalopram			C	Unknown	1 Df, Qd		Not Reported
	Clobetasone Butyrate			C	Unknown	Unk, Apply 1-2 Times/Day		Not Reported
	Clotrimazole			C	Unknown	Unk, Use As Directed		Not Reported
	Hydrocortisone			C	Unknown	1 Df, Bid		Not Reported
	Lactulose			C	Unknown	15 Ml, Bid		Not Reported
	Naproxen			C	Unknown	1 Df, Maximum Three Times Daily		Not Reported
	Omeprazole			C	Unknown	1 Df, Qd		Not Reported
	Paracetamol			C	Unknown	Unk, One To Two To Be Taken Four Times A Day		Not Reported
	Quetiapine			C	Unknown	1 Df, Qd, Night		Not Reported
	Zerobase			C	Unknown	Unk, Apply Liberally		Not Reported
	Zopiclone			C	Unknown	Unk, Take Half To One Tablet At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13317879	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC-2017SUN00062			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Escitalopram			S	Transplacental	Dose At 36 Week: 10		Taro
	Escitalopram			S	Transplacental	Dose Estimated From 36 Week: 10		Taro

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13323525	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1709166US		42 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Skin Exfoliation; Skin Fissures	Escitalopram Oxalate - Bp			S				Allergan
	Canesten			C				Not Reported
	Clotrimazole			C		Use As Directed.		Not Reported
	Hydrocortisone			C				Not Reported
	Lactulose			C	Unknown			Not Reported
	Naproxen			C		Maximum Three Times Daily.		Not Reported
	Omeprazole			C				Not Reported
	Paracetamol			C		One To Two To Be Taken Four Times A Day.		Not Reported
	Quetiapine			C		Night.		Not Reported
	Zopiclone			C	Unknown	Take Half To One Tablet At Night.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13324461	EXPEDITED (15-DAY)		OT	EG-ALLERGAN-1709155US		20 YR	Female	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Vein Occlusion	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13324683	EXPEDITED (15-DAY)		HO	PHHY2016GB153148		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Hot Flush; Loss Of Consciousness; Palpitations; Psoriasis	Propranolol			S	Oral	40 Milligram Daily		Novartis
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported
	Amlodipine			C	Unknown	10 Milligram Daily;		Not Reported
	Capasal			C	Unknown	250 Mg, Unk		Not Reported
	Cetraben			C	Unknown	500 G, Unk		Not Reported
	Dermol			C	Unknown	200 Ml, Unk		Not Reported
	Dovobet			C	Unknown	30 G, Unk		Not Reported
	Loratadine			C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13325360	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1709123US		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Muscle Haemorrhage; Periorbital Haematoma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Previscan (Fluindione)			S	Oral	Unk, Unknown		Allergan
	Lasilix			C	Unknown			Not Reported
	Levothyrox			C	Unknown	Unk Unk, Unknown		Not Reported
	Tahor			C	Unknown	Unk Unk, Unknown		Not Reported
	Atenolol			C	Unknown	Unk, Unknown		Not Reported
	Speciafoldine			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2017	13175838	EXPEDITED (15-DAY)		HO, OT	PT-LANNETT COMPANY, INC.-PT-2017LAN000437		23 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Syndrome; Metastases To Liver; Metastases To Lymph Nodes; Metastases To	Escitalopram Oxalate			S		10 Mg Tablet Unk		Lannett

Ovary; Metastases To Peritoneum; Metastases To Spleen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2017	13254672	EXPEDITED (15-DAY)		HO	PHHY2017SE020858		84 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea; Product Administration Error; Syncope	Citalopram Sandoz			S	Oral	20 Mg, Unk		Novartis
	Cipralex			S	Oral			Not Reported
	Normorix Mite			C	Unknown			Not Reported
	Artrotec			C	Unknown			Not Reported
	Stesolid			C	Unknown			Not Reported
	Alvedon			C	Unknown			Not Reported
	Trombyl			C	Unknown			Not Reported
	Metoprolol Orion			C	Unknown			Not Reported
	Ovesterin			C	Unknown			Not Reported
	Daktacort			C	Unknown			Not Reported
	Loceryl			C	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2017	13329200	EXPEDITED (15-DAY)		OT	ES-HETERO LABS LTD-1064174		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sialoadenitis	Escitalopram			S	Unknown			Hetero
	Ondansetron			S	Unknown			Not Reported
	Temozolomide			S	Unknown			Not Reported
	Levetiracetam			S	Unknown			Not Reported

	Dexamethasone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	10957850	EXPEDITED (15-DAY)		OT	PHHY2015BR032525		29 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Asthenia; Fatigue; Headache; Hemiparesis; Influenza; Lymphocyte Count Decreased; Vision Blurred; Vision Blurred; White Blood Cell Count Decreased	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13257491	NON-EXPEDITED			US-PFIZER INC-2017072673		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyspnoea; Fall; Irritability; Mood Altered; Skin Discolouration	Chantix			S		Unk		Pfizer
	Lexapro			S		20mg One Time A Day		Not Reported
	Klonopin			C		1mg, 1 Tablet 2 Times A Day As Needed		Not Reported
	Amitriptyline			C	Oral	10mg, 2 Tablets At Bedtime		Not Reported
	Ambien			C		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13330243	EXPEDITED (15-DAY)		OT	GB-TEVA-746165ACC		42 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Skin Exfoliation; Skin Fissures	Escitalopram			S				Ivax
	Canesten			C		2 Dosage Forms Daily;		Not Reported

Citalopram	C	1 Dosage Forms Daily;	Not Reported
Clobetasone Butyrate	C	Apply 1-2 Times/Day.	Not Reported
Clotrimazole	C	Use As Directed.	Not Reported
Hydrocortisone	C	2 Dosage Forms Daily;	Not Reported
Lactulose	C	30 Ml Daily;	Not Reported
Naproxen	C	Maximum Three Times Daily.	Not Reported
Omeprazole	C	1 Dosage Forms Daily;	Not Reported
Paracetamol	C	One To Two To Be Taken Four Times A Day.	Not Reported
Quetiapine	C	1 Dosage Forms Daily;	Not Reported
Zerobase	C	Apply Liberally.	Not Reported
Zopiclone	C	Take Half To One Tablet At Night.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13330946	EXPEDITED (15-DAY)		HO	GB-ACCORD-045606		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Hot Flush; Hyperhidrosis; Loss Of Consciousness; Palpitations; Psoriasis	Escitalopram			S				Accord
	Propranolol/Propranolol Hydrochloride/Propranolol			S	Oral			Accord
	Phenobarbital							
	Amlodipine			C				Not Reported
	Capasal			C		Therapeutic Shampoo		Not Reported
	Cetraben			C		Emollient Cream		Not Reported
	Dermol			C		Shower Emollient		Not Reported
	Dovobet			C				Not Reported
	Loratadine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13331232	EXPEDITED (15-DAY)		HO, OT	ES-ZYDUS-014069		49 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Headache; Hyperhidrosis; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Nausea; Paraesthesia; Respiratory Alkalosis; Seizure; Tremor; Vomiting	Escitalopram			S	Unknown			Zydus Pharm
	Valeriana/Passion Flower/White Hawthorn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13331249	EXPEDITED (15-DAY)		OT	ES-ZYDUS-014071		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Salivary Duct Obstruction; Sialoadenitis	Escitalopram			S	Unknown			Zydus Pharm
	Ondansetron			S	Unknown			Not Reported
	Temozolomide			S	Unknown			Not Reported
	Dexamethasone			S	Unknown			Not Reported
	Levetiracetam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13331266	EXPEDITED (15-DAY)		HO	GB-CIPLA LTD.-2017GB02807			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Hot Flush; Loss Of Consciousness; Palpitations; Psoriasis	Escitalopram			S	Unknown	5 Mg, Unk		Invagen
	Propranolol			S	Oral	40 Mg, Qd (40 Milligram Daily)		Not Reported
	Amlodipine			C	Unknown	10 Mg, Qd (10 Milligram Daily)		Not Reported
	Capasal			C	Unknown	250 Mg, Unk		Not Reported
	Cetraben Emollient Cream			C	Unknown	500 G, Unk		Not Reported
	Dermol Shampoo			C	Unknown	200 Ml, Unk		Not Reported

Dovobet	C	Unknown	30 G, Unk		Not Reported
Loratadine	C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13332252	EXPEDITED (15-DAY)		HO	GB-AUROBINDO-AUR-APL-2017-30622		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Hot Flush; Loss Of Consciousness; Palpitations; Psoriasis	Escitalopram			S	Unknown	5 Mg, Unk		Aurobindo
	Propranolol			S	Oral	40 Mg, Once A Day		Not Reported
	Amlodipine			C	Unknown	10 Mg, Once A Day		Not Reported
	Capasal			C	Unknown	250 Mg, Unk		Not Reported
	Cetraben /01007601/			C	Unknown	500 G, Unk		Not Reported
	Dermol /00337102/			C	Unknown	200 Ml, Unk		Not Reported
	Dovobet			C	Unknown	30 G, Unk		Not Reported
	Loratadine			C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13332883	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1709328US		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Zyloric			C		Unk		Not Reported
	Inegy			C		Unk		Not Reported
	Toviaz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13332945	NON-EXPEDITED			US-PFIZER INC-2017108983		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xanax			S		Unk		Pfizer

	Lexapro			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13334663	EXPEDITED (15-DAY)		OT	US-ASTRAZENECA-2017SE24246		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Arthropathy; Bronchitis; Dyspnoea; Fall; Hypotension; Insomnia; Mood Altered; Nephrolithiasis; Panic Attack; Skin Discolouration	Seroquel			S	Oral			Zeneca
	Lexapro			S	Unknown			Not Reported
	Chantix			S	Unknown	Daily		Not Reported
	Corticosteroid Nos			S	Unknown			Not Reported
	Klonopin			C		1 Tablet 2 Times A Day As Needed		Not Reported
	Amitriptyline			C	Oral			Not Reported
	Thyroxine			C				Not Reported
	Vitamin D2			C				Not Reported
	Vitamin D			C				Not Reported
	Ambien			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13336945	EXPEDITED (15-DAY)		OT	GXKR2017DE001615			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Small For Dates Baby	Bupropion			S	Transplacental	150 [Mg/D]		Novartis
	Escitalopram			S	Transplacental	25 [Mg/D]		Not Reported
	L-Thyroxine			C	Transplacental	100 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13261610	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1706544US		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Compulsive Shopping; Diffuse Alopecia; Erection Increased; Hypersexuality	Escitalopram Oxalate - Bp		S	Oral	20 Mg, Qd	Allergan
	Xeroquel		S	Oral	150 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13335965	EXPEDITED (15-DAY)			US-LUNDBECK-DKLU2027679			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Palpitations; Tremor	Lexapro Film-Coated Tablets			S	Unknown	Unk		Forest
	Lithium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13336425	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2017-30626		33 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Fatigue; Tinnitus	Escitalopram			S	Oral	5 Mg, Unk		Aurobindo
	Escitalopram			S	Oral	10 Mg, Unk		Aurobindo
	Escitalopram			S	Oral	20 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13337338	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2017-30689		42 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Skin Exfoliation; Skin Fissures	Escitalopram			S	Unknown	Unk		Aurobindo
	Canesten			C	Unknown	1 Df, Two Times A Day		Not Reported
	Citalopram			C	Unknown	1 Df, Once A Day		Not Reported
	Clobetasone Butyrate			C	Unknown	Apply 1-2 Times/Day.		Not Reported
	Clotrimazole			C	Unknown	Use As Directed.		Not Reported
	Hydrocortisone			C	Unknown	1 Df, Two Times A Day		Not Reported
	Lactulose			C	Unknown	15 Ml, Two Times A Day		Not Reported
	Naproxen			C	Unknown	1 Df, Maximum Three		Not Reported

				Times Daily.	
	Omeprazole	C	Unknown	1 Df, Once A Day	Not Reported
	Paracetamol	C	Unknown	One To Two To Be Taken Four Times A Day.	Not Reported
	Quetiapine	C		1 Df, Once A Day, At Night	Not Reported
	Zerobase /00103901/	C	Unknown	Apply Liberally.	Not Reported
	Zopiclone	C	Unknown	Take Half To One Tablet At Night.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13284567	EXPEDITED (15-DAY)		HO	PL-JNJFOC-20170222386			Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Fear; Feeling Abnormal; Hospitalisation; Tension	Risperidone			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Doxepin			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Propranolol			S	Unknown			Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Chlorprothixene			S	Unknown			Not Reported
	Mirtagen			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Buspirone			S	Unknown			Not Reported
	Flupentixol			S	Unknown			Not Reported
	Amisulpride			S	Unknown			Not Reported
	Hydroxyzine			S	Unknown			Not Reported

	Pridinol	S	Unknown	Not Reported
	Alprazolam	S	Unknown	Not Reported
	Estazolam	S	Unknown	Not Reported
	Lorazepam	S	Unknown	Not Reported
	Lorazepam	S	Unknown	Not Reported
	Lorazepam	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13319661	EXPEDITED (15-DAY)		HO, LT, OT	ES-TEVA-745163ISR		49 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Depression; Dyspnoea; Headache; Hyperhidrosis; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Nausea; Pancreatitis Chronic; Paraesthesia; Respiratory Alkalosis; Tremor; Vomiting	Escitalopram			S	Unknown	5 Milligram Daily;		Ivax
	Enrelax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13336965	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1709589US		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dyskinesia; Dyspepsia; Dysphagia; Energy Increased; Fatigue; Gastric Cyst; Gastrointestinal Disorder; Gastrointestinal Motility Disorder; Hospitalisation; Hyperhidrosis; Insomnia; Loss Of Libido; Malaise;	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Temesta (Lorazepam)			C	Unknown			Not Reported
	Seresta			C	Unknown			Not Reported
	Transilane (Potassium Bicarbonate\Psyllium Husk)			C	Unknown			Not Reported
	Aprovel			C	Unknown			Not Reported

Movement Disorder; Paraesthesia; Prostatomegaly; Pyrexia; Renal Cyst; Serotonin Syndrome; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13340488	EXPEDITED (15-DAY)		OT	GB-ACCORD-048998		42 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Skin Exfoliation; Skin Fissures	Escitalopram			S				Accord
	Canesten			C				Not Reported
	Citalopram			C				Not Reported
	Clobetasone			C		Apply 1-2 Times/Day.		Not Reported
	Clotrimazole			C		Use As Directed.		Not Reported
	Hydrocortisone			C				Not Reported
	Lactulose			C				Not Reported
	Naproxen			C		Maximum Three Times Daily.		Not Reported
	Omeprazole			C				Not Reported
	Paracetamol			C		One To Two To Be Taken Four Times A Day.		Not Reported
	Quetiapine/Quetiapine Fumarate			C		Night.		Not Reported
	Zerobase			C		Apply Liberally.		Not Reported
	Zopiclone			C		Take Half To One Tablet At Night.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13341300	EXPEDITED (15-DAY)		HO	PHHY2017FR035644		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Amoxicilline/Acide Clavulanique Sandoz			S	Unknown	3 G, Qd		Novartis
	Seroplex			S	Oral	1 Df, Qd		Not Reported

	Tenoretic	S	Unknown	1 Df, Qd	Not Reported
	Ultibro Breezhaler	C	Respiratory (inhalation)		Not Reported
	Timolol Maleate	C	Ophthalmic		Not Reported
	Smecta	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13343874	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1710003US		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Loxen (Nicardipine Hydrochloride)			C	Unknown			Not Reported
	Bisoce			C	Unknown			Not Reported
	Kardegic			C	Unknown			Not Reported
	Movicol			C	Unknown			Not Reported
	Lexomil			C	Unknown			Not Reported
	Naaxia			C	Unknown			Not Reported
	Debridat			C	Unknown			Not Reported
	Uvedose			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13345239	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Eye Swelling; Eyelid Exfoliation; Vision Blurred	Escitalopram 10mg Tablet			S	Oral	Quantity:30 Tablet(S);		Accord
	Levothroid			C				Not Reported
	Zyrtec			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Valacyclovir			C				Not Reported
	Fluticasone			C				Not Reported
	B-12			C				Not Reported
	Dramamine (Meclizine)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13296288	EXPEDITED (15-DAY)			BR-009507513-1702BRA011636		73 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Depression; Drug Interaction; Dry Mouth; Dyspepsia; Flatulence; Gastric Polyps; Gastritis; Gastrooesophageal Reflux Disease; Hiatus Hernia; Hypertension; Insomnia; Paraesthesia	Vytorin			S	Oral	1 Tablet (10-20 Mg), Qd		Merck
	Vytorin			S	Oral	1 Tablet (10-20 Mg), Qd		Merck
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13323511	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1709147US		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hidradenitis	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Methotrexate			S	Unknown	Unk Unk, Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unk, Unknown		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Zantac			C	Unknown			Not Reported
	Tylenol W/Codeine			C	Unknown	Unk, Unknown		Not Reported
	Butrans Opoids			C	Transdermal	Unk, Unknown		Not Reported
	Zoledronic Acid			C	Unknown	Unk, Unknown		Not Reported
	Plaquenil			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13344329	EXPEDITED (15-DAY)		OT	NZ-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001607		< 1 DAY	Male	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Withdrawal Syndrome Neonatal; Nystagmus; Optic Atrophy	Clonidine		S	Oral	Not Reported
	Gabapentin		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported
	Allopurinol		S	Oral	Not Reported
	Mercaptopurine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13345016	NON-EXPEDITED		OT	PHEH2017US007063			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis; Skin Plaque	Cosentyx			S	Subcutaneous	300 Mg, Qw		Novartis
	Cosentyx			S				Novartis
	Lopressor			S	Unknown			Not Reported
	Flecainide			S	Unknown			Not Reported
	Protonix			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Vit D3			S	Unknown			Not Reported
	Vitamin B1			S	Unknown			Not Reported
	Vitamin C			S	Unknown			Not Reported
	Klonopin			C	Unknown	Unk Unk, Prn		Not Reported
	Melatonin			C	Unknown	Unk Unk, Prn		Not Reported
	Hydrocodone			C	Unknown	Unk Unk, Prn		Not Reported
	Ipratropium/Albuterol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13349535	DIRECT					27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature	Escitalopram			S	Oral			Not Reported

Increased; Hyperhidrosis; Vomiting	Xanax	C		Not Reported
	Dicyclomine	C		Not Reported
	Omperazole	C		Not Reported
	Imodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2017	13348255	EXPEDITED (15-DAY)			US-LUNDBECK-DKLU2025460		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Feeling Abnormal; Off Label Use	Escitalopram Oral Drops			S	Oral	30 Mg, Qd		Not Reported
	Escitalopram Oral Drops			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13299558	EXPEDITED (15-DAY)		DS, OT	US-ALLERGAN-1708499US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Immobile; Nausea; Paralysis; Tinnitus; Wrong Product Administered	Lexapro			S	Oral	20 Mg, Single		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348842	NON-EXPEDITED			US-TEVA-656308USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Product Substitution Issue	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348843	NON-EXPEDITED			US-TEVA-656789USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348845	NON-EXPEDITED			US-TEVA-700341USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Panic Reaction	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348846	NON-EXPEDITED			US-TEVA-690857USA		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Escitalopram			S	Unknown			Ivax
	Xtandl			S	Oral	160 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348847	NON-EXPEDITED			US-TEVA-648541USA		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mydriasis	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348848	NON-EXPEDITED			US-TEVA-698272USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysgraphia; Dysstasia;	Escitalopram			S				Ivax
Product Use In Unapproved Indication; Therapeutic Product Effect Incomplete	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348849	NON-EXPEDITED			US-TEVA-641850USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hot Flush; Insomnia	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348850	NON-EXPEDITED			US-TEVA-640973USA		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Appetite; Weight Increased	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348851	NON-EXPEDITED			US-TEVA-642536USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Dizziness; Epistaxis; Feeling Abnormal; Inappropriate Schedule Of Product Administration; Nervousness	Escitalopram			S				Ivax
	Flonase			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348852	NON-EXPEDITED			US-TEVA-729396USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Product Label On Wrong Product	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348854	NON-EXPEDITED			US-TEVA-643939USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Depression; Drug Ineffective; Heart Rate Increased	Escitalopram		S	Unknown	Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348855	NON-EXPEDITED			US-TEVA-678102USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Epistaxis; Feeding Disorder; Gingival Bleeding; Gingival Disorder; Headache; Hyperhidrosis; Oral Disorder; Thirst; Weight Increased; Wrong Technique In Product Usage Process	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348856	NON-EXPEDITED			US-TEVA-691095USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anxiety; Bone Pain; Drug Ineffective	Escitalopram			S	Unknown			Ivax
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348857	NON-EXPEDITED			US-TEVA-740550USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Decreased Appetite; Depression; Drug Ineffective; Feeling Abnormal; Mood Swings	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348858	NON-EXPEDITED			US-TEVA-643087USA		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Feeling Abnormal; Flatulence; Nausea; Weight Decreased	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348859	NON-EXPEDITED		OT	US-TEVA-714482USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Procedural Pain; Serotonin Syndrome	Escitalopram			S	Unknown			Ivax
	Subsys			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348860	NON-EXPEDITED			US-TEVA-744291ACC			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348861	NON-EXPEDITED			US-TEVA-647832USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348862	NON-EXPEDITED			US-TEVA-648626USA		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Burning Sensation; Drug Hypersensitivity; Fatigue; Fatigue; Headache; Headache; Rash	Escitalopram			S	Unknown			Ivax
	Baclofen			S	Unknown			Ivax
	Citalopram			S	Unknown			Pliva
	Eszopiclone			S	Unknown			Teva
	Mirtazapine			S	Unknown			Teva
	Penicillin (Benzylpenicillin)			S	Unknown			Teva
	Trazodone			S	Unknown			Barr
	Zolpidem			S	Unknown			Teva
	Lyrica			S	Unknown	200 Milligram Daily;		Not Reported
	Daypro			S	Unknown			Not Reported
	Levoxyl			S	Unknown			Not Reported
	Protonix			S	Unknown			Not Reported
	Zithromax			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Tegretol Xr			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13348863	NON-EXPEDITED			US-TEVA-735961ACC			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Insomnia	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13349738	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2014-00467			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Dyspnoea; Generalised Tonic-Clonic Seizure; Hallucinations,	Escitalopram Tablets Usp 10mg			S	Unknown	Unk Unk,Unk,		Aurobindo
	Depakote			C	Unknown	Unk Unk,Unk,		Not Reported

Mixed; Muscle Rigidity;
Muscle Spasms

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13350614	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1710280US		97 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia; Seizure	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13350820	EXPEDITED (15-DAY)			US-LUNDBECK-DKLU2024398		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Tremor	Lexapro Film-Coated Tablets			S	Unknown	10 Mg, Daily		Forest
	Ativan			C	Unknown	Unk		Not Reported
	Mavik			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Fioricet			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13351777	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017109981		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma Scale Abnormal; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Xanax			S	Oral	1/2-1/2-1/2-2		Pfizer
	Xanax			S	Oral	Unk, Single		Pfizer
	Seroplex			S	Oral	20 Mg, Unk		Not Reported
	Seroplex			S	Oral	Unk, Single		Not Reported
	Solian			S	Oral	100 Mg, 1x/Day		Not Reported
	Solian			S	Oral	Unk, Single		Not Reported
	Nozinan			S	Oral	Between 0.5 And 1		Not Reported

					Dosage Form In The Evening	
	Nozinan		S	Oral	Unk, Single	Not Reported
	Enbrel		C		One Injection Weekly	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13353462	EXPEDITED (15-DAY)			US-LUNDBECK-DKLU2026728			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro Film-Coated Tablets			S	Oral	Unk		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13353465	EXPEDITED (15-DAY)			US-LUNDBECK-DKLU2013746			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Weight Increased; Wrong Technique In Product Usage Process	Lexapro Film-Coated Tablets			S	Oral	10 Mg, Bid		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13353606	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017004464			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Bradycardia Neonatal; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Hypertension Neonatal; Neonatal Gastrointestinal Disorder; Neonatal Hypoxia; Small	Escitalopram			S	Transplacental	25 Mg/D (1 Trimester) (0.-39.4 Gestational Week)		Macleods
	Bupropion			S	Transplacental	150 Mg/Day (1 Trimester) (0.-39.4 Gestational Wee)		Not Reported
	L-Thyroxine Sodium			C	Transplacental	100 Mg/D Qd (1 Trimester) (0.-39.4 Gestational Week)		Not Reported

For Dates Baby; Tremor
Neonatal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13354709	EXPEDITED (15-DAY)		OT	DE-GLAXOSMITHKLINE-DE2017GSK037872		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Bradycardia; Drug Withdrawal Syndrome Neonatal; Gastrointestinal Disorder; Hypertonia; Oxygen Saturation Decreased; Small For Dates Baby; Tremor; Tremor Neonatal	Bupropion			S	Transplacental	150 Mg, Qd		Glaxosmithkline
	Escitalopram			S	Transplacental	25 G, Qd		Glaxosmithkline
	L-Thyroxin			S	Oral	100 Ug, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13356847	EXPEDITED (15-DAY)		OT	ZA-MYLANLABS-2017M1016951			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neck Surgery	Mylan Alprazolam 1mg			S		Unk		Mylan
	Topzol (Tioconazole)			S		Unk		Mylan
	Lexamil			S		Unk		Mylan
	Molipaxin			S		Unk		Mylan
	Altosec			S		Unk		Mylan
	Angeliq			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	12898358	EXPEDITED (15-DAY)		LT	JP-ALLERGAN-1674184US		61 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Bundle Branch	Escitalopram Oxalate - Bp			S	Oral	20 Mg		Allergan

Block Right; Electrocardiogram Qt Prolonged	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd		Allergan
	Magnesium Oxide	C	Oral	1.5 G, Qd		Not Reported
	Reflex	C	Oral	15 Mg, Qd		Not Reported
	Meilax	C	Oral	1 Mg, Qd		Not Reported
	Januvia	C	Oral	Unk		Not Reported
	Gliclazide	C	Oral	Unk		Not Reported
	Paxil Cr	C	Oral	12.5 Mg, Unk		Not Reported
	Paxil Cr	C	Oral	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13323791	EXPEDITED (15-DAY)		OT	ES-TEVA-746229ROM		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sialoadenitis	Ondansetron			S	Unknown			Teva
	Escitalopram			S	Unknown			Ivax
	Temozolomide			C	Unknown			Not Reported
	Levetiracetam			C	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13334202	EXPEDITED (15-DAY)		DS, OT	CH-GILEAD-2017-0261671		65 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Nephritic Syndrome	Harvoni			S	Oral	1 Df, Qd		Gilead
	Escitalopram			S	Oral			Not Reported
	Pantoprazol			S	Oral			Not Reported
	Paracetamol			S	Oral	2000 Mg, Prn		Not Reported
	Etodolac			S	Oral	600 Unk, Unk		Not Reported
	Vitamin D3			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13358602	EXPEDITED (15-DAY)		OT	DE-TEVA-749636GER		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	25 Milligram Daily;		Ivax
	Bupropion			S	Transplacental	150 Milligram Daily;		Not Reported
	L-Thyroxin			C	Transplacental	100 Microgram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13359233	EXPEDITED (15-DAY)		LT, OT	CH-ASTRAZENECA-2017SE27487		85 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemoglobin Decreased; Loss Of Consciousness	Carbostesin			S	Intrathecal	7.5 Mg, Then 2.5 Mg And 5 Mg		Not Reported
	Atacand			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Metoprolol Succinate			S	Oral			Not Reported
	Dexmedetomidine Hydrochloride			S	Intravenous drip	38.1 Ug, Dosing Unknown		Not Reported
	Phenylephrin			S	Intravenous drip	525 Ug, Dosing Unknown		Not Reported
	Sintrom			C				Not Reported
	Aldactone			C				Not Reported
	Omeprazol			C				Not Reported
	Zoldorm			C				Not Reported
	Lexotanil			C				Not Reported
	Colecalciferol			C		6 Drops Once Daily		Not Reported
	Zinacef			C	Intravenous (not otherwise specified)	1.5 G		Not Reported
	Adrenaline			C	Intravenous bolus	0.5 Mg		Not Reported
	Chirocaine			C	Intra-articular	20.0ml Unknown		Not Reported
	Tora Dol			C	Intra-articular	30.0mg Unknown		Not Reported

	Nexium	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13360460	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1710905US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13360729	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1710677US		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram Oxalate - Bp			S	Transplacental	25 Mg, Qd		Allergan
	Bupropion			S	Transplacental	150 Mg, Qd		Not Reported
	L-Thyroxin			C	Transplacental	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13360746	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1000017118		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Dyspepsia; Hair Growth Abnormal; Headache; Nausea; Neoplasm Malignant; Nervousness; Paraesthesia	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lorazepam			C	Oral	.5 Mg, Qid		Not Reported
	Lorazepam			C				Not Reported
	Prilosec			C	Oral	Unk Unk, ,Freq Unit As Required		Not Reported
	Vitamin D3			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13360748	EXPEDITED (15-DAY)		HO	AU-ALLERGAN-1710663US		29 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Polyhydramnios	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13162182	NON-EXPEDITED			US-PFIZER INC-2017038633		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Advil			S		Unk		Pfizer
	Topiramate			S		50 Mg, 2x/Day(One In The Morning And One At Night)		Not Reported
	Escitalopram			S		1 Df, Daily		Not Reported
	Tylenol			S		Unk		Not Reported
	Fioricet			S		Unk		Not Reported
	Sumatriptan			S		100 Mg, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13348310	EXPEDITED (15-DAY)		OT	PHHY2017AU036739		28 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Product Prescribing Error	Ritalin			S	Unknown	Unk		Not Reported
	Tramadol			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported

Zolpidem	S	Unknown	Unk		Not Reported
Oxycodone Hydrochloride	S	Unknown	Unk		Not Reported
Alprazolam	S	Unknown	Unk		Not Reported
Escitalopram	S	Unknown	Unk		Not Reported
Naproxen	S	Unknown	Unk		Not Reported
Pregabalin	S	Unknown	Unk		Not Reported
Buprenorphine	S	Unknown	Unk		Not Reported
Oxazepam	S	Unknown	Unk		Not Reported
Dexamphetamine	S	Unknown	Unk		Not Reported
Prednisolone	S	Unknown	Unk		Not Reported
Folic Acid	S	Unknown	Unk		Not Reported
Clonidine	S	Unknown	Unk		Not Reported
Lorazepam	S	Unknown	Unk		Not Reported
Cocaine	S	Unknown	Unk		Not Reported
Cannabis	S	Unknown	Unk		Not Reported
Temazepam	S	Unknown	Unk		Not Reported
Psilocybine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13362270	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2017-01308		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sialoadenitis	Escitalopram			S		Unk		Lupin
	Ondansetron			S		Unk		Not Reported
	Temozolomide			C		Unk		Not Reported
	Levetiracetam			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13362336	NON-EXPEDITED			US-TAKEDA-2017TUS005861			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Dexilant			S	Oral	60 Mg, Qd		Takeda
	Viberzi			S	Unknown	Unk		Not Reported
	Bupropion			C	Oral	150 Mg, Tid		Not Reported
	Tamsulosin			C	Oral	0.4 Mg, Qd		Not Reported
	Finasteride			C	Oral	5 Mg, Qd		Not Reported
	Methylphenidate			C	Oral	20 Mg, Tid		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13363131	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017119194		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Amlor			S	Oral	5 Mg, 1x/Day		Pfizer
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Zestril			S	Oral	20 Mg, 1x/Day		Not Reported
	Stagid			S	Oral	700 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13365099	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1017868			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	25 [Mg/D]		Not Reported
	Bupropion /00700502/			S	Transplacental	150 [Mg/D]		Mylan
	L-Thyroxin			C	Transplacental	100 [Microgram/D]		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13367331	DIRECT		DS			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systolic Hypertension	Escitalopram			S	Oral	Quantity:30 Tablet(S);		Not Reported
	Xanax			C				Not Reported
	Baby Aspirin			C				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13368040	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Agitation; Drug Interaction; Epistaxis; Logorrhoea	Escitalopram 10mg Aurobindo Pharma			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13360426	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1710610US		43 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Depressed Level Of Consciousness; Disturbance In Attention; Feeling Abnormal; Memory Impairment	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13366863	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2017-31575		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Sopor	Escitalopram	S	Oral	270 Mg, Total		Aurobindo
	Quetiapine	S	Oral	Unk		Aurobindo
	Carbolithium	S	Oral	5 Df, Total		Not Reported
	Etiltox	S	Oral	9 Df, Total		Not Reported
	Ethyl Alcohol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13366932	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2017-31181		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Small For Dates Baby	Escitalopram			S	Transplacental	25 Mg, Once A Day		Aurobindo
	Bupropion			S	Transplacental	150 Mg, Once A Day		Not Reported
	L-Thyroxin			C	Transplacental	100 Mcg, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13371202	EXPEDITED (15-DAY)		LT	PHHY2017CH039123		85 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness	Meto Zerok			S	Oral	50 Mg, Bid		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Atacand			S	Oral	32 Mg, Qd		Not Reported
	Dexdor			S	Intravenous drip	38.1 Ug, Unk		Not Reported
	Phenylephrin			S	Intravenous drip	525 Ug, Unk		Not Reported
	Carbostesin			S	Intrathecal	15 Mg, Unk		Not Reported
	Sintrom			C	Unknown			Not Reported
	Aldactone			C	Unknown			Not Reported
	Omeprazol			C	Unknown			Not Reported
	Zoldorm			C	Unknown			Not Reported
	Lexotanil			C	Unknown			Not Reported
	Colecalciferol			C	Unknown			Not Reported

Zinacef	C	Unknown	1.5 G, Unk		Not Reported
Adrenaline	C	Intravenous bolus	0.5 Mg, Unk		Not Reported
Chirocaine	C	Unknown			Not Reported
Tora Dol	C	Unknown	30 Mg, Unk		Not Reported
Nexium	C	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13371342	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1711190US		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma Scale Abnormal; Road Traffic Accident; Sinus Tachycardia; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Nozinan			C				Not Reported
	Solian			C	Oral			Not Reported
	Xanax			C	Oral			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13371349	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1711227US		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13371352	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1710683US		27 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy	Escitalopram Oxalate - Bp			S	Oral	25 Mg, Qd		Allergan
	Bupropion			S	Oral	150 Mg, Qd		Not Reported
	L-Thyroxin			C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13372277	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine; Nausea; Vomiting	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13030231	EXPEDITED (15-DAY)		HO	FR-SA-2016SA228619		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Cutaneous Lupus Erythematosus	Aprovel			S	Oral			Not Reported
	Loperamide			S	Oral			Not Reported
	Aerius (Desloratadine)			S	Oral			Not Reported
	Aerius (Desloratadine)			S	Oral			Not Reported
	Gaviscon			S	Oral			Not Reported
	Eliquis			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Hemigoxine Nativelle			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13099690	EXPEDITED (15-DAY)		HO	FR-ABBVIE-17K-056-1827945-00		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinomycosis; Headache; Hypoacusis; Osteomyelitis; Osteonecrosis Of Jaw	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Imeth			S	Unknown			Not Reported
	Intelence			S	Oral			Not Reported
	Kivexa			S	Unknown			Not Reported
	Nebivolol			S	Unknown			Not Reported

	Escitalopram	S	Unknown		Not Reported
	Speciafoldine	S	Unknown		Not Reported
	Ketoprofene	C			Not Reported
	Omeprazole	C			Not Reported
	Candesartan Cilexetil	C			Not Reported
	Fenofibrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13281888	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-134628		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sialoadenitis	Escitalopram			S	Unknown	Unk		Not Reported
	Ondansetron			S	Unknown	Unk		Natco Pharma
	Temozolomide			C	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13335845	EXPEDITED (15-DAY)		OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-021116		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug Abuse; Hypokinesia; Movement Disorder	Abilify			S	Oral	1 Df, Unk		Bristol Myers Squibb
	Efexor			S	Oral	1 Df, Unk		Not Reported
	Tavor /00273201/			S	Oral	1 Df, Unk		Not Reported
	Cipralex /01588501/			S	Unknown	60 Mg, Unk		Not Reported
	Talofen			S	Oral	5 Gtt, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13372406	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-		1 DAY	Male	DEU

2017RR-136485

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Small For Dates Baby	Escitalopram			S	Transplacental	25 Mg, Qd		Not Reported
	Bupropion			S	Transplacental	150 Mg, Qd		Sun
	L-Thyroxin			C	Transplacental	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13373909	NON-EXPEDITED			US-PFIZER INC-2017131896		72 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuralgia	Lyrica			S		50 Mg, Unk (At Night)		Pfizer
	Lyrica			S		75 Mg, Unk		Pfizer
	Clonazepam			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13375309	EXPEDITED (15-DAY)		LT, OT	CH-ARALEZ PHARMACEUTICALS R&D INC.-ARA-TP-CH-2017-		85 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemoglobin Decreased; Loss Of Consciousness	Metoprolol Succinate			S	Oral			Aralez Pharmaceuticals
	Carbostesin			S	Intrathecal	7.5 Mg, Then 2.5 Mg And 5 Mg		Not Reported
	Atacand			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Dexmedetomidine Hydrochloride			S	Intravenous drip	38.1 Ug, Dosing Unknown		Not Reported
	Phenylephrin			S	Intravenous drip	525 Ug, Dosing Unknown		Not Reported

	Sintrom	C	Unknown	Not Reported
	Aldactone	C	Unknown	Not Reported
	Omeprazole	C	Unknown	Not Reported
	Zoldem	C	Unknown	Not Reported
	Lexotanil	C	Unknown	Not Reported
	Colecalciferol	C	Unknown	Not Reported
	Zinacef	C	Intravenous (not otherwise specified)	Not Reported
	Adrenaline	C	Intravenous bolus	Not Reported
	Chirocaine	C	Intra-articular	Not Reported
	Toradol	C	Intra-articular	Not Reported
	Nexium For Injection	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2017	12971631	EXPEDITED (15-DAY)		HO	US-LUNDBECK-DKLU2022931		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dizziness; Dizziness Postural; Early Satiety; Muscular Weakness; Orthostatic Hypotension; Syncope; Urinary Tract Infection Pseudomonal; Vomiting	Northera			S	Unknown	Schedule B		Lundbeck
	Northera			S	Unknown			Lundbeck
	Northera			S	Unknown			Lundbeck
	Northera			S	Oral	Schedule B		Lundbeck
	Lexapro Film-Coated Tablets			S	Unknown			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2017	13375495	EXPEDITED (15-DAY)		HO, OT	US-SUNOVION-2017SUN000087			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Blood Glucose Increased; Drug Abuse; Drug Ineffective;	Latuda			S	Oral	Unk		Sunovion
	Latuda			S	Oral	Unk		Sunovion

Heart Rate Increased; Sinus Disorder; Suicidal Ideation	Lexapro	S	Unk	Not Reported
	Sudafed	S	Unk	Not Reported
	Abilify	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2017	13376939	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2014-07832		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Brain Oedema; Cerebral Infarction; Cerebral Infarction; Clonus; Coma; Condition Aggravated; Confusional State; Death; Decerebrate Posture; Heart Rate Abnormal; Hyperreflexia; Mental Status Changes; Muscle Rigidity; Muscle Rigidity; Posterior Reversible Encephalopathy Syndrome; Pyrexia; Reversible Cerebral Vasoconstriction Syndrome; Subarachnoid Haemorrhage; Tachycardia; Thunderclap Headache	Escitalopram			S	Unknown	10 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2017	13380747	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Escitalopram			S				Bluepoint Laboratories

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13026771	EXPEDITED (15-DAY)		HO, OT	FR-009507513-1612FRA006447		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Cutaneous Lupus Erythematosus	Aerius (Desloratadine)			S	Oral	Unk		Merck
	Aprovel			S	Oral	Unk		Not Reported
	Gaviscon Liquid Antacid			S	Oral	Unk		Not Reported
	Eliquis			S	Oral	2.5 Mg, Bid		Not Reported
	Inexium (Esomeprazole Magnesium)			S	Oral	20 Mg, Qd		Not Reported
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Hemigoxine Nativelle			S	Oral	Unk		Not Reported
	Loperamide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13181684	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1703914US		70 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Neoplasm Malignant; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13382898	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017129205		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Diarrhoea; Diverticulum Intestinal	Tahor			S	Oral	Unk		Pfizer
	Coolmetec			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13384321	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1711916US			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Cancer	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13384767	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2016PRN00337		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Feeling Abnormal	Escitalopram			S	Oral	10 Mg, 1x/Day		Prinston Pharmaceutical
	Escitalopram			S				Prinston Pharmaceutical
	Flax Seed Oil			C				Not Reported
	Tramadol			C				Not Reported
	Melatonin			C				Not Reported
	Zyrtec D			C				Not Reported
	Theraflu			C				Not Reported
	Ibuprofen			C				Not Reported
	Sinex Nose Spray			C				Not Reported
	Wellbutrin			S		Unk		Not Reported
	Wellbutrin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13385261	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1711921US		38 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus Generalised; Rash Maculo-Papular	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13385270	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1711928US		82 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Hypoxia; Fall; Hypotension; Loss Of Consciousness	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Trusopt S			C	Ophthalmic	2 Gtt, Qam		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13038964	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-106663		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Cutaneous Lupus Erythematosus	Eliquis			S	Oral	2.5 Mg, Bid		Bristol Myers Squibb
	Aprovel			S	Unknown	150 Mg, Qd		Not Reported
	Aerius /01398501/			S	Unknown	Unk		Not Reported
	Gaviscon			S	Unknown	Unk		Not Reported
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Inexium /01479302/			S	Unknown	20 Mg, Qd		Not Reported
	Hemigoxine Nativelle			S	Oral	0.125 Mg, Unk		Not Reported
	Loperamide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13243124	EXPEDITED (15-DAY)		HO	GR-ABBVIE-17P-066-1878084-00		70 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Aggression; Agitation; Delusion; Fall; Hallucination; Hypotension; Irritability; Nephrolithiasis; Psychotic Disorder; Pyrexia; Staring; Tremor; Unintentional Medical Device Removal; Urinary Tract Infection	Duodopa			S	Other	Morning Dose:10.5 Ml, Extra Dose: 1.5 Ml, Continuous Rate:2.6 Ml/H		Not Reported
	Duodopa			S	Other			Not Reported
	Entact			S	Unknown			Not Reported
	Filicine			C	Oral			Not Reported
	Omnic Tocas			C	Oral			Not Reported
	Stalevo			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13274430	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2017M1000888			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Off Label Use; Somnolence	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13381552	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1711683US			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteomyelitis; Osteonecrosis	Escitalopram Oxalate - Bp			S		15 Gtt, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13381567	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1711841US		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dizziness; Dizziness Postural; Dyspepsia; Early Satiety; Muscular Weakness; Orthostatic Hypotension; Pseudomonas Infection; Syncope; Vomiting	Lexapro			S	Unknown			Allergan
	Northera			S	Oral	300 Mg, Tid		Not Reported
	Northera			S	Oral	1800 Mg, Qd		Not Reported
	Northera			S	Oral	Unk Unk, Qd		Not Reported
	Northera			S	Oral	900 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13385763	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMPANY-US201608000458			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Affect Lability; Agitation;	Cymbalta			S	Oral	30 Mg, Qd		Eli Lilly And Co

Anger; Anhedonia; Anxiety; Arthralgia; Asthenia; Back Pain; Blood Cholesterol Increased; Confusional State; Diarrhoea; Disturbance In Attention; Dizziness; Drug Ineffective; Drug Withdrawal Syndrome; Dysphoria; Fatigue; Fear; Headache; Hepatic Cyst; Hyperhidrosis; Hypertension; Hypomania; Injury; Insomnia; Irritability; Judgement Impaired; Lethargy; Libido Disorder; Lung Neoplasm; Memory Impairment; Myalgia; Nausea; Nausea; Nausea; Nervousness; Nightmare; Restless Legs Syndrome; Sleep Disorder; Soliloquy; Suicidal Ideation; Tinnitus; Tremor; Vertigo; Visual Impairment; Vomiting; Weight Increased	Cymbalta	S	Oral	60 Mg, Qd		Eli Lilly And Co
	Cymbalta	S	Oral	90 Mg, Qd		Eli Lilly And Co
	Cymbalta	S	Oral	120 Mg, Qd		Eli Lilly And Co
	Cymbalta	S	Oral	30 Mg, Qd		Eli Lilly And Co
	Cymbalta	S	Oral	90 Mg, Qd		Eli Lilly And Co
	Cymbalta	S	Oral	60 Mg, Qd		Eli Lilly And Co
	Cymbalta	S	Oral	30 Mg, Qd		Eli Lilly And Co
	Lexapro	S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13386956	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1712260US		73 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Paroxysmal Arrhythmia	Escitalopram Oxalate - Bp			S		20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S		10 Mg, Qd		Allergan
	Xarelto			C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13387382	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2017M1019137			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Product Prescribing Error	Tramadol			S		Unk		Not Reported
	Paracetamol			S		Unk		Not Reported
	Pantoprazole			S		Unk		Not Reported
	Fentanyl			S		Unk		Not Reported
	Zolpidem			S				Not Reported
	Alprazolam			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Oxazepam			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Temazepam			S		Unk		Not Reported
	Methotrexate			S		Unk		Mylan
	Ritalin			S				Mylan
	Oxycodone			S		Unk		Mylan
	Pregabalin			S		Unk		Mylan
	Buprenorphine			S		Unk		Mylan
	Dexamphetamine			S		Unk		Mylan
	Prednisolone			S		Unk		Mylan
	Clonidine			S		Unk		Mylan
	Lorazepam			S		Unk		Mylan
	Cocaine			S		Unk		Mylan
	Cannabis			S		Unk		Mylan
	Psilocybine			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13388024	EXPEDITED (15-DAY)		DE, OT	FR-IMPAX LABORATORIES, INC-2017-IPXL-00751		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest; Off Label Use; Overdose; Unresponsive To Stimuli	Baclofen		S	Unknown	Unk	Impax
	Colchicine		S	Unknown	Unk	Not Reported
	Escitalopram		S	Unknown	Unk	Not Reported
	Metoprolol		S	Unknown	Unk	Not Reported
	Perindopril		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13388029	EXPEDITED (15-DAY)		DE, OT	FR-IMPAX LABORATORIES, INC-2017-IPXL-00755		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Poisoning Deliberate; Unresponsive To Stimuli	Baclofen			S	Unknown	Unk		Impax
	Acetaminophen			S	Unknown	Unk		Not Reported
	Dextropropoxyphene			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Valpromide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13388404	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2017M1019235			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S		10 Df, Total		Not Reported
	Tavor [Lorazepam]			S		2 Df, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13389412	EXPEDITED (15-DAY)		HO	IT-TEVA-752802ACC		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Carbolithium - 300 Mg Capsule Rigide - Teva Italia S.R.L.			S	Oral	5 Df Total		Barr
	Escitalopram			S	Oral	270 Mg Total		Ivax

	Quetiapine	S	Oral			Not Reported
	Etiltox - 200 Mg Compresse - Afom Dipendenze S.R.L.	S	Oral	9 Df Total		Not Reported
	Ethyl Alcohol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2017	13095471	EXPEDITED (15-DAY)		HO	AU-MYLANLABS-2016M1050143		54 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased; Blood Sodium Decreased; Neuroleptic Malignant Syndrome; White Blood Cell Count Increased	Clozapine			S	Oral	25 Mg, Unk		Not Reported
	Clozapine			S	Oral	Unk		Not Reported
	Clozapine			S	Oral	350 Mg, Qd		Not Reported
	Clozapine			S	Oral	775 Mg, Qd		Not Reported
	Amisulpride			S	Oral	400 Mg, Bid		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Oxazepam			S	Oral	30 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2017	13389628	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-136773		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram			S	Oral	270 Mg Total		Not Reported
	Quetiapine			S	Oral	Unk		Sun
	Carbolithium 300 Mg			S	Oral	5 Df Total		Not Reported
	Etiltox 200 Mg			S	Oral	9 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2017	13393624	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2017AP009118		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Sopor	Quetiapina Doc Generici Compresse Rivestite Con Film	S	Oral			Apotex
	Escitalopram	S	Oral	270 Mg, Total		Not Reported
	Carbolithium	S	Oral	5 Df, Total		Not Reported
	Etiltox	S	Oral	9 Df, Total		Not Reported
	Ethyl Alcohol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2017	13393888	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1000082554		70 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Nausea; Urinary Retention; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S		5 Mg, Qd		Allergan
	Valsartan			S	Unknown	120 Mg, Qd		Not Reported
	Diclofenac			S				Not Reported
	L-Thyroxin			C				Not Reported
	Baldrian-Dispert			C				Not Reported
	Homeopathic Preparation			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2017	13393889	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1712510US		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Diarrhoea	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Coolmetec			S	Oral			Not Reported
	Tahor			S	Oral	Unk		Not Reported
	Valium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13047375	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1681364US		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Cutaneous Lupus Erythematosus	Escitalopram Oxalate - Bp		S	Oral	5 Mg, Qd	Allergan
	Seroplex		S	Oral	5 Mg, Qd	Not Reported
	Aprovel		S	Oral	Unk	Not Reported
	Aerius (Desloratadine)		S	Oral	Unk	Not Reported
	Gaviscon		S	Oral	Unk	Not Reported
	Eliquis		S	Oral	2.5 Mg, Bid	Not Reported
	Inexium		S	Oral	20 Mg, Qd	Not Reported
	Hemigoxine Nativelle		S	Oral	Unk	Not Reported
	Loperamide		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13395914	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2017-31676		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S	Unknown	10 Df, Unk		Aurobindo
	Tavor /00273201/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13397478	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1712676US		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cerebrovascular Accident; Dizziness; Headache; Insomnia; Irritability; Nervousness; Nodule; Palpitations; Tremor; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Lexomil			S	Oral	0.25 Df, Single		Not Reported
	Tenoretic			C	Unknown	50/12.5mg		Not Reported
	Kenzen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13397757	EXPEDITED (15-DAY)		DE, LT, OT	JP-PFIZER INC-2017137368		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardio-Respiratory Arrest; Chest Pain; Somnolence	Effexor 37.5mg			S	Oral	Unk		Pfizer
	Effexor 37.5mg			S	Oral	37.5 Mg, Daily		Pfizer
	Lexapro			S	Oral	20 Mg, Daily		Not Reported
	Lamictal			S	Oral	400 Mg, Daily		Not Reported
	Abilify			S	Oral	3 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13397981	EXPEDITED (15-DAY)		OT	FR-DSJP-DSE-2017-109416			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Diarrhoea	Coolmetec			S	Oral	Unk		Daiichi
	Tahor			S	Oral	Unk Unk, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Valium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13398813	EXPEDITED (15-DAY)		CA	CA-TEVA-755466ACC		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Trisomy 21	Act Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Act Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13399586	DIRECT	Y	OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Nausea; Product Substitution Issue	Escitalopram	S	Oral	90 DAY	Exelan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	13399458	EXPEDITED (15-DAY)		OT	DE-HETERO LABS LTD-1064957		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Serotonin Syndrome; Suicidal Behaviour	Lithium			S	Unknown			Hetero
	Escitalopram			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	13399528	EXPEDITED (15-DAY)		OT	IT-ACCORD-049739		44 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S		10 Df Total		Not Reported
	Tavor [Lorazepam]			S		2 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	13400372	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS-2017GMK026982			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Ondansetron			S	Unknown	Unk		Glenmark
	Sertraline			S	Unknown	Unk,For The Initial Two Trimester		Not Reported
	Escitalopram			S	Unknown	Unk,For The Final Trimester		Not Reported
	Progesterone			S	Unknown	Unk,High-Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	13400404	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-GLENMARK PHARMACEUTICALS-		4 YR	Male	USA

2017GMK026983

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Ondansetron			S	Transplacental	Unk		Glenmark
	Sertraline			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported
	Progesterone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	13401899	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1712712US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Human Herpesvirus 6 Infection; Hypersensitivity; Off Label Use	Progesterone Unk			S	Unknown	Unk Unk, Unknown		Allergan
	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Sertraline			S	Unknown			Not Reported
	Ondansetron			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	13401907	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1712723US		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Progesterone Unk			S	Transplacental			Allergan
	Escitalopram Oxalate Unk			S	Transplacental			Allergan
	Sertraline			S	Transplacental			Not Reported
	Ondansetron			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2017	13028220	NON-EXPEDITED			US-PFIZER INC-2016566548		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Calan			S		Unk		Pfizer
	Tessalon			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2017	13404035	EXPEDITED (15-DAY)		HO, OT	US-TORRENT-00002641		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Delirium; Serotonin Syndrome	Escitalopram			S				Unknown
	Lithium			S				Unknown
	Trazodone			S				Unknown
	Paliperidone			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2017	13404929	EXPEDITED (15-DAY)		OT	DE-BAYER-2017-061458		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervicitis; Haematoma; Metrorrhagia; Thrombocytopenia	Mirena			S	Intra-uterine	20 Mcg/24hr, Cont		Bayer
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2017	13406258	EXPEDITED (15-DAY)		CA, DE, OT	DE-IPCA LABORATORIES LIMITED-IPC201703-000332		4 DAY	Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Foetal	Ondansetron			S				Ipca
	Sertraline			S				Not Reported

Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Escitalopram	S	Not Reported
	Progesterone	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2017	13406705	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1713133US		91 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Melaena	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Pradaxa			S	Oral	150 Mg, Bid		Not Reported
	Bisoprolol			C		5 Mg, Qd		Not Reported
	Simvastatine			C		20 Mg, Qd		Not Reported
	Valsartan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2017	13407269	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1713422US		37 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Contusion; Daydreaming; Diarrhoea; Dizziness; Fatigue; Hyperhidrosis; Off Label Use; Pruritus; Vomiting	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2017	13407406	EXPEDITED (15-DAY)		OT	US-IMPAX LABORATORIES, INC-2017-IPXL-00803		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Depressed Level Of Consciousness; Toxicity To Various Agents	Alprazolam Er			S	Unknown	Unk		Impax
	Buspirone Hydrochloride			S	Unknown	Unk		Impax

	Escitalopram	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2017	13408490	DIRECT		OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dizziness; Impaired Work Ability; Palpitations; Paraesthesia; Product Substitution Issue; Product Substitution Issue	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Accord
	Paxil			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	11817837	NON-EXPEDITED			US-JNJFOC-20151116078			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Distress; Gynaecomastia; Off Label Use; Product Use In Unapproved Indication; Weight Increased	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Focalin			S				Not Reported
	Lexapro			S		10-20 Mg		Not Reported
	Strattera			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	11818361	NON-EXPEDITED			US-JNJFOC-20150812399		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Gynaecomastia; Insomnia; Off Label Use; Product	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported

Use In Unapproved Indication	Risperdal		S	Oral	Not Reported
	Lexapro		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	11819317	NON-EXPEDITED			US-JNJFOC-20150923181			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Gynaecomastia; Hyperprolactinaemia; Off Label Use; Pain; Product Use In Unapproved Indication	Risperdal			S	Oral	1 And 2 Mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	12867614	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1673145US		47 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Pericarditis	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	12881333	NON-EXPEDITED		OT	US-JNJFOC-20161003689		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Disorder Male; Hyperprolactinaemia	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	2-4mg		Not Reported
	Risperdal			S	Oral	2-4mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal M-Tab			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13161498	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-DRREDDYS-USA/USA/17/0086577		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congenital Cardiovascular Anomaly; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Ondansetron			S	Transplacental			Not Reported
	Sertraline Hydrochloride			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Progesterone			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13194980	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1704425US		70 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate - Bp			S	Oral	Q		Allergan
	Rohypnol			C				Not Reported
	Tetramide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13247455	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1705822US		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Appendix Disorder; Depression; Drug Ineffective; Gallbladder Disorder; Musculoskeletal Discomfort; Nerve Compression; Spinal Disorder; Suicidal Ideation	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Embeda			C	Oral	20 Mg, Qd		Not Reported
	Valium			C	Oral	10 Mg, Bid		Not Reported
	Valium			C				Not Reported
	Lyrica			C	Oral	150 Mg, Bid		Not Reported
	Lyrica			C	Oral	75 Mg, Bid		Not Reported

	Levothyroxine	C	Oral	125 Mg, Qd	Not Reported
	Ambien	C	Oral	10 Mg, Prn	Not Reported
	Baclofen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13301263	NON-EXPEDITED			US-PFIZER INC-2017092556		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Effexor Xr			S		300 Mg, 1x/Day		Pfizer
	Gabapentin			S				Pfizer
	Zoloft			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13409181	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13410123	EXPEDITED (15-DAY)		OT	DE-TORRENT-00006328		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bradycardia; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Gastrointestinal Disorder;	Bupropion			S				Unknown
	Escitalopram			S				Unknown
	L-Thyroxin			C				Unknown

Hypertension; Neonatal
Hypoxia; Small For Dates
Baby; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13415728	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20170405561		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Bones Fracture; Fall; Haematoma	Tramadol Hydrochloride			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Simvastatine			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Tardyferon			S	Oral			Not Reported
	Doliprane			C	Unknown			Not Reported
	Uvedose			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13416441	EXPEDITED (15-DAY)		CA, OT	FR-ALLERGAN-1713418US			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coarctation Of The Aorta; Congenital Nose Malformation; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Qd		Allergan
	Seresta			S	Transplacental	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13416512	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1713425US		17 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Growth Retardation; Hypothyroidism; Off Label Use; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Eutyrox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13416764	EXPEDITED (15-DAY)		OT	SE-TEVA-757386ISR		19 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersomnia	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13416855	EXPEDITED (15-DAY)		OT	PL-TEVA-756598ISR		93 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choking; Dyspnoea; Incorrect Product Administration Duration; Oral Mucosal Eruption	Escitalopram Actavis			S		10 Milligram Daily; The Patient Took 1 Tablet		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2017	13418022	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-029267			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Presentation; Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal; Premature Baby	Aripiprazole			S	Transplacental	5 Mg, Unk		Bristol Myers Squibb
	Lexapro			S	Transplacental	Unk		Not Reported
	Wellbutrin			S	Transplacental	Unk		Not Reported
	Zofran /00955301/			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2017	13418487	EXPEDITED (15-DAY)		CA, DE, HO	US-CIPLA LTD.-2017US05073			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Sertraline			S	Transplacental	Unk		Invagen
	Escitalopram			S	Transplacental	Unk		Invagen
	Ondansetron			S	Transplacental	Unk		Cipla
	Progesterone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2017	13418490	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US05075			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Human Herpesvirus 6 Infection; Hypersensitivity	Sertraline			S	Unknown	Unk, For The Initial Two Trimester		Invagen
	Escitalopram			S	Unknown	Unk, For The Final Trimester		Invagen
	Ondansetron			S	Unknown	Unk		Cipla
	Progesterone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2017	13422446	DIRECT		DS			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cognitive Disorder; Disease Recurrence; Memory Impairment; Therapy Cessation	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Lexapo			C				Not Reported
	Multi Vitamin			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Claritin			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13036375	EXPEDITED (15-DAY)		OT	US-FERRINGPH-2016FE06513			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy; Off Label Use; Product Use In Unapproved Indication	Sertraline			S	Unknown	For The Initial Two Trimester		Not Reported
	Ondansetron			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	For The Final Trimester		Not Reported
	Progesterone			S	Unknown	High-Dose		Ferring

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13188020	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2017-29211			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Sertraline			S	Unknown	Unk, For The Initial Two Trimester		Aurobindo
	Escitalopram			S		Unk, For The Final Trimester		Aurobindo
	Ondansetron			S	Unknown			Aurobindo
	Progesterone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13295478	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1707900US		53 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Metabolic Acidosis; Nausea; Vomiting	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Reflex			S	Oral	30 Mg, Qd		Not Reported
	Reflex			S	Oral	15 Mg, Qd		Not Reported
	Sodium Picosulfate			S	Unknown	10 Gtt, Qd		Not Reported
	Remeron			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13315214	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-019682		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Abilify			S	Unknown	Unk		Bristol Myers Squibb
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13421069	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APU-2015-06206			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Crying; Depression; Fatigue; Feeling Abnormal; Headache; Insomnia; Nausea; Suicidal Ideation; Vomiting	Escitalopram Tablets Usp 20mg			S	Unknown	20 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13421073	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APU-2015-06220			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Dyspnoea	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13421078	EXPEDITED (15-DAY)		DS, OT	US-AUROBINDO-AUR-APU-2015-06208			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Fatigue; Feeling Abnormal; Loss Of Personal Independence In Daily Activities; Pain;	Escitalopram Tablets Usp 20mg			S	Unknown	20 Mg, Unk		Aurobindo

Product Substitution Issue; Speech Disorder; Suicidal Ideation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13421470	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-ACCORD-049936		4 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Escitalopram			S	Transplacental			Accord
	Ondansetron			S	Transplacental			Accord
	Sertraline			S	Transplacental			Accord
	Progesterone			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13421495	EXPEDITED (15-DAY)		OT	US-ACCORD-049937			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Escitalopram			S		For The Final Trimester		Accord
	Sertraline			S		For The Initial Two Trimester		Accord
	Ondansetron			S				Accord
	Progesterone			S		High Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13423946	EXPEDITED (15-DAY)		DE	CA-ALLERGAN-1713843US		76 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13423964	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1713602US		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Dizziness; Fatigue; Female Orgasmic Disorder; Headache; Heart Rate Increased; Heart Rate Irregular; Hyperhidrosis; Hypotension; Mydriasis; Nausea; Pyrexia; Restlessness; Somnolence; Tremor; Weight Decreased; Yawning	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Diclofenac Sodium			C	Unknown	One Dosage Form Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13423985	EXPEDITED (15-DAY)		HO	NL-ALLERGAN-1713809US		20 DAY	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asterixis; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Mood Swings; Restlessness; Tachypnoea; Tremor	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Remeron Tablet			C	Transplacental	15 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13425930	DIRECT		OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Headache; Insomnia; Muscle Spasms; Muscle Spasms	Escitalopram Oxalate			S	Oral	Quantity:1 Tablet(S);		Cipla
	Wellbutrin Hcl Xl			C				Not Reported
	Acyclovir			C				Not Reported
	Allegra D			C				Not Reported
	Biotin			C				Not Reported
	Vit B-12			C				Not Reported
	Vit D 10			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	9929955	EXPEDITED (15-DAY)		OT	PHHY2014US022507			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Father; Fatigue; Frustration Tolerance Decreased; Psychiatric Symptom	Fluoxetine			S	Unknown	Fetal Drug Exposure Via Father		Novartis
	Citalopram			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Escitalopram			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Sertraline			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Bupropion			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Olanzapine			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Amitriptyline			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Valproic Acid			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Venlafaxine			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Risperidone			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Zolpidem			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Quetiapine			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Trazodone			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Diphenhydramine			S	Unknown	Fetal Drug Exposure Via Father		Not Reported
	Prazosin			S	Unknown	Fetal Drug Exposure Via		Not Reported

	Eszopiclone			S	Unknown	Father Fetal Drug Exposure Via Father				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13187936	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-AUROBINDO-AUR-APL-2017-29456		4 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Dilatation Ventricular; Endocardial Fibroelastosis; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome; Myocardial Fibrosis; Myocarditis; Oedema	Sertraline			S	Transplacental	Unk		Aurobindo
	Escitalopram			S	Transplacental	Unk		Aurobindo
	Escitalopram			S	Transplacental	Unk		Aurobindo
	Ondansetron			S	Transplacental	Unk		Aurobindo
	Progesterone			S	Transplacental	Unk		Not Reported
	Progesterone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13399201	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2017US04877			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia	Escitalopram			S	Unknown	Unk		Invagen
	Lithium			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Paliperidone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13425452	EXPEDITED (15-DAY)			US-LUNDBECK-DKLU2028232			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Insomnia; Nausea; Nervousness	Escitalopram Oral Drops		S	Unknown	5 Mg, Unk	Not Reported
	Escitalopram Oral Drops		S	Unknown	10 Mg, Unk	Not Reported
	Lorazepam		C	Unknown	0.5	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13426933	DIRECT					41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13426935	DIRECT	Y				41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue; Product Substitution Issue	Escitalopram			S			3 MTH	Not Reported
	Citalpram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13426965	DIRECT	Y	HO			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2017	13312964	NON-EXPEDITED			US-INCYTE CORPORATION-2017IN001573		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Off Label Use	Jakafi			S	Oral	10 Mg, Bid		Incyte
	Jakafi			S	Oral	10 Mg, Qd		Incyte
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

	Cholecalciferol	C	Not Reported
	Clobetasol	C	Not Reported
	Dexamethasone	C	Not Reported
	Docusate Sodium	C	Not Reported
	Emla /00675501/	C	Not Reported
	Prednisone	C	Not Reported
	Metoprolol Succinate	C	Not Reported
	Tacrolimus	C	Not Reported
	Bactrim Ds	C	Not Reported
	Ativan	C	Not Reported
	Hydromorphone	C	Not Reported
	Oxycodone	C	Not Reported
	Neurontin	C	Not Reported
	Albuterol /00139501/	C	Not Reported
	Cetirizine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2017	13384351	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2017M1018730			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Sopor	Escitalopram			S	Oral	270 Mg, Total		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Carbolithium			S	Oral	5 Df, Total		Mylan
	Etiltox			S	Oral	9 Df, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2017	13433018	EXPEDITED (15-DAY)		HO	FR-SA-2017SA060547		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Melaena; Peptic Ulcer Haemorrhage	Plavix			S	Oral			Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Intravenous (not otherwise specified)	Dosage Form: Owder And Solution For Parenteral Use		Not Reported
	Seroplex			S	Oral			Not Reported
	Aciclovir			C	Unknown			Not Reported

	Levetiracetam	C	Unknown		Not Reported
	Augmentin	C	Unknown		Not Reported
	Lovenox	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2017	13433599	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1714221US		83 YR	Male	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Escitalopram Oxalate - Bp			S		Unk		Allergan
	Olanzapine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2017	13437968	NON-EXPEDITED			US-SA-2016SA088124			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Head Discomfort	Allegra Allergy 24 Hour			S	Unknown			Not Reported
	Vyvanse			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2017	13438863	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2017-009096			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Prednisolone			S	Unknown			Bausch And Lomb
	Tramadol			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Palexia Sr			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2017	13075118	EXPEDITED (15-DAY)		DE, OT	US-WEST-WARD PHARMACEUTICALS		4 DAY	Male	USA

CORP.-US-H14001-16-03

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy Neonatal; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Neonatal Cardiac Failure; Neonatal Multi-Organ Failure; Vertical Infection Transmission	Progesterone			S	Transplacental			Hikma
	Ondansetron			S	Transplacental			Hikma
	Escitalopram			S	Transplacental			Hikma
	Sertraline			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2017	13387827	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1712393US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Meilax			S	Oral			Not Reported
	Rize			C	Oral	Unk		Not Reported
	Sepazon			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2017	13438251	EXPEDITED (15-DAY)			US-LUNDBECK-DKLU2027595		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Contraindication To Medical Treatment	Lexapro Film-Coated Tablets			S	Oral	Unk		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2017	13441351	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-031208		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Prescribed Overdose	Abilify			S	Unknown	25 Mg, Qd		Bristol Myers Squibb
	Escitalopram			S	Unknown			Not Reported
	Lithium /00033702/			C	Unknown			Not Reported
	Infliximab Recombinant			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2017	13442011	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1675823US		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Hyponatraemia	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Metoprolol			S	Oral	23.75 Mg, Qd		Not Reported
	L-Thyroxin			C	Oral	For Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2017	13442030	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1714325US		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cerebral Ischaemia; Coma; Melaena; Peptic Ulcer Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Plavix			S	Oral	75 Mg, Qd		Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Intravenous (not otherwise specified)	250 Mg, Single		Not Reported
	Novorapid			C	Unknown			Not Reported
	Aciclovir			C	Unknown	750 Mg, Q8hr		Not Reported
	Levetiracetam			C	Unknown	500 Mg, Bid		Not Reported
	Augmentin			C	Unknown	1 G, Q8hr		Not Reported
	Metformin			C	Unknown	1000 Mg, Tid		Not Reported
	Coversyl			C	Unknown	5 Mg, Qd		Not Reported
	Repaglinide			C	Unknown			Not Reported

	Lovenox			C	Unknown	4000 Iu, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2017	13442386	DIRECT		HO, OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Catatonia; Dysphonia; Fine Motor Skill Dysfunction; Gait Disturbance; Hypoaesthesia; Palpitations; Paraesthesia; Tremor	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Lundbeck
	Amitriptyline			C				Not Reported
	Rizatriptan Benzoate			C				Not Reported
	Chlordiazepoxide			C				Not Reported
	Ventolin			C				Not Reported
	Extra Virgin Coconut Oil			C				Not Reported
	Apple Cider Vinegar Tablets			C				Not Reported
	Multi Vitamin			C				Not Reported
	Omega Fish Oil			C				Not Reported
	Krill Oil			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Calcium			C				Not Reported
	Vitamin B-12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2017	13442078	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017004678			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Dizziness; Dyspnoea; Hypersomnia; Musculoskeletal Stiffness; Vision Blurred	Escitalopram			S	Oral	2 Df, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2017	13447218	DIRECT		HO, LT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional	Escitalopram 5mg			S	Oral	Quantity:1 Tablet(S);		Camber

State; Dehydration; Hallucination; Insomnia; Palpitations; Paranoia; Speech Disorder	Clonazepam	S	Oral	Quantity:1 Tablet(S);		Mylan
	Vitamin D Nos	C				Not Reported
	Vitamin B12	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2017	12193187	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2016-02992			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Drug Ineffective; Gingival Disorder; Headache; Hypersensitivity; Mental Disorder; Nausea; Suicidal Ideation	Escitalopram Aurobindo Tablets			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13259140	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017024583		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Intentional Product Misuse; Intentional Underdose; Product Dose Omission; Rales	Incruse Ellipta Inhalation Powder			S	Respiratory (inhalation)	1 Puff(S), Qd		Glaxosmithkline
	Escitalopram Oxalate Tablet			S	Oral	20 Mg, Qd		Glaxosmithkline
	Escitalopram Oxalate Tablet			S	Oral	10 Mg, Bid		Glaxosmithkline
	Ceftin			C				Glaxosmithkline
	Aspirin Low Dose			C				Glaxosmithkline
	Atorvastatin Tablet			C				Glaxosmithkline
	Furosemide Tablet			C				Glaxosmithkline
	Pantoprazole Tablet			C				Glaxosmithkline
	Azithromycin			C				Not Reported
	Prednisone			C				Not Reported
	Clonazepam			C				Not Reported
	Verapamil Cr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13446057	EXPEDITED (15-DAY)		OT	DE-HETERO LABS LTD-1065411		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Small For Dates Baby	Escitalopram			S	Transplacental			Hetero
	Buprenorphine			S	Transplacental			Not Reported
	L-Thyroxin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13447452	EXPEDITED (15-DAY)		HO, OT	FR-ASTELLAS-2017US014405		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia	Vesicare			S	Oral	Unk Unk, Unknown Freq.		Astellas
	Tysabri			S	Intravenous (not otherwise specified)			Not Reported
	Fampyra			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Baclofen			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Gabapentin			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Escitalopram			S	Oral	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13447713	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Crying; Depression; Dizziness; Fatigue; Fear; Irritability; Nausea; Product Substitution Issue; Withdrawal Syndrome	Escitalopram 10mg			S	Oral			Not Reported
	Escitalopram Oxylate			S	Oral			Not Reported
	Paxil Cr			C				Not Reported
	Zoloft			C				Not Reported
	Celexa			C				Not Reported
	Cymbalta			C				Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13447872	DIRECT	Y	LT			14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury	Escitalopram 10mg			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13448254	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1022991			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Dizziness; Dyspnoea; Hypersomnia; Musculoskeletal Stiffness; Vision Blurred	Escitalopram			S	Oral	2 - 0 - 0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13449360	EXPEDITED (15-DAY)		HO	FR-SA-2017SA067641		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Mianserin Hydrochloride			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Lamictal			S	Oral			Not Reported
	Lamictal			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13449372	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1714802US		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Asthenia; Drug Abuse; Overdose; Restlessness	Escitalopram Oxalate Unk		S	Oral	20 Tablets, Overdose	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2017	12554650	EXPEDITED (15-DAY)		OT	DE-FRI-1000086029		59 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortitis	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Ramipril			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2017	13450835	EXPEDITED (15-DAY)		OT	NZ-APOTEX-2017AP010087			Male	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Nystagmus; Optic Atrophy	Apo-Allopurinol			S	Oral	Unk		Apotex
	Apo-Gabapentin			S	Oral	Unk		Apotex
	Apo-Escitalopram			S	Oral	Unk		Apotex
	Clonidine			S	Oral	Unk		Not Reported
	Mercaptopurine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2017	13455241	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1714784US		31 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Dizziness; Dyspnoea; Hypersomnia; Musculoskeletal Stiffness; Vision Blurred	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2017	13455243	EXPEDITED (15-DAY)		DE	CA-ALLERGAN-1714793US		76 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate - Bp			S		10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2017	13455339	EXPEDITED (15-DAY)		HO, LT	AT-ALLERGAN-1714783US			Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Myoclonus; Partial Seizures	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Cefepim Mip			S	Intravenous (not otherwise specified)	1 Df, Tid		Not Reported
	Trittico Retard			S	Unknown	100 Mg, Qd		Not Reported
	Trittico Retard			S	Unknown	0-0-0-1		Not Reported
	Tradolan Tropfen			S	Unknown	10 Drops, Daily		Not Reported
	Neurontin			C	Unknown			Not Reported
	Lovenox			C	Unknown	0-0-1		Not Reported
	Thyrex			C	Unknown			Not Reported
	Temesta (Lorazepam)			C	Unknown			Not Reported
	Spirono			C	Unknown	1/2-0-0		Not Reported
	Novalgine (Metamizole Sodium)			C	Unknown	30-30-30		Not Reported
	Antiflat			C	Unknown			Not Reported
	Concor			C	Unknown	1-0-1		Not Reported
	Lasix			C	Intravenous (not otherwise specified)	1-0-0, Im Kh		Not Reported
	Multivit B			C	Intravenous (not otherwise specified)			Not Reported
	Nexium			C	Unknown	1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13404787	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-MACLEODS PHARMACEUTICALS			Unknown	USA

US LTD-
MAC2017004623

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Escitalopram Oxalate			S	Transplacental	Unk		Macleods
	Sertraline			S	Transplacental	Unk		Not Reported
	Ondansetron			S	Transplacental	Unk		Not Reported
	Progesterone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13456957	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017162430		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Xanax			S	Oral	0.5 Mg, 3x/Day		Pfizer
	Lamictal			S	Oral	50 Mg, Daily		Not Reported
	Lamictal			S		150 Mg, Daily		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Mianserin Hydrochloride			S	Oral	30 Mg, 1x/Day		Not Reported
	Stilnox			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13457905	EXPEDITED (15-DAY)		HO	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-111410		46 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported
	Lithium			S	Unknown	600 Mg, Daily		Sun

Quetiapine	S	Unknown	100 Mg, Daily		Sun
Quetiapine	S		150 Mg, Daily		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13458571	EXPEDITED (15-DAY)		OT	ES-APOTEX-2017AP010261		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram Apotex			S	Unknown	10 Mg Per Day		Apotex
	Escitalopram Apotex			S	Unknown	20 Mg Per Day		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	6067238	EXPEDITED (15-DAY)		HO	PHBS2006US08567		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Pressure Increased; Chest Pain; Confusional State; Dizziness; Fall; Flushing; Hallucination; Headache; Heart Rate Increased; Hyperventilation; Lethargy; Muscle Rigidity; Pallor; Pharyngeal Erythema; Pyrexia; Serotonin Syndrome; Tremor	Methylphenidate			S	Unknown	20 Mg, Qd (10 Mg, 2 Doses)		Novartis
	Venlafaxine			S	Unknown	75 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	150 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	225 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Lamotrigine			C	Unknown	125 Mg, Bid		Not Reported
	Lamotrigine			C	Unknown	150 Mg, Bid		Not Reported
	Lamotrigine			C	Unknown	50 Mg, Bid		Not Reported
	Trazodone			C	Unknown	100 Mg, Qhs		Not Reported
	Trazodone			C	Unknown	100 Mg, Qhs		Not Reported
	Mirtazapine			C	Unknown	15 Mg, Qhs		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13191868	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20170124350			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Blood Glucose Increased; Drug Abuse; Heart Rate Increased; Sinus Disorder; Suicidal Ideation	Sudafed		Y	S	Unknown			Not Reported
	Sudafed			S	Unknown			Not Reported
	Latuda			S	Oral			Not Reported
	Latuda			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13385274	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1712267US		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Plavix			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13459843	NON-EXPEDITED		OT	US-JNJFOC-20170308278		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia; Off Label Use; Product Use In Unapproved Indication	Risperidone			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Pristiq			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Lithium Carbonate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13460396	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2017-32341		31 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Dizziness; Dyspnoea; Hypersomnia; Musculoskeletal Stiffness; Vision Blurred	Escitalopram			S	Oral	1 Df, Two Times A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13461664	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2017GSK054759		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Incorrect Dose Administered	Lamictal			S	Oral	50 Mg, Qd		Glaxosmithkline
	Lamictal			S	Oral	150 Mg, Unk		Glaxosmithkline
	Seroplex			S	Oral	10 Mg, 1d		Glaxosmithkline
	Xanax			S	Oral	0.5 Mg, Tid		Not Reported
	Mianserine			S	Oral	30 Mg, 1d		Not Reported
	Stilnox			S	Oral	10 Mg, 1d		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13461836	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017GSK054032			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stress	Wellbutrin			S		Unk		Glaxosmithkline
	Lexapro			S		Unk		Not Reported
	Xanax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13463272	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1715102US		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Disturbance In Attention; Dysarthria; Gastrointestinal Ulcer Haemorrhage; Hypercapnia; Hypotension; Myoclonus	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Olanzapine Mylan			S	Oral			Not Reported
	Ciprofloxacin Mylan			S	Oral	500 Mg, Bid		Not Reported
	Kardegic			S	Oral	75 Mg, Qd		Not Reported
	Cardensiel			C	Unknown			Not Reported
	Losartan			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Neurontin			C	Unknown			Not Reported
	Letrozole			C	Unknown			Not Reported
	Xgeva			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13463275	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1715269US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Defaecation Urgency; Rectal Discharge; Rectal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Lorazepam			S	Oral			Not Reported
	Imuran			C	Oral			Not Reported
	Imuran			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2017	13423986	EXPEDITED (15-DAY)		HO, OT	CN-ALLERGAN-1713808US		33 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Promyelocytic Leukaemia; Leukopenia; Myelodysplastic Syndrome; Nasopharyngitis; Off Label	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Alprazolam			C	Unknown	Unk		Not Reported

Use

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2017	13466307	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-001999		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amitriptyline Hcl			S	Oral	Unk Unk, Unknown		Vintage
	Escitalopram /01588502/			S	Oral	Unk Unk, Unknown		Not Reported
	Diphenhydramine			S	Oral	Unk Unk, Unknown		Not Reported
	Ethanol			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2017	13468338	EXPEDITED (15-DAY)		HO, OT	FR-INDIVIOR LIMITED-INDV-100536-2017		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Dependence; Drug Dependence; Drug Dependence; Product Use Issue; Substance Abuser; Suicide Attempt; Toxicity To Various Agents	Subutex 8mg Tablet			S	Unknown	8 Mg, Bid		Reckitt Benckiser
	Cocaine			S	Unknown	Unknown		Not Reported
	Cannabis			S	Unknown	Unknown		Not Reported
	Seresta			S	Oral	50 Mg: 1 At Noon And 2 When Going To Sleep		Not Reported
	Seresta			S	Oral	600 Mg, Unk		Not Reported
	Seroplex			S	Oral	15 Mg: 1 When Waking Up		Not Reported
	Seroplex			S	Oral	60 Mg, Unk		Not Reported
	Haldol /00027401/			S	Oral	5 Mg: 1 At Noon And 2 When Going To Sleep		Not Reported
	Haldol /00027401/			S	Oral	60 Mg, Unk		Not Reported
	Largactil /00011901/			S	Oral	100 Mg, 1 When Going To Sleep		Not Reported
	Largactil /00011901/			S	Oral	400 Mg, Unk		Not Reported
	Parkines Lp			C	Unknown	5 Mg: 2 When Waking Up		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2017	13468795	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1715461US		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Dependence; Substance Abuser; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Seresta			S	Oral	600 Mg, Unk		Not Reported
	Seresta			S	Oral			Not Reported
	Subutex			S	Unknown			Not Reported
	Haldol			S	Oral	60 Mg, Unk		Not Reported
	Haldol			S	Oral			Not Reported
	Largactil			S	Oral	400 Mg, Unk		Not Reported
	Largactil			S	Oral			Not Reported
	Cannabis			S	Unknown			Not Reported
	Cocaine			S	Unknown	15 Mg, Unk		Not Reported
	Parkinane Lp			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2017	13470063	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-001951		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone Hcl			S	Oral	Unk Unk, Unknown		Vintage
	Ibuprofen			S	Oral	Unk Unk, Unknown		Par
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	11523981	EXPEDITED (15-DAY)		HO, OT	NL-TEVA-592946ISR		72 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apathy; Confusional State; Daydreaming; Dizziness; Dysphagia; Dysstasia; Hypercalcaemia; Hyperparathyroidism Primary; Malaise; Parathyroid Disorder; Somnolence; Tremor	Escitalopram 10 Mg Teva, Filmomhulde Tabletten	S	Oral	10 Milligram Daily;	Ivax
	Metformine	C			Not Reported
	Amlodipine	C			Not Reported
	Enalaprilmaleaat	C			Not Reported
	Acetylsalicylzuur	C			Not Reported
	Metoprololtartraat	C			Not Reported
	Crestor	C			Not Reported
	Losartan	C			Not Reported
	Omperazol	C			Not Reported
	Divisun	C			Not Reported
	Novomix	C		2 Dosage Forms Daily; In The Morning And At Night	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13404791	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2017004624			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Escitalopram Oxalate			S	Unknown	Unk, (Final Trimester)		Macleods
	Ondansetron			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	Unk,For The Initial Two Trimester		Not Reported
	Progesterone			S	Unknown	High Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13472078	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-001857		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besylate Tablets			S		Unk, Unknown, Ingst+Par		Vintage
	Tamsulosin Hcl			S		Unk Unk, Unknown, Ingst+Par		Par
	Enalapril			S		Unk Unk, Unknown, Ingst+Par		Not Reported

	Escitalopram /01588502/	S	Unk Unk, Unknown, Ingst+Par		Not Reported
	Insulin	S	Unk Unk, Unknown, Ingst+Par		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13472189	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-001872		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besylate Tablets			S		Unk Unk, Unknown, Ingst+Unk		Vintage
	Escitalopram			S		Unk Unk, Unknown, Ingst+Unk		Not Reported
	Ethanol			S		Unk Unk, Unknown, Ingst+Unk		Not Reported
	Drug, Unknown			S		Unk Unk, Unknown, Ingst+Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13473654	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1715452US		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Lamictal			S	Oral	150 Mg, Qd		Not Reported
	Lamictal			S	Oral	50 Mg, Qd		Not Reported
	Xanax			S	Oral	1.5 Mg, Tid		Not Reported
	Mianserine			S	Oral	30 Mg, Qd		Not Reported
	Stilnox			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13476371	DIRECT		DS			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Escitalopram			S	Oral			Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2017	13477547	DIRECT	Y	LT, OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Oral			Not Reported
	Carbamazepine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2017	13479718	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1715644US		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Kardegic			S	Oral	160 Mg, Qd		Not Reported
	Pravastatine			C	Oral			Not Reported
	Xanax			C	Oral			Not Reported
	Dafalgan			C	Oral			Not Reported
	Duotrav			C	Ophthalmic			Not Reported
	Dexeryl (Glycerol And White Soft Paraffin And Liquid Paraffin)			C	Unknown			Not Reported
	Uvedose			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported
	Chondrosulf			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2017	13482670	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-002504		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Clonazepam	S	Oral	Unk Unk, Unknown	Par
	Bupropion Hcl Xl	S	Oral	Unk Unk, Unknown	Par
	Escitalopram	S	Oral	Unk Unk, Unknown	Not Reported
	Amfetamine/ Dextroamfetamine	S	Oral	Unk Unk, Unknown	Not Reported
	Ethanol	S	Oral	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2017	13483306	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2017-01917		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram			S	Unknown	Unk		Lupin
	Escitalopram			S	Unknown	20 Mg, Per Day		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2017	13485044	EXPEDITED (15-DAY)		OT	PHHY2017AU058369		71 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Orthostatic Hypotension; Spinal Cord Disorder	Exforge			S	Unknown			Novartis
	Atorvastatin			S	Unknown			Not Reported
	Pradaxa			S	Unknown			Not Reported
	Temazepam			S	Unknown			Not Reported
	Nexium			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Diamicron			S	Unknown			Not Reported
	Zanidip			S	Unknown			Not Reported
	Lorcaserin			S	Unknown			Not Reported
	Micardis			S	Unknown			Not Reported
	Adalat			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2017	13486655	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-01983			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	10 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2017	13486681	NON-EXPEDITED			US-APOTEX-2017AP008423		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Chills; Confusional State; Dizziness; Drug Interaction; Dysstasia; Gait Disturbance; Hallucination; Heart Rate Increased; Tremor; Vision Blurred	Trazodone Hydrochloride			S	Oral	1 Df, Qd		Apotex
	Trazodone Hydrochloride			S				Apotex
	Lexapro			S	Oral	1 Df, Qd		Not Reported
	Lisinopril			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2017	13488291	NON-EXPEDITED			US-009507513-1704USA011963		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance	Remeron			S	Oral			Merck
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Pregabalin			S				Not Reported
	Pregabalin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	10138717	EXPEDITED (15-DAY)		OT	FR-FRI-1000066843		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Fluctuation; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Novorapid			C	Subcutaneous	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13420943	EXPEDITED (15-DAY)		CA, DE, DS, HO, LT, OT	US-TORRENT-00002648		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Escitalopram			S				Unknown
	Sertraline			S				Unknown
	Progesterone			S				Unknown
	Ondansetron			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13420944	EXPEDITED (15-DAY)		OT	US-TORRENT-00002649			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Ondansetron			S				Unknown
	Sertraline			S				Unknown
	Escitalopram			S				Unknown
	Progesterone			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13454834	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2017M1023676			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Off Label	Baclofen			S	Oral			Not Reported

Use; Toxicity To Various Agents; Unresponsive To Stimuli	Metoprolol	S	Oral		Not Reported
	Escitalopram	S			Not Reported
	Perindopril	S			Not Reported
	Colchicine	S	Oral		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13455769	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2017M1023679			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Poisoning Deliberate; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram			S		Unk		Not Reported
	Baclofen			S	Oral			Not Reported
	Paracetamol			S				Not Reported
	Dextropropoxyphene			S				Mylan
	Valpromide			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13490376	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US07374			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Apathy; Condition Aggravated; Libido Decreased; Sedation	Topiramate			S	Unknown	Unk		Invagen
	Topiramate			S	Unknown	50 Mg/Day		Invagen
	Topiramate			S	Unknown	100 Mg/Day		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	30 Mg/Day		Invagen
	Risperidone			S	Unknown	2 Mg/Day		Cipla
	Fluoxetine			S	Unknown	20 Mg/Day		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13490893	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-762349ROM		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram		S	Unknown	Ivax
	Baclofen		S	Oral	Not Reported
	Paracetamol		C	Unknown	Not Reported
	Dextropropoxyphene		C	Unknown	Not Reported
	Valpromide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13491600	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2017SE41631		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Haematuria; Hyperkalaemia; Limb Discomfort; Myalgia; Testicular Cyst; Testicular Pain	Inexium			S	Oral			Astrazeneca
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Pravastatin			C	Oral			Not Reported
	Pregabalin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13492224	NON-EXPEDITED			US-PFIZER INC-2017175034		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Treximet			S		Unk		Not Reported
	Tramadol Hydrochloride			S		Unk		Not Reported
	Amitriptyline Hcl			S		Unk		Not Reported
	Lunesta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13492433	EXPEDITED (15-DAY)		OT	US-JNJFOC-20170424871			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia; Obesity	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13495316	DIRECT		HO			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Driving Ability; Memory Impairment; Road Traffic Accident	Lexapro			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Omeprazole			S	Oral	Quantity:1 Capsule(S);		Not Reported
	Vitamin C			C				Not Reported
	Calcium			C				Not Reported
	Multivitamin			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2017	13435709	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2017M1022724			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram			S	Unknown	10mg/Day; Later Doubled The Dose		Not Reported
	Escitalopram			S	Unknown	20mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2017	13485677	EXPEDITED (15-DAY)		OT	US-SUNOVION-2017SUN001759		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Intentional Self-Injury; Suicide Attempt	Latuda			S	Oral	20 Mg, Unk		Sunovion
	Clonidine			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2017	13494479	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-002354		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Tramadol			S	Oral	Unk Unk, Unknown		Par
	Baclofen Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Clonazepam			S	Oral	Unk Unk, Unknown		Par
	Hydrocodone Bitartrate / Acetaminophen			S	Oral	Unk Unk, Unknown		Vintage
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2017	13495365	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-002387		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Doxepin			S	Oral	Unk Unk, Unknown		Par
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Hydrochlorothiazide Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Cetirizine Hydrochloride Syrup			S	Oral	Unk Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported

	Hydrocodone	S	Oral	Unk Unk, Unknown	Not Reported
	Olmesartan	S	Oral	Unk Unk, Unknown	Not Reported
	Famotidine	S	Oral	Unk Unk, Unknown	Not Reported
	Pregabalin	S	Oral	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2017	13421802	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-137513			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Ondansetron			S	Unknown	Unk		Natco Pharma
	Sertraline			S	Unknown	For The Initial Two Trimester		Sun
	Escitalopram			S	Unknown	For The Final Trimester		Not Reported
	Progesterone			S	Unknown	High-Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2017	13473653	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1715475US		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Titubation; Prescribed Overdose; Syncope; Tremor	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Qd		Allergan
	Ergenyl			C	Unknown	In The Evening		Not Reported
	Dilatrend			C	Unknown			Not Reported
	Atorvastatin			C	Unknown	(1 In The Evening)		Not Reported
	Marcumar			C	Unknown			Not Reported
	Common Salt			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported
	Trenantone			C	Unknown	3 Months Injection		Not Reported

					Trenantone	
	Remergil		C	Unknown	Unk	Not Reported
	Cymbalta		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2017	13500412	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1716660US		70 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia Oral; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2017	13181847	NON-EXPEDITED			US-IMPAX LABORATORIES, INC-2016-IPXL-01502		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Feeling Jittery; Labelled Drug-Food Interaction Medication Error; Pain; Therapeutic Response Shortened; Tremor	Rytary			S	Oral	Three Capsules 195 Mg At Five To Six Hours Intervals Four Times A Day		Impax
	Rytary			S	Oral	3 Capsules Of 195 Mg And One Capsule Of 95 Mg (Four Capsules)		Impax
	Rytary			S	Oral	48/75mg/195 1 Capsule Four Times A Day Every 5-6 Hrs		Impax
	Gabapentin			S	Unknown	100 Mg, Three Times Daily		Not Reported
	Gabapentin			S	Unknown	Unk, Dose Reduced		Not Reported
	Synthroid			S	Unknown	0.88 Mg, Once A Day In The Morning		Not Reported
	Lexapro			S	Unknown	Two Tablets -One Tablet Of 5 Mg And The Other One Of 10 Mg Once In		Not Reported

				The Morning	
	Senna	C	Unknown	8.6 Mg, Two Tablets At Night	Not Reported
	Centrum Silver	C	Unknown	One Tablet With Food In Afternoon	Not Reported
	Vitamin D3	C	Unknown	2000 Lu Units	Not Reported
	Vitamin B12	C	Unknown	1000 Units	Not Reported
	Aleve	C	Unknown	220 Mg, Once A Day	Not Reported
	Aleve	C			Not Reported
	Aleve	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2017	13468283	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1715469US		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Focal Dyscognitive Seizures	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2017	13502221	EXPEDITED (15-DAY)		DE	FR-ACCORD-050958		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Abuse; Toxicity To Various Agents	Escitalopram			S		Drug Packs		Accord
	Metoprolol			S		Drug Packs		Accord
	Perindopril/Perindopril Erbumine			S		Drug Packs		Not Reported
	Colchicine			S		Drug Pack		Not Reported
	Baclofen			S		Drug Pack		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2017	13502252	EXPEDITED (15-DAY)		OT	ES-ZYDUS-014703		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angle Closure Glaucoma; Chorioretinal Folds; Choroidal Detachment; Choroidal Effusion; Choroiditis; Headache; Myopia; Visual Acuity Reduced	Escitalopram		S	Unknown	Zydus Pharm
	Escitalopram		S	Unknown	Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2017	13503401	EXPEDITED (15-DAY)		HO, OT	AU-APOTEX-2017AP011426		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Serotonin Syndrome	Apo-Desvenlafaxine Mr			S	Oral	500 Mg, Unk		Not Reported
	Apo-Escitalopram			S	Oral	100 Mg, Unk		Apotex
	Apo-Mirtazapine			S	Oral	870 Mg, Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2017	12940543	NON-EXPEDITED			US-JNJFOC-20161103011			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Gynaecomastia	Risperdal			S	Oral	Varying Dose Of 0.50mg ; 1.00mg.		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	Varying Dose Of 0.50mg ; 1.00mg.		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	Varying Dose Of 0.50mg ; 1.00mg.		Not Reported
	Risperdal			S	Oral	Varying Dose Of 0.50mg ; 1.00mg.		Not Reported
	Risperdal			S	Oral			Not Reported
	Lexapro			S	Unknown	At Bed Time		Not Reported

	Lexapro	S	Unknown	At Bed Time		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2017	13507143	EXPEDITED (15-DAY)		OT	TW-CIPLA LTD.-2017TW07824			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Hypertriglyceridaemia; Somnolence	Fenofibrate			S	Unknown	200 Mg, Qod		Cipla
	Fenofibrate			S	Unknown	200 Mg, Daily For 7 Days		Cipla
	Fenofibrate			S	Unknown	200 Mg, Qod		Cipla
	Fenofibrate			S	Unknown	200 Mg, Qod		Cipla
	Carvedilol			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Invagen
	Venlafaxine			S	Unknown	37.5 Mg, Qd		Cipla
	Venlafaxine			S	Unknown	75 Mg, Qd		Cipla
	Clopidogrel			S	Unknown	Unk		Cipla
	Famotidine			S	Unknown	Unk		Not Reported
	Sennosides			S	Unknown	Unk		Not Reported
	Levocetirizine			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Cipla
	Mirtazapine			S	Unknown	Unk		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2017	13510103	EXPEDITED (15-DAY)		HO, OT	IN-MYLANLABS-2017M1025934			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cushing'S Syndrome; Depression; Drug Abuse; Steroid Withdrawal Syndrome	Dexamethasone			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2017	13332681	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1709321US		38 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Abuse	Escitalopram Oxalate Unk			S	Oral	18 Df, Single		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2017	13514240	NON-EXPEDITED			US-ABBVIE-16P-163-1625572-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Major Depression; Panic Attack; Tinnitus	Creon			S	Oral	1 Each Meal		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Percocet			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Multivitamin			C	Unknown			Not Reported
	Vitamin E			C	Unknown			Not Reported
	Calcium With Vitamin D3			C	Unknown			Not Reported
	Calcium With Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13313311	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1709137US		32 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Rib Fracture	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

	Escitalopram Oxalate - Bp	S	Oral	5 Mg, Qd		Allergan
	Depas (Etizolam)	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13517871	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1674498US		45 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Pyrexia; Sexual Dysfunction; White Blood Cell Count Decreased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13518153	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1717257US		1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypotonia Neonatal; Neonatal Respiratory Distress	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan
	Paroxetine Base			S	Transplacental	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	11003288	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2015001678			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Effusion; Extra Dose Administered; Headache; Visual Acuity Reduced	Escitalopram 10mg Tablet			S	Unknown	10 Mg, Qd		Macleods
	Escitalopram 10mg Tablet			S	Unknown	20 Mg, Qd (Three Days Before Onset The Dose Was Doubled At 20 Mg)		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13521864	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-33616		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Off Label Use; Overdose; Toxicity To Various Agents; Unresponsive To Stimuli	Metoprolol			S	Unknown			Aurobindo
	Perindopril			S	Unknown			Aurobindo
	Escitalopram			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13521891	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-33747		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Poisoning Deliberate; Toxicity To Various Agents; Unresponsive To Stimuli	Paracetamol			S	Unknown			Aurobindo
	Escitalopram			S	Unknown			Not Reported
	Dextropropoxyphene			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Valpromide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13522751	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1717675US		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhagic Stroke	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Coumadine			S	Oral	2 Mg, Qd		Not Reported
	Levothyrox			C	Oral	25 Mg, Qd		Not Reported
	Temesta (Lorazepam)			C	Oral	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13523087	EXPEDITED (15-DAY)		OT	ES-SA-2017SA078189		58 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Aubagio			S	Oral			Not Reported
	Amantadine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13524339	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1717677US		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Erythema; Feeling Hot	Escitalopram Oxalate - Bp			S	Oral	10 Mg Once Every 2 Days On Even Days		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg Once Every 2 Days On Uneven Days		Allergan
	Puregon [Follitropin Beta]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13524340	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1717669US		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Xanax			S	Oral	0.5 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13526271	EXPEDITED (15-DAY)		HO, OT	US-TORRENT-00002720		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation;	Quetiapine			S				Unknown

Treatment Noncompliance	Fluoxetine	S	Unknown
	Lithium	S	Unknown
	Aripiprazole	S	Unknown
	Guanfacine Er	S	Unknown
	Escitalopram	S	Unknown
	Sertraline	S	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13532507	EXPEDITED (15-DAY)		DE, OT	FR-TEVA-767720ROM		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Off Label Use; Overdose; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram			S	Unknown			Ivax
	Perindopril			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Colchicine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13532740	EXPEDITED (15-DAY)		OT	DK-ELI_LILLY_AND_COMPANY-DK201705000143			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Compulsions; Dental Caries; Derealisation; Dry Mouth; Headache; Irritability; Mouth Swelling; Mucosal Inflammation; Oral Pain; Pain In Jaw; Periodontitis; Restlessness; Toothache	Cymbalta			S	Oral	30 Mg, Unknown		Eli Lilly And Co
	Cymbalta			S	Unknown	60 Mg, Qd		Eli Lilly And Co
	Cymbalta			S	Unknown	60 Mg, Bid		Eli Lilly And Co
	Akarin			S	Oral	Unk, Unknown		Not Reported
	Cipralex /01588501/			S	Oral	Unk, Unknown		Not Reported
	Efexor			S	Oral	Unk, Unknown		Not Reported
	Medikinet /00083801/			C	Oral	Unk, Unknown		Not Reported
	Ritalin			C	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13532976	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2017SE48842		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Headache; Status Epilepticus	Xeroquel			S	Oral			Astrazeneca
	Xeroquel			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Lysanxia			S	Oral			Not Reported
	Forlax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13533449	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2017M1027621			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Abnormal; Electrocardiogram Qrs Complex Prolonged; Hypotension; Tachycardia	Acetaminophen\Caffeine\Propoxyphene			S	Oral	32 Df, Once		Mylan
	Izalgi 500 Mg/25 Mg, Gélule			S	Oral	16 Df, Once		Mylan
	Alprazolam			S	Oral	30 Df, Once		Not Reported
	Escitalopram			S	Oral	14 Df, Once		Not Reported
	Tramadol			S	Oral	30 Df, Once		Not Reported
	Laroxyl			S	Oral	Unk, Once		Mylan
	Prazepam			S	Oral	40 Df, Once		Mylan
	Skenan			S	Oral	14 Df, Once		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13534689	DIRECT	Y	HO			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Mental Status Changes; Seizure	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13535048	DIRECT		DS			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S				Not Reported
	Lexapro			C				Not Reported
	Metformin			C				Not Reported
	Levemir Flextouch			C				Not Reported
	Novolog Flexpen			C				Not Reported
	Benazepril-Htz			C				Not Reported
	Pioglitazone			C				Not Reported
	Alprazolam			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13535103	DIRECT		DS			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Temporomandibular Joint Syndrome	Escitalopram			S				Not Reported
	Allergy Shots			C				Not Reported
	Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2017	13441013	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-030887			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Blood Glucose Increased; Drug Abuse; Heart Rate Increased; Sinus Disorder; Suicidal Ideation	Abilify			S	Unknown			Bristol Myers Squibb
	Latuda			S	Oral	Unk		Not Reported
	Lexapro			S	Unknown			Not Reported
	Sudafed /00076302/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2017	13443147	EXPEDITED (15-DAY)		OT	US-TORRENT-00002664		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Electrocardiogram Qt Prolonged	Methimazole			C				Unknown
	Warfarin			C				Unknown
	Propranolol			C				Unknown
	Iloperidone			S				Unknown
	Olanzapine			S				Unknown
	Bupropion Hydrochloride			S				Unknown
	Escitalopram			S				Unknown
	Amitriptyline			S				Unknown
	Mirtazapine			S				Unknown
	Lorazepam			S				Unknown
	Alprazolam			S				Unknown
	Quetiapine			C				Unknown
	Clonazepam			C				Unknown
	Trazodone			C				Unknown
	Haloperidol			C				Unknown
	Valproic Acid			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2017	13535070	EXPEDITED (15-DAY)		HO, LT, OT	BR-ASTRAZENECA-2017SE49153		67 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foreign Body Aspiration; Heart Rate Decreased; Hypotension; Loss Of Consciousness; Stupor; Suicide Attempt	Seroquel			S	Oral	25.0mg Once/Single Administration		Zeneca
	Lexapro			S	Oral	20.0mg Once/Single Administration		Not Reported
	Alprazolam			S	Oral	1.0mg Once/Single Administration		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2017	13537409	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1718597US		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Headache; Status Epilepticus	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported
	Xeroquel			S	Oral	600 Mg, Qd		Not Reported
	Lysanxia			S	Oral	Unk		Not Reported
	Stilnox			S	Oral	Unk		Not Reported
	Forlax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2017	13537410	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1718417US		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anger; Cognitive Disorder; Depression; Hallucination; Hospitalisation; Mental Disorder; Panic Attack; Physical Assault; Product Dose Omission; Tobacco User	Lexapro			S	Oral	10 Mg, Bid		Allergan
	Lexapro			S	Oral	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2017	12884918	EXPEDITED (15-DAY)		HO, LT, OT	PL-PFIZER INC-2016496618			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Toxicity To Various Agents	Ramipril			S	Unknown	Unk		Pfizer
	Donepezil Hcl			S	Endocervical	Unk		Pfizer
	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Atorvastatin Calcium			S	Unknown	Unk		Pfizer
	Dextromethorphan Hbr		Y	S	Unknown	Unk		Unknown
	Venlafaxine Hcl			S	Unknown	Unk		Pfizer
	Acetylsalicylic Acid			S	Unknown	Unk		Pfizer

Sertraline Hcl	S	Unknown	Unk		Pfizer
Olanzapine	S	Unknown	Unk		Not Reported
Zolpidem Tartrate	S	Unknown	Unk		Pfizer
Topiramate	S	Unknown	Unk		Not Reported
Bisoprolol Fumarate	S	Unknown	Unk		Not Reported
Simvastatin	S	Unknown	Unk		Not Reported
Valsartan	S	Unknown	Unk		Not Reported
Rosuvastatin Calcium	S	Unknown	Unk		Not Reported
Escitalopram Oxalate	S	Unknown	Unk		Not Reported
Ibuprofen	S	Unknown	Unk		Not Reported
Paracetamol	S	Unknown	Unk		Not Reported
Metformin Hcl	S	Unknown	Unk		Not Reported
Indapamide	S	Unknown	Unk		Not Reported
Carbamazepine	S	Unknown	Unk		Not Reported
Diclofenac	S	Unknown	Unk		Not Reported
Morphine Hcl	S	Unknown	Unk		Not Reported
Risperidone	S	Unknown	Unk		Not Reported
Hydroxyzine	S	Unknown	Unk		Not Reported
Sulpiride	S	Unknown	Unk		Not Reported
Metoprolol	S	Unknown	Unk		Not Reported
Omeprazole	S	Unknown	Unk		Not Reported
Lamotrigine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2017	13538091	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2017US06841			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Dizziness; Drug Ineffective; Feeling Abnormal; Gait	Gabapentin			S	Oral	100 Mg, Unk		Invagen
	Gabapentin			S	Oral	400 Mg, Unk		Invagen

Disturbance; Pain	Gabapentin		S	Oral	300 Mg, Qd	Invagen
	Escitalopram		S	Unknown	20 Mg, At Dinner Time	Invagen
	Escitalopram		S			Invagen
	Zaleplon		S	Unknown	10 Mg, Unk	Cipla
	Buspirone		S	Unknown	15mg In The Morning And 30mg At Night	Not Reported
	Buspirone		S	Unknown	30mg In The Morning And 30mg At Night	Not Reported
	Buspirone		S	Unknown	15mg In The Morning And 30mg At Night	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2017	13541088	EXPEDITED (15-DAY)		HO, OT	GXBR2017US001623		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Gastrooesophageal Reflux Disease; Hyperhidrosis; Hypovitaminosis; Insomnia; Obesity; Serotonin Syndrome; Tardive Dyskinesia; Tremor	Phentermine Hydrochloride Capsules Usp			S	Unknown	Unk Df, Unk		Novartis
	Ampyra			S	Oral	10 Mg, Q12h		Not Reported
	Baclofen			S	Oral	10 Mg, Tid		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Aspirin			C	Unknown	Unk Df, Unk		Not Reported
	Celebrex			C	Unknown	Unk Df, Unk		Not Reported
	Oxycontin			C	Unknown	Unk Df, Unk		Not Reported
	Oxycodone			C	Unknown	Unk Df, Unk		Not Reported
	Levemir			C	Unknown	Unk Df, Unk		Not Reported
	Spironolactone			C	Unknown	Unk Df, Unk		Not Reported
	Zyrtec			C	Unknown	Unk Df, Unk		Not Reported
	Movantik			C	Unknown	Unk Df, Unk		Not Reported
	Ambien			C	Unknown	Unk Df, Unk		Not Reported
	Cholecalciferol			C	Unknown	Unk Df, Unk		Not Reported
	Clonidine			C	Unknown	Unk Df, Unk		Not Reported

	L-Methylfolate	C	Unknown	Unk Df, Unk	Not Reported
	Lisinopril	C	Unknown	Unk Df, Unk	Not Reported
	Maalox	C	Unknown	Unk Df, Unk	Not Reported
	Premarin	C	Unknown	Unk Df, Unk	Not Reported
	Pantoprazole	C	Unknown	Unk Df, Unk	Not Reported
	Multi Vitamin	C	Unknown	Unk Df, Unk	Not Reported
	Lipitor	C	Unknown	Unk Df, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2017	13541295	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1718909US		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Noctamide			S	Oral	Unk		Not Reported
	Risperdal			S	Oral	2 Mg, Qd		Not Reported
	Akineton L.P.			S	Oral	4 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	11155085	EXPEDITED (15-DAY)		OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD-2015R1-98357		35 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rabbit Syndrome	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported
	Clonazepam			C	Unknown	0.5 Mg, Qd (Night)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	12210677	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-021366		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Abilify	S	Unknown	Unk		Bristol Myers Squibb
	Lexapro	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	12341624	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-034246		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Bipolar Disorder; Depression; Dizziness; Drug Ineffective; Dry Mouth; Mania; Rash	Abilify			S	Oral	5 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Oral	2.5 Mg, Qd		Bristol Myers Squibb
	Carbamazepine			S	Unknown	600 Mg, Qd (200mg Tablet In The Morning And Two 200mg Tablets In The Evening)		Not Reported
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	12369161	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2016-05962		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Syncope; Tachycardia; Torsade De Pointes	Escitalopram			S	Unknown			Aurobindo
	Levofloxacin			S	Unknown			Aurobindo
	Sulpiride			S	Unknown			Not Reported
	Solifenacin			S	Unknown			Not Reported
	Amiodarone			S	Intravenous (not			Not Reported

				otherwise specified)	
	Simvastatin		C	Unknown	Not Reported
	Acenocoumarol		C	Unknown	Not Reported
	Furosemide		C	Unknown	Not Reported
	Candesartan		C	Unknown	Not Reported
	Digoxin		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	12516513	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2016-08402		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram			S	Unknown	Unk		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Solifenacin			S	Unknown	Unk		Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulpiride			S	Unknown	Unk		Not Reported
	Digoxin			S	Unknown	Unk		Not Reported
	Candesartan			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Acenocoumarol			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13472018	EXPEDITED (15-DAY)		OT	DE-TORRENT-00006385		31 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Dizziness; Dyspnoea; Hypersomnia; Musculoskeletal Stiffness; Vision Blurred	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13547047	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1719628US		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Use Disorder; Sopor	Escitalopram Oxalate Unk			S	Oral	Unk		Allergan
	Xanax			S	Oral			Not Reported
	Depakin			C	Oral			Not Reported
	Zarelis			C	Oral			Not Reported
	Dobetin (Cyanocobalamin)			C	Intramuscular			Not Reported
	Eutirox			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13509480	EXPEDITED (15-DAY)		HO	PHHY2017IT062339		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Xanax			S	Oral	0.25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13548729	EXPEDITED (15-DAY)		OT	TW-APOTEX-2017AP008767		71 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akinesia; Bradykinesia; Cognitive Disorder; Cognitive Disorder; Drug Intolerance; Extrapyramidal Disorder; Gait Disturbance; Hallucination, Visual; Hypokinesia; Illusion; Muscle Rigidity; Parkinsonism; Progressive	Paroxetine			S	Unknown	25 Mg, Qd		Apotex
	Paroxetine			S				Apotex
	Paroxetine			S				Apotex
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Zolpidem			C	Unknown			Not Reported
	Zolpidem			C				Not Reported
	Zolpidem			C				Not Reported

Supranuclear Palsy; Rapid Eye Movement Sleep Behaviour Disorder; Urinary Incontinence	Clonazepam	C	Unknown		Not Reported
	Clonazepam	C			Not Reported
	Clonazepam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13549836	EXPEDITED (15-DAY)		DE	FR-NORTHSTAR HEALTHCARE HOLDINGS-FR-2017NSR000143		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Overdose; Toxicity To Various Agents	Baclofen			S	Oral	Unk		Northstar
	Colchicine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Metoprolol			S		Unk		Not Reported
	Perindopril			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13549962	EXPEDITED (15-DAY)		DE	FR-NORTHSTAR HEALTHCARE HOLDINGS-FR-2017NSR000147		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose; Poisoning Deliberate; Toxicity To Various Agents	Baclofen			S	Oral	Unk		Northstar
	Acetaminophen			S		Unk		Not Reported
	Dextropropoxyphene			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Valpromide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13550199	EXPEDITED (15-DAY)		DS	CA-APOTEX-2017AP011832		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Depression; Dizziness; Headache; Product Substitution Issue	Apo-Escitalopram		S	Unknown	Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13551044	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-041487		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination	Abilify			S	Unknown	30 Mg, Qd		Bristol Myers Squibb
	Olanzapine			S	Unknown	40 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	3 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13551187	EXPEDITED (15-DAY)		DE, HO, OT	CN-JNJFOC-20170513795		62 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Overdose; Toxicity To Various Agents	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Artane			C	Unknown			Not Reported
	Benzhexol			C	Unknown			Not Reported
	Aripiprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13551653	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1719621US		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Seizure	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Largactil			S	Oral	15 Gtt, Qd		Not Reported
	Xanax			C	Unknown			Not Reported
	Durogesic			C	Unknown			Not Reported
	Pecfent			C	Unknown			Not Reported
	Prazepam			C	Unknown			Not Reported
	Zolpidem			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Carbosymag [Activated Charcoal\Magnesium Oxide\Simethicone]			C	Unknown			Not Reported
	Olimel N7e			C	Unknown			Not Reported
	Aminomix 800e			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13553220	DIRECT		OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Burning Sensation; Condition Aggravated; Depersonalisation/Derealisation Disorder; Erythema; Inflammation; Insomnia; Musculoskeletal Discomfort; Paraesthesia; Rheumatoid Arthritis; Stress; Vomiting	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13521041	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-139660		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram			S	Oral	10 Mg Total		Not Reported
	Xanax 0.25 Mg			S	Oral	0.25 Mg Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13552682	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP012019		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Heart Rate Decreased; Hypotension; Myasthenia Gravis; Myocardial Infarction; Overdose; Presyncope	Clopidogrel Tablets Usp			S	Unknown	Unk		Apotex
	Amlodipine Besylate			S	Unknown	Unk		Apotex
	Carvedilol			S	Unknown	Unk		Apotex
	Losartan Potassium Film-Coated Tablets			S	Unknown	Unk		Apotex
	Escitalopram Oxalate			S	Unknown	Unk		Apotex
	Mirtazapine			S	Unknown	Unk		Apotex
	Pantoprazole Sodium Delayed-Release Tablets Usp			S	Unknown	Unk		Apotex
	Aspirin /00002701/			S	Unknown	Unk		Not Reported
	Hydralazine			S	Unknown	Unk		Not Reported
	Olmesartan			S	Unknown	Unk		Not Reported
	Finasteride			S	Unknown	Unk		Not Reported
	Niacin			S	Unknown	Unk		Not Reported
	Simvastatin			S	Unknown	Unk		Not Reported
	Nitroglycerin			S	Unknown	Unk, Prn		Not Reported
	Tylenol With Codeine			S	Unknown	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13553480	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP011837			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Apo-Escitalopram			S	Unknown			Apotex
	Vyvanse			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13360700	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1710685US			Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Electrocardiogram St Segment Depression; Micturition Urgency; Restlessness; Sucrose Intolerance; Thirst	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S		10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S		5 Mg, Qd		Allergan
	Trittico			C		50 Mg In The Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13546755	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1028921			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Overdose; Nausea; Tremor	Escitalopram			S	Oral	200 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13559564	EXPEDITED (15-DAY)		HO, OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-140518		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Overdose; Poisoning Deliberate; Toxicity To Various Agents	Mirtazapine		S	Oral	870 Mg	Sun
	Escitalopram		S	Oral	100 Mg	Not Reported
	Desvenlafaxine		S	Oral	500 Mg	Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13559799	NON-EXPEDITED		OT	US-APOTEX-2017AP012030		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage	Escitalopram Oxalate			S	Unknown			Apotex
	Rivaroxaban			S	Oral	15 Mg, Bid		Not Reported
	Rivaroxaban			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13560422	EXPEDITED (15-DAY)		DE, HO	US-CIPLA LTD.-2017US08457			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Intentional Overdose; Localised Infection; Suicide Attempt; Vanishing Bile Duct Syndrome	Lamotrigine			S	Unknown	25 Mg, Bid		Cipla
	Escitalopram			S	Unknown	Unk		Invagen
	Meloxicam			S	Unknown	Unk		Cipla
	Cephalexin			S	Unknown	Unk		Cipla
	Moxifloxacin			S	Unknown	Unk		Cipla
	Aripiprazole			S	Unknown	Unk		Cipla
	Lorazepam			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Cipla
	Venlafaxine			S	Unknown	Unk		Cipla
	Levothyroxine			S	Unknown	Unk		Not Reported
	Dextropropoxyphene			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13560591	NON-EXPEDITED		OT	US-ROCHE-724719		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer	Naprosyn			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lyrica			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13561085	NON-EXPEDITED			US-ROCHE-1442754			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Nausea	Naprosyn			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Hydrocodone Hcl			C	Unknown	As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13561162	EXPEDITED (15-DAY)		HO	BE-ALLERGAN-1720132US		86 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Clonus; Renal Impairment	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Loramet			C	Oral	1 Mg, Qd		Not Reported
	Rocaltrol			C	Oral	0.25 Mg, Qd		Not Reported
	Calcium Carbonate			C	Oral	1 G, Qd		Not Reported
	Tamsulosine			C	Oral	0.4 Mg, Qd		Not Reported
	Glurenorm			C	Oral	30 Mg, Qd		Not Reported

L-Thyroxine	C	Oral	125 Mg, Qd		Not Reported
Asaflow	C	Oral	80 Mg, Qd		Not Reported
Cordarone	C	Oral	200 Mg, Qd		Not Reported
Lasix	C	Oral	100 Mg, Qd		Not Reported
Zocor	C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13561163	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1719108US		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Emotional Disorder; Feeling Abnormal; Heart Rate Increased; Paranoia; Product Dose Omission; Self-Injurious Ideation; Violence-Related Symptom	Lexapro			S	Oral	Unk		Allergan
	Glipizide			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Claritin			C	Unknown	Unk		Not Reported
	Biotin			C	Unknown			Not Reported
	Victoza			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13561168	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1720140US		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Previscan (Fluindione)			S	Oral	20 Mg, Qd		Not Reported
	Zamudol Lp			C		Unk		Not Reported

Diffu K	C		Unk		Not Reported
Ikorel	C		Unk		Not Reported
Lasilix	C		125 Mg, Qd		Not Reported
Lasilix	C	Unknown	40 Mg, Qam		Not Reported
Lasilix	C	Unknown	20 Mg, Qd		Not Reported
Metformine	C				Not Reported
Triatec (Codeine Phosphate/Paracetamol)	C				Not Reported
Esomeprazole	C				Not Reported
Gabapentin	C		Unk		Not Reported
Simvastatin	C		Unk		Not Reported
Tardyferon	C		Unk		Not Reported
Imovane	C		Unk		Not Reported
Uvedose	C		Unk		Not Reported
Lumigan	C		Unk		Not Reported
Tamsulosine Lp	C		Unk		Not Reported
Permixon	C		Unk		Not Reported
Bisoce	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13561170	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1720193US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Dizziness; Dyspnoea; Dysstasia; Hot Flush; Lung Infection; Paraesthesia; Sputum Abnormal; Surgery	Escitalopram Oxalate - Bp			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13561193	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1720164US		152 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Foetal Growth Restriction	Escitalopram Oxalate - Bp		S	Transplacental	20 Mg, Unk	Allergan
	Subutex		S	Transplacental	8 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13561576	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1720146US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Disorder; Coagulopathy; Drug Interaction; Gastrointestinal Haemorrhage	Citalopram Hydrobromide - Bp			S				Allergan
	Ass			S				Not Reported
	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13561824	EXPEDITED (15-DAY)		HO, OT	US-TEVA-768813USA		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Gastrooesophageal Reflux Disease; Hyperhidrosis; Insomnia; Obesity; Serotonin Syndrome; Tardive Dyskinesia; Vitamin B6 Deficiency	Phentermine			S	Unknown			Teva
	Baclofen			S	Oral	30 Milligram Daily;		Ivax
	Ampyra			S	Oral	20 Milligram Daily;		Not Reported
	Ampyra			S				Not Reported
	Lexapro			S	Oral	20 Milligram Daily;		Not Reported
	Aspirin			C				Not Reported
	Celebrex			C				Not Reported
	Oxycontin			C				Not Reported
	Oxycodone			C				Not Reported
	Levemir			C				Not Reported
	Spironolactone			C				Not Reported
	Zyrtec			C				Not Reported
	Movantik			C				Not Reported
	Ambien			C				Not Reported
	Clonidine			C				Not Reported
	Vitamin D3			C				Not Reported
	L-Methylfolate			C				Not Reported

Lisinopril	C				Not Reported
Maalox	C				Not Reported
Premarin	C				Not Reported
Pantoprazole	C				Not Reported
Multivitamin	C				Not Reported
Lipitor	C				Not Reported
Clonidine	C	Oral	.2 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13562038	EXPEDITED (15-DAY)			JP-ALLERGAN-1720162US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Seizure	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2017	12563591	EXPEDITED (15-DAY)		OT	US-JAZZ-2016-US-012843			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Depression; Vascular Graft	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S				Not Reported
	Cymbalta			C		Unk		Not Reported
	Diovan			C				Not Reported
	Lantus			C		Unk		Not Reported
	Levemir			C				Not Reported
	Lopressor			C				Not Reported
	Lotensin			C				Not Reported
	Metformin Hcl			C				Not Reported
	Norvasc			C				Not Reported
	Novolog			C				Not Reported
	Potassium Chloride			C				Not Reported
	Ritalin			C				Not Reported
	Vicodin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2017	13485687	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2017175844		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Lyrica			S	Oral	Unk		Pfizer
	Lyrica			S				Pfizer
	Seroplex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2017	13566253	DIRECT					70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaw Disorder; Migraine; Muscle Fatigue; Tremor	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Cvs Caremark
	Dexilant			C				Not Reported
	Synthroid			C				Not Reported
	Glimpiride			C				Not Reported
	Labetalol			C				Not Reported
	Probiotics			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2017	13566975	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Nausea; Palpitations	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13418427	EXPEDITED (15-DAY)		HO, LT, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-027128		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy;	Aripiprazole			S	Transplacental	2 Mg, Unk		Bristol Myers Squibb

Gastrooesophageal Reflux Disease; Selective Eating Disorder	Aripiprazole		S	Transplacental	1 Mg, Unk	Bristol Myers Squibb
	Ambien		S	Transplacental		Not Reported
	Lamictal		S	Transplacental	Unk	Not Reported
	Lexapro		S	Transplacental	Unk	Not Reported
	Synthroid		S	Transplacental	Unk	Not Reported
	Simponi		S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13568227	EXPEDITED (15-DAY)		HO	CN-JNJFOC-20170513802		36 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Irritability; Memory Impairment; Toxicity To Various Agents	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown	Overdose		Not Reported
	Risperdal			S	Unknown	Overdose		Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown	Overdose		Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown	Overdose		Not Reported
	Artane			C	Unknown			Not Reported
	Benzhexol			C	Unknown			Not Reported
	Aripiprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13568326	EXPEDITED (15-DAY)		HO	SE-TEVA-767755ACC			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyspnoea; Lip Swelling; Obesity; Peripheral Swelling	Escitalopram Teva			S					Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13568589	DIRECT		DE			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Eating Disorder; Fall; Insomnia; Intentional Self-Injury; Morbid Thoughts; Paranoia; Restlessness	Escitalopram			S	Oral	Quantity:.5 Tablet(S);		Lundbeck
	Pravastatin Sodium			C				Not Reported
	Irbesartan			C				Not Reported
	Amlodipine Besylate			C				Not Reported
	Zolpidem			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13568872	EXPEDITED (15-DAY)		OT	FR-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00148			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypotonia; Respiratory Distress; Supraventricular Tachycardia	Escitalopram			S	Transplacental	10 Mg, 1x/Day		Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13569154	EXPEDITED (15-DAY)		HO	CH-AKRIMAX-TIR-2017-0489		85 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Overdose	Tirosint (Levothyroxine Sodium) Capsules, 150 Mcg; Akrimax Pharmaceuti			S	Oral	150mcg Daily		Not Reported
	Tirosint (Levothyroxine Sodium) Capsules, 150 Mcg; Akrimax Pharmaceuti			S	Oral	150mcg Daily		Not Reported

	Escitalopram	S	Oral	Unknown	Not Reported
	Amlodipin-Mepha	C			Not Reported
	Atorvastatin	C			Not Reported
	Co Candesartan	C			Not Reported
	Dafalgan	C			Not Reported
	Vi-De 3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13569231	EXPEDITED (15-DAY)		HO	CN-ALLERGAN-1720995US		36 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S				Not Reported
	Artane			C	Unknown			Not Reported
	Benzhexol			C	Unknown			Not Reported
	Aripiprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13570040	EXPEDITED (15-DAY)		OT	FR-PRINSTON PHARMACEUTICAL INC.-2017PRN00214			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypotonia; Respiratory Distress; Supraventricular Tachycardia	Escitalopram			S	Transplacental	10 Mg, 1x/Day		Prinston Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2017	13522525	EXPEDITED (15-DAY)		OT	ES-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00132		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angle Closure Glaucoma; Choroidal Effusion	Escitalopram		S	Unknown	Unk	Jubilant
	Escitalopram		S	Unknown	"Duplicating The Drug Dose"; "Doubled"	Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2017	13570978	EXPEDITED (15-DAY)		HO, OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-140928		49 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Therapy Partial Responder	Olanzapine			S	Unknown	Unk		Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Lithium			S	Unknown	Unk		Sun
	Nortriptyline			S	Unknown	Unk		Taro

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2017	13571201	EXPEDITED (15-DAY)		HO	FR-ROCHE-1936624		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Valium			S	Oral			Not Reported
	Seroplex			S	Oral	56 Tablets Of 20 Mg		Not Reported
	Theralene (France)			S	Oral	3 Vials Of 30ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2017	13571671	NON-EXPEDITED			US-PFIZER INC-2017223057		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lorazepam			S		Unk		Pfizer
	Diazepam			S		Unk		Pfizer
	Paroxetine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported

	Isosorbide			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	12629908	EXPEDITED (15-DAY)		HO	JP-FRI-1000086721			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Withdrawal Syndrome; Hallucination, Visual	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Solanax			C	Oral	Unk		Not Reported
	Reflex			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13418009	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-027249		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Hyperemesis Gravidarum; Maternal Exposure During Pregnancy; Premature Delivery; Premature Rupture Of Membranes; Product Use Issue	Aripiprazole			S	Unknown	5 Mg, Unk		Bristol Myers Squibb
	Lexapro			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Zofran /00955301/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13562042	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1719657US		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder;	Lexapro			S	Oral	20 Mg, Qd		Allergan

Hypotension; Off Label Use; Parkinsonism; Syncope

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13573781	EXPEDITED (15-DAY)		HO	US-JNJFOC-20170520331		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flat Affect; Hostility; Refusal Of Treatment By Patient	Invega Trinza			S	Intramuscular			Not Reported
	Lithium			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13575437	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US08880			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Resistance; Fall; Lafora'S Myoclonic Epilepsy	Lamotrigine			S	Unknown	Unk		Cipla
	Zonisamide			S	Unknown	Unk		Invagen
	Escitalopram			S	Oral	20 Mg, Daily		Invagen
	Levetiracetam			S	Unknown	Unk		Invagen
	Levetiracetam			S	Oral	1500 Mg, Bid		Invagen
	Sodium Valproate			S	Unknown	Unk		Cipla
	Sodium Valproate			S	Oral	300 Mg, Bid, Daily		Cipla
	Phenobarbital			S	Oral	40 Mg, Bid		Not Reported
	Piracetam			S	Oral	1200 Mg, Tid		Not Reported
	Carbamazepine			S	Unknown	Unk		Not Reported
	Clonazepam			S	Sublingual	Unk		Not Reported
	Clonazepam			S	Oral	4.5 Mg, Unk		Not Reported
	Lacosamide			S	Oral	150 Mg, Bid, Daily		Not Reported
	Calcium Carbonate-Vit D3			C	Unknown	Unk		Not Reported

	Ferrous Fumarate		C	Unknown	Unk	Not Reported
	Multivitamin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13576182	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-30439			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13576688	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Nervous System Disorder	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13577572	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1721267US		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13578189	NON-EXPEDITED			US-DRREDDYS-USA/USA/17/0087270		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Quetiapine Fumarate Tablets			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported

	Lisinopril	C	Unknown	Not Reported
	Norvasc	C	Unknown	Not Reported
	Proair	C	Unknown	Not Reported
	Proair	C		Not Reported
	Zantac	C	Unknown	Not Reported
	Citalopram	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13578792	NON-EXPEDITED		OT	US-JAZZ-2017-US-004882			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Road Traffic Accident; Somnambulism; Sudden Onset Of Sleep; Wrong Technique In Product Usage Process	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Xanax			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Armodafinil			S		Unk		Not Reported
	Ropinirole Hcl			C				Not Reported
	Neupro			C		Unk		Not Reported
	Cialis			C		Unk		Not Reported
	Ambien			C		Unk		Not Reported
	L-Methylfolate Calcium			C				Not Reported
	Pramipexole			C		Unk		Not Reported
	Adderall			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13578882	NON-EXPEDITED			US-JAZZ-2017-US-005054		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Pain In Extremity	Xyrem			S	Oral	2.25g, Bid		Jazz
	Xyrem			S	Oral	2.5 G, Bid		Jazz
	Xyrem			S	Oral	3.25 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported
	Tramadol Hcl			C				Not Reported
	Vitamin D3			C				Not Reported
	Chia Seed			C				Not Reported
	Folic Acid			C				Not Reported
	Ibuprofen			C				Not Reported
	Levothyroxine			C				Not Reported
	Nuvigil			C				Not Reported
	Fiber Choice Plus Calcium			C				Not Reported
	Vitamin E /00110501/			C				Not Reported
	Evening Primrose			C				Not Reported
	Flax Seed Oil			C				Not Reported
	Toviaz			C				Not Reported
	Midodrine Hcl			C				Not Reported
	Synthroid			C				Not Reported
	Inderal			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Olive Oil			C				Not Reported
	Protein			C				Not Reported
	Provigil /01265601/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13579139	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1721520US		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychomotor Skills Impaired; Sedation; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Bromazepam			S	Oral	Unk, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2017	13501667	EXPEDITED (15-DAY)		HO	FR-ROCHE-1926254		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Reversible Cerebral Vasoconstriction Syndrome	Avastin			S	Intravenous (not otherwise specified)	Last Dose Prior To Events On 07/Sep/2016		Not Reported
	Seroplex			S	Oral			Not Reported
	Carboplatin			C	Unknown			Not Reported
	Carboplatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2017	13560117	EXPEDITED (15-DAY)		OT	CH-INDIVIOR LIMITED-INDV-101776-2017		34 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Foetal Growth Restriction; Foetal Placental Thrombosis; Induced Labour; Maternal Exposure During Pregnancy	Subutex 8mg Tablet			S	Unknown	8 Mg, Qd		Reckitt Benckiser
	Cipralex /01588502/			S	Unknown	20 Mg Per Day		Not Reported
	Cannabis			S	Unknown	2-3 Joints Per Day		Not Reported
	Nicotine			C	Unknown	5-10 Cigarettes Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2017	13580794	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-106915			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Amitriptyline			S	Unknown	Unk		Sun
	Bupropion			S	Unknown	Unk		Sun
	Citalopram			S	Unknown	Unk		Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Fluoxetine			S	Unknown	Unk		Sun
	Imipramine			S	Unknown	Unk		Mutual
	Paroxetine			S	Unknown	Unk		Sun
	Sertraline			S	Unknown	Unk		Sun

	Venlafaxine	S	Unknown	Unk	Sun
	Carbamazepine	S	Unknown	600-1400 Mg, Daily	Taro
	Clonazepam	S	Unknown	1 Mg, Daily	Sun
	Lamotrigine	S	Unknown	300-600 Mg, Daily	Taro
	Methylphenidate	C	Unknown	5-20 Mg, Daily	Not Reported
	Quetiapine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2017	13582113	EXPEDITED (15-DAY)		HO, OT	CH-INDIVIOR LIMITED-INDV-101696-2017		3 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Low Birth Weight Baby	Subutex 8mg Tablet			S	Transplacental	8 Mg, Qd		Reckitt Benckiser
	Cipralex			S	Transplacental	20 Mg, Qd		Not Reported
	Cannabis			S	Transplacental	2-3 Joints Per Day		Not Reported
	Nicotine			S	Transplacental	5-10 Cigarettes Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2017	13406699	EXPEDITED (15-DAY)		HO, OT	US-ACORDA-ACO_135843_2017			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Hyperhidrosis; Insomnia; Serotonin Syndrome; Tardive Dyskinesia; Vitamin B6 Deficiency	Ampyra			S	Oral	10 Mg, Q 12 Hrs		Acorda
	Ampyra			S				Acorda
	Baclofen			S	Oral	10 Mg, Tid		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Phentermine			S	Unknown			Not Reported
	Aspirin			C	Unknown	81 Mg, Qd		Not Reported
	Celebrex			C	Oral	200 Mg, Qd As Needed		Not Reported
	Oxycontin			C	Unknown	30 Mg At Bedtime		Not Reported
	Oxycodone			C	Oral	15 Mg, 1 To 2 Tablets Tid		Not Reported
	Levemir			C	Unknown	20 Iu, Morning		Not Reported

	Levemir	C	Unknown	25 Iu, At Bedtime	Not Reported
	Spironolactone	C	Unknown	50 Mg, Bid	Not Reported
	Zyrtec	C	Unknown	10 Mg, Qd As Needed	Not Reported
	Movantik	C	Oral	25 Mg, Qd Prn	Not Reported
	Ambien	C		10 Mg, Prn	Not Reported
	Vitamin D3	C	Oral	5000 Iu, Qd	Not Reported
	Clonidine	C	Oral	0.1 Mg, Bid	Not Reported
	L-Methylfolate	C	Unknown	Unk	Not Reported
	Lisinopril	C	Oral	5 Mg, Qd	Not Reported
	Maalox	C	Unknown	10 Ml, 4 Times As Needed	Not Reported
	Premarin	C	Unknown	0.3 Mg, Qd	Not Reported
	Pantoprazole	C	Oral	40 Mg, Bid	Not Reported
	Multivitamin	C	Unknown	1 Df, Bid	Not Reported
	Lipitor	C	Oral	Unk	Not Reported
	Other Therapeutic Products	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2017	13585142	EXPEDITED (15-DAY)		DE	FR-LANNETT COMPANY, INC.-FR-2017LAN000792		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Off Label Use; Toxicity To Various Agents	Baclofen (20mg)			S	Unknown	Unk		Lannett
	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Colchicine			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Perindopril			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2017	13585571	EXPEDITED (15-DAY)		HO, OT	IT-JNJFOC-20170519049			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Electrocardiogram Qt Prolonged; Extrapyramidal Disorder; Gastrointestinal Disorder; Haemorrhage; Hyperkalaemia; Hypokalaemia; Myopathy; Rhabdomyolysis; Serotonin Syndrome	Itraconazole		S	Unknown	Not Reported
	Fluconazole	Y	S	Unknown	Not Reported
	Ketorolac		S	Unknown	Not Reported
	Acetylsalicylic Acid		S	Unknown	Not Reported
	Simvastatin		S	Unknown	Not Reported
	Selegiline		S	Unknown	Not Reported
	Ketoprofen		S	Unknown	Not Reported
	Diclofenac		S	Unknown	Not Reported
	Alfuzosine		S	Unknown	Not Reported
	Venlafaxine		S	Unknown	Not Reported
	Metoclopramide		S	Unknown	Not Reported
	Alginic Acid		S	Unknown	Not Reported
	Trazodone		S	Unknown	Not Reported
	Biperiden		S	Unknown	Not Reported
	Escitalopram		S	Unknown	Not Reported
	Sertraline		S	Unknown	Not Reported
	Trifluoperazine		S	Unknown	Not Reported
	Ezetimibe/Simvastatin		S	Unknown	Not Reported
	Paroxetine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2017	13586397	EXPEDITED (15-DAY)		DE	FR-LANNETT COMPANY, INC.-FR-2017LAN000796		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Poisoning; Toxicity To Various Agents	Baclofen (20mg)			S	Unknown	Unk		Lannett
	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Silapap			S	Unknown	Unk		Lannett
	Dextropropoxyphene			S	Unknown	Unk		Not Reported
	Valpromide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2017	13591620	DIRECT					72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Nightmare; Unevaluable Event	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Aurobindo
	Omeprazole			C				Not Reported
	Lisinopril			C				Not Reported
	Alprazolam			C				Not Reported
	Quetiapine			C				Not Reported
	Meloxicam			C				Not Reported
	Vitamin C			C				Not Reported
	Essential Oils (Brain Calm)			C				Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported
	Zinc			C				Not Reported
	Vitamin D3			C				Not Reported
	Fish Oil			C				Not Reported
	Acidophilius			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2017	13592543	EXPEDITED (15-DAY)		OT	CH-TEVA-771766ISR		18 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Dyspnoea; Gastrointestinal Disorder; Neck Pain	Azithromycin Mepha			S	Intravenous drip	1000 Milligram Daily;		Not Reported
	Cipralex			S	Unknown	160 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	13430455	NON-EXPEDITED			US-PFIZER INC-2017154322			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer

Methotrexate Sodium	S	Unk		Pfizer
Ciprofloxacin	S	Unk		Unknown
Morphine Sulfate	S	Unk		Pfizer
Clindamycin Phosphate	S	Unk		Pfizer
Lexapro	S	Unk		Not Reported
Bentyl	S	Unk		Not Reported
Codeine	S	Unk		Not Reported
Levbid	S	Unk		Not Reported
Dilaudid	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	13595245	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2017US09634			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S	Oral	Unk		Invagen
	Meloxicam			S	Oral	Unk		Cipla
	Loperamide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	13597729	DIRECT					37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Middle Insomnia; Night Sweats	Escitalopram			S	Oral			Teva
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	13600586	DIRECT		DS			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Oral; Arthralgia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	13631178	NON-EXPEDITED			US-ASTELLAS-1357761			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Decreased Appetite; Diarrhoea; Dizziness; Urinary Tract Infection	Tarceva			S	Oral			Not Reported
	Tylenol With Codeine			S	Unknown			Not Reported
	Ativan			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Trental			S	Unknown			Not Reported
	Xanax			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Mag 64			C				Not Reported
	Zantac			C				Not Reported
	Codeine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13479930	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1715830US		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Selincro			S	Oral	18 Mg, Qd		Not Reported
	Brexin [Piroxicam]			S	Oral	20 Mg, Qd		Not Reported
	Lamaline (Acetaminophen\Belladonna Leaf\Caffeine\Opium)			S	Oral	1 Df, Qid		Not Reported
	Multicrom			S	Ophthalmic	1 Gtt, Unk		Not Reported
	Rhinomaxil			S	Nasal	100 Mg, Bid		Not Reported
	Duoresp Spiromax			C	Unknown			Not Reported
	Singulair			C	Unknown			Not Reported
	Bricanyl			C	Unknown			Not Reported
	Tahor			C	Unknown			Not Reported

	Coveram	C	Unknown			Not Reported
	Kestinlyo	C	Unknown			Not Reported
	Valium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13599959	EXPEDITED (15-DAY)		DE, LT	US-CIPLA LTD.-2017US09640			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Lethargy	Escitalopram			S	Oral	Unk		Invagen
	Meloxicam			S	Oral	Unk		Cipla
	Loperamide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13601184	EXPEDITED (15-DAY)		HO	US-APOTEX-2017AP012516		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Above Therapeutic; Somnolence; Toxicity To Various Agents	Aripiprazole Tablets			S	Unknown			Apotex
	Divalproex Sodium Delayed-Release Tablets Usp			S	Unknown			Apotex
	Escitalopram Oxalate			S	Unknown			Apotex
	Clozapine			S	Unknown	400 Mg, Daily		Not Reported
	Clozapine			S	Unknown	200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13602585	EXPEDITED (15-DAY)		HO	US-APOTEX-2017AP012512		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Above Therapeutic; Hypotension; Mental Disorder; Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown			Apotex
	Clozapine			S	Unknown	450 Mg, Per Day		Not Reported
	Clozapine			S	Unknown	200 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13602832	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1722591US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrectomy	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13603274	EXPEDITED (15-DAY)		HO	PHHY2017US075732		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Somnolence	Clozapine			S	Unknown	400 Mg, Qd		Not Reported
	Divalproex Sodium			S	Unknown			Novartis
	Escitalopram			S	Unknown			Not Reported
	Aripiprazole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13145573	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1702720US		42 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Tardive Dyskinesia	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Dogmatyl			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13497466	EXPEDITED (15-DAY)		OT	ES-TEVA-762375ROM		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram			S	Unknown	10 Milligram Daily; 10mg/Day; Later Doubled The Dose		Ivax
	Escitalopram			S	Unknown	20 Milligram Daily;		Ivax

20mg/Day

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13607119	EXPEDITED (15-DAY)		OT	CH-ROCHE-1942216		41 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Avastin			S	Intravenous bolus			Not Reported
	Cipralex			S	Oral			Not Reported
	Trittico			S	Oral			Not Reported
	Campto			C	Unknown			Not Reported
	Paraplatin			C	Unknown			Not Reported
	Taxol			C	Unknown			Not Reported
	Keppra			C	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13607243	EXPEDITED (15-DAY)		HO, OT	TR-LUPIN PHARMACEUTICALS INC.-2017-02810		16 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea; Overdose; Suicide Attempt	Escitalopram			S	Oral	Unk, A Large Amount		Lupin
	Escitalopram			S	Unknown	5 Mg, Per Day		Lupin
	Pseudoephedrine Hydrochloride			S	Oral	Unk, A Large Amount		Not Reported
	Metoclopramide			S	Oral	Unk, A Large Amount		Novel Labs
	Fluoxetine			S	Unknown	20 Mg, Per Day		Not Reported
	Fluoxetine			S	Unknown	10 Mg, Per Day		Not Reported
	Risperidone			C	Unknown	0.5 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13609367	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1722677US		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Rectal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Xarelto			S	Oral	15 Mg, Qd		Not Reported
	Xarelto			S	Oral	15 Mg, Qd		Not Reported
	Lasilix			C		Unk		Not Reported
	Diffu K			C		Unk		Not Reported
	Metformine			C		Unk		Not Reported
	Tardyferon			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Lansoyl			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13609386	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1722675US		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13609388	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1722683US		41 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Avastin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tritticot			S	Oral	50 Mg, Qd		Not Reported
	Temodal			C	Unknown			Not Reported
	Keytruda			C	Unknown			Not Reported
	Campto			C	Unknown	Unk		Not Reported

	Paraplatin	C	Unknown	Unk		Not Reported
	Taxol	C	Unknown			Not Reported
	Keppra	C	Unknown			Not Reported
	Dexamethasone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13609389	EXPEDITED (15-DAY)		OT	EE-ALLERGAN-1722684US			Female	EST

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Lupus Erythematosus; Hyperhidrosis; Photosensitivity Reaction; Rosacea	Escitalopram Oxalate - Bp			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13609644	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1722788US		42 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling; Rash Generalised; Swelling Face; Swollen Tongue	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Q Week		Allergan
	Citalopram			C	Unknown	Reduce By 20mg Every 3 Days, Then Stop- Advice B...		Not Reported
	Promethazine Hydrochloride			C	Unknown	1 At Night As Necessary, Maximum Of 1 Four Times A Day If Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13610351	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Label Issue	Lexapro			S				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2017	13611077	DIRECT		DE			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Poisoning; Asphyxia; Completed Suicide; Nightmare	Escitalopram	Y		S	Oral	Quantity:1 Tablet(S);		Lupin
	Abilify			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2017	13610167	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1032181			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling; Rash Generalised; Swelling Face; Swollen Tongue	Escitalopram			S		On Uptitration		Not Reported
	Citalopram			C		Reduce By 20mg Every 3 Days, Then Stop- Advice B...		Mylan
	Promethazine Hydrochloride			C		1 At Night As Necessary, Maximum Of 1 Four Times A Day If Needed		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2017	13610188	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1032414			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium	Quetiapine			S	Oral	400 Mg, Unk		Not Reported
	Quetiapine			S	Oral	7000 Mg, Unk		Not Reported
	Quilonum			S	Oral			Mylan
	Quetiapin			S	Oral			Mylan
	Cipralex			S	Oral			Mylan
	Tavor [Lorazepam]			S	Oral	2 Mg, Unk		Mylan
	Tavor			S	Oral	4 - 0.5 Mg/D		Mylan

Movicol	C	Oral		Mylan
Beloc Zok	C	Oral		Mylan
Candesartan	C	Oral		Mylan
L-Thyroxin	C	Oral		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2017	13611224	DIRECT		LT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Crying; Depression; Histrionic Personality Disorder; Suicidal Ideation	Escitalopram			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2017	13599335	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1722307US		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Grandiosity; Hallucination, Auditory; Insomnia; Product Use Issue	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Lithium			C	Oral			Not Reported
	Lithium			C	Oral			Not Reported
	Lithium			C	Oral			Not Reported
	Lithium			C	Oral			Not Reported
	Guanfacine			C	Oral			Not Reported
	Guanfacine			C	Oral			Not Reported
	Lamotrigine			C	Oral	25mg Po Qam		Not Reported
	Lamotrigine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2017	13611889	DIRECT	Y	OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Therapy Cessation	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2017	13612463	EXPEDITED (15-DAY)		DE, HO	FR-SYMPLMED PHARMACEUTICALS-2017SYMPLMED000454			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Asthenia; Blood Sodium Increased; Haemorrhage; Pancytopenia	Coveram			S	Oral	1 (5mg/5mg) Tablet, Qd		Unknown
	Previscan /00789001/			S	Oral	0.25 Mg, Qd		Not Reported
	Seroplex			S	Unknown	40 Mg, Bid		Not Reported
	Lorazepam			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2017	13612976	EXPEDITED (15-DAY)		OT	US-SUNOVION-2017SUN002341			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Sluggishness; Suicidal Ideation	Latuda			S	Oral			Sunovion
	Lexapro			S		10 Mg, Qd		Not Reported
	Trazodone			S		50 Mg, Hs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2017	13615525	EXPEDITED (15-DAY)		DE	US-BION-006351		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse	Loperamide Hydrochloride			S				Bionpharma
	Escitalopram			S				Not Reported
	Meloxicam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2017	13615805	EXPEDITED (15-DAY)		DE, LT	US-BION-006368		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Lethargy; Somnolence; Suicide Attempt	Loperamide Unknown Product			S				Bionpharma
	Escitalopram			S				Not Reported
	Meloxicam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2017	13619199	DIRECT					34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Dyspnoea; Fatigue; Feeling Abnormal; Headache; Immune System Disorder; Obsessive-Compulsive Disorder; Palpitations; Panic Reaction; Social Anxiety Disorder	Escitalopram			S	Oral	Quantity:90 Tablet(S);		Not Reported
	Prenatal Vitamins			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	11078183	NON-EXPEDITED			US-JNJFOC-20150414688			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Aggression; Gynaecomastia; Hyperprolactinaemia	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Abilify			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	12953902	EXPEDITED (15-DAY)		HO, OT	CA-ALEMBIC PHARMACUETICALS LIMITED-2016SCAL000916			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Hydrochlorothiazide			S		Unk		Alembic
	Escitalopram			S		Unk		Not Reported
	Trazodone			C		Unk		Not Reported
	Gliclazide			C		Modified-Release		Not Reported
	Insulin			C		Unk		Not Reported
	L-Thyroxine /00068001/			C		Unk		Not Reported
	Telmisartan			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Metformin			C		Increased To 1 Gram Twice A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13537423	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1718851US		47 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Neoplasm; Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Daily		Allergan
	Lamotrigine			C	Unknown	125 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13569880	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017217474		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Xanax Xr			S	Oral	2 Mg, 1x/Day		Pfizer
	Xanax Xr			S				Pfizer
	Xanax			S	Oral	0.5 Mg, 2x/Day		Pfizer

	Xanax	S			Pfizer
	Hydrocodone	S	Unk, As Needed		Not Reported
	Hydrocodone	S			Not Reported
	Lexapro	S	20 Mg, 1x/Day (Am)		Not Reported
	Lexapro	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13585356	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-JP2017JPN075867		70 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dropped Head Syndrome	Lamictal			S	Oral	25 Mg, Qod		Glaxosmithkline
	Lamictal			S	Oral	25 Mg, Qd		Glaxosmithkline
	Lamictal			S	Oral	50 Mg, Qd		Glaxosmithkline
	Lamictal			S	Oral	100 Mg, Qd		Glaxosmithkline
	Reflex (Japan)			S	Oral	20 Mg, 1d		Not Reported
	Solanax			S	Oral	1.2 Mg, 1d		Not Reported
	Lexapro			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13620349	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1723300US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chlamydial Infection	Escitalopram Oxalate Unk			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13621375	NON-EXPEDITED			US-PFIZER INC-2017246431			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Sertraline Hcl			S		Unk		Pfizer
	Buspar			S		Unk		Not Reported

	Escitalopram	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13621691	NON-EXPEDITED			US-ROCHE-1774862			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Erythema; Periorbital Swelling	Klonopin			S	Unknown			Not Reported
	Pristiq			S	Unknown	Only Took One Dose		Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13621812	NON-EXPEDITED			US-ROCHE-1885015		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral Swelling; Weight Increased	Klonopin			S	Oral			Not Reported
	Klonopin			S				Not Reported
	Lyrica			S	Unknown	At Night		Not Reported
	Escitalopram			S	Oral			Not Reported
	Nortriptyline			C	Unknown	At Night		Not Reported
	Flexeril (United States)			C				Not Reported
	Treximet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13625349	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/17/0091158		66 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium	Quetiapine			S	Oral			Not Reported
	Quetiapine			S	Oral	Prolonged Release		Not Reported
	Quetiapine			S	Oral			Not Reported
	Quilonum Retard			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

	Tavor [Lorazepam]	S	Oral		Not Reported
	Tavor	S	Oral		Not Reported
	Movicol	C	Oral		Not Reported
	Beloc Zok	C	Oral		Not Reported
	Candesartan	C	Oral		Not Reported
	Levothyroxine Sodium	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13626559	NON-EXPEDITED		OT	US-JNJFOC-20170424982		12 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Weight Increased	Risperidone			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral	In The Morning		Not Reported
	Adderall			C	Oral	In The Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13627113	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1033322			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Haematoma; Haemorrhagic Disorder; Loss Of Personal Independence In Daily Activities; Menstrual Disorder; Tension	Escitalopram			S	Oral	Seit Wochen		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Risperidon			C	Oral			Mylan
	L-Thyroxin			C	Oral	Seit Jahren		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13627361	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1033324			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety Disorder; Dyskinesia; Dyskinesia; Loss Of Personal Independence In Daily Activities	Escitalopram	S	Oral	5 Mg, Unk		Not Reported
	Escitalopram	S	Oral	10 Mg, Unk		Not Reported
	Escitalopram	S	Oral	5 Mg, Unk		Not Reported
	Bisoprolol	C	Oral	Seit Monaten		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13627649	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-049536		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Somnolence	Aripiprazole			S	Unknown			Bristol Myers Squibb
	Clozapine			S	Unknown	400 Mg, Qd		Not Reported
	Clozapine			S	Unknown	200 Mg, Qd		Not Reported
	Divalproex Sodium			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	11058795	EXPEDITED (15-DAY)		DE	CA-FRI-1000076049		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue; Sudden Cardiac Death	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Diphenhydramine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	11519212	EXPEDITED (15-DAY)		DE	CA-FRI-1000079540		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Clonazepam			C	Unknown	Daily Dose Not Reported		Not Reported
	Lansoprazole			C	Unknown	Daily Dose Not Reported		Not Reported

Lithium Carbonate	C	Unknown	Daily Dose Not Reported		Not Reported
Lorazepam	C	Unknown	Daily Dose Not Reported		Not Reported
Nadolol	C	Unknown	Daily Dose Not Reported		Not Reported
Quetiapine	C	Unknown	Daily Dose Not Reported		Not Reported
Synthroid	C	Unknown	Daily Dose Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13574315	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1720790US		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Rash Maculo-Papular; Tubulointerstitial Nephritis	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13625253	EXPEDITED (15-DAY)		OT	GB-TORRENT-00015329		42 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling; Rash Generalised; Swelling Face; Swollen Tongue	Escitalopram			S				Unknown
	Citalopram			C				Unknown
	Promethazine Hydrochloride			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13628490	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2017248703		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lorazepam			S		0.5 Mg, Unk		Pfizer
	Venclexta			S	Oral	600 Mg, Daily (Take Six Tablets By Mouth Daily)		Not Reported
	Allopurinol			S		100 Mg, Unk		Not Reported
	Zolpidem Tartate			S		10 Mg, Unk		Not Reported
	Escitalopram Oxalate			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13629756	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1723564US		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Dyskinesia; Dyskinesia; Loss Of Personal Independence In Daily Activities	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Bisoprolol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13630243	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1723306US		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Haematoma; Haemorrhagic Disorder; Loss Of Personal Independence In Daily Activities; Menstrual Disorder; Tension	Escitalopram Oxalate Unk			S		10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S		20 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S		15 Mg, Qd		Allergan
	Risperidon			C	Oral	0.5 Mg, Qd		Not Reported
	L-Thyroxin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13631319	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1723099US		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hospitalisation; Menorrhagia; Pain; Postoperative Wound Complication; Stress	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13635303	DIRECT		OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Erectile Dysfunction; Flatulence; Gastric Disorder; Insomnia; Libido Decreased	Lexapro 20mg, Escitalopram 20mg			S	Oral	Quantity:1 Tablet(S);		Torrent
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	11102742	EXPEDITED (15-DAY)		OT	US-JNJFOC-20150504386		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia; Hyperprolactinaemia; Obesity	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	1-5mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	Varying Doses Of 0.5 Mg To 5 Mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	Varying Doses Of 0.5 Mg To 5 Mg		Not Reported
	Risperdal			S	Oral	1-5mg		Not Reported
	Risperdal			S	Oral	1-5mg		Not Reported
	Risperdal			S	Oral	Varying Doses Of 0.5 Mg To 5 Mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13637001	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2017-35063		42 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling; Rash Generalised; Swelling Face; Swollen Tongue	Escitalopram			S	Unknown	5 Mg, Every Week		Aurobindo
	Citalopram			C	Unknown	Reduce By 20mg Every 3 Days, Then Stop- Advice B...		Not Reported
	Promethazine Hydrochloride			C	Unknown	1 Df, 1 At Night As Necessary, Maximum Of 1 Four Times A Day If Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13638793	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1723539US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Drug Withdrawal Syndrome Neonatal; Exposure During Pregnancy; Exposure Via Breast Milk; Facial Asymmetry; Hyperbilirubinaemia; Hypoglycaemia Neonatal; Jaundice Neonatal; Knee Deformity; Respiratory Distress; Selective Eating Disorder; Talipes; Weight Decrease Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	30 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transmammary	30 Mg, Qd		Allergan
	Calcium			S	Transplacental	1000 Mg, Qd		Not Reported
	Calcium			S	Transmammary	1000 Mg, Qd		Not Reported
	Cholecalciferol			S	Transplacental	1000 Iu, Qd		Not Reported
	Cholecalciferol			S	Transmammary	1000 Iu, Qd		Not Reported
	Folic Acid			S	Transplacental	1000 Mg, Qd		Not Reported
	Folic Acid			S	Transmammary	1000 Mg, Qd		Not Reported
	Suboxone			S	Transplacental	12 Mg, Qd		Not Reported
	Suboxone			S	Transplacental	10 Mg, Qd		Not Reported
	Suboxone			S	Transmammary	12 Mg, Qd		Not Reported
	Subutex			S	Transplacental	12 Mg, Qd		Not Reported
	Subutex			S	Transplacental	10 Mg, Qd		Not Reported
	Nicotine			S	Transplacental	4 Cigarettes		Not Reported
	Nicotine			S	Transmammary	4 Cigarettes		Not Reported
	Prenatal Multiple Vitamin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13639154	NON-EXPEDITED			US-ROCHE-682583		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Depressed Mood; Malaise; Poor Quality Sleep; Product Quality Issue; Sleep Disorder; Tremor	Klonopin			S	Oral	Other Indication: Postpartum Depression		Not Reported
	Lexapro			S	Oral	Other Indication: Depression		Not Reported
	Tekturna			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13639184	NON-EXPEDITED		OT	US-ROCHE-798674			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Tremor	Klonopin			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Fioricet			S	Unknown			Not Reported
	Cymbalta			S	Unknown	4 Tablets Taken In Morning		Not Reported
	Reglan			S	Unknown			Not Reported
	Pristiq			S	Unknown	Prolonged Release Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13639225	NON-EXPEDITED			US-ROCHE-683344		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nystagmus	Klonopin			S	Unknown			Not Reported
	Lexapro			S	Oral	Other Indication: Anxiety		Not Reported
	Wellbutrin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13639280	NON-EXPEDITED			US-ROCHE-1233151			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Klonopin			S	Unknown			Not Reported
	Lexapro			S	Oral	Initially 5 Mg In The Morning Later Shifted To 5 Mg At The Bed Time		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13639622	NON-EXPEDITED		HO	US-ROCHE-679942		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Intentional Overdose; Suicide Attempt	Klonopin			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Ambien			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13639641	NON-EXPEDITED			US-ROCHE-1224057		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Klonopin			S	Unknown	Daily		Not Reported
	Escitalopram			S	Oral	Daily		Not Reported
	Valsartan Hct			C	Unknown	81 Mg/12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13639769	NON-EXPEDITED			US-ROCHE-1510226			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psychotic	Klonopin			S	Unknown			Not Reported

Disorder	Lexapro	S	Unknown		Not Reported
	Abilify	S	Unknown		Not Reported
	Ambien	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13639895	NON-EXPEDITED			US-ROCHE-703211		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Appetite; Weight Increased	Klonopin			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Ambien			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13640016	NON-EXPEDITED			US-ROCHE-742882		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pruritus	Klonopin			S	Oral	Co-Indication: Panic Disorder		Not Reported
	Klonopin			S	Oral			Not Reported
	Lexapro			S	Oral	Co-Indication: Generalized Anxeity Disorder And Panic Disorder		Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2017	13641407	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Sweats	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13642026	EXPEDITED (15-DAY)		OT	DE-LUPIN PHARMACEUTICALS INC.-2017-02893		66 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Aspartate Aminotransferase Increased; Delirium; Disorientation; Distractibility	Quilonum			S	Oral	225 Mg, Qd		Not Reported
	Quetiapine Fumarate Extended-Release Tablets			S	Oral	300 Mg, Qd		Lupin
	Quetiapine			S	Oral	400 Mg, Qd		Lupin
	Quetiapine			S	Oral	7000 Mg, Qd		Lupin
	Cipralex			S	Oral	15 Mg, Qd		Not Reported
	Tavor [Lorazepam]			S	Oral	2 Mg, Qd		Not Reported
	Tavor [Lorazepam]			S	Oral	4 - 0.5 Mg/D		Not Reported
	Movicol			C	Oral	3 Df, Qd		Not Reported
	Beloc Zok			C	Oral	47.5 Mg, Qd		Not Reported
	Candesartan			C	Oral	8 Mg, Qd		Not Reported
	L-Thyroxin			C	Oral	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13642107	EXPEDITED (15-DAY)		HO	FR-009507513-1706FRA002435		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Toxicity To Various Agents	Zepatier			S	Oral	100 Mg, Qd		Merck
	Elbasvir			S		50 Mg, Qd		Merck
	Ribavirin			S	Oral	800 Mg, Qd		Merck
	Seresta			S	Oral	25 Mg, Bid		Not Reported
	Seresta			S	Oral	150 Mg (15 Tablet), Once		Not Reported
	Seresta			S	Oral	25 Mg, Bid		Not Reported

	Seroplex			S	1 Df, Qd			Not Reported		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13642952	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723794US		1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury; Nervous System Disorder; Pain	Lexapro			S	Transplacental			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13643008	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723784US		1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury; Nervous System Disorder; Pain	Lexapro			S	Transplacental			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13643009	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723790US		1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress;	Lexapro			S	Transplacental			Allergan

Exposure During Pregnancy; Injury; Nervous System Disorder; Pain

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13643082	EXPEDITED (15-DAY)		OT	DE-TEVA-774754GER		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Dyskinesia; Dyskinesia; Loss Of Personal Independence In Daily Activities	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Bisoprolol			C	Oral	For Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13643106	EXPEDITED (15-DAY)		OT	DE-TEVA-774763GER		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Haematoma; Haemorrhagic Disorder; Loss Of Personal Independence In Daily Activities; Menstrual Disorder; Tension	Escitalopram			S	Oral	For Weeks		Ivax
	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Risperidon			C	Oral			Not Reported
	L-Thyroxin			C	Oral	For Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13643278	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1034366			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia; Dizziness; Eye Paraesthesia; Nausea; Ophthalmoplegia; Vomiting	Escitalopram Mylan Generiques 5 Mg, Comprimé Pelliculé			S		10 Mg, Unk		Mylan
	Escitalopram Mylan Generiques 5 Mg, Comprimé Pelliculé			S		5 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13643845	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723788US		1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury; Nervous System Disorder; Pain	Lexapro			S	Transplacental			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13643846	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723786US		1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury; Nervous System Disorder; Pain	Lexapro			S	Transplacental			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13643847	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723782US		1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury;	Lexapro			S	Transplacental			Allergan

Nervous System Disorder;
Pain

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13643880	EXPEDITED (15-DAY)		DS	CA-ALLERGAN-1723318US		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Lethargy; Sedation	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Magnesium Citrate			C	Unknown			Not Reported
	Riboflavin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13644368	NON-EXPEDITED			US-ROCHE-680036		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Somnolence	Klonopin			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13645438	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1724330US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13089878	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP016176			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hospitalisation; Thinking Abnormal	Apo-Topiramate			S	Unknown	Unk		Apotex
	Apo-Escitalopram			S	Oral	10 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13526012	EXPEDITED (15-DAY)		OT	FR-AMGEN-FRASP2017069297		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Musculoskeletal Pain; Nausea; Underdose	Procoralan			S	Oral	1 Df, Bid		Amgen
	Trivastal			S	Oral	1 Df, Qd		Not Reported
	Epitomax			S	Oral	100 Mg, Bid		Not Reported
	Levocarnil			S	Unknown	30 Ml, Qd		Not Reported
	Seroplex			S	Oral	20 Mg, Qd		Not Reported
	Tecfidera			S	Oral	240 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13553503	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP011836		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Product Substitution Issue	Apo-Escitalopram			S	Unknown	10 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13561220	EXPEDITED (15-DAY)			JP-ALLERGAN-1720157US		23 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Convulsions Local; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Myslee			C	Oral			Not Reported
	Rohypnol			C	Oral			Not Reported
	Depas (Etizolam)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13569940	EXPEDITED (15-DAY)		DE, HO, OT	CN-ALLERGAN-1721036US		62 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk Mg, Unk		Allergan
	Risperdal			S	Unknown	Unk		Not Reported
	Risperdal			S				Not Reported
	Aripiprazole			C	Unknown	Unk		Not Reported
	Artane			C	Unknown	Unk		Not Reported
	Benzhexol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13579141	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1721227US		59 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Daydreaming; Death; Dysarthria; Fear Of Eating; Gait Disturbance; Insomnia; Mydriasis; Obsessive Thoughts; Off Label Use; Paranoia; Weight Decreased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Xanax			S	Oral	0.25 Mg, Bid		Not Reported
	Ambien			C		10 Mg, Unk		Not Reported
	Pravastatin			C	Oral	40 Mg, Qd		Not Reported
	Metoprolol			C	Oral	25 Mg, Unk		Not Reported
	Amlodipine			C	Oral	2.5 Mg, Unk		Not Reported
	Irbesartan			C		300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13646886	EXPEDITED (15-DAY)		DE	US-TORRENT-00002816		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Pantoprazole			S				Unknown
	Escitalopram			S				Unknown
	Amlodipine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13648069	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723792US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury; Nervous System Disorder; Pain	Lexapro			S	Transplacental			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13649072	EXPEDITED (15-DAY)		DS, HO	GB-ALLERGAN-1724292US		35 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Inappropriate Affect; Malaise; Migraine; Muscle Contractions Involuntary; Mydriasis; Nausea; Speech Disorder	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Omega-3 Acids			C	Unknown			Not Reported
	Multivitamin			C	Endocervical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13403486	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1711402US		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctival Haemorrhage; Haematoma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Kardegic			S	Oral	75 Mg, Qd		Not Reported
	Seresta			C	Oral	30 Mg, Qd		Not Reported
	Seresta			C	Oral	10 Mg, Qd		Not Reported
	Simvastatin			C	Oral			Not Reported
	Omeprazole			C	Oral	20 Mg, Qd		Not Reported
	Amlor			C	Oral	5 Mg, Qd		Not Reported
	Imovane			C	Oral	3.75 Mg, Qd		Not Reported
	Tardyferon			C	Oral	20 Mg, Qd		Not Reported

	Uvedose	C	Unknown	Not Reported
	Doliprane	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13649470	EXPEDITED (15-DAY)		HO	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2017-BI-03		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall; Hyponatraemia	Micardis			S	Oral			Boehringer Ingelheim
	Seroplex			S	Oral			Not Reported
	Sotalol (Hydrochlorid Od)			C	Oral	Unknown		Not Reported
	Levemir Flexpen 100 Iu/Ml			C	Subcutaneous	Strength: 100 Iu/Ml		Not Reported
	Kardegic 75mg			C	Oral			Not Reported
	Risperdal 1mg/Ml			C	Oral	Strength: 1mg/Ml		Not Reported
	Seresta 10mg			C	Oral			Not Reported
	Tahor 10mg			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13650908	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2017-35453		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Haematoma; Haemorrhagic Disorder; Loss Of Personal Independence In Daily Activities; Menstrual Disorder; Tension	Escitalopram			S	Oral	15 Mg, Daily		Aurobindo
	Escitalopram			S	Oral	20 Mg, Daily		Aurobindo
	Escitalopram			S	Oral	10 Mg, Daily		Aurobindo
	Risperidon			C	Oral	0.5 Mg, Daily		Not Reported
	L-Thyroxin			C	Oral	175 Mcg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13651067	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2017-35454		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Dyskinesia; Loss Of Personal Independence In Daily Activities	Escitalopram			S	Oral	5 Mg, Daily		Aurobindo
	Escitalopram			S	Oral	10 Mg, Daily		Aurobindo
	Escitalopram			S	Oral	5 Mg, Daily		Aurobindo
	Bisoprolol			C	Oral	2.5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13651716	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US07434			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Heart Rate Increased; Hyperhidrosis	Bupropion Hcl Xl			S	Oral	150 Mg, Unk		Invagen
	Bupropion Hcl Xl			S	Oral	300 Mg, Unk		Invagen
	Escitalopram			S	Unknown	10 Mg, Unk		Invagen
	Gabapentin			S	Unknown	400 Mg, Per Day		Invagen
	Adderall			S	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	0.5 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13653746	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1724560US		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Bones Fracture; Fall; Haematoma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Tramadol			S	Oral	1 Df, Bid		Not Reported
	Seresta			S	Oral	10 Mg, Tid		Not Reported
	Amlodipine			S	Oral	5 Mg, Qd		Not Reported
	Imovane			S	Oral	3.75 Mg, Qd		Not Reported
	Simvastatin			S	Oral	10 Mg, Qd		Not Reported
	Tardyferon			S	Oral	80 Mg, Bid		Not Reported
	Omeprazole			S		20 Mg, Qd		Not Reported

	Kardegic	C	Oral	1 Df, Qd	Not Reported
	Uvedose	C		Unk	Not Reported
	Doliprane	C		Unk	Not Reported
	Movicol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13468609	NON-EXPEDITED			US-PFIZER INC-2017171487			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Zithromax			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13524233	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1717994US		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteoporosis	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Quilonum Retarded			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13577813	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1721293US		18 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Dyspnoea; Gastrointestinal Disorder; Neck Pain; Overdose	Escitalopram Oxalate - Bp			S	Oral	Unk, Qd		Allergan
	Azithromycin Mepha			S	Intravenous drip	500 Mg, Q12h		Not Reported
	Azithromycin Mepha			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13654328	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1724538US		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Epistaxis; Face Injury; Fall; Haematoma	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd		Allergan
	Kardegic	S	Oral	75 Mg, Qd		Not Reported
	Kardegic	S	Oral	75 Mg, Qd		Not Reported
	Donepezil	C	Unknown			Not Reported
	Candesartan	C	Unknown			Not Reported
	Diffu K	C	Unknown			Not Reported
	Seresta	C	Unknown			Not Reported
	Atarax	C	Unknown			Not Reported
	Lactulose	C	Unknown			Not Reported
	Cacit D3	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13654798	EXPEDITED (15-DAY)		DE	US-TORRENT-00002882		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Bupropion Hydrochloride			S				Unknown
	Escitalopram			S				Unknown
	Lamotrigine			S				Unknown
	Clonazepam			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13654874	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00002953		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lamotrigine			S				Unknown
	Escitalopram			S				Unknown
	Atenolol			S				Unknown
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13655048	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS-2017-003119		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Body Mass Index Decreased; Depression; Drug Interaction; Forced Expiratory Volume Decreased; Infective Pulmonary Exacerbation Of Cystic Fibrosis; Substance Abuse	Orkambi			S	Oral	400/250 Mg, Bid		Vertex
	Escitalopram			S	Unknown	30 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Oxycodone			C				Not Reported
	Marijuana			C				Not Reported
	Hydroxyzine			C		25 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13655193	EXPEDITED (15-DAY)		DE	US-TORRENT-00003045		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Trazodone			S				Unknown
	Citalopram			S				Unknown
	Buspirone			S				Unknown
	Atenolol			S				Unknown
	Eszopiclone			S				Unknown
	Levothyroxine			S				Unknown
	Clonazepam			S				Unknown
	Ethanol			S				Unknown
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13655379	EXPEDITED (15-DAY)		OT	SE-ACCORD-052679		61 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Urticaria	Escitalopram Accord			S		Strength: 10 Mg		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13656090	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00002987		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest;	Escitalopram			S				Unknown

Completed Suicide; Toxicity To Various Agents	Propranolol	S	Unknown
	Venlafaxine Hydrochloride	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13657782	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003000		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Toxicity To Various Agents	Trazodone			S				Unknown
	Escitalopram			S				Unknown
	Oxycodone			S				Unknown
	Alprazolam			S				Unknown
	Oxymorphone Hydrochloride			S				Unknown
	Gabapentin			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	10485261	EXPEDITED (15-DAY)		HO	CA-FRI-1000071085		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Dose Omission	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Tylenol			S	Oral	2 Tablets, Tid		Not Reported
	Wellbutrin Xl			S	Oral	150 Mg, Bid		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Tid		Not Reported
	Domperidone			S	Oral	10 Mg, Bid		Not Reported
	Gabapentin			S	Oral	300 Mg, Qam		Not Reported
	Gabapentin			S	Oral	600 Mg, At Noon And Bedtime		Not Reported
	Ferrous Sulfate			S	Oral	300 Mg, Tid		Not Reported
	Vitalux			S	Oral	Unk, Bid		Not Reported
	Temazepam			S	Oral	30 Mg, At Bedtime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13657857	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003025		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Duloxetine			S				Unknown
	Escitalopram			S				Unknown
	Clonazepam			S				Unknown
	Baclofen			S				Unknown
	Metformin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13657877	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00002966		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S				Unknown
	Citalopram			S				Unknown
	Amlodipine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13657883	EXPEDITED (15-DAY)		DE	US-TORRENT-00003062		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Metoprolol			S				Unknown
	Bupropion			S				Unknown
	Escitalopram			S				Unknown
	Amlodipine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13657908	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00002887		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S				Unknown
	Trazodone Hydrochloride			S				Unknown
	Olanzapine			S				Unknown
	Topiramate			S				Unknown
	Dextromethorphan Hydrobromide			S				Unknown
	Cyclobenzaprine Hydrochloride			S				Unknown
	Meloxicam			S				Unknown

Sumatriptan	S		Unknown
Benzonatate	S		Unknown
Chlorphenamine Maleate	S		Unknown
Buspirone Hydrochloride	S		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13657910	EXPEDITED (15-DAY)		DE	US-TORRENT-00002993		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Product Misuse; Toxicity To Various Agents	Escitalopram Oxalate			S				Unknown
	Trazodone			S				Unknown
	Lisinopril			S				Unknown
	Clonazepam			S				Unknown
	Zolpidem			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13658460	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00002996		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Zolpidem			S				Unknown
	Escitalopram			S				Unknown
	Metoprolol			S				Unknown
	Oxycodone			S				Unknown
	Diazepam			S				Unknown
	Venlafaxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13659010	EXPEDITED (15-DAY)		DE	US-TORRENT-00003085		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Sertraline			S				Unknown
	Quetiapine			S				Unknown
	Acetaminophen			S				Unknown
	Escitalopram Oxalate			S				Unknown
	Buspirone			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13660169	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/17/0091490		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Hip Arthroplasty; Somnolence	Divalproex Sodium			S	Unknown			Not Reported
	Clozapine			S	Unknown			Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13661697	EXPEDITED (15-DAY)		DS, HO	GB-MYLANLABS-2017M1034975			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Inappropriate Affect; Malaise; Migraine; Muscle Contractions Involuntary; Mydriasis; Nausea; Speech Disorder	Escitalopram			S	Oral			Not Reported
	Omega-3 Fatty Acids			C				Mylan
	Multivitamin			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13662054	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1724907US		56 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Doxepin			C	Oral	50 Mg, Unk		Not Reported
	Galvus			C	Oral	50 Mg, Unk		Not Reported
	Amlodipin			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13662058	EXPEDITED (15-DAY)		HO	GB-ALLERGAN-1724800US		35 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Essential Tremor	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13662074	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1725070US		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Haematoma; Loss Of Consciousness; Muscle Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Brilique			S	Oral	180 Mg, Qd		Not Reported
	Kardegic			S	Oral	75 Mg, Qd		Not Reported
	Tahor			C	Unknown	40 Mg, Unk		Not Reported
	Bisoce			C	Unknown	5 Mg, Unk		Not Reported
	Aerius (Ebastine)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13662712	DIRECT					65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergic Reaction To Excipient; Hot Flush; Insomnia; Product Substitution Issue; Pruritus; Rash; Restlessness	Eccitalopram 10mg			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Lexapro			C				Not Reported
	Crestor			C				Not Reported
	Evista			C				Not Reported
	Biotin			C				Not Reported
	Pericolace			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13662802	DIRECT	Y				45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13663288	DIRECT	Y				52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Product Substitution Issue	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2017	13662302	EXPEDITED (15-DAY)		DE	US-TORRENT-00003003		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Exposure Via Ingestion; Intentional Overdose; Toxicity To Various Agents	Trazodone			S				Unknown
	Clonazepam			S				Unknown
	Ethanol			S				Unknown
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2017	12397266	NON-EXPEDITED			US-PFIZER INC-2016254576		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Bactrim Ds			S	Oral	800/160 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2017	13515228	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1717408US		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Reversible Cerebral Vasoconstriction Syndrome	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Avastin			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2017	13531325	NON-EXPEDITED			US-PFIZER INC-2017203320		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Effexor Xr			S		150 Mg, 1x/Day		Pfizer
	Pristiq			S		100 Mg, 1x/Day		Pfizer
	Lexapro			S		10 Mg, 1x/Day		Not Reported
	Klonopin			S		1 Mg, 2x/Day		Not Reported
	Remeron			S		7.5 Mg, 1x/Day (Take Half At Night)		Not Reported
	Celexa			S		Unk Unk, 1x/Day		Not Reported
	Buspar			S		15 Mg, 1x/Day		Not Reported
	Cymbalta			S		120 Mg, 1x/Day		Not Reported
	Abilify			S		Unk, 1x/Day (One Half To One Tablet Once A Day)		Not Reported
	Rexulti			S		2 Mg, 1x/Day		Not Reported
	Ativan			S		1 Mg, 3x/Day		Not Reported
	Lithium			S		Unk		Not Reported
	Lithium			S				Not Reported
	Wellbutrin			S		Unk		Not Reported
	Wellbutrin			S				Not Reported
	Mirapex			S		Unk		Not Reported
	Mirapex			S				Not Reported
	Trintellix			S		Unk		Not Reported
	Trintellix			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2017	13663433	NON-EXPEDITED			US-PFIZER INC-2017263320		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xanax			S		Unk		Pfizer

	Effexor	S	Unk	Pfizer
	Lexapro	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported
	Prozac	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2017	13663674	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-051352			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Abilify			S	Unknown			Bristol Myers Squibb
	Rexulti			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13668515	EXPEDITED (15-DAY)		OT	DE-ACCORD-052388		66 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium	Quetiapine			S	Oral			Accord
	Quilonum			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Tavor [Lorazepam]			S	Oral			Not Reported
	Movicol			C	Oral			Not Reported
	Beloc Zok			C	Oral			Not Reported
	Candesartan			C	Oral			Not Reported
	L-Thyroxin			C	Oral			Not Reported
	Tavor			S	Oral	4 - 0.5 Mg/D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13669511	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS-2017-003182		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Mood Altered; Suicide Attempt	Orkambi			S	Oral			Vertex
	Orkambi			S	Oral	Unk		Vertex
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13672057	EXPEDITED (15-DAY)		DS, HO	GB-TEVA-777232ACC		35 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coordination Abnormal; Dizziness; Energy Increased; Gait Disturbance; Hunger; Inappropriate Affect; Malaise; Migraine; Muscle Contractions Involuntary; Mydriasis; Nausea; Speech Disorder; Tremor	Escitalopram			S	Oral			Ivax
	Omega-3 Acids			C				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13672311	EXPEDITED (15-DAY)		OT	DE-TORRENT-00006625		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Dyskinesia; Dyskinesia; Loss Of Personal Independence In Daily Activities	Escitalopram			S				Unknown
	Bisoprolol Fumarate			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13672721	EXPEDITED (15-DAY)		OT	DE-TORRENT-00006621		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety;	Escitalopram			S				Unknown

Haematoma; Haemorrhagic Disorder; Loss Of Personal Independence In Daily Activities; Menstrual Disorder; Tension	Risperidone	C		Unknown
	Levothyroxine Sodium	C		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13673398	EXPEDITED (15-DAY)		DS, HO	GB-CIPLA LTD.-2017GB10530			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Inappropriate Affect; Malaise; Migraine; Muscle Contractions Involuntary; Mydriasis; Nausea; Speech Disorder	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Omega-3 Acids			C	Unknown	Unk		Not Reported
	Multivitamin			C	Unknown	Unk, Vegan		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13675369	EXPEDITED (15-DAY)		LT, OT	DE-ALLERGAN-1725717US		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan
	Folio			C	Transplacental	0.4 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13675370	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1725727US		33 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan
	Folio			C	Transplacental	0.4 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13677352	DIRECT		DS, HO, LT, OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Depersonalisation/Dereali sation Disorder; Depression; Economic Problem; Feeling Abnormal; Hyperacusis; Insomnia; Photophobia; Suicidal Ideation; Withdrawal Syndrome	Ativan			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Klonopin			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Escitalopram			S	Oral			Not Reported
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13676820	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-2017VAL000931		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Subileus	Furosemide			S	Oral	60 Mg, Qd		Validus
	Fumafer			S	Oral	1 Df, Tid		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	20 Mg, Qd		Not Reported
	Rivastigmine			C		Unk		Not Reported
	Amlor			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported
	Eliquis			C		Unk		Not Reported
	Keppra			C		Unk		Not Reported
	Perindopril			C		Unk		Not Reported
	Vimpat			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13681096	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Inlyta 5mg			S	Oral			Pfizer
	Amiodarone			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	B-Complex			C				Not Reported
	Benicar			C				Not Reported
	Clonazepam			C				Not Reported
	Eliquis			S				Not Reported
	Escitalopram			S				Not Reported
	Fluticasone			C				Not Reported
	Hydralazine			C				Not Reported
	Levocetirizi			C				Not Reported
	Metoprol			C				Not Reported
	Pantoprazole			C				Not Reported
	Mirtazapine			C				Not Reported
	Renvela			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13681461	DIRECT		DS			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Impaired Work Ability; Paraesthesia; Seizure	Escitalopram			S	Oral			Forest
	Motrin			C				Not Reported
	Tramadol			C				Not Reported
	Cpap			C				Not Reported
	Multi-Vitamin (No Iron)			C				Not Reported
	Vitamin D Supllement			C				Not Reported
	Calcium Supplement			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13681754	DIRECT		HO			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depression; Suicidal Ideation	Lexapro			S	Oral	Quantity:1 Tablet(S);		Allergan
	Viibryd			C				Not Reported
	Amlodipine			C				Not Reported
	Modafinil			C				Not Reported
	Amitriptyline			C				Not Reported
	Tramadol			C				Not Reported
	Amantadine			C				Not Reported
	Metoprolol			C				Not Reported
	Effexor			C				Not Reported
	Adult Multivitamin			C				Not Reported
	Vitamin C			C				Not Reported
	Calcium With Vitamin D			C				Not Reported
	Fish Oil			C				Not Reported
	Excedrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13681931	DIRECT	Y	DS			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Brain Injury	Simvastatin 20mg Tablet			S				Not Reported
	Alprazolam 0.25mg			S				Not Reported
	Olanzapine 15mg			S				Not Reported
	Aripiprazole 10 Mg			S				Not Reported
	Escitalopram 20mg			S				Not Reported
	Lantus			S				Not Reported
	Metformin			S				Not Reported
	Meloxicam 15mg			S				Not Reported
	Omeprazole 20mg			S				Not Reported
	Toviaz Er			S				Not Reported
	Divalproex Sod			S				Not Reported
	Propranolol 40mg Tab Her			S				Not Reported
	Ibuprofen			S				Not Reported
	Ventolin Hfa			S				Not Reported
	Epipen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	12604755	NON-EXPEDITED			US-PFIZER INC-2016351217		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Benzylpenicillin Potassium			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Oxycodone			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Bupropion			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Remeron			S		Unk		Not Reported
	Sucralfate			S		Unk		Not Reported
	Valium			S		Unk		Not Reported
	Zantac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13680803	EXPEDITED (15-DAY)		LT, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017005241			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lactic Acidosis; Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram			S	Transplacental	20 Mg, Qd (0-40.4 Gestational Week)		Macleods
	Folio			C	Transplacental	0.4 Mg, Qd (0-20. Gestational Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13681377	NON-EXPEDITED			US-PFIZER INC-2017273172		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amlodipine Besilate			S		Unk		Pfizer

	Potassium Chloride	S	Unk	Unknown
	Levofloxacin	S	Unk	Pfizer
	Clonidine	S	Unk	Not Reported
	Escitalopram	S	Unk	Not Reported
	Hydrocodone	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13682547	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20170620138		71 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Subdural Haematoma	Xarelto			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Ventolin			C	Unknown			Not Reported
	Pravastatin Sodium			C	Unknown			Not Reported
	Janumet			C	Unknown			Not Reported
	Targin			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Pulmicort			C	Unknown			Not Reported
	Atrovent			C	Unknown			Not Reported
	Torem			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Cordarone			C	Unknown			Not Reported
	Cardura			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13684763	EXPEDITED (15-DAY)		LT, OT	DE-TEVA-778461GER		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neonatal Asphyxia;	Escitalopram			S	Transplacental	20 Milligram Daily;		Ivax

Neonatal Hypoxia; Small For Dates Baby	Folio		C	Transplacental	.4 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13686748	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1725985US		71 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Zolpidem Streuli			S	Unknown	Unk, Unknown		Not Reported
	Xarelto			S	Unknown	Unk, Unknown		Not Reported
	Cordarone			C	Unknown	Unk, Unknown		Not Reported
	Atacand			C	Unknown	Unk, Unknown		Not Reported
	Torem			C	Unknown	Unk, Unknown		Not Reported
	Cardura			C	Unknown	Unk, Unknown		Not Reported
	Pravalotin			C	Unknown	Unk, Unknown		Not Reported
	Janumet			C	Unknown	Unk, Unknown		Not Reported
	Targin			C	Unknown	Unk, Unknown		Not Reported
	Lyrica			C	Unknown	Unk, Unknown		Not Reported
	Pulmicort			C	Unknown	Unk, Unknown		Not Reported
	Atrovent			C	Unknown	Unk, Unknown		Not Reported
	Ventolin			C	Unknown	Unk, Unknown		Not Reported
	Rivaroxaban			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13687813	DIRECT		OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Muscle Twitching; Serum Serotonin Decreased; Tremor	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Jubilant
	Ibuprofen			C				Not Reported
	Montelukast			C				Not Reported
	Oxycodone			C				Not Reported

	Prolia	C		Not Reported
	Tylenol	C		Not Reported
	Citracal	C		Not Reported
	Vitamin D Nos	C		Not Reported
	Cetrizine Hydrochloride	C		Not Reported
	Nexium	C		Not Reported
	Sudrafed	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2017	13687718	EXPEDITED (15-DAY)		HO	PHHY2017FR091938		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Hyponatraemia	Cotareg			S	Oral	Unk		Novartis
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2017	13687753	EXPEDITED (15-DAY)		LT, OT	DE-MYLANLABS-2017M1036832			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Folio			C	Transplacental	0.4 [Mg/D]		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2017	13689323	DIRECT		OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction; Therapy Cessation	Escitalopram			S	Oral	Other Strength:Mg;Quantity:1 Tablet(S);		Unknown
	Bupropion			C				Not Reported
	Levothyroxine			C				Not Reported
	Albuterol			C				Not Reported

	Vitamin D Nos	C	Not Reported
	Vitamin B	C	Not Reported
	Iron	C	Not Reported
	Fish Oil	C	Not Reported
	Zyrtec	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2017	13688203	EXPEDITED (15-DAY)		HO	FR-009507513-1706FRA009634			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Encephalopathy; Hepatitis	Januvia			S	Oral	100mg At Lunch Qd		Merck
	Loxapac (Loxapine Succinate)			S	Oral	25 Mg/Ml, 5 Drops If Needed		Not Reported
	Mianserine Distrireti			S	Oral	10 Mg, Qd		Not Reported
	Lysanxia			S	Oral	15 Mg/Ml: 10-10-10 Drops		Not Reported
	Contramal			S	Oral	37.5mg, Qd		Not Reported
	Galvus			S	Oral	50 Mg, Qd		Not Reported
	Metformin			S	Oral	1.5 G, Qd		Not Reported
	Memantine			S	Oral	20 Mg, Qd		Not Reported
	Inexium (Esomeprazole Sodium)			S	Oral	20 Mg, Qd		Not Reported
	Doliprane			S	Oral	3 G, Qd		Not Reported
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Lantus			S	Subcutaneous	14 Iu, Qd		Not Reported
	Novorapid			S	Subcutaneous	Depending On Glycernia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2017	13688966	EXPEDITED (15-DAY)		HO	GB-AUROBINDO-AUR-APL-2017-35795		35 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Essential Tremor	Escitalopram			S	Oral	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2017	13691799	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2017PRN00114			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Taste Disorder	Escitalopram			S		Unk		Prinston Pharmaceutical
	Synthroid			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2017	13691800	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2017PRN00066		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Penile Pain	Escitalopram			S	Oral	1 Tablets, Once		Prinston Pharmaceutical
	Metoprolol			C		12.5 Mg, 1x/Day		Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13692487	EXPEDITED (15-DAY)		OT	TW-CIPLA LTD.-2017TW10854			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Major Depression	Atorvastatin			S	Unknown	40 Mg, Daily		Cipla
	Escitalopram			S	Unknown	10 Mg, Daily		Invagen
	Escitalopram			S	Unknown	10 Mg, Daily		Invagen
	Zaleplon			S	Unknown	10 Mg, Nightly		Cipla
	Sevikar			S	Unknown	5mg/20mg, Daily		Not Reported
	Glucomet Plus			S	Unknown	5mg/500mg, Bid		Not Reported
	Clonazepam			S	Unknown	0.75 Mg, Daily		Not Reported
	Clonazepam			S	Unknown	2 Mg, Nightly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13694105	EXPEDITED (15-DAY)		DE	AT-ASTRAZENECA-2017SE65115		74 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Drug Interaction	Esomeprazole			S	Oral			Astrazeneca
	Escitalopram			S	Unknown			Not Reported
	Dominal (Prothipendyl Hydrochloride)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13695292	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1726818US		23 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
	Bupropion			S	Unknown	150 Mg, Unk		Not Reported
	Alprazolam			C	Unknown			Not Reported
	Propranolol			C	Unknown			Not Reported
	Sertraline			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13558253	NON-EXPEDITED			US-PFIZER INC-2017213121		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity	Erythromycin			S	Oral	Unk		Pfizer
	Lexapro			S	Oral	Unk		Not Reported
	Motrin			S	Oral	Unk		Not Reported
	Motrin			S				Not Reported
	Vioxx			S	Oral	Unk		Not Reported
	Vioxx			S				Not Reported
	Ultram			S	Oral	Unk		Not Reported
	Ultram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13609798	EXPEDITED (15-DAY)		HO, OT	TR-ALLERGAN-1722760US		16 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Discomfort; Galactorrhoea; Intentional Overdose; Off Label Use; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Pseudoephedrine			S	Unknown			Not Reported
	Metoclopromide			S	Unknown			Not Reported
	Fluoxetine			C	Unknown	20 Mg, Qd		Not Reported
	Fluoxetine			C	Unknown	10 Mg, Qd		Not Reported
	Risperidone			C	Unknown	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13696325	EXPEDITED (15-DAY)		DE, HO, OT	SE-CIPLA LTD.-2017SE11080			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Blood Pressure Increased; Bradycardia; Confusional State; Dehydration; Dizziness; Nausea; Product Administration Error; Renal Tubular Necrosis; Urinary Tract Infection; Vomiting; Wound	Escitalopram			S	Unknown	20 Mg, Qd		Invagen
	Rivastigmine			S	Transdermal	9.5 Mg, Per 24 H, Patch		Not Reported
	Aspirin			S	Unknown	75 Mg, Qd		Not Reported
	Alprazolam			S	Unknown	0.5 Mg, Qd		Cipla
	Mirtazapine			S	Unknown	15 Mg, Qd		Cipla
	Dimethicone			S	Unknown	200 Mg, Tid		Not Reported
	Etilefrine			S	Unknown	5 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13696597	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2017SE65407		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Encephalopathy; Hepatitis	Inexium			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

Metformin	S	Oral	One Dosage Form In The Morning And Two Dosage Forms At Night (Non Az Product)		Not Reported
Loxapac	S	Oral	5.0mg As Required		Not Reported
Mianserin	S	Oral	10 Mg In The Evening		Not Reported
Lysanxia	S	Oral			Not Reported
Contramal	S	Oral			Not Reported
Januvia	S	Oral	100 Mg At Lunch Time		Not Reported
Galvus	S	Oral	50 Mg In The Evening		Not Reported
Memantine	S	Oral			Not Reported
Doliprane	S	Oral			Not Reported
Lantus	S	Subcutaneous			Not Reported
Novorapid	S	Subcutaneous	As Per Glycemia		Not Reported
Movicol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13697678	EXPEDITED (15-DAY)		LT, OT	DE-AUROBINDO-AUR-APL-2017-35850		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram 20 Mg			S	Transplacental	20 Mg, Daily		Aurobindo
	Folio /00349401/			C	Transplacental	0.4 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13698604	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1726829US		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Flatulence; Hypokalaemia; Subileus; Vomiting	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Fumafer			S	Oral			Not Reported

	Tramadol	S	Oral	Not Reported
	Lasilix	S	Oral	Not Reported
	Amlor	C	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Bisoprolol	C	Unknown	Not Reported
	Eliquis	C	Unknown	Not Reported
	Keppra	C	Unknown	Not Reported
	Perindopril	C	Unknown	Not Reported
	Vimpat	C	Unknown	Not Reported
	Rivastigmine	C	Transdermal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13698657	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1727044US		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Plavix			S	Oral			Not Reported
	Coaprovel			C	Unknown			Not Reported
	Pravastatine			C	Unknown			Not Reported
	Nicorandil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13698902	EXPEDITED (15-DAY)		OT	MX-ALLERGAN-1726812US		35 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cold Sweat; Confusional State; Depression; Dysstasia; Hypotension; Malaise; Nausea; Obsessive-Compulsive Disorder; Paraesthesia; Somnolence; Syncope;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Brintellix			C	Oral			Not Reported
	Brintellix			C				Not Reported
	Brintellix			C				Not Reported

Tachycardia	Valdoxan	C	Unknown			Not Reported
	Valdoxan	C				Not Reported
	Arcalion	C	Oral	100 Mg, Unk		Not Reported
	Macrodantin	C	Oral	100 Mg, Q6hr		Not Reported
	Lamotrigine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13699236	EXPEDITED (15-DAY)		OT	US-IMPAX LABORATORIES, INC-2017-IPXL-01903		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion Of Replacement	Carbidopa-Levodopa Er			S	Unknown	Unk		Impax
	Alprazolam Er			S	Unknown	Unk		Impax
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13654855	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-142935		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	15 Ml Total		Not Reported
	Alprazolam			S	Oral	10 Ml Total		Sun
	Esomeprazole Sodium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13656323	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2017-35424		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	15 Ml, Unk		Aurobindo
	Alprazolam			S	Oral	10 Ml,Total		Not Reported
	Esomeprazol /01479301/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13656942	EXPEDITED (15-DAY)		OT	IT-TEVA-776905ACC		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram Oxalate			S	Oral			Ivax
	Alprazolam			S	Oral			Actavis
	Esomeprazole Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13689560	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-ACTELION-A-CH2013-93009		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Condition Aggravated; Myocardial Infarction; Pneumonia; Pulmonary Arterial Hypertension; Pulmonary Embolism; Pulseless Electrical Activity; Sleep Apnoea Syndrome; Sleep Study; Sudden Death	Selexipag			S	Oral	1400 Mg, Bid		Actelion
	Selexipag			S	Oral	1400 Mg, Bid		Actelion
	Uptravi			S	Oral	1400 Mg, Qd		Actelion
	Tracleer			S	Oral	Unk		Actelion
	Revatio			S	Unknown	Unk		Not Reported
	Inexium			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Aldactone			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown			Not Reported
	Previscan (Fluindione)			S	Unknown			Not Reported
	Acenocoumarol			C		Unk		Not Reported
	Alendronate			C		Unk		Not Reported
	Calcium D3			C		Unk		Not Reported
	Dipotassium Chlorazepate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13703019	EXPEDITED (15-DAY)		DE	FR-VALIDUS PHARMACEUTICALS		79 YR	Female	FRA

LLC-FR-2017VAL000971

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Furosemide			S	Unknown	Unk		Validus
	Selexipag			S	Oral	1400 Mg, Qd		Not Reported
	Uptravi			S	Oral	1400 Mg, Qd		Not Reported
	Tracleer /01587701/			S	Unknown	Unk		Not Reported
	Revatio			S	Unknown	Unk		Not Reported
	Aldactone /00006201/			S	Unknown	Unk		Not Reported
	Previscan /00789001/			S	Unknown	Unk		Not Reported
	Inexium /01479303/			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13703447	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017278306		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Pneumonia Aspiration; Toxicity To Various Agents	Xanax			S	Oral	Unk		Pfizer
	Xanax			S	Oral	Unk		Pfizer
	Seroplex			S	Oral	Unk		Not Reported
	Abilify			S	Oral	Unk		Not Reported
	Risperdal			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13705183	DIRECT					27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Amphetamine Salts 15mg Tablet			S	Oral	Other		Aurobindo

Headache; Product Substitution Issue				Strength:Mg;Quantity:60 Tablet(S);	
	Wellbutrin	C			Not Reported
	Klonopin	C			Not Reported
	Lexapro	S			Not Reported
	Adderall	C			Not Reported
	Soylent	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13640342	EXPEDITED (15-DAY)		HO	DE-TORRENT-00006589		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased	Sertraline			S				Unknown
	Lorazepam			C				Unknown
	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13673765	NON-EXPEDITED			US-VERTEX PHARMACEUTICALS-2017-003245			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Food Interaction; Palpitations	Orkambi			S	Oral	2 Df (200-125mg) Each, Bid		Vertex
	Escitalopram			S	Unknown			Not Reported
	Albuterol			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Montelukast			S	Unknown	Unk		Not Reported
	Cholecalciferol			C				Not Reported
	Dornase Alfa			C				Not Reported
	Flonase			C				Not Reported
	Advair			C				Not Reported
	Zenpep			C				Not Reported
	Loratadine			C				Not Reported
	Adek			C				Not Reported
	Ranitidine			C				Not Reported

Omeprazole	C		Not Reported
Miralax	C		Not Reported
Hypersal	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13682791	EXPEDITED (15-DAY)		DE	JP-JNJFOC-20170619742		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Completed Suicide; Inappropriate Schedule Of Product Administration; Off Label Use; Overdose; Product Use In Unapproved Indication	Concerta			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Brotizolam			S	Oral			Not Reported
	Chlorpromazine			S	Unknown			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Flunitrazepam			S	Unknown			Not Reported
	Invega			C	Oral			Not Reported
	Trazodone Hydrochloride			C	Oral			Not Reported
	Trazodone Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13707865	EXPEDITED (15-DAY)		DE, HO, OT	FR-ALLERGAN-1727456US		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Hyperleukocytosis; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Cotareg			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13707934	EXPEDITED (15-DAY)		DE	AT-ALLERGAN-1727359US		74 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Drug Interaction	Escitalopram Oxalate - Bp			S		1 Df, Qd		Allergan
	Esomeprazole			S		1 Df, Qd		Not Reported
	Dominal (Prothipendyl Hydrochloride)			S		1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13707935	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1727362US		90 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hyponatraemia; Off Label Use; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	Unk, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Qd		Allergan
	Lorazepam			C		Unk		Not Reported
	Atorvastatin Calcium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13708094	NON-EXPEDITED		HO, LT	ES-EISAI MEDICAL RESEARCH-EC-2017-028937		53 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Fycompa			S	Oral			Not Reported
	Fycompa			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Pregabalina			S	Oral	75 Mg, 25 Mg, 75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13708514	NON-EXPEDITED			US-SUNOVION-2017SUN002681			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Somnolence	Latuda			S	Oral	40 Mg, Unk		Sunovion
	Latuda			S	Oral	80 Mg, Unk		Sunovion

	Lamotrigine	S	200 Mg, Unk		Not Reported
	Lamotrigine	S	300 Mg, Unk		Not Reported
	Lexapro	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13710584	DIRECT		DS			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Malaise; Product Substitution Issue; Tremor	Escitalopram			S	Oral	Other Strength:Mg;Quantity:1 Tablet(S); Daily Oral		Aurobindo
	Bupropion			C				Not Reported
	Ibuprofen			C				Not Reported
	Acetomenophen			C				Not Reported
	Zinc			C				Not Reported
	Vitamin B12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2017	13710538	EXPEDITED (15-DAY)		HO	FR-NOVOPROD-551438		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Encephalopathy; Hepatitis	Novorapid			S	Subcutaneous	According To The Glycaemia		Novo Nordisk
	Loxapac /00401801/			S	Oral	25 Mg/Ml (5 Drops As Needed)		Not Reported
	Mianserine Arrow			S	Oral	10 Mg Evening		Not Reported
	Lysanxia			S	Oral	15 Mg, Qd ((10 Droops In Morning, 10 At Noon And 10 Droops In Evening)		Not Reported
	Contramal			S	Oral	37.5 Mg, Qd		Not Reported
	Galvus			S	Oral	50 Mg, Qd (1df In Evening, In Replacement Of Januvia)		Not Reported
	Januvia			S	Oral	100 Mg, Qd		Not Reported

Metformine Arrow	S	Oral	1.5 G, Qd (1 Df In Morning And 2 Df In Evening)	Not Reported
Memantine	S	Oral	20 Mg, Qd	Not Reported
Inexium /01479302/	S	Oral	20 Mg, Qd (1 Df In Evening)	Not Reported
Doliprane	S	Oral	3 G, Qd	Not Reported
Escitalopram Arrow	S	Oral	5 Mg, Qd	Not Reported
Lantus	S	Subcutaneous	14 Iu, Qd	Not Reported
Monoprost	C		50 Microgram/Ml, 1df Evening	Not Reported
Movicol Plain	C		2 Df, Qd	Not Reported
Seresta Expidet	C		10 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2017	13711040	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2017AP013743		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Overdose; Suicide Attempt	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Apotex
	Escitalopram Oxalate			S	Unknown	Unk		Apotex
	Ivacaftor W/Lumacaftor			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2017	13711270	EXPEDITED (15-DAY)		DE, HO	FR-SA-2017SA113845		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Encephalopathy; Hepatitis	Doliprane			S	Oral			Not Reported
	Lantus			S	Subcutaneous			Not Reported
	Mianserine			S	Oral			Not Reported
	Lysanxia			S	Oral			Not Reported
	Contramal			S	Oral			Not Reported

	Galvus	S	Oral		Not Reported
	Januvia	S	Oral	100 Mg At Noon	Not Reported
	Metformin	S	Oral		Not Reported
	Memantine	S	Oral		Not Reported
	Inexium	S	Oral		Not Reported
	Escitalopram	S	Oral		Not Reported
	Novorapid	S	Subcutaneous	According To Glycaemia	Not Reported
	Loxapac	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2017	13711420	EXPEDITED (15-DAY)		DE, OT	AT-MYLANLABS-2017M1039406			Unknown	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia	Escitalopram			S		1 Df, Qd		Not Reported
	Dominal (Prothipendyl Hydrochloride)			S		1 Df, Qd		Mylan
	Esomeprazole			S		1 Df, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2017	10185571	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2014SE33140		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Crestor			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Metformin			S	Oral	Non-Astrazeneca Product, 150 Mg Twice Daily		Not Reported
	Alfuzosin			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported

	Levothyrox			S	Oral					Not Reported
	Aprovel			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2017	13713533	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003926		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Alfuzosin Tablet			S	Oral	Daily		Concordia
	Imovane			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Aprovel			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Amarel			C				Not Reported
	Bromazepam			C				Not Reported
	Meteospasmyl [Alverine Citrate;Dl-Methionine			C				Not Reported
	Montelukast			C				Not Reported
	Symbicort			C				Not Reported
	Valerian			C				Not Reported
	Lepticur			C				Not Reported
	Theralene			C				Not Reported
	Movicol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2017	13713732	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US11382			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Escitalopram			S	Oral	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2017	13713815	EXPEDITED (15-DAY)		HO, OT	DE-HETERO LABS LTD-2022868		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram			S	Transplacental			Hetero
	Cyanocobalamin, Folic Acid			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2017	13714018	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-36302		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Encephalopathy; Hepatitis	Escitalopram Arrow			S	Oral	5 Mg, Once A Day		Aurobindo
	Mianserin Arrow			S	Oral	10 Mg, Daily		Not Reported
	Metformin Arrow			S	Oral	1.5 G, Once A Day		Aurobindo
	Memantine Arrow			S	Oral	20 Mg, Once A Day		Aurobindo
	Loxapac /00401801/			S	Oral	5 Mg If Necessary		Not Reported
	Lysanxia			S	Oral	15 Mg, Once A Day		Not Reported
	Contramal			S	Oral	37.5 Mg, Once A Day		Not Reported
	Galvus			S	Oral	50 Mg, Once A Day		Not Reported
	Januvia			S	Oral	100 Mg, Once A Day		Not Reported
	Inexium /01479302/			S	Oral	20 Mg, Daily		Not Reported
	Doliprane			S	Oral	3 G, Daily		Not Reported
	Lantus			S	Subcutaneous	14 Iu, Daily		Not Reported
	Novorapid			S	Subcutaneous	According To Glycemia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2017	13714121	NON-EXPEDITED			US-TAKEDA-2017TUS014128		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Nausea	Trintellix	S	Oral	10 Mg, Qd		Takeda
	Trintellix	S	Oral	20 Mg, Qd		Takeda
	Lexapro	S	Oral	Unk		Not Reported
	Alprazolam	C	Oral	2 Mg, Qid		Not Reported
	Neurolink	C	Oral	Unk Unk, Qid		Not Reported
	Neurolink	C	Oral	Unk Unk, Bid		Not Reported
	Sam-E	C	Oral	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2017	13714527	EXPEDITED (15-DAY)		OT	ES-ELI_LILLY_AND_COMPANY-ES201706012480			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Olanzapine			S	Unknown	5 Mg, Daily		Eli Lilly And Co
	Olanzapine			S	Unknown	10 Mg, Daily		Eli Lilly And Co
	Olanzapine			S	Unknown	15 Mg, Daily		Eli Lilly And Co
	Mirtazapine			S	Unknown	60 Mg, Daily		Not Reported
	Fluvoxamine			S	Unknown	Unk, Unknown		Not Reported
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported
	Risperidone			S	Unknown	3 Mg, Daily		Not Reported
	Quetiapine			S	Unknown	50 Mg, Daily		Not Reported
	Carbamazepine			C	Unknown	1200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2017	13715294	EXPEDITED (15-DAY)		HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-058957		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Lung Disorder; Toxicity To Various Agents	Abilify			S	Oral	Unk		Bristol Myers Squibb
	Xanax			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported

	Risperdal		S	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2017	13715340	EXPEDITED (15-DAY)		DE	AT-TEVA-781214ISR		74 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia	Escitalopram			S		1 Dosage Forms Daily;		Ivax
	Esomeprazol			S		1 Dosage Forms Daily;		Teva
	Dominal 80mg			S		1 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13658775	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2017-35571		42 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatic Enzyme Increased	Escitalopram			S	Unknown			Aurobindo
	Mirtazapine			S	Unknown	60 Mg, Daily		Aurobindo
	Mirtazapine			S				Aurobindo
	Olanzapine 10mg			S	Unknown	10 Mg, Daily		Aurobindo
	Olanzapine 10mg			S	Unknown	20 Mg, Daily		Aurobindo
	Olanzapine 10mg			S	Unknown	5 Mg, Daily		Aurobindo
	Olanzapine 10mg			S	Unknown	15 Mg, Daily		Aurobindo
	Quetiapine			S	Unknown	50 Mg, Daily		Aurobindo
	Quetiapine			S				Aurobindo
	Risperidone			S	Unknown	3 Mg, Daily		Aurobindo
	Risperidone			S				Aurobindo
	Fluvoxamine			S	Unknown			Not Reported
	Carbamazepine			C	Unknown			Not Reported
	Carbamazepine			C	Unknown	1200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13718075	EXPEDITED (15-DAY)		HO, LT	FR-JNJFOC-20170624009		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose; Pneumonia Aspiration; Toxicity To Various Agents	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	4 Boxes		Not Reported
	Xanax			S	Oral	6 Boxes		Not Reported
	Seroplex			S	Oral	3 Boxes		Not Reported
	Abilify			S	Oral	6 Boxes		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13718297	EXPEDITED (15-DAY)		HO	FR-DSJP-DSE-2017-120981			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Orthostatic Hypotension	Sevikar 20 Mg/ 5 Mg			S	Oral	20/5 Mg, Qd		Daiichi
	Imovane			S	Oral	7.5 Mg, Qd		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Theralene			S		40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13718622	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1727462US		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Previscan (Fluindione)			S	Unknown	Unk		Not Reported
	Selexipag			S	Oral	1400 Mg, Qd		Not Reported
	Tracleer			S	Unknown	Unk		Not Reported
	Uptravi			S	Oral	1400 Mg, Qd		Not Reported
	Revatio			S	Unknown	Unk		Not Reported
	Lasilix			S	Unknown	Unk		Not Reported
	Aldactone			S	Unknown	Unk		Not Reported
	Inexium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13719284	EXPEDITED (15-DAY)		DE	US-BAYER-2017-122659		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Vanishing Bile Duct Syndrome	Moxifloxacin			S		Unk		Bayer
	Cefalexin			S		Unk		Not Reported
	Lamotrigine			S		25 Mg, Bid		Not Reported
	Escitalopram			S		Unk		Not Reported
	Aripiprazole			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Meloxicam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	10196725	EXPEDITED (15-DAY)		OT	FR-FRI-1000067560		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Alfuzosine Hydrochloride			S	Oral	10 Mg, Qd		Not Reported
	Imovane			S	Oral	3.75 Mg, Qd		Not Reported
	Atarax			S	Oral	25 Mg, Bid		Not Reported
	Metformin Hcl			S	Oral	150 Mg, Bid		Not Reported
	Kardegic			S	Oral	75 Mg, Qd		Not Reported
	Levothyrox			S	Oral	125 Mg, Qd		Not Reported
	Crestor			S	Oral	5 Mg, Qd		Not Reported
	Aprovel			S	Oral	150 Mg, Qd		Not Reported
	Eupantol			C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	10282393	EXPEDITED (15-DAY)		DS	FI-FRI-1000068674		20 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Disturbance In Sexual Arousal; Genital Paraesthesia; Libido Decreased; Male Orgasmic Disorder; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Sertralin			S	Oral	50 Mg, Unk		Not Reported
	Moclobemid			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13667838	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT-00006554		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Burning Sensation; Diarrhoea; Fatigue; Feeling Abnormal; Hot Flush; Listless; Nausea; Panic Attack; Skin Burning Sensation; Suicidal Ideation; Vision Blurred	Escitalopram Heumann 10 Mg Filmtabletten			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13700542	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1726821US		20 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tonic Convulsion	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13720146	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1728109US		51 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dry Mouth; Migraine; Nausea; Photophobia; Suicide	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Neurontin			S	Unknown	100 Mg, Qd		Not Reported

Attempt; Trismus; Vomiting	Kliovance		C	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13720182	EXPEDITED (15-DAY)		LT, OT	DE-TORRENT-00006665		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lactic Acidosis; Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram			S				Unknown
	Folio			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13720560	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2028195-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Depression; Emotional Disorder; Fatigue	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13721526	EXPEDITED (15-DAY)		OT	US-TORRENT-00003159		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Sertraline			S				Unknown
	Quetiapine			S				Unknown
	Escitalopram Oxalate			S				Unknown
	Aripiprazole			S				Unknown
	Valproic Acid			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13724554	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017288743		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Insomnia; Pre-Existing Condition Improved; Psoriasis; Therapeutic Response Unexpected	Pristiq	S	50 Mg, Unk	Pfizer
	Lexapro	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13724659	EXPEDITED (15-DAY)		HO	KR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2017-BI-03		66 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection	Giotrif			S	Oral			Boehringer Ingelheim
	Trisonekit			S	Unknown			Not Reported
	Trisonekit			S				Not Reported
	Targin			S	Unknown	Strength: 5mg/Naloxone 2.5mg, Unit Dose And Daily Dose:10/5 Mg		Not Reported
	Targin			S	Unknown	Strength: 10mg/Naloxone 5mg,Unit Dose And Daily Dose: 20/10mg		Not Reported
	Matrifen			S	Unknown			Not Reported
	Respilene (Zipeprol Dihydrochloride)			S	Unknown	Strength: 5mg/Ml, Unit Dose And Daily Dose: 15mg/Ml		Not Reported
	Ircodon			S	Unknown			Not Reported
	Harnal D			S	Unknown			Boehringer Ingelheim
	Folic Acid			S	Unknown			Not Reported
	Bromazepam			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Lithium Carbonate			S	Unknown			Not Reported
	Hilase			S	Unknown			Not Reported
	Saropram			S	Unknown			Not Reported
	Zolmin			S	Unknown			Not Reported

	Hinecol			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13725321	DIRECT		DS			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Anger; Depressed Mood; Flatulence; Hallucination, Visual; Heart Rate Irregular; Hypoaesthesia; Incontinence; Insomnia; Irritability; Neuralgia; Overdose; Pain; Paraesthesia; Pruritus; Scratch; Serotonin Syndrome; Somnolence; Suicidal Ideation; Tachyphrenia; Tremor	Escitalopram			S	Oral	Quantity:1 Tablet(S); Oral		Not Reported
	Vitamin C			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Nattokinase			C				Not Reported
	Krill Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13725397	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Escitalopram			S	Oral	Other Dose:Mg;		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13725905	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1728114US		36 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dengue Fever; Intentional Dose Omission; Therapy Cessation	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Mirtazapine			C	Unknown	45 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13725971	EXPEDITED (15-DAY)		OT	FR-SA-2014SA061839		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Alfuzosin Hydrochloride			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Aprovel			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Amarel			C	Unknown			Not Reported
	Bromazepam			C	Unknown			Not Reported
	Meteospasmyl [Alverine Citrate;Dl-Methionine			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported
	Symbicort			C	Unknown			Not Reported
	Valerian			C	Unknown			Not Reported
	Lepticur			C	Oral			Not Reported
	Theralene			C	Unknown			Not Reported
	Movicol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13726499	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1039833			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Headache; Status	Escitalopram			S		20 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported

Epilepticus	Quetiapine		S	400 Mg, Qd	Not Reported
	Quetiapine		S	600 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13726689	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13386349	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1712392US		26 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Glycosylated Haemoglobin Increased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13726842	EXPEDITED (15-DAY)		HO	IN-TORRENT-00001249		50 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate			S				Unknown
	Bupropion			S				Unknown
	Paroxetine			S				Unknown
	Vilazodone Hydrochloride			S				Unknown
	Mirtazapine			S				Unknown
	Sertraline Hydrochloride			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13732557	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1728380US		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coma; Pneumonia Aspiration; Toxicity To Various Agents	Escitalopram Oxalate - Bp		S	Oral	Allergan
	Xanax		S	Oral	Not Reported
	Abilify		S	Oral	Not Reported
	Risperdal		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13732558	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1728545US		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2017	13734122	EXPEDITED (15-DAY)		OT	FR-ZYDUS-015738		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Headache; Status Epilepticus	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Quetiapine/Quetiapine Fumarate			S	Unknown	400 Mg, Qd		Not Reported
	Quetiapine/Quetiapine Fumarate			S	Unknown	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2017	13734327	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001307			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicidal Ideation	Metformin			S		500 Mg, Unk		Ipca
	Escitalopram			S		20 Mg, Unk		Not Reported
	Paracetamol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2017	13735548	DIRECT					30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Of Body Temperature Change; Formication; Incorrect Dose Administered; Neck Pain; Nervousness; Panic Attack; Paraesthesia	Lexapro (Escitalopram)			S	Oral	Other Strength:Mg;Quantity:30 Tablet(S);		Cipla
	Mirtazapine (Remeron)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	10195739	EXPEDITED (15-DAY)		OT	FR-BRISTOL-MYERS SQUIBB COMPANY-20797627		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Metformin Hydrochloride			S	Oral	150 Mg, Bid		Bristol Myers Squibb
	Metformin Hydrochloride			S	Oral	850 Mg, Bid		Bristol Myers Squibb
	Metformin Hydrochloride			S	Oral	850 Mg, Tid		Bristol Myers Squibb
	Aprovel			S	Oral	150 Mg, Qd		Not Reported
	Levothyrox			S	Oral	125 Mg, Qd		Not Reported
	Imovane			S	Oral	3.75 Mg, Qd		Not Reported
	Atarax			S	Oral	25 Mg, Bid		Not Reported
	Atarax			S	Oral	12.5 Mg, Qd		Not Reported
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Kardegic			S	Oral	75 Mg, Qd		Not Reported
	Crestor			S	Oral	5 Mg, Qd		Not Reported
	Crestor			S	Oral	10 Mg, Unk		Not Reported
	Alfuzosine			S	Oral	10 Mg, Qd		Not Reported
	Eupantol			C	Unknown			Not Reported
	Amarel			C	Unknown	1 Df, Unk		Not Reported
	Meteospasmyl /01017401/			C	Unknown	1 Tab, Tid		Not Reported
	Montelukast			C	Unknown	10 Mg, Qd		Not Reported
	Symbicort			C	Unknown	Unk, Bid		Not Reported

Bromazepam	C	Unknown	Unk, Prn		Not Reported
Valerian	C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	10211428	EXPEDITED (15-DAY)		OT	7291845		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Novothyrox			S	Oral			Merck Kgaa
	Metformin Hydrochloride			S	Oral			Not Reported
	Metformin Hydrochloride			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Alfuzosine Hydrochloride			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Aprovel			S	Oral			Not Reported
	Eupantol			C				Not Reported
	Amarel			C				Not Reported
	Meteospasmyl [Alverine Citrate;Dl-Methionine			C				Not Reported
	Montelukast			C				Not Reported
	Symbicort			C				Not Reported
	Bromazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	11926821	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-109945		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bipolar Disorder; Blood Prolactin Increased; Blunted Affect; Gastrointestinal Disorder; Homicidal Ideation; Overdose; Panic Attack; Suicidal Ideation; Therapeutic Response Decreased	Fluoxetine	S	Unknown	10 Mg		Sun
	Acetaminophen	S	Unknown	Over Dosed		Ohm Lab
	Escitalopram	S	Unknown	Unk		Not Reported
	Risperidone	S	Unknown	0.5 Mg, Bid		Ranbaxy
	Aripiprazole	S	Unknown	2mg		Not Reported
	Aripiprazole	S	Unknown	5mg		Not Reported
	Lamotrigine	C	Unknown	25 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13734793	EXPEDITED (15-DAY)		OT	US-TORRENT-00003147		51 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psychotic Disorder	Bupropion Hydrochloride			S				Unknown
	Escitalopram			S				Unknown
	Sertraline			C				Unknown
	Trazodone			C				Unknown
	Zolpidem			C				Unknown
	Hydroxyzine			C				Unknown
	Aripiprazole			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13734884	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2017005308			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Escitalopram Oxalate			S	Unknown	Unk (Anidepressant)		Macleods
	Olanzapine			S	Unknown	10 Mg, Qd (Low Dose Neuroleptics)		Macleods
	Olanzapine			S	Unknown	15 Mg, Qd		Macleods
	Olanzapine			S	Unknown	5 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd (Low Dose Neuroleptics)		Macleods

	Fluvoxamine	S	Unknown	Unk(Antidepressant)	Not Reported
	Mirtazapine	S	Unknown	60 Mg, Qd (Antidepressant)	Not Reported
	Risperidone	S	Unknown	3 Mg, Qd (Low Dose Neuroleptic)	Not Reported
	Carbamazepine	C	Unknown	Unk	Not Reported
	Carbamazepine	C	Unknown	1200 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13736624	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1710885US		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Off Label Use	Vraylar			S	Oral	1.5 Mg, Unk		Allergan
	Vraylar			S	Oral	6 Mg, Qd		Allergan
	Lexapro			S	Oral	Unk, Qd		Allergan
	Lamictal			C	Oral	Unk		Not Reported
	Abilify			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	10270143	EXPEDITED (15-DAY)		DS	FI-TEVA-490332ISR		19 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Disturbance In Sexual Arousal; Genital Paraesthesia; Libido Decreased; Male Orgasmic Disorder	Sertralin Ratiopharm 50 Mg			S	Oral	50 Milligram Daily;		Not Reported
	Cipralex 10 Mg			S	Oral	10 Milligram Daily;		Not Reported
	Cipralex 10 Mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	12492839	NON-EXPEDITED			US-PFIZER INC-2016285898			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Amoxicillin	S	Unk	Pfizer
	Azithromycin	S	Unk	Pfizer
	Celebrex	S	Unk	Pfizer
	Erythromycin	S	Unk	Pfizer
	Fentanyl Citrate	S	Unk	Unknown
	Norvasc	S	Unk	Pfizer
	Buspar	S	Unk	Not Reported
	Catapres	S	Unk	Not Reported
	Codeine	S	Unk	Not Reported
	Dilaudid	S	Unk	Not Reported
	Kenalog	S	Unk	Not Reported
	Levaquin	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Lisinopril	S	Unk	Not Reported
	Macrobid	S	Unk	Not Reported
	Macrodantin	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13707660	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2017280847		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Transaminases Increased	Duavive			S		Unk		Pfizer
	Lorazepam			S		Unk		Pfizer
	Citalopram			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13708954	EXPEDITED (15-DAY)		HO, OT	DE-HETERO LABS LTD-2022817		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Burning Sensation; Diarrhoea; Fatigue; Fatigue; Feeling Abnormal; Hot Flush; Listless; Nausea; Panic Attack; Skin Burning Sensation; Suicidal Ideation; Vision Blurred	Escitalopram		S	Oral	Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13743076	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1728790US		30 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Platelet Count Decreased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13743404	EXPEDITED (15-DAY)		OT	PHHY2017FR100453		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia	Stalevo			S	Oral	1 Df, Tid		Novartis
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Pradaxa			C	Unknown	Unk		Not Reported
	Corenitec			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13334121	EXPEDITED (15-DAY)		OT	US-JAZZ-2016-US-024512		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Attention; Sleep Apnoea Syndrome; Sleep-Related Eating Disorder; Weight Increased	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Seroquel			S				Not Reported

Lexapro	S	Not Reported
Remeron	S	Not Reported
Cyclobenzaprine	C	Not Reported
Naproxen	C	Not Reported
Vitamin D3	C	Not Reported
Cymbalta	C	Not Reported
Adderall	C	Not Reported
Alprazolam	C	Not Reported
Nexium /01479302/	C	Not Reported
Propranolol	C	Not Reported
Viibryd	C	Not Reported
Nortriptyline Hcl	C	Not Reported
Lortab /00607101/	C	Not Reported
Latuda	C	Not Reported
Lithium Carbonate	C	Not Reported
Effexor Sr	C	Not Reported
Inderal	C	Not Reported
Lisinopril Hctz	C	Not Reported
Trileptal	C	Not Reported
Imipramine Hcl	C	Not Reported
Topamax	C	Not Reported
Lipitor	C	Not Reported
Testosterone Cypionate	C	Not Reported
Klonopin	C	Not Reported
Lamictal	C	Not Reported
Lortab /00607101/	C	Not Reported
Advil /00044201/	C	Not Reported
Amoxicillin	C	Not Reported
Rexulti	C	Not Reported
Vraylar	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13746882	EXPEDITED (15-DAY)		HO, OT	PT-ALLERGAN-1728845US		41 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Conversion Disorder; Decreased Appetite; Derealisation; Eating Disorder; Irritability;	Escitalopram Oxalate - Bp			S	Unknown	Unknown		Allergan
	Olanzapine			C	Unknown			Not Reported
	Mexazolam			C	Unknown			Not Reported
	Buproprion			C	Unknown			Not Reported

Somnolence; Urinary Retention	Carbamazepine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13747968	EXPEDITED (15-DAY)		OT	FR-ORION CORPORATION ORION PHARMA-ENTC2017-0307		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia	Stalevo			S	Oral	Strength: 200/50/200 Mg		Not Reported
	Seroplex			S	Oral			Not Reported
	Pradaxa			C	Unknown			Not Reported
	Corenitec			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13752700	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1729211US		35 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Psychomotor Hyperactivity	Escitalopram Oxalate Unk			S	Oral	Overdose: 14 Dosage Forms		Allergan
	Tavor [Lorazepam]			S	Oral	Overdose: 5 Dosage Forms		Not Reported
	Gabapentin			C	Unknown			Not Reported
	Haldol			C	Unknown			Not Reported
	En			C	Unknown	0.5 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13752703	EXPEDITED (15-DAY)		HO	KR-ALLERGAN-1729191US		52 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Headache; Incorrect Dose Administered; Insomnia;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
	Benzatropine			S	Unknown	2 Mg, Unknown		Not Reported

Parosmia; Schizophrenia	Clonazepam	S	Unknown	0.5 Mg, Unknown	Not Reported
	Quetiapine	S	Unknown	25 Mg, Unknown	Not Reported
	Risperidone	S	Unknown	2 Mg, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	12845652	EXPEDITED (15-DAY)		HO, OT	BR-ABBVIE-16P-020-1752969-00		67 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arrhythmia; Arrhythmia; Blood Potassium Decreased; Depression; Diarrhoea; Fatigue; Gastric Cancer; Gastrointestinal Carcinoma; Generalised Anxiety Disorder; Iron Deficiency; Pain In Extremity; Swelling; Thirst; Weight Decreased	Synthroid			S	Oral			Not Reported
	Esc			S	Unknown	Daily Dose: 20 Mg;At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	13681463	EXPEDITED (15-DAY)		OT	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-143434		71 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Hypertriglyceridaemia; Somnolence	Venlafaxine			S	Unknown	75 Mg, Daily		Sun
	Venlafaxine			S				Sun
	Fenofibrate			C	Unknown	200 Mg, Daily		Not Reported
	Fenofibrate			C	Unknown	200 Mg, Daily		Not Reported
	Clopidogrel			C	Unknown			Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported
	Carvedilol			C	Unknown	Unk		Not Reported
	Famotidine			C				Not Reported
	Sennosides			C	Unknown	Unk		Not Reported

	Levocetirizine	C	Unknown	Not Reported
	Mirtazapine	S	Unknown	Sun
	Escitalopram	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	13753080	EXPEDITED (15-DAY)		DE, LT, OT	JP-GLAXOSMITHKLINE-JP2017JPN106709		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardio-Respiratory Arrest; Chest Pain; Malaise; Somnolence	Lamictal			S	Oral	400 Mg, 1d		Glaxosmithkline
	Effexor			S	Oral	Unk		Not Reported
	Effexor			S	Oral	37.5 Mg, 1d		Not Reported
	Lexapro			S	Oral	20 Mg, 1d		Not Reported
	Abilify			S	Oral	3 Mg, 1d		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2017	13757223	DIRECT		HO, OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diverticulitis; Influenza; Insomnia; Migraine; Myalgia; Nausea	Lexapro Esclopriam			S	Oral	Other Strength:Mg;Quantity:30 Tablet(S);		Not Reported
	Abilify			S	Oral	Other Strength:Mg;Quantity:30 Tablet(S);		Not Reported
	Migraine Meds			C				Not Reported
	Nausea Meds			C				Not Reported
	Bactrim Ds			C				Not Reported
	Flagyl			C				Not Reported
	Klonopin			C				Not Reported
	Benadryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2017	13758591	DIRECT		DS, LT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Amnesia; Blood Glucose Decreased; Chronic Fatigue Syndrome; Cognitive Disorder; Decreased Appetite; Fatigue; Hypotension; Influenza Like Illness; Loss Of Libido; Menstruation Irregular; Muscular Weakness; Neurotoxicity; Sexual Dysfunction; Weight Decreased; Withdrawal Syndrome	Scippa (Escitalopram)			S	Oral	Other Strength:Mg;Quantity:0.5 Tablet(S);		Gedeon Richter

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13759410	NON-EXPEDITED			US-ALLERGAN-1719282US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Hole; Wrong Technique In Product Usage Process	Namenda Xr			S	Oral	28 Mg, Qd		Allergan
	Namzaric			S	Oral	1 Df, Qd		Allergan
	Lexapro			S	Oral			Allergan
	Aleve			C	Oral	220 Mg, Q12h		Not Reported
	Vitamin D2			C	Oral	3000 Units, Unk		Not Reported
	Aspirin			C	Oral	81 Mg, Unk		Not Reported
	Stool Softener			C	Oral	100 Mg, Unk		Not Reported
	Flomax			C	Oral	0.4 Mg, Unk		Not Reported
	Voltaren			C	Transdermal	Unk Unk, Qid		Not Reported
	Oxybutynin Chloride			C	Oral	5 Mg, Bid		Not Reported
	Oxybutynin Chloride			C	Oral	5 Mg, Bid		Not Reported
	Ativan			C	Oral	1 Mg, Tid		Not Reported
	Finasteride			C	Oral	10 Mg, Unk		Not Reported

	Coumadine		C	Oral	5 Mg, Unk	Not Reported
	Coumadine		C	Oral	5 Mg, Unk	Not Reported
	Murine Ear Wax Removal System		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13760756	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1729643US		22 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13760783	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1729608US		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash Erythematous; Toxic Skin Eruption	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Qd		Allergan
	Alprazolam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13760824	EXPEDITED (15-DAY)		DS	AU-ALLERGAN-1729626US		56 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Condition Aggravated; Drug Ineffective; Generalised Anxiety Disorder; Major Depression; Overdose; Psychotic Disorder; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	40 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	60 Mg		Allergan
	Brintellix			S	Unknown			Not Reported
	Avanza			S	Unknown	15 Mg, Qd		Not Reported
	Efexor			S	Unknown	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13761476	EXPEDITED (15-DAY)		OT	PHHY2017US102759		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Hydroxyzine			S	Unknown	25 Mg, Bid		Novartis
	Hydroxyzine			S				Novartis
	Methadone			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Ivacaftor			S	Unknown	400 Mg, Q12h		Not Reported
	Ivacaftor			S	Unknown	250 Mg, Q12h		Not Reported
	Escitalopram			S	Unknown	30 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13761479	EXPEDITED (15-DAY)		OT	PHHY2017US102758		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Lorazepam			S	Unknown			Novartis
	Bupropion			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Ivacaftor			S	Unknown	400 Mg, Q12h		Not Reported
	Ivacaftor			S	Unknown	250 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13698617	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1726615US		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cervical Vertebral Fracture; Hand Fracture; Lower Limb Fracture; Off Label Use; Road Traffic Accident; Surgery	Escitalopram Oxalate 5mg Tablet Prescription F 53 = [Aurobindo Pharma Limited	S	Oral	10 Mg, Qd		Allergan
	Zoloft	C	Oral	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13734298	EXPEDITED (15-DAY)		HO	BE-TEVA-783368ROM		82 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyspnoea; Hyperthermia; Psychomotor Hyperactivity; Serotonin Syndrome	Azilect 1 Mg Tabletten			S				Teva
	Sipralexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13761810	EXPEDITED (15-DAY)		DS, OT	AU-TAKEDA-2017TUS015030			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Condition Aggravated; Drug Ineffective; Generalised Anxiety Disorder; Major Depression; Overdose; Psychotic Disorder; Suicidal Ideation	Brintellix			S	Unknown	Unk		Takeda
	Lexapro			S	Intracardiac	20 Mg, Qd		Not Reported
	Lexapro			S	Intracardiac	40 Mg, Qd		Not Reported
	Lexapro			S	Intracardiac	60 Mg, Qd		Not Reported
	Avanza			S	Unknown	15 Mg, Unk		Not Reported
	Efexor			S	Unknown	75 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13762848	EXPEDITED (15-DAY)		DE, HO, OT	JP-LUPIN PHARMACEUTICALS INC.-2017-03769		20 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Overdose	Methylphenidate			S	Unknown	Unk		Novel Labs

Escitalopram	S	Unknown	Unk		Lupin
Brotizolam	S	Unknown	Unk		Not Reported
Aripiprazole	C	Unknown	1 Df, Unk		Not Reported
Trazodone Hydrochloride	C	Unknown	1 Df, Unk		Not Reported
Risperidone	C	Unknown	0.5 Ml, Single		Not Reported
Flunitrazepam	C	Unknown	Unk		Not Reported
Chlorpromazine	C	Unknown	Unk		Not Reported
Paliperidone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13762902	EXPEDITED (15-DAY)		DE	US-BION-006476			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death	Loperamide Unknown Product			S				Bionpharma
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13764438	EXPEDITED (15-DAY)		HO	CH-ARALEZ PHARMACEUTICALS R&D INC.-ARA-TP-CH-2017-		79 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Orthostatic Hypotension	Metoprolol Succinate			S	Oral			Aralez Pharmaceuticals
	Cipralex			S	Oral			Not Reported
	Aprovel			S	Oral			Not Reported
	Aspirin Cardio			C				Not Reported
	Dafalgan			C				Not Reported
	Calcimagon-D3			C				Not Reported
	Tramal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13765215	EXPEDITED (15-DAY)		OT	HR-TEVA-786288ACC		65 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Hallucination, Auditory; Myalgia; Pruritus; Tinnitus; Vision Blurred	Serpentil [Escitalopram Oxalate]			S	Oral	15 Milligram Daily;		Ivax
	Rosix			C	Oral	10 Milligram Daily;		Not Reported
	Normabel			C	Oral	15 Milligram Daily;		Not Reported
	Brufen Powders, Effervescent Powders/Granules			C	Oral	600 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13765272	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2017306649		29 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Suicide Attempt	Alprazolam			S	Oral	One Blister		Pfizer
	Fluzepam (Flurazepam Hydrochloride)			S	Oral	Two Blisters		Not Reported
	Escitalopram			S	Oral	Two Blisters		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13766128	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2017M1042452			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Interaction; Infective Pulmonary Exacerbation Of Cystic Fibrosis	Escitalopram			S	Unknown	30 Mg Daily		Not Reported
	Escitalopram			S	Unknown	30 Mg Daily		Not Reported
	Hydroxyzine			S	Unknown			Not Reported
	Hydroxyzine			S	Unknown			Not Reported
	Ivacaftor W/Lumacaftor			S	Unknown	250/400 Mg At Every 12 Hours		Mylan
	Methadone			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13766780	EXPEDITED (15-DAY)		CA, OT	IL-CIPLA LTD.-2017IL12338			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Talipes	Lamotrigine			S	Transplacental	Unk		Cipla
	Folic Acid			S	Transplacental	Unk		Invagen
	Escitalopram			S	Transplacental	Unk		Invagen
	Desipramine			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13768193	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS USA.,INC-2017SUN00256		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Anxiety; Depression; Drug Interaction; Drug Use Disorder; Therapeutic Product Effect Decreased	Escitalopram			S	Unknown	30 Mg, Daily		Taro
	Escitalopram			S				Taro
	Alprazolam			S	Unknown	Unk		Not Reported
	Alprazolam			S				Not Reported
	Hydroxyzine			S	Unknown	25 Mg, Bid		Not Reported
	Hydroxyzine			S				Not Reported
	Lumacaftor-Ivacaftor			S	Unknown	400/250 Mg Every 12 Hours		Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported
	Quetiapine			S				Not Reported
	Methadone			C				Not Reported
	Oxycodone			C				Not Reported
	Marijuana			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13768202	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS USA.,INC-2017SUN00255		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Therapeutic Product Effect Decreased	Escitalopram			S	Unknown			Taro
	Bupropion			S	Unknown			Not Reported

Olanzapine	S	Unknown			Not Reported
Trazodone	S	Unknown			Not Reported
Lorazepam	S	Unknown			Not Reported
Lumacaftor-Ivacaftor	S	Unknown	400/250 Mg, Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13768388	DIRECT		OT			30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Eating Disorder; Fear; Unevaluable Event; Withdrawal Syndrome	Lexapro 20mg			S	Oral	Other Strength:Mg;Quantity:1 Tablet(S);		Lundbeck
	Protein Powder			C				Not Reported
	Creatine			C				Not Reported
	Aminoacids			C				Not Reported
	Omega3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13768456	DIRECT	Y	OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache	Escitalopram			S	Oral	Other Dose:Mg;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13770025	EXPEDITED (15-DAY)		DE, OT	JP-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-063555		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardio-Respiratory Arrest; Chest Pain; Somnolence	Abilify			S	Oral	3 Mg, Daily		Bristol Myers Squibb
	Effexor			S	Oral	37.5 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Daily		Not Reported

	Lamictal	S	Oral	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13648068	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1724323US		72 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Interaction; Interstitial Lung Disease	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Amiodarone Hydrochloride			S	Unknown	Unk		Not Reported
	Mexitil			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Bayaspirin			C	Oral	Unk		Not Reported
	Enalapril			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13720140	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1727943US		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Gait Disturbance; Speech Disorder; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Rivastigmine			C	Transdermal			Not Reported
	Nicardipine			C	Oral			Not Reported
	Acide Alendronique			C	Unknown			Not Reported
	Paracetamol			C	Unknown	Once Every 6 Hours If Pain Or Fever		Not Reported
	Paracetamol			C				Not Reported
	Leponex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13740100	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2017-36718		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Toxicity To Various Agents	Alprazolam		S	Unknown	Aurobindo
	Citalopram		S	Unknown	Aurobindo
	Escitalopram		S	Unknown	Aurobindo
	Amphetamine		S	Unknown	Not Reported
	Hydrocodone		S	Unknown	Not Reported
	Morphine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13774754	EXPEDITED (15-DAY)		OT	FR-TEVA-787837ROM			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Disturbance In Attention; Sedation; Somnolence; Somnolence; Vertigo	Modiodal			S	Oral	4 Dosage Forms Daily;		Cephalon
	Xyrem			S	Oral	8 Gram Daily;		Not Reported
	Escitalopram Mylan Generiques 5 Mg, Comprimé Pelliculé			S	Oral	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13360464	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1710674US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Urso			C		Unk		Not Reported
	Halcion			C		Unk		Not Reported
	Travelmin (Diphenhydramine Salicylate/Diprophylline)			C		Unk		Not Reported
	Bezatol			C				Not Reported
	Furosemide			C		Unk		Not Reported
	Luvox			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13777002	DIRECT	Y	HO			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hot Flush	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13777016	EXPEDITED (15-DAY)		OT	US-LANNETT COMPANY, INC.-US-2017LAN000939		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sleep Apnoea Syndrome	Baclofen (20mg)			S	Unknown	20 Mg, Tid		Lannett
	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Gabapentin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13777589	EXPEDITED (15-DAY)		HO, OT	CN-BAUSCH-BL-2017-022064		61 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Gastrointestinal Disorder; Meige'S Syndrome	Clonazepam			S	Intravenous (not otherwise specified)			Not Reported
	Clonazepam			S	Unknown	Per Night		Not Reported
	Clonazepam			S	Unknown	Every Night		Not Reported
	Lorazepam			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Haloperidol			S	Unknown	At Night		Not Reported
	Lexapro			S	Unknown			Not Reported
	Zyprexa			S		1.25-3.75 Mg Per Night		Not Reported
	Nitrazepam			S	Unknown			Not Reported
	Flupentixol			S	Unknown			Not Reported
	Melitracen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13779285	EXPEDITED (15-DAY)		HO, OT	CN-APOTEX-2017AP015981			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Gastrointestinal Disorder; Meige'S Syndrome	Seroxat			S	Unknown	30 Mg, Unk		Apotex
	Clonazepam Solution For Infusion			S	Intravenous (not otherwise specified)	0.5 Mg, Unk		Not Reported
	Haloperidol Tablet			S	Unknown	At Night		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Zyprexa Tablet			S	Unknown	1.25-3.75 Mg Per Night		Not Reported
	Nitrazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Clonazepam Tablet			S	Unknown	Per Night		Not Reported
	Clonazepam			S	Unknown	Every Night		Not Reported
	Flupentixol			S	Unknown	Unk		Not Reported
	Melitracen Tablet			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	11552621	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-15-01		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torticollis	Escitalopram			S	Unknown			Hikma
	Escitalopram			S	Unknown			Hikma
	Escitalopram			S	Unknown			Hikma
	Clonazepam			C	Unknown	At Bedtime		Not Reported
	Clonazepam			C	Unknown	At Bedtime		Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Celecoxib			C	Unknown			Not Reported
	Tamsulosin			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13171868	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2017GB009661		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anaemia; Anger; Anxiety; Atrial Tachycardia; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal; Dizziness; Dyskinesia; Fatigue; Food Intolerance; Functional Gastrointestinal Disorder; Hypervigilance; Lacrimal Disorder; Mood Swings; Muscle Disorder; Muscle Tightness; Musculoskeletal Stiffness; Nausea; Panic Reaction; Paraesthesia; Restless Legs Syndrome; Saliva Altered; Sinus Node Dysfunction; Sleep Disorder; Syncope; Tearfulness; Vision Blurred; Visual Impairment; Vitreous Floaters; Withdrawal Syndrome	Citalopram			S	Oral	10 Mg, Unk		Novartis
	Citalopram			S	Oral	10 Mg, Unk		Novartis
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13690502	EXPEDITED (15-DAY)		HO	PHHY2017IT090219		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech;	Lorazepam			S	Oral	10 Ml, Unk		Novartis
	Escitalopram			S	Oral	6 Df, Unk		Not Reported

Sopor	Carbolithium		C	Unknown	Not Reported
	Quetiapine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13780472	NON-EXPEDITED			US-CELGENEUS-USA-20170703930			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Increased Tendency To Bruise	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	5 Milligram		Celgene
	Revlimid			S	Oral	15 Milligram		Celgene
	Revlimid			S	Oral	25 Milligram		Celgene
	Lexapro			S	Unknown			Not Reported
	Baby Aspirin			S	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported
	Vitamin B-12			C	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13781605	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2017-03884		61 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Gastrointestinal Disorder; Meige'S Syndrome	Escitalopram Tablets			S	Unknown	10 Mg, Qd		Lupin
	Paroxetine			S	Unknown	30 Mg, Qd		Lupin
	Clonazepam			S	Intravenous (not otherwise specified)	0.5 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Qd (At Night)		Not Reported
	Clonazepam			S	Unknown	10 Mg, Qd (At Night)		Not Reported
	Zyprexa			S	Unknown	1.25-3.75 Mg Per Night		Not Reported
	Haloperidol			C	Unknown	2 Mg, Qd (Per Night)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13782527	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-064444			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Cogwheel Rigidity; Depression; Weight Decreased	Aripiprazole			S	Unknown			Bristol Myers Squibb
	Buspar			C	Unknown	Unk		Not Reported
	Lexapro			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Vitamin B12 /00056201/			S	Unknown			Not Reported
	Pristiq			S	Unknown	200 Mg, Unk		Not Reported
	Latuda			S	Unknown	40 Mg, Unk		Not Reported
	Latuda			S	Unknown	60 Mg, Unk		Not Reported
	Latuda			S	Unknown	80 Mg, Unk		Not Reported
	Adderall			S	Unknown	1 Df, Bid		Not Reported
	Adderall			S	Unknown	20 Mg, Bid		Not Reported
	Rexulti			S	Unknown	0.5 Mg, Qd		Not Reported
	Rexulti			S	Unknown	1 Mg, Qd		Not Reported
	Rexulti			S	Unknown	2 Mg, Qd		Not Reported
	Rexulti			S	Unknown	3 Mg, Qd		Not Reported
	Rexulti			S	Unknown	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13784111	EXPEDITED (15-DAY)		HO	US-TEVA-789764USA		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cystic Fibrosis; Depression; Drug Interaction	Escitalopram			S	Unknown	30 Milligram Daily;		Ivax
	Escitalopram			S	Unknown	30 Mg Daily		Ivax

	Hydroxyzine	S	Unknown			Barr
	Hydroxyzine	S	Unknown			Barr
	Ivacaftor, Lumacaftor	S	Unknown	250/400 Mg At Every 12 Hours		Not Reported
	Methadone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13784285	EXPEDITED (15-DAY)		OT	PHHY2017ES105950		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Haemorrhage	Sintrom			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Omeprazole			S	Oral	20 Mg, Qd		Novartis
	Sinemet Plus			C	Oral	1 Df, Tid		Not Reported
	Seguril			C	Oral	40 Mg, Bid		Not Reported
	Aldactone			C	Oral	25 Mg, Qd		Not Reported
	Masdil			C	Oral	60 Mg, Bid		Not Reported
	Singulair			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13698603	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1726828US		20 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Overdose	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Overdose: Dose		Allergan
	Trazodone Hydrochloride			S	Oral			Not Reported
	Concerta			S	Oral	Overdose: Dose		Not Reported
	Lendormin			S	Oral			Not Reported
	Risperdal			C		Unk		Not Reported
	Rohypnol			C	Unknown			Not Reported

	Abilify	C	Unknown			Not Reported
	Contomin	C	Unknown			Not Reported
	Invega	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13786698	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Label Confusion	Escitalopram Oxalate			S	Oral	Type - Bottle 10 Mg		Not Reported
	Escitalopram Montelukast Sodium			S	Oral	Type - Bottle 10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13790185	NON-EXPEDITED			PHEH2017US021842			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Cosentyx			S	Subcutaneous	300 Mg, Unk		Novartis
	Cosentyx			S	Subcutaneous	300 Mg, Unk		Novartis
	Lasix			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Meloxicam			S	Unknown	Unk		Not Reported
	Tribenzor			S	Unknown	Unk		Not Reported
	Xyzal			S	Unknown			Not Reported
	Meclizine			S	Unknown	Unk		Not Reported
	Biotin			S	Unknown	Unk		Not Reported
	B6			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13790931	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-065668			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Affective Disorder; Memory Impairment; Sleep Disorder	Abilify		S	Unknown	Bristol Myers Squibb
	Lexapro		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13791147	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1043041			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Disturbance In Attention; Sedation; Somnolence; Somnolence; Vertigo	Escitalopram Mylan			S	Oral	1 Df, Qd		Mylan
	Modiodal			S	Oral	2 Df, Bid		Mylan
	Modiodal			S		1 Df, Bid		Mylan
	Xyrem			S	Oral	4 G, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13791492	EXPEDITED (15-DAY)		HO	PHHY2017PL105086		23 YR	Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Apathy; Apathy; Asthenia; Bipolar Disorder; Cognitive Disorder; Decreased Activity; Depressed Mood; Drug Resistance; Fear; Increased Appetite; Somnolence; Tearfulness	Aripiprazole			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Novartis
	Escitalopram			S	Unknown			Not Reported
	Lithium Carbonate			S	Unknown	1000 Mg, Qd		Not Reported
	Lithium Carbonate			S	Unknown	1500 Mg, Qd		Not Reported
	Ziprasidone			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Lamotrigine			S	Unknown	50 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown	100 Mg, Qd		Not Reported
	Vortioxetine			S	Unknown	20 Mg, Qd		Not Reported
	Vortioxetine			S	Unknown	10 Mg, Qd		Not Reported
	Reboxetine			S	Unknown			Not Reported
	Atenolol			C	Unknown	25 Mg, Unk		Not Reported
	Atenolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13791728	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1730518US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13792654	EXPEDITED (15-DAY)		HO, OT	CN-ELI_LILLY_AND_COMPANY-CN201707008200		61 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Gastrointestinal Disorder; Meige'S Syndrome	Olanzapine			S	Unknown	Unk Unk, Daily		Eli Lilly And Co
	Clonazepam			S	Intravenous (not otherwise specified)	0.5 Mg, Each Evening		Not Reported
	Clonazepam			S	Unknown	10 Mg, Each Evening		Not Reported
	Paroxetine			S	Unknown	30 Mg, Daily		Not Reported
	Haloperidol			S	Unknown	2 Mg, Each Evening		Not Reported
	Lexapro			S	Unknown	10 Mg, Daily		Not Reported
	Nitrazepam			S	Unknown	Unk, Unknown		Not Reported
	Lorazepam			S	Unknown	Unk, Unknown		Not Reported
	Flupentixol			S	Unknown	Unk, Unknown		Not Reported
	Melitracen			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13777829	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1728639US		20 YR	Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13795467	EXPEDITED (15-DAY)		OT	US-HETERO LABS LTD-2023789		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cystic Fibrosis; Depression	Escitalopram			S	Unknown			Hetero
	Bupropion Hydrochloride			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Ivacaftor W/Lumacaftor			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13795959	EXPEDITED (15-DAY)		HO	CZ-ALLERGAN-1731283US		13 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Intentional Overdose; Intentional Product Misuse; Pupillary Reflex Impaired; Somnolence	Escitalopram Oxalate - Bp			S	Unknown	100 Mg, Unk		Allergan
	Paralen (Acetaminophen)			S	Unknown	6000 Mg, Qd		Not Reported
	Stopex			S	Unknown	Unk		Not Reported
	Tetrahydrocannabinol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13798283	DIRECT	Y	OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations	Lexapro			S	Oral			Not Reported
	Zoloft			C				Not Reported
	Motrin			C				Not Reported
	Colace			C				Not Reported
	Ferrous Sulfate			S				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13181325	EXPEDITED (15-DAY)		HO	AT-ALLERGAN-1703919US		52 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Off Label Use	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Trittico/Trazodon-Hydrochloride			C	Unknown			Not Reported
	Trittico/Trazodon-Hydrochloride			C	Unknown	100 Mg, Qd		Not Reported
	Trittico/Trazodon-Hydrochloride			C	Unknown	150 Mg, Qd		Not Reported
	Pantoprazol/Pantoprazol			C	Unknown			Not Reported
	Sertralin/Sertralin			C	Unknown			Not Reported
	Sertralin/Sertralin			C	Unknown			Not Reported
	Sertralin/Sertralin			C	Unknown			Not Reported
	Mefenabene/Mefenamic Acid			C	Unknown			Not Reported
	Mefenabene/Mefenamic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13769181	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-063375		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury; Ischaemic Stroke; Lymphadenopathy; Off Label Use; Pelvic Mass	Eliquis			S	Oral	5 Mg, Qd		Bristol Myers Squibb
	Tahor			S	Oral	40 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13791630	EXPEDITED (15-DAY)		HO, OT	CN-ALLERGAN-1730788US		61 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Gastrointestinal Disorder;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

Meige'S Syndrome; Product Use In Unapproved Indication	Flupentixol-Form-Unknown	S	Unknown	Unknown	Not Reported
	Clonazepam	S	Intravenous (not otherwise specified)	0.5 Mg, Qd	Not Reported
	Clonazepam	S	Intravenous (not otherwise specified)	0.5 Mg, Qd, At Night	Not Reported
	Clonazepam	S		10 Mg, Qd	Not Reported
	Paroxetine	S	Unknown	30 Mg, Qd	Not Reported
	Haloperidol	S	Unknown		Not Reported
	Zyprexa	S	Unknown		Not Reported
	Nitrazepam	S	Unknown		Not Reported
	Lorazepam	S	Unknown		Not Reported
	Melitracen	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13797064	EXPEDITED (15-DAY)		HO	FR-AMGEN-FRASP2017109982		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diarrhoea	Xgeva			S	Subcutaneous	Unk		Amgen
	Xgeva			S				Amgen
	Aranesp			S	Unknown	300 Mug, Q2wk		Amgen
	Firmagon			S	Unknown	80 Mg, Unk		Not Reported
	Zytiga			S	Oral	1000 Mg, Qd		Not Reported
	Seroplex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13797660	EXPEDITED (15-DAY)		OT	US-ZYDUS-015838		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Forced Expiratory Volume Decreased; Infective	Bupropion/Bupropion Hydrochloride			S	Unknown			Zydus Pharm
	Escitalopram			S	Unknown			Zydus Pharm

Pulmonary Exacerbation Of Cystic Fibrosis	Olanzapine	S	Unknown		Not Reported
	Trazodone	S	Unknown		Not Reported
	Lorazepam	S	Unknown		Not Reported
	Lumacaftor/Ivacaftor	S	Unknown	400/250 Mg Every 12 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13797676	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-015839		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Anxiety; Depressed Mood; Depression; Drug Interaction; Feeling Abnormal; Forced Expiratory Volume Decreased; Infective Pulmonary Exacerbation Of Cystic Fibrosis	Escitalopram			S	Unknown			Zydus Pharm
	Oxycodone			S	Unknown			Nesher
	Hydroxyzine			S	Unknown			Not Reported
	Lumacaftor/Ivacaftor			S	Unknown	400/250 Mg Every 12 Hours		Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Methadone			C	Unknown			Not Reported
	Quetiapine/Quetiapine Fumarate			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Escitalopram			S	Unknown			Zydus Pharm
	Hydroxyzine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13801561	EXPEDITED (15-DAY)		HO	FR-FERRINGPH-2017FE03532			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diarrhoea	Firmagon			S	Subcutaneous	1 Df, Long Term Treatment With Unknown Frequency		Ferring
	Zytiga			S	Oral	1000 Mg, Daily		Not Reported
	Xgeva			S	Subcutaneous	Unk		Not Reported

	Seroplex	S	Oral	Unk	Not Reported
	Aranesp	C	Unknown	300 Mg, Every 2nd Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13801903	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1731567US		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Flagyl			S	Oral	1500 Mg, Qd		Not Reported
	Flagyl			S	Oral	1500 Mg, Qd		Not Reported
	Doxycycline			S	Oral	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	11089516	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-96658		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Drug Withdrawal Syndrome	Clozapine			S	Unknown	Unk		Sun
	Clozapine			S				Sun
	Quetiapine			S	Unknown	Unk		Sun
	Quetiapine			S				Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	12992755	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2016003618			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Acute Kidney Injury; Bezoar; Cardiogenic	Escitalopram 10mg Tablet			S	Oral	28 Df, Unk (Seroplex 10mg)		Macleods

Shock; Coma; Gastrointestinal Ischaemia; Haemodynamic Instability; Hyperlactacidaemia; Intentional Overdose; Loss Of Consciousness; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Overdose; Shock; Skin Necrosis; Toxicity To Various Agents	Sevikar	S	Oral	129 Tablets (1.29 G Of Amlodipine And 5.16 G Of Olmesartan)	Not Reported
	Atarax	S	Oral	28 Df, (700 Mg Of Hydroxyzine)	Not Reported
	Citalopram	S	Unknown	Unk	Not Reported
	Zolpidem	S	Unknown	Unk	Not Reported
	Lysanxia 10 Mg	S	Oral	42 Df, (420 Mg Of Prazepam)	Not Reported
	Nordazepam	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13471326	EXPEDITED (15-DAY)		OT	PHHY2017CA053223		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Inflammation; Rash Macular; Skin Lesion	Atorvastatin Sandoz			S	Oral	20 Mg, Qd		Novartis
	Escitalopram Sandoz			S	Oral	10 Mg, Qd		Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Unknown	Unk Unk, Qd		Not Reported
	Singulair			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13741078	EXPEDITED (15-DAY)		HO, OT	CN-ACCORD-053183		61 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Gastrointestinal Disorder; Loss Of Personal Independence In Daily Activities; Meige'S Syndrome; Social Problem	Clonazepam			S	Intravenous (not otherwise specified)	Later 10 Mg/Day, Every Night Given For Anxiety		Accord
	Paroxetine			S				Not Reported
	Haloperidol			S		Haloperidol Tablets 2mg At Night		Not Reported
	Lexapro			S				Not Reported
	Zyprexa			S		1.25-3.75 Mg Per Night		Not Reported
	Nitrazepam			S				Not Reported

	Lorazepam	S	Not Reported
	Flupentixol/Flupentixol Decanoate/Flupentixol Dihydrochloride	S	Not Reported
	Melitracen/Melitracen Hydrochloride	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13804165	NON-EXPEDITED			US-ABBVIE-17P-163-1923103-00		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Taste Disorder	Synthroid			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Calcium			C				Not Reported
	Probiotic			C				Not Reported
	Cranberry Extract			C				Not Reported
	Preservision			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13805919	EXPEDITED (15-DAY)		OT	CZ-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-144767		69 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Back Pain; Constipation; Disease Progression; Pain; Somnolence; Therapeutic Product Effect Incomplete	Gemcitabine			S	Unknown	Unk		Sun
	Paracetamol			S	Unknown	Unk		Ohm Lab
	Ibuprofen			S	Unknown	In Maximum Dose		Ranbaxy
	Nimesulide			S	Unknown	In Maximum Dose		Not Reported
	Aceclofenac			S	Unknown	In Maximum Dose		Not Reported
	Diclofenac			S	Unknown	In Maximum Dose		Sun
	Tramal			S	Unknown	400 Mg, Daily		Not Reported
	Fentanyl			S	Unknown	Increase To 100 Ug/H		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

	Pregabalin	S	Unknown	In A Maximum Dose Of 300mg Per Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13806079	NON-EXPEDITED			US-ASTRAZENECA-2017SE75619			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Post Procedural Haematoma	Brilinta			S	Oral			Astrazeneca
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13807876	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1731407US		35 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypothermia; Intentional Overdose; Respiratory Rate Decreased	Escitalopram Oxalate - Bp			S	Oral	28 Df, Single		Allergan
	Selincro			S	Oral	504 Mg, Single		Not Reported
	Baclofen			S	Oral	600 Mg, Single		Not Reported
	Alprazolam			S	Oral	60 Df, Single		Not Reported
	Paracetamol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13807896	EXPEDITED (15-DAY)		DS, OT	FR-ALLERGAN-1731568US		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Head Injury; Mydriasis; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Previscan (Fluindione)			S	Oral	20 Mg, Qd		Not Reported
	Janumet			C	Unknown	50/1000		Not Reported
	Repaglinide			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Irbesartan Hct			C	Unknown	150/12.5		Not Reported

	Tercian	C	Unknown	Not Reported
	Seresta	C	Unknown	Not Reported
	Omeprazole	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13814412	DIRECT	Y	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Product Physical Issue; Product Substitution Issue	Lexapro			S	Oral			Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2017	13164697	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-MYLANLABS-2017M1004244			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anaemia; Anger; Anxiety; Atrial Tachycardia; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal; Dizziness; Dyskinesia; Fatigue; Food Intolerance; Functional Gastrointestinal Disorder; Hypervigilance; Lacrimal Disorder; Mood Swings; Muscle Disorder; Muscle Tightness; Musculoskeletal Stiffness; Nausea; Panic Reaction; Paraesthesia; Restless Legs Syndrome; Saliva Altered; Sinus Node Dysfunction; Sleep Disorder; Syncope; Tearfulness; Vision	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Citalopram			S	Oral	10 Mg, Unk		Mylan

Blurred; Visual Impairment; Vitreous Floaters; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13149788	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-ALLERGAN-1702719US		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anaemia; Anger; Anxiety; Atrial Tachycardia; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal; Dizziness; Dyskinesia; Fatigue; Food Intolerance; Functional Gastrointestinal Disorder; Hypervigilance; Lacrimal Disorder; Mood Swings; Muscle Disorder; Muscle Tightness; Musculoskeletal Stiffness; Nausea; Panic Reaction; Paraesthesia; Restless Legs Syndrome; Saliva Altered; Sinus Node Dysfunction; Sleep Disorder; Syncope; Tearfulness; Vision Blurred; Visual Impairment; Vitreous Floaters; Withdrawal Syndrome	Citalopram Hydrobromide - Bp			S	Oral			Allergan
	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13738148	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1728642US		77 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Interstitial Lung Disease	Escitalopram Oxalate - Bp	S	Oral	Unk		Allergan
	Quetiapine	S	Unknown			Not Reported
	Oxycodone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13759489	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017304017		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury; Ischaemic Stroke; Lymphadenopathy; Off Label Use; Pelvic Mass	Tahor			S	Oral	40 Mg, 1x/Day		Pfizer
	Eliquis			S	Oral	5 Mg, 1x/Day		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13812963	EXPEDITED (15-DAY)		HO	US-HETERO LABS LTD-2023935		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Condition Aggravated; Depression; Lung Disorder; Substance Abuse	Escitalopram			S	Unknown			Hetero
	Hydroxyzine			S	Unknown			Not Reported
	Ivacaftor W/Lumacaftor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13813116	EXPEDITED (15-DAY)		OT	HR-ROCHE-1970930		48 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Suicide Attempt; Vomiting	Rivotril			S	Oral			Not Reported
	Trittico			S	Oral			Not Reported
	Prazine (Promazine Hydrochloride)			S	Oral			Not Reported
	Flurazepam Hydrochloride			S	Oral			Not Reported

	Escitalopram	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13814911	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-MEDA-2017070058		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bezoar; Cardiogenic Shock; Coma; Gastrointestinal Ischaemia; Hepatic Failure; Hyperlactacidaemia; Intentional Overdose; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Overdose; Shock; Skin Necrosis; Toxicity To Various Agents	Zolpidem			S				Meda
	Sevikar 10 Mg			S	Oral	129 Tablets, 1.29 G Of Amlodipine And 5.16 G Of Olmesartan		Not Reported
	Atarax 25 Mg			S	Oral			Not Reported
	Lysanxia 10 Mg			S	Oral			Not Reported
	Seroplex 10 Mg			S	Oral			Not Reported
	Citalopram			S				Not Reported
	Nordazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13817481	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1731226US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder	Viibryd			S	Unknown	Unk, Unknown		Allergan
	Lexapro			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13818562	EXPEDITED (15-DAY)		DE, OT	US-ALLERGAN-1731671US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Homicide	Lexapro			S		Unk		Allergan
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13819903	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-GLENMARK PHARMACEUTICALS-2017GMK028308		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bezoar; Cardiogenic Shock; Coma; Gastrointestinal Ischaemia; Hepatic Failure; Hyperlactacidaemia; Intentional Overdose; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Overdose; Shock; Skin Necrosis; Toxicity To Various Agents	Citalopram Hydrobromide			S	Unknown	Unk		Glenmark
	Sevikar			S	Oral	129 Tablets, 1.29 G Of Amlodipine And 5.16 G Of Olmesartan		Not Reported
	Atarax /00058401/			S	Oral	28 Tabets Of 25 Mg In Total		Not Reported
	Lysanxia			S	Oral	42 Tablets Of 10mg In Total		Not Reported
	Seroplex			S	Oral	28 Tablets 10 Mg		Not Reported
	Zolpidem			S	Unknown	Unk		Not Reported
	Nordazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13693008	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-143443		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Lorazepam			S	Oral	10 Ml Total		Sun
	Escitalopram			S	Oral	6 Df Total		Not Reported
	Carbolithium 150 Mg			C	Unknown			Not Reported
	Quetiapine Fumarate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13819978	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2017005418			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Overdose; Pain In Extremity; Photophobia; Somnolence	Escitalopram			S	Oral	300 Mg, Unk		Macleods
	Melatonine			S	Oral	60 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13821173	EXPEDITED (15-DAY)		HO	LT-ORION CORPORATION ORION PHARMA-ENT2016-0253			Male	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Gait Disturbance; Nausea; Product Dispensing Error; Wrong Product Administered	Escitalopram Orion			S	Oral	Not Used		Not Reported
	Entacapone (Trade Name Unknown)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822667	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2017329424		54 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Suicide Attempt	Ziprasidone Hcl			S	Oral	40 Mg		Pfizer
	Mirzaten			S	Oral	30 Mg		Not Reported
	Serpentil /01588502/			S	Oral	10 Mg		Not Reported
	Loquen			S	Oral	200 Mg		Not Reported
	Diazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822729	EXPEDITED (15-DAY)		HO	PHHY2017PT112464		79 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antipsychotic Drug Level Above Therapeutic; Coma;	Clozapine			S	Unknown	Unk		Not Reported

Hallucination, Visual; Hyperhidrosis; Hypertension; Musculoskeletal Stiffness; Mutism; Neuroleptic Malignant Syndrome; Pyrexia; Renal Impairment; Rhabdomyolysis; Urinary Tract Infection	Carbidopa, Levodopa	S	Unknown	Unk		Not Reported
	Escitalopram	S	Unknown	Unk		Not Reported
	Memantine	S	Unknown	Unk		Not Reported
	Pregabalin	S	Unknown	Unk		Not Reported
	Amantadine Sandoz	S	Unknown	Unk		Novartis
	Lithium	S	Unknown	Unk		Not Reported
	Zotepine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13020376	NON-EXPEDITED		OT	FR-EISAI MEDICAL RESEARCH-EC-2016-023171			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Aricept			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral	Dose Reduced (Unspecified)		Not Reported
	Neurontin			S	Oral	1800 Mg		Not Reported
	Neurontin			S	Oral	Dose Reduced (Unspecified)		Not Reported
	Inegy			C		Unknown		Not Reported
	Bisoprolol			C		Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13170106	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-CIPLA LTD.-2017GB01382			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anaemia; Anger; Anxiety; Atrial Tachycardia; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal;	Citalopram			S	Oral	10 Mg		Invagen
	Escitalopram			S	Oral	10 Mg		Invagen

Dizziness; Dyskinesia; Fatigue; Food Intolerance; Functional Gastrointestinal Disorder; Hypervigilance; Lacrimal Disorder; Mood Swings; Muscle Disorder; Muscle Tightness; Musculoskeletal Stiffness; Nausea; Panic Reaction; Paraesthesia; Restless Legs Syndrome; Saliva Altered; Sinus Node Dysfunction; Sleep Disorder; Syncope; Tearfulness; Vision Blurred; Visual Impairment; Vitreous Floaters; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13183374	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-132335		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anaemia; Anger; Anxiety; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal; Dizziness; Dyskinesia; Fatigue; Food Intolerance; Functional Gastrointestinal Disorder; Hypervigilance; Lacrimal Disorder; Mood Swings; Muscle Disorder; Muscle Tightness; Musculoskeletal Stiffness; Nausea; Panic Reaction;	Citalopram			S	Oral	10 Mg		Sun
	Escitalopram			S	Oral	10 Mg		Not Reported

Paraesthesia; Restless Legs Syndrome; Saliva Altered; Sinus Node Dysfunction; Sleep Disorder; Syncope; Tearfulness; Vision Blurred; Visual Impairment; Vitreous Floaters; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13824725	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-TEVA-790033ACC		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Anaemia; Anger; Anxiety; Atrial Tachycardia; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal; Dizziness; Dyskinesia; Fatigue; Food Intolerance; Functional Gastrointestinal Disorder; Hypervigilance; Lacrimal Disorder; Mood Swings; Muscle Disorder; Muscle Tightness; Musculoskeletal Stiffness; Nausea; Panic Reaction; Paraesthesia; Restless Legs Syndrome; Saliva Altered; Sinus Node Dysfunction; Sleep Disorder; Syncope; Tearfulness; Vision Blurred; Visual Impairment; Vitreous Floaters; Withdrawal Syndrome	Escitalopram			S	Oral			Ivax
	Citalopram			S	Oral			Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13825580	NON-EXPEDITED			US-GLENMARK PHARMACEUTICALS-2017GMK027367			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Diarrhoea; Dizziness; Gait Disturbance; Nausea; Product Substitution Issue	Omeprazole			S	Oral	1 Df, Am		Glenmark
	Lexapro			S	Unknown	Unk		Not Reported
	Hydrochloroth			S	Unknown	Unk		Not Reported
	Metoprolol			C	Oral	25 Mg, Qd		Not Reported
	Aspirin /00002701/			C	Oral	81 Mg, Qd		Not Reported
	Vitamin D3			C	Oral	2000 Iu, Qd		Not Reported
	Hydrochlorothiazide			C	Oral	12.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13825896	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-067348			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prolactin-Producing Pituitary Tumour	Abilify			S	Unknown	Unk		Bristol Myers Squibb
	Rexulti			S	Unknown	1 Mg, Unk		Not Reported
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13828786	DIRECT					47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Crying; Drug Ineffective; Mood Altered; Product Colour Issue; Product Substitution Issue	Escitalopram Oxalate Oral Solution 5 Mg5ml Batch No. E162342	Y		S	Oral	Quantity:10 Ml;		Camber
	Zyrtec			C				Not Reported
	Sumatriptan			C				Not Reported
	Valium			C				Not Reported

	Calcium	C	Not Reported
	Vitamin C	C	Not Reported
	Probiotics	C	Not Reported
	Metamucil	C	Not Reported
	Miralax	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13828974	DIRECT		DS			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne Cystic; Drug Ineffective; Pain; Product Substitution Issue	Escitalopram			S	Oral	Quantity:30 Tablet(S);		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13577406	NON-EXPEDITED			US-PFIZER INC-2017228100		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Calan			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Lidocaine Hcl			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Augmentin			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Benicar			S		Unk		Not Reported
	Ceftin			S		Unk		Not Reported
	Compazine			S		Unk		Not Reported
	Entex La /00922801/			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

	Macrobid	S	Unk	Not Reported
	Motrin	S	Unk	Not Reported
	Paxil	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Tamiflu	S	Unk	Not Reported
	Tetanus Vaccines & Toxoid	S	Unk	Not Reported
	Valium	S	Unk	Not Reported
	Xylocaine /00033402/	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13828377	NON-EXPEDITED			US-PFIZER INC-2017333238		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S		Unk		Pfizer
	Pristiq			S		Unk		Pfizer
	Paxil			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Vivactil			S		Unk		Not Reported
	Parnate			S		Unk		Not Reported
	Emsam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13829575	EXPEDITED (15-DAY)		HO, LT, OT	CZ-ELI_LILLY_AND_COMPANY-CZ201707012131		63 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Product Misuse; Overdose; Suicide Attempt	Humalog Lispro		S	Unknown	200 Ug, Bid	Eli Lilly And Co
	Cipralex /01588501/		S	Unknown	20 Mg, Daily	Not Reported
	Spiropent		S	Unknown	Unk Unk, Unknown	Not Reported
	Spiropent		S	Unknown	20 Mg, Daily	Not Reported
	Robitussin /00048102/		S	Unknown	100 Ml, Single	Not Reported
	Metfirex		S	Unknown	20 Df, Single	Not Reported
	Siofor		S	Unknown	500 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13831329	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1732446US		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Malaise; Nervousness; Psychotic Disorder; Tachycardia; Vision Blurred	Lexapro			S	Unknown	5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13143797	EXPEDITED (15-DAY)		HO, LT	FR-ABBVIE-17P-056-1845878-00		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Bronchitis; Coma; Fear; Intentional Product Misuse; Nightmare; Oral Viral Infection; Sleep Disorder; Suicidal Ideation; Suicide Attempt	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Seresta			S	Unknown			Not Reported
	Zopiclone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13727755	EXPEDITED (15-DAY)		OT	PHEH2017US019860		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Faeces Soft; Haematochezia; Hyperhidrosis; Muscle Spasms; Pain; Tremor	Cosentyx	S	Subcutaneous	150 Mg, Qw	Novartis
	Cosentyx	S			Novartis
	Escitalopram Oxalate	S	Unknown	10 Mg, Qd	Not Reported
	Calcium Vitamin D3	C	Unknown	1200 Mg, Unk	Not Reported
	Folic Acid	C	Unknown	Unk Unk, Bid	Not Reported
	Atorvastatin	C	Unknown	40 Mg, Qhs	Not Reported
	Hydrochlorothiazide	C	Unknown	25 Mg, Qhs (Bed Time)	Not Reported
	Methotrexate	C	Unknown	10 Df, Unk (On Monday)	Not Reported
	Oxycodone And Acetaminophen	C	Unknown	Unk Unk, Prn	Not Reported
	Aspirin	C	Unknown	325 Mg, Unk	Not Reported
	Prednisone	C	Unknown	3 Df, Qw	Not Reported
	Eye Drops	C	Unknown		Not Reported
	Oxycodone	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Vitamin D2	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Hydroxyzine	C	Unknown		Not Reported
	Xanax	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13780657	NON-EXPEDITED			US-PFIZER INC-2017318206		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Desvenlafaxine Succinate Monohydrate			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Celexa /00582602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13836244	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-068507		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Therapeutic Response Decreased	Abilify			S	Endocervical	5 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Endocervical	15 Mg, Qd		Bristol Myers Squibb
	Escitalopram			S	Unknown	5 Mg, Qd		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Haloperidol			C	Oral	1 Mg, Q12h		Not Reported
	Haloperidol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13836396	EXPEDITED (15-DAY)		DE	JP-ELI_LILLY_AND_COMPANY-JP201708000775		30 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Completed Suicide; Decreased Appetite; Insomnia	Zyprexa			S	Oral	20 Mg, Daily		Eli Lilly And Co
	Zyprexa			S	Oral	15 Mg, Daily		Eli Lilly And Co
	Abilify			S	Oral	24 Mg, Daily		Not Reported
	Lexapro			S	Oral	10 Mg, Daily		Not Reported
	Reflex /01293201/			S	Oral	15 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2017	13839105	DIRECT		OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Product Substitution Issue; Pruritus; Vision Blurred	Escitalopram Teva	Y		S	Oral	Quantity:1 Tablet(S);		Teva
	Lexapro			C				Not Reported
	Cod Liver Oil			C				Not Reported
	Apple And Ginger Tea			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2017	13839151	DIRECT		LT, OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Self-Injurious Ideation; Suicidal Ideation	Lexapro			S	Oral	Quantity:1 Capsule(S);		Cipla
	Lisinopril			C				Not Reported
	Prilosec			C				Not Reported
	Multi Vitamin			C				Not Reported
	Miralax			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13018272	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2016569456		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Cyanosis; Jaw Disorder; Malaise; Musculoskeletal Disorder; Pallor	Aricept			S	Oral	10 Mg, 1x/Day		Pfizer
	Neurontin			S	Oral	3 Df, Daily (1800 Mg)		Pfizer
	Neurontin			S	Oral	(Dose Reduced (Unspecified) (Unknown)		Pfizer
	Seroplex			S	Oral	20 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	Dose Reduced (Unspecified) (Unknown)		Not Reported
	Inegy			C		Unk		Not Reported
	Bisoprolol Hemifumarate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13506827	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-1960253-00		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apraxia; Colitis Ulcerative; Crying; Depression; Headache; Herpes Zoster; Somnolence; Suicidal Ideation	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Lexapro			S	Unknown			Not Reported
	Allopurinol			C				Not Reported
	Allopurinol			C				Not Reported
	Imuran			C				Not Reported
	Tramadol			C				Not Reported

Omeprazole	C		Not Reported
Calcium	C		Not Reported
Vitamin D Nos	C		Not Reported
Risaquad	C		Not Reported
Combivent	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13778791	NON-EXPEDITED			US-PFIZER INC-2017314617			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressive Symptom; Disease Recurrence; Drug Intolerance; Gastrointestinal Disorder	Sertraline Hcl			S	Oral	100 Mg, 1x/Day		Pfizer
	Sertraline Hcl			S				Pfizer
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13838483	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2014-06285		74 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haemorrhage; Tachycardia	Mirtazapine 30mg			S	Oral	30 Mg, Daily		Aurobindo
	Mirtazapine 30mg			S	Oral	15 Mg, Daily		Aurobindo
	Cipralex /01588501/			S	Oral	5 Mg, Daily		Not Reported
	Cipralex /01588501/			S	Oral	10 Mg, Daily		Not Reported
	Clexane			S	Subcutaneous	0.6 Ml, Unk		Not Reported
	Clexane			S	Subcutaneous	1.2 Ml, Daily		Not Reported
	Clexane			S	Subcutaneous	0.6 Ml, Daily		Not Reported
	Ebixa			C	Oral	10 Mg, Daily		Not Reported
	Ebixa			C	Oral	15 Mg, Daily		Not Reported
	Ebixa			C	Oral	20 Mg, Daily		Not Reported
	Ebixa			C	Oral	15 Mg, Daily		Not Reported
	Ebixa			C	Oral	10 Unk, Unk		Not Reported
	Risperdal			C	Oral	1 Mg, Daily		Not Reported

	Risperdal	C	Oral	0.5 Mg, Daily	Not Reported
	Bisoprolol	C	Oral	5 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13839254	EXPEDITED (15-DAY)		OT	JP-009507513-1707JPN000521J		33 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt	Belsomra Tab 20mg			S	Oral	160 Mg, Unk		Merck
	Tetramide Tablets 10mg			S	Oral	220 Mg, Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Unk		Not Reported
	Loxoprofen			S	Oral	180 Mg, Unk		Not Reported
	Flunitrazepam			S	Oral	4 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13839716	NON-EXPEDITED			US-SUNOVION-2017SUN003249		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flight Of Ideas; Hypomania; Sleep Disorder	Latuda			S	Oral	20 Mg, Unk		Sunovion
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	11054240	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2015-03378		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed; Exposure During Pregnancy	Mirtazapine			S	Oral	7.5 Mg, Unk		Aurobindo
	Cipralex /01588502/			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13463271	EXPEDITED (15-DAY)		DS, OT	IE-ALLERGAN-1715101US		32 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Affect Lability; Anxiety; Back Pain; Constipation; Decreased Appetite; Depressed Mood; Diarrhoea; Disturbance In Attention; Dizziness; Drug Dependence; Dyspepsia; Electrocardiogram Qt Prolonged; Fatigue; Feeling Abnormal; Flatulence; Flushing; Headache; Heart Rate Irregular; Hot Flush; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Insomnia; Irritability; Irritable Bowel Syndrome; Malaise; Nausea; Nervousness; Pain; Palpitations; Panic Attack; Photophobia; Sleep Paralysis; Somnolence; Tension Headache; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	Between 2.5 Mg And 5 Mg, Every 3/4 Days		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Valium			C	Oral	2.5 Mg - 5 Mg Daily, Prn		Not Reported
	Valium			C	Oral	Between 2.5 Mg And 5 Mg Daily Every 3/4 Days		Not Reported
	Valium			C				Not Reported
	Lexapro Film-Coated Tablets			S	Oral			Not Reported
	Lexapro Film-Coated Tablets			S	Oral			Not Reported
	Lexapro Film-Coated Tablets			S	Oral			Not Reported
	Lexapro Film-Coated Tablets			S	Oral			Not Reported
	Lexapro Film-Coated Tablets			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13743647	EXPEDITED (15-DAY)		HO	BE-ALLERGAN-1728858US		82 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Disorientation; Drug Interaction; Dyspnoea; Hyperthermia; Malaise; Nervousness; Psychomotor Hyperactivity; Serotonin	Escitalopram Oxalate - Bp			S	Unknown	Unknown		Allergan
	Azilect			S	Unknown	Unknown		Not Reported
	Fenoterol Hydrobromide W/Ipratropium Bromide			C	Unknown			Not Reported
	Fluticasone Propionate W/Formoterol Fumarate			C	Unknown			Not Reported

Syndrome	Methylprednisolone	C	Unknown		Not Reported
	Pramipexole	C	Unknown		Not Reported
	Levodopa Benserazide	C	Unknown		Not Reported
	Bumetanide	C	Unknown		Not Reported
	Calcium Carbonate	C	Unknown		Not Reported
	Molsidomine	C	Unknown		Not Reported
	Omeprazol	C	Unknown		Not Reported
	Azitromycine	C	Unknown	3 Times A Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13842445	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1733422US		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Overdose; Somnolence	Escitalopram Oxalate - Bp			S	Oral	280 Mg, Single		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Duloxetine Base			S	Oral	840 Mg, Single		Not Reported
	Duloxetine Base			S	Oral	60 Mg, Qd		Not Reported
	Quetiapine			C	Unknown			Not Reported
	Perindopril/Indapamide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13842447	EXPEDITED (15-DAY)		HO, LT	CZ-ALLERGAN-1733418US		63 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown	Overdose: 20x28 Tablet		Allergan
	Robitussin			S	Unknown	Overdose: 100 Ml = 150 Mg		Not Reported
	Spiropent			S	Unknown	Overdose:500 X 10 Tablet		Not Reported
	Siofor			S	Unknown	500mg X 10times		Not Reported
	Metformin			S	Unknown	Overdose: 500x20		Not Reported

	Humalog		S	Unknown	Overdose: 2 X 200 Ug			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13843430	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Wrong Product Administered	Citalopram Hydrobromide			S				Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13847306	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1733483US		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hypotonia Neonatal; Respiratory Distress	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg		Allergan
	Paroxetine Arrow			S	Transplacental	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13847754	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Withdrawal Syndrome	Escitalopram 10mg			S				Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13848425	NON-EXPEDITED			US-PURDUE-USA-2017-0139906			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Butrans			S	Transdermal	10 Mcg/Hr, Weekly		Purdue
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13848942	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Therapy Non-Responder	Escitalopram 20 Mg Mylan			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13849292	DIRECT		OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Lupin
	Lisinopril			C				Not Reported
	Low Dose Aspirin			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13850234	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1733769US		19 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Sopor	Escitalopram Oxalate Unk			S	Oral	Overdose: 120 Mg		Allergan
	Lamictal			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13850574	EXPEDITED (15-DAY)		OT	FR-SA-2017SA143166		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Stilnox			S	Oral			Not Reported
	Valsartan			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13820282	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2017-38399		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depressed Mood; Expiratory Reserve Volume Decreased	Olanzapine			S	Unknown			Aurobindo
	Escitalopram			S	Unknown			Aurobindo
	Trazodone			S				Aurobindo
	Bupropion			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13821081	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2017-38401		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Interaction; Expiratory Reserve Volume Decreased; Failure To Thrive; Lung Disorder	Escitalopram			S	Unknown	30 Mg, Daily		Aurobindo
	Hydroxyzine			S	Unknown	25 Mg, Two Times A Day		Aurobindo
	Hydroxyzine			S				Aurobindo
	Ivacaftor W/Lumacaftor			S	Unknown	250/400mg At Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13853628	EXPEDITED (15-DAY)		HO	CH-BAYER-2017-150291		36 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Haematoma; Mouth Injury; Periorbital Haematoma	Aspirin Cardio 100 Mg			S	Oral	100 Mg, Qd		Bayer
	Cipralex			S		10 Mg, Qd		Not Reported
	Plavix			C	Oral	75 Mg, Qd		Not Reported
	Atorvastatin Calcium			C		40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13854216	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Dispensing Error	Escitalopram Oxalate			S				Not Reported
	Citalopram Hydrobromide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13857141	NON-EXPEDITED			US-ROCHE-766923		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nausea	Tamiflu			S	Oral			Not Reported
	Lexapro			S	Oral	Other Indication: Depression		Not Reported
	Lexapro			S	Oral			Not Reported
	Zocor			C	Oral			Not Reported
	Diovan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13857215	NON-EXPEDITED			US-ROCHE-763066			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Tamiflu			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13752118	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-1728792US		69 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Polyuria; Seizure; Thirst	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

	Bufferin	C	Oral	Unk		Not Reported
	Lansoprazole	C	Oral	Unk		Not Reported
	Lansoprazole	C		15 Mg		Not Reported
	Pravastatin Na	C	Oral	Unk		Not Reported
	Pravastatin Na	C		5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13859048	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004611			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Use Disorder; Product Prescribing Error	Paracetamol			S				Not Reported
	Prednisolone			S				Concordia
	Clonidine			S				Concordia
	Alprazolam			S				Not Reported
	Buprenorphine Hydrochloride			S				Not Reported
	Cocaine			S				Not Reported
	Dexamfetamine Sulphate			S				Not Reported
	Escitalopram			S				Not Reported
	Fentanyl			S				Not Reported
	Folic Acid			S				Not Reported
	Lorazepam			S				Not Reported
	Methotrexate			S				Not Reported
	Naproxen			S				Not Reported
	Oxazepam			S				Not Reported
	Oxycodone			S				Not Reported
	Pantoprazole			S				Not Reported
	Pregabalin			S				Not Reported
	Temazepam			S				Not Reported
	Ritalin			S				Not Reported
	Tramadol			S				Not Reported
	Zolpidem			S				Not Reported
	Cannabis Preparation			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13859810	EXPEDITED (15-DAY)		HO	FR-ASTELLAS-2017US030402		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hepatic Function Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use	Vesicare			S	Oral			Astellas
	Seroplex			S	Oral			Not Reported
	Furosemide			C	Oral	20 Mg, Thrice Daily (Long Term Treatment)		Not Reported
	Metformine			C	Oral			Not Reported
	Bisoprolol			C	Oral			Not Reported
	Simvastatine			C	Oral	20 Mg, Once Daily (Long Term Treatment)		Not Reported
	Aspegic /00002703/			C	Oral			Not Reported
	Permixon			C	Oral	1 Df, Twice Daily (Long Term Treatment)		Not Reported
	Procoralan			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Procoralan			C	Unknown	Unk, Unknown Freq.		Not Reported
	Lexomil			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Diffu K			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Temesta /00273201/			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Timoferol			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13861281	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1734120US			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Feeling Abnormal	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Cymbalta			S	Unknown			Not Reported
	Pristiq			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13795948	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1731418US		38 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aphasia; Drug Abuse; Dysarthria; Self-Injurious Ideation; Sopor	Escitalopram Oxalate Unk	S	Unk		Allergan
	Delorazepam	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13819264	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2017-37896		38 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Drug Abuse; Dysarthria; Intentional Self-Injury; Sopor	Delorazepam			S	Oral	1 Df, Total		Not Reported
	Escitalopram			S	Oral	1 Df Total		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13863454	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP016384			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Syndrome; Condition Aggravated; Drug-Disease Interaction; Insomnia	Escitalopram Oxalate			S	Unknown	20 Mg, Every Day		Apotex
	Escitalopram Oxalate			S				Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13865685	EXPEDITED (15-DAY)		HO, OT	PHFR2017GB006484		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection	Citalopram			S	Unknown			Novartis
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13865881	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1734634US		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Bid		Allergan

Hormone Secretion; Incorrect Dose Administered	Cisplatine	S	Intravenous (not otherwise specified)	Unk Unk, Qd	Not Reported
	Navelbine	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
	Levothyrox	C	Oral	75 Mg, Qd	Not Reported
	Seresta	C	Oral	10 Mg, Bid	Not Reported
	Oxycontin Lp	C	Oral	10 Mg, Bid	Not Reported
	Oxynorm	C	Oral	Unk, Prn	Not Reported
	Emend	C	Unknown	125 Mg, Single	Not Reported
	Emend	C	Unknown	80 Mg, Single	Not Reported
	Emend	C	Unknown	80 Mg, Single	Not Reported
	Primperan	C	Unknown	10 Mg, Qd	Not Reported
	Zophren	C	Unknown		Not Reported
	Acupan	C	Unknown		Not Reported
	Cortancyl	C	Unknown	40 Mg, Qd	Not Reported
	Paracetamol	C	Unknown		Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Tramadol	C	Unknown	Unk	Not Reported
	Tramadol	C	Unknown	Unk	Not Reported
	Buspirone	C	Unknown		Not Reported
	Hydroxyzine	C	Unknown		Not Reported
	Eupantol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13866853	EXPEDITED (15-DAY)		DE, OT	FR-ALLERGAN-1734649US		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Cordarone			S	Oral	200 Mg, Qd		Not Reported
	Eliquis			S	Oral	2.5 Mg, Qd		Not Reported

Tahor	S	Oral	10 Mg, Qd		Not Reported
Lasilix	C	Oral			Not Reported
Coversyl	C	Unknown			Not Reported
Inipomp	C	Unknown			Not Reported
Forlax	C	Unknown			Not Reported
Gaviscon	C	Unknown			Not Reported
Doliprane	C	Unknown			Not Reported
Xanax	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2017	13869720	EXPEDITED (15-DAY)		CA, HO	FR-ASTRAZENECA-2017SE81799		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Drugs Affecting Foetus; Spina Bifida	Inexium			S	Transplacental			Astrazeneca
	Inexium			S	Transplacental			Astrazeneca
	Inexium			S	Transplacental			Astrazeneca
	Inexium			S	Transplacental			Astrazeneca
	Seroplex			S	Transplacental	10 Mg/Ml		Not Reported
	Seroplex			S	Transplacental	10 Mg/Ml		Not Reported
	Colchicine			S	Transplacental			Not Reported
	Colchicine			S	Transplacental			Not Reported
	Coumadine			S	Transplacental			Not Reported
	Coumadine			S	Transplacental			Not Reported
	Dafalgan Codeine			S	Transplacental			Not Reported
	Dalfagan Codeine			S	Transplacental			Not Reported
	Dalfagan Codeine			S	Transplacental			Not Reported
	Dalfagan Codeine			S	Transplacental			Not Reported
	Specialfoldine			S	Transplacental	5mg/J		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2017	13869851	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017345909		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Rhabdomyolysis; Serotonin Syndrome	Zyvoxid			S	Oral	600 Mg, 2x/Day		Pfizer
	Modopar			S	Oral	1 Df, Daily		Not Reported
	Seroplex			S	Oral	1 Df, Daily		Not Reported
	Coveram			C		Unk		Not Reported
	Lasilix /00032601/			C		Unk		Not Reported
	Dermoval /00337102/			C		Unk		Not Reported
	Neo Mercazole			C		Unk		Not Reported
	Doliprane			C		Unk		Not Reported
	Exelon /01383201/			C		Unk		Not Reported
	Kardegic			C		Unk		Not Reported
	Levothyrox			C		Unk		Not Reported
	Atenolol			C		50 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2017	13870100	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1734651US		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypochloraemia; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Lasilix			S	Oral	40 Mg, Qd		Not Reported
	Coversyl			S	Oral	2 Mg, Qd		Not Reported
	Inipomp			S	Oral	20 Mg, Qd		Not Reported
	Forlax			S	Oral	4 G, Qd		Not Reported
	Tahor			C	Unknown			Not Reported
	Eliquis			C	Unknown			Not Reported

	Gaviscon	C	Unknown	Not Reported
	Doliprane	C	Unknown	Not Reported
	Xanax	C	Unknown	Not Reported
	Cordarone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13871290	EXPEDITED (15-DAY)		HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2017005698			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection	Escitalopram			S	Oral	10 Mg, Unk		Macleods
	Citalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13871362	NON-EXPEDITED			US-FRI-1000087220			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S		Unk		Allergan
	Celexa			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13871371	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1000084086		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicide Attempt	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Celexa			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13871463	NON-EXPEDITED			US-ALLERGAN-1679093US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Citalopram Hydrobromide - Bp	S		Allergan
	Lexapro	S		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13871595	NON-EXPEDITED			US-ALLERGAN-1711380US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity;	Lexapro			S				Allergan
Palpitations	Celexa			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13871653	NON-EXPEDITED			US-ALLERGAN-1722214US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia	Celexa			S	Unknown			Allergan
	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13873164	NON-EXPEDITED		HO	FR-EISAI MEDICAL RESEARCH-EC-2017-030159		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder	Aricept			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Kardegic			C	Oral			Not Reported
	Movicol			C	Oral			Not Reported
	Uvedose			C	Oral			Not Reported
	Seresta			C	Oral			Not Reported
	Kayexalate			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13873690	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1734898US		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Disturbance In Attention; Drug Ineffective; Encephalitis; Hallucination; Memory Impairment; Myoclonus; Paranoia; Respiratory Distress; Small Cell Lung Cancer	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13873932	EXPEDITED (15-DAY)		HO	GB-ALLERGAN-1734929US		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection	Citalopram Hydrobromide - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13875208	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2017M1051028			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Amisulpride			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Oxazepam			S		Unk		Not Reported
	Clozapine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	12100319	NON-EXPEDITED			US-CELGENEUS-USA-2016024167		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Increased; Decreased Appetite; Diarrhoea; Heart Rate Increased; Nausea; Weight Decreased	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral	40 Milligram		Celgene
	Lexapro			S	Unknown			Not Reported
	Singulair			C	Unknown			Not Reported
	Buspar			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	12111319	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2016105438		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Suicidal Ideation; Suicide Attempt	Sertraline Hcl			S	Oral	25 Mg, 1x/Day		Pfizer
	Sertraline Hcl			S	Oral	50 Mg, 1x/Day		Pfizer
	Sertraline Hcl			S	Oral	75 Mg, 1x/Day		Pfizer
	Sertraline Hcl			S	Oral	100 Mg, 1x/Day		Pfizer
	Lexapro			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13858372	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-147337		29 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Erectile Dysfunction; Libido Decreased; Sexual Dysfunction; Therapy Cessation	Paroxetine			S	Unknown	10 Mg Every 24h		Sun
	Escitalopram			S	Unknown	15 Mg, Daily		Not Reported
	Lorazepam			S	Unknown	20 Mg, Daily		Sun
	Lorazepam			S				Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13875871	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-			Unknown	GBR

MAC2017005719

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Bruxism	Escitalopram			S	Oral	20 Mg, Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13876461	EXPEDITED (15-DAY)		HO, OT	GB-TORRENT-00015497		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection	Citalopram			S				Unknown
	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13876467	EXPEDITED (15-DAY)		HO, OT	BR-TORRENT-00004111		68 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Headache; Off Label Use; Platelet Count Decreased	Espran			S				Torrent
	Losartan Potassium			C				Unknown
	Glifage			C				Unknown
	Puran T4			C				Unknown
	Azukon Mr			S				Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13876774	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2017FR13909			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis	Escitalopram			S	Unknown	Unk, Titrated From 5 To 20 Mg/Day		Invagen
	Escitalopram			S	Unknown	30 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13878176	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1734887US		36 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Haematoma; Wound	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Aspirin Cardio			S	Oral	100 Mg, Qd		Not Reported
	Plavix			C	Oral	75 Mg, Qd		Not Reported
	Atorvastatin Pfizer			C	Oral	40 Mg, Qd		Not Reported
	Tamesta			C	Unknown	Unk		Not Reported
	Tamesta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13879366	EXPEDITED (15-DAY)		OT	CA-TEVA-796262ACC		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Shock Symptom	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13879575	EXPEDITED (15-DAY)		DS, HO	CA--2017-CA-000007		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Optic Nerve Injury; Shock	Amlodipine Besylate Brand Unspecified (Vivimed)			S	Unknown			Vivimed Labs
	Escitalopram			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	12525811	EXPEDITED (15-DAY)		DE, OT	JP-009507513-1607JPN000690			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Mirtazapine	S	Oral	Unknown		Merck
	Levomepromazine	S	Unknown	Unk		Not Reported
	Duloxetine Hydrochloride	S	Oral	Unk		Not Reported
	Alprazolam	S	Oral	Unk		Not Reported
	Escitalopram Oxalate	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13820787	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1045646			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Drug Abuse; Dysarthria; Intentional Self-Injury; Sopor	Delorazepam			S	Oral	1 Df Total		Not Reported
	Escitalopram			S	Oral	1 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13821971	EXPEDITED (15-DAY)		HO	IT-TEVA-791523ACC		38 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Drug Abuse; Dysarthria; Intentional Self-Injury; Sopor	Delorazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13879898	EXPEDITED (15-DAY)		CA, HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-071694		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Spina Bifida	Coumadine			S	Transplacental	6 Mg, Qd		Bristol Myers Squibb
	Dafalgan Codeine			S	Transplacental	2 Tab, Unk		Bristol Myers Squibb
	Dafalgan Codeine			S	Transplacental	2 Tab, Unk		Bristol Myers Squibb
	Dafalgan			S	Transplacental	3 G, Qd		Bristol Myers Squibb
	Dafalgan			S	Transplacental	3 G, Qd		Bristol Myers Squibb

Colchicine Opocalcium	S	Transplacental	1 Mg, Qd		Not Reported
Lovenox	S	Transplacental	40000 Iu, Qd		Not Reported
Lovenox	S	Transplacental	60000 Iu, Qd		Not Reported
Inexium /01479302/	S	Transplacental	40 Mg, Qd		Not Reported
Inexium /01479302/	S	Transplacental	20 Mg, Qd		Not Reported
Speciafoldine	S	Transplacental	5 Mg, Qd		Not Reported
Seroplex	S	Transplacental	10 Mg, Qd		Not Reported
Cortancyl	S	Transplacental	10 Mg, Qd		Not Reported
Cortancyl	S	Transplacental	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13880278	EXPEDITED (15-DAY)		HO	US-ABBVIE-17K-163-2052012-00		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dermatitis Allergic; Drug Hypersensitivity; Dyspnoea; Perirectal Abscess; Supraventricular Tachycardia	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Lexapro			S	Oral			Not Reported
	Omeprazole			C				Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13880705	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017347072		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypochloraemia; Hyponatraemia	Inipomp			S	Oral	20 Mg, Qd		Pfizer
	Seroplex			S	Oral	10 Mg, Daily		Not Reported
	Lasilix			S	Oral	40 Mg, Qd		Not Reported
	Coversyl			S	Oral	2 Mg, Qd		Not Reported
	Forlax			S	Oral	4 G, Qd		Not Reported
	Cordarone			C		Unk		Not Reported

Eliquis	C	Unk		Not Reported
Tahor	C	Unk		Not Reported
Doliprane	C	Unk		Not Reported
Xanax	C	Unk		Not Reported
Gaviscon	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13881533	EXPEDITED (15-DAY)		CA, HO	FR-ALLERGAN-1735288US		1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spina Bifida	Escitalopram Oxalate - Bp			S	Transplacental			Allergan
	Colchicine			S	Transplacental	1 Mg, Qd		Not Reported
	Coumadin			S	Transplacental			Not Reported
	Dafalgan Codeine			S	Transplacental	6 Df, Unk		Not Reported
	Dafalgan Codeine			S	Transplacental	2 Df, Bid		Not Reported
	Inexium			S	Transplacental	40 Mg, Qd		Not Reported
	Inexium			S	Transplacental	20 Mg, Qd		Not Reported
	Speciafoldine			S	Transplacental	5 Mg, Qd		Not Reported
	Cortancyl			C	Unknown			Not Reported
	Cortancyl			C	Unknown			Not Reported
	Dafalgan			C	Unknown			Not Reported
	Dafalgan			C	Unknown	3 Mg, Unk		Not Reported
	Lovenox			C	Unknown			Not Reported
	Lovenox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13881545	EXPEDITED (15-DAY)		CA, HO	FR-ALLERGAN-1735296US		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During	Escitalopram Oxalate - Bp			S	Oral			Allergan

Pregnancy	Colchicine	S	Unknown	1 Mg, Qd		Not Reported
	Coumadin	S	Unknown			Not Reported
	Dafalgan Codeine	S	Unknown			Not Reported
	Dafalgan Codeine	S	Transplacental			Not Reported
	Inexium	S	Unknown			Not Reported
	Inexium	S	Transplacental			Not Reported
	Speciafoldine	S	Unknown	5 Mg, Qd		Not Reported
	Cortancyl	C	Unknown			Not Reported
	Cortancyl	C	Unknown			Not Reported
	Dafalgan	C	Unknown			Not Reported
	Dafalgan	C	Unknown			Not Reported
	Lovenox	C	Unknown			Not Reported
	Lovenox	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13881728	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1735572US		21 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Bruxism	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13881791	EXPEDITED (15-DAY)		CA, HO, OT	US-APOTEX-2017AP016705			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Cardiac Malposition; Congenital Diaphragmatic Eventration; Deformity Thorax; Foetal Exposure During Pregnancy; Mass; Nipple Disorder; Patent Ductus Arteriosus; Rib	Topiramate			S	Transplacental	Unk		Apotex
	Escitalopram Oxalate			S	Transplacental	Unk		Apotex
	Tramadol Hydrochloride			S	Transplacental	Unk		Apotex
	Oxycodone And Acetaminophen			S	Transplacental	Unk		Not Reported

Deformity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13882230	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1735574US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Feeling Abnormal; Headache; Somnolence; Suicidal Ideation; Thinking Abnormal	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	12523094	EXPEDITED (15-DAY)		DE, OT	JP-009507513-1606JPN012698			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Suicidal Behaviour	Mirtazapine			S	Oral	Daily Dose Unknown		Merck
	Levomepromazine Maleate			S	Oral	Daily Dosage Unknown		Not Reported
	Cymbalta			S	Oral	Daily Dosage Unknown		Not Reported
	Alprazolam			S	Oral	Daily Dosage Unknown		Not Reported
	Lexapro			S	Oral	Daily Dosage Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13043020	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2016578929		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congestive Cardiomyopathy; Drug Reaction With Eosinophilia And Systemic Symptoms; Maternal Exposure During Pregnancy; Multiple Organ	Ondansetron			S	Transplacental	Unk		Pfizer
	Sertraline Hcl			S	Transplacental	Unk		Pfizer
	Progesterone			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported

Dysfunction Syndrome; Transmission Of An Infectious Agent Via Product

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13814061	EXPEDITED (15-DAY)		HO	IT-ACCORD-056432		38 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Drug Abuse; Dysarthria; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Accord
	Delorazepam			S	Oral	1 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13819993	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2017005495			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Abuse; Dysarthria; Somnolence	Escitalopram			S	Oral	Unk		Macleods
	Delorazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13861458	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1724047US		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Toxicity To Various Agents	Lexapro			S		20 Mg, Qam		Allergan
	Lexapro			S				Allergan
	Xanar Xr (Alprazolam)			S	Oral	2 Mg, Qam		Not Reported
	Xanar Xr (Alprazolam)			S				Not Reported
	Xanax			S	Oral	0.5 Mg, Bid		Not Reported
	Xanax			S				Not Reported
	Hydrocodone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13884328	EXPEDITED (15-DAY)		HO, OT	CA-CIPLA LTD.-2017CA13832			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Blindness; Haemolysis; Hypoglycaemia; Hypokalaemia; Intentional Overdose; Optic Atrophy; Optic Nerve Injury; Polyuria; Pulmonary Oedema; Renal Tubular Necrosis; Shock; Toxicity To Various Agents	Amlodipine			S	Unknown	150 Mg		Invagen
	Escitalopram			S	Unknown	60 Mg		Invagen
	Risperidone			S	Unknown	6 Mg		Cipla
	Furosemide			S	Intravenous bolus	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13885358	EXPEDITED (15-DAY)		LT	AT-TEVA-797220ISR		59 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus; Seizure	Fentoron 25µg/H - Transdermales Matrixpflaster			S		Every 3 Days		Actavis
	Trittico Retard 150mg - Tabletten			S		150 Milligram Daily; 0-0-1 (One In The Evening)		Not Reported
	Dibondrin- Ampullen			S	Intravenous (not otherwise specified)	2 Dosage Forms Daily; 1-0-1 (One In The Morning/Evening)		Not Reported
	Suprarenin			S		2 Dosage Forms Daily; 1-0-0(One In The Morning)Inhalative 2mg		Not Reported
	Cefepim-Mip 2g Pulver Zur Herstellung Einer Injektions-/Infusionslösun			S	Intravenous (not otherwise specified)	3 Dosage Forms Daily; 1-1-1 Iv (One In The Morning/Evening And At Noon)		Not Reported
	Aprednislon 5mg - Tabletten			S		5 Milligram Daily; 1-0-0		Not Reported

				(One In The Morning)	
	Vendal 10mg - Ampullen	S		0.5 Till 2 Amp As Needed In Case Of Pain Peaks	Not Reported
	Cipralex 10mg - Filmtabletten	S		10 Milligram Daily; 1-0-0 (One In The Morning)	Not Reported
	Lovenox 4.000 Ie (40mg)/0.4 Ml Injektionslösung In Einer Fertigspritze	C		40 Milligram Daily; 0-0-1 (One In The Evening)	Not Reported
	Pulmicort 0,5 Mg - Suspension Zur Inhalation	C		1 Milligram Daily; 1-0-1 (One In The Morning/Evening)	Not Reported
	Spirono Genericon 50mg Tabletten	C		25 Milligram Daily; 1/2-0-0 (Half In The Morning)	Not Reported
	Lyrica 75mg Hartkapseln	C		150 Milligram Daily; 1-0-1 (One In The Morning/Evening)	Not Reported
	Berodualin - Inhalationslösung	C		40x10 Drops	Not Reported
	Bricanyl 0.5mg - Ampullen	C	Intravenous (not otherwise specified)	.25 Milligram Daily; 1/2 Vial -0-0 (Half In The Morning)	Not Reported
	Nexium 40mg - Magensaftresistente Tablette	C		80 Milligram Daily; 1 -0-1 (One In The Morning/Evening)	Not Reported
	Lasix 40mg Tabletten	C		40 Milligram Daily; 0-1-0 (One At Noon)	Not Reported
	Advantan 0,1% - Creme	C		3xdaily	Not Reported
	Movicol Beutel	C		1 Dosage Forms Daily; 0-1-0 (One At Noon)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13886338	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-796749ACC		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection	Citalopram			S				Not Reported
	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13887761	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1735575US		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Pelvic Fracture	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Aricept			S	Oral	10 Mg, Qd		Not Reported
	Kardegic			C	Oral	75 Mg, Qd		Not Reported
	Movicol			C	Oral	Unk		Not Reported
	Uvedose			C	Oral			Not Reported
	Seresta			C	Oral	10 Mg, Qd		Not Reported
	Paracetamol			C	Oral	500 Mg, Bid		Not Reported
	Kayexalate			C	Oral	1 Spoon Per Day		Not Reported
	Zopiclone			C	Oral	3.75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13896539	DIRECT		DE			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound; Head Injury	Lexapro			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	12505480	EXPEDITED (15-DAY)		HO, LT, OT	FR-JNJFOC-20160307548		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Coma; Drug Interaction; Drug Level Increased; Myoclonus; Neuroleptic Malignant Syndrome; Status Epilepticus	Risperdal Consta			S	Intramuscular			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Risperdal Consta			S	Intramuscular			Not Reported
	Seroplex			S	Unknown			Not Reported

	Seroplex	S	Unknown			Not Reported
	Seresta	S	Unknown			Not Reported
	Clozapine	S	Unknown			Not Reported
	Theralene	S	Unknown	20 Drops At Night If Necessary		Not Reported
	Loxapine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13863457	NON-EXPEDITED			US-PFIZER INC-2017345209		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Medrol			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prinivil			S		Unk		Not Reported
	Reglan			S		Unk		Not Reported
	Salsalate			S		Unk		Not Reported
	Vioxx			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Avapro			S		Unk		Not Reported
	Disalcid			S		Unk		Not Reported
	Forteo			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Miacalcin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13887996	EXPEDITED (15-DAY)		OT	GB-ACCORD-057361		21 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Dreams; Bruxism	Escitalopram	S	Oral		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13890140	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2017GB14132			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Bruxism	Escitalopram			S	Oral	20 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13890977	EXPEDITED (15-DAY)		HO, LT, OT	CA-ACCORD-057474		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Blindness; Hypoglycaemia; Hypokalaemia; Intentional Overdose; Optic Atrophy; Pulmonary Oedema; Shock	Amlodipine			S				Accord
	Escitalopram			S				Accord
	Risperidone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13891021	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-057310		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection	Citalopram			S				Accord
	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13891187	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1050855			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection	Citalopram			S				Not Reported
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13891594	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP016691		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Apo-Hydro			S	Unknown	Unk		Apotex
	Apo-Escitalopram			S	Unknown	Unk		Apotex
	L-Thyroxine /00068001/			C	Unknown	Unk		Not Reported
	Telmisartan			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13891835	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2017-38935		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection	Citalopram			S	Unknown			Aurobindo
	Escitalopram			S	Oral	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13892460	EXPEDITED (15-DAY)		OT	GB-TEVA-796935ACC		21 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Bruxism	Escitalopram Oxalate			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13893652	EXPEDITED (15-DAY)		LT	AT-ALLERGAN-1735877US		59 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myoclonus; Seizure	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Trittico Retard			S	Unknown	150 Mg, Qd		Not Reported

Fentoron	S	Unknown	1 Fentoron 25 Microgram/Hour Every 3 Days	Not Reported
Dibondrin	S	Intravenous (not otherwise specified)	2 Df, Qd	Not Reported
Suprarenin	S	Unknown	2 Mg, Qd	Not Reported
Cefepim	S	Intravenous (not otherwise specified)	3 Df, Qd	Not Reported
Aprednislon	S	Unknown	5 Mg, Qd	Not Reported
Vendal	S	Unknown	Unk	Not Reported
Lovenox	C	Unknown	40 Mg, Qd	Not Reported
Pulmicort	C	Respiratory (inhalation)	0.5 Mg, Bid	Not Reported
Spirono	C	Unknown	25 Mg, Qd	Not Reported
Lyrica	C	Unknown	75 Mg, Bid	Not Reported
Berodualin	C	Respiratory (inhalation)	40 X 10 Drops	Not Reported
Bricanyl	C	Intravenous (not otherwise specified)	1/2 Amp - 0 - 0	Not Reported
Nexium	C	Unknown	1-0-1	Not Reported
Lasix	C	Unknown	40 Mg, Qd	Not Reported
Advantan	C	Unknown	3 X Tg1	Not Reported
Movicol	C	Unknown	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13760796	EXPEDITED (15-DAY)		DE, LT, OT	JP-ALLERGAN-1729779US		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardio-Respiratory Arrest; Chest Pain; Malaise; Somnolence	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Effexor			S	Oral	37.5 Mg, Unk		Not Reported
	Effexor			S	Oral	37.5 Mg, Qd		Not Reported

Lamictal	S	Oral	400 Mg, Qd		Not Reported
Abilify	S	Oral	3 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13790340	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-065694		16 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Incorrect Dose Administered; Oculogyric Crisis; Suicide Attempt	Abilify			S	Unknown			Bristol Myers Squibb
	Lexapro			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported
	Celexa /00582602/			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Klonopin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13895031	NON-EXPEDITED			US-AMGEN-USASL2017124992			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Heart Rate Increased; Rash	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Albuterol			C	Unknown	Unk		Not Reported
	Lipitor			C	Unknown	Unk		Not Reported
	Symbyax			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13895614	NON-EXPEDITED			US-PFIZER INC-2017363063		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13895781	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2017-39000		21 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Bruxism	Escitalopram			S	Oral	20 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13896054	EXPEDITED (15-DAY)		HO, OT	US-HETERO CORPORATE-HET2017US00088		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	10 Mg, Qd		Hetero
	Dextromethorphan Hbr W/Promethazine Hcl			S		Unk		Not Reported
	Labetalol			C	Unknown	100 Mg, Qd		Not Reported
	Amlodipine			C		5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13896695	EXPEDITED (15-DAY)		HO, LT, OT	CA-LUPIN PHARMACEUTICALS INC.-2017-04714		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Depressed	Amlodipine			S	Oral	150 Mg, Unk		Lupin

Level Of Consciousness; Hypotension; Intentional Overdose; Renal Tubular Necrosis; Retinal Ischaemia; Shock; Tachycardia	Escitalopram	S	Oral	60 Mg, Unk	Not Reported
	Risperidone	S	Oral	6 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13897379	EXPEDITED (15-DAY)		OT	DK-ALLERGAN-1746743US			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Apathy; Asthenia; Depressed Mood; Disturbance In Social Behaviour; Drug Dependence; Drug Ineffective; Dyskinesia; Dysphagia; Dyspnoea; Fatigue; Feeling Abnormal; Intentional Product Use Issue; Malaise; Mood Altered; Psychotic Disorder; Restless Legs Syndrome; Somnolence; Stress; Suicidal Ideation; Suicide Attempt; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Rivotril			S	Unknown	Unk, Unknown		Not Reported
	Cisordinol Depot			S	Unknown	100 Mg Every 14 Days		Not Reported
	Cisordinol			S	Unknown	3 X 10 Mg In The Evening		Not Reported
	Cisordinol			S	Unknown	10 Mg, Unk		Not Reported
	Cisordinol			S	Unknown	8 Mg, Unk		Not Reported
	Cisordinol			S	Unknown	4 Mg, Unk		Not Reported
	Cisordinol			S	Unknown	6 Mg, Unk		Not Reported
	Cisordinol			S	Unknown	4x2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13897380	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1746563US		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bezoar; Cardiogenic Shock; Coma; Gastrointestinal	Escitalopram Oxalate - Bp			S	Oral	280 Mg, Unk		Allergan
	Citalopram Hydrobromide - Bp			S	Unknown			Allergan
	Zolpidem			S	Unknown			Not Reported

Ischaemia; Hepatic Failure; Hyperlactacidaemia; Intentional Overdose; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Overdose; Shock; Skin Necrosis; Toxicity To Various Agents	Nordazepam		S	Unknown		Not Reported
	Lysanxia		S	Oral	420 Mg, Unk	Not Reported
	Sevikar		S	Oral	1.29 G, Unk	Not Reported
	Sevikar		S	Oral	5.16 Unk, Unk	Not Reported
	Atarax		S	Oral	700 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13898828	EXPEDITED (15-DAY)		HO	CA-ELI_LILLY_AND_COMPANY-CA201708007582		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aptyalism; Drug Ineffective; Panic Disorder	Zyprexa			S	Oral	2.5 Mg, Daily		Eli Lilly And Co
	Escitalopram			S	Oral	30 Mg, Unknown		Not Reported
	Buspirone			S	Oral	5 Mg, Daily		Not Reported
	Amitriptyline			S	Oral	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13900265	EXPEDITED (15-DAY)		OT	CA-IMPAX LABORATORIES, INC-2017-IPXL-02433		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Drug Ineffective; Hypoglycaemia; Hypokalaemia; Optic Nerve Infarction; Pulmonary Oedema	Adrenaclick			S	Other	30 Mcg/Minute		Amedra
	Adrenaclick			S	Other	40 Mcg/Minute, Unk		Amedra
	Norepinephrine			S	Other	30 Mcg/Minute		Not Reported
	Norepinephrine			S	Other	40 Mcg/Minute, Unk		Not Reported
	Norepinephrine			S	Other	25 Mcg/Minute, Unk		Not Reported
	Norepinephrine			S	Other	10 Mcg/Minutes, Unk		Not Reported
	Vasopressin			S	Other	2.4 Units/Hour		Not Reported
	Amlodipine			S		150 Mg, Unk		Not Reported

Risperidone	S		6 Mg, Unk		Not Reported
Escitalopram	S		60 Mg, Unk		Not Reported
Calcium Gluconate	C	Intravenous (not otherwise specified)	2 G, Unk		Not Reported
Glucagon	C	Intravenous (not otherwise specified)	5 Mg, Unk		Not Reported
Dextrose	C	Intravenous (not otherwise specified)	1 Ampule Of Dextrose 50% In Water		Not Reported
Dextrose	C	Intravenous (not otherwise specified)	10% Dextrose Infusion		Not Reported
Activated Charcoal	C	Nasal	50 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13899065	EXPEDITED (15-DAY)		OT	CA-ALKEM LABORATORIES LIMITED-CA-ALKEM-2017-00553		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cytotoxic Oedema; Hypoglycaemia; Hypokalaemia; Hypotension; Infarction; Intentional Overdose; Optic Atrophy; Optic Nerve Injury; Pulmonary Oedema; Retinal Ischaemia; Shock; Tachycardia	Amlodipine Besylate			S	Unknown	150 Mg, Unk		Alkem
	Risperidone			S	Unknown	6 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	60 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13899696	EXPEDITED (15-DAY)		OT	IN-ASTRAZENECA-2017SE85304		57 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism	Quetiapine			S	Oral	50.0mg Unknown		Zeneca
	Escitalopram			S	Oral	10.0mg Unknown		Not Reported

	Amlodipine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13900623	EXPEDITED (15-DAY)		HO	PHHY2017CA123139		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Amlodipine			S	Unknown	150 Mg		Novartis
	Escitalopram			S	Unknown	60 Mg,		Not Reported
	Risperidone			S	Unknown	6 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13902394	EXPEDITED (15-DAY)		DE, OT	FR-CIPLA LTD.-2017FR14490			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Invagen
	Indapamide			S	Unknown	Unk		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported
	Benzoic Acid			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13910615	DIRECT		DS			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Hot; Palpitations; Product Substitution Issue	Escitalopram 20 Mg, Generic Lexapro			S	Oral	Quantity:1 Tablet(S);		Aurobindo
	Carbidopa-Levadopa			C				Not Reported
	Lexapro			C				Not Reported
	Multi Vitamin			C				Not Reported
	Omega 3 Fish Oil			C				Not Reported
	Coq10			C				Not Reported
	Curcummin			C				Not Reported
	Magnesium Citrate			C				Not Reported
	Low Dose Aspirin			C				Not Reported

	Probiotic			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13896324	EXPEDITED (15-DAY)		HO, LT, OT	CA-ALLERGAN-1735846US		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Circulatory Collapse; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Mitral Valve Stenosis; Optic Atrophy; Optic Nerve Injury; Pulmonary Oedema; Renal Tubular Necrosis; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment	Escitalopram Oxalate Unk			S	Oral	60 Mg, Unk		Allergan
	Amlodipine			S	Oral	150 Mg, Unk		Not Reported
	Risperidone			S	Unknown	6 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13909124	EXPEDITED (15-DAY)		OT	US-HETERO CORPORATE-HET2017US00105			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Syndrome; Condition Aggravated	Escitalopram			S	Unknown	20 Mg, Qd		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13911084	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2017M1052792			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Syndrome; Diarrhoea; Insomnia	Escitalopram			S	Unknown	20mg Every Day For 16 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13911189	EXPEDITED (15-DAY)		DE, OT	FR-INDIVIOR LIMITED-INDV-104138-2017		30 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Death; Drug Abuse; Toxicity To Various Agents	Suboxone			S	Unknown	Unk		Reckitt Benckiser
	Actiskenan			S	Unknown	Unk		Not Reported
	Valium			S	Unknown	Unk		Not Reported
	Seresta			S	Unknown	Unk		Not Reported
	Theralene			S	Unknown	Unk		Not Reported
	Seropram /01588502/			S	Unknown	Unk		Not Reported
	Imovane			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13912799	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1000016435		93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Hyperhidrosis	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qod		Allergan
	Toprol			C		50 Mg, Qd		Not Reported
	Norvasc			C		5 Mg, Unk		Not Reported
	Zocor			C		20 Mg, Unk		Not Reported
	Hytrin			C		5 Mg, Unk		Not Reported
	Nexium			C		40 Mg, Unk		Not Reported
	Nitroglycerin			C	Sublingual	0.4 Df, Prn		Not Reported
	Caltrate			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported
	Tobramycin			C	Ophthalmic	Unk		Not Reported
	Hytrol			C		10 Mg, Qd		Not Reported

	Hytrol	C			Not Reported
	Ectrin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13916139	EXPEDITED (15-DAY)		HO, OT	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2017NSR000188		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Mania	Tramadol Hydrochloride			S		Unk		Northstar
	Escitalopram			S		20 Mg, Qd		Not Reported
	Quetiapine			C		300 Mg, Qd		Not Reported
	Quetiapine			C		1000 Mg, Qd		Not Reported
	Quetiapine			C		800 Mg, Qd		Not Reported
	Oxazepam			C		Unk		Not Reported
	Oxazepam			C		180 Mg, Qd		Not Reported
	Alprazolam			C		Unk		Not Reported
	Zolpidem			C		Unk		Not Reported
	Baclofen			C		Unk		Not Reported
	Candesartan			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Alfuzosin			C		Unk		Not Reported
	Trospium			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported
	Triamcinolone			C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13917735	EXPEDITED (15-DAY)		OT	US-TEVA-800887USA		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Crying; Depression; Headache; Herpes Zoster; Somnolence; Suicidal Ideation	Escitalopram			S	Unknown			Ivax
	Lexapro			S	Unknown			Not Reported
	Lexapro			S				Not Reported
	Humira			S	Unknown	40mg/ 0.8ml		Not Reported
	Fioricet			C				Not Reported
	Gabapentin			C				Not Reported
	Entyvio			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13917911	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1747759US		45 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Memory Impairment; Nausea; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13601158	EXPEDITED (15-DAY)		DE, OT	US-LUPIN (EUROPE) LIMITED-2017-02754		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Completed Suicide; Lethargy; Somnolence	Loperamide			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Lupin
	Meloxicam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13921980	EXPEDITED (15-DAY)		HO	CA-UNICHEM LABORATORIES LIMITED-UCM201708-000219		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria;	Amlodipine			S				Unichem
	Escitalopram			S				Not Reported

Circulatory Collapse; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Optic Atrophy; Pulmonary Oedema; Tachycardia; Visual Impairment	Risperidone	S		Not Reported
	Furosemide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13922661	EXPEDITED (15-DAY)		HO, LT, OT	CA-MYLANLABS-2017M1053479		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Cardiogenic Shock; Cerebral Infarction; Cytotoxic Oedema; Embolism; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Nerve Injury; Pulmonary Oedema; Tachycardia; Toxicity To Various Agents	Amlodipine			S	Oral	150 Mg		Not Reported
	Escitalopram			S	Oral	60 Mg		Not Reported
	Risperidone			C	Oral	6 Mg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13861559	EXPEDITED (15-DAY)		DE, HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-071227		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Dilatation; Cachexia; Chronic Kidney Disease; Death; Failure To Thrive; Hyponatraemia; Inappropriate Antidiuretic	Eliquis			S	Oral	2.5 Mg, Daily		Bristol Myers Squibb
	Eliquis			S	Oral	2.5 Mg, Daily		Bristol Myers Squibb
	Cordarone			S	Oral	200 Mg, Daily		Not Reported

Hormone Secretion; Off Label Use; Transaminases Increased	Tahor	S	Oral	10 Mg, Daily	Not Reported
	Seroplex	S	Oral	10 Mg, Daily	Not Reported
	Lasix /00032601/	C	Unknown	40 Mg, Unk	Not Reported
	Coversyl /00790702/	C	Unknown	Unk	Not Reported
	Inipomp	C	Unknown	Unk	Not Reported
	Forlax	C	Unknown	Unk	Not Reported
	Gaviscon /01405501/	C	Unknown	Unk	Not Reported
	Doliprane	C	Unknown	Unk	Not Reported
	Xanax	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13924337	EXPEDITED (15-DAY)		DE, OT	US-JNJFOC-20170824618		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Lethargy; Somnolence	Loperamide Hydrochloride		Y	S	Unknown			Not Reported
	Loperamide Hydrochloride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13421803	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-131889		4 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Progesterone			S	Transplacental	Unk		Not Reported
	Sertraline			S	Transplacental			Sun
	Ondansetron			S	Transplacental			Natco Pharma
	Escitalopram			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13869365	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC-2017337244		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Dilatation; Cachexia; Chronic Kidney Disease; Death; Failure To Thrive; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Off Label Use; Transaminases Increased	Cordarone			S	Oral	200 Mg, 1x/Day		Pfizer
	Tahor			S	Oral	10 Mg, Daily		Pfizer
	Eliquis			S	Oral	2.5 Mg, 1x/Day		Not Reported
	Eliquis			S	Oral	2.5 Mg, Daily		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Lasilix			C		40 Mg, Unk		Not Reported
	Coversyl			C		Unk		Not Reported
	Inipomp			C		Unk		Not Reported
	Forlax			C		Unk		Not Reported
	Gaviscon			C		Unk		Not Reported
	Doliprane			C		Unk		Not Reported
	Xanax			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13926719	EXPEDITED (15-DAY)		OT	GB-TORRENT-00015556		30 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram			S				Unknown
	Vitamin D Nos			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13928728	EXPEDITED (15-DAY)		LT, OT	IN-TORRENT-00001330		57 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypothyroidism; Myxoedema Coma	Quetiapine			S				Unknown
	Escitalopram			S				Unknown
	Amlodipine			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13928925	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-CIPLA LTD.-2017US15296			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Escitalopram			S	Transplacental	Unk		Invagen
	Sertraline			S	Transplacental	Unk		Invagen
	Ondansetron			S	Transplacental	Unk		Cipla
	Progesterone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13929367	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval Abnormal	Escitalopram			S	Oral			Unknown
	Adderall			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13930152	EXPEDITED (15-DAY)		DE, HO, LT	AT-ASTRAZENECA-2017SE89492		73 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Condition Aggravated; Coronary Artery Disease; Dehydration; Fatigue; Oedema Peripheral; Off Label Use; Pneumonia; Renal Impairment; Weight Decreased	Seroquel			S	Oral	25.0mg Unknown		Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown	2-0-0		Not Reported
	Cipralex			S	Unknown	1-0-0		Not Reported
	Stalevo			S	Unknown	100 Mg/25 Mg/200 Mg, 1-0-0		Not Reported
	Stalevo			S	Unknown	100 Mg/25 Mg/200 Mg, 1-1-0		Not Reported
	Trittico			S	Unknown	0-0-0-0.5		Not Reported

Azilect	S	Unknown	1-0-0	Not Reported
Madopar	S	Unknown		Not Reported
Madopar	S	Unknown	50 Mg/12,5 Mg, 1-1-1	Not Reported
Lovenox	C		1 Time Daily	Not Reported
Elomel	C		1 Time Daily	Not Reported
Optinem	C			Not Reported
Lasix	C			Not Reported
Thrombo Ass	C		0-1-0	Not Reported
Spirobene	C		0-0.5-0	Not Reported
Sedacoron	C		0.5-0-0	Not Reported
Ceftriaxone Sodium	C		2 G In 200 Ml, Once Daily	Not Reported
Dancor	C		1-0-1	Not Reported
Aquaphoril	C		0.5-0-0	Not Reported
Torasemide	C		1-0-0	Not Reported
Pantoloc	C		2-0-0	Not Reported
Insulatard	C		610-0-0	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13930661	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1748733US		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Previscan (Fluindione)			S	Oral	1 Df, Qd		Allergan
	Aldactone			C	Unknown	Unk		Not Reported
	Lasilix			C	Unknown	Unk		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported
	Delursan			C	Unknown	Unk		Not Reported
	Noroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2017	13930893	EXPEDITED (15-DAY)		HO, OT	FR-BAUSCH-BL-2017-025668		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Venlafaxine			S	Unknown			Not Reported
	Venlafaxine			S				Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported
	Sertraline			S	Unknown			Not Reported
	Sertraline			S				Not Reported
	Risperidone			S	Unknown	2 Mg/Day		Not Reported
	Risperidone			S				Not Reported
	Paroxetine			S	Unknown			Not Reported
	Paroxetine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2017	13930997	EXPEDITED (15-DAY)		DS	DE-HETERO CORPORATE-HET2017DE00139		25 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Libido Decreased; Male Orgasmic Disorder	Escitalopram			S	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2017	13931049	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017005797			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During	Escitalopram			S	Transplacental	20 Mg, Qd, (0.-11. Gestational Week)		Macleods
	Loratadin			C	Transplacental	10 Mg, Qd (0.-4.4		Not Reported

Pregnancy; Sinus Tachycardia; Small For Dates Baby	Saisonale	C	Transplacental	Gestational Week) Unk, (It Was Approximate Gestational Week 5 1/7, 5.1. - 5.1. Gestational Week)	Not Reported
	Folio Forte	C	Transplacental	0.8 Mg, Qd (Since October 2016, (0. - 22.2. Gestational Week))	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13931556	EXPEDITED (15-DAY)		CA, DS, OT	DE-TORRENT-00007018			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S				Unknown
	Loratadine			C				Unknown
	Impfstoff Grippe (Saisonale)			C				Unknown
	Folio Forte			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13931661	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00007020		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Premature Baby; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder	Escitalopram			S				Unknown
	Baldrian			C				Unknown
	Protaphane			C				Unknown
	Folic Acid			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13931932	EXPEDITED (15-DAY)		CA, HO, OT	DE-HETERO CORPORATE-HET2017DE00140		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Neonatal Respiratory Distress Syndrome; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder	Escitalopram			S	Transplacental	20 Mg, Qd		Not Reported
	Baldrian			C	Transplacental	20 Mg, Qd		Not Reported
	Protaphane			C	Transplacental	Unk, Qd		Not Reported
	Folsaeure			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13932447	EXPEDITED (15-DAY)		OT	US-ZYDUS-016272			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Syndrome; Condition Aggravated; Diarrhoea; Insomnia	Escitalopram			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13933077	EXPEDITED (15-DAY)		HO, LT, OT	US-JNJFOC-20170900762		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Intentional Overdose; Serotonin Syndrome; Stress Cardiomyopathy	Tramadol Hydrochloride			S	Unknown			Not Reported
	Fentanyl			S	Transdermal			Not Reported
	Norco			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13933148	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1748751US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan
	Loratadin			C	Transplacental	3 Mg, Unk		Not Reported
	Influenza Vaccine			C	Transplacental	Unk Unk, Single		Not Reported
	Folio Forte			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13933155	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1748764US		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Loratadin			C	Unknown	10 Mg, Qd		Not Reported
	Influenza Vaccine			C	Unknown			Not Reported
	Folio Forte			C	Unknown	0.8 Mg, Qd		Not Reported
	Folio Forte			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13934187	EXPEDITED (15-DAY)		OT	IN-HETERO CORPORATE-HET2017IN00146		57 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Myxoedema	Escitalopram			S	Unknown	Unk		Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13935031	EXPEDITED (15-DAY)		OT	GB-ACCORD-058025		30 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram			S	Oral			Accord
	Ergocalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13935142	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2017M1054831		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Baldrian /01561601/			C	Transplacental	500 [Mg/D]/ If Required		Mylan
	Protaphane			C	Transplacental	22 [I.E./D]		Mylan
	Folsaeure			C	Transplacental			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13937462	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-802584USA		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Cardiogenic Shock; Cerebral Infarction; Cytotoxic Oedema; Embolism; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia;	Amlodipine			S	Oral	150 Mg		Teva
	Escitalopram			S	Oral	60 Mg		Ivax
	Risperidone			C	Oral	6 Mg		Not Reported

Optic Nerve Injury; Pulmonary Oedema; Tachycardia; Toxicity To Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13938096	EXPEDITED (15-DAY)		DS	DE-ALLERGAN-1749675US		25 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Libido Decreased; Male Orgasmic Disorder	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13938107	EXPEDITED (15-DAY)		CA, OT	DE-ALLERGAN-1749678US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan
	Baldrian			C	Transplacental			Not Reported
	Protaphane			C	Transplacental	Unk, Single		Not Reported
	Folic Acid			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13938122	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1749660US		30 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram Oxalate - Bp		S	Oral	20 Mg, Unk	Allergan
	Vitamin D2		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13938408	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2017M1053766			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Loratadin			C	Transplacental	10 [Mg/D]		Mylan
	Grippe Impfstoff			C	Transplacental	It Was Approximate Gestational Week 5 1/7		Mylan
	Folio Forte			C	Transplacental	0.8 [Mg/D]/ Since October 2016		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13236318	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP006772			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Resistance; Hypomania; Suicide Attempt; Therapy Cessation	Paroxetine Hydrochloride			S	Unknown			Apotex
	Aripiprazole Tablets			S				Apotex
	Haloperidol			S	Unknown			Apotex
	Duloxetine Hydrochloride Delayed-Release Capsules			S	Unknown			Apotex
	Bupropion Hydrochloride			S	Unknown			Apotex
	Carbamazepine			S	Unknown			Apotex
	Risperidone			S				Apotex
	Lamotrigine			S	Unknown			Apotex
	Quetiapine Fumarate			S	Unknown			Apotex
	Ziprasidone Hcl			S	Unknown			Apotex
	Citalopram			S	Unknown			Apotex
	Escitalopram Oxalate			S	Unknown			Apotex

Trazodone Hydrochloride	S	Unknown		Apotex
Divalproex Sodium Delayed-Release Tablets Usp	S	Unknown		Apotex
Oxcarbazepine	S	Unknown		Apotex
Topiramate	S	Unknown		Apotex
Clonazepam Tablets Usp	S	Unknown		Apotex
Alprazolam	S	Unknown		Apotex
Lithium	S	Unknown		Not Reported
Clozapine	S			Not Reported
Lorazepam	S	Unknown		Not Reported
Chlorpromazine	S	Unknown		Not Reported
Loxapine	S	Unknown		Not Reported
Nefazodone	S	Unknown		Not Reported
Doxepine	S	Unknown		Not Reported
Venlafaxine	S	Unknown		Not Reported
Trihexyphenidyl	S	Unknown		Not Reported
Benztropine	S	Unknown		Not Reported
Chloral Hydrate	S	Unknown		Not Reported
Diazepam	S	Unknown		Not Reported
Phenobarbital	S	Unknown		Not Reported
Temazepam	S	Unknown		Not Reported
Triazolam	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13805318	EXPEDITED (15-DAY)		HO, OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-146182		61 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Gastrointestinal Disorder; Meige'S Syndrome	Haloperidol			S	Unknown	2 Mg, At Night		Sun
	Clonazepam			S	Unknown	0.5 Mg, Per Night		Sun

Nitrazepam	S	Unknown	Unk		Not Reported
Lorazepam	S	Unknown	Unk		Sun
Paroxetine	S	Unknown	30 Mg, Daily		Sun
Clonazepam	S	Unknown	10 Mg, Every Night		Sun
Lexapro	S	Unknown	10 Mg, Daily		Not Reported
Flupentixol	S	Unknown	Unk		Not Reported
Zyprexa	S	Unknown	1.25 - 3.75 Mg Per Night		Not Reported
Clonazepam	S	Intravenous (not otherwise specified)	0.5 Mg, Daily		Not Reported
Melitracen	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13855913	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1733775US		40 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Lymphocyte Stimulation Test Positive; Myalgia; Pyrexia	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan
	Saikokeishito			S	Oral	Unk, Unknown		Not Reported
	Triptan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13893621	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1735906US		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	3 Gtt, Qd		Allergan
	Bisoprolol Hemifumarate			C	Unknown			Not Reported
	Atorvastatine			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Alloprazol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13938709	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017005800			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder	Escitalopram			S	Transplacental	20 Mg, Qd, (0. - 36.1. Gestational Week)		Macleods
	Baldrian			C	Transplacental	500 Mg, Qd (If Required)		Not Reported
	Protaphane			C	Transplacental	22 Iu, Qd (22 [I.E./D]) (2 Trimester, 14. - 36.1. Gestational Week)		Not Reported
	Folsäure			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939235	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2017005803			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram			S	Oral	20 Mg, Unk		Macleods
	Vitamin D Nos			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939248	EXPEDITED (15-DAY)		LT, OT	IN-MACLEODS PHARMACEUTICALS US LTD-MAC2017005808			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dry Skin; Dysarthria; Fatigue;	Escitalopram 10 Mg Film Coated Tablet			S	Oral	10 Mg, Unk		Macleods

Hypokinesia; Hypothyroidism; Macroglossia; Myxoedema Coma; Oedema Peripheral; Periorbital Oedema; Somnolence	Quetiapine 50mg Tablet	S	Oral	50 Mg, Unk	Macleods
	Amlodipine Besylate Tablet	C	Oral	5 Mg, Bid	Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939361	DIRECT		DS				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Loss Of Weight; Agoraphobia; Brain Injury; Cognitive Disorder; Fear; Housebound; Impaired Driving Ability; Impaired Self-Care; Mania; Mental Impairment; Neuralgia; Pain; Paraesthesia; Physical Disability; Seizure; Suicidal Ideation; Tremor; Withdrawal Syndrome	Xanax			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Levothyroxin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939406	EXPEDITED (15-DAY)		LT, OT	IN-ACCORD-058109		57 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypothyroidism; Myxoedema Coma	Escitalopram			S				Accord
	Quetiapine			S				Accord
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939833	EXPEDITED (15-DAY)		CA	DE-TEVA-800304GER		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy	Escitalopram		S	Transplacental	20 Milligram Daily;	Ivax
	Loratadin		C	Transplacental	10 Milligram Daily;	Not Reported
	Impfstoff Grippe (Saisonale)		C	Transplacental		Not Reported
	Folio Forte		C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13940078	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US026247		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Lethargy	Loperamide Hydrochloride			S	Oral	Unknown, Unknown		Perrigo
	Escitalopram			S	Unknown	Unknown, Unknown		Not Reported
	Meloxicam			S	Unknown	Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13940315	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2017VAL001308		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Furosemide			S				Validus
	Escitalopram			S		20 Mg, Unk		Not Reported
	Bisoprolol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13940427	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-801409GER		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Neonatal Respiratory Distress	Escitalopram			S	Transplacental	20 Milligram Daily;		Ivax
	Baldrian			C	Transplacental	500 Mg/D / If Required		Not Reported
	Protaphane			C	Transplacental	22 Iu (International Unit) Daily;		Not Reported
	Folsaeure			C	Transplacental			Not Reported

Syndrome; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13940443	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2017AP017713		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate			S	Unknown			Apotex
	Dextromethorphan W/Promethazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13941953	EXPEDITED (15-DAY)		DE	FR-SA-2017SA160203		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate			S	Unknown			Not Reported
	Sotalol Hydrochloride			S	Unknown			Not Reported
	Indapamide			S	Unknown			Not Reported
	Benzoic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13716356	EXPEDITED (15-DAY)		DE, OT	JP-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-058832		30 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Apathy; Completed Suicide; Decreased Appetite; Insomnia; Refusal Of Treatment By Patient; Suicidal Ideation	Abilify			S	Oral	24 Mg, Qd		Bristol Myers Squibb
	Lexapro			S	Oral	10 Mg, Unk		Not Reported
	Zyprexa			S	Oral	20 Mg, Qd		Not Reported
	Zyprexa			S	Oral	15 Mg, Qd		Not Reported
	Zyprexa			S	Oral	10 Mg, Qd		Not Reported

Reflex /00021218/	S	Oral	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13902525	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-MACLEODS PHARMACEUTICALS US LTD-MAC2017005760			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Cerebral Infarction; Circulatory Collapse; Condition Aggravated; Depressed Level Of Consciousness; Electrocardiogram Qt Prolonged; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Optic Atrophy; Optic Nerve Infarction; Optic Nerve Injury; Pulmonary Oedema; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment	Amlodipine Besylate			S	Oral	150 Mg, Single (Total)		Macleods
	Escitalopram Oxalate			S	Oral	60 Mg, Single (Total)		Macleods
	Risperidone			S	Oral	6 Mg, Single (Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13943761	EXPEDITED (15-DAY)		OT	GB-TEVA-802244ACC		30 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram			S	Oral			Ivax
	Vitamin D2			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13943908	EXPEDITED (15-DAY)		CA	DE-AUROBINDO-AUR-APL-2017-39648			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy	Escitalopram 20 Mg			S	Transplacental	20 Mg, Daily		Aurobindo
	Loratadin			C	Transplacental	10 Mg, Daily		Not Reported
	Folio Forte			C	Transplacental	0.8 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13944245	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017005843			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	15 Mg, Qd (From 0. - 30 Gestational Week)		Macleods
	Escitalopram			S	Transplacental	5 Mg, Qd (30 - 40.3. Gestational Week)		Macleods
	Avitale Folsäure Plus(Nem)			C	Transplacental	0.8 Mg, Qd (0. - 40.3. Gestational Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13945722	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2017M1055711		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Escitalopram Mylan			S		Unk		Mylan
	Rilmenidine Mylan			S		1 In The Morning		Mylan
	Valsartan Mylan			S		80 In The Morning		Mylan
	Alprazolam Mylan			S		Unk		Mylan
	Spiriva			S		Once A Day		Mylan

	Symbicort	S		Morning And Evening	Mylan
	Levothyrox	S		50 And 75 Mcg Alternating Doses	Mylan
	Levothyrox	S		50 And 75 Mcg Alternating Doses	Mylan
	Gaviscon /00237601/	S		Unk	Mylan
	Cardensiel	S		Unk (Morning And Evening)	Mylan
	Escitalopram	C	Oral	Several Years 10 Mg, Noon	Mylan
	Seroplex	C		In The Morning	Mylan
	Arimidex	C		1 Df, Noon	Mylan
	Tanakan	C		1 In The Morning And Evening	Mylan
	Hyperium	C		1 In The Morning	Mylan
	Nidrel	C		Unk	Mylan
	Nisis	C		2 In The Evening	Mylan
	Lexomil	C		One Fourth Morning And Evening	Mylan
	Temesta /00273201/	C		Half At Bed-Time	Mylan
	Aerus	C		If Necessary	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13946758	EXPEDITED (15-DAY)		OT	FR-SA-2017SA160629		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Not Reported
	Irbesartan			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Galantamine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13947176	EXPEDITED (15-DAY)		HO, OT	IN-ALEMBIC PHARMACUETICALS LIMITED-2017SCAL000721			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Activity; Depressed Level Of Consciousness; Dry Skin; Dysarthria; Heart Rate Decreased; Hyporeflexia; Hypothyroidism; Macroglossia; Myxoedema Coma; Oedema Peripheral; Periorbital Oedema; Somnolence	Quetiapine Fumarate			S		50 Mg, For 1 Month		Alembic
	Quetiapine Fumarate			S				Alembic
	Escitalopram			S		10 Mg, For 3 Months		Not Reported
	Amlodipine			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13760825	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1729635US		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Use Disorder; Headache; Overdose; Pain In Extremity; Photophobia; Sopor	Escitalopram Oxalate - Bp			S	Oral	300 Mg		Allergan
	Melatonin			S	Oral	60 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13774485	EXPEDITED (15-DAY)		DE, OT	JP-LUPIN PHARMACEUTICALS INC.-2017-03861		20 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Insufficiency; Completed Suicide; Fall; Overdose; Serotonin Syndrome; Skin Laceration; Toxicity To Various Agents	Methylphenidate			S	Oral	Unk (Extended-Release Tablet)		Novel Labs
	Aripiprazole			S	Oral	Unk		Not Reported
	Flunitrazepam			S	Oral	Unk		Not Reported

	Risperidone	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Brotizolam	S	Oral	Unk		Not Reported
	Paliperidone	S	Oral	Unk		Not Reported
	Chlorpromazine	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13775597	EXPEDITED (15-DAY)		HO	IT-TEVA-787627ACC		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Overdose; Pain In Extremity; Photophobia; Sopor	Escitalopram Oxalate			S	Oral			Ivax
	Melatonin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13829992	EXPEDITED (15-DAY)		OT	CZ-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-146894		43 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Therapeutic Product Effect Incomplete	Cipralex			S	Unknown	Unk		Not Reported
	Zoloft			S	Unknown			Not Reported
	Argofan			S	Unknown	Increades To 150 Mg/Day		Not Reported
	Leviron			S	Unknown	15 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13903405	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1747425US			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Mydriasis; Photophobia; Pupillary Deformity;	Escitalopram Oxalate - Bp			S	Oral	Unk, Qd		Allergan
	Lumigan Rc			C	Unknown			Allergan

Pupillary Reflex Impaired	Timoptol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13947452	EXPEDITED (15-DAY)		HO, OT	FR-CIPLA LTD.-2017FR16090			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen
	Sertraline			S	Unknown	Unk		Invagen
	Sertraline			S				Invagen
	Venlafaxine			S	Unknown	225 Mg, Qd		Not Reported
	Venlafaxine			S				Not Reported
	Risperidone			S	Unknown	2 Mg/Day		Cipla
	Risperidone			S				Cipla
	Paroxetine			S	Unknown	40 Mg, Qd		Not Reported
	Paroxetine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13948194	EXPEDITED (15-DAY)		CA, OT	DE-HETERO-HET2017DE00171		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	15 Mg, Qd		Hetero
	Escitalopram			S	Transplacental	5 Mg, Qd		Hetero
	Avitale Folsäure Plus(Nem)			C	Transplacental	0.4 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13948237	EXPEDITED (15-DAY)		LT, OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-149376		57 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypothyroidism;	Escitalopram			S	Unknown	Unk		Not Reported

Myxoedema Coma	Quetiapine	S	Unknown	Unk		Sun
	Amlodipine	C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13948567	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2017-39693		365 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Neonatal Respiratory Distress Syndrome; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder	Escitalopram 20 Mg			S	Transplacental	20 Mg, Once A Day		Aurobindo
	Baldrian-Dispert			C	Transplacental	500 Mg, As Directed		Not Reported
	Protaphane			C	Transplacental	221 U International Once A Day		Not Reported
	Folsaeure			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13948786	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20170900285		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Coma; Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Miosis; Sinus Bradycardia	Risperdal			S	Oral			Not Reported
	Doliprane			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Nurofen			S	Oral			Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13950220	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1749827US		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Bradyphrenia; Depressed Mood; Muscular Weakness; Psychomotor Skills Impaired; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Single		Allergan
	Paracetamol			S	Oral	8 G, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13950225	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1749841US		91 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemorrhage; Pancytopenia	Escitalopram Oxalate - Bp			S	Oral	40 Mg, Every 2 Days		Allergan
	Coveram			S	Oral	5 Mg, Qd		Not Reported
	Previscan (Fluindione)			S	Oral	0.25 Mg, Qd		Not Reported
	Lorazepam			C	Unknown	Unk, Unknown		Not Reported
	Bisoprolol			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13950229	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1749149US		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Tachycardia; Vomiting	Escitalopram Oxalate Unk			S	Oral	Unk, Unknown		Allergan
	Bromazepam			S	Oral	Unk, Unknown		Not Reported
	Tetrazepam			S	Oral	Unk, Unknown		Not Reported
	Zopiclone			S	Oral	Unk, Unknown		Not Reported
	Lormetazepam			S	Oral	Unk, Unknown		Not Reported
	Surmotil (Trimipramine)			S	Oral	Unk, Unknown		Not Reported
	Fluoxetine			S	Oral	Unk, Unknown		Not Reported
	Mirtazapine			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13950281	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1750055US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Malignant; Weight Decreased	Lexapro			S	Unknown	Unk, Unknown		Allergan
	Adderall			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13950294	EXPEDITED (15-DAY)		DS, OT	IT-ALLERGAN-1750618US		33 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Libido	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2017	13954373	DIRECT		DS			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia	Escitalopram			S	Oral	Quantity:1 Tablet(S); Oral		Torrent
	Escitalopram			C				Not Reported
	Dapaglifozin			C				Not Reported
	Ropinirole			C				Not Reported
	Lisinopril			C				Not Reported
	Amlodipine Besylate			C				Not Reported
	Glimepiride			C				Not Reported
	Rosuvastatin			C				Not Reported
	Welchol			C				Not Reported
	Lantus			C				Not Reported
	Humalog			C				Not Reported
	Melatonin			C				Not Reported
	Aspirin			C				Not Reported
	D3			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	11409850	EXPEDITED (15-DAY)		HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-101854			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported
	Sertraline			S	Unknown			Sun
	Sertraline			S				Sun
	Venlafaxine			S	Unknown			Sun
	Venlafaxine			S				Sun
	Risperidone			S	Unknown	2 Mg/Day		Ranbaxy
	Risperidone			S				Ranbaxy
	Paroxetine			S	Unknown			Sun
	Paroxetine			S				Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13762927	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1042386		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Overdose; Pain In Extremity; Photophobia; Sopor	Escitalopram			S	Oral	300 Mg, Total		Not Reported
	Melatonin			S	Oral	60 Mg, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13945220	EXPEDITED (15-DAY)		LT, OT	IN-ALLERGAN-1749833US		57 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hypothyroidism; Myxoedema Coma	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd, 3 Months		Allergan
	Quetiapine			S	Unknown	50 Mg, Qd Unspecified Interval		Not Reported

	Amlodipine	C	Unknown	10 Mg Daily, 3 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13952019	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1054832		30 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram			S	Oral			Not Reported
	Vitamin D /00107901/			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13952258	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00007044		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S				Unknown
	Avitale Folsaure Plus			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13953126	EXPEDITED (15-DAY)		DS	DE-AUROBINDO-AUR-APL-2017-39938		25 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Libido Decreased; Male Orgasmic Disorder	Escitalopram			S	Oral	20 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13953377	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2017-40253			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Syndrome; Condition Aggravated; Diarrhoea; Insomnia	Escitalopram			S	Unknown	20 Mg, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13955828	NON-EXPEDITED			US-SUNOVION-2017SUN003860			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper	Latuda			S	Oral	Unk		Sunovion
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13957852	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1750578US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypertonia Neonatal; Tension; Tremor Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	Unk Unk, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13959065	EXPEDITED (15-DAY)		DS	DE-MYLANLABS-2017M1055240		25 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Libido Decreased; Male Orgasmic Disorder	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13959726	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1751121US		102 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Acute Kidney Injury; Anaemia; Gastrointestinal Haemorrhage; Haematemesis;	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Kardegic			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported

Hypotension; Melaena; Nutritional Condition Abnormal; Pallor; Tachycardia; Vomiting	Spironolactone	C	Unknown		Not Reported
	Altizide	C	Unknown		Not Reported
	Naftidrofuryl	C	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13959951	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1751007US		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan
	Avitale Folsäure Plus			C	Transplacental	0.8 Mg, Unk		Not Reported
	Avitale Folsäure Plus			C	Transplacental	0.4 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	12484667	EXPEDITED (15-DAY)		HO	US-FRI-1000085498		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Blinded Investigational Medicinal Product (Imp) Non-Partner			S	Oral	1 Mg, Qd		Not Reported
	Lisinopril			C	Oral	40 Mg, Qd		Not Reported
	Albuterol			C	Respiratory (inhalation)	2 Puffs , Prn		Not Reported
	Atenolol			C	Oral	25 Mg, Qd		Not Reported
	Simvastatin			C	Oral	20 Mg, Qd		Not Reported
	Loratadine			C	Oral	10 Mg, Qd		Not Reported
	Flonase			C	Nasal	50 Mg, Qd		Not Reported
	Flomax			C	Oral	.4 Mg, Qd		Not Reported
	Ranitidine			C	Oral	300 Mg, Qd		Not Reported

	Flovent	C	Respiratory (inhalation)	Unk Unk, Bid		Not Reported
	Omeprazole	C	Oral	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	12681166	NON-EXPEDITED			US-FRI-1000081833			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	12681465	NON-EXPEDITED			US-FRI-1000082092		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Off Label Use	Lexapro			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	12688922	NON-EXPEDITED			US-FRI-1000084632			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Weight Increased; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10 Mg, Bid		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	12690812	NON-EXPEDITED			US-FRI-1000078820		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Chills; Decreased Appetite; Dizziness; Fatigue; Hot Flush;	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Bystolic			C	Oral	10 Mg, Qd		Not Reported

Insomnia; Malaise; Off Label Use; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	12690813	NON-EXPEDITED			US-FRI-1000078079		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Anger; Anxiety; Cold-Stimulus Headache; Depressed Mood; Depressed Mood; Depression; Drug Ineffective; Dyspepsia; Emotional Distress; Euphoric Mood; Fat Tissue Increased; Fatigue; Feeling Abnormal; Feeling Hot; Feeling Hot; Feeling Of Relaxation; Flatulence; Hallucination, Auditory; Hypersomnia; Insomnia; Mental Disorder; Mood Swings; Paranoia; Peripheral Swelling; Peripheral Swelling; Poor Quality Sleep; Product Physical Issue; Screaming; Somnolence; Somnolence; Staring; Swelling; Weight Decreased; Weight Increased; Weight Increased	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S		5 Mg, Qd		Allergan
	Lexapro			S		30 Mg, Qd		Allergan
	Risperdal			S	Oral	.5 Mg, Unk		Not Reported
	Valacyclovir			C	Oral	500 Mg, Unk		Not Reported
	Multivitamin			C	Oral	Unk Unk, Qd		Not Reported
	Vit D			C	Oral	Unk Unk, Qd		Not Reported
	Excedrin Otc			C	Oral	Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13753017	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017GSK107683			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Dizziness; Joint Swelling; Peripheral Swelling; Somnolence; Swelling Face	Breo Ellipta Inhalation Powder	S	Respiratory (inhalation)	1 Puff(S), Qd	Glaxosmithkline
	Lyrica	S		150 Mg, Tid	Not Reported
	Aspirin	S		Unk	Glaxosmithkline
	Clopidogrel	S		Unk	Not Reported
	Atorvastatin	S		Unk	Not Reported
	Metoprolol Tartrate	S		Unk	Not Reported
	Metformin Hydrochloride	S		Unk	Not Reported
	Fenofibrate	S		Unk	Not Reported
	Escitalopram	S		10 Mg, Qd	Not Reported
	Xanax	S		0.5 Mg, Tid	Not Reported
	Levothyroxine	S		50 Ug, Qd	Not Reported
	Aleve	S		2 Df, Qd	Not Reported
	Pataday	S	Ophthalmic	Once Every 3 Or So Months, Prn	Not Reported
	Nitroglycerin	S		Unk	Not Reported
	Vicodin	S		Unk, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13855754	EXPEDITED (15-DAY)		HO	SE-PFIZER INC-2017312706		73 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Condition Aggravated; Depression; Gastric Disorder; Hyperglycaemia; Iron Deficiency Anaemia; Leukocytosis; Pancreatic Disorder; Pancreatic Steatosis; Red Blood Cell Sedimentation Rate Increased; Toxicity To Various Agents	Xanor			S		1 Mg, Daily (At Night)		Pfizer
	Xanor			S		20 Mg, Unk		Pfizer
	Escitalopram			S		Unk		Not Reported
	Levaxin			C		Unk		Not Reported
	B12 /00056201/			C		Unk		Not Reported
	Zopiklon			C		Unk		Not Reported
	Zolpidem			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13957596	EXPEDITED (15-DAY)		HO, OT	FR-ZYDUS-008854		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13958363	NON-EXPEDITED			US-PFIZER INC-2017390917		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Nexium 24hr			S		Unk		Pfizer
	Protonix			S		Unk		Pfizer
	Septra			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Methylphenidate Hydrochloride			S		Unk		Pfizer
	Ampicillin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Albuterol Sulfate			S		Unk		Not Reported

	Albuterol Sulfate	S	Unk	Not Reported
	Bactrim	S	Unk	Not Reported
	Bupropion Hcl	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Escitalopram	S	Unk	Not Reported
	Fenofibrate	S	Unk	Not Reported
	Luvox	S	Unk	Not Reported
	Omeprazole	S	Unk	Not Reported
	Paxil /00500401/	S	Unk	Not Reported
	Percocet /00867901/	S	Unk	Not Reported
	Vicodin	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13959448	EXPEDITED (15-DAY)		OT	DE-TORRENT-00007047			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Gestational Diabetes	Risperidone			S				Unknown
	Folio (Nem)			C				Unknown
	Tavor (Lorazepam)			C				Unknown
	Zopiclone			C				Unknown
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960102	EXPEDITED (15-DAY)		OT	DK-ROCHE-1986378			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Apathy; Asthenia; Depressed Mood; Depression; Drug Dependence; Drug Ineffective; Dyskinesia;	Rivotril			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cisordinol			S	Unknown			Not Reported
	Cisordinol			S	Unknown			Not Reported

Dysphagia; Dyspnoea; Fatigue; Feeling Abnormal; Intentional Product Use Issue; Malaise; Maternal Exposure During Pregnancy; Mood Altered; Psychotic Disorder; Restless Legs Syndrome; Social Avoidant Behaviour; Somnolence; Stress; Suicidal Ideation; Suicide Attempt; Withdrawal Syndrome	Cisordinol	S	Unknown	Not Reported
	Cisordinol	S	Unknown	Not Reported
	Cisordinol	S	Unknown	Not Reported
	Cisordinol	S	Unknown	Not Reported
	Cisordinol Depot	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960194	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-803255GER		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	15 (Mg/D)/ Dosage Reduction To 5 Mg/D From Week 30		Ivax
	Avitale Folsaeure Plus(Nem)			C	Transplacental	0.8 (Mg/D)/ Dosage Reduction To 0.4 Mg/D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960215	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2017M1057381		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram			S		Unk		Not Reported
	Escitalopram			S				Not Reported
	Sertraline			S		Unk		Not Reported
	Sertraline			S				Not Reported
	Venlafaxine			S		225 Mg, Qd		Not Reported
	Venlafaxine			S				Not Reported
	Risperidone			S		2 Mg, Qd		Not Reported

	Risperidone	S			Not Reported
	Paroxetine	S	Unk		Not Reported
	Paroxetine	S	40 Mg, Qd		Not Reported
	Quetiapine	S	100 Mg, Qd		Not Reported
	Quetiapine	S			Not Reported
	Diazepam	S	20 Mg, Qd		Not Reported
	Diazepam	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960350	NON-EXPEDITED			US-ALLERGAN-1711369US		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hot Flush	Lexapro			S	Unknown	5 Mg, Unk		Allergan
	Lexapro			S				Allergan
	Remeron			S	Unknown	Unk		Not Reported
	Remeron			S				Not Reported
	Trazodone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960351	NON-EXPEDITED			US-ALLERGAN-1711408US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dosage Administered; Rash	Lexapro			S	Unknown	.5 Df, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960352	NON-EXPEDITED			US-ALLERGAN-1712970US		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Gingival Bleeding; Intentional Product Misuse; Off Label Use	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960353	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1711333US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Hypersensitivity; Tachycardia	Lexapro			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960354	NON-EXPEDITED			US-ALLERGAN-1710257US		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Anger; Anxiety; Drug Ineffective; Dysstasia; Gait Disturbance; Headache; Hyperhidrosis; Insomnia; Mania; Personality Change; Sinusitis	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960355	NON-EXPEDITED			US-ALLERGAN-1710122US		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate - Bp			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960357	NON-EXPEDITED			US-ALLERGAN-1710043US		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Constipation; Dizziness; Dry Mouth; Insomnia;	Lexapro			S	Oral	10 Mg, Unk		Allergan
	Buspirone			C	Oral	300 Mg, Qd		Not Reported

Tremor	Disulfiram		C	Oral	Unk Unk, Qd	Not Reported
	Antabuse		C	Oral	250 Mg, Qd	Not Reported
	Prilosec		C	Oral	Unk Unk, Qd	Not Reported
	Thiamine		C	Oral	100 Mg, Qd	Not Reported
	Naltrexone		C	Oral	50 Mg, Qd	Not Reported
	Asa		C	Oral	Unk Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960358	NON-EXPEDITED			US-ALLERGAN-1710197US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Insomnia; Nausea; Nervousness	Lexapro			S		5 Mg, Unk		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lorazepam			C		0.5		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960362	NON-EXPEDITED			US-ALLERGAN-1710984US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960363	NON-EXPEDITED			US-ALLERGAN-1709990US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960364	NON-EXPEDITED			US-ALLERGAN-1714840US		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Headache	Lexapro	S					Allergan
	Vivitrol	C	Intramuscular	30 Mg, Q Month			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960365	NON-EXPEDITED			US-ALLERGAN-1714716US		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960367	NON-EXPEDITED			US-ALLERGAN-1714852US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased; Withdrawal Syndrome	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan
	Sertraline			C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960368	NON-EXPEDITED			US-ALLERGAN-1713987US		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960369	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1715426US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960371	NON-EXPEDITED			US-ALLERGAN-1714715US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Tremor	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960372	NON-EXPEDITED			US-ALLERGAN-1712505US		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960373	NON-EXPEDITED			US-ALLERGAN-1712640US		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis	Lexapro			S	Oral	10 Mg, Unk		Allergan
	Jakafi			S	Oral	10 Mg, Bid		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Clobetasol			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Docusate Sodium			C		Unk		Not Reported
	Emla			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Metoprolol Succinate			C		Unk		Not Reported
	Tacrolimus			C		Unk		Not Reported
	Bactrim Ds			C		Unk		Not Reported
	Ativan			C		Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported

	Oxycodone	C	Unk	Not Reported
	Neurontin	C	Unk	Not Reported
	Albuterol	C	Unk	Not Reported
	Cetirizine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960374	NON-EXPEDITED			US-ALLERGAN-1713203US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypoaesthesia; Paraesthesia; Withdrawal Syndrome; Wrong Technique In Product Usage Process	Lexapro			S	Oral	Unk, Qd		Allergan
	Lexapro			S				Allergan
	Escitalopram Oxalate Unk			S	Oral	Unk Unk, Unknown		Allergan
	Escitalopram Oxalate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960376	NON-EXPEDITED			US-ALLERGAN-1712144US		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Apathy; Distractibility; Disturbance In Attention; Irritability; Memory Impairment; Sleep Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960377	NON-EXPEDITED			US-ALLERGAN-1711349US		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960378	NON-EXPEDITED			US-ALLERGAN-1712866US		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Symbicort			C	Respiratory (inhalation)	Unk, Bid		Not Reported
	Spiriva			C	Respiratory (inhalation)	Unk, Qd		Not Reported
	Albuterol			C	Respiratory (inhalation)	Unk, Qid		Not Reported
	Oxygen			C	Nasal	2 Lpm		Not Reported
	Xanax			C	Oral	0.25mg 1/2 Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960381	NON-EXPEDITED			US-ALLERGAN-1714524US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960387	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1717316US		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960388	NON-EXPEDITED			US-ALLERGAN-1715886US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Burning Mouth Syndrome; Discomfort; Dysgeusia; Gingival Swelling; Hypersensitivity; Swollen Tongue	Lexapro			S						Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960391	NON-EXPEDITED			US-ALLERGAN-1714914US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Hypoacusis; Lethargy; Nerve Injury; Tinnitus; Weight Increased	Lexapro			S	Unknown	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960392	NON-EXPEDITED			US-ALLERGAN-1714320US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960393	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1716344US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Head Discomfort; Incorrect Dose Administered; Product Solubility Abnormal; Suicidal Ideation; Wrong Technique In Product Usage Process	Lexapro			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960395	NON-EXPEDITED			US-ALLERGAN-1718898US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia	Lexapro			S	Unknown	Unk		Allergan
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960396	NON-EXPEDITED			US-ALLERGAN-1717177US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960397	NON-EXPEDITED			US-ALLERGAN-1716929US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960398	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1721897US		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960400	NON-EXPEDITED			US-ALLERGAN-1721539US		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Sweats	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960401	NON-EXPEDITED			US-ALLERGAN-1722749US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout	Lexapro			S		Unk		Allergan
	Warfarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960402	NON-EXPEDITED			US-ALLERGAN-1720192US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960403	NON-EXPEDITED			US-ALLERGAN-1717278US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960404	NON-EXPEDITED			US-ALLERGAN-1717763US		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Drug Ineffective; Memory Impairment	Lexapro			S		10 Mg, Unk		Allergan
	Synthroid			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960405	NON-EXPEDITED			US-ALLERGAN-1717075US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	10 Mg, Qam		Allergan
	Lexapro			S	Oral	5 Mg, Qam		Allergan

	Adderall		C	Oral	20 Mg, Qam	Not Reported
	Risperidone		C	Oral	1 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960406	NON-EXPEDITED			US-ALLERGAN-1716142US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Malaise; Product Dose Omission	Lexapro			S	Oral	10 Mg, Bid		Allergan
	Propecia			C		Unk, Qd		Not Reported
	Allegra			C		Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960410	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1722465US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Faeces Discoloured; Melaena; Upper Gastrointestinal Haemorrhage	Escitalopram Oxalate - Bp			S		Unk		Allergan
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960414	NON-EXPEDITED			US-ALLERGAN-1721230US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Negative Thoughts; Off Label Use; Off Label Use	Lexapro			S	Unknown	Unk Unk, Qd		Allergan
	Lexapro			S	Unknown	Unk		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960415	NON-EXPEDITED			US-ALLERGAN-1720156US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea | Lexapro | S | Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960416	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1719146US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Gastrooesophageal Reflux Disease; Hyperhidrosis; Insomnia; Obesity; Serotonin Syndrome; Tardive Dyskinesia; Vitamin B6 Deficiency	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Ampyra			S	Oral	10 Mg, Q12h		Not Reported
	Ampyra			S				Not Reported
	Baclofen			S	Oral	10 Mg, Tid		Not Reported
	Phentermine			S	Unknown			Not Reported
	Aspirin			C	Unknown	81 Mg, Qd		Not Reported
	Celebrex			C	Unknown	200 Mg, Qd		Not Reported
	Oxycontin			C	Unknown	30 Mg, Qhs		Not Reported
	Oxycodone			C	Unknown	15 Mg, 4 Times A Day As Needed, Maximum Of 6 Tablets		Not Reported
	Levemir			C	Unknown	20 Units, Qam		Not Reported
	Levemir			C	Unknown	25 Units, Qhs		Not Reported
	Spironolactone			C	Unknown	50 Mg, Bid		Not Reported
	Zyrtec			C	Unknown	10 Mg, Prn		Not Reported
	Naloxegol			C	Oral	25 Mg, Prn		Not Reported
	Ambien			C	Unknown	10 Mg, Qhs		Not Reported
	Vitamin D3			C	Oral	5000 Iu, Qd		Not Reported
	Clonidine			C	Oral	0.1 Mg, Bid		Not Reported
	Levomefolic Acid			C	Unknown			Not Reported
	Lisinopril			C	Unknown	5 Mg, Qpm		Not Reported
	Maalox			C	Unknown	10 Ml, 4 Times Daily		Not Reported
	Premarin			C	Unknown	0.3 Mg, Qd		Not Reported
	Pantoprazole			C	Unknown	40 Mg, Bid		Not Reported
	Lipitor			C	Oral	20 Mg, Qpm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960417	NON-EXPEDITED			US-ALLERGAN-1720734US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hyperhidrosis; Tremor	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960418	NON-EXPEDITED			US-ALLERGAN-1722531US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Simvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960419	NON-EXPEDITED			US-ALLERGAN-1726110US		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960421	NON-EXPEDITED			US-ALLERGAN-1724037US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960423	NON-EXPEDITED			US-ALLERGAN-1723870US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Lexapro			S	Unknown	Unk			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960429	NON-EXPEDITED			US-ALLERGAN-1725049US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy	Lexapro			S	Oral	1 Df, Qd		Allergan
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960431	NON-EXPEDITED			US-ALLERGAN-1727010US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram Oxalate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960432	NON-EXPEDITED			US-ALLERGAN-1723253US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Disorder; Sedation	Lexapro			S		10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960433	NON-EXPEDITED			US-ALLERGAN-1725940US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Feeling Abnormal; Incorrect Dose Administered; Somnolence	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960434	NON-EXPEDITED			US-ALLERGAN-1725246US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960436	NON-EXPEDITED			US-ALLERGAN-1728565US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Behaviour Disorder; Irritability	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lithium			C	Oral	300 Mg, Qhs		Not Reported
	Ativan			C	Oral	0.5 Mg, Qam		Not Reported
	Haldol			C	Oral	1 Mg, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960438	NON-EXPEDITED			US-ALLERGAN-1727615US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Pruritus Generalised	Lexapro			S	Unknown	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960442	NON-EXPEDITED			US-ALLERGAN-1725019US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejaculation Delayed; Incorrect Dose Administered	Lexapro			S		10 Mg, Tid		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960443	NON-EXPEDITED			US-ALLERGAN-1723193US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity	Lexapro			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960446	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1728582US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anger; Irritability; Suicidal Ideation	Lexapro			S	Oral	20 Mg, Unk		Allergan
	Lexapro			S	Oral	10 Mg, Unk		Allergan
	Lorazepam			C	Oral	Unk Unk, Qd		Not Reported
	Tegretol			C	Oral	Unk Unk, Qd		Not Reported
	Abilify			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960447	NON-EXPEDITED			US-ALLERGAN-1728662US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nightmare	Lexapro			S	Unknown			Allergan
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960448	NON-EXPEDITED			US-ALLERGAN-1730992US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Lexapro	S		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960452	NON-EXPEDITED			US-ALLERGAN-1732582US		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heat Stroke	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lorazepam			C				Not Reported
	Crestor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960453	NON-EXPEDITED			US-ALLERGAN-1729773US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Chest Pain; Dizziness; Palpitations; Product Dose Omission; Sensory Disturbance; Wrong Technique In Product Usage Process	Lexapro			S	Oral	5 Mg, Unk		Allergan
	Lexapro			S	Oral	5 Mg, Unk		Allergan
	Lorazepam			C		1 Mg, Unk		Not Reported
	Crestor			C	Unknown	5 Mg, Unk		Not Reported
	Aspirin			C	Unknown	81 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960454	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1730585US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Off Label Use; Vomiting	Lexapro			S	Unknown	Unk		Allergan
	Protonix			C	Unknown	Unk Unk, Qd		Not Reported
	Metoprolol			C	Unknown	100 Mg, Qd		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960455	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1731635US		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Hypomania; Mania; Off Label Use	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Unk		Allergan
	Concerta			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960458	NON-EXPEDITED			US-ALLERGAN-1729169US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment	Lexapro			S	Unknown	Unk		Allergan
	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960461	NON-EXPEDITED			US-ALLERGAN-1730595US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960466	NON-EXPEDITED			US-ALLERGAN-1735369US		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flight Of Ideas; Hypomania; Insomnia	Lexapro			S	Unknown	Unk		Allergan
	Latuda			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960468	NON-EXPEDITED			US-ALLERGAN-1734550US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Off Label Use; Product Dose	Lexapro			S	Unknown	Unk		Allergan

Omission

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960469	NON-EXPEDITED			US-ALLERGAN-1734600US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram Oxalate Unk			S	Unknown			Allergan
	Fluoxetine Hcl Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960470	NON-EXPEDITED			US-ALLERGAN-1733234US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Bystolic			S	Unknown			Allergan
	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960476	NON-EXPEDITED			US-ALLERGAN-1732856US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960477	NON-EXPEDITED			US-ALLERGAN-1733577US		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
	Estring			C	Unknown	Unk		Not Reported
	Buspirone			C	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960478	NON-EXPEDITED			US-ALLERGAN-1733342US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Therapeutic Response Unexpected; Weight Increased	Lexapro			S	Unknown			Allergan
	Levoxyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960489	NON-EXPEDITED			US-ALLERGAN-1750355US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hip Arthroplasty; Intestinal Prolapse	Lexapro			S	Oral	290 Mg, Unk		Allergan
	Seroquel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960506	NON-EXPEDITED			US-ALLERGAN-1000087660			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Crying; Dizziness; Feeling Abnormal; Headache; Incorrect Dose Administered; Night Sweats; Off Label Use; Panic Attack	Lexapro			S		20 Mg, Qd		Allergan
	Lexapro			S		30 Unk, Unk		Allergan
	Synthroid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960507	NON-EXPEDITED			US-FRI-1000087171			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Dose Omission	Lexapro	S	5 Mg/Day		Allergan
	Lexapro	S	5 Mg/Day		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960508	NON-EXPEDITED			US-FRI-1000086885			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Breast Pain; Breast Tenderness; Chest Pain; Drug Interaction; Dyspnoea; Fatigue; Fibromyalgia; General Physical Health Deterioration; Pain; Pharyngitis; Pollakiuria; Sinusitis; Thirst	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Latuda			S	Oral	80 Mg, Qd		Not Reported
	Latuda			S	Oral	120 Mg, Qd		Not Reported
	Latuda			S	Oral	40 Mg, Qd		Not Reported
	Latuda			S	Oral	60 Mg, Qd		Not Reported
	Prilosec			C		Unk		Not Reported
	Risperdal			C		Unk		Not Reported
	Vitamin C With Zinc			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960509	NON-EXPEDITED			US-FRI-1000087003			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Therapeutic Response Shortened	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Zoloft			C	Oral	25 Mg, Qd		Not Reported
	Xanax			C	Oral	.25 Mg, Qd		Not Reported
	Bio-Identical Progesterone			C		100 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960510	NON-EXPEDITED			US-FRI-1000086919			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Faeces Discoloured	Lexapro	S	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960511	NON-EXPEDITED			US-ALLERGAN-1000087484			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960512	NON-EXPEDITED			US-ALLERGAN-1670094US		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cold Sweat; Diarrhoea; Dizziness; Headache; Nausea; Nerve Injury; Tinnitus	Lexapro			S	Oral	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960513	NON-EXPEDITED			US-ALLERGAN-1000087472			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Somnolence	Lexapro			S		10 Mg, Unk		Allergan
	Lexapro			S		5 Mg, Unk		Allergan
	Coumadin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960514	NON-EXPEDITED			US-ALLERGAN-1672112US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S		Unk		Allergan
	Levoxyl			S		224 Mcg, Qd		Not Reported

Lyrica	S	Oral	150 Mg, Bid		Not Reported
Zoloft	S	Oral	100 Mg, Qd		Not Reported
Combivent	C	Respiratory (inhalation)	2 Puffs, Qid		Not Reported
Biotin	C	Oral	1000 Mg, Six Times Daily		Not Reported
Cholecalciferol	C	Oral	15000 Units, Qd		Not Reported
Clonazepam	C	Oral	1-2 Tablets, Qhs		Not Reported
Clonazepam	C				Not Reported
Cyanocobalamin	C	Oral	1000 Mcg, Qd		Not Reported
Fluocinolone	C		Unk		Not Reported
Folic Acid	C	Oral	400 Mcg, Qd		Not Reported
Norco	C	Oral	1 Tablet Every 6 Hours As Needed		Not Reported
Eskalith	C	Oral	450 Mg, Bid		Not Reported
Naratriptan	C	Oral	2.5 Mg, Prn		Not Reported
Taclonex	C	Topical	Unk		Not Reported
Trazodone	C	Oral	100 Mg, Qpm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960515	NON-EXPEDITED			US-ALLERGAN-1000087677		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960516	NON-EXPEDITED			US-ALLERGAN-1670306US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960517	NON-EXPEDITED			US-ALLERGAN-1670396US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nightmare; Sleep Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Lexapro			S				Allergan
	Ibuprofen			C	Oral	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960524	NON-EXPEDITED			US-ALLERGAN-1671666US		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Cough; Diarrhoea; Fear; Headache; Nausea	Lexapro			S		7 Mg, Unk		Allergan
	Tyvaso			S	Respiratory (inhalation)	18 Mg, Qid		Not Reported
	Tyvaso			S	Respiratory (inhalation)	36 Mg, Qid		Not Reported
	Tyvaso			S	Respiratory (inhalation)	54 Mg, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960525	NON-EXPEDITED			US-ALLERGAN-1672528US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Off Label Use; Product Dose Omission; Withdrawal Syndrome	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960526	NON-EXPEDITED			US-ALLERGAN-1671981US		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Jittery; Inappropriate Schedule Of Product Administration	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lorazepam			C	Oral	Unk		Not Reported
	Spiriva Combi			C	Respiratory (inhalation)	Unk		Not Reported
	Ventolin			C	Respiratory (inhalation)	Unk		Not Reported
	Albuterol Sulfate			C	Respiratory (inhalation)	Unk		Not Reported
	Flovent			C	Respiratory (inhalation)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960527	NON-EXPEDITED			US-ALLERGAN-1672611US		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Off Label Use	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Atenolol			C		5 Mg, Qd		Not Reported
	Baby Aspirin			C		Unk		Not Reported
	Lipitor			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960528	NON-EXPEDITED			US-ALLERGAN-1671413US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Off Label Use	Lexapro			S		10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960529	NON-EXPEDITED			US-ALLERGAN-1672412US		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Constipation; Eye Swelling; Formication; Off Label Use; Paraesthesia	Lexapro			S	Oral	5 Mg, Unk		Allergan
	Lexapro			S	Oral	10 Mg, Unk		Allergan
	Cardizem			C	Oral	Unk		Not Reported
	Biotin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960530	NON-EXPEDITED			US-ALLERGAN-1671723US		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vulvovaginal Burning Sensation; Vulvovaginal Dryness	Lexapro			S		10 Mg, Unk		Allergan
	Lisinopril			C		Unk		Not Reported
	Coreg			C		Unk		Not Reported
	Crestor			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960531	NON-EXPEDITED			US-ALLERGAN-1672088US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis	Lexapro			S				Allergan
	Sertraline			C		50 Mg, Unk		Not Reported
	Sertraline			C		100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960532	NON-EXPEDITED			US-ALLERGAN-1671202US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Fatigue; Implantation Complication; Insomnia; Rash	Lexapro			S	Oral	Unk		Allergan
	Lexapro			S				Allergan
	Pravastatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960538	NON-EXPEDITED			US-ALLERGAN-1673514US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hyperhidrosis; Palpitations; Tremor	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Diazepam			C	Oral	Unk		Not Reported
	Gabapentin			C	Oral	Unk		Not Reported
	Progesterone			C		Unk		Not Reported
	Progesterone			C				Not Reported
	Estrogen			C		Unk		Not Reported
	Estrogen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960539	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1673777US		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Product Dose Omission; Suicidal Ideation	Lexapro			S		10 Mg, Qd		Allergan
	Abilify			S		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960540	NON-EXPEDITED			US-ALLERGAN-1673272US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cough; Depressed Level Of Consciousness; Dyspnoea; Rash; Weight Increased	Lexapro			S	Oral	10 Mg, Unk		Allergan
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960541	NON-EXPEDITED			US-ALLERGAN-		65 YR	Female	USA

1674141US

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Off Label Use; Vertigo	Lexapro			S		20 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Horizant			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960542	NON-EXPEDITED			US-ALLERGAN-1674478US		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Abdominal Pain Upper; Diarrhoea; Nausea	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Trintellix			S	Oral	20 Mg, Qd		Not Reported
	Trintellix			S	Oral	10 Mg, Qd		Not Reported
	Verapamil Er			C		Unk		Not Reported
	Hydrochlorothiazide			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported
	Alprazolam			C		Unk		Not Reported
	Carisoprodol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960543	NON-EXPEDITED			US-ALLERGAN-1672698US		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro			S	Oral	Unk Unk, Unknown		Allergan
	Seroquel			C		Unk		Not Reported

	Concerta	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960544	NON-EXPEDITED			US-ALLERGAN-1674720US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Oxycodone			C		10 Mg, Tid		Not Reported
	Losartan			C		100 Mg, Qd		Not Reported
	Alprazolam			C		5 Mg, Qhs		Not Reported
	Claritin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960545	NON-EXPEDITED			US-ALLERGAN-1674662US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective	Lexapro			S				Allergan
	Pristiq			S				Not Reported
	Clonidine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960546	NON-EXPEDITED			US-ALLERGAN-1673932US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Irritability; Peripheral Swelling	Lexapro			S		10 Mg, Qd		Allergan
	Ambien			C		Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960547	NON-EXPEDITED			US-ALLERGAN-1674399US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Feeling Hot; Product Dose Omission	Lexapro			S		Unk			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960549	NON-EXPEDITED			US-ALLERGAN-1674769US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Lexapro			S		20 Unk, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960550	NON-EXPEDITED			US-ALLERGAN-1675551US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960551	NON-EXPEDITED			US-ALLERGAN-1676903US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Tremor; Vomiting; Withdrawal Syndrome	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Metformin			C				Not Reported
	Forxiga			C				Not Reported
	Losartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960552	NON-EXPEDITED			US-ALLERGAN-1677782US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Lexapro			S	Oral	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960553	NON-EXPEDITED			US-ALLERGAN-1678655US		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Confusional State; Dizziness; Dyskinesia; Memory Impairment; Pollakiuria; Tardive Dyskinesia; Weight Increased	Lexapro			S		Unk		Allergan
	Abilify			S		Unk		Not Reported
	Depakote			C				Not Reported
	Klonopin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960554	NON-EXPEDITED			US-ALLERGAN-1677788US		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Diarrhoea; Nausea; Viral Infection; Weight Decreased	Lexapro			S		Unk		Allergan
	Flagyl			S	Oral	Unk		Not Reported
	Amoxicillin			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported
	Tramadol			C				Not Reported
	Lorazepam			C				Not Reported
	Colazal			C				Not Reported
	Zantac			C				Not Reported
	Prilosec			C				Not Reported
	Dicyclomine			C				Not Reported
	Dyazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960555	NON-EXPEDITED			US-ALLERGAN-1677112US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Lexapro			S	Oral	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960556	NON-EXPEDITED			US-ALLERGAN-1675391US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960557	NON-EXPEDITED			US-ALLERGAN-1678166US		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal; Hypoaesthesia Oral; Libido Decreased; Mood Swings; Paraesthesia Oral; Weight Increased	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Omeprazole			C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960562	NON-EXPEDITED			US-ALLERGAN-1680180US		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Insomnia	Lexapro			S	Oral	10 Mg, Unk		Allergan
	Lexapro			S	Oral	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960563	NON-EXPEDITED			US-ALLERGAN-1680011US		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Diarrhoea; Incorrect Dose Administered; Insomnia; Malaise; Nausea; Wrong	Lexapro			S	Oral	Unk, Qd		Allergan
	Lexapro			S				Allergan
	Bupropion			C	Oral	200 Mg, Bid		Not Reported
	Bupropion			C				Not Reported

Technique In Product Usage Process

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960564	NON-EXPEDITED			US-ALLERGAN-1679416US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960565	NON-EXPEDITED			US-ALLERGAN-1679726US		93 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness	Lexapro			S	Oral	2.5 Mg, Qd		Allergan
	Lexapro			S		5 Mg, Unk		Allergan
	Lexapro			S	Oral	2.5 Mg Qd		Allergan
	Prednisone			C				Not Reported
	Keppra			C		Unk		Not Reported
	Depakote			C		Unk		Not Reported
	Plavix			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960566	NON-EXPEDITED			US-ALLERGAN-1681077US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Feeling Abnormal; Motion Sickness	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960567	NON-EXPEDITED			US-ALLERGAN-1681413US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Cough; Decreased Appetite; Dizziness; Drug Ineffective; Dysstasia; Feeling Abnormal; Incontinence; Malaise; Nausea; Pain; Sneezing; Weight Increased; Withdrawal Syndrome	Lexapro			S	Unknown	20 Mg, Qd		Allergan
	Metoprolol			C	Unknown	25 Mg, Unk		Not Reported
	Amlodipine			C	Unknown	5 Mg, Qd		Not Reported
	Protonix			C	Unknown	20 Mg, Qd Or Bid		Not Reported
	Zantac			C	Unknown	150 Mg, Once Or Twice Daily After A Meal		Not Reported
	Ms Contin			C	Unknown	15 Mg, Qd		Not Reported
	Lyrica			C	Unknown	75 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960568	NON-EXPEDITED			US-ALLERGAN-1679069US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960569	NON-EXPEDITED			US-ALLERGAN-1679743US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960571	NON-EXPEDITED			US-ALLERGAN-1677792US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Diarrhoea; Genital Disorder Female; Incorrect Dose Administered; Product Dose Omission; Urinary Tract Infection	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Namenda			S	Oral			Not Reported
	Senna			C	Oral	Unk		Not Reported

	Neurontin	C	Oral	Unk	Not Reported
	Allopurinol	C	Oral	Unk	Not Reported
	Percocet	C	Oral		Not Reported
	Tylenol	C	Oral	Unk	Not Reported
	Valium	C	Oral		Not Reported
	Vitamin C	C	Oral	Unk	Not Reported
	Vitamin D2	C	Oral	Unk	Not Reported
	Iron	C	Oral	Unk	Not Reported
	Humalog	C		Unk	Not Reported
	Lantus	C		Unk	Not Reported
	Fish Oil	C			Not Reported
	Laxative	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960572	NON-EXPEDITED			US-ALLERGAN-1700526US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hair Texture Abnormal; Incorrect Product Dosage Form Administered	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960574	NON-EXPEDITED			US-ALLERGAN-1681432US		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Tremor	Lexapro			S	Unknown	10 Mg, Daily		Allergan
	Ativan			C		Unk		Not Reported
	Mavik			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Fioricet			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960575	NON-EXPEDITED			US-ALLERGAN-1700673US		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Fatigue; Gait Disturbance; Muscular Weakness; Myalgia; Off Label Use	Lexapro			S	Oral	30 Mg, Qd		Allergan
	Lexapro			S	Oral	Unk Unk, Qd		Allergan
	Lexapro			S	Oral	30 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960576	NON-EXPEDITED			US-ALLERGAN-1682074US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Tooth Extraction	Lexapro			S	Oral	20 Mg, Unk		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960577	NON-EXPEDITED			US-ALLERGAN-1700201US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960578	NON-EXPEDITED			US-ALLERGAN-1681582US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960579	NON-EXPEDITED			US-ALLERGAN-1700278US		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Decreased Appetite; Dizziness; Dry Mouth; Hyperhidrosis; Insomnia; Memory Impairment; Nausea; Somnolence; Taste Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Synthroid			C	Oral	Unk		Not Reported
	Aspirin			C	Oral	81 Mg, Qd		Not Reported
	B-12			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960580	NON-EXPEDITED			US-ALLERGAN-1700509US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960581	NON-EXPEDITED			US-ALLERGAN-1700221US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960582	NON-EXPEDITED			US-ALLERGAN-1681420US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Male Sexual Dysfunction	Lexapro			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960584	NON-EXPEDITED			US-ALLERGAN-1701209US		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Level Increased; Road Traffic Accident	Lexapro	S	Unknown			Allergan
	Lamotrigine	S	Unknown	20 Mg, Qd		Not Reported
	Citalopram	S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960585	NON-EXPEDITED			US-ALLERGAN-1701071US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960589	NON-EXPEDITED			US-ALLERGAN-1701060US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Insomnia	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960594	NON-EXPEDITED			US-ALLERGAN-1702271US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960595	NON-EXPEDITED			US-ALLERGAN-1701467US		69 YR	Male	USA

Blood Testosterone Decreased	Lexapro	S	Oral	10 Mg, Qd		Allergan
	Gemfibrocil	C	Oral	Unk		Not Reported
	Allopurinol	C	Oral	300 Mg, Qd		Not Reported
	Alprazolam	C	Oral	0.5 Mg, Qd		Not Reported

Atorvastatin Calcium	C	Oral	40 Mg, Qd		Not Reported
Atenolol	C	Oral	50 Mg, Bid		Not Reported
Hydrochlorothiazide	C	Oral	12.5 Mg, Qd		Not Reported
Klor-Con M20	C	Oral	Unk Unk, Qd		Not Reported
Trazodone	C	Oral	50 Mg, Qhs		Not Reported
Hydrocodone/Acetaminophen /00607101/	C	Oral	Unk Unk, Qhs		Not Reported
Hydrocodone/Acetaminophen /00607101/	C				Not Reported
Enzalutamide	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960596	NON-EXPEDITED			US-ALLERGAN-1701295US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Hydrocodone/Acetaminophen			C	Unknown			Not Reported
	Omeprazole			C	Unknown	40 Mg, Qd		Not Reported
	Naproxen			C		500 Mg, Prn		Not Reported
	Lyrica			C	Unknown	Unk, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960597	NON-EXPEDITED			US-ALLERGAN-1700908US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960603	NON-EXPEDITED			US-ALLERGAN-1700732US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Nausea; Vomiting	Lexapro	S	Unknown	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960604	NON-EXPEDITED			US-ALLERGAN-1701105US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Hypertension; Insomnia; Panic Attack; Panic Attack; Suicidal Ideation; Tobacco User	Lexapro			S		20 Mg, Qd		Allergan
	Lexapro			S		10 Mg, Qd		Allergan
	Chantix			C		Unk		Not Reported
	Trazodone			C		25 Mg, Prn		Not Reported
	Metoprolol Tartrate			C		25 Mg, Bid		Not Reported
	Prozac			C		20 Mg, Unk		Not Reported
	Prozac			C				Not Reported
	Ativan			C		0.5 Mg, Tid		Not Reported
	Ativan			C				Not Reported
	Zoloft			C		Unk		Not Reported
	Zoloft			C				Not Reported
	Buspar			C		Unk		Not Reported
	Quetiapine			C		Unk		Not Reported
	Mirtazapine			C		Unk		Not Reported
	Mirtazapine			C				Not Reported
	Fluoxetine			C		Unk		Not Reported
	Fluoxetine			C				Not Reported
	Cymbalta			C		Unk		Not Reported
	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960605	NON-EXPEDITED			US-ALLERGAN-1702170US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Depressed Mood; Insomnia;	Lexapro			S	Oral	10 Mg, Qd		Allergan

Restlessness

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960606	NON-EXPEDITED			US-ALLERGAN-1701813US		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Feeling Abnormal; Off Label Use	Lexapro			S	Oral	30 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960607	NON-EXPEDITED			US-ALLERGAN-1702189US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Abulia; Amnesia; Apathy; Drug Ineffective; Fatigue; Impulsive Behaviour; Insomnia; Loss Of Consciousness; Urinary Incontinence	Lexapro			S		20 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Effexor			S		37.5 Mg, Qd		Not Reported
	Effexor			S		75 Mg, Qd		Not Reported
	Effexor			S		150 Mg, Qd		Not Reported
	Zoloft			S		25 Mg, Qd		Not Reported
	Zoloft			S		25 Mg, Bid		Not Reported
	Prozac			S		Unk		Not Reported
	Prozac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960609	NON-EXPEDITED			US-ALLERGAN-1702555US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Depression; Fibromyalgia; Gait Disturbance; Loss Of Personal Independence In Daily Activities	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, Single		Not Reported
	Humira			S	Subcutaneous	40 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960610	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1702277US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Inability To Afford Medication; Suicidal Ideation; Suicide Attempt	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960611	NON-EXPEDITED			US-ALLERGAN-1702970US		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fatigue; Mental Disorder; Mood Swings	Lexapro			S		5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960612	NON-EXPEDITED			US-ALLERGAN-1702880US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro			S				Allergan
	Penicillin (Benzylpenicillin)			C				Not Reported
	Wellbutrin			C				Not Reported
	Mobic			C				Not Reported
	Atorvastatin			C				Not Reported
	Simvastatin			C				Not Reported
	Lidocaine			C				Not Reported
	Pravastatin			C				Not Reported
	Norco			C				Not Reported
	Elavil			C				Not Reported
	Effexor			C				Not Reported
	Doxycycline			C				Not Reported
	Viibryd			C				Not Reported
	Lipitor			C				Not Reported
	Sertraline			C				Not Reported
	Azithromycin			C				Not Reported

	Trazodone	C	Unk	Not Reported
	Nitrostat	C		Not Reported
	Ibuprofen	C		Not Reported
	Gemfibrozil	C		Not Reported
	Lisinopril	C		Not Reported
	Methocarbamol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960613	NON-EXPEDITED			US-ALLERGAN-1702196US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown			Allergan
	Fioricet Capsules			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960614	NON-EXPEDITED			US-ALLERGAN-1701970US		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Incorrect Dose Administered; Malaise; Product Dose Omission; Therapeutic Response Unexpected; Wrong Technique In Product Usage Process	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960615	NON-EXPEDITED			US-ALLERGAN-1702240US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hypometabolism; Weight Increased	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960616	NON-EXPEDITED			US-ALLERGAN-1703057US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Disturbance In Attention; Feelings Of Worthlessness; Irritability; Memory Impairment; Off Label Use; Social Avoidant Behaviour; Social Fear	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Lexapro			S	Unknown	20 Mg, Unk		Allergan
	Lexapro			S	Unknown	30 Mg, Unk		Allergan
	Lexapro			S	Unknown	20 Mg, Unk		Allergan
	Wellbutrin			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960617	NON-EXPEDITED			US-ALLERGAN-1703738US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960618	NON-EXPEDITED			US-ALLERGAN-1702551US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Stomatitis	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960619	NON-EXPEDITED			US-ALLERGAN-1702952US		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Rash	Lexapro			S	Oral	5 Mg, Qd		Allergan

	Lexapro		S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960620	NON-EXPEDITED			US-ALLERGAN-1702579US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dehydration; Fatigue; Inappropriate Schedule Of Product Administration; Mental Impairment; Off Label Use; Sexual Dysfunction; Sluggishness; Thirst	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Unknown	15 Mg, Qd		Allergan
	Lexapro			S	Unknown	30 Mg, Qd		Allergan
	Zyrtec			C		Unk Unk, Prn		Not Reported
	Digestive Enzymes			C				Not Reported
	Beano			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960622	NON-EXPEDITED			US-ALLERGAN-1703421US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation	Lexapro			S	Oral	15 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960623	NON-EXPEDITED			US-ALLERGAN-1703621US		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Decreased	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960624	NON-EXPEDITED			US-ALLERGAN-1703728US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Lexapro	S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960625	NON-EXPEDITED			US-ALLERGAN-1703888US		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Insomnia; Pain; Peripheral Swelling; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan
	Klonopin			S	Oral	1 Mg, Tid		Not Reported
	Klonopin			S				Not Reported
	Lyrica			S	Oral	50 Mg, Qhs		Not Reported
	Lyrica			S	Oral	75 Mg, Qhs		Not Reported
	Lyrica			S	Oral	100 Mg, Qhs		Not Reported
	Nortriptylin			C		25 Mg, Qhs		Not Reported
	Flexeril /00428402/			C		Unk		Not Reported
	Treximet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960626	NON-EXPEDITED			US-ALLERGAN-1703803US		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Decreased; Weight Gain Poor	Lexapro			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960627	NON-EXPEDITED			US-ALLERGAN-1703823US		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Memory Impairment	Lexapro			S		5 Mg, Unk		Allergan
	Lexapro			S		10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960636	NON-EXPEDITED			US-ALLERGAN-1704872US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Ativan			C	Unknown	Unk		Not Reported
	Buspirone			C	Unknown	7.5 Mg, Qd		Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Gabapentine			C	Unknown	100 Mg, Tid		Not Reported
	Tramadol			C	Unknown	50 Mg, Prn		Not Reported
	Meloxicam			C		15 Mg, Qhs		Not Reported
	Protonix			C	Unknown	40 Mg, Qhs		Not Reported
	Fluconazole			C	Unknown	Unk		Not Reported
	Robaxin			C	Unknown	Unk Unk, Prn		Not Reported
	Trazodone			C	Unknown	Unk Unk, Prn		Not Reported
	Doxycycline			C	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960637	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1705410US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Fatigue; Injection Site Bruising; Joint Swelling; Musculoskeletal Pain; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Lexapro			S	Unknown	Unk		Allergan
	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960638	NON-EXPEDITED			US-ALLERGAN-1705972US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960639	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1704777US		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Malaise; Suicidal Ideation	Lexapro			S				Allergan
	Morphine Sulfate			S		20 Mg, Bid		Not Reported
	Percocet			C		Unk		Not Reported
	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960640	NON-EXPEDITED			US-ALLERGAN-1705236US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Therapeutic Product Effect Increased; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10-15 Mg		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960641	NON-EXPEDITED			US-ALLERGAN-1705990US		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960642	NON-EXPEDITED			US-ALLERGAN-1704706US		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenopia; Drug Ineffective; Dry Mouth; Feeling Abnormal; Feeling Jittery; Malaise; Nervousness; Palpitations; Visual Impairment	Lexapro		S	Oral	20 Mg, Unknown	Allergan
	Lexapro		S			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960643	NON-EXPEDITED			US-ALLERGAN-1707276US		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Constipation; Decreased Appetite; Insomnia; Off Label Use; Tremor	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Primidone			C	Oral	1 Df, Qhs		Not Reported
	Methotrexate			C	Oral	2.5 Mg, Q Week		Not Reported
	Aspirin			C	Oral	Unk		Not Reported
	Amlodipine			C	Oral	Unk		Not Reported
	Folic Acid			C	Oral	Unk		Not Reported
	Iron			C	Oral	Unk		Not Reported
	Vitamin C			C	Oral	500 Mg, Unk		Not Reported
	Multivitamin			C	Oral	Unk		Not Reported
	Clonidine			C	Transdermal	Unk		Not Reported
	Metamucil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960644	NON-EXPEDITED			US-ALLERGAN-1707811US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960645	NON-EXPEDITED			US-ALLERGAN-1707296US		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dry Mouth; Feeling Jittery; Insomnia	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan
	Trazodone			S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960646	NON-EXPEDITED			US-ALLERGAN-1708019US		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Contraindication To Medical Treatment	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960647	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1706922US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Decreased Appetite; Decubitus Ulcer; Diarrhoea; Serotonin Syndrome; Somnolence	Lexapro			S	Unknown			Allergan
	Prednisone			C				Not Reported
	Calcium			C				Not Reported
	Vitamin D2			C				Not Reported
	Lasix			C				Not Reported
	Hydrocodone/Apap			C				Not Reported
	Lipitor			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Vitamin C			C				Not Reported
	Sandostatin			C				Not Reported
	Pradaxa			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960648	NON-EXPEDITED			US-ALLERGAN-1706994US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960649	NON-EXPEDITED			US-ALLERGAN-1707059US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Ineffective; Dyspepsia; Hyperhidrosis; Insomnia; Retching	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960650	NON-EXPEDITED			US-ALLERGAN-1706965US		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Feeling Jittery	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960654	NON-EXPEDITED			US-ALLERGAN-1706083US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Product Dose Omission; Vision Blurred	Lexapro			S	Unknown	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960655	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1709186US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Dyspnoea; Fall; Mood Altered; Skin Discolouration	Lexapro			S	Unknown	20 Mg, Unk		Allergan
	Chantix			S	Unknown	Unk		Not Reported
	Klonopin			C	Unknown	1 Mg, Bid		Not Reported
	Amitriptyline			C	Oral	20 Mg, Qhs		Not Reported
	Ambien			C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960656	NON-EXPEDITED			US-ALLERGAN-1709508US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Alprazolam			C	Unknown	2 Mg, Prn		Not Reported
	Coumadin			C	Unknown	6 Mg, Bi-Weekly		Not Reported
	Coumadin			C		4 Mg, Rest Of The Week		Not Reported
	Clonazepam			C	Unknown	1 Mg, Bid		Not Reported
	Levothyroxine			C	Unknown	125 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960658	NON-EXPEDITED			US-ALLERGAN-1709341US		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Escitalopram Oxalate - Bp			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960659	NON-EXPEDITED			US-ALLERGAN-1708217US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pollakiuria; Sexual Dysfunction; Tinnitus	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S		5 Mg, Qd		Allergan
	Lexapro			S		10 Mg, Qd		Allergan
	Lisinopril			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960660	NON-EXPEDITED			US-ALLERGAN-1709581US		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Dizziness; Drug Interaction	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960661	NON-EXPEDITED			US-ALLERGAN-1706746US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960662	NON-EXPEDITED			US-ALLERGAN-1708278US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Palpitations; Tremor	Lexapro			S		Unk		Allergan
	Lithium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960668	NON-EXPEDITED			US-ALLERGAN-1709612US		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Mood Swings; Suicidal Ideation	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960669	NON-EXPEDITED			US-ALLERGAN-1709877US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960670	NON-EXPEDITED			US-ALLERGAN-1709955US		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Burning Sensation; Dry Skin; Erythema; Musculoskeletal Stiffness; Taste Disorder	Lexapro			S	Oral	20 Mg At Night		Allergan
	Lexapro			S				Allergan
	Levothyroxine			C	Oral	0.05 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13961895	NON-EXPEDITED		HO, LT	AU-EISAI MEDICAL RESEARCH-EC-2017-031012		34 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Fycompa			S	Oral			Not Reported
	Fycompa			S	Oral	Overdose		Not Reported
	Carbamazepine			S		Unknown		Not Reported
	Carbamazepine			S		Overdose		Not Reported
	Clobazam			S		Unknown		Not Reported
	Clobazam			S		Overdose		Not Reported
	Clonazepam			S		Unknown		Not Reported
	Clonazepam			S		Overdose		Not Reported
	Escitalopram			S		Unknown		Not Reported
	Escitalopram			S		Overdose		Not Reported
	Ferrous Sulphate			S		Unknown		Not Reported
	Ferrous Sulphate			S		Overdose		Not Reported
	Levetiracetam			S		Unknown		Not Reported
	Levetiracetam			S		3500 Mg		Not Reported
	Topiramate			S		Unknown		Not Reported
	Topiramate			S		200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13961946	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1751441US		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram Oxalate - Bp			S	Oral	10, Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13962740	DIRECT		OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Barrett'S Oesophagus; Constipation; Hiatus Hernia; Vomiting; Weight Decreased	Escitalopram Tab 10mg			S	Oral	Quantity:30 Tablet(S);		Teva
	Lansoprazole			C				Not Reported
	Linzess			C				Not Reported
	Daily Vitamin			C				Not Reported
	Probiotic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13423389	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017145646		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Tahor			S	Oral	20 Mg, 1x/Day		Pfizer
	Aromasine			S	Oral	25 Mg, 1x/Day		Pfizer
	Bisoprolol Hemifumarate			S	Oral	3.75 Mg, 1x/Day		Not Reported
	Pyostacine			S	Oral	500 Mg, Twice On The Morning And Twice On The Evening		Not Reported
	Coversyl /00790703/			S	Oral	2 Mg, 1x/Day		Not Reported
	Janumet			S		1000 Mg/500 Mg, Twice A Day		Not Reported
	Kardegic			S	Oral	160 Mg, 1x/Day		Not Reported

	Diamicron		S	Oral	30 Mg, 1x/Day	Not Reported
	Seroplex		S	Oral	10 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13551419	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1719602US		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Cerebrovascular Accident; Drug Intolerance; Hypertension; Lenticular Opacities; Tremor	Escitalopram Oxalate - Bp			S		5 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S		10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S		15 Mg, Unk		Allergan
	Tenoretic			C	Unknown	50mg/12.5mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13940389	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017382872		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Amiodarone Hcl			S	Unknown	Unk		Pfizer
	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Not Reported
	Domperidone			S	Unknown	Unk		Not Reported
	Aliskiren			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13940393	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017382831		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Amiodarone Hcl			S	Unknown	Unk		Pfizer
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13940400	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017382874		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Amiodarone Hcl			S	Unknown	Unk		Pfizer
	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported
	Flecainide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13963400	EXPEDITED (15-DAY)		CA	DE-HETERO CORPORATE-HET2017DE00138			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 Mg, Qd		Not Reported
	Loratadin			C	Transplacental	10 Mg, Qd		Not Reported
	Seasonale			C	Transplacental			Not Reported
	Folio Forte			C	Transplacental	0.8 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13966779	DIRECT	Y	HO, LT			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lactic Acidosis; Liver Injury; Rhabdomyolysis	Escitalopram			S	Oral		1 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13966609	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2017005937			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral	10 Mg, Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13966668	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2017-40000		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	15 Mg, Daily		Aurobindo
	Escitalopram			S	Transplacental	5 Mg, Daily		Aurobindo
	Folsaeure			C	Transplacental	0.8 Mg, Daily		Not Reported
	Folsaeure			C	Transplacental	0.4 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13966730	EXPEDITED (15-DAY)		OT	GB-TORRENT-00015603		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13967954	EXPEDITED (15-DAY)		OT	GB-ACCORD-058474		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13967966	EXPEDITED (15-DAY)		DE, HO, LT	AT-ALLERGAN-1751930US		73 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Condition Aggravated; Coronary	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Escitalopram Oxalate - Bp			S	Unknown	1-0-0		Allergan

Artery Disease; Dehydration; Fatigue; Oedema Peripheral; Pneumonia; Renal Impairment; Weight Decreased	Azilect	S	Unknown	1-0-0	Not Reported
	Stalevo	S	Unknown	Form Strength: 100mg/25mg/200mg	Not Reported
	Stalevo	S	Unknown	1-1-0	Not Reported
	Stalevo	S	Unknown	Form Strength: 50mg/12.5mg/200mg	Not Reported
	Trittico	S	Unknown	0-0-0-0.5	Not Reported
	Seroquel	S	Unknown		Not Reported
	Madopar	S	Unknown	1-1-1	Not Reported
	Lovenox	C	Unknown	1xtgl	Not Reported
	Elomel	C	Unknown	1xtgl	Not Reported
	Optinem	C	Unknown		Not Reported
	Lasix	C	Unknown		Not Reported
	Thrombo Ass	C	Unknown	0-1-0	Not Reported
	Spirobene	C	Unknown	0-0.5-0	Not Reported
	Sedacoron	C	Unknown	0.5-0-0	Not Reported
	Eporatio	C	Unknown		Not Reported
	Ceftriaxone Sodium	C	Unknown	2 G In 200 Ml, 1 X Tgl	Not Reported
	Dancor	C	Unknown	1-0-1	Not Reported
	Aquaphoril	C	Unknown	0.5-0-0	Not Reported
	Torasemide	C	Unknown	1-0-0	Not Reported
	Pantoloc	C	Unknown	2-0-0	Not Reported
	Insulatard	C	Unknown	6ie-0-0	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13970286	EXPEDITED (15-DAY)		CA	FR-ALLERGAN-1751914US		60 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Vesicoureteric Reflux; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			S	Transplacental	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13976877	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2017M1055963		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	15 [Mg/D]/ Dosage Reduction To 5 Mg/D From Week 30		Not Reported
	Folsaeure			C	Transplacental	0.8 [Mg/D]/ Dosage Reduction To 0.4 Mg/D		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13971966	DIRECT		OT			1 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Feeling Abnormal; Product Substitution Issue	Generic Lexapro			S	Oral	Quantity:3 Tablet(S);		Teva
	Lorazepam			C				Not Reported
	Norvasc			C				Not Reported
	Lexapro			C				Not Reported
	Daily Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13973503	EXPEDITED (15-DAY)		OT	FR-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00320		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Spironolactone			S	Unknown			Jubilant
	Escitalopram			S	Unknown	5 Mg		Jubilant
	Candesartan			S	Unknown			Not Reported
	Ivabradine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13973515	EXPEDITED (15-DAY)		OT	FR-JUBILANT CADISTA PHARMACEUTICALS-		85 YR	Female	FRA

2017JUB00322

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Irbesartan			S	Unknown			Jubilant
	Escitalopram			S	Unknown	10 Mg		Jubilant
	Galantamine			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Unspecified Diuretic			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13973589	EXPEDITED (15-DAY)		DS	DK-PFIZER INC-2017397640		18 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Arthralgia; Body Temperature Fluctuation; Constipation; Dyspepsia; Dyspnoea; Emotional Disorder; Head Discomfort; Hyperaesthesia; Middle Insomnia; Muscle Tightness; Nervous System Disorder; Paraesthesia; Stress; Tearfulness; Withdrawal Syndrome	Sertraline Hcl			S	Oral	Dosage: Varying		Pfizer
	Cipralex /01588501/			S	Oral	Dosage: Varying		Not Reported
	Venlafaxin 1a Pharma			S	Oral	Dosage: Varying		Not Reported
	Valdoxan			S	Oral	Dosage: Varying		Not Reported
	Paroxetine			S	Oral	Dosage: Varying		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13974930	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1752048US		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bundle Branch Block Right; Coma; Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Miosis	Escitalopram Oxalate - Bp		S	Oral	580 Mg Once	Allergan
	Doliprane		S	Oral	12000mg Per Oral Once	Not Reported
	Risperdal		S	Oral	10mg Per Oral Once	Not Reported
	Bromazepam		S	Oral	60 Mg Once	Not Reported
	Nurofen		S	Oral	Once	Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)		S	Oral	Once	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13976656	EXPEDITED (15-DAY)		OT	GB-TEVA-804835ACC		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13978095	NON-EXPEDITED			US-ASTRAZENECA-2017SE93490		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Nexium 24hr			S	Oral	Unk		Astrazeneca
	Omeprazole			S	Oral	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Protonix			S	Unknown	Unk		Not Reported
	Septra			S	Unknown	Unk		Not Reported
	Zoloft			S	Unknown	Unk		Not Reported
	Methylphenidate Hydrochloride			S	Unknown	Unk		Not Reported
	Ampicillin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Albuterol Sulfate			S	Unknown	Unk		Not Reported

Albuterol Sulfate	S	Unknown	Unk		Not Reported
Bactrim	S	Unknown	Unk		Not Reported
Bupropion Hydrochloride	S	Unknown	Unk		Not Reported
Cymbalta	S	Unknown	Unk		Not Reported
Fenofibrate	S	Unknown	Unk		Not Reported
Luvox	S	Unknown	Unk		Not Reported
Paxil /00500401/	S	Unknown	Unk		Not Reported
Percocet /00867901/	S	Unknown	Unk		Not Reported
Vicodin	S	Unknown	Unk		Not Reported
Wellbutrin	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13978625	EXPEDITED (15-DAY)		OT	FR-PRINSTON PHARMACEUTICAL INC.-2017PRN00435		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Furosemide			S	Unknown			Prinston Pharmaceutical
	Escitalopram			S	Unknown			Prinston Pharmaceutical
	Bisoprolol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13978632	EXPEDITED (15-DAY)		OT	FR-PRINSTON PHARMACEUTICAL INC.-2017PRN00436		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Irbesartan			S	Unknown			Prinston Pharmaceutical
	Escitalopram			S	Unknown	10mg		Prinston Pharmaceutical
	Galantamine			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported

	Unspecified Diuretic	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2017	13981574	DIRECT					53 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Dry Mouth; Dyspnoea; Palpitations; Panic Reaction; Paraesthesia; Suicidal Ideation; Swollen Tongue	Escitalopram		Y	S	Oral	Quantity:30 Tablet(S);		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13582648	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2017M1031674		42 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder; Condition Aggravated; Hepatic Enzyme Increased	Escitalopram			S	Unknown	Initial Dose Not Stated; Last Dose 5 Mg/Day Was Continued		Not Reported
	Escitalopram			S				Not Reported
	Carbamazepine			S	Unknown	Up To 1200 Mg/Day		Not Reported
	Fluvoxamine			S	Unknown			Not Reported
	Fluvoxamine			S				Not Reported
	Mirtazapine			S	Unknown	60 Mg/Day		Not Reported
	Mirtazapine			S				Not Reported
	Olanzapine			S	Unknown	10 Mg/Day, The Dose Was Further Increased To 15 Mg/Day		Not Reported
	Olanzapine			S	Unknown	15 Mg/Day		Not Reported
	Olanzapine			S	Unknown	5 Mg/Day		Not Reported
	Quetiapine			S	Unknown	50 Mg/Day		Not Reported
	Risperidone			S	Unknown	3 Mg/Day		Not Reported
	Omega 3 /01334101/			S	Unknown	700 Mg/Day, The Dose		Mylan

	Omega 3 /01334101/	S	Unknown	Was Further Increased To Double The Previous Dose Double The Previous Dose Of 700 Mg/Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13654857	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-143076		42 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased	Olanzapine			S	Unknown	10 Mg, Daily		Sun
	Olanzapine			S	Unknown	15 Mg, Daily		Sun
	Olanzapine			S	Unknown	5 Mg, Daily		Sun
	Mirtazapine			S	Unknown	60 Mg, Daily		Sun
	Carbamazepine			S	Unknown	1200 Mg, Daily		Taro
	Risperidone			S	Unknown	3 Mg, Daily		Ranbaxy
	Quetiapine			S	Unknown	50 Mg, Daily		Sun
	Fluvoxamine			S	Unknown	Unk		Sun
	Escitalopram			S	Unknown	5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13718569	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2017SE69060		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Pemphigoid	Inexium			S	Oral			Astrazeneca
	Seroplex			S	Unknown			Not Reported
	Calcium Acetate			S	Unknown			Not Reported
	Kardegic			S	Oral			Not Reported
	Lasilix Special			S	Unknown			Not Reported
	Uvedose			S	Unknown			Not Reported

	Levothyrox	S	Unknown	Not Reported
	Galvus	S	Unknown	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Novonorm	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13934799	EXPEDITED (15-DAY)		LT, OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-149094		16 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea; Suicide Attempt	Metoclopramide			S	Oral	Large Amount		Mutual
	Escitalopram			S	Oral	Large Amount		Not Reported
	Escitalopram			S	Unknown	5 Mg, Daily		Not Reported
	Pseudoephedrine			S	Oral	Large Amount		Sun
	Fluoxetine			S	Unknown	20 Mg, Daily		Sun
	Fluoxetine			S	Unknown	10 Mg, Daily		Sun
	Risperidone			C	Unknown	0.5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13974016	EXPEDITED (15-DAY)		HO, OT	FR-ALEMBIC PHARMACUETICALS LIMITED-2017SCAL000747			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Venlafaxine Hydrochloride			S	Unknown	225 Mg, Qd		Alembic
	Venlafaxine Hydrochloride			S				Alembic
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Sertraline			S	Unknown	Unk		Not Reported
	Sertraline			S				Not Reported
	Risperidone			S	Unknown	2 Mg, Qd		Not Reported
	Risperidone			S				Not Reported

	Paroxetine	S		Unk		Not Reported
	Paroxetine	S	Unknown	40 Mg, Qd		Not Reported
	Diazepam	C	Unknown	20 Mg, Qd		Not Reported
	Diazepam	C				Not Reported
	Quetiapine	C	Unknown	100 Mg, Qd		Not Reported
	Quetiapine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13980429	EXPEDITED (15-DAY)		HO, OT	NO-ASTRAZENECA-2017SE93458		21 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Seroquel			S	Oral	Unk		Zeneca
	Seroquel			S	Oral	Unk		Zeneca
	Seroquel			S	Oral	Unk		Zeneca
	Cipralex			S	Unknown	Unk Unk, Daily		Not Reported
	Efexor Depot			S	Unknown	Unk		Not Reported
	Efexor Depot			S	Unknown	Unk		Not Reported
	Efexor Depot			S	Unknown	Unk		Not Reported
	Efexor Depot			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown			Not Reported
	Cipramil			S	Unknown			Not Reported
	Seroxat			S	Unknown	Unk		Not Reported
	Seroxat			S	Unknown			Not Reported
	Orfiril			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Valproate Sodium			S	Unknown	Increasing Dose		Not Reported
	Lithionit			C		Unk		Not Reported
	Lithionit			C		Unk		Not Reported

Sobril	C	Unk Unk, As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13980670	EXPEDITED (15-DAY)		DE, HO, LT	AT-ORION CORPORATION ORION PHARMA-ENTC2017-0432		73 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Condition Aggravated; Coronary Artery Disease; Dehydration; Fatigue; Oedema Peripheral; Pneumonia; Renal Impairment; Weight Decreased	Stalevo			S	Unknown	Strength: 100/25/200; 1-0-0		Not Reported
	Stalevo			S	Unknown	Strength: 100/25/200; 1-1-0		Not Reported
	Stalevo			S	Unknown	Strength: 50/12.5/200 Mg		Not Reported
	Cipralex			S	Unknown	Strength: 10 Mg; 2-0-0		Not Reported
	Cipralex			S	Unknown	Strength: 10 Mg; 1-0-0		Not Reported
	Trittico			S	Unknown	Strength: 150 Mg; 0-0-0.5		Not Reported
	Azilect			S	Unknown	Strength: 1 Mg; 1-0-0		Not Reported
	Seroquel			S	Unknown	Strength: 25 Mg		Not Reported
	Madopar			S	Unknown	Strength: 50/12.5 Mg; 1-1-1		Not Reported
	Lovenox			C	Unknown	1xtgl		Not Reported
	Elomel			C	Unknown	1xtgl		Not Reported
	Optinem			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Thrombo Ass			C	Unknown	Strength: 100 Mg; 0-1-0		Not Reported
	Spirobene			C	Unknown	0-0.5-0		Not Reported
	Sedacoron			C	Unknown	Strength: 200 Mg; 0.5-0-0		Not Reported
	Eporatio			C	Unknown	1x/Woche		Not Reported
	Ceftriaxone Sodium			C	Unknown	2 G In 200 Ml, 1xtgl		Not Reported
	Dancor			C	Unknown	1-0-1		Not Reported
	Aquaphoril			C	Unknown	0.5-0-0		Not Reported

	Torasemide	C	Unknown	1-0-1	Not Reported
	Pantoloc	C	Unknown	2-0-0	Not Reported
	Insulatard	C	Unknown	61e-0-0	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13983111	DIRECT		DS			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Early Retirement; Neuralgia; Skin Disorder; Withdrawal Syndrome	Escitalopram. 20 Mg			S	Oral	Quantity:1 Tablet(S);		Accord
	Estradiol			C				Not Reported
	Progesterone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13983881	EXPEDITED (15-DAY)		HO, LT	PHHY2017FR137081			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Toxicity To Various Agents	Amlodipine			S	Unknown			Novartis
	Escitalopram			S	Unknown			Not Reported
	Aliskiren			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13984794	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1056745		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13985504	DIRECT		DE			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Drug Interaction; Dyspnoea; Fatigue; Haemorrhagic Stroke; Headache; Paraesthesia; Unresponsive To Stimuli; Vomiting	Eliquis	S	Oral	Quantity:1 Tablet(S);		Not Reported
	Lexapro	S				Not Reported
	Liquis	C				Not Reported
	Levetiracetam (Keppra)	S				Not Reported
	Sotalol	C				Not Reported
	Escitalopram	C				Not Reported
	Dorzolamide	C				Not Reported
	Latanoprost	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13378115	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS-2017-001650		10 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Pulmonary Function Test Abnormal	Orkambi			S	Oral	2 Df (100/125mg Each), Bid With High Fat Food		Vertex
	Lexapro			S	Oral	5 Mg, Daily		Not Reported
	Lexapro			S	Oral	2 Df (10mg Total), Qd		Not Reported
	Remeron			S	Oral	7.5mg Daily		Not Reported
	Actigall			C	Oral	1 Df, Bid		Not Reported
	Sodium Chloride			C	Respiratory (inhalation)	4 Ml, Bid		Not Reported
	Miralax			C		Mix With 4-8 Oz Of Feeds, Water Or Juice. Take 2 Capfuls With Overnight Feeds & 1 Capful In Morning.		Not Reported
	Mephyton			C	Oral	0.5 Mg, Qd		Not Reported
	Pediasure			C	Oral	3 Cans Tid. 3 Cans During The Day		Not Reported
	Complete Multi Vit			C	Oral	2 Df, Qd		Not Reported
	Creon			C	Oral	5 Df, At Bedtime. Prior To Overnight Feed Starting 17-Jun-2017		Not Reported
	Creon			C		5 With Meals And 3 With		Not Reported

			Snacks	
Peptamen	C		2 Cans, Qd By G Tube Route	Not Reported
Humulin R	C	Subcutaneous		Not Reported
Guar Gum	C	Oral	2 Packets Added To Daytime Feeds Or Via G Tube	Not Reported
Flovent Hfa	C	Respiratory (inhalation)	2 Df Inhaled (Oral) W/Spacer, Bid	Not Reported
Flonase	C	Nasal	2 Sprays In Each Nose, Qd	Not Reported
Pulmozyme	C	Respiratory (inhalation)	2.5 Ml, Qd	Not Reported
Colace	C	Oral	1 Df, Qd	Not Reported
Periactin	C	Oral	1 Df, Bid	Not Reported
Vitamin D3	C	Oral	2 Df, Qd	Not Reported
Zyrtec	C		1 Df, Bid	Not Reported
Proair Hfa	C	Respiratory (inhalation)	2 Df, Qid, Prn	Not Reported
Proair Hfa	C			Not Reported
Proair Hfa	C			Not Reported
Proventil	C	Respiratory (inhalation)	2.5 Mg, Bid. May Increase To Tid With Illness	Not Reported
Ocean	C	Nasal	2 Sprays By Nostrils, Bid. Use Prior To Treatment And As Needed	Not Reported
Prevacid	C	Oral	2 Df, Qd	Not Reported
Insulin	C	Subcutaneous	1 Syringe Into The Skin Prn (6-8 Times Daily)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13740041	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-2017VAL001022		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Pemphigoid	Furosemide			S	Oral	Unk		Validus
	Kardegic			S	Oral	Unk		Not Reported
	Paracetamol			S	Oral	Unk		Not Reported
	Phosphosorb			S	Oral	660 Mg, Bid		Not Reported
	Inexium			S	Oral	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Uvedose			S	Oral	Unk		Not Reported
	Levothyrox			S	Oral	Unk		Not Reported
	Galvus			S	Oral	Unk		Not Reported
	Novonorm			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13934568	EXPEDITED (15-DAY)		HO	CN-CIPLA LTD.-2017CN16014			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Insomnia	Escitalopram			S	Unknown	10 Mg, Per Day		Invagen
	Olanzapine			S	Unknown	1.25 To 3.75 Mg Per Night		Invagen
	Paroxetine			S	Unknown	30 Mg, Per Day		Not Reported
	Haloperidol			S	Unknown	2 Mg, Per Night		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Clonazepam			S	Intravenous (not otherwise specified)	0.5 Mg, Per Day, Infusion		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Per Night, Tablets		Not Reported
	Clonazepam			S	Unknown	10 Mg, Per Qn		Not Reported
	Flupentixol			S	Unknown	Unk		Not Reported
	Melitracen			S	Unknown	Unk		Not Reported
	Tiapride Hydrochloride			S	Unknown	100 Mg, Per Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13985012	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2017GB16187			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13985118	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2017-40133		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13986445	EXPEDITED (15-DAY)		HO	JP-LUPIN (EUROPE) LIMITED-2017-05508		63 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Diarrhoea; Dyspnoea; Hyperhidrosis; Malaise; Nausea; Palpitations; Weight Increased	Sertraline			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	50 Mg, Unk (Dose Increased)		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Paroxetine			S	Unknown	12.5 Mg, Qd		Lupin
	Paroxetine			S	Unknown	37.5 Mg, Qd		Lupin
	Paroxetine			S	Unknown	25 Mg, Qd		Lupin
	Paroxetine			S	Unknown	37.5 Mg, Qd		Lupin
	Lorazepam			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	0.5 Mg, Unk		Not Reported

Lorazepam	C	Unknown	3.75 Mg, Qd		Not Reported
Lorazepam	C	Unknown	0.5 Mg Per Week		Not Reported
Bromazepam	C	Unknown	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13986719	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-03		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown			Hikma
	Dextromethorphan W/Promethazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13987994	EXPEDITED (15-DAY)		OT	US-LANNETT COMPANY, INC.-US-2017LAN001045			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Syndrome; Condition Aggravated	Escitalopram Oxalate			S	Unknown	20 Mg, Qd, For 16 Days		Lannett

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	10623465	EXPEDITED (15-DAY)		HO, OT	US-SA-2014SA006425		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acrophobia; Alopecia; Amnesia; Anxiety; Anxiety; Arthritis; Back Disorder; Back Pain; Balance Disorder; Decreased Appetite; Diarrhoea; Diverticulitis; Fatigue; Gait Disturbance; Gastric Ulcer; Hypersomnia;	Aubagio			S	Oral			Not Reported
	Aubagio			S	Oral			Not Reported
	Aubagio			S	Oral			Not Reported
	Aubagio			S	Oral			Not Reported
	Aubagio			S	Oral			Not Reported
	Aubagio			S	Oral			Not Reported
	Aubagio			S	Oral			Not Reported

Hypoaesthesia; Multiple Sclerosis Relapse; Myalgia; Nasopharyngitis; Nausea; Pain; Pain; Pain In Extremity; Paraesthesia; Product Use Issue; Pruritus; Pruritus Generalised; Rhinorrhoea; Sputum Discoloured; Temperature Intolerance; Tinnitus; Unevaluable Event; Vision Blurred; Vomiting	Aubagio		S	Oral	Not Reported
	Aubagio		S	Oral	Not Reported
	Aubagio		S	Oral	Not Reported
	Aubagio		S	Oral	Not Reported
	Aubagio		S	Oral	Not Reported
	Aubagio		S	Oral	Not Reported
	Aubagio		S	Oral	Not Reported
	Flomax		S	Unknown	Not Reported
	Vesicare		S	Unknown	Not Reported
	Lipitor		S	Unknown	Not Reported
	Escitalopram		S	Unknown	Not Reported
	Metformin		S	Unknown	Not Reported
	B Complex		S	Unknown	Not Reported
	Vitamin D3		S	Unknown	Not Reported
	Calcium		S	Unknown	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Tamsulosin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	10990300	NON-EXPEDITED		OT	US-JNJFOC-20150402828			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Gynaecomastia; Hyperprolactinaemia; Off Label Use; Product Use In Unapproved Indication; Sexual Dysfunction	Risperdal			S	Oral	From Mar-2004 To Apr-2004, Risperidone 0.5 Mg Twice Daily		Not Reported
	Risperdal			S	Oral	Risperidone 0.25 Mg Twice Then Increased To 0.5 Mg Twice. Later 0.5 Mg Morning And 0.25 Mg Night		Not Reported
	Abilify			S	Unknown			Not Reported

	Zoloft	S	Unknown	Not Reported
	Lexapro	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13989690	EXPEDITED (15-DAY)		DS	PHHY2017DK135104		18 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Arthralgia; Body Temperature Fluctuation; Constipation; Dyspepsia; Dyspnoea; Emotional Disorder; Head Discomfort; Hyperaesthesia; Middle Insomnia; Muscle Tightness; Nervous System Disorder; Paraesthesia; Stress; Tearfulness; Withdrawal Syndrome	Sertraline			S	Oral	Variable		Novartis
	Paroxetine Hydrochloride			S	Oral	Variable		Not Reported
	Venlafaxin 1a Pharma			S	Oral	Variable		Not Reported
	Cipralex			S	Oral	Variable		Not Reported
	Valdoxan			S	Oral	Variable		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13990383	EXPEDITED (15-DAY)		HO	ES-ALLERGAN-1753522US		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Scleroderma	Escitalopram Oxalate Unk			S	Oral	Unk		Allergan
	Abasaglar			S	Subcutaneous	10 Iu, Qd		Not Reported
	Metformin			S	Oral	850 Mg, Tid		Not Reported
	Repaglinida			S	Oral			Not Reported
	Enalapril			S	Oral	1 Df, Qd		Not Reported
	Omeprazol			S	Oral	1 Df, Qd		Not Reported
	Furosemida			C	Oral	1 Df, Bid		Not Reported
	Tryptizol			C	Oral	75 Mg, Tid		Not Reported

	Brinzolamida	C	Ophthalmic	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13990408	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1752459US		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hypersensitivity; Pharyngeal Swelling	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	12781558	NON-EXPEDITED			US-ALLERGAN-1663612US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Sucralfate Unk			S	Oral			Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13881626	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1735554US		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ehlers-Danlos Syndrome; Pain	Escitalopram Oxalate 20mg Tab (Tbd)			S	Oral	20 Mg, Qd		Allergan
	Gabapentin			C	Oral	200 Mg, Tid		Not Reported
	Fluocinonide			C	Topical	Unk		Not Reported
	Hydrocodone Bitartrate And Acetaminophen			C	Oral	Unk Unk, Prn		Not Reported
	Ketoconazole			C	Topical	Unk		Not Reported
	Benadryl			C	Oral	25 Mg, Qhs		Not Reported
	Dutasteride			C	Oral	0.5 Mg, Qd		Not Reported
	Tretinoin			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13948535	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC-2017SUN00309		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Drug Interaction; Electrocardiogram Qt Prolonged; Serotonin Syndrome	Escitalopram			S	Unknown	10 Mg, Daily		Taro
	Dextromethorphan-Promethazine			S	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	5 Mg, Bid		Not Reported
	Labetalol			C	Unknown	100 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13995499	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-016662		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Chest Discomfort; Cognitive Disorder; Cough; Decreased Appetite; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Hallucination, Auditory; Hallucination, Visual; Leukocytosis; Mental Disorder; Mental Status Changes; Muscle Twitching; Myoclonus; Pain; Poor Quality Sleep; Respiratory Acidosis; Restlessness; Serotonin Syndrome; Sleep Talking; Tongue Biting; Unresponsive To Stimuli; Viral Upper Respiratory	Escitalopram			S	Unknown			Zydus Pharm
	Dextromethorphan/Promethazine			S	Unknown			Not Reported
	Naltrexone			C	Intramuscular			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Labetalol			C	Unknown			Not Reported

Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13995707	NON-EXPEDITED			US-PFIZER INC-2017406959			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Tikosyn			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13997166	EXPEDITED (15-DAY)		HO, OT	US-NAPPMUNDI-USA-2017-0140816			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Insomnia; Neck Surgery	Oxycodone Hcl Cr Tablets (Similar To Nda 22-272)			S	Oral	80 Mg, Bid		Purdue
	Hydrocodone Bitartrate/Acetaminophen			S	Oral	7.5/325 Mg, 2-3 A Day		Unknown
	Hydrocodone Bitartrate/Acetaminophen			S	Oral	7.5/325 Mg, 6 Times A Day		Unknown
	Savella			S	Unknown	100 Mg, Daily		Not Reported
	Savella			S				Not Reported
	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported
	Alprazolam			S	Unknown	0.5 Mg, Prn		Not Reported
	Dicyclomine /00068601/			C	Unknown	10 Mg, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13997359	EXPEDITED (15-DAY)		HO, OT	US-TEVA-808580USA		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Citalopram			S	Unknown			Actavis
	Fentanyl			S	Unknown			Not Reported
	Methylthioninium Chloride			S	Unknown			Not Reported

Escitalopram	S	Unknown	10 Milligram Daily;		Not Reported
Midazolam	C	Unknown			Not Reported
Rocuronium Bromide	C	Unknown			Not Reported
Dexmedetomidine	C	Unknown			Not Reported
Etomidate	C	Unknown			Not Reported
Norepinephrine	C	Unknown			Not Reported
Epinephrine	C	Unknown			Not Reported
Milrinone	C	Unknown			Not Reported
Vancomycin	C	Unknown			Not Reported
Cefepime	C	Unknown			Not Reported
Fluconazole	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13997670	EXPEDITED (15-DAY)		HO	AU-ALLERGAN-1754109US		35 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Chills; Dizziness; Headache; Nausea; Norepinephrine Increased; Paraesthesia; Pyrexia; Tachycardia	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Thyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13998458	EXPEDITED (15-DAY)		CA, OT	IL-GLAXOSMITHKLINE-IL2017GSK142624			Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Lamotrigine			S	Transplacental	200 Mg, Qd		Glaxosmithkline
	Escitalopram			S	Transplacental			Glaxosmithkline
	Folic Acid			S	Transplacental			Glaxosmithkline
	Desipramine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	13555506	EXPEDITED (15-DAY)		DS	CA-ALLERGAN-1719863US		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Bipolar Disorder; Confusional State; Depression; Disturbance In Attention; Fatigue; Feeling Abnormal; Flashback; Impaired Quality Of Life; Influenza; Loss Of Employment; Mental Impairment; Morbid Thoughts; Night Blindness; Nightmare; Paraesthesia; Partner Stress; Post-Traumatic Stress Disorder; Renal Impairment; Sleep Disorder; Social Avoidant Behaviour; Suicidal Behaviour; Visual Impairment; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	13903165	EXPEDITED (15-DAY)		HO	PHHY2017FR122536		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Voltarene (Diclofenac Sodium)			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	40 Mg, Qd		Not Reported
	Prednisone			S	Oral	80 Mg, Qd (Morning)		Not Reported
	Prednisone			S	Oral	60 Mg, Qd (Morning)		Not Reported
	Prednisone			S	Oral	20 Mg, Qd (Morning)		Not Reported
	Prednisone			S	Oral	40 Mg, Qd		Not Reported

	Prednisone	S	Oral	20 Mg, Qd	Not Reported
	Escitalopram	S	Oral	10 Mg, Qd (In The Morning)	Not Reported
	Alprazolam	S	Oral	0.125 Mg, Qd (At Bed Time)	Not Reported
	Lansoprazole	S	Oral	15 Mg, Qd	Not Reported
	Lansoprazole	S	Oral	15 Mg, Qd	Not Reported
	Tramadol	S	Oral	50 Mg, Tid	Novartis
	Paracetamol	S	Oral	1 G, Tid Prn	Not Reported
	Seroplex	S	Oral	Unk	Not Reported
	Lyrica	S	Oral	50 Mg, Unk	Not Reported
	Hexomedine	S	Transdermal	Unk	Not Reported
	Coltramyl	S	Oral	2 Df, Bid	Not Reported
	Acupan	S	Oral	20 Mg, Q6h	Not Reported
	Skenan	S	Oral	10 Mg, Bid (Midday And Evening)	Not Reported
	Skenan	S	Oral	30 Mg, Bid (Midday And Evening)	Not Reported
	Actiskenan	S	Oral	5 Mg, Q4h Prn	Not Reported
	Actiskenan	S	Oral	10 Mg, 1 Df To 4 Df Daily	Not Reported
	Actiskenan	S	Oral	10 Mg, Q6h Prn	Not Reported
	Actiskenan	S	Oral	5 Mg, Q4h Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	13928639	EXPEDITED (15-DAY)		HO, OT	US-TORRENT-00003318		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Seizure; Serotonin Syndrome	Escitalopram			S				Unknown
	Dextromethorphan/Promethazine			S				Unknown
	Amlodipine Besilate			C				Unknown
	Labetalol Hydrochloride			C				Unknown

	Naltrexone Hydrochloride	C		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	13965920	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2017M1056462		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Dextromethorphan			S	Unknown	Unk		Mylan
	Promethazine			C	Unknown	Unk		Mylan
	Amlodipine			C	Unknown	5 Mg, Qd		Mylan
	Labetalol			C	Unknown	100 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	13999926	EXPEDITED (15-DAY)		OT	FR-TEVA-807527ROM		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Dissociative Identity Disorder; Dyspnoea; Suicidal Ideation	Escitalopram Teva 20 Mg			S				Not Reported
	Escitalopram Teva 20 Mg			S		10 Milligram Daily;		Not Reported
	Bisoprolol Teva 10 Mg			S		1 Dosage Forms Daily;		Duramed
	Indapamide Teva Sante			S		1 Dosage Forms Daily;		Actavis
	Lercanidipine Teva Sante 10 Mg			S		2 Dosage Forms Daily;		Not Reported
	Mianserine Teva 10 Mg			S		1 Dosage Forms Daily;		Not Reported
	Inexium 40 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	14002018	EXPEDITED (15-DAY)		DS	DK-TEVA-806608ACC		18 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Arthralgia; Body Temperature Fluctuation; Constipation; Dyspepsia;	Sertraline			S	Oral	Dosage: Varying		Not Reported
	Paroxetine			S	Oral	Dosage: Varying		Teva
	Cipralex			S	Oral	Dosage: Varying		Not Reported

Dyspnoea; Emotional Disorder; Head Discomfort; Hyperaesthesia; Middle Insomnia; Muscle Tightness; Nervous System Disorder; Paraesthesia; Stress; Tearfulness; Withdrawal Syndrome	Venlafaxin 1a Farma	S	Oral	Dosage: Varying	Not Reported
	Valdoxan	S	Oral	Dosage: Varying	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	14004698	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004156		35 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Feeling Guilty; Headache; Logorrhoea; Somnolence; Suicidal Ideation; Weight Increased	Respidon			S				Unknown
	Rivotril			C				Unknown
	Lithium Carbonate			C				Unknown
	Escitalopram Oxalate			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2017	14007133	DIRECT		HO, OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Loss Of Personal Independence In Daily Activities; Psychotic Disorder	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2017	14006181	EXPEDITED (15-DAY)		DS	DK-MYLANLABS-2017M1057997		18 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Arthralgia; Body Temperature Fluctuation; Constipation; Dyspepsia;	Sertraline Mylan			S	Oral	Dosis: Varierende		Mylan
	Cipralex			S	Oral	Dosis: Varierende		Mylan

Dyspnoea; Emotional Disorder; Head Discomfort; Hyperaesthesia; Middle Insomnia; Muscle Tightness; Nervous System Disorder; Paraesthesia; Stress; Tearfulness; Withdrawal Syndrome	Venlafaxin	S	Oral	Dosis: Varierende	Mylan
	Valdoxan	S	Oral	Dosis: Varierende	Mylan
	Paroxetine	S	Oral	Dosis: Varierende	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	13850740	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017339537		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Lyrica			S	Oral	50 Mg, Unk		Pfizer
	Alprazolam			S	Oral	Unk		Pfizer
	Alprazolam			S	Oral	0.125 Mg, 1x/Day		Pfizer
	Prednisone			S	Oral	40 Mg, Daily		Not Reported
	Prednisone			S		80 Mg, 1x/Day		Not Reported
	Prednisone			S		60 Mg, Daily		Not Reported
	Prednisone			S		20 Mg, Unk		Not Reported
	Prednisone			S		40 Mg, Daily		Not Reported
	Prednisone			S		20 Mg, Daily		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day, Morning		Not Reported
	Voltarene (Diclofenac Sodium)			S	Oral	15 Mg, Unk		Not Reported
	Lansoprazole			S	Oral	15 Mg, 1x/Day		Not Reported
	Tramadol Hydrochloride			S	Oral	50 Mg, 3x/Day		Not Reported
	Hexomedine /00799702/			S	Cutaneous	Unk		Not Reported
	Coltramyl			S	Oral	2 Df, 2x/Day		Not Reported
	Acupan			S	Oral	20 Mg, Every 6h		Not Reported

	Skenan	S	Oral	10 Mg, 2x/Day	Not Reported
	Skenan	S		30 Mg, 2x/Day	Not Reported
	Skenan	S		30 Mg, 2x/Day	Not Reported
	Actiskenan	S	Oral	5 Mg, Every 4h As Needed	Not Reported
	Actiskenan	S		10 Mg, 1 Up To 4/Day	Not Reported
	Actiskenan	S		10 Mg, As Needed, Every 6h	Not Reported
	Paracetamol	S	Oral	1 G, 3 Times A Day As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	13861451	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1733980US		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Prescription Drug Used Without A Prescription; Psychotic Behaviour; Rib Fracture; Self-Injurious Ideation	Escitalopram Oxalate 20mg Tab (Tbd)			S	Unknown	20 Mg, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	13905891	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2017GSK131441		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Voltarene (Diclofenac Sodium)			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	10 Mg, Qd, Morning		Glaxosmithkline
	Lansoprazole			S	Oral	15 Mg, Qd		Glaxosmithkline
	Lansoprazole			S	Oral	15 Mg, Qd		Glaxosmithkline
	Paracetamol			S	Oral	1 G, Tid Prn		Glaxosmithkline
	Seroplex			S	Oral	Unk		Glaxosmithkline
	Skenan			S	Oral	10 Mg, Bid, Midday And Evening		Glaxosmithkline

	Skenan	S	Oral	30 Mg, Bid, Midday And Evening	Glaxosmithkline
	Actiskenan	S	Oral	5 Mg, Q4h Prn	Glaxosmithkline
	Actiskenan	S	Oral	10 Mg, 1 Df To 4 Df Daily	Glaxosmithkline
	Actiskenan	S	Oral	10 Mg, Q6h Prn	Glaxosmithkline
	Actiskenan	S	Oral	5 Mg, Q4h Prn	Glaxosmithkline
	Prednisone	S	Oral	40 Mg, Qd	Not Reported
	Prednisone	S	Oral	80 Mg, Qd, Morning	Not Reported
	Prednisone	S	Oral	60 Mg, Qd, Morning	Not Reported
	Prednisone	S	Oral	20 Mg, Qd, Morning	Not Reported
	Prednisone	S	Oral	40 Mg, Qd	Not Reported
	Prednisone	S	Oral	20 Mg, Qd	Not Reported
	Alprazolam	S	Oral	0.125 Mg, Qd, At Bed Time	Not Reported
	Tramadol	S	Oral	50 Mg, Tid	Not Reported
	Lyrica	S	Oral	50 Mg, Unk	Not Reported
	Hexomedine (Hexamidine Isethionate)	S	Transdermal	Unk	Not Reported
	Coltramyl	S	Oral	2 Df, Bid	Not Reported
	Acupan	S	Oral	20 Mg, Q6h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	13945189	EXPEDITED (15-DAY)		DS	DE-TORRENT-00007032		25 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Libido Decreased; Male Orgasmic Disorder	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	13974081	EXPEDITED (15-DAY)		OT	ES-CIPLA LTD.-2017ES16206			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Olanzapine			S	Unknown	10 Mg, Daily		Invagen
	Olanzapine			S	Unknown	15 Mg, Daily		Invagen
	Olanzapine			S	Unknown	5 Mg, Daily		Invagen
	Risperidone			S	Unknown	3 Mg, Daily		Cipla
	Escitalopram			S	Unknown	5 Mg, Per Day		Invagen
	Mirtazapine			S	Unknown	60 Mg, Daily		Cipla
	Quetiapine			S	Unknown	50 Mg, Daily		Not Reported
	Carbamazepine			S	Unknown	Unk		Not Reported
	Carbamazepine			S	Unknown	1200 Mg, Daily		Not Reported
	Fluvoxamine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14008381	DIRECT		DS			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	13754360	EXPEDITED (15-DAY)		HO	FR-MERCK KGAA-2023361		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Pemphigoid	Novothyrox			S	Oral			Merck Kgaa
	Paracetamol			S				Not Reported
	Phosphosorb			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Lasilix Special			S				Not Reported
	Seroplex			S				Not Reported
	Uvedose			S	Oral			Not Reported

	Galvus	S	Oral	Not Reported
	Novonorm	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	14010516	EXPEDITED (15-DAY)		DS	DK-AUROBINDO-AUR-APL-2017-40865			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Aggression; Anxiety; Arthralgia; Body Temperature Fluctuation; Constipation; Crying; Dyspnoea; Emotional Poverty; Functional Gastrointestinal Disorder; Hyperaesthesia; Middle Insomnia; Muscle Tightness; Nervous System Disorder; Pain; Paraesthesia; Stress; Tension; Withdrawal Syndrome	Sertraline Film-Coated Tablet			S	Oral			Aurobindo
	Paroxetine Film-Coated Tablet			S	Oral			Aurobindo
	Cipralex /01588501/			S	Oral			Not Reported
	Venlafaxin 1a Pharma			S	Oral			Not Reported
	Valdoxan			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14015205	EXPEDITED (15-DAY)		DS	DK-ALLERGAN-1754592US		18 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Arthralgia; Body Temperature Fluctuation; Constipation; Dyspepsia; Dyspnoea; Emotional Disorder; Head Discomfort; Hyperaesthesia; Middle Insomnia; Muscle Tightness; Nervous System Disorder;	Escitalopram Oxalate - Bp			S	Oral	Dose: Varying		Allergan
	Venlafaxin "1a Farma"			S	Oral	Dose: Varying		Not Reported
	Valdoxan			S	Oral	Dose: Varying		Not Reported
	Sertraline			S	Oral	Dose: Varying		Not Reported
	Paroxetine			S	Oral	Dose: Varying		Not Reported

Paraesthesia; Stress; Tearfulness; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14015670	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-150822		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Somnolence	Clozapine			S	Unknown	200 Mg, Daily		Sun
	Clozapine			S	Unknown	400 Mg, Daily		Sun
	Aripiprazole			S	Unknown	Unk		Not Reported
	Divalproex			S	Unknown	Unk		Ranbaxy
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14015688	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-150798		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Drug Interaction; Drug Level Increased; Hypotension; Mental Status Changes	Clozapine			S	Unknown	200 Mg, Daily		Sun
	Clozapine			S	Unknown	450 Mg, Daily		Sun
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14015704	NON-EXPEDITED		OT	US-APOTEX-2017AP018814		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Citalopram			S	Unknown			Apotex
	Escitalopram Oxalate			S	Unknown			Apotex

Bupropion Hydrochloride	S	Unknown			Apotex
Mirtazapine	S	Unknown	Unk		Apotex
Paroxetine	S	Unknown	Unk		Apotex
Sertraline Hydrochloride	S	Unknown	Unk		Apotex
Lamotrigine	S	Unknown			Apotex
Lithium Carbonate	S	Unknown			Apotex
Risperidone	S	Unknown			Apotex
Quetiapine Fumarate	S	Unknown			Apotex
Methylphenidate	S	Transdermal			Apotex
Modafinil Tablets Usp	S	Unknown			Apotex
Trazodone Hydrochloride	S	Unknown			Apotex
Buspiprone Hydrochloride Tablets Usp	S	Unknown	Unk		Apotex
Venlafaxine	S	Unknown			Not Reported
Amfetamine W/Dexamfetamine	S	Unknown			Not Reported
Diazepam	S	Unknown			Not Reported
Chlordiazepoxide	S	Unknown			Not Reported
Lorazepam	S	Unknown	Unk		Not Reported
Temazepam	S	Unknown			Not Reported
Prazosin	S	Unknown			Not Reported
Hydroxyzine	S	Unknown			Not Reported
Pyridostigmine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14016838	EXPEDITED (15-DAY)		HO, OT	ES-ELI_LILLY_AND_COMPANY-ES201709005754			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Interstitial Lung Disease; Peripheral Sensory Neuropathy; Pneumonia; Scleroderma	Abasaglar			S	Subcutaneous	10 Iu, Daily		Not Reported
	Metformin			S	Oral	850 Mg, Tid		Not Reported
	Repaglinide			S	Oral	10 Mg, Daily		Not Reported

Esertia	S	Oral	10 Mg, Daily		Not Reported
Enalapril	S	Oral	Unk, Prn		Not Reported
Omeprazole	S	Oral	1 Df, Daily		Not Reported
Furosemida /00032601/	C	Oral	Unk, Bid		Not Reported
Tryptizol /00002202/	C	Oral	75 Mg, Tid		Not Reported
Brinzolamide	C	Ophthalmic	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14017049	EXPEDITED (15-DAY)			US-MORTON GROVE PHARMACEUTICALS, INC.-2027948		63 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Promethazine With Dextromethorphan			S				Morton Grove
	Naltrexone Hydrochloride			C				Not Reported
	Amlodipine			C				Not Reported
	Labetalol			C				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14017158	EXPEDITED (15-DAY)		HO	SG-MYLANLABS-2017M1059781		32 YR	Male	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Hyperkalaemia; Muscle Necrosis; Rhabdomyolysis	Escitalopram			S	Unknown	Every Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14017169	EXPEDITED (15-DAY)		HO, OT	US-PRINSTON PHARMACEUTICAL INC.-2017PRN00452		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Drug Interaction;	Escitalopram			S	Unknown	10 Mg, 1x/Day		Prinston Pharmaceutical

Respiratory Distress; Serotonin Syndrome	Dextromethorphan-Promethazine		S	Unknown	Unk	Not Reported
	Dextromethorphan-Promethazine		S			Not Reported
	Dextromethorphan-Promethazine		S			Not Reported
	Amlodipine		C	Unknown	5 Mg, 2x/Day	Not Reported
	Labetalol		C	Unknown	100 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	13629903	EXPEDITED (15-DAY)		OT	ES-TEVA-775434ROM		42 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder; Condition Aggravated; Hepatic Enzyme Increased	Escitalopram			S	Unknown	Initial Dose Not Stated; Last Dose 5 Mg/Day Was Continued		Ivax
	Escitalopram			S				Ivax
	Mirtazapine			S	Unknown	60 Milligram Daily;		Teva
	Mirtazapine			S	Unknown			Teva
	Olanzapine 10 Mg			S	Unknown	10 Milligram Daily;		Teva
	Olanzapine 10 Mg			S	Unknown	20 Milligram Daily;		Teva
	Olanzapine 10 Mg			S	Unknown	5 Milligram Daily;		Teva
	Olanzapine 10 Mg			S	Unknown	15 Milligram Daily;		Teva
	Omega-3-Fatty-Acid			S	Unknown	700 Mg/Day, The Dose Was Further Increased To Double The Previous Dose		Teva
	Omega-3-Fatty-Acid			S	Unknown	Double The Previous Dose Of 700 Mg/Day		Teva
	Quetiapine			S	Unknown	50 Milligram Daily;		Teva
	Quetiapine			S	Unknown			Teva
	Risperidone			S	Unknown	3 Milligram Daily;		Pliva
	Risperidone			S	Unknown			Pliva
	Fluvoxamine			S	Unknown			Not Reported

	Fluvoxamine	S				Not Reported
	Carbamazepine	S	Unknown	Up To 1200 Mg/ Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	14013937	EXPEDITED (15-DAY)		DE, OT	ZA-MYLANLABS-2017M1058422		82 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Mylan Escitalopram 10			S	Oral	10 Mg, Unk		Mylan
	Co-Tareg			S	Oral	Unk		Mylan
	Lyrica			S	Oral	75 Mg, Unk		Mylan
	Tellerge			S	Oral	120 Mg, Unk		Mylan
	Navalpro			S	Oral	200 Mg, Unk		Mylan
	Xefo Rapid			S	Oral	8 Mg, Unk		Mylan
	Ganfort			S	Oral	5 Ml, Unk		Mylan
	Synaleve /01057301/			S	Oral	Unk		Mylan
	Movicol			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	14018881	EXPEDITED (15-DAY)		HO, OT	SG-ACCORD-059189		32 YR	Male	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Necrosis; Rhabdomyolysis	Escitalopram			S		Every Night		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	14019391	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1754953US		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Asthenia; Balance Disorder; Dizziness; Dry Mouth; Dysphagia;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Lactibiane			C	Unknown			Not Reported
	Zinc			C	Unknown			Not Reported

Epigastric Discomfort; Feeling Abnormal; Feeling Cold; Feeling Hot; Loss Of Consciousness; Myalgia; Nausea; Nervousness; Ocular Discomfort; Paraesthesia; Paraesthesia Oral; Productive Cough; Somnolence; Tremor	Xanax		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	14019405	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1754573US		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Above Therapeutic; Intentional Overdose	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Baclofen			S	Oral	18 Df, Qd		Not Reported
	Seresta			S	Oral	30 Mg, Qd		Not Reported
	Zopiclone			S	Oral	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	14019406	EXPEDITED (15-DAY)		HO, OT	SG-ALLERGAN-1754316US		32 YR	Male	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Necrosis; Rhabdomyolysis	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	14019409	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1754599US		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Faecaloma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan

	Escitalopram Oxalate - Bp	S	Oral	15 Mg, Qd	Allergan
	Risperidone	S	Oral		Not Reported
	Mirtazapine	S	Oral	15 Mg, Qd	Not Reported
	Mirtazapine	S	Oral	30 Mg, Qd	Not Reported
	Seresta	S	Oral	10 Mg, Qd	Not Reported
	Seresta	S	Oral	50 Mg, Qd	Not Reported
	Noctamide	S	Oral	2 Mg, Qd	Not Reported
	Mianserine	C	Oral	30 Mg, Qd	Not Reported
	Mianserine	C	Oral	60 Mg, Qd	Not Reported
	Macrogol 4000 Mylan	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	14019963	NON-EXPEDITED			US-ALLERGAN-1747746US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bladder Pain; Feeling Jittery; Irritability; Mood Swings	Vraylar			S	Oral	1.5 Mg, Qd		Allergan
	Vraylar			S				Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	14021651	DIRECT		OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness Postural; Hypotension; Presyncope	Escitalopram (Lexapro)			S	Oral	15 Mg And 20 Mg 1 Pill Per Day By Mouth		Not Reported
	Simvistatin			C				Not Reported
	Trazodone			C				Not Reported
	Fish Oil			C				Not Reported
	E			C				Not Reported
	Saw Palmetto			C				Not Reported
	Chondroitin			C				Not Reported
	Magnesium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	14022338	EXPEDITED (15-DAY)		CA	CH-ALLERGAN-1755488US		2 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract Congenital; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	13159235	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2017TUS001860			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Suicidal Ideation	Trintellix			S	Unknown	20 Mg, Unk		Takeda
	Cipralex /01588501/			S	Unknown	Unk		Not Reported
	Cipralex /01588501/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	13159678	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2017TUS001946			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Suicidal Ideation	Trintellix			S	Unknown	20 Mg, Unk		Takeda
	Cipralex /01588501/			S	Unknown	Unk		Not Reported
	Cipralex /01588501/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	13909553	NON-EXPEDITED			US-PFIZER INC-2017358715		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Effexor Xr			S	Oral	150 Mg (75 Mg Two Tablets) Daily		Pfizer

Effexor Xr	S	Oral	"187" Mg Daily	Pfizer
Venlafaxine Hcl	S	Oral	Unk	Pfizer
Zoloft	S	Oral	Unk	Pfizer
Gabapentin	S	Oral	Unk	Pfizer
Sildenafil Citrate	S	Oral	Unk	Pfizer
Ketamine Hcl	S	Oral	Unk	Not Reported
Mirtazapine	S	Oral	Unk	Not Reported
Clonazepam	S	Oral	Unk	Not Reported
Trazodone Hcl	S	Oral	50 Mg, 1x/Day (50mg At Night)	Not Reported
Fentanyl	S	Oral	Unk	Not Reported
Fentanyl	S	Transdermal	Unk	Not Reported
Fluoxetine Hcl	S	Oral	Unk	Not Reported
Lithium	S	Oral	Unk	Not Reported
Wellbutrin	S	Oral	Unk	Not Reported
Lexapro	S	Oral	Unk	Not Reported
Buspirone	S	Oral	Unk	Not Reported
Abilify	S	Oral	Unk, 1x/Day At Night	Not Reported
Dextroamphetamine	S	Oral	50 Mg, 1x/Day	Not Reported
Suboxone	S	Oral	Unk	Not Reported
Famotidine	C		Unk (Dosage Via Tpn)	Not Reported
Iron & Vitamin C	C		Unk	Not Reported
Ibuprofen	C		Unk, As Needed	Not Reported
Excedrin	C		Unk, As Needed	Not Reported
Vitamin B12	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	14008603	EXPEDITED (15-DAY)		HO, OT	NO-ELI_LILLY_AND_COMPANY-NO201709005156		35 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accident; Aggression; Depression; Depression; Disturbance In Attention; Dizziness; Irritability; Mania; Memory Impairment; Restlessness	Zyprexa		S	Unknown	Unk, Unknown	Eli Lilly And Co
	Olanzapine		S	Unknown	Unk, Unknown	Eli Lilly And Co
	Seroquel		S	Unknown	Unk	Not Reported
	Seroquel		S	Unknown	Unk	Not Reported
	Seroquel		S	Unknown	Unk, Unknown	Not Reported
	Seroquel		S	Unknown	Unk	Not Reported
	Cipralex /01588501/		S	Unknown	Unk, Daily	Not Reported
	Valproat		S	Unknown	Unk, Unknown	Not Reported
	Efexor		S	Unknown	Unk, Unknown	Not Reported
	Efexor		S	Unknown	Unk	Not Reported
	Efexor		S	Unknown	Unk	Not Reported
	Seroxat		S	Unknown	Unk, Unknown	Not Reported
	Seroxat		S	Unknown	20 Mg, Daily	Not Reported
	Seroxat		S	Unknown	20 Mg, Daily	Not Reported
	Orfiril		S	Unknown	Unk, Unknown	Not Reported
	Lamictal		S	Unknown	Unk, Unknown	Not Reported
	Lithionit		C	Unknown	Unk	Not Reported
	Lithionit		C	Unknown	Unk, Unknown	Not Reported
	Lithionit		C	Unknown	Unk	Not Reported
	Sobril		C	Unknown	Unk, Prn	Not Reported
	Cannabis		C		Unk	Not Reported
	Alcohol		C	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	14024499	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1754955US		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Inexium			C	Unknown	20 Mg,		Not Reported

Levothyrox	C	Unknown	75 Ug		Not Reported
Forlax	C	Unknown			Not Reported
Paracetamol	C	Unknown			Not Reported
Gliclazide	C	Unknown	60, Mg, Tid		Not Reported
Gliclazide	C	Unknown			Not Reported
Fosinopril	C	Unknown			Not Reported
Atorvastatin	C	Unknown			Not Reported
Metoformine	C	Unknown	1000, Mg		Not Reported
Lantus	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	14024595	EXPEDITED (15-DAY)		DE, LT	PHHY2017US142131		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Completed Suicide; Lethargy; Somnolence	Loperamide			S	Unknown			Novartis
	Escitalopram			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	14024764	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017415114		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Desvenlafaxine Succinate Monohydrate			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported
	Quetiapine			S		Unk		Not Reported
	Bupropion			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	14025798	NON-EXPEDITED			US-PFIZER INC-2017419686			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	14025847	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017006008			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Exposure During Pregnancy	Escitalopram			S	Oral	15 Mg, Qd, (Gestational Period At The Time Of Exposure:1 Trimester, 0. - 35.6. Gestational Week)		Macleods
	Cefuroxim			C	Oral	Unk, (Gestational Period At The Time Of Exposure : 2 Trimester, 24.4. - 25.6. Gestational Week)		Not Reported
	Kadefungin			C	Vaginal	Unk, (Unknown Trimester)		Not Reported
	Salbutamol			C	Respiratory (inhalation)	Prn (Unknown Trimester)		Not Reported
	Folsäure			C	Oral	Unk, (1 Trimester, 0. - 24.4. Gestational Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	14026689	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1754094US		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Pemphigoid	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Phosphosorb			S	Oral	660 Mg, Bid		Not Reported
	Kardegic			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Lasilix Special			S	Unknown			Not Reported

Uvedose	S	Oral	100000 Units, Unk		Not Reported
Levothyrox	S	Oral			Not Reported
Galvus	S	Oral			Not Reported
Paracetamol	S	Oral			Not Reported
Novonorm	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	14027504	EXPEDITED (15-DAY)		HO, OT	SG-LUPIN PHARMACEUTICALS INC.-2017-05664		32 YR	Male	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Necrosis; Rhabdomyolysis	Escitalopram			S	Unknown	15 Mg, Qd (Every Night)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2017	12611609	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016363715		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Phenytoin			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported
	Olanzapine			S		Unk		Not Reported
	Quetiapine			S				Not Reported
	Bupropion			S		Unk		Not Reported
	Primidone			S		Unk,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2017	14029519	NON-EXPEDITED		OT	US-JAZZ-2017-US-010651			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Somnolence; Suicidal Ideation	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	2.25 G, Bid		Jazz

	Xyrem	S	Oral	Dose Adjustment		Jazz
	Xyrem	S	Oral	1 G, Bid		Jazz
	Lexapro	S				Not Reported
	Adderall	C				Not Reported
	Amitriptyline Hcl	C				Not Reported
	Effexor	C				Not Reported
	Enpresse-28	C				Not Reported
	Cymbalta	C				Not Reported
	Advil /00044201/	C				Not Reported
	Trivora	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2017	14029884	NON-EXPEDITED			US-PFIZER INC-2017419489		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sertraline Hcl			S		150 Mg, Unk		Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2017	14030275	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1060086		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Death	Escitalopram			S	Oral	15 [Mg/D]		Not Reported
	Cefuroxim			C	Oral			Mylan
	Kadefungin			C	Vaginal			Mylan
	Salbutamol			C	Respiratory (inhalation)	If Required		Mylan
	Folsaeure			C	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2017	14031471	EXPEDITED (15-DAY)		OT	DE-TEVA-809023GER			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death	Escitalopram			S	Oral	15 Milligram Daily;		Ivax
	Cefuroxim			C	Oral			Not Reported
	Kadefungin			C	Vaginal			Not Reported
	Salbutamol			C	Respiratory (inhalation)	If Required		Not Reported
	Folsaeure			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2017	14032467	EXPEDITED (15-DAY)		HO, OT	US-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00341		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Drug Interaction; Electrocardiogram Qt Prolonged; Respiratory Distress; Serotonin Syndrome	Escitalopram			S	Unknown	10 Mg, 1x/Day		Jubilant
	Dextromethorphan-Promethazine			S	Unknown			Not Reported
	Dextromethorphan-Promethazine			S				Not Reported
	Dextromethorphan-Promethazine			S				Not Reported
	Amlodipine			C	Unknown	5 Mg, 2x/Day		Not Reported
	Labetalol			C	Unknown	100 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	13958852	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1751116US		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Coma; Drug Use Disorder; Hypotension; Intentional	Escitalopram Oxalate - Bp			S	Oral	15 Gtt, Unk		Allergan
	Halcion			S	Oral			Not Reported

Self-Injury	Alprazolam		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	14007628	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1058990		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Abuse; Hallucinations, Mixed; Overdose	Escitalopram			S	Oral	110 Gtt, Total		Not Reported
	Alprazolam			S		0.25 Mg, Pm		Not Reported
	Plendil			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	14024520	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1755151US		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Confusional State; Decreased Appetite; Gait Disturbance; Hallucination; Parkinsonian Gait; Weight Decreased	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan
	Azilect			S	Oral	1 Mg, Qd		Not Reported
	Stalevo			C	Unknown	Unk, Unknown		Not Reported
	Modopar			C	Unknown	Unk, Unknown		Not Reported
	Moduretic			C	Unknown	Unk, Unknown		Not Reported
	Levothyrox			C	Unknown	Unk, Unknown		Not Reported
	Ciprofibrate			C	Unknown			Not Reported
	Prazepam			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	14032556	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-151160			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dyskinesia; Dyskinesia; Therapeutic Product Effect Incomplete	Venlafaxine			S	Unknown	75-150 Mg / Day		Sun
	Venlafaxine			S				Sun
	Olanzapine			S	Unknown	5 Mg, Daily		Sun
	Olanzapine			S				Sun
	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Unknown			Sun
	Mirtazapine			S	Unknown			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	14033788	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2017-41140		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death	Escitalopram			S	Oral	15 Mg, Once A Day		Aurobindo
	Cefuroxim /00454602/			C	Oral	Unk		Not Reported
	Kadefungin			C	Vaginal			Not Reported
	Salbutamol			C				Not Reported
	Folsaeure			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	14035634	EXPEDITED (15-DAY)		HO	DK-ALLERGAN-1755493US		46 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Chronic	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	12186603	EXPEDITED (15-DAY)		HO, LT, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-113087		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apnoea; Coma; Drug Interaction; Myoclonus; Neuroleptic Malignant Syndrome	Clozapine		S	Unknown	Unk	Sun
	Risperidal Consta		S	Intramuscular	Unk	Not Reported
	Risperidal Consta		S	Intramuscular	50 Mg, Fortnight (Every 14 Days)	Not Reported
	Seroplex		S	Unknown	20 Mg, Daily	Not Reported
	Theralene		S	Unknown	20 Gtt, Prn (At Night)	Not Reported
	Loxapac		C	Unknown	300 Mg, Daily	Not Reported
	Seresta		C	Unknown	10 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	12538226	EXPEDITED (15-DAY)		HO, LT, OT	FR-FRI-1000085907		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Apnoea; Clonus; Coma; Disease Recurrence; Drug Interaction; Hyperhidrosis; Hypertonia; Loss Of Consciousness; Muscle Rigidity; Myoclonus; Neuroleptic Malignant Syndrome; Off Label Use; Pulmonary Embolism; Pyrexia; Salivary Hypersecretion; Status Epilepticus; Tremor	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Seresta			S	Unknown	10 Mg, Qd		Not Reported
	Theralene			S	Unknown	20 Gtt, Qhs If Needed		Not Reported
	Clozapine			S	Unknown	Unk		Not Reported
	Risperdal Consta			S	Intramuscular	50 Mg, Single (Q2weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	13926727	EXPEDITED (15-DAY)		DE	FR-TAKEDA-2017TUS018236		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Brintellix			S	Oral	10 Mg, Qd		Takeda
	Brintellix			S	Oral	20 Mg, Qd		Takeda
	Seroplex			S	Oral	20 Mg, Qd		Not Reported

	Seroplex	S	Oral	10 Mg, Qd		Not Reported
	Depakote	C	Unknown	1 G, Qd		Not Reported
	Olanzapine	C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14036995	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2017DE00227		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death	Escitalopram			S	Oral	15 Mg, Qd		Hetero
	Cefuroxim /00454602/			C	Oral	Unk		Not Reported
	Kadefungin			C	Vaginal			Not Reported
	Salbutamol			C	Topical			Not Reported
	Folic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14038070	EXPEDITED (15-DAY)		OT	DE-TORRENT-00007163		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Death	Escitalopram			S				Unknown
	Cefuroxime			C				Unknown
	Kadefungin			C				Unknown
	Salbutamol			C				Unknown
	Folsaure			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14038207	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1756117US			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Mood Swings; Suicidal Ideation; Tearfulness	Escitalopram Oxalate - Bp			S	Unknown	20 Unk, Unk		Allergan
	Priadel			C	Unknown			Not Reported
	Lamotrigine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14038448	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1756180US		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Death	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Cefuroxim			C	Oral			Not Reported
	Kadefungin			C	Unknown			Not Reported
	Salbutamol			C	Respiratory (inhalation)			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14045067	DIRECT		HO			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Logorrhoea	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Risperidone			C				Not Reported
	Bc Powder			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	13656651	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2017261732		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Lorazepam			S	Oral	10 Ml, Total		Pfizer
	Escitalopram Oxalate			S	Oral	6 Df, Total		Not Reported
	Carbolithium			C				Not Reported
	Quetiapine Fumarate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	13965056	EXPEDITED (15-DAY)		HO	IT-TEVA-804857ACC		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Coma; Drug Abuse; Hypotension; Intentional Self-Injury	Alprazolam			S	Oral			Actavis
	Cipralex - H. Lundbeck A/S			S	Oral			Not Reported
	Halcion - 125 Microgrammi Compresse			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	13978702	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1056089		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Coma; Drug Abuse; Hypotension; Intentional Self-Injury	Alprazolam			S	Oral	20 Gtt Total		Not Reported
	Cipralex			S	Oral	15 Gtt Total		Mylan
	Halcion			S	Oral	10 Df Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14017458	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS-2017M1059836			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Overdose; Toxicity To Various Agents	Amlodipine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Aliskiren			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14045077	EXPEDITED (15-DAY)		HO	FR-SA-2017SA186099		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Stilnox			S	Oral			Not Reported
	Methadone			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14046585	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP019108		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance	Bupropion Hydrochloride			S	Unknown			Apotex
	Trazodone Hydrochloride			S	Unknown			Apotex
	Mirtazapine			S	Unknown			Apotex
	Lamotrigine			S	Unknown			Apotex
	Escitalopram Oxalate			S	Unknown			Apotex
	Aripiprazole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14046821	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2017M1061379		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Duloxetine			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Modafinil			S	Unknown			Not Reported
	Methylphenidate			S	Unknown			Not Reported
	Calcium Chloride/Potassium Chloride/Sodium Lactate			S	Unknown	2 Litres		Not Reported
	Calcium Chloride/Potassium Chloride/Sodium Lactate			S	Intravenous (not otherwise specified)	7.5 Litres		Not Reported
	Lamotrigine			C	Unknown			Mylan
	Synthroid			C	Unknown			Mylan
	Vitamin D /00107901/			C	Unknown			Mylan
	Folic Acid			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14049113	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2017M1061908		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Lethargy; Somnolence; Suicide Attempt	Loperamide			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Meloxicam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14053265	EXPEDITED (15-DAY)		CA	DE-AUROBINDO-AUR-APL-2017-41405			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias	Citalopram 20mg			S	Transplacental	20 Mg, Daily		Aurobindo
	Escitalopram			S	Transplacental	5 Mg, Daily		Aurobindo
	Folio /00349401/			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14054852	EXPEDITED (15-DAY)		HO, OT	CA-ALVOGEN-2016-ALVOGEN-027002		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Bupropion			S				Not Reported
	Escitalopram			S				Not Reported
	Olanzapine			S				Not Reported
	Quetiapine			S				Not Reported
	Primidone			S				Not Reported
	Phenytoin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14055646	EXPEDITED (15-DAY)		OT	TR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-087669		16 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatine Phosphokinase Mb Increased; Chest Pain; Product Use In Unapproved Indication; Troponin T Increased	Aripiprazole		S	Unknown	Bristol Myers Squibb
	Escitalopram		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14056794	EXPEDITED (15-DAY)		HO	NL-ALLERGAN-1756573US		1 DAY	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Persistent Foetal Circulation	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14057021	EXPEDITED (15-DAY)		CA	DE-TEVA-811201GER		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 Milligram Daily;		Ivax
	Citalopram			S	Transplacental	20 Milligram Daily;		Actavis
	Folio			C	Transplacental	.4 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14057082	EXPEDITED (15-DAY)		HO, OT	IN-IMPAX LABORATORIES, INC-2017-IPXL-02813		23 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperammonaemic Encephalopathy; Status Epilepticus	Divalproex Sodium Er			S	Unknown	400 Mg, 2 /Day		Impax
	Carbamazepine			S	Unknown	200 Mg, 2 /Day		Not Reported
	Escitalopram			S	Unknown	0.5 Mg, 2 /Day		Not Reported
	Lacosamide			S	Intravenous (not otherwise specified)	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14057502	EXPEDITED (15-DAY)		HO, OT	BR-ALLERGAN-1756342US		69 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Paraesthesia; Peripheral Swelling; Vasodilatation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Venalot			C	Unknown			Not Reported
	Seroquel			C	Unknown			Not Reported
	Acertil			C	Unknown			Not Reported
	Propranolol			C	Unknown			Not Reported
	Devit D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14057516	EXPEDITED (15-DAY)		HO, OT	US-TEVA-812770USA		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Duloxetine			S	Unknown			Teva
	Methylphenidate			S	Unknown			Actavis
	Trazodone			S	Unknown			Barr
	Escitalopram			S	Unknown			Not Reported
	Modafinil			S	Unknown			Not Reported
	Ringer'S Lactate			S	Unknown	2 Litres		Not Reported
	Ringer'S Lactate			S	Intravenous (not otherwise specified)	7.5 Litres		Not Reported
	Lamotrigine			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14057602	EXPEDITED (15-DAY)		OT	US-TEVA-812722USA		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Lethargy; Somnolence; Suicide Attempt	Meloxicam			S	Oral			Teva
	Escitalopram			S	Oral			Not Reported
	Loperamide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14057970	EXPEDITED (15-DAY)		OT	IN-MYLANLABS-2017M1062400		57 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism	Escitalopram			S	Unknown	10mg		Not Reported
	Quetiapine			S	Unknown	50mg		Not Reported
	Amlodipine			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	12643595	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000086768		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Olanzapine			S	Unknown	Unk		Not Reported
	Phenytoin			S	Unknown	Unk		Not Reported
	Primidone			S	Unknown	Unk		Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported
	Bupropion			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	13781862	NON-EXPEDITED			US-PFIZER INC-2017320244		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Metoclopramide Hcl			S		Unk		Pfizer
	Aldactone			S		Unk		Pfizer
	Avandia			S		Unk		Not Reported
	Flonase			S		Unk		Not Reported
	Humalog			S		Unk		Not Reported
	Humulin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Zestril			S		Unk		Not Reported
	Levemir			S		Unk		Not Reported
	Valdecoxib			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14060793	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1756580US		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hypospadias	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan
	Citalopram Hydrobromide - Bp			S	Transplacental	Unk		Allergan
	Folio/Folic Acid			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14061822	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS INC.-2017-05422		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder; Sexual Dysfunction; Weight Increased	Sertraline			S	Unknown	100 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	60 Mg, Qd		Lupin
	Lorazepam			S	Unknown	2.5 Mg, Qd		Not Reported

	Alprazolam		C	Unknown	2 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14061896	EXPEDITED (15-DAY)		CA, OT	DE-DRREDDYS-GER/GER/17/0093841		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias	Citalopram			S	Transplacental			Not Reported
	Escitalopram			S	Transplacental			Not Reported
	Folio			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14062011	EXPEDITED (15-DAY)		HO	FR-ABBVIE-17P-056-2125390-00			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Medication Error; Oxygen Saturation Decreased	Depakine Chrono			S	Oral	Extended Release		Not Reported
	Synthroid			S	Oral			Not Reported
	Chondroitin			S	Oral			Not Reported
	Seroplex (Escitalopram Oxalate)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14063740	EXPEDITED (15-DAY)		CA, OT	GXKR2017DE004895		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	Maternal Dose: 5 Mg, Qd		Not Reported
	Citalopram			S	Transplacental	Maternal Dose: 20 Mg, Qd		Novartis
	Folio			C	Transplacental	Maternal Dose: 0.4 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14064527	EXPEDITED (15-DAY)		HO	US-ACELLA PHARMACEUTICALS, LLC-2029333		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Mental Status Changes; Serotonin Syndrome; Upper Respiratory Tract Infection	Brompheniramine Mal, Pseudoephedrine Hcl, And Dextromethorphan Hbr			S				Acella
	Amlodipine			C				Not Reported
	Labetalol			C				Not Reported
	Escitalopram			S				Not Reported
	Promethazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14066104	EXPEDITED (15-DAY)		HO, LT	FR-SA-2017SA190729		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Interaction; Hyponatraemia; Somnolence	Aprovel			S	Oral			Not Reported
	Aldactazine			S	Unknown			Not Reported
	Seroplex			S	Oral			Not Reported
	Esidrex			S	Oral			Not Reported
	Esidrex			S	Oral			Not Reported
	Mianserine			C	Oral			Not Reported
	Levothyrox			C				Not Reported
	Amlor			C				Not Reported
	Flecaine			C				Not Reported
	Eupantol			C				Not Reported
	Lyrica			C				Not Reported
	Xatral			C				Not Reported
	Seresta			C				Not Reported
	Imovane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14066992	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1756557US		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Constipation; Pruritus Generalised;	Milnacipran - Bp			S	Oral	Unk		Allergan

Rash Macular	Escitalopram Oxalate Unk		S	Oral	Unk	Allergan
	Levothyrox		S	Oral	Unknown	Not Reported
	Levothyrox		S	Oral	25 Mg, Qd	Not Reported
	Levothyrox		S	Oral	50 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	13786795	NON-EXPEDITED			US-JNJFOC-20170613240			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Inappropriate Schedule Of Product Administration	Tylenol Extra Strength Caplet		Y	S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Topiramate			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Primidone			C	Unknown			Not Reported
	Doxepine			C	Unknown			Not Reported
	Citalopram			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Citracal			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported
	Milk Of Magnesia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14014511	EXPEDITED (15-DAY)		HO, LT, OT	FR-ZYDUS-016788			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Overdose; Toxicity To Various Agents	Amlodipine			S	Unknown			Zydus Pharm
	Escitalopram			S	Unknown			Zydus Pharm

	Aliskiren	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14025527	EXPEDITED (15-DAY)		DE	JP-ELI_LILLY_AND_COMPANY-JP201709009592AA		35 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose	Strattera Capsule			S	Oral	120 Mg, Daily		Not Reported
	Strattera Capsule			S	Oral	Unk		Not Reported
	Strattera Capsule			S	Oral	Unk		Not Reported
	Strattera Capsule			S	Oral	Unk		Not Reported
	Serenace			S	Oral	4 Mg, Bid		Not Reported
	Biperiden			S	Oral	2 Mg, Bid		Not Reported
	Lexapro			S	Oral	10 Mg, Daily		Not Reported
	Belsomra			S	Oral	20 Mg, Daily		Not Reported
	Contomin /00011902/			S	Oral	25 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14068190	DIRECT		OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctivitis; Vision Blurred	Escitalopram			S	Oral	1 Pill Every Day By Mouth		Mylan
	Amlodipine			C				Not Reported
	Chlorthalidone			C				Not Reported
	Carvedilol			C				Not Reported
	Coq10			C				Not Reported
	Fish Oil			C				Not Reported
	Magnesium			C				Not Reported
	Asprin			C				Not Reported
	Tumeric			C				Not Reported
	Allegra			C				Not Reported
	Red Rice Yeast			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14068925	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2017M1062516		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 [Mg/D]		Not Reported
	Citalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Folio			C	Transplacental	0.4 [Mg/D]		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	12617491	EXPEDITED (15-DAY)		HO, OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-121339		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Bupropion			S	Unknown			Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Sun
	Phenytoin			S	Unknown	Unk		Sun
	Primidone			S	Unknown	Unk		Mutual
	Quetiapine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	12687006	EXPEDITED (15-DAY)		HO, LT, OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-069968		55 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Confusional State; Dysphagia; Hyperreflexia; Muscle Rigidity; Mutism; Neuroleptic Malignant Syndrome; Product Use In	Abilify			S	Oral	15 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Oral	5 Mg, Qd		Bristol Myers Squibb
	Abilify Maintena			S	Intramuscular	400 Mg, Qmo		Not Reported
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Quetiapine Actavis			C	Oral	300 Mg, Qd		Not Reported

Unapproved Indication; Serotonin Syndrome; Tremor	Temesta /00273201/		C	Oral	1 Mg, Tid	Not Reported
	Amlodipin /00972401/		C	Oral	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13899452	EXPEDITED (15-DAY)		DE, OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04764		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Lupin
	Indapamide			S	Unknown	Unk		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported
	Benzoic Acid			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13899467	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04765		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Lupin
	Galantamine			S	Unknown	Unk		Not Reported
	Irbesartan			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13899497	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04797		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Lupin
	Metoclopramide			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13967675	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-149393		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Coma; Drug Abuse; Hypotension; Intentional Self-Injury	Alprazolam			S	Oral	20 Gtt Total		Sun
	Cipralex			S	Oral	15 Gtt Total		Not Reported
	Halcion 125 Micrograms			S	Oral	10 Df Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14070134	EXPEDITED (15-DAY)		HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2017006180			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram			S	Oral	10 Mg, Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14070263	EXPEDITED (15-DAY)		HO, OT	GB-TORRENT-00015683		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14071664	EXPEDITED (15-DAY)		CA, OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-		1 DAY	Male	DEU

2017RR-152065

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 Mg, Daily		Not Reported
	Citalopram			S	Transplacental	20 Mg, Daily		Sun
	Folio			C	Transplacental	0.4 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14073261	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1757128US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Oxygen Saturation Decreased; Wrong Patient Received Product	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Single		Allergan
	Chondrosulf			S	Oral	400 Mg, Single		Not Reported
	Depakine Chrono			S	Oral	500 Mg, Single		Not Reported
	Levothyrox			S	Oral	50 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14073489	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1757183US			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Chills; Discomfort; Muscle Twitching; Therapeutic Product Effect Decreased; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Tamsulusin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14073492	EXPEDITED (15-DAY)		HO	NO-ALLERGAN-1757553US		< 1 DAY	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation Neonatal; Blood Glucose Decreased; Bradycardia; Drug Withdrawal Syndrome Neonatal; Insomnia; Maternal Exposure During Pregnancy; Muscle Twitching; Neonatal Seizure; Tremor Neonatal	Escitalopram Oxalate - Bp	S	Transplacental	Mother'S Dose	Allergan
	Metformin	C	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14074462	EXPEDITED (15-DAY)		HO	DK-TEVA-2014-12189		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Pollakiuria; Suicidal Ideation; Suicide Attempt; Urinary Incontinence; Withdrawal Syndrome	Escitalopram Actavis			S	Oral			Ivax
	Sertralin			C	Oral			Not Reported
	Pamol			C	Oral	3000 Milligram Daily; 1-Aug-2016 To 18-Aug-2016; 20-Jul-2017 To 22-Jul-2017		Not Reported
	Cisordinol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14074932	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2016JUB00383			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Dizziness; Limb Discomfort; Muscle Rigidity; Somnolence; Yawning	Escitalopram			S				Jubilant
	Aspirin			S				Not Reported
	Nortriptyline			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14074934	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2016JUB00397		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Escitalopram			S	Oral	10 Mg, 1x/Day		Jubilant
	Escitalopram			S				Jubilant
	Synthroid			C				Not Reported
	Cytomel			C				Not Reported
	Flax Seed			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14074936	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00098		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Escitalopram			S	Oral	20 Mg, 1x/Day		Jubilant
	Escitalopram			S		10 Mg, 1x/Day		Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14074938	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00101		86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Eye; Feeling Cold; Somnolence	Escitalopram			S	Oral	20 Mg, 1x/Day		Jubilant
	Omeprazole			C		20 Mg, 1x/Day		Not Reported
	Unspecified Vitamins			C		Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14074940	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00204			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Nausea; Night Sweats	Escitalopram			S	Oral	Unk		Jubilant
	Escitalopram			S	Oral	2.5 Mg, 2x/Day Around Noon And At Bedtime		Jubilant

	Bisoprolol Fumarate			C						Not Reported
	Levothyroxine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14074942	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00274			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Escitalopram			S		Unk		Jubilant
	Several Additional Medications			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14076478	EXPEDITED (15-DAY)		OT	NO-ALLERGAN-1757557US			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Pre-Eclampsia; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Metformin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14076496	EXPEDITED (15-DAY)		HO, OT	GB-ALLERGAN-1757428US		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14077201	EXPEDITED (15-DAY)		CA, OT	DE-HETERO CORPORATE-HET2017DE00244		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 Mg, Qd		Hetero

	Citalopram /00582602/	S	Transplacental	20 Mg, Qd	Not Reported
	Folic Acid	C	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14077669	EXPEDITED (15-DAY)		CA	DE-TORRENT-00007194		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S				Unknown
	Citalopram			S				Unknown
	Folio			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14077754	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/17/0093976		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Duloxetine Delayed-Release Capsules			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lamotrigine			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Methylphenidate			C	Unknown			Not Reported
	Modafinil			C	Unknown			Not Reported
	Vitamin D2			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14078837	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-813945ACC		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Feeding Disorder;	Escitalopram			S	Oral			Ivax

Insomnia; Nausea;
Palpitations; Peripheral
Coldness; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14079058	EXPEDITED (15-DAY)		DE, OT	ZA-CIPLA (EU) LIMITED-2016ZA07940			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Death	Atolip			S	Unknown	20 Mg, Nocte		Cipla
	Escitalopram			S	Unknown	10 Mg, Qd		Invagen
	Xalantan			S	Unknown	Unk		Not Reported
	Cardicor			S	Unknown	2.5 Mg, Qd		Not Reported
	Tambocor Sr			S	Unknown	100 Mg, Daily		Not Reported
	Xeralto			S	Unknown	20 Mg, Daily With Meal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14079188	EXPEDITED (15-DAY)		DE	SE-009507513-1710SWE003541		43 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Mirtazapine			S	Oral	30 Mg, Unk		Merck
	Anafranil			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	12436654	EXPEDITED (15-DAY)		HO, LT, OT	CA-ACCORD-041170		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis	Hydrochlorothiazide			S				Accord
	Escitalopram			S				Accord
	Metformin			S				Accord
	Levothyroxine			C				Not Reported
	Telmisartan			C				Not Reported
	Trazodone			C				Not Reported

	Gliclazide	C	Modified Release Dosage		Not Reported
	Insulin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	12646279	EXPEDITED (15-DAY)		CA, OT	TR-009507513-1608TUR005013			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Limb Reduction Defect	Remeron			S	Transplacental			Merck
	Cipralex			S	Transplacental	Unk		Not Reported
	Cipralex			S	Transplacental	10 Mg/Day		Not Reported
	Butylscopolamine Bromide			S	Transplacental	Unk		Not Reported
	Tranko Buskas			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	13693074	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2017-35900		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Escitalopram			S	Oral	6 Df, Total		Aurobindo
	Lorazepam			S	Oral	10 Ml, Total		Not Reported
	Carbolithium			C	Unknown			Not Reported
	Quetiapine Fumarate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	13693293	EXPEDITED (15-DAY)		HO	IT-TEVA-780101ACC		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Lorazepam			S	Oral			Actavis
	Escitalopram Oxalate			S	Oral			Ivax
	Carbolithium - 150 Mg Capsule Rigide			C				Not Reported
	Quetiapine Fumarate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14080407	EXPEDITED (15-DAY)		HO, OT	PHHY2017IT149116		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Product Misuse; Intentional Self-Injury; Sopor	Losartan			S	Oral			Novartis
	Delorazepam			S	Oral	Unk		Not Reported
	Haldol			S	Oral	Unk		Not Reported
	Escitalopram Accord			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14082797	EXPEDITED (15-DAY)		DE	SE-TEVA-813895ISR		43 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Escitalopram			S				Ivax
	Mirtazapine			S	Oral			Teva
	Anafranil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14085177	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-059817		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14085385	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2017-41545		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram 10 Mg		S	Oral	10 Mg, Unk	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14085488	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP020064		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis	Apo-Gliclazide Mr			S	Unknown	Unk		Not Reported
	Apo-Metformin - Tab 500mg			S	Unknown	1 G, Unk		Apotex
	Apo-Hydro			S	Unknown	Unk		Apotex
	Apo-Escitalopram			S	Unknown	Unk		Apotex
	Insulin			S	Unknown	Unk		Not Reported
	L Thyroxine			C	Unknown	Unk		Not Reported
	Telmisartan			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14088672	EXPEDITED (15-DAY)		DE	NZ-SA-2017SA198029			Male	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Completed Suicide	Clopidogrel Bisulfate			S	Oral			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	13675375	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1725731US		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Escitalopram Oxalate Unk			S	Oral			Allergan
	Lorazepam			S	Oral	10 Ml, Unk		Not Reported
	Carbolithium			C	Unknown			Not Reported
	Quetiapine Fumarate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14091379	EXPEDITED (15-DAY)		HO, OT	GB-CIPLA LTD.-2017GB17914			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram			S	Oral	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14091632	EXPEDITED (15-DAY)		DE, LT, OT	US-STRIDES ARCOLAB LIMITED-2017SP013385			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Lethargy; Somnolence; Suicide Attempt; Toxicity To Various Agents	Loperamide			S	Oral	Unk		Not Reported
	Meloxicam			S	Oral	Unk		Strides
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14091681	EXPEDITED (15-DAY)		HO, OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-152188		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Inappropriate Antidiuretic Hormone	Escitalopram			S	Unknown			Not Reported

Secretion	Hydrochlorothiazide	S	Unknown		Sun
	Gliclazide	C	Unknown	Modified-Release	Not Reported
	Insulin	C	Unknown		Not Reported
	Levothyroxine	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Telmisartan	C	Unknown		Not Reported
	Trazodone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14091740	NON-EXPEDITED		OT	US-PFIZER INC-2017439919		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Heart Rate Decreased	Effexor			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Citalopram			S		Unk		Not Reported
	Cyclobenzaprine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14092482	EXPEDITED (15-DAY)		CA, OT	DE-LUPIN PHARMACEUTICALS INC.-2016-05904		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 Mg, Qd		Lupin
	Citalopram			S	Transplacental	20 Mg, Qd		Not Reported
	Folio /00349401/			C	Transplacental	0.4 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14093340	EXPEDITED (15-DAY)		HO, OT	US-LANNETT COMPANY, INC.-US-2017LAN001084		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Methylphenidate Hydrochloride	S	Unknown	Unk	Lannett
	Escitalopram Oxalate	S	Unknown	Unk	Lannett
	Duloxetine	S	Unknown	Unk	Not Reported
	Modafinil	S	Unknown	Unk	Not Reported
	Trazodone	S	Unknown	Unk	Not Reported
	Ringers Lactate	S	Unknown	2 Liters	Not Reported
	Ringers Lactate	S	Intravenous (not otherwise specified)	7.5 Liters	Not Reported
	Ringers Lactate	S	Oral	1.2 Liters	Not Reported
	Lamotrigine	S	Unknown	Unk	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Vitamin D /00107901/	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Oxygen	C		2 Liters	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14093350	DIRECT		DS, HO, OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chills; Depersonalisation/Derealisation Disorder; Depression; Diarrhoea; Eating Disorder; Emotional Distress; Fear; Feeling Abnormal; Hallucination, Visual; Impaired Work Ability; Mental Impairment; Nausea; Panic Attack; Physical Disability; Post-Traumatic Stress Disorder; Pyrexia; Suicidal Ideation; Syncope; Tinnitus; Vision Blurred; Vomiting; Weight Decreased	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Allergan
	Klonopin			C				Not Reported
	Abilify			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14093775	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-M-EU-2012070197		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Balance Disorder; Diarrhoea; Disorientation; Disturbance In Attention; Dizziness; Drug Interaction; Dyspnoea; Euphoric Mood; Gait Disturbance; Gait Inability; Hallucination; Headache; Hypopnoea; Muscle Spasms; Palpitations; Pulse Pressure Increased; Somnolence; Urinary Tract Infection; Vomiting	Cesamet			S	Oral	0.25 Mg, Bid		Mylan
	Escitalopram Mylan			S	Oral	20 Mg, Qd		Mylan
	Escitalopram Mylan			S				Mylan
	Baclofen			S		20 Mg, Tid		Mylan
	Butrans			S	Transdermal	20 Mg, Qh		Mylan
	Butrans			S	Transdermal	15 Mg, Qh		Mylan
	Butrans			S	Transdermal	10 Mg, Qh		Mylan
	Butrans			S	Transdermal	5 Mg, Qh		Mylan
	Clonazepam			S	Oral	1 Mg, Tid		Mylan
	Cipro Xl			C	Oral	1000 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14095087	EXPEDITED (15-DAY)		HO, OT	GB-MYLANLABS-2017M1063651		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	13078451	EXPEDITED (15-DAY)		HO, OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-110446		65 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Bleeding; Immune	Glucophage			S	Unknown	500 Mg, Unk		Bristol Myers Squibb

Thrombocytopenic Purpura; Petechiae; Tinnitus	Eutimil	S	Oral	Unk	Not Reported
	Cipralex /01588501/	S	Unknown		Not Reported
	Sereupin	S	Oral		Not Reported
	Crestor	S	Oral	10 Mg, Unk	Not Reported
	Esopral /01479301/	C	Oral	20 Mg, Unk	Not Reported
	Diamox /00016901/	C	Oral	250 Mg, Unk	Not Reported
	Stiliden	C	Oral		Not Reported
	Muscoril	C	Oral	4 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	13238399	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP006511		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Withdrawal Syndrome; Arrhythmia; Condition Aggravated; Confusional State; Drug Interaction; Hyperthermia; Intentional Overdose; Intentional Product Misuse; Major Depression; Mental Status Changes; Overdose; Pneumonia; Potentiating Drug Interaction; Sepsis; Serotonin Syndrome; Tachycardia; Toxicity To Various Agents	Primidone			S	Oral			Not Reported
	Apo-Escitalopram			S	Oral			Apotex
	Apo-Quetiapine			S	Oral			Apotex
	Apo-Olanzapine			S	Oral			Apotex
	Apo-Citalopram			S	Unknown			Apotex
	Bupropion			S	Oral			Not Reported
	Phenytoin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	13661852	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1725002US		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchial Obstruction; Cerebral Venous	Escitalopram Oxalate - Bp			S	Oral			Allergan

Thrombosis; Coma; Lung Disorder; Neurological Decompensation; Respiratory Distress	Qizenday	S	Oral	100 Mg, Tid	Not Reported
	Baclofene	S	Oral	45 Mg, Qd	Not Reported
	Vesicare	S	Oral	1 Df, Qd	Not Reported
	Xatral	S	Oral	1 Df, Qd	Not Reported
	Dafalgan	S	Oral	500 Mg, Q12h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	13676867	EXPEDITED (15-DAY)		HO	IT-ACCORD-052837		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Escitalopram			S	Oral			Accord
	Lorazepam			S	Oral	10 Ml Total		Not Reported
	Carbolithium			C		Strength: 150 Mg		Not Reported
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	13687805	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1036720		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Overdose; Slow Speech; Sopor	Lorazepam			S	Oral	10 Ml Total		Not Reported
	Escitalopram			S	Oral	6 Df Total		Not Reported
	Carbolithium			C		Unk		Mylan
	Quetiapine Fumarate			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	13923324	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-147977		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria;	Amlodipine			S	Oral	Unk		Sun

Blindness; Circulatory Collapse; Condition Aggravated; Depressed Level Of Consciousness; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Optic Atrophy; Optic Nerve Injury; Pulmonary Oedema; Shock; Tachycardia; Toxicity To Various Agents	Escitalopram	S	Oral	Unk		Not Reported
	Risperidone	S	Oral	Unk		Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14085242	NON-EXPEDITED			US-PFIZER INC-2017440319		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Interaction	Lipitor			S		Unk		Pfizer
	Synthroid			S	Oral	0.112 Mg, 1x/Day		Not Reported
	Monopril			S	Oral	20 Mg, 1x/Day		Not Reported
	Valium			S	Oral	20 Mg, Daily		Not Reported
	Lexapro			S	Oral	20 Mg, Daily		Not Reported
	Lexapro			S				Not Reported
	Zetia			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14096796	NON-EXPEDITED			US-PFIZER INC-2017441674		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Xanax			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer

Ibuprofen	S	Unk	Pfizer
Morphine Sulfate	S	Unk	Unknown
Loperamide Hcl	S	Unk	Not Reported
Buspar	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Luvox	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported
Lithium	S	Unk	Not Reported
Zofran	S	Unk	Not Reported
Amoxicillin	S	Unk	Not Reported
Aspirin	S	Unk	Not Reported
Benadryl	S	Unk	Not Reported
Duloxetine	S	Unk	Not Reported
Ambien	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Zyprexa	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14096866	EXPEDITED (15-DAY)		DE, LT, OT	US-HETERO-HET2017US00274		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Lethargy; Somnolence	Escitalopram			S	Oral	Unk		Hetero
	Meloxicam			S	Oral	Unk		Not Reported
	Loperamide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14098149	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1758680US		66 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Haematoma	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

Muscle	Sintrom	S	Oral	1 Mg Mitis, Unk	Not Reported
	Pantozol	C	Oral	40 Mg, Qd	Not Reported
	Bilol	C	Oral	Form Strength: 2,5	Not Reported
	Aldactone	C	Oral	50 Mg, Qd	Not Reported
	Janumet	C	Oral	50/500 Mg	Not Reported
	Cordarone Comprimes	C	Oral	100 Mg, Qd	Not Reported
	Ezetrol	C	Oral	10 Mg, Qd	Not Reported
	Atorvastatin Pfizer	C	Oral	40 Mg, Qd	Not Reported
	Xanax Retard	C	Oral	0.5 Mg, Q12	Not Reported
	Remeron	C	Oral	30 Mg, Qd	Not Reported
	Trittico	C	Oral	50 Mg, Qd	Not Reported
	Zoldorm	C	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14100117	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1758678US		52 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuritis	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14100264	EXPEDITED (15-DAY)		DE, HO	FR-ABBVIE-17P-056-2134034-00		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Product Administration Error	Depakine Chrono			S	Oral	Extended Release		Not Reported
	Levothyroxine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			S	Oral			Not Reported

	Modopar	S	Oral	Not Reported
	Spironolactone	C		Not Reported
	Levetiracetam	C		Not Reported
	Atarax	C		Not Reported
	Laroxyl	C		Not Reported
	Folic Acid	C		Not Reported
	Magne B6	C		Not Reported
	Chondrosulf	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14036677	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1756172US		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperemesis Gravidarum; Off Label Use; Pregnancy	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Citalopram Hydrobromide - Bp			S	Unknown	Unk, Qd		Allergan
	L-Tyroxin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14088988	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2017-41880		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Duloxetine			S	Unknown			Aurobindo
	Escitalopram			S	Unknown			Aurobindo
	Modafinil			S	Unknown			Aurobindo
	Trazodone			S	Unknown			Aurobindo
	Methylphenidate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14105105	EXPEDITED (15-DAY)		DE, OT	SE-MYLANLABS-2017M1066352		43 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Escitalopram			S		Unk		Not Reported

	Anafranil	S		Unk		Mylan
	Mirtazapine	S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	14024516	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1755154US		37 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Depression; Dysphoria; Nausea; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Lorazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	14108260	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1759248US		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Decreased Appetite; Disorientation; General Physical Health Deterioration; Hyponatraemia; Memory Impairment	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Inexium			S	Oral	20 Mg, Qd		Not Reported
	Triflucan			C	Oral			Not Reported
	Xarelto			C	Oral			Not Reported
	Bisoce			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Novonorm			C	Unknown			Not Reported
	Loperamide Base			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	14108455	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2017LAN001121		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Cardiac Arrest; Completed Suicide; Intentional Product Misuse; Lethargy; Somnolence	Escitalopram Oxalate	S	Oral	Unk		Lannett
	Loperamide	S	Oral	Unk		Not Reported
	Meloxicam	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	14108568	EXPEDITED (15-DAY)		HO	FR-SA-2017SA200581		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Abnormal; Hypotension; Miosis; Overdose; Tachycardia; Tachypnoea	Depakote			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14110765	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2017AP020021		54 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Product Misuse; Intentional Self-Injury; Sopor	Losartan Doc Generici			S	Oral	Unk		Apotex
	Delorazepam			S	Oral	Unk		Not Reported
	Haldol /00027401/			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14111134	EXPEDITED (15-DAY)		HO	FR-ABBVIE-17P-056-2136805-00		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Abnormal; Hypotension; Miosis; Overdose; Tachycardia; Tachypnoea	Depakote			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14111801	DIRECT					45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Generic Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2017	14092490	EXPEDITED (15-DAY)		OT	ZA-LUPIN PHARMACEUTICALS INC.-2017-05972			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Neoplasm	Bilocor Tablets			S	Oral	5 Mg, Qd		Not Reported
	Zytomil			S	Oral	10 Mg, Qd		Lupin
	Puricos			S	Oral	300 Mg, Qd		Not Reported
	Aspavor			S	Oral	20 Mg, Qd		Not Reported
	Estro-Pause			S	Oral	1 Mg, Qd		Not Reported
	Warfarin			S	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2017	14116507	NON-EXPEDITED		HO	US-DEPOMED, INC.-US-2016DEP011915			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Muscle Twitching; Serotonin Syndrome; Syncope	Nucynta Er			S		250 Mg, Bid		Depomed
	Lexapro			S		Unk		Not Reported
	Subsys			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	13784442	NON-EXPEDITED			US-IMPAX LABORATORIES, INC-2017-IPXL-01063		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective For Unapproved Indication; Drug Interaction; Psychotic Symptom	Rytary	S	Oral	(23.75/95 Mg) Unk	Impax
	Rytary	S	Oral	(36.25/145 Mg) Unk	Impax
	Rytary	S	Oral	(48.75/195 Mg)1 Df, 2/Day	Impax
	Carbidopa-Levodopa Er	S	Unknown	Unk	Impax
	Escitalopram	S	Unknown	Unk	Not Reported
	Amiodarone	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Lisinopril	C	Unknown	Unk	Not Reported
	Finasteride	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Tamsulosin	C	Unknown	Unk	Not Reported
	Requip	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14121946	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1760307US		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Abnormal; Hypotension; Miosis; Tachycardia; Tachypnoea	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Depakote			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14121951	EXPEDITED (15-DAY)		DE, OT	FR-ALLERGAN-1759767US		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Product Administration Error	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan
	Depakine Chrono			S	Oral			Not Reported
	Lamaline (Acetaminophen\Belladonna Leaf\Caffeine\Opium)			S	Oral	1 Df, Unk		Not Reported

Alprazolam	S	Oral	0.25 Mg, Unk		Not Reported
Modopar	S	Oral			Not Reported
Levothyrox	S	Oral	50 Mg, Unk		Not Reported
Atarax	C	Unknown	25 Mg, Qd		Not Reported
Atarax	C	Unknown	16 Mg, Unk		Not Reported
Spironolactone	C	Unknown			Not Reported
Levetiracetam	C	Unknown	375 Mg, Bid		Not Reported
Laroxyl	C	Unknown			Not Reported
Folic Acid	C	Unknown	5 Mg, Unk		Not Reported
Magnesium B6	C	Unknown			Not Reported
Chondrosulf	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2017	14017007	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1748674US		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Food Poisoning; Malaise; Nausea; Retching; Serotonin Syndrome; Vomiting	Lexapro			S	Oral	1 Df, Qhs		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2017	14065972	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1757161US		57 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Appetite; Overdose	Escitalopram Oxalate Unk			S	Unknown	30 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Unknown	20 Mg, Unk		Allergan
	Escitalopram Oxalate Unk			S	Unknown	15 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Qd		Allergan
	Zyprexa Velotab			S	Unknown	5 Mg, Qd		Not Reported
	Zyprexa Velotab			S	Unknown	15 Mg, Qd		Not Reported

Zyprexa Velotab	S	Unknown	10 Mg, Qd		Not Reported
Seroquel	C	Unknown	50 Mg, Qd		Not Reported
Quetiapin	C	Unknown			Not Reported
Lamotrigin	C	Unknown	50 Mg, Qd		Not Reported
Temesta (Lorazepam)	C	Unknown	5 Mg, Qd		Not Reported
Rivotril	C	Unknown	1 Mg, Qd		Not Reported
Thyrex	C	Unknown	50 Mg, Qod		Not Reported
Combithyrex Mite	C	Unknown	1 Df, Qod		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2017	14073499	EXPEDITED (15-DAY)		HO, OT	AT-ALLERGAN-1757433US		57 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Prescribed Overdose; Weight Increased	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Zyprexa Velotab			S	Unknown			Not Reported
	Zyprexa Velotab			S	Unknown	15 Mg, Qd		Not Reported
	Zyprexa Velotab			S	Unknown	5 Mg, Qd		Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown	450 Mg, Qd		Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel Xr			S	Unknown			Not Reported

Seroquel Xr	S	Unknown	Not Reported
Seroquel Xr	S	Unknown	Not Reported
Seroquel Xr	S	Unknown	Not Reported
Seroquel Xr	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Quetiapin	C	Unknown	Not Reported
Lamotrigin	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Temesta (Lorazepam)	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Rivotril	C	Unknown	Not Reported
Thyrex	C	Unknown	Not Reported
Combithyrex	C	Unknown	Not Reported
Molaxole	C	Unknown	Not Reported
Molaxole	C	Unknown	Not Reported
Molaxole	C	Unknown	Not Reported
Molaxole	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2017	14124252	EXPEDITED (15-DAY)		CA	DE-GLENMARK PHARMACEUTICALS-2017GMK029102			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 Mg, Qd, Up To 13.2. Gestational Week		Not Reported
	Citalopram Hydrobromide			S	Transplacental	20 Mg, Qd, 13.2 To 26.3 Gestational Week		Glenmark
	Folio /00349401/			C	Transplacental	0.4 Mg, Qd, 0 To 41.2 Gestational Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2017	14126638	EXPEDITED (15-DAY)		OT	US-JAZZ-2017-US-013857			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Appetite; Serotonin Syndrome	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjusments		Jazz
	Xyrem			S	Oral	5 G, Qd; First Dose		Jazz
	Xyrem			S	Oral	4 G, Qd; Second Dose		Jazz
	Lexapro			S		5 Mg		Not Reported
	Lexapro			S		10 Mg		Not Reported
	Lexapro			S		20 Mg		Not Reported
	Ibuprofen			C		Unk		Not Reported
	Naltrexone			C		Unk		Not Reported
	Tylenol Extra-Strength			C		Unk		Not Reported
	Amitriptyline Hcl			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Wellbutrin			C		Unk		Not Reported
	Lactobacillus			C		Unk		Not Reported
	Allegra Allergy			C		Unk		Not Reported
	Zantac			C		Unk		Not Reported
	Adderall			C		5 Mg		Not Reported

	Adderall	C	25 Mg	Not Reported
	Adderall	C	20 Mg	Not Reported
	Adderall	C	30 Mg	Not Reported
	Mestinon	C	Unk	Not Reported
	Bupropion Hcl	C	Unk	Not Reported
	Nuvigil	C	Unk	Not Reported
	Topamax	C	25 Mg	Not Reported
	Topamax	C	50 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	13865982	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1734194US		67 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Sedation Complication	Asenapine Maleate - Bp			S	Sublingual	10 Mg, Qd (Morning And Evening)		Allergan
	Asenapine Maleate - Bp			S	Sublingual	7.5 Mg, Qd (Morning And Evening)		Allergan
	Asenapine Maleate - Bp			S	Sublingual	5 Mg, (Morning And Evening)		Allergan
	Asenapine Maleate - Bp			S	Sublingual	5 Mg, Qd (Evening)		Allergan
	Olanzapine			S	Oral	2.5 Mg, Qd		Not Reported
	Olanzapine			S	Oral	5 Mg, Qd		Not Reported
	Olanzapine			S	Oral	5 Mg, Qd		Not Reported
	Olanzapine			S	Oral	10 Mg, Qd		Not Reported
	Olanzapine			S	Oral	15 Mg, Qd		Not Reported
	Olanzapine			S	Oral	20 Mg, Qd		Not Reported
	Lexapro			S	Oral	5 Mg, Qd		Not Reported
	Lexapro			S	Oral	2.5 Mg, Qd		Not Reported
	Lorazepam			S	Oral	1 Mg, Qd		Not Reported
	Lorazepam			S	Oral	1.5 Mg, Qd		Not Reported

	Flunitrazepam	C	Unk	Not Reported
	Clonazepam	C	Unk	Not Reported
	Urapidil	C	Unk	Not Reported
	Dutasteride	C	Unk	Not Reported
	Sertraline Hydrochloride	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	13926283	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1747950US		67 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Dementia; Fall; Immobile; Parkinsonism; Rhabdomyolysis	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Dogmatyl			C	Oral	50 Mg, Unk		Not Reported
	Natrix			C	Oral	1 Mg, Unk		Not Reported
	Rohypnol			C	Oral	1 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	13967430	NON-EXPEDITED			US-PFIZER INC-2017395349		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Provera			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Metformin			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported

	Tramadol	S	Unk	Not Reported
	Zyrtec	S	Unk	Not Reported
	Allegra	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	14128221	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2017-42592		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Completed Suicide; Lethargy; Somnolence; Suicide Attempt	Loperamide			S		40 Unk, Unk		Aurobindo
	Escitalopram			S	Unknown			Aurobindo
	Meloxicam			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	14128595	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1760596US		< 1 DAY	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	14129390	EXPEDITED (15-DAY)		DE	FR-MERCK KGAA-2031571		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Product Administration Error	Novothyrox			S	Oral			Merck Kgaa
	Depakine Chrono			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Lamaline (Acetaminophen\Belladonna Leaf\Caffeine\Opium)			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

	Modopar	S	Oral		Not Reported
	Folic Acid	C			Not Reported
	Magnis + B6(Dynamag)	C			Not Reported
	Chondrosulf	C			Not Reported
	Spironolactone	C			Not Reported
	Levetiracetam	C			Not Reported
	Atarax	C			Not Reported
	Atarax	C			Not Reported
	Laroxyl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	13857957	EXPEDITED (15-DAY)		OT	PHHY2017FR115523		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Digoxin			S	Unknown	Unk		Novartis
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14133341	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US18551			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Behaviour; Decreased Appetite; Enuresis; Headache; Malaise; Nausea; Product Administered To Patient Of Inappropriate Age; Somnambulism; Somnolence	Escitalopram			S	Oral	5 Mg, Qd		Invagen
	Escitalopram			S				Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14133705	NON-EXPEDITED			US-PFIZER INC-2017459519		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chromaturia; Claustrophobia; Dysuria; Erectile Dysfunction; Sleep Apnoea Syndrome; Urine Odour Abnormal	Lipitor	S	Oral	40 Mg, 1x/Day		Pfizer
	Metoprolol Tartrate	S	Oral	50 Mg, 2x/Day		Not Reported
	Metoprolol Tartrate	S				Not Reported
	Escitalopram	S	Oral	10 Mg, 1x/Day		Not Reported
	Cardizem	S	Oral	180 Mg, 1x/Day		Not Reported
	Clonazepam	S	Oral	1 Mg, 1x/Day (At Night)		Not Reported
	Clonazepam	S				Not Reported
	Seroquel	S		50 Mg, Unk		Not Reported
	Seroquel	S	Oral	150 Mg, 1x/Day		Not Reported
	Seroquel	S				Not Reported
	Abilify	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14134365	NON-EXPEDITED			US-APOTEX-2017AP016527		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Therapeutic Product Effect Incomplete	Escitalopram Oxalate			S	Unknown	10 Mg, Per Day		Apotex
	Escitalopram Oxalate			S				Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14137237	EXPEDITED (15-DAY)		HO, LT	JP-ELI_LILLY_AND_COMPANY-JP201710009793		27 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Zyprexa			S	Oral	5 Mg, Daily		Eli Lilly And Co
	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14137412	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2017456084		91 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Hypertransaminasaemia; Syncope	Cordarone		S	Unknown	Unk	Pfizer
	Entact		S	Oral	Unk	Not Reported
	Durogesic		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	12649157	EXPEDITED (15-DAY)		OT	DK-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-063987			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Placental Disorder; Premature Delivery; Prescribed Overdose; Product Use Issue	Abilify			S	Oral	30 Mg, Qd		Bristol Myers Squibb
	Cipralex /01588501/			S	Oral	Unk		Not Reported
	Peratsin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	13625446	NON-EXPEDITED			US-ACCORD-048752		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Test False Positive	Amlodipine			S	Oral			Accord
	Escitalopram Accord			S	Oral	Dose/Strength: 20 Mg		Accord
	Lisinopril			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140306	NON-EXPEDITED			US-ACCORD-044366			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swelling	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140307	NON-EXPEDITED			US-ACCORD-046573		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Transaminases Increased	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140308	NON-EXPEDITED			US-ACCORD-045303			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140309	EXPEDITED (15-DAY)		OT	US-ACCORD-047083			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Expired Product Administered; Nervousness; Night Sweats; Palpitations; Poor Quality Sleep; Sexual Dysfunction	Escitalopram			S	Oral	In Oct-2015 Restarted,Discontinued In May-2016		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140310	NON-EXPEDITED			US-ACCORD-048611			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Exposure Via Breast Milk	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140311	NON-EXPEDITED			US-ACCORD-047499		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension;	Escitalopram			S	Oral			Accord

Abnormal Faeces; Gastrooesophageal Reflux Disease	Drisdol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140312	NON-EXPEDITED			US-ACCORD-050556			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Insomnia; Nightmare	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140317	NON-EXPEDITED			US-ACCORD-053710		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity; Weight Increased	Escitalopram			S	Oral	Started 10 Mg Qd, Cutting Tablet In Half And Self Received 5 Mg Qd From 15-Jun-2015 To 15-Apr-2017		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140318	NON-EXPEDITED			US-ACCORD-056973		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain; Feeling Abnormal; Headache	Escitalopram Accord			S	Oral	Once A Day		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140319	NON-EXPEDITED			US-ACCORD-052242		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous; Rash Pruritic	Escitalopram			S	Oral			Accord
	Nifedipine			C				Not Reported

	Zetia	C	Not Reported
	Pravastatin	C	Not Reported
	Metoprolol	C	Not Reported
	Irbesartan	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140320	NON-EXPEDITED			US-ACCORD-057882			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Accord			S				Accord
	Fluoxetine			S				Not Reported
	Invega Sustenna			S				Not Reported
	Clonazepam			S				Not Reported
	Paroxetine			S				Not Reported
	Aripiprazole			S				Not Reported
	Risperidone			S				Not Reported
	Risperidone			S				Not Reported
	Lithium			S				Not Reported
	Haloperidol			S				Not Reported
	Pramipexole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140322	NON-EXPEDITED			US-ACCORD-050475			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching; Rash	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140323	NON-EXPEDITED			US-ACCORD-050999			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Feeling Abnormal; Tinnitus	Escitalopram			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140324	NON-EXPEDITED			US-ACCORD-051168			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram Accord			S		Strength: 10 Mg		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140325	NON-EXPEDITED			US-ACCORD-051869		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14141528	EXPEDITED (15-DAY)		OT	PHHY2017FR157560		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Pramipexole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14141529	EXPEDITED (15-DAY)		OT	PHHY2017FR157553		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Novartis
	Furosemide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14142018	EXPEDITED (15-DAY)		OT	PHHY2017FR157550		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported
	Candesartan Cilexetil			S	Unknown			Novartis
	Ivabradine			S	Unknown			Not Reported
	Spironolactone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	13040098	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-SA-2016SA216624		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Bezoar; Blood Bicarbonate Decreased; Blood Pressure Decreased; Cardiogenic Shock; Coma; Drug Level Increased; Gastrointestinal Ischaemia; Haemodynamic Instability; Heart Rate Decreased; Hyperlactacidaemia; Intentional Overdose; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Overdose; Overdose; Renal Failure; Shock; Skin Necrosis; Toxicity To Various Agents	Seroplex			S	Oral	28 Tabs Of 10 Mg Each		Not Reported
	Zolpidem Tartrate			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Nordazepam			S	Unknown			Not Reported
	Olmesartan Medoxomil			S	Unknown			Not Reported
	Amlodipine (Salt Not Specified)			S	Unknown			Not Reported
	Atarax			S	Oral	28 Tabs Of 25 Mg Each		Not Reported
	Sevikar			S	Oral	129 Tabs, 10 Mg Each, 1.29g Amlodipine And 5.16g Olmesartan		Not Reported
	Lysanxia			S	Oral	42 Tabs Of 10 Mg Each		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	13828995	NON-EXPEDITED			US-APOTEX-2017AP016124		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyp2c19 Polymorphism; Cyp2c9 Polymorphism;	Mirtazapine			S	Unknown	30 Mg, Unk		Apotex

Cyp2d6 Polymorphism; Drug Ineffective; Drug Intolerance	Risperidone	S	Unknown		Apotex
	Gabapentin	S	Unknown	200 Mg, Qd	Apotex
	Buspiprone Hydrochloride Tablets Usp	S	Unknown	15 Mg, Bid	Apotex
	Citalopram	S	Unknown		Apotex
	Escitalopram Oxalate	S	Unknown	2.5 Mg, Qd	Apotex
	Paroxetine Hydrochloride	S	Unknown		Apotex
	Sertraline Hydrochloride	S	Unknown	25 Mg, Qd	Apotex
	Olanzapine	S	Unknown		Apotex
	Nortriptyline	S	Unknown	75 Mg, Qd	Not Reported
	Lorazepam	S	Unknown	0.5 Mg, Qd	Not Reported
	Venlafaxine	S	Unknown		Not Reported
	Diazepam	S	Unknown		Not Reported
	Quetiapine	S	Unknown		Not Reported
	Oxcarbazepine	S	Unknown		Not Reported
	Topiramate	S	Unknown		Not Reported
	Clonazepam	S	Unknown		Not Reported
	Flurazepam	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14145184	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2016569750			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Maternal Exposure During Pregnancy; Neonatal Disorder; Sepsis Neonatal; Transient Tachypnoea Of The Newborn	Temesta (Lorazepam)			S	Transplacental	1 Mg, 3x/Day In Reserve		Pfizer
	Cipralex			S	Transplacental	10 Mg, 1x/Day		Not Reported
	Folic Acid			C		5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14148472	DIRECT		DS, OT			37 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Anorgasmia; Disturbance In Attention; Erectile Dysfunction; Erectile Dysfunction; Feeling Abnormal; Hypogeusia; Hyposmia; Loss Of Libido; Memory Impairment	Cipralex			S	Oral	Quantity:1 Tablet(S);		Farmagon
	Vitamin B			C				Not Reported
	C			C				Not Reported
	D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14148499	DIRECT		DS			36 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14148578	DIRECT		OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Apathy; Female Orgasmic Disorder; Loss Of Libido; Sensory Loss; Sexual Dysfunction	Cipralex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14148662	DIRECT		OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Loss Of Libido	Lexapro			S	Oral			Not Reported
	Multivitamin			C				Not Reported
	Spurilina			C				Not Reported
	D3 & K2			C				Not Reported
	Probiotic			C				Not Reported

	L-Lysine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	13418182	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-027204		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Gestational Diabetes; Live Birth; Maternal Exposure During Pregnancy; Prescribed Underdose; Product Use Issue; Prolonged Labour	Aripiprazole			S	Unknown	15 Mg, Unk		Bristol Myers Squibb
	Aripiprazole			S	Unknown	10 Mg, Unk		Bristol Myers Squibb
	Aripiprazole			S	Unknown	15 Mg, Unk		Bristol Myers Squibb
	Lamictal			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Ativan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	13418381	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-028477		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Fluid Replacement; Gestational Diabetes; Maternal Exposure During Pregnancy; Morning Sickness; Nausea; Normal Newborn; Oesophagitis; Pre-Eclampsia; Prescribed Underdose; Product Use Issue	Aripiprazole			S	Unknown	10 Mg, Unk		Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown	Unk		Bristol Myers Squibb
	Lamictal			S	Unknown	Unk		Not Reported
	Celexa /00582602/			S	Unknown	Unk		Not Reported
	Celexa /00582602/			S	Unknown			Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown			Not Reported
	Glyburide			S	Unknown	Unk		Not Reported
	Ativan			S	Unknown	Unk		Not Reported
	Zofran /00955301/			S	Unknown	Unk		Not Reported
	Compazine /00013304/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	14148404	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1760592US		51 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Haematochezia; Intentional Dose Omission; Nausea; Poor Quality Sleep; Visual Impairment	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	14148541	EXPEDITED (15-DAY)		HO	US-APOTEX-2017AP020319		94 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Intolerance; Treatment Failure	Sertraline Hydrochloride			S	Unknown	Unk		Apotex
	Escitalopram Oxalate			S	Unknown	Unk		Apotex
	Mirtazapine			S	Unknown	Unk		Apotex
	Bupropion Hydrochloride			S	Unknown	Unk		Apotex
	Trazodone Hydrochloride			S	Unknown	Unk		Apotex
	Lamotrigine			S	Unknown	Unk		Apotex
	Clonazepam Tablets Usp			S	Unknown	Unk		Apotex
	Donepezil Hydrochloride Tablets Usp			S	Unknown	Unk		Apotex
	Memantine Hydrochloride Extended Release Capsules			S	Unknown	Unk		Apotex
	Venlafaxine			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Methylphenidate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	14149266	EXPEDITED (15-DAY)		DS, OT	US-ACADIA PHARMACEUTICALS			Female	USA

INC.-ACA-2017-006015

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Crying; Drug Ineffective; Gait Inability; Muscle Rigidity; Off Label Use	Nuplazid			S	Oral	34 Mg, Qd		Acadia Pharmaceuticals
	Nuplazid			S				Acadia Pharmaceuticals
	Nuplazid			S				Acadia Pharmaceuticals
	Nuplazid			S				Acadia Pharmaceuticals
	Nuplazid			S				Acadia Pharmaceuticals
	Nuedexta			S				Not Reported
	Escitalopram			S		10 Mg, Unk		Not Reported
	Namenda			S				Not Reported
	Nortriptyline			C		2 Mg, Bid		Not Reported
	Prenatal Vitamins			C				Not Reported
	Depakote			C	Oral	500 Mg, Bid		Not Reported
	Seroquel			C		25 Mg, Bid		Not Reported
	Baby Aspirin			C				Not Reported
	Turmeric			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	14149518	DIRECT		DS			28 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperacusis; Sensory Disturbance; Sexual Dysfunction; Tinnitus; Withdrawal Syndrome	Escitalopram			S				Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	12914074	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-11087			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Insomnia	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151326	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US19120			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis	Escitalopram			S	Unknown	20 Mg, Qd (Camber Manufactured)		Invagen
	Escitalopram			S	Oral	20 Mg, Qd (Cipla Manufactured)		Invagen
	Escitalopram			S	Unknown	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151358	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US13729			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergic Reaction To Excipient; Hypersensitivity; Rash Papular	Escitalopram			S	Oral	10 Mg, Qd, One Half Tablet For One Week Every Morning		Invagen
	Escitalopram			S	Oral	20 Mg, Qd, One Tablet Every Morning		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151359	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US11250			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Dizziness; Product Shape Issue; Product Substitution Issue; Psychomotor Hyperactivity	Escitalopram			S	Unknown	10 Mg, Qd		Invagen
	Klonopin			C	Unknown	Unk		Not Reported
	Vitamin B12			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151360	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US08203			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Oropharyngeal Pain	Escitalopram			S	Oral	10 Mg, Qd, One In The Morning Daily		Invagen
	Vicodin			C	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151377	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US12241			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hypersomnia; Increased Appetite; Product Substitution Issue	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Oral	20 Mg, Qd		Invagen
	Toujeo			C	Unknown	50 Units Once Daily (25u And 25u)		Not Reported
	Lisinopril			C	Unknown	5 Mg, Qd		Not Reported
	Janumet Xr			C	Unknown	50 Mg, Qd		Not Reported
	Janumet Xr			C	Unknown	100 Mg, Qd		Not Reported
	Multimineral Vitamin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151382	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US12240			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hypersomnia; Increased Appetite; Product Substitution Issue; Weight Fluctuation	Escitalopram			S	Oral	20 Mg, Unk, Other Generics For Many Years		Invagen
	Escitalopram			S	Oral	20 Mg, Qd		Invagen
	Tricor			C	Unknown	145 Mg, Qd		Not Reported

Lisinopril	C	Unknown	5 Mg, Qd		Not Reported
Pravastatin	C	Unknown	10 Mg, Qd		Not Reported
Xanax	C	Unknown	0.25 Mg, Qd		Not Reported
Insulin Humalog	C	Unknown	40 U, Bid		Not Reported
Insulin Lantus	C	Unknown	40 U, Bid (20 U And 20 U)		Not Reported
Vitamins	C	Unknown	Unk		Not Reported
Magnesium	C	Unknown	1000 Mg, Qd		Not Reported
Aspirin	C	Unknown	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151602	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US13650			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Throat Irritation; Tongue Discomfort	Escitalopram			S	Oral	10 Mg, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151832	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2015-06147			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Vertigo	Escitalopram Tablets Usp 10mg			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151848	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2015-06200			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapy Non-Responder	Escitalopram Tablets Usp 20mg			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151877	EXPEDITED (15-DAY)		OT	US-CIPLA-2016US18259			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram			S	Oral	20 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151889	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2015-06204			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Headache; Hot Flush; Muscular Weakness; Nausea; Product Substitution Issue	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151892	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2015-06211			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Headache; Insomnia; Panic Attack	Escitalopram Tablets Usp 10mg			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151894	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2015-06202			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Complaint; Therapy Non-Responder	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151895	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2016-09057			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151896	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2015-06201			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Complaint; Therapy Non-Responder	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151908	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2016-14911			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia	Escitalopram Tablets Usp 20mg			S		Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151909	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-29546		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Diarrhoea; Headache; Malaise; Nausea; Product Substitution Issue	Escitalopram Tablets Usp 20mg			S	Oral	20 Mg, Daily		Aurobindo
	Lyrica			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Venaflox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151910	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-29297			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Escitalopram Tablets Usp 10mg			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151912	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-01093		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pharyngeal Swelling	Escitalopram Tablets Usp 20mg			S	Unknown	2 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151977	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-40249			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain	Escitalopram Tablets Usp 5mg			S	Unknown	5 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151978	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-36006			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Respiratory Disorder	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151981	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-36129			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Product Substitution Issue	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14152254	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2017M1069810			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Sinus Tachycardia	Escitalopram			S		Unk		Not Reported
	Clozapine			S		Unk		Not Reported
	Clopine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14154012	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1761787US		37 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14154014	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1761645US		91 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertransaminasaemia; Syncope	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Cardarone			S	Unknown	Unk		Not Reported
	Durogesic			C	Transdermal	25 Mg/Hr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14154309	EXPEDITED (15-DAY)		DE	TR-ALLERGAN-1761530US		36 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Citalopram Hydrobromide - Bp			S	Unknown	Unk		Allergan
	Paracetamol			S	Unknown	Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	13844817	EXPEDITED (15-DAY)			US-HETERO CORPORATE-HET2017US00056		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Escitalopram		S	Oral	10 Ml, Qd	Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155011	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US01041			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thirst	Escitalopram			S	Oral	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155012	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US18536			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Skin Disorder	Escitalopram			S	Oral	20 Mg, Qd, In The Morning		Invagen
	Insulin			C	Unknown	Unk		Not Reported
	Levothyroxin			C	Unknown	300 Mg, Qd		Not Reported
	Crestor			C	Unknown	20 Mg, Qd, 15 Years		Not Reported
	Iron			C	Unknown	700m/ Once Daily, 10 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155013	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US02350			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus Generalised; Skin Haemorrhage	Escitalopram			S	Oral	10 Mg, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155014	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US01014			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased	Escitalopram			S	Oral	20 Mg, Qd		Invagen

Janumet Xr	C	Unknown	100/1000mg		Not Reported
Lamotrigine	C	Unknown	150 Mg, Bid		Not Reported
Levothyroxine	C	Unknown	50 Mcg, Qd		Not Reported
Lisinopril	C	Unknown	20 Mg, Qd, One At Night		Not Reported
Simvastatin	C	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155027	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US20620			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Product Substitution Issue; Pruritus	Escitalopram			S	Unknown	10 Mg, Qd, Lexapro		Invagen
	Escitalopram			S	Unknown	10 Mg, Qd, Camber Pharma		Invagen
	Escitalopram			S	Unknown	10 Mg, Unk, Cipla		Invagen
	Escitalopram			S	Unknown	10 Mg, Qd, Unknown Manufacturer		Invagen
	Escitalopram			S	Unknown	10 Mg, Unk, Cipla		Invagen
	Omeprazole Magnesium			C	Unknown	20.6 Mg, Qd		Not Reported
	Centrum Multivitamin			C	Unknown	Unk, Qd, Every Morning		Not Reported
	Butalbital			C	Unknown	Unk, Prn		Not Reported
	Acetaminophen			C	Unknown	Unk, Prn		Not Reported
	Caffeine			C	Unknown	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155029	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US04622			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error	Escitalopram			S	Oral	5 Mg, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155031	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US04112			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dysphagia; Oropharyngeal Pain	Escitalopram			S	Oral	20 Mg, Qd, Quiet A Long		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155073	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US08901			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Escitalopram			S	Oral	10 Mg, Qd, In Morning		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155074	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US23377			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Nasal Congestion; Ocular Hyperaemia; Rhinorrhoea; Sneezing	Escitalopram			S	Oral	5 Mg, Unk		Invagen
	Escitalopram			S	Oral	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155076	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US01296			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Nausea	Escitalopram			S	Oral	5 Mg, Qd		Invagen
	Levothyroxine			C	Unknown	112 Mcg, Qd		Not Reported
	Aspirin			C	Unknown	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155077	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US23427			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Escitalopram			S	Unknown	20 Mg, Unk		Invagen
	Escitalopram			S	Unknown	Tapering Down 5 Mg Every Month		Invagen
	Escitalopram			S	Unknown	5 Mg		Invagen
	Escitalopram			S	Unknown	10 Mg		Invagen
	Escitalopram			S	Unknown	Tapering For 2 Months		Invagen
	Wellbutrin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155079	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US04070			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Drug Ineffective; Irritability; Medication Error	Escitalopram			S	Oral	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155080	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US19157			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Feeding Disorder; Product Substitution Issue	Escitalopram			S	Oral	40 Mg, Bid		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155081	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US10341			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated	Escitalopram	S	Oral	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155084	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US04308			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Product Substitution Issue	Escitalopram			S	Unknown	10 Mg, Camber		Invagen
	Escitalopram			S	Unknown	10 Mg, Every 30 Days		Invagen
	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Escitalopram			S	Oral	10 Mg, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14156999	DIRECT	Y				66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Apokyn Inj			S	Subcutaneous	0.2-0.4ml Up To 5 Times Sq		Us Worldmeds
	Baclofen			S				Not Reported
	Carbidopa/Levodopa			S				Not Reported
	Clonazepam			S				Not Reported
	Escitalopram			S				Not Reported
	Ropinirole			S				Not Reported
	Trimethobenzamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14157011	DIRECT		DS, HO			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Eating Disorder; Migraine; Sleep Disorder	Lexapro			S	Oral	Quantity:6 Tablet(S);		International Labs
	Gabapentin			C				Not Reported
	Risperidone			C				Not Reported
	Benadryl			C				Not Reported
	Meloxicam			C				Not Reported

	Linzess	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2017	14160781	EXPEDITED (15-DAY)		DE, HO, OT	US-TORRENT-00003557		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amlodipine Besilate			S	Oral			Unknown
	Ethanol			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	13902443	EXPEDITED (15-DAY)		DE, HO	FR-CIPLA LTD.-2017FR14768			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bezoar; Cardiogenic Shock; Coma; Gastrointestinal Ischaemia; Hyperlactacidaemia; Intentional Overdose; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Shock; Skin Necrosis; Toxicity To Various Agents	Hydroxyzine			S	Oral	25 Mg, 28 Tablets Total		Invagen
	Escitalopram			S	Oral	10 Mg, 28 Tablets Total		Invagen
	Citalopram			S	Unknown	Unk		Invagen
	Zolpidem Tartarate			S	Unknown	Unk		Invagen
	Sevikar			S	Oral	129 Tablets, 1.29 G Of Amlodipine And 5.16 G Of Olmesartan		Not Reported
	Lysanxia			S	Oral	10 Mg, 42 Tablets Total		Not Reported
	Nordazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	14100622	EXPEDITED (15-DAY)		OT	PHHY2017MX126694			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Behaviour Disorder; Burning Sensation; Delirium; Hallucination;	Exelon Patch			S	Transdermal	9.5 Mg, Patch 10 (Cm2) (Every Third Day)		Novartis
	Escitalopram			S	Unknown			Not Reported

Impulsive Behaviour; Inappropriate Schedule Of Product Administration; Irritability; Judgement Impaired; Product Prescribing Error; Sleep Disorder; Soliloquy; Somnolence; Weight Decreased	Levothyroxine		C	Unknown	Not Reported
	Diazepam		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	14159136	EXPEDITED (15-DAY)		DS	CA-APOTEX-2017AP020550		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Mental Status Changes	Apo-Escitalopram			S	Oral	10 Mg, Unk		Apotex
	Apo-Lorazepam			S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	14162456	EXPEDITED (15-DAY)		DE, HO, LT	AT-TEVA-822441ISR		73 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Disorder; Condition Aggravated; Coronary Artery Disease; Dehydration; Fatigue; Oedema Peripheral; Pneumonia; Renal Impairment; Weight Decreased	Azilect 1mg			S	Unknown	One In The Morning		Teva
	Stalevo 100mg/25mg/200mg			S	Unknown	One In The Morning		Not Reported
	Stalevo 100mg/25mg/200mg			S		One In The Morning, One At Noon		Not Reported
	Cipralex 10mg - Filmtabletten			S	Unknown	Two In The Morning		Not Reported
	Cipralex 10mg - Filmtabletten			S		One In The Morning		Not Reported
	Trittico 150mg			S	Unknown	Half At Night		Not Reported
	Seroquel 25mg			S	Unknown	As Needed		Not Reported
	Madopar 50mg/12.5mg			S	Unknown	One In The Morning, One At Noon, One In The Evening		Not Reported
	Stalevo 50mg/12.5mg/200mg			S	Unknown			Not Reported

Lovenox	C	1 Daily	Not Reported
Elomel	C	1 Daily	Not Reported
Optinem	C		Not Reported
Lasix	C		Not Reported
Thrombo Ass 100mg	C	One At Noon	Not Reported
Spirobene	C	Half At Noon	Not Reported
Sedacoron 200mg	C	Half In The Morning	Not Reported
Eporatio	C	1 Weekly	Not Reported
Ceftriaxone Sodium	C	2 G In 200 Ml, 1 Daily	Not Reported
Dancor	C	One In The Morning, One In The Evening	Not Reported
Aquaphoril	C	Half In The Morning	Not Reported
Torasemide	C	One In The Morning	Not Reported
Pantoloc	C	Two In The Morning	Not Reported
Insulatard	C	6ie-0-0 (International Unit)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	11749180	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-106192			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Motor Dysfunction; Neurological Decompensation; Neuromyopathy; Suicidal Ideation; Therapeutic Response Decreased	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	11749185	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-106193			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Motor Dysfunction; Pain In Jaw; Periodic Limb Movement Disorder; Rapid Eye Movements Sleep Abnormal	Escitalopram		S	Unknown	Unk	Not Reported
	Bupropion		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	13947490	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2017GB15701			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram			S	Oral	20 Mg, Unk		Invagen
	Vitamin D Nos			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14056792	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1756587US		62 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Unk		Allergan
	Mirtazapin			S	Unknown	15 Mg, Unk		Not Reported
	Cortinson			C	Unknown			Not Reported
	Concor			C	Unknown			Not Reported
	Azathioprine			C				Not Reported
	Atorvastatin			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Brilique			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14167417	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1763755US		42 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd		Allergan
Amlodipine	C	Oral	Unk		Not Reported
Enalapril Maleate	C	Oral	Unk		Not Reported
Furosemide	C	Oral	Unk		Not Reported
Spironolactone	C	Oral	Unk		Not Reported
Enteronon	C	Oral	Unk		Not Reported
Bisoprolol Fumarate	C	Oral	Unk		Not Reported
Lixiana	C	Oral	Unk		Not Reported
Flunitrazepam	C	Oral	Unk		Not Reported
Belsomra	C	Oral	Unk		Not Reported
Reflex	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14168693	DIRECT	Y	LT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14169254	EXPEDITED (15-DAY)		DE, OT	US-TORRENT-00003677		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Duloxetine Hydrochloride			S	Oral			Unknown
	Bupropion Hydrochloride			S	Oral	Extended Release		Unknown
	Escitalopram Oxalate			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14169695	NON-EXPEDITED		OT	US-APOTEX-2017AP020633		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Treatment Noncompliance	Aripiprazole Tablets	S	Unknown	5 Mg, Q.H.S.	Apotex
	Aripiprazole Tablets	S			Apotex
	Olanzapine	S	Unknown	2.5 Mg, Q.6h As Needed	Apotex
	Olanzapine	S			Apotex
	Escitalopram Oxalate	S	Unknown	10 Mg, Daily	Apotex
	Mycophenolate Mofetil	S	Unknown	500 Mg, Bid	Apotex
	Mycophenolate Mofetil	S	Unknown	1000 Mg, Bid	Apotex
	Levothyroxine	C	Unknown	125 Mg, Unk	Not Reported
	Levothyroxine	C	Unknown	150 Mg, Unk	Not Reported
	Cefdinir	C	Oral		Not Reported
	Nitrofurantoin	C	Unknown		Not Reported
	Lorazepam	C	Oral	0.5 Mg, Q.Am	Not Reported
	Lorazepam	C	Oral	0.5 Mg, Q.H.S.	Not Reported
	Prednisone	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	1000 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14169862	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US13026			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torticollis	Escitalopram			S	Unknown	5 Mg, Daily		Invagen
	Escitalopram			S	Unknown	10 Mg, Daily		Invagen
	Escitalopram			S	Unknown	15 Mg, Daily		Invagen
	Clonazepam			C	Unknown	0.25 Mg, At Bedtime		Not Reported
	Clonazepam			C	Unknown	0.25 Mg Qd, At Bedtime		Not Reported
	Clonazepam			C	Unknown	0.5 Mg, At Bedtime As Needed		Not Reported
	Clonazepam			C	Unknown	0.5 Mg, Qd, At Bedtime		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported

Ibuprofen	C	Unknown	Unk		Not Reported
Amlodipine	C	Unknown	Unk		Not Reported
Celecoxib	C	Unknown	Unk		Not Reported
Tamsulosin	C	Unknown	Unk		Not Reported
Omeprazole	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14169977	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2016IT23059			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Diarrhoea	Escitalopram			S	Oral	10 Mg Daily		Invagen
	Cardioaspirin			C	Oral			Not Reported
	Serenase (Haloperidol)			C	Oral			Not Reported
	Quetiapine			C	Oral	25 Mg, Unk		Not Reported
	Enalapril			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14170067	EXPEDITED (15-DAY)		OT	FR-TEVA-822284ROM		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Milligram Daily;		Not Reported
	Bisoprolol			S	Unknown			Duramed

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14170249	EXPEDITED (15-DAY)		OT	FR-TEVA-822294ROM		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Milligram Daily;		Not Reported
	Galantamine			S	Unknown			Barr
	Irbesartan			S	Unknown			Teva

	Paracetamol	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14171264	EXPEDITED (15-DAY)		DE, OT	ZA-MYLANLABS-2017M1069569		71 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Pneumonia	Mylan Oxybutynin 5 Mg			S	Oral	5 Mg, Unk		Mylan
	Mylan Escitalopram 10			S	Oral	10 Mg, Unk		Mylan
	Tranqipam			S	Oral	1 Mg, Unk		Mylan
	Epilim Cr			S	Oral	500 Mg, Unk		Mylan
	Crestor			S	Oral	5 Mg, Unk		Mylan
	Stilnox			S		10 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14171509	EXPEDITED (15-DAY)		OT	CH-SA-2017SA214728		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Plaquenil			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Mabthera			S	Intravenous drip			Not Reported
	Prednisone			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	13036197	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1680884US		27 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Temesta / Lorazepam			S	Oral	1 Mg If Necessary Up To 3 Times Per Day.		Not Reported

	Folic Acid	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14155649	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068688		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20mg Daily		Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14155658	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068709		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5mg Daily		Not Reported
	Bisoprolol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14157202	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068768		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Not Reported
	Digoxin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14173087	EXPEDITED (15-DAY)		OT	CH-ROCHE-2019359		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During	Mabthera			S	Intravenous drip			Not Reported

Pregnancy	Mabthera	S	Intravenous drip		Not Reported
	Plaquenil	S	Oral		Not Reported
	Cipralex	S	Oral		Not Reported
	Stilnox	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14174611	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1760600US		24 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Vacuum Extractor Delivery	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Tandospirone Citrate			C				Not Reported
	Constan [Alprazolam]			C				Not Reported
	Alprazolam			C				Not Reported
	Metligine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	13189385	NON-EXPEDITED		DE	US-MALLINCKRODT-T201607139		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Mixed Amphetamine Salts			S	Oral			Mallinckrodt
	Bupropion			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14025048	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS-2017-005341		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Orkambi			S	Oral	2 Dosage Form, Bid		Vertex
	Lexapro			S	Unknown	Unk		Not Reported

Lexapro	S	Unknown	Unk		Not Reported
Abilify	C		Unk		Not Reported
Intuniv	C		Unk		Not Reported
Omeprazole	C		Unk		Not Reported
Pulmozyme	C		Unk		Not Reported
Zoloft	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14155637	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068690		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5mg Daily		Not Reported
	Bisoprolol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14155661	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068651		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Not Reported
	Metoclopramide			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14157197	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS-2017M1068752		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Not Reported
	Indapamide			S	Unknown			Not Reported
	Sotalol			S	Unknown			Not Reported
	Benzoic Acid			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14157268	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068831		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5mg Daily		Not Reported
	Bisoprolol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14169912	EXPEDITED (15-DAY)		OT	FR-TEVA-822277ROM		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5mg Daily		Not Reported
	Bisoprolol			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14170046	EXPEDITED (15-DAY)		DE	FR-TEVA-822282ROM		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Ivax
	Indapamide			S	Unknown			Actavis
	Sotalol			S	Unknown			Teva
	Benzoic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14170183	EXPEDITED (15-DAY)		OT	FR-TEVA-822293ROM		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Milligram Daily;		Not Reported
	Candesartan-Cilexetil			S	Unknown			Not Reported

	Spironolactone	S	Unknown		Actavis
	Ivabradine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14170286	EXPEDITED (15-DAY)		OT	FR-TEVA-822295ROM		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Milligram Daily;		Not Reported
	Bisoprolol			S	Unknown			Teva
	Furosemide			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14170326	EXPEDITED (15-DAY)		OT	FR-TEVA-822296ROM		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Milligram Daily;		Not Reported
	Pramipexole			S	Unknown			Barr

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14170562	EXPEDITED (15-DAY)		OT	FR-TEVA-822304ROM		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Not Reported
	Diazepam			S	Unknown			Barr
	Metoclopramide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14179416	EXPEDITED (15-DAY)		HO	GB-ALLERGAN-1764474US		70 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gastrointestinal Tube Insertion; Laryngectomy	Escitalopram Oxalate - Bp	S	Unknown	10 Mg, Qd		Allergan
	Salbutamol	C	Unknown	Unk		Not Reported
	Alendronic Acid	C	Unknown			Not Reported
	Bendroflumethiazide	C	Unknown	Unk		Not Reported
	Calciferol [Ergocalciferol]	C	Unknown	Unk		Not Reported
	Gabapentin	C	Unknown	Unk		Not Reported
	Morphine Sulphate	C	Unknown	Unk		Not Reported
	Tiotropium	C	Unknown	Unk		Not Reported
	Prucalopride	C	Unknown	Unk		Not Reported
	Cald3-Therapy	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2017	14180916	EXPEDITED (15-DAY)		HO, OT	CH-SA-2017SA219071			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Stilnox			S	Transplacental			Not Reported
	Seroquel			S	Transplacental			Not Reported
	Abilify			S	Transplacental			Not Reported
	Cipralex			S	Transplacental			Not Reported
	Lamictal			S	Transplacental			Not Reported
	Temesta (Lorazepam)			S	Transplacental	2016		Not Reported
	Brufen			S	Transplacental			Not Reported
	Dafalgan			S	Transplacental			Not Reported
	Lyrica			S	Transplacental	2016		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2017	14181076	EXPEDITED (15-DAY)		DE	US-TORRENT-00003750		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide;	Amlodipine Besilate			S		Ingst + Par		Unknown

Toxicity To Various Agents	Enalapril Maleate	S	Ingst + Par	Unknown
	Escitalopram Oxalate	S	Ingst + Par	Unknown
	Tamsulosin Hydrochloride	S	Ingst + Par	Unknown
	Insulin	S	Ingst + Par	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2017	14181168	EXPEDITED (15-DAY)		HO, OT	CA-ALEMBIC PHARMACUETICALS LIMITED-2017SCAL000901			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Coma Scale Abnormal; Confusional State; Drug Interaction; Electrocardiogram Qt Prolonged; Intentional Overdose; Irritability; Miosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Unresponsive To Stimuli	Quetiapine Fumarate			S		Unk		Alembic
	Temazepam			S		Unk		Not Reported
	Oxazepam			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Topiramate			S		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Clopidogrel			C		Unk		Not Reported
	Ferrous Gluconate			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported
	Spironolactone And Hydrochlorothiazide			C		Unk		Not Reported
	Fluticasone W/Salmeterol			C		Unk		Not Reported
	Ipratropium			C		Unk		Not Reported
	Salbutamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	8459295	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2012064736		25 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression; Agitation; Akathisia; Depressed Mood; Drug Interaction; Ejaculation Failure; Feeling Of Despair; Impulsive Behaviour; Mania; Overdose; Paranoia; Personality Change; Physical Assault; Suicide Attempt; Toxicity To Various Agents	Sertraline Hcl	S	300 Mg, 1x/Day	Pfizer
	Escitalopram Oxalate	S	10 Mg, 1x/Day	Not Reported
	Escitalopram Oxalate	S		Not Reported
	Hypericum	S	900 Mg, 1x/Day	Not Reported
	Hypericum	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14154318	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068647		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10mg Daily		Not Reported
	Pramipexole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14155652	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068689		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10mg Daily		Not Reported
	Galantamine			S	Unknown			Not Reported
	Irbesartan			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14155660	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068700		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5mg Daily		Not Reported

	Candesartan	S	Unknown	Not Reported
	No Drug Name	S	Unknown	Not Reported
	Spironolactone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14181369	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003570		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Hydrocodone Bitartrate			S	Oral			Unknown
	Tramadol Hydrochloride			S	Oral			Unknown
	Baclofen			S	Oral			Unknown
	Clonazepam			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Alprazolam			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14181380	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003618		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Diphenhydramine			S	Oral			Unknown
	Ethanol			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14181382	EXPEDITED (15-DAY)		DE, HO, OT	US-TORRENT-00003637		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Unknown
	Doxepin			S	Oral			Unknown
	Hydrocodone			S	Oral			Unknown

	Olmesartan	S	Oral	Unknown
	Alprazolam	S	Oral	Unknown
	Hydrochlorothiazide	S	Oral	Unknown
	Famotidine	S	Oral	Unknown
	Cetirizine Hydrochloride	S	Oral	Unknown
	Pregabalin	S	Oral	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14181659	NON-EXPEDITED			US-AMGEN-USASP2017168626			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stomatitis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Lyrica			S	Unknown	100 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Nortriptyline Hcl			S	Unknown	10 Mg, Unk		Not Reported
	Amlodipine Besylate			S	Unknown	2.5 Mg, Unk		Not Reported
	Metformin Hcl			S	Unknown	500 Mg, Unk		Not Reported
	Meloxicam			S	Unknown	7.5 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Cal Gest			S	Unknown	200 (500) Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14181696	DIRECT		OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Bupropion			S				Not Reported
	Prozac			S				Not Reported
	Lexapro			S				Not Reported
	Celexa			S				Not Reported
	Zoloft			S				Not Reported
	Effexor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14181739	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003589		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Oxycodone Hydrochloride			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Ibuprofen			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14182097	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US19687			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Electrocardiogram Qt Prolonged; Therapy Non-Responder	Olanzapine			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Bupropion			S	Unknown	Unk		Invagen
	Lorazepam			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Iloperidone			S	Unknown	Unk		Not Reported
	Quetiapine			C	Unknown	50 Mg At Bedtime And 25 Mg During The Day		Not Reported
	Clonazepam			C	Unknown	1 Mg, Bid		Not Reported
	Trazodone			C	Unknown	50 Mg, At Bed Time		Not Reported
	Warfarin			C	Unknown	6 Mg, Daily		Not Reported
	Propranolol			C	Unknown	160 Mg, Daily		Not Reported
	Methimazole			C	Unknown	30 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14184332	NON-EXPEDITED			US-MYLANLABS-2017M1070306		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Headache; Memory Impairment; Nausea; Photosensitivity Reaction; Vomiting	Buspirone			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14184454	EXPEDITED (15-DAY)		OT	IL-ALLERGAN-1764700US		81 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Parkinson'S Disease	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Carbidopa			C	Unknown	0.5 Df, Qid		Not Reported
	Amantadine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14184455	EXPEDITED (15-DAY)		OT	IL-ALLERGAN-1764705US		67 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Parkinson'S Disease	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Ropinirole			C	Unknown	Unk		Not Reported
	Amantadine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14184456	EXPEDITED (15-DAY)		OT	IL-ALLERGAN-1765156US		73 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

Parkinson'S Disease	Ropinirole	C	Unknown		Not Reported
	Carbidopa	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14184457	EXPEDITED (15-DAY)		OT	IL-ALLERGAN-1764704US		83 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Parkinson'S Disease	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Rosagiline			C	Unknown	Unk		Not Reported
	Carbidopa			C	Unknown	0.5 Df, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14184498	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1764810US		1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia Neonatal; Neonatal Behavioural Syndrome; Sepsis Neonatal; Transient Tachypnoea Of The Newborn	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Temesta / Lorazepam			S	Transplacental	1 Mg If Necessary Up To 3 Times Per Day.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14184553	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2017480995		121 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia Neonatal; Maternal Exposure During Pregnancy	Temesta (Lorazepam)			S	Transplacental	In Reserve 1mg 4x/Day, No Regular Intake, Stopped In Early Pregnancy		Pfizer
	Lyrica			S	Transplacental	100mg, 3x/Day (Treatment Stopped In Early Pregnancy)		Pfizer

	Seroquel	S	Transplacental	50 Mg, Daily (In Reserve In The Evening Until The Beginning Of The Pregnancy)	Not Reported
	Seroquel	S	Transplacental	100 Mg At Bedtime + 25 Mg In Reser	Not Reported
	Abilify	S	Transplacental	10mg 2x/Day, Treatment Taken Until Delivery	Not Reported
	Cipralex /01588501/	S	Transplacental	20 Mg, Daily	Not Reported
	Cipralex /01588501/	S	Transplacental	20mg/D Decreased To 10mg/D Until Delivery	Not Reported
	Stilnox	S	Transplacental	10 Mg, Daily	Not Reported
	Stilnox	S	Transplacental	12.5 Mg, Daily	Not Reported
	Lamictal	S	Transplacental	150mg Daily (Treatment Taken Until Delivery)	Not Reported
	Brufen	S	Transplacental	400mg, 3x/Day (Treatment Stopped During Pregnancy)	Not Reported
	Dafalgan	S	Transplacental	1g, 2x/Day (According To Catamnesis In Reserve)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14184658	NON-EXPEDITED			PHEH2017US036190			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Delusion; Lacrimation Increased; Mydriasis; Personality Change; Product Use In Unapproved Indication	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Gilenya			S				Novartis
	Etodolac			S	Unknown	Unk		Not Reported
	Osartan			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Nortriptyline			C	Unknown			Not Reported
	Azithromycin			C	Unknown	250 Mg, Unk		Not Reported

Vitamin D3	C	Unknown	50000 U, Unk		Not Reported
Zetia	C	Unknown	10 Mg, Unk		Not Reported
Diazepam	C	Unknown	5 Mg/Ml, Unk		Not Reported
Lisinopril	C	Unknown			Not Reported
Hydrocodone/Acetaminophen	C	Unknown			Not Reported
Cephalexin	C	Unknown			Not Reported
Trazodone Hcl	C	Unknown			Not Reported
Methocarbamol	C	Unknown			Not Reported
Amlodipine Besylate	C	Unknown			Not Reported
Metoprolol Succinate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	13662423	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2017005237			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Somnolence; Suicidal Ideation	Escitalopram			S	Unknown	6 Df, Unk		Macleods
	Lorazepam			S	Oral	10 Ml, Unk		Not Reported
	Quetiapine			C	Unknown	Unk		Macleods
	Carbaolithium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14186398	EXPEDITED (15-DAY)		OT	CH-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006359		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Plaquenil			S	Oral			Concordia
	Stilnox			S	Oral			Not Reported
	Mabthera			S	Intravenous drip			Not Reported

	Prednisone	S	Oral		Not Reported
	Cipralex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14186962	NON-EXPEDITED			US-PFIZER INC-2017488946		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stomatitis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Lyrica			S	Unknown	100 Mg, Unk		Pfizer
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Nortriptyline Hcl			S	Unknown	10 Mg, Unk		Not Reported
	Amlodipine Besilate			S	Unknown	2.5 Mg, Unk		Pfizer
	Metformin Hcl			S	Unknown	500 Mg, Unk		Not Reported
	Meloxicam			S	Unknown	7.5 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Cal Gest			S	Unknown	200 (500) Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14186987	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1765143US		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Plaquenil			S	Unknown	200 Mg, Q12h		Not Reported
	Mabthera			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Stilnox			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14188121	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1764290US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Operation; Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14064266	EXPEDITED (15-DAY)		OT	US-ACORDA-ACO_142563_2017			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Asthenia; Back Pain; Balance Disorder; Dyssomnia; Fall; Fatigue; Gait Disturbance; Hemiparesis; Hypersomnia; Hypertonic Bladder; Hypoaesthesia; Intermittent Claudication; Joint Lock; Multiple Sclerosis Relapse; Muscle Spasms; Muscular Weakness; Neck Pain; Paraesthesia; Peroneal Nerve Palsy; Rash; Stent Placement; Temperature Intolerance; Vertigo	Ampyra			S	Unknown	Unk		Acorda
	Tecfidera			S	Oral	240 Mg, Bid		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Rebif			S	Unknown	Unk		Not Reported
	Topiramate			C	Oral	100 Mg, Qd		Not Reported
	Zofran			C	Intravenous (not otherwise specified)	4 Mg, Prn		Not Reported
	Abilify			C	Oral	10 Mg, Qd		Not Reported
	Donepezil			C	Oral	5 Mg, Qam With Meal		Not Reported
	Nuvigil			C	Oral	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14134778	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1760607US		29 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	120 Mg Once		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14190033	EXPEDITED (15-DAY)		OT	FR-STRIDES ARCOLAB LIMITED-2017SP013985			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged	Pramipexole Dihydrochloride		S	Unknown	Unk	Strides
	Escitalopram		S	Unknown	10 Mg, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14190782	EXPEDITED (15-DAY)		HO, OT	CH-GLAXOSMITHKLINE-CH2017170465		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Seroquel			S	Transplacental	50 Mg, Unk		Glaxosmithkline
	Cipralex			S	Transplacental	10 Mg, Unk		Glaxosmithkline
	Lamictal			S	Transplacental	150 Mg, Unk		Glaxosmithkline
	Dafalgan			S	Transplacental	1 G, Bid		Glaxosmithkline
	Abilify			S	Transplacental	10 Mg, Bid		Not Reported
	Stilnox			S	Transplacental	10 Mg, Unk		Not Reported
	Temesta (Lorazepam)			S	Transplacental	1 Mg, Unk		Not Reported
	Brufen			S	Transplacental	400 Mg, Tid		Not Reported
	Lyrica			S	Transplacental	100 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14193146	EXPEDITED (15-DAY)		HO, OT	CH-MYLANLABS-2017M1071575		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Brufen			S	Transplacental			Mylan
	Seroquel			S	Transplacental	50 Mg, Qd		Mylan
	Abilify			S	Transplacental	10 Mg, Qd		Mylan
	Cipralex			S	Transplacental	20 Mg, Qd		Mylan
	Cipralex			S	Transplacental	10 Mg, Qd		Mylan
	Stilnox			S	Transplacental	10 Mg, Qd		Mylan
	Lamictal			S	Transplacental	150 Mg, Qd		Mylan
	Temesta (Lorazepam)			S	Transplacental	1 Mg, Qid		Mylan

	Dafalgan	S	Transplacental	Mylan
	Lyrica	S	Transplacental	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	13836098	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1733201US		54 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brugada Syndrome	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Zacras			C	Oral	Unk		Not Reported
	Zacras			C	Oral	Unk		Not Reported
	Belsomra			C	Oral	Unk		Not Reported
	Belsomra			C				Not Reported
	Tasmolin			C	Oral	Unk		Not Reported
	Tasmolin			C	Unknown			Not Reported
	Boiogito			C	Oral			Not Reported
	Boiogito			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14161061	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003574		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Bupropion Hydrochloride			S	Oral			Unknown
	Clonazepam			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Amfetamine/Dextroamfetamine (Extended Release)			S	Oral			Unknown
	Ethanol			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14193633	NON-EXPEDITED		HO, OT	GR-LUPIN PHARMACEUTICALS		76 YR	Male	GRC

INC.-2017-06037

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14194093	EXPEDITED (15-DAY)		HO	PHHY2017FR166383		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Thrombophlebitis	Exelon			S	Transdermal	1 Df, Qd		Novartis
	Escitalopram			S	Oral	Unk Unk, Qd		Not Reported
	Paracetamol			S	Oral	Unk Unk, Prn		Not Reported
	Temesta (Lorazepam)			S	Oral	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14194798	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004162		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Clonazepam			S	Oral			Unknown
	Trazodone Hydrochloride			S	Oral			Unknown
	Oxybutynin			S	Oral			Unknown
	Quetiapine			S	Oral			Unknown
	Lamotrigine			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Finasteride			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14196390	NON-EXPEDITED			US-PFIZER INC-2017495320		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sertraline Hcl			S		Unk		Pfizer
	Bupropion Hcl			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Fluoxetine Hcl			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14196598	EXPEDITED (15-DAY)		DS	AU-ALLERGAN-1765583US		33 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Sexual Arousal; Erectile Dysfunction	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14061827	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS INC.-2017-05202		49 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Affective Disorder; Anxiety; Apathy; Irritability; Sexual Dysfunction; Weight Increased	Paroxetine			S	Unknown	20 Mg, Qd		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Bupropion			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	100 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	225 Mg, Qd		Not Reported
	Reboxetina			C	Unknown	Unk		Not Reported
	Lamotrigine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14198168	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004252		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lamotrigine			S	Oral			Unknown
	Temazepam			S	Oral			Unknown
	Lorazepam			S	Oral			Unknown
	Primidone			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Benzatropine Mesilate			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14198274	EXPEDITED (15-DAY)		DE	US-TORRENT-00004058		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lamotrigine			S		Ingestion Plus Aspiration		Unknown
	Zonisamide			S		Ingestion Plus Aspiration		Unknown
	Lorazepam			S		Ingestion Plus Aspiration		Unknown
	Escitalopram Oxalate			S		Ingestion Plus Aspiration		Unknown
	Lovastatin			S		Ingestion Plus Aspiration		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14199066	EXPEDITED (15-DAY)		DE	US-TORRENT-00004300		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Zolpidem			S		Ingestion Plus Inhalation (Extended Release)		Unknown
	Ethanol			S		Ingestion Plus Inhalation		Unknown
	Metamfetamine			S		Ingestion Plus Inhalation		Unknown

Escitalopram	S	Ingestion Plus Inhalation		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14199146	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004160		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Verapamil Hydrochloride			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Codeine			S	Oral			Unknown
	Topiramate			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14199976	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003891		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Abuse; Toxicity To Various Agents	Escitalopram			S	Oral			Unknown
	Ethanol			S	Oral			Unknown
	Methocarbamol			S	Oral			Unknown
	Oxycodone			S	Oral			Unknown
	Lorazepam			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14199981	EXPEDITED (15-DAY)		DE	US-TORRENT-00004015		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Unknown
	Atomoxetine Hydrochloride			S	Oral			Unknown
	Sertraline			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14199993	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004062		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Amitriptyline Hydrochloride			S	Oral			Unknown
	Tramadol			S	Oral			Unknown
	Hydrocodone			S	Oral			Unknown
	Ondansetron Hydrochloride			S	Oral			Unknown
	Linaclotide			S	Oral			Unknown
	Diclofenac			S	Oral			Unknown
	Lubiprostone			S	Oral			Unknown
	Zolpidem Tartrate			S	Oral			Unknown
	Liothyronine Sodium			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Sertraline Hydrochloride			S	Oral			Unknown
	Gabapentin			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14200001	EXPEDITED (15-DAY)		DE, HO, OT	US-TORRENT-00004056		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Gabapentin			S	Oral			Unknown
	Alprazolam			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14200009	EXPEDITED (15-DAY)		DE	US-TORRENT-00004079		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Promethazine	S	Oral	Unknown
	Verapamil Hydrochloride	S	Oral	Unknown
	Escitalopram Oxalate	S	Oral	Unknown
	Acetaminophen; Hydrocodone Bitartrate	S	Oral	Unknown
	Diazepam	S	Oral	Unknown
	Topiramate	S	Oral	Unknown
	Esomeprazole Magnesium	S	Oral	Unknown
	Diclofenac	S	Oral	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14200058	EXPEDITED (15-DAY)		DE	US-TORRENT-00003913		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Diphenhydramine Hydrochloride/Paracetamol			S	Oral			Unknown
	Warfarin			S	Oral			Unknown
	Olanzapine			S	Oral			Unknown
	Lisinopril			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Prednisone			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14200076	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003945		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Toxicity To Various Agents	Oxycodone			S		Inhalation And Ingestion		Unknown
	Cyclobenzaprine Hydrochloride			S		Inhalation And Ingestion		Unknown
	Metoprolol			S		Inhalation And Ingestion		Unknown
	Clonidine			S		Inhalation And Ingestion		Unknown
	Glyceryl Trinitrate			S		Inhalation And Ingestion		Unknown

	Lisinopril	S	Oral	Inhalation And Ingestion	Unknown
	Escitalopram Oxalate	S		Inhalation And Ingestion	Unknown
	Ibuprofen	S	Oral	Inhalation And Ingestion	Unknown
	Diclofenac	S		Inhalation And Ingestion	Unknown
	Azithromycin	S		Inhalation And Ingestion	Unknown
	Cefalexin	S		Inhalation And Ingestion	Unknown
	Doxycycline	S		Inhalation And Ingestion	Unknown
	Methylprednisolone	S		Inhalation And Ingestion	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14201672	EXPEDITED (15-DAY)		OT	PHHY2017AU169146		63 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myeloid Leukaemia; Anion Gap Increased; Blood Albumin Decreased; Blood Lactate Dehydrogenase Increased; Bundle Branch Block Left; Dysplasia; Fungal Infection; Haematocrit Decreased; Haemoglobin Decreased; Lung Infection; Myelodysplastic Syndrome; Platelet Count Decreased; Red Blood Cell Count Decreased; Red Cell Distribution Width Increased	Famciclovir			S	Unknown			Novartis
	Baclofen			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Idarubicin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Duodart			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14201982	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1766182US		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Circulatory Collapse; Coma; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp		S	Oral	160 Mg, Single	Allergan
	Baclofen		S	Oral	160 Mg, Single	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14202526	EXPEDITED (15-DAY)		OT	FR-ROCHE-2026651		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Mabthera			S	Subcutaneous			Not Reported
	Seroplex			S	Oral			Not Reported
	Levothyrox			C	Oral			Not Reported
	Cotareg			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13411746	EXPEDITED (15-DAY)		OT	US-JNJFOC-20170303422		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Emotional Disorder; Gynaecomastia; Increased Appetite; Initial Insomnia; Obesity; Sleep Disorder	Risperdal			S	Oral	0.5 Mg Every Morning And 1 Mg Every Night Time		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	0.5 Mg Every Morning And 1 Mg Every Night Time		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	0.5 Mg Every Morning And 1 Mg Every Night Time		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	0.5 Mg Every Morning And 1 Mg Every Night Time		Not Reported

	Risperdal	S	Oral	Not Reported
	Risperdal	S	Oral	Not Reported
	Risperdal	S	Oral	Not Reported
	Lexapro	S	Unknown	Not Reported
	Strattera	S	Unknown	Not Reported
	Abilify	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14205187	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1072679		32 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dyskinesia; Extrapyramidal Disorder; Muscle Twitching; Muscle Twitching; Restlessness	Escitalopram			S	Oral			Not Reported
	Trimipramin			S	Oral			Mylan
	Trimipramin			S	Oral	75 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14205924	EXPEDITED (15-DAY)		OT	GR-ALLERGAN-1766611US			Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Aromasin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14205928	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1766394US		1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Unk		Allergan
	Seroquel Xr			S	Transplacental	50 Mg, Qd		Not Reported
	Seroquel Xr			S	Transplacental	100 Mg, Qd		Not Reported

Seroquel Xr	S	Transplacental	25 Mg, Unk		Not Reported
Abilify	S	Transplacental	10 Mg, Unk		Not Reported
Abilify	S	Transplacental	20 Mg, Unk		Not Reported
Abilify	S	Transplacental	10 Mg, Unk		Not Reported
Stilnox	S	Transplacental	10 Mg, Qd		Not Reported
Stilnox	S	Transplacental	12.5 Mg, Qd		Not Reported
Lamictal	S	Transplacental	150 Mg, Unk		Not Reported
Temesta (Lorazepam)	S	Transplacental	4 Df, Qd		Not Reported
Brufen	S	Transplacental	3 Df, Qd		Not Reported
Dafalgan	S	Transplacental	2 Df, Qd		Not Reported
Lyrica	S	Transplacental	3 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	9678754	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-19721703		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Jaundice Neonatal; Neonatal Hypoxia; Tremor	Abilify			S	Transplacental	10 Mg, Qd		Bristol Myers Squibb
	Seroplex			S	Transplacental	20 Mg, Qd		Not Reported
	Seresta			S	Transplacental	25 Mg, Bid		Not Reported
	Tercian			S	Transplacental	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	13430940	EXPEDITED (15-DAY)		OT	IT-ELI_LILLY_AND_COMPANY-IT201704002431		86 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Sedation Complication	Olanzapine			S	Oral	2.5 Mg, Daily		Eli Lilly And Co
	Cipralex /01588501/			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14208328	DIRECT		DE, HO, OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Interaction; Gun Shot Wound	Escitalopram Oxalate			S				Not Reported
	Clonazepam			S				Not Reported
	Ambien			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14210918	EXPEDITED (15-DAY)		CA, HO	FR-SA-2017SA227373		273 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Neonatal Behavioural Syndrome; Neurodevelopmental Disorder	Stilnox			S	Transplacental			Not Reported
	Seroplex			S	Unknown			Not Reported
	Seresta			S	Transplacental			Not Reported
	Donormyl (Doxylamine\Sodium Bromide\Sodium Phosphate, Dibasic, Anhydrous\Sodium Sulfate)			S	Transplacental			Not Reported
	Xanax			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14184502	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1764786US		40 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arrhythmia; Blood Pressure Increased; Extrasystoles; Libido Decreased; Palpitations; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

	Escitalopram Oxalate - Bp	S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp	S	Oral	2.5 Mg, Qd		Allergan
	Estazolam	C	Unknown	1 Tablet, Qd		Not Reported
	Estazolam	C				Not Reported
	Trazodone Hydrochloride	C	Unknown	30 Mg, Qd		Not Reported
	Lorazepam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14186989	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1765178US		28 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperacusis; Pain In Jaw; Restless Legs Syndrome; Sensory Disturbance; Sexual Dysfunction; Therapy Cessation; Tinnitus	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Losartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14213551	EXPEDITED (15-DAY)		HO	US-SCIEGEN PHARMACEUTICALS INC-2017SCILIT00686		2 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product By Child; Aggression; Asthenia; Ataxia; Depressed Level Of Consciousness; Dysstasia; Hypersomnia; Hypertonia; Hypophagia; Irritability; Mental Status Changes; Nuchal Rigidity; Slow Response To Stimuli; Urine Output Decreased	Aripiprazole			S	Unknown	Unk		Sciegen
	Ziprasidone			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14214408	NON-EXPEDITED			US-PFIZER INC-2017497283		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Drug Ineffective; Human Papilloma Virus Test Positive; Hyperphagia; Loss Of Personal Independence In Daily Activities; Mental Disorder; Panic Disorder; Weight Increased	Xanax			S		Unk		Pfizer
	Xanax			S				Pfizer
	Xanax			S				Pfizer
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Wellbutrin			S		Unk		Not Reported
	Wellbutrin			S				Not Reported
	Wellbutrin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14216296	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMPANY-US201711006465			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure	Cymbalta			S	Unknown	30 Mg, Unknown		Eli Lilly And Co
	Lexapro			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14216763	EXPEDITED (15-DAY)		DE, HO, OT	DE-ABBVIE-17S-062-2164899-00		1 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Synagis			S	Intramuscular			Not Reported
	Varivax			S	Intramuscular			Not Reported
	Topiramate			S	Unknown			Not Reported
	Phenobarbital			S	Unknown			Not Reported
	Sildenafil Citrate			S	Unknown			Not Reported

	Exodus//Escitalopram Oxalate	S	Unknown	Not Reported
	Spironolactone	S	Unknown	Not Reported
	Nutrition With Nutrini Mixed With Water	C	Other	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13410533	NON-EXPEDITED			US-JNJFOC-20170300007		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Fatigue; Gynaecomastia; Initial Insomnia; Off Label Use; Product Use In Unapproved Indication	Risperdal			S	Oral	At Variable Doses Of 0.25mg, 0.5 Mg And 1 Mg		Not Reported
	Risperdal			S	Oral	At Variable Doses Of 0.25mg, 0.5 Mg And 1 Mg		Not Reported
	Risperdal			S	Oral	At Variable Doses Of 0.25mg, 0.5 Mg And 1 Mg		Not Reported
	Lexapro			S	Unknown	10 Mg And Then 20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13412845	NON-EXPEDITED			US-JNJFOC-20170309370		12 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Gynaecomastia; Off Label Use; Product Use In Unapproved Indication; Sedation Complication; Treatment Noncompliance	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported

	Risperdal	S	Oral	Not Reported
	Risperdal	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Lexapro	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14217973	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2017-06704		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Serotonin Syndrome	Linezolid			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin
	Vancomycin			S	Unknown	Unk		Not Reported
	Amitriptyline			C	Unknown	10 Mg, Qd, At Bedtime		Not Reported
	Fentanyl			C	Unknown	75 Mcg, Every 72 Hrs		Not Reported
	Hydromorphone			C	Unknown	4 Mg, Prn, Every 4 Hours		Not Reported
	Ondansetron			C	Unknown	4 Mg, Prn, Every 8 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14218409	EXPEDITED (15-DAY)		OT	FR-SCIEGEN PHARMACEUTICALS INC-2017SCILIT00678		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Pramipexole Dihydrochloride Tablets			S	Unknown	Unk		Sciegen
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14220405	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2017504719		63 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myeloid Leukaemia; Anion Gap Increased; Blood Albumin Decreased; Blood Lactate Dehydrogenase Increased; Bundle Branch Block Left; Dysplasia; Fungal Infection; Haematocrit Decreased; Haemoglobin Decreased; Lung Infection; Myelodysplastic Syndrome; Platelet Count Decreased; Red Blood Cell Count Decreased; Red Cell Distribution Width Increased	Pantoprazole			S	Unknown	Unk		Pfizer
	Idarubicin Hcl			S	Unknown	Unk		Pfizer
	Famciclovir			S	Unknown	Unk		Not Reported
	Baclofen			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Allopurinol			S	Unknown	Unk		Not Reported
	Dutasteride And Tamsulosin Hydrochloride			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2017	14224083	DIRECT		DS			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Mood Swings; Penile Pain; Premature Ejaculation; Restlessness	Lexapro 20mg			S	Oral	Quantity:1 Tablet(S);		Forest
	Omeprazole			C				Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported
	Zinc			C				Not Reported
	Folic Acid			C				Not Reported
	Coenzyme Q-10			C				Not Reported
	L-Arginine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14224968	EXPEDITED (15-DAY)		HO	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-106828		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Qd		Bristol Myers Squibb
	Aripiprazole			S	Oral	5 Mg, Qd		Bristol Myers Squibb
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Candesartan			S	Oral	16 Mg, Qd		Not Reported
	L-Thyroxin /00068001/			C	Oral	100 Mg, Qd		Not Reported
	Metformin			C	Oral	1500 Mg, Qd		Not Reported
	Acetylsalicylic Acid			C	Oral	100 Mg, Qd		Not Reported
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported
	Risperdal			C	Unknown	2 Mg, Unk (For Nights)		Not Reported
	Risperdal			C	Unknown	2 Mg, Qd		Not Reported
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported
	Amisulpride			C	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14226884	DIRECT		OT			9 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Enuresis; Somnambulism	Escitalopram 5mg Tablets Cipla			S	Oral			Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14227057	DIRECT	Y	OT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Substitution Issue; Syncope	Escitalopram 20mg			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14228166	DIRECT		DE, HO, OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14239044	DIRECT					56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Incorrect Dose Administered	Escitalopram			S				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	13415084	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Escitalopram			S	Unknown	For The Final Trimester		Hikma
	Ondansetron			S	Unknown			Hikma
	Progesterone			S	Unknown	For The Final Trimester		Hikma
	Sertraline			S	Unknown	For The Initial Two Trimester		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14211332	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1766411US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Emotional Distress; Suicide Attempt	Escitalopram Oxalate - Bp	S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14240018	DIRECT		DS				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory; Hyperhidrosis; Pyrexia	Escitalopram			S	Oral	Quantity:30 Tablet(S);		Not Reported
	Nature Made Vitamin C			C				Not Reported
	Calcium			C				Not Reported
	Iron			C				Not Reported
	Prenatal Capsules			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	14237486	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS-2017AMN01009			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram			S				Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	13007210	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2016M1053128		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bezoar; Cardiogenic Shock; Hyperlactacidaemia; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Toxicity To Various Agents	Zolpidem			S	Unknown			Not Reported
	Sevikar			S	Oral	129 Tablets: Olmesartan Medoxomil 5.16g/Amlodipine 1.29g		Mylan
	Seroplex			S	Oral	280 Mg		Mylan
	Atarax /00058401/			S	Oral	700 Mg		Mylan
	Lysanxia			C	Oral	420 Mg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	13103372	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2016-16245		26 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Poisoning; Sopor	Simvastatin			S	Unknown	14 Df, Total		Aurobindo
	Aspirina			S	Unknown	Unk		Not Reported
	Deursil			S	Oral	14 Df, Total		Not Reported
	Entact			S	Oral	28 Df, Total		Not Reported
	Igroton			S	Oral	15 Df, Total		Not Reported
	Rivotril			S	Oral	10 Ml, Total		Not Reported
	Torvast			S	Oral	8 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	13873933	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1734937US		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dizziness; Hyperhidrosis; Nausea; Pain; Pain In Jaw	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Topamax			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14240115	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1768222US		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury; Hyponatraemia; Overdose	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Paracetamol			S	Oral	8 G, Qd		Not Reported
	Oxynormoro			C		Unk		Not Reported
	Imovane			C	Unknown	0.5 Df, Unk		Not Reported
	Nasonex			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported

	Lercan	C	Unknown	Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Losartan	C		Unk	Not Reported
	Aldactazine	C	Unknown	Unk	Not Reported
	Alprazolam	C		0.25 Mg, Tid	Not Reported
	Movicol	C		1 Df, Bid	Not Reported
	Amoxicillin	C		Unk	Not Reported
	Oxycontin Lp	C		1 Df, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14240126	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1768112US		7 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Headache; Medication Error; Myalgia; Wrong Product Administered	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Zovirax			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14240171	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1768385US		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Abilify			S	Oral	Unk		Not Reported
	Levemir			C	Unknown	Unk		Not Reported
	Novorapid			C	Unknown	Unk		Not Reported
	Levothyrox			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14240686	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMPANY-US201711009829		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Atrial Fibrillation; Panic Attack; Sexual Dysfunction; Sleep Apnoea Syndrome; Wrong Technique In Product Usage Process	Cialis 5mg			S	Unknown	5 Mg, Unk		Eli Lilly And Co
	Cialis 20mg			S	Unknown	5 Mg, Unk		Eli Lilly And Co
	Lexapro			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Klonopin			S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14243801	DIRECT		DS			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Anxiety; Benign Prostatic Hyperplasia; Drug Interaction; Emotional Disorder; Personality Change	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Cipla
	Tamsulosin			S	Oral	Quantity:1 Capsule(S);		Zydus Pharm
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14248115	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1768515US		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lexapro			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14248267	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2017GSK183357		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Bupropion			S	Oral			Glaxosmithkline
	Escitalopram			S	Oral			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14248281	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2017GSK183376		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Bupropion			S	Oral	Unk		Glaxosmithkline
	Amlodipine			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Losartan			S	Oral	Unk		Glaxosmithkline
	Levothyroxine			S	Oral	Unk		Glaxosmithkline
	Ethanol			S	Oral	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14249032	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2017GSK183383		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Venlafaxine			S	Oral	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14249824	DIRECT	Y	HO			19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Amnesia; Paranoia	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	12331971	NON-EXPEDITED			US-PFIZER INC-2016242099		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Morphine Sulfate		S	Unk	Unknown
	Celebrex		S	Unk	Pfizer
	Tramadol		S	Unk	Not Reported
	Duloxetine		S	Unk	Not Reported
	Lexapro		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14250074	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21778			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Unk		Invagen
	Escitalopram			S	Oral	Unk		Invagen
	Acetaminophen			S	Oral	Unk		Cipla
	Hydrocodone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14250490	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2017US21802			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Respiratory Arrest; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Bupropion			S	Oral	Unk		Invagen
	Ethanol			S	Oral	Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14250491	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21801			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Acetaminophen			S	Oral	Unk		Cipla

	Trazodone	S	Oral	Unk		Not Reported
	Hydrocodone	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14250881	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21803			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Alprazolam			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported
	Acetaminophen			S	Oral	Unk		Cipla
	Quetiapine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14250883	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21806			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Quetiapine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14250906	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21804			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Lamotrigine			S	Oral	Unk		Cipla
	Citalopram			S	Unknown	Unk		Invagen
	Gabapentin			S	Oral	Unk		Invagen
	Alprazolam			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

	Carbon Black		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14250908	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21805			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Cyclobenzaprine			S	Oral	Unk		Invagen
	Bupropion			S	Oral	Unk		Invagen
	Acetaminophen			S	Oral	Unk		Cipla
	Ethanol			S	Oral	Unk		Not Reported
	Nifedipine			S	Oral	Unk		Cipla
	Piroxicam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14251092	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1768823US		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; International Normalised Ratio Increased; Melaena	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Previscan (Fluindione)			C	Oral	15 Mg, Qd		Allergan
	Previscan (Fluindione)			C	Unknown	Unk		Allergan
	Bromazepam			C	Unknown			Not Reported
	Celiprolol			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Fumafer			C	Unknown			Not Reported
	Pravastatin			C	Unknown			Not Reported
	Seretide			C	Unknown			Not Reported
	Titanoreine			C	Rectal			Not Reported
	Transipeg (Macrogol 3350)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14251914	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2016US10549			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Meloxicam			S	Oral	Unk		Cipla
	Celecoxib			S	Oral	Unk		Cipla
	Acetaminophen			S	Oral	Unk		Cipla
	Propoxyphene			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14254325	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2017GSK183970		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Propranolol			S		Unk		Glaxosmithkline
	Escitalopram			S		Unk		Glaxosmithkline
	Lamotrigine			S		Unk		Glaxosmithkline
	Buspirone Hcl			S		Unk		Glaxosmithkline
	Activated Charcoal			S		Unk		Glaxosmithkline
	Cyclobenzaprine			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Clonazepam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14254338	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2017GSK184039		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Carvedilol			S	Oral	Unk		Glaxosmithkline

	Escitalopram		S	Oral	Unk	Glaxosmithkline
	Phenytoin		S	Oral	Unk	Glaxosmithkline
	Valproic Acid		S	Oral	Unk	Not Reported
	Sitagliptin		S	Oral	Unk	Not Reported
	Mirtazapine		S	Oral	Unk	Not Reported
	Primidone		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14254342	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2017GSK183407		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Death; Drug Abuse	Bupropion			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	Unk		Glaxosmithkline
	Ethanol			S	Unknown	Unk		Glaxosmithkline
	Cocaine			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14254365	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2017GSK184037		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Propranolol			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Lamotrigine			S	Oral	Unk		Glaxosmithkline
	Ibuprofen			S	Oral	Unk		Glaxosmithkline
	Singular			S	Oral	Unk		Glaxosmithkline
	Acyclovir			S	Oral	Unk		Glaxosmithkline
	Oxycodone And Acetaminophen			S	Oral	Unk		Not Reported
	Ondansetron			S	Oral	Unk		Not Reported

	Alprazolam	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14107503	EXPEDITED (15-DAY)		OT	GR-LUPIN PHARMACEUTICALS INC.-2017-06040		60 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Micturition Urgency; Urinary Retention	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14228009	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1767438US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Contraindicated Product Prescribed	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Phenelzine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14252680	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2016US10561			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amlodipine Besylate			S	Oral	Unk		Invagen
	Escitalopram			S	Oral	Unk		Invagen
	Atenolol			S	Oral	Unk		Not Reported
	Duloxetine			S	Oral	Unk		Cipla
	Losartan			S	Oral	Unk		Not Reported
	Trazodone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14253096	NON-EXPEDITED		HO	US-AUROBINDO-AUR-APL-2015-06984			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Torasemide 20mg			S	Oral	20 Mg, Daily		Aurobindo
	Ascorbic Acid			S	Oral	1000 Mg, Daily		Not Reported
	Lexapro			S		5 Mg, Daily		Not Reported
	Magnesium Oxide			S		400 Mg, Daily		Not Reported
	Vasotec /00574902/			S	Oral	2.5 Mg, Daily		Not Reported
	Vitamin D3			S	Oral	Unk, Daily		Not Reported
	Glucosamine			C	Oral	1 Capsule, Daily		Not Reported
	Fish Oil			C	Oral	1 Tablet, Daily		Not Reported
	Aspirin			C	Oral	81 Mg, Daily		Not Reported
	Mvi			C	Oral	1 Tab, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14255091	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-04			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Escitalopram			S	Oral			Hikma
	Phenelzine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14256041	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2017SF22811		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria; Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence	Triatec (Ramipril)			S	Oral	Unk		Not Reported
	Triatec (Ramipril)			S	Oral	2.5 Mg 2/Day		Not Reported
	Brilique			S	Oral	90 Mg 2/Day		Not Reported
	Brilique			S	Oral			Not Reported
	Seroplex			S	Oral	5 Mg/Day		Not Reported

Seroplex	S	Oral	Unk		Not Reported
Diffu-K	S	Oral	Unk		Not Reported
Diffu-K	S	Oral	Unk		Not Reported
Bisoprolol Fumarate	S	Oral	3.25 Mg In The Morning And 2.5 Mg In The Evening		Not Reported
Bisoprolol Fumarate	S	Oral			Not Reported
Tahor	S	Oral	40 Mg/Day		Not Reported
Tahor	S	Oral	Unk		Not Reported
Inexium	C		20 Mg/Day		Not Reported
Kardegic	C		75 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14256268	EXPEDITED (15-DAY)		DE	FR-ANIPHARMA-2017-FR-000080		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Electrocardiogram Qt Prolonged	Indapamide (Non-Specific)			S				Ani
	Escitalopram			S				Not Reported
	Sotalol			S				Not Reported
	Benzoic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14256269	EXPEDITED (15-DAY)		OT	FR-ANIPHARMA-2017-FR-000081		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Metoclopramide (Non-Specific)			S				Ani
	Escitalopram			S				Not Reported
	Diazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14257260	NON-EXPEDITED		DS, OT	US-ASTRAZENECA-2017SF21487		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Crying; Drug Ineffective; Gait Inability; Muscle Rigidity; Off Label Use	Seroquel		S	Oral		Zeneca
	Escitalopram		S	Unknown	10.0mg Unknown	Not Reported
	Nuedexta		S	Unknown		Not Reported
	Namenda		S	Unknown		Not Reported
	Nortriptyline		C			Not Reported
	Prenatal Vitamine		C			Not Reported
	Depakote		C			Not Reported
	Baby Aspirin		C			Not Reported
	Turmeric		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14257583	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004507		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral			Unknown
	Carvedilol			S	Oral			Unknown
	Bupropion Hydrochloride			S	Oral			Unknown
	Hydrocodone/Acetaminophen			S	Oral			Unknown
	Citalopram Hbr			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Alprazolam			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14257603	EXPEDITED (15-DAY)		DE	US-TORRENT-00004545		93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amlodipine Besylate			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14257776	EXPEDITED (15-DAY)		DE	US-TORRENT-00004457		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Hydrocodone - Acetominophen			S	Oral			Unknown
	Isosorbide Mononitrate			S	Oral			Unknown
	Amlodipine			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Warfarin			S	Oral			Unknown
	Furosemide			S	Oral			Unknown
	Levothyroxine			S	Oral			Unknown
	Doxazosin			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14260476	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1766907US		50 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Off Label Use; Parkinsonism; Road Traffic Accident	Milnacipran - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Tramcet			S	Oral			Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14260569	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201710229		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chills; Hyperhidrosis; Myalgia; Restlessness; Serotonin Syndrome	Linezolid (Manufacturer Unknown)			S	Unknown			Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14260745	EXPEDITED (15-DAY)		DE, HO, OT	US-		56 YR	Female	USA

GLAXOSMITHKLINE-US2017GSK183859

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Lamotrigine			S	Oral	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14261168	DIRECT		OT			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Confusional State; Fatigue; Impaired Work Ability; Insomnia; Scar; Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Calcium			C				Not Reported
	Multivitamin			C				Not Reported
	Opc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	14225685	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT-00007334		32 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dyskinesia; Extrapyramidal Disorder; Muscle Twitching; Muscle Twitching; Restlessness	Trimipramin			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	14261949	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapy Change	Lexapro			S				Not Reported
	Cymbalta			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	14263154	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20171205190		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Rezolsta			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Kivexa			S	Unknown			Not Reported
	Minias			S	Unknown			Not Reported
	Tavor [Lorazepam]			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Ethanol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	14263897	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20171202971		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Diphenhydramine		Y	S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	11277218	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2015_000019			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obesity; Weight Increased	Aripiprazole			S	Oral	10 Mg, Qd		Otsuka
	Aripiprazole			S	Oral	15 Mg, Qd		Otsuka
	Seroquel			S	Oral	800 Mg, Qd		Not Reported
	Cipralex			S	Oral	20 Mg, Qd		Not Reported
	Quetiapine			S	Oral	800 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported

Simvastatin	C	Unknown	Unk		Not Reported
Simvastatin	C				Not Reported
Valium	C	Unknown	Unk		Not Reported
Temesta (Lorazepam)	C	Unknown	Unk		Not Reported
Lorazepam	C	Oral	2.5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	13678507	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2017263969		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Revatio			S		Unk		Pfizer
	Aldactone			S		Unk		Pfizer
	Selexipag			S	Oral	1400 Ug, Daily		Not Reported
	Uptravi			S	Oral	1400 Ug, Daily		Not Reported
	Tracleer			S		Unk		Not Reported
	Lasilix /00032601/			S		Unk		Not Reported
	Previscan /00789001/			S		Unk		Not Reported
	Seroplex			S		Unk		Not Reported
	Inexium /01479302/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	13703042	EXPEDITED (15-DAY)		DE	FR-ASTRAZENECA-2017SE66255		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Inexium			S	Oral			Astrazeneca
	Seroplex			S	Unknown			Not Reported
	Tracleer			S	Unknown	Unknown Daily Dose		Not Reported
	Revatio			S	Unknown	Unknown Daily Dose		Not Reported
	Lasilix			S	Unknown			Not Reported
	Aldactone			S	Unknown			Not Reported

	Previscan (Fluindione)	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14268384	EXPEDITED (15-DAY)		HO	IN-LANNETT COMPANY, INC.-IN-2017LAN001228		57 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Lannett
	Quetiapine			S	Unknown	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14268536	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US030994		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Naproxen			S	Oral	Unk		Perrigo
	Glucophage			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14268636	EXPEDITED (15-DAY)		DE	US-SA-200911019EU		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Pulmonary Congestion; Toxicity To Various Agents	Dextromethorphan Hydrobromide			S		Dose As Used: Unk		Not Reported
	Ambien			S		Dose As Used: Unk		Not Reported
	Temazepam			S		Dose As Used: Unk		Not Reported
	Zyprexa			S		Dose As Used: Unk		Not Reported
	Lexapro			S		Dose As Used: Unk		Not Reported
	Ethanol			S		Dose As Used: Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269139	EXPEDITED (15-DAY)		CA, HO, OT	FR-OTSUKA-DJ20115169		4 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysmorphism; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Large For Dates Baby; Respiratory Distress	Abilify			S	Transplacental	Unk		Otsuka
	Tercian			S	Transplacental	Unk		Not Reported
	Imovane			S	Transplacental	Unk		Not Reported
	Seroplex			S	Transplacental	Unk		Not Reported
	Zopiclone			S	Transplacental	Unk		Not Reported
	Lexapro			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269142	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US030736		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Loratadine			S	Oral	Unknown		Perrigo
	Ethylene Glycol			S	Oral	Unknown		Not Reported
	Escitalopram			S	Oral	Unknown		Not Reported
	Furosemide			S	Oral	Unknown		Not Reported
	Levothyroxine			S	Oral	Unknown		Not Reported
	Folic Acid			S	Oral	Unknown		Not Reported
	Vitamin B1 /00056101/			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269165	EXPEDITED (15-DAY)		DE	US-SA-A01200902224		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Pneumonia; Pulmonary Congestion; Toxicity To	Dextromethorphan Hydrobromide			S	Unknown			Not Reported
	Zolpidem Tartrate			S	Unknown			Not Reported

Various Agents	Temazepam	S	Unknown	Not Reported
	Zyprexa	S	Unknown	Not Reported
	Lexapro	S	Unknown	Not Reported
	Ethanol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269192	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-OTSUKA-2017_025156			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Death; Product Use In Unapproved Indication	Abilify			S	Unknown	Unk		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269222	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2016_016002		27 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Suicidal Ideation; Weight Increased	Abilify Maintena			S	Intramuscular	400 Mg, Unk		Otsuka
	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Escitalopram			S	Unknown	Unk		Not Reported
	Zuclopenthixol			S	Intramuscular	Unk		Not Reported
	Zuclopenthixol			S	Intramuscular	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Olanzapine			S	Intramuscular	Unk		Not Reported
	Haloperidol			S	Intramuscular	Unk		Not Reported
	Paliperidone			S	Oral	Unk		Not Reported
	Paliperidon			S	Unknown	100 Mg, Unk		Not Reported
	Paliperidon			S	Unknown	150 Mg, Unk		Not Reported
	Clozapine			S	Unknown	100 Mg, Bid		Not Reported
	Fluvoxamine			S	Unknown	50 Mg, Unk		Not Reported

Fluvoxamine	S	Unknown	50 Mg, Unk		Not Reported
Olanzapine	S	Intramuscular	Unk		Not Reported
Risperidone	S	Unknown	Unk		Not Reported
Paliperidone	S	Oral	Unk		Not Reported
Haloperidol	S	Intramuscular	Unk		Not Reported
Escitalopram	S	Unknown	Unk		Not Reported
Lorazepam	C	Unknown	4x1 Mg, Later 2x1 Mg		Not Reported
Lorazepam	C	Unknown	4 Mg, Unk		Not Reported
Lorazepam	C	Unknown	2 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269294	EXPEDITED (15-DAY)		OT	KR-OTSUKA-2016_014339AA		40 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Facial Paralysis; Palpitations	Abilify			S	Unknown	2 Mg, Unk		Otsuka
	Alprazolam			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Valproic Acid			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269407	EXPEDITED (15-DAY)		HO, OT	CH-OTSUKA-DJ20122817			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Abilify 3mg			S	Oral			Otsuka
	Seroquel			S	Unknown			Not Reported
	Cipralex			S	Oral			Not Reported

	Quilonorm	S	Oral			Not Reported
	Quetiapine	S		50 Mg, Unk		Not Reported
	Lexapro	S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269625	EXPEDITED (15-DAY)		DE, OT	CH-OTSUKA-DJ20111145		1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death Neonatal; Foetal Exposure During Pregnancy	Abilify			S	Transplacental	15 Mg, Qd		Otsuka
	Cipralex			S	Transplacental	10 Mg, Bid		Not Reported
	Stilnox			S	Transplacental	12.5 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Transplacental	Unk		Not Reported
	Zyprexa			S	Transplacental	7.5 Mg, Qd		Not Reported
	Zolpidem			S	Transplacental	12.5 Mg, Qd		Not Reported
	Lorazepam			S	Transplacental	Unk		Not Reported
	Lexapro			S	Transplacental	10 Mg, Bid		Not Reported
	Olanzapine			S	Transplacental	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269690	EXPEDITED (15-DAY)		OT	CA-OTSUKA-2015_016863		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Abilify			S	Oral	2 Mg, Qd		Otsuka
	Cipralex			S	Unknown	30 Mg, Qd		Not Reported
	Cipralex			S	Unknown	20 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	30 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269693	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20090225			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Abilify 3mg			S	Unknown			Otsuka
	Abilify 3mg			S	Unknown			Otsuka
	Lexapro			S	Unknown			Not Reported
	Lexapro			S		30 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269809	EXPEDITED (15-DAY)		HO	IT-OTSUKA-21247325		69 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Product Use In Unapproved Indication	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Valsartan			C	Oral	Tabs		Not Reported
	Cardioaspirin			C	Oral	Tabs		Not Reported
	Delorazepam			C	Oral	Tabs		Not Reported
	Cotareg			C	Oral	Tabs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269893	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-DJ201308463		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Jaundice Neonatal; Neonatal Hypoxia; Tremor	Abilify			S	Transplacental	10 Mg, Qd		Otsuka
	Seroplex			S	Transplacental	20 Mg, Qd (20mg Film Coated Tabs)		Not Reported
	Seresta			S	Transplacental	25 Mg, Bid (Dose Value:50mg,20mg Scored Tab)		Not Reported
	Tercian			S	Transplacental	25 Mg, Qd (Film Coated Tabs,Dose Value 12.5mg)		Not Reported

	Lexapro	S	Transplacental	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14269913	EXPEDITED (15-DAY)		HO	DE-OTSUKA-DJ20112967			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy; Premature Rupture Of Membranes	Abilify			S	Unknown	10 Mg, Qd		Otsuka
	Cipralex			S	Unknown	10 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Antipsychotics			C	Unknown	Unk		Not Reported
	Folsan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14270304	EXPEDITED (15-DAY)		OT	DK-OTSUKA-2016_020938			Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Intentional Overdose; Restlessness; Sedation; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Weight Increased	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Imoclone			S	Oral	7.5 Mg, Unk		Not Reported
	Oxapax			S	Oral	Unk		Not Reported
	Seroquel			S	Oral	100 Mg, Unk		Not Reported
	Seroquel			S	Unknown	300 Mg, Unk		Not Reported
	Truxal			S	Oral	265 Mg, Unk		Not Reported
	Zeldox			S	Oral	1 Df, Unk		Not Reported
	Solian			S	Oral	1 Df, Unk		Not Reported
	Solian			S	Unknown	50 Mg, Unk		Not Reported
	Risperidon			S	Oral	Unk, 1/2 Mg At Night		Not Reported
	Risperidon			S	Oral	1 Mg, Unk		Not Reported
	Seroquel Prolong			S	Oral	200 Mg, Unk		Not Reported
	Zopiclone			S	Oral	7.5 Mg, Unk		Not Reported

Quetiapine	S	Oral	100 Mg, Unk		Not Reported
Quetiapine	S	Unknown	300 Mg, Unk		Not Reported
Risperidone	S	Oral	Unk, 1/2 Mg At Night		Not Reported
Risperidone	S	Oral	1 Mg, Unk		Not Reported
Escitalopram	S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14270314	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2016_017398		19 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Off Label Use	Abilify Maintena			S	Intramuscular	400 Mg, Monthly		Otsuka
	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Orfiril			S	Oral	1000 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Oral	2.5 Mg, Qd		Not Reported
	Lorazepam			S	Oral	2.5 Mg, Bid		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14270468	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20115158			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Suicide Attempt	Abilify 3mg			S	Unknown			Otsuka
	Abilify 3mg			S				Otsuka
	Lexapro			S	Unknown			Not Reported
	Topamax			S	Unknown			Not Reported
	Lexapro			S		Started 6 Years Ago		Not Reported
	Lexapro			S				Not Reported
	Imitrex			C	Unknown			Not Reported
	Trazodone Hcl			C	Unknown			Not Reported

	Trazodone Hydrochloride	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14270488	EXPEDITED (15-DAY)		HO	AU-OTSUKA-DJ20070799			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Laryngospasm	Abilify 3mg			S	Oral			Otsuka
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14271071	EXPEDITED (15-DAY)		LT, OT	IT-OTSUKA-2016_012556		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Prescribed Underdose	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Cipralex			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14271149	EXPEDITED (15-DAY)		OT	AT-OTSUKA-BMS-2016-010026		47 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Aripiprazole			S	Unknown	2.5 Mg, Unk		Otsuka
	Aripiprazole			S	Unknown	5 Mg, Unk		Otsuka
	Clonazepam			S	Unknown	2 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	2.5 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	1.5 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	1.25 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	1 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Qd		Not Reported

Trazodone Hydrochloride	S	Unknown	150 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	150 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	300 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	200 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	300 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	250 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	200 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	250 Mg, Qd	Not Reported
Quetiapine	S	Unknown	50 Mg, Qd	Not Reported
Quetiapine	S	Unknown	1 Df, Qd	Not Reported
Quetiapine	S	Unknown	100 Mg, Qd	Not Reported
Quetiapine	S	Unknown	75 Mg, Qd	Not Reported
Quetiapine	S	Unknown	50 Mg, Qd	Not Reported
Quetiapine	S	Unknown	25 Mg, Qd	Not Reported
Paroxetine	S	Unknown	40 Mg, Qd	Not Reported
Cymbalta	S	Unknown	60 Mg, Qd	Not Reported
Risperidone	S	Unknown	1 Mg, Qd	Not Reported
Escitalopram	S	Unknown	20 Mg, Qd	Not Reported
Escitalopram	S	Unknown	30 Mg, Qd	Not Reported
Gewacalm	S	Unknown	30 Mg, Qd	Not Reported
Gewacalm	S	Unknown	20 Mg, Qd	Not Reported
Gewacalm	S	Unknown	10 Mg, Qd	Not Reported
Gewacalm	S	Unknown	5 Mg, Qd	Not Reported
Anafranil	S	Unknown	75 Mg, Qd	Not Reported
Ixel	S	Unknown	50 Mg, Qd	Not Reported
Ixel	S	Unknown	100 Mg, Qd	Not Reported
Ixel	S	Unknown	150 Mg, Qd	Not Reported
Ixel	S	Unknown	200 Mg, Qd	Not Reported
Molaxole	S	Unknown	Unk	Not Reported

	Oleovit D3	S	Unknown	30 G, Qwk	Not Reported
	Seroquel	S	Unknown	50 Mg, Qd	Not Reported
	Seroquel	S	Unknown	1 Df, Qd	Not Reported
	Seroquel	S	Unknown	100 Mg, Qd	Not Reported
	Seroquel	S	Unknown	75 Mg, Qd	Not Reported
	Seroquel	S	Unknown	50 Mg, Qd	Not Reported
	Seroquel	S	Unknown	25 Mg, Qd	Not Reported
	Cymbalta	S	Unknown	60 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14271575	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2016_003560		29 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Live Birth; Maternal Exposure During Pregnancy; Off Label Use	Abilify			S	Oral	15 Mg, Qd		Otsuka
	Cipralex			S	Oral	20 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14271599	EXPEDITED (15-DAY)		OT	CH-OTSUKA-DJ201309326		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Oligohydramnios; Vomiting	Abilify			S	Unknown	10 Mg, Qd		Otsuka
	Cipralex			S	Unknown	29jan13 29jan13		Not Reported
	Escitalopram			S	Unknown	29jan13 29jan13		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14271714	EXPEDITED (15-DAY)		OT	FR-OTSUKA-J201300907		35 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rhabdomyolysis	Abilify			S	Oral	15 Mg, Qd		Otsuka
	Seroplex			S	Unknown	Unknown		Not Reported
	Atacand			S	Unknown	Unknown		Not Reported
	Baclofen			S	Unknown	Unknown		Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14271771	EXPEDITED (15-DAY)		OT	FR-OTSUKA-J201408698			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Delirium; Hypertension; Maternal Exposure During Pregnancy; Off Label Use	Abilify			S	Unknown	15 Mg, Unk		Otsuka
	Seroplex			S	Unknown	Unk		Not Reported
	Parkinane			S	Unknown	Unk		Not Reported
	Tenoretic			S	Unknown	1 Df, Qd		Not Reported
	Tercian			S	Unknown	1 Df, Qd		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Loxen (Nicardipine Hydrochloride)			C	Unknown	Unk		Not Reported
	Loxen (Nicardipine Hydrochloride)			C				Not Reported
	Loxapac			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14271914	EXPEDITED (15-DAY)		OT	US-OTSUKA-2016_009602		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Bipolar Disorder; Depression; Dizziness; Drug Ineffective; Dry Mouth; Mania; Rash	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Abilify			S	Oral	2.5 Mg, Qd		Otsuka
	Carbamazepine			S	Unknown	600 Mg, Qd (200mg Tablet In The Morning And Two		Not Reported

				200mg Tablets In The Evening)	
	Lexapro	S	Unknown	10 Mg, Qd	Not Reported
	Wellbutrin	S	Unknown	Unk	Not Reported
	Prozac	S	Unknown	Unk	Not Reported
	Zoloft	S	Unknown	Unk	Not Reported
	Carbamazepine	S	Unknown	600 Mg, Qd (200mg Tablet In The Morning And Two 200mg Tablets In The Evening)	Not Reported
	Sertraline	S	Unknown		Not Reported
	Lexapro	S	Unknown	10 Mg, Qd	Not Reported
	Fluoxetine Hydrochloride	S	Unknown		Not Reported
	Xarelto	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Simvastatin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14272116	EXPEDITED (15-DAY)		OT	US-OTSUKA-BMS-2016-077166			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Cardiac Flutter; Feeling Abnormal; Major Depression; Sleep Disorder; Suicidal Ideation; Therapeutic Response Decreased	Aripiprazole			S	Unknown			Otsuka
	Lexapro			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14272844	EXPEDITED (15-DAY)		OT	IT-OTSUKA-2017_005459		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug	Abilify			S	Oral	1 Df, Unk		Otsuka

Abuse; Hypokinesia; Movement Disorder	Efexor	S	Oral	1 Df, Unk	Not Reported
	Tavor [Lorazepam]	S	Oral	1 Df, Unk	Not Reported
	Cipralex	S	Unknown	60 Mg, Unk	Not Reported
	Talofen	S	Oral	5 Gtt, Unk	Not Reported
	Lorazepam	S	Oral	1 Df, Unk	Not Reported
	Venlafaxine Xr	S	Oral	1 Df, Unk	Not Reported
	Escitalopram	S	Unknown	60 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14272865	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-2017_008051			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Blood Glucose Increased; Drug Abuse; Heart Rate Increased; Sinus Disorder; Suicidal Ideation	Abilify			S	Unknown	Unk		Otsuka
	Latuda			S	Oral	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Sudafed /00076302/			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14272950	EXPEDITED (15-DAY)		OT	CH-OTSUKA-DJ201407960		28 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Metrorrhagia; Off Label Use; Premature Delivery; Premature Rupture Of Membranes	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Abilify			S				Otsuka
	Latuda			S	Unknown	40 Mg, Qd		Not Reported
	Latuda			S				Not Reported
	Cipralex			S	Oral	20 Mg, Qd		Not Reported
	Cipralex			S				Not Reported
	Seropram (Citalopram Hydrobromide)			S	Unknown	20 Mg, Qd		Not Reported
	Seropram (Citalopram Hydrobromide)			S				Not Reported

	Edronax	S	Oral	4 Mg, Qd		Not Reported
	Edronax	S				Not Reported
	Lexapro	S	Oral	20 Mg, Qd		Not Reported
	Lexapro	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14272970	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2016_002594			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Presentation; Foetal Exposure During Pregnancy	Abilify			S	Transplacental	15 Mg, Qd		Otsuka
	Cipralex			S	Transplacental	20 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Transplacental	Unk		Not Reported
	Lorazepam			S	Transplacental	Unk		Not Reported
	Lexapro			S	Transplacental	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14272982	EXPEDITED (15-DAY)		CA, OT	FR-OTSUKA-DJ20096035		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Abilify			S	Transplacental	10 Mg, Unk		Otsuka
	Seroplex			S	Transplacental	20 Mg, Unk		Not Reported
	Dipiperon			S	Transplacental	1 Df, Qd		Not Reported
	Ikaran			S	Transplacental	10 Mg, Unk		Not Reported
	Seresta			S	Transplacental	75 Mg, Unk		Not Reported
	Havlane			S	Transplacental	Unk Unk, Qd		Not Reported
	Tranxene			S	Transplacental	40 Mg, Unk		Not Reported
	Lexapro			S	Transplacental	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14273313	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2017-033625		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diltiazem			S	Oral			Not Reported
	Metformin			S	Oral			Santarus
	Lorazepam			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Glyburide			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14273711	EXPEDITED (15-DAY)		CA, OT	FR-OTSUKA-DJ201408616		3 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Trisomy 21; Ventricular Septal Defect	Abilify			S	Transplacental	15 Mg, Qd		Otsuka
	Seroplex			S	Transplacental	1 Df, Qd		Not Reported
	Parkinane			S	Transplacental	1 Df, Unk		Not Reported
	Tenoretic			S	Transplacental	1 Df, Qd		Not Reported
	Tercian			S	Transplacental	1 Df, Qd		Not Reported
	Lexapro			S	Transplacental	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14273718	EXPEDITED (15-DAY)		DE, LT, OT	JP-OTSUKA-2017_015179		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardio-Respiratory Arrest; Chest Pain; Somnolence	Abilify 3mg			S	Oral	3 Mg, Qd		Otsuka
	Effexor			S	Oral	Unk		Not Reported
	Effexor			S	Oral	37.5 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Daily		Not Reported

Lamictal	S	Oral	400 Mg, Daily		Not Reported
Lamotrigine	S	Oral	400 Mg, Daily		Not Reported
Venlafaxine Xr	S	Oral	37.5 Mg, Qd		Not Reported
Lexapro	S	Oral	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14273953	EXPEDITED (15-DAY)		OT	JP-OTSUKA-BJ201304295		36 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Live Birth; Maternal Exposure During Pregnancy; Off Label Use	Abilify 3mg			S	Oral	3 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	6 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	9 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	15 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	12 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	18 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	24 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	30 Mg, Qd		Otsuka
	Lexapro			S	Oral	10 Mg, Bid		Not Reported
	Silece			S	Oral	2 Mg, Qd		Not Reported
	Contomin			S	Oral	25 Mg, Bid		Not Reported
	Seroquel			S	Oral	25 Mg, Qd		Not Reported
	Cymbalta			S	Oral	30 Mg, Bid		Not Reported
	Pyrethia			C	Oral	25 Mg, Qd		Not Reported
	Anesthetics, General			C	Unknown	Unk		Not Reported
	Tasmolin			C	Oral	1 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14274095	EXPEDITED (15-DAY)		HO, OT	CH-OTSUKA-DJ20105191		37 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Electrocardiogram Qt Prolonged; Mood Altered	Abilify	S	Oral		Otsuka
	Prazine (Promazine Hydrochloride)	S	Oral	Unk	Not Reported
	Haldol Decanoate	S	Unknown	3 Mg, Unk	Not Reported
	Haldol Decanoate	S			Not Reported
	Risperdal	S	Oral	2 Mg, Unk	Not Reported
	Risperdal	S			Not Reported
	Cipralex	S	Oral		Not Reported
	Cipralex	S	Oral	Unk	Not Reported
	Lexapro	S	Oral	20 Mg, Qd	Not Reported
	Stilnox	C	Unknown		Not Reported
	Stilnox	C	Unknown		Not Reported
	Rivotril	C	Oral	4 Mg, Intermittent	Not Reported
	Entumine	C	Unknown		Not Reported
	Zolpidem	C	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14274213	EXPEDITED (15-DAY)		OT	US-OTSUKA-2017_015748		16 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Incorrect Dose Administered; Oculogyric Crisis; Suicide Attempt	Abilify			S	Unknown	Unk		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported
	Prozac			S	Unknown	Unk		Not Reported
	Celexa			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Klonopin			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Fluoxetine Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14274292	EXPEDITED (15-DAY)		HO, OT	DE-OTSUKA-DJ20072544		66 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Serotonin Syndrome	Abilify 3mg			S	Oral			Otsuka
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Lexapro			S	Oral	Daily Dosage:From 18-Jul-07 To 23-Jul-07 Is 5 Mg		Not Reported
	Lamotrigin			C	Unknown	Unk		Not Reported
	Trileptal			C	Unknown	Unk		Not Reported
	Lamotrigine			C	Oral	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14274412	EXPEDITED (15-DAY)		DE, HO, OT	DE-OTSUKA-DJ20100215		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Abilify 3mg			S	Oral	15 Mg, Unknown		Otsuka
	Abilify 3mg			S	Oral	20 Mg, Unk		Otsuka
	Cipralex /01588502/			S	Oral	10 Mg, Unk		Not Reported
	Seroquel			S	Oral	200 Mg, Unk		Not Reported
	Tavor [Lorazepam]			S	Oral	6 Mg, Unk		Not Reported
	Tavor			S	Oral	2 Mg, Unk		Not Reported
	Lorazepam			S	Oral	6 Mg, Qd		Not Reported
	Quetiapine			S	Oral	200 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Eferox			C	Unknown	Unk		Not Reported
	Simeticone			C	Unknown	Unk		Not Reported

	Movicol		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14275117	EXPEDITED (15-DAY)		OT	AU-OTSUKA-DJ201308012		40 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Abilify			S	Unknown	20 Mg, Qd		Otsuka
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14275281	EXPEDITED (15-DAY)		OT	CH-OTSUKA-DJ20111147		32 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Cavity Infection; Maternal Exposure During Pregnancy; Premature Delivery	Abilify			S	Unknown	15 Mg, Qd		Otsuka
	Cipralex			S	Unknown	10 Mg, Bid		Not Reported
	Stilnox			S	Unknown	12.5 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	7.5 Mg, Qd		Not Reported
	Zolpidem			S	Unknown	12.5 Mg, Qd		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Bid		Not Reported
	Olanzapine			S	Unknown	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14275445	EXPEDITED (15-DAY)		HO	AT-OTSUKA-J20127883		27 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Off Label Use	Abilify			S	Unknown	10 Mg:23aug12		Otsuka
	Abilify			S				Otsuka

Abilify	S				Otsuka
Cipralex	S	Unknown	03aug12 Until 19aug12,10mg 20aug12 Until 31aug12. 20mg 10mg:01sep-04sep12		Not Reported
Cipralex	S				Not Reported
Cipralex	S				Not Reported
Zyprexa	S	Unknown	10aug12 Until 20aug12, 20mg 21aug12 Until 22aug12, 10mg 5mg:23aug12		Not Reported
Zyprexa	S				Not Reported
Zyprexa	S				Not Reported
Rivotril	S	Unknown	Unk		Not Reported
Dibondrin	S	Unknown	Unk		Not Reported
Clonazepam	S	Unknown			Not Reported
Lexapro	S	Unknown	03aug12 Until 19aug12,10mg 20aug12 Until 31aug12. 20mg 10mg:01sep-04sep12		Not Reported
Lexapro	S				Not Reported
Lexapro	S				Not Reported
Olanzapine	S	Unknown	10aug12 Until 20aug12, 20mg 21aug12 Until 22aug12, 10mg 5mg:23aug12		Not Reported
Olanzapine	S				Not Reported
Olanzapine	S				Not Reported
Diphenhydramine Hcl	C	Unknown	Unk		Not Reported
Clonazepam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14275507	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20113215			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Failure To Thrive; Foetal	Abilify			S	Transplacental	2.5 Mg, Qd		Otsuka

Exposure During Pregnancy; Gastrooesophageal Reflux Disease; Maternal Exposure During Breast Feeding; Menstrual Disorder	Lexapro		S	Transplacental	20 Mg, Qd	Not Reported
	Lexapro		S	Transplacental	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14275739	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-2015_016226			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Abilify			S	Unknown	Unk, Qd		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14275783	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2016_016049		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Normal Newborn; Off Label Use	Abilify			S	Oral	15 Mg, Qd		Otsuka
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Cipralex			S	Oral	20 Mg, Qd		Not Reported
	Lyrica			S	Oral	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14275919	EXPEDITED (15-DAY)		OT	AU-OTSUKA-2016_027754		40 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Product Use Issue	Abilify			S	Oral	20 Mg, Qd		Otsuka
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14275950	EXPEDITED (15-DAY)		HO, OT	CH-OTSUKA-J201405746		28 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Live Birth; Major Depression; Maternal Exposure During Pregnancy; Off Label Use	Abilify			S	Unknown	10 Mg, Qd		Otsuka
	Topamax			S	Unknown	100 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Unknown	Unk		Not Reported
	Cipralex			S	Unknown	10 Mg, Qd		Not Reported
	Seroquel			S	Unknown	200 Mg, Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Quetiapine			S	Unknown	200 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14275992	EXPEDITED (15-DAY)		HO	US-OTSUKA-BMS-2015-010390		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Hypertension; Hypokalaemia; Mental Status Changes	Aripiprazole			S	Oral	15 Mg, Bid		Otsuka
	Zolpidem			S	Oral	10 Mg, Qd		Not Reported
	Ibuprofen			S	Oral	800 Mg, Tid		Not Reported
	Clonazepam			S	Oral	1 Mg, Bid		Not Reported
	Venlafaxine			S	Oral	50 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Unk		Not Reported
	Fluticasone			S	Unknown	1 Df= 2 Sprays, Qd		Not Reported
	Vicodin			S	Oral	1 Df= 5/500 Units Nos, Prn		Not Reported
	Zestoretic			S	Oral	1 Df= 20/12.5 Units Nos, Qd		Not Reported
	Vivelle /00045401/			S	Transdermal	0.1 Mg, Unk		Not Reported
	Lyrica			S	Oral	75 Mg, Qd		Not Reported

Loratadine	S	Oral	10 Mg, Qd		Not Reported
Robaxin	S	Oral	750 Mg, Tid		Not Reported
Desvenlafaxine	S	Oral	50 Mg, Qd		Not Reported
Lexapro	S	Oral	20 Mg, Unk		Not Reported
Ambien	S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14276065	EXPEDITED (15-DAY)		CA, OT	CH-OTSUKA-DJ20083115		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Presentation; Dysmorphism; Ear Malformation; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Multiple Congenital Abnormalities; Selective Eating Disorder	Abilify			S	Transplacental	30 Mg, Qd		Otsuka
	Cipralex			S	Transplacental	10 Mg, Qd		Not Reported
	Lexapro			S	Transplacental	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14276085	EXPEDITED (15-DAY)		OT	US-OTSUKA-2016_022933		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Suicidal Ideation; Treatment Noncompliance	Abilify			S	Unknown	10 Mg, Qd		Otsuka
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14276402	EXPEDITED (15-DAY)		OT	BE-OTSUKA-DJ20127101		28 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Systemic Lupus Erythematosus	Abilify			S	Unknown	2.5 Mg, Unk		Otsuka

	Escitalopram	S	Unknown	Unknown		Not Reported
	Escitalopram	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14276455	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2016_001345		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Abilify			S	Oral	7 Tab, Unk		Otsuka
	Valium			S	Oral	1 Df, Unk		Not Reported
	Theralene			S	Oral	1 Df, Unk		Not Reported
	Theralene			S	Oral	50 Tab, Unk		Not Reported
	Stilnox			S	Oral	30 Tab, Unk		Not Reported
	Seresta			S	Oral	80 Tab, Unk		Not Reported
	Seroplex			S	Oral	15 Tab, Unk		Not Reported
	Zolpidem			S	Oral	30 Tab, Unk		Not Reported
	Lexapro			S	Oral	15 Tab, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14276651	EXPEDITED (15-DAY)		OT	AU-OTSUKA-DJ20106192		1 DAY	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Premature Baby	Abilify			S	Transplacental	30 Mg, Qd		Otsuka
	Lexapro			S	Transplacental	10 Mg, Qd		Not Reported
	Lexapro			S	Transplacental	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14276730	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2015_010341			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During	Aripiprazole			S	Transplacental	10 Mg, Qd		Otsuka

Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby	Cipralex	S	Transplacental	5 Mg, Qd		Not Reported
	Escitalopram	S	Transplacental	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14276809	EXPEDITED (15-DAY)		HO, LT, OT	FR-OTSUKA-2017_014193		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Lung Disorder; Toxicity To Various Agents	Abilify			S	Oral	Unk		Otsuka
	Xanax			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Risperdal			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Risperidone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14277640	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-2017_005158		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis; Surgery	Abilify			S	Oral	Unk		Otsuka
	Seroplex			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Innohep			C	Unknown	0.8 Ml, Qd		Not Reported
	Ogastoro			C	Unknown	Unk Unk, Qd		Not Reported
	Gaviscon /00237601/			C	Unknown	Unk, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14278411	EXPEDITED (15-DAY)		OT	CH-OTSUKA-DJ201405802			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Foetal Macrosomia; Hypoglycaemia Neonatal	Abilify	S	Transplacental	Unk		Otsuka
	Temesta (Lorazepam)	S	Transplacental	Unk		Not Reported
	Cipralex	S	Transplacental	Unk		Not Reported
	Topamax	S	Transplacental	Unk		Not Reported
	Seroquel	S	Transplacental	Unk		Not Reported
	Lorazepam	S	Transplacental	Unk		Not Reported
	Quetiapine	S	Transplacental	Unk		Not Reported
	Lexapro	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14278439	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-OTSUKA-2016_012076		28 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication; Shoulder Deformity; Weight Increased	Abilify			S	Unknown	Unk		Otsuka
	Cipralex			S	Unknown	Unk		Not Reported
	Xeplion			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Risperdal			S	Unknown	Unk		Not Reported
	Paliperidone Palmitate			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14278504	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ201403271			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Abilify 3mg			S	Unknown			Otsuka
	Lexapro			S	Unknown			Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14272292	NON-EXPEDITED			US-PFIZER INC-2017525488		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Ciprofloxacin			S		Unk		Unknown
	Advair			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14273153	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004822		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Citalopram			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Oral			Unknown
	Bupropion			S	Oral			Unknown
	Clonazepam			S	Oral			Unknown
	Tadalafil			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14273239	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005027		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Quetiapine			S	Oral			Unknown

	Citalopram	S	Oral	Unknown
	Escitalopram	S	Oral	Unknown
	Hydroxyzine Hydrochloride	S	Oral	Unknown
	Buspirone	S	Oral	Unknown
	Cyclobenzaprine Hydrochloride	S	Oral	Unknown
	Levothyroxine Sodium	S	Oral	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14273268	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005036		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Risperidone			S	Oral			Unknown
	Propranolol			S	Oral			Unknown
	Oxycodone			S	Oral			Unknown
	Trazodone			S	Oral			Unknown
	Clonazepam			S	Oral			Unknown
	Hydroxyzine			S	Oral			Unknown
	Temazepam			S	Oral			Unknown
	Benztropine			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Ondansetron			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14273275	EXPEDITED (15-DAY)		DE	US-TORRENT-00005260		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Phenobarbital			S	Oral			Unknown
	Quetiapine			S	Oral			Unknown
	Trazodone			S	Oral			Unknown
	Zolpidem			S	Oral			Unknown

	Phenytoin	S	Oral	Unknown
	Escitalopram	S	Oral	Unknown
	Oxycodone	S	Oral	Unknown
	Emtricitabine Tenofovir	S	Oral	Unknown
	Methylphenidate	S	Oral	Unknown
	Metformin	S	Oral	Unknown
	Ondansetron	S	Oral	Unknown
	Pregabalin	S	Oral	Unknown
	Metoclopramide	S	Oral	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14275034	EXPEDITED (15-DAY)		DE	US-TORRENT-00005275		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Zolpidem Tartrate			S	Oral			Unknown
	Escitalopram			S	Oral	`		Unknown
	Duloxetine			S	Oral			Unknown
	Temazepam			S	Oral			Unknown
	Ethanol			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14275050	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005268		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Toxicity To Various Agents	Sertraline Hydrochloride			S	Unknown			Unknown
	Doxepin Hcl			S	Unknown	`		Unknown
	Ethanol			S	Unknown			Unknown
	Clonazepam			S	Unknown			Unknown
	Clonidine Hydrochloride			S	Unknown			Unknown
	Sildenafil			S	Unknown			Unknown

	Duloxetine	S	Unknown	Unknown
	Diphenhydramine Hydrochloride	S	Unknown	Unknown
	Oxybutynin Chloride	S	Unknown	Unknown
	Escitalopram	S	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14275146	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20171203253		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Ibuprofen		Y	S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14276235	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005183		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral			Unknown
	Venlafaxine			S	Oral			Unknown
	Ethanol			S	Oral			Unknown
	Citalopram			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14276255	EXPEDITED (15-DAY)		DE	US-TORRENT-00005231		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide;	Lamotrigine			S	Oral			Unknown

Toxicity To Various Agents	Clonazepam	S	Oral		Unknown
	Escitalopram	S	Oral		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14276276	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005282		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Desipramine Hcl			S	Oral			Unknown
	Diltiazem			S	Oral	Extended Release		Unknown
	Venlafaxine			S	Oral			Unknown
	Lamotrigine			S	Oral			Unknown
	Hydrochlorothiazide			S	Oral			Unknown
	Armodafinil			S	Oral			Unknown
	Potassium Chloride			S	Oral			Unknown
	Trifluoperazine			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Pantoprazole			S	Oral			Unknown
	Lansoprazole			S	Oral			Unknown
	Naproxen			S	Oral			Unknown
	Nitrofurantoin			S	Oral			Unknown
	Diclofenac			S	Oral			Unknown
	Hydrocodone - Acetominophen			S	Oral			Unknown
	Propoxyphene Napsylate And Acetaminophen			S	Oral			Unknown
	Solifenacin Succinate			S	Oral			Unknown
	Ciprofloxacin			S	Oral			Unknown
	Rosuvastatin			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14276366	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20171203000		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported
	Cocaine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14276620	EXPEDITED (15-DAY)		DE	US-JNJFOC-20171203128		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Ibuprofen		Y	S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Oxycodone W/Paracetamol			S	Oral			Not Reported
	Singulair			S	Oral			Not Reported
	Ondansetron			S	Oral			Not Reported
	Acyclovir			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14276780	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20171203053		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Diphenhydramine	Y	S	Oral		Not Reported
	Risperidone		S	Oral		Not Reported
	Fluoxetine		S	Oral		Not Reported
	Escitalopram		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14277293	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094295		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14279704	EXPEDITED (15-DAY)		OT	FR-NOVAST LABORATORIES, LTD-FR-2017NOV000079		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Butalbital, Acetaminophen, And Caffeine			S				Novast
	Escitalopram			S		Unk		Not Reported
	Galantamine			S				Not Reported
	Irbesartan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14270908	EXPEDITED (15-DAY)		OT	US-OTSUKA-12487039			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Constipation;	Abilify			S	Oral	15 Mg, Qd		Otsuka

Dyskinesia; Fear; Glucose Tolerance Impaired; Insulin Resistance; Nightmare; Polycystic Ovaries; Sleep Disorder; Weight Increased	Lexapro		S	Oral	20 Mg, Qd	Not Reported
	Lexapro		S	Oral	20 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14281208	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2017-45068		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Escitalopram 10 Mg			S	Oral	10 Mg, Daily		Aurobindo
	Escitalopram 10 Mg			S	Oral	20 Mg, Unk		Aurobindo
	Quetiapine 150mg			S	Oral	150 Mg, Daily		Aurobindo
	Quetiapine 150mg			S	Oral	50 Mg, Daily		Aurobindo
	Lorazepam			S	Oral	0.25 Mg, Daily		Not Reported
	Lorazepam			S	Oral	1.5 Mg, Daily		Not Reported
	Lorazepam			S	Oral	1 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14281673	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094387		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Flecainide			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Verapamil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14281676	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094391		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Naproxen		S	Oral	Not Reported
	Alprazolam		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported
	Glucophage		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14282215	EXPEDITED (15-DAY)		HO	FR-TEVA-2017-FR-831078		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria; Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence	Bisoprolol Fumarate			S	Oral	3.25 Mg In The Morning And 2.5 Mg In The Evening		Duramed
	Bisoprolol Fumarate			S	Oral	Unk		Duramed
	Tahor			S	Oral	Unk		Not Reported
	Tahor			S	Oral	40 Mg/Day		Not Reported
	Diffu-K			S	Oral	Unk		Not Reported
	Diffu-K			S	Oral	Unk		Not Reported
	Triatec (Ramipril)			S	Oral	Unk		Not Reported
	Triatec (Ramipril)			S	Oral	2.5 Mg 2/Day		Not Reported
	Brilique			S	Oral	90 Mg 2/Day		Not Reported
	Brilique			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	5 Mg/Day		Not Reported
	Inexium			C		20 Mg/Day		Not Reported
	Kardegic			C		75 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14282284	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US030899		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Ibuprofen	S	Oral	Unk		Perrigo
	Amitriptyline	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Gabapentin	S	Oral	Unk		Not Reported
	Ethanol	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14282995	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1771264US		40 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Face Injury; Fall; Fracture; Visual Impairment	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14283332	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2017PRN00532			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram			S		Unk		Prinston Pharmaceutical
	Fondaparinux Sodium			C	Subcutaneous	Unk, 1x/Day		Not Reported
	Lisinopril			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14283480	EXPEDITED (15-DAY)		HO, LT	ES-ALLERGAN-1771353US		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose	Escitalopram Oxalate Unk			S	Oral	30 Mg, Unk		Allergan
	Clonazepam			S	Oral	22.5 Mg, Unk		Not Reported
	Quetiapina			S	Oral	19 Mg, Unk		Not Reported

	Valproato Sodio	S	Oral	2.6 Mg, Unk	Not Reported
	Antabus	S	Oral		Not Reported
	Abilify	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14283485	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-45118		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria; Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence	Bisoprolol			S	Oral	3.25 Mg In The Morning And 2.5 Mg In The Evening		Aurobindo
	Bisoprolol			S	Oral	Unk ()		Aurobindo
	Tahor			S	Oral	Unk ()		Not Reported
	Tahor			S	Oral	40 Mg/Day ()		Not Reported
	Diffu-K			S	Oral	Unk ()		Not Reported
	Diffu-K			S	Oral	Unk ()		Not Reported
	Triatec /00116401/			S	Oral	Unk ()		Not Reported
	Triatec /00116401/			S	Oral	2.5 Mg 2/Day ()		Not Reported
	Brilique			S	Oral	90 Mg 2/Day ()		Not Reported
	Brilique			S	Oral	Unk ()		Not Reported
	Seroplex			S	Oral	Unk ()		Not Reported
	Seroplex			S	Oral	5 Mg/Day ()		Not Reported
	Kardegic			C		75 Mg/Day ()		Not Reported
	Inexium /01479302/			C		20 Mg/Day ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14284189	EXPEDITED (15-DAY)		DE, OT	US-009507513-1712USA006584		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Loratadine			S	Oral	Unk		Merck

	Furosemide	S	Unk	Merck
	Levothyroxine Sodium	S	Unk	Not Reported
	Ethylene Glycol	S	Unk	Not Reported
	Escitalopram	S		Not Reported
	Folic Acid	S	Unk	Not Reported
	Thiamine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14284475	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094307		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14284486	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094489		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone/Apap			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Ondansetron			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Montelukast Sodium			S				Not Reported
	Aciclovir			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14284600	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094410		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Fluoxetine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Diphenhydramine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14284877	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2017AU22772			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia	Escitalopram			S	Unknown	Unk		Invagen
	Temazepam			S	Unknown	Unk		Not Reported
	Oxycodone			S	Oral	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14285258	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094535		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Bupropion			S				Not Reported
	Escitalopram			S				Not Reported
	Alprazolam			S				Not Reported
	Cocaine			S	Oral			Not Reported
	Ethanol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14285282	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094506		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14285468	NON-EXPEDITED			US-PFIZER INC-2017530623		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Atropine Sulfate/Diphenoxylate Hydrochloride			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported
	Bupropion			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14285561	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US030933		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Acetaminophen			S	Oral	Unk		Perrigo
	Propranolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14285565	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US031077		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Ibuprofen			S	Oral	Unknown, Unknown		Perrigo
	Propranolol			S	Oral	Unknown, Unkknown		Not Reported

	Escitalopram	S	Oral	Unknown, Unknown	Not Reported
	Lamotrigine	S	Oral	Unknown, Unknown	Not Reported
	Acetaminophen W/Oxycodone	S	Oral	Unknown, Unknown	Not Reported
	Singulair	S	Oral	Unknown, Unknown	Not Reported
	Ondansetron	S	Oral	Unknown, Unknown	Not Reported
	Acyclovir /00587301/	S	Oral	Unknown, Unknown	Not Reported
	Alprazolam	S	Oral	Unknown, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14285803	EXPEDITED (15-DAY)		DE	FR-VALIDUS PHARMACEUTICALS LLC-FR-2017VAL001647		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Furosemide			S	Unknown	Unk		Validus
	Uptravi			S	Oral	1400 Mg, Qd		Not Reported
	Inexium /01479302/			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Previscan /00789001/			S	Unknown	Unk		Not Reported
	Revatio			S	Unknown	Unk		Not Reported
	Selexipag			S	Oral	1400 Mg, Qd		Not Reported
	Aldactone /00006201/			S	Unknown	Unk		Not Reported
	Tracleer /01587701/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14288934	EXPEDITED (15-DAY)		HO, OT	FR-TAKEDA-2017TUS025914			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sensation In Eye; Agitation; Anxiety; Fall; Feeling Abnormal; Hypotension; Malaise;	Brintellix			S	Unknown	5 Mg, Qd		Takeda
	Seroplex			S	Oral	15 Mg, Qd		Not Reported

Movement Disorder; Muscle Twitching; Musculoskeletal Stiffness; Panic Attack; Suicidal Ideation	Tranxene		C	Unknown	Unk	Not Reported
	Zopiclone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14289969	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2017-033613		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acyclovir			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Acetaminophen/Oxycodone			S	Oral			Not Reported
	Singulair			S	Oral			Not Reported
	Ondansetron			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	12433729	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-JNJFOC-20160529315		28 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Confusional State; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Seizure; Shoulder Deformity; Weight Increased	Risperdal			S	Unknown			Not Reported
	Xeplion			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	13401513	EXPEDITED (15-DAY)		DE, DS, OT	CH-PFIZER INC-2017138980		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Assisted Suicide; Condition Aggravated; Malnutrition; Muscle Rigidity; Psychomotor Retardation; Somnolence; Tremor	Temesta (Lorazepam)			S	Oral	1 Mg, 3x/Day + 0.5mg 2x/Day As Needed		Pfizer
	Temesta			S	Oral	3.5 Mg, Daily (1mg Morning-And 2.5mg In The Evening + 1mg 2x/Day Prn)		Pfizer
	Quetiapine			S	Oral	25 Mg, 1x/Day		Not Reported
	Quetiapine			S	Oral	25 Mg, 1x/Day + 25mg Prn		Not Reported
	Quetiapine			S	Oral	25 Mg, 3x/Day		Not Reported
	Quetiapine			S	Oral	12.5 Mg, 1x/Day		Not Reported
	Depakine Chrono			S	Oral	1000 Mg, 2x/Day		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Lamictal			S		200 Mg, 1x/Day		Not Reported
	Calciparine			C		Unk		Not Reported
	Ziagen			C		Unk		Not Reported
	Aspirin Cardio			C		Unk		Not Reported
	Quantalan			C		Unk		Not Reported
	Nexium /01479302/			C		Unk		Not Reported
	Intelence			C		Unk		Not Reported
	Zeffix			C		Unk		Not Reported
	Imodium			C		Unk		Not Reported
	Metamucil /00091301/			C		Unk		Not Reported
	Isentress			C		Unk		Not Reported
	Vi-De 3			C		Unk		Not Reported
	Buscopan			C		Unk		Not Reported
	Dafalgan			C		Unk		Not Reported

Zolpidem	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	14217440	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-104040			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Death; Product Use In Unapproved Indication	Abilify			S	Unknown	Unk		Bristol Myers Squibb
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	14288109	EXPEDITED (15-DAY)		HO, LT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2017006717			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Intentional Overdose	Escitalopram Oxalate			S	Oral	30 Mg, Unk, 1 Total		Macleods
	Quetiapine			S	Oral	19 G, Single (1 Total)		Macleods
	Abilify 15 Mg Tablets			S	Oral	15 Mg, Qd		Not Reported
	Antabus 250 Mg Compressed			S	Oral	250 Mg, Qd		Not Reported
	Clonazepam			S	Oral	22.5 Mg, Single (1 Total)		Not Reported
	Valproate Sodium			S	Oral	3.6 Mg, Single (1 Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	14288110	EXPEDITED (15-DAY)		HO, OT	PT-MACLEODS PHARMACEUTICALS US LTD-MAC2017006718			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Depression; Gait Disturbance; Headache; Vision Blurred	Escitalopram			S	Unknown	10 Mg, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	14288613	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2017-FR-002700		61 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Metoclopramide			S				Ipca
	Escitalopram			S				Not Reported
	Diazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	14290743	EXPEDITED (15-DAY)		HO	PT-AUROBINDO-AUR-APL-2017-45390		29 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Depression; Gait Disturbance; Headache; Vision Blurred	Escitalopram			S	Unknown	10 Mg, Qd		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	14293335	EXPEDITED (15-DAY)		DE, HO, OT	US-BAUSCH-BL-2017-033118		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Venlafaxine			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	14293533	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004751		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide;	Lamotrigine			S	Oral			Unknown

Toxicity To Various Agents	Carbamazepine		S	Oral	Unknown
	Alprazolam		S	Oral	Unknown
	Escitalopram		S	Oral	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2017	14293734	EXPEDITED (15-DAY)		OT	US-ACCORD-061823			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Escitalopram			S		Strength: 10 Mg		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2017	14294034	EXPEDITED (15-DAY)		DE, LT	BE-CIPLA LTD.-2017BE25675			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation	Escitalopram			S	Transplacental	Unk		Invagen
	Levocetirizine			S	Transplacental	Unk		Not Reported
	Pantoprazole			S	Transplacental	Unk		Cipla
	Fluticasone Propionate			S	Transplacental	Unk		Not Reported
	Theophylline			S	Transplacental	Unk		Cipla
	Salbutamol Sulphate			S	Transplacental	Unk		Not Reported
	Fluticasone			S	Transplacental	Unk		Cipla
	Nucala Powder For Solution For Injection			S	Transplacental	Unk		Not Reported
	D-Cure			S	Transplacental	Unk		Not Reported
	Relvar Ellipta Inhalation Powder			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	10730958	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2015-001057		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Completed Suicide	Tramadol		S	Oral	Not Reported
	Diclofenac		S	Oral	Bausch And Lomb
	Zolpidem		S	Oral	Not Reported
	Hydrocodone W/Acetaminophen		S	Oral	Not Reported
	Ondansetron		S	Oral	Not Reported
	Linaclotide		S	Oral	Not Reported
	Lubiprostone		S	Oral	Not Reported
	Liothyronine		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported
	Gabapentin		S	Oral	Not Reported
	Sertraline		S	Oral	Not Reported
	Amitriptyline		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	13036364	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-FERRINGPH-2016FE06514			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Sertraline			S	Transplacental	Unk		Not Reported
	Ondansetron			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported
	Progesterone			S	Transplacental	Unk		Ferring

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295045	EXPEDITED (15-DAY)		OT	CZ-CIPLA LTD.-2017CZ24327			Unknown	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sertraline			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295057	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005083		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Lamotrigine			S	Oral			Unknown
	Citalopram			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Venlafaxine Hydrochloride			S	Oral			Unknown
	Ethanol			S	Oral			Unknown
	Hydroxyzine Pamoate			S	Oral			Unknown
	Atenolol			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295158	EXPEDITED (15-DAY)		CA, DE, OT	BE-APOTEX-2017AP022599		7 DAY	Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Maternal Drugs Affecting Foetus	Levocetirizine Apotex			S	Transplacental	5 Mg, Qd		Apotex
	Pantomed /01263204/			S	Transplacental	Unk		Not Reported
	Nucala Powder For Solution For Injection			S	Transplacental	100 Mg, Unk		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported
	Ventolin			S	Unknown	100 Ug, Unk		Not Reported
	Relvar Ellipta Inhalation Powder			S	Transplacental	Unk, Qd		Not Reported
	Sipralexa Tablet			S	Transplacental	10 Mg, Z		Not Reported
	Avamys Nasal Spray			S	Transplacental	Unk Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295218	EXPEDITED (15-DAY)		DE	US-TORRENT-		57 YR	Female	USA

00004910

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Lamotrigine			S	Oral			Unknown
	Diphenhydramine			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Aripiprazole			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295274	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2017006908			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295340	NON-EXPEDITED			US-PFIZER INC-2017534086		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sertraline Hcl			S	Oral	200 Mg, 1x/Day		Pfizer
	Celebrex			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14296003	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004716		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest;	Zolpidem			S	Oral			Unknown

Completed Suicide; Toxicity To Various Agents	Alprazolam		S	Oral	Unknown
	Escitalopram		S	Oral	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14296008	EXPEDITED (15-DAY)		DE, HO, OT	US-TORRENT-00004828		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bradycardia; Cardio-Respiratory Arrest; Completed Suicide; Hyperthermia; Hypotension; Overdose; Pulmonary Oedema; Toxicity To Various Agents; Ventricular Tachycardia	Vilazodone Hydrochloride			S		Ingestion Plus Aspiration Vilazodone 10 Mg 21 Missing		Unknown
	Alprazolam			S		Ingestion Plus Aspiration Alprazolam 0.5 Mg 100 Missing		Unknown
	Escitalopram			S		Ingestion Plus Aspiration		Unknown
	Duloxetine			S		Ingestion Plus Aspiration		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14296075	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201705105		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Oxycodone/Acetaminophen			S	Oral	Unk		Mallinckrodt
	Propranolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported
	Singulair			S	Oral	Unk		Not Reported
	Ondansetron			S	Oral	Unk		Not Reported
	Acyclovir			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14296719	EXPEDITED (15-DAY)		DE, HO, OT	US-BAYER-2017-238536		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Naproxen Sodium (<= 220 Mg)			S	Oral			Bayer
	Glucophage			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14297909	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2017-033727		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lorazepam			S	Oral			Not Reported
	Lithium			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14297969	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2017-033753		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Primidone			S	Oral			Not Reported
	Carvedilol			S	Oral			Not Reported
	Valproic Acid			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Sitagliptin			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Phenytoin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14298567	EXPEDITED (15-DAY)		DE	US-SA-2017SA253412		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diltiazem Hydrochloride			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Propranolol Hydrochloride			S	Oral			Not Reported
	Glyburide			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14273878	EXPEDITED (15-DAY)		DE, HO, OT	DE-OTSUKA-14927875		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Abilify			S	Oral	15 Mg, Qd		Otsuka
	Abilify			S	Oral	20 Mg, Qd		Otsuka
	Abilify			S	Unknown	Unk		Otsuka
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Quetiapine			S	Oral	200 Mg, Qd		Not Reported
	Lorazepam			S	Oral	6 Mg, Qd		Not Reported
	Eferox			C	Oral	50 Mg, Qd		Not Reported
	Simeticone			C	Oral	1 Df= 3x40 Gtts		Not Reported
	Movicol			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14299208	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2017AU22984			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Hyponatraemia	Bupropion Hcl Xl			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Dothiepin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14299484	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US22975			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Pregnancy Test False Positive	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14299755	EXPEDITED (15-DAY)		HO, LT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-157451		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose	Escitalopram			S	Oral	30 Mg, In Total		Not Reported
	Clonazepam			S	Oral	22.5 Mg, In Total		Sun
	Quetiapine			S	Oral	19 G, In Total		Sun
	Valproic Acid			S	Oral	3.6 Mg, In Total		Sun
	Abilify			S	Oral	30 Mg, Daily		Not Reported
	Antabus			S	Oral	250 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14299788	EXPEDITED (15-DAY)		OT	IN-CIPLA (EU) LIMITED-2017IN23201			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Olanzapine			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14299978	EXPEDITED (15-DAY)		HO, LT	IT-CIPLA LTD.-2017IT24393			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Abuse; Sopor; Tremor	Escitalopram			S	Oral	280 Mg, Total		Invagen
	Bromazepam			S	Oral	40 Ml, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300326	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2016IT02796			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Erythema; Pemphigoid; Pruritus	Escitalopram			S	Unknown	10 Mg Daily, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300525	EXPEDITED (15-DAY)		HO, LT	DE-CIPLA LTD.-2017DE23830			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Escitalopram			S	Oral	15 Mg, Qd		Invagen
	Escitalopram			S	Oral	20 Mg, Qd		Invagen
	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Aripiprazole			S	Oral	10 Mg, Qd		Cipla
	Aripiprazole			S	Oral	5 Mg, Qd		Cipla
	Candesartan			S	Oral	16 Mg, Qd		Not Reported
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported
	Risperdal			C	Unknown	2 Mg, Unk (For Nights)		Not Reported
	Risperdal			C	Unknown	2 Mg, Qd		Not Reported
	L-Thyroxin			C	Oral	100 Mg, Qd		Not Reported
	Amisulpride			C	Unknown	200 Mg, Qd		Not Reported
	Metformin			C	Oral	1500 Mg, Qd		Not Reported

Atorvastatin	C	Oral	20 Mg, Qd		Not Reported
Acetylsalicylic Acid	C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300736	EXPEDITED (15-DAY)		OT	TH-CIPLA LTD.-2017TH23200			Unknown	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Invagen
	Rasagiline			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300737	EXPEDITED (15-DAY)		DE, HO	US-BAYER-2017-239544		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Acetylsalicylic Acid (> 100 Mg)		Y	S	Oral			Bayer
	Bupropion			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300893	EXPEDITED (15-DAY)		OT	TR-CIPLA LTD.-2017TR22980			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Escitalopram			S	Unknown	10 Mg Per Day		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14301331	EXPEDITED (15-DAY)		OT	ES-CIPLA LTD.-2017ES23126			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Unknown	Unk		Invagen
	Citalopram			S	Unknown	Unk		Invagen
	Olanzapine			S	Unknown	Unk		Invagen
	Venlafaxine			S	Unknown	Unk		Not Reported
	Haloperidol			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14301693	EXPEDITED (15-DAY)		OT	ES-CIPLA LTD.-2017ES23018			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14301697	EXPEDITED (15-DAY)		HO, LT, OT	ES-CIPLA LTD.-2017ES24386			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine			S	Unknown	1 Df, Per Day		Invagen
	Topiramate			S	Unknown	1 Df, Per Day		Invagen
	Topiramate			S	Unknown	0.5 Df, Per Day		Invagen
	Escitalopram			S	Unknown	1 Df, Per Day		Invagen
	Naproxen			S	Unknown	2 Df, Per Day, 1 Df, Bid		Invagen
	Paracetamol			S	Unknown	3 Df, Per Day, 1 Df, T Id		Cipla
	Simvastatin			S	Unknown	1 Df, Per Day		Cipla
	Simvastatin			S	Unknown	20 Mg, Unk		Cipla
	Glibenclamide			S	Unknown	2 Df, Per Day, 1 Df, Bid		Not Reported
	Omeprazole			S	Unknown	1 Df, Per Day, 1 Df, Qd		Cipla
	Diazepam			S	Unknown	0.5 Df, Per Day		Not Reported

	Tramadol/Paracetamol	S	Unknown	3 Df, Per Day, 1 Df, Tid	Not Reported
	Amitriptyline	S	Unknown	5 Mg, Per Day	Not Reported
	Amitriptyline	S	Unknown	25 Mg, Unk	Not Reported
	Amitriptyline	S	Unknown	12.5 Mg, Per Day, 1 2 .5 Mg, Qd	Not Reported
	Enalapril, Hydrochlorothiazide	S	Unknown	1 Df, Per Day	Not Reported
	Lormetazepam	S	Unknown	1 Df Per Day, 1 Df, Qd	Not Reported
	Tepazepam	S	Unknown	1, Per Day	Not Reported
	Metoclopramide	C	Unknown	Unk, 1 Week Treatment	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14302405	NON-EXPEDITED			US-SUPERNUS PHARMACEUTICALS, INC.-2017SUP00281		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Emotional Disorder; Insomnia; Migraine	Trokendi Xr			S	Oral	50 Mg, 1x/Day		Supernus
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14302875	EXPEDITED (15-DAY)		DE	US-BAYER-2017-239143		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Loratadine			S	Oral	Unk		Bayer
	Ethylene Glycol			S		Unk		Not Reported
	Escitalopram			S				Not Reported
	Furosemide			S		Unk		Not Reported
	Levothyroxine			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Vitamin B1			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14303004	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2017M1079458		29 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Depression; Gait Disturbance; Headache; Vision Blurred	Escitalopram			S		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14303302	EXPEDITED (15-DAY)		OT	US-OTSUKA-17316720		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fatigue; Mania	Abilify			S	Unknown	5 Mg, Unk		Otsuka
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14303403	EXPEDITED (15-DAY)		OT	JP-OTSUKA-2016_015261		26 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothermia; Malaise; Prescribed Underdose	Abilify 3mg			S	Oral	1.5 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	0.75 Mg, Qd		Otsuka
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Lendormin			C	Oral	0.25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14303486	EXPEDITED (15-DAY)		OT	US-OTSUKA-2016_001315			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Maternal Exposure During Pregnancy	Abilify			S	Unknown	20 Mg, Unk		Otsuka
	Lexapro			S	Unknown	Unknown		Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14303499	EXPEDITED (15-DAY)		CA, OT	US-OTSUKA-2016_001252			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Foetal Exposure During Pregnancy	Abilify			S	Transplacental	20 Mg, Unk		Otsuka
	Lexapro			S	Transplacental	Unk		Not Reported
	Lexapro			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14303707	EXPEDITED (15-DAY)		DE, OT	JP-OTSUKA-2017_014254		30 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Completed Suicide; Decreased Appetite; Insomnia; Refusal Of Treatment By Patient; Suicidal Ideation	Abilify 3mg			S	Oral	24 Mg, Qd		Otsuka
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Zyprexa			S	Oral	10 Mg, Qd		Not Reported
	Zyprexa			S	Oral	15 Mg, Qd		Not Reported
	Zyprexa			S	Oral	20 Mg, Qd		Not Reported
	Reflex			S	Oral	15 Mg, Qd		Not Reported
	Olanzapine			S	Oral	20 Mg, Qd		Not Reported
	Olanzapine			S	Oral	15 Mg, Qd		Not Reported
	Olanzapine			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14303782	EXPEDITED (15-DAY)		OT	US-OTSUKA-J20040736		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Pregnancy	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Seroquel			S	Unknown	25 Mg, Qd		Not Reported
	Klonopin			S	Unknown	0.5 Mg, Qd		Not Reported
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported
	Wellbutrin			S	Unknown	300 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Bid		Not Reported
	Quetiapine			S	Unknown	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14303840	EXPEDITED (15-DAY)		DE	US-OTSUKA-DJ20084241		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Abilify			S	Unknown	40 Mg, Unk		Otsuka
	Abilify			S				Otsuka
	Abilify			S				Otsuka
	Abilify			S				Otsuka
	Lexapro			S	Unknown	40 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14303857	EXPEDITED (15-DAY)		DE, OT	US-OTSUKA-DJ20091428		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Atenolol			C	Unknown	Unk		Not Reported
	Prevacid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14303873	EXPEDITED (15-DAY)		LT, OT	ID-OTSUKA-JP-2012-15532		17 YR	Male	IDN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Abilify			S				Otsuka
	Lexapro			S		10 Mg, Qd		Not Reported
	Cipralex			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14303987	EXPEDITED (15-DAY)		HO, LT, OT	US-OTSUKA-KJ20120442			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Dizziness; Drug Ineffective; Dry Mouth; Headache; Major Depression; Medication Error; Overdose; Paranoia; Suicidal Ideation	Aripiprazole			S	Oral			Otsuka
	Aripiprazole			S				Otsuka
	Lexapro			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Wellbutrin			S				Not Reported
	Prozac			S	Unknown			Not Reported
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Fluoxetine Hydrochloride			S		Unk		Not Reported
	Fluoxetine Hydrochloride			S				Not Reported
	Seroquel			C	Unknown			Not Reported
	Neurontin			C	Unknown			Not Reported
	Topamax			C	Unknown			Not Reported
	Misoprostol			C	Unknown			Not Reported
	Actos			C	Unknown			Not Reported
	Prilosec			C	Unknown			Not Reported
	Diovan			C	Unknown			Not Reported

Glimepiride	C	Unknown			Not Reported
Welchol	C	Unknown			Not Reported
Celebrex	C	Unknown			Not Reported
Vesicare	C	Unknown			Not Reported
Singulair	C	Unknown			Not Reported
Gabapentin	C		800 Mg, Unk		Not Reported
Valsartan	C				Not Reported
Glimepiride	C				Not Reported
Quetiapine	C				Not Reported
Omeprazole	C				Not Reported
Misoprostol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14304214	EXPEDITED (15-DAY)		DE, OT	US-OTSUKA-KJ201309353		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression; Diplopia; Disturbance In Attention; Insomnia; Mania	Abilify			S	Unknown	Unk		Otsuka
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported
	Topamax			C	Unknown	Unk		Not Reported
	Risperidone			C	Unknown	0.25 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14304252	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20115996			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Anxiety; Menopausal Symptoms; Sjogren'S Syndrome; Swelling; Weight Increased	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14304276	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20094455		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Gait Disturbance; Hepatic Pain; Hepatomegaly; Mood Swings; Muscle Atrophy; Restlessness	Abilify			S	Oral	2 Mg, Unk		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14304548	EXPEDITED (15-DAY)		OT	FR-OTSUKA-J20127161		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Orthostatic Hypotension	Abilify			S	Oral	5 Milligram 1 Day		Otsuka
	Daflon (Diosmin/Hesperidin)			S	Unknown	Unk		Not Reported
	Haldol			S	Unknown	1 Dosage Form 1/1 Day		Not Reported
	Imovane			S	Unknown	Unk		Not Reported
	Lepticur			S	Unknown	Unk		Not Reported
	Lysanxia			S	Oral	10 Milligram 1 Day		Not Reported
	Seroplex			S	Oral	20 Milligram 1 Day		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Haloperidol			S	Unknown	5 Mg ½ Tab At Bed Time		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14304644	EXPEDITED (15-DAY)		HO	JP-OTSUKA-JP-2015-12027		57 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Mania; Tooth Fracture	Aripiprazole			S	Oral	3 Mg, Qd		Otsuka
	Aripiprazole			S	Oral	6 Mg, Qd		Otsuka
	Aripiprazole			S	Oral	3 Mg, Qd		Otsuka
	Aripiprazole			S	Oral	6 Mg, Qd		Otsuka
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

Lexapro	S	Oral	5 Mg, Qd		Not Reported
Lexapro	S	Oral	15 Mg, Qd		Not Reported
Lexapro	S	Oral	10 Mg, Qd		Not Reported
Cymbalta	S	Oral	20 Mg, Qd		Not Reported
Cymbalta	S	Oral	40 Mg, Qd		Not Reported
Cymbalta	S	Oral	20 Mg, Qd		Not Reported
Cymbalta	S	Oral	40 Mg, Qd		Not Reported
Cymbalta	S	Oral	20 Mg, Qd		Not Reported
Cymbalta	S	Oral	20 Mg, Qd		Not Reported
Cymbalta	S	Oral	40 Mg, Qd		Not Reported
Cymbalta	S	Oral	20 Mg, Qd		Not Reported
Cymbalta	S	Oral	40 Mg, Qd		Not Reported
Cymbalta	S	Oral	20 Mg, Qd		Not Reported
Estazolam	C	Oral	1 Mg, Qd		Not Reported
Lunesta	C	Oral	2 Mg, Qd		Not Reported
Lunesta	C	Oral	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14304675	EXPEDITED (15-DAY)		OT	DK-OTSUKA-15433980		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Initial Insomnia; Mania	Abilify			S	Unknown	26jan09;2.5mg,Discontinued On 04nov09		Otsuka
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14304680	EXPEDITED (15-DAY)		HO	US-OTSUKA-DJ20115950			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Head Injury; Increased	Abilify			S	Oral	10 Mg, Unk		Otsuka

Appetite; Logorrhoea; Loss Of Consciousness; Pollakiuria; Psychomotor Hyperactivity	Lexapro	S	Unknown	Unk		Not Reported
	Lexapro	S				Not Reported
	Gabitril	S	Unknown	Unk		Not Reported
	Gabitril	S				Not Reported
	Ibuprofen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14304956	EXPEDITED (15-DAY)		HO, OT	AT-OTSUKA-15812548		24 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Suicidal Ideation	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Trazodone Hydrochloride			S		150 Mg, Qd		Not Reported
	Lexapro			S		10mg		Not Reported
	Chlorprothixene			S		30mg		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Escitalopram			C	Unknown	10 Mg, Qd		Not Reported
	Chlorprothixene Hcl			C	Unknown	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14305054	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-DJ20060414		< 1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Exposure During Pregnancy; Maternal Exposure During Breast Feeding; Neonatal Disorder; Sedation; Selective Eating Disorder	Abilify			S	Transplacental	Unk		Otsuka
	Topamax			S	Transplacental	Unk		Not Reported
	Lexapro			S	Transplacental	Unk		Not Reported
	Remeron			S	Transplacental	Unk		Not Reported
	Zyprexa			S	Transplacental	Unk		Not Reported
	Mirtazapine			S	Transplacental	Unk		Not Reported
	Lexapro			S	Transplacental	Unk		Not Reported
	Olanzapine			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14305216	EXPEDITED (15-DAY)		DE, HO, OT	US-OTSUKA-DJ20126317		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clavicle Fracture; Dysphagia; Fall; Parkinsonism; Pneumonia Aspiration	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Buspar			S	Unknown	15 Mg, Bid		Not Reported
	Lexapro			S	Unknown	20 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Ambien			S	Unknown	10 Mg, Qd		Not Reported
	Lipitor			C	Unknown	Unk		Not Reported
	Allegra			C	Unknown	Unk		Not Reported
	Vitamin C			C	Unknown	Unk		Not Reported
	Vitamin D3			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14305252	EXPEDITED (15-DAY)		OT	FR-OTSUKA-DJ20100325		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Infertility	Abilify			S	Oral	Unk		Otsuka
	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Abilify			S	Oral	Unk		Otsuka
	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Seroplex			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S		Dose Inreased To 30mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14305437	EXPEDITED (15-DAY)		DE	FR-OTSUKA-DJ20101312		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Abilify			S	Oral	30 Mg, Unk		Otsuka
	Abilify			S				Otsuka
	Donormyl (Doxylamine Succinate)			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Equanil			S	Unknown	Unk		Not Reported
	Doxylamine Succinate			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14305502	EXPEDITED (15-DAY)		HO, OT	AT-OTSUKA-16807471		26 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Abilify			S				Otsuka
	Lorazepam			S		6.25 Mg, Unk		Not Reported
	Trazodone Hydrochloride			S		150mg		Not Reported
	Lexapro			S		10 Mg		Not Reported
	Truxal			S		2 Tabs		Not Reported
	Cipralex			S	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14305732	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1771280US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sensation In Eye; Agitation; Anxiety; Fall; Feeling Abnormal; Hypertension; Hypotension; Malaise; Movement Disorder; Muscle Twitching;	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qam		Allergan
	Brintellix			S	Unknown	5 Mg, Qd		Not Reported
	Tranxene			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

Musculoskeletal Stiffness; Panic Attack; Suicidal Ideation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	13400984	EXPEDITED (15-DAY)		DE, DS	CH-GLAXOSMITHKLINE-CH2017044762		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Assisted Suicide; Muscle Rigidity; Psychomotor Retardation; Somnolence; Tremor	Quetiapine			S	Oral	25 Mg, Tid		Glaxosmithkline
	Lamictal			S	Unknown	200 Mg, Qd		Glaxosmithkline
	Escitalopram			S	Oral	10 Mg, Qd Starting Date Unknown		Glaxosmithkline
	Escitalopram			S	Oral	10 Mg, Qd		Glaxosmithkline
	Depakine Chrono			S	Oral	1000 Mg, Bid Start Of Administration Unkown		Not Reported
	Depakine Chrono			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Oral	1 Mg Morning-Noon And 2.5 Mg In The Evening With A Reserve Of 1 Mg 2 X/Day		Not Reported
	Ziagen			C	Unknown	Unk		Viiv
	Aspirin Cardio			C	Unknown	Unk		Glaxosmithkline
	Zeffix			C	Unknown	Unk		Glaxosmithkline
	Metamucil			C	Unknown	Unk		Glaxosmithkline
	Dafalgan			C	Unknown	Unk		Glaxosmithkline
	Calciparine			C	Unknown	Unk		Not Reported
	Nexium			C	Unknown	Unk		Not Reported
	Intelence			C	Unknown	Unk		Not Reported
	Imodium			C	Unknown	Unk		Not Reported
	Isentress			C	Unknown	Unk		Not Reported
	Vi-De 3			C	Unknown	Unk		Not Reported

	Buscopan	C	Unknown	Unk		Not Reported
	Zolpidem	C	Unknown	Unk		Not Reported
	Colestyramine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14070067	EXPEDITED (15-DAY)		HO	CA-CIPLA LTD.-2017CA17887			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Bupropion			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Olanzapine			S	Unknown	Unk		Invagen
	Quetiapine			S	Unknown	Unk		Not Reported
	Phenytoin			S	Unknown	Unk		Not Reported
	Primidone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14306475	EXPEDITED (15-DAY)		DE	US-TORRENT-00005537		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Zolpidem			S	Oral			Unknown
	Cyclobenzaprine			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Alprazolam			S	Oral			Unknown
	Desogestrel And Ethinyl Estradiol			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14306881	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US23185			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Necrotising Colitis	Escitalopram		S	Transplacental	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14307887	EXPEDITED (15-DAY)		HO, LT	FR-CIPLA LTD.-2017FR24076			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria; Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence	Atorvastatin			S	Oral	Unk		Cipla
	Atorvastatin			S	Oral	40 Mg, Per Day		Cipla
	Ramipril			S	Oral	Unk		Invagen
	Ramipril			S	Oral	2.5 Mg^2/Day		Invagen
	Escitalopram			S	Oral	Unk		Invagen
	Escitalopram			S	Oral	5 Mg, Per Day		Invagen
	Diffu-K			S	Oral	Unk		Not Reported
	Diffu-K			S	Oral	Unk		Not Reported
	Bisoprolol Fumarate			S	Oral	2, Per Day, 3.25 Mg In The Morning And 2.5 Mg In The Evening		Not Reported
	Bisoprolol Fumarate			S	Oral	Unk		Not Reported
	Brilique			S	Oral	90 Mg^2/Day		Not Reported
	Brilique			S	Oral	Unk		Not Reported
	Inexium			C	Unknown	20 Mg, Per Day		Not Reported
	Kardegic			C	Unknown	75 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14308114	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2017US23177			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Foetal Exposure During	Escitalopram			S	Transplacental	Unk		Invagen

Pregnancy; Serotonin Syndrome; Toxicity To Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14309019	EXPEDITED (15-DAY)		HO, OT	DE-DRREDDYS-GER/GER/17/0095161		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Quetiapine			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Lorazepam			S				Not Reported
	Lorazepam			S				Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14309134	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017540187		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Abuse; Respiratory Arrest	Alprazolam			S		Unk		Pfizer
	Cocaine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Bupropion			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14309345	EXPEDITED (15-DAY)		OT	PK-JNJFOC-20171219218			Unknown	PAK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Risperidone			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Domperidone			S	Unknown			Not Reported
	Zuclopenthixol			S	Unknown			Not Reported

Amlodipine	S	Unknown		Not Reported
Quetiapine	S	Unknown		Not Reported
Escitalopram	S	Unknown		Not Reported
Fluoxetine	S	Unknown		Not Reported
Metronidazole	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14310245	EXPEDITED (15-DAY)		HO	AT-OTSUKA-2017_026748			Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Drug Interaction; Gamma-Glutamyltransferase Increased	Abilify			S	Oral	2.5 Mg, Unk		Otsuka
	Abilify			S	Unknown	2.5 Mg, Unk		Otsuka
	Abilify			S	Unknown	5 Mg, Daily		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S	Oral	7.5 Mg, Unk		Otsuka
	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	5 Mg, Unk		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	5 Mg, Unk		Not Reported
	Trittico			S	Oral	100 Mg, Unk		Not Reported
	Trittico			S	Oral	150 Mg, Unk		Not Reported
	Trittico			S	Oral	250 Mg, Unk		Not Reported
	Trittico			S	Oral	300 Mg, Unk		Not Reported
	Trittico			S	Oral	150 Mg, Unk		Not Reported
	Sycrest			S	Unknown	5 Mg, Unk		Not Reported
	Sycrest			S	Unknown	10 Mg, Unk		Not Reported
	Sycrest			S	Unknown	15 Mg, Unk		Not Reported

Sycrest	S	Unknown	20 Mg, Unk	Not Reported
Sycrest	S	Unknown	15 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	25 Mg, Unk	Not Reported
Zyprexa	S	Oral	30 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	30 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Quilonium R	S	Unknown	400 Mg, Unk	Not Reported
Quilonium R	S	Unknown	900 Mg, Unk	Not Reported
Quilonium R	S	Unknown	675 Mg, Unk	Not Reported
Quilonium R	S	Unknown	450 Mg, Unk	Not Reported
Zeldox	S	Unknown	20 Mg, Unk	Not Reported
Zeldox	S	Unknown	40 Mg, Unk	Not Reported
Zeldox	S	Unknown	80 Mg, Unk	Not Reported
Zeldox	S	Unknown	120 Mg, Unk	Not Reported
Fluctine	S	Unknown	20 Mg, Unk	Not Reported
Lamictal	C	Oral	75 Mg, Unk	Not Reported
Lamictal	C	Oral	200 Mg, Unk	Not Reported
Lamictal	C	Oral	100 Mg, Unk	Not Reported
Lamictal	C	Oral	250 Mg, Unk	Not Reported
Lamictal	C	Oral	50 Mg, Unk	Not Reported
Lamictal	C	Oral	300 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported

Temesta (Lorazepam)	C	Oral	4.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	7.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	7.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	10 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5 Mg, Unk	Not Reported
Nozinan	C	Unknown	150 Mg, Unk	Not Reported
Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	25 Mg, Unk	Not Reported

Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	50 Mg, Unk	Not Reported
Praxiten	C	Unknown	50 Mg, Unk	Not Reported
Praxiten	C	Unknown	25 Mg, Unk	Not Reported
Akineton	C	Unknown	4 Mg, Unk	Not Reported
Akineton	C	Unknown	2 Mg, Unk	Not Reported
Akineton	C	Unknown	Unk	Not Reported
Akineton	C	Unknown	2 Mg, Unk	Not Reported
Quilonorm	C	Unknown	Unk	Not Reported
Risperdal	C	Unknown	2 Mg, Unk	Not Reported
Risperdal	C	Unknown	1 Mg, Unk	Not Reported
Nubain	C	Unknown	1 Unk, 1df In 100ml Nacl	Not Reported
Truxal	C	Unknown	50 Mg, Unk	Not Reported
Gastrozepin	C	Unknown	100 Mg, Unk	Not Reported
Neurotrop	C	Oral	600 Mg, Unk	Not Reported
Neurotrop	C	Oral	900 Mg, Unk	Not Reported
Neurotrop	C	Oral	300 Mg, Unk	Not Reported
Neurotrop	C	Oral	600 Mg, Unk	Not Reported
Neurotrop	C	Oral	900 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	40 Mg, Unk	Not Reported
Inderal	C	Oral	50 Mg, Unk	Not Reported
Inderal	C	Oral	90 Mg, Unk	Not Reported
Inderal	C	Oral	40 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	60 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	20 Mg, Unk	Not Reported
Zoldem	C	Unknown	5 Mg, Unk	Not Reported

Rivotril	C	Unknown	4 Mg, Unk		Not Reported
Rivotril	C	Unknown	1 Mg, Unk		Not Reported
Rivotril	C	Unknown	2 Mg, Unk		Not Reported
Rivotril	C	Unknown	4 Mg, Unk		Not Reported
Rivotril	C	Unknown	2 Mg, Unk		Not Reported
Adasuve	C	Unknown	Unk		Not Reported
Dibondrin	C	Unknown	50 Mg, Unk		Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk		Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk		Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	80 Mg, Unk		Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	120 Mg, Unk		Not Reported
Sifrol	C	Unknown	0.26 Mg, Unk		Not Reported
Sifrol	C	Unknown	0.34 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14070525	EXPEDITED (15-DAY)		OT	AT-ELI_LILLY_AND_COMPANY-AT201709012029		57 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Food Craving; Gamma-Glutamyltransferase Increased; Increased Appetite; Neutrophil Percentage Decreased; Weight Increased	Zyprexa Velotab 15mg			S	Oral	10 Mg, Unknown		Not Reported
	Zyprexa Velotab 15mg			S	Oral	15 Mg, Unknown		Not Reported
	Zyprexa Velotab 15mg			S	Oral	5 Mg, Unknown		Not Reported
	Cymbalta 30mg			S	Unknown	30 Mg, Unknown		Eli Lilly And Co
	Seroquel			S	Oral	50 Mg, Unknown		Not Reported
	Seroquel			S	Oral	400 Mg, Unknown		Not Reported
	Seroquel			S	Oral	500 Mg, Unknown		Not Reported
	Seroquel			S	Oral	450 Mg, Unknown		Not Reported
	Seroquel			S	Oral	500 Mg, Unknown		Not Reported

Seroquel	S	Oral	400 Mg, Unknown	Not Reported
Seroquel	S	Oral	300 Mg, Unknown	Not Reported
Seroquel	S	Oral	100 Mg, Unknown	Not Reported
Seroquel	S	Oral	50 Mg, Unknown	Not Reported
Seroquel	S	Oral	100 Mg, Unknown	Not Reported
Seroquel	S	Oral	50 Mg, Unknown	Not Reported
Quetiapine Xr	S	Oral	100 Mg, Unknown	Not Reported
Quetiapine Xr	S	Oral	200 Mg, Unknown	Not Reported
Quetiapine Xr	S	Oral	50 Mg, Unknown	Not Reported
Quetiapine Xr	S	Oral	200 Mg, Unknown	Not Reported
Quetiapine Xr	S	Oral	100 Mg, Unknown	Not Reported
Pregabalin	S	Oral	150 Mg, Unknown	Not Reported
Pregabalin	S	Oral	300 Mg, Unknown	Not Reported
Pregabalin	S	Oral	450 Mg, Unknown	Not Reported
Cipralex /01588502/	S	Oral	10 Mg, Unknown	Not Reported
Cipralex /01588502/	S	Unknown	15 Mg, Unknown	Not Reported
Cipralex /01588502/	S	Unknown	20 Mg, Unknown	Not Reported
Cipralex /01588502/	S	Unknown	30 Mg, Unknown	Not Reported
Lamotrigin	C	Oral	50 Mg, Unknown	Not Reported
Temesta /00273201/	C	Oral	5 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	1.25 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	1.25 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	2.5 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	2.5 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	2.5 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	2.5 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	2.5 Mg, Unknown	Not Reported
Rivotril	C	Unknown	1 Mg, Unknown	Not Reported
Thyrex	C	Oral	50 Ug, Unknown	Not Reported

	Combithyrex		C	Unknown	1 Df, Unknown	Not Reported
	Molaxole		C	Oral	1 Df, Unknown	Not Reported
	Molaxole		C	Unknown	2 Df, Unknown	Not Reported
	Molaxole		C	Unknown	3 Df, Unknown	Not Reported
	Molaxole		C	Unknown	1 Df, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14312426	EXPEDITED (15-DAY)		DE	FR-CIPLA LTD.-2017FR24395			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Escitalopram			S	Unknown	Unk		Invagen
	Uptravi			S	Oral	1400 Mg, Unk		Not Reported
	Inexium			S	Unknown	Unk		Not Reported
	Previscan (Fluindione)			S	Unknown	Unk		Not Reported
	Revatio			S	Unknown	Unk		Not Reported
	Selexipag			S	Oral	1400 Mg, Unk		Not Reported
	Lasilix			S	Unknown	Unk		Not Reported
	Aldactone			S	Unknown	Unk		Not Reported
	Tracleer			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14312430	EXPEDITED (15-DAY)		DS	HU-ALLERGAN-1772824US		22 YR	Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Emotional Poverty; Genital Hypoaesthesia; Loss Of Libido	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14313059	EXPEDITED (15-DAY)		HO, LT	FR-CIPLA LTD.-2017FR24269			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Levofloxacin			S	Oral	2 Df, Unk		Cipla
	Irbesartan			S	Oral	300 Mg, Unk		Cipla
	Amlodipine			S	Oral	10 Mg, Unk		Invagen
	Pantoprazole			S	Oral	20 Mg, Unk		Cipla
	Metformin			S	Oral	1000 Mg, Unk		Not Reported
	Furosemide			S	Oral	30 Mg, Unk		Not Reported
	Alprazolam			S	Oral	0.75 Mg, Unk		Not Reported
	Dafalgan			S	Oral	6 Df, Unk		Not Reported
	Mirtazapine			S	Oral	15 Mg, Unk		Not Reported
	Nefopam Hydrochloride			S	Oral	3 Df, Unk		Not Reported
	Diffu K			S	Oral	3 Df, Unk		Not Reported
	Colchicine Opocalcium			S	Oral	1 Df, Unk		Not Reported
	Xarelto			S	Oral	1 Df, Unk		Not Reported
	Seroplex			S	Oral	1 Df, Unk		Not Reported
	Valium			S	Oral	3 Df, Unk		Not Reported
	Bisoprolol Hemifumarate			S	Oral	1.25 Mg, Unk		Not Reported
	Terbutaline Sulphate			S	Respiratory (inhalation)	1 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14314745	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017544308		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lorazepam			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Lithium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14314747	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017544437		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Phenytoin			S	Oral	Unk		Pfizer
	Carvedilol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Sitagliptin			S	Oral	Unk		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Primidone			S	Oral	Unk		Not Reported
	Valproic Acid			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	11186090	EXPEDITED (15-DAY)		HO, OT	AT-ELI_LILLY_AND_COMPANY-AT201506001187			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Blood Triglycerides Increased; Fatigue; Frustration Tolerance Decreased; Kidney Enlargement; Liver Injury; Neutrophil Count Decreased; Splenomegaly; Tremor; Weight Increased	Cymbalta			S	Oral	60 Mg, Unknown		Eli Lilly And Co
	Lyrica			S	Unknown	300 Mg, Unknown		Not Reported
	Lyrica			S	Unknown	600 Mg, Unknown		Not Reported
	Lyrica			S	Oral	750 Mg, Unknown		Not Reported
	Lyrica			S	Oral	450 Mg, Unknown		Not Reported
	Lyrica			S	Oral	375 Mg, Unknown		Not Reported
	Lyrica			S	Oral	300 Mg, Unknown		Not Reported
	Lyrica			S	Oral	150 Mg, Unknown		Not Reported
	Risperdal			S	Unknown	0.5 Mg, Unknown		Not Reported
	Risperdal			S	Unknown	1 Mg, Unknown		Not Reported
	Risperdal			S	Unknown	2 Mg, Unknown		Not Reported
	Cipralex /01588501/			S	Oral	10 Mg, Unknown		Not Reported

Cipralex /01588501/	S	Oral	10 Mg, Unknown		Not Reported
Cipralex /01588501/	S	Oral	15 Mg, Unknown		Not Reported
Cipralex /01588501/	S	Oral	15 Mg, Unknown		Not Reported
Cipralex /01588501/	S	Oral	10 Mg, Unknown		Not Reported
Topamax	S	Oral	25 Mg, Unknown		Not Reported
Topamax	S	Oral	50 Mg, Unknown		Not Reported
Topamax	S	Oral	100 Mg, Unknown		Not Reported
Topamax	S	Oral	25 Mg, Unknown		Not Reported
Rivotril	C	Unknown	0.5 Mg, Unknown		Not Reported
Wellbutrin	C	Unknown	Unk, Unknown		Not Reported
Pantoloc /01263204/	C	Unknown	40 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	13824271	EXPEDITED (15-DAY)		OT	CH-ELI_LILLY_AND_COMPANY-CH201707011883		23 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Cerebral Cyst; Drug Ineffective; Maternal Exposure During Pregnancy	Zyprexa			S	Oral	20 Mg, Daily		Eli Lilly And Co
	Cipralex /01588501/			S	Oral	15 Mg, Daily		Not Reported
	Trittico			S	Oral	50 Mg, Daily		Not Reported
	Paliperidone			S	Oral	3 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14257389	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-156226		3 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Attention Deficit/Hyperactivity Disorder; Condition Aggravated; Disease	Citoles (Drop Form)			S	Oral	1 To 2 Mg/D		Not Reported
	Citoles (Drop Form)			S				Not Reported
	Risperdal Liquid			S	Oral	0.25 Mg, Daily		Not Reported
	Abilify Liquid			S	Oral	1 To 2 Mg/D		Not Reported

Progression; Energy Increased; Flight Of Ideas; Initial Insomnia; Insomnia; Irritability; Logorrhoea; Mania; Obsessive-Compulsive Disorder; Pressure Of Speech; Self Esteem Inflated; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14259460	EXPEDITED (15-DAY)		HO	TW-ALLERGAN-1769398US		22 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14288415	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1771267US		37 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Loss Of Consciousness; Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Lendormin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14316295	EXPEDITED (15-DAY)		HO	FR-GLENMARK PHARMACEUTICALS-2017GMK030105			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Metformin Hydrochloride			S	Oral	1000 Mg, Qd		Glenmark
	Dafalgan			S	Oral	6 Df, Qd		Not Reported
	Alprazolam			S	Oral	0.75 Mg, Qd		Not Reported
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported

	Nefopam Hydrochloride	S	Oral	3 Df, Qd	Not Reported
	Diffu K	S	Oral	3 Df, Unk	Not Reported
	Amlodipine	S	Oral	10 Mg, Qd	Not Reported
	Colchicine Opocalcium	S	Oral	1 Df, Od	Not Reported
	Xarelto	S	Oral	1 Df, Qd	Not Reported
	Pantoprazole	S	Oral	20 Mg, Qd	Not Reported
	Seroplex	S	Oral	1 Df, Qd	Not Reported
	Tavanic	S	Oral	2 Df, Qd	Not Reported
	Valium	S	Oral	3 Df, Qd	Not Reported
	Bisoprolol Hemifumarate	S	Oral	1.25 Mg, Qd	Not Reported
	Furosemide	S	Oral	30 Mg, Unk	Not Reported
	Terbutaline Sulphate	S	Respiratory (inhalation)	1 Df, Unk	Not Reported
	Irbesartan	S	Oral	300 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14316310	EXPEDITED (15-DAY)		DE, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-115740		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metformin Hydrochloride			S	Oral			Bristol Myers Squibb
	Glyburide,Metformin Hydrochloride			S	Oral			Bristol Myers Squibb
	Diltiazem			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14318974	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2017M1079815			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anxiety Disorder; Cardiometabolic Syndrome; Cholelithiasis; Chronic Kidney Disease; Constipation; Electrocardiogram Qt Prolonged; Gastritis; Gastrooesophageal Reflux Disease; Hepatic Cirrhosis; Hepatic Steatosis; Hepatitis B; Hypertension; Hypertriglyceridaemia; Hypoacusis; Impaired Fasting Glucose; Left Ventricular Dysfunction; Oesophagitis; Renal Cyst; Renal Impairment; Schizophrenia; Tachycardia; Varices Oesophageal; Vitamin D Deficiency	Lipidil			S				Mylan
	Escitalopram			S	Unknown			Not Reported
	Amisulpride			S				Not Reported
	Entecavir			S				Not Reported
	Clozapine			S				Not Reported
	Clopine			S				Mylan
	Movicol			S				Mylan
	Norvask /00972401/			S				Mylan
	Fishaphos (Herbs\Minerals\Vitamins)			S				Mylan
	Ostelin Vitamin D			S				Mylan
	Zantac			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14318991	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017544259		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil Hcl			S	Oral	Unk		Pfizer
	Alprazolam			S	Oral	Unk		Pfizer
	Flecainide			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14319477	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017540513		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Gabapentin			S	Oral	Unk		Pfizer
	Ibuprofen			S	Oral	Unk		Pfizer
	Amitriptyline			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14319521	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2017M1080788		81 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14319740	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017540212		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S	Oral	Unk		Pfizer
	Glucophage			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Naproxen Sodium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2017	14274775	EXPEDITED (15-DAY)		HO, OT	DE-HETERO CORPORATE-HET2017DE00397		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test	Escitalopram			S	Oral	20 Mg, Qd		Not Reported

Increased	Escitalopram	S	Oral	20 Mg, Qd		Not Reported
	Escitalopram	S	Oral	10 Mg		Not Reported
	Quetiapine Fumarate	S	Oral	50 Mg, Qd		Not Reported
	Quetiapine Fumarate	S	Oral	50 Mg, Qd		Not Reported
	Quetiapine Fumarate	S	Oral	150 Mg		Not Reported
	Quetiapine Fumarate	S		50 Unk		Not Reported
	Lorazepam	S	Oral	0.25 Mg, Qd		Not Reported
	Lorazepam	S	Oral	1.5 Mg, Qd		Not Reported
	Lorazepam	S	Oral	1 Mg, Qd		Not Reported
	Lorazepam	S	Oral	0.9 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2017	14300026	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2017-46135		81 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram 10 Mg			S	Oral	10 Mg, Unk		Aurobindo
	Escitalopram 10 Mg 28 Comprimidos			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2017	14320903	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-MACLEODS PHARMACEUTICALS US LTD-MAC2017007131			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication;	Escitalopram Tablet			S	Oral	Unk		Macleods
	Olanzapine Tablet			S	Oral	Unk		Macleods
	Xeplion			S	Unknown	Unk		Not Reported
	Risperidone			S	Oral	Unk		Not Reported
	Risperdal			S	Unknown	Unk		Not Reported
	Paliperidone Palmitate			S	Unknown	Unk, Suspension For		Not Reported

Shoulder Deformity; Weight Increased					Injection	
	Zyprexa		S	Unknown	Unk	Not Reported
	Abilify		S	Oral	Unk	Not Reported
	Cipralex		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2017	14321092	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2017007140			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Off Label Use; Respiratory Distress; Somnolence	Escitalopram Oxalate 20mg Tablet			S	Oral	20 Mg, Qd		Macleods
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Lorazepam			S	Oral	2.5 Mg, Unk		Not Reported
	Seroplex			S	Oral	20 Mg, Unk		Not Reported
	Temesta (Lorazepam)			S	Oral	2.5 Mg, Unk		Not Reported
	Carbamazepine			C	Oral	400 Mg, Unk		Not Reported
	Domperidone			C	Unknown	Unknown		Not Reported
	Pantoprazole			C	Unknown	Unknown		Macleods
	Tamsulosin			C	Unknown	0.4 Mg, Unk		Macleods
	Tamsulosin			C	Unknown	0.4 Mg, Unk		Macleods
	Allopurinol			C	Unknown	Unknown		Not Reported
	Avodart			C	Oral	Unknown		Not Reported
	Bisoce			C	Oral	Unknown		Not Reported
	Dafalgan			C	Oral	Unknown		Not Reported
	Flodil [Felodipine]			C	Oral	Unknown		Not Reported
	Gardenal			C	Oral	Unknown		Not Reported
	Inegy			C	Oral	Unknown		Not Reported
	Kardegic			C	Oral	Unknown		Not Reported
	Loperamide			C	Unknown	Unknown		Not Reported

	Omexel	C	Oral	Unknown	Not Reported
	Omexel	C	Unknown	Unknown	Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Unknown	Unknown	Not Reported
	Tegretol	C	Oral	Unknown	Not Reported
	Topalgic (Tramadol Hydrochloride)	C	Oral	Unknown	Not Reported
	Topalgic (Tramadol Hydrochloride)	C	Unknown	Unknown	Not Reported
	Uvedose	C	Oral	Unknown	Not Reported
	Ventoline	C	Unknown	Unknown	Not Reported
	Vesicare	C	Oral	Unknown	Not Reported
	Vesicare	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2017	14321477	EXPEDITED (15-DAY)		DS, OT	HU-CIPLA LTD.-2017HU24990			Unknown	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Apathy; Emotional Poverty; Genital Hypoaesthesia; Loss Of Libido	Escitalopram			S	Unknown	5 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2017	14321763	EXPEDITED (15-DAY)		DE, OT	US-MYLANLABS-2015010067		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Zolpidem			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Hydrocodone W/Acetaminophen			S	Oral	Unk		Mylan
	Ondansetron			S	Oral	Unk		Not Reported
	Linaclotide			S	Oral	Unk		Mylan

	Diclofenac	S	Oral	Unk		Not Reported
	Lubiprostone	S	Oral	Unk		Mylan
	Liothyronine	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Sertraline	S	Oral	Unk		Not Reported
	Gabapentin	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2017	14322626	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2017SF29132		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Formication; Hyperkalaemia; Myalgia; Testicular Pain	Inexium			S	Oral	1.0df Unknown		Astrazeneca
	Escitalopram			S	Oral	10.0mg Unknown		Not Reported
	Pravastatine Sodique			C	Oral			Not Reported
	Pregabalin			C	Oral	50.0mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	9745762	EXPEDITED (15-DAY)		DE, LT	PHHY2013NO141077		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Self-Injury	Tramadol			S				Novartis
	Tramadol			S	Unknown			Novartis
	Levomepromazine Maleate			S	Unknown	Unk Ukn, Unk		Not Reported
	Atarax			S	Unknown	Unk Ukn, Unk		Not Reported
	Pinex Forte			S	Unknown			Not Reported
	Pinex Forte			S				Not Reported
	Vival			S	Unknown			Not Reported
	Vival			S				Not Reported
	Diazepam			S	Unknown			Not Reported
	Truxal			S	Unknown			Not Reported
	Truxal			S				Not Reported

Hydroxyzine	S	Unknown	Unk Ukn, Unk		Not Reported
Nozinan	S				Not Reported
Imovane	S	Oral			Not Reported
Imovane	S	Oral			Not Reported
Sobril	S	Unknown			Not Reported
Lamictal	S	Unknown			Not Reported
Lamictal	S				Not Reported
Nobligan	S	Unknown			Not Reported
Nobligan	S				Not Reported
Sarotex	S	Unknown			Not Reported
Sarotex	S				Not Reported
Orfiril	S	Unknown			Not Reported
Orfiril	S				Not Reported
Cipralex	S	Unknown			Not Reported
Cipralex	S				Not Reported
Catapresan	S	Unknown			Not Reported
Catapresan	S				Not Reported
Oxynorm	S	Unknown			Not Reported
Oxynorm	S				Not Reported
Seroquel	S	Unknown			Not Reported
Seroquel	S				Not Reported
Rivotril	S	Unknown			Not Reported
Rivotril	S				Not Reported
Remeron	S	Unknown			Not Reported
Remeron	S				Not Reported
Cipramil [Citalopram Hydrochloride]	S	Unknown	Unk Ukn, Unk		Not Reported
Cyanocobalamin	C				Not Reported
Diamorphine	C				Not Reported
Forte	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14255823	EXPEDITED (15-DAY)		OT	JP-JNJFOC-20170728213		60 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Constipation; Hypoaesthesia; Parkinsonism	Tramcet		S	Oral		Not Reported
	Lexapro		S	Oral	Dose: 2.5-5 Mg	Not Reported
	Lexapro		S	Oral		Not Reported
	Toledomin		S	Oral		Not Reported
	Cymbalta		C	Oral		Not Reported
	Voltaren		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14322889	EXPEDITED (15-DAY)		DE, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-115761		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Glucophage			S	Oral			Bristol Myers Squibb
	Alprazolam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14323093	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-157215		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Lethargy; Somnolence; Suicide Attempt	Loperamide			S	Oral	Unk		Ranbaxy
	Escitalopram			S	Unknown	Unk		Not Reported
	Meloxicam			S	Unknown	Unk		Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14323352	NON-EXPEDITED			US-TEVA-2017-US-835719			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyperhidrosis; Product Size Issue	Escitalopram		S	Unknown	Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14323564	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023026		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diphenhydramine			S	Oral	Unk		Apotex
	Fluoxetine			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Risperidone			S	Oral	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14325957	EXPEDITED (15-DAY)		HO, LT	PHHY2017ES190203		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose	Quetiapine			S	Oral	19 G, Unk		Novartis
	Escitalopram			S	Oral	30 Mg, Unk		Not Reported
	Abilify			S	Oral	30 Mg, Unk		Not Reported
	Clonazepam			S	Oral	22.5 Mg, Unk		Not Reported
	Antabus			S	Oral	250 Mg, Unk		Not Reported
	Valproato De Sodio			S	Oral	3.6 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14325981	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1773510US		34 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Timing Unspecified	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
	Abilify Maintena			S	Unknown	1 Df, Unknown		Not Reported
	Abilify			S	Oral	15 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	12412887	NON-EXPEDITED			US-PFIZER INC-2016274985		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Zoloft			S	Oral	100 Mg, Unk		Pfizer
	Lexapro			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	13407051	EXPEDITED (15-DAY)		DS	CH-ABBVIE-17P-151-1932895-00		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Rigidity; Psychomotor Retardation; Somnolence; Tremor	Depakine Chrono			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Oral			Not Reported
	Escitalopram (Escitalopram Oxalate)			S	Oral			Not Reported
	Lamictal (Lamotrigine)			S	Unknown			Not Reported
	Calciparine (Heparin Calcium)			C	Unknown			Not Reported
	Ziagen (Abacavir Sulfate)			C	Unknown			Not Reported
	Aspirin Cardio (Acetylsalicylic Acid)			C	Unknown			Not Reported
	Colestyramin (Colestyramine)			C	Unknown			Not Reported
	Nexium (Esomeprazole)			C	Unknown			Not Reported
	Intelence (Etravirine)			C	Unknown			Not Reported
	Zeffix (Lamivudine)			C	Unknown			Not Reported
	Imodium (Loperamide Hydrochloride)			C	Unknown			Not Reported
	Metamucil (Plantago Ovata)			C	Unknown			Not Reported

	Isentress (Raltelgravir)	C	Unknown	Not Reported
	Vi-De 3 (Colecalciferol)	C	Unknown	Not Reported
	Buscopan (Hyoscine Butylbromide)	C	Unknown	Not Reported
	Dafalgan (Paracetamol)	C	Unknown	Not Reported
	Zolpidem (Zolpidem Tartrate)	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14223843	EXPEDITED (15-DAY)		OT	PHHY2017AT170968		36 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Cipralex			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14280292	EXPEDITED (15-DAY)		HO, OT	FR-009507513-1712FRA003237		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Norset			S	Oral	15 Mg, 1x/Day		Merck
	Furosemide			S	Oral	30 Mg, Unk		Not Reported
	Dafalgan			S	Oral	6 Df, 1x/Day		Not Reported
	Alprazolam			S	Oral	0.75 Mg, 1x/Day		Not Reported
	Nefopam Hydrochloride			S	Oral	3 Df, 1x/Day		Not Reported
	Diffu-K			S	Oral	3 Df, Unk		Not Reported
	Amlodipine			S	Oral	10 Mg, 1x/Day		Not Reported
	Colchicine			S	Oral	1 Df, 1x/Day		Not Reported
	Xarelto			S	Oral	1 Df, 1x/Day		Not Reported
	Pantoprazole			S	Oral	20 Mg, 1x/Day		Not Reported
	Metformin			S	Oral	1000 Mg, 1x/Day		Not Reported

	Seroplex	S	Oral	1 Df, 1x/Day	Not Reported
	Tavanic	S	Oral	30 Mg, 1x/Day	Not Reported
	Valium	S	Oral	3 Df, 1x/Day	Not Reported
	Bisoprolol Fumarate	S	Oral	1.25 Mg, 1x/Day	Not Reported
	Terbutaline Sulfate	S	Respiratory (inhalation)	1 Df, Unk	Not Reported
	Irbesartan	S	Oral	300 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14288884	EXPEDITED (15-DAY)		HO	FR-ZYDUS-018403		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Dafalgan			S	Oral	1000 Mg		Not Reported
	Alprazolam			S	Oral			Not Reported
	Mirtazapine			S	Oral	15 Mg, Once Daily		Not Reported
	Nefopam			S	Oral	1 Df, 3x/Day		Not Reported
	Diffu K			S	Oral	3 Df Daily (2-1-0) 2x/Day		Not Reported
	Amlodipine			S	Oral	10 Mg, Once Daily		Zydus Pharm
	Colchicine			S	Oral	1 Mg, Once Daily		Not Reported
	Xarelto			S	Oral	20 Mg, Once Daily		Not Reported
	Pantoprazole			S	Oral	20 Mg, Once Daily		Not Reported
	Metformin			S	Oral	500 Mg, 2x/Day (Bid)		Not Reported
	Seroplex			S	Oral			Not Reported
	Tavanic			S	Oral			Not Reported
	Valium			S	Oral	10 Mg, 3x/Day		Not Reported
	Bisoprolol			S	Oral	1.25 Mg, Once Daily		Not Reported
	Furosemide			S	Oral	30 Mg Daily (2-1-0), 2x/Day		Not Reported
	Terbutaline			S	Respiratory (inhalation)			Not Reported

	Irbesartan	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14326443	EXPEDITED (15-DAY)		DE	FR-009507513-1712FRA012281		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Mirtazapine			S	Oral	45 Mg, Qd		Merck
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported
	Orozamudol			S	Oral	150 Mg, Qd		Not Reported
	Escitalopram			S	Oral	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14326653	NON-EXPEDITED			US-TEVA-2017-US-830603		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Product Formulation Issue; Product Substitution Issue	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14326847	EXPEDITED (15-DAY)		OT	AU-ABBVIE-17S-008-2204138-00			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anxiety Disorder; Cardiometabolic Syndrome; Cholelithiasis; Chronic Kidney Disease; Constipation; Electrocardiogram Qt Prolonged; Gastritis; Gastrooesophageal Reflux Disease; Hepatic Cirrhosis; Hepatic	Lipidil			S	Unknown			Not Reported
	Amisulpride			S	Unknown			Not Reported
	Entecavir			S	Unknown			Not Reported
	Clozapine			S	Unknown			Not Reported
	Clopine			S	Unknown			Not Reported
	Movicol			S	Unknown			Not Reported
	Norvask			S	Unknown			Not Reported
	Fishaphos			S	Unknown			Not Reported

Steatosis; Hepatitis B; Hypertension; Hypertriglyceridaemia; Hypoacusis; Impaired Fasting Glucose; Left Ventricular Dysfunction; Oesophagitis; Renal Cyst; Renal Impairment; Schizophrenia; Tachycardia; Varices Oesophageal; Vitamin D Deficiency	(Herbs\Minerals\Vitamins) Ostelin Vitamin D	S	Unknown		Not Reported
	Zantac	S	Unknown		Not Reported
	Escitalopram	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14328031	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP023288		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diltiazem			S	Oral	Unk		Apotex
	Metformin			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Losartan			S	Oral	Unk		Apotex
	Propranolol			S	Oral	Unk		Not Reported
	Glyburide			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14328044	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017549342		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Interstitial Lung Disease	Venlafaxine Hcl			S		37.5 Mg, Unk		Pfizer
	Duloxetine			S		15 Mg, Unk		Not Reported
	Escitalopram			S		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14328718	NON-EXPEDITED			US-SUNOVION-2017SUN005266			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Libido; Sexual Dysfunction	Latuda			S	Oral	Unk		Sunovion
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14329417	EXPEDITED (15-DAY)		HO, OT	AT-PFIZER INC-2017543147		26 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Lorazepam			S		6.25 Mg, Unk		Pfizer
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Abilify			S		Unk		Not Reported
	Truxal			S		2 Tabs		Not Reported
	Cipralex			S	Unknown	10 Mg, Unk		Not Reported
	Trazodone Hydrochloride			S		150 Mg		Not Reported
	Lexapro			S		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14329932	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017543386		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Propanolol Hcl			S	Oral	Unk		Unknown
	Alprazolam			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Acetaminophen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14329934	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017543384		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Propanolol Hcl			S	Oral	Unk		Unknown
	Propanolol Hcl			S		Unk (Aspiration)		Unknown
	Escitalopram			S	Oral	Unk		Not Reported
	Escitalopram			S		Unk (Aspiration)		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Lamotrigine			S		Unk (Aspiration)		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Mirtazapine			S		Unk (Aspiration)		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S		Unk (Aspiration)		Not Reported
	Buspirone			S	Oral	Unk		Not Reported
	Buspirone			S		Unk (Aspiration)		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Clonazepam			S		Unk (Aspiration)		Not Reported
	Activated Charcoal			S	Oral	Unk		Not Reported
	Activated Charcoal			S		Unk (Aspiration)		Not Reported
	Citalopram			S	Oral			Not Reported
	Citalopram			S		Unk (Aspiration)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14330000	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017543377		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Propanolol Hcl			S	Oral	Unk		Unknown
	Ibuprofen			S	Oral	Unk		Pfizer

Ondansetron	S	Oral	Unk		Pfizer
Alprazolam	S	Oral	Unk		Pfizer
Escitalopram	S	Oral	Unk		Not Reported
Lamotrigine	S	Oral	Unk		Not Reported
Acetaminophen W/Oxycodone	S	Oral	Unk		Not Reported
Singulair	S	Oral	Unk		Not Reported
Acyclovir /00587301/	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14330253	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1773516US		68 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Burning Sensation; Drug Ineffective; Hyperhidrosis; Nausea; Nervousness; Poor Quality Sleep; Tremor	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	11792123	EXPEDITED (15-DAY)		DE, HO	US-ACTELION PHARMACEUTICALS US, INC.-A-NJ2015-1254		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Ascites; Bronchitis; Cardiac Failure Acute; Clostridium Difficile Infection; Diarrhoea; Disease Progression; Dyspnoea; Fluid Retention; Flushing; Gallbladder Enlargement; Haemoptysis; Headache; Malaise; Muscle Spasms;	Veletri			S	Intravenous (not otherwise specified)	13 Ng/Kg, Per Min		Actelion
	Veletri			S	Intravenous (not otherwise specified)	12 Ng/Kg, Per Min		Actelion
	Tracleer			S	Oral	125 Mg, Bid		Actelion
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported
	Tyvaso			C				Not Reported
	Riociguat			C		2.5 Mg, Qd		Not Reported

Nausea; Pain In Jaw; Paracentesis; Pulmonary Arterial Pressure Increased; Pyrexia; Vomiting; Weight Fluctuation	Riociguat	C	2.5 Mg, Tid		Not Reported
	Warfarin	C			Not Reported
	Escitalopram Oxalate	C	10 Mg, Qd		Not Reported
	Furosemide	C	40 Mg, Qd		Not Reported
	Potassium Chloride	C	10 Mcg, Qd		Not Reported
	Spironolactone	C	100 Mg, 1/2 Tablet Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14077399	EXPEDITED (15-DAY)		HO, OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-090472		14 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Disinhibition; Mental Disorder	Abilify			S	Unknown	Unk		Bristol Myers Squibb
	Cipralex /01588501/			S	Oral	1 Df, Qd		Not Reported
	Cipralex /01588501/			S	Oral	1 Df, Qd		Not Reported
	Cipralex /01588501/			S	Oral	1 Df, Qd		Not Reported
	Calcium 600 Plus Vitamin D			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14330103	EXPEDITED (15-DAY)		OT	PHEH2017US041454			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Malignant Neoplasm Progression; Metastases To Central Nervous System; Metastases To Meninges; Product Use In Unapproved Indication	Tykerb			S	Oral	4 Df, Qd		Not Reported
	Voltaren			S	Topical	1 %, Bid		Not Reported
	Voltaren			S				Not Reported
	Clonazepam Sandoz			S	Unknown			Novartis
	Anastrozole			S	Unknown	1 Mg, Qd		Not Reported
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported
	Potassium Chloride			S	Unknown	10 Ot, Bid		Not Reported
	Nexium			S	Unknown	40 Mg, Bid		Not Reported
	Hydrochlorothiazide			S	Unknown	25 Mg, Qd		Not Reported

	Herceptin		C	Unknown		Not Reported
	Zometa		C	Intravenous (not otherwise specified)	Unk Unk, Qw61d	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14330929	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP023785		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Venlafaxine			S	Unknown	37.5 Mg, Unk, (Standardized To 10 Mg Of Citalopram Equivalent)		Not Reported
	Duloxetine			S	Unknown	15 Mg, Unk, (Standardized To 10 Mg Of Citalopram Equivalent)		Apotex
	Escitalopram			S	Unknown	5 Mg, Unk, (Standardized To 10 Mg Of Citalopram Equivalent)		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14331246	EXPEDITED (15-DAY)		HO, LT	ES-ROCHE-2045252		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Quetiapina			S	Oral			Not Reported
	Valproato			S	Oral			Not Reported
	Antabus			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14331249	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US28893			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Balance Disorder; Cognitive Disorder; Memory Impairment; Psychiatric Symptom; Sleep Disorder; Treatment Failure	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14331375	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2017-FR-002693		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Furosemide			S				Ipca
	Bisoprolol Tablets			S				Not Reported
	Escitalopram			S		20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14332232	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2017540385		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Bupropion			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Acetylsalicylic Acid			S	Oral	Unk		Not Reported
	Losartan			S	Oral	Unk		Not Reported
	Levothyroxine Sodium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14332385	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017540457		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Diltiazem Hcl		S	Oral	Unk	Unknown
	Propanolol Hcl		S	Oral	Unk	Unknown
	Glibenclamide		S	Oral	Unk	Pfizer
	Levothyroxine Sodium		S	Oral	Unk	Pfizer
	Lorazepam		S	Oral	Unk	Pfizer
	Metformin		S	Oral	Unk	Not Reported
	Escitalopram		S	Oral	Unk	Not Reported
	Losartan		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14332787	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-AUROBINDO-AUR-APL-2017-47465		28 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication; Shoulder Deformity; Weight Increased	Olanzapine Tablet			S	Unknown	Unk		Aurobindo
	Xeplion			S	Unknown	Unk ()		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Risperdal			S	Unknown	Unk ()		Not Reported
	Escitalopram			S	Unknown	()		Not Reported
	Paliperidone Palmitate			S	Unknown	()		Not Reported
	Zyprexa			S	Unknown	Unk ()		Not Reported
	Abilify			S	Unknown	Unk ()		Not Reported
	Cipralex /01588501/			S	Unknown	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14332876	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017542709		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Venlafaxine Hcl			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Bupropion			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14332916	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023216		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Bupropion			S	Oral			Apotex
	Escitalopram			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14332939	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP023153		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Valproic Acid			S	Oral	Unk		Apotex
	Carvedilol			S	Oral	Unk		Apotex
	Mirtazapine			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Phenytoin			S	Oral	Unk		Not Reported
	Primidone			S	Oral	Unk		Not Reported
	Sitagliptin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14332940	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP023151		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S	Oral	Unk		Apotex
	Acyclovir			S	Oral	Unk		Apotex
	Alprazolam			S	Oral	Unk		Apotex
	Ondansetron			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Propranolol			S	Oral	Unk		Not Reported

	Acetaminophen W/Oxycodone	S	Oral	Unk		Not Reported
	Ibuprofen	S	Oral	Unk		Not Reported
	Singulair	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14333020	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP023137		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex
	Lithium Carbonate			S	Oral	Unk		Apotex
	Amitriptyline			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14333432	EXPEDITED (15-DAY)		OT	HR-ELI_LILLY_AND_COMPANY-HR201712011138		17 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Somnolence; Suicide Attempt	Olanzapine			S	Oral	20 Mg, Unknown		Eli Lilly And Co
	Aspirin /00002701/			S	Oral	2 Df, Unknown		Not Reported
	Escitalopram			S	Oral	3 Df, Unknown		Not Reported
	Ibuprofen			S	Oral	2 Df, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14333586	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-MYLANLABS-2017M1082524		28 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal	Escitalopram			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Mylan
	Risperidone			S	Unknown	Unk		Mylan

Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication; Shoulder Deformity; Weight Increased	Xeplion	S	Unknown	Unk		Mylan
	Risperdal	S	Unknown	Unk		Mylan
	Paliperidone Palmitate	S	Unknown	Unk		Mylan
	Zyprexa	S	Unknown	Unk		Mylan
	Abilify	S	Unknown	Unk		Mylan
	Cipralex /01588501/	S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14333650	EXPEDITED (15-DAY)		OT	SI-ASTRAZENECA-2017SF30310		49 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Left Ventricular Hypertrophy	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Perindopril			S	Unknown			Not Reported
	Perindopril			S	Unknown			Not Reported
	Indapamide			S	Unknown			Not Reported
	Indapamide			S	Unknown			Not Reported
	Alprazolam			S	Unknown	Unk, Unk, As Needed		Not Reported
	Alprazolam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14333950	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1773734US		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Tahor			S	Oral			Not Reported
	Diffu-K			S	Oral	Unk		Not Reported
	Bisoprolol Fumarate			S	Oral	3.25 Mg, Qam		Not Reported

Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence	Bisoprolol Fumarate		S	Oral	2.5 Mg, Qpm	Not Reported
	Triatec (Codeine Phosphate/Paracetamol)		S	Oral		Not Reported
	Ramipril		S	Oral		Not Reported
	Brilique		S	Oral		Not Reported
	Inexium		C	Unknown	20 Mg, Qd	Not Reported
	Kardegic		C	Unknown	75 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14334769	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023439		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral			Apotex
	Escitalopram			S	Oral			Apotex
	Venlafaxine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	13162567	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/17/0086579			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Ondansetron			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Progesterone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	13401489	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017138586		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper;	Zoloft			S	Oral	700 Mg (14 Tablets), Single		Pfizer

Asthenia; Burning Sensation; Headache; Intentional Overdose; Somnolence; Toxicity To Various Agents	Alprazolam	S	Oral	5 Mg (20 Tablets), Single	Pfizer
	Dafalgan	S	Oral	16 G (32 Tablets), Single	Not Reported
	Seroplex	S	Oral	780 Mg (78 Tablets), Single	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	13841226	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1733376US		23 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Trittico			S	Oral	50 Mg, Unk		Not Reported
	Zyprexa			S	Oral	20 Mg, Qd		Not Reported
	Paliperidone			S	Oral	3 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14317844	EXPEDITED (15-DAY)		HO, OT	AT-ASTRAZENECA-2017SF29252		57 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Increased Appetite; Prescribed Overdose; Weight Increased	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca

Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Cipralex	S	Oral		Not Reported
Cipralex	S	Oral		Not Reported
Cipralex	S	Oral		Not Reported
Cipralex	S	Oral		Not Reported
Zyprexa	S	Unknown		Not Reported
Zyprexa	S	Unknown		Not Reported
Zyprexa	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Rivotril	C	Unknown		Not Reported
Plantago Afra	C	Unknown	Daily	Not Reported
Plantago Afra	C	Unknown	Daily	Not Reported
Plantago Afra	C	Unknown	Daily	Not Reported
Plantago Afra	C	Unknown	Daily	Not Reported
Cymbalta	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported

Temesta (Lorazepam)	C	Unknown			Not Reported
Temesta (Lorazepam)	C	Unknown			Not Reported
Molaxole	C	Unknown	Daily		Not Reported
Molaxole	C	Unknown	Daily		Not Reported
Molaxole	C	Unknown	Daily		Not Reported
Molaxole	C	Unknown	Daily		Not Reported
Combithyrex Mite	C	Unknown	Daily		Not Reported
Lamotrigine	C	Unknown			Not Reported
Thyrex	C	Unknown	50 Ug/Inhalation		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335317	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023042		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Buspirone			S	Oral	Unk		Apotex
	Clonazepam			S	Oral	Unk		Apotex
	Mirtazapine			S	Oral	Unk		Apotex
	Cyclobenzaprine			S	Parenteral	Unk		Not Reported
	Propranolol			S	Parenteral	Unk		Not Reported
	Activated Charcoal			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335330	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023045		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex
	Alprazolam			S	Oral	Unk		Apotex
	Propranolol			S	Oral	Unk		Not Reported

	Amitriptyline	S	Oral	Unk		Not Reported
	Acetaminophen	S	Oral	Unk		Not Reported
	Ethanol	S	Oral	Unk		Not Reported
	Cocaine	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335474	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023441		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Apotex
	Lamotrigine			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335485	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023275		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil			S	Oral	Unk		Apotex
	Flecainide			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Alprazolam			S	Oral	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335502	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP022921		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Abuse	Escitalopram			S	Unknown	Unk		Apotex
	Bupropion			S	Unknown	Unk		Apotex
	Alprazolam			S	Unknown	Unk		Apotex
	Cocaine			S	Unknown	Unk		Not Reported
	Ethanol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335539	EXPEDITED (15-DAY)		HO, OT	FR-IPCA LABORATORIES LIMITED-IPC-2017-FR-003933		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Metformin			S	Oral	500 Mg, Bid		Ipca
	Furosemide			S	Oral	30 Mg, Bid		Ipca
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported
	Bisoprolol Tablets 10mg			S	Oral	1.25 Mg, Qd		Not Reported
	Terbutaline Sulfate			S	Respiratory (inhalation)	1 Df, Qd		Not Reported
	Dafalgan			S	Oral	1000 Mg, Tid		Not Reported
	Irbesartan			S	Oral	300 Mg, Qd		Not Reported
	Alprazolam			S	Oral	0.25 Mg, Tid		Not Reported
	Tavanic			S	Oral	250 Mg, Bid		Not Reported
	Xarelto			S	Oral	20 Mg, Qd		Not Reported
	Diazepam			S	Oral	10 Mg, Tid		Not Reported
	Colchicine Opocalcium			S	Oral	1 Mg, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Nefopam			S	Oral	1 Df, Tid		Not Reported
	Diffu-K			S	Oral	3 Df, Bid		Not Reported
	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335567	EXPEDITED (15-DAY)		HO	ES-TEVA-2017-ES-837863		81 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram 10 Mg 28 Comprimidos			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335659	NON-EXPEDITED		OT	US-TEVA-2017-US-837929			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Suicidal Ideation	Provigil			S	Unknown			Cephalon
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335689	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023032		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral	Unk		Apotex
	Losartan			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Amlodipine			S	Oral	Unk		Apotex
	Salicylate Sodium			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335711	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023005		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Gabapentin			S	Oral			Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Amitriptyline			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335715	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP022991		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Metformin			S	Oral			Apotex
	Naproxen			S	Oral	Unk		Not Reported
	Glucophage			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335740	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP022953		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Other	Unk (Ingstþaspir)		Apotex
	Escitalopram			S	Other	Unk (Aspiration)		Apotex
	Ethanol			S	Other	Unk (Ingstþaspir)		Not Reported
	Ethanol			S	Other	Unk (Aspiration)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14336237	EXPEDITED (15-DAY)		DE	TR-ALLERGAN-1773894US		57 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Remeron			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14336378	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP023417		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Escitalopram	S	Oral	Unk		Apotex
	Loratadine	S	Oral	Unk		Apotex
	Furosemide	S	Oral	Unk		Not Reported
	Levothyroxine	S	Oral	Unk		Not Reported
	Folic Acid	S	Oral	Unk		Not Reported
	Vitamin B-1	S	Oral	Unk		Not Reported
	Ethylene Glycol	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14336401	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023459		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Diphenhydramine			S	Oral			Apotex
	Escitalopram			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14336731	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2017GSK201226			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Malignant Neoplasm Progression; Metastases To Central Nervous System; Metastases To Meninges; Product Use In Unapproved Indication	Diclofenac			S	Topical	1 %, Bid		Glaxosmithkline
	Diclofenac			S				Glaxosmithkline
	Tykerb			S	Oral	4 Df, Qd		Not Reported
	Clonazepam			S		125 Mg, Bid		Not Reported
	Lexapro			S		10 Mg, Qd		Not Reported
	Sulfamethoxazole + Tmp			S		Unk, Z		Not Reported
	Potassium Chloride			S		10 Meq, Bid		Not Reported
	Zofran			S		8 Mg, Prn		Not Reported
	Anastrozole			S		1 Mg, Qd		Not Reported
	Nexium			S		40 Mg, Bid		Not Reported

	Hydrochlorothiazide	S	25 Mg, Qd		Not Reported
	Zometa	C			Not Reported
	Herceptin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14337249	EXPEDITED (15-DAY)		OT	FR-CIPLA LTD.-2017FR27330			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Tongue Oedema	Escitalopram			S	Oral	10 Mg, Daily		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14337621	EXPEDITED (15-DAY)		OT	PHHY2017AU161414		33 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Body Mass Index Increased; Body Temperature Increased; Depressed Mood; Hypoaesthesia; Multiple Sclerosis Relapse; Muscle Spasticity; Musculoskeletal Stiffness; Optic Neuritis; Papilloma Viral Infection; Paraesthesia; Smear Cervix Abnormal; Weight Decreased; Weight Increased	Gilenya			S	Oral	Unk		Novartis
	Gilenya			S	Oral	Unk		Novartis
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Ventolin			C	Unknown	Unk		Not Reported
	Vitamin D2			C	Unknown	Unk		Not Reported
	Multi Vitamin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14337755	EXPEDITED (15-DAY)		OT	SI-PFIZER INC-2017551008		49 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Left Ventricular	Alprazolam			S		Unk Unk, As Needed		Pfizer

Hypertrophy	Escitalopram Oxalate	S	Unk		Not Reported
	Perindopril	S	Unk		Not Reported
	Rosuvastatin	S	Unk		Not Reported
	Indapamide	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14338072	EXPEDITED (15-DAY)		OT	US-CELGENEUS-USA-20171207594			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cerebral Disorder	Revlimid			S	Oral	25 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Lexapro			S	Unknown			Not Reported
	Ativan			S	Unknown			Not Reported
	Eliquis			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported
	Neupogen			C	Unknown			Not Reported
	Lunesta			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Amitriptyline			C	Unknown	50 Milligram		Not Reported
	Simvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14342826	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Below Therapeutic	Escitalopram			S	Oral		6 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2017	14339091	EXPEDITED (15-DAY)		OT	FR-MACLEODS PHARMACEUTICALS US LTD-			Unknown	FRA

MAC2017007680

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Interaction; Formication; Hyperkalaemia; Myalgia; Testicular Pain	Escitalopram Oxalate			S	Oral	10 Mg, Unk		Macleods
	Inexium 20 Mg, Gastro-Resistant Tablet (Esomeprazole Magnesium)			S	Oral	1 Df, Unk		Not Reported
	Pravastatin Sodium			C	Oral	20 Mg, Unk		Not Reported
	Pregabalin			C	Oral	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2017	14339154	EXPEDITED (15-DAY)		HO, OT	JP-ACCORD-062420			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Asphyxia	Escitalopram			S	Transplacental			Accord
	Ethyl Loflazepate			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2017	14339833	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1083080			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Escitalopram			S	Unknown	20 Milligram Daily;		Not Reported
	Zoely			S	Oral	1 Dosage Forms Daily; One Df Contains 2.5mg Nomegestrel And 1.5mg Estradiol		Mylan
	Valdoxan			S	Unknown	25 Milligram Daily;		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2017	14339865	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2017M1083151		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Ketoprofen			S	Oral			Not Reported
	Hydrocortancyl /00016201/			S	Intra-articular			Mylan
	Tercian /00759301/			S	Oral			Mylan
	Seroplex			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2018	12761904	EXPEDITED (15-DAY)		OT	PHHY2016US128699			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Ondansetron			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Progesterone			S	Unknown	Unk (High Dose)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	13621179	EXPEDITED (15-DAY)		HO, OT	AT-ALLERGAN-1704103US		29 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Drug Interaction; Gamma-Glutamyltransferase Increased; Off Label Use	Escitalopram Oxalate Unk			S		10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S		5 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S		10 Mg, Qd		Allergan
	Sycrest			S	Unknown	5 Mg, Qd		Not Reported
	Sycrest			S	Unknown	10 Mg, Qd		Not Reported
	Sycrest			S	Unknown	15 Mg, Qd		Not Reported
	Sycrest			S	Unknown	20 Mg, Qd		Not Reported
	Sycrest			S	Unknown	15 Mg, Qd		Not Reported
	Sycrest			S	Unknown	10 Mg, Qd		Not Reported
	Sycrest			S	Unknown	5 Mg, Qd		Not Reported

Trittico Retard	S	Unknown	100, Qd	Not Reported
Trittico Retard	S	Unknown	150, Qd	Not Reported
Trittico Retard	S	Unknown	300, Qd	Not Reported
Trittico Retard	S	Unknown	250, Qd	Not Reported
Trittico Retard	S	Unknown	150, Qd	Not Reported
Zyprexa	S	Unknown	20 Mg, Qd	Not Reported
Zyprexa	S	Unknown	10 Mg, Qd	Not Reported
Zyprexa	S	Unknown	20 Mg, Qd	Not Reported
Zyprexa	S	Unknown	30 Mg, Qd	Not Reported
Zyprexa	S	Unknown	20 Mg, Qd	Not Reported
Zyprexa	S	Unknown	30 Mg, Qd	Not Reported
Zyprexa	S	Unknown	25 Mg, Qd	Not Reported
Zyprexa	S	Unknown	20 Mg, Qd	Not Reported
Zyprexa	S	Unknown	10 Mg, Qd	Not Reported
Zeldox	S	Unknown	120 Mg, Qd	Not Reported
Zeldox	S	Unknown	80 Mg, Qd	Not Reported
Zeldox	S	Unknown	40 Mg, Qd	Not Reported
Zeldox	S	Unknown	20 Mg, Qd	Not Reported
Quilonorm Retard	S	Unknown	450 Mg, Qd	Not Reported
Quilonorm Retard	S	Unknown	675 Mg, Qd	Not Reported
Quilonorm Retard	S	Unknown	900 Mg, Qd	Not Reported
Quilonorm Retard	S	Unknown	450 Mg, Qd	Not Reported
Fluctine	S	Unknown	20 Mg, Qd	Not Reported
Abilify	S	Unknown	5 Mg, Qd	Not Reported
Abilify	S	Unknown	10 Mg, Qd	Not Reported
Abilify	S	Unknown	7.5 Mg, Qd	Not Reported
Abilify	S	Unknown	5 Mg, Qd	Not Reported
Abilify	S	Unknown	2.5 Mg, Qd	Not Reported
Topiramat	C	Unknown	250 Mg, Qd	Not Reported

Topiramat	C	Unknown	200 Mg, Qd	Not Reported
Topiramat	C	Unknown	175 Mg, Qd	Not Reported
Topiramat	C	Unknown	125 Mg, Qd	Not Reported
Topiramat	C	Unknown	100 Mg, Qd	Not Reported
Topiramat	C	Unknown	75 Mg, Qd	Not Reported
Topiramat	C	Unknown	50 Mg, Qd	Not Reported
Depakine Cr	C	Unknown	250 Mg, Qd	Not Reported
Depakine Cr	C	Unknown	1000 Mg, Qd	Not Reported
Depakine Cr	C	Unknown	750 Mg, Qd	Not Reported
Depakine Cr	C	Unknown	250 Mg, Qd	Not Reported
Lamictal	C	Unknown	300 Mg, Qd	Not Reported
Lamictal	C	Unknown	250 Mg, Qd	Not Reported
Lamictal	C	Unknown	200 Mg, Qd	Not Reported
Lamictal	C	Unknown	100 Mg, Qd	Not Reported
Lamictal	C	Unknown	75 Mg, Qd	Not Reported
Lamictal	C	Unknown	50 Mg, Qd	Not Reported
Leponex	C	Unknown	100 Mg, Qd	Not Reported
Leponex	C	Unknown	150 Mg, Qd	Not Reported
Leponex	C	Unknown	100 Mg, Qd	Not Reported
Leponex	C	Unknown	200 Mg, Qd	Not Reported
Leponex	C	Unknown	100 Mg, Qd	Not Reported
Leponex	C	Unknown	100 Mg, Qd	Not Reported
Rivotril	C	Unknown	2 Mg, Qd	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported

Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C		Unk	Not Reported
Dominal Forte	C	Unknown	160 Mg, Qd	Not Reported
Dominal Forte	C	Unknown	80 Mg, Qd	Not Reported
Dominal Forte	C	Unknown	160 Mg, Qd	Not Reported
Dominal Forte	C	Unknown	120 Mg, Qd	Not Reported
Dominal Forte	C	Unknown	120 Mg, Qd	Not Reported
Neurotop Retard	C	Unknown	300 Mg, Qd	Not Reported
Neurotop Retard	C	Unknown	600 Mg, Qd	Not Reported
Neurotop Retard	C	Unknown	900 Mg, Qd	Not Reported
Neurotop Retard	C	Unknown	Unk	Not Reported
Neurotop Retard	C	Unknown	900 Mg, Qd	Not Reported
Risperdal	C	Unknown	1 Mg, Qd	Not Reported
Risperdal	C	Unknown	2 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	6.25 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	8.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	10 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	7.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	4 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	4.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	6.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	4.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5.5 Mg, Qd	Not Reported

Temesta (Lorazepam)	C	Unknown	8 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	4 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	8 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3.25 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	8.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	6.25 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	8.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	7.5 Mg, Qd	Not Reported
Truxal	C	Unknown	50 Mg, Qd	Not Reported
Sterimar Nose Spray	C	Nasal	Unk	Not Reported
Gastrozepin	C	Unknown	150 Mg, Qd	Not Reported
Gastrozepin	C	Unknown	100 Mg, Qd	Not Reported
Laevolac	C	Unknown	3 Df, Qd	Not Reported
Laevolac	C	Unknown	4 Df, Qd	Not Reported
Laevolac	C	Unknown	6 Df, Qd	Not Reported
Nozinan	C	Unknown	50 Mg, Qd	Not Reported
Nozinan	C	Unknown	50 Mg, Qd	Not Reported
Nozinan	C	Unknown	100 Mg, Qd	Not Reported
Nozinan	C	Unknown	25 Mg, Qd	Not Reported
Nozinan	C	Unknown	100 Mg, Qd	Not Reported
Nozinan	C	Unknown	150 Mg, Qd	Not Reported
Zoldem	C	Unknown	5 Mg, Qd	Not Reported

Dibondrin	C	Unknown	50 Mg, Qd	Not Reported
Praxiten	C	Unknown	25 Mg, Qd	Not Reported
Praxiten	C	Unknown	50 Mg, Qd	Not Reported
Inderal	C	Unknown	20 Mg, Qd	Not Reported
Inderal	C	Unknown	30 Mg, Qd	Not Reported
Inderal	C	Unknown	40 Mg, Qd	Not Reported
Inderal	C	Unknown	50 Mg, Qd	Not Reported
Inderal	C	Unknown	90 Mg, Qd	Not Reported
Inderal	C	Unknown	40 Mg, Qd	Not Reported
Inderal	C	Unknown	60 Mg, Qd	Not Reported
Inderal	C	Unknown	30 Mg, Qd	Not Reported
Inderal	C	Unknown	30 Mg, Qd	Not Reported
Sifrol	C	Unknown	Unk	Not Reported
Sifrol	C	Unknown	Unk	Not Reported
Akineton	C	Unknown	2 Mg, Qd	Not Reported
Akineton	C	Unknown	4 Mg, Qd	Not Reported
Akineton	C	Unknown	2 Mg, Qd	Not Reported
Akineton	C	Unknown	2 Mg, Qd	Not Reported
Akineton	C	Unknown	4 Mg, Qd	Not Reported
Adasuve	C	Unknown	1 Df, Qd	Not Reported
Adasuve	C	Unknown	1 Df, Qd	Not Reported
Nubain	C	Unknown	1 Df, Qd	Not Reported
Mucobene	C	Unknown	600 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14244466	EXPEDITED (15-DAY)		OT	PHHY2017MX176089		78 YR	Male	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arrhythmia; Feeling	Entresto			S	Oral	2 Df (50 Mg), Bid (1 In The Morning And 1 In The		Not Reported

Abnormal; Intestinal Dilatation; Product Use Issue; Vomiting					Afternoon)	
	Atorvastatin		S	Unknown		Novartis
	Escitalopram		S	Unknown		Not Reported
	Concor		C	Unknown		Not Reported
	Lyrica		C	Unknown		Not Reported
	Pentoxifilina		C	Unknown		Not Reported
	Celecoxib		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14341322	EXPEDITED (15-DAY)		HO	KR-TAKEDA-2017TUS027572			Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Burning Sensation; Decreased Appetite; Drug Effect Faster Than Expected; Drug Ineffective; Nausea; Pain; Paraesthesia; Sedation	Brintellix			S	Unknown	5 Mg, Qd		Takeda
	Lexapro			S	Unknown	5 Mg, Qd		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Trestan /00056201/			S	Unknown	Unk		Not Reported
	Zolpiram			S	Unknown	Unk		Not Reported
	Zolpiram			S	Unknown	Unk		Not Reported
	Zolpiram			S	Oral	Unk		Not Reported
	Ganaton			C	Unknown	Unk		Not Reported
	Ganaton			C				Not Reported
	Bearse			C	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk		Not Reported
	Xanax			C	Unknown	0.25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14341352	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2017-ES-839743		81 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14341968	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2017AP021046		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Aripiprazole			S	Unknown	10 Mg, Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Clomipramine			S	Unknown	150 Mg, Qd		Not Reported
	Fluvoxamine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14343628	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1083569		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Formication; Hyperkalaemia; Myalgia; Testicular Pain	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Inexium 20 Mg, Comprimé Gastro-Résistant			S	Oral	1 Df, Unk		Mylan
	Pravastatine			C	Oral	20 Mg, Unk		Mylan
	Pregabaline			C	Oral	50 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14343643	EXPEDITED (15-DAY)		HO, OT	AT-BAUSCH-BL-2017-035456		26 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Lorazepam			S	Unknown			Not Reported
	Abilify			S	Oral			Not Reported
	Abilify			S				Not Reported
	Truxal			S	Unknown	2 Tabs		Not Reported
	Cipralex			S	Unknown	10 Milligram		Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14344241	EXPEDITED (15-DAY)		DE, OT	US-009507513-1712USA014612		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remeron			S	Oral			Merck
	Propranolol			S				Not Reported
	Escitalopram			S				Not Reported
	Lamotrigine			S				Not Reported
	Cyclobenzaprine Hydrochloride			S				Not Reported
	Buspirone Hydrochloride			S				Not Reported
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14347201	DIRECT					64 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Tardive Dyskinesia; Tardive Dyskinesia	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14257578	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004500		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Lamotrigine			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Meloxicam			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14318479	EXPEDITED (15-DAY)		DE, OT	TR-009507513-1712TUR010837		57 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Remeron		S	Oral	Unknown	Merck
	Cipralex		S		Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14343756	EXPEDITED (15-DAY)		HO	AT-PFIZER INC-2017552457		30 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Drug Interaction; Gamma-Glutamyltransferase Increased	Zeldox			S	Oral	20 Mg, Unk		Pfizer
	Zeldox			S	Oral	80 Mg, Unk		Pfizer
	Zeldox			S	Oral	120 Mg, Unk		Pfizer
	Abilify			S	Oral	2.5 Mg, Qd		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Abilify			S	Oral	7.5 Mg, Qd		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Abilify			S	Oral	2.5 Mg, Qd		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Abilify			S	Oral	10 Mg, Qd		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	5 Mg, Unk		Not Reported
	Sycrest			S	Unknown	Unk		Not Reported
	Sycrest			S	Unknown	20 Mg, Unk		Not Reported
	Sycrest			S	Unknown	10 Mg, Unk		Not Reported
	Sycrest			S	Unknown	15 Mg, Unk		Not Reported
	Sycrest			S	Unknown	15 Mg, Unk		Not Reported
	Zyprexa			S	Oral	Unk, Per Day		Not Reported
	Trittico			S	Oral	100 Mg, Unk		Not Reported
	Trittico			S	Oral	150 Mg, Unk		Not Reported
	Trittico			S	Oral	300 Mg, Unk		Not Reported

Trittico	S	Oral	250 Mg, Unk	Not Reported
Trittico	S	Oral	150 Mg, Unk	Not Reported
Fluctine	S	Unknown	20 Mg, Unk	Not Reported
Quilonium R	S		Unk	Not Reported
Rivotril	C	Unknown	2 Mg, Unk	Not Reported
Rivotril	C	Unknown	4 Mg, Unk	Not Reported
Rivotril	C	Unknown	4 Mg, Unk	Not Reported
Rivotril	C	Unknown	2 Mg, Unk	Not Reported
Rivotril	C	Unknown	1 Mg, Unk	Not Reported
Inderal	C	Oral	50 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	60 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	40 Mg, Unk	Not Reported
Inderal	C	Oral	20 Mg, Unk	Not Reported
Inderal	C	Oral	40 Mg, Unk	Not Reported
Inderal	C	Oral	90 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	900 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	600 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	300 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	900 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	600 Mg, Unk	Not Reported
Nozinan	C	Unknown	150 Mg, Unk	Not Reported
Nozinan	C	Unknown	50 Mg, Unk	Not Reported
Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	25 Mg, Unk	Not Reported
Lamictal	C	Oral	250 Mg, Unk	Not Reported

Lamictal	C	Oral	200 Mg, Unk	Not Reported
Lamictal	C	Oral	75 Mg, Unk	Not Reported
Lamictal	C	Oral	100 Mg, Unk	Not Reported
Lamictal	C	Oral	50 Mg, Unk	Not Reported
Lamictal	C	Oral	300 Mg, Unk	Not Reported
Nubain	C	Unknown	1 Unk, 1df In 100ml Nacl	Not Reported
Risperdal	C	Unknown	2 Mg, Unk	Not Reported
Risperdal	C	Unknown	1 Mg, Unk	Not Reported
Akineton /00079502/	C	Oral	2 Mg, Unk	Not Reported
Akineton /00079502/	C	Unknown	4 Mg, Unk	Not Reported
Akineton /00079502/	C	Unknown	2 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	80 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	120 Mg, Unk	Not Reported
Praxiten	C	Unknown	25 Mg, Unk	Not Reported
Praxiten	C	Unknown	50 Mg, Unk	Not Reported
Praxiten	C		Unk	Not Reported
Sifrol	C	Unknown	0.26 Mg, Unk	Not Reported
Sifrol	C	Unknown	0.34 Mg, Unk	Not Reported
Temesta (Lorazepam)	C		Unk	Not Reported
Temesta (Lorazepam)	C		Unk	Not Reported
Zoldem	C	Unknown	Unk	Not Reported
Dibondrin	C	Unknown	50 Mg, Unk	Not Reported
Gastrozepin	C	Unknown	100 Mg, Unk	Not Reported
Truxal	C	Unknown	50 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14345116	EXPEDITED (15-DAY)		OT	SI-MACLEODS PHARMACEUTICALS US LTD-MAC2017007740			Unknown	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Left Ventricular Hypertrophy	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Rosuvastatin			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Indapamide			S	Unknown	Unk		Not Reported
	Perindopril			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14345430	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2017-07602		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis	Venlafaxine			S	Unknown	37.5 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	15 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	5 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14345570	EXPEDITED (15-DAY)		DE, OT	US-009507513-1712USA014579		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Cozaar			S	Oral	Unk		Merck
	Levothyroxine Sodium			S	Oral			Not Reported
	Bupropion Hydrochloride			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Potassium Salicylate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14345975	EXPEDITED (15-DAY)		DE, OT	US-009507513-1712USA014636		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Singulair			S	Oral			Merck
	Propranolol			S				Not Reported
	Escitalopram			S				Not Reported
	Lamotrigine			S				Not Reported
	Acetaminophen (+) Oxycodone Hydrochloride			S				Not Reported
	Ibuprofen			S				Not Reported
	Ondansetron			S				Not Reported
	Acyclovir			S				Not Reported
	Alprazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14346052	EXPEDITED (15-DAY)		DE, OT	US-009507513-1712USA014637		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Januvia			S	Oral			Merck
	Remeron			S	Oral			Merck
	Carvedilol			S				Not Reported
	Valproic Acid			S				Not Reported
	Escitalopram			S				Not Reported
	Phenytoin			S				Not Reported
	Primidone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14347601	EXPEDITED (15-DAY)		OT	HR-BAYER-2017-248072		17 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Poisoning; Somnolence; Suicide Attempt	Aspirin			S	Oral			Bayer
	Escitalopram			S	Oral	3 Df, Unk		Not Reported

	Ibuprofen	S	Oral	Not Reported
	Olanzapine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14347640	EXPEDITED (15-DAY)		DE, OT	US-009507513-1712USA014649			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Cozaar			S	Oral	Unk		Merck
	Levothyroxine Sodium			S	Oral			Not Reported
	Diltiazem			S				Not Reported
	Propranolol			S				Not Reported
	Metformin			S				Not Reported
	Glyburide			S				Not Reported
	Escitalopram			S				Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	12468124	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-FRI-1000085324		28 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Shoulder Deformity; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Xeplion			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Risperdal			S	Unknown	Unk		Not Reported
	Paliperidone Palmitate			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Abilify			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14343293	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-			Male	JPN

1774117US

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis Neonatal; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Premature Baby; Respiratory Disorder Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Ethyl Loflazepate			S	Transplacental	1 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14349054	EXPEDITED (15-DAY)		DE	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2017007807			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Escitalopram Oxalate			S	Oral	30 Mg, Qd		Macleods
	Mirtazapine			S	Oral	45 Mg, Qd		Not Reported
	Orozamudol			S	Oral	150 Mg, Qd		Not Reported
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14349057	EXPEDITED (15-DAY)		OT	PL-MACLEODS PHARMACEUTICALS US LTD-MAC2017007809			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Seizure	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Bupropion			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14349564	EXPEDITED (15-DAY)		HO, OT	AT-MACLEODS PHARMACEUTICALS			Unknown	AUT

US LTD-
MAC2017007814

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Increased Appetite; Prescribed Overdose; Weight Increased	Quetiapine			S	Unknown	200 Mg, Qd		Macleods
	Quetiapine			S	Unknown	100 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd		Macleods
	Quetiapine			S	Unknown	400 Mg, Qd		Macleods
	Quetiapine			S	Unknown	500 Mg, Qd		Macleods
	Quetiapine			S	Unknown	400 Mg, Qd		Macleods
	Quetiapine			S	Unknown	100 Mg, Qd		Macleods
	Quetiapine			S	Unknown	200 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd		Macleods
	Quetiapine			S	Unknown	500 Mg, Qd		Macleods
	Quetiapine			S	Unknown	450 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd		Macleods
	Quetiapine			S	Unknown	100 Mg, Qd		Macleods
	Quetiapine			S	Unknown	100 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd		Macleods
	Quetiapine			S	Unknown	300 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd		Macleods
	Olanzapine			S	Unknown	10 Mg, Qd		Macleods
	Olanzapine			S	Unknown	5 Mg, Qd		Macleods
	Olanzapine			S	Unknown	15 Mg, Qd		Macleods
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Cipralex			S	Unknown	15 Mg, Qd		Not Reported
	Cipralex			S	Unknown	30 Mg, Qd		Not Reported
	Cipralex			S	Unknown	20 Mg, Qd		Not Reported
	Molaxole			C	Unknown	1 Unk, Qd		Not Reported

Molaxole	C	Unknown	1 Unk, Qd	Not Reported
Molaxole	C	Unknown	1 Unk, Unk	Not Reported
Molaxole	C	Unknown	1 Unk, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	1.25 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	1.25 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Rivotril	C	Unknown	1 Mg, Qd	Not Reported
Pregabalin	C	Unknown	450 Mg, Qd	Not Reported
Pregabalin	C	Unknown	300 Mg, Qd	Not Reported
Pregabalin	C	Unknown	150 Mg, Qd	Not Reported
Plantago Indica	C	Unknown	(1)	Not Reported
Plantago Indica	C	Unknown	(1)	Not Reported
Plantago Indica	C	Unknown	(1)	Not Reported
Plantago Indica	C	Unknown	(1)	Not Reported
Cymbalta	C	Unknown	30 Mg, Qd	Not Reported
Combithyrex Mite	C	Unknown	1 Df, Qd	Not Reported
Lamotrigin	C	Unknown	50 Mg, Qd	Not Reported
Thyrex	C	Unknown	50 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14349579	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2017-48575		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Headache; Somnolence	Alprazolam			S	Oral	5 Mg, Unk		Aurobindo

	Dafalgan	S	Oral		Not Reported
	Zoloft	S	Oral		Not Reported
	Seroplex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14349597	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2017AP023737		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	10 Mg, Per Day		Apotex
	Aripiprazole			S	Unknown	5 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14351093	EXPEDITED (15-DAY)		DE	JP-HERITAGE PHARMACEUTICALS-2017HTG00382			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis Coronary Artery; Blister; Drug Abuse; Injury; Overdose; Rhabdomyolysis; Serotonin Syndrome; Skin Abrasion; Toxicity To Various Agents	Fluoxetine			S	Unknown			Heritage
	Chlorpheniramine			S	Unknown			Not Reported
	Diphenhydramine			S	Unknown			Not Reported
	S Citadep			S	Unknown			Not Reported
	Venlor Xr			S	Unknown			Not Reported
	Diazepam			C	Unknown			Not Reported
	Sibutramine			C	Unknown			Not Reported
	Thyroid Gland Powder			C	Unknown			Not Reported
	Bisacodyl			C	Unknown			Not Reported
	Micronase			C	Unknown			Not Reported
	Fastin			C	Unknown			Not Reported
	Dragon			C	Unknown			Not Reported
	666 Xii			C	Unknown			Not Reported
	666 Xiii			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14351414	NON-EXPEDITED			US-TAKEDA-2017TUS027574			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Trintellix			S	Oral	Unk Unk, Qd		Takeda
	Trintellix			S	Oral	10 Mg, Qd		Takeda
	Trintellix			S	Oral	20 Mg, Qd		Takeda
	Lexapro			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14351571	EXPEDITED (15-DAY)		HO	KR-ALLERGAN-1774404US			Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Burning Sensation; Decreased Appetite; Drug Effect Faster Than Expected; Drug Ineffective; Nausea; Pain; Paraesthesia; Sedation	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Tylenol			S	Unknown			Not Reported
	Trestan Cap (Cyanocobalamin)			S	Unknown			Not Reported
	Zolpiram			S	Oral	Less Than Half Tablet		Not Reported
	Ganaton			C	Unknown			Not Reported
	Ganaton			C				Not Reported
	Ganaton			C				Not Reported
	Bearse			C	Unknown			Not Reported
	Bearse			C				Not Reported
	Ativan			C	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14351778	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1000462		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Sedation	Alprazolam			S	Oral	0.13 Df, Unk		Not Reported

Escitalopram	S	Oral	10 Mg, Unk		Not Reported
Risperdal	S	Oral	1.5 G, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352299	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1800151US		16 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Major Depression; Off Label Use; Suspected Counterfeit Product	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Seroquel			C	Unknown	Unk		Not Reported
	Lamotrigine			C	Unknown	Unk		Not Reported
	Ou Lai Ning			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352562	NON-EXPEDITED		OT	US-JAZZ-2017-US-014968			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataplexy; Drug Ineffective; Fatigue; Feeling Abnormal; Myalgia; Night Sweats; Taste Disorder	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Provigil /01265601/			S				Not Reported
	Lexapro			S				Not Reported
	Claritin /00413701/			S				Not Reported
	Augmentin /00756801/			C		Unk		Not Reported
	Diflucan			C		Unk		Not Reported
	Meclizine /00072801/			C		Unk		Not Reported
	Macrobid /00024401/			C		Unk		Not Reported
	Hydroxyzine Hcl			C		Unk		Not Reported
	Metoprolol Tartrate			C		Unk		Not Reported

Adderall	C	Unk	Not Reported
Lidocaine Hcl	C	Unk	Not Reported
Vitamin D3	C	Unk	Not Reported
Prelief	C	Unk	Not Reported
Allegra Allergy	C	Unk	Not Reported
Phentermine Hydrochloride	C	Unk	Not Reported
Codeine Sulfate	C	Unk	Not Reported
Dilaudid	C	Unk	Not Reported
Opana	C	Unk	Not Reported
Buspirone Hcl	C	Unk	Not Reported
Proair Hfa	C	Unk	Not Reported
Sudafed /00076302/	C	Unk	Not Reported
Tizanidine Hcl	C	Unk	Not Reported
Xanax	C	Unk	Not Reported
Marcaine /00330101/	C	Unk	Not Reported
Acyclovir /00587301/	C		Not Reported
Aspirin 81	C		Not Reported
Azo Bladder Control With Go Less	C	Unk	Not Reported
Msm	C		Not Reported
Nasalcrom	C		Not Reported
Oxytrol For Women	C	Unk	Not Reported
Zyrtec	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352914	EXPEDITED (15-DAY)		DE, OT	US-ABBVIE-18P-163-2210518-00		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levothyroxine			S	Oral			Not Reported
	Ethylene Glycol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

Furosemide	S	Oral		Not Reported
Folic Acid	S	Oral		Not Reported
Vitamin B-1	S	Oral		Not Reported
Loratadine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352960	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1000487		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Headache; Somnolence	Alprazolam			S	Oral			Not Reported
	Dafalgan			S	Oral			Mylan
	Zoloft 50 Mg,Gelule			S	Oral			Mylan
	Seroplex			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14355207	DIRECT		HO, LT, OT			16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Panic Attack; Suicidal Ideation	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14324632	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2017-035823			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Breast Cancer; Breast Mass; Coeliac Disease; Colitis Microscopic; Diarrhoea; Irritable Bowel Syndrome; Large Intestine Polyp; Visual Impairment	Xifaxan (Rifaximin) Tablets 550mg			S	Oral			Valeant
	Uceris (Budesonide) Extended Release Tablets			S	Unknown			Santarus
	Budesonide Dr And Er			S	Oral			Santarus
	Bupropion Hcl Xl			S	Oral	24 Hour Extended Release Tablet		Not Reported

	Bupropion Hcl Xl	S	Oral	24 Hour Extended Release Tablet	Not Reported
	Clonazepam	S	Oral	As Needed	Not Reported
	Dexamethasone	S	Unknown		Bausch And Lomb
	Sulfamethoxazole And Trimethoprim	S	Unknown	800/160 Mg	Not Reported
	Buspirone	S	Oral		Not Reported
	Methylphenidate	S	Oral	As Needed	Not Reported
	Minivelle	S		24 Hour Transdermal Patch, Change Patch Twice Weekly As Directed	Not Reported
	Valacyclovir	S	Oral		Not Reported
	Valacyclovir	S	Oral	2 Tablets As Needed	Not Reported
	Bionect	S	Topical		Not Reported
	Anastrozole	S	Oral		Not Reported
	Escitalopram	S	Oral		Not Reported
	Fluvirin	S	Intramuscular	45 Mcg (15 Mcg X 3) 0.5 Ml Intramuscular Suspension	Not Reported
	Ondansetron Hcl	S	Unknown	2 Tablets As Needed	Not Reported
	Entecort	C		Worked Well In The Past	Not Reported
	Entecort	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14353407	EXPEDITED (15-DAY)		HO	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2017007927			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods
	Amlodipine Besylate			S	Oral	5 Mg, Qd		Macleods
	Domperidone			S	Oral	Unk		Not Reported
	Transulose			S	Unknown	Unk, (Oral Jelly In Jar)		Not Reported

	Calcium Carbonate		S	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14354107	EXPEDITED (15-DAY)		OT	FR-CIPLA LTD.-2017FR29904			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Impulsive Behaviour	Escitalopram			S	Oral	Unk		Invagen
	Stresam, Gelule			S	Oral	Unk		Not Reported
	Seresta			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14354148	EXPEDITED (15-DAY)		OT	FR-CIPLA LTD.-2017FR30110			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Formication; Hyperkalaemia; Myalgia; Testicular Pain	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Inexium			S	Oral	1 Df, Unk		Not Reported
	Pravastatine Sodique			C	Oral	20 Mg, Unk		Not Reported
	Pregabaline			C	Oral	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14354243	EXPEDITED (15-DAY)		OT	FR-009507513-1801FRA000761			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus;	Simvastatin			S		20 Mg, Qd		Merck
	Levothyroxine Sodium			S	Oral	1 Df, Qd		Not Reported
	Zyloric			S		1 Df, Qd		Not Reported
	Atenolol			S		50 Microgram, Qd		Not Reported
	Cotareg			S		1 Df, Qd		Not Reported
	Amlor			S		1 Df, Qd		Not Reported
	Seresta			S		12.5 Mg, Qd		Not Reported

Urticaria; Vertigo; Vision Blurred	Uvedose		S	1 Df, Unk	Not Reported
	Imovane		S	0.5 Df, Qd	Not Reported
	Seroplex		S	1 Df, Qd	Not Reported
	Endotelon		S	2 To 3 Tablets/Day	Not Reported
	Voltarene (Diclofenac Sodium)		S	2x / Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14354247	EXPEDITED (15-DAY)		DE	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-158961		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Mirtazapine			S	Oral	45 Mg, Qd		Sun
	Escitalopram			S	Oral	30 Mg, Qd		Not Reported
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported
	Orozamudol			S	Oral	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14354333	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2017007926			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram Oxalate			S	Oral	1 Df, Qd		Macleods
	Rulid			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14354855	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-000296		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Coma; Fall; Rib Fracture	Zolpidem			S	Oral	()		Aurobindo

	Valium	S	Oral	()		Not Reported
	Baclofene	S	Oral	()		Not Reported
	Lexomil	S	Oral	()		Not Reported
	Seroplex	S	Oral	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14354987	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2018-000105		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Escitalopram			S	Oral			Aurobindo
	Mirtazapine			S	Oral			Aurobindo
	Tiapridal			S	Oral			Not Reported
	Orozamudol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14355097	EXPEDITED (15-DAY)		HO, OT	AT-PFIZER INC-2018002508			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Cholesterol Increased; Blood Triglycerides Increased; Drug Interaction; Frustration Tolerance Decreased; Gamma-Glutamyltransferase Increased; Kidney Enlargement; Liver Injury; Neutrophil Count Decreased; Splenomegaly; Weight Increased	Lyrica			S	Oral	750 Mg, Unk		Pfizer
	Lyrica			S	Oral	375 Mg, Unk		Pfizer
	Lyrica			S	Oral	300 Mg, Unk		Pfizer
	Lyrica			S		150 Mg, Unk		Pfizer
	Lyrica			S	Oral	300 Mg, Unk		Pfizer
	Lyrica			S	Oral	450 Mg, Unk		Pfizer
	Lyrica			S	Oral	600 Mg, Unk		Pfizer
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	15 Mg, Unk		Not Reported
	Cymbalta			S	Oral	60 Mg, Unk		Not Reported
	Risperdal			S		0.5 Mg, Unk		Not Reported

	Risperdal	S		1 Mg, Unk	Not Reported
	Risperdal	S		2 Mg, Unk	Not Reported
	Topamax	S	Oral	25 Mg, Unk	Not Reported
	Topamax	S	Oral	25 Mg, Unk	Not Reported
	Topamax	S	Oral	50 Mg, Unk	Not Reported
	Topamax	S	Oral	100 Mg, Unk	Not Reported
	Pantoloc	C		40 Mg, Unk	Not Reported
	Wellbutrin	C		Unk	Not Reported
	Rivotril	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14355281	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017555874		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Amlodipine			S	Oral	5 Mg, 1x/Day		Pfizer
	Transulose			S	Oral	Unk		Not Reported
	Domperidone			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral			Not Reported
	Calcium Carbonate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14355408	EXPEDITED (15-DAY)		DE, OT	US-ABBVIE-18P-163-2210727-00		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levothyroxine			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14355518	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-SA-2018SA003378			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Xyzall			S	Transplacental			Not Reported
	Avamys			S	Transplacental	Form: Nasal Spray		Not Reported
	Seretide			S	Transplacental			Not Reported
	Sipralexa			S	Transplacental			Not Reported
	Vilanterol Trifenatate			S	Transplacental	Form: Inhalation Powder		Not Reported
	Fluticasone Furoate			S	Transplacental	Form: Inhalation Powder		Not Reported
	Flixotide			S	Transplacental			Not Reported
	D-Cure			S	Transplacental			Not Reported
	Pantomed (Pantoprazole Sodium)			S	Transplacental			Not Reported
	Ventolin			S	Transplacental			Not Reported
	Mepolizumab			S	Transplacental			Not Reported
	Xanthium (Theophylline)			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14355532	EXPEDITED (15-DAY)		DE, OT	US-ABBVIE-18P-163-2212383-00		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Valproic Acid			S	Oral			Not Reported
	Carvedilol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Sitagliptin			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Phenytoin			S	Oral			Not Reported
	Primidone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14355613	EXPEDITED (15-DAY)		DE, OT	US-ABBVIE-18P-163-2210729-00		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levothyroxine			S	Oral			Not Reported
	Diltiazem			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Glyburide			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14356537	EXPEDITED (15-DAY)		HO, OT	TR-MYLANLABS-2017M1082641			Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Meconium Aspiration Syndrome; Newborn Persistent Pulmonary Hypertension	Escitalopram			S	Transplacental	10 Mg Per Day		Not Reported
	Passiflora Incarnata			S	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14356678	EXPEDITED (15-DAY)		HO, OT	AT-MYLANLABS-2018M1000582		58 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Intention Tremor; Lethargy; Resting Tremor; Sedation; Social Avoidant Behaviour; Tremor	Pregabalin			S	Unknown	300 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	150 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	375 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	450 Mg, Qd		Not Reported

Pregabalin	S	Oral	750 Mg, Qd		Not Reported
Topiramate	S	Oral	25 Mg, Qd		Not Reported
Topiramate	S	Oral	100 Mg, Qd		Not Reported
Cipralex	S	Oral	10 Mg, Qd		Mylan
Cipralex	S	Oral	15 Mg, Qd		Mylan
Risperidone	S	Unknown	2 Mg, Qd		Mylan
Pantoprazol	C	Unknown	40 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14357034	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2018M1000968		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Orozamudol 50 Mg, Comprimé Orodispersible			S	Oral			Mylan
	Escitalopram			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Tiapridal			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14357081	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1000076		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Coma; Fall; Rib Fracture	Zolpidem			S	Oral	Unk		Not Reported
	Lexomil			S	Oral	Unk		Mylan
	Seroplex			S	Oral	Unk		Mylan
	Baclofene			S	Oral	Unk		Mylan
	Valium			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14361006	DIRECT		DS, OT			22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intellectual Disability; Nervousness	Lexapro			S		Quantity:1 Tablet(S);		Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14363635	DIRECT		OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Sickle Cell Trait; Syndactyly	Lexapro 20mg			S	Oral	20mg One Po Qam Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2018	14360147	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-000503		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Amlodipine			S	Oral	5 Mg, Unk		Aurobindo
	Domperidone			S	Oral	()		Not Reported
	Escitalopram			S	Oral	10 Mg, Unk		Aurobindo
	Transulose			S	Oral	()		Not Reported
	Calcium Carbonate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2018	14360271	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-000562		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram			S	Oral	1 Df, Unk		Aurobindo
	Rulid			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2018	14360425	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-159233		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Amlodipine			S	Oral	5 Mg, Daily		Sun
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Transulose, Gelee Orale En Pot			S	Oral	()		Not Reported
	Domperidone			S	Oral	()		Not Reported
	Carbonate De Calcium			S	Oral	1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2018	14360451	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004172		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Atenolol			S				Unknown
	Escitalopram Oxalate			S				Unknown
	Primidone			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2018	14360454	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004175		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Loperamide Hydrochloride			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Meloxicam			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2018	14360498	EXPEDITED (15-DAY)		OT	CA-HETERO CORPORATE-HET2018CA00005		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Duloxetine			S	Unknown	15 Mg		Hetero
	Escitalopram			S	Unknown	5 Mg		Hetero
	Venlafaxine			S	Unknown	37.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2018	14360640	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1001064		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Amlodipine			S	Oral	5 Mg, Qd		Not Reported
	Domperidone			S	Oral			Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Calcium Carbonate			S	Oral	1 Df, Qd		Not Reported
	Transulose			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14254114	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1768933US		52 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Nitrazepam			C	Unknown			Not Reported
	Omega-3-Acid Ethyl Ester			C	Unknown			Not Reported
	Zyloric			C				Not Reported
	Nexium			C	Unknown			Not Reported
	Urso /00465701/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14334306	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2017GSK200541			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anal Incontinence; Breast Cancer; Breast Mass; Coeliac Disease; Colitis Microscopic; Diarrhoea; Irritable Bowel Syndrome; Large Intestine Polyp; Visual Impairment	Bupropion Hydrochloride Xl	S	Oral	300 Mg, 1d	Glaxosmithkline
	Bupropion Hydrochloride Xl	S	Oral	150 Mg, 1d	Glaxosmithkline
	Valacyclovir	S	Oral	1 Gm Tablet; 2 Tablets, Prn	Glaxosmithkline
	Budesonide	S	Oral	Budesonide Dr And Er 3 Mg Capsule	Glaxosmithkline
	Dexamethasone	S	Unknown		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim	S	Unknown		Glaxosmithkline
	Buspirone Hydrochloride	S	Oral	30 Mg, 1d	Glaxosmithkline
	Methylphenidate	S	Oral	20 Mg Tablet, 2 Daily, Prn	Glaxosmithkline
	Anastrozole	S	Oral	1 Mg, 1d	Glaxosmithkline
	Escitalopram	S	Oral	10 Mg Tablet, 1d	Glaxosmithkline
	Xifaxan	S	Oral	Three 550 Mg Tablets Daily	Not Reported
	Uceris	S	Unknown	9 Mg Extended Release Tablets	Not Reported
	Fluvirin	S	Intramuscular	45 Mcg (15 Mcg X 3) (15 Mcg/0.5ml Im Suspension)	Not Reported
	Ondansetron Hydrochloride	S	Unknown	Two 8mg Tablets (16 Mg), Prn	Not Reported
	Clonazepam	S	Oral	0.5 Mg Tablet, 3 Daily	Not Reported
	Minivelle	S	Transdermal	24 Hour Patch, Change Twice Weekly	Not Reported
	Bionect	S	Topical	0.2 Percent Cream	Not Reported
	Entocort	C		1 Df, We	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14344162	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1774405US		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14362253	NON-EXPEDITED			US-TEVA-2017-US-838628		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash; Rash	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14362333	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.-2017IT30563			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Abilify			C	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14363624	EXPEDITED (15-DAY)		HO, LT	ES-OTSUKA-2017_028769		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose	Abilify			S	Oral	30 Mg, Qd		Otsuka
	Clonazepam			S	Oral	22.5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	30 Mg, Qd		Not Reported
	Quetiapina			S	Oral	19 G, Qd		Not Reported
	Valproate Sodium			S	Oral	3.6 Mg, Qd		Not Reported
	Antabus			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14364176	EXPEDITED (15-DAY)		HO	FR-SA-2017SA269133		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis;	Irbesartan			S	Oral	1-0-0		Not Reported

Hepatocellular Injury	Pantoprazole		S	Oral	0-0-1	Not Reported
	Escitalopram		S	Oral	1-0-0	Not Reported
	Furosemide		S	Oral	1-0-0	Not Reported
	Seresta		C	Oral		Not Reported
	Duphalac		C	Oral		Not Reported
	Havlane		C	Oral	0-0-1 Si Besoin	Not Reported
	Kardegic		C	Oral	0-1-0	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14367580	DIRECT	Y	HO			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Ulcer	Ocrevus			S				Genentech
	Atorvastatin			C				Not Reported
	Baclofen			C				Not Reported
	Carbamazepine Er			C				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Fentanyl			C				Not Reported
	Lorazepam			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Spironolactone			C				Not Reported
	Tizanidine			C				Not Reported
	Tramadol			C				Not Reported
	Multivitamin			C				Not Reported
	Dexilant			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	13854198	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2017GSK121129		19 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Sopor	Lamictal			S	Oral	In Total		Glaxosmithkline
	Lamictal			S	Oral	350 Mg, Single		Glaxosmithkline
	Cipralex			S	Oral	In Total		Glaxosmithkline
	Cipralex			S		120 Mg, Single		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14311899	NON-EXPEDITED			US-009507513-1712USA010434		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Hypotension; Overdose; Presyncope	Olmesartan Medoxomil			S	Unknown	Daily Dose Unknown		Not Reported
	Aspirin			S	Unknown	Daily Dose Unknown		Not Reported
	Finasteride			S	Unknown	Daily Dose Unknown		Merck
	Mirtazapine			S	Unknown	Daily Dose Unknown		Merck
	Simvastatin			S	Unknown	Daily Dose Unknown		Merck
	Nitroglycerin			S	Unknown	Unk Unk,As Needed		Merck
	Tylenol With Codeine			S	Unknown	Unk, As Needed		Not Reported
	Amlodipine			S	Unknown	Daily Dose Unknown		Not Reported
	Carvedilol			S	Unknown	Daily Dose Unknown		Not Reported
	Hydralazine			S	Unknown	Daily Dose Unknown		Not Reported
	Losartan Potassium Tablets			S	Unknown	Daily Dose Unknown		Merck
	Niacin			S	Unknown	Daily Dose Unknown		Not Reported
	Escitalopram			S	Unknown	Daily Dose Unknown		Not Reported
	Pantoprazole			S	Unknown	Daily Dose Unknown		Not Reported
	Clopidogrel			S	Unknown	Daily Dose Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14366028	EXPEDITED (15-DAY)		LT, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2017008183			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Neuroleptic Malignant Syndrome	Escitalopram 10mg Tablet			S	Oral	Unk, Escitalopram Cinfa 10 Mg Film-Coated Compresses Efg, 56 Tablets		Macleods
	Haloperidol			S	Oral	Unk		Not Reported

	Deprax (Fluoxetine Hydrochloride)	S	Unknown	100 Mg, Qd	Not Reported
	Distraneurine Capsules	S	Oral	Unk	Not Reported
	Lormetazepam Cinfa 1 Mg Comprimides Efg, 30 Tablets	S	Unknown	Unk	Not Reported
	Omeprazole	C	Oral	Unk, Omeprazol Cinfamed 20 Mg Gastroresistant Hard Capsules Efg, 56 Capsules	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14366039	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2017IT30945			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematuria; Melaena; Rectal Haemorrhage	Escitalopram			S	Oral	4 Gtt, Per Day		Invagen
	Cadrioaspirin			S	Oral	100 Mg, Per Day		Not Reported
	Plavix			S	Oral	75 Mg, Per Day		Not Reported
	Lasix Fiale			C	Oral	125 Mg, Unk		Not Reported
	Cacit Vitamina D3			C	Oral	Unk		Not Reported
	Fluxum			C	Unknown	Unk		Not Reported
	Kcl Retard			C	Oral	Unk		Not Reported
	Bisoprolol Fumarate			C	Oral	2.5 Mg, Unk		Not Reported
	Lansox			C	Oral	75 Mg, Unk		Not Reported
	Tavor [Lorazepam]			C	Oral	1 Mg, Unk		Not Reported
	Lanoxin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14366420	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2016NO185921		28 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Facial Asymmetry; Gait Disturbance; Head	Olanzapine			S	Unknown			Novartis
	Risperidone			S	Unknown			Not Reported

Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication; Shoulder Deformity; Weight Increased	Xeplion	S	Unknown	Unk		Not Reported
	Risperdal	S	Unknown	Unk		Not Reported
	Escitalopram	S	Unknown			Not Reported
	Paliperidone Palmitate	S	Unknown			Not Reported
	Zyprexa	S	Unknown	Unk		Not Reported
	Abilify	S	Unknown	Unk		Not Reported
	Cipralex	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14367689	NON-EXPEDITED			US-STI PHARMA LLC-2039726			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Tinnitus	Escitalopram			S				Sti Pharma
	Fondaparinux Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14367987	DIRECT					44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Loss Of Libido; Male Orgasmic Disorder	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14368011	DIRECT	Y	OT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Tremor	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14368242	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-		74 YR	Female	FRA

2018VAL000064

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Furosemide			S	Oral	40 Mg, Qd		Validus
	Irbesartan			S	Oral	75 Mg, Qd		Not Reported
	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Seresta			C				Not Reported
	Duphalac /00163401/			C				Not Reported
	Havlane			C				Not Reported
	Kardegic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14368355	EXPEDITED (15-DAY)		OT	HR-MYLANLABS-2018M1001386		17 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Somnolence; Suicide Attempt	Ibuprofen			S	Oral	Unk		Not Reported
	Acetylsalicylic Acid			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14369203	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1800369US		78 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer; Gastrointestinal Haemorrhage; Off Label Use; Tardive Dyskinesia	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Celecoxib			C	Unknown	Unk		Not Reported
	Aricept			C	Unknown			Not Reported

	Lipidil Supra	C	Unknown	Not Reported
	Ultracet Semi	C	Unknown	Not Reported
	Stilnox	C	Unknown	Not Reported
	Seroquel	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14371740	DIRECT		OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Alopecia Areata; Androgenetic Alopecia	Escitalopram (Lexapro 20mg Cut In Half For 10 Mg	Y		S	Oral	Quantity:1 Tablet(S);		Forest
	Metformin Xr			C				Not Reported
	Multivitamin With Biotic			C				Not Reported
	Lysine Spirulina Ginger Lime			C				Not Reported
	Apple Cider Vinegar			C				Not Reported
	Onion Garlic			C				Not Reported
	Coffee			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14208555	EXPEDITED (15-DAY)		DS, HO	GXKR2017DE005827		57 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Chest Pain; Diarrhoea; Gait Disturbance; Haematoma; Haemorrhage; Muscle Disorder; Myalgia; Nerve Injury; Staphylococcal Infection; Walking Aid User	Valproic Acid			S	Unknown	900 Mg, Twice Daily		Novartis
	Cipralex			S	Unknown	5 Mg, Once Daily		Not Reported
	Novaminsulfon			C	Unknown	500 Mg, Tid (On A Regular Basis)		Not Reported
	Ibuprofen			C	Unknown	600 Mg, Qid		Not Reported
	Xarelto			C	Unknown	10 Mg, Qd		Not Reported
	Cefazolin			C	Unknown	2 G, Unk		Not Reported
	Ass			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14274044	EXPEDITED (15-DAY)		HO, LT, OT	FR-OTSUKA-2016_015925		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypotonia; Miosis	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Zopiclone			S	Oral	210 Mg, Qd; (Zopiclone 7.5 Mg Before Sleep)		Not Reported
	Zyprexa			S	Oral	1 Df, Unk; (1df=1050 To 1350mg,Zyprexa)		Not Reported
	Lysanxia			S	Oral	1440 Mg, Unk; (Lysanxia (Prazepam) 10 Mg))		Not Reported
	Seroplex			S	Oral	140 Mg, Unk;(Seroplex (Escitalopram))		Not Reported
	Lexapro			S	Oral	140 Mg, Unk		Not Reported
	Olanzapin			S	Oral	1 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14370190	EXPEDITED (15-DAY)		HO, LT	ES-CIPLA LTD.-2017ES31002			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Intentional Overdose	Escitalopram			S	Oral	30 Mg, In Total		Invagen
	Quetiapine			S	Oral	19 G, In Total		Not Reported
	Valproato Sodio (3194so)			S	Oral	3.6 Mg, In Total		Not Reported
	Abilify 15 Mg Comprimidos, 28 Comprimidos			S	Oral	30 Mg, Daily		Not Reported
	Clonazepam (635a)			S	Oral	22.5 Mg, In Total		Not Reported
	Antabus 250 Mg Comprimidos , 40 Comprimidos			S	Oral	250 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14370191	EXPEDITED (15-DAY)		HO	ES-CIPLA LTD.-2017ES31183			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram			S	Oral	10 Mg, Daily		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14370886	EXPEDITED (15-DAY)		HO, LT, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-159423		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypotonia; Miosis	Zopiclone			S	Oral	210 Mg, Qd (Zopiclone 7.5 Mg Before Sleep)		Not Reported
	Olanzapine			S	Oral	1 Df, Unk		Sun
	Seroplex			S	Oral	140 Mg, Unk		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Lysanxia			S	Oral	1440 Mg, Unk		Not Reported
	Zopiclone			S	Oral	210 Mg, Qd		Not Reported
	Zyprexa			S	Oral	1 Df, Unk		Not Reported
	Lexapro			S	Oral	140 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14371327	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2018-001225		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypotonia; Miosis	Zopiclone			S	Oral	210 Mg, Qd		Not Reported
	Olanzapine			S	Oral	1 Df, Unk		Aurobindo
	Seroplex			S	Oral	140 Mg, Unk		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Lysanxia			S	Oral	1440 Mg, Unk		Not Reported
	Zyprexa			S	Oral	1 Df, Unk		Not Reported
	Lexapro			S	Oral	140 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14371813	EXPEDITED (15-DAY)		OT	SI-GLENMARK PHARMACEUTICALS-2017GMK030499			Unknown	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Left Ventricular Hypertrophy	Rosuvastatin Calcium			S	Unknown	Unk		Glenmark
	Perindopril			S	Unknown	Unk		Not Reported
	Indapamide			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14372170	EXPEDITED (15-DAY)		OT	SG-MYLANLABS-2017M1083829		65 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Withdrawal Syndrome	Escitalopram			S	Unknown	10 Mg/Day		Not Reported
	Metformin			C	Unknown	500 Mg; Three Times Daily		Mylan
	Atenolol			C	Unknown	25 Mg/Day		Mylan
	Hydrochlorothiazide			C	Unknown	12.5 Mg/Day		Mylan
	Lovastatin			C	Unknown	20 Mg/Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14372191	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-844114		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Venlafaxine			S	Unknown			Teva
	Duloxetine			S	Unknown			Teva
	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14373263	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-TEVA-2017-NO-841743		28 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication; Shoulder Deformity; Weight Increased	Escitalopram			S	Unknown			Ivax
	Olanzapine			S	Unknown			Teva
	Risperidone			S	Unknown			Not Reported
	Risperdal			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Abilify			S	Unknown	Unk		Not Reported
	Cipralex			S	Unknown	Unk		Not Reported
	Xeplion			S	Unknown	Unk		Not Reported
	Paliperidone Palmitate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14373509	EXPEDITED (15-DAY)		OT	BE-SA-2017SA259553			Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Congenital Anomaly In Offspring; Exposure During Pregnancy	Levocetirizine			S	Unknown			Not Reported
	D-Cure			S	Unknown			Not Reported
	Seretide			S	Unknown			Not Reported
	Sipralexa			S	Unknown			Not Reported
	Vilanterol Trifenatate			S	Unknown	The Dosage Form Was Inhalation Powder		Not Reported
	Fluticasone Furoate			S	Unknown	The Dosage Form Was Inhalation Powder		Not Reported
	Flixotide			S	Unknown			Not Reported
	Xanthium (Theophylline)			S	Unknown			Not Reported
	Pantomed (Pantoprazole Sodium)			S	Unknown			Not Reported

	Ventolin	S	Unknown		Not Reported
	Avamys	S	Unknown	The Dosage Form Was Nasal Spray And The Dose Was 2 (Unit Unknown)	Not Reported
	Mepolizumab	S	Subcutaneous	The Dosage Form Was Powder For Solution For Injection	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14375326	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Mood Altered	Lexapro 10 Mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14168247	NON-EXPEDITED		OT	US-AMGEN-USASL2017167837		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Zolpidem			C	Unknown	10 Mg, Unk		Not Reported
	Metoprolol			C	Unknown	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14278470	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-2016_008020		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Off Label Use; Respiratory Distress; Somnolence	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Temesta (Lorazepam)			S	Unknown	2.5 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S				Not Reported

Seroplex	S	Oral	20 Mg, Qd	Not Reported
Lexapro	S	Oral	20 Mg, Qd	Not Reported
Kardegic	C	Unknown	Unk	Not Reported
Flodil [Buflomedil Hydrochloride]	C	Unknown	Unk	Not Reported
Tegretol	C	Unknown	400 Mg, Unk	Not Reported
Gardenal	C	Unknown	Unk	Not Reported
Inegy	C	Unknown	Unk	Not Reported
Bisoce	C	Unknown	Unk	Not Reported
Omexel	C	Unknown	Unk	Not Reported
Uvedose	C	Unknown	Unk	Not Reported
Dafalgan	C	Unknown	Unk	Not Reported
Avodart	C	Unknown	Unk	Not Reported
Vesicare	C	Unknown	Unk	Not Reported
Topalgic (Tramadol Hydrochloride)	C	Unknown	Unk	Not Reported
Allopurinol	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Domperidone	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Unknown	Unk	Not Reported
Ventoline	C	Unknown	Unk	Not Reported
Tamsulosin Hydrochloride	C	Unknown	0.4 Mg, Unk	Not Reported
Felodipine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14307284	EXPEDITED (15-DAY)		HO, OT	PHHY2017SI155904		48 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Sclerosis; Palpitations; Product Use	Fty 720			S	Unknown	0.5 Mg, Qd		Novartis
	Escitalopram			S	Unknown	10 Mg, Qd (1 Tablet In		Not Reported

In Unapproved Indication				Morning)		
	Pregabalin		S	Unknown	150 Mg, Bid	Not Reported
	Fampridine		S	Unknown	10 Mg, Bid	Not Reported
	Tolterodine		S	Unknown	4 Mg, Qd (1 Tablet In Morning)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14355684	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2017M1082655		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Venlafaxine			S	Unknown	Unk		Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14373888	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2017008202			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	40 Mg, Qd		Macleods
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods
	Irbesartan			S	Oral	75 Mg, Qd		Macleods
	Furosemide			S	Oral	40 Mg, Qd		Not Reported
	Seresta 10 Mg			C	Oral	1 Df, Qd		Not Reported
	Duphalac			C	Oral	3 Df, Qd		Not Reported
	Havlane			C	Oral	1 Df, Qd		Not Reported
	Kardegic 160 Mg			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14374050	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2017FR31020			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Escitalopram			S	Oral	Unk		Invagen
	Fenofibrate			S	Oral	Unk		Invagen
	Pantoprazole			S	Oral	Unk		Cipla
	Xeloda			S	Oral	Unk		Not Reported
	Novorapid			S	Subcutaneous	Unk		Not Reported
	Primperan			S	Oral	Unk		Not Reported
	Movicol			S	Oral	Unk		Not Reported
	Abasaglar			S	Subcutaneous	Unk		Not Reported
	Fondaparinux Sodique			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14374696	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-159678		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Irbesartan			S	Oral	75 Mg, Qd		Not Reported
	Pantoprazole			S	Oral	40 Mg, Qd		Sun
	Furosemide			S	Oral	40 Mg, Qd		Not Reported
	Duphalac			C	Oral	3 Df, Tid		Not Reported
	Havlane			C	Oral	0-0-1 Si Besoin		Not Reported
	Kardegic 160 Mg, Poudre Pour Solution Buvable En Sachet			C	Oral	1 Df, Qd		Not Reported
	Seresta 10 Mg, Comprime			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14374879	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-159846		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria	Esomeprazole			S	Oral	Unk		Sun
	Venlafaxine			S	Oral	1 Df, Daily		Sun
	Nordazepam			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14375128	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-001290		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral	10 Mg, Daily		Aurobindo
	Furosemide			S	Oral	40 Mg, Daily		Not Reported
	Irbesartan			S	Oral	75 Mg, Daily		Aurobindo
	Pantoprazole			S	Oral	40 Mg, Daily		Aurobindo
	Seresta			C	Oral	0-0-1		Not Reported
	Duphalac /00163401/			C	Oral	1-1-1		Not Reported
	Havlane			C	Oral	0-0-1 Si Besoin		Not Reported
	Kardegic			C	Oral	0-1-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14376002	EXPEDITED (15-DAY)		HO	FR-UCBSA-2018001230		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Raynaud'S Phenomenon	Methylphenidate Hydrochloride			S	Oral	80 Mg In Am 20 Mg In Pm		Ucb
	Methylphenidate Hydrochloride			S	Oral	110 Mg, Once Daily (Qd)		Ucb
	Methylphenidate Hydrochloride			S				Ucb
	Laroxyl			S		Unk		Not Reported
	Laroxyl			S				Not Reported
	Laroxyl			S				Not Reported
	Lexapro			S	Oral	10 Mg, Once Daily (Qd)		Not Reported

	Lexapro	S			Not Reported
	Lexapro	S			Not Reported
	Quetiapine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Quetiapine	S			Not Reported
	Quetiapine	S			Not Reported
	Abilify	S	Oral	15 Mg, Once Daily (Qd)	Not Reported
	Abilify	S			Not Reported
	Abilify	S			Not Reported
	Lepticur	S		15 Mg, Unk	Not Reported
	Lepticur	S			Not Reported
	Lepticur	S			Not Reported
	Ritaline	S	Oral	100 Mg, Unk	Not Reported
	Ritaline	S	Oral	110 Mg, Once Daily (Qd)	Not Reported
	Ritaline	S			Not Reported
	Seroplex	S	Oral	10 Mg, Once Daily (Qd)	Not Reported
	Seroplex	S			Not Reported
	Seroplex	S			Not Reported
	Quetiapine Fumarate	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Quetiapine Fumarate	S			Not Reported
	Quetiapine Fumarate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14376416	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-GLENMARK PHARMACEUTICALS-2017GMK030467			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine			S	Transplacental	5 Mg, Qd		Glenmark
	Avamys Nasal Spray			S	Transplacental	Unk, Bid		Not Reported
	Seretide			S	Transplacental	Unk		Not Reported
	Sipralexa Tablet			S	Transplacental	10 Mg		Not Reported
	Relvar Ellipta Inhalation Powder			S	Transplacental	Unk, Od		Not Reported
	Flixotide			S	Transplacental	500 Mg, Od		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Pantomed (Pantoprazol)			S	Transplacental	Unk		Not Reported

	Ventolin		S	Transplacental	100 Mg, Unk	Not Reported
	Nucala Powder For Solution For Injection		S	Transplacental	100 Mg, Unk	Not Reported
	Xanthium (Theophylline)		S	Transplacental	200 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14376504	EXPEDITED (15-DAY)		OT	CA-LANNETT COMPANY, INC.-CA-2017LAN001304		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Duloxetine			S	Unknown	Unk		Not Reported
	Venlafaxine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14377531	EXPEDITED (15-DAY)		HO, OT	SI-ALLERGAN-1801183US		49 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Left Ventricular Hypertrophy	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Rosuvastatin			S	Unknown			Not Reported
	Perindopril			S	Unknown			Not Reported
	Indapamide			S	Unknown			Not Reported
	Alprazolam			S	Unknown	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14377755	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1002476		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Irbesartan			S	Oral	75 Mg, Qd		Not Reported

Furosemide	S	Oral	40 Mg, Qd		Not Reported
Seresta	C	Oral	1 Df, Qd		Mylan
Duphalac /00163401/	C	Oral	3 Df, Qd		Mylan
Havlane	C	Oral	1 Df, Qd		Mylan
Kardegic	C	Oral	0-1-0		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14380203	DIRECT					27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Decreased Appetite; Influenza; Migraine; Nausea; Product Substitution Issue; Vomiting	Escitalopram		Y	S	Oral	Quantity:1 Tablet(S);		Not Reported
	Omperazole			C				Not Reported
	Cetirizine			C				Not Reported
	Fluticazone			C				Not Reported
	One A Day Women'S Supplement			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14177965	EXPEDITED (15-DAY)		DE, HO, LT	AT-ALLERGAN-1764439US		73 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Disorder; Condition Aggravated; Coronary Artery Disease; Dehydration; Fatigue; Oedema Peripheral; Pneumonia; Renal Impairment; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	2 Df, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qam		Allergan
	Azilect			S	Unknown	1 Df, Qam		Not Reported
	Trittico			S	Unknown	Half At Night		Not Reported
	Seroquel			S	Unknown	As Needed		Not Reported
	Madopar 62.5			S	Unknown	1 Df, Tid		Not Reported
	Stalevo			S	Unknown	1 Df, Qam		Not Reported
	Stalevo			S	Unknown	1 Df, Bid (One In The Morning, One At Noon)		Not Reported
	Stalevo			S	Unknown	Unk		Not Reported

Lovenox	C	Unknown	1 Daily		Not Reported
Elomel	C	Unknown	1 Daily		Not Reported
Optinem	C	Unknown	Unk		Not Reported
Lasix	C	Unknown	Unk		Not Reported
Thrombo Ass	C	Unknown	1 At Noon		Not Reported
Spirobene	C	Unknown	Half At Noon		Not Reported
Sedacoron	C	Unknown	Half In The Morning		Not Reported
Eporatio	C	Unknown	1 Weekly		Not Reported
Ceftriaxone Sodium	C	Unknown	2 G In 200 Ml, 1 Daily		Not Reported
Dancor	C	Unknown	One In The Morning, One In The Evening		Not Reported
Aquaphoril	C	Unknown	Half In The Morning		Not Reported
Torasemide	C	Unknown	One In The Morning		Not Reported
Pantoloc	C	Unknown	Two In The Morning		Not Reported
Insulatard	C	Unknown	6ie-0-0 (International Unit)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14183967	EXPEDITED (15-DAY)		OT	DE-TEVA-825403GER		32 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dyskinesia; Extrapyramidal Disorder; Muscle Twitching; Muscle Twitching; Restlessness	Escitalopram			S	Oral			Not Reported
	Trimipramine			S	Oral			Not Reported
	Trimipramine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14334674	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2017M1082534		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Off Label Use; Respiratory Distress; Somnolence	Lorazepam			S	Unknown	2.5 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Not Reported

Aripiprazole	S	Oral	5 Mg, Qd	Not Reported
Lorazepam	S	Unknown	2.5 Mg, Unk	Not Reported
Escitalopram Oxalate	S	Oral	20 Mg, Qd	Not Reported
Flodil /00641902/	C	Unknown	Unk	Mylan
Ventoline /00139501/	C	Unknown	Unk	Mylan
Spasfon /00765801/	C	Unknown	Unk	Mylan
Pantoprazole	C	Unknown	Unk	Mylan
Allopurinol	C	Unknown	Unk	Mylan
Tamsulosin Hydrochloride	C	Unknown	0.4 Mg, Unk	Mylan
Gardenal /00023201/	C	Unknown	Unk	Mylan
Topalgic /00599202/	C	Unknown	Unk	Mylan
Kardegic	C	Unknown	Unk	Mylan
Vesicare	C	Unknown	Unk	Mylan
Dafalgan	C	Unknown	Unk	Mylan
Inegy	C	Unknown	Unk	Mylan
Uvedose	C	Unknown	Unk	Mylan
Carbamazepine	C	Unknown	400 Mg, Unk	Mylan
Omexel	C	Unknown	Unk	Mylan
Loperamide	C	Unknown	Unk	Mylan
Domperidone	C	Unknown	Unk	Mylan
Tegretol	C	Unknown	Unk	Mylan
Bisoce	C	Unknown	Unk	Mylan
Avodart	C	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379017	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013072		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Furosemide Tablets			S	Oral	Unk Unk, Unknown		Dava

Levothyroxine Sodium	S	Oral	Unk Unk, Unknown		Par
Folic Acid Tablets	S	Oral	Unk Unk, Unknown		Vintage
Ethylene Glycol	S	Oral	Unk Unk, Unknown		Not Reported
Escitalopram	S	Oral	Unk, Unknown		Not Reported
Loratadine	S	Oral	Unk Unk, Unknown		Not Reported
Vitamin B-1	S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379029	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR00560			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Coma; Fall; Rib Fracture	Escitalopram			S	Oral	Unk		Invagen
	Zolpidem Tartarate			S	Oral	Unk		Invagen
	Lexomil Roche			S	Oral	Unk		Not Reported
	Baclofene			S	Oral	Unk		Not Reported
	Valium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379137	EXPEDITED (15-DAY)		DE	FR-CIPLA LTD.-2018FR00029			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Escitalopram			S	Oral	30 Mg, Per Day		Invagen
	Tramadol			S	Oral	150 Mg, Per Day		Not Reported
	Chlorhydrate Detiapri De, Tiapri De (Chlorhydrate De)Tiapri De (Chlor			S	Oral	100 Mg, Per Day		Not Reported
	Mirtazapine			S	Oral	45 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379230	EXPEDITED (15-DAY)		OT	BE-MACLEODS PHARMACEUTICALS US LTD-			Unknown	BEL

MAC2017008241

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Congenital Anomaly In Offspring; Exposure During Pregnancy	Pantoprazole			S	Unknown	20 Mg, Qd		Macleods
	Ventolin			S	Unknown	100 Mg, Unk		Not Reported
	Xanthium (Theophylline)			S	Unknown	200 Mg, Qd		Not Reported
	Avamys Nasal Spray Suspension			S	Nasal	2 Unk, Bid		Not Reported
	Mepolizumab			S	Subcutaneous	100 Mg, Powder For Solution For Injection		Not Reported
	Vilanterol Trifenatate			S	Unknown	1 Df, Qd, Inhalation Powder		Not Reported
	Seretide			S	Unknown	Unk		Not Reported
	Fluticasone Furoate			S	Unknown	1 Df, Qd, Inhalation Powder		Not Reported
	Xyzall			S	Oral	5 Mg, Qd		Not Reported
	Flixotide			S	Unknown	500 Mg, Qd, 250 Mg, 2x/Day (Bid)		Not Reported
	D-Cure			S	Unknown	25 Kiu, Unk		Not Reported
	Sipralexa			S	Oral	10 Mg, Z, Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379307	EXPEDITED (15-DAY)		OT	FR-ALVOGEN-2018-ALVOGEN-094818			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amnesia; Arthralgia; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness;	Atenolol			S	Respiratory (inhalation)	50		Not Reported
	Zyloric			S	Unknown			Not Reported
	Cotareg			S	Unknown	Nonaz		Not Reported
	Seroplex			S	Unknown			Not Reported

Paraesthesia; Pruritus; Thyroid Function Test Abnormal; Urticaria; Vertigo; Vision Blurred	Amlor		S	Unknown		Not Reported
	Levothyroxine Sodium		S	Oral		Not Reported
	Simvastatin		S	Unknown		Not Reported
	Oxazepam		S	Unknown		Not Reported
	Uvedose		S	Unknown	1.0df Unknown	Not Reported
	Zopiclone		S	Unknown		Not Reported
	Endotelon		S	Unknown		Not Reported
	Voltarene Sr		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379555	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2017FR31159			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral	10 Mg, Daily, 1-0-0		Invagen
	Irbesartan			S	Oral	75 Mg, Daily, 1-0-0		Cipla
	Pantoprazole			S	Oral	40 Mg, Daily, 0-0-1		Cipla
	Furosemide			S	Oral	40 Mg, Daily, 1-0-0		Not Reported
	Seresta			C	Oral	1 Df, Daily, 0-0-1		Not Reported
	Duphalac			C	Oral	3 Df, Daily, 1-1-1		Not Reported
	Havlane			C	Oral	1 Df, Daily, 0-0-1 Si Besoin		Not Reported
	Kardegic			C	Oral	1 Df, Daily, 0-1-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379906	EXPEDITED (15-DAY)		HO, OT	AT-GLENMARK PHARMACEUTICALS-2017GMK030460			Unknown	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Intention Tremor; Lethargy; Resting Tremor; Sedation; Social Avoidant Behaviour; Tremor	Topiramate			S	Oral	100 Mg, Unk		Glenmark
	Topiramate			S	Oral	25 Mg, Unk		Glenmark

Pregabalin	S	Unknown	450 Mg, Unk		Not Reported
Pregabalin	S	Unknown	375 Mg, Unk		Not Reported
Pregabalin	S	Unknown	300 Mg, Unk		Not Reported
Pregabalin	S	Unknown	150 Mg, Unk		Not Reported
Risperidone	S	Unknown	2 Mg, Unk		Not Reported
Cipralex /01588501/	S	Oral	15 Mg, Unk		Not Reported
Cipralex /01588501/	S	Oral	10 Mg, Unk		Not Reported
Pantoprazol	C	Unknown	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379914	EXPEDITED (15-DAY)		DS	BE-GLENMARK PHARMACEUTICALS-2017GMK030583			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy	Levocetirizine			S	Unknown	5 Mg, Qd		Glenmark
	D-Cure			S	Unknown	25 Kiu, Unk		Not Reported
	Seretide			S	Unknown	Unk		Not Reported
	Sipralexa			S	Unknown	10 Mg, Z, Tablet, Unk		Not Reported
	Relvar Ellipta			S	Unknown	Unk Unk, Qd		Not Reported
	Flixotide			S	Unknown	500 Mg Qd (250 Mg, Bid)		Not Reported
	Xanthium (Theophylline)			S	Unknown	200 Mg, Qd		Not Reported
	Pantomed /01263204/			S	Unknown	20 Mg, Qd		Not Reported
	Ventolin /00139502/			S	Unknown	100 Mg, Unk		Not Reported
	Avamys			S	Unknown	Unk, Qd (Bid)		Not Reported
	Mepolizumab			S	Subcutaneous	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14380137	EXPEDITED (15-DAY)		DS, OT	CH-AMGEN-CHESP2018003177		63 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Density Decreased; Lumbar Vertebral Fracture; Rebound Effect	Prolia	S	Subcutaneous	60 Mg, Q6mo	Amgen
	Cipralex	S	Oral	20 Mg, Qd	Not Reported
	Pantozol	S	Oral		Not Reported
	Dafalgan	C	Oral	1 G, Qid	Not Reported
	Kalcipos D3	C	Oral	1 Df, Qd	Not Reported
	Novalgine (Metamizole Sodium)	C	Oral	500 Mg, Q6h (2 Tab)	Not Reported
	Requip	C	Oral	4 Mg, Qd	Not Reported
	Temesta (Lorazepam)	C	Oral	1 Df, As Necessary	Not Reported
	Vitamin D3 Streuli	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14380211	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-001533			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus; Urticaria; Vertigo; Vision Blurred	Atenolol			S		50 Mg, Once A Day		Aurobindo
	Zyloric			S		1 Df, Once A Day		Not Reported
	Levothyrox			S	Oral	1 Df, Once A Day		Not Reported
	Simvastatine			S		20 Mg, Once A Day		Not Reported
	Cotareg			S				Not Reported
	Amlor			S				Not Reported
	Seresta			S		12.5 Mg, Once A Day		Not Reported
	Uvedose			S				Not Reported
	Imovane			S		0.5 Df, Once A Day		Not Reported
	Seroplex			S		1 Df, Once A Day		Not Reported
	Endotelon			S		2 À 3 Cp/J ()		Not Reported
	Voltarene /00372302/			S		2x/Semaine ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14380846	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS-2018M1002622		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coma; Electrocardiogram Qt Prolonged; Hypotonia; Miosis	Olanzapine		S	Oral	1 Df, Unk	Not Reported
	Zopiclone		S	Oral	210 Mg, Qd	Not Reported
	Zopiclone		S	Oral	210 Mg, Qd	Not Reported
	Seroplex		S	Oral	140 Mg, Unk	Mylan
	Abilify		S	Oral	5 Mg, Qd	Mylan
	Lysanxia		S	Oral	1440 Mg, Unk	Mylan
	Zyprexa		S	Oral	1 Df, Unk	Mylan
	Lexapro		S	Oral	140 Mg, Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14381110	EXPEDITED (15-DAY)		HO	PHHY2018CO001274		86 YR	Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Renal Disorder; Syncope	Entresto			S	Oral	100 Mg, Q12h		Novartis
	Atorvastatin			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Apixaban			C	Unknown			Not Reported
	Concor			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Methimazole			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14381711	EXPEDITED (15-DAY)		DE	US-GENUS_LIFESCIENCES-USA-POI0580201800056		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levolet (Levothyroxine)			S				Genus Lifesciences
	Ethylene Glycol			S				Not Reported
	Escitalopram			S				Not Reported
	Loratadine			S				Not Reported

	Furosemide	S		Not Reported
	Folic Acid	S		Not Reported
	Vitamin B1	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14381716	EXPEDITED (15-DAY)		DE	US-GENUS_LIFESCIENCES-USA-POI0580201800060		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levolet (Levothyroxine)			S				Genus Lifesciences
	Bupropion			S				Not Reported
	Amlodipine			S				Not Reported
	Escitalopram			S				Not Reported
	Salicylate			S				Not Reported
	Losartan			S				Not Reported
	Ethanol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14381720	EXPEDITED (15-DAY)		DE	US-GENUS_LIFESCIENCES-USA-POI0580201800064		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levolet (Levothyroxine)			S				Genus Lifesciences
	Diltiazem			S				Not Reported
	Propranolol			S				Not Reported
	Metformin			S				Not Reported
	Glyburide			S				Not Reported
	Escitalopram			S				Not Reported
	Losartan			S				Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14382161	EXPEDITED (15-DAY)		OT	CZ-ALLERGAN-1801432US		75 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Halo Vision; Metamorphopsia; Vision Blurred	Escitalopram Oxalate - Bp		S	Oral	5 Mg, Qd	Allergan
	Euthyrox		C	Unknown		Not Reported
	Rosucard		C	Unknown	20 Mg, Unk	Not Reported
	Stacyl		C	Unknown	100 Mg, Unk	Not Reported
	Triplixam		C	Unknown	10/2.5/10	Not Reported
	Rivocor		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14382422	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1801838US		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Tercian			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14343663	EXPEDITED (15-DAY)		HO, OT	FR-BAUSCH-BL-2017-035455		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Off Label Use; Respiratory Distress; Somnolence	Lorazepam			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Unknown			Not Reported
	Seroplex			S	Oral			Not Reported
	Flodil L.P.			C	Unknown	Sustained Release Coated Tablet		Not Reported
	Ventoline			C	Unknown			Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported

	Tamsulosin Hydrochloride	C	Unknown		Not Reported
	Gardenal	C	Unknown		Not Reported
	Topalgic (Tramadol Hydrochloride)	C	Unknown		Not Reported
	Kardegic	C	Unknown	Powder For Oral Solution In Sachet-Dose	Not Reported
	Vesicare	C	Unknown		Not Reported
	Dafalgan	C	Unknown		Not Reported
	Inegy	C	Unknown		Not Reported
	Uvedose	C	Unknown		Not Reported
	Carbamazepine	C	Unknown		Not Reported
	Omexel	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Domperidone	C	Unknown		Not Reported
	Tegretol	C	Unknown		Not Reported
	Bisoce	C	Unknown		Not Reported
	Avodart	C	Unknown		Not Reported
	Flodil [Buflomedil Hydrochloride]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14383197	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR00290			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Daily		Invagen
	Amlodipine			S	Oral	5 Mg, Daily		Invagen
	Domperidone			S	Oral	Unk		Not Reported
	Carbonate De Calcium			S	Oral	1 Df, Daily		Not Reported
	Transulose, Gelee Oraleen Pot			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14383279	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR00042			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram			S	Oral	1 Df, Daily		Invagen
	Rulid			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14383285	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.-2018IT00476			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Sopor	Lamotrigine			S	Oral	350 Mg, In Total		Cipla
	Escitalopram			S	Oral	120 Mg, In Total		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14334903	EXPEDITED (15-DAY)		OT	SG-MACLEODS PHARMACEUTICALS US LTD-MAC2017007442			Unknown	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Withdrawal Syndrome	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Macleods
	Escitalopram Oxalate			S				Macleods
	Venlafaxine			S	Unknown	Unk		Macleods
	Atenolol			C	Unknown	25 Mg, Qd		Not Reported
	Metformin Hydrochloride			C	Unknown	500 Mg, Unk, 8 Hour		Macleods
	Hydrochlorothiazide			C	Unknown	12.5 Mg, Qd		Not Reported
	Lovastatin			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14389806	EXPEDITED (15-DAY)		OT	PHHY2018FR005006			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone Abnormal; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus; Urticaria; Vertigo; Vision Blurred	Cotareg			S	Unknown	1 Df, Qd		Not Reported
	Voltarene Lp			S	Unknown	2 Df, Qw		Not Reported
	Atenolol			S	Unknown	50 Ug, Qd		Novartis
	Simvastatin			S	Unknown	20 Mg, Qd		Not Reported
	Seroplex			S	Unknown	1 Df, Qd		Not Reported
	Endotelon			S	Unknown	2-3 Tablets, Qd		Not Reported
	Imovane			S	Unknown	0.5 Df, Qd		Not Reported
	Uvedose			S	Unknown	1 Df, Q3mo		Not Reported
	Seresta			S	Unknown	12.5 Mg, Qd		Not Reported
	Amlor			S	Unknown	1 Df, Qd		Not Reported
	Zyloric			S	Unknown	1 Df, Qd		Not Reported
	Levothyrox			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14390414	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013295		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S	Oral	Unk Unk, Unknown		Par
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported
	Drug, Unknown			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14390421	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013290		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Valproic Acid			S	Oral	Unk Unk, Unknown		Vintage
	Primidone Tablets			S	Oral	Unk Unk, Unknown		Vintage

Carvedilol	S	Oral	Unk Unk, Unknown		Not Reported
Escitalopram	S	Oral	Unk Unk, Unknown		Not Reported
Sitagliptin	S	Oral	Unk Unk, Unknown		Not Reported
Mirtazapine	S	Oral	Unk Unk, Unknown		Not Reported
Phenytoin	S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14390559	EXPEDITED (15-DAY)		OT	AT-MACLEODS PHARMACEUTICALS US LTD-MAC2018008478			Unknown	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Headache; Pneumonia	Venlafaxine			S	Unknown	Unk		Macleods
	Duloxetine			S	Unknown	Unk		Macleods
	Brintellix			S	Oral	5 Mg, Qd		Not Reported
	Brintellix			S		10 Unk, Unk		Not Reported
	Brintellix			S	Oral	15 Mg, Qd		Not Reported
	Brintellix			S	Oral	20 Mg, Qd		Not Reported
	Brintellix			S	Oral	15 Mg, Qd		Not Reported
	Cipralex			S	Oral	Unk		Not Reported
	Zoldem			C	Oral	5 Mg, Qd		Not Reported
	Zoldem			C	Oral	10 Mg, Qd		Not Reported
	Zoldem			C	Oral	5 Mg, Qd		Not Reported
	Curocef			C	Unknown	9 Gm, Qd		Not Reported
	Curocef			C	Unknown	Unk Unk, Qd		Not Reported
	Trittico Ret			C	Oral	200 Mg, Qd		Not Reported
	Trittico Ret			C	Oral	150 Mg, Qd, Since Months		Not Reported
	Trittico Ret			C	Oral	250 Mg, Unk		Not Reported
	Trittico Ret			C	Oral	300 Mg, Qd		Not Reported
	Cal-D-Vita			C	Oral	1 Df, Qd, Since Years		Not Reported

	Oleovit D3	C	Oral	40 [Drp], 1 Week, Since Years	Not Reported
	Aprednisolon	C	Oral	5 Mg, Qd, Since Years	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14390936	EXPEDITED (15-DAY)		CA	DE-AUROBINDO-AUR-APL-2018-001998		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram			S	Transplacental	7.5 [Mg/D (Mutter)]		Aurobindo
	Ebrantil /00631801/			C	Unknown	()		Not Reported
	Simvastatin			C	Unknown	Probably Either Simvastatin Or Atozet ()		Not Reported
	Valsartan			C	Unknown	160 [Mg/D (Vater)] ()		Not Reported
	Folsan			C	Transplacental	0.4 [Mg/D (Mutter)]		Not Reported
	Ramilich			C	Unknown	10 [Mg/D (Vater)] ()		Not Reported
	Dekristol			C	Unknown	20000 [Ie/D (Alle 2 Wochen) (Vater)] ()		Not Reported
	Paracetamol			C	Transplacental	()		Not Reported
	Bicanorm			C	Unknown	()		Not Reported
	Atozet			C	Unknown	40 [Mg/D] / 10 [Mg/D (Vater)]/ Probably Either Atozet Or Simvastatin ()		Not Reported
	Ass			C	Unknown	100 [Mg/D (Vater)] ()		Not Reported
	Amlodipine			C	Unknown	10 [Mg/D (Vater)] ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14391031	NON-EXPEDITED			US-PFIZER INC-2018014634			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Migraine	Desvenlafaxine Succinate Monohydrate			S		Unk		Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer

	Escitalopram Oxalate			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14391192	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2018-002047		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Aripiprazol			S	Unknown	10 Mg, Unk		Aurobindo
	Escitalopram			S	Unknown	Unk ()		Aurobindo
	Clomipramine			S	Unknown	150 Mg, Qd		Not Reported
	Fluvoxamine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14391216	NON-EXPEDITED			US-PFIZER INC-2018018358		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Bactrim Ds			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Macrobid			S		Unk		Not Reported
	Nubain			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14391603	NON-EXPEDITED			US-APOTEX-2017AP021516		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Libido Disorder; Male Sexual Dysfunction; Marital Problem; Therapeutic	Paxil Tablets			S	Unknown	Unk		Apotex
	Cymbalta			S	Unknown	60 Mg, Unk		Not Reported
	Cymbalta			S	Unknown	90 Mg, Unk		Not Reported

Response Decreased	Lexapro	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14392442	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018015723		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	40 Mg, 1x/Day		Pfizer
	Irbesartan			S	Oral	75 Mg, 1x/Day		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Furosemide			S	Oral	40 Mg, 1x/Day		Not Reported
	Duphalac			C	Oral	1x/Day		Not Reported
	Havlane			C	Oral	1x/Day		Not Reported
	Kardegic			C	Oral	1x/Day		Not Reported
	Seresta			C	Oral	1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14292962	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1770976US		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrocalcinosis Pyrophosphate; Diarrhoea; Fatigue; Rheumatoid Arthritis	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Enbrel			S	Unknown	50 Mg, Q Week		Not Reported
	Zolpidem			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14338904	EXPEDITED (15-DAY)		OT	SG-CIPLA LTD.-2017SG30512			Unknown	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Withdrawal Syndrome	Escitalopram			S	Unknown	10 Mg Per Day		Invagen
	Escitalopram			S	Unknown	10 Mg Per Day		Invagen

	Hydrochlorothiazide	C		12.5 Mg Per Day	Not Reported
	Atenolol	C	Unknown	25 Mg Per Day	Not Reported
	Lovastatin	C	Unknown	20 Mg Per Day	Not Reported
	Metformin	C	Unknown	500 Mg, Every 8 Hours	Not Reported
	Venlafaxine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14401544	EXPEDITED (15-DAY)		DS, HO	DE-ABBVIE-18P-062-2221944-00		57 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Diarrhoea; Gait Disturbance; Haematoma; Haemorrhage; Muscle Disorder; Myalgia; Nerve Injury; Staphylococcal Infection; Walking Aid User	Valproic Acid			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Novaminsulfon			C	Unknown			Not Reported
	Cefazolin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14401663	EXPEDITED (15-DAY)		DE, OT	JP-MYLANLABS-2018M1003647		57 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drowning; Toxicity To Various Agents	Escitalopram			S	Unknown	Drug Toxicology: 0.4microg/Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14403052	DIRECT		OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Diarrhoea; Hallucination, Visual; Headache;	Escitalopram Lexapro			S	Oral	5mg Tab Aur 1@Bedtime Tablet 1 Mouth		Not Reported
	Clopidogrel			C				Not Reported

Nightmare	Estradiol	C	Not Reported
	Montelukast	C	Not Reported
	Armour Thyroid	C	Not Reported
	Losartin	C	Not Reported
	Metoprolol Er	C	Not Reported
	Atorvastatin	C	Not Reported
	D3	C	Not Reported
	Probiotic	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14403895	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-843397		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Generalised Tonic-Clonic Seizure	Ketoprofene			S	Oral			Not Reported
	Hydrocortancyl 2,5 Pour Cent, Suspension Injectable			S	Intra-articular			Not Reported
	Tercian 40 Mg/Ml, Solution Buvable En Gouttes			S	Oral			Not Reported
	Seroplex 20 Mg, Comprimé Pelliculé Sécable			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14403908	EXPEDITED (15-DAY)		HO, OT	AT-ALLERGAN-1801705US			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Blood Triglycerides Increased; Fatigue; Frustration Tolerance Decreased; Kidney Enlargement; Liver Injury; Neutrophil Count Decreased; Splenomegaly; Tremor; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan
	Cymbalta			S	Oral	60 Mg, Unknown		Not Reported
	Lyrica			S	Oral	450 Mg, Unknown		Not Reported
	Lyrica			S	Oral	150 Mg, Unknown		Not Reported
	Lyrica			S	Oral	375 Mg, Unknown		Not Reported

Lyrica	S	Oral	300 Mg, Unknown		Not Reported
Lyrica	S	Oral	750 Mg, Unknown		Not Reported
Lyrica	S	Oral	300 Mg, Unknown		Not Reported
Lyrica	S	Oral	600 Mg, Unknown		Not Reported
Risperdal	S	Unknown	0.5 Mg, Unknown		Not Reported
Risperdal	S	Unknown	2 Mg, Unknown		Not Reported
Risperdal	S	Unknown	1 Mg, Unknown		Not Reported
Topamax	S	Oral	25 Mg, Unknown		Not Reported
Topamax	S	Oral	100 Mg, Unknown		Not Reported
Topamax	S	Oral	50 Mg, Unknown		Not Reported
Topamax	S	Oral	25 Mg, Unknown		Not Reported
Pantoloc	C	Unknown	40 Mg, Unknown		Not Reported
Wellbutrin	C	Unknown	Unk, Unknown		Not Reported
Rivotril	C	Unknown	0.5 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14403970	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1802505US		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Rulid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14404063	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2018M1003939		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram			S	Transplacental	7.5 Mg, Qd		Not Reported
	Ebrantil			C	Unknown			Mylan
	Simvastatin			C	Unknown	Unk		Mylan

Valsartan	C	Unknown	Unk		Mylan
Folsan	C	Transplacental	0.4 Mg, Qd		Mylan
Ramilich	C	Unknown	10 Mg, Qd		Mylan
Dekristol	C	Unknown	20000 [Ie/D (Alle 2 Wochen) (Vater)]		Mylan
Paracetamol	C	Transplacental			Mylan
Bicanorm	C	Unknown			Mylan
Atozet	C	Unknown	40 Mg, Qd		Mylan
Atozet	C		10 Mg, Qd		Mylan
Ass	C	Unknown	100 Mg, Unk		Mylan
Amlodipine	C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	13701821	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1727072US		86 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematuria; Melaena; Rectal Haemorrhage	Escitalopram Oxalate Unk			S				Allergan
	Cardioaspirin			S	Oral	100 Mg, Qd		Not Reported
	Plavix			S	Oral	75 Mg, Qd		Not Reported
	Bisoprolol Fumarate			C	Oral			Not Reported
	Lanoxin			C	Oral			Not Reported
	Kcl Retard			C	Oral			Not Reported
	Lasix Fiale			C	Oral			Not Reported
	Lansox			C	Oral			Not Reported
	Tavor [Lorazepam]			C	Oral			Not Reported
	Fluxum			C	Unknown			Not Reported
	Cacit Vitamina D3			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14404601	EXPEDITED (15-DAY)		HO	KR-JNJFOC-20180105040		58 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Pressure Increased; Coma; Drug Dependence; Liver Injury; Mental Impairment; Overdose	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14406164	NON-EXPEDITED			US-PFIZER INC-2018020904			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14406905	EXPEDITED (15-DAY)		DS, HO, OT	NO-ALLERGAN-1802734US		51 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Cold Sweat; Dyspnoea; Dysstasia; Limb Discomfort; Loss Of Consciousness; Muscular Weakness; Paraesthesia; Presyncope; Seizure; Syncope	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Citalopram Orion			S	Oral	20 Mg, Qd		Not Reported
	Citalopram Orion			S	Unknown	Unk		Not Reported
	Calcigran Forte			C	Unknown			Not Reported
	Telfast			C	Unknown			Not Reported
	Vitamin B12 Depot			C	Unknown			Not Reported
	Cetirizin Bluefish			C	Unknown			Not Reported
	Prolia			C	Unknown			Not Reported
	Marevan			C	Unknown			Not Reported

	Klexane			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14406911	EXPEDITED (15-DAY)		DS, OT	CH-ALLERGAN-1802748US		63 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Decreased; Lumbar Vertebral Fracture; Rebound Effect	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Prolia			S	Subcutaneous	60 Mg, Q6moths		Not Reported
	Pantozol			S	Oral			Not Reported
	Dafalgan			C	Unknown			Not Reported
	Kalpicos D3			C	Unknown			Not Reported
	Novalgine			C	Unknown			Not Reported
	Requip			C	Unknown			Not Reported
	Temesta (Lorazepam)			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14407032	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1802512US		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Formication; Hyperkalaemia; Myalgia; Off Label Use; Testicular Pain	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Inexium			S	Oral	1 Df, Qd		Not Reported
	Pravastatin			C	Oral	20 Mg, Qd		Not Reported
	Pregabalin			C	Oral	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14407041	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1802635US		36 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

Maternal Exposure During Pregnancy	Gilenya	S	Oral	0.5 Mg, Qd		Not Reported
	Gilenya	S	Oral	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14408529	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013305		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Fluoxetine			S	Oral	Unk Unk, Unknown		Par
	Risperidone			S	Oral	Unk Unk, Unknown		Par
	Diphenhydramine			S	Oral	Unk Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14408546	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013338		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metformin Hydrochloride Tablets			S	Oral	Unk Unk, Unknown		Provident Pharmaceutical
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported
	Naproxen			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	13344568	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2017004460			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Salivary Duct Obstruction; Salivary Gland Calculus; Sialoadenitis	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Ondansetron			S	Unknown	Unk		Not Reported
	Temozolomide			C	Unknown	Unk, Cyclical		Not Reported

	Levetiracetam	C	Unknown	Unk	Not Reported
	Dexamethasone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14312856	EXPEDITED (15-DAY)		OT	PHHY2017GT188105		84 YR	Female	GTM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Occlusive Disease; Choking; Malaise; Product Use In Unapproved Indication; Wrong Technique In Product Usage Process	Vymada			S	Unknown	0.5 Df (100 Mg) (Sacubitril 49 Mg/ Valsartan 51 Mg), Bid		Novartis
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Bisoblock			C	Oral	10 Mg, Qd		Not Reported
	Anaflat			C	Oral	One After Meals		Not Reported
	Esomeprazole			C	Oral	Unk Unk, Qd		Not Reported
	Ecotrin			C	Oral	Unk Unk, Qd		Not Reported
	Hydrapress			C	Oral	50 Mg, Every 8 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14409583	EXPEDITED (15-DAY)		HO	FR-ROCHE-2056486		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Coma; Fall; Rib Fracture	Lexomil			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Baclofene			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411462	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018001525		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rash Generalised	Tums Ultra Tablets, Mint Chewable Tablet	S			Glaxosmithkline
	Ranitidine Hydrochloride	S	Unk		Glaxosmithkline
	Furosemide	S	Unk		Glaxosmithkline
	Losartan	S	Unk		Glaxosmithkline
	Escitalopram Tablet	S	Unk		Glaxosmithkline
	Atenolol	S	Unk		Glaxosmithkline
	Warfarin Tablet	S	Unk		Glaxosmithkline
	Vitamin B12 Tablet	S	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14413212	EXPEDITED (15-DAY)		HO, LT	PHHY2017ES190639		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose	Clonazepam			S	Oral	22.5 Mg, Unk		Novartis
	Escitalopram			S	Oral	30 Mg, Unk		Not Reported
	Quetiapine			S	Oral	19 G, Unk		Not Reported
	Valproato De Sodio			S	Oral	3.6 Mg, Unk		Not Reported
	Antabus			S	Oral	250 Mg, Unk		Not Reported
	Abilify			S	Oral	30 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14417815	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Heart Rate Increased; Hypersensitivity	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Cipla
	Adderall			C				Not Reported
	Tenex			C				Not Reported
	Escitalopram			C				Not Reported
	Xanax			C				Not Reported
	Ambien			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2018	14419316	DIRECT		DS			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Economic Problem; Product Substitution Issue	Lexapro Generic			S				Unknown
	Wellbutrin Generic			C				Not Reported
	Verapimal			C				Not Reported
	Lopressor			C				Not Reported
	Calcium			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2018	14415200	EXPEDITED (15-DAY)		HO	FR-GLENMARK PHARMACEUTICALS-2017GMK030843			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Metformin Hydrochloride			S	Oral	1000 Mg, Unk		Glenmark
	Terbutaline			S	Respiratory (inhalation)	1 Df, Unk		Not Reported
	Pantoprazole			S	Oral			Not Reported
	Irbesartan			S	Oral	300 Mg, Unk		Not Reported
	Diffu K			S	Oral			Not Reported
	Furosemide			S	Oral	30 Mg, Unk		Not Reported
	Furosemide			S	Oral	Unk		Not Reported
	Diazepam			S	Oral	30 Mg, Unk		Not Reported
	Xarelto			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Dafalgan			S	Oral	3000 Mg, Unk		Not Reported
	Alprazolam			S	Oral	0.75 Mg, Unk		Not Reported
	Colchicine Opocalcium			S	Oral			Not Reported
	Nefopam			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

	Tavanic	S	Oral		Not Reported
	Bisoprolol	S	Oral	1.25 Mg, Unk	Not Reported
	Mirtazapine	S	Oral	15 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14360619	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1000982		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram			S	Oral			Not Reported
	Rulid			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14375928	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018011166			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone Abnormal; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus; Urticaria; Vertigo; Vision Blurred	Atenolol			S	Respiratory (inhalation)	50 Ug, 1x/Day		Pfizer
	Amlor			S	Unknown	1 Df, 1x/Day		Pfizer
	Simvastatin			S	Unknown	20 Mg, 1x/Day		Not Reported
	Zyloric			S	Unknown	1 Df, 1x/Day		Not Reported
	Cotareg			S	Unknown	Nonaz (Hydrochlorothiazide: 160.0mg Valsartan: 25.0mg)		Not Reported
	Seroplex			S	Unknown	1 Df, 1x/Day		Not Reported
	Levothyrox			S	Oral	1 Df, 1x/Day		Not Reported
	Seresta			S	Unknown	12.5 Mg, 1x/Day		Not Reported
	Uvedose			S	Unknown	1 Df, Unk		Not Reported
	Imovane			S	Unknown	0.5 Df, 1x/Day		Not Reported
	Endotelon			S	Unknown	Unk		Not Reported

	Voltaren Sr	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14416063	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013640		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amitriptyline Hcl			S	Oral	Unk Unk, Unknown		Vintage
	Lorazepam Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported
	Lithium			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14416066	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013634		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amitriptyline Hcl			S	Oral	Unk Unk, Unknown		Vintage
	Ibuprofen			S	Oral	Unk Unk, Unknown		Par
	Escitaopram			S	Oral	Unk Unk, Unknown		Not Reported
	Gabapentin			S	Oral	Unk Unk, Unknown		Not Reported
	Ethanol			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14416191	EXPEDITED (15-DAY)		OT	NO-AUROBINDO-AUR-APL-2018-003210			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour;	Olanzapine			S	Unknown			Aurobindo
	Valproat			S	Unknown			Not Reported
	Seroxat			S	Unknown			Not Reported
	Efexor			S	Unknown			Not Reported

Dizziness; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Cipramil /00582602/	S	Unknown		Not Reported
	Lamictal	S	Unknown		Not Reported
	Seroquel	S	Unknown		Not Reported
	Cipralex /01588501/	S	Unknown		Not Reported
	Orfiril	S	Unknown		Not Reported
	Zyprexa	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14416365	EXPEDITED (15-DAY)		HO	EE-LUPIN PHARMACEUTICALS INC.-2018-00162		46 YR	Female	EST

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Drug Resistance; Somnolence	Fluoxetine			S	Unknown	20 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin
	Venlafaxine			S	Unknown	150 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	225 Mg, Qd		Not Reported
	Bupropion			S	Unknown	150 Mg, Qd		Not Reported
	Bupropion			S	Unknown	300 Mg, Unk		Not Reported
	Agomelatin			S	Unknown	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	12296112	EXPEDITED (15-DAY)		HO	FR-FRI-1000084060		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Off Label Use; Respiratory Distress; Somnolence	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Temesta (Lorazepam)			S	Oral	3.75 Mg, Qd		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Flodil [Felodipine]			C	Unknown	Unk		Not Reported

Tegretol	C	Unknown	Unk		Not Reported
Gardenal	C	Unknown	Unk		Not Reported
Inegy	C	Unknown	10 Mg/40 Mg		Not Reported
Bisoce	C		Unk		Not Reported
Omexel L.P.	C	Unknown	Unk		Not Reported
Allopurinol	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Uvedose	C	Unknown	Unk		Not Reported
Dafalgan	C	Unknown	Unk		Not Reported
Avodart	C	Unknown	Unk		Not Reported
Vesicare	C	Unknown	Unk		Not Reported
Domperidone	C	Unknown	Unk		Not Reported
Topalgic Lp	C	Unknown	Unk		Not Reported
Loperamide	C	Unknown	Unk		Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Unknown	Unk		Not Reported
Ventolin	C	Unknown	Unk		Not Reported
Kardegic	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14319529	EXPEDITED (15-DAY)		DE, LT	NO-BAUSCH-BL-2017-035165		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drowning; Intentional Self-Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Tramadol Hydrochloride			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Sarotex			S	Unknown			Not Reported
	Orfiril			S	Unknown	Strength: 600 Mg-1200 Mg		Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown			Not Reported
	Pinex Forte			S	Unknown	Strength 500/30 Mg And		Not Reported

				Pandeine	
	Truxal	S	Unknown		Not Reported
	Nobligan	S	Unknown	Strength: 50 Mg-200 Mg	Not Reported
	Sobril	S	Unknown		Not Reported
	Oxynorm	S	Unknown	Strength: 5 Mg-10 Mg	Not Reported
	Rivotril	S	Unknown		Not Reported
	Imovane	S	Oral		Not Reported
	Lamictal	S	Unknown	Strength: 25 Mg, 50 Mg, 100 Mg	Not Reported
	Vival	S	Unknown		Not Reported
	Remeron	S	Unknown		Not Reported
	Cipralex	S	Unknown		Not Reported
	Catapresan	S	Unknown	Strength 25 Mg, 50 Mg	Not Reported
	Levomepromazine Maleate	S	Unknown		Not Reported
	Hydroxyzine Hydrochloride	S	Unknown		Not Reported
	Atarax	S	Unknown		Not Reported
	Nozinan	S	Unknown		Not Reported
	Cyanocobalamin	C			Not Reported
	Nozinan	C			Not Reported
	Diamorphine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14422070	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013960		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil			S	Oral	Unk Unk, Unknown		Par
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Flecainide			S	Oral	Unk Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14422327	EXPEDITED (15-DAY)		OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-160595		70 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Quetiapine			S	Unknown	Unk		Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Lithium			S	Unknown	Unk		Sun
	Valproic Acid			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14422372	NON-EXPEDITED		HO	PHEH2018US002166			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness	Tafinlar			S	Unknown			Novartis
	Mekinist			S	Unknown			Not Reported
	Spironolactone			S	Unknown			Not Reported
	Omeprazole			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Hydromorphone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Buspirone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14424794	NON-EXPEDITED			US-OTSUKA-2017_025825			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Rexulti			S	Unknown	Unk		Otsuka

	Lexapro	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14425075	EXPEDITED (15-DAY)		HO	TR-ALLERGAN-1803055US		2 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product By Child	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Single		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14426963	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1803416US		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qam		Allergan
	Pantoprazole			S	Oral	40 Mg, Qpm		Not Reported
	Irbesartan			S	Oral	75 Mg, Qam		Not Reported
	Furosemide			S	Oral	40 Mg, Qam		Not Reported
	Seresta			C	Oral	Unk, Qd		Not Reported
	Duphalac			C	Oral	Unk, Tid		Not Reported
	Havlane			C	Oral	Unk, Qpm		Not Reported
	Kardegic			C	Oral	Unk, Qpm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14256890	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1769294US		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Diabetes Mellitus; Drug Ineffective; Mental Disorder; Product Dose Omission; Suicidal Ideation	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Losartan Potassium			C	Oral	100 Mg, Qd		Not Reported
	Hydrochlorothiazide			C	Oral	50 Mg, Unk		Not Reported

Simvastatin	C	Oral	40 Mg, Qd		Not Reported
Gabapentin	C	Oral	300 Mg, Qd		Not Reported
Metformin	C	Oral	1000 Mg, Qd		Not Reported
Tizanidine	C	Oral	4 Mg, Tid		Not Reported
Aspercreme	C	Topical			Not Reported
Loratadine	C	Oral	10 Mg, Unk		Not Reported
Fluticasone	C	Unknown	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14434589	EXPEDITED (15-DAY)		OT	ES-009507513-1801ESP008415		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sialoadenitis	Dexamethasone			S	Unknown			Merck
	Temozolomide			S	Unknown	Unk		Merck
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Ondansetron			S	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	13928657	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2017IN15120			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myxoedema Coma	Escitalopram			S	Unknown	10 Mg, Unk		Invagen
	Quetiapine			S	Unknown	50 Mg, Unk		Not Reported
	Amlodipine			C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14432427	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2018023226		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agranulocytosis; Condition Aggravated; Craniocerebral Injury; Electrocardiogram Qt Prolonged; Fall; General Physical Health Deterioration; Musculoskeletal Pain; Neoplasm Progression; Vertigo	Ibrance	S	Oral	125 Mg, Once Daily	Pfizer
	Risperidone	S	Oral	2.5 Mg, Twice Daily With Additional 1mg As Needed	Not Reported
	Escitalopram	S	Oral	10 Mg, Once Daily	Not Reported
	Escitalopram	S	Oral	20 Mg, Once Daily	Not Reported
	Motilium /00498201/	S	Oral	10 Mg, Thrice A Day	Not Reported
	Ondansetron	S	Oral	Unk, As Needed	Not Reported
	Nexium /01479302/	S	Oral	20 Mg, Once Daily	Not Reported
	Imodium	S	Oral	Unk, As Needed	Not Reported
	Faslodex	S	Intramuscular	500 Mg, Once A Month	Not Reported
	Imovane	C		Unk	Not Reported
	Calcimagon D3	C		Unk	Not Reported
	Condrosulf	C		Unk	Not Reported
	Euthyrox	C		Unk	Not Reported
	Dafalgan	C		Unk, As Needed	Not Reported
	Irfen	C		Unk, As Needed	Not Reported
	Flector Ep	C		Unk	Not Reported
	Flector Ep	C		Unk	Not Reported
	Temgesic	C		Unk	Not Reported
	Targin	C		Unk	Not Reported
	Oxynorm	C		Unk, As Needed	Not Reported
	Movicol	C		Unk	Not Reported
	Laxoberon	C		Unk, As Needed	Not Reported
	Clexane	C		Unk	Not Reported
	Mycostatine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14434839	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-002509		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Chills; Headache; Loss Of Consciousness; Nausea; Tremor	Escitalopram		S	Oral	5 Mg, Once A Day	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14435174	EXPEDITED (15-DAY)		CA	DE-CIPLA LTD.-2018DE01662			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram			S	Transplacental	Unk		Invagen
	Folsan			C	Transplacental	Unk		Not Reported
	Paracetamol			C	Transplacental	Unk		Not Reported
	Ebrantil /00631801/			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Ramilich			C	Unknown	Unk		Not Reported
	Dekristol			C	Unknown	Unk		Not Reported
	Bicanorm			C	Unknown	Unk		Not Reported
	Atozet			C	Unknown	Unk		Not Reported
	Ass			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14435220	EXPEDITED (15-DAY)		OT	FR-CIPLA LTD.-2018FR01315			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability;	Amlodipine			S	Unknown	1 Df, Daily		Invagen
	Escitalopram			S	Unknown	1 Df, Daily		Invagen
	Atenolol			S	Unknown	50 Mg, Daily		Not Reported
	Simvastatin			S	Unknown	20 Mg, Daily		Not Reported
	Zyloric			S	Unknown	1 Df, Daily		Not Reported

Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus; Urticaria; Vertigo; Vision Blurred	Levothyrox		S	Oral	1 Df, Daily	Not Reported
	Cotareg		S	Unknown	1 Df, Qd	Not Reported
	Seresta		S	Unknown	12.5 Mg, Daily	Not Reported
	Uvedose		S	Unknown	1 Df, Unk	Not Reported
	Imovane		S	Unknown	0.5 Df, Daily	Not Reported
	Endotelon		S	Unknown	2 À 3 Cp/J	Not Reported
	Voltarene /00372302/		S	Unknown	2x/Semaine	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14436399	EXPEDITED (15-DAY)		DS, OT	AU-TAKEDA-2018TUS002086		31 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Brintellix			S	Unknown	10 Mg, Qd		Takeda
	Lexapro			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14437079	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US01324			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Necrotising Colitis	Escitalopram			S	Transmammary	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14440991	EXPEDITED (15-DAY)		OT	PHHY2018FR009186		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Headache; Somnolence	Alprazolam			S	Oral	5 Mg, Unk		Novartis
	Dafalgan			S	Oral	16 G, Unk		Not Reported
	Zoloft			S	Oral	700 Mg, Unk		Not Reported
	Seroplex			S	Oral	780 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14444119	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1803794US		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported
	Orozamudol			S	Oral	150 Mg, Qd		Not Reported
	Mirtazapine			S	Oral	45 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14308028	EXPEDITED (15-DAY)		OT	ES-009507513-1712ESP006251			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Simvastatin			S	Unknown	Unk		Merck
	Simvastatin			S	Unknown	1 Df, Qd		Merck
	Enalapril Maleate (+) Hydrochlorothiazide			S	Unknown	1 Df, Qd		Merck
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown			Not Reported
	Glyburide			S	Unknown	2 Df, Qd		Not Reported
	Omeprazole			S	Unknown	1 Df, Qd		Not Reported
	Diazepam (+) Sulpiride			S	Unknown	1 Df, Qd		Not Reported
	Topiramate			S	Unknown	1 Df, Qd		Not Reported
	Topiramate			S	Unknown	0.5 Df, Qd		Not Reported
	Amlodipine			S	Unknown	1 Df, Qd		Not Reported
	Acetaminophen			S	Unknown	3 Df, Qd		Not Reported
	Diazepam			S	Unknown	0.5 Df, Qd		Not Reported

	Acetaminophen (+) Tramadol Hydrochloride	S	Unknown	3 Df, Qd	Not Reported
	Lormetazepam	S	Unknown	1 Df, Qd	Not Reported
	Escitalopram	S	Unknown	1 Df, Qd	Not Reported
	Metoclopramide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446545	NON-EXPEDITED			US-TELIGENT, INC-IGIL20180038		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Generalised	Ranitidine Hydrochloride			S	Unknown			Not Reported
	Tums Ultra, Mint Flavor			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Losartan			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Atenolol			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Vitamin B12			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447848	EXPEDITED (15-DAY)		DE	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-12-00		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Pradaxa			S	Oral			Boehringer Ingelheim
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14457944	DIRECT					24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Balance Disorder; Dizziness; Flushing; Heart Rate Increased; Hyperhidrosis; Joint Stiffness; Loss Of Consciousness; Nausea; Somnolence; Vomiting	Escotalopram	S	Oral	Quantity:1 Tablet(S);		Not Reported
	Pro Air	C				Not Reported
	Caprylic Acid	C				Not Reported
	Vitamin D Nos	C				Not Reported
	Vitamin E	C				Not Reported
	B12	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2018	13275469	EXPEDITED (15-DAY)		OT	ES-GLENMARK PHARMACEUTICALS-2017GMK026519		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sialoadenitis	Ondansetron			S	Unknown	Unk		Glenmark
	Cipralex /01588501/			S	Oral	10 Mg, Qd		Not Reported
	Temozolomide			C	Unknown	Cyclical		Not Reported
	Levetiracetam			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2018	14449318	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013967		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Poisoning Deliberate	Propranolol Hydrochloride Tablets 80mg			S	Oral	Unk Unk, Unknown		Vintage
	Amitriptyline Hcl			S	Oral	Unk Unk, Unknown		Vintage
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported
	Acetaminophen			S	Oral	Unk Unk, Unknown		Not Reported
	Ethanol			S	Oral	Unk Unk, Unknown		Not Reported
	Cocaine			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2018	14449326	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013975		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion; Poisoning	Propranolol Hydrochloride Tablets 80mg			S	Oral	Unk Unk, Unknown		Vintage
	Lamotrigine			S	Oral	Unk Unk, Unknown		Par
	Percocet			S	Oral	Unk Unk, Unknown		Vintage
	Ibuprofen			S	Oral	Unk Unk, Unknown		Par
	Montelukast Sodium Tablets 10mg			S	Oral	Unk Unk, Unknown		Vintage
	Acyclovir Capsules			S	Oral	Unk Unk, Unknown		Dava
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported
	Ondansetron			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2018	14449329	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013965		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure Via Ingestion; Exposure Via Inhalation; Poisoning	Propranolol Hydrochloride Tablets 80mg			S		Unk Unk, Unknown, Ingst + Aspir		Vintage
	Lamotrigine			S		Unk Unk, Unknown, Ingst + Aspir		Par
	Clonazepam			S		Unk Unk, Unknown, Ingst + Aspir		Par
	Escitalopram			S		Unk Unk, Unknown, Ingst + Aspir		Not Reported
	Mirtazapine			S		Unk Unk, Unknown, Ingst + Aspir		Not Reported
	Cyclobenzaprine			S		Unk Unk, Unknown, Ingst		Not Reported

				+ Aspir	
	Buspirone		S	Unk Unk, Unknown, Ingst + Aspir	Not Reported
	Activated Charcoal		S	Unk Unk, Unknown, Ingst + Aspir	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2018	14449340	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-014027		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Bupropion Hcl Xl			S	Oral	Unk Unk, Unknown		Par
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2018	14449355	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-014045		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion Hcl Xl			S	Oral	Unk Unk, Unknown		Par
	Bupropion Hcl Xl			S		Unk		Par
	Amlodipine Besylate Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported
	Salicylates Nos			S	Oral	Unk Unk, Unknown		Not Reported
	Losartan			S	Oral	Unk Unk, Unknown		Not Reported
	Levothyroxine			S	Oral	Unk Unk, Unknown		Not Reported
	Ethanol			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2018	14449364	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-014052		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Bupropion Hcl Xl		S	Oral	Unk Unk, Unknown	Par
	Venlafaxine Hydrochloride		S	Oral	Unk Unk, Unknown	Par
	Escitalopram		S	Oral	Unk Unk, Unknown	Not Reported
	Alpha Blocker		S	Oral	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2018	14449384	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-014064		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Abuse	Bupropion Hcl Xl			S	Unknown	Unk Unk, Unknown		Par
	Alprazolam Tablets			S	Unknown	Unk Unk, Unknown		Vintage
	Cocaine			S	Unknown	Unk Unk, Unknown		Not Reported
	Escitalopram			S	Unknown	Unk Unk, Unknown		Not Reported
	Ethanol			S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	13260660	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1706547US		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sialoadenitis	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan
	Ondansetron			S	Unknown	Unk, Unknown		Not Reported
	Ondansetron			S	Unknown			Not Reported
	Temozolomide			S	Unknown	Unk, Unknown		Not Reported
	Dexamethasone			S	Unknown	Unk, Unknown		Not Reported
	Levetiracetam			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450666	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013869		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Diltiazem Hcl	S	Oral	Unk Unk, Unknown	Par
	Propranolol Hcl Tablets 80mg	S	Oral	Unk Unk, Unknown	Vintage
	Metformin Hydrochloride Tablets	S	Oral	Unk Unk, Unknown	Provident Pharmaceutical
	Glyburide (Micronized) Tablets	S	Oral	Unk Unk, Unknown	Dava
	Lorazepam Tablets	S	Oral	Unk Unk, Unknown	Vintage
	Escitalopram	S	Oral	Unk Unk, Unknown	Not Reported
	Losartan	S	Oral	Unk Unk, Unknown	Not Reported
	Levothyroxine	S	Oral	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14452734	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2018SE10003		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Xeroquel			S	Oral	2500.0mg Unknown		Astrazeneca
	Escitalopram			S	Oral	880.0mg Unknown		Not Reported
	Prazepam			S	Oral	1200.0mg Unknown		Not Reported
	Valsartan			S	Oral	14400.0mg Unknown		Not Reported
	Bromazepam			S	Oral	144.0mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14453800	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-850313		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Sedation	Alprazolam			S	Oral	Alprazolam 0,25 1/2 Cp/D		Actavis
	Escitalopram			S	Oral			Ivax
	Risperdal 0,50 Mg, Coated Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14455259	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1804424US		68 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Olanzapine			C	Oral	2.5 Mg, Unk		Not Reported
	Etizolam			C	Oral	0.5 Mg, Unk		Not Reported
	Triazolam			C	Oral	0.2 Mg, Unk		Not Reported
	Fluvoxamine Maleate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	13020625	NON-EXPEDITED			US-ALLERGAN-1671209US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Tightness	Escitalopram Oxalate Unk			S		Unk		Allergan
	Escitalopram Oxalate Unk			S				Allergan
	Effexor			C				Not Reported
	Effexor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	13020636	NON-EXPEDITED			US-ALLERGAN-1676643US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Muscle Twitching; Tremor	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	13301802	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2017-30750		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Salivary Duct Obstruction; Sialoadenitis	Cipralex /01588501/			S	Oral			Not Reported
	Ondansetron			S	Unknown			Not Reported
	Ondansetron			S		()		Not Reported
	Temozolomide			C	Unknown			Not Reported

	Temozolomide	C		()Cyclical	Not Reported
	Levetiracetam	C	Unknown		Not Reported
	Levetiracetam	C		()	Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Dexamethasone	C		()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14425099	EXPEDITED (15-DAY)		DS, HO	DE-ALLERGAN-1802880US		57 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Chest Pain; Diarrhoea; Gait Disturbance; Haematoma; Haemorrhage; Muscle Disorder; Myalgia; Nerve Injury; Staphylococcal Infection; Walking Aid User	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Valproic Acid			S	Unknown	900 Mg, Bid		Not Reported
	Ibuprofen			C	Unknown	600 Mg, Qid		Not Reported
	Xarelto			C	Unknown	10 Mg, Qd		Not Reported
	Novaminsulfon			C	Unknown	500 Mg, Tid (On A Regular Basis)		Not Reported
	Cefazolin			C	Unknown	2 G, Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14456098	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR01916			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram			S	Oral	14 Df, In Total		Invagen
	Tramadol			C	Oral	20 Df, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14457036	EXPEDITED (15-DAY)		HO, OT	ZA-LUPIN PHARMACEUTICALS INC.-2018-00371		46 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hospitalisation	Zytomil Tablets		S	Oral	20 Mg, Unk	Lupin
	Dyna Lamotrigine Tablets		S	Oral	100 Mg, Unk	Not Reported
	Urbanol		S	Oral	10 Mg, Unk	Not Reported
	Fluanxol /00109702/		S	Oral	0.5 Mg, Unk	Not Reported
	Dopaquel		S	Oral	200 Mg, Unk	Not Reported
	Euthyrox		S	Oral	75 Mg, Unk	Not Reported
	Metformin Sandoz		S	Oral	850 Mg, Unk	Not Reported
	Diaglucide		S	Oral	30 Mg, Unk	Not Reported
	Levemir		S	Unknown	100 Iu, Unk	Not Reported
	Novorapid		S	Unknown	100 Iu, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14458842	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1804428US		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	14 Df, Single		Allergan
	Tramadol Base			S	Oral	; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14458843	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1804404US		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Exposure Via Father; Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram Oxalate - Bp			S	Transplacental	7.5 Mg, Qd		Allergan
	Folsan			C	Transplacental	0.4 Mg, Qd		Not Reported
	Paracetamol			C	Transplacental			Not Reported
	Ebrantil			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Ramilich			C	Unknown	10 Mg, Qd		Not Reported

Dekristol	C	Unknown	20000 Iu, Q2weeks		Not Reported
Bicanorm	C	Unknown			Not Reported
Ass 100	C	Unknown	100 Mg, Unk		Not Reported
Amlodipine	C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14459339	EXPEDITED (15-DAY)		HO	MY-IMPAX LABORATORIES, INC-2018-IPXL-00221		48 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Cerebellar Ataxia; Ophthalmoplegia	Divalproex Sodium Er			S	Unknown	Unk		Impax
	Phenytoin			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461501	NON-EXPEDITED			US-ALLERGAN-1768445US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Injection Site Pain; Tinnitus	Escitalopram Oxalate Unk			S	Unknown	5 Mg, Unk		Allergan
	Fondaparinux			S	Subcutaneous	Unk Unk, Qd		Not Reported
	Lisinopril			C	Unknown	20 Mg, Unk		Not Reported
	Temazepam			C	Unknown	15 Mg, Unk		Not Reported
	Iron			C	Unknown	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461502	NON-EXPEDITED			US-ALLERGAN-1767157US		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Physical Issue	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461503	NON-EXPEDITED			US-ALLERGAN-1754068US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Citalopram Hydrobromide - Bp			S				Allergan
	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461505	NON-EXPEDITED			US-ALLERGAN-1774049US		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Headache; Nausea; Photophobia; Product Dose Omission; Vomiting	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Buspirone Hydrochloride			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461506	NON-EXPEDITED			US-ALLERGAN-1756013US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective	Escitalopram Oxalate - Bp			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461507	NON-EXPEDITED			US-ALLERGAN-1749181US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Panic Attack	Escitalopram Oxalate Unk			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461512	NON-EXPEDITED			US-ALLERGAN-1763108US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Vomiting	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461513	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1774020US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Depressed Mood; Product Dose Omission; Sexual Dysfunction; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461514	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1747517US		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apraxia; Colitis Ulcerative; Crying; Depression; Headache; Herpes Zoster; Somnolence; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Humira			S	Subcutaneous	40 Mg, Q Week		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q Week		Not Reported
	Allopurinol			C	Unknown			Not Reported
	Imuran			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Vitamin D2			C	Unknown			Not Reported
	Risaquad			C	Unknown			Not Reported
	Combivent			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461515	NON-EXPEDITED			US-ALLERGAN-1765347US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus Generalised	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461516	NON-EXPEDITED			US-ALLERGAN-1766210US		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Stelara			S	Subcutaneous	90 Mg, Q3months		Not Reported
	Losartan			C		50 Mg, Qd		Not Reported
	Fish Oil			C				Not Reported
	Multivitamin			C				Not Reported
	Hyaluronic Acid			C				Not Reported
	Aspirin			C		81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461517	NON-EXPEDITED			US-ALLERGAN-1756926US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lexapro			S	Oral	5 Mg, Unk		Allergan
	Plavix			C	Oral	Unk, Qd		Not Reported
	Colace			C	Oral	Unk, Qd		Not Reported
	Crestor			C	Oral	Unk, Qd		Not Reported
	Miralax			C	Oral			Not Reported
	Sucrose			C	Oral	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461518	NON-EXPEDITED			US-ALLERGAN-1774013US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Decreased Appetite; Dizziness; Drug Ineffective	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461519	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1768085US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Disturbance In Attention; Nausea; Panic Reaction; Self-Injurious Ideation	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Escitalopram Mylan			S	Unknown	15 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461520	NON-EXPEDITED			US-ALLERGAN-1768518US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14461822	EXPEDITED (15-DAY)		OT	SI-TEVA-2018-SI-850286		49 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Left Ventricular Hypertrophy	Rosuvastatin			S	Unknown			Teva
	Perindopril			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Ivax
	Indapamide			S	Unknown			Not Reported
	Alprazolam			S	Unknown	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14463551	NON-EXPEDITED		HO, OT	US-ACORDA-ACO_133421_2017		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Therapy Cessation; Transurethral Prostatectomy; Withdrawal Syndrome	Ampyra			S	Oral	10 Mg, Bid		Acorda
	Lexapro			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Vitamin D3			C	Unknown	1000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14464361	NON-EXPEDITED			US-ACORDA-ACO_134485_2017			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Insomnia; Weight Increased	Ampyra			S	Oral	10 Mg, Q 12 Hrs		Acorda
	Avonex			S	Intramuscular	30 Microgram, 1 For 1 Week		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Celexa			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	11650889	EXPEDITED (15-DAY)		DS, HO, OT	NO-ASTRAZENECA-2015SE99390		24 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Bacteraemia; Alopecia; Anxiety; Atrophy Of Globe; Blister; Cataract;	Seroquel			S	Oral	Unk		Zeneca
	Lamictal			S	Oral	Unk		Not Reported

Confusional State; Dacryostenosis Acquired; Drug Ineffective; Dry Eye; Entropion; Eye Injury; Eye Oedema; Eye Pain; Eyelid Oedema; Face Oedema; Generalised Erythema; Headache; Inappropriate Affect; Injury Corneal; Keratopathy; Lacrimation Increased; Lens Disorder; Migraine; Mucosal Disorder; Obstructive Airways Disorder; Ocular Hyperaemia; Oral Mucosal Blistering; Oral Pain; Photophobia; Pyrexia; Rash; Sepsis; Skin Exfoliation; Staphylococcal Bacteraemia; Stevens-Johnson Syndrome; Symblepharon; Tachycardia; Toxic Epidermal Necrolysis; Trichiasis; Ulcer; Visual Impairment; Vulvovaginal Erythema; Wound Healing Normal; Wound Infection Staphylococcal	Cipralex	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	13599635	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2017M1032256		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Hypotension; Labelled Drug-Drug Interaction Medication Error; Mental Status Changes; Toxicity	Clozapine			S		450 Mg, Qd		Not Reported
	Clozapine			S		200 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported

To Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	13599639	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2017M1032255		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hip Arthroplasty; Labelled Drug-Drug Interaction Medication Error; Somnolence; Toxicity To Various Agents	Clozapine			S		400 Mg, Qd		Not Reported
	Clozapine			S		200 Mg, Qd		Not Reported
	Valproic Acid			S		Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Aripiprazole			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	13815646	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2017M1047163		79 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antipsychotic Drug Level Above Therapeutic; Coma; Hallucination, Visual; Hyperhidrosis; Hypertension; Musculoskeletal Stiffness; Mutism; Neuroleptic Malignant Syndrome; Pyrexia; Renal Impairment; Rhabdomyolysis; Urinary Tract Infection	Clozapine			S		Unk		Not Reported
	Clozapine			S		Unk		Not Reported
	Carbidopa/Levodopa			S				Not Reported
	Escitalopram			S				Not Reported
	Memantine			S				Not Reported
	Lithium			S				Not Reported
	Pregabalin			S				Not Reported
	Amantadine			S				Mylan
	Zotepine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	13818420	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1731982US		97 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome;	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

Pneumonia Aspiration	Tercian	S	Oral	5 Gtt, Tid	Not Reported
	Levothyrox	C	Oral	75 Mg, Qd	Not Reported
	Levothyrox	C	Oral	12.5 Mg, Qd	Not Reported
	Sectral	C	Oral	200 Mg, Qd	Not Reported
	Orocal D3	C	Oral	1 Df, Qd	Not Reported
	Kardegic	C	Oral	75 Mg, Qd	Not Reported
	Ogast	C	Oral	30 Mg, Qd	Not Reported
	Aldactazine	C	Oral	15 Mg, Qd	Not Reported
	Imovane	C	Oral	0.5 Df, Qd	Not Reported
	Bromazepam	C	Oral	1.5 Mg, Bid	Not Reported
	Forlax	C	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14466209	EXPEDITED (15-DAY)		OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-161861			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Hallucination, Visual; Hypotonia; Rapid Eye Movement Sleep Behaviour Disorder; Therapeutic Product Effect Incomplete	Mirtazapine			S	Unknown			Sun
	Escitalopram			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Sun
	Clomipramine			S	Unknown			Taro
	Nortriptyline			S	Unknown			Ranbaxy
	Imipramine			S	Unknown			Mutual
	Solifenacin			S	Unknown			Not Reported
	Donepezil			S	Unknown	10 Mg, Daily		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14466310	EXPEDITED (15-DAY)		DE, OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-161899		57 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram			S	Unknown			Not Reported
	Paracetamol		Y	S	Unknown			Ohm Lab

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14466492	EXPEDITED (15-DAY)		HO, LT	ES-APOTEX-2018AP005533		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose	Quetiapine			S	Oral	19 G, Qd, Intotal		Apotex
	Escitalopram			S	Oral	30 Mg, Qd, In Total		Apotex
	Clonazepam			S	Oral	22.5 Mg, Qd, Intotal		Not Reported
	Valproato			S	Oral	3.6 Mg, Qd, Intotal		Not Reported
	Antabus			S	Oral	250 Mg, Qd		Not Reported
	Abilify			S	Oral	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14467373	EXPEDITED (15-DAY)		DE, OT	ZA-LUPIN PHARMACEUTICALS INC.-2018-00363			Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Zartan (Losartan Potassium)			S	Oral	100 Mg, Unk		Lupin
	Aspavor			S	Oral	10 Mg, Unk		Not Reported
	Lomanor			S	Oral	5 Mg, Unk		Not Reported
	Calciferol /00107901/			S	Oral	50000 Iu, Unk		Not Reported
	Onbrez Breezhaler			S	Oral	150 Mcg, Unk		Not Reported
	Cipla-Simvastatin			S	Oral	40 Mg, Unk		Not Reported
	Alvesco			S	Oral	80 Mcg, Unk		Not Reported
	Forvent			S	Oral	18 Mcg, Unk		Not Reported
	Venteze /00139501/			S	Oral	100 Mcg, Unk		Not Reported
	Lexamil			S				Not Reported

	Ecotrin	S	Oral	81 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14467515	NON-EXPEDITED			US-ALLERGAN-1755351US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Savella			S	Unknown	Unk		Allergan
	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14470069	NON-EXPEDITED			US-ACORDA-ACO_142393_2017		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Insomnia	Ampyra			S	Oral	10 Mg, Qd		Acorda
	Lexapro			S	Unknown	Unk, In The Morning		Not Reported
	Gilenya			C	Unknown	Unk, 6-6:30 Pm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14470488	EXPEDITED (15-DAY)		HO	PHHY2018FR011999		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Coma; Fall; Rib Fracture	Zolpidem			S	Oral	Unk		Novartis
	Lexomil			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Baclofene			S	Oral	Unk		Not Reported
	Valium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14471179	EXPEDITED (15-DAY)		OT	TR-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00021		34 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Sinus Bradycardia	Cetirizine			S	Oral	10 Mg, 1x/Day		Jubilant
	Escitalopram			S	Unknown	10 Mg, 1x/Day		Jubilant
	Ampicillin			C	Intravenous (not otherwise specified)	2 G, 6x/Day (Every 4 H)		Not Reported
	Enoxaparin			C	Unknown	60 Mg, 1x/Day		Not Reported
	Pantoprazole			C	Unknown	40 Mg, 1x/Day		Not Reported
	Aspirin			C	Unknown	100 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14471785	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1804716US		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Lip Oedema; Urticaria	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14471830	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1804710US		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Laryngospasm; Off Label Use; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Xenazine			S	Oral	Unk, Unknown		Not Reported
	Lasilix			C	Unknown			Not Reported
	Plavix			C	Unknown			Not Reported
	Lysanxia			C	Unknown			Not Reported
	Dafalgan			C	Unknown			Not Reported
	Symbicort			C	Unknown			Not Reported
	Chondrosulf			C	Unknown			Not Reported
	Spasmine			C	Unknown			Not Reported
	Hydrea			C	Unknown			Not Reported

	Zyloric	C	Unknown		Not Reported
	Tareg	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14471841	EXPEDITED (15-DAY)		OT	ES-FRESENIUS KABI-FK201801181		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sialoadenitis	Ondansetron (Manufacturer Unknown)			S	Unknown			Not Reported
	Dexamethasone			S	Unknown			Not Reported
	Cipralex			S	Oral			Not Reported
	Temozolomide			S	Unknown			Not Reported
	Levetiracetam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14472061	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1804839US		79 YR	Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Ischaemia; Migraine; Photophobia; Vomiting; Vomiting	Escitalopram Oxalate - Bp			S	Oral	1 Df, Unk		Allergan
	Binocrit			S	Subcutaneous	1 Df, Unk		Not Reported
	Symbicort			C	Unknown			Not Reported
	Losartan Actavis			C	Unknown			Not Reported
	Norvasc			C	Unknown			Not Reported
	Plavix			C	Unknown			Not Reported
	Rocaltrol			C	Unknown			Not Reported
	Seacor			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Dilatrend			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14472310	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1005861		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor; Suicide Attempt	Escitalopram			S	Oral	30 Ml, Total		Not Reported
	Alprazolam			S	Oral	16 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	11624794	EXPEDITED (15-DAY)		DS, HO, OT	NO-GLAXOSMITHKLINE-NO2015GSK142742		24 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Bacteraemia; Alopecia; Anxiety; Atrophy Of Globe; Blister; Cataract; Confusional State; Dacryostenosis Acquired; Drug Ineffective; Dry Eye; Entropion; Eye Injury; Eye Oedema; Eye Pain; Eyelid Oedema; Face Oedema; Generalised Erythema; Headache; Inappropriate Affect; Injury Corneal; Keratopathy; Lacrimation Increased; Lens Disorder; Migraine; Mucosal Disorder; Obstructive Airways Disorder; Ocular Hyperaemia; Oral Mucosal Blistering; Oral Pain; Photophobia; Photophobia; Pyrexia; Rash; Sepsis; Skin Exfoliation; Staphylococcal Bacteraemia; Stevens-	Lamictal			S	Unknown	Unk		Glaxosmithkline
	Cipralex			S	Unknown	Unk		Glaxosmithkline
	Seroquel			S	Unknown	Unk		Glaxosmithkline

Johnson Syndrome; Symblepharon; Tachycardia; Toxic Epidermal Necrolysis; Trichiasis; Ulcer; Visual Impairment; Vulvovaginal Erythema; Wound Healing Normal; Wound Infection Staphylococcal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	13949129	EXPEDITED (15-DAY)		HO, OT	NO-GLAXOSMITHKLINE-NO2017001990		17 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Memory Impairment; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness; Substance Use	Cipralex			S	Unknown	Unk Unk, Qd		Glaxosmithkline
	Efexor Depot			S	Unknown	Unk		Glaxosmithkline
	Efexor Depot			S	Unknown	Unk		Glaxosmithkline
	Efexor Depot			S	Unknown	Unk		Glaxosmithkline
	Efexor Depot			S	Unknown	Unk		Glaxosmithkline
	Efexor			S	Unknown	Unk		Glaxosmithkline
	Olanzapine			S	Unknown	Unk		Glaxosmithkline
	Lamictal			S	Unknown	Unk		Glaxosmithkline
	Lamictal			S	Unknown	Unk		Glaxosmithkline
	Seroxat			S	Unknown	20 Mg, Qd		Glaxosmithkline
	Seroxat			S	Unknown	Unk		Glaxosmithkline
	Seroquel			S	Oral	Unk		Glaxosmithkline
	Seroquel			S	Oral	Unk		Glaxosmithkline
	Seroquel			S	Oral	Unk		Glaxosmithkline
	Zyprexa			S	Unknown	Unk		Glaxosmithkline
	Orfiril			S	Unknown	Unk		Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown	10 Mg, Qd Daily		Not Reported

Cipramil	S	Unknown	60 Mg, Qd		Not Reported
Sobril	C	Unknown	Unk, Prn		Glaxosmithkline
Valproat	S	Unknown	Increasing Dose		Not Reported
Lithionit	C	Unknown	Unk		Not Reported
Lithionit	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14474309	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1804919US		68 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Tachycardia	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Eutirox			S	Oral	1 Df, Cyclical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14474825	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1006110			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus; Urticaria; Vertigo; Vision Blurred	Atenolol			S		50 G, Unk		Not Reported
	Simvastatin			S		20 Mg, Unk		Not Reported
	Zyloric			S		1 Df, Unk		Mylan
	Levothyrox			S	Oral	1 Df, Unk		Mylan
	Cotareg			S		1 Df, Unk		Mylan
	Amlor			S		1 Df, Unk		Mylan
	Seresta			S		12.5 Mg, Unk		Mylan
	Uvedose			S		1 Df, Unk		Mylan
	Imovane			S		0.5 Df, Unk		Mylan
	Seroplex			S		1 Df, Unk		Mylan
	Endotelon			S		2 À 3 Cp/J		Mylan
	Voltarene /00372302/			S		2x/Semaine		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14475599	EXPEDITED (15-DAY)		OT	PHHY2018AU014267			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Ketoacidosis	Clozapine			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Novartis
	Escitalopram			S	Unknown			Not Reported
	Esomeprazole			S	Unknown			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Dapagliflozin			S	Unknown			Not Reported
	Sitagliptin Metformin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14480549	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	13551649	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1719890US		13 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Fear Of Injection; Hereditary Angioedema; Infusion Site Pain; Off Label Use; Pharyngitis Streptococcal; Selective Mutism; Vaginal Infection; Vascular Access Site Occlusion	Escitalopram Oxalate Unk			S	Unknown			Allergan
	Berinert			S	Subcutaneous	Unk		Not Reported
	Berinert			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Berinert			S	Subcutaneous	1500 Iu, Unk		Not Reported
	Berinert			S	Intravenous (not otherwise specified)	3000 Iu (1500 Itx2)		Not Reported
	Berinert			S	Subcutaneous	1500 Iu, Three Times A		Not Reported

					Week	
	Berinert		S	Intravenous (not otherwise specified)	3000 Iu, Unk	Not Reported
	Berinert		S	Intravenous (not otherwise specified)	3000 Iu, Unk	Not Reported
	Berinert		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Berinert		S	Intravenous (not otherwise specified)	1500 Iu, Unk	Not Reported
	Berinert		S	Subcutaneous	1500 Iu, Unk	Not Reported
	Berinert		S	Intravenous (not otherwise specified)	1500 Iu, Three Times A Week	Not Reported
	Firazyr Pre-Filled Syringe		C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14303391	EXPEDITED (15-DAY)			IE-OTSUKA-2017_025246		34 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Abilify			S	Oral	Unk		Otsuka
	Abilify Maintena			S	Unknown	1 Df, Unk		Otsuka
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14473887	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-003727		44 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Type 2 Diabetes Mellitus	Escitalopram			S	Oral	Unk		Aurobindo
	Laroxyl			S	Oral	Unk		Not Reported
	Oxycontin			S	Oral	2 Df, Once A Day		Not Reported
	Triumeq			S	Oral	1 Df, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14478271	EXPEDITED (15-DAY)		HO, OT	AT-TEVA-2018-AT-849637		58 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Intention Tremor; Lethargy; Resting Tremor; Sedation; Social Avoidant Behaviour; Tremor	Risperidone			S	Unknown			Pliva
	Pregabalin			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Pregabalin			S	Oral			Not Reported
	Topiramate			S	Oral			Not Reported
	Topiramate			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Pantoprazol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14479082	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018009087			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Escitalopram Oxalate			S	Oral	880 Mg, Unk		Macleods
	Valsartan			S	Oral	14400 Mg, Unk		Macleods
	Xeroquel			S	Oral	2500 Mg, Unk		Not Reported
	Prazepam			S	Oral	1200 Mg, Unk		Not Reported
	Bromazepam			S	Oral	144 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14479310	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005691		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Extended Release		Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Lorazepam			S	Oral			Unknown
	Oxcarbazepine			S	Oral			Unknown
	Quetiapine Fumarate			S	Oral			Unknown
	Zolpidem			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14480635	EXPEDITED (15-DAY)		OT	PHHY2018AU014247			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Pulmonary Embolism; Tricuspid Valve Incompetence	Clozapine			S	Unknown			Not Reported
	Metformin			S	Unknown			Novartis
	Escitalopram			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Clopine			S	Unknown			Not Reported
	Paliperidone			S	Unknown			Not Reported
	Cholecalciferol			S	Unknown			Not Reported
	Desmopressin			S	Unknown			Not Reported
	Fluticone			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2018	14482714	EXPEDITED (15-DAY)		OT	HR-TEVA-2018-HR-850982		17 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypotension; Somnolence; Suicide Attempt	Escitalopram		S	Oral	3 Tablets	Not Reported
	Ibuprofen		S	Oral	A Couple Of Tablets	Actavis
	Olanzapine		S	Oral		Not Reported
	Aspirin		S	Oral	A Couple Of Tablets	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2018	14482900	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-162230		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Escitalopram			S	Oral	880 Mg, Unk		Not Reported
	Valsartan			S	Oral			Ranbaxy
	Xeroquel			S	Oral			Not Reported
	Prazepam			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2018	14483005	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-004567		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Bromazepam			S	Oral	144 Mg, Unk		Not Reported
	Escitalopram			S	Oral	880 Mg, Unk		Aurobindo
	Prazepam			S	Oral	1200 Mg, Unk		Not Reported
	Valsartan			S	Oral	14400 Mg, Unk		Aurobindo
	Xeroquel			S	Oral	2500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	11676813	EXPEDITED (15-DAY)		DS, HO, OT	NO-FRI-1000080382		24 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acinetobacter Bacteraemia; Alopecia; Anxiety; Atrophy Of Globe; Blister; Body Temperature Increased; Cataract; Confusional State; Dacryostenosis Acquired; Drug Ineffective; Dry Eye; Entropion; Eye Injury; Eye Oedema; Eye Pain; Eyelid Oedema; Face Oedema; Generalised Erythema; Headache; Inappropriate Affect; Injury Corneal; Keratopathy; Lacrimation Increased; Lens Disorder; Migraine; Mucosal Disorder; Obstructive Airways Disorder; Ocular Hyperaemia; Oral Mucosal Blistering; Oral Pain; Photophobia; Rash; Sepsis; Skin Exfoliation; Staphylococcal Bacteraemia; Stevens-Johnson Syndrome; Symblepharon; Tachycardia; Toxic Epidermal Necrolysis; Trichiasis; Ulcer; Visual Impairment; Vulvovaginal Erythema; Wound Healing Normal; Wound Infection Staphylococcal	Escitalopram Oxalate - Bp	S	Unknown	Unk	Allergan
	Lamictal Dispersible Tablet	S		Unk	Not Reported
	Seroquel	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	13926975	EXPEDITED (15-DAY)		HO, LT	CH-ALLERGAN-1748462US		55 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

Phosphokinase Increased; Consciousness Fluctuating; Dysphagia; Hyperreflexia; Muscle Rigidity; Mutism; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tremor	Escitalopram Oxalate - Bp	S		Unk		Allergan
	Abilify	S	Intramuscular			Not Reported
	Abilify	S				Not Reported
	Aripiprazole	S	Oral	15 Mg, Qd		Not Reported
	Aripiprazole	S	Oral	5 Mg, Qd		Not Reported
	Quetiapin Actavis Xr (Quetiapine Fumarate)	C	Oral			Not Reported
	Temesta (Lorazepam)	C	Oral			Not Reported
	Amlodipin (Amlodipine)	C	Oral			Not Reported
	Sandoz	C	Oral	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14325861	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1773529US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Daily		Allergan
	Zoely			S	Oral	One Tablet (2.5mg Nomegestrol Acetate And 1.5 Mg Estradiol), Daily		Not Reported
	Valdoxan			S	Unknown	25 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14407893	EXPEDITED (15-DAY)		DS, OT	CH-PFIZER INC-2018020850		63 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Decreased; Lumbar Vertebral Fracture; Rebound Effect	Pantozol			S	Oral	20 Mg, 1x/Day		Pfizer
	Prolia			S	Subcutaneous	60 Mg, Cyclic (Every Six Months)		Not Reported
	Cipralex			S	Oral	Unk		Not Reported
	Dafalgan			C	Oral	1 G, 4x/Day		Not Reported
	Kalcipos D3			C	Oral	Unk, 1x/Day		Not Reported

Metamizole Sodium	C	Oral	Unk		Not Reported
Requip	C	Oral	4 Mg, 1x/Day		Not Reported
Temesta (Lorazepam)	C	Oral	Unk		Not Reported
Vitamin D3 Streuli	C	Oral	2 Ml, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14452831	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1804318US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Thyroid Stimulating Hormone	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan
	Zyloric			S	Unknown	1 Df, Qd		Not Reported
	Levothyrox			S	Oral	1 Df, Qd		Not Reported
	Atenolol			S	Unknown	50 Mg, Qd		Not Reported
	Simvastatine			S	Unknown	20 Mg, Qd		Not Reported
	Cotareg			S	Unknown	1 Df, Qd		Not Reported
	Amlor			S	Unknown	1 Df, Qd		Not Reported
	Seresta			S	Unknown	12.5 Mg, Qd		Not Reported
	Uvedose			S	Unknown	Time Interval:1		Not Reported
	Imovane			S	Unknown	0.5 Df, Qd		Not Reported
	Endotelon			S	Unknown	Unk		Not Reported
	Voltarene (Diclofenac Sodium)			S	Unknown	Unk, Bi-Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14488227	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2018-002364		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sialoadenitis	Dexamethasone			S	Unknown			Bausch And Lomb
	Cipralex			S	Oral			Not Reported
	Temozolomide			S	Unknown			Not Reported

	Ondansetron	S	Unknown	Not Reported
	Levetiracetam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14488356	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1805719US		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Oracilline			C	Oral	Unk		Not Reported
	Speciafoldine			C	Oral	15 Mg, Q Week		Not Reported
	Doliprane			C	Oral	Unk		Not Reported
	Atarax			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14488357	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1805745US		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Escitalopram Oxalate - Bp			S	Oral	880 Mg, Single		Allergan
	Xeroquel			S	Oral	2500 Mg, Single		Not Reported
	Prazepam			S	Oral	1200 Mg, Single		Not Reported
	Valsartan			S	Oral	14400 Mg, Single		Not Reported
	Bromazepam			S	Oral	144 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14376856	EXPEDITED (15-DAY)		HO	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006955			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Hallucination; Prescribed Underdose; Product Dose Omission; Somnolence	Nuplazid			S	Unknown	17 Mg, Qd		Acadia Pharmaceuticals
	Nuplazid			S	Unknown	34 Mg, Qd		Acadia Pharmaceuticals

	Nuplazid	S	Unknown	17 Mg, Qd		Acadia Pharmaceuticals
	Lexapro	S	Unknown	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14401061	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018008493			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Aripiprazole 10mg Tablet			S	Oral	10 Mg, Unk		Macleods
	Escitalopram Tablet			S	Oral	Unk		Macleods
	Clomipramine			S	Unknown	150 Mg/ 24 Hour (Qd)		Not Reported
	Fluvoxamine			S	Unknown	200 Mg/ 24 Hour (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14490215	NON-EXPEDITED		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-00362		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin
	Ethylene Glycol			S	Oral	Unk		Not Reported
	Loratadine			S	Oral	Unk		Not Reported
	Furosemide			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Folic Acid			S	Oral	Unk		Not Reported
	Vitamin B-1			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14490796	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2018-004571		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Paracetamol Tablet		S	Unknown	()	Aurobindo
	Escitalopram		S	Unknown		Aurobindo
	Baclofen		S	Unknown		Not Reported
	Dextropropoxyphene		S	Unknown		Not Reported
	Valpromide		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14491254	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2018M1009818			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Ketoacidosis	Atorvastatin			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Esomeprazole			S		Unk		Not Reported
	Gliclazide			S		Unk		Not Reported
	Clozapine			S		Unk		Not Reported
	Dapagliflozin			S		Unk		Mylan
	Sitagliptin Metformin			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14491946	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1805653US		44 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Type 2 Diabetes Mellitus	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Laroxyl			S	Oral	Unk		Not Reported
	Oxycontin Lp			S	Oral	2 Dosage Forms Daily		Not Reported
	Triumeq			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14494732	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1007823		44 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Type 2 Diabetes Mellitus	Escitalopram			S	Oral			Not Reported
	Laroxyl			S	Oral			Mylan
	Oxycontin Lp			S	Oral	2 Df, Unk		Mylan
	Triumeq			S	Oral	1 Df, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14497866	DIRECT					16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Sleep Disorder	Escitalopram Tab 10mg			S	Oral	Quantity:1 Tablet(S); At Bedtime		Not Reported
	Vitamin C			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Multivitamin			C				Not Reported
	Folic Acid			C				Not Reported
	Biotin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	13115203	EXPEDITED (15-DAY)		HO, OT	NO-ALLERGAN-1701429US		21 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise;	Citalopram Hydrobromide - Bp			S	Unknown	10 Mg, Qd		Allergan
	Citalopram Hydrobromide - Bp			S	Unknown	60 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Seroxat			S	Unknown	Unk		Not Reported
	Seroxat			S	Unknown	20 Mg, Daily		Not Reported
	Seroxat			S	Unknown	Unk		Not Reported
	Valproat			S	Unknown	Increasing Dose		Not Reported
	Orfiril			S	Unknown	Unk, Qd		Not Reported
	Zyprexa			S	Unknown	Unk, Qd		Not Reported

Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Olanzapine		S	Unknown	Unk, Qd	Not Reported
	Efexor Depot		S	Unknown	Unk, Qd	Not Reported
	Efexor Depot		S	Unknown	Unk, Qd	Not Reported
	Efexor Depot		S	Unknown	Unk, Qd	Not Reported
	Lamictal		S	Unknown	Unk, Qd	Not Reported
	Seroquel		S	Unknown	Unk, Qd	Not Reported
	Seroquel		S	Unknown	Unk, Qd	Not Reported
	Seroquel		S	Unknown	Unk, Qd	Not Reported
	Lithium		C	Unknown	Unk	Not Reported
	Lithionit		C	Unknown	Unk	Not Reported
	Lithionit		C	Unknown	Unk	Not Reported
	Sobril		C	Unknown	Unk, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14322389	EXPEDITED (15-DAY)		HO	AT-OTSUKA-2017_027875		30 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Drug Interaction; Gamma-Glutamyltransferase Increased	Abilify			S	Oral	2.5 Mg, Qd		Otsuka
	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Abilify			S	Oral	7.5 Mg, Qd		Otsuka
	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Abilify			S	Oral	2.5 Mg, Qd		Otsuka
	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	5 Mg, Unk		Not Reported
	Cipralex			S	Oral	5 Mg, Unk		Not Reported
	Sycrest			S	Unknown	5 Mg, Unk		Not Reported

Sycrest	S	Unknown	20 Mg, Unk	Not Reported
Sycrest	S	Unknown	10 Mg, Unk	Not Reported
Sycrest	S	Unknown	15 Mg, Unk	Not Reported
Sycrest	S	Unknown	15 Mg, Unk	Not Reported
Zeldox	S	Oral	20 Mg, Unk	Not Reported
Zeldox	S	Unknown	80 Mg, Unk	Not Reported
Zeldox	S	Unknown	120 Mg, Unk	Not Reported
Zeldox	S	Unknown	40 Mg, Unk	Not Reported
Zeldox	S	Unknown	Unk, Unknown	Not Reported
Zyprexa	S	Oral	1 Mg, Qd (Mg Per Day1)	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	30 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	30 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	25 Mg, Unk	Not Reported
Trittico	S	Oral	100 Mg, Unk	Not Reported
Trittico	S	Oral	150 Mg, Unknown	Not Reported
Trittico	S	Oral	300 Mg, Unknown	Not Reported
Trittico	S	Oral	250 Mg, Unknown	Not Reported
Trittico	S	Oral	150 Mg, Unk	Not Reported
Trittico	S	Oral	100 Mg, Unk	Not Reported
Fluctine	S	Unknown	20 Mg, Unk	Not Reported
Quilonium R	S	Unknown	900 Mg, Unk	Not Reported
Quilonium R	S	Unknown	450 Mg, Unk	Not Reported

Quilonium R	S	Unknown	400 Mg, Unk	Not Reported
Quilonium R	S	Unknown	675 Mg, Unk	Not Reported
Rivotril	C	Unknown	2mg, Unknown	Not Reported
Rivotril	C	Unknown	4 Mg, Unknown	Not Reported
Rivotril	C	Unknown	4 Mg, Unknown	Not Reported
Rivotril	C	Unknown	2 Mg, Unknown	Not Reported
Rivotril	C	Unknown	1 Mg, Unknown	Not Reported
Inderal	C	Oral	50 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unknown	Not Reported
Inderal	C	Oral	60 Mg, Unknown	Not Reported
Inderal	C	Oral	30 Mg, Unknown	Not Reported
Inderal	C	Oral	40 Mg, Unknown	Not Reported
Inderal	C	Oral	20 Mg, Unknown	Not Reported
Inderal	C	Oral	40 Mg, Unknown	Not Reported
Inderal	C	Oral	90 Mg, Unknown	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	Unk	Not Reported
Inderal	C	Oral	40 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	900 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	600 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	300 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	900 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	600 Mg, Unk	Not Reported
Nozinan	C	Unknown	150 Mg, Unk	Not Reported
Nozinan	C	Unknown	50 Mg, Unk	Not Reported
Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	25 Mg, Unk	Not Reported
Nozinan	C	Unknown	50 Mg, Unk	Not Reported

Nozinan	C	Unknown	Unk	Not Reported
Lamictal	C	Oral	250 Mg, Unk	Not Reported
Lamictal	C	Oral	200 Mg, Unk	Not Reported
Lamictal	C	Oral	75 Mg, Unk	Not Reported
Lamictal	C	Oral	100 Mg, Unk	Not Reported
Lamictal	C	Oral	50 Mg, Unk	Not Reported
Lamictal	C	Oral	300 Mg, Unk	Not Reported
Lamictal	C	Oral	300 Mg, Unknown	Not Reported
Lamictal	C	Oral	100 Mg, Unk	Not Reported
Nubain	C	Unknown	1 Unk, 1df In 100ml Nacl	Not Reported
Risperdal	C	Unknown	2 Mg, Unknown	Not Reported
Risperdal	C	Unknown	1 Mg, Unk	Not Reported
Akineton	C	Unknown	2 Mg, Unk	Not Reported
Akineton	C	Unknown	4 Mg, Unk	Not Reported
Akineton	C	Unknown	2 Mg, Unk	Not Reported
Akineton	C	Unknown	Unk, Unknown	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	80 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	120 Mg, Unk	Not Reported
Praxiten	C	Unknown	25 Mg, Unk	Not Reported
Praxiten	C	Unknown	50 Mg, Unk	Not Reported
Sifrol	C	Unknown	0.26 Mg, Unknown	Not Reported
Sifrol	C	Unknown	0.34 Mg, Unknown	Not Reported
Temesta (Lorazepam)	C	Unknown	Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8 Mg, Unk	Not Reported

Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	10 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	7.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	7.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Zoldem	C	Unknown	5 Mg, Unk	Not Reported
Dibondrin	C	Unknown	50 Mg, Unk	Not Reported
Gastrozepin	C	Unknown	100 Mg, Unk	Not Reported
Truxal	C	Unknown	50 Mg, Unk	Not Reported

	Neurotrop		C	Oral	600 Mg, Unk	Not Reported
	Neurotrop		C	Oral	600 Mg, Unk	Not Reported
	Neurotrop		C	Oral	900 Mg, Unk	Not Reported
	Neurotrop		C	Oral	300 Mg, Unk	Not Reported
	Neurotrop		C	Oral	600 Mg, Unk	Not Reported
	Neurotrop		C	Oral	900 Mg, Unk	Not Reported
	Neurotrop		C	Oral	900 Mg, Unk	Not Reported
	Adasuve		C	Unknown	Unk, Unknown	Not Reported
	Quilonorm		C	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14355553	NON-EXPEDITED			US-PFIZER INC-2018003646		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Dilantin Kapseal			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Etodolac			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Lamictal			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Naprosyn			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14496414	EXPEDITED (15-DAY)		OT	IE-MACLEODS PHARMACEUTICALS US LTD-MAC2018009320			Unknown	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Discomfort;	Escitalopram Oxalate 10mg			S	Oral	10 Mg, Unk		Macleods

Insomnia; Motor Dysfunction; Pain In Extremity; Paraesthesia	Tablet Escitalopram Oxalate 10mg Tablet	S		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14496419	EXPEDITED (15-DAY)		DS, HO, OT	NO-MACLEODS PHARMACEUTICALS US LTD-MAC2018009322			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Olanzapine Tablet			S	Oral	Unk		Macleods
	Cipralex			S	Oral	Unk, Qd		Not Reported
	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported
	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported
	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported
	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported
	Efexor Depot			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Seroquel			S	Oral	Unk, Film-Coated Tablet		Not Reported
	Seroquel			S	Oral	Unk, Film-Coated Tablet		Not Reported
	Seroxat			S	Oral	Unk		Not Reported
	Seroxat			S	Oral	20 Mg, Qd		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown	10 Mg, Qd		Not Reported
	Cipramil			S	Unknown	60 Mg, Qd		Not Reported
	Sodium Valproate			S	Unknown	Unk, Increasing Dose		Not Reported
	Sobril			C	Oral	Unk, As Needed		Not Reported
	Lithionit			C	Unknown	Unk		Not Reported

Lithionit	C	Unknown	Unk		Not Reported
Orfiril	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14501794	EXPEDITED (15-DAY)		HO	PHHY2018FR017687		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	40 Mg (0-0-1), Qd		Novartis
	Escitalopram			S	Oral	10 Mg (1-0-0), Qd		Not Reported
	Irbesartan			S	Oral	75 Mg (1-0-0), Qd		Not Reported
	Furosemide			S	Oral	40 Mg (1-0-0), Qd		Not Reported
	Duphalac			C	Oral	1 Df, Tid (1-1-1)		Not Reported
	Havlane			C	Oral	1 Df (0-0-1), Qd		Not Reported
	Kardegic			C	Oral	1 Df (0-1-0), Qd		Not Reported
	Seresta			C	Oral	1 Df (0-0-1), Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	11242199	NON-EXPEDITED		HO, OT	FR-LUPIN PHARMACEUTICALS INC.-2015-01662		20 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis	Escitalopram			S	Unknown	Unk (Dose Progressively Titrated From 5 Mg To 20 Mg)		Lupin
	Escitalopram			S	Unknown	30 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	13093527	EXPEDITED (15-DAY)		HO, OT	NO-PFIZER INC-2017005122		21 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Aggression; Agitation; Alcohol Abuse;	Efexor Depot			S		Unk		Pfizer

Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Efexor Depot	S	Unk	Pfizer
	Efexor Depot	S	Unk	Pfizer
	Efexor Depot	S	Unk	Pfizer
	Olanzapine	S	Unk	Not Reported
	Seroxat	S	Unk	Not Reported
	Seroxat	S	20 Mg, Daily	Not Reported
	Cipramil /00582602/	S	10 Mg, Daily	Not Reported
	Cipramil /00582602/	S	60 Mg, Daily	Not Reported
	Cipralex /01588501/	S	Unk Unk, Daily	Not Reported
	Valproat	S	Increasing Dose	Not Reported
	Seroquel	S	Unk	Not Reported
	Seroquel	S	Unk	Not Reported
	Seroquel	S	Unk	Not Reported
	Zyprexa	S	Unk	Not Reported
	Orfiril	S	Unk	Not Reported
	Lamictal	S	Unk	Not Reported
	Lithionit	C	Unk	Not Reported
	Lithionit	C	Unk	Not Reported
	Sobril	C	Unk Unk, As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	13746883	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1729015US		46 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Headache; Pneumonia	Escitalopram Oxalate Unk			S	Oral			Allergan
	Brintellix			S	Oral	15 Mg, Qd		Not Reported
	Brintellix			S	Oral	20 Mg, Qd		Not Reported
	Brintellix			S	Oral	15 Mg, Qd		Not Reported
	Brintellix			S	Oral	10 Mg, Qd		Not Reported

Brintellix	S	Oral	5 Mg, Qd		Not Reported
Cymbalta	S				Not Reported
Efectin	S				Not Reported
Trittico Ret.	C	Unknown	Unk		Not Reported
Trittico Ret.	C	Unknown	Unk		Not Reported
Trittico Ret.	C	Unknown	Unk		Not Reported
Trittico Ret.	C	Unknown	Unk		Not Reported
Zoldem	C	Unknown	Unk		Not Reported
Zoldem	C	Unknown	Unk		Not Reported
Zoldem	C	Unknown	Unk		Not Reported
Aprednisolon	C	Unknown	Unk		Not Reported
Cal-D-Vita	C	Unknown			Not Reported
Oleovit D3	C	Unknown	N/A		Not Reported
Curocef	C	Unknown	Unk		Not Reported
Curocef	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14063071	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04781		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin
	Bisoprol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14063083	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04778		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14063085	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04780		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14063089	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04777		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin
	Bisoprolol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14063091	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04774		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin
	Cyamemazine			S	Unknown	Unk		Not Reported
	Dextropropoxyphene			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14063093	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04775		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin
	Bisoprolol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14063095	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04776		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin
	Bilastine			S	Unknown	Unk		Not Reported
	Hydroxyzine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14063107	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04779		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067233	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04788		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067234	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04796		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Lupin
	Amiodarone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067236	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04783		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067238	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04791		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Lupin
	Pramipexole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067241	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04787		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067243	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04790		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin
	Furosemide			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067245	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04794		94 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067247	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04789		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin
	Candesartan			S	Unknown	Unk		Not Reported
	Ivabradine			S	Unknown	Unk		Not Reported
	Spironolactone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067251	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04792		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin
	Amiodarone			S	Unknown	Unk		Not Reported
	Flecainide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067252	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04785		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged	Escitalopram	S	Unknown	10 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067253	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04782		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067254	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04786		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067256	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04784		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Lupin
	Amiodarone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067257	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04793		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Lupin
	Digoxine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14067263	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04795		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin
	Alimemazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14132883	NON-EXPEDITED		OT	CH-LUPIN PHARMACEUTICALS INC.-2017-03532			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema; Suicidal Ideation	Escitalopram			S	Unknown	Unk Unk		Lupin
	Venlafaxine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	Unk		Not Reported
	Fluoxetine			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14189507	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-06097			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Wrong Technique In Product Usage Process	Escitalopram Oxalate Tablets Usp, 20 Mg			S	Oral	20 Mg, Qd		Lupin
	Atenolol			C	Oral	25 Mg, Qd		Not Reported
	Valsartan			C	Oral	160 Mg, Qd, Hs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14197865	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS		58 YR	Male	ITA

INC.-2017-05228

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Decreased Appetite; Insomnia; Sexual Dysfunction; Weight Increased	Paroxetine			S	Unknown	20 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin
	Sertraline			S	Unknown	100 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	75 Mg, Qd		Not Reported
	Fluvoxamine			S	Unknown	100 Mg, Qd		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14200676	NON-EXPEDITED		OT	GR-LUPIN PHARMACEUTICALS INC.-2017-06039		63 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14339367	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2017-47973			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Escitalopram			S	Unknown	20 Milligram Daily;		Aurobindo
	Zoely			S	Oral	1 Dosage Forms Daily; One Df Contains 2.5mg Nomegestrel And 1.5mg Estradiol		Not Reported
	Valdoxan			S	Unknown	25 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14374572	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-001266		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Escitalopram Film-Coated Tablets			S	Oral	Non Renseignée ()		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	Non Renseignée ()		Aurobindo
	Pantoprazole			S	Oral	Non Renseignée ()		Aurobindo
	Pantoprazole			S	Oral	Non Renseignée ()		Aurobindo
	Pantoprazole			S		Unk ()		Aurobindo
	Xeloda			S	Oral	Non Renseignée ()		Not Reported
	Xeloda			S	Oral	Unk ()		Not Reported
	Xeloda			S	Oral	Unk ()		Not Reported
	Novorapid			S	Subcutaneous	Non Renseignée ()		Not Reported
	Novorapid			S		Unk ()		Not Reported
	Novorapid			S		Unk ()		Not Reported
	Primperan			S	Oral	Non Renseignée ()		Not Reported
	Primperan			S	Oral	Unk ()		Not Reported
	Primperan			S	Oral	Unk ()		Not Reported
	Lipanthyl			S	Oral	Non Renseignée ()		Not Reported
	Lipanthyl			S	Oral	Unk ()		Not Reported
	Lipanthyl			S	Oral	Unk ()		Not Reported
	Movicol /01749801/			S	Oral	Non Renseignée ()		Not Reported
	Movicol /01749801/			S		Unk ()		Not Reported
	Abasaglar			S	Subcutaneous	Non Renseignée ()		Not Reported
	Abasaglar			S		Unk ()		Not Reported
	Abasaglar			S		Unk ()		Not Reported
	Fondaparinux Sodique			S	Subcutaneous	Non Renseignée ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14501945	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2017-01271		25 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Tract Irritation	Escitalopram			S	Unknown	10 Mg, Daily		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14501951	NON-EXPEDITED			TW-LUPIN PHARMACEUTICALS INC.-2017-03196		70 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Somnolence	Mirtazapine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Lupin
	Fenofibrate			C	Unknown	200 Mg, Qod		Not Reported
	Clopidogrel			C	Unknown	Unk		Not Reported
	Carvedilol			C	Unknown	Unk		Not Reported
	Famotidine			C	Unknown	Unk		Not Reported
	Sennoside /00571901/			C	Unknown	Unk		Not Reported
	Levocetirizine			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502525	NON-EXPEDITED		OT	AU-LUPIN (EUROPE) LIMITED-2017-02379			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Suicidal Ideation	Escitalopram			S	Unknown	2 Df, Qd (2 Tablets Each Morning)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502526	NON-EXPEDITED			ZA-LUPIN PHARMACEUTICALS INC.-2017-03560			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zytomil			S	Oral	20 Mg, Qd		Lupin
	Aspen Trazodone			C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502527	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-02285		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Drug Ineffective; Dry Mouth; Hyperhidrosis; Menstruation Irregular; Rash; Sleep Disorder; Tremor; Vision Blurred	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	10 Mg, Qd		Lupin
	Alprazolam			C	Oral	Unk Unk, Bid		Not Reported
	Complex B /00653501/			C	Oral	1, Qd		Not Reported
	Melatonin			C	Oral	3 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502532	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2017-02140		25 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event; Prescription Drug Used Without A Prescription	Stalopam			S	Oral	1 Df, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502533	NON-EXPEDITED		OT	ZA-LUPIN PHARMACEUTICALS INC.-2017-05515		49 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebrovascular Accident; Drug Ineffective; Hypertension	Fedaloc Sr 30 Mg		S	Oral	30 Mg, Qd	Not Reported
	Zytomil 10 Mg		S	Oral	10 Mg, Qd	Lupin
	Stilnox		S	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502534	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-02514			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia	Escitalopram Oxalate Tablets Usp, 5 Mg			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502535	NON-EXPEDITED			ZA-LUPIN PHARMACEUTICALS INC.-2017-04639		67 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia	Zytomil 20 Mg			S	Oral	20 Mg, Qd		Lupin
	Zytomil 20 Mg			S	Oral	0.5 Df, Unk		Lupin
	Zytomil 20 Mg			S	Oral	Unk		Lupin
	Euthyrox			C	Oral	100 Mcg, Qd		Not Reported
	Aspavor			C	Oral	40 Mg, Qd		Not Reported
	Premarin			C	Oral	0.3 Mg, Qd		Not Reported
	Plenish-K			C	Oral	1200 Mg, Qd		Not Reported
	Bilocor			C	Oral	5 Mg, Qd		Not Reported
	Co Pritor			C	Oral	40/12.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502574	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-06828			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea	Escitalopram	S	Unknown	Unk	Lupin
	Lisinopril	C	Unknown	Unk	Not Reported
	Temazepam	C	Unknown	Unk	Not Reported
	Iron	C	Unknown	Unk Unk, Prn	Not Reported
	Fondaparinux Sodium	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502576	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-03637			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Escitalopram			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502577	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00007427		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Epistaxis; Headache; Hypersomnia; Oxygen Saturation Decreased; Pruritus; Sinusitis	Escitalopram Oxalate Tablets Usp, 20 Mg			S	Oral	20 Mg, Qd		Lupin
	Albuterol /00139501/			S	Respiratory (inhalation)	Nebulization, Once In 4 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502579	NON-EXPEDITED			ZA-LUPIN PHARMACEUTICALS INC.-2017-06375			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza	Zytomil Tablets			S	Oral	20 Mg, Qd		Lupin
	Puricos			S	Oral	100 Mg, Qd		Not Reported
	Carloc			S	Oral	6.25 Mg, Qd		Not Reported
	Ultimag			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502580	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-05676		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502581	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-06822		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Therapeutic Product Effect Incomplete	Escitalopram Oxalate Tablets Usp, 5 Mg			S	Oral	5 Mg, Qd, In Morning		Lupin
	Escitalopram Oxalate Tablets Usp, 5 Mg			S				Lupin
	Estradiol-Norethindrone Acetate 1/0.2 (Grandmark Pharma)			C	Oral	1 Df, Qd, At Night,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502597	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2016-05801			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Unknown	10 Mg,Unk,Unknown		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14505128	NON-EXPEDITED		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2016-05747		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Methylene Blue			S	Unknown	7.5 Mg/Kg,Unk,Unknown		Not Reported
	Escitalopram			S	Unknown	Unk Unk,Unk,Unknown		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14505129	NON-EXPEDITED		HO, OT	ES-LUPIN PHARMACEUTICALS INC.-2017-00841		49 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Unknown	Unk Unk,Unk,		Lupin
	Enrelax			C	Unknown	Unk Unk,Unk,Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14505138	NON-EXPEDITED		HO, OT	IT-LUPIN PHARMACEUTICALS INC.-2017-01650		89 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S		Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14505139	NON-EXPEDITED			DE-LUPIN PHARMACEUTICALS INC.-E2B_00006938			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Weight Increased	Escitalopram			S	Unknown	20 Mg,Qd,		Lupin
	Escitalopram			S	Unknown	20 Mg,Qd,		Lupin
	Citalopram			S	Unknown	30 Mg,Qd,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14505141	NON-EXPEDITED		HO, OT	DE-LUPIN PHARMACEUTICALS INC.-2017-07129		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Lorazepam			S	Oral	1.5 Mg, Unk		Not Reported
	Lorazepam			S	Oral	1 Mg, Unk		Not Reported

Lorazepam	S	Oral	0.25 Mg, Unk		Not Reported
Escitalopram	S	Oral	20 Mg, Unk		Lupin
Escitalopram	S	Oral	10 Mg, Unk		Lupin
Quetiapine	S	Oral	50 Mg, Unk		Not Reported
Quetiapine	S	Oral	150 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14505142	NON-EXPEDITED		OT	JP-LUPIN PHARMACEUTICALS INC.-2017-00705		30 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy	Escitalopram			S	Unknown	Unk Unk,Unk,		Lupin
	Escitalopram			S	Unknown	Unk Unk,Unk,		Lupin
	Escitalopram			S	Unknown	Unk Unk,Unk,		Lupin
	Flunitrazepam			C	Unknown	Unk Unk,Unk,		Not Reported
	Trazodone			C	Unknown	Unk Unk,Unk,		Not Reported
	Trazodone			C	Unknown	Unk Unk,Unk,		Not Reported
	Duloxetine			C	Unknown	Unk Unk,Unk,		Not Reported
	Duloxetine			C	Unknown	Unk Unk,Unk,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14505143	NON-EXPEDITED		HO, OT	IN-LUPIN PHARMACEUTICALS INC.-2016-05743		19 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Overdose; Suicide Attempt	Venlafaxine			S	Oral	37.5 Mg,Qd,		Not Reported
	Venlafaxine			S	Oral	10-15 Tablets		Not Reported
	Escitalopram			S	Oral	Unk Unk,Qd,		Lupin
	Escitalopram			S	Oral	10-15 Tablets		Lupin
	Clonazepam			S	Oral	Unk Unk,Qd,		Not Reported
	Clonazepam			S	Oral	10-15 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14505144	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-02231		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Escitalopram			S	Unknown	5 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14505145	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-03160		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis	Escitalopram			S	Unknown	10 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14505656	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2018-005212		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	()		Aurobindo
	Aripiprazol			S	Unknown	10 Milligram Daily; ()		Aurobindo
	Clomipramine			S	Unknown	150 Milligram Daily;		Not Reported
	Fluvoxamine			S	Unknown	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14506073	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2018M1010751			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Pulmonary Embolism; Tricuspid Valve Incompetence	Metformin			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Paracetamol			S		Unk		Not Reported
	Zopiclone			S		Unk		Not Reported

	Pantoprazole	S	Unk	Not Reported
	Clozapine	S	Unk	Not Reported
	Clopine	S	Unk	Mylan
	Paliperidone	S	Unk	Mylan
	Cholecalciferol	S	Unk	Mylan
	Desmopressin	S	Unk	Mylan
	Fluticone	S	Unk	Mylan
	Lorazepam	S	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14507048	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1806413US		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Pradaxa			S	Oral			Not Reported
	Furosemide			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Anastrozole			C	Unknown			Not Reported
	Repaglinide			C	Unknown			Not Reported
	Fumafer			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	13885057	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-GLENMARK PHARMACEUTICALS-2017GMK028495			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Condition Aggravated; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of	Escitalopram			S	Oral	10 Mg, Hs		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Atorvastatin			S	Oral	Unk (Bedtime)		Not Reported

Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Meloxicam		S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam, For About Two Years Ago	Glenmark
	Meloxicam		S			Glenmark
	Perindopril		S	Oral	Unk	Not Reported
	Tramadol		S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam For About Two Years Ago	Not Reported
	Tramadol		S			Not Reported
	Clarithromycin		S	Oral	Unk (Bedtime), Two, 10-Day Treatment Cycles Courses	Not Reported
	Sertraline		S	Oral	50 Mg, Od, (In The Morning)	Not Reported
	Sertraline		S			Not Reported
	Zolpidem		S	Oral	10 Mg, Od	Not Reported
	Zolpidem		S			Not Reported
	Doxepin		S	Oral	25 Mg, Od, At Bed Time	Not Reported
	Doxepin		S			Not Reported
	Doxepin		S			Not Reported
	Doxepin		S			Not Reported
	Bisoprolol		S	Oral	Unk	Not Reported
	Atoris		S	Unknown	Unk	Not Reported
	Atoris		S			Not Reported
	Polsen		S	Unknown	10 Mg, Od, At Bed Time	Not Reported
	Concor		S	Unknown	Unk	Not Reported
	Trosicam		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14063087	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04773		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged	Escitalopram		S	Unknown	10 Mg, Unk	Lupin
	Aliskiren		S	Unknown	Unk	Not Reported
	Amiodaron /00133101/		S	Unknown	Unk	Not Reported
	Domperidone		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14334021	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1773695US		1 DAY	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Respiratory Depression	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan
	Wypax			S	Transplacental	Unk		Not Reported
	Zolpidem Tartrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14506252	NON-EXPEDITED		OT	CN-LUPIN PHARMACEUTICALS INC.-2017-00837		37 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Escitalopram Oxalate			S	Unknown	Unk Unk,Unk,Unknown		Lupin
	Escitalopram Oxalate			S				Lupin
	Escitalopram Oxalate			S				Lupin
	Risperidone			S	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Risperidone			S				Not Reported
	Risperidone			S				Not Reported
	Sertraline			S	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Sertraline			S				Not Reported
	Sertraline			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14506253	NON-EXPEDITED		OT	TW-LUPIN PHARMACEUTICALS INC.-2017-06368		31 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Thrombocytopenia	Escitalopram		S	Unknown	10 Mg, Qd	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14509295	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00007729		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ebrantil			C	Unknown			Unknown
	Simvastatin			C	Unknown	Probably Either Simvastatin Or Atozet		Unknown
	Valsartan			C	Unknown	160 [Mg/D (Vater)]		Unknown
	Escitalopram			S	Transplacental	7.5 [Mg/D (Mutter)]		Unknown
	Folsan			C	Transplacental	0.4 [Mg/D (Mutter)]		Unknown
	Ramilich			C	Unknown	10 [Mg/D (Vater)]		Unknown
	Dekristol			C	Unknown	20000 [Ie/D (Alle 2 Wochen) (Vater)]		Unknown
	Paracetamol			C	Transplacental			Unknown
	Bicanorm			C	Unknown			Unknown
	Atozet			C	Unknown	40 [Mg/D] / 10 [Mg/D (Vater)]/ Probably Either Atozet Or Simvastatin		Unknown
	Ass 100			C	Unknown	100 [Mg/D (Vater)]		Unknown
	Amlodipine			C	Unknown	10 [Mg/D (Vater)]		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14509991	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2018SE14201		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Lactic Acidosis; Metabolic Disorder; Neurological Decompensation	Seroquel			S	Oral	50.0df Unknown		Zeneca
	Cipralex			S	Oral	10.0df Unknown		Not Reported
	Tegretol			S	Oral	90.0df Unknown		Not Reported
	Depakin Chrono			S	Oral	20.0df Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14511576	NON-EXPEDITED			PHEH2018US004688		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Pyrexia	Gilenya			S	Oral	0.05 Mg/Kg, Qd		Novartis
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2018	14515470	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163-2251670-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Asthenia; Basedow'S Disease; Decreased Appetite; Dermatitis; Disturbance In Sexual Arousal; Dry Skin; Erectile Dysfunction; Fatigue; Gingival Atrophy; Gingivitis; Heart Rate Increased; Libido Decreased; Pain Of Skin; Palpitations; Panic Attack; Prostatomegaly; Pruritus; Rash Macular; Rash Macular; Self-Injurious Ideation; Squamous Cell Carcinoma; Toothache; Urethral Stricture Postoperative; Weight Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Salicylic Acid			S	Topical			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lisinopril			C				Not Reported
	Pantoprazole			C				Not Reported
	Valium			C				Not Reported
	Budesonide			C	Oral			Not Reported
	Carvedilol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2018	14360598	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1800461US		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatine Phosphokinase Increased; Hepatic Function Abnormal; Overdose; Pain In Extremity; Peripheral Swelling; Suicide Attempt	Escitalopram Oxalate - Bp	S	Oral		Allergan
	Escitalopram Oxalate - Bp	S	Oral	Overdose: Unknown Daily Dose	Allergan
	Lunesta	C	Oral	2 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2018	14474307	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1804728US		83 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Asthenia; Chest Discomfort; Chronic Kidney Disease; Constipation; Depressed Mood; Dizziness; Gait Disturbance; Grief Reaction; Hypokalaemia; Hyponatraemia; Malaise; Malnutrition; Nausea; Panic Attack; Restlessness; Tension; Thinking Abnormal; Urinary Tract Infection; Vomiting	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	2.5 Mg, Unknown		Allergan
	Fludex (Indapamide)			S	Unknown	1.5 Mg, Qd		Not Reported
	Aspirin			C				Not Reported
	Ondansetron			C				Not Reported
	Redormin (Remifentanil Hydrochloride)			C		Unk		Not Reported
	B12			C				Not Reported
	Rosuvastatin			C				Not Reported
	Zestril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2018	14516175	EXPEDITED (15-DAY)		HO	NO-ALLERGAN-1806541US		70 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Brexidol			S	Oral	1 Tablet A Day As Required. Used Lately		Not Reported
	Paralgin Forte			C	Oral	Unit Dose= 400 Mg Paracetamol+ 30 Mg Codeine2 Tablets 3 Times		Not Reported

				A Day	
	Micardisplus	C	Oral	Unit Dose: 80 Mg Telmisartan + 12.5mg Hydrochlorotiazide	Not Reported
	Sobril	C	Oral	1 Tablet As Required, Maximum 3 Times Per Day	Not Reported
	Zolpidem	C	Oral	1-2 Tablets As Required In The Evening	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2018	14516176	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1806408US		40 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Discomfort; Insomnia; Motor Dysfunction; Off Label Use; Pain In Extremity; Paraesthesia	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14520145	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1008572		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Escitalopram			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Valsartan			S	Oral			Not Reported
	Xeroquel			S	Oral			Mylan
	Prazepam			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14523481	EXPEDITED (15-DAY)		DE	US-ARBOR PHARMACEUTICALS, LLC-US-		36 YR	Female	USA

2018ARB000150

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Gabapentin Enacarbil			S	Oral	Unk		Arbor
	Amitriptyline			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14523594	EXPEDITED (15-DAY)		DS, OT	CA-ENDO PHARMACEUTICALS INC-2018-016820		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Off Label Use; Optic Atrophy; Pulmonary Oedema; Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents	Adrenalin			S	Unknown	30 Mcg, Unknown		Par
	Amlodipine Besylate Tablets			S	Unknown	150 Mg, Od		Vintage
	Vasostrict			S	Unknown	Unk Unk, Unknown		Par
	Escitalopram			S	Unknown	60 Mg, Od		Not Reported
	Glucose			S	Unknown	Unk Unk, Unknown		Not Reported
	Norepinephrine Bitartrate			S	Unknown	30 Mcg, Unknown		Not Reported
	Risperidone			S	Unknown	6 Mg, Od		Not Reported
	Activated Charcoal			C	Unknown	50 G, Unknown		Not Reported
	Insulin			C	Intravenous bolus	Unk Unk, Unknown		Not Reported
	Insulin			C	Unknown	70 Iu, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	13295490	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1707975US		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Lactic Acidosis; Metabolic Disorder; Neurological Decompensation; Overdose	Escitalopram Oxalate - Bp	S	Oral	10 Tablets, Single		Allergan
	Depakin Chrono	S	Oral	20 Tablets, Single		Not Reported
	Seroquel	S	Oral	40 Tablets, Single		Not Reported
	Tegretol	S	Oral	90 Tablets, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	13753331	EXPEDITED (15-DAY)		OT	AT-TAKEDA-2017TUS014761		46 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Headache; Pneumonia	Vortioxetine			S	Oral	5 Mg, Qd		Takeda
	Vortioxetine			S	Oral	10 Mg, Qd		Takeda
	Vortioxetine			S	Oral	15 Mg, Qd		Takeda
	Vortioxetine			S	Oral	20 Mg, Qd		Takeda
	Vortioxetine			S	Oral	15 Mg, Qd		Takeda
	Cipralex			S	Oral	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Duloxetine Hydrochloride			S	Unknown	60 Mg, Unk		Not Reported
	Oleovit D3			C	Oral	40 Gtt, 1/Week		Not Reported
	Curocef /00454602/			C	Unknown	Unk, Qd		Not Reported
	Curocef /00454602/			C	Unknown	9 G, Qd		Not Reported
	Zoldem			C	Oral	5 Mg, Qd		Not Reported
	Zoldem			C	Oral	10 Mg, Qd		Not Reported
	Zoldem			C	Oral	5 Mg, Qd		Not Reported
	Trittico			C	Oral	150 Mg, Qd		Not Reported
	Trittico			C	Oral	200 Mg, Qd		Not Reported
	Trittico			C	Oral	250 Mg, Qd		Not Reported
	Trittico			C	Oral	300 Mg, Qd		Not Reported
	Cal D Vita			C	Oral	Unk, Qd		Not Reported
	Aprednislon			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14277597	EXPEDITED (15-DAY)		HO	AT-OTSUKA-2017_001835		31 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Off Label Use	Abilify			S	Unknown	2.5 Mg, Qd		Otsuka
	Abilify			S	Unknown	5 Mg, Qd		Otsuka
	Abilify			S	Unknown	7.5 Mg, Qd		Otsuka
	Abilify			S	Unknown	10 Mg, Qd		Otsuka
	Abilify			S	Unknown	5 Mg, Qd		Otsuka
	Cipralex			S	Unknown	10 Mg, Unk		Not Reported
	Cipralex			S	Unknown	5 Mg, Unk		Not Reported
	Cipralex			S	Unknown	5 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	10 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	20 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	25 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	30 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	20 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	30 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	20 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	10 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	20 Mg, Unk		Not Reported
	Trittico			S	Unknown	150 Mg, Unk		Not Reported
	Trittico			S	Oral	250 Mg, Unk		Not Reported
	Trittico			S	Oral	300 Mg, Unk		Not Reported
	Trittico			S	Oral	150 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported
	Trazodone Hydrochloride			S	Unknown	150 Mg, Unk		Not Reported

Trazodone Hydrochloride	S	Unknown	250 Mg, Unk	Not Reported
Trazodone Hydrochloride	S	Unknown	300 Mg, Unk	Not Reported
Trazodone Hydrochloride	S	Unknown	150 Mg, Unk	Not Reported
Olanzapine	S	Unknown	10 Mg, Unk	Not Reported
Olanzapine	S	Unknown	20 Mg, Unk	Not Reported
Olanzapine	S	Unknown	25 Mg, Unk	Not Reported
Olanzapine	S	Unknown	30 Mg, Unk	Not Reported
Olanzapine	S	Unknown	20 Mg, Unk	Not Reported
Olanzapine	S	Unknown	30 Mg, Unk	Not Reported
Olanzapine	S	Unknown	20 Mg, Unk	Not Reported
Olanzapine	S	Unknown	10 Mg, Unk	Not Reported
Olanzapine	S	Unknown	20 Mg, Unk	Not Reported
Risperdal	C	Unknown	Unk	Not Reported
Zeldox	C	Unknown	20 Mg, Unk	Not Reported
Zeldox	C	Unknown	40 Mg, Unk	Not Reported
Zeldox	C	Unknown	80 Mg, Unk	Not Reported
Zeldox	C	Unknown	120 Mg, Unk	Not Reported
Quilonorm	C	Unknown	Unk	Not Reported
Quilonorm	C	Unknown	Unk	Not Reported
Sycrest	C	Unknown	Unk	Not Reported
Leponex	C	Unknown	Unk	Not Reported
Lamictal	C	Unknown	Unk	Not Reported
Neurotop	C	Unknown	Unk	Not Reported
Dominal (Acetylsalicylic Acid)	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Truxal	C	Unknown	Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	Unk	Not Reported
Dibondrin	C	Unknown	Unk	Not Reported
Zoldem	C	Unknown	Unk	Not Reported

Nozinan	C	Unknown	Unk	Not Reported
Propranolol Hydrochloride	C	Unknown	Unk	Not Reported
Akineton	C	Unknown	Unk	Not Reported
Praxiten	C	Unknown	Unk	Not Reported
Fluctine	C	Unknown	Unk	Not Reported
Inderal	C	Unknown	Unk	Not Reported
Sifrol	C	Unknown	Unk	Not Reported
Nubain	C	Unknown	Unk	Not Reported
Adasuve	C	Unknown	Unk	Not Reported
Gastrozepin	C	Unknown	Unk	Not Reported
Risperidone	C	Unknown	Unk	Not Reported
Lamotrigine	C	Unknown	Unk	Not Reported
Carbamazepine	C	Unknown	Unk	Not Reported
Clonazepam	C	Unknown	Unk	Not Reported
Lorazepam	C	Unknown	Unk	Not Reported
Zolpidem	C	Unknown	Unk	Not Reported
Levomepromazine	C	Unknown	Unk	Not Reported
Fluoxetine Hydrochloride	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14329870	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1773715US		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Off Label Use; Stupor; Vertigo	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Aripiprazole			S	Oral	10 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Candesartan			S	Oral	16 Mg, Qd		Not Reported

Risperdal	C	Unknown	1.5 Mg, Qd		Not Reported
Risperdal	C	Unknown	2 Mg, Qhs		Not Reported
Risperdal	C	Unknown	2 Mg, Qd		Not Reported
L-Thyroxin	C	Oral	100 Mg, Qd		Not Reported
Amisulpride	C	Unknown	200 Mg, Qd		Not Reported
Metformin	C	Oral	1500 Mg, Qd		Not Reported
Atorvastatin	C	Oral	20 Mg, Qd		Not Reported
Acetylsalicylic Acid	C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14523853	EXPEDITED (15-DAY)		HO, OT	HU-CIPLA LTD.-2018HU04055			Unknown	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea At Rest; Suicidal Ideation; Violence-Related Symptom	Escitalopram			S	Oral	10 Mg, Daily		Invagen
	Lamolep			C	Oral	150 Mg, Daily, 1 Tablet Mornings And 2 Tablets Evenings		Not Reported
	Kventiax			C	Oral	32.5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524245	EXPEDITED (15-DAY)		OT	FI-CIPLA LTD.-2018FI03366			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Oropharyngeal Oedema; Tracheal Oedema	Escitalopram			S	Oral	2.5 Mg, Daily		Invagen
	Heinix			C	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524420	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR03922			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Long Qt Syndrome; Pneumonia Aspiration	Escitalopram	S	Oral	1 Df, Unk	Invagen
	Tercian /00759301/	S	Oral	15 Gtt, Unk	Not Reported
	Ogast	C	Oral	1 Df, Unk	Not Reported
	Kardegic	C	Oral	1 Df, Unk	Not Reported
	Orocal D3	C	Oral	1 Df, Unk	Not Reported
	Sectral	C	Oral	1 Df, Unk	Not Reported
	Forlax	C	Oral	1 Df, Unk	Not Reported
	Levothyrox	C	Oral	87.5 Mg, Unk	Not Reported
	Aldactazine	C	Oral	15 Mg, Unk	Not Reported
	Bromazepam	C	Oral	3 Mg, Unk	Not Reported
	Imovane	C	Oral	0.5 Df, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524789	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000323		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Levothyroxine Sodium			S	Oral	Unk		Lannett
	Diltiazem			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Metformin			S	Oral	Unk		Not Reported
	Glyburide			S	Oral	Unk		Not Reported
	Losartan			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524796	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000310		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate		S	Oral				Lannett
	Bupropion		S	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524798	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000315		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Lannett
	Bupropion			S	Oral	Unk		Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524799	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000317		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Diphenhydramine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524800	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000311		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S		Unk		Lannett
	Ethanol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524801	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000312		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate		S	Oral	Unk	Lannett
	Amitriptyline		S	Oral	Unk	Not Reported
	Gabapentin		S	Oral	Unk	Not Reported
	Ibuprofen		S	Oral	Unk	Not Reported
	Ethanol		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524802	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000316		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Lannett
	Lamotrigine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524803	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000324		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Metformin			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Naproxen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524804	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000278		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Loratadine			S	Oral	Unk		Lannett
	Ethylene Glycol			S	Oral	Unk		Not Reported

Furosemide	S	Oral	Unk		Not Reported
Levothyroxine Sodium	S	Oral	Unk		Not Reported
Folic Acid	S	Oral	Unk		Not Reported
Vitamin B-1	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524805	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000319		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Acetaminophen			S	Oral	Unk		Lannett
	Propranolol			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported
	Cocaine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524806	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000313		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Lannett
	Bupropionum			S	Oral	Unk		Not Reported
	Amlodipine			S	Oral	Unk		Not Reported
	Salicylate Sodium			S	Oral	Unk		Not Reported
	Losartan			S	Oral	Unk		Not Reported
	Levothyroxine Sodium			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524807	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000325		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Abuse; Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Cocaine			S	Unknown	Unk		Not Reported
	Bupropion			S	Oral	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Ethanol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524808	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000322		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Flecainide			S	Oral	Unk		Not Reported
	Verapamil			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524809	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000314		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Lannett
	Amitriptyline			S	Oral			Not Reported
	Lorazepam			S	Oral	Unk		Not Reported
	Lithium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524810	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000320		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Oxycodone Hcl And Acetaminophen			S	Oral	Unk		Lannett
	Montelukast Sodium			S	Oral	Unk		Lannett
	Ondansetron			S	Oral	Unk		Lannett
	Propranolol			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported
	Acyclovir /00587301/			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524811	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000318		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S		Unk		Lannett
	Propranolol			S		Unk		Not Reported
	Lamotrigine			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Cyclobenzaprine			S		Unk		Not Reported
	Buspirone /00803202/			S		Unk		Not Reported
	Clonazepam			S		Unk		Not Reported
	Activated Charcoal			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524812	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000321		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Lannett
	Phenytoin Sodium			S	Oral	Unk		Lannett
	Primidone			S	Oral	Unk		Lannett
	Carvedilol			S	Oral	Unk		Not Reported
	Valproic Acid			S	Oral	Unk		Not Reported
	Sitagliptin			S	Oral	Unk		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14526925	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1806933US		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Confusional State; Depression	Escitalopram Oxalate - Bp			S	Oral	1 Dosage Form, Unk		Allergan
	Laroxyl			S	Oral	1 Dosage Form, Unk		Not Reported
	Keppra			S	Oral	2 Dosage Forms, Qd		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported
	Eductyl			C	Rectal	Unk		Not Reported
	Stilnox			C	Oral	10 Mg, Unk		Not Reported
	Dimeticone			C	Oral	Unk		Not Reported
	Movicol			C	Oral	Unk		Not Reported
	Pantoprazole			C	Oral	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14527022	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000338		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Fluoxetine Hydrochloride			S	Oral	Unk		Lannett
	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Risperidone			S	Oral	Unk		Not Reported
	Diphenhydramine Hcl			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14527034	EXPEDITED (15-DAY)		OT	IE-MYLANLABS-2018M1009552		40 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Discomfort; Insomnia; Motor Dysfunction; Pain In Extremity; Paraesthesia	Escitalopram			S		10mg		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14527318	EXPEDITED (15-DAY)		HO, OT	NO-MYLANLABS-2018M1009189		21 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Olanzapine			S	Unknown	Unk		Not Reported
	Cipralex			S	Unknown	Unk, Qd		Mylan
	Efexor			S	Unknown	Unk		Mylan
	Lamictal			S	Unknown	Unk		Mylan
	Seroquel			S	Oral	Unk		Mylan
	Seroxat			S	Unknown	Unk		Mylan
	Seroxat			S	Unknown	20 Mg, Qd		Mylan
	Zyprexa			S	Unknown	Unk		Mylan
	Cipramil [Citalopram Hydrobromide]			S	Unknown	10 Mg, Qd		Mylan
	Cipramil			S	Unknown	60 Mg, Qd		Mylan
	Orfiril			S	Unknown	Unk		Mylan

Valproate Sodium	S	Unknown	Increasing Dose		Mylan
Lithionit	C		Unk		Mylan
Sobril	C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14527686	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1806950US		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14075879	EXPEDITED (15-DAY)		HO, OT	AT-ALLERGAN-1757166US		57 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Increased Appetite; Prescribed Overdose; Weight Increased	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	30 Mg, Qd		Allergan
	Zyprexa Velotab			S	Unknown	10 Mg, Qd		Not Reported
	Zyprexa Velotab			S	Unknown	15 Mg, Qd		Not Reported
	Zyprexa Velotab			S	Unknown	5 Mg, Qd		Not Reported
	Seroquel Xr			S	Oral	100 Mg, Qd		Not Reported
	Seroquel Xr			S	Oral	200 Mg, Qd		Not Reported
	Seroquel Xr			S	Oral	50 Mg, Qd		Not Reported
	Seroquel Xr			S	Oral	200 Mg, Qd		Not Reported
	Seroquel Xr			S	Oral	100 Mg, Qd		Not Reported
	Pregabalin			S	Oral	150 Mg, Qd		Not Reported
	Pregabalin			S	Oral	300 Mg, Qd		Not Reported
	Pregabalin			S	Oral	450 Mg, Qd		Not Reported
	Seroquel			S	Unknown	50 Mg, Qd		Not Reported

Seroquel	S	Unknown	400 Mg, Qd	Not Reported
Seroquel	S	Unknown	500 Mg, Qd	Not Reported
Seroquel	S	Unknown	450 Mg, Qd	Not Reported
Seroquel	S	Unknown	50 Mg, Qd	Not Reported
Seroquel	S	Unknown	400 Mg, Qd	Not Reported
Seroquel	S	Unknown	100 Mg, Qd	Not Reported
Seroquel	S	Unknown	50 Mg, Qd	Not Reported
Seroquel	S	Unknown	100 Mg, Qd	Not Reported
Seroquel	S	Unknown	100 Mg, Qd	Not Reported
Seroquel	S	Unknown	300 Mg, Qd	Not Reported
Seroquel	S		Unk	Not Reported
Quetiapin	C	Unknown	50 Mg, Qd	Not Reported
Quetiapin	C	Unknown	50 Mg, Qd	Not Reported
Lamotrigin	C	Unknown	50 Mg, Qd	Not Reported
Lamotrigin	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta	C	Unknown	1.25 Mg, Qd	Not Reported
Temesta	C	Unknown	1.25 Mg, Qd	Not Reported
Temesta	C	Unknown	5 Mg, Qd	Not Reported
Rivotril	C	Unknown		Not Reported
Thyrex	C	Unknown		Not Reported
Thyrex	C	Unknown	50 Mg, Unk	Not Reported
Combithyrex Mite	C	Unknown		Not Reported
Combithyrex Mite	C	Unknown		Not Reported

Optifiber	C	Unknown	Unk		Not Reported
Optifiber	C	Unknown	Unk		Not Reported
Optifiber	C	Unknown	Unk		Not Reported
Optifiber	C	Unknown	Unk		Not Reported
Molaxole	C	Unknown	Unk		Not Reported
Molaxole	C	Unknown	Unk		Not Reported
Molaxole	C	Unknown	Unk		Not Reported
Molaxole	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14319066	EXPEDITED (15-DAY)		OT	ES-SA-2017SA251565			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Myalgia; Pain In Extremity; Somnolence; Treatment Noncompliance	Glibenclamide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Omeprazole			S	Unknown			Not Reported
	Topiramate			S	Unknown			Not Reported
	Topiramate			S	Unknown	Strength: 50 Mg		Not Reported
	Amlodipine			S	Unknown	Strength: 5mg		Not Reported
	Paracetamol			S	Unknown			Not Reported
	Tramadol Hydrochloride/Paracetamol			S	Unknown	Strength: 37.5/325 Mg		Not Reported
	Lormetazepam			S	Unknown			Not Reported

Enalapril/Hydrochlorothiazide	S	Unknown	Strength: 20/12.5 Mg		Not Reported
Escitalopram	S	Unknown			Not Reported
Diazepam/Sulpiride	S	Unknown			Not Reported
Metoclopramide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14334326	EXPEDITED (15-DAY)		OT	PHHY2017CO189498			Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Faeces; Diabetes Insipidus; Diarrhoea; Fatigue; Gait Disturbance; Lip Dry; Neoplasm; Oedema Peripheral; Pain In Extremity; Pituitary Tumour; Pruritus; Thirst; Weight Increased	Signifor			S	Subcutaneous	0.6 Mg, Bid		Not Reported
	Losartan			S	Unknown			Novartis
	Amlodipine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Ketoconazole			C	Unknown			Not Reported
	Apo-Clonazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14529507	EXPEDITED (15-DAY)		HO, LT, OT	JP-LUPIN PHARMACEUTICALS INC.-2018-00740			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis Neonatal; Drug Interaction; Foetal Exposure During Pregnancy; Neonatal Behavioural Syndrome; Neonatal Respiratory Depression; Respiratory Muscle Weakness	Escitalopram Oxalate			S	Transplacental	10 Mg, Unk		Lupin
	Ethyl Loflazepate			S	Transplacental	1 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14530564	EXPEDITED (15-DAY)		DE	US-DEPOMED, INC.-US-2018DEP000304		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Gabapentin			S	Oral	Unk		Depomed
	Amitriptyline			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14530912	EXPEDITED (15-DAY)		OT	DK-ALLERGAN-1806944US		45 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Discomfort; Paraesthesia; Restlessness; Serotonin Syndrome; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14530920	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1806979US		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Xarelto			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14530924	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1806913US			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness;	Escitalopram Oxalate - Bp			S	Unknown			Allergan

Dyspnoea; Gastric Ulcer; Insomnia; Nausea; Panic Attack; Vertigo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	13381536	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1711973US		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Sopor	Escitalopram Oxalate Unk			S	Oral	Overdose: 270 Mg		Allergan
	Carbolithium			S	Oral	5 Df, Overdose		Not Reported
	Etiltox			S	Oral	9 Df, Overdose		Not Reported
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14199748	EXPEDITED (15-DAY)		HO	IT-SA-2017SA221203		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Pulmonary Infarction	Aubagio			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Tirosint			S	Oral	Strength: 75 Mcg/1 Ml		Not Reported
	Xanax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14265997	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2017-45081		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Od		Aurobindo
	Aripiprazole			S	Oral	5mg, Od		Aurobindo
	Candesartan			S	Oral	16 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Aurobindo
	Escitalopram			S	Oral	15 Mg, Qd		Aurobindo

Escitalopram	S	Oral	20 Mg, Qd		Aurobindo
Risperdal	C	Unknown	1.5 Mg, Qd		Not Reported
Risperdal	C	Unknown	2 Mg, Unk (For Nights)		Not Reported
Risperdal	C	Unknown	2 Mg, Qd		Not Reported
Risperdal	C	Unknown	2 Mg, Od		Not Reported
Risperdal	C	Unknown	1.5 Mg, Od		Not Reported
Risperdal	C		2 Mg, Hs		Not Reported
Risperdal	C	Unknown	2 Mg, Qd		Not Reported
L-Thyroxin	C	Oral	100 Mg, Qd		Not Reported
Amisulpride	C	Unknown	200 Mg, Qd		Not Reported
Metformin	C	Oral	1500 Mg, Qd		Not Reported
Metformin	C		1500 Mg, Od		Not Reported
Atorvastatin	C	Oral	20 Mg, Qd		Not Reported
Acetylsalicylic Acid	C	Oral	100 Mg, Qd		Not Reported
Acetylsalicylic Acid	C		100 Mg, Od		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14324369	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2017-47018			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Apathy; Depression; Dizziness; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Naproxen			S	Unknown	2 Df, Unk		Aurobindo
	Simvastatin			S	Unknown	1 Df, Unk		Aurobindo
	Simvastatin			S	Unknown	Unk		Aurobindo
	Omeprazole			S	Unknown	1 Df, Unk		Aurobindo
	Topiramate			S	Unknown	1 Df, Unk		Aurobindo
	Topiramate			S	Unknown	0.5 Df, Unk		Aurobindo
	Amlodipine			S	Unknown	1 Df, Unk		Aurobindo
	Paracetamol			S	Unknown	3 Df, Unk		Aurobindo
	Escitalopram			S	Unknown	(1)		Aurobindo

	Glibenclamide	S	Unknown	2 Df, Unk	Not Reported
	Diazepam	S	Unknown	(1)	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Amitriptyline	S		Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Diazepam	S	Unknown	0.5 Df, Unk	Not Reported
	Tramadol/Acetaminophen	S	Unknown	3 Df, Unk	Not Reported
	Lormetazepam	S	Unknown	1 Df, Unk	Not Reported
	Enalapril/Hydrochlorothiazide	S	Unknown	1 Df= 20/12.5 Mg	Not Reported
	Metoclopramide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14383364	EXPEDITED (15-DAY)		DE	NO-ROCHE-2050712		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drowning; Feeling Abnormal; Intentional Self-Injury; Overdose; Wrong Product Administered	Rivotril			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Orfiril			S	Unknown	Unk		Not Reported
	Sarotex			S	Unknown			Not Reported
	Atarax			S	Unknown			Not Reported
	Sobril			S	Unknown			Not Reported
	Truxal			S	Unknown	600 To 1200mg		Not Reported
	Vival			S	Unknown	Unk		Not Reported
	Oxynorm			S	Unknown	5 To 10mg		Not Reported
	Oxynorm			S	Unknown	Unk		Not Reported
	Nozinan			S	Unknown	Unk		Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown			Not Reported
	Pinex Forte			S	Unknown	300/30 Mg And Pandeine		Not Reported
	Lamictal			S	Unknown	25, 50, 100 Mg.		Not Reported

Remeron	S	Unknown	Unk		Not Reported
Tramadol Hydrochloride	S	Unknown			Not Reported
Nobligan	S	Unknown	50, 200mg		Not Reported
Catapresan	S	Unknown	Unk		Not Reported
Cipralex	S	Unknown			Not Reported
Imovane	S	Oral	Unk		Not Reported
Cyanocobalamin	C	Unknown			Not Reported
Heroin	C	Unknown	Unk		Not Reported
Codeine Phosphate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14533202	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR04681			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia	Escitalopram			S	Oral	5 Mg, Qd		Invagen
	Oracilline /00001801/			C	Oral	Unk		Not Reported
	Speciafoldine			C	Oral	15 Mg, Every Week		Not Reported
	Doliprane			C	Oral	Unk		Not Reported
	Atarax /00058401/			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14533212	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR04417			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Escitalopram			S	Oral	880 Mg, Unk		Invagen
	Valsartan			S	Oral	14400 Mg, Unk		Not Reported
	Xeroquel			S	Oral	2500 Mg, Unk		Not Reported
	Prazepam			S	Oral	1200 Mg, Unk		Not Reported
	Bromazepam			S	Oral	144 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14533874	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR05203			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Fall	Escitalopram			S	Oral	2 Df, Daily		Invagen
	Trospium			S	Oral	1 Df, Daily		Invagen
	Theralene			S	Oral	24 Gtt, Daily		Not Reported
	Seresta			S	Oral	0.5 Df, Daily		Not Reported
	Seresta			S	Unknown	Unk		Not Reported
	Tercian /00759301/			S	Oral	30 Gtt, Daily		Not Reported
	Transipeg /00754501/			C	Oral	1 Df, Daily		Not Reported
	Doliprane			C	Oral	3 Df, Daily		Not Reported
	Tardyferon			C	Oral	1 Df, Daily		Not Reported
	Symbicort			C	Respiratory (inhalation)	1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14534508	EXPEDITED (15-DAY)		HO	FR-TAKEDA-2018TEU000818		91 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Lansoprazole			S	Oral	30 Mg, Qd		Takeda
	Stilnox			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Gliclazide			S	Oral	60 Mg, Qd		Not Reported
	Efferalgan /00020001/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14535007	EXPEDITED (15-DAY)		DS	FI-PFIZER INC-2018066074		19 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Female Orgasmic Disorder; Hypoaesthesia; Libido Decreased	Zoloft		S	Oral	50 Mg, Daily	Pfizer
	Cipralex		S	Oral	10 Mg, Daily	Not Reported
	Brintellix		S	Oral	10 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14535257	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018063817		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Confusional State; Drug Interaction; Electrocardiogram Qt Prolonged; Fall	Cordarone			S	Oral	1000 Mg, Weekly		Pfizer
	Seroplex			S	Oral	5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14535291	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018024606		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Abnormal; Condition Aggravated; Drug Ineffective; Mania; Rash; Sluggishness; Suicidal Ideation	Paroxetine			S	Unknown	Unk		Glaxosmithkline
	Sertraline			S	Unknown	Unk		Glaxosmithkline
	Carbamazepine			S	Unknown	Unk		Glaxosmithkline
	Risperidone			S	Unknown	Unk		Glaxosmithkline
	Quetiapine			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	Unk		Glaxosmithkline
	Duloxetine			S	Unknown	60 Mg, Daily		Glaxosmithkline
	Oxcarbazepine			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Glaxosmithkline
	Venlafaxine			S	Unknown	Unk		Glaxosmithkline
	Lorazepam			S	Unknown	Unk		Glaxosmithkline
	Fluoxetine			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported

Nortriptyline	S	Unknown	Unk		Not Reported
Thioridazine	S	Unknown	Unk		Not Reported
Amitriptyline	C	Unknown	Unk		Not Reported
Chlorpromazine	C	Unknown	100 Mg, Q.H.S.		Not Reported
Gabapentin	C	Unknown	300 Mg, Bid		Not Reported
Gabapentin	C	Unknown	600 Mg, Q.H.S.		Not Reported
Acamprosate	C	Unknown	666 Mg, Tid		Not Reported
Baclofen	C	Unknown	10 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14535392	EXPEDITED (15-DAY)		DE	FR-TEVA-2018-FR-856068		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Mirtazapine			S	Oral	45 Milligram Daily;		Teva
	Escitalopram			S	Oral	30 Milligram Daily;		Ivax
	Tiapridal			S	Oral	100 Milligram Daily;		Not Reported
	Orozamudol			S	Oral	150 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14535959	EXPEDITED (15-DAY)		HO, LT	ES-ALLERGAN-1807897US		79 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Drug Interaction	Escitalopram Oxalate Unk			S	Oral	Unk, Unknown		Allergan
	Enoxaparina Sodica (2482so)			S	Subcutaneous			Not Reported
	Sintrom			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14536033	EXPEDITED (15-DAY)		DS	AU-ALLERGAN-1807892US			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pruritus; Urticaria	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14536129	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1807730US		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Furosemide			S	Oral			Not Reported
	Xarelto			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14536137	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1807096US		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis; Malaise	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Previscan (Fluindione)			S	Oral			Not Reported
	Uvedose			C	Unknown	Unk		Not Reported
	Alteis			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14536663	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-855922		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Coma; Fall; Rib Fracture	Zolpidem			S	Oral			Teva
	Lexomil Roche			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Baclofene			S	Oral			Not Reported
	Valium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14536683	DIRECT	Y	HO			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Encephalopathy; Lethargy; Therapy Cessation	Baclofen			S	Oral			Not Reported
	Oxycodone			S	Topical	50mcg Q3days Topical		Not Reported
	Lyrica			S				Not Reported
	Duragesic Patch			S				Not Reported
	Lexapro			S				Not Reported
	Diclofenac			S				Not Reported
	Lidoderm			S				Not Reported
	Nuedexta			C				Not Reported
	Xarelto			C				Not Reported
	Betapace			C				Not Reported
	Dulera			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14537043	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2018NSR000053		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S		Unk		Northstar
	Escitalopram			S		Unk		Not Reported
	Lamotrigine			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Cyclobenzaprine			S		Unk		Not Reported
	Buspirone			S		Unk		Not Reported
	Clonazepam			S		Unk		Not Reported
	Activated Charcoal			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14537046	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE		36 YR	Female	USA

HOLDINGS-US-2018NSR000055

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk		Northstar
	Escitalopram			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Acetaminophen			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported
	Cocaine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14537185	EXPEDITED (15-DAY)		DE	US-PERNIX THERAPEUTICS-US-2018PER001554		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Treximet			S	Oral	Unk		Pernix
	Metformin			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14537295	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2018NSR000066		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk		Northstar
	Escitalopram			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported

Acetaminophen W/Oxycodone	S	Oral	Unk		Not Reported
Ibuprofen	S	Oral	Unk		Not Reported
Montelukast	S	Oral	Unk		Not Reported
Ondansetron	S	Oral	Unk		Not Reported
Acyclovir /00587301/	S	Oral	Unk		Not Reported
Alprazolam	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14537311	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2018NSR000068		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk		Northstar
	Diltiazem			S	Oral	Unk		Not Reported
	Metformin			S	Oral	Unk		Not Reported
	Glyburide			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Losartan			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14346920	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017551053		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Sedation	Alprazolam			S	Oral	0.125 Mg, Daily		Pfizer
	Risperdal			S	Oral	1.5 G, Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14368636	EXPEDITED (15-DAY)		DS, OT	US-ALLERGAN-1774032US		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dystonia; Erythema; Erythromelalgia; Joint Swelling; Myalgia; Palpitations; Quality Of Life Decreased; Small Fibre Neuropathy; Tremor; Vomiting; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Motrin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14501798	EXPEDITED (15-DAY)		HO	PHHY2018FR017826		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Pantoprazol			S	Oral			Novartis
	Escitalopram			S	Oral			Not Reported
	Xeloda			S	Oral			Not Reported
	Novorapid			S	Subcutaneous			Not Reported
	Primperan			S	Oral			Not Reported
	Lipanthyl			S	Oral	Non Renseignée		Not Reported
	Movicol			S	Oral	Non Renseignée		Not Reported
	Abasaglar			S	Subcutaneous			Not Reported
	Fondaparinux Sodique			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14538073	EXPEDITED (15-DAY)		DE	US-EGALET US INC-US-2018EGA000144		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Oxycodone Hydrochloride	S	Oral	Unk		Egalet
	Propranolol	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Lamotrigine	S	Oral	Unk		Not Reported
	Acetaminophen	S	Oral	Unk		Not Reported
	Ibuprofen	S	Oral	Unk		Not Reported
	Montelukast	S	Oral	Unk		Not Reported
	Ondansetron	S	Oral	Unk		Not Reported
	Acyclovir /00587301/	S	Oral	Unk		Not Reported
	Alprazolam	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14538098	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-163340		21 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertrichosis; Therapeutic Product Effect Incomplete; Weight Increased	Fluoxetine			S	Unknown	20 Mg, Daily		Sun
	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported
	Sertraline			S	Unknown	50 Mg, Daily		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14538464	EXPEDITED (15-DAY)		OT	IE-CIPLA LTD.-2018IE04002			Unknown	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Discomfort; Insomnia; Motor Dysfunction; Pain In Extremity; Paraesthesia	Escitalopram			S	Unknown	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14539268	EXPEDITED (15-DAY)		HO, LT	ES-MACLEODS PHARMACEUTICALS			Unknown	ESP

US LTD-
MAC2018009837

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Drug Interaction	Escitalopram Oxalate			S	Oral	Unk		Macleods
	Enoxaparin Sodium			S	Subcutaneous	Unk		Not Reported
	Sintrom			S	Oral	Unk, Compressed Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14540547	EXPEDITED (15-DAY)		HO, OT	GB-OTSUKA-DJ20071760			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carcinoid Tumour; Hot Flush	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Citalopram			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14540730	EXPEDITED (15-DAY)		HO	IE-OTSUKA-DJ20082802		26 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete	Abilify			S	Oral	20 Mg, Unk		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Escitalopram			S	Unknown	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14540896	EXPEDITED (15-DAY)		HO	BE-OTSUKA-DJ20062354		17 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Abilify			S	Oral	15 Mg, Unk		Otsuka

Solian	S	Oral	600 Mg, Unk		Not Reported
Lexapro	S	Oral	10 Mg, Qd		Not Reported
Sipralexa	C	Unknown	Unk		Not Reported
Trazolan	C	Unknown	100 Mg, Qd		Not Reported
Xanax	C	Unknown	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14540950	EXPEDITED (15-DAY)		HO, OT	CH-OTSUKA-2017_024917		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Abilify			S	Transplacental	1 Df, Qd (1 Df: 10-20mg)		Otsuka
	Dafalgan			S	Transplacental	1 G, Bid		Not Reported
	Seroquel			S	Transplacental	1 Df: 50 Mg Per Day Till Beginning Of Pregnancy Later 100 Mg Per Day And 25 Mg In Reserve		Not Reported
	Cipralex			S	Transplacental	20 Mg, Qd		Not Reported
	Cipralex			S	Transplacental	10 Mg, Qd		Not Reported
	Stilnox			S	Transplacental	10 Mg, Qd		Not Reported
	Stilnox			S	Transplacental	12.5 Mg, Qd		Not Reported
	Lamictal			S	Transplacental	150 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Transplacental	1 Mg, Qd (In Reserve 1mg 4 Times/Day)		Not Reported
	Brufen			S	Transplacental	400 Mg, Tid		Not Reported
	Lyrica			S	Transplacental	100 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541114	EXPEDITED (15-DAY)		OT	FR-OTSUKA-DJ20110308			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour;	Abilify			S	Oral	10 Mg, Unk		Otsuka

Disinhibition; Hypomania; Initial Insomnia; Libido Increased; Logorrhoea; Sexually Inappropriate Behaviour	Abilify	S				Otsuka
	Abilify	S				Otsuka
	Seroplex	S	Oral	Unk		Not Reported
	Seroplex	S	Oral	Unk		Not Reported
	Lexapro	S	Oral	Also 20mg/Day Reduced To 10mg/Day From 07oct10		Not Reported
	Lexapro	S				Not Reported
	Xanax	C	Oral	1 Mg, Qd (Before Jun10 Also :5mg Dosageg:1-3 Tabs)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541133	EXPEDITED (15-DAY)		LT, OT	FR-OTSUKA-DJ20112408		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Multiple Organ Dysfunction Syndrome; Neuroleptic Malignant Syndrome; Status Epilepticus	Abilify			S	Oral	30 Mg, Unk		Otsuka
	Seroplex			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	20mg 1 Df =2 Scored Film-Coated Tabs,Long Term To 20mar11		Not Reported
	Seresta			C	Oral	Unk		Not Reported
	Depamide			C	Unknown	Unk		Not Reported
	Gardenal			C	Oral	Unk		Not Reported
	Gardenal			C	Oral	Unk		Not Reported
	Keppra			C	Oral	500 Mg, Unk		Not Reported
	Omix			C	Oral	Unk		Not Reported
	Noctran			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541156	EXPEDITED (15-DAY)		HO	FR-OTSUKA-DJ20107147		22 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Poisoning Deliberate	Abilify	S	Oral	Unk		Otsuka
	Seroplex	S	Oral	Unk		Not Reported
	Seresta	S	Oral	Unk		Not Reported
	Lexapro	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541282	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-DJ20104518		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Thrombosis	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Xanax			S	Unknown	0.5 Mg, Unk		Not Reported
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported
	Coumadin			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541332	EXPEDITED (15-DAY)		OT	DE-OTSUKA-DJ20103638		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Generalised Oedema	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Quilonum			S	Oral	Unk		Not Reported
	Cipralex			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	Taken Before 06apr2010		Not Reported
	Lithium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541345	EXPEDITED (15-DAY)		HO, OT	GB-OTSUKA-DJ20095729		37 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Body Temperature Increased;	Abilify			S	Oral	30 Mg, Unk		Otsuka
	Clozaril			S	Oral	100 Mg, Unk		Not Reported

Cerebrovascular Accident; Diarrhoea Infectious; Dizziness; Fatigue; Headache; Heart Rate Increased; Malaise; Nausea; Vomiting	Diazepam		S	Oral	Unk	Not Reported
	Escitalopram		S	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541489	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20113089			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Sclerosis; Overdose; Suicide Attempt	Abilify			S	Unknown	Unk		Otsuka
	Trazodone Hcl			S	Unknown	Half A Bottle		Not Reported
	Lexapro			S	Unknown	Half A Bottle		Not Reported
	Copaxone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541507	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-DJ20100128		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Chondromalacia; Hepatitis; Obstructive Airways Disorder; Osteoarthritis; Pneumonia; Umbilical Hernia	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Lamictal			S	Unknown	100 Mg, Bid		Not Reported
	Lamictal			S	Unknown	25mg Bid (1x1wk,Bidx2wk)		Not Reported
	Lexapro			S	Oral	20 Mg, Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Xanax			S	Unknown	0.5 Mg, Prn		Not Reported
	Imdur			C	Unknown	Unk		Not Reported
	Nexium			C	Unknown	Unk		Not Reported
	Potassium			C	Unknown	Unk		Not Reported

	Wellbutrin			C	Unknown	Unk			Not Reported
	Lisinopril			C	Unknown	Unk			Not Reported
	Metoprolol			C	Unknown	Unk			Not Reported
	Requip			C	Unknown	Unk			Not Reported
	Lyrica			C	Unknown	Unk			Not Reported
	Effexor			C	Unknown	Unk			Not Reported
	Prozac			C	Unknown	Unk			Not Reported
	Paxil			C	Unknown	Unk			Not Reported
	Glucophage			C	Unknown	Unk			Not Reported
	Actos			C	Unknown	Unk			Not Reported
	Amaryl			C	Unknown	Unk			Not Reported
	Lopressor			C	Unknown	Unk			Not Reported
	Norvasc			C	Unknown	Unk			Not Reported
	Asa			C	Unknown	Unk			Not Reported
	Multiple Vitamins			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541516	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20104644			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rash	Abilify			S	Oral	Unk		Otsuka
	Atenolol			S	Unknown	Unk		Not Reported
	Ferrous Sulfate			S	Unknown	Unk		Not Reported
	Feldene			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Digoxin			S	Unknown	Unk		Not Reported
	Zyrtec			S	Oral	Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported

Norvir	S	Oral	Unk		Not Reported
Diphenhydramine	S	Unknown	Unk		Not Reported
Loperamide	S	Unknown	Unk		Not Reported
Atrovent	S	Unknown	Unk		Not Reported
Cozaar	S	Oral	Unk		Not Reported
Lexapro	S	Oral	Unk		Not Reported
Epogen	S	Unknown	Unk		Not Reported
Carvedilol	S	Unknown	Unk		Not Reported
Seroquel	S	Unknown	Unk		Not Reported
Lactose	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541527	EXPEDITED (15-DAY)		HO	US-OTSUKA-DJ20102951		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oesophageal Spasm	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S				Otsuka
	Abilify			S				Otsuka
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Seroquel			S	Unknown	100 Mg, Bid		Not Reported
	Daytrana			S	Unknown	Patch		Not Reported
	Clonidine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541582	EXPEDITED (15-DAY)		HO, LT, OT	FR-OTSUKA-DJ20084398		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Thrombosis	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Abilify			S				Otsuka
	Anafranil			S	Oral	50 Mg, Qd		Not Reported

	Seroplex		S	Oral	10 Mg, Qd	Not Reported
	Tercian		S	Oral	100 Mg, Qd	Not Reported
	Tercian		S			Not Reported
	Lexapro		S	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541944	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20121209		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral	Abilify			S	Oral	1 Mg, Unk		Otsuka
	Lipitor			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Xanax			S	Unknown	0.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541949	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20122139		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Oedema Due To Cardiac Disease; Pericardial Effusion; Weight Increased	Abilify			S	Oral	2 Mg, Unk		Otsuka
	Celexa			S	Oral	60 Mg, Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Effexor			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541957	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20121415			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombosis	Abilify			S	Unknown	5 Mg, Unk		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541960	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20121356			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Hypertension; Wrong Technique In Product Usage Process	Abilify			S	Oral	1 Mg, Unk		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541985	EXPEDITED (15-DAY)		DS	AT-OTSUKA-DJ20122876		20 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spinal Disorder; Weight Increased	Abilify			S	Unknown	15 Mg, Unk		Otsuka
	Abilify			S				Otsuka
	Cipralex			S	Unknown	Unk		Not Reported
	Quilonorm			S	Unknown	Unk		Not Reported
	Quilonorm			S				Not Reported
	Quetiapine Fumarate			S	Unknown	Unk		Not Reported
	Quetiapine Fumarate			S				Not Reported
	Zeldox			S	Unknown	Unk		Not Reported
	Zeldox			S				Not Reported
	Lexapro			S	Unknown	20 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Trittico			C	Unknown	150 Mg, Qd		Not Reported
	Euthyrox			C	Unknown	Unk		Not Reported
	Pantoloc			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542013	EXPEDITED (15-DAY)		HO	FR-OTSUKA-DJ20129784		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angle Closure Glaucoma	Abilify	S	Oral	15 Mg, Unk		Otsuka
	Loxapac	S	Oral	Unk		Not Reported
	Risperdal	S	Oral	12 Mg, Qd		Not Reported
	Parkinane	S	Oral	Unk		Not Reported
	Clopixol	S	Oral	Unk		Not Reported
	Seroplex	S	Oral	Unk		Not Reported
	Lexapro	S	Oral	40 Mg, Qd		Not Reported
	Trivastal	C	Unknown	Unk		Not Reported
	Valium	C	Unknown	Unk		Not Reported
	Levothyrox	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542035	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ201303162		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Mania; Pressure Of Speech	Abilify			S	Unknown	5 Mg, Unk		Otsuka
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542123	EXPEDITED (15-DAY)		OT	FR-OTSUKA-DJ201303700		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asphyxia; Rash; Sleep Apnoea Syndrome	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Seroplex			S	Oral	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542213	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-DJ201300088		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Abilify			S	Oral	10 Milligram 1 Day		Otsuka
	Atacand			S	Oral	16 Milligram 1 Day		Not Reported
	Seroplex			S	Oral	5 Milligram 1 Day		Not Reported
	Depakote			S	Unknown	750 Milligram 1 Day		Not Reported
	Depakote			S	Unknown	1 Gram 1 Day		Not Reported
	Depakote			S	Unknown	500 Milligram 1 Day		Not Reported
	Lexapro			S	Oral	Film Coated Tabs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542229	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20126877		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Depression; Expired Product Administered; Feeling Jittery; Mania; Muscle Twitching; Wrong Technique In Product Usage Process	Abilify			S	Oral	1 Df, Unk		Otsuka
	Lithium			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542264	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20125943			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Triglycerides Increased; Constipation; Diarrhoea; Ejaculation Disorder; Libido Decreased; Muscle Spasms; Sleep Disorder; Suicidal Ideation; Thirst; Urinary Retention	Abilify			S	Oral	20 Mg, Unk		Otsuka
	Chantix			S	Unknown	Unk		Not Reported
	Geodon			S	Unknown	40 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Xanax			C	Unknown	Unk		Not Reported
	Lisinopril			C	Unknown	1 Df = 20/25 Mg/Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542271	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-DJ20115156		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cerebral Haematoma; Cerebrovascular Accident; Fall; Hemiplegia	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Seroplex			S	Oral	Unk		Not Reported
	Parkinane			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542366	EXPEDITED (15-DAY)		HO	US-OTSUKA-DJ20127159			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Feeling Abnormal; Knee Arthroplasty; Pain; Wrong Technique In Product Usage Process	Abilify			S	Unknown	20 Mg, Unk		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542478	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-DJ201404958		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Memory Impairment; Myocardial Infarction; Off Label Use	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S				Otsuka
	Lexapro			S	Unknown	Unk		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542577	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-DJ201400835			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Dissociation; Feeling Abnormal; Myalgia; Panic Attack; Suicidal Ideation	Abilify		S	Unknown	7.5 Mg, Unk	Otsuka
	Lexapro		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542670	EXPEDITED (15-DAY)		HO	FR-OTSUKA-DJ201400616		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysarthria; Off Label Use	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Seroplex			S	Oral	10 Mg, Unk		Not Reported
	Lexapro			S	Oral	Seroplex 10 Mg, Scored Film-Coated Tablet		Not Reported
	Valium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542687	EXPEDITED (15-DAY)		HO	FR-OTSUKA-DJ201406511		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pyrexia; Renal Failure; Rhabdomyolysis	Abilify			S	Unknown	10 Mg, Unk		Otsuka
	Imovane			S	Oral	7.5 Mg, Unk		Not Reported
	Mianserin			S	Oral	60 Mg, Unk		Not Reported
	Seroplex			S	Unknown	20 Mg, Unk		Not Reported
	Lexapro			S	Unknown	In Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542688	EXPEDITED (15-DAY)		LT	FR-OTSUKA-DJ201400090		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Liver Injury; Mydriasis; Rhabdomyolysis	Abilify			S	Unknown	Unk		Otsuka
	Paracetamol			S	Unknown	Unk		Not Reported

Zolpidem	S	Unknown	Unk		Not Reported
Paroxetine	S	Unknown	Unk		Not Reported
Hept-A-Myl	S	Unknown	Unk		Not Reported
Cymbalta	S	Unknown	Unk		Not Reported
Lamotrigine	S	Unknown	Unk		Not Reported
Escitalopram	S	Unknown	Unk		Not Reported
Agomelatine	S	Unknown	Unk		Not Reported
Avlocardyl	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542703	EXPEDITED (15-DAY)		HO	US-OTSUKA-DJ201407883		12 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Cyst; Drug Level Above Therapeutic; Headache; Mania; Off Label Use; Unevaluable Event; Weight Increased	Abilify			S	Oral	3 Mg, Unk		Otsuka
	Abilify			S				Otsuka
	Lexapro			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542704	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-DJ201406274		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gambling Disorder; Persistent Depressive Disorder; Suicidal Ideation	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Lamictal			S	Oral	1 Df: 200 To 300 Mg		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Nozinan			S	Oral	100 Mg, Unk		Not Reported
	Teralithe			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542733	EXPEDITED (15-DAY)		OT	US-OTSUKA-J201408697		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Diabetes Mellitus	Abilify			S	Unknown	Unk		Otsuka
	Aripiprazole			S	Unknown	Unk		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14542739	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-DJ201400327		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Overdose; Seizure; Suicide Attempt	Abilify			S	Oral	1 Df, Unk		Otsuka
	Xanax			S	Oral	Unk		Not Reported
	Theralene			S	Unknown	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Tercian			S	Unknown	Unk		Not Reported
	Depakote			S	Oral	Unk		Not Reported
	Teralithe			S	Oral	Unk		Not Reported
	Lexapro			S		1 Df, Unk		Not Reported
	Lysanxia			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2018	14544835	EXPEDITED (15-DAY)		HO, LT	ES-AUROBINDO-AUR-APL-2018-007895		79 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma	Escitalopram			S	Oral	Unk		Aurobindo
	Enoxaparina			S	Subcutaneous	Unk		Not Reported
	Sintrom			S	Oral	1 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2018	14559879	DIRECT		OT			< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankyloglossia Congenital; Jaundice; Lip Disorder	Latuda			S		5 - 18 Wks Gestation		Not Reported
	Lamictal			S		0 - 18 Wks Gestation		Not Reported
	Lexapro			S		5 - 18 Wks Gestation		Not Reported
	Humira			S		0 - 39 Wks Gestation		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2018	14559880	DIRECT		OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Premature Labour	Latuda			S		5 Wks - 18 Wks		Not Reported
	Lamictal			S		Conception - 18 Wks		Not Reported
	Lexapro			S		5 Wks - 18 Wks		Not Reported
	Humira			S		Conception - Delivery		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2018	14554653	DIRECT		OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Panic Attack; Product Substitution Issue	Escitalopram Oxalate			S	Oral	Quantity:1.5 Tablet(S);		Aurobindo
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14265388	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1770344US			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Dizziness; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Escitalopram Oxalate - Bp	S	Unknown	10 Mg, Qd		Allergan
	Amitriptyline	S	Unknown	5 Mg, Qd		Not Reported
	Amitriptyline	S	Unknown	12.5 Mg, Qd		Not Reported
	Amitriptyline	S	Unknown	25 Mg, Qd		Not Reported
	Paracetamol	S	Unknown	3 Df, Qd		Not Reported
	Amlodipine	S	Unknown	1 Df, Qd		Not Reported
	Simvastatin	S	Unknown	40 Mg, Qd		Not Reported
	Simvastatin	S	Unknown	20 Mg, Unk		Not Reported
	Topiramate	S	Unknown	50 Mg, Qd		Not Reported
	Topiramate	S	Unknown	0.5 Df, Qd		Not Reported
	Paracetamol, Tramadol	S	Unknown	3 Df, Qd		Not Reported
	Paracetamol, Tramadol	S		1 Df, Qd		Not Reported
	Naproxen	S	Unknown	1 Df, Bid		Not Reported
	Hydrochlorothiazide, Enalapril Maleate	S	Unknown	1 Df, Qd		Not Reported
	Diazepam	S	Unknown	0.5 Df, Qd		Not Reported
	Glibenclamide	S	Unknown	2 Df, Qd		Not Reported
	Omeprazole	S	Unknown	1 Df, Qd		Not Reported
	Lormetazepam	S	Unknown	1 Df, Qd		Not Reported
	Diazepam, Sulpiride	S	Unknown	Unk, Qd		Not Reported
	Metoclopramide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14325856	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1773533US		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pulmonary Embolism; Thrombosis	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Tirosint			S	Unknown	75 Mg, Qd		Not Reported
	Aubagio			S	Oral	14 Mg, Qd		Not Reported
	Xanax			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14440594	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1769176US		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Furosemide			S	Oral	30 Mg, Qd		Not Reported
	Terbutaline			S	Respiratory (inhalation)			Not Reported
	Amlodipine			S	Oral			Not Reported
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported
	Xarelto			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Alprazolam			S	Oral	0.25 Mg, Tid		Not Reported
	Diazepam			S	Oral	3 Times A Day If Needed		Not Reported
	Tavanic			S	Oral	250 Mg, Bid		Not Reported
	Nefopam			S	Oral	1 Df, Tid		Not Reported
	Colchicine Opocalcium			S	Oral	1 Mg, Qd		Not Reported
	Dafalgan			S	Oral	1000 Mg, Tid		Not Reported
	Bisoprolol			S	Oral	1.25 Mg, Qd		Not Reported
	Diffu K			S	Oral	3 Df, Bid		Not Reported
	Irbesartan			S	Oral	300 Mg, Qd		Not Reported
	Pantoprazole			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14545977	EXPEDITED (15-DAY)		HO	FR-KRKA, D.D., NOVO MESTO-2042205		91 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Lansoprazole			S	Oral			Krka Dd Novo Mesto
	Escitalopram			S	Oral			Not Reported

	Gliclazide	S	Oral	Not Reported
	Stilnox 10 Mg	S	Oral	Not Reported
	Efferalgan	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14546988	NON-EXPEDITED			US-PFIZER INC-2018067988		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Oxaprozin			S		Unk		Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14547471	EXPEDITED (15-DAY)		HO, LT	JP-MYLANLABS-2018M1011657			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Drug Interaction; Foetal Exposure During Pregnancy; Hypopnoea; Irregular Breathing; Respiratory Muscle Weakness	Escitalopram			S	Transplacental	Since 34th Weeks Of Gestation		Not Reported
	Ethyl Loflazepate			S	Transplacental	Since 34th Weeks Of Gestation		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14547802	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1808319US		14 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Toxicity To Various Agents; Vertigo	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Dafalgan			S	Oral			Not Reported
	Lumirelax (Methocarbamol)			S	Oral			Not Reported
	Dafalgan Codeine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14547964	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1808308US		37 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Postpartum Haemorrhage; Pregnancy; Premature Delivery	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Speciafoldine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14549412	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-SE-ALKEM-2017-01916			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Citalopram			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Alkem
	Olanzapine			S	Unknown	Unk		Alkem
	Risperidone			S	Unknown	Unk		Not Reported
	Quetiapine Fumarate			S	Unknown	Unk		Alkem

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14549413	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-SE-ALKEM-2017-01917			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Citalopram			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

	Duloxetine	S	Unknown	Unk		Not Reported
	Lamotrigine	S	Unknown	Unk		Alkem
	Olanzapine	S	Unknown	Unk		Alkem
	Risperidone	S	Unknown	Unk		Not Reported
	Quetiapine Fumarate	S	Unknown	Unk		Alkem

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14549414	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-SE-ALKEM-2017-01915			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Citalopram			S	Unknown	Unk		Not Reported
	Zolpidem Pharmacor			S	Unknown	Unk		Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Alkem
	Olanzapine			S	Unknown	Unk		Alkem
	Risperidone			S	Unknown	Unk		Not Reported
	Quetiapine Fumarate			S	Unknown	Unk		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14549435	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004285		53 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Surgery; Urinary Incontinence	Espran			S	Oral	One Tablet Daily In The Morning		Torrent
	Rivotril			C	Oral	1 Tab (Morning) 1 Tab (Night)		Unknown
	Neuleptil			C	Oral	1 Tab At Night		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14550150	NON-EXPEDITED			US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006611			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Drug Interaction; Memory Impairment; Prescribed Underdose	Nuplazid			S	Unknown	17 Mg, Qd		Acadia Pharmaceuticals
	Nuplazid			S	Unknown	34 Mg, Qd		Acadia Pharmaceuticals
	Nuplazid			S				Acadia Pharmaceuticals
	Pramipexole			C	Oral	2.5 Mg, Qhs		Not Reported
	Clonazepam			C	Oral	0.5 Df, Qhs		Not Reported
	Clonazepam			C	Oral	0.25 Mg, Qam		Not Reported
	Synthroid			C	Oral	100 Mcg, Qd		Not Reported
	Benicar			C	Oral	10 Mg, Qd		Not Reported
	Amlodipine			C	Oral	5 Mg, Qd		Not Reported
	Aspirin			C	Oral	81 Mg, Qd		Not Reported
	Carbidopa/Levodopa			C	Oral	50-200mg-1tab		Not Reported
	Crestor			C	Oral	5 Mg, M/W/F Only At Hs		Not Reported
	Aricept			S	Oral	10 Mg, Qd		Not Reported
	Aricept			S	Unknown	Unk		Not Reported
	Multivitamin			C				Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14550194	NON-EXPEDITED			US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006669			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Euphoric Mood; Libido Increased; Psychomotor	Nuplazid			S	Unknown	34 Mg, Qd		Acadia Pharmaceuticals
	Nuplazid			S				Acadia

Hyperactivity	Nuplazid	S			Pharmaceuticals
	Lexapro	S	Unknown		Acadia Pharmaceuticals
					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	13413209	EXPEDITED (15-DAY)		HO, OT	AU-009507513-1703AUS014177		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Serotonin Syndrome	Mirtazapine			S	Oral	870 Mg, Unk		Merck
	Desvenlafaxine			S		500 Mg, Unk		Not Reported
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14185768	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-43477		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Escitalopram Arrow Film-Coated Tablet 5mg			S	Oral	5 Mg, Daily		Aurobindo
	Eliquis			C	Oral	2 Df, Unk		Not Reported
	Esidrex			S	Oral	0.5 Df, Daily		Not Reported
	Bisoce			C	Oral	2 Df, Unk		Not Reported
	Imovane			C	Oral	0.5 Df, Daily		Not Reported
	Levothyrox			C	Oral	112.5 U/G, Unk		Not Reported
	Levothyrox			C				Not Reported
	Ramipril Mylan			S	Oral	5 Mg, Daily		Not Reported
	Speciafoldine			C	Oral	1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14330267	EXPEDITED (15-DAY)		OT	ES-CANTON LABORATORIES, LLC-2037833			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Dizziness; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Naprosyn		S	Unknown	Canton Laboratories
	Amitriptyline Hydrochloride		S	Unknown	Not Reported
	Amlodipine		S	Unknown	Not Reported
	Diazepam		S	Unknown	Not Reported
	Diazepam And Sulpride		S	Unknown	Not Reported
	Enalapril Maleate And Hydrochlorothiazide		S	Unknown	Not Reported
	Escitalopram		S	Unknown	Not Reported
	Glibenclamide		S	Unknown	Not Reported
	Lormetazepam		S	Unknown	Not Reported
	Omeprazole		S	Unknown	Not Reported
	Paracetamol		S	Unknown	Not Reported
	Simvastatin		S	Unknown	Not Reported
	Topiramate		S	Unknown	Not Reported
	Topiramate		S	Unknown	Not Reported
	Tramadol Hydrochloride And Paracetamol		S	Unknown	Not Reported
	Metoclopramide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14448867	EXPEDITED (15-DAY)		OT	AT-TEVA-2018-AT-848642		46 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Headache; Pneumonia	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Brintellix			S	Oral			Not Reported
	Brintellix			S	Oral			Not Reported
	Brintellix			S	Oral			Not Reported
	Brintellix			S	Oral			Not Reported
	Brintellix			S	Oral			Not Reported
	Cipralex			S	Oral	Unknown		Not Reported
	Duloxetine Hydrochloride			S	Unknown			Teva

Trittico Ret.	C	Oral			Not Reported
Trittico Ret.	C	Oral	Since Months		Not Reported
Trittico Ret.	C	Oral			Not Reported
Trittico Ret.	C	Oral			Not Reported
Oleovit D3	C	Oral	N/A		Not Reported
Aprednisolon	C	Oral			Not Reported
Cal-D-Vita	C	Oral	Since Years		Not Reported
Curocef	C	Unknown			Not Reported
Curocef	C	Unknown			Not Reported
Zoldem	C	Oral			Not Reported
Zoldem	C	Oral			Not Reported
Zoldem	C	Oral	Since Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14488317	EXPEDITED (15-DAY)		HO	ES-ALLERGAN-1804295US		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chronic Gastritis; Condition Aggravated; Depressed Mood; Drug Ineffective; Dysphagia; Feeding Disorder; Gait Disturbance; Irritability; Judgement Impaired; Loss Of Personal Independence In Daily Activities; Parkinsonism; Psychiatric Symptom; Psychomotor Retardation; Speech Disorder; Therapeutic Product Effect Incomplete; Tremor; Vitamin B12 Deficiency; Weight Decreased	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Clomipramine			S	Unknown	150 Mg, Qd		Not Reported
	Aripiprazole			S	Unknown	10 Mg, Unk		Not Reported
	Fluvoxamine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14516230	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT021144		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Sopor; Suicide Attempt	Escitalopram			S	Oral	30 Ml, Unk		Not Reported
	Alprazolam			S	Oral	16 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14552402	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2018SE18722		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Quetiapine			S	Oral			Zeneca
	Escitalopram			S	Oral	270.0mg Once/Single Administration		Not Reported
	Etiltox			S	Oral	9.0df Once/Single Administration		Not Reported
	Carbolithium			S	Oral	5.0df Once/Single Administration		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14554382	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC-2018049112		78 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Aspavor			S	Oral	20 Mg, Unk		Pfizer
	Lyrica			S	Oral	150 Mg, Unk		Pfizer
	Lexamil			S	Oral	10 Mg, Unk		Not Reported
	Lancap			S	Oral	30 Mg, Unk		Not Reported
	Betacor /00008501/			S	Oral	5 Mg, Unk		Not Reported
	Be-Tabs Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Unat /01036501/			S	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14554528	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-856961		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram			S	Oral	1 Dosage Forms Daily;		Ivax
	Rulid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14554590	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2018070723		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction	Amiodarone Hcl			S	Oral	Unk		Pfizer
	Escitalopram Oxalate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14554608	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE-856849		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram			S	Transplacental	7.5 Milligram Daily;		Ivax
	Ebrantil			C	Unknown			Not Reported
	Simvastatin			C	Unknown	Probably Either Simvastatin Or Atozet		Not Reported
	Valsartan			C	Unknown	160 Mg/Day (Father)		Not Reported
	Folsan			C	Transplacental	0.4 Mg/Day (Mother)		Not Reported
	Ramilich			C	Unknown	10 Mg/Day (Father)		Not Reported
	Dekristol			C	Unknown	20000 Iu/Day (Every Second Week) (Father)		Not Reported
	Paracetamol			C	Transplacental			Not Reported
	Bicanorm			C	Unknown			Not Reported

	Atozet	C	Unknown	40 Mg/Day / 10 Mg/D (Father) / Probably Either Atozet Or Simvastatin	Not Reported
	Ass 100	C	Unknown	100 Mg/Day (Father)	Not Reported
	Amlodipine	C	Unknown	10 Mg/Day (Father)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	7990218	EXPEDITED (15-DAY)		OT	GB-TEVA-285135ISR		21 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Disturbance In Social Behaviour; Oculogyric Crisis	Risperidone			S	Oral	0.25-1.5mg		Pliva
	Risperidone			S	Oral			Pliva
	Risperidone			S	Oral	1.5 Milligram Daily;		Pliva
	Escitalopram			S	Oral	10 Milligram Daily;		Not Reported
	Escitalopram			S	Oral	20 Milligram Daily;		Not Reported
	Escitalopram			S		Was Reduced And Then Stopped		Not Reported
	Diazepam			C		1-2 Mg		Not Reported
	Diazepam			C		4 Mg		Not Reported
	Aripiprazole			C		5 Milligram Daily; Every Morning		Not Reported
	Aripiprazole			C		5 Milligram Daily;		Not Reported
	Procyclidine			C		5 Milligram Daily;		Not Reported
	Procyclidine			C		7.5 Milligram Daily;		Not Reported
	Procyclidine			C				Not Reported
	Orphenadrine			C		150 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14473791	EXPEDITED (15-DAY)		HO, OT	FR-DRREDDYS-GER/FRA/18/0095929		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebrovascular Accident	Fondaparinux	S	Subcutaneous			Not Reported
	Xeloda	S	Oral	Non Renseignée		Not Reported
	Novorapid	S	Subcutaneous	Non Renseignée		Not Reported
	Primperan	S	Oral	Non Renseignée		Not Reported
	Lipanthyl	S	Oral	Non Renseignée		Not Reported
	Pantoprazole	S	Oral	Non Renseignée		Not Reported
	Escitalopram	S	Oral	Non Renseignée		Not Reported
	Abasaglar	S	Subcutaneous	Non Renseignée		Not Reported
	Movicol	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14488629	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2018-ES-851020		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown			Ivax
	Aripiprazole			S	Unknown	10 Milligram Daily;		Teva
	Fluvoxamine			S	Unknown	200 Milligram Daily;		Not Reported
	Clomipramine			S	Unknown	150 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14556553	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2018-004439		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Hyponatraemia	Enalapril 20 Mg			S	Oral	28 Tablets		Not Reported
	Heipram 10 Mg			S	Oral	Compressed Films With Film Efg , 56 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14557671	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018066399		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pulmonary Embolism; Pulmonary Infarction	Xanax	S		Unk	Pfizer
	Tirosint	S		75 Ug, 1x/Day	Not Reported
	Aubagio	S	Oral	14 Mg, 1x/Day	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14559343	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1809593US		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Ceftriaxone Sodique			S	Unknown	Unk, Unknown		Not Reported
	Risperidone			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14559348	EXPEDITED (15-DAY)		CA	NL-ALLERGAN-1809603US			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Oral Malformation; Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Folic Acid			C	Transplacental	Unk, Unknown		Not Reported
	Davitamon			C	Transplacental	Unk, Unknown		Not Reported
	Cyklokapron			C	Transplacental	Unk, Unknown		Not Reported
	Calcium Carbonate/Colecalciferol			C	Transplacental	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14560345	EXPEDITED (15-DAY)		HO, LT, OT	TR-VISTAPHARM, INC.-VER201712-001467		24 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypernatraemia; Hypocalcaemia; Intentional Overdose; Leukopenia; Respiratory	Valproic Acid			S	Oral			Vistapharm
	Olanzapine			S	Oral			Not Reported

Depression; Suicide Attempt; Toxicity To Various Agents	Escitalopram		S	Oral	Not Reported
	Fluoxetine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14560905	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018010044			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Off Label Use; Sopor; Toxicity To Various Agents	Escitalopram			S	Oral	270 Mg, Unk		Macleods
	Quetiapine			S	Oral	Unk		Macleods
	Carbolithium 300 Mg Rigid Capsules			S	Oral	5 Df, Unk		Not Reported
	Etiltox 200 Mg Tablets			S	Oral	9 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14562573	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20180227778		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Lower Gastrointestinal Haemorrhage	Xarelto			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Androtardyl			C	Unknown			Not Reported
	Requip			C	Unknown			Not Reported
	Sinemet			C	Unknown			Not Reported
	Zofenil			C	Unknown			Not Reported
	Augmentin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14562933	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1809608US		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Stevens-Johnson Syndrome	Citalopram Hydrobromide - Bp	S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp	S	Unknown	Unk		Allergan
	Cabergoline	S	Unknown	Unk		Not Reported
	Carbidopa	S	Unknown	Unk		Not Reported
	Stalevo	S	Unknown	Unk		Not Reported
	Entacapone	S	Unknown	Unk		Not Reported
	Levodopa	S	Unknown	Unk		Not Reported
	Trimethoprim	S	Unknown	Unk		Not Reported
	Septrin	S	Unknown	Unk		Not Reported
	Co-Beneldopa	C	Unknown			Not Reported
	Macrogol	C	Unknown	Unk		Not Reported
	Duloxetine Hydrochloride	C	Unknown	Unk		Not Reported
	Adcal D3	C	Unknown	Unk		Not Reported
	Rivastigmine Hydrogen Tartrate	C	Transdermal	Unk		Not Reported
	Quetiapine	C	Unknown	Unk		Not Reported
	Paracetamol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14563255	DIRECT		DS			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching; Nerve Injury	Lexapro, 10mg Mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14563638	NON-EXPEDITED		HO	US-AMNEAL PHARMACEUTICALS-2018AMN00076		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Nausea; Stupor; Vertigo	Escitalopram			S	Oral	15 Mg, 1x/Day		Amneal
	Escitalopram			S	Unknown	20 Mg, 1x/Day		Amneal

Escitalopram	S	Oral	10 Mg, 1x/Day		Amneal
Aripiprazole	S	Oral	10 Mg, 1x/Day		Not Reported
Aripiprazole	S	Oral	5 Mg, 1x/Day		Not Reported
Candesartan	S	Unknown	16 Mg, 1x/Day		Not Reported
Risperidone	C	Unknown	2 Mg, 1x/Day		Not Reported
Risperidone	C	Oral	1.5 Mg, 1x/Day		Not Reported
Atorvastatin	C	Unknown	Unk		Not Reported
Metformin	C	Unknown			Not Reported
Acetylsalicylic Acid	C	Unknown	Unk		Not Reported
Amisulpride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14566619	DIRECT	Y	OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Fatigue; Loss Of Personal Independence In Daily Activities; Product Substitution Issue	Escitalopram 20mg Tabs Unknown			S	Oral	20mg 1 Q Am Po	1 MTH	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	11966717	EXPEDITED (15-DAY)		DE	CA-FRI-1000082253		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiomegaly; Drug Therapy; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Syncope; Therapeutic Product Effect Increased	Citalopram Hydrobromide - Bp			S	Oral	20 Mg, Qd		Allergan
	Citalopram Hydrobromide - Bp			S				Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Ativan			C	Unknown	Unk		Not Reported

	Diltiazem	C	Unknown	Unk		Not Reported
	Ethanol	C	Unknown	Unk		Not Reported
	Hydrochlorothiazide	C	Unknown	Unk		Not Reported
	Synthroid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	13526163	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2017004894			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram 10mg Tablet			S	Oral	10 Mg, Qd		Macleods
	Escitalopram 10mg Tablet			S				Macleods
	Xanax			S	Oral	0.25 Mg, Unk		Not Reported
	Xanax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	13569657	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1721000US		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose	Escitalopram Oxalate Unk			S	Oral	140 Mg, In Total		Allergan
	Lorazepam			S	Oral	20 Mg, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	13629865	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1723529US		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Use Disorder; Intentional Overdose; Intentional Self-Injury; Sopor	Escitalopram Oxalate - Bp			S	Oral	15 Ml, Unk		Allergan
	Alprazolam			S	Oral	10 Ml, Unk		Not Reported
	Esomeprazole Sodium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14034968	EXPEDITED (15-DAY)		HO	JP-ASTRAZENECA-2017SE99613		68 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenal Perforation	Symbicort Turbuhaler			S	Respiratory (inhalation)	2 Dosage Form Two Times Daily		Not Reported
	Nexium			S	Oral			Not Reported
	Nexium			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Iguratimod			S	Oral			Not Reported
	Iguratimod			S	Oral			Not Reported
	Diclofenac Sodium			S	Oral			Not Reported
	Prednisolone			S	Oral	4 Mg/Day, Three Times A Day		Not Reported
	Prednisolone			S	Oral	4 Mg/Day, Three Times A Day		Not Reported
	Calcium Lactate			C	Oral			Not Reported
	Calcium Lactate			C	Oral			Not Reported
	Eldecalcitol			C	Oral			Not Reported
	Eldecalcitol			C	Oral			Not Reported
	Minodronic Acid Hydrate			C	Oral			Not Reported
	Micamlo			C	Oral			Not Reported
	Ketoprofen			C	Transdermal	Optimal Dose, Dose Unknown, Every Day		Not Reported
	Meropenem			C				Not Reported
	Sennoside			C	Oral			Not Reported
	Omeprazole Sodium			C				Not Reported
	Elieten			C	Intravenous (not otherwise specified)			Not Reported
	Antibiotics-Resistant Lactic Acid			C	Oral			Not Reported

	Bacteriae Bifidobacterium Bifidum	C	Oral		Not Reported
	Mucodyne	C	Oral	250.0mg Unknown	Not Reported
	Codeine Phosphate	C	Oral		Not Reported
	Meylon	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14541784	EXPEDITED (15-DAY)		DS, HO	DE-TEVA-2018-DE-858284		57 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Chest Pain; Diarrhoea; Gait Disturbance; Haematoma; Haemorrhage; Muscle Disorder; Myalgia; Nerve Injury; Staphylococcal Infection; Walking Aid User	Valproic Acid			S	Unknown	1800 Milligram Daily;		Teva
	Cipralex			S	Unknown	5 Milligram Daily;		Not Reported
	Ibuprofen			C	Unknown	2400 Milligram Daily;		Not Reported
	Xarelto			C	Unknown	10 Milligram Daily;		Not Reported
	Novaminsulfon			C	Unknown	1500 Milligram Daily;		Not Reported
	Cefazolin			C	Unknown	2 G, Unk		Not Reported
	Ass			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565136	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-008964		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Escitalopram			S	Oral	Non Renseignée ()		Aurobindo
	Pantoprazole			S	Oral	Non Renseignée ()		Aurobindo
	Primperan			S	Oral	Non Renseignée ()		Not Reported
	Lipanthyl			S	Oral	Non Renseignée ()		Not Reported
	Novorapid			S	Subcutaneous	Non Renseignée ()		Not Reported
	Fondaparinux Sodium			S	Subcutaneous	Non Renseignée ()		Not Reported
	Xeloda			S	Oral	Non Renseignée ()		Not Reported

Abasaglar	S	Subcutaneous	Non Renseignée ()		Not Reported
Movicol /01749801/	S	Oral	Non Renseignée ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565365	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-009384		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Citalopram			S	Unknown	()		Aurobindo
	Escitalopram			S	Unknown	()		Aurobindo
	Trimethoprim			S	Unknown	()		Not Reported
	Entacapone			S	Unknown	()		Not Reported
	Levodopa			S	Unknown	()		Not Reported
	Septrin			S	Unknown	()		Not Reported
	Stalevo /01530202/			S	Unknown	()		Not Reported
	Duloxetine			C				Not Reported
	Co-Beneldopa			C				Not Reported
	Macrogol			C				Not Reported
	Cabergoline			S	Unknown	()		Not Reported
	Carbidopa			S	Unknown	()		Not Reported
	Adcal D3			C				Not Reported
	Rivastigmine			C				Not Reported
	Quetiapine			C		25 Mg, Unk		Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565497	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2018IT05314			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Abnormal; Intentional Overdose; Intentional Self-Injury; Nausea; Tremor	Escitalopram			S	Oral	200mg, In Total		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565501	EXPEDITED (15-DAY)		DE	FR-CIPLA LTD.-2018FR05962			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram			S	Oral	5 Mg, Per Day		Invagen
	Pradaxa			S	Oral	1 Df, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565726	EXPEDITED (15-DAY)		OT	IN-CIPLA (EU) LIMITED-2018IN05428			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Employment; Memory Impairment; Suicidal Ideation; Treatment Failure	Escitalopram			S	Unknown	20 Mg, Per Day		Invagen
	Mirtazapine			S	Unknown	45 Mg, Per Day		Not Reported
	Amitriptyline			S	Unknown	100 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565729	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US06048			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Drug Withdrawal Syndrome; Fear; Panic Attack; Product Size Issue	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Escitalopram			S				Invagen
	B Complex /00322001/			C	Unknown	Unk, Qd		Not Reported
	Magnesium			C	Unknown	Unk, Qd		Not Reported
	Tylenol Pm			C	Unknown	Unk		Not Reported
	Advil Pm /05810501/			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	0.5 Mg, Prn		Not Reported
	Prozac			C	Unknown	10 Mg, Unk		Not Reported
	Zoloft			C	Unknown	50 Mg, Unk		Not Reported

	Zoloft	C		25 Mg, Unk, For A Week	Not Reported
	Chamomile /00512601/	C	Unknown	Unk	Not Reported
	Lavender /01649201/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565942	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-164390		91 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Lansoprazole			S	Oral	30 Mg, Daily		Sun
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Gliclazide			S	Oral	60 Mg, Daily		Not Reported
	Stilnox 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Df, Daily		Not Reported
	Efferalgan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14566201	EXPEDITED (15-DAY)		CA	NL-AUROBINDO-AUR-APL-2018-009253			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Oral Malformation	Escitalopram 10 Mg			S		1 Dd 1		Aurobindo
	Foliumzuur			C		Unk		Not Reported
	Davitamon			C		Unk		Not Reported
	Cyklokapron			C		Unk		Not Reported
	Calcium Carbonate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14566600	EXPEDITED (15-DAY)		CA, OT	NL-MACLEODS PHARMACEUTICALS US LTD-MAC2018010241			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Congenital Oral Malformation; Foetal Exposure During Pregnancy	Escitalopram Oxalate	S	Transplacental	10 Mg, Qd, 1 Dd 1	Macleods
	Foliumzuur	C	Oral	Unk	Not Reported
	Retinol Palmitate	C	Unknown	Unk	Not Reported
	Cyklokapron	C	Oral	Unk, Use: Up To Ad 5 Weeks And From 12-12 Up To And Including 20-12 (Ad13 Weeks),	Not Reported
	Colecalciferol, Calcium Carbonate	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14566864	EXPEDITED (15-DAY)		OT	GB-GLENMARK PHARMACEUTICALS-2018GMK032292			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Citalopram Hydrobromide			S	Unknown	Unk		Glenmark
	Escitalopram			S	Unknown	Unk		Not Reported
	Trimethoprim			S	Unknown	Unk		Not Reported
	Septrin			S	Unknown	Unk		Not Reported
	Cabergoline			S	Unknown	Unk		Not Reported
	Carbidopa			S	Unknown	Unk		Not Reported
	Stalevo /01530202/			S	Unknown	Unk		Not Reported
	Entacapone			S	Unknown	Unk		Not Reported
	Levodopa			S	Unknown	Unk		Not Reported
	Co-Beneldopa			C	Unknown	Unk		Not Reported
	Co-Beneldopa			C	Unknown	Unk		Not Reported
	Macrogol			C	Unknown	Unk		Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Co-Beneldopa			C	Unknown	Unk		Not Reported
	Adcal D3			C	Unknown	Unk		Not Reported
	Rivastigmine			C	Unknown	Unk		Not Reported
	Quetiapine			C	Unknown	Unk		Not Reported

	Paracetamol			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14566943	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1809800US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Contusion; Feeling Abnormal; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Pallor; Prescribed Overdose; Psychomotor Skills Impaired; Pyrexia; Spinal Cord Neoplasm; Vertigo	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Qd		Allergan
	Fluanxol			S	Unknown	20 Mg, Qd		Not Reported
	Fluanxol			S	Unknown	20 Mg, Qd		Not Reported
	Fluanxol			S	Unknown	10 Mg, Qd		Not Reported
	Solian			S	Unknown	50 Mg, Qd		Not Reported
	Solian			S	Unknown	300 Mg, Qd		Not Reported
	Seresta			S	Unknown	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14567010	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-009574		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Risperidone			S		Unk		Aurobindo
	Escitalopram			S		Unk		Aurobindo
	Ceftriaxone Sodium			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14567961	EXPEDITED (15-DAY)		OT	SE-ASTRAZENECA-2018SE20938		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Nexium			S	Oral			Not Reported
	Faslodex			S	Intramuscular			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ibrance			S	Oral			Not Reported

	Ibrance	S	Oral	Not Reported
	Ibrance	S	Oral	Not Reported
	Ibrance	S	Oral	Not Reported
	Motilium	S	Oral	Not Reported
	Motilium	S	Oral	Not Reported
	Ondansetron	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Imodium	S	Oral	Not Reported
	Imovane	C		Not Reported
	Calcimagon D3	C		Not Reported
	Condrosulf	C		Not Reported
	Euthyrox	C		Not Reported
	Dafalgan	C		Not Reported
	Irfen	C		Not Reported
	Flector [Diclofenac Sodium]	C		Not Reported
	Temgesic	C		Not Reported
	Targin	C		Not Reported
	Oxynorm	C		Not Reported
	Movicol	C		Not Reported
	Laxoberon	C		Not Reported
	Clexane	C		Not Reported
	Mycostatin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14572604	DIRECT					12 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Drug Ineffective; Manufacturing Materials Issue; Product Substitution Issue	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Walgreen
	Prevacid			C				Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14573451	DIRECT		HO, OT			< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Continuous Positive Airway Pressure; Respiratory Distress	Abilify 2mg	S	Dates Of Use 0-4 Wks	Not Reported
	Abilify 1 Mg/Ml Oral Solution	S	Dates Of Use - 5-Delivery For Depression	Not Reported
	Lexapro 10 Mg	S	Dates Of Use - 0-Delivery For Depression	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14573532	DIRECT		HO, OT			< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Jaundice; Premature Baby	Abilify 2 Mg			S		Dates Of Use - Co-4 Wks @ 2mg		Not Reported
	Abilify 1mg			S		Dates Of Use - 5-Delivery @ 1mg For Depression		Not Reported
	Lexapro 10 Mg			S		Dates Of Use (0-Delivery) For Depression		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14573538	DIRECT		HO			< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Maternal Drugs Affecting Foetus; Premature Baby; Respiratory Distress	Abilify			S		0 - 4 Wks 5 - Delivery		Not Reported
	Lexapro			S		0 - Delivery		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14573543	DIRECT		HO, OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Foetal Growth Restriction; Multiple Pregnancy;	Abilify			S		0 - 4 Wks 5 - 33 Wks		Not Reported

Premature Labour	Lexapro	S	0 - Delivery	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2018	14569504	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018010283			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	15 Ml, Single		Macleods
	Alprazolam			S	Oral	10 Ml, Single		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2018	14569505	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018010289			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	9761033	NON-EXPEDITED			US-PFIZER INC-2013356177		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Arthrotec			S		Unk		Pfizer
	Promethazine Hcl			S		Unk		Pfizer
	Erythromycin			S				Pfizer
	Codeine			S		Unk		Not Reported
	Metamucil			S		Unk		Not Reported
	Erythromycin Ethylsuccinate			S		Unk		Not Reported

	Buspar	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Ultracet	S	Unk	Not Reported
	Norco	S		Not Reported
	Phenergan	S		Not Reported
	Probiotica	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	13243640	EXPEDITED (15-DAY)		OT	PHHY2017ES024355		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sialoadenitis	Ondansetron			S	Unknown	Unk		Novartis
	Escitalopram			S	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported
	Temozolomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	13497031	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2017184429		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Xanax			S	Oral	0.25 Mg, Total		Pfizer
	Escitalopram			S	Oral	10 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14013130	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1754578US		20 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug-Induced Liver Injury	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Ashwagandha			S	Oral	Unk, Prn		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

	Propranolol Hydrochloride	S	Oral	Unk	Not Reported
	Lorazepam	S	Oral	Unk	Not Reported
	Quetiapine Fumarate	S	Oral	Unk	Not Reported
	Etizolam	C	Oral	Unk	Not Reported
	Perospirone Hydrochloride Hydrate	C	Oral	Unk	Not Reported
	Bromazepam	C	Oral	Unk	Not Reported
	Tandospirone Citrate	C	Oral	Unk	Not Reported
	Levomepromazine Maleate	C	Oral	Unk	Not Reported
	Sulpiride	C	Oral	Unk	Not Reported
	Mosapride Citrate Hydrate	C	Oral	Unk	Not Reported
	Brotizolam	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14240220	EXPEDITED (15-DAY)		HO, OT	FR-SA-2017SA236468		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Alprazolam			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Oral			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Tavanic			S	Oral	Form: Film Coated Divisible Tablet 250 Mg, 2x/Day (Bid)		Not Reported
	Furosemide			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Diazepam			S	Oral	Form- Divisible Tablet 10		Not Reported

				Mg, 3x/Day (Tid)	
	Diffu K	S	Oral	Dose: 2 Df In Morning And 1 Df In Noon	Not Reported
	Nefopam Hydrochloride	S	Oral		Not Reported
	Colchicine Opocalcium	S	Oral		Not Reported
	Terbutaline Sulfate	S	Respiratory (inhalation)		Not Reported
	Dafalgan	S	Oral	1000 Mg, 3x/Day (Tid)	Not Reported
	Xarelto	S	Oral		Not Reported
	Xarelto	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14412531	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1802864US		94 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Dermatitis Allergic; Hypothyroidism	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Herbesser			S	Oral	100 Mg, Qd		Not Reported
	Diazepam			C	Oral	Unk, Qd		Not Reported
	Isosorbide Dinitrate			C	Oral	20 Mg, Bid		Not Reported
	Pitavastatin Calcium			C	Oral	1 Mg, Qd		Not Reported
	Primperan			C	Oral	5 Mg, Tid		Not Reported
	Dipyridamole			C	Oral	25 Mg, Tid		Not Reported
	Limaprost Alfadex			C	Oral	5 Mg, Tid		Not Reported
	Magnesium Oxide			C	Oral	500 Mg, Tid		Not Reported
	Bayaspirin			C	Oral	100 Mg, Qd		Not Reported
	Rabeprazole Na			C	Oral	10 Mg, Qd		Not Reported
	Alfacalcidol			C	Oral	1 Mg, Unk		Not Reported
	Candesartan			C	Oral	8 Mg, Qd		Not Reported
	Sodium Ferrous Citrate			C	Oral	50 Mg, Qd		Not Reported
	Amlodipine Od			C	Oral	2.5 Mg, Qd		Not Reported

Thyradin S	C	Oral	50 Mg, Unk		Not Reported
Ebastine	C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14570330	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-164170		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Ceftriaxone			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14570481	EXPEDITED (15-DAY)		OT	IT-ACCORD-063904		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Esomeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14570837	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.-2018SE07451			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Escitalopram			S	Unknown	15 Mg, Unk		Invagen
	Anafranil			S	Unknown	50 Mg, Unk		Not Reported
	Mirtazapine			S	Oral	30 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14571517	EXPEDITED (15-DAY)		OT	SE-CIPLA LTD.-2018SE07485			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Hyperhidrosis; Premenstrual Syndrome; Sleep Disorder	Escitalopram			S	Unknown	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14573453	EXPEDITED (15-DAY)		HO	FR-SA-2018SA047972		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Overdose; Sinus Bradycardia	Plavix			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported
	Coveram			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Bisoce			S	Oral			Not Reported
	Aldactazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14573542	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018078070		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Cabergoline			S		Unk		Pfizer
	Trimethoprim			S	Unknown	Unk		Not Reported
	Stalevo /01631201/			S	Unknown	Unk		Not Reported
	Entacapone			S		Unk		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Levodopa			S		Unk		Not Reported
	Septrin			S	Unknown	Unk		Not Reported
	Escitalopram			S		Unk		Not Reported

Carbidopa	S		Unk		Not Reported
Co-Beneldopa	C		50 Mg/12.5 Mg		Not Reported
Co-Beneldopa	C		25/100 Mr Capsules		Not Reported
Co-Beneldopa	C		25/100		Not Reported
Macrogol	C		Unk		Not Reported
Duloxetine	C		90 Mg, Unk		Not Reported
Adcal D3	C		Unk		Not Reported
Rivastigmine	C	Transdermal	4.6 Mg, Unk		Not Reported
Quetiapine	C		25 Mg, Unk		Not Reported
Paracetamol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14349055	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017007810			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Level Decreased; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	30 Mg, Qd, Tablet		Macleods
	Escitalopram			S	Oral	40 Mg, Qd, Overdose: 40 Mg		Macleods
	Olanzapine			C	Unknown	10 Mg, Qd		Macleods
	Lorazepam			C	Unknown	0.5 Mg, Unk		Not Reported
	Pangrol			C	Unknown	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14575743	EXPEDITED (15-DAY)		DS	AU-009507513-1802AUS011005		45 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Major Depression; Psychotic Disorder; Suicidal Ideation	Avanza			S		15 Mg, 1 Time		Merck
	Efexor			S		75 Mg, Qd		Not Reported
	Lexapro			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	13628282	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017247045		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor; Suicide Attempt	Alprazolam			S	Oral	10 Ml, Total		Pfizer
	Escitalopram Oxalate			S	Oral	15 Ml, Total		Not Reported
	Esomeprazole Sodium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	13656341	EXPEDITED (15-DAY)		DE, HO, OT	FR-ASTELLAS-2017US023138		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Venous Thrombosis; Pneumonia; Pseudomonas Infection; Subarachnoid Haemorrhage	Vesicare			S	Oral	1 Df, Once Daily (0-0-1)		Astellas
	Biotin			S	Oral			Not Reported
	Baclofen			S	Oral	1.5-1-1.5, Thrice Daily (Also Reported As 45 Mg Once Daily)		Not Reported
	Xatral			S	Oral	1 Df, Once Daily (0-0-1)		Not Reported
	Seroplex			S	Oral	1 Df, Once Daily (0-0-1)		Not Reported
	Dafalgan			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	13934120	EXPEDITED (15-DAY)		LT, OT	IN-HORMOSAN-2017-05038		57 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypothyroidism; Myxoedema Coma	Escitalopram Tablets			S	Unknown	10 Mg, Unk, For 3 Months		Lupin
	Quetiapine			S	Unknown	50 Mg, Unk, For 1 Month		Not Reported
	Quetiapine			S				Not Reported
	Amlodipine			C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14224455	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2017DE00351		32 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dyskinesia; Extrapyramidal Disorder; Muscle Twitching; Muscle Twitching; Restlessness	Escitalopram			S	Oral	5 Mg, Qd		Hetero
	Trimipramine			S	Oral	25 Mg, Qd		Not Reported
	Trimipramine			S	Oral	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14293993	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2017IT25436			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Abuse; Sopor; Tremor	Escitalopram			S	Oral	14 Df, In Total		Invagen
	Bromazepam			S	Oral	40 Ml, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14579974	EXPEDITED (15-DAY)		DS, OT	IT-CIPLA LTD.-2018IT06408			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Quality Issue; Product Substitution Issue	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14580319	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2018IT06741			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Lactic Acidosis; Metabolic Disorder; Neurological Decompensation	Escitalopram			S	Oral	10 Df, In Total		Invagen
	Tegretol			S	Oral	90 Df, In Total		Not Reported
	Seroquel			S	Oral	50 Df, In Total		Not Reported

	Depakin Chrono /00228502/			S	Oral	20 Df, In Total			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14580367	EXPEDITED (15-DAY)		OT	DK-CIPLA LTD.-2018DK06856			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Head Discomfort; Muscle Discomfort; Restlessness; Serotonin Syndrome; Withdrawal Syndrome	Escitalopram			S	Oral	10 Mg, Unk, Styrke: 20 Mg		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14582768	NON-EXPEDITED			US-MYLANLABS-2018M1009370		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Creatinine Increased; Diarrhoea; Dizziness; Drug Interaction; Dry Skin; Micturition Urgency; Muscle Spasms; Pruritus	Midodrine Hydrochloride Tablets Usp			S	Oral	10 Mg, Tid		Mylan
	Midodrine Hydrochloride Tablets Usp			S	Oral	20mg In Am And Noon, 10mg Before 6 Pm		Mylan
	Multaq			S		Unk		Mylan
	Seroquel			S		Unk		Mylan
	Lexapro			S		Unk		Mylan
	Chlortab /00072502/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14583344	EXPEDITED (15-DAY)		HO	CH-OTSUKA-DJ20112148		38 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Restlessness; Withdrawal Syndrome	Abilify			S	Oral	7.5 Mg, Unk		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S	Oral	2.5 Mg, Unk		Otsuka
	Cipralex			S	Unknown	Unk		Not Reported

Cipralex	S	Unknown	Unk		Not Reported
Heroin	S	Unknown	Unk		Not Reported
Cocaine	S	Unknown	Unk		Not Reported
Methadone	S	Oral	Unk		Not Reported
Methadone	S	Oral	Unk		Not Reported
Quetiapine	S	Oral	1df= 25–200 Mg Daily		Not Reported
Lexapro	S	Oral	22sep-14oct10 20mg 15oct10-Ong 25mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	12546845	EXPEDITED (15-DAY)		HO, LT, OT	FR-ELI_LILLY_AND_COMPANY-FR201607001668			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Antipsychotic Drug Level Above Therapeutic; Benzodiazepine Drug Level; Body Temperature Decreased; Coma; Confusional State; Electrocardiogram Qt Prolonged; Hypotension; Hypotonia; Intentional Overdose; Loss Of Consciousness; Miosis; Pneumonia Aspiration; Prescribed Overdose; Respiratory Rate Increased	Zyprexa			S	Unknown	10 Mg, Each Morning		Eli Lilly And Co
	Zyprexa			S	Unknown	20 Mg, Each Evening		Eli Lilly And Co
	Zyprexa			S	Oral	1050 Mg, Single		Eli Lilly And Co
	Zyprexa			S	Oral	1350 Mg, Single		Eli Lilly And Co
	Zopiclone			S	Unknown	7.5 Mg, At Bedtime		Not Reported
	Zopiclone			S	Oral	210 Mg, Single		Not Reported
	Lysanxia			S	Unknown	10 Mg, Each Morning		Not Reported
	Lysanxia			S	Oral	1440 Mg, Single		Not Reported
	Seroplex			S	Unknown	10 Mg, Each Evening		Not Reported
	Seroplex			S	Oral	140 Mg, Single		Not Reported
	Abilify			S	Oral	0.5 Df, Each Morning		Not Reported
	Abilify			S	Oral	10 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14535460	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-006963		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disorientation; Hallucination, Visual; Persecutory Delusion	Escitalopram Film-Coated Tablets	S	Oral	1 Cp	Aurobindo
	Modopar	S	Oral	1 Cp (1)	Not Reported
	Modopar	S	Oral	1 Cp (1)	Not Reported
	Modopar	S	Oral	50 Mg/12.5 Mg	Not Reported
	Modopar	S	Oral	62.5 Mg, Two Times A Day	Not Reported
	Modopar	S	Oral	1 Dosage Form 3 Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14584955	EXPEDITED (15-DAY)		HO, OT	IN-TORRENT-00001601		58 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Back Pain; Constipation; Inappropriate Antidiuretic Hormone Secretion	Hydroxychloroquine			C				Unknown
	Prednisolone			C	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Insulin			C		Combination Of Fast And Long Acting Insulin		Unknown
	Methotrexate			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14585030	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00010288		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Digoxin			S	Unknown	Unk		Concordia
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14585341	EXPEDITED (15-DAY)		LT, OT	IN-ALKEM LABORATORIES LIMITED-IN-ALKEM-2018-00877		57 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypothyroidism; Myxoedema Coma	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Quetiapine Fumarate			S	Unknown	50 Mg, Unk		Alkem
	Amlodipine			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14585908	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR07338			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Ramipril			S	Oral	5 Mg, Unk		Invagen
	Escitalopram			S	Oral	1 Df, Unk		Invagen
	Esidrex			S	Oral	0.5 Df, Unk		Not Reported
	Speciafoldine			C	Oral	1 Df, Unk		Not Reported
	Bisoce			C	Oral	2 Df, Unk		Not Reported
	Imovane			C	Oral	0.5 Df, Unk		Not Reported
	Levothyrox			C	Oral	112.5 Mg, Unk		Not Reported
	Eliquis			C	Oral	2 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14586350	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR07389			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Escitalopram			S	Oral	1 Df, Per Day		Invagen
	Furosemide			S	Oral	20 Mg, Per Day		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14589611	EXPEDITED (15-DAY)		DE, HO, OT	DE-ASTRAZENECA-2018SE25370		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Seroquel	S	Oral	200.0mg Unknown	Not Reported
	Seroquel	S	Oral	Quetiapine200.0mg Unknown	Not Reported
	Escitalopram Oxalate	S	Oral	10.0mg Unknown	Not Reported
	Lexapro	S	Oral		Not Reported
	Lexapro	S	Oral		Not Reported
	Tavor [Lorazepam]	S	Oral	2.0mg Unknown	Not Reported
	Tavor	S	Oral	2.0mg Unknown	Not Reported
	Tavor	S	Oral	6.0mg Unknown	Not Reported
	Tavor	S	Oral	6.0mg Unknown	Not Reported
	Abilify	S	Oral	20.0mg Unknown	Not Reported
	Abilify	S	Oral	15.0mg Unknown	Not Reported
	Movicol	C	Unknown	Unk	Not Reported
	Simeticone	C	Unknown	Unk	Not Reported
	Eferox	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14590149	EXPEDITED (15-DAY)		HO	FR-ASTELLAS-2018US010550		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Interaction; Hallucination, Visual	Vesicare			S	Oral			Astellas
	Artotec			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Atarax /00058402/			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14590507	EXPEDITED (15-DAY)		HO	PHHY2018FR033854		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Valsartan		S	Oral	14400 Mg, Unk	Novartis
	Escitalopram		S	Oral	880 Mg, Unk	Not Reported
	Bromazepam		S	Oral	144 Mg, Unk	Not Reported
	Xeroquel		S	Oral	2500 Mg, Unk	Not Reported
	Prazepam		S	Oral	1200 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14593279	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC-2018084042		66 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Injury	Aspavor			S		20 Mg, Unk		Pfizer
	Cipralex			S		10 Mg, Unk		Not Reported
	Carloc			S		6.25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14594494	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-863789		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Depression Suicidal	Bupropion Sr			S	Oral			Teva
	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14594611	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1811602US		40 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Negative Thoughts; Off Label Use; Pain; Product Use Issue	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Bid		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Clomipramine			C	Oral	2 Df, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14595375	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2018010659			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral	5 Mg, Unk		Macleods
	Levonelle			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2018	14596247	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2017-40125		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor; Wound	Escitalopram			S	Oral	15 Mg, Once A Day		Aurobindo
	Escitalopram			S	Unknown	7.5mgdaily		Aurobindo
	Escitalopram			S	Oral	20mgdaily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2018	14599091	DIRECT		OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Migraine; Product Substitution Issue	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Cipla
	Vistaril			C				Not Reported
	Buspirone			C				Not Reported
	Loratadine			C				Not Reported
	Cpap			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Citrucel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2018	14596528	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018010686			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Sinus Bradycardia	Escitalopram Oxalate			S	Oral	1120 Mg, Unk		Macleods
	Plavix			S	Oral	2250 Mg, Film-Coated Tablets		Not Reported
	Coveram 10 Mg/10 Mg, Compressed			S	Oral	60 Df, Unk		Not Reported
	Seresta 50 Mg, Scored Tablet			S	Oral	1000 Mg, Unk		Not Reported
	Bisoce 10 Mg, Dry Film Tablet			S	Oral	300 Mg, Unk		Not Reported
	Zopiclone			S	Oral	315 Mg, Unk		Not Reported
	Aldactazine, Scored Film-Coated Tablet			S	Oral	30 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2018	14596622	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-011358		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor; Suicide Attempt	Alprazolam Tablets			S	Oral	In Total		Aurobindo
	Escitalopram			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2018	14596759	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-010901		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral			Aurobindo
	Levonelle /00318901/			C		()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14102612	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1759226US		14 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Disinhibition; Drug Interaction; Mental Disorder; Off Label Use; Overdose	Escitalopram Oxalate - Bp			S	Oral	5 Gtt, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Gtt, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Gtt, Qd		Allergan
	Abilify			S	Oral	Unk		Not Reported
	Calcium 600 Plus Vitamin D			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14349569	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-48574		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Sedation	Alprazolam			S	Oral	Alprazolam 0,25 1/2 Cp/J		Aurobindo
	Alprazolam			S				Aurobindo
	Escitalopram			S	Oral	10 Mg, Unk		Aurobindo
	Escitalopram			S				Aurobindo
	Risperdal			S	Oral	1.5 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14596964	EXPEDITED (15-DAY)		OT	TR-STRIDES ARCOLAB LIMITED-2018SP001362			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bradycardia; Dizziness; Hypotension	Cetirizine			S	Oral	10 Mg Per Day (Administered On The 26th Hospital Day At 2 Pm)		Strides
	Escitalopram			S	Unknown	10 Mg, Per Day (Had Been Started On 11th Hospital Day)		Not Reported

	Enoxaparin		C	Unknown	60 Mg, Per Day	Not Reported
	Ampicillin		C	Intravenous (not otherwise specified)	2 G, Every 4 Hrs	Not Reported
	Pantoprazole		C	Unknown	40 Mg, Per Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14598942	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-011408			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Sinus Bradycardia	Escitalopram			S	Oral	1120 Milligram		Aurobindo
	Zopiclone			S	Oral	315 Milligram		Not Reported
	Aldactazine			S	Oral	30 Dosage Form		Not Reported
	Bisoce			S	Oral	300 Milligram		Not Reported
	Coveram			S	Oral	60 Dosage Form		Not Reported
	Plavix			S	Oral	2250 Milligram		Not Reported
	Seresta			S	Oral	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14604097	DIRECT	Y	HO			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Vomiting	Escitalopram			S				Not Reported
	Levothyroxine			C				Not Reported
	Losartan			C				Not Reported
	Amlodipine			C				Not Reported
	Methocarbamol			C				Not Reported
	Metoprolol Succinate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	13584689	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-051708		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse	Escitalopram	S	Oral		Accord
	Lorazepam	S	Oral		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	13945282	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2017379748		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Coma; Drug Abuse; Hypotension; Intentional Self-Injury	Alprazolam			S	Oral	20 Gtt, Total		Pfizer
	Halcion			S	Oral	10 Df, Total		Pfizer
	Cipralex /01588501/			S	Oral	15 Gtt, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14018921	EXPEDITED (15-DAY)		DE, HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005538		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Venous Thrombosis	Alfuzosin			S	Oral			Concordia
	Baclofen			S	Oral			Not Reported
	Vesicare			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Dafalgan			S	Oral			Not Reported
	Qizenday 100 Mg, Gélule			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14571724	NON-EXPEDITED			US-PFIZER INC-2018074907			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer

	Methotrexate Sodium	S	Unk		Pfizer
	Codeine	S	Unk		Not Reported
	Lexapro	S	Unk		Not Reported
	Leflunomide	S	Unk		Not Reported
	Motrin	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14587258	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180229948		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Ceftriaxone Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14601870	EXPEDITED (15-DAY)		HO, OT	JP-CIPLA LTD.-2018JP10258			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypotonia; Neonatal Respiratory Depression; Premature Baby	Escitalopram			S	Transplacental	Unk		Invagen
	Ethyl Loflazepate			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14601911	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR08282			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Resting Tremor	Risperidone			S	Oral	1 Df Per Day		Cipla
	Escitalopram			S	Oral	1 Df Per Day		Invagen
	Nebivolol			C	Oral	2.5 Mg Per Day		Not Reported

	Kenzen			C	Oral	1 Df Per Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14602002	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018010752			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness; Dyspnoea; Gastric Ulcer; Insomnia; Nausea; Panic Attack; Vertigo	Escitalopram Oxalate			S	Unknown	Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14602207	EXPEDITED (15-DAY)		LT	FR-CIPLA LTD.-2018FR08515			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Postpartum Haemorrhage; Premature Delivery	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Folic Acid			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14602269	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2018IT08541			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Plavix			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14603741	EXPEDITED (15-DAY)		HO, OT	CH-GLAXOSMITHKLINE-CH2018033185		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypothermia Neonatal; Jaundice Neonatal; Poor Weight Gain Neonatal; Premature Baby	Escitalopram			S	Transplacental			Glaxosmithkline
	Seretide			S	Transplacental	Unk		Glaxosmithkline
	Ventolin			S	Transplacental	Unk		Glaxosmithkline
	Seebri Breezhaler			S	Transplacental	50 ?G, Unk		Not Reported
	Celestone			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14604190	EXPEDITED (15-DAY)		HO	FR-MARINA BIOTECH, INC.-2018MARINA000503			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Intentional Overdose; Sinus Bradycardia	Coveram			S	Oral	60 (10mg/10mg) Tablets		Unknown
	Plavix			S	Oral	2250 Mg		Not Reported
	Seresta			S	Oral	1000 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	1120 Mg		Not Reported
	Bisoce			S	Oral	300 Mg		Not Reported
	Zopiclone			S	Oral	315 Mg		Not Reported
	Aldactazine			S	Oral	30 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14605099	EXPEDITED (15-DAY)		HO	IN-MYLANLABS-2018M1014989		26 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Extrapyramidal Disorder	Olanzapine			S	Unknown	20 Mg		Not Reported
	Escitalopram			S	Unknown	20 Mg		Not Reported
	Aripiprazole			S	Unknown	Gradually Titrated Up To 20mg (Initial Dose Not Known)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	9736117	EXPEDITED (15-DAY)		DE, LT, OT	NO-GLAXOSMITHKLINE-B0951220A		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drowning; Intentional Self-Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Lamictal			S	Unknown	25, 50, 100 Mg		Glaxosmithkline
	Sarotex			S	Unknown	Unk		Glaxosmithkline
	Seroquel			S	Unknown	Unk		Glaxosmithkline
	Cipralex			S	Unknown	Unk		Glaxosmithkline
	Atarax			S	Unknown	Unk		Glaxosmithkline
	Sobril			S	Unknown	Unk		Glaxosmithkline
	Imovane			S	Oral	Unk		Glaxosmithkline
	Hydroxyzine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diazepam			S	Unknown	Unk		Glaxosmithkline
	Orfiril			S	Unknown	600 To 1200 Mg		Not Reported
	Nobligan			S	Unknown	50 To 200 Mg		Not Reported
	Nobligan			S	Unknown	Unk		Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Nozinan			S	Unknown	Unk		Not Reported
	Catapresan			S	Unknown	25 To 50 Mg		Not Reported
	Vival			S	Unknown	Unk		Not Reported
	Pinex Forte			S	Unknown	500/30 Mg And Pandeine		Not Reported
	Truxal			S	Unknown	Unk		Not Reported
	Oxynorm			S	Unknown	5 To 10 Mg		Not Reported
	Remeron			S	Unknown	Unk		Not Reported
	Tramadol Hydrochloride			S	Unknown	Unk		Not Reported
	Cyanocobalamin			C	Unknown	Unk		Glaxosmithkline
	Codeine Phosphate			C	Unknown			Not Reported

	Heroin			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	12341717	EXPEDITED (15-DAY)		OT	CA-FRI-1000084495		33 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Therapeutic Product Effect Decreased	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	12439819	EXPEDITED (15-DAY)		DS	CA-FRI-1000085086		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Feeling Abnormal; Vision Blurred	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14325935	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-1773508US		71 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Withdrawal Syndrome; Somnolence; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	10-20 Mg/Day		Allergan
	Amlodipine(Amlodipine Besilate)			C	Oral	2.5 Mg, Unk		Not Reported
	Isosorbide Dinitrate			C	Transdermal	40 Mg, Qd		Not Reported
	Lansoprazole			C	Oral	1 Df, Unk		Not Reported
	Donepezil Hydrochloride			C	Oral	5 Mg, Unk		Not Reported
	Rozerem(Ramelteon)			C	Oral	8 Mg, Unk		Not Reported
	Rozerem(Ramelteon)			C	Oral	4 Mg, Unk		Not Reported
	Miya Bm(Clostridium Butyricum)			C	Oral	1 Df, Unk		Not Reported
	Iopamidol			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14381851	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018014915		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose; Sopor; Suicide Attempt	Alprazolam			S	Oral	16 Mg, Unk		Pfizer
	Escitalopram			S	Oral	30 Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14449057	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1804000US		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	30 Ml, Unk		Allergan
	Alprazolam			S	Oral	16 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14606081	EXPEDITED (15-DAY)		OT	JP-CIPLA LTD.-2018JP10256			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Escitalopram			S	Unknown	10 Mg, Qd		Invagen
	Ethyl Loflazepate			S	Unknown	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14606880	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-165307		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Paracetamol		Y	S	Unknown	Unk ()		Ohm Lab
	Irbesartan			S	Unknown	Unk ()		Not Reported
	Galantamine			S	Unknown	Unk ()		Not Reported

	Escitalopram	S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14606907	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00010336		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Prednisolone			S	Oral			Concordia
	Bevacizumab			S	Intravenous (not otherwise specified)			Not Reported
	Lomustine			S	Oral			Not Reported
	Seroplex Film-Coated Tablets			S	Oral			Not Reported
	Silodyx			C	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14607598	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1812074US		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Off Label Use; Overdose; Sinus Bradycardia	Escitalopram Oxalate - Bp			S	Oral	1120 Mg, Single		Allergan
	Plavix			S	Oral	2250 Mg, Single		Not Reported
	Coveram			S	Oral	60 Df, Single		Not Reported
	Seresta			S	Oral	1000 Mg, Single		Not Reported
	Bisoce			S	Oral	300 Mg, Single		Not Reported
	Zopiclone			S	Oral	315 Mg, Single		Not Reported
	Aldactazine			S	Oral	30 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14607616	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1811881US		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebrovascular Accident; Fall; Product Use Issue; Tobacco Interaction	Escitalopram Oxalate - Bp	S	Unknown	20 Mg, Bid	Allergan
	Clozapin	S	Oral	100 Mg, Qd	Not Reported
	Amisulprid	S	Unknown	500 Mg, Qd	Not Reported
	Tavor [Lorazepam]	C		Taken Only If Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14607617	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1811893US		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Intentional Self-Injury; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	7.5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14607637	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1811873US		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Avastin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Belustine			S	Oral	40 Mg, Cyclical		Not Reported
	Solupred (Prednisolone)			S	Oral	40 Mg, Qd		Not Reported
	Silodyx			C				Not Reported
	Xanax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14607638	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1811820US		31 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Emotional Poverty; Fatigue; Feeling Of Body Temperature Change; Head Discomfort; Hyperhidrosis; Limb Discomfort; Loss Of Libido; Sensory Loss; Somnolence	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14607761	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1811815US		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Depersonalisation/Dereali sation Disorder; Drug Withdrawal Syndrome; Emotional Disorder; Fatigue; Headache; Irritability; Night Sweats; Vertigo	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14607762	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1811803US		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Sedation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan
	Risperdal			S	Oral	1.5 G, Unknown		Not Reported
	Alprazolam			S	Oral	0.125 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14607805	EXPEDITED (15-DAY)		DE, HO, OT	DE-GLENMARK PHARMACEUTICALS-2018GMK032885			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Topiramate			S	Unknown	Unk		Glenmark
	Spironolactone			S	Unknown	Unk		Not Reported
	Phenobarbital			S	Unknown	Unk		Not Reported
	Sildenafil Citrate			S	Unknown	Unk		Not Reported
	Varivax /06643101/			S	Intramuscular	1 Df		Not Reported
	Synagis			S	Intramuscular	150 Mg, Unk		Not Reported
	Exodus /01588502/			S	Unknown	Unk		Not Reported
	Nutrition Care Formula 55at			C	Other	(4)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14608776	NON-EXPEDITED			US-ABBVIE-17K-163-2047366-00		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Disturbance In Attention; Dizziness; Drug Interaction; Hypoacusis; Injury; Joint Swelling; Memory Impairment; Pain; Product Dose Omission; Somnolence; Swelling Face; Weight Increased	Androgel			S	Topical			Not Reported
	Lyrica			S	Oral	Two A Day		Not Reported
	Lyrica			S	Oral	2 At Morning And 1 At Night		Not Reported
	Xanax			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Clopidogrel			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Metoprolol Tartrate			S	Unknown			Not Reported
	Metformin Hcl			S	Unknown			Not Reported
	Tricor			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Nitroglycerin			S	Unknown			Not Reported

	Pataday	S	Unknown	Once Every 3 Or So Month	Not Reported
	Breo	S	Unknown	100 Mcg/25 Mcg	Not Reported
	Oxygen	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14609771	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018090842		66 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Celebrex			S		100 Mg, Unk		Pfizer
	Amloc (Amlodipine Besilate)			S		5 Mg, Unk		Pfizer
	Bilocor			S		5 Mg, Unk		Not Reported
	Forvent			S		18 Mch		Not Reported
	Be-Tabs Folic Acid			S		5 Mg, Unk		Not Reported
	Be-Tabs Prednisone			S		5 Mg, Unk		Not Reported
	Foxair			S		25/250 Mcg		Not Reported
	Ipvent Hfa			S		40 Ucg		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported
	Symbicord			S		160 Ug, Unk		Not Reported
	Tambocor			S		100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14609877	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Citalopram			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14609924	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14610010	DIRECT					43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Erectile Dysfunction; Genital Disorder Male; Libido Decreased; Penile Size Reduced; Sensory Disturbance; Sexual Dysfunction; Testicular Atrophy	Lexapro			S	Oral			Allergan
	Deplin			C				Not Reported
	Advil			C				Not Reported
	Benadryl			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Cbd			C				Not Reported
	Probiotic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	13575475	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2017005064			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram Tablet			S	Oral	140 Mg, 1 Total		Macleods
	Lorzepam			S	Oral	20 Mg, Unk, 1 Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14309887	EXPEDITED (15-DAY)		HO, OT	AT-JNJFOC-20170924847		60 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Blood Triglycerides Increased; Drug Interaction; Fatigue; Frustration Tolerance Decreased; Intention	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported

Tremor; Lethargy; Liver Injury; Neutrophil Count Decreased; Resting Tremor; Sedation; Social Avoidant Behaviour; Splenomegaly; Tremor; Weight Increased	Risperdal	S	Oral	Not Reported
	Risperdal	S	Oral	Not Reported
	Risperdal	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Cymbalta	S	Oral	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Rivotril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14321206	EXPEDITED (15-DAY)		OT	DE-TORRENT-00007432			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Escitalopram			S	Unknown	20 Mg, Daily		Unknown
	Valdoxan			S				Unknown
	Zoely			S	Oral	1 Dosage Forms Daily; One Df Contains 2.5mg Nomegestrel And 1.5mg Estradiol		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14610855	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2018IT08687			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram			S	Oral	In Total		Invagen
	Xanax			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14610897	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2018AU10004			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	15 Mg, Per Day		Invagen
	Ramipril			S	Unknown	2.5 Mg, Per Day		Invagen
	Atorvastatin			S	Unknown	10 Mg, Per Day		Invagen
	Furosemide			S	Unknown	20 Mg, Per Day		Not Reported
	Omeprazole			S	Unknown	20 Mg, Per Day		Not Reported
	Testosterone			S	Unknown	1 G, Per Day (Every 10 To 14 Weeks)		Not Reported
	Amisulpride			S	Unknown	300 Mg, Per Day		Not Reported
	Spironolactone			S	Unknown	25 Mg, Per Day		Not Reported
	Melatonin			S	Unknown	2 Mg, Per Day		Not Reported
	Bisoprolol			S	Unknown	2.5 Mg, Per Day		Not Reported
	Ferrograd /00023503/			S	Unknown	325 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14611101	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2018IT08649			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Asthenia; Drug Abuse; Restlessness	Escitalopram			S	Oral	20 Df, In Total		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14611395	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2017006318			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Drug Interaction; Food Interaction; Haemodynamic Instability; Haemorrhage; Hypoproteinaemia; Oedema; Pain In Extremity; Pulmonary Congestion	Escitalopram Oxalate 5mg Tablet Prescription F 53 = [Aurobindo Pharma Limited			S	Oral	5 Mg, Qd At Breakfast, For Several Years		Macleods
	Escitalopram Oxalate 5mg Tablet Prescription F 53 = [Aurobindo Pharma Limited			S	Unknown	Unk		Macleods
	Emconcor 2.5 Mg			C	Oral	1.25 Mg, Bid At Breakfast And Dinner, Every 12 Hours		Not Reported
	Simvastatin Cinfa 20 Mg			C	Oral	20 Mg, Qd At Dinner		Not Reported
	Hibor (Bemiparin Sodium)			C	Subcutaneous	1 Unk, Qd 3500 Iu Anti-Xa/0.2 Ml Solution For Injection In Pre-Filled Syringe; In The Evening		Not Reported
	Hibor (Bemiparin Sodium)			C	Subcutaneous	2500 Iu, Unk		Not Reported
	Hibor (Bemiparin Sodium)			C	Subcutaneous	10000 Iu, Unk		Not Reported
	Hibor (Bemiparin Sodium)			C	Subcutaneous	7500 Iu, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14612388	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-011864		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Paracetamol			S	Unknown	Unk ()		Aurobindo
	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo
	Irbesartan			S	Unknown	Unk ()		Aurobindo
	Galantamine			S	Unknown	Unk ()		Aurobindo
	Diuretics			S	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14613076	EXPEDITED (15-DAY)		HO, OT	CH-009507513-1802CHE013562		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hypothermia Neonatal; Jaundice Neonatal; Poor Weight Gain Neonatal; Premature Baby	Celestone Chronodose			S	Transplacental	Unk		Merck
	Seebri Breezhaler			S	Transplacental	50 Microgram, Unk		Not Reported
	Seretide			S	Transplacental	Unk		Not Reported
	Ventolin (Albuterol)			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14613978	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-863392		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor; Suicide Attempt	Escitalopram			S	Oral	30 Milliliters		Ivax
	Alprazolam			S	Oral	16 Milligrams		Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14614212	DIRECT		DE			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Antidepressant Drug Level Above Therapeutic; Completed Suicide; Product Label Confusion	Escitalopram	Y		S	Oral	Quantity:1 Tablet(S);		Walgreen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14324359	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2017-46836		14 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Accidental Overdose; Disinhibition; Drug Interaction; Mental Disorder; Product Use Issue; Therapy Change	Aripiprazole		S	Oral	Unk	Aurobindo
	Cipralex /01588501/		S	Oral	5 Gtt, Daily	Not Reported
	Cipralex /01588501/		S	Oral	10 Gtt, Daily	Not Reported
	Cipralex /01588501/		S	Oral	20 Gtt, Daily	Not Reported
	Abilify		S			Not Reported
	Calcium Carbonate W/Vitamin D /01204201/		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14593065	EXPEDITED (15-DAY)		OT	TR-JNJFOC-20180234219		34 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bradycardia; Dizziness; Hypotension	Cetirizine Hydrochloride		Y	S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Oral	Administered On The 26th Hospital Day At 2 Pm And Discontinued On The 28th Hospital Day		Not Reported
	Escitalopram			S	Unknown	Escitalopram Had Been Started On 11th Hospital Day		Not Reported
	Enoxaparin			C	Unknown			Not Reported
	Ampicillin			C	Intravenous (not otherwise specified)			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14595961	EXPEDITED (15-DAY)		HO	CZ-AUROBINDO-AUR-APL-2018-010653		45 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Sertraline			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14607798	EXPEDITED (15-DAY)		DE, OT	CA-ALLERGAN-1812080US		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Homicide; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14615777	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR09300			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Risperidone			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Invagen
	Ceftriaxone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14615856	EXPEDITED (15-DAY)		OT	TR-CIPLA LTD.-2018TR10743			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bradycardia; Dizziness; Hypotension	Escitalopram			S	Unknown	10 Mg, Daily, Escitalopram Had Been Started On 11th Hospital Day		Invagen
	Cetirizine			S	Oral	10 Mg, Administered On The 26th Hospital Day At 2 Pm And Discontinued On The 28th Hospital Day		Cipla
	Enoxaparin			C	Unknown	60 Mg, Daily		Not Reported
	Ampicillin			C	Intravenous (not otherwise specified)	2 G, Four Hourly		Not Reported
	Pantoprazole			C	Unknown	40 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14615872	EXPEDITED (15-DAY)		CA	NL-CIPLA LTD.-2018NL09073			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Oral Malformation; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	10 Mg, Daily		Invagen
	Foliumzuur			C	Transplacental	Unk		Not Reported
	Davitamon			C	Transplacental	Unk		Not Reported
	Cyklokapron			C	Transplacental	Unk		Not Reported
	Calcium Carbonate W/Colecalciferol			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14616078	EXPEDITED (15-DAY)		LT, OT	IT-ACCORD-064258		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Prescribed Underdose	Escitalopram			S	Oral			Not Reported
	Abilify			S	Oral	10 Mg, Qd		Not Reported
	Cipralex			S	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14616192	EXPEDITED (15-DAY)		HO, OT	AU-IPCA LABORATORIES LIMITED-IPC-2018-AU-000441		38 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval Abnormal	Furosemide			S	Unknown	20 Mg, Qd		Ipca
	Escitalopram			S	Unknown	15 Mg, Qd		Not Reported
	Ramipril			S	Unknown	2.5 Mg, Qd		Not Reported
	Atorvastatin			S	Unknown	10 Mg, Qd		Not Reported
	Bisoprolol			S	Unknown	2.5 Mg, Qd		Not Reported
	Melatonin			S		2 Mg, Qd		Not Reported

Omeprazole	S	Unknown	20 Mg, Qd		Not Reported
Testosterone Depot	S	Unknown	1 G, Qd		Not Reported
Amisulpride	S	Unknown	300 Mg, Qd		Not Reported
Spironolactone	S	Unknown	25 Mg, Qd		Not Reported
Ferrograd	S	Unknown	325 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14616715	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.-2018IT09862			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S	Oral	140 Mg, In Total		Invagen
	Lorazepam			S	Oral	20 Mg, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14617179	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-012750		52 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Loss Of Consciousness; Malaise	Escitalopram Film-Coated Tablets			S	Oral	20 Milligram, Daily		Aurobindo
	Depakin			S	Oral	1000 Milligram, Daily		Not Reported
	Carbolithium			S	Oral	900 Milligram, Daily		Not Reported
	Frontal			S	Oral	2 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14617603	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2018-011761			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Tube Insertion; Laryngectomy	Escitalopram			S	Unknown	10 Milligram, Daily		Aurobindo
	Alendronic Acid			C	Unknown			Not Reported
	Bendroflumethiazide			C	Unknown			Not Reported
	Colecalciferol			C				Not Reported

Ergocalciferol	C		Not Reported
Gabapentin	C		Not Reported
Morphine Sulphate	C		Not Reported
Prucalopride	C		Not Reported
Salbutamol	C		Not Reported
Tiotropium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14617759	EXPEDITED (15-DAY)		DE	JP-LANNETT COMPANY, INC.-JP-2018LAN000512		57 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drowning; Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Alcohol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14619130	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-012446		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Hallucinations, Mixed; Overdose	Escitalopram			S	Oral	110 Drop, 1 Days, Total		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14619416	EXPEDITED (15-DAY)		DE, HO, OT	DE-AUROBINDO-AUR-APL-2018-012498		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Quetiapine			S		200 Milligram		Aurobindo
	Lorazepam			S	Oral	6 Milligram, Once A Day		Not Reported
	Abilify			S	Oral	20 Milligram		Not Reported
	Abilify			S	Oral	15 Unk		Not Reported
	Cipralex /01588501/			S	Oral	10 Milligram		Not Reported
	Lexapro			S	Oral	10 Milligram		Not Reported

Lexapro	S				Not Reported
Seroquel	S	Oral	200 Milligram		Not Reported
Movicol /01749801/	S	Unknown			Not Reported
Tavor /00273201/	S	Oral	2 Milligram		Not Reported
Tavor /00273201/	S		6 Mg		Not Reported
Simeticone	C	Unknown			Not Reported
Eferox	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14619428	EXPEDITED (15-DAY)		LT	IT-AUROBINDO-AUR-APL-2018-012581		37 YR	Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Prescribed Underdose	Escitalopram			S	Unknown	5 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14620612	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1813162US		40 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2018	14621213	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-012662		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Spironolactone			S	Oral	50 Milligram, Once A Day		Aurobindo
	Seroplex			S	Oral	1 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2018	14621468	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-012653			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Tardive Dyskinesia	Aripiprazole			S	Unknown			Aurobindo
	Aripiprazole			S	Unknown	5 Milligram		Aurobindo
	Seroplex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2018	14621704	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-012780		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Aripiprazole			S				Aurobindo
	Mirtazapine			S				Aurobindo
	Lexapro			S				Not Reported
	Norset			S				Not Reported
	Seroplex			S				Not Reported
	Aprovel			C				Not Reported
	Inipomp			C				Not Reported
	Irbesartan			C				Not Reported
	Kardegic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2018	14626631	DIRECT	Y	HO, RI			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Dyskinesia; Hyperhidrosis; Hyperreflexia; Hyperthermia; Hypertonia; Mental Status Changes; Myoclonus; Serotonin Syndrome	Escitalopram			S	Oral	1/2 Tab Every Day Po		Not Reported
	Ondansetron			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2018	12341721	EXPEDITED (15-DAY)		DE	CA-FRI-1000084391		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Completed Suicide; Drug Ineffective; Feelings Of Worthlessness; Insomnia	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Seroquel			S	Oral	25 Mg, Q8hr		Not Reported
	Seroquel			S				Not Reported
	Seroquel Xr			S	Oral	50 Mg, Qhs		Not Reported
	Seroquel Xr			S				Not Reported
	Trazodone			C	Oral	25-100 Mg, Qhs		Not Reported
	Vitamin B12			C	Unknown	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2018	14623003	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1813156US		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Lower Gastrointestinal Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Xarelto			S	Unknown	20 Mg, Unk		Not Reported
	Zofenil			C	Unknown	Unk		Not Reported
	Carbidopa, Levodopa			C	Unknown	Unk		Not Reported
	Androtardyl			C	Unknown	Unk		Not Reported
	Amoxicillin Sodium, Potassium Clavulanate			C	Unknown	Unk		Not Reported
	Requip			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2018	14623005	EXPEDITED (15-DAY)		DS	AT-ALLERGAN-1813129US		25 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Body Temperature Decreased; Emotional Poverty; Loss Of Libido; Male Sexual Dysfunction; Urinary Retention; Vision Blurred	Escitalopram Oxalate - Bp		S	Unknown	1 Df, Unk	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2018	14623006	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1813125US		47 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	100 Mg, Single		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	13511018	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1717261US		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Crying; Drug Abuse; Intentional Self-Injury; Off Label Use	Escitalopram Oxalate Unk			S	Oral	10 Mg, In Total		Allergan
	Xanax			S	Oral	0.25 Mg, In Total		Not Reported
	Morphine Derivative			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	13519973	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2017-33450		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram Film-Coated Tablets			S	Oral	10 Mg, Total		Aurobindo
	Xanax			S	Oral	In Total		Not Reported
	Xanax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14000447	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1754095US		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Hallucinations, Mixed; Overdose	Escitalopram Oxalate - Bp			S	Oral	110 Gtt In Total		Allergan
	Alprazolam			C	Unknown	0.25 Mg, Qhs		Not Reported
	Plendil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14327111	EXPEDITED (15-DAY)		HO	PHHY2017DE194307		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Candesartan Cilexetil			S	Oral	16 Mg, Qd		Novartis
	Aripiprazole			S	Oral	10 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported
	Risperdal			C	Unknown	2 Mg, Unk (For Nights)		Not Reported
	Risperdal			C	Unknown	2 Mg, Qd		Not Reported
	L-Thyroxin			C	Oral	100 Ug, Qd		Not Reported
	Amisulpride			C	Unknown	200 Mg, Qd		Not Reported
	Metformin			C	Oral	1500 Mg, Qd		Not Reported
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported
	Acetylsalicylic Acid			C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14438734	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180110996		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Balanitis Candida; Depression;	Stelara			S	Subcutaneous			Not Reported

Gastrointestinal Candidiasis; Type 2 Diabetes Mellitus	Seroplex		S	Oral		Not Reported
	Cardiocalm		S	Oral	3	Not Reported
	Stresam		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14625256	EXPEDITED (15-DAY)		HO, OT	US-SUNOVION-2018SUN000898			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypothermia Neonatal; Jaundice Neonatal; Poor Weight Gain Neonatal; Premature Baby	Glycopyrrolate			S	Transplacental	Maternal Dose: 50 Ug		Sunovion
	Escitalopram			S	Transplacental	Unk		Not Reported
	Seretide			S	Transplacental	Unk		Not Reported
	Ventolin			S	Transplacental	Unk		Not Reported
	Celestone			S	Transdermal	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14626886	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1812909US		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Homicidal Ideation	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14627149	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1014689		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Ramipril Mylan 5 Mg, Comprimé Sécable			S	Oral	5 Mg, Unk		Mylan
	Esidrex			S	Oral	0.5 Df, Unk		Mylan
	Escitalopram Arrow			S	Oral	1 Df, Unk		Mylan
	Speciafoldine			C	Oral	1 Df, Unk		Mylan
	Bisoce			C	Oral	2 Df, Unk		Mylan

Imovane	C	Oral	0.5 Df, Unk		Mylan
Levothyrox	C	Oral	112.5 Mg, Unk		Mylan
Eliquis	C	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14627395	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1014723		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Furosemide			S	Oral	20 Mg, Qd		Not Reported
	Seroplex (Escitalopram Oxalate)			S	Oral	1 Df, Qd		Mylan
	Xarelto			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14627520	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20180306444			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Topamax			S	Oral			Not Reported
	Abilify			S	Oral	10-15 Mg Daily		Not Reported
	Cipralex			S	Unknown			Not Reported
	Elvanse			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14627768	NON-EXPEDITED			US-MYLANLABS-2018M1011933		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Drug Ineffective; Insomnia; Restlessness	Lorazepam			S	Oral	0.5 Mg, Qid		Not Reported
	Lorazepam			S				Not Reported
	Metoprolol			S		25 Mg, Unk		Not Reported
	Risperdal			S		25 Mg, Unk		Mylan
	Lexapro			S		10 Mg, Unk		Mylan

	Lipitor	S	20 Mg, Unk		Mylan
	Flonase /00908302/	S			Mylan
	Omeprazole	S	40 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14628052	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1813211US		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Tardive Dyskinesia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Aripiprazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14628053	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1813188US		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Atarax			S	Oral			Not Reported
	Rivotril			S	Oral	2,5 Mg/Ml, Solution Buvable En Goutte		Not Reported
	Marinol (Dronabinol)			S	Oral			Not Reported
	Acupan			S	Subcutaneous	Unk, Single		Not Reported
	Donormyl (Doxylamine Succinate)			S	Oral			Not Reported
	Levocarnil			C	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported
	Theralene			C	Oral	4 Pour Cent, Sollution Buvable En Gouttes		Not Reported
	Melatonine			C	Oral	3 Mg, Qd		Not Reported
	Dafalgan Codeine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14629343	DIRECT		DE			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Cipla
	Synthroid			C				Not Reported
	Birth Control Pills			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14629444	DIRECT		DS			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Product Contamination Physical	Escitalopram Oxalate			S	Oral	Quantity:1 Tablet(S);		Accord
	Atorvastatin			C				Not Reported
	Buspirone			C				Not Reported
	Choryhalidone			C				Not Reported
	Hydrocodone Acetaminophen			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Ranitidine			C				Not Reported
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Coenzyme			C				Not Reported
	Cranberry			C				Not Reported
	Docusate Sodium			C				Not Reported
	Fish Oil			C				Not Reported
	Probiotic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	13997335	EXPEDITED (15-DAY)		HO, OT	NO-TEVA-806651ACC		17 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Aggression;	Olanzapine			S	Unknown			Not Reported

Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Seroxat	S		20 Milligram Daily;	Not Reported
	Seroxat	S			Not Reported
	Efexor Depot	S	Unknown		Not Reported
	Efexor Depot	S	Unknown		Not Reported
	Efexor Depot	S			Not Reported
	Efexor Depot	S			Not Reported
	Lamictal	S	Unknown		Not Reported
	Seroquel	S	Oral		Not Reported
	Seroquel	S			Not Reported
	Zyprexa	S			Not Reported
	Cipralex	S	Unknown	Daily	Not Reported
	Orfiril	S	Unknown		Not Reported
	Cipramil [Citalopram Hydrobromide]	S		60 Milligram Daily;	Not Reported
	Cipramil	S		10 Milligram Daily; 10 Mg, Daily	Not Reported
	Valproat	S		Increasing Dose	Not Reported
	Lithionit	C	Unknown		Not Reported
	Lithionit	C			Not Reported
	Lithionit	C			Not Reported
	Lithionit	C			Not Reported
	Sobril	C		As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14070085	EXPEDITED (15-DAY)		HO	AT-ALLERGAN-1756954US		58 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sedation; Tremor	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Lyrica			S	Oral	750 Mg, Qd		Not Reported
	Lyrica			S	Oral	450 Mg, Qd		Not Reported
	Lyrica			S	Oral	375 Mg, Qd		Not Reported
	Lyrica			S	Oral	300 Mg, Qd		Not Reported

Lyrica	S	Oral	150 Mg, Qd		Not Reported
Topamax	S	Oral	100 Mg, Qd		Not Reported
Topamax	S	Oral	25 Mg, Qd		Not Reported
Risperdal	S	Unknown	2 Mg, Qd		Not Reported
Risperdal	S	Oral	2 Mg, Unk		Not Reported
Pantoprazole	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14364747	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1800622US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Zoely			S	Oral	1 Dosage Forms Daily; One Df Contains 2.5mg Nomegestrel And 1.5mg Estradiol		Not Reported
	Valdoxan			S	Unknown	25 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14622999	EXPEDITED (15-DAY)			JP-ALLERGAN-1812886US		20 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Off Label Use; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14628526	EXPEDITED (15-DAY)		OT	FR-CIPLA LTD.-2018FR10378			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Depersonalisation/Dereali sation Disorder; Drug	Escitalopram			S	Oral	Unk		Invagen

Withdrawal Syndrome;
Emotional Disorder;
Fatigue; Headache;
Irritability; Night Sweats;
Vertigo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14629607	EXPEDITED (15-DAY)		HO	IN-HETERO CORPORATE-HET2018IN00171		26 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia	Aripiprazole			S	Unknown	20 Mg		Hetero
	Escitalopram			S	Unknown	20 Mg		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14630383	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1813217US		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; International Normalised Ratio Increased; Melaena	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Previscan (Fluindione)			S	Unknown	Unk		Allergan
	Previscan (Fluindione)			S		15 Mg, Qd		Allergan
	Esomeprazole			C	Unknown			Not Reported
	Bromazepam			C	Unknown			Not Reported
	Seretide			C	Unknown			Not Reported
	Celiprolol			C	Unknown			Not Reported
	Transipeg (Macrogol 3350)			C	Unknown			Not Reported
	Fumafer			C	Unknown			Not Reported
	Pravastatin Sodium			C	Unknown			Not Reported
	Titanoreine			C	Rectal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14630384	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1813270US		52 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Loss Of Consciousness; Malaise	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Frontal			S	Oral	2 Mg, Qd		Not Reported
	Carbolithium			S	Oral	900 Mg, Qd		Not Reported
	Depakin			S	Oral	1000 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14630782	EXPEDITED (15-DAY)		HO, OT	AU-MYLANLABS-2018M1015511		50 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delusion; Eczema; Emotional Distress; Eosinophil Count Decreased; Feeling Cold; Frustration Tolerance Decreased; Haemoglobin Decreased; Hallucination, Auditory; Hyperhidrosis; Intentional Self-Injury; Lymphocyte Count Decreased; Mean Cell Haemoglobin Decreased; Mental Impairment; Metamyelocyte Count Increased; Monocyte Count Decreased; Myelocyte Count Increased; Neutropenia; Platelet Count Increased; Thermal Burn; Tinea Infection; Vitamin B12 Deficiency; White Blood Cell Count Decreased	Clozaril			S	Oral	Unk		Mylan
	Clozaril			S	Oral	700 Mg, Pm		Mylan
	Escitalopram			S		10 Mg, Am		Not Reported
	Escitalopram			S		20 Mg, Am		Not Reported
	Olanzapine			S		5 Mg, Bid		Not Reported
	Olanzapine			S		15 Mg, Pm		Not Reported
	Paliperidone			S		100 Mg, Unk		Mylan
	Paliperidone			S		150 Mg, Unk		Mylan
	Caltrate /00944201/			C		10 Mg, Pm		Mylan
	Lorazepam			C		2 Mg, Pm		Mylan
	Lurasidone			C		120 Mg, Pm		Mylan
	Metformin			C		850 Mg, Tid		Mylan
	Mirtazepine Teva			C		30 Mg, Pm		Mylan
	Crestor			C		10 Mg, Pm		Mylan
	Zuclopenthixol			C		400 Mg, Unk		Mylan
	Calcium Carbonate			C		Unk		Mylan
	Rosuvastatin			C		Unk		Mylan
	Coloxyl /00061602/			C		Unk		Mylan
	Senna /00142201/			C		Unk		Mylan

	Movicol	C	Unk	Mylan
	Vitamin B12 /00056201/	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14633047	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2018M1013754			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Ineffective; Dry Mouth; Hangover; Inappropriate Schedule Of Product Administration; Prescription Drug Used Without A Prescription; Stress; Urinary Retention; Wrong Technique In Product Usage Process	Loxalate			S		Unk Unk, Qd		Mylan
	Loxalate			S				Mylan
	Imrest			S		Unk		Mylan
	Kalma 1 (Alprazolam)			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14633358	EXPEDITED (15-DAY)		HO, OT	DE-ASTRAZENECA-2018SE29413		64 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Abdomen; Drug Interaction	Seroquel			S	Oral	125 Dosage Form, 50-25-50		Zeneca
	Cipralex			S	Unknown			Not Reported
	Leponex			C		100-0-75		Not Reported
	Levomepromazine			C				Not Reported
	Eisensulfat			C				Not Reported
	Kalinor (Potassium Chloride)			C		1-0-0		Not Reported
	Delix (Ramipril)			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14637746	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Libido Decreased; Weight Increased	Lexapro			S				Not Reported
	Bupropion			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	13580465	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2017-34344		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram Film-Coated Tablets			S	Oral	140 Mg, Daily		Aurobindo
	Lorazepam Tablets			S	Oral	20 Mg, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14364608	EXPEDITED (15-DAY)		HO, OT	FR-ELI_LILLY_AND_COMPANY-FR201712012922		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Abasaglar			S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Xeloda			S	Oral	Unk, Unknown		Not Reported
	Novorapid			S	Subcutaneous	Unk, Unknown		Not Reported
	Primperan			S	Oral	Unk, Unknown		Not Reported
	Lipanthyl			S	Oral	Unk, Unknown		Not Reported
	Movicol			S	Oral	Unk Unk, Unknown		Not Reported
	Pantoprazole			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Fondaparinux Sodique			S	Subcutaneous	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14633536	EXPEDITED (15-DAY)		HO	US-AMGEN-USACT2018032047		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Decreased Appetite; Weight Decreased	Blinatumomab	S	Intravenous (not otherwise specified)	15 Mcg/M2, Qd	Amgen
	Methotrexate	S	Oral	20 Mg/M2, Unk	Not Reported
	Vincristine	S	Intravenous (not otherwise specified)	1.5 Mg/M2, Unk	Not Reported
	Mercaptopurine	S	Oral	75 Mg/M2, Unk	Not Reported
	Vancomycin	S	Unknown	Unk	Not Reported
	Ativan	S	Oral	Unk	Not Reported
	Clonazepam	S	Unknown	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Morphine	S	Oral	Unk	Not Reported
	Norethindrone	S	Unknown	Unk	Not Reported
	Scopolamine	S	Topical	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14633739	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-166068		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Binge Eating; Overdose; Treatment Failure; Weight Increased	Risperidone			S	Unknown	Unk		Ranbaxy
	Risperidone			S				Ranbaxy
	Aripiprazole			S	Unknown	Unk		Not Reported
	Aripiprazole			S				Not Reported
	Quetiapine			S	Unknown	Unk		Sun
	Quetiapine			S				Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Fluoxetine			S	Unknown	Unk		Sun
	Fluoxetine			S				Sun
	Cyamemazine			S	Unknown	Unk		Not Reported
	Cyamemazine			S				Not Reported
	Propericiazine			S	Unknown	Unk		Not Reported

	Propericiazine			S				Not Reported
	Carbamazepine			S	Unknown	Unk		Not Reported
	Carbamazepine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14634232	EXPEDITED (15-DAY)		OT	DE-CIPLA LTD.-2018DE10716			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor; Wound	Escitalopram			S	Unknown	10 Mg, Unk		Invagen
	Escitalopram			S	Oral	20 Mg, Every Day		Invagen
	Escitalopram			S	Oral	15 Mg, Every Day		Invagen
	Escitalopram			S	Unknown	7.5 Mg, Every Day		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14634347	EXPEDITED (15-DAY)		OT	NO-CIPLA LTD.-2018NO10698			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Galactorrhoea; Insomnia	Escitalopram			S	Oral	Oct/2016: 10 Mg-15 Mg May/2017: 20 Mg Oct/2018: 10 Mg ()		Invagen
	Mirena			C	Intra-uterine	Unk		Not Reported
	Wellbutrin			C	Oral	150 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14635024	EXPEDITED (15-DAY)		DE, HO, OT	DE-ALLERGAN-1813174US		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hyperhidrosis; Off Label Use; Restlessness;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

Schizoaffective Disorder	Tavor [Lorazepam]	S	Oral	2 Mg, Unk		Not Reported
	Tavor	S	Oral	6 Mg, Unk		Not Reported
	Seroquel	S	Oral	200 Mg, Unk		Not Reported
	Lorazepam	S	Oral	6 Mg, Qd		Not Reported
	Quetiapine	S	Oral	200 Mg, Qd		Not Reported
	Abilify	S	Oral	20 Mg, Unk		Not Reported
	Abilify	S	Oral	15 Mg, Unknown		Not Reported
	Movicol	C	Unknown	Unk		Not Reported
	Simeticone	C	Unknown	Unk		Not Reported
	Eferox	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14635027	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1813396US		51 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Uric Acid Increased; Epilepsy; Fall; Increased Appetite; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Fexofenadine Hydrochloride			C	Oral			Not Reported
	Famotidine			C	Oral			Not Reported
	E Keppra			C	Oral			Not Reported
	Depakene			C	Oral			Not Reported
	Azilva			C	Oral			Not Reported
	Loxoprofen Na			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14635028	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1767213US		24 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Abuse; Intentional Product Misuse; Overdose; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Df, Single		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14635029	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-ALLERGAN-S06-FRA-01387-01		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Cardiac Arrest; Chills; Delusion; Feeling Hot; Lactic Acidosis; Malaise; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Respiratory Arrest; Retained Placenta Or Membranes	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported
	Tiapridal			S	Oral	100 Mg, Unk		Not Reported
	Abilify			S	Oral	15 Mg, Qd		Not Reported
	Cytotec			S	Unknown	400 Mg, Bid		Not Reported
	Misoprostol			S	Unknown	800 Mg, Unk		Not Reported
	Mifegyne			S	Oral	600 Mg, Qd		Not Reported
	Mifegyne			S	Oral	200 Mg, Unk		Not Reported
	Lysanxia			C	Unknown	50 Mg, Qd		Not Reported
	Imovane			C	Oral	7 Mg, Qd		Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14635898	EXPEDITED (15-DAY)		OT	DE-TEVA-804347GER			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Zoely 2,5 Mg/1,5 Mg Filmtabletten			S	Oral	1 Dosage Forms Daily; One Df Contains 2.5mg Nomegestrel And 1.5mg Estradiol		Not Reported
	Escitalopram			S	Unknown	20 Milligram Daily;		Ivax
	Valdoxan			S	Unknown	25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14637721	EXPEDITED (15-DAY)		HO, OT	PHHY2018AU043275		50 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delusion; Eczema; Emotional Distress; Eosinophil Count Decreased; Feeling Cold; Frustration Tolerance Decreased; Haemoglobin Decreased; Hallucination, Auditory; Hyperhidrosis; Intentional Self-Injury; Lymphocyte Count Decreased; Mean Cell Haemoglobin Decreased; Mental Impairment; Metamyelocyte Count Increased; Monocyte Count Decreased; Myelocyte Count Increased; Neutropenia; Platelet Count Increased; Thermal Burn; Tinea Infection; Vitamin B12 Deficiency; White Blood Cell Count Decreased	Clozaril			S	Oral	Unk		Not Reported
	Clozaril			S	Oral	700 Mg, Qd (Pm)		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd (Am)		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd (Am)		Not Reported
	Olanzapine			S	Unknown	5 Mg, Bid		Novartis
	Olanzapine			S	Unknown	15 Mg, Qd (Nocte)		Novartis
	Paliperidone			S	Unknown	100 Mg, Unk		Not Reported
	Paliperidone			S	Unknown	150 Mg, Unk		Not Reported
	Caltrate			C	Unknown	10 Ug, Qd (Pm)		Not Reported
	Lorazepam			C	Unknown	2 Mg, Qd (Pm)		Not Reported
	Lurasidone			C	Unknown	120 Mg, Qd (Pm)		Not Reported
	Metformin			C	Unknown	850 Mg, Tid		Not Reported
	Mirtazepine Teva			C	Unknown	30 Mg, Qd (Pm)		Not Reported
	Crestor			C	Unknown	10 Mg, Qd		Not Reported
	Zuclopenthixol			C	Unknown	400 Mg, Unk		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported
	Coloxyl			C	Unknown	Unk		Not Reported
	Senna			C	Unknown	Unk		Not Reported
	Movicol			C	Unknown	Unk		Not Reported
	Vitamin B12			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	12519980	EXPEDITED (15-DAY)		HO, LT	FR-FRI-1000085734		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Confusional State; Electrocardiogram Qt Prolonged; Hypotonia;	Escitalopram Oxalate - Bp			S	Oral	140 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	140 Mg, Unk		Allergan

Miosis; Overdose; Pneumonia Aspiration	Escitalopram Oxalate - Bp		S	Oral	10 Mg, Unk	Allergan
	Zopiclone		S	Oral	210 Mg, Qd	Not Reported
	Zopiclone		S	Oral	7.5 Mg, Qhs	Not Reported
	Zyprexa		S	Oral	1 Df, Unk	Not Reported
	Zyprexa		S	Oral	10 Mg, Qam	Not Reported
	Zyprexa		S	Oral	20 Mg, Qpm	Not Reported
	Lysanxia		S	Oral	1440 Mg, Single	Not Reported
	Lysanxia		S	Oral	10 Mg, Qam	Not Reported
	Abilify		S	Oral	5 Mg, Qd	Not Reported
	Olanzapine		S	Oral	1 Df, Unk	Not Reported
	Olanzapine		S	Oral	10 Mg, Qam	Not Reported
	Olanzapine		S	Oral	20 Mg, Qpm	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	13873202	EXPEDITED (15-DAY)		OT	GB-TORRENT-00015503		21 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Bruxism	Escitalopram Oxalate			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14369458	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2017008165			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Quetiapine 400mg Tablet			S	Oral	400 Mg, Qd		Macleods
	Quetiapine 400mg Tablet			S	Oral	Unk		Macleods
	Quetiapine 400mg Tablet			S	Oral	Unk		Macleods
	Abilify			S	Oral	15 Mg, Qd		Not Reported
	Abilify			S	Oral	Unk		Not Reported

Abilify	S	Oral	Unk	Not Reported
Laroxyl	S		400 Mg, Qd	Not Reported
Laroxyl	S	Unknown	Unk	Not Reported
Laroxyl	S	Unknown	Unk	Not Reported
Lexapro	S	Oral	10 Mg, Qd	Not Reported
Lexapro	S	Oral	Unk	Not Reported
Lexapro	S	Oral	Unk	Not Reported
Lepticur	S	Unknown	15 Mg, Unk	Not Reported
Lepticur	S	Unknown	Unk	Not Reported
Lepticur	S	Unknown	Unk	Not Reported
Methylphenidate Hydrochloride	S	Oral	100 Mg, Unk, ((80 Mg In The Morning And 20 Mg At 4pm))	Not Reported
Methylphenidate Hydrochloride	S	Oral	110 Mg, Qd, (80 Mg In The Morning And 20 Mg At 4pm)	Not Reported
Methylphenidate Hydrochloride	S	Oral	Unk, (80 Mg In The Morning And 20 Mg At 4pm)	Not Reported
Ritaline	S	Oral	100 Mg, Unk	Not Reported
Ritaline	S	Oral	110 Mg, Qd	Not Reported
Ritaline	S	Unknown	Unk	Not Reported
Seroplex	S	Oral	10 Mg, Qd	Not Reported
Seroplex	S	Unknown	Unk	Not Reported
Seroplex	S	Unknown	Unk	Not Reported
Xeroquel	S	Oral	400 Mg, Qd	Not Reported
Xeroquel	S	Unknown	Unk	Not Reported
Xeroquel	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14638996	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR10804			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Escitalopram			S	Oral	1 Df Daily		Invagen
	Irbesartan			S	Oral	300 Mg, Unk		Cipla
	Levofloxacin			S	Oral	2 Df, Unk		Cipla
	Amlodipine			S	Oral	10 Mg, Unk		Invagen
	Terbutaline			S	Respiratory (inhalation)	1 Df, Unk		Not Reported
	Pantoprazole			S	Oral	20 Mg, Unk		Not Reported
	Mirtazapine			S	Oral	15 Mg, Unk		Not Reported
	Xarelto			S	Oral	1 Df, Unk		Not Reported
	Alprazolam			S	Oral	0.75 Mg, Unk		Not Reported
	Metformine /00082701/			S	Oral	1000 Mg, Unk		Not Reported
	Diffu K			S	Oral	3 Df, Unk		Not Reported
	Bisoprolol Hemifumarate			S	Oral	1.25 Mg, Unk		Not Reported
	Valium			S	Oral	3 Df, Unk		Not Reported
	Colchicine Opocalcium			S	Oral	1 Df, Unk		Not Reported
	Nefopam /00396102/			S	Oral	3 Df, Unk		Not Reported
	Dafalgan			S	Oral	6 Df, Unk		Not Reported
	Furosemide			S	Oral	30 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14639713	EXPEDITED (15-DAY)		OT	GB-TORRENT-00016233		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral			Unknown
	Levonelle			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14640395	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02007		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin
	Lamotrigine			S	Oral	Unk		Not Reported
	Oxycodone And Acetaminophen			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported
	Montelukast			S	Oral	Unk		Not Reported
	Ondansetron			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Aciclovir			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14641024	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02009		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Carvedilol			S	Oral	Unk		Lupin
	Escitalopram			S	Oral	Unk		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Valproic Acid			S	Oral	Unk		Not Reported
	Sitagliptin			S	Oral	Unk		Not Reported
	Phenytoin			S	Oral	Unk		Not Reported
	Primidone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14648387	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Acne Pustular; Emotional Distress; Erythema;	Escitalopram (Lexapro)			S	Oral	Quantity:1 Tablet(S);		Lupin
	Pravastatin Sodium			C				Not Reported

Glycosylated Haemoglobin Increased; Hypersensitivity; Lymphadenopathy; Oral Herpes; Rash; Secretion Discharge; Stomatitis	Nasacort Aq	C	Not Reported
	Lutein & Zeaxanthin	C	Not Reported
	Selenium	C	Not Reported
	Multiple Viatamin W/Iron	C	Not Reported
	Vitamin D3	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	12673734	EXPEDITED (15-DAY)		HO, LT, OT	CH-OTSUKA-2016_020311		55 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Confusional State; Disturbance In Attention; Dysphagia; Fall; Hyperreflexia; Muscle Rigidity; Mutism; Neuroleptic Malignant Syndrome; Product Use In Unapproved Indication; Serotonin Syndrome; Tremor	Abilify Maintena			S	Intramuscular	400 Mg, Qm (Every 28 Days)		Otsuka
	Abilify Maintena			S				Otsuka
	Abilify			S	Oral	15 Mg, Qd		Otsuka
	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Escitalopram			S	Unknown	Unk		Not Reported
	Quetiapine Actavis			C	Oral	300 Mg, Bid		Not Reported
	Temesta (Lorazepam)			C	Oral	0.5 Mg, Every 6 Hours		Not Reported
	Amlodipin			C	Oral	5 Mg, Qd		Not Reported
	Escitalopram Sandoz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	13514741	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1716961US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Neonatal Respiratory Distress; Premature Baby; Tachycardia Foetal	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14249147	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1768550US		27 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Inappropriate Schedule Of Product Administration	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Flunitrazepam			C	Oral	1 Mg, Qd		Not Reported
	Flunitrazepam			C	Oral	1 Mg, Unk		Not Reported
	Vegetamin B			C	Oral	1 Df, Unk		Not Reported
	Vegetamin A			C		Unk		Not Reported
	Sertraline			C		Unk		Not Reported
	Benzalin (Nitrazepam)			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14321006	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE-HET2017DE00433		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Qd		Hetero
	Aripiprazole			S	Oral	5 Mg, Qd		Hetero
	Escitalopram			S	Oral	10 Mg, Qd		Hetero
	Escitalopram			S	Oral	15 Mg, Qd		Hetero
	Escitalopram			S	Oral	20 Mg, Qd		Hetero
	Candesartan			S	Oral	16 Mg, Qd		Not Reported
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported
	Risperdal			C	Unknown	2 Mg		Not Reported

	Risperdal	C	Unknown	2 Mg, Qd	Not Reported
	L-Thyroxin	C	Oral	100 Mg, Qd	Not Reported
	Amisulpride	C	Unknown	200 Mg, Qd	Not Reported
	Metformin	C	Oral	1500 Mg, Qd	Not Reported
	Atorvastatin	C	Oral	20 Mg, Qd	Not Reported
	Acetylsalicylic Acid	C	Unknown	100 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14596678	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-011012		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Aurobindo
	Bisoprolol			S	Unknown	()		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14647521	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018011308			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intracranial Haematoma	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Macleods
	Amlodipine Besylate			C	Unknown	5 Mg, Qd		Macleods
	Kardegic			S	Oral	75 Mg, Qd		Not Reported
	Levocetirizine Dihydrochloride			C	Unknown	5 Mg, Qd		Not Reported
	Levothyrox			C	Unknown	50 Mg, Qd, Scored Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14647972	EXPEDITED (15-DAY)		OT	IE-TEVA-2018-IE-869027		40 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Discomfort;	Escitalopram (G)			S	Unknown			Ivax

Insomnia; Motor Dysfunction; Pain In Extremity; Paraesthesia; Paraesthesia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14648213	EXPEDITED (15-DAY)		DE, HO, OT	DE-PFIZER INC-2018108729		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Lorazepam			S	Oral	6 Mg, Qd		Pfizer
	Tavor [Lorazepam]			S	Oral	2 Mg, Unk		Pfizer
	Tavor [Lorazepam]			S	Oral	6 Mg, Unk		Pfizer
	Abilify 3 Mg			S	Oral	20 Mg, Unk		Not Reported
	Abilify 3 Mg			S	Oral	15 Mg, Unknown		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Quetiapine			S	Oral	200 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Seroquel			S	Oral	200 Mg, Unk		Not Reported
	Movicol			C	Unknown	Unk		Not Reported
	Simeticone			C	Unknown	Unk		Not Reported
	Eferox			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14648301	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2018106526		23 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Foetal Death; Nausea	Xanax			S	Oral	0.5 Mg, In Reserve (About 2x Per Day), Practically During The Whole Pregnancy		Pfizer
	Temesta (Lorazepam)			S	Oral	Unk		Pfizer

	Insulin		S	Subcutaneous	Unk	Not Reported
	Escitalopram		S	Oral	10 Mg, 1x/Day	Not Reported
	Citalopram		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14648898	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2018-007062		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Venlafaxine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose, 1 Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14649576	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2017PRN00552			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dysphagia; Lip Dry; Panic Attack; Tremor	Escitalopram			S				Prinston Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14649577	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2018PRN00065		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Fatigue; Heart Rate Increased; Insomnia; Nausea; Palpitations; Panic Reaction; Somnolence; Thirst	Escitalopram			S	Oral	10 Mg, 1x/Day		Prinston Pharmaceutical
	Topamax			S		Unk		Not Reported
	Butalbital, Acetaminophen And Caffeine			C		Unk, 1x/Day		Not Reported
	Lorazepam			C		0.5 Mg, 1x/Day		Not Reported
	Multivitamin			C				Not Reported
	Coconut Oil			C		Unk, 1x/Day		Not Reported

	Probiotic	C	Unk, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14651913	EXPEDITED (15-DAY)		OT	US-HETERO CORPORATE-HET2018US00204		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic	Escitalopram			S	Unknown			Hetero
	Lansoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14660317	DIRECT		DS			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Influenza Like Illness; Nausea	Escitalopram Oxalate			S	Oral	Quantity:2 Mg;		Camber
	Alprazolam			S	Oral	Quantity:120 Tablet(S);		Dava
	Milk Thistle			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2018	14036676	EXPEDITED (15-DAY)		LT	JP-ALLERGAN-1756139US		27 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Zyprexa			C	Oral	2.5 Mg, Unk		Not Reported
	Zyprexa			C	Oral	2.5		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	13214920	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1705051US		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram Oxalate - Bp			S	Oral			Allergan

Venlafaxine	S	Oral	Unk		Not Reported
Tranxene	S	Oral			Not Reported
Loxapac	C	Oral	20 Mg, 813 In Total		Not Reported
Bromazepam	C	Oral	12 Mg, Qd		Not Reported
Debridat	C	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14215559	EXPEDITED (15-DAY)		DE, HO, OT	DE-ASTRAZENECA-2017SF18150		1 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Synagis			S	Intramuscular	150.0mg Unknown		Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Varivax			S	Intramuscular	1.0df Unknown		Not Reported
	Topiramate			S	Unknown			Not Reported
	Phenobarbital			S	Unknown			Not Reported
	Sildenafil Citrate			S	Unknown			Not Reported
	Spironolactone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14655492	EXPEDITED (15-DAY)		HO, OT	IN-IMPAX LABORATORIES, INC-2018-IPXL-00813		29 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Crying; Decreased Appetite; Delusion; Grief Reaction; Headache; Hypomania; Insomnia; Intentional Self-Injury; Suicidal Ideation; Weight Increased	Cabergoline			S	Unknown	0.5 Mg, 1 /Week		Impax
	Escitalopram			S	Unknown	5-10 Mg, Daily		Not Reported
	Escitalopram			S				Not Reported
	Olanzapine			S	Unknown	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14656190	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-869032			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus; Urticaria; Vertigo; Vision Blurred	Atenolol			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Ivax
	Zyloric 200 Mg, Comprimé			S	Unknown			Not Reported
	Levothyrox 175 Microgrammes, Comprimé Sécable			S	Oral			Not Reported
	Cotareg 160 Mg/25 Mg, Comprimé Pelliculé			S	Unknown			Not Reported
	Amlor 10 Mg, Gélule			S	Unknown			Not Reported
	Seresta 50 Mg, Comprimé Sécable			S	Unknown			Not Reported
	Uvedose			S	Unknown			Not Reported
	Imovane			S	Unknown			Not Reported
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Unknown			Not Reported
	Endotelon			S	Unknown	2 À 3 Cp/J		Not Reported
	Voltarene Lp 75 Mg, Comprimé Enrobé À Libération Prolongée			S	Unknown	2x/Semaine		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14656693	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1016963		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14664680	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Drug Ineffective	Escitalopram	S	Oral		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14659521	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02244		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metformin			S	Oral	Unk		Lupin
	Escitalopram			S	Oral	Unk		Not Reported
	Losartan			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported
	Diltiazem			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Glyburide			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14659893	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1016528		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Quetiapine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	270 Mg, Total		Not Reported
	Etiltox			S	Oral	9 Df, Total		Mylan
	Carbolithium			S	Oral	5 Df, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14661168	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018108695		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Drug Interaction; Hallucination,	Lyrica			S	Oral	75 Mg, 1x/Day		Pfizer

Visual	Artotec	S	Oral	2 Df, 1x/Day	Pfizer
	Atarax /00058401/	S	Oral	25 Mg, 1x/Day	Not Reported
	Seroplex	S	Oral	15 Mg, 1x/Day	Not Reported
	Vesicare	S	Oral	10 Mg, 1x/Day	Not Reported
	Cotareg	C		Unk	Not Reported
	Actonel	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14661710	EXPEDITED (15-DAY)		HO	DE-OTSUKA-DJ201500377		50 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Restlessness	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Venlafaxin			S	Oral	150 Mg, Qd		Not Reported
	Venlafaxin			S	Oral	75 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	11548643	EXPEDITED (15-DAY)		OT	CN-FRI-1000079616		43 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Daydreaming; Depression; Discomfort; Dissociation; Drug Dependence; Drug Ineffective For Unapproved Indication; Dysphemia; Emotional Disorder; General Physical Condition Abnormal; Homicidal Ideation; Inappropriate Schedule Of Product Administration;	Escitalopram Oxalate - Bp			S	Oral	40 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	60 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	40 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	80 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	60 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	60 Mg, Bid		Allergan
	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	60 Mg, Qd		Allergan

Intentional Overdose; Irritability; Malaise; Nervousness; Night Sweats; Obsessive-Compulsive Disorder; Off Label Use; Peripheral Coldness; Prescribed Overdose; Psychiatric Symptom; Somnolence; Stress; Suicidal Ideation	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp	S	Oral	40 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp	S	Oral	40 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp	S	Oral	120 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp	S	Oral	40 Mg, Bid		Allergan
	Escitalopram Oxalate - Bp	S	Oral	2 Df, Bid		Allergan
	Buspirone	C	Unknown	1 Df, Tid		Not Reported
	Venlafaxine	C	Unknown	Unk		Not Reported
	Fluvoxamine	C	Unknown	75 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14422332	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-160708		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Homicidal Ideation; Suicidal Ideation	Olanzapine			S	Unknown	15 Mg, Daily		Sun
	Olanzapine			S				Sun
	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14662213	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR11619			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Sinus Bradycardia	Escitalopram			S	Oral	1120 Mg, Unk		Invagen
	Zopiclone			S	Oral	315 Mg, Unk		Not Reported
	Plavix			S	Oral	2250 Mg, Unk		Not Reported
	Coveram			S	Oral	60 Df, Unk		Not Reported
	Seresta			S	Oral	1000 Mg, Unk		Not Reported
	Bisoce			S	Oral	300 Mg, Unk		Not Reported

Aldactazine	S	Oral	30 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14662616	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR11633			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Sedation	Risperidone			S	Oral	1.5 G, Unk		Cipla
	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Alprazolam			S	Oral	0.13 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14662733	EXPEDITED (15-DAY)		OT	NL-CIPLA LTD.-2018NL11792			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrooesophageal Reflux Disease	Escitalopram			S	Unknown	10 Mg, Daily		Invagen
	Levothyroxinenatrium Teva			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14663382	NON-EXPEDITED			US-PFIZER INC-2018107422		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Nervousness	Effexor Xr			S		Unk (She Was Taking 10 Or 20mg Of The Effexor)		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14665238	EXPEDITED (15-DAY)		OT	PHHY2018US040075		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Diarrhoea; Mucosal	Lansoprazole			S	Unknown			Novartis

Ulceration; Rectal Ulcer	Escitalopram	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14665671	EXPEDITED (15-DAY)		HO, LT	CH-ALLERGAN-1815228US		53 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Poisoning	Escitalopram Oxalate - Bp			S	Oral	Overdose: 80 Mg		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Quilonorm			S	Oral	50 Mg, Qd		Not Reported
	Nebivolol			C	Oral	5 Mg, Qd		Not Reported
	Lansoprax			C	Oral	15 Mg, Qd		Not Reported
	Symbicort			C	Other	200/6 Mg, Q12h		Not Reported
	Spiriva			C	Other	18 Mg, Qd		Not Reported
	Durogesic			C	Transdermal	1 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14665676	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1815221US		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroid Mass	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14666038	EXPEDITED (15-DAY)		OT	CH-SHIRE-CH201809425			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Elvanse			S	Unknown			Shire
	Abilify			S	Oral	10-15 Mg, 1x/Day:Qd		Not Reported
	Cipralex			S	Unknown			Not Reported
	Topamax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14668932	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Lexapro			S				Not Reported
	Celexa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	11910446	EXPEDITED (15-DAY)		HO	FR-FRI-1000082056		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Off Label Use; Raynaud'S Phenomenon	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Abilify			S	Oral	15 Mg, Qd		Not Reported
	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Laroxyl			S	Unknown	Unk		Not Reported
	Laroxyl			S				Not Reported
	Laroxyl			S				Not Reported
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported
	Xeroquel			S				Not Reported
	Xeroquel			S				Not Reported
	Lepticur			S	Unknown	15 Mg, Unk		Not Reported
	Lepticur			S				Not Reported
	Lepticur			S				Not Reported
	Ritaline			S	Oral	100 Mg (80 Mg In The Morning And 20 Mg At 4 Pm)		Not Reported
	Ritaline			S	Oral	90 Mg, Qd		Not Reported
	Ritaline			S	Oral	110 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	13514665	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1026501		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram			S	Oral	10 Mg, Total		Not Reported
	Xanax			S	Oral	0.25 Mg, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14274308	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-OTSUKA-DJ20060604		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Chills; Malaise; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Respiratory Arrest	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported
	Seroplex			S	Oral	15 Mg, Qd		Not Reported
	Cytotec			S	Vaginal	800 Mg, Unk		Not Reported
	Misoprostol			S	Unknown	800 Mg, Unk		Not Reported
	Lexapro			S	Unknown	15 Mg, Qd		Not Reported
	Imovane			C	Unknown	7 Mg, Unk		Not Reported
	Lysanxia			C	Unknown	10 Mg, Unk (10 Mg To 40 Mg)		Not Reported
	Mifegyne			C	Oral	600 Mg, Unk (200 Mg, Unk)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14321373	EXPEDITED (15-DAY)		HO	DE-TORRENT-00007417		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	5 Mg, Qd		Unknown
	L-Thyroxin			C	Oral	100 G, Qd		Unknown

Amisulid	C	Unknown	200 Mg, Qd		Unknown
Metformin	C	Oral	1500 Mg, Qd		Unknown
Atorvastatin	C	Oral	20 Mg, Qd		Unknown
Acetylsalicylic Acid	C	Oral	100 Mg, Qd		Unknown
Candesartan	S	Oral	16 Mg, Qd		Unknown
Escitalopram	S	Oral	10 Mg, Qd		Unknown
Risperdal	C		2 Mg, Unk (For Nights)		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14475395	EXPEDITED (15-DAY)		HO, LT	GR-ALLERGAN-1804920US		67 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Clonus; Confusional State; Delayed Recovery From Anaesthesia; Disorientation; Drug Interaction; Fear; Hyperpyrexia; Hyperreflexia; Mental Status Changes; Muscle Rigidity; Mydriasis; Psychomotor Hyperactivity; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Methylene Blue			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Not Reported
	Methylene Blue			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14667239	EXPEDITED (15-DAY)		OT	US-ZYDUS-019308		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Diarrhoea; Rectal Ulcer	Escitalopram			S	Unknown			Zydus Pharm
	Lansoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14667431	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2018-015223		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroid Mass	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14667523	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018011593			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroid Mass	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14670220	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2018094170		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Tolerance; Prescribed Overdose; Somnolence	Lyrica			S		1000 Mg, Daily For 5 Months		Pfizer
	Lyrica			S		5 Df, Daily (2 Df In The Morning And 3 Df In The Evening) For One Month		Pfizer
	Seroplex			S		2 Df, Daily 1 Tablet In The Morning And In The Evening For 1 Month		Not Reported
	Seroplex			S		1 Df, Daily (Pharmacist Dispensed Escitalopram 20 Mg At 1 Tablet Daily As A Maximal Daily Dose)		Not Reported
	Urbanyl			S		0.5 Df, 3x/Day (Half A Tablet In The Morning, At Noon And In The Evening		Not Reported

	Monocrixo	S	For 1 Month) 150 Mg, 1x/Day (One Hard Capsule At Bedtime For One Month)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14670544	EXPEDITED (15-DAY)		OT	NO-ALLERGAN-1815440US		22 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Medication Error	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Ritalin			S	Oral	10 Mg, Unk		Not Reported
	Valium			S	Oral	5 Mg, Unk		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Stesolid			S	Oral	5 Mg, Unk		Not Reported
	Atarax			S	Oral	25 Mg, Unk		Not Reported
	Rohypnol			S	Unknown	Unk		Not Reported
	Imovane			S	Oral	7.5 Mg, Unk		Not Reported
	Sobril			S	Unknown	Unk		Not Reported
	Vallergan			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14670582	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1815443US		40 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Paraesthesia; Product Dose Omission; Sexual Dysfunction	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	12573239	EXPEDITED (15-DAY)		HO, OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-120492		66 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning	Rosuvastatin			S	Unknown			Sun
	Perindopril			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lercanidipine			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Sun
	Atenolol			S	Unknown			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14282969	EXPEDITED (15-DAY)		HO	DE-TEVA-2017-DE-830307		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Qd		Teva
	Aripiprazole			S	Oral	5 Mg, Qd		Teva
	Escitalopram			S	Oral	10 Mg, Qd		Ivax
	Escitalopram			S	Oral	15 Mg, Qd		Ivax
	Escitalopram			S	Oral	20 Mg, Qd		Ivax
	Candesartan			S	Oral	16 Mg, Qd		Not Reported
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported
	Risperdal			C	Unknown	2 Mg, Unk (For Nights)		Not Reported
	Risperdal			C	Unknown	2 Mg, Qd		Not Reported
	L-Thyroxin /00068001/			C	Oral	100 Mg, Qd		Not Reported
	Amisulpride			C	Unknown	200 Mg, Qd		Not Reported
	Metformin			C	Oral	1500 Mg, Qd		Not Reported
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported

	Acetylsalicylic Acid	C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14419460	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2018M1004408		71 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Fluvoxamine			S	Unknown	200 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Clomipramine			S	Unknown	150 Mg, Qd		Not Reported
	Aripiprazole			S	Unknown	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14570558	EXPEDITED (15-DAY)		DE, OT	SK-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-01		72 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage Intracranial	Pradaxa			S	Oral			Boehringer Ingelheim
	Pradaxa			S				Boehringer Ingelheim
	Cipralex			S	Unknown			Not Reported
	Vitacalcin			C	Unknown			Not Reported
	Siofor			C	Unknown			Not Reported
	Carvedilol			C	Unknown			Not Reported
	Valsacor			C	Unknown			Not Reported
	Cynt			C	Unknown			Not Reported
	Preductal			C	Unknown			Not Reported
	Detralex			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Helidac			C	Unknown			Not Reported
	Aricept			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14665576	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018112213		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single		Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14671493	EXPEDITED (15-DAY)		HO	LT-MACLEODS PHARMACEUTICALS US LTD-MAC2018011708			Unknown	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Insomnia; Overdose; Speech Disorder	Escitalopram Oxalate			S	Oral	Unk Overdose		Macleods
	Quetiapine			S	Oral	Unk		Macleods
	Zolpidem			S	Oral	Unk		Not Reported
	Etoricoxib			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14672009	EXPEDITED (15-DAY)		OT	US-ALEMBIC PHARMACUETICALS LIMITED-2018SCAL000221			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Venlafaxine Hydrochloride			S	Unknown	Unk		Alembic
	Escitalopram			S	Unknown	Unk		Not Reported
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, (Single)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14672825	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02418		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metformin			S	Oral	Unk		Lupin
	Alprazolam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Naproxen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14673052	EXPEDITED (15-DAY)		OT	PHHY2018AU048414		63 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myeloid Leukaemia; Anion Gap Increased; Blood Albumin Decreased; Blood Lactate Dehydrogenase Increased; Bundle Branch Block Left; Dysplasia; Fungal Infection; Haematocrit Decreased; Haemoglobin Decreased; Lung Infection; Myelodysplastic Syndrome; Platelet Count Decreased; Red Blood Cell Count Decreased; Red Cell Distribution Width Increased	Famciclovir			S	Unknown			Novartis
	Baclofen			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Idarubicin			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Duodart			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14673530	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS-2018GMK033547		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose,In Total		Glenmark
	Venlafaxine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14674366	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-GLAXOSMITHKLINE-BE2018046286			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Sipralexa			S	Transplacental	10 Mg, Unk		Glaxosmithkline
	Fluticasone Furoate + Vilanterol Trifenatate			S	Transplacental	1 Df, Qd		Glaxosmithkline
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Glaxosmithkline
	Seretide			S	Transplacental	Unk		Glaxosmithkline
	Ventolin			S	Transplacental	100 ?G, Unk		Glaxosmithkline
	Mepolizumab			S	Transplacental	100 Mg, Unk		Glaxosmithkline
	Avamys			S	Transplacental	Unk Unk, Qd		Glaxosmithkline
	Xyzall			S	Transplacental	5 Mg, Qd		Glaxosmithkline
	Flixotide			S	Transplacental	500 ?G, Qd		Glaxosmithkline
	Pantomed (Pantoprazole Sodium Sesquihydrate)			S	Transplacental	Unk		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14674696	EXPEDITED (15-DAY)		HO, OT	CA-MYLANLABS-2018M1017497		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug	Topiramate			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported

Interaction; Irritability; Overdose; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram	S	Unknown	Unk	Not Reported
	Temazepam	S	Oral	Pills	Not Reported
	Quetiapine	S	Oral	Pills	Not Reported
	Naloxone	S	Intramuscular	0.8 Mg	Not Reported
	Oxazepam	S	Oral	Pills	Mylan
	Atorvastatin	C	Unknown	Unk	Mylan
	Ferrous Gluconate	C	Unknown	Unk	Mylan
	Furosemide	C	Unknown	Unk	Mylan
	Metoprolol	C	Unknown	Unk	Mylan
	Ramipril	C	Unknown	Unk	Mylan
	Spironolactone	C	Unknown	Unk	Mylan
	Fluticasone W/Salmeterol	C	Unknown	Unk	Mylan
	Ipratropium	C	Unknown	Unk	Mylan
	Salbutamol	C		Metered Dose Inhalers	Mylan
	Clopidogrel	C	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14675255	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-02		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Hikma
	Ondansetron			S	Intravenous (not otherwise specified)			Hikma
	Venlafaxine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14675261	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1815674US		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Colitis Microscopic	Escitalopram Oxalate - Bp		S	Oral	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14675262	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1815692US		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Venlafaxine			S	Unknown	Unk		Not Reported
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14676021	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-873207		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chills; Headache; Loss Of Consciousness; Nausea; Tremor	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14676160	EXPEDITED (15-DAY)		OT	PHHY2018AU045141			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anion Gap Increased; Blood Albumin Decreased; Blood Lactate Dehydrogenase Increased; Bundle Branch Block Left; Disease Progression; Dysplasia; Fungal Infection; Haematocrit Decreased; Haemoglobin Decreased; Lung Infection; Platelet	Famciclovir			S	Unknown			Novartis
	Baclofen			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Idarubicin			S	Unknown			Not Reported
	Dutasteride			S	Unknown			Not Reported

Count Decreased; Red Blood Cell Count Decreased; Red Cell Distribution Width Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2018	14676805	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2017004988			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Nausea; Tremor	Escitalopram			S	Oral	200 Mg, Total		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2018	14677434	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1017318		91 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Lansoprazole			S	Oral	30 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Gliclazide			S	Oral	60 Mg, Qd		Not Reported
	Stilnox			S	Oral	1 Df, Qd		Mylan
	Efferalgan Cod.			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2018	14677444	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1017341		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Citalopram			S	Unknown			Not Reported
	Trimethoprim			S	Unknown			Mylan

	Septrin	S	Unknown		Mylan
	Escitalopram	S	Unknown		Mylan
	Cabergoline	S	Unknown		Mylan
	Carbidopa	S	Unknown		Mylan
	Entacapone	S	Unknown		Mylan
	Levodopa	S	Unknown		Mylan
	Stalevo /01530202/	S	Unknown		Mylan
	Co-Beneldopa	C		25/100 Capsules	Mylan
	Co-Beneldopa	C			Mylan
	Macrogol	C			Mylan
	Duloxetine	C		Duloxetine 90mg Capsule	Mylan
	Adcal D3	C			Mylan
	Rivastigmine	C			Mylan
	Quetiapine	C			Mylan
	Paracetamol	C			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14076460	EXPEDITED (15-DAY)		HO, OT	ES-ALLERGAN-1757544US		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Food Interaction; Haemodynamic Instability; Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Green Tea			S	Unknown	Unk		Not Reported
	Green Tea			S	Unknown	Unk		Not Reported
	Emconcor Cor			C	Oral	Unk		Not Reported
	Simvastatina Cinfa			C	Oral	20 Mg, Qd		Not Reported
	Hibor (Bemiparin Sodium)			C	Subcutaneous	3500 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14672367	NON-EXPEDITED			US-ASTRAZENECA-2018SE34792		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Increased; Erectile Dysfunction; Heart Rate Increased; Inappropriate Schedule Of Product Administration; Off Label Use	Metoprolol Succinate	S	Oral			Not Reported
	Metoprolol Succinate	S	Oral			Not Reported
	Seroquel	S	Oral			Zeneca
	Seroquel	S	Oral			Zeneca
	Escitalopram	S	Oral	Generic 10mg, Daily		Not Reported
	Cardizem	S	Oral			Not Reported
	Clonazepam	S	Oral			Not Reported
	Clonazepam	S	Oral			Not Reported
	Lipitor	S	Oral			Not Reported
	Metoprolol	S	Oral			Not Reported
	Metoprolol	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14678981	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.-2018IT12257			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree	Escitalopram			S	Oral	10 Mg Per Day		Invagen
	Abilify			S	Oral	10 Mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14679048	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1815704US		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intracranial Haematoma	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Kardegic			S	Oral			Not Reported
	Levocetirizine Dihydrochloride			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Levothyrox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14679739	EXPEDITED (15-DAY)		HO	CH-BAYER-2018-054408		82 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Xarelto			S	Oral	10 Mg, Qd		Unknown
	Aspirin Cardio 100 Mg			S	Oral	100 Mg, Qd		Bayer
	Calcimagon			S	Oral	500 Mg, Qd, Correct Dose: 500mg/800 E		Not Reported
	Cipralex			S	Oral	5 Mg, Qd		Not Reported
	Pantoprazole Sodium			S	Oral	20 Mg, Qd		Not Reported
	Remeron			S	Oral	15 Mg, Qd		Not Reported
	Risperdal			S	Oral	1 Mg, Qd		Not Reported
	Dafalgan			S	Oral	500 Mg, Qid		Not Reported
	Torem			S	Oral	30 Mg, Qd, Correct Dose:X5 Mg 4-2-0		Not Reported
	Aldactone [Spironolactone]			S	Oral	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14680056	EXPEDITED (15-DAY)		DE	FI-BAYER-2018-052023			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Fibrillation	Ciprofloxacin			S				Bayer
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14680419	EXPEDITED (15-DAY)			US-ARALEZ PHARMACEUTICALS R&D INC.-2018-ARA-000643		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Inappropriate Schedule Of	Metoprolol Succinate			S	Oral	50 Mg, Bid		Aralez Pharmaceuticals

Product Administration; Off Label Use	Metoprolol Succinate	S				Aralez Pharmaceuticals
	Escitalopram	S	Oral	10 Mg, Qd		Not Reported
	Cardizem /00489701/	S	Oral	180 Mg, Qd		Not Reported
	Clonazepam	S	Oral	1 Mg, Qd		Not Reported
	Clonazepam	S				Not Reported
	Lipitor	S	Oral	40 Mg, Qd		Not Reported
	Seroquel	S	Oral	50 Mg, Qd		Not Reported
	Seroquel	S	Oral	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14680697	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-872661			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Diarrhoea; Drug Ineffective; Nausea; Vomiting	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14681827	EXPEDITED (15-DAY)		OT	NO-PFIZER INC-2018120857		22 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Medication Error	Efexor Depot			S		Unk		Pfizer
	Sobril			S		Unk		Pfizer
	Ritalin			S	Oral	10 Mg, Unk		Not Reported
	Valium			S	Oral	5 Mg, Unk		Not Reported
	Stesolid			S	Oral	5 Mg, Unk		Not Reported
	Atarax			S	Oral	25 Mg, Unk		Not Reported
	Rohypnol			S	Unknown	Unk		Not Reported
	Imovane			S	Oral	7.5 Mg, Unk		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported

	Vallergan		S	Oral	10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14685991	DIRECT	Y				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Muscle Spasms	Escitalopram			S	Oral			Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14073495	EXPEDITED (15-DAY)		HO	AT-ALLERGAN-1757190US		47 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Off Label Use; Paraesthesia; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Seropram Konzentrat Zur Infusionsbereitung			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Alprazolam			S	Unknown	0.5 Mg, Qd		Not Reported
	Alprazolam			S	Unknown	5 Mg, Qd		Not Reported
	Temesta (Lorazepam)			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14379229	EXPEDITED (15-DAY)		HO, OT	AT-MACLEODS PHARMACEUTICALS US LTD-MAC2017008317			Unknown	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Paraesthesia; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	5 Mg, Qd		Macleods
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods
	Seropram (Citalopram Hydrobromide)			S	Intravenous drip	20 Mg, Qd, (Seropram Concentrate For Infusion Preparation)		Not Reported

Alprazolam	S	Unknown	0.5 Mg, Qd		Not Reported
Alprazolam	S	Unknown	1 Mg, Unk		Not Reported
Temesta (Lorazepam)	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14455269	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1804113US		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Pressure Decreased; Cardiomyopathy	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14627742	EXPEDITED (15-DAY)		LT, OT	IT-ALLERGAN-1813199US		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Incorrect Dose Administered; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Abilify			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14638704	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R5-165596			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Parkinson'S Disease; Product Administration Error; Tremor	Risperidone			S	Unknown	Half Tablet		Ranbaxy
	Escitalopram			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Akineton			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683009	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-159037		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Coma; Fall; Rib Fracture	Zolpidem			S	Oral	Unk		Sun
	Baclofen			S	Oral	Unk		Sun
	Lexomil Roche			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Valium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683417	NON-EXPEDITED			US-PFIZER INC-2018125856		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression	Pristiq			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683944	EXPEDITED (15-DAY)		HO	NO-ALLERGAN-1815832US			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14684145	EXPEDITED (15-DAY)		HO, OT	GB-TORRENT-00016313		70 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gastrointestinal Tube Insertion; Laryngectomy	Salbutimol Inhaler	C	Unknown	Unknown
	Escitalopram	S	Unknown	Unknown
	Prucalopride	C	Unknown	Unknown
	Morphine Sulphate	C	Unknown	Unknown
	Cald-3	C	Unknown	Unknown
	Bendroflumetheaide	C	Unknown	Unknown
	Gabapentin	C	Unknown	Unknown
	Calciferol [Ergocalciferol]	C	Unknown	Unknown
	Tiotropium Inhaler	C	Unknown	Unknown
	Alendronic Acid	C	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14684326	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MYLANLABS-2018M1018897			Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Condition Aggravated; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Escitalopram			S	Oral	10 Mg, Hs		Not Reported
	Escitalopram			S		Unk		Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Zolpidem			S	Oral	10 Mg, Od		Not Reported
	Zolpidem			S				Not Reported
	Clarithromycin			S	Oral	Unk (Bedtime), Two, 10-Day Treatment Cycles Courses		Not Reported
	Doxepin			S		Unk		Not Reported
	Doxepin			S	Oral	25 Mg, Od, At Bed Time		Not Reported
	Doxepin			S				Not Reported
	Doxepin			S				Not Reported
	Sertraline			S				Not Reported
	Sertraline			S	Oral	50 Mg, Od, (In The Morning)		Not Reported
	Bisoprolol			S	Oral	Unk		Not Reported

	Meloxicam	S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam, For About Two Years Ago	Not Reported
	Meloxicam	S		Unk	Not Reported
	Atorvastatin	S	Oral	Unk (Bedtime)	Not Reported
	Tramadol	S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam For About Two Years Ago	Not Reported
	Tramadol	S		Unk	Not Reported
	Perindopril	S	Oral	Unk	Not Reported
	Polsen	S	Unknown	10 Mg, Od, At Bed Time	Mylan
	Atoris	S	Unknown	Unk	Mylan
	Concor	S	Unknown	Unk	Mylan
	Trosicam	S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14685908	EXPEDITED (15-DAY)		OT	ES-BAYER-2018-013966			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Musculoskeletal Pain; Somnolence; Treatment Noncompliance	Paracetamol			S	Unknown	1 Df, Tid		Bayer
	Aleve			S		1 Df, Bid		Bayer
	Noctamid 2 Mg			S	Unknown	1 Df, Qd		Not Reported
	Omeprazole			S		1 Df, Qd		Not Reported
	Glibenclamida			S		2 Df, Qd		Not Reported
	Temazepam			S		Unk, Qd		Not Reported
	Amitriptyline			S		25 Mg, Qd		Not Reported
	Amitriptyline			S		12.5 Mg, Unk		Not Reported
	Amitriptyline			S		5 Mg, Unk		Not Reported
	Amlodipine			S		1 Df, Qd		Not Reported

Simvastatin	S		1 Df, Qd	Not Reported
Simvastatin	S		20 Mg, Unk	Not Reported
Escitalopram	S		1 Df, Qd	Not Reported
Topiramate	S		1 Df, Qd	Not Reported
Topiramate	S	Unknown	2 Df, Qd	Not Reported
Topiramate	S	Unknown	1 Df, Qd	Not Reported
Topiramate	S	Unknown	25 Mg, Qd	Not Reported
Topiramate	S	Unknown	12.5 Mg, Qd	Not Reported
Topiramate	S	Unknown	5 Mg, Qd	Not Reported
Topiramate	S	Unknown	1 Df, Tid	Not Reported
Topiramate	S	Unknown	20 Mg, Unk	Not Reported
Topiramate	S	Unknown	1 Df, Qd	Not Reported
Topiramate	S	Unknown	.5 Df, Unk	Not Reported
Topiramate	S	Unknown	.5 Df, Unk	Not Reported
Topiramate	S	Unknown	1 Df, Qd	Not Reported
Enalaprilhydrochlorothiazide	S		1 Df, Unk	Not Reported
Diazepam	S		.5 Dosage Forms Daily; 5 Mg	Not Reported
Tramadol	S	Unknown	3 Df, Qd; 1 Df = 37.5/325 Mg	Not Reported
Metoclopramide	C			Not Reported
Metoclopramide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14685962	EXPEDITED (15-DAY)		DE	US-MYLANLABS-2018M1020948		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Olanzapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14686686	EXPEDITED (15-DAY)		HO, OT	IN-MYLANLABS-2018M1018234		29 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania; Mood Altered; Psychotic Symptom	Cabergoline			S	Unknown	0.5 Mg, Qw		Not Reported
	Escitalopram			S	Unknown	5-10mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	13042782	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK186963		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Diclofenac Diethylammonium Salt			S	Unknown	Unk Unk, Qw		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Glaxosmithkline
	Vitamin D3			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	Unk, Qd		Glaxosmithkline
	Cosentyx			S	Subcutaneous	150 Mg, Qw		Not Reported
	Cosentyx			S	Subcutaneous	150 Mg, Qmo		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	13537421	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1718950US		19 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional	Escitalopram Oxalate Unk			S	Oral	200 Mg, In Total		Allergan

Self-Injury; Nausea; Off Label Use; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14326568	EXPEDITED (15-DAY)		DE, OT	FI-MACLEODS PHARMACEUTICALS US LTD-MAC2017007498			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Fibrillation	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Ciprofloxacin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14444511	EXPEDITED (15-DAY)		HO, LT, OT	GR-MACLEODS PHARMACEUTICALS US LTD-MAC2018008827			Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Clonus; Confusional State; Delayed Recovery From Anaesthesia; Disorientation; Drug Interaction; Fear; Hyperpyrexia; Hyperreflexia; Mental Status Changes; Muscle Rigidity; Mydriasis; Psychomotor Hyperactivity; Serotonin Syndrome	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Methylene Blue			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Not Reported
	Methylene Blue			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14573676	EXPEDITED (15-DAY)		OT	ES-SA-2018SA041186		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction; Nephrectomy	Lantus Solostar	S	Subcutaneous			Not Reported
	Solostar	S				Not Reported
	Enalapril	S	Oral			Not Reported
	Carvedilol	S	Oral			Not Reported
	Escitalopram	S	Oral			Not Reported
	Seguril	S	Oral			Not Reported
	Orvatez	S	Oral			Not Reported
	Lyxumia	C	Subcutaneous	Dose:20 Unit(S)		Not Reported
	Toujeo	C	Subcutaneous			Not Reported
	Solostar U300	C				Not Reported
	Novorapid	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14637299	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-866885		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	0-0-1		Teva
	Escitalopram			S	Oral	1-0-0		Ivax
	Irbesartan			S	Oral	1-0-0		Actavis
	Furosemide			S	Oral	1-0-0		Ivax
	Seresta 10 Mg, Comprimé			C	Oral	0-0-1		Not Reported
	Duphalac			C	Oral	1-1-1		Not Reported
	Havlane			C	Oral	0-0-1 Si Besoin		Not Reported
	Kardegic 160 Mg, Poudre Pour Solution Buvable En Sachet			C	Oral	0-1-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14654699	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1805711US		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Balanitis	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan

Candida; Depression; Gastrointestinal Candidiasis; Type 2 Diabetes Mellitus	Cardiocalm	S	Oral	3 Df, Qd	Not Reported
	Cardiocalm	S	Oral	1 Df, Qd	Not Reported
	Stelara	S	Subcutaneous	90 Mg, 1 Time Every 12 Weeks	Not Reported
	Stelara	S			Not Reported
	Stresam	S	Oral	150 Mg, Qd	Not Reported
	Stresam	S	Oral	50 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14687067	EXPEDITED (15-DAY)		OT	US-ZYDUS-019478		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Venlafaxine/Venlafaxine Hydrochloride			S				Zydus Pharm
	Escitalopram			S				Zydus Pharm
	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose ; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14687373	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US12827			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Invagen
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single Dose; In Total		Not Reported
	Venlafaxine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14688333	EXPEDITED (15-DAY)		OT	US-ACCORD-064819		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt	Escitalopram			S				Not Reported

Prolonged	Ondansetron		S	Intravenous (not otherwise specified)	Accord
	Venlafaxine/Venlafaxine Hydrochloride		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14688571	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2018011944			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Venlafaxine			S	Unknown	Unk		Macleods
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single (4 Mg,Single Dose)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14688814	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2018-010392			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram 20 Mg			S	Oral	20 Milligram, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14688821	EXPEDITED (15-DAY)		HO	PHHY2018CH049405		73 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia	Exforge Hct			S	Oral	1 Df, Qd		Novartis
	Escitalopram Mepha 5 Mg			S	Oral	5 Mg, Qd		Not Reported
	Simponi			S	Subcutaneous	1 Df, Qmo		Not Reported
	Nebilet			C	Oral	5 Mg, Qd		Not Reported
	Valdoxan			C	Oral	50 Mg, Qd		Not Reported
	Stilnox			C	Oral	5 Mg, Qd		Not Reported

	Pantozol		C	Oral	20 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14689063	EXPEDITED (15-DAY)		HO	FR-ROCHE-2090184		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise	Rivotril			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Marinol (Dronabinol)			S	Oral			Not Reported
	Acupan			S	Subcutaneous			Not Reported
	Donormyl (Doxylamine Succinate)			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Levocarnil			C	Unknown	100 Mg/Ml		Not Reported
	Cymbalta			C	Oral			Not Reported
	Theralene			C	Oral			Not Reported
	Melatonine			C	Oral			Not Reported
	Dafalgan Codeine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14689471	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1816059US		2 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Administration Error; Tachycardia	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14689488	EXPEDITED (15-DAY)		CA	NL-TEVA-2018-NL-874587			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Congenital Oral Malformation	Escitalopram Tablet, 10 Mg (Milligram)	S		10 Milligram Daily; 1 Dd 1	Ivax
	Foliumzuur	C	Unknown		Not Reported
	Davitamon	C	Unknown		Not Reported
	Cyklokapron	C	Unknown		Not Reported
	Calciumcarbonaat/Colecalciferol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14690333	EXPEDITED (15-DAY)		CA	NL-MYLANLABS-2018M1018058			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Oral Malformation	Escitalopram			S	Transplacental	10 Mg, Qd		Not Reported
	Foliumzuur			C	Transplacental			Mylan
	Davitamon			C	Transplacental			Mylan
	Cyklokapron			C	Transplacental			Mylan
	Calciumcarbonaat/Colecalciferol			C	Transplacental			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14690811	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1816318US		69 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pruritic	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14691339	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1816326US		59 YR	Male	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	13638516	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-		50 YR	Female	ITA

2017M1034158

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor; Suicide Attempt	Alprazolam			S	Oral	10 Ml, Total		Not Reported
	Escitalopram Oxalate			S	Oral	15 Ml, Total		Mylan
	Esomeprazole Sodium			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14297404	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.-2017IT26604			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Abuse; Vomiting	Escitalopram			S	Oral	10 Df, Unk In Total		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14692667	NON-EXPEDITED			IN-LUPIN LIMITED-2017-07845		17 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Sertraline			S	Unknown	50 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14692700	EXPEDITED (15-DAY)		DE, HO	FR-CIPLA LTD.-2018FR12799			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Venous Thrombosis	Escitalopram			S	Oral	1 Df, Per Day		Invagen
	Qizenday			S	Oral	3 Df, Unk		Not Reported
	Vesicare			S	Oral	1 Df, Unk		Not Reported
	Dafalgan			S	Oral	Unk		Not Reported

Baclofene	S	Oral	45 Mg, Unk		Not Reported
Xatral /00975301/	S	Oral	1 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14692709	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR12715			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Hallucination, Visual	Hydroxyzine			S	Oral	25 Mg, Per Day		Invagen
	Escitalopram			S	Oral	15 Mg, Per Day		Invagen
	Vesicare			S	Oral	10 Mg, Per Day		Not Reported
	Artotec			S	Oral	2 Df, Per Day		Not Reported
	Lyrica			S	Oral	75 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14692912	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02674		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Cocaine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Lupin
	Bupropion			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Ethanol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14693229	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018011876			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Tachycardia	Escitalopram Oral Solution			S	Oral	45 Ml, 1 Cycle		Macleods

	Risperdal		C	Oral	1 Mg/Ml, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14693480	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20180333510		73 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Dysuria; Hyponatraemia; Upper Respiratory Tract Infection	Simponi			S	Subcutaneous			Not Reported
	Exforge Hct			S	Oral			Not Reported
	Escitalopram Mepha 5 Mg			S	Oral			Not Reported
	Nebilet			C	Unknown			Not Reported
	Valdoxan			C	Unknown			Not Reported
	Stilnox			C	Unknown			Not Reported
	Pantozol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14693521	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018052435		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown	Unk		Glaxosmithkline
	Lansoprazole			S	Unknown	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14694348	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-02		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown			Hikma
	Lansoprazole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14694516	EXPEDITED (15-DAY)		HO	LT-ALLERGAN-1816293US		46 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Insomnia; Overdose; Speech Disorder	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Quetiapine			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported
	Etoricoxib			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14696033	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1816276US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Aplasia	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Qd		Allergan
	Clexane			C	Transplacental	40 Mg, Qd		Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14696233	EXPEDITED (15-DAY)		OT	US-SUNOVION-2018SUN001218			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Feeling Abnormal; Suicidal Ideation; Weight Decreased	Latuda			S	Oral			Sunovion
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	11101412	EXPEDITED (15-DAY)		OT	FR-ASTELLAS-2015EU006269		29 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dizziness	Vesicare			S	Unknown			Astellas
	Seroplex			S	Unknown			Not Reported
	Abilify			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Lexapro /01588501/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14635820	EXPEDITED (15-DAY)		HO	AT-JNJFOC-20180304736		27 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Extrapyramidal Disorder; Fluid Retention; Hospitalisation; Hypotension; Lipoma; Memory Impairment; Off Label Use; Product Prescribing Error; Rash; Schizophrenia; Suicidal Ideation; Visual Impairment	Haldol			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Akineton			S	Unknown			Not Reported
	Prothipendyl			S	Unknown			Not Reported
	Temesta (Lorazepam)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14651819	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-014350		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Furosemide			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	Unk ()		Not Reported
	Bisoprolol			S	Unknown	Unk		Aurobindo
	Bisoprolol			S	Unknown	Unk ()		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	20 Mg, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698702	NON-EXPEDITED			US-PFIZER INC-2018128151		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Ultracet			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698856	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2018-US-000543		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure; Suicide Attempt	Hydrochlorothiazide			S	Unknown	Unk		Ipca
	Amlodipine			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Venlafaxine			S	Unknown	Unk		Not Reported
	Amphetamine/Dextroamphetamine			S	Unknown	Unk		Not Reported
	Buspirone			S	Unknown	Unk		Not Reported
	Fluoxetine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698870	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018011909			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cyst	Escitalopram			S	Oral	15 Mg, Unk		Macleods
	Escitalopram			S	Oral	10 Mg, Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14699039	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2018IN13907			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Delusion; Drug Ineffective; Headache; Hypomania; Weight Increased	Escitalopram			S	Unknown	5 To 10 Mg Per Day		Invagen
	Olanzapine			S	Unknown	10 G, Per Day		Invagen
	Cabergoline			S	Unknown	0.5 Mg, Once A Week		Not Reported
	Aripiprazole			S	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14699312	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017272929		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ear Haemorrhage	Amiodarone Hcl			S	Unknown	Unk		Pfizer
	Cipralex			S	Oral			Not Reported
	Coumadin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14699375	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2018049596		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Qd		Glaxosmithkline
	Esomeprazole			S	Oral	20 Mg, Qd		Glaxosmithkline
	Valaciclovir			S	Oral	500 Mg, Qd		Glaxosmithkline
	Ramipril			S	Oral	Unk		Glaxosmithkline
	Metoclopramide			S	Oral	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14699786	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1019085		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Ceftriaxone			S		Unk		Not Reported
	Risperidone			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14699818	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-874895		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Irritability; Overdose; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Quetiapine			S	Unknown			Teva
	Quetiapine			S	Oral	Pills		Teva
	Escitalopram			S	Unknown			Ivax
	Temazepam			S	Oral	Pills		Actavis
	Oxazepam			S	Oral	Pills		Not Reported
	Naloxone			S	Intramuscular	0.8 Mg		Not Reported
	Citalopram			S	Unknown			Actavis
	Atorvastatin			C	Unknown			Not Reported
	Ferrous-Gluconate			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Spironolactone			C	Unknown			Not Reported
	Fluticasone/Salmeterol			C	Unknown			Not Reported
	Ipratroprium			C	Unknown			Not Reported
	Salbutamol			C	Respiratory (inhalation)	Metered Dose Inhalers		Not Reported

	Clopidogrel		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14700253	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1816521US		35 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antipsychotic Drug Level Increased; Seizure; Syncope	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Clozaril			S	Oral	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14700294	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1816529US		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disturbance In Attention; Poisoning Deliberate	Escitalopram Oxalate - Bp			S	Oral	27 Df, Single		Allergan
	Paracetamol			S	Oral	40 G, Single		Not Reported
	Codeine			S	Oral	6 Df, Single		Not Reported
	Alprazolam			S	Oral	15 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14700339	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-02		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure	Amlodipine			S	Oral			Westward
	Escitalopram			S	Oral			Hikma
	Hydrochlorothiazide			S	Oral			Hikma
	Venlafaxine			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Durophet (Amphetamine, Dextroamfetamine)			S	Oral			Not Reported

	Fluoxetine	S	Oral	Not Reported
	Buspirone	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14700776	EXPEDITED (15-DAY)		HO	PHHY2018FR055600		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Furosemide			S	Oral	20 Mg, Qd		Novartis
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14701107	EXPEDITED (15-DAY)		DE, HO, OT	DE-BAUSCH-BL-2018-007866		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Lorazepam			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Tavor [Lorazepam]			S	Oral			Not Reported
	Tavor			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Movicol			C				Not Reported
	Simeticone			C				Not Reported
	Eferox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14719469	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2018	13890544	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2017-39088		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Circulatory Collapse; Colour Blindness; Depressed Level Of Consciousness; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Optic Atrophy; Optic Nerve Injury; Pulmonary Oedema; Shock; Tachycardia; Toxicity To Various Agents	Amlodipine			S	Oral	150 Mg, Unk		Aurobindo
	Escitalopram			S	Oral	60 Mg, Unk		Aurobindo
	Risperidone			S	Oral	6 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2018	14701879	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-017532		30 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abdominal Pain Upper; Diarrhoea	Escitalopram			S	Oral	5 Milligram		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2018	14701896	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-017102		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyponatraemia	Escitalopram	S	Oral			Aurobindo
	Esomeprazole	S	Oral			Aurobindo
	Esomeprazole	S	Oral			Aurobindo
	Valaciclovir	S	Oral			Aurobindo
	Ramipril	S	Oral	()		Aurobindo
	Ramipril	S	Oral	()		Aurobindo
	Metoclopramide	S	Oral	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2018	14701922	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-017769		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Paraesthesia; Prescribed Underdose	Aripiprazole Tablets			S	Oral	5 Mg, Qd		Aurobindo
	Aripiprazole Tablets			S	Oral	10 Mg, Qd		Aurobindo
	Escitalopram			S	Oral	10 Mg, Qd		Aurobindo
	Escitalopram			S	Oral	20 Mg, Qd		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2018	14702070	NON-EXPEDITED			US-MYLANLABS-2018M1015400		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dyspepsia; Gastrointestinal Disorder; Gastrointestinal Pain; Swollen Tongue; Tongue Discomfort	Escitalopram			S	Oral	Unk		Not Reported
	Alprazolam			C		25 Mg, Hs		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2018	14702089	NON-EXPEDITED			US-JNJFOC-20180323071		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Fatigue; Heart Rate Increased; Insomnia; Nausea; Palpitations; Panic Attack; Thirst	Topamax	S	Oral		Not Reported
	Escitalopram	S	Oral		Not Reported
	Butalbital, Acetaminophen And Caffeine	C	Unknown	50/300/40 Mg	Not Reported
	Lorazepam	C	Unknown		Not Reported
	Coconut Oil	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14206693	EXPEDITED (15-DAY)		HO	FR-ROCHE-2025455		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic; Intentional Product Use Issue; Off Label Use	Avastin			S	Intravenous (not otherwise specified)			Not Reported
	Belustine			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Solupred (France)			S	Oral			Not Reported
	Silodyx			C	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14562928	EXPEDITED (15-DAY)		LT, OT	JP-JNJFOC-20180223737		90 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Dysuria; Feeding Disorder; Renal Impairment	Tramcet			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Furosemide			C	Oral			Not Reported
	Furosemide			C	Oral			Not Reported
	Alfacalcidol			C	Oral			Not Reported
	Nexium			C	Oral			Not Reported
	Spironolactone			C	Oral			Not Reported

	Mecobalamin	C	Oral	Not Reported
	Lyrica	C	Oral	Not Reported
	Amitiza	C	Oral	Not Reported
	Sodium Ferric Citrate	C	Oral	Not Reported
	Limaprost Alfadex	C	Oral	Not Reported
	Magnesium Oxide	C	Oral	Not Reported
	Feburic	C	Oral	Not Reported
	Quetiapine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14599012	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20180238098		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Simponi			S	Subcutaneous			Not Reported
	Seroplex			S	Oral			Not Reported
	Bilaska			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Nocertone			S	Oral			Not Reported
	Tramadol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14648538	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1017273		35 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antipsychotic Drug Level Increased; Seizure; Syncope	Clozaril			S	Oral	Unk		Mylan
	Clozaril			S	Oral	500 Mg, Unk		Mylan
	Cipralex /01588501/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14702754	EXPEDITED (15-DAY)		HO, OT	US-STRIDES ARCOLAB LIMITED-			Unknown	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure	Buspirone Hydrochloride			S	Oral	Unk		Strides
	Fluoxetine			S	Oral	Unk		Not Reported
	Amlodipine			S	Oral	Unk		Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Amphetamine			S	Oral	Unk		Not Reported
	Dextroamphetamine /00016601/			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Atorvastatin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14703326	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-168776		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Esomeprazole			S	Oral	20 Mg, Daily		Sun
	Valaciclovir			S	Oral	500 Mg, Daily		Sun
	Ramipril			S	Oral	Unk		Ranbaxy
	Metoclopramide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14703328	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-168802		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depressed Level Of Consciousness; Disturbance In Attention; Intentional Overdose; Poisoning Deliberate	Escitalopram		S	Oral	Unk			Not Reported
	Paracetamol	Y	S	Oral	Unk			Ohm Lab
	Alprazolam		S	Oral				Not Reported
	Codeine		S	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14704309	EXPEDITED (15-DAY)		HO	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018011959			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Disorder; Priapism	Escitalopram Oxalate			S	Oral	Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14704412	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018011965			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disturbance In Attention; Intentional Overdose; Poisoning Deliberate	Escitalopram Oxalate			S	Oral	27 Df, Unk		Macleods
	Paracetamol			S	Oral	40 G, Unk		Not Reported
	Codeine			S	Oral	6 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14704665	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-017472		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown			Aurobindo
	Loperamide			C	Unknown			Not Reported
	Lansoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14705249	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1020176		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg Single Dose		Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14705768	EXPEDITED (15-DAY)		HO, LT, OT	US-ELI_LILLY_AND_COMPANY-US201803012042		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose	Fluoxetine Hydrochloride			S	Oral	Unk Unk, Unknown		Eli Lilly And Co
	Amlodipine			S	Oral	Unk Unk, Unknown		Not Reported
	Venlafaxine			S	Oral	Unk Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported
	Atorvastatin			S	Oral	Unk Unk, Unknown		Not Reported
	Hydrochlorothiazide			S	Oral	Unk Unk, Unknown		Not Reported
	Amphetamine			S	Oral	Unk Unk, Unknown		Not Reported
	Dextroamphetamine /00016601/			S	Unknown	Unk Unk, Unknown		Not Reported
	Buspirone			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	9733385	EXPEDITED (15-DAY)		DE, LT, OT	NO-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-BI-40		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Self-Injury;	Catapresan			S	Unknown	50 Mg, Unk		Boehringer Ingelheim

Medication Error; Overdose; Sedation; Unevaluable Event	Sobril		S	Unknown	Unk	Not Reported
	Rivotril		S	Unknown	Unk	Not Reported
	Oxynorm		S	Unknown		Not Reported
	Pinex Forte		S	Unknown	Unk	Not Reported
	Tramadol Hydrochloride		S	Unknown	Unk	Not Reported
	Sarotex		S	Unknown	Unk	Not Reported
	Vival		S	Unknown	Unk	Not Reported
	Imovane		S	Oral	Unk	Not Reported
	Orfiril		S	Unknown	1200 Mg, Unk	Not Reported
	Cipralex		S	Unknown	Unk	Not Reported
	Lamictal		S	Unknown	100 Mg, Unk	Not Reported
	Nozinan		S	Unknown	Unk	Not Reported
	Remeron		S	Unknown	Unk	Not Reported
	Atarax		S	Unknown	Unk	Not Reported
	Truxal		S	Unknown	Unk	Not Reported
	Nobligan		S	Unknown	200 Mg, Unk	Not Reported
	Seroquel		S	Unknown	Unk	Not Reported
	Cipramil [Citalopram Hydrobromide]		S	Unknown	Unk	Not Reported
	Cyanocobalamin		C	Unknown	Unk	Not Reported
	Diamorphine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14145390	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1055962		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual	Escitalopram			S	Oral	10 Mg, Bid		Not Reported
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
	Escitalopram			S		7.5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported

Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor; Wound

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14491260	EXPEDITED (15-DAY)		HO, OT	PHHY2017AT199893		57 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Increased Appetite; Prescribed Overdose; Weight Increased	Quetiapine			S	Unknown	50 Mg, Qd		Novartis
	Quetiapine			S	Unknown	100 Mg, Qd		Novartis
	Quetiapine			S	Unknown	200 Mg, Qd		Novartis
	Quetiapine			S	Unknown	50 Mg, Qd		Novartis
	Quetiapine			S	Unknown	400 Mg, Qd		Novartis
	Quetiapine			S	Unknown	500 Mg, Qd		Novartis
	Quetiapine			S	Unknown	450 Mg, Qd		Novartis
	Quetiapine			S	Unknown	500 Mg, Qd		Novartis
	Quetiapine			S	Unknown	400 Mg, Qd		Novartis
	Quetiapine			S	Unknown	300 Mg, Qd		Novartis
	Quetiapine			S	Unknown	200 Mg, Qd		Novartis
	Quetiapine			S	Unknown	100 Mg, Qd		Novartis
	Quetiapine			S	Unknown	100 Mg, Qd		Novartis
	Quetiapine			S	Unknown	50 Mg, Qd		Novartis
	Quetiapine			S	Unknown	100 Mg, Qd		Novartis
	Quetiapine			S	Unknown	50 Mg, Qd		Novartis
	Olanzapine			S	Unknown	10 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	15 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	5 Mg, Qd		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Cipralex			S	Oral	15 Mg, Qd		Not Reported
	Cipralex			S	Oral	20 Mg, Qd		Not Reported

Cipralex	S	Oral	30 Mg, Qd	Not Reported
Pregabalin	S	Unknown	150 Mg, Unk	Not Reported
Pregabalin	S	Oral	300 Mg, Unk	Not Reported
Pregabalin	S	Unknown	450 Mg, Unk	Not Reported
Seroquel	S	Oral	50 Mg, Unk	Not Reported
Seroquel	S	Oral	400 Mg, Unk	Not Reported
Seroquel	S	Oral	500 Mg, Unk	Not Reported
Seroquel	S	Oral	450 Mg, Unk	Not Reported
Seroquel	S	Oral	300 Mg, Unk	Not Reported
Seroquel	S	Oral	100 Mg, Unk	Not Reported
Seroquel	S	Oral	100 Mg, Unk	Not Reported
Seroquel	S	Oral	200 Mg, Unk	Not Reported
Seroquel	S	Oral	50 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	1.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	1.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Unk	Not Reported
Molaxole	C	Unknown	1 Df, Unk	Not Reported
Molaxole	C	Unknown	1 Df, Unk	Not Reported
Molaxole	C	Unknown	1 Df, Unk	Not Reported
Molaxole	C	Unknown	1 Df, Unk	Not Reported
Molaxole	C		2 Df, Unk	Not Reported
Molaxole	C		3 Df, Unk	Not Reported
Rivotril	C	Unknown	1 Mg, Unk	Not Reported
Rivotril	C	Oral	Unk	Not Reported

Cymbalta	C	Unknown	30 Mg, Unk		Not Reported
Cymbalta	C	Unknown	30 Mg, Unk		Not Reported
Combithyrex	C	Unknown	1 Df, Unk		Not Reported
Quetiapin	C	Unknown	50 Mg, Unk		Not Reported
Quetiapin	C	Unknown	50 Mg, Unk		Not Reported
Lamotrigin	C	Unknown	50 Mg, Unk		Not Reported
Lamotrigin	C	Unknown	50 Mg, Unk		Not Reported
Thyrex	C	Oral	50 Ug, Unk		Not Reported
Zyprexa	C		5 Mg, Unk		Not Reported
Zyprexa	C		10 Mg, Unk		Not Reported
Zyprexa	C	Unknown	15 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14681641	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2018117792		83 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Thrombocytopenia	Aldactone			S	Oral	25mg, 1x/Day		Pfizer
	Pantoprazol Sandoz			S	Oral	20mg, 1x/Day		Not Reported
	Aspirin Cardio			S	Oral	100mg, 1x/Day		Not Reported
	Calcimagon /00751501/			S	Oral	500mg/800 E Once Daily		Not Reported
	Cipralex /01588501/			S	Oral	5mg, 1x/Day		Not Reported
	Remeron			S	Oral	15mg, 1x/Day		Not Reported
	Risperdal			S	Oral	1mg, 1x/Day		Not Reported
	Xarelto			S	Oral	10mg, 1x/Day		Not Reported
	Dafalgan			S	Oral	500mg, 4x/Day		Not Reported
	Torem /01036501/			S	Oral	"X5 Mg 4-2-0"		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14704901	EXPEDITED (15-DAY)		OT	PHHY2018TH054307		69 YR	Male	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Ganglia Infarction; Bradykinesia; Cerebral Atrophy; Cerebral Disorder; Cognitive Disorder; Cogwheel Rigidity; Lymphocyte Count Decreased; Mean Cell Volume Decreased; Movement Disorder; Parkinsonian Gait; Periventricular Leukomalacia; Posture Abnormal; Red Cell Distribution Width Increased; Reduced Facial Expression; Resting Tremor; Retention Cyst	Entacapone			S	Oral	1 Df, Tid		Novartis
	Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Levodopa Benserazide			C	Oral	0.75 Df, Tid		Not Reported
	Pramipexole			C	Oral	1 Df, Qd		Not Reported
	Quetiapine			C	Oral	0.5 Df, Qhs		Not Reported
	Omeprazole			C	Oral	1 Df, Qd		Not Reported
	Sennoside			C	Oral	2 Df, Qd		Not Reported
	Fenoterol Hydrobromide			C	Unknown	2 Df, Bid		Not Reported
	Procaterol			C	Oral	1 Df, Bid		Not Reported
	Theophylline			C	Oral	1 Df, Bid		Not Reported
	Manidipine			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14707162	EXPEDITED (15-DAY)		HO, OT	US-ORION CORPORATION ORION PHARMA-18_00003298		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure	Buspirone			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Amfetamine-Dexamfetamine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14707249	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US14446			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Feeling Jittery; Paraesthesia; Product Dose Omission	Sertraline			S	Oral	25 Mg, Qd		Invagen
	Escitalopram			S	Unknown	Unknown		Invagen
	Ritalin			C	Unknown	5 Mg, Tid		Not Reported
	Klonopin			C	Unknown	1 Mg, A Quarter Tablet A Day		Not Reported
	Plaquenil			C	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14707848	EXPEDITED (15-DAY)		OT	PHHY2018GB057617		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Stalevo			S	Unknown	Unk		Novartis
	Entacapone			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Trimethoprim			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Carbidopa, Levodopa			S	Unknown	Unk		Not Reported
	Cabergoline			S	Unknown	Unk		Not Reported
	Septrin			S	Unknown	Unk		Not Reported
	Adcal D3			C	Unknown	Unk		Not Reported
	Rivastigmine			C	Transdermal	Unk		Not Reported
	Quetiapine			C	Unknown	Unk		Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Macrogol			C	Unknown	Unk		Not Reported
	Co-Beneldopa			C	Unknown	50/12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14707856	EXPEDITED (15-DAY)		OT	SE-MACLEODS PHARMACEUTICALS US LTD-MAC2018011966			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14708818	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2018-017893		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Irritability; Overdose; Sinus Tachycardia; Somnolence; Toxicity To Various Agents	Quetiapine			S	Unknown			Aurobindo
	Topiramate			S	Unknown			Aurobindo
	Escitalopram			S	Unknown			Aurobindo
	Citalopram			S	Unknown			Aurobindo
	Temazepam			S	Unknown			Not Reported
	Oxazepam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14709065	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-017224		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disturbance In Attention; Poisoning Deliberate	Alprazolam			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Paracetamol			S	Oral			Aurobindo
	Codeine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14709304	EXPEDITED (15-DAY)		HO	US-OTSUKA-DJ20091276		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dysarthria; Hypertension; Hypokalaemia; Mental Status Changes; Multiple Drug Therapy	Abilify			S	Unknown	15 Mg, Bid		Otsuka
	Desvenlafaxine Succinate			S	Oral	Unk, Qd		Not Reported
	Ibuprofen			S	Unknown	800 Mg, Tid		Not Reported
	Loratadine			S	Unknown	10 Mg, Qd		Not Reported
	Ambien			S	Oral	10 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	1 Mg, Bid		Not Reported
	Fluticasone			S	Unknown	1 Df, Qd (1 Dosage Form = 2 Sprays)		Not Reported
	Lexapro			S	Unknown	20 Mg, Qd		Not Reported
	Lyrica			S	Unknown	75 Mg, Qd		Not Reported
	Methocarbamol			S	Unknown	750 Mg, Tid		Not Reported
	Vicodin			S	Transdermal	1 Df, Unk (1 Dosage Form = 5/500 Units Not Specified), Prn		Not Reported
	Vivelle			S	Transdermal	0.10 Mg, Unk		Not Reported
	Zestoretic			S	Unknown	1 Df, Qd (1 Dosage Form = 20/12.5 (Units) Not Specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14710871	EXPEDITED (15-DAY)		DE	US-TARO PHARMACEUTICALS USA.,INC-2018SUN00193		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram			S	Unknown	Unk		Taro
	Olanzapine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14711508	EXPEDITED (15-DAY)		OT	DE-TEVA-802971GER		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor; Wound	Escitalopram			S	Oral	15 Milligram Daily;		Ivax
	Escitalopram			S	Oral	15 Milligram Daily;		Ivax
	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14732983	DIRECT		HO			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Reaction; Skin Burning Sensation	Escitalopram 5mg Tablets Cipla			S	Oral	Quantity:1 Tablet(S);	2 DAY	Cipla
	Symbicort			C				Not Reported
	Alprazolam			C				Not Reported
	Spiriva Respimat			C				Not Reported
	Fluticasone Nasal Spray			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14713100	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-065230		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure	Amlodipine			S	Oral			Accord
	Escitalopram			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Not Reported

	Atorvastatin	S	Oral		Not Reported
	Amfetamine/Dexamfetamine	S	Oral		Not Reported
	Fluoxetine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14714385	EXPEDITED (15-DAY)		HO	CA-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00169		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Quetiapine			S	Unknown	Unk,		Sciegen
	Temazepam			S	Unknown	Unk		Not Reported
	Oxazepam			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Topiramate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14714902	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1816939US		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Disorder; Priapism	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14714903	EXPEDITED (15-DAY)		OT	NO-ALLERGAN-1816938US		19 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Haemorrhage; Vaginal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Cerazette (Desogestrel)			C	Oral	1 Df (75 Mcg), Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14715637	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2018-		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14715978	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1816945US		33 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14716356	EXPEDITED (15-DAY)		HO	PHHY2018FR058753		91 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Lansoprazole			S	Oral	30 Mg, Unk		Novartis
	Gliclazide			S	Oral	60 Mg, Unk		Not Reported
	Stilnox			S	Oral	1 Df, Unk		Not Reported
	Efferalgan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14716376	EXPEDITED (15-DAY)		OT	PHHY2016CA172003		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract	Voltaren			S	Unknown	Unk		Not Reported
	Voltaren			S	Unknown	Unk, Qw		Not Reported

Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Methotrexate	S	Unknown	Unk		Novartis
	Escitalopram	S	Unknown	Unk, Qd		Not Reported
	Cosentyx	S	Subcutaneous	150 Mg, Qw		Not Reported
	Cosentyx	S	Subcutaneous	150 Mg, Qmo		Not Reported
	Cosentyx	S	Unknown	Unk		Not Reported
	Vitamin D3	S	Unknown	Unk		Not Reported
	Mouth Wash (Eucalyptol\ Menthol\Methyl Salicylate\Thymol)	S	Unknown			Not Reported
	Humira	C	Unknown	Unk		Not Reported
	Enbrel	C	Unknown			Not Reported
	Remicade	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	13383671	EXPEDITED (15-DAY)		HO	PHHY2017IT043382		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram			S	Oral	270 Mg, Once/Single (Total)		Not Reported
	Quetiapine			S	Oral	Unk		Novartis
	Carbolithium			S	Oral	1500 Mg, Once/Single (Total)		Not Reported
	Etiltox			S	Oral	1800 Mg, Once/Single (Total)		Not Reported
	Ethyl Alcohol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14218267	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1767215US		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

	Avastin	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Belustine	S	Oral	40 Mg, Cyclical		Not Reported
	Solupred (Prednisolone)	S	Oral	40 Mg, Qd		Not Reported
	Xanax	C		Unk		Not Reported
	Silodyx	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14378336	EXPEDITED (15-DAY)		HO	AT-ALLERGAN-1000074347		19 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	15 Mg, Qd		Allergan
	Aripiprazole			S	Oral	2.5 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Atarax			C	Oral	Unk (25-50 Mg), Qd		Not Reported
	Atarax			C	Oral	25 Mg, Qd		Not Reported
	Atarax			C	Oral	50 Mg, Qd		Not Reported
	Atarax			C	Oral	25 Mg, Qd		Not Reported
	Seroquel			C	Unknown	50 Mg, Qd		Not Reported
	Seroquel			C	Unknown	75 Mg, Qd		Not Reported
	Sertraline Hydrochloride			C	Unknown	25 Mg, Qd		Not Reported
	Sertraline Hydrochloride			C	Unknown	50 Mg, Qd		Not Reported
	Probiotics			C	Unknown	1 Df, Qd		Not Reported
	Mexalen			C	Oral	500 Mg, Qd		Not Reported
	Mexalen			C	Oral	500 Mg, Qd		Not Reported
	Mexalen			C	Oral	500 Mg, Qd		Not Reported
	Praxiten			C	Oral	15 Mg, Qd		Not Reported
	Praxiten			C	Oral	7.5 Mg, Qd		Not Reported

	Praxiten	C	Oral	15 Mg, Unk	Not Reported
	Methylprednisolone	C		Unk	Not Reported
	Zoldem	C	Oral	10 Mg, Qd	Not Reported
	Zoldem	C	Oral	5 Mg, Qd	Not Reported
	Temesta (Lorazepam)	C	Unknown	1-2 Mg, Qd	Not Reported
	Hova	C	Unknown	1 Df, Unk	Not Reported
	Aerius (Ebastine)	C	Unknown	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14718610	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-877840		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral			Ivax
	Levonelle			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14718676	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-878480		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Escitalopram			S	Oral			Ivax
	Valsartan			S	Oral			Teva
	Bromazepam			S	Oral			Not Reported
	Prazepam			S	Oral			Not Reported
	Xeroquel			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14719438	EXPEDITED (15-DAY)		OT	DE-CIPLA LTD.-2018DE13815			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Abdomen; Drug	Escitalopram			S	Unknown	5 Df, (5-0-0)		Invagen

Interaction	Seroquel	S	Unknown	125 Df, (50-25-50)	Not Reported
	Leponex	C	Unknown	100-0-75	Not Reported
	Levomepromazin /00038601/	C	Unknown	25 Df, (25-25-25)	Not Reported
	Eisensulfat	C	Unknown	1 Df, (1-0-0)	Not Reported
	Kalinor /00031402/	C	Unknown	Unk (1-0-0)	Not Reported
	Delix /00885601/	C	Unknown	5 Df, (5-0-0)	Not Reported
	Pantoprazol Abz Protect	C	Unknown	20 Df, (20-0-0)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14719889	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2018IN14297			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram			S	Unknown	60 Mg, Unk		Invagen
	Sertraline			S	Unknown	100 Mg, Unk		Invagen
	Fluoxetine			S	Unknown	50 Mg, Unk		Not Reported
	Fluvoxamine			S	Unknown	50 Mg, Unk		Not Reported
	Clomipramine			S	Unknown	200 Mg, Unk		Not Reported
	Buspirone			S	Unknown	15 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14719893	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2018IN13985			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Acneiform	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14720015	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US13971			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Escitalopram			S	Unknown	Unk		Invagen

Drug Ineffective; Lethargy; Suicidal Ideation; Weight Increased	Risperidone		S	Unknown	Unk	Cipla
	Risperidone		S	Unknown	Unk	Cipla
	Gabapentin		S	Unknown	Unk	Invagen
	Lorazepam		S	Unknown	Unk	Not Reported
	Aripiprazole		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14720284	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2018-009877		38 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome	Dexamethasone			S	Oral			Valeant
	Escitalopram			S	Oral			Not Reported
	Hidroaltesona			S	Oral	Compress 10 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14720672	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1021268		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma	Escitalopram Mylan			S	Oral	1 Df, Qd		Mylan
	Eliquis			S	Oral	2 Df, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14723027	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1817198US		23 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Paraesthesia	Escitalopram Oxalate Unk			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14723075	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1816951US		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Skin Reaction	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Esomeprazole			C	Oral			Not Reported
	Ventoline			C	Respiratory (inhalation)			Not Reported
	Lasilix Special			C	Oral			Not Reported
	Renitec [Enalapril Maleate]			C	Oral			Not Reported
	Flixotide			C	Respiratory (inhalation)			Not Reported
	Molsidomine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14723077	EXPEDITED (15-DAY)		DS, HO, OT	FR-ALLERGAN-1816535US		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Major Depression	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14744825	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Not Reported
	Paxil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	10930214	NON-EXPEDITED			US-PFIZER INC-2015096821		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer

	Dilantin	S	Unk	Pfizer
	Oxycodone	S	Unk	Not Reported
	Toradol	S	Unk	Not Reported
	Metformin	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Tramadol	S	Unk	Not Reported
	Stadol	S	Unk	Not Reported
	Methadone	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported
	Terbinafine	S	Unk	Not Reported
	Triamterene/Hctz	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14155030	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US02137			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Sertraline			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk, Generic		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14366071	EXPEDITED (15-DAY)		HO	AT-MACLEODS PHARMACEUTICALS US LTD-MAC2017008190			Unknown	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Parkinsonism	Escitalopram Tablet			S	Oral	5 Mg, Unk		Macleods
	Escitalopram Tablet			S	Oral	10 Mg, Unk		Macleods
	Escitalopram Tablet			S	Oral	15 Mg, Unk		Macleods
	Aripiprazole Tablet			S	Oral	2.5 Mg, Qd		Macleods

Aripiprazole Tablet	S	Oral	5 Mg, Qd	Macleods
Cipralex	S	Oral	5 Mg, Qd	Not Reported
Cipralex	S	Oral	10 Mg, Qd	Not Reported
Cipralex	S	Oral	15 Mg, Unk	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported
Aerius (Desloratadine)	C	Unknown	Unk	Not Reported
Atarax	C	Unknown	Unk	Not Reported
Atarax	C	Oral	25 Mg, Unk	Not Reported
Atarax	C	Oral	20-25 Mg	Not Reported
Atarax	C	Oral	50 Mg, Unk	Not Reported
Atarax	C	Unknown	25 Mg, Unk	Not Reported
Hova	C	Unknown	Unk	Not Reported
Proboptics	C	Unknown	1 Df, Qd	Not Reported
Mexalen	C	Oral	500 Mg, Unk	Not Reported
Mexalen	C	Oral	500 Mg, Unk	Not Reported
Mexalen	C	Oral	500 Unk, Unk	Not Reported
Praxiten	C	Unknown	Unk	Not Reported
Praxiten	C	Oral	15 Mg, Unk	Not Reported
Praxiten	C	Oral	7.5 Mg, Unk	Not Reported
Praxiten	C	Oral	15 Mg, Qd	Not Reported
Seroquel	C	Unknown	Unk	Not Reported
Seroquel	C	Unknown	75 Mg, Qd	Not Reported
Sertraline Hydrochloride	C	Unknown	Unk	Not Reported
Sertraline Hydrochloride	C	Oral	50 Mg, Qd, Tablet	Not Reported
Temesta (Lorazepam)	C	Unknown	1-2 Mg, Qd	Not Reported
Zolpidem	C	Oral	10 Mg, Unk	Not Reported
Zoldem	C	Unknown	Unk	Not Reported
Zoldem	C	Oral	5 Mg, Unk	Not Reported
Lactobacillus Acidophilus, Bifidobacterium Longum,	C	Unknown	Unk, Qd	Not Reported

Lactobacillus Rhamn

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14576149	EXPEDITED (15-DAY)		HO	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R3-163891			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Ternelin			C	Oral	1 Mg, Qd		Not Reported
	Wypax			C	Oral	0.5 Mg, Tid		Not Reported
	Depakene-R			C	Oral	400 Mg, Qd		Not Reported
	Myslee			C	Oral	5 Mg, Qd		Not Reported
	Rivotril			C	Oral	0.5 Mg, Qd		Not Reported
	Silece			C	Oral	2 Mg, Qd		Not Reported
	Depas (Etizolam)			C	Oral	0.5 Mg, Prn		Not Reported
	Daikenchuto			C	Oral	2.5 Mg, Tid		Not Reported
	Magnesium Oxide			C	Oral	250 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14726169	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-878234		33 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Chromaturia; Oedema Peripheral	Teva-Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14726204	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-878239		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Hypertension	Escitalopram			S	Oral			Ivax

	Escitalopram			S	Oral					Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14726205	EXPEDITED (15-DAY)		LT	CA-TEVA-2018-CA-878261		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Sexual Dysfunction; Suicidal Ideation	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14726249	EXPEDITED (15-DAY)		DE	US-ZYDUS-019636		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S	Unknown			Zydus Pharm
	Olanzapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14726868	EXPEDITED (15-DAY)		HO, OT	US-TORRENT-00005995		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure	Amlodipine			S	Oral	Unknown		Unknown
	Venlafaxine Hydrochloride			S	Oral	Unknown		Unknown
	Escitalopram Oxalate			S	Oral	Unknown		Unknown
	Atorvastatin Calcium			S	Oral	Unknown		Unknown
	Hydrochlorothiazide			S	Oral	Unknown		Unknown
	Dextroamphetamine			S	Oral	Unknown		Unknown
	Fluoxetine			S	Oral	Unknown		Unknown
	Buspirone Hydrochloride			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14727213	EXPEDITED (15-DAY)		OT	US-LPDUSPRD-20180497		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron Injection (4420-01)			S	Intravenous (not otherwise specified)	Single Dose Of 4 Mg		Luitpold
	Escitalopram			S	Unknown	Unknown		Not Reported
	Venlafaxine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14730573	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1819531US		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Haemorrhagic Stroke	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Eliquis			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14731007	EXPEDITED (15-DAY)		OT	US-XIROMED, LLC-XIRO20180188		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Colitis Microscopic; Diarrhoea; Rectal Tenesmus; Rectal Ulcer	Lansoprazole			S	Unknown	Unknown		Not Reported
	Escitalopram			S	Unknown	Unknown		Not Reported
	Losartan			C	Unknown	Unknown		Not Reported
	Fluticasone/Salmeterol			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731375	EXPEDITED (15-DAY)		HO, OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2018012201			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Cardiogenic Shock; Condition Aggravated; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure	Escitalopram Oxalate	S	Oral	Unk, Overdose	Macleods
	Amlodipine Besylate	S	Oral	Unk, Overdose	Macleods
	Venlafaxine	S	Oral	Unk, Overdose	Macleods
	Atorvastatin	S	Oral	Unk, Overdose	Not Reported
	Fluoxetine	S	Oral	Unk, Overdose	Not Reported
	Hydrochlorothiazide	S	Oral	Unk, Overdose	Not Reported
	Amphetamine, Dextroamphetamine	S	Oral	Unk, Overdose	Not Reported
	Buspirone	S	Oral	Unk, Overdose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731576	NON-EXPEDITED			US-TORRENT-00002671		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram (Escitalopram Oxalate)			S				Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14701951	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-017470		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Diarrhoea; Rectal Ulcer	Escitalopram			S	Unknown			Aurobindo
	Escitalopram			S		()		Aurobindo
	Lansoprazole			S	Unknown	Unk		Not Reported
	Lansoprazole			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14732265	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US14775			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown	Unk		Invagen

	Lansoprazole	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14732471	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2018IN14486			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Extrapyramidal Disorder	Escitalopram			S	Unknown	20 Mg, Unk		Invagen
	Olanzapine			S	Unknown	20 Mg, Unk		Invagen
	Lorazepam			S	Unknown	8 Mg, Unk		Not Reported
	Aripiprazole			S	Unknown	Unk		Not Reported
	Aripiprazole			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14733007	EXPEDITED (15-DAY)		OT	IN-TORRENT-00001656		29 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Drug Ineffective; Headache; Hypomania; Weight Increased	Olanzapine			S		Unknown		Unknown
	Cabergoline			C		Unknown		Unknown
	Lorazepam			C		Unknown		Unknown
	Escitalopram Oxalate			S		5-10 Mg/Day		Unknown
	Aripiprazole			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14733009	EXPEDITED (15-DAY)		OT	US-TORRENT-00005998		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram			S		Unknown		Unknown
	Lansoprazole			S		Unknown		Unknown
	Imodium			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14733039	EXPEDITED (15-DAY)		OT	US-ACCORD-065402		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram			S				Not Reported
	Lansoprazole			S				Not Reported
	Fluticasone/Salmeterol			S				Not Reported
	Losartan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14733170	EXPEDITED (15-DAY)		HO, OT	PHHY2018US054003		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure; Therapy Non-Responder	Hydrochlorothiazide			S	Oral			Not Reported
	Amphetamine+Dextroamphetamine			S	Oral			Novartis
	Fluoxetine			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Calcium			S	Unknown			Not Reported
	Calcium			S				Not Reported
	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Atropine			S	Unknown			Not Reported
	Atropine			S				Not Reported
	Glucagon			S	Unknown			Not Reported
	Glucagon			S				Not Reported
	Intralipid			S	Unknown			Not Reported
	Intralipid			S				Not Reported
	Bicarbonate (Sodium Bicarbonate)			S	Intravenous drip			Not Reported
	Bicarbonate (Sodium			S				Not Reported

Bicarbonate)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14733538	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-02735		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown	Unk		Lupin
	Lansoprazole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14733801	EXPEDITED (15-DAY)		OT	TH-ORION CORPORATION ORION PHARMA-ENT 2018-0040		69 YR	Male	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acalculia; Affective Disorder; Aggression; Anger; Bradykinesia; Cerebral Atrophy; Cerebral Disorder; Cognitive Disorder; Cogwheel Rigidity; Illusion; Irritability; Lacunar Infarction; Lymphocyte Count Decreased; Mean Cell Volume Decreased; Memory Impairment; Movement Disorder; Nightmare; Parkinsonian Gait; Periventricular Leukomalacia; Posture Abnormal; Red Cell Distribution Width Increased; Reduced Facial Expression; Resting Tremor; Retention Cyst; Sleep Talking; Somnolence	Entacapone (Trade Name Unknown)			S	Oral	Strength: 200 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	Strength: 10 Mg		Not Reported
	Levodopa Benserazide			C	Unknown	Strength: 200/50		Not Reported
	Pramipexole			C	Unknown	Strength: 0.25 Mg		Not Reported
	Quetiapine			C	Unknown	Strength: 25 Mg		Not Reported
	Omeprazole			C	Unknown	Strength: 20 Mg		Not Reported
	Sennoside			C	Unknown			Not Reported
	Fenoterol			C	Unknown			Not Reported
	Procaterol			C	Unknown	Strength: 25 Ug		Not Reported
	Theophylline			C	Unknown	Strength: 200 Mg		Not Reported
	Manidipine			C	Unknown	Strength: 10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14737681	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1819569US		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Tolerance; Prescribed Overdose; Somnolence	Escitalopram Oxalate - Bp			S	Oral	1 Df, Bid		Allergan
	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Monocrixo			S	Unknown	150 Mg, Qhs		Not Reported
	Lyrica			S	Unknown	5 Df, Daily (2 Df In The Morning And 3 Df In The Evening)		Not Reported
	Lyrica			S	Unknown	1000 Mg, Qd		Not Reported
	Urbanyl			S	Unknown	0.5 Df, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14737760	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1819604US		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Gilenya			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14738053	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018138744		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Hyponatraemia	Lyrica			S	Oral	25 Mg, 1x/Day		Pfizer
	Lyrica			S	Oral	50 Mg, 1x/Day		Pfizer
	Seresta			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	5 Mg, 1x/Day		Not Reported
	Mianserine			S	Oral	30 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14832867	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Intolerance	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	12537713	NON-EXPEDITED		OT	PHEH2016US016797		6 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mood Altered; Mouth Ulceration; Mouth Ulceration; Peripheral Swelling; Seizure	Afinitor			S	Oral	3 Mg, Qd		Novartis
	Afinitor			S	Oral	2.5 Mg, Qd		Novartis
	Afinitor			S	Oral	5 Mg, Qod (5mg Alternating Every Other Day With 7.5 Mg)		Novartis
	Afinitor			S	Oral	7.5 Mg (5mg Alternating Every Other Day With 7.5 Mg)		Novartis
	Lexapro			S	Unknown			Not Reported
	Carnitor			C	Unknown	Unk		Not Reported
	Zyrtec			C	Unknown	Prn (As Needed)		Not Reported
	Onfi			C	Unknown			Not Reported
	Risperdal			C	Unknown	Prn (As Needed)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14120971	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20171016049		14 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Intentional Overdose; Intentional Self-Injury; Poisoning	Haldol			S	Oral	Dose Was 15 Ml In Total		Not Reported
	Xanax			S	Oral			Not Reported

Deliberate; Sluggishness; Sopor	Cipralex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14421864	EXPEDITED (15-DAY)		HO, OT	DE-HETERO CORPORATE-HET2018DE00047		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Level Decreased; Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	30 Mg, Qd		Hetero
	Escitalopram			S	Oral	40 Mg,Qd		Hetero
	Pangrol /00014701/			C	Unknown	Unk, Bid		Not Reported
	Lorazepam A			C	Unknown	0.5 Mg		Not Reported
	Olanzapine Accord			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14572595	EXPEDITED (15-DAY)		LT	JP-ALLERGAN-1809963US		90 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Tramcet			C	Oral	1 Df, Qd		Not Reported
	Furosemide			C	Oral	40 Mg, Qd		Not Reported
	Furosemide			C	Oral	10 Mg, Qd		Not Reported
	Alfacalcidol			C	Oral	0.5 Mg, Unk		Not Reported
	Nexium			C	Oral	20 Mg, Unk		Not Reported
	Spironolactone			C	Oral	25 Mg, Unk		Not Reported
	Mecobalamin			C	Oral	0.5 Mg, Bid		Not Reported
	Lyrica			C	Oral	25 Mg, Bid		Not Reported
	Amitiza			C	Oral	24 Mg, Bid		Not Reported
	Sodium Ferrous Citrate			C	Oral	50 Mg, Bid		Not Reported
	Limaprost Alfadex			C	Oral	5 Mg, Bid		Not Reported

Magnesium Oxide	C	Oral	330 Mg, Tid		Not Reported
Feburic	C	Oral	20 Mg, Unk		Not Reported
Quetiapine	C	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14730558	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1819419US		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Lansoprazole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14738998	EXPEDITED (15-DAY)		HO	NO-CIPLA LTD.-2018NO14236			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	15 Mg, Daily		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14739266	EXPEDITED (15-DAY)		DS	SE-CIPLA LTD.-2018SE14195			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hyperhidrosis; Influenza Like Illness; Muscle Spasms; Paraesthesia; Pyrexia	Escitalopram			S	Unknown	Unk		Invagen
	Oxascand			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14739297	EXPEDITED (15-DAY)		OT	GB-ORION CORPORATION ORION PHARMA-ENTC2018-0126		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Stalevo			S	Unknown			Not Reported
	Trimethoprim			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Septrin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Carbidopa Levodopa			S	Unknown			Not Reported
	Entacapone (Trade Name Unknown)			S	Unknown			Not Reported
	Cabergoline			S	Unknown			Not Reported
	Co-Beneldopa			C	Unknown	Strength: 25/100 Mg		Not Reported
	Co-Beneldopa			C	Unknown	Strength: 50/12.5 Mg		Not Reported
	Co-Beneldopa			C	Unknown	Strength: 25/100 Mg, Mr		Not Reported
	Macrogol			C	Unknown			Not Reported
	Duloxetine			C	Unknown			Not Reported
	Adcal D3			C	Unknown			Not Reported
	Rivastigmine			C	Transdermal	Strength: 4.6 Mg		Not Reported
	Quetiapine			C	Unknown	Strength: 25 Mg		Not Reported
	Paracetamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14740286	EXPEDITED (15-DAY)		HO	PHHY2018FR062063		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Risperidone			S	Unknown	Unk		Novartis
	Ceftriaxone Sodium			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14740307	EXPEDITED (15-DAY)		OT	IT-VIIV HEALTHCARE LIMITED-IT2018057129		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Kivexa			S	Unknown	In Total		Viiv
	Tavor [Lorazepam]			S	Unknown	In Total		Glaxosmithkline
	Escitalopram			S	Oral	In Total		Glaxosmithkline
	Ethanol			S	Unknown	Dosage Form: Unspecified		Glaxosmithkline
	Lyrica			S	Oral	150 Mg, Unk		Not Reported
	Rezolsta			S	Oral	Unk		Not Reported
	Minias			S	Unknown	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14740480	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2018012509			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Lansoprazole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14740856	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2018057129		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Kivexa			S	Unknown	In Total		Viiv
	Tavor [Lorazepam]			S	Unknown	In Total		Glaxosmithkline
	Escitalopram			S	Oral	In Total		Glaxosmithkline
	Ethanol			S	Unknown	Dosage Form: Unspecified		Glaxosmithkline
	Lyrica			S	Oral	150 Mg, Unk		Not Reported
	Rezolsta			S	Oral	Unk		Not Reported
	Minias			S	Unknown	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14741452	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS USA.,INC-2018SUN00162		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Taro
	Venlafaxine			S	Unknown			Not Reported
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14741841	EXPEDITED (15-DAY)		DE, OT	US-DRREDDYS-USA/USA/18/0097605		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Toxicity To Various Agents	Olanzapine Film-Coated Tablet			S	Unknown			Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14741858	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1819620US		67 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Life Threatening Event; Arrhythmia; Blood Creatine Phosphokinase Abnormal; Coordination Abnormal; Ear Infection; Gustometry Abnormal; Hyperactive Pharyngeal Reflex; Impaired Self-Care; Intentional Self-Injury; Off Label Use; Pharyngitis; Pyrexia; Sepsis; Skin Disorder; Staphylococcal Infection;	Escitalopram Oxalate - Bp			S	Unknown	40 Mg, Unk		Allergan
	Truxal			C	Unknown	Unk		Not Reported
	Pk Merz			C	Unknown			Not Reported
	Trileptal			C	Unknown			Not Reported
	Seroquel			C	Unknown			Not Reported
	Haldol			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	Taxilan			C	Unknown			Not Reported
	Taxilan			C	Unknown			Not Reported

Throat Irritation; Thrombosis; Tooth Loss; Tremor; Urinary Incontinence; Withdrawal Syndrome	Metoprolol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14742843	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1820161US			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14768539	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S				Not Reported
	Ecitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	13649332	EXPEDITED (15-DAY)		OT	PHHY2017IT082145		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor; Suicide Attempt	Alprazolam			S	Oral	10 Ml, Total		Novartis
	Escitalopram			S	Oral	15 Ml, Total		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14665602	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-872986		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown			Ivax

	Lansoprazole			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14744589	EXPEDITED (15-DAY)		HO	LT-CIPLA LTD.-2018LT14658			Unknown	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Insomnia; Speech Disorder	Zolpidem Tartrate			S	Oral	Unk		Invagen
	Escitalopram			S	Oral	Unk		Invagen
	Quetiapine			S	Oral	Unk		Not Reported
	Etoricoxib			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14745720	EXPEDITED (15-DAY)		OT	PHHY2018ES062716		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Hyponatraemia	Enalapril			S	Oral	20 Mg, Qd (1-0-0)		Novartis
	Heipram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14745997	EXPEDITED (15-DAY)		HO, OT	SE-ALLERGAN-1819884US		74 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cerebrovascular Accident; Memory Impairment; Myocardial Infarction; Personality Disorder	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14746114	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1819871US		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction; Nephrectomy; Off Label Use	Escitalopram Oxalate - Bp	S	Oral	1 Df, Unk		Allergan
	Enalapril	S	Oral	2 Df, Qd		Not Reported
	Seguril	S	Oral	1 Df, Qd		Not Reported
	Carvedilol	S	Oral	1 Df, Qd		Not Reported
	Lantus Solostar	S	Subcutaneous	30 Iu, Qd		Not Reported
	Metformin	S	Unknown	0-1-0		Not Reported
	Adiro	S	Unknown	1-0-0		Not Reported
	Lixisenatide	C	Subcutaneous	Dose:20 Unit(S)		Not Reported
	Insulin Glargine	C	Subcutaneous			Not Reported
	Novorapid	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14746488	EXPEDITED (15-DAY)		OT	ES-GLENMARK PHARMACEUTICALS-2018GMK034098			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction; Nephrectomy	Escitalopram			S	Oral	1 Df, Od		Not Reported
	Carvedilol			S	Oral	1 Df, Od		Glenmark
	Lantus			S	Subcutaneous	30 Iu, Unk		Not Reported
	Enalapril			S	Oral	Q2 Df, Od		Not Reported
	Seguril			S	Oral	1 Df, Od		Not Reported
	Orvatez			S	Oral	1 Df, Od		Not Reported
	Lyxumia			C	Subcutaneous	20 Ut, Od		Not Reported
	Toujeo			C	Subcutaneous	32 Iu, Unk		Not Reported
	Novorapid			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14747156	EXPEDITED (15-DAY)		HO	AT-ELI_LILLY_AND_COMPANY-AT201804002014		27 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depressed Mood; Extrapyramidal Disorder; Fluid Retention; Hospitalisation; Hypotension; Lipoma; Memory Impairment; Off Label Use; Product Prescribing Error; Rash; Schizophrenia; Suicidal Ideation; Visual Impairment	Zyprexa	S	Unknown	30 Mg, Unknown	Eli Lilly And Co
	Haldol /00027401/	S	Unknown	40 Mg, Daily	Not Reported
	Akineton /00079501/	S	Unknown	20 Mg, Unknown	Not Reported
	Temesta /00273201/	S	Unknown	Unk Unk, Unknown	Not Reported
	Cipralex /01588501/	S	Unknown	20 Mg, Unknown	Not Reported
	Prothipendyl	S	Unknown	1 Mg, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14747445	EXPEDITED (15-DAY)		HO, OT	US-INCYTE CORPORATION-2018IN003295			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorea; Dementia; Serotonin Syndrome	Jakafi			S	Unknown	20 Mg, Bid		Incyte
	Lexapro			S		Unk		Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Prolia			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Tolterodine			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14747689	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1022495		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral	5 Mg, Unk		Not Reported
	Levonelle /00318901/			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14748245	EXPEDITED (15-DAY)		OT	SE-ANIPHARMA-2018-IT-000034		64 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Hypokalaemia; Hyponatraemia	Candesartan Hct			S	Oral	1 Dosage Form Daily		Ani
	Entact(Escitalopram Oxalate)			S	Oral	1 Df Daily		Not Reported
	Vasexten(Barnidipine Hydrochloride (Nebivolol)			C	Oral	20 Mg Capsule		Not Reported
				C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14770074	DIRECT		DS			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear; Feeling Abnormal; Gait Disturbance	Abilify			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Levothyroxine			C				Not Reported
	Ambien			C				Not Reported
	Glucerna Drinks			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14773955	DIRECT	Y				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Temperature Intolerance	Escitalopram			S	Oral			Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14102002	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1759243US			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14604376	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1015466		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Sinus Bradycardia; Suicide Attempt	Bisoce			S	Oral	300 Mg, Qd		Mylan
	Escitalopram			S	Oral	1120 Mg, Unk		Not Reported
	Zopiclone			S	Oral	315 Mg, Unk		Not Reported
	Plavix			S	Oral	2250 Mg, Qd		Mylan
	Coveram			S	Oral	60 Df, Unk		Mylan
	Seresta			S	Oral	1000 Mg, Unk		Mylan
	Aldactazine			S	Oral	30 Df, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14750048	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-02		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hypotension; Myasthenia Gravis; Overdose; Presyncope	Amlodipine			S	Unknown			Westward
	Amlodipine			S	Unknown			Westward
	Codeine			S	Unknown			Westward
	Escitalopram			S	Unknown			Hikma
	Losartan			S	Unknown			Westward
	Clopidogrel			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Carvedilol			C	Unknown			Not Reported
	Hydralazine			C	Unknown			Not Reported
	Olmesartan			C	Unknown			Not Reported
	Finasteride			C	Unknown			Not Reported
	Niacin			C	Unknown			Not Reported

	Mirtazapine	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Simvastatin	C	Unknown	Not Reported
	Nitroglycerin	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14751328	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018012559			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram Oxalate			S	Oral	7 Df, Total		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14751547	EXPEDITED (15-DAY)		DE, OT	SK-ALLERGAN-1820042US		72 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage Intracranial	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Pradaxa			S	Oral	300 Mg, Qd		Not Reported
	Pradaxa			S				Not Reported
	Cynt			C	Unknown	0.4 Mg, Qd		Not Reported
	Valsacor			C	Unknown	320 Mg, Qd		Not Reported
	Detralex			C	Unknown	Unk		Not Reported
	Aricept			C	Unknown	5 Mg, Qd		Not Reported
	Siofor			C	Unknown	500 Mg, Qd		Not Reported
	Helidac			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	10 Mg, Qd		Not Reported
	Preductal			C	Unknown	Unk		Not Reported
	Carvedilol			C	Unknown	12.5 Mg, Qd		Not Reported
	Vitacalcin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14751948	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-020063		42 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S	Oral	In Total		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14751954	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-019392		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Escitalopram Film-Coated Tablets			S	Oral	In Total		Aurobindo
	Ethanol			S	Unknown	Dosage Form: Unspecified ()		Not Reported
	Lyrica			S	Oral	()		Not Reported
	Rezolsta			S	Oral	()		Not Reported
	Tavor /00273201/			S	Unknown	In Total		Not Reported
	Minias			S	Unknown	In Total		Not Reported
	Kivexa			S	Unknown	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14751993	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2018-019734		38 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Dexametasona /00016001/			S	Oral			Not Reported
	Hidroaltesona			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14753589	EXPEDITED (15-DAY)		DE, LT, OT	US-TEVA-2018-US-879660		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Olanzapine			S	Unknown			Teva
	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14753850	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1820179US		21 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	15 - 20 Tablets		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14779955	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Lexapro			S				Not Reported
	Remeron			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	13156332	EXPEDITED (15-DAY)		DE	CA-ALLERGAN-1702903US		30 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Anxiety; Completed Suicide; Depression; Insomnia; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Ativan			C	Unknown	4 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14234886	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-SYNTHON BV-NL01PV17_45405			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal	Levocetirizine Dihydrochloride			S	Transplacental	5 Mg, Qd (Tablet)		Not Reported

Malformation; Trisomy 18	Levocetirizine Dihydrochloride		S	Transplacental	5 Mg, Qd (Film-Coated Tablet)	Not Reported
	Avamys		S	Transplacental	2 Unk, Qd	Not Reported
	D-Cure		S	Transplacental	25 Kiu, Unk	Not Reported
	Flixotide		S	Transplacental	500 Mg, Qd	Not Reported
	Nucala		S	Transplacental	100 Mg, Unk	Not Reported
	Pantomed /01263204/		S	Transplacental	Unk	Not Reported
	Relvar Ellipta		S	Transplacental	1 Unk, Qd	Not Reported
	Sipralexa		S	Transplacental	10 Mg, Unk	Not Reported
	Ventolin /00139502/		S	Transplacental	100 Mg, Unk	Not Reported
	Xanthium (Theophylline)		S	Transplacental	200 Mg, Qd	Not Reported
	Seretide		S	Transplacental	Unk	Not Reported
	Fluticasone Furoate		S	Transplacental	1 Unk, Qd	Not Reported
	Pantoprazole Sodium Sesquihydrate		S		Unk	Not Reported
	Theophylline		S		Unk	Not Reported
	Vilanterol Trifenatate		S	Transplacental	1 Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14323642	EXPEDITED (15-DAY)		DE, LT, OT	NO-CONCORDIA PHARMACEUTICALS INC.-E2B_00009040		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Self-Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Clonidine			S	Unknown	Strength 25 Mg, 50 Mg		Concordia
	Atarax			S	Unknown	Unk		Not Reported
	Sobril			S	Unknown	Unk		Not Reported
	Truxal			S	Unknown	600 To 1200mg		Not Reported
	Truxal			S				Not Reported
	Vival			S	Unknown	Unk		Not Reported
	Vival			S				Not Reported
	Oxynorm			S	Unknown	10 Mg, Unk, Strength:5 To 10mg		Not Reported

	Oxynorm	S			Not Reported
	Nozinan	S	Unknown	Unk	Not Reported
	Cipramil [Citalopram Hydrobromide]	S	Unknown	Unk	Not Reported
	Seroquel	S	Unknown	Unk	Not Reported
	Pinex Forte	S	Unknown	Strength: 500/30 Mg And Pandeine	Not Reported
	Lamictal	S	Unknown	100 Mg, Unk Strength: 25 Mg, 50 Mg, 100 Mg, 25,50,100mg	Not Reported
	Orfiril	S	Unknown		Not Reported
	Remeron	S	Unknown	Unk	Not Reported
	Tramadol Hydrochloride	S	Unknown	Unk	Not Reported
	Nobligan	S	Unknown	200 Mg, Unk,	Not Reported
	Nobligan	S	Unknown	50, 200mg	Not Reported
	Cipralex	S	Unknown	Unk	Not Reported
	Rivotril	S	Unknown	Unk	Not Reported
	Sarotex	S	Unknown	Unk	Not Reported
	Imovane	S	Oral	Unk	Not Reported
	Cyanocobalamin	C	Unknown	Unk	Not Reported
	Diamorphine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14342222	EXPEDITED (15-DAY)		DS, HO	BE-SYNTHON BV-NL01PV17_45655		41 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy	Levocetirizine Dihydrochloride			S		5 Mg, Qd		Not Reported
	Avamys			S	Unknown	2 Df, Unk		Not Reported
	D-Cure			S	Unknown	25 Kiu, Unk		Not Reported
	Flixotide			S	Unknown	500 Mg, Qd		Not Reported
	Nucala			S	Subcutaneous	100 Mg, Unk		Not Reported
	Nucala			S				Not Reported

Pantomed /01263204/	S	Unknown	20 Mg, Qd		Not Reported
Relvar Ellipta	S		1 Df, Qd (Inhalation Powder)		Not Reported
Sipralexa	S	Unknown	10 Mg, Unk		Not Reported
Seretide	S	Unknown	Unk		Not Reported
Ventolin /00139501/	S		100 Mg, Unk		Not Reported
Xanthium (Theophylline)	S	Unknown	200 Mg, Qd		Not Reported
Vilanterol Trifenatate	S	Unknown	1 Df, Qd		Not Reported
Xyzal	S		5 Mg, Qd		Not Reported
Fluticasone Furoate	S		Unk (Inhalation Powder)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14544700	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-007545		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Lorazepam			S	Oral	1 Mg, Once/Single ; In Total		Aurobindo
	Entact			S	Oral	20 Mg, Once/Single ; In Total		Not Reported
	Entact			S				Not Reported
	Clozapine			S	Oral	100 Mg, Once/Single ; In Total		Not Reported
	Clozapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14611335	EXPEDITED (15-DAY)		DE, HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018010833			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia;	Sildenafil			S	Unknown	Unk		Macleods
	Exodus (Escitalopram Oxalate)			S	Unknown	Unk		Not Reported

Respiratory Failure	Phenobarbital	S	Unknown	Unk	Not Reported
	Spironolactone	S	Unknown	Unk	Not Reported
	Synagis	S	Intramuscular	150 Mg, Unk	Not Reported
	Topiramate	S	Unknown	Unk	Not Reported
	Varivax	S	Intramuscular	1 Df, Unk, Lotno And Exp Dates: M026438 - 30-Apr-2018	Not Reported
	Water	C	Unknown	4 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14755501	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-019880		14 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Overdose; Poisoning Deliberate; Sopor	Escitalopram			S	Oral	10 Dosage Form Units In Total		Aurobindo
	Haldol /00027401/			S	Oral	15 Milliliter In Total		Not Reported
	Xanax			S	Oral	12 Dosage Form Units In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14755623	EXPEDITED (15-DAY)		CA	DE-CIPLA LTD.-2018DE14932			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Renal Aplasia	Escitalopram			S	Transplacental	Unk		Invagen
	Clexane			C	Transplacental	Unk		Not Reported
	Femibion /01597501/			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14755979	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-SE-ALKEM-2017-01918			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy	Citalopram		S	Unknown	Unk	Not Reported
	Zolpidem		S	Unknown	Unk	Not Reported
	Escitalopram		S	Unknown	Unk	Not Reported
	Duloxetine		S	Unknown	Unk	Not Reported
	Lamotrigine		S	Unknown	Unk	Alkem
	Olanzapine		S	Unknown	Unk	Alkem
	Risperidone		S	Unknown	Unk	Not Reported
	Quetiapine Fumarate		S	Unknown	Unk	Alkem

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14756067	EXPEDITED (15-DAY)		OT	ES-ALKEM LABORATORIES LIMITED-ES-ALKEM-2017-00470			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Quetiapine Fumarate			S	Unknown	50 Mg, Qd		Alkem
	Olanzapine			S	Unknown	5 Mg, Qd		Alkem
	Olanzapine			S	Unknown	10 Mg, Qd		Alkem
	Olanzapine			S	Unknown	15 Mg, Qd		Alkem
	Risperidone			S	Unknown	3 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	Unknown		Not Reported
	Mirtazapine			S	Unknown	60 Mg, Qd		Not Reported
	Fluvoxamine			S	Unknown	Unknown		Not Reported
	Carbamazepine			C	Unknown	1200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14756290	EXPEDITED (15-DAY)		HO	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2017-01377		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test	Quetiapine Fumarate			S	Oral	150 Mg, Qd		Alkem

Increased	Quetiapine Fumarate		S	Oral	50 Mg, Qd	Alkem
	Lorazepam		S	Oral	0.25 Mg, Unk	Not Reported
	Lorazepam		S	Oral	1 Mg, Qd	Not Reported
	Lorazepam		S	Oral	1.5 Mg, Qd	Not Reported
	Escitalopram		S	Oral	10 Mg, Qd	Not Reported
	Escitalopram		S	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14756494	EXPEDITED (15-DAY)		OT	NL-MACLEODS PHARMACEUTICALS US LTD-MAC2018012560			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Escitalopram Tablet			S	Oral	15 Mg, Qd, (1x Per Day 1 Piece)		Macleods
	Levocetirizine Dihydrochloride			C	Unknown	Unk		Macleods
	Lorazepam			C	Unknown	1 Mg, Qd, (1mg 1x Per Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14756819	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2018-020083		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction; Nephrectomy	Carvedilol			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Lantus			S	Subcutaneous			Not Reported
	Enalapril			S	Oral			Not Reported
	Orvatez			S	Oral			Not Reported
	Seguril			S	Oral			Not Reported
	Lyxumia			C	Subcutaneous	Dose:20 Unit(S) (1)		Not Reported
	Toujeo			C	Subcutaneous			Not Reported

	Novorapid	C	Subcutaneous	()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14756877	EXPEDITED (15-DAY)		HO	PHHY2018ES064406		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Amiodarone Hydrochloride			S	Oral			Novartis
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14757462	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-019337		67 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Escitalopram Tablets			S	Unknown	1x Per Dag 1 Stuk		Aurobindo
	Lorazepam			C	Unknown	1mg 1x Per Dag		Not Reported
	Levocetirizine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14757474	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018151508		48 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Tract Infection	Celebrex			S		200 Mg, Unk		Pfizer
	Methotrexate Sodium			S		2.5 Mg, Unk		Pfizer
	Euthyrox			S		100 Ug, Unk		Not Reported
	Lipanthyl			S		200 Mg, Unk		Not Reported
	Storwin			S		10 Mg, Unk		Not Reported
	Glucophage Xr			S		500 Mg, Unk		Not Reported
	Cipralex /01588501/			S		10 Mg, Unk		Not Reported
	Zopiclone Sandoz			S		7.5 Mg, Unk		Not Reported
	Be-Tabs Prednisone			S		5 Mg, Unk		Not Reported

	Be-Tabs Folic Acid	S	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14758147	EXPEDITED (15-DAY)		LT	FR-LUNDBECK-DKLU2046569		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Tolerance; Prescribed Overdose; Somnolence	Seroplex Film-Coated Tablets			S		2 Df, Daily 1 Tablet In The Morning And In The Evening For 1 Month		Not Reported
	Seroplex Film-Coated Tablets			S		1 Df, Daily (Pharmacist Dispensed Escitalopram 20 Mg At 1 Tablet Daily As A Maximal Daily Dose)		Not Reported
	Urbanyl			S	Unknown	0.5 Df, 3x/Day (Half A Tablet In The Morning, At Noon And In The Evening For 1 Month)		Lundbeck
	Monocrixo			S	Unknown	150 Mg, 1x/Day (One Hard Capsule At Bedtime For One Month)		Not Reported
	Lyrica			S	Unknown	5 Df, Daily (2 Df In The Morning And 3 Df In The Evening) For One Month		Not Reported
	Lyrica			S	Unknown	1000 Mg, Daily For 5 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14759048	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1022858			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness; Dyspnoea; Gastric Ulcer;	Escitalopram			S	Unknown	Unk		Not Reported

Insomnia; Nausea; Panic Attack; Vertigo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14760138	EXPEDITED (15-DAY)		HO	US-IMPAX LABORATORIES, INC-2018-IPXL-01162		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Bundle Branch Block Left; Chest Discomfort; Confusional State; Dizziness; Electrocardiogram Qt Prolonged; Generalised Tonic-Clonic Seizure; Hypotension; Intentional Overdose; Myoclonus; Sinus Tachycardia; Unresponsive To Stimuli	Bupropion Hydrochloride Sr			S	Oral	22 Tablets Of 300 Mg		Impax
	Escitalopram			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14760379	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018012583			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome; Drug Interaction	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods
	Dexamethasone			S	Oral	Qq		Not Reported
	Hydroaltesone			S	Oral	20 Mg, Qd, 10 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14760402	EXPEDITED (15-DAY)		OT	ES-009507513-1804ESP005247		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Abnormal; Depression; Diabetic	Orvatez 10 Mg/10 Mg Comprimidos Recubiertos Con			S	Oral	1 Df, Qd		Merck

Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction; Nephrectomy	Pelicula					
	Carvedilol		S	Oral	1 Df, Qd	Not Reported
	Lantus		S	Subcutaneous	30 Iu, Qd	Not Reported
	Enalapril		S	Oral	2 Df, Qd	Not Reported
	Escitalopram		S	Oral	1 Df, Qd	Not Reported
	Seguril		S	Oral	1 Df, Qd	Not Reported
	Lyxumia		C	Subcutaneous	Dose:20 Unit(S)	Not Reported
	Toujeo		C	Subcutaneous	32 Iu, Qd	Not Reported
	Novorapid		C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14760523	NON-EXPEDITED			US-TEVA-2018-US-867015			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction; Fatigue; Nervousness	Oxytrol			S	Transdermal			Not Reported
	Lexapro			S				Not Reported
	Vitamin D2			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14760584	EXPEDITED (15-DAY)		OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018012474			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2018	14144902	EXPEDITED (15-DAY)		OT	PHHY2017FR157595		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S	Unknown			Not Reported
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14248863	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-PFIZER INC-2017514075		7 DAY	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Pantomed (Pantoprazole)			S	Transplacental	Unk		Pfizer
	Pantoprazole			S	Unknown	Unk		Pfizer
	Levocetirizine Dihydrochloride			S	Transplacental	5 Mg, Qd		Not Reported
	Nucala			S	Transplacental	100 Mg, Unk		Not Reported
	Nucala			S	Transplacental	100 Mg, Unk		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Seretide			S	Transplacental	Unk		Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported
	Ventolin			S	Transplacental	100 Ug, Unk		Not Reported
	Relvar Ellipta			S	Transplacental	Unk Unk, Qd		Not Reported
	Sipralexa			S	Transplacental	10 Mg, Unk		Not Reported
	Avamys			S	Transplacental	Unk, Bid		Not Reported
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported
	Vilanterol Trifenatate			S	Transplacental	1 Mg, Qd		Not Reported
	Cholecalciferol			S	Unknown	25 Kiu, Unk		Not Reported
	Theophylline			S	Unknown	Unk		Not Reported
	Fluticasone Furoate			S	Transplacental	Unk Unk, 1x/Day		Not Reported
	Xyzall			S	Transplacental	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14514402	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1000074473			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Foetal Exposure During Pregnancy; Hypotonia;	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan

Neonatal Oversedation; Respiratory Disorder Neonatal	Meilax	S	Oral	1 Mg, Qpm	Not Reported
	Meilax	S	Transplacental	1 Mg, Qd	Not Reported
	Sodium Raberprazole	C	Oral	10 Mg, Qd	Not Reported
	Sodium Raberprazole	C	Transplacental	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14719877	NON-EXPEDITED		OT	US-TEVA-2018-US-877192		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective	Lexapro Generic			S		10 Milligram Daily; 10 Mg Tablet Once Daily By Mouth In The Morning		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14741144	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0097471		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Lansoprazole Delayed-Release Capsules			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762501	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-019862		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14763801	NON-EXPEDITED			US-TEVA-2018-US-882479			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Escitalopram	S	Unknown		Ivax
	Prempro	S	Unknown		Not Reported
	Xanax	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14764999	EXPEDITED (15-DAY)		HO, LT, OT	FR-GLAXOSMITHKLINE-FR2018061951		30 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Lamictal			S	Oral	2 Df, Unk		Glaxosmithkline
	Seroplex			S	Oral	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14765429	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1820670US		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14804197	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14833181	DIRECT		OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia	Escitalopram			S	Oral	Quantity:30 Tablet(S); At Bedtime Oral		Walgreen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	12729606	EXPEDITED (15-DAY)		OT	FR-OTSUKA-DJ20071458		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Abilify			S	Transplacental	15 Mg, Qd		Otsuka
	Lexapro			S	Transplacental	10 Mg, Qd		Not Reported
	Seroplex			S	Transplacental	10 Mg, Qd		Not Reported
	Depamide			S	Transplacental	1200 Mg, Qd		Not Reported
	Seresta			S	Transplacental	Unk		Not Reported
	Largactil			S	Transplacental	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	13565376	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1720795US		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Appetite; Inhibitory Drug Interaction; Nausea; Suicidal Ideation	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Orkambi			S	Oral	Unk, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14326720	EXPEDITED (15-DAY)		OT	BE-UCBSA-2017052230		41 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy	Xyzall			S		5 Mg, Once Daily (Qd)		Ucb
	D-Cure			S		25 Kiu, Unk		Not Reported
	Seretide			S		Unk		Not Reported
	Sipralexa			S		10 Mg, Z, Tablet		Not Reported
	Vilanterol Trifenatate			S		Unk , Once Daily (Qd)		Not Reported
	Fluticasone Furoate			S		Unk, Once Daily (Qd)		Not Reported
	Flixotide			S		250 Mg, 2x/Day (Bid)		Not Reported

	Xanthium (Theophylline)	S		20 Mg, Once Daily (Qd)	Not Reported
	Pantomed (Pantoprazole Sodium Sesquihydrate)	S		20 Mg, Once Daily (Qd)	Not Reported
	Ventolin	S		100 Mg, Unk	Not Reported
	Avamys	S		Unk, 2x/Day (Bid)	Not Reported
	Mepolizumab	S	Subcutaneous	100 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14536469	EXPEDITED (15-DAY)		OT	ES-SA-2018SA026783			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Omeprazole			S	Unknown	Dose: 1		Not Reported
	Tramadol Hydrochloride/Paracetamol			S	Oral	Df = 37.5/325 Mg		Not Reported
	Paracetamol			S	Unknown			Not Reported
	Glibenclamide			S	Unknown			Not Reported
	Simvastatin			S	Unknown	Dose 1		Not Reported
	Simvastatin			S	Unknown	Dose; 1		Not Reported
	Topiramate			S	Unknown	Dose 1		Not Reported
	Topiramate			S	Unknown			Not Reported
	Diazepam			S	Unknown	Dose 1		Not Reported
	Diazepam			S	Unknown			Not Reported
	Escitalopram			S	Unknown	Dose; 1		Not Reported
	Diazepam/Sulpiride			S	Unknown	Dose; 1		Not Reported
	Enalapril/Hydrochlorothiazide			S	Unknown	1 Dosage Forms Daily; 1 Df = 20/12.5 Mg		Not Reported
	Amlodipine			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported

Lormetazepam	S	Unknown			Not Reported
Metoclopramide	C	Unknown	1 Week Treatment		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14586720	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1811297US		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Bleeding	Escitalopram Oxalate Unk			S	Unknown			Allergan
	Xarelto			S	Unknown			Not Reported
	Cardioaspirin			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Cardura			C	Unknown			Not Reported
	Lasix Fiale			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14607464	EXPEDITED (15-DAY)		DE, HO, OT	DE-JNJFOC-20180235094		1 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Lung Infiltration; Off Label Use; Oxygen Saturation Decreased; Pain; Pneumonia; Product Use Issue; Respiratory Failure	Topiramate			S	Oral			Not Reported
	Phenobarbital			S	Unknown			Not Reported
	Sildenafil Citrate			S	Unknown			Not Reported
	Varivax Ii			S	Intramuscular			Not Reported
	Spironolactone			S	Unknown			Not Reported
	Synagis			S	Intramuscular			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Nutrini			C	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14652383	NON-EXPEDITED			US-MYLANLABS-2018M1013400			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Drug Interaction	Clonazepam			S	Oral	Unk		Not Reported
	Lexapro			S		10 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14654589	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-PFIZER INC-2006063621		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Chills; Malaise; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Product Use Issue; Respiratory Arrest	Cytotec			S	Vaginal	400 Ug, 2x/Day(Twice Two Tablets At 200 Mg)		Pfizer
	Tiapridal			S	Oral	100 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	15 Mg, 1x/Day		Not Reported
	Abilify			S	Oral	15 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	15 Mg, Daily		Not Reported
	Lysanxia			C	Unknown	10 Mg To 40 Mg		Not Reported
	Imovane			C	Unknown	7 Mg, Unk		Not Reported
	Mifegyne			C	Oral	600 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14681717	EXPEDITED (15-DAY)		HO, LT, OT	CZ-TEVA-2018-CZ-870872			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened; Epilepsy; Loss Of Consciousness; Poisoning	Escitalopram			S	Oral			Ivax
	Olanzapine			S	Oral			Teva
	Metoclopramide			S	Oral			Not Reported
	Venlafaxine			S	Oral			Teva
	Levopromazine			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Melperone			S	Oral			Not Reported

	Ibuprofen		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14767728	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR15308			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Disorder; Priapism	Escitalopram			S	Oral	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14767814	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1820704US		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Depression	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Trittico			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14767871	EXPEDITED (15-DAY)		OT	FR-CIPLA LTD.-2018FR15350			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Skin Reaction	Escitalopram			S	Oral	Unk		Invagen
	Esomeprazole			C	Oral	Unk		Not Reported
	Ventoline /00139501/			C		Unk		Not Reported
	Lasilix /00032601/			C	Oral	Unk		Not Reported
	Renitec /00574902/			C	Oral	Unk		Not Reported
	Molsidomine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14767879	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR15358			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depressed Level Of Consciousness; Disturbance In Attention; Poisoning Deliberate	Escitalopram		S	Oral	27 Df, Unk	Invagen
	Paracetamol		S	Oral	40 G, Unk	Not Reported
	Codeine		S	Oral	6 Df, Unk	Not Reported
	Alprazolam		S	Oral	15 Df, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14768505	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018010950			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Intentional Overdose; Poisoning Deliberate; Sopor	Escitalopram			S	Oral	10 Df, Total,		Macleods
	Xanax			S	Oral	12 Df, Totalal, (0.25 Mg Tablets)		Not Reported
	Haldol			S	Oral	15 Ml, Total, (2 Mg / Ml Oral Drops, Solution)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14770718	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-032915			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage Urinary Tract	Eliquis			S	Oral	5 Mg, Bid		Bristol Myers Squibb
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14771826	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1820565US		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Cutaneous Lupus Erythematosus; General Physical Health Deterioration; Weight	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	12830868	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1671250US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Abilify			S	Transplacental	15 Mg, Qd		Not Reported
	Depamide			S	Transplacental	1200 Mg, Qd		Not Reported
	Seresta			S	Transplacental	Unk		Not Reported
	Largactil			S	Transplacental	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	12841971	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1672057US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Abilify			S	Transplacental	15 Mg, Qd		Not Reported
	Depamide			S	Transplacental	1200 Mg, Qd		Not Reported
	Seresta			S	Transplacental	Unk		Not Reported
	Largactil			S	Transplacental	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14240164	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1768118US		39 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Abuse; Overdose; Sopor; Tremor	Escitalopram Oxalate Unk			S	Oral	560 Mg, Unk		Allergan
	Bromazepam			S	Oral	40 Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14491803	EXPEDITED (15-DAY)		OT	PHJP2017JP009846		73 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Asthenia; Depression; Dizziness; Dyspepsia; Feeling Abnormal; Gait Inability; Gastrooesophageal Reflux Disease; Heart Rate Increased; Hyperventilation; Initial Insomnia; Malaise; Mania; Mental Disorder; Muscle Twitching; Nausea; Pain Of Skin; Phobia Of Driving; Pollakiuria; Restlessness; Sedation; Somnolence; Suicidal Ideation	Tegretol			S	Oral	1 Df, Qd		Novartis
	Tegretol			S	Oral	200 Mg, Qd		Novartis
	Tegretol			S	Oral	3 Df, Qd (2 Tablets In The Early Evening And 1 Tablet At Bedtime)		Novartis
	Tegretol			S	Oral	600 Mg, Qd		Novartis
	Tegretol			S	Oral	400 Mg, Qd		Novartis
	Tegretol			S	Oral	3 Df, Qd		Novartis
	Tegretol			S	Oral	600 Mg, Bid		Novartis
	Tegretol			S	Oral	600 Mg, Unk		Novartis
	Ternelin			S	Oral			Not Reported
	Goodmin			S	Oral	0.25 Mg, Qd		Not Reported
	Goodmin			S	Oral	Unk, Qhs (Before Bedtime)		Not Reported
	Goodmin			S	Oral	1 Df, Unk		Not Reported
	Lexapro			S	Oral	5 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Unk		Not Reported
	Depas (Etizolam)			S	Oral	6 Mg, Unk		Not Reported
	Depas			S	Oral	1.5 Mg, Qd (In 3 Divided Doses)		Not Reported
	Depas			S	Oral	2 Mg, Unk		Not Reported
	Depas			S	Oral	2 Df, Qd		Not Reported
	Depas			S	Oral	2 Mg, Unk		Not Reported

	Valproate Sodium		C	Unknown	200 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14586718	EXPEDITED (15-DAY)		CA	AU-ALLERGAN-1811010US			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14720805	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-877405		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg Single Dose		Teva
	Venlafaxine			S	Unknown			Teva
	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14731395	EXPEDITED (15-DAY)		OT	NL-MACLEODS PHARMACEUTICALS US LTD-MAC2018012212			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Diarrhoea Haemorrhagic; Haematochezia; Hypertension; Tachycardia; Wrong Technique In Product Usage Process	Quetiapine Tablet			S	Oral	12.5 Mg, Qd, Half A Tablet For The Night, Film Coated Tablet		Macleods
	Quetiapine Tablet			S				Macleods
	Escitalopram Oxalate 20mg Tablet			S	Oral	20 Mg, Qd, 1x Daily 2 Tablets		Macleods
	Colecalciferol			C	Unknown	800 Iu, Qd, 1x1		Not Reported
	Melatonin			C	Unknown	1 Mg, Qd, 1 Mg 1x1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14772375	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR15336			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Daily		Invagen
	Esomeprazole			S	Oral	20 Mg, Daily		Not Reported
	Valacyclovir			S	Oral	500 Mg, Daily		Cipla
	Ramipril			S	Oral	Unk		Invagen
	Metoclopramide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14772700	EXPEDITED (15-DAY)		HO, OT	US-HETERO CORPORATE-HET2018US00315		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Intentional Product Misuse; Seizure; Suicide Attempt	Escitalopram			S	Unknown			Hetero
	Venlafaxine			S	Unknown	Unk		Not Reported
	Amfetamine Sulfate W/Dexamfetamine			S	Unknown			Not Reported
	Buspirone /00803202/			S	Unknown	Unk		Not Reported
	Fluoxetine			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Amlodipine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14772737	EXPEDITED (15-DAY)		DE	IT-ROCHE-2108919			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Rivotril			S	Unknown			Not Reported

	Cipralex	S	Unknown		Not Reported
	Zarelis	S	Unknown		Not Reported
	Sonirem	S	Unknown		Not Reported
	Xanax	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773144	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2018-009787		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction; Nephrectomy	Enalapril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lantus Solostar			S	Subcutaneous			Not Reported
	Seguril			S	Oral			Not Reported
	Carvedilol			S	Oral			Not Reported
	Orvatez			S	Oral			Not Reported
	Lyxumia			C	Subcutaneous	Dose:20 Units 1 Unspecified In 1 Day		Not Reported
	Toujeo			C	Subcutaneous			Not Reported
	Novorapid			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773215	NON-EXPEDITED			US-TEVA-815182ACC			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dissociation; Feeling Abnormal; Tremor	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773222	NON-EXPEDITED			US-TEVA-763085ACC			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Panic Attack	Escitalopram		S	Unknown	Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773223	NON-EXPEDITED		DE	US-TEVA-781002USA		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Unknown			Ivax
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773224	NON-EXPEDITED			US-TEVA-793417ACC		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773225	NON-EXPEDITED		OT	US-TEVA-821573USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Nervous System Disorder; Product Quality Issue; Suicidal Ideation	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773226	NON-EXPEDITED			US-TEVA-429550USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773227	NON-EXPEDITED			US-TEVA-796516ACC			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773228	NON-EXPEDITED			US-TEVA-793140ACC			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia	Escitalopram			S				Ivax
	Abilify Maintena			S				Not Reported
	Abilify Maintena			S				Not Reported
	Abilify Maintena			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773245	NON-EXPEDITED			US-TEVA-818651ACC		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Insomnia; Mood Swings; Product Substitution Issue	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773246	NON-EXPEDITED			US-TEVA-786572ACC			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Decreased Appetite; Dizziness	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773247	NON-EXPEDITED			US-TEVA-429766USA		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Escitalopram			S		5 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773248	NON-EXPEDITED			US-TEVA-770158ACC			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773249	NON-EXPEDITED			US-TEVA-778758ACC			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Weight Increased	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773250	NON-EXPEDITED			US-TEVA-765860USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hyperhidrosis	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773251	NON-EXPEDITED			US-TEVA-795777ACC			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour	Escitalopram		S	Unknown	Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773252	NON-EXPEDITED			US-TEVA-2017-US-835787			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Hyperhidrosis; Product Size Issue	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773253	NON-EXPEDITED			US-TEVA-766157ACC		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Hyperhidrosis	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773254	NON-EXPEDITED			US-TEVA-816990USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773258	NON-EXPEDITED			US-TEVA-777223ACC			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective	Escitalopram			S	Unknown			Ivax
	Clonazepam			S	Unknown			Teva
	Bupropion			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773259	NON-EXPEDITED			US-TEVA-747107USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal; Product Substitution Issue	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773260	NON-EXPEDITED			US-TEVA-2017-US-827191			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram			S				Ivax
	Fondaparinux Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773261	NON-EXPEDITED			US-TEVA-784174ACC		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773262	NON-EXPEDITED		OT	US-TEVA-763231USA		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773263	NON-EXPEDITED			US-TEVA-376531USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Depression; Drug Ineffective	Escitalopram			S					Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773265	NON-EXPEDITED			US-TEVA-782498ACC		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Escitalopram			S		20 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773271	NON-EXPEDITED			US-TEVA-772465ACC			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depression; Intentional Product Misuse; Paraesthesia; Product Prescribing Error; Stress; Withdrawal Syndrome	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773272	NON-EXPEDITED			US-TEVA-763087ACC			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Escitalopram			S		10 Or 20 Mg Daily		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14774976	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC-2018SUN00203		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram	Escitalopram			S	Unknown	Unk		Taro

Qrs Complex Prolonged; Muscle Necrosis; Overdose; Rhabdomyolysis; Seizure	Venlafaxine		S	Unknown	Unk	Not Reported
	Amphetamine/Dextroamphetamine		S	Unknown	Unk	Not Reported
	Buspirone		S	Unknown	Unk	Not Reported
	Fluoxetine		S	Unknown	Unk	Not Reported
	Hydrochlorothiazide		S	Unknown	Unk	Not Reported
	Atorvastatin		S	Unknown	Unk	Not Reported
	Amlodipine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14776086	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1816295US		82 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiac Failure; Cardiac Valve Disease; Thrombocytopenia	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Pantoprazol Sandoz			S	Oral	20 Mg, Qd		Not Reported
	Remeron			S	Oral	15 Mg, Qd		Not Reported
	Risperdal			S	Oral	1 Mg, Qd		Not Reported
	Xarelto			S	Oral	10 Mg, Qd		Not Reported
	Dafalgan			S	Oral	500 Mg, Qid		Not Reported
	Torem			S	Oral	30 Mg, Qd		Not Reported
	Aldactone			S	Oral	25 Mg, Qd		Not Reported
	Aspirin Cardio			S	Oral	100 Mg, Qd		Not Reported
	Calcimagon			S	Oral	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14355449	NON-EXPEDITED		OT	US-GLAXOSMITHKLINE-US2018GSK000878			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyp2d6 Polymorphism; Drug Metabolising Enzyme Test Abnormal;	Wellbutrin			S		Unk		Glaxosmithkline
	Pamelor			S				Not Reported

Dyskinesia; Ill-Defined Disorder; Malaise; Nausea; Suicidal Ideation; Tic	Celexa	S			Not Reported
	Lexapro	S	Unk		Not Reported
	Geodon	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14421183	NON-EXPEDITED			US-NEUROCRINE BIOSCIENCES INC.-2017NBI01798		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Discomfort; Drug Interaction; Malaise; Tremor	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences
	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences
	Lexapro			S				Not Reported
	Linzess			C				Not Reported
	Lamictal			C				Not Reported
	Clonazepam			C				Not Reported
	Atorvastatin			C				Not Reported
	Loratadine			C				Not Reported
	Magnesium			C				Not Reported
	Trileptal			C		300 Mg; Take 150 Mg In The Morning, 1.5 Tablets In The Pm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14616413	EXPEDITED (15-DAY)		OT	FR-009507513-1802FRA013685		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Mirtazapine			S	Unknown	Unk		Merck
	Norset			S	Oral	Unk		Merck
	Seroplex			S	Unknown	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Aripiprazole			S	Oral	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported

	Irbesartan	C	Oral	Unk		Not Reported
	Inipomp	C	Unknown	Unk		Not Reported
	Aprovel	C	Unknown	Unk		Not Reported
	Irbesartan	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14715004	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-019551		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure; Shock; Suicide Attempt	Amlodipine			S	Oral			Zydus Pharm
	Buspirone			S	Oral			Zydus Pharm
	Escitalopram			S	Oral			Zydus Pharm
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Zydus Pharm
	Dextroamphetamine/Amphetamine			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14776887	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018012649			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Interaction; Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods
	Haldol			S	Oral	20 Drp, Qd, (Oral Solution Drops)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14778659	EXPEDITED (15-DAY)		HO, OT	US-ALEMBIC PHARMACUETICALS LIMITED-			Unknown	USA

2018SCAL000274

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Prescription Drug Used Without A Prescription; Rhabdomyolysis; Seizure	Venlafaxine Hydrochloride			S	Oral	Unk		Alembic
	Fluoxetine Hydrochloride			S	Oral	Unk		Alembic
	Hydrochlorothiazide			S	Oral	Unk		Alembic
	Amlodipine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Atorvastatin			S	Oral	Unk		Not Reported
	Buspirone			S	Oral	Unk		Not Reported
	Dextroamphetamine Saccharate, Amphe/01345401/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14779506	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2018M1023984		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure; Suicide Attempt	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Amfetamine/Dexamfetamine			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14780469	EXPEDITED (15-DAY)		HO	CZ-BAUSCH-BL-2018-010621			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Venlafaxine			S	Unknown			Not Reported
	Metoclopramide			S	Unknown			Valeant
	Ibuprofen			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Melperon			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Levomepromazine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14780662	EXPEDITED (15-DAY)		HO, OT	GB-MYLANLABS-2018M1026056		70 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Tube Insertion; Laryngectomy	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Salbutamol			C	Unknown			Mylan
	Prucalopride			C	Unknown			Mylan
	Morphine Sulphate			C	Unknown			Mylan
	Cal-D			C	Unknown			Mylan
	Bendroflumethiazide			C	Unknown			Mylan
	Gabapentin			C	Unknown			Mylan
	Calciferol /00107901/			C	Unknown			Mylan
	Tiotropium			C	Unknown			Mylan
	Alendronic Acid			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14781483	EXPEDITED (15-DAY)		HO	PHHY2018US065141		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Overdose; Seizure	Atorvastatin	S	Unknown	Unk		Not Reported
	Hydrochlorothiazide Sandoz	S	Unknown	Unk		Not Reported
	Venlafaxine	S	Unknown	Unk		Not Reported
	Escitalopram	S	Unknown			Not Reported
	Dextroamphetamine	S	Unknown			Not Reported
	Buspirone	S	Unknown	Unk		Not Reported
	Amphetamine	S	Unknown	Unk		Not Reported
	Fluoxetine	S	Unknown	Unk		Not Reported
	Amlodipine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14423876	EXPEDITED (15-DAY)			ES-AUROBINDO-AUR-APL-2018-002290		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sialoadenitis	Escitalopram			S	Unknown	()		Aurobindo
	Ondansetron			S	Unknown	()		Not Reported
	Ondansetron			S		()		Not Reported
	Dexamethasone			C		()		Not Reported
	Dexamethasone			C		()		Not Reported
	Levetiracetam			C		()		Not Reported
	Levetiracetam			C		()		Not Reported
	Temozolomide			C		()		Not Reported
	Temozolomide			C		()		Not Reported
	Cipralex			S	Oral	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14538119	NON-EXPEDITED			US-TEVA-2018-US-852125			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14712377	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2018US14043			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rash Pruritic; Skin Reaction; Suicidal Ideation; Therapy Non-Responder	Lamotrigine			S	Unknown	25 Mg, Daily		Cipla
	Lamotrigine			S	Unknown	50 Mg, Daily		Cipla
	Lamotrigine			S	Unknown	200 Mg, Daily		Cipla
	Lamotrigine			S	Unknown	50 Mg, Daily		Cipla
	Sertraline			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	10 Mg, Daily		Invagen
	Escitalopram			S		10 Mg, Unk		Invagen
	Bupropion			S	Unknown	Unk		Invagen
	Vilazodone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14781750	EXPEDITED (15-DAY)		LT	FR-CIPLA LTD.-2018FR15839			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Haemorrhagic Stroke	Escitalopram			S	Oral	5 Mg, Per Day		Invagen
	Eliquis			S	Oral	10 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14783917	EXPEDITED (15-DAY)		HO, LT, OT	TR-MACLEODS PHARMACEUTICALS US LTD-MAC2016002889			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hot Flush; Hyperhidrosis; Loss Of Consciousness; Muscle Rigidity; Mydriasis; Nervousness; Nystagmus;	Escitalopram Oxalate			S	Unknown	1400 Mg, Single		Macleods
	Escitalopram Oxalate			S				Macleods
	Moclobemide			S	Unknown	6000 Mg, Total		Not Reported
	Moclobemide			S				Not Reported

Overdose; Pupillary Reflex Impaired; Restlessness; Rhabdomyolysis; Serotonin Syndrome; Tachycardia; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14784414	EXPEDITED (15-DAY)		HO	AU-ALLERGAN-1821251US		31 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Fatigue; Feeling Abnormal; Hypoglycaemia; Insomnia; Nausea; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown	Overdose: 60 Milligram Daily		Allergan
	Desvenlafaxine			S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14784450	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1821860US		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alcohol Interaction; Coma; Drug Abuse; Electrocardiogram Qt Prolonged; Mydriasis; Overdose	Escitalopram Oxalate Unk			S	Oral	Overdose: 590 Milligram In Total		Allergan
	Delorazepam			S	Oral	Overdose: 6.5 Milligram In Total		Not Reported
	Mutabon			S	Oral	Form Strength: 2 Mg + 25 Mg; Overdose: 26 Dosage Forms In Total		Not Reported
	Depamide			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14785098	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2018159943		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Shock	Venlafaxine Hcl	S	Unknown			Pfizer
	Escitalopram Oxalate	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14785587	EXPEDITED (15-DAY)		DS	AT-TEVA-2018-AT-882475		25 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Decreased; Emotional Poverty; Loss Of Libido; Male Sexual Dysfunction; Urinary Retention; Vision Blurred	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14785794	EXPEDITED (15-DAY)		DE	CA-ALLERGAN-1822236US		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14785796	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1822352US		49 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14786820	NON-EXPEDITED			JP-ALLERGAN-1822063US		73 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

	Tegretol	S	Oral	Unk	Not Reported
	Depas (Etizolam)	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2018	14731548	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-018455		16 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Pressure Increased; Diarrhoea; Diarrhoea Haemorrhagic; Haematochezia; Heart Rate Increased; Hypertension; Tachycardia	Quetiapine Film-Coated Tablet			S	Unknown	Voor De Nacht Een Halve Tablet		Aurobindo
	Escitalopram Tablets			S	Unknown	1x Daags 2 Tabletten		Aurobindo
	Cholecalciferol			C	Intracardiac	800 International Unit, 1 X 1		Not Reported
	Melatonine			C	Unknown	1 Mg 1 X 1		Not Reported
	Melatonine			C		1 Mg 1 X 1		Not Reported
	Melatonine			C		1 Mg 1 X 1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2018	14787261	EXPEDITED (15-DAY)		LT	CZ-ROCHE-2111027			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Epilepsy; Loss Of Consciousness; Toxicity To Various Agents	Clonazepam			S	Unknown			Not Reported
	Metoclopramide			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Levopromazine			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Melperone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	13144997	EXPEDITED (15-DAY)		HO, OT	NO-APOTEX-2017AP005985		20 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Aggression; Agitation; Anxiety; Balance Disorder; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Ineffective; Feeling Abnormal; Head Injury; Hyperhidrosis; Hypomania; Hypomania; Impaired Work Ability; Impulse-Control Disorder; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Mania; Memory Impairment; Personality Disorder; Psychotic Disorder; Quality Of Life Decreased; Restlessness; Speech Disorder; Stress; Suicidal Ideation	Seroxat			S	Unknown	Unk		Apotex
	Seroxat			S	Unknown	20 Mg, Qd		Apotex
	Efexor			S	Unknown	Unk		Not Reported
	Cipralex /01588501/			S	Unknown	Unk		Not Reported
	Cipramil /00582602/			S	Unknown	10-60 Mg Daily		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Lamictal			S				Not Reported
	Seroquel			S	Unknown	Unk		Not Reported
	Seroquel			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Orfiril			S	Unknown	Unk		Not Reported
	Orfiril			S				Not Reported
	Sobril			S	Unknown	Unk, Prn		Not Reported
	Lithionit			S	Unknown	Unk		Not Reported
	Lithium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14468181	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2018AP005879		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Chronic	Alendronate			S	Unknown			Apotex
	Levetiracetam			S	Unknown	Unk		Apotex

Cholecalciferol	S	Unknown	Unk		Not Reported
Valproic Acid	S	Unknown	Unk		Not Reported
Escitalopram	S	Unknown	Unk		Not Reported
Fenofibrate	S	Unknown	Unk		Not Reported
Emtricitabine W/Tenofovir	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14473169	NON-EXPEDITED			US-APOTEX-2017AP013585		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Paxil Cr Tablets			S	Unknown			Apotex
	Lexapro			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14478548	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006110		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Hypertension	Escitalopram			S	Oral	20 Mg, Qd		Apotex
	Escitalopram			S	Oral	10 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14479030	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2018AP006120		15 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt	Escitalopram			S	Oral	20 Mg, Qd		Apotex
	Bupropion			C	Unknown	Unk		Not Reported
	Cetirizine			C	Unknown	Unk		Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14479387	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006126			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anxiety; Confusional State; Insomnia; Pain In Jaw; Somnolence; Speech Disorder; Vision Blurred	Escitalopram			S	Unknown	10 Mg, Unk		Apotex
	Lorazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14479388	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006091		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Shock Symptom	Escitalopram			S	Oral	20 Mg, Qd		Apotex
	Escitalopram			S				Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14524479	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP006699		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Abnormal; Condition Aggravated; Drug Ineffective; Mania; Rash; Sluggishness; Suicidal Ideation	Sertraline			S	Unknown	Unk		Apotex
	Oxcarbazepine			S	Unknown	Unk		Apotex
	Carbamazepine			S	Unknown	Unk		Apotex
	Risperidone			S	Unknown	Unk		Apotex
	Quetiapine			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Paroxetine			S	Unknown	Unk		Apotex
	Duloxetine			S	Unknown	60 Mg, Daily		Apotex
	Fluoxetine			S	Unknown	Unk		Apotex

Lamotrigine	S	Unknown	Unk		Apotex
Alprazolam	S	Unknown	Unk		Apotex
Venlafaxine	S	Unknown	Unk		Not Reported
Nortriptyline	S	Unknown	Unk		Not Reported
Lorazepam	S	Unknown	Unk		Not Reported
Thioridazine	S	Unknown	Unk		Not Reported
Amitriptyline	C	Unknown	Unk		Not Reported
Chlorpromazine	C	Unknown	100 Mg, Q.H.S.		Not Reported
Gabapentin	C	Unknown	300 Mg, Bid		Not Reported
Gabapentin	C	Unknown	600 Mg, Q.H.S.		Not Reported
Acamprosate	C	Unknown	666 Mg, Tid		Not Reported
Baclofen	C	Unknown	10 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14530485	NON-EXPEDITED			US-APOTEX-2017AP022227		6 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Precocious Puberty; Therapeutic Product Effect Incomplete; Weight Increased	Risperidone			S	Unknown	Unk		Apotex
	Risperidone			S				Apotex
	Aripiprazole Tablets			S	Unknown	Unk		Apotex
	Escitalopram Oxalate			S	Unknown	Unk		Apotex
	Ziprasidone Hcl			S	Unknown	Unk		Apotex
	Buspiprone Hydrochloride Tablets Usp			S	Unknown	Unk		Apotex
	Quetiapine Fumarate			S	Unknown	Unk		Apotex
	Guanfacine			S	Unknown	Unk		Not Reported
	Methylphenidate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14581705	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006913		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Inflammation; Rash Macular; Skin Lesion	Atorvastatin			S	Oral	20 Mg, Qd		Apotex
	Escitalopram Sandoz			S	Oral	10 Mg, Qd		Not Reported
	Reactine /00884302/			C	Unknown	Unk, Qd		Not Reported
	Singulair			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14655288	EXPEDITED (15-DAY)		HO, OT	AU-APOTEX-2018AP007881		66 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Tachycardia	Escitalopram			S	Unknown	10 Mg, Daily		Apotex
	Perindopril			C	Unknown	Unk		Not Reported
	Atenolol			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Lercanidipine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14667926	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP008687		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Apotex
	Ondansetron Injection Usp			S	Unknown	4 Mg, Single		Apotex
	Venlafaxine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14668760	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006129		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Depression; Depression Suicidal; Dizziness	Escitalopram		S	Oral	10 Mg, Qd	Apotex
	Bupropion		S	Oral	150 Mg, Qd	Not Reported
	Bupropion		S	Oral	300 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14672526	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP008286		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Escitalopram			S				Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14672972	EXPEDITED (15-DAY)		LT, OT	CA-APOTEX-2018AP008290		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Sexual Dysfunction; Suicidal Ideation	Escitalopram			S	Oral	Unk Unk, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14674647	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP008074			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Depression; Emotional Disorder; Fatigue	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14694095	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP009166		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Drug Abuse;	Escitalopram			S	Unknown	Unk		Apotex

Electrocardiogram Qrs Complex Prolonged; Muscle Necrosis; Overdose; Rhabdomyolysis; Seizure; Suicide Attempt	Buspirone	S	Unknown	Unk		Apotex
	Fluoxetine	S	Unknown	Unk		Apotex
	Hydrochlorothiazide	S	Unknown	Unk		Apotex
	Atorvastatin	S	Unknown	Unk		Apotex
	Amlodipine	S	Unknown	Unk		Apotex
	Venlafaxine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14713383	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP009543		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lethargy; Psychotic Disorder; Suicidal Ideation; Weight Increased	Risperidone			S	Unknown	Unk		Apotex
	Risperidone			S				Apotex
	Aripiprazole			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Gabapentin			S	Unknown	Unk		Apotex
	Sertraline			S	Unknown	Unk		Apotex
	Bupropion			S	Unknown	Unk		Apotex
	Buspirone			S	Unknown	Unk		Apotex
	Trazodone			S	Unknown	Unk		Apotex
	Lurasidone			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14713621	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP009602		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic	Escitalopram			S	Unknown	Unk		Apotex
	Lansoprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14728179	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP009041		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Fatigue; Headache; Hypersensitivity; Rash; Rash Pruritic; Skin Reaction; Therapeutic Product Effect Incomplete	Bupropion			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	10 Mg, Unk		Apotex
	Sertraline			S	Unknown	Unk		Apotex
	Lamotrigine			S	Unknown	25 Mg, Daily		Apotex
	Lamotrigine			S	Unknown	50 Mg, Daily		Apotex
	Lamotrigine			S	Unknown	200 Mg, Daily		Apotex
	Lamotrigine			S	Unknown	50 Mg, Daily		Apotex
	Divalproex			S	Oral	250 Mg, Bid		Apotex
	Divalproex			S				Apotex
	Vilazodone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14769037	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP010715		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Alprazolam			S	Unknown	27 Unk, Unk		Apotex
	Alprazolam			S				Apotex
	Lithium Carbonate			S	Unknown			Apotex
	Lithium Carbonate			S	Unknown	300 Mg, Daily		Apotex
	Escitalopram			S	Unknown			Apotex
	Sertraline			S	Unknown			Apotex
	Bupropion			S	Unknown			Apotex
	Risperidone			S	Unknown			Apotex
	Quetiapine			S	Unknown			Apotex

	Aripiprazole	S	Unknown	10 Mg, Daily		Apotex
	Aripiprazole	S				Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	13180139	EXPEDITED (15-DAY)		HO, LT, OT	TR-LUPIN PHARMACEUTICALS INC.-2016-04137		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Rhabdomyolysis; Serotonin Syndrome; Suicide Attempt	Escitalopram			S	Unknown	20 Mg, Qd		Lupin
	Escitalopram			S	Unknown	1400 Mg, Qd		Lupin
	Moclobemide			S	Unknown	300 Mg, Unk		Not Reported
	Moclobemide			S	Unknown	6400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14013361	EXPEDITED (15-DAY)		HO	PHHY2017IT130203		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Coma; Drug Abuse; Hypotension; Intentional Self-Injury	Alprazolam			S	Oral	20 Drp, Unk		Novartis
	Cipralex			S	Oral	15 Drp, Unk		Not Reported
	Halcion			S	Oral	10 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14348642	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-UCBSA-2017052565			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Xyzall			S	Transplacental	5 Mg, Once Daily (Qd)		Ucb
	Avamys			S	Transplacental	2x/Day (Bid)		Not Reported
	Seretide			S	Transplacental	Unk		Not Reported
	Sipralexa			S	Transplacental	10 Mg, Z		Not Reported
	Vilanterol Trifenatate			S	Transplacental	1 Df, Once Daily (Qd)		Not Reported
	Fluticasone Furoate			S	Transplacental	1 Df, Once Daily (Qd)		Not Reported

	Flixotide	S	Transplacental	250 Mg, 2x/Day (Bid)	Not Reported
	D-Cure	S	Transplacental	25 Kiu, Unk	Not Reported
	Pantomed (Pantoprazole Sodium Sesquihydrate)	S	Transplacental	Unk	Not Reported
	Ventolin	S		100 Mg, Unk	Not Reported
	Mepolizumab	S	Transplacental	100 Mg, Unk	Not Reported
	Xanthium (Theophylline)	S	Transplacental	200 Mg, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14425792	EXPEDITED (15-DAY)		HO	PHHY2018FR009059		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Sedation	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Alprazolam			S	Oral	0.13 Df, Unk (0,25 1/2 Cp/J)		Novartis
	Risperdal			S	Oral	1.5 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14769491	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1820676US		68 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Height Decreased; Carotid Artery Stenosis; Drug Interaction	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Aas			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14788428	EXPEDITED (15-DAY)		HO	DE-UCBSA-2018017745		44 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dyspepsia	Neupro			S	Transdermal	14 Mg, Once Daily (Qd)		Ucb
	Escitalopram			S		20 Mg, Once Daily (Qd)		Not Reported

	Ibuprofen	S	Unk	Not Reported
	Bornaprine Hydrochloride	S	4 Mg, 1-0.5-1-0	Not Reported
	Benserazide Hydrochloride W/Levodopa	C	100|25 Mg, 0-0-0-1	Not Reported
	Amantadin	C	100 Mg, 2x/Day (Bid)	Not Reported
	Amitriptylin	C	75 Mg, Once Daily (Qd)	Not Reported
	Madopar	C	1.5 Df, 4x/Day (Qid)	Not Reported
	Madopar Lt	C	25 Mg, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14788457	EXPEDITED (15-DAY)		HO, LT, OT	ES-HETERO CORPORATE-HET2018ES00344		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Myocardial Ischaemia; Tachycardia; Torsade De Pointes	Escitalopram			S	Unknown			Hetero
	Haloperidol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14790098	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1822348US		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Interaction; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Haldol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14790102	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1822359US		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

	Coversyl	S	Oral	10 Mg, Qd		Not Reported
	Fycompa	C	Oral	16 Mg, Qd		Not Reported
	Bisoce	C	Oral	10 Mg, Qd		Not Reported
	Mysoline	C	Oral	750 Mg, Qd		Not Reported
	Amlor	C	Oral	10 Mg, Qd		Not Reported
	Esidrex	C	Oral	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14790108	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1822233US		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Faecal Vomiting; Faecaloma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Antarene Codeine			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14790408	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1805527US		38 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Autonomic Nervous System Imbalance; Cognitive Disorder; Hyperhidrosis; Hyperreflexia; Labelled Drug-Drug Interaction Medication Error; Restlessness; Serotonin Syndrome; Tachypnoea; Tremor	Escitalopram Oxalate - Bp			S	Unknown	Doubled Dosage		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14794248	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-882530			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness; Dyspnoea; Gastric Ulcer; Insomnia; Nausea; Panic Attack; Vertigo	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14794551	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2018M1025034		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Condition Aggravated; Hypomagnesaemia; Mental Disorder; Torsade De Pointes	Haloperidol			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	12554651	EXPEDITED (15-DAY)		HO, LT, OT	TR-FRI-1000086063		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Rhabdomyolysis; Serotonin Syndrome; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown	1400 Mg, In Total		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Moclobemide			S	Unknown	6000 Mg, In Total		Not Reported
	Moclobemide			S	Unknown	300 Mg, Qd		Not Reported
	Moclobemide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	12572931	EXPEDITED (15-DAY)		HO, LT, OT	TR-ACCORD-042453		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Overdose; Rhabdomyolysis; Serotonin Syndrome; Suicide Attempt	Escitalopram		S	1400 Mg (Total Dose)	Not Reported
	Moclobemide		S	6000 Mg (Total Dose)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14705752	NON-EXPEDITED		OT	JP-EISAI MEDICAL RESEARCH-EC-2018-037570		77 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Aricept			S	Oral	Unknown		Not Reported
	Escitalopram Oxalate			S	Unknown	Unknown		Not Reported
	Risperidone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14721242	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2018-008812		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Metoclopramide			S	Oral			Valeant
	Ramipril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Valaciclovir			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14746115	EXPEDITED (15-DAY)		OT	NL-ALLERGAN-1819886US		16 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Pressure Increased; Diarrhoea; Haematochezia; Heart	Escitalopram Oxalate - Bp			S	Unknown	2 Tablets At Once, Once A Day		Allergan
	Escitalopram Oxalate - Bp			S		Unk		Allergan

Rate Increased; Product Administered To Patient Of Inappropriate Age	Quetiapine		S	Unknown	Before Going To Bed ½ Tablet	Not Reported
	Quetiapine		S			Not Reported
	Cholecalciferol		C	Unknown	800 Iu, Qd	Not Reported
	Melatonin		C	Unknown	1 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14778591	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180414314		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Interaction; Urinary Retention	Haldol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14797709	EXPEDITED (15-DAY)		HO	PT-ACCORD-065972		29 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Depression; Gait Disturbance; Headache; Vision Blurred	Escitalopram			S		10 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14798197	EXPEDITED (15-DAY)		LT, OT	CZ-BAUSCH-BL-2018-010302			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Epilepsy; Loss Of Consciousness; Toxicity To Various Agents	Metoclopramide			S	Unknown			Valeant
	Venlafaxine			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Levopromazine			S	Unknown			Not Reported

	Melperone	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14798530	EXPEDITED (15-DAY)		OT	PL-TEVA-2018-PL-885092			Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Feeling Abnormal; Head Titubation; Laziness; Miosis	Aviomarin			S	Unknown			Not Reported
	Dextromethorphan			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Ivax
	Thiocodin (Codeine Phosphate\Sulfogaiacol)			S	Unknown	1 Dosage Text = Codeine + Sulfogluacol		Not Reported
	Thiocodin (Codeine Phosphate\Sulfogaiacol)			S		1 Dosage Text = Codeine + Sulfogluacol		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14798668	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1822367US		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Binge Eating; Gastrectomy; Hyperphagia; Insomnia; Off Label Use; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Taxilan (Perazine Dimalonate)			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14799528	EXPEDITED (15-DAY)		OT	US-LANNETT COMPANY, INC.-US-2018LAN000638		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Lansoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14801040	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-884884		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Furosemide			S	Oral	20 Milligram Daily;		Ivax
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported
	Xarelto			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14801178	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1024968		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Bevacizumab			S	Intravenous (not otherwise specified)	Unk		Mylan
	Lomustine			S	Oral	40 Mg, Unk		Mylan
	Seroplex			S	Oral	5 Mg, Qd		Mylan
	Silodyx			C	Unknown	Unk		Mylan
	Xanax			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14802510	EXPEDITED (15-DAY)		OT	CH-GLAXOSMITHKLINE-CH2018066283		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome	Lamotrigine			S	Transplacental	150 Mg, Unk		Glaxosmithkline
	Wellbutrin			S	Transplacental	Unk		Glaxosmithkline
	Trittico			S	Transplacental	50 Mg, Unk		Not Reported
	Cipralex			S	Transplacental	40 Mg, Unk		Not Reported
	Benocten			S	Transplacental	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14802699	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018162059		80 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Dementia Alzheimer'S Type	Neurontin			S		300 Mg, Unk		Pfizer
	Seroquel			S		25 Mg, Unk		Not Reported
	Urbanol			S		10 Mg, Unk		Not Reported
	Donecept			S		10 Mg, Unk		Not Reported
	Trustan			S		40 Mg, Unk		Not Reported
	Sinemet			S		25/100 Mg		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported
	Azilect			S		1 Mg, Unk		Not Reported
	Adco-Simvastatin			S		20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14802739	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018162223		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disturbance In Attention; Intentional Overdose; Poisoning Deliberate	Alprazolam			S	Oral	15 Df, Single		Pfizer
	Paracetamol			S	Oral	40 G, Unk		Not Reported
	Escitalopram			S	Oral	27 Df, Unk		Not Reported
	Codeine			S	Oral	6 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14871197	DIRECT		DS			31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sleep Disorder; Tinnitus	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Torrent
	Ativan			C				Not Reported
	Prilosec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14871244	DIRECT	Y				60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Generic Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14141521	EXPEDITED (15-DAY)		OT	PHHY2017FR157601		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S	Unknown			Not Reported
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14312397	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-ALLERGAN-1772916US			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Premature Baby; Trisomy 18	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Unk		Allergan
	Mepolizumab			S	Transplacental	100 Mg, Unk		Not Reported
	Fluticasone Furoate			S	Transplacental	Unk Unk, Qd		Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported
	Vilanterol Trifenatate			S	Transplacental	1 Df, Qd		Not Reported
	Seretide			S	Transplacental	Unk		Not Reported
	Pantomed (Pantoprazole Sodium Sesquihydrate)			S	Transplacental	Unk		Not Reported
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported
	Ventolin			S	Transplacental	100 Ug, Unk		Not Reported
	Levocetirizine			S	Transplacental	5 Mg, Qd		Not Reported
	Avamys			S	Transplacental	Unk, Bid		Not Reported
	Pantoprazole Sodium			S	Transplacental	Unk		Not Reported

	Sesquihydrate					
	D-Cure	S	Transplacental	25 Kiu, Unk		Not Reported
	Xyzall	S	Transplacental	5 Mg, Qd		Not Reported
	Theophylline	S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14329331	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2017-034443		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Metformine			S	Oral			Santarus
	Dafalgan			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Nefopam Hydrochloride			S	Oral			Not Reported
	Diffu K			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Colchicine Opocalcium			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Tavanic			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Bisoprolol Hemifumarate			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Terbutaline Sulphate			S	Respiratory (inhalation)			Not Reported
	Irbesartan			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14698865	EXPEDITED (15-DAY)		HO, OT	CH-ASTELLAS-2018US015385		88 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Delirium; Infection; Inflammation	Xtandi			S	Oral			Astellas
	Escitalopram			S	Unknown	Unk, Unknown Freq.		Not Reported
	Fragmin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Pantozol /01263204/			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Co Diovan			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Targin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Oxynorm			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Torasemid			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Pregabalin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14702570	NON-EXPEDITED			US-JNJFOC-20180323177		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tooth Socket Haemorrhage	Xarelto			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Aspirin			S	Unknown			Not Reported
	Evoxac			S	Unknown			Not Reported
	Biotin			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Calcium Vitamin D			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Calcifediol			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Bystolic			C	Unknown			Not Reported
	Prilosec			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

	Topamax	C	Oral	Not Reported
	Ferrous Sulfate	C	Unknown	Not Reported
	Hydrodiuril	C	Unknown	Not Reported
	Xiidra	C	Unknown	Not Reported
	Hctz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14803553	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-170847		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Aripiprazole			S	Oral	Unk ()		Not Reported
	Mirtazapine			S	Unknown	()		Sun
	Seroplex			S	Unknown	Unk ()		Not Reported
	Seroplex			S	Oral	Unk ()		Not Reported
	Norset			S	Oral	Unk ()		Not Reported
	Aprovel			C	Unknown	Unk ()		Not Reported
	Inipomp			C	Unknown	Unk ()		Not Reported
	Irbesartan			C	Oral	()		Not Reported
	Kardegic			C	Unknown	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14803935	EXPEDITED (15-DAY)		OT	DE-TORRENT-00007125		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep	Escitalopram			S	Oral	Daily Dose: 15 Mg Milligram(S) Every Day		Unknown

Disorder; Suicidal
Ideation; Tremor; Wound

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14806430	EXPEDITED (15-DAY)		HO	FR-SA-2018SA110424			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Furosemide			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported
	Terbutaline			S		Respiratory (Inhalation)		Not Reported
	Pantoprazole			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Tavanic			S	Oral			Not Reported
	Nefopam			S	Oral			Not Reported
	Colchicine Opocalcium			S	Oral			Not Reported
	Dafalgan			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Diffu K			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14807385	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1822504US		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Spontaneous; Exposure During Pregnancy; Product Use In Unapproved Indication; Toxicity To Various Agents	Escitalopram Oxalate - Bp		S	Unknown	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14807398	EXPEDITED (15-DAY)		HO, OT	DE-ALLERGAN-1815648US		64 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Abdomen; Drug Interaction	Escitalopram Oxalate - Bp			S	Unknown	5-0-0		Allergan
	Seroquel			S	Unknown	50-25-50		Not Reported
	Leponex			C	Unknown	100-0-75		Not Reported
	Levomepromazine			C	Unknown	25-25-25		Not Reported
	Eisensulfat			C	Unknown	1-0-0		Not Reported
	Kalinor (Potassium Bicarbonate\Potassium Citrate)			C	Unknown	1-0-0		Not Reported
	Delix (Ramipril)			C	Unknown	5-0-0		Not Reported
	Pantoprazol Abz			C	Unknown	20-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14808795	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2018-ES-885180		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Condition Aggravated; Hypomagnesaemia; Mental Disorder; Torsade De Pointes	Haloperidol			S	Unknown	2 Milligram Daily;		Actavis
	Haloperidol			S				Actavis
	Escitalopram			S	Unknown	15 Milligram Daily;		Ivax
	Escitalopram			S				Ivax
	Pantoprazole			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14138225	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1761119US		83 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	8 Gtt, Qd		Allergan
	Ramipril + Hydrochlorothiazide			S	Oral	30 Mg, Qd		Not Reported
	Avodart			C	Oral			Not Reported
	Cardirene			C	Oral			Not Reported
	Sivastin			C	Oral			Not Reported
	Vertisec			C	Oral			Not Reported
	Metformine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14707218	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2018AU13541			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Immune Thrombocytopenic Purpura; Neuropathy Peripheral; Steroid Diabetes	Escitalopram			S	Oral	Daily, Unk		Invagen
	Hydroxychloroquine			C	Oral	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14813136	NON-EXPEDITED			US-MALLINCKRODT-T201701853			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypersomnia; Lethargy	Temazepam			S	Unknown	Unk, Unk		Mallinckrodt
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14813288	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2018AU16596			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Fatigue; Pain In Extremity;	Escitalopram			S	Unknown	Unk		Invagen

Withdrawal Syndrome	Escitalopram	S		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14814101	EXPEDITED (15-DAY)		HO, LT, OT	ES-ACCORD-066141		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Condition Aggravated; Electrocardiogram Qt Prolonged; Hypomagnesaemia; Myocardial Ischaemia; Tachycardia; Torsade De Pointes	Escitalopram			S				Not Reported
	Pantoprazole			S				Not Reported
	Haloperidol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14814934	EXPEDITED (15-DAY)		HO, LT, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018012774			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Myocardial Ischaemia; Tachycardia; Torsade De Pointes	Escitalopram Oxalate			S	Unknown	15 Milligram, Qd		Macleods
	Haloperidol			S	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14815425	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-884938		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure	Venlafaxine			S	Oral			Teva
	Escitalopram			S	Oral			Ivax
	Amphetamine W/Dextroamphetamine			S	Oral			Barr
	Bupropion			S	Oral			Teva

Fluoxetine	S	Oral		Barr
Hydrochlorothiazide	S	Oral		Ivax
Atorvastatin	S	Oral		Teva
Amlodipine	S	Oral		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14815845	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180431684		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Hypotension; Hypovolaemia; Paralysis	Rivaroxaban			S	Oral			Not Reported
	Rivaroxaban			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14816457	NON-EXPEDITED			US-TEVA-2018-US-872462		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Autophobia; Decreased Appetite; Depressed Mood; Drug Tolerance; Eye Pain; Feeling Abnormal; Formication; Hypersomnia; Impatience; Irritability; Mental Disorder; Ocular Discomfort; Paraesthesia; Screaming; Social Avoidant Behaviour; Thinking Abnormal	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14895588	DIRECT		DS, HO, LT, OT			16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Concussion; Educational Problem; Fall; Head Injury; Headache; Hypotension; Malaise; Physical Assault; Suicidal Ideation; Upper Limb Fracture	Lexapro			S				Unknown
	Generic Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	12479115	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2016-014302		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State; Electrocardiogram Qt Prolonged; Hypoglycaemia; Intentional Overdose; Nystagmus; Poisoning; Psychomotor Skills Impaired; Suicidal Ideation; Toxicity To Various Agents	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Lormetazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14336898	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-47644		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Furosemide			S	Oral	30 Mg Daily (2-1-0), 2x/Day (Bid)		Not Reported
	Furosemide			S	Oral	Bid ()		Not Reported
	Furosemide			S		Unk		Not Reported
	Furosemide			S	Oral	2 Unk, Qd ()		Not Reported
	Amlodipine Capsules			S	Oral	10 Mg, Once Daily (Qd)		Aurobindo
	Mirtazapine			S	Oral	15 Mg, Once Daily (Qd)		Aurobindo

	Terbutaline	S	Respiratory (inhalation)	1 Df, Qd	Not Reported
	Terbutaline	S			Not Reported
	Irbesartan	S	Oral	300 Mg, Once Daily (Qd)	Aurobindo
	Alprazolam	S	Oral	0.25 Mg, 3x/Day (Tid)	Aurobindo
	Diazepam Tablet	S	Oral	10 Mg, 3x/Day (Tid)	Not Reported
	Bisoprolol	S	Oral	1.25 Mg, Qd	Aurobindo
	Metformin Film-Coated Tablet	S	Oral	500 Mg, Bid	Aurobindo
	Pantoprazole	S	Oral	20 Mg, Once Daily (Qd)	Aurobindo
	Dafalgan	S	Oral	1000 Mg, 3x/Day (Tid)	Not Reported
	Tavanic	S	Oral	250 Mg, 2x/Day (Bid)	Not Reported
	Tavanic	S			Not Reported
	Xarelto	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
	Colchicine Opocalcium	S	Oral	1 Mg, Once Daily (Qd)	Not Reported
	Seroplex	S	Oral	1 Df, Once Daily (Qd)	Not Reported
	Nefopam	S	Oral	1 Df, 3x/Day (Tid)	Not Reported
	Nefopam	S		1 Df, Tid	Not Reported
	Nefopam	S	Oral	1 Df, 3x/Day (Tid)	Not Reported
	Diffu-K	S	Oral	3 Df Daily (2-1-0) 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14703101	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/18/0097358		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure	Amlodipine Besylate			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported

Amphetamine	S	Oral		Not Reported
Buspirone	S	Oral		Not Reported
Dextroamphetamine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14817692	EXPEDITED (15-DAY)		DE, DS, LT, OT	BE-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-170975			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Maternal Drugs Affecting Foetus; Trisomy 18	Pantoprazole			S	Unknown	Unk ()		Sun
	Nucala Powder For Solution For Injection			S	Transplacental	100 Mg, Unk		Not Reported
	Fluticasone Furoate Inhalation Powder			S	Transplacental	Unk Unk, Qd ()		Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported
	Vilanterol Trifenatate Inhalation Powder			S	Transplacental	1 Df, Qd		Not Reported
	Seretide			S	Transplacental	Unk ()		Not Reported
	Pantomed (Pantoprazol)			S	Transplacental	Unk ()		Not Reported
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported
	Ventolin			S	Transplacental	100 Ug, Unk		Not Reported
	Levocetirizine Tablets			S	Transplacental	5 Mg, Qd		Not Reported
	Avamys Nasal Spray			S	Transplacental	Bid		Not Reported
	Relvar Ellipta Inhalation Powder			S	Transplacental	1 Df, Qd		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Xyzall Film-Coated Tablet			S	Transplacental	5 Mg, Qd		Not Reported
	Theophylline			S	Unknown	Unk ()		Not Reported
	Sipralexa Tablet			S	Transplacental	10 Mg,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14818262	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-886960		91 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Lansoprazole			S	Oral	30 Milligram Daily;		Teva
	Escitalopram			S	Oral	10 Milligram Daily;		Not Reported
	Gliclazide			S	Oral	60 Milligram Daily;		Not Reported
	Stilnox 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported
	Efferalgan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14818643	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-665329USA		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Hyponatraemia; Lactic Acidosis	Metformin			S	Unknown	Initial Dose Not Stated, Eventually The Dose Was Increased To 1gram Twice A Day		Not Reported
	Insulin			S	Unknown			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Telmisartan			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14818757	EXPEDITED (15-DAY)		HO, OT	ES-ZYDUS-019848		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Condition Aggravated; Electrocardiogram Qt Prolonged;	Escitalopram			S	Unknown			Zydus Pharm
	Pantoprazole			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported

Hypomagnesaemia;
Mental Disorder;
Myocardial Ischaemia;
Torsade De Pointes

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14819037	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2017DE00170		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor; Wound	Escitalopram			S	Oral	15 Mg, Qd		Hetero
	Escitalopram			S	Unknown	7.5 Mg Qd		Hetero
	Escitalopram			S		20 Mg Qd		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14819297	EXPEDITED (15-DAY)		HO	DE-BAYER-2018-075287		65 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Dizziness; Dyspnoea; Haematochezia; Pain	Acetylsalicylic Acid(<=100 Mg)			S		100 Mg, Qd		Bayer
	Cipralex			S		10 Mg, Qd		Not Reported
	Simvastatin			C		20 Mg, Qd		Not Reported
	Ramipril			C		25 Mg, Qd		Not Reported
	Spiriva			C		18 Mg, Qd		Not Reported
	Pantoprazole			C		40 Mg, Qd		Not Reported
	Euthyrox			C		50 Mg, Qd		Not Reported
	Allopurinol			C		0.5 Df, Qd		Not Reported
	Metamizol			C		15 Gtt, Tid		Not Reported
	Metoprolol			C		47.5 Mg, Bid		Not Reported

	Alna	C	4 Mg, Qd	Not Reported
	Torasemid	C	10 Mg, Qd	Not Reported
	Tramal Long	C	Unk, Prn	Not Reported
	Symbicort	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14819384	NON-EXPEDITED			US-TEVA-2018-US-873443			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Eye Pain; Sexual Dysfunction	Hydrochlorothiazide			S				Ivax
	Aspirin			S		81 Milligram Daily;		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14820136	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-022329		20 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error	Escitalopram			S	Unknown	15 Mg, Nk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14820201	EXPEDITED (15-DAY)		HO, LT, OT	US-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00242		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Muscle Necrosis; Overdose; Rhabdomyolysis; Seizure	Hydrochlorothiazide Tablets			S	Unknown	Unk		Sciegen
	Fluoxetine Capsules, Usp			S	Unknown	Unk		Sciegen
	Atorvastatin Calcium			S	Unknown	Unk		Sciegen
	Venlafaxine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Amphetamine/Dextroamphetami			S	Unknown	Unk		Not Reported

	ne					
	Buspirone	S	Unknown	Unk		Not Reported
	Amlodipine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14820282	EXPEDITED (15-DAY)		HO	PHHY2017FR202566		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Prednisolone			S	Oral	40 Mg, Qd		Novartis
	Bevacizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lomustine			S	Oral	40 Mg, Unk		Not Reported
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Silodyx			C	Unknown	Unk		Not Reported
	Xanax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14820572	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1822986US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome	Escitalopram Oxalate - Bp			S	Transplacental	40 Mg, Unknown		Allergan
	Lamotrigine			S	Transplacental	150 Mg, Unknown		Not Reported
	Wellbutrin			S	Transplacental	150 Mg, Unknown		Not Reported
	Wellbutrin			S	Transplacental	300 Mg, Unknown		Not Reported
	Trittico			S	Transplacental	50 Mg, Unknown		Not Reported
	Benocten			S	Transplacental	50 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14821890	EXPEDITED (15-DAY)		HO	US-ARBOR PHARMACEUTICALS, LLC-US-2018ARB000503		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure; Suicide Attempt	Amphetamine Sulfate			S		Unk		Arbor
	Venlafaxine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Dextroamphetamine /00016601/			S		Unk		Not Reported
	Buspirone			S		Unk		Not Reported
	Fluoxetine			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Atorvastatin			S		Unk		Not Reported
	Amlodipine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14822675	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1823116US		85 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Communication Disorder; Loss Of Personal Independence In Daily Activities; Memory Impairment; Sluggishness	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14822901	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-SA-2018SA109223			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Maternal Drugs Affecting Foetus; Trisomy 18	Xyzall			S	Transplacental			Not Reported
	Pantoprazole Sodium Sesquihydrate			S	Transplacental			Not Reported
	Pantomed (Pantoprazole Sodium Sesquihydrate)			S	Transplacental			Not Reported
	Nucala			S	Transplacental			Not Reported
	Fluticasone Furoate			S	Transplacental	Inhalation Powder		Not Reported

	Xanthium (Theophylline)	S	Transplacental		Not Reported
	Vilanterol Trifenatate	S	Transplacental		Not Reported
	Seretide	S	Transplacental		Not Reported
	Flixotide	S	Transplacental		Not Reported
	Ventolin	S	Transplacental		Not Reported
	Levocetirizine	S	Transplacental		Not Reported
	Avamys	S	Transplacental	Nasal Spray	Not Reported
	Relvar Ellipta	S	Transplacental		Not Reported
	D-Cure	S	Transplacental		Not Reported
	Theophylline	S	Transplacental		Not Reported
	Sipralexa	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2018	14824080	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018012796			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error	Escitalopram Oxalate			S	Unknown	15 Milligram, Medication Errors		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14151884	EXPEDITED (15-DAY)		OT	PHHY2017FR157552		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Galantamine			S	Unknown	Unk		Not Reported
	Irbesartan			S	Unknown	Unk		Novartis
	Paracetamol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14345827	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT-00007501		14 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Accidental Overdose; Disinhibition; Drug Interaction; Mental Disorder; Product Use Issue	Cipralex			S	Oral	Daily Dose: 5 Gtt Drop(S) Every Day		Unknown
	Aripiprazole			S	Unknown			Unknown
	Calcium + Vitamin D			C	Unknown			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14488371	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1805752US		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Hypertension	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14506098	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1805926US		20 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Syncope	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14605169	EXPEDITED (15-DAY)		HO, LT, OT	CA-ALLERGAN-1812266US		15 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

Ibuprofen	C	Unknown	Unk		Not Reported
Bupropion	C	Unknown	Unk		Not Reported
Cetirizine	C	Unknown	Unk		Not Reported
Duloxetine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14699180	EXPEDITED (15-DAY)		HO	CH-TEVA-2018-CH-874485		45 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Escitalopram			S	Unknown	20 Milligram Daily; 20 Mg/Day		Ivax
	Escitalopram			S	Unknown	10 Milligram Daily; 10 Mg/Day		Ivax
	Emtricitabine			C	Unknown			Not Reported
	Tenofovir			C	Unknown			Not Reported
	Dolutegravir			C	Unknown			Not Reported
	Quetiapine			C	Unknown	50 Milligram Daily; 50 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14740283	EXPEDITED (15-DAY)		HO, OT	PHHY2017IT071807		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S	Oral	140 Mg, Once/Single		Not Reported
	Lorazepam			S	Oral	20 Mg, Once/Single		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14825260	EXPEDITED (15-DAY)		OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-171224		29 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Emotional Disorder; Hyperhidrosis; Libido Decreased; Off Label Use; Sexual Dysfunction; Therapeutic Product Effect Incomplete; Weight Increased	Venlafaxine		S	Unknown	150 Mg, Unk	Sun
	Venlafaxine		S	Unknown	Up To 225 Mg	Sun
	Escitalopram		S	Endocervical	30 Mg, Unk	Not Reported
	Escitalopram		S	Unknown	20 Mg, Daily	Not Reported
	Quetiapine		S	Unknown	12.5 Mg, Unk	Sun
	Bupropion		S	Unknown	150 Mg, Daily	Not Reported
	Bupropion		S	Unknown	Up To 300 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14827416	EXPEDITED (15-DAY)		HO, OT	AU-MYLANLABS-2018M1028493			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersomnia; Malaise; Neutropenia; Schizophrenia; Self-Medication	Clozaril			S	Oral	250 Mg, Unk		Mylan
	Clozaril			S	Oral	Unk		Mylan
	Clozaril			S	Oral	275 Mg, Unk		Mylan
	Clozaril			S	Oral	200 Mg, Unk		Mylan
	Clozaril			S	Oral	225 Unk, Unk		Mylan
	Clozaril			S	Oral	212.5 Mg, Unk		Mylan
	Clozaril			S	Oral	225 Mg, Pm		Mylan
	Aripiprazole			S		Unk		Not Reported
	Aripiprazole			S		10 Mg, Am		Not Reported
	Aripiprazole			S	Oral	5 Mg, Unk		Not Reported
	Escitalopram			S		10 Mg, Unk		Not Reported
	Escitalopram			S		20 Mg, Unk		Not Reported
	Escitalopram			S		10 Mg, Unk		Not Reported
	Brexpiprazole			S		0.5 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14273115	EXPEDITED (15-DAY)		OT	FR-OTSUKA-DJ201404328		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Communication Disorder; Gestational Diabetes; Maternal Exposure During Pregnancy; Normal Newborn; Personality Disorder; Pregnancy On Contraceptive; Product Use In Unapproved Indication	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Lexomil			S	Oral	Unk (Half Tab To Three Quarts Tab In The Eve)		Not Reported
	Lexapro			S	Oral	5 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14831541	EXPEDITED (15-DAY)		HO, LT, OT	CZ-MACLEODS PHARMACEUTICALS US LTD-MAC2018012823			Unknown	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning	Escitalopram Tablet			S	Oral	Unk		Macleods
	Olanzapine Tablet			S	Oral	Unk		Macleods
	Venlafaxine			S	Oral	Unk, Tablet		Macleods
	Clonazepam			S	Oral	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Levomepromazine			S	Oral	Unk		Not Reported
	Melperone			S	Oral	Unk		Not Reported
	Metoclopramide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14833205	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2018071441		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Cognitive Disorder; Fall	Lexomil			S	Oral	0.5 Gbq, Unk		Glaxosmithkline
	Bactrim			S	Oral	Unk		Glaxosmithkline

Dexamethasone	S	Oral	Unk		Glaxosmithkline
Zelitrex	S	Oral	Unk		Glaxosmithkline
Seroplex	S	Oral	Unk		Glaxosmithkline
Revlimid	S	Oral	Unk		Not Reported
Imovane	C	Oral	1 Df, Unk		Glaxosmithkline
Spironolactone	C	Oral	Unk		Glaxosmithkline
Lasilix	C	Oral	Unk		Glaxosmithkline
Nebivolol	C	Oral	5 Mg, Unk		Glaxosmithkline
Kardegic	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14834230	EXPEDITED (15-DAY)		OT	GR-ALLERGAN-1823524US		55 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Chorioretinitis; Dry Eye; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown	Unk, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	11587511	EXPEDITED (15-DAY)		OT	US-FRI-1000079855		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torticollis	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
	Clonazepam			C	Unknown	0.5 Mg, Prn (At Bedtime)		Not Reported
	Clonazepam			C		0.25 Mg, Qd (At Bedtime)		Not Reported
	Clonazepam			C				Not Reported
	Amlodipine			C		Unk		Not Reported
	Celecoxib			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported

Tamsulosin	C	Unknown	Unk		Not Reported
Omeprazole	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14204688	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-GLAXOSMITHKLINE-BE2017GSK177076			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Nucala			S	Transplacental	100 Mg, Unk		Glaxosmithkline
	Relvar Ellipta			S	Transplacental	Unk Unk, Qd		Glaxosmithkline
	Sipralexa			S	Transplacental	10 Mg, Z		Glaxosmithkline
	Xyzall			S	Transplacental	5 Mg, Qd		Not Reported
	Fluticasone Furoate			S	Transplacental	Unk Unk, Qd		Glaxosmithkline
	Levocetirizine			S	Transplacental	5 Mg, Qd		Glaxosmithkline
	Avamys			S	Transplacental	Unk Unk, Bid		Glaxosmithkline
	Flixotide			S	Transplacental	250 ?G, 2x/Day (Bid)		Glaxosmithkline
	Ventolin			S	Unknown	100 Ug, Unk		Glaxosmithkline
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Glaxosmithkline
	Seretide			S	Transplacental	Unk		Glaxosmithkline
	Theophylline			S		Unk		Glaxosmithkline
	Vilanterol Trifenatate			S	Transplacental	Unk Unk, Qd		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Pantomed (Pantoprazol)			S	Transplacental	Unk		Not Reported
	Pantoprazole Sodium Sesquihydrate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14676103	EXPEDITED (15-DAY)		HO, LT, OT	CZ-ELI_LILLY_AND_COMPANY-CZ201803010170			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning	Olanzapine		S	Oral	Unk Unk, Unknown	Eli Lilly And Co
	Clonazepam		S	Oral	Unk Unk, Unknown	Not Reported
	Levopromazin		S	Oral	Unk Unk, Unknown	Not Reported
	Metoclopramide		S	Oral	Unk Unk, Unknown	Not Reported
	Ibuprofen		S	Unknown	Unk Unk, Unknown	Not Reported
	Venlafaxine		S	Oral	Unk Unk, Unknown	Not Reported
	Escitalopram		S	Oral	Unk Unk, Unknown	Not Reported
	Melperone		S	Oral	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14765202	EXPEDITED (15-DAY)		HO, LT, OT	ES-JNJFOC-20180414902		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Myocardial Ischaemia; Torsade De Pointes	Haloperidol			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14835950	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018012838			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Contusion; Fall; Syncope	Escitalopram			S	Unknown	Unk		Macleods
	Metoprolol			C	Unknown	47.5 Milligram, 1-0-0-0		Not Reported
	Pantoprazole			C	Unknown	20 Milligram, 1-0-0-0		Macleods
	Valsartan 80 Mg			C	Unknown	80 Milligram, 0.5-0-0-1		Macleods
	Ass 100			C	Unknown	100 Milligram, 0-1-0-0		Not Reported
	Eferox			C	Unknown	50 Microgram, 1-0-0-0		Not Reported
	Hct			C	Unknown	12.5 Milligram, 1-0-0-0		Not Reported

Metamizole	C	Unknown	500 Milligram, 1-1-1-0		Not Reported
Simvastatin	C	Unknown	40 Milligram, 0-0-0-1		Not Reported
Ventolair	C	Unknown	250 Microgram, 2-0-0-2		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14835988	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-BAUSCH-BL-2018-012172			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Theophylline			S	Transplacental			Not Reported
	Levocetirizine			S	Transplacental	5 Mg, Qd		Not Reported
	Xyzall			S	Transplacental	5 Mg, Qd		Not Reported
	Pantomed (Pantoprazole Sodium Sesquihydrate)			S	Transplacental			Not Reported
	Fluticasone Furoate			S	Transplacental	Qd		Not Reported
	Sipralexa			S	Transplacental	10 Mg, Z		Not Reported
	Nucala			S	Transplacental	100 Mg,		Not Reported
	Relvar Ellipta			S	Transplacental	Qd		Not Reported
	Seretide			S	Transplacental			Not Reported
	D-Cure			S	Transplacental	25 Kiu		Not Reported
	Avamys			S	Transplacental	Bid		Not Reported
	Vilanterol Trifenatate			S	Transplacental	Qd		Not Reported
	Ventolin			S	Transplacental	100 Ug		Not Reported
	Pantoprazole Sodium Sesquihydrate			S	Transplacental			Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14836559	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1823527US		20 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error	Escitalopram Oxalate - Bp		S	Unknown	15 Mg, Unknown	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14836822	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-023050		44 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dyspepsia	Escitalopram			S	Unknown	20 Mg, 1-0-0		Aurobindo
	Ibuprofen			S	Unknown	Nk		Aurobindo
	Bornaprine Hydrochloride			S	Unknown	4 Mg, 1-0.5-1-0		Not Reported
	Neupro			S	Transdermal	14 Mg, 1-0-0-0		Not Reported
	Madopar Depot			C	Unknown	100|25 Mg, 0-0-0-1		Not Reported
	Amantadin /00055902/			C	Unknown	100 Milligram, Two Times A Day, (1-1-0-0)		Not Reported
	Amitriptylin			C	Unknown	75 Mg, 0-0-0-1		Not Reported
	Madopar			C	Unknown	100|25 Mg, 1.5-1.5-1.5-1.5		Not Reported
	Madopar Lt			C	Unknown	100|25 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14836937	EXPEDITED (15-DAY)		DS	AT-MYLANLABS-2018M1027264		25 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Decreased; Emotional Poverty; Loss Of Libido; Male Sexual Dysfunction; Urinary Retention; Vision Blurred	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14837467	EXPEDITED (15-DAY)		DE, HO, OT	DE-MYLANLABS-2018M1027341		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Lorazepam			S	Oral	6 Mg, Qd		Not Reported
	Quetiapine			S	Oral	200 Mg, Qd		Not Reported
	Abilify			S	Oral	20 Mg, Unk		Mylan
	Abilify			S	Oral	15 Mg, Unknown		Mylan
	Cipralex /01588501/			S	Oral	10 Mg, Unk		Mylan
	Lexapro			S	Oral	10 Mg, Qd		Mylan
	Lexapro			S				Mylan
	Tavor /00273201/			S	Oral	2 Mg, Unk		Mylan
	Tavor /00273201/			S	Oral	6 Mg, Unk		Mylan
	Seroquel			S	Oral	200 Mg, Unk		Mylan
	Movicol			C	Unknown	Unk		Mylan
	Simeticone			C	Unknown	Unk		Mylan
	Eferox			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14837505	EXPEDITED (15-DAY)		HO	PHHY2016FR186709		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose	Zolpidem			S	Oral	30 Df		Novartis
	Lexapro			S	Oral	15 Df,		Not Reported
	Seroplex			S	Oral	15 Df,		Not Reported
	Stilnox			S	Oral	30 Df,		Not Reported
	Theralene			S	Oral	50 Df,		Not Reported
	Theralene			S	Oral	1 Df		Not Reported
	Seresta			S	Oral	80 Df,		Not Reported
	Abilify			S	Oral	7 Df,		Not Reported
	Valium			S	Oral	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14918150	DIRECT		DS, HO, LT, OT			16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Hypotension; Intentional Overdose; Poverty Of Thought Content; Product Prescribing Issue; School Refusal; Suicidal Ideation; Upper Limb Fracture	Current Lexapro But Other Ssri Has The Same Effects			S	Oral	Quantity:30 Tablet(S);		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14919559	DIRECT		DS, OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Impaired Quality Of Life; Orgasmic Sensation Decreased; Sexual Dysfunction	Escitalopram Oxalate			S	Oral	Quantity:30 Tablet(S);		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14920148	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Night Sweats	Escitalopram 10mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	13180102	EXPEDITED (15-DAY)		HO, OT	FR-LUPIN PHARMACEUTICALS INC.-2016-02723		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State;	Escitalopram			S	Oral	840 Mg, Unk		Lupin

Electrocardiogram Qt Prolonged; Hypoglycaemia; Intentional Overdose; Nystagmus; Psychomotor Retardation; Suicidal Ideation; Toxicity To Various Agents	Venlafaxine	S	Oral	7875 Mg, Unk	Not Reported
	Bromazepam	S	Oral	180 Mg, Single	Not Reported
	Lormetazepam	S	Oral	14 Mg, Single	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14337790	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1773751US		65 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Energy Increased; Euphoric Mood; Impulsive Behaviour; Insomnia; Major Depression; Mania; Pressure Of Speech; Tachyphrenia; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Venlafaxine			S	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown	12.5 Mg, Qd		Not Reported
	Atenolol			C	Unknown	25 Mg, Qd		Not Reported
	Lovastatin			C	Unknown	20 Mg, Qd		Not Reported
	Metformin			C	Unknown	500 Mg, Q8hr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14840170	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-886830		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroid Mass	Escitalopram (2858a)			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14840223	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-023143		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Contusion; Fall; Syncope	Escitalopram			S	Unknown	Nk ()		Aurobindo

	Eferox	C	Unknown	50 Microgram, Once A Day	Not Reported
	Hct	C	Unknown	12.5 Milligram, Once A Day	Not Reported
	Metoprolol	C	Unknown	47.5 Milligram, Once A Day	Not Reported
	Ventolair	C	Unknown	250 Microgram,2-0-0-2	Not Reported
	Metamizole	C	Unknown	500 Milligram	Not Reported
	Valsartan	C	Unknown	80 Milligram,0.5-0-0-1	Not Reported
	Ass	C	Unknown	100 Milligram, Once A Day	Not Reported
	Simvastatin	C	Unknown	40 Milligram, Once A Day	Not Reported
	Pantoprazol /01263201/	C	Unknown	20 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14840507	EXPEDITED (15-DAY)		HO, LT	DE-WEST-WARD PHARMACEUTICALS CORP.-DE-H14001-18-03		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Linezolid			S	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Westward
	Levetiracetam			C	Unknown	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Ivabradin			C	Unknown	Daily Dose: 15 Mg Millgram(S) Every Days		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Naloxone, Tilidine			C	Unknown			Not Reported
	Scopolamin			C	Unknown	()		Not Reported
	Baclofen			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Lorazepam			C	Unknown	Daily Dose: 1 Mg Millgram(S) Every Days		Not Reported

	L-Thyroxin	C	Unknown				Not Reported
	Esomeprazole	S	Unknown				Not Reported
	Escitalopram	S	Unknown	()			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14840769	NON-EXPEDITED			US-PFIZER INC-2018177180		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Pristiq			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Latuda			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported
	Seroquel			S		Unk		Not Reported
	Risperidone			S		Unk		Not Reported
	Lithium			C		Unk		Not Reported
	Rexulti			C		Unk		Not Reported
	Mirtazapine			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14841133	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-889625			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basedow'S Disease; Dermatitis; Dry Skin; Gingival Atrophy; Gingivitis; Prostatomegaly;	Escitalopram			S	Unknown			Not Reported

Pruritus; Squamous Cell Carcinoma; Toothache; Urethral Stricture Postoperative

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14841151	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163-2340501-00		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Cardiac Failure; Pulmonary Embolism; Weight Fluctuation	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	On Saturday		Not Reported
	Methotrexate			S	Oral	Dose Decreased		Not Reported
	Xeljanz			S	Oral			Not Reported
	Progesterone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Remeron			S	Oral	Before Bed		Not Reported
	Atorvastatin			C	Oral	At Bedtime And Taking For At Least 6 Months		Not Reported
	Cardiazem			C	Oral	Taking For At Least 6 Months		Not Reported
	Cardiazem			C				Not Reported
	Carvedilol			C	Oral			Not Reported
	Cozaar			C	Oral			Not Reported
	Potassium			C	Oral			Not Reported
	Potassium			C	Oral			Not Reported
	Pantoprazole			C	Oral			Not Reported
	Folic Acid			C	Oral	Every Day Except Saturday When She Takes Methotrexate And Taking Since Year Or Two		Not Reported

	Aldactone	C	Oral		Not Reported
	Hydrocodone	C	Oral	10/325mg One Tablet By Mouth Two To Three Times Daily	Not Reported
	Tramadol	C			Not Reported
	Bumex	C	Oral		Not Reported
	Gabapentin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14841324	EXPEDITED (15-DAY)		LT, OT	IN-TORRENT-00001709		53 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicidal Ideation; Suicide Attempt	Escitalopram Oxalate			S		Unknown		Unknown
	Amitriptyline Hydrochloride			S		Unknown		Unknown
	Mirtazapine			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14842772	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2010DE101573		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Quetiapine			S	Oral	200 Mg, Qd		Novartis
	Lorazepam			S	Oral	6 Mg, Qd		Not Reported
	Abilify			S	Oral	20 Mg, Unk		Not Reported
	Abilify			S	Oral	15 Mg, Unk		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Tavor [Lorazepam]			S	Oral	2 Mg, Unk		Not Reported
	Tavor			S	Oral	6 Mg, Unk		Not Reported
	Seroquel			S	Oral	200 Mg, Unk		Not Reported
	Movicol			C	Unknown	Unk		Not Reported

	Simeticone		C	Unknown	Unk	Not Reported
	Eferox		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14842789	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2018-012293		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Cognitive Disorder; Fall	Dexamethasone			S	Oral			Valeant
	Seroplex			S	Oral	Divisible Coated Tablet		Not Reported
	Revlimid			S	Oral	21 Days On 28		Not Reported
	Zelitrex			S	Oral			Not Reported
	Bactrim			S	Oral			Not Reported
	Lexomil			S	Oral	Compressed		Not Reported
	Imovane			C	Oral	Coated Tablet		Not Reported
	Spironolactone			C	Oral			Not Reported
	Lasilix			C	Oral	Tablet Breackable		Not Reported
	Kardegic			C	Oral	Dose		Not Reported
	Nebivolol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14843146	EXPEDITED (15-DAY)		HO	DE-JNJFOC-20180427891		44 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dyspepsia	Ibuprofen		Y	S	Unknown			Not Reported
	Ibuprofen			S	Unknown	Nk		Not Reported
	Neupro			S	Transdermal	1-0-0-0		Not Reported
	Escitalopram			S	Unknown	1-0-0		Not Reported
	Bornaprine Hydrochloride			S	Unknown	1-0.5-1-0		Not Reported
	Amantadine			C	Unknown	1-1-0-0		Not Reported
	Amitriptyline			C	Unknown	0-0-0-1		Not Reported

	Madopar	C	Unknown	100/25 Mg 0-0-0-1	Not Reported
	Madopar	C	Unknown	100/25 Mg, 1.5-1.5-1.5-1.5	Not Reported
	Madopar	C	Unknown	100|25 Mg, 1-0-0-0	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14843357	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-888011		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Ceftriaxone Sodique			S	Unknown			Not Reported
	Risperidone			S	Unknown			Pliva
	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14843464	EXPEDITED (15-DAY)		LT, OT	IT-MYLANLABS-2018M1027921		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Prescribed Underdose	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Abilify			S	Oral	10 Mg, Qd		Mylan
	Cipralex /01588501/			S	Oral	5 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14843770	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1028844		7 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Headache; Medication Error; Myalgia; Wrong Product Administered	Aciclovir			S		Unk		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14843949	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018176104		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Lyrica			S	Oral	Unk		Pfizer
	Tavor [Lorazepam]			S	Unknown	3 Df, Single		Pfizer
	Ethanol			S	Unknown	Unk		Not Reported
	Rezolsta			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	3 Df, Single		Not Reported
	Minias			S	Unknown	40 Gtt, Single		Not Reported
	Kivexa			S	Unknown	4 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14844325	EXPEDITED (15-DAY)		OT	PHHY2014BR056233			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Arthropathy; Cardiac Disorder; Diarrhoea; Dizziness; Drug Ineffective; Dyspnoea; Fear; Flatulence; Gastritis; Headache; Hypoaesthesia; Malaise; Nightmare; Pain; Panic Disorder; Restlessness; Sleep Disorder; Tremor; Weight Decreased; Weight Increased; Wrong Technique In Product Usage Process	Olcadil			S	Oral	2 Df, A Day		Not Reported
	Olcadil			S	Oral	3 Df, A Day		Not Reported
	Olcadil			S	Oral	1 To Go Out And 1 At Night		Not Reported
	Cloxazolam			S	Oral	4 Mg And 2 Mg 3 Times A Day		Not Reported
	Cloxazolam			S				Not Reported
	Cloxazolam			S				Not Reported
	Citalopram			S	Oral	1 Df, Qd		Not Reported
	Fluoxetine			S	Oral	1 Df, A Day		Novartis
	Denyl//Citalopram Hydrobromide			S	Oral	1 Df, A Day		Not Reported
	Escitalopram			S	Oral	1 Df, A Day		Not Reported
	Valium			S	Unknown			Not Reported
	Frontal			S	Unknown			Not Reported
	Dorflex			C	Unknown	At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	13339676	EXPEDITED (15-DAY)		HO	PHHY2017IT035607		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Clozapine			S	Oral	100 Mg, Unk (Total)		Not Reported
	Clozapine			S				Not Reported
	Lorazepam			S	Oral	1 Mg, Unk (Total)		Novartis
	Lorazepam			S				Novartis
	Entact			S	Oral	20 Mg, Unk (Total)		Not Reported
	Entact			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14281465	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1077181			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Escitalopram			S		20 Mg, Qd		Not Reported
	Valdoxan			S	Oral	25 Mg, Qd		Mylan
	Zoely			S	Oral	1 Dosage Forms Daily One Df Contains 2.5 Mg Nomegestrel And 1.5mg Estradiol		Mylan
	Estradiol			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14290936	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2017M1078175		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Dizziness; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Candesartan			S	Oral	16 Mg, Qd		Not Reported
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported

	Escitalopram	S	Oral	20 Mg, Qd	Not Reported
	Escitalopram	S	Oral	10 Mg, Qd	Not Reported
	Risperdal	C		1.5 Mg, Qd	Mylan
	Risperdal	C		2 Mg, Unk (For Nights)	Mylan
	Risperdal	C	Unknown	2 Mg, Qd	Mylan
	L-Thyroxin	C	Oral	100 Mg, Qd	Mylan
	L-Thyroxin	C	Oral	100 G, Unk	Mylan
	Amisulpride	C	Unknown	200 Mg, Qd	Mylan
	Metformin	C	Oral	1500 Mg, Qd	Mylan
	Atorvastatin	C	Oral	20 Mg, Qd	Mylan
	Acetylsalicylic Acid	C	Oral	100 Mg, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14803485	EXPEDITED (15-DAY)		OT	CA-ROCHE-2070850			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety Disorder; Decreased Appetite; Diarrhoea; Frequent Bowel Movements; Nasopharyngitis; Weight Decreased	Tecentriq			S	Intravenous (not otherwise specified)	Date Of Most Recent Dose On 18/Apr/2018		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Tamoxifen			S	Unknown			Not Reported
	Mistletoe			C				Not Reported
	Gabapentin			C				Not Reported
	Ativan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2018	14285863	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT-00007377		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Quetiapine Fumarate			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown

	Lorazepam	S	Oral		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2018	14354607	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-000227		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Level Decreased; Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	Overdose: 40 Mg		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	30 Milligram, Once A Day		Aurobindo
	Lorazepam			C	Unknown	0.5 Mg,		Not Reported
	Lorazepam			C	Unknown	0.5 Mg, Unk		Not Reported
	Pangrol /00014701/			C	Unknown	1 Dosage Form		Not Reported
	Olanzapine			C	Unknown	10 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2018	14813489	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2018-020931		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Condition Aggravated; Electrocardiogram Qt Prolonged; Hypomagnesaemia; Mental Disorder; Myocardial Ischaemia; Tachycardia; Torsade De Pointes	Escitalopram			S	Unknown	15 Milligram, Once A Day		Aurobindo
	Pantoprazole			S	Unknown	()		Aurobindo
	Haloperidol			S	Unknown	2 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2018	14850183	EXPEDITED (15-DAY)		HO	LT-TEVA-2018-LT-887365		46 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Insomnia; Speech	Escitalopram			S	Oral			Ivax

Disorder	Zolpidem	S	Oral		Not Reported
	Quetiapine	S	Oral		Not Reported
	Etoricoxib	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	6430818	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2007079081		56 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Hypomania; Serotonin Syndrome	Phenytoin Sodium			S		300 Mg, 1x/Day		Pfizer
	Sertraline			S		100 Mg, 1x/Day		Pfizer
	Trazodone Hydrochloride			S		100 Mg, 1x/Day		Not Reported
	Lithium Carbonate			S		750 Mg, 1x/Day		Not Reported
	Escitalopram			S		10 Mg, 1x/Day		Not Reported
	Amlodipine			C		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	10896249	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2015-01685		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Joint Range Of Motion Decreased; Musculoskeletal Stiffness; Neck Pain; Nuchal Rigidity; Torticollis	Escitalopram			S	Unknown	5 Mg, Daily		Aurobindo
	Escitalopram			S	Unknown	10 Mg, Daily		Aurobindo
	Escitalopram			S	Unknown	15 Mg, Daily		Aurobindo
	Clonazepam			C	Unknown	0.25 Mg, At Bedtime		Not Reported
	Clonazepam			C	Unknown	0.5 Mg, At Bedtime As Needed		Not Reported
	Clonazepam			C		At Bedtime		Not Reported
	Clonazepam			C		At Bedtime		Not Reported
	Clonazepam			C		At Bedtime As Needed		Not Reported
	Clonazepam			C		At Bedtime		Not Reported
	Clonazepam			C		At Bedtime		Not Reported

	Clonazepam	C		.25 Milligram	Not Reported
	Clonazepam	C		At Bedtime As Needed	Not Reported
	Clonazepam	C		At Bedtime	Not Reported
	Clonazepam	C		At Bedtime	Not Reported
	Clonazepam	C		At Bedtime	Not Reported
	Clonazepam	C		At Bedtime As Needed	Not Reported
	Clonazepam	C		()	Not Reported
	Clonazepam	C		At Bedtime	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Ibuprofen	C		()	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Amlodipine	C		()	Not Reported
	Celecoxib	C	Unknown	Unk	Not Reported
	Celecoxib	C		()	Not Reported
	Tamsulosin	C	Unknown	Unk	Not Reported
	Tamsulosin	C		()	Not Reported
	Omeprazole	C	Unknown	Unk	Not Reported
	Omeprazole	C		()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14445994	EXPEDITED (15-DAY)		HO	US-ABBVIE-17K-163-2099796-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Cardiac Failure; Drug Interaction; Joint Swelling; Pulmonary Embolism; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	2.5mg Nine Tablets By Mouth On Saturday Once A Week		Not Reported
	Methotrexate			S	Oral	Dose Decreased		Not Reported
	Xeljanz			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

	Remeron	S	Oral	Before Bed		Not Reported
	Cymbalta	S	Unknown			Not Reported
	Progesterone	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Atorvastatin	C	Oral	At Bedtime		Not Reported
	Cardiazem	C	Oral			Not Reported
	Cardiazem	C				Not Reported
	Carvedilol	C	Oral			Not Reported
	Potassium	C	Oral			Not Reported
	Potassium	C	Oral			Not Reported
	Pantoprazole	C	Oral			Not Reported
	Folic Acid	C	Oral	Six Days A Week		Not Reported
	Aldactone	C	Oral			Not Reported
	Tramadol	C				Not Reported
	Tramadol	C				Not Reported
	Bumex	C	Oral			Not Reported
	Progesterone	C				Not Reported
	Plaquenil	C				Not Reported
	Cozaar	C	Oral			Not Reported
	Hydrocodone	C	Oral	10/325mg One Tablet By Mouth Two To Three Times Daily		Not Reported
	Gabapentin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14652996	EXPEDITED (15-DAY)		OT	IT-ABBVIE-18P-083-2285824-00		52 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Loss Of Consciousness; Malaise	Depakin			S	Oral			Not Reported
	Carbolithium			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Frontal			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14683945	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1815810US		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Communication Disorder; Gestational Diabetes; Maternal Exposure During Pregnancy; Normal Newborn; Personality Disorder; Pregnancy On Contraceptive	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Abilify			S	Oral	10 Mg, Qd		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Lexomil			S	Oral	Half Tab To Three Quarts Tab In The Eve, Qpm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14789951	EXPEDITED (15-DAY)		HO, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-170607		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Ineffective; Electrocardiogram Qt Prolonged; Hypomagnesaemia; Myocardial Ischaemia; Torsade De Pointes	Escitalopram			S	Unknown	15 Mg, Daily		Not Reported
	Pantoprazol			S	Unknown	Unk		Sun
	Haloperidol			S	Unknown	2 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14826911	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2018-023043		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis;	Escitalopram			S	Oral			Aurobindo
	Escitalopram			S	Oral	()		Aurobindo
	Venlafaxine			S	Oral			Aurobindo

Overdose; Rhabdomyolysis; Seizure; Suicide Attempt	Venlafaxine		S	Oral	()	Aurobindo
	Buspirone Hydrochloride		S	Oral		Aurobindo
	Buspirone Hydrochloride		S	Oral	()	Aurobindo
	Fluoxetine		S	Oral		Aurobindo
	Fluoxetine		S	Oral	()	Aurobindo
	Hydrochlorothiazide		S	Oral		Aurobindo
	Hydrochlorothiazide		S	Oral	()	Aurobindo
	Amlodipine		S	Oral		Aurobindo
	Amlodipine		S	Oral	()	Aurobindo
	Amfetamine W/Dexamfetamine		S	Oral		Not Reported
	Atorvastatin		S	Oral		Not Reported
	Atorvastatin		S	Oral	()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14852074	EXPEDITED (15-DAY)		HO	TW-MYLANLABS-2018M1027181		71 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Dyspnoea; Excessive Eye Blinking; Head Titubation; Insomnia; Tremor; Trismus	Quetiapine			S	Unknown	Increased To 100mg/Day		Not Reported
	Quetiapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown	10-15mg/Day For 6 Months; Increased To 20mg/Day Due To Aggravation		Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14852081	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-024339		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During	Escitalopram			S	Unknown			Aurobindo

Pregnancy; Product Use
In Unapproved Indication;
Toxicity To Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14150152	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1762669US		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sepsis; Urticaria	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Temesta (Lorazepam)			S	Oral			Not Reported
	Topalgic (Tramadol Hydrochloride)			S	Oral			Not Reported
	Smecta			C	Endocervical	1 Df, Bid		Not Reported
	Tiorfan			C	Unknown			Not Reported
	Motilium			C	Unknown			Not Reported
	Sandostatine			C	Intramuscular			Not Reported
	Eupantol			C	Unknown			Not Reported
	Creon			C	Oral			Not Reported
	Laroxyl			C	Oral			Not Reported
	Questran			C	Unknown			Not Reported
	Tardyferon B9 [Ferrous Sulfate;Folic Acid]			C	Unknown			Not Reported
	Un-Alfa			C	Oral			Not Reported
	Gaviscon			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Ornithine Oxoglurate			C	Oral			Not Reported
	Debridat			C	Unknown			Not Reported
	Innohep			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14652876	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-		67 YR	Female	USA

2018US-166902

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Lansoprazole			S	Unknown			Sun
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14858223	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US17054			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Overdose	Escitalopram			S	Unknown	Unk		Invagen
	Sertraline			S	Unknown	Unk		Invagen
	Valproic Acid			S	Unknown	Unk		Not Reported
	Quetiapin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14858511	EXPEDITED (15-DAY)		DE, HO	US-CIPLA LTD.-2018US17053			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Overdose	Escitalopram			S	Unknown	Unk		Invagen
	Flurazepam			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14860244	EXPEDITED (15-DAY)		HO, LT	ES-ACCORD-066519		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depressed Level Of Consciousness; Drug Interaction; Intentional Overdose; Off Label Use	Clonazepam	S	Oral			Not Reported
	Escitalopram	S	Oral			Not Reported
	Quetiapine	S	Oral			Not Reported
	Valproic Acid	S	Oral			Not Reported
	Antabus	S	Oral	Strength: 250 Mg 40 Tablets		Not Reported
	Abilify	S	Oral	Strength: 15 Mg 28 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14860871	EXPEDITED (15-DAY)		DS	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2018012994			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Jaw	Escitalopram			S	Oral	5 Milligram		Macleods
	Lansoprazole			C	Unknown	30 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14861213	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180503239		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Extrapyramidal Disorder; Intentional Overdose; Mydriasis; Sinus Tachycardia; Suicide Attempt	Risperidone			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Theralene			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14862138	EXPEDITED (15-DAY)		HO	ES-LANNETT COMPANY, INC.-ES-2018LAN000670		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram Oxalate		S	Unknown	15 Mg, Qd	Lannett
	Haloperidol Lactate		S	Unknown	2 Mg, Unk	Lannett

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14949505	DIRECT					73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Product Effect Decreased	Escitalopram 10 Mg Tablet			S	Oral	Quantity:1 Tablet(S);		Lupin
	Levothyroxine			C				Not Reported
	Nifedipine			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	12544139	EXPEDITED (15-DAY)		HO, OT	FR-ZYDUS-011570		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State; Electrocardiogram Qt Prolonged; Hypoglycaemia; Intentional Overdose; Nystagmus; Psychomotor Retardation; Suicide Attempt; Toxicity To Various Agents	Bromazepam			S	Unknown			Not Reported
	Escitalopram			S	Oral			Zydus Pharm
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Zydus Pharm
	Lormetazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14868064	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2018-012951		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Poisoning Deliberate	Venlafaxine			S	Oral	Unspecified		Not Reported
	Atarax			S	Oral	Unspecified		Not Reported
	Zopiclone			S	Oral	Unspecified		Not Reported

	Previscan (Fluindione)	S	Oral	Unspecified Tablet Breakable	Not Reported
	Seroplex	S	Oral	Unspecified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14868576	NON-EXPEDITED			US-MACLEODS PHARMACEUTICALS US LTD-MAC2017006346			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram Oxalate			S	Unknown	5 Mg, Unk		Macleods
	Lisinopril			C	Unknown	20 Mg, Unk		Not Reported
	Temazepam			C	Unknown	15 Mg, Unk		Not Reported
	Iron Infusion			C	Unknown	Unk, Infusion As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14869083	EXPEDITED (15-DAY)		OT	SE-MACLEODS PHARMACEUTICALS US LTD-MAC2018012995			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Erectile Dysfunction	Escitalopram Oxalate 5mg Tablet Prescription F 53 = [Aurobindo Pharma Limited			S	Oral	5 Milligram, Qd, (Escitalopram Intensity:10)		Macleods
	Lithionit			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14869240	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018013000			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness	Venlafaxine			S	Oral	Unk, (Unspecified)		Macleods
	Atarax			S	Oral	Unk, (Unspecified)		Not Reported

	Zopiclone	S	Oral	Unk (Unspecified)	Not Reported
	Previscan (Fluindione)	S	Oral	Unk, (Unspecified), (Tablet Breackable)	Not Reported
	Seroplex	S	Oral	Unk, (Unspecified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14869419	EXPEDITED (15-DAY)		HO	SE-MACLEODS PHARMACEUTICALS US LTD-MAC2018013004			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block	Escitalopram Oxalate 5mg Tablet Prescription F 53 = [Aurobindo Pharma Limited			S	Oral	5 Milligram, Qd		Macleods
	Desloratadine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14869651	EXPEDITED (15-DAY)		DE	IT-SA-2018SA125273		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14870566	NON-EXPEDITED			US-PFIZER INC-2018190671		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Pristiq			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Prozac			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Fetzima			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Viibryd			S		Unk		Not Reported
	Trintellix			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14870690	EXPEDITED (15-DAY)		HO	AT-PFIZER INC-2018182104		27 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Extrapyramidal Disorder; Fluid Retention; Hypotension; Lipoma; Memory Impairment; Off Label Use; Product Prescribing Error; Rash; Schizophrenia; Suicidal Ideation; Visual Impairment	Temesta (Lorazepam)			S		Unk		Pfizer
	Haldol			S		40 Mg, 1x/Day		Not Reported
	Akineton /00079501/			S		20 Mg, Unk		Not Reported
	Cipralex /01588501/			S		20 Mg, Unk		Not Reported
	Dominal /00018902/			S		1 Mg, Unk		Not Reported
	Zyprexa			S		30 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14871233	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018GSK080988			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Suicidal Ideation	Lamotrigine			S				Glaxosmithkline
	Escitalopram			S				Glaxosmithkline

	Lexapro	C	20 Unk, Unk	Not Reported
	Nifedipine	C	60 Mg, Unk	Not Reported
	Alprazolam	C		Not Reported
	Alprazolam	C		Not Reported
	Cbd	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14871645	EXPEDITED (15-DAY)		DE	IT-BAUSCH-BL-2018-012897		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Cipralex Oral Drops			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	13053480	EXPEDITED (15-DAY)		HO, OT	IT-ROCHE-1869005		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Anxiety; Depressed Mood; Drug Interaction; Feeling Of Despair; Insomnia; Labelled Drug-Drug Interaction Medication Error; Mood Altered;	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral	Total		Not Reported
	Venlafaxine			S	Oral	Total		Not Reported
	Quetiapine			S	Oral	Total		Not Reported
	Alprazolam			S	Oral	Total		Not Reported
	Trazodone Hydrochloride			S	Oral	Total		Not Reported

Retirement; Suicidal Ideation; Tension; Therapeutic Response Decreased	Trazodone Hydrochloride		S	Unknown		Not Reported
	Valproic Acid		S	Oral	Total	Not Reported
	Valproic Acid		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14329207	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1773536US		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Level Decreased; Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram Oxalate - Bp			S	Oral	Overdose: 40 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Overdose: 30 Mg, Qd		Allergan
	Olanzapine			C	Unknown	10 Mg, Qd		Not Reported
	Lorazepam			C	Unknown	0.5 Mg		Not Reported
	Pangrol			C	Unknown	2 Ot, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14549524	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1809266US		13 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Overdose; Pancreatitis Acute; Somnolence	Escitalopram Oxalate - Bp			S	Oral	14 Df In Total		Allergan
	Atarax /00058401/			S	Oral	Unknown		Not Reported
	Seresta			S	Oral	15 Df In Total		Not Reported
	Tramadol Biogaran			S	Oral	10 Df, Qd - In Total		Not Reported
	Stresam			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14742650	EXPEDITED (15-DAY)		HO, LT, OT	CZ-BAUSCH-BL-2018-009329			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged;	Venlafaxine			S	Oral			Not Reported
	Metoclopramide			S	Oral			Valeant

Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning	Ibuprofen		S	Unknown	Not Reported
	Clonazepam		S	Oral	Not Reported
	Levopromazine		S	Oral	Not Reported
	Olanzapine		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported
	Melperone		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14872926	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2018-024557			Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Use; Drug Abuse; Feeling Abnormal; Head Titubation; Laziness; Miosis; Substance Use	Escitalopram			S	Unknown	Unk		Aurobindo
	Dextromethorphan			S	Unknown	60 Milligram		Not Reported
	Thiocodin /01295801/			S	Unknown	1 Dosage Text = Codeine + Sulfogluacol		Not Reported
	Aviomarin			S	Unknown	1 Dosage Form		Not Reported
	Thiocodin /01295801/			S	Unknown	1 Dosage Text = Codeine + Sulfogluacol ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14873123	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-024720		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Lamotrigine 100mg			S	Unknown	100 Milligram, 3 Day, (1-1-1-0)		Aurobindo
	Mirtazapine 45mg			S	Unknown	45 Milligram, Once A Day,At Night		Aurobindo
	Escitalopram 20 Mg			S	Unknown	20 Milligram, Once A Day, (20mg-0mg-0mg-0mg) In The Morning		Aurobindo
	Mirtazapine 15mg			S	Unknown	15 Milligram, Once A Day,(0-0-1) At Night		Aurobindo

	Milnacipran	S	Oral	200 Milligram, Once A Day	Not Reported
	Milnacipran	S	Oral	50 Milligram, Two Times A Day	Not Reported
	Levothyroxin	C	Unknown	100 Microgram, Once A Day,(1-0-0-0) In The Morning	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14874402	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-024694		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness	Zopiclone			S	Oral	Non Précisée		Not Reported
	Venlafaxine			S	Oral	Non Précisée		Aurobindo
	Atarax /00058401/			S	Oral	Non Précisée		Not Reported
	Previscan /00789001/			S	Oral	Non Précisée		Not Reported
	Seroplex			S	Oral	Non Précisée		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14874418	EXPEDITED (15-DAY)		DS	GB-AUROBINDO-AUR-APL-2018-024760		33 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Jaw	Escitalopram Tablets			S	Oral	5 Milligram		Aurobindo
	Lansoprazole			C	Unknown	30 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14877550	EXPEDITED (15-DAY)		HO	DE-009507513-1805DEU003245		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive	Mirtazapine			S	Unknown	At Night		Merck
	Mirtazapine			S	Unknown	(0-0-1) At Night		Merck
	Lamotrigine			S	Unknown	(1-1-1-0)		Not Reported

Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Escitalopram	S	Unknown	(20mg-0mg-0mg-0mg) In The Morning	Not Reported
	Milnacipran	S	Oral	200 Mg, Qd	Not Reported
	Milnacipran	S	Oral	50 Mg, Qod	Not Reported
	Levothyroxine Sodium	C	Unknown	(1-0-0-0) In The Morning	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	12502088	EXPEDITED (15-DAY)		HO, OT	AU-FRI-1000085500		66 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Lercanidipine Hcl Unk			S	Unknown	Unk		Not Reported
	Perindopril			S	Unknown	Unk		Not Reported
	Atenolol			S	Unknown	Unk		Not Reported
	Rosuvastatin			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	12516486	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2016002860			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose; Nystagmus; Overdose; Psychomotor Retardation; Psychomotor Skills Impaired; Suicidal Ideation; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	840 Milligram, (Total)		Macleods
	Escitalopram Oxalate			S				Macleods
	Venlafaxine			S	Oral	7875 Milligram, (Total, Overdose)		Macleods
	Venlafaxine			S				Macleods
	Bromazepam			S	Oral	180 Milligram, (Total, Overdose)		Not Reported
	Bromazepam			S				Not Reported
	Lormetazepam			S	Oral	14 Milligram, (Total, Overdose)		Not Reported

	Lormetazepam	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14480943	EXPEDITED (15-DAY)		HO, OT	NO-ABBVIE-18P-122-2242450-00		21 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Valproate Sodium			S	Oral			Not Reported
	Valproate Sodium			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Efexor			S	Unknown	Extended Release Capsule		Not Reported
	Efexor			S	Unknown	Extended Release Capsule		Not Reported
	Efexor			S	Unknown	Extended Release Capsule		Not Reported
	Lamictal			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Seroquel			S	Oral	Film Coated Tablet		Not Reported
	Seroquel			S	Oral	Film Coated Tablet		Not Reported
	Seroxat			S	Unknown			Not Reported
	Seroxat			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Cipramil [Citalopram Hydrochloride]			S	Unknown			Not Reported
	Cipramil			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Orfiril			S	Unknown			Not Reported
	Lithionit			C				Not Reported
	Sobril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14760818	EXPEDITED (15-DAY)		HO	US-JNJFOC-20180402091		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Atrial Fibrillation; Biliary Sepsis; Blood Loss Anaemia; Cardiac Failure Congestive; Cholecystitis Acute; Electrocardiogram Qt Prolonged; Escherichia Bacteraemia; Haemobilia; Hypocalcaemia; International Normalised Ratio Increased; Lactic Acidosis; Myocardial Ischaemia; Pancytopenia; Pleural Effusion; Pneumonia; Supraventricular Extrasystoles; Thrombocytopenia	Imbruvica			S	Oral			Not Reported
	Imbruvica			S	Oral			Not Reported
	Imbruvica			S	Oral			Not Reported
	Remeron			S				Not Reported
	Lexapro			S				Not Reported
	Plavix			S	Unknown			Not Reported
	Pacerone			C		1 Tablet Twice Daily Until 3/31,Then Transition To 1 Tablet Once Daily		Not Reported
	Cefdinir			C		1 Capsule (300 Mg Total) By Mouth 2 Times A Day At 6:00 Am And 4:00 Pm For 10 Days		Not Reported
	Flagyl			C	Oral	1 Tablet (500 Mg Total) By Mouth 3 (Three) Times A Day For 8 Days		Not Reported
	Roxicodone			C	Oral			Not Reported
	Zanaflex			C	Oral	1 Tablet (2 Mg Total) By Mouth Every 8 (Eight) Hours As Needed		Not Reported
	Prednisone			C	Oral	1 Tablet (10 Mg Total) By Mouth Daily For 7 Days		Not Reported
	Prednisone			C	Oral	1 Tablet (10 Mg Total) By Mouth Daily For 7 Days		Not Reported
	Zyloprim			C	Oral	300 Mg, Daily With Breakfast		Not Reported
	Folvite			C	Oral			Not Reported
	Synthroid			C	Oral	150 Mcg, Daily At 6:00 Am		Not Reported
	Levothroid			C	Oral	150 Mcg, Daily At 6:00 Am		Not Reported
	Prilosec			C	Oral			Not Reported
	Zocor			C	Oral			Not Reported
	Zofran			C				Not Reported
	Kenalog			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14768046	EXPEDITED (15-DAY)		HO, LT, OT	ES-LUPIN PHARMACEUTICALS INC.-2018-02905		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Myocardial Ischaemia; Torsade De Pointes	Escitalopram			S	Unknown	15 Mg, Qd		Lupin
	Escitalopram			S				Lupin
	Haloperidol			S	Unknown	2 Mg, Qd		Not Reported
	Haloperidol			S				Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14878935	EXPEDITED (15-DAY)		DS	GB-CIPLA LTD.-2018GB17520			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Jaw	Escitalopram			S	Oral	5 Mg, Unk		Invagen
	Lansoprazole			C	Unknown	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14880325	EXPEDITED (15-DAY)		HO	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-172540		71 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Disorder; Drug Ineffective; Dyskinesia	Quetiapine			S	Unknown	50 Mg, Daily		Sun
	Quetiapine			S	Unknown	100 Mg, Daily		Sun
	Quetiapine			S	Unknown	Tappered Off		Sun
	Quetiapine			S	Unknown	50 Mg, Daily		Sun
	Venlafaxine			S	Unknown	Up To 150 Mg/D For 4 Weeks		Sun
	Mirtazapine			S	Unknown	Up To 45 Mg/D For 4 Weeks		Sun

	Risperidone	S	Unknown	Up To 1 Mg/Day For 1 Week	Ranbaxy
	Escitalopram	S	Unknown	10 To 15 Mg/D For 6 Months	Not Reported
	Escitalopram	S	Unknown	20 Mg, Daily	Not Reported
	Escitalopram	S	Unknown	10 Mg, Daily	Not Reported
	Sertraline	S	Unknown	Up To 80 Mg/D For 3 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14880371	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018187392		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Faecal Vomiting; Faecaloma	Lyrica			S	Oral	50 Mg, 1x/Day		Pfizer
	Antarene Codeine			S	Oral	3 Df, 1x/Day, [Codeine Phosphate Hemihydrate 400 Mg]/[Ibuprofen 60 Mg]		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14880929	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-025149		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Extrapyramidal Disorder; Mydriasis; Sinus Tachycardia	Risperidone			S	Oral	36 Milligram		Aurobindo
	Escitalopram			S	Oral	9 Milligram		Aurobindo
	Theralene			C	Oral	Posologie Non Précisée		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14882860	EXPEDITED (15-DAY)		HO	PH-ALLERGAN-1824843US			Male	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amoebiasis; Ill-Defined Disorder; Pyrexia; Urinary Tract Infection	Lexapro	S	Unknown	Unk		Allergan
	Lexapro	S				Allergan
	Abilify	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14882881	EXPEDITED (15-DAY)		HO	ES-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00175		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Myocardial Ischaemia; Torsade De Pointes	Escitalopram			S	Unknown	15 Mg, 1x/Day		Jubilant
	Haloperidol			S	Unknown	2 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14884296	EXPEDITED (15-DAY)		HO, OT	US-PRINSTON PHARMACEUTICAL INC.-2018PRN00232		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Abnormal Dreams; Fall; Feeling Abnormal; Hallucination; Head Injury; Hip Arthroplasty; Humerus Fracture; Illusion; Lower Limb Fracture; Pain; Somnolence; Upper Limb Fracture	Escitalopram			S	Oral	10 Mg, 1x/Day		Prinston Pharmaceutical
	Escitalopram			S				Prinston Pharmaceutical
	Hydrocodone Bitartrate And Acetaminophen			S		Unk		Mikart
	Hydrocodone Bitartrate And Acetaminophen			S		0.5 Tablets, Unk		Mikart
	Tramadol			S		Unk		Not Reported
	Carvedilol			C				Not Reported
	Benicar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14884297	EXPEDITED (15-DAY)		HO	ES-PRINSTON PHARMACEUTICAL INC.-2018PRN00235		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Myocardial Ischaemia; Torsade De Pointes	Escitalopram		S	Unknown	15 Mg, 1x/Day	Prinston Pharmaceutical
	Haloperidol		S	Unknown	2 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14885044	EXPEDITED (15-DAY)		HO	IT-BAUSCH-BL-2018-013562		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Partial Responder	Venlafaxine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown	After A Month, Dose Was Doubled		Not Reported
	Clonazepam			S	Unknown			Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Valproic Acid			S	Unknown	After A Month, Dose Was Doubled		Not Reported
	Quetiapine			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14965024	DIRECT	Y	OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Loss Of Consciousness	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14968161	DIRECT	Y	HO			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Dysarthria; Headache; Hypoaesthesia; Muscular Weakness; Nausea; Vomiting	Escitalopram		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	13857722	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-056794		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Eosinophilia; Myocarditis; Pericardial Effusion; Pleural Effusion	Clozapine			S				Accord
	Paliperidone/Paliperidone Palmitate			S				Not Reported
	Benzatropine			S				Not Reported
	Valproic Acid			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14318162	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1772788US		41 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Dependence; Palpitations; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	5 Or 10 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14704307	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018011964			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Prescribed Underdose	Tramadol Hydrochloride			S	Oral	Unk		Macleods
	Decapeptyl (Triptorelin)			S	Intramuscular	1 Df, 1 Cycle		Not Reported
	Innohep			S	Subcutaneous	1 Df, Qd		Not Reported
	Amlor			S	Oral	Unk		Not Reported

Novonorm	S	Oral	Unk		Not Reported
Esomeprazole	S	Oral	Unk		Not Reported
Xtandi	S	Oral	120 Mg, Qd		Not Reported
Xtandi	S	Oral	40 Milligram, Qd		Not Reported
Lipanthyl	S	Oral	145 Mg, Qd		Not Reported
Seroplex	S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14764354	EXPEDITED (15-DAY)		HO, LT, OT	TR-ALLERGAN-1702558US		24 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Drug Abuse; Hypernatraemia; Hypocalcaemia; Intentional Overdose; Leukopenia; Loss Of Consciousness; Respiratory Depression; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Fluoxetine Hcl Unk			S	Oral	Unk		Allergan
	Olanzapine			S	Oral	Unk		Not Reported
	Valproic Acid			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14890887	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1825422US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Product Dose Omission	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Citalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14890922	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1825591US		44 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cognitive Disorder; Fatigue; Loss Of Personal Independence In Daily Activities; Muscle Spasms; Pain	Escitalopram Oxalate - Bp	S	Unknown			Allergan
	Diazepam	S	Unknown	Unk		Not Reported
	Gilenya	S	Unknown	Unk		Not Reported
	Lyrica	S	Unknown	Unk		Not Reported
	Vitamin B Complex	S	Unknown	Unk		Not Reported
	Vitamin D2	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14891590	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1823903US		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Muscle Rigidity; Parkinson'S Disease; Tremor	Lexapro			S	Oral	15 Mg, Bid		Allergan
	Lexapro			S				Allergan
	Metformin			C	Unknown	Unk Unk, Unknown		Not Reported
	Glimepiride			C	Oral	2 Mg, Unknown		Not Reported
	Atenolol			C	Unknown	Unk Unk, Unknown		Not Reported
	Valsartan			C	Unknown	Unk Unk, Unknown		Not Reported
	Insulin			C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14895311	EXPEDITED (15-DAY)		HO	ES-ACCORD-066934		81 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram			S	Oral	Strength: 10 Mg 28 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14895474	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMPANY-FR201805003766		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Epilepsy	Zyprexa 10mg		S	Oral	1 Df, Daily	Not Reported
	Seroplex		S	Oral	1 Df, Daily	Not Reported
	Noctamide		S	Oral	2 Df, Daily	Not Reported
	Xanax		S	Oral	3 Df, Daily	Not Reported
	Tercian /00759302/		S	Oral	100 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14895998	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1825577US		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Cognitive Disorder; Fall	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Revlimid			S	Oral	21 Days On 28		Not Reported
	Dexamethasone			S	Oral	Unk		Not Reported
	Zelitrex			S	Oral	Unk		Not Reported
	Bactrim			S	Oral	Unk		Not Reported
	Lexomil			S	Oral	0.5 Gbq, Unk		Not Reported
	Imovane			C	Oral			Not Reported
	Spironolactone			C	Oral	Unk		Not Reported
	Lasilix			C	Oral	Unk		Not Reported
	Kardegic			C	Oral	Unk		Not Reported
	Nebivolol			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14897694	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1824758US		50 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Overdose	Escitalopram Oxalate - Bp			S	Oral	Unk, Single		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14701084	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180341436		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Tramadol Hydrochloride			S	Oral			Not Reported
	Decapeptyl [Gonadorelin]			S	Intramuscular			Not Reported
	Innohep			S	Subcutaneous			Not Reported
	Amlor			S	Oral			Not Reported
	Novonorm			S	Oral			Not Reported
	Esomeprazole			S	Unknown			Not Reported
	Xtandi			S	Oral			Not Reported
	Lipanthyl			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14741381	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2018TUS007841		20 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Suicidal Ideation	Trintellix			S	Oral	5 Mg, Qd		Takeda
	Trintellix			S	Oral	10 Mg, Qd		Takeda
	Cipralex /01588501/			S	Unknown	20 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Unknown	15 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Unknown	10 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Unknown	5 Mg, Qd		Not Reported
	Abilify			C	Unknown	2 Mg, Qd		Not Reported
	Abilify			C	Unknown	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14854785	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1824648US		65 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Dizziness; Dyspnoea; Haematochezia; Pain	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd (1-0-0-0)		Allergan
	Acetylsalicylsaeure			S	Unknown	100 Mg, Qd (1-0-0-0)		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd (0-0-1-0)		Not Reported
	Ramipril			C	Unknown	2.5 Mg, Qd (0-1-0-0)		Not Reported
	Spiriva			C	Unknown	18 Mg, Qd (1-0-0-0)		Not Reported
	Pantoprazol			C	Unknown	40 Mg, Qd (0-0-1-0)		Not Reported
	Euthyrox			C	Unknown	50 Mg, Qd (1-0-0-0)		Not Reported
	Allopurinol			C	Unknown	50 Mg, Qd (0-0-0.5-0)		Not Reported
	Metamizole			C	Unknown	15 Gtt, Tid (1-1-1-0)		Not Reported
	Metoprolol			C	Unknown	47.5 Mg, Bid (1-0-1-0)		Not Reported
	Alna			C	Unknown	4 Mg, Qd (0-0-1-0)		Not Reported
	Torasemid			C	Unknown	10 Mg, Qd (0-1-0-0)		Not Reported
	Tramal Long			C	Unknown	Unk, Mg, Prn		Not Reported
	Symbicort			C	Unknown	Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14854786	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1824640US		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Contusion; Fall; Syncope	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Eferox			C	Unknown	50 Mg, Qam		Not Reported
	Hct			C	Unknown	12.5 Mg, Qam		Not Reported
	Metoprolol			C	Unknown	4.75 Mg, Qam		Not Reported
	Ventolair			C	Unknown	250 Mg, Qid		Not Reported
	Metamizole			C	Unknown	500 Mg, Tid		Not Reported
	Valsartan			C	Unknown	120 Mg, Unk		Not Reported
	Ass 100			C	Unknown	100 Mg, Unk		Not Reported

	Simvastatin	C	Unknown	40 Mg, Qhs		Not Reported
	Pantoprazol	C	Unknown	20 Mg, Qam		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14899361	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-893244		30 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abdominal Pain Upper; Diarrhoea	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14899388	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-02400		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Guilty; Self Esteem Decreased; Suicidal Ideation; Therapy Partial Responder	Olanzapine			S	Unknown	15 Mg, Qd		Alkem
	Risperidone			S	Unknown	Unk		Not Reported
	Quetiapine Fumarate			S	Unknown	Unk		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Venlafaxine			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	Unk		Not Reported
	Bupropion			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14900053	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018013305			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia; Product Used For Unknown Indication	Escitalopram			S	Unknown	Unknown		Macleods
	Aspirin			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14901831	EXPEDITED (15-DAY)		OT	PL-ALLERGAN-1825871US			Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Feeling Abnormal; Head Titubation; Laziness; Miosis	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Dextromethorphan			S	Unknown	60 Mg, Unk		Not Reported
	Thiocodin (Buflomedil Hydrochloride)			S	Unknown	16 Df, Unk		Not Reported
	Aviomarin			S	Unknown	1 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14901835	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1825864US		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Drug Abuse	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Atarax			S	Oral	Unk		Not Reported
	Zopiclone			S	Oral	Unk		Not Reported
	Previscan (Pentoxifylline)			S	Oral	Unk		Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14903710	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1031954		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Venlafaxine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Tranxene			S	Oral	40 Mg, Qd		Mylan
	Bromazepam			C	Oral	12 Mg, Qd		Mylan
	Debridat /00465201/			C	Oral	2 Df, Qd		Mylan
	Loxapac /00401801/			C	Oral	20 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14979938	DIRECT		DE			24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Emotional Disorder; Impaired Self-Care; Speech Disorder; Therapy Change; Weight Decreased	Escitalopram			S	Oral	Quantity:1 Df Dosage Form;		Not Reported
	Escitalopram			S	Oral	Quantity:0.5 Df Dosage Form;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14874033	EXPEDITED (15-DAY)		OT	AU-APOTEX-2018AP012727			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysstasia; Insomnia; Loss Of Personal Independence In Daily Activities; Restlessness	Apo-Escitalopram			S	Oral	0.5 Df, Daily		Apotex
	Apo-Escitalopram			S	Oral	1 Df, Daily		Apotex
	Sotalol			C	Unknown	Unk		Not Reported
	Sotalol			C				Not Reported
	Amlol /00972402/			C	Unknown	Unk		Not Reported
	Amlol /00972402/			C				Not Reported
	Irbesartan			C	Unknown	Unk		Not Reported
	Irbesartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14907199	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-173019		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Extrapyramidal Disorder; Mydriasis; Sinus Tachycardia	Risperidone			S	Oral	36 Mg, In Total		Ranbaxy
	Escitalopram			S	Oral	9 Mg, In Total		Not Reported
	Theralene			C	Oral	Posologie Non Precisee ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14910464	EXPEDITED (15-DAY)		DS	GB-ALLERGAN-1826167US		33 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Jaw	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Lansoprazole			C	Unknown	30 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14910785	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1825626US		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown	(20mg-0mg-0mg-0mg) In The Morning		Allergan
	Milnacipran Unk			S	Oral	200 Mg, Qd		Allergan
	Milnacipran Unk			S	Oral	50 Mg, Bid		Allergan
	Lamotrigine			S	Unknown	100 Mg, Tid (1-1-1-0)		Not Reported
	Mirtazapine			S	Unknown	45 Mg, Qhs (At Night)		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Qhs (At Night) (0-0-1)		Not Reported
	Levothyroxine			C	Unknown	100 Mg (1-0-0-0) In The Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14169981	EXPEDITED (15-DAY)		OT	FR-TEVA-822279ROM		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Milligram Daily;		Ivax
	Bisoprolol			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14202702	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-061174		88 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Heteroplasia; Syncope; Vomiting	Escitalopram			S	Oral			Accord
	Ceftriaxone			C				Not Reported
	Furosemide			C				Not Reported
	Pentoxifylline			C				Not Reported
	Insulin Human/Insulin Human Biosynthetic/Insulin Human Injection/Isoph/Insulin Human Zinc Suspension			C				Not Reported
	Ramipril			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Dutasteride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14455260	EXPEDITED (15-DAY)		OT	BE-ALLERGAN-1804425US		41 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Seretide			S	Unknown	Unk		Not Reported
	Vilanterol Trifenatate			S	Unknown	Unk, Qd		Not Reported
	Flixotide			S	Unknown	250 Mg, Bid		Not Reported
	Ventolin			S	Unknown	100 Mg, Unk		Not Reported
	Xanthium (Theophylline)			S	Unknown	20 Mg, Qd		Not Reported
	Pantomed (Dexpanthenol)			S	Unknown	20 Mg, Qd		Not Reported
	Xyzall			S	Unknown	5 Mg, Qd		Not Reported
	Fluticasone Furoate			S	Unknown	Unk Unk, Qd		Not Reported
	Avamys			S	Unknown	Unk, Bid		Not Reported
	D-Cure			S	Unknown	25 Iu, Unk		Not Reported
	Mepolizumab			S	Subcutaneous	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14911125	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-173058		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Venlafaxine			S	Oral	300 Mg, Daily		Sun
	Alprazolam			S	Oral	1.5 Mg, Daily		Sun
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported
	Quetiapine			S	Oral	200 Mg, Daily		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Daily		Not Reported
	Valproic Acid			S	Oral	300 Mg, Daily		Not Reported
	Trazodone			S	Oral	75 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14912263	EXPEDITED (15-DAY)		DE, OT	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2010-00003		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Chloride Increased; Blood Creatinine Increased; Blood Lactate Dehydrogenase Increased; Blood Sodium Increased; C-Reactive Protein Increased; Cardio-Respiratory Arrest; Concomitant Disease Aggravated; Condition Aggravated; Hyperhidrosis; Monocyte	Quetiapine Fumarate			S	Oral	200 Mg, Od		Alkem
	Lorazepam			S	Oral	6 Mg, Od		Not Reported
	Abilify 3mg			S	Oral	20 Mg, Unk		Not Reported
	Abilify 3mg			S	Oral	15 Mg, Unknown		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Seroquel			S	Oral	200 Mg, Unk		Not Reported
	Tavor (Lorazepam)			S	Oral	6 Mg, Unk		Not Reported
	Tavor (Lorazepam)			S	Oral	2 Mg, Unk		Not Reported
	Simeticone			C	Unknown	Unk		Not Reported

Percentage Increased; Neutrophil Percentage Increased; Restlessness; Schizoaffective Disorder	Movicol		C	Unknown	Unk	Not Reported
	Eferox		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14912582	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-025892		55 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia; Product Used For Unknown Indication	Escitalopram			S	Unknown	Unk		Aurobindo
	Acetylsalicylsaeure			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14913226	EXPEDITED (15-DAY)		HO	DE-LUPIN PHARMACEUTICALS INC.-2018-03687		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Gait Disturbance; Hallucination; Somnolence	Valproinsaeure			S	Oral	500 Mg, Qd		Not Reported
	Quetiapine			S	Oral	100 Mg, Qd		Lupin
	Quetiapine			S	Unknown	300 Mg, Unk		Lupin
	Cipralex /01588501/			S	Oral	10 Mg, Qd		Not Reported
	Levothyroxin			C	Oral	75 Mcg, Qd		Not Reported
	Torasemid			C	Oral	10 Mg, Qd		Not Reported
	Felodipine			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14914536	NON-EXPEDITED		OT	US-JAZZ-2018-US-003980			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Fatigue; Somnolence	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Abilify			S				Not Reported

	Abilify	S			Not Reported
	Lexapro	S			Not Reported
	Lexapro	S			Not Reported
	Ciprofloxacin	S			Not Reported
	Morniflumate	S			Not Reported
	Hydrocodone Bitartrate And Acetaminophen	C	Unk		Not Reported
	Nuvigil	C	Unk		Not Reported
	Citalopram Hbr	C	Unk		Not Reported
	Citalopram	C			Not Reported
	Ibuprofen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14914597	EXPEDITED (15-DAY)		HO	DE-ASTRAZENECA-2018SE62193		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine			S	Oral	100 Mg, 0-0-0-1		Not Reported
	Quetiapine			S	Oral	Patient Took 300mg Instead Of 100mg.		Not Reported
	Cipralex			S	Oral	10 Mg, 1-0-0-0		Not Reported
	Valproic Acid			S	Oral	500 Mg, 0-0-0-1		Not Reported
	Levothyroxine			C	Oral	1-0-0-0		Not Reported
	Torasemide			C	Oral	1-0-0-0		Not Reported
	Felodipine			C	Oral	10 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14915069	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1825712US		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorea; Dementia; Serotonin Syndrome	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan
	Jakafi			S	Unknown	20 Mg, Bid		Not Reported
	Atorvastatin			C	Unknown	Unk Unk, Unknown		Not Reported
	Prolia			C	Unknown	Unk Unk, Unknown		Not Reported

Levothyroxine	C	Unknown	Unk Unk, Unknown		Not Reported
Ranitidine	C	Unknown	Unk Unk, Unknown		Not Reported
Xarelto	C	Unknown	Unk Unk, Unknown		Not Reported
Tolterodine	C	Unknown	Unk Unk, Unknown		Not Reported
Clonazepam	C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14984970	DIRECT		OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Change; Vision Blurred; Visual Impairment	Escitalopram 10mg			S	Oral	At Bedtime		Lupin
	L-Thyroxine			C				Not Reported
	Olmesartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14987798	DIRECT					37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Memory Impairment; Paraesthesia; Sleep Deficit; Somnolence; Visual Impairment	Escitalopram (Generic)			S	Oral	Quantity:1 Tablet(S);	3 YR	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2018	14321027	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2017DE00434			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported
	Valdoxan			S	Unknown	25 Mg, Qd		Not Reported
	Zoely			S	Oral	One Tablet A Day (One Df Contains 2.5mg		Not Reported

Nomegestrel And 1.5mg Estradiol)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2018	14916438	NON-EXPEDITED			US-JNJFOC-20180434118		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Tachyphrenia	Ibuprofen		Y	S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Atorvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2018	14916510	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-026262		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine Film-Coated Tablet			S	Oral	100 Milligram, 0-0-0-1		Aurobindo
	Valproic Acid			S	Oral	500 Milligram, Once A Day		Not Reported
	Cipralex /01588501/			S	Oral	10 Milligram, Once A Day		Not Reported
	Levothyroxine			C	Oral	75 Microgram, Once A Day		Not Reported
	Torasemid			C	Oral	10 Milligram, Once A Day		Not Reported
	Felodipine			C	Oral	10 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2018	14989304	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Headache; Hypersensitivity; Neck Pain; Pharyngeal Swelling; Product Quality Issue;	Escitalopram			S	Oral	Quantity:5 Ml;		Amneal
	Vitamin D Nos			C				Not Reported
	Vitamin B12			C				Not Reported

Product Substitution Issue; Product Taste Abnormal; Pruritus; Throat Irritation	Iron	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14707245	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-169091		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Prescribed Underdose	Esomeprazole			S	Oral	()		Sun
	Decapeptyl (Triptorelin)			S	Intramuscular	Cyclical		Not Reported
	Innohep			S	Subcutaneous	1 Df, Unk		Not Reported
	Amlor			S	Oral	()		Not Reported
	Novonorm			S	Oral	()		Not Reported
	Tramadol Base			S	Oral	()		Not Reported
	Xtandi			S	Oral	120 Mg, Unk		Not Reported
	Lipanthyl			S	Oral	145 Mg, Unk		Not Reported
	Seroplex			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14790115	EXPEDITED (15-DAY)		LT	JP-ALLERGAN-1822180US		77 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hepatic Enzyme Increased; Nausea; Neurogenic Bladder; Septic Shock; Urinary Retention; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Risperidone			S	Oral	0.5 Mg, Unk		Not Reported
	Risperidone			S	Oral	1 Mg, Unk		Not Reported
	Donepezil Hydrochloride			C	Oral	Unk		Not Reported
	Mosapride Citrate			C	Unknown	Unk		Not Reported
	Magnesium Oxide			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown			Not Reported

	Sodium Risedronate Hydrate		C	Unknown	Unk	Not Reported
	Prednisolone		C	Unknown	Unk	Not Reported
	Januvia		C	Unknown	Unk	Not Reported
	Amlodipine		C	Unknown	Unk	Not Reported
	Lansoprazole		C	Unknown	Unk	Not Reported
	Epalrestat		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14917148	EXPEDITED (15-DAY)		HO, OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-167153		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Depressed Level Of Consciousness; Electrocardiogram Qt Prolonged; Irritability; Miosis; Overdose; Oxygen Saturation Decreased; Sinus Tachycardia; Somnolence	Escitalopram			S	Oral	Unk		Not Reported
	Topiramate			S	Oral	Unk		Sun
	Citalopram			S	Oral	Unk		Sun
	Oxazepam			S	Oral	Unk		Sun
	Quetiapine			S	Oral	Unk		Sun
	Temazepam			S	Oral	Unk		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14918871	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1826718US		27 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Erectile Dysfunction	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Lithionit			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14919266	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2018205793		44 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Dyspepsia	Ibuprofen	S		Unk	Pfizer
	Escitalopram Oxalate	S		20 Mg, 1x/Day (20 Mg, 1-0-0)	Not Reported
	Bornaprine	S		10 Mg, Daily (4 Mg, 1-0.5-1-0)	Not Reported
	Neupro	S	Transdermal	14 Mg, 1x/Day (14 Mg, 1-0-0-0)	Not Reported
	Madopar Depot	C		1 Df, 1x/Day (100|25 Mg, 0-0-0-1)	Not Reported
	Madopar	C		100|25 Mg, 1.5-1.5-1.5-1.5	Not Reported
	Amantadine Hcl	C		100 Mg, 2x/Day (100 Mg, 1-1-0-0)	Not Reported
	Amitriptylin	C		75 Mg, 1x/Day (75 Mg, 0-0-0-1)	Not Reported
	Madopar Lt	C		100|25 Mg, 1-0-0-0	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14920663	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018203360		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Drug Interaction; Dyspnoea; Pulmonary Embolism; Weight Fluctuation	Xeljanz			S	Oral	5 Mg, 2x/Day (5 Mg, 2 In 1 D)		Pfizer
	Cymbalta			S		Unk (2 Weeks)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Lexapro			S	Oral	20 Mg, 1x/Day (20 Mg, 1 In 1 D)		Not Reported
	Methotrexate			S	Oral	9 Df, Weekly (1 In1 Wk)(On Saturday)		Not Reported
	Methotrexate			S	Oral	Unk, Weekly (1 In 1 Wk)		Not Reported
	Progesterone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remeron			S	Oral	15 Mg, 1x/Day (Before		Not Reported

			Bed (15 Mg, 1 In 1 D))	
Atorvastatin	C	Oral	20 Mg, 1x/Day (At Bed Time And Taking For Atleast 6 Months (20 Mg, 1 In 1 D))	Not Reported
Cardiazem	C	Oral	240 Mg, 1x/Day (Taking For At Least 6 Months (240 Mg,1 In 1 D))	Not Reported
Cardiazem	C			Not Reported
Carvedilol	C	Oral	6.25 Mg, 2x/Day (6.25 Mg, 2 In 1 D)	Not Reported
Cozaar	C	Oral	25 Mg, 1x/Day (25 Mg,1 In 1 D)	Not Reported
Potassium	C	Oral	Unk Unk, 2x/Day (2 In 1 D)	Not Reported
Potassium	C	Oral	10 Meq, 1x/Day (10 Milliequivalents,1 In 1 D)	Not Reported
Pantoprazole	C	Oral	40 Mg, 1x/Day (40 Mg,1 In 1 D)	Not Reported
Folic Acid	C	Oral	1 Mg, Unk (1 Mg, 6 In 1 Wk)	Not Reported
Aldactone	C	Oral	2 Df, 1x/Day (2 Dosage Forms, 1 In 1 D)	Not Reported
Hydrocodone Bitartrate And Acetaminophen	C	Oral	1 Df, Unk (Hydrocodone Bitartrate:10 Mg/Acetaminophen:325 Mg One Tablet By Mouth Two To Three Times)	Not Reported
Tramadol	C		Unk, As Needed (As Required)	Not Reported
Bumex	C	Oral	2 Mg, 1x/Day (2 Mg,1 In 1 D)	Not Reported
Gabapentin	C		400 Mg, 3x/Day (400 Mg,3 In 1 D)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14426581	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1004745		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Escitalopram			S	Oral	Unk		Not Reported
	Pantoprazole			S	Oral	Unk		Not Reported
	Lipanthyl			S	Oral	Unk		Mylan
	Fondaparinux Sodium			S	Subcutaneous	Unk		Mylan
	Xeloda			S	Oral	Unk		Mylan
	Primperan			S	Oral	Unk		Mylan
	Abasaglar			S	Subcutaneous	Unk		Mylan
	Movicol			S	Oral	Unk		Mylan
	Novorapid			S	Subcutaneous	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14432694	EXPEDITED (15-DAY)		HO, OT	FR-ABBVIE-18S-056-2233700-00		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Lipanthyl			S	Oral	Unknown		Not Reported
	Fondaparinux Sodium			S	Subcutaneous	Unknown		Not Reported
	Xeloda			S	Oral	Unknown		Not Reported
	Primperan			S	Oral	Unknown		Not Reported
	Abasaglar			S	Subcutaneous	Unknown		Not Reported
	Movicol			S	Oral	Unknown		Not Reported
	Novorapid			S	Subcutaneous	Unknown		Not Reported
	Escitalopram			S	Oral	Unknown		Not Reported
	Pantoprazole			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921476	NON-EXPEDITED			DE-LUPIN PHARMACEUTICALS INC.-2018-01201		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting	Clopidogrel			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Escitalopram Beta			S	Oral	10 Mg, Qd		Not Reported
	Olmesartan			S	Unknown	Unk		Lupin
	Metformin			S	Unknown	Unk		Not Reported
	Insulin			S	Unknown	Unk		Not Reported
	Ass			S	Unknown	Unk		Not Reported
	Molsidomin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921515	EXPEDITED (15-DAY)		LT, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018013501			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Thrombosis	Olanzapine			S	Oral	7.5 Milligram		Macleods
	Teralithe Lp 400 Mg			S	Oral	2 Dosage Form, Breakable Sustained Release Tablet		Not Reported
	Seroplex 5 Mg			S	Oral	1 Dosage Form Of Coated Tablet.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921742	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018013496			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Pulmonary Artery Stenosis Congenital	Escitalopram	S	Transplacental	10 Milligram, Qd, 1 {Trimester}, 7.5. - 11.6. Gestational Week	Macleods
	Quetiapine	C	Transplacental	25 Milligram, Qd, 2 {Trimester}, 14. - 38.1. Gestational Week	Macleods
	Sertraline	C	Transplacental	150 Milligram, Qd, 2 {Trimester}, 14. - 38.1. Gestational Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921743	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018013497			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 Milligram, Qd, (0. - 28.6. Gestational Week) 1 Trimester		Macleods
	Femibion Pregnancy 1 (Nem)			C	Transplacental	0.8 Milligram, Qd, (0. - 40.5. Gestational Week), 1 Trimester		Not Reported
	Influenza Vaccine			C	Transplacental	Unk		Not Reported
	L-Thyroxin			C	Transplacental	Unk, 100 [Mg/D]/ Initial 75µg/D, Dosage Increase To 100µg/D From Week 34+2 (0. - 40.5. Gestational		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14922753	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP014055		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Haemorrhage; Platelet Aggregation Inhibition	Escitalopram			S	Unknown	Unk		Apotex
	Rivaroxaban			S	Unknown	15 Mg, Daily		Not Reported

Rivaroxaban	S				Not Reported
Heparin	S	Subcutaneous	5000 U, Every 12 Hours		Not Reported
Lidocaine	C	Unknown	3 Ml, Unk		Not Reported
Epinephrine	C	Unknown	5 Microgram/ Ml Unk, Unk		Not Reported
Bupivacaine	C	Unknown	1 Mg/Ml, Unk		Not Reported
Hydromorphone	C	Unknown	10 Microgram/ Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14923427	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1826903US		45 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Desloratadine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14923747	NON-EXPEDITED			US-TEVA-2018-US-895053			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	10076441	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000059589		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Underdose	Asenapine Maleate - Bp			S	Oral	1.25 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14908509	NON-EXPEDITED			US-PFIZER INC-2018198368		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cyclic Vomiting Syndrome; Diarrhoea; Fatigue; Hypersomnia; Hypotension; Intentional Product Use Issue; Nausea; Pain; Product Dispensing Error; Product Dose Omission; Retching	Lyrica			S		25 Mg, 3x/Day		Pfizer
	Lyrica			S		50 Mg, 3x/Day		Pfizer
	Lyrica			S		50 Mg, Unk		Pfizer
	Lyrica			S		25 Mg, 3x/Day		Pfizer
	Lyrica			S		75 Mg, Daily (25mg Twice A Day And 50mg At Night)		Pfizer
	Lyrica			S		50 Mg, 3x/Day		Pfizer
	Lyrica			S		50 Mg, 2x/Day		Pfizer
	Bisoprolol			C	Oral	10 Mg, 1x/Day, (Started Taking 5 Years Ago)		Not Reported
	Pantoprazole			C	Oral	40 Mg, 1x/Day, (Started Taking Several Years Ago)		Not Reported
	Vitamin D2			C	Oral	2000 Iu, 1x/Day, (Started Taking About 2 Years Ago)		Not Reported
	Metoclopramide			C	Oral	10 Mg, 2x/Day, (Started Taking 2 Years Ago.)		Not Reported
	Otezla			C	Oral	30 Mg, 2x/Day, (Started Approximately 3 Years Ago.)		Not Reported
	Otezla			C				Not Reported
	Naltrexone			C	Oral	4.5 Mg, 1x/Day, (Started Taking About A Year Ago.)		Not Reported
	Naltrexone			C				Not Reported
	Escitalopram			C	Oral	5 Mg, 1x/Day		Not Reported
	Mirtazapine			C	Oral	15 Mg, 1x/Day		Not Reported
	Mirtazapine			C				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14910375	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018200670		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Hypotension; Hypovolaemia; Paralysis; Spinal Cord Compression; Spinal Cord Oedema	Heparin Sodium			S	Subcutaneous	5000 Iu, 2x/Day		Unknown
	Escitalopram			S		Unk		Not Reported
	Lidocaine			C		3 Ml, Unk (A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 ?G/Ml)		Not Reported
	Hydromorphone			C		10 Ug/Ml, Unk (10 ?G/Ml Was Initiated During The Procedure And Maintained At 6 Ml/H, Infusion)		Not Reported
	Epinephrine			C		5 Ug/Ml, Unk (Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 ?G/Ml)		Not Reported
	Bupivacaine			C		1 Mg/Ml, Unk (Infusion)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14922125	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-03069		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Overdose; Toxicity To Various Agents	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported
	Lamotrigine			S	Unknown	100 Mg, Unk		Alkem

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14926717	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-895188		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Tramadol (Chlorhydrate De)			S	Oral			Teva
	Seroplex			S	Oral			Not Reported
	Bilaska			S	Oral			Not Reported

	Seresta	S	Oral	Not Reported
	Nocertone	S	Oral	Not Reported
	Simponi 50 Mg, Solution Injectable En Seringue Préremplie	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927080	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004412		53 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Espran			S	Oral	Unknown		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927096	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018013572			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	10 Milligram, Qd		Macleods
	Indapamide			S	Oral	2.5 Milligram, Qd		Not Reported
	Enoxaparin Sodium			C	Unknown	Unk		Not Reported
	Lactulose			C	Unknown	Unk		Not Reported
	Perindopril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927768	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2017-36384			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Product Substitution Issue	Escitalopram			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927801	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1827166US		44 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Off Label Use; Somnolence	Escitalopram Oxalate - Bp			S	Oral	70 Mg, Unk		Allergan
	Noctamide			S	Oral	14 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14928313	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-027064		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 [Mg/D] 1 {Trimester} 0. - 28.6. Gestational Week		Aurobindo
	Femibion /07499601/			C	Transplacental	0.8 [Mg/D], 1 {Trimester} 0. - 40.5. Gestational Week		Not Reported
	Influenza Vaccine			C	Transplacental	Unk		Not Reported
	L-Thyroxin /00068001/			C	Transplacental	100 [Mg/D]/ Initial 75µg/D, Dosage Increase To 100µg/D From Week 34+2		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14928343	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2018-027227		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Pulmonary Artery Stenosis Congenital	Escitalopram			S	Transplacental	10 Milligram, Daily		Aurobindo
	Quetiapine			C	Transplacental	25 Milligram, Daily		Not Reported
	Sertraline			C	Transplacental	150 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14928785	EXPEDITED (15-DAY)		HO, LT, OT	US-		25 YR	Female	USA

GLAXOSMITHKLINE-US2018089769

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Rhabdomyolysis; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S				Glaxosmithkline
	Lamotrigine			S	Unknown	Unk		Glaxosmithkline
	Lamotrigine			S				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14929579	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1033126		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intracranial Haematoma	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Kardegic			S		75 Mg, Qd		Mylan
	Levocetirizine Dihydrochloride			C		5 Mg, Qd		Mylan
	Amlodipine			C		5 Mg, Qd		Mylan
	Levothyroxine Sodique			C		50 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14929654	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2018210181			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Xanax			S		Unk		Pfizer
	Sonirem			S		Unk		Not Reported
	Zarelis			S		Unk		Not Reported
	Cipralex /01588501/			S		Unk		Not Reported

	Rivotril	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	13881576	EXPEDITED (15-DAY)		HO, LT	PL-ALLERGAN-1735394US		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Off Label Use; Overdose; Suicide Attempt; Tinnitus	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qhs		Allergan
	Concor			S	Unknown	Unk Unk, Unknown		Not Reported
	Polsen			S	Unknown	10 Mg, Qd		Not Reported
	Clarithromycin			S	Oral	Unk, Qhs		Not Reported
	Perindopril			S	Oral			Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Atoris			S	Unknown	Unk Unk, Unknown		Not Reported
	Sertraline			S	Oral	50 Mg, Qam		Not Reported
	Trosicam			S	Unknown	Unk Unk, Unknown		Not Reported
	Doxepin			S	Oral	25 Mg, Qhs		Not Reported
	Atorvastatin			S	Oral			Not Reported
	Meloxicam			S	Oral	Unk Unk, Qhs		Not Reported
	Zolpidem			S	Oral	10 Mg, Qhs		Not Reported
	Bisoprolol			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14259519	EXPEDITED (15-DAY)		HO	CA-APOTEX-2017AP021993		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aptyalism; Drug Ineffective; Overdose; Panic Disorder	Apo-Buspirone			S	Oral	5 Mg, Qd		Apotex
	Amitriptyline			S	Oral	20 Mg, Qd		Apotex
	Escitalopram			S	Oral	30 Mg, Unk		Apotex
	Zyprexa			S	Oral	2.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14860950	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2018187748		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypomagnesaemia; Mental Disorder	Pantoprazole			S	Unknown	Unk		Pfizer
	Escitalopram Oxalate			S	Unknown	15 Mg, Daily		Not Reported
	Haloperidol			S	Unknown	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14933181	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2018SP003699			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sexual Dysfunction	Fluoxetine			S	Unknown	Up To 40mg Daily		Not Reported
	Citalopram			S	Unknown	Up To 40mg Daily		Not Reported
	Buspirone Hydrochloride			S	Unknown	Up To 45 Mg Daily		Strides
	Escitalopram			S	Unknown	Up To 20mg Daily		Not Reported
	Venlafaxine			S	Unknown	Extended Release, Up To 225mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14933625	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2018-027143		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Escitalopram			S	Oral	15 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14934014	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-027309		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram		S	Oral	10 Milligram, Once A Day	Aurobindo
	Indapamide		S	Oral	2.5 Milligram, Once A Day	Not Reported
	Lactulose		C	Unknown	Unk	Not Reported
	Perindopril		C	Unknown	Unk	Not Reported
	Enoxaparin Sodium		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14935180	EXPEDITED (15-DAY)		HO	BE-ALLERGAN-1827413US		25 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Lactation Disorder; Live Birth; Off Label Use; Pregnancy	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan
	Abilify			S	Oral	20 Mg, Unk		Not Reported
	Abilify			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	15001656	DIRECT		DS			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Impaired Quality Of Life; Intrusive Thoughts; Unevaluable Event; Withdrawal Syndrome	Lexapro			S			6 MTH	Not Reported
	Minocycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	13849471	NON-EXPEDITED			US-PFIZER INC-2017339156		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction	Metoprolol Tartrate			S	Oral	100 Mg, 1x/Day		Not Reported
	Zyprexa			S	Oral	20 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Lexapro			S				Not Reported

	Seroquel	S	Oral	150 Mg, 1x/Day(Every Evening)	Not Reported
	Klonopin	S	Oral	1 Mg, 1x/Day(At Bedtime)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14700247	EXPEDITED (15-DAY)		HO, OT	RU-ALLERGAN-1816286US		61 YR	Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy; Off Label Use; Seizure	Escitalopram Oxalate - Bp			S	Oral	Unk, Qd		Allergan
	Atarax			S	Oral	Unk, Qd		Not Reported
	Betaserc			S	Oral	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14726869	EXPEDITED (15-DAY)		OT	US-TORRENT-00005996			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depersonalisation/Derealisation Disorder; Lethargy; Suicidal Ideation; Therapeutic Response Decreased; Weight Increased	Aripiprazole			S		Unknown		Unknown
	Bupropion			S		Unknown		Unknown
	Buspirone			S		Unknown		Unknown
	Escitalopram			S		Unknown		Unknown
	Gabapentin			S		Unknown		Unknown
	Lorazepam			S		Unknown		Unknown
	Lurasidone			S		Unknown		Unknown
	Risperidone			S		Unknown		Unknown
	Sertraline			S		Unknown		Unknown
	Trazodone			S		Unknown		Unknown
	N-Acetylcysteine			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14738390	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1819479US		95 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Haemorrhage; Skin Haemorrhage; Thrombocytopenia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Cefuroxime			S	Intravenous (not otherwise specified)	0.75 G, Q8hr		Not Reported
	Cefuroxime Sodium			S	Oral	1.5 G, Q8hr		Not Reported
	Nifedipine			C	Oral	1 Df, Qd		Not Reported
	Nicergoline			C	Oral	1 Df, Qd		Not Reported
	Finasteride			C	Oral	2 Df, Qd		Not Reported
	Trimetazidine Dihydrochloride			C	Oral	1 Df, Bid		Not Reported
	Calcium Carbonate			C	Oral			Not Reported
	Alfacalcidol			C	Oral	2 Df, Qd		Not Reported
	Ambroxol Hydrochloride			C	Oral	1 Df, Qd		Not Reported
	Olanzapine			C	Oral	1 Df, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14936803	EXPEDITED (15-DAY)		OT	HR-TEVA-2018-HR-896724		21 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Escitalopram			S	Oral	15 - 20 Tablets Of Unknown Strength		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14937761	EXPEDITED (15-DAY)		OT	US-TORRENT-00006182			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choking; Product Quality Issue; Product Substitution Issue	Escitalopram			S		Once At Night		Torrent
	Aspirin			C				Unknown
	Verapamil			C		One Capsule At Bed Time		Unknown
	Lexapro			C				Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14937893	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1827597US		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Noctamide			S	Oral	2 Df, Qd		Not Reported
	Xanax			S	Oral	3 Df, Qd		Not Reported
	Zyprexa			S	Oral	1 Df, Qd		Not Reported
	Tercian			S	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14940433	EXPEDITED (15-DAY)		DS	FI-GLAXOSMITHKLINE-FI2018088918		37 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Aphasia; Cushingoid; Derealisation; Dizziness; Drug Withdrawal Syndrome; Dysarthria; Dysgraphia; Dyspnoea; Erythema; Face Oedema; Facial Pain; Headache; Hyperhidrosis; Insomnia; Mydriasis; Oedema; Polyuria; Pyrexia; Sympathomimetic Effect; Tremor; Vision Blurred	Voxra			S	Oral	450,Mg,Daily		Glaxosmithkline
	Escitalopram			S	Unknown	Unk		Glaxosmithkline
	Triptyl			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14940747	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1827832US		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Extrapyramidal Disorder;	Escitalopram Oxalate - Bp			S	Oral	9 Mg, In Total		Allergan

Mydriasis; Off Label Use; Off Label Use; Sinus Tachycardia	Risperidone		S	Oral	36 Mg, In Total	Not Reported
	Theralene		C	Oral	Dosage Not Reported	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14941051	EXPEDITED (15-DAY)		HO	JP-OSMOTICA_PHARMACEUTICAL_US_LLC-POI0573201800151		48 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Divigel			S	Transdermal			Osmotica
	Lexapro			S				Not Reported
	Brotizolam			S				Not Reported
	Solanax			S				Not Reported
	Calcitriol			S				Not Reported
	Ternelin			S				Not Reported
	Loxoprofen Na			S				Not Reported
	Hochuekkito Extract Granules For Ethical Use			S				Not Reported
	Tokishigyakukagoshuyushokyoto Extract Granules For Ethical Use			S				Not Reported
	Keiskikaryukotsuboreito Extract Granules For Ethical Use			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2018	14690842	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1816147US		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Off Label Use; Prescription Drug Used Without A Prescription; Rhabdomyolysis; Suicide Attempt	Fluoxetine Hcl Unk			S	Oral	Unk		Allergan
	Hydrochlorothiazide Unk			S	Oral	Unk		Allergan
	Escitalopram Oxalate Unk			S	Oral	Unk		Allergan
	Venlafaxine			S	Oral	Unk		Not Reported
	Buspirone			S	Oral	Unk		Not Reported
	Atorvastatin			S	Oral	Unk		Not Reported

	Amlodipine	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2018	14869817	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1824734US		34 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Activation Syndrome	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Tecipul			S	Oral	2 Mg, Bid		Not Reported
	Depas (Etizolam)			S	Oral	1 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2018	14942965	EXPEDITED (15-DAY)		OT	CA-HETERO CORPORATE-HET2018CA00476		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression	Escitalopram			S	Unknown	Unk		Hetero
	Heparin			S	Subcutaneous	5000 U		Not Reported
	Lidocaine 2 %			C	Unknown	A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 ?G/Ml		Not Reported
	Hydromorphone			C	Unknown	10 ?G/Ml Was Initiated During The Procedure And Maintained At 6 Ml/H, Infusion		Not Reported
	Epinephrine			C	Unknown	A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 ?G/Ml		Not Reported
	Bupivacaine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2018	14942981	EXPEDITED (15-DAY)		HO, LT, OT	US-TORRENT-00006189		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Bundle Branch Block Left; Clonus; Electrocardiogram Qrs Complex Prolonged; Hyperreflexia; Hypotension; Muscle Rigidity; Overdose; Rhabdomyolysis; Sinus Tachycardia; Somnolence; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram	S	Unknown	Unknown
	Lamotrigine	S	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2018	14943335	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1827579US		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Grippe Impfstoff			C	Transplacental			Not Reported
	L-Thyroxin			C	Transplacental	100 Mg, Qd		Not Reported
	L-Thyroxin			C	Transplacental	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2018	14943336	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1827584US		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Pulmonary Artery Stenosis Congenital	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Quetiapine			S	Transplacental	25 Mg, Qd		Not Reported
	Sertraline			S	Transplacental	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14278478	EXPEDITED (15-DAY)		OT	ES-OTSUKA-2016_007918		23 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Use In Unapproved Indication; Suicide Attempt	Abilify	S	Unknown	10 Mg, Qd		Otsuka
	Abilify	S				Otsuka
	Abilify	S				Otsuka
	Escitalopram	S	Oral	15 Mg, Unk		Not Reported
	Escitalopram	S				Not Reported
	Escitalopram	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14702937	EXPEDITED (15-DAY)		HO, OT	US-ALVOGEN-2018-ALVOGEN-095657		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure; Suicide Attempt	Fluoxetine			S	Oral			Not Reported
	Amphetamine/Dextroamphetamine			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944943	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2018-FR-898874		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Intracranial Haematoma	Escitalopram			S		10 Milligram Daily;		Ivax
	Kardegic			S	Oral	75 Milligram Daily;		Not Reported
	Dichlorhydrate De Levocetirizine			C		5 Milligram Daily;		Not Reported
	Amlodipine			C		3 Milligram Daily;		Not Reported
	Levothyrox 50 Microgrammes, Comprimé Sécable			S		50 Microgram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945010	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2018US18690			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Diltiazem			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Metformin			S	Oral	Unk		Not Reported
	Glyburide			S	Oral	Unk		Not Reported
	Losartan			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945011	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2018US18681			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Amitriptyline			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported
	Lithium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945070	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-898589		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disturbance In Attention; Poisoning Deliberate	Paracetamol			S	Oral			Not Reported
	Escitalopram			S	Oral			Ivax
	Alprazolam			S	Oral			Actavis

	Codeine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945101	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18734			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Unk		Invagen
	Escitalopram			S	Oral	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945164	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18689			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Flecainide			S	Oral	Unk		Not Reported
	Verapamil			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945167	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18683			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Diphenhydramine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945168	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18680			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen

	Gabapentin	S	Oral	Unk		Invagen
	Amitriptylline	S	Oral	Unk		Not Reported
	Ibuprofen	S	Oral	Unk		Not Reported
	Ethanol	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945813	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2018US18454			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Unknown	Unk		Invagen
	Ethanol			S	Unknown	Unk		Not Reported
	Benzodiazepine Derivatives			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14948227	NON-EXPEDITED			US-PFIZER INC-2018218063		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Codeine			S		Unk		Not Reported
	Cefuroxime			S		Unk		Unknown
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14948421	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-898843		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Disorder; Priapism	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14949714	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA201805011449		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Duloxetine Hydrochloride			S	Unknown	Unk Unk, Unknown		Eli Lilly And Co
	Escitalopram			S	Unknown	Unk Unk, Unknown		Not Reported
	Venlafaxine			S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	15010683	DIRECT		DE			19 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depersonalisation/Dereali sation Disorder; Dissociation	Cipralex			S	Oral			Lundbeck

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	15011046	DIRECT		DS			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Panic Attack; Suicidal Ideation	Escitalopram			S	Oral	Quantity:.5 Tablet(S);	2 DAY	Accord
	Progesterone			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Fe Gluconate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14344134	EXPEDITED (15-DAY)		HO, OT	FR-BAUSCH-BL-2017-035611		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Metformin Hydrochloride			S	Oral			Santarus
	Terbutaline Sulfate			S	Respiratory (inhalation)			Not Reported
	Terbutaline Sulfate			S	Respiratory (inhalation)	1 Microg, Unknown(8 T)		Not Reported

Dafalgan	S	Oral			Not Reported
Irbesartan	S	Oral			Not Reported
Alprazolam	S	Oral			Not Reported
Tavanic	S	Oral	Divisible Coated Tablet		Not Reported
Xarelto	S	Oral			Not Reported
Colchicine Opocalcium	S	Oral			Not Reported
Bisoprolol Fumarate	S	Oral			Not Reported
Seroplex	S	Oral			Not Reported
Nefopam Hydrochloride	S	Oral			Not Reported
Nefopam Hydrochloride	S	Oral			Not Reported
Nefopam Hydrochloride	S	Oral			Not Reported
Diffu-K	S	Oral			Not Reported
Diffu-K	S	Oral			Not Reported
Pantoprazole	S	Oral			Not Reported
Furosemide	S	Oral			Not Reported
Furosemide	S	Unknown			Not Reported
Amlodipine	S	Oral			Not Reported
Mirtazapine	S	Oral			Not Reported
Valium Roche	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14378479	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-159721		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor; Suicide Attempt	Escitalopram			S	Oral	12 Ml, In Total		Not Reported
	Alprazolam			S	Oral	16 Mg, In Total		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14402289	EXPEDITED (15-DAY)		HO, LT	GR-MYLANLABS-2018M1003908		67 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Clonus; Confusional State; Delayed Recovery From Anaesthesia; Disorientation; Drug Interaction; Fear; Hyperpyrexia; Hyperreflexia; Mental Status Changes; Muscle Rigidity; Mydriasis; Psychomotor Hyperactivity; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Not Reported
	Methylene Blue			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Mylan
	Methylene Blue			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14618374	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018GSK039583		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Anaemia; Arthralgia; Chills; Cold Sweat; Confusional State; Crohn'S Disease; Dizziness; Dyspnoea; Fatigue; Feeling Abnormal; Haemorrhage; Headache; Night Sweats; Pain; Pyrexia	Bupropion Hydrochloride			S		Unk		Glaxosmithkline
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14695532	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018126444		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure	Amlodipine Besilate		S	Oral	Unk	Pfizer
	Atorvastatin Calcium		S	Oral	Unk	Pfizer
	Venlafaxine Hcl		S	Oral	Unk	Pfizer
	Escitalopram		S	Oral	Unk	Not Reported
	Hydrochlorothiazide		S	Oral	Unk	Not Reported
	Amphetamine / Dextroamphetamine		S	Oral	Unk	Not Reported
	Fluoxetine		S	Oral	Unk	Not Reported
	Buspirone		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14731126	EXPEDITED (15-DAY)		HO, OT	US-BAUSCH-BL-2018-008618		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose	Venlafaxine			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Amphetamine, Dextroamphetamine			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14837700	EXPEDITED (15-DAY)		HO	BE-OTSUKA-2018_010222		25 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hospitalisation; Lactation Disorder; Live Birth;	Abilify			S	Unknown	Unk		Otsuka
	Abilify			S	Oral	20 Mg, Unk		Otsuka
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported

Maternal Exposure During Pregnancy; Therapeutic Product Effective For Unapproved Indication

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14915243	EXPEDITED (15-DAY)		HO, OT	US-IMPAX LABORATORIES, INC-2018-IPXL-01652		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Agitation; Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Unresponsive To Stimuli	Lamotrigine Odt			S	Unknown	100 Mg, Tablets Unk		Impax
	Escitalopram			S	Unknown	20 Mg, Tablets Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14949892	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2018US18679			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Folic Acid			S	Oral	Unk		Invagen
	Ethylene Glycol			S	Oral	Unk		Not Reported
	Loratadine			S	Oral	Unk		Not Reported
	Furosemide			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Vitamin B-1			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14949923	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2018US18688			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Valproic Acid /00228502/			S	Oral	Unk		Not Reported
	Carvedilol			S	Oral	Unk		Not Reported
	Sitagliptin			S	Oral	Unk		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Primidone			S	Oral	Unk		Not Reported
	Phenytoin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14949928	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18691			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Naproxen			S	Oral	Unk		Invagen
	Alprazolam			S	Oral	Unk		Not Reported
	Glucophage			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14949990	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18682			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Lamotrigine			S	Oral	Unk		Cipla
	Citalopram			S	Oral	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14950450	EXPEDITED (15-DAY)		DS	FI-MACLEODS PHARMACEUTICALS US LTD-MAC2018013738			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Aphasia; Cushingoid; Derealisation; Dizziness; Drug Withdrawal Syndrome; Dysarthria; Dysgraphia; Dyspnoea; Erythema; Face Oedema; Facial Pain; Headache; Hyperhidrosis; Insomnia; Mydriasis; Oedema; Polyuria; Pyrexia; Sympathomimetic Effect; Tremor; Vision Blurred	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Voxra			S	Oral	450 Milligram, Qd		Not Reported
	Triptyl			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14950504	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18753			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Unk		Invagen
	Amlodipine			S	Oral	Unk		Invagen
	Escitalopram			S	Oral	Unk		Invagen
	Salicylate Sodium			S	Oral	Unk		Not Reported
	Losartan			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14950870	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18780			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To Various Agents	Bupropion			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen

	Cocaine		S	Unknown	Unk	Not Reported
	Alprazolam		S	Unknown	Unk	Not Reported
	Ethanol		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14951276	EXPEDITED (15-DAY)		DE, HO	US-CIPLA LTD.-2018US18684			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Risperidone			S	Oral	Unk		Not Reported
	Fluoxetine			S	Oral	Unk		Not Reported
	Diphenhydramine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14951277	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18686			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Propranolol			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Acetaminophen			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported
	Cocaine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14951278	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2018US18687			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide;	Escitalopram			S	Oral	Unk		Invagen

Toxicity To Various Agents	Lamotrigine		S	Oral	Unk	Cipla
	Propranolol		S	Oral	Unk	Not Reported
	Ibuprofen		S	Oral	Unk	Not Reported
	Ondansetron		S	Oral	Unk	Not Reported
	Acyclovir /00587301/		S	Oral	Unk	Not Reported
	Alprazolam		S	Oral	Unk	Not Reported
	Acetaminophen		S	Oral	Unk	Not Reported
	Oxycodone		S	Oral	Unk	Not Reported
	Singulair		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14951296	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18685			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Unknown	Unk		Invagen
	Cyclobenzaprine			S	Unknown	Unk		Invagen
	Lamotrigine			S	Unknown	Unk		Cipla
	Propranolol			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Buspirone			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Activated Charcoal			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14951567	NON-EXPEDITED			US-TEVA-2018-US-896778		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Insomnia; Tinnitus	Escitalopram			S	Unknown	5 Milligram Daily;		Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14952982	EXPEDITED (15-DAY)		HO	FR-ANIPHARMA-2018-FR-000060		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Atacand			S	Oral	16 Mg Daily		Ani
	Escitalopram			S	Oral	15 Mg Daily		Not Reported
	Plegridy			S	Subcutaneous	125 Mcg Every 14 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14954111	EXPEDITED (15-DAY)		HO	US-IMPAX LABORATORIES, INC-2018-IPXL-01821		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Cardiac Failure Congestive; Respiratory Failure; Serotonin Syndrome	Mirtazapine Odt			S	Unknown	Unk		Impax
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk, Decreased		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk, Decreased		Not Reported
	Olanzapine			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk,Decreased		Not Reported
	Lorazepam			S	Unknown	Unk, Low Dose		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14660045	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS USA.,INC-2018SUN00125		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown	Unk		Taro
	Lansoprazole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14744626	EXPEDITED (15-DAY)		DE, HO, OT	DE-TEVA-2018-DE-880628		1 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Pneumonia; Respiratory Failure	Spironolactone			S	Unknown			Actavis
	Sildenafil Citrate			S	Unknown			Actavis
	Topiramate			S	Unknown			Teva
	Phenobarbital			S	Unknown			Not Reported
	Varivax			S	Intramuscular			Not Reported
	Synagis			S	Intramuscular			Not Reported
	Exodus (Escitalopram Oxalate)			S	Unknown			Not Reported
	Nutrition With Nutrini Mixed With Water			C	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14916463	EXPEDITED (15-DAY)		HO, LT, OT	US-ACCORD-067073		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Overdose; Serotonin Syndrome	Escitalopram			S		20 Mg Tablets		Not Reported
	Lamotrigine			S		100 Mg Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14925309	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1826693US		87 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14949995	EXPEDITED (15-DAY)		HO, LT, OT	US-GLENMARK PHARMACEUTICALS-2018GMK035357		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Rhabdomyolysis; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Lamotrigine Tablets			S	Unknown	Unk		Glenmark
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14955374	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18760			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Unk, (Extended Release)		Invagen
	Escitalopram			S	Oral	Unk		Invagen
	Venlafaxine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14955569	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018013910			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Escitalopram Tablet			S	Oral	15 Milligram, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14955572	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018013913			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram Oxalate			S	Oral	15 Milligram, Qd		Macleods
	Plegridy 125 Micrograms			S	Subcutaneous	125 Microgram (Solution		Not Reported

						For Injection In Pre-Filled Pen) 14 Day				
	Atacand 16 Mg			S	Oral	1 Dosage Form, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14955929	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-027781		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S	Oral	15 Milligram		Aurobindo
	Plegridy			S	Subcutaneous	125 Microgram		Not Reported
	Atacand			S	Oral	1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14956021	EXPEDITED (15-DAY)		OT	US-TORRENT-00006194		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Serotonin Syndrome	Escitalopram			S		Unknown		Unknown
	Lorazepam			C		Unknown		Unknown
	Trazodone			S		Unknown		Unknown
	Mirtazapine			S		Unknown		Unknown
	Gabapentin			C		Unknown		Unknown
	Olanzapine			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14957264	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018216485		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Poisoning Deliberate	Venlafaxine Hcl			S	Oral	Unk		Pfizer
	Atarax /00058401/			S	Oral	Unk		Not Reported
	Zopiclone			S	Oral	Unk		Not Reported

	Previscan /00789001/	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14957302	EXPEDITED (15-DAY)		HO	FR-009507513-1805FRA013262		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse	Norset			S	Oral			Merck
	Valium			S	Oral	Prise Unique		Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14958461	EXPEDITED (15-DAY)		HO, LT	FR-AUROBINDO-AUR-APL-2018-027253		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Escitalopram Arrow Film-Coated Tablet 10mg			S	Oral	10 Milligram, Once A Day		Aurobindo
	Escitalopram Arrow Film-Coated Tablet 10mg			S	Oral	20 Milligram, Once A Day		Aurobindo
	Preterax /01421201/			C	Oral	Unk		Not Reported
	L Thyroxine Serb			C	Oral	40 Microgram, Once A Day		Not Reported
	Efferalgan /00020001/			C	Oral	3 Gram, Once A Day		Not Reported
	Bisoprolol Accord			C	Oral	Unk		Not Reported
	Lactulose Sandoz			C	Oral	40 Milligram, Once A Day		Not Reported
	Primperan			C	Oral	30 Milligram, Once A Day, (Si Nausées Et/Ou Vomissements)		Not Reported
	Lansoprazole Mylan			C	Oral	15 Milligram, Once A Day		Not Reported
	Ogast			C	Unknown	Unk		Not Reported
	Kardegic			C	Oral	75 Milligram, Once A Day		Not Reported
	Crestor			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14958910	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1828425US		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14288593	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2017006770			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Irbesartan			S	Oral	300 Mg, Qd		Macleods
	Metformin Hydrochloride 1000mg Tablet			S	Oral	500 Mg, Bid (Film-Coated Tablet)		Macleods
	Pantoprazole			S	Oral	20 Mg, Qd		Macleods
	Amlodipine Besylate			S	Oral	10 Mg, Qd, (Hard Capsule)		Macleods
	Alprazolam			S	Oral	0.75 Mg, Qd, (0.25 Mg, 3x/Day (Tid))		Not Reported
	Bisoprolol Hemifumarate			S	Oral	1.25 Mg, Qd		Not Reported
	Colchicine Opocalcium			S	Oral	1 Mg, Qd		Not Reported
	Dafalgan			S	Oral	1000 Mg, Tid (3x/Day (Tid)) Capsule		Not Reported
	Diffu K			S	Oral	6 Df, Qd (6df Daily (2-1-0) 2x/Day (Bid) (2 In 1 D))		Not Reported
	Diffu K			S	Oral	3 Df, Unk		Not Reported
	Diazepam			S	Oral	10 Mg, Tid (30 Mg/Day), 3 Df Si Besoin		Not Reported
	Furosemide			S	Oral	2 Df, Qd		Not Reported
	Furosemide			S	Oral	Unk, Bid		Not Reported
	Furosemide			S	Oral	30 Mg, Qd, (30 Mg Daily		Not Reported

				(2-1-0), 2x/Day (Bid))	
	Mirtazapine	S	Oral	15 Mg, Qd	Not Reported
	Nefopam Hydrochloride	S	Oral	3 Df, Qd,1 Df, 3x/Day (Tid) Si Besoin	Not Reported
	Seroplex	S	Oral	1 Df, Qd	Not Reported
	Tavanic	S	Oral	250 Mg, Bid, 250 Mg, (2x/Day (Bid)), 2 Df, Film Coated Tablet	Not Reported
	Terbutaline Sulfate	S	Respiratory (inhalation)	1 Df, Qd	Not Reported
	Xarelto	S	Oral	20 Mg, Qd (Film-Coated Tablet)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14723847	EXPEDITED (15-DAY)		HO, LT, OT	CZ-ALLERGAN-1819304US			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Clonazepam			S	Oral	Unk		Not Reported
	Metoclopramid			S	Oral	Unk		Not Reported
	Melperon			S	Oral			Not Reported
	Olanzapin			S	Oral	Unk		Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported
	Levomepromazine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14765837	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1820695US		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Product	Escitalopram Oxalate - Bp			S	Oral	In Total Overdose: 60 Mg		Allergan

Misuse; Intentional Self-Injury; Sluggishness; Sopor	Minias	S	Unknown	; In Total	Not Reported
	Kivexa	S	Unknown	; In Total, Strength=600 Mg+300 Mg	Not Reported
	Ethanol	S	Unknown	Dosage Form: Unspecified	Not Reported
	Lyrica	S	Oral	Strength=150 Mg	Not Reported
	Rezolsta	S	Oral	Strength=800 Mg/150 Mg	Not Reported
	Tavor (Lorazepam)	S	Unknown	; In Total; Strength=2.5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14802711	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018164795		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Amlor			S	Oral	Unk		Pfizer
	Esomeprazole Magnesium			S	Oral	Unk		Unknown
	Decapeptyl /00486501/			S	Intramuscular	1 Df, Cyclic		Not Reported
	Innohep			S	Subcutaneous	1 Df, 1x/Day		Not Reported
	Novonorm			S	Oral	Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Xtandi			S	Oral	120 Mg, 1x/Day		Not Reported
	Lipanthyl			S	Oral	145 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14859943	EXPEDITED (15-DAY)		DS	PHHY2018DE002216			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Muscle Twitching	Escitalopram			S	Unknown	10 Mg, (In The Morning)		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd (In The Morning)		Not Reported
	Oxazepam Hexal			S	Unknown	10 Mg, (Night)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14948766	EXPEDITED (15-DAY)		HO, LT, OT	US-ALLERGAN-1827996US		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Rhabdomyolysis; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Lamotrigine			S	Unknown	Unk		Not Reported
	Lamotrigine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14962459	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-900784		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14962701	EXPEDITED (15-DAY)		HO, LT, OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2018013983			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Rhabdomyolysis; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram Oxalate 20mg Tablet			S	Unknown	20 Milligram		Macleods
	Escitalopram Oxalate 20mg Tablet			S				Macleods
	Lamotrigine			S	Unknown	100 Milligram		Not Reported
	Lamotrigine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14962887	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-04094		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia	Lorazepam			S	Unknown	Unk (Low Dose)		Lupin
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S		Unk (Decreased Dose)		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk (Decreased Dose)		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk (Decreased Dose)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14963077	EXPEDITED (15-DAY)		OT	US-009507513-1805USA013965		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Remeron			S	Oral			Merck
	Escitalopram			S				Not Reported
	Olanzapine			S				Not Reported
	Trazodone Hydrochloride			S		Unk		Not Reported
	Gabapentin			S				Not Reported
	Lorazepam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14963153	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1035039		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroid Mass	Escitalopram			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	13231794	EXPEDITED (15-DAY)		OT	US-JNJFOC-20151102623		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia; Hyperprolactinaemia; Obesity	Risperdal			S	Oral	0.2 Mg - 1 Mg		Not Reported
	Risperdal			S	Oral	0.2 Mg - 1 Mg		Not Reported
	Risperdal			S	Oral	0.2 Mg - 1 Mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	0.2 To 1 Mg (1 Mg Twice Daily)		Not Reported
	Risperdal			S	Oral	0.2 To 1 Mg (1 Mg Twice Daily)		Not Reported
	Risperdal			S	Oral	0.2 To 1 Mg (1 Mg Twice Daily)		Not Reported
	Invega			S	Oral			Not Reported
	Risperidone			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Depakote			S	Oral			Not Reported
	Abilify			S	Unknown	In Varying Doses Of 2.5 Mg, 5 Mg And 10 Mg.		Not Reported
	Olanzapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14274736	EXPEDITED (15-DAY)		HO, OT	FR-TAKEDA-2017TEU005216		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported
	Pantoprazole			S	Oral	20 Mg, Unk		Not Reported

Metformine	S	Oral	500 Mg, Bid	Not Reported
Amlodipine	S	Oral	10 Mg, Qd	Not Reported
Colchicine	S	Oral	1 Mg, Qd	Not Reported
Dafalgan	S	Oral	1000 Mg, Tid	Not Reported
Dafalgan	S	Oral	3000 Mg, Unk	Not Reported
Valium	S	Oral	10 Mg, Tid	Not Reported
Furosemide	S	Oral	30 Mg, Bid	Not Reported
Alprazolam	S	Oral	0.75 Mg, Tid	Not Reported
Mirtazapine	S	Oral	15 Mg, Qd	Not Reported
Nefopam Hydrochloride	S	Oral	Unk Unk, Tid	Not Reported
Nefopam Hydrochloride	S	Oral	3 Ug, Qd	Not Reported
Diffu K	S	Oral	Unk Unk, Qd	Not Reported
Xarelto	S	Oral	20 Mg, Qd	Not Reported
Seroplex	S	Oral	Unk Unk, Qd	Not Reported
Tavanic	S	Oral	500 Mg, Qd	Not Reported
Bisoprolol Hemifumarate	S	Oral	1.25 Mg, Qd	Not Reported
Terbutaline Sulphate	S	Respiratory (inhalation)	Unk Unk, Qd	Not Reported
Terbutaline Sulphate	S	Respiratory (inhalation)	1 Ug, Unk	Not Reported
Irbesartan	S	Oral	300 Mg, Qd	Not Reported
Irbesartan	S	Oral	300 Mg, Unk	Not Reported
Terbutaline	S	Respiratory (inhalation)	Unk	Not Reported
Colchicine Opocalcium	S	Oral	1 Mg, Unk	Not Reported
Nefopam	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14596614	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2017-30929		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Lorazepam 1mg	S	Oral	1 Mg, Total		Aurobindo
	Lorazepam 1mg	S	Oral	1 Mg, Total		Aurobindo
	Clozapine	S	Oral	100 Mg, Total ; In Total		Not Reported
	Entact	S	Oral	20 Mg, Total		Not Reported
	Entact	S	Oral	20 Mg, Once/Single ; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14853356	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018181688		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor	Efexor Er			S	Oral	7 Df, Single		Pfizer
	Escitalopram Oxalate			S	Oral	300 Mg, Single		Not Reported
	Lexotan			S	Oral	20 Ml, Single		Not Reported
	Lamictal			S	Oral	1400 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14922937	EXPEDITED (15-DAY)		OT	NL-TEVA-2018-NL-894270		16 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Pressure Increased; Diarrhoea; Diarrhoea Haemorrhagic; Haematochezia; Heart Rate Increased; Hypertension; Tachycardia	Quetiapine Tablet Fo 25mg Filmomhulde Tablet, 25 Mg (Milligram)			S	Unknown	12.5 Milligram Daily; For The Night Half A Tablet		Teva
	Quetiapine Tablet Fo 25mg Filmomhulde Tablet, 25 Mg (Milligram)			S				Teva
	Escitalopram Tablet 10mg Tablet, 10 Mg (Milligram)			S	Unknown	40 Milligram Daily;		Not Reported
	Cholecalciferol 800ie			C	Unknown	800 Iu (International Unit) Daily;		Not Reported
	Melatonine			C	Unknown	1 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14966678	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001786		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Pulmonary Embolism; Weight Fluctuation	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	On Saturday		Not Reported
	Methotrexate			S	Oral	Dose Decreased		Not Reported
	Xeljanz			S	Oral			Not Reported
	Progesterone			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Remeron			S	Oral	Before Bed		Not Reported
	Gabapentin			C				Not Reported
	Atorvastatin			C	Oral			Not Reported
	Cardiaze			C	Oral	Taking For At Least 6 Months		Not Reported
	Cardiaze			C				Not Reported
	Carvedilol			C	Oral			Not Reported
	Cozaar			C	Oral			Not Reported
	Potassium			C	Oral			Not Reported
	Potassium			C	Oral			Not Reported
	Pantoprazol			C	Oral			Not Reported
	Folic Acid			C	Oral	Every Day Except Saturday When She Takes Methotrexate And Taking Since Year Or Two (1 Mg, 6 In 1 Wk)		Not Reported
	Aldactone			C	Oral			Not Reported
	Aldactone			C	Oral			Not Reported

	Hydrocodone	C	Oral	10/325mg One Tablet By Mouth Two To Three Times Daily	Not Reported
	Tramadol	C		As Required	Not Reported
	Bumex	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14967655	EXPEDITED (15-DAY)		OT	US-ZYDUS-020292		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Serotonin Syndrome	Gabapentin			S	Unknown			Zydus Pharm
	Escitalopram			S	Unknown			Zydus Pharm
	Mirtazapine			S	Unknown			Zydus Pharm
	Trazodone			S	Unknown			Zydus Pharm
	Olanzapine			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14968325	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-028934			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Dysphoria; Headache; Hyperhidrosis; Insomnia; Sexual Dysfunction; Somnolence; Tachycardia; Vision Blurred; Withdrawal Syndrome	Atomoxetine			S	Unknown	18 Milligram		Aurobindo
	Buspirone Hydrochloride			S	Unknown			Aurobindo
	Citalopram			S	Unknown	40 Milligram, Daily		Aurobindo
	Clonidine			S	Unknown	0.05-0.1 Mg		Aurobindo
	Dexamfetamine			S	Unknown	10 Milligram, Daily		Aurobindo
	Escitalopram			S	Unknown	20 Milligram, Daily		Aurobindo
	Fluoxetine			S	Unknown	40 Milligram, Daily		Aurobindo
	Trazodone			S	Unknown	12.5 Milligram		Aurobindo
	Venlafaxine			S	Unknown	225 Milligram, Daily		Aurobindo

Amfetamine	S	Unknown	5 Milligram, Daily		Not Reported
Bupropion	S	Unknown	18.75 Milligram, Four Times/Day		Not Reported
Bupropion	S	Unknown	37.5mg,		Not Reported
Bupropion	S		150 Unk		Not Reported
Dexmethylphenidate	S	Unknown	0.625-1.25mg Daily		Not Reported
Methylphenidate	S	Unknown			Not Reported
Clonazepam	S	Unknown	0.25 Milligram		Not Reported
Guanfacine /00547902/	S	Unknown	1 Milligram		Not Reported
Guanfacine /00547902/	S	Unknown	0.51 Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14968373	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0099582		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dysphoria; Dyspnoea; Headache; Hyperhidrosis; Product Substitution Issue; Rash Pruritic; Sexual Dysfunction; Social Anxiety Disorder; Somnolence; Vision Blurred; Withdrawal Syndrome	Citalopram 40 Mg			S	Unknown	Up To 40 Mg Daily		Not Reported
	Amoxicillin			S	Unknown			Not Reported
	Fluoxetine Capsules 40 Mg			S	Unknown			Not Reported
	Fluoxetine Capsules 40 Mg			S				Not Reported
	Fluoxetine Capsules 40 Mg			S				Not Reported
	Fluoxetine Capsules 40 Mg			S				Not Reported
	Venlafaxine Hydrochloride Er Capsules			S	Unknown	Extended Release		Not Reported
	Venlafaxine Hydrochloride Er Capsules			S				Not Reported
	Venlafaxine Hydrochloride Er Capsules			S				Not Reported
	Venlafaxine Hydrochloride Er Capsules			S				Not Reported
	Guanfacine Hydrochloride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Buspirone			S	Unknown			Not Reported
	Propranolol			C	Unknown			Not Reported

Bupropion	C	Unknown	Not Reported
Clonazepam	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Amphetamine	C	Unknown	Not Reported
Amphetamine	C	Unknown	Not Reported
Dextroamphetamine	C	Unknown	Not Reported
Methylphenidate	C	Unknown	Not Reported
Dexmethylphenidate	C	Unknown	Not Reported
Atomoxetine	C	Unknown	Not Reported
Clonidine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14968529	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1828573US		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Kardegic			S	Oral	160 Mg, Qd		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14968597	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-04113		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Drug Ineffective; Drug Intolerance; Dysphoria; Headache; Insomnia; Sexual Dysfunction; Somnolence; Withdrawal Syndrome	Citalopram			S	Unknown	40 Mg, Qd		Not Reported
	Citalopram			S				Not Reported
	Citalopram			S				Not Reported
	Citalopram			S				Not Reported
	Escitalopram			S	Unknown	Up To 20 Mg, Qd		Not Reported
	Fluoxetine			S	Unknown	Up To 40 Mg, Qd		Not Reported
	Fluoxetine			S				Not Reported

	Venlafaxine	S	Unknown	Up To 225 Mg, Qd	Not Reported
	Venlafaxine	S			Not Reported
	Venlafaxine	S			Not Reported
	Venlafaxine	S			Not Reported
	Bupropion	S	Unknown	150 Mg, Qd (Extended Release)	Not Reported
	Bupropion	S			Not Reported
	Methylphenidate Hydrochloride	S	Unknown	Unk	Novel Labs
	Dexmethylphenidate	S	Unknown	Unk	Not Reported
	Clonidine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14968681	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2018-015619		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Serotonin Syndrome	Lorazepam			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14969593	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP015075		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dysphoria; Headache; Insomnia; Sexual Dysfunction; Somnolence	Citalopram			S	Unknown	Up To 40 Mg, Daily		Apotex
	Escitalopram			S	Unknown	Up To 20 Mg, Daily		Apotex
	Fluoxetine			S	Unknown	Up To 40 Mg, Daily		Apotex
	Buspirone			S	Unknown	Up To 45 Mg, Daily		Apotex
	Bupropion			S	Unknown	150 Mg, Daily		Apotex

	Clonazepam	S	Unknown	0.25 Mg, Unk	Apotex
	Trazodone	S	Unknown	12.5 Mg, Unk	Apotex
	Atomoxetine	S	Unknown	Unk	Apotex
	Clonidine	S	Unknown	0.05–0.1 Mg	Apotex
	Venlafaxine	S	Unknown	Up To 225 Mg, Daily	Not Reported
	Propranolol	S	Unknown	10 Mg, Unk	Not Reported
	Guanfacine	S	Unknown	0.5-1 Mg	Not Reported
	Guanfacine	S	Unknown	1 Mg, Unk	Not Reported
	Amphetamine	C	Unknown	5 Mg, Daily	Not Reported
	Amphetamine	C	Unknown	30 Mg, Daily	Not Reported
	Dextroamphetamine /00016601/	C	Unknown	10 Mg, Daily	Not Reported
	Methylphenidate	C	Unknown	Unk	Not Reported
	Dexmethylphenidate	C	Unknown	0.625-1.25 Mg Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14969817	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1036398		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Lorazepam			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14845363	NON-EXPEDITED		HO	US-CELGENEUS-USA-20180500178		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State;	Revlimid			S	Oral	5 Milligram		Celgene

Dysarthria; Gait Disturbance; Pneumonia	Revlimid	S	Oral	10 Milligram	Celgene
	Lexapro	S	Unknown	10 Milligram	Not Reported
	Lexapro	S	Unknown	20 Milligram	Not Reported
	Lexapro	S	Unknown	10 Milligram	Not Reported
	Colace	C	Unknown	100 Milligram	Not Reported
	Prednisone	C	Unknown	10 Milligram	Not Reported
	Breo Ellipta	C	Unknown	100-25 Mcg	Not Reported
	Doxycycline Monohydrate	C	Unknown		Not Reported
	Cephalexin	C	Unknown	750 Milligram	Not Reported
	Gabapentin	C	Unknown	100 Milligram	Not Reported
	Ondansetron Hcl	C	Unknown	4 Milligram	Not Reported
	Tylenol Extra Strength	C	Unknown		Not Reported
	Hydrocodone- Acetaminophen	C	Unknown		Not Reported
	Remodulin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14929550	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1033063		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S		5 Mg, Unk		Not Reported
	Bisoprolol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14938651	EXPEDITED (15-DAY)		HO, OT	US-ENDO PHARMACEUTICALS INC-2018-039187		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Overdose; Serotonin Syndrome; Toxicity To	Lamotrigine			S	Oral	Unkmg, Unknown		Par
	Escitalopram			S	Oral	Unk Mg, Unknown		Not Reported

Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14972053	NON-EXPEDITED		OT	US-APOTEX-2018AP015358		94 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Urinary Retention	Oxybutynin			S	Unknown	Unk		Apotex
	Mirtazapine			S	Unknown	Maximum Dose Of 30 Mg, Q.H.S		Apotex
	Mirtazapine			S				Apotex
	Quetiapine			S	Unknown	Unk		Apotex
	Quetiapine			S	Unknown	50 Mg, Per Day		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	10 Mg, Unk		Apotex
	Trazodone			S	Unknown	Unk		Apotex
	Trazodone			S	Unknown	50 Mg, Unk		Apotex
	Melatonin			S	Unknown	3 Mg, Q.H.S.		Not Reported
	Melatonin			S				Not Reported
	Aspirin /00002701/			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Finasteride			C	Unknown	5 Mg, Daily		Not Reported
	Tamsulosin			C	Unknown	0.8 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14972535	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-ACCORD-067611		28 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S	Escitalopram			S				Not Reported
	Olanzapine			S				Not Reported
	Xeplion			S				Not Reported
	Risperidone			S				Not Reported
	Risperdal			S		Unk		Not Reported

Disease; Personality Change; Shoulder Deformity; Weight Increased	Paliperidone	S			Not Reported
	Zyprexa	S			Not Reported
	Abilify	S	Unk		Not Reported
	Cipralex	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14972608	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-174607		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Serotonin Syndrome	Mirtazapine			S	Unknown	Unk		Sun
	Olanzapine			S	Unknown	Unk		Sun
	Trazodone			S	Unknown	Unk		Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14972979	EXPEDITED (15-DAY)		OT	IT-BAUSCH-BL-2018-015843		85 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Venlafaxine			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Delorazepam			S	Oral			Not Reported
	Donepezil			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Madopar			C				Not Reported
	Terazosin Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14973306	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-		69 YR	Female	USA

2018AP015361

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Trazodone			S	Unknown			Apotex
	Escitalopram			S	Unknown			Apotex
	Mirtazapine			S	Unknown			Apotex
	Olanzapine			S	Unknown			Apotex
	Gabapentin			S	Unknown			Apotex
	Lorazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14974332	NON-EXPEDITED			US-APOTEX-2018AP009228			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Ageusia; Diarrhoea; Drug Hypersensitivity; Myalgia; Nausea; Oedema; Swelling; Weight Decreased	Amlodipine			S	Oral	5 Mg, Qd		Apotex
	Amlodipine			S	Unknown	10 Mg, Qd		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Fenofibrate			S	Unknown	Unk		Apotex
	Lisinopril			S	Unknown	Unk		Apotex
	Mirtazapine			S	Unknown	Unk		Apotex
	Pravastatin			S	Unknown	Unk		Apotex
	Tramadol			S	Oral	50 Mg, Tid, When Needed		Apotex
	Triamterene And Hydrochlorothiazide			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown			Apotex
	Ciprofloxacin			C	Oral	1 Df, Q.12h		Not Reported
	Atenolol			C	Oral	1 Df, Qd		Not Reported
	Acetaminophen			C	Oral	2 Df, Q.6h, As Needed		Not Reported

	Prednisone	C	Oral	1 Df, 2 Daily For 4 Days And 1 Daily For 6 Daysunk	Not Reported
	Comfort Gel /00723801/	C	Unknown	Unk	Not Reported
	Losartan	C	Oral	1 Df, Qd	Not Reported
	Lyrica	C	Oral	1 Df, Bid	Not Reported
	Furosemide	C	Oral	1 Df, Qd, As Needed	Not Reported
	Allegra	C	Oral	1 Df, Qd	Not Reported
	Ranitidine	C	Oral	1 Df, Bid	Not Reported
	Calcium + Vit D	C	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14974386	EXPEDITED (15-DAY)		OT	KR-TAKEDA-2018TUS018732		27 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Cold Sweat; Drug Ineffective; Fatigue; Hallucination; Rash; Suicide Attempt; Tremor; Tremor; Weight Increased	Brintellix			S	Unknown	10 Mg, Qd		Takeda
	Brintellix			S	Oral	Unk, Bid		Takeda
	Brintellix			S	Oral	10 Mg, Qd		Takeda
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Bid		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Diazepam			C	Unknown	1 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	10 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	10 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	25 Mg, Unk		Not Reported
	Alprazolam			C	Oral	0.25 Mg, Bid		Not Reported
	Alprazolam			C	Oral	0.5 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	0.75 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	0.125 Mg, Qd		Not Reported
	Quetiapine			C	Oral	125 Mg, Qd		Not Reported
	Trazodone			C	Oral	50 Mg, Qd		Not Reported

Trazodone	C	Oral	25 Mg, Qd		Not Reported
Efexor	C	Unknown	75 Mg, Unk		Not Reported
Clonazepam	C	Unknown	0.25 Mg, Unk		Not Reported
Abilify	C	Unknown	1 Mg, Unk		Not Reported
Wellbutrin	C	Unknown	150 Mg, Unk		Not Reported
Wellbutrin	C	Unknown	300 Mg, Qd		Not Reported
Wellbutrin	C	Unknown	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14974590	EXPEDITED (15-DAY)		HO, LT	PH-OTSUKA-2018_013493		26 YR	Male	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Multiple Drug Therapy; Product Use In Unapproved Indication	Aripiprazole			S	Unknown	Unk Unk, Qd		Otsuka
	Aripiprazole			S				Otsuka
	Aripiprazole			S				Otsuka
	Risperidone			S	Unknown	Unk		Not Reported
	Risperidone			S				Not Reported
	Risperidone			S				Not Reported
	Multiple Vitamins			S	Unknown	Unk		Not Reported
	Valproic Acid			S	Unknown	500 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Clonazepam			C	Unknown	10 Mg, Unk (As Needed)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14974850	EXPEDITED (15-DAY)		DE	FI-MYLANLABS-2017M1080022			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Fibrillation	Ciprofloxacin			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14975064	EXPEDITED (15-DAY)		HO	PHHY2018FR014695		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Valaciclovir			S	Oral	500 Mg, Qd		Novartis
	Metoclopramide			S	Oral			Not Reported
	Esomeprazole			S	Oral	20 Mg, Qd		Not Reported
	Ramipril			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14976451	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1829292US		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Pregnancy	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14576146	EXPEDITED (15-DAY)		OT	ES-ROCHE-2032435			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Musculoskeletal Pain; Somnolence; Treatment Noncompliance	Diazepam			S	Unknown	0.5 Dosage Forms ; 5 Mg		Not Reported
	Naproxen			S	Unknown	2 Dosage Forms Daily; Last Administration On 18/Nov/2016		Not Reported
	Amitriptyline			S	Unknown	12.5 Milligram Daily;		Not Reported
	Amitriptyline			S	Unknown	25 Milligram Daily;		Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Glibenclamide			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Paracetamol/Tramadol			S	Unknown	1 Df = 37.5/325mg		Not Reported

Topiramate	S	Unknown	Last Dose On 09/May/2017 1 Df 50 Mg	Not Reported
Topiramate	S	Unknown		Not Reported
Omeprazole	S	Unknown	20 Mg Date Of Last Dose On 25/Nov/2016	Not Reported
Amlodipine	S	Unknown	1 Dosage Forms Daily; 5 Mg	Not Reported
Simvastatin	S	Unknown	1 Df = 40mg Last Dose On 20/Apr/2017	Not Reported
Simvastatin	S	Unknown		Not Reported
Topiramato	S	Unknown	Last Dose On 20/Apr/2017	Not Reported
Topiramato	S	Unknown	1 Dosage Forms Daily; 50 Mg	Not Reported
Paracetamol	S	Unknown	3 Dosage Forms Daily; 1 G	Not Reported
Paracetamol	S	Unknown		Not Reported
Hydrochlorothiazide	S	Unknown	Qd	Not Reported
Lormetazepam	S	Unknown	1 Dosage Forms Daily; 1 Mg	Not Reported
Enalapril	S	Unknown	1 Df = 20/12.5 Mg	Not Reported
Temazepam	S	Unknown	Qd	Not Reported
Escitalopram	S	Unknown	1 Dosage Forms = 10 Mg	Not Reported
Metoclopramide	C	Unknown	1 Week Treatment	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14701876	EXPEDITED (15-DAY)		HO, LT, OT	CZ-AUROBINDO-AUR-APL-2018-017876			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened; Epilepsy;	Olanzapine			S	Oral	Unk		Aurobindo
	Clonazepam			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	()		Not Reported

Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning; Toxicity To Various Agents	Levopromazin	S	Oral	Unk	Not Reported
	Metoclopramide	S	Oral	Unk	Not Reported
	Metoclopramide	S	Oral	()	Not Reported
	Ibuprofen	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Unknown	()	Not Reported
	Venlafaxine	S	Oral	Unk	Not Reported
	Venlafaxine	S	Oral	()	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	()	Not Reported
	Melperone	S	Oral	Unk	Not Reported
	Melperone	S	Oral	()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14941434	EXPEDITED (15-DAY)		OT	CA-ACCORD-067392		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression	Escitalopram			S				Not Reported
	Heparin			S	Subcutaneous	5000 U		Not Reported
	Lidocaine			C		A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 Ug/Ml		Not Reported
	Hydromorphone/Hydromorphone Hydrochloride			C		10 Ug/Ml Was Initiated During The Procedure And Maintained At 6 Ml/H, Infusion		Not Reported
	Epinephrine			C		A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 Ug/Ml		Not Reported
	Bupivacaine			C		1 Mg/Ml, Infusion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14977618	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-CIPLA LTD.-2018GB18910			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Escitalopram			S	Oral	15 Mg, Unk		Invagen
	Metformin Hydrochloride			C	Unknown	Unk		Not Reported
	Nifedipine			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported
	Nefopam			C	Unknown	Unk		Not Reported
	Tiotropium			C	Unknown	Unk		Not Reported
	Sodium Picosulfate			C	Unknown	Unk		Not Reported
	Cetirizine			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Cassia Senna			C	Unknown	Unk		Not Reported
	Methotrexate Sodium			C	Unknown	Unk		Not Reported
	Budesonide W/Formoterol Fumarate			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Meptazinol			C	Unknown	Unk		Not Reported
	Quetiapine Fumarate			C	Unknown	Unk		Not Reported
	Temazepam			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Not Reported
	Pyridoxine			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Adcal D3			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14977805	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-900690		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction;	Lorazepam			S	Unknown			Actavis

Serotonin Syndrome	Trazodone	S	Unknown	Actavis
	Escitalopram	S	Unknown	Ivax
	Mirtazapine	S	Unknown	Teva
	Gabapentin	S	Unknown	Ivax
	Olanzapine	S	Unknown	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14978546	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-AUROBINDO-AUR-APL-2018-028698		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral	15 Milligram		Aurobindo
	Escitalopram			S	Oral	10 Milligram		Aurobindo
	Metformin Hydrochloride			C	Unknown	Unk		Not Reported
	Nifedipine			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported
	Nefopam			C	Unknown	Unk		Not Reported
	Tiotropium			C	Unknown	Unk		Not Reported
	Sodium Picosulfate			C	Unknown	Unk		Not Reported
	Cetirizine			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Cassia Senna			C	Unknown	Unk		Not Reported
	Methotrexate Sodium			C	Unknown	Unk		Not Reported
	Budesonide W/Formoterol Fumarate			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Meptazinol			C	Unknown	Unk		Not Reported
	Quetiapine Fumarate			C	Unknown	Unk		Not Reported
	Temazepam			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Not Reported

	Pyridoxine		C	Unknown	Unk	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported
	Adcal D3		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14979760	NON-EXPEDITED			US-PFIZER INC-2018230046		12 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Obsessive-Compulsive Disorder; Serum Serotonin Decreased	Methylphenidate Hydrochloride			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14980120	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1829301US		66 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Olanzapine			C	Oral	5 Mg, Unk		Not Reported
	Olanzapine			C	Oral	2.5 Mg, Unk		Not Reported
	Triazolam			C	Oral	0.25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14980121	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1829058US		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan
	Valium			S	Oral	Once		Not Reported
	Norset			S	Oral	Unk, Unknown		Not Reported

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14980408	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1829045US		27 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Cold Sweat; Drug Ineffective; Fatigue; Hallucination; Rash; Suicide Attempt; Tremor; Tremor; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Brintellix			S	Oral	10 Mg, Qd		Not Reported
	Brintellix			S	Oral	10 Mg, Qd		Not Reported
	Brintellix			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Diazepam			C	Unknown	1 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	25 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	10 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	10 Mg, Unk		Not Reported
	Alprazolam			C	Unknown	0.125 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	0.75 Mg, Qd		Not Reported
	Alprazolam			C	Oral	0.5 Mg, Qd		Not Reported
	Alprazolam			C	Oral	0.25 Mg, Bid		Not Reported
	Quetiapine			C	Oral	125 Mg, Qd		Not Reported
	Trazodone			C	Oral	25 Mg, Qd		Not Reported
	Trazodone			C	Oral	50 Mg, Qd		Not Reported
	Efexor			C	Unknown	75 Mg, Unk		Not Reported
	Clonazepam			C	Unknown	0.25 Mg, Unk		Not Reported
	Abilify			C	Unknown	1 Mg, Unk		Not Reported
	Wellbutrin			C	Unknown	150 Mg, Qd		Not Reported
	Wellbutrin			C	Unknown	300 Mg, Qd		Not Reported
	Wellbutrin			C	Unknown	150 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14980880	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1829291US		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Peginterferon			S	Subcutaneous	125 Mg, Q2weeks		Not Reported
	Atacand			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14560005	EXPEDITED (15-DAY)		OT	PHHY2017ES192959			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence	Paracetamol			S	Unknown	1 Df, Tid		Not Reported
	Enalapril, Hydrochlorothiazide			S	Unknown	1 Df, Qd		Not Reported
	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
	Omeprazole			S	Unknown	1 Df, Qd		Not Reported
	Lormetazepam			S	Unknown	1 Df, Qd		Not Reported
	Simvastatin			S	Unknown	40 Mg, Qd		Not Reported
	Simvastatin			S	Unknown	20 Mg, Unk		Not Reported
	Topiramato			S	Unknown	0.5 Df, Qd		Not Reported
	Topiramato			S	Unknown	1 Df (50 Mg), Qd		Not Reported
	Amlodipine			S	Unknown	1 Df, Qd		Not Reported
	Paracetamol + Tramadol			S	Unknown	1 Df, Tid		Not Reported
	Naproxen			S	Unknown	1 Df, Bid		Not Reported
	Amitriptyline			S	Unknown	5 Mg, Qd		Not Reported
	Amitriptyline			S	Unknown	25 Mg, Unk		Not Reported
	Amitriptyline			S	Unknown	12.5 Mg, Qd		Not Reported
	Diazepam			S	Unknown	0.5 Df (5 Mg), Qd		Not Reported
	Glibenclamida			S	Unknown	1 Df, Bid		Not Reported

Tepazepam	S	Unknown	Unk Unk, Qd		Not Reported
Metoclopramide	C	Unknown	Unk (1 Week Treatment)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14672224	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2018SE36458		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Prescribed Underdose	Esomeprazole Magnesium			S	Oral	Unk		Not Reported
	Seroplex			S	Oral			Not Reported
	Amlor			S	Oral	Unk		Not Reported
	Novonorm			S	Oral	Unk		Not Reported
	Lipanthyl			S	Oral			Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Decapeptyl [Triptorelin Acetate]			S	Intramuscular	1 Df, Cyclic		Not Reported
	Innohep			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14981935	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US18931			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Omeprazole			C	Unknown	40 Mg, Qd		Not Reported
	Lorazepam			C	Unknown	0.5 Mg, Upto 8 Hours As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14982133	EXPEDITED (15-DAY)		OT	IT-APOTEX-2018AP015418		85 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Olanzapine			S	Oral	Unk		Apotex

	Venlafaxine		S	Oral	1 Df, Daily	Apotex
	Cipralex /01588501/		S	Oral	Unk	Not Reported
	Delorazepam		S	Oral	Unk	Not Reported
	Donepezil		C	Unknown	Unk	Not Reported
	Bisoprolol Fumarate		C	Unknown	Unk	Not Reported
	Madopar		C	Unknown	Unk	Not Reported
	Terazosin Hydrochloride		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14983566	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-04		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Serotonin Syndrome	Lorazepam			S	Unknown			Westward
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14983680	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1829305US		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Tranxene			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14985048	EXPEDITED (15-DAY)		DS, HO	CA-MYLANLABS-2018M1038221		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Motor Dysfunction; Spinal Cord Compression; Spinal Cord Oedema	Escitalopram			S	Unknown			Not Reported
	Heparin			S	Subcutaneous	5000 U Every 12 Hours		Not Reported
	Rivaroxaban			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14985127	EXPEDITED (15-DAY)		HO, OT	BE-MACLEODS PHARMACEUTICALS US LTD-MAC2018014148			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Lactation Disorder; Live Birth; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Aripiprazole Tablet			S	Oral	Unk, Tablet		Macleods
	Aripiprazole Tablet			S	Oral	20 Milligram		Macleods
	Escitalopram Oxalate			S	Oral	20 Milligram		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14985149	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018014156			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Aripiprazole Tablet			S	Oral	210 Milligram, Total		Macleods
	Escitalopram Tablet			S	Oral	140 Milligram, Total, Abuse / Misuse		Macleods
	Alprazolam			S	Oral	15 Milliliter, Total		Not Reported
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	1200 Milligram, Total, 25 Mg Covered Tablets, Abuse / Misuse		Not Reported
	Zitromax			S	Oral	1500 Milligram, Total, 500 Mg Coated Tablets With Film		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	15076132	DIRECT	N	OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	13323555	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1709333US		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor; Unresponsive To Stimuli	Escitalopram Oxalate - Bp			S	Oral	20 Mg, In Total		Allergan
	Clozapine			S	Oral	100 Mg, In Total		Not Reported
	Lorazepam			S	Oral	1 Mg, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	13335968	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-135809		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Lorazepam			S	Oral	1 Mg Total		Sun
	Clozapine			S	Oral	100 Mg Total		Sun
	Entact			S	Oral	20 Mg Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	13679510	NON-EXPEDITED			US-ALLERGAN-1716426US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown			Allergan

	Bentyl Capsules	S	Unknown	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14336241	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-158208		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Irbesartan			S	Oral	300 Mg, Once Daily (Qd)		Not Reported
	Bisoprolol			S	Oral	1.25 Mg, Once Daily (Qd)		Sun
	Pantoprazole			S	Oral	20 Mg, Once Daily (Qd)		Sun
	Metformine			S	Oral	500 Mg, 2x/Day (Bid)		Sun
	Furosemide			S	Oral	30 Mg Daily (2-1-0), 2x/Day (Bid) ()		Not Reported
	Amlodipine			S	Oral	10 Mg, Once Daily (Qd)		Not Reported
	Mirtazapine			S	Oral	15 Mg, Once Daily (Qd)		Sun
	Terbutaline Sulfate			S	Respiratory (inhalation)	1 Df, Once Daily (Qd)		Not Reported
	Dafalgan			S	Oral	1000 Mg, 3x/Day (Tid)		Not Reported
	Alprazolam			S	Oral	0.25 Mg, 3x/Day (Tid)		Not Reported
	Tavanic			S	Oral	250 Mg, 2x/Day (Bid)		Not Reported
	Xarelto			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Diazepam			S	Oral	10 Mg, 3x/Day (Tid)		Not Reported
	Colchicine Opocalcium			S	Oral	1 Mg, Once Daily (Qd)		Not Reported
	Seroplex			S	Oral	1 Df, Once Daily (Qd)		Not Reported
	Nefopam			S	Oral	1 Df, 3x/Day (Tid)		Not Reported
	Diffu-K			S	Oral	3 Df Daily (2-1-0) 2x/Day (Bid) ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14987961	EXPEDITED (15-DAY)		HO, LT, OT	TR-OTSUKA-DJ201404925		31 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Drug Interaction; Overdose; Suicide Attempt; Urinary Incontinence	Aripiprazole			S	Oral	14 Tabs		Otsuka
	Escitalopram			S	Oral	20 Tabs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14988729	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMPANY-US201805014720		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Serotonin Syndrome	Olanzapine			S	Unknown	Unk Unk, Unknown		Eli Lilly And Co
	Escitalopram			S	Unknown	Unk Unk, Unknown		Not Reported
	Mirtazapine			S	Unknown	Unk Unk, Unknown		Not Reported
	Trazodone			S	Unknown	Unk Unk, Unknown		Not Reported
	Lorazepam			S	Unknown	Unk Unk, Unknown		Not Reported
	Gabapentin			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14991226	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2017-032995			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Diazepam			S	Unknown	5 Mg		Not Reported
	Enalapril/Hydrochlorothiazide			S	Unknown	1 Df = 20/12.5 Mg		Not Reported
	Paracetamol			S	Unknown	3 Dosage Forms Daily 1g		Not Reported
	Simvastatin			S	Unknown	1 Dosage Form Daily 40 Mg		Not Reported
	Simvastatin			S	Unknown	Reduced Dose		Not Reported
	Topiramate			S	Unknown	0.5 Dosage Forms Daily		Not Reported
	Topiramate			S	Unknown	1 Dosage Forms Daily; 50 Mg		Not Reported
	Tramadol/Paracetamol			S	Unknown			Not Reported

	Naproxen	S	Unknown	2 Dosage Forms Daily	Not Reported
	Amitriptyline Hydrochloride	S	Unknown		Not Reported
	Amitriptyline Hydrochloride	S	Unknown		Not Reported
	Amitriptyline Hydrochloride	S	Unknown	Once A Day	Not Reported
	Amitriptyline Hydrochloride	S	Unknown		Not Reported
	Amitriptyline Hydrochloride	S	Unknown		Not Reported
	Topiramato	S	Unknown		Not Reported
	Amlodipine	S	Unknown	1 Dosage Forms Daily	Not Reported
	Glibenclamide	S	Unknown		Not Reported
	Escitalopram	S	Unknown	1 Dosage Forms Daily	Not Reported
	Omeprazole	S	Unknown	1 Dosage Forms Daily; 20 Mg	Not Reported
	Lormetazepam	S	Unknown	1 Mg	Not Reported
	Tepazepam	S	Unknown		Not Reported
	Metoclopramide	C		1 Week Treatment	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2018	14992335	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-029859		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Encephalopathy	Amiodarone			S	Oral	200 Milligram, Once A Day		Aurobindo
	Allopurinol			S	Oral	100 Milligram, Once A Day		Not Reported
	Seroplex			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Topalgic Lp			S	Oral	3 Dosage Form, Once A Day		Not Reported
	Oxynormoro			S	Oral	5 Milligram		Not Reported
	Xanax			S	Oral	0.38 Milligram, Once A Day		Not Reported
	Kardegic			S	Oral	1 Dosage Form, Once A Day		Not Reported

	Tazocilline	S	Intravenous (not otherwise specified)	3 Dosage Form, Once A Day	Not Reported
	Mycophenolate Sodium	C	Oral	360 Milligram, Once A Day	Not Reported
	Ciclosporine	C	Oral	100 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2018	14992410	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-903347		20 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error; Product Prescribing Error; Product Prescribing Error	Escitalopram			S		Nk		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2018	14992415	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018014219			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Olanzapine			S	Oral	Unk		Macleods
	Venlafaxine			S	Oral	1 Dosage Form, Qd		Macleods
	Cipralex			S	Oral	Unk		Not Reported
	Delorazepam			S	Oral			Not Reported
	Donepezil			C	Unknown	Unk		Macleods
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Madopar			C	Unknown	Unk		Not Reported
	Terazosin Hydrochloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2018	14992562	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS			Unknown	USA

US LTD-
MAC2018014213

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Serotonin Syndrome	Olanzapine			S	Unknown	Unk		Macleods
	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Lorazepam			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2018	14676925	EXPEDITED (15-DAY)		OT	US-TORRENT-00005954		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S		Unknown		Unknown
	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose		Unknown
	Venlafaxine			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2018	15097716	DIRECT		OT			18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Substitution Issue	Generic Escitalopram Oxalate	Y		S	Oral	Quantity:1 Tablet(S);		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14678924	EXPEDITED (15-DAY)		OT	DE-ACCORD-064558			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amenorrhoea; Dysmenorrhoea; Menorrhagia	Escitalopram		S		Daily	Not Reported
	Valdoxan		S		Also Received Unknown Dose From Unknown Date	Not Reported
	Zoely		S	Oral	One Tablet A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14931571	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018013579			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Overdose; Sopor	Escitalopram			S	Oral	600 Milligram, Oral Drops, Total		Macleods
	Minias 2.5 Mg / Ml			S	Oral	100 Milligram, Oral Drops, Total		Not Reported
	Paroxethine 20 Mg			S	Oral	200 Milligram, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14954354	EXPEDITED (15-DAY)		OT	PHHY2018FR011469			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxyzine			S	Oral	Unk		Novartis
	Seroplex			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14971924	EXPEDITED (15-DAY)		HO	BE-AUROBINDO-AUR-APL-2018-028824		25 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hospitalisation; Lactation Disorder; Live Birth; Maternal Exposure During Pregnancy; Pregnancy;	Aripiprazole Tablets			S	Oral	20 Mg, Unk		Aurobindo
	Aripiprazole Tablets			S	Unknown	Unk ()		Aurobindo
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported

Product Use In
Unapproved Indication

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14993570	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-030305		85 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Delorazepam			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Aurobindo
	Venlafaxine			S	Oral	1 Dosage Form, Daily		Aurobindo
	Cipralex /01588502/			S	Oral	Unk		Not Reported
	Donepezil			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Madopar			C	Unknown	Unk		Not Reported
	Terazosin Hydrochloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14993731	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-904129		44 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dyspepsia	Escitalopram			S	Unknown	1-0-0		Ivax
	Ibuprofen			S	Unknown	Nk		Actavis
	Neupro			S	Transdermal	14 Mg, 1-0-0-0		Not Reported
	Bornaprin			S	Unknown	1-0.5-1-0		Not Reported
	Madopar Depot			C	Unknown	100|25 Mg, 0-0-0-1		Not Reported
	Madopar Depot			C	Unknown	100|25 Mg, 1.5-1.5-1.5-1.5		Not Reported
	Madopar Depot			C	Unknown	100|25 Mg, 1-0-0-0		Not Reported
	Amantadin			C	Unknown	1-1-0-0		Not Reported
	Amitriptylin			C	Unknown	0-0-0-1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14994053	EXPEDITED (15-DAY)		OT	FR-MERCK KGAA-2049233		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Novothyrox			S	Oral			Merck Kgaa
	Escitalopram			S	Oral			Not Reported
	Naproxene			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported
	Fenofibrate			S	Oral			Not Reported
	Pregabaline			S	Oral			Not Reported
	Pregabaline			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14994869	NON-EXPEDITED			US-PFIZER INC-2018237389		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14995692	EXPEDITED (15-DAY)		OT	AU-TEVA-2018-AU-905663			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Tevaripiprazole			S	Unknown			Teva
	Escitalopram			S	Unknown			Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Elevit			C				Not Reported
	Folate			C				Not Reported

	Aspirin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14996233	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004450		90 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Increased; Dementia Alzheimer'S Type; Dizziness; Seizure; Syncope; Vomiting	Donepezil Hydrochloride			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Alprazolam			C	Oral			Unknown
	Amitriptyline Hydrochloride			C	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14996267	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018230022		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Xanax			S	Oral	3 Df, 1x/Day		Pfizer
	Seroplex			S	Oral	1 Df, 1x/Day		Not Reported
	Noctamide			S	Oral	2 Df, 1x/Day		Not Reported
	Zyprexa			S	Oral	1 Df, 1x/Day		Not Reported
	Tercian /00759301/			S	Oral	100 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14996959	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-905746		37 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Thrombocytopenia	Escitalopram			S	Oral	15 Milligram Daily;		Not Reported
	Naftidrofuryl			C	Oral	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14309429	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-TEVA-2017-BE-832465			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine			S	Transplacental	5 Milligram Daily;		Teva
	Pantomed (Dexpanthenol)			S	Transplacental			Not Reported
	Nucala Powder For Solution For Injection			S	Transplacental			Not Reported
	D-Cure			S	Transplacental	25 Kiu		Not Reported
	Flixotide			S	Transplacental	500 Microgram Daily;		Not Reported
	Avamys Nasal Spray			S	Transplacental			Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Milligram Daily;		Not Reported
	Ventolin			S	Transplacental			Not Reported
	Relvar Ellipta Inhalation Powder			S	Transplacental	1 Dosage Forms Daily;		Not Reported
	Sipralexa Tablet			S	Transplacental			Not Reported
	Seretide			S	Transplacental			Not Reported
	Fluticasone Furoate Inhalation Powder			S	Transplacental			Not Reported
	Vilanterol Trifenatate Inhalation Powder			S	Transplacental			Not Reported
	Pantoprazole Sodium Sesquihydrate			S	Transplacental			Not Reported
	Xyzall			S	Transplacental	5 Milligram Daily;		Not Reported
	Theophylline			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14335627	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MACLEODS PHARMACEUTICALS US LTD-MAC2017007583			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Condition Aggravated; Depression; Drug Abuse; Drug Ineffective; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product	Escitalopram Oxalate			S	Oral	10 Milligram, Qd, 10 Mg, Before Sleeping, Doctor Switched The Patient Fromsertraline Toescitalopram		Macleods
	Escitalopram Oxalate			S	Unknown	Unk		Macleods

Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Escitalopram Oxalate	S			Macleods
	Escitalopram Oxalate	S			Macleods
	Clarithromycin	S	Oral	Unk, Qd, Two 10 Day Courses, Bed Time	Not Reported
	Clarithromycin	S	Unknown	Unk	Not Reported
	Tramadol Hydrochloride	S	Oral	Unk, Qd, Bed Time, Tramadol In Combination With Meloxicam For About Two Years Ago	Macleods
	Tramadol Hydrochloride	S	Unknown	Unk	Macleods
	Tramadol Hydrochloride	S	Unknown	Unk	Macleods
	Tramadol Hydrochloride	S			Macleods
	Atorvastatin	S	Oral	Unk Unk, Qd , Bedtime	Not Reported
	Atorvastatin	S	Unknown	Unk	Not Reported
	Atoris	S	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	S	Intracardiac	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	S	Oral	Unk	Not Reported
	Doxepin	S	Oral	25 Mg, Qd, At Bedtime,At Night	Not Reported
	Doxepin	S			Not Reported
	Doxepin	S			Not Reported
	Doxepin	S			Not Reported
	Perindopril	S	Unknown	Unk	Not Reported
	Perindopril	S	Unknown	Unk	Not Reported
	Perindopril	S	Oral	Unk	Not Reported
	Zolpidem Tartrate	S	Oral	10 Mg, Qd, At Bedtime	Not Reported
	Zolpidem Tartrate	S			Not Reported
	Sertraline	S	Oral	50 Mg, Qd Am, In The Morning	Not Reported
	Sertraline	S			Not Reported
	Movalis	S	Oral	Unk, Qd, Bed Time, Tramadol In Combination With Meloxicam, For	Not Reported

				About Two Years Ago	
	Movalis	S			Not Reported
	Movalis	S			Not Reported
	Polsen	S	Oral	10 Mg, Qd, At Bed Time	Not Reported
	Polsen	S			Not Reported
	Concor	S	Unknown	Unk	Not Reported
	Trosicam	S	Unknown	Unk, Taken Since About 2 Years	Not Reported
	Trosicam	S	Unknown	Unk	Not Reported
	Trosicam	S		Unk, Tramadol In Combination With Meloxicam, For About Two Years Ago	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14893122	EXPEDITED (15-DAY)		HO	AU-ALLERGAN-1825583US		50 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delusion; Eczema; Emotional Distress; Eosinophil Count Decreased; Feeling Cold; Frustration Tolerance Decreased; Haemoglobin Decreased; Hallucination, Auditory; Hyperhidrosis; Intentional Self-Injury; Lymphocyte Count Decreased; Mean Cell Haemoglobin Decreased; Mental Impairment; Metamyelocyte Count Increased; Mitral Valve Incompetence; Monocyte Count Decreased; Myelocyte Count Increased; Neutropenia; Platelet Count Increased;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Clozaril			S	Oral	700 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	5 Mg, Unk		Not Reported
	Paliperidone Depot			S	Unknown	100 Mg, Qd		Not Reported
	Caltrate			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Lurasidone			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Mirtazepine Teva			C	Unknown	Unk		Not Reported
	Crestor			C	Unknown	Unk		Not Reported
	Zuclopenthixol-Form-Unknown			C	Unknown	Unk		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported

Pulmonary Valve Incompetence; Thermal Burn; Tinea Infection; Vitamin B12 Deficiency; White Blood Cell Count Decreased	Coloxyl	C	Unknown	Unk		Not Reported
	Senna	C	Unknown	Unk		Not Reported
	Movicol	C	Unknown	Unk		Not Reported
	Vitamin B12	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14998706	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-905171		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Contusion; Fall; Syncope	Escitalopram			S	Unknown	Nk		Ivax
	Eferox			C		50 Mg, 1-0-0-0		Not Reported
	Hct			C		12.5 Mg, 1-0-0-0		Not Reported
	Metoprolol			C		47.5 Mg, 1-0-0-0		Not Reported
	Ventolair			C		250 Mg, 2-0-0-2		Not Reported
	Metamizole			C		500 Mg, 1-1-1-0		Not Reported
	Valsartan			C		80 Mg, 0.5-0-0-1		Not Reported
	Ass 100			C		100 Mg, 0-1-0-0		Not Reported
	Simvastatin			C		40 Mg, 0-0-0-1		Not Reported
	Pantoprazol			C		20 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14998989	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US19044			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Levetiracetam			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Clonazepam			S	Unknown	Unk		Not Reported
	Valproic Acid			S	Unknown	Unk		Not Reported
	Clobazam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14999667	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1830029US		74 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cognitive Disorder; Delusion; Depression; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Lexotanil			S	Oral	3.5 Mg, Qd		Not Reported
	Olanzapine			C	Unknown			Not Reported
	Enoxaparin			C	Unknown	Unk, Unknown		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk, Unknown		Not Reported
	Ascorbic Acid			C	Unknown	Unk, Unknown		Not Reported
	Gabapentin			C	Unknown	Unk, Unknown		Not Reported
	Ibuprofen			C	Unknown	Unk, Unknown		Not Reported
	Ondansetron			C	Unknown	Unk, Unknown		Not Reported
	Paracetamol			C	Unknown	Unk, Unknown		Not Reported
	Picosulfate			C	Unknown	Unk, Unknown		Not Reported
	Esomeprazole			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	15000980	EXPEDITED (15-DAY)		OT	PHHY2018FR018228		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise	Gilenya			S	Oral	1 Df, Qd		Novartis
	Seroplex			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	15001796	EXPEDITED (15-DAY)		DS	GB-TEVA-2018-GB-906362		33 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Jaw	Escitalopram			S	Oral			Ivax

	Lansoprazole	C	30 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	15002172	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-ALLERGAN-1830406US		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan
	Metformin Hydrochloride			C	Unknown	Unk, Unknown		Not Reported
	Generics Uk Nifedipine			C	Unknown	Unk Unk, Unknown		Not Reported
	Pregabalin			C	Unknown	Unk, Unknown		Not Reported
	Nefopam			C	Unknown	Unk, Unknown		Not Reported
	Tiotropium			C	Unknown	Unk, Unknown		Not Reported
	Sodium Picosulfate			C	Unknown	Unk, Unknown		Not Reported
	Cetirizine			C	Unknown	Unk, Unknown		Not Reported
	Naproxen			C	Unknown	Unk, Unknown		Not Reported
	Diazepam			C	Unknown	Unk, Unknown		Not Reported
	Cassia (Senna Alexandrina)			C	Unknown	Unk, Unknown		Not Reported
	Methotrexate Sodium			C	Unknown	Unk, Unknown		Not Reported
	Budesonide W/Formoterol Fumarate			C	Unknown	Unk, Unknown		Not Reported
	Lansoprazole			C	Unknown	Unk, Unknown		Not Reported
	Meptazinol			C	Unknown	Unk, Unknown		Not Reported
	Quetiapine Fumarate			C	Unknown	Unk, Unknown		Not Reported
	Temazepam			C	Unknown	Unk, Unknown		Not Reported
	Montelukast			C	Unknown	Unk, Unknown		Not Reported
	Pyridoxine			C	Unknown	Unk, Unknown		Not Reported
	Folic Acid			C	Unknown	Unk, Unknown		Not Reported
	Adcal-D3			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14253811	EXPEDITED (15-DAY)		HO	DE-ASTRAZENECA-2017SF20968		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Candesartan			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Risperdal			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	L-Thyroxin			C	Oral	100ug/Inhal Daily		Not Reported
	Amisulpride			C	Unknown			Not Reported
	Metformin			C	Oral			Not Reported
	Atorvastatin			C	Oral			Not Reported
	Acetylsalicylic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14301361	EXPEDITED (15-DAY)		OT	ES-ASTRAZENECA-2017SF23248			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Omeprazole			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Simvastatin			S	Unknown	20 Mg		Not Reported
	Topiramate			S	Unknown			Not Reported
	Topiramate			S	Unknown			Not Reported
	Paracetamol, Tramadol			S	Unknown	37.5/325 Mg, 3 Df Daily		Not Reported
	Enalapril, Hydrochlorothiazide			S	Unknown	1 Dosage Forms Daily; 1 Df = 20/12.5 Mg		Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Tepazepam			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Glibenclamide			S	Unknown			Not Reported
	Lormetazepam			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Metoclopramide			C	Unknown	1 Week Treatment		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14311091	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2017007014			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine Besylate Tablet			S	Oral	1 Df, Qd		Macleods
	Amitriptylline			S	Unknown	12.5 Mg, Qd		Not Reported
	Amitriptylline			S	Unknown	25 Mg, Unk		Not Reported
	Amitriptylline			S	Unknown	5 Mg, Qd		Not Reported
	Amitriptylline			S	Unknown	10 Mg, Qd		Not Reported
	Amitriptylline			S		Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	1 Df, Qd, 1 Dosage Forms Daily; 10 Mg		Macleods
	Paracetamol			S	Unknown	3 Df, Qd;		Not Reported
	Paracetamol			S	Unknown	1 Df, Qd, 3 Dosage Form Daily;1 Df= 37.5/325 Mg		Not Reported
	Tramadol / Acetaminophen			S	Unknown	1 Df, Tid; 1 Df=37.5/325 Mg		Macleods
	Omeprazole			S	Unknown	1 Df, Qd, 1 Dosage Forms Daily; 20 Mg		Not Reported
	Diazepam, Sulpiride			S	Unknown	1 Df, Qd		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	0.5 Df, Qd, 5 Dosage Forms Daily; 5 Mg		Not Reported
	Enalapril, Hydrochlorothiazide			S	Unknown	1 Df, Qd; 1 Df= 20/12.5 Mg		Not Reported
	Lormetazepam			S	Unknown	1 Df, Qd		Not Reported
	Glibenclamide			S	Unknown	2 Df, Qd		Not Reported
	Naproxen			S	Unknown	1 Df, Bid		Not Reported
	Simvastatin			S	Unknown	1 Df, Qd, 1 Dosage Forms Daily; 40 Mg		Not Reported
	Simvastatin			S	Unknown	20 Mg, Unk		Not Reported
	Topiramate			S	Unknown	0.5 Df, Qd		Not Reported
	Topiramate			S	Unknown	1 Df, Qd, 50 Mg		Not Reported
	Metoclopramide			C	Unknown	Unk, 1 Week Treatment		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14339621	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-AUROBINDO-AUR-APL-2017-48301		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Condition Aggravated; Depression; Drug Abuse; Drug Ineffective; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Tramadol			S	Oral	B/D ()		Aurobindo
	Tramadol			S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam For About Two Years Ago ()		Aurobindo
	Tramadol			S		()		Aurobindo
	Tramadol			S	Unknown	()		Aurobindo
	Tramadol			S	Unknown	()		Aurobindo
	Tramadol			S	Unknown	()		Aurobindo
	Tramadol			S	Unknown	()		Aurobindo
	Tramadol			S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago ()		Aurobindo
	Tramadol			S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago ()		Aurobindo
	Tramadol			S	Unknown	()		Aurobindo
	Tramadol			S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago ()		Aurobindo
	Tramadol			S	Unknown	Tramadol In Combination With Meloxicam For About Two Years Ago ()		Aurobindo
	Perindopril			S	Unknown	Unk		Aurobindo
	Perindopril			S	Oral	Unk ()		Aurobindo
	Perindopril			S	Unknown	()		Aurobindo
	Perindopril			S	Unknown	()		Aurobindo
	Perindopril			S	Unknown	()		Aurobindo

Perindopril	S	Unknown	()	Aurobindo
Perindopril	S	Oral	Unk ()	Aurobindo
Perindopril	S	Oral	Unk ()	Aurobindo
Perindopril	S	Oral	Unk ()	Aurobindo
Perindopril	S	Unknown	Unk ()	Aurobindo
Sertraline	S	Unknown	50 Mg In The Morning	Aurobindo
Sertraline	S	Oral	50 Mg, Od, (In The Morning)	Aurobindo
Sertraline	S	Unknown	50 Mg, Qd	Aurobindo
Sertraline	S	Oral	50 Mg, Am (In The Morning)	Aurobindo
Sertraline	S	Unknown	50 Mg, Qd	Aurobindo
Sertraline	S	Oral	50 Mg, Am (In The Morning)	Aurobindo
Sertraline	S	Unknown	50 Mg, Qd	Aurobindo
Sertraline	S	Oral	50 Mg, Am (In The Morning)	Aurobindo
Sertraline	S	Unknown	50 Mg, Qd	Aurobindo
Sertraline	S	Oral	50 Mg, Am (In The Morning)	Aurobindo
Escitalopram	S	Unknown	Unk	Aurobindo
Escitalopram	S	Oral	10 Mg, Before Sleeping	Aurobindo
Escitalopram	S	Unknown	Unk ()	Aurobindo
Escitalopram	S	Oral	10 Mg, Hs	Aurobindo
Escitalopram	S	Unknown	()	Aurobindo
Escitalopram	S	Oral	Doctor Switched The Patient From Sertraline To Escitalopram	Aurobindo
Escitalopram	S	Oral	10 Mg, Hs	Aurobindo
Escitalopram	S	Oral	10 Mg, Hs	Aurobindo
Escitalopram	S	Oral	Doctor Switched The Patient From Sertraline To	Aurobindo

			Escitalopram	
Escitalopram	S	Oral	Doctor Switched The Patient From Sertraline To Escitalopram	Aurobindo
Escitalopram	S	Oral	10 Mg, Hs	Aurobindo
Escitalopram	S	Unknown	Doctor Switched The Patient From Sertraline To Escitalopram	Aurobindo
Escitalopram	S	Oral	10 Mg, Hs	Aurobindo
Atorvastatin	S	Oral	Unk (Bedtime) ()	Not Reported
Atorvastatin	S	Unknown	()	Not Reported
Atorvastatin	S	Oral	Unk (Bedtime) ()	Not Reported
Atorvastatin	S	Oral	Unk (Bedtime) ()	Not Reported
Atorvastatin	S	Oral	Unk (Bedtime) ()	Not Reported
Bisoprolol	S	Unknown	Unk	Aurobindo
Bisoprolol	S	Unknown	Unk ()	Aurobindo
Bisoprolol	S	Unknown	Unk ()	Aurobindo
Bisoprolol	S	Unknown	Unk ()	Aurobindo
Trosicam	S	Unknown	Unk	Not Reported
Trosicam	S	Unknown	()	Not Reported
Trosicam	S	Unknown	Unk ()	Not Reported
Trosicam	S	Oral	Tramadol In Combination With Meloxicam, For About Two Years Ago ()	Not Reported
Trosicam	S	Unknown	Unk ()	Not Reported
Trosicam	S	Oral	Tramadol In Combination With Meloxicam, For About Two Years Ago ()	Not Reported
Trosicam	S	Unknown	Unk ()	Not Reported
Trosicam	S	Unknown	Unk ()	Not Reported
Concor	S	Unknown	Unk	Not Reported
Concor	S	Unknown	Unk ()	Not Reported

Concor	S	Unknown	()	Not Reported
Concor	S	Unknown	()	Not Reported
Concor	S	Unknown	()	Not Reported
Concor	S	Unknown	()	Not Reported
Clarithromycin	S	Unknown	Two 10 Day Courses	Not Reported
Clarithromycin	S	Unknown	()	Not Reported
Clarithromycin	S	Oral	B/D ()	Not Reported
Clarithromycin	S	Oral	Unk (Bedtime), Two, 10-Day Treatment Cycles Courses ()	Not Reported
Clarithromycin	S	Unknown	()	Not Reported
Clarithromycin	S	Unknown	()	Not Reported
Clarithromycin	S	Unknown	()	Not Reported
Clarithromycin	S	Unknown	Two 10 Day Courses ()	Not Reported
Clarithromycin	S	Oral	Two 10 Day Cycles. ()	Not Reported
Clarithromycin	S	Oral	Total Drug Duration: 2 X 10 Days ()	Not Reported
Clarithromycin	S	Oral	Two 10 Day Cycles. ()	Not Reported
Clarithromycin	S	Oral	Two 10 Day Cycles. ()	Not Reported
Atoris	S	Unknown	Unk	Not Reported
Atoris	S	Unknown	()	Not Reported
Atoris	S	Unknown	()	Not Reported
Atoris	S	Unknown	()	Not Reported
Atoris	S	Unknown	()	Not Reported
Polsen	S	Unknown	10 Mg At Bedtime	Not Reported
Polsen	S	Unknown	10 Mg At Bedtime	Not Reported
Polsen	S	Oral	10 Mg At Bedtime	Not Reported
Polsen	S	Oral	10 Mg At Bedtime	Not Reported
Polsen	S	Oral	10 Mg At Bedtime	Not Reported
Doxepin	S	Unknown	25 Mg At Bedtime	Not Reported

Doxepin	S		()	Not Reported
Doxepin	S		()	Not Reported
Doxepin	S		25 Mg, Od, At Bed Time	Not Reported
Doxepin	S		()	Not Reported
Doxepin	S	Unknown		Not Reported
Doxepin	S	Unknown	25 Mg At Bedtime	Not Reported
Doxepin	S	Oral	25 Mg, Hs	Not Reported
Doxepin	S	Oral	25 Mg, Hs	Not Reported
Doxepin	S	Oral	25 Mg, Hs	Not Reported
Doxepin	S	Oral	25 Mg, Hs	Not Reported
Zolpidem	S	Oral	10 Milligram Daily; At Bedtime	Not Reported
Zolpidem	S	Oral	10 Milligram Daily; At Bedtime	Not Reported
Zolpidem	S	Oral	10 Milligram Daily; At Bedtime	Not Reported
Zolpidem	S	Oral	10 Milligram Daily; At Bedtime	Not Reported
Movalis	S	Unknown	Tramadol In Combination With Meloxicam, For About Two Years Ago ()	Not Reported
Perindopril	C		()	Not Reported
Perindopril	C		()	Not Reported
Perindopril	C		()	Not Reported
Atorvastatin	C		()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14649919	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1813926US		45 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyperventilation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qpm		Allergan

	Bisoprolol	C	Oral	2.5 Mg, Q12h	Not Reported
	Amiodarone Hydrochloride	C	Oral	50 Mg, Q12h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14676018	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0097005		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14745797	EXPEDITED (15-DAY)		HO, OT	IT-GLAXOSMITHKLINE-IT2018058180		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral	In Total		Glaxosmithkline
	Efexor			S	Oral	In Total		Glaxosmithkline
	Lamictal			S	Oral	In Total		Glaxosmithkline
	Lexotan			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14903682	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1031929		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S				Not Reported
	Escitalopram			S		5 Mg, Unk		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15003350	EXPEDITED (15-DAY)		OT	AU-TEVA-2018-AU-905662			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Hypotension	Aripiprazole			S	Unknown			Teva
	Escitalopram			S	Unknown			Not Reported
	Elevit			C				Not Reported
	Folate			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15003949	EXPEDITED (15-DAY)		HO	SE-TEVA-2018-SE-906716		45 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block	Escitalopram			S	Oral	5 Milligram Daily;		Ivax
	Desloratadine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15004066	EXPEDITED (15-DAY)		OT	CA-ALKEM LABORATORIES LIMITED-CA-ALKEM-2018-03963		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Seizure; Torsade De Pointes; Ventricular Fibrillation	Quetiapine Fumarate			S	Unknown	100 Mg, Qd		Alkem
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15004134	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-175651		21 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Aripiprazole			S	Oral	In Total		Not Reported
	Zitromax 500 Mg Compresse Rivestite Con Film			S	Oral	In Total		Not Reported
	Prozin 25 Mg Compresse			S	Oral	In Total		Not Reported

	Rivestite				
	Escitalopram	S	Oral	In Total	Not Reported
	Alprazolam	S	Oral	In Total	Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15006597	NON-EXPEDITED			US-US WORLDMEDS, LLC-USW201709-001361			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Delusion	Apokyn			S	Subcutaneous			Us Worldmeds
	Mirapex			S				Not Reported
	Sinemet			S				Not Reported
	Nuplazid			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	11148954	EXPEDITED (15-DAY)		HO, OT	PHHY2015US010045			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthralgia; Asterixis; Asthenia; Device Damage; Dizziness; Drug Withdrawal Syndrome; Headache; Lethargy; Loss Of Consciousness; Memory Impairment; Micturition Urgency; Mood Altered; Pollakiuria; Seizure; Sleep Disorder; Somnolence; Tremor; Urinary Retention; Vision Blurred	Lioresal Intratecal			S	Intrathecal	968.7 Ug, Qd		Not Reported
	Lioresal Intratecal			S	Intrathecal	50 Ug/Bolus		Not Reported
	Lioresal Intratecal			S	Intrathecal	30 Ug/Bolus		Not Reported
	Lioresal Intratecal			S	Intrathecal	968.7 Ug, Qd		Not Reported
	Lioresal Intratecal			S	Intrathecal	931.8 Ug, Qd		Not Reported
	Lioresal Intratecal			S	Intrathecal	1017.7 Ug, Qd		Not Reported
	Lioresal Intratecal			S	Intrathecal	806.3 Ug, Qd		Not Reported
	Carbamazepine			S	Unknown	Unk		Novartis
	Lexapro			S	Oral	Unk		Not Reported
	Vimpat			S	Unknown	Unk		Not Reported
	Efexor Xr			C	Unknown	75 Mg, Qd		Not Reported
	Efexor Xr			C	Unknown	Unk (Increased Dose)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	13926309	EXPEDITED (15-DAY)		HO, LT, OT	US-ALLERGAN-1748408US		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Drug Interaction; Electrocardiogram Qt Prolonged; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Dextromethorphan/Promethazine			S	Unknown			Not Reported
	Dextromethorphan/Promethazine			S				Not Reported
	Amlodipine			C	Unknown	5 Mg, Q12h		Not Reported
	Labetalol			C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	13950218	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-TEVA-803404ISR		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Condition Aggravated; Condition Aggravated; Depression; Drug Abuse; Drug Ineffective; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Movalis			S	Oral	Tramadol In Combination With Meloxicam, At Bedtime.		Teva
	Movalis			S	Unknown			Teva
	Perindopril			S	Oral			Not Reported
	Perindopril			S	Unknown			Not Reported
	Atorvastatin			S	Oral	At Bedtime.		Teva
	Atorvastatin			S	Unknown			Teva
	Sertraline			S	Oral	50 Milligram Daily; At The Morning		Not Reported
	Sertraline			S	Unknown			Not Reported
	Zolpidem			S	Oral	10 Milligram Daily; Before Bedtime		Teva
	Zolpidem			S				Teva
	Zolpidem			S				Teva
	Escitalopram			S	Oral	Doctor Switched The		Ivax

			Patient From Sertraline To Escitalopram, Before Sleeping 10mg.	
Escitalopram	S	Unknown	Doctor Switched Patient From Sertraline To Escitalopram Oxalate	Ivax
Escitalopram	S			Ivax
Doxepin	S	Oral	25 Milligram Daily; At Night	Not Reported
Doxepin	S	Unknown		Not Reported
Doxepin	S			Not Reported
Bisoprolol	S	Oral		Duramed
Tramadol	S	Oral	Tramadol In Combination With Meloxicam; At Bedtime.	Not Reported
Tramadol	S			Not Reported
Tramadol	S			Not Reported
Tramadol	S			Not Reported
Clarithromycin	S	Oral	Total Drug Duration: 2 X 10 Days	Not Reported
Atoris	S	Unknown		Not Reported
Polsen	S	Oral	10 Milligram Daily; At Bed Time	Not Reported
Polsen	S			Not Reported
Concor	S	Unknown		Not Reported
Trosicam	S	Oral		Not Reported
Trosicam	S			Not Reported
Atorvastatin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	14760380	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018012584			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor	Escitalopram	S	Oral	300 Mg, Unk, Toatal	Macleods
	Efexor	S	Oral	7 Df, Unk, 37,5 Mg Prolonged-Release Hard Capsules, Toatal	Not Reported
	Lexotan	S	Oral	20 Ml, Unk, 2,5 Mg/Ml Oral Drops Solution, Toatal	Not Reported
	Lamictal	S	Oral	1400 Mg, Unk, 100 Mg Chewable / Dispersible Tablets, Toatal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	14992582	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-030838		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Serotonin Syndrome	Escitalopram			S	Unknown	()		Aurobindo
	Mirtazapine			S	Unknown	()		Aurobindo
	Olanzapine			S	Unknown	()		Aurobindo
	Trazodone			S	Unknown	()		Aurobindo
	Lorazepam			S	Unknown	()		Aurobindo
	Gabapentin			C		()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15009367	EXPEDITED (15-DAY)		DE	IE-TEVA-2018-IE-907928		40 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Unknown			Ivax
	Escitalopram			S	Oral	Duration: 10mg For 1 Month Moved To 15mg For 1 Month.		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15009797	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS			Unknown	FRA

US LTD-
MAC2018014264

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Vertigo	Escitalopram Oxalate			S	Oral	5 Milligram, Qd		Macleods
	Aldactazine Divisible Coated Tablet			S	Oral	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15009884	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-031125		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor	Escitalopram			S	Oral	In Total		Aurobindo
	Lexotan			S	Oral	In Total		Not Reported
	Efexor			S	Oral	In Total		Not Reported
	Lamictal			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15011260	EXPEDITED (15-DAY)		DS, HO	CA-TEVA-2018-CA-905536		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Motor Dysfunction; Spinal Cord Compression; Spinal Cord Oedema	Escitalopram			S	Unknown			Ivax
	Rivaroxaban			S	Oral			Not Reported
	Unfractionated Heparin			S	Subcutaneous	5000 U Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15011831	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-907562		55 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia; Product Used For Unknown Indication	Escitalopram			S	Unknown	Nk		Ivax
	Acetylsalicylsaeure			C	Unknown	Nk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15013091	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1039907		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Bisoprolol			S	Oral	10 Mg, Unk		Not Reported
	Mirtazapine			S	Oral	15 Mg, Unk		Not Reported
	Modopar			S	Oral	3 Df, Unk		Mylan
	Risperdal			S	Oral	Unk		Mylan
	Seroplex			S	Oral	1 Df, Unk		Mylan
	Kardegic			C	Oral	1 Df, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15013599	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1830857US		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Stresam			S	Oral	2 Df, Unk		Not Reported
	Tanganil			C	Oral	4 Df, Unk		Not Reported
	Mopral			C	Oral	1 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15125285	DIRECT		DS, HO			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Impaired Quality Of Life	Zoloft			S				Not Reported
	Wellbutrin			S				Not Reported

	Lexapro	S	Not Reported
	Seroquel	S	Not Reported
	Adderall	C	Not Reported
	Bystolic	C	Not Reported
	Vitamins	C	Not Reported
	Vitamin D Nos	C	Not Reported
	Vitamin C	C	Not Reported
	Magnesium	C	Not Reported
	Fish Oil	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	14894940	EXPEDITED (15-DAY)		DE, HO, OT	DE-TORRENT-00008396		1 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Product Use Issue; Respiratory Failure	Exodus (Escitalopram Oxalate)			S		Unknown		Unknown
	Phenobarbital			S		Unknown		Unknown
	Sildenafil Citrate			S		Unknown		Unknown
	Spironolactone			S		Unknown		Unknown
	Synagis			S	Intramuscular			Unknown
	Topiramate			S	Unknown	Unknown		Unknown
	Varivax			S	Intramuscular	1 Df		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	14907415	EXPEDITED (15-DAY)		DE, HO, OT	DE-DRREDDYS-GER/GER/18/0098908		1 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Sildenafil			S	Unknown			Not Reported
	Spironolactone			S				Not Reported
	Phenobarbital			S				Not Reported
	Varivax			S	Intramuscular	1 Df		Not Reported
	Topiramate			S				Not Reported
	Synagis			S	Intramuscular			Not Reported
	Exodus (Escitalopram Oxalate)			S				Not Reported
	Nutrition With Nutrini Mixed With			C	Other			Not Reported

Water

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15014558	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-907350		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Extrapyramidal Disorder; Mydriasis; Sinus Tachycardia	Risperidone			S	Oral			Pliva
	Escitalopram			S	Oral			Not Reported
	Theralene			C	Oral	Dosage Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15014644	EXPEDITED (15-DAY)		OT	CH-TEVA-2018-CH-909203		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome	Escitalopram Mepha 5 Mg			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15014907	EXPEDITED (15-DAY)		OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018014268			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Escitalopram Oxalate			S	Oral	20 Milligram		Macleods
	Irbesartan			S	Oral			Macleods
	Bromazepam			S	Oral	18 Milligram		Not Reported
	Fenofibrate			S	Oral			Not Reported
	Levothyroxine Sodium			S	Oral			Not Reported
	Naproxene			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15014917	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018014267			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Hypoglycaemia; Hyponatraemia	Escitalopram Oxalate			S	Oral	5 Milligram, Qd		Macleods
	Omeprazole Mylan 20 Mg			S	Oral	20 Milligram, Qd		Not Reported
	Ramipril Mylan 5 Mg			S	Oral	5 Milligram, Qd, Tablet Breackable		Not Reported
	Alendronic Acid			C	Oral	70 Milligram, 1 Second		Not Reported
	Calperos D3			C	Oral	500 Milligram, Qd, Sucking Tablet		Not Reported
	Ceris 20 Mg			C	Oral	40 Milligram, Qd		Not Reported
	Icaz Lp 2.5 Mg			C	Oral	2.5 Milligram, Qd		Not Reported
	Lactulose Mylan 10 G/15 Ml			C	Oral	10 Gram, Qd, Oral Solution In Sachet		Not Reported
	Sodium Alginate Sodium Bicarbonate Mylan			C	Oral	4 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15014939	EXPEDITED (15-DAY)		DS	DE-AUROBINDO-AUR-APL-2018-027044			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Gait Disturbance; Hyperhidrosis; Hypoaesthesia; Insomnia; Malaise; Muscle Twitching; Off Label Use; Palpitations; Paraesthesia; Tremor	Escitalopram 10 Mg			S	Oral	10 Milligram, Once A Day		Aurobindo
	Escitalopram 10 Mg			S	Oral	20 Milligram, Once A Day		Aurobindo
	Oxazepam			S	Oral	10 Milligram, Once A Day, (At Night)		Not Reported
	Monostep			C	Oral	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15015866	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-031060		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Vertigo	Escitalopram			S	Oral	5 Milligram, Daily		Aurobindo
	Aldactazine			S	Oral	1 Dosage Form, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15016120	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1830894US		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Encephalopathy	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Amiodarone			S	Oral	200 Mg, Qd		Not Reported
	Topalgic Lp			S	Oral	3 Df, Qd		Not Reported
	Oxynormoro			S	Oral	5 Mg, Qd		Not Reported
	Xanax			S	Oral	0.38 Mg, Qd		Not Reported
	Kardegic			S	Oral	1 Df, Qd		Not Reported
	Tazocilline			S	Intravenous (not otherwise specified)	3 Df, Qd		Not Reported
	Allopurinol			S	Oral	100 Mg, Qd		Not Reported
	Mycophenolate Sodium			C	Oral	360 Mg, Qd		Not Reported
	Ciclosporine			C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15016366	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1830912US		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Drug Abuse; Hypotension; Intentional Overdose; Somnolence; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	12 Dosage Forms In Total (Overdose)		Allergan
	Anafranil			S	Oral	30 Df In Total		Not Reported
	Cardensiel			S	Oral	20 Df, In Total		Not Reported
	Nordazepam			S	Oral	4 Df, In Total		Not Reported
	Lysanxia			S	Oral	12 Df, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15016414	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1830909US		86 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Prescription Drug Used Without A Prescription; Spinal Fracture	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15016425	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1830904US		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise; Sinus Bradycardia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15016884	EXPEDITED (15-DAY)		HO, OT	US-PRINSTON PHARMACEUTICAL INC.-2018PRN00286		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Overdose; Rhabdomyolysis; Serotonin Syndrome;	Escitalopram			S	Oral			Prinston Pharmaceutical
	Lamotrigine			S	Oral			Not Reported

Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15017948	EXPEDITED (15-DAY)		HO, OT	US-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00220		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Overdose; Rhabdomyolysis; Serotonin Syndrome; Sinus Tachycardia; Unresponsive To Stimuli	Escitalopram			S	Oral			Jubilant
	Lamotrigine			S	Oral			Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15018271	EXPEDITED (15-DAY)		OT	TR-MYLANLABS-2018M1041109		34 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Sinus Bradycardia	Cetirizine			S	Oral	Started On Hospitalisation Day 26 And Discontinued On Hospitalisation Day 28		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Ampicillin			C	Intravenous (not otherwise specified)			Mylan
	Pantoprazole			C	Unknown			Mylan
	Enoxaparin			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15018400	EXPEDITED (15-DAY)		OT	ES-CANTON LABORATORIES, LLC-2049500			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Naprosyn	S	Unknown	Canton Laboratories
	Amitriptyline Hydrochloride	S	Unknown	Not Reported
	Amitriptyline Hydrochloride	S	Unknown	Not Reported
	Amitriptyline Hydrochloride	S	Unknown	Not Reported
	Amlodipine	S	Unknown	Not Reported
	Diazepam	S	Unknown	Not Reported
	Diazepam	S	Unknown	Not Reported
	Enalapril Maleate And Hydrochlorothiazide	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Glibenclamide	S	Unknown	Not Reported
	Lormetazepam	S	Unknown	Not Reported
	Omeprazole	S	Unknown	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Paracetamol And Tramadol	S	Unknown	Not Reported
	Simvastatin	S	Unknown	Not Reported
	Simvastatin	S	Unknown	Not Reported
	Topiramate	S	Unknown	Not Reported
	Topiramate	S	Unknown	Not Reported
	Metoclopramide	C	Unknown	Not Reported
	Diazepam Sulpride	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2018	15018978	EXPEDITED (15-DAY)		HO	ZA-DRREDDYS-SAF/SAF/18/0100478			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Dopaquel			S	Oral			Not Reported
	Cardicor			S	Oral			Not Reported
	Lexamil			S	Oral			Not Reported
	Lanoxin			S	Oral			Not Reported

	Mylan Furosemide	S	Oral	Not Reported
	Aldactone	S	Oral	Not Reported
	Zopivane	S	Oral	Not Reported
	Brazepam	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	13908939	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-057716		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Withdrawal Syndrome; Atrioventricular Block First Degree; Decreased Appetite; Dehydration; Drug Interaction; Hallucination, Auditory; Hallucination, Visual; Serotonin Syndrome; Sleep Talking; Tongue Biting; Viral Upper Respiratory Tract Infection	Escitalopram			S				Accord
	Dextromethorphan/Promethazine			S				Not Reported
	Amlodipine			C				Not Reported
	Labetalol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	14266983	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017006492			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	5 Mg, Qd		Macleods
	Aripiprazole			S	Oral	10 Mg, Qd		Macleods
	Candesartan			S	Oral	16 Mg, Qd		Macleods
	Escitalopram			S	Oral	10 Mg, Qd		Macleods
	Escitalopram			S	Oral	15 Mg, Qd		Macleods
	Escitalopram			S	Oral	20 Mg, Qd		Macleods
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported

Aspirin	C	Oral	100 Mg, Qd		Not Reported
L-Thyroxine Sodium	C	Oral	100 Mg, Qd		Not Reported
Metformin Hydrochloride	C	Oral	1500 Mg, Qd		Macleods
Amisulpride	C	Unknown	200 Mg, Qd		Not Reported
Risperdal	C	Unknown	2 Mg, Qd		Not Reported
Risperdal	C	Unknown	1.5 Mg, Qd		Not Reported
Risperdal	C	Unknown	2 Mg, Unk (For Nights),Hs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15019629	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-031290		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Escitalopram			S	Oral	20 Milligram		Aurobindo
	Bromazepam			S	Oral	18 Milligram		Not Reported
	Pregabalin			S	Oral	150 Milligram		Not Reported
	Fenofibrate			S	Oral	67 Milligram		Aurobindo
	Irbesartan			S	Oral	75 Milligram		Aurobindo
	Naproxen			S	Oral	1100 Milligram		Aurobindo
	Levothyroxine Sodium			S	Oral	75 Microgram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15019630	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-031288		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Mirtazapine			S	Oral			Aurobindo
	Mirtazapine			S	Oral			Aurobindo
	Bisoprolol			S	Oral			Aurobindo
	Modopar			S	Oral			Not Reported
	Risperdal			S	Oral	Inconnue ()		Not Reported

	Seroplex	S	Oral	Not Reported
	Kardegic	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15019937	EXPEDITED (15-DAY)		OT	US-ACI HEALTHCARE LIMITED-2049536		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Serotonin Syndrome	Gabapentin			S	Unknown			Aci Healthcare
	Lorazepam			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15020348	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2018-032161		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Unknown			Aurobindo
	Hydrochlorothiazide			S	Unknown			Not Reported
	Gliclazide			C				Not Reported
	Insulin			C				Not Reported
	Levothyroxine			C				Not Reported
	Metformin			C				Not Reported
	Telmisartan			C				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15020510	EXPEDITED (15-DAY)		OT	US-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00351			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Akathisia; Serotonin Syndrome	Gabapentin Tablets,Usp	S		Unk	Sciegen
	Lorazepam	S	Unknown	Unk	Not Reported
	Trazodone	S	Unknown	Unk	Not Reported
	Escitalopram	S	Unknown	Unk	Not Reported
	Mirtazapine	S	Unknown	Unk	Not Reported
	Olanzapine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15021112	EXPEDITED (15-DAY)		OT	GB-TORRENT-00016641			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S		Unknown		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15021377	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-031260		16 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypotension; Loss Of Consciousness	Escitalopram Arrow Film-Coated Tablet 20mg			S	Oral	20 Milligram, Once A Day		Aurobindo
	Tercian /00759301/			S	Oral	25 Gtt, Once A Day		Not Reported
	Alprazolam Mylan			S	Oral	1.5 Milligram, Once A Day		Mylan
	Diane			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15021842	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1831224US		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Aldactazine			S	Oral	1 Df, Qd		Not Reported

Inappropriate Antidiuretic Hormone Secretion; Incorrect Dose Administered; Vertigo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15021863	EXPEDITED (15-DAY)		HO, OT	TR-ALLERGAN-1831007US		71 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15023799	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1040541		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Disorder; Priapism	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15023822	EXPEDITED (15-DAY)		OT	PHHY2018ES023314		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction	Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Enalapril			S	Oral	2 Df, Qd		Novartis
	Carvedilol			S	Oral	1 Df, Qd		Not Reported
	Insulin Glargine			S	Unknown	1 Df, Qd		Not Reported
	Orvatez			S	Oral	1 Df, Qd		Not Reported
	Lantus			S	Subcutaneous	30 Iu, Qd		Not Reported
	Seguril			S	Oral	1 Df, Qd		Not Reported
	Lyxumia			C	Subcutaneous	1 Df, Qd (20 Unit(S))		Not Reported
	Toujeo			C	Subcutaneous	32 Iu, Qd		Not Reported
	Novorapid			C	Subcutaneous			Not Reported

	Insulin Glargine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15024059	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1040742		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Paraesthesia; Prescribed Underdose	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15026768	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-175737			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Encephalopathy	Allopurinol			S	Oral	100 Mg, Daily		Sun
	Amiodarone			S	Oral	200 Mg, Daily		Taro
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	1 Df, Daily		Not Reported
	Oxynormoro 5 Mg, Comprime Orodispersible			S	Oral	Unk; 5 Mg		Not Reported
	Seroplex 5 Mg, Comprime Pellicule			S	Oral	1 Df, Daily		Not Reported
	Tazocilline 4 G/500 Mg, Poudre Pour Solution Pour Perfusion			S	Intravenous (not otherwise specified)	3 Df, Daily		Not Reported
	Topalgic Lp 50 Mg, Comprime A Liberation Prolongee			S	Oral	3 Df, Daily		Not Reported
	Xanax 0,25 Mg, Comprime Secable			S	Oral	0.38 Mg, Daily		Not Reported
	Ciclosporine			C	Oral	100 Mg, Daily		Not Reported
	Mycophenolate Sodique			C	Oral	360 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15141328	DIRECT		OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Escitalopram			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	14270696	EXPEDITED (15-DAY)		HO	DE-OTSUKA-2017_025746		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Prescribed Underdose; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Qd		Otsuka
	Aripiprazole			S	Oral	5 Mg, Qd		Otsuka
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Candesartan			S	Oral	16 Mg, Qd		Not Reported
	L-Thyroxine			C	Oral	100 Mg, Qd		Not Reported
	Metformin			C	Oral	1500 Mg, Qd		Not Reported
	Ass			C	Oral	100 Mg, Qd		Not Reported
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported
	Risperdal			C	Unknown	2 Mg, Hs		Not Reported
	Risperdal			C	Unknown	2 Mg, Qd		Not Reported
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported
	Amisulpride			C	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	14280001	EXPEDITED (15-DAY)		HO	DE-LUPIN PHARMACEUTICALS INC.-2017-07072		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole		S	Oral	10 Mg, Qd	Not Reported
	Aripiprazole		S	Oral	5 Mg, Qd	Not Reported
	Escitalopram		S	Oral	15 Mg, Qd	Lupin
	Escitalopram		S	Oral	20 Mg, Qd	Lupin
	Escitalopram		S	Oral	10 Mg, Qd	Lupin
	Candesartan		S	Oral	16 Mg, Qd	Not Reported
	Risperdal		C	Unknown	1.5 Mg, Qd	Not Reported
	Risperdal		C	Unknown	2 Mg, Unk (For Nights)	Not Reported
	Risperdal		C	Unknown	2 Mg, Qd	Not Reported
	L-Thyroxin		C	Oral	100 Mcg, Qd	Not Reported
	Amisulpride		C	Unknown	200 Mg, Qd	Not Reported
	Metformin		C	Oral	1500 Mg, Qd	Not Reported
	Atorvastatin		C	Oral	20 Mg, Qd	Not Reported
	Acetylsalicylic Acid		C	Oral	100 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	14341547	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-158623		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Suicide Attempt; Tinnitus; Tinnitus	Atorvastatin			S	Unknown	Unk		Sun
	Clarithromycin			S	Unknown	Unk		Sun
	Clarithromycin			S	Unknown	Two 10 Day Courses		Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Perindopril			S	Unknown	Unk		Not Reported
	Atoris			S	Unknown	Unk		Not Reported
	Concor			S	Unknown	Unk		Not Reported
	Doxepin			S	Unknown	25 Mg At Bedtime		Not Reported

Polsen	S	Unknown	10 Mg At Bedtime		Not Reported
Sertraline	S	Unknown	50 Mg, Daily; 50 Mg In The Morning		Not Reported
Sertraline	S	Unknown	50 Mg, Qd		Not Reported
Tramadol	S	Unknown	Unk		Not Reported
Tramadol	S	Unknown	Unk		Not Reported
Trosicam	S	Unknown	Unk		Not Reported
Atorvastatin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	14381601	EXPEDITED (15-DAY)		HO, OT	SI-ALLERGAN-1801175US		48 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Sclerosis; Off Label Use; Palpitations	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qam		Allergan
	Tolterodine			S	Unknown	4 Mg, Qam		Not Reported
	Fty 720			S	Unknown	0.5 Mg, Qd		Not Reported
	Fampridine			S	Unknown	10 Mg, Bid		Not Reported
	Pregabalin			S	Unknown	150 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	14684112	EXPEDITED (15-DAY)		OT	PHHY2017FR115515		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Aliskiren			S	Unknown			Not Reported
	Digoxin			S	Unknown	Unk		Novartis
	Amiodarone			S	Unknown			Not Reported
	Domperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	14961360	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-174430		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Sopor	Escitalopram			S	Oral	In Total		Not Reported
	Paroxetine			S	Oral	In Total		Sun
	Minias 2,5 Mg/Ml Gocce Orali, Soluzione			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	14981366	EXPEDITED (15-DAY)		HO	IT-OTSUKA-2018_013993		21 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Intentional Self-Injury; Partner Stress; Prescribed Overdose; Product Administration Error; Product Use In Unapproved Indication; Sopor	Aripiprazole			S	Oral	210 Mg, Unk		Otsuka
	Zitromax			S	Oral	1500 Mg, Unk		Not Reported
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	1200 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	140 Mg, Unk		Not Reported
	Alprazolam			S	Oral	15 Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15005737	EXPEDITED (15-DAY)		DE, HO	GB-BAYER-2018-111680		88 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer; Gastrointestinal Haemorrhage; Gastrointestinal Pain	Acetylsalicylic Acid(<=100 Mg)			S	Oral	75 Mg, Qd		Bayer
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Dihydrocodeine			C	Oral	120 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15027884	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-176001		34 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported
	Cetrizine			S	Oral	10 Mg, Daily		Ranbaxy
	Ampicillin			C	Intravenous (not otherwise specified)	2 G, Q4h		Not Reported
	Enoxaparin			C	Unknown	60 Mg, Daily		Not Reported
	Pantoprazole			C	Unknown	40 Mg, Daily		Not Reported
	Aspirin			C	Unknown	100 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15028966	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2018M1040055		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock	Escitalopram			S	Unknown	Unknown		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15029723	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE-909134		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Pulmonary Artery Stenosis Congenital	Escitalopram			S	Transplacental	10 Milligram Daily;		Ivax
	Sertraline			C	Transplacental	150 Milligram Daily;		Not Reported
	Quetiapine			C	Transplacental	25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15030158	EXPEDITED (15-DAY)		DS, OT	US-OTSUKA-2018_014850		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Seizure; Therapeutic Response Unexpected	Rexulti			S	Unknown	Unk		Otsuka
	Aripiprazole			S	Unknown	Unk		Otsuka
	Wellbutrin			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15030556	EXPEDITED (15-DAY)		OT	FR-CANTON LABORATORIES, LLC-2049639		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Naprosyn			S	Oral			Canton Laboratories
	Bromazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Fenofibrate			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported
	Levothyroxine Sodium			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15031946	EXPEDITED (15-DAY)		OT	PHHY2018DE021143			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Juvenile Myoclonic Epilepsy; Myoclonus	Clozapine			S	Unknown	75 Mg, Unk		Not Reported
	Oxcarbazepine			S	Unknown	2400 Mg, Unk		Novartis
	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported

Brivaracetam	S	Unknown	200-250 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15031959	EXPEDITED (15-DAY)		OT	PL-TEVA-2018-PL-910458		34 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Learning Disorder; Mental Impairment	Escitalopram			S	Unknown	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15031989	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1040378		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disturbance In Attention; Intentional Overdose; Poisoning Deliberate	Paracetamol			S	Oral	40 G, Unk		Not Reported
	Escitalopram			S	Oral	27 Df, Unk		Not Reported
	Alprazolam			S	Oral	15 Df, Unk		Not Reported
	Codeine			S	Oral	6 Df, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	13953115	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2017-39918		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Cognitive Disorder; Decreased Appetite; Drug Interaction; Electrocardiogram Qt Prolonged; Hallucinations, Mixed; Poor Quality Sleep; Serotonin Syndrome; Sleep Talking	Escitalopram			S	Unknown			Aurobindo
	Escitalopram			S				Aurobindo
	Dextromethorphan W/Promethazine			S	Unknown			Not Reported
	Labetalol			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	14310552	EXPEDITED (15-DAY)		DE	FI-ALLERGAN-1772900US			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Fibrillation	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Ciprofloxacin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	14623001	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1813185US		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan
	Bilaska			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Nocertone			S	Oral			Not Reported
	Simponi			S	Subcutaneous	50 Mg, Q Month		Not Reported
	Tramadol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	14770767	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1820706US		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Gases Abnormal; Drug Abuse; Intentional Overdose; Muscle Rigidity; Sopor	Escitalopram Oxalate Unk			S	Oral	300 Mg, Unk (In Total)		Allergan
	Lexotan			S	Oral	20 Ml, Unk (In Total)		Not Reported
	Efexor			S	Oral	7 Df, Unk (In Total)		Not Reported
	Lamictal			S	Oral	1400 Mg, Unk (In Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	14795109	EXPEDITED (15-DAY)		HO, LT	CZ-PFIZER INC-2018162505			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Electrocardiogram Qt Prolonged; Epilepsy; Loss Of Consciousness; Overdose; Poisoning	Venlafaxine Hcl			S	Oral	Unk		Pfizer
	Ibuprofen			S	Unknown	Unk		Pfizer
	Clonazepam			S	Oral	Unk		Not Reported
	Levopromazin			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Not Reported
	Metoclopramide			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Melperone			S	Oral	Unk		Not Reported
	Amphetamine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034235	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00546		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cyst	Escitalopram			S	Oral	15 Milligram		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034415	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-909197		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Valproinsaeure			S	Oral	500 Mg, 0-0-0-1,		Teva
	Quetiapine			S	Oral	100 Mg, 0-0-0-1,		Teva
	Cipralex 10mg - Filmtabletten			S	Oral	10 Mg, 1-0-0-0,		Not Reported
	Levothyroxin			C	Oral	75 Mg, 1-0-0-0,		Not Reported
	Torasemid			C	Oral	10 Mg, 1-0-0-0,		Not Reported
	Felodipine			C	Oral	10 Mg, 1-0-0-0,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15035797	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC-2018248029		83 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Aspavor			S		20 Mg, Unk		Pfizer
	Zanidip			S		10 Mg, Unk		Not Reported
	Lasix			S		20 Mg, Unk		Not Reported
	Spiractin (Spironolactone)			S		25 Mg, Unk		Not Reported
	Ganfort			S		5 Mg, Unk		Not Reported
	Ecotrin			S		81 Mg, Unk		Not Reported
	Glucophage Xr			S		500 Mg, Unk		Not Reported
	Stilpane (Acetaminophen/Caffeine/Codeine/Phosphate/Meprobamate)			S		Unk		Not Reported
	Lexamil			S		5 Mg, Unk		Not Reported
	Bilocor			S		5 Mg, Unk		Not Reported
	Epleptin			S		100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15037372	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-908967		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 Milligram Daily; 10 [Mg/D]		Ivax
	Femibion Pregnancy 1 (Nem)			C	Transplacental	.8 Milligram Daily; 0.8 [Mg/D]		Not Reported
	Vaccine Flu (Seasonal)			C	Transplacental			Not Reported
	L-Thyroxin			C	Transplacental	100 [Mg/D]/ Initial 75µg/D, Dosage Increase To 100µg/D From Week 34+2		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15037402	EXPEDITED (15-DAY)		OT	FR-ROCHE-2142065		26 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Valium			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Lepticur			S	Oral			Not Reported
	Macrogol			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Leponex			S	Oral			Not Reported
	Xeplion			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15037767	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-911578		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Escitalopram 15 Mg 28 Comprimidos			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15038966	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1831358US		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Completed Suicide	Lexapro			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	13932018	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2017-05022		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrioventricular Block First Degree; Drug Interaction; Electrocardiogram Qt Prolonged; Serotonin Syndrome	Escitalopram	S	Unknown	10 Mg, Qd	Lupin
	Dextromethorphan/Promethazine	S	Unknown	Unk	Not Reported
	Dextromethorphan/Promethazine	S			Not Reported
	Naltrexone	C	Intramuscular	Unk	Not Reported
	Amlodipine	C	Unknown	5 Mg, Bid	Not Reported
	Labetalol	C	Unknown	100 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	13939669	EXPEDITED (15-DAY)		HO, OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2017005815			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Lethargy; Mental Status Changes; Myoclonus; Serotonin Syndrome; Tongue Biting; Tongue Haemorrhage; Viral Upper Respiratory Tract Infection	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd		Macleods
	Dextromethorphan/Promethazine			S	Oral	Unk		Not Reported
	Dextromethorphan/Promethazine			S				Not Reported
	Dextromethorphan/Promethazine			S				Not Reported
	Amlodipine Besylate			C	Unknown	5 Milligram, Bid, 12 Hour		Macleods
	Levetiracetam			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Labetalol			C	Unknown	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	14615566	EXPEDITED (15-DAY)		OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018010921			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Tramadol Hydrochloride			S	Oral	Unk, Unknown Dosage		Macleods
	Seroplex			S	Oral	20 Mg, Unk		Not Reported

	Bilaska	S	Oral	Unk	Not Reported
	Seresta	S	Oral	Unk	Not Reported
	Nocertone	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Unk, 50 Mg Solution For Injection In Pre-Filled Pen	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	14961354	EXPEDITED (15-DAY)		HO, LT, OT	US-DRREDDYS-USA/USA/18/0099557		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Rhabdomyolysis; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Lamotrigine Tablets			S	Unknown			Not Reported
	Lamotrigine Tablets			S				Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15041208	EXPEDITED (15-DAY)		HO	FR-009507513-1806FRA006201		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corneal Oedema	Sinemet L.P.			S	Oral	2 Df, Q4d		Merck
	Mantadix			S	Oral	300 Mg, Qd		Not Reported
	Seroplex			S	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15042496	EXPEDITED (15-DAY)		OT	ZA-CIPLA (EU) LIMITED-2018ZA19024			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Condition	Escitalopram			S	Oral	10 Mg, Qd		Invagen

Aggravated; Confusional State; Drug Ineffective; Fatigue; Feeling Cold; Feeling Jittery; Insomnia; Myalgia; Nervousness; Thinking Abnormal; Tinnitus; Treatment Noncompliance; Tremor; Unevaluable Investigation	Escitalopram	S	Unknown	5 Mg, Per Day	Invagen
	Serdep /00724402/	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15042714	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1040908		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Esomeprazole			S	Oral	20 Mg, Qd		Not Reported
	Valaciclovir			S	Oral	500 Mg, Qd		Not Reported
	Ramipril			S	Oral	Unk		Not Reported
	Metoclopramide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15042756	EXPEDITED (15-DAY)		DS	GB-TORRENT-00016683		33 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Jaw	Escitalopram			S	Oral			Unknown
	Lansoprazole			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15042869	EXPEDITED (15-DAY)		HO	FR-009507513-1806FRA008796		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Mirtazapine			S	Oral			Merck
	Bisoprolol Fumarate			S	Oral			Not Reported

	Modopar	S	Oral			Not Reported
	Risperdal	S	Oral	Inconnue		Not Reported
	Seroplex	S	Oral			Not Reported
	Kardegic	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15043579	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018248040		67 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Head Injury; Loss Of Consciousness	Xanor			S		0.5 Mg, Unk		Pfizer
	Zartan (Losartan Potassium)			S		50 Mg, Unk		Not Reported
	Fedaloc			S		30 Mg, Unk		Not Reported
	Spiractin (Spironolactone)			S		25 Mg, Unk		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported
	Foxair			S		50/250mcg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15043676	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1041372		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chills; Headache; Loss Of Consciousness; Nausea; Tremor	Escitalopram			S	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15043809	EXPEDITED (15-DAY)		HO, LT	PH-ABBVIE-18S-128-2393888-00		26 YR	Male	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Drug Ineffective; Emotional Disorder; Flashback; Multiple Drug	Valproic Acid			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported

Therapy; Off Label Use	Abilify	S			Not Reported
	Abilify	S			Not Reported
	Risperidone	S	Unknown		Not Reported
	Risperidone	S			Not Reported
	Risperidone	S			Not Reported
	Escitalopram	S	Unknown		Not Reported
	Clonazepam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15043876	NON-EXPEDITED			US-009507513-1805USA013240			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Dizziness; Feeling Abnormal; Gait Disturbance; Headache; Malaise; Muscular Weakness	Janumet Xr			S	Oral	1 Df (Strenght: 100/1000 Mg), Once Daily		Merck
	Escitalopram			S				Not Reported
	Pravastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15043892	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1831230US		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corneal Oedema	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Mantadix			S	Oral	300 Mg, Qd		Not Reported
	Sinemet			S	Oral	2 Df, Every 4 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15043939	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1831839US		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Hypoglycaemia; Hyponatraemia;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Omeprazole			S	Oral	20 Mg, Qd		Not Reported

Inappropriate Schedule Of Product Administration	Ramipril Mylan	S	Oral	5 Mg, Qd		Not Reported
	Acide Alendronique	C	Oral	70 Mg, Time Interval: 1		Not Reported
	Icaz Lp	C	Oral	2.5 Mg, Qd		Not Reported
	Sodium Alginate Sodium Bicarbonate Mylan	C	Oral			Not Reported
	Ceris	C	Oral	40 Mg, Qd		Not Reported
	Calperos D3	C	Oral	500 Mg, Qd		Not Reported
	Lactulose Mylan	C	Oral	10g/15ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15044775	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1045351		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event; Therapy Non-Responder	Valproic Acid			S				Not Reported
	Levetiracetam			S				Not Reported
	Clonazepam			S				Not Reported
	Escitalopram			S				Not Reported
	Clobazam			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15044904	EXPEDITED (15-DAY)		DS	FI-TEVA-2018-FI-911813		37 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Aphasia; Cushingoid; Derealisation; Dizziness; Drug Withdrawal Syndrome; Dysarthria; Dysgraphia; Dyspnoea; Erythema; Face Oedema; Facial Pain; Headache; Hyperhidrosis; Insomnia; Mydriasis; Oedema; Polyuria; Pyrexia; Sympathomimetic Effect; Tremor; Vision Blurred	Escitalopram			S				Ivax
	Voxra			S	Oral	450,Mg,Daily		Not Reported
	Triptyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	13873251	EXPEDITED (15-DAY)		OT	FR-NODEN PHARMA DAC-NOD-2017-000089		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Aliskiren			S	Unknown	Unk		Noden Pharma
	Digoxin			S	Unknown	Unk		Not Reported
	Amiodarone			S	Unknown	Unk		Not Reported
	Domperidone			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14095395	EXPEDITED (15-DAY)		HO, LT, OT	PL-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-152373		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Insomnia; Loss Of Consciousness; Suicide Attempt; Tinnitus	Tramadol			S	Unknown	Unk		Sun
	Meloxicam			S	Unknown	Unk		Ranbaxy
	Perindopril			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Sun
	Clarithromycin			S	Unknown	Two Cycles Of Treatment Of 10 Days		Sun
	Sertraline			S	Unknown	50 Mg In The Morning		Sun
	Zolpidem			S	Unknown	10 Mg Before Bedtime		Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Doxepin			S	Unknown	25 Mg, Daily, In The Evening		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14415324	EXPEDITED (15-DAY)		OT	ES-009507513-1712ESP000156			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Simvastatin			S	Oral	1 Dosage Forms Daily; 40 Mg		Merck
	Simvastatin			S	Oral	20 Mg, Unk		Merck
	Enalapril Maleate (+) Hydrochlorothiazide			S	Unknown	1 Dosage Form Daily; 1 Df = 20/12.5 Mg		Merck
	Omeprazole			S	Unknown	Dosage Forms Daily; 20 Mg		Not Reported
	Amitriptyline Hydrochloride			S		12.5 Milligram Daily		Not Reported
	Amitriptyline Hydrochloride			S	Oral	25 Milligram Daily		Not Reported
	Amitriptyline Hydrochloride			S	Unknown	5 Mg, Qd		Not Reported
	Topiramate			S	Unknown	1 Dosage Forms Daily; 50 Mg		Not Reported
	Topiramate			S	Unknown	1 Df, Qd		Not Reported
	Diazepam			S	Unknown	0.5 Df, Qd		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Amlodipine			S	Unknown	1 Df, Qd		Not Reported
	Acetaminophen			S	Unknown	1 Df, Tid		Not Reported
	Naproxen			S	Unknown	1 Df, Bid		Not Reported
	Acetaminophen (+) Tramadol Hydrochloride			S	Unknown	1 Df, Tid		Not Reported
	Acetaminophen (+) Tramadol Hydrochloride			S	Unknown	3 Dosage Forms Daily; 1 Df = 37.5/325 Mg		Not Reported
	Glibenclamid			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
	Tepazepam			S	Unknown	Unk, Qd		Not Reported
	Lormetazepam			S	Unknown	1 Df, Qd		Not Reported
	Metoclopramide			C	Unknown	1 Week Treatment		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14702793	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-160286			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Escitalopram			S	Unknown	1 Dosage Forms Daily; 10 Mg		Not Reported
	Omeprazole			S	Unknown	1 Dosage Forms Daily; 20 Mg		Astrazeneca
	Paracetamol		Y	S	Unknown	1 Df, Tid		Ohm Lab
	Simvastatin			S	Unknown	20 Mg, Unk		Sun
	Simvastatin			S	Unknown	1 Dosage Forms Daily; 40 Mg		Sun
	Topiramate			S	Unknown	1 Dosage Forms Daily; 50 Mg		Sun
	Amitriptyline			S	Unknown	25 Milligram Daily;		Not Reported
	Amitriptyline			S	Unknown	12.5 Mg, Qd		Not Reported
	Amitriptyline			S	Unknown	Qd		Not Reported
	Amlodipine			S	Unknown	1 Df, Qd		Not Reported
	Diazepam			S	Unknown	.5 Dosage Forms Daily; 5 Mg		Not Reported
	Enalapril/Hydrochlorothiazide			S	Unknown	1 Dosage Forms Daily; 1 Df = 20/12.5 Mg		Not Reported
	Glibenclamida			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Lormetazepam			S	Unknown	1 Df, Qd		Not Reported
	Naproxen			S	Unknown	1 Df, Bid		Not Reported
	Topiramato			S	Unknown	0.5 Df, Qd		Not Reported
	Tramadol/ Paracetamol			S	Unknown	1 Df, Tid		Not Reported
	Tramadol W/Paracetamol			S	Unknown	3 Dosage Forms Daily; 1 Df = 37.5/325 Mg		Not Reported
	Tepazepam			S	Unknown	Qd ()		Not Reported

	Metoclopramide	C	Unknown	1 Week Treatment ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14936035	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1826976US		85 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Arrhythmia; Confabulation; Disorientation; Electrocardiogram Qt Prolonged	Escitalopram Oxalate Unk			S	Unknown	13 Ml, Single		Allergan
	Acetylsalicylic Acid			C	Oral	100 Mg, Unk		Not Reported
	Triatec (Ramipril)			C	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15048364	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00561		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock	Escitalopram			S	Unknown	Unk		Hetero
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15048414	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-911192		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S	Oral	15 Milligram Daily;		Ivax
	Plegridy 125 Microgrammes, Solution Injectable En Stylo Prérempli			S	Subcutaneous			Not Reported
	Atacand 16 Mg, Comprimé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15049421	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2018-US-910628		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Fall; Feeling Abnormal; Hallucination; Head Injury; Hip Arthroplasty; Humerus Fracture; Upper Limb Fracture	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Escitalopram			S				Ivax
	Hydrocodone Bitartrate And Acetaminophen			S		7.5 Mg/325 Mg		Not Reported
	Tramadol			S				Not Reported
	Carvedilol			C				Not Reported
	Benicar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15051645	EXPEDITED (15-DAY)		OT	US-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00246		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Olanzapine			S	Unknown			Jubilant
	Escitalopram			S	Unknown			Jubilant
	Lorazepam			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15053829	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1043520		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma; Menorrhagia; Sleep Disorder	Escitalopram			S	Unknown	In A Morning Target Dose Of 20 Mg		Not Reported
	Escitalopram			S	Unknown	Reduced To 15 Mg/Day		Not Reported
	Escitalopram			S	Unknown	Increased To A Dose Of 20 Mg Daily		Not Reported
	Risperidone			S	Unknown	0.5 Mg		Not Reported
	Risperidone			S				Not Reported
	Risperidone			S				Not Reported

	Aripiprazole	S	Unknown	5 Mg/Day	Not Reported
	Atorvastatin	C	Unknown		Mylan
	Promethazine	C	Unknown		Mylan
	Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect	Mylan
	Opipramol	C	Unknown	In Crisis Situations With Temporary Effect	Mylan
	Pregabalin	C	Unknown	Evening Dose Of 100 Mg	Mylan
	Pregabalin	C			Mylan
	Pregabalin	C			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15055172	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1831831US		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	14 Df, (In Total)		Allergan
	En			S	Oral	20 Ml, Unk (In Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15055187	EXPEDITED (15-DAY)		DS, OT	US-ALLERGAN-1831859US		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Seizure	Lexapro			S	Unknown			Allergan
	Brexpiprazole			S	Unknown	0.5 Mg, Unk		Not Reported
	Aripiprazole			S	Unknown	2.5 Mg, Unk		Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	14738818	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CZ055149			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dyskinesia; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal Hypermotility; Loss Of Consciousness; Muscle Spasms; Poisoning; Toxicity To Various Agents	Clonazepam			S	Oral			Novartis
	Escitalopram			S	Oral			Not Reported
	Metoclopramide			S	Oral			Not Reported
	Olanzapin			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Melperon			S	Oral			Not Reported
	Levomepromazine			S	Oral			Not Reported
	Ibuprofen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15057412	EXPEDITED (15-DAY)		HO, OT	DK-ACCORD-068490		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S				Not Reported
	Spironolactone			S				Accord
	Venlafaxine/Venlafaxine Hydrochloride			S				Not Reported
	Octreotide/Octreotide Acetate			S				Not Reported
	Victoza			S				Not Reported
	Mercaptopurine/Mercaptopurine Anhydrous			C				Not Reported
	Imodium			C				Not Reported
	Cholestagel			C				Not Reported
	Levetiracetam			C				Not Reported
	Lamotrigine			C				Not Reported
	Infliximab			C				Not Reported
	Adalimumab			C				Not Reported
	Natalizumab			C				Not Reported
	Vedolizumab			C				Not Reported
	Vancomycin			C				Not Reported
	Loperamide			C		2-8 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15057461	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-176432			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Mirtazapine			S	Oral			Sun
	Bisoprolol			S	Oral			Sun
	Modopar 125 (100 Mg/25 Mg), Gelule			S	Oral			Not Reported
	Risperdal 1 Mg, Comprime Pellicule Secable			S	Oral	Inconnue ()		Not Reported
	Seroplex 10 Mg, Comprime Pellicule Secable			S	Oral			Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15057462	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-176461			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Escitalopram			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported
	Fenofibrate			S	Oral			Sun
	Naproxene			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Levothyroxine Sodique			S	Oral			Not Reported
	Pregabaline			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15058615	EXPEDITED (15-DAY)		HO, OT	LU-MACLEODS PHARMACEUTICALS			Unknown	LUX

US LTD-
MAC2018014354

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Actin Antibody Positive; Gamma-Glutamyltransferase Increased; Hepatocellular Injury	Escitalopram Oxalate			S	Oral			Macleods
	Gilenya 0.5 Mg Capsule Novartis			S	Oral	1 Dosage Form, Qd		Not Reported
	Lyrica			C	Oral	100 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15058943	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018251665		21 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Sopor	Alprazolam			S	Oral	15 Ml, Single (Total)		Pfizer
	Zitromax			S	Oral	1500 Mg, Total		Pfizer
	Aripiprazole			S	Oral	210 Mg, Single (Total)		Not Reported
	Prozin /00011902/			S	Oral	1200 Mg, Single (Total)		Not Reported
	Escitalopram Oxalate			S	Oral	140 Mg, Single (Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15059513	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20180626500		80 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Fall	Xarelto			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Vitamin B Nos			C	Oral			Not Reported
	Benerva			C	Oral			Not Reported
	Calcimagon			C	Oral			Not Reported
	Concerta			C	Oral			Not Reported
	Concor			C	Oral			Not Reported

	Cordarone	C	Oral	Not Reported
	Euthyrox	C	Oral	Not Reported
	Magnesium	C	Oral	Not Reported
	Pantoprazole Sodium	C	Oral	Not Reported
	Candesartan Cilexetil	C	Oral	Not Reported
	Quetiapine Fumarate	C	Oral	Not Reported
	Seresta	C	Oral	Not Reported
	Targin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15060403	EXPEDITED (15-DAY)		HO	PH-ALLERGAN-1831865US		26 YR	Male	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Drug Therapy	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Qd		Allergan
	Abilify			S	Unknown	Unk		Not Reported
	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Risperidone			S	Unknown	Unk Unk, Unknown		Not Reported
	Risperidone			S				Not Reported
	Risperidone			S				Not Reported
	Valproic Acid			S	Unknown	500 Mg, Qd		Not Reported
	Clonazepam			C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15061555	EXPEDITED (15-DAY)		OT	TR-EYEVANCE PHARMACEUTICALS-2018EYE00002		34 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Sinus Bradycardia	Cetirizine Hydrochloride			S	Oral	10 Mg, 1x/Day		Eyevance Pharmaceuticals
	Escitalopram			S	Unknown	10 Mg, 1x/Day		Not Reported
	Ampicillin			C	Intravenous (not	2 G, 6x/Day		Not Reported

			otherwise specified)		
	Enoxaparin	C	60 Mg, 1x/Day		Not Reported
	Pantoprazole	C	40 Mg, 1x/Day		Not Reported
	Aspirin	C	100 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15062132	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1831835US		26 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Theralene			S	Oral	20 Mg, Qd		Not Reported
	Valium			S	Oral	40 Mg, Qd		Not Reported
	Lepticur			S	Oral	20 Mg, Qd		Not Reported
	Macrogol			S	Oral	1 Df, Qd		Not Reported
	Tercian			S	Oral	100 Mg, Qd		Not Reported
	Leponex			S	Oral	600 Mg, Qd		Not Reported
	Xeplion			S	Intramuscular	1 Df, Q Month		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	9759936	EXPEDITED (15-DAY)		DE, LT, OT	NO-FRI-1000052215		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Self-Injury; Medication Error	Citalopram Hydrobromide - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Sarotex			S	Unknown	Unk		Not Reported
	Truxal			S	Unknown	Unk		Not Reported
	Levomepromazine Maleate			S	Unknown			Not Reported
	Tramadol			S	Unknown	Unk		Not Reported
	Hydroxyzine Hydrochloride			S	Unknown			Not Reported
	Nobligan			S	Unknown	200 Mg, Unk		Not Reported

Catapresan	S	Unknown	50 Mg, Unk		Not Reported
Lamictal	S	Unknown	100 Mg, Unk		Not Reported
Diazepam	S	Unknown			Not Reported
Remeron	S	Unknown	Unk		Not Reported
Pinex Forte	S	Unknown	Unk		Not Reported
Seroquel	S	Unknown	Unk		Not Reported
Atarax	S	Unknown	Unk		Not Reported
Orfiril	S	Unknown	1200 Mg, Unk		Not Reported
Sobril	S	Unknown	Unk		Not Reported
Imovane	S	Oral	Unk		Not Reported
Nozinan	S	Unknown	Unk		Not Reported
Oxynorm	S	Unknown	10 Mg, Unk		Not Reported
Rivotril	S	Unknown	Unk		Not Reported
Vival	S	Unknown	Unk		Not Reported
Forte	C	Unknown	Unk		Not Reported
Diamorphine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	14617787	EXPEDITED (15-DAY)		HO	CZ-AUROBINDO-AUR-APL-2018-011934		45 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sertraline			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Not Reported
	Venlafaxin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	14968505	EXPEDITED (15-DAY)		DS	DE-ALLERGAN-1827590US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Gait	Escitalopram Oxalate - Bp			S	Oral	10 Mg, In The Morning For		Allergan

Disturbance; Hyperhidrosis; Hypoaesthesia; Insomnia; Malaise; Muscle Twitching; Muscle Twitching; Off Label Use; Palpitations; Paraesthesia; Tremor	Escitalopram Oxalate - Bp	S	Unknown	2 Days 20 Mg, Once In The Morning		Allergan
	Oxazepam Hexal	S	Oral	10 Mg, For Night For Three Days		Not Reported
	Monostep	C	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15002444	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1039008			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Therapy; Electrocardiogram Qt Prolonged	Hydroxyzine			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	20 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15065835	EXPEDITED (15-DAY)		HO, OT	PL-MACLEODS PHARMACEUTICALS US LTD-MAC2018014365			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Palpitations; Syncope	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Venlafaxine 150 Mg			S	Unknown	150 Milligram, Qd		Macleods
	Cyproheptadine			S	Oral	16 Milligram		Not Reported
	Ivabradine			S	Unknown	Unk		Not Reported
	Moklar			S	Unknown	150 Milligram, Qd		Not Reported
	Sertraline			S	Unknown	50 Milligram, Qd		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	Unk (10 Mg Before A Sleep)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15065836	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018014367			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 [Mg/D]/ Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D		Macleods
	Folic Acid, Potassium Iodide			C	Transplacental	0.4 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15065876	EXPEDITED (15-DAY)		OT	DE-TORRENT-00008678		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock	Venlafaxine Hydrochloride			S	Unknown	Unknown		Unknown
	Escitalopram			S	Unknown	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15066005	EXPEDITED (15-DAY)		DE, HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018009160			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Off Label Use; Poisoning Deliberate; Suicide Attempt; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram Tablet			S	Oral	Unk		Macleods
	Paracetamol			S	Oral	245, Tablet		Not Reported
	Baclofen			S	Oral	Unk		Not Reported
	Baclofen			S				Not Reported
	Dextropropoxyphene			S	Oral	Unk		Not Reported
	Valpromide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15067096	EXPEDITED (15-DAY)		DS, OT	US-GLAXOSMITHKLINE-US2018GSK110865		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Ill-Defined Disorder; Seizure; Therapeutic Product Effect Incomplete	Wellbutrin			S				Glaxosmithkline
	Cymbalta			S				Glaxosmithkline
	Rexulti			S		0.5 Mg, Unk		Not Reported
	Rexulti			S		Unk		Not Reported
	Aripiprazole			S		2.5 Mg, U		Not Reported
	Aripiprazole			S		Unk, U		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15067338	EXPEDITED (15-DAY)		OT	US-EPIC PHARMA LLC-2018EPC00308		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Gabapentin			S	Unknown			Epic Pharm
	Olanzapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15067415	EXPEDITED (15-DAY)		HO, OT	ZA-LUPIN PHARMACEUTICALS INC.-2018-04637		67 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Zartan (Losartan Potassium)			S	Oral	50 Mg, Unk		Lupin
	Fedaloc Sr			S	Oral	30 Mg, Unk		Not Reported

Xanor	S	Oral	0.5 Mg, Unk		Not Reported
Spiractin /00006201/	S	Oral	25 Mg, Unk		Not Reported
Lexamil	S	Oral	10 Mg, Unk		Not Reported
Foxair	S	Oral	50/250 Mcg, Unk (Inhalation)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15067703	EXPEDITED (15-DAY)		HO	CH-OTSUKA-2018_016636		45 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Anxiety; Condition Aggravated; Extrapyramidal Disorder; Fear; Impaired Driving Ability; Therapy Cessation; Tinnitus	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Cipralex			S	Unknown	Unk		Not Reported
	Olanzapine			C	Unknown	Unk		Not Reported
	Sequase			C	Unknown	Unk		Not Reported
	Sequase			C	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	14678334	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2018AU13032			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Fatigue; Insomnia; Loss Of Personal Independence In Daily Activities; Memory Impairment; Muscle Spasms; Pain	Escitalopram			S	Unknown	Unk		Invagen
	Diazepam			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Gilenya			S	Oral	Unk		Not Reported
	Vitamin D /00107901/			S	Unknown	Unk		Not Reported
	B Complex /00322001/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15028156	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-032411			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Esomeprazole	S	Oral	40 Milligram, Once A Day		Aurobindo
	Esidrex	S	Oral	0.5 Df, Qd		Not Reported
	Seroplex	S	Oral	1 Dosage Form, Once A Day		Not Reported
	Procoralan	C	Unknown	Unk		Not Reported
	Procoralan	C	Unknown	()		Not Reported
	Aspirine Protect	C	Unknown	Unknown		Not Reported
	Seresta	C	Unknown	Unknown		Not Reported
	Seresta	C	Unknown	Breackable ()		Not Reported
	Dafalgan	C	Unknown	Unknown		Not Reported
	Dafalgan	C	Unknown	()		Not Reported
	Pravastatine /00880401/	C	Unknown	Unknown		Not Reported
	Mediatensyl /00631801/	C	Unknown	Unknown		Not Reported
	Ramipril	C	Unknown	Unknown		Not Reported
	Ramipril	C	Unknown	()		Not Reported
	Acebutolol	C	Unknown	Unknown		Not Reported
	Acebutolol	C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15073217	EXPEDITED (15-DAY)		HO, LT	GR-REGULIS-2050022		67 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Clonus; Confusional State; Delayed Recovery From Anaesthesia; Disorientation; Drug Interaction; Fear; Hyperpyrexia; Hyperreflexia; Mental Status Changes; Muscle Rigidity; Mydriasis; Off Label Use; Psychomotor	Methylene Blue			S	Intravenous (not otherwise specified)			Regulis
	Escitalopram			S				Not Reported

Hyperactivity; Serotonin Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15073219	EXPEDITED (15-DAY)		CA	DE-AUROBINDO-AUR-APL-2018-032632		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 [Mg/D]/ Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D ()		Aurobindo
	Folio /06866801/			C	Transplacental	0.4 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15073612	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-TEVA-2018-GB-912201		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Metformin Hydrochloride			C	Unknown			Not Reported
	Generics Uk Nifedipine			C	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported
	Nefopam			C	Unknown			Not Reported
	Tiotropium			C	Unknown			Not Reported
	Sodium Picosulfate			C	Unknown			Not Reported
	Cetirizine			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Diazepam			C	Unknown			Not Reported
	Cassia (Senna Alexandrina)			C	Unknown			Not Reported
	Methotrexate Sodium			C	Unknown			Not Reported
	Budesonide And Formoterol Fumarate			C	Unknown			Not Reported

	Lansoprazole	C	Unknown	Not Reported
	Meptazinol	C	Unknown	Not Reported
	Quetiapine Fumarate	C	Unknown	Not Reported
	Temazepam	C	Unknown	Not Reported
	Montelukast	C	Unknown	Not Reported
	Pyridoxine	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Adcal-D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15073895	EXPEDITED (15-DAY)		HO	DE-DRREDDYS-GER/GER/18/0100730		44 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dyspepsia	Ibuprofen			S	Unknown	Nk		Not Reported
	Escitalopram			S		20 Mg, 1-0-0		Not Reported
	Neupro			S		14 Mg, 1-0-0-0		Not Reported
	Bornaprin			S		4 Mg, 1-0.5-1-0		Not Reported
	Madopar Depot			C		100|25 Mg, 0-0-0-1		Not Reported
	Amantadin			C		100 Mg, 1-1-0-0		Not Reported
	Amitriptylin			C		75 Mg, 0-0-0-1		Not Reported
	Madopar			C		100|25 Mg, 1.5-1.5-1.5-1.5		Not Reported
	Madopar Lt			C		100|25 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15073924	EXPEDITED (15-DAY)		HO	DE-HETERO-HET2018DE00584		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Paraesthesia; Prescribed Underdose	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported

	Aripiprazole	S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15074121	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018014373			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Impaired Gastric Emptying; Vomiting	Escitalopram			S	Oral	10 Milligram, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15074125	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018014380			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperleukocytosis; Pancreatitis; Renal Failure	Escitalopram Oxalate			S	Oral	140 Milligram		Macleods
	Paracetamol			S	Unknown	8.8 Gram		Not Reported
	Atarax			S	Oral	750 Milligram		Not Reported
	Coltramyl			S	Oral	48 Milligram		Not Reported
	Ibuprofen			S	Oral	6 Gram		Not Reported
	Alprazolam			C	Oral	5 Milligram		Not Reported
	Brexin			C	Oral	20 Milligram		Not Reported
	Cefuroxime			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15074234	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018255702		85 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Venlafaxine Hcl			S	Oral	1 Df, 1x/Day		Pfizer
	Olanzapine			S	Oral	Unk		Not Reported

	Delorazepam	S	Oral	Unk		Not Reported
	Cipralex /01588501/	S	Oral	Unk		Not Reported
	Donepezil	C				Not Reported
	Bisoprolol Fumarate	C		Unk		Not Reported
	Madopar	C		Unk		Not Reported
	Terazosin Hydrochloride	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15074452	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-032565		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperleukocytosis; Pancreatitis; Renal Failure	Escitalopram			S	Oral	140 Milligram		Aurobindo
	Ibuprofen			S	Oral	6 Gram		Aurobindo
	Paracetamol			S	Unknown	8.8 Gram		Aurobindo
	Atarax /00058401/			S	Oral	750 Milligram		Not Reported
	Coltramyl			S	Oral	48mg		Not Reported
	Alprazolam			C	Oral	5mg		Not Reported
	Brexin /00500404/			C	Oral	20mg		Not Reported
	Cefuroxime			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15075528	NON-EXPEDITED		HO, OT	US-SAOL THERAPEUTICS-2018SAO00690		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthralgia; Asterixis; Asthenia; Device Damage; Dizziness; Drug Withdrawal Syndrome; Headache; Lethargy; Loss Of Consciousness; Micturition Urgency; Mood Altered; Muscle Twitching;	Lioresal			S	Intrathecal	806.3 Mg, \Day		Saol Therapeutics
	Lioresal			S	Intrathecal	968.7 Mg, \Day		Saol Therapeutics
	Lioresal			S	Intrathecal	1017.7 Mg, \Day		Saol Therapeutics
	Lexapro			S	Oral			Not Reported
	Vimpat			S				Not Reported
	Carbamazepine			S				Not Reported

Pollakiuria; Seizure; Sleep Disorder; Somnolence; Tremor; Urinary Retention; Vision Blurred

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15076540	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018257495		47 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Henoch-Schonlein Purpura; Lymphoedema	Neurontin			S		600 Mg, Unk		Pfizer
	Zytomil			S		20 Mg, Unk		Not Reported
	Macrodantin			S		100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15076541	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018257325		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hypokinesia; Intentional Overdose; Intentional Self-Injury	Halcion			S	Oral	20 Df, Single		Pfizer
	Escitalopram			S	Oral	200 Mg, Single		Not Reported
	Depakin			S	Oral	3.5 G, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15076669	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018253888		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Encephalopathy	Xanax			S	Oral	0.38 Mg, 1x/Day		Pfizer
	Tazocilline			S	Intravenous (not otherwise specified)	3 Df, 1x/Day		Pfizer
	Amiodarone			S	Oral	200 Mg, 1x/Day		Not Reported
	Topalgic Lp			S	Oral	3 Df, 1x/Day		Not Reported
	Seroplex			S	Oral	1 Df, 1x/Day		Not Reported

Oxynormoro	S	Oral	5 Mg, Unk		Not Reported
Kardegic	S	Oral	1 Df, 1x/Day		Not Reported
Allopurinol	S	Oral	100 Mg, 1x/Day		Not Reported
Mycophenolate Sodium	C	Oral	360 Mg, 1x/Day		Not Reported
Ciclosporine	C	Oral	100 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15076963	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018257574		60 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Aspavor			S		20 Mg, Unk		Pfizer
	Methotrexate			S		2.5 Mg, Unk		Pfizer
	Salazopyrin			S		500 Mg, Unk		Pfizer
	Amloc /00550802/			S		10 Mg, Unk		Not Reported
	Co-Tareg			S		100/12.5 Mg, Unk		Not Reported
	Carloc			S		25 Mg, Unk		Not Reported
	Disprin			S		Unk		Not Reported
	Cardiocare			S		100 Mg, Unk		Not Reported
	Myoprin			S		100 Mg, Unk		Not Reported
	Ciplavasc			S		5 Mg, Unk		Not Reported
	Coxflam			S		7.5 Mg, Unk		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15201812	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Not Reported
	Cymbalta			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15027621	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1827407US		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Long Qt Syndrome; Malaise; Palpitations; Ventricular Extrasystoles	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15080690	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-913729		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Encephalopathy	Amiodarone			S	Oral	200 Milligram Daily;		Teva
	Allopurinol			S	Oral	100 Milligram Daily;		Actavis
	Seroplex 5 Mg, Coated Tablet			S	Oral	1 Dosage Forms Daily;		Not Reported
	Topalgic Lp 50 Mg, Extended Release Tablet			S	Oral	3 Dosage Forms Daily;		Not Reported
	Oxynormoro 5 Mg, Orodispersible Tablet			S	Oral			Not Reported
	Xanax 0.25 Mg, Scored Tablet			S	Oral	.38 Milligram Daily;		Not Reported
	Kardegic 75 Mg, Powder For Oral Solution In Sachet-Dose			S	Oral	1 Dosage Forms Daily;		Not Reported
	Tazocilline 4 G/500 Mg, Powder For Solution For Infusion			S	Intravenous (not otherwise specified)	3 Dosage Forms Daily;		Not Reported
	Mycophenolate Sodique			C	Oral	360 Milligram Daily;		Not Reported
	Ciclosporine			C	Oral	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15082074	NON-EXPEDITED			US-TEVA-2018-US-916310			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Exposure Via Breast Milk	Escitalopram			S	Unknown					Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15082196	NON-EXPEDITED			US-TEVA-2018-US-912975			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vitreous Floaters	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15082277	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-032575		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Impaired Gastric Emptying; Vomiting	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15083137	EXPEDITED (15-DAY)		HO	TR-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00249		71 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral	Escitalopram			S	Unknown	10 Mg, 1x/Day		Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15083994	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1045492			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Therapy; Electrocardiogram Qt Prolonged	Hydroxyzine			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	20 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15084109	EXPEDITED (15-DAY)		HO	TR-PRINSTON PHARMACEUTICAL INC.-2018PRN00329		71 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral	Escitalopram			S	Unknown	10 Mg, 1x/Day		Prinston Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15085104	EXPEDITED (15-DAY)		HO	PHHY2018DE019842			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Respiratory Tract Infection	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	15 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported
	Risperidone			S	Unknown	0.5 Mg, Unk (For 10 Days)		Novartis
	Aripiprazole			S	Unknown	5 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	100 Mg, Unk (Evening Dose)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	12456545	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2016CA078068		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Electrocardiogram T Wave Peaked; Fall; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis	Metformin			S	Unknown	1 G, Bid		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Novartis
	Escitalopram			S	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported
	Gliclazide			C	Unknown	Unk		Not Reported
	L-Thyroxine			C	Unknown	Unk		Not Reported
	Telmisartan			C	Unknown	Unk		Not Reported

	Insulin	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	14320362	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2017511493			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine Besilate			S		1 Dosage Form (Df, 5mg), Once Daily		Pfizer
	Paracetamol			S		1 Df, 1x/Day		Not Reported
	Simvastatin			S		1 Df (40 Mg), 1x/Day		Not Reported
	Simvastatin			S		20 Mg, Unk		Not Reported
	Topiramate			S		0.5 Df, 1x/Day		Not Reported
	Topiramate			S		50 Mg, 1x/Day (1 Df)		Not Reported
	Paracetamol W/Tramadol			S		1 Df, Thrice Daily (3 Dosage Forms Daily, 1 Df =37.5/325 Mg)		Not Reported
	Naproxen			S		1 Df, 1x/Day (1 Df, Bid)		Not Reported
	Amitriptyline			S		5 Mg, 1x/Day		Not Reported
	Amitriptyline			S		12.5 Mg, 1x/Day		Not Reported
	Amitriptyline			S		25 Mg, Daily		Not Reported
	Enalapril, Hydrochlorothiazide			S		1 Df, Once Daily (1df = 20/12.5 Mg)		Not Reported
	Topiramato			S		0.5 Df, Once Daily		Not Reported
	Topiramato			S		1 Df (50mg), 1x/Day		Not Reported
	Diazepam			S		5 Mg, Once Daily (0.5 Df)		Not Reported
	Diazepam			S		Unk		Not Reported
	Glibenclamida			S		2 Df, 1x/Day		Not Reported
	Escitalopram			S		1 Df (10mg), 1x/Day		Not Reported
	Omeprazole			S		1 Df (20 Mg), 1x/Day		Not Reported
	Lormetazepam			S		1 Df, Once Daily (1 Mg)		Not Reported

	Tepazepam	S		1 Df, 1x/Day	Not Reported
	Glibenclamide	S		2 Df, 1x/Day	Not Reported
	Diazepam/Sulpiride	S		1 With Unknown Unit, Daily	Not Reported
	Amlodipine	S	Unknown	1 Df, 1x/Day	Not Reported
	Paracetamol + Tramadol	S		3 Df, 1x/Day (Df0 37.5/325 Mg)	Not Reported
	Paracetamol + Tramadol	S		Unk	Not Reported
	Metoclopramide	C		Unk (1 Week Treatment)	Not Reported
	Metoclopramide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15006971	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-904387		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Fibromyalgia; Peritonitis	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15073044	NON-EXPEDITED			US-TEVA-2018-US-914112			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Therapy Change; Tremor	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15087599	EXPEDITED (15-DAY)		DE, HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018014481			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage Intracranial	Escitalopram Oxalate			S	Oral	10 Milligram, Qd		Macleods
	Duoplavin			S	Oral	75 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15090805	NON-EXPEDITED			US-TEVA-2018-US-912988			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Dose Omission	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15092959	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-915286		28 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyskinesia; Juvenile Myoclonic Epilepsy; Myoclonus; Schizophreniform Disorder	Zopiclone			S	Unknown			Not Reported
	Zopiclone			S				Not Reported
	Fluoxetine			S	Unknown			Barr
	Fluoxetine			S				Barr
	Fluoxetine			S				Barr
	Aripiprazole			S	Unknown	Only Prescribed For Short Time		Teva
	Aripiprazole			S				Teva
	Olanzapine			S	Unknown	Only Prescribed For Short Time		Teva
	Olanzapine			S				Teva
	Quetiapine			S	Unknown	Only Prescribed For Short Time		Teva
	Quetiapine			S				Teva
	Duloxetine			S	Unknown	Only Prescribed For Short Time		Teva
	Duloxetine			S				Teva
	Clozapine			S	Unknown	75 Mg		Ivax
	Clozapine			S				Ivax
	Escitalopram			S	Unknown	20 Mg		Ivax
	Escitalopram			S				Ivax
	Bupropion			S	Unknown			Teva
	Bupropion			S				Teva

Mirtazapine	S	Unknown			Teva
Mirtazapine	S				Teva
Venlafaxine	S	Unknown			Teva
Venlafaxine	S				Teva
Amisulpride	S	Unknown			Not Reported
Amisulpride	S				Not Reported
Risperidone	S	Unknown			Pliva
Risperidone	S				Pliva
Promethazine	S	Unknown	Only Prescribed For Short Time		Not Reported
Promethazine	S				Not Reported
Biperiden	S	Unknown			Not Reported
Biperiden	S				Not Reported
Oxazepam	C	Unknown	At Different Doses		Not Reported
Oxcarbazepine	C	Unknown	Up To 2400mg; Received Over One Year		Not Reported
Brivaracetam	C	Unknown	200-250mg; Received Over One Year		Not Reported
Carbamazepine	C	Unknown	Up To 900 Mg		Not Reported
Zonisamide	C	Unknown	Up To 100mg		Not Reported
Clobazam	C	Unknown	Up To 20mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15208691	DIRECT		OT			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cold Sweat; Nightmare; Poor Quality Sleep; Rapid Eye Movements Sleep Abnormal	Escitalopram Tablets			S	Oral	Quantity:1 Tablet(S);	90 DAY	Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2018	15094292	EXPEDITED (15-DAY)		DE, HO	FR-AUROBINDO-AUR-APL-2018-032854		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage Intracranial	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo
	Duoplavin			S	Oral	75 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2018	15049241	EXPEDITED (15-DAY)		OT	US-TORRENT-00006261		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Disturbance In Attention; Fatigue; Lethargy; Mental Impairment; Product Substitution Issue; Wrong Technique In Product Usage Process	Escitalopram			S		Half A Pill Two Times A Day		Unknown
	Armour Thyroid			S		Unknown		Unknown
	Escitalopram			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2018	15094833	NON-EXPEDITED			US-AMGEN-USASP2018086560			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Morphine			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Nucynta			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	14777871	NON-EXPEDITED			US-PFIZER INC-2018161286		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Abnormal; Drug	Azithromycin			S		Unk		Pfizer
	Lexapro			S		20 Mg, 1x/Day		Not Reported

Interaction; Heart Rate Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15095115	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-917495		52 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Loss Of Consciousness; Malaise	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Carbolithium 300 Mg Capsule Rigide			S	Oral	900 Milligram Daily;		Not Reported
	Frontal 1 Mg Compresse			S	Oral	2 Milligram Daily;		Not Reported
	Depakin			S	Oral	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15095849	EXPEDITED (15-DAY)		HO	FR-ZYDUS-020027		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Extrapyramidal Disorder; Mydriasis; Sinus Tachycardia	Risperidone			S	Oral	In Total		Zydus Pharm
	Escitalopram			S	Oral	In Total		Not Reported
	Theralene			C	Oral	Unspecified Dosage		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15096105	EXPEDITED (15-DAY)		OT	SE-MACLEODS PHARMACEUTICALS US LTD-MAC2018014524			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis; Erythema	Escitalopram Oxalate 5mg Tablet			S	Oral	5 Milligram, Qd		Macleods
	Aclasta			C	Unknown	Unk		Not Reported
	Kalcipos-D			C	Unknown	Unk		Not Reported
	Zopiklon			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15097191	EXPEDITED (15-DAY)		HO, OT	ZA-PFIZER INC-2018261366		56 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cadasil; Cerebrovascular Accident; Dysphagia; Hemiplegia; Mutism	Aspavor			S		Unk		Pfizer
	Epanutin			S		Unk		Pfizer
	Pearinda			S		Unk		Not Reported
	Zytomil			S		Unk		Not Reported
	Epilim			S		Unk		Not Reported
	Plagrol			S		Unk		Not Reported
	Glucophage Xr			S		Unk		Not Reported
	Puricos			S				Not Reported
	Uromax /00538902/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15098250	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1832875US		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Qd		Allergan
	Folio			C	Transplacental	0.4 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15099059	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018265045		79 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Accumax			S		Unk		Pfizer
	Euthyrox			S		Unk		Not Reported
	Carloc			S		Unk		Not Reported

	Lexamil	S	Unk		Not Reported
	Amiloretic /00206601/	S	Unk		Not Reported
	Rivotril	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	14720369	EXPEDITED (15-DAY)		HO	ES-ALLERGAN-1816988US		38 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome; Drug Interaction	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Dexamethasone			S	Oral	0.25 Mg, Qd		Not Reported
	Hidroaltesona			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	14839201	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1823790US		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Delirium; Drug Ineffective; Haematoma; Insomnia; Menorrhagia; Off Label Use; Respiratory Tract Infection; Thinking Abnormal	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Pregabalin			S	Oral	100 Mg, Qpm		Not Reported
	Risperidon			S	Oral	Unk, Unknown		Not Reported
	Risperidon			S	Oral	Unk		Not Reported
	Aripiprazole			S	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15060600	NON-EXPEDITED			US-PFIZER INC-2018256690		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown

Lexapro	S	Unk		Not Reported
Nucynta	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15104238	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-919514		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Ivax
	Paroxetina Ratiopharm 20 Mg Compresse Rivestite Con Film			S	Oral			Teva
	Minias 2,5 Mg/Ml Gocce Orali, Soluzione			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	13546885	EXPEDITED (15-DAY)		HO	IT-TEVA-764815ACC		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram			S	Oral			Ivax
	Xanax - 0,25 Mg Compresse - Pharmacy Value S.R.L			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	14754324	EXPEDITED (15-DAY)		HO	IT-TEVA-768699ACC		19 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Abnormal; Intentional Overdose; Intentional Overdose; Intentional Self-Injury; Nausea; Tremor	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	15105170	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-		46 YR	Female	FRA

2018R1-177135

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperleukocytosis; Pancreatitis; Renal Failure	Escitalopram			S	Oral	Unk		Not Reported
	Ibuprofene		Y	S	Oral	Unk		Ranbaxy
	Atarax			S	Oral	Unk		Not Reported
	Coltramyl			S	Oral	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Alprazolam			C	Oral	Unk		Not Reported
	Cefuroxime			C	Oral	Unk		Not Reported
	Brexin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	15105526	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-919441		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate			S	Oral	10 Milligram Daily;		Not Reported
	Indapamide			S	Oral	2.5 Milligram Daily;		Actavis
	Lactulose			C				Not Reported
	Perindopril			C				Not Reported
	Enoxaparin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	15105910	EXPEDITED (15-DAY)		OT	FR-ZYDUS-018686		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Interaction; Formication; Hyperkalaemia; Myalgia;	Escitalopram			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Pravastatin			C	Unknown			Not Reported

Testicular Pain	Pregabalin		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	13134800	EXPEDITED (15-DAY)		DS, HO, OT	US-JAZZ-JPI-P-008801			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Exposure During Pregnancy; Fatigue; Feeling Abnormal; Hallucination; Intervertebral Disc Protrusion; Mental Disorder; Mood Swings; Morning Sickness; Nausea; Personality Disorder; Somnolence	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S				Not Reported
	Citalopram Hydrobromide			S				Not Reported
	Escitalopram Oxalate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	14869141	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2018-024552		34 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Learning Disorder; Mental Impairment	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Brintellix			S	Unknown	10 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15043885	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1831187US		26 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Zopitan			C	Oral	3.75 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15082189	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-033048		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Feeling Abnormal; Panic Attack	Escitalopram Film-Coated Tablets			S	Unknown	15 Milligram, Once A Day		Aurobindo
	Escitalopram Film-Coated Tablets			S				Aurobindo
	Cipralex /01588501/			S	Unknown	Unk		Not Reported
	Cipralex /01588501/			S	Unknown	15 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15109252	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-919804		14 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Overdose; Poisoning Deliberate; Sopor	Escitalopram			S	Oral	10 Df Units In Total		Ivax
	Xanax			S	Oral	12 Df Units In Total		Not Reported
	Haldol /00027401/			S	Oral	15 Ml In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15109357	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018014634			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram Tablet			S	Oral	280 Milligram, Drug Abuse		Macleods
	Delorazepam Gtt			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15109850	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-033975		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Somnolence; Toxicity To Various Agents	Alprazolam		S	Oral	(1)In Total	Aurobindo
	Seroplex		S	Oral	(1)In Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15110124	EXPEDITED (15-DAY)		HO, OT	ZA-DRREDDYS-SAF/SAF/18/0101743			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hip Arthroplasty; Post Procedural Complication	Dopaquel			S	Oral			Not Reported
	Sereflo			S	Oral			Not Reported
	Alchera			S	Oral			Not Reported
	Mylan Alprazolam			S	Oral			Mylan
	Lexamil			S	Oral			Not Reported
	Amiloretic			S	Oral			Not Reported
	Nexiam			S	Oral			Not Reported
	Avamys			S	Oral			Not Reported
	Dormonoct			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15110310	EXPEDITED (15-DAY)		HO	ZA-LUPIN HEALTHCARE (UK) LIMITED-2018-04727		47 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Henoch-Schonlein Purpura; Lymphoedema; Product Use In Unapproved Indication	Zytomil Tablets			S	Oral	20 Mg, Unk		Lupin
	Neurontin			S	Oral	600 Mg, Unk		Not Reported
	Macrodantin			S	Oral	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15110991	EXPEDITED (15-DAY)		HO	IE-IMPAX LABORATORIES, INC-2018-IPXL-02283		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Lamotrigine Odt		S	Unknown	Unk	Impax
	Lamotrigine Odt		S	Unknown	Unk, Evening Dose Held	Impax
	Escitalopram		S	Unknown	5 Mg, 1 /Day	Not Reported
	Escitalopram		S	Unknown	10 Mg, 1 /Day	Not Reported
	Clobazam		C	Unknown	10 Mg, Bid	Not Reported
	Clobazam		C	Unknown	10 Mg, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15111018	NON-EXPEDITED			US-SA-2018SA168629			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Fatigue; Miliaria; Oropharyngeal Pain; Paraesthesia	Praluent			S		Unk		Sanofi
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15111384	EXPEDITED (15-DAY)		OT	IT-BAUSCH-BL-2017-033083		60 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Major Depression; Sexual Dysfunction; Weight Increased	Lorazepam			S	Unknown	At Bed Time		Not Reported
	Duloxetine			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Ramipril/Idroclorotiazide			C				Not Reported
	Warfarin			C				Not Reported
	Ezetimibe			C				Not Reported
	Lansoprazole			C				Not Reported
	Simvastatin			C				Not Reported
	Amiodarone			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15111796	EXPEDITED (15-DAY)		HO	IT-BAUSCH-BL-2018-018066		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam			S	Oral	In Total		Not Reported
	Tachipirina			S	Oral	In Total		Not Reported
	Cipralex			S	Oral	In Total		Not Reported
	Tolep			S	Oral	In Total		Not Reported
	Brintellix			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15112925	EXPEDITED (15-DAY)		OT	PHEH2018US026950			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cancer; Drug Interaction; Musculoskeletal Chest Pain; Nausea; Second Primary Malignancy	Votrient			S	Oral	4 Df, Qd		Novartis
	Lexapro			S	Unknown			Not Reported
	Glipizide			C	Unknown			Not Reported
	Hydrocodone/Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	14444737	EXPEDITED (15-DAY)		HO	DE-TORRENT-00007662		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Level Decreased; Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	Overdose: 30 Mg		Unknown
	Lorazepam			C	Unknown	0.5 Mg, Unk		Unknown
	Olanzapine			C	Unknown	10 Mg, Qd		Unknown
	Pangrol			C	Unknown	2 In 1 Day, Dose 1, 2 Ot, Qd		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	14585022	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00010176		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis Cholestatic; Intentional Product Use Issue; Off Label Use	Prednisolone		S	Oral	Concordia
	Seroplex		S	Unknown	Not Reported
	Avastin		S	Intravenous (not otherwise specified)	Not Reported
	Belustine		S	Oral	Not Reported
	Silodyx		C		Not Reported
	Xanax		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	14948754	EXPEDITED (15-DAY)		DE	JP-PFIZER INC-2018216975			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Effexor			S	Oral	Unk		Pfizer
	Lexapro			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15074064	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-915283		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma; Menorrhagia; Sleep Disorder	Escitalopram			S	Unknown	20 Milligram Daily; In A Morning Target Dose Of 20 Mg		Ivax
	Escitalopram			S	Unknown	15 Milligram Daily; Reduced To 15 Mg/Day		Ivax
	Escitalopram			S	Unknown	20 Milligram Daily; Increased To A Dose Of 20 Mg Daily		Ivax
	Risperidone			S	Unknown	0.5 Mg		Pliva
	Risperidone			S				Pliva
	Aripiprazole			S	Unknown	5 Milligram Daily;		Teva
	Atorvastatin			C	Unknown			Not Reported
	Promethazine			C	Unknown			Not Reported

	Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
	Opipramol	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
	Pregabalin	C	Unknown	100 Milligram Daily; Evening Dose Of 100 Mg	Not Reported
	Pregabalin	C			Not Reported
	Pregabalin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15113721	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-920994		21 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Aripiprazole			S	Oral			Teva
	Alprazolam			S	Oral			Actavis
	Escitalopram Oxalate			S	Oral			Ivax
	Zitromax 500 Mg Compresse Rivestite Con Film			S	Oral			Not Reported
	Prozin 25 Mg Compresse Rivestite			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15114472	EXPEDITED (15-DAY)		DE	ZA-CIPLA LTD.-2018ZA19814			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram			S	Unknown	5 Mg, Unk		Invagen
	Aspavor			S	Unknown	20 Mg, Unk		Not Reported
	Zanidip			S	Unknown	10 Mg, Unk		Not Reported
	Lasix /00032601/			S	Unknown	20 Mg, Unk		Not Reported
	Spiractin /00006201/			S	Unknown	25 Mg, Unk		Not Reported
	Ganfort			S	Unknown	5 Mg, Unk		Not Reported
	Ecotrin			S	Unknown	81 Mg, Unk		Not Reported

	Glucophage	S	Unknown	500 Mg, Unk		Not Reported
	Stilpane /01152401/	S	Unknown	Unk		Not Reported
	Bilocor	S	Unknown	5 Mg, Unk		Not Reported
	Epleptin	S	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15115274	NON-EXPEDITED			US-ALLERGAN-1831294US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Vraylar			S	Unknown	Unk		Allergan
	Viibryd			S	Unknown	Unk		Allergan
	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15115907	EXPEDITED (15-DAY)		HO, OT	IE-GLAXOSMITHKLINE-IE2018119739		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Lamotrigine			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	5 Mg, Qd		Glaxosmithkline
	Escitalopram			S	Unknown	10 Mg, Qd		Glaxosmithkline
	Clobazam			C		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15115976	NON-EXPEDITED			US-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-919		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching; Tremor	Maximum Strength Mucinex Dm Tablets			S	Unknown	1200 Mg, Bid, Took About 4-5 Doses Of Product		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15116482	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-922283		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Escitalopram			S	Oral			Not Reported
	Naproxene			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Irbesartan			S	Oral			Teva
	Fenofibrate			S	Oral			Not Reported
	Pregabaline			S	Oral			Not Reported
	Levothyroxine Sodique			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15116495	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-922287		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Vertigo	Escitalopram			S	Oral	5 Milligram Daily;		Ivax
	Aldactazine, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15116838	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-922238		16 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypotension; Loss Of Consciousness	Escitalopram Arrow 20 Mg, Comprimé Pelliculé Sécable			S	Oral	20 Milligram Daily;		Ivax
	Tercian 40 Mg/Ml, Solution Buvable En Gouttes			S	Oral	25 Gtt Daily;		Not Reported

	Alprazolam Mylan 0,50 Mg, Comprimé Sécable	S	Oral	1.5 Milligram Daily;		Mylan
	Diane 35 Microgrammes, Comprimé Enrobé	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15116848	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180222203		13 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute; Somnolence	Tramadol Biogaran			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Stresam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15116938	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180637447		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Risperidone			S	Oral	In The Morning And Evening		Not Reported
	Loxapine Succinate			S	Oral	5 Drops As Required		Not Reported
	Escitalopram Arrow			S	Oral	In The Evening		Not Reported
	Olanzapine Mylan			S	Oral	In The Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15116939	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-922239		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Mirtazapine			S	Oral			Teva
	Bisoprolol (Fumarate Acide De)			S	Oral			Teva

	Modopar (Benserazide Hydrochloride, Levodopa)	S	Oral	Not Reported
	Risperdal 1 Mg, Comprimé Pelliculé Sécable	S	Oral	Not Reported
	Seroplex 10 Mg, Comprimé Pelliculé Sécable	S	Oral	Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15117421	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1834021US		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Impaired Gastric Emptying; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15117568	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1834025US		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperleukocytosis; Intentional Overdose; Pancreatitis; Renal Failure	Escitalopram Oxalate - Bp			S	Oral	Overdose: 140mg		Allergan
	Atarax			S	Oral	750 Mg, Unk		Not Reported
	Ibuprofene			S	Oral	6 G, Unk		Not Reported
	Coltramyl			S	Oral	48 Mg, Unk		Not Reported
	Paracetamol			S	Unknown	8.8 G, Unk		Not Reported
	Alprazolam			C	Oral	5 Mg, Unk		Not Reported
	Cefuroxime			C	Oral	Unk		Not Reported
	Brexin			C	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	12981326	EXPEDITED (15-DAY)		HO, OT	PHHY2016FR155274		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose; Nystagmus; Overdose; Suicide Attempt; Toxicity To Various Agents	Bromazepam			S	Unknown	180 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	840 Mg, Unk		Not Reported
	Venlafaxine			S	Unknown	7875 Mg, Unk		Novartis
	Lormetazepam			S	Unknown	14 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	14573366	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-SA-2017SA116590		62 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Zolpidem Tartrate			S	Oral	10 Mg,Hs		Sanofi
	Sertraline			S	Unknown	50 Mg,Hs		Not Reported
	Metoprolol Tartrate			S	Unknown	Unk Unk,Unk		Not Reported
	Venlafaxine Hydrochloride			S	Oral	150 Mg,Qd		Not Reported
	Moclobemide			S	Unknown	150 Mg,Hs		Not Reported
	Trazodone			S				Not Reported
	Escitalopram			S				Not Reported
	Warfarin			C				Not Reported
	Ginkgo Biloba Extract			C				Not Reported
	Sotalol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	14976711	EXPEDITED (15-DAY)			FI-ALLERGAN-1829278US		37 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Voxra			S	Oral	450 Mg, Qd		Not Reported
	Triptyl			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15027889	EXPEDITED (15-DAY)		OT	GB-TORRENT-00016655		53 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Suicidal Ideation	Escitalopram 10 Mg Film-Coated Tablets			S				Unknown
	Gaviscon			C		Unknown		Unknown
	Lansoprazole			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15118767	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-921548		85 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Olanzapine			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Delorazepam			S	Oral			Not Reported
	Venlafaxine			S	Oral	1 Dosage Forms Daily;		Teva
	Donepezil			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Madopar			C	Unknown			Not Reported
	Terazosin Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15118899	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-922496		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Hypoglycaemia; Hyponatraemia	Escitalopram			S	Oral	5 Milligram Daily;		Ivax
	Omeprazole Mylan 20 Mg, Gélule Gastro-Résistante			S	Oral	20 Milligram Daily;		Not Reported
	Ramipril Mylan 5 Mg, Comprimé Sécable			S	Oral	5 Milligram Daily;		Not Reported

	Acide Alendronique	C	Oral	1 S	Not Reported
	Icaz Lp 2,5 Mg, Gélule À Libération Prolongée	C	Oral	2.5 Milligram Daily;	Not Reported
	Sodium Alginate Sodium Bicarbonate Mylan	C	Oral	4 Dosage Forms Daily;	Not Reported
	Ceris 20 Mg, Comprimé Enrobé	C	Oral	40 Milligram Daily;	Not Reported
	Calperos D3, Comprimé À Sucer	C	Oral	500 Milligram Daily;	Not Reported
	Lactulose Mylan 10 G/15 Ml, Solution Buvable En Sachet	C	Oral	10 Gram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15119179	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-033189		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Escitalopram Arrow			S	Oral	10 Milligram, Daily		Aurobindo
	Risperidone			S	Oral	1 Milligram, Daily		Aurobindo
	Loxapine Succinate			S	Oral	5 Gtt, As Necessary		Not Reported
	Olanzapine Mylan			S	Oral	5 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15119638	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018014658			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Medication Error	Escitalopram			S	Oral	35 Drop, Single, Total		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15121251	EXPEDITED (15-DAY)		HO, OT	ZA-PFIZER INC-2018271818		74 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Thrombosis	Celebrex			S		200 Mg, Unk		Pfizer

	Disprin Cardiocare	S	100 Mg, Unk	Not Reported
	Adco-Zolpidem	S	10 Mg, Unk	Not Reported
	Biotech Trazodone	S	50 Mg, Unk	Not Reported
	Cipla-Simvastatin	S		Not Reported
	Citraz	S	10 Mg, Unk	Not Reported
	Ziabeta	S	2.5/6.25mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15121860	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1834013US		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Fatigue; Fear; Feeding Disorder; Hallucination; Hospitalisation; Off Label Use; Pain; Panic Attack; Post-Traumatic Stress Disorder; Suicidal Ideation; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Lysanxia			S	Unknown	10 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15122091	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1834012US		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Diarrhoea	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Meteospasmyl [Alverine Citrate;Dl-Methionine			C	Unknown			Not Reported
	Copper Iud			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15122825	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1833645US		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage Intracranial	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Duoplavin			S	Oral	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15122884	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1048184		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction	Enalapril			S	Oral	2 Df, Qd		Not Reported
	Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Lantus			S	Subcutaneous	30 Iu, Qd		Mylan
	Seguril			S	Oral	1 Df, Qd		Mylan
	Carvedilol			S	Oral	1 Df, Qd		Mylan
	Orvatez			S	Oral	1 Df, Qd		Mylan
	Toujeo			C	Subcutaneous	32 Iu, Qd		Mylan
	Lyxumia			C	Subcutaneous	Dose:20 Unit(S)		Mylan
	Novorapid			C	Subcutaneous			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15123055	EXPEDITED (15-DAY)		HO	PHHY2018DE036797		65 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Dizziness; Dyspnoea; Haematochezia; Pain	Acetylsalicylic Acid			S	Unknown	100 Mg, Qd (1-0-0-0)		Not Reported
	Cipralex			S	Unknown	10 Mg, Qd (1-0-0-0)		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd (0-1-0-0)		Not Reported
	Ramipril			C	Unknown	2.5 Mg, Qd (0-1-0-0)		Not Reported

Spiriva	C	Unknown	18 Ug, Qd (1-0-0-0)		Not Reported
Pantoprazol	C	Unknown	40 Mg, Qd (0-0-1-0)		Not Reported
Euthyrox	C	Unknown	50 Ug, Qd (1-0-0-0)		Not Reported
Allopurinol	C	Unknown	5 Df, Qd (0-0-5-0)		Not Reported
Metamizol	C	Unknown	15 Gtt, Tid (1-1-1-0)		Not Reported
Metoprolol	C	Unknown	47.5 Mg, Bid (1-0-1-0)		Not Reported
Alna	C	Unknown	4 Mg, Qd (0-0-1-0)		Not Reported
Torasemid	C	Unknown	10 Mg, Qd (1-0-0-0)		Not Reported
Tramal Long	C	Unknown	Unk Mg, Unk (Bedarf)		Not Reported
Symbicort	C	Unknown	Unk Ug, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15123460	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018014655			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disinhibition; Suicidal Ideation	Escitalopram Oxalate			S	Oral	20 Milligram, Qd		Macleods
	Zopiclone			S	Oral	7.5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	13333566	EXPEDITED (15-DAY)		HO	IT-TEVA-749190ACC		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Lorazepam			S	Oral	1 Mg, Total		Actavis
	Entact			S	Oral			Not Reported
	Clozapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	14357041	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1000859		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Level Decreased; Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	30 Mg, Qd		Not Reported
	Escitalopram			S	Oral	40 Mg, Qd		Not Reported
	Lorazepam			C		0.5 Mg, Unk		Mylan
	Pangrol			C		Unk, Qd		Mylan
	Olanzapine			C		10 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15107424	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1833492US		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Esidrex			S	Oral	0.5 Df, Qd		Not Reported
	Esomeprazole			S	Oral	40 Mg, Qd		Not Reported
	Ramipril			C	Unknown			Not Reported
	Dafalgan			C	Unknown	Unk G, Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Acebutolol			C	Unknown	Unk		Not Reported
	Seresta			C	Unknown	Unk		Not Reported
	Mediatensyl			C	Unknown	Unk		Not Reported
	Procoralan			C	Unknown	Unk		Not Reported
	Pravastatine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15122077	EXPEDITED (15-DAY)		OT	IL-ALLERGAN-1834004US		65 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan

Product Use In Unapproved Indication	Escitalopram Oxalate - Bp	S	Unknown	10 Mg, Unk	Allergan
	Levetiracetam	C	Unknown	1000 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Omeprazole	C	Unknown	20 Mg, Qd	Not Reported
	Alprazolam	C	Unknown	0.5 Mg, Qd	Not Reported
	Zopiclone	C	Unknown	7.5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15123890	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-922565		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Somnolence	Bisoprolol			S	Oral	1 Dosage Forms Daily;		Teva
	Escitalopram Arrow 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Arrow
	Pravastatine Biogaran 20 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Biogaran
	Zolpidem Sandoz 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Sandoz
	Rilmenidine Sandoz 1 Mg,Compressed			S	Oral	2 Dosage Forms Daily;		Sandoz
	Paracetamol			C	Unknown			Not Reported
	Aerius (Desloratadine)			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15124468	EXPEDITED (15-DAY)		HO	DE-DRREDDYS-GER/GER/18/0101650		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Gait Disturbance; Hallucination; Somnolence	Quetiapine			S	Oral	100 Mg, 0-0-0-1, Tabletten		Not Reported
	Valproinsaeure			S	Oral	500 Mg, 0-0-0-1, Tabletten		Not Reported
	Cipralex 10mg			S	Oral	10 Mg, 1-0-0-0, Tabletten		Not Reported
	Levothyroxine Sodium			C	Oral	75 Ug, 1-0-0-0, Tabletten		Not Reported

	Torasemid	C	Oral	10 Mg, 1-0-0-0, Tabletten	Not Reported
	Felodipine	C		10 Mg, 1-0-0-0, Tabletten	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15124508	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MACLEODS PHARMACEUTICALS US LTD-MAC2018014671			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Venlafaxine 150 Mg			S	Oral	150 Milligram, Qd, In The Morning, In The Afternoon		Macleods
	Metoprolol			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Sertraline			S	Oral	50 Milligram, Qd, At Night		Not Reported
	Zolpidem			S	Oral	10 Milligram, Qd, At Bedtime		Not Reported
	Moclobemide			S	Oral	150 Milligram, Qd, In Afternoon		Not Reported
	Warfarin			C	Unknown	Unk		Not Reported
	Ginkgo Biloba Extract			C	Unknown	Unk		Not Reported
	Sotalol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15124525	EXPEDITED (15-DAY)		OT	HK-ACCORD-069588		43 YR	Male	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Somnolence	Escitalopram			S		5 Mg Nocte In First Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15125412	EXPEDITED (15-DAY)		DS	AU-ALLERGAN-			Female	AUS

1834022US

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15125436	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1048076		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Escitalopram			S	Oral	3 Df, Total		Not Reported
	Ethanol			S	Unknown	Dosage Form: Unspecified		Mylan
	Lyrica			S	Oral			Mylan
	Rezolsta			S	Oral			Mylan
	Tavor /00273201/			S	Unknown	3 Df, Total		Mylan
	Minias			S	Unknown	40 Gtt, Total		Mylan
	Kivexa			S	Unknown	4 Df, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15125449	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1048071		14 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Overdose; Poisoning Deliberate; Sopor	Escitalopram			S	Oral	10 Df Units In Total		Not Reported
	Haldol			S	Oral	15 Ml In Total		Mylan
	Xanax			S	Oral	12 Df Units In Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15125540	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-923609		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction	Enalapril	S	Oral	2 Dosage Forms Daily;	Teva
	Escitalopram	S	Oral	1 Dosage Forms Daily;	Ivax
	Lantus (Insulin Glargine)	S	Subcutaneous	30 Iu (International Unit) Daily;	Not Reported
	Seguril	S	Oral	1 Dosage Forms Daily;	Not Reported
	Carvedilol	S	Oral	1 Dosage Forms Daily;	Not Reported
	Orvatez	S	Oral	1 Dosage Forms Daily;	Not Reported
	Toujeo	C			Not Reported
	Lyxumia	C			Not Reported
	Novorapid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15125640	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018273649		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperleukocytosis; Pancreatitis; Renal Failure	Atarax			S	Oral	750 Mg, Unk		Pfizer
	Ibuprofen			S	Oral	6 G, Unk		Pfizer
	Escitalopram			S	Oral	140 Mg, Unk		Not Reported
	Coltramyl			S	Oral	48 Mg, Unk		Not Reported
	Paracetamol			S		8.8 G, Unk		Not Reported
	Alprazolam			C	Oral	5 Mg, Unk		Not Reported
	Cefuroxime			C	Oral	Unk		Not Reported
	Brexin			C	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15125844	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1834009US			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prescribed Overdose; Short-Bowel Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15127280	EXPEDITED (15-DAY)		HO	CN-ALLERGAN-1834026US		76 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Angle Closure Glaucoma; Eye Pain; Gastric Ph Decreased; Hypertension; Intentional Dose Omission; Prescription Drug Used Without A Prescription; Visual Acuity Reduced	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	0.25 Df, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df (10 Mg), Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	1.5 Df, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan
	Alprazolam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15127363	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2018M1048357		38 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome; Drug Interaction	Escitalopram			S	Oral			Not Reported
	Dexametasona /00016001/			S	Oral	0.25 Mg, Qd		Mylan
	Hidroaltesona			S	Oral	20 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15127578	EXPEDITED (15-DAY)		OT	CN-PRINSTON PHARMACEUTICAL INC.-2018PRN00371		43 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram			S	Unknown	5 Mg, 1x/Day		Prinston Pharmaceutical
	Escitalopram			S	Unknown	10 Mg, 1x/Day		Prinston Pharmaceutical

	Escitalopram		S	Unknown	5 Mg, 1x/Day			Prinston Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15127587	EXPEDITED (15-DAY)		HO, OT	IE-PRINSTON PHARMACEUTICAL INC.-2018PRN00368		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Escitalopram			S	Oral	5 Mg, 1x/Day		Prinston Pharmaceutical
	Escitalopram			S	Oral	10 Mg, 1x/Day		Prinston Pharmaceutical
	Lamotrigine			S	Unknown			Not Reported
	Clobazam			C	Unknown	10 Mg, 2x/Day		Not Reported
	Clobazam			C	Unknown	10 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15127598	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1834665US		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unknown; In Total		Allergan
	Alprazolam			S	Oral	Unknown; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15055075	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1831836US			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anosmia; Mood Altered; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15117007	EXPEDITED (15-DAY)		HO, LT, OT	CH-JNJFOC-20180705628		83 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Delirium; Disturbance In Attention	Haldol	S	Oral		Not Reported
	Tramal	S	Oral		Not Reported
	Morphin Hcl Sintetica	S	Intravenous (not otherwise specified)		Not Reported
	Morphin Hcl Sintetica	S	Intravenous (not otherwise specified)		Not Reported
	Quetiapin Sandoz	S	Oral		Not Reported
	Quetiapin Sandoz	S	Oral		Not Reported
	Quetiapin Sandoz	S	Oral	At Night	Not Reported
	Valium	S	Oral		Not Reported
	Pramipexol	S	Oral	(Once In Evening)	Not Reported
	Cipralex	S	Oral	Once In Morning	Not Reported
	Pantoprazol Sandoz	S	Oral	Once In Morning	Not Reported
	Allopurinol	S	Oral	Once In Morning And Evening	Not Reported
	Allopurinol	S	Oral	Once In Morning	Not Reported
	Lisitril	S	Oral	Once In Morning	Not Reported
	Meto Zerok	S	Oral	Once In Morning	Not Reported
	Plavix	S	Oral	Once In Morning	Not Reported
	Plavix	S	Oral		Not Reported
	Spiricort	S	Unknown	0.75 In The Morning And 0.25 In The Evening	Not Reported
	Oxynorm	S	Oral		Not Reported
	Fentanyl Sintetica	S	Intravenous (not otherwise specified)		Not Reported
	Aspirin Cardio	C	Oral	In Morning	Not Reported
	Atorvastatin Pfizer	C	Oral	In Morning	Not Reported
	Dafalgan	C	Oral	In Morning, Midday And Evening	Not Reported
	Spiriva	C	Respiratory (inhalation)	In Morning	Not Reported

	Torem	C	Unknown	In Morning		Not Reported
	Novalgin (Metamizole Sodium)	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15129360	EXPEDITED (15-DAY)		HO	IT-MERCK KGAA-2051719		83 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Novothyrox			S	Oral			Merck Kgaa
	Cipralex			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Lansox			C				Not Reported
	Folina [Folic Acid]			C				Not Reported
	Torvast			C				Not Reported
	Allopurinol			C				Not Reported
	Luvion			C				Not Reported
	Bisoprolol Hemifumarate			C				Not Reported
	Amiodar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15129980	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1834376US		35 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Abilify			S	Oral	Unk		Not Reported
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Noctran			C	Unknown	Unk		Not Reported
	Tercian			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15130016	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1833595US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Platelet Count Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15130886	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018271166		58 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Aspavor			S		20 Mg, Unk		Pfizer
	Prexum Plus /01421201/			S		5/1.25 Mg		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported
	Trepiline /00002201/			S		25 Mg, Unk		Not Reported
	Wellbutrin Xl			S		150 Mg, Unk		Not Reported
	Glucophage Xr			S		1000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15130888	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018276979		59 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Seizure	Aldactone (Spironolactone)			S				Pfizer
	Lancap			S				Not Reported
	Duovent			S				Not Reported
	Rivotril			S				Not Reported
	Mylan Furosemide			S				Not Reported
	Plenish-K			S				Not Reported
	Lexamil			S				Not Reported
	Euthyrox			S				Not Reported
	Redilev			S				Not Reported
	Epilim Cr			S				Not Reported
	Symbicord			S				Not Reported
	Ipvent			S				Not Reported
	Nexipraz			S				Not Reported
	Venteze (Salbutamol)			S				Not Reported
	Beceze			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15130890	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018276759		53 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Aspavor			S		40 Mg, Unk		Pfizer
	Furosemide			S		40 Mg, Unk		Not Reported
	Purgoxin			S		0.25 Mg, Unk		Not Reported
	Clopiwin			S		75 Mg, Unk		Not Reported
	Disprin Cardiocare			S		100 Mg, Unk		Not Reported
	Zetomax			S		5 Mg, Unk		Not Reported
	Carloc			S		6.25 Mg, Unk		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	14528961	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00009875		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Digoxin			S	Unknown	Unk		Not Reported
	Amiodarone (Ngx)			S	Unknown	Unk		Not Reported
	Bisoprolol (Ngx)			S	Unknown	Unk		Not Reported
	Domperidone (Ngx)			S	Unknown	Unk		Not Reported
	Escitalopram (Ngx)			S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram (Ngx)			S	Unknown	5 Mg, Unk		Not Reported
	Aliskiren			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15017552	NON-EXPEDITED			US-JNJFOC-20180604319			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Fatigue; Feeling Abnormal; Somnolence	Xarelto	S	Oral	Not Reported
	Xarelto	S	Oral	Not Reported
	Xarelto	S	Oral	Not Reported
	Xarelto	S	Oral	Not Reported
	Lexapro	S	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Promeprazole	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15132870	EXPEDITED (15-DAY)		HO	IE-UNICHEM PHARMACEUTICALS (USA) INC-UCM201807-000		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Drug Interaction; Drug Level Increased; Toxicity To Various Agents	Lamotrigine			S				Unichem
	Clobazam			S				Not Reported
	Clobazam			S				Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15132936	EXPEDITED (15-DAY)		HO, LT, OT	CH-TEVA-2018-CH-922614		83 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenocorticotropic Hormone Deficiency; Aspiration; Delirium; Disturbance In Attention; Haemodynamic Instability; Pyrexia	Allopurinol Mepha			S	Oral	200 Milligram Daily;		Actavis
	Allopurinol Mepha			S	Oral	100 Milligram Daily;		Actavis
	Pramipexol Helvepharm			S	Oral	.125 Milligram Daily;		Not Reported
	Cipralex			S	Oral	10 Milligram Daily;		Not Reported
	Pantoprazol Sandoz			S	Oral	40 Milligram Daily;		Not Reported
	Lisitril			S	Oral	20 Milligram Daily;		Not Reported
	Meto Zerok			S	Oral	50 Milligram Daily;		Not Reported
	Plavix			S	Oral	75 Milligram Daily;		Not Reported

Plavix	S	Oral	75 Milligram Daily;	Not Reported
Spiricort	S		Spiricort, Film-Coated Tablets, 20 Mg (Prednisolone); 0.75-0-0.25-0, Until 2 June 2018	Not Reported
Tramal	S	Oral	Tramalâ® Tropfen (100 Mg = 40 Gtt) 100 Mg/1 Ml ; As Necessary	Not Reported
Fentanyl Sintetica	S	Intravenous (not otherwise specified)	In Total	Not Reported
Haldol	S	Oral	In Total	Not Reported
Oxynorm	S	Oral	As Necessary	Not Reported
Morphin Hcl Sintetica	S	Oral	In Total	Not Reported
Morphin Hcl Sintetica	S	Oral	In Total	Not Reported
Quetiapin Sandoz	S	Oral	In Total	Not Reported
Quetiapin Sandoz	S	Oral	In Total	Not Reported
Quetiapin Sandoz	S	Oral	25 Milligram Daily;	Not Reported
Valium	S	Oral	As Necessary	Not Reported
Aspirin Cardio	C	Oral	100 Milligram Daily;	Not Reported
Atorvastatin Pfizer	C	Oral	20 Milligram Daily;	Not Reported
Dafalgan	C	Oral	1500 Milligram Daily;	Not Reported
Spiriva	C		18 Microgram Daily;	Not Reported
Torem	C		5 Milligram Daily;	Not Reported
Novalgin (Metamizole Sodium)	C	Oral	As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15133134	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-924309		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Impaired Gastric Emptying; Vomiting	Escitalopram			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15134094	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-034849		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disinhibition; Suicidal Ideation	Escitalopram			S	Oral	20 Milligram, Daily		Aurobindo
	Zopiclone			S	Oral	7.5 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15135999	NON-EXPEDITED			US-APOTEX-2018AP016806		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Gastritis; Hyperchlorhydria	Fluoxetine			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15136225	NON-EXPEDITED			JP-ALLERGAN-1835035US		45 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Convulsions Local	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Gasmotin			C	Oral	Unk		Not Reported
	Domperidone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15136957	EXPEDITED (15-DAY)		HO	PHHY2018TR039251		52 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Paranoia; Speech Disorder	Quetiapine			S	Unknown	200 Mg, Unk		Novartis
	Quetiapine			S	Unknown	25 Mg, Unk		Novartis
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Aripiprazole			S	Unknown	30 Mg, Unk		Not Reported

	Carbamazepine	S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15137862	EXPEDITED (15-DAY)		HO	IL-ALLERGAN-1834976US		78 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Unk		Allergan
	Stator			C	Unknown			Not Reported
	Sterocort			C	Unknown			Not Reported
	Insulin Degludec			C	Unknown			Not Reported
	Normiten			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15137912	EXPEDITED (15-DAY)		OT	AT-ELI_LILLY_AND_COMPANY-AT201807002331		21 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Zyprexa Velotab			S	Unknown	2.5 Mg, Unknown		Not Reported
	Zyprexa Velotab			S	Unknown	5 Mg, Unknown		Not Reported
	Seroquel			S	Unknown	75 Mg, Unknown		Not Reported
	Seroquel			S	Unknown	100 Mg, Unk		Not Reported
	Cipralex /01588501/			S	Unknown	5 Mg, Unknown		Not Reported
	Cipralex /01588501/			S	Unknown	10 Mg, Unk		Not Reported
	Lamictal			S	Unknown	25 Mg, Unknown		Not Reported
	Lamictal			S	Unknown	50 Mg, Unk		Not Reported
	Lamictal			S	Unknown	100 Mg, Unk		Not Reported
	Gewacalm			S	Unknown	5 Mg, Unk		Not Reported
	Gewacalm			S	Unknown	10 Mg, Unknown		Not Reported
	Gewacalm			S	Unknown	15 Mg, Unk		Not Reported
	Trittico			S		50 Mg, Unk		Not Reported

	Trittico	S	Unknown	100 Mg, Unknown	Not Reported
	Trittico	S	Unknown	150 Mg, Unknown	Not Reported
	Dominal /00018902/	S	Unknown	80 Mg, Unknown	Not Reported
	Dominal /00018902/	S	Unknown	40 Mg, Unknown	Not Reported
	Dominal /00018902/	S		80 Mg, Unk	Not Reported
	Temesta /00273201/	S	Unknown	Unk Unk, Unknown	Not Reported
	Zoldem	C	Unknown	10 Mg, Unknown	Not Reported
	Quilonorm /00033702/	C	Unknown	225 Mg, Unknown	Not Reported
	Halcion	C	Unknown	.25 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15242922	DIRECT		DS, HO			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Pneumonia	Imitrex			S	Oral			Not Reported
	Imitrex			S				Not Reported
	Patanol			S				Not Reported
	Lorsartan			S				Not Reported
	Aggrenox			S				Not Reported
	Atenolol			S				Not Reported
	Tramadol			S				Not Reported
	Levothyronine			S				Not Reported
	Lyrica			S				Not Reported
	Escitalopram			S				Not Reported
	Trazodone			S				Not Reported
	Dok			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Fiber Ion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	12773443	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2016SE99839		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Cough;	Inexium			S	Oral			Astrazeneca

Interstitial Lung Disease	Triatec (Ramipril)		S	Oral		Not Reported
	Seroplex		S	Oral		Not Reported
	Stilnox		S	Oral		Not Reported
	Cellcept		S	Oral		Not Reported
	Cortancyl		S	Oral		Not Reported
	Tahor		S	Oral		Not Reported
	Theralene		S	Oral		Not Reported
	Ixprim		S	Oral	37,5 Mg / 325 Mg Coated Tablet	Not Reported
	Seresta		C			Not Reported
	Lasilix		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	14252402	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017513653		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Bundle Branch Block Right; Diarrhoea; Electrocardiogram Qrs Complex Prolonged; Haematuria; Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence; Vomiting	Tahor			S	Oral	40 Mg, Daily		Pfizer
	Tahor			S	Oral	40 Mg, Daily		Pfizer
	Triatec (Ramipril)			S	Oral	2.5 Mg, 2x/Day		Pfizer
	Bisoprolol Fumarate			S	Oral	2 Df, Daily (3.25 Mg In The Morning And 2.5 Mg In The Evening)		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Diffu-K			S	Oral	Unk		Not Reported
	Brilique			S	Oral	90 Mg, 2x/Day		Not Reported
	Brilique			S	Oral	90 Mg, 2x/Day		Not Reported
	Seroplex			S	Oral	5 Mg, Daily		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Lactibiane (Probiotic)			S	Unknown	Unk		Not Reported
	Inexium			C		20 Mg, Daily		Not Reported
	Kardegic			C		75 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	14281931	EXPEDITED (15-DAY)		HO, LT	ES-ABBVIE-17P-144-2191476-00		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Intentional Overdose	Valproate Sodium			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Antabus			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	14816351	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1027581		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Aripiprazole			S	Oral	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Norset			S	Oral	Unk		Mylan
	Lexapro			S		Unk		Mylan
	Seroplex			S	Oral	Unk		Mylan
	Inipomp			C		Unk		Mylan
	Aprovel			C		Unk		Mylan
	Kardegic			C		Unk		Mylan
	Irbesartan			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	14931584	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2018-ES-896822		38 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cushing'S Syndrome; Drug Interaction	Escitalopram		S	Oral	10 Milligram Daily;	Ivax
	Dexametasona (722a)		S	Oral	.25 Milligram Daily;	Not Reported
	Hidroaltesona Tablets, 10 Tablets		S	Oral	20 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	14978716	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-028985		21 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Aripiprazole Tablets			S	Oral	210 Milligram, In Total		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	140 Milligram, In Total		Aurobindo
	Alprazolam			S	Oral	15 Milliliter, In Total		Not Reported
	Prozin /00011902/			S	Oral	1200 Milligram, In Total		Not Reported
	Zitromax			S	Oral	1500 Milligram,In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15100193	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-918561		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral			Ivax
	Lexotan 2,5 Mg/Ml Gocce Orali Soluzione			S	Oral			Not Reported
	Efexor 37,5 Mg Capsule Rigide A Rilascio Prolungato			S	Oral			Not Reported
	Lamictal 100 Mg Compresse Masticabili/Dispersibili			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138704	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-924521		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperleukocytosis;	Escitalopram			S	Oral			Ivax

Pancreatitis; Renal Failure	Ibuprofene	S	Oral	Actavis
	Paracetamol	S	Unknown	Not Reported
	Atarax	S	Oral	Not Reported
	Coltramyl	S	Oral	Not Reported
	Alprazolam	C	Oral	Not Reported
	Cefuroxime	C	Oral	Not Reported
	Brexin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138918	EXPEDITED (15-DAY)		CA	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00013750			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect;	Prednisolone			S				Concordia
Autism Spectrum	Lorazepam			S				Not Reported
Disorder; Camptodactyly	Fosfomycin			S				Not Reported
Congenital; Clinodactyly;	Valaciclovir			S				Not Reported
Congenital Arterial	Abatacept			S				Not Reported
Malformation; Congenital	Ursodeoxycholic Acid			S				Not Reported
Central Nervous System	Mycophenolate Mofetil			S				Not Reported
Anomaly; Congenital	Tacrolimus			S				Not Reported
Renal Cyst; Dysplasia;	Acebutolol			S				Not Reported
External Auditory Canal	Prednisone			S				Not Reported
Atresia; Foetal Exposure	Colchicine			S				Not Reported
During Pregnancy; Foetal	Cyclosporine			S				Not Reported
Malformation;	Methyldopa			S				Not Reported
Hydronephrosis;	Azathioprine			S				Not Reported
Meningocele; Microtia;	Naproxen			S				Not Reported
Oesophageal Atresia;	Zolpidem			S				Not Reported
Premature Baby	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15139196	NON-EXPEDITED			US-PFIZER INC-2018280417			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Atenolol	S	Unk	Pfizer
	Clindamycin Hcl	S	Unk	Pfizer
	Codeine	S	Unk	Not Reported
	Doxepin Hcl	S	Unk	Pfizer
	Spironolactone	S	Unk	Pfizer
	Vancomycin Hcl	S	Unk	Pfizer
	Zithromax	S	Unk	Pfizer
	Zoloft	S	Unk	Pfizer
	Arimidex	S	Unk	Not Reported
	Ceftin	S	Unk	Not Reported
	Ethacrynic Acid	S	Unk	Not Reported
	Januvia	S	Unk	Not Reported
	Lasix	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Lisinopril	S	Unk	Not Reported
	Losartan	S	Unk	Not Reported
	Lovenox	S	Unk	Not Reported
	Mavik	S	Unk	Not Reported
	Metformin Hcl	S	Unk	Not Reported
	Prandin	S	Unk	Not Reported
	Topamax	S	Unk	Not Reported
	Tramadol	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15139387	EXPEDITED (15-DAY)		OT	FR-ACCORD-069429		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Formication; Hyperkalaemia; Myalgia; Off Label Use; Testicular	Escitalopram			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported

Pain	Pravastatin	C	Oral		Not Reported
	Pregabalin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15139588	EXPEDITED (15-DAY)		DE	AT-ASTRAZENECA-2018SE87806		36 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Seroquel			S	Oral	100.0mg Unknown		Zeneca
	Seroquel			S	Oral	50.0mg Unknown		Not Reported
	Cipralex			S	Oral	10.0mg Unknown		Not Reported
	Cipralex			S	Oral	20.0mg Unknown		Not Reported
	Mirtazapine			S	Unknown	30.0mg Unknown		Not Reported
	Mirtazapine			S	Unknown	15.0mg Unknown		Not Reported
	Inderal			C	Unknown	10.0mg Unknown		Not Reported
	Inderal			C	Unknown	20.0mg Unknown		Not Reported
	Zoldem			C	Unknown	5.0mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15139597	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00646		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inhibitory Drug Interaction; Psychotic Disorder	Escitalopram			S	Unknown	Unk		Hetero
	Lixiana			S	Unknown	60 Mg, Qd		Not Reported
	Olanzapin			S	Unknown	Unk		Not Reported
	Cortisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15141879	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-035860		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Dizziness; Dyschezia; Nausea; Rectal Haemorrhage; Vomiting	Escitalopram		S	Oral	Unk, Once A Day In The Morning	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15142312	EXPEDITED (15-DAY)		HO, OT	IT-GLAXOSMITHKLINE-IT2018120525		24 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperreflexia; Intentional Self-Injury; Loss Of Consciousness; Mydriasis; Nystagmus; Overdose; Tachycardia	Lamictal			S	Oral	In Total		Glaxosmithkline
	Cipralex			S	Unknown	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15143094	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018279087		78 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia	Amlodipine Besilate			S		5 Mg, Unk		Pfizer
	Xalatan			S		50 Ug, Unk		Pfizer
	Lancap			S		30 Mg, Unk		Not Reported
	Tesar			S		80 Mg, Unk		Not Reported
	Clopidogrel			S		75 Mg, Unk		Not Reported
	Glucophage Xr			S		500 Mg, Unk		Not Reported
	Rivotril			S		0.5 Mg, Unk		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported
	Spiractin (Spironolactone)			S		25 Mg, Unk		Not Reported
	Diaglucide			S		30 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15145573	EXPEDITED (15-DAY)		HO, LT, OT	CH-ALLERGAN-1835159US		83 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Aspiration; Delirium; Disturbance In Attention; Haemodynamic Instability; Pyrexia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Pantoprazol Sandoz			S	Oral	40 Mg, Qd		Not Reported
	Allopurinol Mepha			S	Oral	100 Mg, Bid		Not Reported
	Allopurinol Mepha			S	Oral	100 Mg, Qd		Not Reported
	Lisitril			S	Oral	20 Mg, Qd		Not Reported
	Meto Zerok			S	Oral	50 Mg, Qd		Not Reported
	Plavix			S	Oral	75 Mg, Qd		Not Reported
	Plavix			S	Oral	75 Mg, Qd		Not Reported
	Spiricort			S	Unknown	15 Mg - 0 - 5 Mg, Bis Am		Not Reported
	Tramal			S	Oral	10 Gtt, Prn		Not Reported
	Fentanyl Sintetica			S	Intravenous (not otherwise specified)	25 Mg, Single		Not Reported
	Haldol			S	Oral	10 Gtt, Single		Not Reported
	Oxynorm			S	Oral	5 Mg, Prn		Not Reported
	Morphin Hcl Sintetica			S	Oral	7.5 Mg, Single		Not Reported
	Morphin Hcl Sintetica			S	Oral	2.5 Mg, Single		Not Reported
	Quetiapin Sandoz			S	Oral	125 Mg, Single		Not Reported
	Quetiapin Sandoz			S	Oral	200 Mg, Single		Not Reported
	Quetiapin Sandoz			S	Oral	25 Mg, Qd		Not Reported
	Valium			S	Oral	5 Mg, Prn		Not Reported
	Pramipexol Helvepharm			S	Oral	0.125 Mg, Qd		Not Reported
	Aspirin Cardio			C	Oral	100 Mg, Qd		Not Reported
	Atorvastatin Pfizer			C	Oral	20 Mg, Qd		Not Reported
	Dafalgan			C	Oral	500 Mg, Q8hr		Not Reported
	Spiriva			C	Unknown	Unk		Not Reported
	Torem			C	Unknown	5 Mg, Qd		Not Reported
	Novalgin (Metamizole Sodium)			C	Oral	As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2018	15145974	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2018-FR-925219		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage Intracranial	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Duoplavin			S	Oral	75 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2018	15146120	EXPEDITED (15-DAY)		DE, HO	GB-TORRENT-00016874		88 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer; Gastrointestinal Haemorrhage; Gastrointestinal Pain	Acetylsalicylic Acid			S	Oral	Unknown		Unknown
	Dihydrocodeine			C	Oral	Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	13330395	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1015247		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Clozapine			S	Oral	100 Mg, Once		Not Reported
	Clozapine			S		Unk		Not Reported
	Lorazepam			S	Oral	1 Mg, Once		Not Reported
	Entact			S	Oral	20 Mg, Once		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	14445008	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20180119290		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Risperidone			S	Oral			Not Reported

Motilium		S	Oral	Start Unspecified Might Be Between 15-Sep Of An Unspecified Year And 02-Oct Of An Unspecified Year	Not Reported
Motilium		S	Oral		Not Reported
Imodium	Y	S	Oral		Not Reported
Imodium		S	Oral		Not Reported
Ondansetron		S	Oral		Not Reported
Nexium		S	Oral		Not Reported
Faslodex		S	Intramuscular		Not Reported
Ibrance		S	Oral	Interrupted From 19-Sep- Of An Unspecified Year To 12-Nov Of An Unspecified Year	Not Reported
Ibrance		S	Oral		Not Reported
Escitalopram		S	Oral		Not Reported
Escitalopram		S	Oral		Not Reported
Imovane		C	Unknown		Not Reported
Calcimagon		C	Unknown		Not Reported
Condrosulf		C	Unknown		Not Reported
Euthyrox		C	Unknown		Not Reported
Dafalgan		C	Unknown		Not Reported
Irfen		C	Unknown		Not Reported
Diclofenac Epolamine		C	Unknown		Not Reported
Diclofenac Epolamine		C	Unknown	Interrupted From 02-Oct Of An Unspecified Year To 01-Dec Of An Unspecified Year	Not Reported
Temgesic		C	Unknown		Not Reported
Targin		C	Unknown		Not Reported
Oxynorm		C	Unknown		Not Reported

	Sodium Bicarbonate		C	Unknown	Not Reported
	Laxoberon		C	Unknown	Not Reported
	Clexane		C	Unknown	Not Reported
	Mycostatine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	14868033	EXPEDITED (15-DAY)		LT, OT	US-JNJFOC-20180505018		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Ejection Fraction Decreased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Overdose; Syncope	Loperamide Hydrochloride		Y	S	Unknown			Not Reported
	Loperamide Hydrochloride			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15104037	EXPEDITED (15-DAY)		HO	DE-OTSUKA-2018_017640		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma; Menorrhagia; Sleep Disorder	Aripiprazole			S	Unknown	5 Mg, Qd		Otsuka
	Escitalopram			S	Unknown	20 Mg, Qd (Increased To A Dose Of 20 Mg)		Not Reported
	Escitalopram			S	Unknown	15 Mg, Qd (Reduced To 15 Mg/Day)		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd (In A Morning Target Dose Of 20 Mg)		Not Reported
	Risperidone			S	Unknown	0.5 Mg, Qd		Not Reported
	Promethazine			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Opipramol			C	Unknown	Unk (In Crisis Situations With Temporary Effect)		Not Reported

	Lorazepam	C	Unknown	Unk (In Crisis Situations With Temporary Effect)	Not Reported
	Pregabalin	C	Unknown	100 Mg, Qd (Evening Dose Of 100 Mg)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15139598	EXPEDITED (15-DAY)		OT	IN-HETERO LABS LIMITED-HET2018IN00641		72 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Speech Disorder; Suicidal Ideation; Tremor	Escitalopram			S	Oral	Unk, Qd		Hetero
	Rescue			C	Unknown	Unk Unk, Qd		Not Reported
	Bupropion			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15146865	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE-HET2018DE00650		44 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dyspepsia	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Neupro			S	Transdermal	14 Mg, Qd		Not Reported
	Ibuprofen /00109205/			S	Unknown	Unk		Not Reported
	Amantadin /00055901/			S	Unknown	100 Mg, Bid		Not Reported
	Amitriptylin			S	Unknown	75 Mg, Qd		Not Reported
	Bornaprine			S	Unknown	4 Mg (1-0.5-1-0)		Not Reported
	Madopar Depot			C	Unknown	100/25 Mg		Not Reported
	Madopar Depot			C	Unknown	100/25 Mg, 1.5-1.5-1.5-1.5		Not Reported
	Madopar Depot			C	Unknown	100/25 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15147045	EXPEDITED (15-DAY)		HO, OT	IE-CIPLA LTD.-2018IE19846			Unknown	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Drug Interaction; Nausea; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral	5 Mg, Once Daily		Invagen
	Escitalopram			S	Oral	10 Mg, Once Daily		Invagen
	Lamotrigine			S	Unknown	Unk		Not Reported
	Clobazam			S	Unknown	10 Mg, Twice Daily		Not Reported
	Clobazam			S	Unknown	10 Mg, Thrice Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15147143	EXPEDITED (15-DAY)		DE, OT	ZA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-064580		83 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Glucophage Xr			S	Unknown	500 Mg, Unk		Bristol Myers Squibb
	Aspavor			S	Unknown	20 Mg, Unk		Not Reported
	Zanidip			S	Unknown	10 Mg, Unk		Not Reported
	Lasix /00032601/			S	Unknown	20 Mg, Unk		Not Reported
	Spiractin /00006201/			S	Unknown	25 Mg, Unk		Not Reported
	Ganfort			S	Unknown	5 Mg, Unk		Not Reported
	Ecotrin			S	Unknown	81 Mg, Unk		Not Reported
	Stilpane /01152401/			S	Unknown			Not Reported
	Lexamil			S	Unknown	5 Mg, Unk		Not Reported
	Bilocor			S	Unknown	5 Mg, Unk		Not Reported
	Epleptin			S	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15147295	EXPEDITED (15-DAY)		OT	IL-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-178413		65 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported

Inappropriate Antidiuretic Hormone Secretion	Alprazolam	S	Unknown	1 Mg, Daily		Sun
	Zopiclone	C	Unknown	7.5 Mg, Daily		Not Reported
	Levetiracetam	C	Unknown	1000 Mg, Daily		Not Reported
	Omeprazole	C	Unknown	20 Mg, Daily		Not Reported
	Prednisone	C	Unknown	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15147899	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-178496		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Risperidone			S	Oral	0.5 Mg Matin Et Soir		Ranbaxy
	Loxapine (Succinate De)			S	Oral	5 Gouttes Si Besoin ; As Necessary		Not Reported
	Escitalopram Arrow			S	Oral	10 Mg Le Soir		Not Reported
	Olanzapine Mylan			S	Oral	5 Mg Le Soir		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15148219	EXPEDITED (15-DAY)		HO	LU-TEVA-2018-LU-923654		47 YR	Female	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Actin Antibody Positive; Gamma-Glutamyltransferase Increased; Hepatocellular Injury	Escitalopram			S	Oral			Ivax
	Gilenya 0,5 Mg, Gélule			S	Oral			Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15148645	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1050420		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt	Amiodarone			S	Unknown	Unk		Not Reported

Prolonged	Bisoprolol		S	Unknown	Unk	Not Reported
	Domperidone		S	Unknown	Unk	Not Reported
	Escitalopram		S	Unknown	10 Mg, Unk	Not Reported
	Escitalopram		S	Unknown	5 Mg, Unk	Not Reported
	Digoxin		S	Unknown	Unk	Not Reported
	Aliskiren		S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15148801	EXPEDITED (15-DAY)		HO	IE-MYLANLABS-2018M1051409		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Toxicity To Various Agents	Lamotrigine			S	Unknown			Not Reported
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram			S	Oral			Not Reported
	Clobazam			C	Unknown	10 Mg, Unk		Mylan
	Clobazam			C	Unknown	10mg Three Times Daily		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15149008	EXPEDITED (15-DAY)		CA, HO, OT	IT-TEVA-2018-IT-926354			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome; Live Birth	Carbolithium			S	Transplacental	The Treatment Was Continued Till 39 Weeks Of Gestation		Barr
	Escitalopram			S	Transplacental	The Treatment Was Continued Until Six Weeks Of Gestation		Not Reported
	Lorazepam			C	Transplacental	The Treatment Was Continued Until 38 Weeks Of Gestation		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15149124	EXPEDITED (15-DAY)		OT	CN-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00276		43 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram			S	Unknown	5 Mg,		Jubilant
	Escitalopram			S	Unknown	10 Mg, 1x/Day		Jubilant
	Escitalopram			S	Unknown	5 Mg, 1x/Day		Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15149129	EXPEDITED (15-DAY)		HO, OT	IE-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00272		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Escitalopram			S	Oral	5 Mg, 1x/Day		Jubilant
	Escitalopram			S	Oral	10 Mg, 1x/Day		Jubilant
	Lamotrigine			S	Unknown	Unk		Jubilant
	Clobazam			C	Unknown	10 Mg, 2x/Day		Not Reported
	Clobazam			C	Unknown	10 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15149133	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CH044268		83 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Disturbance In Attention	Pantoprazole Sandoz			S	Oral	40 Mg, Qd		Novartis
	Quetiapine Sandoz			S	Oral	125 Mg, Total		Not Reported
	Quetiapine Sandoz			S	Oral	200 Mg, Total		Not Reported
	Quetiapine Sandoz			S	Oral	25 Mg, Qd		Not Reported
	Lisitril			S	Oral	20 Mg, Qd		Not Reported
	Meto Zerok			S	Oral	50 Mg, Qd		Not Reported

Pramipexole Helvepharm	S	Oral	0.125 Mg, Qd		Not Reported
Cipralex	S	Oral	10 Mg, Qd		Not Reported
Plavix	S	Oral	75 Mg, Qd		Not Reported
Spiricort	S	Unknown	20 Mg, Qd		Not Reported
Tramal	S	Oral	10 Gtt, Prn		Not Reported
Fentanyl Sintetica	S	Intravenous (not otherwise specified)	25 Ug, Total		Not Reported
Haldol	S	Oral	10 Gtt, Total		Not Reported
Oxynorm	S	Oral	5 Mg, Prn		Not Reported
Morphin Hcl Sintetica	S	Oral	7.5 Mg, Total		Not Reported
Morphin Hcl Sintetica	S	Oral	2.5 Mg, Total		Not Reported
Valium	S	Oral	5 Mg, Prn		Not Reported
Aspirin Cardio	C	Oral	100 Mg, Qd		Not Reported
Atorvastatin Pfizer	C	Oral	20 Mg, Qd		Not Reported
Dafalgan	C	Oral	500 Mg, Q8h		Not Reported
Spiriva	C	Unknown	Unk		Not Reported
Torem	C	Unknown	5 Mg, Qd		Not Reported
Novalgin (Metamizole Sodium)	C	Oral	500 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15149389	EXPEDITED (15-DAY)		CA, OT	IT-MYLANLABS-2018M1051505			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome	Lithium			S	Transplacental	The Treatment Was Continued Till 39 Weeks Of Gestation		Not Reported
	Escitalopram			S	Transplacental	The Treatment Was Continued Until Six Weeks Of Gestation		Not Reported
	Lorazepam			C	Transplacental	The Treatment Was Continued Until 38 Weeks		Mylan

Of Gestation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15150310	EXPEDITED (15-DAY)		HO	PHHY2018FR044748		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Extrapyramidal Disorder; Mydriasis; Sinus Tachycardia	Risperidone			S	Oral	36 Mg, Total		Novartis
	Escitalopram			S	Oral	9 Mg, Total		Not Reported
	Theralene			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15150474	EXPEDITED (15-DAY)		OT	AT-MYLANLABS-2018M1051115		38 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Autonomic Nervous System Imbalance; Cognitive Disorder; Hyperhidrosis; Hyperreflexia; Labelled Drug-Drug Interaction Medication Error; Restlessness; Serotonin Syndrome; Tachypnoea; Tremor	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Doubled Dosage		Not Reported
	Dextromethorphan Hydrobromide W/Dox/01062901/			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15151310	EXPEDITED (15-DAY)		HO	TR-LANNETT COMPANY, INC.-TR-2018LAN000806		34 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Bradycardia	Cetirizine Hydrochloride			S	Oral	10 Mg, Qd		Lannett
	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Lannett
	Enoxaparin			C		60 Mg, Qd		Not Reported

	Pantoprazole	C	40 Mg, Qd	Not Reported
	Aspirin /00002701/	C	100 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	13078794	EXPEDITED (15-DAY)		HO, OT	IT-ABBVIE-17P-083-1827084-00		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Drug Ineffective; Feeling Of Despair; Insomnia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation; Treatment Noncompliance	Valproic Acid			S	Unknown			Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Clonazepam			S	Oral			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15009685	EXPEDITED (15-DAY)		HO	US-VIVIMED-2018SP004473			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Overdose; Seizure	Amlodipine			S	Oral	Unk		Vivimed Labs
	Escitalopram			S	Oral	Unk		Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported
	Buspirone			S	Oral	Unk		Not Reported
	Atorvastatin			S	Oral	Unk		Not Reported
	Amfetamine W/Dexamfetamine			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Fluoxetine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15137865	EXPEDITED (15-DAY)		HO, OT	IE-ALLERGAN-1835047US		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Lamotrigine			S	Unknown	Unk		Not Reported
	Clobazam			C	Unknown	10 Mg, Bid		Not Reported
	Clobazam			C		10 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15152209	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-926895		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Somnolence; Toxicity To Various Agents	Alprazolam			S	Oral			Actavis
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15152580	EXPEDITED (15-DAY)		HO, OT	IE-ACCORD-069538		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Drug Interaction	Escitalopram			S		Dose Increase To 10mg Od		Accord
	Lamotrigine			S				Not Reported
	Clobazam			C				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15153490	EXPEDITED (15-DAY)		HO	PHHY2018IT047245		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Clonazepam	S	Oral			Not Reported
	Alprazolam	S	Oral	1.5 Mg, Unk		Novartis
	Escitalopram	S	Oral			Not Reported
	Quetiapine	S	Oral			Not Reported
	Venlafaxine	S	Oral			Not Reported
	Valproic Acid	S	Oral	300 Mg, Unk		Not Reported
	Trazodone	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15153578	EXPEDITED (15-DAY)		HO	PHHY2018IE038978		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Ataxia; Cerebellar Syndrome; Coordination Abnormal; Drug Interaction; Drug Level Increased; Dyskinesia; Moaning; Nausea; Nystagmus; Tardive Dyskinesia; Vomiting	Lamotrigine			S	Unknown			Novartis
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Clobazam			C	Unknown	10 Mg, Bid		Not Reported
	Clobazam			C	Unknown	10 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15153596	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1050724		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Interaction; Urinary Retention	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Haldol /00027401/			S	Oral	20 Gtt, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15154141	EXPEDITED (15-DAY)		HO	FR-B. BRAUN MEDICAL INC.-2052230		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Hyponatraemia	Dextrose Injections Usp 0264-7510-00 0264-7510-20	S			B Braun
	Escitalopram	S	Oral		Not Reported
	Glucose	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15154872	EXPEDITED (15-DAY)		OT	DE-TORRENT-00008916		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inhibitory Drug Interaction; Psychotic Disorder	Lixiana			S		60 Mg, Qd		Unknown
	Olanzapin			S		Unknown		Unknown
	Escitalopram			S		Unknown		Unknown
	Cortisone			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15155365	EXPEDITED (15-DAY)		HO, LT, OT	CH-JNJFOC-20180718159		83 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Delirium; Disturbance In Attention; Haemodynamic Instability; Pyrexia	Tramal			S	Oral			Not Reported
	Fentanyl Sintetica			S	Intravenous (not otherwise specified)			Not Reported
	Haldol			S	Oral			Not Reported
	Pantoprazol Sandoz			S	Oral			Not Reported
	Allopurinol Mepha			S	Oral			Not Reported
	Allopurinol Mepha			S	Oral			Not Reported
	Lisitril			S	Oral			Not Reported
	Meto Zerok			S	Oral			Not Reported
	Plavix			S	Oral			Not Reported
	Plavix			S	Oral			Not Reported
	Spiricort			S	Unknown			Not Reported

Pramipexol Helvepharm	S	Oral	Not Reported
Cipralex	S	Oral	Not Reported
Oxynorm	S	Oral	Not Reported
Morphin Hcl Sintetica	S	Oral	Not Reported
Morphin Hcl Sintetica	S	Oral	Not Reported
Quetiapin Sandoz	S	Oral	Not Reported
Quetiapin Sandoz	S	Oral	Not Reported
Quetiapin Sandoz	S	Oral	Not Reported
Valium	S	Oral	Not Reported
Aspirin Cardio	C	Oral	Not Reported
Atorvastatin Pfizer	C	Oral	Not Reported
Dafalgan	C	Oral	Not Reported
Spiriva	C	Unknown	Not Reported
Torem	C	Unknown	Not Reported
Novalgin (Metamizole Sodium)	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15155570	EXPEDITED (15-DAY)		HO	PHHY2018DE042979		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Lamotrigine			S	Unknown	100 Mg, Tid (1-1-1-0)		Novartis
	Mirtazapine			S	Unknown	15 Mg, Qd ((0-0-1) At Night)		Not Reported
	Mirtazapine			S	Unknown	45 Mg, Qd (At Night)		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd ((20mg-0mg-0mg-0mg) In The Morning)		Not Reported
	Milnacipran			S	Oral	50 Mg, Bid		Not Reported
	Milnacipran			S	Oral	200 Mg, Qd		Not Reported
	Levothyroxine			C	Unknown	100 Ug, Qd ((1-0-0-0) In The Morning)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15156197	EXPEDITED (15-DAY)		HO	PHHY2018IT047136		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Quetiapine			S	Oral	200 Mg, Qd		Novartis
	Clonazepam			S	Oral	0.5 Mg, Qd		Not Reported
	Valproic Acid Sandoz			S	Oral	300 Mg, Qd		Not Reported
	Alprazolam			S	Oral	1.5 Mg, Qd		Not Reported
	Venlafaxine			S	Oral	300 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Trazodone			S	Oral	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15255262	DIRECT					72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Interest; Fatigue; Impaired Quality Of Life; Nightmare	Escitalopram 20mg			S	Oral			Not Reported
	Xanax			C				Not Reported
	Clonidine			C				Not Reported
	Metroprolol			C				Not Reported
	Escilopram			C				Not Reported
	B			C				Not Reported
	E			C				Not Reported
	D			C				Not Reported
	Fish Oil			C				Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15104827	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1833200US		47 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Activation Syndrome	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd		Allergan
	Trazodone Hydrochloride	C	Oral	25 Mg, Unk		Not Reported
	Brotizolam	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15157078	EXPEDITED (15-DAY)		HO, OT	IE-LUPIN PHARMACEUTICALS INC.-2018-05061		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Lamotrigine			S	Unknown	Unk		Lupin
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Clobazam			C	Unknown	10 Mg, Bid		Not Reported
	Clobazam			C	Unknown	10 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15157466	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-927565		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disinhibition; Suicidal Ideation	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Zopiclone			S	Oral	7.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15158944	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018282912		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Somnolence; Toxicity To Various Agents	Alprazolam			S	Oral	Unk (Reported As 1, Unit Unspecified), Single		Pfizer
	Seroplex			S	Oral	Unk (Reported As 1, Unit Unspecified), Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15160115	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1835512US		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disinhibition; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Zopiclone			S	Oral	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15160452	EXPEDITED (15-DAY)		HO, LT	ES-JNJFOC-20180713334		18 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypocoagulable State	Ibuprofeno (1769a)		Y	S	Oral			Not Reported
	Ibuprofeno (1769a)			S	Oral	400 Mg X 7 Counts Per Second (Cps); In Total		Not Reported
	Exforge			S	Oral	5 Counts Per Second (Cps); In Total		Not Reported
	Escitalopram			S	Oral	5 Counts Per Second (Cps)		Not Reported
	Paracetamol			S	Oral	12gr Day; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15160633	EXPEDITED (15-DAY)		HO, LT	ES-ALLERGAN-1835767US		18 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hepatitis; Hypocoagulable State	Escitalopram Oxalate - Bp			S	Oral	5 Capsules In Total		Allergan
	Paracetamol			S	Oral	12 G In Total		Not Reported
	Exforge			S	Oral	5 Capsules In Total		Not Reported
	Ibuprofeno			S	Oral	2800 Mg In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15160878	EXPEDITED (15-DAY)		CA	PHHY2018IT043014			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome	Escitalopram			S	Transplacental	Unk		Not Reported
	Lorazepam			S	Transplacental	Unk		Novartis
	Carbolithium			S	Transplacental	Maternal Dose: 750 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15160943	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1835503US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Prescription Form Tampering	Escitalopram Oxalate - Bp			S	Unknown	Unknown		Allergan
	Xanax			S	Unknown	0.25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15160946	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1835913US		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15257766	DIRECT		DS, HO			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder; Refusal Of Treatment By Patient; Schizophrenia	Lexapro			S	Oral	Quantity:1 Tablet(S);		Unknown
	Risperdal			C				Not Reported
	Celexa			C				Not Reported
	Klonopin			C				Not Reported

Lipitor	C		Not Reported
Levothyroxinie	C		Not Reported
Benadryl	C		Not Reported
Dulera	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	13035561	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1680905US			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Autism Spectrum Disorder; Camptodactyly Congenital; Clinodactyly; Congenital Arterial Malformation; Congenital Central Nervous System Anomaly; Congenital Renal Cyst; Dysplasia; External Auditory Canal Atresia; Foetal Exposure During Pregnancy; Foetal Malformation; Hydronephrosis; Meningocele; Microtia; Oesophageal Atresia; Premature Baby	Escitalopram Oxalate Unk			S	Transplacental			Allergan
	Lorazepam			S	Transplacental			Not Reported
	Mycophenolate			S	Transplacental	Unk		Not Reported
	Zolpidem			S	Transplacental			Not Reported
	Fosfomycin			S	Transplacental	Unk		Not Reported
	Valaciclovir			S	Transplacental			Not Reported
	Abatacept			S	Transplacental			Not Reported
	Ursodeoxycholic Acid Unk			S	Transplacental			Allergan
	Tacrolimus			S	Transplacental			Not Reported
	Acebutolol			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported
	Colchicine			S	Transplacental			Not Reported
	Cyclosporine Unk			S	Transplacental	Unk		Allergan
	Methyldopa			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Naproxen			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15163303	EXPEDITED (15-DAY)		HO, OT	IE-MACLEODS PHARMACEUTICALS US LTD-MAC2018015081			Unknown	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown	5 Milligram, Qd		Macleods
	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd		Macleods
	Lamotrigine			S	Unknown	Unk		Not Reported
	Clobazam			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15163427	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-927635		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Risperidone			S	Oral	1 Milligram Daily; 0.5 Mg Morning And Evening		Pliva
	Loxapine (Succinate De)			S	Oral	Drops If Necessary		Not Reported
	Escitalopram Arrow			S	Oral	10 Milligram Daily; 10 Mg In The Evening		Not Reported
	Olanzapine Mylan			S	Oral	5 Milligram Daily; 5 Mg In The Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15163662	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018015178			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram Tablet			S	Oral	15 Milligram, Qd, Tablet		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15164180	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US19932			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stress Cardiomyopathy	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15164890	EXPEDITED (15-DAY)		HO, LT, OT	CH-NAPPMUNDI-GBR-2018-0057594		83 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Disturbance In Attention	Oxynorm			S	Oral	5 Mg, Prn		Purdue
	Morphine Hydrochloride			S	Intravenous (not otherwise specified)	2.5 Mg, Prn		Not Reported
	Morphine Hydrochloride			S	Intravenous (not otherwise specified)	75 Mg, Prn		Not Reported
	Tramal			S	Oral	10 Drop, Prn (100 Mg/1ml; 100 Mg = 40 Drops)		Not Reported
	Pramipexole Dihydrochloride			S	Oral	0.125 Mg, Daily		Not Reported
	Cipralex			S	Oral	10 Mg, Daily		Not Reported
	Pantoprazol			S	Oral	40 Mg, Daily		Not Reported
	Allopurinol			S	Oral	100 Mg, Daily		Not Reported
	Allopurinol			S	Oral	100 Mg, Bid		Not Reported
	Lisitril			S	Oral	20 Mg, Daily		Not Reported
	Meto Zerok			S	Oral	50 Mg, Daily		Not Reported
	Plavix			S	Oral	75 Mg, Daily		Not Reported
	Plavix			S	Oral	75 Mg, Daily		Not Reported
	Spiricort			S	Unknown	20mg, Daily (0.75 - 0 - 0.25 - 0 Dosage)		Not Reported
	Fentanyl /00174602/			S	Intravenous (not otherwise specified)	25 Mcg, Unk		Not Reported
	Haldol /00027401/			S	Oral	10 Drop, Single		Not Reported
	Quetiapine Fumarate			S	Oral	25 Mg, Daily		Not Reported
	Quetiapine Fumarate			S	Oral	200 Mg, Daily		Not Reported
	Quetiapine Fumarate			S	Oral	125 Mg, Daily (100 Mg And 25 Mg = 125 Mg)		Not Reported
	Valium /00017001/			S	Oral	5 Mg, Prn		Not Reported

Aspirin Cardio	C	Oral	100 Mg, Daily		Not Reported
Atorvastatin	C	Oral	20 Mg, Daily		Not Reported
Dafalgan	C	Oral	500 Mg, Tid		Not Reported
Spiriva	C	Oral	18 Mcg, Daily		Not Reported
Torem /01036501/	C	Oral	5 Mg, Daily		Not Reported
Novalgin /00169801/	C	Oral	500 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15166054	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-927070		85 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Medication Error	Escitalopram Oxalate			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15168198	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1835908US		83 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Lasix			S	Oral	Unk		Not Reported
	Eutirox			S	Oral	50 Mg, Qd		Not Reported
	Lansox			C	Unknown			Not Reported
	Folina [Folic Acid]			C	Unknown			Not Reported
	Torvast			C	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Luvion			C	Unknown			Not Reported
	Bisoprolol Hemifumarate			C	Unknown			Not Reported
	Amiodar			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15168221	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1835884US		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Dyschezia; Nausea; Rectal Haemorrhage; Vomiting	Escitalopram Oxalate - Bp			S	Oral	Unk, Qam		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15168845	EXPEDITED (15-DAY)		HO, LT, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018015180			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypocoagulable State	Escitalopram Oxalate			S	Oral	5 Cps		Macleods
	Paracetamol			S	Oral	12 Gram, Qd, 1 Total		Not Reported
	Exforge			S	Oral	5 Dosage Form, Qd, 1 Total, 5 Cps		Not Reported
	Ibuprofen			S	Oral	2800 Milligram, Qd, 1 Total, 400 Mg X 7 Cps		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15168848	EXPEDITED (15-DAY)		DS, HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2018015184			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral	10 Milligram		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15169321	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE-HET2018DE00670		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Contusion; Fall; Syncope	Escitalopram			S	Unknown	Unk		Hetero
	Metoprolol /00376902/			C	Unknown	47.5 Mg, Q.D.		Not Reported
	Metamizole /06276704/			C	Unknown	500 Mg, Tid		Not Reported
	Valsartan			C	Unknown	80 Mg, B.I.D.		Not Reported
	Simvastatin			C	Unknown	40 Mg, Q.D.		Not Reported
	Eferox			C	Unknown	50 Mcg, Qd		Not Reported
	Hct			C	Unknown	12.5 Mg, Qd		Not Reported
	Ventolair			C	Unknown	250 Mcg, Qid		Not Reported
	Ass			C	Unknown	100 Mg, Qd		Not Reported
	Pantoprazol			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15169786	EXPEDITED (15-DAY)		OT	PE-TEVA-2018-PE-926755		86 YR	Female	PER

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Constipation; Renal Disorder	Azilect			S		1 Milligram Daily;		Teva
	Madopar			S	Unknown			Not Reported
	Bivadin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15170161	EXPEDITED (15-DAY)		HO	DE-TORRENT-00008996		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Contusion; Fall; Syncope	Eferox			C		50 G, 1-0-0-0		Unknown
	Hct			C		12.5 Mg, 1-0-0-0		Unknown
	Metoprolol			C		47.5 Mg, 1-0-0-0		Unknown
	Escitalopram			S	Unknown	Nk		Unknown
	Ventolair			C		250 G, 2-0-0-2		Unknown

Metamizole	C	500 Mg, 1-1-1-0	Unknown
Valsartan	C	80 Mg, 0.5-0-0-1	Unknown
Ass 100	C	100 Mg, 0-1-0-0	Unknown
Simvastatin	C	40 Mg, 0-0-0-1	Unknown
Pantoprazol	C	20 Mg, 1-0-0-0	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15170486	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-036606		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Diarrhoea	Escitalopram			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Seroplex			S	Unknown	10 Milligram, Daily		Not Reported
	Meteospasmyl /01017401/			C	Unknown	Unk		Not Reported
	Meteospasmyl /01017401/			C	Unknown	Unk		Not Reported
	Copper Iud			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15170505	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2018-036549		23 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram (Escitalopram)			S	Oral	15 Milligram, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15171348	EXPEDITED (15-DAY)		OT	HK-TEVA-2018-HK-929621		43 YR	Male	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Somnolence	Escitalopram			S	Unknown	5 Milligram Daily; At Night, In The First Week; Dose Was Increased To 10mg At Night		Ivax

	Escitalopram		S	Unknown	10 Milligram Daily; At Night. Dose Reduced And Finally Stopped	Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15171574	EXPEDITED (15-DAY)		HO	FR-FRESENIUS KABI-FK201807949		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia	Glucose (Not Specified)			S	Subcutaneous			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15172063	EXPEDITED (15-DAY)		OT	IT-ASTRAZENECA-2018SE89867		35 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Apathy; Asthenia	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Escitalopram Oxalate			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15172185	EXPEDITED (15-DAY)		OT	HK-MYLANLABS-2018M1052929		43 YR	Male	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Somnolence	Escitalopram			S	Unknown	5 Mg, Qd, At Night, In The First Week; Dose Was Increased To 10mg At Night		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd, At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15172372	EXPEDITED (15-DAY)		HO	ZA-MERCK KGAA-2052473		87 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Fall	Novothyrox			S				Merck Kgaa
	Cardugen			S				Not Reported
	Halcion			S				Not Reported
	Spiractin (Spironolactone)			S				Not Reported
	Dopaquel			S				Not Reported
	Zytomil			S				Not Reported
	Vesicare			S				Not Reported
	Macrodantin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15172385	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-929675		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Dyschezia; Nausea; Rectal Haemorrhage; Vomiting	Escitalopram			S	Oral	1x Täglich Morgens		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15173392	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1053143		20 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error	Escitalopram			S		15 Mg, Nk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15175685	NON-EXPEDITED			US-TEVA-2018-US-927920			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Emotional Disorder; Irritability; Nausea; Tremor	Escitalopram		S	Unknown	Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2018	15178264	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2018-036261		18 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypocoagulable State	Escitalopram			S	Oral	5 Cps, Unk		Aurobindo
	Ibuprofen			S	Oral	2800 Milligram (400 Mg X 7 Cps ; In Total)		Aurobindo
	Paracetamol			S	Oral	12 Gram,In Total		Aurobindo
	Exforge			S	Oral	5 Dosage Form In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2018	15178615	EXPEDITED (15-DAY)		DE	US-TORRENT-00006338		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Ingestion		Unknown
	Vitamin B1			S	Oral	Ingestion		Unknown
	Loratadine			S	Oral	Ingestion		Unknown
	Furosemide			S	Oral	Ingestion		Unknown
	Levothyroxine			S	Oral	Ingestion		Unknown
	Folic Acid			S	Oral	Ingestion		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2018	15178616	EXPEDITED (15-DAY)		DE	US-TORRENT-00006337		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Alprazolam			S	Oral	Unknown		Unknown
	Aciclovir			S	Oral	Unknown		Unknown
	Lamotrigine			S	Oral	Unknown		Unknown

	Escitalopram	S	Oral	Unknown	Unknown
	Oxycodone And Acetaminophen	S	Oral	Unknown	Unknown
	Ibuprofen	S	Oral	Unknown	Unknown
	Propranolol	S	Oral	Unknown	Unknown
	Ondansetron	S	Oral	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	14351768	EXPEDITED (15-DAY)		HO, OT	IT-BAUSCH-BL-2018-000315		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Sopor; Suicide Attempt	Venlafaxine Hydrochloride			S	Oral	525 Mg In Total		Not Reported
	Escitalopram Oxalate			S	Oral	400 Mg In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	14923543	EXPEDITED (15-DAY)			DE-PFIZER INC-2018203881		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Insomnia	Pregabalin			S	Oral	100 Mg, 1x/Day (Evening Dose)		Pfizer
	Pregabalin			S	Oral	Reduced Gradually/Tapered Off		Pfizer
	Escitalopram			S	Oral	20 Mg, 1x/Day (Morning)		Not Reported
	Escitalopram			S	Oral	15 Mg, Daily		Not Reported
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported
	Escitalopram			S	Oral	Half Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15077223	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-MYLANLABS-2017M1077087		7 DAY	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death Neonatal; Foetal Exposure During Pregnancy; Foetal Malformation; Maternal Drugs Affecting Foetus; Trisomy 18	Levocetirizine		S	Transplacental	5 Mg, Qd	Not Reported
	Pantoprazole		S	Transplacental	Unk	Not Reported
	Pantomed (Pantoprazole Sodium Sesquihydrate)		S	Transplacental	Unk	Mylan
	Nucala		S	Transplacental	100 Mg, Qw	Mylan
	D-Cure		S	Transplacental	25 Kiu, Unk	Mylan
	Flixotide		S	Transplacental	250 Mg, Bid	Mylan
	Xanthium (Theophylline)		S	Transplacental	200 Mg, Qd	Mylan
	Ventolin		S	Transplacental	100 Ug, Unk	Mylan
	Relvar Ellipta		S	Transplacental	1 Df, Qd	Mylan
	Sipralexa		S	Transplacental	10 Mg, Z	Mylan
	Avamys		S	Transplacental	2 Df, Qd	Mylan
	Fluticasone Furoate		S	Transplacental	Unk, Qd	Mylan
	Seretide		S	Transplacental	Unk	Mylan
	Theophylline		S	Transplacental	Unk	Mylan
	Vilanterol Trifenatate		S	Transplacental	1 Df, Qd	Mylan
	Xyzall		S	Transplacental	5 Mg, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15167208	EXPEDITED (15-DAY)		OT	HK-ALLERGAN-1835768US		43 YR	Male	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Function Abnormal; Somnolence	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qpm		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qpm		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qpm		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15179179	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00680		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Spontaneous; Exposure During Pregnancy; Product Use In Unapproved Indication; Toxicity To Various Agents	Escitalopram		S	Unknown	20 Mg, Q.D.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15179663	EXPEDITED (15-DAY)		OT	HK-LUPIN PHARMACEUTICALS INC.-2018-05096		43 YR	Male	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Function Abnormal; Somnolence	Escitalopram			S	Unknown	5 Mg, Qd (Nocte In The First Week)		Lupin
	Escitalopram			S	Unknown	10 Mg, Qd (Increased On Day 8-Finally Stopped On Day 80)		Lupin
	Escitalopram			S	Unknown	5 Mg, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15179665	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-874355		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Hyponatraemia	Enalapril 20 Mg 28 Tablets			S	Oral	20 Milligram Daily;		Teva
	Heipram 10 Mg Tablets Film-Coated Tablets, 56 Tablets			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15180312	EXPEDITED (15-DAY)		OT	US-ACCORD-069693		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Akathisia; Amnesia; Bone Pain; Chills; Diarrhoea; Disorganised Speech; Feeling Abnormal;	Aripiprazole			S		Q.H.S		Not Reported
	Buspirone			S				Not Reported
	Escitalopram			S				Not Reported
	Lorazepam			C				Not Reported
	Testosterone			C				Not Reported

Gynaecomastia; Headache; Hyperhidrosis; Pain; Piloerection; Pyrexia; Restlessness; Withdrawal Syndrome	Benzatropine	C	B.I.D. P.R.N	Not Reported
	Lithium	C	Q.H.S.	Not Reported
	Amfetamine	C	Q.A.M	Not Reported
	Lurasidone	C	40 Mg Q. Dinner	Not Reported
	Lamotrigine	C		Not Reported
	Bupropion/Bupropion Hydrochloride	C	150 Mg Q.A.M.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15180539	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018015505			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Apathy; Asthenia	Escitalopram Oxalate			S	Oral	20 Milligram, Qd		Macleods
	Seroquel			S	Oral	1 Dosage Form, Qd		Not Reported
	Seroquel			S		Unk		Not Reported
	Lamotrigine			S	Oral	100 Milligram, Qd		Not Reported
	Seroquel			S	Oral	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15180546	EXPEDITED (15-DAY)		OT	HK-MACLEODS PHARMACEUTICALS US LTD-MAC2018015526			Unknown	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Function Abnormal; Somnolence	Escitalopram Oxalate			S	Unknown	5 Milligram, Qd, 5 Mg Nocte In The First Week		Macleods
	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd (Increased On Day 8-Finally Stopped On Day 80)		Macleods
	Escitalopram Oxalate			S	Unknown	5 Milligram, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15180901	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1836282US		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Loss Of Libido; Prescription Form Tampering	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Lexomil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	14360294	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-000763		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Sopor; Suicide Attempt	Escitalopram Film-Coated Tablets			S	Oral	In Total		Aurobindo
	Venlafaxine			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	14959411	EXPEDITED (15-DAY)		HO	US-OTSUKA-2018_013254		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Body Mass Index Abnormal; Disease Recurrence; Drug Ineffective; Food Craving; Hunger; Hyporesponsive To Stimuli; Increased Appetite; Obesity; Somnolence; Thinking Abnormal; Tooth Disorder; Treatment Noncompliance; Weight Increased	Abilify Maintena			S	Unknown	400 Mg, Qm		Otsuka
	Abilify			S	Unknown	10mg To 15mg		Otsuka
	Lexapro			S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15041374	EXPEDITED (15-DAY)		HO, LT	US-CIPLA LTD.-2017US14107			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Decreased Appetite; Drug Interaction; Electrocardiogram Qt Prolonged; Poor Quality Sleep; Serotonin Syndrome; Sleep Talking	Escitalopram			S	Unknown	10 Mg, Per Day		Invagen
	Dextromethorphan W/Promethazine			S	Unknown	Unk, 5 Days		Not Reported
	Dextromethorphan W/Promethazine			S				Not Reported
	Labetalol			C	Unknown	100 Mg, Per Day		Not Reported
	Amlodipine			C	Unknown	5 Mg, Bid		Not Reported
	Naltrexone			C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15056337	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1831979US		44 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Pr Prolongation; Electrocardiogram Qt Prolonged	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Cymbalta			C	Oral			Not Reported
	Abilify			C	Oral			Not Reported
	Risperdal			C	Oral	1 Ml, Q8hr		Not Reported
	Noritren			C	Oral	50 Mg, Q12h		Not Reported
	Rize			C	Oral	8 G, Q8hr		Not Reported
	Akineton			C	Oral	1.67 Mg, Q8hr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15187710	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-05986			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pain; Vomiting	Escitalopram Oxalate Tablets			S	Unknown			Lupin

Usp, 20 Mg

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15187835	EXPEDITED (15-DAY)		HO, LT	CH-ROCHE-2157082		83 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Disturbance In Attention	Valium			S	Oral			Not Reported
	Allopurinol			S	Oral			Not Reported
	Allopurinol			S	Oral			Not Reported
	Pramipexole Dihydrochloride			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Pantoprazole Sodium Sesquihydrate			S	Oral			Not Reported
	Lisitril			S	Oral			Not Reported
	Meto Zerok			S	Oral			Not Reported
	Plavix			S	Oral			Not Reported
	Plavix			S	Oral			Not Reported
	Spiricort			S	Unknown	15 Mg - 0 - 5 Mg - 0		Not Reported
	Tramal			S	Oral	10 Gtt (100 Mg = 40 Gtt) 100 Mg/1 Ml As Required		Not Reported
	Fentanyl Citrate			S	Intravenous (not otherwise specified)			Not Reported
	Haldol			S	Oral			Not Reported
	Oxynorm			S	Oral			Not Reported
	Morphin Hcl			S	Oral			Not Reported
	Morphin Hcl			S	Oral			Not Reported
	Quetiapine Fumarate			S	Oral			Not Reported
	Quetiapine Fumarate			S	Oral			Not Reported
	Quetiapine Fumarate			S	Oral			Not Reported
	Aspirin Cardio			C	Oral			Not Reported
	Atorvastatin Pfizer			C	Oral			Not Reported

	Dafalgan	C	Oral	Not Reported
	Spiriva	C	Unknown	Not Reported
	Torem	C	Unknown	Not Reported
	Novalgin (Switzerland)	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15189050	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006453		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Ingestion		Unknown
	Bupropion			S	Oral	Ingestion		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15189053	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006433		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Losartan Potassium			S	Oral	Ingestion		Unknown
	Amlodipine			S	Oral	Ingestion		Unknown
	Bupropion			S	Oral	Ingestion		Unknown
	Escitalopram			S	Oral	Ingestion		Unknown
	Levothyroxine Sodium			S	Oral	Ingestion		Unknown
	Ethanol			S	Oral	Ingestion		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15189793	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-036786		35 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Apathy; Asthenia	Escitalopram			S	Oral	20 Milligram, Daily		Aurobindo
	Lamotrigine			S	Oral	100 Milligram, Daily		Aurobindo
	Seroquel			S	Oral	1 Dosage Form, Daily		Not Reported

	Seroquel	S	Oral	1 Dosage Form, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15190297	EXPEDITED (15-DAY)		HO	PHHY2018DE049223		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine			S	Oral	100 Mg, Qd (0-0-0-1)		Novartis
	Valproate Sodium			S	Oral	500 Mg, Qd (0-0-0-1)		Not Reported
	Cipralex			S	Oral	10 Mg, Qd (1-0-0-0)		Not Reported
	Torasemid			C	Oral	10 Mg, Qd (1-0-0-0)		Not Reported
	Felodipine			C	Oral	10 Mg, Qd (1-0-0-0)		Not Reported
	Levothyroxin			C	Oral	75 G, Qd (1-0-0-0)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15190636	EXPEDITED (15-DAY)		DE	AT-TEVA-2018-AT-930210		36 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Mirtazapine			S				Teva
	Mirtazapine			S				Teva
	Cipralex			S				Not Reported
	Cipralex			S				Not Reported
	Seroquel			S				Not Reported
	Seroquel			S				Not Reported
	Inderal			C				Not Reported
	Inderal			C				Not Reported
	Zoldem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15192026	EXPEDITED (15-DAY)		HO	PHHY2018DE048929		81 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Nitrofurantoin			S	Unknown	100 Mg, 1-1-1-0		Novartis

	Metoprolol	C	Unknown	47.5 Mg, 0.5-0-0-0	Not Reported
	Ass	C	Unknown	100 Mg, 1-0-0-0/Alle 2 Tage	Not Reported
	Simvastatin	C	Unknown	20 Mg, 0-0-1-0	Not Reported
	Metamizol	C	Unknown	500 Mg, 0-0-1-0	Not Reported
	Allopurinol	C	Unknown	150 Mg, 1-0-0-0	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	14532005	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1806967US		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Cystitis; Disorientation; Frontotemporal Dementia	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan
	Qizenday			S	Oral	300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15128884	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-034561		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam Tablets			S	Oral	20 Milligram (In Total)		Aurobindo
	Paracetamol			S	Oral	2 G, Unk		Aurobindo
	Tachipirina			S	Oral	2 Gram (In Total)		Not Reported
	Cipralex /01588502/			S	Oral	15 Milliliter (In Total)		Not Reported
	Tolep			S	Oral	In Total		Not Reported
	Brintellix			S	Oral	15 Ml, Unk		Not Reported
	Oxcarbazepine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15130470	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1834616US		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Erythema; Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate - Bp		S	Oral	15 Ml, Unk	Allergan
	Vortioxetine		S	Oral	15 Ml, Unk	Not Reported
	Paracetamol		S	Oral	2 G, Unk	Not Reported
	Lorazepam		S	Oral	20 Mg, Unk	Not Reported
	Oxcarbazepine		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15169230	EXPEDITED (15-DAY)		HO	IE-TEVA-2018-IE-926303		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Toxicity To Various Agents	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Lamotrigine			S	Unknown			Not Reported
	Clobazam			C	Unknown			Not Reported
	Clobazam			C	Unknown	10mg Three Times Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15192472	EXPEDITED (15-DAY)		HO	ES-ROCHE-2157455			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Obinutuzumab			S	Intravenous (not otherwise specified)			Not Reported
	Cotrimoxazole			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Incb050465			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Bendamustine			S	Intravenous (not otherwise specified)			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15193061	EXPEDITED (15-DAY)		HO	IE-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00484			Unknown	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Lamotrigine Tablets			S	Unknown	Unk		Sciegen
	Escitalopram			S	Unknown	5 Mg Daily		Not Reported
	Escitalopram			S	Unknown	10 Mg Daily		Not Reported
	Clobazam			C	Unknown	Unk		Not Reported
	Clobazam			C	Unknown	10 Mg, Bid		Not Reported
	Clobazam			C	Unknown	10 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15193451	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006351		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Clonazepam			S		Ingst Plus Aspir		Unknown
	Escitalopram			S		Ingst Plus Aspir		Unknown
	Buspirone Hydrochloride			S		Ingst Plus Aspir		Unknown
	Propranolol Hydrochloride			S		Ingst Plus Aspir		Unknown
	Lamotrigine			S		Ingst Plus Aspir		Unknown
	Mirtazapine			S		Ingst Plus Aspir		Unknown
	Activated Charcoal			S		Ingst Plus Aspir		Unknown
	Cyclobenzaprine			S		Ingst Plus Aspir		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15193452	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006396		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide;	Escitalopram			S	Oral	Ingestion		Unknown

Toxicity To Various Agents	Lamotrigine		S	Oral	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15193495	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006539		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Diphenhydramine Hydrochloride			S	Oral	Ingestion		Unknown
	Escitalopram			S	Oral	Ingest		Unknown
	Fluoxetine			S	Oral	Ingestion		Unknown
	Risperidone			S	Oral	Ingest		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15193497	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006542		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Verapamil			S	Oral	Ingestion		Unknown
	Escitalopram			S	Oral	Ingest		Unknown
	Flecainide Acetate			S	Oral	Ingestion		Unknown
	Alprazolam			S	Oral	Ingest		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15193508	EXPEDITED (15-DAY)		DE	US-TORRENT-00006565		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Sitagliptin			S	Oral	Ingest		Unknown
	Mirtazapine			S	Oral	Ingest		Unknown
	Phenytoin			S	Oral	Ingestion		Unknown
	Primidone			S	Oral	Ingest		Unknown
	Escitalopram			S	Oral	Ingest		Unknown
	Carvedilol			S	Oral	Ingest		Unknown

	Valproic Acid	S	Oral	Ingestion		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15194421	EXPEDITED (15-DAY)		HO	ZA-LUPIN HEALTHCARE (UK) LIMITED-2018-05158		87 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Fall	Zytomil 20 Mg			S	Unknown	Unk		Lupin
	Halcion			S	Unknown	Unk		Not Reported
	Spiractin /00006201/			S	Unknown	Unk		Not Reported
	Dopaquel			S	Unknown	Unk		Not Reported
	Vesicare			S	Unknown	Unk		Not Reported
	Macrodantin			S	Unknown	Unk		Not Reported
	Euthyrox			S	Unknown	Unk		Not Reported
	Cardugen			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15194782	NON-EXPEDITED			US-LANNETT COMPANY, INC.-US-2017LAN001289			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Depression; Drug Ineffective; Malaise	Escitalopram Oxalate			S	Oral	15 Mg, Qd		Lannett

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15196102	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1836480US		83 YR	Male	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Urticaria	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15196823	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180726701		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autonomic Nervous System Imbalance; Malaise; Orthostatic Hypotension	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15198352	EXPEDITED (15-DAY)		HO	ES-ALLERGAN-1836435US		23 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	14360187	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-000641		36 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swelling Face	Escitalopram Tablets			S	Oral	1x Daags 1 Tablet		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	14526724	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1805717US		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Poisoning Deliberate; Suicide Attempt; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Baclofen			S	Oral	Unk		Not Reported
	Baclofen			S				Not Reported
	Dextropropoxyphene			S	Oral	Unk		Not Reported
	Valpromide			S	Oral	Unk		Not Reported
	Paracetamol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	14701459	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1816524US		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aptyalism; Drug Ineffective; Off Label Use; Overdose; Panic Disorder	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan
	Amitriptyline			S	Oral	20 Mg, Qd		Not Reported
	Apo-Buspirone			S	Oral	5 Mg, Qd		Not Reported
	Zyprexa			S	Unknown	2.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	14790084	EXPEDITED (15-DAY)		HO, LT, OT	DE-AUROBINDO-AUR-APL-2018-021415		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram			S	Unknown	Unknown		Aurobindo
	Linezolid			S	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Aurobindo
	Esomeprazole			S	Unknown	Unknown		Aurobindo
	Levetiracetam			C	Unknown	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Ivabradin Sandoz			C	Unknown	Daily Dose: 15 Mg Millgram(S) Every Days		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Naloxone W/Tilidine			C	Unknown	Unknown		Not Reported
	Scopolamin			C	Unknown	Unknown		Not Reported
	Baclofen			C	Unknown	Unknown		Not Reported
	Prednisolon /00016201/			C	Unknown	Unknown		Not Reported
	Lorazepam			C		Daily Dose: 1 Mg Millgram(S) Every Days		Not Reported
	L-Thyroxin /00068001/			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15200140	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-ASTRAZENECA-2018SE92978		40 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Fibrillation; Dizziness; Eye Disorder; Myalgia; Palpitations; Tooth Injury	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown	Increased Dose		Not Reported
	Quetiapine			S	Unknown	25 Mg, Every 12 Hours, Non-Az (Sandoz)		Zeneca
	Quetiapine			S	Unknown	Increased Dose		Zeneca
	Calcigran Forte Sitron			S	Unknown			Not Reported
	Calcigran Forte Sitron			S	Unknown	Reduced Dose		Not Reported
	Calcium			C				Not Reported
	Etalpha			C	Oral			Not Reported
	Zopiclone			C				Not Reported
	Multiminerals			C				Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15200596	EXPEDITED (15-DAY)		OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018010797			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram Oxalate			S	Unknown	10 Milligram		Macleods
	Irbesartan			S	Unknown			Macleods
	Paracetamol			S	Unknown			Not Reported
	Diuretics			S	Unknown			Not Reported
	Galantamine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201297	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD-			Unknown	ITA

MAC2018015682

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Sopor; Therapy Change	Escitalopram			S	Oral	Overdose		Macleods
	Anafranil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201306	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE-HET2018DE00708		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported
	Lamotrigine			S	Unknown	(1-1-1-0)		Not Reported
	Mirtazapine			S	Unknown	At Night		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Qd		Not Reported
	Milnacipran			S	Oral	200 Milligram, Qd		Not Reported
	Milnacipran			S	Oral	50 Milligram		Not Reported
	Levothyroxine /00068002/			C	Unknown	(1-0-0-0) In The Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201310	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE-HET2018DE00709		45 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety Disorder; Discomfort; Feeling Abnormal; Malaise; Nervousness; Psychomotor Hyperactivity; Stress; Tension Headache;	Escitalopram			S	Unknown	10 Milligram, Qd		Hetero
	Escitalopram			S	Unknown	Unk		Hetero
	Amlodipin			C	Unknown	10 Milligram, Qd		Not Reported

Therapeutic Product Effect
Incomplete

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201379	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006549		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Alprazolam			S	Oral	Ingest		Unknown
	Escitalopram			S	Oral	Ingest		Unknown
	Naproxen			S	Oral	Ingestion		Unknown
	Glucophage			S	Oral	Ingestion		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201380	EXPEDITED (15-DAY)		DE	US-TORRENT-00006552		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Ethanol			S	Oral	Ingest +Aspir		Unknown
	Escitalopram			S	Oral	Ingest +Aspir		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201382	EXPEDITED (15-DAY)		DE	US-TORRENT-00006554		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Ingest		Unknown
	Amitriptyline			S	Oral	Ingest		Unknown
	Lorazepam			S	Oral	Ingest		Unknown
	Lithium Carbonate			S	Oral	Ingest		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201386	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006558		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Ingest		Unknown
	Diphenhydramin Hcl			S	Oral	Ingestion		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201391	EXPEDITED (15-DAY)		DE	US-TORRENT-00006568		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Levothyroxine			S	Oral	Ingest		Unknown
	Escitalopram			S	Oral	Ingest		Unknown
	Diltiazem			S	Oral	Ingest		Unknown
	Propranolol			S	Oral	Ingestion		Unknown
	Metformin			S	Oral	Ingest		Unknown
	Glyburide			S	Oral	Ingest		Unknown
	Losartan			S	Oral	Ingestion		Unknown
	Lorazepam			S	Oral	Ingest		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201400	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006560		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Ingestion (Extended Release)		Unknown
	Escitalopram			S	Oral	Ingestion		Unknown
	Venlafaxine			S	Oral	Ingestion		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201459	EXPEDITED (15-DAY)		HO	FR-ACCORD-070136		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dysphagia; Sedation	Escitalopram		S	Oral		Not Reported
	Risperdal		S	Oral		Not Reported
	Alprazolam		S	Oral	Alprazolam 0,25 1/2 Cp/J	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201631	EXPEDITED (15-DAY)		OT	FR-BAYER-2018-136304		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Ciflox			S	Oral	Unk		Bayer
	Voriconazole			S	Intravenous drip	600 Mg, Qd		Not Reported
	Seroplex			S	Oral	20 Mg, Qd		Not Reported
	Flecaine			S	Oral	200 Mg, Qd		Not Reported
	Rovalcyte			C	Oral	450 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201858	EXPEDITED (15-DAY)		HO	ZA-MYLANLABS-2018M1052484		87 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Fall	Cardugen 1mg			S		Unk		Mylan
	Halcion			S		Unk		Mylan
	Spiractin /00006201/			S		Unk		Mylan
	Dopaquel			S		Unk		Mylan
	Zytomil			S		Unk		Mylan
	Vesicare			S		Unk		Mylan
	Macrodantin			S		Unk		Mylan
	Euthyrox			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15202641	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-037566		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Sopor; Therapy Change	Escitalopram Film-Coated Tablets			S	Oral	3 Dosage Form, In Total		Aurobindo
	Anafranil			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15204185	EXPEDITED (15-DAY)		OT	DK-ALLERGAN-1837115US		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Attention Deficit/Hyperactivity Disorder; Bipolar Disorder; Disturbance In Attention; Fatigue; Fibromyalgia; Hypomania; Memory Impairment; Obsessive-Compulsive Disorder; Psychotic Disorder; Sensory Disturbance; Social Anxiety Disorder; Tinnitus	Escitalopram Oxalate - Bp			S	Oral	Most Of The Time In Treatment She Used 20 Mg		Allergan
	Efexor Depot			S	Oral	75 Mg		Not Reported
	Alopam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15204271	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-929851		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Escitalopram			S	Oral			Ivax
	Amiodarona. Hidrocloruro (392ch)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15205575	NON-EXPEDITED			US-TEVA-2018-US-930837			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Rash	Escitalopram		S	Unknown	Ivax
	Escitalopram		S		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	13428367	EXPEDITED (15-DAY)		HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-028140		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Atrial Fibrillation; Fall; Haematoma Muscle; Haemoglobin Decreased; International Normalised Ratio Abnormal; Labelled Drug-Drug Interaction Medication Error; Overdose; Packed Red Blood Cell Transfusion; Spontaneous Haematoma; Subdural Haematoma	Coumadine			S	Oral	1 Df, Unk		Bristol Myers Squibb
	Seroplex			S	Unknown	1 Df, Unk		Not Reported
	Bisoprolol			C	Unknown	2.5 Mg, Qd		Not Reported
	Allopurinol			C	Unknown	100 Mg, Qd		Not Reported
	Dafalgan			C	Unknown	3 G, Qd		Not Reported
	Lasilix /00032601/			C	Unknown	(Half Tablet Daily)		Not Reported
	Modopar			C	Unknown	4 Tab, Qd		Not Reported
	Skenan			C	Unknown	5 Mg, Qd		Not Reported
	Vogalene			C	Unknown	3 Tab, Qd		Not Reported
	Macrogol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	13901387	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-APOTEX-2017AP017265		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Blindness Cortical; Cardiogenic Shock; Cerebral Infarction; Circulatory Collapse; Colour Blindness; Condition Aggravated; Csf Pressure Increased; Cytotoxic Oedema; Depressed Level Of	Amlodipine			S	Oral	150 Mg, Unk		Apotex
	Amlodipine			S	Oral	Unk		Apotex
	Amlodipine			S	Unknown	150 Unk, Unk Every One Day		Apotex
	Escitalopram			S	Unknown	60 Mg, Unk Every One Day		Apotex
	Escitalopram			S	Oral	60 Unk, Unk		Apotex
	Risperidone			S	Unknown	6 Mg, Unk Every One Day		Apotex

Consciousness; Electrocardiogram P Wave Abnormal; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Amplitude Decreased; Electrocardiogram T Wave Inversion; Electrocardiogram U Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema; Renal Tubular Necrosis; Retinal Ischaemia; Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment	Risperidone	S	Oral	Unk	Apotex
	Risperidone	S	Oral	6 Mg, Unk	Apotex
	Potassium Chloride	S	Oral	Unk	Not Reported
	Potassium Chloride	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Epinephrine	S	Unknown	30 Mg, Unk	Not Reported
	Vasopressin	S	Unknown	Unk	Not Reported
	Norepinephrine Bitartrate	S	Unknown	30 Mg, Unk	Not Reported
	Glucose	S	Unknown	Unk	Not Reported
	Escitalopram Mylan	S	Oral	Unk	Not Reported
	Escitalopram	C	Unknown	60 Mg, Unk	Not Reported
	Activated Charcoal	C	Unknown	50 G, Unk	Not Reported
	Potassium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Potassium Chloride	C	Oral	Unk	Not Reported
	Risperidone	C	Unknown	6 Mg, Unk	Not Reported
	Risperidone	C	Oral	Unk	Not Reported
	Insulin	C	Intravenous bolus	70 Iu, Unk	Not Reported
	Insulin	C	Intravenous (not otherwise specified)	70 Df, Unk One Every One Hour	Not Reported
	Amlodipine	C	Unknown	150 Mg, Unk	Not Reported
	Calcium Gluconate	C	Intravenous (not otherwise specified)	2 G, Unk	Not Reported
	Dextrose	C	Intravenous (not otherwise specified)	1 Df, Unk	Not Reported
	Epinephrine	C	Unknown	25 Mg, Unk	Not Reported
	Epinephrine	C	Unknown	10 Mg, Unk	Not Reported
	Epinephrine	C	Unknown	40 Mg, Unk	Not Reported
	Epinephrine	C	Unknown	30 Mg, Unk	Not Reported
	Glucagon	C	Intravenous (not	5 Mg, Unk	Not Reported

			otherwise specified)			
	Norepinephrine	C	Unknown	40 Mg, Unk		Not Reported
	Norepinephrine	C	Unknown	30 Mg, Unk		Not Reported
	Vasopressin	C	Unknown	2.4 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	14607779	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1812096US		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Somnolence; Sopor; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	400 Mg In Total		Allergan
	Venlafaxine Hydrochloride			S	Oral	525 Mg In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	14651856	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2018-015388		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Furosemide			S	Oral	Unk		Not Reported
	Meropenem			S	Intravenous drip	Unk		Aurobindo
	Bromazepam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Aurobindo
	Escitalopram			S	Unknown	()		Aurobindo
	Ondansetron			S	Oral	Unk		Aurobindo
	Valaciclovir			S	Oral	Unk		Aurobindo
	Doxorubicin			S	Intravenous drip	Unk		Not Reported
	Bisoprolol			S	Oral	Unk		Aurobindo
	Pantoprazole			S	Intravenous drip	Unk		Not Reported
	Prednisone			S	Intravenous drip	Unk		Not Reported
	Ciprofloxacin			S	Intravenous drip	Unk		Not Reported
	Fungizone			S	Buccal	Unk		Not Reported

Exacyl	S	Intravenous drip	Unk	Not Reported
Eprex	S	Subcutaneous	Unk	Not Reported
Zarzio	S	Subcutaneous	Unk	Not Reported
Hextril	S	Buccal	Unk	Not Reported
Lidocaine	S	Buccal	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Calciparine	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Intravenous drip	Unk	Not Reported
Methotrexate	S	Intravenous drip	Unk	Not Reported
Voraxaze	S	Intravenous drip	Unk	Not Reported
Voraxaze	S			Not Reported
Cyclophosphamide	S	Intravenous drip	Unk	Not Reported
Cyclophosphamide	S	Intravenous drip	()	Not Reported
Cyclophosphamide	S	Unknown	()	Not Reported
Cyclophosphamide	S	Unknown	()	Not Reported
Vincristine	S	Intravenous drip	Unk	Not Reported
Bactrim	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	14881674	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-025444		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Drug Ineffective; Drug Interaction; Feeling Of Despair; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation; Treatment Noncompliance	Quetiapine			S	Oral	200 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Alprazolam			S	Oral	1.5 Milligram, Once A Day		Aurobindo
	Alprazolam			S	Unknown	1 Mg		Aurobindo
	Alprazolam			S	Unknown	1.5 Mg,Unk		Aurobindo
	Venlafaxine			S	Oral	300 Milligram, Once A Day		Aurobindo
	Valproic Acid			S	Oral	300 Milligram, Once A Day		Not Reported
	Valproic Acid			S		600 Unk		Not Reported

	Valproic Acid	S		300 Mg,Unk	Not Reported
	Clonazepam	S	Oral	0.5 Milligram, Once A Day	Not Reported
	Trazodone	S	Oral	75 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15107801	EXPEDITED (15-DAY)		HO, OT	IT-TAKEDA-2018TUS021150		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Brintellix			S	Oral	15 Ml, Unk		Takeda
	Paracetamol			S	Oral	2 G, Unk		Not Reported
	Lorazepam			S	Oral	20 Mg, Unk		Not Reported
	Cipralex /01588501/			S	Oral	15 Ml, Unk		Not Reported
	Oxcarbazepine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15166602	NON-EXPEDITED			US-TEVA-2018-US-927913			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Tetany	Escitalopram			S				Not Reported
	Escitalopram			S		Decreased From 10 Mg To 5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15205668	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018015681			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuser	Escitalopram			S	Oral	15 Milliliter, Single Abuse / Misuse		Macleods
	Delorazepam			S	Oral	10 Milliliter, Single Abuse / Misuse		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15205960	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-931018		23 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram			S	Oral	15 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15206408	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2018-03046		19 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Poverty; Hyperhidrosis; Libido Decreased; Off Label Use; Sexual Dysfunction; Sleep Disorder; Weight Increased	Escitalopram			S	Unknown	30 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	150 Mg, Unk		Not Reported
	Venlafaxine			S	Unknown	225 Mg, Unk		Not Reported
	Quetiapine			S	Unknown	12.5 Mg, Qd, At Night		Not Reported
	Bupropion			S	Unknown	150 Mg, Qd		Lupin
	Bupropion			S	Unknown	300 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15207121	EXPEDITED (15-DAY)		OT	SI-ACCORD-070038		49 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Left Ventricular Hypertrophy	Escitalopram			S				Not Reported
	Rosuvastatin			S				Not Reported
	Perindopril/Perindopril Erbumine			S				Not Reported
	Indapamide/Indapamide Hemihydrate			S				Not Reported
	Alprazolam			S		Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15207474	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018015691			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor; Suicidal Ideation	Escitalopram			S	Oral	50 Milligram, Single, Total, Abuse / Misuse		Macleods
	Olanzapine			S	Oral	20 Milligram, Single, Total, Abuse / Misuse		Macleods
	Tavor (Lorazepam)			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15207865	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006561		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amitriptyline			S	Oral	Ingestion		Unknown
	Escitalopram			S	Oral	Ingest		Unknown
	Propranolol			S	Oral	Ingestion		Unknown
	Alprazolam			S	Oral	Ingest		Unknown
	Acetaminophen			S	Oral	Ingest		Unknown
	Ethanol			S	Oral	Ingest		Unknown
	Cocaine			S	Oral	Ingest		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15208012	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2018-ES-930899		18 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypocoagulable State	Ibuprofeno (1769a)			S	Oral	400 Mg X 7 Cps		Actavis
	Paracetamol			S	Oral	12gr Dia		Not Reported
	Escitalopram			S	Oral	5 Cps		Ivax

	Exforge 10 Mg/160 Mg Comprimidos Recubiertos Con Pelicula 28	S	Oral	5 Cps		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15208459	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1837127US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram T Wave Inversion	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15208910	EXPEDITED (15-DAY)		OT	US-TAKEDA-2018TUS023063			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Major Depression; Nausea; Paraesthesia; Suicidal Ideation	Vortioxetine			S	Unknown	5 Mg, Unk		Takeda
	Vortioxetine			S	Unknown	10 Mg, Unk		Takeda
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15208972	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1837069US			Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prescribed Underdose; Somnolence; Suicidal Ideation; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15210332	EXPEDITED (15-DAY)			CA-TEVA-2018-CA-933316		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Condition Aggravated; Mydriasis; Somnambulism	Escitalopram	S	Oral		Not Reported
	Ativan	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2018	15073980	EXPEDITED (15-DAY)		HO	DE-TORRENT-00008683		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Paraesthesia; Prescribed Underdose	Aripiprazole			S	Oral	10 Mg, Qd		Unknown
	Escitalopram			S	Oral	20 Mg, Qd		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2018	15211911	EXPEDITED (15-DAY)		CA, OT	IT-ALEMBIC PHARMACUETICALS LIMITED-2018SCAL000536			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome	Lithium Carbonate			S	Transplacental	Unk		Alembic
	Lithium Carbonate			S				Alembic
	Escitalopram			S		Unk		Not Reported
	Lorazepam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	14323704	EXPEDITED (15-DAY)		OT	PHHY2017ES192734			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence	Amlodipine			S	Unknown	1 Df, Qd (1 Ug/Litre)		Not Reported
	Simvastatin			S	Unknown	Unk, Qd		Not Reported
	Simvastatin			S	Unknown	1 Df, Qd (1 Ug/Litre)		Not Reported
	Simvastatin			S	Unknown	20 Mg, Unk		Not Reported
	Omeprazole			S	Unknown	1 Df, Qd (1 Ug/Litre)		Novartis
	Topiramate			S	Unknown	0.5 Df, Qd (0.5 Ug/Litre)		Not Reported

Topiramate	S	Unknown	1 Df, Qd (1ug/Litre)	Not Reported
Paracetamol	S	Unknown	3 Df, Qd (3 Ug/Litre)	Not Reported
Paracetamol	S	Unknown	1 Df, Tid (3 Ug/Litre)	Not Reported
Escitalopram	S	Unknown	Unk, Qd (1ug/Litre)	Not Reported
Escitalopram	S	Unknown	1 Df, Qd (1 Ug/Litre)	Not Reported
Tramadol+Paracetamol	S	Unknown	3 Df, Qd (3 Ug/Litre)	Not Reported
Tramadol+Paracetamol	S	Unknown	1 Df, Tid (5/325 Mg)	Not Reported
Enalapril Hydrochlorothiazide Bc	S	Unknown	1 Df, Qd (20/12.5 Mg)	Not Reported
Lormetazepam	S	Unknown	1 Df, Qd (1 Ug/Litre)	Not Reported
Glibenclamide	S	Unknown	2 Df, Qd (2 Ug/Litre)	Not Reported
Glibenclamide	S	Unknown	1 Df, Bid (2 Ug/Litre)	Not Reported
Glibenclamide	S	Unknown	Unk	Not Reported
Diazepam	S	Unknown	1 Ot, Qd	Not Reported
Diazepam	S	Unknown	0.5 Df, Qd (0.5 Ug/Litre)	Not Reported
Diazepam	S	Unknown	Unk	Not Reported
Amitriptyline	S	Unknown	Unk	Not Reported
Amitriptyline	S	Unknown	5 Mg, Qd	Not Reported
Amitriptyline	S	Unknown	12.5 Mg, Qd	Not Reported
Amitriptyline	S	Unknown	25 Mg, Unk	Not Reported
Naproxen	S	Unknown	2 Df, Qd (2 Ug/Litre)	Not Reported
Naproxen	S	Unknown	1 Df, Bid (2 Ug/Litre)	Not Reported
Tepazepam	S	Unknown	Unk Unk, Qd	Not Reported
Metoclopramide	C	Unknown	1 Week Treatment	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	14640887	EXPEDITED (15-DAY)		DE, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2018VAL000511		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Furosemide	S	Oral	Unk	Validus
	Pantoprazole	S	Intravenous drip	Unk	Not Reported
	Pantoprazole	S	Unknown	Unk	Not Reported
	Ciprofloxacin /00697202/	S	Intravenous drip	Unk	Not Reported
	Exacyl	S	Intravenous drip	Unk	Not Reported
	Exacyl	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intravenous drip	Unk	Not Reported
	Methotrexate	S	Intravenous drip	Unk	Not Reported
	Prednisone	S	Intravenous drip	Unk	Not Reported
	Ondansetron	S	Oral	Unk	Not Reported
	Bromazepam	S	Oral	Unk	Not Reported
	Bromazepam	S	Unknown	Unk	Not Reported
	Escitalopram Oxalate	S	Oral	Unk	Not Reported
	Escitalopram Oxalate	S	Oral	Unk	Not Reported
	Escitalopram Oxalate	S	Unknown	Unk	Not Reported
	Fungizone	S	Buccal	Unk	Not Reported
	Eprex	S	Subcutaneous	Unk	Not Reported
	Zarzio	S	Subcutaneous	Unk	Not Reported
	Meropenem	S	Intravenous drip	Unk	Not Reported
	Hextril	S	Buccal	Unk	Not Reported
	Hextril	S	Buccal	Unk	Not Reported
	Hextril	S	Unknown	Unk	Not Reported
	Lidocaine	S	Buccal	Unk	Not Reported
	Lidocaine	S	Buccal	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Calciparine	S	Subcutaneous	Unk	Not Reported
	Calciparine	S	Subcutaneous	Unk	Not Reported
	Bisoprolol	S	Oral	Unk	Not Reported
	Doxorubicin	S	Intravenous drip	Unk	Not Reported

	Voraxaze	S	Intravenous drip	Unk		Not Reported
	Valaciclovir	S	Oral	Unk		Not Reported
	Valaciclovir	S	Unknown	Unk		Not Reported
	Valaciclovir	S	Oral	Unk		Not Reported
	Cyclophosphamide	S	Intravenous drip	Unk		Not Reported
	Vincristine	S	Intravenous drip	Unk		Not Reported
	Bactrim	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15084348	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018261695		87 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Dementia; Fall	Halcion			S		Unk		Pfizer
	Spiractin /00006201/			S		Unk		Not Reported
	Dopaquel			S		Unk		Not Reported
	Zytomil			S		Unk		Not Reported
	Vesicare			S		Unk		Not Reported
	Macrodantin			S		Unk		Not Reported
	Euthyrox			S		Unk		Not Reported
	Cardugen			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15213470	NON-EXPEDITED			US-PFIZER INC-2018304914			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Gabapentin			S		Unk		Pfizer
	Ativan			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15213583	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-037813		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram			S	Oral	50 Milligram, In Total		Aurobindo
	Olanzapine			S	Oral	In Total		Aurobindo
	Tavor /00273201/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15213925	EXPEDITED (15-DAY)		HO	PHHY2018FR056263		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Encephalopathy	Amiodarone			S	Oral	200 Mg, Unk		Novartis
	Allopurinol			S	Oral	100 Mg, Unk		Not Reported
	Seroplex			S	Oral	1 Df, Unk		Not Reported
	Topalgic Lp			S	Oral	3 Df, Unk		Not Reported
	Oxynormoro			S	Oral	5 Mg, Unk		Not Reported
	Xanax			S	Oral	0.38 Mg, Unk		Not Reported
	Kardegic			S	Oral	1 Df, Unk		Not Reported
	Tazocilline			S	Intravenous (not otherwise specified)	3 Df, Unk		Not Reported
	Ciclosporine			C	Oral	100 Mg, Unk		Not Reported
	Mycophenolate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15214249	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004502		34 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dyspepsia; Eructation;	Espran			S	Oral	One Tablet Daily		Torrent

Haemangioma Of Liver; Varices Oesophageal	Pantoprazol		C	Oral	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14617659	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-011773		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Prescribed Overdose	Bisoprolol			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	5 Milligram		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14922162	EXPEDITED (15-DAY)		OT	ES-ACCORD-064898			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amitriptyline			S				Accord
	Paracetamol			S	Unknown	1 Df, Tid		Accord
	Simvastatin			S				Accord
	Topiramate			S		1 Df, Qd		Accord
	Diazepam			S		0.5 Df, Qd		Not Reported
	Amlodipine			S		1 Df, Qd		Accord
	Escitalopram			S		1 Df, Qd		Not Reported
	Omeprazole			S		1 Df, Qd		Not Reported
	Lormetazepam			S		1 Df, Qd		Not Reported
	Tepazepam			S		Unk, Qd Dose: 1		Not Reported
	Paracetamol/Tramadol			S		1 Df, Tid		Not Reported
	Naproxen			S		1 Df, Bid		Not Reported
	Enalapril/Hydrochlorothiazide			S		1 Df, Qd		Not Reported
	Glibenclamide			S		1 Df, Bid		Not Reported
	Metoclopramide			C		1 Week Treatment		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15196136	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1836461US		24 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperreflexia; Intentional Self-Injury; Loss Of Consciousness; Mydriasis; Nystagmus; Overdose; Product Use In Unapproved Indication; Tachycardia	Escitalopram Oxalate - Bp			S	Unknown	5 Df; In Total		Allergan
	Lamictal			S	Oral	2800 Mg; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15220201	EXPEDITED (15-DAY)		HO	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018015718			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autonomic Nervous System Imbalance; Malaise; Orthostatic Hypotension	Escitalopram Oxalate			S	Oral	10 Milligram, Qd		Macleods
	Risperdal			S	Oral	1 Unk, Divisible Coated Tablet		Not Reported
	Zopiclone			S	Oral	7.5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15221356	EXPEDITED (15-DAY)		OT	PHHY2018BR060405		85 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Application Site Pruritus; Deafness; Depression	Exelon Patch			S	Unknown			Novartis
	Espran			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15221946	EXPEDITED (15-DAY)		HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-069137		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Eliquis			S	Oral	1 Df, Daily		Bristol Myers Squibb
	Seroplex			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15221980	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1837302US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy; Premature Labour	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Ethyl Loflazepate			C	Unknown	Unk, Unknown		Not Reported
	Alprazolam			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15221985	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1837326US		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Tooth Infection	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15222705	EXPEDITED (15-DAY)		OT	PHEH2018US030749			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Urticaria	Ilevro			S	Ophthalmic	Unk		Novartis
	Durezol			S	Ophthalmic	Unk		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Celexa			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	12763589	EXPEDITED (15-DAY)		HO	FR-SA-2016SA172334		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Interstitial Lung Disease	Cortancyl			S	Oral	5 Mg,Bid		Not Reported
	Triatec (Ramipril)			S	Oral	5 Mg,Qd		Sanofi
	Stilnox			S	Oral	10 Mg,Qd		Sanofi
	Mycophenolate Mofetil			S	Oral	Unk Unk,Bid		Not Reported
	Atorvastatin Calcium			S	Oral	10 Mg,Qd		Not Reported
	Theralene			S	Oral	5 Mg,Bid		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg,Bid		Not Reported
	Ixprim			S	Oral	Unk Unk,Unk,37,5 Mg / 325 Mg Coated Tablets		Not Reported
	Esomeprazole Magnesium			S	Oral	20 Mg,Qd		Not Reported
	Seresta			C		Strength: 50 Mg		Not Reported
	Lasilix [Furosemide]			C		Strength: 40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	14133044	NON-EXPEDITED			JP-ALLERGAN-1750665US		22 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Paxil Cr			S	Oral	37.5 Mg, Qd		Not Reported
	Meilax			C	Unknown			Not Reported
	Meilax			C	Oral			Not Reported
	Akineton			C	Unknown			Not Reported
	Akineton			C	Oral			Not Reported
	Abilify			C	Unknown			Not Reported

	Abilify	C	Oral			Not Reported
	Constan [Alprazolam]	C	Unknown			Not Reported
	Constan	C	Oral			Not Reported
	Methycobal	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	14472465	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-850996		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Level Decreased; Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	30 Milligram Daily;		Ivax
	Escitalopram			S	Oral			Ivax
	Pangrol			C	Unknown	2 Unk, Unk		Not Reported
	Lorazepam			C	Unknown			Not Reported
	Olanzapine			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	14775852	EXPEDITED (15-DAY)			FR-JNJFOC-20180406793		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Tramadol Hydrochloride			S	Oral			Not Reported
	Golimumab			S	Subcutaneous			Not Reported
	Seroplex			S	Oral			Not Reported
	Bilaska			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Nocertone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15013981	NON-EXPEDITED			PHEH2018US023706		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Erythema; Hypersensitivity; Pain Of Skin; Pruritus; Rash; Rash Erythematous; Skin Exfoliation; Skin Irritation; Skin Oedema; Urticaria	Cosentyx	S	Subcutaneous	300 Mg, Qw		Novartis
	Cosentyx	S				Novartis
	Lexapro	S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15049790	EXPEDITED (15-DAY)		HO	PHHY2018FR025250		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Esidrex			S	Oral	0.5 Df, Qd		Novartis
	Esomeprazole			S	Oral	40 Mg, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Procoralan			C	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Seresta			C	Unknown	Breackable		Not Reported
	Dafalgan			C	Unknown	Unk		Not Reported
	Pravastatine			C	Unknown			Not Reported
	Mediatensyl			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown			Not Reported
	Ramipril			C				Not Reported
	Acebutolol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15160037	EXPEDITED (15-DAY)		HO, LT	DE-FRESENIUS KABI-FK201807869		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Linezolid (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	Linezolide 600mg Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Esomeprazole			S	Unknown			Not Reported

	Escitalopram	S	Unknown	Unk	Not Reported
	Levothyroxine Sodium	C			Not Reported
	Lorazepam	C		Daily Dose: 1 Mg Millgram(S) Every Days	Not Reported
	Hyoscine Hydrobromide	C	Transdermal		Not Reported
	Levetiracetam	C		Daily Dose: 2 Df Dosage Form Every Days	Not Reported
	Prednisolone	C			Not Reported
	Ivabradine	C		Daily Dose: 15 Mg Millgram(S) Every Days	Not Reported
	Naloxone/Tilidine	C			Not Reported
	Sulfamethoxazole/Trimethoprim	C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days	Not Reported
	Baclofen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15191730	EXPEDITED (15-DAY)		CA	DE-PFIZER INC-2018292736			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Oesophageal Atresia; Premature Baby	Lorazepam			S	Transplacental	Unk		Pfizer
	Mycophenolate Mofetil			S	Transplacental	Unk		Not Reported
	Zolpidem			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15226032	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006634		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Abuse; Toxicity To Various Agents	Bupropion			S	Unknown	Unknown		Unknown
	Escitalopram			S	Unknown	Unknown		Unknown
	Alprazolam			S	Unknown	Unknown		Unknown
	Ethanol			S	Unknown	Unknown		Unknown

	Cocaine			S	Unknown	Unknown				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15226956	EXPEDITED (15-DAY)		HO	PHHY2018LU061172		47 YR	Female	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Actin Antibody Positive; Gamma-Glutamyltransferase Increased; Hepatocellular Injury	Gilenya			S	Oral	1 Df, Qd		Novartis
	Escitalopram			S	Oral			Not Reported
	Lyrica			C	Oral	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15227112	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1837818US		50 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromaturia; Constipation; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15227132	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1837820US		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Overdose; Sopor; Therapy Change	Escitalopram Oxalate - Bp			S	Oral	3 Df, Total		Allergan
	Anafranil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15227540	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018304932		67 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Gastric Disorder	Aspavor			S		Unk		Pfizer
	Ecotrin			S		Unk		Not Reported

	Bilocor	S	Unk	Not Reported
	Clopiwin	S	Unk	Not Reported
	Zytomil	S	Unk	Not Reported
	Trustan	S	Unk	Not Reported
	Zartan Co	S	Unk	Not Reported
	Humalog Mix	S	Unk	Not Reported
	Diaphage	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15227602	EXPEDITED (15-DAY)		OT	PL-PFIZER INC-2018298726			Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Cyanosis; Syncope	Acetylsalicylic Acid			S		Unk		Pfizer
	Amlodipine Besilate			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported
	Insulin			S		Unk		Not Reported
	Polmatine			S		Unk		Not Reported
	Metoprolol			S		Unk		Not Reported
	Perindopril			S		Unk		Not Reported
	Rivastigmine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15228713	EXPEDITED (15-DAY)		HO	PHHY2017FR204444		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria; Hyperkalaemia; Intentional Overdose; Sinus	Bisoprolol Fumarate			S	Oral	2 Ot, Qd (3.25 Mg In The Morning And 2.5 Mg In The Evening)		Novartis
	Bisoprolol Fumarate			S	Oral	Unk		Novartis
	Tahor			S	Oral	Unk		Not Reported

Bradycardia; Somnolence	Tahor	S	Oral	40 Mg, Qd ((40 Mg/Day)	Not Reported
	Diffu-K	S	Oral	Unk	Not Reported
	Diffu-K	S	Oral	Unk	Not Reported
	Triatec (Ramipril)	S	Oral	Unk	Not Reported
	Triatec (Ramipril)	S	Oral	2.5 Mg, Bid (2.5 Mg 2/Day)	Not Reported
	Brilique	S	Oral	90 Mg, Bid (90 Mg 2/Day)	Not Reported
	Brilique	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	5 Mg, Qd (5 Mg/Day)	Not Reported
	Inexium	C	Unknown	20 Mg, Qd (20 Mg/Day)	Not Reported
	Kardegic	C	Unknown	75 Mg, Qd (75 Mg/Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15285175	DIRECT	Y				25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15120524	EXPEDITED (15-DAY)		HO	PHHY2018ES065501		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Condition Aggravated; Electrocardiogram Qt Prolonged; Hypomagnesaemia; Mental Disorder; Myocardial Ischaemia; Tachycardia; Torsade De Pointes	Escitalopram			S	Unknown	15 Mg, Qd		Not Reported
	Pantoprazole			S	Unknown	Unk		Novartis
	Haloperidol			S	Unknown	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15178796	EXPEDITED (15-DAY)		DS	PHHY2018DE050632			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Gait Disturbance; Hyperhidrosis; Hypoaesthesia; Insomnia; Malaise; Muscle Twitching; Off Label Use; Palpitations; Paraesthesia; Tremor	Escitalopram			S	Oral	1 Df, Qd (10 Mg)		Not Reported
	Escitalopram			S	Oral	1 Df, Qd (20 Mg)		Not Reported
	Oxazepam			S	Oral	10 Mg, Qd		Novartis
	Monostep			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15229691	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-038517		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autonomic Nervous System Imbalance; Malaise; Orthostatic Hypotension	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo
	Zopiclone			S	Oral	7.5 Milligram, Daily		Not Reported
	Risperdal			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15230581	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00737			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15230844	EXPEDITED (15-DAY)		OT	DE-TORRENT-00009105			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Renal Failure	Escitalopram		S	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15231786	EXPEDITED (15-DAY)		OT	CH-SA-2018SA197380		83 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Disturbance In Attention	Pramipexole Hydrochloride			S	Oral	0.125 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported
	Allopurinol			S	Oral	100 Mg, Bid		Not Reported
	Allopurinol			S	Oral	100 Mg, Qd		Not Reported
	Metoprolol Succinate			S	Oral	50 Mg, Qd		Not Reported
	Plavix			S	Oral	75 Mg, Qd		Sanofi
	Plavix			S	Oral	75 Unk		Sanofi
	Prednisolone			S	Unknown	Spiricort® Filmtabl 20 Mg (Prednisolon); 15 Mg - 0 - 5 Mg – 0, Bis Am 02.06.2018		Not Reported
	Tramadol Hydrochloride			S	Oral	Tramal® Tropfen (100 Mg = 40 Gtt) 100 Mg/1 Ml ; As Necessary		Not Reported
	Oxycodone Hydrochloride			S	Oral	As Necessary		Not Reported
	Morphine Hydrochloride			S	Oral	In Total		Not Reported
	Morphine Hydrochloride			S	Oral	In Total		Not Reported
	Quetiapine Fumarate			S	Oral	In Total		Not Reported
	Quetiapine Fumarate			S	Oral	In Total		Not Reported
	Quetiapine Fumarate			S	Oral	25 Mg, Qd		Not Reported
	Diazepam			S	Oral	As Necessary		Not Reported
	Haloperidol			S	Oral	In Total		Not Reported
	Fentanyl Citrate			S	Intravenous (not otherwise specified)	25 Mg, Qd		Not Reported

Lisitril	S	Oral	20 Mg, Qd		Not Reported
Aspirin Cardio	C	Oral	100 Mg, Qd		Not Reported
Atorvastatin Pfizer	C	Oral	20 Mg, Qd		Not Reported
Dafalgan	C	Oral	500 Mg, Tid		Not Reported
Spiriva	C				Not Reported
Torem	C	Unknown	5 Mg, Qd		Not Reported
Novalgin (Metamizole Sodium)	C	Oral	As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15232044	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-ALLERGAN-1838278US		40 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Fibrillation; Dizziness; Eye Disorder; Myalgia; Palpitations; Product Use Issue; Tooth Injury	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Q12h		Allergan
	Quetiapin Sandoz			S	Unknown	25 Mg, Q12h		Not Reported
	Calcigran Forte			S	Unknown	4 Iu, Q12h		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Etalpha			C	Oral			Not Reported
	Zopiklon Mylan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15232552	EXPEDITED (15-DAY)		OT	PHHY2018CA001594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Increased; Drug Ineffective; Fatigue; Lip Swelling; Sleep Deficit	Xolair			S	Subcutaneous	300 Mg, Every 4 Weeks		Not Reported
	Xolair			S	Subcutaneous	300 Mg, Every 4 Weeks		Not Reported
	Xolair			S	Subcutaneous	300 Mg, Every 4 Weeks		Not Reported
	Metformin			S	Oral	2 Df, Bid		Not Reported
	Clonazepam			S	Oral	1 Df, Bid		Not Reported
	Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Candesartan			S	Oral	1 Df, Qd		Not Reported

Candesartan	S	Unknown	16 Mg, Unk		Not Reported
Simvastatin	S	Oral	2 Df, Qd		Not Reported
Prednisone	C	Oral	1 Df, Qd		Not Reported
Abilify	C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15233301	EXPEDITED (15-DAY)		HO	AU-MYLANLABS-2018M1057404		37 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Mental Disorder; Persecutory Delusion	Escitalopram			S	Unknown	7 Months Prior To The Commencement Of Ademetionine.		Not Reported
	S-Adenosyl-L-Methionine			S	Unknown	She Started Ademetionine In Conjunction With An Ssri, Eight Months Prior To Hospitalisation		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15233629	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2018IN20392			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown	20 Mg, Per Day		Invagen
	Amisulpride			S	Unknown	100 Mg, Per Day		Not Reported
	Amisulpride			S	Unknown	400 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	13937162	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2017PL129784			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Condition Aggravated; Depression; Drug Abuse; Drug Ineffective; Impaired	Bisoprolol			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported

Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Atorvastatin	S	Unknown	Unk	Novartis
	Atorvastatin	S	Oral	B/D	Novartis
	Atorvastatin	S	Oral	Unk, Qhs	Novartis
	Zolpidem	S	Unknown	10 Mg, Qhs	Not Reported
	Zolpidem	S	Oral	B/D	Not Reported
	Zolpidem	S	Oral	10 Mg, Qhs	Not Reported
	Zolpidem	S	Oral	10 Mg, Qhs	Not Reported
	Clarithromycin	S	Unknown	Two 10 Day Courses	Not Reported
	Clarithromycin	S	Unknown	Unk	Not Reported
	Clarithromycin	S	Unknown	Unk	Not Reported
	Clarithromycin	S	Oral	Two 10 Day Cycles.	Not Reported
	Sertraline	S	Unknown	50 Mg, Qd	Not Reported
	Sertraline	S	Unknown	50 Mg In The Morning	Not Reported
	Sertraline	S	Oral	50 Mg, Qd	Not Reported
	Escitalopram	S	Unknown	10 Mg, Unk	Not Reported
	Escitalopram	S	Oral	10 Mg, Before Sleeping	Not Reported
	Escitalopram	S	Unknown	Doctor Switched The Patient From Sertraline To Escitalopram	Not Reported
	Escitalopram	S	Oral	10 Mg, Hs (Doctor Switched The Patient From Sertraline To Escitalopram)	Not Reported
	Escitalopram	S	Unknown	Unk	Not Reported
	Tramadol	S	Unknown	Unk	Not Reported
	Tramadol	S	Unknown	Unk	Not Reported
	Tramadol	S	Unknown	Unk	Not Reported
	Tramadol	S	Unknown	Tramadol In Combination With Meloxicam For About Two Years Ago	Not Reported
	Meloxicam	S	Unknown	Unk	Not Reported

	Meloxicam	S	Oral	B/D	Not Reported
	Meloxicam	S	Oral	Tramadol In Combination With Meloxicam, For About Two Years Ago	Not Reported
	Perindopril	S	Unknown	Unk	Not Reported
	Perindopril	S	Unknown	Unk	Not Reported
	Doxepin	S	Unknown	25 Mg, Qhs	Not Reported
	Doxepin	S			Not Reported
	Trosicam	S	Unknown	Unk	Not Reported
	Atoris	S	Unknown		Not Reported
	Atoris	S			Not Reported
	Polsen	S	Unknown	10 Mg, (Od At Bed Time)	Not Reported
	Polsen	S	Oral	10 Mg, (Od At Bedtime)	Not Reported
	Concor	S	Unknown		Not Reported
	Concor	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	14772761	EXPEDITED (15-DAY)		OT	NL-TEVA-2018-NL-850962		36 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swelling Face	Escitalopram Tablet, 5 Mg (Milligram)			S	Unknown	5 Milligram Daily; 1x Daily 1 Tablet		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	14818901	EXPEDITED (15-DAY)		HO, LT, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018012786			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram Oxalate			S	Unknown	5 Milligram		Macleods
	Linezolid			S	Intravenous (not otherwise specified)	2 Dosage Form, Qd, Linezolid 600 Mg		Not Reported
	Esomeprazol			S	Unknown	40 Milligram		Not Reported

	Prednisolone 10 Mg	C	Unknown	10 Milligram	Not Reported
	Levetiracetam	C	Unknown	2 Dosage Form, Qd, 1.5g	Not Reported
	L-Thyroxin	C	Unknown	75 Microgram	Not Reported
	Ivabradine	C	Unknown	15 Milligram, Qd	Not Reported
	Cotrimoxazol	C	Intravenous (not otherwise specified)	2 Dosage Form, Qd (Cotrimoxazol 960mg)	Not Reported
	Naloxone, Tilidine	C	Unknown	10 Drop, 25/2mg	Not Reported
	Scopolamin	C	Transdermal	Unk, Scopolamine Plaster	Not Reported
	Baclofen	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	1 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	14917979	EXPEDITED (15-DAY)		DE, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-167094		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Pantoprazole			S	Intravenous drip	Unk		Sun
	Valaciclovir			S	Oral	Unk		Sun
	Escitalopram			S	Oral	Unk		Not Reported
	Fungizone			S	Buccal	Unk		Not Reported
	Exacyl			S	Intravenous drip	()		Not Reported
	Eprex			S	Subcutaneous	Unk		Not Reported
	Ciprofloxacine			S	Intravenous drip	Unk		Not Reported
	Zarzio			S	Subcutaneous	Unk		Not Reported
	Meropenem Anhydre			S	Intravenous drip	Unk		Not Reported
	Hextril			S	Buccal	Unk		Not Reported
	Furosemide			S	Oral	Unk		Not Reported
	Lidocaine			S	Buccal	Unk		Not Reported
	Rituximab ((Mammifere/Hamster/Cellules Cho))			S	Intravenous drip	Unk		Not Reported

Calciparine	S	Subcutaneous	Unk		Not Reported
Bisoprolol (Fumarate Acide De)	S	Oral	Unk		Not Reported
Methotrexate	S	Intravenous drip	Unk		Not Reported
Doxorubicine (Chlorhydrate De)	S	Intravenous drip	Unk		Not Reported
Voraxaze	S	Intravenous drip	Unk		Not Reported
Cyclophosphamide	S	Intravenous drip	Unk		Not Reported
Prednisone	S	Intravenous drip	Unk		Not Reported
Ondansetron	S	Oral	Unk		Not Reported
Vincristine (Sulfate De)	S	Intravenous drip	Unk		Not Reported
Bactrim	S	Oral	Unk		Not Reported
Bromazepam	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15192711	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US20222			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Deafness; Depression; Dyspnoea; Hallucination; Insomnia; Panic Attack; Somnambulism; Somnolence; Thought Blocking	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Escitalopram			S				Invagen
	Benazepril			C	Unknown	10 Mg, Unk		Not Reported
	Allopurinol			C	Unknown	100 Mg, Bid		Not Reported
	Lasix /00032601/			C	Unknown	Unk, Bid		Not Reported
	Novolin			C	Unknown	50 Units, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15234231	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE-HET2018DE00741		55 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia; Product Used For Unknown Indication	Escitalopram			S	Unknown	Nk		Hetero
	Acetylsalicylsaeure			C	Unknown	Nk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15234423	EXPEDITED (15-DAY)		OT	BR-ROCHE-2147191		24 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Balance Disorder; Coordination Abnormal; Dizziness; Multiple Sclerosis	Rivotril			S	Unknown			Not Reported
	Rivotril			S				Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15235479	EXPEDITED (15-DAY)		HO, OT	AT-ACCORD-070337		58 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Lethargy; Sedation; Social Avoidant Behaviour; Tremor	Topiramate			S	Oral			Accord
	Pregabalin			S	Oral	375 Mg On 08-Feb-2016 300 Mg 09-Feb To 10-Feb-2016		Not Reported
	Risperidone			S				Not Reported
	Cipralex			S	Oral			Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15235484	EXPEDITED (15-DAY)		DE	FR-ACCORD-070434		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Escitalopram			S	Oral			Not Reported
	Tiapridal			S	Oral			Not Reported
	Orozamudol			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15236102	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018015964			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Malaise; Tremor; Vertigo	Escitalopram Oxalate			S	Oral	15 Milligram, Qd		Macleods
	Deniban			S	Oral	25 Milligram, Qd, Compresse		Not Reported
	Valium			S	Oral	16 Drop, Qd		Not Reported
	Leponex			S	Oral	150 Milligram, Qd Compresse		Not Reported
	Arlevertan			S	Oral	3 Dosage Form, Qd, Compress		Not Reported
	Resilient			S	Oral	1 Dosage Form, Qd, Prolonged Release Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15236286	EXPEDITED (15-DAY)		HO	US-APOTEX-2018AP018543		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Priapism; Treatment Noncompliance	Trazodone			S	Unknown	200 Mg, Qd		Apotex
	Escitalopram			S	Unknown	20 Mg, Qd		Apotex
	Valproic Acid			S	Unknown			Apotex
	Buspirone			S	Unknown			Apotex
	Duloxetine			S	Unknown			Apotex
	Modafinil			S	Unknown			Apotex
	Prazosin			S	Unknown	20 Mg, Qd		Not Reported
	Nortriptyline			S	Unknown			Not Reported
	Methylphenidate			S	Unknown	10 Mg, Qd		Not Reported
	Methylphenidate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15236778	EXPEDITED (15-DAY)		HO, OT	AU-TORRENT-00000275		44 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective	Olanzapine			S		Unknown		Unknown
	Escitalopram Oxalate			S				Unknown
	Quetiapine			S				Unknown
	Risperidone			S		Unknown		Unknown
	Clomipramine			S		Unknown		Unknown
	Amisulpride			S		Unknown		Unknown
	Clozapine			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15237197	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-038648			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Escitalopram			S	Unknown	Low Dose, At Last 10-15 Mg Qd ()		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15239002	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-934860		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Sopor; Therapy Change	Escitalopram Oxalate			S	Oral			Ivax
	Anafranil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2018	15067964	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	PHHY2017BE200004			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death Neonatal; Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine	S	Transplacental	Maternal Dose: 5 Mg Qd	Not Reported
	Pantoprazole	S	Transplacental		Novartis
	Ventolin (Salbutamol Sulfate)	S	Transplacental	Maternal Dose: 100 Ug Unk	Not Reported
	Avamys	S	Transplacental	Maternal Dose: 2 Ot Bid	Not Reported
	Seretide	S	Transplacental	Unk	Not Reported
	Sipralexa	S	Transplacental	Maternal Dose: 10 Mg Unk	Not Reported
	Relvar Ellipta	S	Transplacental	Maternal Dose: 1 Ot, Qd	Not Reported
	Flixotide	S	Transplacental	Maternal Dose: 250 Ug, Bid	Not Reported
	D-Cure	S	Transplacental	Maternal Dose: 25 Kiu, Unk	Not Reported
	Pantomed (Pantoprazole Sodium Sesquihydrate)	S	Transplacental		Not Reported
	Nucala	S	Transplacental	Maternal Dose: 100 Mg, Unk	Not Reported
	Xanthium (Theophylline)	S	Transplacental	Maternal Dose: 200 Mg, Qd	Not Reported
	Fluticasone Furoate	S	Transplacental	Maternal Dose: 1 Ot, Qd	Not Reported
	Vilanterol Trifenatate	S	Transplacental	Maternal Dose: 1 Df, Qd	Not Reported
	Xyzall	S	Transplacental	Maternal Dose: 5 Mg, Qd	Not Reported
	Theophylline	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2018	15241436	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-038935		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Somnolence	Escitalopram			S	Oral	28 Dosage Form		Aurobindo
	Paroxetine			S	Oral	12 Dosage Form		Aurobindo
	Ibuprofen			S	Oral	20 Dosage Form		Aurobindo
	Havlane			S	Oral	20 Dosage Form		Not Reported

	Dafalgan		S	Oral	8 Gram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2018	15241670	NON-EXPEDITED			US-JNJFOC-20180730788		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Oedema Peripheral; Weight Increased	Xarelto			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Spironolactone			C	Unknown			Not Reported
	Remeron			C	Unknown			Not Reported
	Digestive Enzyme			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2018	15290650	DIRECT		OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Mental Disorder; Product Substitution Issue	Escitalopram		Y	S	Oral	Quantity:1 Tablet(S);	2 YR	Unknown
	Clonazepam			C				Not Reported
	Omega 3 Fish Oil			C				Not Reported
	Magnesium			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15218734	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US20404			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Noncompliance	Escitalopram			S	Unknown	10 Mg, Daily		Invagen
	Escitalopram			S	Unknown	20 Mg, Per Day		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	20 Mg, Per Day		Invagen
	Amlodipine			C	Unknown	2.5 Mg, Daily		Not Reported

	Pantoprazole	C	Unknown	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15242258	EXPEDITED (15-DAY)		OT	PL-ACCORD-070421			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Seizure	Escitalopram			S				Not Reported
	Bupropion/Bupropion Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15243373	EXPEDITED (15-DAY)		OT	US-TORRENT-00006701		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Hyperkeratosis; Tardive Dyskinesia	Aripiprazole			S		Unknown		Unknown
	Lithium Citrate			S		Unknown		Unknown
	Escitalopram			S		Unknown		Unknown
	Bupropion			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15243463	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1837370US		63 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Restlessness; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Amoban			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15244454	EXPEDITED (15-DAY)		OT	FR-ELI_LILLY_AND_COMPANY-FR201807012758		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyponatraemia	Gemzar	S	Intravenous (not otherwise specified)	1.5 G, Unknown	Eli Lilly And Co
	Cisplatine	S	Intravenous drip	25 Mg/M2, Unk	Not Reported
	Escitalopram	S	Oral	10 Mg, Daily	Not Reported
	Alprazolam	C	Oral	.25 Mg, Daily	Not Reported
	Propranolol	C	Oral	Unk	Not Reported
	Fluconazole	C	Oral	100 Mg, Daily	Not Reported
	Coaprovel	C	Oral		Not Reported
	Levothyroxine Sodique	C	Oral	100 Mg, Daily	Not Reported
	Lansoprazole	C	Oral	30 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15244611	EXPEDITED (15-DAY)		HO, LT, OT	FR-GLAXOSMITHKLINE-FR2018137897		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension; Suicide Attempt	Propranolol			S	Oral	Unk		Glaxosmithkline
	Paracetamol			S	Oral	Unk		Glaxosmithkline
	Lamotrigine			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Alprazolam			S	Oral	Unk		Not Reported
	Ibuprofene			C	Unknown	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15245524	EXPEDITED (15-DAY)		HO	PHHY2018FR061608		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperleukocytosis; Pancreatitis; Renal Failure	Escitalopram			S	Oral	140 Mg, Unk		Not Reported
	Ibuprofen			S	Oral	6 G, Unk		Novartis
	Paracetamol			S	Unknown	8.8 G, Unk		Not Reported

	Atarax	S	Oral	750 Mg, Unk		Not Reported
	Cefuroxime	C	Oral	Unk		Not Reported
	Alprazolam	C	Oral	5 Mg, Unk		Not Reported
	Brexin	C	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15245630	EXPEDITED (15-DAY)		HO	PHHY2018FR058677		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Mirtazapine			S	Oral	15 Mg, Unk		Not Reported
	Bisoprolol Fumarate			S	Oral	10 Mg, Unk		Novartis
	Modopar			S	Oral	3 Df, Unk		Not Reported
	Risperdal			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	1 Df, Unk		Not Reported
	Kardegic			C	Oral	1 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15245646	EXPEDITED (15-DAY)		OT	PHHY2018FR059294		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Bromazepam			S	Oral	18 Mg, Unk		Not Reported
	Irbesartan			S	Oral	75 Mg, Unk		Novartis
	Fenofibrate			S	Oral	67 Mg, Unk		Not Reported
	Naproxene			S	Oral	1100 Mg, Unk		Not Reported
	Levothyroxine Sodique			S	Oral	75 Ug, Unk		Not Reported
	Pregabaline			S	Oral	150 Mg, Unk		Not Reported
	Pregabaline			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15245647	EXPEDITED (15-DAY)	Y	HO	PHHY2018FR059739		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Somnolence	Rilmenidine Sandoz 1 Mg,Compressed			S	Oral	2 Df, Qd		Not Reported
	Zolpidem Sandoz			S	Oral	1 Df, Qd		Novartis
	Bisoprolol Teva			S	Oral	1 Df, Qd		Not Reported
	Escitalopram Arrow			S	Oral	1 Df, Qd		Not Reported
	Pravastatine Biogaran 20 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Df, Qd		Not Reported
	Inexium			C	Unknown	Unk		Not Reported
	Aerius (Desloratadine)			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15246268	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2018M1057981		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy; Product Use In Unapproved Indication; Toxicity To Various Agents	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	13423965	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1713804US		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased; Overdose; Spontaneous Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Coumadine			S	Oral	2 Mg, Bid		Not Reported
	Bisoprolol			C	Unknown	2.5 Mg, Qd		Not Reported

Allopurinol	C	Unknown	100 Mg, Qd		Not Reported
Dafalgan	C	Unknown	3 G, Qd		Not Reported
Lasilix	C	Unknown	500 Mg, Qd		Not Reported
Modopar	C	Unknown	500 Mg, Qid		Not Reported
Skenan	C	Unknown	5 Mg, Qd		Not Reported
Macrogol	C	Unknown			Not Reported
Vogalene	C	Unknown	7.5 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	14347045	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018002426		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Somnolence; Sopor; Suicide Attempt	Venlafaxine Hcl			S	Oral	525 Mg, Single		Pfizer
	Escitalopram			S	Oral	400 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	14944519	EXPEDITED (15-DAY)		OT	CA-MACLEODS PHARMACEUTICALS US LTD-MAC2018013744			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	15 Milligram, Qd		Not Reported
	Heparin			S	Subcutaneous	Unk Unk, 5000 U, 12 Hour		Not Reported
	Heparin			S	Subcutaneous	Unk, Every 12 Hour		Not Reported
	Bupivacaine			C	Intravenous (not otherwise specified)	1 Mg/Ml, Infusion		Not Reported
	Bupivacaine			C	Unknown	Unk		Not Reported
	Epinephrine			C	Unknown	Q, A Test Dose Of 3 Ml Of Lidocaine 2% With		Not Reported

				Epinephrine 5 ?G/Ml	
	Epinephrine	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk,10 ?G/Ml Was Initiated During The Procedure And Maintained At 6 Ml/H, Infusion	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Lidocaine	C	Unknown	3 Milliliter, A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 ?G/Ml	Not Reported
	Lidocaine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15133890	EXPEDITED (15-DAY)		HO, OT	AU-009507513-1807AUS002839		86 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Simvastatin			S		Unk		Merck
	Denosumab			S		Unk, Cyclical		Not Reported
	Escitalopram			S		Unk		Not Reported
	Esomeprazole			S		Unk		Not Reported
	Naloxone Hydrochloride			S				Not Reported
	Oxybutynin			S		Unk		Not Reported
	Pregabalin			S		Unk		Not Reported
	Telmisartan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15204218	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1055049		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Contusion; Fall; Syncope	Escitalopram			S	Unknown	Nk		Not Reported
	Eferox			C		50 Mg, 1-0-0-0		Mylan

Hct	C	12.5 Mg, 1-0-0-0	Mylan
Metoprolol	C	47.5 Mg, 1-0-0-0	Mylan
Ventolair	C	250 Mg, 2-0-0-2	Mylan
Metamizole	C	500 Mg, 1-1-1-0	Mylan
Valsartan	C	80 Mg, 0.5-0-0-1	Mylan
Ass Al	C	100 Mg, 0-1-0-0	Mylan
Simvastatin	C	40 Mg, 0-0-0-1	Mylan
Pantoprazol /01263201/	C	20 Mg, 1-0-0-0	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15240166	NON-EXPEDITED			PHEH2018US031713		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Cold; Migraine; Pain; Tremor	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Lexapro			S	Unknown	Unk		Not Reported
	Topamax			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Sumatriptan			C	Unknown			Not Reported
	Vitamin D2			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Ketorolac Tromethamine			C	Unknown			Not Reported
	Zofran			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15247591	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-180698			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram			S	Oral	In Total		Not Reported

	Olanzapine	S	Oral	In Total	Sun
	Tavor (Lorazepam)	S	Oral	()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15248093	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018015986			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma; Menorrhagia; Sleep Disorder	Aripiprazole 5 Mg			S	Unknown	5 Milligram, Qd		Macleods
	Escitalopram			S	Unknown	15 Milligram, Qd, 15 Milligram Daily; Reduced To 15 Mg/Day, Action Taken: Dose Halved And Withdrawn		Macleods
	Escitalopram			S	Unknown	20 Milligram, Qd, In A Morning Target Dose Of 20 Mg, Action Taken: Dose Halved And Withdrawn		Macleods
	Escitalopram			S	Unknown	Increased To A Dose Of 20 Mg Daily		Macleods
	Risperidone			S	Unknown	0.5 Milligram		Not Reported
	Risperidone			S				Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	100 Milligram, Qd, Evening Dose Of 100 Mg		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	Evening Dose Of 100 Mg		Not Reported
	Opipramol			C	Unknown	Unk, In Crisis Situations With Temporary Effect		Not Reported
	Lorazepam			C	Unknown	Unk, In Crisis Situations With Temporary Effect		Not Reported
	Promethazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15250121	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018271546		46 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity	Methotrexate			S		15 Mg, Weekly (6 Tablets A Week)		Pfizer
	Arcoxia			S		90 Mg, Unk		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported
	Adco Zopimed			S		7.5 Mg, Unk		Not Reported
	Synaleve /01057301/			S		Unk		Not Reported
	Lunar [Cyproterone Acetate\Ethinyl Estradiol]			S		20 Mg, Unk		Not Reported
	Trepiline /00002201/			S		10 Mg, Unk		Not Reported
	Stilpane /01152401/			S		Unk		Not Reported
	Prednisone			S		5 Mg, Unk		Not Reported
	Folic Acid			S		5 Mg, Unk		Not Reported
	Eltroxin			S		100 Ug, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15296267	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Trintillex			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	12786872	EXPEDITED (15-DAY)		HO, LT, OT	FR-ALLERGAN-1669849US		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Interstitial Lung Disease; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Q12h		Allergan
	Cellcept			S	Oral	2 G, Bid		Not Reported

Cortancyl	S	Oral	10 Mg, Bid		Not Reported
Tahor	S	Oral	10 Mg, Qd		Not Reported
Theralene	S	Oral	5 Mg, Q12h		Not Reported
Triatec (Ramipril)	S	Oral	5 Mg, Qd		Not Reported
Stilnox	S	Oral	10 Mg, Qd		Not Reported
Ixprim	S	Oral	Unk		Not Reported
Inexium	S	Oral	20 Mg, Qd		Not Reported
Seresta	C	Unknown	Unk		Not Reported
Lasilix	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15014026	EXPEDITED (15-DAY)		HO, OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-053358		90 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Delirium; Fall; Post Procedural Haemorrhage; Traumatic Haemorrhage	Eliquis			S	Unknown	5 Mg, Bid		Bristol Myers Squibb
	Eliquis			S	Unknown	Unk		Bristol Myers Squibb
	Escitalopram			S	Unknown	15 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15234330	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US20359			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Escitalopram			S	Unknown	5 Mg, Qd (1 Each Every Morning)		Invagen
	Escitalopram			S	Unknown	10 Mg, Qd (1 Each Every Morning)		Invagen
	Motrin			C	Unknown	400 Mg, Evening		Not Reported
	Centrum /02267801/			C	Unknown	Unk		Not Reported
	Clobetasol			C	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15253988	EXPEDITED (15-DAY)		DS	FI-MACLEODS PHARMACEUTICALS US LTD-MAC2018016269			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Hypoaesthesia; Musculoskeletal Pain; Myalgia; Pain In Extremity; Paraesthesia; Sleep Disorder	Escitalopram Oxalate			S	Oral	10 Milligram, Qd		Macleods
	Cohemin Depot			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15254069	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2018-039199		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension	Paracetamol			S	Oral	Unk		Aurobindo
	Lamotrigine			S	Oral	Unk		Aurobindo
	Alprazolam			S	Oral	Unk		Aurobindo
	Escitalopram			S	Oral	Unk		Aurobindo
	Propranolol			S	Oral	Unk		Not Reported
	Ibuprofene			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15254501	EXPEDITED (15-DAY)		HO, LT, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018016259			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension	Escitalopram Oxalate			S	Oral	Unk		Macleods
	Paracetamol			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported

Alprazolam	S	Oral	Unk		Not Reported
Lamotrigine	S	Oral	Unk		Not Reported
Ibuprofene	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15256165	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1839087US		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan
	Tofranil			S	Unknown	Unk, Unknown		Not Reported
	Coumadine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15256336	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1839058US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Escitalopram Oxalate - Bp			S	Unknown	Low Dose, At Last 10-15 Mg Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15256343	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1839101US		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Hyperthermia; Malaise; Nausea; Night Sweats; Pruritus; Serotonin Syndrome; Tremor	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Tramadol			S	Oral	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15257493	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1838288US		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Haemorrhage Subcutaneous	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Bid		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Bid		Allergan
	Ibuprofen			C	Unknown	200 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15009479	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2018-04093		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oromandibular Dystonia	Paroxetine			S	Unknown	Unk		Lupin
	Paroxetine			S	Unknown	Unk		Lupin
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15093243	EXPEDITED (15-DAY)		HO, OT	DE-ALLERGAN-1832633US		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Seizure	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Asenapine Maleate - Bp			S	Oral	5 Mg, Qd		Allergan
	Dexamethasone			S	Oral	8 Mg, Qd		Not Reported
	Pantozol			C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15178047	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2423037-00		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fluid Retention; Skin Fissures; Skin Odour Abnormal; Suicidal Ideation	Mavyret			S	Oral			Not Reported
	Xarelto			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

	Darvocet	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15258700	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-936341		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Trimethoprim			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Cabergoline			S	Unknown			Ivax
	Carbidopa			S	Unknown			Not Reported
	Septrin			S	Unknown			Not Reported
	Stalevo			S	Unknown			Not Reported
	Entacapone			S	Unknown			Not Reported
	Levodopa			S	Unknown			Not Reported
	Co-Beneldopa Capsules			C	Unknown			Not Reported
	Co-Beneldopa Capsules 50 Mg/12.5 Mg			C	Unknown			Not Reported
	Macrogol			C	Unknown			Not Reported
	Duloxetine 90mg Capsule			C	Unknown			Not Reported
	Co-Beneldopa Capsules			C	Unknown			Not Reported
	Adcal D3			C	Unknown			Not Reported
	Rivastigmine 4.6mg Patch - Transdermal Patch			C				Not Reported
	Quetiapine 25 Mg			C	Unknown			Not Reported
	Paracetamol - Tablet			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15259085	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006586		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Escitalopram		S	Oral	Ingestion	Unknown
	Ethanol		S	Oral	Ingestion	Unknown
	Amitriptyline Hydrochloride		S	Oral	Ingestion	Unknown
	Ibuprofen		S	Oral	Ingestion	Unknown
	Gabapentin		S	Oral	Ingestion	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15259451	NON-EXPEDITED			US-PFIZER INC-2018321178		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Cefepime Hcl			S		Unk		Unknown
	Celexa			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15259733	EXPEDITED (15-DAY)		HO	FR-APOTEX-2018AP018506		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Somnolence; Toxicity To Various Agents	Paroxetine Tablet			S	Oral	12 Df, Unk		Apotex
	Ibuprofene			S	Oral	20 Df, Unk		Not Reported
	Escitalopram			S	Oral	28 Df, Unk		Not Reported
	Dafalgan Codein			S	Oral	8 G, Unk		Not Reported
	Havlane			S	Oral	20 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15259768	NON-EXPEDITED			US-MYLANLABS-2018M1057473			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Fatigue; Fear; Heart Rate Decreased; Musculoskeletal Pain;	Nitroglycerin Transdermal System			S	Transdermal	Unk		Mylan

Night Sweats; Pharyngeal Swelling; Pollakiuria; Product Quality Issue; Sleep Disorder; Weight Decreased	Escitalopram	S	Unk		Mylan
	Advair	C	Unk, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15262062	EXPEDITED (15-DAY)		CA	FR-ELI_LILLY_AND_COMPANY-FR201808001408			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Disease Congenital	Cymbalta			S	Transplacental	Unk Unk, Unknown		Eli Lilly And Co
	Cymbalta			S	Transplacental	Unk Unk, Unknown		Eli Lilly And Co
	Seroplex			S	Transplacental	5 Mg, Daily		Not Reported
	Seroplex			S	Transplacental	5 Mg, Daily		Not Reported
	Seroplex			S	Transplacental	10 Mg, Unk		Not Reported
	Seroplex			S	Transplacental	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15262169	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1839384US		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Eliquis			S	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	13077127	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1682625US		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Drug	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Trazodone			S	Unknown	150 Mg, Unk		Not Reported
	Trazodone			S	Oral	75 Mg, Qd		Not Reported

Ineffective; Drug Interaction; Feeling Of Despair; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Clonazepam	S	Oral	0.5 Mg, Qd		Not Reported
	Valproic Acid	S	Oral	300 Mg, Qd		Not Reported
	Valproic Acid	S	Unknown	600 Mg, Unk		Not Reported
	Venlafaxine	S	Oral	300 Mg, Qd		Not Reported
	Quetiapine	S	Oral	200 Mg, Qd		Not Reported
	Alprazolam	S	Oral	1.5 Mg, Qd		Not Reported
	Alprazolam	S	Oral	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	14633062	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-867819		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Pantoprazole			S	Oral	Unspecified		Teva
	Escitalopram			S	Oral	Unspecified		Ivax
	Xeloda			S	Oral	Unspecified		Not Reported
	Novorapid			S	Subcutaneous	Unspecified		Not Reported
	Primperan			S	Oral	Unspecified		Not Reported
	Lipanthyl			S	Oral	Unspecified		Not Reported
	Movicol			S	Oral	Unspecified		Not Reported
	Abasaglar			S	Subcutaneous	Unspecified		Not Reported
	Fondaparinux Sodium			S	Subcutaneous	Unspecified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	14815226	EXPEDITED (15-DAY)		HO, LT	DE-ASTRAZENECA-2018SE51713		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Esomeprazole			S	Oral	40.0mg Unknown		Astrazeneca
	Escitalopram			S	Unknown			Not Reported
	Linezolid			S	Intravenous (not otherwise specified)			Not Reported

	Levetiracetam	C			Not Reported
	Ivabradine	C			Not Reported
	Cotrimoxazol	C	Intravenous (not otherwise specified)		Not Reported
	Naloxone, Tilidine	C		10 Drops	Not Reported
	Scopolamin	C			Not Reported
	Baclofen	C			Not Reported
	Prednisolon	C			Not Reported
	Lorazepam	C			Not Reported
	L-Thyroxin	C		75.0ug Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15262927	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-040535		78 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Incorrect Dose Administered	Escitalopram Arrow Film-Coated Tablet 5mg			S	Oral	20 Milligram, Daily		Aurobindo
	Ramipril Mylan			C	Unknown	Unk		Not Reported
	Lexomil			C	Unknown	Unk		Not Reported
	Dulcolax /00064401/			C	Unknown	Unk		Not Reported
	Imovane			C	Unknown	Unk		Not Reported
	Macrogol 4000			C	Unknown	Unk		Not Reported
	Euthyrox			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15264244	EXPEDITED (15-DAY)		HO	PHHY2018FR069486		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Somnolence; Toxicity To Various Agents	Alprazolam			S	Oral	1 Df, (Total)		Novartis
	Seroplex			S	Oral	1 Df, (Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15265866	EXPEDITED (15-DAY)		OT	DK-PFIZER INC-2018318163		41 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Hypomania; Sensory Disturbance	Efexor Depot			S	Oral	75 Mg, Unk		Pfizer
	Alopam			S	Oral			Not Reported
	Cipralex /01588502/			S	Oral	Most Of The Time Treated With 20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15266054	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1061121		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Valproic Acid			S	Unknown	Unk		Not Reported
	Levetiracetam			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown			Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Clobazam			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15266600	EXPEDITED (15-DAY)		HO	PHHY2018FR068608		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Risperidone			S	Oral	1 Mg, Qd (0.5 Mg Morning And Evening)		Novartis
	Escitalopram			S	Oral	10 Mg, Qd (In The Evening)		Not Reported
	Olanzapine			S	Oral	5 Mg, Qd (In The Evening)		Not Reported
	Loxapine			S	Oral	5 Gtt, Prn (If Needed)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15266987	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-938484			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness; Dyspnoea; Gastric Ulcer; Insomnia; Nausea; Panic Attack; Vertigo	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15267032	EXPEDITED (15-DAY)		HO	PHHY2018FR069546		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Pantoprazole			S	Oral	30 Mg, Qd		Novartis
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2018	15267533	EXPEDITED (15-DAY)		HO	DE-TORRENT-00009252		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Levothyroxin			C	Oral	75 G, 1-0-0-0		Unknown
	Torasemid			C	Oral	10 Mg, 1-0-0-0		Unknown
	Valproinsaeure			S	Oral	500 Mg, 0-0-0-1		Unknown
	Quetiapine			S	Oral	100 Mg, 0-0-0-1		Unknown
	Cipralex			S	Oral	10 Mg, 1-0-0-0		Unknown
	Felodipine			C	Oral	10 Mg, 1-0-0-0		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2018	15267534	EXPEDITED (15-DAY)		HO	IN-TORRENT-00001801		33 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity	Escitalopram			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2018	14338214	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2017-FR-841886		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Diazepam			S	Oral	30 Milligram Daily;		Barr
	Alprazolam			S	Oral	.75 Milligram Daily; 0.25 Mg, 3x/Day		Actavis
	Mirtazapine			S	Oral	15 Milligram Daily;		Teva
	Amlodipine			S	Oral	10 Milligram Daily;		Teva
	Pantoprazole			S	Oral	20 Milligram Daily;		Teva
	Bisoprolol Fumarate			S	Oral	1.25 Milligram Daily; 1.25 Mg, 1x/Day		Duramed
	Furosemide			S	Oral	60 Milligram Daily; 30 Mg (2-1-0), 2x/Day		Ivax
	Furosemide			S	Oral	2 Unk, Qd		Ivax
	Irbesartan			S	Oral	300 Milligram Daily; 300mg, 1x/Day		Teva
	Nefopam Hydrochloride			S	Oral	3 Dosage Forms Daily;		Not Reported
	Diffu K			S	Oral	6 Dosage Forms Daily; 3 Df (2-1-0), 2x/Day		Not Reported
	Colchicine Opocalcium			S	Oral	1 Dosage Forms Daily; 1df, 1x/Day		Not Reported
	Colchicine Opocalcium			S	Oral			Not Reported

Xarelto	S	Oral	20 Milligram Daily;		Not Reported
Xarelto	S	Oral			Not Reported
Seroplex	S	Oral	1 Dosage Forms Daily; 1df, 1x/Day		Not Reported
Tavanic	S	Oral	500 Milligram Daily; 250 Mg, 2x/Day		Not Reported
Tavanic	S	Oral			Not Reported
Valium	S	Oral	3 Dosage Forms Daily; 3 Df, 1x/Day		Not Reported
Terbutaline Sulphate	S	Respiratory (inhalation)	1 Dosage Forms Daily; 1 Df, Unk		Not Reported
Dafalgan	S	Oral	3000 Milligram Daily; 1000 Mg, 3x/Day		Not Reported
Dafalgan	S	Oral			Not Reported
Metformine Pfizer	S	Oral	1000 Milligram Daily; 1000 Mg, 1x/Day		Not Reported
Metformine Pfizer	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2018	15309577	DIRECT		OT			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Depression; Dizziness; Nausea; Vomiting	Escitalopram, Generic For Lexapro			S	Oral	Quantity:1 Tablet(S);		Allergan
	Bentyl (Dicyclomine)			C				Not Reported
	Neurontin (Gabapentin)			C				Not Reported
	Toradol (Ketorolac)			C				Not Reported
	Ativan (Lorazepam)			C				Not Reported
	Lopressor (Metoprolol Tartrate)			C				Not Reported
	Zegerid (Omeprazole)			C				Not Reported
	Zofran (Ondansetron)			C				Not Reported
	Imitrex (Sumatriptan)			C				Not Reported
	Simethicone			C				Not Reported
	Vitamin B12			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	14391026	NON-EXPEDITED			US-PFIZER INC-2018015994		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hallucination; Hallucination, Auditory; Insomnia; Mydriasis; Therapeutic Product Effect Incomplete	Advil Congestion Relief			S	Oral	1 Df, Unk (One Tablet, Once At Around Noon And Again At Around 5 Pm)		Pfizer
	Advil Congestion Relief			S				Pfizer
	Escitalopram			S		10 Mg, Unk		Not Reported
	Escitalopram			S	Oral	20 Mg, Daily(One A Day At Night When She Goes To Bed)		Not Reported
	Escitalopram			S				Not Reported
	Levothyroxine			C		0.112 Ug, Daily		Not Reported
	Metoprolol			C		25 Ug, 3x/Day		Not Reported
	Centrum Silver			C		Unk Unk, 1x/Day		Not Reported
	Vitamin B			C		Unk Unk, 1x/Day		Not Reported
	Fish Oil			C		Unk Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	14598392	EXPEDITED (15-DAY)		HO, LT, OT	FR-TEVA-2018-FR-862991		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypotonia; Miosis	Zopiclone			S	Oral	210 Milligram Daily;		Not Reported
	Olanzapine			S	Oral			Teva
	Seroplex			S	Oral			Not Reported
	Abilify			S	Oral	5 Milligram Daily;		Not Reported
	Lysanxia			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	14665622	EXPEDITED (15-DAY)		LT	CA-ALLERGAN-1815261US		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Sexual Dysfunction; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	Unk, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	14670413	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1815473US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Depression; Emotional Disorder; Fatigue	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Humira			S	Subcutaneous	40 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	14970621	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-901708		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Aripiprazole			S	Oral	Unk		Not Reported
	Mirtazapine			S	Unknown			Teva
	Seroplex			S	Unknown	Unk		Not Reported
	Seroplex			S	Oral			Not Reported
	Norset			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Inipomp			C	Unknown			Not Reported
	Aprovel			C	Unknown			Not Reported
	Irbesartan			C	Oral			Not Reported
	Kardegic			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15269031	EXPEDITED (15-DAY)		OT	US-ACCORD-070714		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritable Bowel Syndrome	Escitalopram Accord			S	Oral	Strength: 20 Mg Took 1/2 Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15271908	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1839565US		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Propranolol			S	Oral	Unk		Not Reported
	Paracetamol			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Ibuprofene			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15271910	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1839570US		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Narcolepsy	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan
	Xanax			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15271921	EXPEDITED (15-DAY)		DE, HO, LT	FR-ALLERGAN-1839573US		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Previscan (Fluindione)			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15272101	EXPEDITED (15-DAY)		OT	HR-ASTRAZENECA-2018SF01746			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; No Adverse Event; Suicide Attempt	Quetiapine			S	Oral			Not Reported
	Citram			S	Oral			Not Reported
	Ketonal			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15310017	DIRECT		OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Decreased Appetite; Hallucination; Influenza Like Illness; Insomnia; Mood Swings; Paranoia; Restlessness; Suicide Attempt; Taste Disorder; Thinking Abnormal	Lexipro-Escitalopram			S	Oral	Quantity:2 Tablet(S);		Unknown
	Celexa Citalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Rosuvastatin			C				Not Reported
	Bupropion Xl			C				Not Reported
	Hydroxyzined			C				Not Reported
	Lamotrigine			C				Not Reported
	Omeprazole			C				Not Reported
	Naproxen			C				Not Reported
	Tizanidine			C				Not Reported
	Multi-Vitamin			C				Not Reported
	B12			C				Not Reported
	Magnesium			C				Not Reported

	Calcium	C	Not Reported
	D3	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	14269135	EXPEDITED (15-DAY)		HO, OT	JP-OTSUKA-BJ201400556		< 1 DAY	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Neonatal Asphyxia; Tremor Neonatal	Abilify 3mg			S	Transplacental	3 Mg, Qd		Otsuka
	Abilify 3mg			S	Transplacental	6 Mg, Qd		Otsuka
	Abilify 3mg			S	Transplacental	9 Mg, Qd		Otsuka
	Abilify 3mg			S	Transplacental	15 Mg, Qd		Otsuka
	Abilify 3mg			S	Transplacental	12 Mg, Qd		Otsuka
	Lexapro			S	Transplacental	10 Mg, Bid		Not Reported
	Silece			S	Transplacental	2 Mg, Qd		Not Reported
	Contomin			S	Transplacental	25 Mg, Bid		Not Reported
	Seroquel			S	Transplacental	25 Mg, Qd		Not Reported
	Cymbalta			S	Transplacental	30 Mg, Bid		Not Reported
	Pyrethia			C	Transplacental	25 Mg, Qd		Not Reported
	Tasmolin			C	Transplacental	1 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	14782095	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-882488		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Hallucination, Visual; Persecutory Delusion	Escitalopram			S	Oral	1 Cp		Ivax
	Modopar 125 Dispersible			S	Oral	100 Mg/ 25 Mg		Not Reported
	Modopar 125 Dispersible			S	Oral	4 Dosage Forms Daily;		Not Reported
	Modopar			S	Oral			Not Reported
	Modopar			S	Oral			Not Reported
	Modopar			S	Oral	1 Cp 62,5 (50 Mg/12,5		Not Reported

Mg), Gelule

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	14816226	EXPEDITED (15-DAY)		HO, LT	DE-ALLERGAN-1822947US		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Esomeprazol			S	Unknown	40 Mg, Unk		Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	2 Df, Qd		Not Reported
	Baclofen			C	Unknown			Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	2 Df, Qd		Not Reported
	Naloxone W/Tilidine			C	Unknown	10 Gtt, Unk		Not Reported
	Ivabradine			C	Unknown	15 Mg, Qd		Not Reported
	Prednisolon			C	Unknown			Not Reported
	Levetiracetam			C	Unknown	2 Df, Qd		Not Reported
	Scopolamin			C	Unknown			Not Reported
	Lorazepam			C	Unknown	1 Mg, Qd		Not Reported
	L-Thyroxin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15253544	EXPEDITED (15-DAY)		HO	IN-CIPLA LTD.-2018IN20507			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity; Sedation	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen
	Escitalopram			S				Invagen
	Escitalopram			S				Invagen
	Escitalopram			S				Invagen
	Quetiapine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15273908	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-939638		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Tardive Dyskinesia	Aripiprazole			S	Unknown			Teva
	Aripiprazole			S	Oral			Teva
	Seroplex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15274348	EXPEDITED (15-DAY)		HO, OT	DE-BAUSCH-BL-2018-021733		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Dexamethason			S	Oral			Valeant
	Sycrest			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Pantoprazol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15274609	EXPEDITED (15-DAY)		HO, LT, OT	NL-AUROBINDO-AUR-APL-2018-041304		69 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram Film-Coated Tablets 10mg			S	Unknown	10 Milligram, Once A Day, 1 X Per Dag 1 Stuk		Aurobindo
	Hydrochlorothiazide 25 Mg			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15274661	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-041186		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Toxic Skin Eruption	Escitalopram	S	Oral	1 Dosage Form, Once A Day	Aurobindo
	Stresam	S	Oral	3 Dosage Form, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15275564	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-2018-GB-939270		70 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Tube Insertion; Laryngectomy	Escitalopram			S	Unknown			Ivax
	Salbutimol Inhaler			C	Unknown			Not Reported
	Prucalopride			C	Unknown			Not Reported
	Morphine Sulphate			C	Unknown			Not Reported
	Cald-3			C	Unknown			Not Reported
	Bendroflumetheaide			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Calciferol [Ergocalciferol]			C	Unknown			Not Reported
	Tiotropium Inhaler			C	Unknown			Not Reported
	Alendronic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15275833	EXPEDITED (15-DAY)		OT	DE-TORRENT-00009358			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Overdose; Seizure	Escitalopram			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15275844	EXPEDITED (15-DAY)		CA, OT	US-TORRENT-00006746			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Congenital Abdominal Hernia; Congenital Diaphragmatic Eventration; Dextrocardia; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Rib Hypoplasia; Supernumerary Nipple	Topiramate	S	Transplacental	Unknown		Unknown
	Escitalopram	S	Transplacental			Unknown
	Tramadol Hydrochloride	S	Transplacental			Unknown
	Oxycodone And Acetaminophen	S	Transplacental			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15275852	EXPEDITED (15-DAY)		OT	DE-TORRENT-00009350			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Overdose; Seizure	Escitalopram			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15276454	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-939749		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Prednisolone			S	Oral	40 Milligram Daily;		Actavis
	Bevacizumab			S				Not Reported
	Lomustine			S	Oral			Not Reported
	Seroplex Film-Coated Tablets			S	Oral	5 Milligram Daily;		Not Reported
	Silodyx			C	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15277122	EXPEDITED (15-DAY)		DE, HO, OT	DE-TEVA-2018-DE-939775		55 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hyperhidrosis;	Lorazepam			S	Oral	6 Milligram Daily;		Actavis

Restlessness; Schizoaffective Disorder	Quetiapine	S	Oral	200 Milligram Daily;	Teva
	Abilify 3mg	S	Oral	Unk	Not Reported
	Abilify 3mg	S	Oral		Not Reported
	Cipralex /01588502/	S	Oral	Unk	Not Reported
	Lexapro	S	Oral	10 Milligram Daily;	Not Reported
	Lexapro	S	Unknown		Not Reported
	Tavor (Lorazepam)	S	Oral	Unk	Not Reported
	Tavor (Lorazepam)	S	Oral	Unk	Not Reported
	Seroquel	S	Oral	Unk	Not Reported
	Movicol	C	Unknown	Unk	Not Reported
	Simeticone	C	Unknown	Unk	Not Reported
	Eferox	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15277706	EXPEDITED (15-DAY)		DE	AU-MYLANLABS-2018M1061179			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Toxicity To Various Agents	Escitalopram			S		Unk		Not Reported
	Diazepam			S		Unk		Not Reported
	Heroin			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15277735	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-939251		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Lower Gastrointestinal Haemorrhage	Escitalopram			S	Unknown	Unk		Ivax
	Xarelto 20 Mg			S	Unknown	20 Mg, Unk		Not Reported
	Zofenil			C	Unknown	Unk		Not Reported
	Carbidopa, Levodopa			C	Unknown	Unk		Not Reported
	Androtardyl			C	Unknown	Unk		Not Reported

	Amoxicillin Sodium, Potassium Clavulanate		C	Unknown	Unk	Not Reported
	Requip		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15277793	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFM-2018-09139			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Propranolol			S	Oral			Pierre Fabre Medicament
	Paracetamol			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Ibuprofene			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15278023	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1839784US		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autonomic Nervous System Imbalance; Malaise; Off Label Use; Orthostatic Hypotension	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Zopiclone			S	Oral	7.5 Mg, Qd		Not Reported
	Risperdal			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15278381	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2017PL204532		62 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Drug Ineffective; Drug Interaction;	Metoprolol Tartrate Sandoz			S	Unknown	Unk		Novartis
	Zolpidem Tartrate			S	Oral	10 Mg,Hs		Not Reported
	Escitalopram			S	Unknown			Not Reported

Electrocardiogram Qt Prolonged; Fatigue; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Venlafaxine	S	Oral	150 Mg,Qd		Not Reported
	Trazodone	S	Unknown			Not Reported
	Moclobemide	S	Unknown	150 Mg, Qhs		Not Reported
	Sertraline	S	Unknown	50 Mg, Qhs		Not Reported
	Ginkgo Biloba Extract	C	Unknown			Not Reported
	Warfarin	C	Unknown			Not Reported
	Sotalol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15311000	DIRECT					20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Blood Glucose Decreased; Impaired Driving Ability; Nausea; Vertigo	Escitalopram			S	Oral			Not Reported
	Ibuprofen			C				Not Reported
	Tylenol			C				Not Reported
	Midol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15314517	DIRECT	Y	HO, RI			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Insomnia; Post-Traumatic Stress Disorder	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15099981	EXPEDITED (15-DAY)		HO, OT	PL-ALLERGAN-1833018US		62 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Electrocardiogram Qt Prolonged; Fatigue; Palpitations; Syncope	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Trazodone			S	Unknown	Unk		Not Reported
	Venlafaxine			S	Unknown	150 Mg, Qd		Not Reported

Moklar	S	Unknown	150 Mg, Qd		Not Reported
Cyproheptadine	S	Oral	16 Mg, Unk		Not Reported
Zolpidem	S	Unknown	10 Mg, Qhs		Not Reported
Ivabradine	S	Unknown	Unk		Not Reported
Sertraline	S	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15276506	EXPEDITED (15-DAY)		HO, LT	ES-JNJFOC-20180815523		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Haloperidol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Enalapril/Hydrochlorothiazide			S	Oral	1-0-0. El 23/01		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15281563	EXPEDITED (15-DAY)		DS	FI-ALLERGAN-1840008US		73 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Hypoaesthesia; Musculoskeletal Pain; Myalgia; Pain In Extremity; Paraesthesia; Sleep Disorder	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Cohemin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	14038961	EXPEDITED (15-DAY)		HO, OT	IT-JNJFOC-20170927217		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sopor	Haldol			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

	Delorazepam	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	14573122	EXPEDITED (15-DAY)		HO, OT	FR-SA-2018SA049203		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Alprazolam			S	Oral	0.25 Mg,Qd		Not Reported
	Alprazolam			S	Oral	.75 Mg,Tid		Not Reported
	Bisoprolol Hemifumarate			S	Oral	1.25 Mg,Qd		Not Reported
	Amlodipine Besilate			S	Oral	10 Mg,Qd		Not Reported
	Irbesartan			S	Oral	300 Mg,Qd		Sanofi
	Irbesartan			S	Oral	300 Mg,Qd		Sanofi
	Pantoprazole			S	Oral	20 Mg,Qd		Not Reported
	Pantoprazole			S	Oral	20 Mg,Qd		Not Reported
	Tavanic			S	Oral	250 Mg,Qd		Not Reported
	Tavanic			S	Oral	500 Mg,Qd		Not Reported
	Furosemide			S	Oral	30 Mg,Qd		Sanofi
	Furosemide			S	Oral	2 Df,Qd		Sanofi
	Furosemide			S	Oral	30 Mg,Bid		Sanofi
	Terbutaline Sulfate			S	Respiratory (inhalation)	1 Df,Qd		Not Reported
	Mirtazapine			S	Oral	15 Mg,Qd		Not Reported
	Xarelto			S	Oral	20 Mg,Qd		Not Reported
	Metformin Hydrochloride			S	Oral	500 Mg,Qd		Not Reported
	Metformin Hydrochloride			S	Oral	1000 Mg,Qd		Not Reported
	Diffu K			S	Oral	3 Df,Qd		Not Reported
	Diffu K			S	Oral	6 Df,Qd		Not Reported
	Seroplex			S	Oral	1 Df,Qd		Not Reported
	Valium			S	Unknown	3 Df,Unk		Not Reported
	Valium			S	Oral	10 Mg,Tid		Not Reported

Colchicine Opocalcium	S	Oral	1 Mg,Qd		Not Reported
Nefopam Hydrochloride	S	Oral	1 Df,Qd		Not Reported
Nefopam Hydrochloride	S	Oral	3 Df,Qd		Not Reported
Nefopam Hydrochloride	S	Oral	3 Df,Tid		Not Reported
Dafalgan	S	Oral	3000 Mg,Qd		Not Reported
Dafalgan	S	Oral	1000 Mg,Tid		Not Reported
Diazepam	S	Oral	30 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	14592868	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-860742		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Sopor; Suicide Attempt	Venlafaxine			S	Oral			Teva
	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	14836236	EXPEDITED (15-DAY)		HO, LT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-171472		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Esomeprazol			S	Unknown	40 Mg, Unk		Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	2 Df, Daily		Not Reported
	Levetiracetam			C	Unknown	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Ivabradin			C	Unknown	Daily Dose: 15 Mg Millgram(S) Every Days		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Naloxone, Tilidine			C	Unknown	10 Gtt, Unk		Not Reported

	Scopolamin	C	Unknown	Unk	Not Reported
	Baclofen	C	Unknown		Not Reported
	Prednisolon	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	Daily Dose: 1 Mg Millgram(S) Every Days	Not Reported
	L-Thyroxin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15118969	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-922706		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Escitalopram			S	Oral	10 Milligram Daily; 10 Mg, Qd		Ivax
	Escitalopram			S	Oral	10 Milligram Daily; 10 Mg, Qd		Ivax
	Escitalopram			S	Oral	15 Milligram Daily; 15 Mg, Qd		Ivax
	Escitalopram			S	Oral	20 Milligram Daily; 20 Mg, Qd		Ivax
	Escitalopram			S	Oral	20 Milligram Daily; 20 Mg, Qd		Ivax
	Escitalopram			S	Oral	15 Milligram Daily; 15 Mg, Qd		Ivax
	Candesartan			S	Oral	16 Milligram Daily; 16 Mg, Od		Not Reported
	Aripiprazole			S	Oral	10 Milligram Daily; 10 Mg, Od		Teva
	Aripiprazole			S	Oral	5 Milligram Daily;		Teva
	L-Thyroxin			C	Oral	100 Microgram Daily; 100 Mg, Qd		Not Reported
	Risperdal			C	Unknown	2 Milligram Daily; 2 Mg, Od		Not Reported
	Risperdal			C	Unknown	2 Mg, Hs		Not Reported

Risperdal	C	Unknown	1.5 Milligram Daily; 1.5 Mg, Od		Not Reported
Risperdal	C	Unknown	2 Milligram Daily; 2 Mg, Od		Not Reported
Metformin	C	Oral	1500 Milligram Daily; 1500 Mg, Od		Not Reported
Atorvastatin	C	Oral	20 Milligram Daily; 20 Mg, Od		Not Reported
Amisulpride	C	Unknown	200 Milligram Daily; 200 Mg, Qd		Not Reported
Acetylsalicylic Acid	C	Oral	100 Milligram Daily; 100 Mg, Od		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15160941	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1835497US		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Lorazepam			S	Oral	2.5 Mg, Qd		Not Reported
	Sertraline Hydrochloride			S	Oral	100 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	30 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	2 Mg, Qd		Not Reported
	Ezetimibe			C	Unknown	10 Mg, Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Coumadin			C	Unknown	Unk		Not Reported
	Triatec Hct			C	Unknown	15 Mg, Qd		Not Reported
	Cordarone			C	Unknown	Unk		Not Reported
	Warfarin Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15204712	EXPEDITED (15-DAY)		HO	PHHY2018IT052890		21 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Aripiprazole			S	Oral	210 Mg, Total		Not Reported
	Escitalopram			S	Oral	140 Mg, Total		Not Reported
	Alprazolam			S	Oral	15 Ml, Total		Novartis
	Zitromax			S	Oral	1500 Mg, Total		Not Reported
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	1200 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15282728	EXPEDITED (15-DAY)		CA, OT	DE-HETERO CORPORATE-HET2018DE00796		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Pulmonary Artery Stenosis Congenital	Escitalopram			S	Transplacental	10 [Mg/D]		Hetero
	Sertraline			C	Transplacental	150 [Mg/D]		Not Reported
	Quetiapine			C	Transplacental	25 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15282869	EXPEDITED (15-DAY)		LT	FR-AUROBINDO-AUR-APL-2018-041258		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Miosis; Prothrombin Time Shortened; Tachycardia; Vomiting	Escitalopram			S	Oral	Unk		Aurobindo
	Dafalgan Codeine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15282876	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2018-FR-942895		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension	Propranolol			S	Oral			Actavis
	Paracetamol			S	Oral			Not Reported
	Lamotrigine			S	Oral			Teva
	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Actavis
	Ibuprofene			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15282942	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00009344		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Pulmonary Artery Stenosis Congenital	Sertraline			C	Transplacental	150 [Mg/D]		Unknown
	Escitalopram			S	Transplacental	10 [Mg/D]		Unknown
	Quetiapine			C	Transplacental	25 [Mg/D]		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15283129	EXPEDITED (15-DAY)		HO	IN-ACCORD-070710		33 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Drug Intolerance; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity; Sedation Complication	Escitalopram			S				Not Reported
	Quetiapine			S				Not Reported
	Lithium			C				Not Reported
	Olanzapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15283314	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-041283		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Gastrointestinal Haemorrhage	Escitalopram			S	Oral	Unk		Aurobindo
	Plavix			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Bisoce			C	Oral	Unk		Not Reported
	Glibenclamide			C	Oral	Unk		Not Reported
	Metformine /00082701/			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15284149	EXPEDITED (15-DAY)		OT	IN-TORRENT-00001806		23 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; General Physical Health Deterioration; Psychotic Disorder	Escitalopram			S		At Adequate Dose		Unknown
	Fluoxetine			S		At Adequate Dose And Duration		Unknown
	Fluvoxamine			S		At Adequate Dose And Duration		Unknown
	Clomipramine			S		At Adequate Dose And Duration		Unknown
	Sertraline			S		At Adequate Dose And Duration		Unknown
	Paroxetine			S		At Adequate Dose And Duration		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15286149	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-942706		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Sopor	Escitalopram Oxalate	S	Oral		Ivax
	Tavor (Lorazepam)	S	Oral		Not Reported
	Olanzapine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15286404	EXPEDITED (15-DAY)		OT	DK-ALLERGAN-1840031US		38 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Sedation; Sensory Disturbance; Social Avoidant Behaviour; Social Problem; Type 2 Diabetes Mellitus; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Unknown		Allergan
	Abilify			S	Oral	Unk, Unknown		Not Reported
	Orap			S	Oral	Unk, Unknown		Not Reported
	Ritalin			S	Oral	120 Mg, Unknown		Not Reported
	Cymbalta			S	Oral	Unk, Unknown		Not Reported
	Ritalin			S	Oral	Unk, Unknown		Not Reported
	Concerta			C	Unknown	54 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	13961665	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-JNJFOC-20170908648		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Suicide Attempt; Tinnitus	Tramadol			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Zolpidem			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Not Reported

Perindopril	S	Oral	Not Reported
Sertraline	S	Unknown	Not Reported
Doxepin	S	Unknown	Not Reported
Doxepin	S	Unknown	Not Reported
Escitalopram Oxalate	S	Unknown	Not Reported
Escitalopram Oxalate	S	Unknown	Not Reported
Atoris	S	Oral	Not Reported
Polsen	S	Unknown	Not Reported
Concor	S	Oral	Not Reported
Trosicam	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	14356511	EXPEDITED (15-DAY)		OT	ES-JNJFOC-20180100857			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Headache; Insomnia; Treatment Noncompliance	Tramadol Hydrochloride/Paracetamol			S	Unknown	Strength: 1 Df= 37.5/ 325 Mg		Not Reported
	Topiramate			S	Unknown			Not Reported
	Topiramate			S	Unknown	Strength= 50 Mg		Not Reported
	Amitriptyline			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Escitalopram			S	Unknown	Strength= 10 Mg		Not Reported
	Omeprazole			S	Unknown	Strength 20 Mg		Not Reported
	Lormetazepam			S	Unknown			Not Reported
	Tepazepam			S	Unknown			Not Reported
	Enalapril Hct			S	Unknown	Strength: 1 Df= 20/ 12.5 Mg		Not Reported
	Diazepam			S	Unknown	Strength= 5 Mg		Not Reported
	Amlodipine			S	Unknown			Not Reported

	Glibenclamida	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Simvastatin	S	Unknown	Strength 40 Mg	Not Reported
	Simvastatin	S	Unknown		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Metoclopramide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	14985218	EXPEDITED (15-DAY)		HO, LT	DE-TEVA-2018-DE-902922		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram			S				Ivax
	Linezolid			S	Intravenous (not otherwise specified)	2 Dosage Forms Daily;		Teva
	Esomeprazole			S	Unknown			Teva
	Levetiracetam			C	Unknown	2 Dosage Forms Daily;		Not Reported
	Ivabradin			C		15 Milligram Daily;		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	2 Dosage Forms Daily;		Not Reported
	Naloxone, Tilidine			C				Not Reported
	Scopolamin			C				Not Reported
	Baclofen			C				Not Reported
	Prednisolon			C				Not Reported
	Lorazepam			C		1 Milligram Daily;		Not Reported
	L-Thyroxin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15027029	NON-EXPEDITED			US-CELGENEUS-USA-20180604568		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Diarrhoea	Otezla			S	Oral	30 Milligram		Celgene
	Otezla			S	Oral	60 Milligram		Celgene

	Lexapro	S	Unknown	Not Reported
	Xanax	S	Unknown	Not Reported
	Humira	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15132983	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2017-45077		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Sertraline			S	Unknown	100 Mg, Once A Day		Aurobindo
	Lorazepam Tablets			S	Unknown	2.5 Mg, Once A Day, At Bed Time		Aurobindo
	Duloxetine Hydrochloride			S	Unknown	60 Mg, Once A Day		Not Reported
	Duloxetine Hydrochloride			S				Not Reported
	Cipralex /01588501/			S	Oral	20 Milligram, Once A Day		Not Reported
	Cipralex /01588501/			S				Not Reported
	Cipralex /01588501/			S				Not Reported
	Brintellix			S	Unknown	15 Mg,Qd		Not Reported
	Brintellix			S	Unknown	10 Mg,Qd		Not Reported
	Brintellix			S	Unknown	5 Mg,Qd		Not Reported
	Coumadin			C	Unknown	Unk Unk,Unk		Not Reported
	Ezetimibe			C	Unknown	10 Mg,Qd		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	30 Mg,Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg,Qd		Not Reported
	Alprazolam			C	Unknown	2 Milligram, Daily		Not Reported
	Triatec Hct			C	Unknown	15 Mg,Qd		Not Reported
	Cordarone			C	Unknown	200 Mg,Unk		Not Reported
	Warfarin Sodium			C	Unknown	Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15287181	EXPEDITED (15-DAY)		HO	IN-MACLEODS PHARMACEUTICALS US LTD-MAC2018016355			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Escitalopram Oxalate			S				Macleods
	Escitalopram Oxalate			S				Macleods
	Escitalopram Oxalate			S				Macleods
	Escitalopram Oxalate			S				Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15287185	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018016345			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Electrocardiogram Qt Prolonged; Moaning	Escitalopram Tablet			S	Oral	Unk, Abuse/Misuse		Macleods
	Alprazolam			S	Oral	Unk, Abuse/Misuse		Not Reported
	Trilafon			S	Oral	Unk, Abuse/Miuse		Not Reported
	Ramipril			C	Oral	2.5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15287591	EXPEDITED (15-DAY)		OT	DE-TORRENT-00009361		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Femibion Schwangerschaft 1			C	Transplacental	0.8 [Mg/D]		Unknown
	Impfstoff Grippe (Saisonale)			C	Transplacental	Unknown		Unknown
	L-Thyroxin			C	Transplacental	100 [G/D]/ Initial 75g/D, Dosage Increase To 100g/D From Week 34+2		Unknown
	Escitalopram			S	Transplacental	10 [Mg/D]		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15287813	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2018-041562		90 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Delirium; Fall; Post Procedural Haemorrhage; Traumatic Haemorrhage	Escitalopram			S	Unknown	15 Milligram, Daily		Aurobindo
	Eliquis			S	Unknown	Unk		Not Reported
	Eliquis			S	Unknown	10 Milligram, Daily (5 Mg, Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15288226	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-041358		59 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Electrocardiogram Qt Prolonged; Moaning	Alprazolam			S	Oral	()		Aurobindo
	Escitalopram Film-Coated Tablets			S	Unknown	Unk		Aurobindo
	Trilafon /00023401/			S	Oral	Unk		Not Reported
	Ramipril			C	Oral	2.5 Milligram, Unk		Not Reported
	Ramipril			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15288829	EXPEDITED (15-DAY)		HO, LT	ES-BAUSCH-BL-2018-022261		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Enalapril/Hidroclorotiazida Lareq Comprimidos Efg			S	Oral	1-0-0. On 23/01 Suspended Hydrochlorotiazide. Continued With Enalapril.		Not Reported
	Escitalopram			S	Oral			Not Reported
	Haloperidol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15290002	EXPEDITED (15-DAY)		DS	FI-TEVA-2018-FI-943289		73 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Hypoaesthesia; Musculoskeletal Pain; Myalgia; Pain In Extremity; Paraesthesia; Sleep Disorder	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Cohemin Depot			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15290080	NON-EXPEDITED			US-NEUROCRINE BIOSCIENCES INC.-2018NBI02336			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences
	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15290488	EXPEDITED (15-DAY)		CA	PHHY2012DE144006			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Autism Spectrum Disorder; Camptodactyly Congenital; Clinodactyly; Congenital Arterial Malformation; Congenital Central Nervous System Anomaly; Congenital Renal Cyst; Dysplasia; External Auditory Canal	Lorazepam			S	Unknown	Unk		Novartis
	Fosfomycin			S	Unknown	Unk		Not Reported
	Valaciclovir			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Ursodeoxycholic Acid			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

Atresia; Foetal Exposure During Pregnancy; Foetal Malformation; Hydronephrosis; Meningocele; Microtia; Oesophageal Atresia; Premature Baby	Acebutolol		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Colchicine		S	Unknown	Unk	Not Reported
	Ciclosporin		S	Unknown	Unk	Not Reported
	Methyldopa		S	Unknown	Unk	Not Reported
	Prednisolone		S	Unknown	Unk	Not Reported
	Azathioprine		S	Unknown	Unk	Not Reported
	Naproxen		S	Unknown	Unk	Not Reported
	Zolpidem		S	Unknown	Unk	Not Reported
	Escitalopram		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15290549	NON-EXPEDITED			US-TEVA-2018-US-945809			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown			Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15290737	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-942189		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Somnolence	Paroxetine Base			S	Oral			Not Reported
	Ibuprofene			S	Oral			Actavis
	Escitalopram			S	Oral			Not Reported
	Havlane			S	Oral			Not Reported
	Dafalgan			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15291315	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-941735		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hyperthermia; Malaise; Nausea; Night Sweats; Pruritus; Serotonin Syndrome; Tremor	Tramadol Base			S	Oral	Inconnue		Teva
	Seroplex 15 Mg, Comprimé Pelliculé Sécable			S	Oral	Inconnue		Not Reported
	Paracetamol			C	Oral	Inconnue		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15291317	NON-EXPEDITED			US-MYLANLABS-2018M1061873		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Fatigue; Feeling Abnormal	Diazepam			S	Oral	5 Mg, Unk		Not Reported
	Lexapro			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15318032	DIRECT	Y	LT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Suicidal Ideation	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2018	15292009	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00795		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 Milligram, Qd		Hetero
	Femibion Schwangerschaft 1 (Nem)			C	Transplacental	0.8 [Mg/D]		Not Reported
	Impfstoff Grippe (Saisonale)			C	Transplacental	Unk		Not Reported
	L-Thyroxin			C	Transplacental	100 [Mg/D]/ Initial 75µg/D, Dosage Increase To 100µg/D From Week 34+2		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2018	15292208	EXPEDITED (15-DAY)		HO	IN-HETERO CORPORATE-HET2018IN00800		33 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity	Escitalopram			S	Unknown	Unk		Hetero
	Escitalopram			S				Hetero
	Escitalopram			S				Hetero
	Escitalopram			S				Hetero
	Escitalopram			S				Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2018	15292276	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018016396			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Delirium; Fall; Post Procedural Haemorrhage; Traumatic Haemorrhage	Escitalopram			S	Unknown	15 Milligram, Qd		Macleods
	Eliquis			S	Unknown	10 Milligram, Qd,5 Mg, Bid,Paused Approx. On 10-May-2018 And Re-Started On 01-Jun-2018		Not Reported
	Eliquis			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2018	15292375	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-042477		26 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction; Dyskinesia; Hyperhidrosis; Muscle Tightness; Musculoskeletal Stiffness; Myalgia; Serotonin Syndrome	Escitalopram Film-Coated Tablets 10mg			S	Other	1 Keer Per Dag 1 Tablet		Aurobindo
	Sumatriptan Tablets 50 Mg			S	Other	Bij Migraine 1 Tablet, Herhaal Zo Nodig 2 Keer Per Dag, Wacht Meer Dan 2 Uur Na De Vorige Tablet.		Aurobindo

	Loperamide	C	Zo Nodig 6 Keer Per Dag 1 Capsule	Not Reported
	Imodium	C	1dd1	Not Reported
	Imodium	C	1dd1	Not Reported
	Colestyramine	C	2dd1	Not Reported
	Oxazepam	C	Zo Nodig 1 Keer Per Dag 1 Tablet	Not Reported
	Psylliumvezels	C	2 Keer Per Dag Zo Nodig 1 Zakje	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2018	15318844	DIRECT	Y	OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Headache; Malaise; Migraine; Nausea; Stress	Escitalopram			S	Oral		14 DAY	Cipla
	Levocetirizine			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	12493393	EXPEDITED (15-DAY)		HO, OT	FR-FRI-1000085530		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose; Nystagmus; Overdose; Psychomotor Retardation; Suicide Attempt; Toxicity To Various Agents; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	840 Mg, Single		Allergan
	Venlafaxine			S	Oral	7875 Mg, Single		Not Reported
	Bromazepam			S	Oral	180 Mg, Single		Not Reported
	Lormetazepam			S	Oral	14 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	13867289	NON-EXPEDITED			US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004671			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dysphagia; Hallucination; Tremor	Nuplazid			S	Oral	34 Mg, Qd		Acadia Pharmaceuticals
	Nuplazid			S	Oral	34 Mg, Qd		Acadia Pharmaceuticals
	Nuplazid			S	Oral	34 Mg, Qd		Acadia Pharmaceuticals
	Escitalopram			S		20 Mg, Unk		Not Reported
	Escitalopram			S		20 Mg		Not Reported
	Escitalopram			S		20 Mg		Not Reported
	Escitalopram			S		20 Mg		Not Reported
	Escitalopram			S		20 Mg		Not Reported
	Vitamin D3			C		2000 U		Not Reported
	Probiotic			C		Unk		Not Reported
	Aleve			C		220 Mg, Unk		Not Reported
	Tylenol			C		325 Mg, Unk		Not Reported
	Ocuvite			C		Unk		Not Reported
	Alfuzosin			C		10 Mg, Unk		Not Reported
	Rivastigmine			C		Unk		Not Reported
	Rivastigmine			C		Unk		Not Reported
	Rivastigmine			C		Unk		Not Reported
	Carbidopa And Levodopa			C		50-200 Mg		Not Reported
	Carbidopa And Levodopa			C		50-200 Mg		Not Reported
	Carbidopa And Levodopa			C		50-200 Mg		Not Reported
	Pilocarpine			C		1% Op		Not Reported
	Pilocarpine			C		1% Op		Not Reported
	Brimonidine			C		0.15 %, Unk		Not Reported

Brimonidine	C	0.15 %, Unk		Not Reported
Brimonidine	C	0.15 %, Unk		Not Reported
Latanoprost	C	0.005 %, Unk		Not Reported
Latanoprost	C	0.005 %, Unk		Not Reported
Cephalexin	C	500 Mg		Not Reported
Ciprofloxacin	C	250 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	14024381	EXPEDITED (15-DAY)		DE, OT	ZA-MYLANLABS-2017M1059414		65 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Insufficiency	Mylacand Plus			S	Oral	1 Df, Unk		Mylan
	Forvent			S	Oral	18 Mg, Unk		Mylan
	Bilocor			S	Oral	5 Mg, Unk		Mylan
	Glucophage Xr			S	Oral	1000 Mg, Unk		Mylan
	Rivotril			S	Oral	0.3 Mg, Unk		Mylan
	Lexamil			S	Oral	10 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	14983140	EXPEDITED (15-DAY)		HO	FR-ACCORD-067832		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Amlodipine			S	Oral	10 Mg, Once Daily (Qd)		Accord
	Furosemide			S	Oral	30 Mg Daily (2-1-0), 2x/Day (Bid)		Accord
	Bisoprolol			S	Oral	1.25 Mg, Once Daily (Qd)		Not Reported
	Irbesartan			S	Oral	300 Mg, Once Daily (Qd)		Accord
	Terbutaline			S	Respiratory (inhalation)	1 Df, Once Daily (Qd)		Not Reported
	Dafalgan			S	Oral	1000 Mg, 3x/Day (Tid)		Not Reported

Alprazolam	S	Oral	0.25 Mg, 3x/Day (Tid)	Not Reported
Tavanic	S	Oral	250 Mg, 2x/Day (Bid)	Not Reported
Xarelto	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Diazepam	S	Oral	10 Mg, 3x/Day (Tid)	Not Reported
Colchicine	S	Oral	1 Mg, Once Daily (Qd)	Not Reported
Seroplex	S	Oral	1 Df, Once Daily (Qd)	Not Reported
Nefopam	S	Oral	1 Df, 3x/Day (Tid)	Not Reported
Diffu-K	S	Oral	3 Df Daily (2-1-0) 2x/Day (Bid)	Not Reported
Pantoprazole	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Metformin	S	Oral	500 Mg, 2x/Day (Bid)	Not Reported
Mirtazapine	S	Oral	15 Mg, Once Daily (Qd)	Not Reported
Valium	S	Oral	Strength: 10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15145579	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1831225US		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma; Haemorrhagic Diathesis; Menometrorrhagia; Respiratory Tract Infection; Sleep Disorder	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Risperidone			S	Unknown	0.5 Mg, Qd		Not Reported
	Risperidone			S	Unknown	0.5 Mg, Qd		Not Reported
	Risperidone			S				Not Reported
	Aripiprazole			S	Unknown	5 Mg, Qd		Not Reported
	Pregabalin			C	Unknown	100 Mg, Qpm		Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported
	Opipramol			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported

	Atorvastatin	C	Unknown	Unk		Not Reported
	Promethazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15156892	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-926893		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam			S	Oral			Actavis
	Paracetamol			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Tolep			S	Oral			Not Reported
	Brintellix			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15260949	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1839200US		43 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Intentional Underdose	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qpm		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qpm		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qpm		Allergan
	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Qpm		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15293471	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-944053		59 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Electrocardiogram Qt Prolonged; Moaning	Alprazolam			S	Oral			Actavis
	Escitalopram			S				Ivax
	Trilafon			S	Oral			Not Reported
	Ramipril			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15294914	EXPEDITED (15-DAY)		OT	NL-ALLERGAN-1840426US		25 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Dissociation; Feeling Abnormal; Loss Of Consciousness	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
	Alcohol			S	Unknown	4 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15294917	NON-EXPEDITED			US-TEVA-2018-US-944230		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Twitching	Escitalopram			S	Unknown			Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15294922	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1840394US		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Fallot'S Tetralogy	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan
	Amitriptyline-Form-Unknown			S	Transplacental	37.5 Mg, Qd		Not Reported
	Metoprolol			S	Transplacental	71.25 Mg, Qd (47.5-0-23.75 Mg/D)		Not Reported
	Paracetamol			C	Transplacental	200 Mg, Qd (1-2 G/D If Required)		Not Reported
	Clexane			C	Transplacental	120 Mg, Qd (Dosage Increase To 2 X 60 Mg/D)		Not Reported
	Clexane			C	Transplacental	40 Mg, Qd		Not Reported
	Ibuprofen			C	Transplacental	600 Mg, Qd (If Requiered)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15296619	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2018328876		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension; Suicide Attempt	Alprazolam			S	Oral	Unk		Pfizer
	Propranolol			S	Oral	Unk		Not Reported
	Paracetamol			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15297045	EXPEDITED (15-DAY)		HO, LT	NL-TEVA-2018-NL-944650		69 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram Tablet, 10 Mg (Milligram)			S	Unknown	10 Milligram Daily; 1 X Per Dag 1 Stuk		Ivax
	Hydrochlorothiazide 25mg			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298000	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1840381US		48 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastritis; Gastrooesophageal Reflux Disease; Gastrooesophageal Sphincter Insufficiency; Off Label Use	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Rivotril			C	Unknown	0.5 Mg, Unknown		Not Reported
	Euthyrox			C	Oral	100-125 Mcg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298004	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1840441US			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Expired Product Administered; Poisoning; Product Storage Error	Escitalopram Oxalate - Bp			S	Unknown	10 Gtt, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298098	EXPEDITED (15-DAY)		DS	PT-ALLERGAN-1840579US		77 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dry Mouth; Headache; Muscular Weakness; Nausea; Product Dosage Form Issue; Taste Disorder; Tinnitus; Vertigo	Escitalopram Oxalate - Bp			S	Oral	5 Gtt, Qd		Allergan
	Victan			C	Oral	Unk		Not Reported
	Vastarel			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298108	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1840578US		59 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Electrocardiogram Qt Prolonged; Moaning	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Alprazolam			S	Oral			Not Reported
	Trilafon			S	Oral			Not Reported
	Ramipril			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298109	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1840390US		48 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Altered State Of Consciousness; Depressed Mood; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp	S	Oral	14 Df, Single		Allergan
	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd		Allergan
	Stilnox	S	Oral	10 Df, Single		Not Reported
	Stilnox	S	Oral	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298253	EXPEDITED (15-DAY)		HO, LT	PHHY2018ES073955		18 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypocoagulable State	Paracetamol			S	Oral	12 G, Total		Not Reported
	Ibuprofeno			S	Oral	2800 Mg, Total (400 Mg X 7 Cps)		Novartis
	Escitalopram			S	Oral	5 Df, Unk		Not Reported
	Exforge			S	Oral	5 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298280	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1840632US		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Intentional Overdose; Miosis	Escitalopram Oxalate - Bp			S	Oral	280 Mg, Unk		Allergan
	Plaquenil			S	Oral	3 G, Unk		Not Reported
	Doliprane			S	Oral	6 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298290	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1840583US		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Miosis; Off Label Use; Prothrombin Time Shortened;	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Unknown		Allergan
	Dafalgan Codeine			S	Oral	Unk, Unknown		Not Reported

Tachycardia; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298291	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1840544US		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Electrocardiogram Qt Prolonged	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Laroxyl			S	Intramuscular	50 Mg/2 Ml		Not Reported
	Theralene			S	Oral	Si Besoin		Not Reported
	Solian			S	Intramuscular	200mg/4ml		Not Reported
	Imovane			C	Oral	Si Besoin		Not Reported
	Dexeryl (Glycerol And White Soft Paraffin And Liquid Paraffin)			C	Cutaneous			Not Reported
	Plavix			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Losartan Potassique			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298356	EXPEDITED (15-DAY)		HO, LT	NL-ALLERGAN-1840566US		69 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Hydrochlorothiazide Unk			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298357	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1840587US		73 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Gait Disturbance	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd (0.5 Df, Qd)		Allergan
	Lorans			S	Oral	1 Mg, Qd (1 Df, Qd)		Not Reported

	Lorans	S	Oral	2.5 Mg, Qd (1df, Qd)	Not Reported
	Quetiapine	S	Oral	150 Mg, Qd	Not Reported
	Carbolithium	S	Oral	225 Mg, Qd (1.5 Df, Qd)	Not Reported
	Motilium	C	Unknown		Not Reported
	Metformina Teva	C	Unknown		Not Reported
	Omeprazen	C	Unknown		Not Reported
	Eskim	C	Unknown		Not Reported
	Totalip	C	Unknown		Not Reported
	Nicetile	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298407	EXPEDITED (15-DAY)		CA	FR-ALLERGAN-1840624US		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Disease Congenital	Escitalopram Oxalate - Bp			S	Transplacental	1 Df, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	1 Df, Qd		Allergan
	Cymbalta			S	Transplacental	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298543	EXPEDITED (15-DAY)		DE, HO	FR-NAPPMUNDI-GBR-2013-0015606		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis	Oxynorm Solution Injectable			S	Intravenous (not otherwise specified)	Unk		Purdue
	Fortum /00559701/			S	Intravenous (not otherwise specified)	4 G, Qid		Not Reported
	Flagyl /00012501/			S	Oral	3 Df, Tid		Not Reported
	Gentamicine Panpharma			S	Intravenous (not otherwise specified)	210 Mg, Daily		Not Reported
	Noxafil			S	Oral	200 Mg, Tid		Not Reported

Cancidas	S	Intravenous (not otherwise specified)	Unk	Not Reported
Ambisome	S	Intravenous (not otherwise specified)	180 Mg, Daily	Not Reported
Bactrim	S	Intravenous (not otherwise specified)	2 Df, 3/Week	Not Reported
Folinic Acid	S	Intravenous (not otherwise specified)	50 Mg, 3/Week	Not Reported
Zelitrex	S	Intravenous (not otherwise specified)	500 Mg, Bid	Not Reported
Cymevan	S	Intravenous (not otherwise specified)	700 Mg, Bid	Not Reported
Foscavir	S	Intravenous (not otherwise specified)	2 Df, Bid	Not Reported
Human Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
Granocyte /03200101/	S	Intravenous (not otherwise specified)	Unk	Not Reported
Heparin Sodium	S		7000 Iu, Daily	Not Reported
Inexium /01479302/	S	Intravenous (not otherwise specified)	1 Df, Daily	Not Reported
Spasfon /00765801/	S	Intravenous (not otherwise specified)	2 Df, Tid	Not Reported
Delursan	S	Oral	3 Df, Bid	Not Reported
Defibrotide	S	Intravenous (not otherwise specified)	25 Mg/Kg, Daily	Not Reported
Largactil /00011901/	S	Intravenous (not otherwise specified)	1 Df, Daily	Not Reported
Tranxene Sd	S	Oral	1 Df, Qid	Not Reported
Exacyl	S	Intravenous (not otherwise specified)	1 Df, Tid	Not Reported
Perfalgan	S	Intravenous (not otherwise specified)	1 G, Tid	Not Reported
Solumedrol	S	Intravenous (not	140 Mg, Daily	Not Reported

		otherwise specified)		
Droleptan	S	Intravenous (not otherwise specified)	0.625 Mg, Qid	Not Reported
Ultiva	S	Intravenous (not otherwise specified)	100 Gbq, Qid	Not Reported
Atarax /00058401/	S	Oral	0.5 Df, Daily	Not Reported
Lasilix /00032601/	S	Intravenous (not otherwise specified)	40 Mg, Bid	Not Reported
Seroplex	S	Oral	10 Mg, Daily	Not Reported
Ceris	S	Oral	2 Df, Bid	Not Reported
Noctamide	S	Oral	1 Df, Daily	Not Reported
Gentamicine	C		Unk	Not Reported
Vancomycine	C		Unk	Not Reported
Ciflox /00697201/	C		Unk	Not Reported
Targocid	C		Unk	Not Reported
Mycostatine	C		Unk	Not Reported
Zovirax /00587301/	C		Unk	Not Reported
Methotrexate	C		Unk	Not Reported
Elvorine	C		Unk	Not Reported
Sandimmun	C		Unk	Not Reported
Mopral /00661201/	C		20 Mg, Unk	Not Reported
Ogastoro	C		Unk	Not Reported
Gelox	C		Unk	Not Reported
Smecta /00837601/	C		Unk	Not Reported
Luteran	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298564	EXPEDITED (15-DAY)		DE, HO	US-ALLERGAN-1840672US		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Overdose	Escitalopram Oxalate Unk	S	Unknown	Unk		Allergan
	Valproic Acid	S	Unknown	Unk		Not Reported
	Sertraline	S	Unknown	Unk		Not Reported
	Quetiapine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	10638234	EXPEDITED (15-DAY)		DS, HO, OT	US-SA-2014SA149672		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Asthenia; Blood Cholesterol Abnormal; Blood Glucose Increased; Brain Oedema; Cognitive Disorder; Cough; Fatigue; Fatigue; Fatigue; Feeding Disorder; Headache; Hypertension; Hypoaesthesia; Hypoaesthesia; Mental Disorder; Migraine; Multiple Sclerosis Relapse; Muscular Weakness; Nasal Congestion; Nasopharyngitis; Nasopharyngitis; Nervous System Disorder; Paraesthesia; Respiratory Disorder; Seizure; Sinus Disorder; Sleep Disorder; Somnolence; Stress; Unevaluable Event; Urinary Incontinence; Vomiting; Weight Decreased	Teriflunomide			S	Oral	14 Mg, Qd		Sanofi
	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
	Lexapro			S	Unknown	20 Mg,Qd		Not Reported
	Lexapro			S				Not Reported
	Lamictal			C		100 Mg,Bid		Not Reported
	Cyanocobalamin			C		1000 Df,Unk		Not Reported
	Cyanocobalamin			C		2500 Ug,Unk		Not Reported
	Vitamin D3			C		5000 Df,Unk		Not Reported
	Vitamin D3			C				Not Reported
	Metformin			C		Unk		Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	13882141	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1735577US		32 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal; Lymphocyte Morphology Abnormal; Rash	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Prodif			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Fluconazole			S	Oral	Unk, Unknown		Not Reported
	Famotidine			C	Unknown	Unk, Unknown		Not Reported
	Miya Bm			C	Oral	2 Df, Unk		Not Reported
	Talion Od			C	Oral	10 Mg, Q12h		Not Reported
	Albumin Tannate			C	Oral	1 G, Unk		Not Reported
	Loperamide Hydrochloride			C	Oral	1 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15160991	NON-EXPEDITED		OT	US-JAZZ-2018-US-007044		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Narcolepsy; Nausea; Vomiting	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Xyrem			S	Oral	1.125 G, Qd		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	3.5 G, Bid		Jazz
	Xyrem			S	Oral	Decreased Dose		Jazz
	Xyrem			S	Oral	3.5 G, Bid		Jazz
	Lexapro			S				Not Reported
	Amoxicillin			C		Unk		Not Reported
	Ritalin			C		Unk		Not Reported
	Allegra Allergy			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15298919	EXPEDITED (15-DAY)		HO, OT	IN-LUPIN PHARMACEUTICALS INC.-2018-05873		33 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Aggression; Drug Intolerance; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity; Sedation	Escitalopram			S	Unknown	Unk		Lupin
	Escitalopram			S				Lupin
	Escitalopram			S				Lupin
	Escitalopram			S				Lupin
	Escitalopram			S				Lupin
	Quetiapine			S	Unknown	Unk		Not Reported
	Lithium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15299516	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE-945309		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Fallot'S Tetralogy	Metoprolol			S	Transplacental	71.25 [Mg/D]/ 47.5-0-23.75 Mg/D		Not Reported
	Amitriptylin			S	Transplacental	37.5 Milligram Daily; 37.5 [Mg/D]		Not Reported
	Cipralex			S	Transplacental	5 Milligram Daily; 5 [Mg/D]		Not Reported
	Paracetamol			C	Transplacental	2000 [Mg/D]/ 1-2 G/D If Required		Not Reported
	Clexane 40			C	Transplacental	120 [Mg/D (-40)]/ Initial 40mg/D, Dosage Increase To 2 X 60 Mg/D		Not Reported
	Ibuprofen			C	Transplacental	6 Milligram Daily; 600 [Mg/D]/ If Required		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15299559	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2018-DE-945262		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Dexamethasone			S	Oral	8 Milligram Daily;		Actavis
	Sycrest			S	Oral	5 Milligram Daily;		Not Reported
	Cipralex			S	Oral	5 Milligram Daily;		Not Reported
	Pantoprazol			C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15301220	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018327013		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Overdose; Somnolence	Ibuprofen			S	Oral	20 Df, Unk		Pfizer
	Havlane			S	Oral	20 Df, Unk		Not Reported
	Paroxetine			S	Oral	12 Df, Unk		Not Reported
	Dafalgan Codein			S	Oral	8 G, Unk		Not Reported
	Escitalopram			S	Oral	28 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15301629	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP019299		81 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram			S	Oral	10 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15301722	EXPEDITED (15-DAY)		LT	FR-TEVA-2018-FR-944775		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Miosis; Prothrombin Time Shortened; Tachycardia;	Escitalopram			S	Oral			Ivax
	Dafalgan Codeine, Comprimé Pelliculé			S	Oral			Not Reported

Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15301978	EXPEDITED (15-DAY)		OT	HR-TEVA-2018-HR-944908		17 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; No Adverse Event; Suicide Attempt	Q Pin			S	Oral	50 Milligram Daily;		Teva
	Aripiprazol			S	Oral	20 Milligram Daily;		Teva
	Citram			S	Oral	90 Milligram Daily;		Not Reported
	Ketonal			S	Oral	1 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15302862	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2018M1061882			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Suicidal Ideation	Loxalate			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15303112	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1840787US		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Musculoskeletal Pain; Neck Pain; Seizure; Tremor	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15170639	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-036628		24 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Prescribed Overdose	Escitalopram			S	Oral	Overdose: 30 Milligram Daily		Aurobindo

Escitalopram	S	Oral	20 Milligram, Daily		Aurobindo
Escitalopram	S	Oral	30 Milligram, Daily		Aurobindo
Prothipendyl	C	Oral	80 Milligram, Daily		Not Reported
Diazepam	C	Oral	10 Milligram, Daily		Not Reported
Diazepam	C	Oral	5 Milligram, Daily		Not Reported
Pantozol /01263204/	C	Oral	20 Milligram, Daily		Not Reported
Pantozol /01263204/	C	Oral	40 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15266964	EXPEDITED (15-DAY)		OT	IT-TAKEDA-2018TUS024416		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Brintellix			S	Unknown	15 Mg, Qd		Takeda
	Brintellix			S	Unknown	10 Mg, Qd		Takeda
	Brintellix			S	Unknown	5 Mg, Qd		Takeda
	Cipralex /01588501/			S	Unknown	20 Mg, Qd		Not Reported
	Cipralex /01588501/			S				Not Reported
	Lorazepam			S	Oral	2.5 Mg, Qd		Not Reported
	Sertraline Hydrochloride			S	Oral	100 Mg, Qd		Not Reported
	Duloxetine Hydrochloride			S	Unknown	60 Mg, Qd		Not Reported
	Duloxetine Hydrochloride			S				Not Reported
	Lansoprazole			C	Unknown	30 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	2 Mg, Qd		Not Reported
	Ezetimibe			C	Unknown	10 Mg, Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Coumadin /00014802/			C	Unknown	Unk		Not Reported
	Triatec Hct			C	Unknown	15 Mg, Qd		Not Reported
	Cordarone			C	Unknown	Unk		Not Reported
	Warfarin Sodium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15297995	EXPEDITED (15-DAY)		OT	SA-ALLERGAN-1840447US		26 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Partial Seizures	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Levetiracetam			S	Unknown	500 Mg, Bid		Not Reported
	Lamotrigine			S	Unknown	50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15297997	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1840453US		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15304888	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-181877		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Not Reported
	Ibuprofene		Y	S	Oral	Unk		Ranbaxy
	Paroxetine			S	Oral	Unk		Sun
	Havlane			S	Oral	Unk		Not Reported
	Dafalgan			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15305409	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2017005849			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Duloxetine 60 Mg			S	Unknown	60 Mg, Qd		Macleods
	Duloxetine 60 Mg			S	Unknown	Unk		Macleods
	Cipralex			S	Unknown	20 Mg, Qd		Not Reported
	Cipralex			S	Unknown	Unk		Not Reported
	Sertraline Hydrochloride			S	Oral	100 Mg, Qd		Not Reported
	Lorazepam			S	Oral	2.5 Mg, Qd, At Bed Time		Not Reported
	Lorazepam			S				Not Reported
	Alprazolam			C	Unknown	2 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	Unk		Not Reported
	Warfarin			C	Unknown	Unk		Not Reported
	Ezetimab			C	Unknown	Unk		Not Reported
	Ezetimab			C	Oral	10 Milligram, Qd		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	30 Milligram, Qd		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	20 Milligram, Qd		Not Reported
	Amidarone			C	Unknown	Unk		Not Reported
	Coumadin			C	Unknown	Unk		Not Reported
	Cordarone			C	Unknown	Unk		Not Reported
	Triatec Hct			C	Unknown	15 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15306661	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2018148847		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphadenitis; Rash Maculo-Papular	Lamictal			S	Oral	75 Mg, Qd		Glaxosmithkline
	Seroplex			S	Oral	5 Mg, Qd		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15306680	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018016399			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Prescribed Overdose	Escitalopram			S	Oral	20 Milligram, Qd		Macleods
	Escitalopram			S	Oral	30 Milligram, Qd		Macleods
	Escitalopram			S	Oral	10 Milligram, Qd,Overdose: 30 Milligram Daily		Macleods
	Diazepam			C	Oral	10 Milligram, Qd		Not Reported
	Diazepam			C	Oral	5 Milligram, Qd		Not Reported
	Pantozol			C	Oral	20 Milligram, Qd		Not Reported
	Pantozol			C	Oral	40 Milligram, Qd		Not Reported
	Prothipendyl			C	Oral	80 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15307061	EXPEDITED (15-DAY)		OT	FR-SA-2018SA219386		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Escitalopram Oxalate			S	Oral	20 Mg Le Matin		Not Reported
	Doxylamine Succinate			S	Oral	Non Renseignée		Sanofi
	Alprazolam			S	Oral	0.5 Mg Puis 0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15307128	NON-EXPEDITED		OT	US-APOTEX-2018AP019587		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Exposure During Pregnancy; Therapeutic	Paroxetine			S	Unknown	Unk		Apotex
	Bupropion			S	Unknown	Unk		Apotex

Product Effect Incomplete; Treatment Failure	Escitalopram		S	Unknown	Unk	Apotex
	Lamotrigine		S	Unknown	400 Mg Per Day	Apotex
	Aripiprazole		S	Unknown	15 Mg Per Day	Apotex
	Venlafaxine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15307694	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-944635		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Escitalopram			S	Oral	1 Dosage Forms Daily;		Ivax
	Stresam			S	Oral	3 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15308533	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1841015US		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Malaise; Off Label Use; Rash	Escitalopram Oxalate Unk			S	Oral	20 Mg, Tid		Allergan
	Escitalopram Oxalate Unk			S	Unknown	Unk, Unknown		Allergan
	Diazepam			C	Oral	10 Mg, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14613081	EXPEDITED (15-DAY)		DE, HO, OT	DE-LUPIN PHARMACEUTICALS INC.-2018-01610		1 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Topiramate			S	Unknown	Unk		Lupin
	Sildenafil Citrate			S	Unknown	Unk		Not Reported
	Spironolactone			S	Unknown	Unk		Not Reported
	Phenobarbital			S	Unknown	Unk		Not Reported
	Varivax /06643105/			S	Intramuscular	1 Df		Not Reported

	Synagis	S	Intramuscular		Not Reported
	Exodus /01588502/	S	Unknown	Unk	Not Reported
	Carbohydrates Nos W/Carnitine/Fats Nos/Minera	C	Other	4 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15145722	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-925080		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Esomeprazole			S	Oral	40 Milligram Daily;		Teva
	Esidrex 25 Mg, Comprimé			S	Oral	.5 Dosage Forms Daily;		Not Reported
	Seroplex 15 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported
	Procoralan 5 Mg, Comprimé Pelliculé			C	Unknown			Not Reported
	Aspirine Protect 100 Mg, Comprimé Gastro-Résistant			C	Unknown			Not Reported
	Seresta 50 Mg, Comprimé Sécable			C	Unknown			Not Reported
	Dafalgan 1 G, Comprimé Pelliculé			C	Unknown			Not Reported
	Pravastatine Sodique			C	Unknown			Not Reported
	Mediatensyl 30 Mg, Gélule			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Acebutolol (Chlorhydrate D')			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15266914	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT069494		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Tolep			S	Oral	38 Df, Total		Novartis
	Oxcarbazepina			S	Oral	Unk		Novartis
	Lorazepam			S	Oral	20 Mg, Total		Not Reported

	Paracetamol	S	Oral	2 G, Unk	Not Reported
	Tachipirina	S	Oral	2 G, Total	Not Reported
	Cipralex	S	Oral	15 Ml, Total	Not Reported
	Brintellix	S	Oral	15 Ml, Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15280401	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2018143794		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Lichen Planus	Lamotrigine			S	Oral	Unk		Glaxosmithkline
	Esomeprazole			S	Oral	Unk		Glaxosmithkline
	Seroplex			S	Oral	Unk		Glaxosmithkline
	Atorvastatine			S	Oral	20 Mg, Unk		Glaxosmithkline
	Macrogol			S	Oral	Unk		Glaxosmithkline
	Hydrochlorothiazide			S	Oral	25 Mg, Unk		Not Reported
	Xeroquel			S	Oral	Unk		Not Reported
	Perindopril			S	Oral	2 Mg, Unk		Not Reported
	Kardegic			S	Oral	Unk		Not Reported
	Verapamil			S	Oral	240 Mg, Unk		Not Reported
	Teralithe			S	Oral	Unk		Not Reported
	Aldactone (Spirolactone)			S	Unknown	Unk Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15310565	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2018NO076406		40 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Fibrillation; Dizziness; Eye Disorder; Myalgia; Palpitations; Tooth Injury	Quetiapine Sandoz			S	Unknown	25 Mg, Q12h		Novartis
	Calcigran Forte			S	Unknown	4 Iu, Q12h		Not Reported
	Cipralex			S	Unknown	20 Mg, Q12h		Not Reported

Cipralex	S	Unknown	20 Mg, Q12h		Not Reported
Calcium	C	Unknown	Unk		Not Reported
Etalpha	C	Oral	Unk		Not Reported
Etalpha	C	Oral	Unk		Not Reported
Zopiklon Mylan	C	Unknown	Unk		Not Reported
Zopiklon Mylan	C	Unknown	Unk		Not Reported
Multi Mineral	C	Unknown	Unk		Not Reported
Vitaman	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15311935	EXPEDITED (15-DAY)		HO	SE-TEVA-2018-SE-947059		60 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Generalised	Escitalopram			S		5 Milligram Daily;		Ivax
	Atarax			S		75 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	12951890	EXPEDITED (15-DAY)		CA	FR-ALLERGAN-1676191US		7 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Intellectual Disability	Escitalopram Oxalate - Bp			S	Transplacental			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14737680	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1812889US		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression Suicidal; Dizziness	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Bupropion Sr			S	Oral	300 Mg, Qd		Not Reported
	Bupropion Sr			S	Oral	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15251481	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018312592		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam			S	Oral	20 Mg, Total		Pfizer
	Tachipirina			S	Oral	2 G, Total		Not Reported
	Brintellix			S	Oral	15 Ml, Total		Not Reported
	Tolep			S	Oral	38 Df, Total		Not Reported
	Cipralex /01588501/			S	Oral	15 Ml, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15288798	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1840041US		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Transient Ischaemic Attack	Escitalopram Oxalate 5mg Tab			S	Unknown	10 Mg, Unknown		Allergan
	Escitalopram Oxalate 5mg Tab			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15313968	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-182428		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension	Paracetamol		Y	S	Oral	()		Ohm Lab
	Escitalopram			S	Oral	()		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	()		Not Reported
	Alprazolam			S	Oral	()		Not Reported
	Ibuprofene			C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15313971	NON-EXPEDITED			US-DRREDDYS-USA/USA/17/0094635			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Injection Site Pain; Product Complaint; Tinnitus	Fondaparinux Sodium			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Temazepam			C	Unknown			Not Reported
	Iron			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15313977	EXPEDITED (15-DAY)		OT	SE-TEVA-2018-SE-946135		24 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Headache; Malaise; Product Substitution Issue; Tremor; Tunnel Vision	Escitalopram Teva			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15314107	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-948269		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Acute Kidney Injury; Anxiety; Dehydration; Depression; Drug Interaction; Hepatocellular Injury; Hypernatraemia; Hypotension; Mucosal Disorder; Neuroleptic Malignant Syndrome; Psychomotor Hyperactivity; Skin	Escitalopram			S	Unknown			Ivax
	Lercanidipine			S	Unknown			Not Reported
	Cyamemazine			S	Unknown			Not Reported
	Cyamemazine			S	Unknown	50 Milligram Daily;		Not Reported
	Cyamemazine			S	Unknown	25 Mg To 75 Mg Daily		Not Reported
	Cyamemazine			S	Unknown	Continued At A Low Dose, 50 Mg To 100 Mg		Not Reported
	Zuclopenthixol Decanoate			S	Unknown	Long-Acting Injectable		Not Reported

Atrophy; Suicide Attempt; Vasoplegia Syndrome; Wrong Product Administered	Zuclopenthixol Acetate	S	Intramuscular	The Short-Acting Form Of The Drug	Not Reported
	Zuclopenthixol Dihydrochloride	S	Unknown	Dose Was Titrated From 5 To 40 Mg Daily Over 2 Weeks	Not Reported
	Bisoprolol	C	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15314529	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-042878		24 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	30 Milligram, Once A Day		Aurobindo
	Diazepam			C	Oral	5 Milligram, Once A Day		Not Reported
	Diazepam			C	Oral	10 Milligram		Not Reported
	Pantozol /01263204/			C	Unknown	20 Milligram, Once A Day		Not Reported
	Pantozol /01263204/			C	Unknown	40 Milligram, Once A Day		Not Reported
	Prothipendyl			C	Oral	80 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15314684	EXPEDITED (15-DAY)		DS, HO, LT	PT-MACLEODS PHARMACEUTICALS US LTD-MAC2018016426			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Confusional State; Decreased Appetite; Hyponatraemia; Panic Attack; Psychomotor	Escitalopram Tablet			S	Oral	1 Dosage Form, Qd, Ram Appeared A Few Days After The Start Of Administration Of The Suspected Drug		Macleods

Hyperactivity; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15314866	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-042978		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Melaena; Rectal Haemorrhage	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo
	Kardegic			S	Oral	1 Dosage Form, Daily		Not Reported
	Crestor			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15315443	EXPEDITED (15-DAY)			US-ASPEN-GLO2018US007643		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia	Benztropine Mesylate			S				Nuvo Research
	Escitalopram			S	Unknown			Not Reported
	Bupropion			S				Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Lithium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15316857	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1841136US		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Rash; Swelling	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Imovane			C	Unknown	Unk, Unknown		Not Reported
	Gravol			C	Unknown	Unk, Unknown		Not Reported
	Ativan			C	Unknown	Unk, Unknown		Not Reported
	Pregvit			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15317558	EXPEDITED (15-DAY)		HO	PHHY2016FR187181		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Interstitial Lung Disease	Atorvastatin Calcium			S	Oral	10 Mg, Qd		Novartis
	Mycophenolate Mofetil			S	Oral	2 Df, Qd		Not Reported
	Inexium			S	Oral	20 Mg, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Bid		Not Reported
	Stilnox			S	Oral	10 Mg, Qd		Not Reported
	Theralene			S	Oral	5 Mg, Bid		Not Reported
	Triatec (Ramipril)			S	Oral	5 Mg, Qd		Not Reported
	Ixprim			S	Oral	Unk		Not Reported
	Cortancyl			S	Oral	5 Mg, Bid		Not Reported
	Lasilix			C	Unknown	Unk		Not Reported
	Seresta			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15333399	DIRECT					52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased	Escitalopram 20 Mg			S	Oral	Quantity:30 Tablets		Aurobindo
	Oxcarbazepine			S	Oral	Quantity:3 Tablets		Breckenridge
	Levothyroxine			C				Not Reported
	Depo Inj.			C				Not Reported
	Eye Ddrop			C				Not Reported
	Iron			C				Not Reported
	Metformin			C				Not Reported
	Aspirin			C				Not Reported
	Omeprazole			C				Not Reported
	Pioglitizone			C				Not Reported
	Clonasepam			C				Not Reported
	Dicyclomine			C				Not Reported

	Divalproex Ec	C	Not Reported
	Aimovig Inj	C	Not Reported
	Lisinopril	C	Not Reported
	Pravastatin	C	Not Reported
	Lexapro	C	Not Reported
	Mirtazapine	C	Not Reported
	Trazadone	C	Not Reported
	Vraylar	C	Not Reported
	Vitamin B-12	C	Not Reported
	Vitamin D-3	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2018	15333879	DIRECT		HO			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombosis; Uterine Haemorrhage	Lexapro			S	Oral	Quantity:1 Tablet(S);		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2018	15334594	DIRECT		DS, HO			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anhedonia; Burning Sensation; Chromaturia; Depression; Dyscalculia; Flatulence; Frustration Tolerance Decreased; Galactorrhoea; Heart Rate Decreased; Nausea; Salt Craving; Somnolence; Somnolence; Weight Increased	Latuda, 60 Mg			S	Oral	Quantity:2 Tablet(S);		Not Reported
	Lexapro			S				Not Reported
	Abilify			S				Not Reported
	Risperidone			S				Not Reported
	Multi-Vitamin			C				Not Reported
	Fish Oil			C				Not Reported
	Zyprexa			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	12934226	EXPEDITED (15-DAY)		LT, OT	JP-ALLERGAN-1675344US		47 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Feeling Abnormal; Pyrexia; Syncope	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Dogmatyl			C	Oral	0.05 G, Q12h		Not Reported
	Sepazon			C	Oral	0.05 G, Q12h		Not Reported
	Lactose			C	Oral	0.75 G, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15154548	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT047244		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Drug Ineffective; Drug Interaction; Feeling Of Despair; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Quetiapine			S	Oral	200 Mg, Qd		Novartis
	Valproic Acid Sandoz			S	Oral	300 Mg, Qd		Not Reported
	Venlafaxine			S	Oral	300 Mg, Qd		Not Reported
	Alprazolam			S	Oral	1.5 Mg, Qd		Not Reported
	Alprazolam			S		1 Mg		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Qd		Not Reported
	Trazodone			S	Oral	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15260542	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2012FR143999		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use; Suicide Attempt	Olanzapine			S	Unknown	15 Mg, Unk		Novartis
	Zopiclone			S	Oral	7.5 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	5 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Anafranil			S	Oral	Daily Dose Increased		Not Reported
	Lepticur			S	Unknown	Unk		Not Reported

Depamide	S	Oral	Unk		Not Reported
Seroplex	S	Unknown	Unk		Not Reported
Seroplex	S				Not Reported
Dopamide	S	Oral	Unk		Not Reported
Abilify	S	Unknown	10 Mg, Unk		Not Reported
Seresta	S	Oral	Unk Unk, Bid (Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening)		Not Reported
Lexapro	S	Unknown	10 Mg, Qd (Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy)		Not Reported
Zyprexa	S	Unknown	Unk		Not Reported
Imovane	S	Oral	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15298300	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1840588US		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Hepatitis Infectious Mononucleosis; Hepatocellular Injury; Myalgia; Pyrexia; Vertigo	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Doliprane			C	Oral	Unk, Unknown		Not Reported
	Fluoxetine Zentiva			C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15319512	EXPEDITED (15-DAY)		HO, OT	FR-ZYDUS-024691		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Acute Kidney Injury; Antipsychotic Drug Level Increased; Anxiety; Confusional State; Dehydration; Depression;	Escitalopram			S	Unknown			Zydus Pharm
	Lercanidipine			S	Unknown			Not Reported
	Cyamemazine			S	Unknown	50 Mg To 100 Mg Daily		Not Reported
	Zuclopenthixol			S	Unknown	Titrated From 5 To 40 Mg		Not Reported

Drug Interaction; Hepatocellular Injury; Hypernatraemia; Hypertension; Hyperthermia; Hypotension; Intentional Overdose; Mucosal Disorder; Muscle Rigidity; Neuroleptic Malignant Syndrome; Product Administration Error; Psychomotor Hyperactivity; Skin Atrophy; Stupor; Suicide Attempt; Vasoplegia Syndrome	Zuclopenthixol	S	Unknown	Daily Over 2 Weeks		Not Reported
	Zuclopenthixol	S	Intramuscular			Not Reported
	Bisoprolol	C	Unknown			Not Reported
	Atorvastatin	C	Unknown			Not Reported
	Metformin	C	Unknown			Not Reported
	Cyamemazine	S	Unknown	25 Mg To 75 Mg		Not Reported
	Cyamemazine	S	Unknown			Not Reported
	Cyamemazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15319850	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-944505		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Hepatitis Infectious Mononucleosis; Hepatocellular Injury; Myalgia; Pyrexia; Vertigo	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Doliprane			C	Oral			Not Reported
	Fluoxetine Zentiva 20 Mg, Comprimé Dispersible Sécable			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15322254	EXPEDITED (15-DAY)		OT	PHHY2018IT076818		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Olanzapine			S	Oral	20 Mg, 813 (Total)		Novartis
	Escitalopram			S	Oral	50 Mg, (Total)		Not Reported
	Tavor (Lorazepam)			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15323229	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1841348US		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Donormyl (Doxylamine Succinate)			S	Oral	Unk		Not Reported
	Xanax			S	Oral	0.5 Mg Puis 0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15336247	DIRECT		DS			22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Odour; Dry Mouth; Intentional Overdose; Unhealthy Diet	Vyvanse			S	Oral	Quantity:1 Capsule(S);		Shire
	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Phenibut			C				Not Reported
	Astaxanthin			C				Not Reported
	Spirulina			C				Not Reported
	Fish Oil			C				Not Reported
	Aged Garlic Extract			C				Not Reported
	Nac			C				Not Reported
	Zinc			C				Not Reported
	Copper			C				Not Reported
	Magnesium			C				Not Reported
	Vitamin C			C				Not Reported
	Calcium			C				Not Reported
	Vitamin D3			C				Not Reported
	Vitamin K2 Mk07			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	12683839	NON-EXPEDITED			US-FRI-1000084257			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Lexapro			S	Unknown	Unk		Allergan

Hyperhidrosis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	12771179	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016434898		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Interstitial Lung Disease	Tahor			S	Oral	10 Mg, Daily		Pfizer
	Triatec (Ramipril)			S	Oral	5 Mg, Daily		Pfizer
	Inexium			S	Oral	20 Mg, Daily		Unknown
	Cellcept			S	Oral	1 G, 2x/Day		Not Reported
	Cortancyl			S	Oral	5 Mg, 2x/Day		Not Reported
	Theralene			S	Oral	5 Mg, 2x/Day		Not Reported
	Stilnox			S	Oral	10 Mg, Daily		Not Reported
	Seroplex			S	Oral	10 Mg, 2x/Day		Not Reported
	Ixprim			S	Oral	Unk		Not Reported
	Seresta			C		50 Mg, Unk		Not Reported
	Lasilix			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960390	NON-EXPEDITED			US-ALLERGAN-1713790US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Hyperhidrosis; Nightmare	Lexapro			S	Oral	5 Mg, Qod		Allergan
	Lexapro			S	Oral	10 Mg, Qam		Allergan
	Carvedilol			C	Oral	(Half Tablet) 3.125 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960420	NON-EXPEDITED			US-ALLERGAN-1725967US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fatigue	Lexapro	S	Oral	10 Mg, Qd		Allergan
	Insulin	C		Unk		Not Reported
	Insulin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960437	NON-EXPEDITED			US-ALLERGAN-1727899US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960440	NON-EXPEDITED			US-ALLERGAN-1728597US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960441	NON-EXPEDITED			US-ALLERGAN-1728083US		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Influenza Like Illness; Night Sweats; Product Dose Omission; Sleep Disorder	Lexapro			S	Unknown	Unk		Allergan
	Synthroid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960456	NON-EXPEDITED			US-ALLERGAN-1731048US		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Retching; Sneezing; Wrong Technique In Product Usage Process; Yawning	Lexapro			S	Oral	10 Mg, Unk		Allergan
	Clonazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960457	NON-EXPEDITED			US-ALLERGAN-1731442US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960459	NON-EXPEDITED			US-ALLERGAN-1731045US		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	0.125 Df, Qd		Allergan
	Lexapro			S	Oral	0.25 Df, Qd		Allergan
	Clonazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960467	NON-EXPEDITED			US-ALLERGAN-1735803US		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Feeling Hot; Hiatus Hernia; Vertigo; Wrong Technique In Product Usage Process	Lexapro			S	Oral	1 Df, Unknown		Allergan
	Lexapro			S	Oral	0.5 Df, Unknown		Allergan
	Lexapro			S	Oral	1 Df, Unknown		Allergan
	Lexapro			S	Oral	0.5 Df, Unknown		Allergan
	Aspirin			S	Unknown	Low Dose		Not Reported
	Synthroid			C	Unknown	25 Mg, Unk		Not Reported
	Premarin			C	Unknown	Lowest Dose		Not Reported
	Benicar			C	Unknown	Unk		Not Reported
	Vitamin E			C	Unknown	Unk		Not Reported
	Vitamin C			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960479	NON-EXPEDITED			US-ALLERGAN-1735884US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anxiety	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Escitalopram Oxalate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960480	NON-EXPEDITED			US-ALLERGAN-1734826US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Malaise; Nausea	Lexapro			S	Oral	20 Mg, Unknown		Allergan
	Lexapro			S	Oral	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960488	NON-EXPEDITED			US-ALLERGAN-1746963US		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Malaise; Palpitations	Lexapro			S	Unknown	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13960657	NON-EXPEDITED			US-ALLERGAN-1708963US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Depression; Drug Ineffective; Labile Blood Pressure; Mental Status Changes	Lexapro			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	14630095	NON-EXPEDITED			US-PFIZER INC-2018098356		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Flagyl			S		Unk		Pfizer
	Doxy			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15093247	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1832855US		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Aggression; Cardiac Failure; Compulsive Shopping; Derealisation; Disinhibition; Grandiosity; Insomnia; Irritability; Mania; Myocardial Infarction; Obsessive-Compulsive Disorder; Oedema; Persecutory Delusion; Stent Placement; Suicidal Ideation; Thinking Abnormal; Verbal Abuse; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan
	Brintellix			S	Unknown	5 Mg, Qd		Not Reported
	Brintellix			S	Unknown	10 Mg, Unk		Not Reported
	Brintellix			S	Unknown	15 Mg, Unk		Not Reported
	Brintellix			S	Unknown	20 Mg, Unk		Not Reported
	Lasilix			C	Unknown			Not Reported
	Aldactone			C	Unknown			Not Reported
	Kardegic			C	Unknown			Not Reported
	Depakote			C	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported
	Noctamide			C	Unknown	2 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15225734	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL		45 YR	Female	ITA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam			S	Oral	In Total		Sun
	Brintellix			S	Oral	In Total		Not Reported
	Cipralex			S	Oral	In Total		Not Reported
	Tachipirina 500 Mg Compresse			S	Oral	In Total		Not Reported
	Tolep			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15249943	EXPEDITED (15-DAY)		OT	CH-GLAXOSMITHKLINE-CH2018136572		41 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Aphasia; Aphasia; Hyperhidrosis	Wellbutrin			S	Oral	150 Mg, Unk		Glaxosmithkline
	Wellbutrin			S	Oral	300 Mg, Unk		Glaxosmithkline
	Wellbutrin			S	Oral	450 Mg, Unk		Glaxosmithkline
	Wellbutrin			S	Oral	300 Mg, Qd		Glaxosmithkline
	Escitalopram			S	Oral	10 Mg, Qd		Glaxosmithkline
	Trittico			S	Oral	50 Mg, Qd		Not Reported
	Benocten			C	Unknown	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15256156	EXPEDITED (15-DAY)		CA, HO, OT	IT-ALLERGAN-1839033US		273 DAY	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome	Escitalopram Oxalate Unk			S	Transplacental	Unk Unk, Unknown		Allergan
	Carbolithium			S	Transplacental	750 Mg, Daily		Not Reported
	Lorazepam			C	Transplacental	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15323774	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-947903		24 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Diazepam			C	Oral	5 Milligram Daily;		Not Reported
	Diazepam			C	Oral			Not Reported
	Pantozol			C	Unknown	40 Milligram Daily;		Not Reported
	Pantozol			C				Not Reported
	Prothipendyl			C	Oral	80 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15325755	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20180828437		82 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Lower Gastrointestinal Haemorrhage; Prescribed Overdose	Xarelto			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Risperidone			C	Unknown			Not Reported
	Pantoprazole			C	Oral			Not Reported
	Benserazide Hydrochloride W/Levodopa			C	Unknown			Not Reported
	Concor			C	Oral			Not Reported
	Calcium Carbonate W/Colecalciferol			C	Oral			Not Reported
	Vitamin D3 Streuli			C	Unknown			Not Reported
	Solmucol			C	Oral			Not Reported
	Tiotropium Bromide			C	Respiratory (inhalation)			Not Reported

	Temesta (Lorazepam)	C	Unknown	Not Reported
	Metoclopramide	C	Unknown	Not Reported
	Imodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15326040	EXPEDITED (15-DAY)		HO	PHHY2018IT082571		73 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Gait Disturbance	Quetiapine			S	Oral	150 Mg, Qd		Novartis
	Cipralex			S	Oral	0.5 Df, Qd		Not Reported
	Lorans			S	Oral	1 Df, Qd		Not Reported
	Carbolithium			S	Oral	1.5 Df, Qd		Not Reported
	Motilium			C	Unknown			Not Reported
	Metformina Teva			C	Unknown			Not Reported
	Nicetile			C	Unknown			Not Reported
	Totalip			C	Unknown			Not Reported
	Eskim			C	Unknown			Not Reported
	Omeprazen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15326464	EXPEDITED (15-DAY)		HO, OT	ES-COVIS PHARMA B.V.-2018COV03741			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Electrocardiogram Qt Prolonged; Erythema; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia; Vomiting	Omeprazole Magnesium			S	Oral			Covis
	Escitalopram			S		Unk		Not Reported
	Incb050465			S	Oral	20 Mg		Not Reported
	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	149.3999939 Mg		Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

Co-Trimoxazol	S		Not Reported
Atorvastatin	C		Not Reported
Valsartan	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15326903	EXPEDITED (15-DAY)		HO, LT	PHHY2018NL082340		69 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram			S	Unknown	10 Mg, Qd (1 Per Dag 1 Stuk)		Not Reported
	Hydrochlorothiazide Sandoz			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327344	NON-EXPEDITED			US-ALLERGAN-1837870US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327345	NON-EXPEDITED			US-ALLERGAN-1838690US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327354	NON-EXPEDITED			US-ALLERGAN-1736000US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Nausea; Panic Attack; Sleep Disorder; Vomiting	Lexapro			S		10 Mg, Unk		Allergan
	Lexapro			S		20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327356	NON-EXPEDITED			IE-ALLERGAN-1839935US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis	Lexapro			S	Unknown	Unk		Allergan
	Vortioxetine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327357	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1748353US		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Suicidal Ideation	Lexapro			S	Oral	2.5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327358	NON-EXPEDITED			US-ALLERGAN-1747875US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Off Label Use; Product Dose Omission	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Toprol			C	Oral	50 Mg, Qd		Not Reported
	Hytrol			C	Oral	10 Mg, Qd		Not Reported
	Nitroglycerin			C	Sublingual	3 Df, Prn		Not Reported
	Amoxicilina /00249603/			C		100 Mg, After Dentist Appointment		Not Reported
	Amoxicilina /00249603/			C				Not Reported
	Levothyroxine			C	Oral	50 Mg, Qd		Not Reported
	Ectrin /00086101/			C	Oral	81 Mg, Qd		Not Reported
	Isosorbide			C	Oral	60 Mg, Qd		Not Reported
	Icaps			C	Oral	2 Df, Bid		Not Reported

Nexium		C	Unknown	1 Df, Bid		Not Reported
Nexium		C	Unknown	2 Df, Bid		Not Reported
Nexium		C	Unknown	1 Df, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327359	NON-EXPEDITED			US-ALLERGAN-1746756US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Fatigue; Hyperhidrosis; Malaise; Somnolence; Yawning	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327360	NON-EXPEDITED			US-ALLERGAN-1735996US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327361	NON-EXPEDITED			US-ALLERGAN-1747490US		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain; Off Label Use; Overdose; Vision Blurred	Lexapro			S	Oral	25 Mg, Unk		Allergan
	Lexapro			S	Oral	5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327363	NON-EXPEDITED			US-ALLERGAN-1747111US		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Unknown	2 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327364	NON-EXPEDITED			US-ALLERGAN-1746780US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Metoprolol			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327367	NON-EXPEDITED			US-ALLERGAN-1735799US		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Anxiety; Gastritis; Headache; Hyperhidrosis; Inflammation; Lethargy; Metrorrhagia; Nausea; Nervousness; Photopsia; Product Dose Omission; Therapeutic Response Decreased; Vulvovaginal Dryness; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10 Mg, Unk		Allergan
	Lexapro			S	Oral	5 Mg, Unk		Allergan
	Lexapro			S	Oral	8 Mg, Unk		Allergan
	Lexapro			S	Oral	20 Mg Cuts In Half For Daily Dose Of 10 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327368	NON-EXPEDITED			US-ALLERGAN-1747109US		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Lexapro			S	Unknown	2 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327369	NON-EXPEDITED			US-ALLERGAN-1736026US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Paraesthesia	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327370	NON-EXPEDITED			US-ALLERGAN-1733941US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered	Lexapro			S	Oral	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327371	NON-EXPEDITED			US-ALLERGAN-1746696US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Functional Gastrointestinal Disorder; Inappropriate Schedule Of Product Administration; Insomnia; Wrong Technique In Product Usage Process	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Baclofen			C	Unknown			Not Reported
	Copaxone			C	Unknown	40mg Mon/Wed/Fri		Not Reported
	Alprazolam			C	Oral	0.5 Mg, Unk		Not Reported
	Centrum /02217401/			C	Unknown			Not Reported
	Vitamin D /00107901/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327372	NON-EXPEDITED			US-ALLERGAN-1756707US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327373	NON-EXPEDITED			US-ALLERGAN-1769283US		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Losartan			C	Oral	100 Mg, Qd		Not Reported
	Amlodipine			C	Oral	10 Mg, Qd		Not Reported
	Ambien			C	Oral	Unk Unk, Qd		Not Reported
	Xanax			C	Oral	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327374	NON-EXPEDITED			US-ALLERGAN-1755733US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Breast Tenderness; Dysmenorrhoea; Menorrhagia; Premenstrual Syndrome	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Lexapro			S	Unknown	5 Mg, Unk		Allergan
	Lexapro			S	Unknown	2.5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327378	NON-EXPEDITED			US-ALLERGAN-1769539US		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Unk		Allergan
	Escitalopram Oxalate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327379	NON-EXPEDITED			US-ALLERGAN-1752109US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyspnoea; Intentional Product Use Issue	Lexapro	S	Oral	20 Mg, Qd		Allergan
	Lexapro	S	Oral	10 Mg, Qd		Allergan
	Oxygen	C				Not Reported
	Xanax	C	Unknown	.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327380	NON-EXPEDITED			US-ALLERGAN-1756709US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327381	NON-EXPEDITED			US-ALLERGAN-1749920US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Mental Disorder; Product Prescribing Error	Lexapro			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327382	NON-EXPEDITED			US-ALLERGAN-1753279US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Paraesthesia	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	Unk		Allergan
	Omega 3			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327383	NON-EXPEDITED			US-ALLERGAN-1749302US		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Lexapro	S	Oral	20 Mg, Unk		Allergan
	Lexapro	S	Oral	10 Mg, Unk		Allergan
	Latanoprost	C	Ophthalmic	Unk		Not Reported
	Tamsulosin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327384	NON-EXPEDITED			US-ALLERGAN-1751308US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Inappropriate Schedule Of Product Administration	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327385	NON-EXPEDITED			US-ALLERGAN-1759292US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Depression	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327386	NON-EXPEDITED			US-ALLERGAN-1748372US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Depression; Drug Ineffective; Feeling Abnormal; Hypersomnia; Joint Swelling; Pain In Extremity	Lexapro			S	Unknown	5 Unk, Unk		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Calcium			C	Oral	Unk		Not Reported
	Xanax			C	Oral	Unk Unk, Prn		Not Reported
	Pantoprazole			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327387	NON-EXPEDITED			US-ALLERGAN-1763064US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327388	NON-EXPEDITED			US-ALLERGAN-1772383US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327389	NON-EXPEDITED			US-ALLERGAN-1769710US		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Head Discomfort; Nervous System Disorder; Prescription Drug Used Without A Prescription	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327391	NON-EXPEDITED			US-ALLERGAN-1763097US		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia	Lexapro			S	Unknown	Unk Unk, Qam		Allergan
	Ampyra			S	Oral	10 Mg, Qam		Not Reported
	Gilenya			C		Unk, Qpm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327392	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1755113US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression; Asthenia; Cardiac Disorder; Chest Pain; Contusion; Decreased Appetite; Fall; Mobility Decreased; Nausea; Speech Disorder; Suicidal Ideation; Tremor; Vision Blurred	Lexapro	S	Oral	10 Mg, Qd		Allergan
	Oxazepam	C	Unknown	Unk, Unknown		Not Reported
	Oxazepam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327393	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1753276US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Omega 3			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327394	NON-EXPEDITED			US-ALLERGAN-1748675US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Insomnia	Lexapro			S	Unknown	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327395	NON-EXPEDITED			US-ALLERGAN-1759035US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro			S	Unknown	30 Mg, Qd		Allergan
	Lexapro			S	Unknown	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327396	NON-EXPEDITED			US-ALLERGAN-1749266US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Eye Pain; Feeling Abnormal; Headache; Photophobia; Visual Impairment	Lexapro		S	Unknown	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327397	NON-EXPEDITED			US-ALLERGAN-1754169US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Product Dose Omission	Lexapro			S	Oral	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327398	NON-EXPEDITED			US-ALLERGAN-1771840US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Fatigue; Menstrual Disorder; Paranoia	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Lexapro			S	Unknown	5 Unk, Unk		Allergan
	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Lexapro			S	Unknown	12.5 Mg, Unk		Allergan
	Lexapro			S	Unknown	15 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327399	NON-EXPEDITED			US-ALLERGAN-1771879US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Medication Error; Off Label Use; Product Dose Omission	Lexapro			S	Unknown	25 Mg, Unk		Allergan
	Diphenoxylate/ Atropine			C	Oral	1 Df, Prn		Not Reported
	Plavix			C	Oral	75 Mg, Qd		Not Reported
	Benazepril			C	Oral	40 Mg, Qd		Not Reported
	Amlodipin			C		5 Mg, Qd		Not Reported
	Ativan			C	Unknown	0.5 Mg, Bid		Not Reported

Zocor	C	Oral	2.5 Mg, Qd		Not Reported
Metoprolol	C	Unknown	25 Mg, Qd		Not Reported
Folic Acid	C		400 Mg, Qd		Not Reported
Vitamin D2	C		1 Df, Q Week		Not Reported
Aspirin	C	Oral	81 Mg, Qd		Not Reported
Gabapentin	C		100 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327400	NON-EXPEDITED			US-ALLERGAN-1769084US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Muscular Weakness	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327401	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1755141US		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Disturbance In Attention	Lexapro			S	Unknown	Unk, Qd		Allergan
	Zoloft			S	Unknown	125 Mg, Qd		Not Reported
	Wellbutrin			S	Unknown	Unk, Qd		Not Reported
	Cymbalta			S	Unknown	30 Mg, Unk		Not Reported
	Concerta			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327402	NON-EXPEDITED			US-ALLERGAN-1755787US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration	Lexapro			S	Unknown	Unk, Bid		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327403	NON-EXPEDITED			US-ALLERGAN-1750058US		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Product Dose Omission; Wrong Technique In Product Usage Process	Lexapro			S	Unknown	10 Mg, Unknown		Allergan
	Lexapro			S	Unknown	5 Mg, Unknown		Allergan
	Adderall			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327404	NON-EXPEDITED			US-ALLERGAN-1764052US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro			S	Unknown			Allergan
	Topamax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327405	NON-EXPEDITED			US-ALLERGAN-1756400US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327406	NON-EXPEDITED			US-ALLERGAN-1752446US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Body Height Decreased; Disturbance In Attention; Dizziness; Drug Ineffective; Weight Increased	Lexapro			S	Unknown			Allergan
	Effexor			S	Oral	Unk, Qd		Not Reported
	Effexor			S				Not Reported
	Effexor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327407	NON-EXPEDITED			US-ALLERGAN-1749085US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327410	NON-EXPEDITED			US-ALLERGAN-1815793US		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Panic Attack; Suicidal Behaviour	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327411	NON-EXPEDITED			US-ALLERGAN-1803583US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Vision Blurred	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327412	NON-EXPEDITED			US-ALLERGAN-1802009US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Anorgasmia; Anxiety; Head Discomfort; Panic Attack; Withdrawal Syndrome	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Lexapro			S	Unknown	7.5 Mg, Unk		Allergan
	Lexapro			S	Unknown	5 Mg, Unk		Allergan
	Lexapro			S	Unknown	2.5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327413	NON-EXPEDITED			US-ALLERGAN-1817150US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Product Dose Omission; Somnolence	Lexapro			S	Unknown	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327414	NON-EXPEDITED			US-ALLERGAN-1773204US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327415	NON-EXPEDITED			US-ALLERGAN-1772819US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Swelling; Hypersensitivity; Off Label Use; Pruritus; Swelling Face; Urticaria	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qod		Allergan
	Imitrex			C	Oral	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327416	NON-EXPEDITED			US-ALLERGAN-1805533US		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Paraesthesia	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Lexapro			S	Unknown	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327417	NON-EXPEDITED			US-ALLERGAN-1812317US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Sweats	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327418	NON-EXPEDITED			US-ALLERGAN-1804416US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Throat; Productive Cough	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327423	NON-EXPEDITED			US-ALLERGAN-1803684US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrooesophageal Reflux Disease	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327424	NON-EXPEDITED			US-ALLERGAN-1803341US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown	7.5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327425	NON-EXPEDITED			US-ALLERGAN-1815255US		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327426	NON-EXPEDITED			US-ALLERGAN-1811680US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Dry Mouth	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327427	NON-EXPEDITED			US-ALLERGAN-1804597US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Eyelid Disorder; Headache	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Detrol La			C	Oral	Unk		Not Reported
	Lisinopril			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327428	NON-EXPEDITED			US-ALLERGAN-1812387US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Off Label Use	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qam		Allergan
	Multivitamins			C	Oral	Unk		Not Reported
	Ergocalciferol			C	Oral	2000 Units, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327429	NON-EXPEDITED			US-ALLERGAN-1816156US		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Lexapro			S	Unknown	80 Mg, Unk		Allergan
	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Ativan			C	Oral	Unk, 1-2 Times A Day		Not Reported
	Lipitor			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327430	NON-EXPEDITED			US-ALLERGAN-1812450US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenopia; Eye Allergy; Off Label Use; Product Dispensing Error	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qhs		Allergan
	Procardia			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Aspirin			C	Unknown	81 Mg, Unk		Not Reported
	Lorazepam			C	Unknown	4 Mg, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327431	NON-EXPEDITED			US-ALLERGAN-1815337US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327432	NON-EXPEDITED			US-ALLERGAN-1814011US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia	Lexapro			S	Oral	Unk		Allergan
	Xanax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327433	NON-EXPEDITED			US-ALLERGAN-1819467US		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Lexapro		S	Oral	5 Mg, Qd	Allergan
	Atenolol		C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327434	NON-EXPEDITED			US-ALLERGAN-1816251US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Chills; Decreased Appetite; Depression; Disturbance In Attention; Drug Ineffective; Hot Flush; Weight Decreased	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Prempro			S		Unk		Not Reported
	Xanax			S	Oral	0.5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327435	NON-EXPEDITED			US-ALLERGAN-1816762US		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327436	NON-EXPEDITED			US-ALLERGAN-1809390US		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327437	NON-EXPEDITED			US-ALLERGAN-1812427US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Eye Pain; Fatigue; Headache; Insomnia	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan

	Lorazepam		C	Unknown	Unk	Not Reported
	Fosamax		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327438	NON-EXPEDITED			US-ALLERGAN-1813935US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Erectile Dysfunction; Eye Pain; Sexual Dysfunction	Lexapro			S	Unknown	5 Mg, Unk		Allergan
	Hydrochlorothiazide			C	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327439	NON-EXPEDITED			US-ALLERGAN-1817309US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Drug Hypersensitivity; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327440	NON-EXPEDITED			US-ALLERGAN-1773401US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sedation	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327441	NON-EXPEDITED			US-ALLERGAN-1816287US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327442	NON-EXPEDITED			US-ALLERGAN-1820022US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Decreased Appetite; Dermatitis; Disturbance In Sexual Arousal; Dry Skin; Erectile Dysfunction; Fatigue; Gingival Atrophy; Gingivitis; Pain Of Skin; Palpitations; Pruritus; Rash Macular; Rash Macular; Self-Injurious Ideation; Squamous Cell Carcinoma; Toothache; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported
	Salicylic Acid			S	Topical	Unk		Not Reported
	Lisinopril			C				Not Reported
	Pantoprazole			C				Not Reported
	Valium			C		Unk		Not Reported
	Budesonide			C	Oral			Not Reported
	Carvedilol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327443	NON-EXPEDITED			US-ALLERGAN-1803085US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Wrong Technique In Product Usage Process	Lexapro			S	Unknown	15 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327444	NON-EXPEDITED			US-ALLERGAN-1827796US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Off Label Use	Lexapro			S	Unknown	60 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327445	NON-EXPEDITED			US-ALLERGAN-1831662US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack; Therapeutic Response Decreased	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Unknown	15 Mg, Unk		Allergan
	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Lexapro			S	Unknown	5 Mg, Unk		Allergan
	Prozac			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327449	NON-EXPEDITED			US-ALLERGAN-1827749US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327450	NON-EXPEDITED			US-ALLERGAN-1823919US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Discharge	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327451	NON-EXPEDITED			US-ALLERGAN-1832673US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Muscle Spasms; Nausea	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Metoprolol			C	Oral	Unk, Qd		Not Reported
	Omeprazole			C	Oral	Unk, Qd		Not Reported

	Hydrocodone	C	Oral	Unk	Not Reported
	Dicyclomine	C	Oral	Unk, Qd	Not Reported
	Potassium	C	Oral	Unk, Qd	Not Reported
	Claritin	C	Oral	Unk	Not Reported
	Magnesium	C	Oral	Unk Unk, Qd	Not Reported
	Cozaar	C	Oral	Unk Unk, Qd	Not Reported
	Albuterol Sulfate	C	Respiratory (inhalation)	Unk Unk, Qd	Not Reported
	Ondansetron	C	Oral	Unk Unk, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327452	NON-EXPEDITED			US-ALLERGAN-1831985US		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sleep Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Protonix			C	Oral	Unk		Not Reported
	Coreg			C	Oral	Unk		Not Reported
	Iron			C	Oral	Unk		Not Reported
	Prenatal Vitamins			C	Oral	Unk		Not Reported
	Lipitor			C	Oral	Unk		Not Reported
	Plavix			C	Oral	Unk		Not Reported
	Flomax			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327453	NON-EXPEDITED			US-ALLERGAN-1830866US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Dose Omission	Lexapro			S	Oral	Unk, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327454	NON-EXPEDITED			US-ALLERGAN-1832570US		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327455	NON-EXPEDITED			US-ALLERGAN-1827993US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Off Label Use	Lexapro			S	Unknown	100 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327456	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1829555US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Suicide Attempt	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327457	NON-EXPEDITED			US-ALLERGAN-1825194US		< 1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasticity	Lexapro			S	Transplacental	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327458	NON-EXPEDITED			US-ALLERGAN-1803800US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Nausea; Off Label Use	Lexapro	S	Unknown	400 Mg, Unk		Allergan
	Lexapro	S	Unknown	300 Mg, Unk		Allergan
	Clonazepam	C	Unknown	0.5 Mg, Unk		Not Reported
	Bupropion Hcl Er	C	Unknown	150 Mg, Unk		Not Reported
	Wellbutrin	C	Unknown	350 Mg, Qd		Not Reported
	Wellbutrin	C	Unknown	150 Mg, Qd		Not Reported
	Gabapentin	C	Unknown	750 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327459	NON-EXPEDITED			US-ALLERGAN-1816843US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Tendency To Bruise; Swelling; Swelling Face	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327460	NON-EXPEDITED			US-ALLERGAN-1826477US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Off Label Use	Lexapro			S	Unknown	20 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Lexapro			S				Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327461	NON-EXPEDITED			US-ALLERGAN-1823001US		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dry Mouth; Off Label Use; Wrong Technique In Product Usage Process	Lexapro			S	Oral	5 Mg, Unk		Allergan
	Temazepam			C	Oral	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327462	NON-EXPEDITED			US-ALLERGAN-1823092US		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Personality Change; Rapid Eye Movements Sleep Abnormal	Lexapro			S	Oral	15 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Lorazepam			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327463	NON-EXPEDITED			US-ALLERGAN-1831327US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro			S	Unknown	25 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327464	NON-EXPEDITED			US-ALLERGAN-1823979US		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	20 Mg, Unk		Allergan
	Remeron			S		15 Mg, Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Oral	9 Df, Q Week		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Cymbalta			S				Not Reported
	Atorvastatin			C				Not Reported
	Atorvastatin			C				Not Reported
	Atorvastatin			C				Not Reported
	Atorvastatin			C				Not Reported
	Cardiazem			C		240 Mg, Qd		Not Reported
	Carvedilol			C	Oral	12.5 Mg, Qd		Not Reported
	Cozaar			C	Oral	25 Mg, Qd		Not Reported

Potassium	C	Oral	10 Meq, Qd		Not Reported
Pantoprazole	C				Not Reported
Folic Acid	C	Oral	1 Mg, Unk		Not Reported
Aldactone	C	Oral	2 Df, Qd		Not Reported
Hydrocodone	C	Oral	1 Df, Unk		Not Reported
Tramadol	C		Unk Unk, Prn		Not Reported
Bumex	C	Oral	2 Mg, Qd		Not Reported
Gabapentin	C		400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327465	NON-EXPEDITED			US-ALLERGAN-1827021US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective	Lexapro			S	Unknown			Allergan
	Cipro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327466	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1833835US		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Confusional State; Dizziness; Drug Ineffective; Dry Eye; Insomnia; Vision Blurred; Wrong Technique In Product Usage Process	Lexapro			S	Oral	7.5 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Unk		Allergan
	Lexapro			S	Oral	2.5 Mg, Qd		Allergan
	Vitamin B-12			C	Unknown	Unk		Not Reported
	Vitamin C			C	Unknown	Unk		Not Reported
	Vitamin D3			C	Unknown	Unk		Not Reported
	Statin			C	Unknown	Unk		Not Reported
	Propafenone			C	Unknown	Unk		Not Reported
	Eliquis			C	Oral	25 Mg, Qd		Not Reported
	Fish Oil			C	Oral	Unk Unk, Qd		Not Reported

	B Vitamin Comp	C	Oral	Unk Unk, Qd	Not Reported
	Melatonin	C	Oral	Unk Unk, Prn	Not Reported
	Mirtazapine	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327468	NON-EXPEDITED			US-ALLERGAN-1827797US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Off Label Use	Lexapro			S	Unknown	60 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327470	NON-EXPEDITED			US-ALLERGAN-1830230US		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Dose Omission	Lexapro			S	Unknown	5 Mg, Qhs		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327471	NON-EXPEDITED			US-ALLERGAN-1833309US		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Vision Blurred	Lexapro			S	Unknown	Unk		Allergan
	Humira			S	Subcutaneous	Unk Unk, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327472	NON-EXPEDITED			US-ALLERGAN-1825187US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327473	NON-EXPEDITED			US-ALLERGAN-1829418US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lexapro			S	Intramuscular	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327474	NON-EXPEDITED			US-ALLERGAN-1832125US		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Cough; Insomnia; Laryngitis; Nasal Dryness; Off Label Use; Weight Decreased; Weight Increased	Lexapro			S	Oral	15 Mg, Unk		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Faslodex			C	Intramuscular	Unk Unk, Q Month		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327475	NON-EXPEDITED			US-ALLERGAN-1824629US		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hypoaesthesia; Influenza Like Illness; Nausea; Night Sweats; Panic Attack; Paraesthesia; Tremor; Withdrawal Syndrome	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327476	NON-EXPEDITED			US-ALLERGAN-1827995US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro			S	Unknown	80 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327477	NON-EXPEDITED			US-ALLERGAN-1832205US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327478	NON-EXPEDITED			US-ALLERGAN-1825193US		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pregnancy	Lexapro			S	Unknown	20 Mg, Qd		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327479	NON-EXPEDITED			US-ALLERGAN-1827994US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro			S	Unknown	100 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327480	NON-EXPEDITED			US-ALLERGAN-1836678US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327481	NON-EXPEDITED			US-ALLERGAN-1835526US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression;	Lexapro			S	Unknown	Unk		Allergan

Dizziness; Lacrimation Increased; Nausea; Oedema	Lexapro		S	Unknown	40 Mg, Unk	Allergan
	Viibryd		S	Unknown	Unk	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327482	NON-EXPEDITED			US-ALLERGAN-1837226US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Unk		Allergan
	Advil			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Lisinopril			C		Unk		Not Reported
	Baby Aspirin			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported
	Omega 3			C		Unk		Not Reported
	D3			C		2000 Mg, Unk		Not Reported
	B12			C		Unk		Not Reported
	Osteo Bi-Flex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327483	NON-EXPEDITED			US-ALLERGAN-1833861US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327484	NON-EXPEDITED			US-ALLERGAN-1834685US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Increased Appetite; Weight Increased	Lexapro			S	Unknown	20 Mg, Unk		Allergan
	Acetaminophen			C				Not Reported

	Bupropion Hydrochloride	C	Not Reported
	Buspirone Hydrochloride	C	Not Reported
	Clonazepam	C	Not Reported
	Docusate Sodium	C	Not Reported
	Gabapentin	C	Not Reported
	Letrozole	C	Not Reported
	Ondansetron	C	Not Reported
	Oxycodone Hydrochloride	C	Not Reported
	Pantoprazole Sodium	C	Not Reported
	Preservision Areds	C	Not Reported
	Promethazine Hydrochloride	C	Not Reported
	Sertraline Hydrochloride	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327485	NON-EXPEDITED			US-ALLERGAN-1834785US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327489	NON-EXPEDITED			US-ALLERGAN-1825972US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan
	Cymbalta			C	Oral	Unk		Not Reported
	Prozac			C	Oral	Unk		Not Reported
	Trazodone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327493	NON-EXPEDITED			US-ALLERGAN-1834457US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Unknown	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327494	NON-EXPEDITED			US-ALLERGAN-1837325US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327495	NON-EXPEDITED			US-ALLERGAN-1835958US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pruritic	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Escitalopram Oxalate Unk			S				Allergan
	Atorvastatin			C	Unknown	Unk		Not Reported
	Flonase			C	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported
	Loratadine			C	Unknown	Unk		Not Reported
	Baby Aspirin			C	Unknown	Unk		Not Reported
	B Complex			C	Unknown	Unk		Not Reported
	Vitamin D2			C				Not Reported
	Fish Oil			C	Unknown	Unk		Not Reported
	Multivitamins			C	Unknown	Unk		Not Reported
	Calcium Citrate			C	Unknown	Unk		Not Reported
	Miralax			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327496	NON-EXPEDITED			US-ALLERGAN-1837791US		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Feeling Abnormal; Libido Decreased; Sexual	Lexapro			S	Oral	Unk, Bid		Allergan
	Lexapro			S				Allergan

Dysfunction

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327497	NON-EXPEDITED			US-ALLERGAN-1834906US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327751	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1000028164		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Hyperhidrosis; Loss Of Consciousness; Presyncope	Escitalopram Oxalate Unk			S	Oral	1 Df, Qd		Allergan
	Microser			S	Oral	2 Df, Qd		Not Reported
	Lyrica			S	Oral	2 Df, Qd		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15341984	DIRECT					22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Enuresis; Intentional Product Misuse; Intentional Product Use Issue	Vyvanse			S	Oral	Quantity:1 Capsule(S);		Not Reported
	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Phenibut			C				Not Reported
	Magnesium			C				Not Reported
	Vitamin D3			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin K2 Mk-7			C				Not Reported
	N-Acetul Cystine			C				Not Reported
	Zinc And Cooper			C				Not Reported
	Calcium			C				Not Reported

	Aged Garlic Powder Pills	C	Not Reported
	Astaxanthin	C	Not Reported
	Spirulina	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15111680	EXPEDITED (15-DAY)		HO, LT	PHHY2018DE036016		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Linezolid			S	Intravenous (not otherwise specified)	2 Df, Qd		Novartis
	Esomeprazole			S	Unknown	40 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown	2 Df, Qd		Not Reported
	Ivabradine			C	Unknown	15 Mg, Qd		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	2 Df, Qd		Not Reported
	Naloxone			C	Unknown	10 Gtt, Unk		Not Reported
	Scopolamine			C	Unknown	Unk		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Prednisolon			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	1 Mg, Qd		Not Reported
	L-Thyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15211689	EXPEDITED (15-DAY)		OT	PHHY2018IT056779		85 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Delorazepam			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Novartis
	Venlafaxine			S	Oral	1 Mg/L, Qd		Not Reported
	Cipralex			S	Oral	Unk		Not Reported

Donepezil	C	Unknown	Unk		Not Reported
Bisoprolol Fumarate	C	Unknown	Unk		Not Reported
Madopar	C	Unknown	Unk		Not Reported
Terazosin Hydrochloride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15298011	EXPEDITED (15-DAY)		HO, OT	DE-ALLERGAN-1840548US		90 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Delirium; Fall; Post Procedural Haemorrhage; Traumatic Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Per Day		Allergan
	Eliquis			S	Unknown	5 Mg, Bid		Not Reported
	Eliquis			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15328964	EXPEDITED (15-DAY)		DE	FR-ACCORD-071082		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Escitalopram			S	Oral			Not Reported
	Furosemide			S	Oral			Accord
	Ciprofloxacin/Ciprofloxacin Hydrochloride/Ciprofloxacin Lactate			S	Intravenous drip			Accord
	Bisoprolol			S				Not Reported
	Methotrexate			S	Intravenous drip			Accord
	Doxorubicin			S	Intravenous drip			Accord
	Pantoprazole			S	Intravenous drip			Not Reported
	Fungizone			S	Buccal			Not Reported
	Exacyl			S	Intravenous drip			Not Reported
	Vincristine			S	Intravenous drip			Not Reported
	Eprex			S	Subcutaneous			Not Reported
	Zarzio			S	Subcutaneous			Not Reported

	Meropenem/Meropenem Trihydrate	S	Intravenous drip	Not Reported
	Hextril	S	Buccal	Not Reported
	Lidocaine	S	Buccal	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Calciparine	S	Subcutaneous	Not Reported
	Voraxaze	S	Intravenous drip	Not Reported
	Valaciclovir	S	Oral	Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate	S	Intravenous drip	Not Reported
	Prednisone	S	Intravenous drip	Not Reported
	Ondansetron	S	Oral	Not Reported
	Sulfamethoxazole/Trimethoprim	S	Oral	Not Reported
	Bromazepam	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15328992	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-182759		59 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Electrocardiogram Qt Prolonged; Moaning	Alprazolam			S	Oral	()		Sun
	Escitalopram			S	Unknown	()		Not Reported
	Trilafon			S	Oral	()		Not Reported
	Ramipril			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15330451	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018341292		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Xanax			S	Oral	0.5 Mg, 1x/Day		Pfizer
	Xanax			S	Oral	0.25 Mg, 1x/Day		Pfizer

	Donormyl [Doxylamine Succinate]	S	Oral	Unk		Not Reported
	Seroplex	S	Oral	20 Mg, 1x/Day (In The Morning)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15331775	EXPEDITED (15-DAY)		LT, OT	NO-OTSUKA-2018_029547		56 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Product Use In Unapproved Indication; Pyrexia; Tremor; Vomiting	Abilify			S	Oral	Unk		Otsuka
	Trilafon			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	Unk		Not Reported
	Remeron			S	Oral	Unk		Not Reported
	Fluoxetine			S	Oral	Unk		Not Reported
	Efexor Depot			S	Oral	Unk		Not Reported
	Stemetil			S	Oral	Unk		Not Reported
	Ibux			S	Oral	Unk		Not Reported
	Fluanxol			S	Oral	Unk		Not Reported
	Vallergan			S	Oral	Unk		Not Reported
	Nozinan			S	Oral	Unk		Not Reported
	Zyprexa			S	Oral	Unk		Not Reported
	Sobril			S	Oral	Unk		Not Reported
	Truxal			S	Oral	Unk		Not Reported
	Cipralex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15331926	EXPEDITED (15-DAY)		LT	NO-ELI_LILLY_AND_COMPANY-NO201808012564		56 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration;	Cymbalta			S	Oral	Unk Unk, Unknown		Eli Lilly And Co

Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Trilafon /00023401/		S	Oral	Unk Unk, Unknown	Not Reported
	Remeron		S	Oral	Unk Unk, Unknown	Not Reported
	Fluoxetine		S	Oral	Unk Unk, Unknown	Not Reported
	Efexor		S	Oral	Unk Unk, Unknown	Not Reported
	Stemetil /00013301/		S	Oral	Unk Unk, Unknown	Not Reported
	Ibux		S	Oral	Unk Unk, Unknown	Not Reported
	Fluanxol /00109702/		S	Oral	Unk Unk, Unknown	Not Reported
	Vallergan		S	Oral	Unk Unk, Unknown	Not Reported
	Nozinan /00038601/		S	Oral	Unk Unk, Unknown	Not Reported
	Zyprexa		S	Oral	Unk Unk, Unknown	Not Reported
	Sobril		S	Oral	Unk Unk, Unknown	Not Reported
	Truxal /00012101/		S	Oral	Unk Unk, Unknown	Not Reported
	Cipralex /01588501/		S	Oral	Unk Unk, Unknown	Not Reported
	Abilify		S	Oral	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15332143	EXPEDITED (15-DAY)		HO	PHHY2018IT082370		59 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Electrocardiogram Qt Prolonged; Moaning	Alprazolam			S	Oral	Unk		Novartis
	Escitalopram			S	Unknown	Unk		Not Reported
	Trilafon			S	Oral	Unk		Not Reported
	Ramipril			C	Oral	2.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15332176	EXPEDITED (15-DAY)		OT	NL-ALLERGAN-1841691US		26 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction; Dyskinesia; Hyperhidrosis;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Sumatriptan			S	Unknown	50 Mg, Unk		Not Reported

Muscle Tightness; Musculoskeletal Stiffness; Myalgia; Serotonin Syndrome	Loperamide	C	Unknown	2 Mg, Unk		Not Reported
	Imodium	C	Unknown	2 Mg, Qd		Not Reported
	Colestyramine	C	Unknown	4 G, Q12h		Not Reported
	Oxazepam	C		10 Mg, Unk		Not Reported
	Psylliumvezels	C		3 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	9660486	NON-EXPEDITED			US-PFIZER INC-2013308886		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Metformin Hcl			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Tramadol Hcl			S		Unk		Pfizer
	Zofran			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	14180649	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1764684US		14 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Intentional Overdose; Intentional Self-Injury; Off Label Use; Poisoning Deliberate; Sluggishness; Sopor	Escitalopram Oxalate - Bp			S	Oral	10 Df, Unk		Allergan
	Haldol			S	Oral	15 Ml, Unk		Not Reported
	Xanax			S	Oral	12 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	14941504	EXPEDITED (15-DAY)		DE	FR-BIOCOMPATIBLES UK LTD-2018BTG01674			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Voraxaze			S	Intravenous drip	Unk		Unknown
	Furosemide			S	Oral	Unk		Not Reported
	Lidocaine			S	Buccal	Unk		Not Reported
	Zarzio			S	Subcutaneous	Unk		Not Reported
	Prednisone			S	Intravenous drip	Unk		Not Reported
	Bisoprolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Amphotericin B			S	Buccal	Unk		Not Reported
	Meropenem Anhydrous			S	Intravenous drip	Unk		Not Reported
	Valaciclovir			S	Oral	Unk		Not Reported
	Tranexamic Acid			S	Intravenous drip	Unk		Not Reported
	Bromazepam			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Ciprofloxacin, Ciprofloxacin Hydrochloride			S	Intravenous drip	Unk		Not Reported
	Pantoprazole			S	Intravenous drip	Unk		Not Reported
	Doxorubicin Hydrochloride			S	Intravenous drip	Unk		Not Reported
	Ondansetron			S	Oral	Unk		Not Reported
	Sulfamethoxazole, Trimethoprim			S	Oral	Unk		Not Reported
	Hexetidine			S	Buccal	Unk		Not Reported
	Methotrexate			S	Intravenous drip	Unk		Not Reported
	Epoetin Alfa			S	Subcutaneous	Unk		Not Reported
	Heparin Calcium			S	Subcutaneous	Unk		Not Reported
	Vincristine			S	Intravenous drip	Unk		Not Reported
	Cyclophosphamide			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15312888	EXPEDITED (15-DAY)		HO, OT	US-SUNOVION-2018SUN003296			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Depression; Suicide Attempt	Latuda			S	Oral	Unk		Sunovion
	Lexapro			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332889	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2018PRN00398			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash Pruritic	Escitalopram			S		Unk		Prinston Pharmaceutical
	Escitalopram			S		Increased Dose		Prinston Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332890	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2018PRN01129			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nervousness; Therapeutic Product Effect Incomplete	Escitalopram			S		10 Mg		Prinston Pharmaceutical
	Escitalopram			S				Prinston Pharmaceutical
	Gabapentin			C		Unk		Not Reported
	Gabapentin			C		100 Mg, 1x/Day At Bedtime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15333472	EXPEDITED (15-DAY)		DE, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-07049		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Lamotrigine			S	Unknown	Unk		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Propranolol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15333543	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00009656		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 [Mg/D]/ Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D		Unknown
	Folio (Nahrungsergnzungsmittel)			C	Transplacental	0.4 [Mg/D]		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15334837	EXPEDITED (15-DAY)		OT	SE-TEVA-2018-SE-949742		24 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Product Substitution Issue; Tremor; Tunnel Vision	Escitalopram Teva 15 Mg Filmdragerad Tablett			S	Oral			Ivax
	Escitalopram Teva 15 Mg Filmdragerad Tablett			S				Ivax
	Liothyronine			C				Not Reported
	Euthyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15335304	EXPEDITED (15-DAY)		HO	PHHY2018FR080602		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Somnolence	Escitalopram			S	Oral	28 Df, Unk		Not Reported
	Ibuprofen			S	Oral	20 Df, Unk		Novartis
	Dafalgan			S	Oral	8 G, Unk		Not Reported

Paroxetin	S	Oral	12 Df, Unk		Not Reported
Havlane	S	Oral	20 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15335314	EXPEDITED (15-DAY)		OT	PHHY2017IT121515		60 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Sertraline			S	Unknown	100 Mg, Qd		Not Reported
	Sertraline			S	Oral	100 Mg,Qd		Not Reported
	Lorazepam			S	Unknown	2.5 Mg, Qd		Novartis
	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
	Cipralex			S	Unknown	20 Mg, Qd		Not Reported
	Brintellix			S	Unknown	15 Mg, Qd		Not Reported
	Brintellix			S	Unknown	10 Mg, Qd		Not Reported
	Brintellix			S	Unknown	5 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	2 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	2 Mg,Qd		Not Reported
	Ezetimibe			C	Unknown	10 Mg,Qd		Not Reported
	Triatec Hct			C	Unknown	15 Mg,Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Cordarone			C	Unknown	200 Mg,Unk		Not Reported
	Lansoprazole			C	Unknown	30 Mg, Qd		Not Reported
	Coumadin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15335645	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1063383		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Xulane® (Norelgestromin And Ethinyl Estradiol Transdermal			S	Transdermal	Unk		Mylan

	System) Escitalopram			S	Topical	Unk				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15336349	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1842131US		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Melaena; Rectal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Kardegic			S	Oral	1 Df, Qd		Not Reported
	Crestor			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15354991	DIRECT		OT			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Self-Injurious Ideation; Withdrawal Syndrome	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Cetirizine			C				Not Reported
	Fluticasone Peopionate Nasal Spray			C				Not Reported
	Propionate Nasal Spray Multi-Vitamin			C				Not Reported
	Docosahexaenoic Acid			C				Not Reported
	Vitamin D3			C				Not Reported
	Kavalactones			C				Not Reported
	Melatonin			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	14170339	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017476660		14 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Intentional Overdose; Intentional Self-	Xanax			S	Oral	12 Df, Total		Pfizer

Injury; Poisoning Deliberate; Sluggishness; Sopor	Haldol		S	Oral	15 Ml, Total	Not Reported
	Cipralex /01588501/		S	Oral	10 Df, Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	14170997	EXPEDITED (15-DAY)		OT	JP-SA-2017SA217862			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Off Label Use; Premature Delivery	Zolpidem Tartrate			S	Oral	Unk		Sanofi
	Escitalopram Oxalate			S	Oral	Unk Unk,Unk		Not Reported
	Yokukansan			S	Oral	Unk Unk,Unk		Not Reported
	Hirnamin (Levomepromazine)			S	Oral	40 To 225 Mg,Qd		Not Reported
	Horizon			S	Oral	2 To 5 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	14648505	EXPEDITED (15-DAY)		DE, HO, OT	DE-PFIZER INC-2018103600		1 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Sildenafil Citrate			S		Unk		Pfizer
	Spironolactone			S		Unk		Not Reported
	Phenobarbital			S		Unk		Not Reported
	Varivax			S	Intramuscular	1 Df, Single		Not Reported
	Topiramate			S		Unk		Not Reported
	Synagis			S	Intramuscular	150 Mg, Unk		Not Reported
	Exodus (Escitalopram Oxalate)			S		Unk		Not Reported
	Nutrition With Nutrini Mixed With Water			C	Other	Unk, 4x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15136760	EXPEDITED (15-DAY)		HO, OT	DE-OTSUKA-2018_009663		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Delirium; Drug Ineffective; Drug Interaction; Haematoma; Haemorrhage; Insomnia; Menorrhagia; Product Use In Unapproved Indication; Respiratory Tract Infection; Restlessness; Sleep Disorder; Thinking Abnormal	Aripiprazole	S	Unknown	5 Mg, Qd	Otsuka
	Aripiprazole	S			Otsuka
	Escitalopram Oxalate	S	Unknown	15 Mg, Qd (Reduced To 15 Mg/Day)	Not Reported
	Escitalopram Oxalate	S	Oral	20 Mg, Qd	Not Reported
	Escitalopram Oxalate	S	Unknown	20 Mg, Qd (In A Morning Target Dose Of 20 Mg)	Not Reported
	Escitalopram Oxalate	S			Not Reported
	Pregabalin	S	Oral	100 Mg, Qd (Evening Dose Of 100 Mg)	Not Reported
	Pregabalin	S			Not Reported
	Pregabalin	S			Not Reported
	Risperidone	S	Oral	0.5 Mg, Unk (For 10 Days)	Not Reported
	Risperidone	S			Not Reported
	Risperidone	S			Not Reported
	Risperidone	S			Not Reported
	Risperidone	S			Not Reported
	Risperidone	S			Not Reported
	Opipramol	C	Unknown	Unk (In Crisis Situations With Temporary Effect)	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	Unk (In Crisis Situations With Temporary Effect)	Not Reported
	Promethazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15338608	NON-EXPEDITED			US-INTERCEPT-PMOCA2018000967			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Fatigue; Pruritus	Ocaliva			S	Oral	5 Mg, Qd		Not Reported
	Ocaliva			S	Oral	10 Mg, Qd		Not Reported
	Ocaliva			S	Oral	5 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Aczone			C	Topical	5 %, Qd		Not Reported

Calcium Carbonate And Vitamin D	C	Oral			Not Reported
Estrace	C	Vaginal	2 G, Qd		Not Reported
Estrace	C		1 G, Qd		Not Reported
Estrace	C		1 G, Unk		Not Reported
Lofibra	C	Oral	54 Mg, Qd		Not Reported
Bactroban	C	Nasal	Unk Unk, Bid		Not Reported
Percocet	C		Unk Mg, Prn		Not Reported
Deltasone	C	Unknown	40 Mg, Qd		Not Reported
Ultracet	C		Unk Mg, Prn		Not Reported
Actigall	C		500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15339088	NON-EXPEDITED			US-TEVA-2018-US-948780		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Gait Disturbance; Nausea	Venlafaxine			S	Unknown			Teva
	Zoloft			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15340389	EXPEDITED (15-DAY)		OT	HK-LANNETT COMPANY, INC.-HK-2018LAN001003		43 YR	Male	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Somnolence	Escitalopram Oxalate			S	Unknown	5 Mg, Unk (Nocte)		Lannett
	Escitalopram Oxalate			S	Unknown	10 Mg, Unk (Nocte; On Day 8)		Lannett
	Escitalopram Oxalate			S	Unknown	5 Mg, Unk (Nocte)		Lannett

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15340608	EXPEDITED (15-DAY)		HO	IE-LANNETT COMPANY, INC.-IE-2018LAN001004			Unknown	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	5 Mg, Qd		Lannett
	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Lannett
	Lamotrigine			S	Unknown	Unk		Not Reported
	Clobazam			C		10 Mg, Bid		Not Reported
	Clobazam			C		10 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2018	15341635	EXPEDITED (15-DAY)		HO, OT	DE-HETERO CORPORATE-HET2018DE00844			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertensive Crisis; Hypokalaemia; Myocardial Infarction; Tachycardia	Escitalopram			S	Oral	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2018	15341636	EXPEDITED (15-DAY)		CA, OT	DE-HETERO CORPORATE-HET2018DE00845		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 Mg, Qd (Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D)		Hetero
	Escitalopram			S	Transplacental	10 Mg, Qd		Hetero
	Folio (Nahrungsergänzungsmittel)			C	Transplacental	0.4 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2018	15366793	DIRECT		DS			18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Dizziness; Feeling Abnormal; Insomnia; Malaise; Migraine; Panic Reaction; Product Quality Issue; Product Substitution Issue	Escitalopram 10mg Tablet		Y	S	Oral	Quantity:1 Df Dosage Form;		Aurobindo
	Escitalopram			C				Not Reported
	Equate Adult Multivitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	8386402	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2012025457		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Hyperhidrosis; Loss Of Consciousness; Presyncope	Lyrica			S	Oral	2 Df, 1x/Day		Pfizer
	Microser			S	Oral	2 Df, 1x/Day		Not Reported
	Entact			S	Oral	1 Df, 1x/Day		Not Reported
	Lansoprazole			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15271574	EXPEDITED (15-DAY)		OT	PHHY2018FR070172		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Lichen Planus	Esidrex			S	Oral	25 Mg, Unk		Novartis
	Atorvastatine			S	Oral	20 Mg, Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Esomeprazole			S	Oral	Unk		Not Reported
	Aldactone			S	Oral	Unk		Not Reported
	Perindopril			S	Oral	2 Mg, Unk		Not Reported

Kardegic	S	Oral	Unk		Not Reported
Verapamil	S	Oral	240 Mg, Unk		Not Reported
Teralithe	S	Oral	Unk		Not Reported
Seroplex	S	Oral	Unk		Not Reported
Macrogol	S	Oral	Unk		Not Reported
Xeroquel	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15297845	EXPEDITED (15-DAY)		OT	PHHY2018AT075991		21 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Olanzapine			S	Unknown	2.5 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	5 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown	25 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown	50 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown	100 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown	80 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Unknown	40 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Unknown	80 Mg, Qd		Not Reported
	Quetiapine Fumarate			S	Unknown	75 Mg, Qd		Not Reported
	Quetiapine Fumarate			S	Unknown	100 Mg, Qd		Not Reported
	Lorazepam			S	Oral	1 Ot, Qd (2-5 Mg)		Not Reported
	Dominal (Prothipendyl Hydrochloride)			S	Unknown	80 Mg, Unk		Not Reported
	Dominal (Prothipendyl Hydrochloride)			S	Unknown	40 Mg, Unk		Not Reported
	Trazodone			S	Unknown	50 Mg, Qd		Not Reported
	Trazodone			S	Unknown	100 Mg, Qd		Not Reported
	Trazodone			S	Unknown	150 Mg, Qd		Not Reported
	Diazepam			S	Unknown	5 Mg, Qd		Not Reported

Diazepam	S	Unknown	10 Mg, Qd		Not Reported
Diazepam	S	Unknown	15 Mg, Qd		Not Reported
Cipralex	S	Unknown	5 Mg, Qd		Not Reported
Cipralex	S	Unknown	10 Mg, Qd		Not Reported
Halcion	C	Unknown	0.25 Mg, Qd		Not Reported
Zoldem	C	Unknown	10 Mg, Qd		Not Reported
Quilonorm	C	Unknown	225 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15343257	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-043885		61 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthyroidism	Escitalopram Film-Coated Tablets 10mg			S	Unknown	10 Milligram, Daily		Aurobindo
	Ptu			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15344186	EXPEDITED (15-DAY)		HO, LT	PHHY2018FR081755		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension	Paracetamol			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Novartis
	Escitalopram			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Ibuprofene			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15344296	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1842164US		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Lymphadenitis; Rash Maculo-Papular	Escitalopram Oxalate - Bp	S	Oral	5 Mg, Qd		Allergan
	Lamictal	S	Oral	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15344402	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018349120		59 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Abuse; Electrocardiogram Qt Prolonged; Moaning	Alprazolam			S	Oral			Pfizer
	Trilafon (Perphenazine)			S	Oral	18 Df, Single		Not Reported
	Escitalopram			S		Unk		Not Reported
	Delorazepam			S		Unk		Not Reported
	Ramipril			C	Oral	2.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15344738	EXPEDITED (15-DAY)		OT	NL-TEVA-2018-NL-950951		61 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthyroidism	Escitalopram Tablet, 10 Mg (Milligram)			S	Unknown	10 Milligram Daily; 1dd		Ivax
	Ptu			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15345093	EXPEDITED (15-DAY)		HO, LT	PHHY2018ES084674		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Oral	Unk		Not Reported
	Enalapril+Hydrochlorothiazide			S	Oral	Unk Unk, Qd (1-0-0)		Not Reported
	Haloperidol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	12878030	EXPEDITED (15-DAY)		HO, LT, OT	FR-OTSUKA-DJ20128687		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Product Use In Unapproved Indication; Suicide Attempt	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Seroplex			S	Unknown	10 Mg, Qd (Dose Increased To 10 Mg/Day)		Not Reported
	Seroplex			S	Unknown	5 Mg, Qd		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Seresta			S	Oral	50 Mg (Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening)		Not Reported
	Imovane			S	Oral	7.5 Mg, Qd (1 Tablet/Dy)		Not Reported
	Imovane			S	Oral	Unk, Qd		Not Reported
	Depamide			S	Oral	300 Mg, Qd		Not Reported
	Depamide			S	Oral	Unk		Not Reported
	Anafranil			S	Oral	75 Mg, Unk (Daily Dose Increased)		Not Reported
	Lepticur			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	15 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Methyldopa			S	Oral	300 Mg, Unk		Not Reported
	Methyldopa			S	Oral	Unk		Not Reported
	Lexapro			S	Unknown	5 Mg, Qd		Not Reported
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported
	Lexapro			S		Unk		Not Reported
	Zopiclone			S	Oral	7.5 Mg, Qd (1tab/Dy)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	12982206	NON-EXPEDITED			US-PFIZER INC-2016545929		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Metronidazole	S	Unk	Pfizer
	Elavil	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Mycelex	S	Unk	Not Reported
	Claritin	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15323984	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-182760		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Esomeprazole			S	Oral	40 Mg, Qd		Sun
	Esidrex			S	Oral	0.5 Df, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Pravastatine			C	Unknown	()		Not Reported
	Seresta			C	Unknown	Breackable ()		Not Reported
	Dafalgan			C	Unknown	()		Not Reported
	Mediatensyl			C	Unknown	()		Not Reported
	Ramipril			C	Unknown	()		Not Reported
	Procoralan			C	Unknown	()		Not Reported
	Acebutolol			C	Unknown	()		Not Reported
	Aspirin			C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15345603	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-183253		10 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Suicide Attempt; Toxicity To Various Agents	Paracetamol		Y	S	Oral	2 G In Total		Ohm Lab
	Seroplex			S	Oral	40 Mg In Total		Not Reported

	Seresta	S	Oral	10 Mg In Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346144	EXPEDITED (15-DAY)		CA, DE, OT	DE-DRREDDYS-GER/GER/18/0103613		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 (Mg/D)		Not Reported
	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Paroxetine			S	Transplacental	30 [Mg/D]		Not Reported
	Nepresol (Hydralazine Hydrochloride)			S	Transplacental	25 (Mg/D)		Not Reported
	Candesartan			S	Transplacental	16 [Mg/D]		Not Reported
	Levothyroxine Sodium			C	Transplacental			Not Reported
	Cytotec			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15347829	EXPEDITED (15-DAY)		HO, OT	TW-MYLANLABS-2018M1064326		87 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Bradycardia; Electrocardiogram Qt Prolonged; Hypotension	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported
	Imipramine			S	Unknown	25 Mg Hs (At The Bed Time)		Not Reported
	Imipramine			S				Not Reported
	Alprazolam			C	Unknown			Mylan
	Estazolam			C	Unknown			Mylan
	Seroquel			C	Unknown	50 Mg Hs (At The Bed Time)		Mylan
	Propranolol			C	Unknown			Mylan
	Fentanyl			C	Intravenous (not otherwise specified)			Mylan
	Lidocaine			C	Intravenous (not			Mylan

			otherwise specified)			
	Propofol	C	Intravenous (not otherwise specified)			Mylan
	Cisatracurium	C	Intravenous (not otherwise specified)			Mylan
	Desflurane	C	Unknown	6% Desflurane With Oxygen		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15348097	NON-EXPEDITED			US-TEVA-2018-US-950074			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Lip Disorder; Oral Disorder	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15348358	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1842492US		34 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Musculoskeletal Pain; Myalgia; Pain; Pain In Extremity	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unknown		Allergan
	Quetiapin			S	Unknown	12.5 Mg, Unknown		Not Reported
	Pantoprazol			C	Unknown	Unk, Unknown		Not Reported
	Novaminsulfon			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15349867	EXPEDITED (15-DAY)		DE, HO	PHHY2018FR089172		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pulmonary Fibrosis	Atorvastatin			S	Oral	10 Mg, Qd		Novartis
	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported
	Paracetamol			S	Oral	1500 Mg, Qd		Not Reported

Amiodarone	S	Oral	200 Mg, Qd		Not Reported
Escitalopram	S	Oral	10 Mg, Qd		Not Reported
Ramipril	S	Oral	5 Mg, Qd		Not Reported
Levothyrox	S	Oral	1 Ot, Qd		Not Reported
Kardegic	S	Oral	1 Df, Qd		Not Reported
Caltrate Vitamine D3	S	Oral	Unk (600 Mg / 400 Iu)		Not Reported
Lorazepam	S	Oral	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15068896	EXPEDITED (15-DAY)		HO, LT, OT	FR-ELI_LILLY_AND_COMPANY-FR201806010763		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Suicide Attempt	Zyprexa			S	Unknown	15 Mg, Unknown		Eli Lilly And Co
	Olanzapine			S	Unknown	15 Mg, Unknown		Eli Lilly And Co
	Lepticur			S	Unknown	Unk Unk, Unknown		Not Reported
	Depamide			S	Oral	Unk Unk, Unknown		Not Reported
	Zopiclone			S	Oral	7.5 Mg, Daily		Not Reported
	Seroplex			S	Unknown	5 Mg, Daily		Not Reported
	Seroplex			S	Unknown	10 Mg, Unknown		Not Reported
	Dopamide			S	Oral	Unk Unk, Unknown		Not Reported
	Abilify			S	Oral	10 Mg, Unknown		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening		Not Reported
	Anafranil			S	Oral	75 Mg, Daily		Not Reported
	Lexapro			S	Unknown	10 Mg, Daily		Not Reported
	Imovane			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15249690	EXPEDITED (15-DAY)		CA, OT	JP-SA-2017SA217880			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Infantile Apnoea; Premature Baby; Speech Disorder Developmental	Zolpidem Tartrate			S	Transplacental			Sanofi
	Lexapro			S	Transplacental	Unk Unk,Unk		Not Reported
	Yokukansan			S	Transplacental	Unk Unk,Unk		Not Reported
	Hirnamin [Levomepromazine]			S	Transplacental	40-225 Mg/Day		Not Reported
	Horizon			S	Transplacental	2-5 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15350471	EXPEDITED (15-DAY)		CA, DE	DE-TEVA-2018-DE-951327		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 Milligram Daily;		Teva
	Escitalopram			S	Transplacental	220 Milligram Daily; 20 [Mg/D]		Ivax
	Candesartan			S	Transplacental	16 Milligram Daily;		Not Reported
	Paroxetin			S	Transplacental	30 Milligram Daily;		Teva
	Nepresol (Dihydralazine Sulfate)			S	Transplacental	25 Milligram Daily;		Not Reported
	L-Thyroxin 50			C	Transplacental			Not Reported
	Cytotec			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15350546	EXPEDITED (15-DAY)		HO, LT, OT	FR-ACCORD-071277		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Dehydration; Drug Interaction; Drug Level Increased; Neuroleptic Malignant Syndrome; Product Administration Error	Escitalopram			S				Not Reported
	Zuclopenthixol			S	Intramuscular			Not Reported
	Zuclopenthixol			S				Not Reported
	Cyamemazine/Cyamemazine Tartrate			S		25 Mg To 75 Mg Daily		Not Reported
	Zuclopenthixol			S		Titrated From 5 To 40mg Daily Over 2 Weeks		Not Reported

	Bisoprolol	C			Not Reported
	Atorvastatin	C			Not Reported
	Metformin	C			Not Reported
	Cyamemazine	S	50 Mg To 100 Mg Daily		Not Reported
	Cyamemazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15350573	EXPEDITED (15-DAY)		DE, HO	FR-MERCK KGAA-2054619		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pulmonary Fibrosis	Novothyrox			S	Oral			Merck Kgaa
	Atorvastatine			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Caltrate Vitamine D3 (Lekovit Ca)			S	Oral			Not Reported
	Amiodarone			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15351541	EXPEDITED (15-DAY)		OT	FR-ACCORD-071330			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amnesia; Arthralgia; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus;	Simvastatin			S				Accord
	Atenolol/Atenolol Hydrochloride			S				Accord
	Zyloric			S				Not Reported
	Levothyroxine			S	Oral			Not Reported
	Cotareg			S				Not Reported
	Amlor			S				Not Reported
	Oxazepam			S				Not Reported
	Uvedose			S				Not Reported

Urticaria; Vertigo; Vision Blurred	Imovane	S			Not Reported
	Seroplex	S			Not Reported
	Herbal Extract Nos/Vitis Vinifera	S	2 To 3 Cp / D		Not Reported
	Diclofenac	S	2x / Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15352555	EXPEDITED (15-DAY)		LT, OT	PHHY2018FR088385		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Alprazolam			S	Oral	Unk (Inconnue)		Novartis
	Mirtazapine			S	Oral	Unk (Inconnue)		Not Reported
	Escitalopram			S	Oral	Unk (Inconnue)		Not Reported
	Methadone			S	Oral	Unk (Inconnue)		Not Reported
	Havlane			S	Oral	Unk (Inconnue)		Not Reported
	Theralene			S	Oral	Unk (Inconnue)		Not Reported
	Tercian			S	Oral	Unk (Inconnue)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15352560	EXPEDITED (15-DAY)		LT	PHHY2018NO089260		56 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Fluoxetine			S	Oral	Unk		Novartis
	Trilafon			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	Unk		Not Reported
	Remeron			S	Oral	Unk		Not Reported
	Efexor			S	Oral	Unk		Not Reported
	Stemetil			S	Oral	Unk		Not Reported
	Ibux			S	Oral	Unk		Not Reported
	Fluanxol			S	Oral	Unk		Not Reported
	Vallergan			S	Oral	Unk		Not Reported

	Nozinan	S	Oral	Unk		Not Reported
	Zyprexa	S	Oral	Unk		Not Reported
	Sobril	S	Oral	Unk		Not Reported
	Truxal	S	Oral	Unk		Not Reported
	Cipralex	S	Oral	Unk		Not Reported
	Abilify	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15353619	EXPEDITED (15-DAY)		CA, DE	DE-ANIPHARMA-2018-DE-000151			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Candesartan Cilexetil			S	Other	16 Mg Daily		Ani
	Escitalopram			S	Other	Daily		Not Reported
	Levetiracetam			S	Other	1500 Mg Daily		Not Reported
	Nepresol (Dihydralazine Mesilate)			S	Other	25 Mg Daily		Not Reported
	Cytotec			S	Other	Unk		Not Reported
	Paroxetin			S	Other	30 Mg Daily		Not Reported
	Thyroxin			C	Other	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	10754169	EXPEDITED (15-DAY)		HO	FR-ROCHE-1529544		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyramidal Tract Syndrome; Tremor	Valium			S	Oral			Not Reported
	Teralithe			S	Oral	Dose 2 Boxes Of 400 Mg Tablets		Not Reported
	Seroplex			S	Oral	10 Mg 60 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	12784788	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20160924928			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Interstitial Lung Disease	Ixprim			S	Oral			Not Reported
	Cellcept			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported
	Triatec (Ramipril)			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Tahor			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Seresta			C	Oral			Not Reported
	Lasilix			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	14823712	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2018-022851		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Delirium; Drug Ineffective; Drug Interaction; Haematoma; Haemorrhage; Insomnia; Menometrorrhagia; Menorrhagia; Respiratory Tract Infection; Sleep Disorder; Thinking Abnormal	Escitalopram			S	Unknown	15 Milligram, Daily (Reduced)		Aurobindo
	Escitalopram			S	Oral	20 Milligram, Daily (Increased To 20 Mg In Morning)		Aurobindo
	Escitalopram			S				Aurobindo
	Pregabalin			S	Oral	(Evening Dose)100 Milligram		Not Reported
	Pregabalin			S				Not Reported
	Pregabalin			S				Not Reported
	Risperidone			S	Unknown	0.5 Mg, Unk (For 10 Days)		Aurobindo
	Risperidone			S				Aurobindo
	Risperidone			S				Aurobindo
	Risperidone			S				Aurobindo
	Risperidone			S				Aurobindo

Aripiprazole	S	Unknown	5 Milligram, Once A Day		Aurobindo
Promethazine	C	Unknown	Unk		Not Reported
Atorvastatin	C	Unknown	Unk		Not Reported
Opipramol	C	Unknown	In Crisis Situations With Temporary Effect ()		Not Reported
Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect		Not Reported
Pregabalin	C	Intracardiac	In The Evening		Not Reported
Pregabalin	C	Unknown	100 Milligram, Once A Day		Not Reported
Pregabalin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15135199	EXPEDITED (15-DAY)		HO	DE-GLAXOSMITHKLINE-DE2018119799		28 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Myoclonus	Risperidone			S	Unknown	Unk		Glaxosmithkline
	Risperidone			S				Glaxosmithkline
	Risperidone			S				Glaxosmithkline
	Quetiapine			S	Unknown	Unk		Glaxosmithkline
	Quetiapine			S				Glaxosmithkline
	Duloxetine			S	Unknown	Unk		Glaxosmithkline
	Bupropion			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	20 Mg, Unk		Glaxosmithkline
	Escitalopram			S				Glaxosmithkline
	Zopiclone			S	Unknown	Unk		Glaxosmithkline
	Oxazepam			S	Unknown	Unk		Glaxosmithkline
	Oxazepam			S				Glaxosmithkline
	Olanzapine			S	Unknown	Unk		Glaxosmithkline
	Venlafaxine			S	Unknown	Unk		Glaxosmithkline
	Promethazine			S	Unknown	Unk		Glaxosmithkline
	Biperiden			S	Unknown	Unk		Not Reported
	Biperiden			S				Not Reported

Clozapine	S	Unknown	75 Mg, Unk		Not Reported
Clozapine	S				Not Reported
Fluoxetine	S	Unknown	Unk		Not Reported
Fluoxetine	S				Not Reported
Aripiprazole	S	Unknown	Unk		Not Reported
Aripiprazole	S				Not Reported
Mirtazapine	S	Unknown	Unk		Not Reported
Amisulpride	S	Unknown	Unk		Not Reported
Amisulpride	S				Not Reported
Zonisamide	C	Unknown	Up To 100mg		Glaxosmithkline
Brivaracetam	C	Unknown	Unk		Not Reported
Oxcarbazepine	C	Unknown	Unk		Not Reported
Carbamazepine	C	Unknown	Unk		Not Reported
Clobazam	C	Unknown	Up To 20mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15289901	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2018331615		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anion Gap; Arrhythmia; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level Of Consciousness; Dystonia; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperreflexia; Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Muscle Rigidity; Myocardial Infarction; Myocardial Ischaemia;	Propanolol Hcl			S		Unk		Unknown
	Escitalopram			S		Unk		Not Reported
	Lamotrigine			S		Unk		Not Reported

Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15320718	EXPEDITED (15-DAY)		OT	PHHY2017IT193539		60 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
	Sertraline			S	Oral	100 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Lorazepam			S	Unknown	2.5 Mg, Qd		Novartis
	Brintellix			S	Unknown	15 Mg, Qd		Not Reported
	Brintellix			S	Unknown	10 Mg, Qd		Not Reported
	Brintellix			S	Unknown	5 Mg, Qd		Not Reported
	Warfarin			C	Unknown			Not Reported
	Ezetimibe			C	Unknown	10 Mg,Qd		Not Reported
	Alprazolam			C	Unknown			Not Reported
	Alprazolam			C	Unknown	2 Mg,Qd		Not Reported
	Lansoprazole			C	Unknown	30 Mg,Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Amiodarone			C	Unknown			Not Reported
	Coumadin			C	Unknown	Unk		Not Reported
	Triatec Hct			C	Unknown	15 Mg,Qd		Not Reported
	Cordarone			C	Unknown	200 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15354658	EXPEDITED (15-DAY)		CA, DE, OT	DE-MACLEODS PHARMACEUTICALS US LTD-			Unknown	DEU

MAC2018016490

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Candesartan			S	Transplacental	16 Milligram, Qd, (0. - 4.4. Gestational Week)		Macleods
	Escitalopram			S	Transplacental	220 Milligram, Qd, 1 {Trimester} , 4.4. - 11.5. Gestational Week, (20mg/D)		Macleods
	Levetiracetam			S	Transplacental	1500 Milligram, Qd, 1 {Trimester}, (0. - 11.5. Gestational Week)		Not Reported
	Nepresol (Dihydralazine Sulfate)			S	Transplacental	25 Milligram, Qd, 1 {Trimester}, (4.4. - 11.5. Gestational Week)		Not Reported
	L-Thyroxine Sodium			C	Transplacental	Unk (0. - 11.5. Gestational Week)		Not Reported
	Cytotec			C	Transplacental	Unk (11. - 11.5. Gestational Week)		Not Reported
	Paroxetin			S	Transplacental	30 Milligram, Qd, 1 {Trimester}, (0. - 4.4. Gestational Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15354815	EXPEDITED (15-DAY)		CA, DE, OT	DE-AUROBINDO-AUR-APL-2018-044247			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Candesartan			S	Transplacental	16 Milligram, Daily		Not Reported
	Escitalopram			S	Transplacental	220 Milligram, Daily		Aurobindo
	Levetiracetam			S	Transplacental	1500 Milligram, Daily		Aurobindo
	Paroxetine			S	Transplacental	30 Milligram, Daily		Aurobindo

	Nepresol /00007602/	S	Transplacental	25 Milligram, Daily	Not Reported
	Cytotec	C	Transplacental	Unk	Not Reported
	Thyroxin	C	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15355454	EXPEDITED (15-DAY)		CA, DE, OT	DE-LUPIN PHARMACEUTICALS INC.-2018-06221			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 Mg, Qd		Lupin
	Escitalopram			S	Transplacental	220 Mg, Qd		Not Reported
	Paroxetine			S	Transplacental	30 Mg, Qd		Not Reported
	Candesartan			S	Transplacental	16 Mg, Qd		Not Reported
	Nepresol /00007602/			S	Transplacental	25 Mg, Qd		Not Reported
	L-Thyroxin /00068001/			C	Transplacental	Unk		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15355530	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00883			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Dyschezia; Nausea; Rectal Haemorrhage; Vomiting	Escitalopram			S	Oral	1x Täglich Morgens		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15355651	EXPEDITED (15-DAY)		HO, LT, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018016505			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Overdose; Dehydration; Drug Interaction; Drug Level Increased; Intentional Overdose; Neuroleptic Malignant Syndrome; Product Administration Error; Vasoplegia Syndrome	Escitalopram Oxalate	S	Unknown	10 Milligram, Qd	Macleods
	Cyamemazine	S	Unknown	Unk, 25 Mg To 75 Mg Daily	Not Reported
	Cyamemazine	S	Unknown	Unk, 50 Mg To 100 Mg Daily	Not Reported
	Cyamemazine	S	Unknown	50 Milligram, Qd	Not Reported
	Cyamemazine	S	Oral	750 Milligram, 1 Total, Tablet	Not Reported
	Lercanidipine	S	Oral	300 Milligram, 1 Total, Tablet	Not Reported
	Lercanidipine	S	Unknown	Unk	Not Reported
	Zuclopenthixol Acetate	S	Intramuscular	100 Milligram	Not Reported
	Zuclopenthixol Decanoate	S	Unknown	300 Milligram, 1 Month, Injection	Not Reported
	Zuclopenthixol Hydrochloride	S	Oral	Unk, Titrated From 5 To 40mg Daily Over 2 Weeks	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Metformin Hydrochloride	C	Unknown	Unk	Macleods
	Bisoprolol	C	Unknown	Unk	Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)	4 Mg/Hour	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15356556	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1842949US		34 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Diabetes Mellitus; Fatigue; Hypersomnia; Off Label Use; Somnolence	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15356558	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1842966US		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Dizziness; Headache; Heart Rate Irregular; Mania	Escitalopram Oxalate - Bp			S	Unknown	20mg/Ml; One Drop		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20mg/Ml; One Drop		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15357767	EXPEDITED (15-DAY)		CA, DE	DE-ALLERGAN-1842819US		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan
	Levetiracetam			S	Transplacental	1500 Mg, Qd		Not Reported
	Nepresol (Hydralazine Hydrochloride)			S	Transplacental	25 Mg, Qd		Not Reported
	Candesartan			S	Transplacental	16 Mg, Qd		Not Reported
	Paroxetin			S	Transplacental	30 Mg, Qd		Not Reported
	L-Thyroxin 50			C	Transplacental	Unk Unk, Qd		Not Reported
	Cytotec			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15357874	EXPEDITED (15-DAY)		CA	PHHY2018DE085657		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Fallot'S Tetralogy	Metoprolol			S	Transplacental	Maternal Dose: 71.25 Mg, Qd (47.5-0-23.75 Mg, Qd)		Novartis
	Amitriptyline			S	Transplacental	Maternal Dose: 37.5 Mg, Qd		Not Reported
	Amitriptyline			S	Transplacental	Maternal Dose: 37.5 Mg, Qd		Not Reported
	Cipralex			S	Transplacental	Maternal Dose: 5 Mg, Qd		Not Reported
	Cipralex			S	Transplacental	Maternal Dose: 5 Mg, Qd		Not Reported
	Paracetamol			C	Transplacental	Maternal Dose: 2000 Mg, Qd (1 To 2 G Per Day If		Not Reported

				Required)	
	Clexane	C	Transplacental	Maternal Dose: 40 Mg, Qd	Not Reported
	Clexane	C	Transplacental	Maternal Dose: 120 Mg, Qd (2x60 Mg, Qd)	Not Reported
	Ibuprofen	C	Transplacental	Maternal Dose: 600 Mg, Qd (If Required)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	10792546	EXPEDITED (15-DAY)		HO	FR-FRI-1000074388		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Pyramidal Tract Syndrome; Tremor	Escitalopram Oxalate Unk			S	Oral	Seroplex 10 Mg 60 Tablets		Allergan
	Theralithe			S	Oral	Dose 2 Boxes Of 400 Mg Tablets		Not Reported
	Valium			S	Oral	30 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15066346	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2018SE79504		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Esomeprazole			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Esidrex			S	Oral			Not Reported
	Procoralan			C				Not Reported
	Aspirine Protect			C				Not Reported
	Seresta			C				Not Reported
	Dafalgan			C	Unknown			Not Reported
	Pravastatin Sodium			C				Not Reported
	Mediatensyl			C				Not Reported
	Ramipril			C				Not Reported
	Acebutolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15066665	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2018-032615		28 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Juvenile Myoclonic Epilepsy; Myoclonus; Schizophreniform Disorder	Quetiapine Film-Coated Tablet			S	Oral	Unk		Aurobindo
	Quetiapine Film-Coated Tablet			S				Aurobindo
	Aripiprazole			S	Unknown	Unk		Aurobindo
	Aripiprazole			S				Aurobindo
	Aripiprazole			S				Aurobindo
	Duloxetine			S	Unknown	Unk		Aurobindo
	Duloxetine			S				Aurobindo
	Olanzapine			S	Unknown	Unk		Aurobindo
	Olanzapine			S				Aurobindo
	Olanzapine			S				Aurobindo
	Olanzapine			S				Aurobindo
	Escitalopram 20 Mg			S	Unknown	20 Milligram		Aurobindo
	Escitalopram 20 Mg			S				Aurobindo
	Mirtazapine Film-Coated Tablet			S	Unknown	Unk		Aurobindo
	Mirtazapine Film-Coated Tablet			S				Aurobindo
	Venlafaxine Prolonged-Release Capsule, Hard			S	Oral	Unk		Aurobindo
	Venlafaxine Prolonged-Release Capsule, Hard			S				Aurobindo
	Amisulpride			S	Unknown	Unk		Not Reported
	Amisulpride			S				Not Reported
	Amisulpride			S				Not Reported
	Amisulpride			S				Not Reported
	Risperidone			S	Unknown	Unk		Aurobindo
	Risperidone			S				Aurobindo
	Zopiclone			S	Unknown	Unk		Not Reported
	Zopiclone			S				Not Reported
	Oxazepam			S	Unknown	At Different Doses		Not Reported
	Biperiden			S	Unknown	Unk		Not Reported
	Biperiden			S				Not Reported

	Bupropion	S	Unknown	Unk	Not Reported
	Bupropion	S			Not Reported
	Clozapine	S	Unknown	75 Milligram	Not Reported
	Fluoxetine	S	Unknown	Unk	Not Reported
	Fluoxetine	S			Not Reported
	Fluoxetine	S			Not Reported
	Fluoxetine	S			Not Reported
	Promethazine	S	Unknown	Unk	Not Reported
	Promethazine	S			Not Reported
	Promethazine	S			Not Reported
	Promethazine	S			Not Reported
	Zonisamide	C	Unknown	Up To 100mg	Not Reported
	Clobazam	C	Unknown	Up To 20mg	Not Reported
	Brivaracetam	C	Unknown	200-250mg; Received Over One Year ()	Not Reported
	Oxcarbazepine	C	Unknown	Up To 2400mg; Received Over One Year ()	Not Reported
	Carbamazepine	C	Unknown	Up To 900 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15135051	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2018-035103		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma; Haemorrhage; Menorrhagia; Respiratory Tract Infection; Restlessness; Sleep Disorder	Aripiprazole			S	Unknown	5 Milligram Daily		Aurobindo
	Risperidone			S	Unknown	0.5 Milligram, Once A Day		Aurobindo
	Risperidone			S				Aurobindo
	Risperidone			S				Aurobindo
	Risperidone			S				Aurobindo
	Escitalopram			S	Unknown	20 Milligram Daily; Increased To A Dose Of 20 Mg Daily (In A Morning Target Dose Of 20 Mg)		Aurobindo
	Escitalopram			S	Unknown	15 Milligram Daily; Reduced To 15 Mg/Day		Aurobindo

	Escitalopram	S	Unknown	20 Milligram Daily; In A Morning Target Dose Of 20 Mg	Aurobindo
	Escitalopram	S			Aurobindo
	Pregabalin	C	Unknown	100 Milligram Daily; Evening Dose Of 100 Mg ()	Not Reported
	Pregabalin	C			Not Reported
	Pregabalin	C			Not Reported
	Pregabalin	C			Not Reported
	Opipramol	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect ()	Not Reported
	Promethazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15214868	EXPEDITED (15-DAY)		OT	AT-PFIZER INC-2018297087		21 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Temesta (Lorazepam)			S		2-5 Mg		Pfizer
	Seroquel			S		75 Mg, Unk		Not Reported
	Seroquel			S		100 Mg, Unk		Not Reported
	Trittico			S		50 Mg, Unk		Not Reported
	Trittico			S		100 Mg, Unk		Not Reported
	Trittico			S		150 Mg, Unk		Not Reported
	Dominal /00018902/			S		80 Mg, Unk		Not Reported
	Dominal /00018902/			S		40 Mg, Unk		Not Reported
	Dominal /00018902/			S		80 Mg, Unk		Not Reported
	Cipralex /01588501/			S		5 Mg, Unk		Not Reported
	Cipralex /01588501/			S		10 Mg, Unk		Not Reported

	Lamictal	S		25 Mg, Unk	Not Reported
	Lamictal	S		50 Mg, Unk	Not Reported
	Lamictal	S		100 Mg, Unk	Not Reported
	Gewacalm	S		5 Mg, Unk	Not Reported
	Gewacalm	S		10 Mg, Unk	Not Reported
	Gewacalm	S		15 Mg, Unk	Not Reported
	Zyprexa	S		2.5 Mg, Unk	Not Reported
	Zyprexa	S		5 Mg, Unk	Not Reported
	Acetylic Acid	S	Unknown	80 Mg, 1x/Day	Not Reported
	Acetylic Acid	S		40 Mg, 1x/Day	Not Reported
	Acetylic Acid	S		80 Mg, 1x/Day	Not Reported
	Quilonorm /00033702/	C		225 Mg, Unk	Not Reported
	Halcion	C		0.25 Mg, Unk	Not Reported
	Zoldem	C		10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15260530	EXPEDITED (15-DAY)		HO, OT	PHHY2018DE040450		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Delirium; Drug Ineffective; Drug Interaction; Haematoma; Haemorrhage; Insomnia; Menometrorrhagia; Menorrhagia; Respiratory Tract Infection; Restlessness; Sleep Disorder; Thinking Abnormal	Risperidone			S	Unknown	0.5 Mg, Qd		Novartis
	Risperidone			S				Novartis
	Risperidone			S				Novartis
	Escitalopram			S	Oral	20 Mg, Qd (Increased To The Dose Of 20 Mg Daily)		Not Reported
	Escitalopram			S	Unknown	15 Mg, Qd (Reduced To 15 Mg/Day)		Not Reported
	Aripiprazole			S	Unknown	5 Mg, Qd		Not Reported
	Aripiprazole			S				Not Reported
	Pregabalin			C	Oral	100 Mg, Qd In The Evening		Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported

	Promethazine	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Opipramol	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
	Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15359154	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018016276			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Myoclonus	Olanzapine			S	Unknown	Unk		Macleods
	Olanzapine			S				Macleods
	Olanzapine			S				Macleods
	Aripiprazole			S	Unknown	Unk		Macleods
	Aripiprazole			S				Macleods
	Aripiprazole			S				Macleods
	Duloxetine			S	Unknown	Unk		Macleods
	Escitalopram			S	Unknown	20 Milligram		Macleods
	Quetiapine Tablet			S	Oral	Unk, Film Coated Tablet		Macleods
	Quetiapine Tablet			S				Macleods
	Venlafaxine Capsules			S	Oral	Unk, Hard		Macleods
	Fluoxetine			S	Unknown	Unk		Not Reported
	Amisulpride			S	Unknown	Unk		Not Reported
	Amisulpride			S				Not Reported
	Amisulpride			S				Not Reported
	Biperiden			S	Unknown	Unk		Not Reported
	Bupropion			S	Unknown	Unk		Not Reported
	Clozapine			S	Unknown	75 Milligram		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported

Risperidone	S			Not Reported
Risperidone	S			Not Reported
Promethazine	S	Unknown	Unk	Not Reported
Promethazine	S			Not Reported
Promethazine	S			Not Reported
Zopiclone	S	Unknown	Unk	Not Reported
Oxazepam	S	Unknown	Unk (At Different Doses)	Not Reported
Carbamazepine	C	Unknown	Unk (Up To 900 Mg)	Not Reported
Brivaracetam	C	Unknown	Unk (200-250mg; Received Over One Year)	Not Reported
Oxcarbazepine	C	Unknown	Unk (Up To 2400mg; Received Over One Year)	Not Reported
Clobazam	C	Unknown	Unk (Up To 20mg)	Not Reported
Zonisamide	C	Unknown	Unk (Up To 100mg)	Not Reported
Benzodiazepine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15359847	EXPEDITED (15-DAY)		DS, HO	CA-VIVIMED-2017SP015463			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Colour Blindness; Cytotoxic Oedema; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Infarction; Intentional Overdose; Mydriasis; Optic Atrophy; Optic Nerve Injury; Shock; Tachycardia; Vasodilatation; Visual Impairment	Amlodipine			S	Unknown	150 Mg		Strides
	Escitalopram			S	Unknown	60 Mg		Not Reported
	Risperidone			S	Unknown	6 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15360789	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-06218		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anion Gap; Arrhythmia; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level Of Consciousness; Dystonia; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperreflexia; Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Muscle Rigidity; Myocardial Ischaemia; Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Tremor	Escitalopram			S	Unknown	Unk		Lupin
	Lamotrigine			S	Unknown	Unk		Not Reported
	Propranolol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15361289	EXPEDITED (15-DAY)		DE	IT-MYLANLABS-2018M1065754		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S	Oral	0.5 Mg, Qd		Not Reported
	Alprazolam			S	Oral	0.75 Mg, Qd		Not Reported
	Clonazepam			S	Oral	7 Gtt, Qd		Mylan
	Venlafaxine Hydrochloride			S	Oral	75 Mg, Qd		Mylan

Venlafaxine Hydrochloride	S	Oral	150 Mg, Qd		Mylan
Venlafaxine Hydrochloride	S	Oral	37.5 Mg, Qd		Mylan
Cipralex /01588501/	S	Oral	2 Gtt, Qd		Mylan
Zolpidem Tartrate	S	Oral	15 Gtt, Qd		Mylan
Zolpidem Tartrate	S	Oral	10 Gtt, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15362423	EXPEDITED (15-DAY)		LT	FR-009507513-1809FRA000963		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Mirtazapine			S	Oral	Unknown		Merck
	Alprazolam			S	Oral	Unknown		Not Reported
	Methadone Hydrochloride			S	Oral	Unknown		Not Reported
	Havlane			S	Oral	Unknown		Not Reported
	Escitalopram			S	Oral	Unknown		Not Reported
	Theralene			S	Oral	Unknown		Not Reported
	Tercian			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15362475	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2018161921		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anion Gap; Arrhythmia; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level Of Consciousness; Dystonia; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperreflexia;	Escitalopram			S	Unknown	Unk		Glaxosmithkline
	Lamotrigine			S	Unknown	Unk		Glaxosmithkline
	Propranolol			S	Unknown	Unk		Glaxosmithkline

Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Muscle Rigidity; Myocardial Ischaemia; Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15363066	EXPEDITED (15-DAY)		LT	NO-009507513-1809NOR000979		56 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Remeron			S	Oral			Merck
	Trilafon (Perphenazine)			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Efexor Depot			S	Oral			Not Reported
	Stemetil (Prochlorperazine)			S	Oral			Not Reported
	Ibux			S	Oral			Not Reported
	Fluanxol			S	Oral			Not Reported
	Vallergan			S	Oral			Not Reported
	Nozinan			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Sobril			S	Oral			Not Reported
	Truxal (Chlorprothixene)			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15363278	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1842973US		40 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Rexulti			S	Oral	2 Mg, Qd		Not Reported
	Rexulti			S	Oral	1 Mg, Qd		Not Reported
	Lonasen			S	Oral			Not Reported
	Rivotril			C	Oral			Not Reported
	Flunitrazepam			C	Oral			Not Reported
	Belsomra			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15363295	EXPEDITED (15-DAY)		OT	US-SUNOVION-2018SUN003450		67 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Indacaterol And Glycopyrrolate			S	Respiratory (inhalation)	1 Df, Qd (Glycopyrronium Bromide: 50 Ug And Indacaterol Maleate: 110 Ug)		Sunovion
	Cipralex			S	Oral	20 Mg, Qd		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Seroquel			S	Oral	25 Mg, Qd		Not Reported
	Steri Neb Ipramol			S	Unknown	4 X 1 Dose, As Necessary		Not Reported
	Beloc Zok			C	Unknown	Unk		Not Reported
	Anxiolit			C	Unknown	Unk		Not Reported
	Zoldorm			C	Unknown	Unk		Not Reported
	Calcimagon D3			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15385120	DIRECT		DS			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral; Oedema Peripheral; Oedema Peripheral	Escitalopram Oxalate	Y		S	Oral	Quantity:30 Tablet(S);		Aurobindo
	Waterpill			C				Not Reported
	Doterra Essential Oils			C				Not Reported
	Magnesium			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2018	15364253	EXPEDITED (15-DAY)		OT	GB-TORRENT-00017362		25 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Libido Decreased; Sexual Dysfunction	Escitalopram Oxalate			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	14416444	EXPEDITED (15-DAY)		OT	US-ACCORD-062823		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Bedridden; Injury; Lyme Disease; Product Quality Issue; Psychotic Disorder; Withdrawal Syndrome	Escitalopram Accord			S	Oral	Strength: 20 Mg Dose: 100		Not Reported
	Xanax			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15365481	EXPEDITED (15-DAY)		OT	US-ACCORD-071520		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Blood Urine	Escitalopram			S	Oral	Strength: 10 Mg		Not Reported

Present; Diarrhoea; Dry Mouth; Haematemesis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15366261	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1065808		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Escitalopram			S	Unknown	(20mg-0mg-0mg-0mg) In The Morning		Not Reported
	Lamotrigine			S	Unknown	(1-1-1-0)		Not Reported
	Mirtazapine			S	Unknown	At Night		Not Reported
	Mirtazapine			S	Unknown	(0-0-1) At Night		Not Reported
	Milnacipran			S	Oral	200 Mg, Qd		Mylan
	Milnacipran			S	Oral	50 Mg, Q2d		Mylan
	Levothyroxine			C	Unknown	(1-0-0-0) In The Morning		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15367456	EXPEDITED (15-DAY)		OT	US-UCBSA-2018037167			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Status Epilepticus	Levetiracetam			S				Ucb
	Vimpat			S				Ucb
	Trileptal			S				Not Reported
	Lexapro			S				Not Reported
	Ativan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15367735	EXPEDITED (15-DAY)		OT	PHEH2018US036987			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mood Altered; Seizure; Vision Blurred	Risperidone			S	Unknown	Unk		Novartis
	Mirtazapine			S	Unknown	Unk		Not Reported

	Oxypro	S	Unknown	Unk		Not Reported
	Lexapro	S	Unknown	Unk		Not Reported
	Vitamin D3	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	14046947	NON-EXPEDITED			US-PFIZER INC-2017427872			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Retching; Vomiting	Metronidazole			S		Unk		Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported
	Chloraprep			S		Unk		Not Reported
	Janumet			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	14371399	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-001341		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Quetiapine Prolonged-Release Tablet			S	Oral	400 Mg, Qd		Aurobindo
	Quetiapine Prolonged-Release Tablet			S				Aurobindo
	Quetiapine Prolonged-Release Tablet			S				Aurobindo
	Laroxyl			S	Unknown	Unk ()		Not Reported
	Laroxyl			S				Not Reported
	Laroxyl			S				Not Reported
	Methylphenidate			S	Oral	110 Mg, Qd		Not Reported
	Methylphenidate			S	Oral	100 Mg, Unk		Not Reported
	Methylphenidate			S				Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported

Xeroquel	S				Not Reported
Xeroquel	S				Not Reported
Seroplex	S	Oral	10 Mg, Qd		Not Reported
Seroplex	S				Not Reported
Seroplex	S				Not Reported
Ritaline	S	Oral	100 Mg, Unk		Not Reported
Ritaline	S	Oral	110 Mg, Qd		Not Reported
Ritaline	S				Not Reported
Lepticur	S	Unknown	15 Mg, Unk		Not Reported
Lepticur	S				Not Reported
Lepticur	S				Not Reported
Abilify	S	Oral	15 Mg, Qd		Not Reported
Abilify	S				Not Reported
Abilify	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	14650225	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1814371US		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Cardiac Fibrillation; Crying; Drug Ineffective; Epilepsy; Libido Disorder; Tongue Biting	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Depakine			C				Not Reported
	Zoloft			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	14901152	EXPEDITED (15-DAY)		HO, OT	ES-ASTRAZENECA-2018SE63409			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Omeprazole			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	149.4mg Unknown		Not Reported
	Obinutuzumab			S	Intravenous (not	1000.0mg Unknown		Not Reported

				otherwise specified)	
	Cotrimoxamol		S	Unknown	Not Reported
	Atorvastatin		C		Not Reported
	Valsartan		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15368703	EXPEDITED (15-DAY)		HO	FR-MERCK KGAA-2054809		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Novothyrox			S	Oral			Merck Kgaa
	Loxapac			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Bendamustine Accord			S	Intravenous (not otherwise specified)			Not Reported
	Fenofibrate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Valaciclovir			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15368853	EXPEDITED (15-DAY)		LT	FR-ACCORD-071472		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Methadone			S	Oral			Not Reported
	Havlane			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported

	Tercian	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15368958	EXPEDITED (15-DAY)		HO	FR-ACCORD-071562		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Encephalopathy	Allopurinol			S	Oral			Accord
	Seroplex			S	Oral	Strength: Mg		Not Reported
	Amiodarone			S	Oral			Not Reported
	Topalgic (Tramadol Hydrochloride)			S	Oral	Strength:50 Mg		Not Reported
	Oxynormoro			S	Oral	Strength:5 Mg		Not Reported
	Tazocilline			S	Intravenous (not otherwise specified)	Strength: 4 G/500 Mg		Not Reported
	Xanax			S	Oral	Strength : 0,25 Mg		Not Reported
	Kardegic			S	Oral	Strength: 75 Mg		Not Reported
	Mycophenolic Acid			C	Oral			Not Reported
	Ciclosporin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15369168	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-044883		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning Deliberate; Somnolence	Prazepam			S	Oral	Unk, Np		Not Reported
	Escitalopram			S	Oral	Unk, Np		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15369299	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2018-045039		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Pneumonia	Alprazolam			S	Oral	Unk		Aurobindo

Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Escitalopram		S	Oral	Inconnue	Aurobindo
	Mirtazapine		S	Oral	Inconnue	Aurobindo
	Methadone		S	Oral	Inconnue	Not Reported
	Havlane		S	Oral	Inconnue	Not Reported
	Theralene		S	Oral	Inconnue	Not Reported
	Tercian /00759301/		S	Oral	Inconnue	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15369339	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-045033		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence	Diazepam			S	Oral	Non Renseignée		Not Reported
	Escitalopram			S	Oral	Non Renseignée		Aurobindo
	Imovane			S	Oral	7.5 Milligram, Daily		Not Reported
	Theralene			S	Oral	20 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15369373	NON-EXPEDITED			US-GLENMARK PHARMACEUTICALS-2018GMK036521			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Product Use In Unapproved Indication	Fluconazole			S	Unknown	Unk		Glenmark
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15369754	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP020260			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Healing	Apo-Escitalopram			S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15370018	EXPEDITED (15-DAY)		OT	ZA-LUPIN HEALTHCARE (UK) LIMITED-2018-06335			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness	Zytomil Tablets			S	Oral	20 Mg, Unk		Lupin
	Lestavor			S	Oral	10 Mg, Unk		Not Reported
	Adco Mirteron			S	Oral	15 Mg, Unk		Not Reported
	Pharmapress Co			S	Oral	20/12.5mg		Not Reported
	Asthavent /00139501/			S	Respiratory (inhalation)	100 Mcg, Unk		Not Reported
	Adco-Zolpidem			S	Oral	10 Mg, Unk		Not Reported
	Disprin Cardiocare			S	Oral	100 Mg, Unk		Not Reported
	Aspavor			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15370500	EXPEDITED (15-DAY)		CA, DE, OT	DE-APOTEX-2018AP020441			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Paroxetine			S	Transplacental	30 Mg, Qd		Apotex
	Levetiracetam			S	Transplacental	1500 Mg, Qd		Not Reported
	Escitalopram			S	Transplacental	220 Mg, Qd		Not Reported
	Candesartan			S	Transplacental	16 Mg, Qd		Not Reported
	Nepresol /00007602/			S	Transplacental	25 Mg, Qd		Not Reported
	L-Thyroxin /00068001/			C	Transplacental	Unk		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15370722	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-953511		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased	Paracetamol			S	Oral	4 Gram Daily; If Necessary		Not Reported
	Tramadol (Chlorhydrate De)			S	Oral	200 Milligram Daily; Form Lp, Morning And Evening If Necessary		Teva
	Coumadine 2 Mg, Comprimé Sécable			S	Oral	3 Milligram Daily;		Not Reported
	Ogastoro 15 Mg, Comprimé Orodispersible			S	Oral	15 Milligram Daily;		Not Reported
	Tahor 40 Mg, Comprimé Pelliculé			S	Oral	40 Milligram Daily;		Not Reported
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral	10 Milligram Daily;		Not Reported
	Coumadine 2 Mg, Comprimé Sécable			S	Oral			Not Reported
	Creon 25 000 U, Granulés Gastro-Résistants En Gélule			C				Not Reported
	Kardegic 160 Mg, Poudre Pour Solution Buvable En Sachet			C				Not Reported
	Nebivolol			C				Not Reported
	Eupressyl 60 Mg, Gélule			C				Not Reported
	Metformine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15370730	EXPEDITED (15-DAY)		LT	FR-TEVA-2018-FR-953646		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Alprazolam			S	Oral	Inconnue		Actavis
	Mirtazapine			S	Oral	Inconnue		Teva
	Escitalopram			S	Oral	Inconnue		Ivax
	Methadone			S	Oral	Inconnue		Not Reported
	Havlane			S	Oral	Inconnue		Not Reported
	Theralene			S	Oral	Inconnue		Not Reported
	Tercian			S	Oral	Inconnue		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15371569	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-953553		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Partial Seizures	Escitalopram			S	Oral	5 Milligram Daily;		Ivax
	Alprazolam			C	Oral	.25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15371624	EXPEDITED (15-DAY)		HO, OT	PHHY2018PL090342		62 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Electrocardiogram Qt Prolonged; Fatigue; Palpitations; Syncope	Cyproheptadine			S	Oral	16 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	10 Mg, Qhs		Novartis
	Ivabradine			S	Unknown	Unk		Not Reported
	Moclobemide			S	Unknown	150 Mg, Qd		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Venlafaxine			S	Unknown	150 Mg, Qd		Not Reported
	Sertraline			S	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15371715	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-953509		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning Deliberate; Somnolence	Escitalopram			S	Oral	Np		Not Reported
	Prazepam			S	Oral	Np		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15371816	EXPEDITED (15-DAY)		LT	NO-TEVA-2018-NO-953598		56 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Fluoxetine			S	Oral			Barr
	Trilafon			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Remeron			S	Oral			Not Reported
	Efexor Depot			S	Oral			Not Reported
	Stemetil			S	Oral			Not Reported
	Ibux			S	Oral			Not Reported
	Fluanxol			S	Oral			Not Reported
	Vallergan			S	Oral			Not Reported
	Nozinan			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Sobril			S	Oral			Not Reported
	Truxal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15371946	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2018-FR-953645		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pulmonary Fibrosis	Atorvastatine			S	Oral	10 Milligram Daily;		Teva
	Paracetamol			S	Oral	1500 Milligram Daily;		Not Reported
	Ramipril			S	Oral			Actavis
	Amiodarone			S	Oral	200 Milligram Daily;		Teva
	Pantoprazole			S	Oral	20 Milligram Daily;		Teva
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Levothyrox			S	Oral			Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-			S	Oral	1 Dosage Forms Daily;		Not Reported

	Dose Caltrate Vitamine D3 600 Mg/400 Ui, Comprimé Pelliculé Sécable	S	Oral			Not Reported
	Lorazepam	S	Oral	1 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15372113	EXPEDITED (15-DAY)		DS, OT	GB-MYLANLABS-2018M1066298		33 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Jaw	Escitalopram			S	Oral	5 Mg, Unk		Not Reported
	Lansoprazole			C		30 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15372144	EXPEDITED (15-DAY)		LT	NO-ALLERGAN-1844326US		56 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Truxal			S	Oral			Not Reported
	Fluanxol Tabletter (Flupentixol Dihydrochloride)			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Trilafon			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Remeron			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Efexor			S	Oral	Efexor Depot		Not Reported
	Stemetil			S	Oral			Not Reported
	Ibux			S	Oral			Not Reported
	Vallergan			S	Oral			Not Reported
	Nozinan			S	Oral			Not Reported

	Zyprexa		S	Oral			Not Reported
	Sobril		S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15372467	EXPEDITED (15-DAY)		HO	PHHY2018FR092469		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Long Cours		Novartis
	Bendamustine			S	Intravenous (not otherwise specified)	346 Mg, Qmo		Not Reported
	Valaciclovir			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Loxapac			S	Oral			Not Reported
	Levothyrox			S	Oral	Unk		Not Reported
	Fenofibrate			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Long Cours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	12623826	NON-EXPEDITED			US-JAZZ-2016-US-003869			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	1.75 G, Bid		Jazz
	Xyrem			S	Oral	Unknown Dose		Jazz
	Lexapro			S				Not Reported
	Colecalciferol			C		Unk		Not Reported
	Bystolic			C		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Nuvigil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	13122629	EXPEDITED (15-DAY)		HO, LT, OT	FR-ALLERGAN-1701647US		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Lepticur			S	Unknown	Unk		Not Reported
	Methyldopa			S	Oral	Unk		Not Reported
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Depamide			S	Oral	300 Mg, Unk		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening		Not Reported
	Anafranil			S	Oral	75 Mg, Unkdaily Dose Increased. Oral Drug Unspecified Form		Not Reported
	Olanzapine			S	Unknown	15 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	15 Mg, Unk		Not Reported
	Zopiclone			S	Oral	7.5 Mg, Qd		Not Reported
	Imovane			S	Oral	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	14272549	EXPEDITED (15-DAY)		OT	US-OTSUKA-2017_016320			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prolactin-Producing Pituitary Tumour	Abilify			S	Unknown	Unk		Otsuka
	Rexulti			S	Unknown	1 Mg, Unk		Otsuka
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	14412552	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1802859US		43 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qpm (Before Sleep)		Allergan
	Antidepressants			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	14699165	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-016526		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cyst	Escitalopram Film Tablets 10 Mg			S	Oral	Currently		Aurobindo
	Escitalopram Film Tablets 10 Mg			S	Oral	15 Milligram		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15372728	EXPEDITED (15-DAY)		OT	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-184117		87 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Electrocardiogram Qt Prolonged; Hypotension; Hypotension	Escitalopram			S	Unknown	Unk		Not Reported
	Imipramine			S	Unknown	25 Mg, Hs		Mutual
	Alprazolam			S	Unknown	0.5 Mg, Bid		Sun
	Fentanyl			S	Intravenous (not otherwise specified)	100 Ug		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Sevoflurane			S	Unknown	Unk		Not Reported
	Estazolam			S	Unknown	2 Mg		Not Reported
	Seroquel			S	Unknown	5 Mg, Hs		Not Reported
	Lidocaine			S	Intravenous (not	50 Mg, Unk		Not Reported

			otherwise specified)			
	Desflurane	S	Unknown	6 %		Not Reported
	Propranolol	C	Unknown	10 Mg		Not Reported
	Cistracurium	C	Intravenous (not otherwise specified)	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15372806	EXPEDITED (15-DAY)		CA, DE	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-184120			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 [Mg/D]		Sun
	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Candesartan			S	Transplacental	16 [Mg/D]		Not Reported
	Nepresol (Dihydralazine Mesilate)			S	Transplacental	25 [Mg/D]		Not Reported
	Paroxetin			S	Transplacental	30 [Mg/D]		Not Reported
	L-Thyroxin 50			C	Transplacental	()		Not Reported
	Cytotec			C	Transplacental	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15374482	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1066330		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Poisoning Deliberate	Venlafaxine			S	Oral	Non Précisée		Not Reported
	Zopiclone			S	Oral	Non Précisée		Not Reported
	Atarax /00058401/			S	Oral	Non Précisée		Mylan
	Previscan /00261401/			S	Oral	Non Précisée		Mylan
	Seroplex			S	Oral	Non Précisée		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15375131	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1844308US		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Poisoning Deliberate; Product Use In Unapproved Indication; Somnolence	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan
	Prazepam			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15375810	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018365959		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Unk		Pfizer
	Valaciclovir			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Pfizer
	Loxapac [Loxapine]			S	Oral	Unk		Not Reported
	Bendamustine Accord			S	Intravenous (not otherwise specified)	346 Mg, Monthly		Not Reported
	Levothyrox			S	Oral	Unk		Not Reported
	Fenofibrate			S	Oral	Unk		Not Reported
	Truxima			S	Intravenous (not otherwise specified)	720 Mg, Monthly		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15376406	EXPEDITED (15-DAY)		HO	PHHY2018DE094496		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysphagia; Nausea; Vertigo	Amiodarone			S	Unknown	Unk		Novartis
	Melperone Hydrochloride			S	Unknown	Unk		Not Reported

Cipralex	S	Unknown	10 Mg, Qd		Not Reported
Escitalopram	C	Unknown	Unk (From Beta Pharm)		Not Reported
L-Tyrosine	C	Unknown	Unk		Not Reported
Candesartan	C	Unknown	Unk		Not Reported
Metoprolol	C	Unknown	Unk		Not Reported
Mcp	C	Unknown	Unk		Not Reported
Xarelto	C	Unknown	Unk		Not Reported
Amlodipin	C	Unknown	Unk		Not Reported
Kalinor (Potassium Chloride)	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15376674	EXPEDITED (15-DAY)		HO, LT, OT	JP-PRINSTON PHARMACEUTICAL INC.-2018PRN01275		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity; Shock	Escitalopram			S	Unknown			Prinston Pharmaceutical
	Lorazepam			S	Unknown			Not Reported
	Adrenaline			S	Unknown	Unk, Once		Not Reported
	Adrenaline			S	Unknown	Three Injection		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15395759	DIRECT		DS, LT, OT			45 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome; Toxicity To Various Agents	Lexapro			S	Oral	Quantity:10 Df Dosage Form;		Astrazeneca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	14906718	EXPEDITED (15-DAY)		DE, OT	FR-BAXTER-2018BAX014039		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Endoxan 1000 Mg, Poudre Pour Solutioninjectable	S	Intravenous drip		Baxter
	Endoxan 1000 Mg, Poudre Pour Solutioninjectable	S	Intravenous drip		Baxter
	Rituximab (Mammal/Hamster/Cho Cells)	S	Intravenous drip		Not Reported
	Rituximab (Mammal/Hamster/Cho Cells)	S	Intravenous drip		Not Reported
	Calciparine	S	Subcutaneous		Not Reported
	Calciparine	S	Subcutaneous		Not Reported
	Bisoprolol (Fumarate Acid)	S	Oral		Not Reported
	Ciprofloxacin, Ciprofloxacin Hydrochloride	S	Intravenous drip		Not Reported
	Ciprofloxacin, Ciprofloxacin Hydrochloride	S	Intravenous drip		Not Reported
	Methotrexate	S	Intravenous drip	Unk	Not Reported
	Methotrexate	S	Intravenous drip		Not Reported
	Doxorubicin Hydrochloride	S	Intravenous drip		Not Reported
	Doxorubicin Hydrochloride	S	Intravenous drip		Not Reported
	Lidocaine	S	Buccal	Unk	Not Reported
	Lidocaine	S	Unknown		Not Reported
	Lidocaine	S	Buccal		Not Reported
	Fungizone	S	Buccal		Not Reported
	Fungizone	S	Buccal		Not Reported
	Voraxaze	S	Intravenous drip		Not Reported
	Voraxaze	S	Intravenous drip		Not Reported
	Zarzio	S	Subcutaneous		Not Reported
	Zarzio	S	Subcutaneous		Not Reported
	Valaciclovir	S	Oral		Not Reported
	Valaciclovir	S	Oral		Not Reported
	Valaciclovir	S	Unknown		Not Reported
	Furosemide	S	Oral		Not Reported
	Furosemide	S	Oral		Not Reported

Exacyl	S	Intravenous drip	Unk	Not Reported
Exacyl	S	Unknown	Unk	Not Reported
Exacyl	S	Intravenous drip		Not Reported
Prednisone	S	Intravenous drip		Not Reported
Prednisone	S	Intravenous drip		Not Reported
Eprex	S	Subcutaneous		Not Reported
Eprex	S	Subcutaneous		Not Reported
Ondansetron	S	Oral		Not Reported
Ondansetron	S	Oral		Not Reported
Vincristine Sulfate	S	Intravenous drip		Not Reported
Vincristine Sulfate	S	Intravenous drip		Not Reported
Bactrim	S	Oral		Not Reported
Bactrim	S	Oral		Not Reported
Hextril	S	Buccal	Unk	Not Reported
Hextril	S	Unknown	Unk	Not Reported
Hextril	S	Buccal		Not Reported
Pantoprazole	S	Intravenous drip		Not Reported
Pantoprazole	S	Intravenous drip		Not Reported
Bromazepam	S	Oral		Not Reported
Bromazepam	S	Oral		Not Reported
Bromazepam	S	Unknown		Not Reported
Escitalopram	S	Oral		Not Reported
Escitalopram	S	Oral		Not Reported
Meropenem Anhydrous	S	Intravenous drip		Not Reported
Meropenem Anhydrous	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15306299	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2018SF05639		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Oral Lichen Planus	Esomeprazole		S	Oral		Astrazeneca
	Xeroquel		S	Oral	Unk	Not Reported
	Seroplex		S	Oral	Unk	Not Reported
	Seroplex		S	Oral	Unk	Not Reported
	Esidrex		S	Oral	25 Mg Unknown Non Az Product	Not Reported
	Kardegic		S	Oral	Unk	Not Reported
	Atorvastatin		S	Oral	20.0mg Unknown	Not Reported
	Lamotrigine		S	Oral	Unk	Not Reported
	Teralithe		S	Oral	Unk	Not Reported
	Macrogol		S	Oral	Unk	Not Reported
	Perindopril		S	Oral	2.0mg Unknown	Not Reported
	Aldactone		S	Oral	Unk	Not Reported
	Verapamil		S	Oral	240.0mg Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15368257	EXPEDITED (15-DAY)		HO, OT	PHHY2018BR094226			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Asthenia; Choking; Disorientation; Disturbance In Attention; Dry Mouth; Emotional Distress; Hallucination; Impatience; Psychiatric Symptom; Screaming; Speech Disorder; Tremor; Weight Decreased	Quetiapine Fumarate			S	Unknown	1 Df, Qn		Not Reported
	Cloxazolam			S	Oral	1 Df, Qn		Not Reported
	Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Escitalopram			S	Oral	2 Df, Qd (At Lunch 11 Am)		Not Reported
	Alprazolam			S	Unknown	1 Mg, Unk		Not Reported
	Losartan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15377039	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2018SF12283		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Seroplex			S	Oral	10.0mg Unknown		Not Reported
	Inexium			S	Oral			Astrazeneca
	Tardyferon			C				Not Reported
	Tahor			C				Not Reported
	Uvedose			C				Not Reported
	Seresta			C				Not Reported
	Doliprane			C				Not Reported
	Zopiclone			C				Not Reported
	Kardegic			C				Not Reported
	Sinemet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15377430	NON-EXPEDITED			US-TEVA-2018-US-953454		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Gluten Sensitivity	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15377451	EXPEDITED (15-DAY)		HO	FR-ZYDUS-026837		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Valaciclovir			S	Oral			Zydus Pharm
	Escitalopram			S	Oral			Zydus Pharm
	Pantoprazole			S	Oral	Long Course		Not Reported
	Fenofibrate			S	Oral			Not Reported
	Bendamustine Accord			S	Intravenous (not otherwise specified)			Not Reported
	Loxapac			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Truxima			S	Intravenous (not otherwise specified)			Not Reported

	Lorazepam	S	Oral	Long Course	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15378082	EXPEDITED (15-DAY)		LT	NO-PFIZER INC-2018369245		56 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Efexor Depot			S	Oral	Unk		Pfizer
	Sobril			S	Oral	Unk		Pfizer
	Trilafon Dekanoat			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	Unk		Not Reported
	Remeron			S	Oral	Unk		Not Reported
	Fluoxetine			S	Oral	Unk		Not Reported
	Stemetil			S	Oral	Unk		Not Reported
	Ibux			S	Oral	Unk		Not Reported
	Fluanxol			S	Oral	Unk		Not Reported
	Vallergan			S	Oral	Unk		Not Reported
	Nozinan			S	Oral	Unk		Not Reported
	Zyprexa			S	Oral	Unk		Not Reported
	Truxal			S	Oral	Unk		Not Reported
	Cipralex			S	Oral	Unk		Not Reported
	Abilify			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15378497	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2018368080		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Alprazolam			S	Oral	Unk		Pfizer
	Mirtazapine			S	Oral	Unk		Not Reported
	Methadone			S	Oral	Unk		Not Reported
	Havlane			S	Oral	Unk		Not Reported

	Escitalopram	S	Oral	Unk		Not Reported
	Theralene	S	Oral	Unk		Not Reported
	Tercian [Cyamemazine Tartrate]	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	14273290	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2015_018135			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Abilify			S	Oral	15 Mg, Qd		Otsuka
	Abilify			S				Otsuka
	Abilify			S				Otsuka
	Lepticur			S	Unknown	15 Mg, Unk		Not Reported
	Lepticur			S				Not Reported
	Lepticur			S				Not Reported
	Ritaline			S	Oral	100 Mg, Qd (80 In The Morning And 20 Mg At 4 Pm)		Not Reported
	Ritaline			S	Oral	110 Mg, Qd (80 Mg In The Morning And 20 Mg At 4pm)		Not Reported
	Ritaline			S				Not Reported
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported
	Xeroquel			S				Not Reported
	Xeroquel			S				Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Seroplex			S				Not Reported
	Seroplex			S				Not Reported
	Laroxyl			S	Unknown	Unk		Not Reported
	Laroxyl			S				Not Reported
	Laroxyl			S				Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	14305604	EXPEDITED (15-DAY)		HO, OT	DE-OTSUKA-2017_021775			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Accidental Overdose; Disinhibition; Drug Interaction; Hospitalisation; Mental Disorder; Product Use Issue; Therapy Change	Abilify			S	Unknown	Unk		Otsuka
	Cipralex			S	Oral	20 Gtt, Qd		Not Reported
	Cipralex			S	Oral	5 Gtt, Qd		Not Reported
	Cipralex			S	Oral	10 Gtt, Qd		Not Reported
	Vitamin D + Calcium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15024042	EXPEDITED (15-DAY)		HO, LT, OT	CZ-MYLANLABS-2018M1040714			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning; Toxicity To Various Agents	Olanzapine			S	Oral	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported
	Levomepromazine			S	Oral	Unk		Mylan
	Metoclopramide			S	Oral	Unk		Mylan
	Melperone			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15084704	EXPEDITED (15-DAY)		HO, OT	FR-TAKEDA-2018TUS020997			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Aggression; Cardiac Failure; Compulsive Shopping;	Brintellix			S	Oral	5 Mg, Qd		Takeda
	Brintellix			S	Unknown	10 Mg, Unk		Takeda

Derealisation; Disinhibition; Grandiosity; Insomnia; Irritability; Mania; Myocardial Infarction; Obsessive-Compulsive Disorder; Oedema; Persecutory Delusion; Stent Placement; Suicidal Ideation; Thinking Abnormal; Verbal Abuse; Weight Increased	Brintellix	S	Unknown	15 Mg, Unk	Takeda
	Brintellix	S	Unknown	20 Mg, Unk	Takeda
	Seroplex	S	Unknown	Unk	Not Reported
	Lasilix /00032601/	C	Unknown	Unk	Not Reported
	Aldactone 50 Hct	C	Unknown	Unk	Not Reported
	Kardegic	C	Unknown	Unk	Not Reported
	Depakote	C	Unknown	Unk	Not Reported
	Xanax	C	Unknown	Unk	Not Reported
	Inexium /01479302/	C	Unknown	Unk	Not Reported
	Noctamide	C	Unknown	2 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15368174	EXPEDITED (15-DAY)		OT	CZ-ALLERGAN-1843352US		58 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Mental Disorder; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Citalopram Hydrobromide - Bp			S	Unknown	Series Of Citalopram Infusions		Allergan
	Aripiprazole			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk Unk,Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Ziprasidone			S	Unknown	Unk		Not Reported
	Clomipramine			S	Unknown			Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Memantine			C				Not Reported
	Melperone			C				Not Reported
	Tiapride			C		Unk		Not Reported
	Clonazepam			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

Haloperidol	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15384319	EXPEDITED (15-DAY)		HO, LT, OT	FR-TEVA-2018-FR-954420		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use; Suicide Attempt	Escitalopram			S	Unknown	10 Milligram Daily; Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Ivax
	Olanzapine			S	Unknown	15 Mg, Unk		Teva
	Zopiclone			S	Oral	7.5 Milligram Daily; 1tab/Dy		Not Reported
	Lepticur			S	Unknown	Unk		Not Reported
	Methyldopa			S	Oral	Unk		Not Reported
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Depamide			S	Oral	300 Milligram Daily; 300 Mg, Oral Drug Unspecified Form		Not Reported
	Seresta			S	Oral	50 Milligram Daily; Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening.		Not Reported
	Seroplex			S	Unknown	10 Milligram Daily; Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Not Reported
	Anafranil			S	Oral	75 Milligram Daily; Daily Dose Increased. Oral Drug Unspecified Form		Not Reported
	Zyprexa			S	Unknown	15 Mg, Unk		Not Reported
	Seroplex			S	Unknown	5 Milligram Daily; 5 Mg, Qd		Not Reported
	Imovane			S	Oral	7.5 Milligram Daily; 1tab/Dy, Oral Drug		Not Reported

Unspecified Form

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15384665	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-045284		25 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Libido Decreased; Sexual Dysfunction	Escitalopram			S	Oral	25 Milligram		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15385495	EXPEDITED (15-DAY)		CA, DE	PHHY2018DE089083			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Nepresol (Hydralazine Hydrochloride)			S	Transplacental	Maternal Dose: 25 Mg Qd		Not Reported
	Paroxetine			S	Transplacental	Maternal Dose: 30 Mg Qd		Not Reported
	Levetiracetam			S	Transplacental	Maternal Dose: 1500 Mg Qd		Novartis
	Escitalopram			S	Transplacental	Maternal Dose: 220 Mg Qd		Not Reported
	Candesartan Cilexetil			S	Transplacental	Maternal Dose: 16 Mg Qd		Not Reported
	L-Thyroxin			C	Transplacental	Unk		Not Reported
	Cytotec			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15385781	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC-2018369570		65 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Aspavor			S		40 Mg, Unk		Pfizer
	Calciferol [Ergocalciferol]			S		50000 Iu, Unk		Not Reported
	Arthrexin			S		25 Mg, Unk		Not Reported

Ciplasyl	S	40 Unk, Unk	Not Reported
Covocort	S	10 Mg, Unk	Not Reported
Dopaquel	S	5 Mg, Unk	Not Reported
Ecotrin	S	81 Mg, Unk	Not Reported
Eltroxin	S	100 Ug, Unk	Not Reported
Ferrimed [Ferric Hydroxide Polymaltose Complex]	S	Unk	Not Reported
Glucophage	S	500 Mg, Unk	Not Reported
Januvia	S	100 Mg, Unk	Not Reported
Lexamil	S	20 Mg, Unk	Not Reported
Omez [Omeprazole]	S	20 Mg, Unk	Not Reported
Puricos	S	300 Mg, Unk	Not Reported
Tamsul	S	0.4 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15386409	EXPEDITED (15-DAY)		HO	DE-ASTRAZENECA-2018SF12771		34 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Musculoskeletal Pain; Myalgia; Pain; Pain In Extremity	Quetiapine Fumarate			S	Oral	12.5mg Unknown		Not Reported
	Escitalopram			S				Not Reported
	Novaminsulfon			C				Not Reported
	Pantoprazol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15387319	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1844529US		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery; Product Use Issue	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Abilify			S	Unknown			Not Reported
	Dihydroergotamine			S	Unknown	Unk, Unknown		Not Reported
	Oxazepam			S	Unknown	Unk, Unknown		Not Reported

Pipamperone	S	Unknown	Unk, Unknown		Not Reported
Dipotassium Clorazepate	S	Unknown	Unk, Unknown		Not Reported
Loprazolam	S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15387469	EXPEDITED (15-DAY)		HO, LT	JP-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00371		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity; Shock	Escitalopram			S	Unknown			Jubilant
	Lorazepam			S	Unknown	Unk		Not Reported
	Adrenaline			S	Unknown	Unk, Once		Not Reported
	Adrenaline			S	Unknown	Three Injections		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15387491	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1067180		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Extrapyramidal Disorder; Mydriasis; Sinus Tachycardia; Suicide Attempt	Escitalopram			S	Oral	9 Mg, Total		Not Reported
	Risperidone			S	Oral	36 Mg, Total		Not Reported
	Theralene			C	Oral	Posologie Non Précisée		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15387684	EXPEDITED (15-DAY)		DS	US-ALLERGAN-1844528US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Withdrawal Syndrome	Escitalopram Oxalate Unk			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2018	14958508	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2018-028429			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Escitalopram			S	Unknown	Unk		Aurobindo
	Omeprazole			S	Oral	Unk		Aurobindo
	Bendamustine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Bendamustine			S				Not Reported
	Bendamustine			S				Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Obinutuzumab			S				Not Reported
	Obinutuzumab			S				Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2018	15139435	EXPEDITED (15-DAY)		HO, LT	DE-HETERO CORPORATE-HET2018DE00645		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram			S	Unknown	5 Mg		Hetero
	Linezolid			S	Intravenous (not otherwise specified)	2 Dosage Form, Qd, 2 Df Dosage Form Every Days		Not Reported
	Esomeprazol /01479301/			S	Unknown	40 Milligram		Not Reported
	Levetiracetam			C	Unknown	2 Dosage Form		Not Reported
	Ivabradina			C	Unknown	15 Milligram, Qd, 15 Mg Millgram(S) Every Days		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	2 Dosage Form, Qd 2 Df Dosage Form Every Days		Not Reported
	Naloxone, Tilidine			C	Unknown	10 Gtt		Not Reported
	Scopolamin			C	Unknown	Unk		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported

Prednisolon	C	Unknown	Unk		Not Reported
Lorazepam	C	Unknown	Daily Dose: 1 Mg Millgram(S) Every Days		Not Reported
L-Thyroxin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2018	15388210	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-045686		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Unk,Long Cours		Aurobindo
	Fenofibrate			S	Oral	Unk		Aurobindo
	Valaciclovir			S	Oral	Unk		Aurobindo
	Escitalopram			S	Oral	Unk		Aurobindo
	Loxapac /00401802/			S	Oral	Unk		Not Reported
	Bendamustine Accord			S	Intravenous (not otherwise specified)	346 Milligram		Not Reported
	Levothyrox			S	Oral	Unk		Not Reported
	Truxima			S	Intravenous (not otherwise specified)	720 Milligram, Monthly		Not Reported
	Lorazepam			S	Oral	Unk, Long Cours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2018	15149903	EXPEDITED (15-DAY)		HO, LT	DE-TORRENT-00008885		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Baclofen			C		Unknown		Unknown
	Cotrimoxazol			C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Unknown
	Ivabradin			C		Daily Dose: 15 Mg Millgram(S) Every Days		Unknown
	L-Thyroxin			C		Unknown		Unknown

	Levetiracetam	C		Daily Dose: 2 Df Dosage Form Every Days	Unknown
	Lorazepam	C		Daily Dose: 1 Mg Millgram(S) Every Days	Unknown
	Naloxone, Tilidine	C			Unknown
	Prednisolon	C			Unknown
	Scopolamin	C			Unknown
	Escitalopram	S			Unknown
	Esomeprazol	S			Unknown
	Linezolid	S	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15060339	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-2018_015891		14 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Abilify			S	Oral	10 Mg, Qd (Progressively Started 5 Mg In The Morning And Evening)		Otsuka
	Tercian			S	Oral	25 Mg, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd (In The Evening)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15126719	EXPEDITED (15-DAY)		CA, OT	DE-GLAXOSMITHKLINE-DE2018117785			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Autism Spectrum Disorder; Camptodactyly Congenital; Clinodactyly; Congenital Arterial Malformation; Congenital Central Nervous System Anomaly; Congenital	Lorazepam			S	Unknown	Unk		Glaxosmithkline
	Valaciclovir			S	Unknown	Unk		Glaxosmithkline
	Mycophenolate Mofetil			S	Unknown	Unk		Glaxosmithkline
	Tacrolimus			S	Unknown	Unk		Glaxosmithkline
	Colchicine			S	Unknown	Unk		Glaxosmithkline
	Cyclosporine			S	Unknown	Unk		Glaxosmithkline

Renal Cyst; Dysplasia; External Auditory Canal Atresia; Foetal Exposure During Pregnancy; Foetal Malformation; Hydronephrosis; Meningocele; Microtia; Oesophageal Atresia; Premature Baby; Product Use Issue	Prednisolone	S	Unknown	Unk		Glaxosmithkline
	Azathioprine	S	Unknown	Unk		Glaxosmithkline
	Escitalopram	S	Unknown	Unk		Glaxosmithkline
	Fosfomycin	S	Unknown	Unk		Not Reported
	Abatacept	S	Unknown	Unk		Not Reported
	Ursodeoxycholic Acid	S	Unknown	Unk		Not Reported
	Acebutolol	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Methyldopa	S	Unknown	Unk		Not Reported
	Naproxen	S	Unknown	Unk		Not Reported
	Zolpidem	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15154410	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1835498US		85 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Medication Error; Product Use In Unapproved Indication	Escitalopram Oxalate Unk			S	Oral	35 Gtt, Unk (In Total)		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15389627	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-955054		25 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Libido Decreased; Sexual Dysfunction	Escitalopram Oxalate			S	Oral	25 Mg		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15390096	EXPEDITED (15-DAY)		DE, HO	FR-SUN PHARMACEUTICAL		87 YR	Female	FRA

INDUSTRIES LTD-
2018RR-184641

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pulmonary Fibrosis	Paracetamol		Y	S	Oral	1500 Mg, Daily		Ohm Lab
	Atorvastatine			S	Oral	10 Mg, Daily		Sun
	Ramipril			S	Oral	5 Mg, Daily		Ranbaxy
	Pantoprazole			S	Oral	20 Mg, Daily		Sun
	Amiodarone			S	Oral	200 Mg, Daily		Taro
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Levothyrox			S	Oral	Daily		Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	1 Df, Daily		Not Reported
	Caltrate Vitamine D3 600 Mg/400 Ui, Comprime Pellicule Secable			S	Oral	()		Not Reported
	Lorazepam			S	Oral	1 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15390175	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00910		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Rash	Escitalopram			S	Oral	5 Milligram, Qd		Hetero
	Candesartan			C	Unknown	8 Milligram, Qd		Not Reported
	Eliquis			C	Oral	10 Milligram, Qd		Not Reported
	Oestradiol			C	Oral	0.5 Milligram, Qd		Not Reported
	Novalgin /06276704/			C	Oral	1.5 Milligram, Qd		Not Reported
	Amlodipin /00972401/			C	Unknown	10 Milligram, Qd		Not Reported
	Sulfasalazin			C	Oral	2 Milligram, Qd		Not Reported

	Concor	C	Oral	5 Milligram, Qd	Not Reported
	Kalinor /00031402/	C	Oral	600 Milligram, Qd	Not Reported
	Cotrimoxazol	C	Oral	960 Milligram, Qd	Not Reported
	Vigantoletten	C	Subcutaneous	1000 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15391041	EXPEDITED (15-DAY)		HO, LT, OT	JP-MACLEODS PHARMACEUTICALS US LTD-MAC2018016552			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Drug Ineffective; Eating Disorder; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Epinephrine			S	Unknown	Unk, Three Adrenaline Injections		Not Reported
	Epinephrine			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15391289	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018164784		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Interaction; Labelled Drug-Drug Interaction Medication Error; Mood Swings; Nicotine Dependence	Nicorette 4mg Lozenge			S		4 Mg, Longer Than 12 Weeks		Glaxosmithkline
	Lorazepam			S		Unk		Glaxosmithkline
	Depakote			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15391631	NON-EXPEDITED			US-TEVA-2018-US-953911			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Skin Disorder	Escitalopram	S		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15392415	EXPEDITED (15-DAY)		HO, LT, OT	JP-OXFORD PHARMACEUTICALS, LLC-2018OXF00099		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity; Shock	Lorazepam			S	Unknown			Oxford Pharmaceuticals
	Escitalopram			S	Unknown			Not Reported
	Adrenaline			S	Unknown	Unk Unk, Once		Not Reported
	Adrenaline			S	Unknown	Three Injections		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15392987	EXPEDITED (15-DAY)		OT	IT-EISAI MEDICAL RESEARCH-EC-2018-045065		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sluggishness	Pariet			S	Oral			Not Reported
	Escitalopram			S	Oral	Unspecified Quantity		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15393170	EXPEDITED (15-DAY)		HO, OT	FR-TAKEDA-2018TEU005040		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Lansoprazole			S	Oral	15 Mg, Qd		Takeda
	Prograf			S	Oral	3 Mg, Qd		Not Reported
	Atorvastatin			S	Oral	10 Mg, Qd		Not Reported
	Fungizone			S	Buccal	Unk Unk, Qd		Not Reported
	Amiodarone			S	Oral	Unk		Not Reported
	Driptane			S	Oral	15 Mg, Qd		Not Reported
	Bisoce			S	Oral	Unk Unk, Qd		Not Reported

	Lactulose	S	Oral	Unk Unk, Qd	Not Reported
	Trimebutine	S	Oral	300 Mg, Qd	Not Reported
	Trimebutine	S			Not Reported
	Repaglinide	S	Oral	2 Mg, Qd	Not Reported
	Repaglinide	S			Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15393842	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1845022US			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Titration Error; Feeling Abnormal; Multiple Sclerosis Relapse; Panic Attack	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qam		Allergan
	Heart Medication			C		Unk, Qpm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	11885504	EXPEDITED (15-DAY)		HO	PHHY2015FR171590			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Ritaline			S	Oral	100 Mg, Qd (80 Mg In Morning And 20 Mg At 4:00 Pm)		Novartis
	Ritaline			S	Oral	90 Mg, Qd (80 Mg In Morning And 20 Mg At 4:00 Pm)		Novartis
	Ritaline			S	Oral	110 Mg, Qd (80 Mg In Morning And 20 Mg At 4:00 Pm)		Novartis
	Quetiapine			S	Oral	400 Mg, Qd		Not Reported
	Quetiapine			S				Not Reported
	Quetiapine			S				Not Reported
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported
	Xeroquel			S				Not Reported

Xeroquel	S				Not Reported
Abilify	S	Oral	15 Mg, Qd		Not Reported
Abilify	S				Not Reported
Abilify	S				Not Reported
Seroplex	S	Oral	10 Mg, Qd		Not Reported
Seroplex	S				Not Reported
Seroplex	S				Not Reported
Laroxyl	S	Unknown			Not Reported
Laroxyl	S				Not Reported
Laroxyl	S				Not Reported
Lexapro	S	Oral	10 Mg, Qd		Not Reported
Lexapro	S				Not Reported
Lexapro	S				Not Reported
Lepticur	S	Unknown	15 Mg, Unk		Not Reported
Lepticur	S				Not Reported
Lepticur	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	11898605	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2016SE00976		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Xeroquel			S	Oral	400 Mg Daily		Astrazeneca
	Xeroquel			S	Oral	400 Mg Daily		Astrazeneca
	Xeroquel			S	Oral	400 Mg Daily		Astrazeneca
	Xeroquel			S	Oral	400 Mg Daily		Astrazeneca
	Xeroquel			S	Oral			Astrazeneca
	Xeroquel			S	Oral			Astrazeneca
	Xeroquel			S	Oral			Astrazeneca
	Xeroquel			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral	Lexapro, 10 Milligrams,		Not Reported

			Daily	
Seroplex	S	Oral	Lexapro, 10 Milligrams, Daily	Not Reported
Seroplex	S	Oral	Lexapro, 10 Milligrams, Daily	Not Reported
Ritaline	S	Oral	100 Mg (80 Mg In The Morning And 20 Mg At 4pm)	Not Reported
Ritaline	S	Oral	100 Mg (80 Mg In The Morning And 20 Mg At 4pm)	Not Reported
Ritaline	S	Oral	100 Mg (80 Mg In The Morning And 20 Mg At 4pm)	Not Reported
Ritaline	S	Oral		Not Reported
Ritaline	S	Oral		Not Reported
Ritaline	S	Oral		Not Reported
Ritaline	S	Oral	110 Mg Daily (80 Mg In The Morning And 20 Mg At 16:00)	Not Reported
Ritaline	S	Oral	110 Mg Daily (80 Mg In The Morning And 20 Mg At 16:00)	Not Reported
Ritaline	S	Oral	110 Mg Daily (80 Mg In The Morning And 20 Mg At 16:00)	Not Reported
Abilify	S	Oral		Not Reported
Abilify	S	Oral		Not Reported
Abilify	S	Oral		Not Reported
Laroxyl	S	Oral		Not Reported
Laroxyl	S	Oral		Not Reported
Laroxyl	S	Oral		Not Reported
Lepticur	S	Unknown	15.0mg Unknown	Not Reported

	Lepticur	S	Unknown	15.0mg Unknown		Not Reported
	Lepticur	S	Unknown	15.0mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	13289144	EXPEDITED (15-DAY)		OT	ES-APOTEX-2017AP007448		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sialoadenitis	Escitalopram			S	Unknown	Unk		Apotex
	Ondansetron			S	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown			Not Reported
	Temozolomide			C	Unknown	Unk		Not Reported
	Temozolomide			C				Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	14875047	NON-EXPEDITED			US-PFIZER INC-2018189481		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Nexium			S		Unk		Unknown
	Septra			S		Unk		Pfizer
	Estrace			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lotrel			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Niacin			S		Unk		Not Reported
	Nickel			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	14879174	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US17516			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15293440	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-041631		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Movement Disorder	Aripiprazole			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unknown		Aurobindo
	Lithium			S	Unknown	Unknown		Not Reported
	Bupropion			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15306203	NON-EXPEDITED			US-PFIZER INC-2018336323		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Ineffective; Drug Intolerance; Personality Change; Tachyphrenia	Zoloft			S	Oral	Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394378	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-046039		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysphagia; Nausea; Vertigo	Amiodarone			S	Unknown	Unk		Aurobindo
	Melperone Hydrochloride			S	Unknown	Unk		Not Reported

Cipralex /01588501/	S	Unknown	10 Milligram, Daily		Not Reported
Escitalopram	C	Unknown	Unk		Not Reported
L-Tyrosine	C	Unknown	Unk		Not Reported
Candesartan	C	Unknown	Unk		Not Reported
Metoprolol	C	Unknown	Unk		Not Reported
Mcp /00041901/	C	Unknown	Unk		Not Reported
Xarelto	C	Unknown	Unk		Not Reported
Amlodipin /00972401/	C	Unknown	Unk		Not Reported
Kalinor /00031402/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394414	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-184683		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Mirtazapine			S	Oral	Inconnue ()		Sun
	Escitalopram			S	Oral	Inconnue ()		Not Reported
	Alprazolam			S	Oral	Inconnue ()		Not Reported
	Methadone			S	Oral	Inconnue ()		Not Reported
	Havlane			S	Oral	Inconnue ()		Not Reported
	Theralene			S	Oral	Inconnue ()		Not Reported
	Tercian			S	Oral	Inconnue ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394432	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-045967		73 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Gait Disturbance	Quetiapine			S	Oral	150 Milligram, Once A Day		Aurobindo
	Lorans			S	Oral	1 Dosage Form, Once A Day		Not Reported

	Lorans	S	Oral	1 Unk	Not Reported
	Carbolithium	S	Oral	1.5 Dosage Form, Once A Day	Not Reported
	Metformin Teva	C	Unknown	Unk	Not Reported
	Omeprazen /00661201/	C	Unknown	Unk	Not Reported
	Nicetile	C	Unknown	Unk	Not Reported
	Eskim	C	Unknown	Unk	Not Reported
	Cipralex /01588501/	S	Oral	0.5 Dosage Form, Once A Day	Not Reported
	Totalip	C	Unknown	Unk	Not Reported
	Motilium /00498201/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15396400	EXPEDITED (15-DAY)		OT	ZA-MYLANLABS-2018M1068100			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Sleep Disorder	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15396455	EXPEDITED (15-DAY)		OT	DE-TORRENT-00010002		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Rash	Candesartan			C		Unk		Unknown
	Eliquis			C	Oral	Unk		Unknown
	Oestradiol			C	Oral	Unk		Unknown
	Novalgin (Metamizole Sodium)			C	Oral	Unk		Unknown
	Amlodipin			C		Unk		Unknown
	Escitalopram			S	Oral	Unk		Unknown
	Sulfasalazin			C	Oral	Unk		Unknown
	Concor			C	Oral	Unk		Unknown

	Kalinor (Potassium Chloride)	C	Oral			Unknown
	Cotrimoxazol	C	Oral	Unk		Unknown
	Vigantoletten	C	Subcutaneous	Unk		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15396523	EXPEDITED (15-DAY)		OT	ZA-MYLANLABS-2018M1068105			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15399289	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1845021US		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Unknown		Allergan
	Loxapac			S	Oral	Unk, Unknown		Not Reported
	Pantoprazole			S	Oral	Unk, Unknown (Long Cours)		Not Reported
	Bendamustine Accord			S	Intravenous (not otherwise specified)	346 Mg, Q Month		Not Reported
	Levothyrox			S	Oral	Unk Unk, Unknown		Not Reported
	Fenofibrate			S	Oral	Unk, Unknown		Not Reported
	Truxima			S	Intravenous (not otherwise specified)	720 Mg, Q Month		Not Reported
	Valaciclovir			S	Oral	Unk, Unknown		Not Reported
	Lorazepam			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15405905	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Escitalopram			S	Oral			Cipla
	Lansoprazole			C				Not Reported
	Levothyroxine 100mcg			C				Not Reported
	Rosuvasatin 20mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	14825575	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-066206		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Amlodipine			S	Oral	10 Mg, 1x/Day		Accord
	Bisoprolol			S	Oral	1.25 Mg, 1x/Day		Not Reported
	Furosemide			S	Oral			Accord
	Irbesartan			S	Oral	300 Mg, 1x/Day		Accord
	Dafalgan			S	Oral	6 Df, 1x/Day		Not Reported
	Alprazolam			S	Oral	0.75 Mg, 1x/Day		Not Reported
	Mirtazapine			S	Oral	15 Mg, 1x/Day		Not Reported
	Nefopam			S	Oral	3 Df, 1x/Day		Not Reported
	Diffu K			S	Oral	3 Df, Unk		Not Reported
	Colchicine			S	Oral	1 Df, 1x/Day		Not Reported
	Xarelto			S	Oral	1 Df, 1x/Day		Not Reported
	Pantoprazole			S	Oral	20 Mg, 1x/Day		Not Reported
	Metformine Pfizer			S	Oral	1000 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	1 Df, 1x/Day		Not Reported
	Tavanic			S	Oral	30 Mg, 1x/Day		Not Reported
	Valium			S	Oral	3 Df, 1x/Day		Not Reported
	Terbutaline			S	Respiratory (inhalation)	1 Df,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	14993667	EXPEDITED (15-DAY)		HO	FR-ABBVIE-18S-056-2382777-00		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Prescribed Underdose	Lipanthyl			S	Oral	145 Mg, Qd		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Esomeprazole			S	Oral	Unk		Not Reported
	Decapeptyl [Gonadorelin]			S	Intramuscular	1 Df, Cycle		Not Reported
	Innohep			S	Subcutaneous	1 Df, Qd		Not Reported
	Amlor			S	Oral	Unk		Not Reported
	Novonorm			S	Oral	Unk		Not Reported
	Xtandi			S	Oral	120 Mg, Qd		Not Reported
	Xtandi			S	Oral	40 Mg, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15014845	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2017-44627			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine Tablets			S	Unknown	1 Df, Qd		Aurobindo
	Enalapril+Hydrochlorothiazide			S	Unknown	1 Df, Qd		Not Reported
	Escitalopram			S	Unknown	1 Df, Qd		Aurobindo
	Escitalopram			S				Aurobindo
	Naproxen			S	Unknown	1 Df, Bid		Aurobindo
	Naproxen			S				Aurobindo
	Omeprazole			S	Unknown	1 Df, Qd		Aurobindo
	Paracetamol			S	Unknown	1 Df, Tid		Aurobindo
	Simvastatin			S	Unknown	1 Df, Qd		Aurobindo
	Simvastatin			S	Unknown	20 Mg, Unk		Aurobindo

	Topiramate	S	Unknown	1 Df, Qd	Aurobindo
	Topiramate	S	Unknown	0.5 Df, Qd	Aurobindo
	Tramadol+Paracetamol	S	Unknown	1 Df, Tid	Aurobindo
	Amitriptyline	S	Unknown	Unk, Qd	Not Reported
	Amitriptyline	S	Unknown	25 Mg, Unk	Not Reported
	Amitriptyline	S	Unknown	12.5 Mg, Qd	Not Reported
	Diazepam	S	Unknown	0.5 Df, Qd	Not Reported
	Diazepam	S	Unknown	Unk	Not Reported
	Glibenclamida	S	Unknown	1 Df, Bid	Not Reported
	Lormetazepam	S	Unknown	1 Df, Qd	Not Reported
	Tepazepam	S	Unknown	Unk, Qd (1)	Not Reported
	Metoclopramide	C	Unknown	1 Week Treatment	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15253608	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US20516			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Blood Pressure Increased; Burning Sensation; Drug Ineffective; Dry Mouth; Glossitis; Glossodynia; Hyperhidrosis; Lip Dry; Nausea; Nervousness; Pyrexia; Stress; Tongue Discomfort; Tremor; Weight Decreased; Wrong Technique In Product Usage Process	Escitalopram			S	Oral	10 Mg, Unk (Unknown Manufacturer)		Invagen
	Escitalopram			S	Oral	20 Mg, Qd		Invagen
	Escitalopram			S	Oral	30 Mg, Unk		Invagen
	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Valsartan			C	Unknown	120 Mg, Unk		Not Reported
	Irbesartan			C	Unknown	150 Mg, Qd		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported
	Vitamin B12 /00056201/			C	Unknown	Unk, Qd		Not Reported
	Vitamin C /00008001/			C	Unknown	500 Mg, Qd		Not Reported
	Vitamin D /00107901/			C	Unknown	1000 Mcg, Qd		Not Reported
	Iron			C	Unknown	325 Mg, Qd		Not Reported
	Norethindrone /00044901/			C	Unknown	0.35 Mg, Unk		Not Reported

	Nicotine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15381962	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1843321US		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Inappropriate Schedule Of Product Administration	Restasis			S	Ophthalmic	2 Gtt, Bid		Allergan
	Botox			S	Intravesical	100 Units, Single		Allergan
	Bentyl Capsules			S	Oral	10 Mg, Bid		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Macrobid			C		Unk		Not Reported
	Lipitor			C	Oral	Unk		Not Reported
	Flonase			C	Nasal	Unk		Not Reported
	Premarin			C	Topical	Unk		Not Reported
	Calcium			C	Oral	Unk		Not Reported
	Probiotic			C	Oral	Unk		Not Reported
	Multivitamin			C	Oral	Unk		Not Reported
	Fish Oil			C	Oral	Unk		Not Reported
	Losartan			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400005	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-955915		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Long Cours		Teva
	Valaciclovir			S	Oral			Teva
	Escitalopram (Oxalate D')			S	Oral			Ivax
	Fenofibrate			S	Oral			Not Reported
	Loxapac			S	Oral			Not Reported
	Bendamustine Accord			S	Intravenous (not			Not Reported

				otherwise specified)		
	Levothyrox		S	Oral		Not Reported
	Truxima		S	Intravenous (not otherwise specified)		Not Reported
	Lorazepam		S	Oral	Long Cours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400676	EXPEDITED (15-DAY)		HO	FR-ACCORD-071837		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Disturbance In Attention; Overdose	Escitalopram			S	Oral			Not Reported
	Paracetamol			S	Oral			Accord
	Codeine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15401208	NON-EXPEDITED			US-DRREDDYS-USA/USA/18/0101806			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash Pruritic; Urticaria	Metoprolol Succinate			S	Unknown			Not Reported
	Metoprolol Succinate			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported
	Zoloft			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Flonase			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Baby Aspirin			C	Unknown			Not Reported

	B Complex	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Calcium Citrate	C	Unknown	Not Reported
	Miralax	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15401452	EXPEDITED (15-DAY)		HO, LT, OT	ES-ACCORD-072481		18 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypocoagulable State; Suicide Attempt	Escitalopram			S	Oral			Not Reported
	Paracetamol			S	Oral	12gr Dia		Accord
	Exforge			S	Oral	5 Cps		Not Reported
	Ibuprofen			S	Oral	400 Mg X 7 Cps		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15401887	EXPEDITED (15-DAY)		OT	IN-TORRENT-00001854		50 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion; Metabolic Encephalopathy	Escitalopram			S		Unknown		Unknown
	Telmisartan			C		Unknown		Unknown
	Acetylsalicylic Acid			C		For Previous 2 Years		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15402280	EXPEDITED (15-DAY)		HO	FR-ACCORD-072234		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported
	Ibuprofen			S	Oral			Accord
	Havlane			S	Oral			Not Reported

	Paroxetine			S	Oral				Not Reported
	Dafalgan			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15402285	EXPEDITED (15-DAY)		HO, LT, OT	FR-ACCORD-072372		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension; Suicide Attempt	Escitalopram			S	Oral			Not Reported
	Paracetamol			S	Oral			Accord
	Propranolol/Propranolol Hydrochloride/Propranolol Phenobarbital			S	Oral			Accord
	Lamotrigine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15402524	EXPEDITED (15-DAY)		HO	FR-ACCORD-072194		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperleukocytosis; Pancreatitis; Renal Failure	Escitalopram			S	Oral			Not Reported
	Ibuprofen			S	Oral			Accord
	Paracetamol			S				Accord
	Atarax			S	Oral			Not Reported
	Coltramyl			S	Oral			Not Reported
	Alprazolam			C	Oral			Not Reported
	Cefuroxime			C	Oral			Not Reported
	Brexin			C	Oral	Drug Intoxication		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15403024	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1845053US		30 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alexithymia; Decreased Appetite; Depression; Drug Ineffective; Erectile Dysfunction; Feeling Abnormal; Genital Disorder Male; Listless; Loss Of Libido; Mood Altered; Nausea; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15404378	EXPEDITED (15-DAY)		HO	EE-BAUSCH-BL-2018-003957		46 YR	Female	EST

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Venlafaxine			S	Unknown	Increasing Dose		Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Venlafaxine			S	Unknown	Increased Dose		Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown	After One Month, The Escitalopram Dose Was Increased To 20 Mg/Day,		Not Reported
	Agomelatine			C	Unknown			Not Reported
	Agomelatine			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Bupropion			C	Unknown	Increased Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15404602	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1834971US		19 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose;	Escitalopram Oxalate Unk			S	Oral	280 Mg, Single		Allergan

Sopor	Delorazepam		S	Unknown	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	13983821	NON-EXPEDITED			US-APOTEX-2017AP009754		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Paroxetine Hydrochloride			S				Apotex
	Fluoxetine Oral Solution Usp			S				Apotex
	Sertraline Hydrochloride			S				Apotex
	Escitalopram Oxalate			S				Apotex
	Bupropion Hydrochloride			S				Apotex
	Venlafaxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	14338487	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2017-DE-838208		14 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Accidental Overdose; Disinhibition; Drug Interaction; Drug Interaction; Hospitalisation; Mental Disorder; Product Use Issue; Product Use Issue; Therapy Change	Aripiprazole			S	Unknown			Teva
	Aripiprazole			S	Oral			Teva
	Cipralex			S	Oral	5 Gtt Daily; Daily Dose: 5 Gtt Drop(S) Every Day		Not Reported
	Cipralex			S	Oral	20 Gtt Daily; Daily Dose: 20 Gtt Drop(S) Every Day		Not Reported
	Cipralex			S	Oral	10 Gtt Daily; Daily Dose: 10 Gtt Drop(S) Every Day		Not Reported
	Cipralex			S	Oral	1 Dosage Forms Daily; Daily Dose: 1 Df Dosage Form Every Day		Not Reported
	Calcium 600 Plus Vitamin D			C	Unknown			Not Reported
	Calcium 600 Plus Vitamin D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	14624261	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-		88 YR	Female	FRA

2018R1-165685

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Spironolactone			S	Oral	50 Mg, Daily		Mutual
	Seroplex 20 Mg, Comprime Pellicule Secable			S	Oral	1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	14950165	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-897008		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Quetiapine			S	Unknown			Teva
	Quetiapine			S	Oral			Teva
	Quetiapine			S				Teva
	Laroxyl			S	Unknown			Not Reported
	Laroxyl			S				Not Reported
	Laroxyl			S				Not Reported
	Xeroquel			S	Unknown			Not Reported
	Xeroquel			S	Oral	400 Milligram Daily;		Not Reported
	Xeroquel			S				Not Reported
	Seroplex			S	Oral	10 Milligram Daily; 10 Mg, Qd		Not Reported
	Seroplex			S				Not Reported
	Seroplex			S				Not Reported
	Abilify			S	Unknown			Not Reported
	Abilify			S				Not Reported
	Abilify			S	Oral			Not Reported
	Ritaline			S	Oral	100 Mg, Unk		Not Reported
	Ritaline			S	Oral			Not Reported
	Ritaline			S				Not Reported
	Methylphenidate			S	Oral	110 Milligram Daily; 110		Not Reported

					Mg, Qd	
	Methylphenidate	S				Not Reported
	Methylphenidate	S	Oral			Not Reported
	Lexapro	S	Oral			Not Reported
	Lexapro	S				Not Reported
	Lexapro	S				Not Reported
	Lepticur	S	Unknown	15 Mg, Unk		Not Reported
	Lepticur	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15114607	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2018-034015		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use; Suicide Attempt	Zopiclone Tablet			S	Oral	1tab/Dy		Not Reported
	Olanzapine Tablet			S	Unknown	15 Mg, Unk		Aurobindo
	Escitalopram			S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Not Reported
	Aripiprazole			S	Oral	10 Mg, Unk		Not Reported
	Lepticur			S	Intracardiac	Unk ()		Not Reported
	Depamide			S	Oral	300 Mg, Oral Drug Unspecified Form		Not Reported
	Seroplex			S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Not Reported
	Seroplex			S	Unknown	5 Mg, Qd		Not Reported
	Dopamide			S	Oral	Unk ()		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening.		Not Reported
	Anafranil			S	Oral	Daily Dose Increased		Not Reported
	Anafranil			S	Oral	Daily Dose Increased. Oral Drug Unspecified Form		Not Reported

	Lexapro	S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy	Not Reported
	Imovane	S	Oral	1tab/Dy, Oral Drug Unspecified Form	Not Reported
	Methyldopa	S	Oral	Unk ()	Not Reported
	Oxazepam	S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening ()	Not Reported
	Tropatepine Hydrochloride	S	Unknown	Unk ()	Not Reported
	Valpromide	S	Oral	Unk ()	Not Reported
	Clomipramine Hydrochloride	S	Oral	75 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15403730	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1000016239		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Inappropriate Schedule Of Product Administration; Melaena; Toxic Skin Eruption; Urticaria	Escitalopram Oxalate Unk			S	Oral	10 Mg, Bid		Allergan
	Previscan (Fluindione)			S	Oral	5 Mg, Qd		Not Reported
	Icaz			S	Oral	5 Mg, Qd		Not Reported
	Frisium			S	Oral	5 Mg, Qd		Not Reported
	Tadenan			S	Oral	50 Mg, Bid		Not Reported
	Diffu K			S	Oral	1 Df, Qd		Not Reported
	Fluindione			S		5 Mg, Qd		Not Reported
	Urbanyl			S	Oral	5 Mg, Qd		Not Reported
	Fucidine (Fusidic Acid)			C		Unk		Not Reported
	Kardegic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405290	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00907			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Escitalopram			S	Oral	30 Mg, Qd		Not Reported
	Diazepam			C	Oral	5 Mg, Qd		Not Reported
	Diazepam			C	Oral	10 Mg, Qd		Not Reported
	Pantozol /01263204/			C	Unknown	40 Mg, Qd		Not Reported
	Pantozol /01263204/			C	Unknown	20 Mg, Qd		Not Reported
	Prothipendyl			C	Oral	80 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405432	EXPEDITED (15-DAY)		HO, LT, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-184915			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use; Suicide Attempt	Escitalopram			S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Not Reported
	Olanzapine			S	Unknown	15 Mg, Unk		Sun
	Zopiclone			S	Oral	1tab/Dy		Not Reported
	Lepticur			S	Unknown	Unk ()		Not Reported
	Methyldopa			S	Oral	Unk ()		Not Reported
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Seroplex			S	Unknown	Unk ()		Not Reported
	Depamide			S	Oral	300 Mg, Oral Drug Unspecified Form		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening.		Not Reported
	Seroplex			S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg.		Not Reported

				1tab/Dy	
	Seroplex	S	Unknown	5 Mg, Qd	Not Reported
	Anafranil	S	Oral	Daily Dose Increased. Oral Drug Unspecified Form	Not Reported
	Zyprexa	S	Unknown	15 Mg, Unk	Not Reported
	Imovane	S	Oral	1tab/Dy, Oral Drug Unspecified Form	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405674	EXPEDITED (15-DAY)		DE, HO, OT	US-ZYDUS-026947		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anion Gap Abnormal; Atrioventricular Block; Bradycardia; Death; Delirium; Depressed Level Of Consciousness; Dystonia; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperreflexia; Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Myocardial Ischaemia; Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Ventricular Arrhythmia	Escitalopram			S	Unknown			Zydus Pharm
	Lamotrigine			S	Unknown			Zydus Pharm
	Propranolol			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15409456	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1845762US		38 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Unspecified Type; Depression; Mania; Overdose; Suicidal Ideation; Therapeutic Product Effect Incomplete	Escitalopram Oxalate - Bp			S	Unknown	50 Mg, Unk		Allergan
	Abilify Maintena			S	Unknown	400 Mg, Q Month		Not Reported
	Brintellix			S	Unknown	10 Mg, Unk		Not Reported
	Abilify/Aripiprazole			S	Oral	15 Mg, Qd		Not Reported
	Abilify/Aripiprazole			S				Not Reported
	Lithium			C	Unknown	2 X 1.5 I.E 1/2 Daily		Not Reported
	Wellbutrin			C	Unknown	300 Mg, Unk		Not Reported
	Trittico			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15429149	DIRECT		OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Uveitis	Escitalopram 10mg		Y	S	Oral	Quantity:1 Tablet(S);		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15429881	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Cyst; Respiratory Tract Neoplasm	Cosentyx Pen			S	Subcutaneous			Not Reported
	Benadryl			C				Not Reported
	Botox			C				Not Reported
	Epipen			C				Not Reported
	Flonase			C				Not Reported
	Hydroxyz Pam			C				Not Reported
	Lexapro			S				Not Reported
	Neurontin			C				Not Reported
	Singulair			C				Not Reported
	Tiazac			C				Not Reported
	Topamax			S				Not Reported
	Traxodone			C				Not Reported
	Ventolin Hfa Aer			C				Not Reported

	Zyrtec			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	14266937	EXPEDITED (15-DAY)		HO, OT	CZ-AUROBINDO-AUR-APL-2017-44385		45 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Therapeutic Product Effect Incomplete	Sertraline Film-Coated Tablet			S	Oral	Unk		Aurobindo
	Sertraline Film-Coated Tablet			S				Aurobindo
	Escitalopram			S	Oral	Unk		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	14797831	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2018-000232			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine Tablets			S	Unknown	1 Df, Qd		Aurobindo
	Enalapril+Hydrochlorothiazide			S	Unknown	1 Dosage Forms Daily; 1 Df = 20/12.5 Mg		Not Reported
	Escitalopram			S	Unknown	1 Dosage Forms Daily; 10 Mg		Aurobindo
	Naproxen			S	Unknown	1 Df, Bid		Aurobindo
	Omeprazole			S	Unknown	1 Dosage Forms Daily; 20 Mg		Aurobindo
	Paracetamol			S	Unknown	1 Df, Tid		Aurobindo
	Simvastatin			S	Unknown	1 Dosage Forms Daily; 40 Mg		Aurobindo
	Simvastatin			S	Unknown	20 Mg, Unk		Aurobindo
	Topiramate			S	Unknown	1 Dosage Forms Daily; 50 Mg		Aurobindo
	Topiramate			S	Unknown	.5 Dosage Forms Daily;		Aurobindo
	Tramadol+Paracetamol			S	Unknown	1 Df, Daily, 3 Dosage Forms Daily; 1 Df = 37.5/325 Mg		Aurobindo

Amitriptyline	S	Unknown	Qd		Not Reported
Amitriptyline	S	Unknown	12.5 Mg, Qd		Not Reported
Glibenclamida	S	Unknown	2 Dosage Forms Daily;		Not Reported
Diazepam W/Sulpiride	S		Unk, Once A Day (Qd)		Not Reported
Lormetazepam	S	Unknown	1 Df, Qd		Not Reported
Diazepam	S	Unknown	.5 Dosage Forms Daily; 5 Mg		Not Reported
Diazepam	S	Unknown	Unk ()		Not Reported
Metoclopramide	C	Unknown	1 Week Treatment ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15324164	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-156511		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Sertraline			S	Oral	100 Mg, Daily		Sun
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Lorazepam			S	Oral	2.5 Mg, Qd		Sun
	Brintellix			S	Unknown	15 Mg, Daily		Not Reported
	Brintellix			S	Unknown	10 Mg, Qd		Not Reported
	Brintellix			S	Unknown	5 Mg, Daily		Not Reported
	Duloxetine Hydrochloride			S	Unknown	60 Mg, Qd		Not Reported
	Ramipril/Idroclorotiazide			C	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported
	Ezetimibe			C	Unknown	10 Mg, Qd		Not Reported
	Lansoprazole			C	Unknown	30 Mg, Daily		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Amiodarone			C	Unknown			Not Reported
	Alprazolam			C	Unknown	2 Mg, Qd		Not Reported
	Triatec Hct			C	Unknown	15 Mg, Qd		Not Reported

	Cordarone	C	Unknown	200 Mg, Unk		Not Reported
	Coumadin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15412240	EXPEDITED (15-DAY)		HO, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-06717		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Duloxetine Hydrochloride			S	Oral	60 Mg, Qd		Alkem
	Duloxetine Hydrochloride			S	Oral	30 Mg, Qd		Alkem
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Amlodipine			C	Oral	5 Mg, Qd		Not Reported
	Aspirin			C	Oral	325 Mg, Qd		Not Reported
	Clopidogrel			C	Oral	75 Mg, Qd		Not Reported
	Gabapentin			C	Oral	300 Mg, Tid		Not Reported
	Hydrocodone/Acetaminophen			C	Oral	7.5/500 Mg Every Six Hours As Needed		Not Reported
	Olmesartan			C	Oral	20 Mg, Qd		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
	Phenytoin			C	Oral	100 Mg, Bid		Not Reported
	Ropinirole			C	Oral	2 Mg, Bedtime		Not Reported
	Simvastatin			C	Oral	20 Mg, Bedtime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15413290	EXPEDITED (15-DAY)		DE, LT, OT	US-MYLANLABS-2018M1067562		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anion Gap Abnormal; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level	Propranolol			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lamotrigine			S	Unknown			Not Reported

Of Consciousness;
Dystonia;
Electrocardiogram Qrs
Complex Prolonged;
Electrocardiogram Qt
Prolonged; Heart Injury;
Hyperreflexia;
Hyperthermia;
Hypoglycaemia;
Hypotension; Metabolic
Acidosis; Muscle Rigidity;
Myocardial Ischaemia;
Respiratory Depression;
Rhabdomyolysis; Seizure;
Tachycardia;
Thrombocytopenia;
Toxicity To Various
Agents; Tremor;
Ventricular Arrhythmia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15413430	EXPEDITED (15-DAY)		OT	CH-TAKEDA-2018TUS027783		38 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Overdose; Suicidal Ideation; Therapeutic Product Effect Incomplete	Brintellix			S	Unknown	10 Mg, Unk		Takeda
	Abilify Maintena			S	Unknown	400 Mg, Q4weeks		Not Reported
	Cipralex /01588501/			S	Unknown	50 Mg, Unk		Not Reported
	Abilify			S	Oral	15 Mg, Qd		Not Reported
	Abilify			S				Not Reported
	Lithium			C	Unknown	660 Mg, Qd		Not Reported
	Wellbutrin			C	Unknown	300 Mg, Unk		Not Reported
	Trittico			C	Unknown	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15415141	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1846006US		64 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Depas (Etizolam)			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15424098	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Treatment Failure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15430807	DIRECT	Y	HO			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Oral		10 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415621	EXPEDITED (15-DAY)		DE, HO	FR-ACCORD-072668		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pulmonary Fibrosis	Atorvastatin/Atorvastatin Calcium			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ramipril			S	Oral			Accord
	Paracetamol			S	Oral			Accord
	Pantoprazole			S	Oral			Not Reported
	Levothyrox			S	Oral	Dose 1 Unk Unit		Not Reported
	Kardegic			S	Oral			Not Reported
	Caltrate Vitamine D3			S	Oral			Not Reported
	Amiodarone			S	Oral			Not Reported

	Lorazepam	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15416251	EXPEDITED (15-DAY)		OT	US-BAXTER-2018BAX024154			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Human Herpesvirus 6 Infection	Ondansetron Injection, Usp-Single Dose			S	Unknown			Claris
	Sertraline			S	Unknown	Initial Two Trimesters		Not Reported
	Escitalopram			S	Unknown	Final Trimester		Not Reported
	Progesterone			S	Unknown	High-Dose Progesterone Administered During Twin Pregnancy		Not Reported
	Progesterone			S	Unknown	High-Dose Progesterone From 16 Weeks Of Gestation		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15416253	EXPEDITED (15-DAY)		DE, OT	US-BAXTER-2018BAX024312		4 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Human Herpesvirus 6 Infection	Ondansetron Injection, Usp-Single Dose			S	Transplacental			Claris
	Sertraline			S	Transplacental	(Mother Dose: Initial Two Trimesters)		Not Reported
	Escitalopram			S	Transplacental	(Mother Dose: Final Trimester)		Not Reported
	Progesterone			S	Transplacental	(Mother Dose: High-Dose Progesterone From 16 Weeks Of Gestation)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15165989	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2018125155		35 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Apathy; Asthenia	Lamotrigine			S	Oral	100 Mg, Qd		Glaxosmithkline
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Glaxosmithkline
	Seroquel			S	Oral	1 Df, Qd		Not Reported
	Seroquel			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15253628	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APU-2018-033894		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asphyxia; Eye Swelling; Gait Inability; Haemorrhage; Nightmare; Rhinorrhoea	Escitalopram Tablets Usp 10mg			S		10 Milligram, Two Times A Day		Aurobindo
	Escitalopram Tablets Usp 10mg			S				Aurobindo
	Escitalopram Tablets Usp 10mg			S				Aurobindo
	Stalevo /01530202/			C		Unk		Not Reported
	Nexpro /01479302/			C		Unk		Not Reported
	Amantadine			C		Unk		Not Reported
	Cobal /00056201/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15417985	EXPEDITED (15-DAY)		HO, OT	JP-MYLANLABS-2018M1068584		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardiogenic Shock; Haemodynamic Instability; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Escitalopram			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Epinephrine			S	Unknown	3 Injections		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	14687806	EXPEDITED (15-DAY)		DE	FI-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-168411			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Fibrillation	Escitalopram			S	Unknown	Unknown		Not Reported
	Ciprofloxacin			S	Oral	Unk		Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	14933313	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2018-03933		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Sinus Tachycardia; Somnolence; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram Tablets			S		Unk		Not Reported
	Escitalopram Tablets			S				Not Reported
	Lamotrigine Tablets 100 Mg			S	Oral	Unk		Lupin
	Lamotrigine Tablets 100 Mg			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15314742	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-042718		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Atorvastatin			S	Oral	10 Milligram, Daily		Not Reported
	Amiodarone			S	Oral	Inconnue		Aurobindo
	Lactulose			S	Oral	2 Dosage Form, Daily		Not Reported

Lansoprazole	S	Oral	15 Milligram, Daily		Not Reported
Trimebutine	S	Oral	300 Milligram, Daily		Not Reported
Repaglinide	S	Oral	2 Milligram, Daily		Aurobindo
Escitalopram	S	Oral	10 Milligram, Daily		Aurobindo
Prograf	S	Oral	3 Milligram, Daily		Not Reported
Bisoce	S	Oral	2 Dosage Form In Total		Not Reported
Fungizone	S	Buccal	3 Dosage Form, Daily		Not Reported
Driptane	S	Oral	3 Dosage Form, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15422477	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-185221		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Long Cours ()		Sun
	Fenofibrate			S	Oral	()		Sun
	Valaciclovir			S	Oral	()		Sun
	Loxapac			S	Oral	()		Not Reported
	Bendamustine Accord			S	Intravenous (not otherwise specified)	346 Mg, Monthly		Not Reported
	Levothyrox			S	Oral	()		Not Reported
	Truxima			S	Intravenous (not otherwise specified)	720 Mg, Daily		Not Reported
	Lorazepam			S	Oral	Long Cours ()		Not Reported
	Escitalopram (Oxalate D')			S	Oral	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15424024	EXPEDITED (15-DAY)		CA, OT	DE-GLAXOSMITHKLINE-DE2018170258		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Congenital Choroid Plexus Cyst; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Lamictal		S	Transplacental	125 Unk, Unk	Glaxosmithkline
	Quetiapine		S	Transplacental	50 [Mg/D]/ Varying Dosage Between 25 And 50 Mg/D	Glaxosmithkline
	Cipralex		S	Transplacental	20 [Mg/D]/ Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D	Not Reported
	Folic Acid		C	Transplacental	Unk	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15424507	EXPEDITED (15-DAY)		OT	GB-TORRENT-00017905		81 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Product Dispensing Error	Escitalopram			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15424877	EXPEDITED (15-DAY)		OT	DE-ROCHE-2188523		59 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Uric Acid Increased; Catatonia; Dental Caries; Disorientation; Dyskinesia; Fatigue; Infection; Muscle Spasms; Off Label Use; Product Use In Unapproved Indication; Serotonin Syndrome; Suicidal Ideation; Tremor	Rivotril			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Remergil			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15425975	EXPEDITED (15-DAY)		CA, OT	PHHY2018DE104647		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Congenital Choroid Plexus Cyst; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine	S	Transplacental	Maternal Dose: 50 Mg, Qd (Varying Dosage Between 25 And 50 Mg/D)	Novartis
	Lamictal	S	Transplacental	Maternal Dose: 125 [Mg/D]/Slowly Reduced	Not Reported
	Cipralex	S	Transplacental	Maternal Dose: 20 Mg, Qd	Not Reported
	Cipralex	S	Transplacental	Maternal Dose: 10 Mg, Qd	Not Reported
	Cipralex	S	Transplacental	Maternal Dose: 5 Mg, Qd	Not Reported
	Femibion [Minerals Nos;Vitamins Nos]	C	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15426956	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1846136US		15 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Product Use Issue	Escitalopram Oxalate - Bp			S	Oral	0.5 Mg, Qd		Allergan
	Lunesta			C	Oral			Not Reported
	Meilax			C	Oral	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15150359	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-926980		19 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram Oxalate			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15302813	EXPEDITED (15-DAY)		OT	PHHY2018IT074689		35 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Apathy; Asthenia	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Lamotrigine			S	Oral	100 Mg, Qd		Novartis

Seroquel	S	Oral	1 Df, Qd (1 Ug/Litre)		Not Reported
Seroquel	S	Oral	1 Mg/L, Qd (1 Ug/Litre)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15428390	NON-EXPEDITED			US-DRREDDYS-USA/USA/17/0094605		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Interaction; Rash	Sumatriptan Succinate Tablets			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Hydroxyurea			C	Unknown			Not Reported
	Baby Aspirin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15428402	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2018GB21372			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Product Dispensing Error	Escitalopram			S	Oral	20 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15429342	EXPEDITED (15-DAY)		CA, DE, OT	DE-TORRENT-00010310			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 [Mg/D]		Unknown
	Nepresol (Hydralazine Hydrochloride)			S	Transplacental	25 [Mg/D]		Unknown
	L-Thyroxin 50			C	Transplacental	Unknown		Unknown
	Escitalopram			S	Transplacental	20 [Mg/D]		Unknown
	Cytotec			C	Transplacental	Unknown		Unknown
	Candesartan			S	Transplacental	16 [Mg/D]		Unknown

	Paroxetin	S	Transplacental	30 [Mg/D]		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15430293	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-MYLANLABS-2018M1070983		25 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardiac Fibrillation; Suicide Attempt; Toxicity To Various Agents; Ventricular Fibrillation	Escitalopram			S	Oral	Ingestion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15430574	EXPEDITED (15-DAY)		OT	CH-TAKEDA-2018TUS020551			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Philadelphia Chromosome Positive; Symmetrical Drug-Related Intertriginous And Flexural Exanthema	Iclusig			S	Oral	45 Mg, Qd		Takeda
	Iclusig			S	Oral	15 Mg, Unk		Takeda
	Iclusig			S	Oral	30 Mg, Unk		Takeda
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15432162	EXPEDITED (15-DAY)		CA, OT	DE-ALLERGAN-1846447US		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd (0. - 40.2. Gestational Week)		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd (0. - 40.2. Gestational Week)		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd (0. - 40.2. Gestational Week)		Allergan
	Lamictal			S	Transplacental	125 Mg, Qd Slowly		Not Reported

					Reduced (0. - 12.4. Gestational Week)	
	Quetiapine		S	Transplacental	50 Mg, Qd (Varying Dosage Between 25 And 50 Mg/D/ 0. - 21.1. Gestational Week)	Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]		C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15432415	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-PRINSTON PHARMACEUTICAL INC.-2018PRN01399		25 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Completed Suicide; Distributive Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Nausea; Serotonin Syndrome; Syncope; Ventricular Fibrillation	Escitalopram			S	Oral	250 Mg, Once		Prinston Pharmaceutical
	Yew Leaves			S	Oral	50 G, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15448342	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15448955	DIRECT	Y	OT			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	14374440	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-159673		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Quetiapine			S	Oral	400 Mg, Qd		Sun
	Laroxyl			S	Unknown	Unk		Not Reported
	Laroxyl			S				Not Reported
	Laroxyl			S				Not Reported
	Methylphenidate			S	Oral	110 Mg, Qd (80 Mg In The Morning And 20 Mg At 4pm)		Not Reported
	Methylphenidate			S	Oral	100 Mg, 80 Mg In The Morning And 20 Mg At 4pm		Not Reported
	Methylphenidate			S	Unknown	80 Mg In The Morning And 20 Mg At 4pm		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported
	Xeroquel			S				Not Reported
	Xeroquel			S				Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Seroplex			S				Not Reported
	Seroplex			S				Not Reported
	Ritaline			S	Oral	100 Mg, Qd		Not Reported
	Ritaline			S	Oral	110 Mg, Qd		Not Reported
	Ritaline			S				Not Reported
	Lepticur			S	Unknown	15 Mg, Unk		Not Reported
	Lepticur			S				Not Reported
	Lepticur			S				Not Reported
	Abilify			S	Oral	15 Mg, Qd		Not Reported
	Abilify			S				Not Reported

	Abilify	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	14908811	EXPEDITED (15-DAY)		DE, OT	PHHY2018FR001671		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Ondansetron			S	Oral	Unk		Novartis
	Pantoprazole			S	Intravenous drip	Unk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Doxorubicin Hydrochloride			S	Intravenous drip	Unk		Not Reported
	Methotrexate			S	Intravenous drip	Unk		Not Reported
	Bromazepam			S	Oral	Unk		Not Reported
	Ciprofloxacine			S	Intravenous drip	Unk		Not Reported
	Furosemide			S	Oral	Unk		Not Reported
	Valaciclovir			S	Oral	Unk		Not Reported
	Prednisone			S	Intravenous drip	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Cyclophosphamide			S	Intravenous drip	Unk		Not Reported
	Zarzio			S	Subcutaneous	Unk		Not Reported
	Lidocaine			S	Buccal	Unk		Not Reported
	Fungizone			S	Buccal			Not Reported
	Exacyl			S	Intravenous drip			Not Reported
	Eprex			S	Subcutaneous			Not Reported
	Meropenem Anhydrous			S	Intravenous drip	Unk		Not Reported
	Hextril			S	Buccal			Not Reported
	Calciparine			S	Subcutaneous	Unk		Not Reported
	Bisoprolol			S	Oral	Unk		Not Reported
	Voraxaze			S	Intravenous drip	Unk		Not Reported
	Vincristine			S	Intravenous drip	Unk		Not Reported
	Bactrim			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	14944550	EXPEDITED (15-DAY)		HO	ES-ROCHE-2129818			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Co-Trimoxazole			S	Unknown			Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	Most Recent Dose On 07/Mar/2018.		Not Reported
	Obinutuzumab			S				Not Reported
	Escitalopram			S	Unknown			Not Reported
	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	Most Recent Dose On 13/Mar/2018.		Not Reported
	Bendamustine Hydrochloride			S				Not Reported
	Incb050465			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15340384	EXPEDITED (15-DAY)		DE, HO, OT	FR-ALLERGAN-1842139US		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute; Septic Shock	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Atorvastatine			S	Oral	10 Mg, Qd		Not Reported
	Repaglinide			S	Oral	2 Mg, Qd		Not Reported
	Driptane			S	Oral	3 Df, Qd		Not Reported
	Amiodarone			S	Oral	Unk		Not Reported
	Prograf			S	Oral	3 Mg, Qd		Not Reported
	Bisoce			S	Oral	2 Df In Total		Not Reported
	Trimebutine			S	Oral	300 Mg, Qd		Not Reported
	Lactulose			S	Oral	2 Df, Qd		Not Reported

Lansoprazole	S	Oral	15 Mg, Qd		Not Reported
Fungizone	S	Buccal	3 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15344298	EXPEDITED (15-DAY)		LT, OT	JP-ALLERGAN-1842132US		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Off Label Use; Pulseless Electrical Activity	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Lorazepam			S	Unknown			Not Reported
	Lorazepam			S				Not Reported
	Epinephrine			S	Unknown	3 Df, Unk; Three Adrenaline Injections		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15388773	EXPEDITED (15-DAY)		HO	DE-TORRENT-00009932		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma; Haemorrhage; Menometrorrhagia; Menorrhagia; Respiratory Tract Infection; Sleep Disorder	Atorvastatin Calcium			C	Unknown	Unknown		Unknown
	Lorazepam			C	Unknown	In Crisis Situations With Temporary Effect		Unknown
	Opipramol Hydrochloride			C	Unknown	In Crisis Situations With Temporary Effect		Unknown
	Pregabalin			C		Unknown		Unknown
	Promethazine Hydrochloride			C	Unknown	Unknown		Unknown
	Aripiprazole			S	Unknown	5 Milligram Daily;		Unknown
	Escitalopram			S	Unknown	20 Milligram Daily; In A Morning Target Dose Of 20 Mg		Unknown
	Risperidone			S	Unknown	0.5 Mg		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15432444	EXPEDITED (15-DAY)		CA, OT	DE-ASTRAZENECA-2018SF19958		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine			S	Transplacental	50 [Mg/D]/ Varying Dosage Between 25 And 50 Mg/D		Zeneca
	Cipralex			S	Transplacental	20 [Mg/D]/ Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D		Not Reported
	Lamictal			S	Transplacental	125 [Mg/D]/ Slowly Reduced		Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15432906	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-958737		39 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Feeling Abnormal; Feeling Hot; Hyperhidrosis; Paraesthesia; Urticaria	Escitalopram Teva			S	Unknown			Ivax
	Escitalopram Teva			S				Ivax
	Escitalopram Teva			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433398	EXPEDITED (15-DAY)		HO, OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-185464		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Haemolytic Anaemia	Lorazepam			S	Unknown			Sun
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433873	EXPEDITED (15-DAY)		HO	FR-NAPPMUNDI-GBR-2018-0059549		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Encephalopathy	Oxynormoro			S	Oral	5 Mg, Unk		Purdue
	Topalgic Lp			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Amiodarone			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported
	Kardegic			S	Oral	1 Df Daily, Strenght 75 Mg		Not Reported
	Tazocilline			S	Intravenous (not otherwise specified)	3 Df Daily, Strenght 4g/500mg		Not Reported
	Allopurinol			S	Oral			Not Reported
	Ciclosporine			C	Oral			Not Reported
	Mycophenolate Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15450918	DIRECT		DS, HO, LT, OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Neoplasm; Blood Cholesterol Increased; Blood Pressure Increased; Cardiac Failure Congestive; Diabetes Mellitus; Gastrooesophageal Reflux Disease; Hyperglycaemia; Hyperlipidaemia; Neoplasm Malignant; Pancreatic Disorder; Parathyroid Tumour; Red Blood Cell Count	Seroquel			S				Unknown
	Abilify			S				Not Reported
	Actos			S				Not Reported
	Metformin			S				Not Reported
	Lexapro			S				Not Reported

Decreased; Thyroid Neoplasm; Unevaluable Event; Viral Infection; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15023859	EXPEDITED (15-DAY)		DE, OT	FR-FRESENIUS KABI-FK201802935		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Ondansetron (Manufacturer Unknown)			S	Oral			Not Reported
	Ciprofloxacin (Manufacturer Unknown)			S	Intravenous drip	Unknown		Not Reported
	Meropenem (Manufacturer Unknown)			S	Intravenous drip	Unknown		Not Reported
	Pantoprazole			S	Intravenous drip	()		Not Reported
	Fungizone			S	Buccal	()		Not Reported
	Exacyl			S	Intravenous drip	()		Not Reported
	Eprex			S	Subcutaneous	()		Not Reported
	Zarzio			S	Subcutaneous	()		Not Reported
	Hextril			S	Buccal	()		Not Reported
	Furosemide			S	Oral	()		Not Reported
	Lidocaine			S	Buccal	()		Not Reported
	Escitalopram			S	Oral			Not Reported
	Calciparine			S	Subcutaneous			Not Reported
	Bisoprolol			S	Oral			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Cyclophosphamide			S	Intravenous drip			Not Reported
	Prednisone			S	Intravenous drip			Not Reported
	Vincristine			S	Intravenous drip			Not Reported
	Methotrexate			S	Intravenous drip			Not Reported
	Doxorubicin			S	Intravenous drip			Not Reported

	Voraxaze	S	Intravenous drip	Not Reported
	Valaciclovir	S	Oral	Not Reported
	Bactrim	S	Oral	Not Reported
	Bromazepam	S	Oral	Not Reported
	Tranexamic Acid	S	Intravenous drip	Not Reported
	Amphotericin B	S	Buccal	Not Reported
	Epoetin Alfa	S	Subcutaneous	Not Reported
	Sulfamethoxazole, Trimethoprim	S	Oral	Not Reported
	Heparin Calcium	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15073839	EXPEDITED (15-DAY)		HO, OT	DE-HETERO CORPORATE-HET2018DE00571		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma; Haematoma; Haemorrhage; Menometrorrhagia; Menorrhagia; Respiratory Tract Infection; Sleep Disorder	Escitalopram			S	Unknown	20 Mg, Qd (Morning)		Not Reported
	Escitalopram			S	Unknown	15 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Aripiprazole			S	Unknown	5 Mg, Qd		Hetero
	Risperidone			S	Unknown	0.5 Mg, Qd		Not Reported
	Risperidone			S				Not Reported
	Risperidone			S				Not Reported
	Pregabalin			C	Unknown	100 Mg, Qd Evening Dose Of 100 Mg		Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported
	Opipramol			C	Unknown	In Crisis Situations With Temporary Effect		Not Reported
	Lorazepam			C	Unknown	In Crisis Situations With Temporary Effect		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Promethazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15336125	EXPEDITED (15-DAY)		HO, OT	SK-ALLERGAN-1842008US		30 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Asthenia; Delusion; Depression; Disturbance In Social Behaviour; Hypomania; Mania; Mental Impairment; Product Use In Unapproved Indication; Sleep Disorder; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Pro Die		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Pro Die		Allergan
	Olanzapine			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	10 Mg, Pro Die		Not Reported
	Olanzapine			S	Oral	15 Mg, Pro Die		Not Reported
	Quetiapine			C	Unknown	500 Mg, Pro Die (Extended-Release Form)		Not Reported
	Valproate			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15410126	EXPEDITED (15-DAY)		OT	CZ-AUROBINDO-AUR-APL-2018-025570		58 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Mental Disorder; Suicide Attempt	Olanzapine			S	Unknown	Unk		Aurobindo
	Mirtazapine			S	Oral	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Aripiprazole			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	Series Of Citalopram Infusions		Not Reported
	Ziprasidone			S	Unknown	Unk		Not Reported
	Clomipramine			S	Unknown	Unk		Not Reported
	Melperone			C	Unknown	Unk		Not Reported
	Tiapride			C	Unknown	Unk		Not Reported

Haloperidol	C	Unknown	Unk		Not Reported
Propofol	C	Unknown	Unk		Not Reported
Clonazepam	C	Unknown	Unk		Not Reported
Memantine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15438691	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-047404		81 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Product Dispensing Error	Escitalopram Tablets			S	Oral	20 Milligram		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15438888	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-047566			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Titration Error; Feeling Abnormal; Multiple Sclerosis Relapse; Panic Attack	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15439323	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2018-047551		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine			S	Transplacental	50 [Mg/D]/ Varying Dosage Between 25 And 50 Mg/D ()		Aurobindo
	Lamictal			S	Transplacental	125 [Mg/D]/ Slowly Reduced ()		Not Reported
	Cipralex /01588501/			S	Transplacental	20 [Mg/D]/ Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D ()		Not Reported

	Femibion /01597501/			C	Transplacental	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15440094	EXPEDITED (15-DAY)		HO, LT, OT	CZ-APOTEX-2018AP021192		25 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Distributive Shock; Electrocardiogram Qrs Complex Prolonged; Loss Of Consciousness; Nausea; Serotonin Syndrome; Suicide Attempt; Syncope; Toxicity To Various Agents; Ventricular Dysfunction; Ventricular Fibrillation; Ventricular Hypokinesia; Ventricular Tachycardia	Escitalopram			S	Unknown	Unk, Unk		Apotex
	Escitalopram			S	Unknown	250 Mg, Unk		Apotex
	Adenosine			C	Intravenous (not otherwise specified)	12 Mg, Unk		Not Reported
	Adenosine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15440318	EXPEDITED (15-DAY)		HO, OT	PHHY2018BE102621		38 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute; Thrombotic Thrombocytopenic Purpura	Quetiapine			S	Unknown	200 Mg, Unk(1 X 1 Per Day)		Novartis
	Quetiapine			S				Novartis
	Escitalopram			S	Unknown	10 Mg, Unk(1 X 1 Per Day)		Not Reported
	Escitalopram			S				Not Reported
	Venlafaxine Almus			C	Unknown			Not Reported
	Sertraline			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15440412	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2018M1070271		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 [Mg/D]		Not Reported
	Grippe Impfstoff			C	Transplacental			Mylan
	L-Thyroxin /00068002/			C	Transplacental	100 [Mg/D]/ Initial 75µg/D, Dosage Increase To 100µg/D From Week 34+2		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15442236	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-041340		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Oxycodone Hcl			S	Unknown	Unk Unknown, Unknown		Vintage
	Hydralazine Hcl			S	Unknown	10 Mg, Unknown		Par
	Isosorbide Mononitrate Er Tablets 30mg			S	Unknown	30 Mg, Unknown		Vintage
	Lamictal			S	Unknown	25 Mg, Unknown		Not Reported
	Lexapro			S	Unknown	20 Mg, Unknown		Not Reported
	Depakote			S	Unknown	500 Mg, Unknown		Not Reported
	Coreg			S	Unknown	3.125 Mg, Unknown		Not Reported
	Lipitor			S	Unknown	10 Mg, Unknown		Not Reported
	Glimepiride			S	Unknown	4 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15448147	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2018016889			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Product Dispensing Error	Escitalopram 20mg Tablet			S	Oral	20 Milligram		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2018	15440283	EXPEDITED (15-DAY)		CA, DE	DE-HETERO CORPORATE-HET2018DE00948			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 Milligram, Qd		Hetero
	Escitalopram			S	Transplacental	220 Milligram, Qd		Hetero
	Paroxetin /00830801/			S	Transplacental	30 Milligram, Qd		Not Reported
	Candesartan			S	Transplacental	16 Milligram, Qd		Not Reported
	Nepresol /00007602/			S	Transplacental	25 [Mg/D]		Not Reported
	L-Thyroxin 50			C	Transplacental	Unk		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2018	15448427	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018016890			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Titration Error; Feeling Abnormal; Multiple Sclerosis Relapse; Panic Attack	Escitalopram			S	Unknown	10 Milligram, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2018	15448457	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2018-048218		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anion Gap; Arrhythmia; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level Of Consciousness;	Escitalopram			S	Unknown	Unk		Aurobindo
	Lamotrigine			S	Unknown	Unk		Aurobindo
	Propranolol			S	Unknown	Unk		Not Reported

Dystonia;
Electrocardiogram Qrs
Complex Prolonged;
Electrocardiogram Qt
Interval; Hyperreflexia;
Hyperthermia;
Hypoglycaemia;
Hypotension; Metabolic
Acidosis; Muscle Rigidity;
Myocardial Ischaemia;
Respiratory Depression;
Rhabdomyolysis; Seizure;
Tachycardia;
Thrombocytopenia;
Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2018	15458233	DIRECT		LT, OT			31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chills; Dizziness; Dizziness; Muscle Twitching; Nausea; Suicidal Ideation	Lexapro			S	Oral	Quantity:1 Tablet(S);		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2018	15458541	DIRECT		OT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Erectile Dysfunction; Erectile Dysfunction	Generic Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	14067504	EXPEDITED (15-DAY)		HO, OT	IT-009507513-1710ITA003705		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Product Misuse; Intentional Self-Injury; Sopor	Losartan Potassium		S	Oral	Unk (Also: "Dosage Form Unspecified")	Merck
	Delorazepam		S	Oral	Unk	Not Reported
	Escitalopram		S	Oral	Unk	Not Reported
	Haldol		S	Oral	Dosage Form: Solution	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15208475	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1837104US			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan
	Myslee			C	Transplacental	Unk		Not Reported
	Yokukansan			C	Transplacental	Unk		Not Reported
	Hirnamin			C	Transplacental	Unk		Not Reported
	Horizon			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15218202	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-113481		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Confusional State; Hyperglycaemia; Hypertension; Weight Increased	Nivolumab			S	Intravenous (not otherwise specified)	480 Mg, Unk		Bristol Myers Squibb
	Amitriptyline			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Unknown
	Prednisone			S	Unknown	Unk		Unknown
	Methylprednisolone			S	Unknown			Unknown
	Gabapentin			S	Unknown			Unknown
	Oxycodone			S	Unknown			Not Reported
	Denosumab			C	Unknown			Not Reported
	Vantas			C	Unknown			Not Reported

Baby Aspirin	C	Unknown	Not Reported
Calcium	C	Unknown	Not Reported
Compazine /00013302/	C	Unknown	Not Reported
Flomax /00889901/	C	Unknown	Not Reported
Imodium	C	Unknown	Not Reported
Lamisil	C	Unknown	Not Reported
Levsin	C	Unknown	Not Reported
Multivitamin /00097801/	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Simvastatin	C	Unknown	Not Reported
Vitamin B 12	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Benadryl /00000402/	C	Unknown	Not Reported
Famotidine	C	Unknown	Not Reported
Fiber	C	Unknown	Not Reported
Flomax /00889901/	C	Unknown	Not Reported
Iron	C	Unknown	Not Reported
Lomotil /00034001/	C	Unknown	Not Reported
Remicade	C	Unknown	Not Reported
Vitamin C /00008001/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15361423	EXPEDITED (15-DAY)		HO, OT	PHHY2018SK088555		30 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Asthenia; Delusion; Depression; Disturbance In Social Behaviour; Drug Ineffective; Hypomania; Mania; Mental Impairment;	Valproate Sodium			S	Unknown			Not Reported
	Escitalopram			S	Unknown	10 Mg, Per Day		Not Reported
	Escitalopram			S	Unknown	5 Mg, Pro Die		Not Reported
	Escitalopram			S	Unknown	5 Mg, Per Day		Not Reported

Off Label Use; Product Use In Unapproved Indication; Sleep Disorder; Weight Increased	Olanzapine	S	Oral	Unk (Dispersion)	Novartis
	Olanzapine	S	Oral	10 Mg, Pro Die	Novartis
	Olanzapine	S	Oral	15 Mg, Pro Die	Novartis
	Olanzapine	S	Unknown	15 Mg, Per Day	Novartis
	Sertraline	S	Unknown	Unk	Not Reported
	Quetiapine	C	Unknown	500 Mg, Pro Die (Extended-Release Form)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15375232	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2018161036		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Unk		Glaxosmithkline
	Levothyrox			S	Oral	Unk		Glaxosmithkline
	Escitalopram Oxalate			S	Oral	Unk		Glaxosmithkline
	Lorazepam			S	Oral	Long Cours		Glaxosmithkline
	Fenofibrate			S	Oral	Unk		Glaxosmithkline
	Valaciclovir			S	Oral	Unk		Glaxosmithkline
	Bendamustine			S	Intravenous (not otherwise specified)	346 Mg, Unk		Not Reported
	Loxapac			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	720 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449371	EXPEDITED (15-DAY)		DE	US-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00645		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Lamotrigine Tablets			S	Unknown	Unk		Sciegen
	Propranolol			S	Unknown	Unk		Not Reported

	Escitalopram			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449735	NON-EXPEDITED			US-APOTEX-2018AP016350		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Rash; Sedation; Therapy Partial Responder	Citalopram			S	Oral	30 Mg, Daily		Apotex
	Citalopram			S				Apotex
	Bupropion			S	Oral	75 Mg, Daily		Apotex
	Bupropion			S				Apotex
	Fluvoxamine			S	Oral	50 Mg, Daily		Apotex
	Fluvoxamine			S				Apotex
	Lamotrigine			S	Unknown			Apotex
	Quetiapine			S	Unknown			Apotex
	Ziprasidone			S	Oral	20 Mg, Bid		Apotex
	Lithium Carbonate			S	Unknown	750 Mg, Daily		Apotex
	Lithium Carbonate			S				Apotex
	Escitalopram			S	Oral	10 Mg, Q.H.S.		Apotex
	Escitalopram			S				Apotex
	Alprazolam			S	Oral	0.5 Mg, Daily		Apotex
	Alprazolam			S				Apotex
	Clonidine Extended Release Transdermal Film			S	Transdermal	0.1 Mg, 24 Hours		Apotex
	Clonidine Extended Release Transdermal Film			S				Apotex
	Clonidine Hydrochloride			S	Oral	Unk		Not Reported
	Clonidine Hydrochloride			S	Oral	0.3 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450127	NON-EXPEDITED			US-PFIZER INC-2018393301			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression;	Xanax			S		Unk		Pfizer

Diarrhoea	Otezla	S	Unk		Not Reported
	Lexapro	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450358	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP021295		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Hyponatraemia	Enalapril			S	Oral	20 Mg, Qd		Apotex
	Heipram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450495	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-ACCORD-072804		25 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardiac Fibrillation; Suicide Attempt; Toxicity To Various Agents; Ventricular Fibrillation	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450850	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1846628US		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sluggishness	Escitalopram Oxalate - Bp			S	Oral	Actual: Unknown Dose But Reported As Overdose		Allergan
	Pariet			S	Oral	240 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450960	EXPEDITED (15-DAY)		CA, OT	DE-LUPIN PHARMACEUTICALS INC.-2018-06664		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Congenital Choroid Plexus Cyst; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine		S	Transplacental	50 Mg/D Varying Dosage Between 25 And 50 Mg/D	Lupin
	Lamictal		S	Transplacental	125 Mg/D	Not Reported
	Lamictal		S	Transplacental	Slowly Reduced	Not Reported
	Cipralex		S	Transplacental	20 Mg, Qd	Not Reported
	Cipralex		S	Transplacental	10 Mg, Qd	Not Reported
	Cipralex		S	Transplacental	5 Mg, Qd	Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]		C	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15451046	EXPEDITED (15-DAY)		HO, LT	ES-APOTEX-2018AP021356		79 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma	Escitalopram			S	Oral	Unk		Apotex
	Enoxaparin Sodium			S	Subcutaneous	Unk		Not Reported
	Sintrom			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15451131	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2018-06701		92 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Aspirin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Omeprazole			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15451132	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS		70 YR	Male	FRA

INC.-2018-06697

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis; Gingival Bleeding; Haematuria	Escitalopram			S	Unknown	Unk		Lupin
	Aspirin			S	Unknown	Unk		Not Reported
	Fluindione			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15451336	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2018M1070807		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Pulmonary Artery Stenosis Congenital	Escitalopram			S	Transplacental	10 Mg, Qd		Not Reported
	Sertraline			C	Transplacental	150 Mg, Qd		Mylan
	Quetiapine			C	Transplacental	25 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15451934	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00391		25 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Completed Suicide; Distributive Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Nausea; Serotonin Syndrome; Syncope; Ventricular Fibrillation	Escitalopram			S	Oral	250 Mg, Once		Jubilant
	Yew Leaves			S	Oral	50 G, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15451996	EXPEDITED (15-DAY)		DE, OT	ZA-PFIZER INC-2018391836		63 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Aspavor			S		40 Mg, Unk		Pfizer
	Cipralex [Escitalopram]			S		20 Mg, Unk		Not Reported
	Clopiwin			S		75 Mg, Unk		Not Reported
	Bezafibrate Sandoz			S		400 Mg, Unk		Not Reported
	Cardicor			S		2.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15452022	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC-2018392114		79 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Aspavor			S		10 Mg, Unk		Pfizer
	Bilocor			S		5 Mg, Unk		Not Reported
	Coveram			S		5/5 Mg		Not Reported
	Ecotrin			S		81 Mg, Unk		Not Reported
	Zytomil			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15452624	NON-EXPEDITED			US-JAZZ-JPI-P-025983		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sleep-Related Event; Chest Discomfort; Chest Pain; Dizziness; Enuresis; Head Discomfort; Headache	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Phentermine			C				Not Reported
	Naltrexone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15452951	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-2018-DE-960085		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine			S	Transplacental	50 [Mg/D]/ Varying Dosage Between 25 And 50 Mg/D		Teva
	Lamictal			S	Transplacental	125 [Mg/D]/ Slowly Reduced		Not Reported
	Cipralex			S	Transplacental	20 [Mg/D]/ Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D		Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15453407	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1071500		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Indapamide			S	Oral	2.5 Mg, Qd		Not Reported
	Lactulose			C		Unk		Mylan
	Perindopril			C		Unk		Mylan
	Enoxaparin Sodium			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15453448	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1847257US		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Blood Prolactin Increased; Hirsutism	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15425189	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1069764		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine			S	Oral	100 Mg, 0-0-0-1, Tablet		Not Reported
	Cipralex 10mg /01588501/			S	Oral	10 Mg, 1-0-0-0, Tablets		Mylan
	Valproinsaeure			S	Oral	500 Mg, 0-0-0-1, Tablets		Mylan
	Levothyroxin			C	Oral	75 Mg, 1-0-0-0, Tablets		Mylan
	Torasemid			C	Oral	10 Mg, 1-0-0-0, Tablets		Mylan
	Felodipine			C	Oral	10 Mg, 1-0-0-0, Tablets		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15454083	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP021485		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Agitation; Bundle Branch Block Left; Clonus; Drug Ineffective; Drug Level Above Therapeutic; Electrocardiogram Qrs Complex Prolonged; Hyperreflexia; Hypotension; Muscle Rigidity; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Somnolence; Tachycardia; Unresponsive To Stimuli	Lamotrigine			S	Unknown	Unk		Apotex
	Escitalopram Oxalate			S	Unknown	Unk		Apotex
	Midazolam			S	Unknown	Unk		Apotex
	Propofol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15454170	EXPEDITED (15-DAY)		HO, OT	US-UNICHEM PHARMACEUTICALS (USA) INC-UCM201809-000		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress	Lamotrigine			S				Unichem

Syndrome; Agitation; Bundle Branch Block Left; Decreased Immune Responsiveness; Electrocardiogram Qrs Complex Prolonged; Endotracheal Intubation; Hypotension; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Somnolence; Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15454306	EXPEDITED (15-DAY)		OT	ES-ZYDUS-027736		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Product Substitution Error	Escitalopram			S	Oral			Zydus Pharm
	Trimetazidine			S	Oral			Not Reported
	Nifedipine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15456847	EXPEDITED (15-DAY)		DE	DE-MYLANLABS-2018M1069897		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15457177	EXPEDITED (15-DAY)		HO	ZA-ALLERGAN-1847460US			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Surgery	Escitalopram Oxalate - Bp	S	Unknown	Unk		Allergan
	Celebrex	C	Unknown	Unk		Not Reported
	Avamys	C	Unknown	Unk		Not Reported
	Xarelto	C	Unknown	Unk		Not Reported
	Synaleve	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	14568851	EXPEDITED (15-DAY)		OT	AU-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-016036			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Pulmonary Embolism; Tricuspid Valve Incompetence	Metformin Hydrochloride			S	Unknown			Bristol Myers Squibb
	Paracetamol			S	Unknown			Bristol Myers Squibb
	Clozapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Cholecalciferol			S	Unknown			Not Reported
	Fluticasone			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Paliperidone			S	Unknown			Not Reported
	Desmopressin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	14853314	EXPEDITED (15-DAY)		HO	DE-TEVA-2017-DE-830799		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Dizziness; Nausea; Stupor; Vertigo	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Escitalopram			S	Oral	15 Milligram Daily;		Ivax
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax

	Aripiprazole	S	Oral	10 Milligram Daily;	Teva
	Aripiprazole	S	Oral	5 Milligram Daily;	Teva
	Candesartan Cilexetil	S	Oral	16 Milligram Daily;	Not Reported
	L-Thyroxin	C	Oral	100 Microgram Daily;	Not Reported
	Acetylsalicylic Acid	C	Oral	100 Milligram Daily;	Not Reported
	Metformin	C	Oral		Not Reported
	Atorvastatin	C	Oral	20 Milligram Daily;	Not Reported
	Risperdal	C			Not Reported
	Amisulpride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15352229	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1842825US		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sopor	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan
	Delorazepam			S	Oral	1 Mg, Unk		Not Reported
	Losartan			S	Oral	Unk Mg, Unk		Not Reported
	Haldol			S	Oral	Unk Mg/Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15368192	EXPEDITED (15-DAY)		HO, LT, OT	FR-ALLERGAN-1843989US		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Contraindicated Product Administered; Drug Interaction; Drug Level Increased; Neuroleptic Malignant Syndrome; Product Administration Error; Wrong Dosage Formulation	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Zuclopenthixol Acetate			S	Intramuscular	100 Mg (Overdose: Medication Error)		Not Reported
	Zuclopenthixol Hydrochloride			S	Unknown	5 Mg, Qd		Not Reported
	Zuclopenthixol Hydrochloride			S	Unknown	40 Mg, Qd		Not Reported
	Zuclopenthixol Decanoate			S	Unknown	300 Mg, Q Month		Not Reported
	Cyamemazine			S	Unknown	25 To 50 Mg, Qd (Overdose)		Not Reported

	Cyamemazine	S	Unknown	50 To 100 Mg, Qd (Overdose)	Not Reported
	Cyamemazine	S	Unknown	50 Mg, Qd (Overdose)	Not Reported
	Cyamemazine	S	Unknown	750 Mg, Single (Overdose)	Not Reported
	Lercanidipine	S	Unknown	300 Mg, Single (Overdose)	Not Reported
	Lercanidipine	S	Unknown	Unk, Unknown	Not Reported
	Bisoprolol	C	Unknown	Unk Unk, Unknown	Not Reported
	Metformin	C	Unknown	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15396923	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018374843		56 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rib Fracture	Aspavor			S		20 Mg, Unk		Pfizer
	Betapam			S		5 Mg, Unk		Not Reported
	Epilizine Cr			S		500 Mg, Unk		Not Reported
	Puricos			S		300 Mg, Unk		Not Reported
	Rivotril			S		0.5 Mg, Unk		Not Reported
	Stilpane [Caffeine;Codeine Phosphate;Meprobamate;Paracetamol]			S		Unk		Not Reported
	Thiamine			S		100 Mg, Unk		Not Reported
	Wellbutrin Xl			S		300 Mg, Unk		Not Reported
	Zytomil			S		20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457785	EXPEDITED (15-DAY)		HO, LT	JP-SAPTALIS PHARMACEUTICALS LLC-2055616		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Left Ventricular Dysfunction;	Lorazepam			S	Unknown			Saptalis Pharmaceuticals

Pulseless Electrical Activity	Escitalopram	S	Unknown	Not Reported
	Adrenaline	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15458277	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-048147		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sluggishness	Escitalopram Film-Coated Tablets			S	Oral	Unspecified Quantity (1)		Aurobindo
	Pariet			S	Oral	240 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15459253	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-LUPIN PHARMACEUTICALS INC.-2018-06779		25 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardiac Fibrillation; Distributive Shock; Electrocardiogram Qrs Complex; Intentional Overdose; Left Ventricular Dysfunction; Loss Of Consciousness; Serotonin Syndrome; Toxicity To Various Agents; Ventricular Fibrillation; Ventricular Hypokinesia	Escitalopram			S	Oral	250 Mg, Unk		Lupin
	Escitalopram			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15460478	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-960135		81 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Product Dispensing Error	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15461310	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1071910			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Ejaculation Disorder; Erectile Dysfunction; Poor Quality Sleep	Escitalopram			S	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Mylan
	Kratom			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15208813	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-931209		35 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Apathy; Asthenia	Escitalopram Oxalate			S	Oral	20 Milligram Daily;		Ivax
	Seroquel 300 Mg Compresse Rivestite Con Film			S	Oral	1 Dosage Forms Daily;		Not Reported
	Lamotrigine			S	Oral	100 Milligram Daily;		Not Reported
	Seroquel 200 Mg Compresse A Rilascio Prolungato			S	Oral	1 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15209537	EXPEDITED (15-DAY)		OT	ZA-PRINSTON PHARMACEUTICAL INC.-2018PRN00442		59 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities	Escitalopram			S	Unknown	10 Mg		Prinston Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15221988	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1837299US		1 DAY	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Maternal Exposure During Breast Feeding	Escitalopram Oxalate - Bp	S	Transplacental	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp	S	Transmammary	20 Mg, Qd		Allergan
	Ethyl Loflazepate	C	Transplacental	Unk		Not Reported
	Ethyl Loflazepate	C	Transmammary	Unk		Not Reported
	Alprazolam	C	Transplacental	Unk		Not Reported
	Alprazolam	C	Transmammary	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15463182	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018016933			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sluggishness	Escitalopram Tablet			S	Oral	1 Dosage Form, Qd (Unspecified Quantity, Film-Coated Tablet)		Macleods
	Pariet			S	Oral	240 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15464014	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1847687US		66 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unknown		Allergan
	Iberogast N			S	Oral	20 Gtt, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15464267	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-MACLEODS PHARMACEUTICALS US LTD-MAC2018017069			Unknown	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardiac Fibrillation; Toxicity To	Escitalopram Oxalate			S	Oral	Unk		Macleods

Various Agents; Ventricular Fibrillation	Yew	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15464404	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1847429US		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Product Substitution Error	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Idaptan			S	Oral			Not Reported
	Nifedipino			C	Oral	20 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15465567	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1072975		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15466213	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1847678US		77 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Haematuria	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Xarelto			S	Oral	15 Mg, Qd		Not Reported
	Xarelto			S				Not Reported
	Concor			C	Oral	1 Df, Qd		Not Reported
	Adalat Crono			C	Oral	30 Mg, Qd		Not Reported
	Aldactone			C	Oral	1 Df, Qd		Not Reported
	Atorvastatin Pfizer			C	Oral	2 Df, Qd		Not Reported
	Cardio Aspirin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15466454	EXPEDITED (15-DAY)		OT	DE-009507513-1810DEU001705		59 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Uric Acid Increased; Catatonia; Dental Caries; Disorientation; Dyskinesia; Fatigue; Infection; Muscle Spasms; Off Label Use; Product Use In Unapproved Indication; Serotonin Syndrome; Suicidal Ideation; Tremor	Remergil			S	Unknown			Merck
	Cipralex			S	Unknown			Not Reported
	Rivotril			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	13288997	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20170226241			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Hypersensitivity; Epistaxis; Hepatitis Acute; Sinusitis; Sjogren'S Syndrome; Vomiting	Zyrtec		Y	S	Unknown			Not Reported
	Zyrtec			S	Unknown			Not Reported
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral	Dose Adjustment		Not Reported
	Xyrem			S	Oral	Dose Adjustment		Not Reported
	Xyrem			S	Oral	Dose Adjustment		Not Reported
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral	Nightly (Dose Strength:500mg/Ml); 5 Gm First Dose And 4 Gm		Not Reported

			Second Dose	
Xyrem	S	Oral	Nightly (Dose Strength:500mg/Ml); 5 Gm First Dose And 4 Gm Second Dose	Not Reported
Xyrem	S	Oral	Nightly (Dose Strength:500mg/Ml); 5 Gm First Dose And 4 Gm Second Dose	Not Reported
Xyrem	S	Oral	Nightly (Dose Strength:500mg/Ml)	Not Reported
Xyrem	S	Oral	Nightly (Dose Strength:500mg/Ml)	Not Reported
Xyrem	S	Oral	Nightly (Dose Strength:500mg/Ml)	Not Reported
Xyrem	S	Oral	Dose Adjustments (Nightly (Dose Strength:500mg/Ml)	Not Reported
Xyrem	S	Oral	Dose Adjustments (Nightly (Dose Strength:500mg/Ml)	Not Reported
Xyrem	S	Oral	Dose Adjustments (Nightly (Dose Strength:500mg/Ml)	Not Reported
Lexapro	S	Unknown		Not Reported
Lexapro	S	Unknown		Not Reported
Trazodone	S	Unknown		Not Reported
Flovent	S	Unknown		Not Reported
Mometasone Furoate	S	Unknown		Not Reported
Promethazine	C	Unknown		Not Reported
Flaxseed Oil	C	Unknown		Not Reported
Metformin Hcl	C	Unknown		Not Reported
Metoprolol Succinate	C	Unknown		Not Reported
Oxycodone Hcl	C	Unknown		Not Reported
Psyllium Husk	C	Unknown		Not Reported
Ritalin	C	Unknown		Not Reported

Wellbutrin	C	Unknown	Not Reported
Diclofenac Sodium Er	C	Unknown	Not Reported
Vicodin	C	Unknown	Not Reported
Provigil	C	Unknown	Not Reported
Omeprazole	C	Unknown	Not Reported
Tigan	C	Unknown	Not Reported
Clonazepam	C	Unknown	Not Reported
Zofran	C	Unknown	Not Reported
Zofran	C	Unknown	Not Reported
Epipen	C	Unknown	Not Reported
Cyclobenzaprine	C	Unknown	Not Reported
Adderall	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Fish Oil	C	Unknown	Not Reported
Fiber	C	Unknown	Not Reported
Diflunisal	C	Unknown	Not Reported
Albuterol Sulfate	C	Unknown	Not Reported
Methocarbamol	C	Unknown	Not Reported
Topiramate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	13768475	EXPEDITED (15-DAY)		OT	US-OTSUKA-2017_011716			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Cogwheel Rigidity; Depression; Ear Discomfort; Pain In Jaw; Weight Decreased	Abilify			S	Unknown	Unk		Otsuka
	Rexulti			S	Unknown	3 Mg, Qd		Otsuka
	Rexulti			S	Unknown	0.5 Mg, Qd (In The Morning For 7 Days)		Otsuka
	Rexulti			S	Unknown	1 Mg, Qd (In The Morning For 7 Days)		Otsuka

Rexulti	S	Unknown	2 Mg,Qd (In The Morning)		Otsuka
Rexulti	S	Unknown	2 Mg, Unk		Otsuka
Lexapro	S	Unknown	Unk		Not Reported
Adderall	S	Unknown	1 Df, Bid		Not Reported
Adderall	S	Unknown	(5 To10 Mg), Bid (End Of October		Not Reported
Adderall	S	Unknown	20 Mg, Bid		Not Reported
Pristiq	C	Unknown	200 Mg, Unk		Not Reported
Hydrochlorothiazide	C	Unknown	25 Mg, Unk		Not Reported
Vitamin D2	C	Unknown	Unk		Not Reported
Buspar	C	Unknown	Unk		Not Reported
Cymbalta	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported
Vitamin B12	C	Unknown	Unk		Not Reported
Latuda	C	Unknown	40 Mg, Unk		Not Reported
Latuda	C	Unknown	60 Mg, Unk		Not Reported
Latuda	C	Unknown	80 Mg, Unk (At The End Of September And In Early October)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	14270855	EXPEDITED (15-DAY)		OT	US-OTSUKA-2017_015562			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Cogwheel Rigidity; Depression; Weight Decreased	Abilify			S	Unknown	Unk		Otsuka
	Rexulti			S	Unknown	0.5 Mg, Qd		Otsuka
	Rexulti			S	Unknown	1 Mg, Qd		Otsuka
	Rexulti			S	Unknown	2 Mg, Qd		Otsuka
	Rexulti			S	Unknown	3 Mg, Qd		Otsuka
	Rexulti			S	Unknown	2 Mg, Qd		Otsuka

Lexapro	S	Unknown	Unk		Not Reported
Cymbalta	S	Unknown	Unk		Not Reported
Trazodone	S	Unknown	Unk		Not Reported
Vitamin B12	S	Unknown	Unk		Not Reported
Pristiq	S	Unknown	200 Mg, Unk		Not Reported
Latuda	S	Unknown	40 Mg, Unk		Not Reported
Latuda	S	Unknown	60 Mg, Unk		Not Reported
Latuda	S	Unknown	80 Mg, Unk		Not Reported
Adderall	S	Unknown	1 Df, Bid		Not Reported
Adderall	S	Unknown	20 Mg, Bid		Not Reported
Buspar	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	14619097	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-012362		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Lower Gastrointestinal Haemorrhage	Escitalopram			S	Unknown	Unk		Aurobindo
	Xarelto			S	Unknown	20 Mg, Unk		Not Reported
	Zofenil			C	Unknown	Unk		Not Reported
	Carbidopa And Levodopa			C	Unknown	Unk		Not Reported
	Androtardyl			C	Unknown	Unk		Not Reported
	Amoxicillin Sodium And Potassium Clavulanate			C	Unknown	Unk		Not Reported
	Requip			C	Unknown	Unk		Not Reported
	Carbidopa, Levodopa			C		Unk ()		Not Reported
	Amoxicillin Sodium, Potassium Clavulanate			C		Unk ()		Not Reported
	Xarelto 20 Mg			S		20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15118608	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS		39 YR	Female	ITA

INC.-2018-04196

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clitoral Engorgement	Venlafaxine			S	Unknown	75 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	Unk		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15468913	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2013000750			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Epistaxis; Hepatitis Acute; Sinusitis; Sjogren'S Syndrome; Vomiting	Zyrtec			S		Unk		Glaxosmithkline
	Xyrem			S	Oral	Nightly (Dose Strength:500mg/Ml)		Not Reported
	Xyrem			S	Oral	Dose Adjustments (Nightly (Dose Strength:500mg/Ml)		Not Reported
	Xyrem			S	Oral	Nightly (Dose Strength:500mg/Ml); 5 Gm First Dose And 4 Gm Second Dose		Not Reported
	Xyrem			S	Oral	2.25 G, Bid		Not Reported
	Xyrem			S	Oral	Dose Adjustment		Not Reported
	Xyrem			S	Oral	4.5 G, Bid		Not Reported
	Mometasone Furoate			S		Unk		Not Reported
	Fluticasone Propionate			S		Unk		Glaxosmithkline
	Trazodone Hydrochloride			S		Unk		Not Reported
	Lexapro (Escitalopram Oxalate)			S		Unk		Not Reported
	Adderall			C		Unk		Not Reported
	Cyclobenzaprine			C		Unk		Not Reported

Epi Pen	C			Not Reported
Flaxseed Oil	C		Unk	Not Reported
Methocarbamol	C		Unk	Not Reported
Metoprolol Succinate	C		Unk	Not Reported
Oxycodone Hydrochloride	C		Unk	Not Reported
Promethazine Hydrochloride	C		Unk	Not Reported
Psyllium Husk	C		Unk	Not Reported
Topiramate	C		Unk	Not Reported
Ritalin	C		Unk	Not Reported
Wellbutrin	C		Unk	Not Reported
Diclofenac Sodium Er	C		Unk	Not Reported
Vicodin	C		Unk	Not Reported
Provigil (Modafinil)	C		Unk	Not Reported
Omeprazole	C		Unk	Not Reported
Tigan	C		Unk	Not Reported
Clonazepam	C		Unk	Not Reported
Zofran (Ondansetron Hydrochloride)	C		Unk	Not Reported
Metformin Hydrochloride	C		Unk	Not Reported
Ondansetron	C		Unk	Not Reported
Plantago Ovata	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15468967	EXPEDITED (15-DAY)		HO	FR-LANNETT COMPANY, INC.-FR-2018LAN001177		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Increased; Neuroleptic Malignant Syndrome; Potentiating Drug Interaction	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Lannett
	Zuclopenthixol Decanoate			S	Unknown	300 Mg, Monthly		Not Reported
	Zuclopenthixol Acetate			S	Intramuscular	100 Mg, Unk		Not Reported
	Zuclopenthixol Dihydrochloride			S	Unknown	5 To 40 Mg, Qd, Titrated Over Two Weeks		Not Reported

	Cyamemazine	S	Unknown	50 Mg, Qd	Not Reported
	Cyamemazine	S	Unknown	25 Mg To 75 Mg, Qd	Not Reported
	Cyamemazine	S	Unknown	50 Mg To 100 Mg, Qd	Not Reported
	Lercanidipine	C		300 Mg, Unk	Not Reported
	Bisoprolol	C		Unk	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Metformin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15469437	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1847692US		59 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Uric Acid Increased; Catatonia; Dental Caries; Disorientation; Dyskinesia; Fatigue; Infection; Muscle Spasms; Off Label Use; Off Label Use; Overdose; Serotonin Syndrome; Suicidal Ideation; Tremor	Escitalopram Oxalate - Bp			S	Unknown	40 Mg, Unknown		Allergan
	Rivotril			S	Unknown	Unk Unk, Unknown		Not Reported
	Seroquel			S	Unknown	800 Mg, Unknown		Not Reported
	Remergil			S	Unknown	60 Mg, Unknown		Not Reported
	Zoloft			S	Unknown	Unk, Unknown		Not Reported
	Allopurinol			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15469459	EXPEDITED (15-DAY)		HO	ZA-JNJFOC-20180936849			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Surgery	Xarelto			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Avamys			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Stilpane (Acetaminophen/Caffeine/Codeine/Phosphate/Meprobamate)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15469743	EXPEDITED (15-DAY)		OT	DE-ASTRAZENECA-2018SF27600		59 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Uric Acid Increased; Catatonia; Dental Caries; Disorientation; Dyskinesia; Fatigue; Infection; Muscle Spasms; Off Label Use; Product Use In Unapproved Indication; Serotonin Syndrome; Suicidal Ideation; Tremor	Seroquel			S	Oral	800.0mg Unknown		Zeneca
	Cipralex			S	Unknown	40.0mg Unknown		Not Reported
	Rivotril			S	Unknown			Not Reported
	Remergil			S	Unknown	60.0mg Unknown		Not Reported
	Zoloft			S	Unknown			Not Reported
	Allopurinol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15470085	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1073454		42 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S	Oral	7 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2018	15337438	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018016441			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Intentional Product Misuse; Intentional Self-Injury; Sopor	Escitalopram Oxalate			S	Oral	20 Milligram, Coated Tablet		Macleods
	Losartan Potassium			S	Oral	Misuse, Unspecified		Macleods
	Haldol			S	Oral	Solution, Misuse		Not Reported
	Delorazepam			S	Oral	1 Milligram, Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2018	15471114	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2018-047950		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Product Substitution Error	Escitalopram			S	Oral	20 Milligram,		Aurobindo
	Idaptan			S	Oral	20 Milligram		Not Reported
	Nifedipine			C	Oral	20 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	8743310	EXPEDITED (15-DAY)		HO	FR-FRI-1000038112		89 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Lasilix			S	Oral	20 Mg, Qd		Not Reported
	Avodart			C		Unk		Not Reported
	Amiodarone Hydrochloride			C		Unk		Not Reported
	Discotrine			C		Unk		Not Reported
	Triatec (Ramipril)			C	Oral	Unk		Not Reported
	Lantus			C	Subcutaneous	Unk		Not Reported
	Eupressyl			C		Unk		Not Reported
	Amlor			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	13398754	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1712671US		29 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphocyte Count Decreased; Thrombocytopenia	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan
	Clozaril			S	Oral	400 Mg, Qd		Not Reported

	Clozaril	S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	14084674	EXPEDITED (15-DAY)		HO, OT	IT-TEVA-815671ACC		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sopor	Losartan			S	Oral			Not Reported
	Delorazepam			S	Oral			Not Reported
	Haldol Janssen Cil			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15276892	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1839422US		44 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Malaise; Tremor; Vertigo	Escitalopram Oxalate Unk			S	Oral	15 Mg, Qd		Allergan
	Arlevertan			S	Oral	3 Df, Qd		Not Reported
	Resilient			S	Oral	1 Df, Qd		Not Reported
	Deniban			S	Oral	25 Mg, Qd		Not Reported
	Valium			S	Oral	16 Gtt, Qd		Not Reported
	Leponex			S	Oral	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15426140	EXPEDITED (15-DAY)		DE, LT, OT	US-TEVA-2018-US-957625		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anion Gap Abnormal; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level Of Consciousness; Dystonia;	Lamotrigine			S	Unknown			Teva
	Escitalopram			S	Unknown			Ivax
	Propranolol			S	Unknown			Not Reported

Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Heart Injury; Hyperreflexia; Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Muscle Rigidity; Myocardial Ischaemia; Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Tremor; Ventricular Arrhythmia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15472091	EXPEDITED (15-DAY)		DE, OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-186243		47 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Mirtazapin			S	Unknown	30 Mg, Daily		Sun
	Cipralex			S	Oral	10 Mg, Daily		Not Reported
	Olynth			C	Unknown	1 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15472340	EXPEDITED (15-DAY)		HO, OT	QA-ACCORD-073042		49 YR	Male	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Liver Injury	Oxybutynin/Oxybutynin Hydrochloride			S	Oral			Accord
	Escitalopram			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15473436	NON-EXPEDITED			US-TEVA-2018-US-960594			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Photopsia; Tremor	Escittab [Escitalopram Oxalate]			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15474690	EXPEDITED (15-DAY)		DE, OT	AU-COLLEGIUM PHARMACEUTICAL, INC.-AU-2018COL014266			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Confusional State; Death; Delirium; Discomfort; Dizziness; Drug Ineffective; Drug Interaction; Gastrointestinal Disorder; Hallucination; Malaise; Mental Disorder; Nausea; Nervous System Disorder; Serotonin Syndrome; Tremor; Vomiting	Tapentadol Extended Release			S		Unk		Collegium Pharmaceutical
	Tramal			S		Unk		Not Reported
	Duloxetine			S		Unk		Not Reported
	Venlafaxine			S		Unk		Not Reported
	Desvenlafaxine			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported
	Sertraline			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15475168	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1073912		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
	Plegridy			S	Subcutaneous			Mylan
	Atacand			S	Oral	1 Df, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15475607	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1000001118		29 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Gastric Haemorrhage; Hypoxia; Intentional Overdose; Seizure; Suicide Attempt	Escitalopram Oxalate Unk			S	Unknown	10		Allergan
	Salbutamol			S		Unk		Not Reported
	Trimipramin Beta			S	Unknown	100		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15475610	EXPEDITED (15-DAY)		HO	SI-ALLERGAN-1848208US		60 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Status Epilepticus	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Ciprobay			S	Oral	1000 Mg, Qd		Not Reported
	Ceftazidim Mylan			S	Intravenous (not otherwise specified)	1 G, Single		Not Reported
	Mirzaten			S	Oral	30 Mg, Qd		Not Reported
	Warfarin			C	Unknown	Unk		Not Reported
	Apaurin			C	Unknown	5 Mg, Unk		Not Reported
	Lanzul			C	Unknown	30 Mg, Qam		Not Reported
	Dulcolax			C	Unknown	1 Df, Unk		Not Reported
	Spiriva Respimat			C	Respiratory (inhalation)	2.5 Mg, Qam		Not Reported
	Lekadol			C	Oral	500 Mg, Tid		Not Reported
	Analgin (Metamizole Sodium Monohydrate)			C	Unknown	500 Mg, Unk		Not Reported
	Clexane			C	Unknown	0.6 Mg, Q12h		Not Reported
	Omnic Ocas			C	Unknown	0.4 Mg, Qam		Not Reported

Folacin [Folic Acid]	C	Unknown	5 Mg, Qam		Not Reported
Kreon	C	Unknown	3 Df, Qd		Not Reported
Sorbisterit	C	Unknown	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15499699	DIRECT	Y	OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Ocular Discomfort; Product Quality Issue; Vibratory Sense Increased	Escitalopram			S	Oral		2 WEEK	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15055180	EXPEDITED (15-DAY)		DE, HO	GB-ALLERGAN-1831849US		88 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer Haemorrhage; Gastrointestinal Pain	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Acetylsalicylic Acid			S	Oral	75 Mg, Qd		Not Reported
	Dihydrocodeine			C	Oral	120 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15455292	EXPEDITED (15-DAY)		HO	PHHY2018LT073001		62 YR	Male	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Off Label Use; Therapeutic Product Effect Incomplete	Carbamazepine			S	Unknown	200 Mg, Tid		Not Reported
	Carbamazepine			S	Unknown	600 Mg, Qd		Not Reported
	Omeprazole			S	Unknown	20 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	30 Mg, Bid		Novartis
	Prednisolone			S	Unknown	60 Mg, Qd		Novartis
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported

	Pyridostigmine	C	Unknown	60 Mg, Qid		Not Reported
	Fraxiparin	C	Unknown	0.3 Ml, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15461106	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2018M1072117		16 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Pressure Increased; Diarrhoea; Diarrhoea Haemorrhagic; Haematochezia; Heart Rate Increased; Hypertension; Tachycardia	Escitalopram			S		20 Mg, Qd (1x Daily 2 Tablets)		Not Reported
	Quetiapine			S		12.5 Mg, Qd (For The Night A Half Tablet)		Not Reported
	Quetiapine			S				Not Reported
	Cholecalciferol			C		800 Iu, Qd (1 X 1)		Mylan
	Melatonine			C		1 Mg, Qd (1 Mg 1 X 1)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15476736	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-028961		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Agitation; Bundle Branch Block Left; Clonus; Drug Level Above Therapeutic; Electrocardiogram Qrs Complex Prolonged; Hyperreflexia; Hypotension; Muscle Rigidity; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Sinus Tachycardia; Somnolence; Unresponsive To Stimuli	Escitalopram			S	Oral			Zydus Pharm
	Lamotrigine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15478180	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00010908			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Lamictal			S	Transplacental	125 [Mg/D]/ Slowly Reduced		Unknown
	Cipralex			S	Transplacental	20 [Mg/D]/ Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D		Unknown
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental	Unknown		Unknown
	Quetiapine			S	Transplacental	50 [Mg/D]/ Varying Dosage Between 25 And 50 Mg/D		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15478715	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1073873			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anxiety; Depression; Dizziness; Feeling Abnormal; Headache; Insomnia; Mood Altered; Nausea; Panic Attack; Suicidal Ideation	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15479865	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2018M1072811		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Drug Ineffective;	Escitalopram			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome	Sodium Chloride		S	Other	Infusion	Not Reported
	Sodium Chloride		S	Other	Increase In The Infusion Rate	Not Reported
	Sodium Chloride		S	Unknown	An Additional 100 Meq Of Sodium Bicarbonate Was Also Given	Not Reported
	Sodium Chloride		S	Other	Repeated Boluses Of Bicarbonate	Not Reported
	Propofol		C	Unknown		Mylan
	Midazolam		C	Unknown		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15504463	DIRECT		DS			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chest Pain; Depersonalisation/Dereali sation Disorder; Depression; Eye Pain; Fear; Heart Rate Increased; Muscle Spasms; Muscle Twitching; Obsessive-Compulsive Disorder; Testicular Pain; Withdrawal Syndrome	Lexapro 20mg			S	Oral	Quantity:1 Capsule(S);	9 YR	Not Reported
	Multi Vitamins			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	14701337	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1816549US		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cyst	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15190972	EXPEDITED (15-DAY)		OT	IT-ELI_LILLY_AND_COMPANY-IT201807009722		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Olanzapine			S	Oral	20 Mg, Unknown		Not Reported
	Tavor /00273201/			S	Oral	Unk Unk, Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	50 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15227242	EXPEDITED (15-DAY)			ZA-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00299		59 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities	Escitalopram			S	Unknown	10 Mg		Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15243183	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1838606US		27 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Suicide Attempt	Escitalopram Oxalate Unk			S	Oral	15 Ml In Total		Allergan
	Delorazepam			S	Oral	10 Ml In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15481484	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-962622		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Product Substitution Error	Escitalopram			S	Oral			Ivax
	Idaptan			S	Oral			Not Reported

Nifedipino (3253a)		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15481976	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004645		22 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Apparent Death; Crying; Feeling Of Relaxation; Hypertension; Insomnia; Obsessive Thoughts; Panic Reaction; Wrong Technique In Product Usage Process	Espran			S	Oral	One Tablet Daily		Torrent
	Rivotril			C		0.25 Mg To 1.5 Mg Once Or Twice A Week		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15485441	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848657US		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15485673	EXPEDITED (15-DAY)		HO	JP-ANIPHARMA-2018-JP-000162		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Lorazepam (Non-Specific)			S				Ani
	Escitalopram			S				Not Reported
	Adrenaline			S	Parenteral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15487161	DIRECT		HO, OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Emotional Distress; Intentional Self-Injury; Suicidal Ideation	Escitalopram	Y		S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	14372786	EXPEDITED (15-DAY)		HO	AT-TEVA-2018-AT-842917		19 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Parkinsonism	Aripiprazole			S	Oral			Teva
	Aripiprazole			S	Oral			Teva
	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Cipralex			S	Oral	5 Milligram Daily;		Not Reported
	Cipralex			S	Oral	15 Milligram Daily;		Not Reported
	Cipralex			S	Oral	10 Milligram Daily;		Not Reported
	Cipralex			S	Oral			Not Reported
	Abilify			S	Oral	5 Milligram Daily;		Not Reported
	Abilify			S	Oral	2.5 Milligram Daily;		Not Reported
	Atarax			C	Oral	25 Milligram Daily;		Not Reported
	Atarax			C	Oral	25 Milligram Daily;		Not Reported
	Methylprednisolone			C	Unknown	Unk		Not Reported
	Probiotics			C	Unknown	Unk, Qd		Not Reported
	Zoldem			C	Oral	10 Milligram Daily; Unk		Not Reported
	Zoldem			C	Oral	5 Milligram Daily;		Not Reported
	Atarax			C	Oral	25 Mg Qd		Not Reported
	Sertraline Hydrochloride			C	Unknown	Unk		Not Reported
	Seroquel			C	Unknown	Unk		Not Reported

Seroquel	C				Not Reported
Hova	C	Unknown	Unk		Not Reported
Temesta (Lorazepam)	C	Unknown	1-2 Mg, Qd		Not Reported
Mexalen	C	Unknown	Unk		Not Reported
Mexalen	C	Oral	500 Milligram Daily;		Not Reported
Aerius (Desloratadine)	C	Unknown	Unk		Not Reported
Praxiten	C	Unknown	Unk		Not Reported
Praxiten	C	Oral	15 Milligram Daily;		Not Reported
Praxiten	C	Oral	7.5 Milligram Daily;		Not Reported
Mexalen	C	Oral	500 Milligram Daily;		Not Reported
Mexalen	C	Oral	500 Milligram Daily;		Not Reported
Atarax	C	Oral	25-50 Mg Qd		Not Reported
Atarax	C	Oral	50 Milligram Daily;		Not Reported
Praxiten	C	Oral	15 Milligram Daily;		Not Reported
Atarax	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15486084	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2018SF29831		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Confusional State; Dermatitis Acneiform; Hyponatraemia; Liver Injury; Nasal Obstruction; Throat Irritation	Tagrisso			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Kardegic			C	Oral			Not Reported
	Lexomil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15486508	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-058			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hypersensitivity; Rash Pruritic	Escitalopram	S	Unknown		Hikma
	Escitalopram	S			Hikma
	Bupropion	S	Unknown		Not Reported
	Bupropion	S	Unknown		Not Reported
	Bupropion	S	Unknown		Not Reported
	Zoloft	S	Unknown		Not Reported
	Metoprolol Er	C	Unknown		Not Reported
	Metoprolol Er	C	Unknown		Not Reported
	Benadryl	C	Unknown		Not Reported
	Benadryl	C	Unknown		Not Reported
	B Complex	C	Unknown		Not Reported
	Loratadine	C	Unknown		Not Reported
	Flonase	C	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Levothyroxine	C	Unknown		Not Reported
	Vitamin D2	C	Unknown		Not Reported
	Fish Oil	C	Unknown		Not Reported
	Calcium Citrate	C	Unknown		Not Reported
	Baby Aspirin	C	Unknown		Not Reported
	Walmart Miralax	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15487603	NON-EXPEDITED			US-TEVA-2018-US-961224		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15488901	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2018404852		59 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Uric Acid Increased; Catatonia; Dental Caries; Disorientation; Dyskinesia; Fatigue; Infection; Muscle Spasms; Off Label Use; Product Use In Unapproved Indication; Serotonin Syndrome; Suicidal Ideation; Tremor	Zoloft			S	Unknown	Unk		Pfizer
	Cipralex [Escitalopram]			S	Unknown	40 Mg		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Seroquel			S	Unknown	800 Mg		Not Reported
	Remergil			S	Unknown	60 Mg		Not Reported
	Allopurinol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15489450	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848666US		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dermatitis Acneiform; Hyponatraemia; Liver Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Tagrisso			S	Oral	80 Mg, Qd		Not Reported
	Kardegic			C	Oral	75 Mg, Qd		Not Reported
	Lexomil			C	Oral	0.25 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15489482	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848716US		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Haematoma Muscle	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd (Reported As 1-0-0)		Allergan
	Clopidogrel			S	Oral	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15490382	EXPEDITED (15-DAY)		HO	PHHY2018FR120449		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall	Exforge	S	Oral	0.5 Df, Unk (0.5 Mg/L)	Novartis
	Atenolol	S	Oral	25 Mg, Unk	Not Reported
	Tramadol	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	1 Df, Unk (1 Mg/L)	Not Reported
	Hemigoxine Nativelle	S	Oral	1 Df, Unk (1 Mg/L)	Not Reported
	Macrogol Stearate	C	Oral	2 Df, Unk (2 Mg/L)	Not Reported
	Caltrate	C	Oral	1 Df, Unk (1 Mg/L)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15490691	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848725US		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram Oxalate - Bp			S	Oral	1 Df, Unk		Allergan
	Atenolol			S	Oral	25 Mg, Unk		Not Reported
	Exforge			S	Oral	0.5 Df, Unk		Not Reported
	Hemigoxine Nativelle			S	Oral	1 Df, Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Macrogol Stearate			C	Oral	2 Df, Unk		Not Reported
	Caltrate			C	Oral	1 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15490692	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848706US		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fall	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Forlax			C	Oral	Unk		Not Reported
	Lantus			C	Subcutaneous	14 Iu, Qd		Not Reported
	Previscan (Fluindione)			C	Unknown	0.5 Df, Qd		Not Reported
	Metformine			C	Oral	1000 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15027389	EXPEDITED (15-DAY)		DE, HO, OT	GB-AUROBINDO-AUR-APL-2018-031621		88 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer Haemorrhage; Gastrointestinal Pain	Escitalopram Tablets			S	Oral	20 Milligram, Daily		Aurobindo
	Acetylsalicylic Acid			S	Oral	75 Milligram, Daily		Not Reported
	Dihydrocodeine			C	Oral	120 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15484792	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1848487US		93 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate Unk			S	Unknown	Unk, Unknown		Allergan
	Aspirin			C	Unknown	Unk, Unknown		Not Reported
	Metoprolol			C	Unknown	Unk, Unknown		Not Reported
	Amlodipine			C	Unknown	Unk, Unknown		Not Reported
	Atorvastatin			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15492126	EXPEDITED (15-DAY)		CA, OT	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2018-08264			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine Fumarate			S	Transplacental	Unknown		Alkem
	Lamotrigine			S	Transplacental	Unknown		Alkem
	Cipralex			S	Transplacental	Unknown		Not Reported
	Femibion [Minerals Nos;Vitamins Nos]			S	Transplacental	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15494009	EXPEDITED (15-DAY)		DE, OT	US-LANNETT COMPANY, INC.-US-2018LAN001218		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anion Gap; Arrhythmia; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level Of Consciousness; Dystonia; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperreflexia; Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Muscle Rigidity; Myocardial Ischaemia; Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Tremor	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Propranolol			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15494203	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018408189		62 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer; Intestinal Obstruction	Avigra			S		100 Mg, Unk		Pfizer
	Bilocor			S		5 Mg, Unk		Not Reported
	Zytomil			S		20 Mg, Unk		Not Reported
	Ecotrin			S		81 Mg, Unk		Not Reported

	Topzole	S	40 Mg, Unk	Not Reported
	Dormonoct	S	2 Mg, Unk	Not Reported
	Rivotril	S	0.5 Mg, Unk	Not Reported
	Adco Mirteron	S	15 Mg, Unk	Not Reported
	Aspen Trazodone	S	50 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2018	15034273	EXPEDITED (15-DAY)		DE, HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2018014295			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer; Gastric Ulcer Haemorrhage; Gastrointestinal Haemorrhage; Gastrointestinal Pain	Escitalopram			S	Oral	20 Milligram, Qd		Macleods
	Aspirin			S	Oral	75 Milligram, Qd		Not Reported
	Dihydrocodeine			C	Oral	120 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2018	15410137	EXPEDITED (15-DAY)		HO, LT	BE-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-12-00		85 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Computerised Tomogram Thorax Abnormal; Drug Interaction; Haemoptysis; Hepatojugular Reflux; Hypoventilation; Lymphadenopathy; Pleural Effusion; Pulmonary Alveolar Haemorrhage	Pradaxa			S	Oral			Boehringer Ingelheim
	Cordarone			S	Oral			Not Reported
	Asaflow			S	Oral			Not Reported
	Clexane			S	Subcutaneous			Not Reported
	Sipralexa			S	Oral			Not Reported
	Forlax			C	Oral			Not Reported
	Prolopa Hbs			C	Oral			Not Reported
	Prolopa			C	Oral			Not Reported
	D-Vital Forte			C	Oral			Not Reported

	Nexiam	C	Oral		Not Reported
	Crestor	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2018	15495394	EXPEDITED (15-DAY)		HO	FR-ZYDUS-021334		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Lactulose/Paraffin/Liquid			S	Oral	Oral Jelly In Jar		Not Reported
	Amlodipine			S	Oral			Zydus Pharm
	Domperidone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Carbonate De Calcium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2018	15495398	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018017430			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Gastric Haemorrhage; Hypoxia; Intentional Overdose; Seizure; Suicide Attempt	Tramadol Hydrochloride			S	Unknown	Unk		Macleods
	Metoprolol			S	Unknown	Unk		Not Reported
	Cipralex			S	Unknown	10		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Trimipramine			S	Unknown	100		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	14321202	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT-00007428		34 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Rash	Opipramol			C	Oral			Unknown
	Pantoprazole			C	Oral			Unknown

	Ramipril	C	Oral		Unknown
	Escitalopram	S	Oral		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15408963	EXPEDITED (15-DAY)		HO	BE-MYLANLABS-2018M1068711		25 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hospitalisation; Lactation Disorder; Live Birth; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Therapeutic Product Effective For Unapproved Indication	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Aripiprazole			S	Unknown	Unk		Not Reported
	Aripiprazole			S	Oral	20 Mg, Unk		Not Reported
	Abilify			S	Oral	20 Mg, Unk		Mylan
	Abilify			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15497515	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-050124		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Liver Disorder	Escitalopram			S	Oral	10 Milligram		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15497667	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-050229		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Atenolol			S	Oral	25 Milligram		Aurobindo
	Tramadol			S	Oral	Unk (Inconnue)		Aurobindo
	Seroplex			S	Oral	1 Dosage Form		Not Reported
	Exforge			S	Oral	0.5 Dosage Form		Not Reported
	Hemigoxine Nativelle			S	Oral	1 Dosage Form		Not Reported

Macrogol Stearate	C	Oral	2 Dosage Form		Not Reported
Caltrate /00944201/	C	Oral	1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15498390	EXPEDITED (15-DAY)		HO, OT	IN-ACCORD-073329		50 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradykinesia; Encephalopathy; Hyperkalaemia; Hypertension; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Osmotic Demyelination Syndrome	Escitalopram			S				Not Reported
	Telmisartan			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15498948	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848906US		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Liver Disorder	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15498955	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1849060US		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Theralene			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15500079	EXPEDITED (15-DAY)		DE, OT	US-TARO PHARMACEUTICALS USA.,INC-		33 YR	Female	USA

2018SUN00518

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anion Gap Increased; Atrioventricular Block; Bradycardia; Delirium; Depressed Level Of Consciousness; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Extrapyramidal Disorder; Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Movement Disorder; Myocardial Ischaemia; Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Ventricular Arrhythmia	Lamotrigine			S	Unknown	Unk		Taro
	Escitalopram			S	Unknown	Unk		Taro
	Propranolol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15523067	DIRECT		OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Frustration Tolerance Decreased; Insomnia; Migraine; Panic Attack; Product Substitution Issue; Quality Of Life Decreased	Escitalopram 20 Mg.	Y		S	Oral	Quantity:6 Df Dosage Form;		Cipla
	Escitalopram 20 Mg.	Y		S				Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15524253	DIRECT	Y	OT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suppressed Lactation	Ortho-Cyclen			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	9835582	EXPEDITED (15-DAY)		DE, LT	NO-TEVA-449104ISR		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drowning; Intentional Self-Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Vival			S	Unknown			Barr
	Tramadol			S	Unknown	Unk		Teva
	Diazepam			S	Unknown	Unk		Barr
	Diazepam			S				Barr
	Pinex Forte			S	Unknown	Strength: 500/30 Mg And Pandeine		Actavis
	Nozinan			S	Unknown			Not Reported
	Oxynorm			S	Unknown	10 Mg, Unk, Strength: 5 Mg-10 Mg		Not Reported
	Oxynorm			S				Not Reported
	Cipralex			S	Unknown			Not Reported
	Sarotex			S	Unknown			Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Orfiril			S	Unknown	Strength: 600 Mg-1200 Mg		Not Reported
	Orfiril			S				Not Reported
	Remeron			S	Unknown	Unk		Not Reported
	Imovane			S	Oral	Unk		Not Reported
	Atarax			S	Unknown			Not Reported
	Truxal			S	Unknown	Unk		Not Reported
	Truxal			S				Not Reported

	Lamictal	S	Unknown	100 Mg, Unk Strength: 25 Mg, 50 Mg, 100 Mg	Not Reported
	Seroquel	S	Unknown		Not Reported
	Sobril	S	Unknown	Unk	Not Reported
	Nobligan	S	Unknown	200 Mg, Unk, Strength: 50 Mg-200 Mg	Not Reported
	Catapresan	S	Unknown	Strength 25 Mg, 50 Mg, Unk	Not Reported
	Cipramil [Citalopram Hydrobromide]	S	Unknown		Not Reported
	Hydroxyzine Hydrochloride	S	Unknown		Not Reported
	Levomepromazine Maleate	S	Unknown		Not Reported
	Forte	C		Unk	Not Reported
	Diamorphine	C	Unknown	Unk	Not Reported
	Heroin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	14390103	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2017IN29021			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Galactorrhoea	Escitalopram			S	Unknown	20 Mg, Per Day, For About 15 Days		Invagen
	Sertraline			S	Unknown	50 Mg, Per Day, For About 15 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15042745	EXPEDITED (15-DAY)		OT	DE-TORRENT-00008656		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cyst	Escitalopram			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15115019	EXPEDITED (15-DAY)		DE, HO	GB-TEVA-2018-GB-922348		88 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer; Gastric Ulcer Haemorrhage; Gastrointestinal Haemorrhage; Gastrointestinal Pain	Acetylsalicylic Acid			S	Oral	75 Milligram Daily;		Not Reported
	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Dihydrocodeine			C	Oral	120 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15280077	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018318000		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor; Suicidal Ideation	Tavor (Lorazepam)			S	Oral	Unk		Pfizer
	Escitalopram Oxalate			S	Oral	50 Mg, Total		Not Reported
	Olanzapine			S	Oral	20 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15328313	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2018-FR-947859		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Atorvastatine			S	Oral	10 Milligram Daily;		Teva
	Amiodarone			S	Oral	Unknown		Not Reported
	Lactulose			S	Oral	2 Dosage Forms Daily;		Actavis
	Lansoprazole			S	Oral	15 Milligram Daily;		Teva
	Trimebutine			S	Oral	300 Milligram Daily;		Not Reported
	Repaglinide			S	Oral	2 Milligram Daily;		Not Reported
	Escitalopram			S	Oral	10 Milligram Daily;		Not Reported
	Prograf			S	Oral	3 Milligram Daily;		Not Reported
	Fungizone 10 Pour Cent,			S	Buccal	3 Dosage Forms Daily;		Not Reported

	Suspension Buvable					
	Driptane 5 Mg, Comprimé Sécable	S	Oral	3 Dosage Forms Daily;		Not Reported
	Bisoce 1,25 Mg, Comprimé Pelliculé	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15507041	EXPEDITED (15-DAY)		DS	PHHY2018IT121680		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder	Escitalopram Oxalate			S	Oral	5 Gtt, Qd		Not Reported
	Risperidone			S	Oropharingeal	1 Mg, Qd		Novartis
	Depakin			C	Oral	100 Mg, Qd		Not Reported
	Rivotril			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15507258	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20181019904		29 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Gastric Haemorrhage; Hypoxia; Intentional Overdose; Seizure; Suicide Attempt	Tramadol Hydrochloride			S	Unknown			Not Reported
	Salbutamol			S	Unknown			Not Reported
	Trimipramine			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15507534	EXPEDITED (15-DAY)		DE, OT	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2018NSR000150		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anion Gap; Atrioventricular Block;	Propranolol Hydrochloride			S		Unk		Northstar

Bradycardia; Coma; Delirium; Depressed Level Of Consciousness; Dystonia; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperreflexia; Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Myocardial Ischaemia; Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Ventricular Arrhythmia	Escitalopram	S	Unk	Not Reported
	Lamotrigine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15507539	EXPEDITED (15-DAY)		HO, OT	FR-SA-2018SA283827		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Paracetamol/Tramadol Hydrochloride			S	Oral			Not Reported
	Coaprovel			S	Oral			Sanofi
	Escitalopram Oxalate			S	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15507580	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1849254US		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Abuse; Drug Dependence; Drug	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd (1-0-0)		Allergan

Dependence; Prescription Form Tampering	Ixprim	S	Oral	3 Df, Tid (1-1-1)		Not Reported
	Imovane	S	Oral	7.5 Mg, Qd (0-0-0-1)		Not Reported
	Xanax	S	Oral	0.75 Mg, Tid (1-1-1)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15508641	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-MYLANLABS-2018M1076056		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral	15 Mg, Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Metformin Hydrochloride			C				Mylan
	Nifedipine			C				Mylan
	Pregabalin			C				Mylan
	Nefopam			C				Mylan
	Tiotropium			C				Mylan
	Sodium Picosulfate			C				Mylan
	Cetirizine			C				Mylan
	Naproxen			C				Mylan
	Diazepam			C				Mylan
	Cassia Senna			C				Mylan
	Methotrexate Sodium			C				Mylan
	Budesonide W/Formoterol Fumarate			C				Mylan
	Lansoprazole			C				Mylan
	Meptazinol			C				Mylan
	Quetiapine Fumarate			C				Mylan
	Temazepam			C				Mylan
	Montelukast			C				Mylan
	Pyridoxine			C				Mylan
	Folic Acid			C				Mylan
	Adcal D3			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15509341	DIRECT		OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Anxiety; Arthralgia; Bone Pain; Chest Pain; Dental Caries; Loss Of Personal Independence In Daily Activities; Suicidal Ideation	Escitalopram	Y	S	Oral	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15511936	EXPEDITED (15-DAY)		OT	FR-TAKEDA-2018TUS030050			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Drug Ineffective; Drug Intolerance; Dysuria	Brintellix			S	Unknown	5 Mg, Unk		Takeda
	Brintellix			S	Unknown	10 Mg, Unk		Takeda
	Brintellix			S	Unknown	15 Mg, Unk		Takeda
	Seroplex			S	Unknown	Unk		Not Reported
	Paroxetine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15514569	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1849271US		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Coaprovel			S	Oral	1 Df, Qd		Not Reported
	Ixprim			S	Oral	3 Df, Qd		Not Reported
	Omeprazole			C	Oral	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15514585	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1849415US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Drug Ineffective; Drug Intolerance; Dysuria	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan
	Brintellix			S	Unknown	5 Mg, Unknown		Not Reported

	Brintellix		S	Unknown	10 Mg, Unknown	Not Reported
	Brintellix		S	Unknown	15 Mg, Unknown	Not Reported
	Paroxetine		C	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	14140765	NON-EXPEDITED			US-AMGEN-USASP2017161996			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Chantix			S	Unknown	Unk		Not Reported
	Indocin			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Lithium			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	14986409	NON-EXPEDITED			US-ASTRAZENECA-2018SE62879		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Nexium			S	Oral	Unk		Astrazeneca
	Lexapro			S	Unknown	Unk		Not Reported
	Estrace			S		Unk		Not Reported
	Gabapentin			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Niacin			S		Unk		Not Reported
	Lotrel			S		Unk		Not Reported
	Septra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15034582	EXPEDITED (15-DAY)		HO	BE-TEVA-2018-BE-911442		25 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hospitalisation; Lactation Disorder; Live Birth; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Therapeutic Product Effective For Unapproved Indication	Abilify			S	Oral	Unk		Teva
	Abilify			S	Unknown	Unk		Teva
	Escitalopram			S	Oral	Unk		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15132168	EXPEDITED (15-DAY)		DE	PHHY2018IT043201		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam			S	Oral	0.5 Mg, Qd		Novartis
	Alprazolam			S	Oral	0.75 Mg, Qd		Novartis
	Venlafaxine Hydrochloride			S	Oral	37.5 Mg, Qd		Not Reported
	Venlafaxine Hydrochloride			S	Oral	75 Mg, Qd		Not Reported
	Venlafaxine Hydrochloride			S	Oral	150 Mg, Qd		Not Reported
	Zolpidem Tartrate			S	Oral	10 Gtt, Qd		Not Reported
	Zolpidem Tartrate			S	Oral	15 Gtt, Qd		Not Reported
	Clonazepam			S	Oral	7 Gtt, Qd		Not Reported
	Cipralex			S	Oral	2 Gtt, Qd		Not Reported
	Cipralex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15515192	EXPEDITED (15-DAY)		HO, OT	IN-HETERO CORPORATE-		22 YR	Female	IND

HET2018IN01040

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased; Typhoid Fever	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Solopose Beta			C	Unknown	0.5 Mg, Qd		Not Reported
	Desilam			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15515433	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-964775		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Haematoma Muscle	Clopidogrel Base			S	Oral	75 Milligram Daily;		Teva
	Escitalopram			S	Oral	5 Milligram Daily; 1-0-0		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15515866	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US20279			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash Pruritic; Urticaria	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk, Dose Increased		Invagen
	Bupropion Hcl Xl			S	Unknown	150 Mg, Daily		Not Reported
	Zoloft			S	Unknown	Unk, For Years		Not Reported
	Metoprolol			S	Unknown	25 Mg, Unk		Not Reported
	Metoprolol			S	Unknown	50 Mg, Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Flonase /00908302/			C	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported
	Loratadine			C	Unknown	Unk		Not Reported

	Baby Aspirin	C	Unknown	Unk	Not Reported
	B Complex /00322001/	C	Unknown	Unk	Not Reported
	Vitamin D /00107901/	C	Unknown	Unk	Not Reported
	Fish Oil	C	Unknown	Unk	Not Reported
	Calcium Citrate	C	Unknown	Unk	Not Reported
	Miralax	C	Unknown	Unk	Not Reported
	Multivitamins /00116001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15515927	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US17958			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Product Quality Issue	Escitalopram			S	Unknown	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15515952	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US00718			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinusitis; Tooth Discolouration	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Escitalopram			S				Invagen
	Amlodipine /00972402/			C	Unknown	5 Mg, Qd		Not Reported
	Amlodipine /00972402/			C	Unknown	1.5 Mg, Qd		Not Reported
	Amoxicillin /00249602/			C	Unknown	500 Mg, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516114	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US21021			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram			S	Unknown	5 Mg, Unk		Invagen
	Lisinopril			C	Unknown	20 Mg, Unk		Not Reported

	Temazepam		C	Unknown	15 Mg, Unk	Not Reported
	Fondaparinux		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516193	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US19565			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura	Escitalopram			S	Oral	20 Mg, Qd		Invagen
	Rosuvastatin Calcium			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516226	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US22153			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Product Administration Error	Escitalopram			S	Unknown	10 Mg, 1/2 Pill/Day		Invagen
	Escitalopram			S	Unknown	10 Mg, Per Day		Invagen
	Escitalopram			S	Unknown	10 Mg, 1/2 Pill/Day		Invagen
	Gabapentin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516243	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US08278			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extra Dose Administered	Escitalopram			S	Oral	10 Mg Tablets (Count Unknown, Beyond The Prescribed Dose)		Invagen
	Alprazolam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516264	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US21089			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Dizziness; Feeding Disorder; Feeling Abnormal; Malaise	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Xanax			C	Unknown	0.25mg Bid, Tablet (Twice A Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516265	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US16921			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Escitalopram			S	Oral	10 Mg, Once A Day		Invagen
	Escitalopram			S				Invagen
	Amitriptyline			C	Unknown	10 Mg, Once A Day		Not Reported
	Diazepam			C	Unknown	5 Mg, Whenever Required		Not Reported
	Myrbetriq			C	Unknown	25 Mg, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516270	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US16598			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective	Escitalopram			S	Unknown	20 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516317	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1074594		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Drug Ineffective	Escitalopram			S	Unknown	Every Other Day		Not Reported
	Xarelto			S	Oral	15 Mg, Unk		Mylan
	Xarelto			S	Oral	20 Mg, Qd		Mylan
	Xarelto			S	Oral	Restarted On Rivaroxaban Therapy After One Year		Mylan

	Aspirin /00002701/	C	Oral	1 Year With Rivaroxaban Followed By 2 Months As Monotherapy	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516332	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US16599			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Fatigue; Head Titubation; Headache; Product Substitution Issue	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Telmisartan			C	Unknown	75 Mcg, Unk		Not Reported
	Synthroid			C	Unknown	160 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516351	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US21205			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Malaise; Migraine; Nausea; Palpitations; Panic Attack; Product Quality Issue; Stress	Escitalopram			S	Oral	10 Mg, Unk, 2 Years		Invagen
	Escitalopram			S	Oral	10 Mg, Unk, Brand New Sealed Bottle		Invagen
	Escitalopram			S	Unknown	Unk, New Bottle Different Lot		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516374	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US19551			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Insomnia; Nausea; Product Substitution Issue	Escitalopram			S	Oral	20 Mg, 3 Tablets Once A Day		Invagen
	Escitalopram			S	Unknown	Unk, Brand Lexapro Manufactured By Actavis		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516384	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US01287			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Incorrect Dose Administered	Escitalopram			S	Oral	5 Mg, Unk		Invagen
	Escitalopram			S	Oral	2.5 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516389	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US22592			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Therapeutic Response Unexpected; Tinnitus	Escitalopram			S	Oral	5 Mg, Qd		Invagen
	Escitalopram			S				Invagen
	Cartia Xt			C	Unknown	300 Mg, Qd		Not Reported
	Liothyronine Sodium (T3)			C	Unknown	5 Mg, Unk		Not Reported
	Levothyroxine /00068002/			C	Unknown	Unk, 2 Tablets 3 Times A Week And One Tablet 4 Times A Week		Not Reported
	Metoprolol			C	Unknown	45 Mg, Qd		Not Reported
	Cardizem /00489701/			C	Unknown	180 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516401	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US17325			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Hypersensitivity	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Levothyroxine			C	Unknown	75 Mcg, Qd, Every Day		Not Reported
	Centrum /02217401/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516962	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1075916		21 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Sopor	Aripiprazole			S	Oral	210 Mg, Total		Not Reported
	Escitalopram			S	Oral	140 Mg, Total		Not Reported
	Alprazolam			S	Oral	15 Ml, Total		Not Reported
	Prozin /00011902/			S	Oral	1200 Mg, Total		Mylan
	Zitromax			S	Oral	1500 Mg, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15518425	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-965149		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Liver Disorder	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	12159585	EXPEDITED (15-DAY)		OT	CA-FRI-1000082991		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Serotonin Syndrome	Escitalopram Oxalate Unk			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Unknown	30 Mg, Qd		Allergan
	Escitalopram Teva			S	Unknown	20 Mg, Qd		Not Reported
	Escitalopram Teva			S	Unknown	30 Mg, Qd		Not Reported
	Abilify			S	Oral	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15414965	EXPEDITED (15-DAY)		HO, OT	PHHY2018CO006004			Male	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Back Pain; Blood Pressure Decreased; Choking; Headache; Heart Rate Decreased; Malaise; Neck Pain; Spinal Pain	Gilenya	S	Oral	0.5 Mg, Qd		Novartis
	Gilenya	S	Unknown	Unk		Novartis
	Escitalopram	S	Unknown	20 Mg, Qd (In The Morning)		Not Reported
	Lebrina	S	Unknown	Unk		Not Reported
	Vigia	C	Unknown	100 Mg, Qd		Not Reported
	Lyrica	C	Unknown	75 Mg, Qhs		Not Reported
	Trazodone	C	Unknown			Not Reported
	Vitamins Nos	C	Unknown			Not Reported
	Fampridine	C	Oral	10 Mg, Bid		Not Reported
	Omeprazole	C	Unknown			Not Reported
	Prednisolone	C	Unknown	50 Mg, Unk (Daily)		Not Reported
	Vitamin D2	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15518069	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15525691	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1078085		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Encephalopathy	Allopurinol			S	Oral	100 Mg, Qd		Not Reported
	Amiodarone			S	Oral	200 Mg, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Mylan
	Topalgic Lp			S	Oral	3 Df, Qd		Mylan
	Oxynormoro			S	Oral	5 Mg, Unk		Mylan
	Xanax			S	Oral	0.38 Mg, Qd		Mylan

	Kardegic	S	Oral	1 Df, Qd		Mylan
	Tazocilline	S	Intravenous (not otherwise specified)	3 Df, Qd		Mylan
	Mycophenolate Sodium	C	Oral	360 Mg, Qd		Mylan
	Ciclosporine	C	Oral	100 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15530381	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2018-US-963664		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Drug Ineffective; Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome	Escitalopram			S	Oral			Ivax
	Lamotrigine			S	Oral			Teva
	Sodium Bicarbonate			S	Other	Infusion		Not Reported
	Sodium Bicarbonate			S	Other	Increase In The Infusion Rate		Not Reported
	Sodium Bicarbonate			S	Unknown	An Additional 100 Meq Of Sodium Bicarbonate Was Also Given		Not Reported
	Sodium Bicarbonate			S	Other	Repeated Boluses Of Bicarbonate		Not Reported
	Propofol			C	Unknown			Not Reported
	Midazolam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	14995516	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1829373US			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Aripiprazole			S	Oral	2 Mg, Unk		Not Reported
	Teva Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Serax			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15305723	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-945279		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Product Substitution Issue	Escitalopram Abz 20 Mg			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15441206	EXPEDITED (15-DAY)		HO, LT	BE-SAKK-2018SA266773AA		85 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Computerised Tomogram Thorax Abnormal; Drug Interaction; Haemoptysis; Hepatojugular Reflux; Hypoventilation; Lymphadenopathy; Pleural Effusion; Pulmonary Alveolar Haemorrhage	Clexane			S	Subcutaneous	80 Mg, Qd		Sanofi
	Acetylsalicylic Acid			S	Oral	80 Mg, Qd		Not Reported
	Cordarone			S	Oral	200 Mg, Qd		Not Reported
	Pradaxa			S	Oral	110 Mg, Qd		Not Reported
	Sipralexa			S	Oral	10 Mg, Qd		Not Reported
	Prolopa Hbs			C	Oral	1 Df, Qd		Not Reported
	Forlax			C	Oral	1 Df, Qd		Not Reported
	Prolopa			C	Oral	7 Df, Qd		Not Reported
	Nexiam [Esomeprazole Magnesium]			C	Oral	20 Mg, Qd		Not Reported
	Crestor			C	Oral	20 Mg, Qd		Not Reported
	D Vital Forte			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15525240	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-966092		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Atenolol			S	Oral			Not Reported
	Tramadol Base			S	Oral	Unknown		Teva

	Seroplex 5 Mg, Comprimé Pelliculé	S	Oral	Not Reported
	Exforge	S	Oral	Not Reported
	Hemigoxine Nativelle 0,125 Mg, Comprimé	S	Oral	Not Reported
	Macrogol (Stearate De)	C	Oral	Not Reported
	Caltrate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15525507	EXPEDITED (15-DAY)		LT	FR-TEVA-2018-FR-966131		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Prednisolone			S	Oral	20 Milligram Daily;		Actavis
	Rhinofluimucil, Solution Pour Pulvérisation Nasale			S	Nasal			Not Reported
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported
	Alprazolam Mylan 0,25 Mg, Comprimé Sécable			C	Oral	1 Dosage Forms Daily;		Not Reported
	Tussipax			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15532084	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US22773			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Musculoskeletal Stiffness	Escitalopram			S	Oral	10 Mg, Qd, In The Morning		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15532089	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US17739			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hyperhidrosis; Vertigo	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Escitalopram			S				Invagen

Metformin	C	Unknown	500 Mg, Qd		Not Reported
Januvia	C	Unknown	40 Mg, Qd		Not Reported
Clopidogrel	C	Unknown	75 Mg, Qd		Not Reported
Pravastatin	C	Unknown	20 Mg, Qd		Cipla
Metoprolol	C	Unknown	Unk		Not Reported
Alprazolam	C	Unknown	10 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15532146	EXPEDITED (15-DAY)		OT	ZA-LUPIN HEALTHCARE (UK) LIMITED-2018-07287			Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer; Large Intestinal Obstruction	Bilocor Tablets			S	Oral	05 Mg, Unk		Not Reported
	Zytomil Tablets			S	Oral	20 Mg, Unk		Lupin
	Avigra			S	Oral	100 Mg, Unk		Not Reported
	Ecotrin			S	Oral	81 Mg, Unk		Not Reported
	Topzole			S	Oral	40 Mg, Unk		Not Reported
	Dormonoct			S	Oral	02 Mg, Unk		Not Reported
	Rivotril			S	Oral	0.5 Mg, Unk		Not Reported
	Adco-Mirteron			S	Oral	15 Mg, Unk		Not Reported
	Aspen Trazodone			S	Oral	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15533499	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1078434		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Malaise; Sinus Bradycardia	Escitalopram			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2018	15264067	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-041285		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Lichen Planus	Lamotrigine			S	Oral	Unk		Aurobindo
	Perindopril			S	Oral	2 Milligram		Aurobindo
	Esomeprazole			S	Oral	Unk		Aurobindo
	Atorvastatin			S	Oral	20 Milligram		Not Reported
	Esidrex			S	Oral	25 Milligram		Not Reported
	Aldactone /00006201/			S	Oral	Unk		Not Reported
	Xeroquel			S	Oral	Unk		Not Reported
	Kardegic			S	Oral	Unk		Not Reported
	Verapamil			S	Oral	240 Milligram		Not Reported
	Teralithe			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Macrogol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2018	15535994	DIRECT	Y	OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Product Substitution Issue; Somnolence; Somnolence	Escitalopram			S	Oral			Camber

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2018	15536332	DIRECT	Y	OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Hypertension; Migraine;	Escitalopram			S	Oral			Torrent

Product Substitution Issue

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	14849361	EXPEDITED (15-DAY)		DE	IT-ROCHE-2117792		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Clonazepam			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	14895102	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-892132		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cyst	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	15440278	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE-HET2018DE00900			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia;	Escitalopram			S	Unknown			Hetero
	Duloxetine			S	Unknown			Hetero

Myoclonus	Aripiprazole	S	Unknown	Unk	Hetero
	Aripiprazole	S			Hetero
	Mirtazapine	S	Unknown		Not Reported
	Biperiden	S	Unknown		Not Reported
	Oxazepam	S	Unknown	At Different Doses	Not Reported
	Fluoxetine	S	Unknown	Unk	Not Reported
	Bupropion	S	Unknown	Unk	Not Reported
	Promethazine	S	Unknown	Unk	Not Reported
	Promethazine	S			Not Reported
	Amisulpride	S	Unknown	Unk	Not Reported
	Amisulpride	S			Not Reported
	Risperidone	S	Unknown	Unk	Not Reported
	Venlafaxine	S	Oral		Not Reported
	Olanzapine	S	Unknown	Unk	Not Reported
	Olanzapine	S			Not Reported
	Clozapine	S	Unknown		Not Reported
	Zopiclone	S	Unknown	Unk	Not Reported
	Quetiapine	S	Oral	Unk	Not Reported
	Oxcarbazepine	C	Unknown	Unk	Not Reported
	Zonisamide	C	Unknown	Up To 100mg	Not Reported
	Brivaracetam	C	Unknown	200-250mg; Received Over One Year	Not Reported
	Carbamazepine	C	Unknown	Up To 900 Mg	Not Reported
	Clobazam	C	Unknown	Up To 20mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	15534487	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-051384		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Escitalopram			S	Oral	15 Milligram, Once A Day		Aurobindo
	Coaprovel			S	Oral	1 Dosage Form, Once A		Not Reported

					Day	
	Ixprim	S	Oral	3 Dosage Form, Once A Day		Not Reported
	Omeprazole	C	Oral	40 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	15534711	NON-EXPEDITED			US-APOTEX-2018AP022382		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	10 Mg Per Day		Apotex
	Escitalopram			S	Unknown	20 Mg		Apotex
	Escitalopram			S	Unknown	10 Mg, Prn		Apotex
	Clonazepam			S	Unknown	0.5 Mg, Prn		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	15536113	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP022750		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroid Mass	Escitalopram			S	Oral	20 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	15537156	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1078884		85 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sopor	Olanzapine			S	Oral	Unk		Not Reported
	Venlafaxine			S	Oral	1 Df, Qd		Not Reported
	Delorazepam			S	Oral	Unk		Not Reported
	Cipralex /01588501/			S	Oral	Unk		Mylan
	Donepezil			C		Unk		Mylan
	Bisoprolol Fumarate			C		Unk		Mylan

	Madopar	C	Unk	Mylan
	Terazosin Hydrochloride	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15539970	EXPEDITED (15-DAY)		HO, OT	ZA-LUPIN HEALTHCARE (UK) LIMITED-2018-07285			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Zytomil			S	Oral	20 Mg, Unk		Lupin
	Pearinda Plus			S	Oral	4/1.25 Mg, Unk		Not Reported
	Wellbutrin			S	Oral	150 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15540115	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-188516		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Atenolol			S	Oral	25 Mg, Unk		Sun
	Tramadol			S	Oral	Inconnue ()		Sun
	Exforge			S	Oral			Not Reported
	Hemigoxine Nativelle 0,125 Mg, Comprime			S	Oral	1 Df, Unk		Not Reported
	Seroplex 5 Mg, Comprime Pellicule			S	Oral	1 Df, Unk		Not Reported
	Macrogol (Stearate De)			C	Oral	2 Df, Unk		Not Reported
	Caltrate			C	Oral	1 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15540325	NON-EXPEDITED			US-PFIZER INC-2018419469		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Chantix			S		Unk		Pfizer

Arava	S	Unk	Not Reported
Indocin	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Lithium	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15541321	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP023248		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Prescription Drug Used Without A Prescription; Serotonin Syndrome	Tramadol			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15541455	NON-EXPEDITED			US-TORRENT-00005631			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram			S				Unknown
	Fondaparinux Sodium			C	Subcutaneous	Ndc: 5511167802 Once Daily In The Stomach		Not Reported
	Lisinopril			C				Unknown
	Temazepam			C				Unknown
	Iron			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15541458	NON-EXPEDITED			US-TORRENT-00005662		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Disorder; Nausea; Wrong Technique In Product Usage Process	Escitalopram			S		Cutting The Tablet Into Quarter And Takes 5 Mg (From Unspecified Date)		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15541459	NON-EXPEDITED			US-TORRENT-00005974			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Drug Ineffective	Escitalopram			S				Unknown
	Escitalopram			C		Lot No: Pw03047, Ndc: 16729-0168-01 (Accord)		Unknown
	Fosamax			C				Unknown
	Lexapro			C				Unknown
	Lorazepam			C				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15541461	NON-EXPEDITED			US-TORRENT-00006148		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Intolerance; Mood Altered; Product Substitution Issue	Escitalopram Oxalate Tablet			S		Always In The Morning		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15541462	NON-EXPEDITED			US-TORRENT-00006162			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Headache	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15541463	NON-EXPEDITED			US-TORRENT-00006263			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Rigidity	Escitalopram			S		5 Mg Tablet		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15541464	NON-EXPEDITED			US-TORRENT-00006228		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Height Decreased; Product Prescribing Error; Wrong Technique In Product Usage Process	Escitalopram			S		5 Mg Of The Tablet Reduce It To Half I.E. 2.5 Mg.		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15541476	NON-EXPEDITED			US-TORRENT-00006265			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper	Escitalopram			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15541477	NON-EXPEDITED			US-TORRENT-00006739			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Drug Ineffective; Fatigue; Somnolence; Yawning	Escitalopram			S		Unknown		Torrent
	Escitalopram			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15541478	NON-EXPEDITED			US-TORRENT-00006485			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash Pruritic	Escitalopram			S		Unknown		Torrent
	Bupropion Hydrochloride			S		Round Shape, White Color, Imprint 144: Rx 7087916		Unknown
	Atorvastatin Calcium			C		Unknown		Unknown

	Flonase	C	Unknown	Unknown
	Levothyroxine Sodium	C	Unknown	Unknown
	Loratadine	C	Unknown	Unknown
	Aspirin	C	Unknown	Unknown
	Vitamin B Complex	C	Unknown	Unknown
	Vitamin D3	C	Unknown	Unknown
	Fish Oil	C	Unknown	Unknown
	Calcium Citrate	C	Unknown	Unknown
	Miralax	C	Unknown	Unknown
	Metoprolol	S	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15542946	EXPEDITED (15-DAY)		HO	ZA-JNJFOC-20181030317			Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Tramacet			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Disprin			S	Unknown			Not Reported
	Atacand Plus			S	Unknown			Not Reported
	Diaglucide			S	Unknown			Not Reported
	Glucophage			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Urbanol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15543061	EXPEDITED (15-DAY)		HO, LT	BE-PFIZER INC-2018430765		85 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Computerised Tomogram Thorax Abnormal; Drug	Cordarone			S	Oral	200 Mg, 1x/Day		Pfizer
	Clexane			S	Subcutaneous	80 Mg, 1x/Day		Not Reported

Interaction; Haemoptysis; Hepatojugular Reflux; Hypoventilation; Lymphadenopathy; Pleural Effusion; Pulmonary Alveolar Haemorrhage	Asaflow	S	Oral	80 Mg, 1x/Day	Not Reported
	Pradaxa	S	Oral	110 Mg, 1x/Day	Not Reported
	Sipralexa	S	Oral	10 Mg, 1x/Day	Not Reported
	Prolopa Hbs	C		Unk	Not Reported
	Forlax	C		Unk	Not Reported
	Prolopa	C		Unk	Not Reported
	Nexiam [Esomeprazole Magnesium]	C	Oral	20 Mg, Unk	Not Reported
	Crestor	C	Oral	20 Mg, Unk	Not Reported
	D Vital Forte	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15543597	EXPEDITED (15-DAY)		HO, LT	BE-ALLERGAN-1850052US		85 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Computerised Tomogram Thorax; Drug Interaction; Haemoptysis; Hepatojugular Reflux; Hypoventilation; Lymphadenopathy; Pleural Effusion; Pulmonary Alveolar Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Cordarone			S	Oral	200 Mg, Qd		Not Reported
	Asaflow			S	Oral	80 Mg, Qd		Not Reported
	Clexane			S	Subcutaneous	80 Mg, Qd		Not Reported
	Pradaxa			S	Oral	110 Mg, Qd		Not Reported
	Forlax			C	Oral	1 Df, Qd		Not Reported
	Prolopa Hbs			C	Oral	1 Df, Qd		Not Reported
	Prolopa 250			C	Oral	7 Df, Qd		Not Reported
	D-Vital Forte			C	Oral	1 Df, Qd		Not Reported
	Nexiam 20 Mg			C	Oral	20 Mg, Qd		Not Reported
	Crestor 20 Mg			C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15543743	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1773548US		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchiectasis; Dyspnoea; Fatigue; Interstitial Lung Disease	Escitalopram Oxalate - Bp	S	Unknown	5 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp	S	Unknown	Unk		Allergan
	Duloxetine Mylan	S	Unknown	15 Mg, Unk		Not Reported
	Duloxetine Mylan	S	Unknown	Unk		Not Reported
	Venlafaxine Mylan	S	Unknown	37.5 Mg, Unk		Not Reported
	Venlafaxine Mylan	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15546474	DIRECT		DS, HO, OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Depression; Diarrhoea; Dizziness; Impaired Work Ability; Nausea; Product Substitution Issue	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Aurobindo
	Lexapro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	11455120	NON-EXPEDITED			US-ACTELION PHARMACEUTICALS US, INC.-A-NJ2015-1185		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne; Anxiety; Burning Sensation; Chest Discomfort; Depression; Dizziness; Fatigue; Gastric Ulcer; Headache; Hypoaesthesia; Insomnia; Laryngitis; Nasal Congestion; Nasopharyngitis; Nausea; Neuralgia; Oral Candidiasis; Paraesthesia Oral; Somnolence;	Tracleer			S	Oral	Unk		Actelion
	Tracleer			S	Oral	125 Mg, Bid		Actelion
	Clonazepam			S	Unknown			Not Reported
	Remeron			S	Unknown	7.5 Mg, Qd		Not Reported
	Remeron			S	Unknown	10 Mg, Qd		Not Reported
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Sildenafil			C				Not Reported

Unevaluable Event;
Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	14111334	EXPEDITED (15-DAY)		OT	US-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00354		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bradycardia; Chest Discomfort; Chest Pain; Diarrhoea; Feeling Abnormal; Hypertensive Urgency; Malaise; Mental Impairment	Escitalopram			S	Oral	10 Mg, 1x/Day		Jubilant
	Hydrochlorothiazide			C				Not Reported
	Dexilant			C				Not Reported
	Potassium			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	14908534	EXPEDITED (15-DAY)		DE, OT	FR-JNJFOC-20180309197		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Hextril		Y	S	Buccal			Not Reported
	Eprex			S	Subcutaneous			Not Reported
	Doxorubicin			S	Intravenous drip			Not Reported
	Exacyl			S	Intravenous drip			Not Reported
	Pantoprazole			S	Intravenous drip			Not Reported
	Ciprofloxacin			S	Intravenous drip			Not Reported
	Zarzio			S	Subcutaneous			Not Reported
	Meropenem			S	Intravenous drip			Not Reported
	Furosemide			S	Oral			Not Reported
	Lidocaine			S	Buccal			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Calciparine			S	Subcutaneous			Not Reported
	Bisoprolol			S	Oral			Not Reported

	Methotrexate	S	Intravenous drip	Not Reported
	Methotrexate	S	Intravenous drip	Not Reported
	Voraxaze	S	Intravenous drip	Not Reported
	Valaciclovir	S	Oral	Not Reported
	Cyclophosphamide	S	Intravenous drip	Not Reported
	Prednisone	S	Intravenous drip	Not Reported
	Ondansetron	S	Oral	Not Reported
	Vincristine	S	Intravenous drip	Not Reported
	Bactrim	S	Oral	Not Reported
	Bromazepam	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Fungizone	S	Buccal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15544241	EXPEDITED (15-DAY)		DS	IT-TEVA-2018-IT-967676		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder	Escitalopram Oxalate			S	Oral	5 Gtt Daily;		Ivax
	Risperidone			S	Oropharingeal	1 Milligram Daily;		Pliva
	Depakin			C	Oral	100 Milligram Daily;		Not Reported
	Rivotril 2,5 Mg/Ml Gocce Orali Soluzione			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15544551	EXPEDITED (15-DAY)		HO	FR-ACCORD-073782		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram			S	Oral			Not Reported
	Rulid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15544568	NON-EXPEDITED			US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-177867			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Interaction; Insomnia	Amphetamine Mixed Salts			S	Unknown	20 Mg In Morning And 10 Mg In Evening		Mutual
	Lexapro			S	Unknown	Unk		Not Reported
	Trinessa			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15544710	EXPEDITED (15-DAY)		HO	FR-ACCORD-073889		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Amlodipine			S	Oral			Accord
	Escitalopram			S	Oral			Not Reported
	Transulose			S	Oral			Not Reported
	Domperidone			S	Oral			Not Reported
	Calcium Carbonate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15544826	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-189028		24 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cycloplegia; Nausea; Somnolence	Duloxetine			S	Unknown	30 Mg, Daily		Sun
	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Unknown			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15544839	NON-EXPEDITED			US-APOTEX-2018AP017646			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Rash Pruritic	Escitalopram			S	Unknown	Unk		Apotex
	Escitalopram			S				Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15545443	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC-2018SUN00526		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Agitation; Bundle Branch Block Left; Clonus; Electrocardiogram Qrs Complex Prolonged; Hyperreflexia; Hypotension; Muscle Rigidity; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Sinus Tachycardia; Somnolence	Lamotrigine Tablets 100mg			S	Unknown	Unk		Taro
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15545727	EXPEDITED (15-DAY)		OT	FI-MYLANLABS-2018M1079226			Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antipsychotic Drug Level Increased; Blood Pressure Increased; Electrocardiogram Qt Prolonged; Hyperparathyroidism; Hypokalaemia;	Leponex			S		450 Mg, Qd		Mylan
	Leponex			S		Unk		Mylan
	Cipralex /01588501/			S		30 Mg, Qd		Mylan
	Cipralex /01588501/			S		10 Mg, Qd		Mylan

Parathyroid Tumour
Benign

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15546017	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018418427		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Abuse; Drug Dependence; Drug Dependence; Prescription Form Tampering	Xanax			S	Oral	0.75 Mg, 1x/Day (1-1-1)		Pfizer
	Ixprim			S	Oral	3 Df, 1x/Day (1-1-1)		Not Reported
	Imovane			S	Oral	7.5 Mg, 1x/Day (0-0-0-1)		Not Reported
	Seroplex			S	Oral	20 Mg, 1x/Day (1-0-0)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	14648303	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2018106685		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Pantoprazole			S	Intravenous drip	Unk		Pfizer
	Ciprofloxacin			S	Intravenous drip	Unk		Unknown
	Meropenem			S	Intravenous drip	Unk		Pfizer
	Doxorubicin Hcl			S	Intravenous drip	Unk		Pfizer
	Vincristine Sulfate			S	Intravenous drip	Unk		Unknown
	Fungizone			S	Buccal	Unk		Not Reported
	Exacyl			S	Intravenous drip	Unk		Not Reported
	Exacyl			S	Intravenous drip	Unk		Not Reported
	Eprex			S	Subcutaneous	Unk		Not Reported
	Zarzio			S	Subcutaneous	Unk		Not Reported
	Hextril			S	Buccal	Unk		Not Reported
	Hextril			S	Unknown	Unk		Not Reported
	Furosemide			S	Oral	Unk		Not Reported
	Lidocaine			S	Buccal	Unk		Not Reported

	Lidocaine	S	Buccal	Unk		Not Reported
	Methotrexate	S	Intravenous drip	Unk		Not Reported
	Methotrexate	S		Unk		Not Reported
	Voraxaze	S	Intravenous drip	Unk		Not Reported
	Valaciclovir Hydrochloride	S	Oral	Unk		Not Reported
	Cyclophosphamide	S	Intravenous drip	Unk		Not Reported
	Prednisone	S	Intravenous drip	Unk		Not Reported
	Ondansetron	S	Oral	Unk		Not Reported
	Bromazepam	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Escitalopram	S				Not Reported
	Bactrim	S	Oral	Unk		Not Reported
	Calciparine	S	Subcutaneous	Unk		Not Reported
	Rituximab	S	Intravenous drip	Unk		Not Reported
	Bisoprolol	S	Oral	Unk		Not Reported
	Bisoprolol Fumarate	S	Oral	Unk		Not Reported
	Tranexamic Acid	S	Intravenous drip	Unk		Not Reported
	Amphotericin B	S	Buccal	Unk		Not Reported
	Epoetin Alfa	S	Subcutaneous	Unk		Not Reported
	Sulfamethoxazole And Trimethoprim	S	Oral	Unk		Not Reported
	Heparin Calcium	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	14873010	EXPEDITED (15-DAY)		DE, OT	IT-AUROBINDO-AUR-APL-2018-024653		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Alprazolam Tablets			S	Oral	0.75 Milligram, Once A Day		Aurobindo
	Alprazolam			S	Oral	0.5 Milligram, Once A Day		Not Reported
	Zolpidem Tartrate			S	Oral	10 Gtt, Daily		Not Reported

Zolpidem Tartrate	S	Oral	15 Gtt, Once A Day		Not Reported
Venlafaxine Hydrochloride	S	Oral	37.5 Milligram, Once A Day		Not Reported
Venlafaxine Hydrochloride	S	Oral	75 Milligram, Once A Day		Not Reported
Venlafaxine Hydrochloride	S	Oral	150 Milligram, Once A Day		Not Reported
Cipralex /01588501/	S	Oral	2 Gtt, Once A Day		Not Reported
Clonazepam	S	Oral	7 Gtt, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15201350	EXPEDITED (15-DAY)		OT	DE-TORRENT-00009064		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy; Overdose; Product Use In Unapproved Indication; Toxicity To Various Agents	Escitalopram			S	Unknown	Unknown		Unknown
	Quetiapine			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15548699	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-934702		27 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuser; Sopor	Escitalopram Oxalate			S	Oral			Ivax
	Escitalopram Oxalate			S				Ivax
	Delorazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15548767	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US21945			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage Intracranial; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Invagen

	Tramadol			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15550422	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2018181487			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone Abnormal; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus; Urticaria; Vertigo; Vision Blurred	Diclofenac Sodium			S	Unknown	2 Df, Qw		Glaxosmithkline
	Simvastatin			S	Unknown	20 Mg, Qd		Glaxosmithkline
	Imovane			S	Unknown	0.5 Df, Qd		Glaxosmithkline
	Uvedose			S	Unknown	1 Df, Q3mo		Glaxosmithkline
	Seresta			S	Unknown	12.5 Mg, Qd		Glaxosmithkline
	Amlor			S	Unknown	1 Df, Qd		Glaxosmithkline
	Zyloric			S	Unknown	1 Df, Qd		Glaxosmithkline
	Levothyrox			S	Oral	1 Df, Qd		Glaxosmithkline
	Cotareg			S	Unknown	1 Df, Qd		Not Reported
	Atenolol			S	Unknown	50 Ug, Qd		Not Reported
	Seroplex			S	Unknown	1 Df, Qd		Not Reported
	Endotelon			S	Unknown	2-3 Tablets, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15551195	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018432736		73 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Aspavor			S		20 Mg, Unk		Pfizer
	Ivedal			S		10 Mg, Unk		Not Reported
	Lexamil			S		5 Mg, Unk		Not Reported
	Pritor [Lacidipine]			S		40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15551586	EXPEDITED (15-DAY)		OT	PHHY2018CA136999			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; No Adverse Event; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Cosentyx			S	Subcutaneous	150 Mg, Unk		Novartis
	Cosentyx			S	Unknown	Unk		Novartis
	Cosentyx			S	Subcutaneous	150 Mg, Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	Unk Unk, Qd		Not Reported
	Colecalciferol			S	Unknown	Unk		Not Reported
	Diclofenac Diethylamine			S	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15554211	DIRECT					71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear; Paraesthesia; Peripheral Coldness	Escitalopram 5 Mg			S	Oral	Quantity:2 Tablet(S);		Torrent
	Lexapro			C				Not Reported
	Xanax			C				Not Reported
	Miftazipine			C				Not Reported
	Anoro Inhaler			C				Not Reported
	Fluticasone Propianate			C				Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	13869396	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017348063		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Oral Lichen Planus	Aldactone		S	Oral	Unk	Pfizer
	Atorvastatin Calcium		S	Oral	20 Mg, Daily	Pfizer
	Esomeprazole Magnesium		S	Oral	Unk	Unknown
	Lamotrigine		S	Oral	Unk	Not Reported
	Teralithe		S	Oral	400 Mg, Unk	Not Reported
	Teralithe		S	Oral	800 Mg, Unk	Not Reported
	Teralithe		S	Oral	600 Mg, Unk	Not Reported
	Kardegic		S	Oral	Unk	Not Reported
	Perindopril		S	Oral	2 Mg, Daily	Not Reported
	Hydrochlorothiazide		S	Oral	25 Mg, Daily	Not Reported
	Verapamil Hydrochloirde		S	Oral	240 Mg, Daily	Not Reported
	Macrogol		S	Oral	Unk	Not Reported
	Seroplex		S	Oral	Unk	Not Reported
	Xeroquel		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	13887760	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1735280US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prolactin-Producing Pituitary Tumour	Lexapro			S	Unknown	20 Mg, Unk		Allergan
	Rexulti			S	Unknown	1 Mg, Unk		Not Reported
	Abilify			S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	13893658	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1735893US		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Lichen Planus	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Hydrochlorothiazide			S	Oral	25 Mg, Unk		Not Reported
	Aldactone			S	Oral	Unk		Not Reported

Lamotrigine	S	Oral			Not Reported
Xeroquel	S	Oral			Not Reported
Perindopril	S	Oral	2 Mg, Qd		Not Reported
Kardegic	S	Oral	Unk		Not Reported
Esomeprazole	S	Oral			Not Reported
Verapamil	S	Oral	240 Mg, Qd		Not Reported
Atorvastatine	S	Oral	20 Mg, Unk		Not Reported
Teralithe	S	Oral	Unk		Not Reported
Macrogol	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14899290	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2018US17810			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Somnolence; Toxicity To Various Agents	Lamotrigine			S	Oral	Unk		Cipla
	Escitalopram			S	Oral	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14955900	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2018-027650		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Electrocardiogram Qrs	Escitalopram Tablets Usp 20mg			S	Unknown	Unk		Aurobindo
	Escitalopram Tablets Usp 20mg			S				Aurobindo
	Lamotrigine Tablets 100 Mg			S	Unknown	Unk		Aurobindo
	Lamotrigine Tablets 100 Mg			S				Aurobindo

Complex Prolonged; Hypotension; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15442896	EXPEDITED (15-DAY)		HO, OT	ZA-PFIZER INC-2018387763		56 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spinal Fracture	Bilocor			S		5 Mg, Unk		Not Reported
	Co-Diovan			S		Unk		Not Reported
	Mylan Pantoprazole			S		40 Mg, Unk		Not Reported
	Lexamil			S		20 Mg, Unk		Not Reported
	Celebrex			C		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15553903	NON-EXPEDITED		OT	FR-APOTEX-2018AP023369		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Paroxetine			S	Unknown	10 Mg, Qd		Glaxosmithkline
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Zopiclone			C	Oral	7.5 Mg, Qd		Not Reported
	Valium			C	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15554039	EXPEDITED (15-DAY)		OT	ZA-ROCHE-2203977			Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Colon Cancer; Gastrointestinal Disorder	Rivotril	S	Unknown	Not Reported
	Bilocor	S	Unknown	Not Reported
	Zytomil	S	Unknown	Not Reported
	Avigra	S	Unknown	Not Reported
	Ecotrin	S	Unknown	Not Reported
	Topzole	S	Unknown	Not Reported
	Dormonoct	S	Unknown	Not Reported
	Adco-Mirteron	S	Unknown	Not Reported
	Aspen Trazodone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15554210	NON-EXPEDITED			US-PFIZER INC-2018428655			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea	Sertraline Hcl			S		Unk		Pfizer
	Sertraline Hcl			S				Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported
	Bupropion			S		Unk		Not Reported
	Bupropion			S				Not Reported
	Fluoxetine			S		Unk		Not Reported
	Levothyroxine			C	Oral	100 Ug, Daily		Not Reported
	Alprazolam			C	Oral	1 Mg, Daily		Not Reported
	Alprazolam			C		0.5 Mg, Daily		Not Reported
	Gabapentin			C	Oral	100 Mg, 2x/Day (100mg Capsule In The Morning, And One 100mg Capsule At Night)		Not Reported
	Gabapentin			C	Oral	100 Mg, Daily		Not Reported
	Gabapentin			C		Unk (Can Take Up To 3 Capsules Daily)		Not Reported

	Esomeprazole Magnesium	C	Oral	1 Capsule, Daily	Not Reported
	Ranitidine	C	Oral	300 Mg, 1 Tablet Taken Once Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15554602	NON-EXPEDITED			US-PFIZER INC-2018438211		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Effexor			S		Unk		Pfizer
	Celexa [Citalopram Hydrobromide]			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Trazodone			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15556329	EXPEDITED (15-DAY)		OT	PHEH2018US044851			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Headache; Rectal Haemorrhage	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15556649	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-968683		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Escitalopram			S	Oral	15 Milligram Daily;		Ivax
	Coaprovel 300 Mg/12,5 Mg, Comprimé			S	Oral	1 Dosage Forms Daily;		Not Reported
	Ixprim 37,5 Mg/325 Mg, Comprimé Pelliculé			S	Oral	3 Dosage Forms Daily;		Not Reported

	Omeprazole		C	Oral	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15556903	EXPEDITED (15-DAY)		HO	NL-ALLERGAN-1850481US			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Hypertonia Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transmammary	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15557358	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1850791US		14 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Product Use Issue; Somnolence; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Qd		Allergan
	Rivotril			S	Oral	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2018	15558416	EXPEDITED (15-DAY)		OT	HR-ROCHE-2206226		14 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Somnolence; Suicide Attempt	Rivotril			S	Oral	Date Of Most Recent Dose: 27/Jul/2018		Not Reported
	Cipralex			S	Oral	Date Of Most Recent Dose: 27/Jul/2018		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	13703596	EXPEDITED (15-DAY)		OT	US-IMPAX LABORATORIES, INC-2017-IPXL-01859		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anorgasmia; Ejaculation Failure; Erectile Dysfunction; Erectile Dysfunction; Loss Of Libido; Treatment Noncompliance	Lamotrigine Odt		S	Unknown	100 Mg, Tid	Impax
	Lamotrigine Odt		S			Impax
	Mirtazapine Odt		S	Unknown	22.5 Mg, Qhs	Impax
	Escitalopram		S	Unknown	20 Mg, Bid	Not Reported
	Alprazolam		S	Unknown	1 Mg, Tid, Prn	Not Reported
	Enalapril		S	Unknown	20 Mg, Qam (Everyday Before Noon)	Not Reported
	Lansoprazole		S	Unknown	30 Mg, Morning	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	13881566	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2017SE82010		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Lichen Planus	Esomeprazole Magnesium			S	Oral			Not Reported
	Xeroquel			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Teralithe			S	Oral	400.0mg Unknown		Not Reported
	Teralithe			S	Oral	800.0mg Unknown		Not Reported
	Teralithe			S	Oral	600.0mg Unknown		Not Reported
	Aldactone			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Atorvastatin Calcium			S	Oral			Not Reported
	Perindopril			S	Oral			Not Reported
	Verapamil Hydrochloride			S	Oral			Not Reported
	Macrogol			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	14151979	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-38840		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Tablets Usp 10mg			S	Unknown	Three And Half Tablet Daily		Aurobindo
	Belsomra			C	Unknown			Not Reported
	Clorazepate			C	Unknown			Not Reported
	Doxepine			C	Unknown			Not Reported
	Hydroxyzine			C	Unknown			Not Reported
	Lamotrigine			C	Unknown			Not Reported
	Linzess			C	Unknown			Not Reported
	Novolog			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	14324545	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2017M1073700			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine			S	Unknown	1 Df, Qd		Not Reported
	Paracetamol			S	Unknown	1 Df, Tid		Not Reported
	Paracetamol/Tramadol			S	Unknown	1 Df, Tid,(37.5/325 Mg)		Not Reported
	Enalapril/Hydrochlorothiazide			S	Unknown	1 Df, Qd,(20/12.5 Mg)		Not Reported
	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
	Omeprazole			S	Unknown	1 Df, Qd		Not Reported
	Simvastatin			S	Unknown	1 Df, Qd		Not Reported
	Simvastatin			S		20 Mg, Unk		Not Reported
	Simvastatin			S		20 Mg, Unk		Not Reported
	Lormetazepam			S	Unknown	1 Df, Qd		Not Reported
	Topiramate			S	Unknown	1 Df, Qd		Not Reported
	Topiramate			S	Unknown	0.5 Df, Qd		Not Reported
	Tepazepam			S	Unknown	Unk, Qd		Mylan

Glibenclamide	S	Unknown	1 Df, Bid		Not Reported
Naproxen	S	Unknown	1 Df, Bid		Mylan
Diazepam	S	Unknown	0.5 Df, Qd		Mylan
Diazepam	S	Unknown	Unk		Mylan
Amitriptyline	S	Unknown	5 Mg, Qd		Mylan
Amitriptyline	S	Unknown	12.5 Mg, Qd		Mylan
Amitriptyline	S		25 Mg, Unk		Mylan
Amitriptyline	S		25 Unk, Unk		Mylan
Metoclopramide	C	Unknown	1 Week Treatment		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15534216	EXPEDITED (15-DAY)		HO	US-JNJFOC-20181016212		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Gynaecomastia; Off Label Use; Product Use In Unapproved Indication; Suicide Attempt; Weight Increased	Risperidone			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	Dose: 3 - 4 Mg		Not Reported
	Risperdal			S	Oral	Dose: 3 - 4 Mg		Not Reported
	Adderall			S	Unknown	Dose: 10 - 30 Mg		Not Reported
	Lexapro			S	Unknown	Dose: 20 - 30 Mg		Not Reported
	Intuniv			S	Unknown	Dose: 1 - 4 Mg		Not Reported
	Sertraline			S	Unknown	Dose: 50 - 150 Mg		Not Reported
	Vyvanse			S	Unknown	Dose: 40 - 70- Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15552628	EXPEDITED (15-DAY)		OT	FR-FRESENIUS KABI-FK201810999		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Maculo-Papular	Linezolid Kabi			S	Intravenous (not otherwise specified)	1200mg/Day		Not Reported
	Voriconazole			S	Intravenous (not otherwise specified)	300mg/Day		Not Reported
	Voriconazole			S	Intravenous (not otherwise specified)	400mg/Day		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Imipenem Monohydrate/Cilastatin Sodium			S	Intravenous (not otherwise specified)	500/500 Milligrammes 3 Fois Par Jour		Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported
	Ponatinib			C				Not Reported
	Trimebutine			C				Not Reported
	Heparin Sodium			C				Not Reported
	Valaciclovir			C				Not Reported
	Phloroglucinol/Trimethylphloroglucinol			C				Not Reported
	Fenofibrate			C				Not Reported
	Paraffin, Liquid			C				Not Reported
	Lansoprazole			C				Not Reported
	Entecavir Monohydrate			C				Not Reported
	Sodium Bicarbonate/Potassium Chloride/Sodium Chloride/Macrogol 3350			C				Not Reported
	Hydroxyzine			C				Not Reported
	Hydrocortisone			C				Not Reported
	Zopiclone			C				Not Reported
	Calcium Folinate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15558926	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2018AU22092			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Urine Present	Escitalopram		S	Unknown	Unk	Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559021	EXPEDITED (15-DAY)		HO	ZA-CIPLA LTD.-2018ZA22066			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Escitalopram			S	Unknown	Unk		Invagen
	Difluzole			S	Unknown	Unk		Not Reported
	Adco-Atenolol			S	Unknown	Unk		Not Reported
	Amloc /00550802/			S	Unknown	Unk		Not Reported
	Zartan Co			S	Unknown	Unk		Not Reported
	Menacal7			S	Unknown	Unk		Not Reported
	Aspavor			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559153	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2018-007087			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram Tablets Usp 20mg			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559158	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2018-021367			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Photophobia; Visual Impairment; Vitreous Floaters	Escitalopram Tablets Usp 10mg			S	Unknown	Unk Unk, Once A Day		Aurobindo
	Escitalopram Tablets Usp 10mg			S				Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559169	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-43557			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour	Escitalopram Tablets Usp 10mg			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559178	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-43694			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram 5 Mg			S	Unknown			Aurobindo
	Fondaparinux Sodium			C	Subcutaneous	2.5/ 0.5 Mg/Ml		Not Reported
	Lisinopril			C	Unknown			Not Reported
	Temazepam			C	Unknown	15 Mg, Unk		Not Reported
	Iron			C	Unknown	Unk, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559180	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-45316		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sleep Disorder	Escitalopram Tablets Usp 20mg			S	Unknown	Unk, 1 Tab Per Day		Aurobindo
	Escitalopram Tablets Usp 20mg			S				Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559194	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2018-002169			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Escitalopram Tablets Usp 5mg			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559196	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2018-004876		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Headache	Escitalopram Tablets Usp 20mg	S	Unknown	Unk Unk, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559203	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2018-018839			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Flatulence	Escitalopram Tablets Usp 5mg			S	Unknown	5 Milligram, Once A Day, (One Tablet Per Day)		Aurobindo
	Meloxicam			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Diacerein			C	Unknown	Unk		Not Reported
	Norco			C	Unknown	Direction Depend On Pain		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559324	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US22251			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Escitalopram			S	Unknown	Unk		Invagen
	Sertraline			S	Unknown	100 Mg, Unk For 4 Months		Invagen
	Sertraline			S	Unknown	200 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15560305	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00403			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Tinnitus	Escitalopram			S		Unk		Jubilant
	Fondaparinux			S	Subcutaneous	Unk, 1x/Day		Not Reported
	Lisinopril			C				Not Reported
	Temazepam			C				Not Reported
	Iron			C		As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15560306	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00105		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Tachyphrenia	Escitalopram			S	Oral	40 Mg, 1x/Day		Jubilant
	Ibuprofen			S	Oral	600 Mg, 3x/Day		Not Reported
	Atorvastatin			C				Not Reported
	Unspecified Dietary Supplements			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15560307	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00291			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash Pruritic	Escitalopram			S		Unk		Jubilant
	Escitalopram			S		Increased Dose		Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15560399	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP023271		38 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Dexametasona /00016001/			S	Oral	0.25 Mg, Qd		Not Reported
	Hidroaltesona			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	14344530	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MYLANLABS-2017M1083628		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Affective Disorder; Condition Aggravated; Depression; Drug Abuse; Drug Ineffective; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Zolpidem	S	Oral	10 Mg, Qd At Bedtime	Not Reported
	Zolpidem	S			Not Reported
	Clarithromycin	S	Oral	Unk, Two 10 Day Courses	Not Reported
	Atorvastatin	S	Oral	(Bed Time)	Not Reported
	Tramadol	S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago	Not Reported
	Tramadol	S			Not Reported
	Escitalopram	S	Oral	10 Mg, Hs, Doctor Switched The Patient From Sertraline To Escitalopram	Not Reported
	Escitalopram	S		10 Mg, Unk	Not Reported
	Escitalopram	S			Not Reported
	Perindopril	S	Oral	Unk	Not Reported
	Sertraline	S	Oral	50 Mg, Qd	Not Reported
	Sertraline	S	Oral	50 Mg, Qd, In The Morning	Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Doxepin	S	Oral	25 Mg, Qd Qhs, At Bedtime	Not Reported
	Concor	S	Unknown	Unk	Mylan
	Concor	S	Unknown	Unk	Mylan
	Trosicam	S	Oral	Unk	Mylan
	Trosicam	S	Oral	Unk, Tramadol In Combination With Meloxicam, For About Two Years Ago	Mylan
	Polsen	S	Oral	10 Mg, Hs At Bedtime	Mylan
	Atorvastatin	C		Unk	Mylan
	Perindopril	C		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15121381	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1048454		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor; Suicide Attempt	Escitalopram			S	Oral	300 Mg, Total		Not Reported
	Lexotan 6			S	Oral	20 Ml, Total		Mylan
	Efexor Xl			S	Oral	7 Df, Total		Mylan
	Lamictal			S	Oral	1400 Mg, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15453428	EXPEDITED (15-DAY)		DS	DE-MYLANLABS-2018M1071005			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Gait Disturbance; Hyperhidrosis; Hypoaesthesia; Insomnia; Malaise; Muscle Twitching; Off Label Use; Palpitations; Paraesthesia; Tremor	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd(Took On 16.11.2017 Escitalopram 20 Mg)		Not Reported
	Oxazepam			S	Oral	10 Mg, Hs,(At Night)		Not Reported
	Monostep			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15543570	EXPEDITED (15-DAY)			US-ALLERGAN-1849899US		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Rexulti			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15565033	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-052486			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Headache	Escitalopram Film-Coated Tablets			S	Unknown	15 Mg, Qhs (Every Bedtime)		Aurobindo

	Mirtazapine Film-Coated Tablet	S	Unknown	30 Mg, Unk	Aurobindo
	Levocarb 1 A Pharma	S	Unknown	0.5 Df, Unk	1a Pharma
	Acetylsalicylic Acid	C	Unknown	100 Milligram, Once A Day	Not Reported
	Atorvastatin	C	Unknown	300 Mg, Qhs	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15565088	EXPEDITED (15-DAY)		HO, OT	ZA-LUPIN PHARMACEUTICALS INC.-2018-07495			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Zartan (Losartan Potassium)			S	Oral	100 Mg, Unk		Lupin
	Novomix			S	Unknown	100 Iu, Unk (30 Flexpen)		Not Reported
	Eltroxin			S	Oral	150 Mcg, Unk		Not Reported
	Lexamil			S	Oral	10 Mg, Unk		Not Reported
	Glucophage			S	Oral	1000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15565730	EXPEDITED (15-DAY)		OT	NL-APOTEX-2018AP023258		16 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea Haemorrhagic; Hypertension; Tachycardia	Quetiapine			S	Unknown	Voor De Nacht Een Halve Tablet		Apotex
	Quetiapine			S				Apotex
	Escitalopram			S	Unknown	1x Daags 2 Tabletten		Not Reported
	Cholecalciferol			C	Unknown	1 X 1		Not Reported
	Melatonine			C	Unknown	1 Mg 1 X 1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15565986	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-100226			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haemorrhagic Stroke	Eliquis	S	Unknown	Unavailable		Bristol Myers Squibb
	Lexapro	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15567192	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-APOTEX-2018AP023301			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine			S	Transplacental	5 Mg, Qd		Apotex
	Pantoprazole			S	Unknown	Unk		Apotex
	Theophylline			S	Unknown	Unk		Not Reported
	Nucala			S	Transplacental	100 Mg, Unk		Not Reported
	Fluticasone Furoate			S	Transplacental	Unk Unk, Qd		Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported
	Vilanterol Trifenatate			S	Transplacental	1 Df, Qd		Not Reported
	Seretide			S	Transplacental	Unk		Not Reported
	Pantomed (Pantoprazol)			S	Transplacental	Unk		Not Reported
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported
	Ventolin /00139501/			S	Transplacental	100 Ug, Unk		Not Reported
	Avamys			S	Transplacental	Unk Unk, Bid		Not Reported
	Relvar Ellipta			S	Transplacental	1 Df, Qd		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Xyzall			S	Transplacental	5 Mg, Qd		Not Reported
	Sipralexa			S	Transplacental	10 Mg, Z		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15567371	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1850860US		18 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; No Adverse Event; Suicide	Escitalopram Oxalate - Bp			S	Oral	Overdose: 210mg		Allergan

Attempt

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15567771	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1080695		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Vertigo	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Aldactazine			S	Oral	1 Df, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15567830	EXPEDITED (15-DAY)		DS	PHHY2018IT141480		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depressed Mood; Insomnia	Risperidone			S	Oral	Unk		Novartis
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Rivotril			S	Oral	30 Gtt, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15569474	DIRECT		OT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Depression; Drug Withdrawal Syndrome	Lexapro			S	Oral			Forest

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	12539373	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2016-08916		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Clonus; Confusional State; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose; Nystagmus; Psychomotor Retardation; Suicide Attempt; Toxicity To Various Agents	Bromazepam	S	Oral	180 Milligram In Total	Not Reported
	Escitalopram	S	Oral	840 Milligram In Total	Aurobindo
	Lormetazepam	S	Oral	14 Milligram In Total	Not Reported
	Venlafaxine	S	Oral	7875 Milligram In Total	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	13716378	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1727471US		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Agitation; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Feeling Abnormal; Feeling Jittery; Gastrointestinal Disorder; Lethargy; Libido Decreased; Mental Impairment; Mental Impairment; Nervousness; Off Label Use; Restlessness; Sexual Dysfunction; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	7.5 Mg (One And One-Half 5mg Tablet), Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Unk		Allergan
	Citalopram Hydrobromide - Bp			S	Unknown	Unk		Allergan
	Trintellix			S	Oral	10 Mg, Qd		Not Reported
	Trintellix			S	Oral	5 Mg, Qd		Not Reported
	Trintellix			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14726623	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2018US14460			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiogenic Shock; Drug Ineffective; Electrocardiogram Qrs	Amlodipine			S	Oral	Unk		Invagen
	Escitalopram			S	Oral	Unk		Invagen

Complex Prolonged; Muscle Necrosis; Overdose; Prescription Drug Used Without A Prescription; Rhabdomyolysis; Seizure	Atorvastatin	S	Oral	Unk		Invagen
	Calcium	S	Unknown	Unk		Not Reported
	Hydrochlorothiazide	S	Oral	Unk		Not Reported
	Atropine	S	Unknown	Unk		Not Reported
	Venlafaxine	S	Oral	Unk		Not Reported
	Fluoxetine	S	Oral	Unk		Not Reported
	Glucagon	S	Unknown	Unk		Not Reported
	Dextroamphetamine Saccharate, Amphe/01345401/	S	Oral	Unk		Not Reported
	Buspirone	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15313577	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-946668		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Lichen Planus	Lamotrigine			S	Oral			Teva
	Perindopril			S	Oral	2 Mg		Not Reported
	Verapamil (Chlorhydrate De)			S	Oral	240 Mg		Actavis
	Atorvastatine			S	Oral	20 Mg		Teva
	Esomeprazole			S	Oral			Teva
	Hydrochlorothiazide			S	Oral			Not Reported
	Aldactone 25 Mg, Comprimé Pelliculé Sécable			S	Oral			Not Reported
	Xeroquel			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Teralithe			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Macrogols			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15357529	EXPEDITED (15-DAY)		HO, LT, OT	JP-PFIZER INC-2018357943		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Lorazepam			S		Unk		Pfizer
	Lorazepam			S				Pfizer
	Epinephrine			S		Three Adrenaline Injections		Not Reported
	Escitalopram			S		Unk		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15397226	EXPEDITED (15-DAY)		OT	US-TAKEDA-2018TUS027019		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Confusional State; Dizziness; Feeling Abnormal; Muscle Spasms; Pain; Paraesthesia; Suicidal Ideation; Urinary Tract Infection	Trintellix			S	Oral	10 Mg, Qd		Takeda
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Xanax			S	Unknown	Unk		Not Reported
	Tramadol			C	Oral	Unk		Not Reported
	Alprazolam			C	Oral	Unk		Not Reported
	Carvedilol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15568458	EXPEDITED (15-DAY)		HO, LT	US-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00688			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bundle Branch Block; Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Toxicity To Various Agents	Lamotrigine Tablets			S	Unknown	100 Mg, Unk		Sciegen
	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15568636	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2018US22217			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Major Depression; Somatic Delusion; Treatment Noncompliance	Escitalopram			S	Unknown	5 Mg, Daily		Invagen
	Escitalopram			S	Unknown	10 Mg, Daily Increased After 3 Days		Invagen
	Escitalopram			S		10 Mg, Daily, Resatrted At Month 14		Invagen
	Escitalopram			S	Unknown	20 Mg, Increased At Month 15 After The Initial Consultation		Invagen
	Haloperidol			S	Unknown	1 Mg, At Bedtime		Not Reported
	Haloperidol			S	Unknown	2 Mg, At Bedtime (Increased After 3 Days)		Not Reported
	Haloperidol			S	Unknown	2 Mg, At 27 Month After The Initial Consultation		Not Reported
	Haloperidol			S	Unknown	3 Mg, Increased At 28 Month After The Initial Consultation		Not Reported
	Trazodone			S	Unknown	25 Mg, Start At 28 Month		Not Reported
	Carvedilol			C	Unknown	Unk		Not Reported
	Digoxin			C	Unknown	Unk		Not Reported
	Digoxin			C				Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Glipizide			C	Unknown	Unk		Not Reported
	Insulin Aspart			C	Unknown	Unk		Not Reported
	Insulin Glargine			C	Unknown	Unk		Not Reported
	Metolazone			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Potassium Chloride			C	Unknown	Unk		Not Reported

	Rivaroxaban	C	Unknown	Unk	Not Reported
	Spironolactone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569920	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2018-07546		20 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cycloplegia; Nausea; Somnolence	Sertraline			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Duloxetine Hydrochloride			S	Unknown	30 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15570086	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS-2018GMK037998		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Lamotrigine			S	Unknown	150 Mg, Qd		Glenmark
	Lamotrigine			S	Unknown	100 Mg, Qd		Glenmark
	Lithium			S	Unknown	600 Mg, Od (Every Bedtime)		Glenmark
	Escitalopram			S	Unknown	5 Mg, Od (Every Morning)		Not Reported
	Escitalopram			S	Unknown	20 Mg, Od		Not Reported
	Escitalopram			S	Unknown	10 Mg, Od (Every Morning)		Not Reported
	Escitalopram			S	Unknown	15 Mg, Od (Every Morning)		Not Reported
	Dextroamphetamine Saccharate, Amphe/01345401/			S	Unknown	20 Mg, Od (Extended Release, Every Morning)		Not Reported
	Dextroamphetamine Saccharate, Amphe/01345401/			S	Unknown	10 Mg, Od (Extended Release, Every Morning)		Not Reported
	Testosterone			S	Topical	Unk, Od (50 Mg/5 G Every Morning On The Right		Not Reported

			Upper Extremity)	
Lurasidone	S	Unknown	40 Mg, Od (After Dinner)	Not Reported
Lorazepam	S	Unknown	0.5 Mg, Tid (As Necessary)	Not Reported
Lorazepam	S	Unknown	1 Mg, Tid (As Necessary)	Not Reported
Bupropion	S	Unknown	150 Mg, Od (Every Morning)	Not Reported
Bupropion	S	Unknown	200 Mg, Od (Every Morning)	Not Reported
Bupropion	S	Unknown	300 Mg, Od (Every Morning)	Not Reported
Buspirone	S	Unknown	15 Mg, Bid (Every 12 Hours)	Not Reported
Buspirone	S	Unknown	15 Mg, Tid (Every 8 Hours)	Not Reported
Buspirone	S	Unknown	10 Mg, Od	Not Reported
Buspirone	S	Unknown	17.5 Mg, Od	Not Reported
Buspirone	S	Unknown	7.5 Mg, Tid (Every 8 Hours)	Not Reported
Buspirone	S	Unknown	15 Mg, Tid (Every 8 Hours)	Not Reported
Buspirone	S	Unknown	15 Mg, Od	Not Reported
Buspirone	S	Unknown	2.5 Mg, Od	Not Reported
Buspirone	S	Unknown	22.5 Mg, Od	Not Reported
Buspirone	S	Unknown	5 Mg, Od	Not Reported
Buspirone	S	Unknown	7.5 Mg, Od	Not Reported
Buspirone	S	Unknown	7.5 Mg, Bid (Every 12 Hours)	Not Reported
Buspirone	S	Unknown	7.5 Mg, Tid (Every 8 Hours)	Not Reported
Buspirone	S	Unknown	20 Mg, Od	Not Reported
Aripiprazole	S	Unknown	4 Mg, Od (Every Bedtime)	Not Reported

	Aripiprazole	S	Unknown	2 Mg, Od (Every Bedtime)	Not Reported
	Benztropine Mesylate	C	Unknown	0.5 Mg, Bid (As Necessary)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15570702	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20181042844		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Tramadol Hydrochloride			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Atenolol			S	Oral			Not Reported
	Exforge			S	Oral			Not Reported
	Hemigoxine Nativelle			S	Oral			Not Reported
	Caltrate			C	Oral			Not Reported
	Macrogol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15571281	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1081339		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Impaired Quality Of Life; Treatment Noncompliance	Escitalopram			S	Unknown	Every Morning		Not Reported
	Gabapentin			S	Unknown	Total Daily Dose		Not Reported
	Nortriptyline			S	Unknown	Every Bedtime		Not Reported
	Alprazolam			S	Unknown	Extended Release; Total Daily Dose		Not Reported
	Alprazolam			S	Unknown	Total Daily Dose (1mg-0.5mg-1mg); Extended Relaese		Not Reported
	Lisdexamfetamine Dimesylate			S	Unknown	Every Morning		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15572534	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1081408		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Hypoglycaemia; Hyponatraemia	Omeprazole Mylan 20 Mg, Gélule Gastro-Résistante			S	Oral	20 Mg, Qd		Mylan
	Ramipril Mylan 5 Mg, Comprimé Sécable			S	Oral	5 Mg, Qd		Mylan
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Acide Alendronique /01220301/			C	Oral	70 Mg, 1 Second		Mylan
	Icaz Lp			C	Oral	2.5 Mg, Qd		Mylan
	Ceris			C	Oral	40 Mg, Qd		Mylan
	Calperos D3			C	Oral	500 Mg, Qd		Mylan
	Lactulose			C	Oral	10 G, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15572710	EXPEDITED (15-DAY)		DS	IT-ALLERGAN-1851564US		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depressed Mood; Insomnia	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Rivotril			S	Oral	30 Gtt, Qd		Not Reported
	Risperidone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15572745	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1851574US			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	100 Mg, Unk		Allergan
	Lithium			S	Oral	6 G, Unk		Not Reported
	Seroquel			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	13692000	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US10855			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disturbance In Attention; Memory Impairment; Physical Product Label Issue	Amlodipine			S	Oral	10 Mg, Qd		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Neurozac			C	Unknown	Unk, Tablet		Not Reported
	Zentel			C	Unknown	Unk, Tablet		Not Reported
	Levothyroxine			C	Unknown	Unk, Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	14355524	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-ABBVIE-18S-129-2213282-00		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Condition Aggravated; Depression; Drug Abuse; Drug Ineffective; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Clarithromycin			S	Oral	Unk, Two 10 Day Courses		Not Reported
	Zolpidem			S	Oral	10 Mg, Qd		Not Reported
	Zolpidem			S	Oral	10 Mg, Qd At Bedtime		Not Reported
	Atorvastatin			S	Oral	Unk		Not Reported
	Atorvastatin			S	Oral	Unk, Pm (Bed Time)		Not Reported
	Atorvastatin			S	Oral	Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported
	Tramadol			S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago		Not Reported
	Escitalopram			S	Oral	10 Mg, Hs, Doctor Switched The Patient From Sertraline To Escitalopram		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Sertraline			S	Oral	50 Mg, Qd		Not Reported

Sertraline	S	Oral	50 Mg, Qd, In The Morning		Not Reported
Bisoprolol	S	Unknown	Unk		Not Reported
Doxepin	S	Oral	25 Mg, Qd Qhs, At Bedtime		Not Reported
Concor	S	Unknown	Unk		Not Reported
Concor	S	Unknown	Unk		Not Reported
Trosicam	S	Oral	Unk		Not Reported
Trosicam	S	Oral	Unk, Tramadol In Combination With Meloxicam, For About Two Years Ago		Not Reported
Polsen	S	Oral	10 Mg, Hs At Bedtime		Not Reported
Perindopril	S	Oral			Not Reported
Perindopril	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	14535767	EXPEDITED (15-DAY)		DE, HO, OT	FR-AUROBINDO-AUR-APL-2018-007041		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Off Label Use; Poisoning Deliberate; Suicide Attempt; Toxicity To Various Agents; Unresponsive To Stimuli	Paracetamol Tablet			S	Oral	Unk		Aurobindo
	Escitalopram			S	Oral	Unk		Aurobindo
	Dextropropoxyphene			S	Oral	Unk		Not Reported
	Baclofen			S	Oral	Unk		Not Reported
	Baclofen			S				Not Reported
	Valpromide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15368319	EXPEDITED (15-DAY)		HO, LT, OT	JP-BAUSCH-BL-2018-024688		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Haemolytic Anaemia; Left	Lorazepam			S	Unknown			Not Reported

Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Lorazepam	S				Not Reported
	Epinephrine	S	Unknown	Three Adrenaline Injections		Not Reported
	Escitalopram	S	Unknown			Not Reported
	Escitalopram	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15553251	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US21976			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cortisol Increased	Escitalopram			S	Oral	5 Mg, Qd (Half Of Escitalopram 10mg)		Invagen
	Escitalopram			S	Oral	10 Mg, Qd, Whole Tablet		Invagen
	Clonazepam			C	Unknown	0.25 Mg, Qd (0.5mg Was Prescribed However, Consumer Stated She Is Taking 0.25mg)		Not Reported
	Lyrica			C	Unknown	75 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15573346	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US22182			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia; Aphasia; Chills; Diarrhoea; Feeling Abnormal; Headache; Hyperhidrosis; Piloerection; Pyrexia; Restlessness; Withdrawal Syndrome	Escitalopram			S	Unknown	5 Mg, Every Mornig		Invagen
	Escitalopram			S	Unknown	20 Mg, Qd		Invagen
	Escitalopram			S	Unknown	10 Mg, Every Morning		Invagen
	Escitalopram			S	Unknown	15 Mg, Every Morning Followed By A Gradual Taper (2.5 Mg/Week)		Invagen
	Buspirone			S	Unknown	7.5 Mg, Bid		Not Reported
	Buspirone			S	Unknown	15 Mg, Tid		Not Reported
	Buspirone			S	Unknown	7.5 Mg, Tid		Not Reported

Buspirone	S	Unknown	15 Mg, Tid		Not Reported
Lorazepam	C	Unknown	0.5 Mg, Prn, Twice Daily		Not Reported
Bupropion	C	Unknown	150 Mg, Every Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15573708	EXPEDITED (15-DAY)		HO, LT, OT	CZ-APOTEX-2018AP023322			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning	Ibuprofen			S	Unknown			Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Olanzapine			S	Oral	Unk		Apotex
	Venlafaxine			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral			Not Reported
	Metoclopramide			S	Oral	Unk		Not Reported
	Levopromazine			S	Oral	Unk		Not Reported
	Melperone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15574600	EXPEDITED (15-DAY)		OT	HR-ASTRAZENECA-2018SF40665			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Suicide Attempt	Seroquel			S	Oral	Once Daily		Zeneca
	Cipralex			S	Oral	100.0mg Unknown		Not Reported
	Lithium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15574631	EXPEDITED (15-DAY)		OT	US-TORRENT-00007134		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia;	Lorazepam			C		As Necessary		Unknown

Aphasia; Chills; Diarrhoea; Feeling Abnormal; Feeling Abnormal; Headache; Hyperhidrosis; Piloerection; Pyrexia; Restlessness; Withdrawal Syndrome	Buspirone	S	Unknown	Unknown
	Escitalopram	S	Unknown	Unknown
	Bupropion	C	Every Morning	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15575077	DIRECT		DS, HO, LT			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depressed Mood; Depression; Discomfort; Disturbance In Attention; Drug Dependence; Fall; Fatigue; Feeling Abnormal; Feeling Hot; Insomnia; Loss Of Libido; Nicotine Dependence; Product Complaint; Speech Disorder; Therapy Cessation; Visual Impairment	Fluoxetine			S			6 YR	Not Reported
	Alprazolam			S				Not Reported
	Sertaline			S				Not Reported
	Venlafaxine			S				Not Reported
	Escitalopram			S				Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15575299	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1081467		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Fenofibrate			S	Oral	67 Mg, Unk		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Irbesartan			S	Oral	75 Mg, Unk		Not Reported
	Pregabalin			S	Oral	150 Mg, Unk		Not Reported
	Bromazepam			S	Oral	18 Mg, Unk		Not Reported
	Levothyroxine Sodique			S	Oral	75 G, Unk		Mylan

	Naproxene /00256201/	S	Oral	1100 Mg, Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15575901	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-970760		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Maculo-Papular	Escitalopram Arrow			S	Oral	10 Milligram Daily;		Ivax
	Vfend			S	Intravenous (not otherwise specified)	300 Milligram Daily;		Not Reported
	Linezolide Kabi			S	Intravenous (not otherwise specified)	1200 Milligram Daily;		Not Reported
	Imipenem Cilastatine Mylan			S	Intravenous (not otherwise specified)	500/500 Milligrams 3 Times Daily		Not Reported
	Vfend 200 Mg, Poudre Pour Solution Pour Perfusion			S		400 Milligram Daily;		Not Reported
	Bactrim Forte, Comprimé			C	Unknown			Not Reported
	Ponatinib			C	Unknown			Not Reported
	Trimebutine			C	Unknown			Not Reported
	Heparine Sodique			C	Unknown			Not Reported
	Valaciclovir			C	Unknown			Not Reported
	Spasfon (Phloroglucinol\Trimethylphloroglucinol)			C	Unknown			Not Reported
	Lipanthyl			C	Unknown			Not Reported
	Lansoyl			C	Unknown			Not Reported
	Ogastoro			C	Unknown			Not Reported
	Movicol			C	Unknown			Not Reported
	Atarax			C	Unknown			Not Reported
	Hydrocortisone			C	Unknown			Not Reported
	Imovane			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576039	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1851634US			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576123	EXPEDITED (15-DAY)		DE, HO	GB-MYLANLABS-2018M1081835		88 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer; Gastrointestinal Haemorrhage; Gastrointestinal Pain	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Oral	75 Mg, Qd		Mylan
	Dihydrocodeine			C	Oral	120 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576738	EXPEDITED (15-DAY)		DS	IT-BAUSCH-BL-2018-029275		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dysgraphia; Dyskinesia; Therapeutic Product Effect Decreased; Tremor	Venlafaxin			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Sertraline			S	Unknown	Dose Reduced		Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Quetiapine			S	Oral			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15578259	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Migraine	Celexa	S		Not Reported
	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	13183771	NON-EXPEDITED		OT	ES-LUPIN PHARMACEUTICALS INC.-2016-01223		85 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram			S	Unknown	Unk Unk,Unk,Unknown		Lupin
	Metoclopramide			S	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Metoclopramide			S				Not Reported
	Amiodarone Hydrochloride			S	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Losartan			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Betahistine			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Simvastatin			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Bisoprolol			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Acenocoumarol			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Metformin			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Iron Sulfate			C	Unknown	Unk Unk,Unk,Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	13709967	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2017TUS014200		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Agitation; Anxiety; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Feeling Abnormal; Feeling Jittery; Gastrointestinal Disorder; Lethargy; Mental Impairment; Mental Impairment; Nervousness;	Trintellix			S	Oral	5 Mg, Qd		Takeda
	Trintellix			S	Oral	10 Mg, Qd		Takeda
	Trintellix			S	Unknown	Unk		Takeda
	Cipralex /01588501/			S	Oral	5 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Oral	10 Mg, Unk		Not Reported
	Cipralex /01588501/			S	Oral	7.5 Mg, Unk		Not Reported
	Cipralex /01588501/			S	Oral	2.5 Mg, Qd		Not Reported

Product Use Issue; Restlessness; Sexual Dysfunction; Wrong Technique In Product Usage Process	Celexa /00582602/	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14165183	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1763512US		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Melaena	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Pradaxa			S	Oral	110 Mg, Qd		Not Reported
	Pradaxa			S	Oral	110 Mg, Qd		Not Reported
	Singulair			C		Unk		Not Reported
	Alprazolam			C		Unk		Not Reported
	Levothyrox			C		Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Aldactone			C		Unk		Not Reported
	Bilaska			C		Unk		Not Reported
	Cardensiel			C	Unknown	Unk		Not Reported
	Seretide			C		Unk		Not Reported
	Hemigoxine Nativelle			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14340017	EXPEDITED (15-DAY)		OT	ES-TEVA-2017-ES-832259			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine			S	Unknown	1 Dosage Forms Daily; 5 Mg		Teva
	Paracetamol			S	Unknown	3 Dosage Forms Daily; 1 G		Not Reported
	Tramadol W/Paracetamol			S	Unknown	3 Dosage Forms Daily; 1		Not Reported

			Df = 37.5/325 Mg	
Enalapril/Hydrochlorothiazide	S	Unknown	1 Dosage Forms Daily; 1 Df = 20/12.5 Mg	Teva
Escitalopram	S	Unknown	1 Dosage Forms Daily; 10 Mg	Ivax
Omeprazole	S	Unknown	1 Dosage Forms Daily; 20 Mg	Actavis
Simvastatin	S	Unknown	1 Dosage Forms Daily; 40 Mg	Ivax
Simvastatin	S	Unknown	20 Mg	Ivax
Simvastatin	S	Unknown	20 Mg	Ivax
Lormetazepam	S	Unknown	1 Dosage Forms Daily; 1 Mg	Not Reported
Topiramate	S	Unknown	1 Dosage Forms Daily; 50 Mg	Teva
Topiramate	S		.5 Dosage Forms Daily; 100 Mg	Teva
Naproxen	S	Unknown	2 Dosage Forms Daily; 500 Mg	Teva
Tepazepam	S	Unknown	Qd	Not Reported
Glibenclamida	S	Unknown	2 Dosage Forms Daily; 5 Mg	Teva
Diazepam	S	Unknown	.5 Dosage Forms Daily; 5 Mg	Barr
Diazepam	S	Unknown	5 Mg	Barr
Amitriptyline 10 Mg	S	Unknown	Qd	Not Reported
Amitriptyline 25 Mg	S	Unknown	12.5 Milligram Daily; 25 Mg	Not Reported
Amitriptyline 25 Mg	S	Unknown	25 Milligram Daily; 25 Mg	Not Reported
Amitriptyline 25 Mg	S	Unknown	25 Unk	Not Reported
Diazepam, Sulpiride	S	Unknown		Not Reported
Amitriptyline Hydrochloride	S	Unknown		Not Reported

	Metoclopramide	C	Unknown	1 Week Treatment		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14913216	EXPEDITED (15-DAY)		DE	FR-TEVA-2018-FR-892337		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Ciprofloxacin			S	Intravenous drip			Not Reported
	Methotrexate			S	Intravenous drip			Barr
	Valaciclovir			S	Oral			Teva
	Furosemide			S	Oral			Ivax
	Ondansetron			S	Oral			Teva
	Bromazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Ivax
	Doxorubicin			S	Intravenous drip			Actavis
	Vincristine			S	Intravenous drip			Teva
	Pantoprazole			S	Intravenous drip			Teva
	Bisoprolol			S	Oral			Duramed
	Prednisone			S	Intravenous drip			Actavis
	Rituximab			S	Intravenous drip			Not Reported
	Calciparine			S	Subcutaneous			Not Reported
	Lidocaine			S	Buccal			Not Reported
	Fungizone			S	Buccal			Not Reported
	Voraxaze			S	Intravenous drip			Not Reported
	Zarzio			S	Subcutaneous			Not Reported
	Cyclophosphamide			S	Intravenous drip			Not Reported
	Exacyl			S	Intravenous drip			Not Reported
	Bactrim			S	Oral			Not Reported
	Hextril			S	Buccal			Not Reported
	Eprex			S	Subcutaneous			Not Reported

	Meropenem Anhydrous	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15204078	EXPEDITED (15-DAY)		DS, HO, OT	GB-ALLERGAN-1837053US		31 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Micturition Urgency; Off Label Use; Pollakiuria	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15271331	EXPEDITED (15-DAY)		DS, HO, OT	GB-TORRENT-00017024		31 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15350971	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-183466		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Lichen Planus	Atorvastatine			S	Oral	Unk		Sun
	Esomeprazole			S	Oral	Unk		Sun
	Perindopril			S	Oral	Unk		Not Reported
	Aldactone 25 Mg, Comprime Pellicule Secable			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Kardegic			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Macrogols			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Teralithe			S	Oral	Unk		Not Reported

Verapamil (Chlorhydrate De)	S	Oral	Unk		Not Reported
Xeroquel	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15578071	EXPEDITED (15-DAY)		HO	FR-ACCORD-090556		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral	1-0-0		Not Reported
	Irbesartan			S	Oral	1-0-0		Accord
	Furosemide			S	Oral	1-0-0		Accord
	Pantoprazole			S	Oral	0-0-1		Not Reported
	Seresta			C	Oral	0-0-1		Not Reported
	Duphalac			C	Oral	1-1-1		Not Reported
	Havlane			C	Oral	0-0-1 Si Besoin		Not Reported
	Kardegic			C	Oral	0-1-0, 160 Mg Powder For Oral Solution In Sachet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15579415	EXPEDITED (15-DAY)		HO	JP-LANNETT COMPANY, INC.-JP-2018LAN001260		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardiogenic Shock; Haemodynamic Instability; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Lorazepam			S	Unknown	Unk		Not Reported
	Adrenaline /00003901/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15579891	EXPEDITED (15-DAY)		DE	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-101076		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis; Iron Deficiency Anaemia	Eliquis			S	Oral	5 Mg, Daily		Bristol Myers Squibb
	Seroplex			S	Oral	5 Gtt, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15580791	EXPEDITED (15-DAY)		DS	FR-ALLERGAN-1851899US		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Vein Occlusion	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Rebif			S	Subcutaneous	66 Mg, Q Week		Not Reported
	Inexium			C	Oral	20 Mg, Qd		Not Reported
	Neurontin			C	Oral	400 Mg, Qd		Not Reported
	Levothyrox			C	Oral	75 Mg, Qd		Not Reported
	Dedrogyl			C	Oral	6 Gtt, Qd		Not Reported
	Furosemide			C	Oral	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15580924	EXPEDITED (15-DAY)		HO	IT-BAUSCH-BL-2018-029895		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Lorazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Aripiprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15584795	EXPEDITED (15-DAY)		OT	HR-TEVA-2018-HR-971458		18 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; No Adverse Event; Suicide	Escitalopram			S	Oral	210 Milligram Daily;		Ivax

Attempt

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15584930	EXPEDITED (15-DAY)		OT	US-TORRENT-00007150		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Breast Tenderness; Gynaecomastia	Escitalopram			S		Every Morning		Unknown
	Amphetamine, Dextroamphetamine			S		Extended Release, Every Morning		Unknown
	Testosterone 50mg/5g - Gel			S	Topical	50 Mg/5 G Every Morning On The Right Upper Extremity		Unknown
	Lithium			S		Every Bedtime		Unknown
	Benztropine Mesylate			C		As Necessary		Unknown
	Lurasidone			S		After Dinner		Unknown
	Lamotrigine			S				Unknown
	Lorazepam			S		As Necessary		Unknown
	Bupropion			S		Every Morning		Unknown
	Buspirone			S		Unknown		Unknown
	Aripiprazole			S		Every Bedtime		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15584990	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1851971US			Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antipsychotic Drug Level Increased; Blood Pressure Increased; Electrocardiogram Qt Prolonged; Hyperparathyroidism; Hypokalaemia; Overdose; Parathyroid Tumour Benign	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Qd (Overdose)		Allergan
	Leponex			S	Unknown	Unk		Not Reported
	Leponex			S	Unknown	450 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15585108	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1851959US		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Pradaxa			S	Oral	Unk		Not Reported
	Irbesartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2018	15582815	EXPEDITED (15-DAY)		DS	IT-AUROBINDO-AUR-APL-2018-053149		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depressed Mood; Insomnia	Risperidone			S	Oral	Unk		Aurobindo
	Escitalopram			S	Oral	Unk		Aurobindo
	Rivotril			S	Oral	30 Gtt, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2018	15583296	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2018018446			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia; Aphasia; Chills; Diarrhoea; Feeling Abnormal; Headache; Hyperhidrosis; Piloerection; Pyrexia; Restlessness; Withdrawal Syndrome	Escitalopram Oxalate			S	Unknown	20 Milligram, Qd		Macleods
	Escitalopram Oxalate			S	Unknown	5 Milligram, Qd, Every Morning		Macleods
	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd, Every Morning		Macleods
	Buspirone			S	Unknown	15 Milligram, Tid		Not Reported
	Buspirone			S	Unknown	7.5 Milligram, Bid		Not Reported
	Buspirone			S	Unknown	7.5 Milligram, Tid		Not Reported
	Bupropion			C	Unknown	150 Milligram, Qd, Every		Not Reported

	Lorazepam		C	Unknown	Morning 0.5 Milligram, Bid, As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2018	15583310	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2018018448			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Escitalopram Oxalate			S		5 Milligram, Qd, Every Morning		Macleods
	Escitalopram Oxalate			S	Unknown	20 Milligram, Qd		Macleods
	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd, Every Morning		Macleods
	Escitalopram Oxalate			S	Unknown	20 Milligram, Qd, Every Morning		Macleods
	Aripiprazole			S	Unknown	4 Milligram, Qd, Every Bedtime		Macleods
	Aripiprazole			S	Unknown	2 Milligram, Qd, Every Bedtime		Macleods
	Amfetamine/Dexamfetamine			S	Unknown	20 Milligram, Qd, Extended Release, Every Morning		Not Reported
	Amfetamine/Dexamfetamine			S	Unknown	10 Milligram, Qd, Extended Release, Every Morning		Not Reported
	Testosterone 50mg/5g			S	Topical	Unk, Qd, 50 Mg/5 G Every Morning On The Right Upper Extremity		Not Reported
	Lithium			S	Unknown	600 Milligram, Qd, Every Bedtime		Not Reported
	Lurasidone			S	Unknown	40 Milligram, Qd, After Dinner		Not Reported
	Lamotrigine			S	Unknown	150 Milligram, Qd		Not Reported

Lamotrigine	S	Unknown	100 Milligram, Qd	Not Reported
Lorazepam	S	Unknown	0.5 Milligram, Tid, Every 8 Hour, As Necessary	Not Reported
Lorazepam	S	Unknown	1 Milligram, Tid, Every 8 Hour, As Necessary	Not Reported
Bupropion	S		1.5 Milligram, Qd, Every Morning	Not Reported
Bupropion	S	Unknown	200 Milligram, Qd, Every Morning	Not Reported
Bupropion	S	Unknown	300 Milligram, Qd, Every Morning	Not Reported
Buspirone	S	Unknown	15 Milligram, Bid, Every 12 Hour	Not Reported
Buspirone	S	Unknown	15 Milligram, Tid, Every 8 Hour	Not Reported
Buspirone	S	Unknown	10 Milligram, Qd	Not Reported
Buspirone	S	Unknown	17.5 Milligram, Qd	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Qd, Every 8 Hour	Not Reported
Buspirone	S	Unknown	15 Milligram, Tid, Every 8 Hour	Not Reported
Buspirone	S	Unknown	15 Milligram, Qd	Not Reported
Buspirone	S	Unknown	2.5 Milligram, Qd	Not Reported
Buspirone	S	Unknown	22.5 Milligram, Qd	Not Reported
Buspirone	S	Unknown	5 Milligram, Qd	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Qd	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Bid	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Tid	Not Reported
Buspirone	S	Unknown	20 Milligram, Qd	Not Reported
Benztropine Mesylate	C	Unknown	0.5 Milligram, Bid, As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2018	13929999	EXPEDITED (15-DAY)		LT, OT	PL-PFIZER INC-2017377512		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Atorvastatin Calcium			S		Unk		Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Perindopril			S		Unk		Not Reported
	Tramadol Hcl			S		Unk		Not Reported
	Tramadol Hcl			S				Not Reported
	Bisoprolol			S	Oral	Unk		Not Reported
	Meloxicam			C		Unk		Not Reported
	Meloxicam			C				Not Reported
	Clarithromycin			C		Unk		Not Reported
	Doxepin			C		25 Mg, 1x/Day At Bedtime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2018	14333109	EXPEDITED (15-DAY)		OT	PL-PFIZER INC-2017370709		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Atorvastatin Calcium			S	Oral	Unk Unk, 2x/Day		Pfizer
	Sertraline Hcl			S	Oral	50 Mg, 1x/Day(In The Morning)		Pfizer
	Zolpidem Pfizer			S	Oral	10 Mg At Bedtime		Not Reported
	Zolpidem Pfizer			S				Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Before Sleeping		Not Reported
	Escitalopram Oxalate			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Doxepin			S	Oral	25 Mg, 1x/Day(At Bedtime)		Not Reported
	Doxepin			S				Not Reported
	Tramadol Hcl			S	Oral	Unk, 2x/Day		Not Reported

Tramadol Hcl	S				Not Reported
Meloxicam	S	Oral	Unk, 2x/Day		Not Reported
Clarithromycin	S	Oral	Unk, 2x/Day (Two 10 Day Courses)		Not Reported
Perindopril	C		Unk		Not Reported
Bisoprolol	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2018	14598973	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-PFIZER INC-2018084248			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Condition Aggravated; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Atorvastatin Calcium			S	Oral	Unk, 1x/Day (Bedtime)		Pfizer
	Sertraline Hcl			S	Oral	50 Mg, Od, (In The Morning), 1x/Day		Pfizer
	Sertraline Hcl			S				Pfizer
	Polsen			S	Unknown	10 Mg, Od, At Bed Time, 1x/Day		Not Reported
	Atoris			S	Unknown	Unk		Not Reported
	Clarithromycin			S	Oral	Unk (Bedtime), Two, 10-Day Treatment Cycles Courses		Not Reported
	Perindopril			S	Oral	Unk		Not Reported
	Tramadol			S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam For About Two Years Ago		Not Reported
	Tramadol			S				Not Reported
	Meloxicam			S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam, For About Two Years Ago		Not Reported
	Meloxicam			S				Not Reported
	Concor			S	Unknown	Unk		Not Reported
	Trosicam			S	Unknown	Unk		Not Reported

Escitalopram	S				Not Reported
Escitalopram	S	Oral	10 Mg, 1x/Day Hs		Not Reported
Escitalopram	S				Not Reported
Zolpidem	S	Oral	10 Mg, 1x/Day Od		Not Reported
Zolpidem	S				Not Reported
Doxepin	S	Oral	25 Mg, 1x/Day Od, At Bed Time		Not Reported
Doxepin	S				Not Reported
Doxepin	S				Not Reported
Bisoprolol	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	13512660	EXPEDITED (15-DAY)		DE, HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-139414		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Poisoning Deliberate; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Not Reported
	Paracetamol		Y	S	Oral	Unk		Ohm Lab
	Baclofen			S	Oral	Unk		Not Reported
	Baclofen			S				Not Reported
	Dextropropoxyphen			S	Oral	Unk		Not Reported
	Valpromide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	14849654	EXPEDITED (15-DAY)		DE, OT	FR-GLAXOSMITHKLINE-FR2018076854		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Ciprofloxacine			S	Intravenous drip	Unk		Glaxosmithkline
	Methotrexate			S	Intravenous drip	Unk		Glaxosmithkline
	Methotrexate			S	Intravenous drip	Unk		Glaxosmithkline
	Lidocaine			S	Other	Unk		Glaxosmithkline

Valaciclovir	S	Oral	Unk		Glaxosmithkline
Furosemide	S	Oral	Unk		Glaxosmithkline
Bactrim	S	Oral	Unk		Glaxosmithkline
Pantoprazole	S	Intravenous drip	Unk		Glaxosmithkline
Bromazepam	S	Oral	Unk		Glaxosmithkline
Escitalopram	S	Oral	Unk		Glaxosmithkline
Rituximab	S	Intravenous drip	Unk		Not Reported
Rituximab	S				Not Reported
Calciparine	S	Subcutaneous	Unk		Not Reported
Bisoprolol	S	Oral	Unk		Not Reported
Doxorubicine	S	Intravenous drip	Unk		Not Reported
Fungizone	S	Other	Unk		Not Reported
Prednisone	S	Intravenous drip	Unk		Not Reported
Zarzio	S	Subcutaneous	Unk		Not Reported
Cyclophosphamide	S		Unk		Not Reported
Exacyl	S		Unk		Not Reported
Eprex	S	Subcutaneous	Unk		Not Reported
Ondansetron	S	Oral	Unk		Not Reported
Vincristine	S	Intravenous drip	Unk		Not Reported
Hextril	S	Other	Unk		Not Reported
Meropenem	S	Intravenous drip	Unk		Not Reported
Voraxaze	S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15550551	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018193757		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Escitalopram			S	Unknown	Every Morning		Glaxosmithkline
	Escitalopram			S	Unknown	20 Mg, Qd		Glaxosmithkline

Escitalopram	S	Unknown	10 Mg, Qd	Glaxosmithkline
Escitalopram	S	Unknown	15 Mg, Qd	Glaxosmithkline
Lithium	S	Unknown	Every Bedtime	Glaxosmithkline
Lamotrigine	S	Unknown	150 Mg, Qd	Glaxosmithkline
Lamotrigine	S	Unknown	100 Mg, Qd	Glaxosmithkline
Lorazepam	S	Unknown	0.5 Mg, Unk	Glaxosmithkline
Lorazepam	S	Unknown	1 Mg, Unk	Glaxosmithkline
Bupropion	S	Unknown	150 Mg, Qd	Glaxosmithkline
Bupropion	S	Unknown	200 Mg, Qd	Glaxosmithkline
Bupropion	S	Unknown	300 Mg, Qd	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	15 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	15 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	10 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	17.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	7.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	15 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	15 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	2.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	22.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	5 Mg, Qd	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	7.5 Mg, Qd	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	7.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	7.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	20 Mg, Qd	Glaxosmithkline
Amphetamine + Dextroamphetamine	S	Unknown	Extended Release, Every Morning	Not Reported
Amphetamine + Dextroamphetamine	S	Unknown	10 Mg, Qd	Not Reported
Testosterone Gel	S	Topical	50 Mg/5 G Every Morning On The Right Upper Extremity	Not Reported

Lurasidone	S	Unknown	After Dinner		Not Reported
Aripiprazole	S	Unknown	Every Bedtime		Not Reported
Aripiprazole	S	Unknown	2 Mg, Qd		Not Reported
Benztropine Mesylate	C	Unknown	As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15581296	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US22437			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Drug Ineffective	Citalopram			S	Unknown	40 Mg, Unk		Invagen
	Citalopram			S				Invagen
	Citalopram			S				Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen
	Escitalopram			S				Invagen
	Lamotrigine			S	Unknown	100 Mg, Daily		Cipla
	Lamotrigine			S	Unknown	Unk, Dose Tapered		Cipla
	Sertraline			S	Unknown	300 Mg, Unk		Invagen
	Sertraline			S				Invagen
	Sertraline			S				Invagen
	Bupropion			S	Unknown	150 Mg, Unk		Invagen
	Bupropion			S				Invagen
	Bupropion			S				Invagen
	Venlafaxine			S	Unknown	375 Mg, Daily		Not Reported
	Venlafaxine			S				Not Reported
	Venlafaxine			S				Not Reported
	Venlafaxine			S				Not Reported
	Mirtazapine			S	Unknown	7.5 Mg, Nightly		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Nightly		Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Clonazepam			S				Not Reported
	Clonazepam			S				Not Reported
	Clonazepam			S				Not Reported
	Haloperidol /00027402/			S	Unknown	0.5 Mg, Unk		Not Reported

	Haloperidol /00027402/	S				Not Reported
	Haloperidol /00027402/	S				Not Reported
	Haloperidol /00027402/	S				Not Reported
	Junel Fe 1/20	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583391	EXPEDITED (15-DAY)		OT	FR-ABBVIE-18S-056-2541618-00		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Fenofibrate			S	Oral	67 Mg, Unk		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Irbesartan			S	Oral	75 Mg, Unk		Not Reported
	Pregabalin			S	Oral	150 Mg, Unk		Not Reported
	Bromazepam			S	Oral	18 Mg, Unk		Not Reported
	Levothyroxine Sodique			S	Oral	75 G, Unk		Not Reported
	Naproxene			S	Oral	1100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583523	NON-EXPEDITED			US-ACCORD-063139			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Sweats	Escitalopram			S		Strength: 15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583524	NON-EXPEDITED			US-ACCORD-063237		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Ineffective; Feeling Abnormal; Tachyphrenia; Wrong Technique In Product Usage Process	Escitalopram Accord			S	Oral	Strength: 10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583526	NON-EXPEDITED			US-ACCORD-064531			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Irritation; Headache	Escitalopram Accord			S		Strength: 10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583529	NON-EXPEDITED			US-ACCORD-059959		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective	Escitalopram Accord			S		Strength: 10 Mg		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583531	NON-EXPEDITED			US-ACCORD-060202		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Feeling Abnormal; Headache; Insomnia; Product Size Issue	Escitalopram			S	Oral	Strength: 20 Mg		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583532	NON-EXPEDITED			US-ACCORD-059228		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Neuralgia; Sensitisation; Withdrawal Syndrome	Escitalopram			S	Oral	Strength: 20 Mg, White Tablet With '20'		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583533	NON-EXPEDITED			US-ACCORD-061390			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Injection Site Pain; Tinnitus	Escitalopram			S		Strength: 5 Mg		Accord
	Fondaparinux Sodium Dr. Reddy'S			S		Strength: 2.5 Mg/0.5 Ml		Not Reported
	Lisinopril			C		Strength: 20 Mg		Not Reported
	Temazepam			C		Strength: 15 Mg		Not Reported
	Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583535	NON-EXPEDITED			US-ACCORD-063618		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Nightmare; Saliva Altered; Tongue Movement Disturbance	Escitalopram			S	Oral	Strength: 10 Mg		Not Reported
	Benicar			C				Not Reported
	Bystolic			C				Not Reported
	Methyldopa			C				Not Reported
	Amlodipine			C				Not Reported
	Lovaza			C				Not Reported
	Crestor			C				Not Reported
	Ergocalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583538	NON-EXPEDITED			US-ACCORD-069060			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Accord			S		Strength: 5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583539	NON-EXPEDITED			US-ACCORD-068931		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Condition Aggravated;	Escitalopram Accord			S	Oral	Strength: 20 Mg		Not Reported

Decreased Interest; Drug Ineffective; Fatigue; Nightmare; Product Physical Issue; Quality Of Life Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583540	NON-EXPEDITED			US-ACCORD-071175			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Accord			S	Oral	Strength: 20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583541	EXPEDITED (15-DAY)		OT	US-ACCORD-070105			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash Pruritic	Escitalopram			S				Not Reported
	Atorvastatin			C				Not Reported
	Fluticasone			C				Not Reported
	Levothyroxine			C				Not Reported
	Loratadine			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Nicotinamide/Pyridoxine Hydrochloride/Riboflavin/Thiamine Hydrochloride			C				Not Reported
	Ergocalciferol			C				Not Reported
	Calcium Citrate			C				Not Reported
	Walmart Miralax			C				Not Reported
	Diphenhydramine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15584095	NON-EXPEDITED		HO	US-APOTEX-2018AP024016		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Noncompliance	Escitalopram			S	Unknown	5 Mg, Daily		Apotex

	Escitalopram	S	Unknown	10 Unk, Daily	Apotex
	Escitalopram	S	Unknown	10 Unk, Daily	Apotex
	Escitalopram	S	Unknown	20 Unk, Unk	Apotex
	Haloperidol	S	Unknown	1 Mg, Q.H.S.	Apotex
	Haloperidol	S	Unknown	2 Mg, Q.H.S.	Apotex
	Haloperidol	S	Unknown	2 Mg, Unk	Apotex
	Haloperidol	S	Unknown	3 Mg, Unk	Apotex
	Carvedilol	S	Unknown	Unk	Apotex
	Glipizide	S	Unknown	Unk	Apotex
	Pantoprazole	S	Unknown	Unk	Apotex
	Potassium Chloride	S	Unknown	Unk	Apotex
	Digoxin	S	Unknown	Unk	Not Reported
	Furosemide	S	Unknown		Not Reported
	Insulin Aspart	S	Unknown		Not Reported
	Insulin Glargine	S	Unknown		Not Reported
	Metolazone	S	Unknown		Not Reported
	Rivaroxaban	S	Unknown		Not Reported
	Spironolactone	S	Unknown		Not Reported
	Trazodone	C	Unknown	25 Mg, As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15584817	EXPEDITED (15-DAY)		HO	PHHY2018IT144773		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Lorazepam			S	Oral	40 Mg, Total		Novartis
	Escitalopram Oxalate			S	Oral	14 Mg, Total		Not Reported
	Aripiprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15585160	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1851960US		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypernatraemia; Hypokalaemia; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Perindopril			S	Oral	4 Mg, Unk		Not Reported
	Lepticur			S	Oral	20 Mg, Qd		Not Reported
	Kardegic			C				Not Reported
	Lansoyl			C				Not Reported
	Vimpat			C				Not Reported
	Mag 2			C				Not Reported
	Tamsulosine			C				Not Reported
	Pravastatine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15585161	EXPEDITED (15-DAY)		DE, OT	FR-ALLERGAN-1851918US		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis; Iron Deficiency Anaemia	Escitalopram Oxalate - Bp			S	Oral	5 Gtt, Qd		Allergan
	Eliquis			S	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15585184	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1851951US		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydrocephalus; Intraventricular Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Kardegic			S	Oral	75 Mg, Qd		Not Reported
	Xarelto			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15585199	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1851961US		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Escitalopram Oxalate - Bp			S	Oral	20 Mg Daily Per Oral		Allergan
	Risedronate Sodium - Bp			S	Oral	35 Mg A Week Per Oral		Allergan
	Cacit [Calcium Carbonate]			S	Oral	500 Mg Strengh Tablet Daily Per Oral		Allergan
	Enbrel			S	Subcutaneous	50mg A Week Subcutaneously		Not Reported
	Speciafoldine			S	Oral	10 Mg A Week Per Oral		Not Reported
	Prednisone			S	Oral	4 Mg Daily Per Oral		Not Reported
	Valaciclovir			S	Oral	1000 Mg Daily Per Oral		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg A Week Subcutaneously		Not Reported
	Codeine			S	Oral	2 Dosage Forms Daily Per Oral		Not Reported
	Desloratadine			S	Oral	5 Mg Daily Per Oral		Not Reported
	Paracetamol			S	Oral	2 Dosage Forms Daily Per Oral		Not Reported
	Lisinopril Dihydrate			S	Oral	10 Mg Daily Per Oral		Not Reported
	Uvedose			S	Oral	Daily Dose Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15587897	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-07656		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Escitalopram			S	Unknown	5 Mg, Qd Every Morning		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin
	Escitalopram			S	Unknown	10 Mg, Qd, In Morning		Lupin
	Escitalopram			S	Unknown	15 Mg, Qd Every Morning		Lupin
	Testosterone			S	Topical	Unk, Qd, 50 Mg/5 G Gel, Every Morning On The Right Upper Extremity		Not Reported

Lamotrigine	S	Unknown	150 Mg, Qd	Not Reported
Lamotrigine	S	Unknown	100 Mg, Unk	Not Reported
Lorazepam	S	Unknown	0.5 Mg, Tid, As Necessary	Not Reported
Lorazepam	S	Unknown	1 Mg, Tid, As Necessary	Not Reported
Bupropion	S	Unknown	150 Mg, Qd, Every Morning	Not Reported
Bupropion	S	Unknown	200 Mg, Qd, Every Morning	Not Reported
Bupropion	S	Unknown	300 Mg, Qd, Every Morning	Not Reported
Aripiprazole	S	Unknown	4 Mg, Qd, Every Bedtime	Not Reported
Aripiprazole	S	Unknown	2 Mg, Qd, Every Bedtime	Not Reported
Amfetamine W/Dexamfetamine	S	Unknown	20 Mg, Qd, Extended Release, Every Morning	Not Reported
Amfetamine W/Dexamfetamine	S	Unknown	10 Mg, Qd, Extended Release, Every Morning	Not Reported
Lurasidone	S	Unknown	40 Mg, Qd, After Dinner	Not Reported
Lithium	S	Unknown	600 Mg, Qd Every Bedtime	Not Reported
Buspirone	S	Unknown	15 Mg, Bid	Not Reported
Buspirone	S	Unknown	15 Mg, Tid	Not Reported
Buspirone	S	Unknown	10 Mg, Qd	Not Reported
Buspirone	S	Unknown	17.5 Mg, Qd	Not Reported
Buspirone	S	Unknown	7.5 Mg, Tid	Not Reported
Buspirone	S	Unknown	15 Mg, Tid	Not Reported
Buspirone	S	Unknown	15 Mg, Qd	Not Reported
Buspirone	S	Unknown	2.5 Mg, Qd	Not Reported
Buspirone	S	Unknown	22.5 Mg, Qd	Not Reported
Buspirone	S	Unknown	5 Mg, Qd	Not Reported
Buspirone	S	Unknown	7.5 Mg, Qd	Not Reported
Buspirone	S	Unknown	7.5 Mg, Bid	Not Reported

	Buspirone	S	Unknown	7.5 Mg, Tid	Not Reported
	Buspirone	S	Unknown	20 Mg, Qd	Not Reported
	Benztropine Mesylate	C	Unknown	0.5 Mg, Bid, As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15587908	NON-EXPEDITED			US-PFIZER INC-2018443311		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Metoprolol Tartrate			S		Unk		Unknown
	Trazodone			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15588250	NON-EXPEDITED			US-JAZZ-2018-US-014379			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Fatigue; Nausea	Xyrem			S	Oral	3.75 G, Bid		Jazz
	Nuvigil			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	12809565	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2016US18971			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Panic Attack; Sleep Disorder; Suicidal Ideation	Escitalopram			S	Unknown	10 Mg, Qd		Invagen
	Escitalopram			S	Unknown	20 Mg, Qd		Invagen
	Chantix			S	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	25 Mg, Bid As Needed, Been On It For 15 Years, Tablet		Not Reported
	Metoprolol Tartrate			C	Unknown	25 Mg, Bid, Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	13297566	EXPEDITED (15-DAY)		HO, OT	ZA-CIPLA LTD.-2017ZA02470			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Hypokalaemia; Hyponatraemia	Escitalopram			S	Unknown	10 Mg, Unk		Invagen
	Amlodipine			C	Oral	Unk, Qd		Not Reported
	Lisinopril			C	Oral	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	13896520	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2017US14053			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Febrile Neutropenia; Leukopenia; Neutropenia; Treatment Noncompliance	Risperidone			S	Oral	1 Mg, Bid		Cipla
	Escitalopram			S	Unknown	20 Mg, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	14077531	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US18065			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Blood Prolactin Increased; Blood Testosterone Increased; Blunted Affect; Drug Ineffective; Gastrointestinal Disorder; Overdose; Psychotic Disorder; Suicidal Ideation	Escitalopram			S	Unknown	Unk		Invagen
	Risperidone			S	Unknown	0.5 Mg, Bid		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Fluoxetine			S	Unknown	10 Mg, Unk		Not Reported
	Aripiprazole			S	Unknown	2 Mg, Unk		Not Reported
	Lamotrigine			C	Unknown	25 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	14229556	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US10618			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Asthenopia; Balance Disorder; Constipation; Depression; Diarrhoea; Dizziness; Fatigue; Headache; Heart Rate Increased; Hyperhidrosis; Insomnia; Nausea; White Blood Cells Urine Positive	Escitalopram	S	Oral	10 Mg, Qd		Invagen
	Escitalopram	S	Oral	10 Mg, Qd		Invagen
	Aspirin /00002701/	C	Unknown	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	14662284	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2018GB11505			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral	5 Mg, Unk		Invagen
	Levonelle /00318901/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	14707758	EXPEDITED (15-DAY)		HO	AU-CIPLA (EU) LIMITED-2018AU13055			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delusion; Eczema; Emotional Distress; Eosinophil Count Decreased; Feeling Cold; Frustration Tolerance Decreased; Haemoglobin Decreased; Hallucination, Auditory; Hyperhidrosis; Intentional Self-Injury; Lymphocyte Count Decreased; Mean Cell Haemoglobin Decreased; Mental Impairment; Metamyelocyte Count Increased; Monocyte Count Decreased;	Escitalopram			S	Unknown	10 Mg, Qd (Am)		Invagen
	Escitalopram			S	Unknown	20 Mg, Qd		Invagen
	Olanzapine			S	Unknown	5 Mg, Bid		Not Reported
	Olanzapine			S	Unknown	15 Mg, Qd		Not Reported
	Clozaril			S	Oral	Unk		Not Reported
	Clozaril			S	Oral	700 Mg, Qd (Pm)		Not Reported
	Paliperidone			S	Unknown	100 Mg, Unk		Not Reported
	Paliperidone			S	Unknown	15 Mg, Unk		Not Reported
	Caltrate /00944201/			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Lurasidone			C	Unknown	Unk		Not Reported

Myelocyte Count Increased; Neutropenia; Platelet Count Increased; Thermal Burn; Tinea Infection; Vitamin B12 Deficiency; White Blood Cell Count Decreased	Metformin		C	Unknown	Unk	Not Reported
	Mirtazapine		C	Unknown	Unk	Not Reported
	Crestor		C	Unknown	Unk	Not Reported
	Zuclopenthixol		C	Unknown	Unk	Not Reported
	Calcium Carbonate		C	Unknown	Unk	Not Reported
	Rosuvastatin		C	Unknown	Unk	Not Reported
	Coloxyl /00061602/		C	Unknown	Unk	Not Reported
	Movicol		C	Unknown	Unk	Not Reported
	Vitamin B12 /00056201/		C	Unknown	Unk	Not Reported
	Senna /00142201/		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	14817776	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US16673			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State	Sertraline			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	14971876	EXPEDITED (15-DAY)		DE, OT	US-CIPLA (EU) LIMITED-2018US18515			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Appetite Disorder; Completed Suicide; Depression; Hallucination, Visual; Sleep Disorder; Treatment Noncompliance	Bupropion			S	Unknown	100 Mg, Unk		Invagen
	Bupropion			S	Unknown	300 Mg, Unk		Invagen
	Donepezil			S	Unknown	10 Mg, Unk		Cipla
	Escitalopram			S	Unknown	Unk		Invagen
	Memantin			S	Unknown	28 Mg, Unk		Not Reported
	Baby Aspirin			C	Unknown	Unk		Not Reported
	Vitamin D /00107901/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15034142	EXPEDITED (15-DAY)		DE, HO	GB-CIPLA LTD.-2018GB19108			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer Haemorrhage; Gastrointestinal Pain	Escitalopram			S	Oral	20 Mg, Per Day		Invagen
	Acetylsalicylic Acid			S	Oral	75 Mg, Per Day, Tablet		Not Reported
	Dihydrocodeine			C	Oral	120 Mg, Per Day, Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15163654	EXPEDITED (15-DAY)		DS, HO, OT	GB-CIPLA LTD.-2018GB20023			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15219924	EXPEDITED (15-DAY)		OT	DE-ALVOGEN-2018-ALVOGEN-096875		28 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Juvenile Myoclonic Epilepsy	Fluoxetine			S				Not Reported
	Bupropion			S				Not Reported
	Aripiprazole			S				Not Reported
	Amisulpride			S				Not Reported
	Olanzapine			S				Not Reported
	Quetiapine			S				Not Reported
	Duloxetine			S				Not Reported
	Clozapine			S				Not Reported
	Escitalopram			S				Not Reported
	Venlafaxine			S				Not Reported
	Risperidone			S				Not Reported
	Biperiden Hydrochloride			S				Not Reported
	Mirtazapine			S				Not Reported
	Promethazine			S				Not Reported
	Zopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15365231	EXPEDITED (15-DAY)		HO, LT, OT	JP-ACCORD-071365		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Escitalopram			S				Not Reported
	Lorazepam			S				Not Reported
	Epinephrine			S		3 l Jections		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15365587	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2018GB21092			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Libido Decreased; Sexual Dysfunction	Escitalopram			S	Oral	25 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15515932	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US22586			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Muscle Twitching	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Paxil /00500401/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15516214	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US21211			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Loss Of Weight; Back Pain; Night Sweats; Poor Quality Sleep	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15516405	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US20559			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown	20 Mg, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15582745	EXPEDITED (15-DAY)		OT	US-HETERO CORPORATE-HET2018US01216		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Escitalopram			S	Unknown	5 Mg, Qd		Hetero
	Escitalopram			S	Unknown	20 Mg, Qd		Hetero
	Escitalopram			S	Unknown	10 Mg, Qd		Hetero
	Escitalopram			S	Unknown	15 Mg, Qd		Hetero
	Lithium			S	Unknown	600 Mg, Qd		Hetero
	Aripiprazole			S	Unknown	4 Mg, Qd		Hetero
	Aripiprazole			S	Unknown	2 Mg, Qd		Hetero
	Amphetamine, Dextroamphetamine			S	Unknown	20 Mg Extended Release, Every Morning		Not Reported
	Amphetamine, Dextroamphetamine			S	Unknown	10 Mg, Qd		Not Reported
	Testosterone			S	Topical	Unk, Qd (50mg/5g)		Not Reported
	Lurasidone			S	Unknown	40 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown	150 Milligram		Not Reported
	Lamotrigine			S	Unknown	100 Milligram		Not Reported
	Lorazepam			S	Unknown	0.5 Milligram As Necessary		Not Reported
	Lorazepam			S	Unknown	1 Milligram As Necessary		Not Reported
	Bupropion			S	Unknown	150 Milligram Every		Not Reported

				Morning	
	Bupropion	S	Unknown	200 Milligram Every Morning	Not Reported
	Bupropion	S	Unknown	300 Milligram Every Morning	Not Reported
	Buspirone	S	Unknown	15 Milligram	Not Reported
	Buspirone	S	Unknown	15 Milligram	Not Reported
	Buspirone	S	Unknown	10 Milligram	Not Reported
	Buspirone	S			Not Reported
	Buspirone	S	Unknown	7.5 Milligram	Not Reported
	Buspirone	S	Unknown	15 Milligram	Not Reported
	Buspirone	S	Unknown	15 Milligram	Not Reported
	Buspirone	S	Unknown	2.5 Milligram	Not Reported
	Buspirone	S	Unknown	22.5 Milligram	Not Reported
	Buspirone	S	Unknown	5 Milligram	Not Reported
	Buspirone	S	Unknown	7.5 Milligram	Not Reported
	Buspirone	S	Unknown	7.5 Milligram	Not Reported
	Buspirone	S	Unknown	7.5 Milligram	Not Reported
	Buspirone	S	Unknown	20 Milligram	Not Reported
	Benztropine Mesylate	C	Unknown	0.5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15584996	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1851764US		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qam		Allergan
	Buspirone			S	Unknown	15 Mg, Tid		Not Reported

Buspirone	S	Unknown	7.5 Mg, Tid		Not Reported
Buspirone	S	Unknown	15 Mg, Tid		Not Reported
Buspirone	S	Unknown	7.5 Mg, Tid		Not Reported
Lorazepam	C	Unknown	0.5 Mg, Bid (As Necessary)		Not Reported
Bupropion	C	Unknown	150 Mg, Qam		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15588932	EXPEDITED (15-DAY)		CA	DE-ACCORD-090687		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram			S	Transplacental	7.5 Mg/D (Mutter) 0. - 40.3. Gestational Week		Not Reported
	Ebrantil			C	Unknown	Exposition: Paternal (Fatherroute Of Admin. Oral)		Not Reported
	Simvastatin			C	Unknown	Probably Either Simvastatin Or Atozet Exposition: Paternal (Fatherroute Of Admin. Oral)		Not Reported
	Valsartan			C	Unknown	160 Mg/D (Vater) Exposition: Paternal (Fatherroute Of Admin. Oral)		Not Reported
	Folsan			C	Transplacental	0.4 Mg/D (Mutter)		Not Reported
	Ramilich			C	Unknown	10 Mg/D (Vater)		Not Reported
	Dekristol			C	Unknown	20000 Ie/D (Alle 2 Wochen) (Vater)		Not Reported
	Paracetamol			C	Transplacental			Not Reported
	Bicanorm			C	Unknown	Exposition: Paternal (Fatherroute Of Admin. Oral)		Not Reported
	Atozet			C	Unknown	40 Mg/D / 10 Mg/D (Vater)		Not Reported

				/ Probably Either Atozet Or Simvastatin	
	Ass 100	C	Unknown	100 Mg/D (Vater)	Not Reported
	Amlodipine	C	Unknown	10 Mg/D (Vater) Exposition: Paternal (Fatherroute Of Admin. Oral)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15589283	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-972690		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Impaired Quality Of Life; Treatment Noncompliance	Escitalopram			S	Unknown	10 Milligram Daily; Every Morning		Ivax
	Gabapentin			S	Unknown	1000 Milligram Daily; Total Daily Dose		Ivax
	Nortriptyline			S	Unknown	60 Milligram Daily; Every Bedtime		Teva
	Alprazolam			S	Unknown	1 Milligram Daily; Extended Release; Total Daily Dose		Actavis
	Alprazolam			S	Unknown	Total Daily Dose (1mg-0.5mg-1mg); Extended Relaese		Actavis
	Lisdexamfetamine Dimesylate			S	Unknown	70 Milligram Daily; Every Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15589746	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-190488		45 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Blood Prolactin Increased; Dizziness;	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported

Drug Ineffective; Galactorrhoea; Hypertension; Nausea; Tachycardia; Therapy Partial Responder	Escitalopram		S	Unknown	20 Mg, Daily	Not Reported
	Sertraline		S	Unknown	50 Mg, Daily	Sun
	Sertraline		S	Unknown	200 Mg, Daily	Sun
	Sertraline		S	Unknown	250 Mg, Daily	Sun
	Sertraline		S		Dose Reduced 50 Mg/Day Each Week	Sun
	Paroxetine		S	Unknown	20 Mg, Daily	Sun
	Paroxetine		S	Unknown	30 Mg, Daily	Sun
	Citalopram		S	Unknown	20 Mg, Daily	Sun
	Citalopram		S	Unknown	60 Mg, Daily	Sun
	Risperidone		S	Unknown	1 Mg, Daily	Ranbaxy
	Venlafaxine		S	Unknown	75 Mg, Daily	Sun
	Venlafaxine		S	Unknown	150 Mg, Daily	Sun
	Venlafaxine		S	Unknown	225 Mg, Daily	Sun
	Valproic Acid		S	Unknown	1000 Mg, Daily	Sun
	Haloperidol		S	Unknown	1 Mg, Daily	Not Reported
	Venlafaxine		S	Unknown	37.5 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15590175	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2018197442		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Speciafoldine			S	Oral	10 Mg, We		Glaxosmithkline
	Valaciclovir			S	Oral	1000 Mg, Qd		Glaxosmithkline
	Codeine			S	Oral	2 Df, Qd		Glaxosmithkline
	Paracetamol			S	Oral	2 Df, Qd		Glaxosmithkline
	Uvedose			S	Oral	1 Df, Unk		Glaxosmithkline
	Escitalopram			S	Oral	20 Mg, Qd		Glaxosmithkline
	Enbrel			S	Subcutaneous	50 Mg, We		Not Reported

Prednisone	S	Oral	4 Mg, Qd		Not Reported
Methotrexate	S	Subcutaneous	20 Mg, We		Not Reported
Desloratadine	S	Oral	5 Mg, Qd		Not Reported
Lisinopril Dihydrate	S	Oral	10 Mg, Qd		Not Reported
Cacit (Calcium Carbonate) Effervescent Tablet, Unkmg	S	Oral	1 Df, Qd		Not Reported
Risedronate Monosodium	S	Oral	35 Mg, We		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15590580	EXPEDITED (15-DAY)		OT	DE-009507513-1810DEU013466			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Headache	Mirtazapine			S	Unknown	30 Mg, Unk		Merck
	Levocarb			S	Unknown	0.5 Df, Unk		Not Reported
	Escitalopram			S	Unknown	15 Mg, Qhs		Not Reported
	Aspirin			C	Unknown	100 Mg, Qd		Not Reported
	Atorvastatin			C	Unknown	300 Mg, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15591757	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram			S	Oral		2 WEEK	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15592726	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1852135US		37 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Mass; Gynaecomastia	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15593927	EXPEDITED (15-DAY)		DE, HO, LT	US-MYLANLABS-2018M1083824		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Ineffective; Overdose; Toxicity To Various Agents	Atenolol			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Norepinephrine			S	Unknown			Not Reported
	Epinephrine			S	Unknown			Not Reported
	Vasopressin			S	Unknown			Mylan
	Dopamine			S	Unknown			Mylan
	Dobutamine			S	Unknown			Mylan
	Fat Emulsion			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15594562	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1852125US		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melaena; Microcytic Anaemia	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Plavix			S	Oral	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15595061	EXPEDITED (15-DAY)		HO	PHHY2018FR147576		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Paracetamol			S	Oral	2 Df, Qd		Not Reported
	Prednisone			S	Oral	4 Mg, Qd		Novartis

Valaciclovir	S	Oral			Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Qd		Not Reported
Desloratadine	S	Oral	5 Mg, Qd		Not Reported
Lisinopril Dihydrate	S	Oral	10 Mg, Qd		Not Reported
Escitalopram	S	Oral	20 Mg, Qd		Not Reported
Codeine	S	Oral			Not Reported
Speciafoldine	S	Oral			Not Reported
Cacit [Calcium Carbonate]	S	Oral	1 Df, Qd		Not Reported
Enbrel	S	Subcutaneous			Not Reported
Uvedose	S	Oral	1 Df, Qd		Not Reported
Risedronate	S	Oral	35 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	14257731	EXPEDITED (15-DAY)		HO, OT	SI-BIOGEN-2017BI00493562		48 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Sclerosis; Palpitations	Fampyra			S	Unknown			Biogen
	Pregabalin			S	Unknown	150 Mg, Bid		Not Reported
	Escitalopram			S	Unknown	1 Tablet In Morning		Not Reported
	Tolterodine			S	Unknown	1 Tablet In Morning		Not Reported
	Fty 720			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	15298001	EXPEDITED (15-DAY)		DS, HO, LT	PT-ALLERGAN-1840382US		94 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Confusional State; Decreased Appetite; Hyponatraemia; Panic Attack; Psychomotor	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan

Hyperactivity; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	15591239	EXPEDITED (15-DAY)		OT	GB-ELI_LILLY_AND_COMPANY-GB201811001982		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Fluoxetine			S	Unknown	Unk Unk, Unknown		Not Reported
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported
	Dosulepin			S	Unknown	Unk, Unknown		Not Reported
	Lofepramine			S	Unknown	Unk, Unknown		Not Reported
	Quetiapine			C	Unknown	300 Mg, Daily		Not Reported
	Citalopram			C	Unknown	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	15593291	NON-EXPEDITED			US-OTSUKA-2017_026184			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Ineffective; Gait Disturbance; Muscle Rigidity; Musculoskeletal Stiffness	Nuedexta			S	Unknown	Unk		Avanir
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Namenda			S	Unknown	Unk		Not Reported
	Prenatal Vitamins			C	Unknown	Unk		Not Reported
	Nortriptyline			C	Unknown	2 Mg, Bid		Not Reported
	Depakote			C	Unknown	500 Mg, Bid		Not Reported
	Seroquel			C	Unknown	25 Mg, Bid		Not Reported
	Baby Aspirin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	15594350	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance	Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	15594805	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2018_035333		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Miosis; Orthostatic Hypotension; Product Use In Unapproved Indication; Somnolence	Aripiprazole			S	Oral	Unk		Otsuka
	Escitalopram			S	Oral	Unk		Not Reported
	Bromazepam			S	Oral	120 Mg, Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	15596089	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20181107344		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence; Prescription Form Tampering	Tramadol/Apap			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15178276	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2018-036405		31 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral	10 Milligram		Aurobindo
	Escitalopram			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15221684	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-010701			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Anxiety; Decreased Appetite; Depression; Fatigue; Insomnia; Mental Disorder; Nausea; Somnolence; Weight Decreased	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	4 G, First Dose		Jazz
	Xyrem			S	Oral	3.5 G, Second Dose		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Ritalin			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Ibuprofen			C				Not Reported
	Loratadine			C				Not Reported
	Tylenol Extra Strength			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15579911	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1851491US		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cerebrovascular Accident; Dysarthria; Feeling Abnormal; Hypersensitivity; Hypoaesthesia; Swelling Face	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Meloxicam			C	Oral	40 Mg, Qpm		Not Reported
	Synthroid			C	Oral	75 Mg, Qam		Not Reported
	Simvastatin			C	Oral	40 Mg, Qd (At Lunch)		Not Reported
	Mobic			C	Unknown	Unk		Not Reported
	Allegra			C	Oral	Unk		Not Reported
	Triamterene			C	Oral	37.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15598376	EXPEDITED (15-DAY)		HO	FR-SANIK-2018SA303414AA		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melaena; Microcytic Anaemia	Plavix			S	Oral	75 Mg, Qd		Sanofi
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15598444	EXPEDITED (15-DAY)		HO	ZA-MYLANLABS-2018M1073989			Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Lumbar Vertebral Fracture	Mylan Pantoprazole 40 Mg			S		Unk		Mylan
	Bilocor			S		Unk		Mylan
	Co-Diovan			S		Unk		Mylan
	Lexamil			S		Unk		Mylan
	Amloc /00550802/			S		Unk		Mylan
	Celebrex			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15599952	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-053957		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Prednisone			S	Oral	4 Milligram, Once A Day		Aurobindo
	Valaciclovir			S	Oral	1000 Milligram, Once A Day		Aurobindo
	Desloratadine			S	Oral	5 Milligram, Once A Day		Not Reported
	Paracetamol			S	Oral	2 Dosage Form, Once A Day		Aurobindo
	Lisinopril			S	Oral	10 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Risedronate			S	Oral	35 Milligram Weekly		Aurobindo
	Enbrel			S	Subcutaneous	50 Milligram Weekly		Not Reported
	Speciafoldine			S	Oral	10 Milligram Weekly		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram Weekly		Not Reported
	Codeine			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Uvedose			S	Oral	1 Dosage Form 1		Not Reported

	Cacit /07357001/	S	Oral	Trimester 1 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15599960	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-053959		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypernatraemia; Hypokalaemia; Urinary Retention	Perindopril			S	Oral	4 Milligram, Once A Day		Aurobindo
	Lepticur			S	Oral	20 Milligram, Once A Day		Not Reported
	Seroplex			S	Oral	10 Milligram, Once A Day		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported
	Lansoyl			C	Unknown	Unk		Not Reported
	Vimpat			C	Unknown	Unk		Not Reported
	Mag 2 /00454301/			C	Unknown	Unk		Not Reported
	Tamsulosine /01280301/			C	Unknown	Unk		Not Reported
	Pravastatin /00880402/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	14915957	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1826729US		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Aggregation Inhibition	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Heparin			S	Subcutaneous	5000 Units, Q12h		Not Reported
	Rivaroxaban			S	Oral	Unk		Not Reported
	Rivaroxaban			S	Oral	Unk		Not Reported
	Rivaroxaban			S	Oral	15 Mg, Qd		Not Reported
	Lidocaine 2%			C	Unknown	A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 Mg/Ml		Not Reported

	Hydromorphone	C	Unknown	10 Mg/Ml Was Initiated During The Procedure And Maintained At 6 Ml/H, Infusion	Not Reported
	Epinephrine	C	Unknown	A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 Mg/Ml	Not Reported
	Bupivacaine	C	Unknown	1 Mg/Ml, Infusion	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15599989	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-054080		56 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hyperhidrosis; Tachycardia; Toxicity To Various Agents; Tremor	Metoprolol			S	Oral	Unk		Aurobindo
	Escitalopram Doc			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15600200	EXPEDITED (15-DAY)		DS	IT-TEVA-2018-IT-973729		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depressed Mood; Insomnia	Risperidone			S	Oral			Pliva
	Rivotril			S	Oral	30 Gtt Daily;		Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15600331	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2018-053935		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydrocephalus; Intraventricular Haemorrhage	Escitalopram			S	Oral	5 Milligram, Once A Day		Aurobindo
	Kardegic			S	Oral	75 Milligram, Once A Day		Not Reported
	Xarelto			S	Oral	20 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15600415	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2018-054431		82 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Alendronic Acid			S	Oral	1 Week		Aurobindo
	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Acetylsalicylic Acid			S	Oral	75 Milligram, Once A Day		Not Reported
	Felodipine			C	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported
	Adcal D3			C	Unknown	Unk		Not Reported
	Doxazosin			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Seretide			C	Unknown	Unk		Not Reported
	Dymista			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Ferrous Fumarate			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15601306	EXPEDITED (15-DAY)		HO, OT	FR-AMGEN-FRASP2018159281		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Amgen
	Methotrexate			S	Subcutaneous	20 Mg, Weekly		Not Reported
	Speciafoldine			S	Oral	10 Mg, Weekly		Not Reported
	Prednisone			S	Oral	4 Mg, 1x/Day		Not Reported
	Valaciclovir			S	Oral	1000 Mg, 1x/Day		Not Reported

Codeine	S	Oral	2 Df, 1x/Day		Not Reported
Desloratadine	S	Oral	5 Mg, 1x/Day		Not Reported
Paracetamol	S	Oral	2 Df, 1x/Day		Not Reported
Lisinopril Dihydrate	S	Oral	10 Mg, 1x/Day		Not Reported
Uvedose	S	Oral	1 Df, Every One Trimester (Oral Solution In Ampoule)		Not Reported
Escitalopram	S	Oral	20 Mg, 1x/Day		Not Reported
Cacit [Calcium Carbonate]	S	Oral	1 Df, 1x/Day		Not Reported
Risedronate Sodium	S	Oral	35 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15601741	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1852664US		28 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Bruxism; Chills; Condition Aggravated; Depression; Gastrooesophageal Reflux Disease; Hot Flush; Loss Of Libido; Migraine; Neuralgia; Palpitations; Paraesthesia; Suicidal Ideation; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Olanzapine			S	Unknown	Unk		Not Reported
	Zoloft			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15601742	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1852401US		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Kardegic			S	Oral	160 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15602065	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018457524		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Lorazepam			S	Oral	40 Mg, Total		Pfizer
	Escitalopram Oxalate			S	Oral	14 Df, Total		Not Reported
	Aripiprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15602991	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20181110885		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haemorrhage; Drug Interaction; Prescription Drug Used Without A Prescription; Serotonin Syndrome	Tramadol Hydrochloride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15603345	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1843095US		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Suicide Attempt	Escitalopram Oxalate Unk			S	Oral	15 Ml, In Total		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15603661	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1852699US		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Intentional Self-Injury; Nausea; Vomiting	Escitalopram Oxalate Unk			S	Oral	7.5 Ml, In Total		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15603664	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1852721US		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Escitalopram Oxalate - Bp		S	Oral	Unk	Allergan
	Aripiprazole		S	Oral	Unk	Not Reported
	Bromazepam		S	Oral	120 Mg, Unk	Not Reported
	Zolpidem		S	Oral	Unk	Not Reported
	Olanzapine		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	14901778	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2018192483		48 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Solanax 0.4mg			S	Oral	0.4 Mg, As Needed		Pfizer
	Brotizolam			S	Oral	1 Df, 1x/Day		Not Reported
	Lexapro			S	Oral	1 Df, 1x/Day		Not Reported
	Calcitriol			C	Oral	1 Df, 2x/Day		Not Reported
	Ternelin			C	Oral	1 Df, 3x/Day		Not Reported
	Loxoprofen Na			C	Oral	1 Df, 3x/Day		Not Reported
	Tsumura Hochuekkito			C	Oral	1 Df, 2x/Day		Not Reported
	Divigel			C	Topical	1 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15274243	EXPEDITED (15-DAY)		DS, HO, LT	PT-AUROBINDO-AUR-APL-2018-041008		94 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Confusional State; Decreased Appetite; Hyponatraemia; Panic Attack; Psychomotor Hyperactivity; Vomiting	Escitalopram Film-Coated Tablets			S	Oral	1 Dosage Form, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15605839	EXPEDITED (15-DAY)		HO, OT	GB-MACLEODS			Unknown	GBR

PHARMACEUTICALS US LTD-MAC2018018555

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Escitalopram			S	Oral	20 Milligram, Qd		Macleods
	Aspirin			S	Oral	75 Milligram, Qd		Not Reported
	Alendronic Acid			S	Oral	70 Milligram, Q.W.		Not Reported
	L-Thyroxine Sodium			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Macleods
	Adcal-D3			C	Unknown	Unk		Not Reported
	Doxazosin			C	Unknown	Unk		Not Reported
	Dymista			C	Unknown	Unk		Not Reported
	Felodipine			C	Unknown	Unk		Not Reported
	Ferrous Fumarate			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown			Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Seretide			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15605840	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018017715			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Foetal Exposure During Pregnancy; Pregnancy	Candesartan			S	Oral	16 Mg, Qd (0-4.4 Gestational Week)		Macleods
	Escitalopram			S	Oral	220 Mg, Qd (4.4-11.5 Gestational Week)		Macleods

Escitalopram	S	Oral	20 Milligram, Qd		Macleods
Levetiracetam	S	Oral	1500 Mg, Qd		Not Reported
Nepresol (Dihydralazine Sulfate)	S	Oral	25 Mg, Qd		Not Reported
Paroxetine	S	Oral	30 Mg, Qd (0-4.4 Gestational Week)		Not Reported
Paroxetine	S	Oral	30 Mg, Qd (0-4.4 Gestational Week)		Not Reported
L-Thyroxine Sodium	C	Oral	Unk (0-11.5 Gestational Week)		Not Reported
Cytotec	C	Unknown	Unk (11-11.5 Gestational Week)		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15606125	EXPEDITED (15-DAY)		HO	GB-TORRENT-00019425		82 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Felodipine			C		Unknown		Unknown
	Levothyroxine			C				Unknown
	Adcal-D3			C				Unknown
	Doxazosin			C		Unknown		Unknown
	Alendronic Acid			S	Oral	Unknown		Unknown
	Simvastatin			C		Unknown		Unknown
	Salbutamol			C		Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown
	Seretide			C		Unknown		Unknown
	Dymista			C		Unknown		Unknown
	Montelukast			C		Unknown		Unknown
	Gabapentin			C		Unknown		Unknown
	Ferrous Fumarate			C		Unknown		Unknown
	Zopiclone			C		Unknown		Unknown

	Acetylsalicylic Acid	S	Oral	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15606730	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1852707US		44 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence; Prescription Form Tampering	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
	Seresta			S	Unknown	Unk		Not Reported
	Lysanxia			S	Unknown	Unk		Not Reported
	Xanax			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15607039	EXPEDITED (15-DAY)		HO, OT	BE-APOTEX-2018AP024298		25 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hospitalisation; Lactation Disorder; Live Birth; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Escitalopram			S	Oral	20 Mg, Unk		Apotex
	Aripiprazole			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15608477	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMPANY-FR201811000224		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Olanzapine			S	Oral	Unk Unk, Unknown		Eli Lilly And Co
	Escitalopram			S	Oral	Dose Exacte Lors De L'Imv Inconnue		Not Reported
	Bromazepam			S	Oral	120 Mg, Unknown		Not Reported
	Aripiprazole			S	Oral	Unk Unk, Unknown		Not Reported

	Zolpidem	S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15609431	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2018M1084874		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 [Mg/D]/ Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D		Not Reported
	Folio /07351001/			C	Transplacental	0.4 [Mg/D]		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	14779251	EXPEDITED (15-DAY)		HO, LT, OT	ES-APOTEX-2018AP010993		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypomagnesaemia; Myocardial Ischaemia; Tachycardia; Torsade De Pointes	Escitalopram			S	Unknown	15 Mg, Daily		Apotex
	Pantoprazole			S	Unknown	Unk		Apotex
	Haloperidol			S	Unknown	2 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15366177	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1066275		45 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety Disorder; Discomfort; Feeling Abnormal; Malaise; Nervousness; Psychomotor Hyperactivity; Stress; Tension Headache; Therapeutic Product Effect	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Amlodipin /00972401/			C	Unknown	10 Mg, Qd		Mylan

Incomplete

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15515899	EXPEDITED (15-DAY)		DS, OT	IT-AUROBINDO-AUR-APL-2018-050606		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder	Escitalopram			S	Oral	5 Gtt, Daily		Aurobindo
	Risperidone			S	Oral	1 Milligram, Daily		Aurobindo
	Depakin			C	Oral	100 Milligram, Daily		Not Reported
	Rivotril			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15558915	EXPEDITED (15-DAY)		CA, DE	DE-UCBSA-2018046834			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 Mg, Once Daily (Qd)		Ucb
	Nepresol (Dihydralazine Mesilate)			S	Transplacental	25 Mg, Once Daily (Qd)		Not Reported
	Escitalopram			S	Transplacental	20 Mg, Once Daily (Qd)		Not Reported
	Candesartan			S	Transplacental	16 Mg, Once Daily (Qd)		Not Reported
	Paroxetin			S	Transplacental	30 Mg, Once Daily (Qd)		Not Reported
	L-Thyroxin			C	Transplacental	Unk		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported
	Folic Acid			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15560088	EXPEDITED (15-DAY)		OT	DE-UCBSA-2018048184		38 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Off Label Use; Pregnancy	Levetiracetam			S	Oral	1500 Mg, Once Daily (Qd)		Ucb
	Nepresol (Dihydralazine Sulfate)			S	Oral	25 Mg, Once Daily (Qd)		Not Reported

	Escitalopram	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
	Candesartan	S	Oral	16 Mg, Once Daily (Qd)	Not Reported
	Paroxetin	S	Oral	30 Mg, Once Daily (Qd)	Not Reported
	L-Thyroxin	C	Oral		Not Reported
	Cytotec	C			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15566253	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP020302			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Tramadol/Acetaminophen			S	Unknown	1 Df, Tid		Apotex
	Paracetamol			S	Unknown	1 Df, Tid		Apotex
	Amlodipine			S	Unknown	1 Df, Qd		Apotex
	Omeprazole			S	Unknown	1 Dosage Forms Daily; 20 Mg		Apotex
	Simvastatin			S	Unknown	1 Dosage Forms Daily; 40 Mg		Not Reported
	Simvastatin			S	Unknown	20 Mg, Unk		Not Reported
	Simvastatin			S	Unknown	20 Mg, Unk		Not Reported
	Enalapril /Hydrochlorothiazide			S	Unknown	1 Dosage Forms Daily; 1 Df = 20/12.5 Mg		Apotex
	Escitalopram			S	Unknown	1 Dosage Forms Daily; 10 Mg		Apotex
	Diazepam			S	Unknown	.5 Dosage Forms Daily; 5 Mg		Not Reported
	Topiramate			S	Unknown	0.5 Df, Qd		Apotex
	Topiramate			S	Unknown	1 Dosage Forms Daily; 50 Mg		Apotex
	Naproxen			S	Unknown	1 Df, Bid		Not Reported
	Amitriptyline			S	Unknown	Qd		Not Reported
	Amitriptyline			S	Unknown	12.5 Mg, Qd		Not Reported

	Amitriptyline	S	Unknown	25 Milligram Daily;		Not Reported
	Amitriptyline	S	Unknown	25 Milligram Daily;		Not Reported
	Glibenclamida	S	Unknown	2 Dosage Forms Daily;		Not Reported
	Tepazepam	S	Unknown	Qd		Not Reported
	Lormetazepam	S	Unknown	1 Df, Qd		Not Reported
	Topiramato	S	Unknown	0.5 Df, Qd		Not Reported
	Metoclopramide	C	Unknown	1 Week Treatment		Not Reported
	Metoclopramide	C	Unknown	1 Week Treatment		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15572709	EXPEDITED (15-DAY)			IT-ALLERGAN-1851569US		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Sertraline			S	Unknown	50 Mg, Qd		Not Reported
	Sertraline			S	Unknown	200 Mg, Qd		Not Reported
	Valproic Acid			S	Unknown	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Venlafaxin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15609991	EXPEDITED (15-DAY)		OT	DK-MACLEODS PHARMACEUTICALS US LTD-MAC2018018593			Unknown	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bile Acid Malabsorption	Venlafaxine			S	Unknown	225 Milligram, Qd		Macleods
	Escitalopram Oxalate			S	Unknown	40 Milligram, Qd		Macleods
	6-Mercaptopurine			C	Unknown	Unk		Not Reported
	Colesevelam			C	Unknown	625 Milligram, Tid		Not Reported

	Loperamide	C	Unknown	Unk, 2-8 Milligram Qd	Not Reported
	Levetiracetam	C	Unknown	Unk	Not Reported
	Lamotrigine	C	Unknown	400 Milligram, Qd	Not Reported
	Infliximab	C	Unknown	Unk	Not Reported
	Adalimumab	C			Not Reported
	Natalizumab	C	Unknown	Unk	Not Reported
	Vedolizumab	C	Unknown	Unk	Not Reported
	Vancomycin	C	Unknown	125 Milligram Four Times Per Day	Not Reported
	Spironolactone	C	Unknown	Unk	Not Reported
	Octreotide	C	Unknown	Unk	Not Reported
	Liraglutide	C	Unknown	Unk	Not Reported
	Potassium	C	Unknown	100 Millimole	Not Reported
	Sodium Chloride	C	Unknown	2000 Ml Of 3% Sodium Chloride	Not Reported
	Ibuprofen	C	Unknown	400 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15611369	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-190791		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	In Total		Not Reported
	Lorazepam			S	Oral	In Total		Sun
	Aripiprazole			C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15611488	EXPEDITED (15-DAY)		HO	FR-ZYDUS-029622		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Aripiprazole	S	Oral	Zydus Pharm
	Escitalopram	S	Oral	Zydus Pharm
	Olanzapine	S	Oral	Zydus Pharm
	Bromazepam	S	Oral	Not Reported
	Zolpidem	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15611530	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-054551		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Aripiprazole			S	Oral	Exact Dose At Unknown Imv, Unk		Aurobindo
	Bromazepam			S	Oral	Estimated Dose Of 20 Cp Bromazepam 6 Mg, Unk		Not Reported
	Escitalopram			S	Oral	Exact Dose At Unknown Imv ()		Aurobindo
	Olanzapine			S	Oral	Exact Dose At Unknown Imv, Unk		Aurobindo
	Zolpidem			S	Oral	Exact Dose At Unknown Imv, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15612092	EXPEDITED (15-DAY)		HO	GB-009507513-1811GBR003175		82 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Alendronate Sodium			S	Oral	70 Milligram, Qw		Merck
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Aspirin			S	Oral	75 Milligram, Qd		Not Reported
	Felodipine			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Adcal-D3			C				Not Reported
	Doxazosin			C				Not Reported
	Simvastatin			C				Not Reported

	Albuterol	C	Not Reported
	Seretide	C	Not Reported
	Dymista	C	Not Reported
	Montelukast	C	Not Reported
	Gabapentin	C	Not Reported
	Ferrous Fumarate	C	Not Reported
	Zopiclone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15612688	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20181114285		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Tramadol/Paracetamol			S	Oral			Not Reported
	Coaprovel			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15612735	EXPEDITED (15-DAY)		DE	FR-TEVA-2018-FR-974914		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydrocephalus; Intraventricular Haemorrhage	Escitalopram			S	Oral	5 Milligram Daily;		Ivax
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	75 Milligram Daily;		Not Reported
	Xarelto 20 Mg, Comprimé Pelliculé			S	Oral	20 Milligram Daily; 20 Mg/J		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15613543	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1085907		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Impaired Gastric Emptying;	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15613747	EXPEDITED (15-DAY)		DE	NO-PURDUE-GBR-2018-0061540		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Medication Error; Overdose	Tramadol Hydrochloride			S	Unknown	Unk		Purdue
	Oxynorm			S	Unknown	Unk		Purdue
	Vival			S	Unknown	Unk		Not Reported
	Seroquel			S	Unknown	Unk		Not Reported
	Cipralex			S	Unknown	Unk		Not Reported
	Nozinan /00038601/			S	Unknown	Unk		Not Reported
	Remeron			S	Unknown	Unk		Not Reported
	Catapresan /00171101/			S	Unknown	Unk		Not Reported
	Atarax /00058401/			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Orfiril			S	Unknown	Unk		Not Reported
	Nobligan			S	Unknown	Unk		Not Reported
	Pinex Forte			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Sarotex			S	Unknown	Unk		Not Reported
	Imovane			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15613818	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC-2018464538		81 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Renal Failure	Methotrexate			S		2.5 Mg, Unk		Pfizer
	Premarin			S		0.625 Mg, Unk		Pfizer
	Puricos			S		300 Mg, Unk		Not Reported

Nivaquine [Chloroquine]	S	200 Mg, Unk	Not Reported
Spiractin (Spironolactone)	S	25 Mg, Unk	Not Reported
Carloc	S	6.25 Mg, Unk	Not Reported
Be-Tabs Folic Acid	S	5 Mg, Unk	Not Reported
Puresis	S	40 Mg, Unk	Not Reported
Slow Mag [Magnesium Chloride]	S	535 Mg, Unk	Not Reported
Allecet [Cetirizine Hydrochloride]	S	10 Mg, Unk	Not Reported
Eltroxin	S	100 Ug, Unk	Not Reported
Nexomist	S	150 Ug, Unk	Not Reported
Citraz	S	20 Mg, Unk	Not Reported
Proben [Ketoprofen]	S	500 Mg, Unk	Not Reported
Aspirin [Acetylsalicylic Acid]	S	80 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15632336	DIRECT					33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Increased Appetite; Insomnia; Irritability; Lack Of Satiety; Tremor; Weight Increased	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Zyrtec			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	12539614	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-119590		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose;	Escitalopram			S	Oral	840 Mg		Not Reported
	Venlafaxine			S	Oral	7875 Mg		Sun
	Bromazepam			S	Oral	180 Mg		Not Reported

Nystagmus; Psychomotor Skills Impaired; Suicide Attempt; Toxicity To Various Agents; Toxicity To Various Agents	Lormetazepam		S	Oral	14 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	14246042	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21762			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Estradiol			S	Oral	Unk		Not Reported
	Paracetamol + Difenhydramina Hasco Noc			S	Oral	Unk		Not Reported
	Paracetamol/Codeine			S	Oral	Unk		Not Reported
	Oxycodone			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Thiazide			S	Oral	Unk		Not Reported
	Progestin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15203919	EXPEDITED (15-DAY)		DS, HO, OT	GB-TEVA-2018-GB-931372		31 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15330467	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-APOTEX-2018AP019342		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Condition Aggravated;	Clarithromycin			S	Oral	Unk, Qd, Two 10 Day Courses		Apotex

Depression; Drug Abuse; Drug Ineffective; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Clarithromycin	S			Apotex
	Escitalopram	S	Oral	10 Mg, Qd	Apotex
	Escitalopram	S			Apotex
	Escitalopram	S			Apotex
	Sertraline	S	Oral	50 Mg, Qd Am (In The Morning)	Apotex
	Sertraline	S			Apotex
	Perindopril	S	Oral	Unk	Apotex
	Perindopril	S			Apotex
	Atorvastatin	S	Oral	Unk, Qd (Bedtime)	Apotex
	Zolpidem	S	Oral	10 Mg, Qd At Bedtime	Apotex
	Zolpidem	S			Apotex
	Meloxicam	S	Oral	Unk, Qd	Apotex
	Atoris	S	Unknown	Unk	Not Reported
	Tramadol	S	Oral	Unk, Qd	Not Reported
	Tramadol	S			Not Reported
	Concor	S	Unknown	Unk	Not Reported
	Polsen	S	Unknown	10 Mg At Bedtime	Not Reported
	Trosicam	S	Unknown	Unk	Not Reported
	Trosicam	S	Unknown	Unk	Not Reported
	Doxepin	S	Oral	25 Mg Qd At Bedtime	Not Reported
	Doxepin	S			Not Reported
	Doxepin	S			Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Perindopril	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15591094	NON-EXPEDITED			US-PFIZER INC-2018447126			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Bronchitis; Emotional Distress;	Chantix			S		Unk (Only Taken One Pill)		Pfizer

Hypertension	Xanax	S	Unk		Pfizer
	Lexapro	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15595765	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-972992		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Escitalopram Oxalate - Bp			S	Oral	20 Milligram Daily;		Ivax
	Risedronate Sodium - Bp			S	Oral			Not Reported
	Prednisone			S	Oral	4 Daily;		Not Reported
	Valaciclovir			S	Oral	1000 Milligram Daily;		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Cacit 500 Mg, Comprimé Effervescent			S	Oral	1 Dosage Forms Daily;		Not Reported
	Desloratadine			S	Oral	5 Milligram Daily;		Not Reported
	Paracetamol			S	Oral	2 Dosage Forms Daily;		Not Reported
	Lisinopril Dihydrate			S	Oral	10 Milligram Daily;		Ivax
	Codeine			S	Oral	2 Dosage Forms Daily;		Not Reported
	Speciafoldine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Uvedose 100 000 Ui, Solution Buvable En Ampoule			S	Oral	Daily Dose Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15614863	EXPEDITED (15-DAY)		OT	GB-TORRENT-00003877		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Quetiapine			S		Unknown		Unknown
	Citalopram			C		Unknown		Unknown
	Escitalopram			S		Unknown		Unknown
	Dosulepin			S		Unknown		Unknown

	Fluoxetine	S	Unknown	Unknown
	Lofepramine	S	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15615020	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP024228		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Escitalopram			S	Unknown	15 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15615328	EXPEDITED (15-DAY)		OT	PT-LUPIN PHARMACEUTICALS INC.-2018-07799		27 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia; Gait Disturbance; Pain	Escitalopram			S	Unknown	20 Mg, Unk		Lupin
	Escitalopram			S				Lupin
	Insulin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15615678	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-029720		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Toxicity To Various Agents	Atenolol			S	Oral			Zydus Pharm
	Escitalopram			S	Oral			Zydus Pharm
	Lisinopril			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Trazodone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15615955	EXPEDITED (15-DAY)		HO	FR-ALVOGEN-2018-ALVOGEN-097744		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Lisinopril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Valaciclovir			S	Oral			Not Reported
	Codeine			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Risedronic Acid			S	Oral			Not Reported
	Desloratadine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Folic Acid			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Colecalciferol			S	Oral			Not Reported
	Calcium Carbonate/Citric Acid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15618833	EXPEDITED (15-DAY)		HO	PHHY2018FR152894		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Zolpidem			S	Oral	Unk		Novartis
	Olanzapine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Bromazepam			S	Oral	120 Mg, Unk		Not Reported
	Aripiprazole			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15448165	EXPEDITED (15-DAY)		HO, LT, OT	US-ALEMBIC PHARMACUETICALS LIMITED-2018SCAL000697			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Distress Syndrome; Agitation; Bundle Branch Block Left; Clonus; Electrocardiogram Qrs Complex Prolonged; Hyperreflexia; Hyporesponsive To Stimuli; Muscle Rigidity; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Tachycardia; Toxicity To Various Agents	Lamotrigine	S	100 Mg Tablets	Alembic
	Escitalopram	S	20 Mg Tablet	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15619679	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-07747		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	10 Mg, Qd		Lupin
	Blisovi Fe 1/20			C	Unknown	Unk		Not Reported
	Lamictal			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15619757	EXPEDITED (15-DAY)		HO	FR-ACCORD-091946		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Methotrexate			S	Subcutaneous			Accord
	Paracetamol			S	Oral			Accord
	Lisinopril			S	Oral			Accord
	Escitalopram			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported

	Prednisone	S	Oral	Not Reported
	Valaciclovir	S	Oral	Not Reported
	Codeine	S	Oral	Not Reported
	Desloratadine	S	Oral	Not Reported
	Colecalciferol	S	Oral	Not Reported
	Calcium Carbonate	S	Oral	Not Reported
	Risedronic Acid	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15619846	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-975361		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram Oxalate			S	Oral			Ivax
	Lorazepam			S	Oral			Actavis
	Aripiprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15619935	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2018-US-975287		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Toxicity To Various Agents	Atenolol			S	Oral			Not Reported
	Lisinopril			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Clonazepam			S	Oral			Teva
	Trazodone			S	Oral			Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15619985	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US22563			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Treatment Failure	Sertraline		S	Unknown	Unk	Invagen
	Escitalopram		S	Unknown	Unk	Invagen
	Fluoxetine		S	Unknown	Unk	Not Reported
	Risperidone		S	Unknown	Unk	Not Reported
	Aripiprazole		S	Unknown	Unk	Not Reported
	Ziprasidone		S	Unknown	Unk	Not Reported
	Methylphenidate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15620588	NON-EXPEDITED			US-BAUSCH-BL-2017-029863		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Hypoaesthesia; Paraesthesia	Ativan			S	Oral	0.25mg At Noon And 0.25mg At 10pm		Not Reported
	Ativan			S				Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15621176	EXPEDITED (15-DAY)		OT	PHHY2018GR151230		86 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Inadequately Controlled	Exforge			S	Unknown			Novartis
	Seropram (Escitalopram Oxalate)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15621964	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1085993		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperleukocytosis; Pancreatitis; Renal Failure; Toxicity To	Escitalopram			S	Oral	140 Mg, Unk		Not Reported
	Ibuprofen			S	Oral	6 G, Unk		Not Reported

Various Agents	Paracetamol	S		8.8 G, Unk	Not Reported
	Atarax /00058401/	S	Oral	750 Mg, Unk	Mylan
	Coltramyl	S	Oral	48 Mg, Unk	Mylan
	Cefuroxime	C	Oral	Unk	Mylan
	Brexin /00500404/	C	Oral	20 Mg, Unk	Mylan
	Alprazolam	C	Oral	5 Mg, Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15622038	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018462735		44 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence; Prescription Form Tampering	Xanax			S	Unknown	0.25 Mg, Unk		Pfizer
	Seresta			S	Unknown	50 Mg, Unk		Not Reported
	Lysanxia			S	Unknown	10 Mg, Unk		Not Reported
	Seroplex			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15622245	NON-EXPEDITED			US-TEVA-2018-US-973290			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15623479	EXPEDITED (15-DAY)		OT	NO-ALLERGAN-1853499US		18 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Dyspepsia; Dyspepsia; Headache; Hypersensitivity; Insomnia; Muscle Spasms; Myalgia; Nausea; Palpitations;	Escitalopram Oxalate - Bp			S		20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

Panic Attack; Tic;
Ventricular Extrasystoles

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	9536493	EXPEDITED (15-DAY)		DE, HO, OT	FR-ASTELLAS-2013US009607		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blister; Eschar; Graft Versus Host Disease In Gastrointestinal Tract; Haematuria; Hepatitis Fulminant; Mucosal Erosion; Multiple Organ Dysfunction Syndrome; Oedema; Skin Erosion; Skin Lesion; Toxic Epidermal Necrolysis	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)			Astellas
	Fortum /00559702/			S	Unknown			Not Reported
	Flagyl /00012501/			S	Oral			Not Reported
	Gentamicine Panpharma			S	Intravenous (not otherwise specified)			Not Reported
	Noxafil			S	Oral			Not Reported
	Cancidas			S	Intravenous (not otherwise specified)			Not Reported
	Bactrim			S	Intravenous (not otherwise specified)			Not Reported
	Folinic Acid			S	Intravenous (not otherwise specified)			Not Reported
	Zelitrex			S	Intravenous (not otherwise specified)			Not Reported
	Cymevan			S	Intravenous (not otherwise specified)			Not Reported
	Foscavir			S	Intravenous (not otherwise specified)			Not Reported
	Clairyg			S	Intravenous (not otherwise specified)			Not Reported
	Granocyte			S	Intravenous (not otherwise specified)			Not Reported
	Heparin Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Inexium /01479302/			S	Intravenous (not otherwise specified)			Not Reported

Spasfon /00765801/	S	Intravenous (not otherwise specified)		Not Reported
Delursan	S	Oral		Not Reported
Defibrotide	S	Intravenous (not otherwise specified)		Not Reported
Largactil /00011901/	S	Intravenous (not otherwise specified)		Not Reported
Tranxene	S	Oral		Not Reported
Oxynorm	S	Intravenous (not otherwise specified)		Not Reported
Exacyl	S	Intravenous (not otherwise specified)		Not Reported
Perfalgan	S	Intravenous (not otherwise specified)		Not Reported
Solumedrol	S	Intravenous (not otherwise specified)		Not Reported
Droleptan	S	Intravenous (not otherwise specified)	0.625 Mg, 4 Times Daily	Not Reported
Ultiva	S	Intravenous (not otherwise specified)		Not Reported
Atarax /00058401/	S	Oral		Not Reported
Lasilix /00032601/	S	Intravenous (not otherwise specified)		Not Reported
Noctamide	S	Unknown		Not Reported
Seroplex	S	Oral		Not Reported
Ceris	S	Oral		Not Reported
Colistine	C	Unknown		Not Reported
Vancomycine Mylan	C	Unknown		Not Reported
Ciflox /00697201/	C	Unknown		Not Reported
Triflucan	C	Unknown		Not Reported
Zovirax /00587301/	C	Unknown		Not Reported
Elvorine	C	Unknown		Not Reported

	Sandimmune	C	Unknown	Not Reported
	Mopral /00661201/	C	Unknown	Not Reported
	Ogastoro	C	Unknown	Not Reported
	Gelox	C	Unknown	Not Reported
	Smecta /00837601/	C	Unknown	Not Reported
	Luteran	C	Unknown	Not Reported
	Lexomil	C	Unknown	Not Reported
	Zophren /00955301/	C	Unknown	Not Reported
	Primperan	C	Unknown	Not Reported
	Acupan	C	Unknown	Not Reported
	Tiorfan	C	Unknown	Not Reported
	Levocarnil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15623938	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-190777		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Risedronate			S	Oral	35 Mg, Daily		Sun
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported
	Lisinopril			S	Oral	10 Mg, Daily		Sun
	Desloratadine			S	Oral	5 Mg, Daily		Sun
	Paracetamol			S	Oral	2 Df, Daily		Ohm Lab
	Valaciclovir			S	Oral	1000 Mg, Daily		Sun
	Enbrel			S	Subcutaneous			Not Reported
	Speciafoldine			S	Oral	10 Mg, 1/Week		Not Reported
	Prednisone			S	Oral	4 Mg, Daily		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Daily		Not Reported
	Codeine			S	Oral	2 Df, Daily		Not Reported

	Uvedose	S	Oral		Not Reported
	Cacit [Calcium Carbonate]	S	Oral	1 Df, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624688	NON-EXPEDITED			IN-ALKEM LABORATORIES LIMITED-IN-ALKEM-2018-06357		33 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sleep-Related Event; Aggression; Depressive Symptom; Derealisation; Drug Intolerance; Economic Problem; Inappropriate Affect; Psychomotor Hyperactivity; Sedation Complication	Escitalopram			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Alkem
	Quetiapine Fumarate			S	Unknown	Unk		Alkem
	Lithium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15625603	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2016GB00691			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Escitalopram			S	Unknown	Unk		Invagen
	Fluoxetine			S	Unknown	Unk		Not Reported
	Dosulepin			S	Unknown	Unk		Not Reported
	Quetiapine			S	Unknown	300 Mg, Per Day		Not Reported
	Lofepramine			S	Unknown	Unk		Not Reported
	Citalopram			C	Unknown	20 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15626389	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1853352US		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Crying; Therapeutic Response Decreased	Lexapro		S	Oral	Unk	Allergan
	Thyroid Medication Unspecified		C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15626456	EXPEDITED (15-DAY)		OT	PT-TEVA-2018-PT-977281		27 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Stiff Person Syndrome	Escitalopram			S	Unknown			Ivax
	Insulin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15626809	EXPEDITED (15-DAY)		OT	TN-MYLANLABS-2018M1086399		38 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Erythema; Hypersensitivity; Pruritus Generalised; Pyrexia	Carbamazepine			S	Unknown			Not Reported
	Escitalopram			S	Unknown	Later, Re-Initiated In September 2017 At An Unknown Dose		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Amoxicillin			S	Unknown			Mylan
	Levomepromazine			C	Unknown			Mylan
	Paracetamol			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15627916	NON-EXPEDITED			US-MYLANLABS-2018M1084068			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Hyperhidrosis; Incorrect Product Administration Duration; Malaise; Product Administered At	Fentanyl Transdermal System			S		100 Unk		Mylan
	Venlafaxine			S		Unk		Mylan
	Losartan Potassium			S		Unk		Mylan

Inappropriate Site; Tremor	Oxazepam	S	Unk		Mylan
	Hydrochlorothiazide	S	Unk		Mylan
	Escitalopram	S	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15628506	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2018M1086225		27 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Stiff Person Syndrome	Escitalopram			S	Unknown			Not Reported
	Insulin			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15628524	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1853645US		45 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cortisol Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15628542	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2018_036365		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Haematoma	Aripiprazole			S	Oral	5 Mg, Qd		Otsuka
	Escitalopram			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	10 Mg, Qd		Not Reported
	Prazepam Arrow			S	Oral	10 Mg, Qd		Not Reported
	Piroxicam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15628545	EXPEDITED (15-DAY)		HO, OT	GB-ALLERGAN-1853812US		85 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Haematemesis	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qam		Allergan
	Clopidogrel			S	Oral	75 Mg, Qam		Not Reported
	Fultium D3			C	Unknown	800 Iu, Unknown		Not Reported
	Alverine			C	Unknown	60 Mg, Unknown		Not Reported
	Co-Beneldopa			C	Unknown	25/100 Mg		Not Reported
	Paracetamol			C	Unknown	1500 Mg, Unknown		Not Reported
	Amlodipine			C	Unknown	5 Mg, Unknown		Not Reported
	Co-Codamol			C	Unknown	8/500mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15628551	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2018_036142		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Extrapyramidal Disorder; Hallucination; Product Use In Unapproved Indication; Tremor	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Lepticur			S	Oral	1 Df, Qd		Not Reported
	Seroplex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15628706	EXPEDITED (15-DAY)		HO	SE-TEVA-2018-SE-974911		45 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Dizziness	Escitalopram			S	Oral			Ivax
	Stilnoct			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15633162	DIRECT	Y				70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged	Lexapro 10mg	S	Oral	6 DAY	Major

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2018	15583509	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-052989		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia; Toxicity To Various Agents	Aripiprazole			S	Unknown	4 Milligram, Daily,Every Bedtime		Aurobindo
	Aripiprazole			S	Unknown	2 Milligram, Daily,Every Bedtime		Aurobindo
	Dexamfetamine+Amfetamine			S	Unknown	20 Milligram, Daily,Extended Release, Every Morning		Aurobindo
	Dexamfetamine+Amfetamine			S	Unknown	10 Milligram, Daily,Extended Release, Every Morning		Aurobindo
	Escitalopram			S	Unknown	5 Milligram, Daily,Every Morning		Aurobindo
	Escitalopram			S	Unknown	20 Milligram, Daily		Aurobindo
	Escitalopram			S	Unknown	10 Milligram, Daily,Every Morning		Aurobindo
	Escitalopram			S	Unknown	15 Milligram, Daily,Every Morning		Aurobindo
	Lamotrigine			S	Unknown	150 Milligram, Daily		Aurobindo
	Lamotrigine			S	Unknown	100 Milligram, Daily		Aurobindo
	Lorazepam			S	Unknown	0.5 Milligram,(8 Hours),As Necessary		Aurobindo
	Lorazepam			S	Unknown	1 Milligram, (8 Hours),As Necessary		Aurobindo
	Bupropion			S	Unknown	150 Milligram, Daily,Every Morning		Not Reported
	Bupropion			S	Unknown	200 Milligram, Daily,Every Morning		Not Reported

Bupropion	S	Unknown	300 Milligram, Daily,Every Morning	Not Reported
Buspirone	S	Unknown	15 Milligram, Two Times A Day	Not Reported
Buspirone	S	Unknown	15 Milligram, (8hour)	Not Reported
Buspirone	S	Unknown	10 Milligram, Daily	Not Reported
Buspirone	S	Unknown	17.5 Milligram, Daily	Not Reported
Buspirone	S	Unknown	7.5 Milligram, (8 Hour)	Not Reported
Buspirone	S	Unknown	15 Milligram, (8 Hour)	Not Reported
Buspirone	S	Unknown	15 Milligram, Daily	Not Reported
Buspirone	S	Unknown	2.5 Milligram, Daily	Not Reported
Buspirone	S	Unknown	22.5 Milligram, Daily	Not Reported
Buspirone	S	Unknown	5 Milligram, Daily	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Daily	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Two Times A Day	Not Reported
Buspirone	S	Unknown	,7.5 Milligram, (8 Hour)	Not Reported
Buspirone	S	Unknown	20 Milligram, Daily	Not Reported
Testosterone	S	Topical	Daily, (50 Mg/5 G Every Morning On The Right Upper Extremity)	Not Reported
Lithium	S	Unknown	600 Milligram, Daily,Every Bedtime	Not Reported
Lurasidone	S	Unknown	40 Milligram, Daily,After Dinner	Not Reported
Benztropine Mesylate	C	Unknown	0.5 Milligram, Two Times A Day,As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	10216201	EXPEDITED (15-DAY)		HO	JP-FRI-1000067816		17 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Altered State Of Consciousness; Electrocardiogram Qt Prolonged; Nausea; Overdose; Product Use Issue; Somnolence; Suicide Attempt; Tetany; Toxicity To Various Agents; Tremor; Vomiting	Escitalopram Oxalate - Bp	S	Oral	750 Mg, Qd; 75 Tablets	Allergan
	Ronlax	C	Oral	4 Df, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	12247424	EXPEDITED (15-DAY)		HO	JP-FRI-1000083766		24 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Overdose	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Overdose: 10 Mgx20tablets		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Amoxan			S	Oral	10 Mg, Bid		Not Reported
	Amoxan			S	Oral	10 Mg, Overdose 10 Mg X32 Capsules		Not Reported
	Amoxan			S	Oral	10 Mg, Bid		Not Reported
	Abilify 1%			S	Oral	0.1 G, Bid		Not Reported
	Abilify 1%			S	Oral	0.1 G, Overdose: 0.1 Gram X 31 Packs		Not Reported
	Abilify 1%			S	Oral	0.1 G, Bid		Not Reported
	Rivotril 0.1%			S	Oral	0.3 G, Bid		Not Reported
	Rivotril 0.1%			S	Oral	0.3 G, Overdose: 0.3 Gram X 31 Packs		Not Reported
	Rivotril 0.1%			S	Oral	0.3 G, Bid		Not Reported
	Lendormin			C	Oral	.25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15290706	EXPEDITED (15-DAY)		DS, HO, LT	PT-TEVA-2018-PT-943124		94 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Confusional State; Decreased Appetite; Hyponatraemia; Panic Attack; Psychomotor Hyperactivity; Vomiting	Escitalopram			S	Oral	1 Dosage Forms Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15600548	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US22407			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Insomnia; Panic Attack; Product Substitution Issue; Unevaluable Event	Escitalopram			S	Unknown	Unk, Generic Aurobindo For Years		Invagen
	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15606729	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1852738US		79 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Product Use In Unapproved Indication; Therapeutic Response Unexpected	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Donepezil Hydrochloride			C	Oral	5 Mg, Qam		Not Reported
	Belsomra			C	Oral	15 Mg, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15630010	EXPEDITED (15-DAY)		HO, OT	US-SHIRE-US201843994		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Emotional Disorder; Gynaecomastia; Off Label Use; Product Use In Unapproved Indication; Suicide Attempt; Weight Increased	Intuniv		S	Unknown	Unk	Shire
	Adderall Xr		S	Unknown	Unk	Shire
	Vyvanse		S	Unknown	Unk	Shire
	Lexapro		S	Unknown	Unk	Not Reported
	Risperidone		S	Oral	Unk	Not Reported
	Risperdal		S	Oral	4 Mg, Unk	Not Reported
	Risperdal		S	Oral	1 Mg, Unk	Not Reported
	Risperdal		S	Oral	2 Mg, Unk	Not Reported
	Risperdal		S	Unknown	Unk	Not Reported
	Sertraline		S	Unknown	Unk	Not Reported
	Strattera		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15630725	EXPEDITED (15-DAY)		OT	ZA-CIPLA LTD.-2018ZA22788			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Escitalopram			S	Unknown	Unk		Invagen
	Aspavor			S	Unknown	Unk		Not Reported
	Ivedal			S	Unknown	Unk		Not Reported
	Pritor /01102601/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15631096	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2018-055247		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Linezolid			S	Unknown	Unk		Aurobindo
	Escitalopram			S		20 Milligram		Aurobindo
	Trazodone			C	Unknown	Dose Was Decreased From 300 Mg To 150 Mg Nightly.		Not Reported

	Trazodone		C	Oral	Nightly At Bedtime	Not Reported
	Trazodone		C	Oral	Nightly	Not Reported
	Clonazepam		C	Unknown	0.5 Mg Two Times A Day	Not Reported
	Clonazepam		C		Given As Needed Doses Of Clonazepam	Not Reported
	Piperacillin, Tazobactam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15632298	EXPEDITED (15-DAY)		OT	SE-BAUSCH-BL-2018-031495		65 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Respiratory Tract Infection	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Brintellix			S	Oral			Not Reported
	Brintellix			S	Oral			Not Reported
	Brintellix			S	Oral			Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Mirtazapin			C	Unknown			Not Reported
	Stesolid			C	Unknown			Not Reported
	Stilnoct			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15632794	DIRECT		OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive	Escitalopram	Y		S	Oral	Quantity:1 Tablet(S);		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15633187	EXPEDITED (15-DAY)		HO	GB-TEVA-2018-GB-975934		82 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Alendronic Acid			S	Oral			Actavis
	Escitalopram			S	Oral	20 Milligram Daily;		Not Reported
	Acetylsalicylic Acid			S	Oral	75 Milligram Daily;		Not Reported
	Felodipine			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Adcal-D3			C	Unknown			Not Reported
	Doxazosin			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported
	Seretide			C	Unknown			Not Reported
	Dymista			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Ferrous Fumarate			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15633454	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-975720		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melaena; Microcytic Anaemia	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Plavix 75 Mg, Comprimé Pelliculé			S	Oral	75 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15634144	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-		73 YR	Male	FRA

1853981US

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Kardegic			S	Oral	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15634300	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1853982US		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Coma; Intentional Overdose; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	9 Dosage Forms In The Context Of An Intentional Overdose		Allergan
	Diazepam			S	Oral	10 Df, Unk		Not Reported
	Tercian			S	Oral	5 Df, Unk		Not Reported
	Zopiclone			S	Oral	14 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	14522186	EXPEDITED (15-DAY)		HO, OT	IT-BAUSCH-BL-2018-003448		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Lorazepam			S	Oral	In Total Once/Single		Not Reported
	Entact			S	Oral	20 Mg, Once/Single ; In Total		Not Reported
	Clozapine			S	Oral	In Total: 100 Mg Once/Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15547862	EXPEDITED (15-DAY)		OT	EE-ALLERGAN-1850343US		27 YR	Female	EST

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Agoraphobia; Akathisia; Anger; Anxiety; Autophobia; Cerebral Disorder; Derealisation; Fatigue; Fear Of Death; Impaired Quality Of Life; Insomnia; Nightmare; Palpitations; Panic Disorder; Restlessness; Suicidal Ideation; Visual Impairment; Vomiting; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Valdoxan			S	Oral	Unk Unk, Qd		Not Reported
	Valdoxan			S	Unknown	12.5 Mg, Qd		Not Reported
	Valdoxan			S	Unknown	25 Mg, Qd		Not Reported
	Effexor			S	Unknown	37.5 Mg, Qd		Not Reported
	Oxazepam			C		Unk		Not Reported
	Diazepam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15635187	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-976368		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Escitalopram			S	Oral	Exact Dose At Unknown Imv		Ivax
	Bromazepam			S	Oral	Intake Estimated At 20 Cp Of Bromazepam 6 Mg		Not Reported
	Aripiprazole			S	Oral	Exact Dose At Unknown Imv		Teva
	Zolpidem			S	Oral	Exact Dose At Unknown Imv		Teva
	Olanzapine			S	Oral	Exact Dose At Unknown Imv		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15635612	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-976507		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional	Escitalopram Oxalate			S	Oral			Ivax

Self-Injury; Nausea;
Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15636464	EXPEDITED (15-DAY)		HO	GB-TORRENT-00019523		84 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Lansoprazole			C		Unknown		Unknown
	Paracetamol			C		Unknown		Unknown
	Co-Beneldopa			C		Unknown		Unknown
	Donepezil Hydrochloride			C		Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown
	Apixaban			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15636776	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2018208639		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Lamotrigine			S	Oral	1 Unk, Unk		Glaxosmithkline
	Tavor (Lorazepam)			S	Oral	In Total		Glaxosmithkline
	Escitalopram Oxalate			S	Oral	In Total		Glaxosmithkline
	Delorazepam			S	Oral	Unk		Not Reported
	Oki			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15638899	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20181118975		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma	Imbruvica			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

	Kardegic	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15640320	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-976263			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Escitalopram Tablets			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15640563	NON-EXPEDITED			US-PFIZER INC-2018030170		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Anticonvulsant Drug Level Decreased; Device Defective; Haematocrit Decreased; Haemoglobin Decreased; Intentional Product Misuse; Red Cell Distribution Width Increased	Genotropin Pen 5			S		4 Mg, 1x/Day		Pfizer
	Genotropin Pen 5			S		Unk		Pfizer
	Genotropin Pen 5			S		Unk		Pfizer
	Genotropin Pen 5			S		0.8 Mg, Daily		Pfizer
	Lexapro			S		20 Mg, 1x/Day		Not Reported
	Trazodone			S		50 Mg, 1x/Day At Night		Not Reported
	Trazodone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	14066975	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1676914US		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hypoglycaemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Gliclazide			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	1 G, Bid		Not Reported
	Insulin			S	Unknown	Unk		Not Reported
	L-Thyroxine			C	Unknown	Unk		Not Reported

	Telmisartan	C	Unknown	Unk		Not Reported
	Trazodone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15285568	EXPEDITED (15-DAY)		HO	PHHY2018DE072864			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Myoclonus	Clozapine			S	Unknown	75 Mg, Unk		Not Reported
	Quetiapine			S	Oral	Unk		Novartis
	Quetiapine			S				Novartis
	Olanzapine			S	Unknown	Unk		Not Reported
	Olanzapine			S				Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Risperidone			S				Not Reported
	Fluoxetine			S	Unknown	Unk		Not Reported
	Fluoxetine			S				Not Reported
	Fluoxetine			S				Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Duloxetine			S				Not Reported
	Bupropion			S	Unknown	Unk		Not Reported
	Bupropion			S				Not Reported
	Escitalopram			S	Unknown	20 Mg		Not Reported
	Escitalopram			S				Not Reported
	Aripiprazole			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown			Not Reported
	Zopiclone			S				Not Reported
	Oxazepam			S	Unknown			Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Mirtazapine			S				Not Reported
	Mirtazapine			S				Not Reported
	Amisulpride			S	Unknown			Not Reported
	Amisulpride			S				Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported

Venlafaxine	S				Not Reported
Promethazine	S	Unknown			Not Reported
Biperiden	S	Unknown	Unk		Not Reported
Oxazepam	C	Unknown	At Different Doses		Not Reported
Brivaracetam	C	Unknown	200-250mg, Received Over One Year		Not Reported
Oxcarbazepine	C	Unknown	Up To 2400mg, Received Over One Year		Not Reported
Zonisamide	C	Unknown	Up To 100mg		Not Reported
Carbamazepine	C	Unknown	Up To 900 Mg		Not Reported
Clobazam	C	Unknown	Up To 20mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15641637	EXPEDITED (15-DAY)		DS	PHHY2018IT157210		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Valproic Acid			S	Unknown	Unk		Novartis
	Quetiapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	200 Mg, Qd		Not Reported
	Sertraline			S	Unknown	50 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15641780	EXPEDITED (15-DAY)		OT	SE-AUROBINDO-AUR-APL-2018-055716		65 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Respiratory Tract Infection	Sertraline			S	Unknown	Unk		Aurobindo
	Sertraline			S	Unknown	Unk		Aurobindo

Brintellix	S	Oral	15 Milligram, Daily		Not Reported
Brintellix	S	Oral	5 Milligram		Not Reported
Brintellix	S	Oral	10 Milligram, Daily		Not Reported
Cipramil /00582603/	S	Unknown	Unk		Not Reported
Cipralex /01588501/	S	Unknown	Unk		Not Reported
Venlafaxine Hydrochloride	S	Unknown	Unk		Not Reported
Mirtazapin	C	Unknown	Unk		Not Reported
Stesolid	C	Unknown	20 Milligram, Daily		Not Reported
Stilnoct	C	Unknown	10 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15641818	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-191149		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Escitalopram			S	Oral	Dose Exacte Lors De L'Imv Inconnue ()		Not Reported
	Aripiprazole			S	Oral	Dose Exacte Lors De L'Imv Inconnue ()		Not Reported
	Zolpidem			S	Oral	Dose Exacte Lors De L'Imv Inconnue ()		Sun
	Olanzapine			S	Oral	Dose Exacte Lors De L'Imv Inconnue ()		Sun
	Bromazepam			S	Oral	Prise Estimee A 20 Cp De Bromazepam 6 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15641878	EXPEDITED (15-DAY)		OT	TN-LUPIN PHARMACEUTICALS INC.-2018-08015		38 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Escitalopram			S	Unknown	Unk		Lupin

Increased; Aspartate Aminotransferase Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Erythema; Hypersensitivity; Pruritus Generalised; Pyrexia	Escitalopram	S	Unknown	Unk		Lupin
	Carbamazepine	S	Unknown	Unk		Not Reported
	Amoxicillin	S	Unknown	Unk		Not Reported
	Levomepromazine	C	Unknown	Unk		Not Reported
	Paracetamol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15643990	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018477761		85 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Aspavor			S		20 Mg, Unk		Pfizer
	Zytomil			S		20 Mg, Unk		Not Reported
	Adco-Zolpidem			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15644041	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018474111		76 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumothorax	Xanor			S		0.25 Mg, Unk		Pfizer
	Pearinda Plus			S		4/1.25 Mg, Unk		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported
	Adco-Simvastatin			S		20 Mg, Unk		Not Reported
	Ecotrin			S		81 Mg, Unk		Not Reported
	Vimovo			S		500/20 Mg, Unk		Not Reported
	Trepiline [Amitriptyline]			S		25 Mg, Unk		Not Reported
	Arcoxia			S		90 Mg, Unk		Not Reported
	Azomid			S		250 Mg, Unk		Not Reported
	Ipvent			S		40 Ug, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15644064	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1854152US		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Intentional Self-Injury; Sopor	Escitalopram Oxalate Unk			S	Oral	50 Mg, Unknown		Allergan
	Tavor (Lorazepam)			S	Oral	4 Dosage Forms; In Total		Not Reported
	Delorazepam			S	Oral	Unk		Not Reported
	Oki			S	Oral	800mg; In Total		Not Reported
	Lamotrigine			S	Oral	4 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15644194	EXPEDITED (15-DAY)		DE	JP-JNJFOC-20180636493		86 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Labelled Drug-Drug Interaction Medication Error; Thalamus Haemorrhage	Xarelto			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Mirtazapine			C	Unknown			Not Reported
	Heparin Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15645791	EXPEDITED (15-DAY)		HO	PHHY2018FR160368		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Haematoma	Escitalopram			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	10 Mg, Qd		Novartis
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Prazepam Arrow			S	Oral	10 Mg, Qd		Not Reported
	Piroxicam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15606020	EXPEDITED (15-DAY)		OT	SE-TAKEDA-2018TUS032321		65 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Respiratory Tract Infection	Brintellix			S	Oral	5 Mg, Unk		Takeda
	Brintellix			S	Oral	10 Mg, Qd		Takeda
	Brintellix			S	Oral	15 Mg, Qd		Takeda
	Cipramil /00582602/			S	Unknown	Unk		Not Reported
	Cipralex /01588501/			S	Unknown	Unk		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Sertralin /01011401/			S	Unknown	Unk		Not Reported
	Zoloft			S	Unknown	Unk		Not Reported
	Mirtazapin			C	Unknown	Unk		Not Reported
	Stesolid			C	Unknown	20 Mg, Qd		Not Reported
	Stilnoct			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15646769	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-056175		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Cerebral Haemorrhage; Ecchymosis; Subdural Haematoma	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo
	Coumadin			S	Oral	5 Milligram, 1 As Necessary		Not Reported
	Plavix			S	Oral	75 Milligram, Daily		Not Reported
	Doxazosin			C	Unknown	Unk		Not Reported
	Esomeprazole Sodium			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15646793	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-055937		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Coma; Somnolence; Toxicity To Various Agents	Diazepam			S	Oral	10 Dosage Form, (In Total)		Not Reported
	Escitalopram			S	Oral	9 Dosage Form, (In Total)		Aurobindo
	Zopiclone			S	Oral	14 Dosage Form, (In Total)		Not Reported
	Tercian /00759302/			S	Oral	5 Dosage Form, (In Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15646802	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2018-056005		85 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Haematemesis	Clopidogrel Film-Coated Tablets			S	Oral	75 Milligram, Daily, (Morning. Suspended During Admission)		Aurobindo
	Escitalopram Tablets			S	Oral	5 Milligram, Daily, (Morning. Continued During Admission With Proton Pump Inhibitor Protection)		Aurobindo
	Alverine			C	Unknown	60 Milligram		Not Reported
	Amlodipine			C	Unknown	5 Milligram		Not Reported
	Co-Codamol			C	Unknown	3 Dosage Form, Daily, (8mg/500mg)		Not Reported
	Co-Beneldopa			C	Unknown	25mg/100mg		Not Reported
	Fultium D3			C	Unknown	800 International Unit		Not Reported
	Paracetamol			C	Unknown	1500 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15647241	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-055307		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Haematoma	Prazepam Arrow 10 Mg Tablet			S	Oral	10 Milligram, Once A Day		Not Reported
	Escitalopram			S	Oral	Unk		Aurobindo
	Zolpidem			S	Oral	10 Milligram, Once A Day		Aurobindo
	Aripiprazole			S	Oral	5 Milligram, Once A Day		Aurobindo
	Piroxicam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15647249	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-056433		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Delorazepam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	50 Milligram, In Total		Aurobindo
	Lamotrigine			S	Oral	4 Dosage Form, In Total		Aurobindo
	Oki			S	Oral	800 Milligram, In Total		Not Reported
	Tavor /00273201/			S	Oral	4 Dosage Form, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15647287	NON-EXPEDITED			US-HETERO CORPORATE-HET2018US01408			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Somnolence	Escitalopram			S	Oral	Unk		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15647288	EXPEDITED (15-DAY)		OT	PT-HETERO CORPORATE-HET2018PT01402		27 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stiff Person Syndrome	Escitalopram			S	Unknown	20 Mg		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15647426	EXPEDITED (15-DAY)		OT	TN-MACLEODS PHARMACEUTICALS US LTD-MAC2018018706			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Erythema; Hypersensitivity; Pruritus Generalised; Pyrexia	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Carbamazepine			S	Unknown	Unk		Not Reported
	Levomepromazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15647832	EXPEDITED (15-DAY)		OT	SE-PFIZER INC-2018475614		65 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Tract Infection	Sertraline Hcl			S		Unk		Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer
	Brintellix			S	Oral	15 Mg, Daily		Not Reported
	Brintellix			S	Oral	5 Mg, Unk		Not Reported
	Brintellix			S	Oral	10 Mg, Daily		Not Reported
	Cipramil [Citalopram Hydrochloride]			S		Unk		Not Reported
	Cipralex [Escitalopram]			S		Unk		Not Reported
	Mirtazapin			C		Unk		Not Reported
	Stesolid			C		20 Mg, Daily		Not Reported
	Stilnoct			C		10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15648469	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2018-032139		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting	Prednisolone			S	Oral			Not Reported
	Hepatoum			S	Oral	Unspecified		Not Reported
	Azithromycine Anhydre			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Arestal			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Inorial			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Augmentin			S	Oral			Not Reported
	Cefpodoxime			S	Oral			Not Reported
	Trimebutine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15648625	NON-EXPEDITED			US-TEVA-2018-US-974229		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alopecia; Anger; Burning Sensation; Crying; Disorganised Speech; Dizziness; Feeling Abnormal; Influenza Like Illness; Irritability; Paraesthesia; Withdrawal Syndrome	Escitalopram			S				Ivax
	Escitalopram			S	Unknown			Ivax
	Escitalopram			S	Unknown			Ivax
	Escitalopram			S				Ivax
	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15648685	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1854401US		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue; Suicidal Ideation; Therapy Change	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15653649	DIRECT		DS, HO			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alopecia; Anxiety; Arthralgia; Arthralgia; Arthritis; Back Pain; Bone Pain; Depression; Disability; Disturbance In Attention; Fibromyalgia; Gait Inability; Joint Noise; Myalgia; Neuralgia; Paralysis; Photophobia; Skin Disorder; Suicide Attempt; Tremor	Escitalopram			S				Not Reported
	Beyaz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	12927787	NON-EXPEDITED		HO, OT	CA-LUPIN PHARMACEUTICALS INC.-2016-02479		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis	Metformin			S	Unknown	Unk Unk,Unk,Unknown		Lupin
	Metformin			S	Unknown	1 G,Bid,		Lupin
	Escitalopram			S	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Gliclazide Modified-Release			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Gliclazide Modified-Release			C	Unknown	Dose Reduced		Not Reported
	Insulin			C	Unknown	Unk Unk,Unk,Unknown		Not Reported

	L-Thyroxine		C	Unknown	Unk Unk,Unk,Unknown	Not Reported
	Telmisartan		C	Unknown	Unk Unk,Unk,Unknown	Not Reported
	Trazodone		C	Unknown	Unk Unk,Unk,Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15588465	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018154014		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Repatha			S	Unknown	140 Mg, Q2wk		Amgen
	Lexapro			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	0.05 Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15612288	EXPEDITED (15-DAY)		HO, LT, OT	US-GLENMARK PHARMACEUTICALS-2018GMK038192		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Linezolid			S	Unknown	Unk		Glenmark
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Trazodone			C	Oral	300 Mg, Hs		Not Reported
	Trazodone			C	Oral	150 Mg, Hs		Not Reported
	Clonazepam			C	Unknown	0.5 Mg, Bid (Given As Needed Doses Of Clonazepam)		Not Reported
	Piperacillin & Tazobactam			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15641556	EXPEDITED (15-DAY)		DS	IT-ASTRAZENECA-2018SF50852		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Quetiapine		S	Oral	Zeneca
	Venlafaxine		S	Unknown	Not Reported
	Valproic Acid		S	Unknown	Not Reported
	Mirtazapine		S	Unknown	Not Reported
	Mirtazapine		S	Unknown	Not Reported
	Sertraline		S	Unknown	Not Reported
	Sertraline		S	Unknown	Not Reported
	Escitalopram		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650075	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP025515		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown	Unk		Apotex
	Metoprolol			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650345	EXPEDITED (15-DAY)		HO, LT, OT	US-APOTEX-2018AP025251		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome; Symptom Masked	Linezolid			S	Unknown			Apotex
	Escitalopram			S	Unknown	20 Mg, Qd		Apotex
	Trazodone			S	Unknown	300 Mg, Q.H.S.		Apotex
	Trazodone			S	Unknown	150 Mg, Q.H.S.		Apotex
	Clonazepam			S	Unknown	0.5 Mg, Bid		Apotex
	Piperacillin / Tazobactam			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650397	EXPEDITED (15-DAY)		HO	FR-ZYDUS-030616		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Escitalopram			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650566	EXPEDITED (15-DAY)		DS	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018018710			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Escitalopram			S	Unknown	Unk		Macleods
	Quetiapine			S	Unknown	Unk		Macleods
	Venlafaxine			S	Unknown	Unk		Macleods
	Valproic Acid			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	200 Milligram, Qd		Not Reported
	Sertraline			S	Unknown	50 Milligram, Qd		Not Reported
	Sertraline			S	Unknown	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650812	NON-EXPEDITED			US-TEVA-2018-US-979227			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Substitution Issue	Escitalopram Teva			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650851	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018018715			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Wall Haematoma; Cerebral Haemorrhage; Drug Interaction; Ecchymosis; Subdural Haematoma	Escitalopram		S	Oral	10 Milligram, Qd	Macleods
	Plavix		S	Oral	75 Milligram, Qd	Not Reported
	Coumadin		S	Oral	5 Milligram, As Necessary	Not Reported
	Esomeprazole		C	Unknown	Unk	Not Reported
	Pregabalin		C	Unknown	Unk	Not Reported
	Furosemide		C	Unknown	Unk	Not Reported
	Doxazosin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15651881	NON-EXPEDITED			US-009507513-1810USA011791		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Ejaculation Failure; Erectile Dysfunction; Loss Of Libido; Sexual Dysfunction	Remeron			S	Oral	22.5 Milligram, Qhs		Merck
	Escitalopram			S		20 Milligram, Bid		Not Reported
	Alprazolam			S		1 Mg Tid, Prn		Not Reported
	Lamotrigine			S		100 Milligram, Tid		Not Reported
	Enalapril			S		20 Milligram, Qam		Not Reported
	Lansoprazole			S		30 Milligram, Qam		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2018	14964536	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-899034		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Prescribed Underdose	Esomeprazole			S	Oral			Teva
	Decapeptyl [Gonadorelin]			S	Intramuscular			Not Reported
	Innohep			S	Subcutaneous	1 Dosage Forms Daily;		Not Reported
	Amlor			S	Oral			Not Reported
	Novonorm			S	Oral			Not Reported
	Tramadol Base			S	Oral			Not Reported
	Xtandi			S	Oral	120 Milligram Daily;		Not Reported

	Xtandi	S	Oral		Not Reported
	Lipanthyl	S	Oral	145 Milligram Daily;	Not Reported
	Seroplex	S	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2018	15653341	EXPEDITED (15-DAY)		HO, LT, OT	US-TORRENT-00007213		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction; Serotonin Syndrome; Toxicity To Various Agents	Clonazepam			S		Given As Needed Doses Of Clonazepam		Unknown
	Escitalopram			S		Unknown		Unknown
	Linezolid			S		Unknown		Unknown
	Trazodone			S	Oral	Nightly At Bedtime		Unknown
	Piperacillin, Tazobactam			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2018	15653913	EXPEDITED (15-DAY)		OT	US-PRINSTON PHARMACEUTICAL INC.-2018PRN01597		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Interaction; Serotonin Syndrome	Clonazepam			S	Unknown			Prinston Pharmaceutical
	Escitalopram			S	Unknown	20 Mg, 1x/Day		Prinston Pharmaceutical
	Linezolid			S	Unknown			Not Reported
	Trazodone			S	Unknown	300 Mg, 1x/Day		Not Reported
	Trazodone			S	Unknown	150 Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2018	15654102	DIRECT					17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Pruritus	Lexapro 5 Mg & 10 Mg	S	Oral	Quantity:30 Tablet(S);	Forest
	Periactin	C			Not Reported
	Albuterol	C			Not Reported
	Flonase	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2018	15654324	EXPEDITED (15-DAY)		HO, LT, OT	US-CIPLA LTD.-2018US22804			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	20 Mg, Qd		Invagen
	Linezolid			S	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	300 Mg, Nightly (Per Day)		Not Reported
	Trazodone			C	Oral	150 Mg, Nightly At Bedtime (Per Day)		Not Reported
	Clonazepam			C	Unknown	0.5 Mg, (Given As Needed Doses Of Clonazepam)		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Vancomycin			C	Unknown	Unk		Not Reported
	Cefepime			C	Unknown	Unk		Not Reported
	Metronidazole			C	Unknown	Unk		Not Reported
	Piperacillin & Tazobactam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2018	15655615	DIRECT		OT			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Ineffective; Product Substitution Issue	Escitalopram Tab 20 Mg			S	Oral	Quantity:90 Tablet(S);		Aurobindo
	Ropenerol			C				Not Reported
	Pravastatin			C				Not Reported
	Metamucil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	14188939	EXPEDITED (15-DAY)		HO, OT	CZ-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-154673		45 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Escitalopram			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15607438	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018457177		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Linezolid			S		Unk		Pfizer
	Escitalopram			S		20 Mg, Daily		Not Reported
	Trazodone			S		300 Mg, Daily (Nightly, High-Dose)		Not Reported
	Trazodone			S	Oral	150 Mg, Daily (Nightly,At Bedtime, Dose Was Decreased, After 3 Days Of Linezolid Therapy)		Not Reported
	Clonazepam			S		0.5 Mg, 2x/Day (Scheduled Doses)		Not Reported
	Clonazepam			S		Unk, As Needed(As Needed Doses)		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Metronidazole			C		Unk		Not Reported
	Piperacillin / Tazobactam			C		Unk		Not Reported
	Piperacillin / Tazobactam			C				Not Reported

Amikacin	C	Unk, Single	Not Reported
Amikacin	C		Not Reported
Levothyroxine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15623218	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1853514US		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Escitalopram Oxalate Unk			S	Oral	140 Mg, 1 Day		Allergan
	Arestal			S	Oral	30 Mg, Total		Not Reported
	Seresta			S	Oral	310 Mg, Total		Not Reported
	Prednisolone			S	Oral	200 Mg, Total		Not Reported
	Inorial			S	Oral	120 Mg, Total		Not Reported
	Paracetamol			S	Oral	79 G, Total		Not Reported
	Augmentin			S	Oral	6 G, 1 Day		Not Reported
	Cefpodoxime			S	Oral	2000 Mg, Total		Not Reported
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported
	Hepatoum			S	Oral	Unk		Not Reported
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15629656	EXPEDITED (15-DAY)		HO, LT, OT	US-ACCORD-092592		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypotension; Pleural Effusion; Pneumonia; Serotonin Syndrome; Staphylococcal Infection	Escitalopram			S		20 Mg Daily		Not Reported
	Trazodone/Trazodone Hydrochloride			S		300 Mg Nightly, Decreased To 150 Mg Nightly.		Not Reported
	Clonazepam			S		0.5 Mg Two Times A Day.		Not Reported
	Linezolid			S				Not Reported
	Ceftriaxone			C				Not Reported

	Azithromycin	C	Not Reported
	Vancomycin/Vancomycin Hydrochloride	C	Not Reported
	Cefepime	C	Not Reported
	Metronidazole	C	Not Reported
	Piperacillin Sodium/Tazobactam Sodium	C	Not Reported
	Amikacin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15647511	EXPEDITED (15-DAY)		HO, OT	JP-ASTRAZENECA-2018SF44731		72 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumothorax; Product Dose Omission; Respiratory Failure	Symbicort Turbuhaler			S	Respiratory (inhalation)			Astrazeneca
	Zacras			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Flunitrazepam			S	Oral			Not Reported
	Desyrel			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15654683	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP025661		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Electrocardiogram Qt Prolonged; Hyperkalaemia; Loss Of Consciousness; Overdose; Sinus Tachycardia	Zopiclone			S	Oral	Maximum Possible Ingestion 187.5 Mg		Not Reported
	Diazepam			S	Unknown	Unk		Apotex
	Lorazepam			S	Unknown	Unk		Apotex
	Citalopram			S	Unknown	Unk		Apotex
	Escitalopram Amneal			S	Unknown	10 Mg, Paer Day		Not Reported
	Escitalopram Amneal			S	Unknown	Maximum Possible Ingestion 140 Mg		Not Reported
	Morphine			S	Unknown	Maximum Possible		Not Reported

				Ingestion: 9500 Mg	
	Morphine	S	Unknown	30 Mg, Per Day	Not Reported
	Morphine	S	Unknown	Maximum Possible Ingestion 2640 Mg	Not Reported
	Morphine	S	Unknown	420 Mg, Unk	Not Reported
	Acetaminophen W/Oxycodone	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	60 Unk, Unk	Not Reported
	Oxycodone	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15654746	EXPEDITED (15-DAY)		HO, OT	GB-CIPLA LTD.-2018GB22890			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Haematemesis	Escitalopram			S	Oral	5 Mg Tablet Per Day, Morning, Continued During Admission With Proton Pump Inhibitor Protection		Invagen
	Clopidogrel			S	Oral	75 Mg Tablet Per Day, Morning, Suspended During Admission		Not Reported
	Fultium D3			C	Unknown	800 Iu, Capsule, Unk		Not Reported
	Alverine			C	Unknown	60 Mg, Capsule, Unk		Not Reported
	Co-Beneldopa			C	Unknown	Unk, 25 Mg/100 Mg Capsule		Not Reported
	Paracetamol			C	Unknown	1500 Mg Capsule Per Day		Not Reported
	Amlodipine			C	Unknown	5 Mg Tablet, Unk		Not Reported
	Co-Codamol			C	Unknown	3 Df, Capsule, Per Day, 8 Mg/500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15656906	EXPEDITED (15-DAY)		HO	IT-SANIK-2018SA316773AA		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Wall Haematoma; Cerebral Haemorrhage; Drug Interaction; Ecchymosis; Subdural Haematoma	Plavix	S	Oral	75 Mg, Qd		Sanofi
	Escitalopram Oxalate	S	Oral			Not Reported
	Warfarin Sodium	S	Oral	5 Mg, Prn		Not Reported
	Pregabalin	C		Unk, Unk		Not Reported
	Furosemide	C		Unk, Unk		Not Reported
	Esomeprazole Sodium	C		Unk, Unk		Not Reported
	Doxazosin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	14830178	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1822944US		45 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety Disorder; Discomfort; Feeling Abnormal; Malaise; Nervousness; Psychomotor Hyperactivity; Stress; Tension Headache	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Amlodipin			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15659087	EXPEDITED (15-DAY)		HO	FR-SA-2018SA316781		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Haematoma	Zolpidem Tartrate			S	Oral	10 Mg, Qd		Sanofi
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Prazepam Arrow			S	Oral	10 Mg, Qd		Not Reported
	Piroxicam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15659722	EXPEDITED (15-DAY)		HO	FR-ZYDUS-030668		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Haematoma	Escitalopram			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Aripiprazole			S	Oral			Zydus Pharm
	Prazepam			S	Oral			Not Reported
	Piroxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660916	NON-EXPEDITED			US-APOTEX-2018AP022835		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Depression; Drug Ineffective; Fatigue; Sedation; Therapeutic Product Effect Incomplete; Weight Increased	Mirtazapine			S	Unknown	7.5 To 15 Mg		Apotex
	Fluvoxamine			S	Unknown	250 Mg, Unk		Apotex
	Fluvoxamine			S	Unknown	200 Mg, Unk		Apotex
	Sertraline			S	Unknown	Up To 300 Mg Daily		Apotex
	Sertraline			S				Apotex
	Sertraline			S				Apotex
	Bupropion			S	Unknown	150 Mg, Unk		Apotex
	Clonazepam			S	Unknown			Apotex
	Citalopram			S	Unknown	40 Mg, Unk		Apotex
	Escitalopram			S	Unknown			Apotex
	Lamotrigine			C	Unknown	100 Mg, Daily		Not Reported
	Fluoxetine			C	Unknown	60 Mg, Daily		Not Reported
	Junel Fe 1/20			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660932	EXPEDITED (15-DAY)		OT	US-OXFORD PHARMACEUTICALS, LLC-2018OXF00142		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Serotonin Syndrome	Trazodone	S	Unknown	300 Mg, 1x/Day	Oxford Pharmaceuticals
	Trazodone	S	Unknown	150 Unk	Oxford Pharmaceuticals
	Clonazepam	S	Unknown		Not Reported
	Escitalopram	S	Unknown	20 Mg, 1x/Day	Not Reported
	Linezolid	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15661090	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018483626		79 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Loss Of Consciousness; Sopor	Xanax			S	Oral	20 Df, Total		Pfizer
	Levopraid [Levosulpiride]			S	Oral	19 Df, Total		Not Reported
	Cipralex [Escitalopram Oxalate]			S	Oral	28 Df, Total		Not Reported
	Rabeprazole Sodium			C				Not Reported
	Olanzapine			C				Not Reported
	Alprazolam			C				Not Reported
	Sucralfate			C				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15661517	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1854794US		27 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Emotional Poverty; Libido Decreased; Memory Impairment	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15661938	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018480018		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradyphrenia; Disturbance In Attention; Hypoglycaemia; Hypotension; Somnolence; Suicide Attempt; Toxicity To Various Agents	Xanax	S	Oral	49 Df, Single	Pfizer
	Cetirizine	S	Oral	50 Mg, Single	Not Reported
	Mag 2 [Magnesium Carbonate]	S	Oral	7 Df, Single	Not Reported
	Zopiclone	S	Oral	30 Mg, Single	Not Reported
	Escitalopram	S	Oral	140 Mg, Single	Not Reported
	Doliprane	S	Oral	3 G, Single	Not Reported
	Flagyl [Metronidazole Benzoate]	S	Oral	9 Df, Single	Not Reported
	Naproxene [Naproxen Sodium]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15662107	NON-EXPEDITED			US-PFIZER INC-2018475915		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Lyrica			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15662428	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1087633		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Renal Failure; Speech Disorder; Tooth Loss	Escitalopram Mylan 5 Mg			S		Unk		Mylan
	Teralithe			C		Adapted Posology: 2.5 Tablets Daily (Lithium 0.84 Mmol/L).		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	14683984	EXPEDITED (15-DAY)		HO	FR-ASTELLAS-2018US014277		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Prescribed Underdose	Xtandi			S	Oral			Astellas
	Decapeptyl /00975902/			S	Intramuscular	1 Df, 1 Cyclical		Not Reported

	Innohep	S	Subcutaneous		Not Reported
	Amlor	S	Oral	Unk, Unknown Freq.	Not Reported
	Novonorm	S	Oral	Unk, Unknown Freq.	Not Reported
	Novonorm	S	Oral	Not Reported	Not Reported
	Tramadol	S	Oral	Unk, Unknown Freq.	Not Reported
	Esomeprazole Magnesium	S	Oral	Unk, Unknown Freq.	Not Reported
	Lipanthyl	S	Oral		Not Reported
	Seroplex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15664147	EXPEDITED (15-DAY)		OT	IT-BAUSCH-BL-2018-032825			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Treatment Failure	Diazepam			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Lamotrigine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Epclusa			S	Unknown			Not Reported
	Flurazepam			S	Unknown			Not Reported
	Chlorpromazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15666231	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1855097US			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Treatment Failure	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Risperidone			S	Unknown			Not Reported
	Epclusa			S	Unknown	Unk		Not Reported

	Lorazepam	S	Unknown	Not Reported
	Flurazepam	S	Unknown	Not Reported
	Chlorpromazine	S	Unknown	Not Reported
	Diazepam	S	Unknown	Not Reported
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Lamotrigine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15705578	DIRECT	Y	HO				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Infection	Humira 40mg/0.8ml Pen			S	Subcutaneous			Abbvie
	Lorazepam			C				Not Reported
	Warferin			C				Not Reported
	Meloxicam			C				Not Reported
	Folic Acid			C				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15665378	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018485360		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Tavor (Lorazepam)			S	Oral	4 Df, Total		Pfizer
	Delorazepam			S	Oral	Unk		Not Reported
	Oki			S	Oral	800 Mg, Total		Not Reported
	Escitalopram Oxalate			S	Oral	50 Mg, Total		Not Reported
	Lamotrigine			S	Oral	4 Df, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15668296	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-2018-GB-979065		85 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gastrointestinal Haemorrhage; Haematemesis	Clopidogrel	S	Oral	75 Milligram Daily; Morning. Suspended During Admission	Teva
	Escitalopram	S	Oral	5 Milligram Daily; Morning. Continued During Admission With Proton Pump Inhibitor Protection	Ivax
	Fultium-D3	C	Unknown		Not Reported
	Alverine	C	Unknown		Not Reported
	Co-Beneldopa	C	Unknown	25mg/100mg	Not Reported
	Paracetamol	C	Unknown	1500 Milligram Daily;	Not Reported
	Amlodipine	C	Unknown		Not Reported
	Co-Codamol	C	Unknown	3 Dosage Forms Daily; 8mg/500mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15668616	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-979664		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Coma; Somnolence; Toxicity To Various Agents	Diazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Ivax
	Zopiclone			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15673376	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1855298US		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rectal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Previscan (Fluindione)			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15673462	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1855301US		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Arthralgia; Back Pain; Chills; Confusional State; Dehydration; Dementia Alzheimer'S Type; Eating Disorder; Gait Disturbance; Hallucination; Headache; Malaise; Myalgia; Speech Disorder; Urinary Tract Infection	Escitalopram Oxalate - Bp			S	Unknown	20 (Units Unspecified)		Allergan
	Tramadol			C	Unknown			Not Reported
	Royal Jelly			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	Exelon			C	Unknown			Not Reported
	Seresta			C	Unknown			Not Reported
	Mianserin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15673600	EXPEDITED (15-DAY)		HO	CN-MYLANLABS-2018M1087931		60 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Dysarthria; Insomnia; Irritability; Sluggishness	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown	10mg At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	13958848	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1750584US		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Drug Ineffective; Ejaculation Disorder; Epilepsy; Heart Rate Increased; Reaction To Excipient; Somnolence; Suicidal Ideation; Tongue Biting; Tremor	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Depakine			C		500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15622005	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1853460US			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Lithium Carbonate			C	Unknown	250 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15628174	EXPEDITED (15-DAY)		HO, OT	CA-MYLANLABS-2018M1084789		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Dislocation; Device Malfunction; Drug Ineffective	Mylan-Nitro Sublingual Spray			S	Oral	Unk		Mylan
	Mylan-Nitro Sublingual Spray			S	Oral	Unk (Administer 1 Spray Under The Tongue If Chest Pain; Repeat After 5 Min If The Pain Persists. I)		Mylan
	Stieprox			S		Unk (2-3 Times Per Week As Directed By Your Doctor)		Mylan
	Emocort			S	Topical	Unk, Qd (Use Locally On The Lesions In Thin Layer 2 Times Per Day)		Mylan
	Amlodipine Sandoz /00972402/			S		1.5 Df, Hs (Take One Tablet Once Daily At The Same Time Each Day)		Mylan
	Apo Rosuvastatin			S		1 Df, Qd (One Tablet Once Daily At The Same Time Each Day)		Mylan
	Dexilant			S		1 Df, Qd (Take One Capsule Once Daily At The Same Time Each Day)		Mylan
	Synthroid			S		1 Df, Qd (Take One Tablet		Mylan

			Once Daily 07:00)	
Ratio-Zopiclone	S		1 Df, Prn (Take 1 Tablet One Time At Bedtime If Needed)	Mylan
Apo-Trazodone	S		1 Df, Hs (One Tablet Once Daily At Bedtime)	Mylan
Cipralex /01588501/	S		1 Df, Am (1 Tablet Once Daily In The Morning)	Mylan
Apo Escitalopram	S		Unk	Mylan
Escitalopram /01588502/	S		Unk	Mylan
Jamp Asa	S		1 Df, Am (Take 1 Tablet Once Daily With Breakfast (Blood Circulation) 07:00)	Mylan
Tevabisoprol	S		1 Df, Qd (1 Tablet Once Daily At The Same Time Each Day)	Mylan
Nitro-Dur	S		1 Df, Am (The Patch On A Dry Hairless Surface At 8:00 In The Morning And Remove At 20:00 In The Eve)	Mylan
Brilinta	S		1 Df, Bid	Mylan
Apo Tamsulosin	S		1 Df, Hs	Mylan
Clonazepam	S		1 Df, Tid	Mylan
Triatec /00116401/	S		1 Df, Qid	Mylan
Metonia	S		1 Df, Tid	Mylan
Nasonex	S	Nasal	2 Sprays In Each Nostril, Qd	Mylan
Delatestryl	S		0.5 Ml, Q2w	Mylan
Diltiazem	S		1 Dosage Form, Qd(Morning)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15644003	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-		40 YR	Female	DEU

1000084338

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram Oxalate - Bp			S	Unknown	Drops		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd (Started With 1 Drop Daily)		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Tablets		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15662097	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1854830US		42 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15674627	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-980505		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Delorazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Ivax
	Tavor (Lorazepam)			S	Oral			Not Reported
	Oki 80 Mg Granulato Per Soluzione Orale			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15674628	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-980490		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Fall; Haematoma	Escitalopram	S	Oral		Not Reported
	Zolpidem	S	Oral	10 Milligram Daily;	Teva
	Aripiprazole	S	Oral	5 Milligram Daily;	Teva
	Prazepam Arrow 10 Mg, Comprimé	S	Oral	10 Milligram Daily;	Not Reported
	Piroxicam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15676567	EXPEDITED (15-DAY)		HO	US-LANNETT COMPANY, INC.-US-2018LAN001361		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	20 Mg, Unk		Lannett
	Lamotrigine			S	Oral	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15676717	EXPEDITED (15-DAY)		DE, HO, OT	US-JNJFOC-20181140769			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Interaction	Fentanyl			S	Unknown			Not Reported
	Hydromorphone Hcl			S	Unknown			Not Reported
	Cocaine			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Hydrocodone			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported

	Clonazepam	S	Unknown	Not Reported
	Cyclobenzaprine	S	Unknown	Not Reported
	Quetiapine	S	Unknown	Not Reported
	Apo-Escitalopram	S	Unknown	Not Reported
	Sertraline	S	Unknown	Not Reported
	Methadone	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Ethanol	S	Unknown	Not Reported
	Diphenhydramine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15677261	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1855459US		19 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pharyngeal Haemorrhage	Citalopram Hydrobromide - Bp			S	Oral	Unk		Allergan
	Citalopram Hydrobromide - Bp			S				Allergan
	Citalopram Hydrobromide - Bp			S				Allergan
	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15677942	EXPEDITED (15-DAY)		HO, LT	CN-ALLERGAN-1855586US		64 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Back Pain; Inappropriate Schedule Of Product Administration; Product Physical Issue; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	0.2 Df, Prn Every 2 To 3 Days		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2018	15730883	DIRECT		OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Diarrhoea; Migraine	Escitalopram			S				Not Reported
	Vyvanse			C				Not Reported
	Adderall			C				Not Reported
	Multi Vit			C				Not Reported
	Vit B			C				Not Reported
	Vit D			C				Not Reported
	Cq 10			C				Not Reported
	Fish Oil			C				Not Reported
	Hydroxiline			C				Not Reported
	Strontium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15665746	EXPEDITED (15-DAY)		HO	PHHY2018FR166791		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Cefpodoxime			S	Oral	2000 Mg, Unk (Total)		Not Reported
	Escitalopram			S	Oral	140 Mg, Unk (One Day)		Not Reported
	Paracetamol			S	Oral	79 G, Unk (Total)		Not Reported
	Trimebutine			S	Oral	14000 Mg, Unk (Total)		Not Reported
	Prednisolon			S	Oral	200 Mg, Unk (Total)		Novartis
	Hepatoum			S	Oral	Unk		Not Reported
	Azithromycin Anhydrous			S	Oral	1500 Mg, Unk (Total)		Not Reported
	Arestal			S	Oral	30 Mg, Unk (Total)		Not Reported
	Seresta			S	Oral	310 Mg, Unk (Total)		Not Reported
	Inorial			S	Oral	120 Mg, Unk (Total)		Not Reported
	Augmentin			S	Oral	6 G, Unk (One Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15679490	NON-EXPEDITED			US-TEVA-2018-US-976922			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Substitution Issue	Escitalopram Teva			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15679524	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-057968		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram Film-Coated Tablets			S	Unknown	Unk		Aurobindo
	Cipralex /01588501/			S	Unknown	Unk		Not Reported
	Cipralex /01588501/			S	Unknown	20 Milligram, Daily (Started With 1 Drop Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15681352	EXPEDITED (15-DAY)		HO, LT, OT	US-GLAXOSMITHKLINE-US2018217135		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15681763	EXPEDITED (15-DAY)		OT	PHHY2018IT169644			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Treatment Failure	Diazepam			S	Unknown	Unk		Not Reported

	Acetylsalicylic Acid		S	Unknown	Unk	Not Reported
	Lamotrigine		S	Unknown	Unk	Not Reported
	Escitalopram		S	Unknown		Not Reported
	Risperidone		S	Unknown	Unk	Not Reported
	Lorazepam		S	Unknown	Unk	Not Reported
	Epclusa		S	Unknown	Unk	Not Reported
	Flurazepam		S	Unknown	Unk	Not Reported
	Chlorpromazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15682958	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-192387		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Haematoma	Escitalopram			S	Oral	()		Not Reported
	Zolpidem			S	Oral	10 Milligram, Daily		Sun
	Aripiprazole			S	Oral	5 Milligram, Daily		Not Reported
	Prazepam Arrow 10 Mg, Comprime			S	Oral	10 Milligram, Daily		Not Reported
	Piroxicam			C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	14528629	EXPEDITED (15-DAY)		OT	IT-ACCORD-063481		54 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vaginal Haemorrhage	Escitalopram			S				Not Reported
	Cardioaspirin			S				Not Reported
	Pritor (Telmisartan)			C				Not Reported
	Bisoprolol			C				Not Reported
	Sertraline			C				Not Reported
	Ranexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15683063	EXPEDITED (15-DAY)		OT	IE-ACCORD-094405		40 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Discomfort; Insomnia; Motor Dysfunction; Pain In Extremity; Paraesthesia	Escitalopram			S		10mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15683468	EXPEDITED (15-DAY)		HO	US-APOTEX-2018AP025931		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Joint Stiffness; Orthostatic Hypotension	Escitalopram			S	Unknown	Unk		Apotex
	Risperidone			S	Unknown	Unk		Apotex
	Topiramate			S	Unknown	Unk		Apotex
	Lorazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15683841	EXPEDITED (15-DAY)		DS	GB-AUROBINDO-AUR-APL-2018-058412			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dysgraphia; Dyskinesia; Off Label Use; Therapeutic Product Effect Decreased; Tremor	Escitalopram			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo
	Mirtazapine			S	Unknown	Unk		Aurobindo
	Quetiapine			S	Unknown	Unk		Aurobindo
	Sertraline			S	Unknown	50 Milligram, Once A Day		Aurobindo
	Sertraline			S	Unknown	200 Milligram, Once A Day		Aurobindo
	Valproic Acid			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15684206	NON-EXPEDITED			US-TEVA-2018-US-984278			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15684356	EXPEDITED (15-DAY)		OT	DE-TORRENT-00012578		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram			S	Unknown	Unknown		Unknown
	Cipralex Oral Drops			S	Unknown	Started With 1 Drop Daily		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15684812	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-058406			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Treatment Failure	Diazepam			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Aurobindo
	Lamotrigine			S	Unknown	Unk		Aurobindo
	Lorazepam			S	Unknown	Unk		Aurobindo
	Risperidone			S	Unknown	Unk		Aurobindo
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Epclusa			S	Unknown	Unk		Not Reported
	Flurazepam			S	Unknown	Unk		Not Reported
	Chlorpromazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15685703	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-981558		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Abuse; Nausea	Escitalopram Oxalate			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15686563	EXPEDITED (15-DAY)		DE, OT	NO-JNJFOC-20181201230		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Medication Error; Overdose	Tramadol Hydrochloride			S	Unknown			Not Reported
	Nobligan			S	Unknown			Not Reported
	Vival			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Nozinan			S	Unknown			Not Reported
	Remeron			S	Unknown			Not Reported
	Catapresan			S	Unknown			Not Reported
	Atarax			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Orfiril			S	Unknown			Not Reported
	Pinex Forte			S	Unknown			Not Reported
	Rivotril			S	Unknown			Not Reported
	Oxynorm			S	Unknown			Not Reported
	Sarotex			S	Unknown			Not Reported
	Imovane			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15687205	EXPEDITED (15-DAY)		DE, OT	FR-BRISTOL-MYERS		64 YR	Female	FRA

SQUIBB COMPANY-
BMS-2018-113313

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Interstitial Lung Disease	Hydrea			S	Oral	500 Mg, (500-500-1000mg)		Bristol Myers Squibb
	Seroplex			S	Oral	5 Mg, 1 Day		Not Reported
	Xagrid			S	Oral	Unk		Not Reported
	Bromazepam			C	Unknown	Unk		Not Reported
	Rovamycine /00074401/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	9745337	EXPEDITED (15-DAY)		DE, LT, OT	NO-JNJFOC-20131204536		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Self-Injury; Medication Error; Sedation; Unevaluable Event	Nobligan			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Catapressan (Clonidine)			S	Unknown			Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown			Not Reported
	Rivotril			S	Unknown			Not Reported
	Nozinan			S	Unknown			Not Reported
	Sobril			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Imovane			S	Oral			Not Reported
	Orfiril			S	Unknown			Not Reported
	Oxynorm			S	Unknown	Dose 5 To 10 Mg		Not Reported
	Oxynorm			S	Unknown	Dose 5 To 10 Mg		Not Reported
	Remeron			S	Unknown			Not Reported
	Atarax			S	Unknown			Not Reported

	Truxal	S	Unknown	600 To 1200 Mg	Not Reported
	Pinex Forte	S	Unknown	Dose: 300/30 Mg	Not Reported
	Vival	S	Unknown		Not Reported
	Lamictal	S	Unknown		Not Reported
	Sarotex	S	Unknown		Not Reported
	Seroquel	S	Unknown		Not Reported
	Codeine Phosphate	C	Unknown		Not Reported
	Cyanocobalamin	C	Unknown		Not Reported
	Diamorphine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15585185	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1851952US		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hyperpyrexia; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Medrol			C	Unknown			Not Reported
	Plavix			C	Unknown			Not Reported
	Omeprazen			C	Unknown			Not Reported
	Desloratadine			C	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15687281	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE01488		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram			S	Unknown	Unk		Not Reported
	Cipralex /01588501/			S	Oral	20 Mg, Qd		Not Reported
	Cipralex /01588501/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15687324	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-057897		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Paracetamol			S	Oral	79 G, Total		Aurobindo
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported
	Escitalopram			S	Oral	Overdose: 140 Mg, 1 Day		Aurobindo
	Prednisolone			S	Oral	200 Mg, Total		Aurobindo
	Cefpodoxime			S	Oral	2000 Mg, Total		Aurobindo
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported
	Oxazepam			S	Oral	310 Mg, Total		Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			S	Oral	6 G, 1 Day		Not Reported
	Loperamide Oxide			S	Oral	30 Mg, Total		Not Reported
	Bilastine			S	Oral	120 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15687623	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2018US23216			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Cipla
	Escitalopram			S	Unknown	Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15687974	EXPEDITED (15-DAY)		OT	IT-ROCHE-2221297			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Treatment Failure	Diazepam			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported

	Lamotrigine	S	Unknown			Not Reported
	Escitalopram	S	Unknown			Not Reported
	Risperidone	S	Unknown			Not Reported
	Epclusa	S	Unknown	Unk		Not Reported
	Lorazepam	S	Unknown			Not Reported
	Flurazepam	S	Unknown			Not Reported
	Chlorpromazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15688334	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP026058		23 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram			S	Oral	15 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15691946	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1856267US		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Weight Decreased; Xerophthalmia	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Lercan			C	Oral			Not Reported
	Lormetazepam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15692027	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1856511US		52 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Tenelia			S	Oral	20 Mg, Qd		Not Reported
	Glimepiride			S	Oral	2 Mg, Qd		Not Reported
	Doral			S	Oral	15 Mg, Qd		Not Reported

Belsomra	S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	8774271	EXPEDITED (15-DAY)		OT	FR-FRI-1000038416		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pruritus; Skin Oedema	Escitalopram Oxalate Unk			S	Oral	15 Mg, Unk		Allergan
	Surgam			S	Oral	200 Mg, Unk		Not Reported
	Crestor			C	Unknown	Unk		Not Reported
	Levothyrox			C	Unknown	Unk		Not Reported
	Daflon			C	Unknown	Unk		Not Reported
	Bromazepam			C	Unknown	Unk		Not Reported
	Tanakan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15058774	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2018M1042987			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Myoclonus; Myoclonus	Zopiclone			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Fluoxetine			S	Unknown	Unk		Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Aripiprazole			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown			Not Reported
	Olanzapine			S	Unknown	Unk		Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Duloxetine			S	Unknown			Not Reported

Duloxetine	S	Unknown	Unk	Not Reported
Clozapine	S	Unknown	75 Mg, Unk	Not Reported
Clozapine	S	Unknown	75 Mg, Unk	Not Reported
Clozapine	S			Not Reported
Escitalopram	S	Unknown	20 Mg	Not Reported
Escitalopram	S	Unknown	20 Mg	Not Reported
Escitalopram	S			Not Reported
Venlafaxine	S	Oral		Not Reported
Venlafaxine	S	Oral	Unk	Not Reported
Mirtazapine	S	Unknown		Not Reported
Mirtazapine	S	Oral	Unk	Not Reported
Risperidone	S	Unknown		Not Reported
Risperidone	S	Unknown	Unk	Not Reported
Amisulpride	S	Unknown		Not Reported
Amisulpride	S	Unknown		Not Reported
Bupropion	S	Unknown		Not Reported
Bupropion	S	Unknown	Unk	Not Reported
Promethazine	S	Unknown		Not Reported
Promethazine	S	Unknown		Not Reported
Biperiden	S	Unknown		Mylan
Biperiden	S	Unknown		Mylan
Oxcarbazepine	C	Unknown	Up To 2400mg; Received Over One Year	Mylan
Oxcarbazepine	C			Mylan
Brivaracetam	C	Unknown	200-250mg; Received Over One Year	Mylan
Brivaracetam	C			Mylan
Carbamazepine	C	Unknown	Up To 900 Mg	Mylan
Carbamazepine	C			Mylan
Oxazepam	C	Unknown	At Different Doses	Not Reported
Oxazepam	C			Not Reported
Oxazepam	C			Not Reported

Zonisamide	C	Unknown	Up To 100mg		Mylan
Zonisamide	C				Mylan
Clobazam	C	Unknown	Up To 20mg		Mylan
Clobazam	C				Mylan
Oxazepam	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15600117	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-053841		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hyperpyrexia; Hyponatraemia	Escitalopram			S	Oral	Unk		Aurobindo
	Desloratadine			C	Unknown	Unk		Not Reported
	Medrol /00049601/			C	Unknown	Unk		Not Reported
	Omeprazen /00661201/			C	Unknown	Unk		Not Reported
	Plavix			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15692966	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-058208		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Weight Decreased; Xerophthalmia	Escitalopram			S	Oral	Unk		Aurobindo
	Lercan			C	Oral	Unk		Not Reported
	Lormetazepam			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15694167	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018019019			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram	S	Oral	Unk, Film Coated Tablet	Macleods
	Cipralex	S	Oral	Unk, Oral Drops	Not Reported
	Cipralex	S	Oral	20 Milligram, Bid, Oral Drops, Started With 1 Drop Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15694301	EXPEDITED (15-DAY)		HO, LT, OT	ES-APOTEX-2018AP026069		18 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypocoagulable State	Ibuprofen			S	Oral	2800 Mg, In Total (400 Mg X 7 Cps)		Apotex
	Paracetamol			S	Oral	12 G, In Total		Apotex
	Escitalopram			S	Oral	Unk Unk, Qd		Apotex
	Exforge			S	Oral	5 Df, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15695622	EXPEDITED (15-DAY)		HO	FR-PROVELL PHARMACEUTICALS-2059777		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Euthyrox			S	Oral			Provell Pharmaceuticals
	Navelbine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15696532	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1856503US		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Interstitial Lung Disease; Multiple Organ	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Hydrea			S	Oral	500-1000 Mg		Not Reported

Dysfunction Syndrome	Xagrid		S	Oral	1 Mg, Qd	Not Reported
	Bromazepam		C	Unknown	Unk, Unknown	Not Reported
	Rovamycine		C	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15697017	EXPEDITED (15-DAY)		HO	US-PRINSTON PHARMACEUTICAL INC.-2018PRN01643		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown			Prinston Pharmaceutical
	Lamotrigine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15645148	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1854396US			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Cancer	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Mirtazapine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15645662	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1854188US		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Lasilix			S	Oral	20 Mg, Qd		Not Reported
	Ramipril			S	Oral	2.5 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Oral	100 Mg, Qd		Not Reported
	Aspirine Protect			S	Oral	100 Mg, Qd		Not Reported

Bisoce	S	Oral	1.25 Mg, Qd		Not Reported
Exemestane	S	Oral	25 Mg, Qd		Not Reported
Gabapentine	S	Oral	200 Mg, Qd		Not Reported
Fluidabak	C	Ophthalmic	3 Gtt, Unknown		Not Reported
Transipeg (Macrogol 3350)	C	Oral	11.8 G, Unknown		Not Reported
Gluconate De Potassium	C	Oral	1 Df, Unknown		Not Reported
Levothyroxine Sodique	C	Oral	30 Gtt, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15697937	EXPEDITED (15-DAY)		HO, LT, OT	US-TORRENT-00007268		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Lamotrigine			S		Unknown		Unknown
	Escitalopram			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15698817	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP026426		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15698938	EXPEDITED (15-DAY)		HO, LT, OT	NL-APOTEX-2018AP026308		69 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug	Hydrochlorothiazide			S	Unknown			Apotex
	Escitalopram			S	Unknown	10 Mg, Qd (1 X Per Day 1		Not Reported

Interaction; Hyponatraemia

Piece)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15699389	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018019059			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety Disorder; Discomfort; Feeling Abnormal; Malaise; Nervousness; Psychomotor Hyperactivity; Stress; Tension Headache; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	10 Milligram, Qd		Macleods
	Escitalopram			S	Unknown	Unk		Macleods
	Amlodipine Besylate			C	Unknown	10 Milligram, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15699747	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018501372			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Gabapentin			S	Oral	300 Mg, 1x/Day		Pfizer
	Gabapentin			S	Oral	600 Mg, 2x/Day		Pfizer
	Cipralex [Escitalopram]			S	Oral	20 Mg, Unk		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, 3x/Day		Not Reported
	Domperidone			S	Unknown	10 Mg, 2x/Day		Not Reported
	Ferrous Sulphate [Ferrous Sulfate]			S	Unknown	300 Mg, 3x/Day		Not Reported
	Temazepam			S	Oral	30 Mg, 1x/Day		Not Reported
	Tylenol With Codeine No.3			S	Oral	2 Df, 3x/Day		Not Reported
	Vitalux [Ascorbic Acid;Betacarotene;Copper;Riboflavin;Selenium;Tocofer			S	Oral	Unk, 2x/Day		Not Reported

	Wellbutrin Xl	S	Oral	150 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15700115	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018480078		60 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spinal Compression Fracture	Lyrica			S		150 Mg, Unk		Pfizer
	Methotrexate Sodium			S		2.5 Mg, Unk		Pfizer
	Celebrex			S		200 Mg, Unk		Pfizer
	Trisequens [Estradiol;Norethisterone Acetate]			S		Unk		Not Reported
	Lexamil			S		20 Mg, Unk		Not Reported
	Peploc [Ranitidine Hydrochloride]			S		40 Mg, Unk		Not Reported
	Be-Tabs Folic Acid			S		5 Mg, Unk		Not Reported
	Rheumalef			S		20 Mg, Unk		Not Reported
	Pexola			S		0375 Mg, Unk (Er)		Not Reported
	Pramex			S		0.25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15701376	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-983383		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting	Azithromycine Anhydre			S	Oral			Not Reported
	Escitalopram			S	Oral	140 Milligram Daily;		Ivax
	Prednisolone			S	Oral			Actavis
	Paracetamol			S	Oral			Not Reported
	Cefpodoxime			S	Oral			Not Reported
	Trimebutine			S	Oral			Not Reported
	Hepatoum, Solution Buvable			S	Oral	Not Informed		Not Reported

	Arestal 1 Mg, Comprimé	S	Oral	Not Reported
	Seresta 10 Mg, Comprimé	S	Oral	Not Reported
	Inorial 20 Mg, Comprimé	S	Oral	Not Reported
	Augmentin	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2018	14160254	EXPEDITED (15-DAY)		HO	CH-ROCHE-2014835		74 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Drug Withdrawal Syndrome	Seresta			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Tramal			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Quetiapin			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Clexane			C	Unknown			Not Reported
	Aspirin Cardio			C	Unknown			Not Reported
	Atorvastatine			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Concor			C	Unknown			Not Reported
	Zanidip			C	Unknown			Not Reported
	Coversum			C	Unknown			Not Reported
	Inderal			C	Unknown			Not Reported
	Atarax			C	Unknown			Not Reported
	Enalapril			C	Unknown			Not Reported

Anxiolit	C	Oral	Not Reported
Vit D3	C	Unknown	Not Reported
Prontalgine	C	Unknown	Not Reported
Nacl	C	Unknown	Not Reported
Torasemide	C	Unknown	Not Reported
Laxoberon	C	Unknown	Not Reported
Dafalgan	C	Unknown	Not Reported
Motilium	C	Unknown	Not Reported
Benerva	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2018	15703439	DIRECT		DS			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Chills; Cold Sweat; Headache; Hyperhidrosis; Hypoaesthesia; Nausea; Paraesthesia; Sexual Dysfunction; Skin Burning Sensation; Tremor; Withdrawal Syndrome	Escitalopram 5 Mg Substitute For Lexapro 5. Mg Tablet			S	Oral	Quantity:1 Tablet(S);		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	13828244	EXPEDITED (15-DAY)		DE, OT	JP-ASTRAZENECA-2017SE78445		77 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Dyspnoea; Interstitial Lung Disease; Off Label Use	Seroquel			S	Oral			Zeneca
	Escitalopram			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15618244	EXPEDITED (15-DAY)		HO	FR-ARBOR PHARMACEUTICALS, LLC-FR-2018ARB001145		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Prescribed Underdose	Triptodur			S	Intramuscular	1 Df, Cyclical		Arbor
	Lipanthyl			S	Oral	145 Mg, 1 D		Not Reported
	Esomeprazole			S	Oral	Unk		Not Reported
	Xtandi			S	Oral	120 Mg, 1 D		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	10 Mg, 1 D		Not Reported
	Amlor			S	Oral	Unk		Not Reported
	Novonorm			S	Oral	Unk		Not Reported
	Innohep			S	Subcutaneous	1 Dosage Forms, 1 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15659820	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-056616		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral	140 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Once A Day (Overdose: 140 Mg, 1 Day)		Aurobindo
	Prednisolone			S	Oral	200 Milligram, In Total		Aurobindo
	Prednisolone			S	Oral	20 Milligram In Total (200 Mg, Total)		Aurobindo
	Paracetamol			S	Oral	79 Gram, In Total		Aurobindo
	Cefpodoxime			S	Oral	2000 Milligram, In Total		Aurobindo
	Cefpodoxime			S	Oral	100 Milligram In Total		Aurobindo
	Trimebutine			S	Oral	14000 Milligram, In Total		Not Reported

Trimebutine	S	Oral	200 Milligram In Total (14000 Mg, Total)		Not Reported
Azithromycin	S	Oral	1500 Milligram, Total		Aurobindo
Azithromycin	S	Oral	250 Milligram Total (1500 Mg, Total)		Aurobindo
Hepatoum	S	Oral	Unk		Not Reported
Seresta	S	Oral	310 Milligram, Total		Not Reported
Seresta	S	Oral	10 Milligram Total (310 Mg, Total)		Not Reported
Arestal	S	Oral	30 Milligram, Total		Not Reported
Arestal	S	Oral	1 Milligram Total (30 Mg, Total)		Not Reported
Inorial	S	Oral	120 Milligram, Total		Not Reported
Inorial	S	Oral	20 Milligram, Total (120 Mg, Total)		Not Reported
Augmentin /00756801/	S	Oral	6 Gram, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15660054	NON-EXPEDITED			US-BIOGEN-2018BI00661716			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Balance Disorder; Depression; Feeling Abnormal; Feeling Hot; Insomnia; Myalgia; Nausea; Pruritus	Tecfidera			S	Unknown	Starter Dose		Biogen
	Tecfidera			S	Unknown	Maintenance Dose		Biogen
	Tecfidera			S	Unknown			Biogen
	Lexapro			S	Unknown			Not Reported
	Ampyra			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15661262	EXPEDITED (15-DAY)			IT-PFIZER INC-2018483377		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Drug Ineffective	Venlafaxine Hcl		S	Unknown	Unk	Pfizer
	Valproic Acid		S	Unknown		Not Reported
	Quetiapine		S	Unknown	Unk	Not Reported
	Escitalopram		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15701507	EXPEDITED (15-DAY)		HO, LT, OT	US-HETERO CORPORATE-HET2018US01504		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown	Unk		Hetero
	Lamotrigine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15702477	EXPEDITED (15-DAY)		HO, LT, OT	ES-ACCORD-095252		79 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Drug Interaction	Escitalopram			S	Oral			Not Reported
	Enoxaparin/Enoxaparin Sodium			S	Subcutaneous			Not Reported
	Sintrom			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15702486	EXPEDITED (15-DAY)		HO	FR-ACCORD-095347		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Furosemide			S	Oral			Accord
	Seroplex			S	Oral	10 Mg Film-Coated Tablets		Not Reported
	Xarelto			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15702537	EXPEDITED (15-DAY)		OT	PL-APOTEX-2018AP025950			Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Learning Disorder; Mental Impairment; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	37.5 Mg, Qd		Apotex
	Tianeptine			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15702817	EXPEDITED (15-DAY)		OT	SE-TEVA-2018-SE-983545		39 YR	Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Suicide Attempt	Escitalopram Teva			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15703541	DIRECT		LT, OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Weight Decreased	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15704077	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018501689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Gabapentin			S	Oral	600 Mg, 2x/Day		Pfizer
	Gabapentin			S	Oral	300 Mg, 1x/Day		Pfizer
	Acetaminophen And Codeine Phosphate			S	Oral	2 Df, 3x/Day		Not Reported
	Cipralex [Escitalopram]			S	Oral	20 Mg, Unk		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, 3x/Day		Not Reported

Co Temazepam	S	Oral	30 Mg, 1x/Day		Not Reported
Domperidone	S	Unknown	10 Mg, 2x/Day		Not Reported
Ferrous Sulfate	S	Unknown	300 Mg, 3x/Day		Not Reported
Wellbutrin Xl	S	Oral	150 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15705229	EXPEDITED (15-DAY)		HO	US-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00493		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown	Unk		Jubilant
	Lamotrigine			S	Unknown			Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15706657	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1856980US		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Overdose; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Oral	40 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15707027	EXPEDITED (15-DAY)		DE, HO	FR-MYLANLABS-2018M1092051		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage Intracranial	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Duoplavin			S	Oral	75 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	10153841	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014121792		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Intentional Product Misuse; Lung Infection; Melanocytic Naevus; Rheumatoid Factor Increased; Stillbirth	Tecta			S	Unknown	30 Mg, Qd		Pfizer
	Cipralex			S	Unknown	10 Mg, Unk		Not Reported
	Imodium			S	Unknown	As Required, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, 1 In 8 Weeks		Not Reported
	Tylenol With Codeine No.3			S	Unknown	Unk		Not Reported
	Ventolin			S	Unknown	Unk		Not Reported
	Loperamide Hydrochloride			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	14144705	EXPEDITED (15-DAY)		HO	CH-UCBSA-2017042706		74 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Drug Withdrawal Syndrome	Keppra			S	Oral	250 Mg, 2x/Day (Bid)		Ucb
	Seresta			S	Oral	Unk		Not Reported
	Valium			S	Oral	5 Mg, 6x/Day (3-4 Caps/Day)		Not Reported
	Risperdal			S	Oral	0.25 Mg, 2x/Day (Bid)		Not Reported
	Quetiapin			S	Oral	50 Mg, Once Daily (Qd)		Not Reported
	Haldol			S	Oral	4 Mg Daily		Not Reported
	Escitalopram			S	Oral	10 Mg, Once Daily (Qd)		Not Reported
	Fluoxetine			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Tramal			S	Oral	12.5 Mg, 2x/Day (Bid)		Not Reported
	Clexane			C		Unk		Not Reported
	Aspirin Cardio			C				Not Reported
	Atorvastatine			C				Not Reported
	Crestor			C				Not Reported
	Tenormin			C				Not Reported
	Concor			C				Not Reported
	Zanidip			C				Not Reported
	Coversum			C				Not Reported

	Inderal	C	Not Reported
	Atarax	C	Not Reported
	Enalapril	C	Not Reported
	Anxiolit	C	Not Reported
	Vit D3	C	Not Reported
	Caffeine W/Codeine Phosphate/Paracetamol	C	Not Reported
	Nacl	C	Not Reported
	Potassium	C	Not Reported
	Laxoberon	C	Not Reported
	Dafalgan	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	14831664	EXPEDITED (15-DAY)		OT	BE-ACCORD-066259		39 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Insomnia; Lacrimation Increased; Tachyphrenia; Vertigo	Escitalopram			S				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15706659	EXPEDITED (15-DAY)		HO, LT, OT	US-ALLERGAN-1856821US		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Lamotrigine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15708066	EXPEDITED (15-DAY)		HO, LT, OT	US-ACCORD-095253		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms;	Escitalopram			S				Not Reported
	Lamotrigine			S				Not Reported

Hepatic Failure; Toxic Epidermal Necrolysis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15708875	EXPEDITED (15-DAY)		HO	SE-COLLEGIUM PHARMACEUTICAL, INC.-SE-2018COL014620			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Tapentadol			S		Unk		Collegium Pharmaceutical
	Fentanyl			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Glytrin /00003201/			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Zopiklon			C		Unk		Not Reported
	Behepan /00056201/			C		Unk		Not Reported
	Panodil			C		Unk		Not Reported
	Trombyl			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15709361	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2018M1089986		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hemiplegia; Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown			Not Reported
	Norepinephrine			S	Unknown			Not Reported
	Phenylephrine			C	Unknown			Mylan
	Valsartan			C	Unknown			Mylan
	Metoprolol			C	Unknown			Mylan
	Nimodipine			C	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15709859	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1856984US		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flight Of Ideas; Off Label Use; Sensory Disturbance	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Lamictal			C	Oral			Not Reported
	Rivotril			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15709946	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1856969US		56 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Metoprolol			S	Oral	Unk		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15710339	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1856983US		22 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown	270 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15711078	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-984923		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram			S	Unknown			Ivax
	Cipralex Oral Drops			S	Unknown	Started With 1 Drop Daily		Not Reported
	Cipralex Oral Drops			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15711351	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1823788US		44 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Drug Ineffective; Dysphemia; Libido Increased; Movement Disorder; Musculoskeletal Stiffness; Off Label Use; Palpitations; Prescribed Overdose; Product Use Issue; Reduced Facial Expression; Suicidal Ideation	Citalopram Hydrobromide - Bp			S	Oral	20 Mg, Unknown		Allergan
	Citalopram Hydrobromide - Bp			S	Oral	20 Mg, Tid (1 Tablet In The Morning And 2 Tablets In The Afternoon)		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Bid		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Bid		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	40 Mg, Bid		Allergan
	Quetiapine			C	Unknown	1 Tablet, Bid (One In The Morning And One In The Evening)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15351976	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC-2018355913		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pulmonary Fibrosis	Pantoprazole			S	Oral	20 Mg, Qd		Pfizer
	Paracetamol			S	Oral	1500 Mg, Qd		Unknown
	Atorvastatine Pfizer			S	Oral	10 Mg, Qd		Pfizer
	Ramipril			S	Oral	5 Mg, Qd		Pfizer
	Lorazepam			S	Oral	1 Mg, Qd		Pfizer
	Amiodarone Hcl			S	Oral	200 Mg, Qd		Pfizer
	Levothyrox			S	Oral	1 Unk, Qd		Not Reported
	Kardegic			S	Oral	1 Df, 1x/Day		Not Reported
	Caltrate Vitamine D3			S	Oral	Unk (600mg/400ui)		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15711584	EXPEDITED (15-DAY)		HO	FR-ZYDUS-030940		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Malaise; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting	Paracetamol			S	Oral			Not Reported
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported
	Cefpodoxime/Cefpodoxime Proxetil			S	Oral			Not Reported
	Escitalopram			S	Oral	Overdose: 140 Mg, 1 Day		Zydus Pharm
	Inorial			S	Oral			Not Reported
	Chloroform/Glycerol/Herbal Extract Nos/Isoamyl Acetate/Menthol [Hepatoum]			S	Oral			Not Reported
	Loperamide			S	Oral			Not Reported
	Oxazepam			S	Oral	310 Mg, Total		Not Reported
	Amoxicillin Sodium/Clavulanate Potassium			S	Oral	6 G, 1 Day		Not Reported
	Prednisolone			S	Oral	200 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15711952	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-030986		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hemiparesis; Hemiplegia; Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown			Zydus Pharm
	Metoprolol			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15712309	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2018-08617		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15712407	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2018-058490		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown			Aurobindo
	Escitalopram			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15713685	EXPEDITED (15-DAY)		OT	SE-TEVA-2018-SE-985433		19 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pharyngeal Haemorrhage	Escitalopram			S	Oral			Ivax
	Escitalopram			S				Ivax
	Escitalopram			S				Ivax
	Citalopram			S	Oral			Actavis
	Citalopram			S				Actavis
	Citalopram			S				Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15714747	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-984996		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Weight Decreased; Xerophthalmia	Escitalopram			S	Oral			Ivax
	Lercan 20 Mg, Comprimé			C	Oral			Not Reported

	Pelliculé Lormetazepam	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15715119	EXPEDITED (15-DAY)		OT	PHHY2018CA183344			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Voltaren			S	Topical	Unk Unk, Qd		Novartis
	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Nortriptyline			S	Oral	25 Mg, Qd		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naprelan			S	Unknown	1000 Mg, Qd		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Tylenol			S	Topical	Unk Unk, Prn		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	700 Mg, Every 6 Weeks		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	600 Mg,/ Q 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Diclofenac			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15486053	EXPEDITED (15-DAY)		HO	ZA-CIPLA (EU) LIMITED-2018ZA21652			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Lumbar Vertebral Fracture	Escitalopram			S	Unknown	Unk		Invagen
	Amloc /00550802/			S	Unknown	Unk		Not Reported
	Bilocor			S	Unknown	Unk		Not Reported
	Co-Diovan			S	Unknown	Unk		Not Reported

	Mylan Pantoprazole		S	Unknown	Unk	Not Reported
	Celebrex		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15687591	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-192631		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral	140 Milligram		Not Reported
	Cefpodoxime			S	Oral	In Total		Sun
	Prednisolone			S	Oral	In Total		Taro
	Trimebutine			S	Oral	In Total		Not Reported
	Paracetamol		Y	S	Oral	In Total		Ohm Lab
	Azithromycine			S	Oral	In Total		Sun
	Hepatoum, Solution Buvable			S	Oral	Non Renseignee ()		Not Reported
	Arestal 1 Mg, Comprime			S	Oral	In Total		Not Reported
	Seresta 10 Mg, Comprime			S	Oral	In Total		Not Reported
	Inorial 20 Mg, Comprime			S	Oral	In Total		Not Reported
	Augmentin			S	Oral	6 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15716308	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2018US23492			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Orthostatic Hypotension	Topiramate			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15716746	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2018-059595		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Escitalopram			S	Oral	40 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15718620	EXPEDITED (15-DAY)		HO, LT, OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2018019184			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Escitalopram Oxalate			S	Unknown	Unk, 2.5 Weeks		Macleods
	Lamotrigine			S	Unknown	Unk, 2.5 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15718711	EXPEDITED (15-DAY)		HO, OT	BE-APOTEX-2018AP026915		67 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Diclofenac Sodium			S	Unknown	Unk, Unknown		Apotex
	Escitalopram			S	Unknown	Unk, Unknown		Apotex
	Rivaroxaban			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15718980	EXPEDITED (15-DAY)		HO, LT, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-088		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown	()		Hikma
	Lamotrigine			S	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15720322	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2018-US-986500		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hemiplegia; Reversible Cerebral Vasoconstriction Syndrome; Thunderclap Headache	Escitalopram			S	Unknown			Ivax
	Escitalopram			S				Ivax
	Norepinephrine			S	Unknown			Teva
	Phenylephrine			S	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Nimodipine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	9767492	EXPEDITED (15-DAY)		DE, LT, OT	NO-NAPPMUNDI-GBR-2013-0016523		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drowning; Intentional Self-Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Tramadol Hydrochloride			S	Unknown	50, 200mg		Purdue
	Oxynorm			S	Unknown	10 Mg, Unk		Purdue
	Oxynorm			S	Unknown	5 To 10mg		Purdue
	Rivotril			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown			Not Reported
	Vival			S	Unknown	Unk		Not Reported
	Catapresan /00171101/			S	Unknown	Strength 25 Mg, 50 Mg, Unk		Not Reported
	Cipralex			S	Unknown			Not Reported
	Nobligan			S	Unknown	200 Mg, Unk, Strength: 50 Mg-200 Mg		Not Reported
	Atarax /00058401/			S	Unknown	Unk		Not Reported
	Orfiril			S	Unknown	1200 Mg, Unk		Not Reported

Orfiril	S	Unknown	Strength: 600 Mg-1200 Mg	Not Reported
Nozinan /00038601/	S	Unknown	Unk	Not Reported
Sobril	S	Unknown	Unk	Not Reported
Sobril	S			Not Reported
Remeron	S	Unknown	Unk	Not Reported
Seroquel	S	Unknown	Unk	Not Reported
Cipramil /00582603/	S	Unknown	Unk	Not Reported
Pinex Forte	S	Unknown	Strength: 500/30 Mg And Pandeine	Not Reported
Pinex Forte	S	Unknown	Strength: 500/30 Mg And Pandeine	Not Reported
Pinex Forte	S	Unknown	Strength: 500/30 Mg And Pandeine	Not Reported
Pinex Forte	S	Unknown	300/30 Mg And Pandeine	Not Reported
Imovane	S	Oral	Unk	Not Reported
Truxal /00012102/	S	Unknown	600 To 1200mg	Not Reported
Sarotex	S	Unknown	Unk	Not Reported
Sarotex	S	Unknown	Unk	Not Reported
Lamictal	S	Unknown	100 Mg, Unk	Not Reported
Lamictal	S	Unknown	100 Mg, Unk Strength: 25 Mg, 50 Mg, 100 Mg	Not Reported
Diazepam	S	Unknown	Unk	Not Reported
Diamorphine	C		Unk	Not Reported
Diamorphine	C	Unknown	Unk	Not Reported
Nozinan /00038601/	C		Unk	Not Reported
Cyanocobalamin	C	Unknown		Not Reported
Cyanocobalamin	C		Unk	Not Reported
Codeine Phosphate Tablet	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	14165657	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20171105275		74 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Drug Interaction; Drug Withdrawal Syndrome; Fall; Hypotension	Tramal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Quetiapin			S	Oral			Not Reported
	Valium			S	Oral	Strength Of Each Capsule: 5 Mg; Dose: 3-6 Capsules		Not Reported
	Fluoxetine			S	Oral			Not Reported
	Sodium Chloride			C	Unknown	0.9 Percent Injectable Perfusion		Not Reported
	Motilium			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Zanidip			C	Unknown			Not Reported
	Coversum			C	Unknown			Not Reported
	Prontalgine			C	Unknown			Not Reported
	Dafalgan			C	Unknown			Not Reported
	Clexane			C	Unknown			Not Reported
	Benerva			C	Unknown			Not Reported
	Aspirin Cardio			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Concor			C	Unknown			Not Reported
	Atarax			C	Unknown			Not Reported
	Enalapril			C	Unknown			Not Reported
	Anxiolit			C	Unknown			Not Reported
	Anxiolit			C	Unknown			Not Reported

Vitamin D3	C	Unknown	Not Reported
Potassium	C	Unknown	Not Reported
Torasemide	C	Unknown	Not Reported
Laxoberon	C	Unknown	Not Reported
Becozyme C	C	Unknown	Not Reported
Inderal	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15351152	EXPEDITED (15-DAY)		DE, HO, OT	FR-BAUSCH-BL-2018-024361		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pulmonary Fibrosis	Lorazepam			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported
	Levothyrox			S	Oral	1 (Unspecified)		Not Reported
	Atorvastatine			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Caltrate Vitamine D3			S	Oral	600 Mg / 400 Iu; Divisible Coated Tablet		Not Reported
	Amiodarone Hydrochloride			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15668963	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-192275		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Gabapentine			S	Oral	200 Milligram, Qd		Ranbaxy
	Ramipril			S	Oral	2.5 Milligram, Qd		Ranbaxy

Exemestane	S	Oral	25 Milligram, Qd		Not Reported
Seroplex 5 Mg, Comprime Pellicule	S	Oral	5 Milligram, Qd		Not Reported
Bisoce 1,25 Mg, Comprime Pellicule	S	Oral	1.25 Milligram, Qd		Not Reported
Lasilix 10 Mg/Ml, Solution Buvable	S	Oral	20 Milligram, Qd		Not Reported
Aspirine Protect 100 Mg, Comprime Gastro Resistant	S	Oral	100 Milligram, Qd		Not Reported
Lamotrigine	S	Oral	100 Milligram, Qd		Not Reported
Fluidabak 1,5 %, Collyre En Solution	C	Ophthalmic	3 Gtt, Qd		Not Reported
Transipeg 5,9 G, Poudre Pour Solution Buvable En Sachet	C	Oral	11.8 Gram, Qd		Not Reported
Gluconate De Potassium	C	Oral	(1 Cs Par Jour)		Not Reported
Levothyroxine Sodique	C	Oral	30 Gtt, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15699736	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018501418		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Gabapentin			S	Oral	600 Mg, 2x/Day		Pfizer
	Gabapentin			S	Oral	300 Mg, 1x/Day		Pfizer
	Cipralex [Escitalopram]			S	Oral	20 Mg, Unk		Not Reported
	Clonazepam			S	Oral	0.5 Mg, 3x/Day		Not Reported
	Domperidone			S	Oral	10 Mg, 2x/Day		Not Reported
	Ferrous Sulfate			S	Oral	300 Mg, 3x/Day		Not Reported
	Temazepam			S	Oral	30 Mg, 1x/Day		Not Reported
	Tylenol With Codeine			S	Oral	2 Df, 3x/Day		Not Reported
	Wellbutrin Xl			S	Oral	150 Mg, 2x/Day		Not Reported
	Vitalux [Ascorbic Acid;Betacarotene;Copper;Riboflavin;Selenium;Tocofer			S	Oral	Unk Unk, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15720982	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018019187			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Macleods
	Metoprolol			S	Oral	Unk		Not Reported
	Xarelto			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15721172	EXPEDITED (15-DAY)		HO, OT	US-HETERO CORPORATE-HET2018US01521		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown	Unk		Hetero
	Phenylephrine			S	Unknown	Unk		Not Reported
	Norepinephrine			S	Unknown	Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15722200	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-060061		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flight Of Ideas; Sensory Disturbance	Escitalopram			S	Oral	15 Milligram, Once A Day		Aurobindo
	Lamictal			C	Oral	200 Milligram		Not Reported
	Rivotril			C	Oral	0.5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15722207	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-059942		56 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Aurobindo
	Metoprolol			S	Oral	Unk		Aurobindo
	Xarelto			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15722988	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2018M1093315		64 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Mania	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported
	Amitriptyline			S	Unknown	25 Milligram, Qd		Not Reported
	Tramadol			S	Unknown			Not Reported
	Levofloxacin			C	Unknown			Mylan
	Acetaminophen			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15725037	EXPEDITED (15-DAY)		HO, OT	SE-ALLERGAN-1000070451		19 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	18 Tablets Of 5 Mg In Total, Overdose 90 Mg		Allergan
	Cerazette [Desogestrel]			S	Oral	6 Tablets Of 75 Mcg In Total		Not Reported
	Alvedon			S	Oral	8 Or 9 Tables, In Total		Not Reported
	Atarax			S	Oral	6 Tablets Of 10 Mg In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2018	15629007	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-975073		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Hyperpyrexia; Hyponatraemia	Escitalopram	S	Oral	Ivax
	Medrol	C	Unknown	Not Reported
	Plavix	C	Unknown	Not Reported
	Omeprazen	C	Unknown	Not Reported
	Desloratadine	C	Unknown	Not Reported
	Pregabalin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2018	15725565	EXPEDITED (15-DAY)		CA, OT	NL-ACCORD-096287			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Oral Malformation; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	1 Dd 1		Not Reported
	Foliumzuur			C				Not Reported
	Retinol			C				Not Reported
	Cyklokapron			C				Not Reported
	Colecalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	13516802	EXPEDITED (15-DAY)		HO	IT-ACCORD-051030		51 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram			S	Oral	Strength: 10 Mg		Accord
	Xanax			S	Oral	Strength: 0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	14294111	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2017M1078502		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged;	Bisoprolol			S	Oral	5.75 Mg, Qd (3.25 Mg In Morning And 2.5 Mg In Evening)		Not Reported
	Bisoprolol			S	Oral	Unk		Not Reported

Haematuria; Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence	Ramipril	S			Not Reported
	Lactibiane (Probiotic)	S			Mylan
	Diffu-K	S	Oral	Unk	Mylan
	Triatec [Ramipril]	S	Oral	5 Mg (2.5 Mg, Bid)	Mylan
	Triatec [Ramipril]	S	Oral	2.5 Milligram, Bid	Mylan
	Brilique	S	Oral	180 Mg (90 Mg, Bid)	Mylan
	Brilique	S	Oral	Unk	Mylan
	Seroplex	S	Oral	5 Mg, Qd	Mylan
	Seroplex	S	Oral	Unk	Mylan
	Tahor	S	Oral	Unk	Mylan
	Tahor	S	Oral	40 Milligram, Qd	Mylan
	Inexium /01479302/	C		20 Mg, Unk	Mylan
	Kardegic	C		75 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15701253	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018501330		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Malaise; Mydriasis; Product Use In Unapproved Indication; Somnolence; Suicide Attempt; Toxicity To Various Agents; Vomiting	Inorial			S	Oral	120 Mg, Single		Not Reported
	Bilastine			S	Oral	120 Mg, Unk		Not Reported
	Azithromycine			S	Oral	1500 Mg, Single		Pfizer
	Trimebutine Maleate			S	Oral	14000 Mg, Single		Not Reported
	Hepatoum			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	140 Mg, 1x/Day		Not Reported
	Arestal			S	Oral	30 Mg, Single		Not Reported
	Seresta			S	Oral	310 Mg, Single		Not Reported
	Prednisolone			S	Oral	200 Mg, Single		Not Reported
	Paracetamol			S	Oral	79 G, Single		Not Reported
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S	Oral	6 G, 1x/Day		Not Reported
	Cefpodoxime			S	Oral	2000 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15726789	EXPEDITED (15-DAY)		HO	DK-ACCORD-095916		82 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Atrial Fibrillation; Muscle Spasms; Muscle Twitching; Somnolence	Escitalopram			S				Not Reported
	Verapamil			S		As Extended Release Tablets 240 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15726878	EXPEDITED (15-DAY)		LT	FR-TEVA-2018-FR-986937		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Escitalopram			S	Oral	40 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15727458	EXPEDITED (15-DAY)		LT	FI-ASTRAZENECA-2018SF62795			Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hyporesponsive To Stimuli; Jaundice Neonatal; Maternal Condition Affecting Foetus; Neonatal Respiratory Distress; Sepsis Neonatal	Ketipinor			S	Transplacental			Zeneca
	Escitalopram			S	Transplacental			Not Reported
	Albetol			C	Transplacental			Not Reported
	Thyroxin			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15727495	EXPEDITED (15-DAY)		HO, OT	BE-APOTEX-2018AP026913		70 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction;	Escitalopram			S	Unknown	Unk, Unknown		Apotex

Gastrointestinal Haemorrhage	Rivaroxaban	S	Oral	15 Mg, Qd		Not Reported
	Rivaroxaban	S				Not Reported
	Clarithromycin	S	Unknown	Unk, Unknown		Not Reported
	Diltiazem	S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15730184	EXPEDITED (15-DAY)		HO, OT	AU-SA-2018SA336954		73 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Asthenia; Blood Creatinine Increased; Hypomagnesaemia; Lethargy; Malaise; Myalgia; Nausea; Vomiting	Irbesartan			S		Unk Unk, Unk		Sanofi
	Metformin Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Ondansetron			S		Unk Unk, Unk		Not Reported
	Escitalopram Oxalate			S		Unk Unk, Unk		Not Reported
	Ranitidine			S	Unknown	Unk Unk, Unk		Sanofi
	Amphotericin B			S		Unk Unk, Unk		Not Reported
	Posaconazole			S		Unk Unk, Unk		Not Reported
	Isavuconazole			S	Unknown	Unk Unk, Unk		Not Reported
	Amlodipine			C	Unknown	Unk Unk, Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk Unk, Unk		Not Reported
	Tapentadol			C		Unk		Not Reported
	Gliclazide			C		Unk Unk, Unk		Not Reported
	Metoclopramide			C		Unk Unk, Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk Unk, Unk		Not Reported
	Oxycodone			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15731630	EXPEDITED (15-DAY)		HO	PHHY2018FR184365		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State;	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

Hyponatraemia	Hydrochlorothiazide		S	Oral	Unk	Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15732154	EXPEDITED (15-DAY)		DE, HO, LT	DK-MYLANLABS-2018M1093886		82 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Atrial Fibrillation; Bradycardia; Bundle Branch Block Left; Cardiotoxicity; Completed Suicide; Hypercapnia; Intentional Overdose; Muscle Spasms; Muscle Twitching; Somnolence; Toxicity To Various Agents	Verapamil			S	Oral	Formulation: Extended Release		Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	13389662	EXPEDITED (15-DAY)		HO	IT-ACCORD-049648		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor; Toxicity To Various Agents	Escitalopram			S	Oral			Accord
	Quetiapine			S	Oral			Accord
	Carbolithium Teva			S	Oral	Strength: 300 Mg, Capsule Rigid		Not Reported
	Etiltox			S	Oral	Strength: 200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15614007	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1085608		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Feeling Abnormal; Panic Attack	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S		15 Milligram, Qd		Not Reported
	Cipralex /01588501/			S		Unk		Mylan

	Cipralex /01588501/	S	Unknown	15 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15700047	EXPEDITED (15-DAY)		HO, OT	GR-ALLERGAN-1856620US		66 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea Exertional; Pleural Effusion; Pleuritic Pain; Pulmonary Embolism	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15734508	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC-2018SUN00617		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Taro
	Escitalopram			S	Unknown	Unk		Taro

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15735605	EXPEDITED (15-DAY)		HO	BE-MYLANLABS-2018M1093872		70 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Diltiazem			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Rivaroxaban			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15736137	EXPEDITED (15-DAY)		HO	SE-TEVA-2018-SE-988719		22 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Toxicity To Various Agents	Escitalopram			S	Unknown	270 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15736700	EXPEDITED (15-DAY)		HO, OT	BE-BAUSCH-BL-2018-035292		67 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Diclofenac			S	Unknown			Bausch And Lomb
	Rivaroxaban			S	Oral	Duration More Than 1 Year		Not Reported
	Rivaroxaban			S				Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15736955	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2018M1091965		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown			Not Reported
	Lamotrigine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	13960570	EXPEDITED (15-DAY)		DS	US-ALLERGAN-1681370US		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Ejaculation Delayed; Hypoaesthesia	Lexapro			S	Unknown	Unk		Allergan
	Lorazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	14461504	NON-EXPEDITED			US-ALLERGAN-1774042US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Lip Dry; Nervousness; Off Label Use; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan
	Inderal			C	Oral	Unk		Not Reported
	Spironolactone			C	Oral	Unk Unk, Prn		Not Reported
	Zocor			C	Oral	20 Mg, Qd		Not Reported
	Linzess			C	Oral	145 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15118007	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2018-034563		34 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Fear-Related Avoidance Of Activities; Learning Disorder; Mental Impairment; Overdose; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	37.5 Milligram, Daily		Aurobindo
	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Tianeptine			C	Unknown	10 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15665794	EXPEDITED (15-DAY)		HO	GR-MYLANLABS-2018M1088424		66 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Mylan-Escitalopram			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739238	EXPEDITED (15-DAY)		OT	GB-TORRENT-00019749		63 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Feeling Cold; Incorrect Dose Administered; Nausea	Escitalopram			S	Oral	Prescribed 10 Mg		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739268	NON-EXPEDITED			US-ALLERGAN-1769657US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739274	NON-EXPEDITED			US-ALLERGAN-1805436US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro			S	Unknown	5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739277	NON-EXPEDITED			US-ALLERGAN-1812188US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739279	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1800825US		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Distractibility; Feeling Abnormal; Memory Impairment; Off Label Use; Pulmonary Embolism	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Latuda			C	Unknown	20 Mg, Qd		Not Reported
	Haldol			C	Unknown	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739280	NON-EXPEDITED			US-ALLERGAN-1827505US		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia	Lexapro			S	Oral	2.5 Mg, Unk		Allergan
	Lexapro			S	Oral	5 Mg, Unk		Allergan
	Ativan			C	Oral	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739282	NON-EXPEDITED			US-ALLERGAN-1803991US		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739283	NON-EXPEDITED			US-ALLERGAN-1834895US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Lexapro			S	Unknown	Unk		Allergan
	Votrient			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739284	NON-EXPEDITED			US-ALLERGAN-1803998US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Cold; Feeling Hot; Nasopharyngitis; Paraesthesia	Lexapro			S	Unknown			Allergan
	Robitussin /00048001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739285	NON-EXPEDITED			US-ALLERGAN-1838837US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Lexapro			S	Oral	20 Mg, Qd		Allergan

Feeling Jittery; Intentional Dose Omission; Lethargy; Seizure; Serum Serotonin Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739286	NON-EXPEDITED			US-ALLERGAN-1803505US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Libido; Sexual Dysfunction	Lexapro			S	Oral			Allergan
	Latuda			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739287	NON-EXPEDITED			US-ALLERGAN-1816775US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nervousness	Lexapro			S	Unknown	Unk		Allergan
	Lexapro			S				Allergan
	Effexor			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739288	NON-EXPEDITED			US-ALLERGAN-1809644US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral	10 Mg, Unk		Allergan
	Lexapro			S	Oral	20 Mg, Unk		Allergan
	Lorazepam			C	Oral	0.5 Mg, Prn		Not Reported
	Garlic			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739290	NON-EXPEDITED			US-ALLERGAN-1811555US		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739291	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1837915US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cognitive Disorder; Confusional State; Depression; Impaired Driving Ability; Malaise; Off Label Use; Withdrawal Syndrome	Lexapro			S	Oral	Unk Unk, Qd		Allergan
	Lexapro			S				Allergan
	Lexapro			S				Allergan
	Xanax			C	Oral	Unk Unk, Unknown		Not Reported
	Xanax			C				Not Reported
	Xanax			C				Not Reported
	Prozac			C	Oral	Unk Unk, Unknown		Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739292	NON-EXPEDITED			US-ALLERGAN-1832357US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Exfoliation	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739293	NON-EXPEDITED			US-ALLERGAN-1801818US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Depression	Lexapro			S	Unknown	Unk		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739294	NON-EXPEDITED			US-ALLERGAN-1833815US		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan
	Seroquel			C	Oral	50 Mg, Qd		Not Reported
	Inderal			C	Oral	120 Mg, Qd		Not Reported
	Klonopin			C	Oral	1 Mg, Qhs		Not Reported
	Xanax			C	Oral	1 Mg, Bed Time		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739295	NON-EXPEDITED			US-ALLERGAN-1800908US		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hyperacusis; Tinnitus	Lexapro			S	Unknown	5 Mg, Unk		Allergan
	Lexapro			S				Allergan
	Prilosec			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739296	NON-EXPEDITED			US-ALLERGAN-1815769US		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15740758	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-987757		56 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To Various Agents	Escitalopram			S	Oral			Ivax
	Metoprolol			S	Oral			Not Reported
	Xarelto 10 Mg Film-Coated Tablets			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15742031	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1858146US		85 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Psychomotor Retardation	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Depalgos			S	Oral	3 Df, Qd		Not Reported
	Aprovel			C	Unknown			Not Reported
	Sinemet			C	Unknown			Not Reported
	Moduretic			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15742219	NON-EXPEDITED			US-TEVA-2018-US-984671			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Nausea	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15742337	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1094357		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Alprazolam			S	Oral	1 Dosage Form, Total		Not Reported
	Seroplex			S	Oral	1 Dosage Form, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15210113	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1055418		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Tramadol			S	Oral	Unk (Posologie Inconnue)		Not Reported
	Seroplex			S	Oral	20 Mg, Unk		Mylan

	Bilaska	S	Oral	Unk (Posologie Inconnue)	Mylan
	Seresta	S	Oral	Unk (Posologie Inconnue)	Mylan
	Nocertone	S	Oral	Unk	Mylan
	Simponi	S	Subcutaneous	50 Mg, Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15715532	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1857142US			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15738577	NON-EXPEDITED			US-PFIZER INC-2018520725		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S		Unk		Pfizer
	Zoloft			S				Pfizer
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Cymbalta			S		Unk		Not Reported
	Cymbalta			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15739590	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP027291		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Product Substitution Error	Escitalopram			S	Oral	20 Mg, Qd		Apotex
	Idaptan			S	Oral	20 Mg, Bid		Not Reported
	Nifedipino			C	Oral	20 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15743829	EXPEDITED (15-DAY)		HO	FR-ACCORD-096656		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Escitalopram			S				Not Reported
	Ceftriaxone			S				Not Reported
	Risperidone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15744209	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20180211067		93 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Fall; Hyponatraemia; Hypotension; Hypovitaminosis	Imodium		Y	S	Unknown			Not Reported
	Imodium			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Tamsulosin			S	Unknown			Not Reported
	Telmisartan			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15744765	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1857933US		63 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Feeling Cold; Intentional Product Misuse; Nausea; Wrong	Escitalopram Oxalate - Bp			S	Oral	Actual: 5 Mg		Allergan

Technique In Product Usage Process

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15745557	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1858332US		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Paraesthesia; Swollen Tongue	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15745746	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-989206		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown			Ivax
	Lamotrigine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15747071	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1858321US		52 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Blood Pressure Fluctuation; Dysstasia; Erythema; Feeling Abnormal; Headache; Heart Rate Abnormal; Heart Rate Increased; Hot Flush; Hyperhidrosis; Hypertension; Hypotension; Insomnia; Malaise; Migraine; Pallor; Sleep Disorder; Syncope; Vertigo	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Laroxyl			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	11987849	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-06543		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Interaction; Dyskinesia; Muscle Twitching; Restless Legs Syndrome; Sleep Disorder	Citalopram 20mg			S	Unknown	20 Mg, Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Quetiapine 300mg			S	Unknown	300 Mg,Once A Day		Aurobindo
	Fluoxetine			S	Unknown	Unk		Aurobindo
	Lofepramine			S	Unknown	Unk		Not Reported
	Dosulepin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	14820665	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1822796US		32 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Product Use In Unapproved Indication; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Saroten Retard			S	Oral	25 Mg, Qd		Not Reported
	Saroten Retard			S	Oral	50 Mg, Qd		Not Reported
	Diazepam			S	Oral	9 Mg, Qd		Not Reported
	Diazepam			S				Not Reported
	Alprazolam			C	Unknown	Delayed-Release Alprazolam 2mg/D + Alprazolam 0.5 Mg As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	14928152	EXPEDITED (15-DAY)		HO, OT	DE-ACCORD-067222		14 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Accidental Overdose; Disinhibition; Drug Interaction; Mental Disorder	Aripiprazole		S	Oral	Not Reported
	Cipralex		S	Oral	Not Reported
	Calcium/Ergocalciferol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15624968	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2018018620			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Escitalopram			S	Unknown	Unk		Macleods
	Quetiapine 300 Mg			S	Unknown	300 Milligram, Qd		Macleods
	Fluoxetine			S	Unknown	Unk		Not Reported
	Dosulepin			S	Unknown	Unk		Not Reported
	Lofepramine			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15633930	EXPEDITED (15-DAY)		OT	PHHY2018GB155213		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Escitalopram			S	Unknown	Unk		Not Reported
	Quetiapine			S	Unknown	300 Mg, Unk		Novartis
	Dosulepin			S	Unknown	Unk		Not Reported
	Fluoxetine			S	Unknown	Unk		Not Reported
	Lofepramine			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15692995	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-983314		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Aggression; Aggression; Drug Ineffective; Extrapyramidal Disorder	Olanzapine			S	Unknown	20 Milligram Daily; Once At Night		Teva
	Aripiprazole			S	Unknown			Teva
	Quetiapine			S	Unknown			Teva
	Lithium			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Escitalopram			S	Unknown	20 Milligram Daily; Once In The Morning		Not Reported
	Trazodone			S	Unknown	200 Milligram Daily; Once At Night		Not Reported
	Dextromethorphan/Quinidine			S		Dextromethorphan 20mg And Quinidine 10mg Daily		Not Reported
	Dextromethorphan/Quinidine			S		Dextromethorphan 20mg And Quinidine 10mg Twice Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15747721	EXPEDITED (15-DAY)		HO, OT	PHHY2018BE185954		70 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Rivaroxaban			S	Unknown	15 Mg, Qd		Not Reported
	Diltiazem			S	Unknown	Unk		Novartis
	Clarithromycin			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15748105	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-031575		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Hepatic Failure; Lymph Node Pain; Lymphadenopathy; Lymphocytosis; Pyrexia; Rash Erythematous; Rash Pruritic; Toxic Epidermal Necrolysis	Escitalopram		S	Unknown	Zydus Pharm
	Lamotrigine		S	Unknown	Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15749027	EXPEDITED (15-DAY)		OT	RO-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-194275		54 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Therapeutic Product Effect Incomplete	Quetiapine			S	Unknown	300 Milligram, Daily		Sun
	Quetiapine			S	Unknown	800 Milligram, Daily		Sun
	Escitalopram			S	Unknown	10 Milligram, Daily		Not Reported
	Risperidone			S	Unknown	6 Milligram, Daily		Ranbaxy
	Olanzapine			S	Unknown	15 Milligram, Daily		Sun
	Duloxetine			S	Unknown	60 Milligram, Daily		Sun
	Doxepin			S	Unknown	100 Milligram, Daily		Sun
	Clonazepam			S	Unknown	0.5 Milligram, Daily		Not Reported
	Mirtazapine			S	Unknown	30 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15749097	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2018019271			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Feeling Cold; Nausea	Escitalopram			S	Oral	Prescribed 10mg.		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15749519	EXPEDITED (15-DAY)		DE, OT	FR-ACCORD-096615		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Not Reported
	Benzoic Acid/Sodium Benzoate			S	Unknown	Unk		Not Reported
	Indapamide			S	Unknown	Unk		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15749779	EXPEDITED (15-DAY)		HO	PHHY2018HR190284			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Amyzol			S	Unknown	Unk		Novartis
	Ketonal			S	Unknown	Unk		Not Reported
	Propranolol			S	Unknown	180 Mg, Unk		Not Reported
	Propranolol			S	Unknown	120 Mg, Unk		Not Reported
	Imigran			S	Unknown	Unk		Not Reported
	Plivadon (Caffeine\Phenacetin\Propyphenazone)			S	Unknown			Not Reported
	Knavon			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Helex			S	Unknown	Unk		Not Reported
	Elicea			S	Unknown	Unk		Not Reported
	Botox			S	Unknown	Unk		Not Reported
	Topiramate			S	Unknown	Unk		Not Reported
	Normabel			S	Unknown	Unk		Not Reported
	Erenumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15750000	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2018GB23779			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Feeling Cold; Nausea	Escitalopram			S	Oral	5 Mg, Tablet, Prescribed 10mg		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15750191	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1858299US			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Medication Error; Overdose	Escitalopram Oxalate - Bp			S	Oral	Overdose: 30 Mg, Total		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15751912	EXPEDITED (15-DAY)		HO	GB-ANIPHARMA-2018-UK-000170		83 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Candesartan			S	Oral	16 Mg Unk		Ani
	Omexel			S	Oral	1 Df Daily		Not Reported
	Imovane			S	Oral	1 Df Daily		Not Reported
	Seebri Breezhaler			C	Unknown	Unk		Not Reported
	Tenordate			S	Oral	1 Df Daily		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported
	Avodart			C	Unknown	Unk		Not Reported
	Lovenox			C	Unknown	Unk		Not Reported
	Escitalopram			S	Oral	5 Mg Daily		Not Reported
	Lasilix			S	Oral	4 Df Daily / Dose Text: Reduced Dose		Not Reported
	Seresta			S	Oral	1 Df Daily		Not Reported

	Spironolactone		S	Oral	25 Mg Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15752223	EXPEDITED (15-DAY)		HO, OT	AT-JNJFOC-20181212522			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alcoholism; Apraxia; Behaviour Disorder; Cognitive Disorder; Dementia; Dementia With Lewy Bodies; Depression; Drug Ineffective; Dysphoria; Hallucination; Hallucination, Visual; Insomnia; Korsakoff'S Syndrome; Mania; Muscle Rigidity; Parkinsonism; Restlessness; Sleep Disorder; Tremor; Urinary Incontinence	Risperdal			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Oral			Not Reported
	Quetiapine Fumarate			S	Oral			Not Reported
	Quetiapine Fumarate			S	Oral	Low Dose		Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Naltrexone			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Pregabalin			S	Oral			Not Reported

	Pregabalin	S	Oral	Not Reported
	Oxazepam	S	Unknown	Not Reported
	Piracetam	S	Unknown	Not Reported
	Cerebrolysin	S	Unknown	Not Reported
	Mirtazapine	S	Unknown	Not Reported
	Rivastigmine	S	Transdermal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15752529	EXPEDITED (15-DAY)		OT	PT-LANNETT COMPANY, INC.-PT-2018LAN004632		27 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stiff Person Syndrome	Escitalopram Oxalate			S	Unknown	20 Mg, Unk		Lannett
	Escitalopram Oxalate			S				Lannett

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15752672	EXPEDITED (15-DAY)		HO	US-LANNETT COMPANY, INC.-US-2018LAN004631		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Norepinephrine			S		Unk		Not Reported
	Phenylephrine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15752924	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1859040US		27 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Headache; Muscle Spasms; Product Use In Unapproved Indication; Tinnitus; Tremor	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Terbinafina			C	Unknown	Un Mes 1comprimido Al Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2018	15720983	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018019188			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flight Of Ideas; Sensory Disturbance	Escitalopram			S	Oral	15 Milligram, Qd, Cipralex		Macleods
	Lamictal			C	Oral	200 Milligram		Not Reported
	Rivotril			C	Oral	0.5 Milligram,Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2018	15753232	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-989608		63 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Feeling Cold; Nausea	Escitalopram			S	Oral	Prescribed 10mg.		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2018	15753663	EXPEDITED (15-DAY)		OT	FR-ACCORD-096618		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Furosemide			S	Unknown	Unk		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2018	15753681	EXPEDITED (15-DAY)		OT	GB-ACCORD-096645		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral			Not Reported
	Levonelle			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2018	15753774	EXPEDITED (15-DAY)		OT	DE-ACCORD-096927		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor; Wound	Escitalopram			S	Oral	Daily Dose: 15 Mg Milligram(S) Every Day		Not Reported
	Escitalopram			S	Oral	Daily Dose: 20 Mg Milligram(S) Every Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2018	15659335	NON-EXPEDITED			US-TEVA-2018-US-973070		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Intentional Product Use Issue; Wrong Technique In Product Usage Process	Escitalopram Teva			S	Unknown			Not Reported
	Escitalopram Teva			S	Unknown	(1 Quarter Of 20mg Pill + 10mg Pill)		Not Reported
	Escitalopram Teva			S	Unknown	(1 Remaining Half Of 20 Mg Pill + 1 Remaining Quarter Of 20 Mg Pill)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	14102003	EXPEDITED (15-DAY)		OT	PK-ALLERGAN-1759174US		68 YR	Male	PAK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Asthenia; Balance Disorder; Blood Pressure Increased; Cough; Deafness; Drug Ineffective; Energy	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Unk		Allergan

Increased; Fall; Fatigue; Gastric Disorder; Heart Rate Increased; Hypoacusis; Insomnia; Laziness; Muscle Atrophy; Nasopharyngitis; Overdose; Product Dose Omission; Prostatic Disorder; Salivary Hypersecretion; Sensory Disturbance; Urine Output Increased; Withdrawal Syndrome	Escitalopram Oxalate - Bp	S	Unknown	20mg After Breakfast And 20mg At About 3 Pm Overdose	Allergan
	Escitalopram Oxalate - Bp	S	Unknown	40 Mg, Unk	Allergan
	Brintellix	S	Unknown	30 Mg, Unk	Not Reported
	Brintellix	S	Unknown	20 Mg, Unk	Not Reported
	Brintellix	S	Unknown	40 Mg, Unk	Not Reported
	Trioptal	C	Unknown	600 + 300 Mg, Unk	Not Reported
	Losec	C	Unknown	20 Mg, Unk	Not Reported
	Lipiget	C	Unknown	5 Mg, Qd	Not Reported
	Vitamin D3	C	Other	1 Df, Q Month	Not Reported
	Ca C 1000	C	Unknown	Unk	Not Reported
	Concor	C	Unknown	2.5 Mg, Unk	Not Reported
	Concor	C	Unknown	5 Mg, Unk	Not Reported
	Tranxene	C	Unknown	30 Mg, Unk	Not Reported
	Lexotanil	C	Unknown	9 Mg, Unk	Not Reported
	Lexotanil	C	Unknown	7.5 Mg, Qd	Not Reported
	Lyrica	C	Unknown	75 Mg, Unk	Not Reported
	Lyrica	C	Unknown	300 Mg, Unk	Not Reported
	Qusel	C	Unknown		Not Reported
	Qusel Xr	C	Unknown		Not Reported
	Zyprexa	C	Unknown	Unk	Not Reported
	Dehydroepiandrosterone	C	Unknown	Unk	Not Reported
	Vitamin B 6	C	Unknown		Not Reported
	Omega 3	C	Unknown		Not Reported
	Tamsolin	C	Unknown	0.5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	14728558	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1817122US		53 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Wypax			C	Oral	0.5 Mg, Q8hr		Not Reported
	Depakene-R			C	Oral	400 Mg, Qd		Not Reported
	Myslee			C	Oral	5 Mg, Qd		Not Reported
	Rivotril			C	Oral	0.5 Mg, Qd		Not Reported
	Silece			C	Oral	2 Mg, Qd		Not Reported
	Depas (Etizolam)			C	Oral	0.5 Mg, Qd		Not Reported
	Ternelin			C	Oral	1 Mg, Qd		Not Reported
	Daikenchuto			C	Oral	2.5 G, Q8hr		Not Reported
	Magnesium Oxide			C	Oral	250 Mg, Q8hr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	14817394	EXPEDITED (15-DAY)		OT	PL-TAKEDA-2018TUS012677		34 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Depression; Dizziness; Mental Impairment	Vortioxetine			S	Unknown	10 Mg, Qd		Takeda
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15587379	EXPEDITED (15-DAY)		OT	PL-ALLERGAN-1851981US			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Agitation; Anxiety; Crying; Exposure Via Breast Milk; Irritability; Myoclonus; Seizure; Sleep Disorder	Escitalopram Oxalate - Bp			S	Transmammary			Allergan
	Bupropion			S	Transmammary			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15743874	EXPEDITED (15-DAY)		HO, OT	PT-LUPIN PHARMACEUTICALS		64 YR	Female	PRT

INC.-2018-08677

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Tramadol			S	Unknown	225 Mg, Qd		Lupin
	Amitriptyline			S	Unknown	25 Mg, Qd		Not Reported
	Paracetamol			C	Unknown	3000 Mg, Qd		Not Reported
	Levofloxacin			C	Unknown	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15755095	EXPEDITED (15-DAY)		HO	FR-ACCORD-097136		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Coma; Sinus Bradycardia; Suicide Attempt	Escitalopram			S	Oral			Not Reported
	Plavix			S	Oral	75 Mg Strength		Not Reported
	Coveram			S	Oral	10 Mg/10 Mg Strength		Not Reported
	Seresta			S	Oral	50 Mg Strength, Scored Tablet		Not Reported
	Bisoce			S	Oral	10 Mg Strength		Not Reported
	Zopiclone			S	Oral			Not Reported
	Aldactazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15755341	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-060945		63 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Feeling Cold; Nausea	Escitalopram Tablets			S	Oral	5 Milligram (Prescribed 10mg)		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15756079	EXPEDITED (15-DAY)		HO	FR-ZYDUS-031871		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Oral	75 Mg Powder For Oral Solution In Sachet-Dose		Not Reported
	Tamsulosin			C		0.4 Mg Prolonged-Release Film-Coated Tablet		Not Reported
	Candesartan/Candesartan Cilexetil			C				Not Reported
	Dutasteride			C		0.5 Mg Soft Capsule		Not Reported
	Oxazepam			C		10 Mg Tablet		Not Reported
	Atenolol/Nifedipine			C				Not Reported
	Zopiclone			C		7.5 Mg Film-Coated Tablets		Not Reported
	Spironolactone			C				Not Reported
	Furosemide			C		40 Mg, Scored Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15756597	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1858423US		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Vomiting	Lexapro			S	Transplacental			Allergan
	Suboxone			S	Transplacental	8 Mg, Bid		Not Reported
	Remeron			S	Transplacental			Not Reported
	Nicotine			S	Transplacental			Not Reported
	Buprenorphine			S	Transplacental	Unk		Not Reported
	Buprenorphine			S	Transmammary	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2018	14822663	EXPEDITED (15-DAY)		OT	PL-ALLERGAN-1822782US		34 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Depression; Dizziness; Mental Impairment	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Brintellix			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2018	15757678	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-060337		28 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Ecchymosis; Thrombocytopenia	Escitalopram			S	Oral	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2018	15758170	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2018-060489		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis; Bradycardia; Hemiplegia; Reversible Cerebral Vasoconstriction Syndrome; Thunderclap Headache; Vasospasm	Escitalopram			S	Unknown	Unk		Aurobindo
	Norepinephrine			S	Unknown	Unk		Not Reported
	Phenylephrine			S	Unknown	Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Nimodipine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2018	15758650	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1859242US		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebral Haemorrhage; Incorrect Dose Administered	Escitalopram Oxalate - Bp	S	Oral	10 Df, Qd		Allergan
	Kardegic	S	Oral	1 Df, Qd		Not Reported
	Omexel	C	Unknown			Not Reported
	Candesartan Cilexetil	C	Unknown			Not Reported
	Seebri Breezhaler	C	Unknown			Not Reported
	Avodart	C	Unknown			Not Reported
	Seresta	C	Unknown			Not Reported
	Tenordate	C	Unknown			Not Reported
	Imovane	C	Unknown			Not Reported
	Spironolactone	C	Unknown			Not Reported
	Lasilix	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	11970104	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-110432			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Quetiapine			S	Unknown	300 Milligram, Qd		Sun
	Escitalopram			S	Unknown			Not Reported
	Dosulepin			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Sun
	Lofepramine			S	Unknown			Not Reported
	Citalopram			C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	12417884	EXPEDITED (15-DAY)		DS	IT-AUROBINDO-AUR-APL-2016-06373		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dysgraphia; Dyskinesia; Therapeutic	Mirtazapine			S	Unknown	Unk		Aurobindo
	Mirtazapine			S				Aurobindo

Product Effect Decreased; Tremor	Sertraline	S	Unknown	200 Mg Daily	Aurobindo
	Sertraline	S	Unknown	50 Milligram, Once A Day	Aurobindo
	Sertraline	S			Aurobindo
	Quetiapine Film-Coated Tablet	S	Oral	Unk	Aurobindo
	Quetiapine Film-Coated Tablet	S			Aurobindo
	Venlafaxine	S	Unknown	Unk	Aurobindo
	Venlafaxine	S			Aurobindo
	Escitalopram	S	Unknown	Unk	Aurobindo
	Escitalopram	S			Aurobindo
	Valproic Acid	S	Unknown	Unk	Not Reported
	Valproic Acid	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	14408904	EXPEDITED (15-DAY)		HO	FR-ACCORD-062847		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Raynaud'S Phenomenon	Quetiapine			S	Oral			Accord
	Laroxyl			S				Not Reported
	Methylphenidate			S	Oral	80 Mg In The Morning And 20 Mg At 4pm		Not Reported
	Lexapro			S	Oral			Not Reported
	Xeroquel			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Ritaline			S	Oral			Not Reported
	Lepticur			S				Not Reported
	Abilify			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15576747	EXPEDITED (15-DAY)		OT	PK-TAKEDA-2018TUS031574		68 YR	Male	PAK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Asthenia; Balance	Brintellix			S	Unknown	30 Mg, Unk		Takeda

Disorder; Blood Pressure Increased; Cough; Deafness; Drug Ineffective; Drug Ineffective; Energy Increased; Fall; Fatigue; Fatigue; Gastric Disorder; Heart Rate Increased; Hypoacusis; Insomnia; Laziness; Muscle Atrophy; Nasopharyngitis; Overdose; Prescribed Overdose; Prostatic Disorder; Salivary Hypersecretion; Sensory Disturbance; Urine Output Increased; Withdrawal Syndrome	Brintellix	S	Unknown	20 Mg, Unk	Takeda
	Brintellix	S	Unknown	30 Mg	Takeda
	Brintellix	S	Unknown	20 Mg, Unk	Takeda
	Brintellix	S	Unknown	40 Mg, Unk	Takeda
	Cipralex /01588501/	S	Unknown	5 Mg, Unk	Not Reported
	Cipralex /01588501/	S	Unknown	10 Mg, Unk	Not Reported
	Cipralex /01588501/	S	Unknown	20 Mg, Unk	Not Reported
	Cipralex /01588501/	S	Unknown	30 Mg, Unk	Not Reported
	Cipralex /01588501/	S	Unknown	20 Mg, Bid	Not Reported
	Cipralex /01588501/	S	Unknown	40 Mg, Unk	Not Reported
	Trioptal	C	Unknown	600/300 Mg, Unk	Not Reported
	Losec /00661201/	C	Unknown	Unk	Not Reported
	Lipigetez	C	Unknown	5 Mg, Qd	Not Reported
	Vitamin D /00318501/	C	Unknown	Unk, Qd	Not Reported
	Cac	C	Unknown	Unk	Not Reported
	Concor	C	Unknown	2.5 Mg, Unk	Not Reported
	Concor	C	Unknown	5 Mg, Unk	Not Reported
	Tranxene	C	Unknown	Unk	Not Reported
	Tranxene	C	Unknown		Not Reported
	Lexotanil	C	Unknown	Unk	Not Reported
	Lexotanil	C	Unknown	7.5 Mg, Qd	Not Reported
	Lyrica	C	Unknown	75 Mg, Unk	Not Reported
	Lyrica	C	Unknown	300 Mg, Unk	Not Reported
	Lyrica	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Qusel	C	Unknown	Unk	Not Reported
	Qusel	C	Unknown		Not Reported

	Zyprexa		C	Unknown	Unk	Not Reported
	Zyprexa		C	Unknown		Not Reported
	Dehydroepiandrosterone		C	Unknown		Not Reported
	Dehydroepiandrosterone		C	Unknown		Not Reported
	Tamsolin		C	Unknown	0.5 Mg, Unk	Not Reported
	Tamsolin		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15759020	EXPEDITED (15-DAY)		HO, OT	JP-LUPIN PHARMACEUTICALS INC.-2018-09001		66 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Euphoric Mood; Flight Of Ideas; Insomnia; Irritability; Mania; Pressure Of Speech; Psychomotor Hyperactivity	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15759292	NON-EXPEDITED			US-ELI_LILLY_AND_COMPANY-US201812008034			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder	Zyprexa			S	Oral	40 Mg, 30mg At Bedtime And 10mg Daily		Eli Lilly And Co
	Latuda			S	Unknown	Unk, Unknown		Not Reported
	Latuda			S	Unknown	120 Mg, Unknown		Not Reported
	Fanapt			S	Unknown	Unk, Unknown		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15760005	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-062410		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S	Oral	10 Dosage Form, Daily		Aurobindo
	Kardegic			S	Oral	1 Dosage Form, Daily		Not Reported
	Omexel			C	Unknown			Not Reported
	Tenordate			C	Unknown			Not Reported
	Lasilix /00032601/			C	Unknown			Not Reported
	Candesartan Cilexetil			C	Unknown			Not Reported
	Avodart			C	Unknown			Not Reported
	Seresta			C	Unknown			Not Reported
	Seebri Breezhaler			C				Not Reported
	Imovane			C	Unknown			Not Reported
	Spironolactone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15760061	EXPEDITED (15-DAY)		CA	DE-TORRENT-00012763			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Kidney Duplex	Magnetrans			C	Transplacental	Unknown		Unknown
	Ibuprofen			C	Transplacental	400 [Mg/D]/ On Demand, Max Once Per Week		Unknown
	Cetirizine			C	Transplacental	Unknown		Unknown
	Escitalopram			S	Transplacental	10 [Mg/D]/ Dosage Reduction To 5mg/D Before Stop		Unknown
	Paracetamol			C	Transplacental	1500 [Mg/D]/ 1000-1500 Mg/D, In Total 2-3 Times		Unknown
	Cytotec			C	Transplacental	Unknown		Unknown
	Olynth			C	Transplacental	If Required		Unknown
	Folio Forte			C	Transplacental	0.8 [Mg/D]/ From Week 14 0.4mg/D		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15760140	EXPEDITED (15-DAY)		HO, OT	RO-AUROBINDO-AUR-APL-2018-061079		54 YR	Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Loss Of Personal Independence In Daily Activities; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Treatment Noncompliance; Weight Decreased	Escitalopram			S	Unknown	10 Milligram		Aurobindo
	Duloxetine			S	Unknown	60 Milligram, Daily		Aurobindo
	Olanzapine			S	Unknown	15 Milligram, Daily		Aurobindo
	Mirtazapine			S	Unknown	30 Milligram, Daily		Aurobindo
	Quetiapine			S	Unknown	300 Milligram, Daily		Not Reported
	Quetiapine			S	Unknown	800 Milligram, Daily		Not Reported
	Clonazepam			S	Unknown	0.5 Milligram, Daily		Not Reported
	Risperidone			S	Unknown	6 Milligram, Daily		Not Reported
	Doxepine			S	Unknown	100 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15760974	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Expiration Date Issue; Product Lot Number Issue	Escitalopram Oxalate			S	Oral			Bluepoint Laboratories

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15761322	EXPEDITED (15-DAY)		HO	PHHY2018IT194748		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Sluggishness	Escitalopram Oxalate			S	Oral	30 Ml, Once/Single (Total)		Not Reported
	Alprazolam			S	Oral	20 Ml, Once/Single (Total)		Not Reported
	Omeprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15761636	EXPEDITED (15-DAY)		OT	FI-GLAXOSMITHKLINE-FI2018GSK231885		46 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acute Sinusitis; Adjustment Disorder With Mixed Anxiety And Depressed Mood; Adrenal Insufficiency; Aggression; Agitation; Akathisia; Anxiety; Blood Cholesterol Increased; Blood Glucose Increased; Cerebrovascular Accident; Confusional State; Craniocerebral Injury; Depression; Dizziness; Drug Dependence; Drug Interaction; Dyskinesia; Dyspnoea; Erectile Dysfunction; Erythema; Euphoric Mood; Fatigue; Fear; Feeling Abnormal; Feeling Cold; Gastric Disorder; General Physical Health Deterioration; Hallucination; Hepatic	Metoclopramide Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Amoxicillin Trihydrate			S	Oral	Unk Tablet		Glaxosmithkline
	Amoxicillin Trihydrate			S				Glaxosmithkline
	Amoxin			S	Oral	Unk		Glaxosmithkline
	Nicorette			S	Unknown	2 Mg, Unk Gum		Glaxosmithkline
	Nicorette			S	Unknown	Unk Patch		Glaxosmithkline
	Sertraline			S	Unknown	0.5 Df, Qd		Glaxosmithkline
	Cipralex			S	Unknown	Unk		Not Reported
	Champix			S	Oral	0.5 Mg, Qd		Not Reported
	Champix			S	Oral	Unk 0.5		Not Reported
	Champix			S	Unknown	1 Mg, Bid		Not Reported
	Rinexin			S	Oral	50 Mg, Unk		Not Reported
	Azithromycin			C		Unk		Glaxosmithkline
	Havrix			C				Glaxosmithkline
	Klacid			C		Unk		Not Reported
	Toclase			C		Unk		Not Reported
	Doximycin			C		Unk		Not Reported

Steatosis; Hyperhidrosis; Hypersensitivity; Hypopituitarism; Hyposmia; Hypothyroidism; Increased Appetite; Infection; Influenza; Irritability; Loss Of Libido; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Medication Error; Memory Impairment; Mood Swings; Musculoskeletal Discomfort; Nausea; Neurotoxicity; Nightmare; Obesity; Olfacto Genital Dysplasia; Overweight; Palpitations; Panic Reaction; Parkinson'S Disease; Personality Change; Restlessness; Secondary Hypogonadism; Sense Of Oppression; Sleep Disorder; Snoring; Swelling; Tinnitus; Tremor; Upper Respiratory Tract Infection; Vasodilatation; Vertigo; Weight Increased; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15762637	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1095751		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disinhibition; Suicidal Ideation	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Zopiclone			S	Oral	7.5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15762686	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1095772		85 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Medication Error	Escitalopram			S	Oral	35 Gtt Drops, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15763032	NON-EXPEDITED			US-AMGEN-USASP2018184248			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Aimovig			S	Unknown	70 Mg, Unk		Amgen
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15763205	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-062408		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Candesartan			S	Oral	16 Milligram, Daily		Not Reported
	Escitalopram			S	Oral	5 Milligram, Daily		Aurobindo
	Spironolactone			S	Oral	25 Milligram, Daily		Aurobindo
	Seresta			S	Oral	1 Dosage Form, Daily		Not Reported
	Imovane			S	Oral	1 Dosage Form, Daily		Not Reported
	Lasilix /00032601/			S	Oral	4 Dosage Form, Daily		Not Reported
	Omexel			S	Oral	1 Dosage Form, Daily		Not Reported
	Tenordate			S	Oral	1 Dosage Form, Daily		Not Reported
	Seebri Breezhaler			C	Unknown	Unk		Not Reported
	Lovenox			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported

	Avodart	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	14313413	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2017M1079666		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose; Labelled Drug-Drug Interaction Medication Error	Quetiapine			S	Oral	19 G, Total		Not Reported
	Escitalopram			S	Oral	30 Mg, Total		Not Reported
	Abilify			S	Oral	30 Mg, Qd		Mylan
	Valproato			S	Oral	3.6 Mg, Total		Mylan
	Antabus			S	Oral	250 Mg, Qd		Mylan
	Clonazepam			S	Oral	22.5 Mg, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15764573	EXPEDITED (15-DAY)		HO	FR-ZYDUS-031797		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral			Zydus Pharm
	Imovane			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Omexel			S	Oral			Not Reported
	Candesartan Cilexetil			S	Oral			Zydus Pharm
	Spironolactone			S	Oral			Zydus Pharm
	Tenordate			S	Oral			Not Reported
	Seebri Breezhaler			C				Not Reported
	Enoxaparin			C				Not Reported
	Acetylsalicylate Lysine/Acetylsalicylic Acid			C				Not Reported
	Dutasteride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15765310	EXPEDITED (15-DAY)		OT	FI-SA-2018SA390556		46 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acute Sinusitis; Adjustment Disorder With Mixed Anxiety And Depressed Mood; Adrenal Insufficiency; Aggression; Agitation; Akathisia; Anxiety; Blood Cholesterol Increased; Blood Glucose Increased; Cerebrovascular Accident; Confusional State; Confusional State; Craniocerebral Injury; Depression; Depression; Dizziness; Drug Dependence; Drug Interaction; Dyskinesia; Dyspnoea; Erectile Dysfunction; Erythema; Euphoric Mood; Fatigue; Fear; Feeling Abnormal; Feeling Cold; Gastric Disorder; General Physical Health Deterioration; Hallucination; Hepatic Steatosis; Hyperhidrosis; Hypersensitivity; Hypopituitarism; Hyposmia; Hypothyroidism; Hypothyroidism; Increased Appetite; Infection; Influenza; Irritability; Loss Of Libido; Loss Of Personal Independence In	Metoclopramide Hydrochloride			S		Unk		Not Reported
	Klacid [Clarithromycin]			C	Oral	Ten Days Course		Not Reported
	Azithromycin			C	Oral	3		Not Reported
	Amoxicillin Trihydrate			S	Oral	Tablet		Not Reported
	Amoxicillin Trihydrate			S				Not Reported
	Cipralex [Escitalopram]			S		Unk		Not Reported
	Havrix			C	Intramuscular	Unk		Not Reported
	Toclase [Pentoxyverine Citrate]			C		Unk		Not Reported
	Amoxin			S	Oral	Unk		Not Reported
	Doximycin			C	Oral	Unk		Not Reported
	Nicorette			S		2 Mg, Unk Gum		Sanofi
	Nicorette			S		Patch		Sanofi
	Champix			S	Oral	0.5 Mg, 1x/Day, Film Coated Tablet		Not Reported
	Champix			S		1 Mg, Bid, Film-Coated Tablet		Not Reported
	Champix			S	Oral	0.5 Unk, Film-Coated Tablet		Not Reported
	Sertraline			S		0.5 Df, Qd		Not Reported
	Rinexin			S	Oral	50 Mg, Unk		Not Reported

Daily Activities; Lower Respiratory Tract Infection; Medication Error; Memory Impairment; Mood Swings; Musculoskeletal Discomfort; Nausea; Neurotoxicity; Nightmare; Obesity; Olfacto Genital Dysplasia; Overweight; Palpitations; Panic Reaction; Parkinson'S Disease; Personality Change; Restlessness; Secondary Hypogonadism; Sense Of Oppression; Sleep Disorder; Snoring; Swelling; Tinnitus; Tremor; Upper Respiratory Tract Infection; Vasodilatation; Vertigo; Weight Increased; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15767263	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1859370US		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Microcytic Anaemia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Xarelto			S	Oral	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15767525	EXPEDITED (15-DAY)		DE, OT	CH-JNJFOC-20181225291		91 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Trismus	Haldol			S	Oral			Not Reported
	Haldol			S	Oral	Max 3 Times A Day		Not Reported

Haldol	S	Oral	Max 3 Times A Day	Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Ondansetron	S	Subcutaneous		Not Reported
Ondansetron	S	Subcutaneous		Not Reported
Cipralex	S	Oral		Not Reported
Cipralex	S	Oral		Not Reported
Ondansetron	S	Oral		Not Reported
Ondansetron	S	Oral		Not Reported
Ondansetron	S	Oral		Not Reported
Calciparine	C	Unknown		Not Reported
Clomethiazole Edisilate	C	Unknown		Not Reported
Temesta [Lorazepam]	C	Unknown		Not Reported
Xanax	C	Unknown		Not Reported
Aprovel	C	Unknown		Not Reported
Physiotens	C	Unknown		Not Reported
Zanidip	C	Unknown		Not Reported
Euthyrox	C	Unknown		Not Reported
Mycostatine	C	Unknown		Not Reported
Laxoberon	C	Unknown		Not Reported

	Laxoberon	C	Unknown	Not Reported
	Aldactone	C	Unknown	Not Reported
	Dafalgan	C	Unknown	Not Reported
	Phosphoric Acid Sodium	C	Unknown	Not Reported
	Midazolam Hydrochloride	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15767827	EXPEDITED (15-DAY)		HO, OT	CH-OTSUKA-2015_014491		93 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Encephalopathy; Enterococcus Test Positive; Extrapyramidal Disorder; Loss Of Consciousness; Malaise; Renal Failure; Rhabdomyolysis; Urinary Tract Infection	Abilify			S	Oral	Unk		Otsuka
	Cipralex			S	Oral	20 Mg, Qd		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Keppra			S	Oral	250 Mg, Bid		Not Reported
	Keppra			S	Oral	250 Mg, Qd		Not Reported
	Amoxicillin Sodium			S	Oral	500 Mg, Bid		Not Reported
	Valdoxan			C	Oral	25 Mg, Qd		Not Reported
	Xanax			C	Oral	0.25 Mg, Qd		Not Reported
	Xanax			C	Oral	0.125 Mg, Qd		Not Reported
	Temesta [Lorazepam]			C	Oral	0.5 Mg, Qd		Not Reported
	Aspirin Cardio			C	Unknown	100 Mg, Unk		Not Reported
	Nexium			C	Oral	20 Mg, Qd		Not Reported
	Anxiolit			C	Oral	15 Mg, Qid		Not Reported
	Anxiolit			C	Oral	15 Mg, Qid		Not Reported
	Anxiolit			C	Oral	7.5 Mg, Qid		Not Reported
	Prednisone			C	Oral	2.5 Mg, Qd		Not Reported
	Prednisone			C	Oral	5 Mg, Qd		Not Reported
	Valtrex			C	Oral	500 Mg, Qd		Not Reported
	Vitamine B6			C	Oral	40 Mg, Qd		Not Reported

	Metoject		C	Subcutaneous	15 Mg, Qwk	Not Reported
	Laxoberon		C	Oral	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15768092	EXPEDITED (15-DAY)		OT	JP-MYLANLABS-2018M1097097		45 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypomania	Venlafaxine			S	Unknown	37.5 Milligram, Qd		Not Reported
	Venlafaxine			S	Unknown	187.5 Milligram, Qd		Not Reported
	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported
	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported
	Prednisolone			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15769889	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Palpitations; Ventricular Extrasystoles	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	14302902	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2017-ES-835842		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Intentional Overdose; Labelled Drug-Drug Interaction Medication Error	Escitalopram			S	Oral	30 Mg, In Total		Not Reported
	Quetiapine			S	Oral	19 Gram In Total		Not Reported
	Clonazepam (635a)			S	Oral	22.5 Mg, In Total		Not Reported
	Valproato Sodio (3194so)			S	Oral	3.6 Mg, In Total		Not Reported
	Antabus 250 Mg Comprimidos , 40 Comprimidos			S	Oral			Not Reported
	Abilify 15 Mg Comprimidos, 28 Comprimidos			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	14574141	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2018M1012872		79 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Drug Interaction	Escitalopram			S	Oral	Unk		Not Reported
	Enoxaparina Sodica			S	Subcutaneous	Unk		Mylan
	Sintrom			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	14987926	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-04		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bundle Branch Block Left; Clonus; Hyperreflexia; Hypotension; Loss Of Consciousness; Muscle Rigidity; Overdose; Rhabdomyolysis; Sinus Tachycardia; Tachycardia	Escitalopram			S	Oral			Hikma
	Lamotrigine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15702482	EXPEDITED (15-DAY)		HO, LT	GR-ACCORD-095165		67 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Clonus; Confusional State; Delayed Recovery From Anaesthesia; Disorientation; Drug Interaction; Fear; Hyperpyrexia; Hyperreflexia; Mental	Escitalopram			S	Unknown			Not Reported
	Methylthioninium			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Not Reported

Status Changes; Muscle Rigidity; Mydriasis; Psychomotor Hyperactivity; Serotonin Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15738152	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-987689		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flight Of Ideas; Sensory Disturbance	Cipralex			S	Oral			Not Reported
	Lamictal			C	Oral			Not Reported
	Rivotril 0,5 Mg Compresse			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15768701	EXPEDITED (15-DAY)		OT	ES-ZYDUS-032127			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Medication Error	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15768833	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-061898		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Gabapentin			S	Oral			Aurobindo
	Ibuprofen			S	Oral			Aurobindo
	Ethanol			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15769171	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-992506		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S	Oral	10 Dosage Forms Daily;		Ivax
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	1 Dosage Forms Daily;		Not Reported
	Omexel L.P. 0,4 Mg, Comprimé Pelliculé À Libération Prolongée			C	Unknown			Not Reported
	Candesartan Cilexetil			C				Not Reported
	Seebri Breezhaler			C				Not Reported
	Avodart 0,5 Mg, Capsule Molle			C				Not Reported
	Seresta 10 Mg, Comprimé			C				Not Reported
	Tenordate			C				Not Reported
	Imovane 7,5 Mg, Comprimé Pelliculé Sécable			C				Not Reported
	Spironolactone			C				Not Reported
	Lasilix 40 Mg, Comprimé Sécable			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15769211	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-AUROBINDO-AUR-APL-2018-062672		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Abuse; Respiratory Arrest	Escitalopram			S	Unknown			Aurobindo
	Alprazolam			S				Aurobindo
	Cocaine			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Ethanol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15769245	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-AUROBINDO-AUR-APL-2018-062757		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram	S	Unknown	Aurobindo
	Diphenhydramine	S	Unknown	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15769358	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-062792		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Unknown			Aurobindo
	Lamotrigine			S	Unknown			Aurobindo
	Mirtazapine			S	Oral			Aurobindo
	Cyclobenzaprine			S	Oral			Aurobindo
	Buspirone Hydrochloride			S	Oral			Aurobindo
	Clonazepam			S				Not Reported
	Activated Charcoal			S	Oral			Not Reported
	Propranolol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15769512	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2018-060653		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Loratadine			S	Oral			Aurobindo
	Ethylene Glycol			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Folic Acid			S	Oral			Not Reported
	Vitamin B1 /00056101/			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15769567	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2018-060703		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Lorazepam			S	Oral			Aurobindo
	Lithium			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15769586	EXPEDITED (15-DAY)		OT	NL-ACCORD-098423		67 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Escitalopram			S				Not Reported
	Lorazepam			C		1mg 1x Per Dag		Not Reported
	Levocetirizine/Levocetirizine Dihydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15769587	EXPEDITED (15-DAY)		OT	NL-ACCORD-098653		16 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea Haemorrhagic; Hypertension; Tachycardia	Escitalopram			S		1x Daily 2 Tablets,10mg		Not Reported
	Quetiapine			S		25 Mg, Half A Tablet For The Night		Not Reported
	Colecalciferol			C		1 X 1		Not Reported
	Melatonin			C		1 Mg 1 X 1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15769785	EXPEDITED (15-DAY)		CA	DE-HETERO CORPORATE-HET2018DE01587			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Kidney Duplex	Escitalopram			S	Transplacental	10 Mg, Qd		Hetero

	Escitalopram	S		5 Mg, Qd	Hetero
	Magnetrans	C	Transplacental	Unk	Not Reported
	Ibuprofen	C	Transplacental	400 Mg, On Demand, Max Once Per Week	Not Reported
	Cetirizine	C	Transplacental	Unk	Not Reported
	Paracetamol	C	Transplacental	1500 Mg (1000-1500 Mg Per Day)	Not Reported
	Cytotec	C	Transplacental	Unk	Not Reported
	Olynth	C	Transplacental	If Required	Not Reported
	Folio Forte	C	Transplacental	0.8 Mg, Qd	Not Reported
	Folio Forte	C		0.4 Mg, Qd (From Week 14)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15769884	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-194822		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported
	Spironolactone			S	Oral	25 Milligram, Qd		Sun
	Candesartan			S	Oral	16 Milligram, Qd		Not Reported
	Omexel L.P. 0,4 Mg, Comprime Pellicule A Liberation Prolongee			S	Oral	1 Dosage Form, Qd		Not Reported
	Imovane			S	Oral	1 Dosage Form, Qd		Not Reported
	Seresta 10 Mg, Comprime			S	Oral	1 Dosage Form, Qd		Not Reported
	Lasilix 40 Mg, Comprime Secable			S	Oral	4 Dosage Form, Qd		Not Reported
	Tenordate, Gelule			S	Oral	1 Dosage Form, Qd		Not Reported
	Seebri Breezhaler			C	Unknown	()		Not Reported
	Lovenox 4 000 Ui Anti-Xa/0,4 Ml, Solution Injectable En Cartouche			C	Unknown	()		Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-			C	Unknown	()		Not Reported

	Dose Avodart 0,5 Mg, Capsule Molle	C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15769972	EXPEDITED (15-DAY)		OT	IT-ACCORD-098383		42 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15770637	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1000014091		46 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acute Sinusitis; Adjustment Disorder With Mixed Anxiety And Depressed Mood; Adrenal Insufficiency; Aggression; Agitation; Akathisia; Anxiety; Blood Cholesterol Increased; Blood Glucose Increased; Cerebrovascular Accident; Confusional State; Confusional State; Craniocerebral Injury; Depression; Depression; Dizziness; Drug Interaction; Dyskinesia; Dyspnoea; Erectile Dysfunction; Erythema; Euphoric Mood; Fatigue; Fear; Feeling Abnormal; Feeling Cold; Gastric Disorder; General Physical Health Deterioration; Hallucination; Hepatic	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Champix			S	Oral	1 Mg, Bid		Not Reported
	Champix			S	Oral	0.5 Mg, Bid		Not Reported
	Champix			S	Oral	.5 Mg, Qd		Not Reported
	Rinexin			S	Oral	50 Mg, Qd		Not Reported
	Metoclopramide			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	50 Mg 1/2 Tablet, Qd		Not Reported
	Nicorette Gum			S		2 Mg, Unk		Not Reported
	Nicorette Patch			S	Transdermal	Unk		Not Reported
	Amoxin			S	Oral	Unk		Not Reported
	Amoxin			S	Oral	Unk		Not Reported
	Klacid			C		10 Days Course		Not Reported
	Havrix			C		Unk		Not Reported
	Doximycin			C	Oral	Unk		Not Reported
	Azithromycin			C	Oral	Unk		Not Reported
	Toclase			C		Unk		Not Reported

Steatosis; Hyperhidrosis; Hypersensitivity; Hypopituitarism; Hyposmia; Hypothyroidism; Hypothyroidism; Increased Appetite; Infection; Influenza; Irritability; Loss Of Libido; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Medication Error; Memory Impairment; Mood Swings; Musculoskeletal Discomfort; Nausea; Neurotoxicity; Nicotine Dependence; Nightmare; Obesity; Olfacto Genital Dysplasia; Overweight; Palpitations; Panic Reaction; Parkinson'S Disease; Personality Change; Restlessness; Secondary Hypogonadism; Sense Of Oppression; Sleep Disorder; Snoring; Swelling; Tinnitus; Tremor; Upper Respiratory Tract Infection; Vasodilatation; Vertigo; Weight Increased; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15770638	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1859390US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan

Pregnancy; Kidney Duplex	Escitalopram Oxalate - Bp	S	Transplacental	10 Mg, Qd		Allergan
	Magnetrans	C	Transplacental	Additional Info: 20. - 36.6. Gestational Week		Not Reported
	Ibuprofen	C	Transplacental	400 Mg, Prn, Max Once Per Week; 0. - 28. Gestational Week, 0. - 28. Gestational Week		Not Reported
	Cetirizine	C	Transplacental	Additional Info: 25.4. - 29.6. Gestational Week		Not Reported
	Paracetamol	C	Transplacental	1500 Mg, Qd; 1000-1500 Mg/D, In Total 2-3 Times; Additional Info: 28. - 36.6. Gestational Week		Not Reported
	Cytotec	C	Transplacental	36.6. Gestational Week		Not Reported
	Olynth	C	Transplacental	Prn; Additional Info: 19.1. - 23.4. Gestational Week		Not Reported
	Folio Forte	C	Transplacental	0.8 Mg, Qd		Not Reported
	Folio Forte	C	Transplacental	0.4 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15772002	EXPEDITED (15-DAY)		HO, OT	PT-ENDO PHARMACEUTICALS INC-2018-043657		64 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Tramadol Hydrochloride			S	Unknown	225 Mg, Daily		Par
	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported
	Amitriptyline			S	Unknown	25 Mg, Daily		Not Reported
	Levofloxacin			C	Unknown	500 Mg, Daily		Not Reported
	Acetaminophen			C	Unknown	3000 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15772389	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-991456		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	5 Milligram Daily;		Not Reported
	Candesartan Cilexetil			S	Oral	16 Milligram Daily;		Not Reported
	Spironolactone			S	Oral	25 Milligram Daily;		Not Reported
	Imovane			S	Oral	1 Dosage Forms Daily;		Not Reported
	Seresta 10 Mg, Comprimé			S	Oral	1 Dosage Forms Daily;		Not Reported
	Lasilix 40 Mg, Comprimé Sécable			S	Oral	4 Dosage Forms Daily;		Not Reported
	Omexel L.P. 0,4 Mg, Comprimé Pelliculé À Libération Prolongée			S	Oral	1 Dosage Forms Daily;		Not Reported
	Tenordate, Gélule			S	Oral	1 Dosage Forms Daily;		Not Reported
	Seebri Breezhaler			C				Not Reported
	Lovenox 4 000 Ui Anti-Xa/0,4 Ml, Solution Injectable En Cartouche			C				Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			C				Not Reported
	Avodart 0,5 Mg, Capsule Molle			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15772781	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20181233876		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Microcytic Anaemia	Xarelto			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15772914	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018019384			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Kidney Duplex	Escitalopram			S	Transplacental	Unk, 10 [Mg/D]/ Dosage Reduction To 5mg/D		Macleods

				Before Stop, 0. - 8. Gestational Week, 1 {Trimester}	
	Paracetamol	C	Transplacental	Unk, 1500 [Mg/D]/ 1000-1500 Mg/D, In Total 2-3 Times, 28. - 36.6. Gestational Week, 3 {Trimester}	Not Reported
	Cetirizine	C	Transplacental	Unk, 25.4. - 29.6. Gestational Week, 2 {Trimester}	Not Reported
	Cytotec	C	Transplacental	Unk, 36.6. - 36.6. Gestational Week, 3 {Trimester}	Not Reported
	Folic Acid	C	Transplacental	Unk, 0.8 [Mg/D]/ From Week 14, 0.4mg/D, 0. - 36.6. Gestational Week, 1 {Trimester}	Not Reported
	Ibuprofen	C	Transplacental	Unk, 400 [Mg/D]/ On Demand, Max Once Per Week, 0. - 28. Gestational Week, 1 {Trimester}	Not Reported
	Magnesium Aspartate Hydrochloride	C	Transplacental	Unk, 20. - 36.6. Gestational Week, 2 {Trimester}	Not Reported
	Olynth	C	Transplacental	Unk, 19.1. - 23.4. Gestational Week , 2 {Trimester}, If Required	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15773522	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2018-061107		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metformin			S	Unknown			Aurobindo
	Glyburide			S	Unknown			Aurobindo

	Escitalopram	S	Oral	Aurobindo
	Losartan	S	Oral	Aurobindo
	Lorazepam	S	Oral	Aurobindo
	Diltiazem	S	Unknown	Not Reported
	Propranolol	S	Unknown	Not Reported
	Levothyroxine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15773542	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-061711		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Alprazolam			S	Oral			Aurobindo
	Acetaminophen			S	Oral			Aurobindo
	Ethanol			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Cocaine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15773546	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-061733		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Flecainide			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Alprazolam			S	Oral			Aurobindo
	Verapamil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15773651	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-063083		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diphenhydramine			S	Unknown			Aurobindo
	Fluoxetine			S	Unknown			Aurobindo
	Escitalopram			S	Unknown			Aurobindo
	Risperidone			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15773657	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-063080		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Venlafaxine			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Bupropion			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15785334	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram							
	Escitalopram Oxalate			S	Oral			Not Reported
	Escitalopram							

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15857362	DIRECT					19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hypersomnia; Malaise; Non-24-Hour Sleep-Wake Disorder; Presyncope; Sedation	Escitalopram (Generic Lexapro) 20mg	Y		S	Oral	Quantity:1 Df Dosage Form;		Not Reported
	Escitalopram (Generic Lexapro) 20mg	Y		S				Not Reported
	Deplin			C				Not Reported

	Vit C	C	Not Reported
	Fish Oil	C	Not Reported
	Zinc	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2018	15725143	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2018-059400		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Auro-Escitalopram Tablets			S	Oral	15 Milligram, Daily		Aurobindo
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2018	15773660	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-063091		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine			S	Unknown			Aurobindo
	Escitalopram			S	Unknown			Aurobindo
	Losartan			S	Oral			Aurobindo
	Salicylic Acid			S	Oral			Not Reported
	Bupropion			S	Unknown			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2018	15773727	EXPEDITED (15-DAY)		DE, LT, OT	US-AUROBINDO-AUR-APL-2018-063564		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram			S	Oral			Aurobindo
	Bupropion			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2018	15773856	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-063417			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Kidney Duplex	Escitalopram			S	Transplacental	Unk, 10 [Mg/D]/ Dosage Reduction To 5mg/D Before Stop		Aurobindo
	Magnesium Aspartate Hydrochloride			C	Transplacental	Unk		Not Reported
	Ibuprofen			C	Transplacental	Unk, 400 [Mg/D]/ On Demand, Max Once Per Week		Not Reported
	Cetirizine			C	Transplacental	Unk		Not Reported
	Paracetamol			C	Transplacental	Unk, 1500 [Mg/D]/ 1000-1500 Mg/D, In Total 2-3 Times		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported
	Olynth			C	Transplacental	Unk		Not Reported
	Folic Acid			C	Transplacental	Unk, 0.8 [Mg/D]/ From Week 14 0.4mg/D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2018	15773915	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-061627		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Metformin			S	Oral	Unk		Aurobindo
	Alprazolam			S	Oral			Aurobindo
	Naproxen			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2018	15773939	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2018-062211		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Carvedilol			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Mirtazapine			S				Aurobindo
	Divalproex			S	Oral			Aurobindo
	Phenytoin			S				Aurobindo
	Primidone			S	Oral			Not Reported
	Sitagliptin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2018	15774000	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-063097		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Unknown			Aurobindo
	Lamotrigine			S	Unknown			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2018	15774188	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2018-061011		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Lamotrigine			S	Oral			Aurobindo
	Oxycodone+Acetaminophen			S	Oral			Aurobindo
	Propranolol			S	Oral			Not Reported
	Ibuprofen			S				Aurobindo
	Montelukast			S				Aurobindo
	Ondansetron			S				Aurobindo
	Aciclovir			S				Aurobindo
	Alprazolam			S				Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2018	15774430	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2018-063628			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Medication Error	Escitalopram			S	Oral	30 Milligram, In Total		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	13553262	EXPEDITED (15-DAY)		HO	IT-ACCORD-051430		19 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Nausea; Tremor	Escitalopram			S	Oral	200 Mg Total		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	14600990	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2018-ES-864907		79 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Drug Interaction	Escitalopram			S	Oral			Ivax
	Enoxaparina Sodica			S	Subcutaneous			Not Reported
	Sintrom			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15756363	EXPEDITED (15-DAY)		OT	PL-PFIZER INC-2018519766		52 YR	Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Alprazolam			S		Unk		Pfizer
	Zoledronic Acid			S	Intravenous (not otherwise specified)	4 Mg, Unk		Unknown
	Gabapentin			S		Dosage Being Set At 300-600-600 Mg/Day		Pfizer

	Trazodone	S		Unk	Not Reported
	Escitalopram	S		Unk	Not Reported
	Lidocaine	S			Not Reported
	Betamethasone	S		Unk	Not Reported
	Betamethasone	S		Unk	Not Reported
	Heparin	S		Unk	Not Reported
	Morphine	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Morphine	S	Subcutaneous	60 Mg + 10 Mg Every 12 Hours	Not Reported
	Morphine	S	Oral	60 Mg + 10 Mg Every 12 Hours	Not Reported
	Valproic Acid	S		400 Mg, Diluted, Was Administered By Infusion Over Three Consecutive Days	Not Reported
	Effentora	S	Buccal	400 Ug, 2x/Day	Not Reported
	Sodium Phosphate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15775225	EXPEDITED (15-DAY)		HO	LT-ACCORD-098326		46 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dizziness; Insomnia; Speech Disorder	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Etoricoxib			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15775260	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-098697		93 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Intracranial Haematoma	Escitalopram	S			Not Reported
	Kardegic	S	Oral		Not Reported
	Levocetirizine	C			Not Reported
	Amlodipine	C			Not Reported
	Levothyroxine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15775271	EXPEDITED (15-DAY)		OT	FR-ACCORD-098473		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15775404	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE-992881		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Kidney Duplex	Escitalopram			S	Transplacental	10 [Mg/D]/ Dosage Reduction To 5mg/D Before Stop		Ivax
	Magnetrans			C	Transplacental			Not Reported
	Ibuprofen			C	Transplacental	400 [Mg/D]/ On Demand, Max Once Per Week		Not Reported
	Cetirizine			C	Transplacental			Not Reported
	Paracetamol			C	Transplacental	1500 [Mg/D]/ 1000-1500 Mg/D, In Total 2-3 Times		Not Reported
	Cytotec			C	Transplacental			Not Reported
	Olynth			C	Transplacental	If Required		Not Reported
	Folio Forte			C	Transplacental	0.8 [Mg/D]/ From Week 14 0.4mg/D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15775512	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-993178		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Abuse; Drug Dependence	Alprazolam			S	Unknown	Not Informed		Not Reported
	Escitalopram			S	Unknown	Not Informed		Ivax
	Dafalgan Codeine			S	Unknown	Not Informed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15775913	EXPEDITED (15-DAY)		HO, OT	AT-ACCORD-060297		47 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Paraesthesia; Serotonin Syndrome	Escitalopram			S	Oral	Also Received At Dose Of 5 Mg From 16-Aug-2017 To 20-Aug-2017.		Accord
	Alprazolam			S	Unknown	Also Received 1 Mg		Not Reported
	Seropram (Citalopram Hydrobromide)			S	Intravenous (not otherwise specified)	Strength: 20 Mg 8 Infusions Total		Not Reported
	Xanor			C				Not Reported
	Temesta [Lorazepam]			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15777149	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1859386US		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Depression; Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Valium			S	Unknown	Unk		Not Reported
	Dapsone			C	Unknown	100 Mg, Qd		Not Reported
	Infliximab			C	Unknown	10 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	15779646	NON-EXPEDITED			DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2018-03356			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Mycophenolate Mofetil			S	Unknown	0.5 G, Qd		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	14083049	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MYLANLABS-M-EU-2017060449		62 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Ivabradine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Trazodone			S		Unk		Not Reported
	Metoprolol			S		Unk		Not Reported
	Sertraline			S	Unknown	50 Mg Millgram(S) Every Days		Not Reported
	Zolpidem			S	Oral	10 Milligram, Hs		Not Reported
	Venlafaxine			S	Oral	150 Mg Millgram(S) Every Days		Not Reported
	Moklar			S		150 Mg Millgram(S) Every Days		Mylan
	Cyproheptadine			S				Mylan
	Sotalol			C				Mylan
	Warfarin			C		Unk		Mylan
	Ginkgo Biloba Extract			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	14332067	EXPEDITED (15-DAY)		HO	IN-CIPLA (EU) LIMITED-2017IN27246			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence;	Escitalopram			S	Unknown	10 Mg, Unk		Invagen

General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Urinary Incontinence	Escitalopram		S	Unknown	20 Mg, Unk	Invagen
	Amlodipine		C	Unknown	10 Mg, Unk	Not Reported
	Rosuvastatin		C	Unknown	20 Mg, Unk	Not Reported
	Metformin		C	Unknown	1 G, Unk	Not Reported
	Sitagliptin		C	Unknown	100 Mg, Unk	Not Reported
	Aspirin /00002701/		C	Unknown	75 Mg, Unk	Not Reported
	Clonazepam		C	Unknown	0.5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	14699281	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2018M1018471		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Hyponatraemia	Enalapril			S	Oral	20 Milligram, Qd (1-0-0)		Not Reported
	Heipram			S	Oral	10 Milligram, Qd (0-0-1)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15363277	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1843980US		65 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15525848	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1849435US		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Asthenia; Confusional State; Delusion; Drug Interaction; Hallucination; Hallucination, Visual; Hypertension; Major	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Unknown	Unk, Unknown		Allergan
	Elavil			S	Unknown	Unk Unk, Unknown		Not Reported
	Amitriptyline			S	Oral	25 Mg, Qd		Not Reported
	Elenbecestat			S	Oral	5 Mg, Unk		Not Reported

Depression; Mental Status Changes; Paranoia	Lipitor		C	Unknown	Unk Unk, Unknown	Not Reported
	Diovan		C	Unknown	Unk Unk, Unknown	Not Reported
	Actos		C	Unknown	Unk Unk, Unknown	Not Reported
	Trazodone		C	Unknown	Unk Unk, Unknown	Not Reported
	Aricept		C	Unknown	Unk Unk, Unknown	Not Reported
	Magnesium Oxide		C	Unknown	Unk Unk, Unknown	Not Reported
	Vitamin D2		C	Unknown	Unk Unk, Unknown	Not Reported
	Centrum Silver		C	Unknown	Unk Unk, Unknown	Not Reported
	Lovaza		C	Unknown	Unk Unk, Unknown	Not Reported
	Pioglitazone		C	Unknown	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15762414	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1095041		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Risperidone			S	Oral	1 Milligram, Qd (0.5 Mg Matin Et Soir)		Not Reported
	Olanzapine Mylan			S	Oral	5 Milligram, Qd (5 Mg Le Soir)		Mylan
	Loxapine Succinate			S	Oral	5 Gtt Drops (5 Gouttes Si Besoin)		Mylan
	Escitalopram Arrow			S	Oral	10 Milligram, Qd (10 Mg Le Soir)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780361	EXPEDITED (15-DAY)		OT	ES-ACCORD-099271		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroid Mass	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780690	NON-EXPEDITED			US-TEVA-2018-US-984680			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Escitalopram			S	Unknown			Ivax
	Alprazolam			C	Unknown	2 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15781856	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2018US040731		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Drug Interaction; Electrocardiogram Qt Prolonged; Febrile Neutropenia; Febrile Neutropenia; Pneumonia; Sinus Bradycardia; Somnolence; Syncope	Asp2215			S	Oral			Astellas
	Asp2215			S	Oral			Astellas
	Asp2215			S	Oral			Astellas
	Amitriptyline			S	Oral			Not Reported
	Amitriptyline			S	Oral	Unk Unk, Unknown Freq. (Reduced Doe)		Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral	Unk Unk, Unknown Freq. (Redced Dose)		Not Reported
	Voriconazole			S	Intravenous (not otherwise specified)			Not Reported
	Voriconazole			S				Not Reported
	Decadron /00016001/			S	Oral			Not Reported
	Decadron /00016001/			S	Oral			Not Reported
	Decadron /00016001/			S	Oral			Not Reported
	Hydrea			C	Oral			Not Reported
	Pentamidine			C	Unknown	Unk Unk, Monthly, Nebulized		Not Reported
	Valtrex			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15782174	EXPEDITED (15-DAY)		OT	QA-IMPAX LABORATORIES, LLC-2018-IPXL-04402		49 YR	Male	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Oxybutynin Chloride Er			S	Oral	5 Milligram, Bid		Impax
	Atorvastatin			S	Oral	40 Milligram, Daily		Not Reported
	Escitalopram			S	Oral	20 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15782524	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018533356		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Spironolactone			S	Oral	25 Mg, 1x/Day		Pfizer
	Escitalopram			S	Oral	5 Mg, 1x/Day		Not Reported
	Imovane			S	Oral	1 Df, 1x/Day		Not Reported
	Seresta			S	Oral	1 Df, 1x/Day		Not Reported
	Lasilix [Furosemide]			S	Oral	4 Df, 1x/Day		Not Reported
	Omexel			S	Oral	1 Df, 1x/Day		Not Reported
	Candesartan Cilexetil			S	Oral	16 Mg, 1x/Day		Not Reported
	Tenordate			S	Oral	1 Df, 1x/Day		Not Reported
	Seebri Breezhaler			C		Unk		Not Reported
	Lovenox			C		Unk		Not Reported
	Kardegic			C		Unk		Not Reported
	Avodart			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15782557	EXPEDITED (15-DAY)		HO, OT	US-TORRENT-00007345		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Catatonia; Condition Aggravated; Depression; Hallucination, Auditory; Joint Stiffness; Off Label Use; Orthostatic Hypotension; Suicidal Ideation	Risperidone	S	Unknown	Unknown
	Topiramate	S	Unknown	Unknown
	Escitalopram	S	Unknown	Unknown
	Lorazepam	S	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15783056	EXPEDITED (15-DAY)		OT	BE-ALLERGAN-1900021US		55 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Parkinson'S Disease	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15783057	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1859821US		35 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Gamma-Glutamyltransferase Increased; Seizure	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Solanax			C	Oral			Not Reported
	Loramet			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15783131	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-994258		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Sluggishness	Escitalopram Oxalate			S	Oral			Ivax
	Alprazolam			S	Oral			Actavis
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15783696	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1900022US		55 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Underdose; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Nauzelin			C	Oral	10 Mg, Qd		Not Reported
	Belsomra			C	Oral	20 Mg, Qd		Not Reported
	Vitaneurin			C	Oral	50 Mg, Unk		Not Reported
	Actos			C	Oral			Not Reported
	Januvia			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15798601	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dispensed To Wrong Patient; Wrong Product Administered	Escitalopram 10mg			S				Not Reported
	Alprazolam 0.25mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	13708554	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-BAUSCH-BL-2017-020458		62 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Initial	Venlafaxine			S	Oral	150 Mg; Every Day		Not Reported
	Zolpidem			S	Oral	10 Mg, At Bedtime (Before A Sleep)		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Ivabradine			S	Unknown			Not Reported

Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Metoprolol	S	Unknown		Not Reported
	Moklar	S	Oral	150 Mg In Afternoon	Not Reported
	Sertraline	S	Oral	50 Mg, At Night	Not Reported
	Moklar	S	Unknown	In The Afternoon	Not Reported
	Cyproheptadine	S	Oral		Not Reported
	Trazodone	S	Unknown		Not Reported
	Sotalol	C			Not Reported
	Warfarin	C			Not Reported
	Ginkgo Biloba Extract	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15784800	EXPEDITED (15-DAY)		OT	IN-HETERO LABS LIMITED-HET2018IN01599		22 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatomegaly; Typhoid Fever	Escitalopram			S	Oral	10 Mg, (0-0-1)		Not Reported
	New Livfit			C	Unknown	Unk		Not Reported
	Atarax /00058401/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15786618	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2018GSK233918		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Methylphenidate			S	Oral	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15786683	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2018GSK233928		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Bupropion	S	Oral	Unk		Glaxosmithkline
	Escitalopram	S	Oral	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15787168	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2018M1019393		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction	Escitalopram Mylan			S	Oral	Unk		Mylan
	Amiodarona Hidrocloruro (392ch)			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15797671	DIRECT	Y				35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Nausea; Product Substitution Issue	Lexapro 10mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15787878	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-195125		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Sluggishness	Escitalopram			S	Oral	In Total		Not Reported
	Alprazolam			S	Oral	In Total		Sun
	Omeprazole			C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15788051	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018019429			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Medication Error	Escitalopram Oxalate			S	Oral	30 Milligram, Single, Total		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15788352	EXPEDITED (15-DAY)		OT	BE-ALLIED PHARMA, LLC-2060840		70 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Clarithromycin			S	Unknown			Allied Pharma
	Rivaroxaban			S	Unknown			Not Reported
	Diltiazem			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15788416	EXPEDITED (15-DAY)		HO	FR-ZYDUS-029605		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral	5 Mg Tablet		Not Reported
	Prednisone			S	Oral			Not Reported
	Valaciclovir			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Codeine			S	Oral			Not Reported
	Desloratadine			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Colecalciferol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Calcium			S	Oral			Not Reported
	Risedronic Acid			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15788472	EXPEDITED (15-DAY)		DE, HO	US-ASTRAZENECA-2019SE00412		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Toxicity To Various Agents	Propranolol			S	Oral			Not Reported
	Quetiapine			S	Oral			Zeneca
	Amlodipine			S	Oral			Not Reported
	Primidone			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15790266	EXPEDITED (15-DAY)		DE	PHHY2019FR000743			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depression	Infliximab			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	Unk		Novartis
	Cyamemazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15790697	EXPEDITED (15-DAY)		DE, HO	US-ASTRAZENECA-2019SE00085		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Metoprolol			S	Oral			Not Reported
	Quetiapine			S	Oral			Zeneca
	Escitalopram			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Potassium Chloride			S	Oral			Not Reported

	Amlodipine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15790950	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2018-036395		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Venlafaxine			S	Oral	Extended Release		Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15793152	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Product Dispensing Error	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2019	15368660	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2018-044136		64 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disinhibition; Euphoric Mood; Hallucination, Visual; Insomnia; Mania; Psychomotor Hyperactivity; Restlessness	Tramadol			S	Unknown	225 Milligram, Once A Day		Aurobindo
	Tramadol			S				Aurobindo
	Escitalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Amitriptyline			S	Unknown	25 Milligram, Once A Day		Not Reported
	Levofloxacin			C	Unknown	500 Milligram, Once A Day		Not Reported
	Acetaminophen			C	Unknown	3000 Milligram, Once A Day		Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	14839063	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018173096		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyp2d6 Polymorphism; Drug Metabolising Enzyme Test Abnormal; Dyskinesia; Malaise; Nausea; Suicidal Ideation; Tic	Geodon			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Pamelor			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15698375	NON-EXPEDITED			US-PFIZER INC-2018498459			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Cefdinir			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Promethazine Hcl			S		Unk		Pfizer
	Baclofen			S		Unk		Not Reported
	Erythromycin Base			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Zolmitriptan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15793675	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC-2018SUN00643		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown	Unk		Taro
	Metoprolol			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15794558	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20190104001		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Methylphenidate			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Melatonin			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15794560	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20190103991		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Methylphenidate			S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15794584	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20190102939		29 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Vomiting	Risperdal			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15794784	EXPEDITED (15-DAY)		DE, HO	US-GLENMARK PHARMACEUTICALS-		39 YR	Female	USA

2019GMK039028

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Potassium Chloride			S	Oral	Unk		Glenmark
	Metoprolol			S	Oral	Unk; Extended Release		Not Reported
	Amlodipine			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15794802	EXPEDITED (15-DAY)		DE, HO	US-GLENMARK PHARMACEUTICALS-2019GMK039027		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Gabapentin			S	Oral	Unk		Glenmark
	Propranolol			S	Oral	Unk		Not Reported
	Levetiracetam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Acetaminophen W/Chlorzoxazone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	14719327	EXPEDITED (15-DAY)		HO	DE-ACCORD-065278		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bedridden; Dizziness; Nausea; Stupor; Vertigo	Escitalopram			S	Oral	10 Mg, Qd Also 15 Mg, Qd From 30-Aug-2016 For Depression		Not Reported
	Aripiprazole			S	Oral	10 Mg, Qd Also 5 Mg, Qd		Not Reported

				From 17-Sep-2016	
	Candesartan	S	Oral	16 Mg, Qd	Not Reported
	Acetylsalicylic Acid	C	Oral	100 Mg, Qd	Not Reported
	Risperdal	C		1.5 Mg, Qd Also, 2 Mg (For Nights)	Not Reported
	Levothyroxine	C	Oral	100 Microgm, Qd	Not Reported
	Amisulpride	C		200 Mg, Qd	Not Reported
	Metformin	C	Oral	1500 Mg, Qd	Not Reported
	Atorvastatin	C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15796928	NON-EXPEDITED			US-APOTEX-2018AP023509		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Bruxism; Gynaecomastia; Intentional Product Use Issue; Pain; Polydipsia; Polyuria; Tenderness; Toothache; Tremor; Withdrawal Syndrome	Aripiprazole			S	Unknown	2 Mg, Q.H.S.		Apotex
	Aripiprazole			S	Unknown	4 Mg, Q.H.S.		Apotex
	Escitalopram			S	Unknown	5 Mg, Q.Am		Apotex
	Escitalopram			S	Unknown	15 Mg, Q.Am, Followed By A Gradual Taper (2.5 Mg/Week)		Apotex
	Buspirone			S	Unknown	7.5 Mg, Bid		Apotex
	Buspirone			S	Unknown	20 Mg, Qd		Apotex
	Buspirone			S	Unknown	15 Mg, Tid		Apotex
	Buspirone			S	Unknown	15 Mg, Bid		Apotex
	Buspirone			S	Unknown	7.5 Mg, Bid		Apotex
	Lithium Carbonate			S	Unknown	600 Mg, Q.H.S.		Apotex
	Lurasidone			S	Unknown	40 Mg, Qd, At Dinner		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15798233	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019006001		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence	Alprazolam			S	Unknown	Unk		Pfizer
	Escitalopram			S	Unknown	Unk		Not Reported
	Dafalgan Codeine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15798932	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007274		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Propanolol Hcl			S	Oral	Unk		Unknown
	Methylphenidate Hydrochloride			S	Oral	Unk, (Extended Release)		Pfizer
	Diazepam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Melatonin			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15799336	EXPEDITED (15-DAY)		DE, HO	US-GLENMARK PHARMACEUTICALS-2019GMK038912		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Gabapentin			S	Oral	Unk		Glenmark
	Tramadol			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15799628	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007065		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Venlafaxine Hcl			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15800025	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2019006935		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Alprazolam			S	Oral	Unk		Pfizer
	Lisinopril			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15803265	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dispensed To Wrong Patient	Metformin Hcl Extended Release Metformin Er			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15811903	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Product Dispensing Error	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	7382300	EXPEDITED (15-DAY)		OT	FI-PFIZER INC-2007078093		46 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Acute Sinusitis; Adjustment Disorder With Mixed Anxiety And Depressed Mood; Adrenal Insufficiency; Aggression; Agitation; Akathisia; Anxiety; Blood Cholesterol Increased; Blood Glucose Increased; Confusional State; Craniocerebral Injury; Depression; Dizziness; Drug Dependence; Drug Interaction; Dyskinesia; Dyspnoea; Erectile Dysfunction; Euphoric Mood; Fatigue; Fear; Feeling Abnormal; Feeling Cold; Gastric Disorder; Hallucination; Hepatic Steatosis; Hyperhidrosis; Hypersensitivity; Hypopituitarism; Hyporeflexia; Hyposmia; Hypothyroidism; Increased Appetite; Infection; Influenza; Irritability; Loss Of Libido; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Memory Impairment; Mood Swings; Musculoskeletal Discomfort; Nausea; Neurotoxicity; Nightmare; Obesity; Olfacto Genital Dysplasia; Palpitations; Panic Reaction; Parkinson'S Disease; Personality Change;	Champix	S	Oral	0.5 Mg, 1x/Day	Pfizer
	Champix	S	Oral	0.5 Mg, 2x/Day	Pfizer
	Champix	S	Oral	1 Mg, 2x/Day	Pfizer
	Zoloft	S		Unk	Pfizer
	Amoxin	S	Oral	Unk	Not Reported
	Amoxin	S			Not Reported
	Rinexin	S	Oral	100 Mg, Unk	Not Reported
	Nicorette Gum	S		4 Mg, Unk	Not Reported
	Nicorette Gum	S		2 Unk, Unk	Not Reported
	Nicorette Patch	S		Unk	Not Reported
	Sertraline	S		50mg, 1/2 Tablet Daily	Not Reported
	Cipralex	S		Unk	Not Reported
	Metoclopramide	S			Not Reported
	Azithromycin	C	Oral	3	Not Reported
	Doximycin	C	Oral	Unk	Not Reported
	Klacid /00984601/	C	Oral	Ten Days Course	Not Reported
	Havrix	C	Intramuscular	Unk	Not Reported
	Toclase	C		Unk	Not Reported

Poisoning; Restlessness; Secondary Hypogonadism; Sense Of Oppression; Sleep Disorder; Snoring; Somnolence; Swelling; Tinnitus; Tremor; Upper Respiratory Tract Infection; Vasodilatation; Vertigo; Weight Increased; Withdrawal Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	14700276	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1816507US		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Lipanthyl			S	Oral	145 Mg, Qd		Not Reported
	Esomeprazole			S	Oral	Unk, Unknown		Not Reported
	Xtandi			S	Oral	120 Mg, Qd		Not Reported
	Decapeptyl [Gonadorelin]			S	Intramuscular	1 Df, Cyclical		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Amlor			S	Oral	Unk		Not Reported
	Novonorm			S	Oral	Unk		Not Reported
	Innohep			S	Subcutaneous	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15800862	NON-EXPEDITED			US-TEVA-2018-US-990294			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Muscular Weakness	Lexapro			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15800913	EXPEDITED (15-DAY)		HO	FR-ZYDUS-029584		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melaena; Microcytic Anaemia	Escitalopram			S	Oral			Zydus Pharm
	Clopidogrel			S	Oral	75 Mg Film-Coated Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15802046	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2018-036444		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Primidone			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15802357	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP028612		27 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Headache; Muscle Spasms; Tinnitus; Tremor	Escitalopram Apotex			S	Oral	Un Comprimido Al Día Por La Mañana		Apotex
	Terbinafina /00992601/			C	Unknown	Un Mes 1comprimido Al Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15803359	EXPEDITED (15-DAY)		DE, LT	NO-B.I. PHARMACEUTICALS,I		20 YR	Female	NOR

NC./RIDGEFIELD-2019-12-00

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Self-Injury	Catapresan			S	Unknown	50 Mg, Unk		Boehringer Ingelheim
	Rivotril			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	100 Mg, Unk		Not Reported
	Sarotex			S	Unknown	Unk		Not Reported
	Truxal			S	Unknown	Unk		Not Reported
	Pinex Forte			S	Unknown	Unk		Not Reported
	Atarax /00058402/			S	Unknown	Unk		Not Reported
	Nozinan /00038601/			S	Unknown	Unk		Not Reported
	Tramadol Hydrochloride			S	Unknown	Unk		Not Reported
	Cipralex			S	Unknown	Unk		Not Reported
	Nobligan			S	Unknown	200 Mg, Unk		Not Reported
	Seroquel			S	Unknown	Unk		Not Reported
	Vival			S	Unknown	Unk		Not Reported
	Orfiril			S	Unknown	1200 Mg, Unk		Not Reported
	Remeron			S	Unknown	Unk		Not Reported
	Sobril			S	Unknown	Unk		Not Reported
	Cipramil /00582602/			S	Unknown	Unk		Not Reported
	Imovane			S	Oral	Unk		Not Reported
	Oxynorm			S	Unknown	10 Mg, Unk		Not Reported
	Diamorphine /00197602/			C	Unknown			Not Reported
	Cyanocobalamin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15803366	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20190105582		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Tramadol			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15803768	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007277		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Propanolol Hcl			S	Oral	Unk		Unknown
	Gabapentin			S	Oral	Unk		Pfizer
	Levetiracetam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Acetaminophen;Chlorzoxazone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15803927	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2019006902		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported
	Naproxen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15804147	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007271		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Propanolol Hcl		S	Oral	Unk	Unknown
	Gabapentin		S	Oral	Unk	Pfizer
	Tramadol		S	Oral	Unk	Not Reported
	Escitalopram		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15804148	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007926		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Alprazolam			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Acetaminophen;Hydrocodone			S	Oral	Unk		Not Reported
	Acetaminophen;Oxycodone Hydrochloride			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15804170	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007287		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil Hcl			S	Oral	Unk		Pfizer
	Diphenhydramine Hcl			S	Oral	Unk		Unknown
	Bupropion			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Lisinopril			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15755320	EXPEDITED (15-DAY)		OT	US-LUPIN HEALTHCARE (UK) LIMITED-2018-08921			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pruritus; Rash Erythematous; Rash Macular; Syphilis	Escitalopram Oxalate Tablets Usp, 10 Mg	S	Oral	10 Mg, Qd		Lupin
	Prezista	C	Unknown	Unk		Not Reported
	Isentress	C	Unknown	Unk		Not Reported
	Norvir	C	Unknown	Unk		Not Reported
	Descovy	C	Unknown	Unk		Not Reported
	Gabapentin	C	Unknown	Unk		Not Reported
	Morphine	C	Unknown	Unk		Not Reported
	Finasteride	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Vitamin D /00107901/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15760958	NON-EXPEDITED			US-PFIZER INC-2018529148		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Hypersensitivity	Ibuprofen			S		Unk		Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer
	Amitriptyline			S		Unk		Not Reported
	Bupropion			S		Unk		Not Reported
	Citalopram			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Omeprazole			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Celexa [Celecoxib]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15802547	EXPEDITED (15-DAY)		HO, OT	QA-ALLERGAN-1900852US		49 YR	Male	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug-Induced Liver Injury; Hypertonic Bladder	Escitalopram Oxalate - Bp		S	Oral	20 Mg, Qd	Allergan
	Atorvastatin		S	Oral	40 Mg, Qd	Not Reported
	Oxybutynin		S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15804992	EXPEDITED (15-DAY)		CA	DE-TEVA-2019-DE-996931		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram			S	Transplacental	10 Milligram Daily;		Ivax
	L-Thyroxin			C	Transplacental	75 Microgram Daily;		Not Reported
	Xanaflu			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15805287	NON-EXPEDITED			US-TEVA-2018-US-988265			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Feeling Hot; Gastrointestinal Disorder; Thinking Abnormal; Tremor; Withdrawal Syndrome; Wrong Technique In Product Usage Process	Clonazepam Teva			S	Unknown			Teva
	Clonazepam Teva			S	Unknown			Teva
	Clonazepam Teva			S	Unknown			Teva
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15805684	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20190100948		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Diphenhydramine		Y	S	Oral			Not Reported
	Bupropion			S	Oral			Not Reported

Verapamil	S	Oral		Not Reported
Escitalopram	S	Oral		Not Reported
Ethanol	S	Oral		Not Reported
Hydrochlorothiazide	S	Oral		Not Reported
Lisinopril	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15806165	EXPEDITED (15-DAY)		OT	QA-MACLEODS PHARMACEUTICALS US LTD-MAC2018017426			Unknown	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hepatotoxicity	Escitalopram Oxalate			S	Oral	20 Milligram, Qd		Macleods
	Atorvastatin			S	Oral	40 Milligram, Qd		Not Reported
	Oxybutynin			S	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15806203	NON-EXPEDITED			US-PFIZER INC-2019008264			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Effexor			S	Unknown	Unk		Pfizer
	Rexulti			S	Oral	2 Mg, 1x/Day		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15807078	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007280		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Propanolol Hcl			S	Oral	Unk		Unknown
	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Quetiapine			S	Oral	Unk		Not Reported

	Primidone		S	Oral	Unk	Not Reported
	Trazodone		S	Oral	Unk	Not Reported
	Escitalopram		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15807118	EXPEDITED (15-DAY)		HO	QA-MYLANLABS-2019M1001257		49 YR	Male	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Atorvastatin			S	Oral	40 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Oxybutynin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15808086	EXPEDITED (15-DAY)		DE, HO	US-BAYER-2019-007558		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Toxicity To Various Agents	Paracetamol		Y	S	Oral			Bayer
	Escitalopram			S	Oral			Not Reported
	Doxepin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15808503	EXPEDITED (15-DAY)		DE	US-BAYER-2019-008332		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Naproxen Sodium (<= 220 Mg)			S	Oral	Unk		Bayer
	Amlodipine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Zolpidem			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15808782	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1901146US		87 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Noncompliance; Tremor; Unresponsive To Stimuli	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15809186	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1001933		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Dyschezia; Nausea; Rectal Haemorrhage; Vomiting	Escitalopram			S	Oral	Unk Unk, Am (1x Täglich Morgens)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	8225828	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2011DK96141		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Hypertrophy; Confusional State; Constipation; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension; Hyperventilation; Lactic Acidosis; Lacunar Infarction; Myocardial Infarction; Neuroleptic Malignant Syndrome; Organ Failure; Pyrexia; Renal Failure; Rhabdomyolysis; Urinary	Mirtazapine			S	Oral	30 Mg, Qd		Not Reported
	Mirtazapine			S				Not Reported
	Zeldox			S	Oral	80 Mg, Qd		Not Reported
	Cipralex			S	Oral	30 Mg, Qd (Daily Dose Of 1 Tablet In The Morning And 1.5 Tablet In The Evening)		Not Reported
	Litarex (Lithium Citrate)			S	Oral	1 Df (In The Morning)		Not Reported
	Litarex (Lithium Citrate)			S	Oral	1.5 Df (In The Evening)		Not Reported
	Alprazolam			C		0.5 Mg, Qd		Not Reported

Tract Infection	Alprazolam	C		0.5 Mg, Qd	Not Reported
	Alprazolam	C		.5 Milligram Daily;	Not Reported
	Alprazolam	C		Unk	Not Reported
	Centyl Med Kaliumklorid	C	Unknown	1 Df, Qd	Not Reported
	Ferro Duretter	C	Unknown	100 Mg Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	14173870	NON-EXPEDITED			US-PFIZER INC-2017481476		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Percocet			S		Unk		Not Reported
	Cognex			S		Unk		Not Reported
	Reminyl			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	14316933	EXPEDITED (15-DAY)		DE	FI-ACCORD-062227			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Fibrillation	Escitalopram			S	Unknown			Accord
	Ciprofloxacin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	14731369	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-017087		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Prescribed Underdose	Esomeprazole			S	Oral	Not Reported		Aurobindo
	Tramadol			S	Oral	Unk, Unknown Freq.		Aurobindo
	Decapeptyl /00486501/			S	Intramuscular	1 Dosage Form, Cyclical		Not Reported

	Innohep	S	Subcutaneous	1 Dosage Form, Once A Day	Not Reported
	Amlor	S	Oral	Unk, Unknown Freq.	Not Reported
	Novonorm	S	Oral	Unk, Unknown Freq.	Not Reported
	Xtandi	S	Oral	120 Milligram	Not Reported
	Xtandi	S	Oral	40 Milligram, Once A Day	Not Reported
	Lipanthyl	S	Oral	145 Milligram	Not Reported
	Seroplex	S	Oral	10 Milligram	Not Reported
	Decapeptyl /00975902/	S	Intramuscular	1 Dosage Form, Cyclical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	14943669	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1772846US		23 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Abilify			S	Unknown	10 Mg, Qd		Not Reported
	Abilify			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15443230	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-2018_016557		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Asthenia; Back Pain; Blood 1,25-Dihydroxycholecalciferol Decreased; Blood Albumin Decreased; Blood Alkaline Phosphatase Increased; Blood Calcium Decreased; Blood Magnesium Decreased; Blood Potassium Increased; Blood Pressure	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Abilify			S	Oral	20 Mg, Qd		Otsuka
	Abilify			S	Oral	15 Mg, Qd (Qam)		Otsuka
	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Lexapro			S	Oral	20 Mg, Qd (Qhs)		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

Fluctuation; Blood Sodium Decreased; Blood Urea Increased; Compulsions; Compulsive Sexual Behaviour; Condition Aggravated; Confusional State; Constipation; Crying; Decreased Appetite; Diabetes Mellitus; Disturbance In Attention; Economic Problem; Gambling Disorder; Hallucination, Auditory; Hyperreflexia; Impulse-Control Disorder; Inappropriate Schedule Of Product Administration; Insomnia; Intervertebral Disc Disorder; Irritability; Lumbar Spinal Stenosis; Memory Impairment; Musculoskeletal Discomfort; Nocturia; Pain; Paralysis; Personal Relationship Issue; Pollakiuria; Poor Quality Sleep; Product Dose Omission; Product Use In Unapproved Indication; Protein Total Increased; Radiculopathy; Restlessness; Self-Medication; Supraventricular Tachycardia; Tearfulness; Tinnitus; Transient Ischaemic Attack; Weight Decreased	Rexulti	C	Oral	0.5 Mg, Qd	Otsuka
	Rexulti	C	Oral	1 Mg, Qd	Otsuka
	Ibuprofen	C	Unknown	800 Mg, Tid	Not Reported
	Trazodone	C	Oral	50 Mg, Qd (Qhs)	Not Reported
	Amoxicillin	C	Unknown	Unk	Not Reported
	Promethazine - Codeine	C	Unknown	Unk	Not Reported
	Escitalopram	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15791403	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-		49 YR	Female	USA

US2018GSK233950

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose	Bupropion			S	Oral	Unk		Glaxosmithkline
	Verapamil			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Ethanol			S	Oral	Unk		Glaxosmithkline
	Diphenhydramine			S	Oral	Unk		Glaxosmithkline
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Lisinopril			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15804615	EXPEDITED (15-DAY)		HO, OT	IN-ALLERGAN-1900877US		39 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Sodium Valproate			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15809441	EXPEDITED (15-DAY)		DE, HO	US-GLENMARK PHARMACEUTICALS-2019GMK038989		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Verapamil			S	Oral	Unk		Glenmark
	Bupropion			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported
	Diphenhydramine			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported

	Lisinopril		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15809443	EXPEDITED (15-DAY)		DE, HO	US-GLENMARK PHARMACEUTICALS-2019GMK039022		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lamotrigine			S	Oral	Unk		Glenmark
	Propranolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Methylphenidate			S	Oral	Unk; Extended Release		Not Reported
	Diazepam			S	Oral	Unk		Not Reported
	Melatonin			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15810712	NON-EXPEDITED			US-TEVA-2018-US-988374			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Escitalopmm 20 Mg Tablets			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15810941	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20190101266		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Doxepin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15811770	EXPEDITED (15-DAY)		HO	PHHY2019ES002963		91 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Carbamazepine			S	Oral	50 Mg, Q24h (200 Mg Por Las Mañanas Un Cuarto De Comprimido)		Not Reported
	Irbesartan+Hydrochlorothiazide			S	Oral	Unk		Novartis
	Gabapentin			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15813056	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007638		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Doxepin Hcl			S	Oral	Unk		Pfizer
	Hydroxyzine Pamoate			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15814437	EXPEDITED (15-DAY)		DS, OT	GB-ALLERGAN-1901442US		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Insomnia; Irritability; Tension	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Kalms			C	Unknown	1 Df, Qhs		Not Reported
	Sleepeezy			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	2 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15814872	EXPEDITED (15-DAY)		HO	ES-ACCORD-101741		38 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome; Drug Interaction	Escitalopram			S	Oral			Not Reported
	Dexamethasone			S	Oral			Not Reported
	Hidroaltesona			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15814935	EXPEDITED (15-DAY)		HO	FR-ACCORD-101613		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Oral			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			S	Oral			Not Reported
	Ramipril			S	Oral			Accord
	Valaciclovir			S	Oral			Not Reported
	Metoclopramide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2019	15594012	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT147757		56 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Hyperhidrosis; Tachycardia; Toxicity To Various Agents; Tremor	Metoprolol			S	Oral	Unk		Novartis
	Escitalopram			S	Oral	Unk		Not Reported
	Xarelto			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2019	15768054	EXPEDITED (15-DAY)		HO	BE-TEVA-2018-BE-992665		67 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Diclofenac			S	Unknown			Actavis
	Escitalopram			S	Unknown			Not Reported
	Rivaroxaban			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2019	15768125	EXPEDITED (15-DAY)		HO	BE-TEVA-2018-BE-992669		70 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Interaction; Gastrointestinal Haemorrhage	Diltiazem			S	Unknown			Teva
	Clarithromycin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Ivax
	Rivaroxaban			S	Oral	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2019	15768154	EXPEDITED (15-DAY)		DE, HO, LT	DK-TEVA-2018-DK-992658		82 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Atrial Fibrillation; Bradycardia; Bundle Branch Block Left; Cardiotoxicity; Completed Suicide; Hypercapnia; Muscle Spasms; Muscle Twitching; Overdose; Somnolence; Toxicity To Various Agents	Escitalopram			S	Unknown			Ivax
	Verapamil			S	Oral	Formulation: Extended Release		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2019	15814981	EXPEDITED (15-DAY)		DE	US-GLENMARK PHARMACEUTICALS-2019GMK039058		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide	Naproxen	S	Oral	Unk		Glenmark
	Amlodipine	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Zolpidem	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2019	15815497	EXPEDITED (15-DAY)		HO	PHHY2018RO184720		54 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Condition Aggravated; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Weight Decreased	Quetiapine			S	Unknown	300 Mg, Qd		Novartis
	Quetiapine			S	Unknown	800 Mg, Qd		Novartis
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Risperidone			S	Unknown	6 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown	30 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	15 Mg, Qd		Not Reported
	Doxepine			S	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2019	15816586	EXPEDITED (15-DAY)		DE	FR-ZYDUS-029556		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hydrocephalus; Intraventricular Haemorrhage	Acetylsalicylic Acid	S	Oral	75 Mg Powder For Oral Solution In Sachet-Dose	Not Reported
	Escitalopram	S	Oral		Zydus Pharm
	Rivaroxaban	S	Oral	20 Mg Film-Coated Tablets	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2019	15817747	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-998246			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Communication Disorder; Dyskinesia; Suicide Attempt	Loquen			S	Oral	4 Gram Daily;		Teva
	Mirzaten Filmom Oblozene Tablete 30 Mg			S	Oral	900 Milligram Daily;		Not Reported
	Elicea			S	Oral	280 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15183944	EXPEDITED (15-DAY)		HO	DK-TAKEDA-2018TUS022777		32 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Bile Acid Malabsorption; Clostridium Difficile Colitis; Drug Ineffective; Drug Ineffective For Unapproved Indication; Functional Gastrointestinal Disorder; Product Use In Unapproved Indication; Therapeutic Response Decreased	Entyvio			S	Unknown	Unk		Takeda
	Spironolactone			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Natalizumab			S	Unknown	Unk		Not Reported
	6-Mercaptopurine Monohydrate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Liraglutide			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	40 Mg, Qd		Not Reported
	Octreotide /00821002/			S	Unknown	Unk		Not Reported
	Lamotrigine			C	Unknown	400 Mg, Qd		Not Reported
	Loperamide			C	Unknown	Unk		Not Reported

Levetiracetam	C	Unknown	1500 Mg, Qd		Not Reported
Colesevelam	C	Unknown	625 Mg, Tid		Not Reported
Colesevelam	C				Not Reported
Codeine Phosphate	C	Unknown	Unk		Not Reported
Colestyramine	C	Unknown	Unk		Not Reported
Venlafaxin	C	Unknown	225 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15298289	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1840590US		1 DAY	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Newborn Persistent Pulmonary Hypertension	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Ronlax			C	Transplacental	0.5 Mg, Qd		Not Reported
	Solanax			C	Transplacental	0.4 Mg, As Needed During Anxiety		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15761731	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181221616			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Drug Interaction; Haemorrhagic Diathesis	Imbruvica			S	Oral	Strength = 140 Mg		Not Reported
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15819399	EXPEDITED (15-DAY)		OT	AU-TEVA-2019-AU-997060		36 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersomnia; Malaise; Neutropenia; Schizophrenia; Self-Medication	Tevaripiprazole			S	Unknown	Dosage Unknown		Teva
	Escitalopram			S	Unknown			Not Reported
	Clozaril			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15819423	EXPEDITED (15-DAY)		OT	SE-TEVA-2019-SE-998413		36 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Persistent Genital Arousal Disorder	Escitalopram			S	Unknown	15 Milligram Daily; One Tablet Daily		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15819502	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2019-ES-998374		91 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Gabapentina (2641a)			S	Oral			Actavis
	Irbesartan / Hidroclorotiazida			S	Oral			Teva
	Escitalopram (2858a)			S	Oral	10 Milligram Daily; 10 Mg		Not Reported
	Carbamazepina (561a)			S	Oral	50 Milligram Daily; 200 Mg Per Morning A Quarter Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15820322	EXPEDITED (15-DAY)		HO, OT	PHHY2018BE185966		67 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Diclofenac			S	Unknown	Unk		Novartis
	Rivaroxaban			S	Oral	20 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15821145	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1901610US		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram Oxalate - Bp	S	Transplacental	10 Mg, Qd		Allergan
	L-Thyroxin	C	Transplacental	75 Mg, Qd		Not Reported
	Xanaflu	C	Transplacental	Unk, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15822091	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unevaluable Event	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15823758	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2019-000855		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Depression; Drug Ineffective	Diazepam			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Dapsone			C	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15574742	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018445210		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Lorazepam			S		0.5 Mg, 3x/Day (As Necessary)		Pfizer
	Lorazepam			S		1 Mg, 3x/Day (As Necessary)		Pfizer
	Lorazepam			S		0.5 Mg, 2x/Day (As Necessary)		Pfizer

Amphetamine, Dextroamphetamine	S	20 Mg, 1x/Day(Extended Release, Every Morning)	Not Reported
Amphetamine, Dextroamphetamine	S	10 Mg, 1x/Day(Extended Release, Every Morning)	Not Reported
Aripiprazole	S	4 Mg, 1x/Day (Every Bedtime)	Not Reported
Aripiprazole	S	2 Mg, 1x/Day (Every Bedtime)	Not Reported
Bupropion	S	150 Mg, 1x/Day (Every Morning)	Not Reported
Bupropion	S	200 Mg, 1x/Day (Every Morning)	Not Reported
Bupropion	S	300 Mg, 1x/Day (Every Morning)	Not Reported
Buspirone	S	15 Mg, 2x/Day	Not Reported
Buspirone	S	15 Mg, 3x/Day	Not Reported
Buspirone	S	10 Mg, 1x/Day	Not Reported
Buspirone	S	17.5 Mg, 1x/Day	Not Reported
Buspirone	S	7.5 Mg, 3x/Day	Not Reported
Buspirone	S	15 Mg, 3x/Day	Not Reported
Buspirone	S	15 Mg, 1x/Day	Not Reported
Buspirone	S	2.5 Mg, 1x/Day	Not Reported
Buspirone	S	22.5 Mg, 1x/Day	Not Reported
Buspirone	S	5 Mg, 1x/Day	Not Reported
Buspirone	S	7.5 Mg, 1x/Day	Not Reported
Buspirone	S	7.5 Mg, 2x/Day	Not Reported
Buspirone	S	7.5 Mg, 3x/Day	Not Reported
Buspirone	S	20 Mg, 1x/Day	Not Reported
Escitalopram	S	5 Mg, 1x/Day (Every Morning, Q.A.M)	Not Reported
Escitalopram	S	20 Mg, 1x/Day	Not Reported
Escitalopram	S	10 Mg, 1x/Day (Every	Not Reported

				Morning)	
	Escitalopram	S		15 Mg, 1x/Day (Every Morning)	Not Reported
	Escitalopram	S		2.5 Mg, Weekly	Not Reported
	Escitalopram	S		7.5 Mg, 1x/Day (Every Morning)	Not Reported
	Lamotrigine	S		150 Mg, 1x/Day	Not Reported
	Lamotrigine	S		100 Mg, 1x/Day	Not Reported
	Lithium	S		600 Mg, 1x/Day (Every Bedtime)	Not Reported
	Lurasidone	S		40 Mg, 1x/Day (After Dinner)	Not Reported
	Testosterone	S	Topical	50 Mg/5 G Every Morning On The Right Upper Extremity	Not Reported
	Benztropine Mesylate	C		0.5 Mg, 2x/Day (As Necessary)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15741249	EXPEDITED (15-DAY)		HO, OT	BE-GLAXOSMITHKLINE-BE2018227367		67 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Diclofenac (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	Unk		Glaxosmithkline
	Rivaroxaban			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15763004	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1859365US		65 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Burnout Syndrome;	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan

Platelet Count Decreased; Serum Serotonin Decreased; Sleep Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15803909	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2019006901		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Metoprolol Tartrate			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15807850	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007020		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Potassium Chloride			S	Oral	Unk		Not Reported
	Metoprolol Tartrate			S	Oral	Unk (Extended Release)		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15811040	EXPEDITED (15-DAY)		OT	AU-ROCHE-2241007		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Rash; Swelling Face	Ceftriaxone			S	Unknown			Not Reported

	Ceftriaxone	S		Not Reported
	Metronidazole	S	Unknown	Not Reported
	Metronidazole	S		Not Reported
	Cephalexin	S	Unknown	Not Reported
	Oseltamivir	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Benzylpenicillin	S	Unknown	Not Reported
	Tazocin	S	Unknown	Not Reported
	Clindamycin	S	Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Not Reported
	Mesalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15821141	EXPEDITED (15-DAY)		HO	QA-ALLERGAN-1901601US		34 YR	Female	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Generalised Tonic-Clonic Seizure; Urinary Incontinence	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Memantine Hcl - Bp			S	Unknown	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15824261	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201900648		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Methylphenidate Hydrochloride			S	Oral	Unk		Mallinckrodt
	Propranolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Diazepam			S	Oral	Unk		Not Reported
	Melatonin			S	Oral	Unk		Not Reported

	Olanzapine	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15824264	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201900609		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydrocodone/Acetaminophen			S	Oral	Unk		Mallinckrodt
	Oxycodone/Acetaminophen			S	Oral	Unk		Mallinckrodt
	Escitalopram			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15824271	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201900611		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Methylphenidate Hydrochloride			S	Oral	Unk		Mallinckrodt
	Bupropion			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15824623	EXPEDITED (15-DAY)		CA, DS, OT	DE-TORRENT-00012944			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	L-Thyroxin			C	Transplacental	75 [G/D]		Unknown
	Escitalopram			S	Transplacental	10 [Mg/D]		Unknown
	Xanaflu			C	Transplacental	Unknown		Unknown

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15827871	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1901867US		25 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Mental Impairment; Product Substitution Issue	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Daily		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Cipralex			S	Unknown			Not Reported
	Acacia			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aczone			C	Unknown			Not Reported
	Azithromycin			C	Unknown			Not Reported
	Benzoyl Peroxide W/Clindamycin Phosphate			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Canesten-Hc			C	Unknown			Not Reported
	Cetaphil Acne Principles			C	Unknown			Not Reported
	Cetaphil			C	Unknown			Not Reported
	Cetaphil Cleansers Oily Skin			C	Unknown			Not Reported
	Constella			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Epival			C	Unknown			Not Reported
	Flovent			C	Unknown	Flovent Diskus		Not Reported
	Flovent Hfa			C	Unknown			Not Reported
	Genteal			C	Unknown			Not Reported
	Nasacort Aq			C	Unknown			Not Reported
	Omega 3-6-9			C	Unknown			Not Reported
	Otrivin Saline			C	Nasal			Not Reported
	Seroquel			C	Unknown	Unk		Not Reported

Seroquel	C	Unknown	Unk		Not Reported
Synthroid	C	Unknown			Not Reported
Tears Plus	C	Unknown			Not Reported
Tecta	C	Unknown			Not Reported
Toviaz	C	Unknown			Not Reported
Tylenol	C	Unknown			Not Reported
Tylenol Extra Strength	C	Unknown			Not Reported
Vitamin D2	C	Unknown			Not Reported
Zinc Gluconate	C	Unknown			Not Reported
Zyloprim	C	Unknown			Not Reported
Clotrimazole W/Hydrocortisone	C	Unknown			Not Reported
Valproate Semisodium	C	Unknown			Not Reported
Polyvinyl Alcohol/Povidone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15827872	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1901807US		36 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Persistent Genital Arousal Disorder	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15828033	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2019-001578		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral	Extended Release		Not Reported
	Escitalopram			S	Oral			Not Reported
	Methylphenidate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15832005	DIRECT	Y	HO			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Lexapro			S				Not Reported
	Sudafed Pe		Y	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	14895470	EXPEDITED (15-DAY)		LT	FR-ELI_LILLY_AND_COMPANY-FR201805004403		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Thrombosis	Olanzapine			S	Oral	7.5 Mg, Unknown		Eli Lilly And Co
	Teralithe			S	Oral	2 Df, Unknown		Not Reported
	Seroplex			S	Oral	1 Df, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15565762	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2018-029468		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Bupropion			S	Unknown	Every Morning		Not Reported
	Bupropion			S	Unknown	Every Morning		Not Reported
	Bupropion			S	Unknown	Every Morning		Not Reported
	Lorazepam			S	Unknown	As Necessary		Not Reported
	Lorazepam			S	Unknown	As Necessary		Not Reported
	Escitalopram			S	Unknown	Every Morning		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown	Every Morning		Not Reported
	Escitalopram			S	Unknown	Every Morning		Not Reported
	Amphetamine, Dextroamphetamine			S	Unknown	Extended Release, Every Morning		Not Reported

Amphetamine, Dextroamphetamine	S	Unknown	Extended Release, Every Morning	Not Reported
Testosterone	S	Topical	50 Mg/5 G Every Morning On The Right Upper Extremity	Not Reported
Lithium	S	Unknown	Every Bedtime	Not Reported
Lurasidone	S	Unknown	After Dinner	Not Reported
Lamotrigine	S	Unknown		Not Reported
Lamotrigine	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Aripiprazole	S	Unknown	Every Bedtime	Not Reported
Aripiprazole	S	Unknown	Every Bedtime	Not Reported
Benztropine Mesylate	C		As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15802506	EXPEDITED (15-DAY)		HO	HR-ALLERGAN-1900604US			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Product Use In Unapproved Indication	Botox		S	Intramuscular	Unk Unk, Single	Allergan
	Escitalopram Oxalate - Bp		S	Unknown	Unk	Allergan
	Propranolol		S	Unknown	180 Mg, Unk	Not Reported
	Propranolol		S	Unknown	120 Mg, Unk	Not Reported
	Ketonal		S	Unknown	Unk	Not Reported
	Helex		S	Unknown	Unk	Not Reported
	Elicea		S	Unknown	Unk	Not Reported
	Plivadon (Caffeine/Phenacetin/Propyphenazone)		S	Unknown	Unk	Not Reported
	Normabel		S	Unknown	Unk	Not Reported
	Amyzol		S	Unknown	Unk	Not Reported
	Knavon		S	Unknown	Unk	Not Reported
	Imigran		S	Unknown	Unk	Not Reported
	Topiramate		S	Unknown	Unk	Not Reported
	Erenumab		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15831214	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP005715		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Acetaminophen			S	Oral			Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Doxepin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15831947	EXPEDITED (15-DAY)		HO, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-09237		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Serotonin Syndrome	Escitalopram	S	Unknown	20 Mg, Qd		Not Reported
	Linezolid	S	Unknown	Unk		Alkem
	Trazodone	S	Unknown	300 Mg, Nightly		Not Reported
	Trazodone	S	Oral	150 Mg, Nightly		Not Reported
	Clonazepam	S	Unknown	0.5 Mg, Bid		Not Reported
	Ceftriaxone	C	Unknown	Unk		Not Reported
	Azithromycin	C	Unknown	Unk		Not Reported
	Piperacillin-Tazobactam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15831950	EXPEDITED (15-DAY)		LT, OT	IN-ALKEM LABORATORIES LIMITED-IN-ALKEM-2018-09546		65 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Serotonin Syndrome	Amoxicillin (As Trihydrate) And Clavulanic Acid (As Potassium)			S	Unknown	Unk		Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	600 Mg, Bid		Alkem
	Escitalopram			S	Unknown	5 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Etophylline			C	Unknown	Unk		Not Reported
	Guaiphenesin			C	Unknown	Unk		Not Reported
	Ambroxol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15831954	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-09555		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction;	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported

Serotonin Syndrome	Linezolid	S	Intravenous (not otherwise specified)	600 Mg, Bid		Alkem
	Cefepime	C	Unknown	1 G, Bid		Not Reported
	Metoclopramide	C	Unknown	10 Mg, Qid		Not Reported
	Ondansetron	C	Unknown	4 Mg, Qid		Not Reported
	Ciprofloxacin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15831959	EXPEDITED (15-DAY)		HO, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-10318		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Linezolid			S	Intravenous (not otherwise specified)	Unk		Alkem
	Duloxetine Hydrochloride			S	Unknown	Unk		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15833893	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1003344		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Diarrhoea	Escitalopram			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	10 Milligram, Qd		Mylan
	Meteospasmyl /01017401/			C	Unknown	Unk		Mylan
	Meteospasmyl /01017401/			C				Mylan
	Copper Iud			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15834797	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1857928US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis; Infectious Mononucleosis; Liver Function Test Increased; Malaise	Escitalopram Oxalate - Bp	S	10 Mg, Qd		Allergan
	Telfast	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15834944	EXPEDITED (15-DAY)		DE	US-INTELLIPHARMACEUTICS CORP.-2061314		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Quetiapine Fumarate			S	Oral			Intellipharmaceutics
	Metoprolol			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15835261	EXPEDITED (15-DAY)		OT	CH-AMGEN-CHESP2019002686		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Decreased; Rebound Effect	Prolia			S	Subcutaneous	60 Mg, Q6mo		Amgen
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Calcimagon D3			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	14813550	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-036074		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma	Eliquis			S	Oral	10 Mg/Day		Bristol Myers Squibb
	Escitalopram Arrow			S	Oral	10 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15721010	EXPEDITED (15-DAY)		HO, OT	AU-ASTELLAS-2018US052496		73 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blindness; Cellulitis Orbital; Diabetes Mellitus; Hypomagnesaemia; Lethargy; Mucormycosis; Myalgia; Nausea; Paraesthesia; Vomiting	Metoclopramide			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Isavuconazole			S	Unknown	Unk Unk, Unknown Freq.		Astellas
	Amphotericin B, Liposome			S	Unknown			Astellas
	Posaconazole			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Irbesartan			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Metformin			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Caspofungin			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Ondansetron			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Escitalopram			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Ranitidine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Amlodipine			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Aspirin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Tapentadol			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Gliclazide			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Rosuvastatin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Oxycodone			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Ceftriaxone			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Clindamycin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Doxycycline			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15762929	EXPEDITED (15-DAY)		HO, OT	AT-PFIZER INC-2018521806			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression; Agitation; Alcoholism; Apraxia; Behaviour Disorder; Cognitive Disorder; Dementia; Dementia With Lewy Bodies; Depression; Drug Ineffective; Dysphoria; Hallucination; Hallucination, Visual; Insomnia; Korsakoff'S Syndrome; Mania; Muscle Rigidity; Parkinsonism; Restlessness; Sleep Disorder; Tremor; Urinary Incontinence	Pregabalin	S	Oral	50 Mg, Unk	Pfizer
	Pregabalin	S	Oral	25 Mg, 2x/Day	Pfizer
	Lorazepam	S		Unk	Pfizer
	Quetiapine Fumarate	S	Oral	25 Mg, 1x/Day, In The Evening	Not Reported
	Quetiapine Fumarate	S	Oral	Slowly Increased	Not Reported
	Quetiapine Fumarate	S	Oral	100 Mg, Unk	Not Reported
	Piracetam	S		1200 Mg, Unk	Not Reported
	Naltrexone	S		Unk	Not Reported
	Rivastigmine	S	Transdermal	Unk (Dose Increased).	Not Reported
	Rivastigmine	S	Transdermal	4.6 Mg, 1x/Day	Not Reported
	Risperidone	S		3 Mg, 1x/Day	Not Reported
	Risperidone	S		Unk	Not Reported
	Risperidone	S		1 Mg, Unk	Not Reported
	Escitalopram	S		10 Mg, Unk	Not Reported
	Escitalopram	S		3 Mg, 1x/Day	Not Reported
	Risperdal	S		Unk	Not Reported
	Cerebrolysin	S		Unk	Not Reported
	Oxazepam	S		Unk	Not Reported
	Mirtazapine	S		15 Mg, Unk	Not Reported
	Valproic Acid	S		1000 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15823280	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1901460US		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hyperhidrosis; Hypertensive Crisis; Insomnia; Malaise; Panic Attack; Tachycardia; Tremor	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Thiocolchicoside			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown			Not Reported

	Bromazepam		S	Unknown	1.5 Mg, Qid	Not Reported
	Amlodipine		C	Unknown	Unk	Not Reported
	Amlodipine		C	Unknown	Unk	Not Reported
	Perindopril		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15827185	EXPEDITED (15-DAY)		HO, OT	AU-ALLERGAN-1901797US		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Ceftriaxone			S				Not Reported
	Cephalexin			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Metronidazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15835441	EXPEDITED (15-DAY)		HO	RO-AUROBINDO-AUR-APL-2019-000452		54 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective	Escitalopram			S	Unknown	10 Mg		Aurobindo
	Quetiapine Fumarate			S	Unknown	300 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	0.5 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15835628	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP005982		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral	Unk		Apotex
	Verapamil			S	Oral	Unk		Apotex

	Escitalopram			S	Oral	Unk		Apotex
	Diphenhydramine			S	Oral	Unk		Apotex
	Hydrochlorothiazide			S	Oral	Unk		Apotex
	Lisinopril			S	Oral	Unk		Apotex
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15835803	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP006124		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue	Amlodipine			S	Oral	Unk		Apotex
	Quetiapine			S	Oral	Unk		Apotex
	Trazodone			S	Oral	Unk		Apotex
	Escitalopram			S	Oral			Apotex
	Propranolol			S	Oral	Unk		Not Reported
	Primidone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15836469	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2019AP006251		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine			S	Oral	Unk		Apotex
	Alprazolam			S	Oral	Unk		Apotex
	Lisinopril			S	Oral	Unk		Apotex
	Escitalopram			S	Oral			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15836806	EXPEDITED (15-DAY)		OT	HR-ROCHE-2246075			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Enzyme Increased; Somnolence; Suicide Attempt	Clonazepam		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported
	Caffetin [Acetaminophen\Caffeine\Codeine\Propyphenazone]		S	Oral	Not Reported
	Alprazolam		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15837476	EXPEDITED (15-DAY)		DE	US-INTELLIPHARMACEUTICS CORP.-2061333		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Quetiapine Fumarate			S	Oral			Intellipharmaceutics
	Propranolol			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Primidone			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15838044	EXPEDITED (15-DAY)		DE, HO, OT	FR-BAUSCH-BL-2019-001367		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Agitation; Delirium; Drug Intolerance; Suicidal Ideation; Withdrawal Syndrome	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Seroplex			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Lysanxia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15838936	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019019512			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram			S	Transplacental	10 Milligram, Qd, 0. - 22.4. Gestational Week During 1 {Trimester}		Macleods
	L-Thyroxine Sodium			C	Transplacental	75 Microgram, Qd, 0. - 22.4. Gestational Week During 1 {Trimester}		Not Reported
	Xanaflu			C	Transplacental	Unk, 20.3. - 20.3. Gestational Week During 2 {Trimester}		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15839437	EXPEDITED (15-DAY)		HO, LT, OT	ES-MYLANLABS-2019M1003844		18 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypocoagulable State; Suicide Attempt	Ibuprofen			S	Oral	2800 Milligram, Total (400 Mg X 7 Cps)		Not Reported
	Paracetamol			S	Oral	12 Gram, Total (12gr Dia)		Not Reported
	Escitalopram			S	Oral	5 Cps		Not Reported
	Exforge			S	Oral	5 Dosage Form (5 Cps)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15839635	EXPEDITED (15-DAY)		DS, OT	GB-TEVA-2019-GB-999868		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Insomnia; Irritability; Tension	Escitalopram			S	Oral			Ivax
	Kalms			C		1 Dosage Forms Daily; Night		Not Reported
	Sleepeezy Valerian			C				Not Reported
	Lansoprazole			C				Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15839649	EXPEDITED (15-DAY)		HO	AU-MYLANLABS-2019M1003515		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Escitalopram			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Ceftriaxone			S				Not Reported
	Ceftriaxone			S				Not Reported
	Benzylpenicillin			S	Unknown			Mylan
	Cephalexin /00145501/			S	Unknown			Mylan
	Tazocin			S	Unknown			Mylan
	Oseltamivir			C	Unknown			Mylan
	Mesalazine			C	Unknown			Mylan
	Metronidazole			C	Unknown			Mylan
	Metronidazole			C				Mylan
	Metronidazole			C				Mylan
	Clindamycin			C	Unknown			Mylan
	Ciprofloxacin			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15839970	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2019M1003433		23 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Escitalopram			S	Oral	15 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15840064	EXPEDITED (15-DAY)		HO, OT	ES-ALLERGAN-1902287US		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness;	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan

Respiratory Depression	Neurontin	S	Oral	300 Mg, Q8hr	Not Reported
	Trankimazin 1 Mg Comprimidos	S	Oral	1 Mg, Qd	Not Reported
	Durogesic	S	Transdermal	150 Mg, Q72hr	Not Reported
	Sevredol	S	Oral	10 Mg, Prn	Not Reported
	Zovirax	C	Unknown	Unk, Unknown	Not Reported
	Nolotil	C	Unknown	Unk, Unknown	Not Reported
	Paracetamol	C	Unknown	Unk, Unknown	Not Reported
	Zyloric	C	Unknown	Unk, Unknown	Not Reported
	Seguril	C	Unknown	Unk, Unknown	Not Reported
	Binocrit	C	Subcutaneous	Unk, Unknown	Not Reported
	Clexane	C	Subcutaneous	Unk, Unknown	Not Reported
	Pantoprazol	C	Unknown	Unk, Unknown	Not Reported
	Natecal D	C	Unknown	Unk, Unknown	Not Reported
	Mycostatin	C	Unknown	Unk, Unknown	Not Reported
	Hidroxil B1-B6-B12	C	Unknown	Unk, Unknown	Not Reported
	Seretide Accuhaler	C	Unknown	Unk, Unknown	Not Reported
	Borea	C	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	14371912	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1001918		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Sopor; Suicide Attempt	Escitalopram			S	Oral	400 Mg, Total		Not Reported
	Venlafaxine			S	Oral	525 Mg, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15700963	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1856633US		30 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Overdose; Serotonin Syndrome	Escitalopram Oxalate - Bp	S	Oral	Overdose: 15 Tablets	Allergan
	Lunesta	C	Oral	15 Df, Unk (Overdose)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15760225	EXPEDITED (15-DAY)			BR-PFIZER INC-2018523766		56 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Feeling Abnormal; Palpitations; Tachycardia	Frontal Xr			S		0.5 Mg, 1x/Day		Pfizer
	Frontal Xr			S				Pfizer
	Reconter			S		Unk		Not Reported
	Procimax			S		Unk		Not Reported
	Xarelto			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15841001	NON-EXPEDITED		DE, HO, OT	US-APOTEX-2019AP005950		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15841181	EXPEDITED (15-DAY)		DE	US-UCBSA-2019002093		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levetiracetam			S	Oral	Unknown Dose		Ucb
	Propranolol			S	Oral	Unknown Dose		Not Reported
	Escitalopram			S	Oral	Unknown Dose		Not Reported
	Gabapentin			S	Oral	Unknown Dose		Not Reported
	Chlorzoxazone W/Acetaminophen			S	Oral	Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15841678	EXPEDITED (15-DAY)		HO, OT	AU-STRIDES ARCOLAB LIMITED-2019SP000504		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatitis Infectious Mononucleosis; Hypersensitivity; Idiosyncratic Drug Reaction; Swelling Face	Metronidazole			S	Unknown	Unk, As Necessary		Strides
	Metronidazole			S				Strides
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Cefalexin			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Ceftriaxone			S				Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported
	Benzylpenicillin			S	Unknown	Unk		Not Reported
	Tazocin			S	Unknown	Unk		Not Reported
	Mesalazine			C	Unknown	Unk, As Necessary		Not Reported
	Oseltamivir			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15842054	EXPEDITED (15-DAY)		HO	RO-ROCHE-2244524		54 YR	Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Drug Resistance; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness;	Clonazepam			S	Unknown	0.5 Milligram, Daily		Not Reported
	Quetiapine			S	Unknown	800 Milligram, Daily		Not Reported
	Quetiapine			S	Unknown	300 Milligram, Daily		Not Reported
	Mirtazapine			S	Unknown	30 Milligram, Daily		Not Reported
	Risperidone			S	Unknown	6 Milligram, Daily		Not Reported
	Escitalopram			S	Unknown	10 Milligram		Not Reported
	Doxepine			S	Unknown	100 Milligram, Daily		Not Reported
	Olanzapine			S	Unknown	15 Milligram, Daily		Not Reported

Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Loss Of Personal Independence In Daily Activities; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Weight Decreased	Duloxetine		S	Unknown	60 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15842115	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP006089		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine			S	Oral	Unk		Apotex
	Hydrochlorothiazide			S	Oral	Unk		Apotex
	Quetiapine			S	Oral	Unk		Apotex
	Potassium Chloride			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Metoprolol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15842947	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Lexapro			S				Not Reported
	Metformin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15843364	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1902048US		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pregnancy; Stillbirth	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd		Allergan
	Quetiapine	S	Oral	25 Mg, Qd		Not Reported
	Presinol	S	Oral	500 Mg, Qd (2 X 250)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15843368	EXPEDITED (15-DAY)		DE	NO-ALLERGAN-1902312US			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Wrong Product Administered	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Vallergan			S	Unknown	Unk		Not Reported
	Codeine Phosphate/Paracetamol			S	Unknown	Unk		Not Reported
	Haldol			S	Subcutaneous	Unk		Not Reported
	Haldol			S	Intramuscular	Unk		Not Reported
	Oxazepam			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15844265	EXPEDITED (15-DAY)		OT	FR-OTSUKA-2019_001172		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Aripiprazole			S	Oral	10 Mg, Qd		Otsuka
	Seresta			S	Oral	100 Mg, Qd(1/2cp-1/2cp-/1cp)		Not Reported
	Tercian			S	Oral	50 Mg, Qd		Not Reported
	Zyprexa			S	Oral	2 Df, Qd		Not Reported
	Dafalgan Codeine			S	Unknown	3 Df, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Not Reported

	Oxycontin Lp	S	Oral	2 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2019	15845716	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP006087		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Levetiracetam			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Gabapentin			S	Oral	Unk		Apotex
	Propranolol			S	Oral			Not Reported
	Acetaminophen W/Chlorzoxazone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2019	15845746	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2019-001076		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram			S	Transplacental	10 Milligram, Daily		Aurobindo
	L-Thyroxin /00068002/			C	Transplacental	75 Microgram, Daily		Not Reported
	Xanaflu			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2019	15845843	NON-EXPEDITED			US-DEXPHARM-20180017		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Food Interaction; Heart Rate Decreased; Malaise; Pulse Abnormal	Omeprazole Delayed Release Tablets 20 Mg			S	Oral	20 Mg, Single		Dexcel
	Lorazepam			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2019	15846340	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100538		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Zolpidem Tartrate			S	Oral	Unk Unknown, Unknown		Vintage
	Amlodipine			S	Oral	Unk Unknown, Unknown		Not Reported
	Escitalopram			S	Oral	Unk Unknown, Unknown		Not Reported
	Naproxen			S	Oral	Unk Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847508	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP005923		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram			S	Oral	Unk		Apotex
	Alprazolam			S	Oral			Apotex
	Acetaminophen W/Hydrocodone			S	Oral	Unk		Not Reported
	Acetaminophen W/Oxycodone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847549	NON-EXPEDITED		DE, HO, OT	US-APOTEX-2019AP005935		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex
	Bupropion Hcl Er			S	Oral	Unk		Not Reported
	Methylphenidate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847550	NON-EXPEDITED		DE, HO, OT	US-APOTEX-2019AP005977		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex
	Doxepin			S	Oral	Unk		Not Reported
	Hydroxyzine			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847552	NON-EXPEDITED		DE, HO, OT	US-APOTEX-2019AP005929		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex
	Venlafaxine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847621	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP005634		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Tramadol			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Gabapentin			S	Oral	Unk		Apotex
	Propranolol			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847753	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-001499		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Depression; Drug Ineffective	Diazepam			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Aurobindo

Dapsone	C	Unknown	100 Milligram, Once A Day		Not Reported
Infliximab	C	Unknown	10 Milligram/Kilogram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15848067	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2019AP006173		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine			S	Oral	Unk		Apotex
	Hydrochlorothiazide			S	Oral	Unk		Apotex
	Clonazepam			S	Oral			Apotex
	Escitalopram			S	Oral			Apotex
	Metoprolol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15848070	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2019AP006174		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine			S	Oral	Unk		Apotex
	Zolpidem			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Naproxen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15848116	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1004137		35 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Apathy; Asthenia	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Lamotrigine			S	Oral	100 Milligram, Qd		Mylan
	Seroquel			S	Oral	1 Dosage Form, Qd		Mylan
	Seroquel			S	Oral	1 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15849090	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP006076		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex
	Lamotrigine			S	Oral	Unk		Apotex
	Olanzapine			S	Oral	Unk		Apotex
	Propranolol			S	Oral	Unk		Not Reported
	Methylphenidate			S	Oral	Unk		Not Reported
	Diazepam			S	Oral	Unk		Not Reported
	Melatonin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15849628	EXPEDITED (15-DAY)		OT	PHHY2019DE009754		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stillbirth	Quetiapine			S	Oral	25 Mg, Qd		Novartis
	Quetiapine			S	Oral	25 Mg, Qd		Novartis
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Presinol			S	Oral	500 Mg, Qd		Not Reported
	Presinol			S	Oral	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15849707	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1004543		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Meningioma	Estradiol Mylan			S	Transdermal	Unk		Mylan
	Androcur			S	Oral	Unk		Mylan

	Seroplex	S	Oral	10 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15849877	EXPEDITED (15-DAY)		HO	HR-PFM-2019-00458			Unknown	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Propranolol			S	Unknown	120 Mg, Unk		Pierre Fabre Medicament
	Propranolol			S	Unknown	180 Mg, Unk		Pierre Fabre Medicament
	Ketonal			S	Unknown	Unk		Not Reported
	Helex			S	Unknown	Unk		Not Reported
	Elicea			S	Unknown	Unk		Not Reported
	Plivadon (Caffeine/Phenacetin/Propyphenazone)			S	Unknown			Not Reported
	Normabel			S	Unknown	Unk		Not Reported
	Amyzol			S	Unknown	Unk		Not Reported
	Cipralex			S	Unknown			Not Reported
	Knavon			S	Unknown			Not Reported
	Botox			S	Unknown	Unk		Not Reported
	Imigran			S	Unknown	Unk		Not Reported
	Topiramate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15850463	EXPEDITED (15-DAY)		DE	PHHY2019NO011937			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Wrong Product Administered	Risperidone			S	Unknown	Unk Unk, Unk		Novartis
	Cipralex			S	Unknown	Unk Unk, Unk		Not Reported
	Vallergan			S	Unknown	Unk Unk, Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk Unk, Unk		Not Reported

Haldol	S	Subcutaneous	Unk Unk, Unk		Not Reported
Haldol	S	Intramuscular	Unk Unk, Unk		Not Reported
Oxazepam	S	Unknown	Unk Unk, Unk		Not Reported
Zopiclone	S	Unknown	Unk Unk, Unk		Not Reported
Paracetamol	S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15955418	DIRECT	Y	OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Withdrawal Syndrome	Escitalopram (Lexapro) 10mg Aurobindo			S	Oral			Aurobindo
	Escitalopram (Lexapro) 20mg Accord Health			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	10511006	NON-EXPEDITED			US-PFIZER INC-2014275816			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Protonix			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Pantoprazole			S		Unk		Pfizer
	Lipitor			S		Unk		Pfizer
	Levaquin			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Elavil			S		Unk		Not Reported
	Victoza			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Trintellix			S		Unk		Not Reported

Valsartan	S	Unk		Not Reported
Levomenol	S	Unk		Not Reported
Bupropion	S	Unk		Not Reported
Escitalopram	S	Unk		Not Reported
Vortioxetine	S	Unk		Not Reported
Liraglutide	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	12465777	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016290972		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State; Electrocardiogram Qt Prolonged; Hypoglycaemia; Intentional Overdose; Psychomotor Retardation; Suicide Attempt; Toxicity To Various Agents	Venlafaxine Hcl			S	Oral	7875 Mg, Single		Pfizer
	Bromazepam			S	Oral	180 Mg, Single		Not Reported
	Escitalopram			S	Oral	840 Mg, Single		Not Reported
	Lormetazepam			S	Oral	14 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	13406285	EXPEDITED (15-DAY)		OT	ES-ACCORD-049440		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sialoadenitis	Escitalopram			S				Not Reported
	Ondansetron			S				Accord
	Cipralex			S	Oral			Not Reported
	Temozolomide			C				Not Reported
	Levetiracetam			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	14278255	NON-EXPEDITED			US-PFIZER INC-2017528959		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Lithium			S		Unk		Not Reported
	Risperdal			S		Unk		Not Reported
	Topamax			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil [Piroxicam]			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Vraylar			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15580271	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018GSK199615		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Bupropion			S	Unknown	150 Mg, 1d Every Morning		Glaxosmithkline
	Bupropion			S	Unknown	200 Mg, 1d		Glaxosmithkline
	Bupropion			S	Unknown	300 Mg, 1d		Glaxosmithkline
	Lorazepam			S	Unknown	0.5 Mg, In 8 Hr As Necessary		Glaxosmithkline
	Lorazepam			S	Unknown	1 Mg, Unk		Glaxosmithkline
	Escitalopram			S	Unknown	5 Mg, 1d		Glaxosmithkline
	Escitalopram			S	Unknown	20 Mg, 1d		Glaxosmithkline
	Escitalopram			S	Unknown	10 Mg, 1d		Glaxosmithkline
	Escitalopram			S	Unknown	15 Mg, 1d		Glaxosmithkline
	Lithium			S	Unknown	600 Mg, 1d Every Bedtime		Glaxosmithkline
	Lamotrigine			S	Unknown	150 Mg, 1d		Glaxosmithkline
	Lamotrigine			S	Unknown	100 Mg, 1d		Glaxosmithkline

Amphetamine + Dextroamphetamine Extended-Release (Generic Adderall)	S	Unknown	20 Mg, 1d	Not Reported
Amphetamine + Dextroamphetamine Extended-Release (Generic Adderall)	S	Unknown	10 Mg, 1d	Not Reported
Testosterone	S	Topical	1 Df, 1d 50 Mg/5 G Every Morning On The Right Upper Extremity	Not Reported
Lurasidone	S	Unknown	40 Mg, 1d After Dinner	Not Reported
Buspirone	S	Unknown	30 Mg, Unk 15 Mg,1 In 12 Hr	Not Reported
Buspirone	S	Unknown	45 Mg, Unk	Not Reported
Buspirone	S	Unknown	10 Mg, 1d	Not Reported
Buspirone	S	Unknown	17.5 Mg, 1d	Not Reported
Buspirone	S	Unknown	22.5 Mg, Unk	Not Reported
Buspirone	S	Unknown	45 Mg, Unk	Not Reported
Buspirone	S	Unknown	15 Mg, 1d	Not Reported
Buspirone	S	Unknown	2.5 Mg, 1d	Not Reported
Buspirone	S	Unknown	22.5 Mg, 1d	Not Reported
Buspirone	S	Unknown	5 Mg, 1d	Not Reported
Buspirone	S	Unknown	7.5 Mg, 1d	Not Reported
Buspirone	S	Unknown	15 Mg, Unk	Not Reported
Buspirone	S	Unknown	22.5 Mg, Unk	Not Reported
Buspirone	S	Unknown	20 Mg, 1d	Not Reported
Aripiprazole	S	Unknown	4 Mg, 1d Every Bedtime	Not Reported
Aripiprazole	S	Unknown	2 Mg, 1d	Not Reported
Benztropine (Benzatropine Mesilate)	C	Unknown	0.5 Mg, Bid As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15762497	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1095140		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam			S	Oral	20 Milligram, Total		Not Reported
	Lorazepam			S	Oral	20 Milligram, Unk		Not Reported
	Tachipirina			S	Oral	2 Gram, Total		Mylan
	Cipralex /01588501/			S	Oral	15 Milliliter, Total		Mylan
	Cipralex /01588501/			S	Oral	15 Milliliter, Unk		Mylan
	Tolep			S	Oral	38 Dosage Form, Total		Mylan
	Brintellix			S	Oral	15 Milliliter, Total		Mylan
	Brintellix			S	Oral	15 Milliliter, Unk		Mylan
	Oxcarbazepine			S	Oral	Unk		Mylan
	Paracetamol			S	Oral	2 Gram, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15773358	EXPEDITED (15-DAY)			JP-ALLERGAN-1859521US		45 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15813040	EXPEDITED (15-DAY)		HO	HR-GLAXOSMITHKLINE-HR2019002976			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Product Use In Unapproved Indication	Botox			S	Intramuscular	Unk Unk, Single		Glaxosmithkline
	Propranolol			S	Unknown	180 Mg, Unk		Glaxosmithkline
	Propranolol			S	Unknown	120 Mg, Unk		Glaxosmithkline
	Imigran			S	Unknown	Unk		Glaxosmithkline
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported
	Ketonal (Ketoprofen)			S	Unknown	Unk		Not Reported
	Helex			S	Unknown	Unk		Not Reported

	Elicea	S	Unknown	Unk	Not Reported
	Propyphenazone + Caffeine	S	Unknown	Unk	Not Reported
	Normabel	S	Unknown	Unk	Not Reported
	Amyzol	S	Unknown	Unk	Not Reported
	Knavon	S	Unknown	Unk	Not Reported
	Topiramate	S	Unknown	Unk	Not Reported
	Erenumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15846435	EXPEDITED (15-DAY)		CA, OT	DE-HETERO CORPORATE-HET2019DE00047			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram			S	Transplacental	10 Mg, Qd		Hetero
	Levothyroxine			C	Transplacental	75 Mg, Qd		Not Reported
	Xanaflu			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15851639	EXPEDITED (15-DAY)		HO, OT	AU-FLAMINGO-002651		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatitis Infectious Mononucleosis; Hypersensitivity; Idiosyncratic Drug Reaction; Rash; Swelling Face	Metronidazole			S				Not Reported
	Piperacillin Sodium/Tazobactam Sodium			S				Not Reported
	Cefalexin			S				Not Reported
	Ciprofloxacin			S				Not Reported
	Oseltamivir/Oseltamivir Phosphate			C				Not Reported
	Ceftriaxone			S				Not Reported
	Escitalopram			S				Not Reported
	Clindamycin			S				Not Reported
	Benzylpenicillin			S				Not Reported

Mesalazine	C		Not Reported
Ceftriaxone	S		Not Reported
Metronidazole	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15851668	EXPEDITED (15-DAY)		OT	IT-ACCORD-102897		14 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Overdose; Poisoning Deliberate; Sopor	Escitalopram			S	Oral	10 Df Units In Total		Not Reported
	Xanax			S	Oral	12 Df Units In Total		Not Reported
	Haldol			S	Oral	15 Ml In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15852023	NON-EXPEDITED			DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2018-06133		45 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Logorrhoea; Mood Swings; Restlessness; Toxicity To Various Agents	Amlodipine Besylate			S	Unknown	Unk		Alkem
	Methadone Hydrochloride			S	Unknown	Unk		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	3,4 Methylenedioxypyrovalerone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15852235	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2019AP006662		30 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Substance Abuse	Quetiapine			S	Oral	25 Mg, In Total		Apotex
	Escitalopram Oxalate			S	Oral	20 Mg, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15852521	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2019-002166		91 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo
	Gabapentin			S	Oral	Unk		Aurobindo
	Irbesartan And Hydrochlorothiazide			S	Oral	Unk		Aurobindo
	Carbamazepine			S	Oral	50 Milligram, Daily(200 Mg In The Morning A Quarter Of A Tablet)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15852523	EXPEDITED (15-DAY)		HO, OT	AU-MICRO LABS LIMITED-ML2019-00065		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatitis Infectious Mononucleosis; Hypersensitivity; Idiosyncratic Drug Reaction; Rash; Swelling Face	Escitalopram			S				Not Reported
	Clindamycin			S				Micro Labs
	Ciprofloxacin			S				Not Reported
	Ceftriaxone			S				Not Reported
	Ceftriaxone			S				Not Reported
	Benzylpenicillin			S				Not Reported
	Metronidazole			S				Not Reported
	Metronidazole			S				Not Reported
	Tazocin			S				Not Reported
	Cephalexin			S				Not Reported
	Oseltamivir			C				Not Reported
	Mesalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15854047	NON-EXPEDITED			US-PFIZER INC-2019027775		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amlodipine Besilate			S		5 Mg, 1x/Day (Every Night		Pfizer

			At Bedtime)	
	Asa	S	8 Mg, Unk	Not Reported
	Avodart	S	Unk, Daily (0.5 Daily)	Not Reported
	Lexapro	S	10 Mg, 1x/Day (Every Night At Bedtime)	Not Reported
	Lisinopril	S	10 Mg, Daily	Not Reported
	Simvastatin	S	20 Mg, Daily	Not Reported
	Tamsulosin	S	Unk, Daily (0.4 Daily)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15855359	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1902418US		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhagic Stroke	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Kardegic			S	Oral	1 Df, Qd		Not Reported
	Cardensiel			C	Oral	1 Df, Qd		Not Reported
	Esomeprazole			C	Oral	20 Mg, Qd		Not Reported
	Lasilix			C	Oral	60 Mg, Qd		Not Reported
	Spironolactone			C	Oral	75 Mg, Qd		Not Reported
	Inegy			C	Oral	10 Mg/40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15855423	EXPEDITED (15-DAY)		OT	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000018		92 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dyspnoea; Feeling Abnormal; Feeling Jittery; Gastrooesophageal Reflux Disease; Haematuria; Insomnia; Unevaluable	Lasix			S	Oral	20 Mg, Qd		Validus
	Coumadin			S	Oral	5 Mg, Qd		Not Reported
	Coumadin			S	Oral	7.5 Saturday And Sunday		Not Reported
	Preservision Areds			S	Oral	2 Df, Qd		Not Reported

Event	Pyridostigmine Bromide	S	Oral	60 Mg, Bid		Not Reported
	Fludrocortisone	S	Oral	0.1 Mg, Qod		Not Reported
	Midodrine	S	Oral	5 Mg, Tid		Not Reported
	Stool Softener	S	Oral	Unk, Qd		Not Reported
	Northera	S	Oral	100 Mg, Tid		Not Reported
	Lexapro	S	Oral	10 Mg, Qd		Not Reported
	Caffeine	S	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15855537	EXPEDITED (15-DAY)		OT	FR-ELI_LILLY_AND_COMPANY-FR201901006324		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Zyprexa 5mg			S	Oral	2 Df, Daily		Not Reported
	Seresta			S	Oral	100 Mg, Daily		Not Reported
	Aripiprazole			S	Oral	10 Mg, Daily		Not Reported
	Cyamemazine Tartrate			S	Oral	50 Mg, Daily		Not Reported
	Dafalgan			S	Unknown	3 Df, Daily		Not Reported
	Seroplex			S	Oral	1 Df, Daily		Not Reported
	Oxycontin			S	Oral	2 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15855705	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1902733US		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Kardegic			S	Oral	75 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15855709	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1902748US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Oral	Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15855710	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1902754US		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Seresta			S	Oral	1/2cp-1/2cp-/1cp		Not Reported
	Seresta			S	Oral	1/2cp-1/2cp-/1cp		Not Reported
	Aripiprazole			S	Oral	10 Mg, Qd		Not Reported
	Tercian			S	Oral	1/2cp-1/2cp-/1cp/J		Not Reported
	Zyprexa			S	Oral	Unk Unk, Qd		Not Reported
	Zyprexa			S	Oral	2 Df, Qd		Not Reported
	Dafalgan Codeine			S	Unknown	3 Df, Qd		Not Reported
	Oxycontin Lp			S	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15856890	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Celexa			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15946703	DIRECT					72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Nasal Dryness; Rhinalgia; Skin Discolouration	Mupirocin 2% Ointment		S	Nasal	Quantity:2 % Percent;Other Frequency:2xday For 7-10days;	Taro
	Synthroid		C			Not Reported
	Escitalopram		S			Not Reported
	Vitamin A		C			Not Reported
	Vitamin A		C			Not Reported
	Methylcobalamin (Vitamin B-12)		C			Not Reported
	Vitamin C With Bioflavonoids		C			Not Reported
	Vitamin D3		C			Not Reported
	Biotin		C			Not Reported
	Calcium		C			Not Reported
	Magnesium With Vitamin D-3		C			Not Reported
	Cholacol (Bile Salt)		C			Not Reported
	Curamin (Bcm-95 Curcumin)		C			Not Reported
	Papaya Enzyme With Chlorophyll Tablet		C			Not Reported
	Potassium		C			Not Reported
	Priobiotic		C			Not Reported
	Zinc		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	14307642	EXPEDITED (15-DAY)		HO	PHHY2017FR185849		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Metformin			S	Oral	500 Mg, Bid		Novartis
	Bisoprolol Fumarate			S	Oral	1.25 Mg, Qd		Not Reported
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported
	Alprazolam			S	Oral	0.25 Mg, Tid		Not Reported
	Irbesartan			S	Oral	300 Mg, Qd		Not Reported
	Terbutaline Sulfate			S	Respiratory (inhalation)	1 Df, Qd		Not Reported
	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported
	Furosemide			S	Oral	30 Mg, Bid		Not Reported
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported

Nefopam Hydrochloride	S	Oral	3 Df, Qd		Not Reported
Dafalgan	S	Oral	1000 Mg, Tid		Not Reported
Diffu K	S	Oral	6 Df, Qd (3 Df Daily (2-1-0) 2x/Day (Bid))		Not Reported
Xarelto	S	Oral	20 Mg, Qd		Not Reported
Seroplex	S	Oral	1 Df, Qd		Not Reported
Tavanic	S	Oral	250 Mg, Bid		Not Reported
Valium	S	Oral	3 Df, Qd		Not Reported
Diazepam	S	Oral	10 Mg, Tid		Not Reported
Colchicine Opocalcium	S	Oral	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	14360707	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2018M1001381		36 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swelling Face	Escitalopram			S	Unknown	5 Mg, Qd (1x Daags 1 Tablet)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	14615756	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-064260		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Clozapine			S	Oral			Not Reported
	Lorazepam			S	Oral			Accord
	Entact			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	14845118	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-042015		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Clonus; Confusional State; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose; Nystagmus; Psychomotor Retardation; Suicide Attempt; Toxicity To Various Agents	Escitalopram	S	Oral	Not Reported
	Venlafaxine/Venlafaxine Hydrochloride	S	Oral	Not Reported
	Bromazepam	S	Oral	Not Reported
	Lormetazepam	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15722013	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2018-US-017928		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Dehydration; Drug Ineffective; Gastrointestinal Disorder; Gastrooesophageal Reflux Disease; Headache; Nausea; Viral Infection; Vomiting	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	3.75 G, Bid		Jazz
	Zolpidem			S				Not Reported
	Escitalopram			S				Not Reported
	Clonazepam			S				Not Reported
	Trazodone			S				Not Reported
	Amitriptyline Hcl			C				Not Reported
	Benadryl A			C				Not Reported
	Botox			C				Not Reported
	Iron			C				Not Reported
	Sumatriptan			C				Not Reported
	Vit D3			C				Not Reported
	Vit B12			C				Not Reported
	Tretinoin			C				Not Reported
	Seasonique			C				Not Reported
	Melatonin			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Ibuprofen			C				Not Reported
	Excedrin Migraine			C				Not Reported
	Allegra Allergy			C				Not Reported
	Ondansetron Hcl			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Methylphenidate			C				Not Reported
	Modafinil			C				Not Reported

Topiramate	C				Not Reported
Sumatriptan Succinate	C				Not Reported
Cymbalta	C				Not Reported
Triamcinolone	C				Not Reported
Singulair	C				Not Reported
Norco	C				Not Reported
Ambien	C				Not Reported
Aleve	C				Not Reported
Amyvid	C				Not Reported
Hydrocodone/Apap	C				Not Reported
Nuvigil	C				Not Reported
Zolpidem Tartrate	C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15804473	EXPEDITED (15-DAY)		HO	RO-ALLERGAN-1900656US		54 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Quetiapine			S	Unknown	800 Mg, Qd		Not Reported
	Quetiapine			S	Unknown	300 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown	30 Mg, Qd		Not Reported
	Risperidone			S	Unknown	6 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
	Doxepine			S	Unknown	100 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15820876	EXPEDITED (15-DAY)		HO	HR-JNJFOC-20190110264			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Topiramate			S	Oral			Not Reported
	Propranolol			S	Unknown			Not Reported
	Propranolol			S	Unknown			Not Reported
	Ketoprofen			S	Unknown			Not Reported
	Helex			S	Unknown			Not Reported
	Elicea			S	Unknown			Not Reported
	Normabel			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Botox			S	Unknown			Not Reported
	Sumatriptan Sulfate			S	Unknown			Not Reported
	Knavon			S	Unknown			Not Reported
	Erenumab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15845176	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-000867		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Back Pain; Chest Pain; Chills; Confusional State; Decreased Appetite; Depression; Fatigue; Insomnia; Irritability; Libido Decreased; Memory Impairment; Somnolence; Suicidal Ideation; Thirst	Auro-Escitalopram Tablets			S	Oral	1 Dosage Form, Daily		Aurobindo
	Atorvastatin Calcium			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15847701	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1902571US		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Quetiapine			S	Unknown	100 Mg, Qd		Not Reported
	Alprazolam			S	Unknown	4 Mg, Qd (4 Separate Dosages Of 1 Mg)		Not Reported
	Alprazolam			S	Unknown	1 Mg, Qd (4 Separate Dosages Of 0.25 Mg)		Not Reported
	Losartan			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Metformin			C	Unknown	500 Mg, Bid		Not Reported
	Sitagliptin			C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15856161	EXPEDITED (15-DAY)		HO, OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-196866		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Rash; Swelling Face	Cefalexin			S	Unknown	Unk		Ranbaxy
	Cefalexin			S				Ranbaxy
	Oseltamivir			S	Unknown	Unk		Not Reported
	Oseltamivir			S				Not Reported
	Mesalazine			S	Unknown	As Necessary		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Metronidazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15856242	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002494		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous	Escitalopram			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15856243	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1002493			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Baclofen			C				Not Reported
	Cialis			C				Not Reported
	Pregabalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15856245	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002497		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Jittery; Nervousness; Panic Attack	Escitalopram			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15856744	EXPEDITED (15-DAY)		HO	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2019019562			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Milligram, 24 Hourly		Macleods
	Irbesartan/Hydrochlorothiazide			S	Oral	Unk		Macleods
	Carbamazepine			S	Oral	50 Milligram, 24 Hourly,		Not Reported

						(200 Mg In The Morning A Quarter Of A Tablet)				
	Gabapentin			S	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15856808	EXPEDITED (15-DAY)		DE	US-OSMOTICA_PHARMACEUTICAL_US_LLC-POI0573201900037		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Methylphenidate Hydrochloride Extended-Release Tablets			S				Osmotica
	Bupropion			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15856809	EXPEDITED (15-DAY)		DE	US-OSMOTICA_PHARMACEUTICAL_US_LLC-POI0573201900038		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Methylphenidate Hydrochloride Extended-Release Tablets			S				Osmotica
	Propranolol			S				Not Reported
	Escitalopram			S				Not Reported
	Lamotrigine			S				Not Reported
	Diazepam			S				Not Reported
	Melatonin			S				Not Reported
	Olanzapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15857080	EXPEDITED (15-DAY)		OT	DE-ASTRAZENECA-2019SE07475		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stillbirth	Quetiapine			S	Oral			Zeneca
	Escitalopram			S	Oral			Not Reported

	Presinol		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15857183	EXPEDITED (15-DAY)		HO, OT	AU-ACCORD-102681		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatitis Infectious Mononucleosis; Hypersensitivity; Idiosyncratic Drug Reaction; Off Label Use; Rash; Swelling Face	Escitalopram			S				Not Reported
	Tazocin			S				Not Reported
	Cefalexin			S				Not Reported
	Ciprofloxacin			S				Not Reported
	Oseltamivir/Oseltamivir Phosphate			C				Not Reported
	Ceftriaxone			S				Not Reported
	Clindamycin			S				Not Reported
	Benzylpenicillin			S				Not Reported
	Mesalazine			C				Not Reported
	Metronidazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15859172	EXPEDITED (15-DAY)		OT	BE-TEVA-2019-BE-1002247		52 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Limb Discomfort; Syncope; Tremor	Escitalopram 10 Mg			S	Oral	5 Milligram Daily;		Ivax
	L-Thyroxine Christiaens 25 Ug, Tablet			C	Oral	Monday -Tuesday - Friday : 25 Microgram/Day Wednesday -Saturday - Sunday : 2.25 Microgram/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15859310	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1902769US		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Meningioma	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan

	Oestrogel	S	Transdermal		Not Reported
	Androcur	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15859315	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1902771US		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Psychomotor Skills Impaired; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Depamide			S	Oral	Unk		Not Reported
	Zyprexa			S	Oral	Unk		Not Reported
	Solian			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15860057	EXPEDITED (15-DAY)		DE	US-PHARMA_RESEARCH_SOFTWARE_SOLUTION-USA-POI058020		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Potassium Chloride For Oral Solution			S				Pharma Research Software Solution
	Metoprolol			S				Not Reported
	Amlodipine			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15860170	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1902926US		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Fall; Haematoma; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Inexium			S	Ophthalmic	1 Df, Qd		Not Reported
	Lasilix			S	Oral	1 Df, Qd		Not Reported

Lipanthyl	S	Oral	1 Df, Qd		Not Reported
Xarelto	S	Oral	1 Df, Unk		Not Reported
Dafalgan	C	Unknown	Unk		Not Reported
Aranesp	C	Unknown	Unk		Not Reported
Cardensiel	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15860260	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1902708US		36 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Sweats; Off Label Use; Withdrawal Syndrome; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	Actual: 1/4 Of 5mg Tablet Once Daily.		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Diazepam			C	Unknown	Actual: Approx 20 Tablets Prescribed Every 2/3 Months.		Not Reported
	Buscopan			C	Unknown	10 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15357950	EXPEDITED (15-DAY)		OT	PHHY2018CZ047147		58 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Mental Disorder; Suicide Attempt	Clomipramine			S	Unknown	Unk Unk, Unknown		Novartis
	Olanzapine			S	Unknown	Unk Ukn, Unknown		Not Reported
	Olanzapine			S				Not Reported
	Escitalopram			S	Unknown	Unk Ukn, Unknown		Not Reported
	Citalopram			S	Unknown	Unk Ukn, Unknown		Not Reported
	Aripiprazole			S	Unknown	Unk Ukn, Unknown		Not Reported
	Mirtazapine			S	Oral	Unk Ukn, Unknown		Not Reported
	Mirtazapine			S				Not Reported
	Mirtazapine			S				Not Reported

	Ziprasidone	S	Unknown	Unk Ukn, Unknown	Not Reported
	Risperidone	S	Unknown	Unk Ukn, Unknown	Not Reported
	Venlafaxine	S	Unknown	Unk Ukn, Unknown	Not Reported
	Melperone	C	Unknown	Unk Ukn, Unknown	Not Reported
	Tiapride	C	Unknown	Unk Ukn, Unknown	Not Reported
	Haloperidol	C	Unknown	Unk Ukn, Unknown	Not Reported
	Propofol	C	Unknown	Unk Ukn, Unknown	Not Reported
	Memantine	C	Unknown	Unk Ukn, Unknown	Not Reported
	Clonazepam	C	Unknown	Unk Ukn, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15612484	EXPEDITED (15-DAY)		HO	FR-009507513-1811FRA002682		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Desloratadine			S	Oral	5 Milligram, 1 Per Day		Merck
	Methotrexate			S	Subcutaneous	20 Milligram, 1 Per Week		Not Reported
	Lisinopril			S	Oral	10 Milligram, 1 Per Day		Merck
	Prednisone			S	Oral	4 Milligram, 1 Per Day		Merck
	Cacit [Calcium Carbonate]			S	Oral	1 Dosage Form, 1 Per Day		Not Reported
	Codeine			S	Oral	2 Dosage Form, 1 Per Day		Not Reported
	Escitalopram			S	Oral	20 Milligram, 1 Per Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Per Week		Not Reported
	Acetaminophen			S	Oral	2 Dosage Form, 1 Per Day		Not Reported
	Risedronate Sodium			S	Oral	35 Milligram, 1 Per Week		Not Reported
	Speciafoldine			S	Oral	10 Milligram, 1 Per Week		Not Reported
	Uvedose			S	Oral	1 Dosage Form, 1 Per Trimester		Not Reported
	Valacyclovir Hydrochloride			S	Oral	1000 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15757434	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2018_039661		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Faeces; Contraindicated Product Administered; Feeling Hot; Hyperhidrosis; Hypotension; Malaise; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Rash; Respiratory Distress	Aripiprazole			S	Unknown	2 Mg, Qd		Otsuka
	Nalmefene			S	Oral	1 Df, Qd		Not Reported
	Seroplex			S	Unknown	20 Mg, Qd		Not Reported
	Lexomil			C	Unknown	1 Df, Qd		Not Reported
	Corgard			C	Unknown	80 Mg, Qd		Not Reported
	Loxen (Nicardipine Hydrochloride)			C	Unknown	1 Df, Qd		Not Reported
	Methadone			C	Unknown	80 Mg, Qd		Not Reported
	Ventolin			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	1 Df, Qd		Not Reported
	Theralene			C	Unknown	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15861093	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1002945		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stillbirth	Quetiapine			S	Oral	25 Milligram Daily; 25 [Mg/D]		Teva
	Escitalopram			S	Oral	20 Milligram Daily; 20 [Mg/D]		Ivax
	Presinol			S	Oral	500 Milligram Daily; 500 [Mg/D (2x250)]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15861416	NON-EXPEDITED			US-APOTEX-2019AP005058		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Gastrointestinal Disorder; Restlessness; Somnolence	Fluoxetine	S	Unknown	5 Mg, Unk		Apotex
	Fluoxetine	S				Apotex
	Sertraline	S	Unknown	12.5 Mg, Unk		Apotex
	Sertraline	S				Apotex
	Citalopram	S	Unknown	5 Mg, Unk		Apotex
	Citalopram	S				Apotex
	Escitalopram	S	Unknown	2.5 Mg, Unk		Apotex
	Escitalopram	S				Apotex
	Dextroamphetamine /00016601/	C	Unknown	25 Mg, Unk		Not Reported
	Dextroamphetamine /00016601/	C				Not Reported
	Methylphenidate	C	Unknown	5 Mg, Unk		Not Reported
	Methylphenidate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15862646	EXPEDITED (15-DAY)		DE	US-PERRIGO-19US000749		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Acetaminophen			S	Oral	Unknown, Unknown		Perrigo
	Escitalopram			S	Unknown	Unknown, Unknown		Not Reported
	Doxepin			S	Unknown	Unknown, Unknown		Not Reported
	Cough And Cold Preparations			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15863017	NON-EXPEDITED			US-TEVA-2018-US-994130			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Malaise	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15863179	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2019SE08060		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Fall; Haematoma; Hyponatraemia	Inexium	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Furosemide	S	Oral	Not Reported
	Lipanthyl 200	S	Oral	Not Reported
	Rivaroxaban	S	Oral	Not Reported
	Cardensiel	C		Not Reported
	Aranesp	C		Not Reported
	Dafalgan	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15865323	NON-EXPEDITED			US-ACORDA-ACO_154566_2018		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Abdominal Pain Upper; Back Pain; Balance Disorder; Burning Sensation; Constipation; Decreased Appetite; Depression; Faeces Discoloured; Feeling Abnormal; Gastric Disorder; Headache; Insomnia; Muscular Weakness; Nausea; Neck Pain; Pruritus; Vitamin D Decreased	Ampyra			S	Oral	10 Milligram, Q 12 Hrs		Acorda
	Lexapro			S	Unknown	Unk		Not Reported
	Tecfidera			S	Unknown	240 Milligram, Bid		Not Reported
	Tecfidera			S	Unknown	240 Milligram, Qd		Not Reported
	Tecfidera			S	Unknown	240 Milligram, Bid		Not Reported
	Alli			C	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15865391	EXPEDITED (15-DAY)		HO, OT	AU-MACLEODS PHARMACEUTICALS US LTD-MAC2019019679			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatitis Infectious	Escitalopram Oxalate			S	Unknown	Unk		Macleods

Mononucleosis; Hypersensitivity; Idiosyncratic Drug Reaction; Rash; Swelling Face	Ceftriaxone	S	Unknown	Unk	Not Reported
	Ceftriaxone	S			Not Reported
	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Benzylpenicillin	S	Unknown	Unk	Not Reported
	Cephalexin	S	Unknown	Unk	Not Reported
	Clindamycin	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	S.O.S.	Not Reported
	Metronidazole	S			Not Reported
	Tazocin	S	Unknown	Unk	Not Reported
	Oseltamivir	C	Unknown	Unk	Macleods
	Mesalazine	C	Unknown	Unk, S.O.S.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	13071337	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2016M1057329		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Drug Ineffective; Drug Interaction; Feeling Of Despair; Insomnia; Intentional Product Misuse; Medication Error; Suicidal Ideation; Treatment Noncompliance	Alprazolam			S	Oral	1.5 Mg Total Qd		Not Reported
	Alprazolam			S		1 Mg, Unk		Not Reported
	Alprazolam			S		1.5 Unk		Not Reported
	Valproic Acid			S	Oral	300 Mg, Total Qd		Not Reported
	Valproic Acid			S		600 Unk		Not Reported
	Valproic Acid			S		300 Unk		Not Reported
	Venlafaxine			S	Oral	300 Mg, Total Qd		Not Reported
	Venlafaxine			S		300 Mg,Unk		Not Reported
	Escitalopram			S	Oral	20 Mg Total Qd		Not Reported
	Escitalopram			S		20 Unk		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Total Qd		Not Reported
	Clonazepam			S	Oral	0.5 Unk		Not Reported
	Quetiapine			S	Oral	200 Mg Total Qd		Not Reported
	Quetiapine			S	Oral	200 Mg,Unk		Not Reported

Trazodone	S	Oral	75 Mg Total Qd		Not Reported
Trazodone	S		150 Unk		Not Reported
Trazodone	S		75 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	13217393	NON-EXPEDITED		HO	US-ACORDA-ACO_121585_2016		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Back Pain; Condition Aggravated; Confusional State; Disease Progression; Fall; Fall; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Neurological Symptom; Urticaria; Vomiting	Ampyra			S	Oral	10 Mg, Q 12 Hrs		Acorda
	Tysabri			S	Intravenous (not otherwise specified)	300 Mg (Infused Over An Hour), Monthly		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	14765858	EXPEDITED (15-DAY)		HO, LT, OT	ES-ALLERGAN-1821233US		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Behaviour Disorder; Cardio-Respiratory Arrest; Condition Aggravated; Electrocardiogram Qt Prolonged; Myocardial Ischaemia; Off Label Use; Torsade De Pointes	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
	Haloperidol			S	Unknown	Unk		Not Reported
	Haloperidol			S	Unknown	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15243075	EXPEDITED (15-DAY)		HO	DE-ACCORD-070543		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Level Decreased; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram	S	Oral	Overdose: 30 Mg,Overdose: 40 Mg Also Received 40 Mg On Dec-2017	Not Reported
	Lorazepam	C			Not Reported
	Pangrol	C		Dose 2 Unk Unit	Not Reported
	Olanzapine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15747063	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1858362US		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Faeces; Contraindicated Product Administered; Feeling Hot; Hyperhidrosis; Hyperhidrosis; Hypotension; Malaise; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Rash; Respiratory Distress	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Selincro			S	Oral	1 Df, Qd		Not Reported
	Abilify			S	Unknown	2 Mg, Unknown		Not Reported
	Lexomil			C	Unknown	1 Df, Unknown		Not Reported
	Corgard			C	Unknown	80 Mg, Qd		Not Reported
	Loxen (Nicardipine Hydrochloride)			C	Unknown	1 Df, Qd		Not Reported
	Methadone			C	Unknown	80 Mg, Qd		Not Reported
	Ventolin			C	Unknown	Unk, Unknown		Not Reported
	Kardegic			C	Unknown	Unk, Qd		Not Reported
	Theralene			C	Unknown	2 Df, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15812097	EXPEDITED (15-DAY)		HO, OT	AU-BAUSCH-BL-2019-000630		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatitis Infectious Mononucleosis; Hypersensitivity; Idiosyncratic Drug Reaction; Rash; Swelling	Clindamycin			S	Unknown			Not Reported
	Metronidazole			S	Unknown	As Required		Not Reported
	Metronidazole			S				Not Reported
	Ceftriaxone Sodium			S	Unknown			Not Reported

Face	Ceftriaxone Sodium	S			Not Reported
	Cephalexin	S	Unknown		Not Reported
	Cephalexin	S			Not Reported
	Escitalopram Oxalate	S	Unknown		Not Reported
	Ciprofloxacin	S	Unknown		Not Reported
	Benzylpenicillin	S	Unknown		Not Reported
	Tazocin	S	Unknown		Not Reported
	Oseltamivir	C			Not Reported
	Oseltamivir	C			Not Reported
	Mesalazine	C	As Required		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15848916	EXPEDITED (15-DAY)		HO, OT	RO-JNJFOC-20190113479		54 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Condition Aggravated; Decreased Appetite; Depressed Mood; Depression; Depression; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Loss Of Personal Independence In Daily Activities; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder;	Risperidone			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Doxepine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported

Treatment
Noncompliance; Weight
Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15865740	EXPEDITED (15-DAY)		OT	DE-LUPIN PHARMACEUTICALS INC.-2019-00188		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Stillbirth	Quetiapine Fumarate			S	Oral	25 Mg, Qd		Lupin
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Presinol			S	Oral	250 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15866881	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2019DE00077		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stillbirth	Escitalopram			S	Oral	20 Milligram, Qd, During First Trimester (0-35.3 Gestational Week)		Hetero
	Quetiapine			S	Oral	25 Milligram, Qd, During First Trimester (0-35.3 Gestational Week)		Not Reported
	Presinol			S	Oral	500 Milligram, Qd, During Third Trimester (33.4-35.3 Gestational Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15866959	EXPEDITED (15-DAY)		HO, LT, OT	CZ-ACCORD-103475			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged;	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning	Ibuprofen	S	Unknown	Not Reported
	Levomepromazine	S	Oral	Not Reported
	Metoclopramide	S	Oral	Not Reported
	Melperone/Melperone Hydrochloride	S	Oral	Not Reported
	Olanzapine	S	Oral	Not Reported
	Venlafaxine/Venlafaxine Hydrochloride	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15866993	EXPEDITED (15-DAY)		HO	FR-ACCORD-103253		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Interaction; Urinary Retention	Escitalopram			S	Oral			Not Reported
	Haldol			S	Oral	Strength:2 Mg/Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15867108	EXPEDITED (15-DAY)		HO, LT, OT	IN-TORRENT-00002101		23 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Postictal State; Seizure; Self-Medication; Sleep Disorder; Tongue Biting	Olanzapine			S		Nearly 4 Years		Unknown
	Fluoxetine			S		Unknown		Unknown
	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15867115	EXPEDITED (15-DAY)		OT	DE-TORRENT-00013050		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy; Stillbirth	Quetiapine		S	Oral	25 [Mg/D]	Unknown
	Escitalopram		S	Oral	20 [Mg/D]	Unknown
	Presinol		S	Oral	500 [Mg/D (2x250)]	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15867582	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20190130474		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Fall; Hyponatraemia; Subcutaneous Haematoma	Xarelto			S	Oral			Not Reported
	Inexium			S	Ophthalmic			Not Reported
	Seroplex			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Lipanthyl			S	Oral			Not Reported
	Cardensiel			C	Unknown			Not Reported
	Dafalgan			C	Unknown			Not Reported
	Aranesp			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15868282	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2019030420		91 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Gabapentin			S	Oral	Unk		Pfizer
	Carbamazepine			S	Oral	50 Mg, 1x/Day (200mg In The Morning 1/4 Of The Tablet)		Not Reported
	Irbesartan And Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15868316	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2019030378			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Somnolence; Suicide Attempt	Alprazolam			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Caffetin [Caffeine;Codeine Phosphate Sesquihydrate;Paracetamol;Propyph			S	Oral	Unk		Not Reported
	Klonazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15868460	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1002872		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Aripiprazole			S	Oral	10 Milligram Daily;		Not Reported
	Seresta 50 Mg, Comprimé Sécable			S	Oral	100 Milligram Daily; 1/2cp-1/2cp-/1cp		Not Reported
	Tercian 25 Mg, Comprimé Pelliculé Sécable			S	Oral	50 Milligram Daily; 1/2cp-1/2cp-/1cp/J		Not Reported
	Zyprexa 5 Mg, Comprimé Enrobé			S	Oral	2 Dosage Forms Daily;		Not Reported
	Dafalgan Codeine, Comprimé Pelliculé			S		3 Dosage Forms Daily;		Not Reported
	Seroplex 20 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported
	Oxycontin Lp 40 Mg, Comprimé Pelliculé À Libération Prolongée			S	Oral	2 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15868731	EXPEDITED (15-DAY)		DE	US-GENUS_LIFESCIENCES-USA-POI0580201900172		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Hydrocodone Bitartrate And Acetaminophen Oral Solution			S				Genus Lifesciences

	Escitalopram	S	Not Reported
	Acetaminophen With Oxycodone	S	Not Reported
	Alprazolam	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15869147	EXPEDITED (15-DAY)		OT	FR-NAPPMUNDI-GBR-2019-0063544		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Oxycontin Lp			S	Oral	2 Df, Daily (Strength 40mg)		Purdue
	Seresta			S	Oral	100 Mg, Daily (1/2cp-1/2cp-/1cp)		Not Reported
	Aripiprazole			S	Oral	10 Mg, Daily		Not Reported
	Tercian /00759301/			S	Oral	50 Mg, Daily (1/2cp-1/2cp-/1cp/J)		Not Reported
	Zyprexa			S	Oral	2 Df, Daily		Not Reported
	Dafalgan Codeine			S	Unknown	3 Df, Daily		Not Reported
	Seroplex			S	Oral	1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2019	14413469	NON-EXPEDITED			US-TAKEDA-2016TEU001693		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Protonix			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Trintellix			S	Unknown	Unk		Takeda
	Vortioxetine			S	Unknown	Unk		Takeda
	Lexapro			S	Unknown	Unk		Not Reported
	Victoza			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	Unk		Not Reported
	Elavil /00002202/			S	Unknown	Unk		Not Reported

Levaquin	S	Unknown	Unk		Not Reported
Lipitor	S	Unknown	Unk		Not Reported
Azithromycin	S	Unknown	Unk		Not Reported
Zithromax	S	Unknown	Unk		Not Reported
Dilantin /00017401/	S	Unknown	Unk		Not Reported
Valsartan	S	Unknown	Unk		Not Reported
Levomenol	S	Unknown	Unk		Not Reported
Bupropion	S	Unknown	Unk		Not Reported
Escitalopram	S	Unknown	Unk		Not Reported
Liraglutide	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2019	15871242	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019019742			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Stillbirth	Escitalopram Oxalate			S	Oral	20 Milligram, Qd,		Macleods
	Quetiapine			S	Oral	25 Milligram, Qd		Macleods
	Presinol			S	Oral	500 Milligram, Qd, 500 [Mg/D (2x250)]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2019	15873420	NON-EXPEDITED			US-ACORDA-ACO_150530_2018			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Thirst	Ampyra			S	Unknown	Unk		Acorda
	Escitalopram			S	Unknown	Unk		Not Reported
	Oxybutynin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2019	15874316	NON-EXPEDITED			US-ACORDA-ACO_152055_2018			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Ampyra			S	Oral	10 Mg, Bid		Acorda
	Ampyra			S	Oral	10 Mg, Bid		Acorda
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Ezetimibe			C	Unknown	Unk		Not Reported
	Gilenya			C	Unknown	Unk		Not Reported
	Fenofibrate			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported
	Neurontin			C	Unknown	Unk		Not Reported
	Pravastatin			C	Unknown	Unk		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported
	Vyvanse			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Copaxone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	10621762	NON-EXPEDITED			US-PFIZER INC-2014331226		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Xanax			S		Unk		Pfizer
	Inderal			S		Unk		Pfizer
	Medrol			S		Unk		Pfizer
	Abilify			S		Unk		Not Reported
	Cefprozil			S		Unk		Not Reported

Lexapro	S		Unk		Not Reported
Ketoconazole	S		Unk		Not Reported
Niaspan	S		Unk		Not Reported
Trileptal	S		Unk		Not Reported
Oxytrol	S	Transdermal	Unk		Not Reported
Risperdal	S		Unk		Not Reported
Ambien	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	12836416	EXPEDITED (15-DAY)		HO, LT	HU-PFIZER INC-2016468953		27 YR	Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Serotonin Syndrome; Suicide Attempt	Sertraline Hcl			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported
	Moclobemid			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	12954971	EXPEDITED (15-DAY)		DE, HO, LT, OT	PHHO2016CH016594		81 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Bradycardia; Death; Dizziness; Dyspnoea; Dyspnoea; Dyspnoea; Ligament Rupture; Pneumonia	Valsartan			S	Oral	160 Mg, Bid		Novartis
	Valsartan			S	Oral	80 Mg, Bid		Novartis
	Valsartan			S	Oral	40 Mg, Bid		Novartis
	Valsartan			S	Oral	Unk		Novartis
	Jardiance			S	Oral	10 Mg, Qd		Not Reported
	Seroquel			S	Oral	25 Mg, Qd		Not Reported
	Cipralex			S	Unknown	No Treatment		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Detrusitol			S	Oral	4 Mg, Qd		Not Reported
	Torem			S	Oral	10 Mg, Qd		Not Reported

Torem	S	Oral	10 Mg, Qd	Not Reported
Aldactone	S	Oral	25 Mg, Qd	Not Reported
Aldactone	S	Oral	12.5 Mg, Qd	Not Reported
Januvia	C	Oral	100 Mg, Qd	Not Reported
Xarelto	C	Oral	20 Mg, Qd	Not Reported
Plavix	C	Unknown	75 Mg, Sid	Not Reported
Symbicort	C	Respiratory (inhalation)	2 Inha Appl,	Not Reported
Magnesiocard	C	Oral	243 Mg, Qd	Not Reported
Ramipril	C	Oral	1.25 Mg, Qd	Not Reported
Nasonex	C	Unknown	1 Appl Spray Qd	Not Reported
Bepanthen	C	Unknown	2 Appl	Not Reported
Spiriva	C	Respiratory (inhalation)	0.018 Mg, Qd	Not Reported
Pradif	C	Oral	400 Ug, Qd	Not Reported
Pantozol	C	Oral	40 Mg, Qd	Not Reported
Crestor	C	Oral	5 Mg, Qd	Not Reported
Movicol	C	Oral	13.25 G, Qd	Not Reported
Movicol	C	Oral	26.250 G, Unk	Not Reported
Movicol	C	Unknown	1 Df, Unk	Not Reported
Vi-De3	C	Oral	8 Gtt, Qd	Not Reported
Allopurinol	C	Oral	100 Mg, Qd	Not Reported
Cardioaspirin	C	Unknown	100 Mg, Sid	Not Reported
Acidum Folicum	C	Unknown	5 Mg, Unk	Not Reported
Atorvastatin	C	Unknown	40 Mg, Sid	Not Reported
Quetiapin	C	Unknown	12.5 Mg, Sid	Not Reported
Quetiapin	C	Unknown	100 Mg, Unk	Not Reported
Ferro Sanol	C	Unknown	200 Mg, Unk	Not Reported
Concor	C	Unknown	1.25 Mg, Sid	Not Reported
Allopur	C	Oral	100 Mg, Qd	Not Reported

	Magnesium	C	Oral	10 Mmol, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	14658504	NON-EXPEDITED			US-PFIZER INC-2018114204			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15830558	EXPEDITED (15-DAY)		HO	RO-009507513-1901ROM001779		54 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Condition Aggravated; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Weight Decreased	Mirtazapine			S	Unknown	30 Milligram, Daily		Merck
	Quetiapine Fumarate			S	Unknown	800 Milligram, Daily		Not Reported
	Quetiapine Fumarate			S	Unknown	300 Milligram, Daily		Not Reported
	Clonazepam			S	Unknown	0.5 Milligram, Daily		Not Reported
	Risperidone			S	Unknown	6 Milligram, Daily		Not Reported
	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported
	Doxepin Hydrochloride			S	Unknown	100 Milligram, Daily		Not Reported
	Olanzapine			S	Unknown	15 Milligram, Daily		Not Reported
	Duloxetine Hydrochloride			S	Unknown	60 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15877035	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1003624			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15877613	EXPEDITED (15-DAY)		HO	FR-ZYDUS-032850			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15877861	EXPEDITED (15-DAY)		OT	US-SA-2019SA021529		92 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dyspnoea; Feeling Abnormal; Feeling Jittery; Gastrooesophageal Reflux Disease; Haematuria; Insomnia; Unevaluable Event	Lasix			S		20 Mg, Qd		Sanofi
	Warfarin Sodium			S	Oral	5 Mg, Qd		Not Reported
	Warfarin Sodium			S	Oral	7.5 Unk		Not Reported
	Docusate Sodium			S	Oral	Unk Unk, Qd		Sanofi
	Caffeine			S	Oral	100 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Preservision Areds			S	Oral	2 Df, Qd		Not Reported
	Pyridostigmine Bromide			S		60 Mg, Bid		Not Reported

	Fludrocortisone	S	0.1 Mg, Qod	Not Reported
	Midodrine	S	5 Mg, Tid	Not Reported
	Northera	S	100 Mg, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15878055	EXPEDITED (15-DAY)		HO, LT, OT	IN-CIPLA LTD.-2019IN00541			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Postictal State; Seizure; Sleep Disorder; Tongue Biting	Escitalopram			S	Unknown	10 Mg, Unk		Invagen
	Olanzapine			S	Unknown	20 Mg, Unk, Nearly 4 Years		Not Reported
	Olanzapine			S	Unknown	20 Mg, Unk		Not Reported
	Olanzapine			S	Unknown	Unk, Cross Tapered With Risperidone		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15878990	EXPEDITED (15-DAY)		HO, OT	ES-ZYDUS-032957		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Respiratory Depression	Gabapentin			S	Oral	Neurontin 300: 1 Tablet With Breakfast, Lunch And Dinner		Not Reported
	Alprazolam			S	Oral	Trankimazin 1: 1 Tablet / Day 30 Minutes Before Bedtime		Not Reported
	Fentanyl			S	Transdermal	Durogesic: 1 Transdermal Patch Of 100 Microgrs. And Another 50 Microgrs. Every 72 Hours		Not Reported
	Morphine			S	Oral	Sevredol 10: 1 Tablet If Significant Pain Despite Treatment With Neurontin 300 And Hard		Not Reported

	Escitalopram	S	Oral		Not Reported
	Aciclovir	C			Not Reported
	Metamizole Sodium	C			Not Reported
	Paracetamol	C			Not Reported
	Allopurinol	C			Not Reported
	Furosemide	C			Not Reported
	Binocrit	C			Not Reported
	Enoxaparin	C	Subcutaneous		Not Reported
	Pantoprazole	C			Not Reported
	Calcium Carbonate/Colecalciferol	C			Not Reported
	Nystatin	C			Not Reported
	Hydroxocobalamin/Pyridoxine Hydrochloride/Thiamine Hydrochloride	C			Not Reported
	Fluticasone Propionate/Salmeterol Xinafoate	C			Not Reported
	Megestrol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15879397	EXPEDITED (15-DAY)		DE	US-PERRIGO-19US001127		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Naproxen Sodium			S	Oral	Unk		Perrigo
	Amlodipine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15879912	EXPEDITED (15-DAY)		DE, OT	FI-MYLANLABS-2017M1083064			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ventricular Fibrillation	Escitalopram			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15879980	EXPEDITED (15-DAY)		OT	BE-ANIPHARMA-2019-BE-000002		70 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Gastrointestinal Haemorrhage	Clarithromycin Extended-Release (Non-Specific)			S				Ani
	Rivaroxaban			S	Oral	15 Mg Daily		Not Reported
	Diltiazem			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15880559	EXPEDITED (15-DAY)		DE	NO-JNJFOC-20190120730			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Wrong Product Administered	Risperidone			S	Unknown			Not Reported
	Haldol			S	Intramuscular			Not Reported
	Vallergan			S	Unknown			Not Reported
	Codeine Phosphate W/Paracetamol			S	Unknown			Not Reported
	Oxazepam			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15880952	EXPEDITED (15-DAY)		DE	US-PERRIGO-19US001018		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Potassium Chloride			S	Oral	Unk		Perrigo
	Metoprolol			S	Oral	Unk		Not Reported
	Amlodipine			S	Oral	Unk		Not Reported

	Hydrochlorothiazide	S	Oral	Unk		Not Reported
	Quetiapine	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15881028	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1007138		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autonomic Nervous System Imbalance; Malaise; Orthostatic Hypotension	Zopiclone			S	Oral	7.5 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Risperdal			S	Oral	1 Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15881038	EXPEDITED (15-DAY)		HO, LT, OT	IN-ELI_LILLY_AND_COMPANY-IN201901011059		23 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Intentional Product Misuse; Postictal State; Seizure; Sleep Disorder; Tongue Biting	Olanzapine			S	Unknown	20 Mg, Unknown		Eli Lilly And Co
	Olanzapine			S	Unknown	20 Mg, Unknown		Eli Lilly And Co
	Escitalopram			S	Unknown	10 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15881305	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1007243		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Olanzapine			S	Oral	20 Milligram, Total		Not Reported
	Escitalopram			S	Oral	50 Milligram, Total		Not Reported
	Tavor /00273201/			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15983763	DIRECT		HO, LT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Dyspnoea; Suicidal Ideation	Methocarbamol			S	Oral		3 YR	Granules India
	Prozac			S				Not Reported
	Seroquel			S				Not Reported
	Topamax			S				Not Reported
	Paxil			S				Not Reported
	Hydroxyzine			S				Not Reported
	Naproxen			S				Not Reported
	Lexapro			S				Not Reported
	Adderall			S				Not Reported
	Trazodone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	8653132	EXPEDITED (15-DAY)		DE, HO, OT	DK-FRI-1000025398		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Hypertrophy; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension; Internal Fixation Of Fracture; Lactic Acidosis; Lacunar Infarction; Neuroleptic Malignant Syndrome; Organ Failure; Overdose; Product Use In Unapproved Indication; Pyrexia; Renal Failure; Rhabdomyolysis	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan
	Mirtazapine			S	Oral	30 Mg, Qd		Not Reported
	Lithium Citrate			S	Oral	Actual: 1 Df Am And 1.5 Df Pm		Not Reported
	Zeldox			S	Oral	40 Mg, Unk		Not Reported
	Amlodipine Actavis			C	Unknown			Not Reported
	Fragmin			C				Not Reported
	Ferro Duretter			C	Unknown	100 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	0.5 Mg, Qd		Not Reported
	Centyl Med Kaliumklorid			C		1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	13505206	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1716970US		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Tecfidera			S	Oral	1 Df, Qd		Not Reported
	Epitomax			S	Oral	100 Mg, Bid		Not Reported
	Levocarnil			S	Oral	30 Ml, Qd		Not Reported
	Procoralan			S	Oral	1 Df, Bid, 1-0-1		Not Reported
	Trivastal			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15084214	EXPEDITED (15-DAY)		LT	FR-TEVA-2018-FR-918275		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Thrombosis	Olanzapine			S	Oral			Teva
	Teralithe Lp 400 Mg, Comprimé Sécable À Libération Prolongée			S	Oral			Not Reported
	Seroplex 5 Mg, Comprimé Pelliculé			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15766587	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1859349US		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Intentional Overdose; Sluggishness	Escitalopram Oxalate Unk			S	Oral	30 Ml, In Total (Overdose)		Allergan
	Alprazolam			S	Oral	20 Ml, In Total		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15793185	EXPEDITED (15-DAY)		HO	RO-ROCHE-2239869		54 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety;	Clonazepam			S	Unknown	0.5 Mg, Qd		Not Reported

Bronchitis; Chest Discomfort; Chronic Gastritis; Condition Aggravated; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Memory Impairment; Obsessive-Compulsive Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Weight Decreased	Mirtazapine	S	Unknown	30 Mg, Qd	Not Reported
	Escitalopram Oxalate	S	Unknown	10 Mg	Not Reported
	Risperidone	S	Unknown	6 Mg, Qd	Not Reported
	Duloxetine	S	Unknown	60 Mg, Qd	Not Reported
	Doxepine	S	Unknown	100 Mg, Qd	Not Reported
	Quetiapine Fumarate	S	Unknown	300 Mg, Qd	Not Reported
	Quetiapine Fumarate	S	Unknown	800 Mg, Qd	Not Reported
	Olanzapine	S	Unknown	15 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15843001	EXPEDITED (15-DAY)		OT	BE-ALLERGAN-1902043US		52 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Limb Discomfort; Off Label Use; Syncope; Tremor	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	L-Thyroxine Christiaens 25 Mcg, Tabletten			C	Oral	Mo-Tu-Fr: 25 Mcg/Day We-Sa-Su: 2/25 Mcg/Day		Not Reported
	Kerutabs			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15882998	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2019019672			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depressed Level Of Consciousness; Drug Interaction; Respiratory Depression	Escitalopram Oxalate	S	Oral	15 Milligram, Qd	Macleods
	Durogesic	S	Transdermal	150 Microgram, 72 Per Hour	Not Reported
	Neurontin	S	Oral	300 Milligram, 8 Per Hour	Not Reported
	Sevredol	S	Oral	10 Milligram, S.O.S.	Not Reported
	Trankimazin	S	Oral	1 Milligram, 24 Per Hour	Not Reported
	Pantoprazole	C	Unknown	Unk	Macleods
	Paracetamol	C	Unknown	Unk	Not Reported
	Borea	C	Unknown	Unk	Not Reported
	Binocrit	C	Subcutaneous	Unk	Not Reported
	Clexane	C	Subcutaneous	Unk	Not Reported
	Hidroxil	C	Unknown	Unk	Not Reported
	Mycostatin	C	Unknown	Unk	Not Reported
	Natecal D	C	Unknown	Unk	Not Reported
	Nolotil	C	Unknown	Unk	Not Reported
	Seguril	C	Unknown	Unk	Not Reported
	Seretide	C	Unknown	Unk	Not Reported
	Zovirax	C	Unknown	Unk	Not Reported
	Zyloric	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15883367	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100861		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Clonazepam			S	Oral	Unk, Unknown		Par
	Amlodipine			S	Oral	Unk, Unknown		Not Reported
	Metoprolol			S	Oral	Unk, Unknown		Not Reported
	Hydrochlorothiazide			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15883394	EXPEDITED (15-DAY)		HO	DE-ACCORD-104083		20 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error	Escitalopram			S		15 Mg, Nk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15883462	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-004660			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Prescription Form Tampering	Quetiapine			S	Unknown	Non Renseignée		Aurobindo
	Escitalopram			S	Unknown	Non Renseignée		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15884074	NON-EXPEDITED			US-APOTEX-2017AP023722			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heat Illness; Mydriasis; Vomiting	Paxil Tablets			S	Unknown	Unk		Apotex
	Lexapro			S	Unknown	Unk		Not Reported
	Zoloft			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15885538	EXPEDITED (15-DAY)		HO	FR-TAKEDA-2019TUS003425		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Depression; Disorientation; Drug Ineffective; Haemorrhoid	Brintellix			S	Unknown	5 Milligram		Takeda
	Brintellix			S	Oral	15 Milligram, Qd		Takeda

Operation; Malaise	Seroplex	S	Oral	Unk, Qd	Not Reported
	Alprazolam	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15885558	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2019-ES-1003508		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Respiratory Depression	Escitalopram 15 Efg Comprimido			S	Oral	15 Milligram Daily; Escitalopram 15 Efg: 1 Tablet/Day With Breakfast. During The Entry Into History		Ivax
	Neurontin 300			S	Oral	Neurontin 300:1 Tablet With Breakfast, Lunch And Dinner		Not Reported
	Trankimazin 1			S	Oral	1 Milligram Daily; Trankimazin 1:1 Tablet/Day 30 Minutes Before Bedtime.		Not Reported
	Durogesic			S	Transdermal	Durogesic: 1 Transdermal Patch Of 100 Microgram. And Another Of 50 Microgram. Every 72 Hours		Not Reported
	Sevredol 10 Comprimidos			S	Oral	Sevredol 10:1 Compressed If Major Pains Despite Treatment With Neurontín 300 And Durogesic 100 + 50.		Not Reported
	Zovirax 800 Mg Comprimidos Dispersables			C				Not Reported
	Nolotil			C				Not Reported
	Paracetamol 1gr. Comprimido			C				Not Reported
	Zyloric 100 Mg Comprimidos			C				Not Reported
	Seguril 40 Mg Comprimidos			C				Not Reported
	Binocrit 30.000 Ui/0,75 Ml Solucion Inyectable En Una			C	Subcutaneous	30,000 Ui/0.75 Ml Injectable Solution In A		Not Reported

	Jeringa Precarga			Preloaded Syringe	
	Clexane	C	Subcutaneous		Not Reported
	Pantoprazol 20 Mg Comprimido	C			Not Reported
	Natecal D	C			Not Reported
	Mycostatin	C			Not Reported
	Hidroxil B1-B6-B12 Comprimidos Recubiertos Con Pelicula	C			Not Reported
	Seretide Accuhaler 50 Microgramos/250 Microgramos/Inhalacion, Polvo Pa	C		50 Micrograms/250 Micrograms/Inhalation, Inhalation Powder.	Not Reported
	Borea	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15885602	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100751		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Propranolol Hydrochloride			S	Oral	Unk, Unknown		Vintage
	Tramadol			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Gabapentin			S	Oral	Unk, Unknown		Not Reported
	Ethanol			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15885605	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100756		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Propranolol Hydrochloride			S	Oral	Unk, Unknown		Vintage
	Lamotrigine			S	Oral	Unk, Unknown		Par
	Diazepam			S	Oral	Unk, Unknown		Dava
	Olanzapine			S	Oral	Unk, Unknown		Par

	Escitalopram		S	Oral	Unk, Unknown	Not Reported
	Methylphenidate		S	Oral	Unk, Unknown	Not Reported
	Melatonin		S	Oral	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15885611	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100762		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk, Unknown		Vintage
	Quetiapine			S	Oral	Unk, Unknown		Not Reported
	Amlodipine			S	Oral	Unk, Unknown		Not Reported
	Primidone			S	Oral	Unk, Unknown		Not Reported
	Trazodone			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15885616	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100759		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Propranolol Hydrochloride			S	Oral	Unk, Unknown		Vintage
	Levetiracetam			S	Oral	Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Gabapentin			S	Oral	Unk, Unknown		Not Reported
	Acetaminophen W/Chlorzoxazone			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15885635	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1003318		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Haemorrhagic Stroke	Escitalopram		S	Oral	5 Milligram Daily;	Ivax
	Kardegic 160 Mg, Poudre Pour Solution Buvable En Sachet		S	Oral	1 Dosage Forms Daily;	Not Reported
	Inegy 10 Mg/40 Mg, Comprimé		C	Oral	1 Dosage Forms Daily;	Not Reported
	Spironolactone		C	Oral	75 Milligram Daily;	Not Reported
	Cardensiel 1,25 Mg, Comprimé Pelliculé		C	Oral	1 Dosage Forms Daily;	Not Reported
	Lasilix		C	Oral	60 Milligram Daily;	Not Reported
	Esomeprazole		C	Oral	20 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15885794	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2019M1007633		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Interstitial Lung Disease	Mycophenolate Mofetil			S	Oral	Unk Unk,Bid		Not Reported
	Esomeprazole Mylan			S	Oral	20 Mg,Qd		Mylan
	Escitalopram			S	Oral	10 Mg,Bid		Not Reported
	Atorvastatin			S	Oral	10 Mg,Qd		Not Reported
	Triatec /00885601/			S	Oral	5 Mg,Qd		Mylan
	Stilnox			S	Oral	10 Mg,Qd		Mylan
	Theralene			S	Oral	5 Mg,Bid		Mylan
	Ixprim			S	Oral	Unk(Unk Unk,Unk,37,5 Mg / 325 Mg Coated Tablets)		Mylan
	Cortancyl			S	Oral	5 Mg,Bid		Mylan
	Seresta			C		Unk(Strength: 50 Mg)		Mylan
	Lasilix /00032601/			C		Unk(Strength: 40 Mg)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15886228	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1904006US		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Dry Skin; Dyspnoea; Fatigue; Hypoaesthesia; Nausea; Paraesthesia; Urticaria	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Unk		Allergan
	Amitriptyline	S	Oral	10 Mg, Unk		Not Reported
	Calcium	C	Unknown	Unk		Not Reported
	Zinc	C	Unknown	Unk		Not Reported
	Vitamin B Complex	C	Unknown	Unk		Not Reported
	Magnesium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15886368	EXPEDITED (15-DAY)		DE	US-GENUS_LIFESCIENCES-USA-POI0580201900218		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Potassium Chloride Oral Solution			S				Genus Lifesciences
	Metoprolol			S				Not Reported
	Amlodipine			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Quetiapine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	14241831	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-106977		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Dafalgan			S	Oral	1000 Mg,3x/Day (Tid)		Bristol Myers Squibb
	Metformin Hydrochloride			S	Oral	1000 Mg, Qd		Bristol Myers Squibb
	Seroplex			S	Oral	1 Df, Once Daily (Qd)		Not Reported
	Seroplex			S	Unknown			Not Reported
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Valium			S	Oral	10 Mg, Tid		Not Reported

Alprazolam	S	Oral	0.25 Mg, Tid	Not Reported
Alprazolam	S	Unknown		Not Reported
Bisoprolol Hemifumarate	S	Oral	1.25 Mg, Qd	Not Reported
Amlodipine	S	Oral	10 Mg, Once Daily (Qd)	Not Reported
Irbesartan	S	Oral	300 Mg, Qd	Not Reported
Irbesartan	S	Unknown		Not Reported
Diffu-K	S	Oral	6 Df, Qd	Not Reported
Pantoprazole	S	Oral	20 Mg, Qd	Not Reported
Pantoprazole	S	Unknown		Not Reported
Nefopam Hydrochloride	S	Oral	3 Mg, Qd	Not Reported
Nefopam Hydrochloride	S	Unknown		Not Reported
Colchicine Opocalcium	S	Oral	1 Mg, Once Daily (Qd)	Not Reported
Tavanic	S	Oral	250 Mg, Bid	Not Reported
Tavanic	S	Oral	250 Mg, 2x/Day (Bid)	Not Reported
Terbutaline Sulfate	S	Respiratory (inhalation)	1 Df, Qd	Not Reported
Terbutaline Sulfate	S	Unknown		Not Reported
Furosemide	S	Oral	30 Mg, Bid	Not Reported
Xarelto	S	Oral	20 Mg, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15172325	EXPEDITED (15-DAY)		HO, LT	DE-MYLANLABS-2018M1052950		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Linezolid			S	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Escitalopram			S		Unk		Not Reported
	Esomeprazol /01479301/			S		40 Mg Unk		Mylan
	Levetiracetam			C		Daily Dose: 2 Df Dosage Form Every Days		Mylan

	Ivabradina	C		Daily Dose: 15 Mg Millgram(S) Every Days	Mylan
	Cotrimoxazol	C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days	Mylan
	Naloxone Hydrochloride W/Tilidine Hydrochlori	C		10 Gtt Drops	Mylan
	Scopolamin	C		Unk	Mylan
	Baclofen	C		Unk	Mylan
	Prednisolon /00016201/	C		10 Milligram	Mylan
	Lorazepam	C		Daily Dose: 1 Mg Millgram(S) Every Days	Mylan
	L-Thyroxin /00068002/	C		75 Microgram	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15779981	EXPEDITED (15-DAY)		OT	CZ-ACCORD-062025		45 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sertraline			S	Oral			Accord
	Escitalopram			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15796625	NON-EXPEDITED			US-LUNDBECK-DKLU2058913			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Northera			S	Oral			Lundbeck
	Northera			S	Oral			Lundbeck
	Lexapro			S	Unknown			Forest
	Tegretol			C	Unknown			Not Reported
	Sodium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15887476	EXPEDITED (15-DAY)		HO, LT, OT	IN-LUPIN PHARMACEUTICALS INC.-2019-00370		23 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Postictal State; Seizure; Self-Medication; Sleep Disorder; Tongue Biting	Olanzapine			S	Unknown	20 Mg, Unk, (Nearly 4 Years)		Not Reported
	Olanzapine			S	Unknown	20 Mg, Unk		Not Reported
	Olanzapine			S				Not Reported
	Fluoxetine			S	Unknown	20 Mg, Unk (Nearly 4 Years)		Not Reported
	Fluoxetine			S	Unknown	Unk		Not Reported
	Fluoxetine			S				Not Reported
	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Lupin
	Escitalopram Oxalate			S				Lupin
	Escitalopram Oxalate			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15887617	EXPEDITED (15-DAY)		HO	DE-ACCORD-104172		44 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dyspepsia	Escitalopram			S		20 Mg, 1-0-0		Not Reported
	Neupro			S	Transdermal	14 Mg, 1-0-0-0		Not Reported
	Ibuprofen			S		Nk		Not Reported
	Bornaprine/Bornaprine Hydrochloride			S		4 Mg, 1-0.5-1-0		Not Reported
	Amantadine			C		100 Mg, 1-1-0-0		Not Reported
	Amitriptyline			C		75 Mg, 0-0-0-1		Not Reported
	Madopar Depot			C		100-25 Mg, 0-0-0-1		Not Reported
	Madopar			C		100-25 Mg, 1.5-1.5-1.5-1.5		Not Reported
	Madopar Lt			C		100-25 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15887894	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-003455		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stillbirth	Quetiapine			S	Oral	25 Milligram, Daily		Aurobindo
	Escitalopram			S	Oral	20 Milligram, Daily		Aurobindo
	Presinol			S	Oral	500 Milligram, Daily,500 [Mg/D (2x250)]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15888033	EXPEDITED (15-DAY)		HO	DE-ACCORD-104016		77 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Contusion; Fall; Syncope	Escitalopram			S	Unknown			Not Reported
	Eferox			C		50 Ug, 1-0-0-0		Not Reported
	Hct			C		12.5 Mg, 1-0-0-0		Not Reported
	Metoprolol			C		47.5 Mg, 1-0-0-0		Not Reported
	Ventolair			C		250 Microgram, 2-0-0-2		Not Reported
	Metamizole Sodium			C		500 Mg, 1-1-1-0		Not Reported
	Valsartan			C		80 Mg, 0.5-0-0-1		Not Reported
	Ass 100			C		100 Mg, 0-1-0-0		Not Reported
	Simvastatin			C		40 Mg, 0-0-0-1		Not Reported
	Pantoprazole			C		20 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15888805	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1003165			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Syncope	Austedo			S	Unknown	24 Milligram Daily; 24 Mg/Day		Teva

	Lexapro	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15891048	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1008795			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Escitalopram			S	Unknown	Low Dose, At Last 10-15 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15891131	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1007924		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Somnolence; Toxicity To Various Agents	Ibuprofen			S	Oral	20 Dosage Form		Not Reported
	Paroxetine			S	Oral	12 Dosage Form		Not Reported
	Escitalopram			S	Oral	28 Dosage Form		Not Reported
	Havlane			S	Oral	20 Dosage Form		Mylan
	Dafalgan			S	Oral	8 Gram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15891156	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1007875		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Hyperthermia; Malaise; Nausea; Night Sweats; Pruritus; Serotonin Syndrome; Tremor	Tramadol			S	Oral	Unk,Inconnue		Not Reported
	Seroplex			S	Oral	Inconnue		Mylan
	Paracetamol			C	Oral	Unk,Inconnue		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15891375	NON-EXPEDITED			US-ALLERGAN-1845917US		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Fatigue; Stupor	Viibryd			S	Oral	20 Mg, Qd		Allergan
	Viibryd			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Unknown	Unk		Not Reported
	Valium			C	Oral	4 Mg, Qhs		Not Reported
	Vitamin B Complex			C		Unk		Not Reported
	Vitamin D2			C		Unk		Not Reported
	Prozac			C				Not Reported
	Paxil			C				Not Reported
	Unithroid			C		Unk		Not Reported
	Topamax			C		Unk		Not Reported
	Primidone			C		Unk		Not Reported
	Allegra			C		Unk		Not Reported
	Unspecified Blood Pressure Medication			C		Unk		Not Reported
	Plavix			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15891956	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1904202US		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Depression; Disorientation; Drug Ineffective; Haemorrhoid Operation; Malaise	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Brintellix			S	Unknown	5 Mg, Unk		Not Reported
	Brintellix			S	Oral	15 Mg, Qd		Not Reported
	Alprazolam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	16005135	DIRECT		RI			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dry Eye; Eye Discharge; Eye Pruritus; Eye Swelling; Retinal Vascular Occlusion	Lexapro	Y	S	Oral	Quantity:5 Mg Milligram(S);	Aurobindo
	Amlodipine Besylate		C			Not Reported
	Lorazepam		C			Not Reported
	Vitamin D3		C			Not Reported
	Miralax		C			Not Reported
	Aleve		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	8236555	EXPEDITED (15-DAY)		DE, HO, OT	DK-TEVA-307344ISR		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Hypertrophy; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension; Internal Fixation Of Fracture; Lactic Acidosis; Lacunar Infarction; Neuroleptic Malignant Syndrome; Organ Failure; Pyrexia; Renal Failure; Rhabdomyolysis	Mirtazapine			S	Oral	30 Milligram Daily;		Teva
	Litarex (Lithium Citrate)			S	Oral	Dose: 1+0+0+1.5, Styrke: 6 Mmol Li+		Not Reported
	Zeldox			S	Oral	80 Milligram Daily;		Not Reported
	Cipralex			S	Oral	30 Milligram Daily;		Not Reported
	Ferro Duretter			C		100 Milligram Daily;		Not Reported
	Centyl Med Kaliumklorid			C		Dose 1 Pcs Daily. Start Date Is Unknown		Not Reported
	Alprazolam			C		.5 Milligram Daily; Start Date Is Unknown		Not Reported
	Fragmin			C				Not Reported
	Amlodipine Actavis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	13574722	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1030214		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Overdose	Lorazepam			S	Oral	20 Milligram, Total		Not Reported
	Escitalopram			S	Oral	140 Milligram, Total		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	14953070	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2018214154		88 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anxiety; Bradypnoea; Drug Interaction; Overdose; Toxicity To Various Agents	Temesta Expidet			S	Oral	0.5 Mg, As Needed		Pfizer
	Nexium			S	Oral	20 Mg, Daily		Unknown
	Cipralex /01588501/			S	Oral	20 Mg, Daily (In The Morning)		Not Reported
	Cipralex /01588501/			S	Oral	15 Mg, 1x/Day		Not Reported
	Omeprazole			S	Oral	20 Mg, Daily		Not Reported
	Durogesic			S	Cutaneous	75 Ug/H		Not Reported
	Durogesic			S	Cutaneous	50 Ug/H		Not Reported
	Anexate			C		1 Mg, Unk (2 X 0.5 Mg)		Not Reported
	Atarax /00058402/			C		Unk		Not Reported
	Calcimagon D3			C		Unk		Not Reported
	Clopidogrel			C		Unk		Not Reported
	Movicol			C		Unk		Not Reported
	Paracetamol			C		Unk, As Needed		Not Reported
	Prednisone			C		Unk		Not Reported
	Quetiapine Xr			C		Unk		Not Reported
	Quetiapine			C		Unk		Not Reported
	Clexane			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Morphine Hcl			C		Unk		Not Reported
	Flector Ep			C		Unk, As Needed		Not Reported
	Beloc Zok			C		Unk		Not Reported
	Laxoberon			C		Unk, As Needed		Not Reported
	Ondansetron			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15851116	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2019-FR-1002109		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Faeces; Feeling Hot; Hyperhidrosis; Hyperhidrosis; Hypotension; Malaise; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Rash; Respiratory Distress	Aripiprazole			S	Unknown	2 Milligram Daily;		Teva
	Selincro			S	Oral	1 Dosage Forms Daily;		Not Reported
	Seroplex			S	Unknown	20 Milligram Daily;		Not Reported
	Ventolin			C	Unknown			Not Reported
	Loxen [Nicardipine Hydrochloride]			C	Unknown	1 Dosage Forms Daily;		Not Reported
	Lexomil			C	Unknown	1 Dosage Forms Daily;		Not Reported
	Methadone			C	Unknown	80 Milligram Daily;		Not Reported
	Kardegic			C	Unknown			Not Reported
	Theralene			C	Unknown	2 Dosage Forms Daily;		Not Reported
	Corgard			C	Unknown	80 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15894226	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2019-00340		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Linezolid			S	Unknown	Unk		Novel Labs
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Bid		Not Reported
	Trazodone			S	Unknown	300 Mg, Qd (Nightly)		Not Reported
	Trazodone			S	Unknown	150 Mg, Qd (Nightly)		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15894374	EXPEDITED (15-DAY)		HO	IT-ACCORD-103842		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Trazodone/Trazodone Hydrochloride			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Not Reported
	Valproic Acid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15895061	EXPEDITED (15-DAY)		OT	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2019-00941		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Stillbirth	Quetiapine Fumarate			S	Oral	25 [Mg/D]		Alkem
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Presinol			S	Oral	500 [Mg/D (2x250)]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15895773	NON-EXPEDITED			US-APOTEX-2016AP014849			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Hallucination; Pain	Paxil Cr Tablets			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Xanax			S	Unknown	Unk		Not Reported

	Neurotin /01003001/		S	Unknown	Unk	Not Reported
	Pregabalin		C	Oral	1 Df, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15895913	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20190138184		92 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Haematoma	Xarelto			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Lovenox			S	Intramuscular	7000 Iu, Unk		Not Reported
	Spironolactone			C	Oral			Not Reported
	Alprazolam			C	Oral			Not Reported
	Bisoprolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15896202	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100905		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion Hydrochloride			S	Oral	Unk, Unknown		Par
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Methylphenidate			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15896749	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2019035206		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Respiratory Depression	Neurontin			S	Oral	300 Mg, 3x/Day (1 Tablet With Breakfast, Dinner And Supper)		Pfizer

	Trankimazin	S	Oral	1 Mg, 1x/Day (Every 24 Hours, 1 Tablet A Day 30 Minutes Before Going To Bed)	Pfizer
	Durogesic	S	Transdermal	150 Ug, Unk (1 Transdermal Patch Of 100 Ug And The Other Of 50 Ug Every 72 Hours)	Not Reported
	Escitalopram	S	Oral	15 Mg, 1x/Day	Not Reported
	Sevredol	S	Oral	10 Mg, As Needed (Sevredol 10: 1 Tablet In Case Of Severe Pains Despite The Treatment With Neuronti)	Not Reported
	Zovirax	C			Not Reported
	Nolotil [Metamizole Magnesium]	C			Not Reported
	Paracetamol	C			Not Reported
	Zyloric	C			Not Reported
	Seguril	C			Not Reported
	Binocrit	C	Subcutaneous		Not Reported
	Clexane	C	Subcutaneous		Not Reported
	Pantoprazole	C			Not Reported
	Natecal D	C			Not Reported
	Mycostatin	C			Not Reported
	Hidroxil B12 B6 B1	C			Not Reported
	Seretide Accuhaler	C			Not Reported
	Borea	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15896921	EXPEDITED (15-DAY)		OT	IN-MYLANLABS-2019M1008365		16 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea	Escitalopram			S	Unknown	Increased Up To A Dose Of 20 Mg; Initial Dose Not Stated		Not Reported
	Sertraline			S	Unknown			Not Reported

	Dexmedetomidine	S	Other	Over 10 Min, Followed By 0.5 Microg/Kg/Hour Dose	Not Reported
	Dexmedetomidine	S	Other	Per Hour Dose	Not Reported
	Clonazepam	C	Unknown		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	16012120	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Appearance	Lexapro			S				Not Reported
Confusion; Product	Celexa			S				Not Reported
Dispensing Error; Wrong	Lortab			S				Not Reported
Product Administered	Percocet			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	16013459	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error	Escitalopram Oxalate			S				Not Reported
	Citalopram Hydrobromide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	11239692	NON-EXPEDITED		HO, OT	TR-LUPIN PHARMACEUTICALS INC.-2015-01108		71 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral	Escitalopram			S	Unknown	10 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	11874246	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-04128		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Priapism	Escitalopram	S	Unknown	Unk	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	12325764	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2015-02170		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Quetiapine			S	Unknown	300 Mg, Qd		Not Reported
	Fluoxetine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Lupin
	Lofepramine			S	Unknown	Unk		Not Reported
	Dosulepin			S	Unknown	Unk		Not Reported
	Citalopram			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	14323556	NON-EXPEDITED		HO	DE-LUPIN PHARMACEUTICALS INC.-2017-07180		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Aripiprazole			S	Oral	10 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	15 Mg, Qd		Lupin
	Escitalopram			S	Oral	20 Mg, Qd		Lupin
	Escitalopram			S	Oral	10 Mg, Qd		Lupin
	Candesartan			S	Oral	16 Mg, Qd		Not Reported
	Metformin			C	Oral	1500 Mg, Unk		Not Reported
	Acetylsalicylic Acid			C	Oral	100 Mg, Qd		Not Reported
	L-Thyroxin			C	Oral	100 Mcg, Qd		Not Reported
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	14501952	NON-EXPEDITED			CA-LUPIN PHARMACEUTICALS INC.-2017-00646		20 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Insomnia	Zopiclone			S	Unknown	7.5 Mg, Qd At Bedtime		Not Reported
	Zopiclone			S	Unknown	15 Mg, Qd At Bedtime		Not Reported
	Zopiclone			S	Unknown	3.75 Mg, Qd At Bedtime		Not Reported
	Escitalopram			S	Unknown	Unk		Lupin
	Escitalopram			S	Unknown	20 Mg,Qd,Every Morning		Lupin
	Mirtazapine			S	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Duloxetine			C	Unknown	Unk Unk,Unk,Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	14505140	NON-EXPEDITED			SG-LUPIN PHARMACEUTICALS INC.-2017-07618		65 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Withdrawal Syndrome	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Metformin			C	Unknown	500 Mg, Tid		Not Reported
	Atenolol			C	Unknown	25 Mg, Qd		Not Reported
	Hydrochlorothiazide			C	Unknown	12.5 Mg, Qd		Not Reported
	Lovastatin			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	14597357	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-07507			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate Tablets Usp, 20 Mg			S	Oral	20 Mg, Qd		Lupin

	Escitalopram Oxalate Tablets Usp, 20 Mg	S				Lupin
	Wellbutrin	C	Oral	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	14976515	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1828737US		88 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anxiety; Bradypnoea	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Omeprazole			S	Oral	20 Mg, Qd		Not Reported
	Nexium			S	Oral	20 Mg, Qd		Not Reported
	Durogesic			S	Unknown	50 Mg, Q1hr		Not Reported
	Durogesic			S	Cutaneous	75 Mg, Q1hr		Not Reported
	Temesta [Lorazepam]			S	Oral	0.5 Mg, Unknown		Not Reported
	Anexate			C		1 Mg, Unk		Not Reported
	Atarax			C		Unk		Not Reported
	Calcimagon D3			C		Unk		Not Reported
	Clopidogrel			C		Unk		Not Reported
	Movicol			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Quetiapine Xr			C		Unk		Not Reported
	Quetiapine			C		Unk		Not Reported
	Clexane			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Morphine Hcl			C		Unk		Not Reported
	Flector			C		Unk		Not Reported
	Beloc Zok			C		Unk		Not Reported
	Laxoberon			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15105323	NON-EXPEDITED		OT	IL-LUPIN PHARMACEUTICALS INC.-2018-04641		65 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S		10 Unk, Unk		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin
	Escitalopram			S		Gradually Increased		Lupin
	Escitalopram			S	Unknown	10 Mg, Unk		Lupin
	Alprazolam			C	Unknown	0.5 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	Double Dose		Not Reported
	Zopiclone			C	Unknown	7.5 Mg, Qd		Not Reported
	Levetiracetam			C	Unknown	1000 Mg, Qd		Not Reported
	Omeprazole			C	Unknown	20 Mg, Qd		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15193759	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-03406		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Aura; Ejaculation Failure; Erectile Dysfunction; Loss Of Libido; Sexual Dysfunction; Treatment Noncompliance; Withdrawal Syndrome	Lamotrigine			S	Unknown	100 Mg, Tid		Not Reported
	Lamotrigine			S				Not Reported
	Escitalopram			S	Intracardiac	20 Mg, Bid		Lupin
	Escitalopram			S				Lupin
	Escitalopram			S				Lupin
	Mirtazapine			S	Intracardiac	22.5 Mg, Qd (Every Night At Bed Time)		Not Reported
	Mirtazapine			S				Not Reported
	Mirtazapine			S				Not Reported
	Enalapril Maleate			S	Unknown	20 Mg, Qd (Every Morning)		Not Reported

	Lansoprazole	S	Unknown	30 Mg, Qd (Every Morning)		Not Reported
	Alprazolam	S	Unknown	1 Mg, Prn (Thrice A Day - Prn)		Not Reported
	Alprazolam	S				Not Reported
	Alprazolam	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15467209	NON-EXPEDITED		HO, OT	IN-LUPIN LIMITED-2018-01431		58 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	Unk		Lupin
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Prednisolone			C	Oral	Unk		Not Reported
	Insulin			C	Unknown	Combination Of Fast And Long Acting Insulin		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15674850	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-980381		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Cerebral Haemorrhage; Ecchymosis; Subdural Haematoma	Escitalopram Oxalate			S	Oral	10 Milligram Daily;		Ivax
	Coumadin 5 Mg Compresse			S	Oral			Not Reported
	Plavix			S	Oral	75 Milligram Daily;		Not Reported
	Pregabalin			C	Unknown			Not Reported
	Doxazosin			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Esomeprazole Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15743775	NON-EXPEDITED		HO, OT	QA-LUPIN PHARMACEUTICALS INC.-2018-07519		49 YR	Male	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Atorvastatin			S	Oral	40 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15852240	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-001296			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Faeces; Contraindicated Product Administered; Feeling Hot; Hyperhidrosis; Hypotension; Malaise; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Rash; Respiratory Distress	Aripiprazole Tablets			S	Unknown	2 Milligram, Once A Day		Aurobindo
	Seroplex			S	Unknown	20 Milligram, Once A Day		Not Reported
	Selincro			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Loxen [Nicardipine Hydrochloride]			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Theralene			C	Unknown	2 Dosage Form, Once A Day		Not Reported
	Corgard			C	Unknown	80 Milligram, Once A Day		Not Reported
	Methadone			C	Unknown	80 Milligram, Once A Day		Not Reported
	Lexomil			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Kardegic			C	Unknown	Unk, Once A Day		Not Reported
	Ventolin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897959	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/19/0107177		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy; Stillbirth	Quetiapine		S	Oral	25 [Mg/D]	Not Reported
	Escitalopram		S	Oral	20 [Mg/D]	Not Reported
	Presinol		S	Oral	500 [Mg/D (2x250)]	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897968	NON-EXPEDITED			IN-LUPIN LIMITED-2018-02638		20 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Acneiform	Escitalopram			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897978	NON-EXPEDITED		HO, OT	IN-LUPIN LIMITED-2017-07453		73 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram Tablets			S	Unknown	10 Mg, Qd		Lupin
	Escitalopram Tablets			S	Unknown	5 Mg, Qd		Lupin
	Duolin /01033501/			C	Unknown	Unk		Not Reported
	Budesonide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897987	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-04685		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Insomnia; Nausea; Torticollis	Citalopram			S	Unknown	10 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	5 Mg, Qd		Lupin
	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Escitalopram			S	Unknown	15 Mg, Qd		Lupin
	Celecoxib			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported

	Ibuprofen		C	Unknown	Unk	Not Reported
	Tamsulosin		C	Unknown	Unk	Not Reported
	Omeprazole		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897988	NON-EXPEDITED		HO, OT	IN-LUPIN LIMITED-2017-07544		54 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Escitalopram			S	Unknown	10 Mg, Unk		Lupin
	Lorazepam			C	Unknown	2 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897989	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-02709			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear; Nightmare; Product Dose Omission	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	10 Mg, Qd (Every Bedtime)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897990	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00124		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Malaise; Product Dispensing Error; Wrong Product Administered	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	10 Mg, Qd		Lupin
	Levothyroxine			S	Oral	Unk Unk, Qd		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897991	NON-EXPEDITED			DE-LUPIN PHARMACEUTICALS INC.-2018-00897			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder; Bruxism; Drug Ineffective; Mental Disorder; Overweight	Citalopram			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	20 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897992	NON-EXPEDITED			DE-LUPIN PHARMACEUTICALS INC.-2017-07918		64 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Nausea; Weight Decreased; Weight Increased	Venlafaxine			S	Unknown	75 Mg, Unk		Not Reported
	Venlafaxine			S	Unknown	150 Mg, Unk		Not Reported
	Venlafaxine			S	Unknown	225 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Lupin
	Escitalopram Oxalate			S	Unknown	20 Mg, Unk		Lupin
	Citalopram			S	Unknown	20 Mg, Unk		Not Reported
	Citalopram			S	Unknown	10 Mg, Unk		Not Reported
	Citalopram			S	Unknown	40 Mg, Unk		Not Reported
	Citalopram			S	Unknown	20 Mg, Unk		Not Reported
	Citalopram			S	Unknown	20 Mg, Unk		Not Reported
	Citalopram			S	Unknown	20 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	40 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	20 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	20 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	40 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	40 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	40 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	20 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	40 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	20 Mg, Unk		Not Reported

Cipramil /00582602/	S	Unknown	20 Mg, Unk		Not Reported
Cipramil /00582602/	S	Unknown	20 Mg, Unk		Not Reported
Cipramil /00582602/	S	Unknown	40 Mg, Unk		Not Reported
Cipramil /00582602/	S	Unknown	40 Mg, Unk		Not Reported
Cipramil /00582602/	S	Unknown	40 Mg, Unk		Not Reported
Cipramil /00582602/	S	Unknown	20 Mg, Unk		Not Reported
Cipralex /01588501/	S	Unknown	20 Mg, Qd		Not Reported
Cipralex /01588501/	S	Unknown	20 Mg, Unk		Not Reported
Cipralex /01588501/	S	Unknown	20 Mg, Unk		Not Reported
Cipralex /01588501/	S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897993	NON-EXPEDITED		HO, OT	ZA-LUPIN PHARMACEUTICALS INC.-2018-00509		76 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Zytomil Tablets			S	Oral	10 Mg, Unk		Lupin
	Pearinda Tablets			S	Oral	4 Mg, Unk		Not Reported
	Carbilev			S	Oral	Unk, 25/100mg		Not Reported
	Latanoprost			S	Intraocular	50 Mcg, Unk		Not Reported
	Estro-Pause			S	Oral	1 Mg, Unk		Not Reported
	Adco-Retic			S	Oral	Unk, 5/50mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897994	NON-EXPEDITED			IN-LUPIN LIMITED-2018-07598		34 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia	Stalopam Film C.Tabs 5 Mg			S	Oral	1 Df, Qd (At Night)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897995	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-08153		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event; Wrong Product Administered	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Unknown	Unk		Lupin
	Alprazolam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897997	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-06870		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate Tablets Usp, 5 Mg			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15897998	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2018-01213			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Escitalopram			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898000	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2018-00423		21 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertrichosis; Weight Increased	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Fluoxetine			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898001	NON-EXPEDITED		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02136		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin
	Flecainide			S	Oral	Unk		Not Reported
	Verapamil			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898002	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-05560		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mydriasis; Vision Blurred	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	10 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898003	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-07679		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Drug Hypersensitivity; Sedation	Mirtazapine			S	Unknown	7.5 Mg, Qd (At Night; 2 Months Before The Patient Was Referred For Evaluation)		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Qd (At Night; 2 Months Before The Patient Was Referred For Evaluation)		Not Reported
	Sertraline			S	Unknown	300 Mg, Qd		Not Reported
	Sertraline			S	Unknown	300 Mg, Qd		Not Reported
	Sertraline			S				Not Reported

Escitalopram	S	Unknown	Unk		Lupin
Citalopram	S	Unknown	40 Mg, Qd		Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Unk		Not Reported
Lamotrigine	C	Unknown	100 Mg, Qd		Not Reported
Venlafaxine	C	Unknown	375 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898004	NON-EXPEDITED			DE-LUPIN PHARMACEUTICALS INC.-2018-01613		27 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Nausea; Palpitations; Pyrexia; Vomiting	Escitalopram			S	Unknown	Unk		Lupin
	Naratriptan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898005	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2018-07583		23 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram			S	Unknown	10 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898006	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-08028			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Hot Flush; Insomnia	Escitalopram Oxalate			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898007	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-02251		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Food Allergy; Vomiting	Escitalopram Oxalate Tablets Usp, 20 Mg			S	Oral	Unk Unk, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898008	NON-EXPEDITED		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01860		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin
	Amitriptyline			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Paracetamol			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Cocaine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898009	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-05218			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pruritus Generalised; Rash; Urticaria	Escitalopram			S	Unknown	Unk		Lupin
	Escitalopram			S	Unknown	Unk		Lupin
	Bupropion Hcl Xl			S	Unknown	150 Mg, Qd		Not Reported
	Metoprolol			S		25 Mg, Unk		Not Reported
	Metoprolol			S	Unknown	50 Mg, Unk		Not Reported
	Zoloft			S				Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Flonase /00908302/			C	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported

Loratadine	C	Unknown	Unk		Not Reported
Baby Aspirin	C	Unknown	Unk		Not Reported
B Complex /00322001/	C	Unknown	Unk		Not Reported
Vitamin D 3	C		Unk		Not Reported
Fish Oil	C	Unknown	Unk		Not Reported
Multivitamins /00116001/	C	Unknown	Unk		Not Reported
Calcium Citrate	C	Unknown	Unk		Not Reported
Miralax	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898049	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2019IN00798			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Erotomanic Type	Escitalopram			S	Unknown	10 Mg, Per Day		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898185	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-004364		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhagic Stroke	Escitalopram			S	Oral	5 Milligram, Daily		Aurobindo
	Kardegic			S	Oral	1 Dosage Form, Daily		Not Reported
	Inegy			C	Oral	1 Dosage Form, Daily		Not Reported
	Spironolactone			C	Oral	75 Milligram, Daily		Not Reported
	Cardensiel			C	Oral	1 Dosage Form, Daily		Not Reported
	Lasilix			C	Oral	60 Milligram, Daily		Not Reported
	Esomeprazole			C	Oral	20 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898209	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-004039			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram			S	Oral	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898693	EXPEDITED (15-DAY)		OT	SE-ACCORD-105011		27 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Erectile Dysfunction	Escitalopram			S	Oral	Tablet		Not Reported
	Lithionit			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898695	EXPEDITED (15-DAY)		HO	SE-ACCORD-105020		45 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block	Escitalopram			S	Oral			Not Reported
	Desloratadine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898746	EXPEDITED (15-DAY)		HO, LT, OT	US-DRREDDYS-USA/USA/18/0105953		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898957	EXPEDITED (15-DAY)		HO, LT, OT	IN-MACLEODS PHARMACEUTICALS US LTD-			Unknown	IND

MAC2019019834

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Postictal State; Seizure; Self-Medication; Sleep Disorder; Tongue Biting	Escitalopram Oxalate			S	Unknown	10 Milligram		Macleods
	Olanzapine			S	Unknown	20 Milligram, Nearly 4 Years		Macleods
	Olanzapine			S	Unknown	20 Milligram		Macleods
	Fluoxetine			S	Unknown	Unk		Not Reported
	Fluoxetine			S	Unknown	20 Milligram, Nearly 4 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15899108	EXPEDITED (15-DAY)		HO, LT, OT	IN-HETERO CORPORATE-HET2019IN00094		23 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Postictal State; Seizure; Sleep Disorder; Tongue Biting	Escitalopram			S	Unknown	10 Milligram		Hetero
	Olanzapine			S	Unknown	20 Milligram		Not Reported
	Olanzapine			S		Nearly 4 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15899110	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-003887		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Aripiprazole			S	Oral	10 Milligram, Once A Day		Aurobindo
	Seresta			S	Oral	100 Milligram, Once A Day		Not Reported
	Tercian			S	Oral	50 Milligram, Once A Day		Not Reported

	Zyprexa	S	Oral	2 Dosage Form, Once A Day	Not Reported
	Dafalgan Codeine	S	Unknown	3 Dosage Form, Once A Day	Not Reported
	Seroplex	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Oxycontin Lp	S	Oral	2 Dosage Form, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15900954	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1904614US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Prescription Form Tampering	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Quetiapine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15901179	EXPEDITED (15-DAY)		HO	US-LANNETT COMPANY, INC.-US-2019LAN000105		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Lamotrigine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2019	15600119	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-053863		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	14 Dosage Form,In Total		Aurobindo
	Lorazepam			S	Oral	40 Milligram, In Total		Aurobindo
	Aripiprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2019	15902869	EXPEDITED (15-DAY)		CA	DE-ACCORD-104411		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Pulmonary Artery Stenosis Congenital	Escitalopram			S	Transplacental	10 Mg/D		Not Reported
	Sertraline			C	Transplacental	150 Mg/D		Not Reported
	Quetiapine/Quetiapine Fumarate			C	Transplacental	25 Mg/D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2019	15903106	EXPEDITED (15-DAY)		HO, OT	RO-AUROBINDO-AUR-APL-2019-004471			Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Condition Aggravated; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Weight Decreased	Duloxetine			S	Unknown	60 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Mirtazapine			S	Unknown	30 Milligram, Once A Day		Aurobindo
	Olanzapine			S	Unknown	15 Milligram, Once A Day		Aurobindo
	Clonazepam			S	Unknown	0.5 Milligram, Once A Day		Not Reported
	Doxepin			S	Unknown	100 Milligram, Once A Day		Not Reported
	Quetiapine			S	Unknown	300 Milligram, Once A Day		Not Reported
	Quetiapine			S	Unknown	800 Milligram		Not Reported
	Risperidone			S	Unknown	6 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2019	15903625	EXPEDITED (15-DAY)		DS	GB-ACCORD-105178		33 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Jaw	Escitalopram			S	Oral			Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2019	15903635	EXPEDITED (15-DAY)		OT	PL-ACCORD-104941			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Myalgia; Ventricular Arrhythmia	Escitalopram			S				Not Reported
	Rhodiola Rosea			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2019	15903636	EXPEDITED (15-DAY)		OT	PL-ACCORD-104943			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage	Escitalopram			S				Not Reported
	Ginkgo Biloba/Ginkgo Biloba Extract/Ginkgo Biloba Leaf Extract			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2019	15903637	EXPEDITED (15-DAY)		OT	PL-ACCORD-104942			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S				Not Reported
	Mirtazapine			S				Not Reported
	Ginseng Nos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2019	15903638	EXPEDITED (15-DAY)		OT	PL-ACCORD-104944			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage	Escitalopram			S				Not Reported
	Ginkgo Biloba/Ginkgo Biloba Extract/Ginkgo Biloba Leaf Extract			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2019	15903639	EXPEDITED (15-DAY)		OT	PL-ACCORD-104945			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage	Escitalopram			S				Not Reported
	Ginkgo Biloba/Ginkgo Biloba Extract/Ginkgo Biloba Leaf Extract			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2019	15906135	DIRECT		OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Opiates Positive	Lexapro Generic	Y		S				Unknown
	Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	14961029	EXPEDITED (15-DAY)		HO, OT	CH-ASTRAZENECA-2018SE68831		88 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anxiety; Bradypnoea; Depression; Drug Interaction; Fall; Movement Disorder;	Nexium			S	Oral			Astrazeneca
	Omeprazole			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

Overdose; Pain; Toxicity To Various Agents	Cipralex	S	Oral		Not Reported
	Durogesic	S	Cutaneous		Not Reported
	Durogesic	S	Cutaneous	50.0ug Unknown	Not Reported
	Temesta Expidet	S	Oral	0.5mg Unknown	Not Reported
	Anexate	C		0.5mg	Not Reported
	Atarax	C			Not Reported
	Calcimagon D3	C			Not Reported
	Clopidogrel	C			Not Reported
	Movicol	C			Not Reported
	Paracetamol	C			Not Reported
	Prednisone	C			Not Reported
	Quetiapine	C			Not Reported
	Quetiapine	C			Not Reported
	Clexane	C			Not Reported
	Morphine	C			Not Reported
	Morphine Hydrochloride	C			Not Reported
	Flector	C		As Required	Not Reported
	Beloc Zok	C			Not Reported
	Laxoberon	C			Not Reported
	Ondansetron	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15362727	EXPEDITED (15-DAY)		OT	PL-MYLANLABS-2018M1065842		34 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Dizziness; Mental Impairment	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Brintellix			S	Unknown	10 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15719103	EXPEDITED (15-DAY)		OT	CZ-APOTEX-2018AP026746		58 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Mental Disorder; Suicide Attempt	Citalopram			S	Unknown	Series Of Citalopram Infusions		Apotex

Risperidone	S	Unknown	Unk Unk,Unk		Apotex
Olanzapine	S	Unknown	Unk Unk,Unk		Apotex
Aripiprazole	S	Unknown	Unk		Apotex
Venlafaxine	S	Unknown	Unk Unk,Unk		Apotex
Escitalopram	S	Unknown	Unk Unk,Unk		Apotex
Mirtazapine	S	Oral	Unk Unk,Unk		Not Reported
Clomipramine	S	Unknown			Not Reported
Ziprasidone	S	Unknown	Unk		Not Reported
Tiapride	C	Unknown	Unk		Not Reported
Memantine	C	Unknown			Not Reported
Clonazepam	C	Unknown	Unk		Not Reported
Melperone	C	Unknown			Not Reported
Propofol	C	Unknown	Unk		Not Reported
Haloperidol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15904268	EXPEDITED (15-DAY)		HO	FR-AMGEN-FRASP2019014467		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura; Rash Pruritic	Xgeva			S	Subcutaneous	120 Mg, Unk		Amgen
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Alprazolam			S	Oral	0.25 Mg, Qd		Not Reported
	Aromasine			C	Oral	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15905254	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004844		59 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Hypersensitivity; Off Label	Espran			S	Oral	1 Tablet Daily		Unknown
	Rosucor			S				Unknown

Use; Pigmentation Disorder; Poor Quality Product Administered; Product Odour Abnormal; Product Taste Abnormal; Pruritus	Synthroid 10 Mg		C	Oral	1 Tablet Daily	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15907754	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100792		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Doxepin Hydrochloride			S	Oral	Unk, Unknown		Par
	Hydroxyzine Hydrochloride			S	Oral	Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Ethanol			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15907759	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100777		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Doxepin Hydrochloride			S	Oral	Unk, Unknown		Par
	Acetaminophen			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Cough And Cold Preparation			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908474	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1904675US		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura; Rash Pruritic	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Alprazolam			S	Oral	0.25 Mg, Qd		Not Reported

	Xgeva		S	Subcutaneous	120 Mg, Single	Not Reported
	Aromasine		C	Oral	25 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908703	EXPEDITED (15-DAY)		DS	FR-ALLERGAN-1904806US		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Eliquis			S	Oral	2 Df, Qd		Not Reported
	Digoxine			C	Unknown	Unk		Not Reported
	Loxen L P			C	Unknown	Unk		Not Reported
	Lopressor			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909032	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1904812US		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan
	Tetanus Vaccine			C	Transplacental	Unk Unk, Single		Not Reported
	L-Thyroxin			C	Transplacental	50 Mg, Qd		Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909035	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1904815US		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy; Premature Labour	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Tetanus Vaccine			C	Intramuscular	Unk Unk, Unknown		Not Reported

	L-Thyroxin	C	Oral	50 Mg, Qd	Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913285	NON-EXPEDITED			US-PFIZER INC-2019048906		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Pristiq			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Citalopram			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Influenza Virus Vaccine			S		Unk		Not Reported
	Xyzal			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	14490645	NON-EXPEDITED		DE, OT	US-LUPIN (EUROPE) LIMITED-2018-00094		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Gun Shot Wound	Escitalopram Oxalate Tablets Usp, 20 Mg			S	Oral	20 Mg, Qd		Lupin
	Luvox Sr			S	Oral	150 Mg, Qd		Not Reported
	Clonidine			C	Unknown	Prn (As Needed)		Not Reported
	Trazodone			C	Unknown	Prn (As Needed)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15917066	EXPEDITED (15-DAY)		HO	DE-ACCORD-105524		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine	S	Oral	100 Mg, 0-0-0-1, Tablet	Not Reported
	Cipralex	S	Oral	Strength :10 Mg, 1-0-0-0, Tablet	Not Reported
	Valproic Acid	S	Oral	500 Mg, 0-0-0-1, Tablet	Not Reported
	Levothyroxine	C	Oral	75 Microgram, 1-0-0-0, Tablet	Not Reported
	Torasemide	C	Oral	10 Mg, 1-0-0-0, Tablet	Not Reported
	Felodipine	C	Oral	10 Mg, 1-0-0-0, Tablet	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15917174	EXPEDITED (15-DAY)		OT	DE-ACCORD-105349		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 Mg/D		Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental	0.8 Mg/D		Not Reported
	Vaccine Flu			C	Transplacental			Not Reported
	Levothyroxine			C	Transplacental	100 /Mcgd / Initial 75mcg/D, Dosage Increase To 100mcg/D From Week 34+2		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15917656	EXPEDITED (15-DAY)		HO, OT	JP-AMEL-2018-07817AA		70 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thirst	Sulpiride			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Lupin
	Ddavp			C	Unknown	5 Mcg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15918204	EXPEDITED (15-DAY)		OT	IN-TORRENT-00002112		23 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Erotomanic Type; Grandiosity; Judgement Impaired	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15918831	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS-2019M1009321		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Hypotension; Suicide Attempt	Paracetamol			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Mylan
	Ibuprofene			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15920480	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-101053		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Venlafaxine Hydrochloride			S	Oral	Unk Unknown, Unknown		Par
	Escitalopram			S	Oral	Unk Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15920891	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100989		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Hydrocodone Bitartrate, Acetaminophen			S	Oral	Unk, Unknown		Vintage
	Oxycodone Hydrochloride, Acetaminophen			S	Oral	Unk, Unknown		Vintage
	Alprazolam			S	Oral	Unk, Unknown		Dava
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15921144	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1008157		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome; Symptom Masked	Linezolid			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Trazodone			S	Unknown	At Night (Nightly); High-Dose		Not Reported
	Clonazepam			S	Unknown			Not Reported
	Piperacillin/Tazobactam			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	14938562	EXPEDITED (15-DAY)		HO, OT	CH-JNJFOC-20180532750		88 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anxiety; Bradypnoea; Decreased Appetite; Drug Interaction; Toxicity To Various Agents	Durogesic			S	Cutaneous			Not Reported
	Durogesic			S	Cutaneous			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Nexium			S	Oral			Not Reported
	Temesta [Lorazepam]			S	Oral			Not Reported
	Morphine Hcl			S	Unknown			Not Reported

Morphine	S	Unknown	Not Reported
Paracetamol	C	Unknown	Not Reported
Calcimagon D3	C	Unknown	Not Reported
Clopidogrel	C	Unknown	Not Reported
Movicol	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Quetiapine Xr	C	Unknown	Not Reported
Quetiapine	C	Unknown	Not Reported
Clexane	C	Unknown	Not Reported
Diclofenac Epolamine	C	Unknown	Not Reported
Beloc Zok	C	Unknown	Not Reported
Laxoberon	C	Unknown	Not Reported
Anexate	C	Unknown	Not Reported
Atarax	C	Unknown	Not Reported
Ondansetron	C	Unknown	Not Reported
Diclofenac Epolamine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	14966922	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2018-022632			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anhedonia; Asthenia; Chest Pain; Decreased Appetite; Depressed Mood; Drug Ineffective; Drug Intolerance; Gastritis; Palpitations; Parkinsonism; Psychiatric Symptom; Sleep Disorder	Escitalopram			S	Unknown	10 Mg, Unk		Aurobindo
	Mirtazapine			S	Unknown	15 Milligram,Unk		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo
	Sertraline			C	Unknown	Unk		Not Reported
	Bupropion Hydrochloride			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15470968	NON-EXPEDITED			US-TEVA-2018-US-960589			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15923508	EXPEDITED (15-DAY)		HO	FR-ACCORD-105801		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S	Oral			Not Reported
	Atacand			S	Oral			Not Reported
	Plegridy			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15923980	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2019GSK017081			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meniscus Injury; Meniscus Removal	Lamictal			S		Unk		Glaxosmithkline
	Lamictal			S				Glaxosmithkline
	Lamictal			S				Glaxosmithkline
	Levoxyl			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Armour Thyroid			C		Unk		Not Reported
	Effexor			C		Unk		Not Reported
	Effexor			C				Not Reported
	Effexor			C				Not Reported
	Venlafaxine			C		150 Mg, Qd		Not Reported
	Venlafaxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15924595	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-010846			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Metformin Hydrochloride			S	Unknown	Unk		Bristol Myers Squibb
	Carbidopa And Levodopa			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Prevacid			S	Unknown	Unk		Not Reported
	Prozac			S	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15926441	NON-EXPEDITED			US-MYLANLABS-2019M1006039		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Agitation; Irritability	Emsam (Selegiline Transdermal System)			S	Transdermal	Unk		Mylan
	Lexapro			S	Oral	20 Milligram, Qd		Mylan
	Amlodipine			C		Unk		Mylan
	Metoprolol			C		50 Milligram, Bid		Mylan
	Trazodone			C		25 Milligram, Prn		Mylan
	Omeprazole			C		20 Milligram, Bid		Mylan
	Flovent			C		110 Microgram, Bid		Mylan
	Zofran /00955301/			C		4-8 Mg, Prn		Mylan
	Insulin			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15927655	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00013207		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Foetal Exposure During Pregnancy; Transposition Of The Great Vessels	Escitalopram		S	Transplacental	10 [Mg/D (5)]	Unknown
	Skinoren		C	Transplacental	Unknown	Unknown
	Folsure		C	Transplacental	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15927660	EXPEDITED (15-DAY)		OT	DE-TORRENT-00013236		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Tetanus Vaccine			C	Transplacental	Unknown		Unknown
	Escitalopram			S	Transplacental	5 [Mg/D]		Unknown
	L-Thyroxin			C	Transplacental	50 [G/D]		Unknown
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15927672	EXPEDITED (15-DAY)		OT	DE-TORRENT-00013208			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15928998	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2019M1010410		26 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction; Dyskinesia; Hyperhidrosis; Muscle Tightness; Musculoskeletal Stiffness; Myalgia; Serotonin Syndrome	Escitalopram			S	Oral	10 Milligram, Qd (1 Keer Per Dag 1 Tablet)		Not Reported
	Sumatriptan			S	Oral	Bij Migraine 1 Tablet, Herhaal Zo Nodig 2 Keer Per Dag, Wacht Meer Dan 2 Uur Na De Vorige Tablet.		Not Reported

	Loperamide	C	2 Milligram (Zo Nodig 6 Keer Per Dag 1 Capsule)	Mylan
	Imodium	C	2 Milligram, Qd (1dd1)	Mylan
	Colestyramine	C	4 Gram, Bid (2dd1)	Mylan
	Oxazepam	C	10 Milligram (Zo Nodig 1 Keer Per Dag 1 Tablet)	Mylan
	Psylliumvezels	C	2 Keer Per Dag Zo Nodig 1 Zakje	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15929791	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1905127US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	13362853	EXPEDITED (15-DAY)		DE, HO	FR-CELGENEUS-FRA-2017032245		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Revlimid			S	Oral	25 Milligram		Celgene
	Zyloric			S	Oral	300 Milligram		Not Reported
	Dexamethasone Oral			S	Oral	5.7143 Milligram		Not Reported
	Augmentin			S	Oral	3 Gram		Not Reported
	Ciprofloxacin			S	Oral	1000 Milligram		Not Reported
	Sodium Pamidronate			S	Intravenous drip	30 Milligram		Not Reported
	Seroplex			S	Oral	1 Dosage Forms		Not Reported
	Bactrim			C	Oral	400 Milligram		Not Reported
	Bactrim			C	Oral			Not Reported
	Lyrica			C	Oral	50 Milligram		Not Reported

	Lyrica	C	Oral		Not Reported
	Seresta	C	Oral	10 Milligram	Not Reported
	Seresta	C	Oral		Not Reported
	Mianserine	C	Oral	30 Milligram	Not Reported
	Mianserine	C	Oral		Not Reported
	Zelitrex	C	Oral	1000 Milligram	Not Reported
	Zelitrex	C	Oral		Not Reported
	Lovenox	C	Subcutaneous	14000 Iu (International Unit)	Not Reported
	Lovenox	C	Subcutaneous		Not Reported
	Durogesic	C	Unknown		Not Reported
	Gaviscon	C	Unknown		Not Reported
	Previscan	C	Unknown	15 Milligram	Not Reported
	Paracetamol	C	Unknown		Not Reported
	Movicol	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Tamiflu	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	14302133	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2017-45878			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Alprazolam			S	Oral	0.75 Milligram, Daily, 0.25 Mg, 3x/Day (Tid)		Aurobindo
	Amlodipine Capsule, Hard			S	Oral	10 Mg, Once Daily (Qd)		Aurobindo
	Bisoprolol			S	Oral	1.25 Milligram, Once A Day, 1.25 Mg, Qd		Aurobindo
	Mirtazapine			S	Oral	15 Mg, Once Daily (Qd)		Aurobindo
	Furosemide			S	Oral	30 Mg Daily (2-1-0), 2x/Day (Bid)		Not Reported
	Furosemide			S	Oral	Bid		Not Reported

Furosemide	S	Oral	Unk Unk, Once A Day	Not Reported
Irbesartan	S	Oral	300 Milligram, Once A Day, 300 Mg, Qd	Aurobindo
Metformin Film-Coated Tablet	S	Oral	1000 Milligram, Once A Day, 500 Mg, 2x/Day (Bid)	Aurobindo
Pantoprazole	S	Oral	20 Mg, Qd	Aurobindo
Terbutaline	S		1 Dosage Form, Daily, 1 Df, Qd	Not Reported
Dafalgan	S	Oral	1000 Mg, 3x/Day (Tid)	Not Reported
Nefopam Hydrochloride	S	Oral	3 Df, Unk	Not Reported
Nefopam Hydrochloride	S	Oral	3 Mg, Qd	Not Reported
Diffu K	S	Oral	6 Df, Qd, 6 Df, Qd (3 Df Daily (2-1-0) 2x/Day (Bid))	Not Reported
Colchicine Opocalium	S	Oral	1 Mg, Once Daily (Qd)	Not Reported
Xarelto	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Seroplex	S	Oral	1 Df, Once Daily (Qd)	Not Reported
Tavanic	S	Oral	250 Mg, 2x/Day (Bid)	Not Reported
Tavanic	S	Oral	500 Milligram, Once A Day,250 Mg, Bid	Not Reported
Valium	S	Oral	3 Dosage Form, Daily, 10 Mg, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	14379249	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-001929			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Alprazolam			S	Oral	0.75 Mg, Qd		Aurobindo
	Amlodipine			S	Oral	10 Mg, Qd		Aurobindo
	Bisoprolol			S	Oral	1.25 Mg, Qd		Aurobindo
	Diazepam			S	Oral	30 Mg, Qd		Not Reported
	Furosemide			S	Oral	30 Mg, Qd		Not Reported

	Furosemide	S	Oral	2 Unk, Qd (1)	Not Reported
	Furosemide	S	Oral	1 Unk, Once A Day, 2 Ot, Qd	Not Reported
	Irbesartan	S	Oral	300 Mg, Qd	Aurobindo
	Irbesartan	S	Oral	300 Mg, Qd	Aurobindo
	Metformin	S	Oral	1000 Mg, Qd	Aurobindo
	Mirtazapine	S	Oral	15 Mg, Qd	Aurobindo
	Pantoprazole	S	Oral	20 Mg, Qd	Aurobindo
	Terbutaline	S	Respiratory (inhalation)	1 Df, Qd	Not Reported
	Diffu K	S	Oral	6 Df, Qd	Not Reported
	Xarelto	S	Oral	20 Mg, Qd	Not Reported
	Dafalgan	S	Oral	3000 Mg, Qd	Not Reported
	Colchicine Opocalcium	S	Oral	1 Mg, Qd	Not Reported
	Nefopam	S	Oral	3 Df, Qd	Not Reported
	Seroplex	S	Oral	1 Df, Qd	Not Reported
	Tavanic	S	Oral	500 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15930338	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-033250		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Drug Interaction; Frequent Bowel Movements; Myoclonus; Serotonin Syndrome; Symptom Masked; Tremor	Escitalopram			S	Unknown			Zydus Pharm
	Linezolid			S	Unknown			Zydus Pharm
	Trazodone			S	Unknown			Zydus Pharm
	Trazodone			S	Unknown			Zydus Pharm
	Clonazepam			S	Unknown			Not Reported
	Piperacillin/Tazobactam			C	Unknown			Not Reported
	Amikacin			C	Unknown			Not Reported
	Ceftaroline			C	Unknown			Not Reported

	Vancomycin	C	Unknown	Not Reported
	Metronidazole	C	Unknown	Not Reported
	Cefepime	C	Unknown	Not Reported
	Ceftriaxone	C	Unknown	Not Reported
	Azithromycin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15931107	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Disorder; Tachyphrenia	Escitalopram			S				Not Reported
	Sertraline			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15931336	EXPEDITED (15-DAY)		HO	US-SA-2019SA034998		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Hypotension; Presyncope; Sinus Tachycardia	Lasix			S	Unknown	40 Mg, Qod		Sanofi
	Metoprolol Tartrate			S	Unknown	25 Mg, Bid		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Qd In Morning		Not Reported
	Rosuvastatin Calcium			S	Oral	10 Mg, Qd		Not Reported
	Senna Alexandrina			S	Oral	8.6 Mg, Bid		Not Reported
	Cabazitaxel			S	Unknown	Unk		Sanofi
	Carboplatin			S	Unknown	Unk		Not Reported
	Methylphenidate			S	Unknown	10 Mg,Twice Daily Prn		Not Reported
	Eliquis			S	Oral	5 Mg, Bid		Not Reported
	Norco			S	Oral	10 Mg, Q8h Prn		Not Reported
	Norco			S	Unknown	Q8 Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15931461	EXPEDITED (15-DAY)		DS	FI-ACCORD-104226		37 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Aphasia; Cushingoid; Derealisation; Dizziness; Drug Withdrawal Syndrome; Dysarthria; Dysgraphia; Dyspnoea; Erythema; Face Oedema; Facial Pain; Headache; Hyperhidrosis; Insomnia; Mydriasis; Oedema; Polyuria; Pyrexia; Sympathomimetic Effect; Tremor; Vision Blurred	Escitalopram			S				Not Reported
	Voxra			S	Oral	450,Mg,Daily		Not Reported
	Triptyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15931984	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2019SE18381		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Nuchal Rigidity; Suicide Attempt	Seroquel			S	Oral	6.0g Once/Single Administration		Zeneca
	Escitalopram Oxalate			S	Oral	3920.0mg Once/Single Administration		Not Reported
	Felison			S	Oral	900.0mg Once/Single Administration		Not Reported
	Tavor (Lorazepam)			S	Oral	50.0mg Once/Single Administration		Not Reported
	Zoloft			S	Oral	6.0g Once/Single Administration		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15933258	EXPEDITED (15-DAY)		HO	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000028		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Hypotension; Presyncope; Sinus Tachycardia	Lasix			S	Unknown	40 Mg, Qod		Validus
	Lopressor			S	Unknown	25 Mg, Bid		Validus
	Lexapro			S	Oral	10 Mg, In Morning		Not Reported
	Norco			S	Oral	10 Mg, Every 8 Hours, Prn		Not Reported
	Norco			S		Q 8, Prn		Not Reported
	Eliquis			S	Oral	5 Mg, Bid		Not Reported
	Crestor			S	Oral	10 Mg, Qd		Not Reported
	Senna /00142201/			S	Oral	8.6 Mg, Bid		Not Reported
	Methylphenidate			S		10 Mg, Bid (Prn)		Not Reported
	Cabazitaxel			S		Unk		Not Reported
	Carboplatin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15934524	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2019M1011088		59 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Moaning	Alprazolam			S	Oral	Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Trilafon /00023401/			S	Oral	Unk		Mylan
	Ramipril			C	Oral	2.5 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15934889	EXPEDITED (15-DAY)		HO	FR-ASCEND THERAPEUTICS-2062319		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Meningioma	Estrogel			S	Transdermal			Ascend
	Androcur (Cyproterone Acetate)			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15934912	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1905271US		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Loss	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Prolia			S	Subcutaneous	60 Mg, Q6mo		Not Reported
	Calcimagon D3			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	13953995	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-ACCORD-058259		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Loss Of Consciousness; Suicide Attempt; Tinnitus; Tinnitus	Escitalopram			S	Oral	Doctor Switched The Patient From Sertraline To Escitalopram		Accord
	Tramadol/Tramadol Hydrochloride			S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago		Accord
	Sertraline			S	Oral	Morning Dose Of 50 Mg		Accord
	Bisoprolol			S	Unknown			Accord
	Clarithromycin/Clarithromycin Lactobionate			S	Oral	Two 10 Day Cycles.		Accord
	Trosicam			S	Oral	Tramadol In Combination With Meloxicam, For About Two Years Ago		Not Reported
	Atorvastatin			S		Unk (Bedtime)		Not Reported
	Perindopril/Perindopril Erbumine			S	Oral			Not Reported

Zolpidem	S	Oral	10 Mg At Bedtime		Not Reported
Doxepin	S	Oral	25 Mg Overnight		Not Reported
Atorvastatin	C				Not Reported
Perindopril/Perindopril Erbumine	C				Not Reported
Movalis	S		Tramadol In Combination With Meloxicam, For About Two Years Ago		Not Reported
Polsen	S	Oral	10 Mg At Bedtime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15935891	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-ACCORD-104977		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral			Not Reported
	Adcal-D3			C				Not Reported
	Metformin			C				Not Reported
	Generics Uk Nifedipine			C				Not Reported
	Pregabalin			C				Not Reported
	Nefopam			C				Not Reported
	Tiotropium			C				Not Reported
	Sodium Picosulfate			C				Not Reported
	Cetirizine			C				Not Reported
	Naproxen			C				Not Reported
	Diazepam			C				Not Reported
	Cassia (Senna Alexandrina)			C				Not Reported
	Methotrexate			C				Not Reported
	Budesonide/Formoterol Fumarate			C				Not Reported
	Lansoprazole			C				Not Reported
	Meptazinol			C				Not Reported
	Quetiapine			C				Not Reported
	Temazepam			C				Not Reported
	Montelukast			C				Not Reported
	Pyridoxine			C				Not Reported
	Folic Acid			C				Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936040	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-006319			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura; Rash Pruritic	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Alprazolam			S	Oral	0.25 Milligram, Once A Day		Aurobindo
	Xgeva			S	Subcutaneous	120 Milligram, In Total		Not Reported
	Aromasine			C	Oral	25 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936067	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2019-006196			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Sluggishness	Alprazolam			S	Oral	20 Milliliter, In Total		Aurobindo
	Escitalopram Oxalate			S	Oral	30 Milliliter, In Total		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936252	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1008720		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura; Rash Pruritic	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Alprazolam			S	Oral	.25 Milligram Daily;		Actavis
	Xgeva 120 Mg, Solution Injectable			S	Subcutaneous			Not Reported
	Aromasine 25 Mg, Comprimé Enrobé			C	Oral	25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936643	EXPEDITED (15-DAY)		OT	PL-PRINSTON PHARMACEUTICAL			Unknown	POL

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown			Prinston Pharmaceutical
	Ginseng			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15937064	EXPEDITED (15-DAY)		HO	BE-ACCORD-104489		25 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Lactation Disorder; Maternal Exposure During Pregnancy	Aripiprazole			S	Oral			Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15937109	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2019AP007214		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Respiratory Depression	Escitalopram			S	Oral	15 Mg, Qd		Apotex
	Neurontin			S	Oral	300 Mg, Tid		Not Reported
	Trankimazin			S	Oral	1 Mg, Qd		Not Reported
	Durogesic			S	Transdermal	150 Mg, 72 Hours		Not Reported
	Sevredol			S	Oral	10 Mg, 1 Necessary		Not Reported
	Zovirax /00587301/			C	Unknown			Not Reported
	Nolotil /00473101/			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Zyloric			C	Unknown			Not Reported

	Seguril	C	Unknown	Not Reported
	Binocrit	C	Subcutaneous	Not Reported
	Clexane	C	Subcutaneous	Not Reported
	Pantoprazol /01263201/	C	Unknown	Not Reported
	Natecal D	C	Unknown	Not Reported
	Mycostatin	C	Unknown	Not Reported
	Hidroxil B12 B6 B1	C	Unknown	Not Reported
	Seretide Accuhaler	C	Unknown	Not Reported
	Borea	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15937391	EXPEDITED (15-DAY)		HO	BR-TORRENT-00004851		58 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder	Espran			S	Oral	Unknown		Torrent
	Lorax//Lorazepam			C	Oral	2 Tablets Daily		Unknown
	Dormonid			C	Unknown	Unknown, She Used It Once		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15939783	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1905600US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15939808	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1905587US		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Food Intolerance;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan

Gastrointestinal Pain; Migraine; Nausea; Nervous System Disorder; Serotonin Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15940612	EXPEDITED (15-DAY)		HO, LT	NL-MYLANLABS-2019M1011240		69 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram			S	Oral	10 Milligram, Qd (1 X Per Dag 1 Stuk)		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15941206	EXPEDITED (15-DAY)		OT	CA-OTSUKA-2019_003295		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Dizziness; Fatigue; Hyperhidrosis; Hypertension; Myalgia; Panic Disorder; Product Use In Unapproved Indication; Salivary Hypersecretion; Vomiting	Abilify			S	Oral	5 Mg (In The Morning)		Otsuka
	Abilify			S				Otsuka
	Escitalopram Oxalate			S	Oral	20 Mg (In The Evening)		Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15941637	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2019	15917147	EXPEDITED (15-DAY)		HO	IT-ACCORD-105519		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported
	Minias			S	Oral	Strength : 2.5 Mg / Ml, Oral Drops, Solution		Not Reported
	Paroxetine			S	Oral	Strength : 20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2019	14764255	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2017PL101604		62 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope; Tachycardia	Metoprolol Succinate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zolpidem			S	Oral	10 Mg, Qd, Before Sleep		Novartis
	Escitalopram			S	Unknown			Not Reported
	Ivabradine			S	Unknown			Not Reported
	Cyproheptadine			S	Unknown	16 Mg, Unk		Not Reported
	Venlafaxine			S	Oral	150 Mg In The Morning, In The Afternoon		Not Reported
	Moclobemide			S	Oral	150 Mg, In Afternoon		Not Reported
	Trazodone			S	Oral	50 Mg, At Night		Not Reported
	Sertraline			S	Oral	50 Mg, At Night		Not Reported
	Moklar			S	Unknown	150 Mg, Qd		Not Reported
	Sotalol			C	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported
	Ginkgo Biloba Extract			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15944239	EXPEDITED (15-DAY)			FR-UCBSA-2019004502		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Thrombocytopenia	Keppra	S	Oral	1500 Mg Daily	Ucb
	Seroplex	S	Oral	20 Mg Daily	Not Reported
	Seroplex	S			Not Reported
	Dantrium	C		25 Mg	Not Reported
	Lovenox	C		Unk	Not Reported
	Lioresal	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15945677	EXPEDITED (15-DAY)		OT	IN-ACCORD-105722		23 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Erotomanic Type	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15946502	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1011513		73 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Gait Disturbance	Quetiapine			S	Oral	150 Milligram, Qd		Not Reported
	Lorans			S	Oral	1 Dosage Form, Qd		Mylan
	Carbolithium			S	Oral	1.5 Dosage Form, Qd		Mylan
	Cipralex /01588501/			S	Oral	0.5 Dosage Form, Qd		Mylan
	Lorans			S	Oral	1 Dosage Form, Qd		Mylan
	Motilium /00498201/			C		Unk		Mylan
	Omeprazen /00661201/			C		Unk		Mylan
	Metformina Teva			C		Unk		Mylan
	Eskim			C		Unk		Mylan
	Totalip			C		Unk		Mylan
	Nicetile			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15950112	NON-EXPEDITED			US-TAKEDA-2019TUS004873			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Trintellix			S	Oral	Unk		Takeda
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15950509	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1011314		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported
	Stresam			S	Oral	3 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	13343976	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1709923US		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Gastrointestinal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Augmentin			S	Oral	1 G, Tid		Not Reported
	Ciprofloxacine			S	Oral	500 Mg, Qd		Not Reported
	Dexamethasone			S	Oral	40 Mg, Qweek		Not Reported
	Disodium Pamidronate			S	Intravenous (not otherwise specified)	30 Mg, Qd		Not Reported
	Revlimid			S	Oral	25 Mg, Qd		Not Reported
	Zyloric			S	Oral	300 Mg, Qd		Not Reported
	Previscan			C	Unknown	15 Mg, Qd		Not Reported
	Previscan			C		Unk		Not Reported
	Bactrim			C	Oral	Unk		Not Reported

Bactrim	C	Oral	400 Mg, Q Week		Not Reported
Durogesic	C	Unknown	Unk		Not Reported
Furosemide	C	Unknown	20 Mg, Unk		Not Reported
Gaviscon	C	Unknown	Unk		Not Reported
Lovenox	C	Subcutaneous	Unk		Not Reported
Lovenox	C	Subcutaneous	7000 Iu, Bid		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Lyrica	C	Oral	25 Mg, Bid		Not Reported
Mianserine	C	Oral	Unk		Not Reported
Mianserine	C	Oral	30 Mg, Qd		Not Reported
Movicol	C	Unknown	Unk		Not Reported
Paracetamol	C	Unknown	Unk		Not Reported
Seresta	C	Oral	Unk		Not Reported
Seresta	C	Oral	10 Mg, Qd		Not Reported
Tamiflu	C	Unknown	Unk		Not Reported
Zelitrex	C	Oral	500 Mg, Bid		Not Reported
Zelitrex	C	Oral	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	14207004	EXPEDITED (15-DAY)		HO, OT	ES-LUPIN PHARMACEUTICALS INC.-2017-06633		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Food Interaction; Haemodynamic Instability; Haemorrhage	Escitalopram Oxalate			S	Oral	5 Mg, Qd (At Breakfast, For Several Years)		Lupin
	Emconcor			C	Oral	1.25 Mg, Bid (At Breakfast And Dinner, Every 12 Hours)		Not Reported
	Simvastatina Cinfa			C	Oral	20 Mg, Qd (At Dinner)		Not Reported
	Hibor (Bemiparin Sodium)			C	Subcutaneous	3500 Iu Anti-Xa/0.2 Ml Solution For Injection In Pre-Filled Syringe; In The		Not Reported

Evening

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	14282047	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017524123		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Alprazolam			S	Oral	0.25 Mg, 3x/Day		Pfizer
	Alprazolam			S	Oral	0.75 Mg, 3x/Day		Pfizer
	Alprazolam			S		0.75 Mg, 1x/Day		Pfizer
	Amlodipine Besilate			S	Oral	10 Mg, 1x/Day		Pfizer
	Pantoprazole			S	Oral	20 Mg, 1x/Day		Pfizer
	Metformin			S	Oral	500 Mg, 2x/Day		Not Reported
	Metformin			S	Oral	1000 Mg, 1x/Day/Qd		Not Reported
	Mirtazapine			S	Oral	15 Mg, 1x/Day		Not Reported
	Furosemide			S	Oral	30 Mg, 1x/Day		Not Reported
	Furosemide			S	Oral	2 Df, 1x/Day		Not Reported
	Irbesartan			S	Oral	300 Mg, 1x/Day		Not Reported
	Irbesartan			S		500 Mg, 2x/Day		Not Reported
	Dafalgan			S	Oral	1000 Mg, 3x/Day		Not Reported
	Dafalgan			S		6 Df, Daily		Not Reported
	Dafalgan			S	Oral	1000 Mg, 3x/Day		Not Reported
	Nefopam			S	Oral	1 Df, 3x/Day		Not Reported
	Nefopam			S	Oral	3 Df, 3x/Day		Not Reported
	Nefopam			S	Oral	3 Ug, 1x/Day		Not Reported
	Nefopam			S		3 Df, 1x/Day		Not Reported
	Diffu K			S	Oral	3 Df (2-1-0), 2x/Day		Not Reported
	Diffu K			S	Oral	6 Df, 1x/Day/Qd		Not Reported
	Colchicine Opocalcium			S	Oral	1 Mg, 1x/Day		Not Reported
	Colchicine Opocalcium			S	Oral	1 Df, 1x/Day/Qd		Not Reported

Xarelto	S	Oral	20 Mg, 1x/Day		Not Reported
Xarelto	S		1 Df, Unk		Not Reported
Xarelto	S		1 Df, 1x/Day		Not Reported
Seroplex	S	Oral	1 Df, 1x/Day		Not Reported
Tavanic	S	Oral	250 Mg, 2x/Day		Not Reported
Tavanic	S	Oral	500 Mg, Daily		Not Reported
Tavanic	S	Oral	2 Df, 1x/Day		Not Reported
Diazepam	S	Oral	10 Mg, 3x/Day (If Needed)		Not Reported
Diazepam	S	Oral	30 Mg, 1x/Day/Qd		Not Reported
Bisoprolol Fumarate	S	Oral	1.25 Mg, 1x/Day		Not Reported
Terbutaline Sulfate	S	Respiratory (inhalation)	1 Df, 1x/Day		Not Reported
Terbutaline Sulfate	S	Respiratory (inhalation)	1 Ug, Unk		Not Reported
Valium	S	Oral	10 Mg, 3x/Day, If Needed		Not Reported
Valium	S	Oral	3 Ug, 1x/Day/Qd		Not Reported
Valium	S		3 Df, Daily		Not Reported
Nefopam Hydrochloride	S	Oral	3 Ug, 1x/Day/Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15580025	EXPEDITED (15-DAY)		HO, OT	PHHY2018AT144314			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Alcoholism; Apraxia; Behaviour Disorder; Cognitive Disorder; Dementia; Dementia With Lewy Bodies; Depression; Drug Ineffective; Dysphoria; Hallucination, Visual; Insomnia; Korsakoff'S Syndrome;	Rivastigmine			S	Transdermal	Unk (Transdermales Pflaster 4,6mg/24h)		Novartis
	Rivastigmine			S	Transdermal	4.6 Mg, Qd		Novartis
	Quetiapine			S	Oral	25 Mg, Qd		Not Reported
	Quetiapine			S	Oral	100 Mg, Qd		Not Reported
	Valproic Acid			S	Unknown	1000 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Unk		Not Reported

Mania; Muscle Rigidity; Parkinsonism; Restlessness; Sleep Disorder; Tremor; Urinary Incontinence	Escitalopram	S	Unknown	10 Mg, Unk	Not Reported
	Escitalopram	S	Unknown	3 Mg, Qd	Not Reported
	Risperidone	S	Unknown	3 Mg, Qd	Not Reported
	Risperidone	S	Unknown	1 Mg, Unk	Not Reported
	Naltrexone	S	Unknown	Unk	Not Reported
	Risperdal	S	Unknown	Unk	Not Reported
	Lorazepam	S	Unknown	Unk	Not Reported
	Piracetam	S	Unknown	1200 Mg, Unk	Not Reported
	Cerebrolysin	S	Unknown	Unk	Not Reported
	Pregabalin	S	Oral	25 Mg, Bid	Not Reported
	Oxazepam	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15613742	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1085728		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Esomeprazole			S	Oral	40 Mg, Qd		Not Reported
	Esidrex			S	Oral	0.5 Df, Qd		Mylan
	Seroplex			S	Oral	1 Dosage Form, Qd		Mylan
	Procoralan			C		Unk		Mylan
	Aspirin /00002701/			C		Unk		Mylan
	Seresta			C		Breackable		Mylan
	Dafalgan			C		Unk		Mylan
	Pravastatine /00880401/			C		Unk		Mylan
	Mediatensyl /00631801/			C		Unk		Mylan
	Ramipril			C		Unk		Mylan
	Acebutolol /00405702/			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15779198	NON-EXPEDITED			US-PFIZER INC-2018534559		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Asa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15805244	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019009533		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Sluggishness	Alprazolam			S	Oral	20 Ml, Single		Pfizer
	Escitalopram Oxalate			S	Oral	30 Ml, Single		Not Reported
	Omeprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15815207	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-101426		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor; Suicide Attempt	Escitalopram			S	Oral			Not Reported
	Lexotan			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Lamictal			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15838200	EXPEDITED (15-DAY)		HO, OT	PHHY2018PL184404		52 YR	Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Constipation; Decreased Appetite; Drug Ineffective; Dyschezia; Medication Error; Pain; Pneumonia; Weight Decreased	Escitalopram		S	Unknown	Unk	Not Reported
	Omeprazole		S	Unknown	20 Mg, In The Morning, Fasting	Novartis
	Tramadol Hydrochloride		S	Unknown	100 Mg, Bid (Sustained Release)	Not Reported
	Metamizole		S	Unknown	Unk	Not Reported
	Ketoprofen		S	Unknown		Not Reported
	Alprazolam		S	Unknown		Not Reported
	Buprenorphine		S	Unknown	35 Ug, Unk (Per Hour Every 4 Days)	Not Reported
	Valproic Acid		C	Unknown		Not Reported
	Betamethason		C	Unknown		Not Reported
	Trazodone		C	Unknown		Not Reported
	Zoledronic Acid		C	Unknown		Not Reported
	Morphine		C	Unknown		Not Reported
	Gabapentin		C	Unknown		Not Reported
	Metoclopramide		C	Unknown	30 Mg, Qd	Not Reported
	Effentora		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15904470	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-105266		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral			Not Reported
	Indapamide			S	Oral			Not Reported
	Lactulose			C				Not Reported
	Perindopril/Perindopril Erbumine			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15917899	NON-EXPEDITED			US-PFIZER INC-2019048861		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Chest Pain; Drug Ineffective For Unapproved Indication	Gabapentin			S		400 Mg, 3x/Day		Pfizer
	Gabapentin			S				Pfizer
	Buspirone			S		Unk		Not Reported
	Buspirone			S				Not Reported
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Lamotrigine			S		Unk		Not Reported
	Lamotrigine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15944840	DIRECT		DS, OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor; Tremor	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Accord
	Atenolol			C				Not Reported
	Brilinta			C				Not Reported
	Aspirin			C				Not Reported
	Celebrex			C				Not Reported
	Multivitamin			C				Not Reported
	Fish Oil			C				Not Reported
	Co Q10			C				Not Reported
	Potassium			C				Not Reported
	Glucosamine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15947303	EXPEDITED (15-DAY)		DS, OT	FR-AUROBINDO-AUR-APL-2019-006726			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral	5 Milligram, Once A Day		Aurobindo
	Eliquis			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Digoxin			C	Unknown	Unk		Not Reported

	Loxen L P	C	Unknown	Unk	Not Reported
	Lopressor	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15948026	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2019-006578			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Nuchal Rigidity; Suicide Attempt	Escitalopram Film-Coated Tablets			S	Oral	3920 Milligram, Total		Aurobindo
	Felison			S	Oral	900 Milligram, Total		Not Reported
	Seroquel			S	Oral	6 Gram, In Total		Not Reported
	Tavor (Lorazepam)			S	Oral	50 Milligram, Total		Not Reported
	Zoloft			S	Oral	6 Gram, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15948259	NON-EXPEDITED			US-TEVA-2019-US-998906			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Escitalopram Oxalate			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15948515	EXPEDITED (15-DAY)		CA	DE-ACCORD-106609		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 (Mg/D) / Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15948581	EXPEDITED (15-DAY)		HO	FR-ACCORD-106653		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Vertigo	Escitalopram			S	Oral			Not Reported
	Aldactazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15948584	EXPEDITED (15-DAY)		DE, HO, OT	FR-ACCORD-106507		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage Intracranial	Escitalopram			S	Oral			Not Reported
	Duoplavin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15948875	EXPEDITED (15-DAY)		HO	IT-ACCORD-106640		31 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Impaired Gastric Emptying; Vomiting	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15949215	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-012443		< 1 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Premature Baby	Nulojix			S	Transplacental	300 Mg (5mg/Kg), Q4wk		Bristol Myers Squibb
	Nulojix			S	Transmammary	300 Mg (5mg/Kg), Q4wk		Bristol Myers Squibb
	Envarsus			S	Transplacental	Unk		Not Reported

	Imuran /00001501/	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Miacalcin	S	Transplacental	Unk	Not Reported
	Zantac	S	Transplacental	Unk	Not Reported
	Imitrex /01044801/	S	Transplacental	Unk	Not Reported
	Lexapro	S	Transplacental	Unk	Not Reported
	Phenergan /00033001/	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15949306	EXPEDITED (15-DAY)		OT	IN-MACLEODS PHARMACEUTICALS US LTD-MAC2019020040			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusional Disorder, Erotomanic Type	Escitalopram 10 Mg Film Coated Tablet			S	Oral	10 Milligram, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15949451	EXPEDITED (15-DAY)		HO	PHHY2019IT030225		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Psychomotor Skills Impaired	Quetiapine Fumarate			S	Oral	500 Mg, Unk (Total)		Not Reported
	Lorazepam			S	Oral	250 Mg, Unk (Total)		Novartis
	Escitalopram Oxalate			S	Oral	100 Mg, Unk (Total)		Not Reported
	Trittico			S	Oral	10 Mg, Unk (Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15951952	EXPEDITED (15-DAY)		LT, OT	FR-MYLANLABS-2019M1012138		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase	Escitalopram			S	Oral	Unk		Not Reported

Increased; Miosis; Prothrombin Time Shortened; Suicide Attempt; Tachycardia; Vomiting	Dafalgan Codeine		S	Oral	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15951983	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2019M1012159		61 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthyroidism	Escitalopram			S	Oral	10 Milligram, Qd (1dd)		Not Reported
	Ptu			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15952816	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019054837		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura; Rash Pruritic	Alprazolam			S	Oral	0.25 Mg, 1x/Day		Pfizer
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Xgeva			S	Subcutaneous	120 Mg, Single		Not Reported
	Aromasine			C	Oral	25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15953528	EXPEDITED (15-DAY)		HO	IT-BAUSCH-BL-2019-003874		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Psychomotor Skills Impaired	Lorazepam			S	Oral	In Total		Not Reported
	Quetiapine Fumarate			S	Oral	In Total		Not Reported
	Escitalopram Oxalate			S	Oral	In Total		Not Reported
	Trittico			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15954292	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2019M1011857		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Metoprolol			S	Transplacental	Unk Unk, Qd (71.25 [Mg/D]/ 47.5-0-23.75 Mg/D)		Not Reported
	Amitriptyline			S	Transplacental	37.5 Milligram, Qd (37.5 [Mg/D])		Not Reported
	Cipralex /01588502/			S	Transplacental	5 [Mg/D]		Mylan
	Paracetamol			C	Transplacental	Unk Unk, Qd (2000 [Mg/D]/ 1-2 G/D If Required)		Mylan
	Clexane			C	Transplacental	Unk Unk, Qd (120 [Mg/D (-40)]/ Initial 40mg/D, Dosage Increase To 2 X 60 Mg/D)		Mylan
	Ibuprofen			C	Transplacental	600 Milligram, Qd (600 [Mg/D]/ If Required)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	14241423	EXPEDITED (15-DAY)		HO	FR-ROCHE-2031433		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Terbutaline Sulphate			S	Respiratory (inhalation)			Not Reported
	Terbutaline Sulphate			S	Respiratory (inhalation)			Not Reported
	Dafalgan			S	Oral			Not Reported
	Dafalgan			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

Amlodipine Besilate	S	Oral		Not Reported
Irbesartan	S	Oral		Not Reported
Irbesartan	S	Oral		Not Reported
Nefopam Hydrochloride	S	Oral		Not Reported
Nefopam Hydrochloride	S	Oral		Not Reported
Bisoprolol Hemifumarate	S	Oral		Not Reported
Diffu K	S	Oral	3 Df Daily (2-1-0), Bid	Not Reported
Valium	S	Oral		Not Reported
Valium	S	Oral		Not Reported
Valium	S	Oral		Not Reported
Mirtazapine	S	Oral		Not Reported
Furosemide	S	Oral	30 Mg Daily (2-1-0), 2 Times A Day	Not Reported
Furosemide	S	Oral	2 Ot, Qd	Not Reported
Tavanic	S	Oral		Not Reported
Metformin Hydrochloride	S	Oral		Not Reported
Colchicine Opocalcium	S	Oral		Not Reported
Alprazolam	S	Oral		Not Reported
Alprazolam	S	Oral	0.75 Mg Three Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15883058	EXPEDITED (15-DAY)		DE, HO, OT	FR-AUROBINDO-AUR-APL-2019-003018			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder; Suicidal Ideation; Withdrawal Syndrome	Mirtazapine Film-Coated Tablet			S	Oral	Unk		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo
	Seroplex			S	Unknown	Unk, Pkgid=Unknown		Not Reported
	Lysanxia			S	Unknown	Unk		Not Reported
	Norset			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15932468	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US-1007529		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Frequent Bowel Movements; Serotonin Syndrome; Symptom Masked	Linezolid			S	Unknown			Teva
	Escitalopram			S	Unknown	20 Milligram Daily;		Ivax
	Trazodone			S	Unknown	300 Milligram Daily; At Night (Nightly); High-Dose		Actavis
	Trazodone			S	Unknown	150 Milligram Daily; At Night		Actavis
	Clonazepam			S	Unknown			Teva
	Piperacillin/Tazobactam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15954759	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-007211			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	5 Milligram, Daily (5 [Mg/D])		Aurobindo
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental	Unk		Not Reported
	L-Thyroxin			C	Transplacental	50 Microgram, Daily (50 [Mg/D])		Not Reported
	Tetanus Vaccine			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15954870	EXPEDITED (15-DAY)		DE, HO, OT	FR-AUROBINDO-AUR-APL-2019-007342			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Reaction With Eosinophilia And Systemic Symptoms	Ciprofloxacin	S	Oral	500 Milligram, Once A Day (1000 Milligram)	Aurobindo
	Dexamethasone	S	Oral	40 Milligram Once In A Week (5.7143 Milligram)	Not Reported
	Revlimid	S	Oral	25 Milligram (28 Day)	Not Reported
	Augmentin	S	Oral	1 Gram, Once A Day (3 Gram)	Not Reported
	Pamidronate Disodium	S	Intravenous drip	30 Milligram, Once A Day	Not Reported
	Zyloric	S	Oral	300 Milligram, Once A Day	Not Reported
	Seroplex	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Zelitrex	C	Oral	Unk	Not Reported
	Zelitrex	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Zelitrex	C	Oral	500 Milligram, Once A Day(1000 Milligram)	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Lyrica	C	Oral	25 Milligram, Once A Day (50 Milligram)	Not Reported
	Durogesic	C	Unknown	Unk	Not Reported
	Gaviscon	C	Unknown	Unk	Not Reported
	Movicol	C	Unknown	Unk	Not Reported
	Lovenox	C	Subcutaneous	Unk	Not Reported
	Lovenox	C	Subcutaneous	7000 International Unit, Once A Day (14000 Iu (International Unit))	Not Reported
	Bactrim	C	Oral	400 Milligram Once In A Week	Not Reported
	Bactrim	C	Oral	Unk	Not Reported
	Seresta	C	Oral	Unk	Not Reported
	Seresta	C	Oral	10 Milligram, Once A Day	Not Reported

Mianserine	C	Oral	30 Milligram, Once A Day		Not Reported
Mianserine	C	Oral	Unk		Not Reported
Furosemide	C	Unknown	20 Milligram, Unk		Not Reported
Previscan	C	Unknown	15 Milligram, Once A Day		Not Reported
Tamiflu	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15954893	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-007406			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram 5 Mg			S	Unknown	5 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15955348	EXPEDITED (15-DAY)		HO	GB-TORRENT-00020313		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyarrhythmia; Circulatory Collapse	Elleste-Solo			C	Transdermal			Unknown
	Escitalopram Oxalate			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15955858	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-00067			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia	Blinded Escitalopram			S				Not Reported
	Blinded Aripiprazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15955941	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1905931US		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Transposition Of The Great Vessels	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd; 0. - 5.5. Gestational Week		Allergan
	Skinoren			C	Transplacental	Preconceptional		Not Reported
	Folsaure			C	Transplacental	4.4. - 5.3. Gestational Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15956823	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1012013		90 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Delirium; Fall; Post Procedural Haemorrhage; Traumatic Haemorrhage	Escitalopram			S	Unknown	15 Milligram, Qd (15 Mg, Per Day)		Not Reported
	Eliquis			S	Unknown	Unk		Mylan
	Eliquis			S	Unknown	10 Milligram, Qd (5 Mg, Bid)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15956935	EXPEDITED (15-DAY)		HO, LT, OT	RO-ALLERGAN-1906116US		51 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Overdose; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Unknown (Overdose)		Allergan
	Phenobarbital/Valerian Dry Hydroalcoholic Extract			S	Oral	Unk, Unknown (Overdose)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15956949	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1906102US		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Balance Disorder; Deep Vein	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S				Allergan

Thrombosis; Dizziness; Headache; Ligament Rupture; Migraine; Paraesthesia; Pulmonary Embolism; Vision Blurred	Neurontin	S	Oral	300 Mg, Tid		Not Reported
	Neurontin	S				Not Reported
	Klonopin	C	Oral	1 Mg, Qd		Not Reported
	Klonopin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14297008	EXPEDITED (15-DAY)		DS, HO	BE-GLAXOSMITHKLINE-BE2017GSK056316		41 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy; Exposure During Pregnancy; Unintended Pregnancy	Nucala			S	Subcutaneous	100 Mg, Unk		Glaxosmithkline
	Relvar Ellipta			S		Unk Unk, Qd		Glaxosmithkline
	Sipralexa			S		10 Mg, Z, Tablet		Glaxosmithkline
	Avamys			S		Unk Unk, Bid		Glaxosmithkline
	Flixotide			S		250 ?G, Bid		Glaxosmithkline
	Ventolin			S	Unknown	100 ?G, Unk		Glaxosmithkline
	Xanthium (Theophylline)			S		20 Mg, Qd		Glaxosmithkline
	Levocetirizine			S		5 Mg, Qd		Glaxosmithkline
	Seretide			S	Unknown	Unk		Glaxosmithkline
	Fluticasone Furoate			S		Unk		Glaxosmithkline
	Xyzall			S		5 Mg, Qd		Glaxosmithkline
	D-Cure			S	Unknown	25 Kiu, Unk		Not Reported
	Pantomed (Pantoprazole)			S	Unknown	20 Mg, Qd		Not Reported
	Vilanterol Trifenatate			S	Unknown	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14567226	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-AUROBINDO-AUR-APL-2018-009821			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac	Metoprolol			S	Unknown	Unk		Aurobindo
	Sertraline			S	Oral	50 Mg, At Night		Aurobindo

Disorder; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Ivabradine	S	Unknown	Unk	Not Reported
	Escitalopram	S	Unknown	Unk	Aurobindo
	Cyproheptadine	S	Oral	16 Milligram	Not Reported
	Venlafaxine	S	Unknown	150 Milligram, Once A Day	Not Reported
	Zolpidem	S	Oral	10 Mg, At Bedtime, Before Sleep	Not Reported
	Trazodone	S	Unknown	Unk	Not Reported
	Moklar	S	Unknown	150 Milligram, Once A Day, Hs	Not Reported
	Sotalol	C	Unknown	Unk	Not Reported
	Warfarin	C	Unknown	Unk	Not Reported
	Ginkgo Biloba Extract	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14597629	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01580		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral	Unk		Lupin
	Escitalopram			S	Oral	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14603027	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01639		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral	Unk		Lupin
	Amlodipine			S	Oral	Unk		Lupin
	Escitalopram			S	Oral	Unk		Lupin
	Losartan			S	Oral	Unk		Lupin
	Salicylates Nos			S	Oral	Unk		Not Reported

	Levothyroxine		S	Oral	Unk	Not Reported
	Ethanol		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14603039	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01640		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin
	Gabapentin			S	Oral	Unk		Lupin
	Ibuprofen			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14603427	EXPEDITED (15-DAY)		OT	ZA-LUPIN (EUROPE) LIMITED-2018-01555			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Visual Impairment	Zytomil Tablets			S	Oral	20 Mg, Unk		Lupin
	Theophylline			S	Oral	200 Mg, Unk		Not Reported
	Estrofem /00045401/			S	Oral	1 Mg, Unk		Not Reported
	Forvent			S	Oral	18 Ï¿½G, Unk		Not Reported
	Dulera			S	Oral	Unk, 200/5 Mg		Not Reported
	Bio-Nifedipine			S	Oral	5 Mg, Unk		Not Reported
	Bayer Aspirin Cardio			S	Oral	100 Mg, Unk		Not Reported
	Purgoxin			S	Oral	0.25 Mg, Unk		Not Reported
	Betacor /00008501/			S	Oral	5 Mg, Unk		Not Reported
	Adco-Bisocor			S	Oral	5 Mg, Unk		Not Reported
	Trepiline /00002201/			S	Oral	25 Mg, Unk		Not Reported
	Puresis			S	Oral	40 Mg, Unk		Not Reported

	Foxair	S	Oral	Unk, 50/500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14603428	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01518		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin
	Escitalopram			S	Respiratory (inhalation)	Unk		Lupin
	Ethanol			S	Oral	Unk		Not Reported
	Ethanol			S	Respiratory (inhalation)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14607395	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01663		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amitriptyline			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Lupin
	Lorazepam			S	Oral	Unk		Lupin
	Lithium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14613085	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01657		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Bupropion			S	Oral	Unk		Lupin
	Escitalopram			S	Oral	Unk		Lupin
	Venlafaxine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14616567	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01753		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin
	Lamotrigine			S	Oral	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14617065	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01719		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin
	Diphenhydramine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14617341	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01801		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Fluoxetine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Lupin
	Risperidone			S	Oral	Unk		Not Reported
	Diphenhydramine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14625161	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01821		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin

Escitalopram	S	Respiratory (inhalation)	Unk		Lupin
Lamotrigine	S	Oral	Unk		Lupin
Lamotrigine	S	Respiratory (inhalation)	Unk		Lupin
Mirtazapine	S	Oral	Unk		Not Reported
Mirtazapine	S	Respiratory (inhalation)	Unk		Not Reported
Cyclobenzaprine	S	Oral	Unk		Not Reported
Cyclobenzaprine	S	Respiratory (inhalation)	Unk		Not Reported
Buspirone	S	Oral	Unk		Not Reported
Buspirone	S	Respiratory (inhalation)	Unk		Not Reported
Clonazepam	S	Oral	Unk		Not Reported
Clonazepam	S	Respiratory (inhalation)	Unk		Not Reported
Propranolol	S	Oral	Unk		Not Reported
Propranolol	S	Respiratory (inhalation)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14731467	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-AUROBINDO-AUR-APL-2017-44076			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine Film-Coated Tablet			S	Transplacental	5 Mg, Qd		Not Reported
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Pantomed (Dexpanthenol)			S	Transplacental	Unk		Not Reported
	Mepolizumab			S	Transplacental	100 Milligram		Not Reported
	D-Cure			S	Transplacental	25 Kilo-International Unit		Not Reported
	Flixotide			S	Transplacental	500 Microgram, Two		Not Reported

				Times A Day	
	Flixotide	S	Transplacental	250 Ug, Bid	Not Reported
	Flixotide	S	Transplacental	250 Ug, Bid	Not Reported
	Avamys	S	Transplacental	Unk Unk, Bid	Not Reported
	Xanthium (Theophylline)	S	Transplacental	200 Mg, Qd	Not Reported
	Xanthium (Theophylline)	S	Transplacental	200 Mg, Qd	Not Reported
	Xanthium (Theophylline)	S	Transplacental	200 Mg, Qd	Not Reported
	Ventolin	S	Transplacental	100 Ug, Unk	Not Reported
	Relvar	S	Transplacental	Unk, Qd	Not Reported
	Seretide	S	Transplacental	Unk	Not Reported
	Fluticasone Furoate	S	Transplacental	Unk Unk, Qd (1)	Not Reported
	Vilanterol Trifenatate	S	Transplacental	Unk	Not Reported
	Nucala	S	Transplacental	100 Mg, Unk	Not Reported
	Xyzall	S	Unknown	5 Mg, Qd	Not Reported
	Sipralexa	S	Transplacental	10 Mg, Z	Not Reported
	Theophylline	S	Unknown	Unk	Not Reported
	Theophylline	S		Unk ()	Not Reported
	Theophylline	S		Unk ()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14790649	EXPEDITED (15-DAY)		DE, HO, OT	DE-MYLANLABS-2018M1025389		1 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Sildenafil			S		Unk		Not Reported
	Spironolactone			S		Unk		Mylan
	Phenobarbital			S		Unk		Mylan
	Varivax (Varicella Zoster Virus Vaccine Live)			S	Intramuscular	1 Df, Unk		Mylan
	Topiramate			S	Unknown	Unk		Mylan
	Synagis			S	Intramuscular	150mg		Mylan

Exodus /01588502/	S	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15959004	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2019-007420			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Transposition Of The Great Vessels	Escitalopram			S	Transplacental	10 [Mg/D (5)], 0. - 5.5. Gestational Week		Aurobindo
	Skinoren			C	Transplacental	Trimester: Preconceptional		Not Reported
	Folic Acid			C	Transplacental	4.4. - 5.3. Gestational Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15959052	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-007596			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Food Intolerance; Gastrointestinal Pain; Migraine; Nausea; Nervous System Disorder; Serotonin Syndrome	Escitalopram Film-Coated Tablets			S	Oral	5 Milligram,Starting Dose 5mg		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15959507	EXPEDITED (15-DAY)		HO	FR-ACCORD-106342		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disinhibition; Suicidal Ideation	Escitalopram			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15959595	EXPEDITED (15-DAY)		OT	SE-ACCORD-107423		85 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis; Erythema	Escitalopram			S	Oral			Not Reported
	Zopiklon			C				Not Reported
	Kalcipos-D			C				Not Reported
	Aclasta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15960726	EXPEDITED (15-DAY)		CA	DE-HETERO CORPORATE-HET2019DE00145		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Transposition Of The Great Vessels	Escitalopram			S	Transplacental	10 Mg, Qd		Hetero
	Skinoren			C	Transplacental	Unk		Not Reported
	Folsäure			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15960919	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2019DE00146		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	5 Milligram, Qd		Hetero
	Tetanus Vaccine			C	Transplacental	Unk		Not Reported
	L-Thyroxin			C	Transplacental	50 Microgram, Qd		Not Reported
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15961183	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019020077			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During	Escitalopram			S	Transplacental	Unk, 10 [Mg/D (5)], 1 {Trimester}, 0-5.5.		Macleods

Pregnancy; Transposition Of The Great Vessels	Skinoren		C	Transplacental	Gestational Week Unk, Trimester: Preconceptional	Not Reported
	Folsaure		C	Transplacental	Unk, 4.4-5.3. Gestational Week, 1 {Trimester}	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15961486	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1010044		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Nuchal Rigidity; Suicide Attempt	Escitalopram Oxalate			S	Oral			Ivax
	Felison 30 Mg Capsule Rigide			S	Oral			Not Reported
	Seroquel 100 Mg Compresse Rivestite Con Film			S	Oral			Not Reported
	Tavor 2,5 Mg Compresse			S	Oral			Not Reported
	Zoloft Compresse Rivestite Con Film 100 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15961833	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2019SE22480		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Psychomotor Skills Impaired	Quetiapine Fumarate			S	Oral	500.0mg Unknown		Not Reported
	Escitalopram Oxalate			S	Oral	100.0mg Unknown		Not Reported
	Lorazepam			S	Oral	250.0mg Unknown		Not Reported
	Trittico			S	Oral	10.0df Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15962057	NON-EXPEDITED			US-009507513-1902USA000588		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Remeron			S	Oral	30 Milligram		Merck

	Sertraline Hydrochloride	S	Oral	150 Milligram	Not Reported
	Ativan	S		1 Milligram	Not Reported
	Lexapro	S		20 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15962342	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1906329US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	9737411	EXPEDITED (15-DAY)		DE, LT, OT	NO-ASTRAZENECA-2013SE88323		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Completed Suicide; Drowning; Intentional Self-Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Seroquel			S	Oral			Zeneca
	Cipralex			S	Unknown			Not Reported
	Rivotril			S	Unknown			Not Reported
	Vival			S	Unknown			Not Reported
	Remeron			S	Unknown			Not Reported
	Catapresan			S	Unknown	50.0mg Unknown		Not Reported
	Imovane			S	Oral			Not Reported
	Oxynorm			S	Oral	5 To 10mg		Not Reported
	Oxynorm			S	Oral	5 To 10mg		Not Reported
	Oxynorm			S	Oral	10.0mg Unknown		Not Reported
	Oxynorm			S	Oral	10.0mg Unknown		Not Reported
	Lamictal			S	Unknown	100.0mg Unknown		Not Reported
	Nozinan			S	Unknown			Not Reported
	Pinex Forte			S	Oral	Strength: 500/30 Mg And Pandeine		Not Reported
	Nobligan			S	Oral	200.0mg Unknown		Not Reported

	Nobligan	S	Oral	50, 200mg Unknown	Not Reported
	Sobril	S	Oral		Not Reported
	Sarotex	S	Oral		Not Reported
	Truxal	S	Oral	600 To 1200mg	Not Reported
	Cipramil [Citalopram Hydrobromide]	S	Oral		Not Reported
	Orfiril	S	Unknown	1200.0mg Unknown	Not Reported
	Atarax	S	Unknown		Not Reported
	Morphine	C			Not Reported
	Diamorphine	C			Not Reported
	Cyanocobalamin	C			Not Reported
	Codeine Phosphate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	14668063	EXPEDITED (15-DAY)		DE, HO, OT	DE-AUROBINDO-AUR-APL-2018-016247			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Topiramate			S	Unknown	Unk		Aurobindo
	Sildenafil			S	Unknown	Unk		Aurobindo
	Phenobarbital			S	Unknown	Unk		Not Reported
	Spironolactone			S	Unknown	Unk		Not Reported
	Exodus (Escitalopram Oxalate)			S	Unknown	Unk		Not Reported
	Synagis			S	Intramuscular	150 Mg, Unk		Not Reported
	Varivax			S	Intramuscular	1 Dosage Form		Not Reported
	Water			C	Unknown	4 Unk, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15744038	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-096972		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction	Escitalopram Oxalato (2858ob)			S	Oral			Not Reported

	Amiodarone Hydrochloride (392ch)	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15801906	NON-EXPEDITED			US-ALKERMES INC.-ALK-2019-000035			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Psychotic Symptom	Aristada			S	Intramuscular	1064 Mg, Qmo		Alkermes
	Aristada			S	Intramuscular	1064 Mg, Q8wk		Alkermes
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15893872	EXPEDITED (15-DAY)		OT	ZA-CIPLA LTD.-2019ZA00683			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhoids	Lexamil			S	Oral	10 Milligram, Qd		Invagen
	Co-Tareg			C	Oral	1 Dosage Form, Qd, Tablet		Not Reported
	Aspavor			C	Oral	1 Dosage Form, Qd, Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15964648	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019020078			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram Oxalate			S	Unknown	5 Milligram, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15966059	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2019-007658			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Psychomotor Skills Impaired	Lorazepam			S	Oral	250 Milligram		Aurobindo
	Quetiapine			S	Oral	500 Milligram		Aurobindo
	Escitalopram			S	Oral	100 Milligram		Aurobindo
	Trittico			S	Oral	10 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15966581	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1011404			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram 5 Mg			S		5 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967079	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019063530		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Nuchal Rigidity; Overdose; Suicide Attempt	Tavor (Lorazepam)			S	Oral	50 Mg, Single		Pfizer
	Zoloft			S	Oral	6 G, Single		Pfizer
	Escitalopram Oxalate			S	Oral	3920 Mg, Single		Not Reported
	Felison			S	Oral	900 Mg, Single		Not Reported
	Seroquel			S	Oral	6 G, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967733	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1013192		24 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Prescribed Overdose	Escitalopram			S	Oral	30 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported

	Escitalopram	S	Oral	10 Milligram, Qd(Overdose: 30 Milligram Daily)	Not Reported
	Diazepam	C	Oral	5 Milligram, Qd	Mylan
	Diazepam	C	Oral	10 Milligram, Qd	Mylan
	Pantozol /01263204/	C	Oral	20 Milligram, Qd	Mylan
	Pantozol /01263204/	C	Oral	40 Milligram, Qd	Mylan
	Prothipendyl	C	Oral	80 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15969018	EXPEDITED (15-DAY)		DE, OT	CH-GLAXOSMITHKLINE-CH2019025266		47 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Brain Oedema; Cardiac Arrest; Cough; Drug Interaction; Dyspnoea; Encephalopathy; Multiple Organ Dysfunction Syndrome; Oropharyngeal Pain; Pyrexia	Ventolin			S	Respiratory (inhalation)	As Necessary		Glaxosmithkline
	Dafalgan			S	Oral	As Necessary		Glaxosmithkline
	Clarithromycin			S	Oral	500 Mg, Unk		Not Reported
	Piperacillin + Tazobactam			S	Intravenous drip	4500 Mg, Unk		Not Reported
	Haloperidol			S	Oral	5 Mg, Unk		Not Reported
	Metfin			S	Oral	500 Mg, Unk		Not Reported
	Betmiga			S	Oral	50 Mg, Qd		Not Reported
	Clopin (Clozapine)			S	Oral	Started At 25 Mg/D The 04.12.2018 And Increased Up To 300 Mg/D The 20.12.2018		Not Reported
	Clopin (Clozapine)			S	Oral	300 Mg, Unk		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Inderal			S	Oral	40 Mg, Unk		Not Reported
	Temesta [Lorazepam]			S	Oral	As Necessary		Not Reported
	Eltroxin			C	Oral	75 ?G, Qd		Glaxosmithkline
	Atorvastatine			C	Oral	20 Mg, Qd		Glaxosmithkline

Zolpidem	C	Oral	As Necessary		Not Reported
Tranxilium	C	Oral	40 Mg, Qd		Not Reported
Calcium D3 (Calcium Carbonate+Colecalciferol)	C	Oral	1 Df, Unk		Not Reported
Duspatalin Retard	C	Oral	400 Mg, Unk		Not Reported
Symbicort	C	Respiratory (inhalation)	2 Inhalations/Days		Not Reported
Spasmo-Urgenin Neo	C	Oral	40 Mg, Unk		Not Reported
Cerazette	C	Oral	0.075 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15969565	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1011603		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	5 Milligram Daily; 5 [Mg/D]		Ivax
	Tetanus Vaccine			C	Transplacental			Not Reported
	L-Thyroxin			C	Transplacental	50 Microgram Daily; 50 [Mg/D]		Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15970180	EXPEDITED (15-DAY)		HO	GB-ALLERGAN-1906608US		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyarrhythmia; Circulatory Collapse	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Elleste-Solo			C	Transdermal	80 Mg, Qd (24 Hrs)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2019	15935585	EXPEDITED (15-DAY)		HO	IT-ACCORD-106317		21 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Aripiprazole			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Zitromax			S	Oral	Strength: 500 Mg		Not Reported
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	Strength: 25 Mg		Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2019	15972618	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2019-FR-1012020		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Ciprofloxacin			S	Oral	500 Milligram Daily; 1000 Milligram		Not Reported
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported
	Augmentin			S	Oral	1 Gram Daily; 3 Gram		Not Reported
	Sodium Pamidronate			S	Intravenous drip	30 Milligram Daily;		Not Reported
	Zyloric			S	Oral	300 Milligram Daily; 300 Milligram		Not Reported
	Seroplex			S	Oral	1 Dosage Forms Daily; 1 Dosage Forms		Not Reported
	Dexamethasone Oral			S	Oral	5.7143 Milligram		Not Reported
	Revlimid			S	Oral	25 Milligram		Not Reported
	Paracetamol			C	Unknown			Not Reported
	Zelitrex			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Durogesic			C	Unknown			Not Reported
	Gaviscon			C	Unknown			Not Reported
	Movicol			C	Unknown			Not Reported
	Lyrica			C	Oral	25 Milligram Daily; 50		Not Reported

			Milligram	
Lovenox	C	Subcutaneous		Not Reported
Bactrim	C	Oral	400 Milligram	Not Reported
Seresta	C	Oral		Not Reported
Lovenox	C	Subcutaneous	7000 Iu (International Unit) Daily; 14000 Iu (International Unit)	Not Reported
Mianserine	C	Oral	30 Milligram Daily; 30 Milligram	Not Reported
Tamiflu	C	Unknown		Not Reported
Zelitrex 500 Mg, Comprimé Enrobé	C	Oral	1 Dosage Forms Daily;	Not Reported
Furosemide	C	Unknown		Not Reported
Zelitrex	C	Oral	500 Milligram Daily; 1000 Milligram	Not Reported
Mianserine	C	Oral		Not Reported
Seresta	C	Oral	10 Milligram Daily; 10 Milligram	Not Reported
Bactrim	C	Oral		Not Reported
Previscan	C	Unknown	15 Milligram Daily; 15 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2019	15972640	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2019DE00147		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Food Intolerance; Gastrointestinal Pain; Migraine; Nausea; Nervous System Disorder; Serotonin Syndrome	Escitalopram			S	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	15573407	EXPEDITED (15-DAY)		OT	US-DEXPHARM-20180828		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Escitalopram			S		Daily Dose: 40 Mg Millgram(S) Every Days		Not Reported
	Mirtazapine			S		Every Night At Bedtime		Not Reported
	Alprazolam			S		When Necessary		Not Reported
	Lamotrigine			S		Daily Dose: 300 Mg Millgram(S) Every Days		Not Reported
	Enalapril			S		Every Morning		Not Reported
	Lansoprazole			S		Every Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	15979486	DIRECT		OT			55 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Feeling Abnormal; Lethargy	Escitalopram			S	Oral	Quantity:1 Tablet(S);	12 YR	Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	15979705	DIRECT					58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Feeling Jittery; Headache; Nausea; Nausea; Nervousness; Restlessness	Escitalopram Oxalate Generic For Lexapro			S	Oral	Quantity:30 Tablet(S);		Accord
	Estradiol			C				Not Reported
	Progesterone			C				Not Reported
	Benedryl			C				Not Reported
	Multi Vitamin,			C				Not Reported
	Vitamin D3			C				Not Reported
	Magnesium			C				Not Reported
	Flaxseed Oil,			C				Not Reported

	Garlic	C	Not Reported
	Vitamin B Complex	C	Not Reported
	Primrose Oil	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15545910	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1079566		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported
	Alprazolam			S		0.75 Mg, Qd, 0.25 Mg, 3x/Day (Tid)		Not Reported
	Bisoprolol			S	Oral	1.25 Mg, Once Daily (Qd)		Not Reported
	Furosemide			S	Oral	30 Milligram, Bid (2-1-0), 2x/Day (Bid)		Not Reported
	Furosemide			S	Oral	2 Unk, Qd		Not Reported
	Terbutaline			S	Respiratory (inhalation)	1 Df, Qd		Not Reported
	Irbesartan			S		300 Mg, Once Daily Qd		Not Reported
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported
	Metformin			S		500 Mg, Bid (1000 Mg Qd)		Not Reported
	Xarelto			S	Oral	20 Mg, Qd (1 Df Qd)		Mylan
	Nefopam			S	Oral	3 Df, Qd, 1 Df, 3x/Day (1 Df, Tid)		Mylan
	Valium			S	Oral	10 Mg, Qd, 3x/Day (Tid) (3 Df Qd)		Mylan
	Diffu-K			S	Oral	6 Df, Qd, 3 Df Daily (2-1-0) 2x/Day (Bid)		Mylan
	Dafalgan			S	Oral	3000 Mg, Qd, 1000 Mg, 3x/Day (Tid) (6 Df, Qd)		Mylan
	Tavanic			S	Oral	250 Mg, Bid (2 Df Qd)		Mylan
	Seroplex			S	Oral	1 Df, Once Daily Qd		Mylan

	Colchicine Opocalcium	S	Oral	1 Mg, Daily Once Qd (1 Df Qd)	Mylan
	Metformine Pfizer	S		500 Mg, Bid	Mylan
	Diazepam	S	Oral	10 Mg, Tid (3 Df Qd)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15936680	EXPEDITED (15-DAY)		HO	ZA-LUPIN PHARMACEUTICALS INC.-2019-00673			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain	Flexocam 7,5 Mg			S	Oral	7.5 Milligram		Lupin
	Lexamil			S	Oral	10 Milligram		Not Reported
	Tramazac Co			S	Oral	37.5/325mg		Not Reported
	Zopax			S	Oral	0.25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15974629	EXPEDITED (15-DAY)		CA	DE-TEVA-2019-DE-1011767		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Transposition Of The Great Vessels	Escitalopram			S	Transplacental	10 [Mg/D (5)]		Ivax
	Skinoren			C	Transplacental			Not Reported
	Folsaure			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15976225	NON-EXPEDITED			US-PFIZER INC-2019060446		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Floxin [Ofloxacin]			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Requip			S		Unk		Not Reported

	Zyprexa	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15977390	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1014139		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence	Escitalopram			S	Oral	Non Renseignée		Not Reported
	Diazepam			S	Oral	Non Renseignée		Mylan
	Imovane			S	Oral	7.5 Milligram, Qd		Mylan
	Theralene			S	Oral	20 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	14382284	EXPEDITED (15-DAY)		HO, OT	AT-PFIZER INC-2018013512		47 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Condition Aggravated; Paraesthesia; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	5 Mg, 1x/Day		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported
	Alprazolam			S	Unknown	0.5 Mg, 1x/Day		Pfizer
	Alprazolam			S	Unknown	1 Mg, Unk		Pfizer
	Seropram (Citalopram Hydrobromide)			S	Intravenous drip	20 Mg, 1x/Day		Not Reported
	Temesta [Lorazepam]			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15454724	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-APOTEX-2018AP021203		62 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Contraindicated Product Administered;	Venlafaxine			S	Oral	150 Mg, Qd, In The Morning		Apotex
	Venlafaxine			S	Unknown	150 Mg, Qd, In The Afternoon		Apotex

Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope; Syncope	Zolpidem		S	Oral	10 Mg, Qd, At Bedtime	Apotex
	Zolpidem		S	Unknown	10 Mg Before A Sleep	Apotex
	Sertraline		S	Oral	50 Mg, At Night	Apotex
	Sertraline		S	Unknown	50 Mg Millgram(S) Every Days	Apotex
	Escitalopram		S	Unknown		Apotex
	Moclobemide		S	Oral	150 Mg, Qd, In Afternoon	Not Reported
	Metoprolol		S	Unknown	Unk	Not Reported
	Moklar		S	Unknown	150 Mg Millgram(S) Every Days	Not Reported
	Cyproheptadine		S	Oral		Not Reported
	Trazodone		S	Unknown		Not Reported
	Ivabradine		S	Unknown	Unk	Not Reported
	Escitalopram		C	Unknown	Unk	Not Reported
	Trazodone		C	Unknown	Unk	Not Reported
	Ginkgo Biloba Extract		C	Unknown	Unk	Not Reported
	Warfarin		C	Unknown	Unk	Not Reported
	Sotalol		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15978415	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1013012		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Psychomotor Skills Impaired	Quetiapine Fumarate			S	Oral			Teva
	Lorazepam			S	Oral			Actavis
	Escitalopram Oxalate			S	Oral			Ivax
	Trittico 150 Mg Compresse A Rilascio Prolungato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15978906	EXPEDITED (15-DAY)		DE, HO	FR-SUN PHARMACEUTICAL		74 YR	Male	FRA

INDUSTRIES LTD-
2019RR-199516

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Ciprofloxacin			S	Oral	1000 Milligram		Ranbaxy
	Seroplex 10 Mg, Comprime Pellicule Secable			S	Oral	1 Dosage Form, Daily		Not Reported
	Augmentin			S	Oral	3 Gram		Not Reported
	Sodium Pamidronate			S	Intravenous drip	30 Milligram		Not Reported
	Zyloric			S	Oral	300 Milligram		Not Reported
	Seroplex			S	Oral	1 Dosage Forms		Not Reported
	Dexamethasone Oral			S	Oral	5.7143 Milligram		Not Reported
	Revlimid			S	Oral	25 Milligram		Not Reported
	Paracetamol			C	Unknown	()		Not Reported
	Zelitrex			C	Oral	()		Not Reported
	Zelitrex			C	Oral	1000 Milligram		Not Reported
	Lyrica			C	Oral	()		Not Reported
	Lyrica			C	Oral	50 Milligram		Not Reported
	Durogesic			C	Unknown	()		Not Reported
	Gaviscon			C	Unknown	()		Not Reported
	Movicol			C	Unknown	()		Not Reported
	Lovenox			C	Subcutaneous	()		Not Reported
	Lovenox			C	Subcutaneous	14000 Iu (International Unit)		Not Reported
	Bactrim			C	Oral	400 Milligram		Not Reported
	Bactrim			C	Oral	()		Not Reported
	Seresta			C	Oral	()		Not Reported
	Seresta			C	Oral	10 Milligram		Not Reported
	Mianserine			C	Oral	30 Milligram		Not Reported

Mianserine	C	Oral	()		Not Reported
Tamiflu	C	Unknown	()		Not Reported
Zelitrex 500 Mg, Comprime Enrobe	C	Oral	1 Dosage Form, Daily		Not Reported
Furosemide	C	Unknown	20 Milligram		Not Reported
Previscan	C	Unknown	15 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15979913	EXPEDITED (15-DAY)		DE, HO, OT	FR-ZYDUS-033545		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder; Suicidal Ideation; Withdrawal Syndrome	Norset			S	Oral	Unk ()		Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S	Unknown			Zydus Pharm
	Seroplex			S	Unknown	Unk ()		Not Reported
	Lysanxia			S	Unknown	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15980348	EXPEDITED (15-DAY)		HO	IT-APOTEX-2019AP008025		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Psychomotor Skills Impaired	Quetiapine			S	Oral	500 Mg, Unk (In Total)		Apotex
	Lorazepam			S	Oral	250 Mg, In Total		Not Reported
	Escitalopram Oxalate			S	Oral	100 Mg, In Total		Not Reported
	Trittico			S	Oral	10 Df, Unk (In Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15980821	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1770585US		32 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia;	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan

Extrapyramidal Disorder; Muscle Twitching; Restlessness	Trimipramin	S	Oral	75 Mg, Qd		Not Reported
	Trimipramin	S	Oral	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15980822	EXPEDITED (15-DAY)		OT	BE-ALLERGAN-1906774US		22 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Obstruction; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
	Abilify Maintena			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15981017	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1015420		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug-Induced Liver Injury	Escitalopram			S	Unknown			Not Reported
	Kratom			S	Oral			Mylan
	Kratom			S	Unknown			Mylan
	Valsartan			C	Unknown			Mylan
	Metoprolol Tartrate			C	Unknown			Mylan
	Clonazepam			C	Unknown			Mylan
	Fexofenadine			C	Unknown			Mylan
	Acetaminophen			C	Unknown	Restricted Use To The Recommended 3000 Mg Per Day Limit		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15983002	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1906785US		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemorrhagic Diathesis;	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Escitalopram Oxalate - Bp			S				Allergan

Injection Site Haemorrhage; Product Use In Unapproved Indication	Fluanxol Depot		C	Unknown	Not Reported
	Nebivolol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15984687	DIRECT		HO			7 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Personality Change; Tibia Fracture; Trismus	Concerta 18 Mg			S	Oral	Quantity:1 Capsule(S);		Alza
	Lexapro			S	Oral	Quantity:1 Tablet(S);		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15823501	EXPEDITED (15-DAY)		HO	PHHY2018CO197794			Male	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Ascites; Cardiac Failure; Fluid Retention; General Physical Health Deterioration; Urethral Stenosis; Viral Infection; Vomiting	Entresto			S	Oral	200 Mg (97 Mg Sacubitril/103 Mg Valsartan), Q12h		Not Reported
	Carvedilol			S	Unknown	2 Df, Q12h		Novartis
	Bosentan			S	Unknown	125 Mg, Q12h		Not Reported
	Escitalopram			S	Unknown	Unk Unk, Qd		Not Reported
	Atorvastatin			S	Unknown	10 Mg, Qd		Not Reported
	Omeprazole			C	Oral	Unk Unk, Qd		Not Reported
	Nifedipine			C	Oral	60 Mg, Q12h		Not Reported
	Furosemide			C	Oral	40 Mg, Qd		Not Reported
	Sevelamer			C	Unknown	2 Df, Qd		Not Reported
	B Complex			C	Unknown	Unk, Qd		Not Reported
	Folic Acid			C	Unknown	5 Df, Qd		Not Reported
	Bupropion			C	Unknown	Unk Unk, Qd		Not Reported
	Levomepromazine			C	Unknown	10 Ot, Qhs (10 Drios) (At Night)		Not Reported

Clonidine	C	Oral	2 Df, Q8h (150 Mg)		Not Reported
Trazodone	C	Unknown			Not Reported
Varenicline	C	Unknown	1 Mg, Qd		Not Reported
Iron	C	Unknown			Not Reported
Bisacodyl	C	Unknown	Unk Unk, Qd		Not Reported
Allopurinol	C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15855702	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1902712US		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Abnormal; Intentional Overdose; Miosis; Off Label Use; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	14 Df, Single (In Total Overdose: 14 Dosage Forms)		Allergan
	Paroxetine			S	Oral	28 Df, Single (In Total)		Not Reported
	Prazepam			S	Oral	20 Df, Single (In Total)		Not Reported
	Cocaine			S	Unknown	0.5 G, Unknown		Not Reported
	Tercian			S	Oral	16 Df, Single (In Total)		Not Reported
	Atarax			S	Oral	10 Df, Single (In Total)		Not Reported
	Valium			S	Oral	3 Df, Single (In Total)		Not Reported
	Alcool			S	Oral	Unk, Unknown		Not Reported
	Diazepam			S	Oral	8 Df, Single (In Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15882008	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC-2019035267		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder;	Venlafaxine Hcl			S	Unknown	Unk		Pfizer
	Norset			S	Oral	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported

Suicidal Ideation; Withdrawal Syndrome	Lysanxia	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15983295	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-199622		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Psychomotor Skills Impaired	Lorazepam			S	Oral	250 Milligram, In Total		Sun
	Escitalopram			S	Oral	100 Milligram, In Total		Not Reported
	Quetiapine Fumarate			S	Oral	500 Milligram, In Total		Not Reported
	Trittico 150 Mg Compresse A Rilascio Prolungato			S	Oral	10 Dosage Form, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15984200	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1012302		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Food Intolerance; Gastrointestinal Pain; Migraine; Nausea; Nervous System Disorder; Serotonin Syndrome	Escitalopram			S	Oral	Startdosis 5mg		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15984495	EXPEDITED (15-DAY)		LT	NO-ALLERGAN-1906992US		54 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Interaction; Drug Interaction	Escitalopram Oxalate - Bp			S	Oral	20 Mg Tablet: 1/2 Tablet Per Day.		Allergan
	Tambocor			S	Oral	100 Mg, Q12h		Not Reported
	Selo-Zok			C	Oral	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15984666	EXPEDITED (15-DAY)		DE, HO, OT	CH-ASTELLAS-2019US006040		47 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Brain Oedema; Cardiac Arrest; Cough; Dyspnoea; Eschar; Hypoxic-Ischaemic Encephalopathy; Multiple Organ Dysfunction Syndrome; Oropharyngeal Pain; Psychomotor Hyperactivity; Pyrexia	Betmiga			S	Oral			Astellas
	Clopin Eco			S	Oral			Not Reported
	Clopin Eco			S	Oral			Not Reported
	Cipralex /01588502/			S	Oral			Not Reported
	Temesta /00273201/			S	Oral	2.5 Mg, As Needed (Maximum 2 Per Day On Hand)		Not Reported
	Temesta /00273201/			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Inderal			S	Oral	40 Mg, Once Daily (Usual Treatment For Several Years)		Not Reported
	Metfin			S	Oral			Not Reported
	Ventolin /00139502/			S	Other	100 Mg, (On Hand Maximum 4 Per Day) As Needed		Not Reported
	Dafalgan			S	Oral	1 G, (3 Per Day On Hand) As Needed		Not Reported
	Clarithromycin			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Piperacillin Tazobactam Pa			S	Intravenous drip	Unk Unk, Unknown Freq.		Not Reported
	Haloperidol			S	Oral			Not Reported
	Tranxilium			C	Oral			Not Reported
	Zolpidem			C	Oral	10 Mg, (On Hand) Once Daily		Not Reported
	Atorvastatine /01326101/			C	Oral			Not Reported
	Eltroxin			C	Oral			Not Reported
	Calcium Sandoz D			C	Oral	1 Df, (Calcium 500 Mg, Cholecalciferol 440 Iu) Unknown Freq.		Not Reported

	Duspatalin /00139402/	C	Oral		Not Reported
	Symbicort Forte	C	Other	2 Df, (Inhalations) (Budesonide 200 Microg, Formoterol 6 Microg) Once Daily	Not Reported
	Spasmo-Urgenin Neo	C	Oral		Not Reported
	Cerazette /00754001/	C	Oral	0.075 Mg, Once Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15984700	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1906998US		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydronephrosis; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Unk		Allergan
	L-Thyroxin			C	Transplacental	112 [Mg/D (Bis 75 Mg/D)]		Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental	0.8 Mg, Qd		Not Reported
	Progestan			C	Transplacental	Actual: 600 [Mg/D (3 X 200 Mg/D)]		Not Reported
	Dekristol			C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]		Not Reported
	Progynova			C	Transplacental	3 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15984747	EXPEDITED (15-DAY)		CA	NL-ALLERGAN-1906804US			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15985679	DIRECT					35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate 20mg Tab			S	Oral	Quantity:135 Tablet(S);Other Frequency:1.5 Tab Per Day;	10 YR	Accord
	Lamictal 100 Mg Tab			C				Not Reported
	Losartan 100 Mg Tabs			C				Not Reported
	Amlodipine 10 Mg			C				Not Reported
	Zantac 150			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15985820	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1906960US		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Hydrochlorothiazide Unk			S	Oral	12.5 Mg, Qd		Allergan
	Metoprolol			C	Unknown	147.5 Mg, Qd		Not Reported
	Kardegic			C	Oral	75 Mg, Qd		Not Reported
	Felodipine			C	Unknown	5 Mg, Qd		Not Reported
	Lexomil			C	Oral	4 Df, Qd		Not Reported
	Colecalciferol			C	Unknown	100000 Iu, Biw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15985854	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00013348			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydronephrosis; Foetal Exposure During	L-Thyroxin			C	Transplacental	112 [G/D (Bis 75 G/D)]		Unknown
	Femibion Schwangerschaft 1			C	Transplacental	0.8 [Mg/D]		Unknown

Pregnancy	Progestan	C	Transplacental	600 [Mg/D (3 X 200 Mg/D)]	Unknown
	Escitalopram	S	Transplacental	20 [Mg/D]	Unknown
	Dekristol	C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]	Unknown
	Progynova	C	Transplacental	3 [Mg/D (3 X 1 Mg/D)]	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	12082727	EXPEDITED (15-DAY)		HO, OT	TW-LUPIN PHARMACEUTICALS INC.-2016-00644		46 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Quetiapine			S	Unknown	100 Milligram, Qd		Lupin
	Quetiapine			S	Unknown	Increased To 150 Milligram, Qd		Lupin
	Escitalopram			S	Unknown	20 Milligram, Qd		Lupin
	Escitalopram			S				Lupin
	Lithium			S	Unknown	600 Milligram, Qd		Not Reported
	Lithium			S				Not Reported
	Sertraline			C	Unknown	Unk		Not Reported
	Aripiprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15947262	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2019-00731		23 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Delusional Disorder, Erotomanic Type; Grandiosity; Judgement Impaired; Mental Disorder; Weight Increased	Escitalopram Tablets			S		10 Milligram, Qd		Lupin
	Olanzapine			S	Unknown	Unk		Not Reported
	Haloperidol			S	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15977323	EXPEDITED (15-DAY)		HO	PT-ALLERGAN-1906602US		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lymphoma	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Bromazepam			S	Unknown	Unk, Unknown		Not Reported
	Oral Contraceptive Nos			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15988466	EXPEDITED (15-DAY)		HO	IT-ACCORD-108225		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Sopor; Therapy Change	Escitalopram			S	Oral			Not Reported
	Anafranil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15988654	EXPEDITED (15-DAY)		DS	FI-ACCORD-107985		73 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Hypoaesthesia; Musculoskeletal Pain; Myalgia; Pain In Extremity; Paraesthesia; Sleep Disorder	Escitalopram			S	Oral	10,Mg,Daily		Not Reported
	Cohemin Depot			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15988657	EXPEDITED (15-DAY)		OT	IT-ACCORD-108600		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor; Suicidal Ideation	Escitalopram			S	Oral			Not Reported

	Olanzapine	S	Oral	Not Reported
	Tavor (Lorazepam)	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15988717	EXPEDITED (15-DAY)		OT	US-ZYDUS-034032		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromaturia; Decreased Appetite; Drug-Induced Liver Injury; Dysuria; Fatigue; Hepatic Steatosis; Hyperbilirubinaemia; Jaundice; Malaise; Micturition Urgency; Pollakiuria; Potentiating Drug Interaction; Pruritus; Pyrexia; Vomiting	Escitalopram			S	Unknown			Zydus Pharm
	Kratom			S	Unknown	Powder Form		Not Reported
	Valsartan			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported
	Fexofenadine			C	Unknown			Not Reported
	Kratom			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15988880	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2019-008779			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyarrhythmia; Circulatory Collapse	Escitalopram			S	Oral	10 Milligram		Aurobindo
	Elleste-Solo			C	Transdermal	80 Microgram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15991256	EXPEDITED (15-DAY)		HO	PHHY2018CO153935		81 YR	Male	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prescribed Underdose; Renal Disorder; Wrong Technique In Product Usage Process	Entresto			S	Oral	(Half A Day)0.5 Df (50 Mg), Qd		Novartis
	Entresto			S	Oral	1df (50 Mg) , Qd		Novartis

Carvedilol	S	Unknown	Unk		Not Reported
Escitalopram	S	Unknown	Unk		Not Reported
Human Insulink	C	Unknown			Not Reported
Tiotropium Bromide	C	Unknown			Not Reported
Salmeterol	C	Unknown			Not Reported
Levothyroxine	C	Unknown			Not Reported
Omeprazole	C	Unknown			Not Reported
Apixaban	C	Unknown			Not Reported
Furosemide	C	Unknown			Not Reported
Spironolactone	C	Unknown			Not Reported
Metildigoxin	C	Unknown			Not Reported
Insuline Glargine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15992768	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1907195US		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Logorrhoea; Off Label Use; Seizure; Tachycardia	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Valium			S	Oral	Unk		Not Reported
	Lithium			S	Oral	1.2 G, Qd		Not Reported
	Tercian			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15994564	DIRECT		DS			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased	Lexapro			S	Oral		15 YR	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	9184821	EXPEDITED (15-DAY)		DE, LT	NO-ROCHE-1203940		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drowning; Intentional Self-Injury; Medication Error; Overdose; Sedation	Rivotril			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Oxynorm			S	Unknown	Strength: 5 Mg- 10 Mg		Not Reported
	Lamictal			S	Unknown	Strength: 25 Mg, 50 Mg, 100 Mg		Not Reported
	Cipralex			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Hydroxyzine Hydrochloride			S	Unknown			Not Reported
	Truxal			S	Unknown	Unk		Not Reported
	Remeron			S	Unknown			Not Reported
	Sobril			S	Unknown	Unk		Not Reported
	Cipramil (Citalopram Hydrobromide)			S	Unknown	Unk		Not Reported
	Catapresan			S	Unknown	Strength 25 Mg, 50 Mg		Not Reported
	Levomepromazine Maleate			S	Unknown			Not Reported
	Sarotex			S	Unknown			Not Reported
	Atarax (Hydroxyzine Hydrochloride)			S	Unknown			Not Reported
	Vival (Diazepam)			S	Unknown			Not Reported
	Nobligan			S	Unknown	Strength: 50 Mg -200 Mg, Unk		Not Reported
	Orfiril			S	Unknown	Strength: 600 Mg -1200 Mg		Not Reported
	Pinex Forte			S	Unknown	Strength: 500/30 Mg And Pandeine		Not Reported
	Imovane			S	Oral			Not Reported
	Seroquel			S	Unknown			Not Reported
	Nozinan			S	Unknown			Not Reported
	Cyanocobalamin			C	Unknown	Unk		Not Reported
	Forte			C	Unknown	Unk		Not Reported

	Diamorphine	C	Unknown	Unk		Not Reported
	Codeine Phosphate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	11376828	EXPEDITED (15-DAY)		HO	FR-FRI-1000078942		20 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Focal Dyscognitive Seizures; Hypoglycaemia; Loss Of Consciousness	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15993322	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-009074			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Herbal Interaction	Escitalopram			S	Unknown	Unk		Aurobindo
	Ginkgo Biloba			S	Unknown	Unk		Not Reported
	Ginkgo Biloba			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15993323	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-009077			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Herbal Interaction	Escitalopram			S	Unknown	Unk		Aurobindo
	Ginkgo Biloba			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15993325	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-009072			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herbal Interaction; Myalgia; Ventricular	Escitalopram			S	Unknown	Unk		Aurobindo

Arrhythmia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15995491	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1907327US		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Decreased Appetite; Depression; Dizziness; Drug Dependence; Hypotension; Irritability; Pruritus; Psychiatric Symptom; Somnolence; Tachycardia; Tinnitus; Withdrawal Syndrome; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	½ Tablet Or ¾ Tablet In The Morning		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Orfida			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15995503	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1907085US		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Mass; Chest Pain; Depression; Drug Ineffective; Hot Flush; Monoplegia; Nerve Injury; Pain	Lexapro			S	Unknown			Allergan
	Effexor Xr			S	Unknown	75 Mg, Qd		Not Reported
	Effexor Xr			S				Not Reported
	Hormones Patch			S	Unknown			Not Reported
	Ritalin			C	Unknown	20 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15995805	EXPEDITED (15-DAY)		DE, HO, OT	CH-ALLERGAN-1906964US		47 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Cardiac Arrest; Cough; Drug Interaction; Dyspnoea;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd (Usual Long Term Treatment)		Allergan

Oropharyngeal Pain; Product Use In Unapproved Indication; Pyrexia	Ventolin	S	Respiratory (inhalation)	100 Mg, Prn (100 Micrograms In Reserve, Maximum 4x/Day; As Necessary)	Not Reported
	Clarithromycin	S	Oral	500 Mg, Bid	Not Reported
	Piperacillin & Tazobactam	S	Intravenous drip	4500 Mg, Tid	Not Reported
	Haloperidol	S	Oral	5 Mg, Bid	Not Reported
	Clopin Eco	S	Oral	300 Mg, Qd	Not Reported
	Clopin Eco	S	Oral	25 Mg, Qd	Not Reported
	Temesta [Lorazepam]	S	Oral	2.5 Mg, Prn (2.5 Mg Maximum 2x J En Serve Depuis Au Moins Mai 2018; As Necessary)	Not Reported
	Inderal	S	Oral	40 Mg, Qd (Usual Treatment Since Several Years)	Not Reported
	Metfin	S	Oral	500 Mg, Qd	Not Reported
	Betmiga	S	Oral	50 Mg, Qd	Not Reported
	Dafalgan	S	Oral	1 G, Prn (1 G Maximum 3x/Day In Reserve; As Necessary)	Not Reported
	Tranxilium	C	Oral	40 Mg, Qd	Not Reported
	Zolpidem	C	Oral	10 Mg, Prn (10 Mg/Day In Reserve At Least Since 26.11.2018; As Necessary)	Not Reported
	Atorvastatine	C	Oral	20 Mg, Qd	Not Reported
	Eltroxin	C	Oral	75 Mg, Qd	Not Reported
	Calcium Sandoz D	C	Oral	1 Df, Qd	Not Reported
	Duspatalin	C	Oral	400 Mg, Qd	Not Reported
	Symbicort	C	Respiratory (inhalation)	2 Df, Qd (2 Inhalations/Day)	Not Reported
	Spasmo-Urgenin Neo	C	Oral	40 Mg, Qd	Not Reported

	Cerazette		C	Oral	0.075 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15996581	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro 20mg			S				Not Reported
	Trazodone 50mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15996937	EXPEDITED (15-DAY)		DE	CH-JNJFOC-20190215504		47 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Cardiac Arrest; Cough; Dyspnoea; Inappropriate Schedule Of Product Administration; Off Label Use; Oropharyngeal Pain; Pyrexia	Haloperidol			S	Oral			Not Reported
	Temesta [Lorazepam]			S	Oral	As Necessary		Not Reported
	Inderal			S	Oral			Not Reported
	Metfin			S	Oral			Not Reported
	Ventolin			S	Respiratory (inhalation)	As Necessary		Not Reported
	Betmiga			S	Oral			Not Reported
	Dafalgan			S	Oral	As Necessary		Not Reported
	Clarithromycin			S	Oral			Not Reported
	Piperacilline/Tazobactam			S	Intravenous drip			Not Reported
	Clopin Eco			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Tranxilium			C	Oral			Not Reported
	Zolpidem			C	Oral	As Necessary		Not Reported
	Atorvastatin			C	Oral			Not Reported
	Eltroxin			C	Oral			Not Reported
	Duspatalin			C	Oral			Not Reported

	Symbicort	C	Respiratory (inhalation)		Not Reported
	Spasmo-Urgenin Neo	C	Oral		Not Reported
	Cerazette	C	Oral		Not Reported
	Calcium Sandoz + Witamin D3	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15997460	NON-EXPEDITED			US-BAUSCH-BL-2019-004387			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Ativan			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Pamelor			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	16122312	DIRECT					62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Irritable Bowel Syndrome	Lexapro Escitalopram			S	Oral	Quantity:20 Mg Milligram(S);		Aurobindo
	Tofranil			C				Not Reported
	Losartan			C				Not Reported
	Toulaz			C				Not Reported
	Multi Vitamin			C				Not Reported
	Chlorella			C				Not Reported
	Minerals			C				Not Reported
	Cbd Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2019	15883296	EXPEDITED (15-DAY)		HO, LT	DE-ACCORD-103666		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram	S		Strength: 5 Mg Milligram(S)	Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium	S			Not Reported
	Linezolid	S	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days	Not Reported
	Levetiracetam	C		Daily Dose: 2 Df Dosage Form Every Days	Not Reported
	Ivabradine/Ivabradine Hydrochloride	C		Daily Dose: 15 Mg Millgram(S) Every Days	Not Reported
	Sulfamethoxazole/Trimethoprim	C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days	Not Reported
	Naloxone Hydrochloride/Tilidine Hydrochloride	C			Not Reported
	Scopolamin	C			Not Reported
	Baclofen	C			Not Reported
	Prednisolone	C		Strength: 10 Mg Milligram(S)	Not Reported
	Lorazepam	C		Daily Dose: 1 Mg Millgram(S) Every Days	Not Reported
	L-Thyroxin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2019	15998171	EXPEDITED (15-DAY)		HO, OT	DE-ACCORD-108483		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma; Haemorrhage; Menorrhagia; Respiratory Tract Infection; Sleep Disorder	Aripiprazole			S	Unknown	5 Milligram Daily;		Not Reported
	Escitalopram			S	Unknown	15 Milligram Daily; Reduced To 15 Mg/Day		Not Reported
	Risperidone			S	Unknown	0.5 Mg		Not Reported
	Atorvastatin			C	Unknown	Evening Dose Of 100 Mg		Not Reported
	Pregabalin			C		100 Milligram Daily, Evening Dose Of 100 Mg		Not Reported
	Promethazine			C	Unknown			Not Reported

	Opipramol/Opipramol Hydrochloride	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
	Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
	Risperidone	S	Unknown	0.5 Mg	Not Reported
	Escitalopram	S	Unknown	20 Milligram Daily; In A Morning Target Dose Of 20 Mg	Not Reported
	Escitalopram	S	Unknown	20 Milligram Daily; Increased To A Dose Of 20 Mg Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2019	15998180	EXPEDITED (15-DAY)		HO	FR-ACCORD-108961		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autonomic Nervous System Imbalance; Malaise; Orthostatic Hypotension	Escitalopram			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported
	Risperdal			S	Oral	Strength: 1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2019	15998519	EXPEDITED (15-DAY)		HO	IT-ACCORD-108908		73 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Gait Disturbance	Quetiapine			S	Oral			Not Reported
	Lorans			S	Oral	Strength:1mg		Not Reported
	Carbolithium			S	Oral	Strength:150 Mg		Not Reported
	Cipralex			S	Oral	Strength:10mg		Not Reported
	Motilium			C		Strength:10 Mg		Not Reported
	Metformina Teva			C		Strength:500 Mg		Not Reported
	Omeprazen			C		Strength:20mg		Not Reported

	Eskim	C	Strength: 1000 Mg	Not Reported
	Totalip	C	Strength:20 Mg	Not Reported
	Nicetile	C	Strength: 500mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2019	15998659	EXPEDITED (15-DAY)		HO, LT	NL-ACCORD-108852		69 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram			S		1 X Per Day 1 Piece		Not Reported
	Hydrochlorothiazide			S		25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2019	15998923	EXPEDITED (15-DAY)		OT	DE-ACCORD-108884		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Rash	Escitalopram			S	Oral			Not Reported
	Candesartan			C		Taking For Months		Not Reported
	Eliquis			C	Oral	Taking For Months		Not Reported
	Estradiol			C	Oral	Dose Not Changed		Not Reported
	Novalgin (Metamizole Sodium)			C	Oral	Taking For Months		Not Reported
	Amlodipine			C		Taking For Months		Not Reported
	Sulfasalazine			C	Oral	Taking For Months		Not Reported
	Concor			C	Oral	Taking For Months		Not Reported
	Kalinor			C	Oral	Taking For Months		Not Reported
	Sulfamethoxazole/Trimethoprim			C	Oral	Taking For Months		Not Reported
	Vigantoletten			C	Subcutaneous	Taking For Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2019	16007766	EXPEDITED (15-DAY)		OT	HR-APOTEX-2019AP008097		17 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Somnolence; Suicide Attempt	Olanzapine			S	Oral	20 Mg, Unk		Apotex
	Aspirin /00002701/			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	14800420	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1026541		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Lichen Planus	Verapamil			S	Oral	240 Milligram		Not Reported
	Atorvastatin			S	Oral	20 Milligram		Not Reported
	Esomeprazole			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Macrogol			S	Oral	Unk		Not Reported
	Perindopril			S	Oral	2 Milligram		Not Reported
	Aldactone /00006201/			S	Oral	Unk		Mylan
	Esidrex			S	Oral	25 Milligram		Mylan
	Kardegic			S	Oral	Unk		Mylan
	Seroplex			S	Oral	Unk		Mylan
	Teralithe			S	Oral	Unk		Mylan
	Xeroquel			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	15986782	EXPEDITED (15-DAY)		DE, HO, OT	CH-PFIZER INC-2019065613		47 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Cardiac Arrest; Cough; Drug Interaction; Dyspnoea;	Temesta [Lorazepam]			S	Oral	2.5 Mg, Maximum Twice Daily In Reserve As Necessary		Pfizer

Haemoglobin Decreased; Oropharyngeal Pain; Po2 Decreased; Pyrexia	Piperacillin/Tazobactam	S	Intravenous drip	4500 Mg, 3x/Day	Unknown
	Clopin Eco	S	Oral	25 Mg, 1x/Day	Not Reported
	Clopin Eco	S	Oral	300 Mg, 1x/Day	Not Reported
	Cipralex [Escitalopram Oxalate]	S	Oral	10 Mg, 1x/Day	Not Reported
	Inderal	S	Oral	40 Mg, 1x/Day	Not Reported
	Metfin	S	Oral	500 Mg, 1x/Day	Not Reported
	Ventolin [Salbutamol Sulfate]	S	Respiratory (inhalation)	100 Ug, Maximum In Reserve Four Times Daily As Necessary	Not Reported
	Betmiga	S	Oral	50 Mg, 1x/Day	Not Reported
	Dafalgan	S	Oral	1g, Maximum Thrice Daily In Reserve As Necessary	Not Reported
	Clarithromycin	S	Oral	500 Mg, 2x/Day	Not Reported
	Haloperidol	S	Oral	5 Mg, 2x/Day	Not Reported
	Tranxilium	C	Oral	40 Mg, 1x/Day	Not Reported
	Zolpidem	C	Oral	10 Mg, Once Daily In Reserve As Necessary	Not Reported
	Atorvastatin	C	Oral	20 Mg, 1x/Day	Not Reported
	Eltroxin	C	Oral	75 Ug, 1x/Day	Not Reported
	Calcium Sandoz + Witamin D3	C	Oral	1 Df = 1tablet (500mg/440 Iu), 1x/Day	Not Reported
	Duspatalin [Mebeverine Hydrochloride]	C	Oral	400 Mg, 1x/Day	Not Reported
	Symbicort	C	Respiratory (inhalation)	2 Inhalations Once Daily (Budesonide 200 Microg, Formoterol 6 Microg)	Not Reported
	Spasmo-Urgenin Neo	C	Oral	40 Mg, 1x/Day	Not Reported
	Cerazette [Desogestrel]	C	Oral	0.075 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	15999578	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2019030170			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Lamictal			S	Transplacental	400 Mci, Qd		Glaxosmithkline
	Seroplex			S	Transplacental	20 Mg, Qd		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16000010	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1907115US		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anxiety; Atrial Septal Defect; Concussion; Depressed Mood; Ehlers-Danlos Syndrome; Hypermobility Syndrome; Loss Of Consciousness; Migraine With Aura; Myofascial Pain Syndrome; Postural Orthostatic Tachycardia Syndrome; Sleep Apnoea Syndrome	Lexapro			S	Oral	5 Mg, Unk		Allergan
	Ester-C [Calcium Ascorbate]			S	Oral	Unk		Not Reported
	Calcium			S	Oral			Not Reported
	Zyrtec			S	Oral			Not Reported
	Liposomal Ubiquinol			S	Oral			Not Reported
	Cyanocobalamin			S	Oral	1000 Mg, Unk		Not Reported
	Diclofenac			S	Topical	Unk		Not Reported
	Epinephrine			S	Unknown	0.3 Mg/0.3 Ml Injection		Not Reported
	Ferrous Sulfate			S	Oral	325 Mg Total Salt (65 Mg Elemental)		Not Reported
	Lactobac			S	Oral	40/Bifido 3/S. Thermop		Not Reported
	Melatonin			S	Oral	Unk		Not Reported
	Mirtazapine			S	Oral	30 Mg, Unk		Not Reported
	Multivitamin			S	Oral	Unk		Not Reported
	Omega 3 Fatty Acids			S	Oral	Unk		Not Reported
	Ondansetron			S	Oral	4 Mg, Unk		Not Reported
	Lyrica			S	Oral	350 Mg, Unk		Not Reported
	Buffered Salt			S	Oral			Not Reported
	Sodium Chloride 0.9%			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16000492	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1015446		24 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	30 Milligram, Qd		Not Reported
	Diazepam			C	Oral	5 Milligram, Qd		Mylan
	Diazepam			C	Oral	10 Milligram, Qd		Mylan
	Pantozol /01263204/			C		20 Milligram, Qd		Mylan
	Pantozol /01263204/			C		40 Milligram, Qd		Mylan
	Prothipendyl			C	Oral	80 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16000558	EXPEDITED (15-DAY)		HO	GB-TEVA-2019-GB-1015038		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyarrhythmia; Circulatory Collapse	Escitalopram Oxalate			S	Oral			Ivax
	Elleste-Solo			C	Transdermal	80 Microgram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16001413	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1907505US		57 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic	Escitalopram Oxalate - Bp			S	Unknown	5mg Upptrappades Till 20 Mg		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Duloxetine			S	Unknown	30 Mg Upptrappat Till 60 Mg		Not Reported
	Duloxetine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16001415	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1907522US		33 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Intentional Overdose; Intentional Self-Injury	Escitalopram Oxalate - Bp			S	Oral	12-20 St Cipralex 10 Mg		Allergan
	Cocillana-Etyfin			S	Oral	125 Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16001431	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1907525US		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Drug Interaction	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Crestor			S	Unknown	Unk		Not Reported
	Previscan (Fluindione)			S	Oral	Unk		Allergan
	Plavix			S	Oral	Unk		Not Reported
	Cordarone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16001783	EXPEDITED (15-DAY)		DS, OT	US-ALLERGAN-1907313US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Attention Deficit/Hyperactivity Disorder; Developmental Delay; Failure To Thrive; Intellectual Disability; Physical Disability; Premature Baby	Lexapro			S	Transplacental	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002033	EXPEDITED (15-DAY)		HO, OT	US-SUNOVION-2019SUN000732			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Brain Injury; Crying; Depression; Frequent Bowel Movements; Galactorrhoea; Hyperhidrosis; Hypomania; Intentional Product Use Issue; Intentional Self-Injury; Mania; Suicide Attempt; Tremor	Latuda			S	Oral	Unk		Sunovion
	Lexapro			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	300 Mg, Qd		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Tegretol			C				Not Reported
	Effexor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002938	NON-EXPEDITED			US-SA-2019SA050657			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Leflunomide			S				Sanofi
	Omeprazole			S		Unk		Not Reported
	Rosuvastatin			S				Not Reported
	Progesterone			S				Not Reported
	Estradiol			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Cimzia			S				Not Reported
	Metformin			S		Unk		Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16003404	EXPEDITED (15-DAY)		OT	US-TORRENT-00007685		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S		Unknown		Unknown
	Diazepam			C		Unknown		Unknown
	Lorazepam			C		Unknown		Unknown

Zolpidem	C	Unknown	Unknown
Fexofenadine	C	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16004021	EXPEDITED (15-DAY)		CA	DE-ACCORD-109136		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Amitriptyline			S	Transplacental			Accord
	Cipralex			S	Transplacental			Not Reported
	Metoprolol			S	Transplacental	71.25 Mg/D, 47.5-0-23.75 Mg/D		Not Reported
	Paracetamol			C	Transplacental	2000mg/D,1-2 G/D If Required		Not Reported
	Clexane			C	Transplacental	120mg/D (-40),Initial 40mg/D, Dosage Increase To 2 X 60 Mg/D		Not Reported
	Ibuprofen			C	Transplacental	600mg/D,If Required		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16004050	EXPEDITED (15-DAY)		LT	FR-ACCORD-109117		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Miosis; Prothrombin Time Shortened; Suicide Attempt; Tachycardia; Vomiting	Escitalopram			S	Oral			Not Reported
	Dafalgan Codeine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16004081	EXPEDITED (15-DAY)		HO	IT-ACCORD-108639		59 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Crying; Electrocardiogram	Escitalopram	S			Not Reported
Qt Prolonged; Moaning	Alprazolam	S	Oral		Not Reported
	Trilafon	S	Oral		Not Reported
	Ramipril	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16127940	DIRECT	Y	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Product Substitution Issue	Escitalopram 10mg			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	9729873	EXPEDITED (15-DAY)		DE, LT, OT	NO-009507513-1312NOR001133		20 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Fatigue Syndrome; Completed Suicide; Drowning; Intentional Self-Injury; Jaw Fracture; Medication Error; Multiple Fractures; Overdose; Sedation; Unevaluable Event	Remeron			S	Unknown	Unk		Merck
	Pinex Forte			S	Unknown	300/30 Mg And Pandeine		Not Reported
	Sarotex			S	Unknown	Unk		Not Reported
	Cipramil (Citalopram Hydrobromide)			S	Unknown	Unk		Not Reported
	Orfiril			S	Unknown	1200 Mg, Unk		Not Reported
	Tramadol Hydrochloride			S	Unknown	50, 200mg		Not Reported
	Catapresan			S	Unknown	50 Mg, Unk		Not Reported
	Imovane			S	Oral	Unk		Not Reported
	Atarax (Hydroxyzine Hydrochloride)			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	100 Mg, Unk Strength: 25 Mg, 50 Mg, 100 Mg		Not Reported
	Vival			S	Unknown	Unk		Not Reported
	Nozinan			S	Unknown	Unk		Not Reported
	Oxynorm			S	Unknown	10 Mg, Unk; Strength: 5		Not Reported

				Mg-10 Mg	
	Oxynorm	S			Not Reported
	Nobligan	S	Unknown	200 Mg, Qd (Also Reported As Unk); Strength: 50 Mg-200 Mg	Not Reported
	Seroquel	S	Unknown	Unk	Not Reported
	Rivotril	S	Unknown	Unk	Not Reported
	Cipralex	S	Unknown	Unk	Not Reported
	Sobril	S	Unknown	Unk	Not Reported
	Truxal (Chlorprothixene Hydrochloride)	S	Unknown	600 To 1200mg	Not Reported
	Hydroxyzine Hydrochloride	S	Unknown	Unk	Not Reported
	Levomepromazine Maleate	S	Unknown		Not Reported
	Diazepam	S	Unknown		Not Reported
	Diacetylmorphine	C	Unknown	Unk	Not Reported
	Cyanocobalamin	C	Unknown	According To Mah Product Name Is "Forte"	Not Reported
	Nozinan	C		Unk	Not Reported
	Codeine Phosphate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	15753702	EXPEDITED (15-DAY)		DE, HO, OT	DE-ACCORD-097178		1 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Flatulence; Immobile; Pain; Pneumonia; Respiratory Failure	Spironolactone			S				Accord
	Sildenafil/Sildenafil Citrate			S				Not Reported
	Topiramate			S	Unknown			Accord
	Phenobarbital			S				Not Reported
	Varivax			S	Intramuscular	1 Df		Not Reported
	Synagis			S	Intramuscular			Not Reported
	Exodus (Escitalopram Oxalate)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	15991406	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2019077396		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatriuria	Pantozol			S	Unknown	Unk		Pfizer
	Cipralex [Escitalopram Oxalate]			S	Unknown	Unk		Not Reported
	Co Valsartan [Hydrochlorothiazide;Valsartan]			S	Unknown	Unk		Not Reported
	Meto Zerok			C	Unknown	Unk		Not Reported
	Prednison Galepharm			C	Unknown	Unk		Not Reported
	Ecofenac			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16003794	EXPEDITED (15-DAY)		HO	FR-ACCORD-108629		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Escitalopram			S	Oral			Not Reported
	Stresam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16004456	EXPEDITED (15-DAY)		HO	DE-ACCORD-108316		37 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haematoma; Menorrhagia; Sleep Disorder	Aripiprazole			S	Unknown	5 Milligram Daily		Not Reported
	Escitalopram			S	Unknown	15 Milligram Daily, Reduced To 15 Mg/Day		Not Reported
	Risperidone			S	Unknown	0.5 Mg		Not Reported
	Pregabalin			C	Unknown	Evening Dose Of 100 Mg		Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pregabalin			C	Unknown	100 Milligram Daily,		Not Reported

				Evening Dose Of 100 Mg	
	Promethazine	C	Unknown		Not Reported
	Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
	Opipramol/Opipramol Hydrochloride	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16004852	EXPEDITED (15-DAY)		LT, OT	FR-APOTEX-2019AP008372		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Thrombosis	Olanzapine			S	Oral	7.5 Mg, Unk		Apotex
	Teralithe			S	Oral	2 Df, Unk		Not Reported
	Seroplex			S	Oral	1 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16004904	EXPEDITED (15-DAY)		CA	DE-HETERO CORPORATE-HET2019DE00239			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydronephrosis	Escitalopram			S	Transplacental	20 Milligram, Qd		Hetero
	L-Thyroxin			C	Transplacental	112 [Mg/D (Bis 75 Mg/D)]		Not Reported
	Femibion /01597501/			C	Transplacental	0.8 Milligram, Qd		Not Reported
	Progestan			C	Transplacental	600 [Mg/D (3 X 200 Mg/D)]		Not Reported
	Dekristol			C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]		Not Reported
	Progynova /00045401/			C	Transplacental	3 [Mg/D (3 X 1 Mg/D)]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16005710	NON-EXPEDITED			US-CELGENEUS-USA-20190207425			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Palpitations	Pomalyst			S	Oral	4 Milligram		Celgene
	Trazodone			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16006868	EXPEDITED (15-DAY)		HO	SG-ALLERGAN-1907760US		56 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	14818968	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2018-022334			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anhedonia; Apathy; Asthenia; Chest Pain; Decreased Appetite; Depressed Mood; Drug Ineffective; Drug Intolerance; Dysphonia; Gastritis; Palpitations; Parkinsonism; Psychiatric Symptom; Sleep Disorder; Tremor	Mirtazapine 15mg			S	Unknown	15 Milligram		Aurobindo
	Escitalopram 10 Mg			S	Unknown	10 Milligram		Aurobindo
	Venlafaxine			S	Oral	Unk		Aurobindo
	Bupropion			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Sertraline			C	Unknown	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16010486	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019020219			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydronephrosis	Escitalopram			S	Transplacental	20 Milligram, Qd,(20 [Mg/D])		Macleods
	L-Thyroxin			C	Transplacental	Unk, (112 [Mg/D (Bis 75 Mg/D)])		Not Reported
	Folic Acid			C	Transplacental	0.8 Milligram, Qd, (0.8 [Mg/D])		Not Reported
	Progestan			C	Transplacental	600 Milligram, Qd,(600 [Mg/D (3 X 200 Mg/D)])		Not Reported
	Dekristol			C	Transplacental	Unk, (2000 [I.E./D (Bis 1000 I.E./D)])		Not Reported
	Progynova			C	Transplacental	3 Milligram, Qd,(3 [Mg/D (3 X 1 Mg/D)])		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16010998	EXPEDITED (15-DAY)		CA, DE	DE-ACCORD-109190			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anencephaly; Congenital Anomaly; Foetal Exposure During Pregnancy; Maternal Drugs Affecting Foetus	Escitalopram			S	Transplacental			Not Reported
	Levetiracetam			S	Transplacental	1500 Mg/ Day		Accord
	Candesartan			S	Transplacental	16 Mg/D		Not Reported
	Paroxetine			S	Transplacental	30 Mg/D		Not Reported
	Nepresol (Dihydralazine)			S	Transplacental	25mg/D		Not Reported
	L-Thyroxine			C	Transplacental			Not Reported
	Cytotec			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16012646	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2019SE29522		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall	Crestor			S	Oral			Astrazeneca

Haematoma	Seroplex	S	Oral		Not Reported
	Cordarone	S	Oral		Not Reported
	Previscan (Fluindione)	S	Oral		Not Reported
	Plavix	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16012990	DIRECT		DS, OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Balance Disorder; Fall; Gait Disturbance; Muscular Weakness; Tremor	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Aurobindo
	Lamotrigine			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16013996	EXPEDITED (15-DAY)		OT	BE-OTSUKA-2019_004192		22 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Obstruction	Abilify Maintena			S	Unknown	400 Mg, Unk		Otsuka
	Sipralexa			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16014096	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2019081883		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Face Oedema; Face Oedema; Rash	Efexor Er			S	Oral	75 Mg, 1x/Day		Pfizer
	Efexor Er			S	Oral	Unk		Pfizer
	Cipralex			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16014767	EXPEDITED (15-DAY)		HO	PHHY2019CH035787		58 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatriuria	Co-Valsartan Sandoz			S	Oral	1 Df, Qd		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Pantozol			S	Oral	20 Mg, Qd		Not Reported
	Meto Zerok			C	Oral	25 Mg, Qd		Not Reported
	Prednison Galepharm			C	Oral	20 Mg, Qd		Not Reported
	Ecofenac			C	Oral	75 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16145879	DIRECT		HO			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Skin Disorder; Skin Haemorrhage; Skin Lesion	Escitalopram (Generic For Lexapro)			S	Oral	Quantity:10 Mg Milligram(S);		Not Reported
	Clobetasol			C				Not Reported
	Loratadine			C				Not Reported
	Ketoconazole			C				Not Reported
	2% Topical Shampoo			C				Not Reported
	Betasept 4% Surgical Scrub			C				Not Reported
	Ibrofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	15885472	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1003426		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Paroxetine (Chlorhydrate De) Anhydre			S	Oral			Teva
	Escitalopram			S	Oral			Ivax
	Diazepam			S	Oral			Barr
	Prazepam			S	Oral			Not Reported
	Cocaine			S	Unknown	0.5g		Not Reported
	Tercian			S	Oral			Not Reported

	Atarax			S	Oral				Not Reported
	Valium			S	Oral				Not Reported
	Alcool			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	15887241	EXPEDITED (15-DAY)		HO	FR-ROCHE-2251342		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Diazepam			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Paroxetine			S	Oral			Not Reported
	Prazepam			S	Oral			Not Reported
	Cocaine			S	Unknown	0.5g		Not Reported
	Escitalopram			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Alcool			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	15899435	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-003883			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Paroxetine			S	Oral	28 Dosage Form, 1 Total		Aurobindo
	Prazepam			S	Oral	20 Dosage Form, 1 Total		Not Reported
	Diazepam			S	Oral	8 Dosage Form, 1 Total		Not Reported
	Escitalopram			S	Oral	14 Dosage Form, 1 Total		Aurobindo
	Cocaine			S	Unknown	0.5 Gram, 0.5g		Not Reported
	Tercian			S	Oral	16 Dosage Form, 1 Total		Not Reported
	Atarax			S	Oral	10 Dosage Form, 1 Total		Not Reported
	Valium			S	Oral	3 Dosage Form, 1 Total		Not Reported

	Alcool	S	Oral	Unk, Non Renseignée	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16015698	EXPEDITED (15-DAY)		CA	NL-TEVA-2019-NL-1017798			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Maternal Exposure During Pregnancy	Escitalopram (Escitalopram)			S		10 Milligram Daily; 1 Dd 10 Mg		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16015758	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1016480		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Logorrhoea; Seizure; Tachycardia	Escitalopram			S	Oral			Ivax
	Valium			S	Oral			Not Reported
	Lithium			S	Oral	1.2 Gram Daily;		Not Reported
	Tercian			S	Oral	250 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16015917	EXPEDITED (15-DAY)		OT	AT-ACCORD-109327		21 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Olanzapine			S	Unknown			Not Reported
	Diazepam			S	Unknown			Accord
	Trazodone/Trazodone Hydrochloride			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Lorazepam			S	Unknown	2-5 Mg		Not Reported
	Dominal (Prothipendyl)			S		80 Mg From 30-Apr-2018 To 02-May-2018(Dose Reduced)		Not Reported

	Acetylsalicylic Acid	S	Unknown	Not Reported
	Lamotrigine	S	Unknown	Not Reported
	Cipralex	S	Unknown	Not Reported
	Halcion	C	Unknown	Not Reported
	Zolpidem	C	Unknown	Not Reported
	Quilonorm	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16015968	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-109705		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Poisoning Deliberate; Somnolence	Escitalopram			S	Oral			Not Reported
	Prazepam			S	Oral	Np		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16016003	EXPEDITED (15-DAY)		OT	GB-ACCORD-109417		25 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Libido Decreased; Sexual Dysfunction	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16016067	EXPEDITED (15-DAY)		HO	FR-SAKK-2019SA050144AA		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Drug Interaction	Plavix			S	Oral	Unk		Sanofi
	Rosuvastatin Calcium			S		Unk		Not Reported
	Fluindione			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Cordarone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16016272	EXPEDITED (15-DAY)		HO	FR-ROCHE-2270333		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Logorrhoea; Seizure; Tachycardia	Valium			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16016504	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2019-010002			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Depression; Dizziness; Drug Dependence; Hypotension; Irritability; Pruritus; Psychiatric Symptom; Somnolence; Tachycardia; Tinnitus; Withdrawal Syndrome	Escitalopram 10 Mg Film-Coated Tablets Efg			S	Oral	10 Milligram, Unk		Aurobindo
	Escitalopram 10 Mg Film-Coated Tablets Efg			S				Aurobindo
	Orfidal			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16017847	DIRECT		OT			14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Grimacing	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Rite Aid

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16019367	EXPEDITED (15-DAY)		CA	DE-TEVA-2019-DE-1015684		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Congenital Hydronephrosis	Escitalopram	S	Transplacental	20 Milligram Daily;	Ivax
	L-Thyroxin	C	Transplacental	112 [Mg/D (Bis 75 Mg/D)]	Not Reported
	Femibion Schwangerschaft 1	C	Transplacental	.8 Milligram Daily; 0.8 [Mg/D]	Not Reported
	Progestan	C	Transplacental	600 Milligram Daily; 600 [Mg/D (3 X 200 Mg/D)]	Not Reported
	Dekristol	C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]	Not Reported
	Progynova	C	Transplacental	3 Milligram Daily; 3 [Mg/D (3 X 1 Mg/D)]	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16020038	EXPEDITED (15-DAY)		HO, OT	US-LUNDBECK-DKLU2061227		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Constipation; Dysphagia; Feeding Disorder; Gastrooesophageal Reflux Disease; Intentional Self-Injury; Liver Function Test Increased; Sedation Complication; Therapeutic Product Effect Incomplete; Vomiting; Weight Decreased	Clobazam			S	Unknown			Lundbeck
	Clobazam			S	Unknown			Lundbeck
	Clobazam			S	Unknown			Lundbeck
	Valproic Acid			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Clonidine			S	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16020101	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMPANY-US201902011641			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Oestrogen Increased; Breast Cancer;	Prozac			S	Unknown	80 Mg, Unknown		Eli Lilly And Co
	Prozac			S				Eli Lilly And Co

Joint Noise; Lactation Puerperal Increased; Lymphoma; Pituitary Tumour Benign; Renal Neoplasm; Weight Decreased	Lexapro		S	Unknown	Unk Unk, Unknown	Not Reported
	Lexapro		S			Not Reported
	Effexor		S	Unknown	Unk, Unknown	Not Reported
	Effexor		S			Not Reported
	Clonazepam		S	Unknown	Unk Unk, Unknown	Not Reported
	Clonazepam		S			Not Reported
	Lithium		S	Unknown	Unk Unk, Unknown	Not Reported
	Lithium		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16151263	DIRECT	Y	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Withdrawal Syndrome	Escitalopram Accord 20mg Tab			S	Oral			Not Reported
	Escitalopram, Accord, 5 Mg Tab			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	15879000	EXPEDITED (15-DAY)		HO	FR-ZYDUS-032976		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Paroxetine			S	Oral			Not Reported
	Escitalopram			S	Oral			Zydus Pharm
	Prazepam			S	Oral			Not Reported
	Cocaine			S	Unknown			Not Reported
	Cyamemazine			S	Oral			Not Reported
	Hydroxyzine			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	15959568	EXPEDITED (15-DAY)		HO	IT-ACCORD-106817		19 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	15989139	EXPEDITED (15-DAY)		OT	IT-ACCORD-053038		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Escitalopram			S	Unknown	20 Mg,Qd		Not Reported
	Sertraline			S				Accord
	Lorazepam			S	Oral	2.5 Mg,Qd		Accord
	Cipralex - H. Lundbeck A/S			S				Not Reported
	Brintellix - H. Lundbeck A/S			S	Unknown	Also Received As 5 Mg On Jun-2016 And 15 Mg Dose.		Not Reported
	Duloxetine			S		60 Mg,Qd		Not Reported
	Triatec Hct			C	Unknown	Strength: 15 Mg		Not Reported
	Cordarone			C	Unknown	Strength: 200 Mg Dose: 100 Mg		Not Reported
	Coumadin			C	Unknown			Not Reported
	Lansoprazole			C	Unknown	30 Mg,Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg,Qd		Not Reported
	Ezetimibe			C	Unknown	10 Mg,Qd		Not Reported
	Alprazolam			C	Unknown	2 Mg,Qd		Not Reported
	Warfarin			C				Not Reported
	Amiodarone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16020422	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-009784			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Herbal Interaction	Escitalopram			S	Unknown	Unk		Aurobindo
	Ginkgo Biloba			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16020423	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-009804			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Logorrhoea; Seizure; Tachycardia	Escitalopram			S	Oral	Unk		Aurobindo
	Valium			S	Oral	Unk		Not Reported
	Lithium			S	Oral	1.2 Gram, Once A Day		Not Reported
	Tercian			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16020447	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-010130			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Tablets			S	Unknown	10 Milligram, Daily,Morning		Aurobindo
	Mirtazapine Film-Coated Tablet			S	Unknown	30 Milligram, Daily,Night		Aurobindo
	Olanzapine Tablet			S	Unknown	5 Milligram, Daily		Aurobindo
	Azathioprine			S	Unknown	75 Milligram, Daily,With Or Just After Food		Not Reported
	Dihydrocodeine			S	Unknown	2 Dosage Form, As Necessary,Two To Be Taken Four Times A Day If Required.		Not Reported
	Ferrous Fumarate			S	Unknown	420 Milligram, Daily,Morning And Night		Not Reported
	Folic Acid			S	Unknown	5 Milligram, Daily,Morning		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16020494	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2019-008271			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness; Dyspnoea; Gastric Ulcer; Insomnia; Nausea; Panic Attack; Vertigo	Escitalopram			S		Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16020536	EXPEDITED (15-DAY)		CA, OT	NL-AUROBINDO-AUR-APL-2019-010261			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Escitalopram Film-Coated Tablets 10mg			S	Transplacental	1 Dd 10 Mg		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16020545	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2019-010273			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydronephrosis	Escitalopram			S	Transplacental	20 Milligram, Once A Day (20 [Mg/D])		Aurobindo
	L-Thyroxin			C	Transplacental	112 Microgram, Once A Day (112 [Mg/D (Bis 75 Mg/D))		Not Reported
	Folic Acid			C	Transplacental	0.8 Milligram, Once A Day		Not Reported
	Progestan			C	Transplacental	600 Milligram, Once A Day (600 [Mg/D (3 X 200 Mg/D)])		Not Reported

	Dekristol		C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]	Not Reported
	Progynova		C	Transplacental	3 Milligram, Once A Day(3 [Mg/D (3 X 1 Mg/D)])	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16021039	NON-EXPEDITED			US-PFIZER INC-2019085830		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Alprazolam			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16021345	EXPEDITED (15-DAY)		HO, OT	FR-APOTEX-2019AP008714		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Paroxetine			S	Oral	28 Df, Single Dose		Glaxosmithkline
	Valium			S	Oral	3 Df, Single Dose		Not Reported
	Diazepam			S	Oral	8 Df, Sindle Dose		Not Reported
	Escitalopram			S	Oral	14 Df, Single Dose		Not Reported
	Atarax /00058401/			S	Oral	10 Df, Single Dose		Not Reported
	Alcool			S	Oral	Unk		Not Reported
	Tercian /00759301/			S	Oral	16 Df, Single Dose		Not Reported
	Prazepam			S	Oral	20 Df, Single Dose		Not Reported
	Cocaine			S	Unknown	0.5 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16022129	DIRECT		OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Feeling Abnormal; Product Storage Error; Suspected Product Quality Issue	Lexapro 10mg Rx #: 182774806256 (1/7/19)	S	Oral	Quantity:1 Tablet(S);		Forest
	Keppra	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16022627	DIRECT	Y	HO			22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16024220	EXPEDITED (15-DAY)		HO	IT-BAUSCH-BL-2019-006286		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dry Mouth; Slow Speech	Lorazepam			S	Oral			Not Reported
	Cipralex			S	Oral	Total		Not Reported
	En			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16024306	EXPEDITED (15-DAY)		OT	AU-OTSUKA-2019_003613			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Neutropenia	Rexulti			S	Oral	1 Mg, Qd		Otsuka
	Rexulti			S	Oral	2 Mg, Qd		Otsuka
	Rexulti			S	Oral	2 Mg, Unk		Otsuka
	Clopixol			S	Unknown	Unk		Not Reported
	Lexapro			S	Oral	30 Mg, Unk		Not Reported
	Clozapine			C	Oral	400 Mg, Qd		Not Reported
	Clozapine			C	Oral	400 Mg, Qd		Not Reported
	Lithium			C	Oral	250 Mg, Unk		Not Reported

Symbicort	C	Unknown	Unk		Not Reported
Mobic	C	Oral	15 Mg, Unk		Not Reported
Fenofibrate	C	Oral	145 Mg, Unk		Not Reported
Pantoprazole	C	Oral	40 Mg, Unk		Not Reported
Targin	C	Unknown	Unk		Not Reported
Colecalciferol	C	Unknown	1000 Iu, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16025353	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1907497US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatriuria	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qam		Allergan
	Co Valsartan [Valsartan]			S	Oral	Actual:160/12.5 Mg, 1-0-0-0		Not Reported
	Pantozol			S	Oral	20 Mg, Qpm		Not Reported
	Meto Zerok			C	Oral	Actual: 50mg, 1/2-0-0-0		Not Reported
	Prednison Galepharm			C	Oral	20 Mg, Qam		Not Reported
	Ecofenac			C	Oral	Actual: 75mg, 1-0-1-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2019	13533497	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170506438		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Exposure During Pregnancy; Lung Infection; Melanocytic Naevus; Rheumatoid Arthritis; Rheumatoid Factor Increased	Imodium		Y	S	Unknown			Not Reported
	Imodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Salbutamol			S	Unknown			Not Reported
	Tecta			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported

	Acetaminophen W/Codeine Phosphate	S	Unknown	Not Reported
	Loperamide Hydrochloride	C	Unknown	Not Reported
	Multivitamins	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2019	14177479	EXPEDITED (15-DAY)		HO	CZ-ACCORD-060891		45 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Escitalopram			S	Oral			Accord
	Sertraline			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2019	14699222	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-017424			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Therapy; Electrocardiogram Qt Prolonged	Hydroxyzine			S	Oral	Unk		Aurobindo
	Seroplex			S	Oral	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2019	15989148	EXPEDITED (15-DAY)		OT	IT-ACCORD-108509		35 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Apathy; Asthenia	Escitalopram			S	Oral			Not Reported
	Seroquel			S	Oral	300 Mg Film-Coated Tablets 200 Mg Prolonged-Release Tablets		Not Reported
	Lamotrigine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2019	16025733	EXPEDITED (15-DAY)		OT	GB-ACCORD-109837		81 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Product Dispensing Error	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2019	16025799	EXPEDITED (15-DAY)		HO, LT, OT	FR-ACCORD-109352		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Suicide Attempt	Escitalopram			S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Not Reported
	Olanzapine			S	Unknown	15 Mg, Unk		Not Reported
	Methyldopa			S	Oral			Accord
	Imovane			S	Oral	1tab/Dy, Oral Drug Unspecified Form		Not Reported
	Lepticur			S	Unknown	Unk		Not Reported
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Seroplex			S	Unknown	Unk,Also Received 10 Mg For Melancholia,5 Mg For Major Depression		Not Reported
	Depamide			S	Oral	300 Mg, Oral Drug Unspecified Form		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening.		Not Reported
	Anafranil			S	Oral	Daily Dose Increased. Oral Drug Unspecified Form		Not Reported
	Zyprexa			S	Unknown	15 Mg, Unk		Not Reported
	Zopiclone			S	Oral	1tab/Dy		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2019	16025924	EXPEDITED (15-DAY)		CA, OT	DE-ACCORD-110150		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Off Label Use; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine			S	Transplacental	50 Mg/D/Varying Dosage Between 25 And 50 Mg/D		Not Reported
	Lamictal			S	Transplacental	125 Mg/D / Slowly Reduced		Not Reported
	Cipralex			S	Transplacental	20 Mg/D / Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D		Not Reported
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2019	16025950	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-009193			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intracranial Haematoma	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Kardegic			S	Oral	75 Milligram, Once A Day		Not Reported
	Levocetirizine			C	Unknown	5 Milligram, Once A Day		Not Reported
	Amlodipine			C	Unknown	5 Milligram, Once A Day		Not Reported
	Levothyroxine			C	Unknown	50 Microgram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2019	16026046	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2019-011087			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lymphoma	Escitalopram			S	Unknown	Unk		Aurobindo
	Bromazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2019	16026696	EXPEDITED (15-DAY)		OT	IT-APOTEX-2019AP008577		43 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Olanzapine			S	Oral	20 Mg, In Total		Apotex
	Escitalopram Oxalate			S	Oral	50 Mg, In Total		Not Reported
	Tavor /00273201/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2019	16026701	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0105076		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia	Lamotrigine Tablets			S	Unknown			Not Reported
	Lamotrigine Tablets			S				Not Reported
	Escitalopram			S	Unknown	Every Morning		Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S		Every Morning		Not Reported
	Escitalopram			S		Every Morning		Not Reported
	Testosterone 50mg/5g - Gel			S	Unknown	50 Mg/5 G Every Morning On The Right Upper Extremity		Not Reported
	Lithium			S	Unknown	Every Bedtime		Not Reported
	Lurasidone			S	Unknown	After Dinner		Not Reported
	Lorazepam			S	Unknown	As Necessary		Not Reported
	Lorazepam			S		As Necessary		Not Reported
	Bupropion			S	Unknown	Every Morning		Not Reported
	Bupropion			S		Every Morning		Not Reported
	Bupropion			S		Every Morning		Not Reported
	Buspirone			S	Unknown			Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported

	Buspirone	S				Not Reported
	Buspirone	S				Not Reported
	Buspirone	S				Not Reported
	Buspirone	S				Not Reported
	Buspirone	S				Not Reported
	Buspirone	S				Not Reported
	Buspirone	S				Not Reported
	Buspirone	S				Not Reported
	Buspirone	S				Not Reported
	Buspirone	S				Not Reported
	Buspirone	S				Not Reported
	Aripiprazole	S	Unknown	Every Bedtime		Not Reported
	Aripiprazole	S		Every Bedtime		Not Reported
	Benztropine Mesylate	C	Unknown	As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2019	16026756	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1017222		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug-Induced Liver Injury	Escitalopram			S	Unknown			Ivax
	Kratom			S	Oral			Not Reported
	Kratom			S	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Metoprolol Tartrate			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported
	Fexofenadine			C	Unknown			Not Reported
	Acetaminophen			C	Unknown	Restricted Use To The Recommended 3000 Mg Per Day Limit		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	12984666	EXPEDITED (15-DAY)		HO	MY-ALLERGAN-1678334US			Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Cognitive Disorder; Hypophagia; Product Compounding Quality Issue	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	14690133	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MYLANLABS-2018M1017925		62 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Moclobemide			S	Oral	150 Mg, In Afternoon		Not Reported
	Zolpidem			S	Oral	10 Mg, At Bedtime		Not Reported
	Sertraline			S	Oral	50 Mg, At Night		Not Reported
	Venlafaxine			S	Oral	150 Mg In The Morning, In The Afternoon		Not Reported
	Metoprolol			S		Unk		Not Reported
	Ivabradine			S	Unknown	Unk		Mylan
	Escitalopram			S	Unknown	Unk		Mylan
	Trazodone			S	Unknown	Unk		Mylan
	Cyproheptadine			S	Oral	16 Milligram		Mylan
	Sotalol			C				Mylan
	Warfarin			C				Mylan
	Ginkgo Biloba Extract /01003110/			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	15720271	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1857410US			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Rize			C	Oral	5 Mg, Q8hr		Not Reported
	Atarax-P			C				Not Reported
	Meylon			C	Intravenous (not otherwise specified)	Unk		Not Reported

	Nauzelin	C	Oral	10 Mg, Q8hr	Not Reported
	Sennoside	C	Oral	Unk	Not Reported
	Merislon	C	Oral	Unk, Prn	Not Reported
	Cercine	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Pl	C	Oral	Unk	Not Reported
	Pariet	C	Oral	Unk	Not Reported
	Amlodipine	C	Oral	Unk	Not Reported
	Mohrus L	C	Topical	Unk	Not Reported
	Tocopheryl Acetate	C	Oral	Unk	Not Reported
	Loxonin	C	Unknown		Not Reported
	Loxonin	C	Topical	Unk	Not Reported
	Rebamipide	C			Not Reported
	Candesartan	C	Oral	Unk	Not Reported
	Brotizolam	C	Oral	Unk	Not Reported
	Adetphos	C	Oral	Unk	Not Reported
	Adetphos	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Methycobal	C			Not Reported
	Kashiwadol	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	15736971	EXPEDITED (15-DAY)		HO, OT	PL-ALLERGAN-1857960US			Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Metamizol			S	Oral	500 Mg, Twice A Day		Not Reported
	Tramadol Hydrochloride			S	Unknown	100 Mg, Bid		Not Reported
	Buprenorphine			S	Unknown	35 Mg, Every 4 Days		Not Reported
	Metoclopramide			S	Oral	10 Mg, Three Times A Day		Not Reported

				For About 3 Weeks	
	Omeprazole	S	Unknown	20 Mg, In The Morning, Fasting	Not Reported
	Alprazolam	S	Unknown	Unk	Not Reported
	Ketoprofen	S	Oral	100 Mg, 3 Times A Day	Not Reported
	Zoledronic Acid	C	Unknown	Unk	Not Reported
	Effentora	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Valproic Acid	C	Unknown	Unk	Not Reported
	Heparin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	15783626	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1026176		60 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Duloxetine			S	Unknown	60 Milligram, Qd		Not Reported
	Duloxetine			S				Not Reported
	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Sertraline			S	Oral	100 Milligram, Qd		Not Reported
	Lorazepam			S	Oral	2.5 Milligram, Qd		Not Reported
	Brintellix			S	Unknown	15 Milligram, Qd		Mylan
	Brintellix			S	Unknown	10 Milligram, Qd		Mylan
	Brintellix			S	Unknown	10 Milligram, Qd		Mylan
	Brintellix			S	Unknown	5 Milligram, Qd		Mylan
	Amiodarone			C	Unknown	Unk		Mylan
	Ezetimibe			C	Unknown	10 Milligram, Qd		Mylan
	Simvastatin			C	Unknown	20 Milligram, Qd		Mylan

Coumadin	C		Unk		Mylan
Lansoprazole	C	Unknown	30 Milligram, Qd		Mylan
Ramipril + Hidroclorotiazida	C	Unknown	Unk		Mylan
Alprazolam	C	Unknown	2 Milligram, Qd		Mylan
Triatec Hct	C		15 Milligram, Qd		Mylan
Cordarone	C	Unknown	200 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16027552	EXPEDITED (15-DAY)		HO, OT	FR-APOTEX-2019AP008629		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Haematoma Muscle	Clopidogrel			S	Oral	75 Mg, Qd		Apotex
	Escitalopram			S	Oral	5 Mg, Qd, 1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16027553	EXPEDITED (15-DAY)		HO, LT, OT	FR-APOTEX-2019AP008610		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use; Suicide Attempt	Olanzapine			S	Unknown	15 Mg, Unk		Apotex
	Lepticur			S	Unknown	Unk		Not Reported
	Methyldopa			S	Oral	Unk		Not Reported
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	10 Mg, Qd		Not Reported
	Seroplex			S	Unknown	5 Mg, Qd		Not Reported
	Depamide			S	Oral	300 Mg, Qd		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening.		Not Reported
	Escitalopram			S	Unknown	Dose Increased To 10		Not Reported

				Mg/Day. Previously 5mg. 1tab/Dy	
	Anafranil	S	Oral	75 Mg, Qd (Daily Dose Increased. Oral Drug Unspecified Form)	Not Reported
	Zyprexa	S	Unknown	15 Mg, Unk	Not Reported
	Zopiclone	S	Oral	7.5 Mg, Qd (1tab/Dy)	Not Reported
	Imovane	S	Oral	7.5 Mg, Qd (1tab/Dy, Oral Drug Unspecified Form)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16027909	EXPEDITED (15-DAY)		HO	PT-APOTEX-2019AP008753		60 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Delusion Of Grandeur; Drug Withdrawal Syndrome; Euphoric Mood; Impulsive Behaviour; Irritability; Mania; Pressure Of Speech; Psychomotor Hyperactivity; Treatment Noncompliance	Escitalopram			S	Unknown	20 Mg, Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16030335	DIRECT		OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eclampsia; Foetal Heart Rate Deceleration Abnormality; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Meconium Abnormal; Placenta	Escitalopram			S	Oral		10 MTH	Not Reported
	Prenatal Vitamins			C				Not Reported
	Tylenol			C				Not Reported

Praevia; Pregnancy; Small Size Placenta

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16030902	NON-EXPEDITED			US-PFIZER INC-2019089788			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash; Scar; Skin Burning Sensation; Skin Haemorrhage	Venlafaxine Hcl			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16031187	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1017143			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S		10 Milligram Daily; Morning		Ivax
	Azathioprine			S		75 Milligram Daily; With Or Just After Food		Not Reported
	Dihydrocodeine			S		Two To Be Taken Four Times A Day If Required.		Not Reported
	Ferrous Fumarate			S		420 Milligram Daily; Morning And Night		Not Reported
	Mirtazapine			S		30 Milligram Daily; Night		Teva
	Folic Acid			S		5 Milligram Daily; Morning		Actavis
	Olanzapine			S		5 Milligram Daily;		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16032138	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1908174US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Bid		Allergan
	Xarelto			S	Oral	1 Df		Not Reported

Quetiapin Sandoz	C	Oral	25 Mg, Qd		Not Reported
Podomexef	C	Oral	200 Mg		Not Reported
Circadin	C	Oral	1.5 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16032579	EXPEDITED (15-DAY)		OT	US-HETERO CORPORATE-HET2019US00249		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug-Induced Liver Injury	Escitalopram			S				Hetero
	Mitragyna Speciosa			S	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Metoprolol Tartrate			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	14776776	EXPEDITED (15-DAY)		HO, OT	SI-ACCORD-065805		48 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Sclerosis; Off Label Use; Palpitations	Escitalopram			S		10 Mg, Qd (1 Tablet In Morning)		Not Reported
	Pregabalin			S		150 Mg, Bid		Not Reported
	Fty 720			S	Unknown	0.5 Mg, Qd		Not Reported
	Fampridine			S		10 Mg, Bid		Not Reported
	Tolterodine/Tolterodine L-Tartrate			S		4 Mg, Qd (1 Tablet In Morning)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	15685235	EXPEDITED (15-DAY)		HO	IE-009507513-1811IRL011820		55 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapy Non-Responder	Mirtazapine	S	Oral	Unk		Merck
	Amitriptyline Hydrochloride	S		Unk		Not Reported
	Trimipramine	S		Unk		Not Reported
	Sertraline Hydrochloride	S		Unk		Not Reported
	Escitalopram	S		Unk		Not Reported
	Fluoxetine	S		Unk		Not Reported
	Fluvoxamine Maleate	S		Unk		Not Reported
	Duloxetine Hydrochloride	S		Unk		Not Reported
	Venlafaxine Hydrochloride	S		Unk		Not Reported
	Phenelzine Sulfate	S		Unk		Not Reported
	Moclobemide	S		Unk		Not Reported
	Agomelatine	S		Unk		Not Reported
	Valproate Sodium	S		Unk		Not Reported
	Lithium	S		Unk		Not Reported
	Olanzapine	S		Unk		Not Reported
	Quetiapine Fumarate	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	15887384	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-197416		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral	In Total		Not Reported
	Paroxetine			S	Oral	In Total		Sun
	Prazepam			S	Oral	In Total		Not Reported
	Cocaine			S	Unknown	0.5g ()		Not Reported
	Tercian			S	Oral	In Total		Not Reported
	Atarax			S	Oral	In Total		Not Reported
	Valium			S	Oral	In Total		Not Reported

	Alcool		S	Oral	Non Renseignee ()	Not Reported
	Diazepam		S	Oral	In Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	15901155	EXPEDITED (15-DAY)		HO	RU-ALLERGAN-1904645US			Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotonia; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	50 Df		Allergan
	Phenibut/Aminophenylbutyric Acid			S	Oral	60 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	15909003	EXPEDITED (15-DAY)		OT	RU-ALLERGAN-1904808US			Male	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Erectile Dysfunction; Hyperhidrosis; Product Use In Unapproved Indication; Salivary Hypersecretion	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Sonapax			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Atarax			C	Unknown	20 Mg, Qd		Not Reported
	Paxil			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16033156	EXPEDITED (15-DAY)		HO	FR-ACCORD-110249		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Bendamustine/Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported
	Escitalopram			S	Oral			Not Reported
	Pantoprazole			S	Oral	Long Cours		Not Reported
	Loxapac			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported

	Fenofibrate		S	Oral		Not Reported
	Truxima		S	Intravenous (not otherwise specified)		Not Reported
	Valaciclovir		S	Oral		Not Reported
	Lorazepam		S	Oral	Long Cours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16033318	EXPEDITED (15-DAY)		OT	BE-AUROBINDO-AUR-APL-2019-011337			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Obstruction; Product Use In Unapproved Indication	Aripiprazole			S	Unknown	400 Milligram		Aurobindo
	Sipralexa			S	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16033618	NON-EXPEDITED			US-IMPAX LABORATORIES, LLC-2018-IPXL-02491		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome; Tremor	Rytary			S	Unknown	Unk		Impax
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035123	EXPEDITED (15-DAY)		HO	FR-APOTEX-2019AP008679		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Olanzapine			S	Oral	Unk, Dose Exacte Lors De L'Imv Inconnue		Apotex
	Escitalopram			S	Oral	Unk (Dose Exacte Lors De L'Imv Inconnue)		Not Reported
	Bromazepam			S	Oral	120 Mg, Unk, Prise Estimée À 20 Cp De Bromazépam 6 Mg		Not Reported

	Aripiprazole	S	Oral	Unk (Dose Exacte Lors De L'Imv Inconnue)	Not Reported
	Zolpidem	S	Oral	Unk, Dose Exacte Lors De L'Imv Inconnue	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16036709	EXPEDITED (15-DAY)		HO	PHHY2019CH039055		57 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome; Serotonin Syndrome	Risperidone			S	Oral	0.5 Mg, Qd		Novartis
	Risperidone			S	Oral	3 Mg, Qd		Novartis
	Risperidone			S	Oral	2 Mg, Qd		Novartis
	Clopin (Clozapine)			S	Oral	25 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Buprenorphine			C	Unknown			Not Reported
	Lorazepam			C	Unknown	Unk Unk, Prn		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Zolpidem			C	Unknown	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16036749	EXPEDITED (15-DAY)		HO	PHHY2019IT047868		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dry Mouth; Slow Speech	Lorazepam			S	Oral	20 Mg, Total		Novartis
	Cipralex			S	Oral	300 Mg, Total		Not Reported
	En			S	Oral	40 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16037464	EXPEDITED (15-DAY)		CA, DE	DE-MYLANLABS-2019M1018800			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam	S	Transplacental	1500 Milligram, Qd (1500 [Mg/D])	Not Reported
	Escitalopram	S	Transplacental	220 Milligram, Qd (20 [Mg/D])	Not Reported
	Candesartan	S	Transplacental	16 Milligram, Qd (16 [Mg/D])	Not Reported
	Paroxetine	S	Transplacental	30 Milligram, Qd (30 [Mg/D])	Not Reported
	Nepresol /00007602/	S	Transplacental	25 Milligram, Qd (25 [Mg/D])	Mylan
	L-Thyroxin /00068001/	C	Transplacental	Unk	Mylan
	Cytotec	C	Transplacental	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16037633	EXPEDITED (15-DAY)		DE, OT	CH-DSJP-DSE-2019-107019			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Death; Drug Interaction; Haematuria; Melaena; Subcutaneous Haematoma	Lixiana			S	Oral	30 Mg, Qd		Daiichi
	Cipralex			S	Oral	20 Mg, Qd		Not Reported
	Coversum N Combi			C		Unk		Not Reported
	Remeron			C		Unk		Not Reported
	Torem /01036501/			C		Unk		Not Reported
	Pantozol /01263204/			C		Unk		Not Reported
	Zolpidem Tartrate			C		Unk		Not Reported
	Novalgin /06276704/			C		Unk		Not Reported
	Kalcipos D3			C		Unk		Not Reported
	Seretide			C		Unk		Not Reported
	Spiriva			C		Unk		Not Reported
	Aldactone /00006201/			C		Unk		Not Reported
	Beloc Zok			C		Unk		Not Reported
	Lasix /00032601/			C		Unk		Not Reported

	Becozym /07503601/	C	Unk	Not Reported
	Benerva Mit Acetylcholin	C	Unk	Not Reported
	Co-Amoxi	C	Unk	Not Reported
	Spiricort	C	Unk	Not Reported
	Spiolto Respimat	C	Unk	Not Reported
	Diclofenac	C	Unk	Not Reported
	Pulmicort	C	Unk	Not Reported
	Ipramol	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16038196	EXPEDITED (15-DAY)		DE, OT	CH-ALLERGAN-1908197US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Death; Drug Interaction; Haematuria; Melaena; Subcutaneous Haematoma	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Lixiana			S	Unknown	30 Mg, Qd		Not Reported
	Coversum N Combi			C	Unknown			Not Reported
	Remeron			C	Unknown			Not Reported
	Torem			C	Unknown			Not Reported
	Pantozol			C	Unknown			Not Reported
	Zolpidem Tartrate			C	Unknown			Not Reported
	Novalgin (Metamizole Sodium)			C	Unknown			Not Reported
	Kalcipos-D			C	Unknown			Not Reported
	Seretide			C	Unknown			Not Reported
	Spiriva			C	Unknown			Not Reported
	Aldactone			C	Unknown			Not Reported
	Beloc Zoc			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Becozyme			C	Unknown			Not Reported
	Benerva Mit Acetylcholin			C	Unknown			Not Reported

Co-Amoxi	C	Unknown		Not Reported
Spiricort	C	Unknown		Not Reported
Spiolto Respimat	C	Unknown		Not Reported
Diclofenac	C	Unknown		Not Reported
Pulmicort	C	Unknown		Not Reported
Ipramol	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16038790	EXPEDITED (15-DAY)		OT	SE-TEVA-2019-SE-1018520		57 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic	Escitalopram			S		5mg Upptrappades Till 20 Mg.		Ivax
	Escitalopram			S	Unknown			Ivax
	Duloxetine			S		30 Mg Upptrappat Till 60 Mg.		Teva
	Duloxetine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	14101684	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-059985		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sopor	Escitalopram Accord			S	Oral	Strength: 20 Mg		Accord
	Losartan			S	Oral			Accord
	Haldol			S	Oral	Strength: 2 Mg/Ml, Oral Drops- Janssen - Cil		Not Reported
	Delorazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	14685232	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-BAUSCH-BL-2018-008064		62 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apallic Syndrome; Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Zolpidem			S	Oral	At Bedtime		Not Reported
	Venlafaxine			S	Oral	In The Morning, In The Afternoon		Not Reported
	Metoprolol Vp			S	Unknown			Not Reported
	Mobemid			S	Oral	In Afternoon		Not Reported
	Ivabradine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Oral	At Night		Not Reported
	Trazodone			S	Unknown			Not Reported
	Cyproheptadine			S	Oral			Not Reported
	Sotalol			C				Not Reported
	Warfarin			C				Not Reported
	Ginkgo Biloba Extract			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	15945670	EXPEDITED (15-DAY)		DE, HO, LT	GB-ACCORD-105825		88 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer Haemorrhage; Gastrointestinal Pain	Escitalopram			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Oral			Not Reported
	Dihydrocodeine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16038965	NON-EXPEDITED			US-APOTEX-2018AP023706		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction; Treatment Noncompliance	Lamotrigine			S	Unknown	100 Mg, Unk		Apotex
	Lamotrigine			S				Apotex
	Lamotrigine			S				Apotex
	Enalapril			S	Unknown	20 Mg, Q.Am		Apotex

	Mirtazapine	S	Unknown	22.5 Mg, Q.H.S.	Apotex
	Mirtazapine	S			Apotex
	Mirtazapine	S			Apotex
	Alprazolam	S	Unknown	1 Mg, Tid, Prn	Apotex
	Alprazolam	S			Apotex
	Alprazolam	S			Apotex
	Escitalopram	S	Unknown	20 Mg, Bid	Apotex
	Escitalopram	S			Apotex
	Escitalopram	S			Apotex
	Lansoprazole	S	Unknown	30 Mg, Q.Am	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16039752	EXPEDITED (15-DAY)		CA, HO	NO-ALLERGAN-1908255US			Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenal Stenosis; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan
	Truxal			S	Transplacental	2 Df, Qhs		Not Reported
	Seroquel			S	Transplacental	100 Mg, Qd		Not Reported
	Furadantin			S	Transplacental	50 Mg, Q8hr		Not Reported
	Mirtazapin Orion			S	Transplacental	15 Mg, Prn (At Night If Necessary, As Required)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16039782	EXPEDITED (15-DAY)		OT	ES-ACCORD-110454		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Product Substitution Error	Escitalopram			S	Oral			Not Reported
	Idaptan			S	Oral			Not Reported
	Nifedipine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16041577	EXPEDITED (15-DAY)		HO, OT	PT-ACCORD-110544		60 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Mania	Escitalopram			S		Less Than 12 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16042627	EXPEDITED (15-DAY)		CA, HO	NO-ASTRAZENECA-2019SE33247		< 1 DAY	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenal Stenosis; Foetal Exposure During Pregnancy	Seroquel			S	Transplacental			Zeneca
	Truxal			S	Transplacental	2 Dosage Forms At Night. Strength Of Dosage Forms Not Known.		Not Reported
	Cipralex			S	Transplacental			Not Reported
	Mirtazapine			S	Transplacental	15 Mg At Night If Necessary.		Not Reported
	Furadantin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16044223	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19P-163-2686375-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Dysphagia; Feeding Disorder; Fluid Intake Reduced; Gastrooesophageal Reflux Disease; Intentional Self-Injury; Liver Function Test Increased; Sedation; Therapeutic Product Effect Incomplete; Vomiting; Weight Decreased; Weight Decreased	Valproic Acid			S	Unknown			Not Reported
	Clobazam			S	Unknown	15mg In The Morning, 15 Mg In The Unknown		Not Reported
	Clobazam			S	Unknown	Hs		Not Reported
	Lorazepam			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Clonidine			S	Unknown	Hs		Not Reported
	Ranitidine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16044381	EXPEDITED (15-DAY)		DE	BE-ALLERGAN-1908340US			Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Q Year		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16044386	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	NO-ALLERGAN-1908346US			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd (5 Mg (1 Tbl) X1 Daglig)		Allergan
	Eliquis			S	Oral	5 Mg, Q12h (5 Mg (1 Tbl) X1 Daglig)		Not Reported
	Albyl-E			S	Oral	75 Mg, Qd (1 Tbl (75 Mg) X1 Daglig)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	15839364	EXPEDITED (15-DAY)		HO, LT	HU-ALLERGAN-1902085US			Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Intentional Overdose; Muscle Rigidity; Myoglobin Blood Increased; Serotonin Syndrome; Serotonin Syndrome; Suicidal Ideation; Suicide Attempt; Tremor	Escitalopram Oxalate - Bp			S	Unknown	Overdose: Unknown Dose		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Moclobemid			S	Unknown	Overdose: Unknown Dose		Not Reported
	Moclobemid			S				Not Reported
	Sertraline Hcl			S	Unknown	Overdose: Unknown Dose		Not Reported
	Sertraline Hcl			S				Not Reported
	Cyproheptadin			C	Unknown	Unk		Not Reported
	Benzodiazepine Derivatives			C				Not Reported
	Monoamine Oxidase A Inhibitors			C				Not Reported
	Ssri			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	15885120	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1903980US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Infective Spondylitis	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Quetiapine Fumarate			C	Oral	100 Mg, Qd		Not Reported
	Quetiapine Fumarate			C	Oral	200 Mg, Qd		Not Reported
	Quetiapine Fumarate			C	Oral	100 Mg, Qd		Not Reported
	Quetiapine Fumarate			C	Oral	200 Mg, Qd		Not Reported
	Quetiapine Fumarate			C	Oral	50 Mg, Qd		Not Reported
	Quetiapine Fumarate			C	Oral	300 Mg, Qd		Not Reported
	Lithium Carbonate			C	Oral	100 Mg, Qd		Not Reported
	Lithium Carbonate			C	Oral	200 Mg, Qd		Not Reported
	Lithium Carbonate			C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16044954	EXPEDITED (15-DAY)		HO	FR-ACCORD-110856		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Liver Disorder	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16049430	EXPEDITED (15-DAY)		OT	SI-ALLERGAN-1908583US			Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Arthralgia; Blood Pressure	Escitalopram Oxalate - Bp			S	Oral	1/2 Tablet		Allergan

Increased; Blood Urea Increased; Cognitive Disorder; Confusional State; Coordination Abnormal; Cough; Depersonalisation/Dereali sation Disorder; Depression; Diabetes Mellitus; Diplopia; Disturbance In Attention; Drug Dependence; Dry Mouth; Dysgeusia; Dysgeusia; Dysphagia; Dysphonia; Dyspnoea; Dysstasia; Erectile Dysfunction; Extrasystoles; Flatulence; Gout; Gynaecomastia; Hot Flush; Hyperglycaemia; Hypertension; Initial Insomnia; Insomnia; Intraocular Pressure Increased; Irritability; Joint Stiffness; Joint Swelling; Libido Decreased; Loss Of Libido; Memory Impairment; Mental Disorder; Mood Altered; Muscle Spasms; Musculoskeletal Stiffness; Nervousness; Nightmare; Nocturia; Oedema Peripheral; Orthopnoea; Penis Disorder; Photopsia; Pruritus; Psychiatric Disorder Prophylaxis; Sexual Dysfunction; Somnolence; Testicular Atrophy; Tinnitus; Urinary Incontinence; Vertigo; Vision Blurred; Visual Impairment	Helex	S	Oral	Unk	Not Reported
	Amlopin	S	Oral	Unk	Not Reported
	Pamorelin	S	Unknown	22.5 Mg	Not Reported
	Symbicort	S	Unknown	Unk	Not Reported
	Valsacor	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16049657	EXPEDITED (15-DAY)		OT	SI-ARBOR PHARMACEUTICALS, LLC-SI-2019ARB000329			Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Arthralgia; Blood Pressure Increased; Blood Urea Increased; Cognitive Disorder; Confusional State; Coordination Abnormal; Cough; Depersonalisation/Dereali sation Disorder; Depression; Depression; Diabetes Mellitus; Diplopia; Disturbance In Attention; Drug Dependence; Dry Mouth; Dysphagia; Dysphonia; Dyspnoea; Dysstasia; Erectile Dysfunction; Erectile Dysfunction; Extrasystoles; Flatulence; Gout; Gynaecomastia; Hot Flush; Hyperglycaemia; Hypertension; Initial Insomnia; Insomnia; Intraocular Pressure Increased; Irritability; Joint Stiffness; Joint Swelling; Joint Swelling; Libido Decreased; Loss Of Libido; Memory Impairment; Mental Disorder; Mood Altered; Muscle Spasms; Musculoskeletal Stiffness; Nervousness; Nightmare; Nocturia; Oedema	Triptodur			S	Intramuscular	Vial (22.5 Mg, Unknown)		Arbor
	Helex			S	Unknown	Unk		Not Reported
	Amlopin /00972401/			S	Oral	Unk		Not Reported
	Cipralex /01588501/			S	Oral	1/2 Tablet In The Morning And Evening , Coated Tablet ,Film (0.5 Dosage Forms,2 In 1 D)		Not Reported
	Symbicort			S	Unknown	Powders, Unit Dose		Not Reported
	Valsacor			S		Unk		Not Reported

Peripheral; Oedema Peripheral; Orthopnoea; Penis Disorder; Photopsia; Pruritus; Sexual Dysfunction; Sexual Dysfunction; Somnolence; Somnolence; Taste Disorder; Taste Disorder; Testicular Atrophy; Tinnitus; Urinary Incontinence; Vertigo; Vision Blurred; Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	15860151	EXPEDITED (15-DAY)		OT	ZA-TAKEDA-2019TUS002168			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Pressure Increased; Constipation; Energy Increased; Irritability; Myoglobin Blood Increased; Rhabdomyolysis	Vortioxetine			S	Oral	10 Milligram, Qd		Takeda
	Aspavor			S	Unknown	20 Milligram, Qd		Not Reported
	Lexamil			S	Unknown	Unk		Not Reported
	Ecotrin			C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16049986	EXPEDITED (15-DAY)		DE, HO, OT	FR-ACCORD-109278		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute; Septic Shock	Repaglinide			S	Oral	2 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Oxybutynin/Oxybutynin Hydrochloride			S	Oral	15 Mg, Qd		Accord
	Tacrolimus			S	Oral	3 Mg, Qd		Accord
	Atorvastatin/Atorvastatin			S	Oral	10 Mg, Qd		Not Reported

Calcium					
Bisoprolol		S	Oral	2 Df, Total	Not Reported
Amphotericin B		S	Buccal	10 Percent	Not Reported
Prograf		S	Oral		Not Reported
Amiodarone		S	Oral		Not Reported
Driptane		S	Oral	5 Mg, Scored Tablet,	Not Reported
Bisoce		S	Oral	Strength 1.25 Mg	Not Reported
Lactulose		S	Oral	2 Df, Qd	Not Reported
Lansoprazole		S	Oral	15 Mg, Qd	Not Reported
Trimebutine		S	Oral	300 Mg, Qd	Not Reported
Amphotericin B/Tetracycline		S	Buccal	3 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16049990	EXPEDITED (15-DAY)		HO	FR-ACCORD-110915		92 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Haematoma Muscle	Clopidogrel			S	Oral			Not Reported
	Escitalopram			S	Oral	1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050506	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-995134			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Feeding Disorder; Hallucination; Product Dose Omission; Sedation; Somnolence	Austedo			S	Unknown	48 Milligram Daily;		Teva
	Austedo			S	Unknown	36 Milligram Daily; One 12 Mg Tablet In The Morning And Two 12 Mg Tablets At Night		Teva
	Austedo			S	Unknown	24 Milligram Daily;		Teva
	Austedo			S	Unknown	12 Milligram Daily; Current Dose		Teva

	Lexapro	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050524	EXPEDITED (15-DAY)		DE, OT	US-009507513-1903USA002288		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide Attempt	Prinivil			S	Oral	Cause Rank: 7		Merck
	Bupropion			S	Oral	Cause Rank: 1; Bupropion Concentration In Blood 12.2 Mcg/Ml (Autopsy)		Not Reported
	Verapamil			S	Oral	Cause Rank: 2; Verapamil Concentration In Blood 2.3 Mcg/Ml (1 H, Peripheral Blood (Pe))		Not Reported
	Escitalopram			S	Oral	Cause Rank: 3		Not Reported
	Alcohol			S	Oral	Cause Rank: 4		Not Reported
	Diphenhydramine			S	Oral	Cause Rank: 5		Not Reported
	Hydrochlorothiazide			S	Oral	Cause Rank: 6		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050558	EXPEDITED (15-DAY)		DE, OT	US-009507513-1903USA003074		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Prinivil			S	Oral			Merck
	Amlodipine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050946	NON-EXPEDITED			US-TAKEDA-2019TUS011027		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypoaesthesia; Paraesthesia	Trintellix		S	Unknown	5 Milligram	Takeda
	Trintellix		S	Unknown	10 Milligram	Takeda
	Trintellix		S	Unknown	20 Milligram	Takeda
	Lexapro		S	Unknown	30 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16051018	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2019-011822			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dry Mouth; Slow Speech	Lorazepam			S	Oral	20 Milligram In Total		Aurobindo
	Cipralex			S	Oral	300 Milligram In Total		Not Reported
	En			S	Oral	40 Milligram In Totlal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16051679	EXPEDITED (15-DAY)		DE, HO, OT	JP-ASTELLAS-2016JP020682		62 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Blood Creatine Phosphokinase Increased; Constipation; Constipation; Deep Vein Thrombosis; Depression; Dysuria; Hot Flush; Hyperglycaemia; Hyponatraemia; Influenza; Insomnia; Insomnia; Insomnia; Interstitial Lung Disease; Mental Disorder; Pneumatosis Intestinalis; Pneumoretroperitoneum; Pulmonary Congestion; Steroid Diabetes; White Blood Cell Count Increased	Tacrolimus			S	Unknown			Astellas
	Tacrolimus			S	Unknown			Astellas
	Tacrolimus			S	Unknown			Astellas
	Tacrolimus			S	Unknown			Astellas
	Tacrolimus			S	Unknown			Astellas
	Tacrolimus			S	Unknown			Astellas
	Tacrolimus			S	Unknown			Astellas
	Predonine /00016201/			S	Oral			Not Reported
	Predonine /00016201/			S	Oral			Not Reported
	Predonine /00016201/			S	Oral			Not Reported
	Predonine /00016201/			S	Oral			Not Reported
	Predonine /00016201/			S	Oral			Not Reported
	Predonine /00016201/			S	Oral			Not Reported

Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral	30 Mg/Day, Unknown Freq.	Not Reported
Predonine /00016201/	S	Oral	25 Mg/Day, Unknown Freq.	Not Reported
Predonine /00016201/	S	Oral	20 Mg/Day, Unknown Freq.	Not Reported
Predonine /00016201/	S	Oral	15 Mg/Day, Unknown Freq.	Not Reported
Basen /01290601/	S	Oral	0.6 Mg, Once Daily	Not Reported
Remeron	S	Oral		Not Reported
Remeron	S	Oral		Not Reported
Remeron	S	Oral		Not Reported
Remeron	S	Oral		Not Reported
Remeron	S	Oral		Not Reported
Lexapro /01588501/	S	Oral		Not Reported
Lexapro /01588501/	S			Not Reported
Lexapro /01588501/	S	Oral		Not Reported
Ursodeoxycholic Acid	C	Oral		Not Reported
Blopress	C	Oral		Not Reported
Bonalon	C	Oral		Not Reported
Hustazol /00398402/	C	Oral		Not Reported
Juvela /00110502/	C	Oral		Not Reported
Baktar	C	Oral		Not Reported
Nexium /01479302/	C	Oral		Not Reported

Humalog	C	Unknown	2-6 Units With Insulin Scale, Once Daily	Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral	3 Mg/Day, Unknown Freq.	Not Reported
Prednisolone	C	Oral	1 Mg/Day, Unknown Freq.	Not Reported
Glufast	C	Oral		Not Reported
Glufast	C	Oral	30 Mg/Day, Unknown Freq.	Not Reported
Seroquel	C	Oral		Not Reported
Amoban	C	Oral		Not Reported
Hustazol /00398402/	C	Oral	Unk Unk, Unknown Freq.	Not Reported
Rize /00624801/	C	Oral		Not Reported
Rize /00624801/	C	Oral		Not Reported
Rize /00624801/	C	Oral	5 Mg/Day, Unknown Freq.	Not Reported
Magnesium Oxide	C	Oral		Not Reported
Magnesium Oxide	C	Oral		Not Reported
Sennoside /00571901/	C	Oral		Not Reported
Risperidone	C	Oral		Not Reported
Abilify	C	Oral		Not Reported
Tetramide	C	Oral		Not Reported
Urso /00465701/	C	Oral		Not Reported
Reslin	C	Oral		Not Reported
Furosemide	C	Oral		Not Reported
Sycrest	C	Oral		Not Reported

Sycrest	C	Oral			Not Reported
Sycrest	C	Oral	10 Mg/Day, Unknown Freq.		Not Reported
Sycrest	C	Oral	15 Mg/Day, Unknown Freq.		Not Reported
Contomin	C	Oral	25-50 Mg, As Needed		Not Reported
Contomin	C	Oral			Not Reported
Contomin	C	Oral			Not Reported
Novorapid	C	Unknown	Scale 2-4 Units, Once Daily		Not Reported
Ebrantil /00631801/	C	Oral			Not Reported
Amitiza	C	Oral			Not Reported
Amitiza	C	Oral	24 Mg/Day, Unknown Freq.		Not Reported
Tryptanol /00002202/	C	Oral	75 Mg/Day		Not Reported
Inavir /00587301/	C	Oral	40 Mg/Day, Unknown Freq.		Not Reported
Calonal	C	Oral	400 Mg/Day, Unknown Freq.		Not Reported
Lixiana	C	Oral	60 Mg/Day, Unknown Freq.		Not Reported
Daiphen	C	Oral	1 Df/Day, Unknown Freq.		Not Reported
Brotizolam	C	Oral	0.25 Mg/Day, Unknown Freq.		Not Reported
Candesartan	C	Oral	2 Mg/Day, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16051951	EXPEDITED (15-DAY)		OT	IE-TEVA-2019-IE-1020533			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Product Substitution Issue	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16052161	NON-EXPEDITED			US-SA-2019SA064337		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Allegra			S				Sanofi
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Duloxetine Hydrochloride			S	Oral	35 Mg, Qd		Not Reported
	Sertraline Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16053461	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1021305		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Dizziness; Headache; Heart Rate Irregular; Mania	Escitalopram			S	Unknown	20mg/Ml; One Drop On 21. And 22. Aug. 2018		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16053620	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1021518		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dry Mouth; Slow Speech	Lorazepam			S	Oral			Actavis
	Cipralex 20 Mg/Ml Gocce Orali, Soluzione			S	Oral			Not Reported
	En 2 Mg Compresse			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16053699	EXPEDITED (15-DAY)		DE, HO	FR-MYLANLABS-2019M1021553		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pulmonary Fibrosis	Atorvastatin			S	Oral	10 Milligram, Qd		Not Reported

Paracetamol	S	Oral	1500 Milligram, Qd		Not Reported
Ramipril	S	Oral	5 Milligram, Qd		Not Reported
Amiodarone	S	Oral	200 Milligram, Qd		Not Reported
Pantoprazole	S	Oral	20 Milligram, Qd		Not Reported
Lorazepam	S	Oral	1 Milligram, Qd		Not Reported
Escitalopram	S	Oral	10 Milligram, Qd		Not Reported
Kardegic	S	Oral	1 Dosage Form, Qd		Mylan
Caltrate Vitamine D3	S	Oral	Unk		Mylan
Levothyrox	S	Oral	1, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16053740	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2019M1021539		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Alprazolam			S	Oral	Inconnue		Not Reported
	Mirtazapine			S	Oral	Inconnue		Not Reported
	Escitalopram			S	Oral	Inconnue		Not Reported
	Methadone			S	Oral	Inconnue		Mylan
	Havlane			S	Oral	Inconnue		Mylan
	Theralene			S	Oral	Inconnue		Mylan
	Tercian /00759301/			S	Oral	Inconnue		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16053761	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1019169		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Neuropathy	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Gabapentin			S	Unknown	600 Milligram Daily;		Ivax
	Sulfonamide (Bactrim)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Peripheral; Product Use In Unapproved Indication; Rash Papular; Skin Burning Sensation	Xeljanz Xr	S	Oral	11 Milligram Daily;	Not Reported
	Lexapro	S	Unknown	20 Milligram Daily;	Not Reported
	Celebrex	S	Unknown		Not Reported
	Omeprazole	C		120 Milligram Daily;	Not Reported
	Folic Acid	C		1 Milligram Daily;	Not Reported
	Duloxetine Hcl	C		600 Milligram Daily;	Not Reported
	Pravastatin Sodium	C		40 Milligram Daily;	Not Reported
	Alendronate Sodium	C		Every Monday Morning	Not Reported
	Amitriptyline	C		Took 20 Or 30 Milligram At Night	Not Reported
	Zyrtec	C			Not Reported
	Cymbalta	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16186130	DIRECT		DS, OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Escitalopram (Generic Lexipro)			S	Oral	Quantity:1 Df Dosage Form;		Cipla
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Valsartan			C				Not Reported
	Asa			C				Not Reported
	Vit C			C				Not Reported
	D3			C				Not Reported
	B6			C				Not Reported
	B12			C				Not Reported
	Fish Oil			C				Not Reported
	Occuvite			C				Not Reported
	Coq10			C				Not Reported
	Acetyl/Carnitine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2019	16054902	EXPEDITED (15-DAY)		OT	PL-ACCORD-111209			Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Learning Disorder; Mental Impairment; Therapeutic Product Effect Incomplete	Escitalopram			S		37.5 Mg Per Day		Not Reported
	Tianeptine/Tianeptine Sodium			C		10 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2019	16056738	DIRECT	Y	HO			88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dysphagia	Escitalopram			S	Oral		4 DAY	Not Reported
	Apixaban			C				Not Reported
	Amlodipine			C				Not Reported
	Cefdinir			C				Not Reported
	Clonidine			C				Not Reported
	Losartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	14632276	NON-EXPEDITED			US-ALLERGAN-1809820US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction; Fatigue; Nervousness	Oxytrol			S	Transdermal	Unk		Allergan
	Lexapro			S	Unknown	Unk		Allergan
	Vitamin D2			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	15022508	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-007213		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Sleep-Related Event; Anxiety; Depressed Mood; Endometriosis; Feeling Abnormal; Heart Rate Increased;	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Estarylla			S				Not Reported

Nervousness; Panic Reaction; Premenstrual Syndrome; Somnolence; Stress	Lexapro	S	Unk	Not Reported
	Adderall	S		Not Reported
	Hydroxyzine	S		Not Reported
	Mometasone Furoate	C		Not Reported
	Terbinafine Hcl	C		Not Reported
	Ritalin	C		Not Reported
	Modafinil	C		Not Reported
	Zingiber Officinale	C		Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported
	Promethazine	C		Not Reported
	Nitrofurantoin	C		Not Reported
	Mefenamic Acid	C		Not Reported
	Ergocalciferol	C		Not Reported
	Ibuprofen	C		Not Reported
	Mucinex	C		Not Reported
	Nuvigil	C		Not Reported
	Prozac	C		Not Reported
	Tylenol Extra Strength	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	15784456	EXPEDITED (15-DAY)		OT	DE-ACCORD-099195		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cyst	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16003811	EXPEDITED (15-DAY)		OT	FR-ACCORD-109010		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Lichen Planus	Hydrochlorothiazide			S	Oral			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			S	Oral			Not Reported
	Atorvastatin/Atorvastatin Calcium			S	Oral			Not Reported
	Aldactone			S	Oral	Strength: 25 Mg		Not Reported

	Lamotrigine	S	Oral	Not Reported
	Xeroquel	S	Oral	Not Reported
	Perindopril/Perindopril Erbumine	S	Oral	Not Reported
	Kardegic	S	Oral	Not Reported
	Verapamil	S	Oral	Not Reported
	Teralithe	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Macrogol/Macrogol Stearate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16015896	EXPEDITED (15-DAY)		HO, OT	PT-LUPIN PHARMACEUTICALS INC.-2019-01132		60 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Mania	Escitalopram Oxalate			S	Unknown	Unk, Less Than 12 Months		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16032648	EXPEDITED (15-DAY)			JP-ALLERGAN-1908200US			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Aggression	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Amlodipine			C	Oral	5 Mg		Not Reported
	Forxiga			C	Oral	5 Mg, Qd		Not Reported
	Clopidogrel			C	Oral	75 Mg		Not Reported
	Glactiv			C	Oral	100 Mg		Not Reported
	Lansoprazole			C	Oral	15 Mg		Not Reported
	Pitavastatin Calcium			C	Oral	2 Mg		Not Reported
	Merislon			C	Oral	18 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16055282	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-201175		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dry Mouth; Slow Speech	Lorazepam			S	Oral	In Total		Sun
	Cipralex 20 Mg/Ml Gocce Orali, Soluzione			S	Oral	In Total		Not Reported
	En 2 Mg Compresse			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16055789	EXPEDITED (15-DAY)		HO, OT	PT-MACLEODS PHARMACEUTICALS US LTD-MAC2019020403			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Mania	Escitalopram			S	Unknown	20 Milligram, Less Than 12 Months		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16055943	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP008992			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Escitalopram			S	Unknown	20.0 Mg, Qd		Apotex
	Aripiprazole			S	Oral	2.0 Mg, Unk		Apotex
	Teva Escitalopram			S	Unknown	20.0 Mg, Qd		Not Reported
	Serax /00040901/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16056641	NON-EXPEDITED			US-SUNOVION-2019SUN000827		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Movement Disorder	Latuda	S	Oral	20 Mg		Sunovion
	Lexapro	S	Unknown	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16057770	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP008991		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Underdose	Escitalopram			S	Oral	5.0 Mg, Unk		Apotex
	Saphris			S	Oral	1.25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16057778	EXPEDITED (15-DAY)		HO	PT-TEVA-2019-PT-1023171		60 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Withdrawal Syndrome	Escitalopram			S		Less Than 12 Months		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16058080	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS USA.,INC-2019SUN00102		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug-Induced Liver Injury	Escitalopram			S	Unknown	Unk		Taro
	Kratom			S	Oral	Used On Multiple Occasions		Not Reported
	Kratom			S	Oral			Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Metoprolol Tartrate			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported

	Fexofenadine	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Recommended 3000 Mg Per Day Limit	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16058515	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1903023US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Prescribed; Dyspnoea; Electrocardiogram Qt Prolonged; Paraesthesia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Xalkori			S	Oral	1 Df, Bid		Not Reported
	Carteol F			C	Ophthalmic	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16059684	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1909665US			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Coaprovel			S	Oral	312.5 Mg, Qd		Not Reported
	Urbason			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Alprazolam			C	Unknown	Unk		Not Reported
	Eutirox			C	Unknown			Not Reported
	Pantoprazole Sodium Sesquihydrate			C	Unknown	Unk		Not Reported
	Alendronic Acid W/Colecalciferol			C	Oral	70 Mg		Not Reported
	Colecalciferol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	14778062	EXPEDITED (15-DAY)		HO, OT	TW-LUPIN PHARMACEUTICALS INC.-2018-02953		71 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Dyskinesia; Insomnia; Respiratory Distress; Trismus	Escitalopram	S	Unknown	10 To 15 Mg, Qd For 6 Months	Lupin
	Escitalopram	S	Unknown	20 Mg, Qd	Lupin
	Escitalopram	S	Unknown	10 To 15 Mg, Qd For 6 Months	Lupin
	Quetiapine	S	Unknown	50 Mg, Qd 3 Days	Lupin
	Quetiapine	S	Unknown	100 Mg, Qd	Lupin
	Quetiapine	S	Unknown	50 Mg, Qd	Lupin
	Sertraline	C	Unknown	80 Mg, Qd	Not Reported
	Venlafaxine	C	Unknown	150 Mg, Qd	Not Reported
	Mirtazapine	C	Unknown	45 Mg, Qd	Not Reported
	Risperidone	C	Unknown	1 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	15453252	EXPEDITED (15-DAY)		HO, OT	SE-ALLERGAN-1847234US			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Anxiety; Bedridden; Decreased Appetite; Depression; Diarrhoea; Fatigue; Feeling Abnormal; Flushing; Hospitalisation; Palpitations; Peripheral Coldness; Product Dose Omission; Serotonin Syndrome; Tremor; Underdose; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Unknown	2.5 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
	Voxra			C	Unknown	150 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	15865467	EXPEDITED (15-DAY)		DS, OT	ES-AUROBINDO-AUR-APL-2018-055547			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Female Sexual Dysfunction; Loss Of Libido	Sertraline			S	Oral	50 Milligram, Daily		Aurobindo
	Sertraline			S	Oral	100 Milligram, Daily		Aurobindo
	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Enalapril			C	Unknown	20 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16060117	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2019-012412			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Mania	Escitalopram			S	Unknown	20 Milligram, Less Than 12 Months		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16060417	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-012534			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Chromaturia; Cytomegalovirus Test Positive; Decreased Appetite; Drug Interaction; Drug-Induced Liver Injury; Dysuria; Fatigue; Hepatic Steatosis; Hyperbilirubinaemia; Malaise; Micturition Urgency; Pollakiuria; Pruritus; Pyrexia; Serum Ferritin Increased;	Escitalopram			S	Unknown	Unk		Aurobindo
	Mitragyna Speciosa			S	Unknown	Unk		Not Reported
	Mitragyna Speciosa			S	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Metoprolol Tartrate			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported

Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16062110	EXPEDITED (15-DAY)		HO	PT-HETERO CORPORATE-HET2019PT00275		60 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Mania; Withdrawal Syndrome	Escitalopram			S	Unknown	20 Mg		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16062375	EXPEDITED (15-DAY)		LT	NO-MYLANLABS-2019M1021648		56 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Fluoxetine			S	Oral	Unk		Not Reported
	Trilafon /00023401/			S	Oral	Unk		Mylan
	Cymbalta			S	Oral	Unk		Mylan
	Remeron			S	Oral	Unk		Mylan
	Efexor			S	Oral	Unk		Mylan
	Stemetil /00013301/			S	Oral	Unk		Mylan
	Ibux			S	Oral	Unk		Mylan
	Fluanxol /00109702/			S	Oral	Unk		Mylan
	Vallergan			S	Oral	Unk		Mylan
	Nozinan /00038601/			S	Oral	Unk		Mylan
	Zyprexa			S	Oral	Unk		Mylan
	Sobril			S	Oral	Unk		Mylan
	Truxal /00012101/			S	Oral	Unk		Mylan
	Cipralex /01588501/			S	Oral	Unk		Mylan
	Abilify			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16062789	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1021731			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S		10 Milligram Daily; Morning		Ivax
	Ferrous Fumarate			S		420 Milligram Daily; Morning And Night		Not Reported
	Olanzapine			S		5 Milligram Daily;		Teva
	Mirtazapine			S	Oral	30 Milligram Daily; Night		Teva
	Folic Acid			S		5 Milligram Daily; Morning		Actavis
	Dihydrocodeine			S		Four Times Daily. With Or Just After Food/Meal		Not Reported
	Azathioprine			S		75 Milligram Daily; Morning, Lunch And Tea Time (With Or Just After Food/Meal)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16063039	EXPEDITED (15-DAY)		OT	SI-ALLERGAN-1909231US			Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anxiety; Arthralgia; Blood Pressure Increased; Blood Urea Increased; Cognitive Disorder; Confusional State; Coordination Abnormal; Cough; Depersonalisation/Dereali sation Disorder; Depression; Depression; Diabetes Mellitus; Diplopia; Disturbance In Attention; Drug	Triptorelin Pamoate - Bp			S	Unknown	22.5 Mg, Unknown		Allergan
	Helex			S	Oral			Not Reported
	Amlopin			S	Oral	Unk Unk, Unknown		Not Reported
	Cipralex			S	Oral	0.5 Df, Bid		Not Reported
	Symbicort			S	Unknown	Unk		Not Reported
	Valsacor			S	Unknown	Unk		Not Reported

Dependence; Dry Mouth; Dysgeusia; Dysphagia; Dysphonia; Dyspnoea; Dysstasia; Erectile Dysfunction; Erectile Dysfunction; Extrasystoles; Flatulence; Gout; Gynaecomastia; Hot Flush; Hyperglycaemia; Hypertension; Initial Insomnia; Insomnia; Intraocular Pressure Increased; Irritability; Joint Stiffness; Joint Swelling; Joint Swelling; Libido Decreased; Loss Of Libido; Memory Impairment; Mental Disorder; Mood Altered; Muscle Spasms; Musculoskeletal Stiffness; Nervousness; Nightmare; Nocturia; Oedema Peripheral; Oedema Peripheral; Off Label Use; Orthopnoea; Penis Disorder; Photopsia; Pruritus; Sexual Dysfunction; Sexual Dysfunction; Somnolence; Somnolence; Taste Disorder; Testicular Atrophy; Tinnitus; Urinary Incontinence; Vertigo; Vision Blurred; Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16063462	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019103474		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Fall; Seizure; Tremor	Xanax	S	Unk		Pfizer
	Fentanyl Citrate	S	1200 Mg, Unk		Unknown
	Lexapro	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16064285	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1022442		87 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypokalaemia	Escitalopram			S		15 Milligram, Qd		Not Reported
	Seguril			S	Oral	1-1/2-0		Mylan
	Lexatin /00424801/			C		1-0-1		Mylan
	Candesartan Ratio			C		16 Milligram, Qd		Mylan
	Dolocatil			C		Unk		Mylan
	Aldocumar			C		Unk		Mylan
	Pantoprazol Kern Pharma			C		20 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16064666	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1022443		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Long Cours		Not Reported
	Fenofibrate			S	Oral	Unk		Not Reported
	Valaciclovir			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Long Cours		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Loxapac /00401802/			S	Oral	Unk		Mylan
	Bendamustine Accord			S	Intravenous (not otherwise specified)	346 Milligram, Monthly		Mylan
	Levothyrox			S	Oral	Unk		Mylan
	Truxima			S	Intravenous (not	720 Milligram, Monthly		Mylan

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16206572	DIRECT					42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Affective Disorder; Emotional Disorder; Therapeutic Response Changed	Generic Escitalopram			S		Quantity:1 Df Dosage Form;		Not Reported
	Lexapro			C				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	15909036	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1904656US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Disturbance In Attention; Feeling Abnormal; Intestinal Obstruction; Medication Error	Memantine Hcl Unk			S	Unknown	5 Mg, Bid		Allergan
	Lexapro			S	Unknown	20 Mg, Qd		Allergan
	Aromasin			S	Oral	25 Mg, Qd		Not Reported
	Lialda			S		1.2 G (4 Df At Once), Qd, Unknown Route		Not Reported
	Klonopin			S	Unknown	0.25 Mg, Bid		Not Reported
	Amlodipine			S	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16066371	EXPEDITED (15-DAY)		OT	GB-TORRENT-00020564		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Tongue Biting	Escitalopram			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16067749	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1022971		34 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Musculoskeletal Pain; Myalgia; Pain; Pain In Extremity	Escitalopram			S	Unknown	5 Milligram		Not Reported
	Quetiapine Fumarate			S	Unknown	12.5 Milligram		Mylan
	Novaminsulfon			C	Unknown	Unk		Mylan
	Pantoprazol /01263201/			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16067756	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1022969		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysphagia; Nausea; Vertigo	Amiodarone			S	Unknown			Not Reported
	Melperone Hydrochloride			S	Unknown			Mylan
	Cipralex /01588501/			S	Unknown	10 Milligram, Qd		Mylan
	Escitalopram			C	Unknown	From Beta Pharm		Mylan
	L-Tyrosine			C	Unknown	Unk		Mylan
	Candesartan			C	Unknown	Unk		Mylan
	Metoprolol			C	Unknown	Unk		Mylan
	Mcp /00041901/			C	Unknown	Unk		Mylan
	Xarelto			C	Unknown	Unk		Mylan
	Amlodipin /00972401/			C	Unknown	Unk		Mylan
	Kalinor /00031402/			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16069191	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1910435US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Seizure; Tremor	Lexapro			S	Unknown			Allergan
	Fentanyl			S	Unknown	1200 Mg		Not Reported
	Xanax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16206839	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bruxism; Muscle Spasms; Tremor	Escitalopram 10mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	14538861	NON-EXPEDITED			US-PFIZER INC-2018065754		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Venlafaxine Hcl			S		Unk		Pfizer
	Amitriptyline			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	15516053	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US16837			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Depression; Drug Ineffective; Feeling Abnormal; General Physical Health Deterioration; Impaired Work Ability; Irritability; Mental Impairment	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Escitalopram			S	Oral	10 Mg, Unk		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	15662130	EXPEDITED (15-DAY)		DS, HO, OT	PT-ALLERGAN-1854945US			Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Dystonia; Gait Disturbance; Stiff Person Syndrome	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
	Insulin			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	15972660	EXPEDITED (15-DAY)		DS, HO, OT	GB-ACCORD-107135		31 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	15998200	EXPEDITED (15-DAY)		HO	IT-ACCORD-108230		27 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor; Suicide Attempt	Escitalopram			S	Oral			Not Reported
	Delorazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16070806	EXPEDITED (15-DAY)		HO	NL-ACCORD-112780			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Exposure Via Breast Milk; Hypertonia Neonatal; Maternal Exposure During Pregnancy	Escitalopram			S		1x Daily 1 Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16070815	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2019-012647			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram			S	Unknown	Unk		Aurobindo
	Coaprovel			S	Oral	312.5 Milligram, Daily		Not Reported
	Alprazolam			C	Unknown	Unk		Not Reported
	Alendronic Acid;Colecalciferol			C	Oral	70 Milligram		Not Reported
	Colecalciferol			C	Unknown	Unk		Not Reported
	Eutirox			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Pantoprazole Sodium Sesquihydrate			C	Unknown	Unk		Not Reported
	Urbason			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16071593	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2019020447			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Interaction; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram			S	Unknown	Unk		Macleods
	Coaprovel			S	Oral	312.5 Milligram, Qd		Not Reported
	Alendronic Acid Sodium Salt Trihydrate/Colecalciferol			C	Oral	70 Milligram		Not Reported
	Alprazolam Abc			C	Oral	Unk		Not Reported
	Colecalciferol			C	Unknown	Unk		Not Reported
	Eutirox			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Pantoprazole Sodium Sesquihydrate			C	Unknown	Unk		Not Reported
	Urbason			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16071911	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-		26 YR	Male	USA

BMS-2019-025245

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Blood Pressure Decreased; Constipation; Contusion; Depression Suicidal; Ejaculation Failure; Gastric Ulcer; Heart Rate Increased; Hypoacusis; Paraesthesia; Sexual Dysfunction; Syncope; Visual Impairment; Weight Decreased	Eliquis			S	Unknown	10 Milligram		Bristol Myers Squibb
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16072139	NON-EXPEDITED			US-SA-2019SA065081			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Dizziness; Fatigue; Headache; Insomnia; Nausea; Pruritus; Rash; Urticaria	Ambien			S				Sanofi
	Diphenhydramine Hydrochloride			S				Sanofi
	Carbidopa/Levodopa			S				Not Reported
	Ciprofloxacin Salt Not Specified			S				Not Reported
	Hydrocortisone			S				Sanofi
	Oxaprozin			S				Not Reported
	Demerol			S				Sanofi
	Donepezil Hydrochloride			S				Not Reported
	Fentanyl			S		Unk		Not Reported
	Gabapentin			S				Not Reported
	Cefalexin			S				Not Reported
	Levetiracetam			S		Unk		Not Reported
	Lamotrigine			S				Not Reported
	Paroxetine Hydrochloride			S				Not Reported
	Promethazine			S				Not Reported
	Venlafaxine Hydrochloride			S				Not Reported
	Zonisamide			S				Not Reported

	Hydrocodone	S		Not Reported
	Talwin [Pentazocine Lactate]	S		Not Reported
	Nabumetone	S		Not Reported
	Indocin [Indometacin Sodium]	S	Unk	Not Reported
	Hycotuss	S		Not Reported
	Provigil [Modafinil]	S		Not Reported
	Amitriptyline	S		Not Reported
	Codeine	S		Not Reported
	Duloxetine	S		Not Reported
	Tiagabine	S		Not Reported
	Escitalopram	S		Not Reported
	Pramipexole	S		Not Reported
	Ropinirole	S		Not Reported
	Trazodone	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16072493	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20190311949			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Drug Interaction; Electrocardiogram Qt Prolonged; Torsade De Pointes	Risperidone			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Domperidone			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16072832	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019106802		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Abuse; Dry Mouth; Intentional Overdose; Slow Speech	Lorazepam			S	Oral	20 Mg, Single		Pfizer
	Cipralex [Escitalopram Oxalate]			S	Oral	300 Mg, Single		Not Reported
	En			S	Oral	40 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16074214	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1023673		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram Oxalate			S				Ivax
	Coaprovel 300/12.5mg Tablets			S	Oral	312.5 Milligram Daily;		Not Reported
	Urbason 4 Mg Compresse			C				Not Reported
	Paracetamol			C				Not Reported
	Alprazolam Abc 0,75 Mg/Ml Gocce Orali, Soluzione			C				Not Reported
	Eutirox 75 Microgrammi Compresse			C				Not Reported
	Pantoprazole Sodium Sesquihydrate			C				Not Reported
	Acido Alendronico Sale Sodico Triidrato/Colecalciferolo			C	Oral			Not Reported
	Colecalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16074346	EXPEDITED (15-DAY)		DE, OT	DE-ALLERGAN-1910683US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Overdose; Road Traffic Accident; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Mirtazapin			S	Unknown	30 Mg, Qd		Not Reported
	Olynth			C	Unknown	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	15735064	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS-2018M1094037		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use;	Zopiclone			S	Oral	7.5 Milligram, Qd (1tab/Dy)		Not Reported
	Olanzapine			S	Unknown	15 Milligram		Not Reported
	Escitalopram			S	Unknown	5 Milligram, Qd		Not Reported

Suicide Attempt	Escitalopram	S	Unknown	10 Milligram, Qd	Not Reported
	Lepticur	S	Unknown	Unk	Mylan
	Depamide	S	Oral	300 Milligram, Qd	Mylan
	Seroplex	S	Unknown	10 Milligram, Qd	Mylan
	Seroplex	S	Unknown	5 Milligram, Qd	Mylan
	Seroplex	S			Mylan
	Dopamide	S	Oral	Unk	Mylan
	Abilify	S	Unknown	10 Milligram	Mylan
	Seresta	S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening	Mylan
	Anafranil	S	Oral	75 Milligram, Qd	Mylan
	Lexapro	S	Unknown	10 Milligram, Qd (Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy)	Mylan
	Zyprexa	S	Unknown	15 Milligram	Mylan
	Imovane	S	Oral	7.5 Milligram, Qd	Mylan
	Methyldopa	S		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	15742726	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1094501		19 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Product Misuse; Sopor	Escitalopram			S	Oral	280 Milligram, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16075866	EXPEDITED (15-DAY)		HO	IT-ACCORD-113077		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported
	Lorazepam			S	Oral			Accord

Aripiprazole	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16076193	EXPEDITED (15-DAY)		DE	FR-ACCORD-112682		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydrocephalus; Intraventricular Haemorrhage	Escitalopram			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Xarelto			S	Oral	20 Mg/J		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16078635	EXPEDITED (15-DAY)		DE	US-PERNIX THERAPEUTICS-US-2019PER000034		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Doxepin			S	Oral	Unk		Pernix
	Acetaminophen			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16078749	EXPEDITED (15-DAY)		CA, HO	CA-GLENMARK PHARMACEUTICALS-2019GMK040203			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Gabapentin			S	Transplacental	1800 Mg, Od (1 Every 1 Day)		Glenmark
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Od (1 Every 1 Day)		Not Reported
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Od (1 Every 1 Day)		Not Reported
	Escitalopram			S	Transplacental	20 Mg, Od (1 Every 1 Day)		Not Reported
	Escitalopram			S	Transplacental	20 Mg, Od (1 Every 1 Day)		Not Reported

	Escitalopram	S	Transplacental	20 Mg, Od (1 Every 1 Day)	Not Reported
	Methadone	S	Transplacental	70 Mg, Od (1 Every 1 Day)	Not Reported
	Nortriptyline	S	Transplacental	20 Mg, Od (1 Every 1 Day)	Not Reported
	Quetiapine	S	Transplacental	300 Mg, Bid (1 Every 12 Hours)	Not Reported
	Rabeprazole	S	Transplacental	Unk	Not Reported
	Zopiclone	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16078948	EXPEDITED (15-DAY)		DE	US-PERNIX THERAPEUTICS-US-2019PER000043		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Doxepin			S	Oral	Unk		Pernix
	Escitalopram			S	Unknown	Unk		Not Reported
	Hydroxyzine			S	Unknown	Unk		Not Reported
	Ethanol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079243	NON-EXPEDITED			US-TEVA-2019-US-1014586			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Escitalopram Tablets			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	15401455	EXPEDITED (15-DAY)		DE, HO, OT	FR-ACCORD-072310		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose; Poisoning Deliberate; Suicide Attempt; Toxicity	Escitalopram			S	Oral			Not Reported
	Paracetamol			S	Oral			Accord
	Dextropropoxyphene/Dextroprop			S	Oral	Unk		Not Reported

To Various Agents; Unresponsive To Stimuli	oxyphene Hydrochlori/Dextropropoxyphene Napsilate					
	Baclofen	S	Oral	Unk		Not Reported
	Valpromide	S	Oral	Unk		Not Reported
	Baclofen	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16080746	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-013729			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Electrocardiogram Qt Prolonged; Hyperkalaemia; Loss Of Consciousness; Overdose; Sinus Tachycardia	Citalopram			S	Unknown	Unk		Aurobindo
	Escitalopram Tablets			S	Unknown	10 Milligram		Aurobindo
	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Acetaminophen;Oxycodone Hydrochloride			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	420 Milligram		Not Reported
	Morphine			S	Unknown	30 Milligram		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Zopiclone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16080836	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013916			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Urticaria	Escitalopram Tablets			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Omalizumab			S	Subcutaneous	300 Milligram		Not Reported
	Reactine [Cetirizine			C	Oral	1 Dosage Form, Two		Not Reported

	Hydrochloride]			Times A Day	
	Ventolin		C	1 Dosage Form, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16080837	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013451		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Drug Ineffective; Haemorrhage; Product Substitution Issue; Pruritus	Escitalopram Tablets			S	Oral	20 Milligram, Two Times A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16080838	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-013644			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Jaundice; Nausea; Vomiting	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16080863	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013877			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Citalopram			S	Unknown	Unk		Aurobindo
	Cipralex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081693	EXPEDITED (15-DAY)		LT	PHEH2019US011774		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Gilenya			S	Oral	0.5 Mg, Qd		Novartis

	Lexapro	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2019	16081891	NON-EXPEDITED		OT	US-DRREDDYS-USA/USA/18/0099939		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Serotonin Syndrome	Olanzapine Film-Coated Tablet			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	14310063	EXPEDITED (15-DAY)		HO, OT	SI-MYLANLABS-2017M1079500		48 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Sclerosis; Palpitations; Product Use In Unapproved Indication	Pregabalin			S	Unknown	150 Mg, Bid		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd (1 Tablet In Morning)		Not Reported
	Tolterodine			S	Unknown	4 Mg, Qd (1 Tablet In Morning)		Not Reported
	Fty 720			S	Unknown	0.5 Mg, Qd		Mylan
	Fampridine			S	Unknown	10 Mg, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	15411294	NON-EXPEDITED			US-PFIZER INC-2018380773			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer

	Procardia	S		Unk	Pfizer
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]	S		Unk	Not Reported
	Biaxin	S		Unk	Not Reported
	Lexapro	S		Unk	Not Reported
	Fetzima	S		Unk	Not Reported
	Viibryd	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16023713	EXPEDITED (15-DAY)		OT	FI-MYLANLABS-2019M1018258			Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Olanzapine			S		Upto 20 Milligram		Not Reported
	Risperdal			S		Increased Upto 4 Milligram		Mylan
	Abilify			S	Intramuscular	400 Milligram		Mylan
	Escitalopram /01588502/			S		Unk		Mylan
	Temesta /00273201/			S		Unk		Mylan
	Xeplion			S		Unk (Injection Was Given Once)		Mylan
	Cisordinol /00876702/			S		50 Milligram		Mylan
	Ativan			S		4 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16066055	EXPEDITED (15-DAY)		DS	IT-ACCORD-112283		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder	Escitalopram			S	Oral			Not Reported
	Risperidone			S	Oral			Accord
	Rivotril			C	Oral	Strength : 2.5 Mg / Ml		Not Reported
	Depakin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16082579	EXPEDITED (15-DAY)		DS	IT-ACCORD-112807		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depressed Mood; Insomnia	Risperidone			S	Oral			Accord
	Escitalopram			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16082859	EXPEDITED (15-DAY)		OT	ES-ZYDUS-034657		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Gabapentin			S	Oral			Zydus Pharm
	Tramadol			S	Oral			Not Reported
	Escitalopram			S	Oral	10 Mg 28 Tablets		Not Reported
	Nebivolol			C	Oral	5 Mg 28 Tablets		Not Reported
	Atorvastatin			C	Oral	40 Mg 28 Tablets		Not Reported
	Acetylsalicylic Acid			C	Oral	Acetylsalicylic Acid 100 Mg 30 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16083105	EXPEDITED (15-DAY)		HO	FR-ACCORD-113399		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Haematoma	Aripiprazole			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Prazepam Arrow			S	Oral			Not Reported
	Piroxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16083128	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-113246		85 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Haematemesis	Clopidogrel			S	Oral	Morning, Suspended During Admission		Not Reported
	Escitalopram			S	Oral	Morning, Continued During Admission With Proton Pump Inhibitor Protection		Not Reported
	Fultium-D3			C				Not Reported
	Alverine			C				Not Reported
	Co-Beneldopa			C		25mg/100mg		Not Reported
	Paracetamol			C				Not Reported
	Amlodipine			C				Not Reported
	Codeine Phosphate/Paracetamol			C		8mg/500mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16084548	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000238		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Methylphenidate Hydrochloride			S	Oral	Unk		Lannett
	Diazepam			S	Oral	Unk		Lannett
	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Propranolol			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Melatonin			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16086248	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1911233US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Off Label Use	Hydrocodone Bitartrate;Acetaminophen Unk			S	Oral			Allergan
	Escitalopram			S	Oral			Not Reported
	Oxycodone / Acetaminophen			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16086305	EXPEDITED (15-DAY)		DE, OT	US-LANNETT COMPANY, INC.-US-2019LAN000237		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Methylphenidate Hydrochloride			S	Oral	Unk		Lannett
	Bupropion Hcl Er			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral			Lannett

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16228182	DIRECT	Y	HO			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anhedonia; Apathy; Asthenia; Depression; Seizure; Serotonin Syndrome	Bupropion			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	11993343	EXPEDITED (15-DAY)		OT	GB-ACCORD-031871		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Restless Legs Syndrome	Quetiapine			S				Accord
	Escitalopram			S				Accord
	Fluoxetine			S				Accord
	Dosulepin			S				Not Reported

Lofepramine	S		Not Reported
Citalopram	S		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	14253950	EXPEDITED (15-DAY)		HO, OT	CZ-MYLANLABS-2017M1075619		45 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Escitalopram			S	Oral	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Sertraline			S	Oral	Unk		Not Reported
	Sertraline			S	Unknown	Unk		Not Reported
	Venlafaxine			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	15297841	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2018M1062706		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Atorvastatin			S	Oral	10 Mg, Qd		Not Reported
	Bisoce 1,25 Mg, Comprimé Pelliculé			S	Oral	2 Df, Total		Mylan
	Lactulose			S	Oral	2 Df, Qd		Not Reported
	Amiodarone			S	Oral	Unk		Not Reported
	Lansoprazole			S	Oral	15 Mg, Qd		Not Reported
	Trimebutine			S	Oral	300 Mg, Qd		Not Reported
	Repaglinide			S	Oral	2 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Driptane 5 Mg, Comprimé Sécable			S	Oral	3 Df, Qd		Mylan
	Prograf			S	Oral	3 Mg, Qd		Mylan
	Fungizone			S	Buccal	3 Df, Qd		Mylan
	Amphotericin B W/Tetracycline			S	Buccal	3 Df, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	15493305	EXPEDITED (15-DAY)		DS	IT-JNJFOC-20181012555		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder; Dyskinesia; Off Label Use; Product Use In Unapproved Indication; Tremor	Risperidone			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Rivotril			C	Oral			Not Reported
	Depakin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16022658	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019092972		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Drug Interaction	Cordarone			S	Oral	Unk		Pfizer
	Crestor			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Plavix			S	Oral	Unk		Not Reported
	Previscan [Fluindione]			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16078892	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-ALLERGAN-1910688US			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardiac Fibrillation; Intentional Overdose; Product Use In Unapproved Indication; Serotonin Syndrome; Suicide Attempt; Toxicity	Escitalopram Oxalate - Bp			S	Oral	Overdose: 250 Mg		Allergan

To Various Agents;
Ventricular Fibrillation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16087538	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2019-014253			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram			S	Transplacental	15 Milligram, Daily		Aurobindo
	Levothyroxine			C	Transplacental	50 Microgram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16087554	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-014324			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Tongue Biting	Escitalopram Tablets			S	Unknown	20 Milligram, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16087653	EXPEDITED (15-DAY)		DS, OT	PT-AUROBINDO-AUR-APL-2019-013996			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Stiff Person Syndrome	Escitalopram 20 Mg			S	Unknown	20 Milligram		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16088283	EXPEDITED (15-DAY)		DE	US-ARBOR PHARMACEUTICALS, LLC-US-2019ARB000385		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Gabapentin Enacarbil			S	Oral	Unk		Arbor

	Propranolol		S	Oral	Unk	Not Reported
	Levetiracetam		S	Oral	Unk	Not Reported
	Escitalopram		S	Oral	Unk	Not Reported
	Acetaminophen W/Chlorzoxazone		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16088288	EXPEDITED (15-DAY)		DE	US-ARBOR PHARMACEUTICALS, LLC-US-2019ARB000346		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Gabapentin Enacarbil			S	Oral	Unk		Arbor
	Tramadol			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16089495	NON-EXPEDITED			US-SA-2019SA067973			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Glucophage "Hoechst"			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported
	Lantus			S	Unknown			Sanofi
	Sertraline Hydrochloride			S	Oral	1.5 For 1 Week Then 2 Tabs		Not Reported
	Victoza			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16089710	EXPEDITED (15-DAY)		DE	US-HQ SPECIALTY-US-2019INT000077		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Levetiracetam In Sodium Chloride			S	Oral	Unk		Hq Specialty
	Propranolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	Unk		Not Reported
	Chlorzoxazone W/Paracetamol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16089941	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1024470		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Product Misuse; Intentional Self-Injury; Nausea; Vomiting	Escitalopram			S	Oral	7.5 Milliliter, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16090026	NON-EXPEDITED			US-SA-2019SA071592			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Myalgia; Nausea; Pruritus; Rash; Swelling; Urticaria; Vomiting	Leflunomide			S				Sanofi
	Ofloxacin			S				Not Reported
	Morphine Salt Not Specified			S				Not Reported
	Metoprolol Succinate			S				Not Reported
	Bupropion Hydrochloride			S				Not Reported
	Talwin			S				Sanofi
	Gabapentin			S				Not Reported
	Atorvastatin			S				Not Reported
	Olanzapine			S				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Duloxetine Hydrochloride			S				Not Reported
	Hydrocodone			S				Not Reported
	Orencia			S				Not Reported
	Oravig			S				Not Reported
	Avandia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16090314	NON-EXPEDITED			US-PERRIGO-18US013591		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Nicotine Polacrilex			S	Buccal	2 Mg, 9 To 10 Times Qd		Perrigo
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Gabapentin			C	Unknown	2100mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16091038	EXPEDITED (15-DAY)		DE	US-NOVAST LABORATORIES, LTD-US-2019NOV000099		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To Various Agents	Quetiapine Fumarate			S	Oral	Unk		Novast
	Propranolol			S	Oral	Unk		Not Reported
	Amlodipine			S	Oral	Unk		Not Reported
	Primidone			S	Oral	Unk		Not Reported
	Trazodone			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16091451	EXPEDITED (15-DAY)		DE	US-NOVAST LABORATORIES, LTD-US-2019NOV000146		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Metoprolol Succinate			S	Oral	Unk		Novast
	Quetiapine Fumarate			S	Oral	Unk		Novast
	Amlodipine			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Potassium Chloride			S	Oral	Unk		Not Reported

	Escitalopram			S	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16091576	EXPEDITED (15-DAY)		DE	US-ASSERTIO THERAPEUTICS, INC.-US-2019DEP000221		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Gabapentin			S	Oral	Unk		Assertio Therapeutics
	Propranolol			S	Oral	Unk		Not Reported
	Levetiracetam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Acetaminophen W/Chlorzoxazone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16091630	EXPEDITED (15-DAY)		DE	US-NOVAST LABORATORIES, LTD-US-2019NOV000172		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Metoprolol Succinate			S	Oral	Unk		Novast
	Amlodipine			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16091959	EXPEDITED (15-DAY)		DE	US-ASSERTIO THERAPEUTICS, INC.-US-2019DEP000183		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Gabapentin			S	Oral	Unk		Assertio Therapeutics
	Tramadol			S	Oral	Unk		Not Reported

	Propranolol	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Ethanol	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16092278	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1911296US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Off Label Use	Hydrochlorothiazide Unk			S				Allergan
	Bupropion			S				Not Reported
	Verapamil			S				Not Reported
	Escitalopram			S				Not Reported
	Ethanol			S				Not Reported
	Diphenhydramine			S				Not Reported
	Lisinopril			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16092282	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1911228US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Off Label Use	Hydrochlorothiazide Unk			S	Oral			Allergan
	Metoprolol			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16092548	EXPEDITED (15-DAY)		DE	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000117		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Metoprolol Tartrate	S	Oral	Unk		Validus
	Amlodipine /00972402/	S	Oral	Unk		Not Reported
	Hydrochlorothiazide	S	Oral	Unk		Not Reported
	Clonazepam	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	12414524	EXPEDITED (15-DAY)		DS, OT	IT-ACCORD-040817		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Sertraline			S		50 Mg		Accord
	Escitalopram			S				Accord
	Quetiapine			S	Oral			Accord
	Venlafaxine/Venlafaxine Hydrochloride			S				Not Reported
	Valproic Acid			S				Not Reported
	Mirtazapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	14305782	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1771196US		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Abdominal Pain; Abdominal Pain Upper; Alopecia; Angiopathy; Atrial Thrombosis; Atrophic Vulvovaginitis; Blister; Bronchitis; Chest Pain; Constipation; Constipation; Diarrhoea; Diarrhoea; Diplopia; Dizziness; Dyspnoea; Fatigue; Feeling	Carafate			S	Oral	1 Df, Tid		Allergan
	Carafate			S				Allergan
	Hydrochlorothiazide Unk			S	Oral	1 Df, Qd		Allergan
	Lexapro			S	Unknown	1 Df, Qd		Allergan
	Bentyl Tablets			S	Unknown	1 Df, Qid		Allergan
	Misoprostol			S	Oral	100 Mg, Qid		Not Reported
	Misoprostol			S				Not Reported
	Norvasc			C	Oral	10 Mg, Qd		Not Reported
	Synthroid			C	Oral	Unk, Qd		Not Reported
	Zetia			C	Oral	1 Df, Bid		Not Reported

Abnormal; Gastrooesophageal Reflux Disease; Limb Injury; Mass; Neck Pain; Neck Pain; Off Label Use; Pain In Extremity; Pollakiuria; Pulmonary Mass; Pulmonary Thrombosis; Sinusitis; Skin Discolouration; Thrombosis; Urinary Tract Infection; Vision Blurred	Klonopin	C	Oral	1 Df, Bid	Not Reported
	Premarin	C	Vaginal	Unk, Bi-Weekly	Not Reported
	Xanax	C	Oral	1 Df, Bid	Not Reported
	Avapro	C	Oral	1 Df, Qd	Not Reported
	Ambien	C	Oral	1 Df, Qhs (As Needed)	Not Reported
	Lipitor	C	Oral	1 Df, Qd	Not Reported
	Zoloft	C	Unknown	25 Mg, Qd	Not Reported
	Zoloft	C	Unknown	50 Mg, Qd	Not Reported
	Clonazepam	C	Oral	1 Df, Bid	Not Reported
	Celebrex	C	Unknown	1 Df, Qd	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported

Ipratropium Bromide	C	Nasal	4 Df; 2-3 Times Daily	Not Reported
Fluzone	C	Unknown	Unk	Not Reported
Fluzone	C	Unknown	Unk	Not Reported
Valium	C	Oral	1 Df, Prn (Bid)	Not Reported
Xarelto	C	Oral	Unk	Not Reported
Prevnar 13	C	Unknown	0.5 Ml, Single	Not Reported
Tramadol	C	Oral	1 Df, Q6hr (Prn)	Not Reported
Tramadol	C	Oral	Unk Unk, Tid	Not Reported
Ciprofloxacin	C	Oral	1 Df, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	14540063	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-007470			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	10 Milligram		Aurobindo
	Escitalopram			S	Unknown	5 Milligram		Aurobindo
	Domperidone			S	Unknown	Unk		Not Reported
	Amiodarone			S	Unknown	Unk		Aurobindo
	Digoxin			S	Unknown	Unk		Not Reported
	Aliskiren			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	14682526	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-016623			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Aurobindo
	Ondansetron			S	Intravenous (not otherwise specified)	4 Milligram Single Dose ; In Total		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16007783	EXPEDITED (15-DAY)		HO, OT	NO-APOTEX-2019AP008092		21 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Olanzapine			S	Unknown	Unk		Apotex
	Cipralex /01588501/			S	Unknown	Unk Unk, Qd		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Seroquel			S	Oral	Unk		Not Reported
	Seroquel			S	Oral	Unk		Not Reported
	Seroquel			S	Oral	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Cipramil /00582602/			S	Unknown	10 Mg, Qd Daily		Not Reported
	Cipramil /00582602/			S	Unknown	60 Mg, Qd		Not Reported
	Orfiril			S	Unknown	Unk		Not Reported
	Valproate Sodium			S	Unknown	Increasing Dose		Not Reported
	Seroxat			S	Unknown	Unk		Not Reported
	Seroxat			S	Unknown	20 Mg, Qd		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Sobril			C	Unknown	Unk Unk, As Needed		Not Reported
	Lithionit			C	Unknown	Unk		Not Reported
	Lithionit			C	Unknown	Unk		Not Reported
	Lithionit			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16093000	EXPEDITED (15-DAY)		HO	FR-ACCORD-113131		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Intentional Overdose; Miosis; Orthostatic Hypotension; Somnolence	Aripiprazole			S	Oral	Exact Dose When Unknown Imv		Not Reported
	Olanzapine			S	Oral	Exact Dose When Unknown Imv		Not Reported
	Escitalopram			S	Oral	Exact Dose When Unknown Imv		Not Reported
	Bromazepam			S	Oral	Estimated Dose Of 20 Cp Bromazepam 6 Mg		Not Reported
	Zolpidem			S	Oral	Exact Dose When Unknown Imv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16093384	EXPEDITED (15-DAY)		HO, OT	ZA-LUPIN PHARMACEUTICALS INC.-2019-01659			Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Malaise	Zartan 50 Mg			S	Oral	50 Milligram		Lupin
	Bilocor 5 Mg			S	Oral	5 Milligram		Not Reported
	Epleptin			S	Oral	100 Milligram		Not Reported
	Rivotril			S	Oral	0.5 Milligram		Not Reported
	Lexamil			S	Oral	10 Milligram		Not Reported
	Ecotrin			S	Oral	81 Milligram		Not Reported
	Spiractin /00006201/			S	Oral	25 Milligram		Not Reported
	Prazoloc			S	Oral	40 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16093742	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-114242		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Mydriasis; Somnolence; Suicide	Escitalopram			S	Oral			Not Reported

Attempt; Toxicity To Various Agents; Vomiting	Paracetamol	S	Oral		Accord
	Hepatoum	S	Oral		Not Reported
	Azithromycin	S	Oral		Not Reported
	Arestal	S	Oral	Strength: 1 Mg	Not Reported
	Seresta	S	Oral	Strength: 10 Mg	Not Reported
	Prednisolone	S	Oral		Not Reported
	Inorial	S	Oral	Strength: 20 Mg	Not Reported
	Augmentin	S	Oral		Not Reported
	Cefpodoxime/Cefpodoxime Proxetil	S	Oral		Not Reported
	Trimebutine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16093795	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2019020517			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Tongue Biting	Escitalopram			S	Unknown	20 Milligram, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16093832	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019020511			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram			S	Transplacental	15 Milligram, Qd 0. - 38.2. Gestational Week, During 1 Trimester		Macleods
	Levothyroxine			C	Transplacental	50 Microgram, Qd, 0. - 38.2. Gestational Week, During 1 Trimester		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16094803	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019020533			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate			S	Oral	5 Milligram		Macleods
	Escitalopram Oxalate			S	Oral	10 Milligram		Macleods
	Olanzapin			C	Oral	15 Milligram, Qd, Daily Dose: 15 Mg Millgram(S) Every Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16094901	EXPEDITED (15-DAY)		HO, LT, OT	CH-GLAXOSMITHKLINE-CH2019048598		56 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Oral	10 Mg, Qd		Glaxosmithkline
	Seretide			S	Respiratory (inhalation)	2 Df, Qd		Glaxosmithkline
	Salbutamol			C	Unknown	As Necessary		Glaxosmithkline
	Mepolizumab			C	Unknown	Unk		Glaxosmithkline
	Ipramol (Ipratropium + Salbutamol)			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Aliskiren			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16096414	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1026122		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Tongue Biting	Escitalopram			S		20 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16096523	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1911805US			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Tongue Biting	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16096559	EXPEDITED (15-DAY)		CA, OT	DE-ALLERGAN-1911810US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg/D, (0. - 38.2. Gestational Week)		Allergan
	L-Thyroxin 50			C	Transplacental	50 [Mg/D] (0. - 38.2. Gestational Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16096591	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1912025US			Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Vision Blurred	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Deanxit			S	Oral	125 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16096617	NON-EXPEDITED			US-SA-2019SA066224			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Dizziness; Fatigue; Headache; Insomnia; Nausea; Pruritus; Rash; Urticaria	Talwin Nx			S				Sanofi
	Ambien			S				Sanofi
	Amitriptyline Hydrochloride			S				Not Reported
	Diphenhydramine Hydrochloride			S				Sanofi
	Carbidopa/Levodopa			S				Not Reported

Ciprofloxacin	S	Not Reported
Codeine	S	Not Reported
Cortizone 10	S	Not Reported
Cymbalta	S	Not Reported
Daypro	S	Not Reported
Demerol	S	Sanofi
Donepezil Hydrochloride	S	Not Reported
Fentanyl	S	Not Reported
Gabapentin	S	Not Reported
Gabitril	S	Not Reported
Hycotuss	S	Not Reported
Indocin [Indometacin Sodium]	S	Not Reported
Keflex [Cefalexin]	S	Not Reported
Levetiracetam	S	Not Reported
Lamotrigine	S	Not Reported
Lexapro	S	Not Reported
Pramipexole Hydrochloride	S	Not Reported
Nabumetone	S	Not Reported
Paroxetine Hydrochloride	S	Not Reported
Promethazine	S	Not Reported
Provigil [Modafinil]	S	Not Reported
Requip	S	Not Reported
Trazodone Hydrochloride	S	Not Reported
Venlafaxine Hydrochloride	S	Not Reported
Zonisamide	S	Not Reported
Hydrocodone	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16096889	EXPEDITED (15-DAY)		DE	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000134		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Metoprolol Tartrate			S	Oral	(Extended Release)		Validus
	Amlodipine			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral			Not Reported
	Potassium Chloride			S	Oral	Unk		Not Reported

	Escitalopram		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16097107	EXPEDITED (15-DAY)		HO, OT	JP-AMNEAL PHARMACEUTICALS-2019AMN00332		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Escitalopram Oxalate			S	Unknown	Unk		Amneal
	Lorazepam			S	Unknown	Unk		Amneal
	Adrenaline			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16098145	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1911289US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Off Label Use	Hydrochlorothiazide Unk			S	Oral	Unk		Allergan
	Amlodipine			S	Oral	Unk		Not Reported
	Metoprolol			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16099969	DIRECT	Y				65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	15484432	EXPEDITED (15-DAY)		DS	IT-ALLERGAN-1848269US			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Autism Spectrum Disorder	Escitalopram Oxalate - Bp	S	Oral	5 Gtt, Qd		Allergan
	Risperidone	S	Oral	1 Mg, Qd		Not Reported
	Depakin	C	Oral	100 Mg		Not Reported
	Rivotril	C	Oral	2.5 Mg/Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16098246	EXPEDITED (15-DAY)		OT	PHHY2019FR061712		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Rash; Transaminases Increased	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Clomipramine			S	Oral	75 Mg, Qd		Novartis
	Lamotrigine			C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16098317	EXPEDITED (15-DAY)		OT	SE-TEVA-2019-SE-1025479		56 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S	Oral	"10-15mg" Daily		Ivax
	Sertraline			S	Oral	50 Milligram Daily;		Not Reported
	Lergigan [Promethazine Hydrochloride]			C	Unknown			Not Reported
	Imovane			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16098455	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-2019-DE-1026089		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile	Escitalopram			S	Transplacental	15 Milligram Daily; 15 [Mg/D]		Ivax

Apnoea; Retrognathia	L-Thyroxin 50		C	Transplacental	50 Microgram Daily; 50 [Mg/D]	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099565	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019GSK041997			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Fibromyalgia; Pain; Product Use In Unapproved Indication; Therapeutic Response Unexpected	Lamotrigine			S				Glaxosmithkline
	Gabapentin			S				Not Reported
	Lexapro			S				Not Reported
	Buspirone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099578	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000386		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Doxepin Hydrochloride			S	Oral	Unk		Lannett
	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Hydroxyzine Hydrochloride			S	Oral	Unk		Lannett
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099627	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000249		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Tramadol			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	Unk		Not Reported

	Ethanol		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099800	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000327		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Hydrochlorothiazide; Triamterene			S	Oral	Unk		Lannett
	Amlodipine			S	Oral	Unk		Not Reported
	Metoprolol			S	Oral	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099805	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000326		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Amlodipine			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported
	Naproxen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099806	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000325		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Amlodipine			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

	Lisinopril			S	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099808	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000328		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Hydrochlorothiazide; Triamterene			S	Oral	Unk		Lannett
	Metoprolol			S	Oral	Unk (Extended Release)		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Potassium Chloride			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099811	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000330		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Bupropion			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099813	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000329		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Hydrochlorothiazide (50mg)			S	Oral	Unk		Lannett
	Bupropion			S	Oral	Unk		Not Reported
	Verapamil			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

	Diphenhydramine		S	Oral	Unk		Not Reported
	Lisinopril		S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099940	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000332		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Venlafaxine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099941	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000331		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Methylphenidate Hydrochloride			S	Oral	Unk		Lannett
	Bupropion			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099954	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000333		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Acetaminophen			S	Oral	Unk		Lannett
	Doxepin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16099977	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2019NSR000040		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk		Northstar
	Tramadol Hydrochloride			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	Unk		Not Reported
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16100113	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2019NSR000091		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Hydroxyzine Hydrochloride			S	Oral	Unk		Northstar
	Doxepin			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16100454	EXPEDITED (15-DAY)		OT	SE-PFIZER INC-2019114897		56 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Sertraline Hcl			S	Oral	50 Mg, 1x/Day		Pfizer
	Escitalopram			S	Oral	1 Df, 1x/Day (10-15 Mg)		Not Reported
	Lergigan [Promethazine Hydrochloride]			C		Unk, As Needed		Not Reported
	Imovane			C		Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16100627	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000274		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To Various Agents	Primidone			S	Oral	Unk		Lannett
	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Propranolol			S	Oral	Unk		Not Reported
	Amlodipine			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Trazodone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16101177	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2019NSR000048		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk		Northstar
	Levetiracetam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	Unk		Not Reported
	Acetaminophen W/Chlorzoxazone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16101372	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2019119444		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Urinary Retention	Gabapentin			S	Oral	300 Mg, 1x/Day For First Week 0-0-1		Pfizer
	Gabapentin			S	Oral	300 Mg, 2x/Day		Pfizer
	Gabapentin			S	Oral	300 Mg, 1x/Day		Pfizer
	Escitalopram			S	Oral	5 Mg, Once (Every 24 Hours) 1/2-0-0		Not Reported

Zytram	S	Oral	75 Mg, 1x/Day For First Week 0-0-1		Not Reported
Zytram	S	Oral	75 Mg, 2x/Day (Every 12 Hours) 1-0-1. First Week 0-0-1 , Second Week 1-0-1 And Continue Till The Rev		Not Reported
Nebivolol	C	Oral	Unk		Not Reported
Atorvastatin	C	Oral	Unk		Not Reported
Acetylsalicylic Acid Enteric Coated	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16101411	EXPEDITED (15-DAY)		HO	FR-ACCORD-114264		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rectal Haemorrhage	Escitalopram			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral	1/2 Cp / D 1 Day / 2 Alternating With 3/4 Cp,Strength: 20mg, Scored Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16101549	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1025859		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Coma; Somnolence; Suicide Attempt; Toxicity To Various Agents	Zopiclone			S	Oral	14 Dosage Form, Total		Not Reported
	Escitalopram			S	Oral	9 Dosage Form, Total		Not Reported
	Diazepam			S	Oral	10 Dosage Form, Total		Mylan
	Tercian /00759301/			S	Oral	5 Dosage Form, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16101954	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-		38 YR	Female	USA

2019LAN000898

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Levetiracetam			S	Oral	Unk		Lannett
	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Propranolol			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	Unk		Not Reported
	Acetaminophen W/Chlorzoxazone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16102400	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1912359US			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16102408	EXPEDITED (15-DAY)		OT	NL-ALLERGAN-1912341US			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Micturition Urgency; Urinary Hesitation; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16105608	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Lexapro			S				Not Reported
	Zoloft			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16060957	EXPEDITED (15-DAY)		HO, OT	PL-APOTEX-2019AP009038		52 YR	Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Decreased Appetite; Drug Ineffective; Dyschezia; Medication Error; Pain; Pneumonia; Weight Decreased	Escitalopram			S	Unknown	Unk		Apotex
	Metamizole			S	Unknown	1000 Mg, Qd, 2 Dosages 500 Mg Daily		Not Reported
	Tramadol			S	Unknown	200 Mg, Qd (100 Mg , Bid)		Not Reported
	Buprenorphine			S	Unknown	35 Ug/Hour Every 4 Days		Not Reported
	Metoclopramide			S	Unknown	30 Mg, Qd, 3 Dosages 10 Mg Daily		Not Reported
	Omeprazole			S	Unknown	20 Mg, Qd (In The Morning, Fasting)		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Ketoprofen			S	Unknown	300 Mg, Qd (3 Dosages 100 Mg Daily)		Not Reported
	Betametazona Fiterman			C	Unknown	Unk		Not Reported
	Zoledronic Acid			C	Endocervical	Unk		Not Reported
	Effentora			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Valproic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16095481	EXPEDITED (15-DAY)		OT	US-009507513-1903USA007224			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy	Remeron			S		Unk		Merck
	Buprenorphine Hydrochloride			S		16 Mg Daily (Two 8 Mg		Not Reported

			Films Once Daily)	
	Buprenorphine Hydrochloride	S	Unk	Not Reported
	Suboxone	S	8 Mg Twice Daily	Not Reported
	Suboxone	S	Unk	Not Reported
	Nicotine	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16104038	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20190321142		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Tylenol		Y	S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Tylenol No.1 Forte Caplets			S	Unknown			Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)			Not Reported
	Cipralex			S	Unknown			Not Reported
	Ciprofloxacin			S	Oral			Not Reported
	Ciprofloxacin			S	Intravenous (not otherwise specified)			Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)			Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)			Not Reported
	Morphine			S	Unknown			Not Reported
	Piperacillin Sodium W/Tazobactam Sodium			S	Unknown			Not Reported
	Trastuzumab			S	Intravenous (not otherwise specified)			Not Reported
	Avastin			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			C	Unknown			Not Reported

Docusate	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Lactulose	C	Unknown	Not Reported
Senna	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16104406	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00013504		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram			S	Transplacental	15 [Mg/D]		Unknown
	L-Thyroxin 50			C	Transplacental	50 [G/D]		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16104463	EXPEDITED (15-DAY)		HO, OT	US-009507513-1903USA007895		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Infantile Vomiting	Remeron			S	Transplacental	Unk		Merck
	Buprenorphine Hydrochloride			S	Transplacental	Unk		Not Reported
	Buprenorphine Hydrochloride			S	Transmammary	Unk		Not Reported
	Suboxone			S	Transplacental	Unk		Not Reported
	Nicotine			S	Transplacental	Unk		Not Reported
	Lexapro			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16104762	EXPEDITED (15-DAY)		HO, OT	GB-TORRENT-00020602			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Potassium	Escitalopram			S	Oral			Unknown

Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Fluoxetine	C		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16105289	EXPEDITED (15-DAY)		DE, HO	EG-JNJFOC-20190318682		16 YR	Female	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Encephalitis; Inappropriate Schedule Of Product Administration; Off Label Use; Pneumonia Aspiration; Pneumonitis	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Cogentin			S	Oral			Not Reported
	Depakine			S	Oral			Not Reported
	Depakine			S	Oral			Not Reported
	Depakine			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16106804	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1026235			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Titration Error; Feeling Abnormal; Multiple Sclerosis Relapse; Panic Attack	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16106957	EXPEDITED (15-DAY)		HO, OT	GB-ALLERGAN-1912329US			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram Oxalate - Bp			S	Oral	40 Mg, Qd		Allergan
	Fluoxetine			C	Unknown	20 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16106980	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1912335US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscle Disorder; Rhabdomyolysis	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unknown		Allergan
	Lavita			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16107914	NON-EXPEDITED			US-TEVA-2019-US-1019751			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Asthenia; Dizziness; Drug Ineffective; Pain	Escitalopram Oxalate			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16107916	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1912284US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Decreased Appetite; Loss Of Personal Independence In Daily	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

Activities; Mental Status Changes; Psychomotor Retardation; Urinary Incontinence	Buproprion	S	Unknown	Unk		Not Reported
	Buproprion	S				Not Reported
	Buspirone	S	Unknown			Not Reported
	Buspirone	S				Not Reported
	Quetiapine	S	Unknown			Not Reported
	Quetiapine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16107944	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1912562US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Rash; Transaminases Increased	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Clomipramine			S	Oral	75 Mg, Qd		Not Reported
	Lamotrigine			C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16107947	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1912343US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depersonalisation/Dereali sation Disorder; Mydriasis; Product Use Issue; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2019	15284902	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-SA-2018SA153669		50 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Condition Aggravated; Depression; Drug Ineffective; Insomnia; Loss	Atorvastatin			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Meloxicam			S				Not Reported

Of Consciousness; Suicide Attempt; Tinnitus	Meloxicam	S				Not Reported
	Zolpidem Tartrate	S	Unknown	10 Mg, Qd		Sanofi
	Bisoprolol Fumarate	S		Unidentified Dose		Not Reported
	Sertraline	S	Unknown	50 Mg, Qd		Not Reported
	Tramadol Hydrochloride	S	Unknown			Not Reported
	Tramadol Hydrochloride	S				Not Reported
	Tramadol Hydrochloride	S				Not Reported
	Escitalopram Oxalate	S	Unknown			Not Reported
	Perindopril	S	Unknown			Not Reported
	Clarithromycin	S	Unknown	Two 10-Day Cycles		Not Reported
	Clarithromycin	S	Unknown	Unk		Not Reported
	Doxepin	S	Unknown	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	13428466	EXPEDITED (15-DAY)		OT	US-JAZZ-2017-US-003667		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Condition Aggravated; Constipation; Dizziness; Fatigue; Feeling Abnormal; Helicobacter Infection; Mast Cell Activation Syndrome; Mood Altered; Nasopharyngitis; Night Sweats; Pain; Pre-Existing Condition Improved; Sexual Dysfunction; Sinusitis Bacterial; Tachycardia; Therapeutic Response Unexpected	Xyrem			S	Oral	3.5 G, Bid		Jazz
	Xyrem			S	Oral	4 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported
	Adderall			S	Unknown			Not Reported
	Diphenhydramine Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	14721516	NON-EXPEDITED			US-PFIZER INC-2018139414		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Nitroglycerin			S		Unk		Pfizer
	Fexofenadine Hcl			S		Unk		Not Reported
	Irbesartan			S		Unk		Not Reported
	Duloxetine Hcl			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Fluoxetine Hcl			S		Unk		Not Reported
	Oxycodone And Acetaminophen			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	14893179	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1825609US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Thrombocytopenia	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Naftidrofuryl			C	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16041082	EXPEDITED (15-DAY)		HO, OT	PL-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-200662		52 YR	Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Decreased Appetite; Drug Ineffective; Dyschezia; Medication Error; Pain; Pneumonia; Weight Decreased	Omeprazole			S	Unknown	20 Milligram, Qd (In The Morning, Fasting)		Astrazeneca
	Escitalopram			S	Unknown	()		Not Reported
	Ketoprofen			S	Unknown	3 Dosages 100 Mg Daily		Not Reported
	Metoclopramide			S	Unknown	3 Dosages 10 Mg Daily		Not Reported
	Metamizole			S	Unknown	2 Dosages 500 Mg Daily		Not Reported
	Tramadol			S	Unknown	100 Milligram, Bid		Not Reported
	Alprazolam			S	Unknown	Unk ()		Not Reported

	Buprenorphine	S	Unknown	35 Ug/Hour Every 4 Days	Not Reported
	Betametazon	C	Unknown	()	Not Reported
	Zoledronic Acid	C	Unknown	Unk	Not Reported
	Effentora	C	Unknown	()	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Valproic Acid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16069212	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1910767US			Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety; Disturbance In Attention; Dizziness; Dizziness; Drug Withdrawal Syndrome; Dyspnoea; Dyspnoea; Ear Discomfort; Fatigue; Fatigue; Fatigue; Impaired Work Ability; Impaired Work Ability; Irritability; Limb Discomfort; Limb Discomfort; Myalgia; Nausea; Panic Reaction; Restlessness; Restlessness; Rhinitis; Somnolence; Trance	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Unknown		Allergan
	Thrombo Ass			C	Unknown	0.5 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16109850	EXPEDITED (15-DAY)		OT	SE-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-202862		56 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Autoimmune Hepatitis	Escitalopram	S	Oral	Unk Unk, Daily, 10-15mg (1)	Not Reported
	Sertraline	S	Oral	50 Milligram, Daily	Sun
	Lergigan [Promethazine Hydrochloride]	C	Unknown	Unk, Prn	Not Reported
	Imovane	C	Unknown	Unk, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16110084	EXPEDITED (15-DAY)		LT	FR-ACCORD-114648		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16110714	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2019-014964			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Escitalopram 10 Mg			S	Oral	5 Milligram, Daily (1/2-0-0)		Aurobindo
	Gabapentin Hard Capsules 300mg			S	Oral	300 Milligram,At Every 8 Hour (1-1-1. 1st Week 0-0-1, 2nd Week 0-1-1, 3rd Wee		Aurobindo
	Zytram Bid			S	Oral	75 Milligram, Two Times A Day (1-0-1. 1st Week 0-0-1, 2nd Week 1-0-1 An		Not Reported
	Nebivolol			C	Oral	Unk		Not Reported
	Atorvastatin			C	Oral	Unk		Not Reported
	Acetylsalicylic Acid			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16110866	EXPEDITED (15-DAY)		OT	IT-ACCORD-114979		56 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Toxicity To Various Agents	Escitalopram	S	Oral		Not Reported
	Metoprolol	S	Oral		Accord
	Xarelto	C		Strength 10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16110951	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-2019-GB-1028338			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram			S	Oral	40 Milligram Daily;		Ivax
	Fluoxetine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16111039	EXPEDITED (15-DAY)		HO	FR-ACCORD-115509		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Malaise; Mydriasis; Somnolence; Suicide Attempt; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral	Overdose: 140 Mg, 1 Day		Not Reported
	Paracetamol			S	Oral	79 G, Total		Accord
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported
	Inorial			S	Oral	120 Mg, Total		Not Reported
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported
	Hepatoum			S	Oral	Unspecified		Not Reported
	Arestal			S	Oral	30 Mg, Total		Not Reported
	Seresta			S	Oral	310 Mg, Total		Not Reported
	Cefpodoxime/Cefpodoxime Proxetil			S	Oral	2000 Mg, Total		Not Reported

	Augmentin		S	Oral	6 G, 1 Day	Not Reported
	Prednisolone		S	Oral	200 Mg, Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16113199	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1912514US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Contusion; Subcutaneous Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Eliquis			S	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16113210	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1912521US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Bleeding; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Kardegic			S	Oral	1 Df, Qd		Not Reported
	Coumadine			S	Oral	1 Df, Qd		Not Reported
	Pantoprazole Arrow			C	Oral	1 Df, Qd		Not Reported
	Lasilix			C	Oral	3 Df, Qd		Not Reported
	Colchicine Opocalcium			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16113255	EXPEDITED (15-DAY)		CA	FR-ALLERGAN-1912527US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Behaviour Disorder; Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Intra-uterine	Unk		Allergan
	Mediator			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16115468	EXPEDITED (15-DAY)		OT	PHHY2019FR065429		19 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hidradenitis	Tafinlar			S	Oral	2 Df, Qd (Ug/Liter)		Novartis
	Prazepam			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Melatonine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16087134	EXPEDITED (15-DAY)		OT	SE-AUROBINDO-AUR-APL-2019-013992			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Sertraline Film-Coated Tablet			S	Oral	50 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	1 Unk, Once A Day, 10-15mg		Not Reported
	Lergigan [Promethazine Hydrochloride]			C	Unknown	As Necessary		Not Reported
	Imovane			C	Unknown	As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16099132	EXPEDITED (15-DAY)		CA, OT	DE-HETERO CORPORATE-HET2019DE00322		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram			S	Transplacental	15 [Mg/D]		Hetero
	L-Thyroxin 50			S	Transplacental	50 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16115906	NON-EXPEDITED			US-TEVA-2019-US-1029683			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive	Escitalopram			S				Ivax
	Escitalopram			S				Ivax
	Ranitidine			C				Not Reported
	Lamotrigine			C				Not Reported
	Trazodone			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16116433	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2019-015545			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram Tablets			S	Oral	40 Milligram, Once A Day		Aurobindo
	Fluoxetine			C	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16116587	EXPEDITED (15-DAY)		OT	GB-ACCORD-114295		63 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Feeling Cold; Nausea	Escitalopram			S	Oral	Prescribed 10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16116952	NON-EXPEDITED			US-PFIZER INC-2019125110		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Venlafaxine Hcl			S		Unk		Pfizer

Acetaminophen	S	Unk	Not Reported
Escitalopram Oxalate	S	Unk	Not Reported
Insulin Glargine	S	Unk	Not Reported
Metformin Hcl	S	Unk	Not Reported
Mirtazapine	S	Unk	Not Reported
Macrobid [Nitrofurantoin]	S	Unk	Not Reported
Oxcarbazepine	S	Unk	Not Reported
Nitrofurantoin Macrocrystalline	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16117817	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1029052		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction	Escitalopram			S	Oral	5 Milligram Daily;		Ivax
	Previscan 20 Mg			S	Oral	15 Milligram Daily; Scored		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16118359	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1025850		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Disturbance In Attention; Hypoglycaemia; Hypotension; Somnolence; Suicide Attempt; Toxicity To Various Agents	Cetirizine			S	Oral	50 Milligram, Total		Not Reported
	Zopiclone			S	Oral	30 Milligram, Total		Not Reported
	Escitalopram			S	Oral	140 Milligram, Total		Not Reported
	Mag 2 /00454301/			S	Oral	7 Dosage Form, Total		Mylan
	Xanax			S	Oral	49 Dosage Form, Total		Mylan
	Doliprane			S	Oral	3 Gram, Total		Mylan
	Flagyl /00012501/			S	Oral	9 Dosage Form, Total		Mylan
	Naproxene /00256201/			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16119036	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1912760US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cephalhaematoma; Foetal Exposure During Pregnancy; Thrombocytopenia Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16119156	EXPEDITED (15-DAY)		OT	ES-TEVA-2019-ES-1027502		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Urinary Retention	Escitalopram 10 Mg 28 Comprimidos			S	Oral	5 Milligram Daily; 1/2-0-0		Ivax
	Gabapentina 300 Mg Cápsulas Duras			S	Oral	1-1-1.1st Week 0-0-1, 2nd Week 0-1-1, 3rd Week 1-1-1 And Continue Until Further Review		Actavis
	Zytram Bid 75 Mg Comprimidos De Liberacion Prolongada , 56 Comprimidos			S	Oral	1-0-1.1st Week 0-0-1, 2nd Week 1-0-1 And Continue To Review		Not Reported
	Nebivolol 5 Mg 28 Comprimidos			C	Oral			Not Reported
	Atorvastatina 40 Mg 28 Comprimidos			C	Oral			Not Reported
	Ácido Acetilsalicílico 100 Mg 30 Comprimidos			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16119285	EXPEDITED (15-DAY)		DS	FR-TAKEDA-2019TUS017411		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Respiration Abnormal; Sleep Apnoea	Brintellix			S	Unknown	Unk		Takeda

Syndrome; Therapeutic Response Decreased	Seroplex		S	Oral	10 Milligram, Qd	Not Reported
	Seroplex		S	Oral	5 Milligram, Qd	Not Reported
	Seroplex		S			Not Reported
	Bilastine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16119488	NON-EXPEDITED			US-TEVA-2019-US-1018901			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased; Palpitations	Escitalopram Tablets			S	Unknown	For 2 Years		Ivax
	Escitalopram Tablets			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16120154	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1913364US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Bactrim			S	Oral	800 Mg Every 2 Days		Not Reported
	Doliprane			S	Oral	3 G		Not Reported
	Vfend			S	Oral	600 Mg		Not Reported
	Augmentin			S	Oral	3 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	12641225	NON-EXPEDITED			US-PFIZER INC-2016365727		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lincocin			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Vimovo			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15976643	NON-EXPEDITED			US-JAZZ-2019-US-000750		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthma; Chest Pain; Drug Hypersensitivity; Headache; Heart Rate Increased; Night Sweats; Obstructive Airways Disorder; Pain In Extremity; Seasonal Allergy; Sinusitis; Snoring; Upper Respiratory Tract Infection	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Cymbalta			S				Not Reported
	Lexapro			S				Not Reported
	Adderall			C				Not Reported
	Evoxac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15987635	NON-EXPEDITED		HO, OT	US-NEUROCRINE BIOSCIENCES INC.-2019NBI00414			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Suicide Attempt	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16044411	EXPEDITED (15-DAY)			US-ALLERGAN-1908458US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hallucination; Initial Insomnia; Mydriasis; Therapeutic Response Unexpected; Tinnitus	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qhs		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qhs		Allergan
	Advil Congestion Relief			S	Oral	Unk Unk, Bid (At Noon And At 5 Pm)		Not Reported
	Advil Congestion Relief			S				Not Reported
	Lexapro			C	Unknown	Unk		Not Reported

	Centrum	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16110103	EXPEDITED (15-DAY)		HO	IT-ACCORD-114256		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flight Of Ideas; Sensory Disturbance	Cipralex			S	Oral			Not Reported
	Lamictal			C	Oral			Not Reported
	Rivotril			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16121850	EXPEDITED (15-DAY)		CA	DE-ACCORD-115453			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Kidney Duplex	Escitalopram			S	Transplacental	10 Mg/D / Dosage Reduction To 5mg/D Before Stop		Not Reported
	Magnetrans			C	Transplacental			Not Reported
	Ibuprofen			C	Transplacental	400 Mg/D / On Demand, Max Once Per Week		Not Reported
	Cetirizine			C	Transplacental			Not Reported
	Paracetamol			C	Transplacental	1500 Mg/D / 1000-1500 Mg/D, In Total 2-3 Times		Not Reported
	Cytotec			C	Transplacental			Not Reported
	Olynth			C	Transplacental	If Required		Not Reported
	Folio Forte			C	Transplacental	0.8 Mg/D / From Week 14 0.4mg/D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16121873	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-028716		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Contusion; Subcutaneous Haematoma	Eliquis			S	Oral	5 Milligram, Qd		Bristol Myers Squibb
	Seroplex			S	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16122018	NON-EXPEDITED			US-PFIZER INC-2019127854		59 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Lexapro			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16122258	EXPEDITED (15-DAY)		HO	FR-ACCORD-115951		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S	Oral			Not Reported
	Kardegic			S	Oral	75 Mg In Sachet-Dose		Not Reported
	Omexel			C		0.4 Mg Prolonged-Release Film-Coated Tablet		Not Reported
	Candesartan			C				Not Reported
	Seebri Breezhaler			C				Not Reported
	Avodart			C		0.50mg		Not Reported
	Seresta			C		10 Mg		Not Reported
	Tenordate			C				Not Reported
	Imovane			C		7.5 Mg		Not Reported
	Spironolactone			C				Not Reported
	Lasilix			C		40 Mg, Scored Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16123454	EXPEDITED (15-DAY)		DE, HO	PHHY2019CH064575		47 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Cardiac Arrest; Cough; Dyspnoea; Oropharyngeal Pain; Pyrexia	Clopin Eco			S	Oral	Beginning At 25 Mg/Day On 04-Dec-2018 And Increased To 300 Mg/Day On 20-Dec-2018		Not Reported
	Clarithromycin			S	Oral			Not Reported
	Piperacillin+Tazobactam			S	Intravenous drip			Novartis
	Metfin			S	Oral	Since At Least 19-Nov-2018		Not Reported
	Betmiga			S	Oral	Since At Least April 2018		Not Reported
	Dafalgan			S	Oral	1g Maximum 3x/Day On Hand; As Necessary		Not Reported
	Cipralex			S	Oral	Normal Long Term Treatment		Not Reported
	Haloperidol			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Oral	2.5 Mg Maximum 2x/Day On Hand Since At Least May 2018; As Necessary		Not Reported
	Ventolin			S	Respiratory (inhalation)	100 Micrograms On Hand Maximum 4x/Day; As Necessary		Not Reported
	Inderal			S	Oral	Normal Treatment For Many Years		Not Reported
	Tranxilium			C	Oral			Not Reported
	Zolpidem			C	Oral	10 Mg/Day On Hand Since At Least 26-Nov-2018; As Necessary		Not Reported
	Atorvastatine			C	Oral	20 Mg/Day Since At Least 19-Nov-2018		Not Reported
	Eltroxin			C	Oral	Since At Least April 2018		Not Reported
	Calcium Sandoz + Witamin D3			C	Oral			Not Reported
	Duspatalin			C	Oral	Since At Least 19-Nov-2018		Not Reported

	Symbicort	C	Respiratory (inhalation)	2 Inhalations/Day	Not Reported
	Spasmo-Urgenin Neo	C	Oral		Not Reported
	Cerazette	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16123545	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1026592		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Abuse; Nausea	Escitalopram			S	Oral	20 Gtt Drops, Total (1/12 Millilitre)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16123571	EXPEDITED (15-DAY)		HO	PHHY2019FR065142		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Tonic Clonic Movements	Cotareg			S	Oral	1 Df, Qd		Novartis
	Seroplex			S	Oral	2 Df, Qd		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Intravenous drip	Unk		Not Reported
	Uvedose			C	Unknown	Unk		Not Reported
	Seresta			C	Unknown	Unk		Not Reported
	Imovane			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16123792	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1026781		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	50 Milligram, Total		Not Reported
	Delorazepam			S	Oral	Unk		Not Reported
	Tavor /00273201/			S	Oral	4 Dosage Form, Total		Mylan

	Oki	S	Oral	800 Milligram, Total	Mylan
	Lamotrigine	S	Oral	4 Dosage Form, Total	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16124017	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1913393US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Tonic Clonic Movements	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Cotareg			S	Oral	1 Df, Qd (80 Mg/12,5 Mg)		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Intravenous drip	Unk, Single (10mg/10ml)		Not Reported
	Uvedose			C				Not Reported
	Seresta			C				Not Reported
	Imovane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16124047	EXPEDITED (15-DAY)		DS	FR-ALLERGAN-1913496US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Respiration Abnormal; Sleep Apnoea Syndrome; Therapeutic Response Decreased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Brintellix			S	Unknown	Unk		Not Reported
	Bilastine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16124048	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1913324US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hidradenitis	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Prazepam			S	Oral	Unk		Not Reported

Melatonine	S	Oral	Unk		Not Reported
Tafinlar	S	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16124071	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1913503US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Traumatic Intracranial Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Coumadine			S	Oral	Unk		Not Reported
	Pregabaline			C	Oral	Unk		Not Reported
	Bisoce			C	Oral	Unk		Not Reported
	Inexium			C	Oral	Unk		Not Reported
	Perindopril			C	Oral	Unk		Not Reported
	Repaglinide			C	Oral	Unk		Not Reported
	Seresta			C	Oral	Unk		Not Reported
	Lasilix			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16124753	NON-EXPEDITED			US-EISAI MEDICAL RESEARCH-EC-2019-053083			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Belviq			S	Oral			Not Reported
	Belviq			S	Oral			Not Reported
	Lexapro			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16125100	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1913608US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Loss Of Consciousness; Neurological Symptom; Parathyroid Disorder; Product Use Issue; Somnolence	Escitalopram Oxalate - Bp		S	Oral	5 Mg, Q12h	Allergan
	Calcium		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	13951821	EXPEDITED (15-DAY)		HO, OT	AT-ALLERGAN-1704413US			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cognitive Disorder; Dyspnoea; Hyperhidrosis; Hyperreflexia; Malaise; Panic Attack; Restlessness; Serotonin Syndrome; Tachycardia; Tremor	Escitalopram Oxalate Unk			S		10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Wick			S	Oral	30 Ml, Qd		Not Reported
	Temesta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	15597965	NON-EXPEDITED			US-PFIZER INC-2018443915		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Weight Increased	Desvenlafaxine Succinate Monohydrate			S		50 Mg, Daily (For 2 Weeks)		Pfizer
	Zoloft			S		Unk		Pfizer
	Fetzima			S		Unk		Not Reported
	Remeron			S		Unk		Not Reported
	Trintellix			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Rexulti			C		Unk		Not Reported
	Sonata [Zaleplon]			C		Unk		Not Reported
	Ambien			C		Unk		Not Reported

	Melatonin	C	Unk	Not Reported
	Abilify	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	15602853	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1852425US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blister; Cellulitis; Chills; Depression; Dyspnoea; Feeling Hot; Gait Disturbance; Headache; Heart Rate Increased; Hypertension; Hypoaesthesia; Insomnia; Intentional Overdose; Nausea; Neuropathy Peripheral; Pain In Extremity; Panic Attack; Peripheral Swelling; Skin Discolouration; Swelling; Tooth Abscess; Tremor; Urinary Incontinence; Vision Blurred	Lexapro			S	Oral	5 Df, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Q6hr		Allergan
	Gocovri			S	Oral	137 Mg, Qhs		Not Reported
	Gocovri			S	Oral	274 Mg, Qhs		Not Reported
	Gocovri			S	Oral	137 Unk, Qhs		Not Reported
	Gocovri			S	Oral	274 Mg, Qhs		Not Reported
	Gocovri			S	Oral	137 Mg, Qhs		Not Reported
	Parcopa			C		25/1000 Mg Unk		Not Reported
	Clonazepam			C		0.5 Mg, Unk		Not Reported
	Allegra			C		60 Mg, "1x/Day, Sometimes 2x/Day And Sometimes None"		Not Reported
	Hydrocortisone			C		5 Mg, Unk		Not Reported
	Metoprolol Succinate			C		0.5 Df, Qhs		Not Reported
	Motrin Ib			C		200 Mg, Prn		Not Reported
	Nyamyc			C		10000 Units, Unk		Not Reported
	Ranitidine			C		150 Mg, Unk		Not Reported
	Ropinirole			C		4 Mg, Unk		Not Reported
	Stalevo 200			C		Unk		Not Reported
	Bepreve			C				Not Reported
	Systane			C		Unk		Not Reported
	Preparation H			C		Unk		Not Reported
	Tums Smooth Dissolve			C		750 Mg, As Needed		Not Reported

	Tylenol	C	650 Mg, 2-3 Per Day	Not Reported
	Miralax	C	Unk	Not Reported
	Cranberry/D3	C		Not Reported
	Vitamin B12	C	1000 Mg, Unk	Not Reported
	Vitamin D2	C	400 Units, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	15995158	EXPEDITED (15-DAY)		HO, OT	FR-LUPIN PHARMACEUTICALS INC.-2019-01086		24 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Cardiac Disorder; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Lupin
	Aripiprazole			S	Unknown	Unk Unk, Qd (10 To 30 Mg)		Not Reported
	Clozapine			C	Unknown	Unk		Not Reported
	Clozapine			C	Unknown	600 Milligram, Qd		Not Reported
	Clozapine			C	Unknown	350 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16125685	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1029539		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Rash; Transaminases Increased	Clomipramine (Chlorhydrate De)			S	Oral	75 Milligram Daily;		Actavis
	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Lamotrigine			C	Oral	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16125726	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2019-015255			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Coronary Syndrome; Anaemia; Haematoma; Haematuria	Escitalopram Arrow Film-Coated Tablet 5mg	S	Oral	1 Dosage Form, Once A Day	Aurobindo
	Allopurinol Arrow Tablets 100 Mg	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Furosemide Arrow 40 Mg Tablets	S	Oral	40 Milligram, Once A Day	Not Reported
	Kardegic	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Pregabaline Teva	S	Oral	3 Dosage Form, Once A Day	Not Reported
	Previscan (Fluindione)	S	Oral	1.5 Dosage Form, Once A Day	Not Reported
	Imovane	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Bisoprolol Hemifumarate	C	Unknown	Unk	Not Reported
	Levemir	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Levothyrox	C	Unknown	Unk	Not Reported
	Galvus	C	Unknown	Unk	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Xatral	C	Unknown	Unk	Not Reported
	Umuline	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16125741	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-015913			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Partial Seizures	Escitalopram			S	Oral	5 Milligram, Once A Day		Aurobindo
	Alprazolam			C	Oral	0.25 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126071	EXPEDITED (15-DAY)		OT	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2019-BI-01		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Movement Disorder; Loss Of Consciousness	Pritor (Telmisartan)			S	Unknown			Boehringer Ingelheim
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126475	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-016097			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral	5 Milligram, Once A Day		Aurobindo
	Previscan (Fluindione)			S	Oral	15 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126614	EXPEDITED (15-DAY)		HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2019020590			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram			S	Oral	40 Milligram, Qd		Macleods
	Fluoxetine			C	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126795	EXPEDITED (15-DAY)		OT	ES-ACCORD-116108			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Medication Error	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126799	EXPEDITED (15-DAY)		HO	FR-ACCORD-115947		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral			Not Reported
	Spironolactone			S	Oral			Accord
	Imovane			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Omexel L.P.			S	Oral			Not Reported
	Candesartan			S	Oral			Not Reported
	Tenordate			S	Oral			Not Reported
	Seebri Breezhaler			C				Not Reported
	Avodart			C				Not Reported
	Kardegic			C				Not Reported
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126859	EXPEDITED (15-DAY)		HO	IT-ACCORD-115361		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Sluggishness	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126860	EXPEDITED (15-DAY)		HO	IT-ACCORD-115597		84 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Medication Error; Off Label Use	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16128357	EXPEDITED (15-DAY)		OT	ES-APOTEX-2019AP010216		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Gabapentine			S	Oral	1-1-1. 1ª Semana 0-0-1 , 2ª Semana 0-1-1, 3ª Semana 1-1-1 Y Seguir Hasta Nueva Revisión		Apotex
	Escitalopram			S	Oral	1/2-0-0		Apotex
	Zytram Bid			S	Oral	1-0-1. 1ª Semana 0-0-1 , 2ª Semana 1-0-1 Y Seguir Hasta Revisión		Not Reported
	Nebivolol			C	Oral			Not Reported
	Atorvastatina /01326101/			C	Oral			Not Reported
	Acetylsalicylic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16129408	EXPEDITED (15-DAY)		LT	FR-TEVA-2019-FR-1028985		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Anaemia; Haematoma; Haematuria	Escitalopram Arrow 5 Mg, Comprimé Pelliculé			S	Oral	1 Dosage Forms Daily;		Ivax
	Pregabaline Teva 50 Mg, Gélule			S	Oral	3 Dosage Forms Daily;		Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	1 Dosage Forms Daily;		Not Reported

	Allopurinol Arrow 100 Mg, Comprimé	S	Oral	1 Dosage Forms Daily;	Not Reported
	Imovane 3,75 Mg, Comprimé Pelliculé	S	Oral	1 Dosage Forms Daily;	Not Reported
	Furosemide Arrow 40 Mg, Comprimé Sécable	S	Oral	40 Milligram Daily;	Not Reported
	Previscan 20 Mg, Comprimé Sécable	S	Oral	1.5 Dosage Forms Daily;	Not Reported
	Bisoprolol (Hemifumarate De)	C			Not Reported
	Levemir	C			Not Reported
	Pantoprazole	C			Not Reported
	Levothyrox	C			Not Reported
	Galvus	C			Not Reported
	Amlodipine	C			Not Reported
	Xatral	C			Not Reported
	Umuline	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16130059	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1028192		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyramidal Tract Syndrome; Toxicity To Various Agents; Tremor	Escitalopram			S	Oral	600 Mg,Unk		Not Reported
	Diazepam			S	Oral	30 Df,Unk		Mylan
	Teralithe			S	Oral	Dose 2 Boxes Of 400 Mg Tabres		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16130834	EXPEDITED (15-DAY)		DE, OT	US-ENDO PHARMACEUTICALS INC-2019-102300		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Drug Interaction; Overdose; Pulmonary Congestion; Pulmonary Oedema; Toxicity To Various Agents	Percodan			S	Unknown	Unk Unknown, Unknown		Endo
	Roxicodone			S	Unknown	Unk Unknown, Unknown		Not Reported
	Oxycontin			S	Unknown	Unk Unknown, Unknown		Not Reported
	Valium			S	Unknown	Unk Unknown, Unknown		Not Reported

	Flexeril /00428402/	S	Unknown	Unk Unknown, Unknown	Not Reported
	Desyrel	S	Unknown	Unk Unknown, Unknown	Not Reported
	Lexapro	S	Unknown	Unk Unknown, Unknown	Not Reported
	Celexa /00582602/	S	Unknown	Unk Unknown, Unknown	Not Reported
	Neurontin	S	Unknown	Unk Unknown, Unknown	Not Reported
	Caffeine	S	Unknown	Unk Unknown, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16131746	DIRECT		LT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Oral	Quantity:1 Capsule(S);		Not Reported
	Norplaxon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	15587155	EXPEDITED (15-DAY)		DE, HO, LT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2018DEP001875		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved Indication	Diclofenac Potassium			S	Oral	50 Mg, Bid		Assertio Therapeutics
	Cipralex /01588501/			S	Oral	10 Mg, Qd		Not Reported
	Ibuprofen			S	Oral	400 Mg, Prn		Not Reported
	Eliquis			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	15905999	NON-EXPEDITED		OT	US-JAZZ-2018-US-018869		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Dizziness; Feeling Abnormal; Libido	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz

Decreased; Nausea	Xyrem	S	Oral	Unknown Decreased Dose	Jazz
	Xyrem	S	Oral	2.25 G, Bid	Jazz
	Xyrem	S	Oral	3 G, Bid	Jazz
	Lexapro	S			Not Reported
	Hydroxyzine Hcl	C			Not Reported
	Ritalin	C			Not Reported
	Marijuana	C			Not Reported
	Spironolactone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16055904	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2019IN01318			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Escitalopram			S	Unknown	Unk		Invagen
	Phenytoin			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Mirtazapine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16083537	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1911070US			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Condition Aggravated	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Antihypertensives			C	Oral			Not Reported
	Sulpiride			C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16121596	NON-EXPEDITED			US-APOTEX-2018AP026501		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Persistent Genital Arousal Disorder	Fluoxetine	S	Unknown	Unk	Apotex
	Paroxetine	S	Unknown	Unk	Apotex
	Sertraline	S	Unknown	Unk	Apotex
	Escitalopram	S	Unknown	Unk	Apotex
	Venlafaxine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16133550	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2019020585			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Urinary Retention	Escitalopram Oxalate			S	Oral	5 Milligram, Qd		Macleods
	Zytram Bid			S	Oral	75 Milligram, Bid		Not Reported
	Gabapentin			S	Oral	300 Milligram, Tid		Not Reported
	Acetylsalicylic Acid			C	Oral	Unk		Not Reported
	Atorvastatin			C	Oral	Unk		Not Reported
	Nebivolol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16133622	EXPEDITED (15-DAY)		HO	FR-ACCORD-116247		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Faeces; Feeling Hot; Hyperhidrosis; Hypotension; Malaise; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Rash; Respiratory Distress	Aripiprazole			S	Unknown	2 Mg, Unk		Not Reported
	Selincro			S	Oral			Not Reported
	Seroplex			S	Unknown	20 Mg, Qd		Not Reported
	Loxen			C	Unknown	1 Df, Qd		Not Reported
	Salbutamol			C	Unknown			Not Reported
	Lexomil			C	Unknown	1 Df, Unk		Not Reported
	Methadone			C	Unknown	80 Mg, Qd		Not Reported
	Kardegic			C	Unknown			Not Reported

	Theralene	C	Unknown	2 Df, Unk		Not Reported
	Corgard	C	Unknown	80 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16133639	EXPEDITED (15-DAY)		OT	SE-ACCORD-116314		36 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Persistent Genital Arousal Disorder	Escitalopram			S		One Tablet Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16133694	EXPEDITED (15-DAY)		OT	HR-ACCORD-116687			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Somnolence; Suicide Attempt	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Caffetin [Aminophenazone\Caffeine\Codeine \Phenacetin]			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16133861	EXPEDITED (15-DAY)		HO, OT	IN-TORRENT-00002153		7 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Ineffective	Paracetamol			S				Unknown
	Amitriptyline			S		Unknown		Unknown
	Pregabalin			S		Unknown		Unknown
	Escitalopram			S		Unknown		Unknown
	Paracetamol			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16134888	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1027891		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Weight Decreased; Xerophthalmia	Escitalopram			S	Oral	Unk		Not Reported
	Lercan			C	Oral	Unk		Mylan
	Lormetazepam			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16135206	EXPEDITED (15-DAY)		DS	SE-ALLERGAN-1913939US			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16135357	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1913999US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Hypothermia; Intentional Overdose	Escitalopram Oxalate - Bp			S	Oral	280 Mg Total		Allergan
	Noctamide			S	Oral	70mg In Total (35 Of 2mg Tablets)		Not Reported
	Prazepam			S	Oral	600mg In Total (60 Of 10 Mg)		Not Reported
	Depakote			S	Oral	850000mg In Total (170 Of 500 Mg)		Not Reported
	Mianserine			S	Oral	98 Tablets In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16135401	EXPEDITED (15-DAY)		DE, OT	US-ENDO PHARMACEUTICALS INC-2019-102287		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Contusion; Drug Abuse; Drug Diversion; Drug Interaction; Haemorrhage; Osteophyte Fracture; Pneumonia; Pulmonary Oedema; Scab; Skin Abrasion; Toxicity To Various Agents	Oxycodone Hydrochloride			S	Unknown	Unk Unknown, Unknown		Vintage
	Hydrocodone Bitartrate, Acetaminophen			S	Unknown	Unk Unknown, Unknown		Vintage
	Celexa /00582602/			S	Unknown	Unk Unknown, Unknown		Not Reported
	Lexapro			S	Unknown	Unk Unknown, Unknown		Not Reported
	Risperdal			S	Unknown	Unk Unknown, Unknown		Not Reported
	Seroquel			S	Unknown	Unk Unknown, Unknown		Not Reported
	Klonopin			S	Unknown	Unk Unknown, Unknown		Not Reported
	Gabapentin			S	Unknown	Unk Unknown, Unknown		Not Reported
	Nicotine			S	Unknown	Unk Unknown, Unknown		Not Reported
	Acetaminophen			S	Unknown	Unk Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2019	16132123	EXPEDITED (15-DAY)		CA	DE-ACCORD-116318		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram			S	Transplacental	10 Mg/D		Not Reported
	Levothyroxine			C	Transplacental	75 Ug/D		Not Reported
	Xanaflu			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2019	16138187	EXPEDITED (15-DAY)		OT	FR-ACCORD-116672		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Aripiprazole			S	Oral			Not Reported
	Seresta			S	Oral	1/2cp-1/2cp-/1cp,Strength:50 Mg, Scored Tablet		Not Reported

	Tercian	S	Oral	1/2cp-1/2cp-/1cp/J,Strength:25mg	Not Reported
	Zyprexa	S	Oral	Strength:5mg	Not Reported
	Dafalgan Codeine	S			Not Reported
	Seroplex	S	Oral	Strength: 20mg	Not Reported
	Oxycontin Lp	S	Oral	Strength:40 Mg Prolonged-Release Film-Coated Tablets	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2019	16138194	EXPEDITED (15-DAY)		HO	FR-ACCORD-116430		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhagic Stroke	Escitalopram			S	Oral			Not Reported
	Kardegic			S	Oral	Strength : 160 Mg Powder For Oral Solution In Sachet		Not Reported
	Inegy			C	Oral	Strength : 10 Mg / 40 Mg		Not Reported
	Spironolactone			C	Oral			Not Reported
	Cardensiel			C	Oral	Strengh : 1.25 Mg		Not Reported
	Lasilix			C	Oral			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2019	16138211	EXPEDITED (15-DAY)		HO	FR-ACCORD-116915			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2019	16138260	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-017053			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Furosemide			S	Oral	10 Milligram, Once A Day		Not Reported
	Candesartan			S	Oral	4 Milligram, Once A Day		Not Reported
	Pantoprazole			S	Oral	40 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Alprazolam			C	Unknown	Unk		Not Reported
	Spagulax Mucilage Pur			C	Unknown	Unk		Not Reported
	Gaviscon			C	Unknown	Unk		Not Reported
	Voltarene (Diclofenac Diethylamine)			C	Unknown	Unk		Not Reported
	Levothyrox			C	Unknown	Unk		Not Reported
	Rilmenidine			C	Unknown	Unk		Not Reported
	Eupressyl			C	Unknown	Unk		Not Reported
	Loxen L P			C	Unknown	Unk		Not Reported
	Uvedose			C	Unknown	Unk		Not Reported
	Doliprane			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2019	16138266	EXPEDITED (15-DAY)		DS, OT	GB-ACCORD-117055		22 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Insomnia; Irritability; Tension	Escitalopram			S	Oral			Not Reported
	Kalms			C		Night		Not Reported
	Sleepeezy Valerian			C				Not Reported
	Lansoprazole			C				Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2019	16138646	EXPEDITED (15-DAY)		OT	DE-ACCORD-116426		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Stillbirth	Quetiapine			S	Oral	25 Mg/D		Not Reported
	Escitalopram			S	Oral	20 Mg/D		Not Reported
	Presinol			S	Oral	500 Mg/D (2x250)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	14634733	NON-EXPEDITED			US-PFIZER INC-2018103433		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Levaquin			S		Unk		Not Reported
	Toradol			S		Unk		Not Reported
	Vioxx			S		Unk		Not Reported
	Imitrex			S		Unk		Not Reported
	Baclofen			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Ambien			S		Unk		Not Reported
	Singulair			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	14801319	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1025119		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Lower Gastrointestinal Haemorrhage	Escitalopram			S		Unk		Not Reported
	Xarelto			S		20 Mg, Unk		Mylan
	Zofenil			C		Unk		Mylan

	Carbidopa/Levodopa	C	Unk	Mylan
	Androtardyl	C	Unk	Mylan
	Amoxicillin Sodium And Potassium Clavulanate	C	Unk	Mylan
	Requip	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	14873407	NON-EXPEDITED			US-PFIZER INC-2018193089		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Buspar			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	15211691	EXPEDITED (15-DAY)		HO, OT	PHHY2018ES053974			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Omeprazole			S	Oral	Unk		Novartis
	Escitalopram			S	Unknown	Unk		Not Reported
	Bendamustine			S	Intravenous (not otherwise specified)	149 Mg, Unk		Not Reported
	Bendamustine			S	Intravenous (not otherwise specified)	149.4 Mg, Unk		Not Reported
	Cotrimoxazol			S	Unknown	Unk		Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Obinutuzumab			S				Not Reported
	Obinutuzumab			S				Not Reported

Atorvastatin	C	Unknown	Unk		Not Reported
Valsartan	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	15686835	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1090125		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Bisoce 1,25 Mg, Comprimé Pelliculé			S	Oral	1.25 Milligram, Qd		Mylan
	Lamotrigine			S	Oral	100 Milligram, Qd		Not Reported
	Exemestane			S	Oral	2.5 Milligram, Qd		Not Reported
	Exemestane			S	Oral	25 Unk		Not Reported
	Ramipril			S	Oral	2.5 Milligram, Qd		Not Reported
	Acetylsalicylic Acid			S	Oral	100 Milligram, Qd		Not Reported
	Seroplex			S	Oral	5 Milligram, Qd		Mylan
	Gabapentine Winthrop			S	Oral	200 Milligram, Qd		Mylan
	Lasilix /00032601/			S	Oral	20 Milligram, Qd		Mylan
	Levothyroxine Sodium			C	Oral	30 Gtt Drops, Qd		Mylan
	Potassium Gluconate			C	Oral	1 Dosage Form, Qd		Mylan
	Fluidabak			C	Ophthalmic	3 Gtt Drops, Qd		Mylan
	Gluconate Sodium W/Potassium Chloride/Sodium			C	Oral	1 Cs Par Jour		Mylan
	Transipeg /00754501/			C	Oral	11.8 Gram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16069203	EXPEDITED (15-DAY)			SE-ALLERGAN-1910995US			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Escitalopram Oxalate - Bp			S	Oral	10-15 Mg		Allergan
	Sertraline			S	Oral	50 Mg		Not Reported
	Lergigan [Promethazine			C	Unknown	Unk Unk, Prn		Not Reported

	Hydrochloride] Imovane			C	Unknown	Unk, Prn				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16136935	EXPEDITED (15-DAY)		HO, LT	HU-ACCORD-117289		27 YR	Female	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Intentional Overdose; Muscle Rigidity; Myoglobin Blood Increased; Serotonin Syndrome; Suicidal Ideation; Suicide Attempt; Tremor	Escitalopram			S				Not Reported
	Sertraline			S				Accord
	Moclobemide			S		Unk		Not Reported
	Cyproheptadine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16138378	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2016-05975		21 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery	Escitalopram			S	Unknown	10 Milligram, Qd		Lupin
	Levofloxacine /01278901/			C	Unknown	500 Milligram, Qd		Not Reported
	Cefprozil			C	Unknown	1000 Milligram, Qd		Not Reported
	Etodolac			C	Unknown	300 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16141463	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1028600		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury; Sluggishness	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported
	Pariet			S	Oral	240 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16142573	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019132467		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Vfend			S	Oral	600 Mg, Unk		Pfizer
	Bactrim			S	Oral	800 Mg, Alternate Day		Not Reported
	Doliprane			S	Oral	3 G, Unk		Not Reported
	Seroplex			S	Oral	20 Mg, 1x/Day		Not Reported
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S	Oral	3 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16142739	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1914002US			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Impaired Work Ability	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16145583	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-09249		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Gastrointestinal Disorder; Restlessness; Somnolence	Citalopram			S	Unknown	5 Mg, Unk		Not Reported
	Citalopram			S				Not Reported
	Sertraline			S	Unknown	12.5 Mg, Unk		Lupin
	Sertraline			S				Lupin
	Fluoxetine			S	Unknown	5 Mg, Unk		Lupin
	Fluoxetine			S				Lupin
	Escitalopram			S	Unknown	2.5 Mg, Unk		Lupin
	Escitalopram			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16145590	NON-EXPEDITED			CN-LUPIN PHARMACEUTICALS INC.-2018-09146		15 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania; Insomnia	Escitalopram Tablets			S	Unknown	10 Mg, Qd (Tablets)		Lupin
	Sertraline			S	Unknown	50 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16145970	EXPEDITED (15-DAY)		OT	DE-ACCORD-117761		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	5 Mg/D		Not Reported
	Tetanus Vaccine			C	Transplacental			Not Reported
	Levothyroxine			C	Transplacental	5 Mg/D		Not Reported
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16145974	EXPEDITED (15-DAY)		OT	DE-ACCORD-117639			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16145985	EXPEDITED (15-DAY)		DS	FR-ACCORD-117236		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral			Not Reported

	Eliquis	S	Oral	Strength 2.5 Mg	Not Reported
	Digoxin	C			Not Reported
	Loxen Lp	C		Strength 50 Mg	Not Reported
	Lopressor Lp	C		Strength 200 Mg, Breakable Sustained Release Tablet	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16146081	EXPEDITED (15-DAY)		HO	IT-ACCORD-117457		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Loss Of Consciousness; Nuchal Rigidity; Pupillary Reflex Impaired; Suicide Attempt	Escitalopram			S	Oral			Not Reported
	Felison			S	Oral	Strength : 30 Mg		Not Reported
	Seroquel			S	Oral	Strength : 100 Mg		Not Reported
	Tavor (Lorazepam)			S	Oral	Strength : 2.5 Mg		Not Reported
	Zoloft			S	Oral	Strength : 100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16146139	EXPEDITED (15-DAY)		HO	IT-ACCORD-116935		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Cerebral Haemorrhage; Drug Interaction; Ecchymosis; Subdural Haematoma	Escitalopram			S	Oral			Not Reported
	Plavix			S	Oral			Not Reported
	Warfarin			S	Oral			Not Reported
	Doxazosin			C				Not Reported
	Esomeprazole			C				Not Reported
	Pregabalin			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16147035	NON-EXPEDITED			PHEH2019US014245			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Crying; Diarrhoea; Hot Flush; Myalgia; Upper Respiratory Tract Infection; Weight Increased	Letrozole			S	Unknown			Novartis
	Ibrance			S	Unknown			Not Reported
	Taxol			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16149459	EXPEDITED (15-DAY)		DE	FR-NAPPMUNDI-GBR-2019-0065408		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Malaise; Pain	Oxynormoro			S	Oral	4 Df, Daily (5mg Strength; Si Douleur)		Purdue
	Alprazolam			S	Oral	1 Df, Daily		Not Reported
	Levodopa-Carbidopa			S	Oral	1 Df, Daily (1 Cp Au Coucher)		Not Reported
	Modopar			S	Oral	4 Df, Daily (2cp A 16h Et 2cp Le Soir)		Not Reported
	Clozapine			S	Oral	1 Df, Daily (1 Cp Le Soir)		Not Reported
	Acupan			S	Sublingual	4 Df, Daily		Not Reported
	Doliprane			S	Oral	Unk		Not Reported
	Sinemet Plus			S	Oral	2 Df, Daily (1cp Matin Et 1cp Midi)		Not Reported
	Dutasteride			S	Oral	1 Df, Daily		Not Reported
	Escitalopram Oxalate			S	Oral	1 Df, Daily (1 Cp Matin)		Not Reported
	Monocrixo			S	Oral	Unk		Not Reported
	Rivastigmine			S	Transdermal	1 Df, Daily (9.5 Mg/24 Heures)		Not Reported
	Tramadol And Acetaminophen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	15680050	EXPEDITED (15-DAY)		OT	PT-MACLEODS PHARMACEUTICALS US LTD-MAC2018018939			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dystonia; Gait Disturbance; Posture Abnormal; Stiff Person Syndrome	Escitalopram			S	Unknown	20 Milligram		Macleods
	Insulin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	15995716	EXPEDITED (15-DAY)		HO	FR-009507513-1902FRA006378		92 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Leukopenia; Thrombocytopenia	Invanz			S	Subcutaneous	1 Gram, Qd		Merck
	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported
	Ceftriaxone Sodium			S	Subcutaneous	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16043750	NON-EXPEDITED			US-SUNOVION-2019SUN000793		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Myalgia; Off Label Use	Latuda			S	Oral	40 Mg		Sunovion
	Latuda			S	Oral	20 Mg		Sunovion
	Lexapro			S		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16150407	EXPEDITED (15-DAY)		OT	SE-TEVA-2019-SE-1032127		44 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Genital Haemorrhage; Paraesthesia	Escitalopram Teva 10 Mg Filmdragerad Tablett	S	Oral	10 Milligram Daily;		Ivax
	Escitalopram Teva 10 Mg Filmdragerad Tablett	S				Ivax
	Montelukast	C				Not Reported
	Symbicort Turbuhaler	C		Inhalator		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16151324	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2019-017143			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Hyperhidrosis; Loss Of Consciousness; Tachycardia; Tremor	Escitalopram			S	Oral	10 Microgram, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16152444	EXPEDITED (15-DAY)		CA	DE-ACCORD-118170		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Transposition Of The Great Vessels	Escitalopram			S	Transplacental	10 Mg/D (5)		Not Reported
	Skinoren			C	Transplacental			Not Reported
	Folic Acid			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16153191	EXPEDITED (15-DAY)		HO	FR-ACCORD-117372		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pruritic	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Xgeva			S	Subcutaneous			Not Reported
	Aromasine			C	Oral	25 Mg, Coated Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16153621	EXPEDITED (15-DAY)		OT	GB-ACCORD-116825		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dry Skin; Dyspnoea; Fatigue; Hypoaesthesia; Nausea; Paraesthesia; Urticaria	Amitriptyline			S	Oral			Accord
	Cipralex			S	Oral			Not Reported
	Calcium Gluconate			C				Not Reported
	Zinc			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Magnesium Hydroxide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16154179	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1032860		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Hyperhidrosis; Loss Of Consciousness; Tachycardia; Tremor	Escitalopram Oxalate			S	Oral	10 Microgram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16154318	EXPEDITED (15-DAY)		DE, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-02934		40 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Amlodipine Besylate			S	Unknown	Unk		Alkem
	Duloxetine Hydrochloride			S	Unknown	Unk		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Atenolol			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Losartan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16154726	EXPEDITED (15-DAY)		DS	SE-TEVA-2019-SE-1031897		61 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16155399	EXPEDITED (15-DAY)		DE	FR-009507513-1903FRA011015		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Malaise; Pain	Sinemet L.P.			S	Oral	1 Tablet In The Morning And 1 Tablet At Lunch		Merck
	Alprazolam			S	Oral	1 Dosage Form, Qd		Not Reported
	Carbidopa (+) Levodopa			S	Oral	One Tablet At Bedtime		Not Reported
	Modopar			S	Oral	Two Tablets At 4 Pm And 2 Tablets In The Evening		Not Reported
	Clozapine			S	Oral	1 Tablet In The Evening		Not Reported
	Acupan			S	Sublingual	4 Dosage Form, Qd		Not Reported
	Doliprane			S	Oral	Formulation: Powder For Oral Solution In Single-Dose		Not Reported
	Dutasteride			S	Oral	1 Dosage Form, Qd. Formulation: Soft Capsule		Not Reported
	Escitalopram			S	Oral	1 Tablet In The Morning. Formulation: Scored Film Coated Tablet		Not Reported
	Oxynormoro			S	Oral	If Pain		Not Reported
	Monocrixo			S	Oral	Unk		Not Reported
	Rivastigmine			S	Transdermal	1 Dosage Form, Qd. Strength: 9.5 Mg/24 Hours		Not Reported
	Acetaminophen (+) Tramadol Hydrochloride			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	14108082	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1064740			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Product Misuse; Intentional Self-Injury; Sopor	Delorazepam			S	Oral	Unk		Not Reported
	Losartan			S	Oral	Unk		Not Reported
	Haldol			S	Oral	Unk		Mylan
	Escitalopram			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	15196839	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2018-ES-932723			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia; Ventricular Tachycardia	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	149.4 Mg, Cyclic		Cephalon
	Escitalopram			S	Unknown	Unk Unk, Unknown Freq.		Ivax
	Omeprazole			S	Oral	Unk Unk, Unknown Freq.		Teva
	Obinutuzumab			S	Intravenous (not otherwise specified)			Not Reported
	Cotrimoxamol			S	Unknown			Not Reported
	Atorvastatin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Valsartan			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	15543065	EXPEDITED (15-DAY)		OT	EE-PFIZER INC-2018430237		27 YR	Female	EST

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agoraphobia; Akathisia; Anger; Anxiety; Autophobia; Derealisation; Fatigue; Fear Of Death;	Efexor Xr			S		37.5 Mg, 1x/Day, Qd		Pfizer
	Escitalopram			S		Unk		Not Reported
	Valdoxan			S		25 Mg, 1x/Day, Qd		Not Reported

Impaired Quality Of Life; Insomnia; Nightmare; Palpitations; Panic Disorder; Paraesthesia; Product Use Issue; Product Use Issue; Restlessness; Suicidal Ideation; Visual Impairment; Vomiting; Weight Decreased	Valdoxan	S		12.5 Mg, 1x/Day, Qd		Not Reported
	Valdoxan	S	Oral	Unk, 1x/Day		Not Reported
	Oxazepam	C		Unk		Not Reported
	Diazepam	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16007373	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1015354		92 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Leukopenia; Thrombocytopenia	Escitalopram Arrow 5 Mg, Comprimé Pelliculé			S	Oral	1 Dosage Forms Daily;		Ivax
	Invanz 1 G, Poudre Pour Solution À Diluer Pour Perfusion			S	Subcutaneous	1 Gram Daily;		Not Reported
	Triacefan			S	Subcutaneous	1 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16070927	EXPEDITED (15-DAY)		HO	DE-TORRENT-00013501		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram			S	Oral			Unknown
	Olanzapin			C	Oral	Daily Dose: 15 Mg Millgram(S) Every Days, 7.5 Mg 2x		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16155898	EXPEDITED (15-DAY)		HO	GB-ACCORD-117613		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyarrhythmia;	Escitalopram			S	Oral			Not Reported

Circulatory Collapse	Elleste-Solo	C	Transdermal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16156800	EXPEDITED (15-DAY)		HO, OT	US-TAKEDA-2019TUS019364		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Macular Degeneration	Trintellix			S	Unknown	5 Milligram		Takeda
	Trintellix			S	Unknown	10 Milligram		Takeda
	Nortriptyline			S	Unknown	Unk		Not Reported
	Seroquel			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Donepezil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16157823	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1032580		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Candesartan Cilexetil			S	Oral	4 Milligram Daily;		Not Reported
	Pantoprazole			S	Oral	40 Milligram Daily;		Teva
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Furosemide			S	Oral	10 Milligram Daily;		Actavis
	Alprazolam			C				Not Reported
	Spagulax Mucilage Pur, Granulés			C				Not Reported
	Gaviscon			C				Not Reported
	Voltarene Emulgel 1 %, Gel			C				Not Reported
	Levothyrox			C				Not Reported
	Rilmenidine			C				Not Reported
	Eupressyl			C				Not Reported
	Loxen L P 50 Mg, Gélule À Libération Prolongée			C				Not Reported
	Uvedose 100 000 Ui, Solution Buvable En Ampoule			C		In Ampoule		Not Reported
	Doliprane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16158036	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1030667		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Product Substitution Error	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Idaptan			S	Oral	20 Milligram, Bid		Mylan
	Nifedipino			C	Oral	20 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16158299	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2019SE48629		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Quetiapine Fumarate			S	Oral	1.0df Once/Single Administration		Zeneca
	Escitalopram Oxalate			S	Oral	1.0df Once/Single Administration		Not Reported
	Lorazepam			C				Not Reported
	Depakin Chrono			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16158319	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1030535		66 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Iberogast			S	Oral	20 Gtt Drops, Tid (60 Drop, Qd)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16158749	EXPEDITED (15-DAY)		DE	FR-TEVA-2019-FR-1031949		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bedridden; Malaise; Pain	Levodopa Carbidopa Teva		S	Oral	1 Dosage Forms Daily; 1 Cp At Bedtime	Not Reported
	Alprazolam Mylan 0,25 Mg, Comprimé Sécable		S	Oral	1 Dosage Forms Daily;	Not Reported
	Modopar		S	Oral	4 Dosage Forms Daily; 2cp At 16h And 2cp In The Evening	Not Reported
	Clozapine Merck 25 Mg, Comprimé Sécable		S	Oral	1 Dosage Forms Daily; 1 Cp In The Evening	Not Reported
	Acupan, Solution Injectable		S	Sublingual	4 Dosage Forms Daily;	Not Reported
	Doliprane 1000 Mg, Poudre Pour Solution Buvable En Sachet-Dose		S	Oral		Not Reported
	Sinemet 250 Mg/25 Mg, Comprimé Sécable		S	Oral	2 Dosage Forms Daily; 1cp Morning And 1cp Noon	Not Reported
	Dutasteride Sandoz 0,5 Mg, Capsule Molle		S	Oral	1 Dosage Forms Daily;	Not Reported
	Escitalopram Mylan Generiques 10 Mg, Comprimé Pelliculé Sécable		S	Oral	1 Dosage Forms Daily; 1 Morning Cp	Not Reported
	Oxynormoro 5 Mg, Comprimé Orodispersible		S	Oral	1 Dosage Forms Daily; If Pain	Not Reported
	Monocrixo		S	Oral		Not Reported
	Rivastigmine Mylan Pharma 9,5 Mg/24 Heures, Dispositif Transdermique		S	Transdermal	1 Dosage Forms Daily;	Not Reported
	Tramadol Paracetamol Mylan Generiques		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16158825	EXPEDITED (15-DAY)		OT	BR-SA-2019SA072678		40 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dengue Fever; Dermatitis; Drug Hypersensitivity; Erythema; Malaise;	Stilnox Cr			S	Oral	1 Df, Qd		Sanofi
	Escitalopram Oxalate			S	Oral	,Half Tablet Before		Not Reported

Urticaria; White Blood Cell Count Decreased	Araceli		C	Oral	Sleeping 1 Df, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	13991608	EXPEDITED (15-DAY)		HO, OT	PHHY2017NO134618		21 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Abuse; Drug Ineffective; Head Injury; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Mania; Memory Impairment; Personality Disorder; Product Complaint; Quality Of Life Decreased; Restlessness	Olanzapine			S	Unknown	Unk		Novartis
	Valproate Sodium			S	Unknown	Unk		Not Reported
	Seroxat			S	Unknown	Unk		Not Reported
	Seroxat			S	Unknown	20 Mg, Qd		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Cipramil (Citalopram Hydrobromide)			S	Unknown	10 Mg, Qd		Not Reported
	Cipramil (Citalopram Hydrobromide)			S	Unknown	60 Mg, Qd		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Seroquel			S	Oral	Unk		Not Reported
	Seroquel			S	Oral	Unk		Not Reported
	Seroquel			S	Oral	Unk		Not Reported
	Cipralex			S	Unknown	Unk Unk, Qd		Not Reported
	Orfiril			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Lithionit			C	Unknown	Unk		Not Reported
	Lithionit			C	Unknown	Unk		Not Reported
	Sobril			C	Unknown	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	15207475	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS			Unknown	ESP

US LTD-
MAC2018015689

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Omeprazole			S	Oral			Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Obinutuzumab			S				Not Reported
	Co-Trimoxazole			S	Unknown			Not Reported
	Bendamustine			S	Intravenous (not otherwise specified)	149.4 Milligram		Not Reported
	Bendamustine			S				Not Reported
	Incb050465			S	Oral	20 Milligram, Tablet		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	15667410	EXPEDITED (15-DAY)		DE, HO, OT	FR-009507513-1811FRA010604		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder; Suicidal Ideation; Withdrawal Syndrome	Mirtazapine			S	Oral	Unk		Merck
	Lysanxia			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	15993212	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-008805			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Leukopenia; Thrombocytopenia	Escitalopram Arrow Film-Coated Tablet 5mg			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Triacefan			S	Subcutaneous	1 Gram, Once A Day		Not Reported
	Invanz			S	Subcutaneous	1 Gram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	15993329	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-009079			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Herbal Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Aurobindo
	Ginseng			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Ginkgo Biloba			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16133582	EXPEDITED (15-DAY)		OT	FR-ACCORD-116710		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Drug Interaction; Drug Withdrawal Syndrome; Hyperhidrosis; Hypertensive Crisis; Insomnia; Malaise; Panic Attack; Tachycardia; Tremor	Escitalopram			S	Unknown	15 Mg, Once A Day		Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Bromazepam			S				Not Reported
	Thiocolchicoside			S	Unknown	8 Mg, Two Times A Day, Also Received Unk Dose From Apr-2016		Not Reported
	Bromazepam			C	Unknown	4.5 Mg, Unk		Not Reported
	Amlodipine			C		Also Received Additionally Unk Dose		Not Reported
	Perindopril/Perindopril Erbumine			C				Not Reported
	Escitalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16136376	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1914003US			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Escitalopram Oxalate Unk			S	Oral	1 Df, In Total		Allergan
	Quetiapine Fumarate			S	Oral	1 Df, In Total		Not Reported
	Lorazepam			C	Unknown			Not Reported
	Depakin Chrono			C	Unknown	1500 Mg		Not Reported
	Clonazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16160472	NON-EXPEDITED			US-TEVA-2019-US-1025851			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram Oxalate			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16160652	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2019IN01674			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Resistance; Treatment Failure	Escitalopram			S	Unknown	Unk		Invagen
	Venlafaxine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16160672	EXPEDITED (15-DAY)		OT	TR-MACLEODS PHARMACEUTICALS US LTD-MAC2016003593			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Macleods

Pregnancy	Nifedipine	C	Unknown	30 Mg, Qd		Not Reported
	Trimetazidine	C	Unknown	40 Mg, Qd		Not Reported
	Zofenopril	C	Unknown	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16161448	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2019-017512			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscle Disorder; Rhabdomyolysis	Escitalopram			S	Unknown	20 Milligram		Aurobindo
	Minerals Nos;Vitamins Nos			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16161734	NON-EXPEDITED			US-PFIZER INC-2019143339			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Niacin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16161875	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2019-018042			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Micturition Urgency; Urinary Hesitation; Urinary Retention	Escitalopram Film-Coated Tablets			S	Oral	1 Dosage Form, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16165207	EXPEDITED (15-DAY)		HO	EG-TAKEDA-2019TUS019045		56 YR	Female	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Drug Ineffective; Hypomania; Irritability; Product Use In Unapproved Indication; Social Avoidant Behaviour; Suicidal Ideation	Brintellix			S	Unknown	10 Milligram		Takeda
	Cipralex /01588501/			S	Unknown	10 Milligram		Not Reported
	Lithium			S	Unknown	400 Milligram		Not Reported
	Lithium			S	Unknown	600 Milligram		Not Reported
	Tegretol Cr			S	Unknown	Unk		Not Reported
	Tegretol Cr			S	Unknown	600 Milligram		Not Reported
	Seroquel			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	5 Milligram, Bid		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	0.5 Milligram, Bid		Not Reported
	Prozac			S	Unknown	Unk		Not Reported
	Effexor			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2019	16133806	EXPEDITED (15-DAY)		HO	FR-ACCORD-116846		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Paroxetine			S	Oral			Not Reported
	Prazepam			S	Oral			Not Reported
	Cocaine			S	Unknown	0.5g		Not Reported
	Tercian			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported

	Valium		S	Oral		Not Reported
	Alcool		S	Oral	Unspecified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2019	16165851	NON-EXPEDITED			US-VIIV HEALTHCARE LIMITED-US2019GSK060618		31 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness	Juluca			S		Unk		Viiv
	Wellbutrin			S		Unk		Glaxosmithkline
	Gabapentin			S		Unk		Glaxosmithkline
	Finasteride			S		Unk		Glaxosmithkline
	Lexapro			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Strattera			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2019	16165852	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019GSK060618		31 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness	Juluca			S		Unk		Viiv
	Wellbutrin			S		Unk		Glaxosmithkline
	Gabapentin			S		Unk		Glaxosmithkline
	Finasteride			S		Unk		Glaxosmithkline
	Lexapro			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Strattera			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2019	16165883	EXPEDITED (15-DAY)		CA	DE-ACCORD-118269			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydronephrosis; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 (Mg/D)		Not Reported
	Levothyroxine			C	Transplacental	112 (Ug/D (Bis 75 Ug/D))		Not Reported
	Femibion Pregnancy 1			C	Transplacental	0.8 (Mg/D)		Not Reported
	Progestan			C	Transplacental	600 (Mg/D (3 X 200 Mg/D))		Not Reported
	Dekristol			C	Transplacental	2000 (I.E./D (Bis 1000 I.E./D))		Not Reported
	Progynova			C	Transplacental	3 (Mg/D (3 X 1 Mg/D))		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2019	16165993	EXPEDITED (15-DAY)		CA	NL-ACCORD-118605			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	1 Dd 10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2019	16166157	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-118938		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Logorrhoea; Seizure; Tachycardia; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported
	Lithium			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported
	Valium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2019	16166201	EXPEDITED (15-DAY)		OT	IE-ACCORD-119106			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hallucination; Product Substitution Issue	Escitalopram Accord		S	Oral	Strength 5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	12316100	NON-EXPEDITED			US-JAZZ-2015-US-012071		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Panic Attack; Stress	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	3.75 G, Bid		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Ritalin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Vortioxetine			S				Not Reported
	Sumatriptan			C		Unk		Not Reported
	Klonopin			C		Unk		Not Reported
	Norco			C		10-325		Not Reported
	Verapamil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	14332694	EXPEDITED (15-DAY)		HO, OT	AT-MYLANLABS-2017M1082248		19 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Parkinsonism	Aripiprazole			S	Oral	2.5 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	15 Milligram, Qd		Not Reported
	Cipralex /01588502/			S	Oral	5 Mg, Qd		Mylan
	Cipralex /01588502/			S	Oral	10 Mg, Qd		Mylan

Cipralex /01588502/	S	Oral	15 Mg, Qd	Mylan
Methylprednisolone	C	Unknown	Unk	Mylan
Probiotics /07325001/	C	Unknown	Unk, Qd	Mylan
Zoldem	C	Oral	Unk	Mylan
Zoldem	C	Oral	5 Mg, Qd	Mylan
Zoldem	C	Oral	10 Mg, Qd	Mylan
Zoldem	C		Unk	Mylan
Zoldem	C		Unk	Mylan
Zolpidem	C	Oral	10 Mg, Unk	Mylan
Atarax /00058401/	C	Unknown	Unk	Mylan
Atarax /00058401/	C	Oral	1 Df, Qd,25-50 Mg 1 Df, Qd	Mylan
Atarax /00058401/	C	Oral	25 Mg, Qd	Mylan
Atarax /00058401/	C	Oral	50 Mg, Qd	Mylan
Atarax /00058401/	C	Oral	25 Mg, Qd	Mylan
Atarax /00058401/	C	Oral	50 Mg, Unk	Mylan
Atarax /00058401/	C		25 Mg, Unk	Mylan
Sertraline Hydrochloride	C	Unknown	50 Mg, Qd	Mylan
Sertraline Hydrochloride	C	Unknown	Unk	Mylan
Sertraline Hydrochloride	C	Unknown	25 Milligram, Qd	Mylan
Seroquel	C	Unknown	75 Mg, Qd	Mylan
Seroquel	C	Unknown	50 Mg, Qd	Mylan
Hova	C	Unknown	1 Df, Unk	Mylan
Temesta /00273201/	C	Unknown	1 Df, Qd, 1-2 Mg, Qd	Mylan
Mexalen	C	Oral	500 Mg, Unk	Mylan
Mexalen	C	Oral	500 Mg, Qd	Mylan
Mexalen	C	Oral	500 Mg ,Qd	Mylan
Mexalen	C	Oral	500 Mg, Qd	Mylan
Mexalen	C	Oral	500 Mg, Unk	Mylan

Aerius /01009701/	C	Unknown	5 Mg, Qd		Mylan
Praxiten	C	Oral	15 Mg, Qd		Mylan
Praxiten	C	Oral	7.5 Mg, Qd		Mylan
Praxiten	C	Oral	15 Mg, Qd		Mylan
Praxiten	C	Unknown	Unk		Mylan
Praxiten	C	Oral	15 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	14972719	NON-EXPEDITED			US-PFIZER INC-2018225421		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer
	Amlodipine Besilate			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Piroxicam			S		Unk		Pfizer
	Advil			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Bystolic			S		Unk		Not Reported
	Elavil			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Paxil [Paroxetine Hydrochloride]			S		Unk		Not Reported
	Coreg Cr			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	15340180	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1064798		44 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Malaise; Tremor; Vertigo	Leponex			S	Oral	150 Mg, Qd		Mylan
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
	Deniban			S	Oral	25 Mg, Qd		Mylan
	Valium			S	Oral	16 Gtt, Qd		Mylan
	Arlevertan			S	Oral	3 Df, Qd		Mylan
	Resilient			S	Oral	1 Df, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	15800258	EXPEDITED (15-DAY)		DE, HO, OT	FR-ALLERGAN-1900871US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder; Suicidal Ideation; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Norset			S	Oral	Unk		Not Reported
	Lysanxia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	15960041	EXPEDITED (15-DAY)		HO	IT-ACCORD-106763		85 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Medication Error; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported
	Glyceryl Trinitrate			C	Transdermal			Not Reported
	Formodual			C	Respiratory (inhalation)			Not Reported
	Annister			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16166956	EXPEDITED (15-DAY)		HO, LT, OT	GB-SA-2019SA093597		84 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypotension	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Furosemide			S	Oral	20 Mg, Qd		Sanofi
	Irbesartan			S	Oral	75 Mg, Qd		Sanofi
	Braltus			C				Not Reported
	Seretide			C		125		Not Reported
	Simvastatin			C		40 Mg		Not Reported
	Zapain			C		1-2 Four Times Daily		Not Reported
	Salbutamol			C		Unk		Not Reported
	Sando K [Potassium Bicarbonate;Potassium Chloride]			C		Various Acute Scripts		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16166972	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-204299		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Candesartan			S	Oral	4 Milligram, Daily		Not Reported
	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Pantoprazole			S	Oral	40 Milligram, Daily		Sun
	Furosemide			S	Oral	10 Milligram, Daily		Not Reported
	Alprazolam			C	Unknown	()		Not Reported
	Spagulax Mucilage Pur, Granules			C	Unknown	()		Not Reported
	Gaviscon			C	Unknown	()		Not Reported
	Voltarene Emulgel 1 %, Gel			C	Unknown	()		Not Reported
	Levothyrox			C	Unknown	()		Not Reported

	Rilmenidine	C	Unknown	()	Not Reported
	Eupressyl	C	Unknown	()	Not Reported
	Loxen L P 50 Mg, Gelule A Liberation Prolongee	C	Unknown	()	Not Reported
	Uvedose 100 000 Ui, Solution Buvable En Ampoule	C	Unknown	()	Not Reported
	Doliprane	C	Unknown	()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16167373	EXPEDITED (15-DAY)		OT	NL-ACCORD-118852		61 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthyroidism	Escitalopram			S		1dd,Strength:10 Mg		Not Reported
	Propylthiouracil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16167456	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1034906		24 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Ivax
	Clozapine			C	Unknown	Dose Was Gradually Increased To 600mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16168898	EXPEDITED (15-DAY)		HO, LT, OT	GB-TORRENT-00020752		84 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypotension	Furosemide			S	Oral			Unknown
	Irbesartan Hydrochloride			S	Oral	Unknown		Unknown
	Braltus			C		Unknown		Unknown
	Seretide			C		125		Unknown
	Simvastatin			C		Unknown		Unknown

	Zapain	C		As Necessary, 1-2 Four Times Daily		Unknown
	Escitalopram	S	Oral			Unknown
	Salbutamol	C				Unknown
	Sando-K	C		Various Acute Scripts		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16169329	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019GSK034221			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Wellbutrin			S				Glaxosmithkline
	Ativan			S				Not Reported
	Lexapro			S				Not Reported
	Pamelor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16171199	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1032221		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence	Alprazolam			S	Unknown	Non Renseignee		Not Reported
	Escitalopram			S	Unknown	Non Renseignee		Not Reported
	Dafalgan Codeine			S	Unknown	Non Renseignée		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16173143	DIRECT		OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Product Substitution Issue	Escitalopram			S	Oral	Quantity:30 Tablet(S);		Cipla

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	14923451	EXPEDITED (15-DAY)		HO, OT	ES-ALLERGAN-1826240US			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Escitalopram Oxalate Unk			S	Unknown	Unk, Unknown		Allergan
	Omeprazol			S	Oral	Unk, Unknown		Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Mg, Unknown		Not Reported
	Bendamustine			S	Intravenous (not otherwise specified)	149.4 Mg, Unknown		Not Reported
	Cotrimoxazol			S	Unknown	Unk Unk, Unknown		Not Reported
	Atorvastatin			C		Unk Unk, Unknown		Not Reported
	Valsartan			C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	15708617	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP026139		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Escitalopram			S	Unknown	Unk, Unknown		Apotex
	Omeprazole			S	Oral	Unk Unk, Unknown		Apotex
	Obinutuzumab			S	Intravenous (not otherwise specified)	)1000 Mg, Unknown (1000 Mg, Unknown)		Not Reported
	Bendamustine			S	Intravenous (not otherwise specified)	149.4 Mg, Unknown (149.4 Mg, Unknown)		Not Reported
	Cotrimoxazol			S	Unknown	Unk, Unknown		Not Reported
	Atorvastatin			C	Unknown	Unk, Unknown		Not Reported
	Valsartan "Nichi Iko"			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	15977322	NON-EXPEDITED			US-SUNOVION-2019SUN000555			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Weight Increased	Latuda			S	Oral	40 Mg		Sunovion

	Lexapro	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16093936	EXPEDITED (15-DAY)		OT	ES-APOTEX-2019AP009688		45 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Decreased; Loss Of Libido; Sexual Dysfunction	Escitalopram			S	Unknown	10 Mg, Qd (10 Milligram, Daily)		Apotex
	Sertraline			S	Oral	50 Mg, Qd (50 Milligram, Daily)		Apotex
	Sertraline			S	Oral	100 Mg, Qd (100 Milligram, Daily)		Apotex
	Enalapril			C	Oral	20 Mg, Qd (20 Milligram)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16120551	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01535		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction; Sexual Dysfunction	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	1.5 Dosage Form, Qd		Lupin
	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	1.5 Dosage Form, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16171954	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-017991			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Herbal Interaction	Escitalopram			S	Unknown	Unk		Aurobindo
	Ginkgo Biloba			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16173353	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2019-017892			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	1 Dosage Form,In Total		Aurobindo
	Quetiapine			S	Oral	1 Dosage Form, In Total		Aurobindo
	Lorazepam			C	Unknown	Unk		Not Reported
	Depakin Chrono			C	Unknown	1500 Milligram		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16174079	EXPEDITED (15-DAY)		HO	CR-GLAXOSMITHKLINE-CR2019062785		38 YR	Male	CRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	50 Mg, Qd		Glaxosmithkline
	Sertraline			S	Unknown	50 Mg, Qd		Glaxosmithkline
	Ibuprofen			S	Unknown	Unk		Glaxosmithkline
	Sumatriptan			S	Unknown	Unk		Glaxosmithkline
	Celecoxib			S	Unknown	Unk		Not Reported
	Topiramate			S	Unknown	50 Mg, Qd		Not Reported
	Valproic Acid			S	Unknown	500 Mg, Qd		Not Reported
	Desvenlafaxine			S	Unknown	50 Mg, Qd		Not Reported
	Propranolol			S	Unknown	40 Mg, Bid		Not Reported
	Ketoprofen			S	Unknown	Unk		Not Reported
	Eletriptan			S	Unknown	Unk		Not Reported
	Rizatriptan			S	Unknown	Unk		Not Reported
	Frovatriptan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16176748	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1915629US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Movement Disorder; Loss Of Consciousness	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unk		Allergan
	Pritor (Telmisartan)			S	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	14228105	EXPEDITED (15-DAY)		CA, HO	FR-ALLERGAN-1767805US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Motor Developmental Delay; Neonatal Behavioural Syndrome; Neurodevelopmental Disorder; Speech Disorder Developmental	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Xanax			S	Transplacental			Not Reported
	Stilnox			S	Transplacental			Not Reported
	Seresta			S	Transplacental			Not Reported
	Donormyl (Doxylamine Succinate)			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15325509	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1841350US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Intentional Overdose; Product Use Issue; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Overdose: 40mg; In Total		Allergan
	Seresta			S	Oral	10 Mg; In Total		Not Reported
	Paracetamol			S	Oral	2 G; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15562774	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1080835		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Ejaculation Failure; Erectile Dysfunction; Loss Of	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported
	Escitalopram			S				Not Reported

Libido	Escitalopram	S			Not Reported
	Mirtazapine	S	Unknown	22.5 Mg, Qd/Every Bedtime	Not Reported
	Mirtazapine	S			Not Reported
	Mirtazapine	S			Not Reported
	Alprazolam	S	Unknown	1 Mg/Tid When Necessary	Not Reported
	Alprazolam	S			Not Reported
	Alprazolam	S			Not Reported
	Lamotrigine	S	Unknown	100 Mg, Tid	Not Reported
	Lamotrigine	S			Not Reported
	Lamotrigine	S			Not Reported
	Enalapril	S	Unknown	20 Mg, Qd/Every Morning	Not Reported
	Lansoprazole	S	Unknown	30 Mg, Qd/Every Morning	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15566692	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20181028115		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Electrocardiogram Qt Prolonged	Apalutamide			S	Oral			Not Reported
	Seroplex			S	Unknown			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Decapeptyl [Gonadorelin]			C	Unknown			Not Reported
	Cotareg			C	Unknown			Not Reported
	Lercan			C	Unknown			Not Reported
	Tahor			C	Unknown			Not Reported
	Escitalopram			C	Oral			Not Reported
	Valsartan			C	Oral			Not Reported
	Lercanidipine			C				Not Reported
	Rabeprazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15629042	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1853816US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15752886	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1858509US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Fall	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15968465	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1906475US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Clozapine			C	Unknown	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177239	EXPEDITED (15-DAY)		HO	FR-ACCORD-120278		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Disorder; Priapism	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177944	NON-EXPEDITED			AU-ALKEM LABORATORIES LIMITED-AU-ALKEM-2018-02513		29 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Poverty; Libido Decreased; Off Label Use	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Quetiapine Fumarate			S	Unknown	12.5 Mg, At Night		Alkem

	Quetiapine Fumarate	S		Alkem

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16178002	EXPEDITED (15-DAY)		OT	FR-ACCORD-120090		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence	Escitalopram			S	Oral			Not Reported
	Diazepam			S	Oral			Accord
	Imovane			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16178009	EXPEDITED (15-DAY)		OT	IT-ACCORD-120233		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Incorrect Dose Administered; Sopor	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16178182	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-019307			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16178329	EXPEDITED (15-DAY)		HO, LT, OT	GB-LUPIN PHARMACEUTICALS INC.-2019-02153		84 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypotension	Irbesartan			S	Oral	75 Milligram, Qd		Lupin

	Escitalopram	S	Oral	10 Milligram, Qd	Lupin
	Furosemide	S	Oral	20 Milligram, Qd	Not Reported
	Zapain	C	Unknown	Unk Unk, Prn (1-2 Four Times Daily)	Not Reported
	Simvastatin	C	Unknown	40 Milligram	Not Reported
	Seretide	C		Unk (125)	Not Reported
	Salbutamol	C	Unknown	Unk	Not Reported
	Braltus	C	Unknown	Unk	Not Reported
	Sando K /00031402/	C	Unknown	Unk (Various Acute Scripts)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16180926	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1915608US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Macular Degeneration	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Trintellix			S	Unknown	10 Mg		Not Reported
	Trintellix			S	Unknown	5 Milligram		Not Reported
	Nortriptyline			S	Unknown	Unk		Not Reported
	Seroquel			S	Unknown	Unk		Not Reported
	Donepezil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16181104	EXPEDITED (15-DAY)		HO, OT	PHHY2018FR085207		10 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Suicide Attempt; Toxicity To Various Agents	Paracetamol			S	Oral	2 G, Total		Not Reported
	Seroplex			S	Oral	40 Mg, Total		Not Reported
	Seresta			S	Oral	10 Mg, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16181623	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1033063		68 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Liver Disorder	Escitalopram			S	Oral	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16181712	EXPEDITED (15-DAY)		OT	NP-DSJP-DSU-2019-112814			Unknown	NPL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis	Olmesartan Medoxomil			S	Unknown	Unk		Daiichi
	Amlodipine			S	Unknown	Unk		Not Reported
	Carvedilol			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Aspirin /00002701/			S	Unknown	Unk		Not Reported
	Hydralazine			S	Unknown	Unk		Not Reported
	Losartan			S	Unknown	Unk		Not Reported
	Finasteride			S	Unknown	Unk		Not Reported
	Niacin			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Simvastatin			S	Unknown	Unk		Not Reported
	Nitroglycerin			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16182042	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1915634US			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Drug Interaction; Dry Mouth; Hyperhidrosis; Sleep Disorder	Escitalopram Oxalate - Bp		S	Oral	10 Mg, Qd	Allergan
	Escitalopram Oxalate - Bp		S	Oral	5 Mg, Qd	Allergan
	Omeprazole		S	Oral	40 Mg, Qd	Not Reported
	Tranxilium		C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16182045	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1915771US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Product Use Issue; Suicidal Ideation; Thinking Abnormal	Escitalopram Oxalate - Bp			S	Unknown	15 Mg		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16183856	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea	Lexapro			S	Oral		3 WEEK	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16182341	EXPEDITED (15-DAY)		OT	GB-ROCHE-2157437			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Fatigue; Hypoaesthesia; Indifference; Myalgia; Oropharyngeal Pain; Seizure	Klonopin			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Celexa			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Effexor			S	Unknown			Not Reported

	Ambien	S	Unknown		Not Reported
	Adderall	S	Unknown		Not Reported
	Desipramine	S	Unknown		Not Reported
	Zyprexa	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16182462	NON-EXPEDITED			US-APOTEX-2019AP009750		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Rash; Rash Papular; Rash Pruritic	Escitalopram			S	Unknown	5 Mg, Qd		Apotex
	Escitalopram			S				Apotex
	Loratadine			C	Unknown	Unk		Not Reported
	Albuterol /00139501/			C	Unknown	Unk		Not Reported
	Budesonide W/Formoterol			C	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16183108	EXPEDITED (15-DAY)		OT	US-ACCORD-119872		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dysuria; Eye Irritation; Malaise	Escitalopram Accord			S				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16183222	NON-EXPEDITED			US-SHIRE-US201911842			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Concussion; Disturbance In Attention	Vyvanse			S	Unknown	50 Milligram, 1x/Day:Qd		Shire
	Adderall Xr			S	Unknown	Unk, 1x/Day:Qd		Shire
	Lexapro			S	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16184129	NON-EXPEDITED			TW-ALKEM LABORATORIES LIMITED-TW-ALKEM-2018-02932		58 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Partial Responder	Quetiapine Fumarate			S	Unknown	25 Mg, Unk		Alkem
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16184177	NON-EXPEDITED			TW-ALKEM LABORATORIES LIMITED-TW-ALKEM-2018-01462		71 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyskinesia	Quetiapine Fumarate			S	Unknown	50 Mg, Qd		Alkem
	Quetiapine Fumarate			S	Unknown	100 Mg, Qd		Alkem
	Escitalopram			S	Unknown	10 To 15 Mg/Qd For 6 Months		Not Reported
	Risperidone			S	Unknown	1 Mg, Qd		Not Reported
	Sertraline			C	Unknown	80 Mg, Unk		Not Reported
	Venlafaxine			C	Unknown	150 Mg, Qd		Not Reported
	Mirtazapine			C	Unknown	45 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16184193	NON-EXPEDITED			FR-ALKEM LABORATORIES LIMITED-FR-ALKEM-2018-01410		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Quetiapine Fumarate			S	Unknown	Unk		Alkem

	Quetiapine Fumarate		S				Alkem
	Risperidone		S	Unknown	Unk		Not Reported
	Risperidone		S				Not Reported
	Aripiprazole		S	Unknown	Unk		Not Reported
	Aripiprazole		S				Not Reported
	Cyamemazine		S	Unknown	Unk		Not Reported
	Cyamemazine		S				Not Reported
	Propericiazine		S	Unknown	Unk		Not Reported
	Propericiazine		S				Not Reported
	Fluoxetine		S	Unknown	Unk		Not Reported
	Fluoxetine		S				Not Reported
	Benzodiazepine		S	Unknown	Unk		Not Reported
	Benzodiazepine		S				Not Reported
	Carbamazepine		S	Unknown	Unk		Not Reported
	Carbamazepine		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16184212	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-04468		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash; Sedation	Lamotrigine			S	Unknown	Unk		Alkem
	Quetiapine Fumarate			S	Unknown	Unk		Alkem
	Citalopram			S	Oral	30 Mg, Qd		Not Reported
	Citalopram			S				Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Lithium			S	Oral	750 Mg, Qd		Not Reported
	Lithium			S				Not Reported
	Ziprasidone Hydrochloride			S	Oral	20 Mg, Bid		Not Reported
	Ziprasidone Hydrochloride			S				Not Reported
	Ziprasidone Hydrochloride			S				Not Reported
	Bupropion Hydrochloride			S	Oral	75 Mg, Qd		Not Reported
	Bupropion Hydrochloride			S				Not Reported

	Guanfacine	C	Oral	1 Mg, Bid		Not Reported
	Fluvoxamine Maleate	C	Oral	Un50 Mg, Qd		Not Reported
	Amphetamine–Dextroamphetamine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16184309	NON-EXPEDITED			US-PFIZER INC-2019144950		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Demerol			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Phenergan [Promethazine]			S		Unk		Not Reported
	Zofran [Ondansetron]			S		Unk		Not Reported
	Oxycodone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16185358	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1034073		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Atenolol			S	Oral	25 Milligram		Not Reported
	Tramadol			S	Oral	Inconnue		Not Reported
	Seroplex			S	Oral	1 Dosage Form		Mylan
	Exforge			S	Oral	0.5 Dosage Form		Mylan
	Hemigoxine Nativelle			S	Oral	1 Dosage Form		Mylan
	Macrogol Stearate			C	Oral	2 Dosage Form		Mylan
	Caltrate /00944201/			C	Oral	1 Dosage Form		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16186813	EXPEDITED (15-DAY)		DE, OT	DK-ALLERGAN-1915784US			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Hypertrophy; Confusional State; Constipation; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension; Hyperventilation; Lactic Acidosis; Lacunar Infarction; Neuroleptic Malignant Syndrome; Organ Failure; Overdose; Product Use In Unapproved Indication; Pyrexia; Renal Failure; Rhabdomyolysis; Urinary Tract Infection	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd (Daily Dose Of 1 Tablet In The Morning And 1.5 Tablet In The Evening)Overdose: 30 Mg		Allergan
	Zeldox			S	Oral	80 Mg, Qd		Not Reported
	Litarex (Lithium Citrate)			S	Oral	1 Df (In The Morning)		Not Reported
	Mirtazapine			S	Oral	30 Mg, Qd		Not Reported
	Mirtazapine			S				Not Reported
	Ferro Duretter			C	Unknown	100 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	0.5 Mg, Qd		Not Reported
	Centyl Med Kaliumklorid			C	Unknown	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16186817	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1915793US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperreflexia; Intentional Overdose; Mydriasis; Poisoning Deliberate; Product Use Issue	Escitalopram Oxalate - Bp			S	Oral	Overdose 25 Dosage Forms; In Total		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16324559	DIRECT	N				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Libido Decreased; Sexual Dysfunction; Therapy Cessation; Vulvovaginal Hypoaesthesia	Escitalopram Lexapro			S	Oral		1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	13935159	EXPEDITED (15-DAY)		HO, OT	CA-ALKEM LABORATORIES LIMITED-CA-ALKEM-2017-00575		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Seizure Like Phenomena; Ventricular Tachycardia	Quetiapine Fumarate			S	Unknown	50 Mg, Qid		Alkem
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	15982382	EXPEDITED (15-DAY)		DE, HO, OT	FR-TEVA-2019-FR-1012958		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder; Suicidal Ideation; Withdrawal Syndrome	Venlafaxine Hydrochloride			S	Unknown			Teva
	Norset			S	Oral	Unk		Not Reported
	Seroplex			S	Unknown			Not Reported
	Lysanxia			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16021036	NON-EXPEDITED			US-PFIZER INC-2019085867		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sertraline Hcl			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16103509	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1026757		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Olanzapin			C	Oral	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16183252	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1034741		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Escitalopram Oxalate			S	Oral			Ivax
	Quetiapine Fumarate			S	Oral			Teva
	Lorazepam			C				Not Reported
	Depakin Chrono 500 Mg Compresse A Rilascio Prolungato			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16187440	EXPEDITED (15-DAY)		HO	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2018-07142		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine Fumarate			S	Oral	100 Mg, 0-0-0-1, Tabletten		Alkem
	Valproinsaeure			S	Oral	500 Mg, 0-0-0-1, Tabletten		Not Reported
	Cipralex 10 Mg			S	Oral	10 Mg, 1-0-0-0, Tabletten		Not Reported
	Levothyroxine			C	Oral	75 Mg, 1-0-0-0, Tabletten		Not Reported
	Torasemide			C	Oral	10 Mg, 1-0-0-0, Tabletten		Not Reported
	Felodipine			C	Oral	10 Mg, 1-0-0-0, Tabletten		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16187459	EXPEDITED (15-DAY)		OT	DE-ALKEM LABORATORIES			Unknown	DEU

LIMITED-DE-ALKEM-2018-08294

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Quetiapine Fumarate			S	Oral	50 Mg, Od		Alkem
	Cipralex			S	Oral	20 Mg, 10 Mg And 5 Mg Od		Not Reported
	Lamictal			S	Oral	125 Mg, Od		Not Reported
	Femibion [Minerals Nos;Vitamins Nos]			C	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16187546	EXPEDITED (15-DAY)		HO, LT, OT	GB-AUROBINDO-AUR-APL-2019-019129			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypotension	Furosemide			S	Oral	20 Milligram, Daily		Not Reported
	Irbesartan			S	Oral	75 Milligram, Daily		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo
	Braltus			C	Unknown	Unk		Not Reported
	Seretide			C	Unknown	125		Not Reported
	Simvastatin			C	Unknown	40 Milligram		Not Reported
	Zapain			C	Unknown	1-2 Four Times Daily		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Sando K			C	Unknown	Various Acute Scripts		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16188006	EXPEDITED (15-DAY)		OT	TW-ALKEM LABORATORIES LIMITED-TW-ALKEM-2019-01138		42 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradykinesia; Electrocardiogram Qt Prolonged; Muscle Rigidity	Escitalopram	S	Unknown	5 Mg, Qd		Not Reported
	Escitalopram	S				Not Reported
	Quetiapine Fumarate	S	Unknown	75 Mg, Qd		Alkem
	Valproate	S	Unknown	1000 Mg, Qd		Not Reported
	Lorazepam	C	Unknown	Unk		Not Reported
	Clonazepam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16188112	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-019016			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Movement Disorder; Loss Of Consciousness	Escitalopram			S	Unknown	15 Milligram		Aurobindo
	Pritor (Telmisartan)			S	Oral	40 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16188710	EXPEDITED (15-DAY)		HO	GB-APOTEX-2019AP011429		82 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Alendronic Acid			S	Oral	70 Mg, Q.Wk.		Apotex
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Oral	75 Mg, Qd		Not Reported
	Felodipine			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Adcal D3			C	Unknown			Not Reported
	Doxazosin			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported
	Seretide			C	Unknown			Not Reported
	Dymista			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported

	Gabapentin	C	Unknown	Not Reported
	Ferrous Fumarate	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16188712	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2019AP011616		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Quetiapine			S	Oral	1 Df, Unk (In Total)		Apotex
	Escitalopram Oxalate			S	Oral	1 Df, Unk (In Total)		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Depakin Chrono /00228502/			C	Unknown	1500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16189526	NON-EXPEDITED			US-PFIZER INC-2019154119		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16190845	NON-EXPEDITED			US-PFIZER INC-2019157476		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S	Oral	50 Mg, 1x/Day (1 Capsule Orally At Bedtime)		Pfizer
	Lyrica			S	Oral	25 Mg, 2x/Day (1 Capsule		Pfizer

			Orally Bid(Twice A Day))	
	Atorvastatin Calcium	S	Unk	Pfizer
	Gabapentin	S	Unk	Pfizer
	Gemfibrozil	S	Unk	Pfizer
	Crestor	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Dyazide	S	Unk	Not Reported
	Keflex [Cefalexin]	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Norco	S	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unk	Not Reported
	Amitriptyline	S	Unk	Not Reported
	Cefdinir	S	Unk	Not Reported
	Chlorthalidone	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16191517	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1035597		75 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous	Serpentil [Escitalopram Oxalate]			S	Oral	5 Milligram Daily;		Ivax
	Tulip			C	Oral	10 Milligram Daily;		Not Reported
	Brunoq			C	Oral	10 Milligram Daily;		Not Reported
	Valsacor			C	Nasal	160 Milligram Daily;		Not Reported
	Praxiten			C	Oral			Not Reported
	Peptoran			C	Oral	150 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16192452	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1915806US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Abuse; Overdose; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Single		Allergan
	Cocaine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16196452	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Fluoxetine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2019	15973610	NON-EXPEDITED			US-009507513-1902USA005780		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Belsomra			S	Oral	Unk, Nightly		Merck
	Lexapro			S	Oral	5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2019	16193499	EXPEDITED (15-DAY)		HO, LT, OT	GB-TEVA-2019-GB-1036446		84 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypotension	Furosemide			S	Oral	20 Milligram Daily;		Ivax
	Irbesartan Hydrochloride			S	Oral	75 Milligram Daily;		Teva
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Braltus			C				Not Reported
	Seretide			C		125		Not Reported
	Simvastatin			C				Not Reported
	Zapain			C		1-2 Four Times Daily		Not Reported
	Salbutamol			C				Not Reported
	Sando-K			C		Various Acute Scripts		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	15983294	EXPEDITED (15-DAY)		DE, HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-199588		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder; Suicidal Ideation; Withdrawal Syndrome	Venlafaxine			S	Unknown	Unk ()		Sun
	Venlafaxine			S	Unknown	Unk ()		Sun
	Mirtazapine			S	Oral	Unk ()		Sun
	Norset			S	Oral	Unk ()		Not Reported
	Seroplex			S	Unknown	Unk ()		Not Reported
	Lysanxia			S	Unknown	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16169409	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019146750		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Pantoprazole			S	Oral	40 Milligram, Qd		Pfizer
	Candesartan			S	Oral	4 Milligram		Not Reported
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Furosemide			S	Oral	10 Milligram		Not Reported
	Alprazolam			C		Unk		Not Reported
	Spagulax			C		Unk		Not Reported
	Gaviscon [Alginic Acid;Aluminium Hydroxide Gel, Dried;Magnesium Trisil			C		Unk		Not Reported
	Voltarene [Diclofenac Sodium]			C		Unk		Not Reported
	Levothyrox			C		Unk		Not Reported
	Rilmenidine			C		Unk		Not Reported
	Eupressyl [Urapidil]			C		Unk		Not Reported
	Loxen L P			C		Unk		Not Reported

Uvedose	C	Unk	Not Reported
Doliprane	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16196703	EXPEDITED (15-DAY)		DE, OT	US-ENDO PHARMACEUTICALS INC-2019-102406		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Completed Suicide; Drug Interaction; Pain In Extremity; Pneumonia; Pulmonary Congestion; Pulmonary Oedema; Skin Abrasion; Toxicity To Various Agents	Opana			S	Unknown	Unk Unknown, Unknown		Endo
	Oxycodone Hydrochloride			S	Unknown	Unk Unknown, Unknown		Vintage
	Ultram /00599202/			S	Unknown	Unk Unknown, Unknown		Not Reported
	Klonopin			S	Unknown	Unk Unknown, Unknown		Not Reported
	Celexa /00582602/			S	Unknown	Unk Unknown, Unknown		Not Reported
	Lexapro			S	Unknown	Unk Unknown, Unknown		Not Reported
	Seroquel			S	Unknown	Unk Unknown, Unknown		Not Reported
	Cardizem /00489701/			S	Unknown	Unk Unknown, Unknown		Not Reported
	Caffeine			S	Unknown	Unk Unknown, Unknown		Not Reported
	Fentanyl			S	Unknown	Unk Unknown, Unknown		Not Reported
	Gabapentin			C	Unknown	Unk Unknown, Unknown		Not Reported
	Isosorbide Dinitrate			C	Unknown	Unk Unknown, Unknown		Par

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16197522	EXPEDITED (15-DAY)		HO, OT	BH-GLAXOSMITHKLINE-BH2019GSK061603		18 YR	Female	BHR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bulimia Nervosa; Drug Intolerance; Intentional Overdose; Intentional Product Misuse; Suicide Attempt; Weight Increased	Escitalopram			S		20 Mg, Unk		Glaxosmithkline
	Escitalopram			S				Glaxosmithkline
	Bupropion			S		150 Mg, Qd		Glaxosmithkline
	Fluoxetine			S		20 Mg, Qd		Not Reported
	Fluoxetine			S		40 Mg, Qd		Not Reported

	Mirtazapine	S	15 Mg, Unk		Not Reported
	Mirtazapine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16198186	EXPEDITED (15-DAY)		DE, OT	US-ENDO PHARMACEUTICALS INC-2019-102414		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Cardiac Failure Acute; Contusion; Hypertensive Heart Disease; Pulmonary Oedema; Skin Abrasion; Toxicity To Various Agents	Opana			S	Unknown	Unk Unknown, Unknown		Endo
	Oxycodone Hydrochloride			S	Unknown	Unk Unknown, Unknown		Vintage
	Numorphan			S	Unknown	Unk Unknown, Unknown		Not Reported
	Klonopin			S	Unknown	Unk Unknown, Unknown		Not Reported
	Celexa /00582602/			S	Unknown	Unk Unknown, Unknown		Not Reported
	Lexapro			S	Unknown	Unk Unknown, Unknown		Not Reported
	Abilify			S	Unknown	Unk Unknown, Unknown		Not Reported
	Desyrel			S	Unknown	Unk Unknown, Unknown		Not Reported
	Caffeine			S	Unknown	Unk Unknown, Unknown		Not Reported
	Warfarin			S	Unknown	Unk Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16198902	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1035340		80 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hyperhidrosis; Malaise	Escitalopram			S	Oral	20 Milligram, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16199942	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1916159US			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Escitalopram Oxalate - Bp			S	Oral	10 Mg Q24hr		Allergan

Lixiana	S	Oral	60 Mg Q24hr		Not Reported
Paracetamol	C	Oral	Unk		Not Reported
Combiprasal	C	Respiratory (inhalation)	0.5 Mg / 2.5 Mg		Not Reported
Seguril	C	Oral	Unk		Not Reported
Sebiprox	C	Cutaneous	15 Mg/G		Not Reported
Omeprazol	C	Oral	Unk		Not Reported
Omnic Ocas	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15651338	EXPEDITED (15-DAY)		CA, HO	CA-ALLERGAN-1854400US			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Qd		Not Reported
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Qd		Not Reported
	Gabapentin			S	Transplacental	1800 Mg, Qd		Not Reported
	Methadose			S	Transplacental	70 Mg, Qd		Not Reported
	Nortriptyline			S	Transplacental	20 Mg, Qd		Not Reported
	Quetiapine			S	Transplacental	300 Mg, Q12h		Not Reported
	Rabeprazole			S	Transplacental	Unk		Not Reported
	Zopiclone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15720344	EXPEDITED (15-DAY)		HO, LT	US-009507513-1812USA003811		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Prinivil			S	Oral	20 Milligram, Qd		Merck
	Metformin			S	Oral	1000 Milligram, Bid		Not Reported

				(2x/Day)	
	Lexapro	S	Oral	10 Milligram, Qd	Not Reported
	Trazodone Hydrochloride	S	Oral	50 Milligram, Qd	Not Reported
	Trazodone Hydrochloride	S	Oral	100 Milligram, Qd	Not Reported
	Glyburide	C		Unk	Not Reported
	Gemfibrozil	C		Unk	Not Reported
	Pravachol	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Combivent	C		Unk	Not Reported
	Gabapentin	C		Unk	Not Reported
	Valium	C		Unk	Not Reported
	Victoza	C		Unk	Not Reported
	Lunesta	C		Unk	Not Reported
	Anoro	C		Unk	Not Reported
	Proair (Albuterol Sulfate)	C		Unk	Not Reported
	Cyclizine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16170908	EXPEDITED (15-DAY)		OT	PHHY2019FR076011		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Syncope; Withdrawal Syndrome	Telmisartan			S	Unknown	Unk		Novartis
	Citalopram			S	Oral	15 Mg, Qd		Not Reported
	Seroplex			S	Oral	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16200453	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01407		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Sedation; Therapeutic Product Effect Incomplete	Escitalopram	S	Unknown	10 Milligram	Lupin
	Lorazepam	S	Unknown	0.5 Milligram, Qd	Lupin
	Clonazepam	S	Unknown	0.5 Milligram, Qd	Not Reported
	Clobazam	C	Unknown	Unk Unk, Tid (15 Mg In The Morning, 15mg In The)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16200626	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US02039			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia	Gabapentin			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Olanzapine			S	Unknown	Unk		Invagen
	Mirtazapine			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk, Low Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16201819	EXPEDITED (15-DAY)		HO, OT	IN-MACLEODS PHARMACEUTICALS US LTD-MAC2019020871			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Olanzapine			S	Unknown	10 Milligram		Macleods
	Escitalopram Oxalate			S	Unknown	5 Milligram		Macleods
	Escitalopram Oxalate			S	Unknown	20 Milligram		Macleods
	Fluoxetine			S	Unknown	20 Milligram		Not Reported
	Valproate Semisodium			C	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16202016	EXPEDITED (15-DAY)		HO, OT	BH-LUPIN PHARMACEUTICALS INC.-2019-02312		18 YR	Female	BHR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bulimia Nervosa; Impulsive Behaviour; Intentional Product Misuse; Overdose; Paradoxical Drug Reaction; Suicide Attempt; Weight Increased	Escitalopram			S	Unknown	Unk		Lupin
	Escitalopram			S	Unknown	20 Milligram, Qd		Lupin
	Mirtazapine			S	Unknown	15 Milligram, Qd		Not Reported
	Bupropion Hydrochloride Extended-Release Tablets			S	Unknown	150 Milligram, Qd		Lupin
	Bupropion Hydrochloride Extended-Release Tablets			S	Unknown	30 Dosage Form		Lupin
	Bupropion Hydrochloride Extended-Release Tablets			S				Lupin
	Fluoxetine			S	Unknown	20 Milligram, Qd		Lupin
	Fluoxetine			S	Unknown	40 Milligram, Qd, Dose Increased		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16202636	EXPEDITED (15-DAY)		HO, OT	IN-ELI_LILLY_AND_COMPANY-IN201904003481		45 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Olanzapine			S	Unknown	10 Mg, Unknown		Eli Lilly And Co
	Fluoxetine Hydrochloride			S	Unknown	20 Mg, Unknown		Eli Lilly And Co
	Escitalopram			S	Unknown	5 Mg, Unknown		Not Reported
	Escitalopram			S	Unknown	20 Mg, Unknown		Not Reported
	Divalproex Sodium			C	Unknown	500 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16203251	EXPEDITED (15-DAY)		OT	ES-DSJP-DSE-2019-113378			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pruritus; Rash	Lixiana	S	Oral	1 Cada 24 Horas	Daiichi
	Escitalopram	S	Oral	10 Mg, Qd	Not Reported
	Paracetamol	C	Oral	Unk	Not Reported
	Omeprazol /00661201/	C	Oral	Unk	Not Reported
	Combiprasal	C	Respiratory (inhalation)	0.5mg/2.5mg	Not Reported
	Sebiprox	C	Cutaneous	Unk	Not Reported
	Seguril	C	Oral	Unk	Not Reported
	Omnic Ocas	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16203382	EXPEDITED (15-DAY)		DE, OT	SE-GLAXOSMITHKLINE-SE2019067745		28 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Toxicity To Various Agents	Lamictal			S	Oral	200 Mg, Qd		Glaxosmithkline
	Voxra			S	Oral	150 Mg, Qd		Glaxosmithkline
	Elvanse			S	Oral	40 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Melatonin			C	Unknown	4 Mg, Prn (Max 2 Per Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16205106	EXPEDITED (15-DAY)		OT	US-009507513-1904USA004119		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Anger; Breast Enlargement; Condition Aggravated; Constipation; Deafness; Dependence; Disturbance In Attention; Drug Ineffective; Ear Disorder; Erection Increased; Fatigue;	Remeron			S		Unk		Merck
	Risperdal			S		Unk		Not Reported
	Seroquel			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

Gastric Ulcer; Influenza Like Illness; Insomnia; Memory Impairment; Mood Swings; Muscle Spasms; Rash; Rectal Haemorrhage; Suicidal Ideation; Therapeutic Product Effect Increased; Weight Increased	Lamictal	S	Unk	Not Reported
	Tegretol	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported
	Buspar	S	Unk	Not Reported
	Valium	S	Unk	Not Reported
	Valium	S	Unk	Not Reported
	Valium	S		Not Reported
	Trazodone Hydrochloride	S	Unk	Not Reported
	Trazodone Hydrochloride	S	Unk	Not Reported
	Paxil	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Cymbalta	S		Not Reported
	Elavil (Amitriptyline Hydrochloride)	S	Unk	Not Reported
	Klonopin	S	Unk	Not Reported
	Ritalin	S	Unk	Not Reported
	Pamelor	S	Unk	Not Reported
	Zoloft	S	Unk	Not Reported
	Skelaxin	S	Unk	Not Reported
	Effexor	S	37.5 Mg, Unk	Not Reported
	Effexor Xr	S	Unk	Not Reported
	Celebrex	S	Unk	Not Reported
	Geodon	S	Unk	Not Reported
	Depakote	S	Unk	Not Reported
	Zomig	S	Unk	Not Reported
	Imitrex (Sumatriptan Succinate)	S	Unk	Not Reported
	Soma (Carisoprodol)	S	Unk	Not Reported
	Lithium	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16338532	DIRECT					69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Agitation; Irritability; Nightmare; Product Substitution Issue; Sleep Disorder	Escitalopram Oxalate			S	Oral	Quantity:1 Df Dosage Form;		Aurobindo
	Probiotic			C				Not Reported
	Atorvastatin Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	15722727	EXPEDITED (15-DAY)		HO, LT	US-EMD SERONO-9057702		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Metformin			S	Oral			Not Reported
	Placebo			S	Intramuscular	Daily Dose: Single Dose		Not Reported
	Placebo			S	Intramuscular	Daily Dose: Single Dose		Not Reported
	Placebo			S	Intramuscular	Daily Dose: Single Dose		Not Reported
	Lisinopril			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral	Restarted At Lower Dose		Not Reported
	Trazodone			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Gemfibrozil			C				Not Reported
	Glyburide			C				Not Reported
	Pravachol			C				Not Reported
	Pantoprazole			C				Not Reported
	Combivent			C				Not Reported
	Valium			C				Not Reported
	Victoza			C				Not Reported
	Lunesta			C				Not Reported
	Anoro			C				Not Reported
	Gabapentin			C				Not Reported
	Proair /00139502/			C				Not Reported

	Medizine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16017286	NON-EXPEDITED		OT	US-NEUROCRINE BIOSCIENCES INC.-2019NBI00447		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Fatigue; Influenza; Migraine; Somnolence; Swollen Tongue; Therapeutic Product Effect Decreased	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences
	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences
	Ciprofloxacin			S				Not Reported
	Medrol Dp (Methylprednisolone)			S				Not Reported
	Divalproex			S				Not Reported
	Lorazepam			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16205829	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-020592			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Balance Disorder; Bradycardia; Dizziness; Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder	Amlodipine			S	Unknown	2.5 Milligram, Daily		Aurobindo
	Escitalopram			S	Unknown	10.0 Milligram, Daily		Aurobindo
	Escitalopram			S				Aurobindo
	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Ramipril			S	Unknown	5.0 Milligram, Daily		Aurobindo
	Codeine			S	Unknown	30.0 Milligram, Two Times A Day		Not Reported
	Furosemide			S	Unknown	40.0 Milligram, Daily		Not Reported
	Furosemide			S	Unknown	20.0 Milligram, Daily		Not Reported
	Glyceryl Trinitrate			S	Transdermal	0.4 Milligram, Two Times A Day		Not Reported
	Metoprolol			S	Unknown	25.0 Milligram, Daily		Not Reported

	Oxazepam	S	Unknown	10.0 Milligram, Two Times A Day	Not Reported
	Zopiclone	S	Unknown	2.5 Milligram, Daily	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Clopidogrel	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Macrogol	C	Unknown	Unk	Not Reported
	Rabeprazole	C	Unknown	Unk	Not Reported
	Vitamin C	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16205947	EXPEDITED (15-DAY)		OT	IT-ACCORD-122086		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Nausea; Vomiting	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16205950	EXPEDITED (15-DAY)		OT	IT-ACCORD-122467		23 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported
	Delorazepam			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Oki			S	Oral	Strength 80 Mg		Not Reported
	Tavor (Lorazepam)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16206210	EXPEDITED (15-DAY)		OT	IT-ACCORD-121964		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Abuse; Nausea	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16207198	EXPEDITED (15-DAY)		DE	US-TORRENT-00008034		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral	Unknown		Unknown
	Hydrochlorothiazide			S	Oral	Unknown		Unknown
	Clonazepam			S	Oral	Unknown		Unknown
	Metoprolol			S	Oral	Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16207204	EXPEDITED (15-DAY)		DE	US-TORRENT-00008049		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral	Unknown		Unknown
	Naproxen			S	Oral	Unknown		Unknown
	Zolpidem			S	Oral	Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16207448	NON-EXPEDITED			US-PFIZER INC-2019162129		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Celebrex	S	Unk	Pfizer
	Venlafaxine Hcl	S	Unk	Pfizer
	Tagamet [Cimetidine]	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Hydrocodone	S	Unk	Not Reported
	Nabumetone	S	Unk	Not Reported
	Nortriptyline	S	Unk	Not Reported
	Vioxx	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16209772	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1916485US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Interstitial Lung Disease	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Duloxetine Teva			S	Unknown	15 Mg		Not Reported
	Venlafaxine			S	Unknown	37.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16209827	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1916574US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Pantoprazole			S	Oral			Not Reported
	Tinzaparine Sodique			S	Subcutaneous			Not Reported
	Spironolactone			S	Oral			Not Reported
	Trileptal			S	Oral			Not Reported
	Lacosamide			S	Oral			Not Reported
	Diltiazem			S	Oral			Not Reported
	Bactrim			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16209855	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1916571US			Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16209863	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1916593US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Pentasa			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Premarin			S	Oral	0.625 Mg, Qd		Not Reported
	Propanolol Hydrochloride			S	Oral	40 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16211702	DIRECT		DS, HO, OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar I Disorder; Hypomania; Insomnia; Therapy Change	Escitalopram; Generic For: Lexapro			S	Oral	Quantity:100 Tablet(S);		Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16180946	EXPEDITED (15-DAY)			TR-ALLERGAN-1915661US			Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Nausea; Visual	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan

Impairment	Escitalopram Oxalate - Bp	S	Unknown	5 Mg, Unknown		Allergan
	Dideral	C	Unknown	50 Mg, Unknown		Not Reported
	Dideral	C	Unknown	25 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16210442	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020672			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Escitalopram Tablets			S	Oral	20 Milligram, Daily		Aurobindo
	Cimzia			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	50 Milligram		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	1000 Milligram, Daily		Not Reported
	Nortriptyline			S	Oral	25 Milligram, Daily		Not Reported
	Tylenol			S	Topical	Unk		Not Reported
	Voltaren			S	Topical	Unk, Daily		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	600 Milligram		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	700 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16211201	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP011722		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug	Citalopram			S	Unknown	Unk		Apotex
	Citalopram			S	Unknown	Unk		Apotex

Interaction; Electrocardiogram Qt Prolonged; Heart Rate Increased; Irritability; Miosis; Overdose; Oxygen Saturation Decreased; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram	S	Unknown	Unk	Apotex
	Escitalopram	S	Unknown		Apotex
	Oxazepam	S	Oral		Not Reported
	Oxazepam	S	Oral		Not Reported
	Quetiapine	S	Oral	Unk	Apotex
	Quetiapine	S	Unknown	Unk	Apotex
	Temazepam	S	Oral	Unk	Not Reported
	Topiramate	S	Unknown	Unk	Apotex
	Topiramate	S	Oral	Unk	Apotex
	Quetiapine Mylan	S	Oral	Unk	Not Reported
	Naloxone	S	Intramuscular	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Clopidogrel	C	Unknown	Unk	Not Reported
	Clopidogrel	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Fluticasone W/Salmeterol	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Ipratropium	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown		Not Reported
	Ramipril	C	Endocervical		Not Reported
	Salbutamol	C		Unk	Not Reported
	Salbutamol	C	Other	Unk	Not Reported
	Spironolactone	C	Unknown		Not Reported
	Spironolactone	C	Unknown		Not Reported
	Advair	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16211262	EXPEDITED (15-DAY)		OT	FR-ACCORD-122627		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Weight Decreased; Xerophthalmia	Escitalopram			S	Oral			Not Reported
	Lercan			C	Oral	Strength: 20 Mg		Not Reported
	Lormetazepam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16211372	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-020685			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Escitalopram			S	Oral	20 Milligram		Aurobindo
	Gabapentin			S	Oral	600 Milligram, Two Times A Day		Aurobindo
	Clonazepam			S	Oral	0.5 Milligram, 3 Times A Day		Not Reported
	Domperidone			S	Oral	10 Milligram, Two Times A Day		Not Reported
	Ferrous Sulfate			S	Oral	300 Milligram, 3 Times A Day		Not Reported
	Temazepam			S	Oral	30 Milligram, Daily		Not Reported
	Tylenol With Codeine			S	Oral	2 Dosage Form, 3 Times A Day		Not Reported
	Vitalux			S	Oral	Unk Unk, Two Times A Day		Not Reported
	Wellbutrin			S	Oral	150 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16211409	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-020679			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Escitalopram			S	Oral	20 Milligram		Aurobindo
	Gabapentin			S	Oral	300 Milligram, Daily		Aurobindo
	Gabapentin Capsules			S	Oral	600 Milligram, Two Times A Day		Aurobindo
	Clonazepam			S	Unknown	0.5 Milligram, Three Times A Day		Not Reported
	Domperidone			S	Unknown	10 Milligram, Two Times A Day		Not Reported
	Ferrous Sulphate			S	Unknown	300 Milligram, 3 Times A Day		Not Reported
	Temazepam			S	Oral	30 Milligram, Daily		Not Reported
	Tylenol With Codein #3			S	Oral	2 Dosage Form, 3times A Day		Not Reported
	Vitalux			S	Oral	Unk, Two Times Daily		Not Reported
	Wellbutrin			S	Oral	150 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16212023	EXPEDITED (15-DAY)		LT, OT	FR-GLAXOSMITHKLINE-FR2019069701		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine			S	Oral	Unk		Glaxosmithkline
	Racecadotril			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Levothyrox			S	Oral	Unk		Glaxosmithkline
	Mirtazapine			S	Oral	Unk		Not Reported
	Coveram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16212140	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008080		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral	Unknown		Unknown
	Metoprolol			S	Oral	Extended Release		Unknown
	Hydrochlorothiazide			S	Oral	Unknown		Unknown
	Quetiapine			S	Oral	Unknown		Unknown
	Potassium Chloride			S	Oral	Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16212164	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008200		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Amlodipine			S	Oral	Unknown		Unknown
	Propranolol			S	Oral	Unknown		Unknown
	Quetiapine			S	Oral	Unknown		Unknown
	Primidone			S	Oral	Unknown		Unknown
	Trazodone			S	Oral	Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16212213	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008164		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Venlafaxine			S	Oral	Extended Release		Unknown
	Escitalopram			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16100332	NON-EXPEDITED			US-APOTEX-2019AP008942			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Muscle Twitching	Paxil	S	Unknown	Unk	Apotex
	Wellbutrin	S	Unknown	Unk	Not Reported
	Bactrim Ds	S	Unknown		Not Reported
	Lexapro	S	Unknown		Not Reported
	Macrobid /00024401/	S	Unknown		Not Reported
	Nubain	S	Unknown		Not Reported
	Prozac	S	Unknown		Not Reported
	Zoloft	S	Unknown		Not Reported
	Ranitidine	C	Oral	1 Df, Bid	Not Reported
	Gabapentin	C	Oral	1 Df, Tid	Not Reported
	Lorazepam	C	Oral	Unk, Prn (1-2 Tablets Every 6 Hours As Needed Orally Daily)	Not Reported
	Neurontin	C	Oral	2 Df, Tid	Not Reported
	Hydrocodone/Acetaminophen	C	Oral	1 Df, Q.4h. (As Needed)	Not Reported
	Lisinopril	C	Oral	1 Df, Bid	Not Reported
	Tylenol With Codeine	C	Oral	Unk, Q.6h (1 To 2 Tablets As Needed Orally Every 6 Hrs)	Not Reported
	Prednisone	C	Oral	4 Df, Qd (For 2 Days) As Directed	Not Reported
	Prednisone	C	Oral	3 Df, Qd (For 2 Days) As Directed	Not Reported
	Prednisone	C	Oral	2 Df, Qd (For 2 Days) As Directed	Not Reported
	Prednisone	C	Oral	1 Df, Qd (For 2 Days) As Directed	Not Reported
	Lovastatin	C	Oral	1 Df, Qd (With A Meal Orally)	Not Reported
	Azithromycin	C	Oral	2 Df, Qd (On The First Day)	Not Reported
	Azithromycin	C	Oral	1 Df, Qd (Daily For 4	Not Reported

						Days)				
	Celexa /00582602/			C	Unknown	1 Df, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16216373	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020327			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Quetiapine			S	Unknown	150 Milligram		Aurobindo
	Teva Escitalopram			S	Unknown	15 Milligram		Not Reported
	Teva Escitalopram			S				Not Reported
	Teva Escitalopram			S				Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16216933	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008100		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unknown		Unknown
	Acetaminophen			S	Oral	Unknown		Unknown
	Doxepin			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16216979	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008269		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unknown		Unknown
	Alprazolam			S	Oral	Unknown		Unknown
	Acetaminophen And Hydrocodone 300 Mg / 10 Mg			S	Oral	Unknown		Unknown
	Acetaminophen And Oxycodone			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16217290	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2019SP003246			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Fatigue; Hypoaesthesia; Indifference; Myalgia; Oropharyngeal Pain; Seizure	Zolpidem			S	Unknown	Unk		Strides
	Fluoxetine			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Zoloft			S	Unknown	Unk		Not Reported
	Desipramine			S	Unknown	Unk		Not Reported
	Adderall			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Effexor			S	Unknown	Unk		Not Reported
	Zyprexa			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16218136	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008243		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unknown		Unknown
	Doxepin			S	Oral	Unknown		Unknown
	Hydroxyzine			S	Oral	Unknown		Unknown
	Ethanol			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16218764	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008186		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Escitalopram	S	Oral	Unknown	Unknown
	Bupropion	S	Oral	Extended Release	Unknown
	Methylphenidate	S	Oral	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16219250	EXPEDITED (15-DAY)		LT	PHHY2019FR091323		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine			S	Oral			Novartis
	Mirtazapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Racecadotril Biogaran 100 Mg			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Coveram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16219268	EXPEDITED (15-DAY)		OT	PHHY2019GB085858			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental Disorder; Wrong Technique In Product Usage Process	Escitalopram			S	Unknown	Unk (Reduce To 12.5 Mg Over 8 Weeks)		Not Reported
	Escitalopram			S	Unknown	15 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	15 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	15 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	Unk (Cutting Bits To 5 Mg To Reach Approx. 12.5 Mg In 6 Weeks)		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported

	Mirtazapine	S	Unknown	Unk	Not Reported
	Mirtazapine	S	Unknown	15 Mg, Unk	Not Reported
	Lorazepam	S	Unknown	Unk	Novartis
	Lorazepam	S			Novartis
	Lorazepam	S			Novartis
	Lorazepam	S			Novartis
	Lorazepam	S			Novartis
	Buspirone	S	Unknown	Unk	Not Reported
	Buspirone	S			Not Reported
	Buspirone	S			Not Reported
	Buspirone	S			Not Reported
	Buspirone	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16219306	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1037339		38 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Off Label Use	Paroxetine			S	Oral	30 Mg, Once Daily (Qd)		Not Reported
	Candesartan			S	Oral	16 Mg, Once Daily (Qd)		Not Reported
	Escitalopram			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Levetiracetam			S	Oral	1500 Mg, Once Daily (Qd)		Not Reported
	Nepresol /00017902/			S	Oral	25 Mg, Once Daily (Qd)		Mylan
	L-Thyroxin /00068001/			C	Oral	Unk		Mylan
	Cytotec			C		Unk		Mylan
	Folic Acid			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2019	16219570	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2019-021092			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperreflexia; Mydriasis; Poisoning Deliberate	Escitalopram			S	Oral	25 Dosage Form, Total		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2019	16219820	EXPEDITED (15-DAY)		OT	IN-HETERO CORPORATE-HET2019IN00483		45 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Escitalopram			S	Unknown	05 Mg		Hetero
	Escitalopram			S		20 Unk		Hetero
	Fluoxetine			S	Unknown	20 Mg		Not Reported
	Valproate Semisodium			C	Unknown	Unk		Not Reported
	Olanzapine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2019	16219863	EXPEDITED (15-DAY)		OT	SE-ACCORD-122801		19 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pharyngeal Haemorrhage	Escitalopram			S	Oral			Not Reported
	Citalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2019	16220327	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008361		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unknown		Unknown
	Tramadol			S	Oral	Unknown		Unknown
	Propranolol			S	Oral	Unknown		Unknown
	Gabapentin			S	Oral	Unknown		Unknown
	Ethanol			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2019	16220372	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008245		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2019	16220442	EXPEDITED (15-DAY)		LT	PHHY2019FR091335		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Paracetamol			S	Oral	12 G, Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Diazepam			S	Oral	100 Mg, Unk		Not Reported
	Seroplex			S	Oral	560 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2019	16220601	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008120		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Propranolol			S	Oral	Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown
	Methylphenidate			S	Oral	Unknown		Unknown
	Lamotrigine			S	Oral	Unknown		Unknown
	Diazepam			S	Oral	Unknown		Unknown
	Melatonin			S	Oral	Unknown		Unknown
	Olanzapine			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2019	16220613	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008325		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Bupropion		S	Oral	Unknown	Unknown
	Verapamil		S	Oral	Unknown	Unknown
	Escitalopram		S	Oral	Unknown	Unknown
	Ethanol		S	Oral	Unknown	Unknown
	Diphenhydramine		S	Oral	Unknown	Unknown
	Hydrochlorothiazide		S	Oral	Unknown	Unknown
	Lisinopril		S	Oral	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2019	16220620	EXPEDITED (15-DAY)		DE	US-TORRENT-00008081		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral	Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown
	Lisinopril			S	Oral	Unknown		Unknown
	Alprazolam			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2019	16220899	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008276		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Propranolol			S	Oral	Unknown		Unknown
	Levetiracetam			S	Oral	Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown
	Gabapentin			S	Oral	Unknown		Unknown
	Acetaminophen/Chlorzoxazone			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	15734485	EXPEDITED (15-DAY)		HO, LT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-116064		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Metformin Hydrochloride			S	Oral	1000 Mg, Bid		Bristol Myers Squibb
	Lisinopril			S	Oral	20 Mg, Qd		Not Reported
	Trazodone			S	Oral	50 Mg, Qd		Not Reported
	Trazodone			S	Oral	100 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Glyburide			C	Unknown	Unk		Not Reported
	Gemfibrozil			C	Unknown	Unk		Not Reported
	Pravachol			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Combivent			C	Unknown	Unk		Not Reported
	Valium			C	Unknown	Unk		Not Reported
	Victoza			C	Unknown	Unk		Not Reported
	Lunesta			C	Unknown	Unk		Not Reported
	Anoro			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Proair /00139502/			C	Unknown	Unk		Not Reported
	Medizine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	15991597	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019074542		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Psychomotor Skills Impaired	Lorazepam			S	Oral	250 Mg, Single		Pfizer
	Quetiapine Fumarate			S	Oral	500 Mg, Single		Not Reported
	Escitalopram Oxalate			S	Oral	100 Mg, Single		Not Reported
	Trittico			S	Oral	10 Df, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16003746	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-009338			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Anxiety; Cardiac Disorder; Drug Ineffective; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Thinking Abnormal	Escitalopram			S	Unknown	Unk		Aurobindo
	Aripiprazole Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Aripiprazole Tablets			S	Unknown	30 Milligram, Once A Day		Aurobindo
	Clozapine			C	Unknown	600 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16052814	EXPEDITED (15-DAY)		OT	CZ-MYLANLABS-2019M1020954		58 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Mental Disorder; Suicide Attempt	Olanzapine			S	Unknown	Unk Unk,Unk		Not Reported
	Escitalopram			S	Unknown	Unk Unk,Unk		Not Reported
	Aripiprazole			S		Unk		Not Reported
	Venlafaxine			S	Unknown	Unk		Not Reported
	Ziprasidone			S		Unk		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Citalopram			S		Series Of Citalopram Infusions		Mylan
	Risperidone			S	Unknown	Unk Unk,Unk		Mylan
	Clomipramine			S		Unk		Mylan
	Tiapride			C		Unk		Mylan
	Melperone			C		Unk		Mylan
	Clonazepam			C		Unk		Mylan
	Propofol			C		Unk		Mylan
	Memantine			C		Unk		Mylan
	Haloperidol			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16138359	EXPEDITED (15-DAY)		HO, OT	PL-ACCORD-116599		52 YR	Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Decreased Appetite; Drug Ineffective; Dyschezia; Medication Error; Pain; Pneumonia; Weight Decreased	Escitalopram			S	Unknown			Not Reported
	Metoclopramide			S	Unknown	3 Dosages 10 Mg Daily		Accord
	Buprenorphine			S	Unknown	35 Ug/Hour Every 4 Days		Not Reported
	Tramadol			S	Unknown	100 Mg, Bid (200 Mg)		Not Reported
	Alprazolam			S	Unknown			Not Reported
	Metamizole Sodium			S	Unknown	2 Dosages 500 Mg Daily		Not Reported
	Omeprazole			S	Unknown	20 Mg, Qd (In The Morning Fasting)		Not Reported
	Ketoprofen/Ketoprofen Arginate/Ketoprofen Lysine/Ketoprofen Sodium			S	Unknown	3 Dosages 100 Mg Daily		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown			Not Reported
	Valproic Acid			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Zoledronic Acid			C	Unknown			Not Reported
	Betamethasone			C				Not Reported
	Effentora			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16222032	EXPEDITED (15-DAY)		OT	FR-ACCORD-123456		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Dependence	Escitalopram			S	Unknown	Unspecified		Not Reported
	Alprazolam			S	Unknown	Unspecified		Not Reported
	Dafalgan Codeine			S	Unknown	Unspecified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16223283	NON-EXPEDITED			US-PFIZER INC-2019162079			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Effexor Xr			S		37.5 Mg, Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16223798	EXPEDITED (15-DAY)		DS	IT-MYLANLABS-2019M1036546		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Quetiapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	50 Milligram, Qd		Not Reported
	Sertraline			S		200 Milligram, Qd		Not Reported
	Venlafaxine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Valproic Acid			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16224388	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1036720		81 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Cerebral Haemorrhage; Ecchymosis; Subdural Haematoma	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Plavix			S	Oral	75 Milligram, Qd		Mylan
	Coumadin			S	Oral	5 Milligram		Mylan
	Pregabalin			C		Unk		Mylan
	Furosemide			C		Unk		Mylan
	Doxazosin			C		Unk		Mylan

	Esomeprazole Sodium	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16224451	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1036751		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fall; Haematoma	Escitalopram			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	10 Milligram, Qd		Not Reported
	Aripiprazole			S	Oral	5 Milligram, Qd		Not Reported
	Prazepam Arrow			S	Oral	10 Milligram, Qd		Mylan
	Piroxicam			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16224944	EXPEDITED (15-DAY)		OT	SE-MYLANLABS-2019M1037021		65 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Respiratory Tract Infection	Sertraline			S	Unknown	Unk		Not Reported
	Venlafaxine			S	Unknown	Unk		Not Reported
	Brintellix			S	Oral	5 Milligram, Qd		Mylan
	Brintellix			S	Oral	10 Milligram, Qd		Mylan
	Brintellix			S	Oral	15 Milligram, Qd		Mylan
	Cipramil /00582602/			S	Unknown	Unk		Mylan
	Cipralex /01588501/			S	Unknown	Unk		Mylan
	Mirtazapin			C	Unknown	Unk		Mylan
	Stesolid			C	Unknown	20 Milligram, Qd		Mylan
	Stilnoct			C	Unknown	10 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16225505	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1917168US			Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16225668	EXPEDITED (15-DAY)		OT	PHHY2019FR088499		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Trileptal			S	Oral	Unk		Novartis
	Pantoprazole			S	Oral	Unk		Not Reported
	Spironolactone			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Lacosamide			S	Oral	Unk		Not Reported
	Diltiazem			S	Oral	Unk		Not Reported
	Bactrim			S	Oral	Unk		Not Reported
	Tinzaparine Sodique			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	14213348	EXPEDITED (15-DAY)		CA, DS, HO	FR-PFIZER INC-2017493671		273 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Maternal Exposure During Pregnancy; Motor Developmental Delay; Neonatal Behavioural Syndrome; Neurodevelopmental Disorder; Speech Disorder Developmental	Xanax			S	Transplacental	Unk		Pfizer
	Seroplex			S	Transplacental	10 Mg, 1x/Day		Not Reported
	Stilnox			S	Transplacental	Unk		Not Reported
	Seresta			S	Transplacental	Unk		Not Reported
	Donormyl (Doxylamine Succinate)			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	15351216	NON-EXPEDITED			US-PFIZER INC-2018354224		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer
	Metoprolol Tartrate			S		Unk		Unknown
	Catapres [Clonidine Hydrochloride]			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16044404	EXPEDITED (15-DAY)		DE, HO, OT	SG-ALLERGAN-1908607US			Male	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisocial Behaviour; Compulsive Shopping; Depressed Mood; Mood Swings; Product Use Issue; Seizure; Suicide Attempt; Underdose	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	2.5 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16076780	NON-EXPEDITED			US-TAKEDA-2019TUS013412			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Diabetes Mellitus	Trintellix			S	Oral	Unk		Takeda
	Lexapro			S	Oral	Unk		Not Reported
	Rexulti			S	Oral	0.5 Milligram, Qd		Not Reported
	Rexulti			S	Oral	3 Milligram, Qd		Not Reported
	Prozac			C	Oral	20 Milligram, Qd		Not Reported
	Lamictal			C	Oral	200 Milligram, Qd		Not Reported
	Trazodon			C	Oral	150 Milligram, Qd		Not Reported
	Deplin			C	Oral	15 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226909	EXPEDITED (15-DAY)		LT	FR-TEVA-2019-FR-1040900		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperreflexia; Mydriasis; Poisoning Deliberate	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16230314	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019164650		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Dislocation; Device Malfunction; Drug Ineffective	Amlodipine Besilate			S	Unknown	1.5 Df, 1x/Day		Pfizer
	Apo Escitalopram			S	Unknown	Unk		Not Reported
	Apo Tamsulosin			S	Unknown	1 Df, 1x/Day		Not Reported
	Apo-Trazodone			S	Unknown	1 Df, 1x/Day		Not Reported
	Brilinta			S	Unknown	1 Df, 2x/Day		Not Reported
	Ciclopirox Olamine			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	1 Df, 3x/Day		Not Reported
	Delatestryl			S	Unknown	0.5 Ml, 1 Every 2 Weeks		Not Reported
	Dexilant			S	Unknown	1 Df, 1x/Day		Not Reported
	Diltiazem			S	Unknown	1 Df, 1x/Day		Not Reported
	Emo Cort			S	Topical	Unk Unk, 1x/Day		Not Reported
	Escitalopram			S	Unknown	1 Df, 1x/Day		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Jamp Asa			S	Unknown	1 Df, 1x/Day		Not Reported
	Metonia			S	Unknown	1 Df, 3x/Day		Not Reported
	Mylan Nitro Sl			S	Oral	Unk		Not Reported
	Mylan Nitro Sl			S	Oral	Unk		Not Reported
	Nasonex			S	Nasal	Unk Unk, 1x/Day		Not Reported

Nitro-Dur	S	Unknown	1 Df, 1x/Day		Not Reported
Ratio-Zopiclone	S	Unknown	1 Df, Unk		Not Reported
Rosuvastatin Calcium	S	Unknown	1 Df, 1x/Day		Not Reported
Synthroid	S	Unknown	1 Df, 1x/Day		Not Reported
Tevabisoprol	S	Unknown	1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16230495	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1917196US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan
	Lamotrigine			S	Oral	Unk, Unknown		Not Reported
	Racecadotril Bgr			S	Oral	Unk, Unknown		Not Reported
	Levothyrox			S	Oral	Unk, Unknown		Not Reported
	Mirtazapine			S	Oral	Unk, Unknown		Not Reported
	Coveram			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231791	EXPEDITED (15-DAY)		OT	GB-ACCORD-123735		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Tongue Biting	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231840	EXPEDITED (15-DAY)		HO, OT	GB-CIPLA LTD.-2019GB02132			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt	Escitalopram			S	Oral	40 Milligram, Per Day		Invagen
	Fluoxetine			C	Unknown	20 Milligram (Capsules)		Not Reported

Prolonged;
Gastrooesophageal Reflux
Disease; Lethargy;
Malaise; Product
Dispensing Error;
Somnolence

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16235351	EXPEDITED (15-DAY)		LT	FR-009507513-1904FRA009494		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Mirtazapine			S	Oral			Merck
	Lamotrigine			S	Oral			Not Reported
	Racecadotril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Coveram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16235488	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1917372US			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Syncope; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Titrated 10 Mg Till 12,5 Mg Under Terapitiden.		Allergan
	Alfuzosin			C	Unknown			Not Reported
	Mirtazapin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16235489	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1917155US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Bradypnoea; Intentional Overdose; Off Label Use; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Escitalopram Oxalate - Bp		S	Oral	Actual: Overdose: 560 Mg	Allergan
	Tramadol		S	Oral	Unk	Not Reported
	Paracetamol		S	Oral	12 G	Not Reported
	Diazepam		S	Oral	100 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	15597623	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-972702		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia; Ejaculation Failure; Erectile Dysfunction; Erectile Dysfunction; Loss Of Libido; Male Sexual Dysfunction	Escitalopram			S	Unknown	40 Milligram Daily;		Ivax
	Escitalopram			S				Ivax
	Escitalopram			S				Ivax
	Mirtazapine			S	Unknown	22.5 Milligram Daily; Every Bedtime		Teva
	Mirtazapine			S				Teva
	Mirtazapine			S				Teva
	Alprazolam			S	Unknown	Tid When Necessary		Actavis
	Alprazolam			S				Actavis
	Alprazolam			S				Actavis
	Lamotrigine			S	Unknown	Tid		Teva
	Lamotrigine			S				Teva
	Enalapril			S	Unknown	20 Milligram Daily; Every Morning		Teva
	Lansoprazole			S	Unknown	30 Milligram Daily; Every Morning		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	15675033	EXPEDITED (15-DAY)		DS, OT	PT-AUROBINDO-AUR-APL-2018-057308			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dystonia; Gait Disturbance; Gait Inability; Posture Abnormal; Stiff	Escitalopram 20 Mg			S	Unknown	20 Milligram		Aurobindo
	Escitalopram 20 Mg			S				Aurobindo
	Insulin			C	Unknown	Unk		Not Reported

Person Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16236323	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2019GB02145			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Tongue Biting	Escitalopram			S	Unknown	20 Milligram, Per Day, Tablet		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16237021	EXPEDITED (15-DAY)		CA, OT	DE-ACCORD-123927		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Infantile Apnoea; Retrognathia	Escitalopram			S	Transplacental	15 Mg/D		Not Reported
	L-Thyroxin 50			C	Transplacental	50 Mg/D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16237073	EXPEDITED (15-DAY)		HO, OT	GB-CIPLA LTD.-2019GB02377			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyarrhythmia; Circulatory Collapse	Escitalopram			S	Oral	10 Milligram		Invagen
	Elleste-Solo			C	Transdermal	80 Microgram, Qd (Every 24 Hrs), Transdermal Patch		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16237259	EXPEDITED (15-DAY)		OT	NO-TEVA-2019-NO-1042888			Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Hypomania	Escitalopram Actavis			S	Oral	20 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16237451	EXPEDITED (15-DAY)		HO, LT, OT	FR-GLAXOSMITHKLINE-FR2019073865		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Zelitrex			S	Oral	6 Df, Qd		Glaxosmithkline
	Seroplex			S	Oral	1 Df, Qd		Glaxosmithkline
	Fludex (Indapamide)			S	Oral	Unk		Not Reported
	Ditropan			S	Oral	2 Df, Qd		Not Reported
	Perindopril			S	Oral	8 Mg, Qd		Not Reported
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported
	Paracetamol			C	Oral	3 Df, Qd		Glaxosmithkline
	Cortancyl			C	Oral	2 Mg, Qd		Not Reported
	Movicol			C	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16238201	NON-EXPEDITED			US-PFIZER INC-2019176876		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16240547	NON-EXPEDITED			US-TAKEDA-2019TUS023465			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Dry Mouth; Headache; Initial Insomnia; Nausea; Paraesthesia; Poor Quality	Trintellix			S	Unknown	Unk		Takeda
	Lexapro			S	Unknown	Unk		Not Reported
	Lexapro			S				Not Reported
	Celexa /00582602/			S	Unknown	Unk		Not Reported

Sleep; Restlessness; Therapy Partial Responder	Abilify		S	Unknown	Unk	Not Reported
	Abilify		S			Not Reported
	Gabapentin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	15481816	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2018-027084		29 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Gastric Haemorrhage; Hypoxia; Intentional Overdose; Seizure; Suicide Attempt	Salbutamol			S	Unknown			Bausch And Lomb
	Trimipramine Beta			S	Unknown	100		Not Reported
	Tramadol			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Cipralex			S	Unknown	10		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16241742	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-022644			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Product Use Issue; Suicidal Ideation; Thinking Abnormal	Escitalopram			S	Unknown	5 Milligram		Aurobindo
	Escitalopram			S	Unknown	15 Milligram		Aurobindo
	Escitalopram			S	Unknown	10 Milligram		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16242520	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-206381		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	Unk		Sun
	Escitalopram			S	Oral	Unk		Not Reported
	Spironolactone			S	Oral	Unk		Sun

Tinzaparine Sodique ((Mammifere/Porc/Muqueuse Intestinale))	S	Subcutaneous	Unk		Not Reported
Trileptal	S	Oral	Unk		Not Reported
Lacosamide	S	Oral	Unk		Not Reported
Diltiazem (Chlorhydrate De)	S	Oral	Unk		Not Reported
Bactrim	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16242606	EXPEDITED (15-DAY)		HO	IT-ACCORD-124176		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Interaction; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram			S				Not Reported
	Coaprovel 300 / 12.5			S	Oral			Not Reported
	Urbason			C				Not Reported
	Paracetamol			C				Not Reported
	Alprazolam			C				Not Reported
	Eutirox			C				Not Reported
	Pantoprazole			C				Not Reported
	Alendronic Acid/Cholecalciferol			C	Oral			Not Reported
	Colecalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16243716	NON-EXPEDITED			US-PFIZER INC-2019173755		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer
	Apriso			S		Unk		Not Reported
	Calcium			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Norco			S		Unk		Not Reported
	Pravastatin			S		Unk		Not Reported
	Singulair			S		Unk		Not Reported

Vit D	S	Unk		Not Reported
Zyloprim	S	Unk		Not Reported
Folic Acid	S	Unk		Not Reported
Baby Aspirin	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16244202	EXPEDITED (15-DAY)		OT	GB-ELI_LILLY_AND_COMPANY-GB201904008235			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Fatigue; Hypoaesthesia; Indifference; Myalgia; Oropharyngeal Pain; Seizure	Prozac			S	Unknown	Unk Unk, Unknown		Eli Lilly And Co
	Zoloft			S	Unknown	Unk, Unknown		Not Reported
	Desipramine			S	Unknown	Unk, Unknown		Not Reported
	Klonopin			S	Unknown	Unk, Unknown		Not Reported
	Adderall			S	Unknown	Unk, Unknown		Not Reported
	Wellbutrin			S	Unknown	Unk, Unknown		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Effexor			S	Unknown	Unk, Unknown		Not Reported
	Ambien			S	Unknown	Unk, Unknown		Not Reported
	Celexa [Citalopram Hydrobromide]			S	Unknown	Unk Unk, Unknown		Not Reported
	Zyprexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16244577	EXPEDITED (15-DAY)		OT	US-APOTEX-2019AP012786		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Electrocardiogram Qt Prolonged; Paraesthesia	Buspirone			S	Unknown	Unk		Apotex
	Sertraline			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Citalopram			S	Unknown	Unk		Apotex

	Aripiprazole	S	Unknown	Unk		Apotex
	Albuterol	S	Unknown	Unk		Apotex
	Montelukast	S	Unknown			Apotex
	Clonazepam Auden	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16246178	EXPEDITED (15-DAY)		DE, OT	SE-SHIRE-SE201913147			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Toxicity To Various Agents	Elvanse			S	Oral	40 Milligram, 1x/Day:Qd		Shire
	Lamictal			S	Oral	200 Milligram, 1x/Day:Qd		Not Reported
	Escitalopram Accord			S	Oral	10 Milligram, 1x/Day:Qd		Not Reported
	Voxra			S	Oral	150 Milligram, 1x/Day:Qd		Not Reported
	Melatonin Agb			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2019	16246785	EXPEDITED (15-DAY)		DE	BE-ACCORD-124115		38 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2019	16246854	EXPEDITED (15-DAY)		OT	SE-ACCORD-124226		56 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S	Oral	10-15mg		Not Reported
	Sertraline			S	Oral			Accord
	Lergigan [Promethazine Hydrochloride]			C				Not Reported
	Imovane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2019	16247640	EXPEDITED (15-DAY)		HO, OT	LU-APOTEX-2019AP012363		47 YR	Female	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Actin Antibody Positive; Gamma-Glutamyltransferase Increased; Hepatocellular Injury	Escitalopram			S	Oral	Unk		Apotex
	Gilenya			S	Oral	1 Df, Qd		Not Reported
	Lyrica			C	Oral	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2019	16248048	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1918189US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Mental Impairment; Sexual Dysfunction	Citalopram Hydrobromide - Bp			S	Unknown			Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	7.5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Trintellix			S	Unknown	10 Mg, Qd (Once Every 24 Hours)		Not Reported
	Trintellix			S	Unknown	10 Mg, Qd (Once Every 24 Hours)		Not Reported
	Trintellix			S	Unknown	10 Mg, Qd (Once Every 24 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2019	16251644	DIRECT		LT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Paralysis; Headache; Heart Rate Increased; Pain In Extremity; Pyrexia;	Lexapro			S	Oral			Not Reported

Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	14370638	NON-EXPEDITED			US-PFIZER INC-2018005289		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Interaction; Inhibitory Drug Interaction	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer
	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Lexapro			S		Unk		Not Reported
	Plaquenil			C		200 Mg, 1x/Day (Two Pills In The Evening)		Not Reported
	Plaquenil			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	15993802	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-108376			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Bendamustine/Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	149.4 Mg, Unknown		Not Reported
	Escitalopram			S				Not Reported
	Cotrimoxamol			S				Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Mg, Unknown		Not Reported
	Omeprazole			S	Oral			Not Reported
	Rituximab			S	Oral			Not Reported
	Valsartan Nichi Iko			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16186388	EXPEDITED (15-DAY)		DE, OT	PHHY2018FR054397		49 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Asthenia; Blood Albumin Decreased; Blood Creatinine Increased; Death; Diarrhoea; Gamma-Glutamyltransferase Increased; Urinary Retention	Votrient			S	Oral	800 Mg, Daily		Novartis
	Seroplex			S	Unknown	15 Ot, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16248572	EXPEDITED (15-DAY)		LT	FR-AUROBINDO-AUR-APL-2019-023150			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Tramadol			S	Oral	Unk		Aurobindo
	Paracetamol			S	Oral	12 Gram		Aurobindo
	Diazepam			S	Oral	100 Milligram		Not Reported
	Seroplex			S	Oral	560 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16248832	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-124339			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram			S	Oral			Not Reported
	Fluoxetine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16248932	EXPEDITED (15-DAY)		OT	ES-ACCORD-124567		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Urinary Retention	Escitalopram			S	Oral	Strength: 10 Mg 28 Tablets, 1/2-0-0		Not Reported
	Gabapentin			S	Oral	1-1-1. 0-0-1 1st Week, 2nd Week 0-1-1, 1-1-1 3rd Week And Continue To Further Review		Not Reported
	Zytram Bid			S	Oral	Strength: 75 Mg, 56 Tablets, 1-0-1. 1st Week 0-0-1, 2nd Week 1-0-1 And Continue Until Revision		Not Reported
	Nebivolol			C	Oral	Strength: 5 Mg 28 Tablets		Not Reported
	Atorvastatin			C	Oral	Strength: 40 Mg 28 Tablets		Not Reported
	Acetylsalicylic Acid			C	Oral	Strength: 100 Mg 30 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16249312	EXPEDITED (15-DAY)		HO	FR-ACCORD-124554		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction	Escitalopram			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral	Strength 20 Mg, Scored Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16249944	EXPEDITED (15-DAY)		LT	FR-MARINA BIOTECH, INC.-2019MARINA000566			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Coveram Nos			S	Oral	Unk		Unknown
	Lamotrigine			S	Oral	Unk		Not Reported

	Racecadotril	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Levothyroxine Sodium	S	Oral	Unk		Not Reported
	Mirtazapine	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16250823	NON-EXPEDITED			US-TEVA-2019-US-1041720			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Escitalopram Tablets, Usp Teva			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16251989	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1039316			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Prescription Form Tampering	Escitalopram			S	Unknown	Non Renseignée		Not Reported
	Quetiapine			S	Unknown	Non Renseignée		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16252613	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1039434		40 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram			S	Unknown	Unk		Not Reported
	Cipralex /01588501/			S		20 Gram, Qd (Started With 1 Drop Daily)		Mylan
	Cipralex /01588501/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16253358	EXPEDITED (15-DAY)		LT	FR-ZYDUS-036083		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine	S	Oral	()		Not Reported
	Racecadotril	S	Oral	()		Not Reported
	Escitalopram	S	Oral			Cadila
	Levothyroxine	S	Oral	()		Not Reported
	Mirtazapine	S	Oral			Zydus Pharm
	Coveram	S	Oral	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	15375512	EXPEDITED (15-DAY)		OT	CZ-ACCORD-071688		58 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Mental Disorder; Suicide Attempt	Aripiprazole			S				Not Reported
	Escitalopram			S	Unknown			Not Reported
	Citalopram			S		Series Of Citalopram Infusions		Not Reported
	Risperidone			S	Unknown	Unk Unk,Unk		Not Reported
	Olanzapine			S	Unknown			Not Reported
	Venlafaxine			S	Unknown	Unk Unk,Unk		Not Reported
	Ziprasidone/Ziprasidone Hydrochloride/Ziprasidone Mesilate			S		Unk		Not Reported
	Mirtazapine			S	Oral	Unk Unk,Unk		Not Reported
	Clomipramine			S				Not Reported
	Tiapride			C		Unk		Not Reported
	Memantine/Memantine Hydrochloride			C				Not Reported
	Propofol			C		Unk		Not Reported
	Melperone/Melperone Hydrochloride			C				Not Reported
	Haloperidol			C		Unk		Not Reported
	Clonazepam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	15876530	EXPEDITED (15-DAY)		OT	PHHY2019GB004960		46 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Heart Rate Increased; Myocarditis	Clozaril			S	Oral	175 Mg, Qd (50 Mg Am And 125 Mg Pm)		Not Reported
	Clozaril			S	Oral	Unk		Not Reported
	Clozaril			S	Oral	Unk		Not Reported
	Clozaril			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	20 Mg, Qd		Novartis
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Omeprazole			C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	15900047	EXPEDITED (15-DAY)		HO, OT	JP-SUNOVION-2019SUN000331		30 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Glossoptosis; Overdose; Serotonin Syndrome; Tonic Convulsion	Lunesta			S	Oral	15 Df, 2mg Tablets		Sunovion
	Lexapro			S	Oral	15 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16073573	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1023573		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hyperpyrexia; Hyponatraemia	Escitalopram			S	Oral	Unk		Not Reported
	Medrol /00049601/			C				Mylan
	Plavix			C				Mylan
	Omeprazen /00661201/			C				Mylan
	Desloratadine			C				Mylan

Pregabalin		C		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16108610	EXPEDITED (15-DAY)		OT	IT-ACCORD-114238		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hyperpyrexia; Hyponatraemia	Escitalopram			S	Oral			Not Reported
	Medrol			C				Not Reported
	Plavix			C				Not Reported
	Desloratadine			C				Not Reported
	Omepazen			C				Not Reported
	Pregabalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16239131	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019172513		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	Unk		Pfizer
	Spironolactone			S	Oral	Unk		Pfizer
	Tinzaparine Sodique			S	Subcutaneous	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Trileptal			S	Oral	Unk		Not Reported
	Lacosamide			S	Oral	Unk		Not Reported
	Diltiazem			S	Oral	Unk		Not Reported
	Bactrim			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16253460	NON-EXPEDITED			US-TEVA-2019-US-1039868			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16253462	NON-EXPEDITED			US-TEVA-2019-US-1045292			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gluten Sensitivity	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16253819	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2019-023151			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine			S	Oral	Unk		Aurobindo
	Escitalopram			S	Oral	Unk		Aurobindo
	Mirtazapine			S	Oral	Unk		Aurobindo
	Levothyrox			S	Oral	Unk		Not Reported
	Racecadotril			S	Oral	Unk		Not Reported
	Coveram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16253831	EXPEDITED (15-DAY)		HO, OT	PHHY2019DE090529			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Novartis
	Escitalopram			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	1.25 Mg, Unk		Not Reported
	Trigoa			C	Oral	Unk (6x Lng 50?G/Ee 30?G; 5x Lng 75?G/Ee 40?G; 10x Lng 125?G/Ee 30?G)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16254093	EXPEDITED (15-DAY)		HO, LT	PHHY2019FR096102		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Amlodipine			S	Oral	10 Mg, Qd		Novartis
	Perindopril			S	Oral	8 Mg, Qd		Not Reported
	Fludex (Indapamide)			S	Oral	Unk (Inconnue)		Not Reported
	Zelitrex			S	Oral	6 Df, Qd		Not Reported
	Ditropan			S	Oral	2 Df, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Movicol			C	Oral	2 Df, Qd		Not Reported
	Paracetamol			C	Oral	3 Df, Qd		Not Reported
	Cortancyl			C	Oral	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16255104	EXPEDITED (15-DAY)		OT	PT-ACCORD-124718		27 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dystonia; Gait Disturbance; Posture Abnormal; Stiff Person Syndrome	Escitalopram			S	Unknown			Not Reported
	Insulin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16255112	EXPEDITED (15-DAY)		HO	SE-BIODELIVERY SCIENCES INTERNATIONAL-2019BDSI0338		69 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Fentanyl Citrate			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported

	Tapentadol Hydrochloride	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16255530	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1039862		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rectal Haemorrhage	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Previscan /00789001/			S	Oral	1/2 Cp/J 1 Jours/2 En Alternance Avec 3/4 Cp		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16255959	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS-2018AMN00435			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Rash Pruritic	Escitalopram Oxalate			S	Unknown	Unk		Amneal
	Escitalopram Oxalate			S				Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16255962	NON-EXPEDITED		OT	US-AMNEAL PHARMACEUTICALS-2018AMN00396			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dysgeusia; Dyspnoea; Headache; Hypersensitivity; Neck Pain; Pharyngeal Swelling; Pruritus; Throat Irritation	Escitalopram Oxalate			S		5 Mg, 1x/Day		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16256122	EXPEDITED (15-DAY)		HO, OT	DE-HORMOSAN PHARMA GMBH-2019-02631			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Deep Vein Thrombosis; Pulmonary Embolism	Quetiapine		S	Oral	Unk	Lupin
	Escitalopram		S	Unknown	Unk	Lupin
	Bisoprolol		S	Unknown	1.25 Milligram	Not Reported
	Trigoa		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16256865	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1039954			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Treatment Failure	Diazepam			S	Unknown			Not Reported
	Flurazepam			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Mylan
	Lamotrigine			S	Unknown	Unk		Mylan
	Epclusa			S	Unknown	Unk		Mylan
	Chlorpromazine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16257402	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1918363US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Citalopram Hydrobromide - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16257561	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2019178552			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Drug Ineffective; Fatigue; Hypoaesthesia; Indifference; Myalgia; Oropharyngeal Pain; Seizure	Efexor Xl		S	Unknown		Pfizer
	Zoloft		S	Unknown		Pfizer
	Prozac		S	Unknown		Not Reported
	Desipramine		S	Unknown	Unk	Not Reported
	Klonopin		S	Unknown		Not Reported
	Adderall		S	Unknown		Not Reported
	Wellbutrin		S	Unknown		Not Reported
	Lexapro		S	Unknown		Not Reported
	Ambien		S	Unknown		Not Reported
	Celexa [Citalopram Hydrobromide]		S	Unknown		Not Reported
	Zyprexa		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16258355	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1918457US			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Product Use In Unapproved Indication; Restlessness; Tremor	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	14114520	NON-EXPEDITED			US-PFIZER INC-2017454452		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer
	Erythrocin			S		Unk		Unknown
	Clindamycin Hcl			S		Unk		Pfizer
	Relpax			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer

Mobic	S	Unk	Not Reported
Elavil	S	Unk	Not Reported
Levbid	S	Unk	Not Reported
Aspirin	S	Unk	Not Reported
Allegra	S	Unk	Not Reported
Ambien	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported
Ditropan	S	Unk	Not Reported
Flexeril	S	Unk	Not Reported
Januvia	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Metformin	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Zantac	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	15839133	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1001820		46 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Heart Rate Increased; Myocarditis	Clozaril			S	Oral	50 Milligram, Am		Mylan
	Clozaril			S	Oral	125 Milligram, Pm		Mylan
	Clozaril			S	Oral	Unk		Mylan
	Clozaril			S	Oral	Unk		Mylan
	Clozaril			S	Oral	Unk		Mylan
	Olanzapine			S	Oral	20 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	20 Milligram, Qd		Mylan
	Omeprazole			C	Oral	20 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16180947	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1915639US			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressive Symptom; Weight Decreased	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Lithium Carbonate			C	Oral			Not Reported
	Lithium Carbonate			C	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16242839	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2019M1039557		17 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Suicide Attempt; Toxicity To Various Agents; Vomiting	Azithromycin			S	Oral	1500 Milligram, Total		Not Reported
	Escitalopram			S	Oral	140 Milligram, Qd		Not Reported
	Prednisolone			S	Oral	200 Milligram, Total		Not Reported
	Paracetamol			S	Oral	79 Gram, Total		Not Reported
	Cefpodoxime			S	Oral	2000 Milligram, Total		Not Reported
	Trimebutine			S	Oral	14000 Milligram, Total		Not Reported
	Amoxicillin/Clavulanic Acid			S	Oral	6 Gram, Qd		Not Reported
	Loperamide			S	Oral	30 Milligram, Total		Not Reported
	Arestal			S	Oral	30 Milligram, Total		Mylan
	Seresta			S	Oral	310 Milligram, Total		Mylan
	Inorial			S	Oral	120 Milligram, Total		Mylan
	Augmentin /00756801/			S	Oral	6 Gram, Qd		Mylan
	Oxazepam			S	Oral	310 Milligram, Total		Mylan
	Bilastine			S	Oral	120 Milligram, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16259321	EXPEDITED (15-DAY)		HO	SE-TEVA-2019-SE-1043381		64 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Syncope	Escitalopram			S	Oral	Titrated 10 Mg To 12.5 Mg During The Therapy Period.		Ivax
	Escitalopram			S	Oral	15 Milligram Daily;		Ivax
	Alfuzosin			C				Not Reported
	Mirtazapin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16259378	EXPEDITED (15-DAY)		DS	SE-ACCORD-125307		61 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Escitalopram			S	Oral	10mg 1x1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16259541	EXPEDITED (15-DAY)		HO, OT	US-ASTELLAS-2019US017878		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acrophobia; Alopecia; Amnesia; Anxiety; Anxiety; Arthritis; Back Disorder; Balance Disorder; Decreased Appetite; Depression; Diarrhoea; Diverticulitis; Fatigue; Gait Disturbance; Gastric Ulcer; Hypersomnia; Hypoaesthesia; Multiple Sclerosis Relapse; Myalgia; Nasopharyngitis; Nausea; Pain; Pain; Paraesthesia; Product Use In Unapproved Indication; Product Use Issue; Pruritus; Pruritus	Tamsulosin			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Solifenacin			S	Unknown			Astellas
	Atorvastatin			S	Unknown			Not Reported
	Teriflunomide			S	Oral			Not Reported
	Teriflunomide			S	Oral			Not Reported
	Teriflunomide			S	Oral			Not Reported
	Teriflunomide			S	Oral			Not Reported
	Teriflunomide			S	Oral			Not Reported
	Teriflunomide			S	Oral			Not Reported
	Teriflunomide			S	Oral			Not Reported
	Teriflunomide			S	Oral			Not Reported
	Morniflumate			S	Unknown	Unk Unk, At Bedtime		Not Reported

Generalised; Temperature Intolerance; Tinnitus; Vertigo; Vision Blurred; Vomiting	Escitalopram Oxalate		S	Unknown		Not Reported
	Metformin Hydrochloride		S	Unknown		Not Reported
	Vitamin B-Complex /00228301/		S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Colecalciferol		S	Unknown		Not Reported
	Calcium		S	Unknown		Not Reported
	Calcium		S	Unknown	Unk, Unknown Freq.	Not Reported
	Folic Acid		S	Unknown		Not Reported
	Mirtazapine		C	Unknown	Unk Unk, Unknown Freq.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16260399	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1045002		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral			Teva
	Escitalopram			S	Oral			Ivax
	Spironolactone			S	Oral			Actavis
	Lacosamide			S	Oral			Not Reported
	Diltiazem (Chlorhydrate De)			S	Oral			Teva
	Trileptal			S	Oral			Not Reported
	Tinzaparine Sodique ((Mammifere/Porc/Muqueuse Intestinale))			S	Subcutaneous			Not Reported
	Bactrim			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16260644	EXPEDITED (15-DAY)		OT	GR-ALLERGAN-1918478US			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Lymphocytic Leukaemia; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan
	Ladose			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16262200	EXPEDITED (15-DAY)		HO	CA-BAUSCH-BL-2019-012772			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Wellbutrin Xl			S	Oral			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Domperidone			S	Unknown			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ferrous Sulphate			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Temazepam			S	Oral			Not Reported
	Tylenol With Codeine No.3			S	Oral			Not Reported
	Vitalux			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16262218	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1918323US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Electrocardiogram Qt Prolonged; Hyperkalaemia; Loss Of Consciousness; Overdose; Sinus Tachycardia	Citalopram Hydrobromide - Bp			S	Unknown	Unk, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
	Acetaminophen W/Oxycodone			S	Unknown	Unk, Unknown		Not Reported
	Diazepam			S	Unknown	Unk, Unknown		Not Reported
	Lorazepam			S	Unknown	Unk, Unknown		Not Reported
	Morphine			S	Unknown	420 Mg, Unknown		Not Reported
	Morphine			S	Unknown	30 Mg, Unknown		Not Reported
	Morphine			S	Unknown	30 Mg, Unknown		Not Reported
	Oxycodone			S	Unknown	Unk, Unknown		Not Reported
	Zopiclone			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16262219	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1918186US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Jaundice; Nausea; Vomiting	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16264340	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft 25mg			S				Not Reported
	Lexapro 20mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	15030176	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1040164		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Prescribed Underdose	Tramadol			S	Oral	Unk		Not Reported
	Esomeprazole			S	Oral	Unk		Not Reported
	Lipanthyl			S	Oral	145 Mg, Qd		Mylan
	Decapeptyl /00975902/			S	Intramuscular	1 Df, Cycle		Mylan
	Innohep			S	Subcutaneous	1 Df, Qd		Mylan
	Amlor			S	Oral	Unk		Mylan
	Amlor			S	Oral	Unk		Mylan
	Novonorm			S	Oral	Unk		Mylan
	Novonorm			S	Oral	Unk		Mylan
	Xtandi			S	Oral	120 Mg, Qd		Mylan
	Xtandi			S	Oral	40 Mg, Qd		Mylan
	Seroplex			S	Oral	10 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262578	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2019TUS026516			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Mental Impairment; Sexual Dysfunction	Trintellix			S	Unknown	10 Milligram, Qd		Takeda
	Trintellix			S				Takeda
	Trintellix			S				Takeda
	Citalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	10 Milligram		Not Reported
	Escitalopram			S	Unknown	7.5 Milligram		Not Reported
	Escitalopram			S	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262773	EXPEDITED (15-DAY)		LT	FR-TEVA-2019-FR-1043519		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Tramadol Base			S	Oral			Teva
	Paracetamol			S	Oral	12 Gram		Not Reported
	Diazepam			S	Oral	100 Milligram		Barr
	Seroplex 20 Mg, Comprimé Pelliculé Sécable			S	Oral	560 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262787	EXPEDITED (15-DAY)		LT	FR-PROVELL PHARMACEUTICALS-2066517		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Euthyrox			S	Oral			Provell Pharmaceuticals
	Racecadotril Bgr			S	Oral			Not Reported
	Coveram			S	Oral			Not Reported

	Mirtazapine	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Lamotrigine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16263384	EXPEDITED (15-DAY)		LT	FR-TEVA-2019-FR-1045352		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine			S	Oral			Teva
	Escitalopram			S	Oral			Ivax
	Mirtazapine			S	Oral			Teva
	Levothyrox			S	Oral			Not Reported
	Racecadotril Bgr			S	Oral			Not Reported
	Coveram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16263412	EXPEDITED (15-DAY)		OT	IT-ACCORD-125513		80 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Hyperhidrosis; Malaise	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16266222	EXPEDITED (15-DAY)		HO, OT	CA-BAUSCH-BL-2019-012774		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Wellbutrin Xl			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Domperidone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

	Ferrous Sulfate	S	Oral	Not Reported
	Gabapentin	S	Oral	Not Reported
	Temazepam	S	Oral	Not Reported
	Tylenol With Codeine	S	Oral	Not Reported
	Vitalux	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16266605	EXPEDITED (15-DAY)		LT	FR-JNJFOC-20190441815		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Tramadol Hydrochloride			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16267041	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1918614US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Dislocation; Device Malfunction; Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan
	Amlodipine Besilate			S	Unknown	1.5 Df, Qd		Not Reported
	Apo-Escitalopram			S	Unknown			Not Reported
	Apo Tamsulosin			S	Unknown	1 Df, Qd		Not Reported
	Apo-Trazodone			S	Unknown	1 Df, Qd		Not Reported
	Brilinta			S	Unknown	1 Df, Q12h		Not Reported
	Ciclopirox Olamine			S	Unknown			Not Reported
	Clonazepam			S	Unknown	1 Df, Q8hr		Not Reported
	Delatestryl			S	Unknown	0.5 Ml, Q2weeks		Not Reported
	Dexilant			S	Unknown	1 Df, Qd		Not Reported
	Diltiazem			S	Unknown	1 Df, Qd		Not Reported

Emo Cort	S	Topical	Unk, Qd		Not Reported
Jamp Asa	S	Unknown	1 Df, Qd		Not Reported
Metonia	S	Unknown	1 Df, Q8hr		Not Reported
Mylan Nitro	S	Oral			Not Reported
Mylan Nitro	S	Oral	Unk		Not Reported
Nasonex	S	Nasal	Unk, Qd		Not Reported
Nitro-Dur	S	Unknown	1 Df, Qd		Not Reported
Ratio-Zopiclone	S	Unknown	1 Df		Not Reported
Rosuvastatin Calcium	S	Unknown	1 Df, Qd		Not Reported
Synthroid	S	Unknown	1 Df, Qd		Not Reported
Tevabisoprol	S	Unknown	1 Df, Qd		Not Reported
Triatec (Acetaminophen\Codeine Phosphate)	S	Unknown	1 Df, Q6hr		Not Reported
Escitalopram	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16269058	DIRECT		OT			14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Kelnor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16269393	NON-EXPEDITED			US-TEVA-2019-US-1044604			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Emotional Disorder; Palpitations	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16269432	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-CA2019GSK078975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Wellbutrin Xl			S	Oral	150 Mg, Bid (150 Mg,2 In 1 D)		Glaxosmithkline
	Domperidone			S	Unknown	10 Mg, Bid (10 Mg,2 In 1 D)		Glaxosmithkline
	Escitalopram			S	Oral	20 Mg, Unk		Glaxosmithkline
	Ferrous Sulphate			S	Unknown	300 Mg, Tid (300 Mg,3 In 1 D)		Glaxosmithkline
	Gabapentin			S	Oral	300 Mg, 1d (300 Mg,1 In 1 D)		Glaxosmithkline
	Gabapentin			S	Oral	600 Mg, Bid (600 Mg,2 In 1 D)		Glaxosmithkline
	Clonazepam			S	Unknown	0.5 Mg, Tid (0.5 Mg,3 In 1 D)		Not Reported
	Temazepam			S	Oral	30 Mg, 1d (30 Mg,1 In 1 D)		Not Reported
	Tylenol # 3 (Codeine + Acetaminophen)			S	Oral	2 Df, Tid (2 Dosage Forms,3 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16269530	NON-EXPEDITED			US-PFIZER INC-2019182274		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16270009	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019185390			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apparent Death; Burnout Syndrome; Drug Interaction; Hyperhidrosis; Hypertension; Palpitations; Panic Attack; Restlessness; Stress	Ibuprofen	S	Unknown	Unk	Pfizer
	Cipralex [Escitalopram]	S	Unknown	5 Mg, Unk	Not Reported
	Cipralex [Escitalopram]	S	Unknown	5 Mg, 1x/Day	Not Reported
	Cipralex [Escitalopram]	S	Unknown	7.5 Mg, Alternate Day	Not Reported
	Cipralex [Escitalopram]	S		Unk	Not Reported
	Escitalopram	S		Unk	Not Reported
	Escitalopram	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16271465	EXPEDITED (15-DAY)		OT	GR-ELI_LILLY_AND_COMPANY-GR201904013112		212 DAY	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Lymphocytic Leukaemia; Foetal Exposure During Pregnancy	Ladose 20mg			S	Transplacental	20 Mg, Daily		Not Reported
	Ladose 20mg			S	Transplacental	20 Mg, Daily		Not Reported
	Entact			S	Transplacental	5 Mg, Daily		Not Reported
	Entact			S	Transplacental	5 Mg, Daily		Not Reported
	Fugentin [Amoxicillin Trihydrate;Clavulanate			C	Unknown	Unk, Unknown		Not Reported
	Fugentin [Amoxicillin Trihydrate;Clavulanate			C	Unknown	Unk, Unknown		Not Reported
	Utrogestan			C	Unknown	Unk, Unknown		Not Reported
	Utrogestan			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16271878	EXPEDITED (15-DAY)		DS	FR-MYLANLABS-2019M1042179		25 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Disorientation; Drug Ineffective; Hypersensitivity; Movement Disorder; Product Substitution Issue;	Escitalopram Mylan Generiques 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Form, Qd		Mylan

Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16271952	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1042422		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flight Of Ideas; Sensory Disturbance	Escitalopram			S	Oral	15 Milligram, Qd		Not Reported
	Lamictal			C	Oral	200 Milligram		Mylan
	Rivotril			C	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2019	16274369	EXPEDITED (15-DAY)		HO, LT	FR-ZYDUS-036243		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Indapamide			S	Oral	1.5 Mg Prolonged-Release Film-Coated Tablet		Not Reported
	Valaciclovir			S	Oral			Not Reported
	Oxybutynin			S	Oral	5 Mg, Scored Tablet		Not Reported
	Perindopril/Perindopril Erbumine			S	Oral			Not Reported
	Escitalopram			S	Oral	5 Mg Film-Coated Tablets		Not Reported
	Amlodipine			S	Oral			Zydus Pharm
	Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride			C	Oral	Powder For Oral Solution In Sachet		Not Reported
	Paracetamol			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	15072563	EXPEDITED (15-DAY)		HO	LU-ALLERGAN-1832491US			Female	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Actin Antibody Positive; Gamma-Glutamyltransferase Increased; Hepatocellular Injury	Escitalopram Oxalate - Bp	S	Oral	Unk	Allergan
	Gilenya	S	Oral	1 Df, Qd	Not Reported
	Lyrica	C	Oral	100 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16199453	EXPEDITED (15-DAY)		OT	DE-ARALEZ PHARMACEUTICALS R&D INC.-2019-ARA-001126		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Metoprolol Succinate			S	Oral	Unk, Hexal		Aralez Pharmaceuticals
	Metoprolol Succinate			S	Oral	Unk		Aralez Pharmaceuticals
	Escitalopram			S		Unk		Not Reported
	Escitalopram			S		Unk, Mylan		Not Reported
	Escitalopram			S		Unk, Stada		Not Reported
	Escitalopram			S		Unk, Hexal		Not Reported
	Metoprolol Tartrate			S		Unk, Stada		Not Reported
	Metoprolol Tartrate			S		Unk, Mylan		Not Reported
	Ibuprofen			S		Unk, Stada		Not Reported
	Ibuprofen			S		Unk, Hormosan		Not Reported
	Ibuprofen			S		Unk		Not Reported
	Ibuprofen			S		Unk, Hexal		Not Reported
	Prednisolon /00016201/			S		Unk, Stada		Not Reported
	Prednisolon /00016201/			S		25 Mg, Unk		Not Reported
	Prednisolon /00016201/			S		Unk, Jenapharm		Not Reported
	Prednisolon /00016201/			S		Unk		Not Reported
	Golimumab			S		Unk		Not Reported
	Pantozol /01263204/			S		Unk		Not Reported
	Implanon			S		Unk		Not Reported

Salbutamol	S	Unk, Stada	Not Reported
Salbutamol	S	Unk	Not Reported
Salbutamol	S	Unk	Not Reported
Amitriptyline	S	Unk	Not Reported
Methotrexate	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16240189	EXPEDITED (15-DAY)		DE, OT	FR-ALLERGAN-1845971US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Asthenia; Blood Albumin Decreased; Blood Creatinine Increased; Death; Diarrhoea; Gamma-Glutamyltransferase Increased; Urinary Retention	Escitalopram Oxalate Unk			S	Unknown	15 Ot, Unk		Allergan
	Votrient			S	Oral	800 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16271749	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-206741		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Paracetamol		Y	S	Oral	12 Grams, Unk		Ohm Lab
	Tramadol			S	Oral	()		Sun
	Seroplex 20 Mg, Comprime Pellicule Secable			S	Oral	560 Mg, Unk		Not Reported
	Diazepam			S	Oral	100mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16271759	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL		53 YR	Female	FRA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral	()		Not Reported
	Mirtazapine			S	Oral	()		Sun
	Lamotrigine			S	Oral	()		Not Reported
	Racecadotril Bgr			S	Oral	()		Not Reported
	Levothyrox			S	Oral	()		Not Reported
	Coveram			S	Oral	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16275765	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019GSK080041		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Wellbutrin Xl			S	Oral	150 Mg, Bid		Glaxosmithkline
	Domperidone			S	Oral	10 Mg, Bid		Glaxosmithkline
	Escitalopram			S	Oral	20 Mg, Unk		Glaxosmithkline
	Ferrous Sulfate			S	Oral	300 Mg, Tid		Glaxosmithkline
	Gabapentin			S	Oral	600 Mg, Bid		Glaxosmithkline
	Clonazepam			S	Oral	0.5 Mg, Tid		Not Reported
	Temazepam			S	Oral	30 Mg, 1d		Not Reported
	Tylenol With Codeine			S	Oral	2 Df, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16277606	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1042396		56 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To	Escitalopram			S	Oral	Unk		Not Reported

Various Agents	Metoprolol		S	Oral	Unk	Mylan
	Xarelto		C		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16279004	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1904434US			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Heart Rate Increased; Myocarditis	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Clozaril			S	Oral	Unk		Not Reported
	Clozaril			S	Oral	Unk		Not Reported
	Clozaril			S	Oral	Unk		Not Reported
	Clozaril			S	Oral	50 Mg, Qam		Not Reported
	Clozaril			S	Oral	125 Mg, Qpm		Not Reported
	Olanzapine			S	Oral	20 Mg, Qd		Not Reported
	Omeprazole			C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16279105	EXPEDITED (15-DAY)		HO	AU-TAKEDA-2019TUS027869			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Irritability; Suicidal Ideation	Brintellix			S	Unknown	10 Milligram		Takeda
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	14373900	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2017008205			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Pantoprazole			S	Oral	Unk, Unspecified		Macleods
	Escitalopram Tablet			S	Oral	Unk, Unspecified		Macleods

Abasaglar	S	Subcutaneous	Unk, Unspecified		Not Reported
Fondaparinux Sodium	S	Subcutaneous	Unk, (Solution For Injection), Unspecified		Not Reported
Lipanthyl	S	Oral	Unk, Unspecified		Not Reported
Movicol	S	Oral	Unk, Unspecified		Not Reported
Novorapid	S	Subcutaneous	Unk, Unspecified		Not Reported
Primperan	S	Oral	Unk, Unspecified		Not Reported
Xeloda	S	Oral	Unk, Unspecified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	14376008	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1002399		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Quetiapine			S	Oral	400 Mg, Qd		Not Reported
	Quetiapine			S		Unk		Not Reported
	Quetiapine			S		Unk		Not Reported
	Methylphenidate			S	Oral	110 Mg, Qd		Not Reported
	Methylphenidate			S		Unk		Not Reported
	Methylphenidate			S	Oral	100 Mg, Unk		Not Reported
	Laroxyl			S	Unknown	Unk		Mylan
	Laroxyl			S		Unk		Mylan
	Laroxyl			S		Unk		Mylan
	Lexapro			S	Oral	10 Mg, Qd		Mylan
	Lexapro			S		Unk		Mylan
	Lexapro			S		Unk		Mylan
	Xeroquel			S		Unk		Mylan
	Xeroquel			S		Unk		Mylan
	Xeroquel			S	Oral	400 Mg, Qd		Mylan
	Seroplex			S	Oral	10 Mg, Qd		Mylan
	Seroplex			S		Unk		Mylan

Seroplex	S		Unk		Mylan
Ritaline	S	Oral	100 Mg, Unk		Mylan
Ritaline	S		Unk		Mylan
Ritaline	S	Oral	110 Mg, Qd		Mylan
Ritaline	S		Unk		Mylan
Lepticur	S	Unknown	15 Mg, Unk		Mylan
Lepticur	S		Unk		Mylan
Lepticur	S		Unk		Mylan
Abilify	S		Unk		Mylan
Abilify	S	Oral	15 Mg, Qd		Mylan
Abilify	S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	15897568	EXPEDITED (15-DAY)		OT	GB-ELI_LILLY_AND_COMPANY-GB201901013817		46 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Heart Rate Increased; Myocarditis	Olanzapine			S	Oral	20 Mg, Daily		Eli Lilly And Co
	Clozaril			S	Oral	175 Mg, Each Morning		Not Reported
	Clozaril			S	Oral	125 Mg, Each Evening		Not Reported
	Clozaril			S	Oral	50 Mg, Each Morning		Not Reported
	Clozaril			S	Oral	Unk, Unknown		Not Reported
	Clozaril			S	Oral	Unk Unk, Unknown		Not Reported
	Clozaril			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported
	Omeprazole			C	Oral	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16279637	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US02879			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Product Substitution Issue	Escitalopram		S	Unknown	Unk	Invagen
	Escitalopram		S			Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16279673	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US02881			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16279699	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2019IN02904			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective	Escitalopram			S	Unknown	30 Milligram, Per Day, For Past 5 Years		Invagen
	Risperidone			S	Unknown	Unk, Augmentation Therapy, For Past 5 Years		Not Reported
	Fluvoxamine			S	Unknown	Upto 350 Mg/Day, For Past 5 Years		Not Reported
	Sertraline			S	Unknown	Up To 100mg/Day, For Past 5 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16279774	EXPEDITED (15-DAY)		LT	FR-ROCHE-2312038		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Diazepam			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16279795	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-207133			Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Blood Prolactin Increased; Breast Pain; Galactorrhoea; Intentional Product Misuse	Escitalopram			S	Unknown	10 Milligram, Daily		Not Reported
	Escitalopram			S	Unknown	20 Milligram, Daily		Not Reported
	Fluoxetine			S	Unknown	20 Milligram, Daily		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16280043	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US02953			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall; Gait Disturbance; Loss Of Consciousness; Seizure	Escitalopram			S	Oral	10 Milligram, Unk		Invagen
	Escitalopram			S				Invagen
	Ibgard			C	Unknown	Unk, Tid (3 Times A Day Before Meals)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16280633	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2019-024337			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Perindopril			S	Oral	8 Milligram, Once A Day		Aurobindo
	Amlodipine			S	Oral	10 Milligram, Once A Day		Aurobindo
	Ditropan			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Seroplex			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Fludex (Indapamide)			S	Oral	Inconnue		Not Reported
	Zelitrex			S	Oral	6 Dosage Form, Once A		Not Reported

				Day		
	Cortancyl	C	Oral	2 Milligram, Once A Day		Not Reported
	Paracetamol	C	Oral	3 Dosage Form, Once A Day		Not Reported
	Movicol	C	Oral	2 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16283975	EXPEDITED (15-DAY)		HO, OT	PT-ALLERGAN-1919091US			Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram Oxalate - Bp			S	Oral	14 Cp De 20 Mg + 27 Cp De 10 Mg		Allergan
	Lorazepam			S	Oral	72 Cp De 2.5 Mg		Not Reported
	Bupropion			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Diazepam			C				Not Reported
	Venlafaxine			C				Not Reported
	Olanzapine			C				Not Reported
	Topiramate			C				Not Reported
	Hydroxycarbamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16283976	EXPEDITED (15-DAY)		DS	DE-ALLERGAN-1919068US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Feeling Hot; Headache; Hyperhidrosis; Hypogeusia; Hyposmia; Pain In Extremity; Presyncope; Product Use In Unapproved Indication; Tremor	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Gtt, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	14781731	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018012697			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Communication Disorder; Lethargy; Loss Of Personal Independence In Daily Activities; Memory Impairment; Sluggishness	Escitalopram 10mg Tablet			S	Oral	10 Mg, Qd, (1 Tablet Per Day 10mg)		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	15795074	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007588		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Doxepin Hcl			S	Oral	Unk		Pfizer
	Acetaminophen			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	16284905	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US02878			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	16285202	EXPEDITED (15-DAY)		HO, LT, OT	GB-ACCORD-126336		84 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury;	Escitalopram			S	Oral			Not Reported

Hypotension	Furosemide	S	Oral		Accord
	Irbesartan	S	Oral		Accord
	Braltus	C			Not Reported
	Seretide	C		125	Not Reported
	Simvastatin	C			Not Reported
	Zapain	C		1-2 Four Times Daily	Not Reported
	Salbutamol	C			Not Reported
	Sando-K	C		Various Acute Scripts	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	16286356	EXPEDITED (15-DAY)		OT	FR-ROCHE-2310609			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyperkalaemia; Hypokalaemia; Nephropathy Toxic; Ototoxicity; Sedation	Mycophenolate Mofetil			S	Unknown			Not Reported
	Fluconazole			S	Unknown			Not Reported
	Nicardipine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Roxithromycine			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Ursodesoxycholic Acid			S	Unknown			Not Reported
	Voriconazole			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Posaconazole			S	Unknown			Not Reported
	Piperacilline [Piperacillin]			S	Unknown			Not Reported
	Esomeprazole			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Vincristine			S	Unknown			Not Reported
	Trimetoprim			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	16286559	NON-EXPEDITED			US-PFIZER INC-2019191839		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Phytomenadione			S		Unk		Unknown
	Bromine			S		Unk		Not Reported
	Toradol			S		Unk		Not Reported
	Darvocet			S		Unk		Not Reported
	Flexeril [Cyclobenzaprine Hydrochloride]			S		Unk		Not Reported
	Lopressor			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Tenormin			S		Unk		Not Reported
	Carvedilol			S		Unk		Not Reported
	Lamictal			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Losartan Potassium			S		Unk		Not Reported
	Metrogel			S		Unk		Not Reported
	Propoxyphene			S		Unk		Not Reported
	Thimerosal			S		Unk		Not Reported
	Topamax			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	16288101	EXPEDITED (15-DAY)		DS	PHHY2019ES103835		32 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Derealisation; Disturbance In Attention; Feeling	Alprazolam			S	Unknown	0,25 Por La Mañana, Y A Veces Por La Tarde		Novartis

Abnormal; Palpitations; Somnolence					Noche	
	Escitalopram		S	Unknown	5 Mg, Unk (Diarios)	Not Reported
	Rhodiola Rosea		C	Unknown	Unk	Not Reported
	Pantoprazol		C	Unknown	Unk (1 Al Día)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	16289847	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro 20mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	13997082	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2017403746		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt	Pf-06886992			S	Intramuscular	0.5 Ml, Single		Pfizer
	Pf-06886992			S		0.5 Ml, Single		Pfizer
	Geodon			S	Oral	20 Mg, Qhs		Pfizer
	Lexapro			S	Oral	10 Mg, Daily		Not Reported
	Lexapro			S	Oral	20 Mg, Daily		Not Reported
	Lexapro			S	Oral	10 Mg, 2x/Day		Not Reported
	Celexa /00582602/			C	Oral	20 Mg, Daily		Not Reported
	Celexa /00582602/			C	Oral	20 Mg, 2x/Day		Not Reported
	Trileptal			C	Oral	150 Mg, 2x/Day		Not Reported
	Gianvi			C	Oral	1 Tab, Daily		Not Reported
	Buspirone			C	Oral	10 Mg, 2x/Day		Not Reported
	Ambien			C	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16261340	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1918464US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Fludex (Indapamide)			S	Oral	Unk		Not Reported
	Zelitrex			S	Oral	6 Df, Qd		Not Reported
	Zelitrex			S				Not Reported
	Ditropan			S	Oral	2 Df, Qd		Not Reported
	Perindopril			S	Oral	8 Mg, Qd		Not Reported
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported
	Movicol			C	Oral	2 Df, Qd		Not Reported
	Paracetamol			C	Oral	3 Df, Qd		Not Reported
	Cortancyl			C	Oral	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16288562	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-02855		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Headache; Hyperhidrosis; Hypothalamic Pituitary Adrenal Axis Suppression; Nausea; Oedema	Levothyroxine			S	Unknown	Unk		Lupin
	Escitalopram			S	Unknown	10 Milligram, Qd		Lupin
	Escitalopram			S	Unknown	5 Milligram, Qd (Decrease)		Lupin
	Escitalopram			S	Unknown	10 Milligram, Qd		Lupin
	Premarin			C	Unknown	625 Microgram, Bid (12 Hour)		Not Reported
	Biotin			C	Unknown	10000 Microgram, Qd		Not Reported
	Fish Oil			C	Unknown	1200 Milligram, Qd		Not Reported
	Vitamin B12 Aaa			C	Unknown	5000 Microgram, Qd		Not Reported
	Selenium			C	Unknown	200 Microgram, Qd		Not Reported
	Dexilant			C	Unknown	30 Milligram, Qd		Not Reported
	Magnesium			C	Unknown	250 Milligram, Qd		Not Reported
	Vitamin D3			C	Unknown	5000 International Unit, Qd		Not Reported

	Glucosamine Chondroitin & Msm	C	Unknown	1500 Milligram, Qd	Not Reported
	Armour Thyroid	C	Unknown	7.5 Milligram, Qd (On Mondays And Thursdays)	Not Reported
	Tirosint	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16290607	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087695			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Aleve			S	Unknown	1000 Mg, Qd		Bayer
	Aleve			S	Unknown	Unk		Bayer
	Cimzia			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown	50 Mg		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Nortriptyline			S	Oral	25 Mg, Qd		Not Reported
	Tylenol [Paracetamol]			S	Topical			Not Reported
	Diclofenac			S	Topical	Unk Unk, Qd		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	700 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16290610	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087696			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Aleve			S	Unknown	Unk		Bayer
	Aleve			S	Unknown	1000 Mg, Qd		Bayer

	Cimzia	S	Unknown	Unk	Not Reported
	Diclofenac Potassium	S	Unknown	50 Mg	Not Reported
	Escitalopram	S	Oral	20 Mg, Qd	Not Reported
	Nortriptyline	S		25 Mg, Qd	Not Reported
	Tylenol [Paracetamol]	S	Topical	Unk	Not Reported
	Voltaren [Diclofenac]	S	Topical	Unk Unk, Qd	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	700 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16290834	EXPEDITED (15-DAY)		OT	PHHY2019US102561		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Delirium; Delusion; Depression; Hallucination; Paranoia; Therapeutic Response Decreased	Pramipexole			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Novartis
	Selegiline			S	Unknown			Not Reported
	Levodopa/Carbidopa			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16291689	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019AMR079671			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Product Use In Unapproved Indication; Therapy	Wellbutrin Sr Prolonged-Release Tablet			S		20 Mg, Bid		Glaxosmithkline
	Lexapro			S		Unk		Not Reported

Change

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16296687	DIRECT					58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram Oxalate 10 Mg			S	Oral	Quantity:1 Tablet(S);		Accord
	Telmisartan			C				Not Reported
	One A Day Multi Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	15920586	EXPEDITED (15-DAY)		OT	PL-MYLANLABS-2019M1009721		34 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Fear-Related Avoidance Of Activities; Learning Disorder; Mental Impairment; Overdose; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	Unk (Overdose: 37.5 Mg Per Day)		Not Reported
	Escitalopram			S		10 Milligram, Qd		Not Reported
	Tianeptine			C	Unknown	10 Milligram, Qd (10 Mg Daily)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16248927	EXPEDITED (15-DAY)		HO	DE-ACCORD-124522		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram			S	Oral	Also Taken 5 Mg From 11-Jan-2019 To 19-Jan-2019(9 Days)Dose Increased		Not Reported
	Olanzapine			C	Oral	Taking Since> 2016, Daily Dose: 15 Mg Millgram(S) Every Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16296285	NON-EXPEDITED			US-PFIZER INC-2019197183		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Effexor Xr			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16297416	EXPEDITED (15-DAY)		DS	ES-AUROBINDO-AUR-APL-2019-024772			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam			S	Unknown	0,25 Por La Mañana, Y A Veces Por La Tarde Noche		Aurobindo
	Escitalopram 10 Mg Film-Coated Tablets Efg			S	Unknown	5mg Diarios		Aurobindo
	Rhodiola			C	Unknown	Unk		Not Reported
	Pantoprazol			C	Unknown	1 Al Día		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16298729	EXPEDITED (15-DAY)		HO, OT	DE-ASTRAZENECA-2019SE68070			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Zeneca
	Escitalopram			S	Unknown	Unk		Not Reported
	Trigoa			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	1.25mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16299196	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2019-FR-1046587		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Fludex (Indapamide)			S	Oral	Unknown		Not Reported
	Zelitrex 500 Mg, Comprime Enrobe			S	Oral			Not Reported
	Ditropan 5 Mg, Comprime Secable			S	Oral			Not Reported
	Perindopril			S	Oral			Not Reported
	Seroplex 5 Mg, Comprime Pellicule			S	Oral			Not Reported
	Amlodipine			S	Oral			Teva
	Movicol, Poudre Pour Solution Buvable En Sachet			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported
	Cortancyl			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16299547	EXPEDITED (15-DAY)		HO	IT-ACCORD-126790		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Lorazepam			C				Not Reported
	Depakin Chrono			C		500 Mg Prolonged-Release Tablets		Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16300125	EXPEDITED (15-DAY)		HO	FI-TEVA-2019-FI-1047433		71 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Lip Oedema; Oral Discomfort; Skin Burning Sensation	Escitalopram			S	Oral	10,Mg,Daily		Ivax
	Vagifem			C	Vaginal	10,Mg,Daily		Not Reported

Betaserc	C	Oral	8,Mg,Daily		Not Reported
Brilique	C	Oral	180,Mg,Daily		Not Reported
Kalcipos-D	C	Oral			Not Reported
Cardace	C	Oral			Not Reported
Primaspan	C	Oral	100,Mg,Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16301213	EXPEDITED (15-DAY)		HO, OT	US-EMD SERONO-7058874			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Anxiety; Bacterial Colitis; Catheter Site Infection; Coeliac Disease; Cognitive Disorder; Colitis Ulcerative; Crohn'S Disease; Depression; Hip Arthroplasty; Hypoaesthesia; Incoherent; Injection Site Reaction; Malignant Melanoma; Oesophageal Stenosis; Paranoia; Renal Disorder; Staphylococcal Infection; Wrong Device Used	Rebif			S	Subcutaneous			Not Reported
	Lexapro			S				Not Reported
	Prednisone			S				Not Reported
	Asacol			C				Not Reported
	Coumadin /00014802/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16301314	EXPEDITED (15-DAY)		HO	NO-ALLERGAN-1919876US			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dissociation; Pneumothorax; Psychotic Disorder; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2019	16301927	EXPEDITED (15-DAY)		HO	PHHY2019FR106762		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Loss Of Consciousness; Malaise	Fentanyl			S	Transdermal	1 Df, Q72h		Not Reported
	Zolpidem			S	Oral	10 Mg, Qd		Novartis
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Bisoprolol Fumarate			S	Oral	10 Mg, Qd		Not Reported
	Lyrica			S	Oral	1 Df, Qd		Not Reported
	Lasilix			S	Oral	1 Df, Qd		Not Reported
	Oxynormoro			S	Oral	3 Df, Qd		Not Reported
	Ebixa			S	Oral	1 Df, Qd		Not Reported
	Eliquis			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Diffu K			C	Unknown			Not Reported
	Transipeg			C	Unknown			Not Reported
	Gaviscon			C	Unknown			Not Reported
	Okimus			C	Unknown	Unk		Not Reported
	Melaxose			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	15204006	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-933317		25 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Mental Impairment; Product Substitution Issue	Escitalopram			S	Oral	15 Milligram Daily;		Ivax
	Escitalopram			S				Ivax
	Acetaminophen			C				Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aczone			C				Not Reported
	Azithromycin			C		Form Of Admin: Not		Not Reported

			Specified	
Benzaclin Topical	C			Not Reported
Calcium	C		Form Of Admin: Not Specified	Not Reported
Canesten-Hc 1% Cream-Powder Mixture	C			Not Reported
Cetaphil Acne Principles	C			Not Reported
Cetaphil Moisturizing Lotion	C			Not Reported
Cetaphil Oily Skin Cleanser	C			Not Reported
Cipralex	C			Not Reported
Diclofenac	C			Not Reported
Domperidone	C			Not Reported
Epival Ect 250mg	C			Not Reported
Flovent Diskus	C			Not Reported
Flovent Hfa	C			Not Reported
Genteal	C			Not Reported
Nasacort Aq	C		Form Of Admin:Spray, Metered Dose	Not Reported
Omega 3-6-9	C		Form Of Admin: Not Specified	Not Reported
Otrivin Saline Hypertonic Nasal Spray	C	Nasal		Not Reported
Seroquel	C			Not Reported
Seroquel	C			Not Reported
Synthroid	C		Form Of Admin: Not Specified	Not Reported
Tears Plus 1.4%	C			Not Reported
Tecta	C			Not Reported
Toviaz	C			Not Reported
Tylenol	C			Not Reported
Tylenol Extra-Strength Tab 500mg	C			Not Reported
Vitamin D2 1000 International Units Tablet	C			Not Reported
Zinc Gluconate	C		Form Of Admin: Not Specified	Not Reported
Zyloprim	C			Not Reported
Benzoyl Peroxide/Clindamycin Phosphate	C			Not Reported
Clotrimazole/Hydrocortisone	C			Not Reported

Polyvinyl Alcohol/Povidone	C		Not Reported
Valproate Semisodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	15856239	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1002492		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Motor Dysfunction; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression; Spinal Cord Oedema	Escitalopram			S	Unknown			Ivax
	Heparin Sodium			S	Subcutaneous	Form Of Admin : Solution Intravenous Dose:5000.0 Units		Not Reported
	Heparin Sodium			S				Not Reported
	Rivaroxaban (Bay59-7939)			S	Oral	15 Milligram Daily;		Not Reported
	Asa			S				Not Reported
	Rivaroxaban (Bay59-7939)			S				Not Reported
	Bupivacaine			C	Unknown	Form Of Admin :Solution Block/Infiltration		Not Reported
	Epinephrine			C	Unknown	Form Of Admin : Not Specified		Not Reported
	Hydromorphone			C	Unknown	Form Of Admin : Not Specified		Not Reported
	Lidocaine			C	Unknown	Form Of Admin : Not Specified		Not Reported
	Asa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	15947429	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-006751			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Heart Rate Increased; Myocarditis	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Olanzapine			S	Oral	20 Milligram, Once A Day		Aurobindo
	Clozaril			S	Oral	125 Milligram, Once A Day,125 Milligram, Pm		Not Reported
	Clozaril			S	Oral	50 Milligram, Once A		Not Reported

					Day,50 Milligram, Am	
	Clozaril		S	Unknown	Unk	Not Reported
	Clozaril		S	Oral	Unk	Not Reported
	Omeprazole		C	Oral	20 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16303656	NON-EXPEDITED		HO	US-JNJFOC-20190500102			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Noncompliance	Haloperidol			S	Oral			Not Reported
	Abilify Maintena			S	Other			Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16304233	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1919878US		49 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Cerebellar Syndrome; Drug Abuse; Hepatomegaly; Incorrect Route Of Product Administration	Escitalopram Oxalate - Bp			S	Nasal	1 Df (Tablet), Qam		Allergan
	Cannabis			S	Respiratory (inhalation)	1 Day Per Month		Not Reported
	Alcohol			S	Oral	20 Units, Qd		Not Reported
	Nicotiana Tabacum			S	Respiratory (inhalation)	10 Cigarettes, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16305221	EXPEDITED (15-DAY)		HO, OT	AT-MYLANLABS-2019M1044133			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression; Agitation; Alcoholism; Apraxia; Behaviour Disorder; Cognitive Disorder; Dementia; Dementia With Lewy Bodies; Depression; Drug Ineffective; Dysphoria; Hallucination; Hallucination, Visual; Insomnia; Korsakoff'S Syndrome; Mania; Muscle Rigidity; Parkinsonism; Restlessness; Sleep Disorder; Tremor; Urinary Incontinence	Escitalopram	S		10 Mg	Not Reported
	Escitalopram	S		3 Mg, Qd	Not Reported
	Pregabalin	S	Oral	25 Mg, Bid	Not Reported
	Pregabalin	S	Oral	50 Mg	Not Reported
	Oxazepam	S		Unk	Not Reported
	Lorazepam	S		Unk	Mylan
	Piracetam	S		1200 Mg	Mylan
	Cerebrolysin	S		Unk	Mylan
	Mirtazapine	S		15 Mg	Mylan
	Rivastigmine	S	Transdermal	4.6 Mg, Qd	Mylan
	Rivastigmine	S	Transdermal	Unk (Dose Increased).	Mylan
	Risperdal	S		Unk	Mylan
	Risperidone	S		3 Mg, Qd	Mylan
	Risperidone	S		1 Mg	Mylan
	Risperidone	S		Unk	Mylan
	Quetiapine	S	Oral	100 Mg	Mylan
	Quetiapine	S		25 Mg In The Eveningunk	Mylan
	Quetiapine	S		Slowly Increased Unk	Mylan
	Valproic Acid	S		1000 Mg, Qd	Mylan
	Naltrexone	S		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16305434	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1047609		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dry Mouth; Tension Headache	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Apixaban			C				Not Reported
	Rosuvastatin Tablet			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16305435	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1047610		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Affective Disorder; Condition Aggravated; Insomnia	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Atorvastatin Calcium			C				Not Reported
	Candesartan			C				Not Reported
	Januvia			C				Not Reported
	Pantoloc /01263204/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16305439	EXPEDITED (15-DAY)		LT	CA-TEVA-2019-CA-1047600		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Bradycardia; Syncope; Torsade De Pointes	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Pramipexole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16306117	EXPEDITED (15-DAY)		HO	US-GLAXOSMITHKLINE-US2019AMR082943			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Noncompliance	Wellbutrin			S		Unk		Glaxosmithkline
	Escitalopram			S		Unk		Glaxosmithkline
	Aripiprazole			S		Unk		Not Reported
	Haloperidol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16306876	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1919875US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Escitalopram Oxalate - Bp	S	Transplacental	20 Mg, Qd		Allergan
	Saroten Retard	S	Transplacental	25 Mg, Qd		Not Reported
	Atarax	S	Transplacental	12.5 Mg, Qd		Not Reported
	Dafalgan	S	Transplacental	Unk, Prn		Not Reported
	Pantoprazol	S	Transplacental	Usual Treatment		Not Reported
	Levetiracetam	S	Transplacental	500 Mg, Qod		Not Reported
	Pregabalin	S	Unknown	150 Mg, Qod		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16307403	EXPEDITED (15-DAY)		HO, OT	CH-UCBSA-2019018502		< 1 DAY	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia Neonatal; Maternal Exposure During Pregnancy	Levetiracetam			S	Transplacental	500 Milligram, 2x/Day (Bid)		Not Reported
	Atarax			S	Transplacental	12.5 Milligram, Once Daily (Qd)		Not Reported
	Dafalgan			S	Transplacental	As Necessary		Not Reported
	Saroten Retard			S	Transplacental	25 Milligram, Once Daily (Qd)		Not Reported
	Pantoprazol			S	Transplacental	40 Milligram, Once Daily (Qd)		Not Reported
	Pregabalin			S	Transplacental	150 Milligram, 2x/Day (Bid)		Not Reported
	Cipralex			S	Transplacental	20 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16307598	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2019AP013765		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Partial Seizures	Olanzapine			S	Unknown	Unk		Apotex

	Tramadol	S	Unknown	Unk		Apotex
	Escitalopram	S	Unknown	Unk		Apotex
	Clopidogrel	S	Unknown	Unk		Apotex
	Ciprofloxacin	S	Unknown	Unk		Apotex
	Prednisone	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16307713	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-207706		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Perindopril			S	Oral	8 Milligram, Daily		Not Reported
	Amlodipine			S	Oral	10 Milligram, Daily		Sun
	Fludex 1,5 Mg, Comprime Pellicule A Liberation Prolongee			S	Oral	Unk		Not Reported
	Zelitrex 500 Mg, Comprime Enrobe			S	Oral	6 Dosage Form, Daily		Not Reported
	Ditropan 5 Mg, Comprime Secable			S	Oral	2 Dosage Form, Daily		Not Reported
	Seroplex 5 Mg, Comprime Pellicule			S	Oral	1 Dosage Form, Daily		Not Reported
	Movicol, Poudre Pour Solution Buvable En Sachet			C	Oral	2 Dosage Form, Daily		Not Reported
	Paracetamol			C	Oral	3 Dosage Form, Daily		Not Reported
	Cortancyl			C	Oral	2 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16307961	EXPEDITED (15-DAY)		HO	US-APOTEX-2019AP013773		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Condition Aggravated; Delusion; Hallucination;	Escitalopram			S	Unknown	Unk		Apotex
	Quetiapine			S	Unknown	Unk		Apotex

Paranoia; Therapeutic Product Effect Incomplete	Carbidopa Levodopa		C	Unknown	Unk	Not Reported
	Pramipexole		C	Unknown	Unk	Not Reported
	Selegiline		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16309055	NON-EXPEDITED			US-PFIZER INC-2019200923			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Levofloxacin			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16309120	EXPEDITED (15-DAY)		OT	US-BAYER-2019-093902		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoptysis; Labelled Drug-Drug Interaction Medication Error; Pulmonary Alveolar Haemorrhage	Acetylsalicylic Acid (Cardio)		Y	S				Bayer
	Warfarin			S				Not Reported
	Metoprolol			S				Not Reported
	Atorvastatin			S				Not Reported
	Escitalopram			S				Not Reported
	Glipizide			S				Not Reported
	Loratadine			S				Not Reported
	Losartan			C				Not Reported
	Omeprazole			C				Not Reported
	Pirfenidone			C		801 Mg, Tid		Not Reported
	Acetaminophen			C				Not Reported
	Multivitamins [Vitamins Nos]			C				Not Reported
	Paracetamol			C				Bayer
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16310999	NON-EXPEDITED			US-VALIDUS PHARMACEUTICALS LLC-US-			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Dizziness; Fatigue; Headache; Insomnia; Nausea; Pruritus; Rash; Urticaria	Demerol			S	Unknown	Unk		Validus
	Ambien			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Carbidopa/Levodopa			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Hydrocortisone			S	Unknown	Unk		Not Reported
	Oxaprozin			S	Unknown			Not Reported
	Donepezil Hydrochloride			S	Unknown	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Cefalexin			S	Unknown			Not Reported
	Levetiracetam			S	Unknown			Not Reported
	Lamotrigine			S	Unknown			Not Reported
	Paroxetine Hydrochloride			S	Unknown			Not Reported
	Promethazine			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Zonisamide			S	Unknown			Not Reported
	Hydrocodone			S	Unknown			Not Reported
	Talwin /00052102/			S	Unknown			Not Reported
	Nabumetone			S	Unknown			Not Reported
	Indocin /00003805/			S	Unknown			Not Reported
	Hycotuss			S	Unknown			Not Reported
	Provigil /01265601/			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

	Duloxetine	S	Unknown			Not Reported
	Tiagabine	S	Unknown			Not Reported
	Escitalopram	S	Unknown			Not Reported
	Pramipexole	S	Unknown			Not Reported
	Ropinirole	S	Unknown	Unk		Not Reported
	Trazodone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16311002	NON-EXPEDITED			US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000168			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Confusional State; Dizziness; Fatigue; Headache; Insomnia; Nausea; Pruritus; Rash; Urticaria	Demerol			S	Unknown			Validus
	Talwin Nx			S	Unknown	Unk		Not Reported
	Ambien			S	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Carbidopa/Levodopa			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Cortizone 10			S	Unknown			Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Daypro			S	Unknown	Unk		Not Reported
	Donepezil Hydrochloride			S		Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Gabitril			S	Unknown			Not Reported
	Hycotuss			S	Unknown	Unk		Not Reported
	Indocin /00003801/			S	Unknown			Not Reported

Keflex /00145501/	S	Unknown			Not Reported
Levetiracetam	S	Unknown	Unk		Not Reported
Lamotrigine	S	Unknown	Unk		Not Reported
Lexapro	S	Unknown	Unk		Not Reported
Pramipexole Hydrochloride	S	Unknown	Unk		Not Reported
Nabumetone	S	Unknown	Unk		Not Reported
Paroxetine Hydrochloride	S	Unknown			Not Reported
Promethazine	S		Unk		Not Reported
Provigil /01265601/	S	Unknown			Not Reported
Requip	S	Unknown			Not Reported
Trazodone Hydrochloride	S				Not Reported
Venlafaxine Hydrochloride	S	Unknown	Unk		Not Reported
Zonisamide	S	Unknown	Unk		Not Reported
Hydrocodone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16311842	EXPEDITED (15-DAY)		DS	ES-TEVA-2019-ES-1048255		32 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam O,25			S	Unknown	0.25 In The Morning, And Sometimes In The Evening		Actavis
	Escitalopram Flas Cinfa 10 Mg Tablets Bucodispersables Efg, 28 Tablets			S	Oral	5 Mg Daily		Not Reported
	Rhodiola			C	Unknown			Not Reported
	Pantoprazol 20,Mg			C	Unknown	1 A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	15001540	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2018M1038482		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cyst	Escitalopram	S	Oral	10 Mg, Unk (Currently)	Not Reported
	Escitalopram	S	Oral	15 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	15545805	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018433138		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anger; Anxiety; Arthropod Bite; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cerebrovascular Accident; Contusion; Cough; Crying; Depressed Mood; Depression; Diarrhoea; Drug Hypersensitivity; Emotional Distress; Erythema; Fall; Fatigue; Feeling Abnormal; Feeling Jittery; Gait Disturbance; Head Banging; Headache; Hypertension; Hypoacusis; Inappropriate Schedule Of Product Administration; Joint Swelling; Malaise; Malignant Neoplasm Progression; Mental Disorder; Muscular Weakness; Nasopharyngitis; Nausea; Nervousness; Pain In Extremity; Peripheral Swelling; Pneumonia; Pollakiuria; Productive Cough; Psychiatric Symptom; Rash; Rib Fracture; Screaming;	Pantoprazole			S	Unknown	Unk		Pfizer
	Amlodipine Besilate			S	Unknown	10 Mg, 1x/Day		Pfizer
	Calcium Carbonate			S	Unknown	Unk		Pfizer
	Hydromorphone Hydrochloride			S	Unknown	Unk		Unknown
	Ergocalciferol			S	Unknown	Unk		Not Reported
	Sandostatin			S	Intramuscular	20 Mg, Monthly		Not Reported
	Sandostatin			S	Intramuscular	30 Mg, Monthly		Not Reported
	Sandostatin			S	Intramuscular	20 Mg, Monthly		Not Reported
	Sandostatin			S	Intramuscular	30 Mg, Unk		Not Reported
	Sandostatin			S		20 Mg, Monthly		Not Reported
	Sandostatin			S	Subcutaneous	Unk, Bid		Not Reported
	Sandostatin			S	Subcutaneous	20 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Olanzapine			C	Unknown	Unk		Not Reported
	Prucalopride Succinate			C	Unknown	Unk		Not Reported
	Perindopril			C	Unknown	4 Mg, 1x/Day		Not Reported
	Prednisone			C		35 Mg, Unk		Not Reported
	Hydromorphone Hcl			C		Unk		Not Reported

Suicidal Ideation; Suicide Attempt; Tremor; Unresponsive To Stimuli; Vasculitis; Wound; Wrist Fracture

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16310375	EXPEDITED (15-DAY)		OT	FR-ACCORD-127174			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Prescription Form Tampering	Escitalopram			S	Unknown	Unspecified		Not Reported
	Quetiapine			S	Unknown	Unspecified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16312715	EXPEDITED (15-DAY)		HO, OT	PT-MACLEODS PHARMACEUTICALS US LTD-MAC2019021249			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram			S	Oral	14 Mg Of 20 Mg + 27 Mg Of 10 Mg, Autointoxication		Macleods
	Lorazepam			S	Oral	Unk, 72 Mg Of 2.5 Mg		Not Reported
	Bupropiom			C	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Venlafaxine			C	Unknown	Unk		Not Reported
	Olanzapine			C	Unknown	Unk		Not Reported
	Topiramate			C	Unknown	Unk		Not Reported
	Hydroxycarbamide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16312717	EXPEDITED (15-DAY)		DS	DE-MACLEODS PHARMACEUTICALS US LTD-			Unknown	DEU

MAC2019021255

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Feeling Hot; Headache; Hyperhidrosis; Hypogeusia; Hyposmia; Pain In Extremity; Presyncope; Tremor	Escitalopram			S	Unknown	5 (Drp)		Macleods
	Escitalopram			S	Unknown	20 Mg/Ml, 6-7 Tropfen		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16314139	EXPEDITED (15-DAY)		OT	US-APOTEX-2019AP013768		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Sexually Inappropriate Behaviour	Escitalopram			S	Unknown			Apotex
	Donepezil			C	Unknown	10 Mg, Qd		Not Reported
	Memantine			C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16317170	NON-EXPEDITED			US-SA-2019SA129843			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyspnoea; Feeling Abnormal	Multaq			S		Unk Unk, Unk		Sanofi
	Escitalopram Oxalate			S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16320331	DIRECT		OT			25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported

	Allegra			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16109405	EXPEDITED (15-DAY)		HO	PHHY2019FR063146		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Pantoprazol			S	Unknown	40 Mg, Qd		Novartis
	Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Lasilix Special			S	Oral	2 Df, Qd		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Coumadine			C	Oral	2 Df, Qd		Not Reported
	Spironolactone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16115195	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1912513US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate - Bp			S	Oral	1 Df, Daily		Allergan
	Pantoprazole			S	Unknown	40 Mg, Daily		Not Reported
	Lasilix Special			S	Oral	2 Df, Daily		Not Reported
	Bisoprolol			C				Not Reported
	Coumadine			C	Oral	2 Df, Qd		Not Reported
	Spironolactone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16179374	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2019151433		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Pantoprazole			S	Unknown	40 Milligram, Qd		Pfizer
	Lasilix Special [Furosemide]			S	Oral	1000 Milligram, Qd (Two Dosage Form)		Not Reported

Escitalopram	S	Oral	1 Df, 1x/Day		Not Reported
Bisoprolol Fumarate	C		Unk		Not Reported
Coumadine	C	Oral	4 Milligram, Qd		Not Reported
Spironolactone	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16318276	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2019-027137			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram			S	Oral	14 Cp De 20 Mg + 27 Cp De 10 Mg		Aurobindo
	Lorazepam			S	Oral	72 Cp De 2.5 Mg		Aurobindo
	Bupropion			C	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Venlafaxine			C	Unknown	Unk		Not Reported
	Olanzapine			C	Unknown	Unk		Not Reported
	Topiramate			C	Unknown	Unk		Not Reported
	Hydroxycarbamide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16319648	EXPEDITED (15-DAY)		OT	US-AKORN PHARMACEUTICALS-2019AKN01020		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Off Label Use; Underdose	Myorisan			S	Oral	20 Mg, 1x/Day		Akorn
	Lexapro			S		5 Mg, 1x/Day		Not Reported
	Lexapro			S		"Dose Increased"		Not Reported
	Buspirone			S		5 Mg, 3x/Day		Not Reported
	Buspirone			S		"Dose Increased"		Not Reported

	Lo Loestrin Fe	C	10 Mg, 1x/Day	Not Reported
	Methylfolate	C	400 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16320812	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2019M1046824		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Loss Of Consciousness; Malaise	Bisoprolol			S	Oral	10 Milligram, Qd		Not Reported
	Zolpidem			S	Oral	10 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported
	Fentanyl			S	Transdermal	1 Dosage Form, Q3d		Not Reported
	Lyrica			S	Oral	1 Dosage Form, Qd		Mylan
	Ebixa			S	Oral	1 Dosage Form, Qd		Mylan
	Oxynormoro			S	Oral	3 Dosage Form, Qd		Mylan
	Lasilix /00032601/			S	Oral	1 Dosage Form, Qd		Mylan
	Esomeprazole			C				Mylan
	Diffu K			C				Mylan
	Transipeg /00754501/			C				Mylan
	Gaviscon /00237601/			C				Mylan
	Okimus			C				Mylan
	Eliquis			C				Mylan
	Melaxose			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16320878	EXPEDITED (15-DAY)		HO, OT	PT-PFIZER INC-2019204342		57 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Hypotension; Intentional Overdose; Poisoning; Somnolence	Lorazepam			S	Oral	Seventy Two (72) 2.5 Mg Tablets		Pfizer
	Escitalopram			S	Oral	Fourteen (14) 20 Mg Tablets + Twenty Seven (27) 10 Mg Tablets		Not Reported

Bupropion	C	150		Not Reported
Acetylsalicylic Acid	C	100		Not Reported
Diazepam	C	5		Not Reported
Venlafaxine	C	225		Not Reported
Olanzapine	C	5		Not Reported
Topiramate	C	25		Not Reported
Hydroxycarbamide	C	500		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16321489	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2019M1006457		27 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Abuser; Sopor; Suicide Attempt	Escitalopram			S	Oral	15 Milliliter, Total		Not Reported
	Delorazepam			S	Oral	10 Milliliter, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16321515	NON-EXPEDITED			US-TEVA-2019-US-1049312		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fall; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Vision Blurred	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16321774	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1920570US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Overdose; Postictal State; Tongue Biting	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Qd		Allergan
	Dipiperon			S	Unknown	40 Mg, Qd		Not Reported

Tavor	C	Unknown	1 Mg, Prn		Not Reported
Zopiclon	C	Unknown	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16321974	EXPEDITED (15-DAY)		HO, OT	PT-TEVA-2019-PT-1050137		57 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram			S	Oral	14 Cp Of 20 Mg + 27 Cp Of 10 Mg		Ivax
	Lorazepam			S	Oral	72 Cp Of 2.5 Mg		Not Reported
	Bupropion			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Diazepam			C				Not Reported
	Venlafaxine			C				Not Reported
	Olanzapine			C				Not Reported
	Topiramate			C				Not Reported
	Hydroxycarbamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16322080	EXPEDITED (15-DAY)		DS	ES-PFIZER INC-2019201771		32 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam			S		0.25 Unk, Unk (0.25 In The Morning And Somtimes At Night)		Pfizer
	Escitalopram Cinfa			S		5 Mg, Daily		Not Reported
	Rhodiola Rosea			C		Unk		Not Reported
	Pantoprazol [Pantoprazole]			C		1 Df, Daily (1 A Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	13115532	EXPEDITED (15-DAY)		OT	IE-JNJFOC-20170100967			Unknown	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Overdose; Intentional Self-Injury	Paracetamol	Y	S	Unknown	Not Reported
	Paracetamol		S	Unknown	Not Reported
	Diazepam		S	Unknown	Not Reported
	Zopiclone		S	Unknown	Not Reported
	Alprazolam		S	Unknown	Not Reported
	Escitalopram		S	Unknown	Not Reported
	Zolpidem		S	Unknown	Not Reported
	Pregabalin		S	Unknown	Not Reported
	Venlafaxine		S	Unknown	Not Reported
	Flurazepam		S	Unknown	Not Reported
	Diclofenac		S	Unknown	Not Reported
	Ibuprofen		S	Unknown	Not Reported
	Alcohol		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16195824	EXPEDITED (15-DAY)		OT	ZA-CIPLA LTD.-2019ZA01906			Unknown	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout	Lexamil			S	Oral	10 Milligram, Qd		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16287999	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1919446US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metabolic Acidosis; Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Overdose: 28 Tablets		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Zolpidem Tartrate			C	Oral	Overdose: 22 Tablets		Not Reported
	Zolpidem Tartrate			C	Oral	Unk		Not Reported
	Marvelon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16323226	EXPEDITED (15-DAY)		DS	ES-APOTEX-2019AP014078		32 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam			S	Unknown	Unk (0.25 In The Morning, And Sometimes In The Evening)		Apotex
	Escitalopram			S	Unknown	5 Mg, Qd		Not Reported
	Rhodiola /02220301/			C	Unknown	Unk		Not Reported
	Pantoprazol /01263201/			C	Unknown	1 Al Día		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16323739	EXPEDITED (15-DAY)		HO	ZA-LUPIN PHARMACEUTICALS INC.-2019-02952			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block	Zartan Tablets			S	Oral	100 Milligram		Lupin
	Bilocor Tablets			S	Oral	5 Milligram		Not Reported
	Lexamil			S	Oral	10 Milligram		Not Reported
	Humalog Mix			S	Intramuscular	Unk		Not Reported
	Puresis			S	Oral	40 Milligram		Not Reported
	Aspavor			S	Oral	20 Milligram		Not Reported
	Ecotrin			S	Oral	81 Milligram		Not Reported
	B-Cal-D			S	Oral	Unk (Swallow)		Not Reported
	Puricos			S	Oral	100 Milligram		Not Reported
	Coxflam			S	Oral	15 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16324095	EXPEDITED (15-DAY)		LT	FR-ACCORD-127776		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyperreflexia; Mydriasis; Poisoning Deliberate	Escitalopram	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16324185	EXPEDITED (15-DAY)		DS	DE-TEVA-2019-DE-1049129		57 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Feeling Hot; Headache; Hyperhidrosis; Hypogeusia; Hyposmia; Pain In Extremity; Presyncope; Tremor	Escitalopram 20 Mg/Ml			S		5gtt		Ivax
	Escitalopram 20 Mg/Ml			S		6-7 Tropfen		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16324249	EXPEDITED (15-DAY)		DS	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-207875		32 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam			S	Unknown	0,25 Por La Manana, Y A Veces Por La Tarde Noche ()		Sun
	Escitalopram Flas Cinfa 10 Mg Comprimidos Bucodispersables Efg , 28...			S	Unknown	5mg Diarios ()		Not Reported
	Rhodiola			C	Unknown	()		Not Reported
	Pantoprazol 20,Mg			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16325132	EXPEDITED (15-DAY)		HO, OT	PT-APOTEX-2019AP014010		57 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Hypotension; Intentional	Escitalopram			S	Oral	Unk		Apotex
	Lorazepam			S	Oral	Unk		Not Reported

Overdose; Somnolence	Bupropion		C	Unknown	Unk	Not Reported
	Acetylsalicylic Acid		C	Unknown	Unk	Not Reported
	Diazepam		C	Unknown	Unk	Not Reported
	Venlafaxine		C	Unknown	Unk	Not Reported
	Olanzapine		C	Unknown	Unk	Not Reported
	Topiramate		C	Unknown	Unk	Not Reported
	Hydroxycarbamide		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16325196	EXPEDITED (15-DAY)		OT	PT-APOTEX-2018AP025261		27 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dystonia; Gait Disturbance; Posture Abnormal; Stiff Person Syndrome	Escitalopram			S	Unknown	20 Mg, Unknown		Apotex
	Escitalopram			S				Apotex
	Insulin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16325528	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2019206937		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Amlodipine			S	Oral	10 Mg, 1x/Day		Pfizer
	Zelitrex			S	Oral	3000 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	5 Mg, 1x/Day		Not Reported
	Fludex [Indapamide]			S	Oral	Unk		Not Reported
	Perindopril			S	Oral	8 Mg, 1x/Day		Not Reported
	Ditropan			S	Oral	10 Mg, 1x/Day		Not Reported
	Paracetamol			C	Oral	3 Df, 1x/Day		Not Reported
	Movicol			C	Oral	2 Df, 1x/Day		Not Reported
	Cortancyl			C	Oral	2 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16326497	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1920582US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Intentional Overdose	Escitalopram Oxalate - Bp			S	Oral	120 Mg In Total		Allergan
	Seresta			S	Oral	48 Df In Total		Not Reported
	Bromazepam			S	Oral	180 Mg In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16326621	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA-2019SE73316		59 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Drug Interaction; Electrocardiogram Qt Prolonged; Psychomotor Skills Impaired	Escitalopram			S	Oral			Not Reported
	Nexium Mups			S	Oral			Astrazeneca
	Novorapid			C				Not Reported
	Lantus			C				Not Reported
	Aspirin Cardio			C				Not Reported
	Wellvone			C				Not Reported
	Atacand			C				Not Reported
	Beloc Zok			C				Not Reported
	Tivicay			C				Not Reported
	Descovy			C				Not Reported
	Laxoberon			C				Not Reported
	Pregabalin			C				Not Reported
	Colecalciferol			C				Not Reported
	Transtec			C				Not Reported
	Temgesic			C		As Necessary		Not Reported
	Bulboid			C		As Necessary		Not Reported
	Riopan			C		As Necessary		Not Reported
	Dafalgan			C		As Necessary		Not Reported
	Capecitabine			C				Not Reported
	Capecitabine			C		Cyclical		Not Reported
	Temozolomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16327324	EXPEDITED (15-DAY)		DS	IT-MYLANLABS-2019M1046576		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autism Spectrum Disorder	Escitalopram			S	Oral	5 Gtt Drops, Qd		Not Reported
	Risperidone			S	Oropharingeal	1 Milligram, Qd		Not Reported
	Depakin			C	Oral	100 Milligram, Qd		Mylan
	Rivotril			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16327673	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1920837US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anhedonia; Apathy; Depression; Fatigue; Flatulence; Frequent Bowel Movements; Gastrointestinal Sounds Abnormal; Malaise; Negative Thoughts; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Allopurinol			C	Unknown	1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16327838	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-027795			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective; Feeling Abnormal; Muscular Weakness; Suicidal Ideation	Escitalopram Tablets			S	Oral	Unk Unk, Once A Day		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Clonazepam			S	Oral	0.5 Milligram, 3 Times A Day		Not Reported
	Clonazepam			S				Not Reported

	Clonazepam	S				Not Reported
	Zopiclone	S	Oral	7.5 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16327966	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-027906			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angle Closure Glaucoma; Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Underdose	Escitalopram Tablets			S	Oral	5 Milligram, Unk		Aurobindo
	Saphris			S	Oral	1.25 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16327974	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027628			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Duloxetine			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16327975	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-026644			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Duloxetine			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16327976	EXPEDITED (15-DAY)		DS, HO, OT	CA-AUROBINDO-AUR-APL-2019-027622			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Motor Dysfunction; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression; Spinal Cord Oedema	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Heparin Sodium			S	Subcutaneous	Two Times A Day		Not Reported
	Heparin Sodium			S				Not Reported
	Rivaroxaban			S	Unknown	15 Milligram, Once A Day		Not Reported
	Rivaroxaban			S				Not Reported
	Rivaroxaban			S				Not Reported
	Bupivacaine			C	Unknown	Unk		Not Reported
	Epinephrine			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Lidocaine			C	Unknown	3 Milliliter		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328029	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027428			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Tablets			S	Unknown	15 Milligram		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Quetiapine Film-Coated Tablet			S	Unknown	150 Milligram		Aurobindo
	Levothyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328084	EXPEDITED (15-DAY)		HO	FR-ZYDUS-036741		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Loss Of Consciousness; Malaise	Zolpidem			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported
	Memantine			S	Oral			Not Reported
	Oxynormoro			S	Oral	5 Mg, Orodispersible Tablet		Not Reported

Furosemide	S	Oral	40 Mg, Scored Tablet		Not Reported
Escitalopram	S	Oral			Cadila
Bisoprolol Hemifumarate	S	Oral			Not Reported
Esomeprazole	C	Unknown			Not Reported
Potassium	C	Unknown			Not Reported
Macrogol	C	Unknown			Not Reported
Alginic Acid/Aluminium Hydroxide Gel/Dried/Magnesium Trisilicate/Sodium Bicarbonate	C	Unknown			Not Reported
Okimus	C	Unknown			Not Reported
Fentanyl	S	Transdermal			Not Reported
Apixaban	C	Unknown			Not Reported
Lactulose	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328454	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-026662			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Incorrect Dose Administered; Suicidal Ideation	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Unknown	112.5 Milligram		Aurobindo
	Cipralex			S	Unknown	15 Milligram, Daily		Not Reported
	Cipralex			S	Unknown	20 Milligram		Not Reported
	Effexor			S	Unknown	75 Milligram		Not Reported
	Effexor			S	Unknown	37.5 Milligram		Not Reported
	Quetiapine			C	Unknown	Unk		Not Reported
	Seroquel			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16331733	DIRECT		DS, HO, LT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Akathisia; Anxiety; Fear; Malaise	Lorazepam	S	Oral		Pfizer
	Escitalopram	S			Not Reported
	Olanzapine	S			Not Reported
	Risperidone	S			Not Reported
	Abilify	S			Not Reported
	Aripiprazole	S			Not Reported
	Alprazolam	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328736	EXPEDITED (15-DAY)		OT	TN-PRINSTON PHARMACEUTICAL INC.-2019PRN00493		38 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram			S	Unknown	Unk		Prinston Pharmaceutical
	Carbamazepine			S	Unknown	Unk		Not Reported
	Levomepromazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16307366	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US03035			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Off Label Use; Product Use In Unapproved Indication; Sexually Inappropriate Behaviour	Escitalopram			S	Unknown	Unk		Invagen
	Gabapentin			S	Unknown	300 Milligram, Tid		Invagen
	Donepezil			C	Unknown	10 Milligram		Not Reported
	Memantine			C	Unknown	10 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329841	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2019-027926			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Escitalopram 10 Mg Film-Coated Tablets Efg			S	Oral	10 Milligram, Once A Day		Aurobindo

	Torasemide	S	Oral	5 Milligram, Once A Day	Aurobindo
	Torasemide	S	Oral	10 Milligram (10 Mg Dia)	Aurobindo
	Aldactone	S	Oral	25 Milligram, Once A Day (1-0-0)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330184	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019GSK088551		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; General Physical Health Deterioration; Overdose; Seizure; Toxicity To Various Agents	Bupropion Hydrochloride Xl			S		Unk		Glaxosmithkline
	Escitalopram			S		Unk		Glaxosmithkline
	Quetiapine			S		Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16334217	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019208397		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Loss Of Consciousness; Malaise	Fentanyl			S	Transdermal	1 Df, Unk		Unknown
	Lyrica			S	Oral	75 Mg, 1x/Day		Pfizer
	Bisoprolol Fumarate			S	Oral	10 Mg, 1x/Day		Not Reported
	Oxynormoro			S	Oral	15 Mg, 1x/Day		Not Reported
	Lasilix [Furosemide]			S	Oral	40 Mg, 1x/Day		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Zolpidem			S	Oral	10 Mg, 1x/Day		Not Reported
	Ebixa			S	Oral	20 Mg, 1x/Day		Not Reported
	Esomeprazole			C				Not Reported
	Diffu K			C				Not Reported
	Transipeg [Macrogol]			C				Not Reported
	Gaviscon [Alginic Acid;Aluminium Hydroxide;Sodium			C				Not Reported

Alginate;Sodium Bica			
Okimus	C		Not Reported
Eliquis	C		Not Reported
Melaxose	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16334623	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1920862US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Subarachnoid Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	40 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	14561323	NON-EXPEDITED			US-PFIZER INC-2018074666		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		300 Mg, Unk		Pfizer
	Prazosin Hcl			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Zoloft			S		50 Mg, Unk		Pfizer
	Ziprasidone Hcl			S		Unk		Pfizer
	Bupropion			S		Unk		Not Reported
	Citalopram			S		Unk		Not Reported
	Duloxetine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Olanzapine			S		Unk		Not Reported
	Prilosec			S		Unk		Not Reported
	Paroxetine			S		Unk		Not Reported
	Prochlorperazine			S		Unk		Not Reported
	Tizanidine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	15594986	EXPEDITED (15-DAY)		HO, OT	JP-AMGEN-JPNCT2018155553		83 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis Perforated; Dehydration; Hepatic Function Abnormal; Renal Impairment	Cinacalcet Hcl			S	Oral	25 Milligram, Bid		Amgen
	Cinacalcet Hcl			S	Oral	25 Milligram, Tid		Amgen
	Lexapro			S	Oral	5 Milligram		Not Reported
	Bonalon			C	Oral	35 Milligram		Not Reported
	Tramcet			C	Oral	4 Dosage Form		Not Reported
	Hachimijiogan			C	Oral	5 Gram		Not Reported
	Ninjinto [Atractylodes Lancea Rhizome;Glycyrrhiza Spp. Root;Panax Gins			C	Oral	5 Gram		Not Reported
	Tokishigyakukagoshuyushokyoto			C	Oral	5 Gram		Not Reported
	Hochuekkito [Angelica Acutiloba Root;Astragalus Spp. Root;Atractylodes			C	Oral	5 Gram		Not Reported
	Yokukansankachimpihange [Angelica Acutiloba Root;Atractylodes Lancea R			C	Oral	5 Gram		Not Reported
	Seishinrenshiin			C	Oral	5 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16038129	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1908236US			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dry Mouth; Intentional Overdose; Slow Speech	Escitalopram Oxalate Unk			S	Oral	In Total: Overdose 300 Mg		Allergan
	Lorazepam			S	Oral	20 Mg (In Total)		Not Reported
	En			S	Oral	40 Mg (In Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16200479	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-019422			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Suicide Attempt; Toxicity To Various Agents	Paracetamol			S	Oral	2 G, 1 Total		Aurobindo
	Seroplex			S	Oral	40 Mg, 1 Total		Not Reported
	Seresta			S	Oral	10 Mg, 1 Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335135	EXPEDITED (15-DAY)		OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-208256		38 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	15 Milligram, Daily		Not Reported
	Omeprazole			S	Unknown	20 Milligram, Daily		Sun
	Ramipril			S	Unknown	2.5 Milligram, Daily		Ranbaxy
	Amisulpride			S	Unknown	300 Milligram, Daily		Not Reported
	Atorvastatin			S	Unknown	10 Milligram, Daily		Sun
	Spironolactone			S	Unknown	25 Milligram, Daily		Sun
	Bisoprolol			S	Unknown	2.5 Milligram, Daily		Sun
	Frusemide			S	Unknown	20 Milligram, Daily		Not Reported
	Melatonin			S	Unknown	2 Milligram, Daily		Not Reported
	Testosterone Depot			S	Unknown	1 Gram Every 10-14 W		Not Reported
	Ferrograd			S	Unknown	325 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335170	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-027718			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Loss Of Consciousness; Malaise	Fentanyl	S	Transdermal	1 Dosage Form, Every 72 Hours	Not Reported
	Escitalopram	S	Oral	10 Milligram, Once A Day	Aurobindo
	Bisoprolol	S	Oral	10 Milligram, Once A Day	Aurobindo
	Zolpidem	S	Oral	10 Milligram, Once A Day	Aurobindo
	Lyrica	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Ebixa	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Oxynormoro	S	Oral	3 Dosage Form, Once A Day	Not Reported
	Lasilix	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Diffu K	C	Unknown	Unk	Not Reported
	Transipeg	C	Unknown	Unk	Not Reported
	Gaviscon	C	Unknown	Unk	Not Reported
	Okimus	C	Unknown	Unk	Not Reported
	Eliquis	C	Unknown	Unk	Not Reported
	Melaxose	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16336396	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-192866		24 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Drug Ineffective; Drug Intolerance; Electrocardiogram Qt Prolonged; Schizophrenia	Clozapine			S	Unknown	350 Milligram, Daily		Sun
	Clozapine			S	Unknown	600 Milligram, Daily		Sun
	Clozapine			S	Unknown	5 Milligram, Daily		Sun
	Clozapine			S	Unknown	30 Milligram, Daily		Sun
	Aripiprazole			S	Unknown	Unk Unk, Daily		Not Reported

	Escitalopram	S	Unknown	Unk	Not Reported
	Mirtazapine	S	Unknown	15 Milligram, Daily	Sun
	Mirtazapine	S	Unknown	30 Milligram, Daily	Sun
	Olanzapine	S	Unknown	5 Milligram, Daily	Sun
	Olanzapine	S	Unknown	30 Milligram, Daily	Sun
	Risperidone	S	Unknown	Unk	Ranbaxy
	Prazepam	S	Unknown	20 Milligram, Daily	Not Reported
	Paliperidone Palmitate	C	Unknown	150 Milligram, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16336457	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2019-028512			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Malaise; Oedema Peripheral; Orthostatic Hypotension; Syncope	Potassium Chloride			S	Unknown	Unk		Aurobindo
	Zyloprim			S	Unknown	Unk		Not Reported
	Eliquis			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Lipitor			S	Unknown	Unk		Not Reported
	Thalitone			S	Unknown	Unk		Not Reported
	Colace			S	Unknown	Unk		Not Reported
	Inspra			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Neurontin			S	Unknown	Unk		Not Reported
	Humulin R			S	Unknown	Unk		Not Reported
	Imdur			S	Unknown	Unk		Not Reported
	Victoza			S	Unknown	Unk		Not Reported
	Mobic			S	Unknown	Unk		Not Reported
	Zaroxolyn			S	Unknown	Unk		Not Reported
	Lopressor			S	Unknown	Unk		Not Reported

Proamatine	S	Unknown	Unk		Not Reported
Protonix	S	Unknown	Unk		Not Reported
Demadex	S	Unknown	Unk		Not Reported
Anoro Ellipta	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16337965	EXPEDITED (15-DAY)		OT	TN-JUBILANT CADISTA PHARMACEUTICALS-2019JUB00189		38 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram			S	Unknown	Unk		Jubilant
	Carbamazepine			S	Unknown	Unk		Jubilant
	Levomepromazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16339968	EXPEDITED (15-DAY)		HO	ES-TEVA-2019-ES-1051192		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Escitalopram 10 Mg Comprimido			S	Oral	10 Milligram Daily;		Ivax
	Torasemida (2351a)			S	Oral	5 Milligram Daily;		Teva
	Torasemida (2351a)			S	Oral	10 Mg A Day .		Teva
	Aldactone 25 Mg			S	Oral	25 Milligram Daily; 1-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16123763	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1030442		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Pantoprazole			S	Unknown	40 Milligram Daily;		Teva
	Escitalopram			S	Oral	1 Dosage Forms Daily;		Ivax
	Lasilix Special 500 Mg, Comprime Secable			S	Oral	2 Dosage Forms Daily; Lasilix Special 500 Mg,		Not Reported

					Comprime Secable	
	Bisoprolol (Fumarate Acide De)		C			Not Reported
	Coumadine 2 Mg, Comprime Secable		C	Oral	2 Dosage Forms Daily;	Not Reported
	Spironolactone		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16126890	EXPEDITED (15-DAY)		HO	FR-ZYDUS-034889		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Pantoprazole			S	Unknown			Not Reported
	Furosemide			S	Oral			Not Reported
	Escitalopram			S	Oral			Zydus Pharm
	Spironolactone			C	Oral			Not Reported
	Warfarin			C	Oral			Not Reported
	Bisoprolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16138982	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-203402		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Pantoprazole			S	Unknown	40 Milligram, Daily		Sun
	Escitalopram			S	Oral	1 Dosage Form, Daily		Not Reported
	Lasilix Special 500 Mg, Comprime Secable			S	Oral	2 Dosage Form, Daily		Not Reported
	Bisoprolol (Fumarate Acide De)			C	Unknown	Unk		Not Reported
	Coumadine 2 Mg, Comprime Secable			C	Oral	2 Dosage Form, Daily		Not Reported
	Spironolactone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16189055	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2019SP003105			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental Disorder; Off Label Use; Wrong Technique In Product Usage Process	Buspirone Hydrochloride			S	Unknown	Unk		Strides
	Buspirone Hydrochloride			S	Unknown	Unk		Strides
	Buspirone Hydrochloride			S	Unknown	Unk		Strides
	Buspirone Hydrochloride			S	Unknown	Unk		Strides
	Buspirone Hydrochloride			S	Unknown	Unk		Strides
	Buspirone Hydrochloride			S	Unknown	Unk		Strides
	Buspirone Hydrochloride			S	Unknown	Unk		Strides
	Buspirone Hydrochloride			S	Unknown	Unk		Strides
	Mirtazapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Unknown		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Cutting Bits To 5 Mg To Reach Approx. 12.5 Mg In 6 Weeks		Not Reported
	Escitalopram			S	Unknown	Reduce To 12.5 Mg Over Eight Weeks		Not Reported
	Escitalopram			S	Unknown	15 Mg, Unknown		Not Reported
	Escitalopram			S	Unknown	15 Mg, Unknown		Not Reported

	Escitalopram	S	Unknown	15 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16340268	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-208519		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Loss Of Consciousness; Malaise	Bisoprolol			S	Oral	10 Milligram, Daily		Sun
	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Fentanyl			S	Transdermal	1 Dosage Form, Once In 72 Hours		Not Reported
	Zolpidem			S	Oral	10 Milligram, Daily		Sun
	Lyrica 75 Mg, Gelule			S	Oral	1 Dosage Form, Daily		Not Reported
	Ebixa 20 Mg, Comprime Pellicule			S	Oral	1 Dosage Form, Daily		Not Reported
	Oxynormoro 5 Mg, Comprime Orodispersible			S	Oral	3 Dosage Form, Daily		Not Reported
	Lasilix 40 Mg, Comprime Secable			S	Oral	1 Dosage Form, Daily		Not Reported
	Esomeprazole			C	Unknown	()		Not Reported
	Diffu K			C	Unknown	()		Not Reported
	Transipeg			C	Unknown	()		Not Reported
	Gaviscon			C	Unknown	()		Not Reported
	Melaxose			C	Unknown	()		Not Reported
	Okimus			C	Unknown	()		Not Reported
	Eliquis 5 Mg, Comprime Pellicule			C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16341250	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1051173		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Loss Of	Fentanyl			S	Transdermal	1 Dosage Forms		Actavis

Consciousness; Malaise	Zolpidem		S	Oral	10 Milligram Daily;	Teva
	Escitalopram		S	Oral	10 Milligram Daily;	Ivax
	Bisoprolol (Hemifumarate De)		S	Oral	10 Milligram Daily;	Teva
	Lyrica 75 Mg, Gélule		S	Oral	1 Dosage Forms Daily;	Not Reported
	Ebixa 20 Mg, Comprimé Pelliculé		S	Oral	1 Dosage Forms Daily;	Not Reported
	Oxynormoro 5 Mg, Comprimé Orodispersible		S	Oral	3 Dosage Forms Daily;	Not Reported
	Lasilix 40 Mg, Comprimé Sécable		S	Oral	1 Dosage Forms Daily;	Not Reported
	Esomeprazole		C			Not Reported
	Diffu K		C			Not Reported
	Transipeg		C			Not Reported
	Gaviscon		C			Not Reported
	Okimus		C			Not Reported
	Eliquis 5 Mg, Comprimé Pelliculé		C			Not Reported
	Melaxose		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16341550	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-028434			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Pantoprazole			S	Unknown	40 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Lasilix Special			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Spironolactone			C	Oral	Unk		Not Reported
	Coumadine			C	Oral	2 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16344151	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2019209205		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Aldactone			S	Oral	25 Mg, Once Daily In The Morning (1-0-0)		Pfizer
	Escitalopram			S	Oral	10 Mg, Once Daily		Not Reported
	Escitalopram			S		Unk		Not Reported
	Torasemide			S	Oral	5 Mg, Once Daily		Not Reported
	Torasemide			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16344476	EXPEDITED (15-DAY)		HO, OT	CN-ELI_LILLY_AND_COMPANY-CN201905005245			Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Asthenia; Depression; Dizziness; Headache; Off Label Use; Restlessness; Somatic Symptom Disorder; Tinnitus	Zyprexa			S	Oral	3.75 Mg, Daily		Eli Lilly And Co
	Escitalopram Oxalate			S	Oral	15 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16344699	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1921361US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Cimzia			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown	1000 Mg, Qd		Not Reported
	Nortriptyline			S	Oral	25 Mg, Qd		Not Reported
	Tylenol			S	Topical			Not Reported
	Voltaren			S	Topical			Not Reported
	Diclofenac Potassium			S	Unknown	50 Mg		Not Reported

Diclofenac	C	Ophthalmic			Not Reported
Infliximab	C	Intravenous (not otherwise specified)	Unk		Not Reported
Infliximab	C	Intravenous (not otherwise specified)	600 Mg		Not Reported
Infliximab	C	Intravenous (not otherwise specified)	700 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16344701	EXPEDITED (15-DAY)		LT	CA-ALLERGAN-1921434US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Product Use In Unapproved Indication; Swelling; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Apo-Sulfatrim			S	Unknown	160 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	14876032	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS-2018M1031837		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Off Label Use; Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Escitalopram			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Oral	Unk		Not Reported
	Bisoprolol			S	Oral	Unk		Not Reported
	Ciprofloxacin			S	Intravenous drip	Unk		Not Reported
	Ciprofloxacin			S	Intravenous drip	Unk		Not Reported
	Methotrexate			S	Intravenous drip	Unk		Not Reported
	Methotrexate			S	Intravenous drip	Unk		Not Reported
	Methotrexate			S	Intravenous drip	Unk		Not Reported
	Valaciclovir			S	Oral	Unk		Not Reported

Valaciclovir	S	Oral	Unk	Not Reported
Furosemide	S	Oral	Unk	Not Reported
Furosemide	S	Oral	Unk	Not Reported
Ondansetron	S	Oral	Unk	Not Reported
Ondansetron	S	Oral	Unk	Not Reported
Bromazepam	S	Oral	Unk	Not Reported
Bromazepam	S	Oral	Unk	Not Reported
Pantoprazole	S	Intravenous drip	Unk	Mylan
Pantoprazole	S	Intravenous drip	Unk	Mylan
Pantoprazole	S	Unknown	Unk	Mylan
Rituximab	S	Intravenous drip	Unk	Mylan
Rituximab	S	Intravenous drip	Unk	Mylan
Rituximab	S	Oral	Unk	Mylan
Calciparine	S	Subcutaneous	Unk	Mylan
Calciparine	S	Subcutaneous	Unk	Mylan
Doxorubicine /00330901/	S	Intravenous drip	Unk	Mylan
Doxorubicine /00330901/	S	Intravenous drip	Unk	Mylan
Lidocaine	S	Buccal	Unk	Mylan
Lidocaine	S	Buccal	Unk	Mylan
Lidocaine	S	Unknown	Unk	Mylan
Fungizone	S	Buccal	Unk	Mylan
Fungizone	S	Buccal	Unk	Mylan
Fungizone	S	Unknown	Unk	Mylan
Voraxaze	S	Intravenous drip	Unk	Mylan
Voraxaze	S	Intravenous drip	Unk	Mylan
Zarzio	S	Subcutaneous	Unk	Mylan
Zarzio	S	Subcutaneous	Unk	Mylan
Cyclophosphamide	S	Intravenous drip	Unk	Mylan
Cyclophosphamide	S	Intravenous drip	Unk	Mylan

	Exacyl	S	Intravenous drip	Unk	Mylan
	Exacyl	S	Intravenous drip	Unk	Mylan
	Exacyl	S	Unknown	Unk	Mylan
	Prednisone	S	Intravenous drip	Unk	Mylan
	Prednisone	S	Intravenous drip	Unk	Mylan
	Eprex	S	Subcutaneous	Unk	Mylan
	Eprex	S	Subcutaneous	Unk	Mylan
	Vincristine	S	Intravenous drip	Unk	Mylan
	Vincristine	S	Intravenous drip	Unk	Mylan
	Bactrim	S	Oral	Unk	Mylan
	Bactrim	S	Oral	Unk	Mylan
	Hextril	S	Buccal	Unk	Mylan
	Hextril	S	Buccal	Unk	Mylan
	Hextril	S	Unknown	Unk	Mylan
	Meropenem Anhydrous	S	Intravenous drip	Unk	Mylan
	Meropenem Anhydrous	S	Intravenous drip	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	15241302	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-038910			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Malaise; Tremor; Vertigo	Escitalopram			S	Oral	15 Milligram, Once A Day		Aurobindo
	Deniban			S	Oral	25 Milligram, Once A Day		Not Reported
	Valium			S	Oral	16 Gtt, Once A Day		Not Reported
	Leponex			S	Oral	150 Milligram, Once A Day		Not Reported
	Arlevertan			S	Oral	3 Dosage Form, Once A Day		Not Reported
	Resilient			S	Oral	1 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16343221	EXPEDITED (15-DAY)		DE, OT	DE-JNJFOC-20190526600		70 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Haldol			S	Unknown			Not Reported
	Valproate Sodium			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Remergil			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16346186	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-026927			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Haematoma Muscle	Clopidogrel			S	Oral	75 Milligram, Daily		Aurobindo
	Escitalopram			S	Oral	5 Milligram, Daily (1-0-0)		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16346419	EXPEDITED (15-DAY)		OT	SE-ACCORD-128893		57 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic	Escitalopram			S		5 Mg Is Escalated To 20 Mg		Not Reported
	Duloxetine/Duloxetine Hydrochloride			S		30 Mg Escalated To 60 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16348649	EXPEDITED (15-DAY)		OT	FR-UCBSA-2019021161		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cholestasis; Hepatocellular Injury	Vimpat	S	Oral			Ucb
	Pantoprazole	S	Oral	Unk		Not Reported
	Tinzaparine Sodique	S	Subcutaneous	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Spironolactone	S	Oral			Not Reported
	Trileptal	S	Oral	Unk		Not Reported
	Diltiazem	S	Oral	Unk		Not Reported
	Bactrim	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16349942	EXPEDITED (15-DAY)		DS, OT	AT-ALLERGAN-1921445US			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradyphrenia; Confusional State; Depressed Level Of Consciousness; Disturbance In Attention; Emotional Poverty; Erectile Dysfunction; Fatigue; Feeling Abnormal; Hyperhidrosis; Hypoaesthesia; Hypoaesthesia; Illusion; Loss Of Libido; Malaise; Memory Impairment; Orgasm Abnormal; Orgasmic Sensation Decreased; Personality Change; Poisoning; Tremor; Tunnel Vision	Escitalopram Oxalate - Bp			S	Unknown	20 Mg		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16349947	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1921460US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pemphigoid	Escitalopram Oxalate - Bp	S	Oral	Unk, Unknown	Allergan
	Furosemide	S	Oral	60 Mg, Qd	Not Reported
	Esomeprazole	C	Unknown	Unk, Unknown	Not Reported
	Toujeo	C	Unknown	Unk, Unknown	Not Reported
	Dafalgan	C	Unknown	Unk, Unknown	Not Reported
	Dermoval	C	Unknown	Unk, Unknown	Not Reported
	Vitabact	C	Unknown	Unk, Unknown	Not Reported
	Innohep	C	Unknown	Unk, Unknown	Not Reported
	Desloratadine	C	Unknown	Unk, Unknown	Not Reported
	Novorapid	C	Unknown	Unk, Unknown	Not Reported
	Diffu K	C	Unknown	Unk, Unknown	Not Reported
	Theralene	C	Unknown	Unk, Unknown	Not Reported
	Ventoline	C	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	10447316	EXPEDITED (15-DAY)		CA, HO, OT	CA-FRI-1000070527			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Premature Baby; Trismus	Escitalopram Oxalate Unk			S	Transplacental	20 Mg, Qd		Allergan
	Quetiapine			S	Transplacental	300 Mg, Bid (300 Mg Sustained Release And 300 Mg Immediate Release)		Not Reported
	Nortriptyline			S	Transplacental	20 Mg, Qd		Not Reported
	Gabapentin			S	Transplacental	1800 Mg, Qd		Not Reported
	Benztropine			S	Transplacental	1.5 Mg, Qd		Not Reported
	Zopiclone			S	Transplacental	Unk		Not Reported
	Rabeprazole			S	Transplacental	Unk		Not Reported
	Methadone			S	Transplacental	70 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	15571782	EXPEDITED (15-DAY)		HO, OT	CA-MALLINCKRODT-T201804686		1 DAY	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Methadose			S	Transplacental	70mg, Qd		Mallinckrodt
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Qd		Not Reported
	Escitalopram			S	Transplacental	20 Mg, Qd		Not Reported
	Gabapentin			S	Transplacental	1800 Mg, Qd		Not Reported
	Nortriptyline			S	Transplacental	20 Mg, Qd		Not Reported
	Quetiapine			S	Transplacental	300 Mg, Q12h		Not Reported
	Rabeprazole			S	Transplacental	Unknown		Not Reported
	Zopiclone			S	Transplacental	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	16351333	EXPEDITED (15-DAY)		OT	PHHY2019AU117895		38 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	15 Mg, Unk		Not Reported
	Furosemide			S	Unknown	20 Mg, Unk		Novartis
	Omeprazole			S	Unknown	20 Mg, Unk		Not Reported
	Ramipril			S	Unknown	2.5 Mg, Unk		Not Reported
	Amisulpride			S	Unknown	300 Mg, Unk		Not Reported
	Atorvastatin			S	Unknown	10 Mg, Unk		Not Reported
	Bisoprolol			S	Unknown	2.5 Mg, Unk		Not Reported
	Melatonin			S	Unknown	2 Mg, Unk		Not Reported
	Testosterone			S	Unknown	1 G, Unk (Every 10-14 W)		Not Reported
	Spironolactone			S	Unknown	25 Mg, Unk		Not Reported
	Ferrograd			S	Unknown	325 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	16351562	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US03904			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sedation Complication	Escitalopram			S	Unknown	10 Milligram		Invagen
	Escitalopram			S				Invagen
	Lorazepam			S	Unknown	0.5 Milligram, Per Day		Not Reported
	Lorazepam			S				Not Reported
	Clonazepam			S	Unknown	0.5 Milligram, Per Day		Not Reported
	Clonazepam			S				Not Reported
	Clonidine			C	Unknown	0.2 Milligram, At Night		Not Reported
	Clobazam			C	Unknown	15 Mg In Am, 15 Mg Noon, 40 Mg At Night		Not Reported
	Clobazam			C				Not Reported
	Ranitidine			C	Unknown	150 Milligram, Qd (Daily At Bed Time)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	16352035	NON-EXPEDITED			US-NOVEN PHARMACEUTICALS, INC.-US2019000137			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Pruritus; Fatigue; Somnolence	Daytrana			S	Transdermal	Unk, Unknown		Noven
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	16353918	EXPEDITED (15-DAY)		HO	CH-OTSUKA-2019_020637		21 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Suicidal	Abilify Maintena			S	Unknown	400 Mg, Unk		Otsuka
	Cipralex			S	Unknown	15 Mg, Unk		Not Reported

Ideation; Thinking Abnormal; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	16354119	EXPEDITED (15-DAY)		DE, OT	DE-ASTRAZENECA-2019SE75650		70 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Seroquel			S	Unknown	Slowly Increased Dosage Since 13-Dec-2008		Astrazeneca
	Diazepam			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Haldol			S	Unknown			Not Reported
	Remergil			S	Unknown			Not Reported
	Ergenyl			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	16355092	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1920015US			Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Pallor; Shock; Somnolence; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	16355097	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1921726US			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Suicidal Ideation; Thinking Abnormal; Weight	Escitalopram Oxalate - Bp			S	Unknown	15 Mg		Allergan
	Abilify			S	Unknown	400 Mg		Not Reported
	Reagila			C	Unknown	3 Mg		Not Reported

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2019	15993805	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-094209		24 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Cardiac Disorder; Drug Ineffective; Drug Intolerance; Electrocardiogram Qt Prolonged	Escitalopram			S				Not Reported
	Aripiprazole			S		10 To 30 Mg Daily		Not Reported
	Clozapine			C				Not Reported
	Mirtazapine			C		15 Mg, 30 Mg Daily		Not Reported
	Loxapine/Loxapine Hydrochloride/Loxapine Succinate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16161938	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-117753		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Psychomotor Skills Impaired	Escitalopram			S	Oral	Date And Time Of Last Administration: 20-Jan-2019		Not Reported
	Lorazepam			S	Oral	Date And Time Of Last Administration: 20-Jan-2019		Accord
	Quetiapine			S	Oral	Date And Time Of Last Administration: 20-Jan-2019		Not Reported
	Trittico			S	Oral	Date And Time Of Last Administration: 20-Jan-2019		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16356507	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1054438		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram Oxalate	S	Oral	Ivax
	Vortioxetine Hydrobromide	C		Not Reported
	Sertraline	C		Not Reported
	Asenapine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16356554	EXPEDITED (15-DAY)		DE, OT	DE-009507513-1905DEU010170		70 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remergil Soltab			S		30 Mg, Qd		Merck
	Ergenyl Chrono			S		1000 Mg, Qd		Not Reported
	Haldol			S		10 Mg, Qd		Not Reported
	Diazepam			S		5 Mg, Qd		Not Reported
	Seroquel			S		Slowly Titrated From 13-Dec-2008		Not Reported
	Cipralex			S		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16356975	EXPEDITED (15-DAY)		DS	CA-APOTEX-2019AP014646		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Generalised	Apo-Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Pms Escitalopram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16357572	EXPEDITED (15-DAY)		OT	FR-ACCORD-129265		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral			Unknown
	Spironolactone			S	Oral			Accord
	Lacosamide			S	Oral			Not Reported

Pantoprazole	S	Oral		Not Reported
Tinzaparin	S	Subcutaneous		Not Reported
Trileptal	S	Oral		Not Reported
Diltiazem	S	Oral		Not Reported
Sulfamethoxazole/Trimethoprim	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16357594	EXPEDITED (15-DAY)		DE	SE-ACCORD-129266		28 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram Accord			S	Oral	Strength: 10 Mg		Not Reported
	Elvanse			S	Oral			Not Reported
	Lamictal			S	Oral	Strength: 100 Mg		Not Reported
	Voxra			S	Oral	Strength: 150 Mg		Not Reported
	Melatonin Agb			C		Strength: 4 G, Max 2 Pcs Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16357675	EXPEDITED (15-DAY)		HO, LT, OT	CA-BAUSCH-BL-2019-015164		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Bupropion Xl			S	Oral	Unknown Amount		Not Reported
	Escitalopram			S	Oral	Unknown Amount		Not Reported
	Quetiapine			C	Oral	Unknown Amount		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16358741	EXPEDITED (15-DAY)		HO	PHHY2019FR117006		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Valsartan			S	Oral	160 Mg, Qd		Novartis

Esomeprazole	S	Oral	20 Mg, Qd		Not Reported
Lasilix	S	Oral	40 Mg, Qd		Not Reported
Seroplex	S	Oral	1 Df, Qd		Not Reported
Discotrine	C	Transdermal	1 Df, Qd		Not Reported
Simvastatine	C	Oral	20 Mg, Qd		Not Reported
Manidipine Hydrochloride	C	Oral	10 Mg, Qd		Not Reported
Seresta	C	Oral	1 Df, Qd		Not Reported
Bisoce	C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	15206555	NON-EXPEDITED			US-PFIZER INC-2018299471		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Neurontin			S		300 Mg, As Needed		Pfizer
	Neurontin			S		600 Mg, As Needed		Pfizer
	Geodon			S		20 Mg, Unk		Pfizer
	Xanax			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Ziprasidone Hcl			S		Unk		Pfizer
	Prazosin Hcl			S		Unk		Pfizer
	Metoprolol Tartrate			S		75 Mg, Unk		Unknown
	Prozac			S		Unk		Not Reported
	Adderall			S		Unk		Not Reported
	Buspar			S		90 Mg, Unk		Not Reported
	Latuda			S		Unk		Not Reported
	Ritalin			S		Unk		Not Reported
	Seroquel			S		Unk		Not Reported
	Topamax			S		Unk		Not Reported
	Viibryd			S		Unk		Not Reported

	Zyprexa	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Trazodone	S	Unk	Not Reported
	L-Methylfolate	S	Unk	Not Reported
	Concerta	S	Unk	Not Reported
	L-Tyrosine	S	Unk	Not Reported
	Klonopin	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Guanfacine	S	Unk	Not Reported
	Lamictal	S	75 Mg, Unk	Not Reported
	5 Htp [Ascorbic Acid;Biotin;Folic Acid;Nicotinamide;Oxitriptan;Pyridoxine Hydrochloride;Zinc Citrate]	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	15367652	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016488459		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Thinking Abnormal; Withdrawal Syndrome	Lyrica			S	Oral	225 Mg, 2x/Day		Pfizer
	Lyrica			S		225 Mg, 2x/Day		Pfizer
	Lyrica			S				Pfizer
	Amlodipine Besilate			S		5 Mg, 1x/Day		Pfizer
	Escitalopram			S		20 Mg, 1x/Day		Not Reported
	Meloxicam			S		15 Mg, 1x/Day		Not Reported
	Clonazepam			S		1 Mg, Unk (Up To 3 Times Daily)		Not Reported
	Carisoprodol			C		350 Mg, Unk (2x 350 Mg)		Not Reported
	Amphetamine Salts			C		30 Mg, Unk (2x 30 Mg)		Not Reported
	Tramadol			C		50 Mg, Unk (Up To 6x		Not Reported

				Daily)	
	Triamterene Hctz		C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16209748	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1916535US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Muscle Spasms; Peripheral Venous Disease	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Daily		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Daily		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Daily		Allergan
	Magnesium			S	Unknown	Unk, Q Month		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16280460	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-004244		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Dizziness; Electrocardiogram Qt Prolonged; Heart Rate Increased; Irritability; Middle Insomnia; Panic Attack; Supraventricular Tachycardia	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	4.25 G, Bid		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S	Oral	10 Mg, Unk		Not Reported
	Lexapro			S		5 Mg, Unk		Not Reported
	Wellbutrin			S	Oral	150 Mg Xl		Not Reported
	Wellbutrin			S		100 Mg Xl		Not Reported
	Propranolol			S	Unknown			Not Reported
	Adderall			S				Not Reported
	Armodafinil			C				Not Reported
	Diurex Water Pills			C				Not Reported
	Ibuprofen			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Methylphenidate			C				Not Reported
	Nuvigil			C				Not Reported

Senna Lax	C		Not Reported
Vitamin B Complex	C		Not Reported
Vitamin D3	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16359428	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-029510			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram			S	Oral	5 Milligram, Once A Day		Aurobindo
	Lormetazepam Arrow 2 Mg, Tablet			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Trileptal			C	Unknown	Unk		Not Reported
	Urorec			C	Unknown	Unk		Not Reported
	Coveram			C	Unknown	Unk		Not Reported
	Simvastatine			C	Unknown	Unk		Not Reported
	Gabapentine			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16359452	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-029507			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Valsartan			S	Oral	160 Milligram, Once A Day		Aurobindo
	Esomeprazole			S	Oral	20 Milligram, Once A Day		Aurobindo
	Seroplex			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Lasilix			S	Oral	40 Milligram, Once A Day		Not Reported
	Discotrine			C	Transdermal	1 Dosage Form, Once A Day		Not Reported
	Simvastatine			C	Oral	20 Milligram, Once A Day		Not Reported
	Manidipine Hydrochloride			C	Oral	10 Milligram, Once A Day		Not Reported

	Seresta		C	Oral	1 Dosage Form, Once A Day	Not Reported
	Bisoce		C	Oral	1 Dosage Form, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16359459	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2019-029370			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Bromazepam			S	Oral	180 Milligram, Daily		Not Reported
	Escitalopram			S	Oral	120 Milligram, 1 Total		Aurobindo
	Seresta			S	Oral	48 Dosage Form, 1 Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16359494	EXPEDITED (15-DAY)		DE	DE-ROCHE-2323381		70 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Interaction	Diazepam			S	Unknown			Not Reported
	Ergenyl Chrono			S	Unknown			Not Reported
	Haldol [Haloperidol]			S	Unknown			Not Reported
	Remergil			S	Unknown			Not Reported
	Seroquel			S	Unknown	Langsam Aufdosiert Ab 13.12.2008		Not Reported
	Cipralex [Escitalopram]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16360002	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2018-044728			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Loss Of Personal Independence In Daily Activities; Palpitations;	Escitalopram			S	Unknown			Aurobindo

Product Substitution Issue

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16360464	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2018-044853			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Feeling Hot; Hypersensitivity	Escitalopram			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16360621	EXPEDITED (15-DAY)		HO, LT, OT	CA-ACCORD-129655		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Seizure; Sympathomimetic Effect	Bupropion/Bupropion Hydrochloride			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Quetiapine/Quetiapine Fumarate			C	Oral	Unknown Amount		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16361802	NON-EXPEDITED			US-PFIZER INC-2019225352		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Product Use Issue	Neurontin			S		Unk Unk, As Needed As Needed [300-600 Mg (As Needed)]		Pfizer
	Latuda			S		Unk		Not Reported
	Viibryd			S		Unk		Not Reported
	Seroquel			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Trazodone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16362150	NON-EXPEDITED			US-SUNOVION-2019SUN002066			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Migraine	Latuda			S	Oral			Sunovion
	Rexulti			S		1/4 Of A Tablet Or 1/2 A Tablet		Not Reported
	Abilify			S	Unknown			Not Reported
	Lexapro			S	Unknown	60 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16363245	EXPEDITED (15-DAY)		DE, OT	DE-ALLERGAN-1922180US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Ergenyl Chrono			S	Unknown	1000 Mg, Qd		Not Reported
	Haldol			S	Unknown	10 Mg, Qd		Not Reported
	Diazepam			S	Unknown	5 Mg, Qd		Not Reported
	Remergil			S	Unknown	30 Mg, Qd		Not Reported
	Seroquel			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16363246	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1922156US			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental	Escitalopram Oxalate - Bp			S	Unknown	Cutting Bits To 5 Mg To Reach Approx. 12.5 Mg In 6 Weeks		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unk		Allergan

Disorder; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp	S	Unknown	15 Mg, Unk	Allergan
	Escitalopram Oxalate - Bp	S	Unknown	Reduced To 12.5 Mg Over 8 Weeks	Allergan
	Lorazepam	S	Unknown	Unk	Not Reported
	Lorazepam	S			Not Reported
	Lorazepam	S			Not Reported
	Lorazepam	S			Not Reported
	Lorazepam	S			Not Reported
	Mirtazapine	S	Unknown	15 Mg, Unk	Not Reported
	Mirtazapine	S		Unk	Not Reported
	Mirtazapine	S		Unk	Not Reported
	Mirtazapine	S		Unk	Not Reported
	Mirtazapine	S		Unk	Not Reported
	Buspirone	S	Unknown	Unk	Not Reported
	Buspirone	S	Unknown	Unk	Not Reported
	Buspirone	S	Unknown	Unk	Not Reported
	Buspirone	S	Unknown	Unk	Not Reported
	Buspirone	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16363255	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1922192US			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia; Breast Tenderness; Condition Aggravated; Condition Aggravated; Confusional State; Depression; Diarrhoea; Disturbance In Attention; Dizziness; Drug Interaction; Fatigue; Headache; Infection; Irritability; Mental Impairment; Muscle	Citalopram Hydrobromide - Bp			S	Unknown			Allergan
	Lexapro			S	Unknown			Not Reported
	Provera			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

Spasms; Nervousness; Pain In Extremity; Premenstrual Syndrome; Somnolence; Suicidal Ideation; Syncope; Varicose Vein; Vision Blurred

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16363294	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1048185			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Headache	Mirtazapine			S	Unknown	30 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	15 Mg, Qhs		Not Reported
	Levocarb 1 A Pharma			S	Unknown	0.5 Df, Unk		Mylan
	Acetylsalicylic Acid			C	Unknown	100 Mg, Qd		Mylan
	Atorvastatin			C	Unknown	300 Mg, Qhs		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	15359280	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2018-043532			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Anxiety; Contraindicated Product Administered; Dehydration; Depression; Drug Interaction; Drug Level Increased; Intentional Overdose; Intentional Product Misuse; Neuroleptic Malignant Syndrome; Product Administration Error; Psychomotor Hyperactivity; Suicide Attempt; Vasoplegia	Lercanidipine Film-Coated			S	Unknown	300 Milligram, Total,(Overdose: 300 Mg)		Not Reported
	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Zuclopenthixol Decanoate			S	Unknown	300 Milligram, Monthly		Not Reported
	Zuclopenthixol Decanoate			S	Unknown	300 Milligram, 1 Month		Not Reported
	Zuclopenthixol Decanoate			S	Unknown	300 Milligram		Not Reported
	Zuclopenthixol Decanoate			S				Not Reported
	Zuclopenthixol Acetate			S	Intramuscular	100 Milligram		Not Reported
	Zuclopenthixol Hydrochloride			S	Unknown	Titrated From 5 To 40mg Daily Over 2 Weeks		Not Reported
	Cyamemazine			S	Unknown	50 Milligram, Once A Day		Not Reported

Syndrome; Wrong Dosage Formulation	Cyamemazine	S	Unknown	50 Mg To 100 Mg Daily	Not Reported
	Cyamemazine	S	Unknown	In Total (Overdose 750 Mg)	Not Reported
	Cyamemazine	S	Unknown	25 Mg To 75 Mg Daily (Overdose) ()	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Metformine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16365122	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP015264		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Seizure; Sympathomimetic Effect	Escitalopram			S	Oral	Unk		Apotex
	Bupropion			S	Oral	Unk		Not Reported
	Quetiapine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16366408	EXPEDITED (15-DAY)		OT	CH-TEVA-2019-CH-1056289		59 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Prostatic Hyperplasia; Urinary Retention; Urinary Retention	Escitalopram-Mepha Lactab 10mg			S	Unknown	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16366448	EXPEDITED (15-DAY)		DS, OT	AT-TEVA-2019-AT-1055324		25 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradyphrenia; Confusional State; Depressed Level Of	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

Consciousness;
Disturbance In Attention;
Emotional Poverty;
Erectile Dysfunction;
Fatigue; Feeling
Abnormal; Hyperhidrosis;
Hypoaesthesia;
Hypoaesthesia; Illusion;
Loss Of Libido; Malaise;
Memory Impairment;
Orgasm Abnormal;
Orgasmic Sensation
Decreased; Personality
Change; Poisoning;
Tremor; Tunnel Vision

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16368029	EXPEDITED (15-DAY)		OT	TN-AMNEAL PHARMACEUTICALS-2019AMN00616		38 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate			S	Unknown	Unk		Amneal
	Escitalopram Oxalate			S		Unk		Amneal
	Carbamazepine			S	Unknown	Unk		Not Reported
	Amoxicilline			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Levomepromazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16368154	EXPEDITED (15-DAY)		DS	IT-MYLANLABS-2019M1050045		19 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depressed Mood; Insomnia	Risperidone			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Rivotril			S	Oral	30 Gtt Drops, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16369080	EXPEDITED (15-DAY)		OT	GR-ALLERGAN-1922342US			Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transient Ischaemic Attack	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	14184336	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-16X-056-1260803-00		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State; Drug Abuse; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose; Intentional Product Misuse; Medication Error; Nystagmus; Overdose; Psychomotor Retardation; Psychomotor Skills Impaired; Suicidal Ideation; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral	840 Milligram		Not Reported
	Escitalopram			S	Oral	840 Milligram, Total		Not Reported
	Venlafaxine			S	Oral	7875 Mg, Unk		Not Reported
	Venlafaxine			S	Oral	7875 Milligram, Total		Not Reported
	Bromazepam			S	Oral	180 Mg, Unk		Not Reported
	Bromazepam			S	Oral	180 Milligram, Total		Not Reported
	Lormetazepam			S	Oral	14 Mg, Unk		Mylan
	Lormetazepam			S	Oral	14 Milligram, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16209518	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS-2019M1033344		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Dehydration; Drug Interaction; Drug Level Increased; Intentional Overdose; Neuroleptic	Lercanidipine			S		Unk		Not Reported
	Lercanidipine			S		300 Milligram, Total		Not Reported
	Escitalopram			S		10 Milligram, Qd		Not Reported
	Zuclopenthixol Dihydrochloride			S		Titrated From 5 To 40mg		Mylan

Malignant Syndrome; Product Administration Error; Suicidal Ideation; Vasoplegia Syndrome	Zuclopenthixol Decanoate	S		Daily Over 2 Weeks		
				300 Milligram, Monthly		Mylan
	Zuclopenthixol Acetate	S	Intramuscular	100 Milligram		Mylan
	Cyamemazine	S		750 Milligram, Total		Mylan
	Cyamemazine	S		50 Mg To 100 Mg Daily		Mylan
	Cyamemazine	S		25 Mg To 75 Mg Daily		Mylan
	Cyamemazine	S		50 Milligram, Qd		Mylan
	Atorvastatin	C		Unk		Mylan
	Metformin	C		Unk		Mylan
	Bisoprolol	C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16357728	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019223542		89 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Haemorrhage	Amiodar			S	Oral	200 Mg, Daily		Not Reported
	Duoplavin			S	Oral	175 Mg, Qd		Not Reported
	Cipralex [Escitalopram Oxalate]			S	Oral	10 Mg, Qd		Not Reported
	Ranexa			C	Unknown	Unk		Not Reported
	Ebixa			C	Unknown	Unk		Not Reported
	Tareg			C	Unknown	Unk		Not Reported
	Minitran [Glyceryl Trinitrate]			C	Unknown	Unk		Not Reported
	Crestor			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16369558	EXPEDITED (15-DAY)		HO, LT, OT	CA-LUPIN PHARMACEUTICALS INC.-2019-03338		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Intentional	Quetiapine			S	Oral	Unk		Lupin

Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Escitalopram	S	Oral	Unk	Lupin
	Bupropion	S	Oral	Unk (Overdose)	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16370807	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-029828			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hyponatraemia	Escitalopram			S	Oral	5 Milligram		Aurobindo
	Spironolactone			S	Oral	75 Milligram, Daily		Aurobindo
	Keppra			S	Oral	2000 Milligram, Daily		Not Reported
	Zebinix			S	Oral	800 Milligram (800mg X 1.5)		Not Reported
	Chronadalate			C	Unknown	Unk		Not Reported
	Fenofibrate			C	Unknown	Unk		Not Reported
	Sotalol Hydrochloride			C	Unknown	Unk		Not Reported
	Januvia			C	Unknown	Unk		Not Reported
	Urbanyl			C	Unknown	Unk		Not Reported
	Fortzaar			C	Unknown	Unk		Not Reported
	Glimepiride			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16372056	EXPEDITED (15-DAY)		OT	CA-ALEMBIC PHARMACUETICALS LIMITED-2019SCAL000324			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Overdose; Seizure; Sympathomimetic Effect	Bupropion Hydrochloride			S		Unk		Alembic
	Quetiapine Fumarate			S		Unk		Alembic
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16372718	EXPEDITED (15-DAY)		HO, LT, OT	CA-MYLANLABS-2019M1050760		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Overdose; Seizure; Sympathomimetic Effect	Bupropion			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Quetiapine			C	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16372879	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1922346US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Lormetazepam Arrow			S	Oral	1 Df, Qd		Not Reported
	Trileptal			C	Unknown	Unk		Not Reported
	Urorec			C	Unknown	Unk		Not Reported
	Coveram			C	Unknown	Unk		Not Reported
	Simvastatine			C	Unknown	Unk		Not Reported
	Gabapentine			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16372886	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1922339US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Premature Ejaculation; Spontaneous Ejaculation	Escitalopram Oxalate - Bp			S	Oral	1 Df		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16372908	EXPEDITED (15-DAY)		OT	PL-ALLERGAN-1922349US			Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dry Mouth; Headache; Nausea; Sedation; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan
	Atenolol			S	Oral	25 Mg, Unknown		Not Reported
	Oxynorm			S	Intravenous (not otherwise specified)	Unk, Unknown		Not Reported
	Hydroxyzine			S	Oral	Unk, Unknown		Not Reported
	Hydroxyzine			S	Unknown	Unk, Unknown		Not Reported
	Ketonal (Ketoprofen)			S	Intravenous (not otherwise specified)	Unk, Unknown		Not Reported
	Pyralgin [Metamizole\Nimesulide]			S	Intravenous (not otherwise specified)	Unk, Unknown		Not Reported
	Fenactil			S	Intravenous (not otherwise specified)	Unk, Unknown		Not Reported
	Oxycontin			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16374776	EXPEDITED (15-DAY)		OT	CA-PRINSTON PHARMACEUTICAL INC.-2019PRN00533		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Overdose; Seizure	Bupropion Hydrochloride			S	Oral			Prinston Pharmaceutical
	Escitalopram			S	Oral			Prinston Pharmaceutical
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16376807	DIRECT					16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Depression; Galactorrhoea; Suicide Attempt	Escitalopram			S	Oral			Not Reported
	Duloxetine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	10349162	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014205300		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hallucination; Muscle Spasms; Muscle Tightness; Muscle Twitching; Nausea; Restlessness; Serotonin Syndrome; Skin Burning Sensation; Tachycardia; Tremor; Vomiting	Effexor Xr			S	Oral	37.5 Mg (1 Capsule), 1x/Day		Pfizer
	Cipralex			S	Oral	5 Mg, 1x/Day (At Night)		Not Reported
	Cipralex			S	Oral	5 Mg (1 Df), 1x/Day (In The Morning)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	14413400	EXPEDITED (15-DAY)		DE	NO-TAKEDA-2018TUS001617		60 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective; Prescribed Overdose	Brintellix			S	Oral	10 Milligram		Takeda
	Brintellix			S	Oral	5 Milligram		Takeda
	Cipralex /01588501/			S	Oral	10 Milligram, Qd		Not Reported
	Cipralex /01588501/			S	Oral	20 Milligram, Qd		Not Reported
	Cipralex /01588501/			S	Unknown	30 Milligram		Not Reported
	Cipralex /01588501/			S	Oral	Unk		Not Reported
	Seretide Discus			C	Unknown	250/50 Microgram, Unk		Not Reported
	Amlodipin Sandoz /00972402/			C	Oral	5 Milligram, Qd		Not Reported
	Ventoline /00139501/			C	Other	Unk		Not Reported
	Crestor			C	Oral	40 Milligram, Qd		Not Reported
	Valsartan Actavis			C	Oral	160 Milligram, Qd		Not Reported
	Imovane			C	Oral	Unk		Not Reported
	Loratadin Orifarm			C	Oral	Unk Unk, Qd		Not Reported
	Emconcor			C	Oral	5 Milligram, Qd		Not Reported

Ezetrol	C	Oral	10 Milligram, Qd		Not Reported
Lansoprazol Krka	C	Oral	Unk		Not Reported
Albyl-E	C	Oral	75 Milligram, Qd		Not Reported
Nitrolingual	C	Unknown	0.4 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	14463774	NON-EXPEDITED			US-HETERO CORPORATE-HET2018US00073		9 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Pruritus; Rash	Escitalopram			S	Oral	Unk Unk, Qd (2.5 Ml Every Morning)		Hetero
	Intuniv			C	Unknown			Not Reported
	Clonidine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16227151	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-021301			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental Disorder; Wrong Technique In Product Usage Process	Mirtazapine			S	Unknown	15 Milligram		Aurobindo
	Mirtazapine			S				Aurobindo
	Mirtazapine			S				Aurobindo
	Mirtazapine			S				Aurobindo
	Mirtazapine			S				Aurobindo
	Buspirone			S	Unknown	Unk		Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S				Not Reported
	Lorazepam			S				Not Reported
	Lorazepam			S				Not Reported
	Lorazepam			S				Not Reported

Escitalopram	S	Unknown	15 Milligram		Not Reported
Escitalopram	S	Unknown	Cutting Bits To 5 Mg To Reach Approx. 12.5 Mg In 6 Weeks		Not Reported
Escitalopram	S	Unknown	Reduce To 12.5 Mg Over 8 Weeks		Not Reported
Escitalopram	S				Not Reported
Escitalopram	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16280638	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2019-024430			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Decreased Appetite; Restlessness; Tremor	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16375195	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US04055			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Feeling Abnormal; Headache; Malaise; Withdrawal Syndrome	Escitalopram			S	Unknown	Unk, 15 Years		Invagen
	Escitalopram			S	Oral	20 Milligram, Qd (In Morning)		Invagen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16375407	EXPEDITED (15-DAY)		DE	FR-ZYDUS-037112		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral			Cadila
	Rivaroxaban			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16375994	EXPEDITED (15-DAY)		LT	FR-ACCORD-130171		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported
	Racecadotril Bgr			S	Oral			Not Reported
	Coveram			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16376299	EXPEDITED (15-DAY)		DE	FR-TEVA-2019-FR-1055944		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral	Unspecified		Ivax
	Xarelto			S	Oral	Unspecified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16376482	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2019-030153			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral	Unk (Unspecified)		Aurobindo
	Xarelto			S	Oral	Unk (Unspecified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16376596	EXPEDITED (15-DAY)		DE, OT	DE-TEVA-2019-DE-1056169		70 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Interaction	Diazepam			S				Barr

	Ergenyl Chrono		S			Not Reported
	Haldol		S			Not Reported
	Remergil		S			Not Reported
	Seroquel		S		Slowly Added Up From 13.12.2008	Not Reported
	Cipralex		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16376861	EXPEDITED (15-DAY)		OT	HR-ASTRAZENECA-2019SE77623			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Foaming At Mouth; Intentional Overdose; Suicide Attempt; Tremor	Quetiapine			S	Oral	4.0g Unknown		Zeneca
	Elicea			S	Oral	360.0mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16377296	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019229721		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Flushing; Headache; Hyperhidrosis; Nausea; Nervousness; Pain; Serotonin Syndrome; Tremor	Effexor Xr			S	Oral	150 Mg, 1x/Day		Pfizer
	Cipralex [Escitalopram Oxalate]			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16378995	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1050366		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Thrombosis	Prednisone			S	Oral	4 Milligram, Qd		Not Reported
	Valaciclovir			S	Oral	1000 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qw		Not Reported

Desloratadine	S	Oral	5 Milligram, Qd		Not Reported
Paracetamol	S	Oral	2 Dosage Form, Qd		Not Reported
Lisinopril	S	Oral	10 Milligram, Qd		Not Reported
Escitalopram	S	Oral	20 Milligram, Qd		Not Reported
Risedronate	S	Oral	35 Milligram, Qw		Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Qw		Mylan
Speciafoldine	S	Oral	10 Milligram, Qw		Mylan
Codeine	S	Oral	2 Dosage Form, Qd		Mylan
Uvedose	S	Oral	1 Dosage Form		Mylan
Cacit /07357001/	S	Oral	1 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16379004	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2019M1050285		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydrocephalus; Intraventricular Haemorrhage	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported
	Kardegic			S	Oral	75 Milligram, Qd		Mylan
	Xarelto			S	Oral	20 Mg/J		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16379023	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1051030		49 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	14 Dosage Form, Total		Not Reported
	Lorazepam			S	Oral	40 Milligram, Total		Not Reported
	Aripiprazole			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16383614	DIRECT		DS			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Impaired Quality Of Life; Palpitations; Paraesthesia; Pollakiuria; Sexual Dysfunction; Skin Burning Sensation; Withdrawal Syndrome	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16570246	DIRECT	Y	LT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2019	16380579	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-031821			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dry Mouth; Headache; Nausea; Sedation; Vomiting	Escitalopram			S	Oral	10 Milligram		Aurobindo
	Atenolol			S	Oral	25 Milligram		Not Reported
	Oxynorm			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxizinum			S	Oral	Unk		Not Reported
	Hydroxizinum			S				Not Reported
	Ketonal			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pyralgin [Metamizole Sodium]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Fenactil			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Oxycontin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16381306	EXPEDITED (15-DAY)		OT	CA-TWI PHARMACEUTICAL, INC-2019SCTW000012			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Intentional Overdose; Seizure	Bupropion Hydrochloride			S	Oral	Unk		Twi Pharmaceuticals
	Escitalopram			S	Oral	Unk		Not Reported
	Quetiapine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16381880	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1057100		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Valsartan			S	Oral	160 Milligram Daily;		Teva
	Esomeprazole			S	Oral	20 Milligram Daily;		Teva
	Lasilix 40 Mg, Comprimé Sécable			S	Oral	40 Milligram Daily;		Not Reported
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported
	Discotrine			C	Transdermal	1 Dosage Forms Daily;		Not Reported
	Simvastatine			C	Oral	20 Milligram Daily;		Not Reported
	Manidipine (Chlorhydrate De)			C	Oral	10 Milligram Daily;		Not Reported
	Seresta 10 Mg, Comprimé			C	Oral	1 Dosage Forms Daily;		Not Reported
	Bisoce 2,5 Mg, Comprimé Pelliculé Sécable			C	Oral	1 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16382120	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-209524		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State;	Spironolactone			S	Oral	75 Milligram, Daily		Sun

Hyponatraemia	Escitalopram	S	Oral	5 Milligram	Not Reported
	Keppra 1000 Mg, Comprime Pellicule	S	Oral	2000 Milligram, Daily	Not Reported
	Zebinix 800 Mg, Comprime	S	Oral	800mg X 1.5	Not Reported
	Chronadalate	C	Unknown	Unk	Not Reported
	Fenofibrate	C	Unknown	Unk	Not Reported
	Chlorhydrate De Sotalol	C	Unknown	Unk	Not Reported
	Januvia	C	Unknown	Unk	Not Reported
	Urbanyl 10 Mg, Comprime Secable	C	Unknown	Unk	Not Reported
	Fortzaar 100 Mg/25 Mg, Comprime Pellicule	C	Unknown	Unk	Not Reported
	Glimepiride	C	Unknown	Unk	Not Reported
	Kardegic	C	Unknown	Unk	Not Reported
	Metformine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16382440	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1057087		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram			S	Oral	5 Milligram Daily;		Ivax
	Lormetazepam Arrow 2 Mg, Scored Tablet			S	Oral	1 Dosage Forms Daily;		Not Reported
	Trileptal 300 Mg Film-Coated Tablets			C				Not Reported
	Urorec			C				Not Reported
	Coveram			C				Not Reported
	Simvastatine			C				Not Reported
	Gabapentine			C				Not Reported
	Kardegic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16382854	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2019227203		85 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Gait Disturbance; Somnolence	Lorazepam	S	Oral	1 Mg, 1x/Day (Every 24 Hours, 0-0-1)	Pfizer
	Escitalopram Cinfa	S	Oral	15 Mg, 1x/Day(1 Every 24 Hours)	Not Reported
	Lexatin [Bromazepam]	S	Oral	1.5 Mg, 3x/Day (Every 8 Hours, 1-1-1)	Not Reported
	Deprax [Sertraline Hydrochloride]	S	Oral	50 Mg, 1x/Day(Every 24 Hours, 0-0-1/2)	Not Reported
	Zyloric	C	Oral	Unk	Not Reported
	Omeprazole	C	Oral	Unk	Not Reported
	Uniket	C	Oral	Unk	Not Reported
	Monoprost	C	Ophthalmic	Unk	Not Reported
	Crestor	C	Oral	Unk	Not Reported
	Secalip	C	Oral	Unk	Not Reported
	Tesavel	C	Oral	Unk	Not Reported
	Emconcor Cor	C	Oral	Unk	Not Reported
	Acfol	C	Oral	Unk	Not Reported
	Seguril	C	Oral	Unk	Not Reported
	Sintrom	C	Oral	Unk	Not Reported
	Zaldiar	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16382917	EXPEDITED (15-DAY)		HO	FR-ZYDUS-037291		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral			Cadila
	Rhinomaxil			S	Nasal			Not Reported
	Galantamine/Galantamine Hydrobromide			S	Oral			Zydus Pharm
	Fenofibrate			S	Oral			Not Reported
	Spironolactone			S	Oral			Zydus Pharm

Cholecalciferol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16383099	EXPEDITED (15-DAY)		OT	CA-JUBILANT CADISTA PHARMACEUTICALS-2019JUB00202		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Overdose; Seizure	Bupropion			S	Oral			Jubilant
	Escitalopram			S	Oral			Jubilant
	Quetiapine			S	Oral			Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16384052	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-2019M1051090		82 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Alendronate			S	Oral	70 Milligram, Qw		Not Reported
	Escitalopram			S	Oral	20 Milligram, Qd		Mylan
	Acetylsalicylic Acid			S	Oral	75 Milligram, Qd		Mylan
	Felodipine			C		Unk		Mylan
	Levothyroxine			C		Unk		Mylan
	Adcal D3			C		Unk		Mylan
	Doxazosin			C		Unk		Mylan
	Simvastatin			C		Unk		Mylan
	Salbutamol			C		Unk		Mylan
	Seretide			C		Unk		Mylan
	Dymista			C		Unk		Mylan
	Montelukast			C		Unk		Mylan
	Gabapentin			C		Unk		Mylan
	Ferrous Fumarate			C		Unk		Mylan
	Zopiclone			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16384377	EXPEDITED (15-DAY)		OT	CA-HERITAGE PHARMACEUTICALS-2019HTG00240		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Overdose; Seizure	Bupropion Hydrochloride			S	Oral			Heritage
	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16385780	NON-EXPEDITED			PHEH2019US022446		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Gilenya			S	Unknown	0.5 Mg, Unk		Novartis
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16158159	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-APOTEX-2019AP010534		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved Indication	Ibuprofen			S	Oral	400 Mg, Prn		Apotex
	Diclofenac Sodium			S	Oral	50 Mg, Bid		Apotex
	Diclofenac Sodium			S	Oral	2 Df, Qd		Apotex
	Cipralex /01588501/			S	Oral	10 Mg, Qd		Not Reported
	Eliquis			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16230461	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2019166272			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental Disorder; Wrong Technique In Product Usage Process	Lorazepam			S	Unknown	Unk		Pfizer
	Lorazepam			S				Pfizer
	Lorazepam			S				Pfizer
	Lorazepam			S				Pfizer
	Lorazepam			S				Pfizer
	Escitalopram			S		12.5 Mg, Unk		Not Reported
	Escitalopram			S		15 Mg, Unk		Not Reported
	Escitalopram			S		5 Mg To Reach Approx. 12.5 Mg In 6 Weeks'		Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Mirtazapine			S		15 Mg, Unk		Not Reported
	Mirtazapine			S				Not Reported
	Mirtazapine			S				Not Reported
	Mirtazapine			S				Not Reported
	Mirtazapine			S				Not Reported
	Buspirone			S	Unknown	Unk		Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16386562	NON-EXPEDITED		HO, OT	IN-LUPIN LIMITED-2019-02343		45 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Escitalopram			S	Unknown	20 Milligram		Lupin
	Escitalopram			S	Unknown	5 Milligram		Lupin
	Olanzapine			S	Unknown	10 Milligram		Not Reported
	Fluoxetine			S	Unknown	20 Milligram		Lupin
	Divalproex Sodium			C	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387190	EXPEDITED (15-DAY)		OT	CA-HETERO CORPORATE-HET2019CA00784		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Seizure; Sympathomimetic Effect	Quetiapine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Hetero
	Bupropion Xl			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387681	EXPEDITED (15-DAY)		OT	FR-ACCORD-130930		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral			Not Reported
	Furosemide			S	Oral			Accord
	Pantoprazole			S	Oral			Not Reported
	Candesartan			S	Oral			Not Reported
	Alprazolam			C				Not Reported
	Spagulax Pure Mucilage			C				Not Reported
	Gaviscon			C				Not Reported
	Voltarene Emulgel			C		1%		Not Reported
	Levothyrox			C				Not Reported
	Rilmenidine/Rilmenidine Phosphate			C				Not Reported
	Eupressyl			C				Not Reported
	Loxen L P			C		50 Mg		Not Reported
	Uvedose			C		100 000 Ui, Oral Solution In Ampoule		Not Reported
	Doliprane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387696	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2019-032690			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypomagnesaemia; Ventricular Extrasystoles	Escitalopram			S	Unknown	Unk		Aurobindo
	Omeprazole			S	Unknown	Unk		Aurobindo
	Enalapril;Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387699	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-032118			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Spinal Fracture	Escitalopram			S	Oral			Aurobindo
	Lormetazepam			S	Oral	2 Milligram, Once A Day		Not Reported
	Risperidone			S	Oral	1 Milligram, Once A Day		Aurobindo
	Phenergan			S	Oral	25 Milligram, Once A Day		Not Reported
	Agomelatine			S	Oral	25 Milligram, Once A Day		Not Reported
	Clotiazepam			S	Oral	Non		Not Reported
	Tilcotil			C	Unknown	Unk		Not Reported
	Atorvastatine			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388550	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-030996			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo
	Fenofibrate			S	Oral	67 Milligram, Daily		Aurobindo

Galantamine	S	Oral	16 Milligram, Daily		Aurobindo
Spironolactone	S	Oral	50 Milligram, Daily		Aurobindo
Rhinomaxil	S	Nasal	Unk		Not Reported
Cholecalciferol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388563	EXPEDITED (15-DAY)		OT	FR-ELI_LILLY_AND_COMPANY-FR201905015563		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence	Cymbalta			S	Oral	1 Dosage Form, Daily		Eli Lilly And Co
	Baclofene			S	Oral	Unk, Unknown		Not Reported
	Laroxyl			S	Oral	1 Dosage Form, Daily		Not Reported
	Seroplex			S	Oral	Unk, Unknown		Not Reported
	Seresta			S	Oral	1 Dosage Form, Daily		Not Reported
	Noctamide			S	Oral	Unk, Unknown		Not Reported
	Gabapentine			S	Oral	1 Dosage Form, Daily		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Weekly (1/W)		Not Reported
	Effexor			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388641	EXPEDITED (15-DAY)		OT	PL-TEVA-2019-PL-1057369		77 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dry Mouth; Headache; Nausea; Sedation; Vomiting	Escitalopram			S	Oral			Ivax
	Atenolol			S	Oral			Not Reported
	Oxynorm			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxizinum			S	Oral			Not Reported
	Hydroxizinum			S				Not Reported

	Ketonal (Ketoprofen)	S	Intravenous (not otherwise specified)	Not Reported
	Pyralgin [Metamizole Sodium]	S	Intravenous (not otherwise specified)	Not Reported
	Fenactil	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16389649	NON-EXPEDITED			US-TEVA-2019-US-1049613		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Escitalopram			S	Unknown	5 Milligram Daily;		Ivax
	Escitalopram			S				Ivax
	Loratadine			C	Unknown			Not Reported
	Albuterol			C	Respiratory (inhalation)			Not Reported
	Budesonide /Formoterol			C	Respiratory (inhalation)			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16389980	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1923427US			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Meilax			C	Oral			Not Reported
	Olanzapine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16585606	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error	Escitalopram 20mg Tablets			S				Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16391581	EXPEDITED (15-DAY)		HO, LT, OT	CA-MACLEODS PHARMACEUTICALS US LTD-MAC2019021528			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk,Unknown Amount		Macleods
	Bupropion			S	Oral	Unk, Unknown Amount		Not Reported
	Quetiapine			C	Oral	Unk, Unknown Amount		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16392568	EXPEDITED (15-DAY)		OT	PL-ALVOGEN-2019-ALVOGEN-099931		77 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dry Mouth; Headache; Nausea; Sedation; Vomiting	Atenolol			S	Oral	25.0mg Unknown		Not Reported
	Hydroxyzine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Oxycodone Hydrochloride			S	Oral			Not Reported
	Oxycodone Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported
	Ketoprofen			S	Intravenous (not otherwise specified)			Not Reported
	Metamizole Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Chlorpromazine Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxyzine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16393971	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1923327US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd: 0. - 11.3. Gestational Week		Allergan
	Femi Baby			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16394148	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019233325		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Spironolactone			S	Oral	50 Mg, 1x/Day		Pfizer
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Rhinomaxil			S	Nasal	Unk		Not Reported
	Galantamine Base			S	Oral	16 Mg, 1x/Day		Not Reported
	Fenofibrate			S	Oral	67 Mg, 1x/Day		Not Reported
	Cholecalciferol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16395507	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1051448		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Intentional Overdose; Miosis; Orthostatic Hypotension; Somnolence	Escitalopram			S	Oral	Dose Exacte Lors De L'Imv Inconnue		Not Reported
	Bromazepam			S	Oral	Prise Estimée À 20 Cp De Bromazépam 6 Mg		Not Reported
	Aripiprazole			S	Oral	Dose Exacte Lors De L'Imv Inconnue		Not Reported

	Zolpidem		S	Oral	Dose Exacte Lors De L'Imv Inconnue	Not Reported
	Olanzapine		S	Oral	Dose Exacte Lors De L'Imv Inconnue	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	15270581	EXPEDITED (15-DAY)		DS	IT-ALLERGAN-1839414US			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaesthesia; Anorgasmia; Disturbance In Attention; Erectile Dysfunction	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16225578	EXPEDITED (15-DAY)		OT	GB-009507513-1904GBR005968			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental Disorder; Wrong Technique In Product Usage Process	Mirtazapine			S	Unknown	15 Milligram		Merck
	Mirtazapine			S				Merck
	Mirtazapine			S				Merck
	Mirtazapine			S				Merck
	Mirtazapine			S				Merck
	Buspirone			S		Unk		Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported
	Lorazepam			S		Unk		Not Reported
	Lorazepam			S				Not Reported
	Lorazepam			S				Not Reported
	Lorazepam			S				Not Reported
	Lorazepam			S				Not Reported
	Escitalopram 5 Mg Film-Coated Tablets			S	Unknown	Reduce To 12.5 Mg Over 8 Weeks		Not Reported
	Escitalopram 5 Mg Film-Coated Tablets			S	Unknown	15 Mg		Not Reported

	Escitalopram 5 Mg Film-Coated Tablets	S	Unknown	Cutting Bits To 5 Mg To Reach Approx. 12.5 Mg In 6 Weeks	Not Reported
	Escitalopram 5 Mg Film-Coated Tablets	S	Unknown	15 Milligram	Not Reported
	Escitalopram 5 Mg Film-Coated Tablets	S	Unknown	15 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16246871	EXPEDITED (15-DAY)		DS, OT	ES-ACCORD-124378		45 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Female Sexual Dysfunction; Loss Of Libido	Escitalopram			S	Unknown	10 Mg, 1x/Day		Not Reported
	Sertraline			S	Oral	Also Received 100 Mg For 90 Days		Accord
	Enalapril			C	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16376648	EXPEDITED (15-DAY)		HO	ES-ASTRAZENECA-2019SE78869		61 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Hypomagnesaemia; Ventricular Extrasystoles	Omeprazole			S	Unknown			Not Reported
	Enalapril, Hydrochlorothiazide			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Metformin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16397065	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2019021479			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate		S	Unknown	Unk	Macleods
	Tiaprizal		S	Oral	100 Milligram, Tid, Per 8 Hour	Not Reported
	Tiaprizal		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16397326	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-031493			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Escitalopram			S	Oral	Unknown Amount		Aurobindo
	Bupropione			S	Oral	Unknown Amount		Not Reported
	Quetiapine			C	Oral	Unknown Amount		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16399515	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00014174		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Femi Baby			C	Transplacental	0.6 [Mg/D (Bis 0.8 Mg/D)]		Unknown
	Escitalopram			S	Transplacental	10 [Mg/D]		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16399999	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1923647US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram Oxalate - Bp			S	Oral	1 Df		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16400009	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1923585US			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Epistaxis; Fatigue; Oromandibular Dystonia	Escitalopram Oxalate - Bp		S	Oral	10 Mg, Qd	Allergan
	Escitalopram Oxalate - Bp		S	Oral	5 Mg, Qd	Allergan
	Escitalopram Oxalate - Bp		S	Oral	Increased Up To 20 Mg, Qd	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16400013	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1923423US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Spinal Fracture	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Agomelatine			S	Oral			Not Reported
	Phenergan			S	Oral			Not Reported
	Clotiazepam			S	Oral	15 Mg		Not Reported
	Risperidone			S	Oral			Not Reported
	Lormetazepam			S	Oral			Not Reported
	Tilcotil			C	Unknown			Not Reported
	Atorvastatine			C	Unknown			Not Reported
	Kardegic			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16400015	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1923642US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Baclofen			S	Oral	Unk		Not Reported
	Laroxyl			S	Oral	1 Df, Qd		Not Reported
	Seresta			S	Oral	1 Df, Qd		Not Reported
	Noctamide			S	Oral	Unk		Not Reported

Gabapentine	S	Oral	1 Df, Qd		Not Reported
Cymbalta	S	Oral	1 Df, Qd		Not Reported
Methotrexate	S	Subcutaneous	1 Df, Q Week		Not Reported
Effexor	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16400017	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1923361US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Loss Of Consciousness; Malaise; Orthostatic Hypotension; Vomiting	Escitalopram Oxalate - Bp			S	Oral	7.5 Mg, Qd		Allergan
	Contramal L.P.			S	Oral	200 Mg, Qd		Not Reported
	Xatral Lp			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16401059	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1923672US			Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16401230	EXPEDITED (15-DAY)		DS, OT	ES-ALLERGAN-1923583US			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Feeling Abnormal; Walking Disability	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16401429	EXPEDITED (15-DAY)		CA, HO	FR-ALLERGAN-1923983US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Induced; Pregnancy	Escitalopram Oxalate - Bp		S	Oral	10 Mg, Qd	Allergan
	Imovane		S	Oral		Not Reported
	Donormyl (Doxylamine Succinate)		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16404221	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Escitalopram			S				Not Reported
	Mirtazapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	15948882	EXPEDITED (15-DAY)		HO	LU-ACCORD-106585		47 YR	Female	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Actin Antibody Positive; Gamma-Glutamyltransferase Increased; Hepatocellular Injury	Escitalopram			S	Oral			Not Reported
	Gilenya			S	Oral			Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16214465	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1916563US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Burnout Syndrome; Depression; Drug Interaction; Drug Intolerance; Heart Rate Increased; Hyperhidrosis; Hypertension; Palpitations; Panic Attack; Restlessness; Stress; Underdose	Escitalopram Oxalate - Bp			S	Unknown	5 Mg		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	7.5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16251255	EXPEDITED (15-DAY)		DS	IT-MYLANLABS-2019M1039123		61 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dysgraphia; Dyskinesia; Off Label Use; Therapeutic Product Effect Decreased; Tremor	Escitalopram			S		Unk		Not Reported
	Sertraline			S	Unknown	50 Milligram, Qd		Not Reported
	Sertraline			S		200 Milligram, Qd		Not Reported
	Sertraline			S				Not Reported
	Venlafaxine			S		Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S				Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Valproic Acid			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16279023	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1918879US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral; Pruritus	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Irbesartan			C	Oral	300 Mg, Qd		Not Reported
	Kardegic			C	Oral	1 Df, Qd		Not Reported
	Lercanidipine			C	Oral	10 Mg, Qd		Not Reported
	Physiotens			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16301322	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1919880US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan

Prolonged; Syncope; Torsade De Pointes	Escitalopram Oxalate - Bp		S	Unknown	10 Mg, Qd	Allergan
	Escitalopram Oxalate - Bp		S	Unknown	5 Mg, Qd	Allergan
	Captohexal		S	Unknown	25 Mg, Qd	Not Reported
	Captohexal		S	Unknown	50 Mg, Qd	Not Reported
	Dipiperon		S	Unknown	80 Mg, Qd	Not Reported
	Esidrix		S	Unknown	25 Mg, Qd	Not Reported
	Esidrix		S	Unknown	12.5 Mg, Qd	Not Reported
	Galantamine Hydrobromide		S	Unknown	2.5 Mg, Qd	Not Reported
	Galantamine Hydrobromide		S	Unknown	8 Mg, Qd	Not Reported
	Galantamine Hydrobromide		S	Unknown	5 Mg, Qd	Not Reported
	Amlodipin		C	Unknown	2.5 Mg, Qd	Not Reported
	Amlodipin		C	Unknown	5 Mg, Qd	Not Reported
	Marcumar		C	Unknown	Nach Inr	Not Reported
	Calcium Carbonate		C	Unknown	2 Df, Qd	Not Reported
	Trazodone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16402878	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-209863		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Valsartan			S	Oral	160 Milligram, Daily		Ranbaxy
	Esomeprazole			S	Oral	20 Milligram, Daily		Sun
	Lasilix 40 Mg, Comprime Secable			S	Oral	40 Milligram, Daily		Not Reported
	Seroplex 10 Mg, Comprime Pellicule Secable			S	Oral	1 Dosage Form, Daily		Not Reported
	Discotrine			C	Transdermal	1 Dosage Form, Daily		Not Reported
	Simvastatine			C	Oral	20 Milligram, Daily		Not Reported
	Manidipine (Chlorhydrate De)			C	Oral	10 Milligram, Daily		Not Reported
	Seresta 10 Mg, Comprime			C	Oral	1 Dosage Form, Daily		Not Reported

	Bisoce 2,5 Mg, Comprime Pellicule Secable	C	Oral	1 Dosage Form, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16403214	EXPEDITED (15-DAY)		CA, OT	FR-ALKEM LABORATORIES LIMITED-FR-ALKEM-2019-05155			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Aortic Anomaly; Foetal Exposure During Pregnancy; Premature Baby; Pulmonary Artery Stenosis Congenital; Ventricular Septal Defect	Aripiprazole			S	Transplacental	Unk		Alkem
	Escitalopram			S	Transplacental	Unk		Not Reported
	Dihydroergotamine			S	Transplacental	Unk		Not Reported
	Oxazepam			S	Transplacental	Unk		Not Reported
	Pipamperone			S	Transplacental	Unk		Not Reported
	Loprazolam			S	Transplacental	Unk		Not Reported
	Dipotassium Clorazepate			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16403224	EXPEDITED (15-DAY)		OT	FR-ALKEM LABORATORIES LIMITED-FR-ALKEM-2019-05179			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Aripiprazole			S	Transplacental	Unk		Alkem
	Escitalopram			S	Transplacental	Unk		Not Reported
	Methadone Hydrochloride			S	Transplacental	Unk		Alkem
	Zopiclone			S	Transplacental	Unk		Not Reported
	Alprazolam			S	Transplacental	Unk		Not Reported
	Mirtazapine			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16403455	EXPEDITED (15-DAY)		HO, LT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-		17 YR	Female	CAN

2019R1-210090

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Seizure; Toxicity To Various Agents	Bupropion			S	Oral	Unk		Sun
	Escitalopram			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16403505	EXPEDITED (15-DAY)		CA	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019021585			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	10 Milligram, Qd, 0. - 11.3. Gestational Week		Macleods
	Minerals Nos/Vitamins Nos			C	Transplacental	Unk, 0.6 [Mg/D (Bis 0.8 Mg/D)]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16403752	EXPEDITED (15-DAY)		CA	DE-HETERO CORPORATE-HET2019DE00792		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	10 [Mg/D]		Hetero
	Femi Baby			C	Transplacental	0.6 [Mg/D (Bis 0.8 Mg/D)]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16404211	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20190601728		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Spinal Fracture	Risperidone		S	Oral	Not Reported
	Agomelatine		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported
	Phenergan		S	Oral	Not Reported
	Clotiazepam		S	Oral	Not Reported
	Lormetazepam		S	Oral	Not Reported
	Atorvastatin		C	Unknown	Not Reported
	Kardegic		C	Unknown	Not Reported
	Esomeprazole		C	Unknown	Not Reported
	Ramipril		C	Unknown	Not Reported
	Tilcotil		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16405824	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1058115			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Foaming At Mouth; Intentional Overdose; Suicide Attempt; Tremor	Quetiapine			S	Oral			Teva
	Elicea			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16410338	DIRECT					84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Oral	Quantity:1 Tablet(S);	90 DAY	Teva
	Flomax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16410660	DIRECT		OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergic Reaction To Excipient; Product Substitution Issue; Rash; Urticaria	Benazepril, 20 Mg	Y		S	Oral	Quantity:1 Tablet(S);	1 DAY	Prinston Pharmaceutical
	Estradiol	Y		S	Oral	Quantity:1 Tablet(S);		Barr
	Metoprolol Succinate			S				Not Reported
	Sertraline			S				Not Reported
	Hydralazine			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2019	16407695	EXPEDITED (15-DAY)		HO	PHHY2019FR127994		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Spinal Fracture	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Risperidone			S	Oral	1 Mg, Qd		Novartis
	Lormetazepam			S	Oral	2 Mg, Qd		Not Reported
	Agomelatine			S	Oral	25 Mg, Qd		Not Reported
	Phenergan			S	Oral	25 Mg, Qd		Not Reported
	Clotiazepam			S	Oral	15 Mg, Qd		Not Reported
	Tilcotil			C	Unknown	Unk		Not Reported
	Atorvastatine			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16363375	EXPEDITED (15-DAY)			JP-JNJFOC-20190533993		48 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Pain	Invega			S	Oral			Not Reported
	Lonasen			S	Oral			Not Reported

	Loxonin	S	Unknown		Not Reported
	Metgluco	S	Oral		Not Reported
	Irbetan	S	Oral		Not Reported
	Lexapro	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16391237	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1923348US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Product Use Issue; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Quetiapine			S	Unknown	Unk		Not Reported
	Bupropion Xl			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16391245	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1923607US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Cyproheptadine			S	Unknown			Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16408582	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-209946		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Spironolactone			S	Oral	50 Milligram, Daily		Sun
	Fenofibrate			S	Oral	67 Milligram, Daily		Not Reported

Galantamine Base	S	Oral	16 Milligram, Daily		Not Reported
Rhinomaxil 100 Microgrammes/Dose, Suspension Pour Pulverisation Nasale	S	Nasal	()		Not Reported
Cholecalciferol	C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16408589	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1057671		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Galantamine Base			S	Oral	16 Milligram Daily;		Barr
	Fenofibrate			S	Oral	67 Milligram Daily;		Teva
	Spironolactone			S	Oral	50 Milligram Daily;		Actavis
	Rhinomaxil 100 Micrograms/Dose, Nasal Spray Suspension			S	Nasal			Not Reported
	Cholecalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16408641	NON-EXPEDITED			US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-206562		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Hypoaesthesia; Paraesthesia; Product Dose Omission	Absorica			S	Unknown	30 Milligram, Bid		Sun
	Levocetirizine			S	Unknown			Sun
	Adderall			S	Unknown	Unk		Not Reported
	Singulair			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16409107	NON-EXPEDITED			US-TEVA-2019-US-1052744		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexually Inappropriate Behaviour	Escitalopram			S	Unknown			Ivax
	Donepezil			C	Unknown			Not Reported
	Memantine			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16409627	EXPEDITED (15-DAY)		OT	PL-JUBILANT CADISTA PHARMACEUTICALS-2019JUB00220			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown			Jubilant
	Ginseng			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16410777	EXPEDITED (15-DAY)		OT	PHHY2019FR128033		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence	Baclofen			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Novartis
	Gabapentin			S	Oral	1 Df, Qd		Not Reported
	Laroxyl			S	Oral	1 Df, Qd		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Seresta			S	Oral	1 Df, Qd		Not Reported
	Noctamide			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	1 Df, Qd		Not Reported
	Effexor			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16411548	EXPEDITED (15-DAY)		OT	HR-INDIVIOR LIMITED-INDV-119938-2019		16 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Potassium Increased; Bradycardia; Drug Abuse; Product Use Issue	Subutex Tablet			S	Oral	1 Dose, Unk		Reckitt Benckiser
	Pregabalin			S	Oral	1 Dose, Unk		Not Reported
	Misar /00595201/			S	Oral	1 Dose, Unk		Not Reported
	Serpentil /01588502/			S	Oral	1 Dose, Unk		Not Reported
	Sanval			S	Oral	1 Dose, Unk		Not Reported
	Kventiax			S	Oral	1 Dose, Unk		Not Reported
	Normabel			S	Oral	1 Dose, Unk		Not Reported
	Xanax			S	Oral	1 Dose, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16411713	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2019M1053655			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Kidney Duplex	Escitalopram			S	Transplacental	10 Milligram, Qd		Not Reported
	Escitalopram			S	Transplacental	5 Milligram, Qd		Not Reported
	Magnetrans /01486820/			C	Transplacental	Unk		Mylan
	Ibuprofen			C	Transplacental	400 [Mg/D]/ On Demand, Max Once Per Week		Mylan
	Cetirizine			C	Transplacental			Mylan
	Paracetamol			C	Transplacental	1500 [Mg/D]/ 1000-1500 Mg/D, In Total 2-3 Times		Mylan
	Cytotec			C	Transplacental	Unk		Mylan
	Olynth			C	Transplacental	If Required		Mylan
	Folio Forte			C	Transplacental	0.8 [Mg/D]/ From Week 14 0.4mg/D		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16412209	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1923640US			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; No Adverse Event; Product Administered To Patient Of Inappropriate Age; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	70 Mg, Overdose		Allergan
	Aripiprazole			S	Oral	30 Mg, Unknown		Not Reported
	Xanax			S	Oral	2 Df, Unknown		Not Reported
	Diazepam			S	Oral	20 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16248696	EXPEDITED (15-DAY)		HO	FR-ACCORD-124498		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Pantoprazole			S				Not Reported
	Escitalopram			S	Oral			Not Reported
	Lasilix			S	Oral	500 Mg, Scored Tablet		Not Reported
	Spironolactone			C	Oral			Not Reported
	Coumadine			C	Oral	2 Mg Scored Tablet		Not Reported
	Bisoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16254732	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-018012			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Intentional Product Use Issue; Muscle Spasms; Peripheral Venous Disease; Seasonal Affective Disorder; Vein Disorder	Magnesium			S	Unknown	Unk		Aurobindo
	Seroplex			S	Unknown	5 Milligram, Once A Day		Not Reported
	Seroplex			S	Unknown	10 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16385005	EXPEDITED (15-DAY)			JP-ALLERGAN-1923132US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Oedema; Proteinuria	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16412966	EXPEDITED (15-DAY)		CA	DE-AUROBINDO-AUR-APL-2019-032482			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	10 Milligram, Daily (10 [Mg/D]		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16413224	EXPEDITED (15-DAY)		OT	PL-APOTEX-2019AP015917		77 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dry Mouth; Headache; Nausea; Sedation; Vomiting	Escitalopram			S	Oral	10 Mg, Unk		Apotex
	Atenolol			S	Oral	25 Mg, Unk		Not Reported
	Oxynorm			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxizinum			S	Oral	Unk		Not Reported
	Hydroxizinum			S				Not Reported
	Ketonal /00321701/			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pyralgin /03155201/			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Fenactil			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Oxycontin			S	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16413504	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-03479			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Confusional State; Delirium; Drug Hypersensitivity; Dyspepsia; Fatigue; Mental Status Changes; Nausea; Pruritus; Vomiting	Escitalopram			S	Unknown	Unk		Lupin
	Fluoxetine			S	Unknown	Unk		Lupin
	Cephalexin			S	Unknown	Unk		Lupin
	Duloxetine			S	Unknown	Unk		Lupin
	Oxycodone			S	Unknown	Unk		Novel Labs
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Novel Labs

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16413595	EXPEDITED (15-DAY)		HO, LT, OT	CA-GLAXOSMITHKLINE-CA2019GSK096346		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Bupropion Hydrochloride Xl			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Quetiapine			C	Oral	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16413892	EXPEDITED (15-DAY)		HO, LT	FR-ACCORD-131912		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Amlodipine			S	Oral			Accord
	Zelitrex			S	Oral	Strength:500 Mg		Not Reported
	Seroplex			S	Oral	Strength: 5 Mg		Not Reported

Perindopril	S	Oral			Not Reported
Ditropan	S	Oral	Strength: 5 Mg		Not Reported
Fludex (Indapamide)	S	Oral	Strength: 1.5 Mg		Not Reported
Cortancyl	C	Oral			Not Reported
Paracetamol	C	Oral			Not Reported
Movicol	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16413899	EXPEDITED (15-DAY)		HO, OT	PT-ACCORD-131813		57 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram			S	Oral	14 Cp Of 20 Mg + 27 Cp Of 10 Mg		Not Reported
	Lorazepam			S	Oral	72 Cp Of 2.5 Mg		Not Reported
	Bupropion/Bupropion Hydrochloride			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Diazepam			C				Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			C				Not Reported
	Olanzapine			C				Not Reported
	Topiramate			C				Not Reported
	Hydroxycarbamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16414773	NON-EXPEDITED			US-PFIZER INC-2019240987		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Ineffective; Loss Of Personal Independence In Daily Activities	Zoloft			S		100 Mg, Unk [30 Ds/30 Quantity]		Pfizer
	Pristiq			S		Unk		Pfizer
	Prozac			S		10 Mg, Unk [30 Ds/ 30 Quantity]		Not Reported

	Remeron	S	Unk, 1x/Day		Not Reported
	Lexapro	S	Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16415310	EXPEDITED (15-DAY)		OT	PHHY2019HR131063		16 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Potassium Increased; Bradycardia; Drug Abuse	Sanval			S	Oral	1 Ot, Unk		Novartis
	Pregabalin			S	Oral	1 Ot, Unk		Not Reported
	Cocaine			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Misar (Alprazolam)			S	Oral	1 Df, Unk		Not Reported
	Serpentil (Escitalopram Oxalate)			S	Oral	1 Ot, Unk		Not Reported
	Kventiax			S	Oral	1 Ot, Unk		Not Reported
	Subutex			S	Oral	1 Ot, Unk		Not Reported
	Normabel (Diazepam)			S	Oral	1 Ot, Unk		Not Reported
	Xanax			S	Oral	1 Ot, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16417208	EXPEDITED (15-DAY)		HO	FR-NAPPMUNDI-GBR-2019-0067165			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertonia Neonatal; Respiratory Depression	Oxynorm			S	Transplacental	30 Mg, Daily		Purdue
	Oxycontin Lp			S	Transplacental	(Strength 5mg)		Purdue
	Seroplex			S	Transplacental	20 Mg, Daily		Not Reported
	Seresta			S	Transplacental	Cf Commentaire		Not Reported
	Laroxyl			S	Transplacental	2 Df, Daily		Not Reported
	Inexium /01479302/			C	Transplacental	40 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16417449	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1054505			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Medication Error; Overdose	Escitalopram			S	Oral	30 Milligram, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16421126	DIRECT		HO			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Ii Disorder; Mania; Serotonin Syndrome; Weight Decreased	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Lamotrigine			C				Not Reported
	Lisinopril			C				Not Reported
	Clonazepam			C				Not Reported
	Propranolol Er			C				Not Reported
	Hydroxyzine Pamoate			C				Not Reported
	Gabapentin			C				Not Reported
	Norlyda			C				Not Reported
	Sumatriptan			C				Not Reported
	Meloxicam			C				Not Reported
	Ketorolac			C				Not Reported
	Carisoprodol			C				Not Reported
	Lexapro			C				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	14099163	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2017-41966			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Intentional Self-Injury; Sopor	Delorazepam Tablet			S	Oral	1mg		Not Reported
	Losartan Film-Coated Tablets			S	Oral	Dosage Form: Unspecified,Tablets, 50		Aurobindo

					Mg	
	Escitalopram Accord		S	Oral	20 Milligram	Not Reported
	Haldol		S	Oral	Dosage Form: Solution	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	15125501	EXPEDITED (15-DAY)		OT	CN-APOTEX-2018AP016929		37 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chorioretinopathy; Cough; Depressed Mood; Depression; Disease Recurrence; Drug Ineffective; Dry Eye; Fear; Product Use In Unapproved Indication; Product Use Issue; Productive Cough; Soft Tissue Disorder; Somnolence; Visual Impairment; Weight Increased	Seroxat			S	Oral	0.5 Df, Qd, 20 Mg		Apotex
	Seroxat			S	Oral	1.5 Df, Qd (Tablet 20 Mg)		Apotex
	Seroxat			S	Oral	0.5 Df, Qd (Tablet)		Apotex
	Seroxat			S	Oral	0.5 Df, Qod (Tablet)		Apotex
	Seroxat			S	Oral	1 Df, Qd		Apotex
	Seroxat			S	Oral	1 Df, Qd (Tablet), 25 Mg		Apotex
	Seroxat			S	Oral	1 Df, Qd (Tablet), 25 Mg		Apotex
	Seroxat			S	Oral	0.5 Df, Qd		Apotex
	Seroxat			S	Oral	1.5 Df, Qd		Apotex
	Seroxat			S	Oral	0.5 Df, Q.O.D.		Apotex
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16246935	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20190433124			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Burnout Syndrome; Depression; Drug Interaction; Drug Intolerance; Heart Rate Increased; Hyperhidrosis; Hypertension; Palpitations; Panic Attack;	Ibuprofen		Y	S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

Restlessness; Stress; Underdose	Escitalopram		S	Unknown	Not Reported
	Cipralex		S	Unknown	Not Reported
	Cipralex		S	Unknown	Not Reported
	Cipralex		S	Unknown	Not Reported
	Cipralex		S	Unknown	Not Reported
	Cipralex		S	Unknown	Not Reported
	Cipralex		S	Unknown	Not Reported
	Cipralex		S	Unknown	Not Reported
	Cipralex		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16406407	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1052606		83 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported
	Candesartan			S	Oral	16 Milligram, Qd		Not Reported
	Spironolactone			S	Oral	25 Milligram, Qd		Not Reported
	Imovane			S	Oral	1 Dosage Form, Qd		Mylan
	Seresta			S	Oral	1 Dosage Form, Qd		Mylan
	Lasilix /00032601/			S	Oral	4 Dosage Form, Qd		Mylan
	Omexel			S	Oral	1 Dosage Form, Qd		Mylan
	Tenordate			S	Oral	1 Dosage Form, Qd		Mylan
	Lovenox			C		Unk		Mylan
	Kardegic			C		Unk		Mylan
	Seebri Breezhaler			C		Unk		Mylan
	Avodart			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16418264	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-031939			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Decreased; Cardiotoxicity; Coma; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haemodynamic Instability; Hypocalcaemia; Hypokalaemia; Hypotension; Intentional Overdose; Pulse Absent; Suicide Attempt; Tachycardia	Fluoxetine			S	Unknown	Unk		Aurobindo
	Gabapentin			S	Unknown	Unk		Aurobindo
	Olanzapine			S	Unknown	Unk		Aurobindo
	Quetiapine Film-Coated Tablet			S	Unknown	Unk		Aurobindo
	Amitriptyline			S	Oral	Unk		Not Reported
	Amitriptyline			S				Not Reported
	Cipralex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16420014	NON-EXPEDITED		HO	CA-SCIEGEN PHARMACEUTICALS INC-2019SCILIT00194		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Bupropion Hydrochloride			S				Sciegen
	Escitalopram			S				Unknown
	Quetiapine			S				Sciegen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16420232	NON-EXPEDITED			US-PFIZER INC-2019242187			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Benzylpenicillin Potassium			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Simvastatin			S		Unk		Not Reported
	Sulfacetamide Sodium			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16421905	EXPEDITED (15-DAY)		CA	DE-TEVA-2019-DE-1060176		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	10 [Mg/D]		Ivax
	Femi Baby			C	Transplacental	0.6 [Mg/D (Bis 0.8 Mg/D)]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16421907	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1054405		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Headache; Sluggishness	Escitalopram			S	Oral	30 Milliliter, Total		Not Reported
	Alprazolam			S	Oral	20 Milliliter, Total		Not Reported
	Omeprazole			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16422474	EXPEDITED (15-DAY)		CA, HO	FR-SA-2019SA151986			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy	Imovane			S	Oral	7.5 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg Qd		Not Reported
	Doxylamine Succinate			S	Oral	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16423601	EXPEDITED (15-DAY)		HO	JP-PRINSTON PHARMACEUTICAL INC.-2019PRN00586		26 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction;	Escitalopram			S	Unknown	20 Mg, 1x/Day		Prinston

Rhabdomyolysis; Serotonin Syndrome	Clomipramine	S	Unknown	50 Mg, 1x/Day		Pharmaceutical Not Reported
	Alcohol	S	Oral	350 Ml		Not Reported
	Flunitrazepam	C	Unknown	2 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16424054	EXPEDITED (15-DAY)		HO	FR-ACCORD-132548		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pemphigoid	Furosemide			S	Oral			Accord
	Seroplex			S	Oral			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			C				Not Reported
	Toujeo			C				Not Reported
	Dafalgan			C				Not Reported
	Dermoval			C				Not Reported
	Picloxydine			C				Not Reported
	Innohep			C				Not Reported
	Desloratadine			C				Not Reported
	Novorapid			C				Not Reported
	Diffu K			C				Not Reported
	Theralene			C				Not Reported
	Ventolin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16426530	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2019-CA-1061421		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Overdose; Seizure; Sympathomimetic Effect	Bupropion Xl			S	Oral			Actavis
	Escitalopram			S	Oral			Ivax
	Quetiapine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16427604	EXPEDITED (15-DAY)		HO	MY-JNJFOC-20190612214		12 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Vitreous Anomaly; Schizophrenia; Sedation	Risperdone			S	Unknown			Not Reported
	Methylphenidate			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Bromazepam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	15484174	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1848211US			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypotension; Loss Of Consciousness	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qhs		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Zolpidem Tartrate			C	Oral	Unk, Prn		Not Reported
	Bayaspirin			C	Oral	100 Mg, Qd		Not Reported
	Carvedilol			C	Oral	1.25 Mg, Qd		Not Reported
	Lansoprazole			C	Oral	15 Mg, Qd		Not Reported
	Amlodipine			C	Oral	5 Mg, Qd		Not Reported
	K-Supply			C	Oral	1200 Mg, Q12h		Not Reported
	Pentasa			C	Oral	500 Mg, Q8hr		Not Reported
	Wypax			C	Oral	0.5 Mg, Q12h		Not Reported
	Urief			C	Oral	4 Mg, Q12h		Not Reported
	Fluconazole			C	Oral	100 Mg, Qd		Not Reported
	Levofloxacin Hydrate			C	Oral	500 Mg, Qd		Not Reported
	Magnesium Oxide			C	Oral	660 Mg, Q8hr		Not Reported
	Sennoside			C	Oral	24 Mg, Prn		Not Reported
	Filgrastim Bs			C	Subcutaneous	75 Mg, Qd		Not Reported

	Cyloside	C	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16429272	EXPEDITED (15-DAY)		OT	FR-ZYDUS-037548		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence	Baclofene			S	Oral	()		Not Reported
	Amitriptyline			S	Oral			Not Reported
	Escitalopram			S	Oral	()		Not Reported
	Oxazepam			S	Oral			Not Reported
	Lormetazepam			S	Oral	()		Not Reported
	Gabapentin			S	Oral			Zydus Pharm
	Duloxetine			S	Oral			Not Reported
	Methotrexate/Methotrexate Sodium			S	Subcutaneous			Not Reported
	Venlafaxine			S	Oral	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16429274	EXPEDITED (15-DAY)		HO	FR-ZYDUS-037567		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Spinal Fracture	Agomelatine			S	Oral			Not Reported
	Escitalopram			S	Oral			Cadila
	Promethazine			S	Oral			Not Reported
	Clotiazepam			S	Oral	Non		Not Reported
	Risperidone			S	Oral			Not Reported
	Lormetazepam			S	Oral			Not Reported
	Tenoxicam			C				Not Reported
	Atorvastatin			C				Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Esomeprazole			C				Not Reported

	Ramipril			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16429320	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-033212			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence	Gabapentin			S	Oral	1 Dosage Form, Daily		Aurobindo
	Baclofen			S	Oral	Unk		Not Reported
	Laroxyl			S	Oral	1 Dosage Form, Daily		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Seresta			S	Oral	1 Dosage Form, Daily		Not Reported
	Noctamide			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	1 Dosage Form, Daily		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Every Week		Not Reported
	Effexor			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16429769	EXPEDITED (15-DAY)		HO	IT-ACCORD-132784		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported
	Vortioxetine			C				Not Reported
	Sertraline			C				Not Reported
	Asenapine/Asenapine Maleate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16429832	EXPEDITED (15-DAY)		OT	ES-APOTEX-2019AP016552		61 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block; Electrocardiogram Qt	Escitalopram			S	Unknown	Unk		Apotex

Prolonged; Hypocalcaemia; Hypomagnesaemia; Ventricular Extrasystoles	Omeprazole	S	Unknown	Unk		Apotex
	Enalapril + Hidroclorotiazida	S	Unknown	Unk		Not Reported
	Trazodone	S	Unknown	Unk		Not Reported
	Metformin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16430036	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019248496		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence	Gabapentin			S	Oral	1 Df, 1x/Day		Pfizer
	Effexor			S	Oral	Unk		Pfizer
	Methotrexate			S	Subcutaneous	1 Df, Weekly		Not Reported
	Baclofene			S	Oral	Unk		Not Reported
	Laroxyl			S	Oral	1 Df, 1x/Day		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Seresta			S	Oral	1 Df, 1x/Day		Not Reported
	Noctamide			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16430579	EXPEDITED (15-DAY)		LT	FR-ACCORD-132676		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Escitalopram			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16430585	EXPEDITED (15-DAY)		DS, OT	AT-ACCORD-132855		25 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradyphrenia; Confusional State; Depressed Level Of Consciousness; Disturbance In Attention; Emotional Poverty; Erectile Dysfunction; Fatigue; Feeling Abnormal; Hyperhidrosis; Hypoaesthesia; Illusion; Loss Of Libido; Malaise; Memory Impairment; Orgasm Abnormal; Orgasmic Sensation Decreased; Personality Change; Poisoning; Tremor; Tunnel Vision	Escitalopram			S		Also Taken 10 Mg From 17-Dec-2018 To 20-Dec-2018(Dose Increased)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16432026	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1061866		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Spinal Fracture	Agomelatine			S	Oral			Not Reported
	Escitalopram			S	Oral			Ivax
	Risperidone			S	Oral			Actavis
	Phenergan (Promethazine)			S	Oral			Not Reported
	Clotiazepam			S	Oral	Non		Not Reported
	Lormetazepam			S	Oral			Not Reported
	Tilcotil			C				Not Reported
	Atorvastatine			C				Not Reported
	Kardegic			C				Not Reported
	Esomeprazole			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16432770	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1062427		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence	Gabapentine			S	Oral	1 Dosage Forms		Actavis
	Methotrexate			S	Subcutaneous	1 Dosage Forms		Barr
	Baclofene			S	Oral			Not Reported
	Laroxyl			S	Oral	1 Dosage Forms		Not Reported
	Seroplex			S	Oral			Not Reported
	Seresta			S	Oral	1 Dosage Forms		Not Reported
	Noctamide			S	Oral			Not Reported
	Cymbalta			S	Oral	1 Dosage Forms		Not Reported
	Effexor			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16434334	EXPEDITED (15-DAY)		OT	HR-SA-2019SA156402		16 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Potassium Increased; Bradycardia; Drug Abuse	Pregabalin			S	Oral	1 Unk		Not Reported
	Alprazolam			S	Oral	1 Unk		Not Reported
	Escitalopram Oxalate			S	Oral	1 Unk		Not Reported
	Zolpidem Tartrate			S	Oral	1 Unk		Sanofi
	Quetiapine Fumarate			S	Oral	1 Unk		Not Reported
	Buprenorphine Hydrochloride			S	Oral	1 Unk		Not Reported
	Diazepam			S	Oral	1 Unk		Not Reported
	Alprazolam			S	Oral	1 Unk		Not Reported
	Cocaine			S		Unk		Not Reported
	Marijuana			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16435147	EXPEDITED (15-DAY)		DE, HO, LT, OT	CH-ASTRAZENECA-2019SE87035		81 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Bradycardia; Dizziness; Dyspnoea; Fall; Ligament Rupture; Multiple Organ Dysfunction Syndrome; Pneumonia	Seroquel			S	Oral			Astrazeneca
	Diovan			S	Oral			Not Reported
	Diovan			S	Oral			Not Reported
	Diovan			S	Oral			Not Reported
	Jardiance			S	Oral			Not Reported
	Torem			S	Oral			Not Reported
	Torem			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Detrusitol			S	Oral			Not Reported
	Aldactone (Spironolactone)			S	Oral			Not Reported
	Aldactone (Spironolactone)			S	Oral			Not Reported
	Januvia			C				Not Reported
	Xarelto			C				Not Reported
	Plavix			C				Not Reported
	Symbicort			C				Not Reported
	Magnesiocard			C				Not Reported
	Ramipril			C				Not Reported
	Nasonex			C				Not Reported
	Bepanthen			C				Not Reported
	Spiriva			C				Not Reported
	Pradif			C				Not Reported
	Pantozol			C				Not Reported
	Crestor			C				Not Reported
	Movicol			C				Not Reported
	Colecalciferol			C				Not Reported
	Allopurinol			C				Not Reported
	Cardioaspirin			C				Not Reported
	Acidum Folicum			C				Not Reported
	Atorvastatin			C				Not Reported
	Ferro Sanol			C				Not Reported
	Concor			C				Not Reported

	Magnesium	C		Not Reported
	Clcz696d	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16435263	EXPEDITED (15-DAY)		CA, HO	NO-ALLERGAN-1924724US			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	The Mother Was Treated With Cipralex 20 Mg Daily Throughout The Whole Pregnancy.		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16435277	EXPEDITED (15-DAY)		HO	JP-JUBILANT CADISTA PHARMACEUTICALS-2019JUB00237		26 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rhabdomyolysis; Serotonin Syndrome	Escitalopram			S	Unknown	20 Mg, 1x/Day		Jubilant
	Clomipramine			S	Unknown	50 Mg, 1x/Day		Not Reported
	Alcohol			S	Oral	350 Ml		Not Reported
	Flunitrazepam			C	Unknown	2 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16439644	DIRECT					27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Obsessive-Compulsive Disorder; Panic Attack	Ach-Escitolopram			S	Oral	Quantity:1 Tablet(S);		Accord
	Cetirizine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2019	16437096	EXPEDITED (15-DAY)		HO	PHHY2019FR133743		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Allopurinol			S	Oral	100 Mg, Qd		Novartis
	Lyrica			S	Unknown	1 Df, Qd		Not Reported
	Lyrica			S	Unknown	1 Df, Qd		Not Reported
	Imovane			S	Oral	1 Df, Qd		Not Reported
	Smofkabiven			S	Intravenous drip	986 Ml, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Methotrexate			C	Intravenous (not otherwise specified)	Unk (Variable)		Not Reported
	Cyclophosphamide			C	Intravenous (not otherwise specified)	Unk (Variable)		Not Reported
	Vincristine Sulphate			C	Intravenous (not otherwise specified)	Unk (Variable)		Not Reported
	Doxorubicine			C	Intravenous (not otherwise specified)	Unk (Variable)		Not Reported
	Prednisone			C	Oral	Unk (Variable)		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	Unk (Variable)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2019	16232180	EXPEDITED (15-DAY)		OT	PHHY2019DE091199			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Burnout Syndrome; Depression; Drug Interaction; Drug Intolerance; Heart Rate Increased; Hyperhidrosis; Hypertension; Palpitations; Panic Attack; Product Use Issue; Product Use Issue; Restlessness; Stress; Underdose	Ibuprofen			S	Unknown	Unk		Novartis
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Cipralex			S	Unknown	10 Mg, Unk		Not Reported
	Cipralex			S	Unknown	7.5 Mg, Bid		Not Reported
	Cipralex			S	Unknown	5 Mg, Qd		Not Reported
	Cipralex			S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	15603335	EXPEDITED (15-DAY)		DE, HO, LT	CA-ALLERGAN-1852375US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Diclofenac Potassium			S	Oral	2 Df, Qd		Not Reported
	Ibuprofen			S	Oral	400 Mg, Unk		Not Reported
	Eliquis			C	Unknown	5 Mg, Q12h		Not Reported
	Pantoprazole			C	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	15644068	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1854178US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Jittery; Nervousness; Panic Attack	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16438401	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033347			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Escitalopram Tablets			S	Unknown	Unk, Once A Day		Aurobindo
	Cosentyx			S	Subcutaneous	150 Milligram, Every Week		Not Reported
	Cosentyx			S	Subcutaneous	150 Milligram, Every Month		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Povidone-Iodine			S	Unknown	Unk		Not Reported
	Vitamin D3			S	Unknown	Unk		Not Reported

	Voltaren	S	Unknown	Unk, Every Week		Not Reported
	Voltaren	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16438745	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01425			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Hypersensitivity; Fatigue; Irritability; Oedema; Palpitations; Tinnitus	Amlodipine Besylate Tablets			S	Unknown	Unk		Lupin
	Duloxetine Delayed-Release Capsules			S	Unknown	Unk		Lupin
	Escitalopram Tablets			S	Unknown	Unk		Lupin
	Gabapentin Tablet			S	Unknown	Unk		Lupin
	Lorazepam Oral Concentrate			S	Unknown	Unk		Lupin
	Losartan Potassium Tablet			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16442893	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1924839US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Overdose: 18 Dosage Forms In Total (In One Day)		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16442895	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1924740US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Anaphylactoid Shock; Diarrhoea; Hypotension; Rash Macular; Respiratory	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Selincro			S	Oral	18 Mg, Qd		Not Reported
	Methadone Ap-Hp			S	Oral	80 Mg, Qd		Not Reported
	Kardegic			C	Unknown			Not Reported

Distress	Lexomil Roche	C	Unknown	Not Reported
	Theralene	C	Unknown	Not Reported
	Loxen	C	Unknown	Not Reported
	Corgard	C	Unknown	Not Reported
	Abilify	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	15603885	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1852505US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Baclofen			C	Unknown			Not Reported
	Cialis			C	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16387677	EXPEDITED (15-DAY)		HO	FI-ACCORD-130509		71 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Lip Oedema; Oral Discomfort; Skin Burning Sensation	Escitalopram			S	Oral	10,Mg,Daily		Not Reported
	Vagifem			C	Vaginal	10,Mcg,Daily		Not Reported
	Betaserc			C	Oral	8,Mg,Daily		Not Reported
	Brilique			C	Oral	180,Mg,Daily		Not Reported
	Kalcipos-D			C	Oral			Not Reported
	Cardace			C	Oral			Not Reported
	Primaspan			C	Oral	100,Mg,Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16443785	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1063298		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram			S	Oral	1 Dosage Forms Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16444138	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033477			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Product Substitution Issue	Escitalopram Tablets			S	Oral	Unk Unk, Once A Day		Aurobindo
	Olanzapine			S	Oral	Unk Unk, Once A Day		Aurobindo
	Lorazepam			S	Oral	Unk Unk, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16444142	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033492			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Dizziness; Fatigue; Hyperhidrosis; Hypertension; Myalgia; Panic Disorder; Product Use In Unapproved Indication; Salivary Hypersecretion; Vomiting	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Escitalopram			S	Oral	20 Milligram, Unk		Aurobindo
	Escitalopram			S				Aurobindo
	Abilify			S	Oral	5 Milligram, Unk		Not Reported
	Abilify			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16444146	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-209681		26 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Procalcitonin Increased	Carbamazepine			S	Unknown	Unk		Taro
	Quetiapine			S	Unknown	Unk		Sun
	Escitalopram			S	Unknown	Unk		Not Reported

	Risperidone			S	Unknown	Unk			Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16444236	EXPEDITED (15-DAY)		OT	DK-ALKEM LABORATORIES LIMITED-DK-ALKEM-2019-03055		27 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Exposure During Pregnancy	Aripiprazole			S	Unknown	30 Milligram, Qd		Alkem
	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported
	Risperidone			S	Unknown	4 Milligram		Not Reported
	Risperidone			S	Unknown	0.5 Mg		Not Reported
	Citalopram			S	Unknown	20 Milligram		Not Reported
	Citalopram			S	Unknown	40 Milligram, Qd		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16446860	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2019252720		15 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Xanax			S	Oral	2 Df, Unk		Pfizer
	Aripiprazol			S	Oral	30 Mg, Unk		Not Reported
	Escitalopram			S	Oral	70 Mg, Unk		Not Reported
	Diazepam			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16447132	EXPEDITED (15-DAY)		HO	NL-ALLERGAN-1925183US			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Burning Sensation; Condition Aggravated; Depression;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

Skin Irritation	Diazepam	C	Unknown	5 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16448865	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1064016		18 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Insomnia; Intentional Self-Injury; Psychotic Disorder; Sleep Disorder; Visual Impairment; Withdrawal Syndrome	Escitalopram Abz 10 Mg Filmtabletten			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16449020	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1063940		16 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Potassium Increased; Bradycardia; Drug Abuse	Pregabalin			S	Oral			Not Reported
	Serpentil [Escitalopram Oxalate]			S	Oral			Ivax
	Kventiax			S	Oral			Not Reported
	Marijuana			S				Not Reported
	Cocaine			S				Not Reported
	Misar (Alprazolam)			S	Oral			Not Reported
	Sanval			S	Oral			Not Reported
	Subutex			S	Oral			Not Reported
	Normabel			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16449079	EXPEDITED (15-DAY)			FR-ALKEM LABORATORIES LIMITED-FR-ALKEM-2019-04849		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Tardive Dyskinesia; Therapy Partial Responder	Aripiprazole		S	Unknown	5 Milligram, Qd	Alkem
	Escitalopram		S	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16449829	EXPEDITED (15-DAY)		OT	JP-MACLEODS PHARMACEUTICALS US LTD-MAC2019021727			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate			S	Unknown	20 Milligram, Qd		Macleods
	Clomipramine			S	Unknown	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16451365	NON-EXPEDITED			US-PFIZER INC-2019256732		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Fesoterodine			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Pantoprazole			S		Unk		Pfizer
	Pregabalin			S		Unk		Pfizer
	Spironolactone			S		Unk		Pfizer
	Testosterone Cipionate			S		Unk		Unknown
	Tetracycline Hcl			S		Unk		Pfizer
	Amitriptyline			S				Not Reported
	Bethanechol Chloride			S				Not Reported
	Escitalopram			S				Not Reported
	Hydrocodeine			S				Not Reported
	Hyoscyamine Sulfate			S				Not Reported
	Propantheline			S				Not Reported
	Simvastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16451910	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2019M1056283		64 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported
	Tramadol			S	Unknown	225 Milligram, Qd		Not Reported
	Amitriptyline			S	Unknown	25 Milligram, Qd		Mylan
	Acetaminophen			C	Unknown	3000 Milligram, Qd		Mylan
	Levofloxacin			C	Unknown	500 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16452417	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2019255230		16 YR	Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Blood Potassium Increased; Bradycardia; Drug Abuse	Pregabalin			S	Oral	1 (Unit Of Measure Not Reported), Unk		Pfizer
	Xanax			S	Oral	1 (Unit Of Measure Not Reported), Unk		Pfizer
	Marijuana			S		Unk		Not Reported
	Cocaine			S		Unk		Not Reported
	Misar [Alprazolam]			S	Oral	1 (Unit Of Measure Not Reported), Unk		Not Reported
	Serpentil [Escitalopram Oxalate]			S	Oral	1 (Unit Of Measure Not Reported), Unk		Not Reported
	Sanval			S	Oral	1 (Unit Of Measure Not Reported), Unk		Not Reported
	Kventiax			S	Oral	1 (Unit Of Measure Not Reported), Unk		Not Reported
	Subutex			S	Oral	1 (Unit Of Measure Not Reported), Unk		Not Reported
	Normabel			S	Oral	1 (Unit Of Measure Not		Not Reported

Reported), Unk

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16454262	EXPEDITED (15-DAY)		OT	SE-MYLANLABS-2019M1057377		36 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Persistent Genital Arousal Disorder	Escitalopram			S		En Tablett Dagligen		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16455144	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-1925575US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Product Use Issue; Suicide Attempt; Vomiting	Escitalopram Oxalate - Bp			S	Oral	Overdose: 44 Tablets At A Time		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15585502	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1840999US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Heart Rate Increased; Irritability; Miosis; Overdose; Oxygen Saturation Decreased; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To	Celexa			S	Oral	Unk Unk, Unknown		Allergan
	Cipralex			S	Oral	Unk, Unknown		Not Reported
	Oxazepam			S	Oral	Unk Unk, Unknown		Not Reported
	Quetiapine			S	Oral	Unk, Unknown		Not Reported
	Temazepam			S	Oral	Unk, Unknown		Not Reported
	Topiramate			S	Oral	Unk, Unknown		Not Reported
	Naloxone			S	Intramuscular	0.8 Mg, Unknown		Not Reported
	Clopidogrel			C	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Fluticasone W/Salmeterol			C	Unknown	Unk		Not Reported

Various Agents	Ipratropium	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Ramipril	C	Unknown	Unk	Not Reported
	Salbutamol	C	Respiratory (inhalation)	Unk	Not Reported
	Spironolactone	C	Unknown	Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported
	Advair	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15969520	EXPEDITED (15-DAY)		HO, OT	CA-PFM-2019-01931			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis; Off Label Use; Product Use In Unapproved Indication	Propranolol Hydrochloride			S	Oral	40 Mg Twice A Day		Pierre Fabre Medicament
	Azathioprine			S	Unknown	Unknown		Not Reported
	Escitalopram			S	Unknown	10 Mg Daily		Not Reported
	Marijuana			S	Unknown	1 Dosage Form Daily		Not Reported
	Pentasa			S	Unknown	Unknown		Not Reported
	Premarin			S	Unknown	0.625 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16256103	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-022613			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Burnout Syndrome; Depression; Drug Interaction; Drug Intolerance; Heart Rate Increased; Hyperhidrosis; Hypertension; Palpitations; Panic Attack; Product Use	Escitalopram Film-Coated Tablets			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Ibuprofen			S	Unknown	Unk		Aurobindo
	Cipralex			S	Unknown	5 Milligram, Once A Day		Not Reported

Issue; Restlessness; Stress; Underdose	Cipralex		S	Unknown	10 Milligram	Not Reported
	Cipralex		S	Unknown	7.5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16288240	EXPEDITED (15-DAY)		LT, OT	PHHY2019DE105598		75 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Syncope; Torsade De Pointes	Esidrix			S	Unknown	12.5 Mg, Qd		Novartis
	Esidrix			S	Unknown	25 Mg, Qd		Novartis
	Captohexal			S	Unknown	50 Mg, Qd		Not Reported
	Captohexal			S	Unknown	25 Mg, Qd		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Reminyl			S	Unknown	8 Mg, Qd		Not Reported
	Reminyl			S	Unknown	5 Mg, Qd		Not Reported
	Reminyl			S	Unknown	2.5 Mg, Unk		Not Reported
	Cipralex			S	Unknown	5 Mg, Qd		Not Reported
	Cipralex			S	Unknown	10 Mg, Qd		Not Reported
	Cipralex			S	Unknown	15 Mg, Qd		Not Reported
	Cipralex			S	Unknown	20 Mg, Qd		Not Reported
	Dipiperon			S	Unknown	80 Mg, Qd		Not Reported
	Amlodipin			C	Unknown	5 Mg, Qd		Not Reported
	Amlodipin			C	Unknown	2.5 Mg, Qd		Not Reported
	Marcumar			C	Unknown	Unk		Not Reported
	Calcium Carbonate			C	Unknown	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16374911	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-209103		47 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Paraesthesia Oral	Paxil			S	Unknown	10 Milligram, Daily		Not Reported
	Paxil			S	Unknown	By The Third Week The Dose Was Increased: 30 Milligram, Daily		Not Reported
	Paxil			S	Unknown	Decreased To: 20 Mg/Day		Not Reported
	Xanax			S	Unknown	0.5 Milligram, Bid		Not Reported
	Xanax			S	Unknown	1.5 Milligram, Daily		Not Reported
	Cipralex			S	Unknown	20 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16454162	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1063301		15 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; No Adverse Event; Suicide Attempt	Aripiprazol			S	Oral			Teva
	Xanax			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16454876	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-210887		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence	Gabapentin			S	Oral	1 Dosage Form, Daily		Ranbaxy
	Baclofene			S	Oral	()		Not Reported
	Laroxyl			S	Oral	1 Dosage Form, Daily		Not Reported
	Seroplex			S	Oral	()		Not Reported
	Seresta			S	Oral	1 Dosage Form, Daily		Not Reported
	Noctamide			S	Oral	()		Not Reported

	Cymbalta		S	Oral	1 Dosage Form, Daily	Not Reported
	Methotrexate		S	Subcutaneous	1 Dosage Form, Weekly	Not Reported
	Effexor		S	Oral	()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16455933	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-211046		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Amlodipine			S	Oral	Unk		Sun
	Lamotrigine			S	Oral	4 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16456847	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2019021746			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Therapeutic Product Ineffective	Escitalopram 10mg Tablet			S	Oral	10 Milligram, Qd, Tablet		Macleods
	Xanax 0.5 Mg Prolonged Release Tablet			S	Oral	0.5 Milligram, Qd, Orodispersible Tablet, Prolonged Release Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16457269	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1065500		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Allopurinol			S	Oral			Actavis
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral			Not Reported

	Smofkabiven E, Émulsion Pour Perfusion	S	Intravenous drip		Not Reported
	Lyrica 50 Mg, Gélule	S	Oral		Not Reported
	Imovane 3,75 Mg, Comprimé Pelliculé	S	Oral		Not Reported
	Methotrexate	C	Intravenous (not otherwise specified)	Variable	Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)	Variable	Not Reported
	Vincristine (Sulfate De)	C	Intravenous (not otherwise specified)	Variable	Not Reported
	Doxorubicine	C	Intravenous (not otherwise specified)	Variable	Not Reported
	Prednisone	C	Oral	Variable	Not Reported
	Rituximab ((Mammifere/Hamster/Cellules Cho))	C	Intravenous (not otherwise specified)	Variable	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16458250	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1056941		30 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Substance Abuse	Escitalopram			S	Oral	20 Milligram, Total		Not Reported
	Quetiapine			S	Oral	25 Milligram, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16459208	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1057368		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Depression; Drug Ineffective	Escitalopram			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Mylan
	Dapsone			C	Unknown	100 Milligram, Qd		Mylan
	Infliximab			C	Unknown	10 Milligram/Kilogram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16460098	NON-EXPEDITED			US-TEVA-2019-US-1055127			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue; Rash; Urticaria	Escitalopram			S	Unknown			Ivax
	Bupropion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16464517	DIRECT		LT, OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressive Symptom; Product Substitution Issue	Escitalopram	Y		S	Oral	Quantity:1 Tablet(S);	25 DAY	Aurobindo
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16671931	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Paraesthesia; Tinnitus	Bupropion 150mg			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16462459	EXPEDITED (15-DAY)		OT	PL-ACCORD-134099		77 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dry Mouth; Headache; Nausea; Sedation; Vomiting	Escitalopram			S	Oral			Not Reported
	Atenolol/Atenolol Hydrochloride			S	Oral			Not Reported
	Oxynorm			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxyzine			S	Oral			Not Reported

	Ketonal	S	Intravenous (not otherwise specified)	Not Reported
	Pyralgin [Metamizole Sodium]	S	Intravenous (not otherwise specified)	Not Reported
	Fenactil	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16464620	NON-EXPEDITED			US-TEVA-2019-US-1059427			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Headache; Migraine; Vision Blurred	Buspirone			S	Unknown			Teva
	Rexulti			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16465005	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1925511US			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Dizziness	Escitalopram Oxalate - Bp			S	Unknown	Overdose: 25 Mg		Allergan
	Propavan			S	Unknown	5 St -25 Mg - 125 Mg		Not Reported
	Lergigan (Promethazine Hydrochloride)			S	Oral	7 St 25 Mg - 125 Mg		Not Reported
	Atarax			S	Unknown	25 Mg 7 St- 175 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16465785	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1058002		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Stillbirth	Quetiapine			S	Oral	25 [Mg/D] (0. - 35.3. Gestational Week)		Not Reported

	Escitalopram	S	Oral	20 [Mg/D] (0. - 35.3. Gestational Week)	Not Reported
	Presinol	S	Oral	500 [Mg/D (2x250)] (33.4. - 35.3. Gestational Week)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2019	16466391	EXPEDITED (15-DAY)		OT	HR-ACCORD-134212			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Foaming At Mouth; Intentional Overdose; Suicide Attempt; Tremor	Quetiapine			S	Oral	Unspecified, Consciousness Disturbed, Foaming At Mouth		Not Reported
	Elicea			S	Oral	Consciousness Disturbed, Foaming At Mou		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2019	16466447	EXPEDITED (15-DAY)		HO	FR-ACCORD-133991		83 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral			Not Reported
	Spironolactone			S	Oral			Accord
	Fenofibrate			S	Oral			Not Reported
	Galantamine/Galantamine Hydrobromide			S	Oral			Not Reported
	Beclometasone			S	Nasal	100 Micrograms / Dose, Nasal Spray Suspension		Not Reported
	Colecalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2019	16466449	EXPEDITED (15-DAY)		DE	FR-ACCORD-134045		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral			Not Reported

	Xarelto	S	Oral	Unspecified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2019	16466506	EXPEDITED (15-DAY)		DE	CA-ALLERGAN-1851643US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective; Feeling Abnormal; Muscular Weakness; Suicidal Ideation	Escitalopram Oxalate - Bp			S		0.5 Df, Qd		Allergan
	Escitalopram Oxalate - Bp			S		1 Df, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Clonazepam			S		0.5 Mg, Q8hr		Not Reported
	Clonazepam			S				Not Reported
	Clonazepam			S				Not Reported
	Zopiclone			S	Oral	7.5 Mg, Q12h		Not Reported
	Zopiclone			S	Oral	Unk, Unknown		Not Reported
	Zopiclone			S		Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	9564978	EXPEDITED (15-DAY)		OT	PHHY2013CA107716		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Cough; Depressed Level Of Consciousness; Depression; Diplopia; Dizziness; Drug Withdrawal Syndrome; Eye Pain; Headache; Malaise; Multiple Sclerosis Relapse; Nasopharyngitis; Neuralgia; Ocular Discomfort; Optic Nerve Disorder; Optic Neuritis; Oropharyngeal Pain; Palpitations; Paraesthesia; Pupillary Disorder; Sleep Disorder; Vision Blurred;	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Gilenya			S	Oral	Unk		Novartis
	Gilenya			S	Oral	Unk		Novartis
	Cipralex /Den/			S	Unknown	Unk		Not Reported
	Cipralex /Den/			S	Unknown	Unk		Not Reported
	Cymbalta			C	Unknown			Not Reported
	Topamax			C	Unknown	50 Mg, Bid		Not Reported

Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	15779138	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-ICU MEDICAL, INC.-ICU2018CA00241		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Blindness Cortical; Cardiogenic Shock; Cerebral Infarction; Circulatory Collapse; Colour Blindness; Condition Aggravated; Csf Pressure Increased; Cytotoxic Oedema; Depressed Level Of Consciousness; Electrocardiogram P Wave Abnormal; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Amplitude Decreased; Electrocardiogram T Wave Inversion; Electrocardiogram U Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema; Renal Tubular Necrosis; Retinal Ischaemia;	Dextrose Injection			S	Unknown			Icu Medical
	Amlodipine Besilate			S	Oral	150 Milligram, Every 1 Day(S)		Not Reported
	Amlodipine Besilate			S	Unknown	Unk		Not Reported
	Epinephrine			S	Unknown	30.0 Microgram		Not Reported
	Escitalopram			S	Unknown	60 Milligram, Every 1 Day(S)		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Norepinephrine Bitartrate			S	Unknown	30 Microgram		Not Reported
	Risperidone			S	Oral	6.0 Milligram, Every 1 Day(S)		Not Reported
	Vasopressin			S	Unknown			Not Reported
	Escitalopram Mylan			S	Oral			Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Potassium Chloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Activated Charcoal			C		50 Gram		Not Reported
	Insulin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Insulin			C		70 International Unit		Not Reported
	Amlodipine			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Dextrose			C				Not Reported
	Glucagon			C		Unk		Not Reported
	Glucagon			C		Unk		Not Reported

Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16322504	EXPEDITED (15-DAY)		HO, OT	US-VERTEX PHARMACEUTICALS-2019-004390		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicide Attempt	Symdeko			S	Oral	100mg Tezacaftor/150mg Ivacaftor Am; 150mg Ivacaftor Pm		Vertex
	Lexapro			S	Unknown	Unk		Not Reported
	Buspar			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16444859	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2019M1055610		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram			S	Transplacental	10 Milligram, Qd		Not Reported
	L-Thyroxin /00068001/			C	Transplacental	75 Microgram, Qd,75 [Mg/D]		Mylan
	Xanaflu			C	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16467541	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2019-034963			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Depression; Therapeutic Product Ineffective	Escitalopram Film-Coated Tablets		S	Oral	10 Milligram, Daily	Aurobindo
	Xanax		S	Oral	0.5 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16467714	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016753		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Abdominal Pain; Arthralgia; Basedow'S Disease; Blood Thyroid Stimulating Hormone Decreased; Blood Urine Present; Burning Sensation; Chest Discomfort; Decreased Appetite; Depression; Diarrhoea; Disturbance In Attention; Dizziness; Drug Hypersensitivity; Dysgeusia; Dysphagia; Dyspnoea; Dysuria; Fatigue; Headache; Hyperhidrosis; Influenza; Insomnia; Migraine; Mood Altered; Muscle Spasms; Nasopharyngitis; Nausea; Pain In Extremity; Pruritus; Rash; Rash Erythematous; Rash Macular; Somnolence; Stress; Swelling Face; Temperature Intolerance; Throat Irritation; Thyroid Hormones Increased; Thyroiditis; Urinary Tract Infection; Urticaria; Vomiting; Weight	Escitalopram			S	Oral	20 Mg, Unk		Apotex
	Escitalopram			S	Oral	10 Mg, Unk		Apotex
	Escitalopram			S	Oral	10 Mg, Unk		Apotex
	Escitalopram			S	Oral	5 Mg, Unk		Apotex
	Alemtuzumab			S	Intravenous drip	12 Mg, Qd		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Aciclovir			C	Oral	200 Mg, Unk		Not Reported
	Benadryl /00000402/			C	Intravenous (not otherwise specified)	25 Mg, Unk		Not Reported
	Benadryl /00000402/			C	Oral	Unk		Not Reported
	Dimenhydrinate			C	Oral	50 Mg, Unk		Not Reported
	Diphenhydramine			C	Oral	50 Mg, Unk		Not Reported
	Gabapentin			C	Oral	Unk		Not Reported
	Losartan Potassium			C	Oral	1 Df, Qd		Not Reported
	Losartan Potassium			C	Oral	100 Mg, Qd		Not Reported
	Losartan Potassium			C	Oral	100 Mg, Unk		Not Reported
	Methimazole			C	Oral	4 Df, Qd		Not Reported
	Methimazole			C	Oral	2 Df, Qd		Not Reported
	Methimazole			C	Oral	5 Mg, Q.O.D.		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
	Propranolol			C	Oral	Unk		Not Reported

Decreased; Wheezing; White Blood Cell Count Decreased	Sertraline		C	Oral	100 Mg, Q.12h	Not Reported
	Sertraline		C	Oral	50 Mg, Unk	Not Reported
	Zantac		C	Oral	150 Mg, Qd	Not Reported
	Zantac		C	Oral	150 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16467769	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016703		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Jittery; Nervousness; Panic Attack	Escitalopram			S	Oral	10 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16467867	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016711		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous	Escitalopram			S	Oral	10 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16468132	EXPEDITED (15-DAY)		HO, OT	PHHY2019CO130630		39 YR	Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Gait Disturbance; Nephrolithiasis; Urinary Retention; Urinary Tract Infection	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Escitalopram			S	Unknown	10 Mg, One After The Breakfast		Not Reported
	Oxybutynin			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16468239	NON-EXPEDITED			US-APOTEX-2017AP006153			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression; Depressed Mood; Diarrhoea; Drug Ineffective; Insomnia; Partner Stress; Psychomotor Hyperactivity	Paxil Capsules	S	Unknown	50 Mg, Qd		Apotex
	Wellbutrin Tablet	S	Unknown	10 Mg, Qd		Not Reported
	Lexapro	S	Unknown	10 Mg, Qd		Not Reported
	Zoloft	S	Unknown	20 Mg, Unk		Not Reported
	Omeprazole	C	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16468305	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016730		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Decreased; Breath Sounds Abnormal; Cystic Fibrosis; Dizziness; Dyspnoea; Generalised Erythema; Lung Infection; Moaning; Nasal Congestion; Nasopharyngitis; Nausea; Oropharyngeal Pain; Pulmonary Contusion; Pyrexia; Rash Erythematous; Sinus Congestion; Sinus Headache; Sinusitis; Skin Sensitisation; Skin Warm; Smoke Sensitivity; Upper Respiratory Tract Congestion	Escitalopram			S	Oral	1 Df, Qd		Apotex
	Escitalopram			S				Apotex
	Omalizumab			S	Subcutaneous	300 Mg, Q.O.Wk.		Not Reported
	Omalizumab			S	Subcutaneous	Unk		Not Reported
	Omalizumab			S	Subcutaneous	300 Mg, Unk		Not Reported
	Pulmicort			C	Unknown	1 Df, Qd		Not Reported
	Zenhale			C	Respiratory (inhalation)	1 Df, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16468341	EXPEDITED (15-DAY)		HO	FR-ZYDUS-037840		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral			Not Reported

	Smofkabiven E	S	Intravenous drip	Not Reported
	Pregabalin	S	Oral	Not Reported
	Zopiclone	S	Oral	Not Reported
	Allopurinol	S	Oral	Zydus Pharm
	Methotrexate	C	Intravenous (not otherwise specified)	Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)	Not Reported
	Vincristine Sulfate	C	Intravenous (not otherwise specified)	Not Reported
	Doxorubicin	C	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Oral	Not Reported
	Rituximab ((Mammifere/Hamster/Cellules Cho))	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16468421	EXPEDITED (15-DAY)		DS	CA-APOTEX-2019AP016734		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dysaesthesia; Fatigue; Nausea	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Allopurinol			C	Unknown			Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Diltiazem			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Tylenol W/Codeine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16468524	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP016737		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	10.0 Mg, Qd		Apotex
	Baclofen			C	Unknown	Unk		Not Reported
	Cialis			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16468661	NON-EXPEDITED			US-TEVA-2019-US-1060405			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Fatigue; Heart Rate Increased; Hunger; Muscle Twitching; Pruritus; Somnolence	Escitalopram Tablets Teva			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16468729	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP016958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety Disorder; Breast Cancer; Breast Disorder; Decreased Appetite; Diarrhoea; Ear Discomfort; Frequent Bowel Movements; Hot Flush; Nasopharyngitis; Nausea; Nervousness; Pain; Weight Decreased	Escitalopram			S	Unknown	Unk, Qd		Apotex
	Tamioxifen			S	Unknown	Unk		Apotex
	Atezolizumab			S	Intravenous (not otherwise specified)	1200 Mg, Q.3w		Not Reported
	Ativan			C	Unknown	0.5 Mg, As Required		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16468828	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016959			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angioedema; Chronic Spontaneous Urticaria; Urticaria	Escitalopram		S	Unknown	10 Mg, Unk	Apotex
	Tegretol		S	Oral	1 Df, Qd	Not Reported
	Benadryl /00000402/		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Reactine /00884302/		C	Unknown	1 Df, Bid	Not Reported
	Claritin /00917501/		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16469200	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1067262		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Therapeutic Product Ineffective	Escitalopram			S	Oral			Ivax
	Xanax 0,5 Mg Compresse A Rilascio Prolungato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16469394	EXPEDITED (15-DAY)		DS	CA-APOTEX-2019AP016740		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dysaesthesia; Fatigue; Nausea	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Allopurinol			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Diltiazem			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Tylenol With Codeine No.3			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16469395	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016739		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Musculoskeletal Pain; Neck Pain; Tremor	Escitalopram			S	Oral	10 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16469398	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016743		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Musculoskeletal Pain; Neck Pain; Seizure; Tremor	Escitalopram			S	Oral	10 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16469566	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP016757		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anger; Anxiety; Arthropod Bite; Blood Pressure Increased; Bronchitis; Cerebrovascular Accident; Contusion; Cough; Crying; Depressed Mood; Depression; Diarrhoea; Emotional Distress; Erythema; Fall; Fatigue; Feeling Abnormal; Feeling Jittery; Gait Disturbance; Head Banging; Headache; Hypertension; Hypoacusis; Inappropriate Schedule Of Product Administration; Joint Swelling; Malaise; Malignant Neoplasm Progression; Mental Disorder; Muscular Weakness;	Escitalopram			S	Unknown	Unk		Apotex
	Amlodipine			S	Unknown	10 Mg, Qd		Apotex
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Hydromorphone			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Apotex
	Ergocalciferol			S	Unknown	Unk		Not Reported
	Sandostatin			S	Intramuscular	20 Mg, Q.M.T.		Not Reported
	Sandostatin			S	Subcutaneous	Unk Unk, Bid		Not Reported
	Sandostatin			S	Intramuscular	30 Mg, Q.M.T.		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Olanzapine			C	Unknown	Unk		Not Reported
	Perindopril			C	Unknown	4 Mg, Qd		Not Reported
	Prednisone			C	Unknown	35 Mg, Unk		Not Reported
	Prucalopride Succinate			C	Unknown	Unk		Not Reported

Nasopharyngitis; Nausea; Nervousness; Pain In Extremity; Peripheral Swelling; Pneumonia; Pollakiuria; Productive Cough; Psychiatric Symptom; Rash; Rib Fracture; Screaming; Suicidal Ideation; Suicide Attempt; Tremor; Unresponsive To Stimuli; Vasculitis; Wound; Wrist Fracture

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16470074	EXPEDITED (15-DAY)		DS	CA-APOTEX-2019AP016715		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dry Mouth; Tension Headache	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Apixaban			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16470144	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019259609		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Lyrica			S	Oral	1 Df, 1x/Day		Pfizer
	Seroplex			S	Oral	1 Df, 1x/Day		Not Reported
	Imovane			S	Oral	1 Df, 1x/Day		Not Reported
	Smofkabiven E			S	Intravenous drip	986 Ml, 1x/Day		Not Reported
	Allopurinol			S	Oral	100 Mg, 1x/Day		Not Reported
	Methotrexate			C	Intravenous (not otherwise specified)	Unk, Variable		Not Reported

	Cyclophosphamide	C	Intravenous (not otherwise specified)	Variable	Not Reported
	Vincristine	C	Intravenous (not otherwise specified)	Unk, Variable	Not Reported
	Doxorubicine [Doxorubicin]	C	Intravenous (not otherwise specified)	Variable	Not Reported
	Prednisone	C	Oral	Unk, Variable	Not Reported
	Rituximab	C	Intravenous (not otherwise specified)	Unk, Variable	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16470204	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016718		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Affective Disorder; Condition Aggravated; Insomnia; Nasal Dryness	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Atorvastatin Calcium			C	Unknown	Unk		Not Reported
	Candesartan			C	Unknown	Unk		Not Reported
	Januvia			C	Unknown	Unk		Not Reported
	Pantoloc /01263201/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16470264	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016725		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anger; Depressed Mood; Diarrhoea; Mental Disorder; Multiple Sclerosis	Escitalopram			S	Oral	Unk		Apotex
	Teriflunomide			S	Oral	14 Mg, Qd		Not Reported
	Acetaminophen			C	Oral	Unk		Not Reported
	Cbd Oil			C	Unknown	Unk		Not Reported
	Colloidal Silver			C	Oral	Unk		Not Reported
	Magnesium			C	Oral	Unk		Not Reported
	Vitamin D 3			C	Oral	3000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16470361	NON-EXPEDITED			US-TEVA-2019-US-1060430			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Fatigue; Heart Rate Increased; Hunger; Muscle Twitching; Pruritus; Pruritus; Somnolence	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16470382	NON-EXPEDITED			US-TEVA-2019-US-1060424			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Dry Mouth; Lethargy; Libido Decreased; Malaise	Teva Escitalopram			S				Ivax
	Accord Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16470779	EXPEDITED (15-DAY)		HO, OT	PHHY2019TR143463		21 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Borderline Personality Disorder; Depression; Impulsive Behaviour; Intentional Self-Injury; Product Use In Unapproved Indication; Suicidal Ideation; Suicide Attempt; Therapy Non-Responder	Carbamazepine			S	Unknown			Novartis
	Valproic Acid			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Sertraline			S				Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Fluoxetine			S				Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S				Not Reported

	Olanzapine	S	Unknown		Not Reported
	Olanzapine	S			Not Reported
	Trifluoperazine	S	Unknown		Not Reported
	Trifluoperazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16474221	DIRECT		DS			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Adhesions; Confusional State; Disorientation; Drug Ineffective; Hallucination; Irritability; Nervous System Disorder	Escitalopram (Lexapro)	Y		S		Quantity:1 Tablet(S);		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16687952	DIRECT	N	CA, OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydronephrosis; Maternal Drugs Affecting Foetus; Renal Dysplasia	Lexapro			S				Not Reported
	Keppra			C				Not Reported
	Desyryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16688038	DIRECT	N	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Latuda			S				Not Reported
	Lithium			S				Not Reported
	Buspar			S				Not Reported
	Lexapro			S				Not Reported
	Letrozole			C				Not Reported
	L-Thyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	15434547	EXPEDITED (15-DAY)		HO	DE-TORRENT-00009895		28 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Myoclonus	Amisulpride			S	Unknown	Unknown		Unknown
	Aripiprazole			S	Unknown	Unknown		Unknown
	Biperiden			S	Unknown	Unknown		Unknown
	Bupropion			S	Unknown	Unknown		Unknown
	Clozapine			S	Unknown	75 Mg		Unknown
	Duloxetine			S	Unknown	Unknown		Unknown
	Escitalopram			S	Unknown	20 Mg		Unknown
	Fluoxetine			S	Unknown	Unknown		Unknown
	Mirtazapine			S	Unknown	Unknown		Unknown
	Olanzapine			S	Unknown	Unknown		Unknown
	Promethazine			S	Unknown	Unknown		Unknown
	Quetiapine			S	Oral	Unknown		Unknown
	Risperidone			S	Unknown	Unknown		Unknown
	Venlafaxine			S	Oral	Unknown		Unknown
	Zopiclone			S	Unknown	Unknown		Unknown
	Brivaracetam			C	Unknown	200-250mg; Received Over One Year		Unknown
	Carbamazepine			C	Unknown	Up To 900 Mg		Unknown
	Clobazam			C	Unknown	Up To 20mg		Unknown
	Oxazepam			S	Unknown	At Different Doses		Unknown
	Oxcarbazepine			C	Unknown	Up To 2400mg; Received Over One Year		Unknown
	Zonisamide			C	Unknown	Up To 100mg		Unknown
	Benzodiazepine			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	15758328	EXPEDITED (15-DAY)		HO, OT	PL-AUROBINDO-AUR-APL-2018-060437			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Decreased Appetite; Drug Ineffective; Dyschezia; Inadequate Analgesia; Medication Error; Off Label Use; Pain; Pneumonia; Weight Decreased	Escitalopram			S	Unknown	Unk		Aurobindo
	Omeprazole 20mg			S	Unknown	20 Milligram, Qd (In The Morning, Fasting), 1 Dosage 20 Mg Daily		Aurobindo
	Alprazolam			S	Unknown	Unk		Aurobindo
	Tramadol			S	Unknown	100 Milligram, Bid (200 Milligram Daily; Controlled-Release)		Not Reported
	Tramadol			S				Not Reported
	Metoclopramide			S	Unknown	30 Milligram Daily; For About 3 Weeks, 3 Dosages 10 Mg Daily		Not Reported
	Metamizole			S	Oral	1000 Milligram, Once A Day, 2 Dosages 500 Mg Daily		Not Reported
	Buprenorphine			S	Unknown	Unk		Not Reported
	Buprenorphine			S	Unknown	35 Ug/Hour Every 4 Days		Not Reported
	Buprenorphine			S	Unknown	1 Dosage Form, Qd (35 Ug/H Every 4 Days)		Not Reported
	Ketoprofen			S	Unknown	Unk		Not Reported
	Ketoprofen			S	Oral	3 Dosages 100 Mg Daily/300 Milligram, Qd		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Betamethasone			C	Unknown	Unk		Not Reported
	Zoledronic Acid			C	Unknown	Unk		Not Reported
	Valproic Acid			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

	Effentora			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16021272	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-010025			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Escitalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Abilify			S	Oral	2 Milligram		Not Reported
	Escitalopram Teva			S	Unknown	20 Milligram, Once A Day		Not Reported
	Serax			C	Unknown	45 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16043271	EXPEDITED (15-DAY)		OT	PHHY2018CO106563		49 YR	Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dry Throat; Dysphonia; Eye Irritation; Furuncle; Headache; Hypertension; Latent Tuberculosis; Malaise; Nasal Congestion; Oropharyngeal Pain; Overweight; Pain; Pyrexia; Subcutaneous Abscess; Tuberculin Test Positive; Weight Increased	Cosentyx			S	Subcutaneous	150 Mg, Qmo		Not Reported
	Losartan			S	Unknown	50 Mg, Q12h		Novartis
	Escitalopram Oxalate			S	Unknown	10 Mg, Qd (1 In The Morning)		Not Reported
	Amlodipine			C	Unknown	5 Mg, Qd		Not Reported
	Hydrochlorothiazide			C	Unknown	1 Df, Qd		Not Reported
	Trazodon			C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16080840	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013878			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Foot Fracture; Headache; Influenza; Stress; Weight	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Omalizumab			S	Subcutaneous	150 Milligram		Not Reported

Decreased	Omalizumab	S	Subcutaneous	150 Milligram	Not Reported
	Omalizumab	S	Subcutaneous	Unk	Not Reported
	Omalizumab	S	Subcutaneous	150 Milligram	Not Reported
	Omalizumab	S	Subcutaneous	Unk	Not Reported
	Claritin	C	Unknown	2 Dosage Form, Two Times A Day	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Pulmicort	C	Unknown	2 Dosage Form, Two Times A Day	Not Reported
	Singulair	C	Unknown	2 Dosage Form, Once A Day	Not Reported
	Singulair	C	Unknown	1 Dosage Form, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16080841	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-014582			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Base Excess Decreased; Confusional State; Electrocardiogram T Wave Peaked; Fall; Hypoglycaemia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis; Pco2 Decreased	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Metformin Tablet			S	Unknown	1 Gram, Two Times A Day		Aurobindo
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Gliclazide			S	Unknown	Unk		Not Reported
	Insulin			S	Unknown	Unk		Not Reported
	Apo-Gliclazide			S	Unknown	Unk		Not Reported
	Apo-Hydro			S	Unknown	Unk		Not Reported
	Apo-Metformin			S	Unknown	1 Gram		Not Reported
	Levothyroxine Sodique			C	Unknown	Unk		Not Reported
	Telmisartan			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16327846	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027685			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Chronic Spontaneous Urticaria; Urticaria	Escitalopram Tablets			S	Unknown	10 Milligram, Unk		Aurobindo
	Tegretol			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Benadryl			C	Unknown	Unk		Not Reported
	Claritin			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Reactine			C	Unknown	1 Dosage Form, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16327847	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027752			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Decreased; Breath Sounds Abnormal; Cystic Fibrosis; Dizziness; Dyspnoea; Generalised Erythema; Lung Infection; Moaning; Nasal Congestion; Nasopharyngitis; Nausea; Oropharyngeal Pain; Pulmonary Contusion; Pyrexia; Rash Erythematous; Sinus Congestion; Sinus Headache; Sinusitis; Skin Sensitisation; Skin Warm; Smoke Sensitivity; Upper Respiratory Tract	Escitalopram Tablets			S	Oral	1 Dosage Form		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Xolair			S	Subcutaneous	300 Milligram		Not Reported
	Xolair			S	Subcutaneous	300 Milligram, 1 Every 2 Week		Not Reported
	Pulmicort			C	Unknown	Unk		Not Reported
	Pulmicort			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Zenhale			C	Unknown	Unk		Not Reported
	Zenhale			C		1 Dosage Form, Two Times A Day		Not Reported

Congestion

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16327961	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-026637			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Abdominal Pain; Arthralgia; Basedow'S Disease; Blood Thyroid Stimulating Hormone Decreased; Blood Urine Present; Burning Sensation; Chest Discomfort; Decreased Appetite; Depression; Diarrhoea; Disturbance In Attention; Dizziness; Drug Hypersensitivity; Dysgeusia; Dysphagia; Dyspnoea; Dysuria; Fatigue; Headache; Hyperhidrosis; Influenza; Insomnia; Migraine; Mood Altered; Muscle Spasms; Nasopharyngitis; Nausea; Pain In Extremity; Pruritus; Rash; Rash Erythematous; Rash Macular; Somnolence; Stress; Swelling Face; Temperature Intolerance; Throat Irritation; Thyroid Hormones Increased; Thyroiditis; Urinary Tract Infection; Urticaria; Vomiting; Weight Increased; Wheezing; White Blood Cell Count	Escitalopram Tablets			S	Oral	10 Milligram		Aurobindo
	Escitalopram Tablets			S	Oral	10 Milligram		Aurobindo
	Escitalopram Tablets			S	Oral	5 Milligram		Aurobindo
	Escitalopram Tablets			S	Oral	20 Milligram		Aurobindo
	Escitalopram			S	Oral	5 Milligram		Aurobindo
	Alemtuzumab			S	Intravenous drip	12 Milligram, Once A Day		Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Acyclovir			C	Oral	200 Milligram		Not Reported
	Benadryl			C	Intravenous (not otherwise specified)	25 Milligram		Not Reported
	Benadryl			C	Oral	Unk		Not Reported
	Dimenhydrinate			C	Oral	50 Milligram		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Losartan			C	Oral	1 Dosage Form, Once A Day		Not Reported
	Losartan			C	Oral	100 Milligram		Not Reported
	Methimazole			C	Oral	4 Dosage Form, Once A Day		Not Reported
	Methimazole			C	Oral	2 Dosage Form, Once A Day		Not Reported
	Methimazole			C	Oral	5 Milligram, Two Times A Day		Not Reported
	Methylprednisolone			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Oral	40 Milligram, Once A Day		Not Reported
	Propranolol			C	Oral	Unk		Not Reported

Decreased	Sertraline	C	Oral	100 Milligram, Two Times A Day	Not Reported
	Sertraline	C	Oral	50 Milligram	Not Reported
	Zantac	C	Oral	150 Milligram, Once A Day	Not Reported
	Zantac	C	Oral	150 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16327962	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-027634			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aptyalism; Drug Ineffective; Overdose; Panic Disorder	Escitalopram Tablets			S	Oral	30 Milligram		Aurobindo
	Amitriptyline			S	Oral	20 Milligram, Once A Day		Not Reported
	Apo-Buspirone			S	Oral	5 Milligram, Once A Day		Not Reported
	Zyprexa			S	Oral	2.5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16328198	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027683			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Escitalopram Tablets			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Aripiprazole Tablets			S	Oral	2 Milligram		Aurobindo
	Escitalopram Teva			S	Unknown	20 Milligram, Daily		Not Reported
	Abilify			S	Oral	2 Milligram		Not Reported
	Serax			C	Unknown	45 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16328210	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027984			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration;	Escitalopram Tablets			S	Unknown	Unk, Once A Day		Aurobindo

Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Cosentyx	S	Subcutaneous	150 Milligram, Every Week	Not Reported
	Vitamin D3	S	Unknown	Unk	Not Reported
	Povidone-Iodine	S	Unknown	Unk	Not Reported
	Cosentyx	S	Subcutaneous	150 Milligram, 1 Month	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Vitamin D3	S	Unknown	Unk	Not Reported
	Voltaren	S	Unknown	Unk	Not Reported
	Voltaren	S	Unknown	Unk, 1 Every Week	Not Reported
	Enbrel	C	Unknown	Unk	Not Reported
	Humira	C	Unknown	Unk	Not Reported
	Remicade	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16328423	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-027449			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Blindness Cortical; Cardiogenic Shock; Cerebral Infarction; Circulatory Collapse; Colour Blindness; Condition Aggravated; Csf Pressure Increased; Cytotoxic Oedema; Depressed Level Of Consciousness; Electrocardiogram P Wave Abnormal; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Amplitude Decreased;	Amlodipine Tablets			S	Oral	150 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Unknown	60 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Oral	Unk		Aurobindo
	Potassium Chloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Potassium Chloride			S	Oral	Unk		Not Reported
	Epinephrine			S	Unknown	30 Microgram		Not Reported
	Dextrose			S	Unknown	Solution Intravenous		Not Reported
	Vasopressin			S	Unknown	Unk		Not Reported
	Norepinephrine Bitartrate			S	Unknown	30 Microgram, Liquid Intravenous		Not Reported
	Risperidone			S	Oral	6 Milligram, Once A Day		Not Reported
	Activated Charcoal			C	Unknown	50 Gram		Not Reported

Electrocardiogram T Wave Inversion; Electrocardiogram U Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema; Renal Tubular Necrosis; Retinal Ischaemia; Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment	Amlodipine	C	Unknown	Unk	Not Reported
	Calcium Gluconate	C	Unknown	Unk	Not Reported
	Dextrose	C	Unknown	Unk	Not Reported
	Glucagon	C	Unknown	Kit	Not Reported
	Insulin	C	Unknown	70 International Unit	Not Reported
	Insulin	C	Intravenous bolus	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16444137	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-033470			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis; Off Label Use; Product Use In Unapproved Indication	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	1 Dosage Form, Once A Day		Not Reported
	Pentasa			S	Unknown	Unk		Not Reported
	Premarin			S	Oral	0.625 Milligram, Once A Day		Not Reported
	Propranolol			S	Oral	40 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472250	EXPEDITED (15-DAY)		OT	FR-ACCORD-134840		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence	Methotrexate			S	Subcutaneous			Accord
	Gabapentin			S	Oral			Not Reported
	Baclofen			S	Oral			Not Reported
	Laroxyl			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Noctamide			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Effexor			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472316	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034860			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Escitalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Unknown	30 Milligram, Once A Day		Aurobindo
	Abilify			S	Oral	2 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472329	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034864			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Suicidal Ideation	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Trintellix			S	Oral	Unk		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported

Clonazepam	C	Unknown	Unk		Not Reported
Lorazepam	C	Unknown	Unk		Not Reported
Quetiapine Fumarate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472339	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034843			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Seizure; Therapeutic Agent Urine Positive; Vomiting	Escitalopram Tablets			S	Transmammary	Unk		Aurobindo
	Bupropion			S	Transmammary	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472484	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034934			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Musculoskeletal Pain; Neck Pain; Seizure; Tremor	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472487	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035014			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Therapy Change	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472885	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034863			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Inappropriate	Escitalopram Tablets			S	Oral	10 Milligram, 1 Every 1		Aurobindo

Antidiuretic Hormone Secretion					Day	
	Baclofen		C	Unknown	Unk	Not Reported
	Cialis		C	Unknown	Unk	Not Reported
	Pregabalin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472894	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034855			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Caesarean Section; Exposure During Pregnancy; Female Sterilisation; Malaise; Morning Sickness; Nausea; Procedural Pain; Uterine Abscess; Vomiting	Escitalopram			S	Unknown	Unk Unk, Two Times A Day		Aurobindo
	Acetaminophen;Codeine Phosphate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 8 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 8 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 8 Weeks		Not Reported
	Toradol			S	Unknown	Unk		Not Reported
	Ergocalciferol			C	Oral	800 International Unit, Once A Day		Not Reported
	Folic Acid			C	Oral	Unk Unk, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472897	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034871			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Escitalopram			S	Oral	20 Milligram		Aurobindo
	Gabapentin			S	Oral	300 Milligram, Once A Day		Aurobindo
	Gabapentin			S	Oral	600 Milligram, Once A Day		Aurobindo
	Ferrous Sulfate			S	Unknown	300 Milligram, 3 Every		Not Reported

				Once A Day	
	Temazepam	S	Oral	30 Milligram, Once A Day	Not Reported
	Wellbutrin	S	Oral	150 Milligram, 2 Every Once A Day	Not Reported
	Acetaminophen;Codeine Phosphate	S	Oral	2.0 Dosage Form, 3 Every Once A Day	Not Reported
	Clonazepam	S	Oral	0.5 Milligram, 3 Every Once A Day	Not Reported
	Domperidone	S	Oral	10 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472899	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-034791			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chest Discomfort; Chronic Obstructive Pulmonary Disease; Cough; Decreased Appetite; Depression; Diarrhoea; Drug Ineffective; Dyspnoea; Fatigue; Feeling Abnormal; Gait Disturbance; General Physical Health Deterioration; Hernia Pain; Hiatus Hernia; Hypoaesthesia; Insomnia; Lung Infection; Malaise; Moaning; Mobility Decreased; Pain; Panic Disorder; Poor Quality Sleep; Pruritus; Restlessness; Skin Discolouration	Escitalopram			S	Unknown	Unk		Aurobindo
	Clarithromycin			S	Unknown	Unk		Not Reported
	Glycopyrronium			S		Unk		Not Reported
	Meloxicam			C	Oral	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Fluticasone Propionate;Salmeterol Xinafoate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472900	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034900			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Hypertension	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Oral	20 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472902	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-034829			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Asthenia; Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Diarrhoea; Fatigue; Nephritic Syndrome; Shock	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Mycophenolate Sodium			S	Oral	Unk, Two Times A Day		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Ranitidine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472904	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034885			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Quetiapine Film-Coated Tablet			S	Unknown	Unk		Aurobindo
	Olanzapine			S	Unknown	Unk		Aurobindo
	Bupropion			S	Unknown	Unk		Not Reported
	Phenytoin			S	Unknown	Unk		Not Reported
	Primidone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472906	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035116			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Escitalopram Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo
	Lorazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472908	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035067			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Shock Symptom	Escitalopram Tablets			S	Oral	20 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S				Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472925	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-035008			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depressed Mood; Diarrhoea; Dizziness; Fall; Hyponatraemia; Hypotension; Hypovitaminosis; Poor Quality Sleep	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Pantoprazole			S	Unknown	40 Milligram, Two Times A Day		Aurobindo
	Telmisartan Tablets			S	Unknown	80 Milligram, Once A Day		Aurobindo
	Telmisartan Tablets			S				Aurobindo
	Lorazepam			S	Unknown	1 Milligram, As Required		Not Reported
	Lorazepam			S	Unknown	1 Milligram, Once A Day		Not Reported
	Metoprolol			S	Unknown	50 Milligram, Once A Day		Not Reported
	Metoprolol			S				Not Reported
	Loperamide			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported
	Tamsulosin Cr			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472929	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034903			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Drug Ineffective; Eye Pain; Fear Of Injection; Hereditary Angioedema; Infusion Site Pain; Pharyngeal Swelling; Pharyngitis Streptococcal; Selective Mutism; Vaginal Infection; Vascular Access Site Occlusion	Escitalopram			S	Unknown	Unk		Aurobindo
	C1 Esterase Inhibitor (Human)			S	Intravenous (not otherwise specified)	3000 International Unit		Not Reported
	C1 Esterase Inhibitor (Human)			S	Intravenous (not otherwise specified)	3000 International Unit		Not Reported
	C1 Esterase Inhibitor (Human)			S	Intravenous (not otherwise specified)	1500 International Unit, 3 Times In 1 Week		Not Reported
	C1 Esterase Inhibitor (Human)			S	Intravenous (not otherwise specified)	1500 International Unit		Not Reported
	C1 Esterase Inhibitor (Human)			S	Subcutaneous	1500 International Unit, 3 Times In 1 Week		Not Reported
	C1 Esterase Inhibitor (Human)			S	Subcutaneous	1500 International Unit, 3 Times In 1 Week		Not Reported
	C1 Esterase Inhibitor (Human)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Icatibant Acetate			C	Subcutaneous	Unk		Not Reported
	Icatibant Acetate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472947	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-034730			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Dizziness; Fall; Hypotension; Orthostatic Hypotension; Pain; Visual Impairment	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Amlodipine Tablets			S	Unknown	2.5 Milligram, Two Times A Day		Aurobindo
	Oxazepam			S	Unknown	2 Dosage Form, Once A Day		Not Reported

	Furosemide	S	Unknown	40 Milligram, Once A Day	Not Reported
	Metoprolol	S	Unknown	25 Milligram, Two Times A Day	Not Reported
	Metoprolol	S			Not Reported
	Nitroglycerin	S	Transdermal	Unk	Not Reported
	Zopiclone	S	Unknown	5 Milligram, Once A Day	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported
	Clopidogrel	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Nitroglycerin	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Polyethylene Glycol	C	Unknown	Unk	Not Reported
	Ramipril	C	Unknown	Unk	Not Reported
	Vitamin D	C	Unknown	Unk	Not Reported
	Acetaminophen;Codeine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472951	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034925			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Mental Impairment; Product Substitution Issue	Escitalopram Tablets			S	Oral	15 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Acacia			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Aczone			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Benzaclin			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Canesten Hc			C	Unknown	Unk		Not Reported

Cetaphil Acne Principles	C	Unknown	Unk	Not Reported
Cetaphil	C	Unknown	Unk	Not Reported
Cetaphil Cleansers Oily Skin	C	Unknown	Unk	Not Reported
Cipralex	C	Unknown	Unk	Not Reported
Constella	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Domperidone	C	Unknown	Unk	Not Reported
Epival	C	Unknown	Unk	Not Reported
Flovent Hfa	C	Unknown	Unk	Not Reported
Genteal	C	Unknown	Unk	Not Reported
Nasacort Aq	C	Unknown	Unk	Not Reported
Omega 3 6 9	C	Unknown	Unk	Not Reported
Otrivin Saline	C	Unknown	Unk	Not Reported
Seroquel	C	Unknown	Unk	Not Reported
Seroquel	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Tears Plus	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	Unk	Not Reported
Toviaz	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Vitamin D2	C	Unknown	Unk	Not Reported
Zinc Gluconate	C	Unknown	Unk	Not Reported
Zyloprim	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472952	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034849			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depression; Drug Ineffective; Product Substitution Issue; Suicidal Ideation	Escitalopram Tablets		S	Oral	20 Milligram, Once A Day	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472956	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-034930			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Fall; Hyponatraemia; Hypotension; Hypovitaminosis	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Telmisartan Tablets			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	40 Milligram, Two Times A Day		Aurobindo
	Loperamide			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	50 Milligram, Once A Day		Not Reported
	Metoprolol			S				Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Tamsulosin Cr			S	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472966	EXPEDITED (15-DAY)		LT, OT	CA-AUROBINDO-AUR-APL-2019-035075			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Suicidal Ideation	Escitalopram Tablets			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472967	EXPEDITED (15-DAY)		LT, OT	CA-AUROBINDO-AUR-APL-2019-034886			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depressive Symptom; Sexual Dysfunction; Suicidal Ideation	Escitalopram Tablets	S	Oral	Unk Unk, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472969	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035124			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal; Negative Thoughts; Paranoia	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Ibuprofen			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472972	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-035582			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aptyalism; Drug Ineffective; Overdose; Panic Disorder	Escitalopram			S	Oral	30 Milligram		Aurobindo
	Escitalopram			S	Oral	30 Milligram		Aurobindo
	Amitriptyline			S	Oral	20 Milligram, Once A Day		Not Reported
	Buspirone			S	Oral	5 Milligram, Once A Day		Not Reported
	Zyprexa			S	Oral	2.5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472977	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034861			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Insomnia; Pharyngeal Swelling; Product Substitution Issue; Swollen Tongue	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Aldactone			C	Unknown	Unk		Not Reported
	Arthrotec			C	Unknown	Unk		Not Reported

	Ativan		C	Unknown	Unk	Not Reported
	Imitrex		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472979	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034814			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Loss Of Consciousness; Seizure	Escitalopram Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo
	Dayquil			S	Unknown	2 Dosage Form, Once A Day		Not Reported
	Dalacin C			C	Unknown	Unk		Not Reported
	Stieva-A			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472981	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034801			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Disorder; Chest Discomfort; Cough; Cyanosis; Decreased Appetite; Depression; Diarrhoea; Dizziness; Drug Ineffective; Dyspnoea Exertional; Emphysema; Fall; Fatigue; Headache; Hiatus Hernia; Hypoaesthesia; Insomnia; Malaise; Overdose; Pain; Panic Reaction; Pneumonia; Pruritus; Pulmonary Mass; Tremor	Escitalopram			S	Unknown	Unk		Aurobindo
	Atrovent			S	Unknown	Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Not Reported
	Fluticasone Propionate;Salmeterol Xinafoate			S		Unk, Two Times A Day		Not Reported
	Fluticasone Propionate;Salmeterol Xinafoate			S		Unk		Not Reported
	Glycopyrronium Bromide			S	Unknown	Unk		Not Reported
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Tiotropium Bromide			S	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	4 Dosage Form, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472984	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035140			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glossodynia	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Pantoloc			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472987	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-035589			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aptyalism; Drug Ineffective; Panic Disorder	Escitalopram Tablets			S	Oral	30 Milligram, Unk		Aurobindo
	Amitriptyline			S	Oral	20 Milligram, Once A Day		Not Reported
	Buspirone			S	Oral	5 Milligram, Once A Day		Not Reported
	Zyprexa			S	Oral	2.5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472989	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035118			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Aurobindo
	Vyvanse			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472992	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-034945			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dysaesthesia; Fatigue; Nausea	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Baclofen			C	Unknown	Unk		Not Reported

Amlodipine	C	Unknown	Unk		Not Reported
Allopurinol	C	Unknown	Unk		Not Reported
Diltiazem	C	Unknown	Unk		Not Reported
Gabapentin	C	Unknown	Unk		Not Reported
Ramipril	C	Unknown	Unk		Not Reported
Tylenol W/Codeine No. 3	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16475473	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1068120			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Intentional Overdose; Suicide Attempt	Serpentil (Escitalopram Oxalate)			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	15826005	EXPEDITED (15-DAY)		HO, OT	SK-MYLANLABS-2019M1002654		30 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Antisocial Behaviour; Apathy; Asthenia; Bradyphrenia; Delusion; Depression; Drug Ineffective; Hypomania; Mania; Mental Impairment; Off Label Use; Product Use In Unapproved Indication; Sleep Disorder; Weight Increased	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported
	Escitalopram			S	Unknown	5 Milligram, Qd		Not Reported
	Olanzapine			S	Oral	15 Milligram, Qd		Not Reported
	Olanzapine			S	Oral	10 Milligram, Qd		Not Reported
	Olanzapine			S	Oral	Unk (Dispersion)		Not Reported
	Valproic Acid			S	Oral	Unk		Not Reported
	Sertraline			S		Unk		Not Reported
	Quetiapine			C	Unknown	500 Milligram (Pro Die (Extended-Release Form)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16327958	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-026303			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Interstitial Lung Disease; Pulmonary Fibrosis	Duloxetine			S	Unknown	15 Milligram		Aurobindo
	Escitalopram Tablets			S	Unknown	5 Milligram		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Unknown	37.5 Milligram		Aurobindo
	Paroxetine Tablet			S	Unknown	10 Milligram		Aurobindo
	Mylan Duloxetine			S	Unknown	Unk		Not Reported
	Venlafaxin Mylan			S	Unknown	Unk		Not Reported
	Venlafaxin Mylan			S	Unknown	37.5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16328325	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-027747			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Anxiety; Anxiety Disorder; Breast Cancer; Breast Disorder; Decreased Appetite; Diarrhoea; Ear Discomfort; Frequent Bowel Movements; Hot Flush; Nasopharyngitis; Nausea; Nervousness; Pain; Weight Increased	Escitalopram Tablets			S	Unknown	Unk, Once A Day		Aurobindo
	Tamoxifen			S	Unknown	Unk		Not Reported
	Atezolizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Atezolizumab			S	Intravenous (not otherwise specified)	1200 Milligram		Not Reported
	Tecentriq			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tecentriq			S	Intravenous (not otherwise specified)	Unk, Every 3 Weeks		Not Reported
	Tecentriq			S	Intravenous (not otherwise specified)	1200 Milligram, Every 3 Weeks		Not Reported
	Ativan			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16337161	NON-EXPEDITED		OT	US-PFIZER INC-2019208061		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Zoloft			S	Oral	25 Mg, Unk		Pfizer
	Zoloft			S	Oral	50 Mg, Daily		Pfizer
	Zoloft			S				Pfizer
	Zoloft			S				Pfizer
	Lexapro			S	Oral	20 Mg, Daily		Not Reported
	Lexapro			S		5 Mg, Unk		Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported
	Lexapro			S				Not Reported
	Wellbutrin			S		Unk		Not Reported
	Wellbutrin			S				Not Reported
	Wellbutrin			S				Not Reported
	Wellbutrin			S				Not Reported
	Zyrtec [Cetirizine Hydrochloride]			C		Unk		Not Reported
	Buspirone			C		Unk		Not Reported
	Amfetamine/Dexamfetamine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16468769	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016710		25 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Mental Impairment; Product Substitution Issue	Escitalopram			S	Oral	15 Mg, Qd		Apotex
	Escitalopram			S				Apotex
	Acacia			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Aczone			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Benzaclin Topical			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Canesten Hc			C	Unknown	Unk (1 Percentage Cream Powder Mixture)		Not Reported

Cetaphil Acne Principles	C	Unknown	Unk	Not Reported
Cetaphil /02314901/	C	Unknown	Unk	Not Reported
Cetaphil Cleansers Oily Skin	C	Unknown	Unk	Not Reported
Cipralex /01588501/	C	Unknown	Unk	Not Reported
Constella	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Domperidone	C	Unknown	Unk	Not Reported
Epival /00017001/	C	Unknown	Unk	Not Reported
Flovent	C	Unknown	Unk (Powder)	Not Reported
Flovent Hfa	C	Unknown	Unk (Aerosol)	Not Reported
Genteal /00445101/	C	Unknown	Unk	Not Reported
Nasacort Aq	C	Unknown	Unk (Metered Dose)	Not Reported
Omega 3 6 9 /01334101/	C	Unknown	Unk	Not Reported
Otrivin Saline	C	Unknown	Unk (Hypertonic Nasal Spray)	Not Reported
Seroquel	C	Unknown	Unk	Not Reported
Seroquel	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Tears Plus	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	Unk	Not Reported
Toviaz	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Tylenol Extra Strength	C	Unknown	Unk	Not Reported
Vitamin D2	C	Unknown	Unk	Not Reported
Zinc Gluconate	C	Unknown	Unk	Not Reported
Zyloprim	C	Unknown	Unk	Not Reported
Benzoyl Peroxide W/Clindamycin Phosphate	C	Unknown	Unk	Not Reported
Clotrimazole W/Hydrocortisone	C	Unknown	Unk	Not Reported
Valproate Semisodium	C	Unknown	Unk	Not Reported

	Polyvinyl Alcohol W/Povidone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476596	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2019M1058202		91 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyponatraemia	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Hydrochlorothiazide/Irbesartan			S	Oral	Unk		Not Reported
	Gabapentina			S	Oral	Unk		Mylan
	Carbamazepina			S	Oral	200 Mg Por Las Mañanas Un Cuarto De Comprimido		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476711	EXPEDITED (15-DAY)		OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-211394			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Exposure During Pregnancy; Live Birth	Escitalopram			S	Unknown	Unk		Not Reported
	Nitrazepam			S	Unknown	Unk		Not Reported
	Lormetazepam			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Sun
	Alprazolam			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476902	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034806			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Exposure During Pregnancy; Lung Infection; Melanocytic	Escitalopram Tablets			S	Unknown	10 Milligram		Aurobindo
	Imodium			S	Unknown	Unk		Not Reported
	Acetaminophen;Codeine Phosphate			S	Unknown	Unk		Not Reported

Naevus; Rheumatoid Factor Increased	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, 3 Times A Day	Not Reported
	Salbutamol	S	Unknown	Unk	Not Reported
	Tecta	S	Unknown	30 Milligram, Once A Day	Not Reported
	Loperamide Hydrochloride	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476903	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-034783			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dry Mouth; Tension Headache	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Apixabanum			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476905	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034909			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Therapy Change	Escitalopram Tablets			S	Oral	Unk, Once A Day		Aurobindo
	Bupropion			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476910	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035056			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual; Visual Impairment	Escitalopram Tablets			S	Unknown	5.0 Milligram		Aurobindo
	Escitalopram			S	Unknown	10.0 Milligram		Aurobindo
	Lorazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476912	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035575			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Escitalopram			S	Unknown	Unk, Once A Day		Aurobindo
	Cosentyx			S	Subcutaneous	150 Milligram, Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cosentyx			S	Subcutaneous	150 Milligram, Unk		Not Reported
	Diclofenac Diethylamine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Vitamin D3			S	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476913	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034853			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Fatigue; Headache; Heart Rate Increased; Heart Rate Irregular; Myalgia; Nausea; Palpitations	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476914	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034784			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Affective	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo

Disorder; Condition Aggravated; Insomnia; Nasal Dryness	Atorvastatin Calcium		C	Unknown	Unk	Not Reported
	Candesartan		C	Unknown	Unk	Not Reported
	Januvia		C	Unknown	Unk	Not Reported
	Pantoloc		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476916	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-035005			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Insomnia; Muscle Twitching; Pain In Extremity; Syncope; Tachycardia; Tremor	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Norfloxacin			S	Oral	400 Milligram, Two Times A Day		Not Reported
	Advil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476917	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-035636			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Product Substitution Issue	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476924	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-035127			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Substitution Issue	Escitalopram Tablets			S	Oral	10 Milligram, Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476925	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-034807			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Dizziness; Headache; Product Substitution Issue	Escitalopram Tablets			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476926	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-034875			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Withdrawal Syndrome; Arrhythmia; Drug Interaction; Hyperthermia; Intentional Overdose; Intentional Product Misuse; Major Depression; Overdose; Pneumonia; Potentiating Drug Interaction; Sepsis; Serotonin Syndrome; Tachycardia; Toxicity To Various Agents	Escitalopram Tablets			S	Oral	Unk		Aurobindo
	Citalopram Tablets			S	Unknown	Unk		Aurobindo
	Quetiapine Film-Coated Tablet			S	Oral	Unk		Aurobindo
	Olanzapine			S	Oral	Unk		Aurobindo
	Bupropion			S	Oral	Unk		Not Reported
	Phenytoin			S	Oral	Unk		Not Reported
	Primidone			S	Oral	Unk		Not Reported
	Valproic Acid			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476929	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-034790			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Depression; Product Substitution Issue; Therapeutic Product Effect Decreased	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476930	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035117			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Fatigue; Obsessive Thoughts; Psychomotor Retardation; Somnolence	Escitalopram Tablets		S	Unknown	10 Milligram, 1 Every 1 Day	Aurobindo
	Escitalopram Tablets		S			Aurobindo
	Citalopram Tablets		S	Oral	50 Milligram, 1 Every 1 Day	Aurobindo
	Citalopram Tablets		S			Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476931	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035628			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Chills; Condition Aggravated; Dizziness; Dyspnoea; Fatigue; Heart Rate Increased; Heart Rate Irregular; Hyperhidrosis; Loss Of Consciousness; Nausea; Photophobia	Escitalopram Tablets			S	Oral	10.0 Milligram, Daily		Aurobindo
	Diclofenac Sodium			C	Unknown	Unk		Not Reported
	Dayquil			C	Unknown	Unk		Not Reported
	Ferrous Sulphate			C	Unknown	Unk		Not Reported
	Misoprostol			C	Unknown	Unk		Not Reported
	Vitamin C			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476934	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034821			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Product Substitution Issue; Restlessness; Therapeutic Product Effect Decreased	Escitalopram Tablets			S	Oral	10 Milligram		Aurobindo
	Lorazepam			C	Unknown	Unk		Not Reported
	Olanzapine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476935	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-034834			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Mental Status	Escitalopram Tablets			S	Oral	10 Milligram		Aurobindo

Changes	Lorazepam		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476937	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034958			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Jittery; Nervousness; Panic Attack	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476938	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-034929			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt	Escitalopram Tablets			S	Oral	20 Milligram, Once A Day		Aurobindo
	Duloxetine			S	Unknown	Unk		Not Reported
	Bupropion			C	Unknown	Unk		Not Reported
	Cetirizine			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476939	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034949			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anxiety; Confusional State; Insomnia; Pain In Jaw; Somnolence; Speech Disorder; Vision Blurred	Escitalopram Tablets			S	Unknown	10 Milligram		Aurobindo
	Lorazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476940	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034990			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Exposure During Pregnancy	Escitalopram			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Bupropion			S	Unknown	Unk		Not Reported
	Domperidone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	500 Milligram, 1 Every 8 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476941	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034728			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Product Substitution Issue	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476944	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035626			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Escitalopram Tablets			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476945	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-035134			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Temazepam			S	Unknown	Unk		Not Reported
	Tylenol With Codein #3			S	Unknown	Unk		Not Reported
	Advair			C	Unknown	Unk		Not Reported
	Atrovent			C	Unknown	Unk		Not Reported

Gabapentin	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	Unk		Not Reported
Ranitidine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476948	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035149			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Escitalopram Tablets			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Cosentyx			S	Subcutaneous	150 Milligram, 1 Month		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cosentyx			S	Subcutaneous	150 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Povidone-Iodine			S	Unknown	Unk		Not Reported
	Vitamin D3			S	Unknown	Unk		Not Reported
	Voltaren			S	Unknown	Unk		Not Reported
	Voltaren			S	Unknown	Unk, 1 Every Week		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16477900	EXPEDITED (15-DAY)		OT	HR-ACCORD-135040		15 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Aripiprazole			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16477904	EXPEDITED (15-DAY)		OT	IT-ACCORD-135171		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Therapeutic Product Ineffective	Escitalopram			S	Oral			Not Reported
	Xanax			S	Oral	Strength: 0,5 Mg Prolonged-Release Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16477911	EXPEDITED (15-DAY)		CA	DE-ACCORD-135008		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	Dosage Text: 10 Mg/D		Not Reported
	Femi Baby			C	Transplacental	Dosage Text: 0.6 Mg/D (Bis 0.8 Mg/D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16477912	EXPEDITED (15-DAY)		HO	FR-ACCORD-134957		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Spinal Fracture	Escitalopram			S	Oral			Not Reported
	Agomelatine			S	Oral			Not Reported
	Phenergan			S	Oral			Not Reported
	Clotiazepam			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Lormetazepam			S	Oral			Not Reported
	Tilcotil			C				Not Reported
	Atorvastatin			C				Not Reported
	Kardegic			C				Not Reported
	Esomeprazole			C				Not Reported

	Ramipril			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16477979	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035598			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Cough; Dyspnoea; Interstitial Lung Disease; Secretion Discharge; Wheezing	Duloxetine			S	Unknown	15 Milligram		Aurobindo
	Escitalopram Tablets			S	Unknown	5 Milligram		Aurobindo
	Venlafaxine			S	Unknown	37.5 Milligram, Once A Day		Aurobindo
	Venlafaxine Xr Extended Release Capsule			S	Unknown	37.5 Milligram		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16478018	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035620			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Dyspnoea; Fatigue; Interstitial Lung Disease	Duloxetine			S	Unknown	15.0 Milligram		Aurobindo
	Duloxetine			S				Aurobindo
	Escitalopram Tablets			S	Unknown	5.0 Milligram		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Venlafaxine			S	Unknown	37.5 Milligram		Aurobindo
	Venlafaxine			S				Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16478197	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1926084US			Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16478470	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1058084		84 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Medication Error	Escitalopram			S	Oral	25 Milligram, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16478845	EXPEDITED (15-DAY)		HO	ES-DSJP-DSE-2019-123684			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Balzak Plus			S	Oral	40/10/25 Mg, Qd		Daiichi
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Apixaban			C	Oral	2.5 Mg, Once Every 12hr		Not Reported
	Atenolol			C	Oral	25 Mg, Qd		Not Reported
	Potassium Citrate			C	Oral	1.08 G, Qd		Not Reported
	Omeprazole			C	Oral	20 Mg, Once Every 12hr		Not Reported
	Paracetamol			C	Oral	1 G, Once Every 8hr		Not Reported
	Glimepiride			C	Oral	4 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16487616	DIRECT	Y	OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dry Mouth	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16487691	DIRECT		OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Hypotension	Escitalopram 20 Mgs Tablet			S	Oral	Quantity:30 Tablet(S);		Accord
	Ranitadine			C				Not Reported
	Levothyroxine			C				Not Reported
	Wellbutrin Xl			C				Not Reported
	Albuterol			C				Not Reported

	Multi Vitamin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16487784	DIRECT		DS			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dysgeusia	Escitalopram Oxalate			S	Oral	Quantity:1 Tablet(S);		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16368484	EXPEDITED (15-DAY)		HO, LT, OT	US-GLAXOSMITHKLINE-US2019AMR095883		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Drug Ineffective; Jaundice; Liver Transplant; Nausea; Sexual Dysfunction	Wellbutrin Xl			S	Unknown	150 Mg, Unk		Glaxosmithkline
	Wellbutrin Xl			S	Unknown	150 Mg, Unk		Glaxosmithkline
	Wellbutrin Sr			S	Unknown	100 Mg, Unk		Glaxosmithkline
	Wellbutrin Sr			S				Glaxosmithkline
	Wellbutrin Sr			S				Glaxosmithkline
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram			C	Unknown	10 Mg, Unk		Glaxosmithkline
	Escitalopram			C				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16482311	EXPEDITED (15-DAY)		HO	SE-TEVA-2019-SE-1069598			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Level Of Consciousness; Dyskinesia; Intentional Overdose; Intentional Self-Injury; Tachycardia	Ibuprofen			S	Oral			Actavis
	Paracetamol			S	Oral			Not Reported
	Escitalopram			S	Oral			Ivax
	Lergigan (Promethazine Hydrochloride)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16482674	EXPEDITED (15-DAY)		HO	FR-ACCORD-135441		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Allopurinol			S	Oral			Accord
	Seroplex			S	Oral	Strength: 10 Mg		Not Reported
	Smofkabiven E			S	Intravenous drip			Not Reported
	Lyrica			S	Oral	Strength: 50 Mg		Not Reported
	Imovane			S	Oral	Strength: 3.75 Mg		Not Reported
	Methotrexate/Methotrexate Sodium			C	Intravenous (not otherwise specified)	Variable		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			C	Intravenous (not otherwise specified)	Variable		Not Reported
	Vincristine			C	Intravenous (not otherwise specified)	Variable		Not Reported
	Doxorubicin			C	Intravenous (not otherwise specified)	Variable		Not Reported
	Prednisone/Prednisone Acetate			C	Oral	Variable		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	Variable		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16482734	EXPEDITED (15-DAY)		OT	US-ACCORD-135190		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Sleep Paralysis; Treatment Failure; Withdrawal Syndrome	Bupropion/Bupropion Hydrochloride			S				Not Reported
	Escitalopram			S				Not Reported
	Mirtazapine			S				Not Reported
	Fluoxetine			C				Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16482893	EXPEDITED (15-DAY)		HO	SE-TEVA-2019-SE-1069922		21 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Dizziness	Escitalopram			S		25 Mg		Ivax
	Atarax (Hydroxyzine)			S		25 Mg 7 St- 175 Mg		Not Reported
	Lergigan (Promethazine Hydrochloride)			S	Oral	7 St 25 Mg - 125 Mg		Not Reported
	Propavan			S		5 St -25 Mg - 125 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16483605	NON-EXPEDITED			US-PFIZER INC-2019272084		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Pregabalin			S		Unk		Pfizer
	Indomethacin			S		Unk		Unknown
	Midazolam			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Aspirin			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Sedinol			S		Unk		Not Reported
	Escitalopram [Escitalopram Oxalate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16483676	EXPEDITED (15-DAY)		HO, LT, OT	US-ELI_LILLY_AND_COMPANY-US201906012656		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperemesis Gravidarum;	Prozac			S	Unknown	Unk, Unknown		Eli Lilly And Co

Live Birth; Maternal Exposure During Pregnancy; Morning Sickness; Nausea; Placenta Praevia; Pre-Eclampsia; Premature Delivery; Premature Rupture Of Membranes; Premature Separation Of Placenta	Cymbalta	S	Unknown	Unk Unk, Unknown	Eli Lilly And Co
	Duloxetine Hydrochloride	S	Unknown	Unk, Unknown	Not Reported
	Fluoxetine Hydrochloride	S	Unknown	Unk Unk, Unknown	Eli Lilly And Co
	Clonazepam	S			Not Reported
	Methylphenidate	S	Unknown		Not Reported
	Quetiapine	S	Unknown	50 Mg, Prn	Not Reported
	Quetiapine	S	Unknown	25 Mg, Prn	Not Reported
	Seroquel	S	Unknown	25 Mg, Prn	Not Reported
	Seroquel	S	Unknown	50 Mg, Prn	Not Reported
	Zoloft	S	Unknown	Unk	Not Reported
	Zolpidem	S	Unknown		Not Reported
	Prevacid	S	Unknown	Unk	Not Reported
	Topamax	S	Unknown	Unk	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Concerta	S	Unknown	Unk	Not Reported
	Klonopin	S	Unknown	Unk	Not Reported
	Klonopin	S			Not Reported
	Aripiprazole	S	Unknown	2.5 Mg, Unk	Not Reported
	Aripiprazole	S	Unknown	2.5 Mg, Unk	Not Reported
	Aripiprazole	S	Unknown	2.5 Mg, Unk	Not Reported
	Prazosin	S	Unknown	Unk	Not Reported
	Ambien	S	Unknown	Unk	Not Reported
	Wellbutrin	S	Unknown	Unk	Not Reported
	Lexapro	S	Unknown	Unk	Not Reported
	Ativan	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Zofran [Ondansetron Hydrochloride]	S	Unknown	Unk	Not Reported
	Lorazepam	S	Unknown		Not Reported
	Celexa [Celecoxib]	S	Unknown	Unk	Not Reported

	Sertraline	S	Unknown	Unk		Not Reported
	Vitamin B Complex	C	Unknown	Unk		Not Reported
	Prenatal Vitamins [Ascorbic Acid;Calcium Pant	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16484229	EXPEDITED (15-DAY)		CA, HO, LT, OT	US-ELI_LILLY_AND_COMPANY-US201906012676			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Blood Glucose Decreased; Body Temperature Abnormal; Bradycardia Neonatal; Congenital Foot Malformation; Continuous Positive Airway Pressure; Dyspnoea; Foetal Exposure During Pregnancy; Gastrooesophageal Reflux Disease; Heart Rate Decreased; Hydrocele; Hyperbilirubinaemia Neonatal; Hypotonia Neonatal; Infantile Apnoea; Large For Dates Baby; Macrocephaly; Neonatal Respiratory Distress; Plagiocephaly; Premature Baby; Selective Eating Disorder	Cymbalta			S	Transplacental	Unk Unk, Unknown		Eli Lilly And Co
	Fluoxetine Hydrochloride			S	Transplacental	Unk Unk, Unknown		Eli Lilly And Co
	Fluoxetine Hydrochloride			S	Transplacental	Unk, Unknown		Eli Lilly And Co
	Seroquel			S	Transplacental	100 Mg, Unk		Not Reported
	Ambien			S	Transplacental	Unk Unk, Unknown		Not Reported
	Ursodiol			S	Transplacental	Unk, Unknown		Not Reported
	Insulin			S	Transplacental	Unk Unk, Unknown		Not Reported
	Lexapro			S	Transplacental	Unk Unk, Unknown		Not Reported
	Metformin Hydrochloride			S	Transplacental	Unk Unk, Unknown		Not Reported
	Colace			S	Transplacental	Unk Unk, Unknown		Not Reported
	Lovaza			S	Transplacental	Unk, Unknown		Not Reported
	Lithium Carbonate			S	Transplacental	Unk Unk, Unknown		Not Reported
	Amoxicillin			S	Transplacental	Unk Unk, Unknown		Not Reported
	Elavil [Amitriptyline Hydrochloride]			S	Transplacental	75 Mg, Unk		Not Reported
	Lithium			S	Transplacental	900 Mg, Unk		Not Reported
	Lamictal			S	Transplacental	Unk Unk, Unknown		Not Reported
	Levothyroxine			S	Transplacental	Unk Unk, Unknown		Not Reported
	Lisinopril			S	Transplacental	Unk Unk, Unknown		Not Reported
	Simponi			S	Transplacental	Unk Unk, Unknown		Not Reported
	Effexor			S	Transplacental	300 Mg, Unk		Not Reported

Reglan [Metoclopramide Hydrochloride]	S	Transplacental	Unk Unk, Unknown	Not Reported
Lamotrigine	S	Transplacental	Unk, Unknown	Not Reported
Levemir	S	Transplacental	Unk Unk, Unknown	Not Reported
Trazodone	S	Transplacental	Unk Unk, Unknown	Not Reported
Clonazepam	S	Transplacental	Unk Unk, Unknown	Not Reported
Wellbutrin	S	Transplacental	Unk Unk, Unknown	Not Reported
Victoza	S	Transplacental	Unk Unk, Unknown	Not Reported
Venlafaxine Xr	S	Transplacental	300 Mg, Unk	Not Reported
Zolpidem	S	Transplacental	Unk Unk, Unknown	Not Reported
Zofran [Ondansetron Hydrochloride]	S	Transplacental	Unk Unk, Unknown	Not Reported
Flexeril [Cyclobenzaprine Hydrochloride]	S	Transplacental	Unk Unk, Unknown	Not Reported
Quetiapine	S	Transplacental	100 Mg, Unk	Not Reported
Lovenox [Enoxaparin Sodium]	S	Transplacental	Unk Unk, Unknown	Not Reported
Adderall	S	Transplacental	Unk Unk, Unknown	Not Reported
Metoclopramide	S	Transplacental	Unk Unk, Unknown	Not Reported
Aripiprazole	S	Transplacental	5 Mg, Unk	Not Reported
Novolog	S	Transplacental	Unk Unk, Unknown	Not Reported
Amoxicillin Trihydrate	S	Transplacental	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16487996	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1059475		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhagic Stroke	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported
	Kardegic			S	Oral	1 Dosage Form, Qd		Mylan
	Inegy			C	Oral	1 Dosage Form, Qd		Mylan
	Spironolactone			C	Oral	75 Milligram, Qd		Mylan
	Cardensiel			C	Oral	1 Dosage Form, Qd		Mylan

Lasilix /00032601/	C	Oral	60 Milligram, Qd		Mylan
Esomeprazole	C	Oral	20 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	13895603	NON-EXPEDITED			US-PFIZER INC-2017361004		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Flagyl			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Venlafaxine Hcl			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported
	Macrobid			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Augmentin			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paroxetine Hcl			S		Unk		Not Reported
	Nitrofurantoin Monohyd/M-Cryst			S		Unk		Not Reported
	Amoxicillin-Pot Clavulanate			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16455973	EXPEDITED (15-DAY)		DE, HO, OT	CH-GLAXOSMITHKLINE-CH2019109286		78 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplasia; Febrile Neutropenia; Oesophageal Candidiasis;	Wellvone			S	Oral	1500 Mg In The Morning		Glaxosmithkline
	Diflucan			S	Unknown	400 Mg, Qd		Not Reported

Off Label Use; Oral Candidiasis; Pseudomonal Sepsis	Benerva	S	Unknown	300 Mg, Qd	Not Reported
	Mabthera	S	Intravenous (not otherwise specified)	1000 Mg Unique Total	Not Reported
	Amlodipin	S	Unknown	10 Mg, Unk	Not Reported
	Cipralex	S	Unknown	10 Mg, Unk	Not Reported
	Brufen (Ibuprofen)	S	Unknown	400 Mg, Unk	Not Reported
	Imodium	S	Unknown	2 Mg, Unk	Not Reported
	Novorapid	S	Unknown	Unk	Not Reported
	Levemir	S	Unknown	100 Unk, Unk	Not Reported
	Cefepime	C	Unknown	Unk	Glaxosmithkline
	Bactrim Ds	C	Unknown	Unk	Glaxosmithkline
	Dafalgan	C	Unknown	1 G, Tid	Not Reported
	Aspirin Cardio	C	Unknown	100 Mg, Qd	Not Reported
	Diovan	C	Unknown	80 Mg, Qd	Not Reported
	Diovan	C	Unknown	160 Mg, Qd	Not Reported
	Spiricort	C	Unknown	50 Mg, Qd	Not Reported
	Piperacillin Sodium And Tazobactam Sodium	C	Unknown	Unk	Not Reported
	Esomep	C	Unknown	20 Mg, Qd	Not Reported
	Fragmin	C	Unknown	Unk	Not Reported
	Beloc Zok	C	Unknown	50 Mg, Qd	Not Reported
	Atorvastatin Pfizer	C	Unknown	40 Mg, Qd	Not Reported
	Mestinon	C	Unknown	60 Mg, 6 Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16494695	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-035641			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Bradykinesia; Cogwheel Rigidity;	Paroxetine Tablet			S	Unknown	5 Milligram, Once A Day		Aurobindo
	Paroxetine Tablet			S	Unknown	10 Milligram, Once A Day		Aurobindo

Confusional State; Drug Ineffective; Drug Intolerance; Hyperhidrosis; Myalgia; Parkinsonism; Resting Tremor; Therapy Non-Responder	Paroxetine Tablet		S	Unknown	15 Milligram, Once A Day	Aurobindo
	Olanzapine		S	Oral	15 Milligram, Once A Day	Aurobindo
	Sertraline Capsules		S	Unknown	50 Milligram	Aurobindo
	Citalopram Tablets		S	Oral	10 Milligram, Two Times A Day	Aurobindo
	Citalopram Tablets		S	Oral	100 Milligram, Once A Day	Aurobindo
	Quetiapine Film-Coated Tablet		S	Unknown	25 Milligram, Once A Day	Aurobindo
	Haloperidol		S	Unknown	1 Milligram, Once A Day	Not Reported
	Trazodone		S	Unknown	100 Milligram, Once A Day	Not Reported
	Aricept		S	Unknown	10 Milligram, Once A Day	Not Reported
	Clomipramine		S	Oral	100 Milligram, Once A Day	Not Reported
	Clomipramine		S	Oral	25 Milligram, Once A Day	Not Reported
	Cipralex		S	Unknown	10 Milligram, Two Times A Day	Not Reported
	Valproic Acid		S	Unknown	Unk	Not Reported
	Escitalopram		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16497680	EXPEDITED (15-DAY)		CA, HO, OT	US-ELI_LILLY_AND_COMPANY-US201906012718		2 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chordee; Deformity; Developmental Delay; Drug Withdrawal Syndrome Neonatal; Emotional Distress; Encephalopathy; Eustachian Tube Dysfunction; Foetal Exposure During Pregnancy; Muscular Weakness; Otitis Media Acute; Pain; Penile Torsion; Periventricular	Cymbalta			S	Transplacental	Unk, Unknown		Eli Lilly And Co
	Cymbalta			S	Transplacental	Unk, Unknown		Eli Lilly And Co
	Bentyl			S	Transplacental	Unk, Unknown		Not Reported
	Bentyl			S	Transplacental	Unk, Unknown		Not Reported
	Protonix [Pantoprazole Sodium Sesquihydrate]			S	Transplacental	Unk, Unknown		Not Reported
	Protonix [Pantoprazole Sodium Sesquihydrate]			S	Transplacental	Unk, Unknown		Not Reported
	Lortab [Hydrocodone Bitartrate;Paracetamol]			S	Transplacental	Unk, Unknown		Not Reported

Leukomalacia; Premature Baby; Prepuce Redundant; Skull Malformation; Social Avoidant Behaviour; Tachypnoea	Lortab [Hydrocodone Bitartrate;Paracetamol]	S	Transplacental	Unk, Unknown	Not Reported
	Neurontin	S	Transplacental	Unk, Unknown	Not Reported
	Neurontin	S	Transplacental	Unk, Unknown	Not Reported
	Dilaudid Hp	S	Transplacental	Unk, Unknown	Not Reported
	Dilaudid Hp	S	Transplacental	Unk, Unknown	Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol	S	Transplacental	Unk, Unknown	Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol	S	Transplacental	Unk, Unknown	Not Reported
	Topamax	S	Transplacental	Unk, Unknown	Not Reported
	Topamax	S	Transplacental	Unk, Unknown	Not Reported
	Dulcolax [Bisacodyl]	S	Transplacental	Unk, Unknown	Not Reported
	Dulcolax [Bisacodyl]	S	Transplacental	Unk, Unknown	Not Reported
	Zofran [Ondansetron]	S	Transplacental	Unk, Unknown	Not Reported
	Zofran [Ondansetron]	S	Transplacental	Unk, Unknown	Not Reported
	Methadone	S	Transplacental	Unk, Unknown	Not Reported
	Methadone	S	Transplacental	Unk, Unknown	Not Reported
	Reglan [Metoclopramide]	S	Transplacental	Unk, Unknown	Not Reported
	Reglan [Metoclopramide]	S	Transplacental	Unk, Unknown	Not Reported
	Lexapro	S	Transplacental	Unk, Unknown	Not Reported
	Lexapro	S	Transplacental	Unk, Unknown	Not Reported
	Stadol	S	Transplacental	Unk, Unknown	Not Reported
	Stadol	S	Transplacental	Unk, Unknown	Not Reported
	Miralax	S	Transplacental	Unk, Unknown	Not Reported
	Miralax	S	Transplacental	Unk, Unknown	Not Reported
	Prenatal Vitamins [Minerals Nos;Vitamins Nos]	C	Transplacental	Unk, Unknown	Not Reported
	Prenatal Vitamins [Minerals Nos;Vitamins Nos]	C	Transplacental	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16497681	EXPEDITED (15-DAY)		HO	US-ELI_LILLY_AND_COMPANY-US201906012594		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Emotional Disorder; Exposure During Pregnancy; Premature Labour	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Lexapro			S	Unknown	Unk Unk, Unknown		Not Reported
	Dulcolax [Bisacodyl]			S	Unknown	Unk Unk, Unknown		Not Reported
	Dilaudid			S	Unknown	Unk Unk, Unknown		Not Reported
	Lortab [Hydrocodone Bitartrate;Paracetamol]			S	Unknown	Unk Unk, Unknown		Not Reported
	Zofran [Ondansetron]			S	Unknown	Unk Unk, Unknown		Not Reported
	Zofran [Ondansetron]			S				Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol			S	Unknown	Unk Unk, Unknown		Not Reported
	Stadol			S	Unknown	Unk, Unknown		Not Reported
	Miralax			S	Unknown	Unk, Unknown		Not Reported
	Bentyl			S	Unknown	Unk, Unknown		Not Reported
	Reglan [Metoclopramide]			S	Unknown	Unk Unk, Unknown		Not Reported
	Neurontin			S	Unknown	Unk, Unknown		Not Reported
	Methadone			S	Unknown	Unk, Unknown		Not Reported
	Topamax			S	Oral	Dosage Form: Unspecified		Not Reported
	Protonix [Pantoprazole Sodium Sesquihydrate]			S	Unknown	Unk Unk, Unknown		Not Reported
	Prenatal Vitamins [Minerals Nos;Vitamins Nos]			C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16707175	DIRECT		OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Fear; Panic Reaction; Restlessness;	Escitalopram Generic For Lexapro			S	Oral	1 Pill Per Day Mouty	1 MTH	Forest

Tension

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2019	16498543	NON-EXPEDITED		OT	US-TEVA-2019-US-1069069			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Hypersensitivity	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2019	16502109	DIRECT		OT			29 YR	Transgender	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychosexual Disorder	Lexapro			S	Oral	Quantity:30 Tablet(S);		Not Reported
	Invega Susstenna			C				Not Reported
	Cymbalta			C				Not Reported
	Spironlactone			C				Not Reported
	Progesterone			C				Not Reported
	Vitamin D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	15083465	NON-EXPEDITED			US-CLOVIS ONCOLOGY-CLO-2018-000580		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Blood Cholesterol Increased; Constipation; Cough; Diarrhoea; Dizziness; Fatigue; Increased Upper Airway Secretion; Joint Stiffness; Myalgia; Nasopharyngitis; Nausea; Product Dose Omission; Rhinorrhoea; Unevaluable Event	Rubraca			S	Oral	600mg Am/ 300mgpm		Clovis Oncology
	Rubraca			S	Oral	600 Mg, Bid		Clovis Oncology
	Rubraca			S	Oral	600 Mg, Bid		Clovis Oncology
	Rubraca			S	Oral	600 Mg Am/300 Mg Pm		Clovis Oncology
	Lexapro			S		Unk		Not Reported
	Wellbutrin			C				Not Reported
	Trintellix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	15667650	EXPEDITED (15-DAY)		OT	PHHY2018DE151907		38 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Off Label Use	Nepresol (Dihydralazine Sulfate)			S	Oral	25 Mg, Qd		Not Reported
	Levetiracetam			S	Oral	1500 Mg, Qd		Novartis
	Paroxetine Hydrochloride			S	Oral	30 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Candesartan Cilexetil			S	Oral	16 Mg, Qd		Not Reported
	Keppra			S	Unknown	1 Df, Qd		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	L-Thyroxine			C	Oral	Unk		Not Reported
	Cytotec			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16452191	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2019M1056386		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Faeces; Contraindicated Product Administered; Feeling Hot; Hyperhidrosis; Hypotension; Malaise; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Rash; Respiratory Distress	Aripiprazole			S	Unknown	2 Milligram, Qd		Not Reported
	Seroplex			S	Unknown	20 Milligram, Qd		Mylan
	Selincro			S	Oral	1 Dosage Form, Qd		Mylan
	Loxen /00639802/			C	Unknown	1 Dosage Form, Qd		Mylan
	Theralene			C	Unknown	2 Dosage Form, Qd		Mylan
	Corgard			C	Unknown	80 Milligram, Qd		Mylan
	Methadone			C	Unknown	80 Milligram, Qd		Mylan
	Lexomil			C	Unknown	1 Dosage Form, Qd		Mylan
	Kardegic			C	Unknown	Unk Unk, Qd		Mylan
	Ventolin /00139501/			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16457530	EXPEDITED (15-DAY)		HO, OT	RO-MYLANLABS-2019M1056582		54 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Condition Aggravated; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Loss Of Personal Independence In Daily Activities; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Treatment Noncompliance; Weight Decreased	Olanzapine			S	Unknown	15 Milligram, Qd		Not Reported
	Duloxetine			S	Unknown	60 Milligram, Qd		Not Reported
	Quetiapine			S	Unknown	800 Milligram, Qd		Mylan
	Quetiapine			S	Unknown	300 Milligram, Qd		Mylan
	Mirtazapine			S	Unknown	30 Milligram, Qd		Mylan
	Clonazepam			S	Unknown	0.5 Milligram, Qd		Mylan
	Risperidone			S	Unknown	6 Milligram, Qd		Mylan
	Escitalopram			S	Unknown	10 Milligram, Qd		Mylan
	Doxepine			S	Unknown	100 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16458217	EXPEDITED (15-DAY)		DE, HO, OT	CH-PFIZER INC-2019261492		78 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Aplasia; Febrile Neutropenia; Off Label Use; Product Use	Diflucan			S		400 Mg, 1x/Day		Pfizer
	Wellvone			S	Oral	1500 Mg, 1x/Day (In The		Not Reported

Issue				Morning)	
	Mabthera	S	Intravenous (not otherwise specified)	1000 Mg, Single (1000 Mg Once; In Total)	Not Reported
	Benerva	S		300 Mg, 1x/Day	Not Reported
	Amlodipin Generics	S		10 Mg, Unk	Not Reported
	Cipralex [Escitalopram Oxalate]	S		10 Mg, Unk	Not Reported
	Brufen	S		400 Mg, Unk (2-3x/Day)	Not Reported
	Imodium	S		2 Mg, Unk (2-3x/Day)	Not Reported
	Novorapid	S		Unk	Not Reported
	Levemir	S		Unk	Not Reported
	Bactrim Ds	C		Unk	Not Reported
	Cefepime	C		Unk	Not Reported
	Piperacillin Sodium And Tazobactam Sodium	C		Unk	Not Reported
	Dafalgan	C		1 G, 3x/Day	Not Reported
	Esomep [Esomeprazole]	C		20 Mg, 1x/Day (1-0-0)	Not Reported
	Fragmin	C		Unk	Not Reported
	Aspirin Cardio	C		100 Mg, 1x/Day (1-0-0)	Not Reported
	Beloc Zok	C		25 Mg, Daily	Not Reported
	Beloc Zok	C		50 Mg, Daily (1-0-0)	Not Reported
	Diovan	C		80 Mg, Daily	Not Reported
	Diovan	C		160 Mg, Daily	Not Reported
	Atorvastatin Pfizer	C		40 Mg, Daily	Not Reported
	Spiricort	C		50 Mg, Daily	Not Reported
	Mestinon	C		60 Mg, 6x/Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499090	EXPEDITED (15-DAY)		OT	AR-ABBVIE-19K-007-2837340-00			Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Epilepsy; Fatigue; Rash Generalised; Somnolence	Humira 40mg/0.4ml		S	Subcutaneous	Not Reported
	Meridian (Escitalopram Oxalate)		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499167	EXPEDITED (15-DAY)		HO	SE-JNJFOC-20190631084			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Level Of Consciousness; Dyskinesia; Intentional Overdose; Intentional Self-Injury; Tachycardia	Ipren Unspecified			S	Oral			Not Reported
	Lergigan (Promethazine Hydrochloride)			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16502629	NON-EXPEDITED			US-TEVA-2019-US-1062920			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram			S	Unknown			Ivax
	Sertraline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16507491	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1059284		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Aripiprazole			S	Oral	10 Milligram, Qd		Not Reported
	Seresta			S	Oral	1/2cp-1/2cp-/1cp		Mylan
	Tercian /00759302/			S	Oral	1/2cp-1/2cp-/1cp/J		Mylan
	Zyprexa			S	Oral	2 Dosage Form, Qd		Mylan
	Dafalgan Codeine			S		3 Dosage Form, Qd		Mylan
	Seroplex			S	Oral	1 Dosage Form, Qd		Mylan
	Oxycontin			S	Oral	2 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16508747	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2019M1059727		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Interaction; Respiratory Depression	Escitalopram			S	Oral	Escitalopram 15 Efg: 1 Comprimido/Día Con El Desayuno. Durante El Ingreso En Histórico De Líneas De		Not Reported
	Neurontin			S	Oral	Neurontín 300: 1 Comprimido Con El Desayuno, Comida Y Cena		Mylan
	Trankimazin			S	Oral	Trankimazín 1: 1 Comprimido/Día 30 Minutos Antes De Acostarse.		Mylan
	Durogesic			S	Transdermal	Durogesic: 1 Parche Transdérmico De 100 Microgrs. Y Otro De 50 Microgrs. Cada 72 Horas		Mylan
	Sevredol			S	Oral	Sevredol 10: 1 Comprimido Si Dolores Importantes A Pesar Del Tratamiento Con Neurontín 300 Y Duroges		Mylan
	Zovirax /00587301/			S		Unk		Mylan
	Nolotil /00473101/			C		Unk		Mylan
	Paracetamol			C		Unk		Mylan
	Zyloric			C		Unk		Mylan
	Seguril			C		Unk		Mylan
	Binocrit			C	Subcutaneous	Unk		Mylan
	Clexane			C	Subcutaneous	Unk		Mylan
	Pantoprazol /01263201/			C		Unk		Mylan

Natecal D	C	Unk	Mylan
Mycostatin	C	Unk	Mylan
Hidroxil B12 B6 B1	C	Unk	Mylan
Seretide Accuhaler	C	Unk	Mylan
Borea	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16509421	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1059420			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16513595	EXPEDITED (15-DAY)		HO, LT	PHHY2019JP150225		26 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alcohol Interaction; Discomfort; Disorientation; Hyperhidrosis; Hyperreflexia; Muscle Rigidity; Muscular Weakness; Myoclonus; Serotonin Syndrome; Tremor	Clomipramine			S	Unknown	50 Mg, Qd		Novartis
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Flunitrazepam			C	Unknown	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16513980	EXPEDITED (15-DAY)			US-ROCHE-2301395		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Sedation Complication	Clonazepam	S	Unknown		Not Reported
	Lorazepam	S	Unknown		Not Reported
	Escitalopram	S	Unknown		Not Reported
	Clobazam	C	Unknown	15 Mg In The Morning 15mg In The Afternoon 40mg At Night	Not Reported
	Clonidine	C	Unknown	At Night	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16709357	DIRECT	Y	HO			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Pneumonia	Tadalafil Tab			S				Mylan
	Albuterol			C				Not Reported
	Aricept			C				Not Reported
	Escitalopam			S				Not Reported
	Gabapentin			C				Not Reported
	Ipratrofium/Sol Albuter			S				Not Reported
	Laxative Tab			C				Not Reported
	Levetiraceta Sl			C				Not Reported
	Losartan Pot Tab			C				Not Reported
	Metamucil Pow			C				Not Reported
	Mometasne Cre			C				Not Reported
	Montelukast Tab			C				Not Reported
	Omega-3 Cap			C				Not Reported
	Stool Softner			C				Not Reported
	Synthroid			C				Not Reported
	Tadalafil			C				Not Reported
	Tolterodine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16510697	EXPEDITED (15-DAY)		OT	BR-TORRENT-00005031		43 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gynaecomastia; Nodule; Swelling; Tremor	Espran			S	Oral	Unknown		Torrent

	Addera D3	C		One Capsule Every Monday, Wednesday And Friday	Unknown
	Magnesium	C		One Tablet Every Monday, Wednesday, Saturday And Sunday	Unknown
	Xenical	C		Unknown	Unknown
	Vitamin C	C		Unknown	Unknown
	Noripurum	C	Intramuscular	1 Ampoule Of 100 Mg/2ml	Unknown
	Aripiprazole	C		One Tablet Of 10 Mg In The Morning	Sandoz
	Decan Haloper	C		1 Ampoule Monthly	Unknown
	Flavenos	C		2 Tablets In The Morning	Not Reported
	Chlorthalidone	C		1 Tablet Daily	Unknown
	Zinpass	C		2 Tablets	Not Reported
	Cronobe	C		Unknown	Unknown
	Omega 3	C		One Tablet Daily, 500/400 Mg	Not Reported
	Garlic Oil	C		700 Mg 1 Or 2 Capsules Daily	Unknown
	Hidrion	C		1 Tablet Daily	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16514372	EXPEDITED (15-DAY)		DE, HO, OT	CH-JNJFOC-20190627136		78 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Aplasia; Febrile Neutropenia; Off Label Use; Product Use Issue	Fluconazole			S	Unknown	400 Mg, 1x/Day		Not Reported
	Imodium			S	Unknown	2 Mg, Unk (2-3x/Day)		Not Reported
	Wellvone			S	Oral	1500 Mg, 1x/Day (In The Morning)		Not Reported
	Benerva			S	Unknown	300 Mg, 1x/Day		Not Reported
	Mabthera			S	Intravenous (not	1000 Mg, Single (1000 Mg		Not Reported

			otherwise specified)	Once; In Total)	
	Amlodipin Generics	S	Unknown	10 Mg, Unk	Not Reported
	Cipralex [Escitalopram Oxalate]	S	Unknown	10 Mg, Unk	Not Reported
	Brufen /00109201/	S		400 Mg, Unk (2-3x/Day)	Not Reported
	Novorapid	S	Unknown	Unk	Not Reported
	Levemir	S	Unknown	Unk	Not Reported
	Bactrim Ds	C	Unknown		Not Reported
	Cefepime	C	Unknown		Not Reported
	Piperacillin Sodium And Tazobactam Sodium	C	Unknown		Not Reported
	Dafalgan	C		1 G, 3x/Day	Not Reported
	Esomep [Esomeprazole]	C	Unknown	20 Mg, 1x/Day (1-0-0)	Not Reported
	Fragmin	C	Unknown		Not Reported
	Aspirin Cardio	C	Unknown	100 Mg, 1x/Day (1-0-0)	Not Reported
	Beloc Zok	C	Unknown	25 Mg, Daily	Not Reported
	Beloc Zok	C	Unknown	50 Mg, Daily (1-0-0)	Not Reported
	Diovan	C	Unknown	80 Mg, Daily	Not Reported
	Diovan	C	Unknown	160 Mg, Daily	Not Reported
	Atorvastatin Calcium	C	Unknown	40 Mg, Daily	Not Reported
	Spiricort	C	Unknown	50 Mg, Daily	Not Reported
	Mestinon	C	Unknown	60 Mg, 6x/Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16522112	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1060827		89 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Candesartan			S	Oral	4 Milligram, Qd		Not Reported
	Pantoprazole			S	Oral	40 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Furosemide			S	Oral	10 Milligram, Qd		Not Reported

	Alprazolam	C			Mylan
	Spagulax Mucilage Pur	C			Mylan
	Gaviscon /00480201/	C			Mylan
	Voltarene /00372303/	C			Mylan
	Levothyrox	C			Mylan
	Rilmenidine	C			Mylan
	Eupressyl /00631801/	C			Mylan
	Loxen L P	C			Mylan
	Uvedose	C			Mylan
	Doliprane	C	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	12696910	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP010675		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Escitalopram			S	Oral	20 Mg, Unk		Apotex
	Clonazepam			S	Oral	0.5 Mg, Tid		Apotex
	Domperidone Maleate Tablets			S	Oral	10 Mg, Bid		Apotex
	Apc-Ferrous Sulfate			S	Oral	300 Mg, Tid		Not Reported
	Gabapentin			S	Oral	300 Mg, Qd		Apotex
	Gabapentin			S	Oral	600 Mg, Bid		Apotex
	Temazepam			S	Oral	30 Mg, Qd		Not Reported
	Acetaminophen W/Codeine Phosphate			S	Oral	2 Df, Tid		Not Reported
	Wellbutrin			S	Oral	150 Mg, Bid		Not Reported
	Multivitamins W/Minerals			S	Oral	2 Df, Qd		Not Reported
	Cipralex /01588501/			S	Oral			Not Reported
	Cipralex /01588501/			S	Oral	20 Mg, Unk		Not Reported
	Tylenol With Codeine			S	Oral	2 Df, Tid, 3 Every 1 Day		Not Reported
	Vitalux /01586901/			S	Oral	Unk, Bid, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	15710328	NON-EXPEDITED			US-PFIZER INC-2018507704		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Tramadol			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Benadryl			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16469396	EXPEDITED (15-DAY)		CA, HO	CA-APOTEX-2019AP016709		1 DAY	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; High-Pitched Crying; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Escitalopram			S	Transplacental	20 Mg, Qd, 1 Every 1 Day		Apotex
	Gabapentin			S	Transplacental	1800 Mg, Qd, 1 Every 1 Day		Apotex
	Nortriptyline			S	Transplacental	20 Mg, Qd, 1 Every 1 Day		Not Reported
	Quetiapine			S	Transplacental	300 Mg, Q.12h, 1 Every 12 Hours		Apotex
	Rabeprazole			S	Transplacental	Unk		Apotex
	Zopiclone			S	Transplacental	Unk		Not Reported
	Benztropine			S	Transplacental	1.5 Mg, Qd, 1 Every 1 Day		Not Reported
	Benztropine			S	Transplacental	1.5 Mg, Qd		Not Reported
	Methadone			S	Transplacental	70 Mg, Qd, 1 Every 1 Day		Not Reported
	Methadose Dye-Free, Sugar-Free, Unflavored			S	Transplacental	70 Mg, Qd		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16503964	EXPEDITED (15-DAY)		DE, HO	CH-MYLANLABS-2019M1061082		78 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplasia; Febrile Neutropenia; Off Label Use	Brufen			S		400 Milligram, (2 -3 Per Day)		Mylan
	Wellvone			S	Oral	1500 Milligram (Morgens)		Mylan
	Mabthera			S	Intravenous (not otherwise specified)	1000 Milligram, Total (1st And Only Administration)		Mylan
	Diflucan			S		400 Milligram, Qd		Mylan
	Benerva			S		300 Milligram, Qd		Mylan
	Amlodipin Generics			S		10 Milligram		Mylan
	Cipralex /01588502/			S		10 Milligram		Mylan
	Imodium			S		2 Milligram, (2-3 Per Day)		Mylan
	Novorapid			S		Unk		Mylan
	Novorapid			S		Unk		Mylan
	Levemir			S		Unk		Mylan
	Levemir			S		Unk		Mylan
	Esomep /01479301/			C		20 Milligram, Qd		Mylan
	Fragmin			C		5000 International Unit		Mylan
	Aspirin Cardio			C		100 Milligram, Qd		Mylan
	Beloc Zok			C		25 Milligram		Mylan
	Beloc Zok			C		50 Milligram, Qd		Mylan
	Diovan			C		80 Milligram, Qd		Mylan
	Diovan			C		160 Milligram, Qd		Mylan
	Atorvastatin Pfizer			C		40 Milligram, Qd		Mylan
	Spiricort			C		50 Milligram, Qd		Mylan
	Mestinon			C	Oral	60 Milligram, 6xd		Mylan
	Bactrim Ds			C		Unk		Mylan

	Cefepime	C	Unk	Mylan
	Piperacillin Sodium And Tazobactam Sodium	C	Unk	Mylan
	Dafalgan	C	1 Gram, Tid	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16528763	NON-EXPEDITED			US-TEVA-2019-US-1062613			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Gluten Sensitivity	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16532558	DIRECT					30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Contusion; Erythema; Joint Swelling	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16489399	EXPEDITED (15-DAY)		OT	CH-ALKEM LABORATORIES LIMITED-CH-ALKEM-2019-05886		46 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Esomeprazole Magnesium			S	Unknown	40 Milligram, Qd		Alkem
	Escitalopram			S	Unknown	10 Milligram, Bid		Not Reported
	Ritonavir-Boosted Darunavir			S	Unknown	Darunavir 600 Mg/Ritonavir 100 Mg, Bid		Not Reported
	Ritonavir-Boosted Darunavir			S				Not Reported
	Emtricitabine/Tenofovir			C	Unknown	200 Mg/245 Mg, Qd		Not Reported
	Emtricitabine/Tenofovir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16527442	EXPEDITED (15-DAY)		OT	IT-SA-2019SA176219		73 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased	Aprovel			S	Oral	1 Df, Qd		Sanofi
	Coaprovel			S	Oral	1 Df, Qd		Sanofi
	Escitalopram Oxalate			S		1 Df, Qd		Not Reported
	Lorazepam			C				Not Reported
	Debridat [Trimebutine]			C				Not Reported
	Movicol [Macrogol;Potassium Chloride;Sodium Bicarbonate;Sodium Chlorid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16529852	EXPEDITED (15-DAY)		OT	FR-ACCORD-137015		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16530009	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1071938			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Acetaminophen/Codeine Phosphate			S	Oral	6 Dosage Forms Daily;		Actavis
	Clonazepam			S	Unknown	1.5 Milligram Daily;		Teva
	Domperidone			S	Unknown	20 Milligram Daily;		Not Reported
	Gabapentin			S	Oral	300 Milligram Daily;		Actavis
	Gabapentin			S	Oral	1200 Milligram Daily;		Actavis
	Cipralex [Escitalopram]			S	Oral			Not Reported
	Co Temazepam			S	Oral	30 Milligram Daily;		Not Reported

Ferrous Sulfate	S	Unknown	900 Milligram Daily;		Not Reported
Wellbutrin Xl	S	Oral	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16530844	EXPEDITED (15-DAY)		DE, HO, OT	PL-LUPIN PHARMACEUTICALS INC.-2019-03940		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Antibodies; Pulmonary Embolism	Mirtazapine			S	Unknown	30 Milligram, Qd		Not Reported
	Mirtazapine			S	Unknown	45 Milligram, Qd (Another 12 Months To The Second Vte Episode)		Not Reported
	Paroxetine			S	Unknown	20 Milligram, Qd		Lupin
	Sertraline			S	Unknown	100 Milligram, Qd		Lupin
	Venlafaxine			S	Unknown	225 Milligram, Qd		Not Reported
	Quetiapine			S	Unknown	100 Milligram, Qd		Lupin
	Quetiapine			S		300 Milligram, Qd (Another 12 Months To The Second Vte Episode))		Lupin
	Escitalopram			S	Unknown	20 Milligram, Qd		Lupin
	Olanzapine			S	Unknown	5 Milligram, Qd		Not Reported
	Reboxetine			S	Unknown	4 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16531290	EXPEDITED (15-DAY)		OT	KR-ROCHE-2344679		35 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Clonazepam			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported

	Zolpidem	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16532026	EXPEDITED (15-DAY)		HO	SE-ACCORD-136791			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Depressed Level Of Consciousness; Dyskinesia; Intentional Overdose; Intentional Self-Injury; Tachycardia	Escitalopram			S	Oral			Not Reported
	Paracetamol			S	Oral			Accord
	Ibuprofen			S	Oral			Accord
	Lergigan (Promethazine)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	15585112	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1851976US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Muscle Spasms; Thirst; Vomiting	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Sulpiride			S	Oral	Unk		Not Reported
	Desmopressin			C	Nasal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16450184	EXPEDITED (15-DAY)		OT	US-TORRENT-00008900		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Choking; Condition Aggravated; Drug Ineffective; Dysphagia; Extrapyramidal Disorder; Oesophageal Obstruction	Olanzapine			S	Oral	At Bedtime		Unknown
	Escitalopram			S	Oral			Unknown
	Lorazepam			C	Oral			Unknown
	Mirtazapine			S	Oral	At Bedtime		Unknown
	Temazepam			C	Oral	At Bedtime As Needed (Prn)		Unknown

Levothyroxine	C	Oral			Unknown
Metoprolol Tartrate	C	Oral	25 Mg Every 12 Hours		Unknown
Potassium Chloride	C				Unknown
Pantoprazole	C	Oral			Unknown
Losartan	C	Oral			Unknown
Benztropine	C		Unknown		Unknown
Haloperidol	C	Intramuscular	2 To 4 Mg Prn		Unknown
Docusate	C		Unknown		Unknown
Olanzapine	S	Intramuscular	As Needed (Maximum Of 5 Mg Im Per Day)		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16534660	NON-EXPEDITED			US-SUNOVION-2019SUN002768		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Latuda			S	Oral	40 Mg		Sunovion
	Lexapro			S	Unknown	Unk (Decreased)		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16534702	EXPEDITED (15-DAY)		OT	PHHY2019KR152143		35 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Freezing Phenomenon; Gait Disturbance; Movement Disorder; Parkinsonism; Product Use In Unapproved Indication; Reduced Facial Expression; Speech Disorder	Clonazepam			S	Unknown	0.5 Mg, Qd		Not Reported
	Zolpidem			S	Unknown	12.5 Mg, Qd		Novartis
	Escitalopram			S	Unknown	5 Mg, Qd		Not Reported
	Risperidone			S	Unknown	3 Mg, Qd		Not Reported
	Risperidone			S	Unknown	1.5 Mg, Qd		Not Reported
	Lorazepam			S	Unknown	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16535621	NON-EXPEDITED			US-PFIZER INC-2019286122			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Flagyl			S		Unk		Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer
	Amoxicillin			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Nitrofurantoin			S		Unk		Not Reported
	Paroxetine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16535753	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-137117		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram			S	Oral	Morning, Started On 5mg Increasing To 15mg Once A Day In The Morning		Not Reported
	Evorel Conti			C				Not Reported
	Diazepam			C		At Night.		Not Reported
	Ropinirole/Ropinirole Hydrochloride			C				Not Reported
	Fexofenadine/Fexofenadine Hydrochloride			C				Not Reported
	Codeine Phosphate/Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16535831	EXPEDITED (15-DAY)		OT	KR-STRIDES ARCOLAB LIMITED-2019SP005710		35 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Movement Disorder; Parkinsonism; Reduced Facial Expression; Speech Disorder	Zolpidem			S	Unknown	12.5 Mg/Day, Unk		Strides
	Clonazepam			S	Unknown	0.5 Mg/Day, Unk		Not Reported
	Risperidone			S	Unknown	3 Mg/Day, Unk		Not Reported
	Risperidone			S	Unknown	1.5 Mg/Day, Unk,(Dose Decreased)		Not Reported
	Lorazepam			S	Unknown	1 Mg/Day, Unk		Not Reported
	Escitalopram			S	Unknown	5 Mg/Day, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16536095	NON-EXPEDITED			US-PFIZER INC-2019284124		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Confusional State; Cough; Decreased Appetite; Depression; Disturbance In Attention; Dysphonia; Fatigue; Insomnia; Memory Impairment; Muscle Tightness; Musculoskeletal Stiffness; Peripheral Swelling; Speech Disorder; Weight Decreased	Desvenlafaxine Succinate Monohydrate			S	Oral	10 Mg, Daily		Pfizer
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2019	15603666	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1852706US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Pregnancy	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Paroxetin			S	Oral	30 Mg, Qd		Not Reported
	Levetiracetam			S	Oral	1500 Mg, Qd		Not Reported

Nepresol (Dihydralazine Sulfate)	S	Oral	25 Mg, Qd		Not Reported
Candesartan	S	Oral	16 Mg, Qd		Not Reported
L-Thyroxin	C	Oral			Not Reported
Cytotec	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2019	15605519	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-054457			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy; Off Label Use	Levetiracetam			S	Oral	1500 Milligram, Once A Day		Aurobindo
	Paroxetine			S	Oral	30 Milligram, Once A Day Stopped On 03-Nov-2017		Aurobindo
	Candesartan			S	Oral	16 Milligram, Once A Day Stopped On 03-Nov-2017		Not Reported
	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Nepresol (Dihydralazine Sulfate)			S	Oral	25 Milligram, Once A Day		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	L-Thyroxin			C	Oral	Unk		Not Reported
	Cytotec			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2019	16540282	DIRECT		DS			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Manufacturing Materials Issue; Product Quality Issue; Product Substitution Issue; Symptom Recurrence	Escitalopram 20 Mg Tab - Shape Round, Color White, Side 1 P20			S	Oral	Quantity:1 Tablet(S);		Prinston Pharmaceutical

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	15932618	EXPEDITED (15-DAY)		DE, HO, LT	CA-PFIZER INC-2019050581		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved Indication	Ibuprofen			S	Oral	400 Mg, As Needed		Pfizer
	Cipralex [Escitalopram]			S	Oral	10 Mg, 1x/Day		Not Reported
	Diclofenac			S	Oral	50 Mg, 2x/Day		Not Reported
	Diclofenac			S	Oral	2 Df(Dosage Form), 1x/Day		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Eliquis			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16366044	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020591		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Product Substitution Issue; Sleep Disorder	Mirtazapine			S	Oral	30 Mg, Qd		Apotex
	Mirtazapine			S				Apotex
	Cipralex /01588501/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16539264	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP017589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis	Azathioprine			S	Unknown	Unk		Apotex
	Propranolol			S	Oral	40 Mg, Bid		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Marijuana			S	Unknown	Unk, Qd		Not Reported
	Pentasa			S	Unknown	Unk		Not Reported

	Premarin	S	Oral	0.625 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16539562	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1034664			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Drug Abuse; Fall; Malaise; Overdose; Presyncope	Olanzapine			S	Oral	20 Mg, Total		Not Reported
	Olanzapine			S		10 Mg, Qd		Not Reported
	Mirtazapine			S	Oral	60 Mg, Total		Not Reported
	Mirtazapine			S		30 Mg, Qd		Not Reported
	Cipralex /01588502/			S	Oral	2 Df, Total		Mylan
	Cipralex /01588502/			S		20 Mg, Qd		Mylan
	Lyrica			C		Unk		Mylan
	Folina /00024201/			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16539901	NON-EXPEDITED			US-PFIZER INC-2019287635		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Spironolactone			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16540000	EXPEDITED (15-DAY)		DE, HO, OT	CH-NOVOPROD-670240		78 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplasia; Febrile Neutropenia; Oesophageal Candidiasis; Off Label Use; Oral	Levemir			S	Unknown	Unk		Novo Nordisk
	Levemir			S	Unknown	Unk		Novo Nordisk
	Levemir			S	Unknown	100ie/Ml		Novo Nordisk

Candidiasis; Pneumocystis Jirovecii Pneumonia; Pseudomonal Sepsis	Novorapid	S	Unknown	Unk	Novo Nordisk
	Novorapid	S	Unknown	Unk	Novo Nordisk
	Novorapid	S	Unknown	100iu/Ml	Novo Nordisk
	Wellvone	S	Oral	1500 Mg, Qd	Not Reported
	Mabthera	S	Intravenous (not otherwise specified)	1000 Mg, Single	Not Reported
	Diflucan	S	Unknown	400 Mg, Qd	Not Reported
	Benerva	S	Unknown	300 Mg	Not Reported
	Amlodipin Generics	S	Unknown	10 Mg	Not Reported
	Cipralex [Escitalopram Oxalate]	S	Unknown	10 Mg	Not Reported
	Ibuprofen	S	Unknown	400 Mg 2- 3/Per Day	Not Reported
	Loperamide	S	Unknown	2mg 2-3/Per Day	Not Reported
	Dafalgan	C	Unknown	1 G, Tid	Not Reported
	Esomep [Esomeprazole]	C	Unknown	20 Mg, Qd	Not Reported
	Fragmin	C	Unknown	5000 Ui Admission Medication From Rehab	Not Reported
	Aspirin Cardio	C	Unknown	100 Mg, Qd	Not Reported
	Beloc Zok	C	Unknown	25 Mg, Qd	Not Reported
	Beloc Zok	C	Unknown	50 Mg, Qd	Not Reported
	Diovan	C	Unknown	40 Mg, Qd	Not Reported
	Diovan	C	Unknown	160 Mg, Qd	Not Reported
	Atorvastatin Pfizer	C	Unknown	40 Mg, Qd	Not Reported
	Spiricort	C		50 Mg, Qd	Not Reported
	Mestinon	C		60 Mg 6x/Per Day	Not Reported
	Neostigmine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16541333	EXPEDITED (15-DAY)		DE, HO, LT	DE-ASTRAZENECA-2019SE95881		74 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Depressed Mood; Gastrointestinal Haemorrhage; Haematochezia; Hypertension; Hyponatraemia; Product Prescribing Error; Suicidal Ideation	Brilique		S	Oral		Astrazeneca
	Aspirin Protect		S	Oral		Not Reported
	Cipralex		S	Oral	20 Mg, Pause, Drops	Not Reported
	Mirtazapine		C	Oral		Not Reported
	Aprovel		C	Oral		Not Reported
	Beloc-Zok		C	Oral		Not Reported
	Pantoprazol		C	Oral		Not Reported
	Spironolactone		C	Oral	50 Mg, 0.5-0-0-0	Not Reported
	Torasemide		C	Oral		Not Reported
	Sortis		C	Oral		Not Reported
	Zopiclon		C	Oral	7.5 Mg, On Demand	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16541939	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2018M1026098		68 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Food Interaction; Haemodynamic Instability; Haemorrhage	Escitalopram			S	Unknown	Unk		Not Reported
	Emconcor			C	Oral	At Breakfast And Dinner, Every 12 Hours		Mylan
	Simvastatin			C	Oral	At Dinner		Mylan
	Hibor			C	Subcutaneous	3500 Iu Anti-Xa/0.2 Ml Solution For Injection In Pre-Filled Syringe; In The Evening		Mylan
	Cipralex /01588501/			C		At Breakfast, For Several Years		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16739027	DIRECT		HO			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Affect Lability; Anxiety; Depression; Fear; Hyperhidrosis; Palpitations; Panic Attack; Product Substitution Issue; Sleep Disorder; Withdrawal Syndrome	Escitalopram 20 Mg Daily	S	Teva
	Escitalopram 20 Mg Daily	S	Teva
	Nexium	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16460905	EXPEDITED (15-DAY)			FR-ALLERGAN-1925506US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Aripiprazole			S	Unknown	20 Mg, Qd		Not Reported
	Aripiprazole			S	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16542776	EXPEDITED (15-DAY)		HO, OT	GB-CIPLA LTD.-2019GB04929			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram			S	Oral	5 Milligram Increasing To 15mg Once A Day In The Morning		Invagen
	Escitalopram			S	Oral	15 Milligram, Qd (Morning)		Invagen
	Diazepam			C	Unknown	2 Milligram, Qd At Night		Not Reported
	Ropinirole			C	Unknown	0.5 Milligram, Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported
	Co-Codamol			C	Unknown	Unk		Not Reported
	Evorel Conti			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16543445	EXPEDITED (15-DAY)		OT	SE-ACCORD-137661		63 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Discomfort; Drug Interaction; Palpitations; Tremor	Escitalopram			S				Not Reported
	Phenylephrine			S		Strength 2.5% One Drop Per Eye		Not Reported
	Selokenzoc			C				Not Reported
	Trombyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16545328	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1062450		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura; Rash Pruritic	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Alprazolam			S	Oral	0.25 Milligram, Qd		Not Reported
	Xgeva			S	Subcutaneous	120 Milligram, Total		Mylan
	Aromasine			C	Oral	25 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16545728	EXPEDITED (15-DAY)		OT	SE-TEVA-2019-SE-1074200		63 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Discomfort; Drug Interaction; Palpitations; Tremor	Escitalopram			S	Unknown	10mg		Ivax
	Phenylephrine Hydrochloride			S		"2.5% Strength" One Drop Per Eye		Not Reported
	Selokenzoc			C		50mg		Not Reported
	Trombyl			C		75mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16547007	EXPEDITED (15-DAY)		HO	PHHY2019DE155948		70 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Pregabalin			S	Unknown	75 Mg, Unk		Not Reported

	Zolpidem	S	Unknown	10 Mg, Qd (0-0-1-0)	Novartis
	Mirtazapine	S	Unknown	45 Mg, Qd (0-0-1-0)	Not Reported
	Lamotrigine	S	Unknown	50 Mg, Qd (1-0-1-0)	Not Reported
	Cipralex	S	Unknown	10 Mg, Qd (1-0-0-0)	Not Reported
	Elontril	S	Unknown	150 Mg, Qd (1-0-0-0)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16548302	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1923145US			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Overdose; Vertigo	Escitalopram Oxalate - Bp			S	Oral	40 Gtt		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16167699	EXPEDITED (15-DAY)		CA, HO	CA-MALLINCKRODT-T201902873		1 DAY	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Methadose			S	Transplacental	Unk		Mallinckrodt
	Benztropine Mesylate			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported
	Gabapentin			S	Transplacental	Unk		Not Reported
	Nortriptyline			S	Transplacental	Unk		Not Reported
	Quetiapine			S	Transplacental	Unk		Not Reported
	Rabeprazole			S	Transplacental	Unk		Not Reported
	Zopiclone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16245265	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-CA2019GSK069199			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthma; Blood Count Abnormal; Chest Discomfort; Chest X-Ray Abnormal; Condition Aggravated; Cough; Drug Ineffective; Dyspnoea; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Gastrooesophageal Reflux Disease; Lung Disorder; Lung Hyperinflation; Malaise; Nasal Congestion; Obstructive Airways Disorder; Obstructive Airways Disorder; Oropharyngeal Pain; Pain In Extremity; Rhinorrhoea; Sputum Discoloured; Therapeutic Product Effect Incomplete; Total Lung Capacity Abnormal; Weight Increased; Wheezing	Salbutamol Sulphate	S	Unk	Glaxosmithkline
	Breo Ellipta	S	Unk	Glaxosmithkline
	Levothyroxine	S	Unk	Glaxosmithkline
	Theophylline	S	Unk	Glaxosmithkline
	Escitalopram	S	Unk	Glaxosmithkline
	Zantac	S	Unk	Glaxosmithkline
	Singular	S	Unk	Glaxosmithkline
	Solu-Medrol	S	Unk	Not Reported
	Zithromax	S	Unk	Not Reported
	Tazocin	S	Unk	Not Reported
	Cipralex	S	Unk	Not Reported
	Inspiolto	S	Unk	Not Reported
	Atrovent	S	Unk	Not Reported
	Amlodipine	S	Unk	Not Reported
	Uniphyl	S	Unk	Not Reported
	Synthroid	S	Unk	Not Reported
	Spiriva	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16551432	EXPEDITED (15-DAY)		HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2019022017			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram			S	Oral	5 Milligram, Started On 5mg Increasing To 15mg Once A Day In The Morning		Macleods
	Escitalopram			S	Oral	15 Milligram, Qd Morning		Macleods
	Diazepam			C	Unknown	2 Milligram, Qd At Night		Not Reported

Ropinirole	C	Unknown	0.5 Milligram		Not Reported
Fexofenadine	C	Unknown	Unk		Not Reported
Co-Codamol	C	Unknown	Unk		Not Reported
Evorel Conti	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16551464	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1063264		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Food Intolerance; Gastrointestinal Pain; Migraine; Nausea; Nervous System Disorder; Serotonin Syndrome	Escitalopram			S	Oral	Startdosis 5mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16551538	EXPEDITED (15-DAY)			US-ELI_LILLY_AND_COMPANY-US201906009777			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Dyspnoea; Nausea; Oropharyngeal Pain; Pruritus; Psoriasis; Vomiting	Prozac			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Abilify			S	Unknown	Unk, Unknown		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Lithium			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16553002	NON-EXPEDITED			US-TEVA-2019-US-1073310			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	13047349	EXPEDITED (15-DAY)		OT	DE-GILEAD-2016-0249810		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pancreatitis; Skin Ulcer; Skin Ulcer	Ledipasvir/Sofosbuvir			S	Oral	90 Mg, Qd		Gilead
	Ribavirin			S	Oral	600 Mg, Bid		Not Reported
	Ribavirin			S	Oral	400 Mg, Bid		Not Reported
	Ribavirin			S	Oral	400mg-0-200mg		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Braunovidon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	14319717	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2017539420		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Loratadine			S	Oral	Unk		Pfizer
	Levothyroxine Sodium			S	Oral	Unk		Pfizer
	Folic Acid			S	Oral	Unk		Pfizer
	Furosemide			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ethylene Glycol			S	Oral	Unk		Not Reported
	Vitamin B-1			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16372916	EXPEDITED (15-DAY)		HO	ES-ALLERGAN-1922523US			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Extrasystoles; Hypomagnesaemia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Trazodone			S	Unknown	Unk		Not Reported

Enalapril, Hydrochlorothiazida Aristo	S	Unknown	Unk		Not Reported
Omeprazole	S	Unknown	Unk		Not Reported
Metformin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16557136	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-038411			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Prescribed Overdose; Rash; Vasculitis	Terbinafine			S	Oral	250 Milligram, Once A Day		Aurobindo
	Cipralex			S	Oral	30 Milligram, Once A Day		Not Reported
	Cipralex			S				Not Reported
	Trintellix			S	Oral	10 Milligram, Once A Day		Not Reported
	Trintellix			S				Not Reported
	Amitriptyline			C	Oral	100 Milligram, Once A Day		Not Reported
	Clonazepam			C	Oral	1 Milligram, 3 Times A Day		Not Reported
	Clonazepam			C				Not Reported
	Isophane Insulin			C	Subcutaneous	Unk		Not Reported
	Nozinan			C	Oral	37.5 Milligram, Once A Day		Not Reported
	Rosuvastatin Calcium			C	Oral	5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16557650	EXPEDITED (15-DAY)		LT	PHHY2019FR158972		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Mirtazapine			S	Oral	30 Mg, Unk		Not Reported
	Alprazolam			S	Oral	20 Mg, Unk		Novartis
	Escitalopram			S	Oral	60 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16557660	EXPEDITED (15-DAY)		HO	PHHY2019FR158989		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage	Pantoprazole			S	Oral	10 Mg, Qd		Novartis
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Coumadine			S	Oral	6 Mg, Qd		Not Reported
	Coumadine			S	Oral	6 Mg, Qd		Not Reported
	Doliprane			S	Oral	3 G, Qd		Not Reported
	Lasilix			C	Oral	60 Mg, Qd		Not Reported
	Diffu K			C	Oral	600 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16557692	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019295009		92 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Interstitial Lung Disease	Venlafaxine Hcl			S		37.5 Mg, 1x/Day		Pfizer
	Escitalopram			S		Unk		Not Reported
	Duloxetine Dr			S		15 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16557971	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-213363		35 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Risperidone			S	Unknown	3 Milligram, Daily		Ranbaxy
	Risperidone			S	Unknown	Tappered Off Gradually Over 4 Weeks		Ranbaxy
	Risperidone			S	Unknown	1.5 Milligram, Daily		Not Reported
	Lorazepam			S	Unknown	1 Milligram, Daily		Sun
	Lorazepam			S	Unknown	Tappered Off Gradually Over 4 Weeks		Sun
	Zolpidem			S	Unknown	12.5 Milligram, Daily		Sun

Zolpidem	S	Unknown	Tappered Off Gradually Over 4 Weeks		Sun
Escitalopram	S	Unknown	5 Milligram, Daily		Not Reported
Escitalopram	S	Unknown	Tappered Off Gradually Over 4 Week		Not Reported
Clonazepam	S	Unknown	0.5 Milligram, Daily		Sun
Clonazepam	S	Unknown	Tappered Off Gradually Over 4 Weeks		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16558187	EXPEDITED (15-DAY)		HO, OT	GB-TORRENT-00021359		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram			S	Oral	Morning		Unknown
	Diazepam			C		At Night		Unknown
	Ropinirole			C		Unknown		Unknown
	Fexofenadine			C		Unknown		Unknown
	Co-Codamol			C		Unknown		Unknown
	Evorel Conti			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16558365	EXPEDITED (15-DAY)		DE, HO	FR-MYLANLABS-2019M1063208		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Ciprofloxacin			S	Oral	500 Milligram, Qd,1000 Milligram		Not Reported
	Pamidronate			S	Intravenous drip	30 Milligram, Qd		Not Reported
	Seroplex			S	Oral	1 Dosage Form, Qd		Mylan
	Seroplex			S	Oral	1 Dosage Form, Qd		Mylan
	Augmentin /00756801/			S	Oral	1 Gram, Qd,3 Gram		Mylan
	Dexamethasone			S	Oral	40 Milligram, Qw,5.7143		Mylan

			Milligram	
Zyloric	S	Oral	300 Milligram, Qd	Mylan
Revlimid	S	Oral	25 Milligram, Q28d,25 Milligram	Mylan
Paracetamol	C	Unknown	Unk	Mylan
Zelitrex	C	Oral	Unk	Mylan
Zelitrex	C	Oral	1 Dosage Form, Qd	Mylan
Zelitrex	C	Oral	500 Milligram, Qd,1000 Milligram	Mylan
Lyrica	C	Oral	Unk	Mylan
Lyrica	C	Oral	25 Milligram, Qd,50 Milligram	Mylan
Durogesic	C	Unknown	Unk	Mylan
Gaviscon /01405501/	C	Unknown	Unk	Mylan
Movicol /01749801/	C	Unknown	Unk	Mylan
Lovenox	C	Subcutaneous	Unk	Mylan
Lovenox	C	Subcutaneous	7000 International Unit, Qd,14000 Iu (International Unit)	Mylan
Bactrim	C	Oral	400 Milligram, Qw,400 Milligram	Mylan
Bactrim	C	Oral	Unk	Mylan
Seresta	C	Oral	Unk	Mylan
Seresta	C	Oral	10 Milligram, Qd	Mylan
Mianserine /00390602/	C	Oral	30 Milligram, Qd,30 Milligram	Mylan
Mianserine /00390602/	C	Oral	Unk	Mylan
Tamiflu	C	Unknown	Unk	Mylan
Furosemide	C	Unknown	20 Milligram	Mylan
Previscan /00261401/	C	Unknown	15 Milligram, Qd,15 Milligram	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16558713	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2019M1063232			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Transposition Of The Great Vessels	Escitalopram			S	Transplacental	10 [Mg/D (5)]		Not Reported
	Skinoren			C	Transplacental	Unk		Mylan
	Folic Acid			C	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16561413	NON-EXPEDITED			US-TEVA-2019-US-1073765			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity; Rash Macular; Reaction To Excipient; Urticaria	Hydralazine			S	Unknown			Actavis
	Benazepril Hydrochloride Tablet 20 Mg			S	Oral	20 Milligram Daily;		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Metoprolol Succinate Er			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16561955	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-2019-GB-1074942		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram			S	Oral	Morning, 15mg		Ivax
	Escitalopram			S	Oral	Started On 5mg Increasing To 15mg Once A Day In The Morning		Ivax
	Diazepam			C		At Night.		Not Reported
	Ropinirole			C				Not Reported

	Fexofenadine	C	Not Reported
	Co-Codamol	C	Not Reported
	Evorel Conti	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16562012	NON-EXPEDITED			US-PFIZER INC-2019292527		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Crying; Drug Ineffective; Feeling Abnormal; Heart Rate Increased; Hyperhidrosis; Impaired Work Ability; Memory Impairment; Panic Attack; Tremor	Gabapentin			S		Unk		Pfizer
	Abilify			S		Unk		Not Reported
	Abilify			S		2 Mg, Unk		Not Reported
	Aripiprazole			S		5 Mg, Unk		Not Reported
	Rexulti			S		Unk		Not Reported
	Rexulti			S				Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil [Piroxicam]			C		Unk		Not Reported
	Lithium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16562462	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1064151			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram			S		5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16562494	EXPEDITED (15-DAY)		HO, LT	DE-ALLERGAN-1928164US		74 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Gastrointestinal Haemorrhage;	Escitalopram Oxalate - Bp			S	Oral	Actual: 20 Mg, Pause, Tropfen20mg/Ml		Allergan

Haematochezia; Hypertension; Hyponatraemia; Product Prescribing Error; Suicidal Ideation	Brilique	S	Oral	Actual: 90 Mg, 1-0-1-0, Tabletten	Not Reported
	Aspirin Protect	S	Oral	Actual: 100 Mg, 1-0-0-0, Tabletten	Not Reported
	Mirtazapin Hexal	C	Oral	7.5 Mg, 1-0-0-0, Tabletten	Not Reported
	Aprovel	C	Oral	75 Mg, 1-0-0-0, Tabletten	Not Reported
	Beloc-Zok	C	Oral	47.5 Mg, 1-0-0-0, Retard-Tabletten	Not Reported
	Pantoprazol	C	Oral	40 Mg, 1-0-0-0, Tabletten	Not Reported
	Spironolacton	C	Oral	50 Mg, 0.5-0-0-0, Tabletten	Not Reported
	Torasemid	C	Oral	5 Mg, 1-0-0-0, Tabletten	Not Reported
	Sortis	C	Oral	20 Mg, 0-0-1-0, Tabletten	Not Reported
	Zopiclon	C	Oral	7.5 Mg, Bedarf, Tabletten	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16008673	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1906192US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Breast Cancer Recurrent; Depression; Disturbance In Attention; Fatigue; Feeling Abnormal; Panic Attack; Therapy Cessation	Escitalopram Oxalate 10mg Tab (Tbd)			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate 10mg Tab (Tbd)			S				Allergan
	Clonopine			C				Not Reported
	Clonopine			C				Not Reported
	Atenolol			C	Oral	50 Mg Qam, 25 Mg Qhs		Not Reported
	Hctz			C	Oral	12.5 Mg, Unk		Not Reported
	Hydroxyzine			C		5 Mg, Unk		Not Reported
	Hydroxyzine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16564382	EXPEDITED (15-DAY)		HO, LT, OT	PT-ACCORD-137985		67 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ischaemic Stroke	Escitalopram			S	Oral	10 Mg / Day		Not Reported
	Warfarin			S				Not Reported
	Perindopril			C				Not Reported
	Metformin			C				Not Reported
	Isosorbide			C				Not Reported
	Atorvastatin/Ezetimibe			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16564464	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2019-040005			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram			S	Oral	Started On 5mg Increasing To 15mg Once A Day In The Morning		Aurobindo
	Escitalopram			S	Oral	Morning		Aurobindo
	Diazepam			C	Unknown	At Night.		Not Reported
	Ropinirole			C	Unknown	0.5 Milligram		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported
	Co-Codamol			C	Unknown	Unk		Not Reported
	Evorel Conti			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16564674	EXPEDITED (15-DAY)		HO	DE-ACCORD-138161		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram			S		20 Mg, 1-0-0-0		Not Reported
	Loratadine			S		10 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16566596	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019293275		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Heart Rate Increased; Hepatic Enzyme Increased; Hypertension; Hypotension; Infusion Related Reaction; Rheumatoid Arthritis; Somnolence; Vein Collapse; Weight Increased	Methotrexate Sodium			S		14 Mg, Weekly		Pfizer
	Mirtazapine			S		Unk		Not Reported
	Venlafaxine Hcl			S	Unknown	Unk		Pfizer
	Cipralex [Escitalopram]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Abilify			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			C	Oral	50 Mg, Unk		Not Reported
	Fluoxetine			C	Unknown	Unk		Not Reported
	Lisinopril			C		Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Oxycontin			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Sertraline Hydrochloride			C		Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16567136	EXPEDITED (15-DAY)		HO, OT	GB-ALLERGAN-1928503US			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qam		Allergan
	Diazepam			C	Unknown	2 Mg, Qpm		Not Reported
	Ropinirole			C	Unknown	0.5 Mg, Unknown		Not Reported

	Fexofenadine	C	Unknown	Unk, Unknown	Not Reported
	Co-Codamol	C	Unknown	Unk, Unknown	Not Reported
	Evorel Conti	C	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16567185	NON-EXPEDITED			US-TEVA-2019-US-1073307			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Teva Escitalopram			S		10 Milligram Daily;		Ivax
	Amiodarone Zydus			S		400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16567320	NON-EXPEDITED			US-TEVA-2019-US-1073411			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram Oxalate			S	Oral	10 Milligram Daily; Daily By Mouth		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16567343	EXPEDITED (15-DAY)		OT	KR-BAUSCH-BL-2019-019339		35 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Lorazepam			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Zolpidem			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16568275	EXPEDITED (15-DAY)		DS	FR-MYLANLABS-2019M1064167		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported
	Eliquis			S	Oral	2 Dosage Form, Qd		Mylan
	Digoxine			C		Unk		Mylan
	Loxen L P			C		Unk		Mylan
	Lopressor			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2019	16568864	EXPEDITED (15-DAY)		DS	GB-TEVA-2019-GB-1076110		55 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bladder Disorder; Bowel Movement Irregularity; Burning Sensation; Decreased Appetite; Extrasystoles; Eye Irritation; Fear; Feeling Cold; Headache; Hyperhidrosis; Hypersensitivity; Insomnia; Intracranial Mass; Irritability; Memory Impairment; Muscle Spasms; Musculoskeletal Stiffness; Myalgia; Nail Disorder; Nervousness; Panic Reaction; Paraesthesia; Paraesthesia; Presyncope; Sneezing; Social Anxiety Disorder; Tinnitus	Escitalopram Oxalate			S	Oral			Ivax
	Nelson Bach Rescue Remedy			C				Not Reported
	Paracetamol			C				Not Reported
	Aconite			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	9321374	EXPEDITED (15-DAY)		HO, LT	JP-FRI-1000045519			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rhabdomyolysis; Serotonin Syndrome; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Anafranil			S	Oral	25 Mg, Q12h		Not Reported
	Anafranil			S	Oral	Unk		Not Reported
	Rohypnol			S	Oral	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16569610	EXPEDITED (15-DAY)		HO, OT	DE-LUPIN PHARMACEUTICALS INC.-2019-04375		70 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lamotrigine			S	Unknown	50 Milligram, Bid (1-0-1-0)		Lupin
	Zolpidem			S	Unknown	10 Milligram, Qd (0-0-1-0)		Lupin
	Mirtazapine			S	Unknown	45 Milligram, Qd (0-0-1-0)		Not Reported
	Pregabalin			S	Unknown	75 Milligram, Unk		Not Reported
	Elontril			S	Unknown	150 Milligram, Qd (1-0-0-0)		Not Reported
	Cipralex [Escitalopram]			S	Unknown	10 Milligram, Qd (1-0-0-0)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16569669	EXPEDITED (15-DAY)		HO, OT	PL-AUROBINDO-AUR-APL-2019-036079			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epilepsy; Galactorrhoea; Parkinsonism; Product Use In Unapproved	Escitalopram			S	Unknown	10 Milligram		Aurobindo
	Lamotrigine			S	Unknown	200 Milligram		Aurobindo
	Quetiapine Film Coated Tablets			S	Unknown	800 Milligram, Once A Day		Aurobindo

Indication; Somnolence	Clozapine		S	Unknown	500 Milligram	Not Reported
	Clozapine		S	Unknown	Unk	Not Reported
	Clozapine		S	Unknown	900 Milligram, Once A Day	Not Reported
	Clozapine		S	Unknown	300 Milligram, Once A Day	Not Reported
	Clozapine		S	Unknown	400 Milligram, Once A Day	Not Reported
	Clozapine		S	Unknown	400 Milligram, Once A Day	Not Reported
	Clozapine		S	Unknown	600 Milligram, Once A Day	Not Reported
	Clozapine		S	Unknown	200 Milligram, Once A Day	Not Reported
	Clozapine		S	Unknown	200 Milligram, Once A Day	Not Reported
	Citalopram		S	Unknown	20 Milligram, Once A Day	Not Reported
	Haloperidol		S	Unknown	13 Milligram	Not Reported
	Ziprasidone Hydrochloride		S	Unknown	160 Milligram, Once A Day	Not Reported
	Chlorpromazine		S	Unknown	300 Milligram, Once A Day	Not Reported
	Perphenazine		S	Unknown	100 Milligram, Every 2 Weeks	Not Reported
	Risperidone		S	Unknown	50 Milligram (Every 2 Weeks)	Not Reported
	Sertindole		S	Unknown	12 Milligram, Once A Day	Not Reported
	Valproic Acid		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16569870	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1076454		70 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Pregabalin			S	Unknown	75 Mg, Discontinued		Not Reported
	Zolpidem			S	Unknown	10 Mg, 0-0-1-0		Teva
	Lamotrigin			S	Unknown	50 Mg, 1-0-1-0		Teva
	Mirtazapin			S	Unknown	45 Mg, 0-0-1-0		Teva
	Cipralex			S	Unknown	10 Mg, 1-0-0-0		Not Reported
	Elontril			S	Unknown	150 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16570641	EXPEDITED (15-DAY)		OT	IT-ACCORD-138436		54 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported
	Depakin Chrono			C		Strength: 300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16570686	EXPEDITED (15-DAY)		DE, HO, LT	CA-TEVA-2019-CA-1075160		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved Indication	Diclofenac			S	Oral			Actavis
	Ibuprofen			S	Oral			Actavis
	Cipralex			S	Oral	10 Milligram Daily;		Not Reported
	Eliquis Film Coated			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16570781	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2019126413		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Rhabdomyolysis	Seroplex			S	Oral	10 Mg, Qd		Glaxosmithkline
	Lamictal			S	Oral	100 Mg, Qd		Glaxosmithkline
	Vitamin B12			C	Oral	250 ?G, Qd		Glaxosmithkline
	Speciafoldine			C	Oral	5 Mg, Qd		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16571653	EXPEDITED (15-DAY)		HO	DE-BAYER-2019-130565		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Loratadine			S		10 Mg, Qd		Bayer
	Escitalopram			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16572814	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1076698		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram			S	Unknown	20 Mg, 1-0-0-0		Ivax
	Loratadine			S	Unknown	10 Mg, 1-0-0-0		Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16573034	EXPEDITED (15-DAY)		LT	FR-009507513-1907FRA005031		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Mirtazapine			S	Oral	30 Milligram		Merck
	Alprazolam			S	Oral	20 Milligram		Not Reported
	Escitalopram			S	Oral	60 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16573047	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1063563		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Nuchal Rigidity; Suicide Attempt	Escitalopram			S	Oral	3920 Milligram, Total		Not Reported
	Felison			S	Oral	900 Milligram, Total		Mylan
	Seroquel			S	Oral	6 Gram, Total		Mylan
	Tavor /00273201/			S	Oral	50 Milligram, Total		Mylan
	Zoloft			S	Oral	6 Gram, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16573067	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1075123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; No Adverse Event; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Diclofenac Diethylamine			S	Unknown			Actavis
	Escitalopram Oxalate			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Vitamin D3			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16574742	EXPEDITED (15-DAY)		DS	GB-ALLERGAN-1928505US			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bladder Disorder; Bowel Movement Irregularity; Burning Sensation; Decreased Appetite; Extrasystoles; Eye Irritation; Fear; Feeling Cold; Headache; Hyperhidrosis; Hypersensitivity; Insomnia; Intracranial Mass; Irritability; Memory Impairment; Muscle	Escitalopram Oxalate - Bp			S	Oral	5 Mg		Allergan
	Paracetamol			C	Unknown			Not Reported
	Aconite			C	Unknown			Not Reported

Spasms; Musculoskeletal Stiffness; Myalgia; Nail Disorder; Nervousness; Panic Reaction; Paraesthesia; Paraesthesia; Presyncope; Sneezing; Social Anxiety Disorder; Tinnitus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16575138	EXPEDITED (15-DAY)		HO	PHHY2019FR159171		95 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Esidrex			S	Oral	0.5 Df, Unk		Novartis
	Escitalopram			S	Oral	0.5 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	9285538	NON-EXPEDITED			US-PFIZER INC-2013145521		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Talwin			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Deconamine			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Provigil			S		Unk		Not Reported
	Opana			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16569351	EXPEDITED (15-DAY)		LT	FR-ASTRAZENECA-2019SE99251		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Electrocardiogram Qt Prolonged; Miosis; Toxicity To Various Agents	Xeroquel			S	Oral	1.8g Unknown		Zeneca
	Depakote			S	Oral	1.5g Unknown		Not Reported
	Depakote			S	Oral	3.0g Unknown		Not Reported
	Seroplex			S	Oral	30.0mg Unknown		Not Reported
	Seresta			S	Oral	100.0mg Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16575394	EXPEDITED (15-DAY)		HO, OT	DE-HETERO-HET2019DE00938		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram			S	Unknown	20 Mg, Q.D.(1-0-0-0)		Hetero
	Loratadin			S	Unknown	10 Mg, Q.D.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16575685	EXPEDITED (15-DAY)		OT	JP-SA-2019SA190909		81 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Harnal			S	Oral	Unk		Sanofi
	Aripiprazole			S	Oral	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16576876	NON-EXPEDITED		OT	US-APOTEX-2019AP018249		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Seizure; Sleep Paralysis; Therapeutic Product Effect Incomplete; Weight Increased; Withdrawal Syndrome	Bupropion	S	Unknown	Unk	Apotex
	Bupropion	S	Unknown	300 Mg, Unk	Apotex
	Fluoxetine	S	Unknown	Unk	Apotex
	Escitalopram	S	Unknown	Unk	Apotex
	Mirtazapine	S	Unknown	15 Mg, Unk	Apotex
	Venlafaxine Xr	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16577204	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2019-025994			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Hypersomnia	Prednisone Tablet 10 Mg			S	Oral	1 Tablet Every Other Day		Aurobindo
	Valacyclovir Hydrochloride Tablets 1g			S	Oral	1/2 Tablet Every 12 Hrs		Aurobindo
	Sulfamethoxazole And Trimethoprim Tablets Usp 800/160 Mg			S	Oral	1 Tablet Twice A Day On Saturday And Sunday		Aurobindo
	Premarin			S	Oral	1.25 Milligram, Once A Day For 28 Days Out Of The Month		Not Reported
	Provera			S	Oral	1 Tablet , Once A Day, 10 Days Out Of Each Month		Not Reported
	Tacrolimus			S	Oral	2.5 Milligram, Two Times A Day		Not Reported
	Genotropin			S	Subcutaneous	2.6 Milligram Three Times A Week		Not Reported
	Mg-Plus-Protein [Dietary Supplement]			S	Oral	1 Tablet Twice A Day		Not Reported
	Jakafi			S	Oral	1 Tablet Twice A Day		Not Reported
	Lexapro			S	Oral	1 Tablet Once A Day		Not Reported
	Cyproheptadine Hcl			S	Oral	1 Tablet Twice A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16577757	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2019M1065754			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection; Malaise; Nasopharyngitis	Asmol (Salbutamol)			S		Up To 12 Puffs Per Day As Necessary		Mylan
	Nucala			S	Subcutaneous	100 Milligram		Mylan
	Spiriva			S		2 Puffs Each Night		Mylan
	Seretide			S		250/25mg/2 Puffs Twice A Day		Mylan
	Prednisone			S		10 Milligram, Qd		Mylan
	Ondansetron			S		10 Milligram When Required,		Mylan
	Omeprazole			S		20 Milligram, Qd		Mylan
	Lexamil			S		10 Milligram, Qd		Mylan
	Hypertonic Saline Solution			S		Via Nebuliser Qd		Mylan
	Colistimethate Sodium			S		Unk Via Nebuliser		Mylan
	Azithromycin			S		500 Milligram, Mon/Wed/Fri		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16578273	EXPEDITED (15-DAY)		HO	FR-009507513-1907FRA004833		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Poisoning Deliberate	Aerius (Desloratadine)			S	Oral	35 Milligram		Merck
	Escitalopram			S	Oral			Not Reported
	Lexomil			S	Oral			Not Reported
	Doliprane			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16580854	NON-EXPEDITED			US-TEVA-2019-US-1077840		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Intolerance; Restlessness	Escitalopram			S	Unknown			Ivax
	Escitalopram			S				Ivax
	Fluoxetine			S	Unknown			Barr
	Fluoxetine			S				Barr
	Sertraline			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Methylphenidate			S	Unknown			Not Reported
	Methylphenidate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16580951	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR122610		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Exposure During Pregnancy; Lung Infection; Melanocytic Naevus; Rheumatoid Arthritis; Rheumatoid Factor Increased	Salbutamol			S		Unk		Glaxosmithkline
	Escitalopram Oxalate			S		10 Mg, Unk		Glaxosmithkline
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Every 8 Weeks		Not Reported
	Acetaminophen + Codeine Phosphate			S		Unk		Not Reported
	Imodium			S		Unk		Not Reported
	Pantoprazole Magnesium			S		30 Mg, Qd		Not Reported
	Loperamide Hydrochloride			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16581455	EXPEDITED (15-DAY)		HO, LT, OT	PT-ALLERGAN-1928854US			Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Ischaemic Stroke	Escitalopram Oxalate - Bp	S	Oral	10 Mg/Dia	Allergan
	Warfarin	S	Unknown		Not Reported
	Perindopril	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Isosorbide Mononitrate	C	Unknown		Not Reported
	Atorvastatina + Ezetimiba	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16581460	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1928853US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram Oxalate - Bp			S		20 Mg, 1-0-0-0		Allergan
	Loratadin			S		10 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16581596	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1928833US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Overdose; Poisoning Deliberate	Escitalopram Oxalate - Bp			S	Oral	Overdose: 140mg		Allergan
	Doliprane			S	Oral			Not Reported
	Aerius (Desloratadine)			S	Oral			Not Reported
	Lexomil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16581643	NON-EXPEDITED			US-US WORLDMEDS, LLC-USW201904-000820		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Drug Interaction; Dyskinesia; Flushing; Mania	Xadago			S				Us Worldmeds
	Lexapro			S				Not Reported
	Simvastatin			C				Not Reported
	Botox			C				Not Reported

	Xanax	C	Not Reported
	Diclofenac	C	Not Reported
	Omeprazole	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	10013343	NON-EXPEDITED			US-PFIZER INC-2014073917		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Methocarbamol			S		Unk		Pfizer
	Amrix			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16567148	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1074914			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Diclofenac Potassium			S	Unknown			Actavis
	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Naproxen			S	Unknown			Teva
	Naproxen Sodium			S	Unknown	1000 Milligram Daily;		Teva
	Nortriptyline			S	Oral	25 Milligram Daily;		Teva
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Tylenol			S	Topical			Not Reported
	Voltaren			S	Topical			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported

	Infliximab	C	Intravenous (not otherwise specified)	Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16582124	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-040714			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State	Alprazolam			S	Oral	0.5 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Esomeprazole			S	Oral	40 Milligram, Once A Day		Aurobindo
	Gabapentin			S	Oral	1200 Milligram, Once A Day		Aurobindo
	Lamotrigine			S	Oral	200 Milligram, Once A Day		Aurobindo
	Oxynormoro			S	Oral	Unk		Not Reported
	Nefopam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16582801	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-132892		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Cipro 1000 Mg			S	Oral	1000 Mg		Bayer
	Cipro			S	Intravenous (not otherwise specified)	Unk		Bayer
	Avastin [Simvastatin]			S	Intravenous (not otherwise specified)	15 Mg		Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cipralex [Escitalopram]			S	Unknown	10 Mg, Qd		Not Reported
	Codeine			C	Unknown	Unk		Not Reported

Docetaxel	S	Intravenous (not otherwise specified)	75.0 Mg/M2		Not Reported
Docetaxel	S		75.0 Mg/M2		Not Reported
Gravol	C	Unknown	Unk		Not Reported
Docusate	C		Unk		Not Reported
Lactulose	C	Unknown	Unk		Not Reported
Laxasene	C	Unknown	Unk		Not Reported
Morphine	S	Unknown	2.5 Mg, Q4hr		Not Reported
Piperacillin Sodium;Tazobactam Sodium	S	Unknown	Unk		Not Reported
Trastuzumab	S	Intravenous (not otherwise specified)	8 Mg		Not Reported
Trazodone	C		Unk		Not Reported
Tylenol [Paracetamol]	S	Unknown	Unk		Not Reported
Tylenol No.1 Forte	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16583260	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019022095			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram Oxalate			S	Unknown	20 Milligram, Qd		Macleods
	Loratadin			S	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16583819	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1078074		75 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dizziness; Hypertension	Diazepam-Ratiopharm 10mg/Ml			S	Oral	5 Gtt, Need, Drops		Barr
	Trimipramin			S	Oral	25 Mg, Pause, Solution		Not Reported
	Concor 2,5 Mg			S	Oral	2.5 Mg, 1-0-0-0, Tablets		Not Reported

	Cipralex	S	Oral	10 Mg, 1-0-0-0, Tabletten	Not Reported
	Ximovan	C	Oral	0.5-1-0-0, Tablets	Not Reported
	Ass 100	C	Oral	100 Mg, 1-0-0-0, Tablets	Not Reported
	L-Thyroxin 125µg	C	Oral	125 Mg, 1-0-0-0, Tablets	Not Reported
	Magnesium Verla	C	Oral	0-0-1-0	Not Reported
	Lexotanil 6mg	C	Oral	6 Mg, 0.25-0-0.25-0, Tablets	Not Reported
	Tromcardin Complex	C	Oral	1-1-0-0, Tablets	Not Reported
	Diovan 80	C			Not Reported
	Nitrolingual	C	Respiratory (inhalation)	Need, Spray	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16586416	EXPEDITED (15-DAY)		HO, LT, OT	PT-TEVA-2019-PT-1077464		67 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ischaemic Stroke	Escitalopram			S	Oral	10 Mg/Dia		Ivax
	Warfarin			S	Unknown			Not Reported
	Perindopril			C				Not Reported
	Metformin			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Atorvastatina + Ezetimiba			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16586502	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1078027		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive; Electrocardiogram Qt Prolonged; Hyperkalaemia; Loss Of Consciousness; Overdose; Sinus Tachycardia	Escitalopram Oxalate			S	Unknown			Ivax
	Escitalopram Oxalate			S	Unknown			Ivax
	Citalopram Hydrobromide			S	Unknown			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			S	Unknown			Actavis

	Lorazepam	S	Unknown	Actavis
	Morphine	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Actavis
	Oxycodone	S	Unknown	Actavis
	Zopiclone	S	Oral	Not Reported
	Diazepam	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16586791	NON-EXPEDITED			US-TEVA-2019-US-1079107			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Flushing	Escitalopram			S	Unknown			Ivax
	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16586815	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1078145		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral	10mg Per Day		Ivax
	Lamotrigine			S	Oral	Unknown		Teva
	Alprazolam			C				Not Reported
	Verapamil (Chlorhydrate De)			C				Not Reported
	Trandolapril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16587676	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2019126580		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall	Escitalopram	S	Oral	10 Mg, Qd	Glaxosmithkline
	Lamotrigine	S	Oral	200 Mg, Qd	Glaxosmithkline
	Clopidogrel	S	Oral	75 Mg, Qd	Glaxosmithkline
	Ramipril	S	Oral	5 Mg, Qd	Glaxosmithkline
	Furosemide	S	Oral	40 Mg, Qd	Glaxosmithkline
	Bisoprolol Fumarate	S	Oral	10 Mg, Qd	Not Reported
	Amlodipine	S	Oral	5 Mg, Qd	Not Reported
	Gabapentine	S	Oral	1200 Mg, Qd	Not Reported
	Alprazolam	S	Oral	0.5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	8432641	NON-EXPEDITED			US-PFIZER INC-2012051184		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Interaction	Norvasc			S	Oral	Unk		Pfizer
	Amlodipine Besilate			S		Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Cardura			S	Oral	Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Zoloft			S	Oral	Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Lotensin			S		Unk		Not Reported
	Lotensin Hct			S		Unk		Not Reported
	Benazepril And Hydrochlorothiazide			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Symbyax			S		Unk		Not Reported
	Naprosyn			S		Unk		Not Reported
	Percocet			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16209808	EXPEDITED (15-DAY)		CA	FR-ALLERGAN-1916581US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16388241	EXPEDITED (15-DAY)		HO, OT	PHHY2019ES122146		61 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Extrasystoles; Hypocalcaemia; Hypomagnesaemia; Ventricular Extrasystoles	Escitalopram			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown			Not Reported
	Omeprazole			S	Unknown			Novartis
	Enalapril, Hydrochlorothiazide			S	Unknown			Not Reported
	Metformin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16535430	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1071927		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Clonazepam			S	Oral	1.5 Milligram Daily;		Teva
	Domperidone			S	Oral	20 Milligram Daily;		Not Reported
	Escitalopram			S	Oral	20 Milligram		Ivax
	Gabapentin			S	Oral	1200 Milligram Daily;		Actavis
	Temazepam			S	Oral	30 Milligram Daily;		Actavis
	Ferrous Sulfate			S	Oral	900 Milligram Daily;		Not Reported
	Tylenol With Codeine			S	Oral	6 Dosage Forms Daily;		Not Reported
	Vitalux [Ascorbic Acid;Betacarotene;Coum;Tocofe			S	Oral			Not Reported

	r Wellbutrin Xl	S	Oral	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16588621	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2019-040411			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Pregabalin			S	Unknown	75 Mg, Abgesetzt		Not Reported
	Zolpidem			S	Unknown	10 Mg, 0-0-1-0		Aurobindo
	Cipralex			S	Unknown	10 Mg, 1-0-0-0		Not Reported
	Elontril			S	Unknown	150 Mg, 1-0-0-0		Not Reported
	Lamotrigin			S	Unknown	50 Mg, 1-0-1-0		Not Reported
	Mirtazapin			S	Unknown	45 Mg, 0-0-1-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16589188	EXPEDITED (15-DAY)		HO	FR-ACCORD-138603		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Alprazolam			C				Not Reported
	Verapamil			C				Not Reported
	Trandolapril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16589873	EXPEDITED (15-DAY)		HO, LT, OT	PT-MACLEODS PHARMACEUTICALS US LTD-MAC2019022117			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ischaemic Stroke	Escitalopram			S	Oral	10 Milligram, Qd, 10 Mg/Daily		Macleods

	Warfarin	S	Unknown	Not Reported
	Perindopril	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Isosorbide Mononitrate	C	Unknown	Not Reported
	Atorvastatina/Ezetimiba	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16590757	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2019-040695			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram			S	Unknown	20 Milligram, Once A Day,20 Mg, 1-0-0-0		Aurobindo
	Loratadine			S	Unknown	10 Milligram, Once A Day,10 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16590955	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2019300028		70 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Pregabalin			S		75 Mg, Unk		Pfizer
	Zolpidem			S		10 Mg, 1x/Day		Not Reported
	Cipralex Meltz [Escitalopram]			S		10 Mg, 1x/Day		Not Reported
	Elontril			S		150 Mg, 1x/Day		Not Reported
	Lamotrigin			S		50 Mg, 1x/Day		Not Reported
	Mirtazapin			S		45 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16592964	EXPEDITED (15-DAY)		HO	JP-ELI_LILLY_AND_COMPANY-JP201907006822		59 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Locked-In Syndrome; Withdrawal Syndrome	Duloxetine Hydrochloride	S	Oral	20 Mg, Daily	Eli Lilly And Co
	Adco Mirteron	S	Oral	45 Mg, Daily	Not Reported
	Lexapro	S	Oral	5 Mg, Daily	Not Reported
	Myslee	C	Oral	32 International Unit	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16593087	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1077324		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Poisoning Deliberate	Escitalopram			S	Oral	140 Milligram		Ivax
	Doliprane			S	Oral	4 Gram		Not Reported
	Aerius (Desloratadine)			S	Oral	35 Milligram		Not Reported
	Lexomil Roche			S	Oral	30 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16594176	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-2019M1066848		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyarrhythmia; Circulatory Collapse	Escitalopram			S	Oral	10 Milligram		Not Reported
	Elleste-Solo			C	Transdermal	80 Microgram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16594746	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1929126US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16594778	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1929281US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haemorrhagic Stroke	Escitalopram Oxalate - Bp	S	Oral	5 Mg		Allergan
	Kardegic	S	Oral			Not Reported
	Dacryoserum	C	Unknown	Unk		Not Reported
	Diffu K	C	Unknown	Unk		Not Reported
	Dafalgan	C	Unknown	Unk		Not Reported
	Keppra	C	Unknown	Unk		Not Reported
	Zymad	C	Unknown			Not Reported
	Cokenzen	C	Unknown			Not Reported
	Hemifumarate Bisoprolol	C	Unknown			Not Reported
	Tramadol (Chlorhydrate De)	C	Unknown			Not Reported
	Macrogol 4000	C	Unknown			Not Reported
	Levemir	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16594902	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1929293US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Overdose; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Overdose: 60mg Unit Dose		Allergan
	Mirtazapine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	15551355	EXPEDITED (15-DAY)		CA, HO, OT	CA-GLENMARK PHARMACEUTICALS-2018GMK037887			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby;	Gabapentin			S	Transplacental	1800 Mg, Od		Glenmark
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Od		Not Reported
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Od		Not Reported

Sleep Disorder; Tremor; Trismus	Escitalopram	S	Transplacental	20 Mg, Od	Not Reported
	Escitalopram	S	Transplacental	20 Mg, Od	Not Reported
	Escitalopram	S	Transplacental	20 Mg, Od	Not Reported
	Methadone	S	Transplacental	70 Mg, Od	Not Reported
	Nortriptyline	S	Transplacental	20 Mg, Od	Not Reported
	Quetiapine	S	Transplacental	300 Mg, Bid, (One Every 12 Hours)	Not Reported
	Rabeprazole	S	Transplacental	Unk	Not Reported
	Zopiclone	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	15569031	EXPEDITED (15-DAY)		DE	CA-TEVA-2018-CA-967648		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective; Feeling Abnormal; Muscular Weakness; Suicidal Ideation	Clonazepam			S	Oral	1.5 Milligram Daily;		Teva
	Clonazepam			S				Teva
	Clonazepam			S				Teva
	Escitalopram			S	Oral			Ivax
	Escitalopram			S				Ivax
	Escitalopram			S				Ivax
	Zopiclone			S	Oral	15 Milligram Daily;		Not Reported
	Zopiclone			S				Not Reported
	Zopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	15626479	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-976639		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Unknown			Ivax
	Hydrochlorothiazide			S	Unknown			Ivax
	Gliclazide			C				Not Reported
	Insulin			C				Not Reported
	Levothyroxine			C				Not Reported

Metformin	C		Not Reported
Telmisartan	C		Not Reported
Trazodone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	15668447	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-980609			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Mental Impairment; Sexual Dysfunction	Citalopram Hydrobromide			S	Unknown			Actavis
	Escitalopram			S	Unknown			Ivax
	Escitalopram			S	Unknown			Ivax
	Escitalopram			S	Unknown			Ivax
	Trintellix			S	Unknown	10 Milligram Daily;		Not Reported
	Trintellix			S				Not Reported
	Trintellix			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	15679889	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-981621		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Teva-Escitalopram			S	Unknown			Ivax
	Teva-Escitalopram			S				Ivax
	Teva-Escitalopram			S				Ivax
	Quetiapine Fumarate			S	Unknown			Teva
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16530957	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-037455			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Dementia; Fatigue; Insomnia; Loss Of Libido; Nausea; Weight	Auro-Escitalopram Tablets			S	Unknown	10 Milligram, Daily		Aurobindo
	Auro-Paroxetine 20 Tablets			S	Unknown	20 Milligram, Daily		Aurobindo

Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16536622	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1073053		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Measurement; Delirium; Diabetes Mellitus; Drug Level Increased; Fall; Myocardial Infarction; Neuroleptic Malignant Syndrome; Rhabdomyolysis; Sedation; Serotonin Syndrome	Teva-Quetiapine Xr			S	Oral	30 Milligram Daily;		Teva
	Teva-Quetiapine Xr			S				Teva
	Escitalopram			S	Unknown	20 Milligram Daily;		Ivax
	Lorazepam 2 Mg			C		6 Milligram Daily; (As Needed)		Not Reported
	Lorazepam 2 Mg			C				Not Reported
	Triazide 50-25			C		50-25		Not Reported
	Baclofen 10mg			C		30 Milligram Daily; Prn		Not Reported
	Anacin 325-30mg			C		325-30mg		Not Reported
	T3			C		Patient States Took About Once A Week Leg Pain		Not Reported
	Spiriva 18mcg			C		18 Microgram Daily;		Not Reported
	Ventolin			C		1-2 Puffs Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16595619	EXPEDITED (15-DAY)		HO, LT, OT	PT-AUROBINDO-AUR-APL-2019-040988			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemic Stroke	Escitalopram			S	Oral	10 Milligram, Once A Day, 10 Mg/Dia		Aurobindo
	Warfarin			S	Unknown	Unk		Not Reported
	Perindopril			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Isosorbide Mononitrate			C	Unknown	Unk		Not Reported
	Atorvastatin;Ezetimibe			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16595867	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-040308			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Escitalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Unknown	20 Milligram, 1 Every 24 Hour(S)		Aurobindo
	Aripiprazole			S	Oral	2 Milligram, Unk		Aurobindo
	Serax			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16595880	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-041034			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypotension; Poisoning Deliberate	Escitalopram			S	Oral	140 Milligram		Aurobindo
	Doliprane			S	Oral	4 Gram		Not Reported
	Aerius (Desloratadine)			S	Oral	35 Milligram		Not Reported
	Lexomil			S	Oral	30 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16596079	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2019-041423			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Escitalopram			S	Oral	200 Milligram, Total		Aurobindo
	Depakin Chrono			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16596265	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1078887		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Traumatic Haemothorax	Escitalopram		S	Oral	10 Milligram Daily;	Ivax
	Eliquis		S	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16597036	EXPEDITED (15-DAY)		LT	FR-TEVA-2019-FR-1078465		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Mirtazapine			S	Oral			Teva
	Alprazolam			S	Oral			Actavis
	Escitalopram			S	Oral			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16597072	EXPEDITED (15-DAY)		HO	PHHY2019FR162638		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Furosemide			S	Oral	40 Mg, Qd		Not Reported
	Bisoprolol			S	Oral	10 Mg, Qd		Not Reported
	Amlodipine			S	Oral	5 Mg, Qd		Novartis
	Lamotrigine			S	Oral	200 Mg, Qd		Not Reported
	Ramipril			S	Oral	5 Mg, Qd		Not Reported
	Gabapentin			S	Oral	1200 Mg, Qd		Not Reported
	Clopidogrel			S	Oral	75 Mg, Qd		Not Reported
	Alprazolam			S	Oral	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16597077	EXPEDITED (15-DAY)		OT	IE-TEVA-2019-IE-1069498		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Escitalopram			S	Oral	15 Milligram Daily;		Ivax

Adverse Drug Reaction; Bruxism; Restless Legs Syndrome

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16597223	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019306999		94 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage	Pantoprazole			S	Oral	10 Milligram, Qd		Pfizer
	Doliprane			S	Oral	3 Gram, Qd		Not Reported
	Coumadine			S	Oral	6 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Lasilix [Furosemide]			C	Oral	60 Milligram, Qd		Not Reported
	Diffu K			C	Oral	600 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16597732	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2019304485		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Alprazolam			S	Oral	20 Mg, Unk		Pfizer
	Mirtazapine			S	Oral	30 Mg, Unk		Not Reported
	Escitalopram			S	Oral	60 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16597937	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1077702		18 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Jaundice; Nausea; Vomiting	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Escitalopram			S	Oral	5 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16598161	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1077998		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Jittery; Nervousness; Panic Attack	Escitalopram			S	Oral	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16599092	EXPEDITED (15-DAY)		OT	PH-OTSUKA-2019_026259		22 YR	Female	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Inflammation	Abilify			S	Unknown	5 Mg, Qd		Otsuka
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16599506	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1078045		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Escitalopram Oxalate			S	Oral	1 Dosage Forms Daily;		Ivax
	Methotrexate			S	Unknown			Barr
	Pantoprazole Magnesium			S	Oral	1 Dosage Forms Daily;		Teva
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	2 Dosage Forms Daily;		Not Reported
	Prednisone			C		5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16599852	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1929188US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan
	Lamotrigine			S	Oral	Unk		Not Reported
	Alprazolam			C				Not Reported
	Verapamil			C				Not Reported
	Trandolapril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16601747	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-CA2019AMR127715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspirin-Exacerbated Respiratory Disease; Asthma; Blood Count Abnormal; Condition Aggravated; Drug Hypersensitivity; Dyspnoea; Eczema; Nasal Polyps; Therapeutic Product Effect Incomplete	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, 1 Month		Glaxosmithkline
	Ventolin			S		Unk, Prn		Glaxosmithkline
	Incruse Ellipta			S		Unk		Glaxosmithkline
	Avamys			S		Unk		Glaxosmithkline
	Rhinocort			S		2 Puff(S) In To Each Nostrilat Bedtime Prn		Glaxosmithkline
	Bupropion			S		300 Mg, Qd		Glaxosmithkline
	Levothyroxine			S		150 Mg, Qd		Glaxosmithkline
	Pantoprazole			S		40 Mg, Qd		Glaxosmithkline
	Escitalopram			S		20 Mg, Qd		Glaxosmithkline
	Singulair			S		Unk		Glaxosmithkline
	Fluticasone			S		Unk		Glaxosmithkline
	Zenhale			S		2 Puff(S), Bid		Not Reported
	Spiriva			S		2 Puff(S), Qd		Not Reported
	Gabapentin			S		100 Mg, Qd		Not Reported

	Symbicort	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2019	16081411	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-014149			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Escitalopram			S	Oral	1 Dosage Form, Daily		Aurobindo
	Pantoprazole			S	Oral	1 Dosage Form, Daily		Aurobindo
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	1 Dosage Form, Two Times A Day		Not Reported
	Prednisone			C	Unknown	5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2019	16328202	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-027687			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Motor Dysfunction; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression; Spinal Cord Oedema	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Heparin Sodium			S	Subcutaneous	5000 International Unit		Not Reported
	Heparin Sodium			S				Not Reported
	Heparin Sodium			S				Not Reported
	Rivaroxaban			S	Unknown	15 Milligram, Once A Day		Not Reported
	Rivaroxaban			S				Not Reported
	Rivaroxaban			S				Not Reported
	Xarelto			S	Unknown	15 Milligram, Once A Day		Not Reported

	Xarelto	S				Not Reported
	Bupivacaine	C	Unknown	Unk, Sloution Block/Infiltration		Not Reported
	Epinephrine	C	Unknown	Unk		Not Reported
	Hydromorphone	C	Unknown	Unk		Not Reported
	Lidocaine	C	Unknown	3 Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2019	16599634	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-041935			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	0.5 Dosage Form		Aurobindo
	Esidrex			S	Oral	0.5 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2019	16599642	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-041955			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage	Escitalopram			S	Oral	10 Milligram, Daily (1-0-0)		Aurobindo
	Pantoprazole			S	Oral	10 Milligram, Daily (0-0-1)		Aurobindo
	Coumadine			S	Oral	6 Milligram, Daily (0-0-1)		Not Reported
	Doliprane			S	Oral	3 Gram, Daily		Not Reported
	Lasilix			C	Oral	60 Milligram, Daily (1-0-0)		Not Reported
	Diffu K			C	Oral	600 Milligram, Daily (1-0-0)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2019	16600117	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2019-042396			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram	Mirtazapine			S	Oral	30 Milligram, Unk		Aurobindo

Qt Prolonged; Toxicity To Various Agents	Alprazolam		S	Oral	20 Milligram, Unk	Aurobindo
	Escitalopram		S	Oral	60 Milligram, Unk	Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2019	16600533	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-041959			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo
	Lamotrigine			S	Oral	Unk		Aurobindo
	Alprazolam			C	Unknown	Unk		Not Reported
	Verapamil Hydrochloride			C	Unknown	Unk		Not Reported
	Trandolapril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2019	16600710	EXPEDITED (15-DAY)		OT	FR-ACCORD-138747		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Pregabalin			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Xanax			S	Oral			Not Reported
	Pantoprazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2019	16600739	EXPEDITED (15-DAY)		HO	FR-ACCORD-139256		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall	Amlodipine			S	Oral			Accord
	Bisoprolol			S	Oral			Not Reported
	Clopidogrel			S	Oral			Not Reported

	Escitalopram	S	Oral		Not Reported
	Furosemide	S	Oral		Accord
	Ramipril	S	Oral		Accord
	Oxynormoro	S	Oral	Strength: 5 Mg	Not Reported
	Nefopam	S	Oral		Not Reported
	Gabapentin	S	Oral		Not Reported
	Alprazolam	S	Oral		Not Reported
	Lamotrigine	S	Oral		Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	12889556	NON-EXPEDITED			US-PFIZER INC-2016499444		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Xanax Xr			S		Unk		Pfizer
	Doxepin Hcl			S		Unk		Pfizer
	Nexium 24hr			S		Unk		Unknown
	Neurontin			S		Unk		Pfizer
	Hydroxyzine Pamoate			S		Unk		Pfizer
	Lorazepam			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Aspirin			S		Unk		Not Reported
	Depakote			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Mevacor			S		Unk		Not Reported
	Nefazodone			S		Unk		Not Reported
	Oxycontin			S		Unk		Not Reported

	Paxil	S	Unk	Not Reported
	Paxil Cr	S	Unk	Not Reported
	Reglan	S	Unk	Not Reported
	Risperidone	S	Unk	Not Reported
	Trazodone	S	Unk	Not Reported
	Ultram	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported
	Zofran	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16108617	EXPEDITED (15-DAY)		HO, LT, OT	JP-ACCORD-114227		26 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Rhabdomyolysis; Serotonin Syndrome	Escitalopram			S	Oral			Not Reported
	Clomipramine			S	Oral			Not Reported
	Flunitrazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16467630	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016748		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; No Adverse Event; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Escitalopram			S	Unknown	Unk, Qd		Apotex
	Cosentyx			S	Subcutaneous	150 Mg, Q.M.T.		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cosentyx			S	Subcutaneous	150 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Povidone-Iodine			S	Unknown	Unk		Not Reported
	Vitamin D3			S	Unknown	Unk		Not Reported
	Voltaren /00372301/			S	Unknown	Unk, Q.Wk.		Not Reported
	Voltaren /00372301/			S	Unknown	Unk		Not Reported

Diclofenac Diethylamine	S	Unknown	Unk		Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk		Not Reported
Humira	C	Subcutaneous	Unk		Not Reported
Enbrel	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16566795	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP008950		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue; Suicidal Ideation; Therapy Change	Escitalopram			S	Unknown	20 Mg, Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16607009	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-040986			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Confusional State; Dizziness; Flushing; Heart Rate Increased; Loss Of Consciousness; Nausea	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16607031	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-040880			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Base Excess Decreased; Confusional State; Fall; Hypoglycaemia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis; Pco2 Decreased	Escitalopram			S	Unknown	Unk		Aurobindo
	Metformin Tablet			S	Unknown	1 Gram		Aurobindo
	Metformin Tablet			S	Unknown	1 Gram, Two Times A Day		Aurobindo
	Apo-Gliclazide			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported

	Insulin	S	Unknown	Unk		Not Reported
	Insulin	S	Unknown	Unk		Not Reported
	Gliclazide	C	Unknown	Unk		Not Reported
	Levothyroxine Sodium	C	Unknown	Unk		Not Reported
	Metformin	C	Unknown	Unk		Not Reported
	Telmisartan	C	Unknown	Unk		Not Reported
	Trazodone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16607532	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-041633			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Ciprofloxacin			S	Intravenous (not otherwise specified)	Unk, 1 Every 3 Weeks		Aurobindo
	Ciprofloxacin			S	Oral	1000 Milligram		Aurobindo
	Docetaxel			S	Intravenous (not otherwise specified)	75 Milligram/Sq. Meter, 1 Every 3 Weeks		Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)	75 Milligram/Sq. Meter		Not Reported
	Morphine			S	Unknown	2.5 Milligram, 1 Every 4 Hours		Not Reported
	Piperacillin Sodium;Tazobactam Sodium			S	Unknown	Unk		Not Reported
	Trastuzumab			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, 1 Every 3 Weeks		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Avastin			S	Intravenous (not otherwise specified)	15 Milligram/Kilogram, 1 Every 3 Weeks		Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)	Unk, 1 Every 3 Weeks		Not Reported
	Cipralex			S	Unknown	10 Milligram, Once A Day		Not Reported

Codeine	C	Unknown	Unk		Not Reported
Docusate	C	Unknown	Unk		Not Reported
Gravol	C	Unknown	Unk		Not Reported
Lactulose	C	Unknown	Unk		Not Reported
Laxasene	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16607541	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-040870			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Exposure During Pregnancy; Lung Infection; Melanocytic Naevus; Rheumatoid Arthritis; Rheumatoid Factor Increased	Escitalopram			S	Unknown	10 Milligram		Aurobindo
	Pantoprazole			S	Unknown	30 Milligram, Once A Day		Aurobindo
	Acetaminophen;Codeine Phosphate			S	Unknown	Unk		Not Reported
	Imodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 8 Week		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Loperamide Hydrochloride			C	Unknown	Unk		Not Reported
	Multi Vitamin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16607753	EXPEDITED (15-DAY)		HO	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-214229		70 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Pregabalin			S	Unknown	75 Mg, Abgesetzt ()		Not Reported
	Mirtazapin			S	Unknown	45 Mg, 0-0-1-0 ()		Sun
	Zolpidem			S	Unknown	10 Mg, 0-0-1-0 ()		Not Reported

Cipralex	S	Unknown	10 Mg, 1-0-0-0 ()		Not Reported
Elontril	S	Unknown	150 Mg, 1-0-0-0 ()		Not Reported
Lamotrigin	S	Unknown	50 Mg, 1-0-1-0 ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16608068	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019022174			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pancreatitis; Skin Ulcer	Escitalopram			S	Oral	10 Milligram, Qd		Macleods
	Ledipasvir/Sofosbuvir			S	Oral	90 Milligram, Qd		Not Reported
	Ribavirin			S	Oral	600 Milligram, Bid		Not Reported
	Ribavirin			S	Oral	400 Milligram, Bid		Not Reported
	Ribavirin			S	Oral	400mg-0-200mg		Not Reported
	Braunovidon			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16609116	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP018478		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Escitalopram			S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16610207	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1929466US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Coma; Electrocardiogram Qt Prolonged; Miosis; Product Use In Unapproved Indication; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	30 Mg		Allergan
	Depakote			S	Oral	3 G		Not Reported
	Depakote			S	Unknown	1.5 G		Not Reported
	Seresta			S	Oral	100 Mg		Not Reported

	Xeroquel Lp	S	Oral	1.8 G	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16611681	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2019M1067348			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hydronephrosis; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	L-Thyroxin /00068002/			C	Transplacental	112 [Mg/D (Bis 75 Mg/D)]		Mylan
	Progestan			C	Transplacental	600 [Mg/D (3 X 200 Mg/D)]		Mylan
	Dekristol			C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]		Mylan
	Progynova /00045402/			C	Transplacental	3 [Mg/D (3 X 1 Mg/D)]		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	13550558	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP011838		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Base Excess Decreased; Confusional State; Fall; Hypoglycaemia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis; Pco2 Decreased	Escitalopram			S	Unknown			Apotex
	Hydrochlorothiazide			S	Unknown			Apotex
	Gliclazide			S	Unknown			Not Reported
	Metformin			S	Unknown	1 G, Bid		Apotex
	Metformin			S	Unknown	1 G, Unk		Apotex
	Insulin			S	Unknown			Not Reported
	Insulin			S				Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Levothyroxine Sodium			C				Not Reported
	Telmisartan			C	Unknown			Not Reported
	Telmisartan			C				Not Reported
	Trazodone			C	Unknown			Not Reported
	Insulin			C	Unknown			Not Reported

	Metformin	C	Unknown	Not Reported
	Metformin	C		Not Reported
	Gliclazide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	15203873	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1837101US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Deafness; Ototoxicity; Tympanometry; Vertigo	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Lyrica			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xenical			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	15222340	EXPEDITED (15-DAY)		DS	CA-ALLERGAN-1837599US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Flushing; Joint Stiffness; Sensory Disturbance; Tremor	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Hctz			C	Unknown	Unk		Not Reported
	Imovane			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	15316856	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1841138US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Aphonia; Arthritis; Asthma; Blood Pressure Increased; Blood	Escitalopram Oxalate Unk			S	Unknown	1 Df, Qd		Allergan
	Amlodipine			S	Oral	1 Df, Qd		Not Reported

Pressure Systolic Increased; Bone Density Abnormal; Cardiac Murmur; Chest Discomfort; Dysgraphia; Dyspnoea; Fall; Forced Expiratory Volume Decreased; Malaise; Malaise; Mental Disorder; Post-Traumatic Stress Disorder; Rib Fracture; Weight Decreased	Ranitidine	S	Oral	2 Df, Qd	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Q2weeks	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Q2weeks	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Q2weeks	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Advair	C	Respiratory (inhalation)	2 Df, Q12h	Not Reported
	Arava	C		Unk	Not Reported
	Darifenacin	C	Oral	1 Df, Qd	Not Reported
	Levothyroxine Sodium	C	Oral	1 Df, Qd	Not Reported
	Plaquenil	C		Unk	Not Reported
	Prednisone	C		2.5 Mg, Qd	Not Reported
	Prednisone	C		15 Mg, Qd	Not Reported
	Prednisone	C		20 Mg, Qd	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Qvar	C	Respiratory (inhalation)	2 Df, Q12h	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Ventolin	C	Respiratory (inhalation)	2 Df	Not Reported
	Ventolin	C	Respiratory (inhalation)	2 Df, Q12h	Not Reported
	Ventolin	C	Respiratory (inhalation)	2 Df, Qd	Not Reported
	Mirtazapine	C	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	15625848	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2018207113		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cholestasis	Lasilix	S	Oral	20 Mg, Qd	Glaxosmithkline
	Ramipril	S	Oral	2.5 Mg, Qd	Glaxosmithkline
	Lamotrigine	S	Oral	100 Mg, Qd	Glaxosmithkline
	Seroplex	S	Oral	5 Mg, Qd	Glaxosmithkline
	Gabapentine	S	Oral	200 Mg, Qd	Not Reported
	Aspirine Protect	S	Oral	100 Mg, Qd	Not Reported
	Bisoce	S	Oral	1.25 Mg, Qd	Not Reported
	Exemestane	S	Oral	25 Mg, Qd	Not Reported
	Levothyroxine Sodium	C	Oral	30 Gtt, Qd	Glaxosmithkline
	Fluidabak	C	Ophthalmic	3 Gtt, Qd	Not Reported
	Macrogol 3350	C	Oral	11.8 G, Qd	Not Reported
	Potassium Gluconate	C	Oral	1 Cs Per Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16076723	EXPEDITED (15-DAY)		CA, HO	CA-AUROBINDO-AUR-APL-2019-013708			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Gabapentin			S	Transplacental	1800 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Transplacental	20 Milligram, Once A Day		Aurobindo
	Quetiapine Film-Coated Tablet			S	Transplacental	300 Milligram, Two Times A Day		Aurobindo
	Benztropine Mesylate			S	Transplacental	1.5 Milligram, Once A Day		Not Reported
	Methadone			S	Transplacental	70 Milligram, Once A Day		Not Reported
	Nortriptyline			S	Transplacental	20 Milligram, Once A Day		Not Reported
	Rabeprazole			S	Transplacental	Unk		Not Reported
	Zopiclone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16080820	EXPEDITED (15-DAY)		CA, HO, OT	CA-AUROBINDO-AUR-APL-2019-013670			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; High-Pitched Crying; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Escitalopram Tablets			S	Transplacental	20 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Transplacental	20 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Transplacental	20 Milligram, Once A Day		Aurobindo
	Gabapentin			S	Transplacental	1800 Milligram, Once A Day		Aurobindo
	Quetiapine Film-Coated Tablet			S	Transplacental	300 Milligram, Two Times A Day		Aurobindo
	Methadose Dye-Free, Sugar-Free, Unflavored			S	Transplacental	70 Milligram, Once A Day		Not Reported
	Benztropine Mesylate			S	Transplacental	1.5 Milligram, Once A Day		Not Reported
	Benztropine Mesylate			S	Transplacental	1.5 Milligram, Once A Day		Not Reported
	Nortriptyline			S	Transplacental	20 Milligram, Once A Day		Not Reported
	Rabeprazole			S	Transplacental	Unk		Not Reported
	Zopiclone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16613909	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP018482		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Diarrhoea	Apo-Escitalopram			S	Oral	10 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16614269	EXPEDITED (15-DAY)		LT	FR-ZYDUS-038803		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Mirtazapine			S	Oral			Zydus Pharm
	Alprazolam			S	Oral			Not Reported
	Escitalopram			S	Oral			Cadila

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16617512	EXPEDITED (15-DAY)		HO	CA-APOTEX-2019AP018471		18 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Jaundice; Nausea; Vomiting	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Escitalopram			S	Oral	5 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16618494	EXPEDITED (15-DAY)		HO	FR-SA-2019SA198700		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Ramipril			S	Oral	5 Mg, Qd		Sanofi
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Furosemide			S	Oral	40 Mg, Qd		Sanofi
	Bisoprolol Fumarate			S	Oral	10 Mg, Qd		Not Reported
	Bisoprolol Fumarate			S		Unk		Not Reported
	Amlodipine (Salt Not Specified)			S	Oral	5 Mg, Qd		Not Reported
	Lamotrigine			S	Oral	200 Mg, Unk		Not Reported
	Clopidogrel Bisulfate			S	Oral	75 Mg, Qd		Sanofi
	Gabapentin			S	Oral	1200 Mg, Unk		Not Reported
	Alprazolam			S	Oral	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16620220	NON-EXPEDITED			US-OTSUKA-2019_010527			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Incorrect Dose Administered; Migraine; Product Use In Unapproved Indication	Rexulti			S	Unknown	1/4 Of A Tablet Or 1/2 A Tablet		Otsuka
	Rexulti			S				Otsuka
	Abilify			S	Unknown	Unk		Otsuka

	Lexapro		S	Unknown	Unk	Not Reported
	Latuda		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16620243	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1068219		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Logorrhoea; Seizure; Tachycardia; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Not Reported
	Valium			S	Oral	Unk		Mylan
	Lithium			S	Oral	1.2 Gram, Qd		Mylan
	Tercian /00759301/			S	Oral	250 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16620339	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1080623		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Pregabaline			S	Oral	225mg Per Day		Not Reported
	Escitalopram			S	Oral	10mg Per Day		Ivax
	Metoject			S	Subcutaneous	25mg Per Weeks		Not Reported
	Xanax 0,25 Mg, Comprimé Sécable			S	Oral	0.25mg Per Day		Not Reported
	Pantoprazole			C	Oral	40mg Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16621156	EXPEDITED (15-DAY)		OT	US-OTSUKA-2018_031126		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depressed Mood; Fatigue; Incorrect Dose Administered; Lethargy; Suicidal Ideation	Rexulti			S	Oral	2 Mg, Qd		Otsuka
	Rexulti			S				Otsuka
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16621694	NON-EXPEDITED			US-OTSUKA-2018_038821			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Rexulti			S	Oral	2mg Once Daily By Mouth		Otsuka
	Rexulti			S				Otsuka
	Effexor			S	Unknown	Unk		Not Reported
	Effexor			S				Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16622092	NON-EXPEDITED			US-OTSUKA-2019_023477			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Crying; Drug Ineffective; Feeling Abnormal; Heart Rate Increased; Homeless; Hyperhidrosis; Impaired Work Ability; Inability To Afford Medication; Insurance Issue; Memory Impairment; Panic Attack; Tremor	Abilify			S	Unknown	Unk		Otsuka
	Abilify			S	Unknown	2 Mg, Unk		Otsuka
	Abilify			S	Unknown	5 Mg, Unk		Otsuka
	Aripiprazole			S	Unknown	5 Mg, Unk		Otsuka
	Rexulti			S	Unknown	Unk		Otsuka
	Rexulti			S				Otsuka
	Gabapentin			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Paxil			C	Unknown	Unk		Not Reported
	Lithium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16622749	NON-EXPEDITED			US-OTSUKA-2019_009346		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Anxiety; Blood Glucose Increased; Diabetes Mellitus; Glycosylated Haemoglobin Increased; Weight Increased	Rexulti	S	Oral	3 Mg, Qd		Otsuka
	Rexulti	S	Oral	0.5 Mg, Qd		Otsuka
	Trazodone	S	Unknown	Unk		Not Reported
	Deplin	S	Unknown	Unk		Not Reported
	Lamictal	S	Unknown	Unk		Not Reported
	Prozac	S	Unknown	Unk		Not Reported
	Trintellix	S	Oral	10 Mg, Unk		Not Reported
	Lexapro	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16622781	EXPEDITED (15-DAY)		OT	US-OTSUKA-2019_018144			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Burning Sensation; Dysphagia; Hypersensitivity; Insomnia; Nervousness; Overdose; Pain; Rash Pruritic; Therapy Cessation; Tinnitus; Urticaria	Rexulti			S	Unknown	Low Dose Once Daily		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16623076	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019AMR129774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Count Abnormal; Bronchial Secretion Retention; Cough; Drug Ineffective; Dyspnoea; Eosinophil Count Increased; Multiple Allergies; Obstructive Airways Disorder; Pneumonia; Pulmonary	Mepolizumab			S		100 Mg, Z(Months)		Glaxosmithkline
	Ventolin			S		Unk, Prn		Glaxosmithkline
	Ventolin Nebules			S		Unk		Glaxosmithkline
	Escitalopram			S		10 Mg, Qd		Glaxosmithkline
	Crestor			S		10 Mg, Qd		Glaxosmithkline
	Rosuvastatin			S		Unk		Glaxosmithkline

Mass; Respiratory Tract Infection; Reversible Airways Obstruction; Sputum Culture; Sputum Culture Positive; Upper-Airway Cough Syndrome; Vital Capacity Decreased	Diazepam	S	Unk	Glaxosmithkline
	Spironolactone	S	Unk	Glaxosmithkline
	Ferrous Gluconate	S	0.125 Mg, Qd	Glaxosmithkline
	Singulair	S	Unk	Glaxosmithkline
	Symbicort	S	2 Puff(S), Qd	Not Reported
	Spiriva Respimat	S	2 Puff(S), Qd	Not Reported
	Pulmicort	S	Unk Unk, Qd	Not Reported
	Rabeprazole	S	10 Mg, Qd	Not Reported
	Bisoprolol	S	5 Mg, Qd	Not Reported
	Triazide (Trichlormethiazide)	S	Unk, Qd(50/25)	Not Reported
	Xolair	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Alendronate	S	Unk	Not Reported
	Meloxicam	S	Unk	Not Reported
	Tylenol	S	Unk	Not Reported
	Lasix	S	Unk	Not Reported
	Synthroid	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16623309	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1081030		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Furosemide			S	Oral	40mg		Not Reported
	Escitalopram			S	Oral	10mg		Ivax
	Bisoprolol (Fumarate De)			S	Oral	10mg		Teva
	Amlodipine			S	Oral	5mg		Teva
	Lamotrigine			S	Oral	200mg		Teva
	Ramipril			S	Oral	5mg		Actavis
	Gabapentine			S	Oral	1200mg		Actavis

	Clopidogrel Base	S	Oral	75mg		Teva
	Alprazolam	S	Oral	0.5mg		Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	15302825	EXPEDITED (15-DAY)		DS	CA-ALLERGAN-1840798US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dysaesthesia; Fatigue; Nausea	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Allopurinol			C	Oral	300 Mg, Qd		Not Reported
	Amlodipine			C	Oral	10 Mg, Qd		Not Reported
	Amlodipine			C	Oral	10 Mg, Q8hr		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Diltiazem			C	Oral	240 Mg, Qd		Not Reported
	Gabapentin			C	Unknown	300 Mg, Q8hr		Not Reported
	Ramipril			C	Oral	10 Mg, Qd		Not Reported
	Tylenol With Codein #3			C	Oral	1 Df, Q8hr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16510059	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1059587		36 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Paroxetine			S	Oral	28 Dosage Form, Total		Not Reported
	Escitalopram			S	Oral	14 Dosage Form, Total		Not Reported
	Prazepam			S	Oral	20 Dosage Form, Total		Mylan
	Cocaine			S	Unknown	0.5 Gram		Mylan
	Tercian /00759302/			S	Oral	16 Dosage Form, Total		Mylan
	Atarax /00058402/			S	Oral	10 Dosage Form, Total		Mylan
	Valium			S	Oral	3 Dosage Form, Total		Mylan
	Alcool			S	Oral	Non Renseignée		Mylan
	Diazepam			S	Oral	8 Dosage Form, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16588485	EXPEDITED (15-DAY)		HO	IT-ACCORD-138806		6 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Tremor	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16624784	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-042924			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Lamotrigine			S	Oral	200 Milligram, Once A Day		Aurobindo
	Gabapentin			S	Oral	1200 Milligram, Once A Day		Aurobindo
	Alprazolam			S	Oral	0.5 Milligram, Once A Day		Aurobindo
	Amlodipine			S	Oral	5 Milligram, Once A Day		Aurobindo
	Bisoprolol			S	Oral	10 Milligram, Once A Day		Aurobindo
	Clopidogrel			S	Oral	75 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Furosemide			S	Oral	40 Milligram, Once A Day		Aurobindo
	Ramipril			S	Oral	5 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16624889	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019309914		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Xanax			S	Oral	0.25 Mg, 1x/Day		Pfizer
	Pregabalin			S	Oral	225 Mg, 1x/Day		Pfizer
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Metoject			S	Subcutaneous	25 Mg, Weekly		Not Reported

Pantoprazole	C	Oral	40 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16624966	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019310014		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State	Gabapentin			S	Oral	1200 Mg, Daily		Pfizer
	Alprazolam			S	Oral	0.5 Mg, Daily		Pfizer
	Esomeprazole Magnesium			S	Oral	40 Mg, Daily		Unknown
	Oxynormoro			S	Oral	Unk		Not Reported
	Nefopam [Nefopam Hydrochloride]			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	200 Mg, Daily		Not Reported
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16627925	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019317215		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Ramipril			S	Oral	5 Mg, Qd		Pfizer
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Furosemide			S	Oral	40 Mg, Qd		Unknown
	Bisoprolol Fumarate			S	Oral	10 Mg, Qd		Not Reported
	Bisoprolol Fumarate			S		Unk		Not Reported
	Amlodipine			S	Oral	5 Mg, Qd		Pfizer
	Lamotrigine			S	Oral	200 Mg, Unk		Not Reported
	Clopidogrel			S	Oral	75 Mg, Qd		Not Reported
	Gabapentin			S	Oral	1200 Mg, Unk		Pfizer
	Alprazolam			S	Oral	0.5 Mg, Qd		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16627997	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1929768US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Pregabalin			S	Oral	225 Mg, Qd		Not Reported
	Metoject			S	Subcutaneous	25 Mg, Q Week		Not Reported
	Xanax			S	Oral	0.25 Mg, Qd		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	12922283	NON-EXPEDITED			US-ASTRAZENECA-2016SF13739		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Nexium 24 Hr			S	Oral	Unknown Dose Of Frequency		Astrazeneca
	Aspirin			S	Oral	Unknown Dose Of Frequency		Not Reported
	Escitalopram Oxalate			S	Unknown	Unknown Dose Of Frequency		Not Reported
	Paxil			S	Unknown	Unknown Dose Of Frequency		Not Reported
	Zoloft			S	Unknown	Unknown Dose Of Frequency		Not Reported
	Doxepin Hydrochloride			S	Oral	Unknown Dose Of Frequency		Not Reported
	Depakote			S	Unknown	Unknown Dose Of Frequency		Not Reported
	Flexeril			S	Unknown	Unknown Dose Of Frequency		Not Reported
	Nefazodone			S	Unknown	Unknown Dose Of Frequency		Not Reported

Oxycontin	S	Unknown	Unknown Dose Of Frequency		Not Reported
Risperidone	S	Unknown	Unknown Dose Of Frequency		Not Reported
Trazodone	S	Unknown	Unknown Dose Of Frequency		Not Reported
Zofran	S	Unknown	Unknown Dose Of Frequency		Not Reported
Xanax Xr	S	Unknown	Unknown Dose Of Frequency		Not Reported
Lorazepam	S	Unknown	Unknown Dose Of Frequency		Not Reported
Hydroxyzine Pamoate	S	Unknown	Unknown Dose Of Frequency		Not Reported
Wellbutrin	S	Unknown	Unknown Dose Of Frequency		Not Reported
Mevacor	S	Unknown	Unknown Dose Of Frequency		Not Reported
Paxil Cr	S	Unknown	Unknown Dose Of Frequency		Not Reported
Reglan	S	Unknown	Unknown Dose Of Frequency		Not Reported
Ultram	S	Unknown	Unknown Dose Of Frequency		Not Reported
Neurontin	S	Unknown	Unknown Dose Of Frequency		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16208883	EXPEDITED (15-DAY)		HO	IT-TAKEDA-2019TUS023263		53 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Glaucoma; Headache; Vertigo	Brintellix			S	Oral	10 Milligram, Qd		Takeda
	Escitalopram Zentiva			S	Unknown	10 Milligram, Qd		Not Reported

	Lormetazepam	C	Oral	40 Gtt Drops, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16548532	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1928174US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metrorrhagia	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16628108	NON-EXPEDITED			US-TEVA-2019-US-1080283			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Escitalopram Tablet			S	Unknown			Ivax
	Adderall Teva			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16628907	EXPEDITED (15-DAY)		DE, HO, OT	CH-TAKEDA-2019TEU008739		78 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Respiratory Failure	Dexilant			S	Oral	Unk		Takeda
	Atorvastatin Pfizer			S	Unknown	Unk		Not Reported
	Metoprolol Succinate			S	Oral	Unk		Not Reported
	Cipralex /01588502/			S	Oral	Unk		Not Reported
	Aspirin Cardio			C	Oral	Unk		Not Reported
	Pregabalin Pfizer			C	Oral	Unk		Not Reported
	Toviaz			C	Oral	Unk		Not Reported
	Mirtazapin			C		Unk		Not Reported
	Temesta /00273201/			C		Unk		Not Reported
	Brilique			C		Unk		Not Reported
	Mst Continus			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16629838	EXPEDITED (15-DAY)		CA	NL-MYLANLABS-2019M1068148			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	1 Dd 10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16630694	EXPEDITED (15-DAY)		HO	FR-ACCORD-148607		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall	Amlodipine			S	Oral			Accord
	Escitalopram			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Mirtazapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16630844	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1069474		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Bisoprolol			S	Oral	10 Milligram, Qd		Not Reported
	Bisoprolol			S	Oral	Dose Reduced		Not Reported
	Furosemide			S	Oral	40 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Amlodipine			S	Oral	5 Milligram, Qd		Not Reported
	Lamotrigine			S	Oral	200 Milligram, Qd		Not Reported
	Ramipril			S	Oral	5 Milligram, Qd		Not Reported
	Gabapentin			S	Oral	1200 Milligram, Qd		Not Reported

Clopidogrel	S	Oral	75 Milligram, Qd		Not Reported
Alprazolam	S	Oral	0.5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16631043	EXPEDITED (15-DAY)		OT	FR-BAYER-2019-135344		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Thrombocytopenia	Glucobay			S	Oral	150 Mg, Qd		Bayer
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Alfuzosin Hydrochloride			S	Oral	10 Mg, Qd		Not Reported
	Risperdal			C	Oral	1 Mg/Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16631224	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2019-US-000926			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Haemorrhage; Drug Interaction; Serotonin Syndrome	Tramadol			S	Unknown	Unk		Ipca
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16631443	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1929780US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Ischaemic Syndrome	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Trimipramine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16631597	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019309871		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Alprazolam			S	Oral	0.5 Mg, Daily		Pfizer
	Amlodipine Besilate			S	Oral	5 Mg, Daily		Pfizer
	Gabapentin			S	Oral	1200 Mg, Daily		Pfizer
	Furosemide			S	Oral	40 Mg, Daily		Not Reported
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Bisoprolol Fumarate			S	Oral	10 Mg, Daily		Not Reported
	Lamotrigine			S	Oral	200 Mg, Daily		Not Reported
	Ramipril			S	Oral	5 Mg, Daily		Not Reported
	Clopidogrel Basics			S	Oral	75 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16632766	NON-EXPEDITED			US-SUNOVION-2019SUN002975			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Withdrawal Syndrome	Latuda			S	Oral	Unk		Sunovion
	Xanax			S				Not Reported
	Lexapro			S				Not Reported
	Vyvanse			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16632845	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1068840		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lymphoma	Escitalopram			S	Unknown	Unk		Not Reported
	Bromazepam			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16633799	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1929807US			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Medication Error; Product Administered To Patient Of Inappropriate Age; Tremor	Escitalopram Oxalate - Bp		S	Oral	12 Gtt	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	8114669	EXPEDITED (15-DAY)		DE, OT	PHHY2011PL76431		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Deep Vein Thrombosis; Embolism Venous; Embolism Venous; Pulmonary Embolism	Mirtazapine			S	Unknown	45 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown	30 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Quetiapine			S	Unknown	100 Mg, Qd		Novartis
	Paroxetine			S	Unknown	20 Mg, Qd		Not Reported
	Reboxetine			S	Unknown	4 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	5 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	25 Mg, Qd		Not Reported
	Sertraline			S	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16635509	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039007		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Furosemide			S	Oral			Not Reported
	Escitalopram			S	Oral			Cadila
	Bisoprolol			S	Oral			Not Reported
	Amlodipine			S	Oral			Zydus Pharm
	Lamotrigine			S	Oral			Not Reported
	Ramipril			S	Oral			Zydus Pharm
	Gabapentin			S	Oral			Not Reported
	Clopidogrel			S	Oral			Cadila

	Alprazolam		S	Oral		Not Reported
	Bisoprolol		S	Oral	Reduced Dose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16636726	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-215324		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Mirtazapine			S	Oral	30 Milligram Unk		Sun
	Escitalopram			S	Oral	60 Milligram Unik		Not Reported
	Alprazolam			S	Oral	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16639417	EXPEDITED (15-DAY)		DS, OT	BE-ALLERGAN-1930163US			Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tourette'S Disorder	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Trazolan			S	Unknown	Unk		Not Reported
	Rodizen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16639433	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1930164US			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Pancreatitis	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Valium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	14269725	EXPEDITED (15-DAY)		OT	CA-OTSUKA-2015_005094		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Abilify		S	Oral	2 Mg, Unk	Otsuka
	Cipralex		S	Unknown	20 Mg, Qd	Not Reported
	Serax		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16559973	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1063293		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	5 [Mg/D]		Not Reported
	Tetanus Vaccine			C	Transplacental	Unk		Mylan
	L-Thyroxin /00068002/			C	Transplacental	50 [Mg/D]		Mylan
	Folic Acid			C	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16640554	EXPEDITED (15-DAY)		OT	GB-ACCORD-149358		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642038	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2019022259			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Escitalopram			S	Oral	5 Milligram		Macleods
	Livial			C	Unknown	Unk		Not Reported
	Candesartan			C	Unknown	Unk		Not Reported
	Ezetimibe			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642498	NON-EXPEDITED			US-PFIZER INC-2019318210			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Doxepin Hcl			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Medrol			S		Unk		Pfizer
	Piroxicam			S		Unk		Pfizer
	Lodine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Savella			S		Unk		Not Reported
	Nucynta			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642590	NON-EXPEDITED			US-MYLANLABS-2019M1065555			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Tramadol			S	Oral	Unk		Not Reported
	Escitalopram			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16643033	EXPEDITED (15-DAY)		HO	FR-009507513-1907FRA013465		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall	Mirtazapine			S		30 Milligram, Qd		Merck
	Zopiclone			S	Oral	0.5 Dosage Form		Not Reported
	Escitalopram			S	Oral	15 Milligram, Qd		Not Reported

Seresta	S	Oral	5 Milligram, Qd		Not Reported
Amlodipine	S	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16643447	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1070445		62 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemorrhagic Diathesis; Injection Site Haemorrhage; Product Use In Unapproved Indication	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported
	Escitalopram			S		Unk		Not Reported
	Fluanxol Depot			C	Unknown	0.5 Milliliter		Mylan
	Nebivolol			C	Unknown	5 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16643869	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019320764		38 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bipolar Disorder; Drug Ineffective	Effexor			S		225 Mg, Unk		Pfizer
	Jzoloft			S				Pfizer
	Lexapro			S				Not Reported
	Cymbalta			S				Not Reported
	Mirtazapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16644242	EXPEDITED (15-DAY)		LT	FI-ASTRAZENECA-2019SF06175		51 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholic Pancreatitis	Ketipinor			S	Oral	Unknown, Every 12 Hours		Zeneca
	Ketipinor			S	Oral	Unknown, Every 12 Hours		Zeneca
	Escitalopram			S		Strength: 5mg		Not Reported
	Melatonin			S	Unknown	Strength: 3mg		Not Reported
	Burana			S	Unknown	As Needed		Not Reported

Paracetamol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16644493	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2019M1069893		22 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Obstruction; Product Use In Unapproved Indication	Aripiprazole			S	Unknown	400 Milligram		Not Reported
	Sipralexa			S	Unknown	20 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16644535	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1930304US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapyramidal Disorder; Overdose	Escitalopram Oxalate - Bp			S	Oral	30 Mg		Allergan
	Trevicta			S	Intramuscular			Not Reported
	Esidrex			C	Oral			Not Reported
	Irbesartan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16644772	EXPEDITED (15-DAY)		HO	KR-ANIPHARMA-2019-KR-000023		35 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinsonism	Lorazepam (Non-Specific)			S		1 Mg Daily		Ani
	Risperidone			S		3 Mg Daily		Not Reported
	Escitalopram			S		5 Mg Daily		Not Reported
	Zolpidem			S		12.5 Mg Daily		Not Reported
	Clonazepam			S		0.5 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16463162	NON-EXPEDITED			US-PFIZER INC-2019266999			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Pristiq			S		Unk		Pfizer
	Wellbutrin Sr			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16503672	EXPEDITED (15-DAY)		OT	PHHY2019LT148490		40 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Cough; Drug Reaction With Eosinophilia And Systemic Symptoms; Febrile Neutropenia; Hepatic Enzyme Increased; Intentional Self-Injury; Leukopenia; Liver Injury; Pneumonia; Product Use In Unapproved Indication; Pyrexia; Rash Maculo-Papular; Rash Pruritic; Thrombocytopenia	Carbamazepine			S	Unknown	600 Mg, Qd		Not Reported
	Carbamazepine			S	Unknown	300 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	15 Mg, Qd		Novartis
	Olanzapine			S	Unknown	10 Mg, Qhs		Novartis
	Olanzapine			S	Unknown	5 Mg, Qd		Novartis
	Olanzapine			S	Unknown	10 Mg, Qd		Novartis
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Bromazepam			S	Unknown	9 Mg, Qd		Not Reported
	Bromazepam			S	Unknown	3 Mg, Unk		Not Reported
	Zuclopentixol			S	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648085	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2019M1071215		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Abuse; Dry Mouth; Slow Speech	Lorazepam			S	Oral	20 Milligram, Total		Not Reported
	En 2 Mg Compresse			S	Oral	40 Milligram, Total		Mylan
	Cipralex /01588501/			S	Oral	300 Milligram, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648818	EXPEDITED (15-DAY)		OT	PHHY2019BR148441		43 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Lip Disorder; Memory Impairment; Nodule; Speech Disorder; Swelling; Tremor; Tremor; Weight Increased	Aripiprazole Sandoz			S	Unknown	10 Mg, Unk		Not Reported
	Aripiprazole Sandoz			S	Oral	15 Mg, Bid		Not Reported
	Aripiprazole Sandoz			S	Unknown	25 Mg, Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Rosuvastatin			S	Oral	10 Mg, Qd		Novartis
	Vitamin D			C	Oral	70000 Iu, Bid		Not Reported
	Xenical			C	Oral	120 Mg, Qd		Not Reported
	Omega 3			C	Oral	Unk, Qd		Not Reported
	Garlic			C	Oral	500 Mg, Bid		Not Reported
	Bio C			C	Oral	1000 Mg, Qd		Not Reported
	Citoneurin			C	Intramuscular	1 Df, Qmo		Not Reported
	Chlorthalidone			C	Oral	12.5 Mg, Qd		Not Reported
	Chlorthalidone			C				Not Reported
	Noripurum			C	Intramuscular	Unk Unk, Qmo (One Vial)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16649208	EXPEDITED (15-DAY)		DE	BE-MYLANLABS-2019M1071760		38 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Off Label Use	Escitalopram			S		1 Dosage Form, Qy		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16465592	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2019M1057781		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder; Suicidal Ideation; Withdrawal Syndrome	Venlafaxine		S	Unknown	Unk	Not Reported
	Venlafaxine		S	Unknown	Unk	Not Reported
	Mirtazapine		S	Oral	Unk	Not Reported
	Seroplex		S	Unknown	Unk	Mylan
	Seroplex		S	Unknown	Unk	Mylan
	Lysanxia		S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650061	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-215817		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Amlodipine			S	Oral	5 Milligram, Daily		Sun
	Bisoprolol			S	Oral	10 Milligram, Daily		Sun
	Clopidogrel			S	Oral	75 Milligram, Daily		Sun
	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Gabapentin			S	Oral	1200 Milligram, Daily		Ranbaxy
	Ramipril			S	Oral	5 Milligram, Daily		Ranbaxy
	Furosemide			S	Oral	40 Milligram, Daily		Not Reported
	Lamotrigine			S	Oral	200 Milligram, Daily		Not Reported
	Alprazolam			S	Oral	0.5 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650451	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-215818		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Esomeprazole			S	Oral	40 Milligram, Daily		Sun
	Gabapentin			S	Oral	1200 Milligram, Daily		Ranbaxy

	Oxynormoro 5 Mg, Comprime Orodispersible		S	Oral	()	Not Reported
	Nefopam (Chlorhydrate De)		S	Oral	()	Not Reported
	Alprazolam		S	Oral	0.5 Milligram, Daily	Not Reported
	Lamotrigine		S	Oral	200 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650467	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-215800		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Thrombocytopenia	Escitalopram			S	Oral	1/Jour		Not Reported
	Alfuzosin			S	Oral	1/Jour		Sun
	Acarbose			S	Oral	150 Milligram, Daily		Not Reported
	Risperdal 1 Mg/Ml, Solution Buvable			C	Oral	25/Jour (1), Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650918	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-044150			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Escitalopram			S	Oral	5 Milligram		Aurobindo
	Livial			C	Unknown	Unk		Not Reported
	Candesartan			C	Unknown	Unk		Not Reported
	Ezetimibe			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16652354	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20190740604		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Haemorrhage;	Rivaroxaban			S	Oral	15.0 Mg, Qd		Not Reported

Hypotension; Hypovolaemia; Motor Dysfunction; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression; Spinal Cord Oedema	Rivaroxaban	S				Not Reported
	Heparin Sodium	S	Subcutaneous	Unk, Bid		Not Reported
	Heparin Sodium	S				Not Reported
	Escitalopram	S	Unknown	Unk		Not Reported
	Bupivacaine	C		Unk		Not Reported
	Epinephrine	C		Unk		Not Reported
	Lidocaine	C	Topical	3.0 Ml		Not Reported
	Hydromorphone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16653725	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-2019VAL000320			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Furosemide			S	Oral	40 Mg, Qd		Validus
	Ramipril			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Bisoprolol Fumarate			S	Oral	10 Mg, Qd		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Amlodipine			S	Oral	5 Mg, Qd		Not Reported
	Lamotrigine			S	Oral	200 Mg, Unk		Not Reported
	Clopidogrel Bisulfate			S	Oral	75 Mg, Qd		Not Reported
	Gabapentin			S	Oral	1200 Mg, Unk		Not Reported
	Alprazolam			S	Oral	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16653739	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1930431US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Dependence; Dyspnoea; Expired	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

Product Administered; Malaise; Nervousness; Overdose; Poor Quality Sleep	Escitalopram Oxalate - Bp		S	Oral	Allergan
	Xarelto		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16653799	EXPEDITED (15-DAY)		LT	FI-ALLERGAN-1930429US			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholic Pancreatitis	Escitalopram Oxalate - Bp			S	Unknown	Strength: 5mg		Allergan
	Melatonin			S	Unknown	Strength: 3mg		Not Reported
	Burana			S	Unknown	As Needed		Not Reported
	Ketipinor			S	Oral	Strenght 25 Mg, Q12h		Not Reported
	Ketipinor			S				Not Reported
	Pandol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16653808	EXPEDITED (15-DAY)		HO	NO-MYLANLABS-2019M1071545			Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenal Stenosis; Foetal Exposure During Pregnancy	Furadantin			S	Transplacental	50 Milligram, Q8h		Mylan
	Mirtazapin Orion			S	Transplacental	15 Mg At Night If Necessary.		Mylan
	Seroquel			S	Transplacental	100 Milligram, Qd		Mylan
	Truxal /00012101/			S	Transplacental	2 Dosage Forms At Night. Strength Of Dosage Forms Not Known.		Mylan
	Cipralex /01588501/			S	Transplacental	5 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16653860	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1931021US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrioventricular Block; Bradycardia; Electrocardiogram Qt Prolonged; Syncope	Escitalopram Oxalate - Bp	S	Oral		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16653877	EXPEDITED (15-DAY)		OT	HR-JNJFOC-20190738493			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Loss Of Consciousness	Rispolept			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Kvetiapin Pharmas			S	Unknown			Not Reported
	Serpentil /01588502/			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16838762	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Product Dispensing Error; Product Dispensing Error	Lexapro			S	Oral			Not Reported
	Humalog			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	8026713	EXPEDITED (15-DAY)		DE, HO, OT	PL-PFIZER INC-2011153072		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Antibodies; Deep Vein Thrombosis; Pulmonary Embolism	Mirtazapine			S		30 Mg, Unk		Not Reported
	Mirtazapine			S		45 Mg, Unk		Not Reported
	Paroxetine			S		20 Mg, Unk		Unknown
	Reboxetine			S		4 Mg, Unk		Pfizer
	Sertraline Hcl			S		100 Mg, Unk		Pfizer
	Venlafaxine Hcl			S		225 Mg, Unk		Pfizer

	Escitalopram	S	20 Mg, Unk	Not Reported
	Quetiapine	S	100 Mg, Unk	Not Reported
	Quetiapine	S	300 Mg, Unk	Not Reported
	Olanzapine	S	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16456030	EXPEDITED (15-DAY)		HO, LT, OT	JP-LUPIN PHARMACEUTICALS INC.-2019-03748		26 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Interaction; Drug Interaction; Rhabdomyolysis; Serotonin Syndrome	Escitalopram Tablets			S	Oral	20 Milligram, Qd		Lupin
	Clomipramine			S	Oral	50 Milligram, Qd (Tablet)		Lupin
	Flunitrazepam			S	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16470246	EXPEDITED (15-DAY)		DE, OT	CA-APOTEX-2019AP016722		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective; Feeling Abnormal; Muscular Weakness; Suicidal Ideation	Escitalopram			S	Oral	Unk, Qd		Apotex
	Escitalopram			S				Apotex
	Escitalopram			S				Apotex
	Clonazepam			S	Oral	0.5 Mg, Tid		Apotex
	Clonazepam			S				Apotex
	Clonazepam			S				Apotex
	Zopiclone			S	Oral	7.5 Mg, Bid		Not Reported
	Zopiclone			S				Not Reported
	Zopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16577233	EXPEDITED (15-DAY)		HO	DE-TORRENT-00014623		19 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram		S	20 Mg, 1-0-0-0	Unknown
	Loratadin		S	10 Mg	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655496	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039243		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall	Zopiclone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Oxazepam			S	Oral			Not Reported
	Mirtazapine			S				Not Reported
	Amlodipine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655564	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-04749			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Mania	Escitalopram			S	Unknown	5 Milligram		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655907	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1086022		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall	Zopiclone			S	Oral	0.5 Dosage Form		Not Reported
	Escitalopram			S	Oral	15 Mg		Ivax
	Mirtazapine			S		30 Mg		Teva
	Amlodipine			S	Oral	5 Mg		Teva
	Seresta 10 Mg, Comprime			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655932	EXPEDITED (15-DAY)		CA, OT	US-ACCORD-149568			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Persistent Left Superior Vena Cava; Ventricular Septal Defect	Escitalopram			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16656683	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019323138		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall	Amlodipine Besilate			S	Oral	5 Mg, 1x/Day		Pfizer
	Zopiclone			S	Oral	0.5 Df, Unk		Not Reported
	Escitalopram			S	Oral	15 Mg, 1x/Day		Not Reported
	Seresta			S	Oral	5 Mg, 1x/Day		Not Reported
	Mirtazapine			S		30 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657858	EXPEDITED (15-DAY)		HO	PHHY2019FR176164		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Diltiazem			S	Oral	90 Mg, Qd		Novartis
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Ramipril			S	Oral	10 Mg, Qd		Not Reported
	Bromazepam			S	Oral	3 Mg, Qd		Not Reported
	Humalog			S	Subcutaneous	2 Iu, Unk		Not Reported
	Umuline			S	Subcutaneous	16 Ui Le Matin Et 3 Ui Le Soir		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658258	EXPEDITED (15-DAY)		OT	US-PRINSTON PHARMACEUTICAL INC.-2019PRN00720			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Colectomy; Crohn'S Disease; Depressed Mood; Malaise; Renal Cancer	Escitalopram			S		Unk		Prinston Pharmaceutical
	Apriso			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658270	EXPEDITED (15-DAY)		OT	IE-MYLANLABS-2019M1071512			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Product Substitution Issue	Escitalopram			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658725	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1931013US			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Medication Error; Tremor; Vomiting	Escitalopram Oxalate - Bp			S	Oral	1 Df, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	8111543	EXPEDITED (15-DAY)		DE, OT	PHHY2011PL76023		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Antibodies; Death; Deep Vein Thrombosis; Embolism Venous; Embolism Venous;	Paroxetine			S	Unknown	20 Mg, Qd		Not Reported
	Sertraline			S	Unknown	100 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	225 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown	30 Mg, Qd		Not Reported

Pulmonary Embolism	Mirtazapine		S	Unknown	45 Mg, Qd	Not Reported
	Escitalopram		S	Unknown	20 Mg, Qd	Not Reported
	Quetiapine		S	Unknown	100 Mg, Qd	Novartis
	Quetiapine		S	Unknown	300 Mg, Qd	Novartis
	Olanzapine		S	Unknown	5 Mg, Qd	Not Reported
	Reboxetine		S	Unknown	4 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16062343	EXPEDITED (15-DAY)		DE	BE-TEVA-2019-BE-1021544		38 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Off Label Use	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16600767	NON-EXPEDITED			US-CELGENEUS-USA-20190704170		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Gastric Disorder; Vomiting	Otezla			S	Oral	60 Milligram		Celgene
	Lexapro			S	Unknown			Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16617592	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP018511		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased;	Escitalopram			S	Oral	1 Df, Qd		Apotex
	Pantoprazole			S	Oral	1 Df, Qd		Apotex
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Xeljanz		S	Oral	1 Df, Bid	Not Reported
	Prednisone		C	Unknown	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16627898	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1068187			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram			S		Morning		Not Reported
	Azathioprine			S		With Or Just After Food		Not Reported
	Azathioprine			S		Morning, Lunch And Tea Time (With Or Just After Food/Meal)		Not Reported
	Mirtazapine			S		Night		Not Reported
	Olanzapine			S		5 Milligram, Qd		Not Reported
	Folic Acid			S		Morning		Not Reported
	Dihydrocodeine Mylan			S		Two To Be Taken Four Times A Day If Required.		Mylan
	Dihydrocodeine Mylan			S		Four Times Daily. With Or Just After Food/Meal		Mylan
	Ferrous Fumarate			S		Morning And Night		Mylan
	Ferrous Fumarate			S		Morning And Night		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16627977	EXPEDITED (15-DAY)		HO, LT, OT	JP-ALLERGAN-1929651US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Off Label Use; Seizure; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Overdose: 100 Tablets		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

Mirtazapine	C	Oral	3 Mg, Qd		Not Reported
Mirtazapine	C	Oral	6 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16629670	EXPEDITED (15-DAY)		DE, OT	PL-ELI_LILLY_AND_COMPANY-PL201907011955		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Antibodies; Antiphospholipid Antibodies Positive; Deep Vein Thrombosis; Embolism Venous; Embolism Venous; Pulmonary Embolism	Olanzapine			S	Unknown	5 Mg, Daily		Eli Lilly And Co
	Reboxetine			S	Unknown	4 Mg, Daily		Not Reported
	Quetiapine			S	Unknown	100 Mg, Daily		Not Reported
	Quetiapine			S	Unknown	300 Mg, Daily		Not Reported
	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported
	Escitalopram			S	Unknown	5 Mg, Daily		Not Reported
	Venlafaxine			S	Unknown	225 Mg, Daily		Not Reported
	Paroxetine			S	Unknown	20 Mg, Daily		Not Reported
	Sertraline			S	Unknown	100 Mg, Daily		Not Reported
	Mirtazapine			S	Unknown	30 Mg, Daily		Not Reported
	Mirtazapine			S	Unknown	45 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16659394	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-044308			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall	Zopiclone			S	Oral	0.5 Dosage Form		Not Reported
	Escitalopram			S	Oral	15 Milligram, Once A Day		Aurobindo
	Mirtazapine			S	Unknown	30 Milligram, Once A Day		Aurobindo
	Amlodipine			S	Oral	5 Milligram, Once A Day		Aurobindo
	Seresta			S	Oral	5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16659493	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019022305			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Attention Deficit/Hyperactivity Disorder; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 Milligram, Qd, 0. - 40.2. Gestational Week (First Trimester)		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16660040	EXPEDITED (15-DAY)		DE, HO, OT	PL-AUROBINDO-AUR-APL-2011-03696			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Antibodies; Death; Deep Vein Thrombosis; Embolism Venous; Pulmonary Embolism	Paroxetine			S	Unknown	20 Milligram, Daily		Aurobindo
	Sertraline			S	Unknown	100 Milligram, Daily		Aurobindo
	Mirtazapine			S	Unknown	30 Milligram, Daily		Not Reported
	Mirtazapine			S	Unknown	45 Milligram, Daily		Not Reported
	Venlafaxine			S	Unknown	225 Milligram, Daily		Not Reported
	Reboxetine			S	Unknown	4 Milligram, Daily		Not Reported
	Escitalopram			S	Unknown	20 Milligram, Daily		Not Reported
	Quetiapine			S	Unknown	100 Milligram, Daily		Not Reported
	Quetiapine			S	Unknown	300 Milligram, Daily		Not Reported
	Olanzapine			S	Unknown	5 Milligram, Daily		Not Reported
	Olanzapine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16660356	EXPEDITED (15-DAY)		DE, OT	PL-AUROBINDO-AUR-APL-2011-03601			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Embolism Venous;	Olanzapine			S	Unknown	Maximum Daily Dose Of		Aurobindo

Pulmonary Embolism				5mg	
	Paroxetine	S	Unknown	Maximum Daily Dose Of 20mg	Aurobindo
	Escitalopram	S	Unknown		Aurobindo
	Quetiapine	S	Unknown	Maximum Daily Dose Of 100mg	Aurobindo
	Quetiapine	S	Unknown	300 Milligram	Aurobindo
	Sertraline	S	Unknown	Maximum Daily Dose Of 100mg	Aurobindo
	Venlafaxine	S	Unknown	Maximum Daily Dose Of 225mg	Aurobindo
	Mirtazapine	S	Unknown	45 Mg,Unk,	Not Reported
	Mirtazapine	S	Unknown	Maximum Daily Dose Of 30mg	Not Reported
	Reboxetina	S	Unknown	Maximum Daily Dose Of 4mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664430	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1931006US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Attention Deficit/Hyperactivity Disorder; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664431	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1931011US			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Bruxism; Restless Legs Syndrome	Escitalopram Oxalate - Bp			S	Oral	15 Milligram Daily		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665120	EXPEDITED (15-DAY)		HO	FR-ACCORD-149930		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral			Not Reported
	Ramipril			S	Oral			Accord
	Bromazepam			S	Oral			Not Reported
	Diltiazem			S	Oral			Not Reported
	Humalog			S	Subcutaneous			Not Reported
	Umuline			S	Subcutaneous	16 Iu In The Morning And 3 Iu In The Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665212	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2019022361			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram			S	Unknown	Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	15244173	NON-EXPEDITED			US-PFIZER INC-2018315144		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Fentanyl Citrate			S		Unk		Unknown
	Gabapentin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Boniva			S		Unk		Not Reported

Lisinopril	S	Unk		Not Reported
Fosamax	S	Unk		Not Reported
Carbamazepine	S	Unk		Not Reported
Escitalopram	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16198661	EXPEDITED (15-DAY)		DS, OT	ES-MYLANLABS-2019M1034739		45 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Libido	Sertraline			S	Oral	50 Milligram, Qd		Not Reported
	Sertraline			S	Oral	100 Milligram, Qd		Not Reported
	Escitalopram			S		10 Mg, 1x/Day		Not Reported
	Enalapril			C		20 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16412184	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1924235US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Breast Feeding; Neonatal Respiratory Depression; Pregnancy	Escitalopram Oxalate - Bp			S	Transmammary	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16559711	NON-EXPEDITED			US-PFIZER INC-2019291589		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity; Rash Macular; Reaction To Excipient; Urticaria	Sertraline Hcl			S		25 Mg, 1x/Day		Pfizer
	Metoprolol Succinate			S		50 Mg, 1x/Day		Not Reported
	Benazepril Hydrochloride			S	Oral	20 Mg, 1x/Day		Not Reported
	Escitalopram			S		5 Mg, 1x/Day (10mg 1/2		Not Reported

				Pill At Bed)	
	Escitalopram	S		5 Mg, 1x/Day	Not Reported
	Hydralazine	S	Oral	12.5 Mg, 2x/Day (25mg 1/2 By Mouth)	Not Reported
	Silicon Dioxide, Colloidal	S		Unk	Not Reported
	Sodium Starch Glycolate Type A Potato	S		Unk	Not Reported
	Premarin	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16634813	EXPEDITED (15-DAY)		DE, OT	PL-ASTRAZENECA-2019SF05029		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Antibodies; Death; Deep Vein Thrombosis; Embolism Venous; Pulmonary Embolism	Quetiapine			S	Unknown			Zeneca
	Quetiapine			S	Unknown			Zeneca
	Reboxetine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16667886	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20190743390		42 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cognitive Disorder; Confusional	Tramadol/Apap			S	Unknown			Not Reported

State; Drug Interaction; Drug Interaction	Escitalopram	S	Oral			Not Reported
	Escitalopram	S	Oral			Not Reported
	Topiramate	S	Oral			Not Reported
	Trazodone	S	Oral			Not Reported
	Cannabidiol	S	Oral			Not Reported
	Olanzapine	S	Unknown			Not Reported
	Desloratadine	C	Oral	5 Mg, Unk		Not Reported
	Tizanidine	C	Oral	4 Mg, 1/Day		Not Reported
	Ibuprofen	C	Oral	Unk		Not Reported
	Dienogest	C	Oral	2 Mg, 1/Day		Not Reported
	Calcitriol	C	Oral	Unk		Not Reported
	Euthyrox	C	Unknown	175 Mcg, 1/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16669129	DIRECT					32 YR	Transgender	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Substitution Issue	Escitalopram 10 Mg Tablet			S	Oral	Quantity:1 Tablet(S);	1 WEEK	Torrent
	Tylenol			C				Not Reported
	Claratin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16669247	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1931934US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Incorrect Dose Administered; Off Label Use; Suicidal Ideation	Escitalopram Oxalate - Bp			S		20 Mg		Allergan
	Escitalopram Oxalate - Bp			S		15 Mg		Allergan
	Escitalopram Oxalate - Bp			S		Unk		Allergan
	Effexor Xr			S	Unknown	37.5 Mg		Not Reported
	Effexor Xr			S	Unknown	75 Mg		Not Reported

	Venlafaxine Hydrochloride	S	Unknown		Not Reported
	Quetiapine	C			Not Reported
	Seroquel	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16669957	EXPEDITED (15-DAY)		OT	GR-MYLANLABS-2019M1072611		39 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Insomnia; Psychomotor Hyperactivity	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	15979662	NON-EXPEDITED			US-PFIZER INC-2019064474		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ceftriaxone Sodium			S		Unk		Unknown
	Ciprofloxacin			S		Unk		Unknown
	Ibuprofen			S		Unk		Pfizer
	Aspirin [Acetylsalicylic Acid]			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Duloxetine Hcl			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671810	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-045981			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram			S	Unknown	Unk		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671915	EXPEDITED (15-DAY)		OT	HR-ROCHE-2366339			Male	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Loss Of Consciousness	Rivotril			S	Oral			Not Reported
	Kvetiapin Pharmas			S	Unknown			Not Reported
	Risperidon			S	Oral			Not Reported
	Serpentil [Escitalopram Oxalate]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672775	EXPEDITED (15-DAY)		HO	IE-MYLANLABS-2019M1072971		55 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Moclobemide			S		Unk		Not Reported
	Agomelatine			S		Unk		Not Reported
	Duloxetine			S		Unk		Not Reported
	Sertraline			S		Unk		Not Reported
	Fluoxetine			S		Unk		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Quetiapine			S		Unk		Not Reported
	Olanzapine			S		Unk		Not Reported
	Fluvoxamine			S		Unk		Not Reported
	Venlafaxine			S		Unk		Not Reported
	Amitriptyline Hydrochloride			S		Unk		Mylan
	Phenelzine Sulfate			S		Unk		Mylan
	Sodium Valproate			S		Unk		Mylan
	Lithium			S		Unk		Mylan
	Trimipramine			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672852	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1072733		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram			S		Unk		Not Reported
	Coaprovel			S	Oral			Mylan
	Urbason /00049601/			C				Mylan
	Paracetamol			C		Unk		Mylan
	Alprazolam			C		Unk		Mylan
	Eutirox			C				Mylan
	Pantoprazole Sodium Sesquihydrate			C		Unk		Mylan
	Alendronic Acid Sodium			C	Oral	70 Milligram		Mylan
	Colecalciferol			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672871	EXPEDITED (15-DAY)		HO, OT	CZ-MYLANLABS-2009S1002345		53 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Pulmonary Embolism; Sedation; Weight Increased	Olanzapine			S	Unknown	5 Mg,Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg/Day		Not Reported
	Alprazolam			S	Unknown	1 Mg/Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16673562	EXPEDITED (15-DAY)		HO	US-APOTEX-2019AP019728		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Headache; Hot Flush	Trazodone			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Citalopram			S	Unknown	Unk		Apotex

	Sertraline		S	Unknown	Unk	Apotex
	Fluoxetine		S	Unknown	Unk	Apotex
	Lurasidone		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674176	EXPEDITED (15-DAY)		DS, OT	CA-ALLERGAN-1931944US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Back Pain; Chest Pain; Chills; Confusional State; Decreased Appetite; Depression; Fatigue; Insomnia; Irritability; Libido Decreased; Memory Impairment; Somnolence; Suicidal Ideation; Thirst	Escitalopram Oxalate - Bp			S	Oral	97		Allergan
	Atorvastatin Calcium			C	Unknown	97		Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674177	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1931942US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mastitis	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	8123119	EXPEDITED (15-DAY)		DE, OT	PL-RANBAXY-2011RR-47274		69 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Embolism Venous	Paroxetine			S	Unknown	20 Mg/Day		Sun
	Sertraline			S	Unknown	100 Mg/Day		Sun
	Venlafaxine			S	Unknown	225 Mg/Day		Sun
	Mirtazapine			S	Unknown	30 Mg/Day		Sun
	Mirtazapine			S	Unknown	45 Mg/Day		Sun

Quetiapine	S	Unknown	100 Mg/Day		Sun
Quetiapine	S	Unknown	300 Mg/Day		Sun
Reboxetine	S	Unknown	4 Mg/Day		Not Reported
Escitalopram	S	Unknown	20 Mg/Day		Not Reported
Olanzapine	S	Unknown	5 Mg/Day		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16591013	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2019300678		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Neutropenia; Platelet Count Decreased; Tinnitus	Ibrance			S		125 (Unknown Unit), Cyclic		Pfizer
	Ibrance			S		100 Mg, Cyclic		Pfizer
	Ibrance			S		75 Mg, Cyclic (X21 Days)		Pfizer
	Lexapro			S		20 Mg, Unk		Not Reported
	Lexapro			S		10 Mg, Daily		Not Reported
	Zofran [Ondansetron]			C		4 Mg, As Needed		Not Reported
	Ativan			C		Unk, As Needed (0.5 To 1 Mg)		Not Reported
	Ativan			C				Not Reported
	Tylenol [Paracetamol]			C		500 Mg, As Needed		Not Reported
	Tizanidine			C		Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16675860	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2019-04726		72 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Escitalopram			S	Unknown	10 Milligram, Qd		Lupin
	Escitalopram			S	Unknown	5 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676931	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-216664		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Fall	Zopiclone			S	Oral	0.5 Dosage Form Unk		Not Reported
	Escitalopram			S	Oral	15 Milligram, Daily		Not Reported
	Mirtazapine			S	Unknown	30 Milligram, Daily		Sun
	Amlodipine			S	Oral	5 Milligram, Daily		Sun
	Seresta 10 Mg, Comprime			S	Oral	5 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676968	EXPEDITED (15-DAY)		OT	GB-TORRENT-00021455		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16677230	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-052440			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo
	Esomeprazole			S	Oral	20 Milligram, Daily		Aurobindo
	Furosemide			S	Oral	40 Milligram, Daily		Aurobindo
	Simvastatin			S	Oral	20 Milligram, Daily		Aurobindo
	Spironolactone			S	Oral	25 Milligram, Daily		Aurobindo
	Seresta			S	Oral	2 Dosage Form, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16677363	NON-EXPEDITED		OT	US-JNJFOC-20190743964			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cystitis Interstitial; Headache; Off Label Use; Pharyngeal Swelling; Product Use Issue; Swollen Tongue	Elmiron			S	Oral			Not Reported
	Elmiron			S	Oral			Not Reported
	Elmiron			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16677577	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019336372		22 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Linezolid			S		Unk		Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16678453	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMPANY-FR201907015331		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Humalog Lispro			S	Subcutaneous	2 International Unit, Unknown		Eli Lilly And Co
	Umuline			S	Subcutaneous	16 International Unit, In The Morning		Not Reported
	Umuline			S	Subcutaneous	3 International Unit, In The Evening		Not Reported
	Escitalopram			S	Oral			Not Reported
	Diltiazem			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported

	Bromazepam	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16678831	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-022136		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis	Venlafaxine			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16679357	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2019M1073222		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram			S	Transplacental	15 [Mg/D]		Not Reported
	L-Thyroxin /00068002/			C	Transplacental	50 [Mg/D]		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16680250	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1931951US			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Decreased	Escitalopram Oxalate - Bp			S		20 Mg, Unk		Allergan
	Mirtazapine			C				Not Reported
	Diazepam			C				Not Reported
	Ramipril			C				Not Reported
	Atorvastatin			C				Not Reported
	Apixaban			C				Not Reported
	Tamsulosin			C				Not Reported
	Torasemide			C				Not Reported
	Metformine			C				Not Reported
	Baldorat			C				Not Reported
	Levocarbidopa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16680255	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1931707US			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Overdose: 120mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16680313	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1931722US			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16680314	EXPEDITED (15-DAY)		HO	AT-ALLERGAN-1932039US			Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Airway Burns; Burning Sensation; Paraesthesia; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16682814	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Yawning	Celexa			S				Not Reported
	Lexapro			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681019	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS			Unknown	USA

INC.-2019-04637

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Confusional State; Delirium; Drug Hypersensitivity; Dyspepsia; Fatigue; Mental Status Changes; Nausea; Pruritus; Vomiting	Escitalopram			S	Unknown	Unk		Lupin
	Fluoxetine			S	Unknown	Unk		Lupin
	Cephalexin			S	Unknown	Unk		Lupin
	Duloxetine			S	Unknown	Unk		Lupin
	Oxycodone			S	Unknown	Unk		Novel Labs
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Novel Labs

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681314	EXPEDITED (15-DAY)		HO	FR-ACCORD-150541		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram			S	Oral			Not Reported
	Levothyrox			S	Oral	50 Micrograms, Scored Tablet		Not Reported
	Coumadine			S	Oral	5 Mg, Scored Tablet		Not Reported
	Ezetrol			S	Oral	10 Mg Tablet		Not Reported
	Clotiazepam			C	Oral			Not Reported
	Alfuzosine			C	Oral			Not Reported
	Cordarone			C		200 Mg, Scored Tablet		Not Reported
	Spiriva Respimat			C	Respiratory (inhalation)			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			C	Oral			Not Reported
	Pulmicort			C	Respiratory (inhalation)	200 Microg / Dose, Suspension For Inhalation In A Pressurized Bottle		Not Reported

	Coaprovel	C	Oral	300 Mg / 12.5 Mg Tablets	Not Reported
	Fucidine	C	Cutaneous	2 Percent, Ointment	Not Reported
	Janumet	C	Oral	50 Mg / 1000 Mg Film-Coated Tablets	Not Reported
	Tadenan	C	Oral	50 Mg Soft Capsule	Not Reported
	Mono Tildiem	C	Oral	300 Mg, Prolonged Release Capsule	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681336	EXPEDITED (15-DAY)		CA	US-HETERO-HET2019US01076			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S	Transplacental	Unk		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681425	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-046468			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Bromazepam			S	Oral	3 Milligram, Once A Day		Not Reported
	Diltiazem			S	Oral	90 Milligram, Once A Day		Not Reported
	Escitalopram			S	Oral	5 Milligram, Once A Day		Aurobindo
	Ramipril			S	Oral	10 Milligram, Once A Day		Aurobindo
	Umuline			S	Subcutaneous	16 Iu In The Morning And 3 Iu In The Evening		Not Reported
	Humalog			S	Subcutaneous	2 International Unit		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16682731	NON-EXPEDITED			US-PFIZER INC-2019338961		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Gabapentin			S		300 Mg, 3x/Day		Pfizer
	Pantoprazole			S	Oral	20 Mg, Daily		Pfizer
	Dexamethasone			S	Oral	4 Mg, 2x/Day		Not Reported
	Escitalopram			S	Oral	20 Mg, Daily (10 Mg, 2 Tablets Daily By Mouth)		Not Reported
	Tegretol			S	Oral	200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16684680	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1932262US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Dizziness; Fatigue; Hyperhidrosis; Hypertension; Myalgia; Panic Disorder; Salivary Hypersecretion; Vomiting	Escitalopram Oxalate - Bp			S	Oral	20 Mg		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Abilify			S	Unknown			Not Reported
	Abilify			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16684715	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1839199US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Fall	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Tercian			S	Oral	Unk		Not Reported
	Ciflox			S	Unknown	Unk		Not Reported
	Trivastal			S	Oral	50 Mg, Unk		Not Reported
	Lyrica			S	Oral	75 Mg, Unk		Not Reported
	Baclofene			S	Unknown	2 Df, Unk		Not Reported
	Takadol			S	Oral	1.5 Df, Unk		Not Reported
	Temesta (Lorazepam)			S	Oral	1 Df, Unk		Not Reported

Levothyrox	C	Oral	1 Df, Unk		Not Reported
Tahor	C	Oral	1 Df, Unk		Not Reported
Furosemide	C	Oral	20 Mg, Unk		Not Reported
Daflon	C	Oral	2 Df, Unk		Not Reported
Paralyoc	C	Oral	Unk		Not Reported
Previscan	C	Oral	Unk		Not Reported
Cordarone	C	Oral	0.5 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16684735	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1073757		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Tongue Biting	Escitalopram			S		20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16684952	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2019M1074249		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Clozapine			S	Oral	500 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Inexium			S	Oral	1500 Milligram, Qd		Mylan
	Xanax			S	Oral	0.75 Milligram, Qd		Mylan
	Ditropan			S	Oral	5 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16684955	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1932542US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Hot Flush	Escitalopram Oxalate - Bp			S	Unknown			Allergan

	Citalopram Hydrobromide - Bp	S	Unknown	Allergan
	Fluoxetine Hcl Unk	S	Unknown	Allergan
	Trazodone	S	Unknown	Not Reported
	Lurasidone	S	Unknown	Not Reported
	Sertraline	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16685066	EXPEDITED (15-DAY)		HO	FR-009507513-1908FRA002570		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Ezetrol			S	Oral	1 Dosage Form, Qd		Merck
	Levothyrox			S	Oral	1 Dosage Form, Qd		Not Reported
	Coumadine			S	Oral	1 Dosage Form, Qd		Not Reported
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Clotiazepam			C	Oral	5 Milligram, Qd		Not Reported
	Alfuzosin Hydrochloride			C	Oral	10 Milligram, Qd		Not Reported
	Cordarone			C		1 Dosage Form, Qd		Not Reported
	Spiriva Respimat			C	Respiratory (inhalation)	2 Dosage Form, Qd		Not Reported
	Esomeprazole			C	Oral	40 Milligram, Qd		Not Reported
	Pulmicort			C	Respiratory (inhalation)	4 Dosage Form, Qd; Formulation: Suspension For Inhalation		Not Reported
	Coaprovel			C	Oral	1 Dosage Form, Qd		Not Reported
	Fucidine (Fusidate Sodium)			C	Cutaneous	1 Dosage Form, Qd		Not Reported
	Janumet			C	Oral	2 Dosage Form, Qd		Not Reported
	Tadenan			C	Oral	2 Dosage Form, Qd		Not Reported
	Mono-Tildiem			C	Oral	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	15285226	EXPEDITED (15-DAY)		LT	FR-BAYER-2018-146724		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Fall	Ciflox			S	Unknown	Unk		Bayer
	Seroplex			S	Oral	1 Df, Unk		Not Reported
	Tercian			S	Oral	Unk		Not Reported
	Trivastal [Piribedil]			S	Oral	1 Df, Unk		Not Reported
	Lyrica			S	Oral	1 Df, Unk		Not Reported
	Baclofen			S	Unknown	2 Df, Unk		Not Reported
	Takadol			S	Oral	1.5 Df, Unk		Not Reported
	Temesta (Lorazepam)			S	Oral	1 Df, Unk		Not Reported
	Levothyrox			C	Oral	1 Df, Unk		Not Reported
	Tahor			C	Oral	1 Df, Unk		Not Reported
	Furosemide			C	Oral	20 Mg, Unk		Not Reported
	Paralyoc			C	Oral	Unk		Not Reported
	Previscan [Fluindione]			C	Oral	Unk		Not Reported
	Cordarone			C	Oral	0.5 Df, Unk		Not Reported
	Daflon [Diosmin;Hesperidin]			C	Oral	2 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16278163	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019184504		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Blood Pressure Fluctuation; Cardiac Disorder; Palpitations	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Lexapro			S		1 Pill		Not Reported
	Cymbalta			S		Unk		Not Reported
	Aspirin 81			C		81 Mg, Unk		Not Reported
	Biotin			C		1 Mg, Unk		Not Reported

	Caltrate [Calcium Carbonate;Colecalciferol]	C	Unk (Calcium Carbonate 250mg+ Colecalciferol 4iu)	Not Reported
	Prilosec [Omeprazole]	C	20 Mg, Unk	Not Reported
	Vitamin B12 [Cyanocobalamin]	C	Unk (2500 Mc)	Not Reported
	Meloxicam	C	Unk (7.5)	Not Reported
	Folic Acid	C	1 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16685409	EXPEDITED (15-DAY)		HO	FR-SA-2019SA219039		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Ramipril			S	Oral	10 Mg, Qd		Sanofi
	Escitalopram Oxalate			S	Oral	5 Mg, Qd		Not Reported
	Bromazepam			S	Oral	3 Mg, Qd		Not Reported
	Bromazepam			S	Unknown	Unk		Not Reported
	Diltiazem Hydrochloride			S	Oral	90 Mg, Unk		Sanofi
	Insulin Lispro			S	Subcutaneous	2 Iu, Unk		Sanofi
	Umuline			S	Subcutaneous	16 Ui Le Matin Et 3 Ui Le Soir		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16686059	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/19/0112897		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Fluoxetine Delayed-Release Capsules			S				Not Reported
	Venlafaxine Hydrochloride			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16686345	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1090117		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram			S				Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16686453	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1089456			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis	Amitriptyline			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Ivax
	Metoprolol /00376903/			S	Unknown	Unk		Actavis
	Ibuprofen			S	Unknown	Unk		Actavis
	Prednisolone			S	Unknown	25 Mg, Unk		Actavis
	Salbutamol			S	Unknown	Unk		Barr
	Prednisolon /00016201/			S	Unknown	Unk		Actavis
	Ibuprofen Hexal			S	Unknown	Unk		Not Reported
	Metoprolol Mylan /00376902/			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Implanon			S	Unknown	Unk		Not Reported
	Escitalopram Mylan			S	Unknown	Unk		Not Reported
	Escitalopram Hexal			S	Unknown	Unk		Not Reported
	Metoprolol Hexal			S	Unknown	Unk		Not Reported
	Metoprolol Stada			S	Unknown	Unk		Not Reported
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported
	Pantozol /01263204/			S	Unknown	Unk		Not Reported
	Ibuprofen Stada			S	Unknown	Unk		Not Reported
	Salbutamol Stada			S	Unknown	Unk		Not Reported
	Methotrexate Mylan			S	Unknown	Unk		Not Reported
	Prednisolon Jenapharm			S	Unknown	Unk		Not Reported

	Prednisolon Stada	S	Unknown	Unk	Not Reported
	Escitalopram Stada	S	Unknown	Unk	Not Reported
	Ellipta [Fluticasone Furoate\Vilanterol Trifenatate]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16687752	NON-EXPEDITED			US-PFIZER INC-2019342333		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nightmare; Off Label Use; Product Use In Unapproved Indication	Sertraline Hcl			S	Oral	25 Mg, 3x/Day		Pfizer
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16688939	EXPEDITED (15-DAY)		OT	CZ-MYLANLABS-2019M1072714			Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Sedation; Weight Increased	Olanzapine			S	Unknown	20 Milligram, Qd		Not Reported
	Escitalopram			S	Unknown	10 Milligram		Not Reported
	Lamotrigine			S	Unknown	25 Milligram		Not Reported
	Trazodone			S	Unknown	150 Milligram		Mylan
	Oxazepam			S	Unknown	15 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16689904	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1074225		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Hot Flush	Escitalopram			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Fluoxetine			S	Oral			Not Reported

	Sertraline	S	Unknown	Not Reported
	Alprazolam	S	Oral	Not Reported
	Lurasidone	S	Unknown	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	14510860	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2018TUS002973		34 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Crohn'S Disease; Fatigue; Headache; Hyperhidrosis; Hypoaesthesia; Insomnia; Loss Of Consciousness; Malaise; Male Orgasmic Disorder; Off Label Use; Rectal Haemorrhage	Vedolizumab			S	Intravenous (not otherwise specified)	300 Milligram		Takeda
	Vedolizumab			S	Intravenous (not otherwise specified)	300 Milligram		Takeda
	Vedolizumab			S	Intravenous (not otherwise specified)	300 Milligram, Q4weeks		Takeda
	Cipralex /01588501/			S	Unknown	Unk		Not Reported
	Allopurinol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15296536	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2018328674		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Fall	Lyrica			S	Oral	1 Df, Unk		Pfizer
	Seroplex			S	Oral	1 Df, Unk		Not Reported
	Tercian /00759302/			S	Oral	Unk		Not Reported
	Ciflox /00697202/			S	Unknown	Unk		Not Reported
	Trivastal /00397201/			S	Oral	1 Df, Unk		Not Reported
	Baclofen			S	Unknown	2 Df, Unk		Not Reported
	Takadol			S	Oral	1.5 Df, Unk		Not Reported
	Temesta /00273201/			S	Oral	1 Df, Unk		Not Reported
	Levothyrox			C	Oral	1 Df, Unk		Not Reported

Tahor	C	Oral	1 Df, Unk		Not Reported
Furosemide	C	Oral	20 Mg, Unk		Not Reported
Daflon /01026201/	C	Oral	2 Df, Unk		Not Reported
Paralyoc	C	Oral	Unk		Not Reported
Previscan /00789001/	C	Oral	Unk (According To Inr)		Not Reported
Cordarone	C	Oral	0.5 Df, Unk (5 Days A Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15508194	EXPEDITED (15-DAY)		DE, HO, OT	BE-ALLERGAN-1849439US			Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Dementia; Loss Of Consciousness; Mental Disorder; Psychotic Disorder; Wrong Product Administered	Escitalopram Oxalate - Bp			S	Oral	0.5 Df, Qd		Allergan
	Afebryl			C	Unknown	Unk		Not Reported
	Loortan			C				Not Reported
	Nobiten			C				Not Reported
	Amlor			C				Not Reported
	Venuroton			C				Not Reported
	Cardioasperine			C				Not Reported
	Cholemed			C				Not Reported
	Lormetazepan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15722239	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018224866			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Voltaren (Diclofenac Sodium)			S	Topical	Unk Unk, Qd		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Glaxosmithkline
	Escitalopram			S	Oral	20 Mg, Qd		Glaxosmithkline
	Nortriptyline			S	Oral	25 Mg, Qd		Not Reported
	Naproxen			S	Unknown	1000 Mg, Qd		Not Reported
	Naprelan			S	Unknown	1000 Mg, Qd		Not Reported

Cimzia	S	Subcutaneous	Unk		Not Reported
Tylenol	S	Topical	Unk Unk, Prn		Not Reported
Diclofenac (Diclofenac Sodium)	C	Unknown	Unk		Glaxosmithkline
Inflectra	C	Intravenous (not otherwise specified)	700 Mg, Every 6 Weeks		Not Reported
Inflectra	C	Intravenous (not otherwise specified)	600 Mg,/ Q 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
Inflectra	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15736924	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1857959US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alcohol Increased; Impulsive Behaviour	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Xanax			C	Unknown	Unk		Not Reported
	Kenzen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16558342	EXPEDITED (15-DAY)		HO	PHHY2019IT158363		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Diplopia; Malaise; Nausea; Vomiting	Tolep			S	Oral	Unk		Novartis
	Cipralex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16592140	EXPEDITED (15-DAY)		OT	PL-MYLANLABS-2019M1066498			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herbal Interaction; Serotonin Syndrome	Sertraline			S		Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported

	Escitalopram		S	Unknown	Unk	Mylan
	Ginseng /01384001/		S	Unknown	Unk	Mylan
	Echinacea Purpurea		S		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691130	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2019-052159			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Escitalopram			S	Oral	Unk		Aurobindo
	Baclofene			S	Oral	200 Milligram Total		Not Reported
	Antalnox			S	Oral	3300 Milligram Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691535	EXPEDITED (15-DAY)		HO	FR-ACCORD-150716		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral			Not Reported
	Furosemide			S	Oral			Accord
	Simvastatin			S	Oral			Accord
	Spironolactone			S	Oral			Accord
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			S	Oral			Not Reported
	Seresta			S	Oral	Strength: 10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691919	EXPEDITED (15-DAY)		DE	FR-ACCORD-150957		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Clozapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

	Inexium	S	Oral			Not Reported
	Ditropan	S	Oral	Scored Tablet		Not Reported
	Xanax	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691948	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1086618		7 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Attention Deficit/Hyperactivity Disorder; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 Milligram/Day		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691975	EXPEDITED (15-DAY)		HO	AT-LUPIN PHARMACEUTICALS INC.-2019-04942		64 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Escitalopram			S	Unknown	10 Milligram, Unk		Lupin
	Mirtazapine			S	Unknown	30 Milligram, Unk		Not Reported
	Bromazepam			S	Unknown	1.5 Milligram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691976	EXPEDITED (15-DAY)		HO	AT-LUPIN PHARMACEUTICALS INC.-2019-04929		65 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Escitalopram			S	Unknown	20 Milligram, Unk		Lupin
	Bupropion			S	Unknown	300 Milligram, Unk		Lupin
	Ziprasidone			S	Unknown	Unk		Lupin
	Mirtazapine			S	Unknown	30 Milligram, Unk		Not Reported
	Trazodone			S	Unknown	100 Milligram, Unk		Not Reported

	Thyroxine		S	Unknown	50 Microgram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691979	EXPEDITED (15-DAY)		HO	AT-LUPIN PHARMACEUTICALS INC.-2019-04943		35 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Escitalopram			S	Unknown	20 Milligram, Unk		Lupin
	Paroxetine			S	Unknown	100 Milligram, Unk		Lupin
	Quetiapine Fumarate			S	Unknown	300 Milligram, Unk		Lupin
	Olanzapine			S	Unknown	05 Milligram, Unk		Not Reported
	Pregabalin			S	Unknown	300 Milligram		Not Reported
	Amitriptyline			S	Unknown	100 Milligram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692211	EXPEDITED (15-DAY)		HO	AT-LUPIN PHARMACEUTICALS INC.-2019-04946		70 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Escitalopram			S	Unknown	20 Milligram, Unk (Dose Increased)		Lupin
	Pregabalin			S	Unknown	150 Milligram, Unk (Dose Increased)		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692212	EXPEDITED (15-DAY)		HO	AT-LUPIN PHARMACEUTICALS INC.-2019-04947		68 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Escitalopram			S	Unknown	15 Milligram, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692482	EXPEDITED (15-DAY)		HO	PHHY2019FR181862		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Furosemide			S	Oral	40 Mg, Qd		Novartis
	Simvastatine			S	Oral	20 Mg, Qd		Not Reported
	Esomeprazole			S	Oral	20 Mg, Qd		Not Reported
	Spironolactone			S	Oral	25 Mg, Qd		Not Reported
	Seresta			S	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692550	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019340500		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning; Somnolence	Xanax			S	Oral	20 Tablets		Pfizer
	Risperdal			S	Oral	4 Mg, Unk		Not Reported
	Zyprexa			S	Intramuscular	1 Vial (10 Mg)		Not Reported
	Escitalopram			S	Unknown	15 Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693760	EXPEDITED (15-DAY)		DE	FR-ASTRAZENECA-2019SF12983		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Inexium			S	Oral			Astrazeneca
	Escitalopram			S	Oral			Not Reported
	Ditropan			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported
	Clozapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694079	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR141115		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Voltaren Emulgel			S		1 Every 1 Week		Glaxosmithkline
	Escitalopram			S		1 Tablet, Qd		Glaxosmithkline
	Cosentyx			S	Subcutaneous	150 Mg, Once Every Week		Not Reported
	Methotrexate			S		Unk		Not Reported
	Povidone-Iodine			S		Unk		Not Reported
	Vitamin D3			S		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Remicade			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694577	EXPEDITED (15-DAY)		HO	FR-009507513-1908FRA002837		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Simvastatin			S	Oral	20 Milligram, Qd		Merck
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Furosemide			S	Oral	40 Milligram, Qd		Not Reported
	Seresta			S	Oral	2 Dosage Form, Qd		Not Reported
	Esomeprazole			S	Oral	20 Milligram, Qd		Not Reported
	Spironolactone			S	Oral	25 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694684	EXPEDITED (15-DAY)		HO, OT	GB-MYLANLABS-2019M1074710			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram	S	Oral	40 Milligram, Qd	Not Reported
	Fluoxetine	C		20 Milligram	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16485428	NON-EXPEDITED			US-JNJFOC-20190619402		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Blood Pressure Increased; Depression; Dizziness; Heart Rate Increased; Nausea; Pain; Palpitations; Panic Disorder; Vision Blurred	Ibrutinib			S	Oral	420 Mg, Qd		Not Reported
	Escitalopram			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16587744	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1928929US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Cyanosis; Foetal Exposure During Pregnancy; Hypotonia Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Tercian			S	Transplacental	45 Mg		Not Reported
	Seresta			S	Transplacental	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16686614	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1088015		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Confusional State; Decreased Appetite; Disorientation; Dry Mouth; Dyspnoea; Fatigue; Headache; Hypertension; Micturition Urgency; Nausea; Pallor; Palpitations; Pyrexia; Somnolence; Vertigo; Vomiting; Weight Decreased	Escitalopram Teva 10 Mg	S	Oral	10 Milligram Daily;		Ivax
	Noctamide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16695137	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039563		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral			Cadila
	Ramipril			S	Oral			Zydus Pharm
	Bromazepam			S	Oral			Not Reported
	Umuline			S	Subcutaneous	16 Iu At Am And 3 Iu At Pm		Not Reported
	Diltiazem/Diltiazem Hydrochloride/Diltiazem Malate			S	Oral			Not Reported
	Humalog			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16695266	EXPEDITED (15-DAY)		OT	IT-ACCORD-151145		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Escitalopram			S	Oral			Not Reported
	En			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16695751	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2019SF11372		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Esomeprazole			S	Oral			Astrazeneca
	Escitalopram			S	Oral			Not Reported
	Spironolactone			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Simvastatin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16695875	EXPEDITED (15-DAY)		HO	DE-DRREDDYS-GER/GER/19/0112970		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Vomiting	Escitalopram			S		20 Mg, 0-0-1-0		Not Reported
	Quetiapine			S		400 Mg, 0-0-1-0		Not Reported
	Pipamperon			S		40 Mg, 0-0-1-0		Not Reported
	Levothyroxine Sodium			C		112 Microgram, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16696174	EXPEDITED (15-DAY)		HO	DE-ACCORD-151211		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Vomiting	Quetiapine			S		400 Mg, 0-0-1-0		Not Reported
	Escitalopram			S		20 Mg, 0-0-1-0		Not Reported
	Pipamperone			S		40 Mg, 0-0-1-0		Not Reported
	Levothyroxine/Levothyroxine Sodium			C		112 Microg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699117	EXPEDITED (15-DAY)		OT	PHHY2019CA188460		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Voltaren Emulgel	S	Unknown	1 Df, Qw (1 Every 1 Week)	Not Reported
	Cosentyx	S	Subcutaneous	150 Mg, Qw (Once Every Week)	Novartis
	Escitalopram	S	Unknown	1 Df, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Povidone-Iodine	S	Unknown	Unk	Not Reported
	Vitamin D3	S	Unknown	Unk	Not Reported
	Enbrel	C	Unknown	Unk	Not Reported
	Humira	C	Unknown	Unk	Not Reported
	Remicade	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699331	EXPEDITED (15-DAY)		HO	PHHY2019DE182303		56 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations	Metoprolol			S	Unknown	47.5 Mg, Bid (1-0-1-0)		Not Reported
	Ramipril+Amlodipine			S	Unknown	1 Df, Qd		Not Reported
	Ramipril			S	Unknown	1 Df, Qd		Not Reported
	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
	Teriflunomide			C	Unknown	14 Mg, Qd (1-0-0-0)		Not Reported
	Atorvastatin			C	Unknown	40 Mg, Qd (0-0-1-0)		Not Reported
	Dabigatran			C	Unknown	150 Mg, Bid (1-0-1)		Not Reported
	Magnesium			C	Unknown	Nk Mg, 1-0-0-0, Brausetabletten		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699534	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1932101US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Escitalopram Oxalate - Bp			S	Oral			Allergan

Baclofene	S	Oral	200 Mg		Not Reported
Antalnox	S	Oral	3300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699614	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1932552US			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning; Somnolence	Escitalopram Oxalate - Bp			S	Unknown	15 Ml		Allergan
	Xanax			S	Oral	20 Tablets		Not Reported
	Risperdal			S	Oral	4 Mg		Not Reported
	Zyprexa			S	Intramuscular	1 Vial		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699652	EXPEDITED (15-DAY)		CA, OT	US-ALLERGAN-1932768US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Persistent Left Superior Vena Cava; Ventricular Septal Defect	Escitalopram Oxalate Unk			S	Transplacental	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699823	EXPEDITED (15-DAY)		HO	PHHY2019DE184930		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Vomiting	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Quetiapine			S	Unknown	400 Mg, Qd		Novartis
	Pipamperone			S	Unknown	40 Mg, Qd		Not Reported
	Levothyroxine Sodium			C	Unknown	112 Ug, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16702170	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	15305579	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-182217		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hyperthermia; Malaise; Nausea; Night Sweats; Pruritus; Serotonin Syndrome; Tremor	Tramadol			S	Oral	Inconnue ()		Sun
	Seroplex 15 Mg, Comprime Pellicule Secable			S	Oral	Inconnue ()		Not Reported
	Paracetamol			C	Oral	Inconnue ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	15724405	EXPEDITED (15-DAY)		HO	IE-BAUSCH-BL-2018-034714		55 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Moclobemide			S	Unknown			Not Reported
	Lithium			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported
	Duloxetine Hydrochloride			S	Unknown			Not Reported
	Sodium Valproate			S	Unknown			Not Reported

	Olanzapine	S	Unknown	Not Reported
	Mirtazapine	S	Oral	Not Reported
	Agomelatine	S	Unknown	Not Reported
	Trimipramine	S	Unknown	Not Reported
	Fluvoxamine Maleate	S	Unknown	Not Reported
	Phenelzine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700738	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-217490			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis	Metoprolol			S	Unknown	Unk		Sun
	Ibuprofen			S	Unknown	Unk		Ranbaxy
	Escitalopram			S	Unknown	Unk		Not Reported
	Salbutamol Stada			S	Unknown	Unk		Not Reported
	Metoprolol Stada			S	Unknown	Unk		Not Reported
	Escitalopram Mylan			S	Unknown	Unk		Not Reported
	Methotrexate Mylan			S	Unknown	Unk		Not Reported
	Prednisolon Jenapharm			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	25 Milligram, Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Pantozol			S	Unknown	Unk		Not Reported
	Metoprolol Mylan			S	Unknown	Unk		Not Reported
	Implanon			S	Unknown	Unk		Not Reported
	Metoprolol Hexal			S	Unknown	Unk		Not Reported
	Ibuprofen Hexal			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported

Prednisolon	S	Unknown	Unk		Not Reported
Escitalopram Hexal	S	Unknown	Unk		Not Reported
Prednisolon Stada	S	Unknown	Unk		Not Reported
Amitriptylin	S	Unknown	Unk		Not Reported
Escitalopram Stada	S	Unknown	Unk		Not Reported
Ibuprofen Stada	S	Unknown	Unk		Not Reported
Ellipta [Fluticasone Furoate\Vilanterol Trifenatate]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701334	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-052182			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Body Temperature Increased; Diarrhoea; Drug Interaction; Hyperhidrosis; Influenza Like Illness; Nasopharyngitis; Pain; Serotonin Syndrome	Mirtazapine Tablet			S	Oral	15.0 Milligram, Daily		Aurobindo
	Cipralex			S	Oral	5.0 Milligram, Daily		Not Reported
	Cipralex			S	Oral	20 Milligram, Daily		Not Reported
	Cipralex			S	Oral	10.0 Milligram, Daily		Not Reported
	Fluconazole			S	Oral	400.0 Milligram, Daily		Not Reported
	Fluconazole			S				Not Reported
	Zyvoxam			S	Oral	600 Milligram, Two Times A Day		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Atorvastatin Calcium			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Dimenhydrinate			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Ondansetron			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701739	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-052391			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Heart Rate Increased; Hepatic Enzyme Increased; Hypertension; Hypotension; Infusion Related Reaction; Rheumatoid Arthritis; Somnolence; Vein Collapse; Weight Increased	Mirtazapine Tablet			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo
	Cipralex			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	14 Milligram, Every Week		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Abilify			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			C	Oral	50 Milligram		Not Reported
	Fluoxetine			C	Unknown	Unk		Not Reported
	Lisinopril			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
	Oxycontin			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Sertraline Hydrochloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701750	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-052957			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Subdural Haematoma	Escitalopram	S	Oral	20 Milligram, Once A Day	Aurobindo
	Ezetrol	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Levothyrox	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Coumadine	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Clotiazepam	C	Oral	5 Milligram, Once A Day	Not Reported
	Alfuzosin	C	Oral	10 Milligram, Once A Day	Not Reported
	Cordarone	C	Unknown	1 Dosage Form, Once A Day	Not Reported
	Spiriva Respimat	C	Respiratory (inhalation)	2 Dosage Form, Once A Day	Not Reported
	Esomeprazole	C	Oral	40 Milligram, Once A Day	Not Reported
	Pulmicort	C	Respiratory (inhalation)	4 Dosage Form, Once A Day	Not Reported
	Coaprovel	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Janumet	C	Oral	2 Dosage Form, Once A Day	Not Reported
	Mono Tiazem Lp	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Tadenan	C	Oral	2 Dosage Form, Once A Day	Not Reported
	Fucidine	C	Cutaneous	1 Dosage Form, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701796	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1932717US		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	20 Mg		Allergan
	Ezetrol			S	Oral	1 Df, Unknown		Not Reported

Levothyrox	S	Oral	1 Df, Unknown		Not Reported
Coumadine	S	Oral	1 Df, Unknown		Not Reported
Clotiazepam	C	Oral			Not Reported
Alfuzosine	C	Oral			Not Reported
Cordarone	C	Unknown			Not Reported
Spiriva Respimat	C	Respiratory (inhalation)			Not Reported
Esomeprazole	C	Oral			Not Reported
Pulmicort	C	Respiratory (inhalation)			Not Reported
Coaprovel	C	Oral			Not Reported
Fucidine	C	Cutaneous	1 Df		Not Reported
Janumet	C	Oral			Not Reported
Tadenan	C	Oral			Not Reported
Mono Tildiem	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701944	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2019348520		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Xanax			S	Oral	0.75 Mg, 1x/Day		Pfizer
	Inexium [Esomeprazole Sodium]			S	Oral	1500 Mg, 1x/Day		Not Reported
	Ditropan			S	Oral	5 Mg, 1x/Day		Not Reported
	Escitalopram			S	Oral	20 Mg, 1x/Day		Not Reported
	Clozapine			S	Oral	500 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16702863	EXPEDITED (15-DAY)		HO, OT	CZ-TEVA-648211ISR		53 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Deep Vein Thrombosis; Pulmonary Embolism; Sedation; Weight Increased	Olanzapine		S	Oral	5 Milligram Daily;	Teva
	Escitalopram		S		10 Milligram Daily;	Ivax
	Alprazolam		S	Unknown	1 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16703039	EXPEDITED (15-DAY)		HO	DE-ASTRAZENECA-2019SF13715		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Vomiting	Quetiapine			S	Oral	400 Mg, 0-0-1-0		Zeneca
	Escitalopram			S	Unknown	20 Mg, 0-0-1-0 Non Az Product		Not Reported
	Pipamperone			S	Unknown	40 Mg, 0-0-1-0		Not Reported
	Levothyroxine Sodium			C		112 Ï¿½G, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16703054	EXPEDITED (15-DAY)		OT	CZ-TEVA-648359ISR		71 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Sedation; Weight Increased	Olanzapine			S	Oral	20 Milligram Daily; Antipsychotic Treatment		Teva
	Escitalopram			S	Unknown	10 Milligram Daily;		Ivax
	Trazodone			S	Unknown	150 Milligram Daily;		Not Reported
	Oxazepam			S	Unknown	15 Milligram Daily;		Not Reported
	Lamotrigine			S		25 Milligram Daily;		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16704039	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1075070		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Drug Interaction	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported

	Previscan /00789001/		S	Oral	15 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16704172	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1091201		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral			Ivax
	Diltiazem (Chlorhydrate De)			S	Oral			Teva
	Ramipril			S	Oral			Actavis
	Bromazepam			S	Oral			Not Reported
	Umuline			S	Subcutaneous	16 Iu In The Morning And 3 Iu In The Evening		Not Reported
	Humalog			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16704591	EXPEDITED (15-DAY)		OT	IT-ELI_LILLY_AND_COMPANY-IT201907016853		54 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poisoning; Somnolence	Zyprexa Im 10mg			S	Intramuscular	10 Mg, Unknown		Eli Lilly And Co
	Xanax			S	Oral	0.25 Mg, Other (20 Tablets)		Not Reported
	Risperdal			S	Oral	4 Mg, Unknown		Not Reported
	Escitalopram			S	Unknown	15 Ml, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	15709435	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018503440		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Balance Disorder; Bradycardia; Dizziness;	Amlodipine Besilate			S	Unknown	2.5 Mg, 1x/Day		Pfizer
	Amlodipine Besilate			S	Unknown	2.5 Mg, 2x/Day		Pfizer

Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder	Codeine	S	Unknown	30 Mg, 2x/Day	Not Reported
	Codeine	S	Unknown	30 Mg, 3x/Day	Not Reported
	Furosemide	S	Unknown	20 Mg, 1x/Day	Unknown
	Furosemide	S	Unknown	40 Mg, 1x/Day	Unknown
	Oxazepam	S	Unknown	10 Mg, 2x/Day	Pfizer
	Cipralex [Escitalopram]	S	Unknown	10 Mg, 1x/Day	Not Reported
	Cipralex [Escitalopram]	S			Not Reported
	Glyceryl Trinitrate	S	Transdermal	0.4 Mg, 2x/Day	Not Reported
	Glyceryl Trinitrate	S	Unknown	0.4 Mg, 1x/Day	Not Reported
	Metoprolol	S	Unknown	25 Mg, 1x/Day	Not Reported
	Metoprolol	S	Unknown	50 Mg, 1x/Day	Not Reported
	Ramipril	S	Unknown	5 Mg, 1x/Day	Not Reported
	Zopiclone	S	Unknown	2.5 Mg, 1x/Day	Not Reported
	Zopiclone	S	Unknown	5 Mg, 1x/Day	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Clopidogrel	C		Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Polyethylene Glycol	C		Unk	Not Reported
	Rabeprazole	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16670232	EXPEDITED (15-DAY)		OT	LT-BAUSCH-BL-2019-021837		40 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Treatment Noncompliance	Lorazepam			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Dexamethasone			S	Intravenous (not			Not Reported

			otherwise specified)		
	Dexamethasone	S			Not Reported
	Olanzapine	S	Unknown	Up To 15 Mg/Day	Not Reported
	Olanzapine	S	Unknown		Not Reported
	Olanzapine	S	Unknown		Not Reported
	Escitalopram	S	Unknown		Not Reported
	Sertraline	S	Unknown		Not Reported
	Quetiapine	S	Unknown		Not Reported
	Carbamazepine	S	Unknown	Up To 600 Mg/Day	Not Reported
	Carbamazepine	S	Unknown		Not Reported
	Carbamazepine	S	Unknown	After A Month Of Treatment	Not Reported
	Zuclopenthixol	S	Unknown		Not Reported
	Biseptol	S	Unknown		Not Reported
	Clemastine	S	Intramuscular		Not Reported
	Clemastine	S			Not Reported
	Bromazepam	S	Unknown		Not Reported
	Bromazepam	S	Unknown	3 Mg As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16707207	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019346811			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis	Premarin			S	Oral	0.625 Mg, 1x/Day		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Marijuana			S	Unknown	Unk, 1x/Day		Not Reported
	Pentasa			S	Unknown	Unk		Not Reported
	Propranolol Hydrochloride			S	Oral	40 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16707383	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1933029US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Labelled Drug-Disease Interaction Medication Error; Metrorrhagia; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Dinagest			S	Oral	1 Mg, Q12h		Not Reported
	Dinagest			S	Oral	1 Mg, Bid		Not Reported
	Bayaspirin			S	Oral	100 Mg, Qd		Not Reported
	Lamictal			C	Oral	150 Mg, Q12h		Not Reported
	E Keppra			C	Oral	500 Mg, Q12h		Not Reported
	Leuprorelin			C		1.88 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16707658	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2019-023106		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Diltiazem Hydrochloride			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Bromazepam			S	Unknown	Dose Reduced		Not Reported
	Humalog			S	Subcutaneous			Not Reported
	Humalog			S	Subcutaneous	Dose Increased		Not Reported
	Umuline			S	Subcutaneous	16 Iu In The Morning And 3 Iu In The Evening		Not Reported
	Umuline			S	Subcutaneous	Dose Increased		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16707978	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2019348636		56 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Glomerular Filtration Rate Decreased; Palpitations	Ramipril			S		5 Mg, Qd, 0-0-1-0		Pfizer
	Escitalopram Oxalate			S		5 Mg, Qd, 1-0-0-0		Not Reported
	Metoprolol			S		47.5 Mg, Bid, 1-0-1-0		Not Reported
	Amlodipine/Ramipril			S		5/5 Mg, 1-0-0-0		Not Reported
	Magnesium			C		1-0-0-0		Not Reported
	Teriflunomide			C		14 Mg, Qd, 1-0-0-0		Not Reported
	Atorvastatin			C		40 Mg, Qd, 0-0-1-0		Not Reported
	Dabigatran			C		150 Mg, Bid, 1-0-1-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	15808936	EXPEDITED (15-DAY)		HO	PHHY2019IT004170		30 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval Abnormal; Sopor; Speech Disorder; Substance Abuse	Escitalopram Oxalate			S	Oral	20 Mg, Total		Not Reported
	Quetiapine			S	Oral	25 Mg, Total		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16595899	EXPEDITED (15-DAY)		HO	ES-ZYDUS-038525		61 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Extrasystoles; Hypomagnesaemia	Enalapril/Hydrochlorothiazide			S				Not Reported
	Escitalopram			S				Cadila
	Omeprazole			S				Not Reported
	Trazodone/Trazodone Hydrochloride			S		()		Not Reported
	Metformin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16599649	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1929132US			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Diplopia; Malaise; Nausea; Product Use In Unapproved Indication; Vomiting	Escitalopram Oxalate - Bp			S		Overdose: Unknown Dose		Allergan
	Tolep			S	Oral	Overdose: Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16672466	EXPEDITED (15-DAY)		CA, OT	US-TORRENT-00009053			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Persistent Left Superior Vena Cava; Ventricular Septal Defect	Escitalopram			S	Transplacental	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16692147	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1074409		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Urinary Retention	Escitalopram			S	Oral	1/2-0-0		Not Reported
	Gabapentin			S	Oral	1-1-1. 1ª Semana 0-0-1 , 2ª Semana 0-1-1, 3ª Semana 1-1-1 Y Seguir Hasta Nueva Revisión		Mylan
	Zytram Bid			S	Oral	1-0-1. 1ª Semana 0-0-1 , 2ª Semana 1-0-1 Y Seguir Hasta Revisión		Mylan
	Nebivolol			C	Oral	Unk		Mylan
	Atorvastatina /01326101/			C	Oral	Unk		Mylan
	Acetylsalicylic Acid			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16708420	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01109			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Postpartum Haemorrhage	Escitalopram			S	Unknown	Unk		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16708430	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01131			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Postpartum Haemorrhage	Escitalopram			S	Unknown	Unk		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16708439	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01134			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Postpartum Haemorrhage	Escitalopram			S	Unknown	Unk		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16708482	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01135			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Postpartum Haemorrhage	Escitalopram			S	Unknown	Unk		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16708520	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01133			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maternal Exposure During Pregnancy; Postpartum Haemorrhage	Escitalopram		S	Unknown	Unk	Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16708528	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01132			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Postpartum Haemorrhage	Escitalopram			S	Unknown	Unk		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16708903	NON-EXPEDITED			PHEH2019US033733		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Lexapro			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16709004	EXPEDITED (15-DAY)		OT	US-APOTEX-2019AP020000		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Ineffective; Fatigue; Irritability	Fluoxetine			S	Unknown	Unk		Apotex
	Paroxetine			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16709221	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039724		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall	Escitalopram		S	Oral	Cadila
	Simvastatin		S	Oral	Zydus Pharm
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium		S	Oral	Not Reported
	Furosemide		S	Oral	Not Reported
	Spironolactone		S	Oral	Zydus Pharm
	Seresta		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16709229	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039693		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Ezetrol			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Coumadine			S	Oral			Not Reported
	Escitalopram			S	Oral			Zydus Pharm
	Clotiazepam			C	Oral			Not Reported
	Alfuzosin			C	Oral			Not Reported
	Cordarone			C				Not Reported
	Esomeprazole			C	Oral			Not Reported
	Pulmicort			C	Respiratory (inhalation)			Not Reported
	Coaprovel			C	Oral			Not Reported
	Fucidine			C	Cutaneous			Not Reported
	Janumet			C	Oral			Not Reported
	Tadenan			C	Oral			Not Reported
	Diltiazem			C	Oral			Not Reported
	Spiriva Respimat			C	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16709518	EXPEDITED (15-DAY)		HO, LT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2019022598			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Intentional Overdose	Escitalopram Oxalate			S	Oral	560 Milligram, Qd		Macleods
	Armopl - Armolipid Plus 20			S	Oral	6 Gram, Qd		Not Reported
	Magnesium			S	Oral	18 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16710350	NON-EXPEDITED			US-PFIZER INC-2019349799		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Effexor Xr			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16710610	EXPEDITED (15-DAY)		HO	DE-TORRENT-00015196		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Vomiting	Escitalopram			S		20 Mg, 0-0-1-0		Unknown
	Pipamperon			S		40 Mg, 0-0-1-0		Unknown
	Levothyroxine Sodium			C		112 G, 1-0-0-0		Unknown
	Quetiapin			S		400 Mg, 0-0-1-0		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16710899	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019344557		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall	Spironolactone	S	Oral	25 Mg, 1x/Day		Pfizer
	Esomeprazole Magnesium	S	Oral	20 Mg, 1x/Day		Unknown
	Escitalopram	S	Oral	10 Mg, 1x/Day		Not Reported
	Furosemide	S	Oral	40 Mg, 1x/Day		Not Reported
	Seresta	S	Oral	2 Df, 1x/Day		Not Reported
	Simvastatine	S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16711054	EXPEDITED (15-DAY)		HO	FR-PROVELL PHARMACEUTICALS-2073250		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Euthyrox			S	Oral			Provell Pharmaceuticals
	Ezetrol			S	Oral			Not Reported
	Coumadine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Clotiazepam			C				Not Reported
	Alfuzosine			C	Oral			Not Reported
	Cordarone			C				Not Reported
	Spiriva			C				Not Reported
	Esomeprazole			C	Oral			Not Reported
	Pulmicort			C				Not Reported
	Coaprovel			C	Oral			Not Reported
	Fucidine			C	Cutaneous			Not Reported
	Janumet			C	Oral			Not Reported
	Tadenan			C	Oral			Not Reported
	Mono Tildiem			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16711137	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1933560US			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Intentional Overdose	Escitalopram Oxalate - Bp	S	Oral	Overdose 1200 Mg	Allergan
	En	S	Oral	Overdose : 20 Ml	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16712671	EXPEDITED (15-DAY)		HO	PHHY2019AT188072		35 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Depressed Mood; Depression; Drug Resistance; Merycism	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported
	Quetiapine			S	Unknown	300 Mg, Unk		Novartis
	Pregabalin			S	Unknown	300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2019	15230890	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2018-033340			Unknown	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Depression; Dizziness; Fear-Related Avoidance Of Activities; Mental Impairment; Overdose; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Brintellix			S	Unknown	10 Milligram, Once A Day		Not Reported
	Tianeptine			C	Unknown	10 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2019	16558145	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-137849		61 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Extrasystoles;	Escitalopram			S				Not Reported
	Trazodone/Trazodone Hydrochloride			S				Not Reported
	Enalapril			S				Not Reported

Hypocalcaemia; Hypomagnesaemia	Maleate/Hydrochlorothiazide		
	Omeprazole	S	Not Reported
	Metformin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2019	16712803	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2019-053186			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Clozapine			S	Oral	500 Milligram, Once A Day		Aurobindo
	Inexium			S	Oral	1500 Milligram, Once A Day		Not Reported
	Ditropan			S	Oral	5 Milligram, Once A Day		Not Reported
	Xanax			S	Oral	0.75 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2019	16712981	EXPEDITED (15-DAY)		HO	DE-HETERO-HET2019DE01138		56 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations	Escitalopram			S	Unknown	5 Mg, A.M. (1-0-0-0)		Hetero
	Amlodipine W/Ramipril			S	Unknown	5/5 Mg, 1-0-0-0		Not Reported
	Ramipril			S	Unknown	5 Mg (0-0-1-0)		Not Reported
	Metoprolol			S	Unknown	47.5 Mg (1-0-1-0)		Not Reported
	Teriflunomide			C	Unknown	14 Mg, A.M. (1-0-0-0)		Not Reported
	Magnesium			C	Unknown	Nk Mg, 1-0-0-0, Brausetabletten		Not Reported
	Atorvastatin			C	Unknown	40 Mg (0-0-1-0)		Not Reported
	Dabigatran			C	Unknown	150 Mg, 1-0-1-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2019	16713018	EXPEDITED (15-DAY)		OT	GB-ACCORD-151409		74 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibromyalgia; Musculoskeletal Chest Pain	Escitalopram			S	Oral			Not Reported
	Bedranol			C				Not Reported
	Atorvastatin			C				Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2019	16713032	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2019-053569			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations	Ramipril			S	Unknown	5 Milligram, 0-0-1-0		Aurobindo
	Escitalopram			S	Unknown	5 Milligram, 1-0-0-0		Aurobindo
	Amlodipine;Ramipril			S	Unknown	5|5 Mg, 1-0-0-0		Not Reported
	Metoprolol			S	Unknown	47.5 Milligram, 1-0-1-0		Not Reported
	Magnesium			C	Unknown	Nk Mg, 1-0-0-0, Brausetabletten		Not Reported
	Teriflunomida			C	Unknown	14 Milligram, 1-0-0-0		Not Reported
	Atorvastatin			C	Unknown	40 Milligram, 0-0-1-0		Not Reported
	Dabigatran			C	Unknown	150 Milligram, 1-0-1-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16267767	EXPEDITED (15-DAY)			US-ELI_LILLY_AND_COMPANY-US201905000023			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Blood Pressure Abnormal; Drug Hypersensitivity; Palpitations	Cymbalta			S	Unknown	Unk Unk, Unknown		Eli Lilly And Co
	Lexapro			S	Unknown	Unk Unk, Unknown		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Biotin			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Caltrate [Calcium Carbonate;Colecalciferol]			C				Not Reported
	Prilosec [Omeprazole			C				Not Reported

Magnesium]			
Vitamin B12 [Cobamamide]	C		Not Reported
Meloxicam	C		Not Reported
Prilosec [Omeprazole]	C		Not Reported
Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16678341	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019331502		22 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Linezolid			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16682491	EXPEDITED (15-DAY)		OT	LT-PFIZER INC-2019334268		40 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Mood Altered; Treatment Noncompliance	Venlafaxine Hcl			S		150 Mg, Daily		Pfizer
	Olanzapine			S		5 Mg, Daily		Not Reported
	Olanzapine			S		10 Mg, Daily		Not Reported
	Escitalopram			S		10 Mg, Daily		Not Reported
	Lorazepam			S		1 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16685456	EXPEDITED (15-DAY)		OT	DE-HETERO-HET2019DE01055		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Escitalopram			S	Unknown	Unk		Hetero
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported
	Pantozol /01263204/			S	Unknown	Unk		Not Reported
	Amitriptylin			S	Unknown	Unk		Not Reported

	Metoprolol Hexal	S	Unknown	Unk	Not Reported
	Escitalopram Stada	S	Unknown	Unk	Not Reported
	Escitalopram Hexal	S	Unknown	Unk	Not Reported
	Metoprolol	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Metoprolol Stada	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Unknown	Unk (Ibuprofen Hexal)	Not Reported
	Ibuprofen Stada	S	Unknown	Unk	Not Reported
	Salbutamol Stada	S	Unknown	Unk	Not Reported
	Escitalopram Mylan	S	Unknown	Unk	Not Reported
	Prednisolon Stada	S	Unknown	Unk	Not Reported
	Implanon	S	Unknown	Unk	Not Reported
	Metoprolol /00376903/	S	Unknown	Unk	Not Reported
	Prednisolon Jenapharm	S	Unknown	Unk	Not Reported
	Prednisolon /00016201/	S	Unknown	Unk	Not Reported
	Methotrexate Mylan	S	Unknown	Unk, Qw	Not Reported
	Ibuprofen	S	Unknown	Ibuprofen Hormosan	Not Reported
	Prednisolone	S	Unknown	2.5 Milligram	Not Reported
	Salbutamol	S	Unknown	Unk	Not Reported
	Ellipta [Fluticasone Furoate\Vilanterol Trifenatate]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16696336	EXPEDITED (15-DAY)		DS, HO, LT	FI-JNJFOC-20190809768		75 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Imbruvica			S	Oral			Not Reported
	Primaspan			S	Oral	Once		Not Reported
	Cipralex /01588501/			S	Unknown			Not Reported
	Madopar			C	Unknown			Not Reported

	Florinef			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16714527	EXPEDITED (15-DAY)		HO	DE-LUPIN PHARMACEUTICALS INC.-2019-05194		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Vomiting	Escitalopram			S	Unknown	20 Milligram, Qd (0-0-1-0)		Lupin
	Quetiapine Fumarate			S	Unknown	400 Milligram, Qd (0-0-1-0)		Lupin
	Pipamperon			S	Unknown	40 Milligram, Qd (0-0-1-0)		Not Reported
	Levothyroxine Sodium			C	Unknown	112 Microgram, Qd (1-0-0-0)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16714765	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2019022604			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibromyalgia; Musculoskeletal Chest Pain	Escitalopram			S	Oral	5 Milligram		Macleods
	Bedranol			C	Unknown	10 Milligram		Not Reported
	Diazepam			C	Unknown	2 Milligram		Not Reported
	Atorvastatin			C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16714863	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019022559			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Vomiting	Escitalopram			S	Unknown	20 Milligram, Qd(0-0-1-0)		Macleods
	Quetiapine 400 Mg			S	Unknown	400 Milligram, Qd (0-0-1-		Macleods

				0)	
	Pipamperone	S	Unknown	40 Milligram, Qd (0-0-1-0)	Not Reported
	Levothyroxine Sodium	C	Unknown	112 Microgram, Qd (1-0-0-0)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16714900	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1076580		38 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sertraline			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lithium			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16715463	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR142097		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Voltaren Emulgel			S		Unk		Glaxosmithkline
	Voltaren Emulgel			S		Unk, Z		Glaxosmithkline
	Cosentyx			S	Subcutaneous	150.0 Ug, Unk (1 Every 1 Week)		Not Reported
	Cosentyx			S	Subcutaneous	150.0 Ug, Unk (1 Every 1 Month)		Not Reported
	Cosentyx			S		Unk		Not Reported
	Escitalopram			S		1 Df, Qd		Not Reported
	Methotrexate			S		Unk		Not Reported
	Povidone-Iodine			S		Unk		Not Reported
	Vitamin D3			S		Unk		Not Reported
	Remicade			C		Unk		Not Reported

Enbrel	C	Unk	Not Reported
Humira	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716089	EXPEDITED (15-DAY)		OT	HR-MYLANLABS-2019M1076778		27 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Suicide Attempt	Leponex			S	Oral	1250 Milligram		Mylan
	Byol Cor			S	Oral	75 Milligram		Mylan
	Elicea			S	Oral	280 Milligram		Mylan
	Zoloft			S	Oral	2800 Milligram		Mylan
	Siofor			S	Oral	120 Gram		Mylan
	Lacipil			S	Oral	112 Gram		Mylan
	Xanax			S	Oral	30 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717029	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2019-FR-1092930		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma	Escitalopram			S	Oral			Ivax
	Antalnox 550 Mg, Comprimé Pelliculé Sécable			S	Oral	3300 Milligram For Every 1 Total		Not Reported
	Baclofene			S	Oral	200 Milligram For Every 1 Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717259	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1933430US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anger; Anxiety; Arthropod	Escitalopram Oxalate - Bp			S	Unknown			Allergan

Bite; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cerebrovascular Accident; Contusion; Cough; Crying; Depressed Mood; Depression; Diarrhoea; Emotional Distress; Erythema; Fall; Fatigue; Feeling Jittery; Gait Disturbance; Head Banging; Headache; Hypoacusis; Inappropriate Schedule Of Product Administration; Joint Swelling; Malaise; Malignant Neoplasm Progression; Mental Disorder; Muscular Weakness; Nasopharyngitis; Nausea; Nervousness; Pain In Extremity; Peripheral Swelling; Pneumonia; Pollakiuria; Productive Cough; Psychiatric Symptom; Rash; Rib Fracture; Screaming; Suicidal Ideation; Suicide Attempt; Tremor; Unresponsive To Stimuli; Vasculitis; Wound; Wrist Fracture	Amlodipine	S	Unknown		Not Reported
	Ergocalciferol	S	Unknown		Not Reported
	Calcium Carbonate	S	Unknown		Not Reported
	Hydromorphone	S	Unknown		Not Reported
	Pantoprazole	S	Unknown		Not Reported
	Sandostatin	S	Subcutaneous	1 Df, Bid	Not Reported
	Sandostatin	S	Unknown	30 Mg, Q Month	Not Reported
	Sandostatin	S	Intramuscular	20 Mg, Q Month	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Perindopril	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Resotran	C	Unknown	28	Not Reported
	Olanzapine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717295	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1933505US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

Confusional State; Dizziness; Flushing; Heart Rate Increased; Loss Of Consciousness; Nausea

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717343	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1077407		15 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Derealisation; Drug Ineffective; Nausea	Escitalopram			S	Unknown			Not Reported
	Fluvoxamine			S	Unknown			Not Reported
	Imipramine			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Clonazepam			S				Not Reported
	Lorazepam			S	Unknown			Not Reported
	Lorazepam			S				Not Reported
	Prazosin			S	Unknown			Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Ziprasidone			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Ketamine			S	Other	Received Six Infusions Of Ketamine 0.5 Mg/Kg Per Infusion For A Span Of 3 Weeks, Beginning With T...		Not Reported
	Chlorpromazine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717461	EXPEDITED (15-DAY)		OT	HR-TAKEDA-2019TUS048595			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Mydriasis; Somnolence; Suicide Attempt	Brintellix	S	Oral	10 Milligram		Takeda
	Elicea /01588502/	S	Oral	100 Milligram		Not Reported
	Velafax	S	Oral	1500 Milligram		Not Reported
	Tramadol	S	Oral	Unk		Not Reported
	Olandix	S	Oral	2.5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717849	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-1933606US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Disturbance In Attention; Inappropriate Antidiuretic Hormone Secretion; Pneumonia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Amaluet			C	Oral	1 Df, Qd		Not Reported
	Zolpidem Tartrate			C	Oral			Not Reported
	Belsomra			C	Oral	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16560184	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2019022056			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Extrasystoles; Hypocalcaemia; Hypomagnesaemia	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Omeprazole			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Tablet, Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16691987	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019344074		86 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Ramipril			S	Oral	10 Mg, Qd		Pfizer
	Escitalopram Oxalate			S	Oral	5 Mg, Qd		Not Reported
	Bromazepam			S	Oral	3 Mg, Qd		Not Reported
	Bromazepam			S	Unknown	Unk		Not Reported
	Diltiazem Hydrochloride			S	Oral	90 Mg, Unk		Not Reported
	Humalog			S	Subcutaneous	2 Iu, Unk		Not Reported
	Umuline			S	Subcutaneous	16 Iu In The Morning And 3 Iu In The Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718891	EXPEDITED (15-DAY)		OT	DE-HETERO-HET2019DE01154		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Vomiting	Escitalopram			S	Unknown	20 Mg, Qd, 0-0-1-0		Not Reported
	Pipamperon			S	Unknown	40 Mg, Qd, 0-0-1-0		Not Reported
	Quetiapin			S	Unknown	400 Mg, Qd, 0-0-1-0		Not Reported
	Levothyroxine Sodium			C	Unknown	112 Ug 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718921	EXPEDITED (15-DAY)		DE	FR-ZYDUS-039769		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Escitalopram			S	Oral			Cadila
	Inexium			S	Oral			Not Reported
	Ditropan			S	Oral	Scored Tablet		Not Reported
	Xanax			S	Oral	Scored Tablet		Not Reported
	Clozapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718936	EXPEDITED (15-DAY)		HO, LT	ES-ZYDUS-039841		32 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Intentional Overdose	Escitalopram			S	Oral			Cadila
	Magnesium Lactate			S	Oral	In Total		Not Reported
	Armopl/Armolipid Plus 20			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16719127	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-054877			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dehydration; Hyperkalaemia	Esomeprazole			S	Oral	20 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Aldactone			S	Oral	12.5 Milligram, Once A Day		Not Reported
	Fungizone			S	Unknown	Unk		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported
	Lasilix			S	Oral	40 Milligram, Once A Day		Not Reported
	Diffu K			S	Oral	1800 Milligram, Once A Day		Not Reported
	Renutryl			C	Unknown	Unk		Not Reported
	Lysanxia			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16719322	NON-EXPEDITED			US-TAKEDA-2019TJP018935		87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Prevacid			S	Unknown	Unk		Takeda
	Metformin			S	Unknown	Unk		Not Reported

	Lexapro		S	Unknown	Unk	Not Reported
	Prozac		S	Unknown	Unk	Not Reported
	Carbidopa Monohydrate W/Levodopa		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16719664	EXPEDITED (15-DAY)		CA, HO	CA-GLENMARK PHARMACEUTICALS-2019GMK042712			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Gabapentin			S	Transplacental	1800 Mg, Od		Glenmark
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Od		Not Reported
	Rabeprazole			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	20 Mg, Od		Not Reported
	Quetiapine			S	Transplacental	300 Mg, Bid (1 Every 12 Hours)		Not Reported
	Zopiclone			S	Transplacental	Unk		Not Reported
	Methadose Dye-Free, Sugar-Free, Unflavored			S	Transplacental	70 Mg, Od		Not Reported
	Nortriptyline			S	Transplacental	20 Mg, Od		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16720488	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1933490US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Escitalopram Oxalate - Bp			S	Oral	20 Mg		Allergan
	Inexium			S	Oral	1500 Mg		Not Reported
	Ditropan			S	Oral	5 Mg		Not Reported
	Xanax			S	Oral	0.75 Mg		Not Reported
	Clozapine			S	Oral	500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16720508	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1933796US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Vomiting	Escitalopram Oxalate - Bp			S		20 Mg, 0-0-1-0		Allergan
	Pipamperon			S		40 Mg, 0-0-1-0		Not Reported
	Quetiapin			S		400 Mg, 0-0-1-0		Not Reported
	Levothyroxine Sodium			C		112 Mg, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721616	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS-2019M1076507		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Malaise; Pain	Alprazolam Mylan 0,25 Mg			S	Oral	1 Dosage Form, Qd		Mylan
	Rivastigmine Mylan Pharma 9,5 Mg/24 Heures, Dispositif Transdermique			S	Transdermal	1 Dosage Form, Qd		Mylan
	Paracetamol,Tramadol Mylan			S	Oral	Unk		Mylan
	Escitalopram Mylan Generiques 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Form, Qd,1 Cp Matin		Mylan
	Levodopa/Carbidopa Teva			S	Oral	1 Dosage Form, Qd,1 Cp Au Coucher		Mylan
	Modopar			S	Oral	4 Dosage Form, Qd, 2cp À 16h Et 2cp Le Soir		Mylan
	Clozapine Merck			S	Oral	1 Dosage Form, Qd,1 Cp Le Soir		Mylan
	Acupan			S		4 Dosage Form, Qd		Mylan
	Doliprane			S	Oral	Unk		Mylan
	Sinemet			S	Oral	2 Dosage Form, Qd,1cp Matin Et 1cp Midi		Mylan
	Dutasteride Sandoz			S	Oral	1 Dosage Form, Qd		Mylan

Oxynormoro	S	Oral	4 Dosage Form, Qd,Si Douleur		Mylan
Monocrixo	S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721708	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1093265		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haematoma	Escitalopram			S	Oral			Ivax
	Ezetrol 10 Mg, Comprimé			S	Oral			Not Reported
	Levothyrox 50 Microgrammes, Comprimé Sécable			S	Oral			Not Reported
	Coumadine 5 Mg, Comprimé Sécable			S	Oral			Not Reported
	Clotiazepam			C	Oral			Not Reported
	Alfuzosine (Chlorhydrate D')			C	Oral			Not Reported
	Cordarone 200 Mg, Comprimé Sécable			C				Not Reported
	Spiriva Respimat			C	Respiratory (inhalation)			Not Reported
	Esomeprazole			C	Oral			Not Reported
	Pulmicort 200 Ug/Dose, Suspension Pour Inhalation En Flacon Pressurisé			C	Respiratory (inhalation)			Not Reported
	Coaprovel 300 Mg/12,5 Mg, Comprimé			C	Oral			Not Reported
	Fucidine 2 Pour Cent, Pommade			C	Cutaneous			Not Reported
	Janumet 50 Mg/1000 Mg, Comprimé Pelliculé			C	Oral			Not Reported
	Tadenan 50 Mg, Capsule Molle			C	Oral			Not Reported
	Mono Tildiem Lp 300 Mg, Gélule À Libération Prolongée			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721745	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-MYLANLABS-2019M1077239		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Blindness Cortical; Cardiogenic Shock; Cerebral Infarction; Circulatory Collapse; Colour Blindness; Condition Aggravated; Csf Pressure Increased; Cytotoxic Oedema; Depressed Level Of Consciousness; Electrocardiogram P Wave Abnormal; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Amplitude Decreased; Electrocardiogram T Wave Inversion; Electrocardiogram U Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema; Renal Tubular Necrosis; Retinal Ischaemia; Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment	Mylan-Escitalopram			S	Oral	Unk		Mylan
	Amlodipine			S	Oral	Unk		Mylan
	Amlodipine			S	Oral	150 Milligram		Mylan
	Epinephrine			S	Unknown	30 Microgram		Mylan
	Escitalopram			S	Unknown	60 Milligram, Qd		Mylan
	Escitalopram			S	Oral	Unk		Mylan
	Glucose			S	Unknown	Unk		Mylan
	Norepinephrine Bitartrate			S	Intravenous (not otherwise specified)	30 Microgram		Mylan
	Potassium Chloride			S	Intravenous (not otherwise specified)	Unk		Mylan
	Potassium Chloride			S	Oral	Unk		Mylan
	Risperidone			S	Unknown	6 Milligram, Qd		Mylan
	Risperidone			S	Oral	6 Milligram		Mylan
	Vasopressin			S	Unknown	Unk		Mylan
	Activated Charcoal			C		Unk		Mylan
	Calcium Gluconate			C		Unk		Mylan
	Dextrose			C		Unk		Mylan
	Epinephrine			C		Unk		Mylan
	Escitalopram			C		Unk		Mylan
	Glucagon			C		Unk		Mylan
	Insulin			C		Unk		Mylan
	Norepinephrine			C		Unk		Mylan
	Potassium Chloride			C		Unk		Mylan
	Risperidone			C		Unk		Mylan
	Vasopressin			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722010	EXPEDITED (15-DAY)		OT	PHHY2019CA194095		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Cosentyx			S	Subcutaneous	150 Ug, Qw (1 Every 1 Week)		Novartis
	Cosentyx			S	Subcutaneous	150 Ug, Qmo (1 Every 1 Month)		Novartis
	Cosentyx			S	Unknown	Unk		Novartis
	Voltaren Emulgel			S	Unknown	Unk		Not Reported
	Voltaren Emulgel			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Povidone-Iodine			S	Unknown	Unk		Not Reported
	Vitamin D3			S	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	14461442	EXPEDITED (15-DAY)		OT	BE-TEVA-2018-BE-851750		41 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy	Xyzall Tablet			S	Unknown	5 Mg, Once Daily (Qd)		Teva
	Ventolin			S	Unknown	100 ?G, Unk		Not Reported
	Xanthium (Theophylline)			S	Unknown	200 Mg, Once Daily Qd		Not Reported
	Avamys Nasal Spray			S	Unknown	2 Unk, Bid		Not Reported
	Mepolizumab Powder For Solution For Injection			S	Subcutaneous	100 Mg, Unk		Not Reported
	Vilanterol Trifenatate Inhalation Powder			S		1 Daily; Unk, Unk, Qd		Not Reported

	Seretide	S	Unknown	Unk	Not Reported
	Fluticasone Furoate Inhalation Powder	S		Unk, Once Daily (Qd)	Not Reported
	Flixotide	S	Unknown	500 Milligram Daily; 250 ?G, 2x/Day (Bid)	Not Reported
	Pantomed (Pantoprazole)	S	Unknown	20 Milligram Daily; 20 Mg, Once Daily (Qd)	Not Reported
	D-Cure	S	Unknown	25 Kiu, Unk	Not Reported
	Sipralexa Tablet	S	Unknown	10 Mg, Z, Tablet	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	14760635	EXPEDITED (15-DAY)		HO, LT	CZ-ROCHE-2102288			Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning; Toxicity To Various Agents	Clonazepam			S	Oral			Not Reported
	Melperone			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Levomepromazine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Metoclopramide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	15830438	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2019SE04570		30 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval Abnormal; Sopor; Speech Disorder; Substance Abuse	Quetiapine			S	Oral	25.0mg Once/Single Administration		Zeneca
	Escitalopram Oxalate			S	Oral	20.0mg Once/Single Administration		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16078756	EXPEDITED (15-DAY)		CA, HO	CA-GLENMARK PHARMACEUTICALS-2019GMK040190			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Gabapentin			S	Transplacental	1800 Mg, Od (1 Every 1 Day)		Glenmark
	Gabapentin			S	Transplacental	Unk		Glenmark
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Od (1 Every 1 Day)		Not Reported
	Benztropine Mesylate			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	20 Mg, Od (1 Every 1 Day)		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported
	Methadose Dye-Free, Sugar-Free, Unflavored			S	Transplacental	70 Mg, Od (1 Every 1 Day)		Not Reported
	Methadose Dye-Free, Sugar-Free, Unflavored			S	Transplacental	Unk		Not Reported
	Nortriptyline			S	Transplacental	20 Mg, Od (1 Every 1 Day)		Not Reported
	Nortriptyline			S	Transplacental	Unk		Not Reported
	Quetiapine			S	Transplacental	300 Mg, Bid (1 Every 12 Hours)		Not Reported
	Quetiapine			S	Transplacental	Unk		Not Reported
	Rabeprazole			S	Transplacental	Unk		Not Reported
	Zopiclone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16259829	EXPEDITED (15-DAY)		HO, OT	CA-USPHARMA LIMITED-2019-CA-000026		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Dislocation; Device Malfunction; Drug Ineffective	Nitro-Dur			S	Unknown			Uspharma
	Dexilant			S	Unknown	Delayed Release Capsule		Not Reported

Diltiazem	S	Unknown	Not Reported
Emo Cort	S	Topical	Not Reported
Escitalopram	S	Unknown	Not Reported
Jamp Asa	S	Unknown	Not Reported
Metonia	S	Unknown	Not Reported
Mylan Nitro	S	Oral	Not Reported
Nasonex	S	Nasal	Not Reported
Ratio-Zopiclone	S	Unknown	Not Reported
Rosuvastatin Calcium	S	Unknown	Not Reported
Amlodipine Besilate	S	Unknown	Not Reported
Synthroid	S	Unknown	Not Reported
Bisoprolol	S	Unknown	Not Reported
Triatec [Ramipril]	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Tamsulosin	S	Unknown	Not Reported
Trazodone	S	Unknown	Not Reported
Brilinta	S	Unknown	Not Reported
Ciclopirox Olamine	S	Unknown	Not Reported
Clonazepam	S	Unknown	Not Reported
Delatestryl	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16723290	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-182445		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Fall	Baclofen			S	Unknown	2 Dosage Form, Unk		Sun
	Seroplex			S	Oral	1 Dosage Form, Unk		Not Reported
	Tercian			S	Oral	Unk		Not Reported

	Ciflox	S	Unknown	Inconnue	Not Reported
	Trivastal	S	Oral	Unk	Not Reported
	Lyrica	S	Oral	1 Dosage Form, Unk	Not Reported
	Takadol	S	Oral	1 Df, Unk	Not Reported
	Temesta (Lorazepam)	S	Oral	1 Dosage Form, Unk	Not Reported
	Levothyrox	C	Oral	1 Dosage Form	Not Reported
	Tahor	C	Oral	1 Dosage Form	Not Reported
	Furosemide	C	Oral	20 Mg, Unk	Not Reported
	Daflon	C	Oral	2 Dosage Form, Unk	Not Reported
	Paralyoc	C	Oral	Inconnue ()	Not Reported
	Previscan	C	Oral	Selon Inr ()	Not Reported
	Cordarone	C	Oral	0.5 Dosage Form, 5 Jours Par Semaine	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16723381	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2019-054444			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Vomiting	Escitalopram			S	Unknown	20 Milligram, Once A Day, 0-0-1-0		Aurobindo
	Quetiapine			S	Unknown	400 Milligram, Once A Day, 0-0-1-0		Aurobindo
	Pipamperone			S	Unknown	40 Milligram, Once A Day, 0-0-1-0		Not Reported
	Levothyroxine Sodium			C	Unknown	112 Microgram, Once A Day, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16724184	EXPEDITED (15-DAY)		OT	GB-TORRENT-00021626		74 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fibromyalgia; Musculoskeletal Chest Pain	Bedranol	C			Unknown
	Atorvastatin	C			Unknown
	Escitalopram	S	Oral		Unknown
	Diazepam	C			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16724547	EXPEDITED (15-DAY)		OT	US-VANDA PHARMACEUTICALS, INC-2019TASUS003285			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Hetlioz			S		20 Mg, Qd		Vanda Pharmaceuticals
	Wellbutrin			S				Not Reported
	Lexapro			S				Not Reported
	Zantac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16725436	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1934200US			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibromyalgia; Musculoskeletal Chest Pain	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Bedranol			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Diazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16725438	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1077994			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscle Disorder; Rhabdomyolysis	Escitalopram			S	Unknown	20 Milligram		Not Reported
	Lavitan A Z Mais			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16725464	NON-EXPEDITED			US-TEVA-2019-US-1093852			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hyperhidrosis	Escitalopram Tablets			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726035	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1934402US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Jaundice; Nausea; Pruritus	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Theralene			S	Oral	20 Mg, Qd		Not Reported
	Largactil			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726241	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1094670		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	10mg		Ivax
	Furosemide			S	Oral	40mg		Not Reported
	Simvastatine			S	Oral	20mg		Ivax
	Esomeprazole			S	Oral	20mg		Teva
	Spironolactone			S	Oral	25mg		Actavis
	Seresta 10 Mg, Comprimé			S	Oral	2 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726368	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019AMR149267			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arteriosclerosis Coronary Artery; Asthma; Blood Count Abnormal; Condition Aggravated; Conjunctivitis Allergic; Dust Allergy; Hypoxia; Mite Allergy; Mycotic Allergy; Productive Cough; Pulmonary Embolism; Spirometry Abnormal; Therapeutic Product Effect Incomplete; Wheezing	Salbutamol Sulphate	S	Unk Unk, Qd(3-4 Times)	Glaxosmithkline
	Advair	S	Unk	Glaxosmithkline
	Avelox	S	Unk	Glaxosmithkline
	Doxazosin	S	4 Mg, Unk	Glaxosmithkline
	Dutasteride	S	0.5 Mg, Unk	Glaxosmithkline
	Rosuvastatin	C	20 Mg, Unk	Glaxosmithkline
	Levofloxacin	S	500 Mg, Unk	Glaxosmithkline
	Vitamin D	S	Unk	Glaxosmithkline
	Escitalopram	S	10 Mg, Unk	Glaxosmithkline
	Budesonide	S	Unk	Glaxosmithkline
	Tiazac	S	120 Mg, Unk	Glaxosmithkline
	Amoxi Clav	S	Unk(875)	Not Reported
	Spiriva	S	Unk	Not Reported
	Omnaris	S	Unk	Not Reported
	Eliquis	S	Unk	Not Reported
	Prednisone	S	15 Mg, Qd	Not Reported
	Prednisone	S	10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726629	EXPEDITED (15-DAY)		LT, OT	ES-GLAXOSMITHKLINE-ES2019GSK148139		44 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Gene Mutation; Arrhythmia; Cardio-Respiratory Arrest; Cardiotoxicity; Long Qt Syndrome; Torsade De Pointes	Escitalopram Oxalate			S		Unk		Glaxosmithkline
	Salbutamol			S		Unk		Glaxosmithkline
	Olanzapine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726824	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1934405US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Supraventricular Extrasystoles	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Exelon			S	Transdermal	9.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726893	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-2019VAL000430			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Furosemide			S	Oral	40 Mg, Qd		Validus
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Oxazepam			S	Oral	2 Df, Qd		Not Reported
	Oxazepam			S	Unknown	Unk		Not Reported
	Simvastatin			S	Oral	20 Mg, Qd		Not Reported
	Esomeprazole			S	Oral	20 Mg, Qd		Not Reported
	Spironolactone			S	Oral	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	12978391	NON-EXPEDITED			US-PFIZER INC-2016542784		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Zosyn			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Vancomycin Hcl			S	Intravenous (not otherwise specified)	Unk		Unknown
	Voltaren			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Evista			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	13408354	NON-EXPEDITED			US-JNJFOC-20161010489		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Emotional Distress; Gynaecomastia; Off Label Use; Product Use In Unapproved Indication; Weight Increased	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Adderall			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Depakote			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	15534068	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2018M1078404			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	149 Milligram		Not Reported
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported
	Omeprazole			S	Oral	Unk		Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Mg, Unknown		Mylan
	Obinutuzumab			S				Mylan
	Sulfamethoxazole And Trimethoprim			S		Unk		Mylan
	Atorvastatin			C	Unknown	Unk Unk, Unknown		Mylan
	Valsartan			C	Unknown	Unk Unk, Unknown		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16080839	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-013657			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective; Feeling Abnormal; Muscular Weakness; Suicidal Ideation	Escitalopram Tablets			S	Oral	Unk Unk, Once A Day		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Clonazepam			S	Oral	0.5 Milligram, 3 Times A Day		Not Reported
	Clonazepam			S				Not Reported
	Clonazepam			S				Not Reported
	Zopiclone			S	Oral	7.5 Milligram, Two Times A Day		Not Reported
	Zopiclone			S				Not Reported
	Zopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16438399	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-033491			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Ibuprofen			S	Oral	400 Milligram,As Required		Not Reported
	Diclofenac Potassium			S	Oral	50 Milligram, Two Times A Day		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Eliquis			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16476904	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035629			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; No Adverse Event; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Escitalopram Tablets	S	Unknown	Unk Unk, Daily	Aurobindo
	Cosentyx	S	Subcutaneous	150 Milligram, Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Cosentyx	S	Subcutaneous	150 Milligram	Not Reported
	Voltaren	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Vitamin D3	S	Unknown	Unk	Not Reported
	Cholecalciferol	S	Unknown	Unk	Not Reported
	Enbrel	C	Unknown	Unk	Not Reported
	Humira	C	Subcutaneous	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16476908	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035634			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Interstitial Lung Disease	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Venlafaxine Xr Extended Release Capsule			S	Unknown	37.5 Milligram, Once A Day		Aurobindo
	Venlafaxine			S	Unknown	37.5 Milligram, Daily		Aurobindo
	Duloxetine Dr			S	Unknown	15.0 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16727255	EXPEDITED (15-DAY)		HO	US-SA-2019SA221933		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Drug Ineffective; Dystonia; Muscle Contractions Involuntary; Tardive Dyskinesia; Tenderness	Escitalopram Oxalate			S		10 Mg		Not Reported
	Escitalopram Oxalate			S		20 Unk		Not Reported
	Lorazepam			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Lorazepam		S	Oral	Lorazepam1 Mg 3 Times Per Day As Needed	Not Reported
	Diphenhydramine	Y	S		50 Mg, Tid	Sanofi
	Propranolol Hydrochloride		S		20 Mg	Not Reported
	Trihexyphenidyl Hydrochloride		S			Not Reported
	Diazepam		S			Not Reported
	Benztropine [Benzatropine]		S			Not Reported
	Estrogen		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16727582	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-054112			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Blood Count Abnormal; Chest Discomfort; Chest X-Ray Abnormal; Cough; Drug Ineffective; Dyspnoea; Gastrooesophageal Reflux Disease; Lung Disorder; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Rhinorrhoea; Sputum Discoloured; Weight Increased; Wheezing	Amlodipine Tablets			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Atrovent			S	Unknown	Unk		Not Reported
	Breo Ellipta			S	Unknown	Unk		Not Reported
	Cipralex			S	Unknown	Unk		Not Reported
	Levothyroxine Sodium			S	Unknown	Unk		Not Reported
	Olodaterol + Tiotropium			S	Unknown	Unk		Not Reported
	Piperacillin Sodium;Tazobactam Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Singulair			S	Unknown	Unk		Not Reported
	Solu-Medrol			S	Unknown	Unk		Not Reported
	Spiriva			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Theophylline			S	Unknown	Unk		Not Reported
	Uniphyl			S	Unknown	Unk		Not Reported

	Zantac	S	Unknown	Unk		Not Reported
	Zithromax	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16727676	EXPEDITED (15-DAY)		HO	IT-ACCORD-115805		30 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval Abnormal; Sopor; Speech Disorder; Substance Abuse	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728150	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-218325		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Esomeprazole			S	Oral	20 Milligram, Daily		Sun
	Simvastatin			S	Oral	20 Milligram, Daily		Sun
	Furosemide			S	Oral	40 Milligram, Daily		Not Reported
	Seresta 10 Mg, Comprime			S	Oral	2 Dosage Form, Daily		Not Reported
	Spironolactone			S	Oral	25 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16729150	EXPEDITED (15-DAY)		OT	US-TORRENT-00009110		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Fluoxetine			S				Unknown
	Escitalopram			S				Unknown
	Levonorgestrel			C	Intra-uterine	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16729216	EXPEDITED (15-DAY)		HO	US-ASTELLAS-2019US027490		96 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Fatigue; Feeling Abnormal; Hypersomnia; Weight Increased	Enzalutamide			S	Oral	Unk, Once Daily		Astellas
	Lexapro /01588501/			S	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16729939	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1078024		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Hyperhidrosis; Loss Of Consciousness; Tachycardia; Tremor	Escitalopram Mylan			S	Oral	10 Microgram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731314	EXPEDITED (15-DAY)		DE	FR-TEVA-2019-FR-1094729		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Escitalopram			S	Oral			Ivax
	Clozapine			S	Oral			Ivax
	Inexium			S	Oral			Not Reported
	Ditropan 5 Mg, Comprime Secable			S	Oral			Not Reported
	Xanax 0,25 Mg, Comprime Secable			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731412	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2019M1078255		26 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Micturition Urgency; Urinary Hesitation; Urinary Retention	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732004	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1934210US			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Discomfort; Drug Interaction; Palpitations; Tremor	Escitalopram Oxalate - Bp			S		10 Mg		Allergan
	Phenylephrine Hydrochloride			S		Strength 2.5%, One Drop Per Eye		Not Reported
	Selokenzoc			C	Unknown	50 Mg, Qd		Not Reported
	Trombyl			C	Unknown	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732008	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1934427US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dehydration; General Physical Health Deterioration; Hyperkalaemia	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Aldactone			S	Oral			Not Reported
	Fungizone			S	Unknown			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Lasilix			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Diffu K			S	Oral			Not Reported
	Lysanxia			C	Unknown			Not Reported
	Renutryl			C	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	13434099	EXPEDITED (15-DAY)		DS, HO, OT	US-SA-2017SA061824		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Ankle Fracture; Cystitis; Diarrhoea; Drug Hypersensitivity; Eye Swelling; Fall; Fall; Fatigue; Gait Disturbance; Head Discomfort; Head Titubation; Hospitalisation; Injury; Kidney Infection; Memory Impairment; Mood Swings; Muscle Spasms; Musculoskeletal Pain; Pain In Extremity; Paraesthesia; Product Dose Omission; Pruritus; Rash; Rash; Unevaluable Event; Urinary Retention; Urinary Tract Infection; Walking Aid User	Teriflunomide			S	Oral	14 Mg, Qd		Sanofi
	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
	Escitalopram Oxalate			S		10 Mg		Not Reported
	Tizanidine Hydrochloride			S	Unknown	2 Mg,Unk		Not Reported
	Ampyra			S	Unknown	10 Mg,Bid		Not Reported
	Ampyra			S	Unknown	10 Mg,Bid		Not Reported
	Tecfidera			C	Unknown	1 Df,Bid		Not Reported
	Aciclovir			C	Unknown	1 Df,Tid		Not Reported
	Atorvastatin			C	Unknown	1 Df,Hs		Not Reported
	Cyanocobalamin			C	Unknown	1000 Mg,Qd		Not Reported
	Baclofen			C	Unknown	10 Mg,Unk		Not Reported
	Fish Oil			C	Unknown	1200 Mg,Unk		Not Reported
	Fish Oil			C		360 Mg, Bid		Not Reported
	Gabapentin			C	Unknown	600 Mg,Tid		Not Reported
	Gabapentin			C	Unknown	300 Mg,Unk		Not Reported
	Levothyroxine			C	Unknown	25 Ug,Qd		Not Reported
	Magnesium			C	Unknown	400 Mg,Qd		Not Reported
	Magnesium			C	Unknown	250 Mg,Unk		Not Reported
	Montelukast			C	Unknown	10 Mg,Qd		Not Reported
	Ropinirole			C	Unknown	1 Mg,Tid		Not Reported
	Sertraline			C	Unknown	50 Mg,Prn		Not Reported
	Sertraline			C	Unknown	25 Mg,Unk		Not Reported
	Venlafaxine			C	Unknown	75 Mg,Bid		Not Reported

	Venlafaxine	C	Unknown	25 Mg,Unk	Not Reported
	Venlafaxine	C	Unknown	150 Mg,Unk	Not Reported
	Vesicare	C	Unknown	10 Mg,Prn	Not Reported
	Vitamin D2	C	Unknown	50000 Df,Qw	Not Reported
	Hydrocodone	C	Unknown	Unk Unk,Prn	Not Reported
	Levofloxacin	C	Unknown	Unk Unk,Unk	Not Reported
	Methylphenidate Hydrochloride	C	Unknown	10 Mg,Unk	Not Reported
	Nitrofurantoin	C	Unknown	10 Mg,Unk	Not Reported
	Vitamin D3	C	Unknown	2000 Iu,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16125335	EXPEDITED (15-DAY)		OT	PHHY2019DE063579		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Metoprolol Hexal			S	Unknown	Unk		Not Reported
	Ibuprofen Hexal			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	2.5 Mg, Unk		Novartis
	Salbutamol			S	Unknown	Unk		Not Reported
	Escitalopram Hexal			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S				Not Reported
	Implanon			S	Unknown	Unk		Not Reported
	Pantozol			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Prednisolon Jenapharm			S	Unknown	Unk		Not Reported
	Prednisolon Stada			S	Unknown	Unk		Not Reported
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported
	Ibuprofen Stada			S	Unknown	Unk		Not Reported
	Escitalopram Mylan			S	Unknown	Unk		Not Reported
	Escitalopram Stada			S	Unknown	Unk		Not Reported

Metoprolol Stada	S	Unknown	Unk		Not Reported
Metoprolol Mylan	S	Unknown	Unk		Not Reported
Salbutamol Stada	S	Unknown	Unk		Not Reported
Methotrexate Mylan	S	Unknown	1 Df, Qw		Not Reported
Fluticasone;Vilanterol	S	Unknown	Unk (6 Months Before Diagnosis)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16404344	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2019-031647			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Extrasystoles; Hypocalcaemia; Hypomagnesaemia	Escitalopram			S	Unknown	Unk		Aurobindo
	Omeprazole			S	Unknown	Unk		Aurobindo
	Enalapril Tablets			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Enalapril Maleate;Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16609127	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP018502		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Dislocation; Device Malfunction; Drug Ineffective	Apo-Escitalopram			S	Unknown	Unk		Apotex
	Apo-Trazodone			S	Unknown	1 Df, Qd		Apotex
	Apo-Tamsulosin Cr			S	Unknown	1 Df, Qd		Not Reported
	Amlodipine			S	Unknown	1.5 Df, Qd		Apotex
	Diltiazem			S	Unknown	1 Df, Qd		Apotex
	Escitalopram			S	Unknown	1 Df, Unk		Apotex
	Clonazepam			S	Unknown	1 Df, Tid		Apotex

	Rosuvastatin	S	Unknown	1 Df, Qd	Apotex
	Ciclopirox	S	Unknown	Unk	Apotex
	Brilinta	S	Unknown	1 Df, Bid	Not Reported
	Delatestryl	S	Unknown	0.5 Ml, Q.O.Wk.	Not Reported
	Dexilant	S	Unknown	1 Df, Qd	Not Reported
	Emo Cort	S	Topical	Unk, Qd	Not Reported
	Jamp Asa	S	Unknown	1 Df, Qd	Not Reported
	Metonia	S	Unknown	1 Df, Tid	Not Reported
	Nasonex	S	Other	Unk, Qd,(Intra-Nasal)	Not Reported
	Nitro-Dur	S	Unknown	1 Df, Qd	Not Reported
	Ratio-Zopiclone	S	Unknown	1 Df, Unk	Not Reported
	Synthroid	S	Unknown	1 Df, Qd	Not Reported
	Triatec /00116401/	S	Unknown	1 Df, Qid	Not Reported
	Tevabisoprol	S	Unknown	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16635309	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2019-044186			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Gastrointestinal Disorder; Off Label Use; Somnolence	Zolpidem			S	Unknown	Unk		Aurobindo
	Zolpidem			S				Aurobindo
	Zolpidem			S				Aurobindo
	Quetiapine			S	Unknown	Unk		Aurobindo
	Mirtazapine			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Sertraline			S	Unknown	Unk		Aurobindo
	Fluoxetine			S	Unknown	Unk		Aurobindo
	Trazodone			S	Unknown	Unk(Low Dose)		Not Reported
	Trazodone			S				Not Reported
	Agomelatine			C	Unknown	Unk		Not Reported

	Diazepam	C	Unknown	Unk		Not Reported
	Perampanel	C	Unknown	Unk		Not Reported
	Lormetazepam	C	Unknown	Unk		Not Reported
	Zolpidem	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16733350	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-055246			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibromyalgia; Musculoskeletal Chest Pain	Escitalopram			S	Oral	5 Milligram		Aurobindo
	Bedranol			C	Unknown	10 Milligram		Not Reported
	Atorvastatin			C	Unknown	10 Milligram		Not Reported
	Diazepam			C	Unknown	2 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16733401	NON-EXPEDITED			US-DRREDDYS-USA/USA/19/0113307		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Fluoxetine Tablets			S				Not Reported
	Escitalopram			S				Not Reported
	Levonorgestrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16733678	EXPEDITED (15-DAY)		DE, HO	FR-ASTRAZENECA-2019SF18391		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dehydration; Hyperkalaemia	Esomeprazole			S	Oral			Astrazeneca
	Escitalopram			S	Oral			Not Reported
	Aldactone			S	Oral			Not Reported
	Fungizone			S	Unknown			Not Reported
	Lovenox			S	Subcutaneous			Not Reported

	Lasilix		S	Oral		Not Reported
	Diffu K, Gelule		S	Oral		Not Reported
	Lysanxia		C			Not Reported
	Renutryl 500, Emulsion Buvable En Boite		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16733971	EXPEDITED (15-DAY)		DE, HO	FR-ACCORD-152690		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dehydration; Hyperkalaemia	Escitalopram			S	Oral			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			S	Oral			Not Reported
	Aldactone			S	Oral			Not Reported
	Fungizone			S	Unknown			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Lasilix			S	Oral			Not Reported
	Diffu K			S	Oral			Not Reported
	Lysanxia			C				Not Reported
	Renutryl			C		Drinkable Emulsion In Box		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16734032	NON-EXPEDITED			US-ALLERGAN-1853417US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Celexa			S	Unknown	Unk		Allergan
	Celexa			S				Allergan
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Sertraline			C		Unk		Not Reported
	Sertraline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16734067	NON-EXPEDITED			US-ALLERGAN-1905273US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Feeling Abnormal; Hypoaesthesia	Celexa			S	Unknown	Unk		Allergan
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16735395	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2019358434		27 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Suicide Attempt	Zoloft			S	Oral	2800 Mg, Unk		Pfizer
	Xanax			S	Oral	30 Mg, Unk		Pfizer
	Elicea			S	Oral	280 Mg, Unk		Not Reported
	Leponex			S	Oral	1250 Mg, Unk		Not Reported
	Siofor			S	Oral	120 G, Unk		Not Reported
	Lacipil			S	Oral	112 G, Unk		Not Reported
	Byol Cor			S	Oral	75 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16736761	EXPEDITED (15-DAY)		HO, OT	CA-009507513-1908CAN008061		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Dislocation; Device Malfunction; Drug Ineffective	Nitroglycerin			S	Unknown	1 Dosage Form X 1 Per 1 Days		Merck
	Nasonex			S	Nasal	X 1 Per 1 Days		Merck
	Amlodipine Besylate			S	Unknown	1.5 Dosage Form X 1 Per 1 Days		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Tamsulosin Hydrochloride			S	Unknown	1 Dosage Form X 1 Per 1		Not Reported

			Days	
Trazodone Hydrochloride	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Brilinta	S	Unknown	1 Dosage Form X 2 Per 1 Days	Not Reported
Ciclopirox Olamine	S	Unknown		Not Reported
Clonazepam	S	Unknown	1 Dosage Form X 3 Per 1 Days	Not Reported
Delatestryl	S	Unknown	0.5 Ml X 1 Per 2 Weeks	Not Reported
Dexilant	S	Unknown	Delayed Release Capsule, 1 Dosage Form X 1 Per 1	Not Reported
Diltiazem	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Emo-Cort	S	Topical	X 1 Per 1 Days	Not Reported
Escitalopram	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Aspirin	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Metonia	S	Unknown	1 Dosage Form X 3 Per 1 Days	Not Reported
Mylan Nitro	S	Oral	Unk,	Not Reported
Mylan Nitro	S	Oral	Metered-Dose Aerosol	Not Reported
Zopiclone	S	Unknown	1 Dosage Form	Not Reported
Rosuvastatin Calcium	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Synthroid	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Bisoprolol	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Triatec (Ramipril)	S	Unknown	1 Dosage Form X 4 Per 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16736769	EXPEDITED (15-DAY)		DE, HO	CH-ALLERGAN-1934571US			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Respiratory Failure	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qam (2-0-0-0)		Allergan
	Dexilant			S	Oral	60 Mg		Not Reported
	Atorvastatin Pfizer			S	Unknown	40 Mg, Qpm (0-0-1-0)		Not Reported
	Beloc Zok			S	Oral	50 Mg, Qam (1-0-0-0)		Not Reported
	Aspirin Cardio			C	Oral			Not Reported
	Pregabalin Pfizer			C	Oral			Not Reported
	Toviaz			C	Oral			Not Reported
	Mirtazapin			C		15 Mg		Not Reported
	Temesta			C		2.5 Mg		Not Reported
	Brilique			C		90 Mg		Not Reported
	Mst Continus			C		1 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16737644	EXPEDITED (15-DAY)		HO	US-PRINSTON PHARMACEUTICAL INC.-2019PRN00765		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Tardive Dyskinesia; Torticollis	Escitalopram			S	Unknown	10 Mg		Prinston Pharmaceutical
	Estrogen Oral Contraceptive			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2019	13752508	EXPEDITED (15-DAY)		HO, OT	SE-TEVA-784948ISR			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Persistent	Escitalopram			S	Transplacental			Ivax

Foetal Circulation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	13155136	NON-EXPEDITED			US-PFIZER INC-2017034216		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Hypersensitivity; Off Label Use; Product Use In Unapproved Indication	Neurontin			S		Unk		Pfizer
	Neurontin			S				Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16651331	NON-EXPEDITED			US-TAKEDA-2019TJP017299			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Prevacid			S	Unknown	Unk		Takeda
	Edarbi			S	Unknown	Unk		Takeda
	Lexapro			S	Unknown	Unk		Not Reported
	Azactam			S	Unknown	Unk		Not Reported
	Butrans			S	Unknown	Unk		Not Reported
	Cortisone			S	Unknown	Unk		Not Reported
	Scopolamine Aminoxide			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16682369	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019335906		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Myoclonus; Serotonin Syndrome	Ondansetron			S		40 Mg, Unk (He Was Using Ondansetron Up To 5 Times A Day)		Pfizer
	Ondansetron			S		Unk (He Reduced His		Pfizer

			Ondansetron To 3 Times A Day)	
	Escitalopram	S	5 Mg, Unk	Not Reported
	Escitalopram	S	15 Mg, Unk (Escitalopram Was Titrated Gradually To 15 Mg Within 4 Months)	Not Reported
	Escitalopram	S	10 Mg, Unk (Reduction Of Escitalopram To 10 Mg)	Not Reported
	Escitalopram	S	15 Mg, Unk (Three Months Later, His Escitalopram Was Increased Again To 15 Mg)	Not Reported
	Stribild	S	Unk	Not Reported
	Alprazolam	C	0.5 Mg, 4x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739063	EXPEDITED (15-DAY)		HO	US-APOTEX-2019AP020771		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Galactorrhoea	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Risperidone			S	Oral	Unk		Apotex
	Duloxetine			S	Oral	20 Mg, Qd		Apotex
	Duloxetine			S	Oral	40 Mg, Qd		Apotex
	Duloxetine			S	Oral	20 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739686	EXPEDITED (15-DAY)		OT	US-TORRENT-00009115		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S	Oral	Up To 5 Times A Day, Ingestion		Unknown
	Escitalopram			S		Titrated Gradually To 15		Unknown

			Mg Within 4 Months.		
	Alprazolam	C			Unknown
	Stribild	S	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741177	EXPEDITED (15-DAY)		OT	HR-JNJFOC-20190828778			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Mydriasis; Somnolence; Suicide Attempt; Toxicity To Various Agents	Tramadol Hydrochloride			S	Oral	Unk		Not Reported
	Elicea			S	Oral	100 Mg, Unk		Not Reported
	Velafax			S	Oral	1500 Unk, Unk		Not Reported
	Brintellix			S	Oral	10 Mg, Unk		Not Reported
	Olandix			S	Oral	Adr Adequately Labelled: Somnolencexadr Not Adequately Labelled: Mydriasis		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741604	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1934765US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Decreased Appetite; Nausea; Vomiting	Escitalopram Oxalate - Bp			S	Unknown	97		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741880	EXPEDITED (15-DAY)		OT	PHHY2019DE196338		65 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Hypertension; Muscle Spasms; Tremor	Tegretal			S	Unknown	Unk		Novartis
	Tegretal			S	Unknown	400 Mg, Qd		Not Reported

	Escitalopram	S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram	S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16742215	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR152779			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation Neonatal; Drug Withdrawal Syndrome Neonatal; Facial Asymmetry; Foetal Exposure During Pregnancy; Hyperbilirubinaemia Neonatal; Hypoglycaemia Neonatal; Jaundice Neonatal; Knee Deformity; Maternal Exposure During Breast Feeding; Neonatal Respiratory Distress Syndrome; Selective Eating Disorder; Talipes; Weight Decrease Neonatal	Nicotine			S	Transplacental	Unk		Glaxosmithkline
	Calcium			S	Transplacental	Unk		Glaxosmithkline
	Cholecalciferol			S	Transplacental	Unk		Glaxosmithkline
	Folic Acid			S	Transplacental	Unk		Glaxosmithkline
	Cipralex Tablet			S	Transplacental	Unk		Not Reported
	Suboxone			S	Transplacental	Unk		Not Reported
	Subutex			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	12645979	NON-EXPEDITED			US-PFIZER INC-2016246041			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Butamben-Tetracaine-Benzocaine			S		Unk		Not Reported
	Cetacaine			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

Prozac	S	Unk	Not Reported
Vicodin	S	Unk	Not Reported
Reglan	S	Unk	Not Reported
Zofran	S	Unk	Not Reported
Percocet	S	Unk	Not Reported
Tylenol	S	Unk	Not Reported
Tetanus Toxoid	S	Unk	Not Reported
Amylase/Lipase/Protease	S	Unk	Not Reported
Creon 10	S	Unk	Not Reported
Paxil	S	Unk	Not Reported
Hctz	S	Unk	Not Reported
Levaquin	S	Unk	Not Reported
Paroxetine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16170479	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1915122US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Golimumab			S	Unknown	Unk		Not Reported
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported
	Escitalopram Mylan			S	Unknown	Unk		Not Reported
	Implanon			S	Unknown	Unk		Not Reported
	Prednisolon Jenapharm			S	Unknown	Unk		Not Reported
	Ibuprofen Stada			S	Unknown	Unk		Not Reported
	Ibuprofen Hexal			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Salbutamol Stada			S	Unknown	Unk		Not Reported

	Pantozol	S	Unknown	Unk	Not Reported
	Metoprolol Stada	S	Unknown	Unk	Not Reported
	Fluticasone; Vilanterol	S	Unknown	Unk (6 Months Before Diagnosis)	Not Reported
	Escitalopram Stada	S	Unknown	Unk	Not Reported
	Prednisolon Stada	S	Unknown	Unk	Not Reported
	Metoprolol Mylan	S	Unknown	Unk	Not Reported
	Escitalopram Hexal	S	Unknown	Unk	Not Reported
	Prednisolone	S	Unknown	2.5 Mg	Not Reported
	Methotrexate Mylan	S	Unknown	1 Df, Q Week	Not Reported
	Salbutamol	S	Unknown	Unk	Not Reported
	Metoprolol Hexal	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16227792	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2019-011478		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Prednisolone			S	Unknown			Bausch And Lomb
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Salbutamol			S	Unknown			Bausch And Lomb
	Ibuprofen			S	Unknown			Not Reported
	Methotrexate Mylan			S	Unknown			Not Reported
	Implanon			S	Unknown			Not Reported
	Metoprolol Mylan			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Escitalopram Stada			S	Unknown			Not Reported
	Escitalopram Hexal			S	Unknown			Not Reported
	Metoprolol Stada			S	Unknown			Not Reported

Escitalopram Mylan	S	Unknown			Not Reported
Prednisolon Jenapharm	S	Unknown			Not Reported
Ibuprofen Hormosan	S	Unknown			Not Reported
Metoprolol	S	Unknown			Not Reported
Escitalopram	S	Unknown			Not Reported
Metoprolol Hexal	S	Unknown			Not Reported
Pantozol	S	Unknown			Not Reported
Ibuprofen Stada	S	Unknown			Not Reported
Prednisolon Stada	S	Unknown			Not Reported
Salbutamol Stada	S	Unknown			Not Reported
Ibuhexal	S	Unknown			Not Reported
Fluticasone;Vilanterol	C	Unknown	6 Months Before Diagnosis		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16568514	EXPEDITED (15-DAY)		OT	PHHY2019BR160623		33 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear; Malaise; Skin Lesion; Systemic Lupus Erythematosus	Cosentyx			S	Subcutaneous	Unk Unk, Qmo		Novartis
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Prednisona			S	Oral	40 Mg, Qd (Approximatly 5 Years Ago)		Not Reported
	Rivotril			S	Oral	0.5 Mg, Unk		Not Reported
	Leflunomida			C	Oral	20 Mg, Qd (End Of Jun After Apperence Of The Lesions		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16686954	EXPEDITED (15-DAY)		HO	US-ACCORD-150888		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Prolactin Increased; Galactorrhoea	Escitalopram	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16743178	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2019-002183			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval Abnormal; Sopor; Speech Disorder; Substance Abuse	Escitalopram			S	Oral	20 Milligram, In Total		Aurobindo
	Quetiapine			S	Oral	25 Milligram, In Total		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16744868	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS-2019GMK042785		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S	Oral	40 Mg, Unk (Up To 5 Times A Day, Ingestion)		Glenmark
	Escitalopram			S	Unknown	15 Mg, Unk (Titrated Gradually To 15 Mg Within 4 Months)		Not Reported
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported
	Stribild			S	Unknown	Unk		Not Reported
	Alprazolam			C	Unknown	0.5 Mg, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16745112	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2019154395		39 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Doliprane			S	Unknown	Unspecified		Glaxosmithkline
	Ventoline			S	Unknown	Unspecified		Glaxosmithkline
	Seroplex			S	Unknown	Unspecified		Glaxosmithkline

	Lexomil	S	Unknown	Unspecified		Glaxosmithkline
	Tramadol Hydrochloride	S	Oral	1-0-1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16746066	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1079435		58 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	1 Dosage Form, Total		Not Reported
	Quetiapine Fumarate			S	Oral	1 Dosage Form, Total		Mylan
	Clonazepam			C		Unk		Mylan
	Lorazepam			C		Unk		Mylan
	Depakin Chrono /00228502/			C		1500 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16747179	EXPEDITED (15-DAY)		OT	PHHY2019US194620		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S	Oral	40 Mg, Up To 5 Times A Day		Novartis
	Ondansetron			S	Oral	40 Mg, Tid		Novartis
	Escitalopram			S	Unknown	5 Mg, Titrated Gradually To 15 Mg Within 4 Months		Not Reported
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	15 Mg, Unk		Not Reported
	Stribild			S	Unknown	Elvitegravir 150 Mg, Cobicistat 150 Mg, Emtricitabine 200 Mg, And Tenofovir Disoproxil Fumarate 300		Not Reported
	Alprazolam			C	Unknown	0.5 Mg, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16747696	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1096563		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Vomiting	Escitalopram			S		20 Mg, 0-0-1-0		Ivax
	Quetiapin			S		40 Mg, 0-0-1-0		Teva
	Pipamperon			S		40 Mg, 0-0-1-0		Not Reported
	Levothyroxine Sodium			C		112 Microgram, 1-0-0-0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16748617	EXPEDITED (15-DAY)		LT, OT	BE-RANBAXY-2014RR-90201		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome	Escitalopram			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Omeprazole			S	Unknown			Astrazeneca
	Sotalol			S	Unknown			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16749021	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1097242			Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Mydriasis; Somnolence; Suicide Attempt	Olandix			S	Oral			Teva
	Tramadol			S	Oral			Teva
	Velafax			S	Oral			Teva
	Elicea			S	Oral			Not Reported
	Brintellix			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16749596	EXPEDITED (15-DAY)		OT	US-ACCORD-151416		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S		Up To 5 Times A Day		Accord
	Escitalopram			S				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16749635	EXPEDITED (15-DAY)		HO	US-JUBILANT CADISTA PHARMACEUTICALS-2019JUB00321		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conversion Disorder; Tardive Dyskinesia; Torticollis	Escitalopram			S	Unknown	10 Mg		Jubilant
	Escitalopram			S	Unknown	20 Mg		Jubilant
	Estrogen Oral Contraceptive			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16750920	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1080683		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Escitalopram			S	Oral	1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16752093	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1097360		74 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibromyalgia; Musculoskeletal Chest Pain	Escitalopram			S	Oral			Ivax
	Bedranol			C				Not Reported
	Atorvastatin			C				Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	15832915	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-997687		30 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval Abnormal; Sopor; Speech Disorder; Substance Abuse	Escitalopram Oxalate			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16683748	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1073230		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Escitalopram			S	Oral	5 Milligram		Not Reported
	Escitalopram			S	Oral	5 Milligram		Not Reported
	Escitalopram			S	Oral	10 Milligram		Not Reported
	Olanzapin			C	Oral	15 Milligram, Qd (Daily Dose: 15 Mg Millgram(S) Every Days)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16732564	NON-EXPEDITED		OT	US-DRREDDYS-USA/USA/19/0113551		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S	Oral	Up To 5 Times A Day, Ingestion		Not Reported
	Escitalopram			S		Titrated Gradually To 15 Mg Within 4 Months.		Not Reported
	Escitalopram			S				Not Reported
	Stribild			S				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16752881	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2019-05483		44 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardio-Respiratory Arrest; Drug Level Increased; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram			S	Unknown	Unk		Lupin
	Olanzapine			S	Unknown	Unk		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16753086	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US06017			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Escitalopram			S	Unknown	5 Milligram		Invagen
	Escitalopram			S	Unknown	15 Milligram, (Titrated Gradually To 15 Mg Within 4 Months)		Invagen
	Ondansetron			S	Oral	40 Milligram, Up To 5 Times A Day, Ingestion		Not Reported
	Stribild			S	Unknown	Unk		Not Reported
	Alprazolam			C	Unknown	0.5 Milligram, Qid (Every 6 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16753163	NON-EXPEDITED			US-009507513-1908USA000225		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Weight Increased	Remeron			S	Oral	45 Milligram, Unk		Merck
	Escitalopram			S		20 Milligram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16753469	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1099066		38 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective	Venlafaxine			S	Unknown	225 Milligram Daily;		Teva
	Sertraline			S	Unknown	100 Milligram Daily;		Not Reported
	Mirtazapine			S	Unknown	30 Milligram Daily;		Teva
	Escitalopram			S	Unknown			Ivax
	Lithium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16754223	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2019022737			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardio-Respiratory Arrest; Drug Level Increased; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Olanzapine			S	Unknown	Unk		Macleods
	Salbutamol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16756099	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1081062		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Movement Disorder; Loss Of Consciousness	Escitalopram			S		15 Mg, Unk		Not Reported
	Pritor /01421801/			S		40 Mg, Om		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16756348	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2019-ES-1098054		32 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Intentional Overdose	Escitalopram (2858a)			S	Oral	560 Milligram		Ivax
	Magnesio [Magnesium]			S	Oral	18 Gram		Not Reported
	Armopl - Armolipid Plus 20 Comp (Diet)			S	Oral	6 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16756626	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC-2019364693		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dehydration; Hyperkalaemia	Aldactone			S	Oral	12.5 Mg, 1x/Day		Pfizer
	Esomeprazole Magnesium			S	Oral	20 Mg, 1x/Day		Unknown
	Fungizone			S		Unk		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported
	Lasilix			S	Oral	40 Mg, 1x/Day		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Diffu K			S	Oral	1800 Mg, 1x/Day		Not Reported
	Lysanxia			C		Unk		Not Reported
	Renutryl			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16180279	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20190404775		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Simponi			S	Subcutaneous			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Pantozol			S	Unknown			Not Reported
	Implanon			S	Unknown			Not Reported

Ibuprofen	S	Unknown		Not Reported
Metoprolol Tartrate	S	Unknown		Not Reported
Salbutamol Sulfate	S	Unknown		Not Reported
Escitalopram Oxalate	S	Unknown		Not Reported
Prednisolon Jenapharm	S	Unknown		Not Reported
Metoprolol Hexal	S	Unknown		Not Reported
Amitriptylin	S	Unknown		Not Reported
Methotrexate Mylan	S	Unknown	1 Df, Ow	Not Reported
Metoprolol Succinate	S			Not Reported
Amitriptyline	S	Unknown		Not Reported
Prednisolone	S	Unknown		Not Reported
Prednisolone	S	Unknown		Not Reported
Fluticasone;Vilanterol	S	Unknown		Not Reported
Escitalopram	S	Unknown		Not Reported
Prednisolon /00016201/	S	Unknown		Not Reported
Salbutamol	S	Unknown		Not Reported
Escitalopram Hexal	S	Unknown		Not Reported
Metoprolol /00376903/	S	Unknown		Not Reported
Escitalopram Stada	S	Unknown		Not Reported
Metoprolol Mylan /00376902/	S	Unknown		Not Reported
Salbutamol Stada	S	Unknown		Not Reported
Salbutamol Stada	S	Unknown		Not Reported
Escitalopram Mylan	S	Unknown		Not Reported
Metoprolol Stada	S	Unknown		Not Reported
Prednisolon Stada	S	Unknown		Not Reported
Ibuhexal /00109201/	S	Unknown		Not Reported
Prednisolon Jenapharm	S	Unknown		Not Reported
Fluticasone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16567173	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1928431US			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Anxiety Disorder; Autonomic Nervous System Imbalance; Decreased Activity; Depression; Dizziness; Dysgeusia; Dyspepsia; Feeling Abnormal; Insomnia; Malaise; Mania; Nausea; Nausea; Neuralgia; Off Label Use; Palpitations; Somnolence; Somnolence; Therapeutic Product Effect Incomplete	Ursodeoxycholic Acid - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd For 5-6 Years		Allergan
	Depas (Etizolam)			S	Oral	Unk		Not Reported
	Depas (Etizolam)			S	Oral	Unk		Not Reported
	Brotizolam			S	Oral	Unk, Qhs		Not Reported
	Goodmin			S	Oral	Unk		Not Reported
	Tegretol			S	Oral	800 Mg, Qd		Not Reported
	Tegretol			S	Oral	400 Mg, Qd		Not Reported
	Tegretol			S	Oral	200 Mg In The Evening And 400 Mg At Bedtime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16607790	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-214382		61 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Extrasystoles; Hypomagnesaemia	Enalapril			S	Unknown	(), Unk		Ranbaxy
	Escitalopram			S	Unknown	(), Unk		Not Reported
	Omeprazole			S	Unknown	(), Unk		Astrazeneca
	Trazodone			S	Unknown	(), Unk		Not Reported
	Metformin			C	Unknown	(), Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16757923	EXPEDITED (15-DAY)		DE, HO	FR-SA-2019SA231378		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Dehydration; Hyperkalaemia	Lovenox	S	Subcutaneous	Unk Unk, Unk	Sanofi
	Lasilix	S	Oral	40 Mg, Qd	Sanofi
	Esomeprazole	S	Oral	20 Mg, Qd	Not Reported
	Spironolactone	S	Oral	12.5 Mg, Qd	Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg, Qd	Not Reported
	Potassium Chloride	S	Oral	1800 Mg, Qd	Not Reported
	Fungizone	S	Unknown	Unk Unk, Unk	Not Reported
	Lysanxia	C	Unknown	Unk Unk, Unk	Not Reported
	Renutryl	C	Unknown	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16758473	EXPEDITED (15-DAY)		OT	ES-ACCORD-152839		44 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardio-Respiratory Arrest; Drug Level Increased; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram			S				Not Reported
	Olanzapine			S				Not Reported
	Salbutamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16759279	EXPEDITED (15-DAY)		OT	BR-TORRENT-00005083			Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Decreased Appetite; Dyspnoea; Insomnia; Pallor; Product Administration Error; Product Prescribing Error; Somnolence	Escitalopram			S	Oral	Qne Tablet Daily		Torrent
	Menelat			S		Half Tablet Daily		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16759511	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1100632		65 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Language Disorder; Muscle Twitching; Tremor	Escitalopram Abz 5 Mg Filmtabletten			S	Oral	5 Milligram Daily;		Ivax
	Escitalopram Abz 5 Mg Filmtabletten			S	Oral	10 Milligram Daily;		Ivax
	Escitalopram Abz 5 Mg Filmtabletten			S	Oral	7.5 Milligram Daily;		Ivax
	Escitalopram Abz 5 Mg Filmtabletten			S	Oral	5 Milligram Daily;		Ivax
	Tegretal			C		Intake For One Year		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16759807	NON-EXPEDITED			US-TEVA-2019-US-1101540			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16761525	EXPEDITED (15-DAY)		HO, LT	PHHY2019US202613		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Dyspnoea; Overdose; Pulseless Electrical Activity; Unresponsive To Stimuli	Quetiapine			S	Oral	3000 Mg, Unk		Novartis
	Clonazepam			S	Oral	5 Mg, Unk		Not Reported
	Bisoprolol			S	Oral	25 Mg, Unk		Not Reported
	Escitalopram			S	Oral	250 Mg, Unk		Not Reported
	Venlafaxin			S	Oral	1000 Mg, Unk		Not Reported
	Flecainide			S	Oral	2500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16762045	EXPEDITED (15-DAY)		HO	CA-VIIV HEALTHCARE LIMITED-CA2019GSK155978			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Lung Disorder	Triumeq			S		Unk		Viiv
	Cipralex			S		Unk		Not Reported
	Ecasa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2019	16762281	EXPEDITED (15-DAY)		DE, HO	FR-ZYDUS-040119		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dehydration; Hyperkalaemia	Spironolactone			S	Oral			Not Reported
	Amphotericin B			S	Unknown			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Lasilix			S	Oral			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			S	Oral			Not Reported
	Escitalopram			S	Oral			Cadila
	Diffu K			S	Oral			Not Reported
	Lysanxia			C				Not Reported
	Renutryl			C		Drinkable Emulsion In Box		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2019	16762440	EXPEDITED (15-DAY)		HO	US-HETERO-HET2019US01169		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Galactorrhoea	Escitalopram			S	Unknown	10 Milligrams		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2019	16762485	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2019-057670			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Sinus Bradycardia; Somnolence	Quetiapine			S	Oral	1000 Milligram, In Totoal		Aurobindo
	Escitalopram			S	Oral	10 Milligram, In Total		Aurobindo
	Propranolol			S	Oral	4000 Milligram, In Totoal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	15458413	EXPEDITED (15-DAY)		DE, HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-185951		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Amiodarone			S	Oral	Inconnue ()		Taro
	Lansoprazole			S	Oral	15 Mg, Daily		Sun
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Lactulose			S	Oral	2 Df, Daily		Not Reported
	Atorvastatine			S	Oral	10 Mg, Daily		Sun
	Repaglinide			S	Oral	2 Mg, Daily		Sun
	Trimebutine			S	Oral	300 Mg, Daily		Not Reported
	Bisoce 1,25 Mg, Comprime Pellicule			S	Oral	In Total		Not Reported
	Fungizone 10 Pour Cent, Suspension Buvable			S	Buccal	3 Df, Daily		Not Reported
	Prograf			S	Oral	3 Mg, Qd		Not Reported
	Driptane 5 Mg, Comprime Secable			S	Oral	3 Df, Daily, 15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	16763210	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S	Oral	Up To 5 Times A Day, Ingestion		Westward
	Escitalopram			S	Unknown	Titrated Gradually From 5 To 15 Mg Within 4 Months.		Hikma
	Escitalopram			S	Unknown			Hikma
	Cobicistat			S	Unknown	()		Not Reported
	Alprazolam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	16764258	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2019-FR-1099761		90 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dehydration; Hyperkalaemia	Esomeprazole			S	Oral			Teva
	Escitalopram			S	Oral			Ivax
	Aldactone			S	Oral			Not Reported
	Fungizone			S	Unknown			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Lasilix			S	Oral			Not Reported
	Diffu K, Gélule			S	Oral			Not Reported
	Lysanxia			C				Not Reported
	Renutryl 500, Émulsion Buvable En Boite			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	16764432	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1935388US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Disorder; Fatigue; Feeling Abnormal; Hypersomnia; Weight Increased	Lexapro		S	Unknown		Allergan
	Xtandi		S	Oral	Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16570141	EXPEDITED (15-DAY)		HO	FR-ACCORD-138345		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Pleural Effusion; Somnolence; Traumatic Haemothorax	Clozapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Eliquis			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16639432	EXPEDITED (15-DAY)		DE, LT, OT	PL-ALLERGAN-1930434US			Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Pulmonary Embolism	Escitalopram Oxalate Unk			S	Unknown	20 Mg, Qd		Allergan
	Reboxetine			S	Unknown	4 Mg, Qd		Not Reported
	Quetiapine			S	Unknown	100 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	5 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	25 Mg, Qd		Not Reported
	Paroxetine			S	Unknown	20 Mg, Qd		Not Reported
	Sertraline			S	Unknown	100 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown	30 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown	45 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16751451	EXPEDITED (15-DAY)		OT	ES-ELI_LILLY_AND_COMPANY-ES201908009715		44 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arrhythmia; Cardio-Respiratory Arrest; Drug Level Increased; Electrocardiogram Qt Prolonged; Torsade De Pointes	Olanzapine	S	Unknown	Unk, Unknown	Not Reported
	Escitalopram	S	Unknown	Unk Unk, Unknown	Not Reported
	Salbutamol	S	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16764967	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2019-055865			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardio-Respiratory Arrest; Drug Level Increased; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram			S	Unknown	Unk		Aurobindo
	Olanzapine			S	Unknown	Unk		Aurobindo
	Salbutamol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16765420	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-055873			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S	Oral	40 Milligram, Up To 5 Times A Day, Ingestion		Aurobindo
	Escitalopram			S	Unknown	15 Milligram, Titrated Gradually To 15 Mg Within 4 Months.		Aurobindo
	Escitalopram			S	Unknown	5 Milligram		Aurobindo
	Stribild			S	Unknown	Unk		Not Reported
	Alprazolam			C	Unknown	0.5 Milligram, Four Times/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16765815	EXPEDITED (15-DAY)		DE, HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-		90 YR	Male	FRA

2019RR-219559

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dehydration; Hyperkalaemia	Esomeprazole			S	Oral	20 Milligram, Daily		Sun
	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Aldactone			S	Oral	12.5 Milligram, Daily		Not Reported
	Fungizone			S	Unknown	Unk		Not Reported
	Diffu K, Gelule			S	Oral	1800 Milligram, Daily		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported
	Lasilix			S	Oral	40 Milligram, Daily		Not Reported
	Lysanxia			C	Unknown	Unk		Not Reported
	Renutryl 500, Emulsion Buvable En Boite			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16765965	EXPEDITED (15-DAY)		HO, LT	FR-ACCORD-153474		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Poisoning Deliberate; Sinus Bradycardia; Somnolence	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Propranolol/Propranolol Hydrochloride/Propranolol Phenobarbital			S	Oral			Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16766308	NON-EXPEDITED			US-NEOPHARMA INC-000190			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Amoxicillin			S				Not Reported
	Neurontin			S	Oral	Take 1 Capsule 300 Mg		Not Reported

			Total By Mouth Nightly	
	Escitalopram	S		Not Reported
	Fluoxetine	S		Not Reported
	Cephalexin	S		Not Reported
	Duloxetine/Duloxetine Hydrochloride	S		Not Reported
	Erythromycin Base	S		Not Reported
	Oxycodone	S		Not Reported
	Phenylephrine	S		Not Reported
	Guaifenesin	S		Not Reported
	Sulfamethoxazole	S		Not Reported
	Trimethoprim	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16769650	EXPEDITED (15-DAY)		HO	PHHY2019SE201683		18 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury	Escitalopram			S	Oral	140 Mg, Unk		Not Reported
	Desloratadine			S	Oral	60 Mg, Unk		Novartis
	Lergigan (Promethazine Hydrochloride)			S	Oral	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16723366	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2019-053382			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Prolactin Increased; Galactorrhoea	Duloxetine			S	Unknown	20 Milligram, Daily		Aurobindo
	Duloxetine			S	Unknown	40 Milligram, Daily, After 5 Days		Aurobindo
	Escitalopram			S	Unknown	10 Milligram, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16770280	EXPEDITED (15-DAY)		OT	ES-ALKEM LABORATORIES LIMITED-ES-ALKEM-2019-07667		44 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes	Olanzapine			S	Unknown	Unk		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16770496	NON-EXPEDITED		HO	ZA-LUPIN PHARMACEUTICALS INC.-2018-06634			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chest Pain	Amlodipine			S	Oral	10 Mg, Unk		Lupin
	Indapamide Mylan			S	Oral	2.5 Mg, Unk		Not Reported
	Ecotrin			S	Oral	81 Mg, Unk		Not Reported
	Zolnoxs			S	Oral	10 Mg, Unk		Not Reported
	Lexamil			S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16770628	EXPEDITED (15-DAY)		OT	PHHY2019FR204273			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Convulsive Threshold Lowered; Drug Interaction; Epilepsy; Fatigue; Incorrect Dose Administered	Escitalopram Sandoz			S	Unknown	10 Mg, Bid		Not Reported
	Tramadol			S	Unknown	100 Mg, Bid		Not Reported
	Tramadol			S	Unknown	500 Mg, Qid (If It Was Needed)		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Depakine Chrono			C	Unknown	1.5 Mg, Bid		Not Reported
	Urbanyl			C	Unknown	2 Df (20 Units Not Specified), Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16771183	EXPEDITED (15-DAY)		HO, LT	FR-ASTRAZENECA-2019SF24765		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Sinus Bradycardia; Somnolence	Quetiapine			S	Oral	1000.0mg Once/Single Administration		Zeneca
	Propranolol			S	Oral	4000.0mg Once/Single Administration		Not Reported
	Escitalopram			S	Oral	10.0mg Once/Single Administration		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16772253	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019373295		28 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Decreased Interest; Loss Of Personal Independence In Daily Activities	Xanax			S	Oral	2 Df, 1x/Day		Pfizer
	Tercian [Cyamemazine Tartrate]			S	Oral	2 Df, 1x/Day		Not Reported
	Parkinane Lp			S	Oral	2 Df, 1x/Day		Not Reported
	Risperdal			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16772764	EXPEDITED (15-DAY)		DE, HO	CH-ALLERGAN-1935238US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplasia; Febrile Neutropenia	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Wellvone			S	Oral	1500 Mg		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1000 Mg; In Total		Not Reported
	Diflucan			S	Unknown	400 Mg/D		Not Reported
	Benerva			S	Unknown			Not Reported
	Amlodipin-Mepha			S	Unknown	10 Mg		Not Reported
	Brufen			S	Unknown	400 Mg 2-3/D		Not Reported

	Imodium	S	Unknown	2 Mg 2-3/D	Not Reported
	Novorapid	S	Unknown		Not Reported
	Levemir	S	Unknown	Unk	Not Reported
	Bactrim Ds	C	Unknown	Unk	Not Reported
	Cefepime	C	Unknown		Not Reported
	Piperacillin And Tazobactam	C	Unknown		Not Reported
	Dafalgan	C	Unknown	1 G, Tid	Not Reported
	Esomep	C	Unknown	20 Mg	Not Reported
	Fragmin	C	Unknown		Not Reported
	Aspirin Cardio	C	Unknown	100 Mg	Not Reported
	Beloc Zok	C	Unknown	25 Mg, Qd	Not Reported
	Beloc Zok	C	Unknown	50 Mg, Qd	Not Reported
	Diovan	C	Unknown	80 Mg, Qd	Not Reported
	Diovan	C	Unknown	160 Unk	Not Reported
	Atorvastatin Pfizer	C	Unknown	40 Mg, Qd	Not Reported
	Spiricort	C	Unknown	50 Mg, Qd	Not Reported
	Mestinon	C	Unknown	60 Mg 6x/D	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16772775	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1935646US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Tachycardia Paroxysmal	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Amlodipine			C	Unknown	In The Evening		Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Candesartan			C	Unknown	In The Morning		Not Reported
	Xarelto			C	Unknown	In The Morning		Not Reported
	Trazodone			C	Unknown	In The Evening		Not Reported
	Trazodone			C	Unknown	In The Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	8242547	EXPEDITED (15-DAY)		DE, HO, OT	DK-MYLANLABS-2011S1022479			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Hypertrophy; Confusional State; Constipation; Depressed Level Of Consciousness; Dyspnoea; Fall; Hepatic Cirrhosis; Hepatic Enzyme Increased; Humerus Fracture; Hyperdynamic Left Ventricle; Hypertension; Hyperventilation; Internal Fixation Of Fracture; Lactic Acidosis; Lacunar Infarction; Myocardial Infarction; Neuroleptic Malignant Syndrome; Organ Failure; Pyrexia; Renal Failure; Rhabdomyolysis; Urinary Tract Infection	Mirtazapine			S	Oral	30 Mg,Qd		Not Reported
	Mirtazapine			S				Not Reported
	Zeldox /01487003/			S	Oral	40 Mg,Bid		Mylan
	Litarex /00033708/			S	Oral	1.5 Df (In The Evening)		Mylan
	Cipralex /01588501/			S	Oral	30 Mg, Qd (Daily Dose Of 1 Tablet In The Morning And 1.5 Tablet In The Evening)		Mylan
	Fragmin			C		Unk		Mylan
	Ferro Duretter			C	Unknown	100 Milligram, Qd		Mylan
	Centyl Med Kaliumklorid			C	Unknown	1 Dosage Form, Qd		Mylan
	Furix			C		Unk		Mylan
	Amlodipine			C		Unk		Mylan
	Alprazolam			C		0.5 Milligram Daily		Mylan
	Alprazolam			C		0.5 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16595645	EXPEDITED (15-DAY)		OT	DE-ACCORD-138972		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pancreatitis; Skin Ulcer	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Ledipasvir/Sofosbuvir			S	Oral	90 Mg, Qd		Not Reported
	Ribavirin			S	Oral	600 Mg, Bid		Not Reported
	Braunovidon			C				Not Reported
	Ribavirin			S	Oral	400mg-0-200mg		Not Reported
	Ribavirin			S	Oral	400 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16639176	EXPEDITED (15-DAY)		DE, HO, OT	CH-PFIZER INC-2019317201		78 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Interstitial Lung Disease; Respiratory Failure	Atorvastatin Pfizer			S		40 Mg, 1x/Day (0-0-1-0)		Pfizer
	Pregabalin Pfizer			S	Oral	50 Mg, 4x/Day (1-1-1-1)		Pfizer
	Toviaz			S	Oral	8 Mg, 1x/Day		Pfizer
	Toviaz			S	Oral	8 Mg, 1x/Day (0-0-1-0)		Pfizer
	Temesta [Lorazepam]			S	Oral	2.5 Mg, 2x/Day (1-0-0-1)		Pfizer
	Temesta [Lorazepam]			S	Oral	2.5 Mg, 2x/Day (1-0-0-1, Already For 40 Years In Different Dosage)		Pfizer
	Beloc Zok			S	Oral	50 Mg, 1x/Day		Not Reported
	Beloc Zok			S	Oral	50 Mg, 1x/Day (1-0-0-0)		Not Reported
	Cipralex [Escitalopram Oxalate]			S	Oral	20 Mg, Daily (2-0-0-0)		Not Reported
	Dexilant			S	Oral	60 Mg, 1x/Day		Not Reported
	Pantoprazole Sandoz			S	Oral	40 Mg, 1x/Day (1-0-0-0)		Not Reported
	Aspirin Cardio			S	Oral	100 Mg, 1x/Day (1-0-0-0)		Not Reported
	Quetiapin Sandoz			S	Oral	12.5 Mg, 2x/Day		Not Reported
	Quetiapin Sandoz			S	Oral	12.5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16653405	EXPEDITED (15-DAY)		HO, OT	PHHY2019DE176104		22 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Linezolid			S	Unknown	Unk		Novartis
	Escitalopram			S	Unknown	Unk, (Long Term Medication)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16774550	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-04010			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Hypersensitivity; Fatigue; Irritability; Oedema; Palpitations; Tinnitus	Duloxetine			S	Unknown	Unk		Lupin
	Amlodipine Besylate Tablets			S	Unknown	Unk		Lupin
	Escitalopram			S	Unknown	Unk		Lupin
	Gabapentin			S	Unknown	Unk		Lupin
	Lorazepam			S	Unknown	Unk		Lupin
	Losartan Potassium			S	Unknown	Unk		Lupin
	Metoprolol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16778002	EXPEDITED (15-DAY)		HO, LT, OT	CA-BAUSCH-BL-2019-024991		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Potassium Increased; Blood Pressure Decreased; Bradycardia; Coma; Coma Scale Abnormal; Drug Interaction; Drug Screen Positive; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Heart Rate Decreased; Hyperkalaemia; Hypotension; Intentional	Lorazepam			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Diazepam			S	Unknown			Not Reported
	Altace			S	Unknown			Not Reported
	Diazepam			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Unknown			Not Reported
	Morphine			S	Oral			Not Reported
	Morphine			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported

Overdose; Loss Of Consciousness; Mechanical Ventilation; Opiates Positive; Overdose; Oxygen Saturation Decreased; Sinus Tachycardia; Suicide Attempt	Morphine	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported
	Morphine	S	Oral	Not Reported
	Morphine	S	Oral	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Oxycodone	S	Oral	Not Reported
	Oxycodone	S	Oral	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Zopiclone	S	Unknown	Not Reported
	Zopiclone	S	Oral	Not Reported
	Zopiclone	S	Oral	Not Reported
	Oxycodone-Acetaminophen	S	Oral	Not Reported
	Citalopram	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16778098	NON-EXPEDITED			US-TEVA-2019-US-1103807		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Orthostatic Hypotension	Escitalopram Tablets			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16479768	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1067478			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematemesis; Off Label Use; Product Use In Unapproved Indication	Azathioprine			S	Unknown			Not Reported
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Propranolol Hydrochloride			S	Oral	80 Milligram Daily;		Actavis
	Marijuana			S	Oral	1 Dosage Forms Daily;		Not Reported
	Pentasa			S	Unknown			Not Reported

	Premarin	S	Oral	.625 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16678876	EXPEDITED (15-DAY)		OT	DE-TOPROL ACQUISITION LLC-2019-TOP-000790		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Metoprolol Succinate			S	Oral	Unk		Not Reported
	Metoprolol Stada			S		Stada		Not Reported
	Metoprolol Stada			S		Mylan		Not Reported
	Metoprolol Stada			S		Hexal		Not Reported
	Metoprolol Tartrate			S	Oral	Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Escitalopram			S		Unk, Hexal		Not Reported
	Escitalopram			S		Unk, Mylan		Not Reported
	Escitalopram			S		Unk, Stada		Not Reported
	Prednisolone			S		25 Mg, Unk		Not Reported
	Prednisolone			S		Unk, Jenapharm		Not Reported
	Prednisolone			S		Unk, Stada		Not Reported
	Salbutamol			S		Unk		Not Reported
	Salbutamol			S		Unk, Stada		Not Reported
	Pantozol /01263204/			S		Unk		Not Reported
	Golimumab			S		Unk		Not Reported
	Methotrexate			S		1 Df, Weekly		Not Reported
	Amitriptyline Hydrochloride			S		Unk		Not Reported
	Implanon			S		Unk		Not Reported
	Ibuprofen			S		Stada		Not Reported
	Ibuprofen			S		Hexal		Not Reported
	Ibuprofen			S		Hormosan		Not Reported
	Ibuprofen			S		Unk		Not Reported

	Fluticasone Furoate W/Vilanterol Trifenatate			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16779525	EXPEDITED (15-DAY)		HO	FR-ACCORD-153980		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sinus Bradycardia; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16779533	EXPEDITED (15-DAY)		HO	IT-ACCORD-153959		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram			S				Not Reported
	Xanax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16779871	EXPEDITED (15-DAY)		OT	DE-KADMON PHARMACEUTICALS, LLC-KAD-201907-01471		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pancreatitis; Skin Ulcer; Skin Ulcer	Ribavirin			S	Oral	600 Mg (1200 Mg)		Kadmon
	Ribavirin			S	Oral	800 Mg		Kadmon
	Ribavirin			S	Oral	400 Mg-0-200 Mg (600 Mg)		Kadmon
	Ledipasvir W/Sofosbuvir			S	Oral	90mg		Not Reported
	Escitalopram			S	Oral	10 Mg		Not Reported
	Braunovidon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16780410	EXPEDITED (15-DAY)		HO, LT	IL-AMNEAL PHARMACEUTICALS-2019-AMRX-01804		35 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Overdose; Pulse Absent; Pulseless Electrical Activity; Unresponsive To Stimuli	Escitalopram Oxalate			S	Oral	250 Milligram, Once		Amneal
	Flecainide Acetate			S	Oral	2500 Milligram, Once		Amneal
	Quetiapine Fumarate			S	Oral	3000 Milligram, Once		Amneal
	Venlafaxine Hydrochloride			S	Oral	1000 Milligram, Once		Amneal
	Bisoprolol			S	Oral	25 Milligram, Once		Not Reported
	Clonazepam			S	Oral	5 Milligram, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16780521	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1083170		16 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Product Use Issue; Suicidal Ideation; Thinking Abnormal	Escitalopram			S	Unknown	5 Milligram		Not Reported
	Escitalopram			S	Unknown	15 Milligram		Not Reported
	Escitalopram			S	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16782580	EXPEDITED (15-DAY)		HO	SE-009507513-1909SWE000349		18 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury	Desloratadine			S	Oral	60 Milligram, "Total"		Merck
	Lergigan (Promethazine Hydrochloride)			S	Oral	200 Milligram, "Total"		Not Reported
	Escitalopram			S	Oral	140 Milligram, "Total"		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16782679	NON-EXPEDITED			US-SA-2019SA244397			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Ambien			S		Unk		Sanofi
	Spironolactone			S		Unk		Not Reported
	Amitriptyline Hydrochloride			S		Unk		Not Reported
	Loratadine			S	Unknown	Unk		Not Reported
	Clopidogrel Bisulfate			S	Unknown	Unk		Sanofi
	Escitalopram Oxalate			S	Unknown			Not Reported
	Metronidazole			S	Unknown	Unk		Sanofi
	Morphine Salt Not Specified			S	Unknown	Unk		Not Reported
	Clotrimazole			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Penicillin Nos			S	Unknown	Unk		Not Reported
	Fluticasone			S	Unknown			Not Reported
	Tylox [Oxycodone Hydrochloride;Paracetamol]			S	Unknown			Not Reported
	Mucinex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2019	16735158	EXPEDITED (15-DAY)		OT	DE-009507513-1904DEU001849		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Implanon			S	Unknown	Unk		Merck
	Golimumab			S	Unknown	Unk		Not Reported
	Albuterol Sulfate			S	Unknown	Unk		Not Reported
	Metoprolol Stada			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported

Methotrexate Sodium	S	Unknown	1 Dosage Form, Qw	Not Reported
Prednisolone	S	Unknown	25 Mg, Unk	Not Reported
Prednisolone	S	Unknown	Unk	Not Reported
Prednisolone	S	Unknown	2.5 Mg, Unk	Not Reported
Pantozol	S	Unknown	Unk	Not Reported
Metoprolol Mylan	S	Unknown	Unk	Not Reported
Metoprolol Succinate	S	Unknown	Unk	Not Reported
Metoprololo Hexal	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Escitalopram	S	Unknown	Unk	Not Reported
Albuterol	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Prednisolon	S	Unknown	Unk	Not Reported
Escitalopram	S	Unknown	Unk	Not Reported
Escitalopram Oxalate	S			Not Reported
Prednisolone	S	Unknown	Unk	Not Reported
Prednisolone	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Amitriptylin	S	Unknown	Unk	Not Reported
Amitriptylin	S			Not Reported
Ibuprofen Stada	S	Unknown	Unk	Not Reported
Ibuprofen Stada	S	Unknown	Unk	Not Reported
Fluticasone Furoate (+) Vilanterol Trifenatate	S	Unknown	Unk (6 Months Before Diagnosis)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16399426	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS-2019-005100		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Agitation; Chest	Symdeko			S	Oral	Unk, Bid		Vertex

Discomfort; Cough; Depressed Mood; Dyspnoea; Fatigue; Respiratory Tract Inflammation; Weight Increased	Lexapro		S	Unknown		Not Reported
	Lexapro		S	Oral	Decreased Dose	Not Reported
	Voriconazole		C	Oral	200 Mg, Bid	Not Reported
	Azithromycin		C	Oral	500 Mg, Qd	Not Reported
	Cayston		C	Respiratory (inhalation)	75 Mg, Tid	Not Reported
	Insulin		C			Not Reported
	Pulmozyme		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16675534	EXPEDITED (15-DAY)		HO	LT-ALLERGAN-1932121US			Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Major Depression; Off Label Use; Treatment Noncompliance	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Qd		Allergan
	Olanzapine			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16739899	EXPEDITED (15-DAY)		HO, LT	US-ASTRAZENECA-2019SF20397		35 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiac Arrest; Circulatory Collapse; Infection; Intentional Overdose; Pulseless Electrical Activity; Thrombocytopenia	Quetiapine			S	Oral	3,000 Mg		Zeneca
	Venlafaxine			S	Oral	1,000mg,		Not Reported
	Flecainide			S	Oral	2,500mg		Not Reported
	Escitalopram			S	Oral	250mg		Not Reported
	Bisoprolol			S	Oral	25mg		Not Reported
	Clonazepam			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16785110	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2014-00507			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Balance Disorder; Bradycardia; Dizziness; Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder	Amlodipine Tablets			S	Unknown	2.5 Mg,Two Times A Day,		Aurobindo
	Amlodipine Tablets			S	Unknown	2.5 Milligram, Once A Day		Aurobindo
	Ramipril			S	Unknown	5 Milligram, Once A Day		Aurobindo
	Furosemide			S	Unknown	40 Milligram, Once A Day		Not Reported
	Furosemide			S	Unknown	20 Milligram, Once A Day		Not Reported
	Metoprolol Tartrate			S	Unknown	25 Milligram, Once A Day		Not Reported
	Metoprolol Tartrate			S	Unknown	50 Milligram, Once A Day		Not Reported
	Glyceryl Trinitrate			S	Transdermal	Unk		Not Reported
	Glyceryl Trinitrate			S	Transdermal	0.4 Milligram, Two Times A Day		Not Reported
	Glyceryl Trinitrate			S	Transdermal	0.4 Milligram, 3 Times A Day		Not Reported
	Oxazepam			S	Unknown	20 Milligram, Once A Day		Not Reported
	Zopiclone			S	Unknown	5 Milligram, Once A Day		Not Reported
	Zopiclone			S	Unknown	2.5 Milligram, Once A Day		Not Reported
	Cipralex			S	Unknown	Unk		Not Reported
	Cipralex			S	Unknown	10 Milligram, Once A Day		Not Reported
	Codeine			S	Unknown	30 Milligram, Two Times A Day		Not Reported
	Codeine			S	Unknown	30 Milligram, 3 Times A Day		Not Reported
	Clopidogrel			C	Unknown	Unk		Not Reported
	Clopidogrel			C				Not Reported
	Clopidogrel			C				Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Atorvastatin			C				Not Reported
	Atorvastatin			C				Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Acetaminophen And Codeine			C	Unknown	Unk		Not Reported

Acetaminophen	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Polyethylene Glycol	C	Unknown	Unk		Not Reported
Amitriptyline	C	Unknown	Unk		Not Reported
Gabapentin	C	Unknown	Unk		Not Reported
Iron	C	Unknown	Unk		Not Reported
Acetylsalicylic Acid	C	Unknown	Unk		Not Reported
Ascorbic Acid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16785213	NON-EXPEDITED			US-MYLANLABS-2019M1080868			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Somnolence	Armodafinil			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Daily		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16786287	EXPEDITED (15-DAY)		HO	IL-UNICHEM PHARMACEUTICALS (USA) INC-UCM201908-000		35 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Infection; Overdose; Pulseless Electrical Activity; Thrombocytopenia	Quetiapine			S	Oral	3000 Mg		Unichem
	Bisoprolol Fumarate			S	Oral	25 Mg		Not Reported
	Flecainide			S	Oral	2500 Mg		Not Reported
	Venlafaxine			S	Oral	1000 Mg		Not Reported
	Escitalopram			S	Oral	250 Mg		Not Reported
	Clonazepam			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16786570	EXPEDITED (15-DAY)		HO, LT, OT	US-MYLANLABS-2019M1082851		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiac Arrest; Fall; Infection; Intentional Overdose; Suicide Attempt; Thrombocytopenia; Unresponsive To Stimuli	Quetiapine			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Bisoprolol			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Flecainide			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787717	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC-2019388979		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Potassium Increased; Blood Pressure Decreased; Bradycardia; Coma; Coma Scale Abnormal; Drug Interaction; Drug Screen Positive; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Heart Rate Decreased; Hyperkalaemia; Hypotension; Intentional Overdose; Loss Of Consciousness; Mechanical Ventilation; Opiates Positive; Overdose; Oxygen Saturation Decreased; Sinus Tachycardia;	Altace			S	Unknown	Unk		Pfizer
	Lorazepam			S	Oral	30 Mg, Unk		Pfizer
	Lorazepam			S	Oral	1 Mg, Unk		Pfizer
	Diazepam			S	Unknown	10 Mg, Unk		Pfizer
	Morphine Sulfate			S	Unknown	100 Mg, Unk		Unknown
	Morphine Sulfate			S	Unknown	2640 Mg, Unk		Unknown
	Morphine Sulfate			S	Unknown	420 Mg, Unk		Unknown
	Morphine Sulfate			S	Unknown	9500 Mg, Unk		Unknown
	Morphine Sulfate			S	Unknown	15 Mg, Unk		Unknown
	Morphine Sulfate			S	Unknown	Unk		Unknown
	Diazepam			S	Oral	1800 Mg, Unk		Not Reported
	Morphine			S	Oral	30 Mg, Qd		Not Reported
	Morphine			S	Oral	30 Mg, Unk		Not Reported
	Citalopram			S	Oral	Unk		Not Reported
	Cipralex [Escitalopram Oxalate]			S	Unknown	10 Mg, Qd		Not Reported
	Cipralex [Escitalopram Oxalate]			S	Oral	140 Mg, Unk		Not Reported
	Cipralex [Escitalopram Oxalate]			S	Unknown	10 Mg, Unk		Not Reported

Suicide Attempt	Oxycodone		S	Unknown	10 Mg, Unk	Not Reported
	Oxycodone		S	Oral	Unk	Not Reported
	Oxycodone		S	Oral	20 Mg, Unk	Not Reported
	Oxycodone		S		Unk	Not Reported
	Zopiclone		S	Unknown	7.5 Mg, Unk	Not Reported
	Zopiclone		S	Oral	187.5 Mg, Unk	Not Reported
	Zopiclone		S	Oral	15 Mg, Qd	Not Reported
	Acetaminophen;Oxycodone Hydrochloride		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16197891	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019154782		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Ibuprofen			S	Unknown	Unk		Pfizer
	Pantozol			S	Unknown	Unk		Pfizer
	Metoprolol Stada			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Ibuprofen Stada			S	Unknown	Unk		Not Reported
	Prednisolon Stada			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Implanon			S	Unknown	Unk		Not Reported
	Ibuprofen Hormosan			S		Unk		Not Reported
	Metoprolol Hexal			S	Unknown	Unk		Not Reported
	Salbutamol Stada			S	Unknown	Unk		Not Reported
	Escitalopram Mylan			S	Unknown	25 Mg, Unk		Not Reported
	Prednisolone			S	Unknown	2.5 Mg, Unk		Not Reported
	Prednisolone			S	Unknown	25 Mg, Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Escitalopram Stada			S	Unknown	Unk		Not Reported

	Escitalopram Hexal	S	Unknown	Unk	Not Reported
	Prednisolon Jenapharm	S	Unknown	Unk	Not Reported
	Metoprolol	S	Unknown	Unk	Not Reported
	Metoprolol Mylan	S	Unknown	Unk	Not Reported
	Ibuhexal [Ibuprofen]	S	Unknown	Unk	Not Reported
	Amitriptylin	S	Unknown	Unk	Not Reported
	Amitriptylin	S	Unknown	Unk	Not Reported
	Prednisolon [Prednisolone]	S	Unknown	25 Milligram	Not Reported
	Prednisolon [Prednisolone]	S	Unknown	2.5 Mg, Unk	Not Reported
	Methotrexate Mylan	S	Unknown	1 Df, Weekly	Not Reported
	Fluticasone Furoate/Vilanterol	S	Unknown	Unk, 6 Months Before Diagnosis	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16573205	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2019M1064989		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Overdose; Intentional Product Misuse; Psychomotor Skills Impaired	Escitalopram			S	Oral	100 Milligram, Total		Not Reported
	Quetiapine			S	Oral	500 Milligram, Total		Not Reported
	Lorazepam			S	Oral	250 Milligram, Total		Not Reported
	Trittico			S	Oral	10 Dosage Form, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16600054	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-042524			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Traumatic Haemothorax	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Eliquis			S	Oral	10 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16610198	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1929283US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Traumatic Haemothorax	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Eliquis			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16742439	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1934933US			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma Benign; Treatment Noncompliance	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S		5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16788239	EXPEDITED (15-DAY)		HO, LT, OT	IL-ALEMBIC PHARMACUETICALS LIMITED-2019SCAL000623		35 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiac Arrest; Cardiotoxicity; Infection; Intentional Overdose; Thrombocytopenia	Venlafaxine			S	Oral	Unknown		Alembic
	Quetiapine Fumarate			S	Oral	Unknown		Alembic
	Clonazepam			S	Oral	Unknown		Alembic
	Flecainide			S	Oral	Unknown		Not Reported
	Bisoprolol			S	Oral	Unknown		Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16789400	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2019-05739		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brugada Syndrome	Escitalopram			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16789494	EXPEDITED (15-DAY)		LT	US-ROCHE-2397440		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Infection; Overdose; Thrombocytopenia	Clonazepam			S	Unknown			Not Reported
	Flecainide			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16789674	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1082061		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral	18 Dosage Form, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16789883	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS-2019AMN00884		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Feeling Jittery	Escitalopram			S	Unknown	Unk		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16790072	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2019M1084042		50 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delusion; Eczema; Emotional Distress; Eosinophil Count Decreased; Feeling Cold; Frustration Tolerance Decreased; Haemoglobin Decreased; Hallucination, Auditory; Hyperhidrosis; Intentional Self-Injury; Lymphocyte Count Decreased; Mean Cell Haemoglobin Decreased; Mental Impairment; Metamyelocyte Count Increased; Monocyte Count Decreased; Myelocyte Count Increased	Escitalopram			S		Unk		Not Reported
	Clozaril			S		Unk		Mylan
	Olanzapine			S		Unk		Not Reported
	Paliperidone			S		Unk		Mylan
	Movicol /01749801/			C				Mylan
	Senna /00142201/			C				Mylan
	Lorazepam			C				Mylan
	Calcium Carbonate			C				Mylan
	Lurasidone Hydrochloride			C				Mylan
	Zuclopenthixol			C				Mylan
	Rosuvastatin Calcium			C				Mylan
	Caltrate /00944201/			C				Mylan
	Vitamin B12 /00056201/			C				Mylan
	Metformin			C				Mylan
	Mirtazapine			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16790167	EXPEDITED (15-DAY)		HO, LT, OT	IL-LUPIN PHARMACEUTICALS INC.-2019-05721		35 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiac Arrest; Cardiotoxicity; Circulatory Collapse; Dyspnoea; Infection; Intentional Overdose; Pulse Absent; Thrombocytopenia; Unresponsive To Stimuli	Quetiapine			S	Oral	3000 Milligram, Single		Lupin
	Escitalopram			S	Oral	250 Milligram		Lupin
	Venlafaxine			S	Oral	1000 Milligram, Single		Not Reported
	Bisoprolol			S	Oral	25 Milligram, Single		Not Reported
	Flecainide			S	Oral	2500 Milligram, Single		Not Reported
	Clonazepam			S	Oral	5 Milligram, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16790220	EXPEDITED (15-DAY)		OT	PHHY2019AU209334		50 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Delusion; Eczema; Emotional Distress; Eosinophil Count Decreased; Feeling Cold; Frustration Tolerance Decreased; Haemoglobin Decreased; Hallucination, Auditory; Hyperhidrosis; Intentional Self-Injury; Lymphocyte Count Decreased; Mean Cell Haemoglobin Decreased; Mental Impairment; Metamyelocyte Count Increased; Monocyte Count Decreased; Myelocyte Count Increased	Clozaril	S	Unknown	Unk		Not Reported
	Escitalopram	S	Unknown	Unk		Not Reported
	Olanzapine	S	Unknown	Unk		Novartis
	Paliperidone	S	Unknown	Unk		Not Reported
	Movicol	C	Unknown	Unk		Not Reported
	Senna	C	Unknown	Unk		Not Reported
	Lorazepam	C	Unknown	Unk		Not Reported
	Calcium Carbonate	C	Unknown	Unk		Not Reported
	Lurasidone Hydrochloride	C	Unknown	Unk		Not Reported
	Zuclopenthixol	C	Unknown	Unk		Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk		Not Reported
	Vitamin B 12 Lichtenstein	C	Unknown	Unk		Not Reported
	Metformin	C	Unknown	Unk		Not Reported
	Mirtazapine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16791524	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2019M1084023		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperreflexia; Mydriasis; Poisoning Deliberate	Escitalopram			S	Oral	25 Dosage Form, Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16791592	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1936501US			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Intentional Self-Injury	Escitalopram Oxalate - Bp			S	Oral	Overdose: 140mg		Allergan
	Lergigan [Promethazine Hydrochloride]			S	Oral	200 Mg		Not Reported
	Desloratadine			S	Oral	60 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16791597	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1936500US			Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Condition Aggravated	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16791600	EXPEDITED (15-DAY)		HO, LT, OT	FR-ALLERGAN-1936499US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Poisoning Deliberate; Sinus Bradycardia; Somnolence	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan
	Propranolol			S	Oral	4000 Mg		Not Reported
	Quetiapine			S	Oral	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16792919	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-022169			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Drug Ineffective; Drug Interaction; Ligament Sprain; Musculoskeletal Stiffness; Prostatic Specific Antigen; Psoriasis Area Severity Index; Seborrhoeic Keratosis; Skin Hyperpigmentation; Tenosynovitis; Visual Analogue Scale; Weight Decreased	Acitretin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Every Week		Not Reported
	Escitalopram			S	Unknown	Unk		Aurobindo
	Apremilast			S	Oral	30 Milligram, Two Times A Day		Not Reported
	Apremilast			S	Oral	30 Mg, Bid,12 Hour		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Infliximab			S				Not Reported
	Infliximab			S				Not Reported

	Adalimumab	S	Unknown	Unk		Not Reported
	Adalimumab	S				Not Reported
	Adalimumab	S				Not Reported
	Cardioaspirin	S	Unknown	Unk		Not Reported
	Atenolol	S	Unknown	Unk		Not Reported
	Propafenone	S	Unknown	Unk		Not Reported
	Colecalciferol	S	Unknown	Unk		Not Reported
	Aspirin	S	Unknown	Unk		Not Reported
	Calcipotriol	S	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	12569713	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2016US09743			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	10 Mg, Qd		Invagen
	Zolpidem Tartrate			C	Unknown	Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	13078818	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2016ES159974		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis	Sintrom			S	Oral	1 Mg, Qd		Not Reported
	Bisoprolol			S	Oral	5 Mg, Bid		Novartis
	Furosemide			S	Oral	60 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Alendronate		S	Oral	70 Mg, Qw	Not Reported
	Omeprazole		S	Oral	20 Mg, Qd	Not Reported
	Allopurinol		S	Oral	100 Mg, Qd	Not Reported
	Spironolactone		S	Oral	50 Mg, Qd	Not Reported
	Lisinopril		S	Oral	5 Mg, Qd	Not Reported
	Ipratropium Bromide		S	Respiratory (inhalation)	2 Inh, Q8h	Not Reported
	Iron Sulphate		S	Oral	256.3 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	15889566	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-1904181US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activation Syndrome; Nausea; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Gasmotin			C	Oral	5 Mg, Qd		Not Reported
	Dogmatyl			C	Oral	100 Mg, Q12h		Not Reported
	Lendormin			C	Oral	0.25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16143243	EXPEDITED (15-DAY)		HO, OT	FR-WHANIN PHARM. CO., LTD.-2019M1030186		24 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Anxiety; Cardiac Disorder; Drug Ineffective; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Thinking Abnormal	Clozapine			S		600 Mg, Qd		Not Reported
	Clozapine			S		Unk		Not Reported
	Aripiprazole			S	Unknown	30 Mg, Qd		Not Reported
	Aripiprazole			S	Unknown	10 Mg, Qd		Not Reported
	Aripiprazole			S	Unknown	Unk		Not Reported
	Mirtazapine			S		15 Mg, Qd		Not Reported
	Mirtazapine			S		30 Mg, Qd		Not Reported

	Escitalopram	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16753047	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2019US06045			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clonus; Confusional State; Delirium; Dysdiadochokinesis; Electrocardiogram Qt Prolonged; Intentional Overdose; Mydriasis; Prescription Drug Used Without A Prescription; Toxicity To Various Agents; Treatment Failure; Tremor	Sertraline			S	Oral	3000 Milligram (Toxic Ingestion), In Total		Invagen
	Sertraline			S	Unknown	Unk (Antidepressant Trial)		Invagen
	Escitalopram			S	Unknown	20 Milligram, Per Day		Invagen
	Olanzapine			S	Unknown	Unk		Invagen
	Fluvoxamine			S	Unknown	Unk		Not Reported
	Imipramine			S	Unknown	Unk		Not Reported
	Venlafaxine			S	Unknown	Unk		Not Reported
	Venlafaxine			S	Unknown	Unk (Last Medication Regimen)		Not Reported
	Aripiprazole			S	Unknown	Unk		Not Reported
	Chlorpromazine			S	Unknown	Unk		Not Reported
	Ziprasidone			S	Unknown	Unk		Not Reported
	Ziprasidone			S	Unknown	Unk (Last Medication Regimen)		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Prazosin			S	Unknown	Unk		Not Reported
	Prazosin			S	Unknown	Unk (Last Medication Regimen)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16761330	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2019-024587		44 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Long Qt Syndrome; Torsade De Pointes	Salbutamol		S	Unknown	Bausch And Lomb
	Olanzapine		S	Unknown	Not Reported
	Escitalopram		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16793130	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2019-US-1105410		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiac Arrest; Infection; Intentional Overdose; Suicide Attempt; Thrombocytopenia	Clonazepam			S	Oral			Barr
	Quetiapine			S	Oral			Teva
	Venlafaxine			S	Oral			Teva
	Escitalopram			S	Oral			Ivax
	Bisoprolol			S	Oral			Teva
	Flecainide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16793893	EXPEDITED (15-DAY)		OT	PHHY2018FI180473			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Cavity Infection; Failed Induction Of Labour; Gestational Diabetes; Maternal Exposure During Pregnancy	Gilenya			S	Unknown	Unk		Novartis
	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
	Losatrix Comp			C	Unknown			Not Reported
	Edronax			C	Unknown			Not Reported
	Brintellix			C	Unknown	1 Df, Qd		Not Reported
	Albetol			C	Unknown	1 Df, (1 To 2)		Not Reported
	Vitamin D			C	Unknown	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16794132	EXPEDITED (15-DAY)		OT	GB-ACCORD-154281		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration	Escitalopram			S				Not Reported
	Ventolin			C	Respiratory (inhalation)			Not Reported
	Otomize			C				Not Reported
	Duloxetine			C		Night		Not Reported
	Pregabalin			C				Not Reported
	Hydroxocobalamin			C	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16794179	EXPEDITED (15-DAY)		HO	FR-ACCORD-154578		101 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Orthostatic Hypotension	Escitalopram			S	Oral			Not Reported
	Ramipril			S	Oral			Accord
	Diosmectite			C				Not Reported
	Paracetamol			C				Not Reported
	Econazole			C				Not Reported
	Levetiracetam			C				Not Reported
	Colecalciferol			C				Not Reported
	Valpromide			C				Not Reported
	Dexpanthenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16794517	EXPEDITED (15-DAY)		DE, HO	ES-ASTRAZENECA-2019SF27224		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder;	Omeprazol			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Alendronic Acid			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Iron Sulfate			S	Oral			Not Reported

Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Bisoprolol		S	Oral		Not Reported
	Bromide Ipratrope		S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated	Not Reported
	Sintrom		S	Oral		Not Reported
	Spironolactone		S	Oral		Not Reported
	Allopurinol		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16795166	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2019M1085174		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Tramadol			S	Oral	Unk		Not Reported
	Paracetamol			S	Oral	12 Gram		Not Reported
	Diazepam			S	Oral	100 Milligram		Mylan
	Seroplex			S	Oral	560 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16795353	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019384952			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anxiety; Decreased Interest; Depressed Mood; Feeling Guilty; Headache; Hyperventilation; Initial Insomnia; Mental Impairment; Pallor; Palpitations	Triazolam			S		0.5mg, Daily		Pfizer
	Mirtazapine			S		45 Mg, Daily		Not Reported
	Escitalopram			S		20 Mg, Daily		Not Reported
	Brotizolam			S		0.25 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16795999	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2019M1085164		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine		S	Oral	Unk	Not Reported
	Mirtazapine		S	Oral	Unk	Not Reported
	Escitalopram		S	Oral	Unk	Not Reported
	Racecadotril Bgr		S	Oral	Unk	Mylan
	Levothyrox		S	Oral	Unk	Mylan
	Coveram		S	Oral	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16796130	EXPEDITED (15-DAY)		HO, LT, OT	IL-PRINSTON PHARMACEUTICAL INC.-2019PRN00792		35 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Unresponsive To Stimuli	Clonazepam			S	Oral	5 Mg		Prinston Pharmaceutical
	Escitalopram			S	Oral	250 Mg		Prinston Pharmaceutical
	Venlafaxine			S	Oral	1000 Mg		Prinston Pharmaceutical
	Quetiapine			S	Oral	3000 Mg		Not Reported
	Flecainide			S	Oral	2500 Mg		Not Reported
	Bisoprolol			S	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16796567	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1936611US			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Cardiac Event; Seizure; Seizure; Seizure; Seizure; Tachycardia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Epilim			C	Unknown			Not Reported
	Trileptal			C	Unknown			Not Reported
	Florinef			C	Unknown			Not Reported
	Keppra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16796648	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1936683US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Overdose; Sinus Bradycardia	Escitalopram Oxalate - Bp			S	Oral	28 Df, Single		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16796667	EXPEDITED (15-DAY)		DS	FR-ALLERGAN-1936870US			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Product Use In Unapproved Indication; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	20 Mg		Allergan
	Inegy			S	Unknown			Not Reported
	Inexium			S	Oral	1 Df		Not Reported
	Kardegic			S	Oral	1 Df		Not Reported
	Keppra			C	Unknown			Not Reported
	Tenormine			C	Unknown			Not Reported
	Tiapridal			C	Unknown			Not Reported
	Coaprovel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16796674	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFM-2019-10933			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Off Label Use; Poisoning Deliberate; Product Use Issue; Sinus Bradycardia; Somnolence	Propranolol			S	Oral	4000mg In Total		Pierre Fabre Medicament
	Quetiapine			S	Oral	1000mg In Total		Not Reported
	Escitalopram			S	Oral	10mg In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16797083	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2019-059126		27 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Diarrhoea; Influenza Like Illness; Malaise; Product Prescribing Error; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Aurobindo
	Trazodone			S	Unknown	Unk		Not Reported
	Tramagit			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	12594481	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2016-09711		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Autoimmune Hepatitis; Blood Bilirubin Increased; Hepatic Necrosis; Hepatitis Cholestatic; Hepatomegaly; Hepatosplenomegaly	Escitalopram			S	Unknown	Unk		Aurobindo
	Diazepam			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Zolpidem			C	Unknown	Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	14351486	EXPEDITED (15-DAY)		HO, OT	FR-NOVOPROD-579479		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Novorapid			S	Subcutaneous	Unk		Novo Nordisk
	Xeloda			S	Oral	Unk		Not Reported
	Primperan			S	Oral	Unk		Not Reported
	Lipanthyl			S	Oral	Unk		Not Reported
	Movicol			S	Oral	Unk		Not Reported

	Pantoprazole	S	Oral	Unk		Not Reported
	Escitalopram	S	Oral	Unk		Not Reported
	Abasaglar	S	Subcutaneous	Unk		Not Reported
	Fondaparinux Sodium	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16114803	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019044230		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	1 Dosage Form, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			S	Oral	1 Dosage Form, Qd		Not Reported
	Xeljanz			S	Oral	1 Dosage Form, Bid		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Prednisone			C	Oral	10 Milligram, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16600443	EXPEDITED (15-DAY)		OT	DE-HETERO-HET2019DE00975		48 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pancreatitis; Skin Ulcer; Skin Ulcer	Escitalopram			S	Oral	Qd		Hetero
	Ledipasvir W/Sofosbuvir			S	Oral	90 Mg, Q.D.		Not Reported
	Ribavirin			S	Oral	600 Mg, Q.D.		Not Reported

Ribavirin	S	Oral	600 Mg (400mg-0-200 Mg)		Not Reported
Ribavirin	S	Oral	400 Mg, Bid		Not Reported
Ribavirin	S	Oral	600 Mg, Bid		Not Reported
Braunovidon	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16771080	EXPEDITED (15-DAY)		DS	US-TORRENT-00009144		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Impaired Quality Of Life; Sexual Dysfunction	Escitalopram			S	Oral	Dosage Of 5-10 Mg		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16797514	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-059121			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Hypertension; Muscle Spasms; Tremor	Escitalopram			S	Unknown	10 Milligram		Aurobindo
	Escitalopram			S	Unknown	5 Milligram		Aurobindo
	Tegretal			S	Unknown	Unk		Not Reported
	Tegretal			S	Unknown	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16797910	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2019-FR-1104865		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Sinus Bradycardia; Somnolence	Quetiapine			S	Oral	1000 Milligram		Teva
	Escitalopram			S	Oral	10 Milligram		Ivax
	Propranolol			S	Oral	4000 Milligram		Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16797965	EXPEDITED (15-DAY)		HO, LT, OT	IL-MACLEODS PHARMACEUTICALS US LTD-MAC2019022898			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiac Arrest; Cardiotoxicity; Infection; Intentional Overdose; Thrombocytopenia	Escitalopram			S	Oral	250 Milligram		Macleods
	Quetiapine			S	Oral	3000 Milligram		Macleods
	Venlafaxine			S	Oral	1000 Milligram		Macleods
	Flecainide			S	Oral	2500 Milligram		Not Reported
	Clonazepam			S	Oral	5 Milligram		Not Reported
	Bisoprolol			S	Oral	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16798043	EXPEDITED (15-DAY)		HO, OT	AU-APOTEX-2019AP021644		79 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Hyponatraemia; Stress Cardiomyopathy	Mirtazapine			S	Unknown	45 Mg, Q.H.S.		Apotex
	Desvenlafaxine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	10 Mg, Unk		Apotex
	Oxazepam			C	Unknown	7.5 Mg, Qid		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Olmesartan			C	Unknown	Unk		Not Reported
	Amiodarone			C	Unknown	Unk		Not Reported
	Rivaroxaban			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16798177	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-219857		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dyspnoea; Infection; Intentional Overdose; Loss Of Consciousness; Pulseless Electrical Activity; Thrombocytopenia; Unresponsive To Stimuli	Clonazepam			S	Oral	5 Mg, Unk		Sun
	Flecainide Acetate			S	Oral	2500 Mg, Unk		Sun
	Quetiapine			S	Oral	3000 Mg, Unk		Sun
	Venlafaxine			S	Oral	1000 Mg, Unk		Sun
	Escilatopram			S	Oral	250 Mg, Unk		Not Reported
	Bisoprolol			S	Oral	25 Mg, Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16798321	EXPEDITED (15-DAY)		HO	NL-ACCORD-154619			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteoporosis	Escitalopram			S		1x Pd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16799331	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019388392		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Xanax			S	Oral	9 Df, Single		Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16799360	EXPEDITED (15-DAY)		HO, LT	FR-MYLANLABS-2019M1085843		91 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Perindopril			S	Oral	8 Milligram, Qd		Not Reported
	Amlodipine			S	Oral	10 Milligram, Qd		Not Reported
	Fludex /00340101/			S	Oral	Inconnue		Mylan
	Zelitrex			S	Oral	6 Dosage Form, Qd		Mylan

Ditropan	S	Oral	2 Dosage Form, Qd		Mylan
Seroplex	S	Oral	1 Dosage Form, Qd		Mylan
Movicol /01749801/	C	Oral	2 Dosage Form, Qd		Mylan
Paracetamol	C	Oral	3 Dosage Form, Qd		Mylan
Cortancyl	C	Oral	2 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16799978	NON-EXPEDITED			US-TEVA-2019-US-1105745			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Depression; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16800966	EXPEDITED (15-DAY)		OT	PHHY2019FI211224		34 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Behaviour Disorder; Drug Ineffective For Unapproved Indication; Intentional Product Use Issue; Intentional Self-Injury; Multiple Drug Therapy	Carbamazepine			S	Unknown	Unk		Novartis
	Candesartan Cilexetil			S	Unknown	16 Mg, Qd		Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported
	Topiramate			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	4 Mg, Qd		Not Reported
	Risperidone			S	Unknown	3 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	20 Mg, Qd		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	10 Mg, Qd		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported

	Macrogol 3350	S	Unknown	Unk, 3 Bags / Day	Not Reported
	Levomepromazine	S	Unknown	100 Mg, Qd	Not Reported
	Melatonin	S	Unknown	3 Mg, Qd	Not Reported
	Citalopram	S	Unknown	Unk	Not Reported
	Lorazepam	S	Unknown	3 Mg, Qd	Not Reported
	Oxcarbazepine	C	Unknown	900 Mg, Qd	Not Reported
	Valproate Sodium	C	Unknown	1200 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16801579	EXPEDITED (15-DAY)		DE, HO, OT	CH-ASTRAZENECA-2019SF09219		78 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Interstitial Lung Disease; Respiratory Failure	Beloc Zok			S	Oral			Not Reported
	Aspirin Cardio			S	Unknown			Not Reported
	Quetiapin Sandoz			S	Oral	12.5 Mg,1-2x/24h		Not Reported
	Quetiapin Sandoz			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Dexilant			S	Oral	60.0mg Unknown		Not Reported
	Pregabalin Pfizer			S	Unknown			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Unknown			Not Reported
	Toviaz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16801697	EXPEDITED (15-DAY)		HO, LT, OT	IL-JUBILANT CADISTA PHARMACEUTICALS-2019JUB00342		35 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Unresponsive To Stimuli	Quetiapine			S	Oral	3000 Mg		Jubilant

Escitalopram	S	Oral	250 Mg		Jubilant
Clonazepam	S	Oral	5 Mg		Not Reported
Venlafaxine	S	Oral	1000 Mg		Not Reported
Flecainide	S	Oral	2500 Mg		Not Reported
Bisoprolol	S	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16802007	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1084465			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Burnout Syndrome; Drug Interaction; Drug Intolerance; Heart Rate Increased; Hyperhidrosis; Hypertension; Palpitations; Panic Attack; Product Use Issue; Restlessness; Stress	Escitalopram			S		Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Cipralex /01588501/			S	Unknown	5 Milligram, Qd		Mylan
	Cipralex /01588501/			S	Unknown	10 Milligram		Mylan
	Cipralex /01588501/			S	Unknown	7.5 Milligram, Qod		Mylan
	Ibuprofen			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16802226	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1107764		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aptyalism; Drug Ineffective; Overdose; Panic Disorder	Amitriptyline			S	Oral	20 Milligram Daily;		Not Reported
	Buspirone			S	Oral	5 Milligram Daily;		Teva
	Escitalopram			S	Oral			Ivax
	Zyprexa			S	Oral	2.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16802368	EXPEDITED (15-DAY)		HO	KR-ALLERGAN-1936868US			Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Mental Impairment; Off Label Use	Escitalopram Oxalate - Bp		S	Unknown	Unk	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16802379	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1936875US			Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Product Administered To Patient Of Inappropriate Age; Underdose	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16802792	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2019-059417			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram			S	Unknown	Unk		Aurobindo
	Xanax			S	Oral	9 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	13940299	NON-EXPEDITED			US-MALLINCKRODT-T201606073			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Dizziness; Limb Discomfort; Muscle Rigidity; Somnolence; Yawning	Pamelor			S	Oral	Unk		Mallinckrodt
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	14389660	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018015554		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebrovascular Accident	Pantoprazole	S	Oral	Unk		Pfizer
	Xeloda	S	Oral	Unk		Not Reported
	Novorapid	S	Subcutaneous	Unk		Not Reported
	Primperan	S	Oral	Unk		Not Reported
	Lipanthyl	S	Oral	Unk		Not Reported
	Movicol	S	Oral	Unk		Not Reported
	Escitalopram Oxalate	S	Oral	Unk		Not Reported
	Abasaglar	S	Subcutaneous	Unk		Not Reported
	Fondaparinux Sodique	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	14651809	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-015001		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Pantoprazole			S	Oral	Unk		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	Unk		Aurobindo
	Novorapid			S	Subcutaneous	Unk		Not Reported
	Primperan			S	Oral	Unk		Not Reported
	Xeloda			S	Oral	Unk		Not Reported
	Movicol			S	Oral	Unk		Not Reported
	Fondaparinux Sodium			S	Subcutaneous	Unk		Not Reported
	Abasaglar			S	Subcutaneous	Unk		Not Reported
	Lipanthyl			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	14678740	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-015719		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Pantoprazole			S	Oral	Unk ()		Aurobindo

	Escitalopram Film-Coated Tablets	S	Oral	Unk ()	Aurobindo
	Novorapid	S	Subcutaneous	Unk ()	Not Reported
	Lipanthyl	S	Oral	Unk ()	Not Reported
	Primperan	S	Oral	Unk ()	Not Reported
	Fondaparinux Sodium	S	Subcutaneous	Unk ()	Not Reported
	Movicol	S	Oral	Non Renseignée ()	Not Reported
	Abasaglar	S	Subcutaneous	Unk ()	Not Reported
	Xeloda	S	Oral	Unk ()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16122591	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019132015		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Xeljanz			S	Oral	1 Dosage Form, Bid		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk		Pfizer
	Pantoprazole			S	Oral	1 Dosage Form, Qd		Pfizer
	Escitalopram Oxalate			S	Oral	1 Dosage Form, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Prednisone			C	Oral	10 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16616927	EXPEDITED (15-DAY)		HO	FR-ZYDUS-038753		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Traumatic Haemothorax	Escitalopram			S	Oral			Cadila
	Eliquis			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16733443	NON-EXPEDITED		DS, OT	CA-AMGEN-CANCT2019059800		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Abnormal; Cluster Headache; Constipation; Depression; Diarrhoea; Dysarthria; Hemiplegia; Hemiplegic Migraine; Influenza; Lower Respiratory Tract Infection; Malaise; Migraine; Muscle Spasms; Oropharyngeal Pain; Pain; Palpitations; Personality Change; Pyrexia; Serotonin Syndrome; Speech Disorder; Tremor; Viral Infection	Aimovig			S	Subcutaneous	140 Milligram, Qmo		Amgen
	Aimovig			S	Subcutaneous	140 Milligram, Qmo		Amgen
	Aimovig			S	Subcutaneous	140 Milligram, Qmo		Amgen
	Mmr			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd		Not Reported
	Escitalopram Oxalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16767736	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1081639			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Escitalopram Mylan			S	Unknown	Unk		Mylan
	Methotrexate Mylan			S	Unknown	Unk		Mylan
	Metoprolol Mylan			S	Unknown	Unk		Mylan
	Salbutamol			S	Unknown	Unk		Not Reported
	Metoprolol Stada			S	Unknown	Unk		Mylan

	Ibuprofen Stada	S	Unknown	Unk	Mylan
	Prednisolon Stada	S	Unknown	Unk	Mylan
	Golimumab	S	Unknown	Unk	Mylan
	Pantozol /01263204/	S	Unknown	Unk	Mylan
	Implanon	S	Unknown	Unk	Mylan
	Ibuprofen Hormosan	S	Unknown	Unk	Mylan
	Metoprolol Hexal	S	Unknown	Unk	Mylan
	Salbutamol Stada	S	Unknown	Unk	Mylan
	Ibuprofen	S	Unknown	Unk	Mylan
	Prednisolone	S	Unknown	25 Milligram	Mylan
	Prednisolone	S	Unknown	Unk	Mylan
	Escitalopram Stada	S	Unknown	Unk	Mylan
	Escitalopram Hexal	S	Unknown	Unk	Mylan
	Prednisolon Jenapharm	S	Unknown	Unk	Mylan
	Ibuprofen	S	Unknown	Unk	Mylan
	Amitriptylin	S	Unknown	Unk	Mylan
	Prednisolon /00016201/	S	Unknown	Unk	Mylan
	Metoprolol	S	Unknown	Unk	Mylan
	Escitalopram	S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16791568	EXPEDITED (15-DAY)		LT	IL-ALLERGAN-1936621US			Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Loss Of Consciousness; Pulseless Electrical Activity; Respiration Abnormal	Escitalopram Oxalate - Bp			S	Unknown	Overdose: 250 Mg		Allergan
	Flecainide			S	Unknown	2500 Mg		Not Reported
	Quetiapine			S	Unknown	3000 Mg		Not Reported
	Venlafaxine			S	Unknown	1000 Mg		Not Reported
	Bisoprolol			S	Unknown	25 Mg		Not Reported

	Clonazepam	S	Unknown	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16803241	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1105667		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sinus Bradycardia	Escitalopram (Oxalate D')			S	Oral	28 Dosage Forms		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16803566	EXPEDITED (15-DAY)		HO, LT	FR-ZYDUS-040500		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Sinus Bradycardia; Somnolence	Escitalopram			S	Oral			Cadila
	Quetiapine			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16803583	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-040601		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiac Arrest; Circulatory Collapse; Dyspnoea; Infection; Intentional Overdose; Pulse Absent; Pulseless Electrical Activity; Suicide Attempt; Thrombocytopenia; Unresponsive To Stimuli	Escitalopram			S	Oral			Cadila
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Zydus Pharm
	Bisoprolol			S	Oral			Not Reported
	Flecainide			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16804051	EXPEDITED (15-DAY)		HO, OT	AU-ACCORD-154878		79 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyponatraemia; Stress Cardiomyopathy	Escitalopram			S				Not Reported
	Amlodipine			C				Not Reported
	Rivaroxaban			C				Not Reported
	Amiodarone			C				Not Reported
	Olmesartan/Olmesartan Medoxomil			C				Not Reported
	Diazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16804055	EXPEDITED (15-DAY)		HO, LT, OT	IL-ACCORD-154876		35 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiac Arrest; Cardiotoxicity; Infection; Intentional Overdose; Thrombocytopenia	Clonazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Flecainide			S	Oral			Not Reported
	Bisoprolol			S	Oral			Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16804292	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1105891		45 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Sopor	Escitalopram Oxalate			S	Unknown			Ivax
	Xanax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16804504	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1084487		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hyperhidrosis; Nausea; Night Sweats; Oedema	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported
	Escitalopram			S	Unknown	5 Milligram, Qd		Not Reported
	Tirosint			C	Unknown	Initially Given Every 4 Days With A Goal Of Reaching Daily Dosing		Mylan
	Armour Thyroid			C	Unknown	7.5 Mg On Mondays And Thursdays		Mylan
	Biotin			C	Unknown			Mylan
	Dexilant			C	Unknown			Mylan
	Fish Oil			C	Unknown			Mylan
	Glucosamine Chondroitin /01430901/			C	Unknown			Mylan
	Magnesium			C	Unknown			Mylan
	Premarin			C	Unknown			Mylan
	Selenium			C	Unknown			Mylan
	Vitamin B 12			C	Unknown			Mylan
	Vitamin D3			C	Unknown	5000 Units Daily		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16804751	EXPEDITED (15-DAY)		DS	FR-ASTRAZENECA-2019SF26553		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Subdural Haematoma	Inexium			S	Oral			Astrazeneca
	Kardegic			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Inegy			S	Unknown			Not Reported
	Keppra			C				Not Reported

	Tenormine	C	Not Reported
	Tiapridal	C	Not Reported
	Coaprovel	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16805766	NON-EXPEDITED			US-APOTEX-2019AP017832		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Treatment Failure	Risperidone			S	Unknown	Unk		Apotex
	Fluoxetine			S	Unknown	Unk		Apotex
	Fluvoxamine			S	Unknown	Unk		Apotex
	Aripiprazole			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Quetiapine			S	Unknown	200 Mg, Per Day		Apotex
	Venlafaxine			S	Unknown	Unk		Not Reported
	Clonidine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16807184	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1085289		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral	Unk		Not Reported
	Spironolactone			S	Oral	Unk		Not Reported
	Diltiazem Mylan			S	Oral	Unk		Mylan
	Pantoprazole			S	Oral	Unk		Not Reported
	Trileptal			S	Oral	Unk		Mylan
	Tinzaparine Sodique			S	Subcutaneous	Unk		Mylan
	Lacosamide			S	Oral	Unk		Mylan
	Bactrim			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16807292	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1935061US			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Belsomra			C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16807301	EXPEDITED (15-DAY)		HO	NL-ALLERGAN-1937420US			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteoporosis	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd (1x Pd)		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16807370	NON-EXPEDITED			PHEH2019US036908			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Lorazepam			S	Unknown	1 Mg, Qd		Novartis
	Lorazepam			S	Unknown	1 Mg, Prn		Novartis
	Lexapro			S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2019	16726678	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1093613		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Hot Flush	Escitalopram			S	Unknown			Ivax
	Trazodone			S	Unknown			Barr
	Citalopram			S	Unknown			Not Reported
	Fluoxetine			S	Oral			Not Reported

	Lurasidone	S	Unknown	Not Reported
	Sertraline	S	Unknown	Not Reported
	Alprazolam	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2019	16807871	EXPEDITED (15-DAY)		OT	PHHY2019FI205677		34 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Drug Ineffective; Off Label Use	Bisoprolol			S	Unknown	Unk		Not Reported
	Bisoprolol			S				Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Metoprolol			S				Not Reported
	Candesartan Sandoz			S	Unknown	16 Mg, Qd		Not Reported
	Candesartan Sandoz			S				Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Trileptal			S	Unknown	900 Mg, Qd		Novartis
	Trileptal			S				Novartis
	Topiramate			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	4 Mg, Qd		Not Reported
	Risperidone			S	Unknown	3 Mg, Qd		Not Reported
	Pantoprazole			S	Unknown	20 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	10 Mg, Qd		Not Reported
	Valproate			S	Unknown	1200 Mg, Qd		Not Reported
	Valproate			S				Not Reported
	Valproate			S				Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported
	Carbamazepine			S	Unknown	Unk		Not Reported
	Carbamazepine			S				Not Reported
	Melatonin			S	Unknown	3 Mg, Qd		Not Reported
	Levomepromazine			S	Unknown	100 Mg, Qd		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported

Amitriptyline	S	Unknown	Unk		Not Reported
Lorazepam	S	Unknown	3 Mg, Qd		Not Reported
Macrogol	S	Unknown	Unk (3350 With Dosage 3 Bags/Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2019	16807953	EXPEDITED (15-DAY)		HO	US-ELI_LILLY_AND_COMPANY-US201909004154			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Hypothermia; Insomnia; Off Label Use; Somnolence; Suicidal Behaviour; Suicidal Ideation	Prozac			S	Unknown	20 Mg, Unknown		Eli Lilly And Co
	Prozac			S	Unknown	40 Mg, Unknown		Eli Lilly And Co
	Prozac			S	Unknown	60 Mg, Unknown		Eli Lilly And Co
	Prozac			S	Unknown	80 Mg, Unknown		Eli Lilly And Co
	Lamictal			S	Unknown	Unk, Unknown		Not Reported
	Lamictal			S	Unknown	6000 Mg, Unknown		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Lexapro			S	Unknown	8000 Mg, Unknown		Not Reported
	Seroquel			S	Unknown	Unk, Unknown		Not Reported
	Klonopin			S	Unknown	Unk, Unknown		Not Reported
	Klonopin			S	Unknown	80 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16454865	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-210942		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Spinal Fracture	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Risperidone			S	Oral	1 Milligram, Daily		Ranbaxy
	Agomelatine			S	Oral	25 Milligram, Daily		Not Reported
	Phenergan 25 Mg, Comprime			S	Oral	25 Milligram, Daily		Not Reported

Enrobe					
Lormetazepam	S	Oral	2 Milligram, Daily		Not Reported
Clotiazepam	S	Oral	Non		Not Reported
Tilcotil	C	Unknown	()		Not Reported
Atorvastatine	C	Unknown	()		Not Reported
Kardegic	C	Unknown	()		Not Reported
Esomeprazole	C	Unknown	()		Not Reported
Ramipril	C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16661874	EXPEDITED (15-DAY)		DE, HO, OT	CH-TOPROL ACQUISITION LLC-2019-TOP-000759		78 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Interstitial Lung Disease; Respiratory Failure	Metoprolol Succinate			S	Oral	50 Mg, Qd		Not Reported
	Atorvastatin			S	Oral	40 Mg, Qd		Not Reported
	Cipralex /01588501/			S	Oral	10 Mg, Bid		Not Reported
	Dexilant			S	Oral	60 Mg, Unk		Not Reported
	Aspirin Cardio			S		100 Mg, Qd		Not Reported
	Pregabalin			S		50 Mg, Qid		Not Reported
	Toviaz			S	Oral	8 Mg, Qd		Not Reported
	Temesta /00273201/			S		2.2 Mg, Bid		Not Reported
	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported
	Sandoz Quetiapine Xrt 50mg			S	Oral	12.5 Mg,1-2x/24h		Not Reported
	Sandoz Quetiapine Xrt 50mg			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16756241	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1081100		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Loss Of Consciousness; Malaise; Syncope; Withdrawal Syndrome	Telmisartan		S	Unknown	Unk	Not Reported
	Seroplex		S	Oral	15 Milligram, Qd	Mylan
	Seroplex		S	Oral	10 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16785711	EXPEDITED (15-DAY)		HO, LT	IL-PFIZER INC-2019378445		35 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose	Venlafaxine Hcl			S	Oral	1000 Mg, Unk		Pfizer
	Bisoprolol			S	Oral	25 Mg, Unk		Not Reported
	Flecainide			S	Oral	2500 Mg, Unk		Not Reported
	Quetiapine			S	Oral	3000 Mg, Unk		Not Reported
	Escitalopram			S	Oral	250 Mg, Unk		Not Reported
	Clonazepam			S	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16807987	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190906065			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Tylenol			S	Topical	%Frequency%		Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Voltaren /00372301/			S	Unknown			Not Reported
	Nortriptyline			S	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Infliximab, Recombinant Unspecified			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16808776	EXPEDITED (15-DAY)		HO, OT	AU-CIPLA LTD.-2019AU06237			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyponatraemia; Stress Cardiomyopathy	Escitalopram			S	Unknown	10 Milligram, 5 Days		Invagen
	Diazepam			C	Unknown	Unk		Not Reported
	Mirtazapine			C	Unknown	45 Milligram, At Night		Not Reported
	Oxazepam			C	Unknown	7.5 Milligram, Qid		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Amiodarone			C	Unknown	Unk		Not Reported
	Rivaroxaban			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16808848	EXPEDITED (15-DAY)		HO	MX-TORRENT-00000155		78 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Head Injury; Surgery	Escitalopram			S	Oral	One 10 Mg Tablet Per Day, Orally		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16808865	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-220689		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Sinus Bradycardia; Somnolence	Quetiapine			S	Oral	In Total		Sun
	Escitalopram			S	Oral	In Total		Not Reported
	Propranolol			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16809148	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2019022941			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration	Escitalopram 10mg Tablet			S	Oral	10 Milligram, Qd		Macleods
	Ventolin			C		2 Dosage Form, Prn		Not Reported
	Otomize			C	Unknown	Unk		Not Reported
	Duloxetine			C	Unknown	1 Dosage Form, Qd, Night		Not Reported
	Pregabalin			C	Unknown	2 Dosage Form, Qd		Not Reported
	Hydroxocobalamin			C	Intramuscular	1 Dosage Form, 2 Month		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16810240	EXPEDITED (15-DAY)		HO	SE-MYLANLABS-2019M1085470		64 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Syncope	Escitalopram			S	Oral	Titrerad 10 Mg Till 12,5 Mg Under Terapitiden.		Not Reported
	Escitalopram			S	Oral	15 Milligram, Qd		Not Reported
	Alfuzosin			C		Unk		Mylan
	Mirtazapin			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16811360	EXPEDITED (15-DAY)		DE, HO	ES-PFIZER INC-2019398076		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Blindness Unilateral; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia;	Spironolactone			S	Oral	50 Mg, 1x/Day		Pfizer
	Bisoprolol Fumarate			S	Oral	5 Mg, (Twice A Day)		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported

Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Thermohypoaesthesia; Urinary Retention	Lisinopril		S	Oral	5 Mg, 1x/Day	Not Reported
	Omeprazole		S	Oral	20 Mg, 1x/Day	Not Reported
	Alendronic Acid		S	Oral	70 Mg, Weekly	Not Reported
	Furosemida [Furosemide]		S	Oral	60 Mg, 1x/Day	Not Reported
	Hierro [Ferrous Sulfate]		S	Oral	256.3 Mg, 1x/Day	Not Reported
	Ipratropio Bromuro		S	Respiratory (inhalation)	2 Inh Every 8 Hours	Not Reported
	Sintrom		S	Oral	1 Mg, 1x/Day	Not Reported
	Alopurinol		S	Oral	100 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16811579	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1933792US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Weight Gain; Gingival Bleeding; Increased Appetite; Narrow Anterior Chamber Angle	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Theralene			S	Unknown	2 Tablets In The Evening		Not Reported
	Lexomil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16314505	EXPEDITED (15-DAY)		LT, OT	DE-JNJFOC-20190509081		75 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Syncope; Torsade De Pointes	Reminyl			S	Unknown			Not Reported
	Reminyl			S	Unknown			Not Reported
	Reminyl			S	Unknown			Not Reported
	Dipiperon			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported

	Cipralex	S	Unknown	Not Reported
	Esidrix	S	Unknown	Not Reported
	Esidrix	S	Unknown	Not Reported
	Captohexal	S	Unknown	Not Reported
	Captohexal	S	Unknown	Not Reported
	Trazodone	S	Unknown	Not Reported
	Calciumcarbonate	C	Unknown	Not Reported
	Marcumar	C	Unknown	Not Reported
	Amlodipine	C	Unknown	Not Reported
	Amlodipine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16776365	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2019382024		38 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Ramipril			S	Unknown	2.5 Mg, Daily		Pfizer
	Atorvastatin Calcium			S	Unknown	10 Mg, Daily		Pfizer
	Spironolactone			S	Unknown	25 Mg, Daily		Pfizer
	Bisoprolol Fumarate			S	Unknown	2.5 Mg, Daily		Not Reported
	Furosemide			S	Unknown	20 Mg, Daily		Unknown
	Melatonin			S	Unknown	2 Mg, Daily		Not Reported
	Amisulpride			S	Unknown	300 Mg, Daily		Not Reported
	Escitalopram Oxalate			S	Unknown	15 Mg, Daily		Not Reported
	Ferrograd [Ferrous Sulfate]			S	Unknown	325 Mg, Daily		Not Reported
	Omeprazole			S	Unknown	20 Mg, Daily		Not Reported
	Testosterone			S	Unknown	1 G, Daily (Every 10-14 W)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16796322	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2019164157		14 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypotension; Malaise	Diclofenac			S	Oral	In Total		Glaxosmithkline
	Diazepam			S	Oral	In Total		Glaxosmithkline
	Ibuprofen			S	Oral	In Total		Glaxosmithkline
	Paracetamol			S	Oral	In Total		Glaxosmithkline
	Escitalopram			S	Oral	In Total		Glaxosmithkline
	Dietary Supplement			S	Oral	In Total		Glaxosmithkline
	Colchicine			S	Oral	In Total		Glaxosmithkline
	Diane			S	Oral	In Total		Not Reported
	Cialis			S	Oral	In Total		Not Reported
	Donormyl (Doxylamine Succinate)			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16813964	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2019GMK043204			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Gabapentin			S	Oral	600 Mg, Bid		Glenmark
	Clonazepam			S	Oral	0.5 Mg, Tid		Not Reported
	Domperidone			S	Unknown	10 Mg, Bid		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Iron Sulphate			S	Oral	300 Mg, Tid		Not Reported
	Temazepam			S	Oral	30 Mg, Od		Not Reported
	Tylenol W/Codeine			S	Oral	2 Df, Tid		Not Reported
	Wellbutrin			S	Oral	150 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16814077	EXPEDITED (15-DAY)		HO, LT, OT	IL-ALVOGEN-2019-ALVOGEN-101321		35 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Cardiac Arrest; Infection; Intentional Overdose; Thrombocytopenia	Flecainide		S	Oral	Not Reported
	Bisoprolol		S	Oral	Not Reported
	Escitalopram		S	Oral	Not Reported
	Quetiapine		S	Oral	Not Reported
	Clonazepam		S	Oral	Not Reported
	Venlafaxine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16815342	EXPEDITED (15-DAY)			FR-ALKEM LABORATORIES LIMITED-FR-ALKEM-2019-05178		22 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Aripiprazole			S	Unknown	10 Milligram, Qd		Alkem
	Methadone Hydrochloride			S	Unknown	Unk		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16815369	EXPEDITED (15-DAY)			FR-ALKEM LABORATORIES LIMITED-FR-ALKEM-2019-05154		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Aripiprazole			S	Unknown	10 Milligram, Qd		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Dihydroergotamine			S	Unknown	Unk		Not Reported
	Oxazepam			S	Unknown	Unk		Not Reported
	Pipamperone			S	Unknown	Unk		Not Reported
	Loprazolam			S	Unknown	Unk		Not Reported

	Dipotassium Clorazepate	S	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16815977	EXPEDITED (15-DAY)		DE, HO	ES-ACCORD-154523		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Allopurinol			S	Oral	100 Mg, Qd		Accord
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Furosemide			S	Oral	60 Mg, Qd		Accord
	Lisinopril			S	Oral	5 Mg, Qd		Accord
	Spironolactone			S	Oral	50 Mg, Qd		Accord
	Omeprazole			S	Oral	20 Mg, Qd		Not Reported
	Alendronate Sodium/Alendronic Acid			S	Oral	70 Mg, Qwk		Not Reported
	Iron			S	Oral	256.3 Mg, Qd		Not Reported
	Bisoprolol			S	Oral	5 Mg, Bid		Not Reported
	Ipratropium			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Not Reported
	Sintrom			S	Oral	1 Mg, Qd, Strength: 1 Mg Tablets, 60 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16815988	EXPEDITED (15-DAY)		OT	GB-TORRENT-00021828		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration	Ventolin			C	Respiratory (inhalation)	As Necessary		Unknown
	Otomize			C				Unknown
	Duloxetine			C		Night		Unknown
	Escitalopram			S				Unknown
	Pregabalin			C				Unknown
	Hydroxocobalamin			C	Intramuscular			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16817061	EXPEDITED (15-DAY)		HO	CA-GLENMARK PHARMACEUTICALS-2019GMK043219			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Gabapentin			S	Oral	300 Mg, Tid (1 Every 1 Day)		Glenmark
	Gabapentin			S	Oral	600 Mg, Bid, Capsule (2 Every 1 Days)		Glenmark
	Acetaminophen W/Codeine Phosphate			S	Oral	2 Df, Tid (3 Every 1 Day)		Not Reported
	Cipralex /01588501/			S	Oral	20 Mg, Unk		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Tid (3 Every 1 Day)		Not Reported
	Domperidone			S	Unknown	10 Mg, Bid (2 Every 1 Day)		Not Reported
	Iron Sulphate			S	Unknown	300 Mg, Tid (3 Every 1 Day)		Not Reported
	Temazepam			S	Oral	30 Mg, Od (1 Every 1 Day)		Not Reported
	Wellbutrin			S	Oral	150 Mg, Bid (2 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16817079	EXPEDITED (15-DAY)		HO, OT	AU-MACLEODS PHARMACEUTICALS US LTD-MAC2019022942			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyponatraemia; Stress Cardiomyopathy	Escitalopram			S	Unknown	10 Milligram		Macleods
	Amlodipine			C	Unknown	Unk		Not Reported
	Rivaroxaban			C	Unknown	Unk		Not Reported
	Amiodarone			C	Unknown	Unk		Not Reported
	Olmesartan			C	Unknown	Unk		Not Reported

	Diazepam		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16817992	EXPEDITED (15-DAY)		DS	ES-MYLANLABS-2019M1086769		32 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam			S		0.25 In The Morning, And Sometimes In The Evening Night		Not Reported
	Escitalopram			S		5 Milligram, Qd		Not Reported
	Rhodiola /02220301/			C		Unk		Mylan
	Pantoprazol /01263201/			C		Unk Unk, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16818397	EXPEDITED (15-DAY)		DE, HO	ES-ALLERGAN-1937398US			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Omeprazol			S	Oral	20 Mg, Qd		Not Reported
	Lisinopril			S	Oral	5 Mg, Qd		Not Reported
	Alendronico Acido (Alendronate Sodium)			S	Oral	70 Mg, Qwk		Not Reported
	Furosemida			S	Oral	60 Mg, Qd		Not Reported
	Hierro Sulfato (Ferrous Sulfate)			S	Oral	256.3 Mg, Qd		Not Reported
	Bisoprolol			S	Oral	5 Mg, Bid		Not Reported
	Ipratropio Bromuro			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Not Reported
	Sintrom			S	Oral	1 Mg, Qd		Not Reported
	Espironolactona			S	Oral	50 Mg, Qd		Not Reported
	Alopurinol			S	Unknown	100 Mg, Qd		Not Reported

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	14908305	EXPEDITED (15-DAY)		HO, LT, OT	DE-PFIZER INC-2018201596		21 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Esomeprazole Magnesium			S		40 Mg, Unk		Unknown
	Linezolid			S	Intravenous (not otherwise specified)	2 Df, Daily (1-0-1)		Pfizer
	Linezolid			S		Unk		Pfizer
	Escitalopram			S		5 Ug, As Needed		Not Reported
	Levetiracetam			C		1.5 G, 2x/Day (1-0-1)		Not Reported
	Ivabradine			C		7.5 Mg, 2x/Day		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	960 Mg (2 Df), Daily, 1-0-1		Not Reported
	Cotrimoxazol			C				Not Reported
	Naloxone/Tilidine			C		10 Gtt, As Needed (Tilidine/Naloxon 25/2mg)		Not Reported
	Scopolamin			C	Transdermal	Unk (Change Every 3 Days)		Not Reported
	Baclofen			C		5 Mg, Unk (2-1-2-1)		Not Reported
	Prednisolone			C		10 Mg, Unk		Not Reported
	Prednisolone			C		7.5 Mg, 1x/Day (1-0-0)		Not Reported
	Prednisolone			C		5 Mg, 1x/Day		Not Reported
	Lorazepam			C		1 Mg, Daily, 0-0-1		Not Reported
	L-Thyroxin			C		75 Ug, 1x/Day (1-0-0)		Not Reported
	Floxal			C		Unk, 4x/Day (Both Eyes)		Not Reported
	Floxal			C				Not Reported
	Floxal			C				Not Reported
	Novalgin [Metamizole Sodium]			C		1 G, Unk		Not Reported
	Noradrenalin [Norepinephrine]			C		Unk		Not Reported
	Polamidon			C		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	15760654	NON-EXPEDITED			US-PFIZER INC-2018525513		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Zocor			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16138961	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0910		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Pantoprazole Magnesium			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Plaquenil Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16656595	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1084342		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Anger; Anxiety; Arthropod Bite; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cerebrovascular Accident; Contusion; Cough; Crying; Depressed Mood; Depression; Diarrhoea; Drug Hypersensitivity; Emotional Distress; Erythema; Fall; Fatigue; Feeling Jittery; Gait Disturbance; Head Banging; Headache; Hypoacusis; Inappropriate Schedule Of Product Administration; Joint Swelling; Malaise; Malignant Neoplasm Progression; Mental Disorder; Muscular Weakness; Nasopharyngitis; Nausea; Nervousness; Pain In Extremity; Peripheral Swelling; Pneumonia; Pollakiuria; Productive Cough; Psychiatric Symptom; Rash; Rib Fracture; Screaming; Suicidal Ideation; Suicide Attempt; Tremor; Unresponsive To Stimuli; Vasculitis; Wound; Wrist Fracture	Calcium Carbonate	S	Unknown		Not Reported
	Pantoprazole	S	Unknown		Teva
	Amlodipine	S	Unknown	10 Milligram Daily;	Teva
	Hydromorphone	S	Oral		Actavis
	Escitalopram	S	Unknown		Ivax
	Ergocalciferol	S	Unknown		Not Reported
	Sandostatin	S	Intramuscular		Not Reported
	Sandostatin	S	Subcutaneous		Not Reported
	Sandostatin	S	Intramuscular		Not Reported
	Sandostatin	S	Intramuscular		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Olanzapine	C	Unknown		Not Reported
	Resotran Film-Coated	C	Unknown		Not Reported
	Perindopril	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16820596	EXPEDITED (15-DAY)		HO, OT	AU-LUPIN PHARMACEUTICALS INC.-2019-05968		79 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hyponatraemia; Stress Cardiomyopathy	Escitalopram			S	Unknown	10 Milligram		Lupin
	Amlodipine			C	Unknown	Unk		Not Reported
	Rivaroxaban			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Olmesartan			C	Unknown	Unk		Not Reported
	Amiodarone			C	Unknown	Unk		Not Reported
	Mirtazapine			C	Unknown	45 Milligram, Qd (At Night)		Not Reported
	Oxazepam			C	Unknown	7.5 Milligram, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16820643	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1107586		101 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Orthostatic Hypotension	Ramipril			S	Oral	5 Milligram Per Day		Actavis
	Escitalopram			S	Oral	10 Milligram Per Day		Ivax
	Diosmectite			C				Not Reported
	Paracetamol			C				Not Reported
	Econazole			C				Not Reported
	Levetiracetam			C				Not Reported
	Cholecalciferol			C				Not Reported
	Valpromide			C				Not Reported
	Dexpanthenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16820901	EXPEDITED (15-DAY)		HO, LT, OT	IL-ALKEM LABORATORIES LIMITED-IL-ALKEM-2019-07994		35 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose	Quetiapine Fumarate			S	Oral	3000 Milligram		Alkem
	Flecainide			S	Oral	2500 Milligram		Not Reported

	Venlafaxine		S	Oral	1000 Milligram	Not Reported
	Escitalopram		S	Oral	250 Milligram	Not Reported
	Bisoprolol		S	Oral	25 Milligram	Not Reported
	Clonazepam		S	Oral	5 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16820976	EXPEDITED (15-DAY)		HO	TR-ALKEM LABORATORIES LIMITED-TR-ALKEM-2019-03822		56 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Tardive Dyskinesia; Treatment Noncompliance	Aripiprazole			S	Unknown	10 Milligram, Qd		Alkem
	Aripiprazole			S	Unknown	30 Milligram		Alkem
	Risperidone			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	4 Milligram, Qd		Not Reported
	Risperidone			S	Unknown	2 Milligram, Qd		Not Reported
	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported
	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	Unk		Not Reported
	Haloperidole			S	Unknown	20 Milligram, Qd		Not Reported
	Biperiden			S	Unknown	4-10 Mg/Day		Not Reported
	Biperiden			S	Unknown	4 Milligram, Qd		Not Reported
	Diazepam			S	Unknown	10 Milligram, Qd		Not Reported
	Valproic Acid			S	Unknown	1500 Milligram, Qd		Not Reported
	Amisulpride			S	Unknown	800 Milligram, Qd		Not Reported
	Amisulpride			S	Unknown	400 Milligram		Not Reported
	Lithium			S	Unknown	900 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16821767	EXPEDITED (15-DAY)		DE, HO	ES-TEVA-2019-ES-1107690		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Alendronico Acido (Alendronate Sodium)			S	Oral	70 Mg, Qwk		Actavis
	Alopurinol			S	Oral	100 Mg, Qd		Actavis
	Bisoprolol			S	Oral	5 Mg, Bid		Duramed
	Escitalopram			S	Oral	10 Mg, Qd		Ivax
	Ipratropio Bromuro			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Actavis
	Lisinopril			S	Oral	5 Mg, Qd		Not Reported
	Omeprazole			S	Oral	20 Mg, Qd		Teva
	Furosemida			S	Oral	60 Mg, Qd		Not Reported
	Hierro Sulfato (Ferrous Sulfate)			S	Oral	256.3 Mg, Qd		Not Reported
	Sintrom 1 Mg Comprimidos , 60 Comprimidos			S	Oral	1 Mg, Qd		Not Reported
	Espironolactona			S	Oral	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16821924	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019398427		14 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypotension; Intentional Overdose; Malaise	Ibuprofen			S	Oral	4400 Mg, Single		Pfizer
	Diane			S	Oral	21 Df, Single		Not Reported
	Cialis			S	Oral	40 Mg, Single		Not Reported
	Diclofenac			S	Oral	5000 Mg, Single		Not Reported
	Colchicine			S	Oral	6 Mg, Single		Not Reported
	Diazepam			S	Oral	480 Mg, Single		Not Reported
	Paracetamol			S	Oral	2 G, Single		Not Reported

Escitalopram	S	Oral	820 Mg, Single		Not Reported
Donormyl [Doxylamine Succinate]	S	Oral	300 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16822786	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019401379		101 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Orthostatic Hypotension	Ramipril			S	Oral	5 Mg, Qd		Pfizer
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Diosmectite			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Econazole			C	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown	Unk		Not Reported
	Calciferol [Ergocalciferol]			C		Unk		Not Reported
	Valpromide			C	Unknown	Unk		Not Reported
	Dexpanthenol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16823010	NON-EXPEDITED		OT	US-CELGENEUS-USA-20190903593			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Rash; Rib Fracture; Upper Respiratory Tract Infection	Revlimid			S	Oral	25 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	15 Milligram		Celgene
	Revlimid			S	Oral	10mg-25 Mg		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Lexapro			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16823268	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1937603US			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Ventolin			C	Respiratory (inhalation)			Not Reported
	Otomize			C	Unknown			Not Reported
	Duloxetine			C	Unknown	Night		Not Reported
	Pregabalin			C	Unknown			Not Reported
	Hydroxocobalamin			C	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16823570	NON-EXPEDITED			US-PFIZER INC-2019402897			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amlodipine Besilate			S		Unk		Pfizer
	Cefuroxime			S		Unk		Unknown
	Ciprofloxacin			S		Unk		Unknown
	Escitalopram Oxalate			S		Unk		Not Reported
	Methylnaltrexone			S		Unk		Not Reported
	Ranolazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	14654580	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007730			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue;	Citalopram			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	10 Mg, Unk		Apotex

Mental Impairment; Sexual Dysfunction	Escitalopram		S	Unknown	7.5 Mg, Unk	Apotex
	Escitalopram		S	Unknown	5 Mg, Unk	Apotex
	Cipralex /01588501/		S	Unknown	7.5 Mg, Unk	Not Reported
	Cipralex /01588501/		S	Unknown	5 Mg, Unk	Not Reported
	Cipralex /01588501/		S	Unknown	10 Mg, Unk	Not Reported
	Trintellix		S	Unknown	10 Mg, Qd	Not Reported
	Trintellix		S			Not Reported
	Trintellix		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16212212	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2019GMK040668			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Gabapentin			S	Oral	600 Mg, Bid		Glenmark
	Gabapentin			S	Oral	600 Mg, Unk		Glenmark
	Clonazepam			S	Oral	0.5 Mg, Tid		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Unk		Not Reported
	Domperidone			S	Oral	10 Mg, Bid		Not Reported
	Domperidone			S	Oral	10 Mg, Unk		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Iron Sulphate			S	Oral	300 Mg, Tid		Not Reported
	Iron Sulphate			S	Oral	300 Mg, Unk		Not Reported
	Temazepam			S	Oral	30 Mg, Od		Not Reported
	Temazepam			S	Oral	30 Mg, Unk		Not Reported
	Tylenol With Codeine			S	Oral	2 Df, Tid		Not Reported
	Vitalux /01586901/			S	Oral	Unk, Bid		Not Reported
	Vitalux /01586901/			S	Oral	Unk		Not Reported
	Wellbutrin			S	Oral	150 Mg, Bid		Not Reported

	Wellbutrin		S	Oral	150 Mg, Bid	Not Reported
	Escitalopram Oxalate		S	Oral	20 Mg, Unk	Not Reported
	Tylenol With Codeine		S	Oral	2 Df, Tid	Not Reported
	Tylenol With Codeine		S	Oral	2 Df, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16577089	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2334		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Heart Rate Increased; Hepatic Enzyme Increased; Hypertension; Hypotension; Rheumatoid Arthritis; Somnolence; Vein Collapse; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abilify			C	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Oxycontin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sertraline Hydrochloride			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Fluoxetine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16653601	EXPEDITED (15-DAY)		OT	DE-GLAXOSMITHKLINE-DE2019136203		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Prednisolone			S	Unknown	25 Mg, Unk		Glaxosmithkline
	Escitalopram			S	Unknown	Unk		Glaxosmithkline
	Salbutamol			S	Unknown	Unk		Glaxosmithkline
	Prednisolone			S	Unknown	2.5 Mg, Unk		Glaxosmithkline
	Ibuprofen			S	Unknown	Unk		Glaxosmithkline
	Fluticasone Furoate + Vilanterol Trifenatate			S	Unknown	6 Months Before Diagnosis		Glaxosmithkline
	Salbutamol Stada			S	Unknown	Unk		Not Reported
	Metoprolol Stada			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1 Df, We		Not Reported
	Prednisolon Jenapharm			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Pantozol (Pantoprazole Sodium Sesquihydrate)			S	Unknown	Unk		Not Reported
	Metoprolol Mylan			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Implanon			S	Unknown	Unk		Not Reported
	Metoprolol Hexal			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Prednisolon Stada			S	Unknown	Unk		Not Reported
	Amitriptylin			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

Ibuprofen Stada	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825004	EXPEDITED (15-DAY)		HO, LT	US-ORCHID HEALTHCARE-2074640		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiac Arrest; Circulatory Collapse; Infection; Overdose; Suicide Attempt; Thrombocytopenia; Unresponsive To Stimuli	Venlafaxine Hydrochloride			S	Unknown			Orchid
	Flecainide			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825306	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2019AU06381			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delusion; Eczema; Emotional Distress; Eosinophil Count Decreased; Feeling Cold; Frustration Tolerance Decreased; Haemoglobin Decreased; Hallucination, Auditory; Hyperhidrosis; Intentional Self-Injury; Lymphocyte Count Decreased; Mean Cell Haemoglobin Decreased; Mental Impairment; Metamyelocyte Count Increased; Monocyte Count Decreased; Myelocyte Count Increased	Escitalopram			S	Unknown	Unk		Invagen
	Clozaril			S	Unknown	Unk, Tablet		Not Reported
	Paliperidone			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Not Reported
	Movicol			C	Unknown	Unk		Not Reported
	Senna Alexandrina			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Lurasidone Hydrochloride			C	Unknown	Unk		Not Reported
	Zuclopenthixol			C	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			C	Unknown	Unk		Not Reported
	Vitamin B 12 Lichtenstein			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

Mirtazapine	C	Unknown	Unk		Not Reported
Caltrate [Calcium Carbonate;Colecalciferol]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825777	EXPEDITED (15-DAY)		HO	NL-TEVA-2019-NL-1108128			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteoporosis	Escitalopram			S		1 Dosage Forms, 1x Pd		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825804	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1108995		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration	Escitalopram			S	Unknown	10 Milligram		Ivax
	Ventolin			C	Respiratory (inhalation)	2 Dosage Forms		Not Reported
	Otomize			C		3 Dosage Forms		Not Reported
	Duloxetine			C		Night, 1 Dosage Forms		Not Reported
	Pregabalin			C		2 Dosage Forms		Not Reported
	Hydroxocobalamin			C	Intramuscular	1 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825954	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1109307		14 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypotension; Malaise	Diclofenac			S	Oral	5000 Mg Per Total		Actavis
	Diazepam			S	Oral	480 Mg Per Total		Barr
	Escitalopram			S	Oral	820 Mg Per Total		Ivax
	Paracetamol			S	Oral	2 Gm Per Total		Not Reported
	Ibuprofene			S	Oral	4400 Mg Per Total		Actavis

Complement Alimentaire	S	Oral	45 Dosage Forms		Not Reported
Diane, Comprime Enrobe	S	Oral	21 Dosage Forms		Not Reported
Cialis	S	Oral	40mg Per Total		Not Reported
Colchicine	S	Oral	6mg Per Total		Not Reported
Donormyl (Doxylamine Succinate\Sodium Phosphate Dibasic\Sodium Bromide\Sodium Sulfate)	S	Oral	300mg Per Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16826019	EXPEDITED (15-DAY)		HO, OT	DE-ACCORD-155076		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Escitalopram			S	Unknown			Not Reported
	Bisoprolol			S	Unknown	1.25 Mg, Unk		Not Reported
	Quetiapine			S	Oral			Not Reported
	Chlormadinone Acetate/Ethinylestradiol Trigoa			S		Unk		Not Reported
				C	Oral	(6x Lng 50microg/Ee 30microg: 5x Lng 75microg/Ee 40microg: 10x Lng 125microg/Ee 30microg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16826146	EXPEDITED (15-DAY)		OT	BR-TORRENT-00005108			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Insomnia	Lamitor			S	Oral	Administered At Night		Torrent
	Depo-Provera			C	Intramuscular	Every 3 Months		Pfizer
	Venvanse			C		Unknown		Shire
	Lamitor			S	Oral	Unknown		Torrent
	Escitalopram			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16828843	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1087454			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	1.25 Milligram		Not Reported
	Trigoa			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16829712	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110357		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Exposure During Pregnancy; Lung Infection; Melanocytic Naevus; Rheumatoid Arthritis; Rheumatoid Factor Increased	Acetaminophen W/Codeine Phosphate			S	Unknown			Actavis
	Escitalopram Oxalate			S	Unknown			Ivax
	Pantoprazole Magnesium			S	Unknown	30 Milligram Daily;		Teva
	Salbutamol			S	Unknown			Barr
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Imodium			S	Unknown			Not Reported
	Loperamide Hydrochloride			C	Unknown			Not Reported
	Multivitamins			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16829726	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110668		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster;	Escitalopram Oxalate			S	Oral	1 Dosage Forms Daily;		Ivax
	Methotrexate			S	Unknown			Barr

Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Pantoprazole Magnesium		S	Oral	1 Dosage Forms Daily;	Teva
	Celebrex		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Oral	2 Dosage Forms Daily;	Not Reported
	Prednisone		C	Unknown	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	14374564	EXPEDITED (15-DAY)		HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-159672		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Escitalopram			S	Oral	Non Renseignee		Not Reported
	Pantoprazole			S	Oral	Non Renseignee		Sun
	Xeloda			S	Oral	Non Renseignee		Not Reported
	Novorapid			S	Subcutaneous	Non Renseignee		Not Reported
	Primperan			S	Oral	Non Renseignee		Not Reported
	Lipanthyl			S	Oral	Non Renseignee		Not Reported
	Movicol			S	Oral	Non Renseignee		Not Reported
	Abasaglar			S	Subcutaneous	Non Renseignee		Not Reported
	Fondaparinux Sodique			S	Subcutaneous	Non Renseignee		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	15949217	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011237		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Maternal Exposure	Nulojix			S	Intravenous (not otherwise specified)	300 Mg (5mg/Kg), Q4wk		Bristol Myers Squibb

During Pregnancy; Premature Delivery	Envarsus	S	Unknown	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Miacalcin	S	Unknown	Unk	Not Reported
	Zantac	S	Unknown	Unk	Not Reported
	Imitrex /01044801/	S	Unknown	Unk	Not Reported
	Lexapro	S	Unknown	Unk	Not Reported
	Phenergan /00033001/	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16328331	EXPEDITED (15-DAY)		CA, DS, HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-027611		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Blindness Cortical; Cardiogenic Shock; Cerebral Infarction; Circulatory Collapse; Colour Blindness; Condition Aggravated; Csf Pressure Increased; Cytotoxic Oedema; Depressed Level Of Consciousness; Electrocardiogram P Wave Abnormal; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Amplitude Decreased; Electrocardiogram T Wave Inversion; Electrocardiogram U Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left	Amlodipine Tablets			S	Oral	Unk		Aurobindo
	Amlodipine Tablets			S	Oral	150 Milligram, Unk		Aurobindo
	Escitalopram Tablets			S	Unknown	60 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Oral	Unk		Aurobindo
	Escitalopram Mylan			S	Oral	Unk		Not Reported
	Epinephrine			S	Unknown	30 Microgram, Unk		Not Reported
	Potassium Chloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Potassium Chloride			S	Oral	Unk		Not Reported
	Risperidone			S	Unknown	6 Milligram, Once A Day		Not Reported
	Risperidone			S	Oral	6 Milligram, Once A Day		Not Reported
	Risperidone			S	Oral	Unk		Not Reported
	Vasopressin			S	Unknown	Unk		Not Reported
	Norepinephrine Bitartrate			S	Unknown	30 Microgram, Unk		Not Reported
	Glucose			S	Unknown	Unk		Not Reported
	Mylan Escitalopram 10			S	Oral	Unk		Not Reported
	Activated Charcoal			C	Unknown	Unk		Not Reported

Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema; Renal Tubular Necrosis; Retinal Ischaemia; Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment	Calcium Gluconate	C	Unknown	Unk	Not Reported
	Dextrose	C	Unknown	Unk	Not Reported
	Epinephrine	C	Unknown	Unk	Not Reported
	Escitalopram	C	Unknown	Unk	Not Reported
	Glucagon	C	Unknown	Unk	Not Reported
	Insulin	C	Unknown	Unk	Not Reported
	Norepinephrine	C	Unknown	Unk	Not Reported
	Potassium Chloride	C	Unknown	Unk	Not Reported
	Risperidone	C	Unknown	Unk	Not Reported
	Vasopressin	C	Unknown	Unk	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Norepinephrine;Procaine Hydrochloride	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16477295	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-035133		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anger; Anxiety; Arthropod Bite; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cerebrovascular Accident; Contusion; Cough; Crying; Depressed Mood; Depression; Diarrhoea; Emotional Distress; Erythema; Fall; Fatigue; Feeling Abnormal; Feeling Jittery; Gait Disturbance; Head Banging; Headache; Hypertension; Hypoacusis; Inappropriate Schedule Of	Amlodipine Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Calcium Carbonate			S	Oral	Unk		Not Reported
	Ergocalciferol			S	Oral	Unk		Not Reported
	Hydromorphone			S	Oral	Unk		Not Reported
	Sandostatin			S	Intramuscular	20 Milligram		Not Reported
	Sandostatin			S	Intramuscular	30 Milligram, Once A Month		Not Reported
	Sandostatin			S	Intramuscular	20 Milligram, Once A Month		Not Reported
	Sandostatin			S	Subcutaneous	Unk Unk, Two Times A Day		Not Reported

Product Administration; Joint Swelling; Malaise; Malignant Neoplasm Progression; Mental Disorder; Muscular Weakness; Nasopharyngitis; Nausea; Nervousness; Pain In Extremity; Peripheral Swelling; Pneumonia; Pollakiuria; Productive Cough; Psychiatric Symptom; Rash; Rib Fracture; Screaming; Suicidal Ideation; Suicide Attempt; Tremor; Unresponsive To Stimuli; Vasculitis; Wound; Wrist Fracture	Acetaminophene	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Olanzapine	C	Unknown	Unk	Not Reported
	Perindopril	C	Unknown	4 Milligram, Once A Day	Not Reported
	Prednisone	C	Unknown	35 Milligram	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prucalopride Succinate	C	Unknown	Unk	Not Reported
	Resotran	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16646616	EXPEDITED (15-DAY)		OT	DE-ACCORD-149359		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Escitalopram			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Accord
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported
	Pantozol			S	Unknown	Unk		Not Reported
	Metoprolol Hexal			S	Unknown	Unk		Not Reported
	Escitalopram Stada			S	Unknown	Unk		Not Reported
	Escitalopram Hexal			S	Unknown	Unk		Not Reported
	Metoprolol Mylan			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Metoprolol Stada			S	Unknown	Unk		Not Reported
	Ibuprofen Hexal			S	Unknown	Unk		Not Reported

	Ibuprofen Stada	S	Unknown	Unk	Not Reported
	Salbutamol Stada	S	Unknown	Unk	Not Reported
	Escitalopram Mylan	S	Unknown	Unk	Not Reported
	Prednisolon Stada	S	Unknown	Unk	Not Reported
	Implanon	S	Unknown	Unk	Not Reported
	Metoprolol	S	Unknown	Unk	Not Reported
	Prednisolon Jenapharm	S	Unknown	Unk	Not Reported
	Methotrexate Mylan	S	Unknown	Unk, Qw	Not Reported
	Ibuprofen	S	Unknown	Unk	Not Reported
	Prednisolone	S	Unknown	25 Mg, Unk	Not Reported
	Salbutamol	S	Unknown	Unk	Not Reported
	Ellipta [Fluticasone Furoate\Vilanterol Trifenatate]	S		Unk (6 Months Before Diagnosis)	Not Reported
	Vilanterol Trifenatate/Fluticasone Furoate	S	Unknown	Unk (6 Months Before Diagnosis)	Not Reported
	Amitriptyline	S	Unknown		Accord
	Prednisolone	S	Unknown	2.5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831380	EXPEDITED (15-DAY)		HO	FR-ZYDUS-040669		101 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Orthostatic Hypotension	Ramipril			S	Oral			Zydus Pharm
	Escitalopram			S	Oral			Cadila
	Diosmectite			C				Not Reported
	Paracetamol			C				Not Reported
	Econazole			C				Not Reported
	Levetiracetam			C				Not Reported
	Cholecalciferol			C				Not Reported
	Valpromide			C				Not Reported
	Dexpanthenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831382	EXPEDITED (15-DAY)		DE, HO	ES-ZYDUS-040713		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Escitalopram			S	Oral			Cadila
	Omeprazole			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Alendronic Acid			S	Oral			Not Reported
	Iron			S	Oral			Not Reported
	Bisoprolol			S	Oral			Not Reported
	Ipratropium/Ipratropium Bromide			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Not Reported
	Sintrom			S	Oral			Not Reported
	Spironolactone			S	Oral			Not Reported
	Allopurinol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831503	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-059873		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Hypoglycaemia; Hypokalaemia; Optic Atrophy; Pulmonary Oedema; Reversible Cerebral Vasoconstriction Syndrome	Amlodipine Tablets			S	Unknown	150 Milligram, Daily		Aurobindo
	Escitalopram Tablets			S	Unknown	60 Milligram, Daily		Aurobindo
	Epinephrine			S	Unknown	30 Milligram		Not Reported
	Glucose			S	Unknown	Unk		Not Reported
	Norepinephrine Bitartrate			S	Unknown	30 Milligram		Not Reported
	Risperidone			S	Unknown	6 Milligram		Not Reported
	Vasopressin			S	Unknown	Unk		Not Reported
	Activated Charcoal			C	Unknown	Unk		Not Reported

	Insulin		C	Unknown	Unk	Not Reported
	Insulin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831507	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-060608			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Convulsive Threshold Lowered; Drug Interaction; Epilepsy; Fatigue; Incorrect Dose Administered	Paracetamol			S	Unknown	Unk		Aurobindo
	Tramadol			S	Unknown	100 Milligram, Two Times A Day		Aurobindo
	Tramadol			S	Unknown	500 Milligram, Four Times/Day		Aurobindo
	Escitalopram Sandoz			S	Unknown	10 Mg, Bid		Not Reported
	Urbanyl			C	Unknown	2 Dosage Form, Once A Day (20 Units Not Specified)		Not Reported
	Depakine Chrono			C	Unknown	3 Milligram, Once A Day (1.5 Mg, Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831581	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-ACCORD-155222		73 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Myeloma Cast Nephropathy; Myocardial Infarction; Renal Failure; Serotonin Syndrome; Ventricular Fibrillation	Escitalopram			S		Increased To Its Current Dose 3 Months Ago		Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S				Not Reported
	Erythromycin			S				Not Reported
	Furosemide			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831780	EXPEDITED (15-DAY)		OT	MY-TORRENT-00000193		71 YR	Male	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypersensitivity	Risperidone			S		Unknown		Unknown
	Atorvastatin			C		Unknown		Unknown
	Escitalopram			S		Unknown		Unknown
	Amlodipine			C		Unknown		Unknown
	Acetylsalicylic Acid			C		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16832076	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-060514		101 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Orthostatic Hypotension	Ramipril			S	Oral	5 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Diosmectite			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Econazole			C	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown	Unk		Not Reported
	Cholecalciferol			C	Unknown	Unk		Not Reported
	Valpromide			C	Unknown	Unk		Not Reported
	Dexpanthenol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16832103	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-059864		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Balance Disorder;	Amlodipine Tablets			S	Unknown	2.5 Milligram, Daily		Aurobindo

Bradycardia; Dizziness; Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder	Escitalopram Tablets	S	Unknown	Unk	Aurobindo
	Escitalopram Tablets	S	Unknown	10.0 Milligram, Daily	Aurobindo
	Ramipril	S	Unknown	5.0 Milligram, Daily	Aurobindo
	Codeine	S	Unknown	30.0 Milligram, Two Times A Day	Not Reported
	Furosemide	S	Unknown	20.0 Milligram, Daily	Not Reported
	Furosemide	S	Unknown	40.0 Milligram, Daily	Not Reported
	Glyceryl Trinitrate	S	Transdermal	0.4 Milligram, Two Times A Day	Not Reported
	Metoprolol	S	Unknown	25.0 Milligram, Daily	Not Reported
	Oxazepam	S	Unknown	10 Milligram, Two Times A Day	Not Reported
	Zopiclone	S	Unknown	2.5 Milligram, Daily	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Clopidogrel	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Macrogol	C	Unknown	Unk	Not Reported
	Rabeprazole	C	Unknown	Unk	Not Reported
	Vitamin C	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16834340	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1087775		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported
	Pradaxa			S	Oral	75 Milligram, Qd		Mylan
	Seropram /00582602/			S	Oral	1 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16834609	EXPEDITED (15-DAY)		OT	JP-ASTRAZENECA-2019SF31648		85 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Quetiapine			S	Oral			Zeneca
	Quetiapine			S	Oral			Zeneca
	Escitalopram			S				Not Reported
	Mirtazapine			S				Not Reported
	Olanzapine			S				Not Reported
	Sulpiride			C				Not Reported
	Clotiazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16834701	EXPEDITED (15-DAY)		DE, HO	ES-BAUSCH-BL-2019-025762		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Ipratropio Bromuro			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Bausch And Lomb
	Omeprazol			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Alendronico Acido (Alendronate Sodium)			S	Oral			Not Reported
	Furosemida			S	Oral			Not Reported
	Hierro Sulfato (Ferrous Sulfate)			S	Oral			Not Reported
	Bisoprolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Sintrom			S	Oral	60 Tablets		Not Reported
	Espironolactona			S	Oral			Not Reported
	Alopurinol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16834802	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20190918084			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Convulsive Threshold Lowered; Drug Interaction; Epilepsy; Fatigue; Overdose	Tramadol Hydrochloride			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Escitalopram Sandoz			S	Unknown			Not Reported
	Depakine Chrono			C	Unknown	1.5 Mg, 2/Day		Not Reported
	Urbanyl			C	Unknown	2 Df, 1/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2019	16080835	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-013728		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Heart Rate Increased; Irritability; Miosis; Overdose; Oxygen Saturation Decreased; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Citalopram			S	Unknown	Unk		Aurobindo
	Quetiapine Film-Coated Tablet			S	Oral	Unk		Aurobindo
	Topiramate			S	Oral	Unk		Aurobindo
	Oxazepam			S	Unknown	Unk		Not Reported
	Oxazepam			S	Unknown	Unk		Not Reported
	Temazepam			S	Oral	Unk		Not Reported
	Naloxone			S	Intramuscular	Unk		Not Reported
	Ramipril			C	Endocervical	Unk		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Spironolactone			C	Unknown	Unk		Not Reported
	Advair			C	Unknown	Unk		Not Reported
	Atorvastatin Calcium			C	Unknown	Unk		Not Reported
	Clopidogrel			C	Unknown	Unk		Not Reported

	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Ipratropium	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Spironolactone	C	Unknown	Unk	Not Reported
	Spironolactone	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Clopidogrel	C	Unknown	Unk	Not Reported
	Fluticasone;Salmeterol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2019	16714604	EXPEDITED (15-DAY)		HO, LT, OT	BE-ACCORD-151488		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Arrhythmia; Blood Pressure Decreased; Drug Intolerance; Hypokalaemia; Labelled Drug-Drug Interaction Medication Error; Long Qt Syndrome; Loss Of Consciousness; Metabolic Disorder; Pallor; Torsade De Pointes; Vomiting	Escitalopram			S		Unk		Not Reported
	Tacrolimus			S		Unk		Accord
	Omeprazole			S		Form: Gastro-Resistant Coated Tablet		Not Reported
	Sotalol			S		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2019	16836462	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-060780		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Ventolin			C	Respiratory (inhalation)	2 Dosage Form, As Necessary		Not Reported

	Otomize	C	Unknown	3 Dosage Form, Once A Day	Not Reported
	Duloxetine	C	Unknown	1 Dosage Form, Once A Day, Night	Not Reported
	Pregabalin	C	Unknown	2 Dosage Form, Once A Day	Not Reported
	Hydroxocobalamin	C	Intramuscular	1 Dosage Form, 2 Month	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2019	16836480	EXPEDITED (15-DAY)		OT	FI-AUROBINDO-AUR-APL-2019-061000		34 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Behaviour Disorder; Behaviour Disorder; Condition Aggravated; Drug Ineffective; Drug Ineffective For Unapproved Indication; Intentional Product Use Issue; Intentional Self-Injury; Multiple Drug Therapy; Product Use In Unapproved Indication	Olanzapine Film Coated Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Olanzapine Film Coated Tablets			S				Aurobindo
	Olanzapine Film Coated Tablets			S				Aurobindo
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S				Not Reported
	Amitriptyline			S				Not Reported
	Candesartan			S	Unknown	16 Milligram, Once A Day		Not Reported
	Candesartan			S				Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported
	Quetiapine			S				Not Reported
	Quetiapine			S				Not Reported
	Macrogol 3350			S	Unknown	3 Dosage Form, Once A Day, (3 Sachets Per Day)		Not Reported
	Topiramate			S	Unknown	Unk		Not Reported
	Topiramate			S				Not Reported
	Carbamazepine			S	Unknown	Unk		Not Reported
	Carbamazepine			S				Not Reported
	Risperidone			S	Unknown	3 Milligram, Once A Day		Not Reported
	Risperidone			S	Unknown	4 Milligram, Once A Day		Not Reported
	Risperidone			S				Not Reported
	Escitalopram			S	Unknown	10 Milligram, Once A Day		Not Reported
	Escitalopram			S				Not Reported

Levomepromazine	S	Unknown	100 Milligram, Once A Day	Not Reported
Levomepromazine	S			Not Reported
Levomepromazine	S			Not Reported
Metoprolol	S	Unknown	Unk	Not Reported
Pantoprazole	S	Unknown	20 Milligram, Once A Day	Not Reported
Bisoprolol	S	Unknown	Unk	Not Reported
Melatonin	S	Unknown	3 Milligram, Once A Day	Not Reported
Citalopram	S	Unknown	Unk	Not Reported
Citalopram	S			Not Reported
Citalopram	S			Not Reported
Lorazepam	S	Unknown	3 Milligram, Once A Day	Not Reported
Lorazepam	S			Not Reported
Lorazepam	S			Not Reported
Oxcarbazepine	C	Unknown	900 Milligram, Once A Day	Not Reported
Valproate Sodium	C	Unknown	1200 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	13893657	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017360842		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Hypoglycaemia; Hypokalaemia; Optic Atrophy; Overdose; Pulmonary Oedema; Reversible Cerebral Vasoconstriction Syndrome	Norepinephrine Bitartrate			S		30 Mcg/Minute		Pfizer
	Norepinephrine Bitartrate			S		40 Mcg/Minute		Pfizer
	Norepinephrine Bitartrate			S		10 Mcg/Minute		Pfizer
	Amlodipine Besilate			S		150 Mg, Daily		Pfizer
	Glucose			S				Pfizer
	Glucose			S	Intravenous bolus	Unk		Pfizer
	Epinephrine			S		30 Mcg/Minute		Pfizer
	Epinephrine			S		40 Mcg/Minute		Pfizer
	Epinephrine			S		25 Mcg/Minute		Pfizer
	Epinephrine			S		10 Mcg/Minute		Pfizer
	Vasopressin			S		Unk (2.4 Units/Hour)		Not Reported

Escitalopram	S	Oral	Unk		Not Reported
Escitalopram	S		60 Mg, Daily		Not Reported
Risperidone	S	Oral	6 Mg, Daily		Not Reported
Risperidone	S	Oral	Unk		Not Reported
Insulin	C	Intravenous bolus	Unk, 70 Units/Hour Infusion		Not Reported
Insulin	C		70 Iu, Unk		Not Reported
Activated Charcoal	C		50 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	14861830	EXPEDITED (15-DAY)		HO	CA-TAKEDA-2018TUS013693		20 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Concussion; Fall; Head Injury	Vedolizumab			S	Intravenous (not otherwise specified)	300 Milligram		Takeda
	Vedolizumab			S	Intravenous (not otherwise specified)	300 Milligram		Takeda
	Cipralex /01588501/			S	Unknown	Unk		Not Reported
	Pentasa			C		4 Gram, Qd		Not Reported
	Imuran /00001501/			C		150 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16080860	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013835			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Ankylosing Spondylitis; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Mental Impairment; Sexual Dysfunction	Citalopram			S	Unknown	Unk		Aurobindo
	Escitalopram Tablets			S	Unknown	5 Milligram		Aurobindo
	Escitalopram Tablets			S	Unknown	7.5 Milligram		Aurobindo
	Escitalopram Tablets			S	Unknown	10 Milligram		Aurobindo
	Escitalopram Tablets			S	Unknown	20 Unk		Aurobindo

Trintellix	S	Unknown	10 Milligram, Once A Day		Not Reported
Trintellix	S				Not Reported
Trintellix	S				Not Reported
Diclofenac	C	Unknown	Unk		Not Reported
Diclofenac Potassium	S	Unknown	50 Milligram		Not Reported
Infliximab	C	Unknown	Unk		Not Reported
Naproxen	S	Unknown	Unk		Not Reported
Naproxen	S	Unknown	1000 Milligram		Not Reported
Nortriptyline	S	Oral	250 Milligram		Not Reported
Tylenol	S	Topical	Unk		Not Reported
Voltaren	S	Unknown	Unk		Not Reported
Cimzia	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16150339	EXPEDITED (15-DAY)		HO, OT	PHHY2019PL003472		52 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Gastrointestinal Haemorrhage; Haemorrhage; Herbal Interaction; Hyperhidrosis; Myalgia; Urinary Tract Infection	Duloxetine Hydrochloride			S	Unknown	10 Mg, Qd		Not Reported
	Ciprofloxacin			S	Oral	500 Mg, Bid		Novartis
	Ciprofloxacin			S	Unknown	1500 Mg, Qd		Novartis
	Tramadol			S	Unknown	Unk		Not Reported
	Tramadol			S				Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Ginkgo Biloba			S	Unknown	Unk		Not Reported
	Ketoprofen			C	Oral	50 Mg, Tid		Not Reported
	Ketoprofen			C				Not Reported
	Zolpidem			C	Unknown	10 Mg, Qd (Each Evening)		Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16157660	EXPEDITED (15-DAY)		HO	IN-TORRENT-00002181		45 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Serotonin Syndrome	Divalproex			C				Unknown
	Escitalopram			S				Unknown
	Olanzapine			S				Unknown
	Fluoxetine			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16210441	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020621			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Escitalopram Tablets			S	Oral	20 Milligram, Daily		Aurobindo
	Cimzia			S	Unknown	50 Milligram		Not Reported
	Diclofenac Potassium			S	Unknown	50 Milligram		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	1000 Milligram, Daily		Not Reported
	Nortriptyline			S	Oral	25 Milligram, Daily		Not Reported
	Tylenol			S	Topical	Unk		Not Reported
	Voltaren			S	Topical	Unk, Daily		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	600 Milligram		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	700 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16210977	EXPEDITED (15-DAY)		OT	FR-ACCORD-122043		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Ramipril			S	Oral			Accord
	Exemestane			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Bisoce			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Fluidabak			C	Ophthalmic			Not Reported
	Transipeg			C	Oral			Not Reported
	Potassium Gluconate			C	Oral	1 Table Spoon Per Day		Not Reported
	Levothyroxine			C	Oral			Not Reported
	Gluconate Sodium/Potassium Chloride/Sodium Acetate/Sodium Chloride			C	Oral	1 Cs Per Day Route		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16211393	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-020682		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Escitalopram Tablets			S	Oral	20.0 Milligram		Aurobindo
	Gabapentin			S	Oral	600.0 Milligram, Two Times A Day		Aurobindo
	Clonazepam			S	Oral	0.5 Milligram, 3 Times A Day		Not Reported
	Domperidone			S	Oral	10.0 Milligram, Two Times A Day		Not Reported
	Iron Sulfate			S	Oral	300.0 Milligram, 3 Times A Day		Not Reported
	Temazepam			S	Oral	30.0 Milligram, Daily		Not Reported

	Tylenol With Codeine	S	Oral	2.0 Dosage Form, 3 Times A Day	Not Reported
	Vitalux	S	Oral	Unk, Two Times A Day	Not Reported
	Wellbutrin	S	Oral	150.0 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16476909	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035615		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anger; Depressed Mood; Diarrhoea; Mental Disorder; Multiple Sclerosis	Escitalopram Tablets			S	Oral	Unk		Aurobindo
	Aubagio			S	Oral	14 Milligram, Once A Day		Not Reported
	Aubagio			S				Not Reported
	Acetaminophen			C	Oral	Unk		Not Reported
	Cbd Oil			C	Unknown	Unk		Not Reported
	Colloidal Silver			C	Oral	Unk		Not Reported
	Magnesium			C	Oral	Unk		Not Reported
	Vitamin D3			C	Oral	3000 International Unit, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16838332	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1111024		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal; Visual Impairment	Sertraline			S	Oral	50 Mg		Not Reported
	Escitalopram			S	Oral	20mg		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16839277	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019394455		22 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Serotonin Syndrome	Linezolid	S	Unk	Pfizer
	Escitalopram	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16839349	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110716		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Escitalopram Oxalate			S		1 Dosage Forms Daily;		Ivax
	Methotrexate			S	Unknown			Barr
	Pantoprazole Magnesium			S		1 Dosage Forms Daily;		Teva
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Prednisone			S	Oral			Actavis
	Xeljanz			S	Oral	2 Dosage Forms Daily;		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16839762	EXPEDITED (15-DAY)		DS	DE-MYLANLABS-2019M1088054		57 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Feeling Hot; Headache; Hyperhidrosis; Hypogeusia; Hyposmia; Pain In Extremity; Presyncope; Tremor	Escitalopram			S		5 Gtt Drops		Not Reported
	Escitalopram			S		6-7 Tropfen		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16840166	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2019405568		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal; Visual Impairment	Sertraline Hcl			S	Oral	50 Mg, Unk		Pfizer
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16841666	EXPEDITED (15-DAY)		OT	FI-BAUSCH-BL-2019-026058		34 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Condition Aggravated; Multiple Drug Therapy; Therapy Non-Responder	Lorazepam			S	Unknown	Was Slowly Stopped		Not Reported
	Levomepromazine			S	Unknown			Not Reported
	Levomepromazine			S	Unknown	Gradually Stopped		Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown	Reduced To 4-3 Mg/Day		Not Reported
	Citalopram			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Carbamazepine			S	Unknown			Not Reported
	Escitalopram			S	Unknown	Stopped Due To No		Not Reported

				Response.	
	Pantoprazole	S	Unknown		Not Reported
	Bisoprolol	S	Unknown		Not Reported
	Macrogol 3350	S	Unknown	3350 With Dosage 3 Bags/Day	Not Reported
	Olanzapine	S	Unknown		Not Reported
	Quetiapine	S	Unknown		Not Reported
	Metoprolol	S	Unknown		Not Reported
	Topiramate	S	Unknown		Not Reported
	Candesartan	S	Unknown		Not Reported
	Melatonin	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16842120	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2019-061838		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiac Arrest; Dyspnoea; Infection; Overdose; Pulse Absent; Pulseless Electrical Activity; Suicide Attempt; Thrombocytopenia; Unresponsive To Stimuli	Quetiapine			S	Unknown	3000 Milligram		Aurobindo
	Flecainide			S	Unknown	25. Milligram		Aurobindo
	Venlafaxine			S	Unknown	1000 Milligram		Aurobindo
	Escitalopram			S	Unknown	250 Milligram		Aurobindo
	Bisoprolol			S	Unknown	25 Milligram		Aurobindo
	Clonazepam			S	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16842121	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-060872		88 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Interaction; Dyspnoea; Fall; Nightmare	Escitalopram			S	Oral	1 Dosage Form, Daily		Aurobindo
	Dextromethorphan Hydrobromide			S	Unknown	Unk		Not Reported

	Ebixa		S	Oral	10 Milligram, Daily	Not Reported
	Ebixa		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16842135	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-060757		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis	Escitalopram			S	Unknown	5 Milligram, Daily		Aurobindo
	Escitalopram			S	Unknown	20 Milligram, Daily		Aurobindo
	Escitalopram			S	Unknown	10 Milligram, Daily		Aurobindo
	Escitalopram			S	Unknown	15 Milligram, Daily		Aurobindo
	Omega-3 Fatty Acids			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16842139	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-060445		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Escitalopram Tablets			S	Oral	Unk		Aurobindo
	Wellbutrin			S	Oral	Unk		Not Reported
	Quetiapine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16842141	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-060878		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Flushing; Headache; Hyperhidrosis; Nausea; Nervousness; Pain; Serotonin	Escitalopram			S	Oral	20 Milligram, Daily		Aurobindo
	Venlafaxine			S	Oral	150 Milligram, Daily		Aurobindo

Syndrome; Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	13960485	NON-EXPEDITED			US-FRI-1000075876			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anxiety; Drug Ineffective; Headache; Nightmare; Product Dose Omission	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15327343	NON-EXPEDITED			US-ALLERGAN-1838059US		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Bedridden; Fall; Fatigue; Gait Disturbance; Malaise; Somnolence; Therapy Cessation; Wrong Technique In Product Usage Process	Lexapro			S	Oral	20 Mg		Allergan
	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Ampyra			S	Oral	10 Mg, Bid		Not Reported
	Ampyra			S	Oral	10 Mg, Bid		Not Reported
	Ampyra			S	Unknown	10 Mg, Bid		Not Reported
	Dalfampridine			S				Not Reported
	Clonazepam			C	Unknown	1 Mg, Qd		Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Ezetimibe			C	Unknown	10 Mg		Not Reported
	Gilenya			C	Unknown	Unk		Not Reported
	Fenofibrate			C	Unknown	54 Mg		Not Reported
	Losartan			C	Unknown	100 Mg		Not Reported
	Neurontin			C	Unknown	600 Mg		Not Reported
	Pravastatin			C	Unknown	10 Mg		Not Reported

Propranolol	C	Unknown	Unk		Not Reported
Vyvanse	C	Unknown	20 Mg		Not Reported
Vyvanse	C		Unk		Not Reported
Cymbalta	C	Oral	Unk		Not Reported
Gabapentin	C				Not Reported
Copaxone	C				Not Reported
Amlodipine	C		2.5 Mg		Not Reported
Memantine	C		Unk		Not Reported
Memantine	C		Unk		Not Reported
Rosuvastatin	C		10 Mg		Not Reported
Rosuvastatin	C		5 Mg		Not Reported
Topiramate	C		25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15327355	NON-EXPEDITED			US-ALLERGAN-1838856US		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Synthroid			C	Oral	Unk		Not Reported
	Hydrochlorothiazide			C	Oral	Unk		Not Reported
	Norvasc			C	Oral	5 Mg, Unk		Not Reported
	Protonix			C	Oral	Unk		Not Reported
	Melatonin			C	Oral	Unk Unk, Prn		Not Reported
	Statin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15327366	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1838847US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fluid Retention; Off Label Use; Skin Fissures; Skin	Escitalopram Oxalate Unk			S	Unknown	Unk Unk, Unknown		Allergan

Odour Abnormal; Suicidal Ideation; Suicide Attempt; Weight Increased	Xarelto		S	Unknown	Unk Unk, Unknown	Not Reported
	Aporex		S	Unknown	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15327469	NON-EXPEDITED			US-ALLERGAN-1831144US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10 Mg (1/2 Pill A Day For Two Week)		Allergan
	Atorvastatin			C	Oral	Unk		Not Reported
	Metoprolol			C	Oral	Unk		Not Reported
	Lisinopril			C	Oral	Unk		Not Reported
	Aspirin			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15739275	NON-EXPEDITED			US-ALLERGAN-1841976US		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15739276	NON-EXPEDITED			US-ALLERGAN-1840313US		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15739281	NON-EXPEDITED			US-ALLERGAN-1848633US		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp	S				Allergan
	Three Unspecified Heart Medications	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15739289	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1851776US		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Confusional State; Dizziness; Feeling Abnormal; Muscle Spasms; Pain; Paraesthesia; Suicidal Ideation; Urinary Tract Infection	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
	Vortioxetine			S	Oral	10 Mg, Qd		Not Reported
	Xanax			S	Unknown	Unk		Not Reported
	Xanax			S	Oral	Unk		Not Reported
	Tramadol			C	Oral	Unk		Not Reported
	Alprazolam			C	Oral	Unk		Not Reported
	Carvedilol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15739297	NON-EXPEDITED			US-ALLERGAN-1852551US		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Abnormal	Escitalopram Oxalate Unk			S	Oral	Unk Unk, Unknown		Allergan
	Naltrexone Hcl			C	Oral	50 Mg, Qd		Not Reported
	Naltrexone Hcl			C				Not Reported
	Gabapentin			C	Oral	600 Mg, Tid		Not Reported
	Prozac			C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15869783	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1903558US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Activation Syndrome; Diarrhoea; Headache; Malaise; Nausea	Escitalopram Oxalate - Bp		S	Oral	10 Mg, Qd (After Dinner)	Allergan
	Gasmotin		C	Oral	5 Mg, Qd	Not Reported
	Solanax		C	Oral	1.2 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16696741	NON-EXPEDITED			US-ALLERGAN-1908987US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased; Nausea; Vomiting	Lexapro			S	Unknown	Unk		Allergan
	Morphine Sulfate Unk			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16696766	NON-EXPEDITED			US-ALLERGAN-1911657US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram Oxalate - Bp			S				Allergan
	Morphine Sulfate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16696777	NON-EXPEDITED			US-ALLERGAN-1911124US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan
	Morphine Sulfate Unk			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16702534	NON-EXPEDITED			US-ALLERGAN-1908936US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Weight Increased	Fetzima			S	Unknown	Unknown		Allergan
	Lexapro			S	Unknown	Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16714638	EXPEDITED (15-DAY)		OT	DE-TORRENT-00015048		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Amitriptyline			S	Unknown	Unknown		Unknown
	Escitalopram			S	Unknown	Unknown		Mylan
	Escitalopram			S	Unknown	Unknown		Unknown
	Escitalopram			S	Unknown	Unknown		Hexal
	Escitalopram			S	Unknown	Unknown		Stada
	Golimumab			S	Unknown	Unknown		Unknown
	Ibuprofen			S	Unknown	Unknown		Hexal
	Ibuprofen			S	Unknown	Unknown		Torrent
	Ibuprofen			S	Unknown	Unknown		Unknown
	Ibuprofen			S	Unknown	Unknown		Stada
	Implanon			S	Unknown	Unknown		Unknown
	Methotrexate			S	Unknown	1 Week; Qw, 1df		Mylan
	Metoprolol			S	Unknown	Unknown		Stada
	Metoprolol			S		Unknown		Mylan
	Metoprolol			S	Unknown	Unknown		Unknown
	Metoprolol			S	Unknown	Unknown		Hexal
	Pantozol			S	Unknown	Unknown		Unknown
	Prednisolon			S	Unknown	Unknown		Stada
	Prednisolone			S	Unknown	Unknown		Jenapharm
	Prednisolone			S	Unknown	25 Mg, Unk		Unknown
	Salbutamol			S	Unknown	Unknown		Stada
	Salbutamol			S	Unknown	Unknown		Unknown
	Ellipta			C		Unk (6 Months Before Diagnosis)		Unknown
	Fluticasone And Vilanterol			S		6 Months Before		Unknown

Diagnosis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16734068	NON-EXPEDITED			US-ALLERGAN-1905252US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blunted Affect; Fatigue	Lexapro			S				Allergan
	Celexa			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16734116	NON-EXPEDITED			US-ALLERGAN-1909215US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Citalopram Hydrobromide - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16734125	NON-EXPEDITED			US-ALLERGAN-1915717US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Dry Mouth; Headache; Initial Insomnia; Nausea; Paraesthesia; Poor Quality Sleep; Product Use In Unapproved Indication; Restlessness; Therapy Partial Responder	Lexapro			S				Allergan
	Lexapro			S				Allergan
	Celexa			S				Allergan
	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Trintellix			S				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16734162	NON-EXPEDITED			US-ALLERGAN-1919600US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Lexapro		S	Unknown	Unk	Allergan
	Celexa		S	Unknown	Unk	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16811578	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1937397US			Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administered To Patient Of Inappropriate Age; Suicidal Ideation	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16813457	EXPEDITED (15-DAY)		HO	PHHY2019FR210556		14 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypotension; Malaise	Diclofenac			S	Oral	5000 Mg, Unk (In Total)		Not Reported
	Escitalopram			S	Oral	820 Mg, Unk (In Total)		Not Reported
	Paracetamol			S	Oral	2 G, Unk (In Total)		Not Reported
	Ibuprofen			S	Oral	4400 Mg, Unk (In Total)		Not Reported
	Donormyl (Doxylamine Succinate\Sodium Phosphate Dibasic\Sodium Bromide\Sodium Sulfate)			S	Oral	300 Mg, Unk (In Total)		Not Reported
	Diazepam			S	Oral	480 Mg, Unk (In Total)		Not Reported
	Colchicine			S	Oral	6 Mg, Unk (In Total)		Not Reported
	Cialis			S	Oral	40 Mg, Unk (In Total)		Not Reported
	Diane			S	Oral	21 Df, Unk (In Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842671	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1113154		17 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Incorrect Dose Administered; Suicidal Ideation	Venlafaxine Hydrochloride	S	Teva
	Escitalopram	S	Ivax
	Cipralex [Escitalopram]	S	Not Reported
	Cipralex [Escitalopram]	S	Not Reported
	Effexor Xr	S	Not Reported
	Effexor Xr	S	Not Reported
	Quetiapine	C	Not Reported
	Seroquel	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842945	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1111983		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Base Excess Decreased; Confusional State; Fall; Hypoglycaemia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis; Pco2 Decreased	Escitalopram Oxalate			S	Unknown			Ivax
	Hydrochlorothiazide			S	Unknown			Ivax
	Metformin			S	Unknown	2 Gram Daily;		Actavis
	Metformin			S	Unknown			Actavis
	Apo-Gliclazide			S	Unknown			Not Reported
	Insulin			S	Unknown			Not Reported
	Insulin			S	Unknown			Not Reported
	Gliclazide			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Telmisartan			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842989	NON-EXPEDITED			US-ALLERGAN-1915126US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842990	NON-EXPEDITED			US-ALLERGAN-1914603US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Lexapro			S		10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842991	NON-EXPEDITED			US-ALLERGAN-1914883US		6 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapy Cessation	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Guanfacine			C	Oral	2 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842992	NON-EXPEDITED			US-ALLERGAN-1914807US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842994	NON-EXPEDITED			US-ALLERGAN-1918502US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate Unk			S	Unknown	10 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842995	NON-EXPEDITED			US-ALLERGAN-1918731US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersensitivity	Lexapro			S						Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842996	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1917605US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Suicidal Ideation	Lexapro			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842997	NON-EXPEDITED			US-ALLERGAN-1916434US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842999	NON-EXPEDITED			US-ALLERGAN-1918122US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder	Lexapro			S				Allergan
	Cymbalta			S				Not Reported
	Xeljanz			C				Not Reported
	Aspirin			C				Not Reported
	Caltrate Gummy Bites 250mg-4			C				Not Reported
	Prilosec			C				Not Reported
	Vitamin B12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843000	NON-EXPEDITED			US-ALLERGAN-1916415US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843005	NON-EXPEDITED			US-ALLERGAN-1918085US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843007	NON-EXPEDITED			US-ALLERGAN-1917255US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; White Blood Cell Count Decreased	Lexapro			S	Unknown			Allergan
	Lexapro			S				Allergan
	Valium			S	Unknown	Unk, Prn		Not Reported
	Ibrance			S	Unknown	100 Mg		Not Reported
	Ibrance			S	Unknown	125 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843008	NON-EXPEDITED			US-ALLERGAN-1915893US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatic Enzymes Increased	Lexapro			S	Unknown	Unk		Allergan
	Praluent			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843009	NON-EXPEDITED			US-ALLERGAN-1918779US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843010	NON-EXPEDITED			US-ALLERGAN-1918664US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Ineffective; Headache; Migraine; Vision Blurred	Lexapro			S				Allergan
	Brexpiprazole			S		Actual: 1/4 Tablet Or 1/2 Tablet Of A 2 Mg Tablet With Unknown Frequency		Not Reported
	Abilify			S				Not Reported
	Buspirone			S		60 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843011	NON-EXPEDITED			US-ALLERGAN-1917431US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eczema	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843012	NON-EXPEDITED			US-ALLERGAN-1916508US		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hyperhidrosis; Nausea; Night Sweats; Night Sweats; Oedema; Oedema Peripheral	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Armour Thyroid			C	Unknown	7.5 Mg, Qd		Not Reported
	Armour Thyroid			C	Unknown	Actual: On Mondays And Thursdays		Not Reported
	Armour Thyroid			C	Unknown	7.5 Mg, Qd		Not Reported
	Armour Thyroid			C	Unknown			Not Reported
	Tirosint			C	Unknown	Actual: Every 4 Days With A Goal Of Reaching Daily		Not Reported

			Dosing	
Biotin	C	Unknown	10000 Mg, Qd	Not Reported
Biotin	C	Unknown	10,000 Mg Daily	Not Reported
Dexilant	C	Unknown	30 Mg, Qd	Not Reported
Dexilant	C	Unknown		Not Reported
Fish Oil	C	Unknown	1200 Mg, Qd	Not Reported
Fish Oil	C	Unknown		Not Reported
Glucosamine Chondroitin	C	Unknown	1500 Mg, Qd	Not Reported
Glucosamine Chondroitin	C	Unknown		Not Reported
Magnesium	C	Unknown	250 Mg, Qd	Not Reported
Magnesium	C	Unknown		Not Reported
Premarin	C	Unknown	0.625 Mg, Bid	Not Reported
Premarin	C	Unknown	.625 Mg	Not Reported
Selenium	C	Unknown	200 Mg, Qd	Not Reported
Selenium	C	Unknown	200 Mg Daily	Not Reported
Vitamin B12	C	Unknown	5000 Mg, Qd	Not Reported
Vitamin B12	C	Unknown	5000 Mg Daily	Not Reported
Vitamin D3	C	Unknown	5000 Iu, Qd	Not Reported
Vitamin D3	C	Unknown	5000 Units Daily	Not Reported
Escitalopram-Form-Unknown	S	Unknown		Not Reported
Escitalopram-Form-Unknown	S	Unknown		Not Reported
Escitalopram-Form-Unknown	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843014	NON-EXPEDITED			US-ALLERGAN-1916321US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843015	NON-EXPEDITED			US-ALLERGAN-1915561US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Bystolic			S	Unknown	Unk		Allergan
	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843016	NON-EXPEDITED			US-ALLERGAN-1921944US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843017	NON-EXPEDITED			US-ALLERGAN-1923290US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Eye; Dry Mouth	Lexapro			S	Unknown	Unk		Allergan
	Refresh Plus Pf			C	Ophthalmic	Unk		Not Reported
	Sustaine			C	Ophthalmic	Unk		Not Reported
	Sustaine Ultra			C	Ophthalmic	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843019	NON-EXPEDITED			US-ALLERGAN-1923997US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843020	NON-EXPEDITED			US-ALLERGAN-1922466US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Burning Sensation; Drug Ineffective; Dysphagia; Hypersensitivity; Insomnia; Rash Pruritic; Tinnitus; Urticaria	Lexapro			S		Unk		Allergan
	Rexulti			S		25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843021	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1919669US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Product Administration Duration	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Aripiprazole			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Abilify			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843022	NON-EXPEDITED			US-ALLERGAN-1921093US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Lexapro			S	Unknown	Unk		Allergan
	Humira			S	Subcutaneous	Unk, Single		Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843023	NON-EXPEDITED			US-ALLERGAN-1921213US		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off	Lexapro			S	Unknown	Unk		Allergan
	Effexor			C		Unk		Not Reported

Label Use	Plavix	C	Unk		Not Reported
	Crestor	C	Unk		Not Reported
	Lotranex	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843025	NON-EXPEDITED			US-ALLERGAN-1921911US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder	Lexapro			S	Unknown			Allergan
	Oxycodone			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843026	NON-EXPEDITED			US-ALLERGAN-1923067US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843027	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1921208US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hallucination, Visual; Hyperhidrosis; Nausea; Thirst	Lexapro			S	Unknown			Allergan
	Amantadine			S	Oral	274 Mg, Qhs		Not Reported
	Amantadine			S	Oral	137 Mg, Qd		Not Reported
	Pramipexole Dihydrochloride			C				Not Reported
	Fluticasone Propionate			C				Not Reported
	Rasagiline Mesylate			C				Not Reported
	Gabapentin			C				Not Reported
	Rytary			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843028	NON-EXPEDITED			US-ALLERGAN-1924860US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843029	NON-EXPEDITED			US-ALLERGAN-1925024US		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Intentional Product Misuse; Off Label Use; Panic Attack	Lexapro			S	Oral	5 Mg, Qd		Allergan
	Zyrtec			C	Oral	10 Mg, Qd		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Prozac			C	Oral	10 Mg, Qd		Not Reported
	Tylenol			C	Oral	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843030	NON-EXPEDITED			US-ALLERGAN-1922439US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843031	NON-EXPEDITED			US-ALLERGAN-1924169US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843032	NON-EXPEDITED			US-ALLERGAN-1921002US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Dizziness; Drug Interaction; Dyskinesia; Flushing; Mania	Lexapro			S	Unknown	Unk		Allergan
	Xadago			S	Unknown	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843034	NON-EXPEDITED			US-ALLERGAN-1921757US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Feeling Of Despair	Lexapro			S		10 Mg, Qhs		Allergan
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843035	NON-EXPEDITED			US-ALLERGAN-1921285US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843036	NON-EXPEDITED			US-ALLERGAN-1920251US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Lexapro			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843037	NON-EXPEDITED			US-ALLERGAN-1920094US		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro			S	Oral	Unk, Qod		Allergan
	Lexapro			S	Oral	Unk, Qd		Allergan

	Lexapro		S					Allergan
	Ativan		C	Oral	Unk			Not Reported
	Ativan		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843038	NON-EXPEDITED			US-ALLERGAN-1920772US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Stress; Weight Increased	Lexapro			S	Unknown	10 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843039	NON-EXPEDITED			US-ALLERGAN-1924175US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restlessness	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843040	NON-EXPEDITED			US-ALLERGAN-1924441US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Muscle Spasms; Off Label Use; Tinnitus	Lexapro			S	Unknown			Allergan
	Klonopin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843041	NON-EXPEDITED			US-ALLERGAN-1929170US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan
	Ciprofloxacin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843042	NON-EXPEDITED			US-ALLERGAN-1928579US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dyspnoea; Product Taste Abnormal; Wrong Technique In Product Usage Process	Lexapro			S	Unknown	20 Mg, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843043	NON-EXPEDITED			US-ALLERGAN-1928624US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erectile Dysfunction	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843044	NON-EXPEDITED			US-ALLERGAN-1929184US		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Ineffective; Incorrect Dose Administered; Product Label Issue	Lexapro			S	Oral	20 Mg, Qhs		Allergan
	Paxil			C	Unknown	Unk		Not Reported
	Paxil			C				Not Reported
	Prozac			C	Unknown	Unk		Not Reported
	Prozac			C				Not Reported
	Synthroid			C		Unk		Not Reported
	Oxycodone			C				Not Reported
	Gabapentin			C				Not Reported
	Lorazepam			C		Unk		Not Reported
	Vitamin B12			C				Not Reported
	Centrum			C				Not Reported
	Omega-3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843047	NON-EXPEDITED			US-ALLERGAN-1927456US		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Escitalopram Oxalate Unk			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843048	NON-EXPEDITED			US-ALLERGAN-1929460US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anxiety; Asthenia; Burning Sensation; Decreased Appetite	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843049	NON-EXPEDITED			US-ALLERGAN-1929540US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Escitalopram Oxalate - Bp			S		10 Mg		Allergan
	Tramadol			S		50 Mg		Not Reported
	Lyrica			S		20 Mg		Not Reported
	Valium			S		5 Mg		Not Reported
	Lidocaine			C	Topical	5%		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843050	NON-EXPEDITED			US-ALLERGAN-1925713US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843051	NON-EXPEDITED			US-ALLERGAN-1927738US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tardive Dyskinesia	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843052	NON-EXPEDITED			US-ALLERGAN-1925291US		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Product Dispensing Error	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843053	NON-EXPEDITED			US-ALLERGAN-1926263US		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Drug Ineffective	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843054	NON-EXPEDITED			US-ALLERGAN-1928834US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depressed Mood; Drug Ineffective	Lexapro			S	Oral			Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843055	NON-EXPEDITED			US-ALLERGAN-1928574US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Erythema; Flushing	Escitalopram Oxalate Unk	S	Unk	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843056	NON-EXPEDITED			US-ALLERGAN-1928886US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Lethargy	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843057	NON-EXPEDITED			US-ALLERGAN-1926061US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Asthenia; Decreased Appetite; Decreased Interest; Disturbance In Attention; Feeling Guilty; Headache; Hypersomnia; Major Depression; Memory Impairment; Palpitations; Panic Attack; Post-Traumatic Stress Disorder; Psychomotor Retardation; Slow Speech; Suicidal Ideation	Lexapro			S	Unknown	20 Mg		Allergan
	Venlafaxine			S	Unknown	150 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843058	NON-EXPEDITED			US-ALLERGAN-1928760US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Caries; Feeling Abnormal; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843059	NON-EXPEDITED			US-ALLERGAN-		98 YR	Male	USA

1929064US

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Aggression; Agitation; Drug Ineffective; Drug Intolerance; Mental Disorder	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843060	NON-EXPEDITED			US-ALLERGAN-1929350US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity	Lexapro			S		Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843062	NON-EXPEDITED			US-ALLERGAN-1926160US		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nephrolithiasis	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843063	NON-EXPEDITED			US-ALLERGAN-1927667US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Hallucination	Escitalopram Oxalate Unk			S		Unk		Allergan
	Apokyn			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843064	NON-EXPEDITED			US-ALLERGAN-1929178US		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sexual Dysfunction	Lexapro			S	Unknown	Unk		Allergan
	Latuda			S	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843065	NON-EXPEDITED			US-ALLERGAN-1927905US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Crying; Drug Ineffective; Feeling Abnormal; Heart Rate Increased; Homeless; Hyperhidrosis; Impaired Work Ability; Memory Impairment; Panic Attack; Tremor	Lexapro			S	Unknown	Unk, Unknown		Allergan
	Abilify			S	Unknown	5 Mg, Unknown		Not Reported
	Abilify			S	Unknown	2 Mg, Unknown		Not Reported
	Abilify			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk, Unknown		Not Reported
	Aripiprazole			S	Unknown	Unk Unk, Unknown		Not Reported
	Lithium			C				Not Reported
	Paxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843068	NON-EXPEDITED			US-ALLERGAN-1930999US		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Disturbance In Attention; Dizziness; Feeling Abnormal; Growth Retardation; Headache	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843069	NON-EXPEDITED			US-ALLERGAN-1933012US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hyperhidrosis; Nausea	Lexapro			S	Unknown	10 Mg		Allergan
	Lexapro			S				Allergan

	Escitalopram Oxalate Unk	S	Unknown	10 Mg, Unk		Allergan
	Escitalopram Oxalate Unk	S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843070	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1930328US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Escitalopram Oxalate Unk			S	Unknown			Allergan
	Estradiol Unk			S	Unknown			Allergan
	Genotropin Miniquik			S	Subcutaneous	0.6 Mg, Qd		Not Reported
	Hizentra			S	Unknown			Not Reported
	Hydrocortisone			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Nascobal			S	Unknown			Not Reported
	Promethazine			S	Unknown			Not Reported
	Montelukast Sodium			S	Unknown			Not Reported
	Creon			S	Unknown			Not Reported
	Acyclovir			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Levetiracetam			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Rizatriptan			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Acetaminophen And Codeine			S	Unknown			Not Reported
	Levoxyl			S	Unknown			Not Reported
	Liothyronine Sodium			S	Unknown			Not Reported
	Pantoprazole Sodium			S	Unknown			Not Reported
	Proair Hfa			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843072	NON-EXPEDITED			US-ALLERGAN-1932796US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Incorrect Dose Administered; Insomnia; Paraesthesia; Paraesthesia; Product Dose Omission; Withdrawal Syndrome	Lexapro			S	Unknown	5 Mg		Allergan
	Lexapro			S	Unknown	10 Mg		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843073	NON-EXPEDITED			US-ALLERGAN-1930556US		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Irregular; Insomnia; Product Dose Omission; Sleep Disorder; Therapeutic Response Unexpected	Lexapro			S	Oral	5 Mg, Qam		Allergan
	Sinemet			C	Oral	25/250 Every Bedtime		Not Reported
	Rytari Er			C	Oral	48.75 Mg Qid(6 Am, Noon, 2 Pm And Dinner Time		Not Reported
	Synthroid			C	Oral	Unk		Not Reported
	Atorvastatin			C	Oral	Unk		Not Reported
	Armodafinil			C		Unk		Not Reported
	Move Free (Glucosaminechondroitin)			C	Oral	Unk		Not Reported
	Stool Softener(Unspecified)			C	Oral	Unk		Not Reported
	Coq 10			C	Oral	Unk		Not Reported
	Multi-Vitamin (Unspecified)			C	Oral	Unk		Not Reported
	Ginko Biloba			C	Oral	Unk		Not Reported
	Saw Palmetto			C	Oral	Unk		Not Reported
	Namzaric			C	Oral	28/10 Mg At Bedtime		Not Reported
	Melatonin			C	Oral	Unk		Not Reported
	Tadalafil			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843074	NON-EXPEDITED			US-ALLERGAN-1930079US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843075	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1931550US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Platelet Count Decreased; Tinnitus	Lexapro			S		10 Mg, Qd		Allergan
	Lexapro			S		20 Mg, Qd		Allergan
	Ibrance			S		75 Mg		Not Reported
	Ibrance			S		100 Unk		Not Reported
	Ibrance			S		125 Mg		Not Reported
	Zofran			C		4 Mg, Prn		Not Reported
	Ativan			C		0.5 - 1 Mg Prn		Not Reported
	Ativan			C				Not Reported
	Tylenol			C		500 Mg, Prn		Not Reported
	Tizanidine			C		Unk, Prn		Not Reported
	Drobranol			C		2.5 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843076	NON-EXPEDITED			US-ALLERGAN-1932878US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nightmare	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843077	NON-EXPEDITED			US-ALLERGAN-1930986US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration; Oesophageal Ulcer	Lexapro			S	Unknown	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843078	NON-EXPEDITED			US-ALLERGAN-1932516US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Blood Pressure Fluctuation; Off Label Use; Palpitations	Lexapro			S				Allergan
	Cymbalta			S				Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported
	Aspirin 81			C				Not Reported
	Biotin			C				Not Reported
	Caltrate			C				Not Reported
	Prilosec			C				Not Reported
	Vitamin B12			C				Not Reported
	Meloxicam			C		7.5 Mg		Not Reported
	Folic Acid			C		1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843079	NON-EXPEDITED			US-ALLERGAN-1931526US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843080	NON-EXPEDITED			US-ALLERGAN-1931271US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abnormal Behaviour; Feeling Jittery; Off Label Use; Wrong Technique In Product Usage Process	Escitalopram Oxalate Unk		S	30 Mg, Qd	Allergan
	Escitalopram Oxalate Unk		S		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843082	NON-EXPEDITED			US-ALLERGAN-1850462US		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Somnolence	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843083	NON-EXPEDITED			US-ALLERGAN-1845685US		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro			S	Unknown	40 Unk, Unk		Allergan
	Lexapro			S	Unknown	30 Mg, Qd		Allergan
	Lexapro			S	Unknown	20 Mg, Unk		Allergan
	Lexapro			S	Unknown	15 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843084	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1846326US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Depression; Drug Ineffective; Suicide Attempt	Lexapro			S	Oral	Unk, Unknown		Allergan
	Latuda			C	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843085	NON-EXPEDITED			US-ALLERGAN-1933027US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Dyspepsia; Rash; Sexual Dysfunction	Lexapro	S		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843086	NON-EXPEDITED			US-ALLERGAN-1931527US		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843087	NON-EXPEDITED			US-ALLERGAN-1856562US		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Asthenia; Diplopia; Dizziness; Fatigue; Headache; Insomnia; Malaise; Movement Disorder; Somnolence; Vision Blurred; Wrong Technique In Product Usage Process	Lexapro			S	Unknown	10 Mg, Qd		Allergan
	Plavix			C		Unk		Not Reported
	Norvasc			C		Unk		Not Reported
	Incontinence Medication			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843088	NON-EXPEDITED			US-ALLERGAN-1840023US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan
	Plaquenil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843089	NON-EXPEDITED			US-ALLERGAN-1840810US		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use	Lexapro		S	Oral	20 Mg, Tid	Allergan
	Diazepam		C	Oral	10 Mg, Qid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843091	NON-EXPEDITED			US-ALLERGAN-1846261US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Crying; Decreased Appetite; Disorientation; Fear; Feeling Abnormal; Food Intolerance; Nervousness; Nightmare; Off Label Use; Paraesthesia; Restlessness; Suicidal Ideation	Lexapro			S	Oral	5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843092	NON-EXPEDITED			US-ALLERGAN-1844987US		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Gastritis; Hiatus Hernia; Irritable Bowel Syndrome; Rash	Lexapro			S	Oral	1 Df, Qd		Allergan
	Pristiq			S	Unknown	25 Mg, Unk		Not Reported
	Levothyroxine			C	Oral	75 Mg, Qd		Not Reported
	Atorvastatin			C	Oral	40 Mg, Qd		Not Reported
	Cardizem			C	Oral	240 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843094	NON-EXPEDITED			US-ALLERGAN-1842604US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Intentional Dose Omission	Lexapro			S	Oral	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843095	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1851387US		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Expired Product Administered; Suicidal Ideation; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Meloxicam			C	Oral	40 Mg, Qpm		Not Reported
	Synthroid			C	Oral	75 Mg, Qam		Not Reported
	Simvastatin			C	Oral	40 Mg, Qd (At Lunch)		Not Reported
	Mobic			C	Unknown	Unk		Not Reported
	Allegra			C	Oral	Unknown		Not Reported
	Triamterene			C	Oral	37.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843096	NON-EXPEDITED			US-ALLERGAN-1855567US		19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Escitalopram Oxalate - Bp			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843097	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1844958US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mood Altered; Seizure; Vision Blurred	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843098	NON-EXPEDITED			US-ALLERGAN-1846503US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Feeling Jittery; Product Dose Omission; Vomiting	Lexapro		S	Unknown	20 Mg, Unk	Allergan
	Lexapro		S	Unknown	10 Mg, Unk	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843099	NON-EXPEDITED			US-ALLERGAN-1846224US		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Vision Blurred; Wrong Technique In Product Usage Process	Lexapro			S	Unknown	5 Mg, Unk		Allergan
	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Gabapentin			C	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Vit D			C	Unknown	Unk		Not Reported
	Amiodarone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843100	NON-EXPEDITED			US-ALLERGAN-1855709US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843101	NON-EXPEDITED			US-ALLERGAN-1840830US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Somnambulism	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843102	NON-EXPEDITED			US-ALLERGAN-1840809US		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gait Inability; Movement Disorder; Somnambulism; Somnolence	Lexapro	S	Unknown	Unk Unk, Qd		Allergan
	Xeljanz	S	Oral	11 Mg, Qd		Not Reported
	Simponi	C		Unk		Not Reported
	Meloxicam	C	Oral	15 Mg, Qd		Not Reported
	Novolog	C		100 Ml, Unk		Not Reported
	Lantus	C	Subcutaneous	15 Units, Qd		Not Reported
	Humalog	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843103	NON-EXPEDITED			US-ALLERGAN-1845145US		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Menstrual Disorder	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843104	NON-EXPEDITED			US-ALLERGAN-1843348US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Nausea	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843105	NON-EXPEDITED			US-ALLERGAN-1854268US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Sleep Disorder	Lexapro			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843106	NON-EXPEDITED			US-ALLERGAN-1844698US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Reaction; Drug Ineffective	Lexapro	S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843107	NON-EXPEDITED			US-ALLERGAN-1841799US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843108	NON-EXPEDITED			US-ALLERGAN-1852402US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Lexapro			S	Unknown	30 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843109	NON-EXPEDITED			US-ALLERGAN-1852086US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843110	NON-EXPEDITED			US-ALLERGAN-1856219US		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Abdominal Pain Upper; Back Pain; Balance Disorder; Burning Sensation; Constipation; Decreased Appetite; Depression; Faeces	Lexapro			S	Unknown			Allergan
	Ampyra			S	Oral	10 Mg, Q12h		Not Reported
	Tecfidera			S	Unknown	240 Mg, Qd		Not Reported
	Tecfidera			S	Unknown	240 Mg, Bid		Not Reported

Discoloured; Feeling Abnormal; Insomnia; Muscular Weakness; Nausea; Neck Pain; Pruritus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843111	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1849523US		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depressed Mood; Drug Dose Titration Not Performed; Fatigue; Lethargy; Suicidal Ideation	Lexapro			S	Unknown	Unk		Allergan
	Brexpiprazole			S	Oral	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843112	NON-EXPEDITED			US-ALLERGAN-1843319US		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Fatigue; Pruritus Generalised	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Obeticholic Acid			S	Oral	5 Mg, Qd		Not Reported
	Obeticholic Acid			S	Oral	5 Mg, Qd		Not Reported
	Obeticholic Acid			S	Oral	10 Mg, Qd		Not Reported
	Aczone			C	Unknown	Unk		Not Reported
	Calcium Carbonate/ Vitamin D3			C	Unknown	Unk		Not Reported
	Estrace			C	Unknown	Unk		Not Reported
	Lofibra			C	Unknown	Unk		Not Reported
	Bactroban			C	Unknown	Unk		Not Reported
	Percocet			C	Unknown	Unk		Not Reported
	Deltasone			C	Unknown	Unk		Not Reported
	Ultracet			C	Unknown	Unk		Not Reported
	Actigall			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843117	NON-EXPEDITED			US-ALLERGAN-1903662US		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Hot Flush; Menopause; Palpitations; Sleep Disorder	Lexapro			S	Oral	10 Mg, Qhs		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843118	NON-EXPEDITED			US-ALLERGAN-1847504US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Incorrect Dose Administered; Off Label Use; Saliva Altered; Wrong Technique In Product Usage Process	Lexapro			S	Oral	7.5 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843120	NON-EXPEDITED			US-ALLERGAN-1902653US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Lexapro			S	Unknown	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843121	NON-EXPEDITED			US-ALLERGAN-1844246US		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nervousness	Lexapro			S	Unknown	5 Mg, Unk		Allergan
	Aubagio			S	Oral	14 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843122	NON-EXPEDITED			US-ALLERGAN-1902322US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Pain; Breast Tenderness	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	20 Mg, Unk		Allergan
	Nexium			C	Unknown	Unk		Not Reported
	Antihypertensives			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843126	NON-EXPEDITED			US-ALLERGAN-1901454US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Feeling Abnormal; Insomnia; Nausea	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843127	NON-EXPEDITED			US-ALLERGAN-1847536US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Ejaculation Disorder; Fatigue; Hallucination, Auditory	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843128	NON-EXPEDITED			US-ALLERGAN-1900616US		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Dose Omission	Lexapro	S	Unknown	10 Mg, Qd		Allergan
	Vraylar	C	Unknown	3 Mg, Qd		Not Reported
	Phentermine	C	Unknown	35 Mg, Qd		Not Reported
	Cocaine	C	Unknown	Unk (Abuse)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843129	NON-EXPEDITED			US-ALLERGAN-1901102US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram Oxalate Unk			S	Unknown	Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843130	NON-EXPEDITED			US-ALLERGAN-1846516US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Breast Feeding	Lexapro			S	Transmammary	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843132	NON-EXPEDITED			US-ALLERGAN-1902016US		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Fear; Feeling Abnormal; Thinking Abnormal	Lexapro			S	Oral	20 Mg, Unk		Allergan
	Lexapro			S	Oral	20 Mg, Unk		Allergan
	Lexapro			S	Oral	20 Mg, Unk		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843133	NON-EXPEDITED			US-ALLERGAN-1902324US		73 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Pain; Breast Tenderness	Lexapro		S	Oral	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843134	NON-EXPEDITED			US-ALLERGAN-1900970US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mood Altered	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843135	NON-EXPEDITED			US-ALLERGAN-1847841US		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Off Label Use	Lexapro			S	Unknown	Unk		Allergan
	Lexapro			S				Allergan
	Lexapro			S				Allergan
	Aubagio			C	Oral	14 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843136	NON-EXPEDITED			US-ALLERGAN-1903501US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843137	NON-EXPEDITED			US-ALLERGAN-1849497US		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Suicidal Ideation; Tremor	Lexapro			S	Unknown	30 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843139	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1902138US		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Lexapro			S	Unknown	Unk		Allergan
	Northera			S	Oral	2 Capsules (600 Mg) In The Morning And 1 Capsule (300 Mg) At Noon		Not Reported
	Tegretol			S	Unknown			Not Reported
	Sodium Chloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843140	NON-EXPEDITED			US-ALLERGAN-1851106US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843141	NON-EXPEDITED			US-ALLERGAN-1900121US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843142	NON-EXPEDITED			US-ALLERGAN-1858292US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Inflammation; Pain	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843143	NON-EXPEDITED			US-ALLERGAN-1906382US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843145	NON-EXPEDITED			US-ALLERGAN-1905614US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843146	NON-EXPEDITED			US-ALLERGAN-1859670US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Lisinopril			S	Unknown	Unk		Not Reported
	Atenolol			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Calcium Channel Blockers			S	Unknown	Unk		Not Reported
	Penicillin G			S	Unknown	Unk		Not Reported
	Penicillins With Extended Spectrum			S	Unknown	Unk		Not Reported
	Simvastatin			S	Unknown	Unk		Not Reported
	Sulfacetamide Sodium			S	Unknown	Unk		Not Reported
	Lovastatin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843147	NON-EXPEDITED			US-ALLERGAN-1905405US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843148	NON-EXPEDITED			US-ALLERGAN-1858388US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Pruritus; Urticaria	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843149	NON-EXPEDITED			US-ALLERGAN-1906008US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Lexapro			S	Oral			Allergan
	Wellbutrin			C	Oral	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843151	NON-EXPEDITED			US-ALLERGAN-1857514US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Lexapro			S	Unknown	Unk		Allergan
	Repatha			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843152	NON-EXPEDITED			US-ALLERGAN-1900325US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Unknown	Unk		Allergan
	Brexpiprazole			S	Oral	2 Mg, Qd		Not Reported

	Effexor			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843153	NON-EXPEDITED			US-ALLERGAN-1857439US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sleep Disorder; Tinnitus	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843154	NON-EXPEDITED			US-ALLERGAN-1906259US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843155	NON-EXPEDITED			US-ALLERGAN-1906078US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Fluctuation	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843156	NON-EXPEDITED			US-ALLERGAN-1906513US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	20 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843158	NON-EXPEDITED			US-ALLERGAN-1905925US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Malaise	Lexapro	S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843159	NON-EXPEDITED			US-ALLERGAN-1906438US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Trintellix			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843160	NON-EXPEDITED			US-ALLERGAN-1857461US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Intentional Dose Omission; Migraine; Product Dose Omission; Sinus Disorder	Lexapro			S	Unknown	5 Mg, Unk		Allergan
	Lexapro			S	Unknown	10 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843161	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1857483US		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tremor	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan
	Repatha			S	Unknown	140 Mg, Q2weeks		Not Reported
	Levothyroxine			S	Unknown	0.5 Unk, Qd		Not Reported
	Beta Blocker			C	Unknown	Unk, Unknown		Not Reported
	Statins			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843162	NON-EXPEDITED			US-ALLERGAN-1906339US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Oral Mucosal Blistering	Escitalopram Oxalate Unk		S	Oral	Unk	Allergan
	Escitalopram Oxalate Unk		S			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843164	NON-EXPEDITED			US-ALLERGAN-1858338US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Dose Omission; Off Label Use	Lexapro			S	Unknown	5 Mg, Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843165	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1905906US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan
	Levothyroxine			C	Oral	75 Mg, Qd		Not Reported
	Atorvastatin			C	Oral	40 Mg, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843166	NON-EXPEDITED			US-ALLERGAN-1905323US		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Decreased Appetite; Depressed Mood; Drug Ineffective; Haemorrhage; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Razapam			S	Unknown	Unk		Not Reported
	Xanax			S	Unknown	Unk		Not Reported
	Prempro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843167	NON-EXPEDITED			US-ALLERGAN-1900308US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective For Unapproved Indication; Off Label Use	Escitalopram Oxalate - Bp	S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp	S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843168	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1856769US		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Off Label Use	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Metformin			S	Oral	1000 Mg, Bid		Not Reported
	Lisinopril			S	Oral	20 Mg, Qd		Not Reported
	Trazodone			S	Oral	100 Mg, Qd		Not Reported
	Trazodone			S	Oral	50 Mg, Qd		Not Reported
	Glyburide			C		Unk		Not Reported
	Gemfibrozil			C		Unk		Not Reported
	Pravachol			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Combivent			C		Unk		Not Reported
	Valium			C		Unk		Not Reported
	Victoza			C		Unk		Not Reported
	Lunesta			C		Unk		Not Reported
	Anorol			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Proair			C		Unk		Not Reported
	Medizime			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843170	NON-EXPEDITED			US-ALLERGAN-1857618US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843172	NON-EXPEDITED			US-ALLERGAN-1904221US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan
	Trokendi Xr			C	Oral	200 Mg, Qd		Not Reported
	Lamictal			C	Oral	150mg 2 Tablets Once A Day		Not Reported
	Lamictal			C				Not Reported
	Invokamet			C	Oral	150/500mg Tablet Twice A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843173	NON-EXPEDITED			US-ALLERGAN-1904459US		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843175	NON-EXPEDITED			US-ALLERGAN-1907218US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843177	NON-EXPEDITED			US-ALLERGAN-1904289US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843178	NON-EXPEDITED			US-ALLERGAN-1907738US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased; Wrong Technique In Product Usage Process	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Protonix			C		40 Mg		Not Reported
	Gabapentin			C	Oral	300 Mg, Tid		Not Reported
	Meloxicam			C		15 Mg		Not Reported
	Cyclobenzaprine			C		10 Mg		Not Reported
	Calcium			C		1200 Mg		Not Reported
	Clonazepam			C		0.5 Mg, Prn		Not Reported
	Clonazepam			C				Not Reported
	Oxycodone / Acetaminophen			C		7.5-325mg As Needed		Not Reported
	Tylenol			C		325 Mg		Not Reported
	Aspirin			C		325 Mg		Not Reported
	Centrum Silver			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843179	NON-EXPEDITED			US-ALLERGAN-1903719US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypersensitivity; Nausea; Off Label Use; Vomiting	Lexapro			S	Unknown	Unk		Allergan
	Amitriptyline			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Buspirone			S	Unknown	Unk		Not Reported
	Effexor			S	Unknown	Unk		Not Reported
	Omeprazole			S	Unknown	Unk		Not Reported
	Meloxicam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843181	NON-EXPEDITED			US-ALLERGAN-1908037US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear; Feeling Abnormal; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843182	NON-EXPEDITED			US-ALLERGAN-1907295US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843183	NON-EXPEDITED			US-ALLERGAN-1907308US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pregnancy; Premature Labour	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843184	NON-EXPEDITED			US-ALLERGAN-1907747US		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Lexapro			S	Unknown	Unk		Allergan
	Effexor			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843185	NON-EXPEDITED			US-ALLERGAN-1904314US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ejaculation Delayed; Erectile Dysfunction	Escitalopram Oxalate - Bp		S	Unknown	Unk	Allergan
	Escitalopram Oxalate - Bp		S	Unknown	20 Mg, Unk	Allergan
	Escitalopram Oxalate - Bp		S	Unknown	10 Mg, Unk	Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843186	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1904096US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Interaction; Serotonin Syndrome	Lexapro			S	Unknown	Unk (Low Dose)		Allergan
	Dextromethorphan Hydrobromide W/Guaifenesin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843188	NON-EXPEDITED			US-ALLERGAN-1907369US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorgasmia	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843189	NON-EXPEDITED			US-ALLERGAN-1907906US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan
	Tacrolimus			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843190	NON-EXPEDITED			US-ALLERGAN-1907367US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843191	NON-EXPEDITED			US-ALLERGAN-1907907US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843192	NON-EXPEDITED			US-ALLERGAN-1907398US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Feeling Abnormal	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Levothyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843193	NON-EXPEDITED			US-ALLERGAN-1904111US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843194	NON-EXPEDITED			US-ALLERGAN-1908483US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843195	NON-EXPEDITED			US-ALLERGAN-1907894US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Drug Ineffective; Gastroenteritis; Malaise	Lexapro			S	Unknown	Unk				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843196	NON-EXPEDITED			US-ALLERGAN-1904727US		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843197	NON-EXPEDITED			US-ALLERGAN-1907407US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retching; Vomiting	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Metronidazole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843198	NON-EXPEDITED			US-ALLERGAN-1907563US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Tremor	Lexapro			S	Unknown	100 Mg, Unk		Allergan
	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843199	NON-EXPEDITED			US-ALLERGAN-1904539US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Headache; Muscle Spasms; Musculoskeletal Stiffness;	Lexapro			S	Unknown	Unk		Allergan

Palpitations; Panic Attack;
Tachyphrenia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843200	NON-EXPEDITED			US-ALLERGAN-1905295US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine; Off Label Use	Lexapro			S	Unknown	Unk		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843202	NON-EXPEDITED			US-ALLERGAN-1904272US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Dizziness; Nausea; Paraesthesia	Lexapro			S	Oral	10 Mg, Unk		Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Blood Pressure Pill			C	Oral	Unk		Not Reported
	Klonopin			C	Oral	Unk Unk, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843203	NON-EXPEDITED			US-ALLERGAN-1907213US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Gastrooesophageal Reflux Disease; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843205	NON-EXPEDITED			US-ALLERGAN-1907074US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea;	Lexapro			S	Unknown	Unk		Allergan

Hypersensitivity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843206	NON-EXPEDITED			US-ALLERGAN-1904537US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843207	NON-EXPEDITED			US-ALLERGAN-1908570US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro			S	Unknown	40 Mg, Unk		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843208	NON-EXPEDITED			US-ALLERGAN-1909392US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843209	NON-EXPEDITED			US-ALLERGAN-1909048US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Hyperhidrosis	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843210	NON-EXPEDITED			US-ALLERGAN-1909786US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Drug Ineffective; Headache; Insomnia	Lexapro	S	Oral	1/4 Of A 20mg Tablet, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843211	NON-EXPEDITED			US-ALLERGAN-1906738US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843212	NON-EXPEDITED			US-ALLERGAN-1909233US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Trazodone			S	Unknown	Unk		Not Reported
	Duloxetine			C	Oral	30 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843213	NON-EXPEDITED			US-ALLERGAN-1908978US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Lexapro			S	Unknown	Unk		Allergan
	Xanax			C		Unk		Not Reported
	Flexeril			C		Unk		Not Reported
	Flexeril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843214	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1910841US		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased	Lexapro			S	Oral	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843215	NON-EXPEDITED			US-ALLERGAN-1906571US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Crying; Feeling Abnormal; Food Refusal; Insomnia	Lexapro			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843216	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1908508US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hallucination	Lexapro			S	Unknown	Unk		Allergan
	Lorazepam			C	Unknown	0.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843217	NON-EXPEDITED			US-ALLERGAN-1909242US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Panic Attack	Lexapro			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843218	NON-EXPEDITED			US-ALLERGAN-1909043US		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swelling	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843219	NON-EXPEDITED			US-ALLERGAN-1908061US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Off Label Use	Lexapro		S	Unknown	40 Mg		Allergan
	Xanax		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843220	NON-EXPEDITED			US-ALLERGAN-1909627US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Lexapro			S				Allergan
	Lexapro			S				Allergan
	Lamotrigine			S				Not Reported
	Lamotrigine			S				Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843221	NON-EXPEDITED			US-ALLERGAN-1909295US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843222	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1909040US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Escitalopram Oxalate Unk			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843223	NON-EXPEDITED			US-ALLERGAN-1906556US		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Contact; Erythema; Off Label Use; Pruritus; Somnolence	Lexapro			S	Oral	30 Mg, Qd		Allergan
	Cholesterol			C	Oral	Unk		Not Reported

	Blood Pressure Medication			C	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843224	NON-EXPEDITED			US-ALLERGAN-1908558US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843225	NON-EXPEDITED			US-ALLERGAN-1909014US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Headache	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843226	NON-EXPEDITED			US-ALLERGAN-1908490US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Off Label Use	Lexapro			S	Unknown	30 Mg		Allergan
	Lexapro			S	Unknown	20 Mg, Qd		Allergan
	Xanax			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843227	NON-EXPEDITED			US-ALLERGAN-1907068US		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Dizziness; Fatigue; Hyperhidrosis; Hypertension; Myalgia;	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qpm		Allergan
	Abilify			S	Oral	5 Mg, Qam		Not Reported

Panic Disorder; Salivary Hypersecretion; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843228	NON-EXPEDITED			US-ALLERGAN-1906864US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Pharyngeal Swelling	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843229	NON-EXPEDITED			US-ALLERGAN-1909019US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Dissociation; Emotional Distress; Emotional Poverty; Laboratory Test Abnormal; Off Label Use; Spinal Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843230	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1909293US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843233	NON-EXPEDITED			US-ALLERGAN-1910882US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram Oxalate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843234	NON-EXPEDITED			US-ALLERGAN-1911728US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843235	NON-EXPEDITED			US-ALLERGAN-1913782US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843237	NON-EXPEDITED			US-ALLERGAN-1910927US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S	Unknown	10 Mg		Allergan
	Multivitamin			C				Not Reported
	Vitamin D3			C		10000 Units		Not Reported
	Glucosamine & Chondroitin			C				Not Reported
	Magnesium			C		100 Mg		Not Reported
	Effexor Xr			C		75 Mg, Qd		Not Reported
	Methotrexate			C		2.5 Mg		Not Reported
	Lyrica			C		100 Mg		Not Reported
	Buspirone Hcl			C		15 Mg		Not Reported
	Acyclovir			C		200 Mg		Not Reported
	Folic Acid			C		1 Mg		Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Estradiol			C	Transdermal	0.025 Mg		Not Reported

Trazodone	C	100 Mg		Not Reported
Claritin	C	10 Mg		Not Reported
Prilosec	C	20 Mg		Not Reported
Meloxicam	C	15 Mg		Not Reported
Prednisone	C	1 Mg		Not Reported
Apriso	C	0.375 G, Sr 24 Hr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843238	NON-EXPEDITED			US-ALLERGAN-1911553US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843239	NON-EXPEDITED			US-ALLERGAN-1912793US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Jittery; Insomnia; Irritability; Tremor	Lexapro			S	Unknown	10 Mg, Qam		Allergan
	Lexapro			S	Unknown	5 Mg, Qam		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843240	NON-EXPEDITED			US-ALLERGAN-1912358US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Thinking Abnormal	Escitalopram Oxalate - Bp			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843241	NON-EXPEDITED			US-ALLERGAN-1911058US		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash; Skin Burning Sensation	Lexapro			S	Unknown	Unk		Allergan
	Venlafaxine Xr			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843243	NON-EXPEDITED			US-ALLERGAN-1912624US		92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania; Product Dose Omission; Restlessness	Lexapro			S	Unknown	10 Mg, Qd		Allergan
	Lexapro			S	Unknown	5 Mg, Qd		Allergan
	Heart Medication			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843244	NON-EXPEDITED			US-ALLERGAN-1914083US		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Lexapro			S	Unknown	25 Df, Single (Or Almost The Whole Bottle)		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843245	NON-EXPEDITED			US-ALLERGAN-1914340US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843246	NON-EXPEDITED			US-ALLERGAN-1914031US		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased; Off Label Use; Somnolence;	Lexapro			S	Oral	5 Mg, Qd		Allergan

Tremor	Lexapro	S	Oral	5 Mg, Qam	Allergan
	Lexapro	S	Oral	5 Mg, Qpm	Allergan
	Ativan	C			Not Reported
	Gabapentin	C			Not Reported
	Lantus	C			Not Reported
	Atenolol	C			Not Reported
	Lisinopril	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843247	NON-EXPEDITED			US-ALLERGAN-1912288US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Lexapro			S	Unknown	Unk		Allergan
	Xanax			C		Unk		Not Reported
	Restoril /00054301/			C		Unk		Not Reported
	Cytomel			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Hydrocortisone			C		Unk		Not Reported
	Liothyronine			C		Unk		Not Reported
	Levonorgestrel			C		Unk		Not Reported
	Estradiol			C		Unk		Not Reported
	Alprazolam			C		Unk		Not Reported
	Temazepam			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Multivitamin /00097801/			C		Unk		Not Reported
	Omega 3 /01333901/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843249	NON-EXPEDITED			US-ALLERGAN-1912045US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agitation; Anxiety; Diabetes Mellitus	Escitalopram Oxalate - Bp	S	Oral	0.5 Mg		Allergan
	Vortioxetine	S	Oral	10 Mg Tablet		Not Reported
	Brexpiprazole	S	Oral	3 Mg, Qd		Not Reported
	Brexpiprazole	S	Oral	0.5 Mg, Qd		Not Reported
	Prozac	C	Unknown	Unk		Not Reported
	Lamictal	C	Unknown	Unk		Not Reported
	Trazodone Hydrochloride	C	Unknown	Unk		Not Reported
	Deplin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843250	NON-EXPEDITED			US-ALLERGAN-1913904US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Lexapro			S	Unknown	Unk		Allergan
	Vivitrol			S	Intramuscular	380 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843252	NON-EXPEDITED			US-ALLERGAN-1910931US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Escitalopram Oxalate Unk			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843253	NON-EXPEDITED			US-ALLERGAN-1914540US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843256	NON-EXPEDITED			US-ALLERGAN-1910925US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan
	Miralax			C		17 G		Not Reported
	Advil			C		Unk		Not Reported
	Dilaudid			C		Unk		Not Reported
	Imodium			C		Unk		Not Reported
	Tylenol			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843257	NON-EXPEDITED			US-ALLERGAN-1912459US		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Movement Disorder	Lexapro			S	Unknown	20 Mg		Allergan
	Latuda			S	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843258	NON-EXPEDITED			US-ALLERGAN-1913522US		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Incorrect Dose Administered; Paraesthesia	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Unk		Allergan
	Trintellix			S	Unknown	20 Milligram		Not Reported
	Trintellix			S	Unknown	10 Milligram		Not Reported
	Trintellix			S	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843259	NON-EXPEDITED			US-ALLERGAN-1913471US		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Pruritus; Fatigue; Somnolence	Lexapro			S				Allergan

	Daytrana	S	Transdermal	Unk		Not Reported
	Tylenol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843264	NON-EXPEDITED			US-ALLERGAN-1914342US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan
	Nitrofurantoin Monohydrate Unk			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843266	NON-EXPEDITED			US-ALLERGAN-1914514US		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Depression; Hyperphagia; Weight Increased	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843412	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-060957		25 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Mental Impairment; Product Substitution Issue	Pantoprazole			S	Oral	40 Milligram, Daily		Aurobindo
	Toviaz			S	Oral	4 Milligram, Daily		Not Reported
	Aczone			C	Topical	Unk		Not Reported
	Azithromycin			C	Unknown	500 Milligram, Daily		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Daily		Not Reported
	Benzoyl Peroxide;Clindamycin Phosphate			C	Topical	Unk, Daily		Not Reported
	Budesonide			C	Nasal	55 Microgram, Two Times A Day		Not Reported
	Calcium			C	Oral	500 Milligram, 3 Times A		Not Reported

			Day	
Cipralex	S	Oral	Unk	Not Reported
Constella	C	Oral	290 Microgram, Daily	Not Reported
Fish Oil;Tocopherol	C	Oral	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Oral	2000 International Unit, Daily	Not Reported
Flovent Hfa	C	Oral	250 Microgram, Two Times A Day	Not Reported
Genteal	C	Ophthalmic	Unk	Not Reported
Otrivin	C	Nasal	Unk Unk, Two Times A Day	Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Daily	Not Reported
Polyvinyl Alcohol;Povidone	C	Ophthalmic	2 Gtt Drops, Cyclical	Not Reported
Quetiapine Fumarate	C	Oral	25 Milligram, Two Times A Day	Not Reported
Quetiapine Fumarate	C	Oral	100 Milligram, Daily	Not Reported
Valproate Sodium	C	Oral	250 Milligram, 3 Times A Day	Not Reported
Synthroid	C	Oral	150 Microgram, Daily	Not Reported
Toviaz	C	Unknown	Unk	Not Reported
Tylenol	C	Oral	Unk Unk, 3 Times A Day	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Zinc Gluconate	C	Unknown	50 Milligram, Daily	Not Reported
Zyloprim	C	Oral	100 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843662	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1111021			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Autoscopy; Seizure	Promethazine Hydrochloride		S	At Night.	Actavis
	Olanzapine		S		Teva
	Folic Acid		S		Actavis
	Azathioprine		S		Not Reported
	Escitalopram		S	Each Morning.	Ivax
	Dihydrocodeine		S	Four Times A Day. Take With Or Just After Food.	Not Reported
	Ferrous Fumarate		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843833	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-221714		14 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypotension; Malaise	Ibuprofen		Y	S	Oral	In Total		Ranbaxy
	Paracetamol			S	Oral	In Total		Ohm Lab
	Escitalopram			S	Oral	In Total		Not Reported
	Diane, Comprime Enrobe			S	Oral	In Total		Not Reported
	Cialis			S	Oral	In Total		Not Reported
	Diclofenac			S	Oral	In Total		Not Reported
	Colchicine			S	Oral	In Total		Not Reported
	Diazepam			S	Oral	In Total		Not Reported
	Donormyl [Doxylamine Succinate]			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16844268	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2019022998			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal; Visual Impairment	Escitalopram			S	Oral	20 Milligram		Macleods
	Sertraline			S	Oral	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16844421	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR171595			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Voltaren (Diclofenac Diethylammonium Salt)			S	Topical	Unk		Glaxosmithkline
	Diclofenac Potassium			S		50 Mg, Unk		Glaxosmithkline
	Escitalopram			S	Oral	20 Mg, Unk		Glaxosmithkline
	Cimzia			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Naproxen Sodium			S		1000 Mg, Unk		Not Reported
	Nortriptyline			S	Oral	25 Mg, Unk		Not Reported
	Tylenol			S	Topical	Unk		Not Reported
	Diclofenac			C		Unk		Not Reported
	Infliximab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16844613	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-ALEMBIC PHARMACUETICALS LIMITED-2019SCAL000665			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anuria; Atrial Fibrillation; Cardiac Arrest; Clonus; Coma Scale Abnormal; Depressed Level Of Consciousness; Drug Ineffective; Drug Interaction; Extensor Plantar Response; Eye Movement Disorder; Hyperkalaemia; Hyperreflexia; Hypertension;	Venlafaxine Hydrochloride			S		225 Milligram		Alembic
	Clonidine Hydrochloride			S	Intravenous (not otherwise specified)	150 Milligram		Alembic
	Clonidine Hydrochloride			S	Intravenous (not otherwise specified)	75 Milligram		Alembic
	Metoprolol Tartrate			S	Intravenous (not otherwise specified)	4 Milligram		Alembic
	Metoprolol Tartrate			S	Intravenous (not otherwise specified)	1 Mg		Alembic

Hypotension; Muscle Rigidity; Mydriasis; Myocardial Infarction; Nervous System Disorder; Renal Failure; Serotonin Syndrome; Tachypnoea; Ventricular Fibrillation; Ventricular Tachycardia	Metoprolol Tartrate	S	Intravenous (not otherwise specified)	2.5 Mg	Alembic
	Erythromycin	S		Unk	Not Reported
	Escitalopram	S		15 Milligram	Not Reported
	Escitalopram	S		Had Been Increased To Its Current Dose 3 Months Ago	Not Reported
	Insulin	C		Unk	Not Reported
	Calcium	C		Unk	Not Reported
	Sodium Bicarbonate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16844685	EXPEDITED (15-DAY)		HO	CN-ALLERGAN-1938580US			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Product Use In Unapproved Indication; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Oral	Overdose With 40mg Of Escitalopram		Allergan
	Paroxetine			S	Oral	80 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16846059	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1938542US			Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16846583	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1113005		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Duloxetine			S	Unknown			Teva
	Escitalopram			S	Unknown			Ivax

	Venlafaxine Hydrochloride	S	Unknown		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16846600	EXPEDITED (15-DAY)		DS	FR-009507513-1909FRA006068		77 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Subdural Haematoma	Inegy			S		Unk		Merck
	Nexium (Esomeprazole Magnesium)			S	Oral	1 Dosage Form, Qd		Not Reported
	Kardegic			S	Oral	1 Dosage Form, Qd		Not Reported
	Seroplex			S	Oral	1 Dosage Form, Qd		Not Reported
	Keppra			C		Unk		Not Reported
	Tenormine			C		Unk		Not Reported
	Tiapridal			C		Unk		Not Reported
	Coaprovel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16847189	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1000013800			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan
	Baklofen			C		10 Mg, Unk		Not Reported
	Brufen			C		600 Mg, Unk		Not Reported
	Alvedon			C		1000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16847208	EXPEDITED (15-DAY)		LT	JP-ALLERGAN-1929470US			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

Prolonged; Extrasystoles	Escitalopram Oxalate - Bp		S	Oral	10 Mg, Qd	Allergan
	Abilify		C	Oral		Not Reported
	Paxil Cr		C	Oral		Not Reported
	Thyradin		C	Oral	100 Mg, 100 Mg/ Day	Not Reported
	Solanax		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	15676892	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-980395		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Ramipril			S	Oral	2.5 Milligram Daily;		Actavis
	Lamotrigine			S	Oral	100 Milligram Daily; 100 Mg, Qd		Teva
	Exemestane			S	Oral	25 Milligram Daily; 25 Mg, Qd		Not Reported
	Gabapentine			S	Oral	200 Milligram Daily; 200 Mg, Qd		Actavis
	Lasilix 10 Mg/Ml, Solution Buvable			S	Oral	20 Milligram Daily; 10 Mg/Ml, Solution Buvable Lasilix 10 Mg/Ml, Solution Buvable, 20 Mg, Qd		Not Reported
	Aspirine Protect 100 Mg, Comprimé Gastro-Résistant			S	Oral	100 Milligram Daily;		Not Reported
	Bisoce 1,25 Mg, Comprimé Pelliculé			S	Oral	1.25 Milligram Daily; 1.25 Mg, Qd		Not Reported
	Seroplex 5 Mg, Comprimé Pelliculé			S	Oral	5 Milligram Daily; 5 Mg, Qd		Not Reported
	Fluidabak 1,5 %, Collyre En Solution			C	Ophthalmic	3 Gtt Daily; 3 Gtt Drops, Qd		Not Reported
	Transipeg 5,9 G, Poudre Pour Solution Buvable En Sachet			C	Oral	11.8 Gram Daily; 11.8 G, Qd		Not Reported
	Gluconate De Potassium			C	Oral	1 Df, Qd (1 Cs Per Day)		Not Reported
	Levothyroxine Sodique			C	Oral	30 Gtt Daily; 30 Gtt Drops,		Not Reported

Qd

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16548382	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1072415		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Balance Disorder; Bradycardia; Dizziness; Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder	Amlodipine Besilate			S	Unknown	2.5 Milligram Daily;		Teva
	Codeine			S	Unknown	60 Milligram Daily;		Not Reported
	Escitalopram			S	Unknown	10 Milligram Daily;		Ivax
	Escitalopram			S	Unknown			Ivax
	Furosemide			S	Unknown	40 Milligram Daily;		Not Reported
	Furosemide			S	Unknown	20 Milligram Daily;		Not Reported
	Metoprolol			S	Unknown	25 Milligram Daily;		Actavis
	Ramipril			S	Unknown	5 Milligram Daily;		Actavis
	Zopiclone			S	Unknown	2.5 Milligram Daily;		Not Reported
	Glyceryl Trinitrate			S	Transdermal	.8 Milligram Daily;		Not Reported
	Oxazepam			S	Unknown	20 Milligram Daily;		Not Reported
	Clopidogrel			C				Not Reported
	Acetaminophen			C				Not Reported
	Atorvastatin			C				Not Reported
	Ergocalciferol			C				Not Reported
	Pantoprazole			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Rabeprazole			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16665276	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20190744218		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Ibuprofen			S	Unknown			Not Reported
	Ibuprofen Hexal			S	Unknown			Not Reported

Pantozol /01263204/	S	Unknown	Unk		Not Reported
Amitriptylin	S	Unknown	Unk		Not Reported
Metoprolol Hexal	S	Unknown			Not Reported
Escitalopram Stada	S	Unknown			Not Reported
Escitalopram Hexal	S	Unknown			Not Reported
Metoprolol Mylan /00376902/	S	Unknown			Not Reported
Golimumab	S	Unknown			Not Reported
Escitalopram	S	Unknown			Not Reported
Metoprolol Stada	S	Unknown			Not Reported
Ibuhexal /00109201/	S	Unknown			Not Reported
Ibuprofen Stada	S	Unknown			Not Reported
Salbutamol Stada	S	Unknown			Not Reported
Escitalopram Mylan	S	Unknown			Not Reported
Prednisolon Stada	S	Unknown			Not Reported
Implanon	S	Unknown			Not Reported
Metoprolol /00376903/	S	Unknown	Unk		Not Reported
Prednisolon Jenapharm	S	Unknown			Not Reported
Prednisolon /00016201/	S	Unknown			Not Reported
Methotrexate Mylan	S	Unknown			Not Reported
Ibuprofen Hormosan	S	Unknown			Not Reported
Salbutamol	S	Unknown			Not Reported
Prednisolone	S	Unknown	25 Mg, Unk		Not Reported
Fluticasone;Vilanterol	S	Unknown	6 Months Before Diagnosis		Not Reported
Ellipta	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16705928	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1075230		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Escitalopram	S	Oral	1 Dosage Form, Qd	Not Reported
	Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
	Lasilix Special /00032601/	S	Oral	2 Dosage Form, Qd	Mylan
	Spironolactone	C	Oral	Unk	Mylan
	Bisoprolol /00802602/	C		Unk	Mylan
	Coumadine	C	Oral	2 Dosage Form, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16727272	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-054120		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Blood Creatine Phosphokinase Increased; Blood Potassium Increased; Blood Pressure Decreased; Bradycardia; Coma; Coma Scale Abnormal; Drug Interaction; Drug Screen Positive; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Heart Rate Decreased; Hyperkalaemia; Hypotension; Intentional Overdose; Loss Of Consciousness; Mechanical Ventilation; Opiates Positive; Overdose; Oxygen Saturation Decreased; Sinus Tachycardia; Suicide Attempt	Citalopram			S	Oral	Unk		Aurobindo
	Altace			S	Unknown	Unk		Not Reported
	Cipralex			S	Unknown	10.0 Milligram, Daily		Not Reported
	Cipralex			S	Oral	140.0 Milligram, Daily		Not Reported
	Cipralex			S	Unknown	10.0 Milligram		Not Reported
	Diazepam			S	Oral	Unk		Not Reported
	Diazepam			S	Oral	1800.0 Milligram		Not Reported
	Diazepam			S	Unknown	10.0 Milligram		Not Reported
	Lorazepam			S	Oral	30.0 Milligram		Not Reported
	Lorazepam			S	Oral	1.0 Milligram		Not Reported
	Morphine			S	Oral	30.0 Milligram, Daily		Not Reported
	Morphine			S	Unknown	100.0 Milligram		Not Reported
	Morphine			S	Unknown	2640.0 Milligram		Not Reported
	Morphine			S	Unknown	420.0 Milligram		Not Reported
	Morphine			S	Unknown	9500.0 Milligram		Not Reported
	Morphine			S	Oral	Unk		Not Reported
	Morphine			S	Unknown	15.0 Milligram		Not Reported
	Morphine			S	Oral	30 Milligram, Once A Day		Not Reported

	Oxycodone	S	Unknown	10.0 Milligram	Not Reported
	Oxycodone	S	Oral	Unk	Not Reported
	Oxycodone	S	Oral	20.0 Milligram	Not Reported
	Oxycodone	S	Unknown	Unk	Not Reported
	Oxycodone And Acetaminophen	S	Oral	Unk	Not Reported
	Zopiclone	S	Unknown	7.5 Milligram	Not Reported
	Zopiclone	S	Oral	187.5 Milligram	Not Reported
	Zopiclone	S	Oral	15.0 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16728083	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-054119		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Dislocation; Device Malfunction; Drug Ineffective	Amlodipine Tablets			S	Unknown	1.5 Dosage Form, Daily		Aurobindo
	Escitalopram Tablets			S	Topical	1 Dosage Form, Daily		Aurobindo
	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Rosuvastatin Tablet			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Apo-Escitalopram			S	Unknown	1 Dosage Form, Daily		Not Reported
	Apo-Escitalopram			S	Unknown	Unk		Not Reported
	Ciclopirox Olamine			S	Unknown	1 Dosage Form		Not Reported
	Emo Cort			S	Topical	1 Dosage Form, Daily		Not Reported
	Mylan Nitro Sl			S	Oral	Unk		Not Reported
	Synthroid			S	Unknown	1 Dosage Form, Daily		Not Reported
	Apo-Trazodone			S	Unknown	1 Dosage Form, Daily		Not Reported
	Brilinta			S	Unknown	1 Dosage Form, Two Times A Day		Not Reported
	Clonazepam			S	Unknown	1 Dosage Form, 3 Times A Day		Not Reported
	Delatestryl			S	Unknown	0.5 Milliliter,1 Every 2 Weeks		Not Reported

	Delatestryl	S	Unknown	1 Dosage Form, 1 Every 2 Week	Not Reported
	Dexilant	S	Unknown	1 Dosage Form, Daily	Not Reported
	Dexilant	S	Unknown	0.5 Milliliter, Once A Day	Not Reported
	Diltiazem	S	Unknown	1 Dosage Form, Daily	Not Reported
	Jamp Asa	S	Unknown	1 Dosage Form, Daily	Not Reported
	Metonia	S	Unknown	1 Dosage Form, 3 Times A Day	Not Reported
	Mylan Nitro Sl	S	Oral	Unk	Not Reported
	Mylan Nitro Sl	S	Oral	1 Dosage Form	Not Reported
	Nasonex	S	Nasal	Unk, Daily	Not Reported
	Nitro Dur	S	Unknown	1 Dosage Form, Daily	Not Reported
	Ratio-Zopiclone	S	Unknown	1 Dosage Form	Not Reported
	Apo Tamsulosin	S	Unknown	1 Dosage Form, Daily	Not Reported
	Tevabisoprol	S	Unknown	1 Dosage Form, Daily	Not Reported
	Bisoprolol Teva	S	Unknown	1 Dosage Form, Once A Day	Not Reported
	Nasonex	S	Nasal	Unk, Once A Day	Not Reported
	Trazodone	S	Unknown	1 Dosage Form, Once A Day	Not Reported
	Triatec [Caffeine Citrate/Codeine Phosphate/Paracetamol]	S	Unknown	1 Dosage Form, Four Times/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16808805	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190905053			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Tylenol			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Cimzia			S	Unknown	Dosage Form:Solution Subcutaneous		Not Reported

	Diclofenac Potassium	S	Unknown	Not Reported
	Escitalopram	S	Oral	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Nortriptyline	S	Oral	Not Reported
	Voltaren	S	Topical	Not Reported
	Infliximab, Recombinant	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16825446	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2019-US-012826			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Chest Pain; Swelling; Weight Decreased	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Unkown Dose		Jazz
	Lexapro			S		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Carafate			C		Unk		Not Reported
	Isosorbide Mononite			C		Unk		Not Reported
	Meclizine Hcl			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Keflex-C			C		Unk		Not Reported
	Valtrex			C		Unk		Not Reported
	Diphenhydramine Hydrochloride			C		Unk		Not Reported
	Breo Ellipta			C		Unk		Not Reported
	Mucinex			C		Unk		Not Reported
	Benzonatate			C		Unk		Not Reported

Prednisone	C	Unk	Not Reported
Ativan	C	Unk	Not Reported
Gabapentin	C	Unk	Not Reported
Levothyroxine	C	Unk	Not Reported
Hydrocodone/Acetaminophen	C	Unk	Not Reported
Lorazepam	C	Unk	Not Reported
Cyclobenzaprine	C	Unk	Not Reported
Benztropine Mesilate	C	Unk	Not Reported
Lisinopril	C	Unk	Not Reported
Nystatin	C	Unk	Not Reported
Pantoprazole Sodium	C	Unk	Not Reported
Robaxin	C	Unk	Not Reported
Abilify	C	Unk	Not Reported
Advair	C	Unk	Not Reported
Allegra Allergy	C	Unk	Not Reported
Amerge	C	Unk	Not Reported
Anaprox	C		Not Reported
Bentyl	C	Unk	Not Reported
Depakote	C		Not Reported
Dexamethasone	C	Unk	Not Reported
Cyclobenzaprine Hydrochloride	C	Unk	Not Reported
Flonase Allergy Relief	C	Unk	Not Reported
Modafinil	C	Unk	Not Reported
Seroquel	C	Unk	Not Reported
Ventolin Hfa	C	Unk	Not Reported
Proair Hfa	C	Unk	Not Reported
Neurontin	C	Unk	Not Reported
Ondansetron	C	Unk	Not Reported
Calcium + Magnesium	C	Unk	Not Reported
Fibercon	C	Unk	Not Reported

Imodium	C	Unk	Not Reported
Klonopin	C	Unk	Not Reported
Loperamide Hydrochloride	C	Unk	Not Reported
Lunesta	C	Unk	Not Reported
Medrol Dosepak	C	Unk	Not Reported
Meloxicam	C	Unk	Not Reported
Methocarbamol	C	Unk	Not Reported
Singulair	C	Unk	Not Reported
Welchol	C	Unk	Not Reported
Albuterol Sulfate	C	Unk	Not Reported
Astepro	C		Not Reported
Coreg	C	Unk	Not Reported
Dicyclomine-S	C	Unk	Not Reported
Epipen	C		Not Reported
Ibuprofen	C		Not Reported
Ipratropium/Albuterol	C		Not Reported
Isosorbide	C	Unk	Not Reported
Methylergonovine Maleate	C	Unk	Not Reported
Naproxen	C	Unk	Not Reported
Nitroglycerin	C		Not Reported
Pristiq	C	Unk	Not Reported
Zantac	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16835822	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1938343US			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Melaena	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Marcoumar			S	Unknown	Dosage Adapted To Inr		Not Reported
	Calcimagon			C	Oral	Unk, Qd		Not Reported
	Cansartan			C	Oral			Not Reported

Ciproxin	C	Oral	500 Mg, Qod		Not Reported
Cordarone	C	Oral	200 Mg, Qd		Not Reported
Deanxit Dragees	C	Oral			Not Reported
Euthyrox	C	Oral	50 Mg, Qd		Not Reported
Inderal	C	Oral			Not Reported
Luvit D3	C	Oral	7 Gtt, Bi-Weekly		Not Reported
Palexia	C	Oral	200 Mg, Qod		Not Reported
Rosuvastax	C	Oral	10 Mg, Qd		Not Reported
Torem	C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16848305	EXPEDITED (15-DAY)		DE, HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-221618		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Omeprazole			S	Oral	20 Mg, Qd		Astrazeneca
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Alendronic Acid			S	Oral	70 Mg, Qwk		Sun
	Allopurinol			S	Oral	100 Mg, Qd		Sun
	Lisinopril			S	Oral	5 Mg, Qd		Not Reported
	Furosemida			S	Oral	60 Mg, Qd		Not Reported
	Hierro Sulfato (Ferrous Sulfate)			S	Oral	256.3 Mg, Qd		Not Reported
	Bisoprolol			S	Oral	5 Mg, Bid		Not Reported
	Ipratropio Bromuro			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Not Reported
	Sintrom 1 Mg Comprimidos , 60 Comprimidos			S	Oral	1 Mg, Qd		Not Reported
	Espironolactona			S	Oral	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16848497	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1113241		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Flushing; Headache; Hyperhidrosis; Nausea; Nervousness; Pain; Serotonin Syndrome; Tremor	Escitalopram Oxalate			S	Oral	20 Milligram Daily;		Ivax
	Venlafaxine Hydrochloride			S	Oral	150 Milligram Daily;		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16848509	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-062428		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Citalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Cipralex			S	Oral	Unk		Not Reported
	Clonazepam			C	Oral	0.5 Milligram		Not Reported
	Flomax			C	Unknown	0.4 Milligram		Not Reported
	Rosuvastatin Calcium			C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16849074	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2018SP009309		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Amnesia; Aphasia; Breast Tenderness; Chills; Diarrhoea; Drug Withdrawal Syndrome; Feeling Abnormal; Gynaecomastia; Headache; Hyperhidrosis; Piloerection; Pyrexia;	Buspirone Hydrochloride			S	Unknown	7.5 Mg, Bid		Strides
	Buspirone Hydrochloride			S	Unknown	15 Mg, Tid		Strides
	Buspirone Hydrochloride			S	Unknown	7.5 Mg, Tid		Strides
	Buspirone Hydrochloride			S	Unknown	15 Mg, Tid		Strides
	Buspirone Hydrochloride			S	Unknown	15 Mg, Bid		Strides
	Buspirone Hydrochloride			S	Unknown	7.5 Mg, Tid		Strides

Restlessness; Toothache	Buspirone Hydrochloride	S	Unknown	22.5mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	20 Mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	17.5mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	15 Mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	15 Mg, Bid	Strides
	Buspirone Hydrochloride	S	Unknown	15 Mg, Qd	Strides
	Buspirone Hydrochloride	S	Unknown	10 Mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	7.5 Mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	5 Mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	2.5 Mg Per Day	Strides
	Escitalopram	S	Unknown	5 Mg, Every Morning	Not Reported
	Escitalopram	S	Unknown	20 Mg, Qd	Not Reported
	Escitalopram	S	Unknown	10mg Every Morning	Not Reported
	Escitalopram	S	Unknown	Increased 15 Mg, Every Morning	Not Reported
	Escitalopram	S	Unknown	2.5 Mg/Week	Not Reported
	Lorazepam	S	Unknown	0.5 Mg, Bid, As Necessary	Not Reported
	Lorazepam	S	Unknown	Increased To 0.5-1 Mg Three Times A Day As Necessary	Not Reported
	Bupropion	S	Unknown	150 Mg, Every Morning	Not Reported
	Bupropion	S	Unknown	200 Mg, Every Morning	Not Reported
	Bupropion	S	Unknown	300 Mg, Every Morning	Not Reported
	Bupropion	S	Unknown	30 Mg, Every Morning	Not Reported
	Bupropion	S	Unknown	300 Mg, Every Morning	Not Reported
	Testosterone	S	Unknown	50 Mg/5g, Every Morning	Not Reported
	Amfetamine W/Dexamfetamine	S	Unknown	10 Mg, Every Morning	Not Reported
	Amfetamine W/Dexamfetamine	S	Unknown	20 Mg, Every Morning	Not Reported
	Amfetamine W/Dexamfetamine	S	Unknown	20 Mg, Every Morning	Not Reported
	Lamotrigine	S	Unknown	Unk	Not Reported

	Lamotrigine	S	Unknown	150 Mg, At Bed Time	Not Reported
	Benztropine Mesylate	C	Unknown	0.5 Mg, Bid, Prn	Not Reported
	Aripiprazole	C	Unknown	2 Mg, At Bed Time	Not Reported
	Aripiprazole	C	Unknown	4 Mg, At Bed Time	Not Reported
	Lithium	C	Unknown	600 Mg, At Bed Time	Not Reported
	Lurasidone	C	Unknown	40 Mg, At Night	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16849329	EXPEDITED (15-DAY)		HO, LT	IL-SCIEGEN PHARMACEUTICALS INC-2019SCILIT00267			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Infection; Intentional Overdose; Suicide Attempt; Thrombocytopenia; Toxicity To Various Agents; Unresponsive To Stimuli	Quetiapine			S				Not Reported
	Flecainide			S				Not Reported
	Venlafaxine			S				Not Reported
	Escitalopram			S				Not Reported
	Bisoprolol			S				Not Reported
	Clonazepam			S				Not Reported
	Glucagon			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16849413	EXPEDITED (15-DAY)		HO	NL-ACCORD-155748			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Dyspnoea; Gait Disturbance; Heart Rate Decreased; Somnolence; Weight Increased	Escitalopram			S		1x Per Day 1 Tablet, Srtrength: 15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16849467	EXPEDITED (15-DAY)		HO, OT	DE-HETERO-HET2019DE01318		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Escitalopram		S	Unknown	Unk	Hetero
	Quetiapin		S	Oral	Unk	Not Reported
	Bisoprolol		S	Unknown	1.25 Mg	Not Reported
	Chlormadinone W/Ethinylestradiol Trigoa		S	Unknown	Unk	Not Reported
			C	Oral	Unk (6x Lng 50?G/Ee 30?G; 5x Lng 75?G/Ee 40?G; 10x Lng 125?G/Ee 30?G)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16849488	EXPEDITED (15-DAY)		OT	GB-LUPIN PHARMACEUTICALS INC.-2019-06036		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal; Visual Impairment	Sertraline			S	Oral			Lupin
	Escitalopram			S	Oral	20 Milligram		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16851517	EXPEDITED (15-DAY)		OT	KR-PFIZER INC-2019409668			Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Xanax			S	Oral			Pfizer
	Lexapro			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16852932	EXPEDITED (15-DAY)		OT	GR-ALLERGAN-1938592US			Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Dyskinesia; Dysuria; Ecchymosis; Female Orgasmic Disorder; Nervousness;	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Escitalopram Oxalate - Bp			S				Allergan

Restlessness; Tremor;
Weight

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16299002	EXPEDITED (15-DAY)		HO, OT	DE-ASTRAZENECA-2019SE67983		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Zeneca
	Escitalopram			S	Oral	Unk		Not Reported
	Bisoprolol			S	Oral	1.25mg Unknown		Not Reported
	Chlormadinone/Ethinylestradiol			S	Unknown			Not Reported
	Trigoa			C	Oral	Unk (6x Lng 50?G/Ee 30?G; 5x Lng 75?G/Ee 40?G; 10x Lng 125?G/Ee 30?G)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16699147	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2014BE152355		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Arrhythmia; Blood Pressure Decreased; Drug Interaction; Drug Intolerance; Hypokalaemia; Labelled Drug-Drug Interaction Medication Error; Long Qt Syndrome; Loss Of Consciousness; Metabolic Disorder; Off Label Use; Pallor; Torsade De Pointes; Vomiting	Bisoprolol			S	Unknown			Novartis
	Escitalopram			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Omeprazole			S	Unknown	Gastroresistant Coated Tablet		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16792009	EXPEDITED (15-DAY)		OT	NZ-MYLANLABS-2019M1084180		75 YR	Male	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Condition Aggravated; Diarrhoea Haemorrhagic	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16827844	NON-EXPEDITED			US-PFIZER INC-2016458580		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ciprofloxacin Hcl			S		Unk		Unknown
	Sulfadiazine Silver			S		Unk		Pfizer
	Penicillin G Sodium			S		Unk		Not Reported
	Ceclor			S		Unk		Not Reported
	Cefaclor			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported
	Relafen			S		Unk		Not Reported
	Ciprocinonide			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16839183	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2019M1087852		57 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram			S	Oral	14 Cp De 20 Mg + 27 Cp De 10 Mg		Not Reported
	Lorazepam			S	Oral	72 Cp De 2.5 Mg		Mylan
	Bupropion			C		Unk		Mylan

	Acetylsalicylic Acid	C	Unk	Mylan
	Diazepam	C	Unk	Mylan
	Venlafaxine	C	Unk	Mylan
	Olanzapine	C	Unk	Mylan
	Topiramate	C	Unk	Mylan
	Hydroxycarbamide	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16844567	EXPEDITED (15-DAY)		OT	FI-PFIZER INC-2019402441		34 YR	Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Behaviour Disorder; Drug Ineffective For Unapproved Indication; Intentional Self-Injury; Off Label Use	Lorazepam			S	Unknown	3 Mg, 1x/Day		Pfizer
	Pantoprazole			S	Unknown	20 Mg, 1x/Day		Pfizer
	Levomepromazine			S	Unknown	100 Mg, 1x/Day		Not Reported
	Melatonin			S	Unknown	3 Mg, 1x/Day		Not Reported
	Risperidone			S	Unknown	4 Mg, 1x/Day		Not Reported
	Risperidone			S	Unknown	3 Mg, 1x/Day		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Oxcarbazepine			S	Unknown	900 Mg, 1x/Day		Not Reported
	Carbamazepine			S	Unknown	Unk		Not Reported
	Carbamazepine			S				Not Reported
	Escitalopram			S	Unknown	10 Mg, 1x/Day		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Bisoprolol			S				Not Reported
	Macrogol			S	Unknown	3350 With Dosage 3 Bags / Day		Not Reported
	Olanzapine			S	Unknown	10 Mg, 1x/Day		Not Reported
	Valproate			S	Unknown	1200 Mg, 1x/Day		Not Reported
	Valproate			S				Not Reported
	Valproate			S				Not Reported

Valproate	S				Not Reported
Quetiapine	S	Unknown	Unk		Not Reported
Metoprolol	S	Unknown	Unk		Not Reported
Metoprolol	S				Not Reported
Metoprolol	S				Not Reported
Topiramate	S	Unknown	Unk		Not Reported
Candesartan	S	Oral	16 Mg, 1x/Day		Not Reported
Candesartan	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16853692	EXPEDITED (15-DAY)		HO, OT	DE-DRREDDYS-GER/GER/19/0114396		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Escitalopram			S	Unknown	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Bisoprolol			S	Unknown	1.25 Mg, Unk		Not Reported
	Chlormadinone/Ethinylestradiol			S		Unk		Not Reported
	Trigoa			C	Oral	Unk (6x Lng 50mcg/Ee 3050mcg; 5x Lng 75mcg/Ee 40mcg; 10x Lng 125mcg/Ee 30mcg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16853734	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-062032		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal; Visual Impairment	Sertraline			S	Oral	50 Milligram		Aurobindo
	Escitalopram			S	Oral	20 Milligram		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16854333	EXPEDITED (15-DAY)		OT	GB-EMCURE PHARMACEUTICALS LTD-2019-EPL-0849		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal; Visual Impairment	Sertraline Hydrochloride			S	Oral	50 Milligram, Received Up To 25-Aug-2019		Heritage
	Escitalopram			S	Oral	20 Milligram, Received Up To 01-Jan-2012		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16854892	EXPEDITED (15-DAY)		HO, OT	DE-LUPIN PHARMACEUTICALS INC.-2019-06145		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine Fumarate			S	Oral	Unk		Lupin
	Escitalopram			S	Unknown	Unk		Lupin
	Bisoprolol			S	Unknown	1.25 Milligram		Not Reported
	Chlormadinone;Ethinylestradiol			S	Unknown	Unk		Not Reported
	Trigoa			C	Oral	Unk (6x Lng 50?G/Ee 30?G; 5x Lng 75?G/Ee 40?G; 10x Lng 125?G/Ee 30?G)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16855701	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-PFIZER INC-2019401857		73 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Myeloma Cast Nephropathy; Myocardial Infarction; Renal Failure; Serotonin Syndrome; Ventricular Fibrillation	Venlafaxine Hcl			S		225 Mg, Unk		Pfizer
	Erythromycin			S		Unk		Not Reported
	Escitalopram			S		Increased To Its Current Dose 3 Months Ago		Not Reported
	Escitalopram			S		15 Mg, Unk		Not Reported
	Acetylsalicylic Acid			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16855915	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-MACLEODS PHARMACEUTICALS US LTD-MAC2019023027			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Myeloma Cast Nephropathy; Myocardial Infarction; Renal Failure; Serotonin Syndrome; Ventricular Fibrillation	Escitalopram			S	Unknown	Unk, Increased To Its Current Dose 3 Months Ago		Macleods
	Escitalopram			S	Unknown	15 Milligram		Macleods
	Venlafaxine			S	Unknown	225 Milligram		Macleods
	Erythromycin			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	1240 Milligram, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16856099	EXPEDITED (15-DAY)		LT, OT	FR-MYLANLABS-2019M1090132		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Suicide Attempt	Bromazepam			S	Oral	180 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	120 Milligram, Total		Not Reported
	Seresta			S	Oral	48 Dosage Form, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16856119	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1089067		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Loss Of Consciousness; Malaise	Zolpidem			S	Oral			Not Reported
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported

	Bisoprolol	S	Oral	10 Milligram, Qd	Not Reported
	Fentanyl	S	Transdermal	1 Dosage Form, Tid	Not Reported
	Lyrica	S	Oral	1 Dosage Form, Qd	Mylan
	Lasilix /00032601/	S	Oral	1 Dosage Form, Qd	Mylan
	Oxynormoro	S	Oral	3 Dosage Form, Qd	Mylan
	Ebixa	S	Oral	1 Dosage Form, Qd	Mylan
	Esomeprazole	C			Mylan
	Diffu K	C			Mylan
	Transipeg /00754501/	C			Mylan
	Gaviscon /00902401/	C			Mylan
	Okimus	C			Mylan
	Eliquis	C			Mylan
	Melaxose	C			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16856550	EXPEDITED (15-DAY)		DE, HO	ES-009507513-1909ESP006179		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Lisinopril			S	Oral	5 Mg, Qd		Merck
	Alendronate Sodium			S	Oral	70 Mg, Qwk		Merck
	Omeprazole			S	Oral	20 Mg, Qd		Not Reported
	Furosemide			S	Oral	60 Mg, Qd		Not Reported
	Iron (Unspecified)			S	Oral	256.3 Mg, Qd		Not Reported
	Bisoprolol			S	Oral	5 Milligram, Qd (5 Mg, Bid)		Not Reported
	Ipratropium Bromide			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Sintrom			S	Oral	1 Mg, Qd (60 Tablets)		Not Reported
	Spironolactone			S	Oral	50 Mg, Qd		Not Reported
	Allopurinol			S	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16856760	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2019M1089105		83 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Torasemide			S	Oral	5 Milligram, Qd		Not Reported
	Torasemide			S	Oral	10 Milligram. Dia		Not Reported
	Escitalopram 10 Mg Film-Coated Tablets			S	Oral	10 Milligram, Qd		Mylan
	Aldactone /00006201/			S	Oral	1-0-0		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16858959	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-ALLERGAN-1938985US			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Myeloma Cast Nephropathy; Myocardial Infarction; Renal Failure; Serotonin Syndrome; Ventricular Fibrillation	Escitalopram Oxalate Unk			S	Unknown	15 Mg, Increased To Its Current Dose 3 Months Ago		Allergan
	Escitalopram Oxalate Unk			S	Unknown	15 Mg		Allergan
	Venlafaxine			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	15560099	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-966996		92 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Dyspnoea; Fatigue; Interstitial Lung Disease	Duloxetine Hydrochloride			S	Unknown			Teva
	Duloxetine Hydrochloride			S	Unknown			Teva
	Duloxetine Hydrochloride			S				Teva
	Escitalopram			S	Unknown			Ivax

Escitalopram	S				Ivax
Escitalopram	S				Ivax
Venlafaxine Hydrrochloride	S	Unknown			Teva
Venlafaxine Hydrrochloride	S				Teva
Venlafaxine Xr	S	Unknown	37.5 Milligram Daily;		Teva
Teva-Duloxetine Dr	S	Unknown			Teva
Venlafaxine	S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	15626480	EXPEDITED (15-DAY)		DE, HO, LT	CA-TEVA-2018-CA-976256		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage	Diclofenac			S	Oral	100 Milligram Daily;		Actavis
	Ibuprofen			S	Oral			Actavis
	Ibuprofen			S	Oral			Actavis
	Diclofenac Potassium			S	Oral	100 Milligram Daily;		Actavis
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Cipralex			S	Oral	10 Milligram Daily;		Not Reported
	Eliquis Film-Coated			C				Not Reported
	Pantoprazole Enteric-Coated Tablet			C	Unknown			Not Reported
	Eliquis			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	15814346	EXPEDITED (15-DAY)		DE, OT	DK-009507513-2011SP051883		72 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Hypertrophy; Confusional State; Constipation; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension;	Mirtazapine			S	Oral	30 Mg, Qd		Merck
	Mirtazapine			S		Unk		Merck
	Litarex (Lithium Citrate)			S	Oral	1 Df (In The Morning)		Not Reported
	Litarex (Lithium Citrate)			S	Oral	1.5 Dosage Form, Qpm		Not Reported

Hyperventilation; Lactic Acidosis; Lacunar Infarction; Neuroleptic Malignant Syndrome; Organ Failure; Pyrexia; Renal Failure; Rhabdomyolysis; Urinary Tract Infection	Zeldox	S	Oral	80 Mg, Qd	Not Reported
	Cipralex	S	Oral	30 Mg, Qd (Daily Dose Of 1 Tablet In The Morning And 1.5 Tablet In The Evening)	Not Reported
	Alprazolam	C		0.5 Mg, Daily	Not Reported
	Centyl Med Kaliumklorid	C	Unknown	1 Dosage Form, Qd	Not Reported
	Ferro Duretter	C	Unknown	100 Mg Qd	Not Reported
	Amlodipin Actavis (Amlodipine Maleate)	C			Not Reported
	Fragmin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16274304	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2019-024199		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Aurobindo
	Bisoprolol			S	Unknown	1.25 Milligram		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Chlormadinone;Ethinylestradiol			S	Unknown	Unk		Not Reported
	Trigoa			S	Unknown	6x Lng 50µg/Ee 30µg; 5x Lng 75µg/Ee 40µg; 10x Lng 125µg/Ee 30µg		Not Reported
	Trigoa			S	Unknown	5x		Not Reported
	Trigoa			S	Unknown	6x		Not Reported
	Trigoa			S	Unknown	10x		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16338115	NON-EXPEDITED			US-PFIZER INC-2019212920		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Venlafaxine Hcl			S		Unk		Pfizer

	Glipizide	S	Unk	Pfizer
	Duloxetine	S	Unk	Not Reported
	Escitalopram	S	Unk	Not Reported
	Carbamazepine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16859727	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2019-DE-1112535		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Escitalopram			S	Unknown	Unk		Ivax
	Quetiapine			S	Oral	Unk		Teva
	Zebeta			S	Unknown	1.25 Mg, Unk		Duramed
	Chlormadinone/Ethinylestradiol			S		Unk		Not Reported
	Trigoa			C	Oral	Unk (6x Lng 50ug/Ee 30ug; 5x Lng 75ug/Ee 40ug; 10x Lng 125ug/Ee 30ug)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16860441	EXPEDITED (15-DAY)		HO	NO-ALLERGAN-1938926US			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysarthria; Fatigue; Malaise; Visual Impairment	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan
	Elvanse			S	Oral	Dosage 60 + 40 Mg, Not Further Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16860445	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1938963US			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Cavity Infection; Failed Induction Of	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan

Labour; Gestational Diabetes; Pregnancy	Gilenya		S	Unknown	Unk, Unknown	Not Reported
	Brintellix		C	Unknown	1 Df, Qd	Not Reported
	Edronax		C	Unknown		Not Reported
	Albetol		C	Unknown	1 Df, (1 To 2)	Not Reported
	Losatrix Comp		C	Unknown		Not Reported
	Vitamin D		C	Unknown	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16860683	EXPEDITED (15-DAY)		OT	PHHY2019CA223971			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Voltaren			S	Topical	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Novartis
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	1000 Mg, Unk		Not Reported
	Nortriptyline			S	Oral	25 Mg, Unk		Not Reported
	Tylenol			S	Topical	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16860854	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-TEVA-2019-CA-1113862		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved	Diclofenac Sodium			S	Oral	100 Milligram Daily;		Actavis
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Ibuprofen			S	Oral			Actavis

Indication	Eliquis	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16860915	NON-EXPEDITED			US-PFIZER INC-2019415274			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Dyspnoea	Clindamycin			S		Unk		Pfizer
	Bentyl			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16861692	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-222109		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal; Visual Impairment	Sertraline			S	Oral	50 Milligram, Unk		Sun
	Escitalopram			S	Oral	20 Milligram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16861896	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-06119		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Electrolytes Decreased; Blood Pressure Decreased; Dizziness; Feeling Abnormal; Gait Disturbance; Loss Of Consciousness; Vertigo	Escitalopram Oxalate			S	Oral	Unk Unk, Qd		Lupin
	Lisinopril Tablets			S	Oral	Unk Unk, Qd		Lupin
	Lisinopril Tablets			S	Oral	1 Dosage Form, Qd		Lupin
	Metoprolol			S	Oral	Unk Unk, Qd		Not Reported
	Metoprolol			S	Oral	1 Dosage Form, Qd		Not Reported
	Metformin			C	Oral	Unk		Not Reported

Jardiance	C	Oral	Unk		Not Reported
Trajenta	C	Oral	Unk		Not Reported
Atorvastatin	C	Oral	Unk		Not Reported
Fenofibrate	C	Oral	Unk		Not Reported
Tenoretic	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16862287	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT-00015581		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Trigoa			C	Oral	Unk (6x Lng 50g/Ee 30g; 5x Lng 75g/Ee 40g; 10x Lng 125g/Ee 30g)		Unknown
	Bisoprolol			S	Unknown	1.25 Mg, Unk		Unknown
	Quetiapine			S	Oral	Unknown		Unknown
	Chlormadinone And Ethinylestradiol			S		Unknown		Unknown
	Escitalopram			S	Unknown	Unk		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16862368	EXPEDITED (15-DAY)		OT	MY-AUROBINDO-AUR-APL-2019-061083		71 YR	Male	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypersensitivity	Risperidone			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16862630	EXPEDITED (15-DAY)		HO	CN-ALLERGAN-1939225US			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Estazolam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16862878	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019023039			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Macleods
	Escitalopram			S	Unknown	Unk		Macleods
	Bisoprolol			S	Unknown	1.25 Milligram		Not Reported
	Chlormadinone/Ethinylestradiol			S	Unknown	Unk		Not Reported
	Trigoa			C	Oral	Unk, 6x Lng 50?G/Ee 30?G; 5x Lng 75?G/Ee 40?G; 10x Lng 125?G/Ee 30?G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16863101	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT-00015600		47 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticholinergic Syndrome; Blood Creatine Phosphokinase Increased; Blood Pressure Increased; Dehydration; Drug Interaction; Hyperthermia; Hypokinesia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tachycardia; Tachypnoea; Transaminases Increased	Ramipril			C	Oral	1-0-0		Unknown
	Aripiprazol			S	Oral	1-0-0		Stada
	Bisoprolol			C	Oral	1-0-0		Unknown
	Escitalopram			S	Oral			Unknown
	Diazepam			C	Oral	1-1-1		Ratiopharm
	Chlorprothixen			S	Oral	30-30-30-100		Neuraxpharm
	Haloperidol			S	Oral	1-0-1		Ratiopharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16863769	EXPEDITED (15-DAY)		DE	SE-BAUSCH-BL-2019-054459		73 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Feeling Abnormal; Serotonin Syndrome; Therapy Non-Responder	Venlafaxine			S	Unknown	Along With Mianserin		Not Reported
	Venlafaxine			S	Unknown	With Escitalopram, (Totally Given For Over A Period Of 9 Months).		Not Reported
	Erythromycin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown	Dose Increased To 15 Mg (Totally Given For Over A Period Of 9 Months).		Not Reported
	Mianserin			S	Unknown			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Furosemide			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16863911	EXPEDITED (15-DAY)		HO	NO-SHIRE-NO201931274			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Fatigue; Malaise; Visual Impairment	Elvanse			S	Oral	100 Milligram (Dosage 60 + 40 Mg)		Shire
	Cipralex [Escitalopram]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16864038	EXPEDITED (15-DAY)		DS, LT	IN-ALLERGAN-1939152US			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Escitalopram Oxalate Unk			S		Unk		Allergan

	Ciprofloxacin			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2019	16864499	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-156024		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Constipation; Depression; Hypothyroidism; Suicidal Ideation; Temperature Intolerance	Escitalopram			S		10 Mg Per Day, 10 Days Earlier		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2019	16864501	EXPEDITED (15-DAY)		HO, OT	DE-ACCORD-155747		47 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticholinergic Syndrome; Blood Creatine Phosphokinase Increased; Blood Pressure Increased; Dehydration; Drug Interaction; Hyperthermia; Hypokinesia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tachycardia; Tachypnoea; Transaminases Increased	Escitalopram			S	Oral	Long-Term Use		Not Reported
	Aripiprazole Stada			S	Oral	Recording Medication - 26.08.2019; 1-0-0		Not Reported
	Chlorprothixen Neuraxpharm (Chlorprothixene Hydrochloride)			S	Oral	30-30-30-100		Not Reported
	Haloperidol Ratiopharm 5 Mg/Ml Solução Injectável			S	Oral	1-0-1		Not Reported
	Ramipril			C	Oral	1-0-0; Intake Medication, Not Paused;		Not Reported
	Bisoprolol			C	Oral	1-0-0; Intake Medication, Not Paused		Not Reported
	Diazepam			C	Oral	1-1-1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2019	16864522	EXPEDITED (15-DAY)		OT	ES-ACCORD-155956		36 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Generalised Tonic-Clonic Seizure	Trazodone Accord	S	Oral	100 Mg Efg Tablets, 30 Tablets (Blister Pvc / Al)	Not Reported
	Escitalopram Sandoz	S	Oral	10 Mg Orodispersible Tablets Efg, 56 Tablets	Not Reported
	Naltrexone Accord	C	Oral	50 Mg Film-Coated Tablets Efg, 28 Tablets	Not Reported
	Bromazepam Pens	C	Oral	3 Mg Efg Capsules, 30 Capsules	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2019	16254208	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2019CA095349		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Blindness Cortical; Cardiogenic Shock; Cerebral Infarction; Circulatory Collapse; Colour Blindness; Condition Aggravated; Csf Pressure Increased; Cytotoxic Oedema; Depressed Level Of Consciousness; Electrocardiogram P Wave Abnormal; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Amplitude Decreased; Electrocardiogram T Wave Inversion; Electrocardiogram U Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia;	Potassium Chloride			S	Oral	Unk		Novartis
	Amlodipine			S	Oral	150 Mg, Qd		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Escitalopram			S	Unknown	60 Mg, Qd		Not Reported
	Norepinephrine Bitartrate Inj Usp			S	Intravenous (not otherwise specified)	30 Ug, Unk		Not Reported
	Risperidone			S	Oral	6 Mg, Qd		Not Reported
	Vasopressin			S	Unknown	Unk		Not Reported
	Potassium Chloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Escitalopram Mylan			S	Oral	Unk		Not Reported
	Epinephrine			S	Unknown	30 Ug, Unk		Not Reported
	Dextrose			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Glucose			S	Unknown	Unk		Not Reported
	Glucagon			C	Unknown	Unk		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	30 Ug, Unk		Not Reported

Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema; Renal Tubular Necrosis; Retinal Ischaemia; Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment	Calcium Gluconate		C	Unknown	Unk	Not Reported
	Activated Charcoal		C	Unknown	Unk	Not Reported
	Dextrose		C	Unknown		Not Reported
	Amlodipine		C	Oral	Unk	Not Reported
	Risperidone		C	Unknown	Unk	Not Reported
	Vasopressin		C	Unknown	Unk	Not Reported
	Potassium Chloride		C	Unknown	Unk	Not Reported
	Epinephrine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2019	16328082	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027588			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Agitation; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Feeling Abnormal; Feeling Jittery; Gastrointestinal Disorder; Lethargy; Mental Impairment; Nervousness; Product Use Issue; Restlessness; Sexual Dysfunction; Wrong Technique In Product Usage Process	Escitalopram Tablets			S	Sublingual	7.5 Milligram		Aurobindo
	Escitalopram Tablets			S	Unknown	7.5 Milligram		Aurobindo
	Escitalopram Tablets			S	Unknown	10 Milligram		Aurobindo
	Escitalopram Tablets			S	Unknown	5 Milligram		Aurobindo
	Citalopram			S	Unknown	Unk		Aurobindo
	Trintellix			S	Unknown	10 Milligram, Once A Day		Not Reported
	Trintellix			S	Unknown	5 Milligram, Once A Day		Not Reported
	Trintellix			S				Not Reported
	Cipralex			S	Oral	2.5 Milligram, Once A Day		Not Reported
	Cipralex			S	Oral	5.0 Milligram, Once A Day		Not Reported
	Cipralex			S	Oral	7.5 Milligram		Not Reported
	Cipralex			S	Oral	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2019	16328115	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-027420		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Heart Rate Increased; Irritability; Miosis; Overdose; Oxygen Saturation Decreased; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram Tablets			S	Oral	Unk		Aurobindo
	Citalopram Tablets			S	Oral	Unk		Aurobindo
	Quetiapine Film-Coated Tablet			S	Oral	Unk		Aurobindo
	Quetiapine Film-Coated Tablet			S	Unknown	Unk		Aurobindo
	Citalopram			S	Unknown	Unk		Aurobindo
	Topiramate			S	Oral	Unk		Aurobindo
	Oxazepam			S	Oral	Unk		Not Reported
	Temazepam			S	Oral	Unk		Not Reported
	Naloxone			S	Intramuscular	Unk		Not Reported
	Naloxone			S	Intramuscular	Unk		Not Reported
	Temazepam			S	Oral	Unk		Not Reported
	Quetiapine Mylan			S	Oral	Unk		Not Reported
	Atorvastatin Calcium			C	Unknown	Unk		Not Reported
	Clopidogrel			C	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Fluticasone			C	Unknown	Unk		Not Reported
	Ipratropium			C	Unknown	Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Spironolactone			C	Unknown	Unk		Not Reported
	Advair			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Fluticasone;Salmeterol			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	14937784	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2018-04001		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression	Escitalopram			S	Unknown	Unk		Lupin
	Heparin			S	Subcutaneous	5000 Iu, Bid		Not Reported
	Lidocaine			C	Unknown	3 Ml, Unk (A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 Mcg/Ml)		Not Reported
	Hydromorphone			C	Unknown	Unk (10 Mcg/Ml Was Initiated During The Procedure And Maintained At 6 Ml/H, Infusion)		Not Reported
	Epinephrine			C	Unknown	Unk (A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 Mcg/Ml)		Not Reported
	Bupivacaine			C	Unknown	1 Mg/Ml, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16038942	EXPEDITED (15-DAY)		OT	PHHY2019CO047048		56 YR	Male	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Erythema; Haematuria; Prostatitis; Psoriasis; Skin Plaque	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Not Reported
	Atorvastatin			S	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16125958	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-028365		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling;	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qwk		Bristol Myers Squibb
	Celebrex			S	Unknown			Not Reported

Liver Disorder; Liver Function Test Increased; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Unknown	Unk	Not Reported
	Escitalopram Oxalate	S	Oral	1 Dosage Form, Qd	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Oral	1 Dosage Form, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	1 Dosage Form, Bid	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Milligram, Qd	Not Reported
	Prednisone	S	Oral	12.5 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Pantoprazole	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Clonazepam	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16569674	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-024906		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Asthenia; Blood Pressure Abnormal; Confusional State; Constipation; Decreased	Escitalopram Tablets Usp 10mg			S	Unknown	1 Dosage Form, Daily		Aurobindo
	Escitalopram Tablets Usp 10mg			S	Unknown	Dose Reduced		Aurobindo
	Zotac			C	Unknown	Unk		Not Reported

Appetite; Diarrhoea; Dizziness; Drug Withdrawal Syndrome; Dry Mouth; Dysuria; Feeling Jittery; Heart Rate Abnormal; Hyperhidrosis; Hypoaesthesia; Insomnia; Micturition Disorder; Muscle Disorder; Muscle Rigidity; Muscle Spasms; Pruritus Generalised; Pyrexia; Suicidal Ideation; Throat Tightness	Zantac	C	Unknown	Unk		Not Reported
	Ranitidine	C	Unknown	Unk		Not Reported
	Librium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16762107	EXPEDITED (15-DAY)		OT	PHHY2019ES198861		44 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Torsade De Pointes	Olanzapine			S	Unknown	Unk		Novartis
	Salbutamol			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16843061	NON-EXPEDITED			PA-ALLERGAN-1929606US		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Mood Swings	Vraylar			S		1.5 Mg, Qd		Allergan
	Lexapro			S				Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16843071	NON-EXPEDITED			US-ALLERGAN-1931553US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysarthria; Muscle	Vraylar			S				Allergan

Spasms	Lexapro	S	10 Mg	Allergan
	Seroquel	S	50 Mg	Not Reported
	Cholesterol Medication	C	Unk	Not Reported
	Blood Pressure Medication	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16865260	EXPEDITED (15-DAY)		OT	MY-MACLEODS PHARMACEUTICALS US LTD-MAC2019023052			Unknown	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypersensitivity	Escitalopram			S	Unknown	Unk		Macleods
	Risperidone			S	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16865600	EXPEDITED (15-DAY)		HO	FR-ROCHE-2414222		14 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypotension; Malaise	Diazepam			S	Oral			Not Reported
	Dietary Supplement			S	Oral			Not Reported
	Diane			S	Oral			Not Reported
	Cialis			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Colchicine			S	Oral			Not Reported
	Ibuprofene			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Donormyl [Doxylamine			S	Oral			Not Reported

Succinate]

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16866604	EXPEDITED (15-DAY)		HO	NL-TEVA-2019-NL-1114671			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Dyspnoea; Gait Disturbance; Heart Rate Decreased; Somnolence; Weight Increased	Escitalopram Tablet, 15 Mg (Milligram)			S		15 Milligram Daily; 1x Per Day 1 Tablet		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16866661	EXPEDITED (15-DAY)		HO, OT	US-HETERO-HET2019US01340		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism; Major Depression; Suicidal Ideation; Suicide Attempt	Escitalopram			S	Unknown	10 Mg, Qd		Hetero

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16866887	EXPEDITED (15-DAY)		OT	GB-ACCORD-118241			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoscopy; Seizure	Escitalopram			S	Oral	Morning		Not Reported
	Mirtazapine			S		Night		Not Reported
	Olanzapine			S		Also Received 10 Mg		Not Reported
	Azathioprine			S		With Or Just After Food		Not Reported
	Dihydrocodeine			S		Two To Be Taken Four Times A Day If Required.		Not Reported
	Iron			S		Morning And Night, 210 Mg Also Received		Not Reported

	Folic Acid	S	Morning	Not Reported
	Promethazine	S	At Night.	Not Reported
	Dihydrocodeine	S	Four Times A Day. Take With Or Just After Food.	Not Reported
	Azathioprine	S	Morning, Lunch And Tea Time (With Or Just After Food/Meal)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16868146	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1091101		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective For Unapproved Indication; Off Label Use	Escitalopram			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Clonazepam			S				Not Reported
	Procainamide			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16868271	EXPEDITED (15-DAY)		DE	FR-TAKEDA-2019TUS054412			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Condition Aggravated	Brintellix			S	Unknown	10 Milligram		Takeda
	Brintellix			S	Unknown	20 Milligram		Takeda
	Seroplex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16869159	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1938903US			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal; Visual Impairment	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Sertraline			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16869160	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1939228US			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoscopy; Seizure	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd, Each Morning		Allergan
	Dihydrocodeine			S	Unknown	60 Mg, Qid, With Or Just After Food		Not Reported
	Promethazine Hydrochloride			S	Unknown	25 Mg, Qhs		Not Reported
	Olanzapine			S	Unknown	10 Mg, Qd		Not Reported
	Ferrous Fumarate			S	Unknown	420 Mg, Qd		Not Reported
	Folic Acid			S	Unknown	5 Mg, Qd		Not Reported
	Azathioprine			S	Unknown	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16869173	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1938923US			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Product Use In Unapproved Indication; Sopor	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16869249	EXPEDITED (15-DAY)		HO	PHHY2019CH222002		87 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Syncope; Vertigo; Vomiting	Quetiapine Sandoz			S	Unknown	Dose Increase Over Time		Novartis
	Quetiapine Sandoz			S	Unknown	Quetiapine Xr Sandoz Ret. 200 Mg 0-0-1, Quetiapine 25 Mg 0-0.5-0		Novartis
	Escitalopram			S	Unknown	Unk Ukn, Unk		Not Reported

	Aspirin Cardio		C	Unknown	Unk Ukn, Unk	Not Reported
	Vi-De 3		C	Unknown	Unk Ukn, Unk	Not Reported
	Pantoprazol Mepha		C	Unknown	Unk Ukn, Unk	Not Reported
	Vesicare		C	Unknown	Unk Ukn, Unk	Not Reported
	Acidum Folicum Streuli		C	Unknown	Unk Ukn, Unk	Not Reported
	Irbesartan		C	Unknown	Unk Ukn, Unk	Not Reported
	Magnesiocard		C	Unknown	Unk Ukn, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16869277	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1089967		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	15 Milliliter, Total		Not Reported
	Vortioxetine Hydrobromide			C		Unk		Mylan
	Sertraline			C		Unk		Mylan
	Asenapine			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16870105	EXPEDITED (15-DAY)		HO	CN-ALLERGAN-1939774US			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuroleptic Malignant Syndrome	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Clozapine			S	Unknown	200 Mg, Qd		Not Reported
	Clozapine			S	Unknown	100 Mg, Qd		Not Reported
	Clozapine			S	Unknown	50 Mg, Qd		Not Reported
	Risperidone			S	Unknown	4 Mg, Qd		Not Reported
	Haloperidol			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16870145	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2019M1091557		79 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma	Escitalopram			S	Oral	Unk		Not Reported
	Xarelto			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	14942542	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2018-027745		89 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression	Escitalopram			S	Unknown	Unk		Aurobindo
	Heparin			S	Subcutaneous	5000 U		Not Reported
	Lidocaine			C	Unknown	A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 ?G/Ml		Not Reported
	Hydromorphone			C	Unknown	10 ?G/Ml Was Initiated During The Procedure And Maintained At 6 Ml/H, Infusion ()		Not Reported
	Epinephrine			C	Unknown	A Test Dose Of 3 Ml Of Lidocaine 2% With Epinephrine 5 ?G/Ml ()		Not Reported
	Bupivacaine			C	Unknown	1 Milligram Per Millilitre		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16060805	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-011959			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoscopy; Seizure	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day, Morning		Aurobindo
	Olanzapine Tablet			S	Unknown	5 Milligram, Once A Day		Aurobindo
	Olanzapine Tablet			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Mirtazapine Film-Coated Tablet			S	Oral	30 Milligram, Once A Day, Night		Aurobindo

	Ferrous Fumarate	S	Unknown	Morning And Night	Not Reported
	Ferrous Fumarate	S	Unknown	210 Milligram, Once A Day, Morning And Night	Not Reported
	Folic Acid	S	Unknown	5 Milligram, Once A Day, Morning	Not Reported
	Dihydrocodeine	S	Unknown	60 Milligram, Four Times Daily.With Or Just After Food/Meal, As Necessary	Not Reported
	Azathioprine	S	Unknown	75 Milligram, Once A Day, Morning, Lunch And Tea Time (With Or Just After Food/Meal)	Not Reported
	Azathioprine	S	Unknown	25 Milligram, Once A Day, Morning, Lunch And Tea Time (With Or Just After Food/Meal)	Not Reported
	Promethazine Hydrochloride	S	Unknown	25 Milligram, Once A Day, At Night	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16419463	NON-EXPEDITED			US-TEVA-2019-US-1051212			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Escitalopram Oxalate			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16529993	EXPEDITED (15-DAY)		CA, HO	CA-TEVA-2019-CA-1071068		1 DAY	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor;	Escitalopram			S	Transplacental	20 Milligram Daily;		Ivax
	Gabapentin			S	Transplacental	1800 Milligram Daily;		Actavis
	Nortriptyline			S	Transplacental	20 Milligram Daily;		Teva
	Quetiapine			S	Transplacental			Teva

Trismus	Rabeprazole	S	Transplacental			Teva
	Zopiclone	S	Transplacental			Not Reported
	Benztropine Mesylate	S	Transplacental	1.5 Milligram Daily;		Not Reported
	Methadose Dye Free,Sugar Free,Unflavored	S	Transplacental	70 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16616087	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP018418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Drug Ineffective	Escitalopram			S	Oral	20 Mg, Qd		Apotex
	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Apotex
	Naproxen			S	Unknown	Unk		Apotex
	Naproxen			S	Unknown	1000 Mg, Qd		Apotex
	Nortriptyline			S	Oral	25 Mg, Qd		Not Reported
	Cimzia			S	Unknown			Not Reported
	Tylenol /00020001/			S	Topical			Not Reported
	Voltaren /00372301/			S	Topical	Unk, Qd		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	600 Mg, Unk		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	700 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16676510	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/19/0112679		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Discomfort; Muscular	Escitalopram			S	Unknown	Unk		Not Reported

Weakness; Myalgia	Ibuprofen	S	Unknown	Unk	Not Reported
	Metoprolol	S	Unknown	Unk	Not Reported
	Ibuprofen Hormosan	S	Unknown	Unk	Not Reported
	Pantozol	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Amitriptyline	S			Not Reported
	Metoprolol Hexal	S	Unknown	Unk	Not Reported
	Escitalopram Stada	S	Unknown	Unk	Not Reported
	Escitalopram Hexal	S	Unknown	Unk	Not Reported
	Metoprolol Mylan	S	Unknown	1 Df, Ow	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Metoprolol Stada	S	Unknown	Unk	Not Reported
	Ibuhexal	S	Unknown	Unk	Not Reported
	Ibuprofen Stada	S	Unknown	Unk	Not Reported
	Salbutamol Stada	S	Unknown	Unk	Not Reported
	Escitalopram Mylan	S	Unknown	Unk	Not Reported
	Prednisolone Stada	S	Unknown	Unk	Not Reported
	Implanon	S	Unknown	Unk	Not Reported
	Prednisolone Jenapharm	S	Unknown	Unk	Not Reported
	Prednisolon	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Prednisolone	S	Unknown	25 Mg, Unk	Not Reported
	Prednisolone	S	Unknown	2.5 Mg	Not Reported
	Salbutamol	S	Unknown	Unk	Not Reported
	Fluticasone /Vilanterol	S	Unknown	Unk, 6 Months Before Diagnosis	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16701224	EXPEDITED (15-DAY)		HO, LT, OT	BE-ASTELLAS-2014US019985		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome; Product Use In Unapproved Indication; Torsade De Pointes	Tacrolimus			S	Unknown	Unk, Unknown Freq.		Astellas
	Sotalol			S	Unknown	Unk, Unknown Freq.		Not Reported
	Sotalol			S	Unknown	Unk, Unknown Freq.		Not Reported
	Escitalopram			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Omeprazole			S	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16723676	EXPEDITED (15-DAY)		HO, LT, OT	BE-AUROBINDO-AUR-APL-2017-22429		65 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Arrhythmia; Blood Pressure Decreased; Drug Interaction; Drug Intolerance; Hypokalaemia; Labelled Drug-Drug Interaction Medication Error; Long Qt Syndrome; Loss Of Consciousness; Metabolic Disorder; Off Label Use; Pallor; Product Use In Unapproved Indication; Torsade De Pointes; Vomiting	Escitalopram			S	Unknown	Unk		Aurobindo
	Bisoprolol			S	Unknown	Unk		Aurobindo
	Tacrolimus			S	Unknown	Unk		Not Reported
	Omeprazole			S	Unknown	Unk		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16741552	EXPEDITED (15-DAY)		OT	CZ-ALLERGAN-1934780US			Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis	Escitalopram Oxalate Unk			S	Unknown	10 Mg,Unk		Allergan
	Olanzapine			S	Unknown	20 Mg, Qd		Not Reported
	Trazodone			S	Unknown	150 Mg		Not Reported

	Lamotrigine	S	Unknown	25 Mg		Not Reported
	Oxazepam	S	Unknown	15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16838743	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2567569-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Liver Function Test Increased; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Pantoprazole Magnesium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Pantoprazole			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872277	EXPEDITED (15-DAY)		OT	PHHY2019TN226009		38 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature; Drug Reaction With Eosinophilia And Systemic Symptoms; Face Oedema; Lymphadenopathy; Rash Generalised	Carbamazepine			S	Unknown	Unk		Novartis
	Levomepromazine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872421	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2019-DE-1114700		47 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticholinergic Syndrome; Blood Creatine Phosphokinase Increased; Blood Pressure Increased; Dehydration; Drug Interaction; Hyperthermia; Hypokinesia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tachycardia; Tachypnoea; Transaminases Increased	Escitalopram			S	Oral	Permanent Ingestion Dose : 10 Milligram		Ivax
	Haloperidol Ratiopharm 10 Mg			S	Oral	1-0-1, 10 Milligram		Actavis
	Chlorprothixen Neuraxpharm			S	Oral	30-30-30-100		Not Reported
	Aripiprazol Stada 10 Mg			S	Oral	10 Milligram, Admission Medication - 26.08.2019 1-0-0		Not Reported
	Ramipril 2.5 Mg			C	Oral	1-0-0, 2.5 Milligram Admission Medication, Not Paused		Not Reported
	Bisoprolol 2.5 Mg			C	Oral	1-0-0, 2.5 Milligram Admission Medication, Not Paused		Not Reported
	Diazepam-Ratiopharm 10 Mg			C	Oral	1-1-1, 10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872471	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1091103		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use	Escitalopram			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872474	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1091107		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use	Escitalopram			S	Unknown			Not Reported
	Clonazepam			S	Unknown	4 Milligram		Not Reported
	Clonazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872488	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2019-063339		47 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticholinergic Syndrome; Blood Creatine Phosphokinase Increased; Blood Pressure Increased; Dehydration; Hyperthermia; Hypokinesia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tachycardia; Tachypnoea; Transaminases Increased	Escitalopram			S	Oral	10 Milligram,Permanent Intake		Aurobindo
	Chlorprothixen Neuraxpharm			S	Oral	30-30-30-100		Not Reported
	Haloperidol-Ratiopharm			S	Oral	10 Milligram, Two Times A Day,1-0-1		Not Reported
	Aripiprazol Stada			S	Oral	10 Milligram,Recording Medication - 26.08.2019; 1-0-0		Not Reported
	Ramipril			C	Oral	2.5 Milligram,1-0-0;Admission Medication, Not Paused;		Not Reported
	Bisoprolol			C	Oral	2.5 Milligram,1-0-0;Admission Medication, Not Paused;		Not Reported
	Diazepam-Ratiopharm			C	Oral	10 Milligram,1-1-1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872648	EXPEDITED (15-DAY)		HO	NL-AUROBINDO-AUR-APL-2019-063421			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Dyspnoea; Gait Disturbance; Heart Rate Decreased; Somnolence; Weight Increased	Escitalopram Film-Coated Tablets 15mg			S	Oral	15 Milligram, Once A Day		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16873319	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2019M1091131		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	Unk		Not Reported
	Tiaprizal			S	Oral	100 Milligram, Q8h		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16873801	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-093171		93 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epistaxis	Eliquis			S	Oral	2 Dosage Form, Daily		Bristol Myers Squibb
	Seroplex			S	Oral	5 Gtt Drops, Daily		Not Reported
	Esomeprazole			C	Oral	20 Milligram, Daily		Not Reported
	Oramorph [Morphine Sulfate]			C	Oral			Not Reported
	Doliprane			C	Oral	4 Dosage Form, Prn		Not Reported
	Risperdaloro			C	Oral	1 Dosage Form, Daily		Not Reported
	Seresta			C	Oral	20 Milligram, Daily		Not Reported
	Bisoce			C	Oral	1 Dosage Form, Daily		Not Reported

	Midazolam	C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16873907	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1091115		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective For Unapproved Indication; Off Label Use	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported
	Clonazepam			S	Unknown	3 Milligram		Not Reported
	Clonazepam			S				Not Reported
	Metoprolol			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16874399	EXPEDITED (15-DAY)		OT	IT-BAUSCH-BL-2019-055040		64 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Hypoglycaemia; Oedema Peripheral; Weight Increased	Metformin			S	Unknown	2500 Mg		Santarus
	Fenofibrate			S	Unknown	145 Mg		Not Reported
	Victoza			S	Unknown	1.80 Mg		Not Reported
	Escitalopram			S	Unknown	20 Mg		Not Reported
	Budesonide;Formoterol			S	Unknown	2 Puf/Day		Not Reported
	Olmesartan			S	Unknown	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16874929	EXPEDITED (15-DAY)		CA, HO	CA-TEVA-2019-CA-1115011		1 DAY	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor;	Rabeprazole			S	Transplacental			Teva
	Escitalopram			S	Transplacental	20 Milligram Daily;		Ivax
	Gabapentin			S	Transplacental	1800 Milligram Daily;		Ivax
	Nortriptyline			S	Transplacental	20 Milligram Daily;		Teva

Trismus	Quetiapine	S	Transplacental		Teva
	Zopiclone	S	Transplacental		Not Reported
	Benztropine Mesylate	S	Transplacental	1.5 Milligram Daily;	Not Reported
	Methadose Dye Free,Sugar Free,Unflavored	S	Transplacental	70 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	12579870	EXPEDITED (15-DAY)		HO, OT	PHHY2016PA099776		58 YR	Male	PAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alanine Aminotransferase Increased; Amnesia; Anaphylactic Reaction; Asphyxia; Asthenia; Blood Cholesterol Increased; Blood Lactate Dehydrogenase Decreased; Blood Potassium Decreased; Blood Pressure Decreased; Blood Sodium Decreased; Blood Triglycerides Increased; Cardiac Disorder; Cardiac Dysfunction; Choking; Cold Type Haemolytic Anaemia; Dehydration; Dyskinesia; Dysstasia; Eosinophil Percentage Increased; Fatigue; Fear; Feeling Abnormal; Gastrointestinal Pain; Granulocyte Count Decreased; Haemoglobin Decreased; Heat Stroke; Hernia Pain; Ileus Paralytic; Infection; Intervertebral Disc	Gilenya			S	Unknown	0.5 Mg, Qd		Novartis
	Gilenya			S	Unknown	0.5 Mg, Qd		Novartis
	Gilenya			S	Unknown	0.5 Mg, Qd		Novartis
	Gilenya			S	Unknown	0.5 Mg, Qd		Novartis
	Gilenya			S	Unknown	0.5 Mg, Qod		Novartis
	Carbamazepine			S	Unknown	200 Mg, Q8h		Not Reported
	Amlodipine			S	Unknown	1 Df, Bid (One Every 12 Hours)		Not Reported
	Amlodipine			S	Unknown	5 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Oxycodone Hydrochloride			S	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	10 Mg, Bid		Not Reported
	Fenofibrate			C	Unknown	250 Mg, Qn		Not Reported

Disorder; Intervertebral Disc Protrusion; Intervertebral Discitis; Lethargy; Leukopenia; Low Density Lipoprotein Increased; Lymphocyte Count Decreased; Malaise; Mean Cell Volume Increased; Memory Impairment; Mobility Decreased; Monocyte Percentage Increased; Multiple Sclerosis Relapse; Muscle Contractions Involuntary; Muscle Disorder; Muscle Rigidity; Muscle Spasticity; Muscle Strain; Myalgia; Myopathy; Nausea; Neuralgia; Neuropathy Peripheral; Nuchal Rigidity; Pain; Plateletcrit Decreased; Prescribed Underdose; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Seizure; Seizure; Sleep Disorder; Somnolence; Speech Disorder; Tonsillitis; Visual Impairment; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16187606	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-018826		43 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Ibuprofen	S	Unknown	Unk	Aurobindo
	Escitalopram	S	Unknown	Unk	Aurobindo
	Pantozol	S	Unknown	Unk	Not Reported
	Implanon	S	Unknown	Unk	Not Reported
	Ibuprofen Hormosan	S	Unknown	Unk	Not Reported
	Metoprolol Hexal	S	Unknown	Unk	Not Reported
	Salbutamol Stada	S	Unknown	Unk	Not Reported
	Salbutamol	S	Unknown	Unk	Not Reported
	Prednisolon Jenapharm	S	Unknown	Unk	Not Reported
	Metoprolol	S	Unknown	Unk	Not Reported
	Metoprolol Mylan	S	Unknown	Unk	Not Reported
	Amitriptylin	S	Unknown	Unk	Not Reported
	Prednisolon	S	Intracardiac	Unk	Not Reported
	Prednisolon	S	Unknown	25 Milligram	Not Reported
	Prednisolon	S	Unknown	2.5 Milligram	Not Reported
	Metoprolol Stada	S	Unknown	Unk	Not Reported
	Ibuprofen Stada	S	Unknown	Unk	Not Reported
	Prednisolon Stada	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Escitalopram Mylan	S	Unknown	Unk	Not Reported
	Escitalopram Stada	S	Unknown	Unk	Not Reported
	Escitalopram Hexal	S	Unknown	Unk	Not Reported
	Methotrexate Mylan	S	Unknown	1 Dosage Form, Every Week	Not Reported
	Ibuhexal	S	Unknown	Unk	Not Reported
	Fluticasone;Vilanterol	C	Unknown	Unk (6 Months Before Diagnosis)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16509339	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1069210		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Dislocation; Device Malfunction; Drug Ineffective	Amlodipine Besilate			S	Unknown	1.5 Dosage Forms Daily;		Teva
	Clonazepam			S	Unknown	3 Dosage Forms Daily;		Teva
	Diltiazem			S	Unknown	1 Dosage Forms Daily;		Teva
	Escitalopram Oxalate			S	Unknown	1 Dosage Forms Daily;		Ivax
	Escitalopram Oxalate			S	Unknown			Ivax
	Escitalopram Oxalate			S	Unknown			Ivax
	Ratio-Zopiclone			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown	1 Dosage Forms Daily;		Actavis
	Tevabisoprol			S	Unknown	1 Dosage Forms Daily;		Duramed
	Apo Escitalopram			S	Unknown			Not Reported
	Tamsulosin Cr Controlled-Release Tablet			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Apo-Trazodone			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Brilinta			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Ciclopirox Olamine			S	Unknown			Not Reported
	Delatestryl			S	Unknown			Not Reported
	Dexilant			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Emo Cort			S	Topical	1 Dosage Forms Daily;		Not Reported
	Jamp Asa 81mg Ec			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Metonia			S	Unknown	3 Dosage Forms Daily;		Not Reported
	Mylan-Nitro Sublingual Spray			S	Oral			Not Reported
	Mylan-Nitro Sublingual Spray			S	Oral			Not Reported
	Nasonex			S	Nasal			Not Reported
	Nitro-Dur			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Ratio-Zopiclone			S	Unknown			Not Reported
	Synthroid			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Triatec /00116401/			S	Unknown	4 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16877554	NON-EXPEDITED			US-PFIZER INC-2019422947		50 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer
	Amlodipine Besilate			S		Unk		Pfizer
	Cefdinir			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Naproxen Sodium			S		Unk		Pfizer
	Aspirin (E.C.)			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Keflex [Cefalexin Monohydrate]			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Macrodantin			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Pseudoephedrine			S		Unk		Not Reported
	Singula			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16878468	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2019-055844		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple-Drug Resistance	Venlafaxine			S	Unknown			Not Reported
	Venlafaxine			S	Oral	Extended Release		Not Reported
	Bupropion			S	Unknown			Not Reported
	Bupropion			S				Not Reported
	Lorazepam			S	Unknown			Not Reported

Lorazepam	S			Not Reported
Fluoxetine	S	Unknown		Not Reported
Fluoxetine	S			Not Reported
Sertraline	S	Unknown		Not Reported
Sertraline	S			Not Reported
Paroxetine	S	Unknown		Not Reported
Paroxetine	S			Not Reported
Escitalopram	S	Unknown		Not Reported
Escitalopram	S			Not Reported
Duloxetine	S	Unknown		Not Reported
Duloxetine	S			Not Reported
Aripiprazole	S	Unknown		Not Reported
Aripiprazole	S			Not Reported
Quetiapine	S	Unknown		Not Reported
Quetiapine	S			Not Reported
Gabapentin	S	Unknown		Not Reported
Gabapentin	S			Not Reported
Pregabalin	S	Unknown		Not Reported
Pregabalin	S			Not Reported
Topiramate	S	Unknown		Not Reported
Topiramate	S			Not Reported
Alprazolam	S	Unknown		Not Reported
Alprazolam	S	Unknown	As Needed	Not Reported
Alprazolam	S			Not Reported
Methylphenidate	S	Unknown		Not Reported
Methylphenidate	S	Unknown		Not Reported
Modafinil	C		In Divided Doses	Not Reported
Fingolimod	C	Oral	3 Times Per Week	Not Reported
Omeprazole	C			Not Reported
Trospium	C		Xr (Extended Release)	Not Reported
Naproxen	C		As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	14349561	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-MACLEODS PHARMACEUTICALS US LTD-MAC2017007867			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine Dihydrochloride 5mg Tablet			S	Transplacental	5 Mg, Qd		Macleods
	Pantoprazole			S	Transplacental	Unk		Macleods
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported
	Nucala Powder For Solution For Injection			S	Transplacental	100 Mg, Unk, Gestation Period At Time Of Exposure- 1 Week, Powder For Solution For Injection		Not Reported
	Ventolin			S	Transplacental	100 Mg, Unk		Not Reported
	Pantomed [Pantoprazole]			S	Transplacental	Unk		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Flixotide			S	Transplacental	500 Mg, Qd, (250 Ug, Bid)		Not Reported
	Relvar Ellipta			S	Transplacental	1 Df, Qd (Inhalation Powder, Pre-Dispensed)		Not Reported
	Sipralexa			S	Transplacental	10 Mg, Z		Not Reported
	Seretide			S	Transplacental	Unk		Not Reported
	Avamys			S	Transplacental	2 Df, Qd (Unk Bid) (Nasal Spray)		Not Reported
	Fluticasone Propionate			S	Transplacental	Unk, Qd (Inhalation Powder)		Not Reported
	Vilanterol Trifenatate			S	Transplacental	1 Dosage Form, Qd (Inhalation Powder)		Not Reported
	Xyzall			S	Transplacental	5 Milligram, Qd		Not Reported
	Theophylline			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	15650766	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-056286		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Ramipril			S	Oral	2.5 Milligram, Once A Day		Aurobindo
	Lamotrigine			S	Oral	100 Milligram, Once A Day		Aurobindo
	Exemestane			S	Oral	25 Milligram, Once A Day		Not Reported
	Gabapentin			S	Oral	200 Milligram, Once A Day		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo
	Lasilix			S	Oral	20 Milligram, Once A Day		Not Reported
	Aspirine Protect			S	Oral	100 Milligram, Once A Day		Not Reported
	Bisoce			S	Oral	1.25 Milligram, Once A Day		Not Reported
	Seroplex			S	Oral	5 Milligram, Once A Day		Not Reported
	Fluidabak			C	Ophthalmic	3 Gtt, Once A Day		Not Reported
	Transipeglib			C	Oral	11.8 Gram, Once A Day		Not Reported
	Gluconate De Potassium			C	Oral	1 Cs Par Jour		Not Reported
	Gluconate De Potassium			C	Oral	1 Dosage Form, Once A Day		Not Reported
	Levothyroxine Sodique			C	Oral	30 Gtt, Once A Day		Not Reported
	Potassium Chloride;Sodium Acetate;Sodium Chloride			C	Oral	Unk,1 Cs Par Jour Route		Not Reported
	Sodium Gluconate			C	Oral	Unk,1 Cs Par Jour Route		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	15663581	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-980666			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Citalopram			S	Unknown			Actavis
	Cipralex			S	Unknown	10 Milligram Daily;		Not Reported

	Escitalopram	S	Unknown	10 Milligram Daily;		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	15668452	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-980471		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Heart Rate Increased; Irritability; Miosis; Overdose; Oxygen Saturation Decreased; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown			Ivax
	Escitalopram Oxalate			S	Unknown			Ivax
	Escitalopram Oxalate			S	Oral			Ivax
	Quetiapine Fumarate			S	Unknown			Teva
	Quetiapine Fumarate			S	Oral			Teva
	Quetiapine Fumarate			S	Oral			Teva
	Topiramate			S	Oral			Teva
	Topiramate			S	Unknown	Form Of Admin : Not Specified		Teva
	Citalopram Hydrobromide			S	Unknown			Not Reported
	Citalopram Hydrobromide			S	Unknown			Not Reported
	Citalopram Hydrobromide			S	Oral			Not Reported
	Temazepam			S	Oral			Actavis
	Temazepam			S	Unknown			Actavis
	Oxazepam			S	Unknown			Not Reported
	Oxazepam			S	Oral			Not Reported
	Ctp 30			S	Unknown			Not Reported
	Naloxone			S	Intramuscular	Form Of Admin : Not Specified		Not Reported
	Naloxone			S	Intramuscular			Not Reported
	Advair			C	Unknown			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Clopidogrel (Unspecified Brand)			C	Unknown			Not Reported

	Clopidogrel (Unspecified Brand)	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Furosemide	C	Unknown	Form Of Admin : Not Specified	Not Reported
	Ipratropium	C	Unknown	Form Of Admin : Not Specified	Not Reported
	Metoprolol	C	Unknown	Form Of Admin : Not Specified	Not Reported
	Ramipril	C	Endocervical	Form Of Admin : Not Specified	Not Reported
	Salbutamol	C	Other	Form Of Admin : Not Specified	Not Reported
	Spironolactone	C	Unknown		Not Reported
	Spironolactone	C	Unknown		Not Reported
	Fluticasone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16836433	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-060867		14 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypotension; Malaise	Diclofenac			S	Oral	5000 Milligram, In Total		Not Reported
	Diazepam			S	Oral	480 Milligram, In Total		Not Reported
	Ibuprofen			S	Oral	4400 Milligram, In Total		Aurobindo
	Paracetamol			S	Oral	2 Gram, In Total		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	820 Milligram, In Total		Aurobindo
	Diane			S	Oral	21 Dosage Form, In Total		Not Reported
	Cialis			S	Oral	40 Milligram, In Total		Not Reported
	Colchicine			S	Oral	6 Milligram, In Total		Not Reported
	Donormyl [Doxylamine			S	Oral	300 Milligram, In Total		Not Reported

Succinate]

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16854030	EXPEDITED (15-DAY)		OT	GB-DRREDDYS-GER/UKI/19/0114321			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoscopy; Seizure	Olanzapine			S				Not Reported
	Promethazine Hydrochloride			S		At Night.		Not Reported
	Ferrous Fumarate			S				Not Reported
	Azathioprine			S				Not Reported
	Escitalopram			S		Each Morning.		Not Reported
	Dihydrocodeine			S		Four Times A Day. Take With Or Just After Food.		Not Reported
	Folic Acid			S				Not Reported
	Mirtazapine			S	Oral	Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16880083	EXPEDITED (15-DAY)		HO	IT-ACCORD-156226		85 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Medication Error; Muscle Contractions Involuntary; Paraesthesia; Sopor	Escitalopram			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16880275	EXPEDITED (15-DAY)		DS, OT	AT-MYLANLABS-2019M1091285		25 YR	Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradyphrenia; Confusional State; Depressed Level Of Consciousness; Disturbance In Attention; Emotional Poverty;	Escitalopram			S	Unknown	10 Milligram		Not Reported
	Escitalopram			S	Unknown	20 Milligram		Not Reported

Erectile Dysfunction; Fatigue; Feeling Abnormal; Hyperhidrosis; Hypoaesthesia; Illusion; Loss Of Libido; Malaise; Memory Impairment; Orgasm Abnormal; Orgasmic Sensation Decreased; Personality Change; Poisoning; Tremor; Tunnel Vision

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16880505	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019023087			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticholinergic Syndrome; Blood Creatine Phosphokinase Increased; Blood Pressure Increased; Dehydration; Drug Interaction; Hyperthermia; Hypokinesia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tachycardia; Tachypnoea; Transaminases Increased	Escitalopram			S	Oral	10 Milligram, Permanent Intake		Macleods
	Chlorprothixen Neuraxpharm			S	Oral	Unk, 30-30-30-100		Not Reported
	Haloperidol Ratiopharm			S	Oral	10 Milligram, Bid (1-0-1)		Not Reported
	Aripiprazol Stada			S	Oral	10 Milligram, Qd (1-0-0), Recording Medication- 26 08 2019		Not Reported
	Ramipril			C	Oral	2.5 Milligram, Qd, Recording Medication, Not Paused		Not Reported
	Bisoprolol			C	Oral	2.5 Milligram, Qd (1-0-0), Recording Medication, Not Paused		Not Reported
	Diazepam-Ratiopharm			C	Oral	10 Milligram, Tid (1-1-1)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16880872	NON-EXPEDITED			US-PFIZER INC-2019424527		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Flagyl	S	Unk		Pfizer
	Amoxicillin	S	Unk		Not Reported
	Lexapro	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16882368	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1940063US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prescribed Overdose; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	30 Mg		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan
	Surmontil			S	Oral	Unk Mg		Not Reported
	Pregabalin			C	Oral			Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Prostasan			C	Unknown			Not Reported
	Aspirin Cardio			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16882512	NON-EXPEDITED		OT	US-JAZZ-2018-US-010128		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Back Pain; Depressive Symptom; Dizziness; Fatigue; Headache; Orthostatic Hypotension; Overweight; Poor Quality Sleep; Somnolence; Stress; Suicidal Ideation	Xyrem			S	Oral	2.5 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S				Not Reported
	Adderall			S				Not Reported
	Citalopram			S				Not Reported
	Vitamin D2			C				Not Reported
	Modafinil			C				Not Reported
	Mefenamic Acid			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Anusol Plus H			C				Not Reported
	Symbicort			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16882808	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-063150		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Neutropenia; Pleural Effusion	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo
	Ciprofloxacin			S	Intravenous (not otherwise specified)	Unk, 1 Every 3 Weeks		Aurobindo
	Avastin			S	Intravenous (not otherwise specified)	15 Milligram, 1 Every 3 Weeks		Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)	Unk, 1 Every 3 Weeks		Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)	Unk, 1 Every 3 Weeks		Not Reported
	Cipralex			S	Intravenous (not otherwise specified)	10 Milligram		Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)	75 Milligram/Sq. Meter, 1 Every 3 Weeks		Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)	75 Milligram/Sq. Meter, Trimester		Not Reported
	Herceptin			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Herceptin			S	Unknown	8 Milligram/Kilogram, 1 Everry 3 Weeks		Not Reported
	Morphine			S	Intravenous (not otherwise specified)	2.5 Milligram		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Senna			C	Unknown	Unk		Not Reported
	Docusate			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported
	Lactulose			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	13696842	EXPEDITED (15-DAY)		HO, OT	CO-INCYTE CORPORATION-2017IN005035			Unknown	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abnormal Behaviour; Agitation; Amnesia; Anal Haemorrhage; Anger; Anxiety; Arthralgia; Asthenia; Bone Pain; Boredom; Chest Discomfort; Chills; Cough; Cystitis; Decreased Appetite; Depression; Diarrhoea; Dizziness; Dyspnoea; Fall; Feeling Abnormal; Fungal Infection; Gastric Ulcer; Gastrointestinal Haemorrhage; General Physical Health Deterioration; Haematemesis; Headache; Heart Rate Increased; Hypersensitivity; Ill-Defined Disorder; Inappropriate Schedule Of Product Administration; Insomnia; Malaise; Mouth Haemorrhage; Muscle Spasms; Nausea; Pain; Pain In Extremity; Platelet Count Increased; Polycythaemia Vera; Pruritus; Psychiatric Symptom; Pyrexia; Rectal Haemorrhage; Renal Colic; Skin Disorder; Skin	Jakavi			S	Oral	5 Mg, Bid		Incyte
	Jakavi			S	Oral	2 Df, Qd (5 Mg)		Incyte
	Jakavi			S	Oral	15 Mg, Bid		Incyte
	Jakavi			S	Unknown	20 Mg, Qd		Incyte
	Jakavi			S	Oral	30 Mg, Qd		Incyte
	Jakavi			S	Oral	Unk		Incyte
	Jakavi			S	Oral	20 Mg, Q12h		Incyte
	Jakavi			S	Oral	40 Mg, Qd		Incyte
	Jakavi			S	Oral	20 Mg, Q12h		Incyte
	Jakavi			S	Oral	40 Mg, Qd (Once)		Incyte
	Esomeprazole			S	Unknown	Unk Unk, Qd		Not Reported
	Loratadine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Hydroxyurea			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Aspirin /00002701/			C	Unknown	Unk		Not Reported
	Dolex /01495801/			C	Unknown	Unk		Not Reported

Haemorrhage; Sleep Disorder; Sneezing; Spleen Disorder; Tuberculosis; Viral Infection; Vision Blurred; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	15644004	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018477058		96 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Ramipril			S	Oral	2.5 Mg, 1x/Day		Pfizer
	Bisoprolol Fumarate			S	Oral	1.25 Mg, 1x/Day		Not Reported
	Acetylsalicylic Acid			S	Oral	100 Mg, 1x/Day		Not Reported
	Lamotrigine			S	Oral	100 Mg, Qd		Not Reported
	Exemestane			S	Oral	25 Mg, 1x/Day		Pfizer
	Gabapentine Pfizer			S	Oral	200 Mg, Qd		Pfizer
	Seroplex			S	Oral	5 Mg, 1x/Day		Not Reported
	Lasilix			S	Oral	20 Mg, 1x/Day		Not Reported
	Gluconate De Potassium			C	Oral	1 Df, Qd (1 Cs Per Day)		Not Reported
	Transipeg [Macrogol]			C	Oral	11.8 G, 1x/Day		Not Reported
	Levothyroxine Sodique			C	Oral	30 Gtt Drops, Qd		Not Reported
	Fluidabak			C	Ophthalmic	3 Gtt Drops, Qd		Not Reported
	Gluconate Sodium/Potassium Chloride/Sodium Acetate/Sodium Chloride			C	Oral	1 Cs Par Jour Route		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	15651346	EXPEDITED (15-DAY)		CA, HO	CA-TEVA-2018-CA-978993		1 DAY	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Withdrawal Syndrome Neonatal;	Escitalopram			S	Transplacental	20 Milligram Daily;		Ivax

Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Escitalopram		S	Transplacental	20 Milligram Daily;	Ivax
	Escitalopram		S	Transplacental	20 Milligram Daily;	Ivax
	Nortriptyline		S	Transplacental	20 Milligram Daily;	Teva
	Quetiapine		S	Transplacental		Teva
	Rabeprazole		S	Transplacental		Teva
	Zopiclone		S	Transplacental		Not Reported
	Benztropine Mesylate		S	Transplacental	1.5 Milligram Daily;	Not Reported
	Benztropine Mesylate		S	Transplacental	1.5 Milligram Daily;	Not Reported
	Gabapentin		S	Transplacental	1800 Milligram Daily;	Actavis
	Methadone		S	Transplacental	70 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16266075	EXPEDITED (15-DAY)		CA, DS, HO, LT, OT	CA-TEVA-2019-CA-1042363		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Blindness Cortical; Cardiogenic Shock; Cerebral Infarction; Circulatory Collapse; Colour Blindness; Condition Aggravated; Csf Pressure Increased; Cytotoxic Oedema; Depressed Level Of Consciousness; Electrocardiogram P Wave Abnormal; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Amplitude Decreased; Electrocardiogram T Wave Inversion; Electrocardiogram U	Amlodipine			S	Unknown			Teva
	Amlodipine			S	Oral			Teva
	Amlodipine			S	Oral			Teva
	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Unknown	60 Milligram Daily;		Ivax
	Risperidone			S	Oral			Pliva
	Risperidone			S	Oral			Pliva
	Risperidone			S	Unknown	6 Milligram Daily;		Pliva
	Epinephrine			S	Unknown			Not Reported
	Glucose			S	Unknown			Not Reported
	Mylan-Escitalopram			S	Oral			Not Reported
	Norepinephrine Bitartrate Inj 1mg/Ml Usp			S	Unknown	Form Of Admin:Liquid Intravenous		Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Potassium Chloride			S	Intravenous (not			Not Reported

Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema; Renal Tubular Necrosis; Retinal Ischaemia; Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment			otherwise specified)			
	Vasopressin Injection, Usp	S	Unknown			Not Reported
	Activated Charcoal	C	Unknown			Not Reported
	Amlodipine	C				Not Reported
	Calcium Gluconate	C	Unknown			Not Reported
	Dextrose	C	Unknown			Not Reported
	Epinephrine	C	Unknown	Form Of Admin:Not Specified		Not Reported
	Escitalopram	C	Unknown			Not Reported
	Glucagon	C	Unknown	Form Of Admin:Kit		Not Reported
	Insulin	C	Unknown			Not Reported
	Norepinephrine	C	Unknown			Not Reported
	Potassium Chloride	C	Unknown	Form Of Admin:Not Specified		Not Reported
	Risperidone	C	Unknown			Not Reported
	Vasopressin Injection, Usp	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16653236	EXPEDITED (15-DAY)			FR-VALIDUS PHARMACEUTICALS LLC-FR-2019VAL000339			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Furosemide			S	Oral	20 Mg, Qd		Validus
	Escitalopram Oxalate			S	Oral	5 Mg, Qd		Not Reported
	Bisoprolol Fumarate			S	Oral	1.25 Mg, Qd		Not Reported
	Gabapentin			S	Oral	200 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Oral	100 Mg, Qd		Not Reported
	Lamotrigine			S	Oral	100 Mg, Qd		Not Reported
	Exemestane			S	Oral	25 Mg, Qd		Not Reported
	Ramipril			S	Oral	2.5 Mg, Qd		Not Reported

	Gluconate De Potassium	C	Unk	Not Reported
	Transipeg /00754501/	C	Unk	Not Reported
	Levothyroxine Sodique	C	Unk	Not Reported
	Fluidabak	C	Unk	Not Reported
	Gluconate Sodium W/Potassium Chloride/Sodium	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16749512	EXPEDITED (15-DAY)		HO	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2019022727			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Escitalopram			S	Oral	5 Milligram, Qd		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16804506	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1083269			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental Disorder; Suicidal Ideation; Wrong Technique In Product Usage Process	Mirtazapine			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Mirtazapine			S	Unknown	15 Milligram		Not Reported
	Buspirone			S		Unk		Not Reported
	Buspirone			S	Unknown	Unk		Not Reported
	Buspirone			S		Unk		Not Reported
	Buspirone			S		Unk		Not Reported
	Buspirone			S		Unk		Not Reported
	Escitalopram			S	Unknown	Reduce To 12.5 Mg Over 8 Weeks		Not Reported

Escitalopram	S	Unknown	15 Milligram		Not Reported
Escitalopram	S	Unknown	12.5 Mg In 6 Weeks (Cutting Bits To 5 Mg To Reach Approx.)		Not Reported
Escitalopram	S	Unknown	15 Milligram, Qd		Not Reported
Lorazepam	S		Unk		Mylan
Lorazepam	S		Unk		Mylan
Lorazepam	S		Unk		Mylan
Lorazepam	S		Unk		Mylan
Lorazepam	S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16838634	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-ALEMBIC PHARMACUETICALS LIMITED-2019SCAL000694			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Myeloma Cast Nephropathy; Myocardial Infarction; Renal Failure; Serotonin Syndrome; Ventricular Fibrillation	Venlafaxine			S	Unknown			Alembic
	Escitalopram			S	Unknown	15 Mg		Not Reported
	Escitalopram			S				Not Reported
	Erythromycin			S	Unknown	Unknown		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unknown		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	1240 Mg/6 H		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16853673	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-061961			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoscopy; Seizure	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day (Each Morning.)		Aurobindo
	Mirtazapine Film-Coated Tablet			S	Oral	30 Milligram, Once A Day,		Aurobindo

				Night	
	Olanzapine Tablet	S	Unknown	10 Milligram, Once A Day	Aurobindo
	Azathioprine	S	Unknown	75 Milligram, Once A Day	Not Reported
	Dihydrocodeine	S	Unknown	60 Milligram, As Necessary (Four Times A Day. Take With Or Just After Food)	Not Reported
	Ferrous Fumarate	S	Unknown	420 Milligram, Once A Day	Not Reported
	Folic Acid	S	Unknown	5 Milligram, Once A Day	Not Reported
	Promethazine Hydrochloride	S	Unknown	25 Milligram, Once A Day (At Night)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16882878	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2018010117			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Entacapone			S	Unknown	Unk		Macleods
	Escitalopram			S	Unknown	Unk		Macleods
	Trimethoprim			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Septrin			S	Unknown	Unk		Not Reported
	Cabergoline			S	Unknown	Unk		Not Reported
	Carbidopa			S	Unknown	Unk		Not Reported
	Stalevo			S	Unknown	Unk		Not Reported
	Levodopa			S	Unknown	Unk		Not Reported
	Duloxetine 90mg Capsule			C	Oral	90 Milligram		Not Reported
	Rivastigmine			C	Transdermal	4.6 Milligram, Patch		Not Reported
	Quetiapine			C	Unknown	25 Milligram		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported
	Co-Beneldopa Capsules			C	Oral	Unk, Co-Beneldopa		Not Reported

				25/100 Capsules	
	Co-Beneldopa Capsules	C	Oral	Unk, 50 Mg/12.5 Mg Capsules	Not Reported
	Co-Beneldopa Capsules	C	Oral	Unk, Co-Beneldopa 25/100 Mr Capsules	Not Reported
	Macrogol	C	Unknown	Unk	Not Reported
	Adcal D3	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16882950	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US06644			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Akathisia; Drug Ineffective; Drug Intolerance; Irritability	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen
	Escitalopram			S				Invagen
	Olanzapine			S	Unknown	Unk		Invagen
	Clonazepam			S	Unknown	Unk		Not Reported
	Clonazepam			S				Not Reported
	Clonazepam			S				Not Reported
	Tetrabenazine			C	Unknown	Unk		Not Reported
	Tetrabenazine			C	Unknown	12.5 Milligram, Tid		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16883849	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2019424971		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyskinesia; Hallucination, Auditory; Headache; Suicidal Ideation	Lorazepam			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884437	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2019-064606		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Coma	Escitalopram			S	Oral	200 Milligram		Aurobindo
	Lormetazepam			S	Oral	3 Milligram		Not Reported
	Imovane			S	Oral	30 Milligram		Not Reported
	Actiskenan			S	Oral	210 Milligram		Not Reported
	Toviaz			S	Oral	32 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884449	EXPEDITED (15-DAY)		HO	AU-MYLANLABS-2019M1093022		79 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Stress Cardiomyopathy	Desvenlafaxine Succinate			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown	45 Milligram, Qd		Not Reported
	Oxazepam			C	Unknown			Mylan
	Amlodipine			C	Unknown			Mylan
	Olmesartan			C	Unknown			Mylan
	Amiodarone			C	Unknown			Mylan
	Rivaroxaban			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884967	NON-EXPEDITED			US-PFIZER INC-2019424328		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gemfibrozil			S		Unk		Pfizer
	Acetaminophen			S				Not Reported

	Celexa [Citalopram Hydrobromide]	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Strattera	S	Unk	Not Reported
	Atomoxetine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16885001	EXPEDITED (15-DAY)		HO, OT	DE-SA-2019SA200898		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Gastritis; Hiatus Hernia; Intra-Abdominal Haemorrhage; Jaundice; Lipase Increased; Malaise; Nausea; Pancreatitis Acute; Pyrexia; Tumour Marker Increased; Vomiting; Weight Decreased	Aubagio			S	Oral	14 Mg, Qd		Sanofi
	Citalopram			S				Not Reported
	Escitalopram			S		Unk		Not Reported
	Metypred [Methylprednisolone]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16885298	NON-EXPEDITED			US-BAYER-2019-177584			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Hypersensitivity	Bayer Aspirin 81 Mg			S				Bayer
	Aleve Caplet			S				Bayer
	Pregabalin			S	Oral	1 Df, Qid		Not Reported
	Pseudoephedrine			S				Not Reported
	Ibuprofen			S				Not Reported
	Keflex [Cefalexin Monohydrate]			S				Not Reported
	Amoxicillin			S				Not Reported
	Singula			S				Not Reported
	Biaxin			S				Not Reported
	Macrodantin			S				Not Reported
	Flagyl 250			S				Not Reported
	Lisinopril			S				Not Reported

Cefdinir	S		Not Reported
Lexapro	S		Not Reported
Prednison	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16886785	EXPEDITED (15-DAY)		CA, DS, HO, LT, OT	CA-TEVA-2019-CA-1115767		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Anuria; Blindness; Blindness Cortical; Cardiogenic Shock; Cerebral Infarction; Circulatory Collapse; Colour Blindness; Condition Aggravated; Csf Pressure Increased; Cytotoxic Oedema; Depressed Level Of Consciousness; Electrocardiogram P Wave Abnormal; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Amplitude Decreased; Electrocardiogram T Wave Inversion; Electrocardiogram U Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema;	Amlodipine			S	Oral			Teva
	Escitalopram			S	Unknown	60 Milligram Daily;		Ivax
	Escitalopram			S	Oral			Ivax
	Escitalopram Oxalate			S	Oral			Ivax
	Risperidone			S	Oral			Actavis
	Risperidone			S	Oral			Actavis
	Epinephrine			S	Unknown			Not Reported
	Glucose			S	Unknown			Not Reported
	Norepinephrine Bitartrate Inj 1mg/Ml Usp			S	Intravenous (not otherwise specified)			Not Reported
	Potassium Chloride			S	Intravenous (not otherwise specified)			Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Vasopressin Inj Usp			S	Unknown			Not Reported
	Activated Charcoal			C	Unknown			Not Reported
	Calcium Gluconate			C	Unknown			Not Reported
	Dextrose			C	Unknown			Not Reported
	Glucagon			C	Unknown			Not Reported
	Insulin			C	Unknown			Not Reported
	Norepinephrine/Procaine Hydrochloride			C	Unknown			Not Reported

Renal Tubular Necrosis; Retinal Ischaemia; Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16887212	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1939887US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administered To Patient Of Inappropriate Age	Escitalopram Oxalate - Bp			S	Oral	Mistakenly Take 20 Drops (Equal To 20 Mg) At Once; In Total		Allergan
	Feniallerg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16887238	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1940215US			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Overdose	Escitalopram Oxalate - Bp			S		Overdose: 40mg		Allergan
	Mirtazapine			S		90 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2019	16887571	NON-EXPEDITED			US-TEVA-2019-US-1117217			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2019	16887640	EXPEDITED (15-DAY)		HO, OT	DE-HETERO-HET2019DE01347		47 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticholinergic Syndrome; Blood Creatine Phosphokinase Increased; Blood Pressure Increased; Dehydration; Hyperthermia; Hypokinesia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tachycardia; Tachypnoea; Transaminases Increased	Escitalopram			S	Oral	10 Mg Permanent Intake		Hetero
	Ramipril			C	Oral	Unk, Qd Admission Medication, Not Paused;		Not Reported
	Aripiprazole			S	Oral	10 Mg		Not Reported
	Bisoprolol			C	Oral	2.5 Mg, Qd		Not Reported
	Diazepam			C	Oral	10 Mg, Tid		Not Reported
	Chlorprothixen Neuraxpharm			S	Oral	Unk 30-30-30-100		Not Reported
	Haloperidol			S	Oral	10 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2019	16887643	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2019-064029		85 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Medication Error; Muscle Contractions Involuntary; Paraesthesia; Sopor	Escitalopram			S	Oral	25 Gtt Drops, Total		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2019	16788234	EXPEDITED (15-DAY)		DE, HO	ES-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2019-12-10		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic	Atrovent			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Boehringer Ingelheim
	Omeprazol [Omeprazole]			S	Oral	20 Mg, Qd		Not Reported
	Lisinopril			S	Oral	5 Mg, Qd		Not Reported
	Alendronate Sodium Hydrate			S	Oral	70 Mg, Qwk		Not Reported
	Furosemide			S	Oral	60 Mg, Qd		Not Reported

Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Iron Sulfate	S	Oral	256.3 Mg, Qd	Not Reported
	Bisoprolol	S	Oral	5 Mg, Bid	Not Reported
	Escitalopram	S	Oral	10 Mg, Qd	Not Reported
	Sintrom	S	Oral	1 Mg, Qd, 60 Tablets	Not Reported
	Spironolactone	S	Oral	50 Mg, Qd	Not Reported
	Allopurinol	S	Oral	100 Mg, Qd	Not Reported